Laparoscopic radical hysterectomy for early stage cervical cancer

Interventional procedures guidance
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nice.org.uk/guidance/ipg338

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. However, 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.

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.

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.

This guidance replaces IPG24.
1 **Guidance**

This guidance replaces previous guidance on laparoscopic radical hysterectomy for early stage cervical cancer (interventional procedure guidance 24).

1.1 Current evidence on the efficacy and safety of laparoscopic radical hysterectomy for early stage cervical 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 should be carried out by a multidisciplinary gynaecological oncology team. The procedure should be carried out in units specialising in the treatment of gynaecological malignancies.

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 radical hysterectomy for early stage cervical cancer.

2 **The procedure**

2.1 *Indications and current treatments*

2.1.1 Cervical cancer is the second most common cancer in women under 35 years in the UK. The most common symptoms are abnormal vaginal bleeding or discharge, and discomfort during intercourse.

2.1.2 The International Federation of Gynecology and Obstetrics (FIGO) system is used to stage cervical cancer from I to IV. Early stage cervical cancer includes stages I (cancer confined to the cervix) to IIA (tumour invades the cervix with endocervical glandular involvement only).

2.1.3 Early stage cervical cancer is usually treated by radical hysterectomy. Radiotherapy may be used, with or without surgery, and is usually combined with chemotherapy. More advanced cervical cancer is generally treated with radiotherapy and chemotherapy.
2.2 Outline of the procedure

2.2.1 Laparoscopic radical hysterectomy for early stage cervical cancer is 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 along with pelvic lymph nodes and sometimes the para-aortic lymph nodes.

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 A non-randomised comparative study of 102 patients with stage IA–IIB cervical cancer reported 3-year overall survival of 82% for patients treated by both abdominal and laparoscopic radical hysterectomy.

2.3.2 A non-randomised comparative study of 127 patients with stage IA–IB cervical cancer reported a disease-free survival rate of 92% for laparoscopic radical hysterectomy and 94% for abdominal radical hysterectomy at median follow-up of 53 and 72 months respectively (p = 0.29) (absolute figures not stated).

2.3.3 A case series of 78 patients with stage IA–IB cervical cancer reported an estimated 5-year overall survival rate of 94% (absolute figures not stated).

2.3.4 A non-randomised comparative study of 125 patients with stage IB–IIA cervical cancer reported a recurrence rate of 14% for laparoscopic radical hysterectomy and 12% for abdominal radical hysterectomy, at a median follow-up of 26 months (reported as ‘not significant’) (absolute figures not stated).

2.3.5 The non-randomised comparative study of 127 patients reported that significantly fewer lymph nodes were removed in patients treated by laparoscopic radical hysterectomy than abdominal radical hysterectomy (mean 23.5 and 25.2 respectively) (p < 0.01).
The Specialist Advisers listed key efficacy outcomes as completing the procedure without conversion to open surgery, number of lymph nodes removed, recovery time and length of hospital stay, rate of cancer recurrence, and 5-year survival.

### Safety

#### 2.4.1 Rates of intraoperative bladder injury during laparoscopic radical hysterectomy and abdominal radical hysterectomy ranged from 1% (3/248 and 1/101) to 10% (5/50), and from 0% (0/35) to 4% (2/48) respectively across the studies.

#### 2.4.2 A case report described complete bladder gangrene 3 weeks after laparoscopic radical hysterectomy in 1 patient. The patient underwent a total cystectomy and cutaneous ureterostomy and recovered fully with no cancer recurrence at 33-month follow-up.

#### 2.4.3 Intraoperative ureteric injury rates ranged from 0% (0/90) to 4% (2/50) during laparoscopic radical hysterectomy (2 were treated laparoscopically) and from 0% (0/48) to 6% (2/35) during abdominal radical hysterectomy (no further details given).

#### 2.4.4 Intraoperative bowel injury was reported in 2% (1/46), 1% (2/248; laparoscopically sutured) and 1% (3/295; 2 sutured vaginally and 1 conversion to open surgery) of patients in the non-randomised comparative study of 102, and case series of 248 and 295 patients respectively.

#### 2.4.5 The non-randomised comparative studies of 98 and 125 patients reported, respectively, ureteric fistula in 2% (1/50; from ischaemic necrosis requiring further open surgery at 14-day follow-up) and 1% (1/90; postoperative, managed conservatively) of patients treated by laparoscopic radical hysterectomy. No ureteric fistulae were reported in patients treated by abdominal radical hysterectomy. Postoperative ureteric fistula was reported in 5% (5/101) of patients in the case series of 101 patients (1 required ureteral reimplantation, 4 treated with stents; timing of events not stated).

#### 2.4.6 Postoperative vesicovaginal fistula was reported in 1% (1/90) and 2% (1/50) of patients treated by laparoscopic radical hysterectomy compared with no
patients treated by abdominal radical hysterectomy in the non-randomised comparative studies of 125 and 98 patients (not otherwise described).

2.4.7 Splenic rupture 5 days after laparoscopic radical hysterectomy was reported in a case report; the patient was treated by a splenectomy.

2.4.8 The Specialist Advisers considered theoretical adverse events to include inadequate lymph node sampling and excision of the primary tumour.

2.5 Other comments

2.5.1 The Committee recognised that there are different classification systems for defining stages of cervical cancer. The evidence the Committee considered on early cervical cancer was in patients with cervical cancer up to and including stage IIA.

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.

It updates and replaces NICE interventional procedure guidance 24.
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

4 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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