

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of laparoscopic techniques for hysterectomy

Hysterectomy is the surgical removal of the uterus. This may be indicated for women with various conditions including chronic pelvic pain, heavy periods, fibroids, or cancer of the uterus or the ovaries. Conventional hysterectomy is performed via an incision in the abdomen or via the vagina. In laparoscopic techniques for hysterectomy, special surgical instruments are inserted through small incisions made in the abdomen, and the operation is carried out with the aid of an internal telescope and camera system. This is sometimes described as 'keyhole surgery'. Part of the operation may also be performed vaginally.

## 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 2002 by Bazian Ltd, updated by NICE in May 2004 and again in December 2006.

## Procedure name

Laparoscopic techniques for hysterectomy

## Specialty societies

- Royal College of Obstetricians and Gynaecologists
- British Society for Gynaecological Endoscopy
- British Gynaecological Cancer Society

## Description

### *Indications*

Hysterectomy is performed for a variety of benign conditions, including heavy menstrual bleeding, fibroids, chronic pelvic pain and uterine prolapse, that have not responded to medical treatment, and also for cancer of the uterus, the endometrium and the ovaries.

### *Current treatment and alternatives*

A conventional 'open' hysterectomy involves removal of the uterus through an abdominal incision or via the vagina.

### *What the procedure involves*

Under general anaesthesia, a laparoscope is introduced through a small incision in the abdomen and two or three further small incisions are made in the lower abdomen to allow the insertion of ports, through which additional surgical instruments are inserted. A manipulator may be placed in the uterus via the vagina. The remainder of the procedure, in which the uterus is detached from supporting structures and blood vessels, varies according to the amount of surgery performed laparoscopically. This overview does not cover laparoscopic radical hysterectomy (see Related NICE Guidance, below).

In both laparoscopically-assisted vaginal hysterectomy (LAVH) and laparoscopic hysterectomy (LH), part of the operation is performed laparoscopically and part vaginally. LAVH and LH differ in the method used to divide the uterine vessels; in LAVH this is performed vaginally, but in LH this is performed laparoscopically. The cervix may be removed along with the uterus (total hysterectomy) or it can be left in situ (subtotal or supracervical hysterectomy).

In total laparoscopic hysterectomy (TLH) and laparoscopic supracervical hysterectomy (LSH), the entire procedure is performed laparoscopically, including division of the uterine vessels. In TLH the cervix is removed, while in LSH it is left in situ.

The uterus is removed either through the open vault of the vagina or one of the abdominal ports. It may be cut into small pieces (morcellated) before removal.

### *Efficacy*

Laparoscopic techniques for hysterectomy are efficacious in that they achieve removal of the uterus. However, the different techniques may also be evaluated with respect to other efficacy outcomes. The evidence mainly focusses on frequency of conversion to laparotomy, length of hospital stay, time taken for patients to return to work/normal activities and operating time.

## Conversion to laparotomy

### *Studies including any laparoscopic techniques for hysterectomy*

A Cochrane review meta-analysis of randomised controlled trials (RCTs) found no significant difference between laparoscopic techniques (type not specified) and vaginal hysterectomy (VH) in the occurrence of unintended laparotomy (6 RCTs, n = 842).<sup>1</sup> In a non-randomised controlled study, conversion to laparotomy was required in 7% (82/1242) of patients who underwent laparoscopic procedures.<sup>5,6</sup>

### *LSH*

A case series reported conversion to laparotomy in 14/1692 patients (0.83%).<sup>4</sup>

### *TLH*

A case series reported conversion to laparotomy in 46/1647 (2.79%) of patients.<sup>7</sup>

## Length of hospital stay

The Cochrane meta-analysis found that patients who underwent laparoscopic techniques for hysterectomy (type not specified) returned home on average 2.0 days earlier (95% CI 1.9 to 2.2; 9 RCTs, n = 948) than patients who underwent abdominal hysterectomy (AH).<sup>1</sup> Two non-randomised controlled studies reported that hospital stay was shorter following laparoscopic procedures (type not specified) than after VH or AH (mode 3, 4 and 5 days respectively in one study of 298 patients;<sup>5,6</sup> mean 3.4 [SD 2.0], 5.9 [SD 2.7] and 6.0 days [SD 2.2] respectively in a second study of 10,110 patients).<sup>2</sup>

A case series of 1648 patients who underwent LH reported that mean length of hospital stay was 36 hours (range 24–216)<sup>3</sup>. The case series of 1692 patients who underwent LSH reported that mean length of hospital stay was 2.2 days (SD 0.6).<sup>4</sup>

## Time to return to work/normal activities

The meta-analysis found that patients who underwent laparoscopic techniques for hysterectomy (type not specified) returned to normal activities on average 13.6 days earlier than patients who underwent AH (95% confidence interval [CI] 11.8 to 15.4; 6 RCTs, n = 520).<sup>1</sup> The non-randomised controlled study of 10,110 patients, reported that the 2434 patients who underwent laparoscopic techniques for hysterectomy (type not specified) returned to work more quickly on average than those who underwent VH or AH (22 [SD 9], 34 [SD 9] and 34 days [SD 5], respectively).<sup>2</sup>

The case series of 1648 patients who underwent LH reported that mean time to return to work was 3 weeks [range 1–13].<sup>3</sup>

## Operating time

The meta-analysis found that, compared with other methods of hysterectomy, laparoscopic techniques for hysterectomy (type not specified) took longer than VH (weighted mean difference [WMD]: 41.5 minutes, 95% confidence intervals [CI] 33.7 to 49.4; 4 RCTs, n = 293 patients).<sup>1</sup> Laparoscopic

techniques also took longer than AH (WMD 10.6 minutes, 95% CI 7.4 to 13.8; 10 RCTs, n = 988), with the exception of LAVH, which was quicker than AH (WMD 7.6 minutes, 95% CI 3.0 to 12.2; 4 RCTs, n = 466). The non-randomised controlled study of 10,110 patients also found that laparoscopic techniques (type not specified) took longer than AH or VH: mean operating times were 124 (standard deviation [SD] 48), 86 (SD 32) and 88 minutes (SD 32) for laparoscopic techniques, AH and VH, respectively.<sup>2</sup>

The case series of 1648 patients who underwent LH reported that median operating time was 36 minutes (range 24–104 minutes).<sup>3</sup>

The case series of 1692 patients who underwent LSH reported that mean operating time decreased from 159 minutes (SD 64) in the first year of the study to 81 minutes (SD 29) in the sixth year (significance not reported).<sup>4</sup> Mean operating time over the 6 years of the study was 91 minutes (SD 33).

## Safety

### Death

The non-randomised controlled study of 37,048 hysterectomy patients reported that 14 died (0.04%, 95% CI 0.025–0.064), none of whom had undergone a laparoscopic procedure.<sup>5,6</sup> The non-randomised controlled study of 10,110 patients reported that 0.04% of those who underwent laparoscopic procedures (type not specified) died, compared with 0.06% of patients who had VH and 0.02% of patients who had AH.<sup>2</sup>

### Blood loss

#### *Studies including any laparoscopic techniques for hysterectomy*

The Cochrane meta-analysis reported that mean intraoperative blood loss was lower with laparoscopic techniques (type not specified) than with AH (WMD: 45.3 ml, 95% CI 17.9 to 72.7 ml; 7 RCTs, n = 693) and laparoscopic techniques were associated with a smaller decrease in haemoglobin level (WMD: 0.55 g/L, 95% CI 0.28 to 0.82 g/L; 3 RCTs, n = 288).<sup>1</sup> There were no significant differences between laparoscopic techniques and VH in these outcomes (3 RCTs; n = 196 for mean blood loss; 2 RCTs, n = 157 for decrease in haemoglobin levels). The non-randomised controlled study of 10,110 patients also reported that mean blood loss was significantly less with laparoscopic techniques (type not specified) (262 ml) than with VH (342 ml) or AH (305 ml);  $p < 0.0001$  for laparoscopic techniques compared with VH or AH.<sup>2</sup>

The non-randomised controlled study of 37,048 patients reported that the incidence of major operative haemorrhage was significantly higher ( $p < 0.001$ ) during laparoscopic techniques (4.4%, 51/1154 patients) than with VH (2.0%, 218/11,122 patients) or AH (2.3%, 571/24,772 patients).<sup>5,6</sup> The non-randomised controlled study of 10,110 patients reported no significant difference in peri-operative haemorrhage between laparoscopic techniques, VH and AH.<sup>2</sup>

### LH

A case series reported haemorrhage requiring blood transfusion in 0.3% (5/1648) of patients.<sup>3</sup>

#### LSH

A case series reported abnormal levels of bleeding intraoperatively in 1 of 1692 patients (0.06%).<sup>4</sup>

#### TLH

A case series reported that blood transfusion was required for 0.97% of patients (16/1647), and excessive haemorrhage occurred in 0.85% (14/1647) of patients.<sup>7</sup>

### Visceral or vascular injury

#### *Studies including any laparoscopic techniques for hysterectomy*

The meta-analysis<sup>1</sup> and the non-randomised controlled study of 10,110 patients<sup>2</sup> found that the incidence of urinary tract injuries was significantly higher among patients who underwent laparoscopic techniques (type not specified) than those who had AH (odds ratio from meta-analysis [OR] 2.61, 95% CI 1.22 to 5.60; 10 RCTs, n = 1912; non-randomised study 1.1% vs 0.2% for ureter injury and 1.3% vs 0.5% for bladder injury, p < 0.0001). There was no significant difference in the incidence of bowel injury between laparoscopic techniques and AH in either study (meta-analysis: 2 RCTs, n = 1066; non-randomised study n = 8309).

Comparing laparoscopic techniques with VH, the meta-analysis found no significant difference in any of these outcomes (6 RCTs, 805 patients for urinary tract injury; 1 RCT, 504 patients for bowel injury; 4 RCTs, 685 patients for vascular injury).<sup>1</sup> Comparing laparoscopic techniques with VH, the non-randomised controlled study reported a higher incidence of injuries to the ureter (1.1% vs 0%) and bladder (1.3% vs 0.2%) (p not stated for either outcome), but a similar incidence of bowel injury (0.4% vs 0.5%).<sup>2</sup>

There was no significant difference between laparoscopic techniques and AH for vascular injury (2 RCTs, 956 patients).<sup>1</sup>

A non-randomised controlled study reported that the incidence of visceral damage was higher in patients who underwent laparoscopic procedures (1.1%, 13/1154) compared with those who had VH (0.6%, 68/11,122) or AH (0.76%, 189/24,772), but the difference was not significant.<sup>5,6</sup>

A case series of 5104 patients reported ureter injury in 66 patients (3%), simple bladder injury in 22 (0.4%), vesicovaginal fistula in 12 (0.2%), intestinal injury in 15 (0.3%) and major vascular injury in 1 (0.02%).<sup>8</sup>

#### LAVH

A case series of 2702 patients reported bladder injury in 11 (0.4%), ureter injury in 4 (0.2%), bowel injury in 11 (0.4%) and vessel injury in 2 (0.1%).<sup>9</sup>

#### LH

A case series of 1648 patients reported one case each of bladder injury and bowel injury (0.06%), no cases of ureter injury, and 9 cases of vascular injury (0.55%).<sup>3</sup>

#### *LSH*

A case series reported ureter injury in 1/1692 patients (0.06%) and bladder injury in 3/1692 (0.18%).<sup>4</sup>

#### *TLH*

The case series of 1647 patients reported ureter injury in 6 patients (0.36%), bladder injury in 17 patients (1.03%),<sup>7</sup> and bowel injury in one patient (0.06%).<sup>7</sup>

## Literature review

### *Rapid review of literature*

The medical literature was searched to identify studies and reviews relevant to laparoscopic techniques for hysterectomy. Searches were conducted via the following databases, covering the period from their commencement to 21 December 2006: 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 C 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 or laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with uterine malignancy, or benign conditions such as fibroids, heavy periods or chronic pelvic pain
Intervention/test	Laparoscopic techniques for hysterectomy
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
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 one Cochrane review with meta-analysis of 25 RCTs, two non-randomised controlled studies (one of which is described by two articles) and five case series.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (Table 2) are listed in Appendix A.

### ***Existing reviews on this procedure***

A Cochrane review of RCTs comparing laparoscopic techniques for hysterectomy with AH or VH for benign conditions (published in 2006) is described in Table 2 and in the sections on Safety and Efficacy, above.<sup>1</sup>

A systematic review of laparoscopic techniques for hysterectomy, covering studies published between 1989 and 1995, was identified.<sup>10</sup> The review excluded TLH and supracervical procedures and was restricted to benign conditions. This review identified 34 studies, 2 of which were RCTs, including 3112 patients who underwent laparoscopic procedures, 1618 patients who underwent AH and 690 patients who underwent VH. The review reported that mean operating time was significantly longer for laparoscopic techniques compared with AH (115 minutes [SD 37] vs 87 minutes [SD 18],  $p < 0.001$ ). Mean length of hospital stay was shorter for laparoscopic techniques than AH (49 hours [SD 16] vs 79 hours [SD 20],  $p < 0.001$ ). Time to return to work ranged from 2 to 6 weeks for laparoscopic techniques and from 5 to 9 weeks for AH, in four studies. The incidence of bladder injury was significantly higher with laparoscopic techniques than AH (1.7% [39/2273] vs 0% [0/434],  $p = 0.001$ ). Blood transfusion was needed by a significantly smaller proportion of patients who underwent laparoscopic techniques than patients who had AH (1.4% [43/3112] vs 2.7% [43/1618],  $p = 0.01$ )

The authors concluded that “although laparoscopy-assisted vaginal hysterectomy involves a shorter hospital stay, speedier postoperative recovery, and less analgesia use, there is also a higher rate of bladder injury and lengthier surgery. These outcomes must be weighed when choosing an intervention”.

### ***Related NICE guidance***

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

#### **Interventional procedures**

Laparoscopic hysterectomy, NICE consultation document (November 2004), Available from [http://guidance.nice.org.uk/ipcat.aspx?o=IP\\_55](http://guidance.nice.org.uk/ipcat.aspx?o=IP_55)

Microwave endometrial ablation *NICE Interventional Procedures Guidance No. 7* (August 2003). Available from [www.nice.org.uk/guidance/IPG7](http://www.nice.org.uk/guidance/IPG7)

Balloon thermal endometrial ablation *NICE Interventional Procedures Guidance No. 6* (August 2003). Available from [www.nice.org.uk/guidance/IPG6](http://www.nice.org.uk/guidance/IPG6)

Laparoscopic laser myomectomy *NICE Interventional Procedures Guidance* No. 23 (November 2003). Available from [www.nice.org.uk/guidance/IPG23](http://www.nice.org.uk/guidance/IPG23)

Laparoscopic radical hysterectomy for early stage cervical cancer *NICE Interventional Procedures Guidance* No. 24 (November 2003). Available from [www.nice.org.uk/guidance/IPG24](http://www.nice.org.uk/guidance/IPG24)

Magnetic resonance (MR) image-guided percutaneous laser ablation of uterine fibroids *NICE Interventional Procedures Guidance* No. 30 (December 2003). Available from [www.nice.org.uk/guidance/IPG30](http://www.nice.org.uk/guidance/IPG30)

Photodynamic endometrial ablation *NICE Interventional Procedures Guidance* No. 47 (March 2004). Available from, [www.nice.org.uk/guidance/IPG47](http://www.nice.org.uk/guidance/IPG47)

Free fluid thermal endometrial ablation *NICE Interventional Procedures Guidance* No. 51 (March 2004). Available from, [www.nice.org.uk/guidance/IPG51](http://www.nice.org.uk/guidance/IPG51)

Uterine artery embolisation for fibroids, *NICE Interventional Procedures Guidance* No. 94 (October 2004). Available from [www.nice.org.uk/guidance/IPG94](http://www.nice.org.uk/guidance/IPG94)

Impedance-controlled endometrial ablation for menorrhagia *NICE Interventional Procedures Guidance* No. 104 (December 2004). Available from ([www.nice.org.uk/guidance/IPG104](http://www.nice.org.uk/guidance/IPG104))

Endometrial cryotherapy for menorrhagia *NICE Interventional Procedures Guidance* No. 157 (March 2006). Available from, [www.nice.org.uk/guidance/IPG157](http://www.nice.org.uk/guidance/IPG157)

Laparoscopic helium plasma coagulation for the treatment of endometriosis *NICE Interventional Procedures Guidance* No. 171 (May 2006). Available from [www.nice.org.uk/guidance/IPG171](http://www.nice.org.uk/guidance/IPG171)

### **Technology appraisals**

Menstrual bleeding - fluid-filled thermal balloon and microwave endometrial ablation, *NICE Technology Appraisal* No. 78 (April 2004; updated April 2007) Available from [www.nice.org.uk/guidance/TA78](http://www.nice.org.uk/guidance/TA78)

### **Clinical guidelines**

Heavy menstrual bleeding *NICE Clinical Guideline* No. 44 (January 2007) Available from [www.nice.org.uk/guidance/CG44](http://www.nice.org.uk/guidance/CG44)

### **Public health**

None

**Table 2 Summary of key efficacy and safety findings on laparoscopic techniques for hysterectomy**

Study details	Key efficacy findings and key safety findings	Comments
<p>Abbreviations used: CI: 95% confidence interval; AH: abdominal hysterectomy; LAVH: laparoscopically assisted vaginal hysterectomy; LH: laparoscopic hysterectomy; OR: odds ratio; RCT: randomised controlled trial; SD: standard deviation; VH : vaginal hysterectomy; WMD: weighted mean difference.</p> <p>Johnson N et al (2006)<sup>1</sup></p> <p><b>Cochrane systematic review and meta-analysis</b></p> <p>Literature search conducted March 2004</p> <p><b>25 RCTs included laparoscopic techniques for hysterectomy: Laparoscopic vs AH: 20 trials, n = 2532 Laparoscopic vs VH: 8 trials, n = 945 LAVH vs LH: 1 trial, n =101</b> (Some trials compared LH, VH and AH together.)</p> <p>Indications: benign conditions only</p> <p>Only RCTs that compared one surgical approach to hysterectomy with another were included.</p> <p>Conflict of interest: One author (Garry) was also principal investigator in one of the RCTs included.</p>	<p>The following text is taken from the Cochrane review, but has been edited so that only results relating to laparoscopic hysterectomy are presented. The numbers of RCTs that provided data and numbers of patients have been inserted.</p> <p><b>Main results</b></p> <p>The benefits of <b>laparoscopic techniques versus AH</b> were lower intraoperative blood loss (WMD 45.3 ml, CI 17.9 to 72.7; 7 RCTs, n = 693) and a smaller decrease in haemoglobin level (WMD 0.55 g/L, CI 0.28 to 0.82; 3 RCTs, n = 288), shorter duration of hospital stay (WMD 2.0 days, CI 1.9 to 2.2; 9 RCTs, n = 948), quicker return to normal activities (WMD 13.6 days, CI 11.8 to 15.4; 6 RCTs, n = 520), fewer wound or abdominal wall infections (OR 0.32, CI 0.12 to 0.85; 5 RCTs, n = 449), fewer unspecified infections or febrile episodes (OR 0.65, CI 0.49 to 0.87; 12 RCTs, n = 1879), at the cost of longer operating time (WMD 10.6 minutes, CI 7.4 to 13.8; 10 RCTs, n = 988) and more urinary tract (bladder or ureter) injuries (OR 2.61, CI 1.22 to 5.60; 10 RCTs, n = 1912).</p> <p>There was no evidence of benefits of <b>laparoscopic techniques versus VH</b> and the operating time was increased (WMD 41.5 minutes, CI 33.7 to 49.4; 4 RCTs, n = 293).</p> <p>There was no evidence of benefits of <b>LH versus LAVH</b> and the operating time was increased for LH(a) (WMD 25.3 minutes, CI 10.0 to 40.6; 1 RCT, n = 101).</p> <p>No other statistically significant differences were found.</p> <p><b>Additional comparisons of sub-categories of laparoscopic techniques compared with non-laparoscopic techniques</b></p> <p>LAVH had a significantly shorter operation time than AH (WMD 7.6 minutes, 95% CI 3.0 to 12.2; 4 RCTS, n = 466), whilst other subcategories of LH took significantly longer than AH (LH(a) versus AH, WMD 30.6 minutes, 95% CI 25.6 to 35.7; 5 RCTS, n = 420; TLH versus AH, WMD 16.3 minutes, 95% CI 7.0 to 25.6; 1 RCT, n = 101). LH was associated with significantly fewer blood transfusions than AH (OR 0.48, 95% CI 0.24 to 0.97; 7 RCTs, n = 522). All other subcategory meta-analyses of LH versus AH and LH versus VH showed results that were similar to meta-analysis of LH as a pooled group versus AH and versus VH.</p>	<p><b>Power</b></p> <p>“This meta-analysis of RCTs was underpowered to detect a clinically significant increase in the incidence of bladder damage and ureter damage from a laparoscopic approach”.</p> <p>15 trials did not report that a power calculation was performed to assess adequate sample size.</p> <p><b>Surgeon experience</b></p> <p>This was reported in 15 of the 25 trials. Four of these specified that the same group of surgeons performed operations for both the interventions being compared.</p> <p><b>Randomisation</b></p> <p>Five trials did not report randomisation method, and in 1 trial the reported method may have been inadequate. Concealment of allocation was adequate in 11 trials but was not described in 16.</p> <p><b>Intent-to-treat (ITT) analysis</b></p> <p>20 trials reported that no patients dropped out. Of the remaining 6, 2 conducted an ITT analysis.</p> <p>For some important outcomes, the analyses were underpowered to detect important differences,</p>

Abbreviations used: CI: 95% confidence interval; AH: abdominal hysterectomy; LAVH: laparoscopically assisted vaginal hysterectomy; LH: laparoscopic hysterectomy; OR: odds ratio; RCT: randomised controlled trial; SD: standard deviation; VH : vaginal hysterectomy; WMD: weighted mean difference.

Study details	Key efficacy findings and key safety findings	Comments
	<p><b>Authors' conclusions</b>            Significantly improved outcomes suggest that VH should be performed in preference to AH where possible. Where VH is not possible, LH may avoid the need for AH; however, the duration of surgery increases as the extent of the surgery performed laparoscopically increases, particularly when the uterine arteries are divided laparoscopically; laparoscopic approaches also require greater surgical expertise. The surgical approach to hysterectomy should be decided by a woman in discussion with her surgeon in light of the relative benefits and hazards. Further research is required with full reporting of all relevant outcomes, particularly important long-term outcomes, in large RCTs, to minimise the possibility of reporting bias. Further research is also required to define the role of the newer approaches to hysterectomy such as TLH.</p>	<p>or they were simply not reported in trials. Data were notably absent for many important long-term outcome measures.</p>

Abbreviations used: CI: 95% confidence interval; AH: abdominal hysterectomy; LAVH: laparoscopically assisted vaginal hysterectomy; LH: laparoscopic hysterectomy; OR: odds ratio; RCT: randomised controlled trial; SD: standard deviation; VH : vaginal hysterectomy; WMD: weighted mean difference.

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<p>Mäkinen J et al (2001)<sup>2</sup></p> <p><b>Non-randomised controlled study</b></p> <p>Finland</p> <p>Study period: 1996</p> <p><b>Total n = 10,110</b>  <b>AH: n = 5875</b> (mean age 49 years)  <b>VH: n = 1801</b> (mean age 59 years)  <b>LH: n = 2434</b> (mean age 47 years)</p> <p>Population: all hysterectomies registered in Finland</p> <p>Indications: benign conditions only</p> <p>Technique: Laparoscopic techniques for hysterectomy (type not specified)</p> <p><b>Follow-up: until end of patients' convalescence / return to work</b></p> <p>Conflict of interest: None stated</p>	<p><b>EFFICACY</b></p> <p><b>Mean operating time (minutes)</b>                      AH: 86 (SD 32), VH: 88 (SD 32), Laparoscopic: 124 (SD 48)</p> <p><b>Mean length of hospital stay (days)</b>                      AH: 6.0 (SD 2.2), VH: 5.9 (SD 2.7), Laparoscopic: 3.4 (SD 2.0)</p> <p><b>Mean time to return to work (days)</b>                      AH: 34 (SD 5), VH: 34 (SD 9), Laparoscopic: 22 (SD 9)</p> <p>p &lt; 0.0001 for laparoscopic techniques compared with AH, for all outcomes above</p> <p><b>SAFETY</b></p> <table border="1" data-bbox="638 746 1794 1182"> <thead> <tr> <th rowspan="3"></th> <th colspan="6">Percentage of patients experiencing complication, relative risk (RR) (and 95% CI) compared with the AH group</th> </tr> <tr> <th colspan="2">AH</th> <th colspan="2">VH</th> <th colspan="2">Laparoscopic techniques</th> </tr> <tr> <th>%</th> <th>RR</th> <th>%</th> <th>RR</th> <th>%</th> <th>RR</th> </tr> </thead> <tbody> <tr> <td>Ureter injury</td> <td>0.2</td> <td>1.0</td> <td>0</td> <td>–</td> <td>1.1</td> <td>7.2 (3.4–15.4) ****</td> </tr> <tr> <td>Bladder injury</td> <td>0.5</td> <td>1.0</td> <td>0.2</td> <td>0.3 (0.1– 1.1)</td> <td>1.3</td> <td>2.7 (1.6–4.4) ****</td> </tr> <tr> <td>Bowel injury</td> <td>0.2</td> <td>1.0</td> <td>0.5</td> <td>2.5 (1.0–5.8) *</td> <td>0.4</td> <td>1.8 (0.8–4.3)</td> </tr> <tr> <td>Urinary tract infection</td> <td>4.2</td> <td>1.0</td> <td>7.3</td> <td>1.7 (1.4–2.1) ****</td> <td>2.6</td> <td>0.6 (0.5–0.8) ***</td> </tr> <tr> <td>Infection (any site)</td> <td>10.5</td> <td>1.0</td> <td>13.0</td> <td>1.2 (1.1–1.4) **</td> <td>9.0</td> <td>0.9 (0.8–1.0)</td> </tr> <tr> <td>Peri-operative haemorrhage (any site)</td> <td>4.0</td> <td>1.0</td> <td>4.6</td> <td>1.1 (0.9–1.5)</td> <td>4.7</td> <td>1.2 (1.0–1.5)</td> </tr> <tr> <td>Thromboembolism</td> <td>0.2</td> <td>1.0</td> <td>0.2</td> <td>1.3 (0.4–4.2)</td> <td>0.3</td> <td>1.7 (0.6–4.4)</td> </tr> <tr> <td>Death</td> <td>0.02</td> <td>1.0</td> <td>0.06</td> <td>not stated</td> <td>0.04</td> <td>not stated</td> </tr> <tr> <td>Other complications</td> <td>1.7</td> <td>1.0</td> <td>4.8</td> <td>2.8 (2.1–3.7) ****</td> <td>2.1</td> <td>1.2 (0.9–1.7)</td> </tr> <tr> <td>All complications</td> <td>17.1</td> <td>1.0</td> <td>23.3</td> <td>1.4 (1.2–1.5) ****</td> <td>19.0</td> <td>1.1 (1.1–1.2)</td> </tr> </tbody> </table> <p>* indicates p &lt; 0.05; ** = p &lt; 0.01; *** = p &lt; 0.001; **** = p &lt; 0.0001</p> <p>Mild and serious complications are included here. Absolute numbers of patients are not stated for most events. There was one death in each group. These were “not directly related to the operation (alcoholic cirrhosis, cardiac infarct, pulmonary embolism)”.</p> <p><b>Mean estimated blood loss (ml)</b></p>		Percentage of patients experiencing complication, relative risk (RR) (and 95% CI) compared with the AH group						AH		VH		Laparoscopic techniques		%	RR	%	RR	%	RR	Ureter injury	0.2	1.0	0	–	1.1	7.2 (3.4–15.4) ****	Bladder injury	0.5	1.0	0.2	0.3 (0.1– 1.1)	1.3	2.7 (1.6–4.4) ****	Bowel injury	0.2	1.0	0.5	2.5 (1.0–5.8) *	0.4	1.8 (0.8–4.3)	Urinary tract infection	4.2	1.0	7.3	1.7 (1.4–2.1) ****	2.6	0.6 (0.5–0.8) ***	Infection (any site)	10.5	1.0	13.0	1.2 (1.1–1.4) **	9.0	0.9 (0.8–1.0)	Peri-operative haemorrhage (any site)	4.0	1.0	4.6	1.1 (0.9–1.5)	4.7	1.2 (1.0–1.5)	Thromboembolism	0.2	1.0	0.2	1.3 (0.4–4.2)	0.3	1.7 (0.6–4.4)	Death	0.02	1.0	0.06	not stated	0.04	not stated	Other complications	1.7	1.0	4.8	2.8 (2.1–3.7) ****	2.1	1.2 (0.9–1.7)	All complications	17.1	1.0	23.3	1.4 (1.2–1.5) ****	19.0	1.1 (1.1–1.2)	<p>Prospective study</p> <p>All patients in this study are the same as those treated during 1996 in the study reported by Härkki-Siren P et al (1999).</p> <p>The authors believe that data were collected on all hysterectomies performed in Finland for benign indications during 1996, and so are an unbiased sample.</p> <p>Patients who had VH were significantly older than those in the AH and laparoscopic groups (p &lt; 0.001).</p> <p>Operations were performed by more than 100 operators from 58 hospitals.</p> <p>11.6% of AHs and 2.1% of laparoscopic procedures were subtotal.</p> <p>It is not clear from the paper whether complications reported occurred up to the end of the 'convalescent period' or whether they occurred perioperatively.</p>
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Study details	Key efficacy findings and key safety findings	Comments
	<p>AH: 305 (SD 312), VH: 342 (SD 352), Laparoscopic: 262 (SD 271)  <math>p &lt; 0.0001</math> for laparoscopic techniques compared with AH.</p> <p>For LH, surgeons who had performed more than 30 procedures were less likely to cause ureter or bladder injury compared with less-experienced surgeons (ureter injury: 0.5% vs 2.2%, <math>p &lt; 0.0001</math>; bladder injury: 0.8% vs 2.0%, <math>p = 0.05</math>).</p>	

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Study details	Key efficacy findings and key safety findings		Comments														
<p>Ben-Hur H et al (2000)<sup>3</sup></p> <p><b>Case series</b></p> <p>UK</p> <p>Study period: 1992–1996</p> <p><b>n = 1648</b> (mean age: 46 years)</p> <p>Indications: Intractable menorrhagia, myoma, previous low-segment Caesarean section, endometriosis, suspected adhesions or other conditions that were not stated</p> <p>Exclusion criteria: Uterine size greater than 17 weeks' gestation, extensive endometriosis, or suspected malignancy</p> <p>Technique: LH (The uterine artery was ligated laparoscopically but part of the operation was performed vaginally.)</p> <p>Follow-up: Not stated</p> <p>Conflict of interest: None stated</p>	<p><b>Median operating time</b> 36 minutes (range 24–104)</p> <p><b>Median length of hospital stay</b> 36 hours (range 24–216)</p> <p><b>Median time to return to work</b> 3 weeks (range 1–13)</p>	<table border="1" data-bbox="1234 304 1760 715"> <thead> <tr> <th></th> <th>Number of patients with complications (%) (n = 1648)</th> </tr> </thead> <tbody> <tr> <td>Bladder injury</td> <td>1 (0.06)</td> </tr> <tr> <td>Bowel injury</td> <td>1 (0.06)</td> </tr> <tr> <td>Ureter injury</td> <td>0</td> </tr> <tr> <td>Pulmonary embolism or deep vein thrombosis</td> <td>0</td> </tr> <tr> <td>Vascular injury</td> <td>9 (0.55)</td> </tr> <tr> <td>Haemorrhage requiring blood transfusion</td> <td>5 (0.3)</td> </tr> </tbody> </table> <p>All complications occurred in the first 2 years of this 5-year study (number of procedures in this time period was not stated).</p>		Number of patients with complications (%) (n = 1648)	Bladder injury	1 (0.06)	Bowel injury	1 (0.06)	Ureter injury	0	Pulmonary embolism or deep vein thrombosis	0	Vascular injury	9 (0.55)	Haemorrhage requiring blood transfusion	5 (0.3)	<p>Retrospective case review of consecutive patients treated by one surgical team.</p> <p>All complications occurred in the first 2 years of the study. No complications occurred in the last 3 years of the study.</p>
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Study details	Key efficacy findings and key safety findings		Comments
<p>Bojahr B et al (2006)<sup>4</sup></p> <p><b>Case series</b></p> <p>Germany</p> <p>Study period: 1998–2003</p> <p><b>n = 1692</b> (mean age 46 years)</p> <p>Population: consecutive patients at a private hospital</p> <p>Indications: Uterine myomata with either pain or enlargement, therapy-resistant dysfunctional uterine bleeding, suspected uterine adenomyosis, recurrent bleeding after endometrial ablation or resection.</p> <p>Exclusions: patients with abnormal cervical cytology or colposcopy, or evidence of endometrial malignancy</p> <p>Technique: Laparoscopic supracervical hysterectomy. Performed entirely laparoscopically. The uterine vessels are ligated laparoscopically and the uterus was morcellated and removed through the initial abdominal incisions (enlarged to 2 cm and an additional small port created if necessary).</p> <p><b>Follow-up: Not stated</b></p>	<p><b>Mean operation time</b> 91 minutes (SD 33)</p> <p>Operating time reduced over the study period: 1998: 159 minutes (SD 64) 2003: 81 minutes (SD 29)</p> <p><b>Mean length of hospital stay</b> 2.2 days (SD 0.6)</p>	<p><b>Conversion to laparotomy</b> 0.83% (14/1692)</p> <p><b>All complications</b> 1.48% (25/1692)</p> <p><b>Intraoperative complications</b></p> <ul style="list-style-type: none"> <li>Abnormal bleeding 0.06% (1/1692)</li> <li>Bladder injury 0.18% (3/1692)</li> <li>Ureter injury 0.06% (1/1692)</li> </ul> <p><b>Postoperative complications</b></p> <ul style="list-style-type: none"> <li>Adhesions 0.30% (5/1692)</li> <li>Incisional hernia 0.06% (1/1692)</li> <li>Abdominal wound infection 0.18% (3/1692)</li> <li>Pouch of Douglas abscess 0.06% (1/1692)</li> <li>Bleeding disorder 0.30% (5/1692)</li> <li>Cervical stump infection 0.24% (4/1692)</li> <li>Pelvic pain 0.06% (1/1692)</li> </ul>	<p>Three surgeons performed the procedures.</p>

Abbreviations used: CI: 95% confidence interval; AH: abdominal hysterectomy; LAVH: laparoscopically assisted vaginal hysterectomy; LH: laparoscopic hysterectomy; OR: odds ratio; RCT: randomised controlled trial; SD: standard deviation; VH : vaginal hysterectomy; WMD: weighted mean difference.

Study details	Key efficacy findings and key safety findings		Comments
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<p>Maresh MJA et al (2002)<sup>5</sup> McPherson K et al (2004)<sup>6</sup> [Reporting on the same study]</p> <p><b>Non-randomised controlled study</b></p> <p>UK</p> <p>Study period: 1994–1995</p> <p>Population: national sample of pre-menopausal women, under 60 years of age</p> <p><b>Total n = 37,048</b> <b>Laparoscopic techniques for hysterectomy n = 1154</b> <b>(133 = total, 74 = subtotal, 997 = LAVH)</b> <b>AH = 24,772</b> <b>VH = 11,122</b></p> <p>Indications: any benign condition</p> <p><b>Follow-up:</b> <b>Until hospital follow-up appointment or discharge for post-operative complications</b></p> <p>Conflict of interest: None</p>	<p><b>EFFICACY</b></p> <p><b>Length of hospital stay</b> All patients: median 5 days, mode 5 days, range: 1–205 days</p> <p>Mode (most frequent value) AH: 5 days, VH: 4 days, laparoscopic techniques: 3 days</p> <p><b>Conversion to open procedure</b> "Of the 1242 planned laparoscopic procedures, 7% (82) were performed abdominally." (It is not clear from the paper how these numbers of patients correspond with the 1154 patients on whom other data were presented.)</p>			<p>This is the 'VALUE' study. NHS and private hospitals were asked for data on all patients undergoing hysterectomy during a 12-month period in England, Wales and Northern Ireland. Data were received on about 40% of all hysterectomies that took place.</p> <p>Serious operative complications included death, deep venous thrombosis, pulmonary embolism, myocardial infarction, renal failure, cerebrovascular accident, septicaemia, necrotising fasciitis, secondary haemorrhage, fistula, ureteric obstruction and visceral damage.</p> <p>Odds ratios and rate ratios for operative and postoperative complications were adjusted for age, parity, indication, history of serious illness and grade of operator and supervisor.</p>																									
	<p><b>SAFETY</b></p> <p><b>Deaths within 6 weeks of surgery</b> 14 in total (0.38 per thousand; CI: 0.25–0.64). No deaths were associated with laparoscopic techniques.</p> <p><b>Serious operative complications</b></p> <table border="1"> <thead> <tr> <th rowspan="2"></th> <th colspan="3">% of patients having the event (no.)</th> </tr> <tr> <th><b>AH</b> <b>n = 24,772</b></th> <th><b>VH</b> <b>n = 11,122</b></th> <th><b>Laparoscopic</b> <b>n = 1154</b></th> </tr> </thead> <tbody> <tr> <td>Respiratory or heart-related complications</td> <td>0.36 (88)</td> <td>0.33 (37)</td> <td>0.35 (4)</td> </tr> <tr> <td>Visceral damage</td> <td>0.76 (189)</td> <td>0.61 (68)</td> <td>1.13 (13)</td> </tr> <tr> <td>Major operative haemorrhage*</td> <td>2.31 (571)</td> <td>1.96 (218)</td> <td>4.42 (51)</td> </tr> <tr> <td>Return to theatre*</td> <td>0.73 (181)</td> <td>0.75 (83)</td> <td>1.56 (18)</td> </tr> <tr> <td>All serious complications and deaths*</td> <td>3.6 (884)</td> <td>3.1 (34)</td> <td>6.1 (70)</td> </tr> </tbody> </table> <p>*Significantly higher risk (unadjusted) for laparoscopic techniques compared with AH and VH. P &lt; 0.001 for haemorrhage and all events; p = 0.02 for return to theatre. There was no difference in risk of bladder damage between the approaches (0.5–0.6%).</p> <p><i>Adjusted odds ratios for any serious event</i> AH: 1.00; VH: 1.07 (CI 0.89 to 1.27); laparoscopic techniques: 1.92 (CI 1.48 to 2.50) p &lt; 0.001 for laparoscopic techniques vs AH and VH</p>					% of patients having the event (no.)			<b>AH</b> <b>n = 24,772</b>	<b>VH</b> <b>n = 11,122</b>	<b>Laparoscopic</b> <b>n = 1154</b>	Respiratory or heart-related complications	0.36 (88)	0.33 (37)	0.35 (4)	Visceral damage	0.76 (189)	0.61 (68)	1.13 (13)	Major operative haemorrhage*	2.31 (571)	1.96 (218)	4.42 (51)	Return to theatre*	0.73 (181)	0.75 (83)	1.56 (18)	All serious complications and deaths*	3.6 (884)
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<p>Wattiez A et al (2002)<sup>7</sup></p> <p><b>Case series</b></p> <p>France</p> <p>Study period: 1989–1999</p> <p><b>n = 1647</b></p> <p>1989–1995: n = 695 (median age 47 years) 1996–1999: n = 952 (median age 50 years)</p> <p>Indications: benign conditions only</p> <p>Exclusion criteria: Patients with anaesthetic contraindications or total uterine prolapse</p> <p>Technique: Total laparoscopic hysterectomy. The uterus was removed vaginally and the vagina was closed laparoscopically.</p> <p>Follow-up: “Immediate and long-term postoperative outcome” was available from review of patient records.</p> <p>Conflict of interest: None stated</p>	<p>Not stated.</p> <table border="1" data-bbox="1234 301 1760 1050"> <thead> <tr> <th></th> <th>Number of patients with complications (%) (n = 1647)</th> </tr> </thead> <tbody> <tr><td>Excessive haemorrhage</td><td>14 (0.85)</td></tr> <tr><td>Blood transfusion</td><td>16 (0.97)</td></tr> <tr><td>Major vessel injury</td><td>0</td></tr> <tr><td>Urinary tract injury</td><td>25 (1.52)</td></tr> <tr><td>Bladder laceration</td><td>17 (1.03)</td></tr> <tr><td>Ureter injury</td><td>6 (0.36)</td></tr> <tr><td>Vesicovaginal fistula</td><td>2 (0.12)</td></tr> <tr><td>Bowel injury</td><td>1 (0.06)</td></tr> <tr><td>Bowel obstruction</td><td>1 (0.06)</td></tr> <tr><td>Neurological injury</td><td>4 (0.24)</td></tr> <tr><td>Thromboembolism</td><td>4 (0.24)</td></tr> <tr><td>Reoperation</td><td>12 (0.73)</td></tr> <tr><td>Abdominal wall haematoma</td><td>15 (0.91)</td></tr> <tr><td>Vaginal cuff haematoma</td><td>7 (0.43)</td></tr> <tr><td>Pyrexia</td><td>18 (1.09)</td></tr> <tr><td>Vaginal cuff infection</td><td>4 (0.24)</td></tr> <tr><td>Abdominal wall infection</td><td>2 (0.12)</td></tr> <tr><td>Conversion to laparotomy</td><td>46 (2.79)</td></tr> </tbody> </table> <p>The overall complication rate decreased significantly from 10.4% in 1989–1995 to 2.6% in 1996–1999 (<math>p &lt; 0.005</math>), with significant reductions in occurrence of excessive haemorrhage, blood transfusion, urinary tract injury and reoperation.</p>		Number of patients with complications (%) (n = 1647)	Excessive haemorrhage	14 (0.85)	Blood transfusion	16 (0.97)	Major vessel injury	0	Urinary tract injury	25 (1.52)	Bladder laceration	17 (1.03)	Ureter injury	6 (0.36)	Vesicovaginal fistula	2 (0.12)	Bowel injury	1 (0.06)	Bowel obstruction	1 (0.06)	Neurological injury	4 (0.24)	Thromboembolism	4 (0.24)	Reoperation	12 (0.73)	Abdominal wall haematoma	15 (0.91)	Vaginal cuff haematoma	7 (0.43)	Pyrexia	18 (1.09)	Vaginal cuff infection	4 (0.24)	Abdominal wall infection	2 (0.12)	Conversion to laparotomy	46 (2.79)	<p>Participants were patients at a university tertiary referral centre for endoscopic surgery.</p> <p>Authors state that a ‘new uterine manipulator’ was introduced in 1996 to reduce the incidence of complications.</p>
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Study details	Key efficacy findings and key safety findings		Comments																
<p>Härkki-Siren P et al (1999)<sup>8</sup></p> <p><b>Case series</b></p> <p>Finland</p> <p>Study period: 1992–1996</p> <p><b>n = 5104</b></p> <p>Population: all patients in Finnish hospitals</p> <p>Indications: Hysterectomy was part of a larger set of interventions labelled ‘operative laparoscopies’, defined as, “procedures performed for endometriosis, ectopic pregnancy, adhesions, ovarian cysts and incontinence”.</p> <p>Technique: laparoscopic techniques for hysterectomy (type not specified)</p> <p><b>Follow-up: Until discharge</b></p> <p>Conflict of interest: None stated</p>	<p>None stated.</p>	<p><b>Major complications</b></p> <table border="1" data-bbox="1234 331 1760 807"> <thead> <tr> <th></th> <th>Number of patients with complications (%) ( n = 5104)</th> </tr> </thead> <tbody> <tr> <td>Ureter injury</td> <td>66 (1.3)</td> </tr> <tr> <td>Simple bladder injury</td> <td>22 (0.4)</td> </tr> <tr> <td>Vesicovaginal fistula</td> <td>12 (0.2)</td> </tr> <tr> <td>Intestinal injury (including incisional hernia)</td> <td>15 (0.3)</td> </tr> <tr> <td>Major vascular injury</td> <td>1 (0.02)</td> </tr> <tr> <td>Other injury</td> <td>13 (0.3)</td> </tr> <tr> <td>All</td> <td>129 (2.5)</td> </tr> </tbody> </table>		Number of patients with complications (%) ( n = 5104)	Ureter injury	66 (1.3)	Simple bladder injury	22 (0.4)	Vesicovaginal fistula	12 (0.2)	Intestinal injury (including incisional hernia)	15 (0.3)	Major vascular injury	1 (0.02)	Other injury	13 (0.3)	All	129 (2.5)	<p>“Two of the most reliable Finnish register databases were used in this study”. The Finnish Hospital Discharge Register provided the denominators (total number of procedures) and the National Patient Insurance Association provided the number of complications.</p> <p>Patients treated in 1996 are the same set of patients reported on in the study by Mäkinen J et al (2001).</p>
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Study details	Key efficacy findings and key safety findings		Comments																
<p>Shen C-C et al (2003)<sup>9</sup></p> <p><b>Case series</b></p> <p>Taiwan</p> <p>Study period: 1992–2002</p> <p><b>n = 2702</b> (mean age: 46 years)</p> <p>Population: patients at one hospital</p> <p>Indications: Myomata uteri, adenomyosis, intractable menorrhagia, endometriosis, severe pelvic adhesions, cervical intraepithelial neoplasia, endometrial polyps, hyperplasia</p> <p>Technique: LAVH</p> <p><b>Follow-up: None</b></p> <p>Conflict of interest: None stated</p>	<p>None stated.</p>	<table border="1" data-bbox="1234 301 1760 622"> <thead> <tr> <th></th> <th>Number of patients with complications (%) (n = 2702)</th> </tr> </thead> <tbody> <tr> <td>Bladder injury</td> <td>11 (0.4)</td> </tr> <tr> <td>Ureter injury</td> <td>4 (0.2)</td> </tr> <tr> <td>Bowel injury</td> <td>11 (0.4)</td> </tr> <tr> <td>Vessel injury</td> <td>2 (0.1)</td> </tr> <tr> <td>Stump bleeding</td> <td>2 (0.1)</td> </tr> <tr> <td>Ileus</td> <td>2 (0.1)</td> </tr> <tr> <td>Abscess</td> <td>2 (0.1)</td> </tr> </tbody> </table> <p><b>Complication rate by experience of surgeon</b></p> <p>Bladder injury</p> <ul style="list-style-type: none"> <li>Experienced = 0.2% (3/2053)</li> <li>Inexperienced = 1.2% (8/649)</li> </ul> <p>p = 0.001</p> <p>Ureter injury</p> <ul style="list-style-type: none"> <li>Experienced = 0.05% (1/2053)</li> <li>Inexperienced = 0.5% (3/649)</li> </ul> <p>p = 0.045</p> <p>Bowel injury</p> <ul style="list-style-type: none"> <li>Experienced = 0.1% (3/2053)</li> <li>Inexperienced = 1.2% (8/649)</li> </ul> <p>p = 0.001</p>		Number of patients with complications (%) (n = 2702)	Bladder injury	11 (0.4)	Ureter injury	4 (0.2)	Bowel injury	11 (0.4)	Vessel injury	2 (0.1)	Stump bleeding	2 (0.1)	Ileus	2 (0.1)	Abscess	2 (0.1)	<p>Retrospective case review</p> <p>Study focused on major complications.</p> <p>76% of procedures were carried out by qualified instructors of the Taiwan Association of Obstetric and Gynecologic Endoscopists and 24% by relatively inexperienced general gynaecologists.</p>
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### ***Validity and generalisability of the studies***

- A number of large case series and non-randomised controlled studies were included in this overview, two of which were intended to be nationally representative. The smallest of these included 1647 patients; the largest included 37,048 patients.
- The authors of the Cochrane review commented that the meta-analysis was underpowered to detect significant differences in the incidence of some safety outcomes between laparoscopic techniques, VH and AH.
- Some studies included in the overview combined patients who underwent hysterectomy by any laparoscopic method. LAVH was the most common type, however.
- Only one of the studies in Table 2 included patients who underwent hysterectomy for malignant conditions.

### **Issues for consideration by IPAC**

- This procedure is being considered as a review of the consultation document on laparoscopic hysterectomy that was issued in November 2004. Interventional procedures guidance has not yet been issued on this procedure.
- A special skills training module in intermediate-level laparoscopic surgery is available from the Royal College of Obstetricians and Gynaecologists in collaboration with the British Society for Gynaecological Endoscopy (<http://www.rcog.org.uk/index.asp?PageID=949>).

### **Specialist advisers' opinions**

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

Mr Richard Penketh, Mr Marcus Setchell

- One Specialist Adviser considered laparoscopic techniques for hysterectomy to be established practice and another considered these to be novel techniques of uncertain safety and efficacy.
- Key efficacy outcomes identified were complication rates, rates of conversion to laparotomy, length of hospital stay, analgesia use, readmission rates, length of time taken for patients to return to work/normal activities, time to resumption of sexual intercourse and patient satisfaction.
- Theoretical adverse events were considered to include injury to the ureter and bowel, vascular injury, haemorrhage and need for blood transfusion.
- Both Specialist Advisers commented that special training was necessary and has implications for safety. One Specialist Adviser considered there to be a quite long learning curve for these procedures. One Specialist

Adviser commented that laparoscopy training at Level 2 (Royal College of Obstetrics and Gynaecology standards) or 'grandfathering', plus some mentorship, was important for surgeons conducting these procedures.

- One Specialist Adviser suggested that registries may be available.
- Both Specialist Advisers highlighted the range of hysterectomy techniques that have a laparoscopic component, and one commented that LAVH can mean a laparoscopic oophorectomy performed after VH, where the ovaries could not be removed during VH.

## References

1. Johnson N, Barlow D, Lethaby A et al (2006) Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database of Systematic Reviews Issue 2. Art. No.: CD003677. DOI: 10.1002/14651858.CD003677.pub3.
2. Mäkinen J, Johansson J, Tomas C et al (2001) Morbidity of 10110 hysterectomies by type of approach. *Human Reproduction* 16: 1473–1478.
3. Ben-Hur H, Phipps JH. (2000) Laparoscopic hysterectomy. *Journal of the American Association of Gynecologic Laparoscopists* 7: 103–106.
4. Bojahr B, Raatz D, Schonleber G, Abri C, Ohlinger R. (2006) Perioperative complication rate in 1706 patients after a standardized laparoscopic supracervical hysterectomy technique. *Journal of Minimally Invasive Gynecology* 13: 183–189.
5. Maresh MJA, Metcalfe MA, McPherson K et al. (2002) The VALUE national hysterectomy study: description of the patients and their surgery. *International Journal of Obstetrics and Gynaecology* 109: 302–312.
6. McPherson K, Metcalfe MA, Herbert A et al. (2004) Severe complications of hysterectomy: the VALUE study. *International Journal of Obstetrics and Gynaecology* 111: 688–694.
7. Wattiez A, Soriano D, Cohen SB et al. (2002) The learning curve of total laparoscopic hysterectomy: comparative analysis of 1647 cases. *Journal of the American Association of Gynecologic Laparoscopists* 9: 339–345.
8. Härkki-Siren P, Sjöberg J, Kurki T. (1999) Major complications of laparoscopy: a follow-up Finnish study. *Obstetrics and Gynecology* 94: 94–98.
9. Shen CC, Wu MP, Kung FT et al. (2003) Major complications associated with laparoscopic-assisted vaginal hysterectomy: ten-year experience. *Journal of the American Association of Gynecologic Laparoscopists* 10: 147–153.
10. Meikle SF, Weston Nugent E, Orleans M. (1997) Complications and recovery from laparoscopy-assisted vaginal hysterectomy compared with abdominal and vaginal hysterectomy. *Obstetrics and Gynecology* 89: 304–311.

## Appendix A: Additional papers on laparoscopic techniques for hysterectomy not included in summary

### Table 2

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (Table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
<b>Randomised controlled trials</b>			
Ayoubi JM, Fanchin R, Monrozies X, Imbert P, Reme JM, Pons JC. Respective consequences of abdominal, vaginal, and laparoscopic hysterectomies on women's sexuality. <i>European Journal of Obstetrics, Gynecology, &amp; Reproductive Biology</i> 2003; 111: 179-182.	170 (35 laparoscopic)	Deterioration of sexual function was more common after AH compared with VH and laparoscopic techniques for hysterectomy.	Given the inclusion of the Cochrane review of RCTs in Table 2 and several very large non-randomised studies, this RCT did not add substantially to the evidence base.
Darai E, Soriano D, Kimata P, Laplace C, Lecuru F. Vaginal hysterectomy for enlarged uteri, with or without laparoscopic assistance: randomized study. <i>Obstetrics &amp; Gynecology</i> 2001; 97: 712-716.	80 (number of LAVH patients not stated in abstract)	LAVH vs AH  There were significantly fewer complications in LAVH. Operating time was significantly shorter for VH. There was no difference in first-day haemoglobin drop or hospital stay.	This paper was included in the Cochrane review which is described in Table 2.
Ellström M, Ferraz-Nunes J, Hahlin M, Olsson J-H. A randomized trial with a cost-consequence analysis after laparoscopic and abdominal hysterectomy. <i>Obstetrics and Gynecology</i> 1998; 91: 30—34.	143 (71 laparoscopic)  Follow-up: 12 weeks	AH vs TLH  Operating time was significantly longer for TLH but hospital stay was significantly shorter. There was no significant difference between AH and TLH in quality of life 12 weeks after surgery	Given the inclusion of the Cochrane review of RCTs in Table 2 and several very large non-randomised studies, this RCT did not add substantially to the evidence base.
Ellström M, Olsen MF, Olsson JH, Nordberg G, Bengtsson A, Hahlin M. Pain and pulmonary function following laparoscopic and abdominal hysterectomy: a randomized study. <i>Acta Obstetrica et Gynecologica Scandinavica</i> 1998; 77: 923-928.	40 (20 laparoscopic)	Laparoscopic methods (type not specified) vs AH  On the first and second postoperative day, pain scores were significantly lower and lung function	This paper was included in the Cochrane review which is described in Table 2.

		significantly less impaired after the laparoscopic procedure compared with AH.	
Ellström MA, Astrom M, Moller A, Olsson JH, Hahlin M. A randomized trial comparing changes in psychological well-being and sexuality after laparoscopic and abdominal hysterectomy. <i>Acta Obstetrica et Gynecologica Scandinavica</i> 2003; 82: 871-875.	74 (36 laparoscopic) Follow-up: 1 year	There were no significant differences in psychological wellbeing and sexuality one year after surgery.	Given the inclusion of the Cochrane review of RCTs in Table 2 and several very large non-randomised studies, this RCT did not add substantially to the evidence base.
Falcone T, Paraiso MF, Mascha E. Prospective randomized clinical trial of laparoscopically assisted vaginal hysterectomy versus total abdominal hysterectomy. <i>American Journal of Obstetrics &amp; Gynecology</i> 1999; 180: 955-962.	48 (24 laparoscopic)	LAVH vs AH  Operating time was longer for LAVH.  Hospital stay was shorter, intravenous analgesia use was lower and return to work was quicker for LAVH.	This paper was included in the Cochrane review which is described in Table 2.
Ferrari MM, Berlanda N, Mezzopane R, Ragusa G, Cavallo M, Pardi G. Identifying the indications for laparoscopically assisted vaginal hysterectomy: a prospective, randomised comparison with abdominal hysterectomy in patients with symptomatic uterine fibroids. <i>BJOG: an International Journal of Obstetrics &amp; Gynecology</i> 2000; 107: 620-625.	62 (number of LAVH patients not stated in abstract)	LAVH vs AH  Operating time was significantly longer for LAVH. LAVH patients received significantly less analgesics and had a significantly shorter hospital stay.	This paper was included in the Cochrane review which is described in Table 2.
Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M, Napp V, Bridgman S, Gray J, Lilford R. EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy. <i>Health Technology Assessment</i> 2004; 8(26).	1346 Follow-up: 1 year	<u>LH vs AH</u> (584 LH, 292 AH)  LH had a significantly higher risk of major complications and operations took longer but LH was less painful, needed a shorter hospital stay and was associated with better quality of life 6 weeks after surgery.	This paper was included in the Cochrane review which is described in Table 2.
Garry R, Fountain J, Mason S, Napp V, Brown J, Hawe J, Clayton R, Abbott J, Phillips G, Whittaker M, Lilford R, Bridgman S. The eVALuate study: two parallel randomised trials, one comparing laparoscopic with abdominal hysterectomy, the other comparing laparoscopic with vaginal hysterectomy. <i>British Medical Journal</i> 2004; 328: 129-135.		<u>LH vs VH</u> (336 LH, 168 VH) No significant difference between VH and LH in risk of major complications. LH operations took longer. No difference in hospital stay or quality of life but authors say this trial was underpowered.	This paper was included in the Cochrane review which is described in Table 2.
Ghezzi, F., Cromi, A., Bergamini, V.,	72	LAVH vs TLH	Larger studies

<p>Uccella, S., Beretta, P., Franchi, M., and Bolis, P. Laparoscopic-assisted vaginal hysterectomy versus total laparoscopic hysterectomy for the management of endometrial cancer: a randomized clinical trial. <i>Journal of Minimally Invasive Gynecology</i> 13 (2) 114-120.2006.</p>	<p>(37 LAVH, 35 TLH)  Median follow-up: 10 months</p>	<p>All patients had endometrial cancer.  There was no significant difference in blood loss, intraoperative or postoperative complications between LAVH and TLH. With a median follow-up of 10 months, 2 LAVH patients developed recurrent disease. No port site metastasis and no vaginal cuff recurrence was detected in either group.</p>	<p>of patients who underwent these procedures are included in Table 2.</p>
<p>Harkki-Siren P, Sjoberg J, Toivonen J, Tiitinen A. Clinical outcome and tissue trauma after laparoscopic and abdominal hysterectomy: a randomized controlled study. <i>Acta Obstetrica et Gynecologica Scandinavica</i> 2000; 79: 866-871.</p>	<p>50 (25 laparoscopic)</p>	<p>Laparoscopic techniques (type not stated) vs AH  "In uncomplicated hysterectomies (n = 18" operating time was significantly longer for laparoscopic techniques, but hospital stay and time to return to work were significantly shorter.</p>	<p>This paper was included in the Cochrane review which is described in Table 2.</p>
<p>Hwang JL, Seow KM, Tsai YL, Huang LW, Hsieh BC, Lee C. Comparative study of vaginal, laparoscopically assisted vaginal and abdominal hysterectomies for uterine myoma larger than 6 cm in diameter or uterus weighing at least 450 g: a prospective randomized trial. <i>Acta Obstetrica et Gynecologica Scandinavica</i> 2002; 81: 1132-1138.</p>	<p>90 (30 LAVH)</p>	<p>LAVH vs VH vs AH  LAVH operations took significantly longer.  VH had significantly less blood loss than AH or LAVH.  VH and LH both had significantly shorter hospital stays, lower postoperative pain scores, more rapid bowel recover and lower postoperative antibiotic use than AH.</p>	<p>This paper was included in the Cochrane review which is described in Table 2.</p>
<p>Kung FT, Hwang FR, Lin H, Tai MC, Hsieh CH, Chang SY. Comparison of laparoscopically assisted vaginal hysterectomy and abdominal hysterectomy in Taiwan. <i>Journal of the Formosan Medical Association</i> 1996; 95: 769-775.</p>	<p>301 (144 LAVH)</p>	<p>LAVH vs AH  4.2% of LAVH operations were converted to laparotomy. Operating time was significantly longer for LAVH. There was no significant difference in intraoperative blood loss or complications.</p>	<p>Given the inclusion of the Cochrane review of RCTs in Table 2 and several very large non-randomised studies, this RCT did not add substantially to the evidence base.</p>
<p>Langebrekke A, Eraker R, Nesheim BI, Urnes A, Busund B, Sponland</p>	<p>100 (46 laparoscopic)</p>	<p>LAVH vs AH</p>	<p>This paper was included in the</p>

<p>G. Abdominal hysterectomy should not be considered as a primary method for uterine removal - a prospective randomised study of 100 patients referred to hysterectomy. <i>Acta Obstetrica et Gynecologica Scandinavica</i> 1996;75:404-7.</p>		<p>Operating time was longer for LAVH. Hospital stay, time to return to normal activities and use of analgesics were lower for LAVH. (Significance not reported in the abstract of the paper).</p>	<p>Cochrane review which is described in Table 2.</p>
<p>Lumsden MA, Twaddle S, Hawthorn R, Traynor I, Gilmore D, Davis J, Deeny M, Cameron IT, Walker JJ. A randomised comparison and economic evaluation of laparoscopic-assisted hysterectomy and abdominal hysterectomy. <i>British Journal of Obstetrics and Gynaecology</i> 2000; 107: 1386-1391.</p>	<p>200 (100 laparoscopic)  Follow-up: 1 year</p>	<p>LAVH vs AH</p> <p>Operation time was significantly greater for LAVH but hospital stay was significantly shorter.</p> <p>Overall incidence of complications was 14% for AH and 8% for LAVH (significance not reported). 8% of LAVH were converted to laparotomy.</p> <p>There were no differences in postoperative recovery, satisfaction or quality of life at 4 weeks after surgery.</p>	<p>This paper was included in the Cochrane review which is described in Table 2.</p>
<p>Marana R, Busacca M, Zupi E, Garcea N, Paparella P, Catalano GF. Laparoscopically assisted vaginal hysterectomy versus total abdominal hysterectomy: a prospective, randomized, multicenter study. <i>American Journal of Obstetrics &amp; Gynecology</i> 1999; 180: 270-275.</p>	<p>116 (58 LH)</p>	<p>LAVH vs AH</p> <p>No difference in operating time between LAVH and AH.</p> <p>Blood loss and postoperative day 1 haemoglobin drop were significantly lower for LAVH.</p> <p>There were more complications with AH, but this was not significant.</p>	<p>This paper was included in the Cochrane review which is described in Table 2.</p>
<p>Olsson JH, Ellstrom M, Hahlin M. A randomised prospective trial comparing laparoscopic and abdominal hysterectomy. <i>British Journal of Obstetrics &amp; Gynaecology</i> 1996; 103: 345-350.</p>	<p>143 (71 laparoscopic)</p>	<p>Laparoscopic techniques (type not specified) vs AH</p> <p>Laparoscopic techniques took significantly longer, but laparoscopic patients had significantly less pain, a smaller reduction in erythrocyte volume fraction and a significantly shorter hospital stay and time to return to work. There was no</p>	<p>This paper was included in the Cochrane review which is described in Table 2.</p>

		significant difference in incidence of complications between groups.	
Ottosen C, Lingman G, Ottosen L. Three methods for hysterectomy: a randomised, prospective study of short term outcome. <i>BJOG: an International Journal of Obstetrics &amp; Gynecology</i> 2000; 107: 1380-1385.	120 (40 laparoscopic) Follow-up: not stated	LAVH vs AH & VH  LAVH operations took significantly longer. Hospital stay and convalescence time were significantly shorter for LAVH than AH, but there was no significant difference between VH and LAVH.  10% of LAVH operations were converted to laparotomy compare with 2.5% of VH.  Reoperation and blood transfusion were required after 2.5% of LAVH and 5% of VH.	This paper was included in the Cochrane review which is described in Table 2.
Perino A, Cucinella G, Venezia R, Castelli A, Cittadini E. Total laparoscopic hysterectomy versus total abdominal hysterectomy: an assessment of the learning curve in a prospective randomized study. <i>Human Reproduction</i> 1999; 14: 2996-2999.	102 (51 laparoscopic)	TLH vs AH  Intraoperative blood loss was significantly lower for TLH. Operating times for TLH reached a plateau, at which point there was no significant difference compared with AH operating times. Hospital stay was significantly shorter for TLH.	This paper was included in the Cochrane review which is described in Table 2.
Raju KS, Auld BJ. A randomised prospective study of laparoscopic vaginal hysterectomy versus abdominal hysterectomy each with bilateral salpingo-oophorectomy. <i>British Journal of Obstetrics &amp; Gynaecology</i> 1994;101:1068-71.	80 (number treated laparoscopically not stated in the abstract)	LAVH vs AH  LAVH operations took significantly longer but hospital stay and time to return to work were significantly shorter for LAVH. There was no significant difference in complications.	This paper was included in the Cochrane review which is described in Table 2.
Ribeiro SC, Ribeiro RM, Santos NC, Pinotti JA. A randomized study of total abdominal, vaginal and laparoscopic hysterectomy. <i>International Journal of Gynaecology &amp; Obstetrics</i> 2003; 83: 37-43.	60 (20 laparoscopic)	Operation time was significantly shorter for VH, but there was no significant difference between AH and laparoscopic techniques. Drop in haemoglobin was least for laparoscopic techniques.	This paper was included in the Cochrane review which is described in Table 2.
Richardson RE, Bournas N, Magos AL. Is laparoscopic hysterectomy a waste of time?. <i>Lancet</i> 1995;345:36-	98 (75 laparoscopic)	Laparoscopic techniques (type not specified in the	This paper was included in the Cochrane

41.		abstract) vs VH  Operating time was longer for laparoscopic techniques. There was no difference between groups in complications, blood loss, analgesia use or recovery time.	review which is described in Table 2.
Schutz K, Possover M, Merker A, Michels W, Schneider A. Prospective randomized comparison of laparoscopic-assisted vaginal hysterectomy (LAVH) with abdominal hysterectomy (AH) for the treatment of uterus weighing >200 g. <i>Surgical Endoscopy</i> 2002; 16: 121-125.	48 (28 Laparoscopic)	LAVH vs AH  Operation time and convalescence time were not significantly different. Blood loss, haemoglobin drop, and pain 4 days after surgery were significantly lower for LAVH. There was no significant difference in the incidence of postoperative complications.	This paper was included in the Cochrane review which is described in Table 2.
Seracchioli R, Venturoli S, Vianello F, Govoni F, Cantarelli M, Gualerzi B, Colombo FM. Total laparoscopic hysterectomy compared with abdominal hysterectomy in the presence of a large uterus. <i>Journal of the American Association of Gynecologic Laparoscopists</i> 2002; 9: 333-338.	122 (60 laparoscopic)	TLH vs AH  There was no significant difference in operating time but hospital stay and convalescence time were significantly shorter for TLH.  1 conversion to laparotomy was required due to bowel injury (1.7%). There were no other complications with TLH. 10% of AH patients experienced wound infection (6/62) but no TLH patients. There was no significant difference in blood loss, haemoglobin drop or blood transfusion between TLH and AH.	This paper was included in the Cochrane review which is described in Table 2.
Shen CC, Wu MP, Lu CH, Huang EY, Chang HW, Huang FJ, Hsu TY, Chang SY. Short and long-term clinical results of laparoscopic-assisted vaginal hysterectomy and total abdominal hysterectomy. <i>Journal of the American Association of Gynecologic Laparoscopists</i> 2003; 10: 49-54.	296 (150 laparoscopic)  Follow-up: mean 8 years	LAVH vs AH  Operation time was significantly higher for LAVH but hospital stay and convalescence time were significantly shorter and intraoperative blood loss was significantly less. There was no significant difference in risk of major	Given the inclusion of the Cochrane review of RCTs in Table 2 and several very large non-randomised studies, this RCT did not add substantially to the evidence base.

		<p>complications.</p> <p>After 8 years' follow-up, there were no significant differences between LAVH and AH in risk of vaginal vault prolapse, cystocele, rectocele, enterocele, cuff granulation or postcoital spotting.</p>	
<p>Soriano D, Goldstein A, Lecuru F, Darai E. Recovery from vaginal hysterectomy compared with laparoscopy-assisted vaginal hysterectomy: a prospective, randomized, multicenter study. <i>Acta Obstetrica et Gynecologica Scandinavica</i> 2001; 80: 337-341.</p>	<p>80 (40 laparoscopic)</p>	<p>LAVH vs VH</p> <p>7.5% of LAVH patients required conversion to laparotomy. Operating time was significantly shorter for VH. There were no significant differences in use of analgesia, haemoglobin drop or hospital stay between the groups.</p>	<p>This paper was included in the Cochrane review which is described in Table 2.</p>
<p>Summitt RL Jr, Stovall TG, Lipscomb GH, Ling FW. Randomized comparison of laparoscopy-assisted vaginal hysterectomy with standard vaginal hysterectomy in an outpatient setting. <i>Obstetrics &amp; Gynecology</i> 1992; 80: 895-901.</p>	<p>56 (29 laparoscopic)</p>	<p>LAVH vs VH</p> <p>There was one complication, in a LAVH patient (not further described in the abstract). Operating time was significantly longer for LAVH and patients required significantly more pain medication. The incidence of febrile mortality was similar in the two groups.</p>	<p>This paper was included in the Cochrane review which is described in Table 2.</p>
<p>Summitt RL Jr, Stovall TG, Steege JF, Lipscomb GH. A multicenter randomized comparison of laparoscopically assisted vaginal hysterectomy and abdominal hysterectomy in abdominal hysterectomy candidates. <i>Obstetrics &amp; Gynecology</i> 1998; 92: 321-326.</p>	<p>65 (34 laparoscopic)</p>	<p>LAVH vs AH</p> <p>9% of LAVH patients required conversion to laparotomy.</p> <p>Operating time was longer for LAVH, but hospital stay and convalescence were shorter (all significant).</p> <p>No significant difference in blood loss, intraoperative complications, or postoperative complications.</p>	<p>This paper was included in the Cochrane review which is described in Table 2.</p>
<p>Tozzi, R., Malur, S., Koehler, C., and Schneider, A. Laparoscopy versus laparotomy in endometrial cancer: first analysis of survival of a randomized prospective study. <i>Journal of Minimally</i></p>	<p>122 (63 laparoscopic)</p> <p>Median follow-up: 44</p>	<p>Laparoscopic techniques (type not stated in abstract) vs AH</p>	<p>Larger studies of patients who underwent these procedures are included in</p>

<i>Invasive Gynecology</i> 2005; 12; 130-136.	months	There was no significant difference in recurrence during follow-up between the two groups. At median follow-up, disease free survival was 87% in the laparoscopic group and 92% in the AH group.	Table 2.
Tsai EM, Chen HS, Long CY, Yang CH, Hsu SC, Wu CH, Lee JN. Laparoscopically assisted vaginal hysterectomy versus total abdominal hysterectomy: a study of 100 cases on light-endorsed transvaginal section. <i>Gynecologic &amp; Obstetric Investigation</i> 2003; 55: 105-109.	200 (100 laparoscopic)  Follow-up: not stated	Operation time, hospital stay, dose of analgesics and complication rates were significantly lower for LAVH ( $p < 0.001$ ).	This paper was included in the Cochrane review which is described in Table 2.
Yuen PM, Mak TW, Yim SF, Kee WD, Lam CW, Rogers MS, Chang AM. Metabolic and inflammatory responses after laparoscopic and abdominal hysterectomy. <i>American Journal of Obstetrics &amp; Gynecology</i> 1998; 179:1-5.	44 (20 laparoscopic)	Laparoscopic techniques (type not specified in abstract) vs AH  There were no differences in operation time or incidence of complications between groups (significance not reported in the abstract). Laparoscopic patients had significantly lower postoperative morphine consumption, less febrile morbidity, a shorter hospital stay and a less intense hormonal stress response.	This paper was included in the Cochrane review which is described in Table 2.
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## Appendix B: Related published NICE guidance for laparoscopic techniques for hysterectomy

Guidance programme	Recommendation
Interventional procedures	<p><i>IP055 Consultation document: Laparoscopic hysterectomy [being reviewed here]</i></p> <p>1 Provisional recommendations</p> <p>The term laparoscopic hysterectomy includes laparoscopic-assisted vaginal hysterectomy, laparoscopic hysterectomy, laparoscopic supracervical hysterectomy and total laparoscopic hysterectomy. The evidence on these procedures differs and, in addition, there are variations in these techniques.</p> <p><i>Laparoscopic-assisted vaginal hysterectomy, laparoscopic hysterectomy and laparoscopic supracervical hysterectomy</i></p> <p>1.1 Current evidence on the safety and efficacy of these procedures appears adequate to support their use, provided that normal arrangements are in place for audit and clinical governance.</p> <p>1.2 Complication rates are higher than for abdominal hysterectomy, and patients should be fully informed about this during the consent process. Use of the Institute's Information for the Public is recommended.</p> <p><i>Total laparoscopic hysterectomy</i></p> <p>1.3 Current evidence on the safety of total laparoscopic hysterectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research.</p> <p>1.4 Clinicians wishing to undertake total laparoscopic hysterectomy should take the following actions.</p> <ul style="list-style-type: none"> <li>▪ Inform the clinical governance leads in their Trusts.</li> <li>▪ Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's Information for the Public is recommended.</li> <li>▪ Audit and review clinical outcomes of all patients having total laparoscopic</li> </ul>

	<p>hysterectomy</p> <p>1.5 Publication of safety outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.</p> <p>1.6 Clinicians undertaking these procedures should have adequate training before performing them. The British Society for Gynaecological Endoscopy has been asked to produce standards for training.</p> <p><i>IPG24 Laparoscopic radical hysterectomy for early stage cervical cancer (November 2003)</i></p> <p>1.1 Current evidence on the safety and efficacy of laparoscopic radical hysterectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake laparoscopic radical hysterectomy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. Use of the Institute's Information for the Public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and longer-term efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking any further investigation at present.</p> <p>1.2 Clinicians undertaking this procedure should undergo training as recommended by the Royal College of Obstetricians and Gynaecologists Working Party on Training in Endoscopic Surgery (<a href="http://www.rcog.org.uk">www.rcog.org.uk</a>).</p> <p>See Related NICE Guidance, above, for web addresses of other interventional procedures.</p>
Technology appraisals	See Related NICE Guidance above for web address.
Clinical guidelines	<p>CG44: Heavy Menstrual Bleeding (January 2007)</p> <p><i>Recommendations on hysterectomy</i> [only sections relating to laparoscopic</p>

	<p>hysterectomy have been reproduced here]</p> <p>Taking into account the need for individual assessment, the route of hysterectomy should be considered in the following order: first line vaginal; second line abdominal. [A] Under circumstances such as morbid obesity or the need for oophorectomy during vaginal hysterectomy, the laparoscopic approach should be considered, and appropriate expertise sought. [D(GPP)] When abdominal hysterectomy is decided upon then both the total method (removal of the uterus and the cervix) and subtotal method (removal of the uterus and preservation of the cervix) should be discussed with the woman. D[(GPP)]</p> <p><i>Research recommendations for hysterectomy</i></p> <ul style="list-style-type: none"> <li>• An investigation into the medium- and long-term outcomes of sub-total and total hysterectomy.</li> <li>• An investigation into the effect of hysterectomy and oophorectomy on cancer.</li> </ul> <p><i>Training recommendations</i></p> <p>Training programmes must be long enough to enable healthcare professionals to achieve competency in complex procedures when these are appropriate (for example, operations for fibroids that are large or in an awkward position, or using laparoscopic techniques). These training programmes will usually be located in units with a particular interest and sufficient workload to allow experience of these procedures. [D(GPP)]</p>
Public health	None applicable

## Appendix C: Literature search for laparoscopic techniques for hysterectomy

IP: 055 Laparoscopic techniques for hysterectomy		
Database	Date searched	Version searched
Cochrane Library	21/12/06	2006, Issue 4
CRD databases (DARE & HTA)	21/12/06	2006, Issue 4
Embase	21/12/06	1988 to 2006 Week 50
Medline	21/12/06	1966 to November Week 3 2006
Premedline	21/12/06	December 20, 2006
CINAHL	21/12/06	1982 to December Week 2 2006
British Library Inside Conferences	21/12/06	-
NRR	21/12/06	2006, Issue 4
Controlled Trials Registry	21/12/06	-

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

1	laparoscopy/	33999
2	laparoscopes/	2718
3	surgical procedures, Minimally Invasive/	7491
4	laparoscop\$.tw.	43630
5	or/1-4	55798
6	exp Hysterectomy/	17982
7	(hysterctom\$ or hysterectom\$).tw.	17002
8	or/6-7	25187
9	5 and 8	2066
10	(Isch or lavh or larvh or tlh).tw.	283
11	9 or 10	2123

12	Leiomyoma/	11204
13	Myoma/	542
14	Leiomyomatosis/	461
15	(leiomyoma or leiomyomata or leiomyomatosis or myoma or fibromyoma).tw.	7320
16	((uter\$ or subserosal or intramural or submucosal) adj3 fibroid\$).tw.	1053
17	Adenofibroma/	1933
18	Adenomyoma/	215
19	(adenofibroma or adenomyoma).tw.	347
20	or/12-19	15941
21	Menorrhagia/	2108
22	(Menometrorrhagia or menorrhagia).tw.	1669
23	((heavy or excess\$) adj3 (menstrua\$ or vaginal or menses) adj3 (bleed\$ or blood or period\$ or cycle)).tw.	266
24	or/21-23	2870
25	Pelvic Pain/	1752
26	(pelv\$ adj3 pain).tw.	3333
27	or/25-26	3834
28	Dysmenorrhea/	1889
29	(dysmenorrhea or dysmenorrhoea).tw.	2054
30	((cramp\$ or pain\$) adj3 (period\$ or menstrua\$)).tw.	1583
31	or/28-30	4173
32	Endometrial Neoplasms/	8529
33	Uterine Neoplasms/	26840
34	(endometria\$ adj3 (neoplasm\$ or cancer\$ or carcinoma\$ or adenocarcinom\$ or tumour\$ or tumor\$ or malignan\$)).tw.	12702
35	(uter\$ adj (neoplasm\$ or cancer\$ or carcinoma\$ or adenocarcinom\$ or tumour\$ or tumor\$ or malignan\$)).tw.	3162
36	(endometroid adj3 adenocarcinoma\$).tw.	19
37	or/32-36	38623
38	20 or 24 or 27 or 31 or 37	56322

39	11 and 38	655
40	animals/	4172974
41	humans/	10026435
42	40 not (40 and 41)	3152830
43	39 not 42	654
44	limit 43 to yr="2004 - 2007"	156