



Endopyelotomy for pelviureteric junction obstruction

Interventional procedures guidance Published: 16 December 2009

www.nice.org.uk/guidance/ipg325

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

1 Guidance

- 1.1 Current evidence shows that endopyelotomy for pelviureteric junction (PUJ) obstruction is efficacious in the short and medium term although there is a risk of obstruction recurrence in the long term. The evidence on safety raises no major concerns. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.
- This procedure should be carried out only in units with specific expertise in endopyelotomy for PUJ obstruction, by specialist teams who can offer a range of procedures including laparoscopic pyeloplasty.

2 The procedure

2.1 Indications and current treatments

- Pelviureteric junction obstruction (PUJ) is a congenital or acquired stenosis of the junction between the renal pelvis and the ureter, which inhibits normal urine flow. It can cause chronic or recurrent flank pain as well as urinary tract infections.
- 2.1.2 Conservative treatment may include long-term use of low-dose antibiotics.

 Current surgical options to reconstruct and normalise the anatomy of the PUJ include open or laparoscopic pyeloplasty (with or without robotic assistance) and electrocautery cutting balloon treatment.

2.2 Outline of the procedure

2.2.1 The aim of the procedure is to widen the abnormally narrowed part of the PUJ. With the patient under general anaesthesia, a cutting device (which may be a laser or a diathermy probe, or an endoscopic knife) is inserted into the PUJ area endoscopically via the ureter, or via a percutaneous approach in the flank. Under endoscopic visualisation a full-thickness incision is made, through the wall of the ureter, into the periureteric fat. A stent is inserted across the PUJ, with the aim of maintaining patency, and is removed after several weeks.

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 (RCT) of 40 patients treated by laser endopyelotomy versus electrocautery cutting balloon reported a successful outcome (defined as subjective relief or symptom improvement, plus objective relief of obstruction and improvement in glomerular filtration rate) in 85% (17 out of 20) and 65% (13 out of 20) of patients respectively at a mean follow-up of 30 months (p=0.14). There was no significant difference between the treatment groups in the success rates for patients with primary or secondary PUJ obstruction (p=0.38 and p=0.26 respectively).
- A non-RCT of 436 patients reported that success (defined as complete symptomatic relief plus resolution or improvement in obstruction on imaging) was achieved in 61% (111 out of 182) of endopyelotomy-treated patients and 82% (144 out of 175) of pyeloplasty-treated patients at a mean follow-up of 3.5 years (significance not stated).
- A non-RCT of 273 patients reported that success (defined as symptom resolution plus improvement or stability of radiographic parameters) was achieved in 60% of patients in the endopyelotomy group, 89% of the laparoscopic pyeloplasty group, and 100% of the robotically assisted pyeloplasty group at a mean follow-up of 20 months (absolute numbers and significance not stated). Multivariate analysis

(excluding the robotically assisted group) showed that endopyelotomy (compared with laparoscopic pyeloplasty) was an independent predictor of treatment failure (hazard ratio 3.16; 95% confidence interval 1.70 to 5.86, p<0.001).

- In the non-RCT of 436 patients, the 10-year estimated recurrence-free survival was 41% (n=8) in the endopyelotomy group and 75% (n=21) in the pyeloplasty group (absolute figures not stated).
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as short-term pain relief, resolution of symptoms and normalisation of renographic obstruction, preservation of renal function and no obstruction recurrence in the long term.

2.4 Safety

- 2.4.1 The RCT of 40 patients treated by laser endopyelotomy versus electrocautery cutting balloon reported no significant difference in the rate of overall complications (not otherwise defined) between treatment groups (10% [2 out of 20] and 25% [5 out of 20] respectively; p=0.20; mean follow-up 30 months). The non-RCT of 436 patients reported that the rate of overall complications was not significantly different between the endopyelotomy (11% [25 out of 225]) and the pyeloplasty groups (8% [17 out of 211]; p=0.33) at a mean follow-up of 3.5 years.
- 2.4.2 Bleeding requiring transfusion occurred in 1% (3 out of 225) of patients in the endopyelotomy group and 1% (2 out of 211) of patients in the pyeloplasty group in the non-RCT of 436 patients (significance not stated). Haemorrhage requiring electrocoagulation occurred in 1% (4 out of 320) and haemorrhage requiring transfusion in 1% (2 out of 212) of patients (1 patient required further intervention [not otherwise stated]) in case series of 320 and 212 patients, respectively.
- 2.4.3 Ureteral avulsion requiring an open procedure was reported in 1 of 212 patients in a case series.
- 2.4.4 One case report described a patient who developed renal atrophy, renal hypertension, perinephric fibrosis and calcification, vena caval stenosis and renal vein obstruction after endopyelotomy: the patient needed a nephrectomy 8 years later. The primary event was thought to have been development of a subcapsular

haematoma after endopyelotomy. A second case report described ureteral intussusception following endopyelotomy at 3-month follow-up, treated by pyeloplasty reconstruction (not otherwise described).

- 2.4.5 Reoperation (repeat endopyelotomy, open pyeloplasty or nephrectomy) was required in 10% (33 out of 320) of patients in the case series of 320 patients. In the case series of 212 patients, repeat endopyelotomy was required in less than 1% (1 out of 212), secondary intervention by pyeloplasty in 8% (18 out of 212), ureterocalicostomy in 2% (4 out of 212), and ileal interposition in 1 patient.
- 2.4.6 The Specialist Advisers listed adverse events as haemorrhage, stent-related problems and aorto-ureteral fistula. They considered theoretical adverse events to include failure or obstruction recurrence, infection, perforation and fibrosis.

2.5 Other comments

The Committee was advised that endopyelotomy for PUJ obstruction is used less frequently than in the past because of the increased use of laparoscopic pyeloplasty, but that it may have a particular role in the management of obstruction recurrence.

3 Further information

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

ISBN: 978-1-4731-6328-7

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.