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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg356

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 assess and reduce the environmental impact of implementing NICE recommendations 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.

1.2 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.

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 **Efficacy**

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% (169/184) and 88% (154/175) respectively (p = 0.976) and disease-free survival rates of 88% (161/184) and 88% (154/175) respectively (p = 0.986) at follow-up of a maximum of 36 months.

2.3.2 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 vs 5 days, p < 0.01; 8 days vs 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% vs 52%, p < 0.0001) in the RCT of 2616 patients.

2.3.4 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**

2.4.1 Rates of conversion to laparotomy were reported as 26% (434/1682), 0% (0/81), 8% (5/63), 5% (10/188), 5% (11/226) and 5% (4/73) among patients treated by laparoscopic hysterectomy in RCTs of 2616, 159 and 122 patients, and non-randomised comparative studies of 309, 510 and 169 patients respectively.

2.4.2 The RCT of 2616 patients treated by laparoscopic or abdominal hysterectomy reported no significant difference in the rate of intraoperative complications (10% [160/1682] vs 8% [69/909], p = 0.106) but significantly fewer postoperative complications after laparoscopic
compared with abdominal hysterectomy (14% [240/1682] vs 21% [191/909], 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% [14/169] vs 12% [19/162], p = 0.39). Significantly fewer postoperative complications were reported associated with laparoscopic compared with abdominal hysterectomy in the same study (17% [27/158] vs 32% [50/155], 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% [37/1682] and less than 1% [1/165]), vascular injury (4% [75/1682] and 1% [2/165]), bladder injury (1% [21/1682 and 2/165]) and ureter injury (less than 1% [14/1682 and 1/165]) among patients treated by laparoscopic hysterectomy.

2.4.5 In the non-randomised comparative study of 309 patients treated by laparoscopic or abdominal hysterectomy, intra-abdominal abscess was reported in 2% (4/165) and 6% (8/144) 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 (1/165 and 1/144 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

3.1 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

3 January 2012: minor maintenance.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.
Accreditation

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