# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

## Interventional procedure overview of electrocautery cutting balloon treatment for pelviureteric junction obstruction

Pelviureteric junction obstruction is a condition caused by a narrowing of the funnel-shaped part of the kidney (known as the renal pelvis) where urine collects before being carried to the bladder by tubes called ureters. The obstruction may cause episodes of loin pain and/or nausea and vomiting, urinary infections and kidney stones. In some patients the condition could also affect the normal function of the kidney.

This procedure (electrocautery cutting balloon treatment) aims to widen the renal pelvis by inserting a catheter with a balloon and wire into the urinary tract. The wire is used to cut away the tissue that is causing the obstruction.

## Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

## Date prepared

This overview was prepared in June 2009.

## Procedure name

- Electrocautery cutting balloon treatment for pelviureteric junction obstruction

## Specialty societies

- British Association of Urological Surgeons

# Description

## *Indications and current treatment*

Pelviureteric junction (PUJ) obstruction is a stenosis of the junction between the renal pelvis and the ureter that inhibits the flow of urine. The condition is usually congenital (primary PUJ obstruction) but can be acquired secondary to scar formation from another disorder (for example, nephrolithiasis or infection). PUJ can cause chronic or recurrent flank pain as well as kidney infections (pyelonephritis in particular).

Conservative management may involve medical therapy with chronic low-dose antibiotics

Interventional treatments aim to reconstruct and normalise the anatomy of the PUJ. These include open pyeloplasty, laparoscopic pyeloplasty (with or without robotic assistance) and endopyelotomy using laser, cold steel or ablative techniques.

## *What the procedure involves*

The aim of the procedure is to widen the abnormally narrowed part of the PUJ using a relatively less invasive procedure than open pyeloplasty.

Under general anaesthesia and fluoroscopic guidance a device containing a monopolar electrosurgical cutting wire and a low-pressure tamponade balloon are introduced though a catheter via a retrograde approach into the urethra and through the ureter to the PUJ. The balloon is partially inflated to determine the area of stenosis (seen as a waist in the balloon) and fix it in position for incision. A diathermy wire attached to the balloon surface incises the target area of the PUJ by direct electrocautery to the level of periureteric fat. The balloon is also used to apply pressure (tamponade) on the lesion post incision to promote haemostasis. A stent is inserted during the same procedure following incision, with the aim of maintaining patency and removed after a number of weeks. Patency may be checked with a contrast retrograde pyelogram.

## *List of studies included in the overview*

This overview is based on 397 patients from one randomised controlled trial[1], three non-randomised controlled trials[2–4], one case series[5] and three case reports[6–8].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

## *Efficacy*

A randomised controlled trial of 40 patients reported that a successful outcome (defined as subjective relief or improvement in symptoms plus objective relief of obstruction and improvement in glomerular filtration rate) was not significantly more common following cutting balloon treatment (65% [13/20]) than following laser endopyelotomy (85% [17/20]) ($p = 0.14$) at 30-month follow-up[1]. Similarly there was no statistically significant difference in the rate of success between the treatment groups in subgroup analysis of patients with primary PUJ obstruction ($p = 0.38$) versus those with secondary PUJ obstruction ($p = 0.26$).

A non-randomised controlled trial of 64 patients reported no significant difference in success rate (defined as relief of symptoms, decreased caliectasis and a non-obstructed half-time on diuretic renography) between patients treated by cutting balloon (78% [21/27]) and those treated by laser endopyelotomy (74% [26/35]) at 76-month follow-up[2]. Again there was no difference in terms of success between patients with primary PUJ obstruction ($p = 0.58$) and those with secondary obstruction ($p = 0.99$). There was also no significant difference in success rate between subgroups of male and female patients.

A non-randomised controlled trial of 149 patients reported that subjective success (defined as a 50% improvement over baseline in a patient questionnaire score) was achieved in 85% of patients with primary PUJ obstruction treated by cutting balloon and 90% of patients treated by antegrade electrode ablation endopyelotomy at 16-month follow-up (measurement of significance not reported)[3].

A non-randomised controlled trial of 64 patients reported that there was no significant difference in the proportion of patients satisfied with their procedure following cutting balloon treatment (73%), antegrade endopyelotomy (100%) or retrograde endopyelotomy (86%) ($p = 0.09$)[4].

There was no significant difference in the mean length of hospital stay following cutting balloon treatment (1.6 days) and laser endopyelotomy (1.1 days) in a randomised controlled trial of 40 patients ($p = 0.13$)[1]. However, in a non-randomised controlled trial of 149 patients the mean length of hospital stay for patients with primary PUJ obstruction was significantly shorter following cutting balloon therapy (2.3 days) than following antegrade electrode ablation endopyelotomy (3.6 days) ($p < 0.05$)[3].

## *Safety*

A randomised controlled trial of 40 patients reported that there was no statistically significant difference in the rate of overall complications between patients treated by cutting balloon (25% [5/20]) and those treated by laser endopyelotomy (10% [2/20]) ($p = 0.20$)[1]. In the cutting balloon group haematuria was reported in 15% (3/20) of patients at 2, 4 and 5 days of follow-up respectively, and was treated conservatively.

A non-randomised controlled trial of 64 patients reported that 7% (2/27) of patients in the cutting balloon group had bleeding requiring transfusion and embolisation of a lower-pole vessel, compared with 0% (0/37) of patients in the laser endopyelotomy group (p = 0.13)[2]. A non-randomised controlled trial of 149 patients reported that intraoperative haemorrhage occurred in 2% (1/52) of patients treated by cutting balloon and 3% (2/36) of those treated by antegrade electrode ablation endopyelotomy (no significant difference)[3].

A case series of 76 patients treated with a cutting balloon for PUJ obstruction reported significant ureteral bleeding requiring transfusion in 4% (3/76) of patients; in two of these patients angiography and embolisation of a lower-pole branching artery was required[5].

A case series of two patients describes one patient with a large perirenal haematoma and a cut aberrant artery following cutting balloon treatment, which was ligated during open surgery, and one patient with an aberrant lower-pole artery with a pseudoaneurysm, which was embolised[6].

There was one case report of a broken cutting balloon wire causing calcification that required ureteroscopically guided laser ablation[7].

A non-randomised controlled trial of 64 patients reported that there was no significant difference in the rate of re-operation following cutting balloon treatment (6% [1/17]), antegrade endopyelotomy 0% (0/18) or retrograde cold knife endopyelotomy (17% [5/29]) (p = 0.13)[4].

A randomised controlled trial of 40 patients reported that in the cutting balloon group balloon rupture occurred in 5% (1/20) of patients[1]. A case series of 76 patients treated with a cutting balloon for PUJ obstruction reported that there was one case of stent migration (1% [1/76])[5]. There was one case report of device failure due to balloon malfunction[8].

A case series of 76 patients treated with a cutting balloon for PUJ obstruction reported that there was also one case each of urinary tract infection and clot retention (1% [1/76] for each)[5].

# Literature review

## *Rapid review of literature*

The medical literature was searched to identify studies and reviews relevant to electrocautery cutting balloon treatment for PUJ obstruction. Searches were conducted of the following databases, covering the period from their commencement to 12 May 2009: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during the consultation or resolution process that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

**Table 1 Inclusion criteria for identification of relevant studies**

| Characteristic | Criteria |
|---|---|
| Publication type | Clinical studies were included. Emphasis was placed on identifying good quality studies.<br>Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.<br>Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature. |
| Patient | Patients with PUJ obstruction |
| Intervention/test | Electrocautery cutting balloon treatment |
| Outcome | Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy. |
| Language | Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base. |

## *Existing assessments of this procedure*

There were no published assessments from other organisations identified at the time of the literature search.

## *Related NICE guidance*

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

### Interventional procedures

- Laparoscopic pyeloplasty. NICE interventional procedures guidance 046 (2004). Available from www.nice.org.uk/IPG046

## Table 2 Summary of key efficacy and safety findings on electrocautery cutting balloon treatment for pelviureteric junction obstruction

Abbreviations used: N/R, not reported; PUJ/UPJ, pelviureteric junction

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>el-Nahas AR (2006)[1]<br><br>Randomised controlled trial<br><br>Country: Egypt<br><br>Study period: Jan 2001 to Oct 2003<br><br>Study population: patients with PUJ confirmed by radiological assessment. Age: 39 years (mean). Sex: 55% male. Primary UPJ n = 14; secondary UPJ n = 26.<br><br>n = 40 (20 cutting balloon)<br><br>Inclusion criteria: patients without ‘hugely dilated’ renal pelvis, or renal stones or crossing vessel at the UPJ.<br><br>Technique: holmium YAG laser incision under endoscopic visualisation via a ureteroscope to incise UPJ layer by layer to periureteral and peripelvic fat vs cutting balloon with the Acucise device under fluoroscopic control, cutting wire activated at 75–100 W and balloon inflated to incise the waist of the stricture. Stent inserted into UPJ for 6 weeks in both groups.<br><br>Follow-up: 30 months (mean)<br>Conflict of interest: not reported.</td>
<td>Overall success<br>Success was defined as a subjective relief or improvement in symptoms plus objective relief of obstruction (half-time less than 20 min [not otherwise described] and improvement in glomerular filtration rate).
<table>
<tr><th>Outcome</th><th>Balloon</th><th>Laser</th><th>p</th></tr>
<tr><td>Success</td><td>65.0% (13/20)</td><td>85.0% (17/20)</td><td>0.14</td></tr>
<tr><td>Success primary UPJ</td><td>66.7% (4/6)</td><td>87.5% (7/8)</td><td>0.38</td></tr>
<tr><td>Success secondary UPJ</td><td>64.3% (9/14)</td><td>83.3% (10/12)</td><td>0.26</td></tr>
</table>
Operative characteristics
<table>
<tr><th>Outcome</th><th>Balloon</th><th>Laser</th><th>p</th></tr>
<tr><td>Operative time (min)</td><td>58.7 ± 20.1</td><td>64.7 ± 22.4</td><td>0.44</td></tr>
<tr><td>Length of hospital stay (days)</td><td>1.6 ± 1.26</td><td>1.1± 0.25</td><td>0.13</td></tr>
</table>
</td>
<td>Complications<br>There was one intraoperative complication in each group.<br><br>In the laser group 5% (1/20) of patients had bleeding from the edge of the pelvis which was managed with low pressure balloon tamponade without transfusion.<br><br>In the balloon cutting group the catheter balloon ruptured in 5% (1/20) of patients. Ureteroscopy confirmed adequate incision had been achieved.<br><br>Failure of extravasation of contrast medium occurred in 15% (3/20) of patients in the cutting balloon group.<br><br>Haematuria (not otherwise described) was reported in 15% (3/20) of patients in the cutting balloon group at 2, 4 and 5 days respectively. This was treated conservatively and with blood transfusion in each.
<table>
<tr><th>Outcome</th><th>Balloon</th><th>Laser</th><th>p</th></tr>
<tr><td>Overall complications</td><td>25% (5/20)</td><td>10% (2/20)</td><td>0.20</td></tr>
</table>
</td>
<td>Concealment of treatment allocation by sealed envelopes; method of randomisation is not reported.<br><br>Blinding of outcome assessment is not reported.<br><br>No significant difference between treatment groups in terms of demographic or clinical characteristics except that 65% of the laser group had left side obstruction compared with 75% right side in the balloon cutting group (p = 0.01).</td>
</tr>
</table>

Abbreviations used: N/R, not reported; PUJ/UPJ, pelviureteric junction

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Ponsky LE (2006)[2]<br><br>Non-randomised controlled trial<br><br>Country: USA<br><br>Study period: Mar 1994 to Jan 2002<br><br>Study population: patients with functionally significant PUJ obstruction confirmed radiographically with one or more clinical signs. Age: 39 years (mean). Sex: 28% male. Primary UPJ obstruction n = 52; secondary UPJ obstruction n = 12.<br><br>n = 64 (27 cutting balloon)<br><br>Inclusion criteria: without concomitant upper tract stones, obstruction > 2 cm or significant entanglement by crossing vessels.<br><br>Technique: retrograde approach with ureteroscope and holmium laser incision vs Acucise cutting balloon with fluoroscopic guidance at 60–70 W for 3 seconds. Stent placed for 4–6 weeks in both groups.<br><br>Follow-up: 76 months (mean)<br><br>Conflict of interest: not reported</td>
<td>Overall success<br>Success was defined as a relief of symptoms, decreased caliectasis on imaging and a non-obstructed half-time on diuretic renography.
<table>
<tr><th>Outcome</th><th>Balloon</th><th>Laser</th><th>p</th></tr>
<tr><td>Success</td><td>78% (21/27)</td><td>74% (26/35)</td><td>0.64</td></tr>
<tr><td>Success primary UPJ</td><td>76% (16/21)</td><td>73% (22/30)</td><td>0.58</td></tr>
<tr><td>Success secondary UPJ</td><td>83% (5/6)</td><td>80% (4/5)</td><td>0.99</td></tr>
</table>
There was no significant difference in success rate between the treatment groups in the subgroups of male and female patients.<br><br>Operative characteristics<br>Group mean (range)
<table>
<tr><th>Outcome</th><th>Balloon</th><th>Laser</th><th>p</th></tr>
<tr><td>Operative time (min)</td><td>82 (75–100)</td><td>89 (45–155)</td><td>0.54</td></tr>
<tr><td>Length of stay (days)</td><td>0.96 (0–7)</td><td>1.03 (0–2)</td><td>0.015</td></tr>
</table>
</td>
<td>Complications
<table>
<tr><th>Outcome</th><th>Balloon</th><th>Laser</th><th>p</th></tr>
<tr><td>Major</td><td>7% (2/27)</td><td>0%</td><td>0.13</td></tr>
<tr><td>Bleeding requiring transfusion and embolisation of lower pole vessel</td><td>7% (2/27)</td><td>0%</td><td>N/R</td></tr>
<tr><td>Minor</td><td>18% (5/27)</td><td>10% (4/37)</td><td>0.42</td></tr>
<tr><td>Severe flank pain < 24 h requiring replacement of Foley catheter</td><td>4% (1/27)</td><td>0%</td><td>N/R</td></tr>
<tr><td>Retention</td><td>7% (2/27)</td><td>0%</td><td>N/R</td></tr>
<tr><td>Temporary stent insertion</td><td>7% (2/27)</td><td>3% (1/37)</td><td>N/R</td></tr>
<tr><td>Subcapsular haematoma</td><td>0%</td><td>3% (1/37)</td><td>N/R</td></tr>
<tr><td>Urinary tract infection</td><td>0%</td><td>3% (1/37)</td><td>N/R</td></tr>
<tr><td>Sinus bradycardia (resolved spontaneously)</td><td>0%</td><td>3% (1/37)</td><td>N/R</td></tr>
</table>
</td>
<td>Prospective follow-up. Tests at various time points well described.<br><br>5% (2/37) of patients in the laser group were lost to follow-up (failed to return) and were excluded from analysis.<br><br>Clinical and demographic characteristics of the patients in the two treatment groups were not analysed for differences.</td>
</tr>
</table>

Abbreviations used: N/R, not reported; PUJ/UPJ, pelviureteric junction

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Shalav AL (1998)[3]<br><br>**Non-randomised controlled trial**<br><br>Country: USA<br><br>Study period: Oct 1989 to May 1996<br><br>Study population: age: 44 years (mean). Sex: 44% male. Primary UPJ n = 109; secondary UPJ n = 40.<br><br>**n = 149 (66 cutting balloon)**<br><br>Inclusion criteria: not reported<br><br>Technique: general or intravenous sedation. Antegrade approach with ureteroscope and electrode ablation vs Acucise cutting balloon with fluoroscopic guidance. Stent placed for 4–6 weeks in all patients.<br><br>**Follow-up: 16 months (mean)**<br><br>Conflict of interest: supported by manufacturer | ***Overall success***<br>Subjective success defined as 50% improvement over baseline in questionnaire score (including VAS scale).<br><br>Objective success defined as normalisation of half-time on renal scan, no pressure on Whitaker test, no stricture on retrograde pyelography and/or improved draining of the collecting system, and visualisation of the lower ureter on excretory urography.<br><br>**Primary UPJ** / **Balloon n = 52** / **Antegrade n = 40** / **p**<br>Subjective success: 85% / 90% / N/R<br>Objective success: 71% / 89% / N/R<br><br>**Secondary UPJ** / **Balloon n = 14** / **Antegrade n = 23** / **p**<br>Subjective success: 86% / 87% / N/R<br>Objective success: 83% / 77% / N/R<br><br>***Operative characteristics***<br>**Primary UPJ** / **Balloon n = 52** / **Antegrade n = 40** / **p**<br>Operative time (min): 70 / 113 / <0.05<br>Length of stay (days): 2.3 / 3.6 / <0.05<br><br>**Secondary UPJ** / **Balloon n = 14** / **Antegrade n = 23** / **p**<br>Operative time (min): 92 / 129 / <0.05<br>Length of stay (days): 2.0 / 4.4 / <0.05 | ***Complications***<br>**Balloon n = 52** / **Antegrade n = 63**<br>Major (total): 4% (2/52) / 5% (3/63)<br>Intraoperative haemorrhage: 2% (1/52) / 3% (2/63)<br>Transfusion: 2% (1/52) / 2% (1/63)<br>Embolisation: 4% (2/52) / 2% (1/63)<br>Respiratory distress: 0% / 2% (1/63)<br>Minor<br>Self-limiting bleeding: 4% (2/52) / 2% (1/63)<br>Urine extravasation: 0% / 2% (1/63)<br>Stent malfunction: 4% (2/52) / 2% (1/63)<br>Obstruction after stent removal: 4% (2/52) / 0%<br>Occlusion of percutaneous nephostomy: 0% / 2% (1/63)<br>Ileus: 0% / 10% (6/63)<br>Fever: 0% / 2% (1/63)<br>Urinary retention: 0% / 2% (1/63)<br>Urinary tract retention: 0% / 2% (1/63)<br><br>No statistically significant difference between groups.<br><br>Outcomes were also reported separately for primary and secondary UPJ obstruction. | Retrospective study.<br><br>Outcome reporting is complicated as many subgroups are analysed separately.<br><br>Outcome evaluation undertaken using different techniques across patients.<br><br>Only point estimates are reported for efficacy outcomes.<br><br>Efficacy outcomes are reported separately for primary and secondary UPJ.<br><br>Antegrade procedure not well described.<br><br>All patients with secondary UPJ obstruction were treated with antegrade endopyelotomy.<br><br>73% of antegrade procedures were performed before Dec 1992 whereas 71% of the cutting balloon procedures were carried out after Dec 1991. |

Abbreviations used: N/R, not reported; PUJ/UPJ, pelviureteric junction

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Vaarala MH (2008)[4]<br><br>**Non-randomised controlled trial**<br><br>Country: Finland<br><br>Study period: Oct 1987 to Jun 2007<br><br>Study population: patients with PUJ confirmed by radiological assessment. Age: 47 years (mean). Sex: 33 % male. Left side UPJ obstruction n = 31.<br><br>**n = 64 (17 cutting balloon)**<br><br>Inclusion criteria: patients with PUJ obstruction not otherwise defined<br><br>Technique: antegrade endopyelotomy (not otherwise described vs retrograde endopyelotomy with cold knife vs endopyelotomy with cutting balloon with the Acucise device. Stent inserted into UPJ in each group.<br><br>**Follow-up: 67 months (mean) for cutting balloon patients**<br><br>Conflict of interest: not reported | ***Subjective outcomes***<br>**Pain** / **Balloon** / **Antegrade** / **Retrograde**<br>Painless: 71% (12/17) / 83% (15/18) / 62% (18/29)<br>Decreased pain: 18% (3/17) / 17% (3/18) / 21% (6/29)<br>No change: 12% (2/17) / 0% / 17% (5/29)<br>p = 0.44 across groups<br>***Objective outcomes***<br>**Radiographic** / **Balloon** / **Antegrade** / **Retrograde**<br>Better (%): 76% (13/17) / 94% (17/18) / 62% (18/29)<br>No change (%): 24% (4/17) / 6% (1/18) / 24% (7/29)<br>Worse (%): 0% / 0% / 14% (4/29)<br>p = 0.085 across groups<br><br>**Outcome** / **Balloon** / **Antegrade** / **Retrograde** / **p**<br>Satisfaction (%): 73% / 100% / 86% / 0.09<br>Willing to undergo again (%): 67% / 100% / 75% / 0.047<br><br>***Operative characteristics***<br>Group mean (standard deviation)<br>**Outcome** / **Balloon** / **Ante-grade** / **Retro-grade** / **p**<br>Operative time (min): 71.4 (33.7) / 131.4 (38.3) / 76.5 (33.6) / <0.001<br>Length of stay (days): 6.9 (3.9) / 11.6 (6.9) / 4.9 (1.6) / <0.001<br>p value from one-way analysis of variance test | ***Complications***<br>**Outcome** / **Balloon** / **Antegrade** / **Retro-grade**<br>Reoperation (%): 6% (1/17) / 0% / 17% (5/29)<br><br>Severe complications were seen in 24% (4/17) of patients in the cutting balloon group, 39% (7/18) in the antegrade group and 14% (4/29) in the retrograde group.<br><br>**Cutting balloon**<br>Stent misplacement requiring correction by antegrade endopyelotomy 6% (1/17); renal calculus displacement 6% (1/17); severe infection and stent blockage (punction nephrostomy) 6% (1/17); severe bleeding from ovaric artery (transfusion and embolisation) 6% (1/17).<br><br>Technical complications occurred in 18% (3/17) of patients treated by cutting balloon. In two patients there was no cutting effect, and in one the cutting wire broke.<br><br>**Antegrade group**<br>Septicaemia 6% (1/18); wound infection 6% (1/18); stent leakage requiring replacement 6% (1/18); bleeding from endopyelotomy tube (intravenous tranexamic acid treatment) 6% (1/18); haematoma (rinsed out) 6% (1/18); pneumothorax (chest tube placement) 6% (1/18); solitary kidney (severe bleeding, open haemostatic operation and transfusion – permanent dysfunction requiring dialysis) 6% (1/18).<br><br>**Retrograde group**<br>Urinary tract infection 3% (1/29); septicaemia after stent removal 3% (1/29); severe pain (stent replacement) 6% (2/29). | Retrospective study<br><br>Consecutive patients treated<br><br>Two participating centres<br><br>Selection for treating with endopyelotomy was made on clinical decision. Method of selection for which technique is not reported.<br><br>Patients analysed in groups according to which technique was used to complete the procedure and not as intention to treat.<br><br>Significant difference between the group in terms of proportion of patients who underwent concomitant treatment for renal pelvic stone during the same procedure.<br><br>Follow-up length is not consistent across groups. |

| Abbreviations used: N/R, not reported; PUJ/UPJ, pelviureteric junction | | | |
|---|---|---|---|
| **Study details** | **Key efficacy findings** | **Key safety findings** | **Comments** |
| Kim FJ (1998)[5]<br><br>**Case series**<br><br>Country: USA<br><br>Study period: Jan 1991 to Dec 1995<br><br>Study population: patients with PUJ confirmed by diuretic renal scan, intravenous urogram or both. Age: 44 years (mean). Sex: 55% male. Right side UPJ obstruction n = 45. Primary PUJ obstruction n = 61; secondary PUJ obstruction n = 15.<br><br>**n = 76**<br><br>Inclusion criteria: patients with PUJ obstruction < 2.5 cm on retrograde pyelogram.<br><br>Technique: retrograde endopyelotomy with cutting balloon with the Acucise device at 75 W via guide wire and sheath. Stent inserted into UPJ for 6–8 weeks.<br><br>**Follow-up: not reported – to discharge**<br><br>Conflict of interest: not reported | ***Operative characteristics***<br>Mean operative time was 56 min;, and length of stay 1.8 days.<br><br>Contrast material extravasation was seen on retrograde pyelogram in 100% (76/76) of patients following the procedure.<br><br>Overall success (not defined) was achieved in 78% (59/76) of patients. | ***Complications***<br>All complications were categorised as major, minor or procedure failure. Definitions of grouping not reported.<br><br>**Major**<br>Significant ureteral bleeding requiring transfusion occurred in 4% (3/76) of patients. In two patients angiography and embolisation of a lower-pole branching artery was required. One patient stopped bleeding spontaneously.<br><br>**Minor**<br>Stent migration 1% (1/76)<br>Urinary tract infection 1% (1/76)<br>Clot retention 1% (1/76)<br><br>**Failure**<br>Failure occurred in 22% (17/76) of patients, 15 patients with primary PUJ obstruction and 2 with secondary. Retreatment was successful in 24% (4/17) of these and the rest underwent open pyeloplasty. | Patient accrual method not described<br><br>All patients received preoperative ureteral stenting for 1 week before the procedure.<br><br>Authors state that bleeding events occurred early in the series when a posterolateral incision was used. The technique was then changed to a lateral incision. |

| Abbreviations used: N/R, not reported; PUJ/UPJ, pelviureteric junction | | | |
|---|---|---|---|
| **Study details** | **Key efficacy findings** | **Key safety findings** | **Comments** |
| Angelsen A (2000)[6]<br><br>**Case report**<br><br>Country: Norway<br><br>Study period: not reported<br><br>Study population: patients with primary PUJ obstruction not otherwise defined. Age: 33 years (mean). Sex: 100% female.<br><br>**n = 2**<br><br>Inclusion criteria: not reported<br><br>Technique: retrograde endopyelotomy cutting balloon with the Acucise device<br><br>**Follow-up: up to 6 months**<br><br>Conflict of interest: not reported | **Patient 1**<br>Following cutting balloon treatment at 75 W for 4 seconds with immediate expansion of the balloon waist the procedure was repeated at 80 W as no extravasation of the contrast material was demonstrated, but again no extravasation of the material was seen. At 3 hours' follow-up the patient became haemodynamically unstable. Open surgery was performed and a large perirenal haematoma was revealed; the lower kidney pole was cyanotic. A cut aberrant artery was ligated. Postoperatively the patient developed hypertension (215/130) mmHg, which was treated successfully with medical intervention.<br><br>**Patient 2**<br>Postoperatively the patient had low grade fever and moderate flank pain which was interpreted as a urinary tract infection. Haemoglobin decreased from 10.6 g/l on day 1 to 8.3 g/l at 11 days' follow-up when the patient was discharged.<br><br>The patient was readmitted at 15 days' follow-up with haemoglobin level of 4.4 g/l. Renal angiography revealed an aberrant lower pole artery with a pseudoaneurysm which was embolised. Persistent pain continued and because of reduced function (< 15%) a laparoscopic nephrectomy was performed at 6 months' follow-up. | | Number of patients treated at the centre is not reported.<br><br>Direct cause of adverse events is not hypothesised (stated) in publications, but would seem to relate to inadvertent damage to renal artery branches |

| Abbreviations used: N/R, not reported; PUJ/UPJ, pelviureteric junction | | | |
|---|---|---|---|
| **Study details** | **Key efficacy findings** | **Key safety findings** | **Comments** |
| Johnson JE (2001)[7]<br><br>**Case report**<br><br>Country: USA<br><br>Study period: post 1993<br><br>Study population: patient with long-standing right flank pain and right PUJ obstruction confirmed by intravenous urogram. Age: 29 years. Sex: 100% male.<br><br>**n = 1**<br><br>Inclusion criteria: not reported<br><br>Technique: retrograde endopyelotomy cutting balloon with the Acucise device not otherwise described<br><br>**Follow-up: 9 months**<br><br>Conflict of interest: not reported | Following cutting balloon procedure the patient suffered intermittent gross haematuria and continued mild pain, and was referred to urology division at 5 months' follow-up. A repeat intravenous urogram revealed a small calcification at the location of the prior PUJ incision, and mild proximal collecting system dilation.<br><br>Ureteroscopy discovered a 6–7 mm stone embedded in the posterolateral urothelium of the right PUJ which was fragmented with a holmium laser. A small diameter wire was seen protruding from the middle of the stone presumed to be a retained cutting balloon wire. The wire and stone fragments were removed uretoscopically and the PUJ was balloon dilated and a stent left in place for 4 weeks.<br><br>The patient continued to have right flank pain following stent removal; further intravenous urogram identified a 3 mm residual calculus at the PUJ with mild obstruction, and confirmed on ureteroscopy. The overlying epithelium was incised with holmium laser and another stent placed for 6 weeks. At 9 months' follow-up renal scintigraphy demonstrated symmetric renal function bilaterally without evidence of obstruction. | | The number of patients treated at the centre from which the patient was referred is not reported.<br><br>Few details are provided of the original procedure.<br><br>Little efficacy data are provided.<br><br>Authors state that use of endoluminal ultrasound during ureteroscopic endopyeloplasty reduces the risk of haemorrhage and virtually eliminates the risk of retention of foreign bodies. |

| Abbreviations used: N/R, not reported; PUJ/UPJ, pelviureteric junction | | | |
|---|---|---|---|
| **Study details** | **Key efficacy findings** | **Key safety findings** | **Comments** |
| McGuire EJ (1997)[8]<br><br>**Case report**<br><br>Country: USA<br><br>Study period: not reported<br><br>Study population: patient with severe right flank pain > 1 year. Investigation showed hydronephrotic collecting system and normal calibre ureter consistent with PUJ obstruction confirmed. Age: 69 years. Sex: 100% male.<br><br>**n = 1**<br><br>Inclusion criteria: not reported<br><br>Technique: retrograde endopyelotomy cutting balloon with the Acucise device not otherwise described<br><br>**Follow-up: 4 days**<br><br>Conflict of interest: not reported | At the time of inflation of the cutting balloon it developed a waist as expected across what was considered to be the PUJ obstruction. However as the balloon was inflated further a twisted appearance developed which resulted in a tear in the ureter beneath the ureteropelvic junction obstruction. A stent could not be passed through the PUJ obstruction and a nephrostomy tube was placed. An antegrade ureteral catheter was passed at 4 days' follow-up.<br><br>Once the cutting balloon had been removed it was again inflated and the waist was found to be caused by a defect in the balloon part of the device. | | The number of patients treated at the centre from which the patient was referred is not reported.<br><br>Little clinical data are presented. |

### *Validity and generalisability of the studies*

- Controlled studies only reported on other minimally invasive surgical procedures as comparators rather than open pyeloplasty.
- Patient selection process is not generally well described in the studies available.
- Efficacy outcomes reported tend to focus on urological function rather than improvement in symptoms.
- Composite efficacy outcomes combine a subjective and objective improvement but it is not clear how these elements are derived or applied.
- Some studies report outcomes from patients with primary and secondary PUJ obstruction separately, while some have described results for the overall group.
- Validation of subjective outcomes scoring systems is not described.

## Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr R C Calvert (British Association of Urological Surgeons), Mr S Irving (British Association of Urological Surgeons)

- One Specialist Adviser classified the procedure as established practice and no longer new, and one was unable to classify the status of the procedure within the categories provided.
- The main comparator would now be laparoscopic pyeloplasty.
- The key efficacy outcomes for this procedure include short-term relief of pain and symptoms, normalisation of renographic obstruction, transfusion rate, infection rate, and long-term success in terms of restenosis.

- Reported adverse events relating to the procedure include restenosis and vessel injury calculus formation on a retained/broken wire.
- Additional theoretical adverse events may include bleeding, adjacent organ injury perioperatively and late complications such as restenosis (scarring).
- The restenosis rate appears to be high if used for primary PUJ obstruction in standard patients.
- The procedure requires experienced radiology support for preoperative imaging and selection. It is easy to learn and not challenging technically, and could be learned in a wet lab setting.

## Patient Commentators' opinions

NICE's Patient and Public Involvement Programme were unable to obtain patient commentary for this procedure.

## Issues for consideration by IPAC

- Only English language studies are included in this overview.
- Some studies that included a mixed cohort with patients with PUJ obstruction and some with ureteral structure have not been prioritised in table 2.
- Smaller studies including paediatric patients are available in appendix A.
- Length of follow-up is of particular concern in this procedure where late failure may occur.

# References

1 el-Nahas AR, Shoma AM, Eraky I et al. (2006) Prospective, randomized comparison of ureteroscopic endopyelotomy using holmium:YAG laser and balloon catheter. Journal of Urology 175: 614-18

2 Ponsky LE, Streem SB (2006) Retrograde endopyelotomy: a comparative study of hot-wire balloon and ureteroscopic laser. Journal of Endourology 20: 823-6

3 Shalhav AL, Giusti G, Elbahnasy AM et al. (1998) Adult endopyelotomy: impact of etiology and antegrade versus retrograde approach on outcome. Journal of Urology 160: 685-9

4 Vaarala MH, Marttila T, Paananen I et al. (2008) Retrospective analysis of long-term outcomes of 64 patients treated by endopyelotomy in two low-volume hospitals: good and durable results. Journal of Endourology 22: 1659-64

5 Kim FJ, Herrell SD, Jahoda AE et al. (1998) Complications of acucise endopyelotomy. Journal of Endourology 12: 433-6

6 Angelsen A, Talseth T, Mjones JG et al. (2000) Hypertension and pseudoaneurism on the renal artery following retrograde endopyelotomy (Acucise). Scandinavian Journal of Urology & Nephrology 34: 79-80

7 Johnson JE and Conlin M (2001) Calculus formation on a retained Acucise wire. Urology 57: 168i-ii

8 McGuire EJ, English SF (1997) Failure of an acucise balloon device to inflate resulting in treatment failure. Journal of Urology 158: 1902

# Appendix A: Additional papers on electrocautery cutting balloon treatment for pelviureteric junction obstruction

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Baldwin DD, Dunbar JA, Wells N (2003) Single–center comparison of laparoscopic pyeloplasty, Acucise endopyelotomy, and open pyeloplasty. Journal of Endourology 17(3): 155–60 | Non-randomised controlled trial<br><br>n = 32 (9 cutting balloon)<br><br>Follow-up = 10 months | Laparoscopic pyeloplasty achieves a success rate equal to that of open pyeloplasty while providing a recovery similar to that obtained with cutting balloon treatment and is gaining popularity as the treatment of choice for UPJ obstruction | Larger studies included in table 2 |
| Bolton DM., Bogaert GA, Mevorach RA (1993) Pediatric ureteropelvic junction obstruction treated with retrograde endopyelotomy. Urology 44(4): 609–13 | Case series<br><br>n = 2<br><br>Follow-up = 6–11 months | Ureteropelvic junction obstruction in children may be treated by retrograde endopyelotomy with the balloon cutting device. The principal potential advantage of this procedure is reduced morbidity. | Larger studies included in table 2 |
| Biyani CS, Minhas S, Cast JE (2002) The role of Acucise endopyelotomy in the treatment of ureteropelvic junction obstruction. European Urology 41(3): 305–11 | Case series<br><br>n = 42<br><br>Follow-up = 27 months | Cutting balloon endopyelotomy is a safe and minimally invasive procedure for the management of UPJ obstruction | Larger studies included in table 2 |
| Chandhoke PS, Clayman RV, Stone AM (1993) Endopyelotomy and endoureterotomy with the acucise ureteral cutting balloon device: preliminary experience. Journal of Endourology 7(1): 45–51 | Case series<br><br>n = 28<br><br>Follow-up = 4 months | The ureteral cutting balloon device provides an effective and efficient means for performing a retrograde endoureterotomy or endopyelotomy | Larger studies included in table 2<br><br>Mixture of indications: both UPJ obstruction and ureteral structures |
| Cohen TD, Gross MB, Preminger GM (1996) Long–term follow–up of Acucise incision of ureteropelvic junction obstruction and ureteral strictures. Urology 47(3): 317–23 | Case series<br><br>n = 15<br><br>Follow-up = 15 months | The cutting balloon offers the urologist a rapid and effective alternative for the management of ureteral strictures and UPJ obstruction | Larger studies included in table 2<br><br>Mixture of indications: both UPJ obstruction and ureteral structures |

| | | | |
|---|---|---|---|
| Faerber GJ, Richardson TD, Farah N (1997) Retrograde treatment of ureteropelvic junction obstruction using the ureteral cutting balloon catheter. Journal of Urology 157(2): 454–8 | Case series<br><br>n = 32<br><br>Follow-up = 14 months | Retrograde balloon incision endopyelotomy appears to be a safe and effective treatment for ureteropelvic junction obstruction | Larger studies included in table 2 |
| Gelet A, Combe M, Ramackers, JM (1997) Endopyelotomy with the Acucise cutting balloon device. Early clinical experience. European Urology 31(4): 389–93 | Case series<br><br>n = 44<br><br>Follow-up = 12months | We do not approve the use of the cutting balloon device for treatment of primary UPJ strictures | Studies with longer follow-up included in table 2 |
| Gill HS, Liao JC (1998) Pelvi–ureteric junction obstruction treated with Acucise retrograde endopyelotomy. British Journal of Urology 82(1): 8–11 | Case series<br><br>n = 13<br><br>Follow-up = 18 months | Endopyelotomy was a safe procedure that offered effective, expeditious first-line treatment for PUJ obstruction | Larger studies included in table 2 |
| Lechevallier E, Eghazarian C, Ortega J–C (1995) Retrograde Acucise endopyelotomy: long–term results. Journal of Endourology 13(8): 575–80 | Case series<br><br>n = 23<br><br>Follow-up = 24 months | Retrograde cutting balloon endopyelotomy is an efficient long-term treatment of UPJO with low morbidity | Larger studies included in table 2 |
| Nadler RB, Rao GS, Pearle MS (1996) Acucise endopyelotomy: assessment of long–term durability. Journal of Urology 156(3): 1094–8 | Case series<br><br>n = 28<br><br>Follow-up = 33 months | Cutting balloon endopyelotomy is an effective and durable method for treating ureteropelvic junction obstruction | Larger studies included in table 2 |
| Nakada SY, Wolf JS Jr, Brink JA (1998) Retrospective analysis of the effect of crossing vessels on successful retrograde endopyelotomy outcomes using spiral computerized tomography angiography. Journal of Urology 159(1): 62–5 | Case series<br><br>n = 16<br><br>Follow-up = 2 years | In our series nearly 40% of patients with anterior or posterior crossing vessels had a long-term (greater than 2 years) successful outcome with retrograde endopyelotomy | Larger studies included in table 2 |

| | | | |
|---|---|---|---|
| Preminger GM, Clayman RV, Nakada SY (1997) A multicenter clinical trial investigating the use of a fluoroscopically controlled cutting balloon catheter for the management of ureteral and ureteropelvic junction obstruction. Journal of Urology 157(5): 1625-9 | Case series<br><br>n = 115 (66 UPJ obstruction)<br><br>Follow-up = 8 months | A cutting balloon endoscopic incision is effective in the majority of cases, with patency rates for endopyelotomies and endoureterotomies that mirror current endourological reports using other, albeit more time intensive and more invasive, incisional techniques | Studies with longer follow up are included in table 2<br><br>Mixture of indications both UPJ obstruction and ureteral structures |
| Sofras F, Livadas K, Alivizatos G (2004) Retrograde acucise endopyelotomy: is it worth its cost? Journal of Endourology 18(5): 466-8 | Non-randomised controlled trial<br><br>n = 40 (22 cutting balloon)<br><br>Follow-up = 3 months | Cutting balloon endopyelotomy will improve or cure only patients with good renal function and mild dilation of the pelvicaliceal system | Larger studies included in table 2 |
| Umekawa T, Ishikawa Y, Kajikawa H et al. (1996) A pediatric case of ureteropelvic junction obstruction treated with retrograde endopyelotomy. Hinyokika Kiyo - Acta Urologica Japonica 42 (11): 895-8 | Case report<br><br>n = 1<br><br>Follow-up = 8 months | UPJ obstruction in children may be treated by retrograde endopyelotomy with the cutting balloon catheter as well as adults | Larger studies included in table 2 |
| Wagner JR, D'Agostino R, Babayan RK (1996) Renal arterioureteral hemorrhage: a complication of acucise endopyelotomy. Urology 48(1): 139-41 | Case report<br><br>n = 1<br><br>Follow-up = 1 month | We report a case of a postoperative lower pole renal arterioureteral hemorrhage after retrograde endopyelotomy requiring interventional radiographic treatment | Larger studies included in table 2<br><br>Safety outcomes reported in table 2 |
| Weikert S, Christoph F, Muller M (2005) Acucise endopyelotomy: a technique with limited efficacy for primary ureteropelvic junction obstruction in adults. International Journal of Urology 12(10): 864-8 | Case series<br><br>n = 24<br><br>Follow-up = 32 months | Our experience with cutting balloon endopyelotomy indicates that the success rate is lower than initially reported. Larger studies are needed to clarify the role of this procedure in comparison with other techniques | Larger studies included in table 2 |
| Willard TB, Williams C, Krishnan R et al. (1998) Acucise endopyelotomy: a successful therapeutic intervention in the treatment of ureteropelvic junction obstruction. Techniques in Urology 4(3): 118-23 | Case series<br><br>n = 12<br><br>Follow-up = 8 months | Cutting balloon endopyelotomy is a successful therapeutic intervention in treating ureteropelvic junction obstruction | Larger studies included in table 2 |

# Appendix B: Related NICE guidance for electrocautery cutting balloon treatment for pelviureteric junction obstruction

| Guidance | Recommendations |
|---|---|
| Interventional procedures | **Laparoscopic pyeloplasty. NICE interventional procedure guidance 046 (2004)**<br><br>1.1 Current evidence on the safety and efficacy of laparoscopic pyeloplasty appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.<br><br>1.2 Clinicians undertaking this procedure should have adequate training before performing the technique. The British Association of Urological Surgeons has agreed to produce standards for training. |

# Appendix C: Literature search for electrocautery cutting balloon treatment for pelviureteric junction obstruction

| Database | Date searched | Version/files |
|---|---|---|
| Cochrane Database of Systematic Reviews – CDSR (Cochrane Library) | 12/05/09 | Issue 2, 2009 |
| Database of Abstracts of Reviews of Effects – DARE (CRD website) | 12/05/09 | N/A |
| HTA database (CRD website) | 12/05/09 | N/A |
| Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library) | 12/05/09 | Issue 2, 2009 |
| MEDLINE (Ovid) | 12/05/09 | 1950 to May Week 1 2009 |
| MEDLINE In-Process (Ovid) | 12/05/09 | May 11, 2009 |
| EMBASE (Ovid) | 12/05/09 | 1980 to 2009 Week 19 |
| CINAHL (NLH Search 2.0) | 12/05/09 | 1981 to present |
| BLIC (Dialog DataStar) | 12/05/09 | 1995 to date |

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

| | |
|---|---|
| 1 | Electrocoagulation/ |
| 2 | Electro*.tw. |
| 3 | Thermo*.tw. |
| 4 | Galvano*.tw. |
| 5 | (Endo* adj3 Fulgurat*).tw. |
| 6 | Catheter Ablation/ |
| 7 | (Cathet* adj3 Ablat*).tw. |
| 8 | Electrosurgery/ |
| 9 | (Electrosurg* or Electricsurg* or Electr*-surg*).tw. |
| 10 | (Electr* adj3 (surg* or ablat*)).tw. |
| 11 | (Surg* adj3 Diatherm*).tw. |
| 12 | Retrograd*.tw. |
| 13 | Monopolar*.tw. |
| 14 | Fluoroscopy/ |

| | |
|---|---|
| 15 | Fluoroscop*.tw. |
| 16 | or/1-15 |
| 17 | exp Balloon Dilatation/ |
| 18 | (Balloon* adj3 (Dilat* or Cathet* or Tampon* or Valvulo* or Valvotom*)).tw. |
| 19 | or/17-18 |
| 20 | 16 and 19 |
| 21 | Acucise*.tw. |
| 22 | or/20-21 |
| 23 | Ureteral Obstruction/ |
| 24 | (Ureter* adj3 (Obstruct* or Stenos* or Occlus* or Constrict*)).tw. |
| 25 | ((Pelviureter* or Pelvi-ureter* or Pelvi* Ureter*) adj3 Junct* adj3 (Obstruct* or Stenos*)).tw. |
| 26 | ((Ureteropelvic* or Uretero-pelvic* or Uretero* pelvic*) adj3 Junct* adj3 (Obstruct* or Stenos*)).tw. |
| 27 | (PUJ or UPJ).tw. |
| 28 | exp Hydronephrosis/ |
| 29 | (Hydronephros* or Hydro-nephros* or Hydro nephros*).tw. |
| 30 | Pyonephrosis/ |
| 31 | (Pyonephros* or Pyo-nephros* or Pyo nephros*).tw. |
| 32 | (Pyelonephros* or Pyelo-nephros* or Pyelo nephros*).tw. |
| 33 | Nephrohydros*.tw. |
| 34 | (Kidn* adj3 Dilate*).tw. |
| 35 | Aperistal*.tw. |
| 36 | or/23-35 |
| 37 | 22 and 36 |
| 38 | Animals/ not Humans/ |
| 39 | 37 not 38 |