Excisional versus ablative surgery for endometriosis

Protocol information

Review No
TB1322

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Dates
Assessed as Up-to-date: Not provided
Date of Search: Not provided
Next Stage Expected: 30 August 2010
Protocol First Published: Not specified
Review First Published: Not specified
Last Citation Issue: Not specified

What's new

Abstract
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Plain language summary
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[Summary text]

Background
Description of the condition
Endometriosis is defined as the presence of endometrial like tissue outside the uterus which induces a chronic inflammatory reaction (RCOG 2006). Endometriosis occurs in approximately 70% of patients with chronic pelvic pain (ASRM Practice Committee 2008). The revised American Fertility Society (rAFS) classification (Am Fert Soc

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1985) provides a score of severity based on visual findings at laparoscopy. There are medical and surgical treatment options for endometriosis (Cochrane 2009, Vercellini 2009, Giudice 2010). Surgery is often required when medical options fail or cause unacceptable side effects, or in the case infertility is an issue. The surgical treatment of endometriosis aims to remove all visible areas of endometriosis and to restore anatomy by division of adhesions and relieve painful symptoms.

**Description of the intervention**

Generally, the surgical treatment of endometriosis may be divided into ablative or excisional techniques. Historically the initial treatment of endometriosis involved surgical excision of the disease using scalpels or scissors (Cullen 1920, Sampson 1921). With the advent of minimally invasive surgery, diathermy, laser, helium plasma coagulation or ultrasound have all been used via the laparoscopic trocars to ablate the endometriosis implants (Sutton 1994). More recently, thanks to the improvements in laparoscopic tools and surgical techniques, the same energy sources can be used for the sharp excision of the diseased tissue (Redwine DB 1993, Wood 1996).

**How the intervention might work**

The optimal surgical management of endometriosis, either excisional or ablative procedures, is still controversial. Theoretically, ablative procedures are more likely to be incomplete because of the risk of thermal damage to underlying structures, which might lead to a greater necrotic tissue with a potentially greater inflammatory reaction. On the other hand, excisional procedures carry the benefit of allowing histological confirmation and might be considered more complete techniques; however excision might be more complex to perform, potentially requiring longer operating times.

**Why it is important to do this review**

This review will clarify which is the most effective technique of treating endometriosis; either excision of the peritoneal implants or ablation techniques. It will also serve to highlight the lack of randomised controlled trial evidence in this field.

**Objectives**

The objective of this review is to determine the most effective technique of treating endometriosis; either excision of the peritoneal implants or ablation techniques.

**Methods**

**Criteria for considering studies for this review**

**Types of studies**

Only randomised controlled trials (RCTs) will be eligible for inclusion. Non RCTs and quasi-randomised RCTs will be excluded. Cross-over trials will not be included.

**Types of participants**

Inclusion criteria:
- Women with endometriosis who are undergoing surgery for pain or infertility
- Endometriosis is defined as direct visualization of peritoneal endometriosis implants at surgery, with or without histological confirmation

Exclusion criteria:
- Women with gynaecological cancer
- Women with peritoneal lesions other than endometriosis

**Types of interventions**

All randomised controlled trials (RCTs) comparing excision and ablation of endometriosis will be included. Also RCTs comparing different ablation methods with each other, or different excisional methods with each other, will be included in this review. Both laparotomy and laparoscopic approaches will be included. Analysis of ablation techniques will be stratified according to the modality used (electrosurgery, laser, helium plasma coagulation, ultrasound). Studies with pain treatments other than excision or ablation, like laparoscopic uterine nerve ablation (LUNA) or presacral neurectomy, will be excluded from this review.

**Types of outcome measures**

Patient-reported outcomes and adverse events.

**Primary outcomes**
- Relief from pelvic pain as measured by visual analogue scores or dichotomous data
- Subsequent fertility including pregnancy and live birth rate, either spontaneous or as result of fertility treatment

**Secondary outcomes**
Recurrence of endometriosis
Any adverse event if discussed in the study
Operating time, analgesia requirements and recovery period
Quality of life as measured by patient satisfaction or objective quality of life scales (if studies report more than one scale, preference will be given to the EHP–30)

Search methods for identification of studies
All published and unpublished RCTs of excision versus ablation of endometriosis will be sought using the following search strategy, without language restriction and in consultation with the Menstrual Disorders and Subfertility Group (MDSG) Trials Search Co-ordinator:

Electronic searches
The following electronic databases, trial registers and websites will be searched until September 2010: The Menstrual Disorders and Subfertility Group (MDSG) Specialised Register of Controlled Trials, the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, PSYCINFO and CINAHL.
The MEDLINE search was combined with the Cochrane highly sensitive search strategy for identifying randomised trials, which appears in the searching chapter of The Cochrane Handbook of Systematic Reviews of Interventions. The EMBASE search will be combined with trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) (http://www.sign.ac.uk/methodology/filters.html#random)

Other electronic sources of trials will include:
– Citation indexes – http://scientific.thomson.com/products/sci/
– Conference abstracts in the ISI Web of Knowledge http://isibo.sknowledge.com/)
– LILACS database, as a source of trials from the Portuguese and Spanish speaking world http://bases.bireme.br/cgi-bin/wxislind.exe/iah/online/?IsisScript=iah/iah.xis&base=LILACS&lang=i&form=F
– Clinical Study Results for clinical trial results of marketed pharmaceuticals http://www.clinicalstudyresults.org/
– OpenSIGLE database http://opensigle.inist.fr/ and Google for grey literature

Searching other resources
The reference lists of articles retrieved by the search will be hand searched and personal contact will be made with experts in the field to obtain any additional relevant data.
Any relevant journals and conference abstracts that are not covered in the MDSG register will be hand-searched in liaison with the Trial Search Coordinator.

Data collection and analysis
Data collection and analysis will be conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008).

Selection of studies
One review author will scan the titles and abstracts of articles retrieved by the search and remove those that are very clearly irrelevant. The full text of all potentially eligible studies will be retrieved. Two review authors will independently examine the full text articles for compliance with the inclusion criteria and will select studies eligible for inclusion in the review. Authors will correspond with study investigators if required, to clarify study eligibility (e.g. with respect to participant eligibility criteria and allocation method). Disagreements as to study eligibility will be resolved by consensus or by discussion with a third author.

Data extraction and management
Data will be extracted from eligible studies using a data extraction form designed and pilot–tested by the authors. Where studies have multiple publications, the main trial report will be used as the reference and additional details supplemented from secondary papers. Review authors will correspond with study investigators in order to resolve any data queries as required .Two review authors (one a methodologist and one a topic area specialist) will independently extract the data any disagreement between these reviewer authors will be resolved by a third review author.

Assessment of risk of bias in included studies
The included studies will be assessed for risk of bias using the Cochrane risk of bias assessment tool (see Appendix C) to assess: sequence generation; allocation concealment; blinding of participants, providers and outcome assessors; completeness of outcome data; selective outcome reporting; and other potential sources of bias. Two authors will assess these six domains, with any disagreements resolved by consensus or by discussion with a third author. All judgments will be fully described. The conclusions will be presented in the Risk of Bias table and will be incorporated into the interpretation of review findings by means of sensitivity analyses (see below).
Measures of treatment effect
For dichotomous data the numbers of events in the control and intervention groups of each study will be used to calculate Peto odds ratios. For continuous data, mean differences between treatment groups will be calculated if all studies report exactly the same outcomes. If similar outcomes are reported on different scales the standardised mean difference will be calculated. Ordinal data (e.g. quality of life scores) will be treated as continuous data. 95% confidence intervals will be presented for all outcomes.

Unit of analysis issues
The primary analysis will be per woman randomised. Data reported that do not allow valid analysis will be briefly summarised in an additional table and will not be meta-analysed.

Dealing with missing data
The data will be analysed on an intention-to-treat basis as far as possible and attempts will be made to obtain missing data from the original investigators. Where these are unobtainable, imputation of individual values will be undertaken for the primary outcomes only. If studies report sufficient detail to calculate mean differences but no information on associated standard deviation (SD), the outcome will be assumed to have standard deviation equal to the highest SD from other studies within the same analysis. For other outcomes, only the available data will be analysed. Any imputation undertaken will be subjected to sensitivity analysis (see below).

Assessment of heterogeneity
The authors will consider whether the clinical and methodological characteristics of the included studies are sufficiently similar for meta-analysis to provide a meaningful summary. Statistical heterogeneity will be assessed by the measure of the I^2. An I^2 measurement greater than 50% will be taken to indicate a substantial heterogeneity (Higgins 2003, 2008). If substantial heterogeneity is detected, possible explanations will be explored in sensitivity analyses (see below).

Assessment of reporting biases
In view of the difficulty in detecting and correcting for publication bias and other reporting biases, the authors will aim to minimise their potential impact by ensuring a comprehensive search for eligible studies and by being alert for duplication of data. If there are ten or more studies in an analysis, a funnel plot will be used to explore the possibility of small study effects (a tendency for estimates of the intervention effect to be more beneficial in smaller studies). Within study reporting bias will be detected by seeking published protocols and comparing the outcomes between the protocol and the final published study.

Data synthesis
The data from primary studies will be combined using fixed effect models in the following comparisons:
1. Excision vs ablation (diathermy, laser, helium plasma coagulation, ultrasound).
2. Laparoscopic surgical intervention (excision, diathermy, laser, helium plasma coagulation, ultrasound) vs open surgical intervention.
3. Diathermy ablation vs alternative ablation techniques, stratified by alternative (laser, helium plasma coagulation, ultrasound)
4. Sharp excision vs alternative excision techniques, stratified by alternative (diathermy, laser, helium plasma coagulation, ultrasound)

Subgroup analysis and investigation of heterogeneity
Subgroup analysis by looking at the indication for surgery (pain or infertility).

Sensitivity analysis
Sensitivity analyses will be conducted for the primary outcomes to determine whether the conclusions are robust to arbitrary decisions made regarding the eligibility and analysis. These analyses will include consideration of whether conclusions would have differed if:
1. Eligibility were restricted to studies without high risk of bias;
2. Alternative imputation strategies had been adopted;
3. A random effect model had been adopted.
4. The summary effect measure was relative risk rather than odds ratio.

Results
Description of studies
Results of the search
Included studies
Excluded studies