

Laparoscopic radical hysterectomy for early stage cervical cancer

1 Guidance

- 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.
- 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 (www.rcog.org.uk).

2 The procedure

2.1 Indications

- 2.1.1 Laparoscopic radical hysterectomy can be used to treat stage I and stage IIA cervical cancer. Stage I cervical cancer is confined to the cervix. Stage IIA cervical cancer has spread to the top of the vagina, but not into the uterus.

- 2.1.2 Laparoscopic radical hysterectomy is a minimally invasive alternative to traditional open radical hysterectomy, and is performed through an incision in the abdomen.

2.2 Outline of the procedure

- 2.2.1 Laparoscopic radical hysterectomy involves surgical removal of the uterus, the supporting ligaments and the upper vagina, together with removal of the pelvic lymph nodes and sometimes the para-aortic lymph nodes.
- 2.2.2 The technique is distinct from laparoscopically assisted radical vaginal hysterectomy, which combines laparoscopy and radical vaginal hysterectomy.

2.3 Efficacy

- 2.3.1 The evidence relating to this procedure was based entirely on two case series. In the larger series involving 78 women, with a mean follow up of 67 months, there were eight cases of recurrence (10%). The estimated 5-year disease-free interval after treatment was 89%. No recurrences were reported in the smaller case series involving 41 women. For more details refer to the sources of evidence below.
- 2.3.2 All the Specialist Advisors thought that laparoscopic radical hysterectomy was not a new procedure but a variation on established practice. They noted that only a few gynaecological oncologists, in a few specialised units, performed the procedure regularly, and that it required considerable laparoscopic expertise.

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This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

2.4 Safety

- 2.4.1 The larger case series reported a post-operative complication rate of 9%, including one patient with a ureterovaginal fistula and two patients with pelvic lymphocysts. However, these observations should be interpreted with caution, given the limited data available. For more details refer to the sources of evidence below.
- 2.4.2 The Specialist Advisors considered that the potential complications associated with laparoscopic radical hysterectomy were similar to those associated with open radical hysterectomy, but the technical demands of laparoscopic radical hysterectomy increased the risks. They specifically reported instances of injury to the bowel, to vessels in the abdominal wall and to the urinary tract. They also expressed concern about long-term survival following use of this procedure.
- 2.4.3 It was noted that there were inadequate long-term data for this procedure, and a lack of data on comparisons between laparoscopic and open radical hysterectomy.

2.5 Other comments

- 2.5.1 The Interventional Procedures Advisory Committee noted that the thoroughness of lymph node excision is important, both diagnostically and prognostically, and that there is uncertainty about whether lymph node staging can be carried out adequately via a laparoscope.

Andrew Dillon
Chief Executive
November 2003

Information for the Public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG024publicinfoenglish and in English and Welsh from www.nice.org.uk/IPG024publicinfowelsh.

Sources of evidence

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

Interventional procedure overview of laparoscopic radical hysterectomy, April 2003.

Available from: www.nice.org.uk/IP051overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference: N0363. *Information for the Public* can be obtained by quoting reference number N0364 for the English version and N0365 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL www.nice.org.uk/IPG024distributionlist

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