Bilaga 1 Tabellverk

4.2 Tryck–flödesmätning

<table>
<tr><td colspan="2">Ball 1986 United Kingdom
J Urol 1986;28:256-8</td><td>Study quality
Moderate</td><td colspan="2">Index test
Pressure-flow measurement
Reference test
Subjectively better</td></tr>
<tr><td colspan="3">Inclusion criteria
TURP or open operation 5 years earlier, flow and pressure-flow measurements

Exclusion criteria
4 not stated</td><td colspan="2">Execution index test
Standard technique, ref

Execution reference test
Subjectively better</td></tr>
<tr><td>Number</td><td>84</td><td rowspan="9"></td><td>Definition reference test</td><td>--</td></tr>
<tr><td>Exclusions</td><td>1</td><td>Cut off value</td><td>--</td></tr>
<tr><td>Consecutive</td><td>Not stated</td><td>True positives</td><td>--</td></tr>
<tr><td>Demographic description</td><td>No</td><td>False positives</td><td>--</td></tr>
<tr><td>Uninterpretable results</td><td>Not stated</td><td>False negatives</td><td>--</td></tr>
<tr><td>Time interval</td><td>Mean 61.5 months</td><td>True negatives</td><td>--</td></tr>
<tr><td>Verification bias</td><td>No</td><td>Prevalence</td><td>--</td></tr>
<tr><td>Index test independent</td><td>Not stated</td><td>Sensitivity</td><td>--</td></tr>
<tr><td>Reference test independent</td><td>Not stated</td><td>Specificity</td><td>--</td></tr>
<tr><td colspan="2" rowspan="2">Reliability

--</td><td>LR+</td><td>--</td></tr>
<tr><td>LR –</td><td>--</td></tr>
<tr><td colspan="2">Other results</td><td>$p_{detQmax}$ 103 vs 53 sign</td><td>Area under ROC curve</td><td>--</td></tr>
<tr><td colspan="2"></td><td></td><td>Correlation</td><td>--</td></tr>
<tr><td colspan="3">Comments results
--</td><td colspan="2">Comments
--</td></tr>
</table>

Eri 2001 Norway J Urol 2001;165:1188-92	**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria Randomised study, moderate to severe symptoms, prostate volume >30 ml, Q_{max}<12 ml/s, residual urine <300 ml, $pdet^{Q}$ >45 cm H_2O, mean age 69.8 years SD 5.8 **Exclusion criteria** Not stated		**Execution index test** Transurethral 8 Ch catheter, rectal balloon, flow peaks <2 s discarded, one examiner **Execution reference test** --

Number	84	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	7 min, 24/48 weeks	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.82
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Within session AG-number -10.7 and 19.2%. Long term no change		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results SD not studied		**Comments** --	

Gotoh 1999 Japan World J Urol 1999;17:274-8	**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** Subjective outcome
Inclusion criteria TURP, subjective symptoms, Q_{max} <15 ml/s, 50–86 years **Exclusion criteria** Neurogenic bladder		**Execution index test** Transurethral, 6+8 Ch catheter, rectal balloon, Menuet Urodynamic System, Dantec, Schäfer obstruction grade and contractility, values read manually **Execution reference test** Subjective outcome 6–8 weeks postoperatively

Number	74	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	Between Schäfer grade 2 and 3
Consecutive	Not stated	**True positives**	50
Demographic description	No	**False positives**	2
Uninterpretable results	Not stated	**False negatives**	21
Time interval	6-8 weeks	**True negatives**	1
Verification bias	Unclear	**Prevalence**	0.96
Index test independent	Not stated	**Sensitivity**	0.70
Reference test independent	Not stated	**Specificity**	0.05
Reliability --		**LR+** **LR–** **Area under ROC curve**	0.74 0.85 --
Other results		**Correlation**	--
Comments results Too short follow-up		**Comments** Too short follow-up	

Hansen 1997 Denmark Neurourol Urodyn 1997;16:521-32		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria Men submitted due to LUTS, urodynamic study, 43–88 years **Exclusion criteria** Not stated			**Execution index test** Transurethral 8 Ch or suprapubic catheter, 9 Ch rectal catheter, MMS UD 2000, junior registrars **Execution reference test** --
Number	110		**Definition reference test** --
Exclusions	5		**Cut off value** --
Consecutive	Yes		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Excluded		**False negatives** --
Time interval	0 days		**True negatives** --
Verification bias	--		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	--		**Specificity** --
Reliability SD Q_{max} 3.3, $p_{detQmax}$ 13.1, 2nd measurement Qmax ns lower, $p_{detQmax}$ sign 2.8 cm H_2O lower			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

Hansen 1999 Denmark Neurourol Urodyn 1999;18:205-14		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria Men with LUTS, 58–81 years **Exclusion criteria** Not stated			**Execution index test** 8 Ch transuretral and 9 Ch rectal catheters, exernal transducers, Dantec 2000 **Execution reference test** --
Number	22		**Definition reference test** --
Exclusions	2		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	0 and mean 15 days		**True negatives** --
Verification bias	--		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	--		**Specificity** --
Reliability $P_{detQmax}$ 9 and 6 cm H_2O lower within session, Q_{max} and between sessions ns			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

Hashim 2007 Multinational Eur Urol 2007;52:1186-93		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria Drug trial, LUTS suggestive of BOO, IPSS >11, Q_{max} <12 ml/s, prostate volume >30 ml, 51–84 years **Exclusion criteria** Residual urine >250 ml, PSA <1.5 or >10.0, previous surgery, acute urinary retention, urethral manipulation or drug treatment short time before study			**Execution index test** Transurethral 6 Ch catheter, rectal balloon with hole, local and central review of curves, BOOI, BCI **Execution reference test** --
Number	114		**Definition reference test** --
Exclusions	29		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Same session		**True negatives** --
Verification bias	--		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	--		**Specificity** --
Reliability ICC BOOI 0.76, BCI 0.75, BOOI 4.6 and BCI 8.0 lower at 2nd measurement			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results ICC calculated from table			**Comments** --

Ignjatovic 1997 Yugoslavia Int Urol Nephrol 1997;29:653-60		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** IPSS <8
Inclusion criteria Moderate-severe symptoms, enlarged prostate, TURP **Exclusion criteria** Not stated			**Execution index test** Transurethral 9 or 6 Ch catheter **Execution reference test** IPSS
Number	48		**Definition reference test** --
Exclusions	Not stated		**Cut off value** Not stated
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	6 months		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.50
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results	Success 63% conventional, 86% IPSS+ Q_{max}, 90% pQ		**Correlation** --
Comments results Obstruction not defined			**Comments** --

Javlé 1998 United Kingdom J Urol 1998;160:1713-7	**Study quality**	**Index test** Pressure-flow measurement **Reference test** Improvement in IPSS, Q_{max} and PVR
Inclusion criteria TURP, IPSS >12, Q_{max} <13 ml/s, residual urine 60–300 ml, 55–85 years **Exclusion criteria** Prostate cancer, PSA > 4, previous surgery, neurogenic bladder		**Execution index test** 5 + 8 Ch urethral catheters, rectal balloon ccatheter, Schäfer obstruction grade and contractility **Execution reference test** IPSS <50% and/or <7, Q_{max} >50% and >15 ml/s, PVR >50% and <60 ml

Number	55	**Definition reference test**	--
Exclusions	2	**Cut off value**	Schäfer grade 2–3
Consecutive	Not stated	**True positives**	22
Demographic description	Yes	**False positives**	5
Uninterpretable results	Not stated	**False negatives**	9
Time interval	3 months	**True negatives**	17
Verification bias	Yes	**Prevalence**	0.58
Index test independent	Not stated	**Sensitivity**	0.71
Reference test independent	Not stated	**Specificity**	0.77
Reliability --		**LR+**	3.12
		LR–	0.38
		Area under ROC curve	--
Other results		**Correlation**	--
Comments results Short follow-up		**Comments** --	

Knutson 2001 Sweden Scand J Urol Nephrol 2001;35:463-9	**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** New treatment		
Inclusion criteria Patients with low resistance accepting watchful waiting and patients with moderate-severe obstruction electing watchful waiting **Exclusion criteria** Not stated		**Execution index test** Classification with DAMPF, otherwise not described **Execution reference test** Treatment		
Number	37	**Definition reference test**	--	
Exclusions	0	**Cut off value**	43	65
Consecutive	Yes	**True positives**	17	8
Demographic description	Yes	**False positives**	6;	15
Uninterpretable results	Not stated	**False negatives**	4	1
Time interval	4 years	**True negatives**	10	13
Verification bias	Yes	**Prevalence**	0.62	
Index test independent	Not stated	**Sensitivity**	0.74	0.35
Reference test independent	Not stated	**Specificity**	0.71	0.93
Reliability --		**LR+**	2.6	4.9
		LR–	0.37	0.70
		Area under ROC curve	--	
Other results		**Correlation**	--	
Comments results --		**Comments** --		

Kortmann 2000 Multinational Neurourol Urodyn 2000;19:221-32	**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria Pretreatment pressure-flow studies **Exclusion criteria** Not stated		**Execution index test** 8 Ch urethral catheter, one half microtip and one half fluidfilled, 8 Ch microtip or balloon catheter for rectal pressure, rotating disc flowmeter, Urodyn 2000 or own computer program, 6 examiners **Execution reference test** --

Number	200	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	--	**Prevalence**	--
Index test independent	Yes	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability SD AG-number intraexam 10.0, interexamin 3.7, combined 10.7 cm H_2O		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--

Comments results --	**Comments** --

Kranse 2003 The Netherlands Urology 2003;61:930-4; discussion 934-5	**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria Unselected males performing pressure-flow studies **Exclusion criteria** Not stated		**Execution index test** Fluid-filled catheters, rotating disc flowmeter **Execution reference test** --

Number	131	**Definition reference test**	--
Exclusions	0	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	0 days	**True negatives**	--
Verification bias	--	**Prevalence**	0.29
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability SD Q_{max} 2.0 ml/s, $p_{det\ Qmax}$ 8.9, BOOI 9.7, W20 1.85		**LR+** **LR-** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results Calculated from SE of differences		**Comments** --	

Kuo 1993 Taiwan Eur Urol 1993;24:12-9.		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** Outcome of surgery
Inclusion criteria Diagnosis of BPH and operated, with and without a catheter, 45–96 years (TURP 335, open op 16, TUIP 49) (202 cystometry, 146 voiding pressure) **Exclusion criteria** Not stated			**Execution index test** Infusion rate 50 ml/s, included UPP **Execution reference test** Patient satisfied with voiding condition, improved irritative symptoms and Q_{max} >15 ml/s
Number	400		**Definition reference test** --
Exclusions	Not stated		**Cut off value** Maximum detrusor contraction pressure >50 cm H_2O
Consecutive	Yes		**True positives** 107
Demographic description	No		**False positives** 11
Uninterpretable results	Not stated		**False negatives** 23
Time interval	Not stated		**True negatives** 5
Verification bias	Yes		**Prevalence** 0.81
Index test independent	Not stated		**Sensitivity** 0.82
Reference test independent	Not stated		**Specificity** 0.31
Reliability --			**LR+** 1.20 **LR-** 0.57 **Area under ROC curve** -- **Correlation** --
Other results			
Comments results Wide definition of obstruction, high prevalence of obstruction			**Comments** --

Madsen 1995 USA Urology 1995;46:816-20	**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria Symptoms of BPH, screening for drug trial **Exclusion criteria** Not stated		**Execution index test** Suprapubic and transurethral 4 Ch catheter, rectal pressure, Menuet Dantec, curves read manually **Execution reference test** --

Number	25	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Same session	**True negatives**	--
Verification bias	--	**Prevalence**	--
Index test independent	Yes	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability SD_{Qmax} 1.44, $p_{det\ Qmax}$ 8.84		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results SD calculated from percentiles		**Comments** --	

Radomski 1995 Canada J Urol 1995;153:685-8		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** Voding without catheter postoperatively
Inclusion criteria Acute urinary retention, 50–85 years **Exclusion criteria** Chronic retention, neurologic disease, suspicion of prostate cancer, previous prostatic surgery			**Execution index test** Within 2 weeks after retention, multichannel **Execution reference test** Voiding without catheter after prostatectomy
Number	50		**Definition reference test** --
Exclusions	0		**Cut off value** p_{det} opening 50 cm H_2O
Consecutive	Yes		**True positives** 19
Demographic description	No		**False positives** 1
Uninterpretable results	Not stated		**False negatives** 8
Time interval	3 months		**True negatives** 1
Verification bias	Yes		**Prevalence** 0.93
Index test independent	Not stated		**Sensitivity** 0.70
Reference test independent	Not stated		**Specificity** 0.50
Reliability --			**LR+** 1.4 **LR–** 0.59 **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

Rodrigues 2001 Brazil J Urol 2001;165:499-502	**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** IPSS and bother question
Inclusion criteria Symptoms suggestive of obstruction, worsening at clinical follow-up or following drug treatment, 51–91 years **Exclusion criteria** Not stated		**Execution index test** Transurethral with peridural catheter, groups according to $p_{detQmax}$, performed day before surgery without influencing treatment decision **Execution reference test** Change in IPSS and bother question

Number	277	**Definition reference test**	--
Exclusions	40	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.58
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0,9 for group means
Comments results Almost no improvement if $p_{detQmax}$ <40 cm H_2O		**Comments** --	

Rosier 1995 The Netherlands J Urol 1995;153:1520-5	**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria Untreated BPH patients or evaluation after treatment **Exclusion criteria** Not stated		**Execution index test** Transuretral and rectal 8 Ch catheters, microtips, own computer program **Execution reference test** --

Number	91	**Definition reference test**	--
Exclusions	16	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Same session	**True negatives**	--
Verification bias	--	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Mean absolute diff Q_{max} 1.2; $p_{detQmax}$ 10.2; URA 5.8		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Sonke 2000 The Netherlands Neurourol Urodyn 2000;19:637-51; discussion 651-6		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria LUTS suggestive of BOO, living in neighbourhood **Exclusion criteria** Medication, severe problems during first examination			**Execution index test** 8 Ch microtip transducers, MTC Dräger, Dantec Urodyn Flowmeter, AG-number **Execution reference test** --
Number	89		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	<4 weeks		**True negatives** --
Verification bias	--		**Prevalence** 0.28
Index test independent	Not stated		**Sensitivity** --
Reference test independent	--		**Specificity** --
Reliability AG-number intraindividuell sd 14,URA 7, $p_{detQmax}$ 12 och Q_{max} 2			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

Tammela 1999 Multinational Neurourol Urodyn 1999;18:17-24		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria LUTS due to benign prostatic enlargement **Exclusion criteria** Previous LUTS disease except BPE, previous treatment			**Execution index test** Suprapubic catheter, 12 Ch rectal balloon catheter, three voidings **Execution reference test** --
Number	216		**Definition reference test** --
Exclusions	29		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	0 days		**True negatives** --
Verification bias	--		**Prevalence** 0.63
Index test independent	Not stated		**Sensitivity** --
Reference test independent	--		**Specificity** --
Reliability SD $p_{detQmax}$ 10.6; 12.5; 14.5%. Interobserver 0.92; 0.94; 0.96			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results SD calculated from SE of pairwise differences			**Comments** --

Tanaka 2006 Japan Int J Urol 2006;13:1398-404		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** Outcome after TURP		
Inclusion criteria LUTS/BPH considered appropriate candidates for TURP, age >50 years **Exclusion criteria** Prostate cancer, urinary retention, previous prostatic surgery			**Execution index test** 18 gauge suprapubic catheter, rectal balloon catheter, filling with Foley catheter **Execution reference test** Outcome of TURP according to Homma, symptom, bother question and Qmax		
Number	92		**Definition reference test**	Excellent; good; fair; poor/worse	
Exclusions	Not stated		**Cut off value**	Schäfer grade $^{3}/_{4}$	Schäfer grade ½
Consecutive	Not stated		**True positives**	11;15;15	30;47;49
Demographic description	Yes		**False positives**	30;55;65	11;23:31
Uninterpretable results	Not stated		**False negatives**	6;2;2	25;8;6
Time interval	3 months post surger		**True negatives**	45;20;10	26;14;6
Verification bias	Unclear		**Prevalence**	0.18	0.53
Index test independent	Not stated		**Sensitivity**	0.65;0.88;0.88	0.55;0.85;0.89
Reference test independent	Not stated		**Specificity**	0.60;0.27;0.13	0.70;0.38;0.16
Reliability --			**LR+**	1.61;1.20;1.02	1.83;1.37;1.06
			LR–	0.59;0.44;0.88	0.65;0.38;0.67
			Area under ROC curve	--	
Other results			**Correlation**	--	
Comments results --			**Comments** --		

Tubaro 1995 Europe J Urol 1995;153:1526-30		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** Madsen-Iversen score >50%; Q_{max} >3 ml/s
Inclusion criteria Madsen-Iversen score >7, Q_{max} <15 ml/s, residual urine <300 ml, bilobar prostatic enlargement, >45 years **Exclusion criteria** Prostate or bladder cancer, neurogenic bladder, pelvic metallic implant, pacemaker, bladder stone, stricture, prostate length <35 mm, pelvic surgery, hemostatis disorder			**Execution index test** Curves read manually by two examiners **Execution reference test** Madsen-Iversen score, Q_{max}
Number	100		**Definition reference test** --
Exclusions	Not stated		**Cut off value** Constrictive vs compressive
Consecutive	Not stated		**True positives** 19; 25
Demographic description	No		**False positives** 10; 4
Uninterpretable results	Not stated		**False negatives** 11; 6
Time interval	6 months		**True negatives** 60; 65
Verification bias	Unclear		**Prevalence** 0.30; 0.31
Index test independent	Yes		**Sensitivity** 0,63; 0.81
Reference test independent	Not stated		**Specificity** 0.86; 0.94
Reliability --			**LR+** 3.3; 14.8 **LR–** 0.45; 0.15 **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

Turner 1998 USA Tech Urol 1998;4:136-40	**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** IPSS improvement >50%
Inclusion criteria LUTS presumed to be caused by BPH, IPSS >9 **Exclusion criteria** Previous surgery, prostate cancer, stricture, finasteride within 6 months, alpha-blocker within 1 month		**Execution index test** Transurethral 8 Ch catheter, 14 Ch rectal catheter, AG-number **Execution reference test** Outcome of doxazosin treatment, IPSS >50% improvement

Number	50	**Definition reference test**	--
Exclusions	6	**Cut off value**	AG number >40 cm H_2O
Consecutive	Not stated	**True positives**	15
Demographic description	No	**False positives**	17
Uninterpretable results	Not stated	**False negatives**	7
Time interval	3 months	**True negatives**	5
Verification bias	Yes	**Prevalence**	0.50
Index test independent	Not stated	**Sensitivity**	0.68
Reference test independent	Not stated	**Specificity**	0.23
Reliability --		**LR+**	0.88
		LR–	1.4
		Area under ROC curve	--
Other results		**Correlation**	--

Comments results --	**Comments** --

Valentini 2005 France, Canada, USA Ann Readapt Med Phys 2005;48(1):11-9.	**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria BPH, TURP or drug trial, 45–86 years **Exclusion criteria** Voided volume <100ml, Q_{max} <2 ml/s, urethral catheter falling out		**Execution index test** 6 or 7 Ch transurethral catheter, Aquarius, Laborie or Menuet, Medtronic **Execution reference test** --

Number	71	**Definition reference test**	--
Exclusions	26	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Excluded	**False negatives**	--
Time interval	0	**True negatives**	--
Verification bias	No	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability AG-number 3 cm H_2O lower at second measurement. SD 13.7 cm H_2O.		**LR+** **LR-** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Witjes 1996 The Netherlands J Urol 1996;156:1026-34		**Study quality** Moderate	**Index test** Pressure-flow measurement **Reference test** --
Inclusion criteria Consecutive patients with LUTS and BPH managed with watchful waiting, 64 years SD 8 **Exclusion criteria** Not stated			**Execution index test** Transurethral and rectal 8 Ch catheters, microtips, PURR, URA **Execution reference test** --
Number	178		**Definition reference test** --
Exclusions	57		**Cut off value** --
Consecutive	Yes		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	6 months		**True negatives** --
Verification bias	No		**Prevalence** 0.53
Index test independent	Not stated		**Sensitivity** --
Reference test independent	--		**Specificity** --
Reliability Mean absolute difference Q_{max} 2.3, $p_{det\ Qmax}$ 15.6, URA 7.6, $p_{det\ Qmax}$ 3.7 lower sign, Q_{max} and URA ns			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

4.3 Flödesmätning

<table>
<tr><td colspan="2">Abrams 1977 USA
J Urol 1977;117:70-1</td><td>Study quality
Moderate</td><td colspan="2">Index test
Flow measurement
Reference test
Subjective outcome, flow measurement postoperatively</td></tr>
<tr><td colspan="3">Inclusion criteria
TURP or retropubic prostatectomy, benign histology

Exclusion criteria
Not stated</td><td colspan="2">Execution index test
E.M.T. 435, Elema-Schönander, M. 81 Mingograf recorder, voided volume not stated, visual inspection

Execution reference test
Subjective outcome, symptom score, Qmax postoperatively</td></tr>
<tr><td>Number</td><td>53 (33+20)</td><td rowspan="9"></td><td>Definition reference test</td><td>Unimproved symptom score or Q_{max}</td></tr>
<tr><td>Exclusions</td><td>Not stated</td><td>Cut off value</td><td>Not stated</td></tr>
<tr><td>Consecutive</td><td>Not stated</td><td>True positives</td><td>Not stated</td></tr>
<tr><td>Demographic description</td><td>Yes</td><td>False positives</td><td>Not stated</td></tr>
<tr><td>Uninterpretable results</td><td>Not stated</td><td>False negatives</td><td>Not stated</td></tr>
<tr><td>Time interval</td><td>3 and 12 months</td><td>True negatives</td><td>Not stated</td></tr>
<tr><td>Verification bias</td><td>Yes</td><td>Prevalence</td><td>Not stated</td></tr>
<tr><td>Index test independent</td><td>Not stated</td><td>Sensitivity</td><td>Not stated</td></tr>
<tr><td>Reference test independent</td><td>Not stated</td><td>Specificity</td><td>Not stated</td></tr>
<tr><td colspan="2" rowspan="2">Reliability</td><td>LR+</td><td>Not stated</td></tr>
<tr><td>LR–</td><td>Not stated</td></tr>
<tr><td colspan="2"></td><td>Area under ROC curve</td><td>--</td></tr>
<tr><td colspan="2">Other results</td><td colspan="2">Mean Q_{max} preop 8.0, unimproved symptom score 11.0, unimproved Q_{max} 10.5 ml/s, differences sign</td><td>Correlation</td><td>--</td></tr>
<tr><td colspan="3">Comments results
47 cured or better, 5 unimproved, 2 worse</td><td colspan="2">Comments
--</td></tr>
</table>

Barry 1995 USA J Urol 1995;153:99-103	**Study quality** Moderate	**Index test** Flow measurement **Reference test** --
Inclusion criteria Placebo group of finasteride study, LUTS, enlarged prostate, Q_{max} <15 ml/s, voided volume >150 ml, residual urine <350 ml **Exclusion criteria** Evidence of prostate cancer, infection, prostatitis, neurogenic bladder		**Execution index test** UroDyn 1000, Dantec, voided volume >150 ml, visual inspection not stated **Execution reference test** --

Number	300	**Definition reference test**	--
Exclusions	69	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	2 weeks	**True negatives**	--
Verification bias	--	**Prevalence**	Not stated
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability m2-m1=-0,1 ml/s. Intraclass corr coeff 0,68. SD within subjects 2.79 ml/s. 80% within +3.6 och -3.8 ml/s		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results	--	**Correlation**	--

Comments results --	**Comments** --

Boci 1999 Sweden Neurourol Urodyn 1999;18:25-32		**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow measurement
Inclusion criteria Symptomatic BPH, 54–82 years **Exclusion criteria** Prostate cancer, stricture, previous urological or pelvic surgery			**Execution index test** Office UFS 1005, NEC, portable flowmeter PUFS 2000, MMS, manually read curves **Execution reference test** 5 Ch urethral and 12 Ch rectal catheters, LinPURR
Number	25		**Definition reference test** DAMPF <56 cm H_2O
Exclusions	1 no pressure-flow		**Cut off value** 10 ml/s; 14 ml/s
Consecutive	Not stated		**True positives** 7; 17
Demographic description	Yes		**False positives** 0; 2
Uninterpretable results	Excluded		**False negatives** 10; 0
Time interval	Not stated		**True negatives** 7; 5
Verification bias	Unclear		**Prevalence** 0.71
Index test independent	Not stated		**Sensitivity** 0.41; 1.00
Reference test independent	Not stated		**Specificity** 1.00; 0.71
Reliability --			**LR+** Infinite; 3.50 **LR-** 0.59; 0.00 **Area under ROC curve** --
Other results			**Correlation** -0,62 P
Comments results Mean Q_{max} of home flow rates analysed			**Comments** 459 flows analysed, 56 with artefacts

Botker-Rasmussen 1999 Denmark Neurourol Urodyn 1999;18:545-51; discussion 551-2	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow study

Inclusion criteria Volunteers, no LUTS when interviewed carefully, age 51–85	**Execution index test** Urodyn 1000, Dantec, standing
Exclusion criteria Past or present urological complaints	**Execution reference test** 5 Ch transurethral catheter, saline, 50 ml/min, Menuet or DISA URO-system 21F16 2100, Dantec or Urodyn 1000, Dantec, Abrams-Griffiths nomogram

Number	29	**Definition reference test**	Abrams-Griffiths nomogram	
Exclusions	Not stated	**Cut off value**	10 ml/s	15ml/s
Consecutive	Yes	**True positives**	5	9
Demographic description	Yes	**False positives**	0	8
Uninterpretable results	Not stated	**False negatives**	10	6
Time interval	0 days	**True negatives**	14	6
Verification bias	Yes	**Prevalence**	0.52	
Index test independent	Not stated	**Sensitivity**	0.33	0.60
Reference test independent	Not stated	**Specificity**	1.00	0.43
		LR+	Infinite	1.05
		LR–	0.67	0.53
		Area under ROC curve	--	
		Correlation	--	

Reliability --	**Other results**
Comments results --	**Comments** --

Caffarel 2008 Great Britain Neurourol Urodyn 2008;27:797-801		**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow study
Inclusion criteria Pressure-flow study, attendees at a LUTS clinic, performed flow measurement and at least 2 of IPSS, IPSS bother question, prostate specific antigen and postvoid residual urine **Exclusion criteria** Voided volume at flow measurement <150 ml, performed less than two IPSS, IPSS bother question, PSA and PVR			**Execution index test** Voided volume >150 ml **Execution reference test** According to Good Urodynamic Practise
Number	95		**Definition reference test** BOOI 20; 40 cm H_2O
Exclusions	45		**Cut off value** 11.7 ml/s
Consecutive	Not stated		**True positives** 16; 8
Demographic description	No		**False positives** 19; 10
Uninterpretable results	Not stated		**False negatives** 2; 3
Time interval	Not stated		**True negatives** 13; 29
Verification bias	Unclear		**Prevalence** 0.36; 0.22
Index test independent	Not stated		**Sensitivity** 0.89; 0.73
Reference test independent	Not stated		**Specificity** 0.41; 0.74
Reliability --			**LR+** 1.5; 2.8 **LR–** 0.27; 0.37 **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

Comiter 1996 USA Urology 1996;48:723-9; discussion 729-30	**Study quality** Moderate	**Index test** Flow measurement **Reference test** MUPP, >10 cm H_2O obstructed
Inclusion criteria Adult men with LUTS performing multiple videourodynamics, Q_{max}, piso or MUPP gradient not missing, mean age 68.3 years **Exclusion criteria** Bladder cancer, hematuria, spinal cord injury, Parkinson's disease, multiple sclerosis		**Execution index test** Standing **Execution reference test** Filling with radiocontrast, 10 Ch triple lumen catheter, gradient >10 cm H_2O obstructed

Number	205	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	12 ml/s
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	0 days	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.50
Index test independent	Not stated	**Sensitivity**	0.78
Reference test independent	Not stated	**Specificity**	0.74
Reliability --		**LR+**	3.0
		LR–	0.30
		Area under ROC curve	--
Other results		**Correlation**	-0.48
Comments results Wide definition of obstruction		**Comments** --	

D'Ancona 1999 The Netherlands Prostate Cancer Prostatic Dis 1999;2:98-105		**Study quality** Moderate	**Index test** Flow measurement **Reference test** IPSS, flow rate or resistance after TUMT
Inclusion criteria Treatment with TUMT, >45 years, PV >30 ml, Madsen SS >7, Q_{max} <15 ml/s, PVR <350 ml **Exclusion criteria** Neurogenic disorders, prostatic cancer, earlier surgery, indwelling catheter, median lobe			**Execution index test** Voided volume >100 ml, otherwise not described **Execution reference test** Either IPSS, Q_{max} or LinPURR at 26 weeks
Number	247		**Definition reference test** --
Exclusions	At least 26		**Cut off value** Nr
Consecutive	Yes		**True positives** Nr
Demographic description	Yes		**False positives** Nr
Uninterpretable results	Not stated		**False negatives** Nr
Time interval	Nr		**True negatives** Nr
Verification bias	Yes		**Prevalence** Nr
Index test independent	Not stated		**Sensitivity** Nr
Reference test independent	Not stated		**Specificity** Nr
Reliability --			**LR+** Nr **LR–** Nr **Area under ROC curve** --
Other results			**Correlation** OR IPSS ns; Q_{max} 1,14; pQ ns, multip regr ns; ns
Comments results Q_{max} only prognostic for flow rate response and not when LinPURR is included in analysis			**Comments** --

Dib 2008 Brazil Urol Int 2008;80:378-82. Epub 2008 Jun 27		**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow study
Inclusion criteria LUTS, diabetes, age 47–86 years **Exclusion criteria** Prostate cancer, bladder stones or tumour, previous surgery, renal failure, pelvic radiation, neurological disease			**Execution index test** Q_{max}, method not described **Execution reference test** Pressure-flow study, according to ICS Schäfer grade >=2 obstructed
Number	50		**Definition reference test** Schäfer grade >=2 obstructed
Exclusions	0		**Cut off value** 10 ml/s; 12 ml/s; 15 ml/s
Consecutive	Yes		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Yes		**Prevalence** 0.46
Index test independent	Not stated		**Sensitivity** 0.57; 0.70; 0.83
Reference test independent	Not stated		**Specificity** 0.11; 0.15; 0.48
Reliability --			**LR+** 5.2; 4.7; 1.7 **LR–** 0.48; 0.35; 0.33 **Area under ROC curve** --
Other results			**Correlation** --
Comments results Wide definition of obstruction, only diabetics			**Comments** --

Dorflinger 1986 USA Urology 1986;27:569-73		**Study quality** Low	**Index test** Flow measurement **Reference test** Pressure-flow, subjective outcome of TURP
Inclusion criteria TURP, indication om non-urodynamic data, 50–91 years **Exclusion criteria** Prostate cancer, prostatic or pelvic surgery, serious neurologic or psychiatric disease. Stricture and infection temporarily excluded			**Execution index test** Not described **Execution reference test** 8.3 Ch urethral and 18 Ch rectal catheter, water, resistance=$_{pdet/Qmax}$ 2. Subjective outcome graded 1–5
Number	84		**Definition reference test** --
Exclusions	30		**Cut off value** 7 ml/s
Consecutive	Not stated		**True positives** Not stated
Demographic description	Yes		**False positives** Not stated
Uninterpretable results	Not stated		**False negatives** Not stated
Time interval	0 days, 12 months		**True negatives** Not stated
Verification bias	Unclear		**Prevalence** Not stated
Index test independent	Not stated		**Sensitivity** Not stated
Reference test independent	Not stated		**Specificity** Not stated
Reliability --			**LR+** Not stated **LR–** Not stated **Area under ROC curve** --
Other results	100 (<7) and 84% (>7) better or much better, ns		**Correlation** --
Comments results Why not cut-off at 10.5 ml/s?			**Comments** Subdivision in groups of 18 (Q_{max} <7) and 66 (>7) patients. Many exclusions and size of small group at 12 months not stated

DuBeau 1998 USA J Am Geriatr Soc 1998;46:1118-24		**Study quality** Moderate	**Index test** Flow measurement **Reference test** Micturitional urethral pressure profile	
Inclusion criteria LUTS patients, community-dwelling or institutional older men, >51 years **Exclusion criteria** Gross hematuria, urinary retention, inability to void, prostate or bladder cancer, stricture, neurologic disorder, dementia			**Execution index test** Not described, Q_{max} was read manually **Execution reference test** As described previously, videourodynamics including MUPP and UPP	
Number	111		**Definition reference test**	Pressure drop >10 cm H_2O
Exclusions	12 incomplete data		**Cut off value**	10 ml/s; <2 SD in Siroky nomogram
Consecutive	No		**True positives**	37 --
Demographic description	Yes		**False positives**	9 --
Uninterpretable results	Not stated		**False negatives**	3 --
Time interval	Not stated		**True negatives**	23 --
Verification bias	Yes		**Prevalence**	0.68
Index test independent	Yes		**Sensitivity**	0.55 0.72
Reference test independent	Yes		**Specificity**	0.72 0.50
Reliability --			**LR+** **LR–**	1.96 -- 0.62 --
Other results	--		**Area under ROC curve** **Correlation**	-- --
Comments results An algoritm with Q_{max}, age and PVR much better			**Comments** --	

Hansen 1997 Sweden Eur Urol 1997;32:34-8		**Study quality** Moderate	**Index test** Flow measurement **Reference test** Outcome after TURP or TUMT
Inclusion criteria Treatment with TURP or TUMT **Exclusion criteria** None			**Execution index test** Dantec Urodyn 2000, patients not voiding >100 ml excluded, manual reading not stated **Execution reference test** 2 questions, much better-much worse, treatment still needed
Number	172, 110 TURP 62 TUMT		**Definition reference test** --
Exclusions	Not stated		**Cut off value** Nr
Consecutive	Not stated		**True positives** Nr
Demographic description	No		**False positives** Nr
Uninterpretable results	Not stated		**False negatives** Nr
Time interval	Nr		**True negatives** Nr
Verification bias	Yes		**Prevalence** Not stated
Index test independent	Not stated		**Sensitivity** Nr
Reference test independent	Not stated		**Specificity** Nr
Reliability --			**LR+** Nr **LR–** Nr **Area under ROC curve** --
Other results			**Correlation** Q_{max} before 0.07; after 0.35; difference 0.27 S
Comments results --			**Comments** --

Hong 2003 South Korea Eur Urol 2003;44:94-9; discussion 99-100	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Not satisfied with continuing medical therapy, surgery
Inclusion criteria LUTS, diagnosis of BPH, medication at least 3 months **Exclusion criteria** Prostate cancer, previous surgery, other condition affecting urinary tract, severe disease		**Execution index test** Q_{max}, Dantec Urodyn 1000 **Execution reference test** Not satisfied with continuing medical therapy, surgery
Number 437 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** Yes **Uninterpretable results** Not stated **Time interval** Not relevant **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** 0.23 **Sensitivity** -- **Specificity** -- **LR+** Multivariate Hazard ratio 0.97 ns **LR–** -- **Area under ROC curve** -- **Correlation** --
Reliability --		
Other results		
Comments results Age, IPSS and prostate volume sign		**Comments** --

Ignjatovic 1997 Yugoslavia Int Urol Nephrol 1997;29:653-60	**Study quality** Moderate	**Index test** Flow measurement **Reference test** IPSS <8
Inclusion criteria LUTS, enlarged prostate, candidate for TURP **Exclusion criteria** Not stated		**Execution index test** Strong desire to void, 2 measurements and the highest value selected **Execution reference test** Transurethral examination with a 9 Ch dubble lumen catheter or two 6 Ch catheters, Schäfer nomogram

Number	48	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	10 ml/s
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.63
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+**	Low Q_{max} sign better outcome
		LR–	--
		Area under ROC curve	--
Other results		**Correlation**	--
Comments results --		**Comments** --	

Itoh 2006 Japan Int J Urol 2006;13:1058-65	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Nr
Inclusion criteria 50–88 years, LUTS, completed examinations **Exclusion criteria** Prostate cancer, stricture, other LUTS diseases		**Execution index test** TU 1067C, Takei, vv >99 ml, manual reading not stated **Execution reference test** Nr

Number	13 of 206 + 13	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	Nr
Consecutive	Not stated	**True positives**	Nr
Demographic description	Not for the 13 + 13	**False positives**	Nr
Uninterpretable results	Not stated	**False negatives**	Nr
Time interval	Not stated	**True negatives**	Nr
Verification bias	Nr	**Prevalence**	Nr
Index test independent	Not stated	**Sensitivity**	Nr
Reference test independent	Nr	**Specificity**	Nr
Reliability Q_{max} r=0,812, Qave r=0,890		**LR+** **LR–** **Area under ROC curve**	Nr Nr --
Other results		**Correlation**	0.812 S

Comments results Qave 0.890 S	**Comments** Only reproducibility

Jepsen 1998 USA J Urol 1998;160:1689-94		**Study quality** Moderate	**Index test** Flow measurement **Reference test** Nr
Inclusion criteria The placebo group of a finasteride study, LUTS, enlarged prostate, Q_{max} <15 ml/s, voided volume >150 ml, residual urine <350 ml **Exclusion criteria** Elevated creatinine or liver enzymes, severe allergy, previous surgery, drug or alcohol abuse, prostate cancer, stricture, infection, neurologic disorder			**Execution index test** Not described **Execution reference test** Nr
Number	300		**Definition reference test** --
Exclusions	16		**Cut off value** Nr
Consecutive	Not stated		**True positives** Nr
Demographic description	Yes		**False positives** Nr
Uninterpretable results	Not stated		**False negatives** Nr
Time interval	1 week		**True negatives** Nr
Verification bias	Yes		**Prevalence** Not stated
Index test independent	Not stated		**Sensitivity** Nr
Reference test independent	Not stated		**Specificity** Nr
Reliability Q_{max} increases with several measurements. Graph of measurement 1 and 2, but no value of reliability			**LR+** Nr **LR-** Nr **Area under ROC curve** --
Other results			**Correlation** Nr
Comments results 1st flow range 2nd flow; 3 3–10; 5 3.5–15; 7 3–13; 9 4–14; 11 5–19; 13 6.5–15, values from graph			**Comments** --

Ko 1995 Canada J Urol 1995;154:396-8	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow measurement, Schäfer grade
Inclusion criteria Symptoms of prostatism, 67.9 years **Exclusion criteria** Not stated		**Execution index test** Q_{max}, method not described **Execution reference test** Pressure-flow study, 8 Ch transurethral catheter, manual reading, Schäfer grade
Number 121 **Exclusions** 18 **Consecutive** Yes **Demographic description** No **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** No **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** 0.17
Reliability -- **Other results**		
Comments results Pearson correlation coefficient		**Comments** --

Kranse 2002 The Netherlands Eur Urol 2002;42:506-15	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow, ICS, LinPURR >=2
Inclusion criteria Performed pressure-flow study and had a free flow rate performed before **Exclusion criteria** None		**Execution index test** Dantec 1000 with 5 Hz low pass filter **Execution reference test** Same flowmeter, 0.6 s time lag

Number	131	**Definition reference test**	--
Exclusions	42 no free flow	**Cut off value**	15 ml/s
Consecutive	Yes	**True positives**	Nr
Demographic description	No	**False positives**	Nr
Uninterpretable results	Not stated	**False negatives**	Nr
Time interval	Same day	**True negatives**	Nr
Verification bias	Yes	**Prevalence**	Not stated
Index test independent	Not stated	**Sensitivity**	Nr
Reference test independent	Not stated	**Specificity**	Nr
Reliability --		**LR+** **LR–**	Nr Nr
		Area under ROC curve	--
Other results		**Correlation**	>15 ml/s low risk obstruction
Comments results 21% of pressure-flow studies can be avoided, 5% of obstruction may be missed		**Comments** --	

Kuo 1993 Taiwan Eur Urol 1993;24:12-9		**Study quality** Moderate	**Index test** Flow measurement **Reference test** Outcome of surgery
Inclusion criteria Diagnosis of BPH and operated, with and without a catheter, 45–96 years (TURP 335, open op 16, TUIP 49) (flow measurement 217) **Exclusion criteria** Not stated			**Execution index test** Q_{max} and flow pattern were evaluated **Execution reference test** Patient satisfied with voiding condition, improved irritative symptoms and Q_{max} >15 ml/s
Number	400		**Definition reference test** --
Exclusions	Not stated		**Cut off value** Q_{max} 10 ml/s; 15 ml/s
Consecutive	Yes		**True positives** 129; 168
Demographic description	No		**False positives** 18; 38
Uninterpretable results	Not stated		**False negatives** 45; 6
Time interval	Not stated		**True negatives** 35; 15
Verification bias	Yes		**Prevalence** 0.81
Index test independent	Not stated		**Sensitivity** 0.74; 0.97
Reference test independent	Not stated		**Specificity** 0.66; 0.28
Reliability --			**LR+** 2.18; 1.35 **LR–** 0.39; 0.12 **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

Kuo 1999 Taiwan Urology 1999;54:90-6	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow, $p_{detQmax}$ $p_{detQmax}$ >50 cm H_2O, Q_{max} <15 ml/s, if low pressure and low Q_{max} video
Inclusion criteria LUTS, 45–88 years, prostate volume <60 ml **Exclusion criteria** Acute urinary retention, neuropathy, diabetes, acute infection, previous TURP		**Execution index test** Highest of free flow rate and during pressure-flow study. Not described **Execution reference test** First 7 Ch transurethral catheter which was changed to suprapubic, 10 Ch rectal balloon, video, EMG, 20% urographin in saline

Number	324	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	10 ml/s; 15 ml/s
Consecutive	Yes	**True positives**	135; 179
Demographic description	Yes	**False positives**	44; 75
Uninterpretable results	Not stated	**False negatives**	77; 33
Time interval	0 days	**True negatives**	68; 37
Verification bias	Yes	**Prevalence**	0.65
Index test independent	Not stated	**Sensitivity**	0.64; 0.84
Reference test independent	Not stated	**Specificity**	0.61; 0.33
Reliability --		**LR+**	1.62; 1.26
		LR–	0.60; 0.47
		Area under ROC curve	--
Other results		**Correlation**	--

Comments results Wide definition of obstruction	**Comments** --

Marya 1992 India Urol Int 1992;48:307-9	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Postoperative retention
Inclusion criteria Men scheduled for abdominal, perineal or scrotal surgery, 51–76 years **Exclusion criteria** Not stated		**Execution index test** DISA 2100 Urosystem, voided volume >150 ml **Execution reference test** Postoperative retention

Number	500	**Definition reference test**	--
Exclusions	0	**Cut off value**	6 ml/s; 10 ml/s; 15 ml/s
Consecutive	Yes	**True positives**	7; 19; 56
Demographic description	No	**False positives**	0; 26; 342
Uninterpretable results	Not stated	**False negatives**	51; 39; 2
Time interval	Not stated	**True negatives**	442; 416; 100
Verification bias	Yes	**Prevalence**	0.12
Index test independent	Not stated	**Sensitivity**	0.12; 0.33; 0.97
Reference test independent	Not stated	**Specificity**	1.0; 0.94; 0.23
Reliability --		**LR+**	Infinite; 5.6; 1.25
		LR–	0.88; 0.71; 0.15
		Area under ROC curve	--
Other results		**Correlation**	--
Comments results --		**Comments** --	

Matzkin 1993 USA Br J Urol 1993;72:181-6	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Nr
Inclusion criteria Placebo group in drug trial, 56–79 years, prostatism, prostate volume >30 g, Q_{max} <15 ml/s **Exclusion criteria** Prostate cancer, serious neurological disease, stricture		**Execution index test** Dantec-1000, visual inspection **Execution reference test** Nr

Number	26	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	Nr
Consecutive	Not stated	**True positives**	Nr
Demographic description	No	**False positives**	Nr
Uninterpretable results	Not stated	**False negatives**	Nr
Time interval	Nr	**True negatives**	Nr
Verification bias	Nr	**Prevalence**	Not stated
Index test independent	Not stated	**Sensitivity**	Nr
Reference test independent	Nr	**Specificity**	Nr
Reliability		**LR+**	Nr
		LR–	Nr
		Area under ROC curve	--
Other results		**Correlation**	Nr
Comments results Median intraindividual SD 1.95, range 0.8–5.5. Korrelation mean vs SD 0.44 P		**Comments** --	

Reynard 1996 United Kingdom Br J Urol 1996;77:813-8		**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow, ICS normal + equivocal = unobstructed
Inclusion criteria LUTS suggestive of BPO, 50–84 years **Exclusion criteria** Diabetes, infection, Previous surgery, evidence of prostate cancer, medication			**Execution index test** Dantec Urodyn 1000, visual inspection, 4 flows, 17 patients only 3 **Execution reference test** Dantec Menuet or Dantec 5500, 1.1 mm outer diameter urethral catheter, saline
Number	165		**Definition reference test** --
Exclusions	8 no pressure-flow		**Cut off value** 8; 10; 12; 15 ml/s
Consecutive	Yes		**True positives** 17;37;53;76
Demographic description	Yes		**False positives** 1;4;8;24
Uninterpretable results	Excluded		**False negatives** 78;58;42;19
Time interval	Not stated		**True negatives** 61;58;54;38
Verification bias	Yes		**Prevalence** 0.61
Index test independent	Not stated		**Sensitivity** 0.18;0.39;0.56;0.80
Reference test independent	Not stated		**Specificity** 0.98;0.94;0.87;0.61
Reliability			**LR+** 11.09;6.04;4.32;2.07 **LR–** 0.83;0.65;0.51;0.37 **Area under ROC curve** --
Other results			**Correlation** --
Comments results Calculations for best Q_{max} of 3 flows. Figures for best of 1, 3 or 4 in paper. Mean Q_{max} increased for every flow			**Comments** --

Reynard 1998 Europe and Asia Br J Urol 1998;82:619-23	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow, Schäfer grade 0–2 unobstructed
Inclusion criteria LUTS, BPE, >45 (45–88) years **Exclusion criteria** Prostate cancer, neurological disease, diabetes, previous surgery, medication		**Execution index test** 0–3 flows, not described **Execution reference test** Not described, Grading with LinPURR

Number	1 272	**Definition reference test**	--
Exclusions	81 no flow, 339 no pressure-flow	**Cut off value**	10 ml/s; 15 ml/s
Consecutive	No	**True positives**	252; 440
Demographic description	Yes	**False positives**	107; 221
Uninterpretable results	Excluded	**False negatives**	288; 100
Time interval	Not stated	**True negatives**	250; 136
Verification bias	Yes	**Prevalence**	0.60
Index test independent	Not stated	**Sensitivity**	0.47; 0.82
Reference test independent	Not stated	**Specificity**	0.70; 0.38
Reliability		**LR+**	1.56; 1.32
		LR–	0.76; 0.49
		Area under ROC curve	--
Other results		**Correlation**	-0.3, age-corr -0.29 S, volume-corr -0.2 to -0.25

Comments results --	**Comments** --

Schacterle 1996 USA Neurourol Urodyn 1996;15:459-70; discussion 470-2	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Micturitional urethral pressure profile, <10 cm H_2O unobstructed
Inclusion criteria Adult males referred for urodynamics **Exclusion criteria** Neurological disease		**Execution index test** Not described **Execution reference test** Video-urodynamics with MUPP described in reference, dilute contrast

Number	134	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	10; 15 ml/s
Consecutive	Not stated	**True positives**	41; 59
Demographic description	Yes	**False positives**	13; 38
Uninterpretable results	Not stated	**False negatives**	25; 6
Time interval	Not stated	**True negatives**	55; 30
Verification bias	Unclear	**Prevalence**	0.49
Index test independent	Not stated	**Sensitivity**	0.62; 0.89
Reference test independent	Not stated	**Specificity**	0.81; 0.44
Reliability --		**LR+**	3.25; 1.60
		LR–	0.47; 0.24
		Area under ROC curve	--
Other results		**Correlation**	-0.45 P
Comments results --		**Comments** --	

Schou 1993 Denmark Scand J Urol Nephrol 1993;27:489-92	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow study, Abrams-Griffiths diagram
Inclusion criteria Referral for BPH, urodynamic investigation, 38–88 years **Exclusion criteria** Diagnosis of other disease than BPH		**Execution index test** Q_{max}, method not described **Execution reference test** Pressure-flow study, Dantec Urodyn 5500, 3.5 Ch suprapubic cather, rectal balloon, Abrams-Griffiths diagram

Number	54	**Definition reference test**	--
Exclusions	4	**Cut off value**	10 ml/s; 15 ml/s
Consecutive	Yes	**True positives**	23; 30
Demographic description	No	**False positives**	3; 8
Uninterpretable results	Excluded	**False negatives**	12; 5
Time interval	Not stated	**True negatives**	12; 7
Verification bias	No	**Prevalence**	0.70
Index test independent	Not stated	**Sensitivity**	0.66; 0.86
Reference test independent	Not stated	**Specificity**	0.80; 0.47
Reliability --		**LR+**	3.29; 1.61
		LR–	0.43; 0.31
		Area under ROC curve	--
Other results		**Correlation**	--

Comments results --	**Comments** --

Slawin 2006 USA Urology 2006;67:84-8	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Acute urinary retention or BPH-related surgery
Inclusion criteria 3 randomised dutasteride trials, moderate–severe LUTS, prostate volume >30 ml, PSA 1.5–10 ng/ml, >50 years **Exclusion criteria** Not stated		**Execution index test** Q_{max}, method not described **Execution reference test** Acute urinary retention or BPH-related surgery

Number	4325	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	No	**Prevalence**	0.05
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR-** **Area under ROC curve**	Multivariate Hazard ratio 0.60 sign -- --
Other results		**Correlation**	--
Comments results IPSS ns, BII, earlier alfablocker, PV, PSA, Q_{max}, dutasteride sign i multivariatanalys. Q_{max} most important. HR 0,60/ml (0,50–0,73)		**Comments** --	

Sonke 1999 The Netherlands Neurourol Urodyn 1999;18:183-91		**Study quality** Moderate	**Index test** Flow measurement **Reference test** Nr
Inclusion criteria LUTS suggestive of BOO or bladder dysfunction, mean age 62.1 SD 8.7 years **Exclusion criteria** Previous treatment, not able to handle the portable flowmeter			**Execution index test** P-flow portable flowmeter, manually read curves, voided volumes >100 and <150 ml excluded **Execution reference test** Nr
Number	212, 2544 flows		**Definition reference test** --
Exclusions	Not stated		**Cut off value** Nr
Consecutive	Not stated		**True positives** Nr
Demographic description	Yes		**False positives** Nr
Uninterpretable results	Excluded, 18%		**False negatives** Nr
Time interval	Not stated		**True negatives** Nr
Verification bias	Unclear		**Prevalence** Not stated
Index test independent	Not stated		**Sensitivity** Nr
Reference test independent	Nr		**Specificity** Nr
Reliability			**LR+** Nr **LR–** Nr **Area under ROC curve** --
Other results			**Correlation** Nr
Comments results Intraindividual CV 24%			**Comments** 1 854 and 1 378 flow analysed

Sonke 2002 The Netherlands Urology 2002;59:368-72	**Study quality** High	**Index test** Flow measurement **Reference test** Nr
Inclusion criteria Men with LUTS examined with home flowmeter **Exclusion criteria** None		**Execution index test** P-flow portable flowmeter, curves read manually, log-transformed values **Execution reference test** Nr

Number	208	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	Nr
Consecutive	Not stated	**True positives**	Nr
Demographic description	Yes	**False positives**	Nr
Uninterpretable results	Not stated	**False negatives**	Nr
Time interval	Not stated	**True negatives**	Nr
Verification bias	Nr	**Prevalence**	Nr
Index test independent	Not stated	**Sensitivity**	Nr
Reference test independent	Nr	**Specificity**	Nr
Reliability No vol corr between sd=1.48, intraind 1.32. Vol corr between 1.49, intraind 1.26, slope log values mean 0.212, sd of slopes 0.288		**LR+**	Nr
		LR–	Nr
		Area under ROC curve	--
Other results		**Correlation**	--
Comments results		**Comments** --	

Steele 2000 USA J Urol 2000;164:344-8	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow
Inclusion criteria Men with LUTS, mean age 66.7, SD 7.5 years **Exclusion criteria** Previous treatment, neurologic history, co-morbid disease, stricture, prostate cancer		**Execution index test** Not described **Execution reference test** Transurethral catheter 7 Ch, ICS criteria, equivocal classified by slope

Number	204	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	10 ml/s
Consecutive	Not stated	**True positives**	Not stated
Demographic description	Yes	**False positives**	Not stated
Uninterpretable results	Not stated	**False negatives**	Not stated
Time interval	Not stated	**True negatives**	Not stated
Verification bias	Unclear	**Prevalence**	0.25
Index test independent	Not stated	**Sensitivity**	0.73
Reference test independent	Not stated	**Specificity**	0.60
Reliability --		**LR+** **LR–** **Area under ROC curve**	1.83 0.45 --
Other results		**Correlation**	-0.28 P
Comments results --		**Comments** --	

Van de Beek 1997 The Netherlands J Urol 1997;157:164-8		**Study quality** High	**Index test** Flow measurement **Reference test** Nr
Inclusion criteria 21 randomly selected flow curves **Exclusion criteria** Nr			**Execution index test** Dantec Urodyn 1000, 19/21 voided volume >150 ml **Execution reference test** Nr
Number	21+4 duplicates		**Definition reference test** --
Exclusions	Nr		**Cut off value** Nr
Consecutive	Nr		**True positives** Nr
Demographic description	Yes		**False positives** Nr
Uninterpretable results	Nr		**False negatives** Nr
Time interval	Nr		**True negatives** Nr
Verification bias	Nr		**Prevalence** Abnormality 0.81
Index test independent	Yes		**Sensitivity** Nr
Reference test independent	Nr		**Specificity** Nr
Reliability			**LR+** Nr **LR–** Nr **Area under ROC curve** --
Other results			**Correlation** Nr
Comments results Kappa normalcy 0.46, diagnosis 0.30, intraobserver same normalcy 71%, diagnosis 59%			**Comments** --

van Venrooij 1995 The Netherlands J Urol 1995;153:1540-2	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow study, Schäfer grade 0 and 1 unobstructed
Inclusion criteria BPH symptoms, urodynamic study, 45–86 years **Exclusion criteria** Not stated		**Execution index test** Q_{max}, voided volume >150 ml **Execution reference test** 5 Ch transurethral and 14 Ch rectal catheters, Schäfer grade, >1 obstructed
Number 211 **Exclusions** 4+20% **Consecutive** Not stated **Demographic description** Yes **Uninterpretable results** Not stated **Time interval** 0 days **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** 10 ml/s; 12 ml/s 15 ml/s **True positives** 47%; 64%; 83% **False positives** 41%; 44%; 61% **False negatives** 53%; 36%; 17% **True negatives** 51%; 56%; 39% **Prevalence** 0.76 **Sensitivity** 0.47; 0.64; 0.83 **Specificity** 0.59; 0.56; 0.39 **LR+** 1.14; 1.47; 1.37 **LR–** 0.90; 0.64; 0.43 **Area under ROC curve** -- **Correlation** --
Reliability -- **Other results**		
Comments results Values calculated from figure		**Comments** Wide definition of obstruction

van Venrooij 1996 The Netherlands J Urol 1996;155:2014-8	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow, grade 0–1 unobstructed
Inclusion criteria Men with prostatism, >50 years, pressure-flow study performed when evaluation suggested BOO, reliable pressure-flow relation, Flow with VV >150 ml **Exclusion criteria** Cystometric bladder capacity, PVR, TRUL not performed		**Execution index test** Not described, voided volume >150 ml **Execution reference test** 5 Ch urethral and 14 Ch rectal catheter, saline, grading with LinPURR
Number 196 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** Yes **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** Nr **True positives** Nr **False positives** Nr **False negatives** Nr **True negatives** Nr **Prevalence** 0.79 **Sensitivity** Nr **Specificity** Nr **LR+** Nr **LR–** Nr **Area under ROC curve** -- **Correlation** -0.37 P, -0.22 K
Reliability --		
Other results		
Comments results Wide definition of obstruction		**Comments** --

van Venrooij 2004 The Netherlands Urology 2004;63:476-80		**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow
Inclusion criteria LUTS, 50–85 years, all examinations, voided volume >150 ml, reliable pressure-flow relationship **Exclusion criteria** According to International Consensus Commitee			**Execution index test** Not described **Execution reference test** Obstruction according to AG-number, URA and Schäfer. Execution not described
Number	160		**Definition reference test** --
Exclusions	Not stated		**Cut off value** Nr
Consecutive	Not stated		**True positives** Nr
Demographic description	Yes		**False positives** Nr
Uninterpretable results	Not stated		**False negatives** Nr
Time interval	Not stated		**True negatives** Nr
Verification bias	Unclear		**Prevalence** 0,54
Index test independent	Not stated		**Sensitivity** Nr
Reference test independent	Not stated		**Specificity** Nr
Reliability --			**LR+** Nr **LR–** Nr **Area under ROC curve** --
Other results			**Correlation** AG -0,41 URA -0,48 Schäfer K
Comments results --			**Comments** --

Vesely 2003 Sweden Neurourol Urodyn 2003;22:301-5	**Study quality** Moderate	**Index test** Flow measurement **Reference test** Pressure-flow DAMPF
Inclusion criteria LUTS and suspected BOO **Exclusion criteria** Neurogenic bladder, positive ice water test		**Execution index test** Not described **Execution reference test** UroDyn UD2000, MMS, obstruction according to DAMPF. Execution not described

Number	153	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	Nr
Consecutive	Not stated	**True positives**	Nr
Demographic description	Yes	**False positives**	Nr
Uninterpretable results	Not stated	**False negatives**	Nr
Time interval	Not stated	**True negatives**	Nr
Verification bias	Unclear	**Prevalence**	0.84
Index test independent	Not stated	**Sensitivity**	Nr
Reference test independent	Not stated	**Specificity**	Nr
Reliability --		**LR+** **LR–** **Area under ROC curve**	Nr Nr --
Other results		**Correlation**	-0.41 P
Comments results --		**Comments** --	

Witjes 2002 The Netherlands Eur Urol 2002;41:206-13; discussion 213		**Study quality** High	**Index test** Flow measurement **Reference test** Nr
Inclusion criteria Randolmly chosen patients from a randomised trial **Exclusion criteria** None			**Execution index test** Different flowmeters, several countries, manuall read curves + computer **Execution reference test** Nr
Number	223 pat, 1 147 flows		**Definition reference test** --
Exclusions	Nr		**Cut off value** Nr
Consecutive	No		**True positives** Nr
Demographic description	No		**False positives** Nr
Uninterpretable results	Nr		**False negatives** Nr
Time interval	Nr		**True negatives** Nr
Verification bias	Yes		**Prevalence** Nr
Index test independent	Yes		**Sensitivity** Nr
Reference test independent	Nr		**Specificity** Nr
Reliability			**LR+** Nr **LR–** Nr **Area under ROC curve** --
Other results			**Correlation** One expert 0,4 ml/s higher
Comments results SD 3 experts 2.09; 2.61;3.02; exp-comp 1.29; 2.11; 2.44			**Comments** Variabliity between 3 experts and a computer algor

4.4 Tidsmiktion

Folkestad 2004 Sweden Scand J Urol Nephrol 2004;38:136-42	**Study quality** Moderate	**Index test** Timed micturition **Reference test**
Inclusion criteria Random sample from general population, 26–76 years **Exclusion criteria** Voiding problems, practical difficulties to perform home flow measurements		**Execution index test** Timed micturition with DaCapo home flow meter, visual inspection of curves, asked for 20 measurements **Execution reference test** Not relevant
Number 58 **Exclusions** 198 **Consecutive** Not relevant **Demographic description** Yes **Uninterpretable results** Excluded **Time interval** 0-several days **Verification bias** Not relevant **Index test independent** Not relevant **Reference test independent** Not relevant		**Definition reference test** -- **Cut off value** **True positives** **False positives** **False negatives** **True negatives** **Prevalence** Not relevant **Sensitivity** **Specificity** **LR+** **LR–** **Area under ROC curve** -- **Correlation**
Reliability		
Other results		
Comments results <55 years: all vol SD 2.0 same vol 2.0, non-param. -2.4 to 5.3; -2.4 to 5.0 >55 years: 3.5; 2.9; -4.0 to 9.7; -4.0 to 6.5		**Comments** --

Hansen 1997 Sweden Eur Urol 1997;32:34-8	**Study quality** Moderate	**Index test** Timed micturition **Reference test** Flow measurement, subjective outcome
Inclusion criteria 110 TURP, 62 TUMT **Exclusion criteria** Voided volume <100 ml		**Execution index test** Asked to perform 10 measurements, mean used **Execution reference test** Urodyn 2000 Dantec, voided volume >100 ml, visual inspection not stated
Number 172 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** Yes **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** **True positives** **False positives** **False negatives** **True negatives** **Prevalence** Not stated **Sensitivity** **Specificity**
Reliability --		**LR+** **LR–** **Area under ROC curve** --
Other results		**Correlation** Q_{max} 0.41, subj. 0.04
Comments results Q_{max} Pearson, subjective outcome Spearman correlation coefficients		**Comments** --

Zdanowski 1995 Sweden Scand J Urol Nephrol 1995;29:173-81	**Study quality** Moderate	**Index test** Timed micturition **Reference test** Flow measurement
Inclusion criteria Prostatism **Exclusion criteria** Neurologic disease, severe heart disease, suspicion prostate cancer, indwelling catheter		**Execution index test** Asked to perform 10 measurements, mean used **Execution reference test** Not described

Number	421	**Definition reference test**	--
Exclusions	92 no timed micturition, 262 or 189 no flow rate	**Cut off value**	
Consecutive	Yes	**True positives**	
Demographic description	Yes	**False positives**	
Uninterpretable results	Not stated	**False negatives**	
Time interval	Not stated	**True negatives**	
Verification bias	Unclear	**Prevalence**	Not stated
Index test independent	Not stated	**Sensitivity**	
Reference test independent	Not stated	**Specificity**	
Reliability		**LR+**	
		LR–	
		Area under ROC curve	--
Other results		**Correlation**	-0.36
Comments results Pearson correlation coefficient		**Comments** --	

4.5 Miktionslista

Homma 2002 Japan Neurourol Urodyn 2002;21:204-9	**Study quality** Moderate	**Index test** Frequency-volume chart **Reference test** --
Inclusion criteria Urinary frequency and/or incontinence, mentally fit, stable symptoms, 14 men and 60 women, 63.5 years SD 11.3 **Exclusion criteria** Urinary tract infection, obvious outlet obstruction, bladder tumour or stones		**Execution index test** 14 days voiding diary **Execution reference test** --

Number	80	**Definition reference test**	--
Exclusions	6	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Excluded	**False negatives**	--
Time interval	1–13 days	**True negatives**	--
Verification bias	--	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
		LR+	--
		LR-	--
		Area under ROC curve	--
		Correlation	-

Reliability Daytime voiding frequency SD 1.35. Nocturnal voidings and incontinence episodes Poisson distributed; variance = number of episodes, observed variance was slightly lower	
Other results	
Comments results --	**Comments** --

van Venrooij 2004 The Netherlands Urology 2004;63:476-80	**Study quality** Moderate	**Index test** Frequency-volume chart **Reference test** Pressure-flow study, AG-number, URA, Schäfer grade
Inclusion criteria LUTS suggestive of BPH, performed all examinations, 65.3 years SD 7.7 **Exclusion criteria** Exclusion criteria according to International Consensus Committee on BPH		**Execution index test** At least 24 h voiding diary **Execution reference test** Analysed according to ICS, URA and Schäfer grade

Number	160	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.54
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	-0.23, -0.25, -0.23
Comments results Kendall and Gibbons correlation coefficient		**Comments** --	

4.6 Resturin

Beacock 1985 United Kingdom Br J Urol 1985;57:410-3		**Study quality** Moderate	**Index test** Residual urine **Reference test** --
Inclusion criteria Investigation for BOO, 55–80 years **Exclusion criteria** Not stated			**Execution index test** Siemens Phosonic SM with a digital scan converter, planimetry 0.5 cm intervals, catheterization immediately after scanning **Execution reference test** --
Number	15, 25 examinations		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Few minutes		**True negatives** --
Verification bias	--		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	--		**Specificity** --
Reliability US 8 ml less, SD difference 23 ml			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

Birch 1988 United Kingdom Br J Urol 1988;62:571-5	**Study quality** Moderate	**Index test** Residual urine **Reference test** --
Inclusion criteria TURP patients **Exclusion criteria** Not stated		**Execution index test** Transabdominal US, Siemens Sonoline SX, 3.5 MHz, 5 different formulas, 3 measurements the same day **Execution reference test** --

Number	30	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	0 days	**True negatives**	--
Verification bias	--	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability 1/3 smallvariation 2/3 large variation, single measurement not useful		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Bruskewitz 1997 USA J Urol 1997;157:1304-8		**Study quality** Moderate	**Index test** Residual urine **Reference test** Improvement in IPSS and bother
Inclusion criteria TURP arm of randomised study TURP vs WW, clinical BPH **Exclusion criteria** <55 years, previous surgery or radiation, nonambulatory status, ongoing infection, prostate or bladder cancer, PVR >350 ml, neurogenic bladder, serious medical condition			**Execution index test** Not described **Execution reference test** Improvement in IPSS or bother score
Number	249		**Definition reference test** --
Exclusions	Not stated		**Cut off value** 100
Consecutive	Yes		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	1 and 3 years		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** <100 ml larger improvement
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results IPSS10.6 vs 9.5 ns, both 36 vs 26 sign			**Comments** --

Caffarel 2008 Great Britain Neurourol Urodyn 2008;27:797-801		**Study quality** Moderate	**Index test** Residual urine **Reference test** Q_{max}
Inclusion criteria Pressure-flow study, attendees at a LUTS clinic, performed flow measurement and at least two of IPSS, IPSS bother question, prostate specific antigen and postvoid residual urine			**Execution index test** Method not described
Exclusion criteria Voided volume at flow measurement <150 ml, performed less than two IPSS, IPSS bother question, PSA and PVR			**Execution reference test** Q_{max}, voided volume >150 ml
Number	95		**Definition reference test** --
Exclusions	45		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.37
Comments results Pearson correlation coefficient			**Comments** ---

Dunsmuir 1996 United Kingdom Br J Urol 1996;77:192-3	**Study quality** Moderate	**Index test** Residual urine **Reference test** --
Inclusion criteria Volunteers, BPH according to DRE and PSA, 55–82 years **Exclusion criteria** Anticholinergics, urinary tract infection		**Execution index test** Transabdominal US by two experienced examiners, 6 times after voiding >150 ml **Execution reference test** --

Number	40	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not relevant	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	--	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test indepen.	--	**Specificity**	--
Reliability Between individuals 57%,CIi 93–252 ml, within individuals 42%, CI 55–228 ml		**LR+** **LR-** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results Logarithmic values		**Comments** --	

Ignjatovic 1997 Yugoslavia Int Urol Nephrol 1997;29:653-60		**Study quality** Moderate	**Index test** Residual urine **Reference test** IPSS <8
Inclusion criteria LUTS, enlarged prostate, candidate for TURP **Exclusion criteria** Not stated			**Execution index test** Catheterized before pressure-flow study **Execution reference test** One 9 Ch or two 6 Ch transurethral catheters, Schäfer grade
Number	48		**Definition reference test** --
Exclusions	Not stated		**Cut off value** 100 ml
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	6 months		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.37 poor result
Index test independent	Not stated		**Sensitivity** 8 vs 10 p ns
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results >100 larger improvement			**Comments** --

Kjeldsen-Kragh 1988 Denmark Paraplegia 1988;26:192-9	**Study quality** Moderate	**Index test** Residual urine **Reference test** --
Inclusion criteria Neurogenic bladder **Exclusion criteria** Not stated		**Execution index test** Transabdominal US, 3 MHz, 3 different formulas, also catheterization **Execution reference test** --

Number	20, 107 examinations	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	<10 minutes	**True negatives**	--
Verification bias	..	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Mean difference 28, 11, 16%		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Kuo 1999 Taiwan Urology 1999;54:90-6		**Study quality** Moderate	**Index test** Residual urine **Reference test** Video pressure-flow study
Inclusion criteria LUTS, prostate volume <60 ml, 45–88 years			**Execution index test** The least of catheterized after free flow and calculated after pressure-flow
Exclusion criteria Acute urinary retention, neuropathy, diabetes, acute urinary infection, previous TURP			**Execution reference test** Suprapubic epidural catheter, 10 Ch rectal balloon catheter, video, p_{det} >50 cm H_2O obstructed, low pressure and Q_{max} <15 ml/s obstruction decided by video
Number	324		**Definition reference test** --
Exclusions	Not stated		**Cut off value** 100 ml
Consecutive	Yes		**True positives** 31
Demographic description	Yes		**False positives** 5
Uninterpretable results	Not stated		**False negatives** 181
Time interval	0 days		**True negatives** 107
Verification bias	Unclear		**Prevalence** 0.65
Index test independent	Not stated		**Sensitivity** 0.15
Reference test independent	Not stated		**Specificity** 0.96
Reliability --			**LR+** 1.7 **LR–** 0.11 **Area under ROC curve** -- **Correlation** --
Other results			
Comments results Wide definition of obstruction			**Comments** --

Mochtar 2006 The Netherlands J Urol 2006;175:213-6		**Study quality** Moderate	**Index test** Residual urine **Reference test** Invasive treatment during 5 years follow-up
Inclusion criteria Clinical BPH, watchful waiting or alfa-blocker, PSA <10, prostate volume 200 ml or less			**Execution index test** Transabdominal US, ellipsoidal formula
Exclusion criteria Prostate or bladder cancer, neurogenic bladder			**Execution reference test** Invasiv treatment during 5 years follow-up
Number	942		**Definition reference test** --
Exclusions	28		**Cut off value** 50, 100 or 300 ml
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	5 years		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.13
Index test independent	Not stated		**Sensitivity** Hazard ratio 1.9–4.1
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.15 with Schäfer grade
Comments results HR ns in multivariate analysis but sign in univariate			**Comments** --

Ockrim 2001 Multinational J Urol 2001;166:2221-5		**Study quality** Moderate	**Index test** Residual urine **Reference test** Q_{max}; pressure-flow study, BOOI
Inclusion criteria Interventional therapy considered, 64 years SD 12.3 **Exclusion criteria** Neurological disease, previous treatment, insufficient data documentation			**Execution index test** Transabdominal US **Execution reference test** Best of 2 voids, VV >100 ml; 8 Ch transurethral catheter, BOOI
Number	384		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Yes		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.45
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** Q_{max} -0.26; BOOI 0.30
Comments results Probably Pearson			**Comments** --

Oelke 2007 Multinational Eur Urol 2007;52:827-34. Epub 2006 Dec 22	**Study quality** High	**Index test** Residual urine **Reference test** Pressure-flow study, CHESS classification, A1-2, B1 non-obstructed
Inclusion criteria >40 years, LUTS or prostate volume >25 ml **Exclusion criteria** BPH-treatment, previus pelvic surgery, neurogenic deficit, prostate cancer, PSA >4		**Execution index test** SonoDIAGNOST360, Philips, 3.5 MHz **Execution reference test** Ellipse, Andromeda, acording to good urodynamic practise, CHESS classification, experienced residents

Number	168	**Definition reference test**	--
Exclusions	8	**Cut off value**	>50 ml
Consecutive	Yes	**True positives**	54
Demographic description	Yes	**False positives**	21
Uninterpretable results	Not stated	**False negatives**	49
Time interval	1–3 weeks	**True negatives**	36
Verification bias	Unclear	**Prevalence**	0.47
Index test independent	Not stated	**Sensitivity**	0.72
Reference test independent	Yes	**Specificity**	0.42
Reliability --		**LR+**	1.25
		LR–	0.66
		Area under ROC curve	--
Other results		**Correlation**	--
Comments results --		**Comments** --	

Roehrborn 1999 USA Urology 1999;53:473-80	**Study quality** Moderate	**Index test** Residual urine **Reference test** Acute urinary retention or surgical therapy
Inclusion criteria Randomised study, moderate–severe LUTS, Q_{max} <15 ml/s, voided volume >150 ml, enlarged prostate, negative biopsy if PSA 4-10, 64 years SD 7 **Exclusion criteria** Prostate and bladder cancer, PSA <10, BPH treatment, chronic prostatitis, recurrent urinary tract infections		**Execution index test** Not described **Execution reference test** Acute urinary retention or surgical therapy

Number	3040	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	4 years	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.10; 0.05
Index test independent	Not stated	**Sensitivity**	AUROC 0.52; 0.60
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Schacterle RS 1996 USA Neurourol Urodyn 1996;15:459-70; discussion 470-2		**Study quality** Moderate	**Index test** Residual urine **Reference test** Micturitional urethral pressure profile
Inclusion criteria Referral urodynamic study, mean age 68 years **Exclusion criteria** Overt neurological disease			**Execution index test** Catheterization **Execution reference test** Micturitional urethral pressure profile, gradient >9 cm H_2O obstruction
Number	134		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Yes		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	0 days		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.49
Index test independent	Not stated		**Sensitivity** Obstr 145 vs 90 ml
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results Sign difference			**Comments** ..

Walden 1995 Sweden Scand J Urol Nephrol 1995;29:469-76		**Study quality** Moderate	**Index test** Residual urine **Reference test** Pressure-flow study, Schäfer grade
Inclusion criteria Candidate for TUP or TUMT, Madsen-Iversen score >8, Q_{max} <15 ml/s, ASA calss 1–3, 46–86 years **Exclusion criteria** Neurologic or mental disorder, indwelling catheter, PVR >350 mlprostate or bladder cancer, infection, previous BPH treatment			**Execution index test** Transabdominal US **Execution reference test** Uro Gyn UD2000, MMS, suprapubic catheter, rectal balloon catheter, Schäfer grade
Number	70		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.57
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** No correlation
Comments results --			**Comments** --

Vesely 2003 Sweden Neurourol Urodyn 2003;22:301-5		**Study quality** Moderate	**Index test** Residual urine **Reference test** Q_{max}; pressure-flow study, DAMPF
Inclusion criteria LUTS and suspected BOO, no neurological disease **Exclusion criteria** Positive ice water test			**Execution index test** UA 1082, Brüel & Kjaer, formula not stated **Execution reference test** UroDyn UD 2000, MMS, DAMPF
Number	153		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.84
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** Q_{max} -0.22; DAMPF 0.18
Comments results Pearson			**Comments** --

4.7 Storleksbestämning med transrektalt ultraljud (TRUL)

<table>
<tr><td colspan="2">Aarnink 1996 The Netherlands
Eur Urol 1996;29:399-402</td><td>Study quality
Moderate</td><td colspan="2">Index test
Transrectal ultrasound investigation (TRUS)
Reference test
Planimetry</td></tr>
<tr><td colspan="3">Inclusion criteria
Consecutive examinations

Exclusion criteria
None</td><td colspan="2">Execution index test
Kretz Combison 330, 7.5 MHz, 4 mm sections, 4 formulas compared to planimetry

Execution reference test
--</td></tr>
<tr><td>Number</td><td>247</td><td rowspan="9">Definition reference test --
Cut off value --
True positives --
False positives --
False negatives --
True negatives --
Prevalence --
Sensitivity --
Specificity --</td><td rowspan="9">LR+ --
LR– --
Area under ROC curve --
Correlation --</td></tr>
<tr><td>Exclusions</td><td>Not stated</td></tr>
<tr><td>Consecutive</td><td>Yes</td></tr>
<tr><td>Demographic description</td><td>No</td></tr>
<tr><td>Uninterpretable results</td><td>Not stated</td></tr>
<tr><td>Time interval</td><td>--</td></tr>
<tr><td>Verification bias</td><td>--</td></tr>
<tr><td>Index test independent</td><td>--</td></tr>
<tr><td>Reference test independent</td><td>--</td></tr>
<tr><td colspan="3">Reliability

Decreasing order: h^2*w, (h*w*l)/3, h*w*l, ((h+l)/2)^3</td></tr>
<tr><td colspan="3">Other results</td></tr>
<tr><td colspan="3">Comments results
Common ellipsoidal formula not best, formulas underestimate volume</td><td colspan="2">Comments
--</td></tr>
</table>

Aarnink 1996 The Netherlands Br J Urol 1996;78:219-23	**Study quality** High	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** --
Inclusion criteria Men with LUTS, 38–83 years **Exclusion criteria** None		**Execution index test** Kretz Combison 330, 7.5 MHz, 3D transducer, planimetry **Execution reference test** --
Number 30 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Not stated **Time interval** 0 days **Verification bias** -- **Index test independent** Yes **Reference test independent** --		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** --
Reliability Pearson r=0.977. Mean variation 3.4 and 3.5%, 3.6 and 3.2 ml. Maximum variation 11.1 resp 10.0%, 30 resp 21 ml		
Other results		
Comments results 3D technique		**Comments** --

Agrawal 2008 Nepal Nepal Med Coll J 2008;10:104-7	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Flow measurement, Q_{max}
Inclusion criteria Diagnosis of BPH, age 67.5 years, SD 8.5, range 48–85 years **Exclusion criteria** Previous surgery, prostate cancer, urethral stricture, neuropathic bladder		**Execution index test** Abdominal US **Execution reference test** Q_{max}, flow measurement not described

Number	100	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	-0.42
Comments results Pearson correlation coefficient		**Comments** --	

al-Rimawi 1994 Canada Br J Urol 1994;74:596-600		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** --
Inclusion criteria Symptoms of obstruction, enlarged prostate at DRE, Q_{max} <15 ml/s, randomized finasteride trial **Exclusion criteria** Not stated			**Execution index test** General Electric RT 3600, 6 MHz, experienced radiologist **Execution reference test** MRI, Philips Gyroscan F15, 1.5 T, 5 mm thick images, experienced radiologist
Number	21		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Within 2 days		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability TRUS underestimate 23%, variation between sessions 10–12%, combining simplicity and correlation with MRI usual ellipsoid formula best r=0.81			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

Cabello Benavente 2006 Spain Actas Urol Esp 2006;30:175-80	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Weight of surgical specimen
Inclusion criteria Radical prostatectomy or retropubic prostatectomy, no tertiary lobe, good delimitation of prostate and transision zone with US **Exclusion criteria** Previous prostatic surgery		**Execution index test** Brüel and Kjaer 3535 with transducer 8551, transrectal, 7 MHz, ellipsoidal formula **Execution reference test** Specimen weight

Number	33+37	**Definition reference test**	--
Exclusions	0	**Cut off value**	--
Consecutive	No	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Excluded	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Yes	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability PV 0.79; TZ 0.84 P		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Elliot 1996 Canada Acad Radiol 1996;3:401-6	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Water displacement in graduated cylinder
Inclusion criteria Cadaver prostates, 25–100 ml **Exclusion criteria** Not stated		**Execution index test** 5 MHz side-fireig probe, ATL UM-9, Advanced Technology Laboratories, fixed probe holder recording 2D images at different angles, own computer program for 3D reconstruction, planimetry of slices **Execution reference test** Water displacement in graduated cylinder
Number 6 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** 1.00
Reliability SD 0.43 ml or 1.7%. Error >4 ml compared to reference		
Other results		
Comments results --		**Comments** --

Eri 2002 Norway Prostate Cancer Prostatic Dis 2002;5:273-8	**Study quality** High	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** --
Inclusion criteria Placebo group of BPH trial **Exclusion criteria** Not stated		**Execution index test** Brüel & Kjaer 1846, transducer 8531; 10 measurements, 6 ways to measure volume **Execution reference test** --

Number	41	**Definition reference test**	--
Exclusions	4–33 at measurement 2–10	**Cut off value**	--
Consecutive	Not relevant	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	8–24 weeks	**True negatives**	--
Verification bias	Unclear	**Prevalence**	Not stated
Index test independent	Yes	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Ellipsoidal SD 6.04, planimetry SD 5.14, ellipsoidal underestimation 5.7 ml		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--

Comments results --	**Comments** --

Girman 1995 USA J Urol 1995;153:1510-5	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Q_{max}
Inclusion criteria Men 40–79 years, 55% response rate, 25% invited for examination **Exclusion criteria** Prostate cancer, prostatic surgery, conditions interfering with voiding except BPH		**Execution index test** Ellipsoidal formula **Execution reference test** Q_{max}, portable flowmeter

Number	471	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not relevant	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	-0.214
Comments results Spearman		**Comments** --	

<table>
<tr><td colspan="2">Griffiths 2007 Australia
J Urol 2007;178:1375-9; discussion 1379-80</td><td>Study quality
Moderate</td><td colspan="2">Index test
Transrectal ultrasound investigation (TRUS)
Reference test
--</td></tr>
<tr><td colspan="3">Inclusion criteria
Healthy men without prostatic disease, 54–64 years

Exclusion criteria
Not stated</td><td colspan="2">Execution index test
Sonoline Adara, 5–7.5 MHz, ellipsoidal formula

Execution reference test
__</td></tr>
<tr><td>Number</td><td>13</td><td colspan="2" rowspan="8"></td><td>Definition reference test</td><td>--</td></tr>
<tr><td>Exclusions</td><td>Not stated</td><td>Cut off value</td><td>--</td></tr>
<tr><td>Consecutive</td><td>Not relevant</td><td>True positives</td><td>--</td></tr>
<tr><td>Demographic description</td><td>Not relevant</td><td>False positives</td><td>--</td></tr>
<tr><td>Uninterpretable results</td><td>Not stated</td><td>False negatives</td><td>--</td></tr>
<tr><td>Time interval</td><td><2 weeks</td><td>True negatives</td><td>--</td></tr>
<tr><td>Verification bias</td><td>Not relevant</td><td>Prevalence</td><td>Not stated</td></tr>
<tr><td>Index test independent</td><td>Not stated</td><td>Sensitivity</td><td>--</td></tr>
<tr><td>Reference test independent</td><td>--</td><td>Specificity</td><td>--</td></tr>
<tr><td colspan="3" rowspan="2">Reliability

icc for trus: pv 0.965; central vol 0.735; for tpul: pv 0.921; central vol 0.742</td><td>LR+</td><td>--</td></tr>
<tr><td>LR–</td><td>--</td></tr>
<tr><td colspan="3">Other results</td><td>Area under ROC curve</td><td>--</td></tr>
<tr><td colspan="3" rowspan="2">Comments results
ICC 0.965, CV 5.1%</td><td>Correlation</td><td>--</td></tr>
<tr><td colspan="2">Comments
Also comparison with perineal US</td></tr>
</table>

Hendrikx 1991 The Netherlands Scand J Urol Nephrol Suppl 1991;137:95-100	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** --
Inclusion criteria Cadavers and patients **Exclusion criteria** Not stated		**Execution index test** Bruel & Kjaer 1846 and 1850, 7 MHz, double measurements with both manual and automatic method, planimetry **Execution reference test** --

Number	9, 20	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	--	**True negatives**	--
Verification bias	--	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Intraindividual SD planimetry 1.61 ml		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--

Comments results --	**Comments** --

Huang Foen Chung 2004 The Netherlands Eur Urol 2004;46:352-6	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Transabdominal US
Inclusion criteria From screening study PC or longitudinal urodynamic study of volunteers **Exclusion criteria** Not stated		**Execution index test** Brüel and Kjaer Falcon 2101, transducer 8808, 7.5 MHz, planimetry **Execution reference test** Aloka SSD-1700, USI-4140, 3.5 MHz, ellipsoidal formula

Number	100	**Definition reference test**	--
Exclusions	0	**Cut off value**	--
Consecutive	Not relevant	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability 0.84 P pearson r for trus-taus 0.84; taus vs taus 0.73. Diff more than 10, 20 resp 30%: trus-taus 70, 40, 26%; taus-taus 65, 44, 20%		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Kaplan 1995 USA J Urol 1995;154:1764-9		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Pressure-flow, $p_{det\ Qmax}$, Q_{max}
Inclusion criteria Symptomatic prostatism **Exclusion criteria** Prostate cancer, neurogenic bladder, previous therapy			**Execution index test** Brüel & Kjaer 1846 with 1850 radial and 8537 longitudinal probes, ellipsoidal formula, 1 examiner **Execution reference test** 10 Ch transurethral catheter, Lifetech Janus system, Dantec 1000 flowmeter
Number	61		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Yes		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** Q_{max} -0.20, $p_{det\ Qmax}$ 0.13
Comments results TZV and TZI better			**Comments** --

Kimura 1995 Japan Int J Urol 1995;2:252-6	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** --
Inclusion criteria Prostate cancer, BPH + surgery, BPH + hormonal therapy, hematospermia or bladder tumor **Exclusion criteria** Not stated		**Execution index test** Aloka SSD-60 or Toshiba SSL-51C chair type, serial tomograms and 3D reconstruction, planimetry regarded as correct volume **Execution reference test** --

Number	5+5+5+5	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	--	**True negatives**	--
Verification bias	--	**Prevalence**	--
Index test independent	--	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Prolate ellipsoidal formula with axes at right angles best, angles are important, ellipsoid formula worse		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Kojima 1997 Japan Urology 1997;50:548-55		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Flow and pressure-flow measurement
Inclusion criteria Moderate to severe symptoms according to IPSS, performed TRUS and pressure-flow study, 51–89 years **Exclusion criteria** Neurgenic bladder, prostate cancer, urethral stricture			**Execution index test** Chair-type scanner, SSD 520, Aloka, 5.0 MHz, planimertry with 5 mm intervals, Finetec Image Measuring System **Execution reference test** Q_{max} not described, 5 Ch transurethral catheter, rectal catheter, polygraph system, Nihon Koden
Number	85		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.67
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** Q_{max} 0.11, $p_{det\ Qmax}$ 0.35, AG-number 0.36, Schäfer grade 0.35
Comments results PCAR better sensitivity 0.77 and specificity 0.75			**Comments** --

Kuo 1993 Taiwan Eur Urol 1993;24:12-9.		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Symptoms and flowrate after surgery
Inclusion criteria Diagnosis of BPH and operated, with and without a catheter, 45–96 years (TURP 335, Open op 16, TUIP 49) **Exclusion criteria** Not stated			**Execution index test** Prostatic size and intravesical growth were evaluated **Execution reference test** Patient satisfied with voiding condition, improved irritative symptoms and Q_{max} >15 ml/s
Number	400		**Definition reference test** --
Exclusions	10 without TRUS		**Cut off value** Between large adenoma and prominent small adenoma; between prominent small adenoma and no definite adenoma
Consecutive	Yes		**True positives** 114; 277
Demographic description	No		**False positives** 5; 52
Uninterpretable results	Not stated		**False negatives** 205; 42
Time interval	Not stated		**True negatives** 66; 19
Verification bias	Yes		**Prevalence** 0.81
Index test independent	Not stated		**Sensitivity** 0.36; 0.87
Reference test independent	Not stated		**Specificity** 0.93; 0.27
Reliability --			**LR+** 5.07; 1.19 **LR–** 0.69; 0.49 **Area under ROC curve** -- **Correlation** --
Other results			
Comments results --			**Comments** --

Kurita 1996 Japan Int J Urol 1996;3:361-6	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Q_{max}
Inclusion criteria BPH diagnosed from history, symptoms, physical examination, TRUS, biopsy if elevated PSA, treatment with tamulosine, 55–88 years **Exclusion criteria** Prostate cancer, prostatitis, bladder stones, stricture, diabetic neuropathy, urinary retention, previous surgery, severe disease		**Execution index test** One examiner, 5 MHz, Aloka UST-670P-5 with SSD-2000 us system, formula for ellipsoid **Execution reference test** Not stated

Number	64	**Definition reference test**	--
Exclusions	4	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.053

Comments results Data for responders but questionable definition	**Comments** --

Kurita 1996 Japan Int J Urol 1996;3:448-53	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Q_{max}
Inclusion criteria BPH diagnosed from history, symptoms, physical examination, TRUS or X-ray, treatment with TUMT **Exclusion criteria** Prostate cancer, urinary retention, neurogenic bladder, infection, stricture, previous therapy		**Execution index test** TRUS, one examiner, Aloka SSD-650CL with UST-665P-5 transducer, 5 MHz, ellipsoidal formula **Execution reference test** Q_{max}, Dantec UD 5500, VV >150 ml
Number 43 **Exclusions** 0 **Consecutive** Not stated **Demographic description** Yes **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** -0.117
Reliability --		
Other results		
Comments results --		**Comments** --

Kurita 1997 Japan Br J Urol 1997;80:78-83	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Q_{max}
Inclusion criteria BPH diagnosed from history, symptoms, physical findings, TRUS or X-ray, 51–80 years, IPSS >13 or Q_{max} <15 ml/s, biopsy if elevated PSA or suspicious DRE, randomised drug trial **Exclusion criteria** Prostate cancer, prostatitis, stricture, diabetic neuropathy, urinary retention, previous therapy		**Execution index test** Aloka SSD-2000 with UST-670P-5, ellipsoid formula, one examiner **Execution reference test** Dantec UD 5500

Number	128	**Definition reference test**	--
Exclusions	7	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–**	-- --
		Area under ROC curve	--
Other results		**Correlation**	-0.042
Comments results --		**Comments** --	

Kurita 1998 Japan Urology 1998;51:595-600.		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Flow measurement, Q_{max}
Inclusion criteria Symptomatic BPH, with and without acute urinary retention, IPSS >7, 51–84 years **Exclusion criteria** Prostate cancer, prostatitis, stricture, neurogenic bladder, chronic urinary retention, TURP or drug treatment for BPH			**Execution index test** 1 examiner, SSD 2000, Aloka, UST-670P-5 probe, 5 MHz, ellipsoidal formula **Execution reference test** UD 5500, Dantec
Number	331 (64 AUR)		**Definition reference test** --
Exclusions	14 with prostate cancer		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** -0.37
Comments results Pearson correlation coefficient, PCAR worse			**Comments** --

Lepor 1997 USA J Urol 1997;158:85-8	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Q_{max}
Inclusion criteria Referral for BPH, elevated PSA or abnormal DRE, biopsy if elevated PSA, abnormal DRE and life expectancy >10 years **Exclusion criteria** Prostate cancer		**Execution index test** TRUS, Bruel & Kjaer 1846 with B551 transducer, 7.5 MHz, ellipsoidal formula **Execution reference test** Q_{max}, not described

Number	93	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	-0.40
Comments results --		**Comments** --	

Lim 2006 Singapore Int J Urol 2006;13:1509-13		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Pressure-flow study, AG-number >40 cm H_2O
Inclusion criteria LUTS suggestive of BPE, >50 years **Exclusion criteria** Previous pelvic surgery, previous pelvic trauma, radiation therapy, diabetic cystopathy, neurogenic bladder, high PSA had biopsy before inclusion			**Execution index test** Transabdominal, not described otherwise, reference to previous paper **Execution reference test** According to ICS, AG-number, not described otherwise
Number	114		**Definition reference test** --
Exclusions	19 incomplete data		**Cut off value** 20; 40 ml
Consecutive	Yes		**True positives** 43; 24
Demographic description	Yes		**False positives** 36; 12
Uninterpretable results	Not stated		**False negatives** 4; 23
Time interval	Not stated		**True negatives** 12; 36
Verification bias	Yes		**Prevalence** 0.49
Index test independent	Not stated		**Sensitivity** 0.91; 0.51
Reference test independent	Not stated		**Specificity** 0.25; 0.75
Reliability --			**LR+** 1.22; 2.04 **LR–** 0.34; 0.65 **Area under ROC curve** -- **Correlation** Between 0.31 and 0.51
Other results			
Comments results IPP and PSA are also evaluated, IPP best, PSA second best			**Comments** --

Littrup 1991 USA Radiology 1991;179:49-53	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** --
Inclusion criteria In vitro models and consecutive patients **Exclusion criteria** Not stated		**Execution index test** Brüel & Kjaer 1846, 7 MHz, planimetry with 5 mm intervals **Execution reference test** --

Number	20, 100	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Yes	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Ellipsoid formula better than rotating ellips		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--

Comments results --	**Comments** --

Marberger 2000 Multinational Eur Urol 2000;38:563-8.		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Acute urinary retention within 2 years
Inclusion criteria Patients from 3 randomised finasteride trials, at least 2 moderate but no more than 2 severe symptoms, enlarged prostate, PSA <10 ng/ml, PVR <151 ml, Q_{max} 5–15 ml/s and voided volume >150 ml **Exclusion criteria** Prostate cancer			**Execution index test** Not stated **Execution reference test** Acute urinary retention assessed by investigator and an independent endpoint committee
Number	4 222, 2 785 with TRUS		**Definition reference test** --
Exclusions	Not stated		**Cut off value** >=40 ml
Consecutive	Not stated		**True positives** 31
Demographic description	No		**False positives** 1 095
Uninterpretable results	Not stated		**False negatives** 20
Time interval	2 year follow-up		**True negatives** 1639
Verification bias	No		**Prevalence** 0.018
Index test independent	Not stated		**Sensitivity** 0.61
Reference test independent	Not stated		**Specificity** 0.60
Reliability --			**LR+** 1.52 **LR–** 0.65 **Area under ROC curve** --
Other results			**Correlation** --
Comments results --			**Comments** --

Mariappan 2007 United Kingdom J Urol 2007;178:573-7; discussion 577		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Trial without catheter
Inclusion criteria Men with AUR, >50 years, clinically benign prostate, retention volume <1500 ml **Exclusion criteria** Prostate cancer, neurological disease, severe disease, prostatic surgery, stricture, renal insufficiency, anticholinergics, previously failed TWOC, did not receive alpha-blocker			**Execution index test** Machine not stated, 7 MHz, ellipsoidal formula, PV and IPP measured **Execution reference test** TWOC
Number	57 of 121		**Definition reference test** --
Exclusions	0		**Cut off value** 50 ml
Consecutive	Yes		**True positives** Not given
Demographic description	Yes		**False positives** Not given
Uninterpretable results	Not stated		**False negatives** Not given
Time interval	0 days		**True negatives** Not given
Verification bias	Yes		**Prevalence** 0.44
Index test independent	Not stated		**Sensitivity** 0.71
Reference test independent	Not stated		**Specificity** 0.71
Reliability --			**LR+** 2.45 **LR–** 0.41 **Area under ROC curve** -- **Correlation** --
Other results			
Comments results Sensitivity estimated from graph, figures for IPP also given			**Comments**

Milonas 2003 Lithuania Medicina (Kaunas) 2003;39:1071-7	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Acute urinary retention, flow measurement
Inclusion criteria Patients with BPH, mean age 68.3 years **Exclusion criteria** Neurogenic bladder, prostate cancer		**Execution index test** Siemens Sonoline SI-250, 5–7.5 MHz, ellipsoidal formula **Execution reference test** Acute urinary retention; Q_{max} Urodyn 1000, visual inspection not stated

Number	89	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	Not stated
Consecutive	Not stated	**True positives**	Not stated
Demographic description	Yes	**False positives**	Not stated
Uninterpretable results	Not stated	**False negatives**	Not stated
Time interval	Not stated	**True negatives**	Not stated
Verification bias	Unclear	**Prevalence**	0.24
Index test independent	Not stated	**Sensitivity**	0.62
Reference test independent	Yes	**Specificity**	0.62
Reliability --		**LR+** **LR–** **Area under ROC curve**	1.63 0.61 --
Other results		**Correlation**	0.04 P

Comments results Values from graph	**Comments** --

Miyashita 2002 Japan Ultrasound Med Biol 2002;28:985-90		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Presenting with AUR
Inclusion criteria LUTS suggestive of BPH, 50–94 years **Exclusion criteria** Neurogenic bladder, according to WHO			**Execution index test** Aloka chair SSD-520, planimetry **Execution reference test** Presenting with AUR
Number	160		**Definition reference test** --
Exclusions	Not stated		**Cut off value** Not stated
Consecutive	Not stated		**True positives** Not stated
Demographic description	Yes		**False positives** Not stated
Uninterpretable results	Not stated		**False negatives** Not stated
Time interval	Not stated		**True negatives** Not stated
Verification bias	Unclear		**Prevalence** 0.19
Index test independent	Not stated		**Sensitivity** 0.65
Reference test independent	Yes		**Specificity** 0.65
Reliability			**LR+** 1.86 **LR–** 0.54 **Area under ROC curve** --
Other results			**Correlation** --
Comments results Values estimated from graph, bladder weight better			**Comments** --

Miyazaki 1983 Japan J Urol 1983;129:48-50	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** --
Inclusion criteria Healthy men, TURP patients, open prostatectomy patients **Exclusion criteria** Not stated		**Execution index test** Aloka SSD-120, 3.5 MHz, chair model, planimetry with 5 mm intervals **Execution reference test** Specimen weight
Number 19, 226, 14 **Exclusions** Not stated **Consecutive** Yes **Demographic description** No **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Yes **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** --
Reliability Open prostatectomi r=0.83 slope=0.72, TURP r=0.83 slope=0.53		
Other results		
Comments results --		**Comments** --

Ockrim 2001 UK, Italy J Urol 2001;166:2221-5	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Pressure-flow, BOOI, Q_{max}
Inclusion criteria Consecutive patients, 64 years (SD 12.3), interventional treatment considered **Exclusion criteria** Neurologic disease, previous therapy		**Execution index test** TRUS, Sonoline SI 250, Siemens, ellipsoidal formula **Execution reference test** Pressure-flow, BOOI, 8 Ch transurethral catheter, Q_{max}, best of two voidings

Number	384	**Definition reference test**	--
Exclusions	<10% with missing data	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Yes	**Prevalence**	0.45
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.40; -0.28

Comments results log PV, log Q_{max}	**Comments** --

Ohtani 1999 Japan Eur Urol 1999;35:185-91		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Q_{max}, improvement in IPSS, bother and Q_{max}
Inclusion criteria TURP, 53–84 years **Exclusion criteria** Previous treatment, neurogenic bladder, prostate and bladder cancer			**Execution index test** Aloka SSD-1200 with UST 671, 5/7.5 MHz, ellipsoid formula **Execution reference test** Flowmetry not described, IPSS, bother question
Number	56		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	<1 month		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** **Area under ROC curve** --
Other results			**Correlation** Q_{max} 0.05 change IPSS 0.22 bother 0.11 Q_{max} 0.35
Comments results TZV and TZI better			**Comments** --

Passas 1994 Spain Actas Urol Esp 1994;18 Suppl:365-8	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Weight of specimen at open prostatectomy
Inclusion criteria Open prostatectomy for BPH, 55–82 years **Exclusion criteria** Not stated		**Execution index test** 7 MHz **Execution reference test** Weight of specimen
Number 40 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Unclear **Index test independent** Yes **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** --
Reliability US overestimate weight 17 g, ((T+AP)/2)^3 best		
Other results		
Comments results --		**Comments** --

Rahmouni 1992 USA J Comput Assist Tomogr 1992;16:935-40	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Specimen weight, MRI with contuoring method
Inclusion criteria Radical prostatectomy, cancer stage A or B **Exclusion criteria** Previous TURP		**Execution index test** General Electric 3600, 7 MHz, ellipsoid formula **Execution reference test** Specimen weight, MRI with contouring method
Number 48 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Not stated **Time interval** 1 day **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** --
Reliability TRUS underestimate mean 35.5 vs 50.6, SD 16.8 assuming weight is correct		
Other results		
Comments results Calculated values from graph		**Comments** Also MRI vs weight

Rosier 1995 The Netherlands World J Urol 1995;13:9-13		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Q_{max}, pressure-flow
Inclusion criteria Men with LUTS who performed pressure-flow studies			**Execution index test** Kretz Combison 330, 7.5 MHz, planimetry with 4 mm intervals
Exclusion criteria Not stated			**Execution reference test** Transuretral, 8 Ch catheters, microtip, MMS UD 2000 system, URA, pmuo, Atheo, Schäfer class
Number	521		**Definition reference test** --
Exclusions	Not stated		**Cut off value** 40 ml
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.73 S2–6, 0.49 S3–6
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** Q_{max} -0.20, $p_{det\ Qmax}$ 0.29, pmuo 0.32, Atheo -0.19, URA 0.32
Comments results PPV 0.80 S 2–6, 0.69 URA			**Comments** --

Rathaus V 1991 Israel Clin Radiol 1991;44:383-5.	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Specimen weight
Inclusion criteria Patients with BPH undergoing suprapubic prostatectomy **Exclusion criteria** Not stated		**Execution index test** Transperineal US, 5 MHz, ellipsoid formula **Execution reference test** Suprapubic prostatectomy, specimen weight
Number 89 **Exclusions** 9 **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Excluded **Time interval** Not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** 0.89
Reliability -- **Other results**		
Comments results Correlation coefficient not stated, large prostates underestimated		**Comments** --

Reis 2008 Brazil Int Braz J Urol 2008;34:627-33; discussion 634-7		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Pressure-flow study
Inclusion criteria LUTS, normal urinalysis, age 64.9 years (56–73) **Exclusion criteria** Previous surgery, neoplasia, bladder stone, neurological abnormality, alpha-blocker, anticholinergics, antiandrogens			**Execution index test** Abdominal US, Toshiba Powervision 6000, 3–6 MHz, >100 ml in bladder **Execution reference test** Pressure-flow study according to Good Urodynamic Practise, BOOI
Number	42		**Definition reference test** Not stated
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	One week		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.48
Index test independent	Yes		**Sensitivity** 0.69
Reference test independent	Not stated		**Specificity** 0.69
Reliability --			**LR+** 2.23 **LR–** 0.45 **Area under ROC curve** -- **Correlation** --
Other results			
Comments results Area under ROC 0.72, values estimated from figure			**Comments** --

Sajadi 2007 USA J Urol 2007;178:990-5	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Specimen weight after radical prostatectomy
Inclusion criteria SEARCH database, radical prostatectomy after 1995 **Exclusion criteria** Andogen deprivation, radiation therapy, T1a, T1b, missing data		**Execution index test** Different machines, ellipsoidal formula sometimes using W2 or W3 **Execution reference test** Specimen weight

Number	1 309	**Definition reference test**	--
Exclusions	812	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not relevant	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Not stated	**Prevalence**	Not relevant
Index test independent	Yes	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
		LR+	--
		LR–	--
		Area under ROC curve	--
		Correlation	--

Reliability 0.692 S, Mdiff 9.6 SDdiff 11.4, % error 22.9 +-20.6, median rel error 41% for trusvol <20, 17–21% at vol >20. Abs wrong 12 ml at vol <20 and 18 at vol >20, not sign rel to volym	
Other results	
Comments results --	**Comments** --

Slawin 2006 USA Urology 2006;67:84-8	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Acute urinary retention or surgical intervention
Inclusion criteria 3 randomised trials, >50 years, PSA 1.5–10, enlarged prostate, IPSS >7 **Exclusion criteria** Not stated in this paper		**Execution index test** Q_{max}, not described **Execution reference test** Acute urinary retention or surgical intervention

Number	4 325	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	Not stated	**Prevalence**	0.05
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	Hazard ratio 1.29 sign -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Steele 2000 USA J Urol 2000;164:344-8		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Pressure-flow, $p_{det\ Qmax}$
Inclusion criteria LUTS, 66.7 years (SD 7.5) **Exclusion criteria** Prostate cancer, stricture, previous therapy, neurologic history, significant disease			**Execution index test** TRUS, 7.5 MHz **Execution reference test** Pressure-flow, 7 Ch urethral catheter, 8 Ch rectal catheter, ICS diagram
Number	230		**Definition reference test** --
Exclusions	26		**Cut off value** 40 ml
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.75
Index test independent	Not stated		**Sensitivity** 0.66
Reference test independent	Not stated		**Specificity** 0.67
Reliability --			**LR+** 1.94 **LR–** 0.53 **Area under ROC curve** --
Other results			**Correlation** 0.57 P
Comments results --			**Comments** --

Tan 2003 Singapore J Urol 2003;170:2339-41	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Trial without catheter
Inclusion criteria Acute urinary retention, 50–90 years **Exclusion criteria** Prostatic cancer, recurrent or chronic retention, infection, hydronephrosis, renal impairment, neurologic disease		**Execution index test** Transabdominal US, 3.5 MHz, not described otherwise **Execution reference test** TWOC, successful if Q_{max} >10 ml/s and PVR <100 ml

Number	100	**Definition reference test**	--
Exclusions	0	**Cut off value**	Not stated
Consecutive	Yes	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Yes	**Prevalence**	Failure 0.54
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	Same mean PV in both groups
Comments results --		**Comments** --	

Terris 1998 USA Urology 1998;52:462-6		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Q_{max}
Inclusion criteria TRUS + biopsy, no BPH, infection or prostate cancer diagnosis **Exclusion criteria** Androgen and radiation therapy, incomplete data, no consent			**Execution index test** Ellipsoid formula, T^2*AP and T^3 used as diameters för PV <80 and >80 ml respectively **Execution reference test** Q_{max}, not described
Number	42		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Yes		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	0 days		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** -0.33
Comments results TZ better			**Comments** --

Tewari 1995 USA Urology 1995;45:258-64; discussion 265		**Study quality** Low	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Change in Q_{max}
Inclusion criteria Symptoms of BPH, Q_{max} <15 ml/s, PVR <300 ml, randomized finasteride trial **Exclusion criteria** Prostate cancer, PSA >40, high creatinine or liver function tests			**Execution index test** Siemens SI-200, 5, 6 and 7.5 MHz, ellipsoidal formula, 1 examiner **Execution reference test** Change in Q_{max}, not described
Number	36		**Definition reference test** --
Exclusions	13		**Cut off value** 3 ml/s
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not relevant		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.61 (improved)
Index test independent	Yes		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 42.4 vs 36.7 ml
Comments results TZI better			**Comments** High withdrawal rate

Tewari 1996 USA J Clin Ultrasound 1996;24:169-74		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** MRI, radical prostatectomy specimen
Inclusion criteria LUTS, Q_{max} <15 ml/s, PVR <300 ml, PSA <40, randomized finasteride study **Exclusion criteria** Prostate cancer, neurogenic bladder			**Execution index test** Siemens SI-200, 5, 6 and 7.5 MHz, ellipsoidal formula **Execution reference test** MRI, Siemens Magnetom SPP63, radical prostatectomy specimens
Number	36, 48		**Definition reference test** --
Exclusions	6		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability MRI SD intraind 6.8 ml, 19.9%, specimen weight SD 28 ml, 34.6%			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results Assumptions: SD US = SD MRI, specimen weight is correct			**Comments** --

Tong 1998 Canada Ultrasound Med Biol 1998;24:673-81		**Study quality** High	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** --
Inclusion criteria Images from patients **Exclusion criteria** Not stated			**Execution index test** 3D-studies. 2D images obtained from these **Execution reference test** --
Number	15, 4+4 observers		**Definition reference test** --
Exclusions	0		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not relevant		**True negatives** --
Verification bias	--		**Prevalence** --
Index test independent	--		**Sensitivity** --
Reference test independent	--		**Specificity** --
Reliability SD intra abs 9.5 ml, rel 11.5%, inter abs 11.6, rel 13.5%			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results Unexperienced examiners larger SD			**Comments** --

Tsukamoto 2007 Japan Int J Urol 2007;14:321-4; discussion 325	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Maximum flow rate
Inclusion criteria LUTS, 2 measurements of prostate volume, 69.5 years SD 6.5 **Exclusion criteria** Prostate cancer, surgery or hormonal reatment between visits		**Execution index test** TRUS, Bruel & Kjaer type 2002, ellipsoidal formula **Execution reference test** Q_{max}, method not described
Number 67 **Exclusions** 22 **Consecutive** Yes **Demographic description** Yes **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** -0.03
Reliability --		
Other results		
Comments results Spearman		**Comments** --

Watanabe 2002 Japan Int J Urol 2002;9:204-9	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Pressure-flow, URA
Inclusion criteria LUTS, men 49–84 years **Exclusion criteria** Stricture, bladder neck stenosis		**Execution index test** Abdominal US, Toshiba SSA–2604, 3.75 MHz, ellipsoid formula **Execution reference test** Pressure-flow, Dantec UD5500, transurethral 8 Ch and rectal balloon, URA and Schäfer grade
Number 51 **Exclusions** 0 **Consecutive** Not stated **Demographic description** Yes **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** 0.69
Reliability --		
Other results		
Comments results --		**Comments** --

Vesely 2003 Sweden Neurourol Urodyn 2003;22:301-5	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Pressure-flow study, DAMPF
Inclusion criteria LUTS and suspected BOO without neurological disease, 48–86 years **Exclusion criteria** Not stated		**Execution index test** Brüel & Kjaer UA 1082, ellipsoidal formula **Execution reference test** Pressure-flow study, Uro Dyn 2000, MMS, DAMPF

Number	153	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	Not stated
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.84
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	Q_{max} -0.16; DAMPF 0.36 P
Comments results --		**Comments** --	

Vesely 2003 Sweden Scand J Urol Nephrol 2003;37:322-8		**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** Q_{max}
Inclusion criteria LUTS suggestive of BPE referred to dept of urology **Exclusion criteria** Biopsy if suspicion of cancer, prostate cancer excluded, incomplete investigations			**Execution index test** Brüel & Kjaer UA1082r, ellipsoidal formula **Execution reference test** Uro Dyn 2000, MMS, voided volume >125 ml, visual inspection not stated
Number	946		**Definition reference test** --
Exclusions	592		**Cut off value** Not stated
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** Not stated
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** -0.18 S
Comments results --			**Comments** --

Yip 1991 Hong Kong Br J Urol 1991;67:79-82	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** --
Inclusion criteria Autopsy specimens without prostatic pathology **Exclusion criteria** Not stated		**Execution index test** Aloka Echocamera LS SSD-248 with UST-658-5, 5 MHz, 2 examiners, prostate mounted in water bath **Execution reference test** --
Number 61 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Not stated **Time interval** -- **Verification bias** -- **Index test independent** Not stated **Reference test independent** --		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** --
Reliability Regression with L and AP best and better than ellipsoid formula		
Other results		
Comments results Largest error for length		**Comments** --

Yuen 2002 Singapore Int J Urol 2002;9:225-9	**Study quality** Moderate	**Index test** Transrectal ultrasound investigation (TRUS) **Reference test** --
Inclusion criteria TURP, retention or severe symptoms, 56–79 years **Exclusion criteria** Not stated		**Execution index test** Aloka Dynaview SSD 1700, 3.5 and 7.5 MHz, ellipsoidal formula, bladder filled with 100–500 ml **Execution reference test** --

Number	22	**Definition reference test**	--
Exclusions	0	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	0 days	**True negatives**	--
Verification bias	--	**Prevalence**	Not stated
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability PV 2.7 and 9.2 ml smaller at BV 400 and 500 ml		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

4.8 Storleksbestämning med rektalpalpation

<table>
<tr><td colspan="2">Bohnen 2007 The Netherlands
Eur Urol 2007;51:1645-52; discussion 1652-3</td><td>Study quality
Moderate</td><td colspan="2">Index test
Digital rectal examination
Reference test
TRUS</td></tr>
<tr><td colspan="3">Inclusion criteria
All men 50–75 years in the population

Exclusion criteria
Prostate or bladder cancer, neurogenic disorder</td><td colspan="2">Execution index test
Estimates in increments of 5 ml

Execution reference test
Brüel & Kjaer, transrectal ultrasound, 7 MHz, planimetry</td></tr>
<tr><td>Number</td><td>1 524</td><td rowspan="9"></td><td>Definition reference test</td><td>--</td></tr>
<tr><td>Exclusions</td><td>50% + 164</td><td>Cut off value</td><td>30, 40 and 50 ml</td></tr>
<tr><td>Consecutive</td><td>Not relevant</td><td>True positives</td><td>--</td></tr>
<tr><td>Demographic description</td><td>No</td><td>False positives</td><td>--</td></tr>
<tr><td>Uninterpretable results</td><td>Not stated</td><td>False negatives</td><td>--</td></tr>
<tr><td>Time interval</td><td>0 days</td><td>True negatives</td><td>--</td></tr>
<tr><td>Verification bias</td><td>Yes</td><td>Prevalence</td><td>0.49; 0.20 and 0.09</td></tr>
<tr><td>Index test independent</td><td>Yes, probably</td><td>Sensitivity</td><td>--</td></tr>
<tr><td>Reference test independent</td><td>Probably not</td><td>Specificity</td><td>--</td></tr>
<tr><td colspan="2" rowspan="2">Reliability

--</td><td>LR+</td><td>--</td></tr>
<tr><td>LR–</td><td>--</td></tr>
<tr><td colspan="2">Other results</td><td>Area under ROC curve</td><td>--</td></tr>
<tr><td colspan="2"></td><td>Correlation</td><td>--</td></tr>
<tr><td colspan="3">Comments results
Area under ROC-curve 0.69; 0.74 and 0.82</td><td colspan="2">Comments
--</td></tr>
</table>

Cheng 2004 China Int Braz J Urol 2004;30:466-71	**Study quality** High	**Index test** Digital rectal examination **Reference test** TRUS
Inclusion criteria Consecutive patients with acute urinary retention **Exclusion criteria** Not stated		**Execution index test** 2 trainees with different experience, 1 specialist **Execution reference test** Brüel & Kjaer 2003 with transducer 8551, 7.0 MHz, formula for ellipsoid
Number 39 **Exclusions** 0 **Consecutive** Yes **Demographic description** No **Uninterpretable results** Not relevant **Time interval** <14 days **Verification bias** Yes **Index test independent** Yes **Reference test independent** Yes		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** --
Reliability Correlation 0.57, 0.54 and 0.64, large volumes underestimated, small volumes overestimated, underestimations are larger		
Other results		
Comments results Pearson correlation coefficient		**Comments** --

Kumar 2000 United Kingdom BJU Int 2000;86:816-9	**Study quality** Moderate	**Index test** Digital rectal examination **Reference test** Successful trial without catheter (TWOC) and follow-up
Inclusion criteria Acute urinary retention, men **Exclusion criteria** Prostate cancer, urethral or penile disease, pelvic colon cancer, neurogenic bladder, high PSA		**Execution index test** 1 urologist **Execution reference test** Successful TWOC and follow-up up to 20 months

Number	40	**Definition reference test**	--
Exclusions	0	**Cut off value**	Not stated
Consecutive	Yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	Yes	**Prevalence**	0.45
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--

Comments results Prostate volume sign different, 27.5 and 15.9 ml respectively	**Comments** --

McNeill 2004 United Kingdom BJU Int 2004;94:559-62	**Study quality** Moderate	**Index test** Digital rectal examination **Reference test** No second acute urinary retention (AUR), no surgery
Inclusion criteria Successful TWOC **Exclusion criteria** None		**Execution index test** Admitting urologist, 3 cathegories: <20, 21–50 and >50 ml **Execution reference test** No new AUR and no surgery

Number	34	**Definition reference test**	--
Exclusions	0	**Cut off value**	20; 50 ml
Consecutive	Yes	**True positives**	23; 10
Demographic description	Yes	**False positives**	4; 1
Uninterpretable results	Not stated	**False negatives**	3; 16
Time interval	Not relevant	**True negatives**	4; 7
Verification bias	Yes	**Prevalence**	0.76
Index test independent	Yes	**Sensitivity**	0.88; 0.38
Reference test independent	Not stated	**Specificity**	0.50; 0.68
Reliability --		**LR+** **LR–** **Area under ROC curve**	1.77; 3.08 0.23; 0.70 --
Other results		**Correlation**	--

Comments results --	**Comments** --

Meyhoff 1981 Denmark Scand J Urol Nephrol 1981;15:45-51	**Study quality** High	**Index test** Digital rectal examination **Reference test** Specimen weight open operation
Inclusion criteria Moderately enlarged prostate, benign at DRE, randomized trial URP vs open operation, 53–8 years **Exclusion criteria** None		**Execution index test** Urologic residents or specialists **Execution reference test** Specimen weight at open operation

Number	75, 32 open operation	**Definition reference test**	--
Exclusions	0	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	0 days	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Yes	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.27
Comments results Spearman		**Comments** --	

Pinsky 2006 USA Urology 2006;68:352-6		**Study quality** Moderate	**Index test** Digital rectal examination **Reference test** TRUS
Inclusion criteria One arm of creening study, men 55–74 years **Exclusion criteria** Prostate, pulmonary, colorectal cancer, finasteride			**Execution index test** Nurses, >100 examinations, length and width estimated in 0.5 cm increments, ellipsoid formula **Execution reference test** TRUS, ellipsoid formula
Number	DRE 35323, TRUS 653		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not relevant		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability 28% variation PV, 37% observer, 36% intraobserver			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.30 single, 0.41 corrected for examiner
Comments results --			**Comments** Average error 13 ml, 5 ml with correction for examiner

Roehrborn 1997 USA Urology 1997;49:548-57		**Study quality** Moderate	**Index test** Digital rectal examination **Reference test** TRUS
Inclusion criteria 4 studies: 2 epidemiological, 1 randomised, 1 clinical **Exclusion criteria** --			**Execution index test** 1 nurse, 1 urologist, several urologists, 1 urologist **Execution reference test** 3 Brüel & Kjaer, 7,5 MHz, 1 Dornier Performa 7.5 MHz, radiologists, 1 urologist, urologists, 1 urologist
Number	471, 480, 1 222, 100		**Definition reference test** --
Exclusions	74, 3 not stated		**Cut off value** 30; 40
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** 30 ml: 0.85; 1.00, 40 ml: 0.87–1.00
Reference test independent	Not stated		**Specificity** 30ml: 0.47; 0.30, 40 ml: 0.38–0.58
Reliability --			**LR+** 30 ml: 1.60; 1.52 **LR–** 30 ml: 0.32; 0.00 **Area under ROC curve** --
Other results			**Correlation** 0.40; 0.56; 0.48; 0.90
Comments results Pearson, large volumes underestimation, small overestimation, AUROC 30 ml: -; 0.78; 0.74; 0.97, 40 ml: -; 0.83; 0.74; 0.96			**Comments** More methods in other papers

4.9 Prostataspecifikt antigen (PSA)

<table>
<tr><td colspan="2">Barry 1995 USA
J Urol 1995;153:99-103</td><td>Study quality
Moderate</td><td colspan="2">Index test
Prostate specific antigen (PSA)
Reference test
--</td></tr>
<tr><td colspan="3">Inclusion criteria
Placebo group, moderate–severe symptoms, enlarged prostate, Q_{max} <15 ml/s

Exclusion criteria
Voided volume <150 ml, residual urine >350 ml, prostate cancer, neurogenic bladder, prostatitis, urinary infection</td><td colspan="2">Execution index test
Tandem-R, Hybritech

Execution reference test
--</td></tr>
<tr><td>Number</td><td>300</td><td rowspan="9"></td><td>Definition reference test</td><td>--</td></tr>
<tr><td>Exclusions</td><td>61</td><td>Cut off value</td><td>--</td></tr>
<tr><td>Consecutive</td><td>Not stated</td><td>True positives</td><td>--</td></tr>
<tr><td>Demographic description</td><td>No</td><td>False positives</td><td>--</td></tr>
<tr><td>Uninterpretable results</td><td>Not stated</td><td>False negatives</td><td>--</td></tr>
<tr><td>Time interval</td><td>3 months</td><td>True negatives</td><td>--</td></tr>
<tr><td>Verification bias</td><td>--</td><td>Prevalence</td><td>--</td></tr>
<tr><td>Index test independent</td><td>--</td><td>Sensitivity</td><td>--</td></tr>
<tr><td>Reference test independent</td><td>--</td><td>Specificity</td><td>--</td></tr>
<tr><td colspan="2" rowspan="2">Reliability

SD 0.88</td><td rowspan="3"></td><td>LR+</td><td>--</td></tr>
<tr><td>LR–</td><td>--</td></tr>
<tr><td colspan="2">Other results</td><td>Area under ROC curve</td><td>--</td></tr>
<tr><td colspan="2"></td><td></td><td>Correlation</td><td>--</td></tr>
<tr><td colspan="3">Comments results
--</td><td colspan="2">Comments
--</td></tr>
</table>

Bo 2003 Italy Crit Rev Oncol Hematol 2003;47:207-11		**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria 60–90 years, admitted to geriatric or urologic ward, if PSA >4 negative biopsy **Exclusion criteria** Prostat cancer, drug that could influence PSA, prostatic phlogosis			**Execution index test** Immulite 2000, before DRE and TRUS **Execution reference test** 5 MHZ, radiologists, ellipsoidal formula
Number	569		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Yes		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.539
Comments results Pearson			**Comments** --

Bohnen 2007 The Netherlands Eur Urol 2007;51:1645-52; discussion 1652-3	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS, 30; 40; 50 ml
Inclusion criteria Men 50–75 years in one municipality **Exclusion criteria** Prostate cancer, biopsy if PSA >4		**Execution index test** Not described **Execution reference test** Brüel & Kjaer, 7 MHz, planimetric method with 5 mm intervals

Number	1 688 of 3 924	**Definition reference test**	--
Exclusions	50%	**Cut off value**	1.0; 1.5; unknown
Consecutive	Not relevant	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.49; 0.20; 0.09
Index test independent	Not stated	**Sensitivity**	0.71; 0.79; 0.84
Reference test independent	Not stated	**Specificity**	0.71; 0.79; 0.84
Reliability --		**LR+** **LR-** **Area under ROC curve**	2.45; 3.76; 5.25 0.41; 0.27; 0.19 --
Other results		**Correlation**	--
Comments results From graph		**Comments** --	

Bosch 1995 The Netherlands Prostate 1995;27:241-9	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria Prostate cancer screening, response rate 35%, one half randomised to screening **Exclusion criteria** Prostate cancer, PSA >10, previous surgery, refusal of TRUS		**Execution index test** Hybritech assay **Execution reference test** Brüel & Kjaer, 7 MHz, planimery 5 mm intervals

Number	502	**Definition reference test**	--
Exclusions	3	**Cut off value**	--
Consecutive	Not relevant	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.58
Comments results Spearman		**Comments** --	

Caffarel 2008 Great Britain Neurourol Urodyn 2008;27:797-801		**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Flow measurement, Q_{max}
Inclusion criteria Pressure-flow study, attendees at a LUTS clinic, performed flow measurement and at least 2 of IPSS, IPSS bother question, prostate specific antigen and postvoid residual urine **Exclusion criteria** Voided volume at flow measurement <150 ml, performed less than 2 IPSS, IPSS bother question, PSA and PVR			**Execution index test** Method not described **Execution reference test** Q_{max}, voided volume >150 ml
Number	95		**Definition reference test** --
Exclusions	45		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.22
Comments results Pearson correlation coefficient			**Comments** --

Chung 2006 South Korea BJU Int 2006;97:742-6		**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS, 30; 40; 50 ml
Inclusion criteria LUTS, IPSS>8, Q_{max} <15 ml/s, 50–80 years, biopsy if PSA >4 **Exclusion criteria** Acute prostatitis, infection, 5-ARI, PSA >10			**Execution index test** Elecsys, Architect or Immulite, calibration against Stanford 90:10 PSA Calibrator **Execution reference test** 7.5 MHz, ellipsoid formula
Number	57 16		**Definition reference test** --
Exclusions	Not stated		**Cut off value** 2.2 ng/ml
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Not stated		**Prevalence** --
Index test independent	Not stated		**Sensitivity** AUROC 0.755; 0.814; 0.826
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results Also results for age-groups			**Comments** --

<table>
<tr><td colspan="2">Clements 1992 United Kingdom Prostate Suppl 1992;4:51-7</td><td>Study quality
Moderate</td><td colspan="2">Index test
Prostate specific antigen (PSA)
Reference test
TRUS</td></tr>
<tr><td colspan="3">Inclusion criteria
Benign digital rectal examination, benign transrectal ultrasound, benign histology at TURP, 53–86 years

Exclusion criteria
Not stated</td><td colspan="2">Execution index test
Immuno-radiometric assay, Hybritech

Execution reference test
Brüel & Kjaer1846, 4 or 7 MHz, planimetric method, 0.5 cm intervals</td></tr>
<tr><td>Number</td><td>50</td><td rowspan="9"></td><td>Definition reference test</td><td>--</td></tr>
<tr><td>Exclusions</td><td>Not stated</td><td>Cut off value</td><td>--</td></tr>
<tr><td>Consecutive</td><td>Not stated</td><td>True positives</td><td>--</td></tr>
<tr><td>Demographic description</td><td>No</td><td>False positives</td><td>--</td></tr>
<tr><td>Uninterpretable results</td><td>Not stated</td><td>False negatives</td><td>--</td></tr>
<tr><td>Time interval</td><td>Less than 4 weeks</td><td>True negatives</td><td>--</td></tr>
<tr><td>Verification bias</td><td>Unclear</td><td>Prevalence</td><td>--</td></tr>
<tr><td>Index test independent</td><td>Not stated</td><td>Sensitivity</td><td>--</td></tr>
<tr><td>Reference test independent</td><td>Not stated</td><td>Specificity</td><td>--</td></tr>
<tr><td colspan="2">Reliability

--</td><td>LR+

LR-

Area under ROC curve</td><td>--

--

--</td></tr>
<tr><td colspan="2">Other results</td><td>Correlation</td><td>0.62</td></tr>
<tr><td colspan="3">Comments results
Pearson</td><td colspan="2">Comments
--</td></tr>
</table>

D'Ancona 1999 The Netherlands Prostate Cancer Prostatic Dis 1999;2:98-105.	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** IPSS, Q_{max} or resistance after TUMT; Q_{max}; Schäfer grade, URA
Inclusion criteria Treatment with TUMT, >45 years, PV >30 ml, Madsen SS >7, Q_{max} <15 ml/s, PVR <350 ml **Exclusion criteria** Neurogenic disorders, prostatic cancer, earlier surgery, indwelling catheter, median lobe		**Execution index test** PSA, method not described **Execution reference test** IPSS, Q_{max} or resistance after TUMT
Number 247 **Exclusions** At least 26 **Consecutive** Yes **Demographic description** Yes **Uninterpretable results** Not stated **Time interval** Not relevant **Verification bias** No **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** **LR–** **Area under ROC curve** -- **Correlation** --
Reliability --		
Other results OR IPSS 0.88 sign; Q_{max} 1.01 ns; pQ 0.91 sign Multivariate analysis ns x 3		
Comments results --		**Comments** --

Dutkiewicz 1995 Poland Int Urol Nephrol 1995;27:763-8	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Abdominal US
Inclusion criteria Diagnosed with BPH, 48–85 years **Exclusion criteria** Not stated		**Execution index test** Enzyme immunoassay PSA Beckmann kit **Execution reference test** Abdominal ultrasound, ellipsoidal formula

Number	112	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.34
Comments results CC not stated		**Comments** --	

Fukatsu 2003 Japan Urology 2003;61:370-4	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria TURP because of BPH, 53–87 years **Exclusion criteria** Prostate cancer		**Execution index test** Immulyze-PSA kit, no prostatic manipulation **Execution reference test** SSD-520, Aloka, 5 MHz, ellipsoid formula

Number	122	**Definition reference test**	--
Exclusions	0	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	<1 week	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.51

Comments results Pearson correlation coefficient	**Comments** --

Furuya 2000 Japan Int J Urol 2000;7:447-51		**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria TURP or open operation, 52–92 years **Exclusion criteria** Urinary retention, prostatitis, androgen deprivation, testosteron treatment			**Execution index test** Tandem-R kit, Eiken kit converted to Tandem-R values, before DRE or urethral manipulation **Execution reference test** Ellipsoidal formula
Number	204		**Definition reference test** --
Exclusions	11		**Cut off value** --
Consecutive	No stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.497
Comments results --			**Comments** --

Furuya 2001 Japan Int Urol Nephrol 2001;33:645-8		**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria LUTS, high PSA or abnormal DRE, BPH at biopsy **Exclusion criteria** Not stated			**Execution index test** Tandem-R kit, before DRE or other prostatic manipulation **Execution reference test** Ellipsoidal formula
Number	218		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.40
Comments results Pearson, odd population			**Comments** --

Hong 2003 South Korea Eur Urol 2003;44:94-9; discussion 99-100	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Surgery and failed medical therapy
Inclusion criteria LUTS, diagnosis of BPH, medication at least 3 months **Exclusion criteria** Prostate cancer, previous surgery, other condition affecting urinary tract, severe disease		**Execution index test** Not described **Execution reference test** Not satisfied with continuing medical therapy, surgery

Number	437	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.23
Index test independent	Yes	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	Multivariate PSA ns
Comments results Age, IPSS and prostate volume sign		**Comments** --	

Hosseini 2005 Iran Urol J. 2005;2:183-8		**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria Referral for BPH surgery, urinary retention, gross hematuria, failed medical therapy, age >50 years **Exclusion criteria** Malignancy, liver disease, previous prostatic surgery, antiandrogen therapy, postoperative death, prostate cancer			**Execution index test** Microwell Eliza kit **Execution reference test** TRUS, ellipsoid formula
Number	104		**Definition reference test** --
Exclusions	18		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.70
Comments results Pearson correlation coefficient			**Comments** --

Kirschenbaum 1996 USA World J Urol 1996;14:360-2	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria Moderate symptoms, clinical diagnosis of BPH, finasteride treatment, 59–88 years, biopsy if PSA >4 or suspicious DRE **Exclusion criteria** None		**Execution index test** Tandem-R, Hybritech **Execution reference test** 3.5 MHz, Aloka chair mounted scanner, planimetry
Number 55 **Exclusions** 0 **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** 0.57
Reliability --		
Other results		
Comments results Pearson		**Comments** --

Laguna 2002 The Netherlands J Urol 2002;167:1727-30	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** IPSS <8, bother question 1 or 2, Q_{max} >12 ml/s
Inclusion criteria TUMT, mean age 66, range 44–89 years, flow-up 1 year **Exclusion criteria** Previous treatment, neurogenic disorder		**Execution index test** Tandem-R kit **Execution reference test** IPSS <8, bother question 1 or 2, Q_{max} >12 ml/s

Number	404	**Definition reference test**	--
Exclusions	16	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Yes	**Sensitivity**	AUROC 0.56; 0.57; 0.59
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Lepor 1994 USA Urology 1994;44:199-205	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria PSA >4 or suspicious digital rectal examination, 50–79 years **Exclusion criteria** Prostate cancer		**Execution index test** Not stated **Execution reference test** Brüel & Kjaer 1 846 with transducer 8 551, 7.5 MHz, ellipsoidal formula

Number	42	**Definition reference test**	--
Exclusions	21	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Uclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.53
Comments results Pearson		**Comments** --	

Lim 2006 Singapore Int J Urol 2006;13:1509-13	**Study quality**	**Index test** Prostate specific antigen (PSA) **Reference test** Pressure flow, BOOI >40 cm H_2O
Inclusion criteria LUTS suggestive of BPE, 52–88 years, biopsy if high PSA **Exclusion criteria** Previous surgery, radiation, neurogenic bladder disorder		**Execution index test** Not stated **Execution reference test** Pressure-flow study according to ICS

Number	114	**Definition reference test**	--
Exclusions	19	**Cut off value**	1.5; 4
Consecutive	Yes	**True positives**	35; 15
Demographic description	No	**False positives**	21; 7
Uninterpretable results	Not stated	**False negatives**	12; 32
Time interval	Not stated	**True negatives**	27; 41
Verification bias	Unclear	**Prevalence**	0.49
Index test independent	Not stated	**Sensitivity**	0.74; 0.32
Reference test independent	Not stated	**Specificity**	0.56; 0.85
Reliability --		**LR+**	1.67; 2.14
		LR–	0.44; 0.78
		Area under ROC curve	--
Other results		**Correlation**	0.592
Comments results --		**Comments** --	

Liu 2008 Taiwan Urology 2007;70:677-80		**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS, prostate volume
Inclusion criteria Free health screening, mean age 59.8 years, quartiles 54, 61 and 66 years **Exclusion criteria** Malignansy, liver cirrhosis, men taking hormons, antiandrogens, antifungal agents, steroides, surgical or medical therapy for BPH			**Execution index test** Immulite 2000 **Execution reference test** TRUS, 7 MHz, type 2001 medical Ultrasound Scanner, B&K Medical, probe 8551, ellipsoid formula
Number	148		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.46
Comments results Pearson correlation coefficient			**Comments** --

Marberger 2000 Multinational Eur Urol 2000;38(5):563-8	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Acute urinary retention
Inclusion criteria Patients from 3 randomised finasteride trials, at least 2 moderate but no more than 2 severe symptoms, enlarged prostate, PSA <10 ng/ml, PVR <151 ml, Q_{max} 5–15 ml/s and voided volume >150 ml **Exclusion criteria** Prostate cancer		**Execution index test** Not stated **Execution reference test** Acute urinary retention assessed by investigator and an independent endpoint committee

Number	4 222, 4 198 with PSA	**Definition reference test**	--
Exclusions	326	**Cut off value**	≥1.4 ng/ml
Consecutive	Not stated	**True positives**	74
Demographic description	No	**False positives**	2 674
Uninterpretable results	Not stated	**False negatives**	7
Time interval	2 year follow-up	**True negatives**	1 443
Verification bias	No	**Prevalence**	0.019
Index test independent	Not stated	**Sensitivity**	0.91
Reference test independent	Not stated	**Specificity**	0.35
Reliability --		**LR+** **LR–** **Area under ROC curve**	1.41 0.25 --
Other results		**Correlation**	--
Comments results Low cut-off		**Comments** --	

Milonas 2003 Lithuania Medicina (Kaunas) 2003;39:1071-7	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria LUTS suggestive of BPO, age 67.3 SD 7.35 **Exclusion criteria** Acute urinary retention, prostate cancer, neurogenic bladder disorder		**Execution index test** Not described **Execution reference test** Siemens Sonoline SI.250, 5–7.5 MHz, ellipsoidal formula, 2 examiners

Number	68	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Not stated	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.618
Comments results --		**Comments** --	

Ojea Calvo 1994 Spain Actas Urol Esp 1994;18:178-80	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Abdominal US
Inclusion criteria Patients with histologically confirmed BPH, age not stated **Exclusion criteria** Not stated		**Execution index test** IRMA I125, before manipulation **Execution reference test** Abdominal ultrasound, ellipsoidal formula

Number	44	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–**	-- --
		Area under ROC curve	--
Other results		**Correlation**	0.13
Comments results Pearson		**Comments** --	

Roehrborn 1999 USA Urology 1999;53:473-80	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Acute urinary retention or surgery
Inclusion criteria Moderate–severe symptoms, enlarged prostate, Q_{max} <15 ml/s, biopsy if PSA 4–10 **Exclusion criteria** Prostate or bladder cancer, previous surgery, prostatitis, recurrent infections, alpha-blocker or antiandrogen treatment, PSA >10		**Execution index test** Hybritech assay **Execution reference test** Acute urinary retention or surgery
Number 3 040 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** Yes **Uninterpretable results** Not stated **Time interval** Not relevant **Verification bias** Unclear **Index test independent** Yes **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** AUROC 0.53–0.70 **Specificity** -- **LR+** -- **LR-** -- **Area under ROC curve** -- **Correlation** --
Reliability --		
Other results		
Comments results --		**Comments** --

Roehrborn 2000 USA J Urol 2000;163:13-20	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Prostate volume with MRI, increase of 5 ml in 4 years
Inclusion criteria Subset of placebo group, moderate–severe symptoms, enlarged prostate, Q_{max} <15 ml/s, biopsy if PSA 4–10 **Exclusion criteria** Prostate or bladder cancer, PSA >10, prostatitis, recurrent infections, previous surgery		**Execution index test** Hybritech assay **Execution reference test** Change in volume measured by MRI; pretreatment MRI

Number	164	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	AUROC 0.787
Reference test independent	Yes	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.53
Comments results PSA better than prostate volume		**Comments** --	

Roehrborn 2001 USA Urology 2001;58:210-6	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Spontaneous acute urinary retention
Inclusion criteria Placebo group of 4 finasteride trials, moderate or severe symptoms, enlarged prostate, Q_{max} <15 ml/s, biopsy if PSA 4–10 **Exclusion criteria** PSA >10		**Execution index test** Hybritech assay **Execution reference test** Spontaneous acute urinary retention

Number	3 798	**Definition reference test**	--
Exclusions	8%	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Yes	**Sensitivity**	AUROC 0.716
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–**	-- --
Other results		**Area under ROC curve** **Correlation**	-- --
Comments results Prostate volume better than PSA		**Comments** --	

Romics 1997 Hungary Int Urol Nephrol 1997;29:449-55	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Suprapubic US
Inclusion criteria 49–90 years, histologically proven BPH at operation **Exclusion criteria** None		**Execution index test** Hybritech kit **Execution reference test** Suprapubic US, Kretz-Combison 310

Number	131	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.63
Comments results Cc not stated		**Comments** --	

Sanchez Sanchez 1995 Spain Actas Urol Esp 1995;19:181-6	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Abdominal US
Inclusion criteria Prostatectomy, histology benign, 50–90 years **Exclusion criteria** Not stated		**Execution index test** Immunoenzymatic assay with monoclonal antibodies **Execution reference test** Abdominal ultrasound, 3.5 MHz, ellisoidal formula
Number 163 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Not stated **Time interval** <30 days **Verification bias** Unclear **Index test independent** Not stated **Reference test indepen.** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** --- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** 0.61
Reliability --		
Other results		
Comments results Pearson		**Comments** --

Scattoni 1999 Italy Eur Urol 1999;36:621-30	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria Waiting list for open surgery of BPH **Exclusion criteria** Suspicion of prostate cancer		**Execution index test** Prostatus Free/Total assay, Delfia Reagents, 2 weeks prior to prostatic manipulation **Execution reference test** TRUS with Ansaldo AU 560, multiplanar transducer, 5–7 MHz, ellipsoidal formula

Number	50	**Definition reference test**	--
Exclusions	4	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Yes	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability		**LR+**	--
--		**LR–**	--
		Area under ROC curve	--
Other results		**Correlation**	0.57

Comments results	**Comments**
--	--

Shim 2007 South Korea Prostate Cancer Prostatic Dis 2007;10:143-8	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS, 30; 40; 50 ml
Inclusion criteria LUTS, 50–80 years, negative biopsy if PSA >10 **Exclusion criteria** Surgery or radiation, 5-AR, prostate cancer, indwelling catheter, infection, acute urinary retention		**Execution index test** Izotop, before examination, blood stored <1 week at –70 C **Execution reference test** Ultramake 9, 7.0 MHz, radiologist, estimation not described
Number 3 566 **Exclusions** 135 **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** 1.26; 1.44; 1.51 **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** AUROC 0.80; 0.86; 0.90 **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** --
Reliability -- **Other results**		
Comments results --		**Comments** --

Slawin 2006 USA Urology 2006;67:84-8	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** Acute urinary retention or surgical intervention
Inclusion criteria 3 randomised trials, >50 years, PSA 1.5–10, enlarged prostate, IPSS >7 **Exclusion criteria** Not stated in this paper		**Execution index test** Not stated **Execution reference test** Acute urinary retention or surgical intervention

Number	4 325	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	Not stated	**Prevalence**	0.05
Index test independent	Not stated	**Sensitivity**	--
Reference test indepen.	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	Hazard ratio 1.35 -- --
Other results		**Correlation**	--

Comments results --	**Comments** --

Stephan 1997 Germany Cancer 1997;79:104-9	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria Healthy men; men with prostatic cancer; BPH patients, 32 benign surgical specimen, 12 clinical diagnosis **Exclusion criteria** Not stated		**Execution index test** Immulite PSA kit **Execution reference test** Combison 330

Number	54; 36; 44	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.66
Comments results Spearman		**Comments** --	

Svindland 1996 Norway Scand J Urol Nephrol Suppl 1996;179:113-7	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria Randomised study of lueprolide in BPH **Exclusion criteria** Not stated		**Execution index test** Enzyme immunoassay, Abbott laboratories, Frozen at –20, 2–4 weeks after biopsy **Execution reference test** Brüel & Kjaer 1846 and transducer 8 531, mean of 2 planimetries, 1 examiner

Number	55	**Definition reference test**	--
Exclusions	14	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	2–4 weeks	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test indepen.	Yes	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.66
Comments results CC not stated		**Comments** --	

Terris1998 USA Urology 1998;52:462-6	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria Referral for biopsies, 50–82 years **Exclusion criteria** Prostate cancer, treatment for BPH, LUTS, infections		**Execution index test** Not stated **Execution reference test** 1 examiner, ellipsoidal formula, T^2 * AP om <80 ml otherwize T^3

Number	42	**Definition reference test**	--
Exclusions	(18)	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	<1 month	**True negatives**	--
Verification bias	Yes	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR-** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.41
Comments results Pearson		**Comments** --	

Tsukamoto 2007 Japan Int J Urol 2007;14:321-4; discussion 325		**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS, Q_{max}
Inclusion criteria LUTS, 2 prostate volume measurements, 55–82 years **Exclusion criteria** Prostate cancer, surgery or hormonal treatment between measurements			**Execution index test** Not described **Execution reference test** Brüel & Kjaer, type 2002, ellipsoidal formula, 5 examiners, Q_{max} not described
Number	67		**Definition reference test** --
Exclusions	PSA 7, Q_{max} 25		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** PV 0.65, Q_{max} 0.11
Comments results Spearman			**Comments** --

Vesely 2003 Sweden Scand J Urol Nephrol 2003;37:322-8	**Study quality** Moderate	**Index test** Prostate specific antigen (PSA) **Reference test** TRUS
Inclusion criteria LUTS, 45–91 years, biopsy if suspected malignancy **Exclusion criteria** Prostate cancer, not complete examinaations		**Execution index test** Not described **Execution reference test** Brüel & Kjaer UA 1082r, ellipsoidal formula

Number	946	**Definition reference test**	--
Exclusions	592	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.54
Comments results Spearman		**Comments** --	

4.10 Symtomskalor

Agrawal CS 2008 Nepal Nepal Med Coll J 2008;10:104-7.	**Study quality** Moderate	**Index test** Symptom score **Reference test** Transabdominal US
Inclusion criteria Diagnosis of BPH, age 67.5 years, SD 8.5, range 48–85 years **Exclusion criteria** Previous surgery, prostate cancer, urethral stricture, neuropathic bladder		**Execution index test** IPSS **Execution reference test** Transabdominal US

Number	100	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.19
Comments results Pearson correlation coefficient		**Comments** --	

Badia 1998 Spain Urology 1998;52:614-20	**Study quality** Moderate	**Index test** Symptom score **Reference test** --
Inclusion criteria Diagnosis of BPH made by urologist, >50 years, able to understand and answer questions; 18–49 years, same centers, men without current problems and history or present diagnosis of urinary tract **Exclusion criteria** Prostata cancer, diabetes, neurologic disease, current prostatitis, urinary infection, kidney stones, psychiatric disorder, pelvic trauma or surgery, catheter, drugs affecting bladder function		**Execution index test** IPSS **Execution reference test** Clinical diagnosis
Number 59 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Not stated **Time interval** 1 week **Verification bias** No **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** ICC 0.87; Pearson 0.92
Reliability Cronbach's alpha 0.79. ICC 0.87 and Pearson r 0.92 (n=57). Effect size -2.52, Guyatt statistic -2.49		
Other results		
Comments results AUROC 0.95 no LUTS		**Comments** --

Barry 1992 USA J Urol 1992;148:1558-63; discussion 1564	**Study quality** Moderate	**Index test** Symptom score **Reference test** --
Inclusion criteria Believed to have definite clinical BPH; non-urologic complaints in general medical practise **Exclusion criteria** Previous surgery		**Execution index test** IPSS **Execution reference test** --

Number	76+59	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Approximately 1 week	**True negatives**	--
Verification bias	--	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Pearson r 0.92		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Barry 1993 USA J Urol 1993;150:351-8	**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS, prostate volume, ellipsoidal formula*1.05; Q_{max}
Inclusion criteria Symptoms suggesting BPH **Exclusion criteria** Prostate or bladder cancer, urethral stricture, previous surgery, less likely to return for follow-up, drug treatment		**Execution index test** IPSS **Execution reference test** Prostate volume, ellipsoid formula *1,05, Q_{max}

Number	219	**Definition reference test**	--
Exclusions	At least 21	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	No	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability ICC 0.82		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	-0.09; – 0.07

Comments results Pearson	**Comments** --

Barry 1995 USA J Urol 1995;153:99-103	**Study quality** Moderate	**Index test** Symptom score **Reference test** --
Inclusion criteria Patients considered to have BPH of a urologist after a standardized evaluation **Exclusion criteria** Not stated		**Execution index test** IPSS **Execution reference test** --

Number	274	**Definition reference test**	--
Exclusions	115	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	<30 days	**True negatives**	--
Verification bias	Not relevant	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Mean diff –1.0, SD 2.69, ICC 0.86		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--

Comments results --	**Comments** --

Barry 1995 USA J Urol 1995;154:1770-4	**Study quality** Moderate	**Index test** Symptom score **Reference test** --
Inclusion criteria Randomised study, diagnosis of BPH, Q_{max} 4–15 ml/s, voided volume 125–500 ml, IPSS >7, no antihypertensive agent other than diuretics and ACE inhibitors, 45–80 years **Exclusion criteria** Prostate cancer, stricture, pelvic irradiation, surgery, PSA >12, neurologic disease, urinary infection, drug treatment		**Execution index test** IPSS **Execution reference test** --

Number	1 229	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	1 week	**True negatives**	--
Verification bias	Not relevant	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability ICC 0.74		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--

Comments results --	**Comments** --

Barry 2000 USA J Urol 2000;164:1559-64		**Study quality** Moderate	**Index test** Symptom score **Reference test** Prostate volume; Q_{max}
Inclusion criteria Diagnosis of BPH, IPSS >7, Q_{max} 4–15 ml/s, voided volume >125 ml, residual urine <300 ml, 45–80 years **Exclusion criteria** Not stated			**Execution index test** IPSS, mean of 2 **Execution reference test** Prostate volume; Q_{max}, not described
Number	1 229		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** -0.06; -0.17
Comments results Pearson			**Comments** --

Bosch 1995 The Netherlands Prostate 1995;27:241-9	**Study quality** Moderate	**Index test** Symptom score **Reference test** Q_{max}; TRUS, prostate volume, planimetry
Inclusion criteria Randomised community sample, 55–74 years **Exclusion criteria** PSA >10, prostate cancer, previous surgery, refusing TRUS		**Execution index test** IPSS **Execution reference test** Urodyn 1000, Dantec, Q_{max}; TRUS, Brüel & Kjaer, 7 MHz, planimetry, prostate volume

Number	554	**Definition reference test**	--
Exclusions	52, 35% participating	**Cut off value**	--
Consecutive	Not relevant	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	-0.18; 0.19
Comments results Spearman		**Comments** --	

Caffarel 2008 Great Britain Neurourol Urodyn 2008;27:797-801	**Study quality** Moderate	**Index test** Symptom score **Reference test** Q_{max}, voided volume >150 ml
Inclusion criteria Pressure-flow study, attendees at a LUTS clinic, performed flow measurement and at least 2 of IPSS, IPSS bother question, prostate specific antigen and postvoid residual urine **Exclusion criteria** Voided volume at flow measurement <150 ml, performed less than 2 IPSS, IPSS bother question, PSA and PVR		**Execution index test** IPSS **Execution reference test** Q_{max}, voided volume >150 ml

Number	95	**Definition reference test**	--
Exclusions	45	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.26
Comments results Pearson correlation coefficient		**Comments** --	

Chancellor 1994 USA Br J Urol 1994;74:200-3	**Study quality** Low	**Index test** Symptom score **Reference test** Video-urodynamic study
Inclusion criteria Voiding symptoms, PSA <4 or PSA 4–10 and negative biopsy, Q_{max} <10 ml/s and pves >80 cm H_2O or Q_{max} >15 ml/s and pves <60 cm H_2O **Exclusion criteria** Drug treatment		**Execution index test** IPSS **Execution reference test** Video-urodynamic study

Number	57	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--

Comments results No difference in IPSS between groups	**Comments** Excluded due to exclusion of intermediate patients

Chuang 2003 Taiwan Arch Androl 2003;49:129-37	**Study quality** Moderate	**Index test** Symptom score **Reference test** Improvement in IPSS after TURP, 7; 10 points
Inclusion criteria TURP, 30% acute urinary retention **Exclusion criteria** Prostate cancer, previous prostatic surgery		**Execution index test** IPSS **Execution reference test** Improvement in IPSS 6–12 months after TURP

Number	99	**Definition reference test**	--
Exclusions	Nor stated	**Cut off value**	17; 19
Consecutive	Yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	Yes	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	0.80: 0.77
Reference test independent	Not stated	**Specificity**	0.77; 0.70
Reliability --		**LR+**	3.5; 2.6
		LR-	0.26; 0.33
		Area under ROC curve	--
Other results		**Correlation**	--
Comments results Cut off selected at analysis, regression towards the mean		**Comments** --	

D'Ancona 1999 The Netherlands Prostate Cancer Prostatic Dis 1999;2:98-105	**Study quality** Moderate	**Index test** Symptom score **Reference test** IPSS, Q_{max} or resistance after TUMT; Q_{max}; Schäfer grade, URA
Inclusion criteria Treatment with TUMT, >45 years, PV >30 ml, Madsen SS >7, Q_{max} <15 ml/s, PVR <350 ml **Exclusion criteria** Neurogenic disorders, prostatic cancer, earlier surgery, indwelling catheter, median lobe		**Execution index test** IPSS **Execution reference test** IPSS, Q_{max} or resistance after TUMT

Number	247	**Definition reference test**	--
Exclusions	At least 26	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	No	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+**	OR IPSS 0.80; Q_{max} 0.96; pQ ns, mult regr nsx3
		LR–	--
		Area under ROC curve	--
Other results		**Correlation**	Q_{max}, Schäfer grade, URA ns

Comments results --	**Comments** --

Eckhardt 2001 The Netherlands Urology 2001;57:695-700	**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS, prostate volume; pressure-flow study, Schäfer grade
Inclusion criteria LUTS, >50 years, voided volume >150 ml at uroflow, residual urine and prostate volume measurement performed **Exclusion criteria** According to the International Consensus Committee on BPH		**Execution index test** IPSS **Execution reference test** TRUS, not described; 5 Ch transurethral catheter, Schäfer grade

Number	565	**Definition reference test**	--
Exclusions	5%	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Yes	**Prevalence**	0.53
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	ns; ns

Comments results --	**Comments** --

Ezz el Din 1996 The Netherlands J Urol 1996;155:1959-64	**Study quality** High	**Index test** Symptom score **Reference test** --
Inclusion criteria LUTS, 44–83 years **Exclusion criteria** Not stated		**Execution index test** IPSS **Execution reference test** --

Number	71	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	8 weeks	**True negatives**	--
Verification bias	Not relevant	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Mean diff 1.6 ns, SD 4.3		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Girman 1995 USA J Urol 1995;153:1510-5		**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS, ellipsoid formula; Qmax
Inclusion criteria Random sample, 40–79 years **Exclusion criteria** Prostate surgery, prostate cancer, conditions interfering with voiding except BPH			**Execution index test** Score similar to IPSS **Execution reference test** TRUS, ellipsoid formula; Q_{max}, portable device
Number	471		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not relevant		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.185; –0.35
Comments results Pearson			**Comments** --

Gregoire 1996 Canada Prog Urol 1996;6:240-9		**Study quality** Moderate	**Index test** Symptom score **Reference test** Qmax
Inclusion criteria Volunteers, 50–84 years **Exclusion criteria** Previous treatment, long travelling			**Execution index test** IPSS **Execution reference test** Disa 21, Dantec, Q_{max}
Number	238		**Definition reference test** --
Exclusions	23		**Cut off value** --
Consecutive	Not relevant		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Mean 10,5 days		**True negatives** --
Verification bias	Not relevant		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability Spearman 0.90			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** –0.289
Comments results Spearman			**Comments** --

Hakenberg 1997 Australia J Urol 1997;158:94-9	**Study quality** Moderate	**Index test** Symptom score **Reference test** IPSS, change 7; 10; correlation Q_{max}
Inclusion criteria TURP, LUTS, 55–88 years **Exclusion criteria** Previous surgery, prostate cancer		**Execution index test** IPSS **Execution reference test** IPSS improvement, correlation Q_{max}

Number	112	**Definition reference test**	--
Exclusions	7	**Cut off value**	21; 17
Consecutive	Yes	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	No	**Prevalence**	0.72; 0.65
Index test independent	Not stated	**Sensitivity**	0.65; 0.88
Reference test independent	Not stated	**Specificity**	0.76; 0.71
Reliability --		**LR+**	2.76; 3.03
		LR–	0.45; 0.18
		Area under ROC curve	--
Other results		**Correlation**	Q_{max} ns
Comments results Regression towards the mean		**Comments** --	

Hald 1991 Denmark Scand J Urol Nephrol Suppl 1991;138:59-62	**Study quality** Moderate	**Index test** Symptom score **Reference test** Qmax
Inclusion criteria Uncomplicated BPH, waiting list for surgery, 46–84 years **Exclusion criteria** Not stated		**Execution index test** Dan-PSS **Execution reference test** Q_{max}

Number	29	**Definition reference test**	--
Exclusions	0	**Cut off value**	T>20; S >13; B >13
Consecutive	Not stated	**True positives**	9; 8; 8
Demographic description	No	**False positives**	5; 5; 6
Uninterpretable results	Not stated	**False negatives**	9; 10; 10
Time interval	Not stated	**True negatives**	6; 6; 5
Verification bias	Unclear	**Prevalence**	0.62
Index test independent	Not stated	**Sensitivity**	0.5; 0.44; 0.44
Reference test independent	Not stated	**Specificity**	0.55; 0.55; 0.45
Reliability --		**LR+**	1.1; 0.98; 0.81
		LR–	0.91; 1.02; 1.22
		Area under ROC curve	--
Other results		**Correlation**	-0.12; -0.12; 0.09
Comments results Pearson		**Comments** --	

Hong 2003 South Korea Eur Urol 2003;44:94-9; discussion 99-100	**Study quality** Moderate	**Index test** Symptom score **Reference test** Not satisfied with continuing medical therapy, surgery
Inclusion criteria LUTS, diagnosis of BPH, medication at least 3 months **Exclusion criteria** Prostate cancer, previous surgery, other condition affecting urinary tract, severe disease		**Execution index test** IPSS **Execution reference test** Not satisfied with continuing medical therapy, surgery

Number	437	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not relevant	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.23
Index test independent	Yes	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+**	Multivariate hazard ratio 1.082
		LR–	--
		Area under ROC curve	--
Other results		**Correlation**	--

Comments results Age, IPSS and prostate volume sign	**Comments** --

Ko 1995 Canada J Urol 1995;154:396-8	**Study quality** Moderate	**Index test** Symptom score **Reference test** Q_{max}; pressure-flow study, Schäfer grade
Inclusion criteria Symptoms of prostatism, 67.9 years **Exclusion criteria** Not stated		**Execution index test** IPSS **Execution reference test** Q_{max}; pressure-flow study, 8 Ch transurethral catheter, manual reading, Schäfer grade
Number 121 **Exclusions** 18 **Consecutive** Yes **Demographic description** No **Uninterpretable results** Not stated **Time interval** 0 days **Verification bias** No **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** 0.14; 0.14
Reliability --		
Other results		
Comments results Pearson		**Comments** --

Kojima 1997 Japan J Urol 1997;157:2160-5		**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS, planimetry
Inclusion criteria Screening, >55 years			**Execution index test** IPSS
Exclusion criteria Prostate cancer or stone, prostatitis			**Execution reference test** TRUS, chair-type scanner, planimetry
Number	929		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not relevant		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.072
Comments results Pearson			**Comments** Partially same as Taneike

Kurita 1998 Japan Urology 1998;51:595-600		**Study quality** Moderate	**Index test** Symptom score **Reference test** Symptom scale
Inclusion criteria Symptomatic BPH, with and without acute urinary retention, IPSS >7, 51–84 years **Exclusion criteria** Prostate cancer, prostatitis, stricture, diabetic neuropathy, urinary retention, previous therapy			**Execution index test** IPSS **Execution reference test** One examiner, SSD 2000, Aloka, UST-670P-5 probe, 5 MHz, ellipsoidal formula
Number	331 (64 AUR)		**Definition reference test** --
Exclusions	14 with prostate cancer		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.34
Comments results Pearson correlation coefficient, PCAR worse			**Comments** --

Lujan Galan 1997 Spain Arch Esp Urol 1997;50:847-53	**Study quality** Moderate	**Index test** Symptom score **Reference test** --
Inclusion criteria TURP or open operation, 50–86 years **Exclusion criteria** Not stated		**Execution index test** IPSS **Execution reference test** --

Number	513	**Definition reference test**	--
Exclusions	361	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	30–60 days	**True negatives**	--
Verification bias	No	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability 0.50–0.76 Pearson, Spearman, Kendall		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	--
Comments results --		**Comments** --	

Netto Junior 1996 Brazil J Urol 1996;155:200-2	**Study quality** Moderate	**Index test** Symptom score **Reference test** Pressure-flow study, own definition of obstruction
Inclusion criteria Urinary symptoms attributed to BPH, IPSS >7, 51–80 years **Exclusion criteria** Prostate cancer, pelvic irradiation, neurogenic bladder, urinary infection, stricture, hydronephrosis, stone disease, drug treatment within 2 weeks		**Execution index test** IPSS **Execution reference test** 6 and 8 Ch-catheters transurethrally, Urosystem-DS-5600, obstruction when $p_{detQmax}$ >75 cm H_2O and Q_{max} <12 (age 46–55) or <9 ml/s (age >55), $p_{detQmax}$ >100 cm H_2O
Number 227 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** No **Uninterpretable results** Not stated **Time interval** not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** >18 **True positives** 107 **False positives** 23 **False negatives** 47 **True negatives** 50 **Prevalence** 0.68 **Sensitivity** 0.69 **Specificity** 0.68 **LR+** 2.21 **LR–** 0.45 **Area under ROC curve** -- **Correlation** --
Reliability Not studed		
Other results		
Comments results --		**Comments** --

Pannek 1998 Germany Neurourol Urodyn 1998;17:9-18		**Study quality** Moderate	**Index test** Symptom score **Reference test** Pressure-flow study; clinical outcome
Inclusion criteria TURP, symptomatic uncomplicated BPH, benign histology, 65.8 years **Exclusion criteria** Neurologic disease, bladder cancer, diabetes, acute urinary tract infection			**Execution index test** IPSS, Dan-PSS **Execution reference test** Pressure-flow study, suprapubic or 8 Ch transurethral catheter, AG-diagram and Schäfer grade, Urodyn 8000, Wiest Co; Clinical outcome
Number	25		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Yes		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** AUROC <0.65 **LR–** -- **Area under ROC curve** --
Other results			**Correlation** pQ ns
Comments results --			**Comments** --

Quek 2001 Malaysia BJU Int 2001;88:21-5	**Study quality** Moderate	**Index test** Symptom score **Reference test** --
Inclusion criteria BPH, TURP, stable condition; renal stones, no or mild symptoms, freedom from major diseases, no LUTS treatment **Exclusion criteria** Analphabetism, major medical history, physical disability; treatment for urological problems		**Execution index test** IPSS **Execution reference test** --

Number	237	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	3 months	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	--	**Specificity**	--
Reliability Cronbach's alpha 0.79. ICC 0.77. Guyatt statistic 1.58 resp 1.75.		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	ICC 0.77
Comments results --		**Comments** --	

Quek 2005 Malaysia Int J Urol 2005;12:39-45		**Study quality** Modrate	**Index test** Symptom score **Reference test** --
Inclusion criteria BPH, TURP, stable condition; renal stones, no or mild symptoms, freedom from major diseases, no LUTS treatment, **Exclusion criteria** Analphabetism, major medical history, physical disability; treatment for urological problems			**Execution index test** IPSS **Execution reference test** --
Number	39; 29		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Yes		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	1 week		**True negatives** --
Verification bias	--		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	--		**Specificity** --
Reliability ICC >0.93 in both groups. Guyatt statistic 1.92 for TURP. Cronbach's alpha not given.			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** ICC 0.98
Comments results --			**Comments** --

Schacterle 1996 USA Neurourol Urodyn 1996;15:459-70; discussion 470-2		**Study quality** Moderate	**Index test** Symptom score **Reference test** Q_{max} MUPP >9 cm H_2O
Inclusion criteria LUTS, performed urodynamic study, IPSS, flow rate and residual urine, 68.0 years SD 6.6 and 67.6 years SD 10.8 **Exclusion criteria** Neurologic disease			**Execution index test** IPSS **Execution reference test** Q_{max} standing; MUPP, >9 cm H_2O obstructed
Number	134		**Definition reference test** --
Exclusions	Not stated		**Cut off value** >19
Consecutive	Yes		**True positives** 17
Demographic description	Yes		**False positives** 17
Uninterpretable results	Not stated		**False negatives** 49
Time interval	Not stated		**True negatives** 51
Verification bias	Unclear		**Prevalence** 0.49
Index test independent	Not stated		**Sensitivity** 0.26
Reference test independent	Not stated		**Specificity** 0.75
Reliability --			**LR+** 1.03 **LR–** 0.99 **Area under ROC curve** --
Other results			**Correlation** Q_{max} 0.04
Comments results Pearson			**Comments** --

Schou 1993 Denmark Scand J Urol Nephrol 1993;27:489-92	**Study quality** Moderate	**Index test** Symptom score **Reference test** Pressure-flow study, Abrams-Griffiths diagram
Inclusion criteria Referral for BPH, urodynamic investigation, 38–88 years **Exclusion criteria** Diagnosis of other disease than BPH		**Execution index test** Dan-PSS **Execution reference test** Pressure-flow study, Dantec Urodyn 5500, 3.5 Ch suprapubic cather, rectal balloon, Abrams-Griffiths diagram

Number	54	**Definition reference test**	--
Exclusions	4	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Excluded	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	No	**Prevalence**	0.70
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+**	No sign difference
		LR–	--
		Area under ROC curve	--
Other results		**Correlation**	--

Comments results --	**Comments** --

Slawin 2006 USA Urology 2006;67:84-8		**Study quality** Moderate	**Index test** Symptom score **Reference test** Acute urinary retention or surgical intervention
Inclusion criteria 3 randomised trials, >50 years, PSA 1.5–10, enlarged prostate, IPSS >7 **Exclusion criteria** Not stated in this paper			**Execution index test** IPSS **Execution reference test** Acute urinary retention or surgical intervention
Number	4 325		**Definition reference test** --
Exclusions	Not stated		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	No		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not relevant		**True negatives** --
Verification bias	Not stated		**Prevalence** 0.05
Index test independent	Not stated		**Sensitivity** --
Reference test indepen.	Not stated		**Specificity** --
Reliability --			**LR+** Hazard ratio 1.17 ns **LR–** -- **Area under ROC curve** --
Other results			**Correlation** --
Comments results BII better			**Comments** --

Steele 2000 USA J Urol 2000;164:344-8		**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS prostate volume; Q_{max}; $p_{det\ Qmax}$
Inclusion criteria LUTS, 66.7 years SD 7.5 **Exclusion criteria** Previous treatment voiding dysfunction, neurologic history, significant co-morbidity, urethral stricture, prostate cancer			**Execution index test** IPSS **Execution reference test** TRUS, saggital and transverse planes: flow measurement not described; pressure-flow, 7 Ch transurethral and 8 Ch rectal catheters, visual inspection, ICS classification, slope <2 and $p_{det\ min}$ <40 unobst
Number	204		**Definition reference test** --
Exclusions	0		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.75
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** 0.18
Comments results Pearson ns			**Comments** --

Stoevelaar 1996 The Netherlands Br J Urol 1996;77:181-5	**Study quality** Moderate	**Index test** Symptom score **Reference test** Clinical diagnosis according to urologist
Inclusion criteria Referral to urologic department, <50 years **Exclusion criteria** Not stated		**Execution index test** IPSS **Execution reference test** Clinical diagnosis according to urologist

Number	1 703; 58	**Definition reference test**	--
Exclusions	17%; 5	**Cut off value**	--
Consecutive	yes	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	1 week	**True negatives**	--
Verification bias	No	**Prevalence**	0.49
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability Spearman 0.67		**LR+**	AUROC LUT 0.57–0.65; other 0.79–0.85; normal 0.84
		LR–	--
		Area under ROC curve	--
Other results		**Correlation**	--
Comments results --		**Comments** --	

Taneike 1997 Japan Tohoku J Exp Med 1997;183:135-50	**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS, planimetry
Inclusion criteria Screening, >55 years **Exclusion criteria** Prostate cancer or stone, prostatitis		**Execution index test** IPSS **Execution reference test** TRUS, chair-type scanner, planimetry

Number	647	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not relevant	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.077
Comments results Pearson		**Comments** --	

Terris 1998 USA Urology 1998;52:462-6	**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS, prostate volume, ellipsoid formula
Inclusion criteria TRUS + biopsy, no BPH, infection or prostate cancer diagnosis **Exclusion criteria** Androgen and radiation therapy, incomplete data, no consent		**Execution index test** IPSS **Execution reference test** Ellipsoid formula, T^2*AP and T^3 used as diameters för PV <80 and >80 ml respectively

Number	42	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Yes	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.21
Comments results Pearson		**Comments** --	

Tsukamoto 2007 Japan Int J Urol. 2007;14:321-4; discussion 325		**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS prostate volume; Q_{max}
Inclusion criteria LUTS, 2 measurements of prostate volume, 69.5 years SD 6.5 **Exclusion criteria** Prostate cancer, surgery or hormonal reatment between visits			**Execution index test** IPSS **Execution reference test** TRUS, Brüel & Kjaer type 2002, ellipsoidal formula
Number	67		**Definition reference test** --
Exclusions	22		**Cut off value** --
Consecutive	Yes		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** --
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** -0.16; -0.08
Comments results Spearman			**Comments** --

van Venrooij 1995 The Netherlands J Urol 1995;153:1516-9.		**Study quality** Moderate	**Index test** Symptom score **Reference test** Pressure-flow study, Schäfer grade
Inclusion criteria BPH symptoms, urodynamic study, 45–86 years **Exclusion criteria** Not stated			**Execution index test** IPSS **Execution reference test** 5 Ch transurethral and 14 Ch rectal catheters, Schäfer grade, >1 obstructed
Number	211		**Definition reference test** --
Exclusions	4		**Cut off value** --
Consecutive	Not stated		**True positives** --
Demographic description	Yes		**False positives** --
Uninterpretable results	Not stated		**False negatives** --
Time interval	Not stated		**True negatives** --
Verification bias	Unclear		**Prevalence** 0.76
Index test independent	Not stated		**Sensitivity** --
Reference test independent	Not stated		**Specificity** --
Reliability --			**LR+** -- **LR–** -- **Area under ROC curve** --
Other results			**Correlation** -0.02
Comments results Pearson			**Comments** --

van Venrooij 1996 The Netherlands J Urol 1996;155:2014-8	**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS, prostate volume; Q_{max}; pressure-flow study, Schäfer grade
Inclusion criteria LUTS, clinical judgement suggests bladder outlet obstruction, >50 years **Exclusion criteria** According to International Consensus Committee on BPH, voided volume <150 ml, missing examinations		**Execution index test** IPSS **Execution reference test** TRUS, not described; Q_{max} not described; pressure-flow study, 5 Ch transurethral catheter, Schäfer grade

Number	196	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	0.79
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	0.03; -0.12; 0.02
Comments results Pearson, Schäfer grade 2–6=obstr		**Comments** --	

Vesely 2003 Sweden Scand J Urol Nephrol 2003;37:322-8	**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS, prostate volume; Q_{max}
Inclusion criteria LUTS suggestive of BPE referred to dept of urology **Exclusion criteria** Biopsy if suspicion of cancer, prostate cancer excluded, incomplete investigations		**Execution index test** IPSS **Execution reference test** TRUS, Brüel & Kjaer UA1082r, ellipsoidal formula; Uro Dyn 2000, Q_{max}, MMS, voided volume >125 ml, visual inspection not stated

Number	946	**Definition reference test**	--
Exclusions	592	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	Yes	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	PV 0.05; Q_{max} -0.14
Comments results Spearman		**Comments** --	

Wang 2008 China Chin Med J (Engl) 2008;20;121:2042-5.	**Study quality** Moderate	**Index test** Symptom score **Reference test** Q_{max}; prostate volume
Inclusion criteria New diagnosis of BPH or discontinued medication 3 months or longer, age 50–89 years **Exclusion criteria** Severe heart disease, renal disease, neurological disease, UTI or previous surgery		**Execution index test** IPSS **Execution reference test** Flow measurement and TRUS not described
Number 1 295 **Exclusions** Not stated **Consecutive** Not stated **Demographic description** Yes **Uninterpretable results** Not stated **Time interval** Not stated **Verification bias** Unclear **Index test independent** Not stated **Reference test independent** Not stated		**Definition reference test** -- **Cut off value** -- **True positives** -- **False positives** -- **False negatives** -- **True negatives** -- **Prevalence** -- **Sensitivity** -- **Specificity** -- **LR+** -- **LR–** -- **Area under ROC curve** -- **Correlation** Q_{max} -0.42; PV 0.27
Reliability --		
Other results		
Comments results Spearman correlation coefficient		**Comments** --

Yalla 1995 USA J Urol 1995;153:674-9 discussion 679-80	**Study quality** Moderate	**Index test** Symptom score **Reference test** Micturitional urethral pressure profile, gradient >0 cm H_2O
Inclusion criteria Prostatism, urodynamic study, 66.0 years SD 8.9 **Exclusion criteria** Prostate cancer, previous surgery, neurologic disease		**Execution index test** IPSS, self-administered, help if needed **Execution reference test** Micturitional urethral pressure profile, pressure gradient >0 cm H_2O

Number	78	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	7; 19
Consecutive	Yes	**True positives**	53; 18
Demographic description	Yes	**False positives**	16; 5
Uninterpretable results	Not stated	**False negatives**	9; 44
Time interval	Not stated	**True negatives**	0; 11
Verification bias	Yes	**Prevalence**	0.79
Index test independent	Not stated	**Sensitivity**	0.85; 0.29
Reference test independent	Not stated	**Specificity**	0.00; 0.69
Reliability --		**LR+** **LR–**	0.85; 0.93 Infinite; 1.03
		Area under ROC curve	--
Other results		**Correlation**	0.25
Comments results Pearson		**Comments** --	

Yano 2004 Japan Int J Urol 2004;11:288-94	**Study quality** Moderate	**Index test** Symptom score **Reference test** TRUS, prostate volume; Q_{max}; pressure-flow study, Schäfer grade and AG-number
Inclusion criteria Flow rate suggestive of BPO, prostata volume >20 ml with adenoma, 51–80 years **Exclusion criteria** Acute or chronic retention, infection, bladder stone, renal impairment, prostate surgery, prostate cancer or other condition interfering with voiding		**Execution index test** IPSS **Execution reference test** TRUS not described; flow measurement not described; 4.6 Ch transurethral catheter, Schäfer grade and AG-number

Number	59	**Definition reference test**	--
Exclusions	Not stated	**Cut off value**	--
Consecutive	Not stated	**True positives**	--
Demographic description	No	**False positives**	--
Uninterpretable results	Not stated	**False negatives**	--
Time interval	Not stated	**True negatives**	--
Verification bias	Unclear	**Prevalence**	--
Index test independent	Not stated	**Sensitivity**	--
Reference test independent	Not stated	**Specificity**	--
Reliability --		**LR+** **LR–** **Area under ROC curve**	-- -- --
Other results		**Correlation**	PV 0.265; Q_{max} -0.448; pQ ns
Comments results Spearman		**Comments** --	

Farmakologi

5.2 Alfablockare

Terazosin

Lepor 1992 RCT USA
J Urol 1992;148:1467-74

Intervention
Terazosin 2mg vs 5mg vs 10mg vs placebo

Population
Terazosin 216 pat Drop-outs 35 (16,2%)
- 6,9% due to AE

Placebo 69 pat Drop-outs 13 (18,8%)
- 4,3% due to AE

	Terazosin	Placebo
Age	61.8	62.5
Q_{max}	9.0	10.1
Pvolume	37.0	36.7
Boyarsky	10.3	9.7
PVR	90.2	99.1

Mean values calculated from table. The only parameter which differed significantly was Q_{max}, which was higher in the placebo group (p<0,05)

Inclusion criteria:
Men age 50–75 years with diagnosis of BPH, and a Boyarsky score ≥1on ≥2 obstructive symptoms, Q_{max} 5–12 ml/s, voided volume ≥150 ml, diastolic blood pressure <115 mm

Exclusion criteria:
Medication that could interfere with voiding pattern, cardiovascular disease, invasive surgery/procedure in the urinary tract, PCA, other urological disease/dysfunction, hepatic/renal dysfunction, recurrent UTI, recent UTI or hydronephrosis

Results

Boyarsky	2 mg	5 mg	10 mg	Placebo
BL	10.0	10.7	10.1	9.7
12 w	6.6	7.2*	5.5**	7.4
Change	-3,3±3,2	-3,6±3,1	-4,5±3,7	-2,3±3,7

Mean±SD calc from SE
*p=0,042 and **p<0,001 vs placebo. 2 mg did not reach significance vs placebo

Q_{max}	2 mg	5 mg	10 mg	Placebo
BL	8.8	9.3	8.8	10.1
12 w	11.3	10.9	12.2*	10.2
Change	2.1±3.9	1.7±3.9	3.0±3.6	1.0±3.7

Mean±SD calc from SE
* p=0.009, only group which differed significantly vs placebo

	2mg	5mg	10mg	Placebo
% pts	51%	51%	69%	40%

No of pts who improved more than 30% in total symptom scores. The 10 mg group reached significance vs placebo (p=0.003)

IPSS*	2mg	5mg	10mg	Placebo
BL	12.9	13.8	13.0	12.5
12 w	8.5	9.3*	7.1**	9.6
Change	-4.3±4.2	-4.7±4.0	-5.8±4.8	-3.0±4.8

Mean±SD calc from SE
*calc from Boyarsky. Max-IPSS=35, Max-B=27. 35/27≈1.29→IPSS=1.29 x B

Adverse events
Adverse effects:

	2mg	5mg	10m	Placebo
Dizziness	8.1	2.8	10	2.9
Headache	5.4	1.4	2.9	5.8
Hypotension	2.7	8.3*	5.7	0
Flulike symptoms	1.4	4.2	4.3	1.4
UTI	0	1.4	4.3	1.4
Asthenia/ fa□igue	6.8	5.6	1	2.9
Syncope		0	1.4	0

% of patients in groups with AE.
*p<0.05 vs placebo

Quality of evidence: Moderate
Conclusion: Terazosin alleviates symptoms and increases flow.
Internal validity: Randomization and blinding adequately described. External validity: Eligible patients reported. Comments: ITT used. Sponsorship: Not stated.

Brawer 1993 RCT USA
Arch Fam Med 1993;929-935

Intervention
Terazosin 1–10mg (titrated according to clinical response) vs placebo
24 weeks

Population
Terazosin 81 pat drop-outs due to AE 18 (22%)

Placebo 79 pat drop-outs due to AE 9 (11,5%

Average age 64 years. "No significant baseline differences in age, height, weight or baseline urodynamics and symptoms"

Inclusion criteria:
≥45 years, symptomatic BPH, Q_{max} 5–12 ml/s

Exclusion criteria:
Absolute indication for prostatectomy, detrusor instability, carcinoma of the prostate, significant cardiopulmonary disease

Results

Boyarsky	Terazosin	Placebo	*p*
BL	10.9	10.4	
12w	-4.6±3.4	-1.1±3.4	≤0.05

Mean±SD.

IPSS*	Terazosin	Placebo	*p*
B	1□.9	10.4	
12w	-5.9±4.4	-1.4±4.4	≤0.05

Mean±SD.
* calc from Boyarsky. Max-IPSS=35, Max-B=27. 35/27≈1.29→IPSS=1.29 x B

Qmax	Terazosin	Placebo	*p*
BL	8.6	8.8	
12w	2.6±3.4	1.2±3.4	≤0.05

Mean±SD

Adverse events

	Terazo□in	Placebo
Dizziness	**15 (19%)***	4 (5%)
Headache	5 (6%)	7 (9%)
Erectile dysfunction	6 (7%)	1 (1%)
Fatigue	6 (7%)	2 (3%)
UTI	1 (1%)	8 (10%)

Cumulative incidence.
**p*=≤0.05 vs placebo

Quality of evidence: Low–moderate.
Conclusion: Terazosin provides greater improvement in IPSS and Q_{max} than placebo
Internal validity: Randomization and blinding not described. Baseline values not reported.
External validity: Eligible patients not reported.
Comments: ITT not used.
Sponsorship: Abbott Lab

Elhilali 1996 RCT Canada
Urology 1996;47:335-42.

Intervention
Terazosin (dose titrated according to response) vs placebo.
8w +16w maintenance

Population
Terazosin 80 pat
7 (8.8%) dropped out due to AE

Placebo 81 pat
4 (4.9%) dropped out due to AE

Total drop-outrate 18.3% in the randomized material

	Terazosin	Placebo
Age	64.1	64.8
Q_{max}	10.6	9.8
Boyarsky Mean	10.9	10.5

Inclusion criteria:
Men age 50–80 years with diagnosis of BPH, and a Boyarsky score ≥1on ≥2 obstructive symptoms, ≥1 irritative symptom, Q_{max} 15 ml/s, voided volume ≥150 ml, PVR<250 ml

Exclusion criteria:
Medication that could interfere with voiding pattern, cardiovascular or neurological disease, invasive surgery/procedure in the urinary tract, PCA, other urological disease/dysfunction, hepatic/renal dysfunction etc

Results

Q_{max}	Terazosin	Placebo	*p*
BL	10.3±2.7	9.7±3.6	
End of study	12.6±8.9	10.3±3.6	<0.001

Mean ±SD from graph.

Boyarsky	Terazosin	Placebo	*p*
BL	11.0±1.8	11.0±6.3	
End of study	8.0±3.6	9.2±5.4	Unclear/ NR

Mean ±SD from graph

IPSS*	Terazosin	Placebo	*p*
BL	14.2±2.3	14.2±8.2	
End of study	10.3±4.6	11.9±7.0	Unclear/ NR

Mean±SD
*calc from Boyarsky. Max-IPSS=35, Max-B=27. 35/27≈1.29→IPSS=1.29 x B

Adverse events

Adverse effects: 64% in the terazosin group and 52% in the placebo group experienced some form of adverse event.

%	Terazosin	Placebo
Dizziness	19.8	11.0
Headache	7.4	3.7
Hypotension	2.5	1.2
Flulike symptoms	2.5	7.3
Arthralgia	6.2*	0
Asthenia/ fatigue	12.3	8.5
Amblyopia	11.1**	1.2

*p=0.028 **p=0.009

Quality of evidence: Moderate
Conclusion: Terazosin provides significant improvement in IPSS and Q_{max} compared to placebo.
Internal validity: Randomization and blinding not reported. External validity: Eligible patients reported.
Comments: ITT used.
Sponsorship: Abbott Laboratories

Lepor 1996 RCT USA

N Engl J Med 1998;335:533-9, J Urology 160:1358-67, Nocturia in Johnson 2003 J Urology 170:145-8

Intervention

Dutasteride 0,5mg vs terazosin 5/10mg vs combination vs placebo.

12 months

Population

Combination 309 pattiens DO: 12mo 17,8%

Terazosin 305 patients DO: 12mo 16,1%

Finasteride 310 patients DO: 12mo 21,6%

Placebo 305 patients DO: 12mo 16,7%

	Comb	Tera	Fina	Placebo
Age	65±7	65±6	65±7	65±7
Q_{max}	10.4 ±3.5	10.5 ±3.5	10.6 ±2.5	10.4 ±2.6
Pvol	37.2 ±19.3	37.5 ±19.2	36.2 ±17.6	38.4 ±22.6
AUA-SS	15.9 ±5.3	16.2 ±5.2	16.2 ±5.4	15.8 ±5.5

Inclusion criteria: :

45–80 years, symptom score ≥8, Q_{max} ≥4 and ≤15 ml/s with a minimal voided volume of 125 ml, post void residual urine volume <300 ml

Exclusion criteria:

Unwilling or unable to give informed consent, taken experimental drug within 4 weeks before screening, taken α-adrenergic agonist, cholinergics, anticholinergics, topical β-adrenergicantagonist for glaucoma or any antihypertensive drug except a diuretic or an ACE-inhibitor within 2 weeks before lead-in, taken estrogen, androgen or androgen inhibitor within 3 months before screening, episode of unstable angina pectoris, myocardial infarction, transient ischemic attack or cerebrovascular lesion in the past 6 months, insulindependent diabetes mellitus, orthostatic hypotension, history of syncope, blood pressure below 90/ 70 mm Hg (sitting), history of carcinoma of the prostate, pelvic irradiation, urethral stricture, surgery for BPH or BOO, current evidence of prostatic carcinoma, active urinary tract disease, cystoscopy or biopsy of the prostate within the previous 2 weeks, a history of recurrent UTI or UTI within the preceding 2 months, prior pelvic surgery likely to interfere with bladder function , progressive disorder that might prevent the evaluation of drug safety and efficacy, clinically important renal or hepatic impairment, PSA >10 ng/ ml

Results

AUASS	Com	Ter	Fin	Pla
BL	15.9 ±5.3	16.2 ±5.2	16.2 ±5.4	15.8 ±5.5
12 mo	9.8 ±5.0	10.2 ±5.0	13.0 ±4.8	13.2 ±4.9

Mean±SD

Q_{max}	Com	Ter	Fin	Pla
BL	10.4 ±3.5	10.5 ±3.5	10.6 ±2.5	10.4 ±2.6
12 mo	13.6 ±5.0	13.2 ±5.0	12.2 ±4.9	11.8 ±4.8

Mean±SD

Nocturia	Com	Ter	Fin	Pla
BL	2.5	2.5	2.5	2.5
12 mo	2.0	1.8	2.1	2.1

Mean number of episodes

Adverse events

%	Com	Ter	Fin	Pla
Death	0.6	0.7	2.3	1.0
Surgery	0.6	0.7	1.6	1.3
AUR	Not reported			
Impotence	9.3	5.9	9.4	4.6
Decr. libido	4.9	2.6	4.5	1.3
Ejac disorder	6.8	0.3	1.9	1.3
Asthenia	13.9	13.8	7.4	6.9
Headache	5.2	5.9	6.1	3.2
Dizziness	21.4	25.9	8.4	7.2
Rhinitis	7.8	6.6	2.6	4.6
Sinusitis	2.3	2.0	1.3	1.3
Postural hypotension	8.7	7.5	2.3	1.0
Syncope	1.6	1.0	1.0	0

1-year incidence (%)

Quality of evidence: High. **Conclusion**: Terazosin superior to Finasteride in relieving LUTS due to BPH. The addition of Finasteride to Terazosin does not increase efficacy or affect safety.Internal validity: Randomization not described. Blinding described. External validity: Eligible patients reported. Comments: ITT used. Sponsorship: Merck, Abbott Laboratories. Study conducted by Department of Veteran Affairs independently of sponsors

Doxazosin

Chapple 1994 RCT UK
Br J Urol 1994;74:50-6

Intervention
Doxazosin 4mg vs placebo.
12 weeks

Population
Doxazosin 67 pat drop-out 7 (10.5%)
2 (3%) due to AE

Placebo 68 pat Drop-out 5 (7.4%)
- 0 due to AE

	Doxazosin	Placebo
Age Mean ±SD	67±7.3	67±7.5
Q_{max} <10	53%	64%
Q_{max} 10.1–15 ml/s	47%	36%

Inclusion criteria:
Symptomatic of bladder outflow obstruction, Q_{max} <15 ml/s, PVR<200 ml, outflow obstruction at level of prostate as confirmed by VCMG

Exclusion criteria:
Prostate carcinoma, previous prostatic surgery, serum creatinine >200, cardiovascular disease or poorly controlled diabetes

Results

Qmax	Doxazosin	Placebo	*p*
Inclusion	9.1±3.9	9.1±3.9	
12 w	11.7	10.2	
Change Mean ±SD	+2.6±5.4	+1.1±4.7	0.09

Symptom score improvement	Doxazosin	Placebo	*p*
Hesitancy	59%	26%	0.003
Nocturia	39%	19%	0.017
Urgency	60%	38%	0.041
Impaired flow	56%	33%	0.019
Frequency	44%	27%	0.062

Adverse events
Adverse effects: 37.3% in the treatment group and 16.4% in the placebo group experienced some form of adverse event. The most frequent were dizziness and headache

No table on AE given

Quality of evidence: Low-moderate.
Conclusion: Doxazosin provides greater improvement in Q_{max} compared to placebo.
Internal validity: Randomization described. Blinding not adequately described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Pfizer UK

Fawzy 1995 RCT USA
J Urol 1995;154:105-9

Intervention
Run in on placebo 2 weeks, then randomised to doxazosin titration 2, 4 or 8 mg according to response during 8 weeks and then held constant for the last 6 weeks. A total of 14 weeks of active drug/placebo. 87.8% of the patients in the doxazosin group were titrated to 8 mg, 2.4% to 4 mg and 9.8% to 2 mg

Population
Doxazosin 50 pat drop-outs 11 (22%)
7 (14%) due to AE

Placebo 48 pat drop-outs 11 (22,9%)
1 (2.1%) due to AE

	Doxazosin	Placebo
Age	62.1±7.8	61.6±8.7
Mean duration of BPH (yrs)	6.0±8.1	4.6±4.6
Q_{max}	9.7±2.5	9.9±2.4
AUA	14.4±3.6	15.7±3.2
PVR	53.9±43.0	42.3±37.9
Bothersomeness	30.8±4.6	29.5±4.7

Mean ±SD

Inclusion criteria:
Normotensive men older than 45 and with symptomatic BPH, AUA ≥10, Q_{max} 5–15 ml/s, voided volume 125–500 ml, PVR <250 ml

Exclusion criteria:
Recent urinary retention, severe outflow obstruction, non-BPH conditions causing symptoms, serious concurrent disease, cardiac/renal/hepatic failure, poorly placeboled diabetes, urinary calculi, allergy to quinazoline

Results

Qmax	Doxazosin	Placebo	*p*
BL	9.7±2.5	9.9±2.4	
14w	12.6	10.6	<0.01
Change	2.9±5.4	0.7±5.4	

Mean±SD (calc for change)

AUA	Doxazosin	Placebo	*p*
BL	14.4±3.6	15.7±3.2	
14w	8.7	13.2	
Change	-5.7±6	-2.5±6	0.002

Mean±SD (calc for change)

Bothersomeness*	Doxazosin	Placebo	*p*
BL	30.8±4.6	29.5±4.7	
14w	35.5	31.5	
Change	4.7	2.0	0.008

Mean±SD
*Based on a modified Boyarsky scale which measures a combination of obstructive and irritative symptoms. Higher figure means less bothersomeness

Adverse events

%	Doxazosin	Placebo
Dizziness	24	4
Headache	12	4
Hypotension	8	0
Somnolence	10	4
Nausea	8	0
Asthenia/ fatigue	12	4

Quality of evidence: Low–moderate. **Conclusion**: Doxazosin superior to placebo in normotensive patients. Internal validity: Blinding and randomization not described. External validity: Eligible patients not reported. Comments: ITT not used. Sponsorship: Pfizer

Andersen 2000 RCT Norway
Eur Urol 2000;38:400-9

Intervention
Doxazosin gastrointestinal therapeutic system 4 or 8 mg vs doxazosin standard 1 to 8 mg vs placebo.
13 weeks

Population
1020 screened

Doxazosin GITS 317 pat drop-outs 22 (7%)
3.5% due to AE

Doxazosin standard 322 pat drop-outs 38 (11.8%)
6.2% due to AE

Placebo 156 pat drop-outs 8 (5.1%)
0.6% due to AE

	Doxa GITS	Doxa std	Placebo
Age	64.9	65.3	65.4
Q_{max}	10.3±2.6	10.0±2.8	9.9±2.6
IPSS	17.7±4.3	17.8±4.5	18.0±4.3
LUTS (mo)	45.6	40.8	44.4

Mean±SD

Inclusion criteria:
Men age 50–80 with symptomatic BPH, Q_{max} 5–15 ml/s, IPSS ≥12, voided volume >150 ml

Exclusion criteria:
Previous prostatic surgical intervention, abnormal liver function, prostatic cancer and other urological diseases, episodes of AUR, bladder stones, repeat UTI, hypotension, hypersensitivity to alphablockers etc

Results

IPSS	Doxa GITS	Doxa Std	Placebo	*p*
Inclusion	17.7±4.3	17.8±4.5	18.0±4.3	
13 w	9.7	9.4	12.0	
Change	-8.0±5.3	-8.4±5.3	-6.0±4.9	<0.001

Mean±SD (calc)

Qmax	Doxa GITS	Doxa Std	Placebo	*p*
Inclusion	10.3±2.6	10.0±2.8	9.9±2.6	
13 w	12.9	12.2	11.7	
Change	2.6±3.5	2.2±3.5	0.8±3.7	<0.001

Mean±SD (calc)

QoL	Doxa GITS	Doxa Std	Placebo	*p*
Change	-1.3±1.8	-1.4±1.8	-0.9±1.3	<0.001

Mean±SD

Adverse events

Adverse effects: 23% in the treatment group and 15% in the placebo group experienced some form of adverse event

	Doxa-GITS	Dox std	Placebo
Dizziness	18 (5.7%)	27 (8.4%)	3 (1.9%)
Headache	18 (5.7%)	13 (4%)	7 (4.5%)
Hypotension	4 (1.3%)	7 (2.2%)	1 (0.6%)
Vertigo	8 (2.5%)	24 (7.5%)	1 (0.6%)
Asthenia/ fatigue	10 (3.2%)	16 (5.0%)	2 (1.3%)

Quality of evidence: Moderate
Conclusion: Both doxazosin-GITS and standard doxazosin significantly more effective than placebo in improving IPSS and Q_{max}
Internal validity: Blinding and randomization not described. External validity: Eligible patients reported.
Comments: ITT used. Power calculated.
Sponsorship: Pfizer Inc

PREDICT Kirby 2003 RCT Europe
Urology 2003;61:119-26

Intervention
Finasteride 5 mg vs Doxazosin 2 or 4 or 8 mg vs combination vs placebo

Population
Doxazosin 275 pat DO 28.4%
11.6% due to AE

Finasteride 264 pat DO 81 30.7%
12.9% due to AE

Combination 286 pat DO 89 31.1%
12.2% due to AE

Placebo 270 pat DO 28.1%
11.1% due to AE

	Com	Dox	Fin	Pla
Age	64±7	63±7	63±7	64±7
Q_{max}	10.4±2.7	10.4±2.5	10.2±2.5	10.8±2.5
Pvol*	37±14	36±14	36±14	36±15
IPSS	17.3±4.3	17.1±4.2	17.1±4.4	17.2±4.5

Mean±SD
*=estimated by DRE in 5g increments

Inclusion criteria:
Age 50–80, symptomatic BPH, Q_{max} 5–15 ml/s for Vvoid>150ml, IPSS≥12, DRE-confirmed enlarged prostate

Exclusion criteria:
Previous prostate surgery or invasive treatment of BPH, PSA>10ng/ml (PSA 4-10 ng/ml required had to provide documentation of negative DRE, TRUS and biopsy findings to exclude cancer of the prostate), LUTS or reduced urinary flow for reasons other than BPH, large bladder diverticulum, bladder stones, recurrent urinary infection, 2 or more episodes of AUR requiring catheterization within a year before study entry, Vres >200ml, active UTI, serious disease, alcohol or drug abuse, hypotension, orthostatic hypotension, history of sensitivity to alpha-adrenergic blocking agents, quinazolines or finasteride

Results

Q_{max}	Doxa	Finast	Comb	Pbo	*p*
BL	10.4±2.5	10.2±2.5	10.4±2.7	10.8±2.5	*
Endpt	14.0±4.9	12.1±4.7	14.5±5.1	12.1±4.2	
Change	3.6±4.7	1.8±4.6	3.8±4.9	1.4±4.8	**

Mean±SD. (Change SD calc from SE)

*$p \leq 0.0001$ vs placebo at baseline, the only characteristic which differed between the groups. Absolute difference 0.6 ml/s
**$p \leq 0.0001$ doxazosin and combination vs placebo, $p \leq 0.0001$ doxazosin and combination vs finasteride alone

IPSS	Doxa	Finast	Comb	Pbo	*p*
BL	17.1±4.2	17.1±4.4	17.3±4.7	17.2±4.5	
Endpt	8.7±5.8	10.9±6.2	8.7±6.2	11.8±6.9	
Change	-8.3±6.3	-6.6±6.2	8.5±6.5	-5.7±0.4	*

Mean±SD. (Change SD calc from SE)

**$p \leq 0.0001$ doxazosin and combination vs placebo, $p \leq 0.01$ doxazosin and combination vs finasteride alone.

Adverse events

%	Com	Dox	Fin	Pla
Vertigo	2.8	2.9	2.3	1.1
Hypotension	2.8	5.1	0.8	1.5
Impotence	10.5	5.8	4	3.3
Urinary retentio	0	0	1.1	4.5
Surgery	0	0.4	1.1	2.6
Death	0.3	0	0.8	0.7
Myocardial infarction/ ischemia	1.05	0.36	1.12	0.74
Congestive heart failure	0.7	0.72	0.37	0
Asthenia	9.1	10.5	4.2	4.1
Hypertension	1.4	1.8	4.2	5.6
Postural hypotension	2.8	5.8	0.8	1.5
Dizziness	13.6	15.6	8.0	7.4
Syncope	2.1	0.7	0	0.4
Decreased libido	2.1	3.6	3.4	1.9
Somnolence	3.1	4.0	3.0	1.9
Abnormal ejaculation	2.4	0.4	2.3	1.5

Quality of evidence: Moderate **Conclusion**: Doxazosin superior to Finasteride in relieving LUTS due to BPH. The addition of Finasteride to Doxazosin does not increase efficacy but elevates the risk of erectile dysfunction. Internal validity: Blinding and randomization not described. External validity: Eligible patients reported. Comments: ITT used. Power calculated. Sponsorship: Pfizer, Merck

MTOPS McConnell 2003 RCT USA**.** N Engl J Med. 2003;349:2387-98. Study design in Bautista Control Clin Trials 2003;24:224-43. Kaplan J Urology2006;175:217-20 (Analysis based on prostate volume). Kaplan J Urology 2008;180:1030-2 (Volume reduction study). Nocturia in Johnson J Urology 2007;178: 2045-51

Intervention
Finasteride 5 mg vs Doxazosin 2/4/8 mg vs combination vs placebo
48 months

Population
Combination 786 patients
Doxazosin 756 patients
Finasteride 768 patients
Placebo 737 patients

	Com	Dox	Fin	Pla
Age	62,7±7,1	62,7±7,2	62,6±7,3	62,5±7,5
Q_{max}	10,6±2,5	10,3±2,5	10,5±2,5	10,5±2,6
Pvolume	36,4±19,2	36,9±21,6	36,9±20,6	35,2±18,8
AUASS	16,8±5,8	17,0±5,8	17,6±5,9	16,8±5,9

Mean±SD

Inclusion criteria: ≥ 50 years, symptomatic BPH, Q_{max} 4–15 ml/s for Vvoid>125 ml, AUASS 8–30

Exclusion criteria: Prior intervention for BPH, any prior intervention for prostate disease, currently enrolled in other study, history or evidence of prostate or bladder cancer, pelvic radiation, urethral stricture, prostate surgery or surgery for bladder neck obstruction, evidence of any other cancer (except basal cell or squamous cell carcinoma of the skin) within 5 years before rand-omization, PSA >10 ng/ml, supine blood pressure <90/70 mm Hg, creatinine >2,0 mg/dl, ALT>1,5ULN, bacterial prostatitis within the last year, 2 UTI during last year, active urinary tract disease, cystoscopy or biopsy of the prostate within 1 month prior to screening, immediate need for surgery, inability to urinate, previous reaction to study medication, neurologic disease known to affect bladder function, any serious medical condition likely to impede successful completion of study etc

Results

AUASS	Com	Dox	Fin	Pla
BL	16.8±5.8	17.0±5.8	17.6±5.9	16.8±5.9
Change 48 mo	-7.4	-6.6	-5.6	-4.9

Mean±SD

AUASS	Com	Dox	Fin	Pla
BL	16	17	17	17
Change 12 mo	-6	-6	-4	-4
Change 48 mo	-7	-6	-5	-4

Median

Q_{max}	Com	Dox	Fin	Pla
BL	10.7	10.4	10.5	10.6
Change 12 mo	+3.6	+3.0	+1.8	+1.3
Change 48 mo	+3.7	+2.5	+2.2	+1.4

Median

	Com	Dox	Fin	Pla
Clin. Progression	1.5	2.7	2.9	4.5
≥4 AUASS increase	1.3	1.9	2.5	3.6

Rate/100 person-year

Nocturia	Com	Dox	Fin	Pla
BL	2.3	2.3	2.4	2.3
Change 12 mo	-0.58	-0.54	-0.4	-0.35
Change 48 mo	-0.55	-0.□3	-0.42	-0.38

Mean number of episodes

Adverse events

	Com	Dox	Fin	Pla
Urinary retention	0.1	0.4	0.2	0.6
Surgery	0.4	1.3	0.5	1.3
Erectile dysfunction	5.11	3.56	4.53	3.32
Dizziness	5.35	4.41	2.33	2.29
Postural hypo-tension	4.33	4.03	2.56	2.29
Asthenia	4.20	4.08	1.56	2.06
Decresed libido	2.51	1.56	2.36	1.40
Abnormal ejacula-tion	3.05	1.10	1.78	0.83
Peri-pheral edema	1.25	0.88	0.72	0.66
Dyspnea	1.20	0.93	0.56	0.57
Allergic reaction	0.73	0.85	0.58	0.46
Somnolence	0.78	0.82	0.39	0.37

Rate/100 person-year. Stopped treatment due to AE by end of study: Doxazosin treatment: 27%. Finasteride treatment: 24%. Both: 18%

Quality of evidence: Moderate–high.
Conclusion: Combination therapy reduces the risk of BPH prog-ression compared to either finasteride or doxazosin used alone. Combination or finasteride monotherrapy reduces the risk for AUR or need for surgery. Internal validity: Randomization described. Blinding not described. External validity: High.
Comments: ITT used. Power calculated.
Sponsorship: Merck, Pfizer, NIH

Alfuzosin

Jardin 1991 RCT France
The BPH-ALF Group Lancet. 1991;15;337:1457-61

Intervention
Alfuzosin 2,5 mg x 3 vs placebo
Evening dose could be doubled depending on therapeutic response
26 weeks

Population
Alfuzosin 251 pat Drop-out 70 (28%)
Placebo 267 pat Drop-out 92 (34.5%)

	Alfuzosin	Placebo
Age	65.2 ± 0.5	65.6 ± 0.5
(range)	(46-86)	(41-83)
Boyarsky	9.52±0.17	9.44±0.15
LUTS (mo)	50.6 ± 2.9	42.1 ± 2.2

Mean ±SE

Inclusion criteria:
Men with symptomatic BPH, Boyarsky score ≥6

Exclusion criteria:
Concomitant urological or neurological disease, severe cardiac/renal/hepatic failure, recent AMI or drugs likely to interact with study medication

Results

	Alfuzosin	Placebo	
Q_{max}	n=102	n=132	*p*
BL	12.1±6.1	12.0±6.1	NS
6w	14 ±7.1	12.1±6.1	<0.01
26w	13.5±7.1	13.3±7.1	NS

Mean±SD (calc)

	Alfuzosin	Placebo	
Boyarsky	n=181	n=175	*p*
BL	9.52±2.7	9.44±2.5	
26w	5.5±3.2	6.4±3.3	<0.0004

Mean±SD (calc)

IPSS*	Alfuzosin	Placebo	*p*
BL	12.3±3.5	12.2±3.2	
26w	7.1±4.1	8.3±4.3	<0.0004

Mean±SD
*calc from Boyarsky. Max-IPSS=35, Max-B=27. 35/27≈1.29→IPSS=1.29 x B
Data on effects on residual volume and prostate size are given but as these were only measured on some patients they are not included here

Adverse events
Adverse effects: 36.3% in the treatment group and 36.3% in the placebo group experienced some form of adverse event

	Alfuzosin %	Placebo %
Dizziness	7.2	5.2
Headache	6.4	4.9
Hypotension	1.9	1.2
Drowsiness	1.6	<1
Impotence	<1	2.3
Asthenia/ fatigue	2.0	3.8

More data on GI-effects are given

Rates of AE:s were broadly similar but during the first 2 weeks of treatment AE:s 1–4 above were more common in the alfuzosin group

Quality of evidence: Moderate
Conclusion: Alfuzosin provides long-lasting improvement of BPH. Significant placebo effect.
Internal validity: Randomization and blinding not described. External validity: Eligible patients not reported. Comments: Power calculated. ITT not used.
Sponsorship: Synthélabo recherche

Buzelin 1997 RCT France
ALGEBI Study Group. Eur Urol. 1997;31:190-8

Intervention
Alfuzosin SR 5 mg x 2 vs placebo.
12 weeks

Population
Alfuzosin 194 pat
Drop-out 13 (7%) 9 (4,6%) due to AE
Placebo 196 pat
Drop-out 16 (8%) 14 (7,8%) due to AE

	Alfuzosin	Placebo
Age	65±8.4	65±8.5
Q_{max}	10.4±2.7	10.1±2.8
Boyarsky	9.9±2.9	10.3±2.7
IPSS	15±5.3	15.9±5.4
PVR	58±48	63±48
LUTS (mos)	38±28	35±23
QOL index	3.2±1.1	3.2±1.1

Mean ±SD
At baseline, 6% of patients had mild BPH (IPSS≤7), 71% had moderate BPH (IPSS 8-19) and 23% had severe BPH (IPSS≥20).

Inclusion criteria:
Men aged 45 years or older with symptomatic BPH for ≥6 months, micturition ≥8, nocturnal micturitions ≥2, Q_{max} 5–15 ml/s, voided volume ≥150 ml, PVR≤150 ml

Exclusion criteria:
Concomitant lower UT disease, previous prostatic surgery, severe visceral disease, postural hypotension or medication altering voiding pattern

Results

IPSS	Alfuzosin	Placebo	*p*
Inclusion	15.0±5.3	15.9±5.4	
12 w	10.0±6.1	12.5±6.5	
Change	-5.0	-3.4	0.007

Mean±SD

QOL index	Alfuzosin	Placebo	*p*
Inclusion	3.2±1.1	3.2±1.1	
12 w	2.1±1.3	2.6±1.4	
Change	-1.0	-0.5	<0.001

Mean±SD

Q_{max}	Alfuzosin	Placebo	*p*
Inclusion	10.4±2.7	10.1±2.8	
12 w	12.7±4.8	11.2±4.1	
Change	2.4	1.1	0.006

Mean±SD
Subgroup analysis of more pronounced BPH.

IPSS≥13 Qmax≤12	Alfuzosin	Placebo	*p*
Inclusion	17.8±3.9	18.3±4.1	
12 w	11.2±6.5	14.4±6.5	
Change	-6.7	-4.0	0.002

Mean±SD

Adverse events

Adverse effects: 20,6% in the treatment group and 16,8% in the placebo group experienced some form of adverse event.

%	Alfuzosin	Placebo
Dizziness	2,6	2,0
Headache	0,5	0,5
Syncope	0,5	0
Palpitations	0	1,5
Asthenia/ fatigue	0	0

Quality of evidence: Moderate
Conclusion: Alfuzosin provides greater improvement in IPSS and Qmax than placebo. Internal validity: Randomization and blinding not described. External validity: Eligible patients not reported. Comments: ITT used. Sponsorship: Unclear. One of authors employed by Synthélabo Recherche.

Van Kerrebroeck 2000 RCT Europe
European Urology 2000;37:306–313

Intervention
Alfuzosin 1x10 mg vs 3x2,5 mg vs placebo.
3 months

Population
Alfuzosin once daily 143 pat Do: 3mo 16
Alfuzosin thrice daily 150 pat Do: 3mo 14
Placebo 154 pat Do: 10

	Alfu o.d.	Alfu t.i.d.	Placebo
Age	64.9 ±7.4	64.7 ±7.5	64.2 ±7.8
Q_{max}	9.3 ±1.9	8.8 ±1.9	9.1 ±2.0
IPSS	17.2 ±3.5	16.8 ±3.7	17.8 ±4.3
QoL	3.3 ±0.9	3.3 ±1.0	3.3 ±1.0

Mean±SD

Inclusion criteria:
Age >50, micturition disorder related to BPH, IPSS ≥13, Q_{max} 5–12ml/s for Vvoid ≥150ml and Vres ≤350ml

Exclusion criteria:
Other concomitant urinary tract diseases, previous prostatic surgery or other invasive procedures for the treatment of BPH, associated severe visceral disease, history of postural hypotension or syncopes, clinically relevant biological abnormalities, treatment with alphablockers within 1 months or treatment with antiandrogenics, 5-ARI or LHRH analogues within 3 months previous to selection

Results

Q_{max}	Alfu o.d.	Alfu t.i.d.	Placebo
BL	9.3 ±1.9	8.8 ±1.9	9.1 ±2.0
3 mo	11.7 ±3.9	11.9 ±4.3	10.6 ±3.3

Mean±SD

IPSS	Alfu o.d.	Alfu t.i.d.	Placebo
BL	17.2 ±3.5	16.8 ±3.7	17.8 ±4.3
3 mo	10.4 ±4.7	10.5 ±6.1	12.8 ±6.7

Mean±SD

QoL	Alfu o.d.	Alfu t.i.d.	Placebo
BL	3.3 ±0.9	3.3 ±1.0	3.3 ±1.0
3 mo	2.2 ±1.1	2.2 ±1.1	2.6 ±1.3

Mean±SD

Adverse events

%	Alfu o.d.	Alfu t.i.d.	Placebo
Syncope	0	0.7	0
Dizziness	2.1	4.7	1.3
Headache	1.4	2	0.6
Hypotension	0.7	1.3	0
Malaise	1.4	0.7	0
Asthenia	3.5	0.7	2.6
Sexual dysfunction	0	0.7	1.3

3 month incidence

Quality of evidence: Moderate-High.
Conclusion: Alfuzosin demonstrated efficacy and was well tolerated.
Internal validity: Randomization not described. Blinding sparsely described.
External validity: Eligible patients not reported. Comments: ITT used.
Sponsorship: Not reported

Roehrborn 2001 RCT USA
Urology 2001;58:953-9.

Intervention
Alfuzosin OD 10 mg vs alfuzosin OD 15 mg vs placebo.
12 weeks

Population
Alfuzosin 10 mg OD 177 pat drop-outs 20 (11%)
- 8 (4.5%) due to AE.
- 0% due to lack of efficacy

Alfuzosin 15 mg OD 181 pat Drop-outs 33 (18%)
- 8 (4.4%) due to AE.
- 1% due to lack of efficacy

Placebo 178 pat drop-outs 20 (11%)
- 4 (2.2%) due to AE
- 0.5% due to lack of efficacy

	10 mg	15 mg	Placebo
Age	64.3	63.9	62.7
<65 yrs	55.7%	53.1%	62.3%
>65 yrs	44.3%	46.9%	37.7%
IPSS	21.2	21.7	21.5
Q_{max}	8.7	8.9	8.4
QOL	4.2	4.1	4.1
Prostate volume	36.8	40.2*	38.3

Mean values from entire population.
*=significant difference between groups.

Inclusion criteria:
≥50 years, symptomatic BPH >6 months, Q_{max} 5–12 ml/s, IPSS>13, QOL index >3

Exclusion criteria:
Condition affecting micturition, prostatic surgery, postural hypotension, medications altering voiding patterns, PSA >10 etc

Results

IPSS	10 mg	15 mg	Placebo	*p*
BL	18.2±6.3	17.7±5.7	18.2±6.4	
12 w	-3.6±4.8	-3.4±5.7	-1.6±5.8	0.001*

Mean±SD
* 10 mg vs placebo. 15 mg vs placebo p=0.004

Q_{max}	10 mg	15 mg	Placebo	*p*
BL	9.9±3.9	10.0±3.2	10.2±4.0	
12 w	1.7±4.2	0.9±3.6	0.2±3.5	0.0004**

Mean±SD
** 10 mg vs placebo. 15 mg vs placebo non significant

QOL	10 mg	15 mg	Placebo	*p*
BL	3.8±1.1	3.7±1.1	3.7±1.1	
12 w	-0.7±1.1	-0.7±1.2	-0.3±1.1	0.002***

Mean±SD *** both vs placebo

Adverse events
Adverse effects: 4,5% in the alfuzosin 10 mg group, 3,4% in the 15 mg group and 2,9% in the placebo group experienced some form of adverse event

	10 mg	15 mg	Pbo
Dizziness	13 (7,4%)	16 (9%)	5 (2,9%)
Headache	9 (5,1%)	4 (2,3%)	4 (2,3%)
Impotence	5 (2,8%)	2 (1,1%)	2 (1,1%)
Fatigue	4 (2,3%)	3 (1,7%)	4 (2,3%)

Quality of evidence: Moderate
Conclusion: Alfuzosin 10 mg provides effective relief from symptoms of BPH and is well tolerated.
Internal validity: Randomization not described. Blinding partly described.
External validity: Eligible patients not described. Comments: ITT used.
Sponsorship: Sanofi-Synthelabo

Roehrborn 2003 RCT International
BJU Int 2003;92:257-61

Intervention
Alfuzosin OD 10 mg vs placebo
12 weeks

Population
Alfuzosin 473 pat 156 severe drop-outs 45 (9.5%)
Placebo 482 pat 163 severe drop-outs 42 (8.7%)
Reasons for drop-out not given

	Alfuzosin	Placebo
Age	64.6 (49–92)	63.7 (49–85)
Q_{max}	8.8 ±1.9	8.8 ±1.9
Pvolume	36.8 (10–110)	36.8 (15–90)
IPSS	17.8 (4–27)	17.9 (2–33)
QOL	3.6 ±1.0	3.5 ±1.0
LUTS (mo)	54.1 (5–360)	55.8 (6–341)

Mean ±SD and mean (range)

Inclusion criteria:
≥ 50 years, LUTS consistent with clinical BPH for ≥ 6 months , Q_{max} 5–12 ml/s IPSS≥13, bother score ≥3 points at both day 0 and 28

Exclusion criteria:
Previous prostate surgery, post hypotension/syncope, use of medication altering voiding pattern, use of alfa-blockers etc, ALAT/ASAT elevated, PSA >10, creatinine >150. If PSA was 4–10, prostate cancer had to be excluded by the investigator

Results

Q_{max}	Alfuzosin	Placebo	*p*
BL	8.8 ±1.9	8.8 ±1.9	
4 w	8.8 ±1.9	8.8 ±1.9	
12 w	11.2 ±4.0	9.9 ±3.1	
Change	+2.3 ±3.8	+1.1 ±3.1	<0.001

Mean ±SD

IPSS	Alfuzosin	Placebo	*p*
BL	17.8 (4-27)	17.9 (2-33)	
4 w	18.7 ±4.6	18.8 ±4.4	
12 w	12.7 ±6.1	14.6 ±6.8	
Change	-6.0 ±5.1	-4.2 ±5.7	<0.001

Mean ±SD and mean (range)

QOL	Alfuzosin	Placebo	*p*
BL	3.6 ±1.0	3.5 ±1.0	
4 w	3.6 ±1.0	3.6 ±1.0	
12 w	2.6 ±1.2	2.9 ±1.3	
Change	-1.0 ±1.1	-0.7 ±1.1	<0.001

Mean ±SD

Adverse events
Adverse effects: 41,6% in the alfuzosin group and 35,9% in the placebo group experienced some form of adverse event

	Alfuzosin	Placebo
Dizziness	25 (5.3%)	14 (2.9%)
Headache	14 (3.0%)	4 (0.8%)
Hypotension	2 (0.4%)	0
Syncope	1 (0.2%)	0
Impotence	7 (1.5%)	3 (0.6%)
Asthenia/fatigue	13 (2.7%)	11 (2.2%)
UTI	2 (0.4%)	7 (1.5%)
AUR	0	2 (0.4%)

Quality of evidence: Moderate
Conclusion: Alfuzosin effective, with good safety profile.
Internal validity: Randommization and blinding not described. External validity: Eligible patients not reported. Comments: ITT used. Pooled analysis, contains Roehrborn 2001 and Van Kerrebroeck.
Sponsorship: Unclear

Nordling 2005 RCT Denmark
BJU Int 2005;95:1006-12

Intervention
Alfuzosin OD 10 mg vs alfuzosin OD 15mg vs tamsulosin OD 0.4mg vs placebo
12 weeks

Population
Alfuzosin 10 mg 154 pts drop-out: 9 (5.8%)
-4 (2.6%) due to adverse event

Alfuzosin 15 mg 158 pts drop-out: 17 (11%)
-14 (9%)due to AE

Tamsulosin 158 pts drop-out: 9 (5.2%)
-6 (3.5%) due to AE

Placebo 154 pts drop-out: 12 (7.8%)
-5 (3%) due to adverse event

	Treatment	Placebo
Age	65 (51–85)	64 (50–82)
Q_{max}	8.9 (5.0–12.6)	9.0 (4.0–12.5)
IPSS	20 (13–35)	20 (5–32)
Months LUTS	45 (6–294)	50 (6–307)

Mean(range)

Inclusion criteria:
≥ 50 years, symptomatic BPH (from DRE/TRUS within last 3 months), Q_{max} ≤12 ml/s for a voided volume of ≥ 150ml and a residual urine volume of ≤350 ml , 6 months history of LUTS, IPSS ≥13, nocturia twice or more

Exclusion criteria:
Concomitant urological disease, previous BPH surgery or X-ray, concomitant medication with effect on voiding pattern, other diseases such as diabetes or Parkinson, previous treatment failure on alfa-blockers etc

Results

IPSS	Alf 10 mg	Alf 15 mg	Tams	Placebo
Incl	20±3.7	20±3.5	20.0±3.3	20±4.5
BL	18.0 ±5.4	17.4±4.8	17.4±5.6	17.7±5.0
12w	11.5	11.4	10.9	13.1
Change	-6.5±5.2	-6.0±5.6	-6.5±6.2	-4.6±5.8

Mean±SD
p=0.007 at 12 weeks for alfu 10 mg vs placebo, 0.05 for alfu 15 mg vs placebo, 0.014 for tamsu vs placebo

Q_{max}	Alfu 10 mg	Alfu 15mg	Tams	Pbo
Incl	8.9	8.7	8.8	9.0
BL	9.2	8.9	9.4	9.0
Change	1.5	1.4	1.4	0.5
12w	10.7	10.3	10.8	9.5

Mean values. No SD given
p=0.02 at 12 weeks all groups vs placebo

Adverse events

Adverse effects: 2% in the placebo and alfuzosin 10 mg group had one serious AE. 4% in the tamsulosin and alfuzosin groups had a serious AE

Dizziness occurred in 6% in the 10 mg group, 7% in the 15 mg alfuzosin group, in 2% of the tamsulosin group and 4% in the placebo group

Ejaculation disorders occurred more often within the tamsulosin group (3%) than the others (0–1%)

Quality of evidence: High.
Conclusion: Treatment with alfuzosin 10 mg significantly improved urinary symptoms and Q_{max} compared with placebo and was well tolerated.
Internal validity: Randomization and blinding not reported. External validity: Eligible patients not reported. Comments: ITT used. Power calculated.
Sponsorship: Sanofi-Synthélabo

Roehrborn 2006 RCT USA
BJU Int 2006;97:734-41

Intervention
Alfuzosin OD 10 mg vs placebo.
2 years

Population
Alfuzosin - 763 pat drop-outs 230 (30.3%)
- 71 (9.4%) due to adverse events
- 75 (9.9%) due to lack of efficacy
Placebo - 759 pat drop-outs 283 (37.1%)
- 62 (8.1%) due to adverse events
- 111 (14.5%) due to lack of efficacy

	Alfuzosin	Placebo
Age	66.4 ± 6.7	66.5 ±7
Qmax	8.9 ± 2.0	8.8 ± 2.0
Pvolume	46.9 ± 17.1	46.6 ± 16.7
IPSS	19.2 ± 4.7	19.2 ± 4.7
PVR	95.3 ± 75	89.0 ± 69.8
S-PSA	3.4 ± 2.0	3.6 ± 2.1
QoL	3.8 ± 1.1	3.8 ± 1.1

Mean±SD

Inclusion criteria:
≥ 55 years, ≥ 6 month LUTS related to BPH, Q_{max} 5–12 ml/s IPSS≥13, PVR of ≥350 ml, prostate ≥ 30 g estimated by DRE, PSA 1.4–10 ng/ml

Exclusion criteria:
Previous AUR or prostatic surgery, concomitant urological diseases, prostate carcinoma among others

Results

(Approx values from graph)	Alfuzosin	Placebo	*p*
IPSS BL	19.2±4.7	19.2±4.7	
IPSS 12 w	13.5	14.8	
IPSS 24 w	12.5	14.2	
IPSS 48 w	12.8	14.0	
IPSS 2 yrs	12.0	13.0	
Decrease* (exact value given)	-5.9±6.9	-4.7±6.9	0.0017

*=mean±SD

Outcome	Alfuzosin	Placebo	*p*
AUR	2.1%	1.8%	0.82
Surgery	5.1%	6.5%	0.18
IPSS+ ≥4 p	11.7%	16.8%	0.0013
Progression event	16.3%	22.1%	<0.001
Bother*	-1.3±1.5	-0.9±1.6	<0.001
Q_{max} *	+2.0±3.8	+1.3±3.6	0.001

*=mean±SD

The primary endpoint was a first occurrence of AUR. The endpoint "Progression event" was analysed post hoc and defined as AUR and/or surgery and/or IPSS deterioration of ≥4 p. The outcome IPSS+ ≥4 p was also analysed post hoc

Adverse events

Adverse events:
Alfuzosin: 53.1% (11.7% severe)

Placebo: 51.2%. (11.4% severe)

	Alfuzosin	Placebo
Dizziness	45 (6%)	35 (4.□%)
Headache	25 (3.3%)	17 (2.2%)
Hypotension	9 (1.2%)	4 (0.5%)
Syncope	5 (0.7%)	2 (0.3)
Malaise	1 (0.1%)	0
Erectile dysf	18 (2.4%)	14 (1.8%)
Asthenia	16 (2.1%)	8 (1.1%)
Somnolence	0	3 (0.4%)

Quality of evidence: Low–moderate. **Conclusion**: Alfuzosin significantly improves LUTS and quality of life over 2 years, and is well tolerated. Internal validity: Randomization and blinding not described. External validity: Eligible patients reported. Comments: ITT used. Sponsorship: Sanofi-Aventis

Tamsulosin

Abrams 1995 RCT International
The European Tamsulosin Study Group. Br J Urol 1995;76:325-36

Intervention
Tamsulosin 0.4mg vs placebo
12 weeks

Population
Tamsulosin 198 pat drop-outs 14 (7%)
- 8 due to AE
- 2 due to lack of efficacy

Placebo 98 pat drop-outs 6 (6%)
- 3 due to AE
- 1 due to lack of efficacy

	Tamsulosin	Placebo
Age	63.3±8.3	64.4±8.1
PSA	3.7	3.7

Mean±SD

Inclusion criteria:
≥45 years, symptomatic BPH, Q_{max} <12 ml/s, Boyarsky>6

Exclusion criteria:
PVR>400ml, condition affecting micturition, prostatic or pelvic region surgery, hepatic/renal/cardiovascular disease, medications which could influence outcome of study etc

Results

Q_{max}	Tamsulosin	Placebo	*p*
BL	10.7±4.1	10.4±2.9	
12w	12.0±4.1	10.8±3.9	
Change	1.4±4.1	0.4±3.9	0.028

Mean±SD

Boyarsky	Tamsulosin	Placebo	*p*
BL	9.5±2.8	9.3±3.0	
12w	6.1±2.8	7.1±4.0	
Change	-3.4±2.8	-2.2±3.0	0.002

Mean±SD

IPSS*	Tamsulosin	Placebo	*p*
BL	12.3±3.6	12.0±3.9	
12w	7.9±3.6	9.2±5.2	
Change	-4.4±3.6	-2.9±3.9	0.002

Mean±SD.
*calc from Boyarsky. Max-IPSS=35, Max-B=27
35/27≈1.29→IPSS=1.29 x B

	Tamsulosin	Placebo	*p*
Q_{max} +≥30%	55 (29%)	20 (21%)	0.137
Q_{max} +≥3 ml/s	53 (28%)	20 (21%)	0.200
Symptoms -≥25%	128 (67%)	43 (44%)	<0.001

No. patients

Adverse events
Adverse effects: 34% in the treatment group and 24% in the placebo group experienced some form of adverse event

	Tamsulosin	Placebo
Dizziness	5 (3%)	2 (2%)
Headache	6 (3%)	1 (1%)
Hypotension	0	1 (1%)
Syncope	1 (0.5%)	1 (1%)
Abn ejac	7 (4%)	1 (1%)

Cumulative incidence

There were no significant difference in incidence between the groups but abnormal ejaculation in the tamsulosin group was deemed as due to study medication

Quality of evidence: High.
Conclusion: Tamsulosin provides greater improvement in IPSS and Q_{max} than placebo.
Internal validity: Randomization not described. Blinding partly described. External validity: Eligible patients described. Comments: ITT used. Power calculated.
Sponsorship: Unclear

Chapple 1996 RCT Europe
European Tamsulosin Study Group. Eur Urol 1996;29:155-67

Intervention
Tamsulosin 0.4mg vs placebo
12 weeks

Population
627 screened

Tamsulosin 382 pat drop-outs 40 (8%)
4% due to AE
1% due to lack of efficacy

Placebo 193 pat drop-outs 25 (7%)
4% due to AE
1% due to lack of efficacy

	Tamsulosin	Placebo
Age	63.6±8.3	64.4±8.1
Qmax	10.2±3.5	10.1±3.0
Boyarsky	9.4±2.8	9.4±2.8

Inclusion criteria:
Symptomatic LUTS, Q_{max} 4–12 ml/s, Boyarsky ≥6, voided volume >120 ml

Exclusion criteria:
Previous bladder neck, prostate or pelvic region surgery, any other condition which could affect micturition, hepatic or renal insufficiency, concomitant medication which may interfere with alpha blockers etc

Results

Boyarsky	Tamsulosin	Placebo	*p*
Inclusion	9.4±2.8	9.4±2.8	
12 w	6.1±3.2	7.0±3.4	
Change	-3.3±3.1	-2.4±3.2	0.002

Mean±SD
p-value tamsulosin vs placebo

IPSS*	Tamsulosin	Placebo	*p*
Inclusion	13.1±3.6	12.1±3.6	
12 w	7.9±4.1	9.0±4.4	
Change	-4.3±4.0	-3.1±4.1	0.002

Mean±SD
*calc from Boyarsky. Max-IPSS=35, Max-B=27
35/27≈1.29→IPSS=1.29 x B

Q_{max}	Tamsulosin	Placebo	*p*
Inclusion	10.2±3.5	10.1±3.0	
12 w	11.8±4.4	10.7±3.3	
Change	1.6±3.6	0.6±3.1	0.002

Mean±SD
p-value tamsulosin vs placebo

Adverse events

Adverse effects: 23% in the treatment group and 15% in the placebo group experienced some form of adverse event

	Tamsulosin 381	Placebo 193
Dizziness	13 (3.4%)	6 (3.1%)
Headache	8 (2.1%)	4 (2.1%)
Hypotension	0	1(0.5%)
Syncope	1 (0.3%)	1 (0.5%)
Abn ejac	17 (4.5%)	2 (1%)
Asthenia/ fatigue	4 (1%)	2 (1%)

Cumulative incidence.
Abnormal ejaculation was the only statistically significant adverse event

Quality of evidence: Moderate.
Conclusion: Tamsulosin improves both subjective symptoms and urinary flow in patients with BPH.
Internal validity: Randomization and blinding not described. External validity: Eligible patients described.
Comments: ITT used.
Sponsorship: Not reported

Lepor 1998 RCT USA
Tamsulosin Investigator Group. Urology 1998;51:892-900. Extension in Urology 1998;51:901-906

Intervention
Tamsulosin 0.4mg vs 0.8mg vs placebo.
13 weeks. Extension: another 40 weeks

Population
The three groups were comparable with respect to race, weight and severity of symptoms. The tamsulosin 0,4mg group had a significantly younger population than the other 2 groups. Approx 50% of patients in all groups had severe BPH (AUA more than 20)
Tamsulosin 0,4 mg 254 pts drop-out 41 (16%)
-7% due to AE
Tamsulosin 0,8 mg 248 pts drop-out 50 (20%)
-13% due to AE
Placebo 254 pts drop-out 47 (19%)
-9% due to AE
Extension:
A disproportionate number of younger patients (45–54 yrs) were in the 0,4 mg group compared to the others. (44% vs 27% and 28%, respectively)

Tamsulosin 0,4 mg 142 pts drop-out 19 (13,4%)
-5% due to AE
Tamsulosin 0,8 mg 144 pts drop-out 38 (26,4%)
-16% due to AE
Placebo 132 pts drop-out 26 (19,7%)
-6% due to AE

Inclusion criteria:
Men ≥45 years, symptomatic BPH, Q_{max} 4–15 ml/s AUA≥13, PVR≤300 ml

Exclusion criteria:
Recent treatment with alpha-blocker or antiandrogen, medications altering voiding patterns, neurological or cardiovascular disease, PCA, previous invasive surgery/procedure, recurrent UTI, other urological disorder etc

Results

AUA	Placebo	0,4mg	0,8 mg
BL	19,6±4,9	19,8±4,9	19,9±4,7
Change 12 w	-5,5±6,3	-8,3±6,3*	-9,6±6,2**
Change 40 w	-6,5	-9,4***	-9,7***

Mean±SD
*p<0,001 vs placebo
** p<0,001 vs placebo, p<0,02 vs 0,4 mg
*** p<0,05 vs placebo

Q_{max}	Placebo	0,4mg	0,8 mg
BL	9,75±2,5	9,46±2,5	9,57±2,5
Change 12 w	0,52±3,3	1,75±3,5*	1,78±3,3*
Change 40 w	0,43	1,69	2,10

Mean±SD
*p<0,001 vs placebo

Adverse events
Adverse effects: serious AE:s happened to 4 (2%) in the 0,4 mg group, 6 (2%) in the 0,8 mg group and 3 (1%) in the placebo group. Syncope was counted as serious

	Placebo	0,4mg	0,8mg
Dizziness	13 (5%)	25 (10%)	**28 (11%)**
Headache	46 (18%)	48 (19%)	45 (18%)
Abn ejac	0	**15 (6%)**	**44 (18%)**
Asthenia/ fatigue	5 (2%)	12 (5%)	13 (5%)

Numbers in bold mean significant increase vs placebo
Extension:

	Placebo	0,4mg	0,8mg
Asthenia	4 (3%)	**10 (7%)**	**12 (9%)**
Abn ejac	0	14 (10%)	36 (26%

Numbers in bold mean significant increase vs placebo

Quality of evidence: Moderate. **Conclusion**: Tamsulosin was effective, safe, and well tolerated in the target BPH population at both the 0.4-and 0.8-mg/day dose levels. Internal validity: Randomization and blinding not described. External validity: Eligible patients not reported. Comments: ITT used. Sponsorship: Unclear

Narayan 1998 RCT USA
United States 93-01 Study Group. J Urol 1998;160:1701-6

Intervention
Tamsulosin 0.4 mg vs 0.8 mg vs placebo
13 weeks

Population
1 476 screened

Tamsulosin 0.4 mg 248 pts drop-out 22 (9%)
Tamsulosin 0.8 mg 244 pts drop-out 30 (12%)
Placebo 239 pts drop-out 20 (8%)

	Mean
Age	58 (44–79)

There was no significant difference in severity of symptoms at baseline in the different groups

Inclusion criteria:
Men ≥45 years with moderate to severe symptomatic BPH

Exclusion criteria:
Not reported

Results
No baseline data are given, only mean change.

Q_{max} +≥3ml/s	0.4mg	0.8 mg	Placebo
No pts	72/244	71/237	53/235
	29.5%	30.0%	22.5%
p vs placebo	0.085 NS	0.0□1 NS	

Boyarsky	0.4 mg	0.8 mg	Placebo
Change	-2.97±4.1	-3.25±3.7	-1.89±3.7
p vs placebo	0.002	<0.001	

Mean±SD (calc from SE)

IPSS*	0.4mg	0.8 mg	Placebo
Change	-3.8±5.3	-4.2±4.8	-2.4±4.8
p vs placebo	0.002	<0.001	

Mean±SD
*calc from Boyarsky. Max-IPSS=35, Max-B=27. 35/27≈1.29→IPSS=1.29 x B

QOL	0.4 mg	0.8 mg	Placebo
Change	-0.95±2.4	-1.4±2.6	-0.56±2.3
p vs placebo	0.089 NS	<0.001	

Mean±SD

Adverse events

	0.4mg	0.8mg	Placebo
Dizziness	50 20%)	56 (23%)	37(15%)
Headache	49 20%)	59 (24%)	53(22%)
Somnolence	10 (4%)	19 (8%)	7(3%)
Abnormal ejaculation	27 11%)	45 (18%)	1(<1%)
Asthenia/ fatigue	27 11%)	29 (12%)	22 (9%)

Quality of evidence: Low–moderate.
Conclusion: Tamsulosin was safe and effective, and clinically and statistically superior to placebo in relieving symptoms of benign prostatic hyperplasia in men with moderate to severe symptoms at baseline.
Internal validity: Randomization and blinding not described. External validity: Eligible patients reported.
Comments: ITT used.
Sponsorship: Veterans Administration

Chapple 2005 RCT International
Eur Urol Suppl 4 2005; 25-32

Intervention
Tamsulosin oral controlled absorption system (OCAS) 0.4 mg vs 0.8 mg vs 1.2 mg vs placebo.
12 weeks

Population
0.4 mg 206 pat drop-outs 10 (4.9%)
-2.9% due to AE

0.8 mg 209 pat drop-outs 12 (5.6%)
-2.4% due to AE

1.2 mg 211 pat drop-outs 11 (5.2%)
-3.3% due to AE

Placebo 213 pat drop-outs 7 (3.3%)
-0.5% due to AE

	Tamsulosin	Placebo
Age	65.7	64.8
PSA	2.79	2.86
IPSS	18.0	17.8
Q_{max}	9.69	9.82
Prostate volume	41.9	40.9

Mean values calc from table

Inclusion criteria:
45 years, symptomatic BPH, Q_{max} 4–12 ml/s for a voided volume of at least 120 ml, IPSS≥13

Exclusion criteria:
Other condition affecting micturation, prostatic or pelvic region surgery, hepatic/renal/cardiovascular disease, medications which could influence outcome of study etc

Results

IPSS	Placebo	0.4 mg	0.8 mg	1.2 mg
BL	17.8±4.0	18.0±4.3	17.7±4.5	18.2±4.4
12 w	11.8	11.5	9.7	9.7
Change	-6.0	-7.5*	-8.0*	-8.5*

Mean±SD for BL.
Mean values from graphs for results.
*p=0.0016, <0.0001, <0.0001 vs placebo for groups

QOL	Placebo	0.4 mg	0.8 mg	1.2 mg
BL	3.7±1.0	3.7±1.0	3.7±1.0	3.8±1.0
12 w	2.8	2.4	2.3	2.4
Change	-0.9±1.3	-1.3±1.3*	-1.4±1.2*	-1.4±1.2*

Mean±SD
*p=0.0005, <0.0001, <0.0001 vs placebo for groups

	Placebo	0.4 mg	0.8 mg	1.2 mg
IPSS -≥25%	63.0%	73.4%	80.1%	76.7%
p vs placebo		0.024	<0.001	0.002

No of pts whose IPSS score decreased by at least 25%

Adverse events
Adverse effects: 29–36% in the treatment group and 26% in the placebo group experienced some form of adverse event

13 patients experienced a severe TAE. 2/212 (0.9%) in placebo group, 2/203 (1%) in the 0.4mg group, 4/206 (1.9%) in the 0.8 mg group and 5/210 (2.4%) in the 1.2 mg group

	Tamsulosin	Placebo
Dizziness	22/619 (3.6%)	3/212 (1.4%)
Abnormal ejaculation	30/619 (4.9%)	2/619 (0.9%)

Cumulative incidence

Quality of evidence: High.
Conclusion: Tamsulosin was effective in improving IPSS and Q_{max} in three different doses. The number of adverse events increased at higher dosage. Internal validity: Randomization and blinding not described. External validity: Eligible patients reported. Comments: ITT used. Power calculated.
Sponsorship: Yamanouchi Europe

Nordling 2005 RCT Denmark
BJU Int. 2005;95:1006-12.

Intervention
Alfuzosin OD 10 mg vs alfuzosin OD 15mg vs tamsulosin OD 0.4 mg vs placebo.
12 weeks

Population
Alfuzosin 10 mg 154 pts DO: 9 (5.8%)
- 4 (2.6%) due to adverse event

Alfuzosin 15 mg 158 pts DO: 17 (11%)
- 14 (9%)due to AE

Tamsulosin 158 pts DO: 9 (5.2%)
- 6 (3.5%) due to AE

Placebo 154 pts DO: 12 (7.8%)
- 5 (3%) due to adverse event

	Treatment	Placebo
Age	65 (51–85)	64 (50–82)
Q_{max}	8.9 (5.0–12.6)	9.0 (4.0–12.5)
IPSS	20 (13–35)	20 (5–32)
Months LUTS	45 (6–294)	50 (6–307)

Mean(range)

Inclusion criteria:
≥50 years, symptomatic BPH (from DRE/TRUS within last 3 months), Q_{max} ≤12 ml/s for a voided volume of ≥150ml and a residual urine volume of ≤350 ml , 6 months history of LUTS, IPSS ≥13, nocturia twice or more

Exclusion criteria:
Concomitant urological disease, previous BPH surgery or X-ray, concomitant medication with effect on voiding pattern, other diseases such as diabetes or Parkinson, previous treatment failure on alfa-blockers etc

Results

IPSS	Alf 10 mg	Alf 15 mg	Tams	Placebo
Incl	20±3.7	20±3.5	20.0±3.3	20±4.5
BL	18.0 ±5.4	17.4±4.8	17.4±5.6	17.7±5.0
12 w	11.5	11.4	10.9	13.1
Change	-6.5±5.2	-6.0±5.6	-6.5±6.2	-4.6±5.8

Mean±SD
p=0.007 at 12 weeks for alfu 10 mg vs placebo, 0.05 for alfu 15 mg vs placebo, 0.014 for tamsu vs placebo

	Alfu	Alfu	Tams	
Q_{max}	10 mg	15mg		Pbo
Incl	8.9	8.7	8.8	9.0
BL	9.2	8.9	9.4	9.0
Change	1.5	1.4	1.4	0.5
12 w	10.7	10.3	10.8	9.5

Mean values. No SD given.
p=0.02 at 12 weeks all groups vs placebo

Adverse events

Adverse effects: 2% in the placebo and alfuzosin 10 mg group had one serious AE. 4% in the tamsulosin and alfuzosin groups had a serious AE

Dizziness occurred in 6% in the 10 mg group, 7% in the 15 mg alfuzosin group, in 2% of the tamsulosin group and 4% in the placebo group

Ejaculation disorders occurred more often within the tamsulosin group (3%) than the others (0–1%)

Quality of evidence: High.
Conclusion: Treatment with alfuzosin 10 mg significantly improved urinary symptoms and Q_{max} compared with placebo and was well tolerated.
Internal validity: Randomization and blinding not described. External validity: Eligible patients not described. Comments: Power calculated. ITT used.
Sponsorship: Sanofi-Synthélabo

5.3 5-alfa-reduktashämmare

Beisland 1992 RCT Norway
European Urology 22:271-7

Intervention
Finasteride 5 mg vs placebo
24 weeks

Population
Finasteride 94 patients DO 6,4%
Placebo 88 patients DO 3,4%

	Finasteride	Placebo
Age	66.6	68.0
Q_{max}	8.0±3.0	7.6±3.1
Pvolume	44.2±22.4	43.8±24.1
Boyarsky*	8.8±6.1	7.8±4.9

Mean ±SD
*Modified Boyarsky, range 0–36

Inclusion criteria:
Age 40–80 yrs, good physical and mental health, symptoms of urinary obstruction, Q_{max} less than 15 ml/s, enlarged prostate on digital rectal examination

Exclusion criteria:
Clinical abnormalities detected at prestudy evaluation

Results

Boyarsky	Finasteride	Placebo	*p*
BL	8.8±6.1	7.8±4.9	
Change 12 w	-2.1±4.4	-0.8±4.0	0,046
Change 16 w*	-2.1±4.2	-0.9±4.0	
Change 24 w	-2.4±4.7	-1.2±4.3	0,05

Mean ±SD

Q_{max}	Finasteride	Placebo	*p*
BL	8.0±3.0	7.6±3.1	
Change 12 w	+1.1±6.4	+0.7±5.8	
Change 16 w*	+1.0±3.3	+0.6±3.8	
Change 24 w	+1.6±7.9	+1.1±6.1	0,022

Mean ±SD
All mean and SE data extracted from figure.
SD calculated from SE.
*SD imputated

Adverse events

	Finasteride	Placebo
Surgery	1.1	0
AUR	1.1	0
Impotence	4.3	4.5
Decreased libido	1.1	0
Headache	9.6	6.8

24-week incidence

Quality of evidence: Moderate
Conclusion: Significant improvement in IPSS and Q_{max} achieved with finasteride compared to placebo. Internal validity: Randomization and blinding not described. External validity: Eligible patients not reported. Comments: Analysed according to ITT
Sponsorship: Not reported

Gormley 1992 RCT USA
New England Journal of Medicine 1992;327:1185-91

Intervention
Finasteride vs placebo
12 months

Population
Finasteride 297 patients DO 13,5%
Placebo 300 patients DO 12,3%

	Finasteride	Placebo
Age (and range)	64 (40-80)	64 (45-82)
Q_{max}	9.6±3.7	9.6±3.5
Pvolume	58.6±30.5	61.0±36.5
Boyarsky*	10.2±5.5	9.8±5.3

Mean ±SD
*Modified Boyarsky, range 0–36

Inclusion criteria:
Symptoms of urinary obstruction, enlarged prostate on DRE, Q_{max} <15ml/s with voided volume of 150 ml or more

Exclusion criteria:
Vres >350 ml, PSA ≥40µg/l, evidence of prostatic cancer, UTI, chronic prostatitis, neurogenic bladder

Results

Boyarsky	Finasteride	Placebo
BL	10.2±5.5	9.8±5.3
Change 4 mo**	-1.8±4.2	-1.6±4.0
Change 8 mo**	-1.8±4.2	-1.2±4.2
Change 12 mo***	-2.7±5.0	-□.0±5.0

Mean ±SD

Q_{max}	Finasteride	Placebo
BL	9.6±3.7	9.6±3.5
4 mo****	10.6±4.9	10.0±5.0
8 mo****	11.0±5.4	9.9±5.4
12 mo	11.2±4.7	9.8±3.7

Mean ±SD
All mean and SE data extracted from figures, except Q_{max} 12 mo
** SD imputated
*** SD calculated from SE
**** SD calculated from the p-value

Adverse events
1-year incidence (%)

	Finasteride	Placebo
Surgery	1.0	1.0
AUR	nr	nr
Impotence	3.4	1.7
Decreased libido	4.7	1.3
Ejac disorder	4.4	1.7
Asthenia	1.0	1.0
Headache	0.7	0.7
Prostate cancer	0.3	0.3

Quality of evidence: Moderate
Conclusion: Finasteride decreases symptoms and increases maximum flow but has a risk for sexual side-effects.
Internal validity: Randomization procedure not adequately described External validity: Eligible patients not reported. Comments: Analysed according to ITT.
Sponsorship: Merck Research Laboratories

The Finasteride Study Group 1993 RCT USA
Prostate 1993; 22:291-9

Intervention
Finasteride vs placebo
12 months

Population
Finasteride 246 patients
Placebo 255 pateints
Drop-outs not reported

	Finasteride	Placebo
Age	66 (46-83)	66 (46-81)
Q_{max}	9.2±4.0	8.6±3.4
Pvolume	47.0±20.8	46.3±23.4
Boyarsky*	18.6±6.0	18.2±5.9

Mean ±SD (range)
*Modified Boyarsky, range 0–36

Inclusion criteria:
Age 40–80 years, good physical and mental health, Q_{max} <15ml/s, Pvolume ≥30ml, symptoms of urinary obstruction

Exclusion criteria:
Bacterial prostatitis, previous prostate or testicular surgery, prostate cancer, PSA ≥40 ng/ml, Vres >350 ml, suspicion of neurogenic bladder, repeated urinary catheterizations, using drugs with antiandrogenic properties

Results

Boyarsky	Finasteride	Placebo
BL	18.6±6.0	18.2±5.9
Change12 mo**	-3.3±5.6	-2.0±5.8

Mean ±SD

Q_{max}	Finasteride	Placebo
BL	9.2±4.0	8.6±3.4
Change 12 mo**	+1.7±4.2	+0.4±3.8

Mean ±SD
**SD imputated

Adverse events
1-year incidence (%)

	Finasteride	Placebo
Surgery	1.2	1.6
AUR	1.2	1.2
Impotence	4.9	0.4
Decreased libido	nr	nr
Ejac disorder	nr	nr
Prostate cancer	1.6	1.2

Quality of evidence: Moderate
Conclusion: Increases maximum flow for 33% and reduces prostate size for 50% of the population. Erectile dysfunction the most common adverse effect.
Internal validity: Randomization procedure and reason for drop-outs not described.
External validity: Eligible patients not reported. Comments: ITT used.
Sponsorship: Merck Research Laboratories

Andersen 1995 RCT Denmark
Urology 1995;46: 631-7

Intervention
Finasteride vs placebo
24 months

Population
Finasteride 353 patients DO 24 mo: 18,7%
Placebo 354 patients DO 24 mo: 18,1%

	Finasteride	Placebo
Age	Nr	Nr
Q_{max}	10.2	10.5
Pvolume	40.6	41.7
Boyarsky*	13.4	13.1

Mean
*Modified Boyarsky, range 0–54

Inclusion criteria:
≤80 years, Q_{max} ≥5 and ≤15 ml/s, at least 2 symptoms indicating moderate BPH but no more than 2 severe symptoms, enlarged prostate on digital rectal examination, PSA ≤10 ng/ml, postvoid residual urine volume ≤150 ml.

Exclusion criteria:
Hematuria associated with untreated active UTI, prostatitis or urinary bladder carcinoma, use of drugs with antiandrogenic properties, previous condition predisposing patients to urethral strictures, chronic bacterial prostatitis, previous prostate or urinary tract surgery, evidence or suggestion of prostate cancer, neurogenic bladder dysfunction, serum creatinine >150mmol/l or liver function tests ≥50% above upper normal limit, significant abnormalities in prestudy clinical examination or laboratory measures, ≥2 catheterizations for acute urinary retention in the previous 2 years, urinary tract infection unless satisfactory treated

Results

Boyarsky	Finaster□de	Placebo
BL	13.4	13.1
Change 4 mo	-0.9±6.4**	-0.6±6.2**
Change 8 mo	-1.5±6.8**	-0.3±6.2**
Change 12 mo	-1.8±6.8**	-0.6±6.2**
Change 24 mo	-2.0±5.6**	+0.2±6.9**

Mean ±SD

Q_{max}	Finasteride	Placebo
BL	10.2	10.5
Change 4 mo	+1.1±3.8**	+0.5±3.8**
Change 8 mo	+1.9±5.4**	+0.1±3.8**
Change 12 mo	+1.3±3.8**	-0.1±3.8**
Change 24 mo	+1.5±3.5**	-0.3±3.1**

Mean ±SD
Mean and CI data from 4, 8 and 12 mo extracted from figure, except mean for Boyarsky 12 mo.
**SD calculated from 95% CI

Adverse events
2-year incidence (%)

	Finasteride	Placebo
Surgery***	0	2.5
AUR***	1.1	4.2
Impotence	15.6	8.5
Decreased libido	nr	nr
Ejac disorder	nr	nr

***post hoc analysis

Quality of evidence: Moderate
Conclusion: Finasteride provides greater improvement in IPSS and Q_{max} compared to placebo. Internal validity: Blinding and randomization not described.. External validity: Eligible patients not reported. Comments: ITT used. Post hoc analysis of AUR and surgery. Power calculated.
Sponsorship: Not reported

Byrnes 1995 RCT USA
Clinical Therapeutics 1995;17:956-69

Intervention
Finasteride 5 mg vs placebo
12 months

Population
Finasteride: 1 821 patiens DO: 19.4%
Placebo: 596 patients DO: 20.5%

	Finasterid	Placebo
Age	65.0 (42–91)	65.1 (45–91)
Q_{max}	nr	nr
Pvolume	nr	nr
IPSS	nr	nr
BII	5.1±3.2	5.0±3.1

Mean ±SD (range)
*BPH Impact Index. Worst possible score 13

Inclusion criteria:
Diagnosis of BPH based on moderate to severe symptoms with prostate enlargment on digital rectal examination and PSA≤10ng/ml

Exclusion criteria:
Evidence of urethral stricture, previous prostatectomy or other invasive procedure to treat BPH, pelvic radiotherapy, recurrent episodes of urinary retention, chronic prostatitis, neurogenic bladder, recurrent UTI, current use of alpha-adrenergic antagonists or use of hormonal therapy affecting the prostate, suspicion of prostate cancer

Results

IPSS	Finasteride	Placebo	*P*
BL	nr	nr	
Change 12 mo*	-4.8±8.1	-3.4±7.8	<0,01

Mean ±SD
*Mean and CI data extracted from figure

BII	Finasteride	Placebo	*P*
BL	5.1±3.2	5.0±3.1	
Change 12 mo	-1.2±4.2**	-0.9±3.7**	0,0465

Mean ±SD
**SD calculated from 95% CI

Adverse events
1-year incidence (%)

	Finasteride	Placebo
Surgery	1.6	1.3
AUR	0.6	0.7
Impotence	6.8	3.2
Decreased libido	3.1	1.2
Ejac disorder	2.3	0.5
Prostate cancer	0.3	0.3

Quality of evidence: Moderate
Conclusion: Finasteride provides greater improvement than placebo in IPSS and Qmax.
Internal validity: Blinding and randomization not described. External validity: Eligible patients reported.
Comments: Uncertain whether ITT was performed
Sponsorship: Merck

Lepor 1996 RCT USA. N Engl J Med 1996;335:533-9 (1998, J Urology 1998;160:1358-67, Nocturia in Johnson 2003 J Urology 2003;170:145-8)

Intervention

Dutasteride 0,5 mg vs Terazosin 5/10 mg vs combination vs placebo.

12 months

Population

Combination 309 pattiens DO: 12 mo 17,8%
Terazosin 305 patients DO: 12 mo 16,1%
Finasteride 310 patients DO: 12 mo 21,6%
Placebo 305 patients DO: 12 mo 16,7%

	Comb	Tera	Fina	Placebo
Age	65±7	65±6	65±7	65±7
Q_{max}	10,4 ±3,5	10,5 ±3,5	10,6 ±2,5	10,4 ±2,6
Pvol	37,2 ±19,3	37,5 ±19,2	36,2 ±17,6	38,4 ±22,6
AUA-SS	15,9 ±5,3	16,2 ±5,2	16,2 ±5,4	15,8 ±5,5

Inclusion criteria: :

45–80 years, symptom score ≥8, Q_{max} ≥4 and ≤15 ml/s with a minimal voided volume of 125 ml, post void residual urine volume <300 ml

Exclusion criteria:

Unwilling or unable to give informed consent, taken experimental drug within 4 weeks before screening, taken α-adrenergic agonist, cholinergics, anticholinergics, topical β-adrenergic-antagonist for glaucoma or any anti-hypertensive drug except a diuretic or an ACE-inhibitor within 2 weeks before lead-in, taken estrogen, androgen or androgen inhibitor within 3 months before screening, episode of unstable angina pectoris, myocardial infarction, transient ischemic attack or cerebrovascular lesion in the past 6 months, insulindependent diabetes mellitus, orthostatic hypotension, history of syncope, blood pressure below 90/70 mm Hg (sitting), history of carcinoma of the prostate, pelvic irradiation, urethral stricture, surgery for BPH or BOO, current evidence of prostatic carcinoma, active urinary tract disease, cystoscopy or biopsy of the prostate within the previous two weeks, a history of recurrent UTI or UTI within the preceding two months, prior pelvic surgery likely to interfere with bladder function , progressive disorder that might prevent the evaluation of drug safety and efficacy, clinically important renal or hepatic impairment, PSA >10ng/ml

Results

AUASS	Com	Ter	Fin	Pla
BL	15,9 ±5,3	16,2 ±5,2	16,2 ±5,4	15,8 ±5,5
12 mo	9,8 ±5,0	10,2 ±5,0	13,0 ±4,8	13,2 ±4,9

Mean±SD

Q_{max}	Com	Ter	Fin	Pla
BL	10,4 ±3,5	10,5 ±3,5	10,6 ±2,5	10,4 ±2,6
12 mo	13,6 ±5,0	13,2 ±5,0	12,2 ±4,9	11,8 ±4,8

Mean±SD

Nocturia	Com	Ter	Fin	Pla
BL	2,5	2,5	2,5	2,5
12 mo	2,0	1,8	2,1	2,1

Mean number of episodes

Adverse events

%	Com	Ter	Fin	Pla
Death	0,6	0,7	2,3	1,0
Surgery	0,6	0,7	1,6	1,3
AUR	Not reported			
Impotence	9,3	5,9	9,4	4,6
Decr. libido	4,9	2,6	4,5	1,3
Ejac disorder	6,8	0,3	1,9	1,3
Asthenia	13,9	13,8	7,4	6,9
Headache	5,2	5,9	6,1	3,2
Dizziness	21,4	25,9	8,4	7,2
Rhinitis	7,8	6,6	2,6	4,6
Sinusitis	2,3	2,0	1,3	1,3
Postural hypotension	8,7	7,5	2,3	1,0
Syncope	1,6	1,0	1,0	0

1-year incidence (%)

Quality of evidence: High. **Conclusion**: Terazosin superior to Finasteride in relieving LUTS due to BPH. The addition of Finasteride to Terazosin does not increase efficacy or affect safety. Internal validity: Randomization not described. Blinding described. External validity: Eligible patients reported. Comments: ITT used. Sponsorship: Merck, Abbott Laboratories. Study conducted by Department of Veteran Affairs independently of sponsors

Nickel 1996 RCT Canada
Canadian Medical Association Journal 1996;155:1251-9

Intervention
Finasteride vs placebo
24 months

Population
Finasteride: 310 patients DO 24 mo: 20.6%
Placebo: 303 patients DO 24 mo: 25.4%

	Finasteride	Placebo
Age	63.0 (46–79)	63.5 (47–80)
Q_{max}	11.1±3.7	10.9±3.5
Pvolume	44.1±23.5	45.8±2.4
Boyarsky*	15.8±7.6	16.6±7.2

Mean ±SD (range)
*Modified Boyarsky, range 0–54

Inclusion criteria:
Age ≤80 years, Q_{max} 5–15 ml/s with voided volume at least 150 ml, 2 moderate symptoms of BPH but no more than 2 severe symptoms, enlarged prostate on digital rectal examination, PSA ≤10 ng/ml, postvoid residual urine volume ≤150 ml

Exclusion criteria:
Evidence or suggestion of prostate cancer, neurogenic bladder dysfunction, 2 or more AUR during the previous 2 years, history of prostate surgery or other invasive procedure, condition predisposing patient to urethral strictures, chronic bacterial prostatitis, serum creatinine >150 mmol/l or liver function tests >50% more than normal, use of antiandrogenics, hematuria associated with UTI, prostatitis or bladder cancer, any condition jeopardizing patient's ability to complete the study

Results

Boyarsky	Finasteride	Placebo
BL	15.8±7.6	16.6±7.2
Change 4 mo	-1.3±6.0	-1.3±5.8
Change 8 mo	-1.8±6.2	-1.6±6.5
Change 12 mo	-1.8±6.0	-0.9±6.5
Change 24 mo	-2.1±6.2	-0.7±7.3

Mean ±SD

Q_{max}	Finasteride	Placebo
BL	11.1±3.7	10.9±3.5
Change 4 mo	+0.7±3.3	+0.6±4.6
Change 8 mo	+0.8±3.7	+0.2±3.8
Change 12 mo	+1.0±3.7	+0.3±3.7
Change 24 mo	+1.3±3.8	+0.3±4.3

Mean ±SD
All mean and CI data extracted from figure.
SD calculated from 95% CI

Adverse events
2-year incidence (%)

	Finasteride	Placebo
Surgery	nr	nr
AUR	nr	nr
Surgery or AUR	6.1	10.2
Impotence	15.8	6.3
Decreased libido	10.0	6.3
Ejac disorder	7.7	1.7
Prostate cancer	1.0	2.0

Quality of evidence: Moderate
Conclusion: Finasterides alleviates symptoms, improves flow and reduces prostate volume.
Internal validity: Randomization procedure and blinding well described. Reason for drop-outs and number described External validity: Comments: Analysed according to ITT. Power analysis not performed.
Sponsorship: Merck Frosst Canada, Inc

Tenover 1997 RCT USA
Clinical Therapeutics 1997;19:243-58

Intervention
Finasteride vs placebo.
12 months

Population
Finasteride 1 589 patients DO 12 mo: 16.6%
Placebo 523 patients DO 12 mo: 16,4%

	Finasteride	Placebo
Age	63.6±8.7 (45–87)	62.7±8.9 (45–94)
Q_{max}	nr	nr
Pvolume	nr	nr
AUA	19.0	18.4
BII*	4.8±2.9	4.7±2.6

Mean ±SD (range)
*BPH Impact Index. Worst possible score 13

Inclusion criteria:
45 years, diagnosis of BPH based on moderate to severe symptoms with prostate enlargment on digital rectal examination and a PSA <10 ng/ml

Exclusion criteria:
Urethral stricture, previous prostatectomy or other invasive procedures for BPH, repeated catheterizations, previous pelvic radiotherapy, recurrent episodes of urinary retention, chronic prostatitis, neurogenic bladder, recurrent UTI or active UTI, treatment with alphablockers, high-dose ketoconazole or hormonal therapy affecting the prostate, suspicion of prostate cancer unless cleared by prostate biopsy

Results

AUA	Finasteride	Placebo
BL	19.0	18.4
Change 12 mo*	–5.0±7.8	–3.1±6.9

Mean ±SD
*mean and CI data extracted from figure

BII	Finasteride	Placebo
BL	4.8±2.9	4.7±2.6
Change 12 mo	–1.1±3.5	–0.7±3.1

Mean ±SD
SD calculated from 95% CI

Adverse events
1-year incidence (%)

	Finasteride	Placebo
Surgery	0.8	0.9
AUR	0.2	0.4
Impotence	8.1	3.8
Decreased libido	5.4	3.3
Ejac disorder	4.0	0.9
Prostate cancer	0.5	0.5

Quality of evidence: Moderate
Conclusion: Finasteride is effective and generally well tolerated.
Internal validity: Randomization procedure not adequately described. Reason for drop-outs and number described. External validity: Eligible patients not reported. Comments: Analysed according to ITT. Power analysis not performed
Sponsorship: Merck & Co, Inc., Whitehouse, New Jersey

Marberger 1998 RCT Austria
Urology 1998;51:677-86

Intervention
Finasteride 5 mg vs placebo.
24 months

Population
Finasteride 1 450 patients DO: 24 mo 23%
Placebo 1 452 patients DO: 24 mo 25%

	Finasteride	Placebo
Age	63.0±6.3	63.4±6.1
Q_{max}	11.2±5.9	10.9±3.6
Pvolume	38.7±20.1	39.2±20.2
Boyarsky*	14.5±7.3	14.3±7.2

Mean±SD
*Modified Boyarsky, range 0–54

Inclusion criteria:
BPH diagnosis, age 50–75 in good general health, Q_{max} 5–15ml/s with voided volume of 150 ml or more, at least 2 urinary symptoms indicating moderate BPH but not more than 2 severe symptoms, enlarged prostate on digital rectal examination, PSA <10ng/ml, postvoid residual urine <150ml

Exclusion criteria:
History of illness that might confound study results or present additional risk, dysuria, hematuria or UTI, abnormalities on clinical examination or in laboratory tests, liver function tests elevated ≥50%, multiple or severe allergies, treatment with antiandrogenics, alphablockers, clonidine or plant extracts, history of drug or alcoholic abuse, history of predisposing conditions to urethral strictures, chronic bacterial prostatitis, previous prostatectomy or invasive treatment for BPH, evidence or suggestion of prostate cancer, history suggestive of neurogenic bladder, catheterization for AUR twice during the last 2 years, compliance <80% during placebo run-in, planned fatherhood

Results

Boyarsky	Finasteride	Placebo
BL	14.5±7.3	14.3±7.2
Change 4 mo	-2.3±9.2	-1.8±9.2
Change 8 mo	-2.4±9.3	-1.8±9.3
Change 12 mo	-2.9±9.3	-1.9±9.8
Change 24 mo	-3.2±11.2	-1.5±11.2

Mean±SD
Mean and CI data extracted from figure (except BL)
SD calculated from 95% CI

Q_{max}	Finasteride	Placebo
BL	11.2±5.9	10.9±3.6
Change 4 mo**	+0.9±3.3	+0.6±3.8
Change 12 mo	+1.2±8.5	+0.6±8.5
Change 24 mo	+1.5±9.5	+0.7±9.4

Mean±SD
SD for Q_{max} calculated from p-values
**SD imputated

Adverse events
2-year incidence (%)

	Finasteride	Placebo
Surgery	3.5	5.9
AUR	1.0	2.5
Impotence	6.6	4.7
Decreased libido	4.0	2.8
Ejac disorder	2.1	0.6
Asthenia, fatigue	0.7	1.5
Headache	2.1	2.3

Quality of evidence: Moderate
Conclusion: Finasteride is effective and well tolerated in the treatment of BPH.
Internal validity: Randomization procedure described. Reason for drop-outs and number described. External validity: Eligible patients reported. Comments: Analysed according to ITT. Power analysis performed. Sponsorship: Not reported

McConnell 1998 RCT USA
New England Journal of Medicine 1998;338:557-63.

Intervention
Finasteride 5 mg vs placebo.
48 months

Population
Finasteride 1 524 patients DO: 48 mo 34%
Placebo 1 516 patients DO: 48 mo 42%

	Finasteride	Placebo
Age	64±6	64±7
Q_{max}	11±4	11±4
Pvolume	54±25	55±26
IPSS*	15±6	15±6

Mean±SD
*Quasi-AUA symptom score, range 0–34.

Inclusion criteria:
BPH on basis of moderate to severe symptoms of urinary obstruction, Q_{max} <15ml/s with voided volume of 150 ml or more, enlarged prostate on digital rectal examination

Exclusion criteria:
History of chronic prostatitis, recurrent UTI, prostate or bladder cancer or surgery, PSA > 10 ng/ml, treatment with alphablockers or antiandrogens

Results

IPSS	Finasteride	Placebo
BL	15±6	15±6
Change 4 mo	-1.4±3.5	-1.1±3.5
Change 8 mo	-1.9±3.5	-1.7±3.4
Change 12 mo	-2.3±3.5	-1.6±3.4
Change 24 mo	-2.9±6.5	-1.3±6.3
Change 36 mo	-3.1±6.2	-1.3±5.9
Change 48 mo	-3.2±5.9	-1.1±5.6

Mean±SD
SD calculated from SE.
All mean and SE data extracted from figure

Q_{max}	Finasteride	Placebo
BL	11±4	11±4
Change 4 mo	+1.0±3.2	+0.3±3.1
Change 8 mo	+0.8±3.2	+0.3±3.1
Change 12 mo	+1.2±3.2	+0.2±3.1
Change 24 mo	+1.6±5.8	+0.4±5.6
Change 36 mo	+1.7±5.5	0.0±5.1
Change 48 mo	+1.9±5.1	+0.2±4.6

Mean±SD
SD calculated from SE.
All mean and SE data extracted from figure

Adverse events
2–4 year incidence (%)

	Finasteride	Placebo
Surgery*	5	10
AUR*	3	7
Impotence	5.1	5.1
Decreased libido	2.6	2.6
Ejac disorder	0.2	0.1
Breast enlargement	1.8	1.1
Breast tenderness	0.7	0.3
Rash	0.5	0.1

* Only 4 year incidence

Quality of evidence: Moderate
Conclusion: Finasteride reduced the 4-year risk of requiring surgery and of AUR.
Internal validity: Randomization procedure described. Reason for drop-outs and number described.
External validity: Eligible patients not reported. Comments: Analysed according to ITT. Power analysis not performed.
Sponsorship: Merck

PREDICT Kirby 2003 RCT Europe
Urology 2003;61:119-26.

Intervention
Finasteride 5 mg vs Doxazosin 2/4/8 mg vs combination vs placebo.
12 months

Population
Combination 265 patients DO: 12 mo 31,1%
Doxazosin 250 patients DO: 12 mo 28,4%
Finasteride 239 patients DO: 12 mo 30,7%
Placebo 253 patients DO: 12 mo 28,1%

	Comb	Doxa	Fina	Plac
Age	64±7	63±7	63±7	64±7
Q_{max}	10,4±2,7	10,4±2,5	10,2±2,5	10,8±2,5
Pvol*	37±14	36±14	36±14	36±15
IPSS	17,3±4,3	17,1±4,2	17,1±4,4	17,2±4,5

*=Estimated by DRE in 5 g increments
Mean±SD

Inclusion criteria:
Age 50–80, symptomatic BPH, Q_{max} 5–15 ml/s for Vvoid>150 ml, IPSS≥12, DRE-confirmed enlarged prostate

Exclusion criteria:
Previous prostate surgery or invasive treatment of BPH, PSA >10 ng/ml (PSA 4–10 ng/ml required had to provide documentation of negative DRE, TRUS and biopsy findings to exclude cancer of the prostate), LUTS or reduced urinary flow for reasons other than BPH, large bladder diverticulum, bladder stones, recurrent urinary infection, two or more episodes of AUR requiring catheterization within a year before study entry, Vres >200ml, active UTI, serious disease, alcohol or drug abuse, hypotension, orthostatic hypotension, history of sensitivity to alpha-adrenergic blockig agents, quinazolines or finasteride

Results

IPSS	Com	Dox	Fin	Pla
BL	17,3±4,3	17,1±4,2	17,1±4,4	17,2±4,5
12mo	8,7±6,2	8,7±5,8	10,9±6,2	11,8±6,9

Mean±SD

Q_{max}	Com	Dox	Fin	Pla
BL	10,4±2,7	10,4±2,5	10,2±2,5	10,8±2,5
12mo	14,5±5,1	14,0±4,9	12,1±4,7	12,1±4,2

Mean±SD

Adverse events

	Com	Dox	Fin	Pla
Vertigo	2,8	2,9	2,3	1,1
Hypotension	2,8	5,1	0,8	1,5
Impotence	10,5	5,8	4,9	3,3
Urinary retention	0	0	1,1	4,5
Surgery	0	0,4	1,1	2,6
Death	0,3	0	0,8	0,7
Myocardial infarction/ ischemia	1,05	0,36	1,12	0,74
Congestive heart failure	0,7	0,72	0,37	0
Asthenia	9,1	10,5	4,2	4,1
Hypertension	1,4	1,8	4,2	5,6
Postural hypo-tension	2,8	5,8	0,8	1,5
Dizziness	13,6	15,6	8,0	7,4
Syncope	2,1	0,7	0	0,4
Decreased libido	2,1	3,6	3,4	1,9
Somnolence	3,1	4,0	3,0	1,9
Abnormal ejaculation	2,4	0,4	2,3	1,5

1-year incidence%

Quality of evidence: Moderate
Conclusion: Doxazosin superior to Finasteride in relieving LUTS due to BPH. The addition of Finasteride to Doxazosin does not increase efficacy but elevates the risk of impotence.
Internal validity: Randomization not described. External validity: Eligible patients reported. Comments: ITT used. Power calculated.
Sponsorship: Pfizer, Merck

MTOPS McConnell 2003 RCT USA**.** N Engl J Med. 2003;349:2387-98 **.** Study design in Bautista, Control Clin Trials 2003;24:224-43. Kaplan, J Urology 2006;175:217-20 (Analysis based on prostate volume). Kaplan, J Urology 2008;180:1030-2 (Volume reduction study). Nocturia in Johnson 2007 J Urology 178: 2045-51

Intervention

Finasteride 5 mg vs Doxazosin2/4/8 mg vs combination vs placebo.

48 months

Population

Combination 786 patients

Doxazosin 756 patients

Finasteride 768 patients

Placebo 737 patients

	Com	Dox	Fin	Pla
Age	62.7±7.1	62.7±7.2	62.6±7.3	62.5±7.5
Q_{max}	10.6±2.5	10.3±2.5	10.5±2.5	10.5±2.6
Pvolume	36.4±19.2	36.9±21.6	36.9±20.6	35.2±18.8
AUASS	16.8±5.8	17.0±5.8	17.6±5.9	16.8±5.9

Mean±SD

Inclusion criteria: ≥ 50 years, symptomatic BPH, Q_{max} 4–15 ml/s for Vvoid>125 ml, AUASS 8-30**. Exclusion criteria:** Prior intervention for BPH, any prior intervention for prostate disease, currently enrolled in other study, history or evidence of prostate or bladder cancer, pelvic radiation, urethral stricture, prostate surgery or surgery for bladder neck obstruction, evidence of any other cancer (except basal cell or squamous cell carcinoma of the skin) within 5 yrs before randomization, PSA>10 ng/ ml, supine blood pressure <90/70 mm Hg, creatinine >2,0 mg/dl, ALT> 1,5 ULN, bacterial prostatitis within the last yr, 2 UTI during last year, active urinary tract disease, cystoscopy or biopsy of the prostate within 1 month prior to screening, immediate need for surgery, inability to urinate, previous reaction to study medication, neurologic disease known to affect bladder function, any serious medical condition likely to impede successful completion of study etc

Results

AUASS	Com	Dox	Fin	Pla
BL	16.8±5.8	17.0±5.8	17.6±5.9	16.8±5.9
Change48mo	-7.4	-6.6	-5.6	-4.9

Mean±SD

AUASS	Com	Dox	Fin	Pla
BL	16	17	17	17
Change 12mo	-6	-6	-4	-4
Change 48mo	-7	-6	-5	-4

Median

Q_{max}	Com	Dox	Fin	Pla
BL	10.7	10.4	10.5	10.6
Change 12mo	+3.6	+3.0	+1.8	+1.3
Change 48mo	+3.7	+2.5	+2.2	+1.4

Median

	Com	Dox	Fin	Pla
Clin. Progression	1.5	2.7	2.9	4.5
≥4 AUASS increase	1.3	1.9	2.5	3.6

Rate/100 person-year

Nocturia	Com	Dox	Fin	Pla
BL	2.3	2.3	2.4	2.3
Change 12mo	-0.58	-0.54	-0.4	-0.35
Change48mo	-0.55	-0.53	-0.42	-0.38

Mean number of episodes

Adverse events

	Com	Dox	Fin	Pla
Urinary retention	0.1	0.4	0.2	0.6
Surgery	0.4	1.3	0.5	1.3
Erectile dysfunction	5.11	3.56	4.53	3.32
Dizziness	5.35	4.41	2.33	2.29
Postural hypotension	4.33	4.03	2.56	2.29
Asthenia	4.20	4.08	1.56	2.06
Decresed libido	2.51	1.56	2.36	1.40
Abnormal ejaculation	3.05	1.10	1.78	0.83
Peripheral edema	1.25	0.88	0.72	0.66
Dyspnea	1.20	0.93	0.56	0.57
Allergic reaction	0.73	0.85	0.58	0.46
Somnolence	0.78	0.82	0.39	0.37

Rate/100 person-year

Stopped treatment due to AE by end of study: Doxazosin treatment: 27%, finasteride treatment: 24%, both: 18%

Quality of evidence: Moderate–high. **Conclusion**: Combination therapy reduces the risk of BPH progression compared to either finasteride or doxazosin used alone. Combination or finasteride monotherapy reduces the risk for AUR or need for surgery. Internal validity: Randomization described. Blinding not described. External validity: High. Comments: ITT used. Power calculated. Sponsorship: Merck, Pfizer, NIH

Roehrborn 2002 RCT USA
Urology 2002;60:434-41 (BII in O'Leary 2003, British Journal of Urology International 2003;92:262-6)

Intervention
Dutasteride vs placebo
24 months

Population
Dutasteride 2 167 patients DO 24 mo: 30,3%
Placebo 2 158 patients DO 24 mo: 33,2%

	Dutasteride	Placebo
Age	66.5±7.6	66.1±7.4
Q_{max}	10.1±3.5	10.4±3.6
Pvolume	54.9±23.9	54.0±21.9
AUA	17.0±6.0	17.1±6.1
BII*	4.1±2.7	4.0±2.8

Mean ±SD
*Bother Impact Index. Worst possible score 13

Inclusion criteria:
Diagnosis of BPH, age ≥50 years, prostate vol (TRUS) ≥30 ml, AUA-SI ≥12, Q_{max} ≤ 15 mL/s

Exclusion criteria:
Vres >250 ml, history of prostate cancer, prior prostate surgery, AUR within 3 months of screening, any use of 5-ARI, use of alpha-blocker within 4 weeks, PSA <1,5 ng/ml or >10 ng/ml

Results

AUA	Dutasteride	Placebo
BL	17.0±6.0	17.1±6.1
Change 12 mo	-3.8±5.4**	-2.5±5.6**
Change 24 mo	-4.5±6.6	-2.3±6.8

Mean ±SD
**SD imputated

Q_{max}	Dutasteride	Placebo
BL	10.1±3.5	10.4±3.6
Change 12 mo	+1.9±4.2**	+0.6±3.8**
Change 24 mo	+2.2±5.2	+0.6±4.7

Mean ±SD
**SD imputated

BII	Dutasteride	Placebo
BL	4.1±2.7	4.0±2.8
Change 24 mo	-1.0±8.3***	-0.3±8.1***

Mean ±SD
*** mean data extracted from figure, SD calculated from p-value

Adverse events
2-year incidence (%)

	Dutasteride	Placebo
Surgery	2.2	4.1
AUR	1.8	4.2
Impotence	7.3	4.0
Decreased libido	4.2	2.1
Ejac disorder	2.2	0.8
Prostate cancer	nr	nr
Gynecomastia	2.3	0.74

Quality of evidence: Moderate
Conclusion: Dutasteride reduces progression of BPH.
Internal validity: Randomization procedure not adequately described. Reason for drop-outs and number described. External validity: Eligible patients not reported. Comments: Analysed according to ITT. Power analysis not performed.
Sponsorship: GlaxoSmithKline

Hematuri

Foley 2000 RCT UK
J Urol. 2000;163:496-8

Intervention
Finasteride 5 mg vs watchful waiting (no placebo). 12 months

Population
Finasteride 28 patients DO: 12 mo 1 patient
WW 27 patients DO: 12 mo 1 patient

Baseline	Finasteride	WW
Age Mean (range)	76 (55–89)	79 (55–86)
Previous TURP No. patients	19	18

Inclusion criteria:
Negative evaluations for tumor, including a normal digital rectal examination, evidence of bleeding from friable prostatic tissue on flexible cystoscopy, at least 2 episodes of gross hematuria during the preceding 6 months

Exclusion criteria:
None reported

Results

Hematuria grade	Finasteride	WW	*P*
Overall:			
Minor	7	8	
Moderate	18	16	
Severe	3	3	
After 12 months			
Minor	3	7	
Moderate	1*	6*	
Severe	0	4*	
Rebleeding	14%	63%	<0,05

* Previous TURP

Adverse events

	Finasteride	WW
Clot retention	0	4
TURP	0	4
Cystoscopy	0	3
Death	1*	0

Cumulative incidence
*Due to unrelated condition

Quality of evidence: Moderate
Conclusion: Finasteride appears to be effective for suppressing hematuria caused by BPH.
Internal validity: Randomization not described. Not blinded. External validity: Eligible patients not reported. Comments: Not analysed according to ITT
Sponsorship: Not reported

Delakas 2001 RCT Greece
Urol Int. 2001;67:69-72

Intervention
Finasteride 5 mg vs watchful waiting.
Up to 4 years follow-up, mean follow-up 22 months

Population
Finasteride 50 patients DO: unclear
WW 30 patients DO: unclear

Baseline	Finasteride	WW
Age Mean (range)	74 (62–84)	
Previous TURP No. patients	7	10

Inclusion criteria:
Hematuria caused by BPH

Exclusion criteria:
Genitourinary cause of hematuria other than BPH, signs of prostate cancer

Results

	Finasteride	WW
Rebleeding	12%	77%

Adverse events

	Finasteride	WW
TURP	4	9
Fulguration	2	10
Erectile dysfunction	4	0
Decreased libido	6	0

Cumulative incidence

Quality of evidence: Low–moderate
Conclusion: Finasteride is effective in reducing the recurrence of hemtauria caused by BPH.
Internal validity: Randomization not described. Not blinded. External validity: Eligible patients not reported. Comments: Not analysed according to ITT.
Sponsorship: Not reported

Perimenis 2002 RCT Greece
Urology. 2002;59:373-7

Intervention
Finasteride 5 mg vs watchful waiting (vs cyproterone).
12 months

Population
Finasteride: 14 pat DO: 1 (death)
Placebo: 14 pat No drop-outs

Baseline	Finasteride	WW
Age Mean (range)	76.5 (58–88)	74.5 (60–82)
Previous TURP No. patients	4	4

Inclusion criteria:
Clinically documented BPH and no evidence of other urologic disorders, at least 2 episodes of macroscopic hematuria during the preceding 6 months

Exclusion criteria:
Medications that might predispose to bleeding (eg, nonsteroidal anti-inflammatory drugs or anticoagulants)

Results

	Finasteride	WW
Rebleeding	30%	57%

Adverse events

	Finasteride	WW
TURP	0	2
Clot retention	0	2
Decreased libido	1	0
Death	1*	0

Cumulative incidence
*due to unrelated condition

Quality of evidence: Moderate
Conclusion: Clear benefit of finasteride compared to watchful waiting.
Internal validity: Randomization unclear. Not blinded. External validity: Eligible patients reported.
Comments:
Sponsorship: None reported

Sandfeldt 2001 RCT Sweden
Urology. 2001;58:972-6

Intervention
Finasteride 5 mg vs placebo.
3 month treatment before TURP, final checkup 3 months after TURP

Population
Finasteride: 26 patients DO: 4 patients
Placebo: 29 patients DO: 1 patient

Baseline	Finasteride	Placebo
Age	69 (56–78)	68 (54–76)
IPSS	19 (12–29)	18 (10–27)
Q_{max}	6 (3–9.4)	5.1 (1.8–9.8)
QoL	4 (3–5)	4 (2–5)
Pvolume	56 (44–76)	55 (37–67)

Mean (range)

Inclusion criteria:
Prostate volume between 30 and 90 cm 3 as determined by transrectal ultrasonography and a prostate-specific antigen density less than 0.14 _g/L/g

Exclusion criteria:
Previous invasive procedures on the prostate, treatment with finasteride, malignancy, and coagulation disorders

Results

	Finasteride	Placebo
Blood loss (ml)	279 (84–555)	287 (71–777)
Blood loss/ resection weight (ml/g)	14.5 (6.6 –26.8)	16.4 (7.1–29.3)

Mean (range)

Adverse events

	Finasteride	Placebo
Sexual disorder	2	0
Blood transfusion	0	1
Bleeding	3	2
Repeat TURP	0	1

Cumulative incidence (n)

Quality of evidence: Moderate–high
Conclusion: Pretreatment with finasteride may help reduce the blood loss in TURP, except in the smallest resections.
Internal validity: Randomization and blinding not described. External validity: Eligible patients not reported. Sponsorship: Merck

Donohue 2002 RCT United Kingdom
J Urol. 2002;168:2024-6

Intervention
Finasteride 5 mg vs placebo.
2 weeks treatment before TURP, check-up 1 day postop

Population
Finasteride: 32 patients
Placebo: 36 patients
2 patients withdraw before surgery

Baseline	Finasteride	Placebo
Age Mean (range)	69.9 (52–81)	70.2 (54–86)
Catheter in situ	10	9
Aspirin	6	4
Spinal anesthesia	19	16
Prostate cancer	4	6
No. patients		

Inclusion criteria:
Scheduled for elective TURP

Exclusion criteria:
Previously on finasteride, known prostate cancer, renal impairment

Results

	Finasteride	Placebo
Hemoglobin loss (g)	43.6 (6–182)	69.3 (7–228)
-"./resectate weight (g/g)	2.64 (0.3–6.33)	4.65 (1.04–28)

Adverse events

	Finasteride	Placebo
Blood transfusion	0	1
Cumulative incidence		

Quality of evidence: Moderate
Conclusion: Finasteride given daily for 2 weeks before transurethral prostate resection decreases bleeding.
Internal validity: Randomization unclear. Patients and surgeons blinded. External validity: 2 patients excluded after inclusion before trial start.
Sponsorship: None reported

Özdal 2005 RCT Turkey
Prostate Cancer Prostatic Dis 2005;8:215-8.

Intervention
Finasteride 5 mg vs no treatment
Treatment 4 weeks before TURP, final check-up 3 months after TURP

Population
Finasteride: 20 pat
Control: 20 pat
Drop-out not reported

Baseline	Finasteride	Control
Age	66.9 ±9.43	66.3 ±5.18
IPSS	12.8 ±2.54	13.75 ±2.17
Pvolume	38.31 ±9.86	36.71 ±8.03

Mean ±SD

Inclusion criteria:
Lower urinary tract symptoms with BPH who were candidates for surgery

Exclusion criteria:
Prior prostate or urethral surgery and had a diagnosis of prostate cancer or chronic renal failure, patients who received finasteride, aspirin, coumadin or similar anticoagulant drugs prior to surgery and patients who had capsule perforations or open sinuses during the surgery

Results

	Finasteride	Control
Blood loss (ml)	173.47 ±86.18	235.46 ±67.03
Blood loss/ resection weight (ml/g)	7.6 ±2.37	13.99 ±4.16

Adverse events

	Finasteride	Control
Erectile dysfunction	1	0
Decreased libido	2	0

Quality of evidence: Moderate
Conclusion: 4 weeks of finasteride pretreatment provided a significant decrease in peroperative bleeding regardless of prostate volume without any major side effects.
Internal validity: Open study, no placebo. External validity: Comments:
Sponsorship: None reported

Lund 2005 RCT Denmark
Scand J Urol Nephrol. 2005;39:160-2

Intervention
Finasteride 5 mg vs placebo.
3 months treatment before TURP, final checkup 3 months after TURP

Population
Finasteride: 18 patients DO: 2 patients died before TURP and were not included in the analysis
Placebo: 17 patients
2 patients with prostate cancer were excluded, group unknown

Baseline	Finasteride	Placebo
Age	66.5	67

Inclusion criteria:
Clinical LUTS

Exclusion criteria:
Prostate cancer

Results

	Finasteride	Placebo
Blood loss (ml) Mean (range)	312 (90–2 040)	525 (5–1 200)

Adverse events

No blood transfusions or perioperative bleeding needing treatment

Quality of evidence: Low–moderate
Conclusion: The study was inconclusive because it did not show any benefit in terms of reducing perioperative bleeding during or after the resection but there is a need for a large, prospective, randomized study.
Internal validity: Randomization described. Blinding not described. External validity: Eligible patients somewhat described. Comments: Power calculated to 20–30%. Trial stopped prematurely.
Sponsorship: None reported

Hahn 2007
BJU Int. 2007;99:587-94

Intervention
Dutasteride 0.5 mg vs placebo.
Treatment 2 or 4 weeks before and 2 weeks after TURP, final check-up 14 weeks after TURP

Population
Dutasteride 6 weeks total: 71 patients DO: 6%
Dutasteride 4 weeks total: 72 patients DO: 8%
Placebo: 70 patients DO: 9%

Baseline	Dutasteride 4 w	Dutasterid 6 w	Placebo
Age	67 ±7	67 ±8	66 ±7
Pvolume Mean ±SD	56 ±23	62 ±27	53 ±20

Inclusion criteria:
Scheduled for TURP to treat BPH in a period that allowed 28–32 days of preoperative treatment with study medication, prostate volume of ≥30 mL

Exclusion criteria:
History or evidence of prostate disease other than BPH, previous prostate surgery, treatment with any 5-ARI within 12 months, requirement for treatment with aspirin or NSAIDs during the restricted periods, and severe medical conditions such as liver disease, bleeding disorders (e g haemophilia, von Willebrand's disease, etc) and unstable cardiovascular problems

Results

	Duta 4 w	Duta 6 w	Placebo
Blood loss (ml)	320 ±50	430 ±50	370 ±50
Hemoglobin loss (g) -"- /resected weight (g/g) Mean ±SD	61.1 ±7.19	45.7 ±7.33	54.5 ±7.45
	2.55 ±0.39	2.15 ±0.4	2.55 ±0.41

Adverse events

	Dutasteride 4 w	Dutasterid 6 w	Placebo
Blood transfusion	1	2	2
Severe bleeding	2	1	4
Clot retention	4	8	4
AUR	9	12	8
UTI	22	19	14
Incontinence	11	10	10

Cumulative incidence

Quality of evidence: High
Conclusion: No effect of pretreatment with oral dutasteride daily for 2 weeks or 4 weeks before TURP, followed by 2 weeks continued medication after TURP, on blood loss during or after TURP, or on the complication rate. Internal validity: Randomization and blinding unclear. External validity: Comments: Sponsorship: GlaxoSmithKline

5.4 Kombinationsbehandling

Lepor 1996 RCT USA. N Engl J Med 1996;335:533-9 (1998, J Urology 160(4):1358-67, Nocturia in Johnson 2003 J Urology 170:145-8)

Intervention

Dutasteride 0,5mg vs Terazosin 5/10mg vs combination vs placebo.
12 months

Population

Combination 309 patiens DO: 12 mo 17,8%
Terazosin 305 patients DO: 12 mo 16,1%
Finasteride 310 patients DO: 12 mo 21,6%
Placebo 305 patients DO: 12 mo 16,7%

	Comb	Tera	Fina	Placebo
Age	65±7	65±6	65±7	65±7
Q_{max}	10.4 ±3.5	10.5 ±3.5	10.6 ±2.5	10.4 ±2.6
Pvol	37.2 ±19.3	37.5 ±19.2	36.2 ±17.6	38.4 ±22.6
AUA-SS	15.9 ±5.3	16.2 ±5.2	16.2 ±5.4	15.8 ±5.5

Inclusion criteria: 45–80 years, symptom score ≥8, Q_{max} ≥4 and ≤15 ml/s with a minimal voided volume of 125 ml, post void residual urine volume <300 ml

Exclusion criteria:

Unwilling or unable to give informed consent, taken experimental drug within 4 w before screening, taken α-adrenergic agonist, cholinergics, anticholinergics, topical β-adrenergic-antagonist for glaucoma or any antihypertensive drug except a diuretic or an ACE-inhibitor within 2 w before lead-in, taken estrogen, androgen or androgen inhibitor within 3 months before screening, episode of unstable angina pectoris, myocardial infarction, transient ischemic attack or cerebrovascular lesion in the past six months, insulindependent diabetes mellitus, orthostatic hypotension, history of syncope, blood pressure below 90/70 mm Hg (sitting), history of carcinoma of the prostate, pelvic irradiation, urethral stricture, surgery for BPH or BOO, current evidence of prostatic carcinoma, active urinary tract disease, cystoscopy or biopsy of the prostate within the previous two weeks, a history of recurrent UTI or UTI within the preceding two months, prior pelvic surgery likely to interfere with bladder function, progressive disorder that might prevent the evaluation of drug safety and efficacy, clinically important renal or hepatic impairment, PSA >10 ng/ml

Results

AUASS	Com	Ter	Fin	Pla
BL	15.9 ±5.3	16.2 ±5.2	16.2 ±5.4	15.8 ±5.5
12 mo	9.8 ±5.0	10.2 ±5.0	13.0 ±4.8	13.2 ±4.9

Mean±SD

Q_{max}	Com	Ter	Fin	Pla
BL	10.4 ±3.5	10.5 ±3.5	10.6 ±2.5	10.4 ±2.6
12 mo	13.6 ±5.0	13.2 ±5.0	12.2 ±4.9	11.8 ±4.8

Mean±SD

Nocturia	Com	Ter	Fin	Pla
BL	2.5	2.5	2.5	2.5
12 mo	2.0	1.8	2.1	2.1

Mean number of episodes

Adverse events

%	Com	Ter	Fin	Pla
Death	0.6	0.7	2.3	1.0
Surgery	0.6	0.7	1.6	1.3
AUR	Not reported			
Impotence	9.3	5.9	9.4	4.6
Decr libido	4.9	2.6	4.5	1.3
Ejac disorder	6.8	0.3	1.9	1.3
Asthenia	13.9	13.8	7.4	6.9
Headache	5.2	5.9	6.1	3.2
Dizziness	21.4	25.9	8.4	7.2
Rhinitis	7.8	6.6	2.6	4.6
Sinusitis	2.3	2.0	1.3	1.3
Postural hypotension	8.7	7.5	2.3	1.0
Syncope	1.6	1.0	1.0	0

1-year incidence (%)

Quality of evidence: High. **Conclusion**: Terazosin superior to Finasteride in relieving LUTS due to BPH. The addition of Finasteride to Terazosin does not increase efficacy or affect safety. Internal validity: Randomization not described. Blinding described. External validity: Eligible patients reported. Com-ments: ITT used. Sponsorship: Merck, Abbott Laboratories. Study conducted by Department of Veteran Affairs independently of sponsors

ALFIN Debruyne 1998 RCT Europe
Eur Urol 1998;34:169–175

Intervention
Finasteride 5 mg vs Sustained release Alfuzosin 5 mg x 2 vs combination
6 months

Population
Combination 349 patients DO: 6 mo 15%
Alfuzosin 358 patients DO: 6 mo 11%
Finasteride 344 patients DO: 6 mo 11%

	Comb	Alfu	Fina
Age	63.7±6.7	63.2±6.4	63.0±6.4
Q_{max}	10.1±3.5	9.7±2.8	9.8±2.6
Pvolume	41.1 ±22.6	41.4 ±25.7	40.9 ±23.5
IPSS	15.6±5.7	15.3±5.5	15.5±5.2

Mean±SD

Inclusion criteria:
≥50 years, LUTS related to BPH, Q_{max} 5–15 ml/s for Vvoid >150 ml IPSS >7

Exclusion criteria:
Concomitant urinary tract disease, previous invasive treatment of BPH, associated severe visceral disease, postural hypotension, any concomitant medication affecting the voiding pattern, clinically relevant biological abnormalities, PSA >10 ng/ml

Results

IPSS	Comb	Alfu	Fina
BL	15.6±5.7	15.3±5.5	15.5±5.2
Change 6 mo	–6.1 ±5.6*	–6.3 ±5.8**	–.2 ±5.7

Mean±SD
*p vs finasteride = 0.005
**p vs finasteride = 0.003

Q_{max}	Comb	Alfu	Fina
BL	10.1±3.5	9.7±2.8	9.8±2.6
Change 6 mo	+2.3±4.7	+1.8±3.8	+1.8±4.5

Mean±SD
No statistical difference between groups

Adverse events

%	Comb	Alfu	Fina
Vertigo	2.3	1.7	1.2
Hypotension	0.6	0.6	0.9
Impotence	7.4	2.2	6.7
Malaise	0.3	0.3	0.3
Urinary retention	0.3	0.6	0.3
Surgery			
Myocardial infarction	0.3	0	0.3
Headache	1.4	2.0	1.2
Decreased libido	2.0	0.6	1.7
Ejaculation failure	0.9	0	1.5
Asthenia	0	1.1	0.6
Somnolence	0.6	0	0.3

Quality of evidence: Moderate–good
Conclusion: SR Alfuzosin superior to Finasteride in relieving LUTS due to BPH. The addition of finasteride to SR alfuzosin does not affect efficacy but increases the incidence of sexually related adverse events
Internal validity: Randomization and blinding not described. External validity: Eligible patients not reported. Comments: ITT used.
Sponsorship: Sanofi-Aventis

PREDICT Kirby 2003 RCT Europe
Urology 2003;61:119-26

Intervention
Finasteride 5 mg vs doxazosin 2/4/8 mg vs combination vs placebo.
12 months

Population
Combination 265 patients DO: 12 mo 31.1%
Doxazosin 250 patients DO: 12 mo 28.4%
Finasteride 239 patients DO: 12 mo 30.7%
Placebo 253 patients DO: 12 mo 28.1%

	Comb	Doxa	Fina	Plac
Age	64±7	63±7	63±7	64±7
Q_{max}	10.4±2.7	10.4±2.5	10.2±2.5	10.8±2.5
Pvol*	37±14	36±14	36±14	36±15
IPSS	17.3±4.3	17.1±4.2	17.1±4.4	17.2±4.5

*=Estimated by DRE in 5 g increments
Mean±SD

Inclusion criteria:
Age 50–80, symptomatic BPH, Q_{max} 5–15 ml/s for Vvoid>150ml, IPSS≥12, DRE-confirmed enlarged prostate

Exclusion criteria:
Previous prostate surgery or invasive treatment of BPH, PSA>10 ng/ml (PSA 4—0 ng/ml required had to provide documentation of negative DRE, TRUS and biopsy findings to exclude cancer of the prostate), LUTS or reduced urinary flow for reasons other than BPH, large bladder diverticulum, bladder stones, recurrent urinary infection, 2 or more episodes of AUR requiring catheterization within a year before study entry, Vres>200 ml, active UTI, serious disease, alcohol or drug abuse, hypotension, orthostatic hypotension, history of sensitivity to alpha-adrenergic blockig agents, quinazolines or finasteride

Results

IPSS	Com	Dox	Fin	Pla
BL	17.3±4.3	17.1±4.2	17.1±4.4	17.2±4.5
12 mo	8.7±6.2	8.7±5.8	10.9±6.2	11.8±6.9

Mean±SD

Q_{max}	Com	Dox	Fin	Pla
BL	10.4±2.7	10.4±2.5	10.2±2.5	10.8±2.5
12mo	14.5±5.1	14.0±4.9	12.1±4.7	12.1±4.2

Mean±SD

Adverse events

	Com	Dox	Fin	Pla
Vertigo	2.8	2.9	2.3	1.1
Hypotension	2.8	5.1	0.8	1.5
Impotence	10.5	5.8	4.9	3.3
Urinary retention	0	0	1.1	4.5
Surgery	0	0.4	1.1	2.6
Death	0.3	0	0.8	0.7
Myocardial infarction/ ischemia	1.05	0.36	1.12	0.74
Congestive heart failure	0.7	0.72	0.37	0
Asthenia	9.1	10.5	4.2	4.1
Hypertension	1.4	1.8	4.2	5.6
Postural hypo-tension	2.8	5.8	0.8	1.5
Dizziness	13.6	15.6	8.0	7.4
Syncope	2.1	0.7	0	0.4
Decreased libido	2.1	3.6	3.4	1.9
Somnolence	3.1	4.0	3.0	1.9
Abnormal ejaculation	2.4	0.4	2.3	1.5

1-year incidence %

Quality of evidence: Moderate
Conclusion: Doxazosin superior to finasteride in relieving LUTS due to BPH. The addition of finasteride to doxazosin does not increase efficacy but elevates the risk of impotence.
Internal validity: Randomization not described. External validity: Eligible patients reported. Comments: ITT used. Power calculated.
Sponsorship: Pfizer Merck

MTOPS McConnell 2003 RCT USA**.** N Engl J Med. 2003;349:2387-98**.** Study design in Bautista 2003 Control Clin Trials 24:224-43. Kaplan, J Urology 2006;175:217-20 (analysis based on prostate volume). Kaplan, J Urology 2008;180:1030-2 (volume reduction study), Nocturia in Johnson, J Urology 2007;178: 2045-51

Intervention

Finasteride 5 mg vs doxazosin 2/4/8 mg vs combination vs placebo.

48 months

Population

Combination 786 patients

Doxazosin 756 patients

Finasteride 768 patients

Placebo 737 patients

	Com	Dox	Fin	Pla
Age	62.7±7.1	62.7±7.2	62.6±7.3	62.5±7.5
Q_{max}	10.6±2.5	10.3±2.5	10.5±2.5	10.5±2.6
Pvolume	36.4±19.2	36.9±21.6	36.9±20.6	35.2±18.8
AUASS	16.8±5.8	17.0±5.8	17.6±5.9	16.8±5.9

Mean±SD

Inclusion criteria:

≥50 years, symptomatic BPH, Q_{max} 4–15 ml/s for Vvoid >125 ml, AUASS 8–30

Exclusion criteria:

Prior intervention for BPH, any prior intervention for prostate disease, currently enrolled in other study, history or evidence of prostate or bladder cancer, pelvic radiation, urethral stricture, prostate surgery or surgery for bladder neck obstruction, evidence of any other cancer (except basal cell or squamous cell carcinoma of the skin) within 5 years before randomization, PSA >10 ng/ml, supine blood pressure <90/70 mm Hg, creatinine >2,0 mg/dl, ALT>1,5ULN, bacterial prostatitis within the last year, 2 UTI during last year, active urinary tract disease, cystoscopy or biopsy of the prostate within 1 month prior to screening, immediate need for surgery, inability to urinate, previous reaction to study medication, neurologic disease known to affect bladder function, any serious medical condition likely to impede successful completion of study etc

Results

AUASS	Com	Dox	Fin	Pla
BL	16.8±5.8	17.0±5.8	17.6±5.9	16.8±5.9
Change 48 mo	-7.4	-6.6	-5.6	-4.9

Mean±SD

AUASS	Com	Dox	Fin	Pla
BL	16	17	17	17
Change 12 mo	-6	-6	-4	-4
Change 48 mo	-7	-6	-5	-4

Median

Q_{max}	Com	Dox	Fin	Pla
BL	10.7	10.4	10.5	10.6
Change 12 mo	+3.6	+3.0	+1.8	+1.3
Change 48 mo	+3.7	+2.5	+2.2	+1.4

Median

	Com	Dox	Fin	Pla
Clin progression	1.5	2.7	2.9	4.5
≥4 AUASS increase	1.3	1.9	2.5	3.6

Rate/100 person-year

Nocturia	Com	Dox	Fin	Pla
BL	2.3	2.3	2.4	2.3
Change 12 mo	-0.58	-0.54	-0.4	-0.35
Change 48 mo	-0.55	-0.53	-0.42	-0.38

Mean number of episodes

Adverse events

	Com	Dox	Fin	Pla
Urinary retention	0.	0.4	0.2	0.6
Surgery	0.4	1.3	0.5	1.3
Erectile dys-function	5.11	3.56	4.53	3.32
Dizziness	5.35	4.41	2.33	2.29
Postural hypotension	4.33	4.03	2.56	2.29
Asthenia	4.20	4.08	1.56	2.06
Decresed libido	2.51	1.56	2.36	1.40
Abnormal ejaculation	3.05	1.10	1.78	0.83
Peri-pheral edema	1.25	0.88	0.72	0.66
Dyspnea	1.20	0.93	0.56	0.57
Allergic reaction	0.73	0.85	0.58	0.46
Somnolence	0.78	0.82	0.39	0.37

Rate/100 person-year

Stopped treatment due to AE by end of study:
Doxazosin treatment: 27%
Finasteride treatment: 24%
Both: 18%

Quality of evidence: Moderate–high. **Conclusion**: Combination therapy reduces the risk of BPH progression compared to either finasteride or doxazosin used alone. Combination or finasteride monotherapy reduces the risk for AUR or need for surgery. Internal validity: Randomization described. Blinding not described. External validity: High. Comments: ITT used. Power calculated. Sponsorship: Merck, Pfizer, NIH

Roehrborn 2008 COMBAT RCT International
J Urology 2008;179:616-21
(48 month data in Roehrborn 2010 Eur Urol 57:123-31, Study design in Siami 2007 Contemp Clin Trials 28:770-9, QoL in Barkin BJU Int 2009;103:919-926)

Intervention
Dutasteride 0,5 mg vs tamsulosin 0,4 mg vs combination of both
24 months (study continues to 48 months)

Population
Combination 1 610 patients DO: 24 mo 21%
Tamsulosin 1 611 patients DO: 24 mo 22%
Dutasteride 1 623 patients DO: 24 mo 20%

	Comb	Tamsu	Duta
Age	66.0±7.05	66.2±7.00	66.0±6.99
n	10.9±3.62	10.7±3.66	10.6±3.57
Pvolume	54.7±23.51	55.8±24.18	54.6±23.02
IPSS	16.6±6.35	16.4±6.10	16.4±6.03
QoL	3.6	3.6	3.6

Mean ±SD

Inclusion criteria:
≥50 years, clinical diagnosis of BPH by medical history and physical examination (including DRE), Q_{max} 5–15 ml/s and minimum Vvoid ≥125ml, IPSS ≥12, Pvolume ≥30 cm^3 on TRUS, total serum PSA ≥1,5 ng/ml, willing and able to give written informed consent and comply with study procedures, fluent and literate in local language with the ability to read, comprehend and record information on the IPSS, BII and PPSM questionnaires

Exclusion criteria:
Total serum PSA >10 ng/ml, history or evidence of prostate cancer, previous prostate surgery or other invasive procedure to treat BPH, history of flexible/rigid cystoscopy or other instruments of the urethra ithin 7 days prior to screening, history of AUR within 3 months prior to screening, Vres >250 ml, use of phytotherapy for BPH within 2 weeks of screening, use of alpha-blocker within 2 weeks of screening, use of alpha-agonist, cholinergics or anticholinergics within 48 h prior to uroflometry assessments, history of postural hypotension dizziness, vertigo or any other symptoms of orthostasis

Results

IPSS	Comb	Tamsu	Duta
BL	16.6±6.35	16.4±6.10	16.4±6.03
24 mo	10.1±6.42*	11.9±6.82	11.4±6.46

Mean±SD
*p vs either monotherapy = <0.001

Q_{max}	Comb	Tamsu	Duta
BL	10.9±3.62	10.7±3.66	10.6±3.57
24 mo	13.3±5.62**	11.7±4.82	12.7±5.64

Mean ±SD
**p vs either monotherapy = ≤0.003

QoL	Comb	Tamsu	Duta
BL	3.6	3.6	3.6
Change 24 mo	−1.4±1.2*	−1.1±1.2	−1.1±1.2

Mean ±SD
*p vs either monotherapy = <0.001

48 mo Incidence	Comb	Tamsu	Duta
AUR	2.2%	6.8%	2.7%
BPH-surgery	2.4%	7.8%	3.5%
BPH-progression	12.6%	21.5%	17.8%

Adverse events

%	Comb	Tamsu	Duta
Impotence	7.4	3.8	6.0
Retrograde ejaculation	4.2	1.1	0.6
Decreased libido	3.4	1.7	2.8
Loss of libido	1.7	0.9	1.3
Dizziness	1.6	1.7	0.7
Any event	65	63	64
Any drugrelated event	24	16	18

Quality of evidence: Moderate. **Conclusion**: Combination therapy provides a small added benefit in relieving symptoms of LUTS in men with prostates >30 cm^3. The number of drug-related adverse events are increased. Internal validity: Randomization and blinding described. External validity: Eligible patients reported. Comments: ITT used. Sponsorship: Study sponsored and managed by GlaxoSmithKline

5.5 Naturläkemedel

Berges 1995 RCT Germany
Lancet 1995;345:1529-32

Intervention
β-sitosterol 3x20 mg vs placebo
26 weeks

Population
β-sitosterol 100 patients DO: 26 w 4%
Placebo 100 patients DO: 26 w 9%

	β-sitosterol	Placebo
Age	65.2±6.6	65.5±7.0
Q_{max}	9.9±2.5	10.1±2.8
P_{vol}	44.6±19.4	48.7±29.9
IPSS	14.9±4.7	15.3±4.3
QoL	3.1±0.8	3.0±0.8

Mean ±SD

Results

IPSS	β-sitosterol	Placebo	*p*
BL	14.9±4.7	15.3±4.3	
26 w	7.5±4.4	12.8±4.5	<0.01

Mean ±SD

Q_{max}	β-sitosterol	Placebo	*p*
BL	9.9±2.5	10.1±2.8	
26 w	15.2±5.7	11.4±4.7	<0.01

Mean ±SD

QoL	β-sitosterol	Placebo	*p*
BL	3.1±0.8	3.0±0.8	
26 w	1.8±0.8	2.8±0.9	<0.01

Mean ±SD

Intervention
β-sitosterol 3x20 mg vs placebo
26 weeks

Population
β-sitosterol 100 patients DO: 26 w 4%
Placebo 100 patients DO: 26 w 9%

	β-sitosterol	Placebo
Age	65.2±6.6	65.5±7.0
Q_{max}	9.9±2.5	10.1±2.8
P_{vol}	44.6±19.4	48.7±29.9
IPSS	14.9±4.7	15.3±4.3
QoL	3.1±0.	3.0±0.8

Mean ±SD

Results

IPSS	β-sitosterol	Placebo	*p*
BL	14.9±4.7	15.3±4.3	
26 w	7.5±4.4	12.8±4.5	<0.01

Mean ±SD

Q_{max}	β-sitosterol	Placebo	*p*
BL	9.9±2.5	10.1±2.8	
26 w	15.2±5.7	11.4±4.7	<0.01

Mean ±SD

QoL	β-sitosterol	Placebo	*p*
BL	3.1±0.8	3.0±0.8	
26	1.8±0.8	2.8±0.9	<0.01

Mean ±SD

Quality of evidence: High
Conclusion: Clinically important difference achieved with β-ss but not with placebo.
Internal validity: Randomization and blinding described. External validity: Eligible patients not reported.
Comments: Power calculated. Very conservative ITT used, last value only used if deterioration from baseline. Sponsorship: Hoyer GmbH &Co

Klippel 1997 RCT Germany
Br J Urology 1997;80:427

Intervention
β -sitosterol 2x65 mg vs placebo
26 weeks

Population
β -sitosterol 88 patients DO: 26 w 13%
Placebo 89 patients DO: 26 w 12%

	β-sitosterol	Placebo
Age	64.8±8.06	65.9±7.43
Q_{max}	10.6±3.33	11.3±2.70
IPSS	16.0±4.58	14.9±5.17
QOL	3.2±0.79	3.0±0.91

Mean ±SD

Inclusion criteria:
IPSS ≥6, V_{res} 30–150 ml, Q_{max} ≤15ml/s (V_{void} ≥150 ml), BPH, age 50–80, body weight 55–100 kg

Exclusion criteria:
IPSS <6, Prostatic malignancy, PSA >10 ng/ml, bacterial prostatitis, urinary infection, history of acute retention, history of surgical prostatic intervention, need for surgical intervention in case of urethral stricture or bladder diverticulae, bladder stones, phimosis and meatal stenosis, insulin-dependent DM, abnormal laboratory values, severe cardiopulmonary disease, neurological or psychological disorders, concomitant prostatropic treatment, abuse of alcohol or drugs, expected non-compliance

Results

IPSS	β-sitosterol	Placebo
BL	16.0±4.58	14.9±5.17
26 w	7.8±4.93	12.1±5.56

Mean ±SD

Q_{max}	β-sitosterol	Placebo
BL	10.6±3.33	11.3±2.70
26 w	19.4±8.62	15.7±6.12

Mean ±SD

QoL	β-sitosterol	Placebo
BL	3.2±0.79	3.0±0.91
26 w	1.4±0.65	2.2±0.98

Mean ±SD

Adverse events

	β-sitosterol	Placebo
Acute myocardial infarction	0	1
Indigestion	1	0
Sudden cardiac infarction	2	0
Stroke	1	0
Worsening of LUTS	1	0

Cumulative incidence

Quality of evidence: Moderate
Conclusion: Clinically important difference achieved with β-ss but not placebo.
Internal validity: Randomization and blinding described. External validity: Eligible patients not reported.
Comments: Power calculated. ITT used.
Sponsorship: Azupharma, German Society for Oncology

Bent 2006 RCT USA
NEJM 2006;354:557-566 (Safety assessment in Avins 2008 Comp Ther Med 16:147-54)

Intervention
Serenoa Repens 2x160 mg vs placebo
52 weeks

Population
Serenoa 112 patients DO: 52 w 9%
Placebo 113 patients DO: 52 w 8%

	Serenoa	Placebo
Age	62.9±8.0	63.0±7.4
Q_{max}	11.4±3.5	11.6±4.3
P_{vol}	34.7±13.9	33.9±15.2
AUASI	15.7±5.7	15.0±5.3

Mean ±SD

Inclusion criteria:
AUASI >7, Q_{max} 4–15ml/s, age >49

Exclusion criteria:
V_{res} >250 ml, cancer of the prostate, surgery for BPH, urethral stricture, neurogenic bladder, creatinine >177 µmol/l, PSA >4,0 ng/dl, medication affecting urination, severe concomitant disease

Results

AUASI	Serenoa	Placebo	*P*
BL	15.7±5.7	15.0±5.3	
Change 52 w	-0.68±0.35	-0.72±0.35	0.73

Mean ±SD

Q_{max}	Serenoa	Placebo	*P*
BL	11.4±3.5	11.6±4.3	
Change 52 w	+0.42±0.34	-0.01±0.35	0.65

Mean ±SD

Adverse events

	Serenoa	Placebo
Cardiovascular event	2	7
Elective ort. surgery	3	3
GI-bleed	2	1
Bladder cancer	0	1
Colon cancer	0	1
Elective hernia repair	0	1
Hematoma	0	1
Melanoma	1	0
Prostate cancer	0	1
Shortness of breath	0	1
Rhabdomyolysis	0	1
Upper resp infection	12	10
Back pain	4	4
Rash	1	3
Diarrhea	2	2
Gout	2	2
GERD	0	3
Abdominal Pain	2	1
Joint pain/ swelling	2	1
Trauma	2	1
Cough	1	2

Cumulative incidence

Quality of evidence: High
Conclusion: No significant difference between s. repens and placebo.
Internal validity: Randomization and blinding described. External validity: Eligible patients well reported.
Comments: Almost no placebo effect. ITT used. Power calculated.
Sponsorship: National Institute of Diabetes and Digestive and Kidney Diseases
National Center for Complementary and Alternative Medicine

Schneider 2004 RCT Germany
Der Urologe [A] 2004;43:302-306

Inervention
Urtica 459 mg vs placebo
52 weeks

Population
Urtica 114 patients DO: 52 w 9%
Placebo 112 patients DO: 52 w 9%

	Urtica	Placebo
Q_{max}	11.0 ±0.2	10.7 ±0.3
IPSS	18.7 ±0.3	18.5 ±0.3

Mean ±SD

Inclusion criteria:
IPSS ≥13, age 50–75, V_{void} ≥150 ml, Q_{max} ≤15 ml/s, V_{res} <200 ml

Exclusion criteria:
Previous or planned operations of the prostate, cancer of the prostate, prostatitis, bladder stones, bladder diverticulum, neurogenic bladder disorders, urethral stricture, acute urethral tract infection, creatinine ≥1,5 mg/dl, hypersensitivity towards urtica, other medications for BPH

Results

IPSS	Urtica	Placebo
BL	18.7±0.3	18.5±0.3
52 w	13.0±0.5	13.8±0.5

Mean ±SD

Q_{max}	Urtica	Placebo
BL	11.0 ±0.2	10.7 ±0.3
52 w	13.8 ±0.5	12.3 ±0

Mean ±SD

Adverse events

	Urtica	Placebo
Cumulative incidence	29	38

Quality of evidence: Low-moderate
Conclusion: Clinically relevant improvement achieved with both urtica and placebo.
Internal validity: Randomization and blinding not described. External validity: Eligible patients reported.
Comments: ITT used. Sparse information regarding study design.
Sponsorship: Stated independent

Safarinejad 2005 RCT Iran
J Herbal Pharmacotherapy 2005;5: 1-11

Intervention
Urtica 3x120 mg vs placebo
26 weeks

Population
Urtica 305 patients DO: 26 w 9%
Placebo 315 patients DO: 26 w 14%

	Urtica	Placebo
Age	64 (57–71)	62(53–73)
Q_{max}	10.7±2.4	10.8±2.8
P_{vol}	40.1±6.8	40.8±6.2
IPSS	19.8±4.9	19.2±4.6

Mean ±SD (range)

Inclusion criteria:
No cancer, normal laboratory findings, no other lower urinary tract problem than BPH

Exclusion criteria:
Loss to follow-up, surgical intervention for BPH, discontinuation of study medication, α-blocker, 5-α-reductase inhibitor or other drug therapy during trial and follow-up, other phytotherapeutic agent, insufficient follow-up

Results

IPSS	Urtica	Placebo
BL	19.8±4.9	19.2±4.6
26 w	11.8±4	17.7±3.1

Mean ±SD

Q_{max}	Urtica	Placebo
BL	10.7±2.4	10.8±2.8
26 w	18.9±4.7	14.2±3.7

Mean ±SD

Adverse events

	Urtica	Placebo
Surgery	5	22

Quality of evidence: Moderate
Conclusion: Clinically important difference achieved with Urtica but not placebo.
Internal validity: Randomization and blinding described. External validity: Eligible patients not reported.
Comments: Per protocol analysis.No reports of adverse events. Very high increase of Q_{max}.
Sponsorship: None stated

Lopatkin 2005 RCT Russia-Germany
World J Urology 2005;23:139-146

Intervention
2 x serenoa repens 160 mg/urtica 120 mg vs placebo
24 weeks

Population
SR/Urtica 129 patients DO: 24 w 2%
Placebo 128 patients DO: 24 w 2%

FAS	SR/Urtica	Placebo
Age	68±7	67±7
Q_{max}	10.4±2.4	10.5±2.6
P_{vol}	44.9±18.1	46.4±19.2 (n=124)
IPSS	18±4	18±3 (n=122)
QOL	4.3±0.5	4.4±0.5

Inclusion criteria:
Written informed consent, symptomatic BPH, age ≥50, Q_{max} <15 ml/s, change in Q_{max} between screening and end of run-in period <3 ml/s, urinary output >100 ml at baseline, IPSS ≥14, QoL ≥4

Exclusion criteria:
Mental condition interfering with ability to give informed consent or complete the self-ratings, previous or scheduled surgery to pelvis or urinary tract, urethral stricture, history of pelvic radiotherapy, PSA >10 ng/ml, V_{res} >350 ml, symptomatic urinary tract infection, chronic bacterial prostatitis, DM, diabetic neuropathy, cancer of the prostate, serious general and specific risk, concomitant medication affecting the micturation pattern

Results

IPSS	SR/Urtica	Placebo (n=122)
BL	18±4	18±3
Change 24 w	-6±4	-5±5

Q_{max}	SR/Urtica	Placebo
BL	10.4±2.4	10.5±2.6
Change 24 w	1.8±4.6	1.9±4.5

Adverse events

	SR/Urtica	Placebo
Adverse events	23	24

Quality of evidence: Moderate
Conclusion: Clinically relevant improvement in both groups.
Internal validity: Randomization and blinding described. External validity: Eligible patients reported.
Comments: Adverse events not described in detail. ITT used.
Sponsorship: Dr Willmar Schwabe GmbH. Part of group employed by manufacturer

Preuss 2001 RCT USA
International Urology and Nephrology 2001;33:217-225

Intervention
2 x 189 mg Cernitin, 143 mg serenoa repens + β-sitosterol and 50 IU Vitamin E vs placebo
12 weeks

Population
Phytotherapy 75 patients DO: 12 w 7%
Placebo 69 patients DO: 12 w 17%

	Phyto	Placebo
IPSS	18.9	17.7
Q_{max}	11.2+6.7	12.1+6.8

Mean ±SD

Inclusion criteria:
Diagnosis of BPH, Q_{max} 5–15ml/s (for Vvoid >100 mk), read speak and understand English, written informed consent, no evidence of cancer by digital rectal examination and/or PSA

Exclusion criteria:
Age >80, tumor, malformation or infection of the genitourinary tract, severe concomitant medical condition making participation undesirable or jeopardizing the study protocol, severe laboratory abnormalities at baseline (WHO toxicity grade 2–4), medical treatment for BPH with finasteride within last 4 weeks, currently treated with antibiotics for genitourinary tract infection

Results

IPSS	Phyto	Placebo
BL	18.9	17.7
Change 12 w	-6.171+6.4	-3.241+5.8

Mean ±SD

Q_{max}	Phyto	Placebo
BL	11.2+6.7	12.1+6.8
12 w	11.8+5.9	13.1+7.6

Mean ±SD

Adverse events

	Phyto	Placebo
Flatulence	3	0
Lower abd rash	0	1
Dizziness	0	1
Headache	1	1
Nausea	0	2
Urinary tract infection	1	0
Otitis	0	1
Lumbar spine surgery	0	1
Herpes zoster	1	0
Hypertension	0	1
Chest pain	0	1
Right arm laceration	1	0

Cumulative incidence

Quality of evidence: Moderate
Conclusion: Clinically relevant improvement in both groups.

Internal validity: Randomization and blinding described.. External validity: Eligible patients reported.
Comments: No information on the composition of the groups regarding to age and non-urinary parameters. Power calculated. ITT unclear.
Sponsorship: Rexall/Sundown, Inc

Bach 2000 RCT Germany
Der Urologe [B] 2000;40:437-443

Intervention
2x Pumpkin seed 500 mg vs placebo
52 weeks

Population
Pumpkin seed 233 patients DO: 52 w 15%
Placebo 243 patients DO: 52 w 16%

	Pumpkin	Placebo
Q_{max}	10.9+3.1	11.1+2.9
Pvol	34.8+15.9 n=135	35.2+19.6 n=126
IPSS	17.6+3.7	17.7+3.8
QOL	4.2+0.9	4.2+0.9

Mean ±SD

Inclusion criteria:
IPSS ≥7

Exclusion criteria:
Not reported

Results

IPSS	Pumpkin	Placebo	*p*
BL	17.6+3.7	17.7+3.8	
52 w	10.9+4.5	12.2+5.1	0.014

Mean ±SD

Adverse events

	Pumpkin	Placebo
Flulike symtoms	6.9%	3.7%
Back pain	3.9%	1.6%
Pain	2.6%	2.1%
GI-symtoms	2.6%	2.1%
Diarrhea	0.9%	2.5%
Abd l pain	2.1%	0%
Headache	3.9%	5.3%
Surgery	2.6%	1.6%
Hypertension	2.1%	0.8%

1-year incidence

Quality of evidence: Low–moderate
Conclusion: Clinically relevant improvement in both groups.
Internal validity: Randomization and blinding not described. External validity: Eligible patients not reported. Comments: Few details regarding study design. ITT used.
Sponsorship: None stated

Carraro 1996 RCT International
Prostate 1996;29:231-240

ntervention
Permixon (serenoa repens) 2 x 160 mg vs finasteride 5 mg
6 months

Population
Permixon 553 patients DO: 6 mo 16%
Finasteride 545 patients DO: 6 mo 11%

	S repens	Finasteride
Age	64.3 (49–87)	64.7 (49–88)
Q_{max}	10.6 ±2.8	10.8 ±3.1
Pvolume	43.0 ±19.6	44.0 ±20.6
IPSS	15.7 ±5.8	15.7 ±5.7
QOL	3.63 ±1.28	3.66 ±1.17

Mean ±SD

Inclusion criteria:
BPH (diagnosed PR). IPSS >6, Q_{max} 4–15ml/s (V_{void} >150 ml, V_{res} <200 ml), Pvolume >25 ml, PSA <10 ng/ml if Pvolume <60 ml or PSA <15 ng/ml if Pvolume >60 ml, good physical and mental condition

Exclusion criteria:
Cancer of the prostate, history of bladder disease, LUT pathology or infection, disease potentially affecting micturation, abnormal liver function, diuretics, antiandrogenics, α-receptorblockers within 3 months, prior treatment with permixon or finasteride

Results

IPSS	S repens	Finasteride	*P*
BL	15.7±5.8	15.7±5.7	
26 w	9.9±5.4	9.5±5.5	0.17

Mean ±SD

Q_{max}	S repens	Finasteride	*P*
BL	10.6±2.8	10.8±3.1	
26 w	13.3±6.7	14.0±7.	0.035

Mean ±SD

QoL	S repens	Finasteride	*P*
BL	3.63±1.28	3.66±1.17	
26 w	2.25±1.29	2.15±1.26	0.14

Mean ±SD

Adverse events

	S repens	Finasteride
Erectile dysfunction	8	15
Loss of libido	12	16
Urinary retention	7	3
Surgery	3	3
Vertigo	0	0
Hypotension	0	0
Fatal myocardial infarction	1	1
Acute prostatitis	1	0
Acute cholecystitis	1	0
Spastic reaction	0	1
Abdominal pain	10	15
Hypertension	17	12
Back pain	9	3
Diarrhea	5	6
Nausea	3	6
Constipation	2	6
Flulike symptoms	5	6
Headache	7	2
Dysuria	2	6

Cumulative incidence

Quality of evidence: Moderate
Conclusion: Equal effect of Permixon and finasteride.
Internal validity: Randomization described. Blinding not described. External validity: Eligible patients not reported. Comments: ITT used.
Sponsorship: Pierre Fabre Medicament

Debruyne 2002 RCT Europe
European Urology 202;41:497-507

ntervention
Permixon (serenoa repens) 320 mg vs tamsulosin 0.4 mg
12 months

Population
Permixon 269 patients DO: 12 mo 15%
Tamsulosin 273 patients DO: 12 mo 16%

Baseline	S repens	Tamsulosin
Age	65.7 ±7.6	65.3 ±7.4
Q_{max}	10.9 ±3.9	11.2 ±4.0
Pvolume	48.0 ±18.0	48.0 ±18.9
IPSS	15.3 ±4.3	15.4 ±5.2

Mean ±SD.

Inclusion criteria:
50 <age <85, IPSS ≥8, Q_{max} 5–15 ml/s (V_{void} >150 ml), V_{res} <150 ml, Pvolume >25 ml, PSA <4 ng/ml or PSa 4–10 ng/ml and a free/total ratio ≥15%

Exclusion criteria:
History of bladder disease, urethral stenosis, cancer of the prostate, pelvic radiotherapy, repeated urinary tract infections, chronic bacterial prostatitis, disease likely to cause urinary problems, significant cardiovascular disease, haematuria, insulin-dependent DM, history of severe liver failure, abnormal liver function tests, known hypersensitivity to study medications, part of another clinical trial within 3 months

Results

IPSS	S repens	Tamsulosin	*P*
BL	15.3±4.3	15.4±5.2	
52 w	10.8±5.5	11.0±6.0	0.99

Mean ±SD

Q_{max}	S repens	Tamsulosin	*P*
BL	10.9±3.9	11.2±4.0	
52 w	12.7±5.2	13.0±4.9	0.79

Mean ±SD

Adverse events

	S repens	Finasteride
Erectile dysfunction	0	0
Loss of libido	1	4
Urinary retention	0	0
Surgery	0	0
Vertigo	10	6
Hypotension	4	3
Rhinitis	30	43
Headache	28	37
Fatigue	6	5
Asthenia	4	5
Dry mouth	3	2
Ejaculation disorder	2	15

Cumulative incidence

Quality of evidence: Moderate
Conclusion: Equal effect of Permixon and Tamsulosin.
Internal validity: Randomization not described. Blinding described.
External validity: Eligible patients reported.
Comments: Per protocol analysis used. Power calculated.
Sponsorship: Pierre Fabre Medicament

Glemain 2002 RCT France
Progrès en urologie 2002;12:395-404

Intervention
Serenoa repens 2x160 mg + tamsulosin 0.4 mg vs tamsulosin 0.4 mg
12 months

Population
Serenoa repens 165 patients DO: 18%
Tamsulosin 161 patients 20%

Baseline	S repens	Tamsulosin
Age	65.2 ±7.9	64.4 ±7.7
Q_{max}	11.1 ±4.1	10.8 ±3.4
IPSS	16.2 ±5.2	16.3 ±5.6
QOL	3.72 ±1.2	3.6 ±1.1

Mean ±SD

Inclusion criteria:
Age >50, IPSS ≥13, BPH, BPH-associated LUTS, Q_{max} 7–15ml/s (V_{void} >120 ml)

Exclusion criteria:
Previous surgery of the bladder, prostate or pelvic region, V_{res} >300 ml, disease affecting micturation or interfering with the final evaluation, treatment with α-blockers within 15 days, treatment with plant extracts or finasteride within a month, medication affecting the pharmodynamics of tamsulosin, liver failure, cardiovascular or cerebrovascular event, neurological disorder, allergy against α-blockers, pathology affecting the vital statistics

Results

IPSS	S repens	Tamsulosin
BL	16.2±5.2	16.3±5.6
Change 52 w	-6.0±6.0	-5.2±6.4

Mean ±SD

Q_{max}	S repens	Tamsulosin
BL	11.1±4.1	10.8±3.4
Change 52 w	1.2±4.6	1.3±5.2

Mean ±SD

QoL	S repens	Tamsulosin
BL	3.72±1.2	3.6±1.1
Change 52 w	-1.3±1.4	-1.0±1.4

Mean ±SD

Adverse events

	S repens	Tamsulosin
Ejaculation disorders	13	8
Vertigo	4	3
Total adverse events	27	16
Severe adverse events	1	1
Adverse events leading to dropout	7	5

Cumulative incidence

Quality of evidence: Moderate
Conclusion: The addition of serenoa repens to tamsulosin does not have any significant effect.
Internal validity: Randomization and blinding not reported.
External validity: Eligible patients reported.
Comments: Adverse events sparsely reported. ITT used. Power calculated.
Sponsorship: None stated

Sökeland 1997 RCT Germany
Der Urologe [A] 1997;36:327-333

Intervention
2 x serenoa repens 160 mg/urtica120 mg vs finasteride 5 mg.
48 weeks

Population
S repens/urtica 258 patients DO: 48 w 5%
Finasteride 255 patients DO: 48 w 4%

Inclusion criteria:
Symtomatic BPH stage I–II, Q_{max} <20 ml/s (for Vvoid >150 ml), change in Q_{max} between study beginning and end of run-in phase <3 ml/s

Exclusion criteria:
Age <50, instrumental procedure of lower urinary tract during study (one-time catheterization and infusion-urogram allowed), symptomatic urinary tract infection requiring treatment at study start, treatment with medication that interacts with study drug, manifest cardiac insufficiency, grave disease that requires different therapies, participation in other clinical studies within 4 weeks, cancer of the prostate, PSA >10 ng/ml, BPH stage III

Results

IPSS	S repens/urtica	Finasteride
BL	11.3 ±6.5	11.8 ±6.6
48 w	6.5 ±5.8	6.2 ±5.2

Mean ±SD

Q_{max}	S repens/urtica	Finasteride
BL	12.7 ±4.4	12.7 ±4.5
48 w	14.6 ±6.4	15.4 ±6.8

Mean ±SD

Adverse events

	SR/urtica	Finasteride
Infection	7	9
Apoplex/ acute ocular ischemia	3	2
Lessened ejaculate volume	0	5
Erectile dysfunction	1	7
Jointpain	1	5
Urinary urgency	5	3
Urinary retention	2	7
Cardiovascular disorder	5	1
Headache	2	6
Loss of libido/ Impotence	5	3
GI-disorder	10	13
Others	33	43

Cumulative incidence

Quality of evidence: Low–moderate
Conclusion: No statistically significant difference in IPSS and Q_{max} between serona repens/urtica and finasteride.
Internal validity: Randomization described. Blinding not described.
External validity: Eligible patients not reported.
Comments: IPSS not inclusion criteria. Study includes patients that would not qualify for treatment. ITT unclear.
Sponsorship: None stated

Engelmann 2006 RCT Germany
ArzneimForsch 2006;56:222-229

Intervention
2 x Serenoa repens 160 mg/urtica120 mg vs tamsulosin 0.4mg
60 weeks

Population
S repens/urtica 71 patients DO: 60 w 15%
Tamsulosin 69 patients DO: 60 w 12%

	S repens/urtica	Tamsulosin
Age	65 ±8	65 ±8
Q_{max}	9.6 ±1.9	9.7 ±2.2
Pvolume	38.5 ±16.6	38.2 ±18.5
IPSS	20 ±4	21 ±4
QOL	4 ±1	4 ±1

Mean ±SD

Inclusion criteria:
BPH not requiring surgery, Q_{max} ≤12ml/s (V_{void} ≥150 ml), age ≥50, IPSS ≥13, QoL ≥3

Exclusion criteria:
Change in Q_{max} during run-in >3 ml/s, V_{res} >150 ml, congested urinary tract passages, indication for BPH surgery, urinary tract infection, prostate carcinoma, diabetes, neurogenic or bladder dysfunction, previous treatment with 5α-reductase, concomitant treatment with mediction that could alter study results

Results

IPSS	S repens/Urtica	Tamsulosin
BL	21 ±4	20 ±4
Change 60 w Median (IQR)	-11(7–17)	-10(7–15)

QoL	S. repens/Urti□a	Tamsulosin
BL	4 ±1	4 ±1
Change 60 w Median (IQR)	-2(0–3)	-1(1–3)

Adverse events

	S repens/urtica	Tamsulosin
Adverse events	15	19

Cumulative incidence

Quality of evidence: Moderate
Conclusion: No statistically significant difference between serenoa repens/urtica and tamsulosin.
Internal validity: Randomization and blinding described.
External validity: Eligible patients reported.
Comments: ITT used.
Sponsorship: Member of study group employed by manufacturer

Kirurgi

6.4 Bipolär TURP (B-TURP) vs monopolär teknik

Yang 2004 RCT Taiwan
Urol Int 2004;73:258-61

Intervention
B-TURP (Gyrus Medical) vs TURP
Isotonic saline (B-TURP) or distilled water (TURP) irrigation.
3 months

Population
B-TURP 58 patients
TURP 59 patients
No drop-outs

Baseline	B-TURP	TURP
Age	NR	NR
Q_{max}	10.4	10.9
P volume	45.8	48.9
IPSS	20.9	21.6
QOL	3.7	4.0
PVR	99.0	150.0

Mean

Inclusion criteria:
Bladder outlet obstruction due to BPH

Exclusion criteria:
Patients with high PSA, old age or not suitable for surgery were excluded. Patient with little or no improvement in voiding symptoms after surgical management were excluded

Results

Q_{max}	B-TURP	TURP	*p*
Preop	10.4	10.9	NR
1 mo	NR	NR	NR
3 mo	17.1	14.8	NR

Mean

IPSS	B-TURP	TURP	*p*
Pre op	20.9	21.6	NR
1 mo	NR	NR	NR
3 mo	10.8	11.1	NR

Mean

QoL	B-TURP	TURP	*p*
Pre op	3.7	4.0	NR
1 mo	NR	NR	NR
3 mo	2.1	2.2	NR

Mean

Adverse events

	B-TURP	TURP	*p*
Postop (days)	3.2	3.8	NR
Op time (min)	46	55	0.08
Cath time (days)	2.7	3.2	<0.05

Mean

Early	B-TURP	TURP	*p*
Transfusion	2(1)	2(1)	NR
Acute urinary retention	10(6)	12(7)	NR
UTI	NR	NR	NR
TUR syndr	0	2(1)	NR
Death	NR	NR	NR
Sepsis	NR	NR	NR
Clot retention	NR	NR	NR

% (n)

Late	B-TURP	TURP	*p*
Urethral stricture	2(1)	3(2)	NR
Erect dysf	NR	NR	NR
Incontinence	0	2(1)	NR
Reoperation	NR	NR	NR
Hemorrage	NR	NR	NR

% (n)

Quality of evidence: Moderate
Conclusion: The bipolar resection show advantages when it comes to decreased blood loss and shorter catheterization time. IPSS and Qmax improved in both groups. Internal validity: Randomization not described. Not blinded. External validity: Eligible patients not reported. Comments: ITT not usedSponsorship: Not reported

Fung 2005 RCT China
Asian Journal of Surgery 2005;28:24-28

Intervention
B-TURP (240 W) vs TURP
Gyrus plasmakinetic loop
3 months

Population
B-TUVP: 21 patients (8 DO before treatment)
TURP: 30 patients (1 DO after treatment)

	B-TUVP	TURP
Age	72.5 (59–91)	73 (59–88)
Q_{max}	nr	nr
Pvolume	nr	nr
IPSS	15.82	19.36
QoL	3.55	3.64
Mean (range)		
AUR/CUR	17	25
Number of patients		

Inclusion criteria:
AUR with failure to remove catheter, CUR causing renal impairment, severe LUTS (IPSS>20 and Q_{max} <10ml/s)

Exclusion criteria:
Known neurogenic bladder, known/suspected prostate cancer, previous prostate surgery, urethral stricture, bladder stone, warfarin therapy

Results

Q_{max}	B-TUVP	TURP	*p*
BL	nr	nr	
3 mo	16.57	14.71	0.96
Mean			

IPSS	B-TUVP	TURP	*p*
BL	15.82	19.36	
3 mo	8.81	9.63	0.862
Mean			

QOL	B-TUVP	TURP	*p*
BL	3.55	3.64	
3 mo	0.55	1.54	0.169
Mean			

Adverse events

Days in hosp		
Op time	36.6 (12–76)	32.9 (12–105)
Cath days	1.14	1.21
Mean (range)		

Early	B-TUVP	TURP
Transfusion		
AUR/CUR	19(4)	10(3)
Sepsis	5(1)	0
TURP syndrome	0	0
Death	NR	NR
Clot retention	5(1)	17(5)
Overall	23.8%	34.7%
	% (n)	

Late	B-TUVP	TURP
Reoperation	NR	NR
Neck scler	NR	NR
Meatus stenosis	NR	NR
Erectile dysfunction	NR	NR
Incontinence	NR	NR
UTI	19(4)	13(4)
	% (n)	

Quality of evidence: Low–moderate
Conclusion: PKVP achieved comparable results to conventional TURP and is a safe procedure. However, PKVP did not demonstrate an obvious advantage over TURP in an acute regional hospital regular TURP list setting.
Internal validity: Randomization described. Patients and assessors blinded. Patients excluded after randomization. External validity: Eligible patients not reported. Comments: Exclusion due to machine failure. ITT not used.
Sponsorship: Not commented

Singh 2005 RCT India
J Endourology 2005;19:333-8

Intervention
B-TURP (Vista CTR, ACMI) vs TURP
Physiological saline solution with 1% ethanol.
3 months

Population
B-TURP 30 patients
TURP 30 patients
No drop-outs

	B-TURP	TURP
Age	68.9 ±7.6	67.9 ±9.8
Q_{max}	5.8 ±3.0	5.1 ±2.0
P.volume	NR	NR
IPSS	20.5 ±4.8	21.6 ±6.3
QOL	4.6 ±0.9	4.4 ±1.0
PVR	124 ±58	136 ±52

Mean ±SD

Inclusion criteria:
Symptomatic BPH. Older than 50 yrs. IPSS >7, Q_{max} >12ml/s

Exclusion criteria:
IPSS <7 Q_{max} >12 Patients with neurologic illness, renal insufficiency, bladder stone, urethral stricture. Patients taking finasteride

Results

Q_{max}	B-TURP	TURP	*p*
Preop	5.1 ±2.0	5.8 ±3.0	NR
1 mo	19.8	18.6	NR
3 mo	19.0	17.8	NR

Mean ±SD

IPSS	B-TURP	TURP	*p*
Pre op	20.5 ±4.8	21.6 ±6.3	NR
1 mo	6.0	7.0	NR
3 mo	5.3	6.2	NR

Mean ±SD

QOL	B-TURP	TURP	*p*
Pre op	4.6 ±0.9	4.4 ±1.0	NR
1 mo	1.4	1.5	NR
3 mo	1.1	1.0	NR

Mean ±SD

Adverse events

	B-TURP	TURP	*p*
Hospital stay (days)	3.02 ±0.55	3.88 ±0.58	
Op time (min)	39.3 ±17.8	36.9 ±14.6	NR
Cath time (days)	2.52 ±0.5	3.41 ±0.53	0.019

Mean ±SD

Early	B-TURP	TURP	*p*
Transfusion	NR	NR	NR
Acute urinary retention	NR	NR	NR
UTI	10(3)	13(4)	NR
TUR syndr	0	0	NR
Death	NR	NR	NR
Sepsis	NR	NR	NR
Clot retention	NR	NR	NR

% (n)

Late	B-TURP	TURP	*p*
Bladder stenosis	0	3(1)	NR
Urethral Sructure	3(1)	0	NR
Erect dysf	NR	NR	NR
Incontinence	NR	NR	NR
Reoperation	NR	NR	NR
Haemorrhage	3(1)	3(1)	NR

% (n)

Quality of evidence: Moderate. **Conclusion**: Bipolar TURP is an effective alternative to monopolar TURP. Internal validity: Randomization described. Post-operative care personnel blinded. External validity: Eligible patients not reported. Comments: ITT used. Sponsorship: Not reported

Patankar 2006 RCT India
J Endourology 2006;20:215-9

Intervention
B-TURP (Plasmikinetic Superpulse) vs TURP
Saline (B-TURP) or glycine (TURP) irrigation.
3 weeks

Population
B-TURP 53 patients DO: 3 w 1 patients
TURP 51 patients DO: No drop-outs

Baseline	B-TURP	TURP
Age	NR	NR
Q_{max}	5.9 ±1.98	6.4 ±1.77
P volume	51.3 ±12.44	52.26 ±10.71
IPSS	23.3 ±4.85	23.73 ±4.6

Mean ±SD

Inclusion criteria:
AUA score ≥18, Pvol 35–70 ml, Q_{max} ≤10 ml/s

Exclusion criteria:
Previous prostate surgery. History or evidence of prostate cancer

Results

Q_{max}	B-TURP	TURP	*p*
Preop	5.9 ±1.98	6.4 ±1.77	NR
3 w	19.16 ±1.9	20.67 ±1.□3	NS

Mean ±SD

IPSS	B-TURP	TURP	*p*
P□e op	23.3 ±4.85	23.73 ±4.6	NR
3 w	6.11 ±1.02	7.7 ±1.86	NS

Mean ±SD

Adverse events

	B-TURP	TURP	*p*
Postop (days)	NR	NR	NR
Op time (min)	49.99 ±12.35	57.88 ±18.95	NS
Cath time (hrs)	18.44 ±2.7	42.4 ±15.12	<0.05

Mean ±SD

Early	B-TURP	TURP
Transfusion	0	2(1)
Hematuria	6(3)	18(9)
TURP syndr	NR	NR
Death	NR	NR
Clot retention	0	4(2)
UTI	12(6)	14(7)

% (n)

Late	B-TURP	TURP
Bladder neck sclerosis	NR	NR
Erect dysf	NR	NR
Incontinence	NR	NR
Reoperation	NR	NR
Haemorrhage	NR	NR

% (n)

Quality of evidence: Moderate
Conclusion:Treatments appear comparable in efficacy, further research needed.
Internal validity: Randomization described. Patients and assessors blinded. External validity: Baseline data not reported. Eligible patients reported. Comments: ITT not used.
Sponsorship: Not reported

De Sio 2006 RCT Italy
Urology 2006;67:69-72

Intervention
B-TURP (Gyrus Medical) vs TURP
Saline irrigation.
12 months

Population
B-TURP 35 patients
TURP 35 patients
Drop-outs 12 mo: 12 total, groups unknown

Baseline	B-TURP	TURP
Age	59 ±5.9	61 ±5.9
Q_{max}	7.1 ±2	6.3 ±3
P volume	51.6 ±3.9	47.5 ±5.1
IPSS	24.18 ±4	24.3 ±5
QOL	4.2 ±1	3.9 ±1
PVR	80 ±22.5	75 ±35.5

Mean ±SD

Inclusion criteria:
Older than 50 yrs. Acute urinary retention, chronic urinary retention, IPSS >18, QOL score ≥3, Q_{max} <15 ml/s

Exclusion criteria:
Suspected or documented prostate cancer. Prostate volyme <30 cm^3. Neurogenic bladder, maximal bladder capacity >500 ml. Previous prostate surgery. Warfarin therapy

Results

Q_{max}	B-TURP	TURP	*p*
Preop	7.1 ±2	6.3 ±3	NR
12 mo	21*	22*	NR

Mean ±SD

IPSS	B-TURP	TURP	*p*
Pre op	24.18 ±4	24.3 ±5	NR
12 mo	4*	4*	NR

Mean ±SD

QOL	B-TURP	TURP	*p*
Pre op	4.2 ±1	3.9 ±1	
12 mo	1*	0.8*	NR

Mean ±SD

*Data extracted from figures. Exact values or SD were not reported.

Adverse events

	B-TURP	TURP	*p*
Postop (days)	NR	NR	NR
Op time (min)	49	53	NS
Cath time (hrs)	72	100	<0.05

Mean

Early	B-TURP	TURP	*p*
Transfusion	3(1)	0	NS
Acute urinary retention	0	0	
TURP syndr	0	0	NS
Death	NR	NR	NR
Sepsis	NR	NR	NR
Clot retention	6(2)	11(4)	NR

% (n)

Late	B-TURP	TURP	*p*
Bladder neck sclerosis	3(1)	3(1)	NS
Erect dysf	NR	NR	NR
Incontinence	NR	NR	NR
Reoperation	3(1)	3(1)	NS
Haemorrhage	NR	NR	NR

% (n)

Quality of evidence: Moderate. **Conclusion**: Comparable results in IPSS, QoL and Q_{max} in both groups. Internal validity: Randomization described. Not blinded. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not reported

Nuhoglu 2006 RCT Turkey
International Journal of Urology 2006;13:21-24

Intervention
B-TURP (Sheet Gyrus) vs TURP
12 months

Population
B-TURP 27 patients DO: 12 mo 3
TURP 30 patients Do: 12 mo 4

Baseline	B-TURP	TURP
Age	64,6±8.8	65.0±9.3
Q_{max}	6.9±2.8	7.3±2.1
P volume	47±7.7	49±8.1
IPSS	17.6±6.1	17.3±5.8
QOL	NR	NR
PVR	96±27	88±20
ALPHA 1-blocker	18	21

Mean ±SD

Inclusion criteria:
Symptoms of the lower urinary system. IPSS <15 and Q_{max} <10 ml/s

Exclusion criteria:
Patients with known neurogenic bladder, prostate cancer, previous prostatic or urethral surgery

Results

Q_{max}	B-TURP	TURP	*p*
Preop	6.9±2.8	7.3±2.1	NR
1 mo	17.6±4.3	17.7±2.3	NR
12 mo	17.1±2.7	17.9±3.1	NR

Mean ±SD

IPSS	B-TURP	TURP	*p*
Pre op	17.6±6.1	17.3±5.8	NR
1 mo	4.8±3.4	4.7±3.1	NR
12 mo	5.4±3.7	5.2±3.2	NR

Mean ±SD

Adverse events

	B-TURP	TURP	*p*
Postop (days)	NR	NR	NR
Op time (min)	55±9.7	52±13.2	NS
Cath time (h)	47±5.6	75.7±12.5	<0.01

Mean ±SD

Early	B-TURP	TURP	*p*
Transfusion	4(1)	7(2)	NR
Acute urinary retention	4(1)	0	NR
UTI	NR	NR	NR
TUR syndr	0	0	NR
Death	NR	NR	NR
Sepsis	NR	NR	NR
Clot retention	NR	NR	NR

% (n)

Late	B-TURP	TURP	*p*
Meatal stenosis	4(1)	0	NR
Erect dysf	NR	NR	NR
Incontinence	0	0	NR
Reoperation	0	0	NR
Hemorrage	NR	NR	NR

% (n)

Quality of evidence: Moderate
Conclusion: B-TURP is as effective as TURP.
Internal validity: Randomization not described. Not blinded. External validity: Eligible patients not reported. Comments: ITT not used. Sponsorship: Not reported

Ertuhan 2007 RCT Turkey
Prostate Cancer and Prostatic Diseases 2007;10:97-100

Intervention
B-TURP (Gyrus Medical, up to 200W) vs TURP (120W)
Saline irrigation (B-TURP) or 5% glycine (TURP)
12 months

Population
B-TURP 120 pat
TURP 120 pat
Drop-outs not reported

Baseline	B-TURP	TURP
Age	68.5	67.4
Q_{max}	10.9±1.2	9.2±1.7
P volume	43±9	42±11
IPSS	23±5	24±6
QOL	3±1	3±1
PVR	114±19	135±25

Mean ±SD

Inclusion criteria:
BPH-related urinary tract symtoms. IPSS ≥18, pvr >50 ml

Exclusion criteria:
Patients with known neurogenic bladder, prostate cancer, previous prostatic surgery. Urethral stricture

Results

Q_{max}	B-TURP	TURP	*p*
Preop	10.9±1.2	9.2±1.7	NR
1 mo	17.4±2.5	16.4±3.5	NR
12 mo	19.5±3.5	18.5±3	<0.001

Mean ±SD

IPSS	B-TURP	TURP	*p*
Pre op	23±5	24±6	NR
1 mo	5±2	5.2±2	NR
12 mo	4±2	4±2	NS

Mean ±SD

QOL	B-TURP	TURP	*p*
Pre op	3±1	3±1	NR
1 mo	2±1	2±1	NR
12 mo	2±1	2±1	NS

Mean ±SD

Adverse events

	B-TURP	TURP	*p*
Postop (days)	3±1.2	5±1.2	<0.001
Op time (min)	36±19	57±24	<0.001
Cath time (days)	3±1.2	4.5±1.2	<0.001

Mean ±SD

Early	B-TURP	TURP	*p*
Transfusion	1(1)	6(7)	0.0001
Acute urinary retention	2(2)	4(5)	0.083
TUR syndr	0	2(2)	0.15
Death	0	0	NR
Bleeding	0	3(3)	
Sepsis	NR	NR	NR
Clot retention	2(2)	14(17)	0.0001

% (n)

Late	B-TURP	TURP	*p*
Urethral/Meatal stricture	4(5)	3(4)	NR
Erect dysf	NR	NR	NS
Incontinence	0	0	NR
Reoperation	0	4(5)	0.025

% (n)

Quality of evidence: Moderate. **Conclusion**: No difference in efficacy. Less reoperations, blood transfusion and clot retentions with B-TURP. Internal validity: Randomization not described. Not blinded. External validity: Eligible patients not described. Comments: ITT not used. Sponsorship: Not reported

Ho 2007 RCT Singapore
European Urology 2007;52:517-524

Intervention
B-TURP (Olympus TURIS) vs TURP
12 months

Population
B-TURP 48 patients
TURP 52 patients
Drop-outs not reported

Baseline	B-TURP	TURP
Age	66.6±6.8	66.5±7.2
Q_{max}	6.8±4.8	6.5±3.2
Pvolume	56.5±17.9	54.8±19.2
IPSS	22.6±5.5	24.6±6
QOL	NR	NR

Mean ±SD

Inclusion criteria:
Older than 50 yrs and fit for anesthesia. IPSS >18, Q_{max} <15 ml/s. Patients with acute urinary retention and failed trail of voiding without urinary catheter. Urinary tract infection and hematuria

Exclusion criteria:
Documented or suspected prostate cancer, bladder calculus, neurogenic bladder, previous prostate surgery, renal impairment, associated hydronephrosis, and urethral stricture

Results

Q_{max}	B-TURP	TURP	*p*
Preop	6.8±4.8	6.5±3.2	NR
12 mo	17*	17*	NR

Mean ±SD

IPSS	B-TURP	TURP	*p*
Pre op	22.6±5.5	24.6±6	NR
12 mo	7*	7*	NR

Mean ±SD

*Data extracted from firgues. Exact values or SD were not reported

Adverse events

	TURIS	TURP	*p*
Postop (days)	NR	NR	NR
Op time (min)	59±18	58±16	NS
Cath time (days)	NR	NR	NR

Mean ±SD

Early	B-TURP	TURP	*p*
Transfusion	2(1)	2(1)	NS
Acute urinary retention	NR	NR	NR
UTI	4(2)	4(2)	NS
TUR syndr	0	4(2)	<0.05
Death	NR	NR	NR
Sepsis	NR	NR	NR
Clot retention	6(3)	4(2)	NS

% (n)

Late	B-TURP	TURP	*p*
Bladder neck stenosis	6(3)	2(1)	NS
Erect dysf	NR	NR	NR
Incontinence	NR	NR	NR
Reoperation	NR	NR	NR
Hemorrage	NR	NR	NR

% (n)

Quality of evidence: Moderate
Conclusion: Postoperative clinical efficacy is comparable. IPSS, Q_{max} improved in both groups after surgery. Internal validity: Randomization not described. Not blinded. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not reported

Michielsen 2007 RCT Belgium
Journal of Urology 2007;178:2035-9

Intervention
B-TURP (Olympus TURIS, 270 W) vs TURP
Perioperative data only

Population
B-TURP 118 patients DO: No follow-up
TURP 120 patients DO: No follow-up

Baseline	B-TURP	TURP
Age	73.8 ±8.1	73.1 ±8.6

Mean ±SD

Inclusion criteria:
IPSS ≥13, QOL ≥3, Q_{max} <15ml/s

Exclusion criteria:
Known neurogenic bladder, prostate cancer, previous prostate or urethral surgery, bladder stones, anticoagulant therapy

Results

Not evaluated

Adverse events

	B-TURP	TURP	*p*
Postop (days)	4.9	5□1	*0.591*
Op time (min)	56 ±25	44 ±20	*0.001*
Cath days	4.0 ±3.0	4.5 ±3.5	*0.201*

Mean ±SD

Early	B-TURP	TURP	*p*
Transfusion	3.4(4)	0.8(1)	*0.211*
Acute urinary retention	2.5(3)	4.2(5)	*0.722*
UTI	NR	NR	*NR*
TUR syndr	0	0.8(1)	*1.00*
Death	0	0	*NR*
Sepsis	NR	NR	*NR*
Clot retention	3.4(4)	5(6)	*0.749*
Revision/ catheterization	0	1.6(2)	*NR*

% (n)

Quality of evidence: Low-Moderate
Conclusion: B-TURP seems safer than TURP.
Internal validity: Randomization described. Not blinded. External validity: Eligible patients not reported.
Comments: ITT not used.
Sponsorship: Not reported

6.5 Transuretral elektrovaporisation, TUVP

Cetinkaya 1996 RCT Turkey
British Journal of Urology 1996;78: 901-903 (1998 British Journal of Urology 1998;81:652-654)

Intervention
TUVP (240–400 W) vs TURP, 12 months follow-up.
Storz spike electrode.
Glycine irrigation.
Prophylactic antibiotics for all patients

Population
TUVP 30 patients DO: 12 mo 7%
TURP 33 patients DO: 12 mo 12%

	TUVP	TURP
Age	68.4±8.3	62.5±10.1
Q_{max}	3.8±4.8	3.8±4.5
P_{vol}	48.4±9.7	48.8±15.4
IPSS	26.4±9.8	26.4±10.7

Mean ±SD

9 patients in cronic urinary retention, groups not reported

Inclusion criteria:
Moderate or severe prostatism, Q_{max} <15ml/s

Exclusion criteria:
Previous prostate surgery, abnormality of liver or kidney function, urethral strictures, neurogenic defects, bladder stones, confirmed or suspected prostate cancer

Results

AUASS	TUVP	TURP	*p*
BL	26.4±9.8	26.4±10.7	
3 mo	6.5±5.1	6.3±3.9	
12 mo	5.6±5.1	4.7±1.9	ns

Mean ±SD

Q_{max}	TUVP	TURP	*p*
BL	3.8±4.8	3.8±4.5	
3 mo	18.3±10	20.9±11.4	
12 mo	25.6±12.4	20.9±8.7	ns

Mean ±SD

Adverse events

Days in hosp	Not reported	
Op time	41.6±22.1	52.4±20.0
Cath days	1.4±0.8	1.9±0.8

Mean ±SD

Early	TUVP	TURP
Transfusion	0	6(2)
AUR/CUR	12(4)	0
Sepsis	Not reported	
TURP syndr	Not reported	
Death	3(1)	6(2)

Late	TUVP	TURP
Reoperation	Not reported	
Meatal stricture	3(1)	6(2)
Urethral stricture	3(1)	6(2)
Erect dysf	Not reported	
Incontinence	Not reported	
UTI	0	0

Quality of evidence: Low–moderate
Conclusion: Efficacy and early morbidity similar for TUVP and TURP.
Internal validity: Not blinded. Randomisation not described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not commented

Shokeir 1997 RCT Turkey
British Journal of Urology 1997;80:570-4

Intervention
TUVP (200–300 W) vs TURP, 12 months follow-up.
Storz spiky roller electrode.
Glycine irrigation.
No prophylactic antibiotics reported

Population
TUVP 35 patients No dropouts
TURP 35 patients No dropouts

	TUVP	TURP
Age	68,4±9,5 (54–85)	68,4±9,6 (51–86)
Q_{max}	7,8±2,1 (4,1–11,4)	6,9±1,7 (3,4–10)
Prostate size (g)	44,6±10,1 (30–60)	48,8±10,6 (28–60)
AUA-7	26,3±5,2 (16–29)	25,1±5,5 (18–30)

Mean ±SD (range)

Inclusion criteria:
AUA-7 symtom score >15, Q_{max} <12 ml/s, prostate size <60 g (TRUS)

Exclusion criteria:
Neurogenic bladder, prostate cancer, bladder stone, previous prostate surgery, prostate size >60 g, AUR, indwelling urethral catheter

Results

AUASS	TUVP	TURP	*p*
BL	26,3±5,2 (16–29)	25,1±5,5 (18–30)	
3 mo	4,5±1,9 (6–15)	4,8±2,2 (5–14)	
6 mo	4,6±1,2 (3–7)	4,5±1,3 (3–8)	
12 mo	5,2±1,4 (4–8)	4,7±1,5 (4–9)	

Mean ±SD (range)

Q_{max}	TUVP	TURP	*p*
BL	7,8±2,1 (4,1–11,4)	6,9±1,7 (3,4–10)	
3 mo	19,4±2,2 (15–24)	19,4±2,1 (16–26)	ns
6 mo	19,2±2 (16–23)	19,3±2 (16–24)	ns
12 mo	20,1±3,2 (18–25)	18,2±3 (15–25)	ns

Mean ±SD (range)

Adverse events

Days in hosp	1,5±0,7 (1–3)	2,5±1 (1–4)
Op time	52±12,5 (30–76)	39,7±8,8 (25–60)
Cath day	1.1±0.4 (1–2)	2±0.8 (1–4)

Mean ±SD (range)

Early	TUVP	TURP
Transfusion	0	0
AUR/CUR	0	0
Sepsis	0	0
TURP syndr	0	0
Death	0	0

Late	TUVP	TURP
Retrograde ejaculation	18/18	15/15
Erect dysf	2/18	0/15
Irritative symtoms	3	2

Quality of evidence: Low–moderate
Conclusion: No significant difference in efficacy. Shorter hospital stays for TUVP.
Internal validity: Not blinded. Randomisation not described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not commented

Gallucci 1998 RCT Italy
European Urology 1998;33:359-364

Intervention
TUVP (200–250 W) vs TURP, 12 months follow-up.
Vaportrode grooved roller electrode.
Mannitol-sorbitol irrigation.
Prophylactic antibiotics for all patients

Population
TUVP 70 patients No dropouts
TURP 80 patients No dropouts

	TUVP	TURP
Age	Not stated	
Q_{max}	7.26±3.1	7.26±3.1
P_{vol}	36.61±12.7	36.61±12.7
IPSS	18.84±5.7	18.84±5.7

Mean ±SD

Inclusion criteria:
Symptomatic BPH with urodynamically assessed obstruction

Exclusion criteria:
Complete urinary retention, bladder calculi, neurogenic bladder, prostate weight >70 g, bladder cancer, prostate cancer confirmed or suspected, mental or psychological illness

Results

AUASS	TUVP	TURP	*p*
BL	18.84±5.7	18.19±5.9	
3 mo	5.50±4.8	5.52±4.1	ns
6 mo	4.94±4.7	3.77±3.3	ns
12 mo	4.04±4.3	3.52±3.0	ns

Mean ±SD (calculated from SE)

Q_{max}	TUVP	TURP	*p*
BL	7.26±3.1	8.78±10.4	
3 mo	18.18±7.7	19.21±8.1	ns
6 mo	20.13±7.9	20.77±10.3	ns
12 mo	20.31±6.0	20.30±6.4	ns

Mean ±SD (calculated from SE)

P/F 3 mo	TUVP	TURP
Borderline obstructed	7	6
Obstructed	1	0

Number of patients

Adverse events

Days in hosp	3.9±2.0	4.69±2.0
Op time	Not reported	
Cath days	1.96±1.1	2.71±1.1

Mean ±SD

Early	TUVP	TURP
Transfusion	0	0
AUR	17.1	3.75
TURP syndr	Not reported	
Death	0	0
Hematuria	5.7	8.75
Incontinence	18.6	0
Capsular perforation	1.4	0

Late	TUVP	TURP
Reoperation	1.4	0
Neck scler	0	1.25
Urethral stenosis	4.2	3.75
Erect dysf	Not reported	
Incontinence	5.7	1.25
Epididimitis	1.4	5.0

Quality of evidence: Low–moderate
Conclusion: No significant difference in efficacy. Shorter hospital stays for TUVP.
Internal validity: Not blinded. Randomisation not described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not commented

Kaplan 1998 RCT USA
Journal of Urology 1998;159:454-458

Intervention
TUVP (240–270 W) vs TURP, 12 months follow-up.
Fluted roller electrode.
Irrigation fluid not reported.
No prophylactic antibiotics reported

Population
TUVP 32 patients DO: 12 mo 6%
TURP 32 patients DO: 12 mo 3%

	TUVP	TURP
Age	68.9±8.7	72.8±6.9
Q_{max}	7.2±2.8	8.3±3.6
Pvolume	47.8±22.3	41.5±19.7
AUASS	19.4±3.5	18.3±4.7

Mean ±SD

Inclusion criteria:
AUA-SS ≥10, Q_{max} ≤15, prostate volume 15–60ml

Exclusion criteria:
Age <50, known neurogenic bladder, cancer of prostate or bladder, previous prostate surgery, medication known to affect voiding function

Results

AUASS	TUVP	TURP	*p*
BL	19.4±3.5	18.3±4.7	
3 m	9.2±2.7	8.6±2.5	
6 mo	7.4±2.9	7.9±3.1	
12 mo	6.6±2.4	6.1±1.9	

Mean ±SD

Q_{max}	TUVP	TURP	*p*
BL	7.2±2.8	8.3±3.6	
3 mo	14.8±3.9	16.8±3.6	
6 mo	15.6±3.2	18.1±4.2	
12 mo	16.9±4.1	19.6±4.9	

Mean ±SD

Adverse events

Days in hosp	1.3±0.5	2.6±0.9
Op time	47.6±17.6	34.6±11.2
Cath time (h)	12.9±4.6	67.4±13.6

Mean ±SD

Early	TUVP	TURP
Transfusion	0	1
AUR/CUR	Not reported	
Sepsis	Not reported	
TURP syndr	0	1
Death	Not reported	
Clot retention	3	2

Late	TUVP	TURP
Reoperation	0	0
Neck scler	0	0
Urethral stricture	1	1
UTI	5	4
Incontinence	0	0
Erect dysf	1/20	0/18
Retrograde ejaculation	17/20	13/17

Quality of evidence: Moderate
Conclusion: TUVP safe and effective. TURP better effect on maximum flow. Less time in hospital and with catheter in TUVP group.
Internal validity: Blinded observer. Not randomized. External validity: Eligible patients not reported.
Comments: ITT not used.
Sponsorship: Not commented

Kupeli B 1998 RCT USA
Journal of Endourology 1998;12:591-594

Intervention
TUVP (180–250 W) vs TURP, 12 months follow-up.
Storz shipe electrode.
Glycine irrigation.
No prophylactic antibiotics reported

Population
TUVP 30 patients DO: 12 mo 13%
TURP 36 patients DO: 12 mo 17%

	TUVP	TURP
Age	65,7 (52–72)	62,4 (56–70)
Q_{max}	8,3 (2,7–11,8)	8,8 (3,0–12,4)
Pvolume	43,57±12,01	41,46±10,7
AUASS	13,7 (7–29)	14,6 (8–32)

Mean ±SD (range)

Inclusion criteria:
AUASS ≥7, Q_{max} ≤15 ml/s

Exclusion criteria:
Not reported, excluded patients with prostate cancer, prostate size ≥60 g

Results

IPSS	TUVP	TURP	*p*
BL	13,7 (7–29)	14,6 (8–32)	
6 mo	7,9 (0–12)	7,3 (1–12)	
12 mo	6,1 (0–11)	7,0 (0–14)	

Mean (range)

Qm	TU□P	TURP	*p*
BL	8,3 (2,7–11,8)	8,8 (3,0–12,4)	
6 mo	13,8 (8,2–16,4)	14,3 (7,2–17,5)	
12 mo	17,3 (11,5–23,8)	19,6 (9,4–24,5)	

Mean (range)

Adverse events

Days in hosp	1,92±0,89	4,16±1,46
Op time	38,61±7,32	41,40±7,95
Cath days	1,61±0,80	3,83±1,39

Mean ±SD

Early	TUVP	TURP
Transfusion	0	2
TURP syndr	Not reported	
AUR/CUR	1	0
Death	Not reported	
Perforation	1	0
Irritative symtoms	10	3

Late	TUVP	TURP
Reoperation	1	0
Urethral stricture	0	0
UTI	4	3
Incontinence	1	1
Erect dysf	Not reported	
Retrograde ejaculation	Not reported	

Quality of evidence: Low–moderate
Conclusion: Similar efficacy between TUVP and TURP. Shorter hospital stay and catheter time with TUVP. Less bleeding with TUVP.
Internal validity: Not blinded. Randomization described. External validity: Eligible patients reported.
Comments: ITT not used.
Sponsorship: Not commented

Kupeli S 1998 RCT Turkey
European Urology 1998;34:15-18

Intervention
TUVP (250–300 W) vs TURP, 3 months follow-up.
Storz spike electrode.
Irrigation fluid not reported.
No prophylactic antibiotics reported

Population
TUVP 30 patients No dropouts
TURP 30 patients No dropouts

	TUVP	TURP
Age	62.4±3.2	59.8±2.6
Q_{max}	7.9±2.1	9.2±2.6
Pvolume	48.9±8.7	51.7±9.1
AUASS	19.4*	21.6*

Mean ±SD
*SD not reported

Inclusion criteria:
IPSS ≥8, Q_{max} <15 ml/s

Exclusion criteria:
Neurogenic bladder, prostate cancer, history of prostate surgery

Results

IPSS	TUVP	TURP	*p*
BL	19.4	21.6	
3 mo	4.1	5.2	ns

Mean

Q_{max}	TUVP	TURP	*p*
BL	7.9±2.1	9.2±2.6	
3 mo	19.7±3.2	17.7±3.6	

Mean ±SD

Adverse events

Days in hosp	2.5	4.5
Op time	47.3	41.6
Cath time (h)	48 h	96 h

Mean

Early	TUVP	TURP
Transfusion	0	0
AUR/CUR	0	0
TURP syndr	0	0
Death	0	0
Hematuria	20	43

Late	TUVP	TURP
Neck scler	0	0
Meatus stenosis	0	0
Erect dysf	53*	63**
Incontinence	0	0

*pre-op 47% **pre-op 43%

Quality of evidence: Low–moderate
Conclusion: TUVP comparable to TURP in efficacy and safety. Shorter hospitalization with TUVP.
Internal validity: Not blinded. Randomisation not described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not commented

Hammadeh 2000 RCT United Kingdom**.** BJU International 2000;86:648-651 (Previously published in 1998 British Journal of Urology 81721-725, European Urology 34188-192 and Urology 2003;61:1166-71)

Intervention

TUVP (240 W) vs TURP, 60 months follow-up. Vaportrode grooved roller electrode. Irrigation fluid not reported. No prophylactic antibiotics reported

Population

TUVP 55 patients DO: 12 mo 7%, 24 mo 15%, 36 mo 27%, 60 mo 51%.
TURP 54 patients DO: 12 mo 6%, 24 mo 13%, 36 mo 26%, 60 mo 50%

	TUVP	TURP
Age	67.5±6.7 (52–82)	70.2±7.2 (52–87)
Q_{max}	8.9±3.2	8.6±3.2
Pvolume	25.9±8.3 (10–50)	27±12.2 (10–60)
AUASS	26.5±4.5	26.6±4.8
QoL	4.9±0.9	5±0.7

Mean ±SD (range)

Inclusion criteria:

IPSS ≥13, QoL ≥3, Q_{max} <15 ml/s

Exclusion criteria:

Known neurogenic bladder, prostate cancer, previous prostatic or urethral surgery, bladder stone, anticoagulant therapy

Results

Q_{max}	TUVP	TURP	*p*
BL	8.9±3.2	8.6±3.2	0.7
12 mo	22.5±9	20.8±7.7	0
24 m	22.4±7.7	21.2±8.5	0.5
36 mo	22.2±8.5	18±7.1	0.02
60 mo	21±9	17.9±13.1	0.17

Mean ±SD

IPSS	TUVP	TURP	*p*
BL	26.5±4.5	26.6±4.8	0.9
12 mo	4.4±3.8	5.9±5.2	0.3
24 mo	4.3±3.5	6.3±4.6	0.02
36 mo	4.1±3.3	7.1±6.2	0.01
60 mo	5.9±6.3	8.6±7.1	0.16

Mean ±SD

QOL	TUVP	TURP	*p*
BL	4.9±0.9	5±0.7	0.6
12 mo	1.2±1	1.5±1	0.3
24 mo	1.1±1	1.7±1.1	0.004
36 mo	1±0.9	1.6±1.4	0.04
60 mo	1.1±1.2	1.7±1.4	0.09

Mean ±SD

Adverse events

Days in hosp	2.2±0.59 (1.7–3.8)	3.1±0.76 (1.6–5.7)
Op time	25.9±8.3 (10–50)	21.6±8.4 (10–50)
Cath time (h)	20.9±7 (9–42)	46.6±12.5 (14–92)

Mean ±SD (range)

Early	TUVP	TURP
Transfusion	0	1
AUR/CUR	12	4
UTI	3	2
TURP syndr	0	0
Death	0	0
Clot retention	0	4
Secondary haemorrhage	2	2
Irritative symptoms	13	18
36 mo	TUVP	TURP
Reoperation	6	6
Cervical stenosis	1	2
Urethral stricture	2	2
Death	1	2
Incontinence	0	0
Impotence	5	3
Retrograde ejaculation	21	25
60 mo	TUVP	TURP
Reoperation	7	7

Quality of evidence: Moderate. **Conclusion**: TUVP similar to TURP in medium-term safety and efficacy. Shorter duration of catheterization and hospital stay with TUVP. Internal validity: Not blinded. Randomization described. External validity: Eligible patients not reported. Comments: ITT not used. Sponsorship: Not commented

Van Melick 2003 RCT The Netherlands
Urology 2003; 62:1029-1034
(Previously published in 2002 Journal of Urology168:1058-1062 and Journal of Urology169:1411-1416)

Intervention
TUVP (?W) vs TURP (vs contact laser)
12 months follow-up.
Vaportrode electrode.
Glycine irrigation.
Prophylactic antibiotics for all patients

Population
TUVP 50 patients DO: 12 mo 32%
TURP 46 patients DO: 12 mo 11%

	TUVP	TURP
Age	64±10	66±8
Q_{max}	11±4	11±4
Pvolume	35±11	37±11
IPSS	20.2±6.6	16.8±6.0
Bother	14.1±6.7	11.9±6.7
QoL	3.7±1.6	3.8±1.5

Mean ±SD

Inclusion criteria:
Prostate volume 20–65 ml, Schäfer obstruction grade ≥2

Exclusion criteria:
Those of the International Consensus Committee on BPH

Results

Q_{max}	TUVP	TURP	*p*
BL	11±4	11±4	
6 mo	23±10	24±7	

Mean ±SD

IPSS	TUVP	TURP	*p*
BL	20.2±6.6	16.8±6.0	
6 mo	7.2±6.7	5.3±5.1	
12 mo	6.7±6.4	4.6±4.8	

Mean ±SD

QOL	TUVP	TURP	*p*
BL	3.7±1.6	3.8±1.5	
6 mo	1.6±1.6	0.9±1.2	
12 mo	1.4±1.4	0.9±1.2	

Mean ±SD

Bother	TUVP	TURP	*p*
BL	14.1±6.7	11.9±6.7	
6 mo	3.5±4.6	2.1±2.2	
12 mo	4.2±5.2	2.4±4.7	

Mean ±SD

Adverse events

Days in hosp	3.4±0.9 [3.0]	3.9±0.9 [4.0]
Op time	50±16 (20–90)	28±26 (25–150)
Cath days	1.9±0.6	2.1±0.7

Mean ±SD (range) [median]

Early	TUVP	TURP
Transfusion	1	0
AUR/CUR	0	0
Sepsis	Not reported	
TURP syndr	Not reported	
Death	2	0
Change to TURP	1	0
Fausse route	0	1
Capsule perforation	2	5
Urethral injury	1	0
Clot retention	1	0

Late	TUVP	TURP
Reoperation	2	2
Urethral stricture	1	2
Meatus stenosis	0	1
Erect dysf	Not reported	
Incontinence	Not reported	

Quality of evidence: Low–moderate
Conclusion: Similar results with TUVP and TURP.
Internal validity: Not blinded. Randomization described. External validity: Eligible patients not reported.
Comments: ITT not used. Power calculation reported. Sponsorship: Not commented

Fowler 2005 RCT United Kingdom**.** Health Technol Assess. 2005;9:1-30
(Previously published in McAllister 2002 BJU International 91 211-214)

Intervention

TUVP (180 W) vs TURP, 24 months follow-up. Vaport-rode fluted electrode. Mannitol irrigation fluid (±ethanol in one center). Prophylactic antibiotics according to surgeon's normal practice

Population

TUVP 115 patients DO: 6 mo 8%, 24 mo 22%
TURP 120 patients DO: 6 mo 10%, 24 mo 36%

	TUVP	TURP
Age	70.2	69.7
Q_{max}	10.10±4.35	10.52±5.04
Pvolume	54.3	51.1
IPSS	20.7±7.2	20.7±6.9
QoL	4.6±1.17	4.9±0.98
Mean ±SD		
AUR/CUR	25	20
Number of patients		

Inclusion criteria:

Candidate for surgical treatment of BOO, completed pretreatment evaluation for prostate surgery, able to give written informed consent

Exclusion criteria:

Previous bladder outlet surgery, ASA >3, clinically significant acute illness, medication that precludes entry, known disease of the central or peripheral nervous system, clinical evidence of carcinoma of the prostate

Results

Q_{max}	TUVP	TURP	*p*
BL	10.10±4.35 (9.2–11.0)	10.52±5.04 (9.5–11.5)	
6 mo	19.6±11.04 (17.5–21.7)	22.29±10.25 (20.3–24.2)	

Mean ±SD (range)

IPSS	TUVP	TURP	*p*
BL	20.7±7.2 (19.3–22.1)	20.7±6.9 (19.4–22.0)	
6 mo	8.5±7.4 (7.1–10.0)	6.9±5.5 (5.8–7.9)	
24 mo	8.6±7.2	7.5±5.8	

Mean ±SD (range)

QoL	TUVP	TURP	*p*
BL	4.6±1.17 (4.4–4.8)	4.9±0.98 (4.7–5.0)	
6 mo	2.0±1.63 (1.6–2.3)	1.6±1.34 (1.4–1.9)	
24 mo	1.9±1.62	1.8±1.34	

Mean ±SD (range)

IPSS change >5	TUVP	TURP
6 mo	74 %	85.4 %
24 mo	73.8 %	84 %

P/F	Obstruct	Equivoc	Unobstr
TUVP BL	32	7	4
TUVP6 mo	9	6	28
TURP BL	30	18	6
TURP 6 mo	13	17	24

Erect dysf	TUVP	TURP
6 mo	12/69	5/58
24 mo	12/64	8/43
Ejac prob	25% increase	

Adverse events

Days in hosp	4.4 [3.0]	4.6 [4.0]
Op time	49.0	44.7
Cath days	4.9	3.1

Mean [median]

Early	TUVP	TURP
Transfusion	2 (1TURP)	9
AUR/CUR	5	0
Sepsis	Not reported	
TURP syndr	Not reported	
Death	1	
Heavy bleeding	1	7
Perforation	6	4
Cardiovascular problem	1	1
Other	5	1
Late	TUVP	TURP
Reoperation	See below	
Death	9	
Incontinence	1	1
UTI	Not reported	
Other procedure	TUVP	TURP
Meatotomy	4	8
Oris urethrotomy	47	48
Urethral dilatation	13	10
TUIP	5	17
Optical urethrotomy	2	0
Litholapaxy	2	0
TUR-B	2	1
Other	0	2

Quality of evidence: Very high. **Conclusion**: TUVP and TURP produce equivalent results with similar morbidity. Less bleeding with TUVP. Internal validity: Blinding very well described. Patients somewhat blinded, blinded analysis of data. Randomization very well described. External validity: Eligible patients well described. Comments: ITT used. Power calculation reported. Sponsorship: National Health Service R & D Executive. Circon-ACMI and Valleylab contributed with equipment

Nuhoglu 2005 RCT Turkey
Journal of Endourology 2005;1979-82

Intervention
TUVP (250 W) vs TURP, 60 months follow-up
Storz spike loop electrode.
Irrigation fluid not reported.
Prophylactic antibiotics according to surgeon's normal practice

Population
TUVP 37 patients DO: 3 mo 5%, 60 mo 43%
TURP 40 patients DO: 3 mo 5%, 60 mo 43%

	TUVP	TURP
Age	64.5±8.7	65.1±9.4
Q_{max}	6.3±2.1	5.9±2.6
Pvolume	39±8.1	39±7.7
IPSS	17.3±6.8	17.6±7.2

Mean ±SD

Inclusion criteria:
IPSS >15, Q_{max} <10ml/s

Exclusion criteria:
Previous prostate or urethral surgery, suspected carcinoma of the prostate, neurogenic bladder

Results

Q_{max}	TUVP	TURP	*p*
BL	6.3±2.1	5.9±2.6	
3 mo	17.7±2.3	17.5±3.3	
60 mo	12.9±3.1	13.8±2.9	

Mean ±SD

IPSS	TUVP	TURP	*p*
BL	17.3±6.8	17.6±7.2	
3 mo	4.7±3.1	4.8±4.2	
60 mo	6.5 ±3.2	6.1±3.5	

Mean ±SD

Adverse events

Days in hosp	Not reported	
Op time	45±13.2	45±13.2
Cath time (h)	22±5.7	22±5.7

Mean ±SD

Early	TUVP	TURP
Transfusion	0	2
AUR/CUR	1	0
Sepsis	Not reported	
TURP syndr	0	0
Death	Not reported	

Late	TUVP	TURP
Reoperation	1	0
Neck scler	Not reported	
Meatus stenosis	1	0
Erect dysf	4	2
Incontinence	Not reported	
UTI	Not reported	
Retrograde ejaculation	5	4

Quality of evidence: Low–moderate
Conclusion: TUVP similar to TURP in efficacy and safety. Shorter catheterization and less bleeding with TUVP.
Internal validity: Not blinded. Randomisation not described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not commented

6.6 Bipolär TUVP vs TURP

Dunsmuir 2003 RCT Australia
Prostate Cancer and Prostatic Diseases 2006;6:182-6

Intervention
B-TUVP (?W) vs TURP
Gyrus plasmakinetic electrode
12 months

Population
Preliminary results, planned for 120 patients.
B-TUVP: 30 patients DO: 3 mo 0, 6 mo 6, 12 mo 10
TURP: 21 patients DO: 3 mo 0, 6 mo 1, 12 mo 1

	B-TUVP	TURP
Age	63±7.1	60±6.5
Q_{max}	12±3.4	10.4±3.1
Pvolume	36±19	42±21
IPSS	24±6.9	17±6.2

Mean ±SD

Inclusion criteria:
Age <80, LUTS secondary to BPH and appropriate for TURP

Exclusion criteria:
Presenting with AUR, anticoagulant therapy, Pvol >80 cm^3, previous prostate surgery, suspicion of prostate cancer. PSA >4 ng/ml unless cleared by negative biopsies

Only perioperative data used in meta-analysis

Adverse events

Days in hosp	1.45	1.5
Op time	33	26
Cath time (min)	1 193	1 007

Mean

Early	B-TUVP	TURP
Transfusion	NR	NR
AUR/CUR	30 (10)	5 (1)
Sepsis	NR	NR
TURP syndrome	NR	NR
Death	NR	NR
Clot evacuation	0	19 (4)
	% (n)	

Quality of evidence: Low–m oderate
Conclusion: B-TURP produces comparable results to TURP.
Internal validity: Blinded evaluation. Randomization described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not commented

Tefekli 2005 RCT Turkey
J Urology 2005;174:1339-43

Intervention
B-TUVP (200 W) vs TURP
Gyrus plasmakinetic electrode
Vaporization and resection
12 months

Population
B-TUVP: 51 patients DO: 12 mo 2
TURP: 50 patients DO: 12 mo 3

	B-TUVP	TURP
Age	68.7 ±7	69.4 ±5.9
Q_{max}	7.8 ±3.7	8.3 ±3.6
Pvolume	50.1 ±17.3	54.0 ±15.2
IPSS	21.3 ±3.2	20.4 ±3.5
Mean ±SD		
Retention	16	13
Number of patients		

Inclusion criteria:
Failed medical therapy, recurrent urinary retention

Exclusion criteria:
Abnormal DRE, increased serum PSA, evidence of neurologic bladder (ie history of diabetes, cerebrovascular accident etc), urethral stricture, bladder stone, bladder tumor, previous prostate surgery

All patients:

Q_{max}	B-TUVP	TURP	n
BL	7.8±3.7	8.3±3.6	33/34
3 mo	16.9±2.8	15.8±3.7	49/47
6 mo	18.3±3.5	17.3±4.5	49/47
12 mo	17.2±3.9	17.6±4.3	49/47

Mean ±SD

IPSS	B-TUVP	TURP	n
BL	21.3±3.2	20.4±3.5	33/34
3 mo	9.2±2.1	9.8±2.9	49/47
6 mo	7.2±1.3	7.5±1.1	49/47
12 mo	7.9±1.5	7.2±1.6	49/47

Mean ±SD

Not including patients in retention:

Q_{max}	B-TUVP	TURP	n
BL	7.8±3.7	8.3±3.6	33/34
3 mo	17.1±2.6	16.1±3.3	33/34
6 mo	18.1±3.1	17.6±3.9	33/34
12 mo	16.5±3.1	16.7±3.5	33/34

Mean ±SD

IPSS	B-TUVP	TURP	n
BL	21.3±3.2	20.4±3.5	33/34
3 mo	10.1±2.2	10.5±3.1	33/34
6 mo	7.2±0.9	7.5±1.2	33/34
12 mo	8.1±1.6	7.3±1.5	33/34

Mean ±SD

Adverse events

Days in hosp	2.3±0.7	3.8±0.7
Op time	40.3±11.4	57.8±13.4
Cath days	2.3±0.7	3.8±0.7

Mean ±SD

Early	B-TUVP	TURP
Transfusion	2 (1)	2 (1)
AUR/CUR	2 (1)	2 (1)
Sepsis	NR	NR
TURP syndrome	0	0
Death	0	0
Severe irritative symtoms	12 (6)	4 (2)
	% (n)	

Late	B-TUVP	TURP
Reoperation	4 (2)	2 (1)
Neck scler		
Urethral stricture	6 (3)	2 (1)
Erect dysf	0	0
Incontinence	0	2 (1)
Retrograde ejaculation	59 (29)	64 (30)
Erectile dysfunction	0	0
Death	0	2 (1)*
	% (n)	

*death due to myocardial infarction

Quality of evidence: Low–moderate. **Conclusion**: B-TURP produces comparable results to TURP. Internal validity: Not blinded. Randomization not described. External validity: Eligible patients not reported. Comments: ITT not used. Sponsorship: Not commented

Hon 2006 RCT United Kingdom
J Urology 2006;176: 205-209

Intervention
B-TUVP (160 W) vs TURP
Gyrus plasmakinetic Plasma V
All patients treated with Otis urethrotomy
9 months average follow-up

Population
B-TUVP: 81 patients DO: 5
TURP: 79 patients DO:6

	B-TUVP	TURP
Age	66.1±8.5	68.1±7.5
Q_{max}	12.0±6.4	11.9±6.0
Pvolume	38±17.5	40±17.1
IPSS	21.3±6.2	20.6±7
QoL	4.2±1.1	4.3±1.3
Mean ±SD		
Catheter	9.9%	16%

Inclusion criteria:
BOO undergoing elective TURP

Exclusion criteria:
Myocardial infarction within 6 months, previous TURP, confirmed or suspected prostate cancer, serum creatinine >200 mmol/l, Pvol >80cc. If abnormal DRE or PSA then TRUS + biopsy before inclusion

Results

Q_{max}	B-TUVP	TURP	*p*
BL	12.0±6.4	11.9±6.0	
9 mo	25.6±15.6	23.5±15.2	0.41
Mean ±SD			

IPSS	B-TUVP	TURP	*p*
BL	21.3±6.2	20.6±7	
9 mo	7.7±6.8	6.9±5.8	0.44
Mean ±SD			

QoL	B-TUVP	TURP	*p*
BL	4.2±1.1	4.3±1.3	
9 mo	1.7±1.5	1.5±1.5	0.64
Mean ±SD			

Adverse events

Days in hosp	3,0±0.9	3,4±1.1
Op time	32,6±13.4	28,5±15.2
Cath days	NR	NR
Mean ±SD		

Early	B-TUVP	TURP
Transfusion	0	5,3(4)
AUR/CUR	1.3(1)	2.7(2)
Sepsis	NR	NR
TURP syndrome	NR	NR
Death	NR	NR
Rehospitalisation due to bleeding	1.3(1)	2.7(2)
Clot retention	9.2(7)	15.1(11)
	% (n)	

Late	B-TUVP	TURP
Reoperation	NR	NR
Bladder neck stenosis	1.3(1)	2.7(2)
Urethtral stricture	0	1.4(1)
Ecrect dysf	NR	NR
Incontinence	NR	NR
UTI	NR	NR
	% (n)	

Quality of evidence: Low–moderate
Conclusion: B-TURP as effective as TURP. No histologic tissue for cancer sampling.
Internal validity: Randomization described. Not blinded. External validity: Eligible patients not described.
Comments: ITT used.
Sponsorship: Not commented

6.7 Transuretral incision, TUIP

Dörflinger 1992 RCT Denmark
Scand J Urol Nephrol 1992;26:333-338

Intervention
Transurethral prostatomy (TUIP) vs transurethral prostatectomy (TURP)
1 incision

Population
TUIP: 29 patients (9 KAD) DO: 3 mo 7
TURP: 31 patients (5 KAD) DO: 3 mo 2

	TUIP	TURP
Age	69	71
Q_{max}	10	8
Madsen	15	16

Median

Inclusion criteria:
Prostatism and urinary retention, prostate < 20 g, prostatic urethra < 2 cm

Exclusion criteria:
Previous prostatic surgery, prostatic cancer, urethral stricture, previous pelvic operations, neurological or psychiatric disease, poor surgical risk

Results

Q_{max}	TUIP	TURP	*p*
BL	10.0	8.0	
3 mo	15.2	18.8	NS
12 mo	14.5	20.2	NS

Median

Madsen-Iversen	TUIP	TURP	*p*
BL	14.5	16	
3 mo	2.5	1	NS
12 mo	2	2	NS

Median

IPSS*	TUIP	TURP	*p*
BL	18.7	20.6	
3 mo	3.2	1.3	NS
12 mo	2.6	2.6	NS

Median
*calc from Madsen-Iversen. Max-IPSS=35, Max-MI=27. 35/27≈1.29→IPSS=1.29 x MI

Adverse events

	TUIP	TURP
Days in hosp	3	3
Op time	15	30
Cath time	2	2

Median

Early	TUIP	TURP
Transfusion	0	13 (4
TU□P syndrome	□R	
Death	NR	□R
Retention - KAD	0	3(1)

% (n)

Late	TUIP	TURP
Reoperation	28(8)	13(4)
Stricture	0	3(1)
Incontinence	NR	NR
Retrograde ejaculation	5(1/19)	50(12/24)
Erectile dysfunction	5(1/19)	17(4/24)
Bladder neck sclerosis	0	0

% (n)

Quality of evidence: Low–moderate.
Conclusion: Similar to TURP in small glands. Can preserve antegrade ejaculation.
Internal validity: Not blinded. Randomization not described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not reported

Soonawalla 1992 RCT India
British Journal of Urology 1992;70:174-7

Intervention
Transurethral prostatomy (TUIP) vs transurethral prostatectomy (TURP)
1 incision 5 or 7 o´clock

Population
TUIP: 110 patients DO: 12 mo 40 24 mo: 84
TURP: 110 patients DO: 12 mo 43 24 mo: 89

	TUIP	TURP
Age	62.2	65.03
Q_{max}	7.91	8.04
Pvolume	14.8	15.6

Mean

Inclusion criteria:
Prostatic hypertrophy

Exclusion criteria:
Prostate > 30 g. Suspicion of malignancy

Results

Q_{max}	TUIP	TURP	*p*
BL	7.91	8.04	
3 mo	19.38	20.69	NS
12 mo	19.45	20.10	NS
24 mo	18.91	19.86	NS

Mean

Adverse events

	TUIP	TURP
Days in hosp	6.03	7.16
Op time	20.4	59.2
Cath time	2.62	3.01

Mean

Early	TUIP	TURP
Transfusion	0	35(38)
TURP syndrome	0	6(7)
Death	1(1)	2(2)
Emergency reoperation	2(2)	5(6)
Renal failure	0	1(1)

% (n)

Late	TUIP	TURP
Reoperation	6(7)	4(4)
Stricture	5(5)	3(3)
Incontinence	2(2)	4(4)
Retrograde ejaculation	23(14/60)	27(13/49)
UTI	5(5)	2(2)

% (n)

Quality of evidence: Low–moderate.
Conclusion: Comparable results in small benign prostates
Internal validity: Not blinded. Not randomized. External validity: Eligible patients not reported.
Comments: ITT not used.
Sponsorship: Not reported

Riehmann 1995 RCT USA
Urology 1995;45:768-775
(Earlier results in Larsen 1987 Scand J Urol Nephrol (Suppl) 104:83-86
and Christensen 1990 Urol Clin North Am 17:621-30)

Intervention
Transurethral prostatomy (TUIP) vs transurethral prostatectomy (TURP)
1 incision 6 o´clock

Population
TUIP: 56 patients DO: 3 mo 5, 12 mo 6, 24 mo 15
TURP: 61 patients DO: 3 mo 9, 12 mo 15, 24 mo 21

	TUIP	TURP
Age	64 (42–78)	65 (51–77)
Madsen	16.0	15.1
Q_{max}	9.1±5.1	11.1±5.0

Mean ±SD (range)

Inclusion criteria:
Symptoms of bladder outlet obstruction

Exclusion criteria:
Prostate >20 g prostatic urethra >3 cm, median lobe >2 g, suspected cancer. Previous prostatic or major pelvic surgery, high operative risk, overt neurologic or psychiatric disease

Results

Q_{max}	TUIP	TURP	*p*
BL	9.1±5.1	11.1±5.0	
3 mo	14.9±7.1	20.0±10.1	<0.05
12 mo	16.1±10.7	19.3±12.2	<0.05

Mean ±SD

Madsen-Iversen	TUIP	TURP	*p*
BL	16.0	15.1	NS
3 mo	5.0	4.9	NS
12 mo	6.0	5.6	NS

Mean

Results only in figures in original report, used results reported in metaanalysis.
(Yang 2001 Urology 45:768-775)

IPSS*	TUIP	TURP	*p*
BL	20.6	19.5	NS
3 mo	6.5	6.3	NS
12 mo	7.7	7.2	NS

Mean
*calc from Madsen-Iversen. Max-IPSS=35, Max-MI=27. 35/27≈1.29→IPSS=1.29 x MI

Adverse events

	TUIP	TURP
Days in hosp	3.0 (1–8)	4.3 (2–14)
Op time	23 (7–95)	55 (5–135)
Cath time	1.4 (1–3)	2.5 (1–12)

Mean (range)

Early	TUIP	TURP
Transfusion	0	0
Sepsis	Not reported	
TURP syndr	Not reporte	
Death	0	2 (1)

% (n)

Late	TUIP	TURP
Reoperation	23 (13)	15 (9)
Bladder neck sclerosis	2 (1)	13 (8)
Erectile dysfunction	0	0
Retrograde ejaculation	35 (8/23)	68 (15/22)

% (n)

Quality of evidence: Low–moderate.
Conclusion: TUIP is a safe method. The results after 12 months are inferior to TURP.
Internal validity: Not blinded. Randomization not described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not reported

Jahnson 1998 RCT Sweden
Br J Urol 1998;81:276-81

Intervention
Transurethral prostatomy (TUIP) vs transurethral prostatectomy (TURP).
2 incisions, 4 and 8 o'clock

Population
TUIP: 43 patients (7 KAD) DO: 3 mo: 2, 6 mo: 7, 12 mo: 17, 24 mo: 10, 60 mo: 21
TURP: 42 patients (8 KAD) DO: 3 mo: 3, 6 mo: 8, 12 mo: 10, 24 mo: 11, 60 mo: 18

	TUIP	TURP
Age	70.2 (52–87)	70.8 (56–85)
Q_{max}	10	8
Madsen Mean (range)	15.4	15.8
Pvolume		
20.–29.9	19	24
30.0–39.9	7	5
No. patients		

Inclusion criteria:
Admitted from the waiting list, No previous treatment for BPH, Estimated weight (DRE) 20–40 g, Prostatic urethra <4.0 cm. Size of the prostate 20–40 ml, (TRUS if available), Informed consent

Exclusion criteria:
Bladder stone, bladder cancer, prostatitis, chronic cystitis, clinical prostate cancer, prominent median lobe, adequate follow-up not possible

Results

Q_{max}	TUIP	TURP	*p*
BL	10.0	8.0	
3 mo	15.2	18.8	<0.05
6 mo	14.5	20.2	<0.05
Mean			

Madsen-Iversen	TUIP	TURP	*p*
BL	15.4	15.8	
3 mo	3.5	3.8	
6 mo	4.3	3.5	
60 mo	4.5	4.7	
Mean			

IPSS*	TUIP	TURP
BL	19.9	20.4
3 mo	4.5	4.9
6 mo	5.5	4.5
60 mo	5.8	6.1
Mean		

*calc from Madsen-Iversen. Max-IPSS=35, Max-MI=27. 35/27≈1.29→IPSS=1.29 x MI

Adverse events

	TUIP	TURP
Days in hosp	NR	NR
Op time	15 (5–40)	32 (15–60)
Cath time	2.8	1.4
Median (range)		

Early	TUIP	TURP
Transfusion	0	2 (1)
TURP syndrome	NR	NR
Death	0	2 (1. CVL)
Retention - KAD	5 (2)	2 (1)
	% (n)	

Late	TUIP	TURP
Reoperation	23 (10)	7 (3)
Stricture	NR	NR
Incontinence	NR	NR
Retrograde ejaculation	NR	NR
Erectile dysfunction	NR	NR
Bladder neck sclerosis	NR	NR
	% (n)	

Quality of evidence: Low–moderate.
Conclusion: Transurethral resection is preferable to incision in small to medium benign prostates.
Internal validity: Not blinded. Randomization not described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: Not reported

Tkocz 2002 RCT Poland
Neurourology and urodynamics 2002;21: 112-116

Intervention
Transurethral prostatomy (TUIP) vs transurethral prostatectomy (TURP).
2 incisions 5 and 7 o´clock

Population
TUIP: 50 patients (0 KAD) No drop-outs
TURP: 50 patients (0 KAD) No drop-outs

	TUIP	TURP
Age	63±6.7	64±6.7
Q_{max}	7.6±1.8	6.9±1.5
Pvolume	28.2±2	27.2±2
IPSS	17.1±2.2	17.2±1.9
QOL	4.6±0.5	4.4±0.3

Mean ±SD (assumed to be SEM)

Inclusion criteria:
History, DRE, TRUS, urodynamics

Exclusion criteria:
Prostate >30 g (TRUS)

Results

Q_{max}	TUIP	TURP	*p*
BL	7.6±12.7	6.9±10.6	
24 mo	16.9±13.4	17.6±12.0	NS

Mean ±SD (SD calc from SEM)

IPSS	TUIP	TURP	*p*
BL	17.1±15.6	17.1±13.4	
24 mo	4.1±12.7	5.1±13.4	NS

Mean ±SD (SD calc from SEM)

QOL	TUIP	TURP	*p*
BL	4.6±3.5	4.4±2.1	
24 mo	2.1±2.1	1.9±4.2	<0.05

Mean ±SD (SD calc from SEM)

Very low SD reported, assumed to be SEM

Adverse events

Days in hosp	NR	NR
Op time	NR	NR
Cath time	NR	NR

Early	TUIP	TURP
Transfusion	0	2 (1)
AUR/CUR	NR	NR
Sepsis	NR	NR
TURP syndr	NR	NR
Death	NR	NR
Clot ret	NR	NR

% (n)

Late	TUIP	TURP
Reoperation	NR	NR
Stricture	NR	NR
Incontinence	0	0
Retrograde ejaculation	12 (6)	32 (16)

% (n)

Quality of evidence: Low–moderate.
Conclusion: TUIP can be an alternative to TURP in glands <30 g.
Internal validity: Not blinded. Not randomised. External validity: Inclusion/exclusion criteria minimal.
Comments: ITT not used.
Sponsorship: Not reported

6.8 Transuretral ultraljudsbehandling TUMT

Ahmed 1997 RCT United Kingdom
British Journal of Urology 1997;79:181-5

Intervention
High energy TUMT, Prostatron device, Prostasoft 2.5 vs TURP. Less optimal level of energy (81 mean, 32–203 range) compared to other studies.
6 months

Population
TUMT 30
TURP 30
No dropouts

	TUMT	TURP
Age	69.36 (56–88)	69.45 (58–82)
Q_{max}	10.1 ±2.2 (9.2–10.9)	9.5 ±1.7 (8.9–10.1)
Pvolume	36.6 (31.8–41.4)	46.1 (38.1–54.1)
I-PSS/AUA	18.5 ±4.5 (17.1–20.1)	18.4 ±4.8 (16.7–20.1)
QoL	NR	NR
LUTS	>1 year	>1 year

Mean ±SD (95% CI) *
*Recalculated: 95 % CI = mean ± 1,96 x S.E.M

Inclusion criteria:
Symptomatic uncomplicated BPH >1 year history, AUA score ≥12, flow rate <15 mL/s, PVR <300 mL, Pdet max ≥70 cmH2O, prostate volume 25-100 mL, obstructed as assessed on the Abrams-Griffith nomogram, aged >55 years,

Exclusion criteria:
Technically unsuitable, metallic implants, rectal or pelvic surgery or disease, previous prostatic surgery, prostatic abscess, uncontrolled coagulation disorder, active UTI, prominent middle lobe, other urinary tract disease

Results

Q_{max}	TUMT	TURP	*p*
BL	10.1±2.2 (9.2–10.9)	9.5±1.7 (8.9–10.1)	NR
6 mo	9.1±3.1 (8.0–10.2)	14.6±3.4 (13.4–15.8)	NR

Mean ±SD (95% CI)*

IPSS	TUMT	TURP	*P*
BL	18.5±4.5 (17.1–20.1)	18.4±4.8 (16.7–20.1)	NR
6 mo	5.3±3.1 (3.9–6.4)	5.2±3.6 (3.9–6.5)	NR

Mean (95 % CI)*

Obstruction	TUMT	TURP
BL	30	30
6 mo	30	3

According to Abrams-Griffith nomogram

Detrusor instablitity	TUMT	TURP
BL	25	22
6 mo	21	0

Adverse events

	TUMT	TURP
Days in hosp	NR	NR
Op time	60 min	NR
Kath time	**	3–4 days***

** Intermittent self-catheterization, 3 patients required an indwelling catheter, 2 had it for 10 days and 1 for 6 weeks.
** *Except for 2 who had catheters for 4 weeks

Early	TUMT	TURP
Transfusion	0	13(4)
Sepsis	0	3(1)
TURP syndr	NR	NR
	% (n)	

Late	TUMT	TURP
Reoperation	NR	NR
Neck scler	0	3(1)
Erect dysf	0	13(4)
Incontinence	NR	NR
UTI	3(1)	10(3)
Retrograde ejaculation	13(4)	40(12)
Meatal stenosis	0	7(2)
CUR	10(3)	7(2)
	% (n)	

Quality of evidence: Low–moderate.
Conclusion: For TUMT only the symptom decreased significantly but none of the objective measures like Q_{max}, as it did for TURP. Low energy was used.
Internal validity: Not blinded. Randomization described. External validity: Eligible patients not reported.
Comments: PP- analysis. Significant differences in prostate volume at baseline between TUMT and TURP.
Sponsorship: Not reported

D'Ancona 1998 RCT Netherlands
Br J Urol 1998;98:259-64 (12 mo results in D'Ancona 1997 J Urol 158:120-5)

Intervention
High energy TUMT, Prostatron device, Prostasoft 2.5 vs TURP.
30 months

Population
TUMT 31 pat DO: 1 y 12.9% 2 y 45.2%
TURP 21 pat DO: 1 y 19.0% 2 y 42.9%

	TUMT	TURP
Age	69.3±5.9	69.6±8.5
Q_{max}	9.3±3.9	9.3±3.4
Pvolume	43.4±11.8	44.9±15.3
I-PSS	18,3±6.3	16.7±5.6
LUTS (mo)	>3 months	>3 months

Mean ±SD

Inclusion criteria:
Aged ≥45 years, candidates for TURP, prostatic length 25–50 mm, prostate volume 30–100 mL, symptoms suggestive of BOO >3 months, Madsen symptom score ≥8, Q_{max} ≤15 mL/s, post-void residual volume ≤350 mL

Exclusion criteria:
Neurogenic disorders that might affect bladder function, prostatic carcinoma, prior surgery of the prostate, diabetic neuropathy, urinary retention requiring an indwelling catheter, renal impairment or an obstructed bladder neck due to an enlarged median lobe of the prostate,

Results

Q_{max}	TUMT	TURP	*p*
BL	9.3±3.9	9.3±3.4	NR
3 mo	15.5±8.0	19.6±11.2	NR
6 mo	17.0±7.5	15.3±5.9	NR
12 mo	17.1±7.8	19.3±10.7	NR
30 mo	15.1±9.6	19.1±8.2	NR

Mean ±SD

I-PSS	TUMT	TURP	*p*
BL	18.3±6.3	16.7±5.6	NR
3 mo	15.1±8.2	5.1±3.1	NR
6 mo	6.7±5.5	4.0±2.1	NR
12 mo	5.0±2.7	3.4±2.2	NR
30 mo	7.9±6.3	6.3±4.8	NR

Mean ±SD

Adverse events

	TUMT	TURP
Days in hosp	0	4.1; 4–5
Op time min	60	51±35–70
Kath time	12.7±7.25* (6–35)	4.1±0.25* (4–5)

Mean ±SD (range)
*calculated SD=R/4

Early	TUMT	TURP
Transfusion	0	0
Sepsis	NR	NR
TURP syndr	NR	NR
Death	NR	NR
Irritative voiding symptoms	29 (9)	19 (4)

% (n)

Late	TUMT	TURP
Reoperation	19 (6)	5 (1)
Neck scler	NR	5 (1)
Erect dysf	NR	NR
Incontinence	NR	NR
UTI	16 (5)	5 (1)
Retrograde ejaculation	NR	NR
Meatal stenosis	NR	NR
CUR	NR	NR

% (n)

Quality of evidence: Low–moderate.
Conclusion: There was significant improvement for symptom scores and uroflow-metry variables in both groups. Although the results were somewhat more pronounced after TURP there was no significant difference between the two groups when comparing symptom scores and Q_{max}. In this study most retreatments occurred after 1 year follow up. Internal validity: Randomization not described. No blinding External validity: Eligible patients not reported. Comments: PP- analysis
Sponsorship: Non-affiliated hospital

Floratos 2001 RCT Netherlands
J Urology 2001;165:1533-8 (QoL in Francisca 2000 Eur Urol 1998;38:569-75)

Intervention
High energy TUMT, Prostatron device, Prostasoft 2.5 vs TURP

Population
TUMT 78 Drop-outs: 29.5 %
TURP 66 Drop-outs: 31.8 %

	TUMT	TURP
Age	67±8.4 (54–77)	65±8.3 (55–77)
Q_{max}	9.6±3.0 (5.0–14.0)	7.9±2.8 (4,0–11.7)
Pvolume	50±19.4 (30–82)	52±19.2 (31–84)
IPSS	20.1±6.5 (10–28)	20.8±6.2 (11–29)
QoL	4±0.5 (3–5)	4±0.5 (3–5)
LUTS	>3 months	>3 months

Mean ±SD (range)

Inclusion criteria:
Age ≥45, LUTS >3 months, prostate volume ≥30 mL, prostatic urethral length ≥25 mm, Madsen symptom score ≥8, Qmax ≤15 mL/s, post-void residual volume ≤350 mL

Exclusion criteria:
Acute prostatitis, UTI, evidence of prostatic carcinoma, an isolated prostatic middle lobe protruding in the bladder, urethral stricture, neurological disorders affecting lower urinary tract function, previous prostatic surgery, patients not suitable for resection due to severe co-morbidity

Results

Q_{max}	TUMT	TURP	*p*
BL	9.6±3.0	7.9±2.8	<0.01
3 mo	15.5±12.1	25.0±7.5	0.000
6 mo	NR	NR	NR
12 mo	15.2±7.6	23.5±9.9	0.000
24 mo	14,5±5.25	23.0±10.75	NR
36 mo	11.9±4.75	24.7±7.0	NR

Mean ±SD*

IPSS	TUMT	TURP	*p*
BL	20.1±6.5 (10-28)	20.8±6.2 (11-29)	NR
3 mo	10.5±7.9	5.3±5.2	0.000
6 mo	NR	NR	NR
12 mo	7.6±5.6	3.2±2.5	0.000
24 mo	9±6.5	4±2.5	NR
36 mo	12±6.25	3±2.0	NR

Mean ±SD* (range)

QoL	TUMT	TURP	*p*
BL	4±0.5	4±0.5	0.000
3 mo	2.1±1.5	1.3±1.25	0.000
6 mo	NR	NR	0.000
12mo	2.25±1.25	0.5±0.5	0.000
24 mo	2.25±1.15	1.0±0.5	NR
36 mo	2.25±0.75	0.5±0.5	NR

Mean ±SD*
Unclear QoL score used
* Recalculated with x=(a+mx2+b)/4 and SD=range/4 (normal distribution of data)

Adverse events

	TUMT	TURP
Days in hosp	NR	NR
Op time	NR	NR
Kath time	Minimum 2 weeks **	NR

First voiding trial for TUMT after 2 weeks

Early	TUMT	TURP
Transfusion	NR	NR
Sepsis	NR	NR
TURP syndr	NR	NR
Death	NR	NR

Late	TUMT	TURP
Reoperation	14(11)	9(6)
Neck scler	NR	5(3)
Erect dysf	NR	NR
Incontinence	NR	2(1)
UTI	NR	NR
Retrograde ejaculation	NR	NR
Urethral stricture	1(1)	3(2)
CUR	NR	NR
	%(n)	

Quality of evidence: Low-moderate. **Conclusion**: Significant higher improvement and more durable results after TURP compared to TUMT. The results for TUMT are overestimated because they are only based on results from the patients who responded well to treatment, while the rest are excluded from the analysis.Internal validity: No details about randomization. External validity: Eligible patients not reported. Comments: PP- analysis. Sponsorship: Not reported

Nørby 2002 RCT Denmark
BJU International 2002;90:853-862

Intervention
TUMT vs TURP/TUIP (vs ILC).
6 months

Population
TUMT: 46 pat DO: 4%
TURP: 24 pat DO: 8%

	TUMT	TURP
Age	66±7	68±7
Q_{max}	9.1±4.2	9.6±3.2
IPSS	20.5±5.7	21.3±6.6
Mean ±SD		
Pvol	43 (35–79)	44 (35–50)
Median (IQR)		

Inclusion criteria:
Age ≥50, IPSS ≥7, QoL ≥3, Q_{max} <12 ml/s or obstructed according to ICS nomogram, able to understand project information, written consent

Exclusion criteria:
Suspicion of prostate cancer, Vres >350 ml or urinary catheter, prostatic urethra >25 mm long, neurological disease or diabetes with abnormal cystometry, previous prostate operation, ongoing UTI, previous diagnosis of rectal cancer, intake of medication known to influence voiding, sever peripheral arterial insufficiency, previous pelvic radiation therapy, general health condition contraindicating surgery

Results

Q_{max}	TUMT	TURP
BL	9.1±4.2	9.6±3.2
6 mo	13.2±6.9	20.6±12.8
Mean ±SD		

IPSS	TUMT	TURP
BL	20.5±5.7	21.3 ±6.6
6 mo	9.5±7.1	6.8±5.7
Mean ±SD		

QOL	TUMT	TURP
BL	4 (4–4)	4 (4–5)
6 mo	2 (1–3)	1 (1–2)
Median (IQR)		

Adverse events

Days in hosp	Not reported
Op time	Not reported
Cath time	Not reported

Early	TUMT	TURP
Transfusion	0	9(2)
Bladder evacuation	2(1)	0
Re-retention	7(3)	5(1)
Persistent retention	2(1)	0
TURP syndr	0	5(1)
Death	0	0
Penile oedema	0	0
	% (n)	

Late	TUMT	TURP
Urethral stricture	0	5(1)
Erect dysf	9(4)	14(3)
Incontinence	0	5(1)
UTI	30(14)	14(3)
Retrograde ejaculation	22(10)	50(12)
	% (n)	

Quality of evidence: Moderate
Conclusion: ILC and TUMT are viable alternatives to TURP. Both are associated with morbidity with different complication patterns. Care must be used when deciding which treatment to use for each individual patient.
Internal validity: External validity:
Comments: ITT-analysis used.
Sponsorship: Vejle County

Schelin 2006 RCT Scandinavia
Urology 2006;68:795-9

Intervention
ProstaLund Feedback Treatment vs TURP/open enucleation.
6 months

Population
TUMT 61 pat DO: 6 mo 11%
TURP/OE 59 pat DO: 6 mo 12%

	TUMT	TURP/OE
Age	73	73
Pvolume	71.6	66.8
PSA	7.7	6.0
Mean Indwelling catheter	86.9%	86.4%

All patients in retention

Inclusion criteria:
Symptomatic BPH and persistent urinary retention requiring an indwelling catheter or clean intermittent catheterization for at least 1 month before screening, P_{volume} >30 cm^3, P_{length}>35 mm (by TRUS), V_{res}>300ml or an inability to micturate on 2 separate attempts to remove the catheter or discontinue clean intermittent catheterization, with the second attempt made at least 1 month after the initial catheterization, age ≥45

Exclusion criteria:
Medically or psychologically unable to tolerate surgery

Results

Q_{max}	TUMT	TURP	*p*
BL	NR	NR	NR
3 mo	13.2±8.6	17.2±9.1	NR
6 m	13.4±8.3	18.0±9.7	NR

Mean ±SD

I-PSS	TUMT	TURP	*p*
BL	NR	NR	NR
3 mo	7.□±6.1	5.1±5.1	NR
6 mo	7.3±7.3	4.4±4.9	NR

Mean ±SD

Bother	TUMT	TURP/PE	*p*
BL	4.6±1.3	4.6±1.2	NR
3 mo	1.6±1.6	1.0±1.3	NR
6 mo	1.4±1.6	0.8±1.2	NR

Mean ±SD

Catheter removed	TUMT	TURP/PE	*p*
3 mo	79%	86%	0.3385
6 mo	79%	88%	0.2216

Adverse events

	TUMT	TURP
Days in hosp	NR	NR
Op time (min)	47(12–71)	NR
Cath time (days)	34	5

Mean (range)

Early	TUMT	TURP
Transfusion	NR	NR
Hematuria	2(1)	2(1)
TURP syndr	NR	NR
Death	NR	NR
Hemorrhage	0	2(1)
Stroke	0	2(1)

% (n)

Late	TUMT	TURP
Reoperation	NR	NR
Neck scler	0	2(1)
Erect dysf	NR	NR
Incontinence	NR	NR
UTI	33(20)	22(13)
Retrograde ejaculation	NR	NR
Meatal stenosis	NR	NR
Treatment failure	7(4)	3(2)
Withdrawal due to adverse events	3 (2)	5 (3)

% (n)

Quality of evidence: Moderate
Conclusion: TUMT is an effective alternative to surgery, with less adverse events. Internal validity: Randomization not described. No blinding. Lacking relevant baseline statistics. External validity: No set IPSS as inclusion criteria. Eligible patients not reported. Comments: Considers difference in IPSS irrelevant as both groups are below 8. Sponsorship: Main author employed by and holds stock in the company that produced the TUMT-instrument

6.9 Holmiumlaserenukleation av prostate, HoLEP

Gupta 2006 RCT India
BJU International 2006;97:85-89

Intervention
Holmium laser enucleation vs TURP (vs TUVP)
12 months

Population
HoLEP 50 patients
TURP 50 patients
Drop-outs not reported

	HoLEP	TURP
Age	65.88±10.1 (42–88)	65.67±7.5 (48–85)
Q_{max}	5.15±4.4 (0–12)	4.5±4.7 (0–13)
Psize (g)	57.9±17.6 (41–125)	59.8±16.5 (40–110)
IPSS	23.4±4.5 (13–34)	23.3±3.9 (17–31)

Mean ±SD(range)

Catheterr No. patients	18	16

Inclusion criteria:
Patients with BPH who were candidates for TURP and with glands of >40 g

Exclusion criteria:
Previous history of prostatic or urethral surgery, neurovesical dysfunction, carcinoma of the prostate

Results

Q_{max}	HoLEP	TURP	*p*
BL	5.15±4.4 (0–12)	4.5±4.7 (0–13)	0.73
6 mo	23.1±8.5* (15–40)	20.7±9.3* (10–39)	0.33
12 mo	25.1±7.50* (12–45)	23.7±11.17* (9–41)	0.62

Mean ±SD (range)

IPSS	HoLEP	TURP	*p*
BL	23.4±31.8 (13–34)	23.3±25.6 (17–31)	0.10
6 mo	5.2 ±2.19* (0–14)	6.1±2.97* (0–16)	0.14
12 mo	5.2±1.20* (0–8)	5.6±2.26* (0–9)	0.6

Mean ±SD (range)
*Calculated from presumed SE

Adverse events

	HoLEP	TURP
Time in hospital	NR	NR
Op time (min)	75.4±22.8 (40–145)	64.1±13.1 (40–110)
Cath time (h)	28.6±20.5 (18–168)	45.7±12.7 (18–140)

Mean ±SD (range)

Early	HoLEP	TURP
Transfusion	0	2(1)
Capsular perforation	2(1)	0
Hyponatremia	0	2(1)
Mucosal injury	4(2)	0
Transient dysuria	10(5)	2(1)
Recatheterization	4(2)	6(3)
Fever	2(1)	2(1)

%(n)

Late	HoLEP	TURP
Incontinence	2(1)	2(1)
Stricture	2(1)	4(2)

%(n)

Quality of evidence: Low–moderate
Conclusion: HoLEP provides comparable results to TURP but is difficult to learn.
Internal validity: No details about randomization or blinding. No account for drop-outs. External validity:
Comments: ITT not used.
Sponsorship: None declared.

Rigatti 2006 RCT Italy
Urology 2006;67:1193-8
(Sexual function in Briganti 2006 J Urology 175:1817-21,
earlier results in Montorsi 2004 J Urology 172:1926-9)

Intervention
Holmium laser enucleation vs TURP.
12 months

Population
HoLEP 52 pat
TURP 48 pat

	HoLEP	TURP
Age	65.14±7.3	64.5±6.4
Q_{max}	8.2±3.2	7.8±3.6
Pvolume	60.3±36,7	56.2±19.4
IPSS	21.6±6.7	21.9±7.2
QoL	4.6±1.1	4.7±1

Mean ±SD

Inclusion criteria:
< 75 years, Q_{max} <15 ml/s, PVR <100 ml, medical therapy failure, transrectal US adenoma <100 ml, schäfer >grade 2

Exclusion criteria:
Neurogenic bladder, cancer, previous prostatic, bladder neck or urethral surgery

Results

Q_{max}	HoLEP	TURP	*p*
BL	8.2±3.2	7.8±3.6	*0.61*
6 mo	23.1±8.6	26.5±15.5	*0.007*
12 mo	25.1±7.2	24.7±10	*0.25*

Mean ±SD

IPSS	HoLEP	TURP	*p*
BL	21.6±6.7	21.9±7.2	*0.83*
6 mo	3.9±2.9	2.9±2.6	*0.72*
12 mo	4.1±2.3	3.9±3.6	*0.58*

Mean ±SD

QoL	HoLEP	TURP	*P*
BL	4.6±1.1	4.7±1	*0.7*
6 mo	1±0.8	0.6±0.2	*0.25*
12 mo	1.4 ±0.9	0.8±1.28	*0.31*

Mean ±SD

Adverse events

	HoLEP	TURP	*p*
Time in hospital (h)	59 ±19.9	85.8 ±18.9	<0.001
Op Time (min)	74 ±19.5	57 ±15	<0.05
Cath Time (h)	31 ±13	57.78 ±17.5	<0.001

Mean ±SD

Early	HoLEP	TURP
Bladder mucosal injury	18(9)	0
Re-intervention for bleeding	2(1)	2(1)
TURP syndrome	0	2(1)
Acute urinary retention	5(3)	2(1)
Dysuria	59(30)	30(14)
Transitory urge incontinence	44(23)	39(18)

Late	HoLEP	TURP
Urethral stricture	2(1)	7(4)
Stress incontinence	2(1)	2(1)

Quality of evidence: Low–moderate
Conclusion: HoLEP and TURP equally effective.
Internal validity: Randomization described. Not blinded. External validity: Eligible patients not reported.
Comments: ITT not used.
Sponsorship: Not reported

Wilson 2006 RCT New Zealand
European Urology 2006;50:569-573 (Earlier results in Tan 2003 J Urology 170:1270-1274)

Intervention
Holmium laser enucleation (100 W) vs TURP.
12 months

Population
HoLEP 30 pat DO: 6 mo 13% 12 mo 17% 24 mo 27%
TURP 30 pat DO: 6 mo 3% 12 mo 10% 24 mo 13%

	HoLEP	TURP
Age	71.7±6.1* (54–84)	70.3±5.5* (59–83)
Q_{max}	8.4±2.8* (2–14)	8.3±2.2* (3–12)
Pvolume	77.8±31.2* (42–152)	70.0±27.4* (46–156)
IPSS	26.0±6.1* (14–35)	23.7±6.6* (9–35)
QoL	4.8±1.1* (2–6)	4.7±1.1* (2–6)

Mean ±SD (range)
*Calculated from SE

Inclusion criteria:
Candidates for TURP to treat BOO due to BPH, Pvolume 40–200 ml, Q_{max} </= 15 ml/s, AUA >/= 8, PVR <400 ml, schäfer >/= grade 2

Exclusion criteria:
Catheterized, urethral or prostatic surgery

Results

Q_{max}	HoLEP	TURP	*p*
BL	8.4±2.8*(2–14)	8.3±2.2*(3–12)	
6 mo	26.4±9.2*(13–65)	20.8±12.4*(7–48)	NS
12 mo	21.8±10.5*(8–36)	18.4±14.5*(2–40)	NS
24 mo	21.0±11.0	19.3±12.0	NS

Mean ±SD (range)

IPSS	HoLEP	TURP	*p*
BL	26.0±6.1*(14–35)	23.7±6.6*(9–35)	
6 mo	6.0±5.1*(0–17)	4.8±3.8*(0–18)	NS
12 mo	4.3±3.5*(1–14)	5.0±4.7*(0–21)	NS
24 mo	6.1±3.8	5.2±4.4	NS

Mean ±SD(range)

QoL	HoLEP	TURP	*p*
BL	4.8±1.1*(2–6)	4.7±1.1*(2–6)	
6 mo	1.6±1.5*(0–5)	1.5±1.1*(0–6)	NS
12 mo	1.5±2.5*(0–5)	1.4±1.6*(0–6)	NS
24 mo	1.25± 1.1	1.25± 1.1	NS

Mean ±SD(range)
*Calculated from SE

Sexual function	HoLEP	TURP
BL	13	12
Reduced	2	2
	+2, group was not reported	
Improved	2, group not reported	
Incontinence	HoLEP	TURP
BL	15	11
Regained continence	6	8

Number of patients

Adverse events

	HoLEP	TURP
Time in hospital (h)	27.6±4.8* (8–45)	49.9±30.7* (24–144)
Op Time (min)	62.1±32.3* (20–176)	33.1±20.3* (10–95)
Cath Time (h)	17.7±3.8* (11–26)	44.9±55.3* (17–312)

Mean ±SD (range)
*Calculated from SE

Early (%)	HoLEP	TURP
Transfusion	0	3(1)
Recatheterization	17(5)	13(4)
	%(n)	

Late (%)	HoLEP	TURP
Reoperation	0	7(2)
Stricture	3(1)	10(3)
UTI	0	7(2)
Death	0	3(1)*
	%(n)	

*15 months postop

Quality of evidence: Moderate
Conclusion: HoLEP as effective and durable as TURP. Internal validity: Not blinded. Randomization described. External validity: Eligible patients not reported. Comments: ITT not used. Power calculated. Sponsorship: One author has financial interest and/or other relationship with Lumenis, Inc

Ahyai 2007 RCT Germany/Egypt
European Urology 2007;52:1456–63 (Earlier results in Kuntz 2004 J Urology 172:1012-6)

Intervention
Holmium laser enucleation vs TURP.
36 months

Population
200 patients
HoLEP DO 12 mo 11%, 24 mo 20%, 36 mo 25%
TURP DO 12 mo 14%, 24 mo 25%, 36 mo 31%

	HoLEP	TURP
Age	68.0±7.3 (56–88)	68.7±8.2 (52–86)
Q_{max}	4.9±3.8 (0–11)	5.9±3.9 (0–12)
Pvolume	53.3±20.0 (20–95)	49.9±21.1 (20–99)
IPSS	22.1±3.8 (13–33)	21.4±5.2 (9–32)

Mean ±SD (range)

Inclusion criteria:
LUTS due to BPH, AUA >/= 12, Q_{max} </= 12 ml/s, PVR >50 ml, Schäfer >/= grade 2, prostate vol < 100 ml

Exclusion criteria:
Carcinoma or the prostate, urethral and prostatic surgery

Results

Q_{max}	HoLEP	TURP	*p*
BL	4.9±3.8 (0–11)	5.9±3.9 (0–12)	*0.08*
6 mo	25.1±6.9 (10–49)	25.1±9.4 (8–47)	*0.72*
12 mo	27.9±9.9 (5–53)	27.7±12.2 (8–56)	*0.76*
24 mo	28.0±9.0 (7–49)	29.1±10.9 (9–55)	*0.82*
36 mo	29.0±11.0 (6–54)	27.5±9.9 (8–50)	*0.41*

Mean ±SD (range)

IPSS	HoLEP	TURP	*P*
BL	22.1±3.8(13–34)	21.4±5.2 (9–32)	*0.56*
6 mo	2.2±1.6 (0–9)	3.7±3.4 (0–16)	*0.006*
12 mo	1.7±1.8 (0–9)	3.9±3.9 (0–19)	*0.0001*
24 mo	1.7±1.7 (0–9)	3.9±3.7 (0–15)	*0.0001*
36 mo	2.7±3.2 (0–10)	3.3±3.0 (0–15)	*0.15*

Mean ±SD (range)

Adverse events

	HoLEP	TURP
Time in hospital (h)	53.3±15.9 (24–100)	85.8±39.1 (48–240)
Op time (min)	94.6±35.1 (39–209)	73.8±24.0 (30–170)
Cath time (h)	27.6±10.4 (24–72)	43.4±21.1 (24–192)

Mean ±SD (range)

Early (%)	HoLEP	TURP
Transfusion	0	2(2)
Recath	0	5(5)
Sec Art Coag	1(1)	2(2)
Sec Apical resection	1(1)	3(3)

Late (%)	HoLEP	TURP
Bladder neck contracture	3(3)	3(3)
Stricture	4(4)	3(3)
Incontinence	1(1)	1(1)
BPH recurrence	1(1)	0
Death	3(3)	3(3)

Quality of evidence: Low–moderate
Conclusion: HoLEP compare favourably with TURP after 3 years of follow-up.
Internal validity: Few details about randomization. Not blinded. External validity: Eligible patients not reported. Comments: Power calculated. ITT unclear.
Sponsorship: Denies any relationship related to the article. Main author is a consultant for Lumenis, Inc and Karl Storz, Inc

Naspro 2006 RCT Italy
European Urology 2006;50:563-8

Intervention
Holmium laser enucleation vs open enucleation
24 months

Population
HoLEP 41 pat DO: 12 mo % 24 mo
OE 39 pat DO: 12 mo % 24 mo

	HoLEP	OE
Age	66.26±6.55	67.27±6.72
Q_{max}	7.83±3.42	8.32±2.37
Pvol	113.27±35.33	124-21±38.52
IPSS	20.11±5.84	21.60±3.24
QoL	4.07±0.93	4.44±0.96

Mean ±SD

Inclusion criteria:
AUASS ≥8, Q_{max} ≤12ml/s, Vres ≥50ml, Schäfer grade ≥2, Pvolume ≥100 cm^3on TRUS

Exclusion criteria:
Previous prostate or urethral surgery, non-BPH-related voiding issues, positive for prostate cancer in prestudy screening biopsies

Results

Q_{max}	HoLEP	OE	*p*
BL	7.83±3.42	8.32±2.37	
12 mo	22.32±3.8	24.21±6.49	*0.27*
24 mo	19.19±6.3	20.11±8.8	*0.91*

Mean ±SD

IPSS	HoLEP	OE	*p*
BL	20.11±5.84	21.60±3.24	
12 mo	8.45±5.87	8.40±6.0	*0.98*
24 mo	7.9±6.2	8.1±7.1	*0.44*

Mean ±SD

QoL	HoLEP	OE	*p*
BL	4.07±0.93	4.44±0.96	
12 mo	1.7±0.94	1.77±0.83	*0.85*
24 mo	1.5±0.87	1.66±0.76	*0.76*

Mean ±SD

Adverse events

	HoLEP	OE	*p*
Hospital time (days)	2.7±1.1	5.43±1.05	*<0.0001*
Op time (min)	72.09±21.22	58.31±11.95	*<0.0001*
Cath days	1.5±1.07	4.1±0.5	*<0.0001*

Mean ±SD

Early	HoLEP	OE
Transfusion	4(2)	18(7)
Bladder mucosal injury	7(3)	0
Hemorrhage	2(1)	0
Transitory urge incontinence	34(14)	39(17)
Stress incontinence	2(1)	3(1)
AUR	12(5)	5(2)

%(n)

Late	HoLEP	OE
Urge incontinence	5(2)	9(3)
Bladder/Urethral Stricture	8(3)	9(3)
Prostate cancer	11(4)	11(4)
Dysuria	14(5)	11(4)
Reintervention	5(2)	6(2)

%(n)

Quality of evidence: Low–moderate
Conclusion: HoLEP provides comparable function to OE and is safer.
Internal validity: Not blinded. Randomization described. External validity: Eligible patients not reported.
Comments: ITT not used.
Sponsorship: None declared

Kuntz 2008 RCT Germany
European Urology 2008;53:160-8
(Earlier results in Kuntz 2004 J Endourology 18:189-91 and Kuntz 2002 J Urology 2002;168:1465-9)

Intervention
Holmium laser enucleation vs open enucleation
60 months

Population
HoLEP 60 pat DO: 12 mo 7% 36 mo 20% 60 mo 30%
OE 60 pat DO: 12 mo 18% 36 mo 33% 60 mo 53%

	HoLEP	OE
Age	69.2±8.4 (56–89)	71.2±8.3 (54–89)
Q_{max}	3.8±3.6 (0–10)	3.6±3.8 (0–12)
Pvol	114.6±21.6 (100–230)	113.0±19.2 (100–200)
IPSS	22.1±3.3 (11–30)	21.0±3.6 (13–28)

Mean ±SD(range)

Inclusion criteria:
AUASS ≥8, Q_{max} ≤12 ml/s, Vres ≥50 ml, Schäfer grade ≥2, Pvolume ≥100 cm^3 on TRUS

Exclusion criteria:
Previous prostate or urethral surgery, non-BPH-related voiding issues, positive for prostate cancer in prestudy screening biopsies

Results

Q_{max}	HoLEP	OE	*p*
BL	3.8±3.6 (0–10)	3.6±3.8 □0–12)	*0.60*
12 mo	27.4±9.7 (11–49)	28.3±7.5 (12–49)	*0.86*
24 mo	26.7±8.3 (14–57)	27.4±6.8 (13–51)	*0.65*
36 mo	27.0±9.8 (8–50)	25.3±6.9 (11–47)	*0.32*
48 mo	27.7±9.6 (8–53)	25.0±8.3 (11–54)	*0.20*
60 mo	24.3±10.1 (8–54)	24.4±7.4 (11–49)	*0.97*

Mean ±SD (range)

IPSS	HoLEP	OE	*p*
BL	22.1±3.3 (11–30)	21.0±3.6 (13–28)	*0.09*
12 mo	2.3±2.0 (0–11)	2.3±1.7 (0–7)	*0.94*
24 mo	2.3±2.2 (0–12)	2.4±1.6 (0–8)	*0.89*
36 mo	3.0±3.1 (0–16)	2.8±1.6 (0–9)	*0.82*
48 mo	3.0±3.1 (0–10)	2.8±1.9 (0–9)	*0.68*
60 mo	3.0±3.2 (0–10)	3.0±1.7 (1–9)	*0.98*

Mean ±SD (range)

Adverse events

	HoLEP	OE	*p*
Hospital time (h)	69.6±36.4 (24–192)	251.0±45.5 (216–552)	*<0.0001*
Op time (min)	135.9±31.2 (80–216)	90.6±19.5 (55–135)	*<0.0001*
Cath time (h)	30.8±17.3 (24–144)	194.4±20.1 (168–288)	*<0.0001*

Mean ±SD (range)

Early	HoLEP	OE
Transfusion	0	13(8)
Recatheterization	5(3)	5(3)
Hemorrhage	5(3)	5(3)
Second resection	3(2)	0
	%(n)	
Late	HoLEP	OE
Bladder neck stenosis	2(1)	5(3)
Urethral Stricture	3(2)	2(1)
Death	5(3)	13(8)
Persistent Incontinence	3(2)	0
	%(n)	
Sexual function	HoLEP	OE
Retrograde ejaculation	70	79
Erectile dysfunction	9	10
Improved erectile function	2	0

% of sexually active patients

Quality of evidence: Moderate
Conclusion: HoLEP highly effective for deobstruction of BOO.
Internal validity: Not blinded. Randomization sparsely described. External validity: Eligible patients not reported. Comments: ITT not used.
Sponsorship: None declared

Horasanli 2008 RCT Turkey
Urology 71: 247–251

Intervention
PVP 80 W vs TURP
6 months

Population
PVP 39 patients
TURP 37 patients
No dropouts

	PVP	TURP
Age	69.2±7.1 (59–78)	68.3±6.7 (58–76)
Q_{max}	8.6±5.2 (4–14)	9.2±5.6 (5–14)
Pvolume	86.1±8.8 (73–103)	88±9.2 (72–108)
IPSS	18.9±5.1 (7–32)	20.2±6.8 (6–32)
PSA	5.2±4.5 (2.8–20)	4.7±3.8 (2.2–19)
Vres	183±50.1 (156–360)	176.9±45.3 (154–340)

Mean ±SD (Range)

Inclusion criteria:
Symptoms of BOO due to BPH, Q_{max} <15 ml/s or Vres>150 ml IPSS>7, Pvol 70–100ml

Exclusion criteria:
Neurogenic bladder disorder, urethral strictures, Vres>400 ml, history of adenocarcinoma of the prostate or any previous prostatic, bladder neck or urethral surgery

Results

Q_{max}	PVP	TURP	*p*
BL	8.6±5.2	9.2±5.6	
3 mo	14.1±8.7	21.3±12.8	0.02
6 mo	13.3±7.9	20.7±11.3	0.02

Mean ±SD

IPSS	PVP	TURP	*p*
BL	18.9±5.1 (7–32)	20.2±6.8 (6–32)	
3 mo	11.2±7.6 (4–24)	6.1±5.4 (2–14)	0.01
6 mo	13.1±5.8 (4–26)	6.4±7.9 (2–16)	0.01

Mean ±SD (range)

Adverse events

	PVP	TURP
Days in hosp	2±0.7 (1–3)	4.8±1.2 (1–6)
Op time	87±18.3 (60–110)	51±17.2 (43–95)
Kath time	1.7±0.8 (1–3)	3.9±1.2 (2–7)

Early	PVP	TURP
Transfusion	0	8 (3)
AUR/CUR	15(6)	3(1)
Capsular perforation	0	3(1)
TURP syndr	0	0
Death	0	0

Late	PVP	TURP
Reoperation	18(7)	0
Urethral stricture	5(2)	8(3)
Retrograde ejaculation	51(19)	57(21)
Incontinence	0	0
UTI	15(6)	14(5)

Quality of evidence: Low.
Conclusion: Treatment with PVP results in higher intraoperative safety than TURP. Functional results lower with PVP, especially when treating larger glands.
Internal validity: Randomization not described. Not blinded. External validity: Eligible patients not reported. Comments: Surgical procedure well documented.
Sponsorship: Not mentioned

6.10 KTP - laser

Bouchier-Hayes 2009 RCT Australia
BJU International 105:964-969 (Early results in J Endourology 20:580-5)

Intervention
PVP 80 W vs TURP
12 months

Population
PVP 60 patients DO: 12 mo 7
TURP 59 patients DO: 12 mo 9
No dropouts

	PVP	TURP
Age	65.06 (51–81)	66.36 (55–80)
Q_{max}	8,86±2.99 (3.1–15)	8.81±2.55 (4–14.3)
Pvolume	38.78 (15.02–82.6)	33.36 (15.3–67.54)
IPSS	25.41±5,72 (14–35)	25.28±5.93 (16–35)
Bother score	3,26±0,97 (1–4)	3,45±0,85 (1–4)

Mean ±SD (Range)

Inclusion criteria:
>50 years, referred by family physician for LUTS, Q_{max} ≤15 ml/s, IPSS ≥12, gland 15–85 cm^3 on TRUS, obstructed on A-G nomogram, able to complete QoL, Bother score and BSFQ questionnaires, able to give fully informed consent

Exclusion criteria:
Neurogenic bladder, known or suspected prostate cancer, chronic retention, taking alpha-blocker (unless stopped 2 weeks before study entry), taking herbal medication believed active in the prostate (unless stopped 1 week before study entry), permanently on anticoagulant, taking finasteride or dutasteride

Results

Q_{max}	PVP	TURP	*p*
BL	8.86 ±2.99 (3.1–15)	8.81 ±2.55 (4–14.3)	
3 mo	17.99 ±10.06 (4.7–48)	19.52 ±7.60 (9.5–44.8)	NS
6 mo	17.31 ±8.27 (4.9–39.5)	20.43 ±6.59 (10–33.3)	<0,05
12 mo	19.37 ±8.67 (7.2–40.9)	18.6 ±8.2 (1.7–43.1)	0.286

Mean ±SD (range)

IPSS	PVP	TURP	*p*
BL	25.41±5.72 (14–35)	25.28±5.93 (16–35)	
3 mo	11.36 ±8.5 (0–28)	11.13 ±7.3 (1–30)	NS
6 mo	11.69 ±9.98 (0–32)	11.15 ±8.61 (0–30)	NS
12 mo	10.91 ±9.38 (0–35)	8.86 ±7.6 (1–35)	0.101

Mean ±SD (range)

Bother	PVP	TURP	*p*
BL	3.26±0.97 (1–4)	3.45±0.85 (1–4)	
3 mo	1.84 ±1.08 (0–4)	2.27 ±1.48 (1–4)	NS
6 mo	1.77 ±1.09 (0–4)	1.71 ±0.9 (1–4)	NS
12 mo	1.64 ±1.02 (1–4)	1.63 ±1.15 (0–4)	NS

Mean ±SD (range)

Adverse events

	PVP	TURP
Days in hosp	1.1 ±0.44 (1–2)	3.28 ±1.01 (2–9)
Op time	30.13 (9–70)	34.3 (5–70)
Cath time (h)	13.8 ±9.6 (0–24)	44.2 ±33.6 (6–192)

Mean ±SD (range)

Early	PVP	TURP
Transfusion	0	2(1)
AUR/CUR	2(1)	3(2)
Clot retention	5(3)	29(17)
TURP syndr	0	2(1)
Death	0	2(1)*
Hemorrhage	2(1)	5(3)
Re-admission	2(1)	5(3)
Dysuria	8(5)	12(7)
	% (n)	

*Patient died before treatment

Late	PVP	TURP
Reoperation	10(6)	3(2)
Bladder neck/ meatal stenosis	7(4)	7(4)
Retrograde ejaculation	NR	NR
Incontinence	NR	NR
UTI	8(5)	3(2)
	% (n)	

No difference in sexual function before and after treatment or between groups.

Quality of evidence: High.
Conclusion: PVP effective compared to TURP.
Internal validity: Randomization described. Not blinded. External validity: Eligible patients not reported.
Comments: Power calculated. ITT used.
Sponsorship: None declared