NICE guidance

Electrocautery cutting balloon treatment for pelviureteric junction obstruction

Interventional procedures guidance
Published: 16 December 2009

www.nice.org.uk/guidance/ipg324

1 Guidance

1.1 Current evidence on the efficacy of electrocautery cutting balloon treatment for pelviureteric junction (PUJ) obstruction is limited in quantity. The evidence on safety raises concern about the risk of bleeding. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake electrocautery cutting balloon treatment for PUJ obstruction should take the following actions.

- Inform the clinical governance leads in their Trusts.

- Ensure that patients and their parents/carers understand that there is a risk of bleeding as a result of the procedure, and a risk of obstruction recurrence in the longer term, and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of all patients having electrocautery cutting balloon treatment for PUJ obstruction (see section 3.1).

1.3 Patient selection and treatment should be carried out only in units that can offer a range of procedures including laparoscopic pyeloplasty.

2 The procedure

2.1 Indications and current treatments

2.1.1 Pelviureteric junction obstruction 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 endopyelotomy.

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 and using fluoroscopic guidance, a device containing a monopolar diathermy wire on the surface of a low-pressure tamponade balloon is inserted through the ureter and into the PUJ. The balloon is partially inflated to determine the area of stenosis (seen as a waist in the balloon) and to fix it in position for incision. The diathermy wire incises the target area of the PUJ, through the wall of the ureter, into the periureteric fat. The balloon is fully inflated to apply pressure (tamponade) following incision to

promote haemostasis. A stent is inserted across the PUJ, with the aim of maintaining patency, and is removed after several weeks.

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 Efficacy

2.3.1 A randomised controlled trial (RCT) of 40 patients treated by electrocautery cutting balloon versus laser endopyelotomy reported a 'successful outcome' (defined as subjective relief or symptom improvement plus objective relief of obstruction and improvement in glomerular filtration rate) in 65% (13/20) and 85% (17/20) of patients respectively at a mean follow-up of 30 months (p = 0.14).

2.3.2 A non-randomised controlled trial of 64 patients reported no significant difference in success rate (defined as relief of symptoms, decreased caliectasis, and diuretic renography half-time values indicating absence of obstruction) between patients treated by electrocautery cutting balloon (78% [21/27]) and those treated by laser endopyelotomy (74% [26/35]) at a mean follow-up of 76 months.

2.3.3 A non-randomised controlled trial of 149 patients reported 'subjective success' (defined as a 50% improvement in preoperative discomfort) in 85% of 52 patients with primary PUJ obstruction treated by electrocautery cutting balloon and 90% of 40 patients treated by antegrade electrode ablation endopyelotomy at a mean follow-up of 16 months (absolute numbers and significance not stated).

2.3.4 The non-randomised controlled trial of 64 patients reported no significant difference in reoperation rates following electrocautery cutting balloon treatment (6% [1/17]), antegrade endopyelotomy (0% [0/18]) or retrograde cold knife endopyelotomy (17% [5/29]) (p = 0.13) (mean follow-up 67 months).

2.3.5 The Specialist Advisers listed key efficacy outcomes as short-term pain

relief, resolution of obstruction on imaging and no obstruction recurrence in the long term.

2.4 Safety

2.4.1 Bleeding requiring transfusion and embolisation of a lower-pole vessel was reported in 7% (2/27) of patients in the electrocautery cutting balloon group compared with 0% (0/37) of patients in the laser endopyelotomy treatment group in the non-randomised controlled trial of 64 patients ($p = 0.13$). Ureteral bleeding requiring transfusion was reported in 4% (3/76) of patients in a case series of 76 patients treated by electrocautery cutting balloon for PUJ obstruction; embolisation of a lower-pole artery was required in 2 patients. Haematuria (managed conservatively) was reported in 15% (3/20) of patients treated by electrocautery cutting balloon at follow-ups ranging from 2 to 5 days in the RCT of 40 patients.

2.4.2 A case report of 2 patients described 1 patient with a large perirenal haematoma caused by incision of an aberrant renal artery during electrocautery cutting balloon treatment, which was ligated at open surgery, and 1 patient who developed a pseudoaneurysm of an aberrant lower-pole artery, which was embolised.

2.4.3 One case report described a broken cutting balloon wire in the PUJ, which had become calcified and required ureteroscopically-guided laser ablation. Balloon rupture was reported in 1 patient in the RCT of 40 patients.

2.4.4 The Specialist Advisers listed adverse events as infection and need for transfusion.

2.5 Other comments

2.5.1 The Committee was advised that electrocautery cutting balloon treatment for PUJ obstruction is used infrequently 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

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

3.2 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

5 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration

of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

Copyright

Contact NICE

National Institute for Health and Clinical Excellence
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk
nice@nice.org.uk
0845 033 7780

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation