NICE guidance

# Electrocautery cutting balloon treatment for pelviureteric junction obstruction

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 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 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 the information for the public 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.

2.2.2 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 of 20) and 85% (17 of 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 of 27]) and those treated by laser endopyelotomy (74% [26 of 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 of 17]), antegrade endopyelotomy (0% [0 of 18]) or retrograde cold knife endopyelotomy (17% [5 of 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 of 27) of patients in the electrocautery cutting balloon group compared with 0% (0 of 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 of 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 of 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

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).

# Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with

patient consent in mind.

# 4 Update information

**Changes since publication**

**January 2012:** Minor maintenance.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

# Accreditation