Diagnostics and treatment of provoked vestibulodynia

SBU ASSESSMENTS | ASSESSMENT OF METHODS IN HEALTH CARE AND SOCIAL SERVICES

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Summary and conclusions

Background

Provoked vestibulodynia (localised provoked vulvodynia) is a condition characterised by pain in the vestibular region of the vulva, present in sexual and nonsexual situations. The prevalence is highest among young women. Provoked vestibulodynia has a negative impact on the women's sexual relations, wellbeing and quality of life.

Aim

The aim was to assess the scientific evidence for methods of diagnosing and treating provoked vestibulodynia through a systematic review. In addition, social and ethical aspects were addressed.

Method

A systematic review was conducted in accordance with the PRISMA statement. The certainty of evidence was assessed with GRADE.

Inclusion criteria:

PICO for treatment studies

Population: Women with provoked vestibulodynia in premenopausal age (study populations with up to 25% postmenopausal women were accepted).

Interventions:

- Pharmaceutical treatment
- Surgery
- Physiotherapy
- Psychological and psychosocial treatment or counselling

Conclusions

- It is not possible to estimate the effects of pharmacological treatment for provoked vestibulodynia from scientific studies, as the certainty of evidence is very low. For the same reason, it is not possible to estimate the effects of psychological treatments (various forms of cognitive behavioral therapy and mindfulness) or surgery.
- Multi modal physiotherapy (manual treatment, patient education, pelvic floor treatment and home exercises) may significantly reduce dyspareunia and improve sexual function, compared with topical treatment with lidocaine gel (low certainty of evidence).
- There are no well-conducted studies on diagnostic methods for provoked vestibulodynia.
- There is a need for well-conducted studies on treatment of provoked vestibulodynia. In particular, there is a need for studies on the effect of combined and multi professional treatments. To facilitate evidence synthesis and effect estimates, it is desirable to establish a core outcome set (an agreed set of outcomes that should be measured and reported in all clinical trials).

Several different treatments with diverse mechanisms of action were identified in the review but in most cases only one small or medium-sized study was found. This limited the possibilities to synthesize results and reach reliable conclusions about effects. Lack of evidence does not imply, however, that an intervention lacks effect, but rather that its effect has not been sufficiently researched.

The lack of evidence regarding diagnostic methods is regarded as less problematic, while a patient's anamnesis in addition to the clinical investigation often is sufficient for an experienced clinician to confirm diagnosis.

- Team based/ multiprofessional treatment
- Multimodal/ combined treatment
- Other treatments

Control: No treatment, wait-list, placebo or other defined treatment.

Outcome:
- Dyspareunia
- Pain upon pressure or touch
- Sexual function or satisfaction
- Quality of life
- Anxiety and depression
- Adverse effects and complications

Study design: Randomized controlled trials (RCT) and non-randomized studies of interventions (NRSI) with a comparison group.

PIRO for diagnostic studies

Population: Women with provoked vestibulodynia in premenopausal age

Intervention: All diagnostic tests and methods

Reference test: Clinical diagnosis

Outcome: Sensitivity and specificity

PICO for diagnostic studies

Population: Women with provoked vestibulodynia in premenopausal age

Intervention: All diagnostic tests and methods

Control: No diagnostic test or another diagnostic test

Outcome: Positive and negative effects of the test

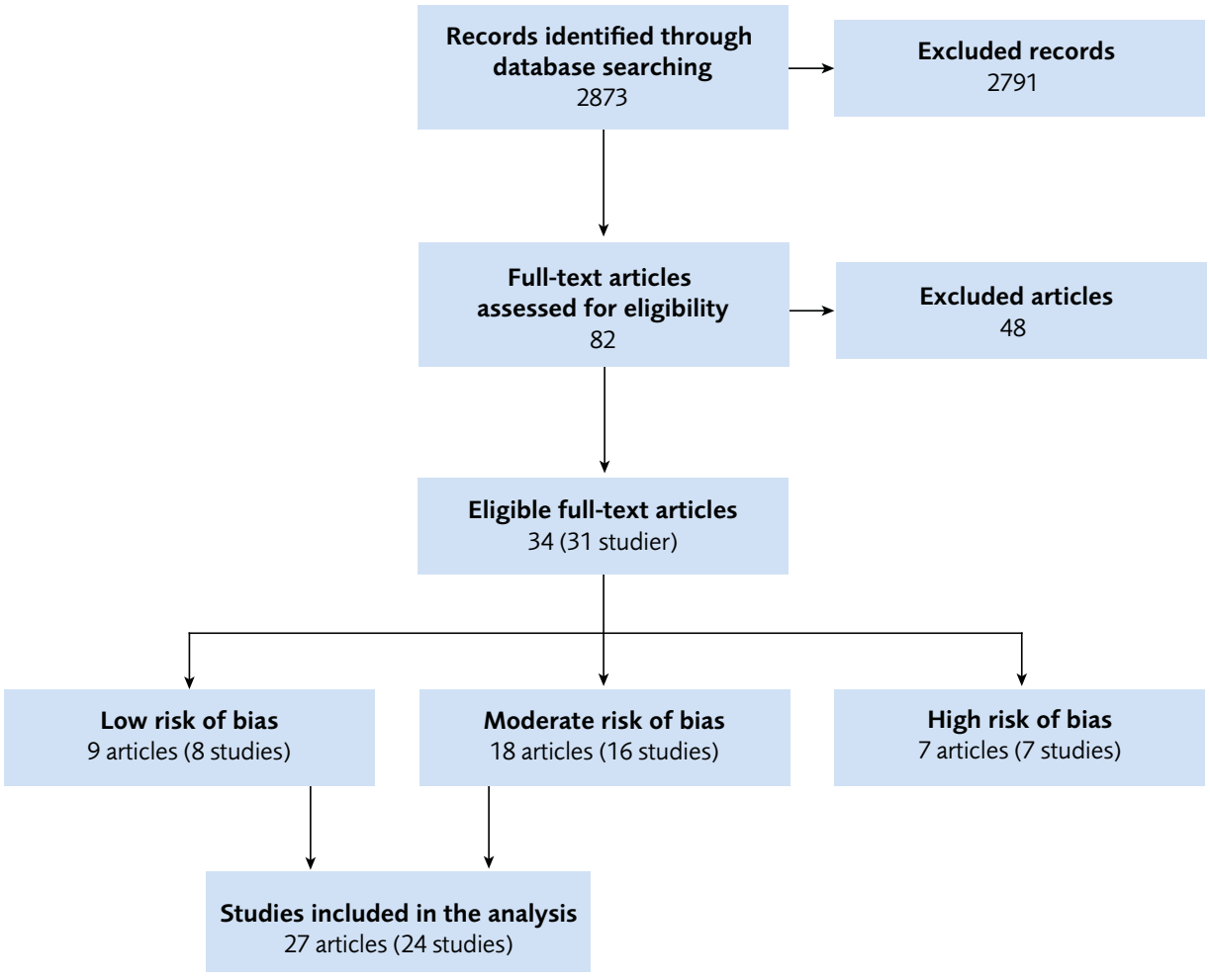

Figure 1 Flow Chart.

Language:
English, Swedish, Norwegian or Danish.

Search period:
From 1990 to 2021. Final search January 2021.

Databases searched:
CINAHL (EBSCO), Cochrane Library (Wiley), Embase (Elsevier), Ovid (MEDLINE), PsycINFO (EBSCO) and Scopus (Elsevier).

In addition, the following sources were searched for systematic reviews used for information: International HTA database, CRD Database (including HTA Database, DARE, NHS EED), Epistemonikos, Evidence search (NICE), KSR Evidence and PROSPERO.

Client/patient involvement:
Yes.

Results

No eligible studies on diagnostic methods with low or moderate risk of bias were identified in the assessment.

Regarding treatment methods, 24 studies with low or moderate risk of bias were identified that investigated 26 unique comparisons of interventions (Table 1).

Table 1 Overview of treatment methods that are included in the assessment.

Treatment form	Intervention	Comparison	Number of studies, study design	Number of study participants
Pharmacological treatment, oral	Gabapentin	Placebo	1 RCT	89
	Desipramine	Placebo	1 RCT	65
	Desipramine + lidocaine	Placebo	1 RCT	67
	Palmitoylethanolamide+ transpolydatine	Placebo	1 RCT	20
Pharmacological treatment, topical	Nifedinpine	Placebo	1 NRSI	50
	Fibroblast lysate	Placebo	1 RCT	30
	Lidocaine	Placebo	1 RCT	66
	Estrogen	Placebo	1 RCT	20
	Diazepam	Placebo	1 RCT	42
	Cromolyn	Placebo	1 RCT	34
Pharmacological treatment, injection	Botulinum toxin	Placebo	3 RCT	174
	Enoxaparin	Placebo	1 RCT	38
Physiotherapy	EMG biofeedback	Lidocaine	1 RCT	46
	Traditional acupuncture	Non-traditional acupuncture	1 RCT	19
	Multimodal physiotherapy	Lidocaine	1 RCT	212
	TENS	Sham treatment	1 RCT	20
Psychological treatment	Group CBT	Hydrocortisone	1 RCT	87
	Group CBT	Biofeedback or vestibulectomy (3-arm)	1 RCT	97
	Mindfulness-based cognitive therapy	CBT	1 NRSI	47
	CBT	Physiotherapy	1 RCT	20
	Mindfulness-based CBT	Education support	1 RCT	31
Other treatments	Low-level laser therapy	Sham treatment	1 RCT	34
	Transcranial direct-current stimulation	Sham treatment	1 RCT	40
	Shock wave therapy	Sham treatment	1 RCT	34

CBT = *Cognitive Behavioral Therapy*; **NRSI** = *Non-Randomised Studies of Interventions*; **RCT** = *Randomised Controlled Study*; **TENS** = *Transcutaneous Electric Nerve Stimulation*

Ethical and Social Aspects

The uncertainty regarding the effects of treatments for provoked vestibulodynia makes it difficult to help affected patients. This is unfortunate as the condition not only causes pain but also has psychosocial consequences. According to a previous Swedish report, patients have experienced difficulties in gaining access to investigation and treatment, and they do not always feel that they are taken seriously by the care staff. It is therefore important to improve the knowledge about provoked vulvodynia for healthcare professionals who meet women with the condition.

Conflicts of Interest

In accordance with SBU's requirements, the experts and scientific reviewers participating in this project have submitted statements about conflicts of interest. These documents are available at SBU's secretariat. SBU has determined that the conditions described in the submissions are compatible with the experts' participation in the project.

The full report in Swedish

The full report "Diagnostik och behandling av provocerad vulvodyni" (in Swedish), www.sbu.se/325

Appendices

- Characteristics of included studies
- Search strategies
- Excluded articles and studies with high risk of bias

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