

Endoscopic radical inguinal lymphadenectomy

Interventional procedures guidance

Published: 22 June 2011

www.nice.org.uk/guidance/ipg398

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 endoscopic radical inguinal lymphadenectomy is inadequate in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake endoscopic radical inguinal lymphadenectomy should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended
 - Audit and review clinical outcomes of all patients having endoscopic radical inguinal lymphadenectomy (see section 3.1).
- 1.3 This procedure should be carried out only in centres which specialise in the treatment of cancers requiring radical inguinal lymphadenectomy as part of their management, and by surgeons with training and experience in this type of endoscopic surgery.
- 1.4 Publications on the use of this procedure should clearly describe case selection, and should report rates of local recurrence and survival, as well as adverse events. NICE may review this procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Patients with penile, vulval or anal cancer, or melanoma of the leg, may require radical inguinal lymphadenectomy as part of the management of their condition.
- 2.1.2 The standard method for radical inguinal lymphadenectomy is an open operation through an incision in the groin.

2.2 Outline of the procedure

- 2.2.1 The endoscopic approach has theoretical advantages of reduced postoperative pain, morbidity and recovery time compared with the open procedure.
- 2.2.2 Endoscopic radical inguinal lymphadenectomy is carried out with the patient under general anaesthesia. Ultrasound guidance may be used. Three or four small incisions are made in the area of the femoral triangle for insertion of ports, and the working space is insufflated with carbon dioxide (CO₂). The lymph nodes are dissected endoscopically. Resected nodes are placed in an impermeable sac and removed through one of the port sites. Resection of the saphenous vein may also be required. A suction drain is normally inserted at the end of the procedure.

2.3 Efficacy

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](#).

- 2.3.1 A non-randomised study of 15 patients (30 limbs) treated by endoscopic (20 limbs) or open (10 limbs) radical inguinal lymphadenectomy reported that the mean number of lymph nodes removed was 10.75 and 9.7 respectively (p=0.3).

- 2.3.2 A case series of 5 patients reported recurrence in 2 patients. One patient had recurrence with multiple visceral metastases after the procedure. The other patient had recurrence in a lymph node outside of the inguinal area, which was subsequently resected (follow-up not stated).
- 2.3.3 In the non-randomised study of 15 patients treated by endoscopic or open radical inguinal lymphadenectomy, mean length of hospital stay in patients who had the endoscopic procedure in 1 lower limb and the open procedure in the other (n=10) was 6.4 days compared with 24 hours for patients who had bilateral endoscopic procedures (n=5; $p<0.001$). Mean times to return to usual activities were 21 days and 14 days respectively ($p=0.032$).
- 2.3.4 The non-randomised study of 15 patients reported that wound drains remained in place for a shorter time after the endoscopic procedure compared with the open procedure (4.9 days versus 6.4 days, $p=0.008$).
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as conversion to open procedure, length of hospital stay and time to full recovery, adequate clearance of lymph nodes and recurrence of cancer.

2.4 Safety

- 2.4.1 The non-randomised study of 15 patients treated by endoscopic or open radical inguinal lymphadenectomy reported lymphatic complications in both groups (10% [2 out of 20] versus 20% [2 out of 10], $p=0.58$) during 32-month follow-up. In the endoscopic group, lymphorrhoea was reported in 1 patient and unilateral limited lymphocele (requiring 3 evacuation punctures) in 1 patient. In the open group, chronic lymphoedema was reported in 1 patient and lymphocele (which spontaneously resolved within 2 months) in 1 patient. A case series of 8 patients reported 3 patients with lymphoceles.
- 2.4.2 Skin-related complications were reported in 5% (1 out of 20) and 50% (5 out of 10) of limbs in the non-randomised study of 15 patients (30 treated limbs) treated by either endoscopic or open radical inguinal lymphadenectomy respectively ($p=0.009$). A case series of 5 patients reported cellulitis in 2 patients; 1 of these patients had a severe infection at the site of prior sentinel node biopsy (follow-up

not stated).

- 2.4.3 Flap necrosis was reported in 6% (1 out of 16) and 44% (7 out of 16) of limbs in a non-randomised controlled study of 16 patients (32 limbs) treated by endoscopic inguinal lymphadenectomy or open groin node dissection respectively.
- 2.4.4 The Specialist Advisers considered theoretical adverse events to include damage to femoral vessel or femoral nerve, port-site metastasis, gas embolus, lymph leak, lymphocele and seroma.

2.5 Other comments

- 2.5.1 The Committee noted that endoscopic radical inguinal lymphadenectomy has the potential to achieve lower morbidity rates than those associated with the open procedure. They also noted that endoscopic radical inguinal lymphadenectomy is an uncommon procedure and considered that acquisition of comparative data may therefore be difficult.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant [audit criteria](#) and has developed an [audit tool](#) (which is for use at local discretion).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient

consent in mind.

ISBN: 978-1-4731-6382-9

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).