Laparoscopic techniques for hysterectomy

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1 Guidance

- 1.1 Current evidence on the safety and efficacy of laparoscopic techniques for hysterectomy (including laparoscopically-assisted vaginal hysterectomy [LAVH], laparoscopic hysterectomy [LH], laparoscopic supracervical hysterectomy [LSH] and total laparoscopic hysterectomy [TLH]) appears adequate to support their use, provided that normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Clinicians should advise women that there is a higher risk of urinary tract injury and of severe bleeding associated with these procedures, in comparison with open surgery.
- 1.3 Advanced laparoscopic skills are required for these procedures, and clinicians should undergo special training and mentorship. The Royal College of Obstetricians and Gynaecologists has developed an Advanced Training Skills Module, <u>'Benign Gynaecological Surgery: Laparoscopy'</u>. This would need to be supplemented by further training in order to

achieve the skills required for total laparoscopic hysterectomy.

2 The procedure

2.1 Indications

- Hysterectomy is performed for a variety of benign conditions that have 2.1.1 not responded to conservative management, including heavy menstrual bleeding, symptomatic uterine fibroids, chronic pelvic pain and uterine prolapse. Hysterectomy is also performed for cancer of the uterus (including cervical cancer) and ovaries.
- 2.1.2 A conventional 'open' hysterectomy involves removal of the uterus through an abdominal or a vaginal approach.

Outline of the procedure 2.2

- This guidance does not cover laparoscopic radical hysterectomy (see 2.2.1 3.1). Under general anaesthesia, small incisions are made in the abdomen to allow insertion of a laparoscope and surgical instruments.
- 2.2.2 In TLH and LSH, the entire procedure is performed laparoscopically, including division of the uterine vessels. In TLH the cervix is removed, while in LSH it is left in situ.
- 2.2.3 In LAVH and LH, part of the operation is performed laparoscopically and part vaginally. Uterine vessel division is performed vaginally in LAVH and laparoscopically in LH.
- 2.2.4 In all of the above procedures, the uterus can be removed either through the open vault of the vagina or one of the abdominal ports.

2.3 Efficacy

A systematic review and meta-analysis reported that in nine randomised 2.3.1 controlled trials (RCTs) including 948 women and comparing

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laparoscopic techniques for hysterectomy (type not specified) with abdominal hysterectomy (AH), the average length of hospital stay was 2.0 days shorter (95% confidence interval [CI] 1.9 to 2.2) in the laparoscopic group.

- 2.3.2 The systematic review and meta-analysis reported that in six RCTs including 520 women and comparing laparoscopic techniques (type not specified) with AH, women in the laparoscopic group returned to normal activities on average 13.6 days earlier (95% CI 11.8 to 15.4) than those in the AH group.
- 2.3.3 The systematic review and meta-analysis reported that in six RCTs including 842 women and comparing laparoscopic techniques (type not specified) with vaginal hysterectomy (VH), there was no significant difference between the techniques in the need for unintended laparotomy (odds ratio [OR] 1.55, 95% CI 0.75 to 3.21). In a non-randomised controlled study, conversion to laparotomy was required in 7% (82/1242) of women who underwent laparoscopic procedures.
- 2.3.4 One case series reported conversion to laparotomy in 0.83% (14/1692) of women undergoing LSH. Another case series reported conversion to laparotomy in 2.79% (46/1647) of women who underwent TLH. For more details, refer to the 'Sources of evidence' section. One Specialist Adviser considered laparoscopic techniques for hysterectomy to be established practice and another considered them to be novel and of uncertain efficacy and safety.
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2.4 Safety

2.4.1 In a non-randomised controlled study of 37,048 women undergoing hysterectomy, 0/1154 of those treated with laparoscopic techniques for hysterectomy (type not specified) died, but 14 treated with nonlaparoscopic techniques died within 6 weeks of the surgery (0.04%, 95% CI 0.025 to 0.064). A non-randomised controlled study of 10,110 women reported that 0.04% (1/2434) of those who underwent laparoscopic procedures (type not specified) died during the convalescence period (not otherwise defined), compared with 0.06% (1/1801) of women who had VH and 0.02% (1/5875) of women who had AH (significance level not stated). The authors stated that the causes of death were alcoholic cirrhosis, cardiac infarct and pulmonary embolism, and were not directly related to the operation.

- 2.4.2 The non-randomised controlled study of 37,048 women reported that the incidence of major operative haemorrhage was significantly higher (p < 0.001) for laparoscopic techniques (4.4%, 51/1154) than for VH (2.0%, 218/11,122) or AH (2.3%, 571/24,772). However, the non-randomised controlled study of 10,110 women reported no significant difference in perioperative haemorrhage between laparoscopic techniques, VH and AH.</p>
- 2.4.3 A case series of women undergoing LH reported haemorrhage requiring blood transfusion in 0.3% (5/1648). The case series of women undergoing TLH reported that blood transfusion was required for 0.97% (16/1647).
- 2.4.4 The systematic review and meta-analysis and the non-randomised controlled study of 10,110 women found that the incidence of urinary tract injuries was significantly higher among women who underwent laparoscopic procedures (type not specified) than those who had AH (meta-analysis: OR 2.61, 95% CI 1.22 to 5.60, 10 RCTs, n = 1912; non-randomised study: 1.1% vs 0.2% for ureteric injury and 1.3% vs 0.5% for bladder injury, p < 0.0001). There was no significant difference in the incidence of bowel injury between laparoscopic techniques and AH in either study (meta-analysis: two RCTs, n = 1066; non-randomised study: n = 8309).
- 2.4.5 Comparing laparoscopic techniques with VH, the meta-analysis found no significant difference for urinary tract injury (six RCTs, n = 805), bowel injury (one RCT, n = 504) or vascular injury (four RCTs, n = 685). Comparing laparoscopic techniques with VH, the non-randomised controlled study reported a higher incidence of injuries to the ureter in the laparoscopic group (1.1% vs 0%) and bladder (1.3% vs 0.2%) (p value

not stated for either outcome), but a similar incidence of bowel injury (0.4% vs 0.5%) in the two groups (absolute numbers not provided).

- 2.4.6 In the meta-analysis, there was no significant difference between laparoscopic techniques and AH for vascular injury (two RCTs, n = 956, OR 1.76, 95% CI 0.52 to 5.87).
- 2.4.7 The larger non-randomised controlled study reported that the incidence of visceral damage was higher in women who underwent laparoscopic procedures (1.1%, 13/1154) compared with those who had VH (0.6%, 68/ 11,122) or AH (0.76%, 189/24,772), but the difference was not significant.
- 2.4.8 A case series of 5104 women who underwent laparoscopic procedures (type not specified) reported ureteric injury in 66 women (1.3%), simple bladder injury in 22 (0.4%), vesicovaginal fistula in 12 (0.2%), intestinal injury in 15 (0.3%) and major vascular injury in 1 (0.02%).
- 2.4.9 In a case series of 1405 women undergoing LSH involving electric morcellation of the uterus, adenomyosis was reported in 0.6% (8/1405) of women, all of whom had been treated for symptomatic menorrhagia due to submucosal myomas. Symptoms of the adenomyosis occurred between 2 and 9 years after LSH and included pelvic pain and deep dyspareunia. Laparoscopic surgery was required to make a final diagnosis of the tumours and to remove them. For more details, refer to the 'Sources of evidence' section.
- 2.4.10 Both Specialist Advisers considered special training to be necessary and to have important implications for safety. They considered theoretical adverse events to be injury to the ureter and bowel, vascular injury, haemorrhage and the need for blood transfusion.

3 Further information

3.1 The Institute has issued guidance for a number of interventional procedures with the same indications. These include <u>laparoscopic radical</u> <u>hysterectomy for early stage cervical cancer</u>, <u>laparoscopic laser</u> <u>myomectomy</u>, <u>magnetic resonance image-guided percutaneous laser</u> <u>ablation of uterine fibroids</u>, <u>uterine artery embolisation for fibroids</u>, impedance-controlled endometrial ablation for menorrhagia, endometrial cryotherapy for menorrhagia, laparoscopic helium plasma coagulation for the treatment of endometriosis, and microwave, balloon thermal, photodynamic and free fluid thermal endometrial ablation. The Institute has also issued a technology appraisal on <u>fluid-filled thermal balloon and</u> microwave endometrial ablation for menstrual bleeding and a clinical guideline on <u>heavy menstrual bleeding</u>.

Andrew Dillon Chief Executive November 2007

Sources of evidence

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

<u>'Interventional procedure overview of laparoscopic techniques for hysterectomy</u>', December 2006.

Information for patients

NICE has produced <u>information describing its guidance on this procedure for patients and</u> <u>their carers</u> ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, 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

14 January 2012: minor maintenance.

Your responsibility

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

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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Contact NICE

National Institute for Health and Clinical Excellence Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk nice@nice.org.uk 0845 033 7780

Endorsing organisation

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