

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

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# Summary and conclusions

# Background

Diastasis of the rectus abdominis muscle (DRAM) occurs when the midline fascia (linea alba) widens. It is a common condition in women after pregnancy but can also occur after significant weight loss or due to other causes. In some women the gap between the abdominal muscles spontaneously close during the first year after childbirth. The proportion of women with a persisting DRAM is not known, nor are the long-term consequences of the condition understood. The symptoms caused by DRAM are currently uncertain, but some studies indicate it may be associated with abdominal pain, impaired physical function, and reduced health related quality of life. DRAM can also affect the aesthetic appearance negatively and has been suggested to be linked to pain in the lower back and pelvis as well as urogenital conditions.

Treatment usually starts with physical exercise to reduce the slack of linea alba and improve the ability of the abdominal and core muscles to maintain stability of the torso. In some cases, where physical treatment fails, surgical correction can be considered. There is currently no clear consensus in Sweden regarding how or when DRAM should be treated, correspondingly there are regional differences in the care provided.

# Aim

This systematic review was conducted to assess the current evidence for treatment of symptomatic DRAM in women, this includes:

- 1. the effect of interventions for treating DRAM: reduction of the inter-recti distance (IRD), alleviation of symptoms, improvement of function and health related quality of life
- 2. the adverse effects of treatments for DRAM
- 3. the cost-effectiveness of treatments for DRAM

The report also includes a chapter on ethical considerations.

#### Method

A systematic review conducted in accordance with the PRISMA statement. The protocol is registered in Prospero (CRD42021236961). The certainty of evidence was assessed with GRADE.

The chapter on ethical considerations is based on discussions with the clinical experts involved in the project as well as with a focus group. The focus group consisted of women who had experienced DRAM personally or who were a close relative to a woman who had experienced DRAM. The purpose was to bring up important ethical aspects to consider in relation to DRAM and possible treatment of the condition and its consequences.

# Conslusions

- The available evidence is insufficient to evaluate the effect of physiotherapeutic or surgical interventions for treating women with symptomatic diastasis recti.
- There is insufficient evidence to determine the cost-effectiveness of treatments for diastasis recti in women.
- There is a need for more research with a prospective and controlled study design to guide clinicians on if and how diastasis recti should be treated, and which women will benefit from physiotherapy or surgery. Future clinical trials should further evaluate outcomes such as physical function, disability, and health related quality of life.

#### Inclusion criteria:

#### Population

Women with symptomatic DRAM after pregnancy, weight loss or caused by unspecified/unknown causes.

All participants must have a clinical diagnosis of DRAM of >2 cm or two finger widths. Women must comprise at least 3⁄4 of the study population, if not reported separately.

## Intervention

Methods intended to treat DRAM or consequences of the condition: relevant modalities include physiotherapy and surgery. The methods must be deemed to be relevant for the Swedish health-care system.

# Control

No treatment, sham treatment, treatment as usual or an active treatment option.

## Outcome

- Diastasis (curative effect, diastasis width, recurrence)
- Effect on symptoms
- Physical function
- Disability
- Health related quality of life
- Adverse effects and complications, as reported in the included intervention studies

# Study design

Prospective clinical trials, with or without randomisation, and with a control group.

Language: Danish, English, Norwegian, Swedish.

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

**Databases searched:** Medline, EMBASE, Cochrane Library (CDSR, DARE & CENTRAL), PEDRO and Cinahl

# Client/patient involvement: Yes

# Results

Outcomes from five RCT:s (including one quasi-RCT) are included in this systematic review (Figure 1). Four focused on physiotherapeutic interventions and one on a comparison of two surgical interventions.

## **Health Economic Assessment**

No studies on the cost-effectiveness of interventions were identified. The cost-effectiveness of treatments could not be estimated due to the lack of evidence on treatment effects. Studies on the effect of treatment as well as the direct and indirect costs associated with treatment of DRAM are needed to estimate the cost-effectiveness of physiotherapeutic and surgical treatment of DRAM.

# Ethics

In brief, it is important that women with symptomatic DRAM receives a good level of care and that the symptoms attributed to DRAM are examined. There is a risk that the lack of evidence for the treatment of DRAM may lead to women not receiving adequate care, or qualitative differences in the care provided. For healthcare providers the current situation is challenging due to the lack of evidence for treatments, and the insufficient knowledge regarding the symptoms caused by DRAM or of the long-term consequences of DRAM if left untreated. The condition has potentially both aesthetic and medical consequences, further complicating the clinical assessment.

## Discussion

Only five studies were identified that reported the effects of treatment of DRAM in women. The studies were heterogenous with respect to the treatment, the control, and the outcomes reported. Due to this heterogeneity only the results from two studies could be combined. The certainty of the evidence is therefore very low ( $\oplus OOO$ ) across all interventions and outcomes.

Different forms of physiotherapy were investigated in four studies. In general, the women had a moderate DRAM and the treatment started within a few months post-partum. However, the symptoms attributed to the condition at enrollment were not reported. This leads to uncertainty on the effect of treatment for women with more severe or more persistent DRAM, or for those reporting specific symptoms. None of the studies reported adverse events of the treatment, and only one study reported a long term follow up after the end of the treatment.

One study compared surgical correction of DRAM with reinforcement of the linea alba using a surgical mesh implant to using sutures alone, in parous women. The study also reported the effect of the two surgical techniques to that of physical exercise on physical function (VHPQ), at the end of the 3-month exercise programme. For the patients undergoing surgery, adverse effects were reported at 3 months after surgery and the outcomes were reported for up to one to five years after the intervention. However, the lack of more studies limits the certainty of the evidence.

Further research is needed to assess the effect of interventions for DRAM, and on patient groups with different indications for treatment. There is a need for studies which assess how the treatment effect is affected by factors such as age, cause of and duration of the DRAM. Clinical studies need to put greater emphasis on evaluating the effect of treatment on potential consequences of DRAM by including outcomes on physical function, disability, and health-related quality of life. Also, studies investigating the long-term effects and cost-effectiveness of treatments are needed.

The lack of evidence should not be interpreted as a lack of effect for the treatments, at present the evidence is too limited to draw any conclusion. For a study to be included in this review, the participants had to have a DRAM of more than 2 cm. However, a DRAM of more than 2 cm may not cause any symptoms and should not in itself be regarded as a condition that requires medical treatment.



# Table 1 Summary of findings.

Outcome	Number of studies	Results	Certainty
	and participants	MD/RR (95% CI)	of evidence
Physical exercise compared w	ith no treatment, end o	of treatment	
Width of DRAM	1 RCT	MD (SD): −1.09 cm (0.63) vs. −0.13 cm (0.31)	Very low <sup>3</sup>
	n=17	(p≤0.05)	⊕○○○
Resolution of DRAM	1 RCT	RR: 1.11 (0.5 to 2.49) <sup>A</sup>	Very low <sup>3</sup>
(<2 fingerwidths)	n=96	(n.s., p>0.05)	⊕○○○
Physical function – Pelvic floor	1 RCT	MD: 2.80 (–10.01 to 15.61) <sup>E</sup>	Very low <sup>3</sup>
(PFDI-20)	n=13	(n.s., p>0.05)	⊕○○○
Disability – Pain related	1 RCT	MD: -0.30 (-5.63 to 5.03) <sup>F</sup>	Very low <sup>3</sup>
disability (RDQ)	n=13	(n.s., p>0.05)	⊕○○○
Physical exercise in combinati	on with taping compar	ed with no treatment, end of treatment	
Reduction in width of DRAM	1 RCT	MD (SD): −1.07 cm (0.66) vs. −0.13 cm (0.31)	Very low <sup>3</sup>
	n=12	(p≤0.05)	⊕○○○
Physical function – Pelvic floor	1 RCT	MD: 14.80 (–11.65 to 41.25) <sup>E</sup>	Very low <sup>3</sup>
(PFDI-20)	n=10	(n.s., p>0.05)	⊕○○○
Disability – Pain related	1 RCT	MD: −1.00 (−6.26 to 4.26) <sup>F</sup>	Very low <sup>3</sup>
disability (RDQ)	n=10	(n.s., p>0.05)	⊕○○○
Taping compared with no trea	tment, end of treatme	nt	
Width of DRAM	1 RCT	MD (SD): -0.29 cm (0.28) vs0.13 cm (0.31)	Very low <sup>3</sup>
	n=15	(n.s., p>0.05)	⊕○○○
Physical function – Pelvic floor	1 RCT	MD: 10.40 (–3.67 to 24.47) <sup>E</sup>	Very low <sup>3</sup>
(PFDI-20)	n=9	(n.s., p>0.05)	⊕○○○
Disability – Pain related	1 RCT	MD: −0.30 (−6.99 to 6.39) <sup>⊧</sup>	Very low <sup>3</sup>
disability (RDQ)	n=9	(n.s., p>0.05)	⊕○○○
Physical exercise in combinati	on with NMES compar	ed with physical exercise, end of treatment	
Width of DRAM	1 RCT & 1 quasi-RCT n=93	MD: -0.36 cm (-0.46 to -0.26)	Very low <sup>1,2</sup> ⊕○○○
Symptoms – body image (BAS)	1 RCT	MD: 0.71 (0.52 to 0.90) <sup>в</sup>	Very low <sup>3</sup>
	n=36	(p≤0.05)	⊕○○○
Physical function – abdominal muscle strength (dynamometer)	1 RCT & 1 quasi-RCT n=93	Peak torque (Nm): MD: 5.14 (3.29 to 6.99) <sup>c</sup> Average power (W): MD: 3.85 (2.64 to 5.07) <sup>c</sup> Total work (J): MD: 6.05 (4.14 to 7.95) <sup>c</sup> Endurance (reps.) <sup>D</sup> : MD: 8.33 (6.38 to 10.28) <sup>c</sup>	Very low <sup>1,2</sup> ⊕○○○
Physical exercise compared w	ith surgical treatment	with mesh implant, 3 months after treatment	
Physical function – effect of	1 RCT	No significant difference between the groups for 8/9 items on the VHPQ	Very low <sup>3</sup>
pain on function (VHPQ)	n=57		⊕○○○
Physical exercise compared w	ith surgical treatment	with suture alone, 3 months after treatment	
Physical function – disability	1 RCT	No significant difference between the groups for any of the items on the VHPQ	Very low <sup>3</sup>
(VHPQ)	n=58		⊕○○○
Surgical treatment with mesh	implant compared wit	h suture alone, 1 year after treatment	
Recurrence of DRAM (≥3 cm)	1 RCT n=57	RR: 3.10 (0.13 to 73.12), (n.s., p>0.05) <sup>g</sup>	Very low <sup>3</sup> ⊕○○○
Physical function – abdominal	1 RCT	Difference between groups reported to be n.s. (p>0.05)	Very low <sup>3</sup>
muscle strength (dynamometer)	n=56		⊕○○○
Physical function – abdominal	1 RCT	Median (SD): 7 (2.62) vs. 8 (2.08)	Very low <sup>3</sup>
muscle strength (self-reported)	n=56	(n.s., p>0.05)	⊕○○○

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#### Table 1 continued

Outcome	Number of studies and participants	Results MD/RR (95% CI)	Certainty of evidence
Physical function – effect of pain on function (VHPQ)	1 RCT n=56	No statistically significant difference between the groups for 6/9 items on the VHPQ	Very low <sup>3</sup> ⊕○○○
HRQoL (SF-36, reported for 8 subscales)	1 RCT n=57	3/8 subscales (GH, VT & MH) indicate benefit for mesh implant (p $\leq$ 0.05).	Very low <sup>3</sup> ⊕○○○

**BAS** = Body Appreciation Scale; **CI** = Confidence Interval; **HRQoL** = Health-Related Quality of Life; **MD** = Mean Difference; **n.s.** = Non-Significant result; **PFDI-20** = Pelvic Floor Distress Inventory, 20-items; **RCT** = Randomised Controlled Trial; **RDQ** = Roland-Morris Disability Questionnaire; **reps.** = Repetitions; **RR** = Relative Risk; **SD** = Standard Deviation; **SF-36** = Medical Outcomes Study 36-item Short-Form Health Survey; **VHPQ** = Ventral Hernia Pain Questionnaire.

<sup>A</sup> RR over 1 indicates a higher proportion of resolution in DRAM in the intervention group compared to the control group.

- <sup>B</sup> BAS. A positive value indicates a better outcome for the combination treatment. Range 1–5, higher score indicates greater body appreciation.
- <sup>c</sup> A positive value indicate a better outcome for the combination treatment compared to physical exercise alone.
- <sup>D</sup> Results from 1 RCT with 36 participants.
- <sup>E</sup> A positive value indicates a worse outcome for the intervention, range 0 (least distress) to 300 (greatest distress).
- <sup>F</sup> A negative value indicates a better outcome for the intervention group compared to the control group, range 0 (no disability) to 24 (severe disability).
- <sup>*G*</sup> RR over 1 indicate a higher proportion of recurrence in the mesh group compared to the suture groups.
- <sup>1</sup> Risk of Bias –2. Few studies with relatively few participants. Concerns about the RoB for one study. One study with per protocol analysis.
- <sup>2</sup> Directness –1. Both studies are from a specific context and have included a narrowly defined population.

<sup>3</sup> Only one study with relatively few participants, insufficient evidence to support any conclusions.

## **Conflicts of Interest**

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

#### Appendices

- Search strategies
- Excluded articles
- Risk of bias assessments
- Characteristics of included studies

#### The full report in Swedish

The full report in Swedish <u>Behandling av rektusdiastas</u> <u>hos kvinnor</u>

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