



Laparoscopic nephrolithotomy and pyelolithotomy

Interventional procedures guidance

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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> impact of implementing NICE recommendations wherever possible.

1 Guidance

- Limited evidence suggests that laparoscopic nephrolithotomy and pyelolithotomy are safe and efficacious enough, provided that normal arrangements are in place for consent, audit and clinical governance.
- 1.2 These procedures should only be performed by surgeons who have advanced laparoscopic skills working within a multidisciplinary team experienced in the management of renal stones.
- 1.3 Since the majority of patients with renal stones can be managed by less invasive treatments, clinicians are encouraged to collect and publish data to inform selection of patients for this procedure.

2 The procedure

2.1 Indications

- 2.1.1 Renal stones are hard masses that form from crystals in urine. They range in size from small gravel-like stones to large stones that extend into more than one calyx (staghorn calculi). Although kidney stones are often asymptomatic, they can cause pain in the abdomen, lower back or groin, and blood in the urine.

 Depending on its size and position, an untreated stone can obstruct the passage of urine or lead to infection and permanent kidney damage.
- 2.1.2 Small renal stones will usually pass out of the kidney in the urine without any treatment. However, larger stones and those that cause persistent symptoms

may need to be broken into smaller pieces or removed. A variety of techniques are available, depending on the number and size of stones and their site and type. These techniques include open surgery, percutaneous nephrolithotomy (PCNL), ureteroscopic techniques and extracorporeal shockwave lithotripsy.

2.2 Outline of the procedure

- 2.2.1 Laparoscopic nephrolithotomy and pyelolithotomy are similar procedures, performed under general anaesthesia using a transperitoneal or retroperitoneal approach.
- 2.2.2 The abdomen is insufflated with an inert gas and small incisions are made to allow insertion of instruments. In laparoscopic nephrolithotomy, incisions are made in the renal capsule and parenchyma (nephrotomy) and the stone or stones are removed from the affected calices. The nephrotomy site may or may not be closed with sutures, and a stent running from the kidney to the bladder may be inserted and left in place for several weeks after surgery. In pyelolithotomy, the stone is removed via an incision in the renal pelvis (pyelotomy), which is usually then closed with sutures, with or without insertion of a stent.

2.3 Efficacy

- Two non-randomised controlled trials reported that similar proportions of patients were stone-free after laparoscopic pyelolithotomy and PCNL (88% [14 out of 16] versus 81% [13 out of 16], respectively, in one trial and 100% in both groups [16 out of 16, and 12 out of 12] in the other). A third non-randomised controlled trial of 89 patients reported that none of those treated with laparoscopic pyelolithotomy had residual stones, compared with 13% of patients treated with PCNL. In one case series, 6 of 7 patients were stone-free after treatment. In another, all 8 patients were stone-free 3 months after laparoscopic pyelolithotomy and 7 were still stone-free at 12 months' follow-up.
- 2.3.2 Three non-randomised controlled trials (149 patients in total) reported mean lengths of hospital stay of 3.9, 6.5 and 3.8 days for laparoscopic pyelolithotomy,

compared with 5.4, 5.6 and 3.0 days for PCNL (p=0.17 in one study; p values were not reported in the other studies). Two of these non-randomised controlled trials reported that the mean time to return to normal activities was 13 days after laparoscopic pyelolithotomy (both studies), compared with 14 and 10 days after PCNL (p values not reported; not significant, respectively).

2.3.3 The Specialist Advisers noted that these procedures are likely to be suitable for only a small proportion of patients with renal stones. They also noted that both experience in stone management and special training in laparoscopic surgery are necessary to carry out this procedure.

2.4 Safety

- Two non-randomised controlled trials reported peritoneal tears in 12% (5 out of 43) and 19% (3 out of 16) of patients treated with laparoscopic pyelolithotomy using a retroperitoneal approach, but in none of the patients treated with PCNL. Peritoneal tears may lead to a requirement for conversion to open surgery, due to loss of operative space. Conversion to open surgery was required in 1 of the 8 reported cases in these two studies. Three studies reported urinary leakage (not further defined) in 7% (1 out of 15), 10% (2 out of 20) and 13% (2 out of 16) of patients treated laparoscopically.
- 2.4.2 Three non-randomised controlled trials reported that 13% to 16% of laparoscopic pyelolithotomy procedures (7 out of 43, and 2 out of 16 in two separate studies) had to be converted to open surgery, compared with 0% to 2% of percutaneous procedures (1 out of 48, 0 out of 16, 0 out of 12). In one case series, none of eight laparoscopic procedures required conversion to open surgery; in another, 20% (4 out of 20) were converted to open surgery.
- 2.4.3 The Specialist Advisers listed potential adverse events as the need for nephrectomy or conversion to open surgery, urinary fistula, urinary leakage, haemorrhage and infection.

2.5 Other comments

2.5.1 It was noted that procedures of this kind are seldom needed, as most renal stones can be managed in other ways. The fact that these technically advanced procedures are likely to be used infrequently underpins the recommendation in section 1.2.

3 Further information

Sources of evidence

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

Information for patients

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

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Endorsing organisation

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