

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 through 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 trial¹, three non-randomised controlled trials²⁻⁴, one case series⁵ and three case reports⁶⁻⁸.

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-up¹. 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-up². 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 required⁵.

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 embolised⁶.

There was one case report of a broken cutting balloon wire causing calcification that required ureteroscopically guided laser ablation⁷.

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 patients¹. 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 malfunction⁸.

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. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. 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					
Study details	Key efficacy findings			Key safety findings	Comments
el-Nahas AR (2006) ¹	Overall success 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).			Complications There was one intraoperative complication in each group.	Concealment of treatment allocation by sealed envelopes; method of randomisation is not reported.
Randomised controlled trial	Outcome	Balloon	Laser	p	
Country: Egypt	Success	65.0% (13/20)	85.0% (17/20)	0.14	
Study period: Jan 2001 to Oct 2003	Success primary UPJ	66.7% (4/6)	87.5% (7/8)	0.38	Blinding of outcome assessment is not reported.
Study population: patients with PUJ confirmed by radiological assessment. Age: 39 years (mean). Sex: 55% male. Primary UPJ n = 14; secondary UPJ n = 26.	Success secondary UPJ	64.3% (9/14)	83.3% (10/12)	0.26	
n = 40 (20 cutting balloon)	Operative characteristics			Failure of extravasation of contrast medium occurred in 15% (3/20) of patients in the cutting balloon group.	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).
Inclusion criteria: patients without 'hugely dilated' renal pelvis, or renal stones or crossing vessel at the UPJ.	Outcome	Balloon	Laser	p	
	Operative time (min)	58.7 ± 20.1	64.7 ± 22.4	0.44	
	Length of hospital stay (days)	1.6 ± 1.26	1.1± 0.25	0.13	
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.					
Follow-up: 30 months (mean)					
Conflict of interest: not reported.					

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

Abbreviations used: N/R, not reported; PUJ/UPJ, pelviureteric junction									
Study details		Key efficacy findings			Key safety findings		Comments		
Shalav AL (1998) ³		Overall success Subjective success defined as 50% improvement over baseline in questionnaire score (including VAS scale).			Complications		Retrospective study.		
Non-randomised controlled trial						Balloon n = 52	Antegrade n = 63	Outcome reporting is complicated as many subgroups are analysed separately.	
Country: USA		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.			Major (total)	4% (2/52)	5% (3/63)		
Study period: Oct 1989 to May 1996					Intraoperative haemorrhage	2% (1/52)	3% (2/63)		
Study population: age: 44 years (mean). Sex: 44% male. Primary UPJ n = 109; secondary UPJ n = 40.		Primary UPJ	Balloon n = 52	Antegrade n = 40	p	Transfusion	2% (1/52)	2% (1/63)	Outcome evaluation undertaken using different techniques across patients.
		Subjective success	85%	90%	N/R	Embolisation	4% (2/52)	2% (1/63)	
		Objective success	71%	89%	N/R	Respiratory distress	0%	2% (1/63)	
n = 149 (66 cutting balloon)		Secondary UPJ	Balloon n = 14	Antegrade n = 23	p	Minor			Only point estimates are reported for efficacy outcomes.
Inclusion criteria: not reported		Subjective success	86%	87%	N/R	Self-limiting bleeding	4% (2/52)	2% (1/63)	
		Objective success	83%	77%	N/R	Urine extravasation	0%	2% (1/63)	
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.		Operative characteristics				Stent malfunction	4% (2/52)	2% (1/63)	Efficacy outcomes are reported separately for primary and secondary UPJ.
		Primary UPJ	Balloon n = 52	Antegrade n = 40	p	Obstruction after stent removal	4% (2/52)	0%	
		Operative time (min)	70	113	<0.05	Occlusion of percutaneous nephrostomy	0%	2% (1/63)	
Follow-up: 16 months (mean)		Length of stay (days)	2.3	3.6	<0.05	Ileus	0%	10% (6/63)	Antegrade procedure not well described.
						Fever	0%	2% (1/63)	
						Urinary retention	0%	2% (1/63)	
Conflict of interest: supported by manufacturer		Secondary UPJ	Balloon n = 14	Antegrade n = 23	p	Urinary tract retention	0%	2% (1/63)	All patients with secondary UPJ obstruction were treated with antegrade endopyelotomy.
		Operative time (min)	92	129	<0.05	No statistically significant difference between groups.			
		Length of stay (days)	2.0	4.4	<0.05	Outcomes were also reported separately for primary and secondary UPJ obstruction.			
						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		Subjective outcomes				Complications				Retrospective study		
Non-randomised controlled trial		Pain	Balloon	Antegrade	Retrograde	Outcome	Balloon	Antegrade	Retro-grade	Consecutive patients treated		
		Painless	71% (12/17)	83% (15/18)	62% (18/29)	Reoperation (%)	6% (1/17)	0%	17% (5/29)			
Country: Finland		Decreased pain	18% (3/17)	17% (3/18)	21% (6/29)	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.					Two participating centres	
		No change	12% (2/17)	0%	17% (5/29)							
Study period: Oct 1987 to Jun 2007		p = 0.44 across groups										
		Objective outcomes				Cutting balloon 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).					Selection for treating with endopyelotomy was made on clinical decision. Method of selection for which technique is not reported.	
Study population: patients with PUJ confirmed by radiological assessment. Age: 47 years (mean). Sex: 33 % male. Left side UPJ obstruction n = 31.		Radiographic	Balloon	Antegrade	Retrograde							
		Better (%)	76% (13/17)	94% (17/18)	62% (18/29)							
		No change (%)	24% (4/17)	6% (1/18)	24% (7/29)	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.						
		Worse (%)	0%	0%	14% (4/29)							
n = 64 (17 cutting balloon)		p = 0.085 across groups										
		Outcome	Balloon	Antegrade	Retrograde	p	Antegrade group 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).					Patients analysed in groups according to which technique was used to complete the procedure and not as intention to treat.
Inclusion criteria: patients with PUJ obstruction not otherwise defined		Satisfaction (%)	73%	100%	86%	0.09						
		Willing to undergo again (%)	67%	100%	75%	0.047						
		Operative characteristics				Retrograde group Urinary tract infection 3% (1/29); septicaemia after stent removal 3% (1/29); severe pain (stent replacement) 6% (2/29).						
		Group mean (standard deviation)										
		Outcome	Balloon	Ante-grade	Retro-grade						p	
		Operative time (min)	71.4 (33.7)	131.4 (38.3)	76.5 (33.6)	<0.001	Significant difference between the group in terms of proportion of patients who underwent concomitant treatment for renal pelvic stone during the same procedure.					
		Length of stay (days)	6.9 (3.9)	11.6 (6.9)	4.9 (1.6)	<0.001						
Follow-up: 67 months (mean) for cutting balloon patients		p value from one-way analysis of variance test										
Conflict of interest: not reported											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 Case series Country: USA Study period: Jan 1991 to Dec 1995 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. n = 76 Inclusion criteria: patients with PUJ obstruction < 2.5 cm on retrograde pyelogram. 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. Follow-up: not reported – to discharge Conflict of interest: not reported	<i>Operative characteristics</i> Mean operative time was 56 min;, and length of stay 1.8 days. Contrast material extravasation was seen on retrograde pyelogram in 100% (76/76) of patients following the procedure. Overall success (not defined) was achieved in 78% (59/76) of patients.	<i>Complications</i> All complications were categorised as major, minor or procedure failure. Definitions of grouping not reported. Major 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. Minor Stent migration 1% (1/76) Urinary tract infection 1% (1/76) Clot retention 1% (1/76) Failure 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 All patients received preoperative ureteral stenting for 1 week before the procedure. 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 Case report Country: Norway Study period: not reported Study population: patients with primary PUJ obstruction not otherwise defined. Age: 33 years (mean). Sex: 100% female. n = 2 Inclusion criteria: not reported Technique: retrograde endopyelotomy cutting balloon with the Acucise device Follow-up: up to 6 months Conflict of interest: not reported	Patient 1 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. Patient 2 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. 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. 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 Case report Country: USA Study period: post 1993 Study population: patient with long-standing right flank pain and right PUJ obstruction confirmed by intravenous urogram. Age: 29 years. Sex: 100% male. n = 1 Inclusion criteria: not reported Technique: retrograde endopyelotomy cutting balloon with the Acucise device not otherwise described Follow-up: 9 months 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. 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 ureoscopically and the PUJ was balloon dilated and a stent left in place for 4 weeks. 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. Few details are provided of the original procedure. Little efficacy data are provided. 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 Case report Country: USA Study period: not reported 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. n = 1 Inclusion criteria: not reported Technique: retrograde endopyelotomy cutting balloon with the Acucise device not otherwise described Follow-up: 4 days 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. 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. 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. <i>Journal of Endourology</i> 17(3): 155–60	Non-randomised controlled trial n = 32 (9 cutting balloon) 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. <i>Urology</i> 44(4): 609–13	Case series n = 2 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. <i>European Urology</i> 41(3): 305–11	Case series n = 42 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. <i>Journal of Endourology</i> 7(1): 45–51	Case series n = 28 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 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. <i>Urology</i> 47(3): 317–23	Case series n = 15 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 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. <i>Journal of Urology</i> 157(2): 454–8	Case series n = 32 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. <i>European Urology</i> 31(4): 389–93	Case series n = 44 Follow-up = 12 months	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. <i>British Journal of Urology</i> 82(1): 8–11	Case series n = 13 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. <i>Journal of Endourology</i> 13(8): 575–80	Case series n = 23 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. <i>Journal of Urology</i> 156(3): 1094–8	Case series n = 28 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. <i>Journal of Urology</i> 159(1): 62–5	Case series n = 16 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. <i>Journal of Urology</i> 157(5): 1625-9	Case series n = 115 (66 UPJ obstruction) 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 Mixture of indications both UPJ obstruction and ureteral structures
Sofras F, Livadas K, Alivizatos G (2004) Retrograde acucise endopyelotomy: is it worth its cost? <i>Journal of Endourology</i> 18(5): 466-8	Non-randomised controlled trial n = 40 (22 cutting balloon) 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. <i>Hinyokika Kiyo - Acta Urologica Japonica</i> 42 (11): 895-8	Case report n = 1 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. <i>Urology</i> 48(1): 139-41	Case report n = 1 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 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. <i>International Journal of Urology</i> 12(10): 864-8	Case series n = 24 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. <i>Techniques in Urology</i> 4(3): 118-23	Case series n = 12 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) 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. 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