

The eVALuate study: two parallel randomised trials, one comparing laparoscopic with abdominal hysterectomy, the other comparing laparoscopic with vaginal hysterectomy

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Abstract

Objective To compare the effects of laparoscopic hysterectomy and abdominal hysterectomy in the abdominal trial, and laparoscopic hysterectomy and vaginal hysterectomy in the vaginal trial.

Design Two parallel, multicentre, randomised trials.

Setting 28 UK centres and two South African centres.

Participants 1380 women were recruited; 1346 had surgery; 937 were followed up at one year.

Primary outcome Rate of major complications.

Results In the abdominal trial laparoscopic hysterectomy was associated with a higher rate of major complications than abdominal hysterectomy (11.1% *v* 6.2%, $P = 0.02$; difference 4.9%, 95% confidence interval 0.9% to 9.1%) and the number needed to treat to harm was 20. Laparoscopic hysterectomy also took longer to perform (84 minutes *v* 50 minutes) but was less painful (visual analogue scale 3.51 *v* 3.88, $P = 0.01$) and resulted in a shorter stay in hospital after the operation (3 days *v* 4 days). Six weeks after the operation, laparoscopic hysterectomy was associated with less pain and better quality of life than abdominal hysterectomy (SF-12, body image scale, and sexual activity questionnaires). In the vaginal trial we found no evidence of a difference in major complication rates between laparoscopic hysterectomy and vaginal hysterectomy (9.8% *v* 9.5%, $P = 0.92$; difference 0.3%, -5.2% to 5.8%), and the number needed to treat to harm was 333. We found no evidence of other differences between laparoscopic hysterectomy and vaginal hysterectomy except that laparoscopic hysterectomy took longer to perform (72 minutes *v* 39 minutes) and was associated with a higher rate of detecting unexpected pathology (16.4% *v* 4.8%, $P < 0.01$). However, this trial was underpowered.

Conclusions Laparoscopic hysterectomy was associated with a significantly higher rate of major complications than abdominal hysterectomy. It also took longer to perform but was associated with less pain, quicker recovery, and better short term quality of life. The trial comparing vaginal hysterectomy with laparoscopic hysterectomy was underpowered and is

inconclusive on the rate of major complications; however, vaginal hysterectomy took less time.

Introduction

Ten previous randomised trials have compared outcomes for abdominal hysterectomy with laparoscopic hysterectomy.¹⁻¹⁰ Most of these were from single centres of endoscopic surgical excellence and had small study populations. Each trial showed that laparoscopic hysterectomy was associated with reduced hospital stay and, in most studies, a shorter time to convalescence and notably less pain than abdominal hysterectomy.

Only four previously published randomised trials have compared the outcomes of vaginal hysterectomy and laparoscopic hysterectomy.¹¹⁻¹⁴ The only difference shown in these studies was that laparoscopic hysterectomy took longer to perform.

We know of no previous trials that were powered to investigate the safety of the various procedures. We have therefore undertaken a concurrent pair of randomised controlled trials to eVALuate the relative roles of Vaginal, Abdominal, and Laparoscopic hysterectomy in routine gynaecological practice.

Methods

Design

One trial compared laparoscopic hysterectomy with abdominal hysterectomy (abdominal trial), and the second compared laparoscopic hysterectomy with vaginal hysterectomy (vaginal trial).

Participants

Patients who needed a hysterectomy for non-malignant conditions were eligible; excluded were patients who had a second or third degree uterine prolapse, a uterine mass greater than the size of a 12 week

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A complete list of members of the study group is on bmj.com



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Major complications

- Major haemorrhage (requiring transfusion)
- Haematoma requiring transfusion or surgical drainage
- Bowel injury
- Ureteric injury
- Bladder injury
- Pulmonary embolus
- Major anaesthesia problems
- Unintended laparotomy
- Wound dehiscence

pregnancy, a medical illness precluding laparoscopic surgery, or a requirement for bladder or other pelvic support surgery, and patients who refused consent.

Gynaecologists were responsible for recruitment and on clinical grounds entered patients for randomisation into either the abdominal or the vaginal trial. Follow up of patients took place in a clinic at six weeks and then by postal questionnaire, at four months and one year after their operation.

Interventions

Surgical procedures were as currently practised, with four approaches to laparoscopic hysterectomy: laparoscopic hysterectomy, laparoscopic assisted vaginal hysterectomy, laparoscopic supracervical hysterectomy, and total laparoscopic hysterectomy. All conversions were documented. Each surgeon's practice standardised antibiotics, analgesia, anticoagulants, anaesthetic care, and advice concerning resumption of normal activities over the three types of operation.

Outcome measures

The primary end point of the trials was the occurrence of at least one major complication (box). Secondary end points were minor complications (haemorrhage not requiring transfusion; infection; haematoma; deep vein thrombosis; cervical stump problems; minor anaesthesia problems), blood loss, pain measured by a visual analogue scale and analgesia requirements, and questionnaire assessments of sexual activity,¹⁵ body image,¹⁶ and health status (SF-12).¹⁷

Sample size and analysis

The sample size for the abdominal trial was based on detecting a relative reduction in complication rates of

50% from 9%¹⁸; 487 patients in each arm were 80% power and 5% significance (two sided). The complication rate in the vaginal trial was expected to be 4% for vaginal hysterectomy.¹⁹ To detect a 50% reduction in this rate, 1141 patients were required per treatment arm. We did not expect to recruit this number but wanted to collect the randomised data as this would represent the largest such trial of vaginal hysterectomy that we are aware of.

The primary analysis was by intention to treat.

Results

Forty three gynaecologists from 28 UK and two South African centres recruited 876 patients into the abdominal trial and 504 into the vaginal trial between November 1996 and September 2000.

Demography

Baseline characteristics were well matched in each of the allocated trials (table 1).

The main indications for hysterectomy were dysfunctional uterine bleeding (874/1380 cases, 63%), fibroids (235 cases, 17%), pelvic pain (151 cases, 11%), endometriosis (126 cases, 9%), and failed ablation (104 cases, 8%).

Numbers analysed

The figure shows the flow of patients through the trials.

Primary outcome

In the abdominal trial significantly more patients undergoing laparoscopic hysterectomy than patients undergoing abdominal hysterectomy had at least one major complication (mean difference 4.9%, 95% confidence interval 0.9% to 9.1%; odds ratio 1.91, 1.11 to 3.28) (table 2). The number needed to treat to harm is 20.

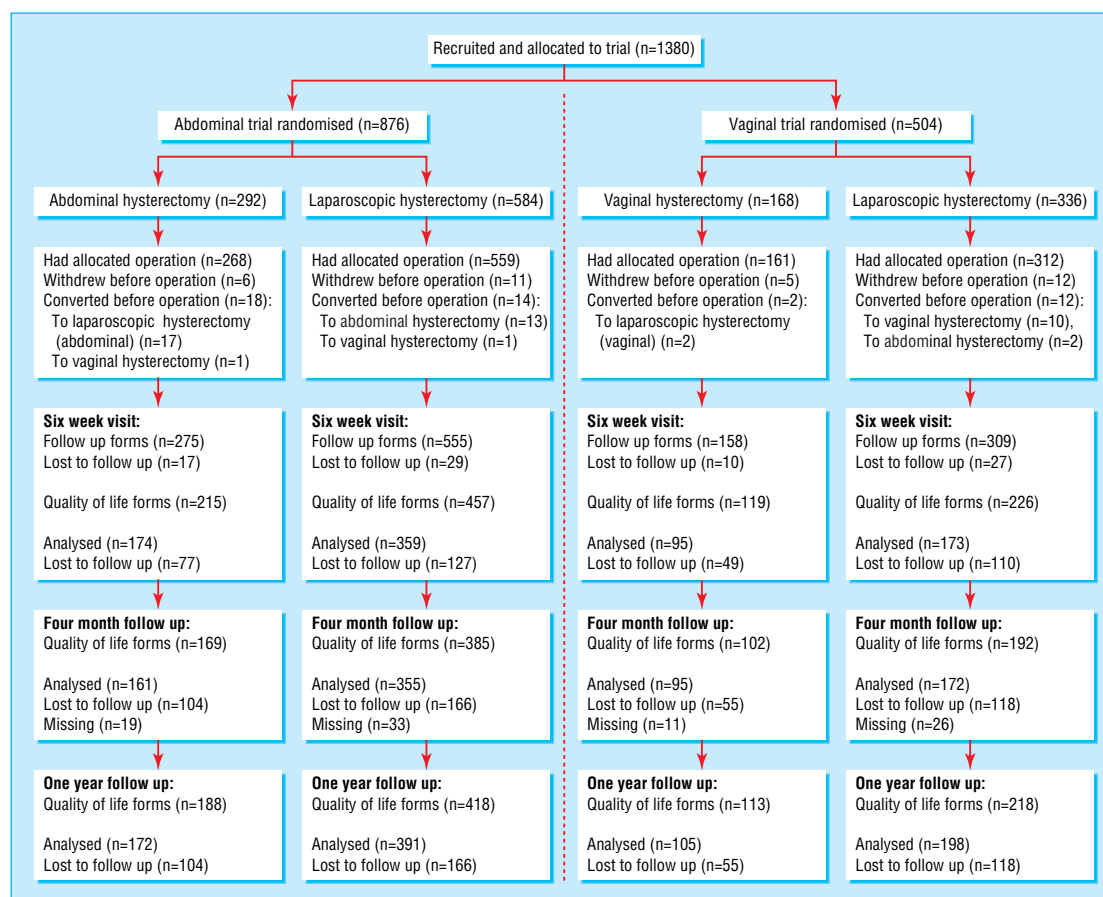
We found no difference in the complication rates after the two procedures in the vaginal trial (mean difference 0.3%, - 5.2% to 5.8%, P = 0.92; odds ratio 0.97, 0.52 to 1.81), the number needed to treat to harm is 333. However, the confidence interval is wide and includes harmful and beneficial effect of clinical relevance.

Secondary outcomes

Minor complications—In the abdominal trial the percentage of patients who had at least one minor complication was 27.1% in patients undergoing abdominal

Table 1 Baseline characteristics of participants in the two trials. Values are numbers (percentages) of participants unless otherwise indicated

Characteristic	Abdominal trial		Vaginal trial	
	Abdominal hysterectomy (n=292)	Laparoscopic hysterectomy (n=584)	Vaginal hysterectomy (n=168)	Laparoscopic hysterectomy (n=336)
Mean (SD) age	41.2 (7.6)	41.7 (7.2)	40.8 (6.5)	40.9 (6.9)
Mean (SD) body mass index	25.9 (5.4)	26.6 (5.1)	26.5 (4.7)	26.4 (5.1)
Mode number of pregnancies (% ever pregnant)	2 (90.7)	2 (91.4)	2 (95.2)	2 (96.7)
Vaginal deliveries mode (% having at least one vaginal delivery)	2 (83.4)	2 (80.9)	2 (91.0)	2 (94.3)
Caesarean deliveries mode (% having at least one caesarean section)	0 (16.9)	0 (19.1)	0 (9.6)	0 (10.2)
Vaginal capacity:				
Narrow	14 (4.8)	32 (5.5)	8 (4.8)	7 (2.1)
Normal	275 (94.2)	549 (94.0)	157 (93.5)	322 (95.8)
Large	2 (0.7)	2 (0.3)	2 (1.2)	4 (1.2)
Palpable endometriosis	10 (3.4)	19 (3.3)	1 (0.6)	0 (0.0)
Current smoker	142 (48.6)	241 (41.3)	72 (42.9)	131 (39.0)
Previous pelvic surgery	185 (63.3)	368 (63.0)	102 (60.7)	197 (58.6)
Mean (minimum to maximum) uterine size (expressed as equivalent to weeks of pregnancy)	6 (0 to 12)	6 (0 to 12)	6 (0 to 12)	6 (0 to 12)



Flow of participants through the trials. Follow up forms not received within the appropriate time frames were not included in the analysis. The time frames were 14 days at six weeks and 28 days at four months and one year

hysterectomy compared with 25.2% for laparoscopic hysterectomy, and for the vaginal trial 27.9% in patients undergoing vaginal hysterectomy and 23.2% for laparoscopic hysterectomy (table 3). We found no evidence to show that there was any difference in minor complication rates between the procedures in any of the comparisons.

Additional pathology found during the operation—In the abdominal trial additional pathology was reported in 12.7% (373/292) of patients undergoing abdominal hysterectomy compared with 22.6% (132/584) undergoing laparoscopic hysterectomy, (mean difference -9.9%, -15.4 to -4.4%, $P = < 0.01$). In the vaginal trial the rates were 4.8% (8/168) for vaginal

Table 2 Primary end point of both trials: major complications. Values are numbers (percentages) of participants

	Abdominal trial		Vaginal trial	
	Abdominal hysterectomy (n=292)	Laparoscopic hysterectomy (n=584)	Vaginal hysterectomy (n=168)	Laparoscopic hysterectomy (n=336)
Major haemorrhage	7* (2.4)	27* (4.6)	5 (2.9)	17 (5.1)
Bowel injury	3 (1)	1 (0.2)	0	0
Ureteric injury	0	5 (0.9)	0	1 (0.3)
Bladder injury	3 (1)	12* (2.1)	2 (1.2)	3 (0.9)
Pulmonary embolus	2 (0.7)	1 (0.2)	0	2 (0.6)
Anaesthesia problems	0	5* (0.9)	0	2 (0.6)
Unintended laparotomy:				
Intraoperative conversion	1† (0.3)	23 (3.9)	7 (4.2)	9 (2.7)
Return to theatre	1 (0.3)	3 (0.5)	0	1 (0.3)
Wound dehiscence	1 (0.3)	1 (0.2)	0	1 (0.3)
Haematoma	2 (0.7)	4 (0.7)	2 (1.2)	7 (2.1)
Other complications	0	0	1 (0.6)	0
At least one major complication	18 (6.2)	65 (11.1)	16 (9.5)	33 (9.8)

A patient may have had more than one complication.

*These patients converted procedure before the operation: one patient undergoing abdominal hysterectomy converted to laparoscopic hysterectomy before the operation in the abdominal trial and had a major haemorrhage. Two patients in the abdominal trial who were undergoing laparoscopic hysterectomy converted to abdominal hysterectomy before the operation and had a major haemorrhage. One patients undergoing laparoscopic hysterectomy in the abdominal trial converted to abdominal hysterectomy before the operation and had a major anaesthetic problem. One patient undergoing laparoscopic hysterectomy in the abdominal trial converted to abdominal hysterectomy before the operation and had a bladder injury.

†This patient in the abdominal trial was randomised to abdominal hysterectomy, converted to laparoscopic hysterectomy before the operation, and then converted back to abdominal hysterectomy during the operation.

Table 3 Secondary end points of both trials: minor complications. Values are numbers (percentages) of patients

	Abdominal trial		Vaginal trial	
	Abdominal hysterectomy (n=292)	Laparoscopic hysterectomy (n=584)	Vaginal hysterectomy (n=168)	Laparoscopic hysterectomy (n=336)
Major haemorrhage	3 (1)	8 (1.4)	2 (1.2)	8 (2.4)
Anaesthesia problems	0	2 (0.3)	1 (0.6)	3 (0.9)
Fever	9 (3.1)	29 (4.9)	12 (7.1)	18 (5.4)
Infection	47 (16.1)	86 (14.7)	24 (14.3)	36 (10.7)
Haematoma	17 (5.8)	25 (4.3)	10 (5.9)	14 (4.2)
Deep vein thrombosis	0	2 (0.3)	0	0
Other complications	22 (7.5)	40 (6.8)	17 (10.1)	24 (7.1)
At least one minor complication	79 (27.1)	147 (25.2)	47 (27.9)	78 (23.2)

A patient may have had more than one complication.

hysterectomy and 16.4% (53/336) for laparoscopic hysterectomy (mean difference -11.6%, -17.7% to -5.5%, $P < 0.01$). The main additional findings were adhesions, endometriosis, and fibroids.

Pain—In the abdominal trial abdominal hysterectomy was more painful than laparoscopic hysterectomy (adjusted mean pain score 3.9 abdominal hysterectomy, 3.5 laparoscopic hysterectomy; mean difference 0.4, 0.09 to 0.7, $P = 0.01$). We found no evidence of a difference in pain scores in the vaginal trial.

Length of surgery and length of stay—In the abdominal trial the median length of stay after abdominal hysterectomy was four days and three days after laparoscopic hysterectomy, but was three days in both arms of the vaginal trial. We undertook no formal statistical testing, but these differences may be clinically important.

Quality of life—All procedures were associated with improvements in the physical and mental components of SF-12, body image scale, and aspects of sexual activity at four months compared with baseline (see bmj.com). These changes were maintained or improved further at 12 months. In the abdominal trial we found a highly significant difference in the physical component summary score of the SF-12 at six weeks between abdominal hysterectomy and laparoscopic hysterectomy. We also found highly significant differences in body image scale between abdominal hysterectomy and laparoscopic hysterectomy in the abdominal trial at six weeks, a borderline significant difference at four months but no difference at 12 months. According to the sexual activity questionnaire “habit” scores in this trial were higher at six weeks after laparoscopic hysterectomy than after abdominal hysterectomy (-0.3, 0.1 to 0.6, $P \leq 0.01$). We found no evidence of a difference in quality of life at any time point in the vaginal trial.

Discussion

The results of the two trials confirm the advantages to the patient of avoiding a laparotomy incision. In the abdominal trial laparoscopic hysterectomy was associated with a clinically relevant higher incidence of major complications and took longer to perform. These disadvantages were offset by patient friendly benefits of less pain, shorter hospital stay, quicker recovery, and improved quality of life indicators in the short term. The comparison between laparoscopic and vaginal methods was underpowered but did not show any significant differences between the two methods, except that vaginal hysterectomy was performed in a shorter time.

Limitations of the study

Abdominal and vaginal hysterectomy are both commonly performed; 564 865 were performed in the United States²⁰ and more than 65 000 in the United Kingdom in 1995.²¹ Despite this large number of potential patients we anticipated that recruiting sufficient numbers of surgeons and patients to this trial would be difficult. Most gynaecologists have well defined indications for each approach, and few would feel comfortable in randomising all patients to any approach. To allow each surgeon to maintain equipoise and maximise recruitment we designed this study as two separate but parallel trials. For similar reasons we excluded some conditions, such as large fibroids, for which most surgeons would prefer to undertake an abdominal hysterectomy, and major degrees of uterovaginal prolapse, for which almost all would undertake a vaginal

What is already known on this topic

Hysterectomy is one of the most often performed of all major surgical operations

It has traditionally been performed by either the vaginal or the abdominal method

Either method has advantages and disadvantages, but the indications for each remain controversial and have never been compared in a randomised controlled trial

More recently a third method of hysterectomy has been developed, the laparoscopic hysterectomy

What this study adds

The results confirm the advantages to the patient of avoiding a laparotomy incision

Laparoscopic hysterectomy was associated with a clinically relevant higher incidence of major complications and took longer to perform than the abdominal method

With laparoscopic hysterectomy patients have less pain, shorter hospital stay, quicker recovery, and improved quality of life indicators in the short term

Vaginal hysterectomy is quicker than laparoscopic hysterectomy

hysterectomy. This pragmatic approach excluded many patients and several of the most important indications for hysterectomy. These decisions will reduce the generalisability of the study. We believe, however, that the design maximised recruitment of surgeons and patients and concentrated the study where the indications as to preferred method were least clear.

Including unintended laparotomy as a major complication caused debate in the trial's steering committee. It represented the second most common major complication, and a large proportion of these patients did not have any other complication. It could be considered that such conversions represented prudent surgery rather than a major complication. Excluding them would have substantially reduced the overall complication rates associated with both laparoscopic hysterectomy and vaginal hysterectomy. We think that on balance they represented a failure of planned procedure and should be considered as major complications.

We thank all members of the trial steering committee, data monitoring, and ethics committee for their hard work in the conduct of this trial, and Derek Tuffnell for his assistance with the independent clinical review of the research data. We thank the Simon Foundation and the University of Teesside for their support of the principal investigator as Simon professor of gynaecology during this study. In addition, the trial would not have been possible without the valued contributions of the women who were willing to give their time and share their experiences to extend our knowledge in this area. The eVALuate trial including the full data analysis is reported in a submission to the HTA Monograph Series.

Contributors: See bmj.com

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The internet—friend or foe?

Most of us feel at least a little apprehensive when a patient or parent begins: "I was looking on the internet, and I found..." Experience has shown that information fished from cyberspace has often been inaccurate or alarmist, but one recent patient challenged our scepticism. What follows is a mother's account of a correct internet diagnosis.

"I was worried about Andrew's thirst and couldn't understand how he could consume so much liquid, so I used the Google search engine and typed in the query 'extreme thirst in children.' The search returned a list of websites all mentioning diabetes, so I clicked on the first link, www.childrenwithdiabetes.com/clinic/signs.htm. I knew Andrew had lost weight, he was weeing a lot, and was very tired and weak, so he had some but not all of the signs of diabetes mentioned on the site.

"So I ran another Google search: 'signs of diabetes.' This gave me a great website, www.defeatdiabetes.org/screeningtest.htm, which had a free screening tool for diabetes. Andrew's score came back at 60, which is very high. This was in spite of my not having answers to all the questions, such as whether his eyesight was blurred. At 14 months, he couldn't tell me, so I answered no. The

site advised me to seek urgent medical advice. The last sign mentioned was a high sugar content in the child's wee, for which it said a glucose stick could be bought over the counter at a chemist's.

"By now I was starting to worry that he was very ill, but I was I was still afraid the doctor may think I was over-reacting, so I went ahead and bought the test. The results were the darkest colour on the stick, which meant a high level of sugar. Armed with my evidence, I went to the doctor's surgery, where he agreed with the diagnosis. After performing another test with a 'keto stick,' he sent us up to the hospital."

As paediatricians, we are quite used to childhood diabetes being diagnosed by a relative or friend of the family, and even once by a 9 year old friend with type 1 diabetes. However, the internet as a tool for self diagnosis is surely something we will become increasingly familiar with and could perhaps even encourage.

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