

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of laparoscopic helium plasma coagulation of endometriosis

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in November 2005

Procedure name

- Laparoscopic helium plasma coagulation
- Laparoscopic helium thermal coagulation

Specialty societies

- Royal College of Obstetricians and Gynaecologists

Description

Indications

Endometriosis is a common condition. Women with endometriosis have deposits of endometrial tissue (usually confined to the lining of the uterus) outside the uterus. Many women are asymptomatic, although others may experience pelvic pain, dyspareunia, dysmenorrhoea or infertility. Endometriosis is a dynamic benign disease and the majority of women will not improve if left untreated.

The severity of endometriosis is described using the stages I to IV (minimal to severe) based on the location and depth of endometrial deposits and the extent to which scar tissue has formed around them.

Current treatment and alternatives

Most women with endometriosis can be treated with analgesia and hormone treatment. Women who do not respond may be offered minimally invasive surgery to excise or vaporise the endometrial deposits, most commonly by electrocautery or laser through a laparoscope. Women with very severe symptoms may be offered more radical treatment with hysterectomy and removal of the ovaries.

What the procedure involves

Laparoscopic helium plasma coagulation of endometriosis is another way of vaporising endometrial deposits. Using a laparoscope, an ionised beam of helium gas is directed at the endometrial deposits to destroy the affected tissue. The proposed advantages of laparoscopic helium plasma coagulation of endometriosis over electrocautery and laser are that a lower wattage is used and the tissue penetration is more superficial, so the instrument is less likely to damage normal tissue if contact occurs.

Efficacy

The method of evaluation of symptoms following the procedure varied between studies making comparison difficult. Symptomatic relief was achieved in 49% (39/79)¹, 72% (179/250)², and 81% (17/21)⁵ of cases at 3 months of follow-up across three series, and at 14 months of follow-up in another case series, continuing symptoms were reported in 38% (5/13) of patients³.

Only one case series of 50 women, including 9 who presented with infertility and 15 who were both symptomatic and infertile, reported fertility outcomes⁵. 44% (4/9) of the infertility group and 20% (3/15) of the women who were also symptomatic had conceived within 6 months of the procedure.

In one case series none of 250 procedures had to be converted to open surgery, and there were no readmissions after 3 months², whereas a repeat procedure was required in 16% (5/31) of patients in another case series in which the mean period to return to normal daily activities was 12 days³.

Safety

One case series did not report on complications relating to the procedure. Three of the series^{1,3,4} recorded no side effects or complications related to the procedure in a total of 130 women. After 3 months of follow-up of 250 cases, one case series reported no major postoperative complications and no surgical complications when the cutting blade attachment to the laparoscope was not used².

There was no long term follow up of patients for more than 6 months in published case series

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to laparoscopic helium plasma coagulation of endometriosis. Searches were conducted via the following databases, covering the period from their commencement to 10 November 2005: Medline, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See Appendix B for details of search strategy.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with endometriosis
Intervention/test	Laparoscopic helium plasma coagulation
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy. [Insert a list of outcomes e.g. from Specialist Advisor questionnaires].
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on two studies published in peer-reviewed publications^{1,2}, and three case series published on the manufacturer's website^{3,4,5}.

There were no studies that were considered to be relevant to the procedure but that were not included in the main extraction table (Table 2).

Existing reviews on this procedure

There were no published reviews identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix A details the recommendations made in each piece of guidance listed below.

Interventional procedures

Radical laparoscopic excision of endometriosis

Technology appraisals

None

Clinical guidelines

None

Public health

None

Table 2 Summary of key efficacy and safety findings on laparoscopic helium plasma coagulation of endometriosis

Abbreviations used: rAFS, Revised American Fertility Society.			
Study Details	Key efficacy findings	Key safety findings	Comments
Hill N (2005) ² Case series UK n = 250 Age = 29 years, all stage I or II endometriosis Follow-up = 3 months Disclosure of interest: Not stated	Symptomatic relief was achieved in 72% (179/250) of the patients (assessment method not stated). None of the procedures required conversion to open surgery There were no incidents of requirement for blood transfusion, return to theatre, venous thrombosis, or readmission at 3 months.	No major surgical complications when the cutting blade attachment was not used < 1% (1/250) vaginal perforation, in a patient with vaginal vault endometriotic nodule, where excision with cutting blade was attempted Postoperatively no major complications reported at 3 months	Consecutive cases with chronic pain and stage I or II endometriosis. Thermal coagulator vs YAG laser RCT is planned. Not clear how many investigators undertook the procedure.

Abbreviations used: rAFS, Revised American Fertility Society.																				
Study Details		Key efficacy findings		Key safety findings	Comments															
Nardo L (2005)¹ Case series UK. 2001 to 2003 n = 81 women Age = 32years, rAFS stage 1 = 44%, stage II = 56%. Non-cyclical pelvic pain = 94%, deep dyspareunia = 75%, dysmenorrhoea = 48% Patients had no treatment for endometriosis during the previous 6 months, and no medical treratment was prescribed during follow-up Follow-up = 6 months Disclosure of interest: Not stated		Clinical outcomes Subjective assessment of presence and severity of symptoms <table><tr><td>Symptom</td><td>3 months</td><td>6 months</td></tr><tr><td>Symptom relief</td><td>49% (39/79)</td><td>57% (45/79)</td></tr><tr><td>Symptom improvement</td><td>25% (20/79)</td><td>30% (24/79)</td></tr><tr><td>No change</td><td>25% (20/79)</td><td>11% (9/79)</td></tr><tr><td>Worsening</td><td>0</td><td>1% (1/79)</td></tr></table> There was no association between symptom relief and minimal or mild endometriosis The majority of women remained in hospital overnight, some were discharged the same day		Symptom	3 months	6 months	Symptom relief	49% (39/79)	57% (45/79)	Symptom improvement	25% (20/79)	30% (24/79)	No change	25% (20/79)	11% (9/79)	Worsening	0	1% (1/79)	No surgical complications were encountered	Uncontrolled case series. 2 patients lost to follow-up and not included in analysis, with no comparison of baseline characteristics. Authors state that it may be difficult to evaluate efficacy of treatments as chronic pelvic pain may have different organic components, and may be influenced by external factors A laparoscopy itself may result in temporary improvement in symptoms Randomised controlled trials with longer follow-up period are required
Symptom	3 months	6 months																		
Symptom relief	49% (39/79)	57% (45/79)																		
Symptom improvement	25% (20/79)	30% (24/79)																		
No change	25% (20/79)	11% (9/79)																		
Worsening	0	1% (1/79)																		

Abbreviations used: rAFS, Revised American Fertility Society.			
Study Details	Key efficacy findings	Key safety findings	Comments
Dewart P ³ Case series UK 1996 to 1997 n = 39 women with symptomatic stage I or II endometriosis Mean age 32, range 21–49 years Follow-up = 14 months	Procedure success Repeat procedure: 16% (5/31) Additional medical treatment: 23% (7/31) Continuing symptoms: 16% (5/31) Mean length of time between returning to work/normal activity: 12 days (range 3–42 days)	“No unanticipated side effects or complications occurred”	Uncontrolled case series Published on manufacturer’s website No inclusion/exclusion criteria provided
Forbes Donaldson K ⁴ Case series UK 1995 n = 10 women with symptomatic endometriosis (stage not reported) Age not reported Length of follow-up not reported	Persistent pain: 1 patient	Adverse effects reported as zero	Uncontrolled case series Published on manufacturer’s website No inclusion/exclusion criteria provided

Abbreviations used: rAFS, Revised American Fertility Society.			
Study Details	Key efficacy findings	Key safety findings	Comments
Macrow P ⁵ Case series UK 1998 to 2000 n = 50 women n = 9 infertility n = 24 'symptomatic endometriosis' (not further defined) n = 15 both 'symptomatic endometriosis' and infertility n = 2 indication stated as 'miscellaneous'	Infertility group: conceived within 6 months: 44% (4/9) Symptomatic endometriosis group: symptoms resolved or improved at 3 months: 81% (17/21) Further medical treatment at 6 months: 48% (10/21) Symptomatic endometriosis plus infertility group: symptoms resolved or improved at 3 months: 67% (10/15) Conceived within 6 months: 20% (3/15)	Complications not reported	Uncontrolled case series Published on manufacturer's website Medical treatment given in addition to the procedure for 13 women Outcomes in 'miscellaneous' group not reported

Validity and generalisability of the studies

- Three of the studies included in this overview are small, uncontrolled case series and were all published on the manufacturer's website, and as such have not been subjected to independent scientific scrutiny.
- In all studies, complications were not reported in detail, and inclusion and exclusion criteria were unclear.
- There is a potential placebo effect of any laparoscopic intervention in this indication.
- There was very little follow-up of over a year.
- The degree of endometriosis of cases included in studies not well reported.
- Pelvic pain is difficult to evaluate as it may be due to more than one problem.

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr J Zaidi, Professor C Sutton, Mr K Edwards

- The opinion of the advisors regarding the status of the procedure varied from a novel to an established procedure.
- The aim of the procedure is to reduce pelvic pain and infertility. It may cause less lateral burning than the diathermy technique, and may allow for patients to be treated as a day case.
- The advisors were aware of one case of vaginal laceration; however, this occurred when the cutting blade was employed.
- Theoretical adverse events might include damage to normal tissue (common to other energy sources), bowel injury, haemorrhage, infection and, potentially, helium embolisation.
- All advisors noted that there are no RCT/comparative data available to date comparing this with existing techniques, although these would be difficult to develop.
- Minimal training would be required for experienced laparoscopic surgeons, although an understanding of the mode of action would be useful.
- The technique is in line with the trend for increasing use of disposable devices/units.
- This procedure will have a relatively small impact on the NHS due to the low incidence of this indication.
- Audit criteria might include evaluation of pain relief, quality of life, cumulative pregnancy rates, readmission, damage to pelvic organs, haemorrhage, conversion to laparotomy and percentage treated as a day case.

Issues for consideration by IPAC

- The overview has included in Table 2 studies reported on the manufacturers website, as only two case series are available at present in the peer-reviewed literature.

References

1. Nardo LG, Moustafa M, Gareth Beynon DW (2005) Laparoscopic treatment of pelvic pain associated with minimal and mild endometriosis with use of the Helica Thermal Coagulator. *Fertility and Sterility* 83:735–738.
2. Hill NCW, El-Toukhy T, Grigoriades T et al. (2005) Safety of the Helica Thermal Coagulator in the treatment of early stage endometriosis. *Journal of Obstetrics and Gynaecology* 25:52–54.
3. Dewart P. Helica Thermal Coagulator. Stage I and II endometriosis treatment with the HELICA T.C. Available on <http://www.helica.co.uk/papers/dr-paul.pdf>
4. Forbes Donaldson K, Hawthorn FJS. Helica Thermal Coagulator. Laparoscopic use of the Helica thermal coagulator: The first report on endometriosis treatment. Available on <http://www.helica.co.uk/papers/lap.pdf>
5. Macrow P. An audit of the use of the Helica coagulator as a modality of treatment for endometriosis. Available on http://www.helica.co.uk/papers/p_macrow_pinderfields.pdf

Appendix A: Related NICE guidance for laparoscopic helium plasma coagulation of endometriosis

Guidance	Recommendation
Interventional procedures	Radical laparoscopic excision of endometriosis Although special expertise is necessary, this is not a discrete new procedure and therefore does not call for a safety and efficacy decision by the Committee. NICE will not issue guidance on this procedure.
Technology appraisals	N/A
Clinical guidelines	N/A
Public health	N/A

Appendix B: Literature search for laparoscopic helium plasma coagulation of endometriosis

Procedure number: 167 Date Completed: 11/11/2005	Procedure name: laparoscopic helium plasma coagulation of endometriosis
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Action	Comments	Version searched (if applicable)	Date searched
Search for similar NICE topics	IPG1 04 Impedance-controlled endometrial ablation for menstrual bleeding IPG0 54 Laparoscopic helium plasma coagulation of endometriosis Radical laparoscopic excision of endometriosis IPG0 51 Free fluid thermal endometrial ablation IPG0 06 Balloon thermal endometrial ablation (using data from Cavaterm and Gynecare as specified by SERNIP) IPG0 47 Photodynamic endometrial ablation IPG0 07 Microwave endometrial ablation	N/A	10/11/2005
Consult notification and specialist advisors questionnaires for additional papers	Two papers identified already in RefMan.	N/A	10/11/2005
Conduct general internet search for background	Geneva Foundation for Medical Education and Research Helica website, including papers published on the procedure	N/A	10/11/2005
Search for Cochrane systematic review	No Cochrane review on this procedure	2005 Issue 4	10/11/2005
ASERNIP website	No information of relevance found	N/A	10/11/2005
FDA website	Helica FDA summary FDA safety and effectiveness summary	N/A	10/11/2005
Search conferences websites	No information or conference abstracts of relevance found.	N/A	10/11/2005
Search Databases:			
The Cochrane Library	12 hits	2005 Issue 4	10/11/2005
CRD Databases	0 hit	October 2005	10/11/2005
Embase	13 hits	1980 to 2005 Week 45	10/11/2005
Medline	25 hits	1966 to November Week 1 2005	10/11/2005
Premedline	2 hits	November 10, 2005	10/11/2005
CINAHL	0 hit	1982 to November Week 1 2005	10/11/2005
BLIC (limit to current year only)	0 hit	1993-date	10/11/2005
National Research Register	2 hits	2005 Issue 4	10/11/2005
Controlled Trials Registry	0 hit	N/A	10/11/2005

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

Procedure number: 167		Procedure name: laparoscopic helium plasma coagulation of endometriosis	
Database: Cochrane Library 2005 Issue 4		Date searched: 10/11/2005	
	#1	MeSH descriptor Laparoscopy explode all trees in MeSH products	
	#2	MeSH descriptor Laparoscopes explode all trees in MeSH products	
	#3	MeSH descriptor Laparotomy explode all trees in MeSH products	
	#4	MeSH descriptor Surgical Procedures, Minimally Invasive explode all trees in MeSH products	
	#5	laparo* in All Fields in all products	
	#6	telescope* or keyhole* in All Fields in all products	
	#7	peritoneo* in All Fields in all products	
	#8	endoscop* in All Fields in all products	
	#9	minimal* near/3 surg* in All Fields in all products	
	#10	minimal* near/3 invasive in All Fields in all products	
	#11	minimal* near/3 access in All Fields in all products	
	#12	MIS in All Fields in all products	
	#13	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12)	
	#14	helium in All Fields in all products	
	#15	MeSH descriptor Helium, this term only in MeSH products	
	#16	thermal* near/3 (coagulat* or ablat*) in All Fields in all products	
	#17	(#14 OR #15 OR #16)	
	#18	(#13 AND #17)	
	#19	helica in All Fields in all products	
	#20	(#18 OR #19)	
	#21	MeSH descriptor Endometriosis explode all trees in MeSH products	
	#22	endometri* in All Fields in all products	
	#23	(#21 OR #22)	
	#24	(#20 AND #23)	