NICE guidance

Single-port laparoscopic nephrectomy

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg414

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 Evidence on the safety and efficacy of single-port laparoscopic nephrectomy is based on limited numbers of patients. Any advantage for patients of the procedure over conventional laparoscopic nephrectomy is uncertain and there is inadequate evidence on safety, including insufficient information about warm ischaemia time when used to harvest kidneys from live donors for transplantation. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake single-port laparoscopic nephrectomy should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients 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 single-port laparoscopic nephrectomy (see section 3.1).

1.3 Patient selection is particularly important when the procedure is being considered for the treatment of patients with malignant disease.

1.4 Single-port laparoscopic nephrectomy is technically challenging and should only be carried out by experienced laparoscopic surgeons who have received specific training in the procedure.

1.5 NICE encourages the publication of further evidence on single-port laparoscopic nephrectomy. In particular, clinicians are encouraged to collect and publish data

on long-term recurrence rates when the procedure is used to treat malignancy and on subsequent graft survival and renal function when it is used for donor nephrectomy. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Indications for nephrectomy (including nephroureterectomy) include benign and malignant tumours; conditions that damage renal function such as chronic infection; and donation for transplantation. For these indications, other procedures that can be performed through a single port include partial nephrectomy and needle cryoablative therapy.

2.2 Outline of the procedure

2.2.1 Single-port laparoscopic nephrectomy aims to reduce pain and recovery time, and to improve cosmesis, compared with standard laparoscopic nephrectomy.

2.2.2 Single-port laparoscopic nephrectomy is performed with the patient under general anaesthesia, usually using a transperitoneal approach. A single umbilical skin incision is used to insert multiple instruments, typically via a specially designed system. Following laparoscopic dissection, the kidney is usually enclosed in a retrieval bag and removed through the umbilicus or vagina, either intact or morcellated.

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 randomised controlled trial of 50 renal donors treated by single-port laparoscopic donor nephrectomy or standard laparoscopic donor nephrectomy reported significantly lower pain scores (on a visual analogue scale of 1 to 10) of 1.24 and 2.08 respectively at 96 postoperative hours (p=0.0004).

2.3.2 A non-randomised comparative study of 57 patients treated by single-port or conventional laparoscopic nephrectomy reported no significant difference in analgesic use (40 mg versus 45 mg of pethidine), although the pain score was significantly lower on postoperative days 1 to 3 for patients in the single-port group (4.7, 3.4 and 2.7 versus 5.8, 4.6 and 4.0, respectively [p=0.001, p<0.001 and p=0.008]).

2.3.3 A randomised controlled trial of 27 patients treated by single-port or conventional laparoscopic nephrectomy reported a return to normal activities within 11 days and 14 days respectively (p=0.001). A non-randomised comparative study of 35 patients reported a faster return to work and shorter time to complete physical recovery for patients in the single-port group compared with those who had conventional laparoscopic nephrectomy (18 days versus 46 days, p=0.0009, and 29 days versus 83 days, p=0.03, respectively).

2.3.4 The Specialist Advisers listed key efficacy outcomes as improved cosmesis, and, when treating cancer, no new or recurrent cancer.

2.4 Safety

2.4.1 Allograft thrombosis was reported in 1 patient in a non-randomised comparative study including 17 single-port laparoscopic donor nephrectomies: the recipient underwent an allograft nephrectomy after 1 week.

2.4.2 A case series of 18 patients reported 1 bowel injury and 1 diaphragm injury, both of which were repaired without the need for additional ports.

2.4.3 A case series of 62 patients reported that 1 single-port laparoscopic simple nephrectomy was converted to conventional laparoscopy to aid in dissection and 1 single-port nephroureterectomy was converted to conventional laparoscopy to control bleeding.

2.4.4 A case series of 12 patients reported that 1 single-port procedure was converted to conventional laparoscopy because of adhesions and bleeding (requiring blood transfusion). Two single-port laparoscopic nephroureterectomies were converted to open surgery, 1 for complete renal hilar lymphadenectomy and the other for severe adhesions.

2.4.5 In a case series of 15 patients, 1 patient who had bilateral nephrectomy developed severe abdominal distension and dehiscence of the umbilical extraction site. The authors noted that the patient had multiple comorbidities and was on chronic steroid therapy. Postoperative small bowel obstruction was reported in 1 patient 14 days after an uncomplicated single-port procedure: this required surgical exploration.

2.4.6 The Specialist Advisers considered theoretical adverse events to include injury to the great vessels and to adjacent organs including the spleen.

2.5 Other comments

2.5.1 The Committee noted that the technology used for this procedure is evolving rapidly and these developments may influence its safety and efficacy.

2.5.2 The Committee noted that warm ischaemia time may be longer than with standard laparoscopic nephrectomy when using this procedure to harvest kidneys from live donors for transplantation, but any clinical effect of this is uncertain.

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), available when the guidance is published.

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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.