

## Evidence-based gynecological practice—clinical review 2: Surgery for pain in endometriosis. What is the evidence?

S. Khazali · E. Dimitriou · J. T. Wright

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**Abstract** In the second review of the series of evidence-based reviews of clinical practice, we demonstrate the search methods to find available high quality evidence from the literature. Using techniques described in the first review in the series, we formulate an answerable question based on a clinical scenario of a patient with endometriosis where medical treatment has failed. We then look into selected papers found by our search and demonstrate how to present the evidence to our imaginary patient.

**Keywords** Endometriosis · Evidence-based medicine · Endoscopy

### Introduction

Endometriosis accounts for a significant proportion of a gynecologist's workload [1]. Surgical treatment of endo-

metriosis has become such a standard practice that we often forget to think about the evidence supporting this. Are we really helping our patients by operating on them? Or are we operating on them because we have the appropriate skills?

The first paper in this series [2] reviewed the literature on management of endometriomas. It demonstrated how to formulate a question to be asked of the literature and went into some details about levels of evidence and how to critically appraise relevant papers. This paper is not a systematic review of the literature; systematic reviews require a more extensive system for search, including hand searching of conference proceedings and should also have a clear set of criteria for inclusion or exclusion of relevant papers. This paper is written to demonstrate, by giving an example, how to search for available evidence in day-to-day practice. We briefly introduce the available databases to be searched and concentrate on how to perform a literature search to answer a clinical question. We will also give a short description of some of the better quality papers we found and how we used these to answer our hypothetical patient's question.

It could be argued that it is both unreasonable and impractical to perform an extensive and comprehensive search to answer each clinical question we come across in clinical practice and we agree; however, our patients expect that the advice that they receive should be based on the best available evidence as it relates to their specific problem. Often, a properly performed systematic review can be found in reputable databases like the Cochrane database to answer our question; however, Cochrane reviews only include randomized controlled trials (RCTs) and as demonstrated in this review, good quality RCTs are rare, especially in surgical practice. Clinical trials too, may only answer a specific question which may not be appropriate in a patient's specific clinical problem. This is where possess-

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S. Khazali (✉)  
Royal Hampshire County Hospital,  
Winchester, UK  
e-mail: s.khazali@me.com

S. Khazali · E. Dimitriou · J. T. Wright  
Women's Health Research Unit, Postgraduate Medical School,  
University of Surrey,  
Guildford, Surrey, UK

E. Dimitriou  
RCSI, The Coombe Women's Hospital,  
Dublin, Ireland

J. T. Wright  
Centre for Endometriosis and Pelvic Pain,  
Ashford and St. Peters Hospital NHS Trust,  
Chippenham, UK

ing skills to perform our own search and to recognize good quality papers will be very useful.

### Our patient

Mrs. A, a lecturer in marine biology, is a 35-year-old mother of two who has been suffering from pelvic pain and deep dyspareunia for the last 15 years. She has tried different medical treatments, including NSAIDs, combined oral contraceptive pills, various progestogens, and even a short course of a GnRH agonist with temporary pain relief and recurrence of both pain and dyspareunia after discontinuation of these medical treatments. When she had her laparoscopic sterilization by a junior doctor 5 years ago, “moderate endometriosis” was noted, but no further details were provided nor were any pictures taken. A recent pelvic ultrasound scan was unremarkable. She is now seeking further treatment for the pain and is asking you: “is an operation going to help me?”

### What question do you want to ask of the literature?

This lady’s pain is likely to be caused by her endometriosis which has been previously noted, given that she had temporary pain relief while on GnRH agonists. The severity of the disease is, however, uncertain as the diagnostic laparoscopy is 5 years old and not very informative. Her main concern is chronic and ongoing pain which presumably affects her quality of life, and she has no fertility desires. Using the “population, intervention, comparison, outcome (PICO)” model, this question could be formulated:

Is conservative laparoscopic surgery effective in reducing pain or improving quality of life in women with endometriosis when compared to non-surgical treatments or no treatment?

### How to search, where to look, and what to look for

When the question is on treatment effectiveness, the best quality papers are systematic reviews of randomized controlled trials followed by individual randomized controlled trials (RCTs) and then by observational studies. However, an important caveat is that randomized trials with all the strict inclusion and exclusion clauses that they have end up with a highly selected population that may not represent the patients that we see. Systematic reviews of RCTs usually use meta-analysis to pool the results and give a cumulative report. The studies lower in the hierarchy of evidence [2] should be used with caution as they are more

prone to bias but may also more truly represent the population that we are dealing with.

You may choose to delegate the search to your librarian who is usually trained in doing a search properly or you may want to simply do a quick “google” search. “Googling” for your clinical question may not sound very sophisticated, but “google scholar” has a very important feature that makes it useful in certain circumstances. Unlike most biomedical databases, Google Scholar sorts articles the way researchers do, weighing the full text of each article, the author, the publication in which the article appears, and how often the piece has been cited in other papers; the most relevant results will always appear on the first page. This, however, will be an unrefined and very broad result and certainly not suitable for a systematic and thorough search. Google scholar is accessible at [www.scholar.google.com](http://www.scholar.google.com).

The Cochrane Library houses the full text of all the systematic reviews that have been conducted by Cochrane Collaboration Groups. It is easily accessible ([www.thecochranelibrary.com](http://www.thecochranelibrary.com)), and it also publishes a database solely of RCTs. There are now more than 400 Cochrane reviews relevant to the specialty of obstetrics and gynecology and a similar number at a protocol stage, so it is quite likely to find one that addresses your question. Database of abstracts of reviews of effects (DARE) is a component of Cochrane Library and indexes systematic reviews produced by non-Cochrane bodies. It provides full record with a structured abstract and a comment on the review.

Medline is currently the biggest database of published papers. It covers about 4,000 journal titles in all the medical specialties; therefore, Medline is probably the best place to look for evidence if Cochrane has not given an answer. However, many of the journals which are germane to our subject such as gynecological surgery and the Journal of Minimal Access Gynecology are not available on Medline, and you may have to look for these separately. Finally, breaking news on new treatment modalities or the results of case series have only been published in abstracts of meetings and you may have to try to access this “gray” literature. You can access Medline in several ways. Most people are familiar with the PubMed ([www.pubmed.com](http://www.pubmed.com)) which is provided free by the National Library of Medicine. Other interfaces like Dialog or Ovid can be provided by your institute. All of these are slightly different, but the search mechanism is basically the same. A very thorough search strategy based on the question on Mrs. A is shown later, and we used the Ovid search machine. EMBASE, which is similar to Medline, is produced by Elsevier and includes more European literature.

You can also search for guidelines through Turning Research Into Practice or TRIP ([www.tripdatabase.com](http://www.tripdatabase.com)).

Simply type your search term (i.e., endometriosis) in the search box and your results will come up according to the type of the information that they represent: guidelines, evidence-based, electronic textbooks, etc.

#### Aim of the search

The aim of the search demonstrated here was to identify level-1 evidence and high quality reviews and guidelines written in English that can answer our search question. Here, we only include systematic reviews from Cochrane database, DARE, and HTA and search Medline for relevant controlled trials. This method is more likely to reveal higher quality reviews without the need for studying a large number of papers.

#### Creating the list of keywords

##### *What is MeSH?*

MeSH stands for Medical Subject Headings and is the National Library of Health's (NLM) controlled vocabulary thesaurus. NLM used these standardized terms when indexing papers. Therefore, using a MeSH term when possible will result in a more refined set of results and will avoid missing important papers because of spelling differences (e.g., Gynaecology and Gynecology) or different names for the same procedure.

In this example, lists of potential useful keywords were generated for each section of the formulated question. Complete references of some relevant papers [3–6] were studied to look for any other potential keywords. These keywords were then tested using the MeSH database to distinguish controlled text (MeSH) from free text words. Searching the MeSH database occasionally reveals other useful related MeSH terms.

The complete list of keywords used is shown in Appendix 1.

#### Databases searched

##### *Medline (Ovid)*

Medline was searched using the Ovid interface. There are different interfaces to search Medline; they all search the same database with slightly different software. You can use the one you are more familiar with or the one your institution has access to. The details of this search are illustrated in Table 1. This search resulted in 81 hits. After studying the title and, in some cases, the abstract of these items, 29 papers were selected. These were later combined with the outcome of other database searches. The final list of selected papers is shown in Appendix 2.

It is not always necessary to do such a detailed and extensive search to get to the answer and this is only to demonstrate some of the search techniques used by systematic reviewers.

##### *Cochrane library*

The following search was performed:

(endometriosis or endometrio\*) in Record Title and (surgery or gynecologic surgical procedures or surgical procedures, laparoscopic or surgical procedures, minimally invasive or surgical procedures, operative or surg\*) in Title, Abstract or Keywords in The Cochrane Database of Systematic Reviews

One of ten Cochrane reviews, 22 of 127 clinical trials and three of three other reviews were relevant to the question. These citations were exported to separate text files to be compared against and combined with the final Medline search. Of the 22 trials, 15 were already found by Medline search and the other seven were added to the list. These were largely from journals not included in Medline.

##### *DARE*

DARE database was searched using “Endometriosis or endometrio\*” as search terms. This returned 44 items, six of which were relevant to the question. All but one had been already found by Cochrane search.

##### *HTA*

HTA database was searched using “Endometriosis or endometrio\*” in the search box. Ten items were found of which two were relevant.

##### *Combining the results*

The outcomes of the above searches were combined which resulted in 43 citations in total. The complete list of these is shown in Appendix 1.

##### *Description of selected papers*

The Cochrane review [7] that addresses our question only includes one RCT in the analysis [6] as this was the only RCT available at the time the Cochrane review was performed in 2001. The study by Sutton et al in 1994 randomized 63 women with minimal, mild, and moderate endometriosis into treatment group and placebo group. The treatment group received laser vaporization of all visible lesions with CO<sub>2</sub> laser and uterine nerve ablation and the placebo group had only a diagnostic laparoscopy. There

**Table 1** Medline (Ovid) search table

		Search word	Hits
Population	1	exp Endometriosis/	12091
	2	endometrio\$.mp.	16493
	3	1 or 2	16493
Intervention	4	exp Surgery/	26648
	5	exp Gynecologic Surgical Procedures/	47820
	6	exp Laparoscopy/	43617
	7	exp Surgical Procedures, Minimally Invasive/	186780
	8	exp Surgical Procedures, Operative/	1712612
	9	exp Electrocoagulation/	19657
	10	exp Catheter ablation/	11077
	11	(minimal\$ adj2 invasiv\$).mp.	20337
	12	(resect\$ adj5 endometrio\$).mp.	185
	13	(ablat\$ adj5 endometrio\$).mp.	55
	14	(remov\$ adj5 endometrio\$).mp.	122
	15	(diathermy\$ adj5 endometrio\$).mp.	9
	16	(cauter\$ adj5 endometrio\$).mp.	8
	17	(laser adj5 endometrio\$).mp.	118
	18	(Denervation adj5 uter\$).mp.	35
	19	uterine nerve ablation.mp.	21
	20	presacral neurectomy.mp.	65
	21	or/4-20	1749600
	Outcome	22	exp Pain/
23		exp Pelvic Pain/	4255
24		exp Dysmenorrhea/	2361
25		dysmenorrh\$.mp.	3364
26		painful menstruat\$.mp.	31
27		exp Dyspareunia/	923
28		exp "Quality of Life"/	65164
29		exp Questionnaires/	172204
30		exp treatment outcome/	333941
31		or/22-30	735954
32		3 and 21 and 31	1062
33		limit 32 to (English language and female and humans and ("adolescent (13 to 18 years)" or "adult (19 to 44 years)"))	610
34		limit 33 to (addresses or bibliography or biography or case reports or comment or dictionary or directory or editorial or historical article or in vitro or interview or legal cases or legislation or letter or news or newspaper article or patient education handout)	158
35		33 not 34	452
Study design		36	exp Randomized Controlled Trial/
	37	exp Controlled Clinical Trial/	76168
	38	exp Random Allocation/	59709
	39	exp Double-Blind Method/	94724
	40	exp Single-Blind Method/	11622
	41	exp clinical trial/	524006
	42	exp Placebos/	26640
	43	exp principal component analysis/	3107
	44	exp statistics, nonparametric/	34202
	45	or/36-44	605883
	46	35 and 45	81

was a significant reduction of pain scores in the treatment group at the 6 months follow-up (62.5% vs. 22.6%,  $P < 0.01$ ). The effect of treatment was higher if minimal disease was excluded from the results (73.7% vs. 20%). A follow-up study of these patients after 12 months showed a symptom recurrence rate of 10% [8].

This study was the first RCT to compare surgery with no treatment. The study, however, was not free of problems. Apart from laser vaporization, patients in the treatment arm received other interventions (LUNA and/or adhesiolysis), and the paper does not report the number of patients who received each intervention. A Cochrane review of six RCTs comparing LUNA combined with surgical treatment of endometriosis with surgical treatment without LUNA concluded that laparoscopic uterine nerve ablation for treatment of endometriosis-related pain does not confer any advantage over excision and/or ablation alone [9]. Despite this, the fact that some patients in Sutton's paper underwent other procedures makes it difficult to interpret the results. On the other hand, as this study used laser ablation for treatment of endometriotic lesions, it is questionable whether the results can be extrapolated for other surgical methods of treatment of endometriosis.

In a more recent RCT, Abbott et al. [3] randomized 39 patients to receive initially either a diagnostic procedure (the delayed surgical group, DSG) or full excisional surgery (the immediate surgery group). After 6 months, repeat laparoscopy was performed, with removal of any pathology present.

At 6 months, more women in immediate surgery group (IMG) reported "some improvement" than the women in delayed surgery group (80% vs. 32%). The results beyond 6 months are difficult to interpret due to the presence of significant confounding factors (high dropout rate and second surgical resection in the IMG). When the visual analog scale scores were used, no difference was seen between the decrease in the scores between DSG and ISG after 6 or 12 months. The only statistically significant difference is seen when within-group comparison is utilized. This shows a considerable decrease in pain scores in most pain parameters in both groups after 6 months indicating a significant placebo effect.

A small study from Canada [10] also addressed the same question. They randomized 29 women with histologically proven endometriosis into excisional treatment and sham surgery and followed them up for 12 months. There were significant reductions in pain scores in both groups with no significant difference between the groups. However, the study was flawed by the high dropout rate (45%), although no firm conclusion can be made using these results.

All these studies show how large the placebo effect in laparoscopic surgery can be.

Our search strategy was set to exclusively look for level I evidence. Other study designs can be useful in answering clinical questions if designed appropriately and have sufficient sample size. One example is a prospective cohort of 176 patients with endometriosis who were followed up for up to 5 years [11]. Various tools for assessment of pain, quality of life, and sexual activity were used before treatment and repeated between 2 and 5 years after surgery which showed significant improvement in almost all outcomes. Apart from inherent shortcomings of a cohort study compared to RCTs, the population of this study consisted of women who had previously had different forms of treatments for their disease, and there was a significant dropout rate in long-term follow-up. The operations performed varied from resection of stage I endometriosis to radical surgery involving anterior resection and colostomy and patients received varying forms of adjuvant treatment postoperatively. It should be borne in mind that 18% of these women underwent hysterectomy in the observation period and dysmenorrhea was a major component of the pain score in both the preoperative and postoperative global pain scores; thus, hysterectomy contributed a major component to the perceived reduction in pain. Despite the above, this is an important study and deserves serious consideration when presenting evidence to our patient.

There are many large case series and non-randomized studies in the literature mostly favoring surgical management in the treatment of endometriosis, but it is true that the lower the study is in the hierarchy of evidence, the more prone to bias they will be. On the other hand, we excluded several other studies evaluating the effect of adjuvant medical treatment postoperatively, either GnRH analogs [12–15] or danazol [16, 17], Mirena® device [18], the combines oral contraceptive pill [19], and a systematic review of all the above [20]. Critically appraising these papers is out of the scope of this article as they do not directly address our clinical question.

### **How would you present the evidence to Mrs. A in order to help her make an informed choice about treatment?**

Our patient has been suffering from a chronic painful disease and therefore sufficient time should be allowed for a thorough consultation. The decision on whether or not surgical treatment is the right modality for Mrs. A should be made jointly.

The above studies have shown some degree of improvement in pain and some of the quality of life scores; however, the results are not robust and the numbers are small. Number Needed to Treat (NNT) is probably the best way of presenting the results to Mrs.



A. The RCT by Abbott et al. [11] has shown an NNT of three for the improvement of pain at 6 months. Meaning, three patients needed to undergo surgery so that one patient reported at least some reduction in pain after 6 months; however, it is not clear from this study what the long-term outcome of surgical treatment is likely to be.

To be able to help our patient in making her decision, clinical judgment and a holistic approach are needed. Considering the fact that she has been trying medical management for a long time with no avail, surgical treatment could be considered as a reasonable option providing the expertise is available and Mrs. A is made fully aware of the potential complications. The proposed surgery can be anything from a simple ablation of mild endometriosis to an extensive operation involving hysterectomy and resection of parts of colon or ureter.

In this case, the extent of the disease is not known as the laparoscopy done 5 years ago is not very informative. A better knowledge of the disease severity and the organs involved would provide more information in order to suggest an appropriate surgical treatment and to be able to counsel about the complexity of the proposed procedure and the morbidity and complications associated with the operation. An operation involving bowel resection and colostomy is not the same as resection of a small endometriotic lesion, and they require a different surgical team, different set up, different time allocation, and of course, different preoperative counseling.

It would be reasonable to perform an initial laparoscopy with the aim to treat mild or moderate endometriosis. If this proves unsuccessful despite sufficient treatment, hysterectomy with or without removal of ovaries can be considered at a later stage. If severe disease requiring more complex surgery is found or if there is major involvement of other pelvic organs like rectum and ureter, this is best treated by a multidisciplinary team consisting of a colorectal surgeon with appropriate laparoscopic skills and possibly a urologist.

Endometriosis is a very complex disease with variable severity and extent and the patients have often been living with its consequences for a long time. Surgical intervention has yet to be shown to have a good long term outcome and the paucity of good quality evidence adds to the complexity of situation. The evidence for surgical treatment of endometriosis for pain relief is not robust enough to firmly advise or discourage surgical treatment, especially when only “high quality” RCTs are included to make the decision. However, “no evidence of benefit” is not the same as “evidence of no benefit.” The paucity of RCTs in this area is not surprising as there are many hurdles to perform such studies. Performing sham operations is difficult to justify ethically; it is difficult to recruit patients

into such trials and patients often dropout to seek definitive treatment.

Gynecologists practicing evidence-based medicine should have the skills to search for, critically appraise, and interpret new evidence both to provide appropriate counseling to their patient and to adjust their practice accordingly. But as demonstrated in Mrs. A’s case, evidence will not always prescribe an answer directly and robustly and the decision should be made considering the best available evidence, patient’s expectations as well as surgeon’s skills and experience.

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## Appendix 1: List of keywords used

### Population

Human/  
Female/  
Endometriosis/  
Endometrio\$.mp

### Intervention

surgery/  
gynecologic surgical procedures/  
laparoscopy/  
surgical procedures, minimally invasive/  
surgical procedures, operative/  
electrocoagulation/  
Catheter ablation/  
(minimal\$ adj2 invasiv\$).mp  
(resect\$ adj5 endometrio\$).mp  
(ablat\$ adj5 endometrio\$).mp  
(remov\$ adj5 endometrio\$).mp  
(diathermy\$ adj5 endometrio\$).mp  
(cauter\$ adj5 endometrio\$).mp  
(laser adj5 endometrio\$).mp  
(Denervation adj5 uter\$).mp  
uterine nerve ablation.mp  
presacral neurectomy.mp

### Comparison

No keywords for nonsurgical treatments were selected as all controlled trials studying the effects of surgical treatments will be included, regardless of the type of treatment the control group has received.

## Outcome

Pain/  
 pelvic pain/  
 dysmenorrhea/  
 dysmenorrh\$.mp  
 painful menstruat\$.mp  
 dyspareunia/  
 “quality of life”/  
 questionnaires/

## Study design

Randomized Controlled Trial/

## Appendix 2: list of papers found using the demonstrated search

Abbott J, Hawe J, Hunter D, Holmes M, Finn P, Garry R, Abbott J, Hawe J, Hunter D, Holmes M, Finn P, Garry R (2004) Laparoscopic excision of endometriosis: a randomized, placebo-controlled trial.[see comment]. *Fertility & Sterility*, 82, 878-884.

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