Laparoskopi ved endometriose mindsker smerte og bedrer fertilitetsprognosen – en gennemgang af to Cochranereview

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Endometriose er en hyppig, smertegivende sygdom hos kvinder i den fertile alder. Den nøjagtige incidens er vanskelig at angive, men oftest taler man om 6-10% af alle yngre kvinder. Symptomatologien er meget varierende og strækker sig fra moderate menstruationssmerter, som kan fjernes med smertestillende håndkøbsmidler, til svært invaliderende smerter, der medfører stort sygefravær og sociale problemer – ud over nedsat fertilitet. Diversiteten af symptomer medfører dels problemer i diagnosticering af tilstanden med udtalt *doctors delay* [1] og dels stor variation i behandlingen.

Behandlingen er en kombination af medicinsk og kirurgisk intervention. Førstevalg vil almindeligvis være medicinsk behandling i form af enten p-piller eller gestagenspiral. Den endelige diagnose stilles ved laparoskopisk verificering af endometrioseforandringer, men den medicinske behandling kan fint initieres på mistanken alene. Ved manglende effekt bør patienten henvises til en gynækologisk vurdering. Den medicinske behandling i form af enten p-piller eller gestagenspiral forhindrer opnåelse af graviditet, og patienter med endometriose og graviditetsønske har derfor en særlig problemstilling; hos en del af disse patienter vil kirurgisk behandling være indiceret.

Laparoskopisk kirurgi har gennem de seneste år været betragtet som guldstandard til både diagnosticering og kirurgisk behandling. *Duffy et al* [2] har i 2014 udarbejdet et Cochranereview under Cochrane Menstrual Disorder and Subfertility Group. I artiklen gennemgås litteraturen om effektivitet og sikkerhed af laparoskopisk kirurgi til behandling af smerter og subfertilitet ved endometriose. Der indgår ti randomiserede kliniske studier med i alt 973 patienter. I studierne sammenligner man laparoskopisk kirurgi med simpel diagnostisk laparoskopi eller én type laparoskopisk kirurgi med en anden type laparoskopisk kirurgi (excision vs. ablation).

Laparoskopisk kirurgi medfører sammenlignet med diagnostisk laparoskopi færre smerter efter seks måneder (oddsratio (OR): 6,58; 95% konfidens-interval (KI): 3,31-13,10; *grading of recommandations assessment, development and evaluation* (GRADE): moderat kvalitet) og efter 12 måneder. Laparoskopisk kirurgi bedrer *live birth rate* og *ongoing pregnancy rate* sammenlignet med diagnostisk laparoskopi (OR: 1,94; KI: 1,25-3,16; GRADE: moderat kvalitet). Tilsvarende bedring findes for *clinical pregnancy rate*. Data for komplikationsrate og spontan abort er inkonklusive. Man finder ingen forskel mellem laparoskopisk excision og laparoskopisk ablation med hensyn til smerteniveau.

Brown & Farquhar [3] har i 2014 publiceret et Cochranereview, som er en samlet gennemgang af tidligere Cochranereview om behandling af smerte og subfertilitet hos patienter med endometriose. Der beskrives 17 Cochranereview, der alle vurderes at være af høj kvalitet, men kvaliteten af de tilgrundliggende studier angives som meget lav til moderat.

Dette review omhandler både medicinsk, kirurgisk og alternativ behandling.

Hvad angår kirurgisk behandling af endometriose gentages resultaterne fra *Duffy et al* [2] og derudover resultaterne fra *Hart et al* [4]. Heri sammenlignes behandling af endometriosecyster (endometriomer), dvs. laparoskopisk excision (fuldstændig fjernelse) med laparoskopisk ablation (åbning af cystekapsel og koagulering af cystelejet). Der konkluderes, at der er færre recidiver af endometriomer ved laparoskopisk excision (OR: 0,41; KI: 0,18-0,93; GRADE: lav kvalitet), og at der er højere *clinical pregnancy rate* ved excision frem for ablation. Der er ingen forskel mellem kirurgisk behandling og ingen behandling af endometriomer, hvad graviditetsresultat angår (GRADE: lav kvalitet).

For den medicinske behandling er der evidens for, at gonadotropinfrisættende hormonanaloger (GnRHa) giver lavere smertescore end både placebobehandling og ingen behandling (relativ risiko: 3,93; KI: 1,37-11,28; GRADE: lav kvalitet) [5, 6]. Samtidig synes GnRHa at give flere bivirkninger end placebo. Behandling med gestagenspiral giver sjældnere recidiv af smerter end ingen behandling.

Hvad angår fertilitetsfremmende behandling, giver lang nedregulering med GnRHa forud for in vitro-fertilitetsbehandling højere *clinical pregnancy rate*

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ABSTRACT – OVERVIEW OF REVIEW

Endometriosis: an overview of Cochrane Reviews

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BACKGROUND

This overview reports on interventions for pain relief and for subfertility in pre-menopausal women with clinically diagnosed endometriosis.

OBJECTIVES

The objective of this overview was to summarise the evidence from Cochrane systematic reviews on treatment options for women with pain or subfertility associated with endometriosis.

METHODS

Published Cochrane systematic reviews reporting pain or fertility outcomes in women with clinically diagnosed endometriosis were eligible for inclusion in the overview. We also identified Cochrane reviews in preparation (protocols and titles) for future inclusion. The reviews, protocols and titles were identified by searching the Cochrane Database of Systematic Reviews and Archie (the Cochrane information management system) in March 2014.

Pain-related outcomes of the overviewwere pain relief, clinical improvement or resolution and pain recurrence. Fertility-related outcomes were live birth, clinical pregnancy, ongoing pregnancy, miscarriage and adverse events.

Selection of systematic reviews, data extraction and quality assessment were undertaken in duplicate. Review quality was assessed using the AMSTAR tool. The quality of the evidence for each outcome was assessed using GRADE methods. Review findings were summarised in the text and the data for each outcome were reported in 'Additional tables'.

MAIN RESULTS

Seventeen systematic reviews published in The Cochrane Library were included. All the reviews were high quality. The quality of the evidence for specific comparisons ranged from very low to moderate. Limitations in the evidence included risk of bias in the primary studies, inconsistency between the studies, and imprecision in effect estimates.

PAIN RELIEF (14 REVIEWS)

Gonadotrophin-releasing hormone (GnRH) analogues
One systematic review reported low quality evidence of an overall benefit for GnRH analogues compared with placebo or no treatment.

Ovulation suppression
Five systematic reviews reported on medical treatment using ovulation suppression. There was moderate quality evidence that the levonorgestrel-releasing intrauterine system (LNG-IUD) was more effective than expectant management, and very low quality evidence that danazol wasmore effective than placebo.Therewas no consistent evidence of a difference in effectiveness between oral contraceptives and goserelin, estrogen plus progestogen and placebo, or progestogens and placebo, though in all cases the relevant evidence was of low or very low quality.

Non-steroidal anti-inflammatory drugs (NSAIDS)
A review of NSAIDs reported inconclusive evidence of a benefit in symptom relief compared with placebo.

Surgical interventions
Therewere two reviews of surgical interventions.One reportedmoderate quality evidence of a benefit in pain relief following laparoscopic surgery compared to diagnostic laparoscopy only. The other reported very low quality evidence that recurrence rates of endometriomata were lower after excisional surgery than after ablative surgery.

Post-surgical medical interventions
Two reviews reported on post-surgical medical interventions. Neither found evidence of an effect on pain outcomes, though in both cases the evidence was of low or very low quality.

Alternative medicine
There were two systematic reviews of alternative medicine. One reported evidence of a benefit from auricular acupuncture compared to Chinese herbal medicine, and the other reported no evidence of a difference between Chinese herbal medicine and danazol. In both cases the evidence was of low or very low quality.

Anti-TNF- α drugs
One review found no evidence of a difference in effectiveness between anti-TNF-α drugs and placebo. However, the evidence was of low quality.

REVIEWS REPORTING FERTILITY OUTCOMES (8 REVIEWS)

Medical interventions
Four reviews reported on medical interventions for improving fertility in women with endometriosis. One compared three months of GnRH agonists with a control in women undergoing assisted reproduction and found very low quality evidence of an increase in clinical pregnancies in the treatment group. There was no evidence of a difference in effectiveness between the interventions in the other three reviews, which compared GnRH agonists versus antagonists, ovulation suppression versus placebo or no treatment, and pre-surgical medical therapy versus surgery alone. In all cases the evidence was of low or very low quality.

Surgical interventions
Three reviews reported on surgical interventions. There was moderate quality evidence that both live births or ongoing pregnancy rates and clinical pregnancy rates were higher after laparoscopic surgery than after diagnostic laparoscopy alone. There was low quality evidence of no difference in effectiveness between surgery and expectant management for endometrioma. One review found low quality evidence that excisional surgery resulted in higher clinical pregnancy rates than drainage or ablation of endometriomata.

Post-surgical interventions
Two reviews reported on post-surgical medical interventions. They found no evidence of an effect on clinical pregnancy rates. The evidence was of low or very low quality.

Alternative medicine
A review of Chinese herbal medicine in comparison with gestrinone found no evidence of a difference between the groups in clinical pregnancy rates. However, the evidence was of low quality.

ABSTRACT, CONTINUED

ADVERSE EVENTS

Reviews of GnRH analogues and of danazol reported that the interventions were associated with higher rates of adverse effects than placebo; and depot progestagens were associated with higher rates of adverse events than other treatments. Chinese herbal medicine was associated with fewer side effects than gestrinone or danazol.

Three reviews reported miscarriage as an outcome. No difference was found between surgical and diagnostic laparoscopy, between GnRH agonists and antagonists, or between aspiration of endometrioma and expectant management. However, in all cases the quality of the evidence was of low quality.

AUTHORS' CONCLUSIONS

For women with pain and endometriosis, suppression of menstrual cycles with gonadotrophin-releasing hormone (GnRH) analogues, the levonorgestrel-releasing intrauterine system (LNG-IUD) and danazol were beneficial interventions. Laparoscopic treatment of endometriosis and excision of endometriomata were also associated with improvements in pain. The evidence on NSAIDs was inconclusive. There was no evidence of benefit with post-surgical medical treatment.

In women with endometriosis undergoing assisted reproduction, three months of treatment with GnRH agonist improved pregnancy rates. Excisional surgery improved spontaneous pregnancy rates in the nine to 12 months after surgery compared to ablative surgery. Laparoscopic surgery improved live birth and pregnancy rates compared to diagnostic laparoscopy alone. There was no evidence that medical treatment improved clinical pregnancy rates.

Evidence on harms was scanty, but GnRH analogues, danazol and depot progestagens were associated with higher rates than other interventions.

(OR: 4,28; KI: 2,0-9,15, GRADE: meget lav kvalitet). Den spontane graviditetsrate bedres ikke af medicinsk behandling [7].

Evidensen for alternativ behandling er generelt meget sparsom. Akupunktur giver bedre smertereduktion end behandling med kinesiske urter (GRADE: lav kvalitet).

Dansk Selskab for Obstetrik og Gynækologi har udarbejdet guidelines om endometriose. I guideline for behandling af endometriomer anbefales det, at man generelt kun opererer endometriomer, hvis de giver smerter eller besværliggør oocytaspiration i forbindelse med in vitro-fertilitetsbehandling. Ved operation på grund af endometriomer anbefales excison frem for ablation. Den danske guideline er i fuld overensstemmelse med de omtalte Cochranereview.

I guideline for behandling af peritoneal endometriose angives, at laparoskopisk kirurgi reducerer underlivssmerter og forbedrer graviditetschancen. Det anbefales, at man ved fund af peritoneal endometriose fjerner alle synlige forandringer, idet dette giver bedre resultat vedrørende underlivssmerter og samtidig bedrer den spontane graviditetschance. Den danske guideline er også her i fuld overensstemmelse med Cochranereviewene.

De omtalte Cochranereview omhandler peritoneal eller mild til moderat endometriose. Behandling af infiltrerende eller avanceret endometriose omtales overhovedet ikke. Der foreligger ikke randomiserede undersøgelser, hvor man sammenligner laparoskopisk kirurgi af infiltrerende endometriose med diagnostisk kirurgi eller ingen behandling. Patienter med infiltrerende endometriose har ofte meget udtalte smerter og gennemgår ofte flere operationer. Det er hos denne patientgruppe vanskeligt at forestille sig randomiserede kliniske undersøgelser, idet patientpopulationen er meget heterogen, og det vil ikke være rimeligt kun at foretage diagnostisk laparoskopi. Der findes dog adskillige undersøgelser af operationer for avanceret endometriose, men der er tale om prospektive opgørelser af effekt på smerteniveau og fertilitet. Talrige undersøgelser viser god effekt af disse operationer, men fordi studierne ikke er randomiserede, indgår resultaterne ikke i Cochraneanalyserne.

Behandling af avanceret endometriose er en højtspecialiseret funktion, som varetages to steder i Danmark. Ifølge specialeplanen omfatter dette be-

Endometriosekirurgi skal være laparoskopisk. Foto: *Lars Kruse*, Aarhus Universitet.

ABSTRACT – INTERVENTION REVIEW

Laparoscopic surgery for endometriosis

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BACKGROUND
Endometriosis is the presence of endometrial glands or stroma in sites other than the uterine cavity and is associated with pain and subfertility. Surgical interventions aim to remove visible areas of endometriosis and restore the anatomy.

OBJECTIVES
To assess the effectiveness and safety of laparoscopic surgery in the treatment of painful symptoms and subfertility associated with endometriosis.

SEARCH METHODS
This reviewhas drawn on the search strategy developed by theCochraneMenstrualDisorders and SubfertilityGroup including searching CENTRAL, MEDLINE, EMBASE, PsycINFO, and trial registries from inception to July 2013.

SELECTION CRITERIA
Randomised controlled trials (RCTs) were selected in which the effectiveness and safety of laparoscopic surgery used to treat pain or subfertility associated with endometriosis was compared with any other laparoscopic or robotic intervention, holistic or medical treatment or diagnostic laparoscopy only.

DATA COLLECTION AND ANALYSIS
Selection of studies, assessment of trial quality and extraction of relevant data were performed independently by two review authors with disagreements resolved by a third review author. The quality of evidence was evaluated using GRADE methods.

MAIN RESULTS
Ten RCTs were included in the review. The studies randomised 973 participants experiencing pain or subfertility associated with endometriosis. Five RCTs compared laparoscopic ablation or excision versus diagnostic laparoscopy only. Two RCTs compared laparoscopic excision versus diagnostic laparoscopy only. Two RCTs compared laparoscopic excision versus ablation. One RCT compared laparoscopic ablation versus diagnostic laparoscopy and injectable gonadotropin-releasing hormone analogue (GnRHa) (goserelin) with add-back therapy. Common limitations in the primary studies included lack of clearly-described blinding, failure to fully describe methods of randomisation and allocation concealment, and risk of attrition bias.

Laparoscopic surgery was associated with decreased overall pain (measured as 'pain better or improved') compared with diagnostic laparoscopy, both at six months (odds ratio (OR) 6.58, 95% CI 3.31 to 13.10, 3 RCTs, 171 participants, I2 = 0%, moderate quality evidence) and at 12 months (OR 10.00, 95% CI 3.21 to 31.17, 1 RCT, 69 participants, low quality evidence). Compared with diagnostic laparoscopy, laparoscopic surgery was also associated with an increased live birth or ongoing pregnancy rate (OR 1.94, 95% CI 1.20 to 3.16, P = 0.007, 2 RCTs, 382 participants, I2 = 0%, moderate quality evidence) and increased clinical pregnancy rate (OR 1.89, 95% CI 1.25 to 2.86, P = 0.003, 3 RCTs, 528 participants, I2 = 0%, moderate quality evidence). Two studies collected data on adverse events (including infection, vascular and visceral injury and conversion to laparotomy) and reported no events in either arm. Other studies did not report this outcome. The similar effect of laparoscopic surgery and diagnostic laparotomy on the rate of miscarriage per pregnancy was imprecise (OR 0.94, 95% CI 0.35 to 2.54, 2 studies, 112 women, moderate quality evidence).

When laparoscopic ablation was compared with diagnostic laparoscopy plus medical therapy (GnRHa plus add-back therapy), more women in the ablation group reported that they were pain free at 12 months (OR 5.63, 95% CI 1.18 to 26.85, 1 RCT, 35 participants, low quality evidence).

The difference between laparoscopic ablation and laparoscopic excision in the proportion of women reporting overall pain relief at 12 months on a VAS 0 to 10 pain scale was 0 (95% CI -1.22 to 1.22, P = 1.00, 1 RCT, 103 participants, low quality evidence).

AUTHORS' CONCLUSIONS
There ismoderate quality evidence that laparoscopic surgery to treatmild andmoderate endometriosis reduces overall pain and increases live birth or ongoing pregnancy rates. There is low quality evidence that laparoscopic excision and ablation were similarly effective in relieving pain, although there was only one relevant study. More research is needed considering severe endometriosis, different types of pain associated with endometriosis (for example dysmenorrhoea (pain with menstruation)) and comparing laparoscopic interventions with holistic andmedical interventions.Therewas insufficient evidence on adverse events to allowany conclusions to be drawn regarding safety.

handling af endometriose i relation til septum rectovaginale eller retroperitoneal endometriose. Men andre typer af endometriose burde være tilføjet denne liste, f.eks. tarminfiltrater, blæreinfiltrater og infiltrater i relation til ureter. Patienter med såkaldt *kissing ovaries* (bilaterale endometriomer, der er beliggende tæt samlet bag uterus) burde også henvises til en højtspecialiseret funktion, idet der hos disse patienter er en klart øget forekomst af dyb infiltrerende endometriose [8]. Ved fund af avanceret endometriose eller mistanke herom bør patienten henvises til et højtspecialiseret center for diagnostik og vejledning, også selvom man ikke forventer, at der skal foretages operation.

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Postural ortostatisk takykardi-syndrom

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Stillingsændring fra liggende til stående er en basal fysiologisk udfordring, som kræver et effektivt kardiovaskulært kontrolsystem. Ved dysfunktion af dette kontrolsystem ses ortostatisk intolerans – typisk i form af utilstrækkelig vasokonstriktion og dermed ortostatisk hypotension eller i form af excessiv stigning i hjertefrekvensen.

Ortostatisk intolerans er en tilstand, hvor patienten i stående stilling har symptomer, som bedres i liggende stilling. Forbigående, let ortostatisk intolerans er normalt forekommende hos de fleste – f.eks. i form af svimmelhed ved hurtig overgang fra siddende til stående stilling. Nogle oplever sværere grader af ortostatisk intolerans. Dette kan være i form af akut ortostatisk intolerans, der er karakteriseret ved pludselige bevidsthedstab i oprejst stilling (synkope), ofte uden symptomer mellem episoderne, eller mere kroniske former for ortostatisk intolerans, hvor symptomerne er svimmelhed, palpitationer, træthed, kvalme og åndenød.

Yngre patienter med kronisk ortostatisk intolerans har sjældent egentlig ortostatisk hypotension, men ofte ortostatisk takykardi dvs. høj puls i forbindelse med ortostatisk stress [1] og tilstanden er ofte ledsaget af et betydeligt funktionstab og ses ikke sjældent med akutte forværringer i form af synkoper.

Sammen med en grundig anamnese er vippelejetest (**Figur 1**) central i diagnosticeringen af kronisk ortostatisk intolerans, men det er formentlig kun en brøkdel af patienterne med ortostatisk intolerans, der får foretaget en vippelejetest, og tilstanden skønnes at være markant underdiagnosticeret. Estimering af prævalensen er således vanskelig. I USA var antallet af patienter med kronisk ortostatisk intolerans estimeret til en halv million i 1999 [2]. Omsat til danske forhold vil det svare til, at ca. 10.000 er afficeret herhjemme.

I det efterfølgende beskrives postural ortostatisk takykardi-syndrom (POTS), da POTS i forhold til andre former for kronisk ortostatisk intolerans er en relativt veldefineret tilstand.

POTS er i henhold til Sundhedsstyrelsen klassificeret under supraventrikulære takykardier med diagnosekoden DI471J og defineres som en tilstand, hvor hjertefrekvensen stiger mindst 30 slag/min eller til mere end 120 slag/min inden for de første 10 min efter overgang fra liggende til stående stilling, og som ledsages af labilt blodtryk og symptomer på ortostatisk intolerans [3, 4]. Hos børn og unge skal det diagnostiske krav formentlig sættes til en stigning i hjerte-

FAKTABOKS

Postural ortostatisk takykardi-syndrom

Diagnostiske kriterier:
Stigning i hjertefrekvens på ≥ 30 slag/min eller til ≥ 120 slag/min inden for de første 10 min efter overgang til oprejst stilling.

Ortostatisk betinget ubehag, der svinder, når patienten igen er i liggende stilling.

Labilt blodtryk i stående stilling.

Fravær af andre tilstande, der kan forklare takykardien.