



Laparoscopic hysterectomy (including laparoscopic total hysterectomy and laparoscopically assisted vaginal hysterectomy) for endometrial cancer

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of laparoscopic hysterectomy (including laparoscopic total hysterectomy and laparoscopically assisted vaginal hysterectomy) for endometrial cancer is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- Patient selection for laparoscopic hysterectomy for endometrial cancer should be carried out by a multidisciplinary gynaecological oncology team.
- 1.3 Advanced laparoscopic skills are required for this procedure and clinicians should undergo special training and mentorship. The Royal College of Obstetricians and Gynaecologists has developed an Advanced Training Skills Module. This needs to be supplemented by further training to achieve the skills required for laparoscopic hysterectomy for endometrial cancer.
- 1.4 Long-term follow-up data on recurrence and survival following laparoscopic hysterectomy for endometrial cancer would assist any future review of the procedure by NICE.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 The uterus is the fourth most common site of malignancy among women in the UK, and endometrial cancer is the most common type of uterine cancer. The predominant symptom of endometrial cancer is abnormal vaginal bleeding, especially in postmenopausal women.
- 2.1.2 The International Federation of Gynecology and Obstetrics (FIGO) system is used to stage endometrial cancer from stage I (cancer confined to the uterus) to stage IV (cancer that has spread to another body organ).
- 2.1.3 Endometrial cancer is usually treated by total hysterectomy with bilateral salpingo-oophorectomy. Radiotherapy, hormone therapy and chemotherapy may also be used.

2.2 Outline of the procedure

- 2.2.1 The aim of a laparoscopic approach to hysterectomy is to provide a treatment option with smaller incisions and scars, shorter hospital stay and shorter recovery period than for open surgery.
- 2.2.2 Laparoscopic hysterectomy is usually carried out with the patient under general anaesthesia. Several small incisions provide access for the laparoscope and surgical instruments. The abdomen is insufflated with carbon dioxide. The uterus, supporting ligaments and the upper vagina are removed. Sometimes, the pelvic and para-aortic lymph nodes are also removed. The uterus is removed vaginally. The other tissues can be removed vaginally or through the abdominal incisions.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more

detailed information on the evidence, see the overview.

- 2.3.1 In a meta-analysis, 3 randomised-controlled trials (RCTs) including a total of 359 patients treated by laparoscopic hysterectomy or by abdominal hysterectomy reported overall survival rates of 92% (169 out of 184) and 88% (154 out of 175) respectively (p=0.976) and disease-free survival rates of 88% (161 out of 184) and 88% (154 out of 175) respectively (p=0.986) at follow-up of a maximum of 36 months.
- A non-randomised comparative study of 309 patients reported 5-year overall survival rates of 98% both for patients treated by laparoscopic (n=165) and abdominal (n=144) hysterectomy. The 5-year progression-free survival rate was 96% for patients after laparoscopic hysterectomy and 97% for patients after abdominal hysterectomy (p=0.74).
- 2.3.3 Hospital stay after laparoscopic hysterectomy was significantly shorter than after abdominal hysterectomy in the RCTs of 159 and 122 patients (2 days versus 5 days, p<0.01; 8 days versus 11 days, p=0.001 respectively). The proportion of patients staying in hospital for more than 2 days was significantly higher after abdominal hysterectomy compared with laparoscopic hysterectomy (94% versus 52%, p<0.0001) in the RCT of 2,616 patients.
- The Specialist Advisers listed key efficacy outcomes as overall survival, recurrence rate, quality of life, operative time and length of hospital stay.

2.4 Safety

- Rates of conversion to laparotomy were reported as 26% (434 out of 1,682), 0% (0 out of 81), 8% (5 out of 63), 5% (10 out of 188), 5% (11 out of 226) and 5% (4 out of 73) among patients treated by laparoscopic hysterectomy in RCTs of 2,616, 159 and 122 patients, and non-randomised comparative studies of 309, 510 and 169 patients respectively.
- The RCT of 2,616 patients treated by laparoscopic or abdominal hysterectomy reported no significant difference in the rate of intraoperative complications (10% [160 out of 1,682] versus 8% [69 out of 909], p=0.106) but significantly fewer

- postoperative complications after laparoscopic compared with abdominal hysterectomy (14% [240 out of 1,682] versus 21% [191 out of 909], p<0.001).
- 2.4.3 The meta-analysis including a total of 498 patients reported no significant difference in the rate of intraoperative complications for patients treated by laparoscopic compared with abdominal hysterectomy (8% [14 out of 169] versus 12% [19 out of 162], p=0.39). Significantly fewer postoperative complications were reported associated with laparoscopic compared with abdominal hysterectomy in the same study (17% [27 out of 158] versus 32% [50 out of 155], p=0.007).
- 2.4.4 The RCT of 2616 patients and the non-randomised comparative study of 309 patients reported intraoperative complications of bowel injury (2% [37 out of 1,682] and less than 1% [1 out of 165]), vascular injury (4% [75 out of 1,682] and 1% [2 out of 165]), bladder injury (1% [21 out of 1,682 and 2 out of 165]) and ureter injury (less than 1% [14 out of 1,682 and 1 out of 165]) among patients treated by laparoscopic hysterectomy.
- In the non-randomised comparative study of 309 patients treated by laparoscopic or abdominal hysterectomy, intra-abdominal abscess was reported in 2% (4 out of 165) and 6% (8 out of 144) of patients respectively.
- 2.4.6 The RCT of 84 patients reported port-site recurrence in 1 of 40 patients treated by laparoscopic hysterectomy after a median 79-month follow-up.
- 2.4.7 The non-randomised comparative study of 309 patients treated by laparoscopic or abdominal hysterectomy reported bladder dysfunction in 1 patient in each group (1 out of 165 and 1 out of 144 respectively).
- 2.4.8 The Specialist Advisers listed adverse events reported in the literature as conversion to open surgery, damage to abdominal or pelvic structures, respiratory difficulties, port-site herniation and port-site metastasis. They reported dehiscence of the vaginal vault after laparoscopic suturing as an anecdotal adverse event.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.