# Laparoscopic techniques for hysterectomy

Interventional procedures guidance Published: 28 November 2007

www.nice.org.uk/guidance/ipg239

## 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 <u>Yellow Card Scheme</u>.

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</u> <u>impact of implementing NICE recommendations</u> wherever possible.

## 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 <u>Royal College of</u> <u>Obstetricians and Gynaecologists (RCOG) has developed an Advanced Training</u> <u>Skills Module, 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

2.1.1 Hysterectomy is performed for a variety of benign conditions that have 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.

#### 2.2 Outline of the procedure

- 2.2.1 This guidance does not cover laparoscopic radical hysterectomy (see <u>section 3.1</u>). Under general anaesthesia, small incisions are made in the abdomen to allow insertion of a laparoscope and surgical instruments.
- 2.2.2 In total laparoscopic hysterectomy (TLH) and laparoscopic supracervical hysterectomy (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 laparoscopically assisted vaginal hysterectomy (LAVH) and laparoscopic hysterectomy (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

- 2.3.1 A systematic review and meta-analysis reported that in nine randomised controlled trials (RCTs) including 948 women and comparing 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 out of 1,242) of women who underwent laparoscopic procedures.
- 2.3.4 One case series reported conversion to laparotomy in 0.83% (14 out of 1,692) of women undergoing LSH. Another case series reported conversion to laparotomy in 2.79% (46 out of 1,647) of women who underwent TLH. For more details, see the <u>overview</u>.
- 2.3.5 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.

#### 2.4 Safety

- 2.4.1 In a non-randomised controlled study of 37,048 women undergoing hysterectomy, 0 out of 1,154 of those treated with laparoscopic techniques for hysterectomy (type not specified) died, but 14 treated with non-laparoscopic 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 out of 2,434) of those who underwent laparoscopic procedures (type not specified) died during the convalescence period (not otherwise defined), compared with 0.06% (1 out of 1,801) of women who had VH and 0.02% (1 out of 5,875) 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 out of 1,154) than for VH (2.0%, 218 out of 11,122) or AH (2.3%, 571 out of 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.

- 2.4.3 A case series of women undergoing LH reported haemorrhage requiring blood transfusion in 0.3% (5 out of 1,648). The case series of women undergoing TLH reported that blood transfusion was required for 0.97% (16 out of 1,647).
- 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=1,912; non-randomised study: 1.1% versus 0.2% for ureteric injury and 1.3% versus 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=1,066; non-randomised study: n=8,309).
- 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% versus 0%) and bladder (1.3% versus 0.2%; p value not stated for either outcome), but a similar incidence of bowel injury (0.4% versus 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 out of 1,154) compared with those who had VH (0.6%, 68 out of 11,122) or AH (0.76%, 189 out of 24,772), but the difference was not significant.

- 2.4.8 A case series of 5,104 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 1,405 women undergoing LSH involving electric morcellation of the uterus, adenomyosis was reported in 0.6% (8 out of 1,405) 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, see the <u>overview</u>.
- 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 NICE has issued guidance for a number of interventional procedures with the same indications. These include <u>minimally invasive radical hysterectomy for early</u> stage cervical cancer, laparoscopic laser myomectomy, magnetic resonance (MR) image-guided percutaneous laser ablation of uterine fibroids, <u>uterine artery</u> embolisation for fibroids, <u>endometrial cryotherapy for menorrhagia</u>, laparoscopic helium plasma coagulation for the treatment of endometriosis, and photodynamic endometrial ablation. NICE has also issued technology appraisal guidance on fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding and a guideline on heavy menstrual bleeding: assessment and management.

#### Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

#### Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

ISBN: 978-1-4731-6261-7

# **Endorsing organisation**

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