

# ENDOPYELOPLASTY VERSUS ENDOPYELOTOMY VERSUS LAPAROSCOPIC PYELOPLASTY FOR PRIMARY URETEROPELVIC JUNCTION OBSTRUCTION

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## ABSTRACT

**Objectives.** To present our intermediate-term (1-year) data on endopyeloplasty and retrospectively compare it with endopyelotomy and laparoscopic pyeloplasty in 44 patients with primary ureteropelvic junction (UPJ) obstruction. Endopyeloplasty, horizontal percutaneous suturing of a conventional longitudinal endopyelotomy incision, is a promising novel option for minimally invasive management of UPJ obstruction. We recently developed the technique and demonstrated the clinical feasibility of percutaneous endopyeloplasty.

**Methods.** At our two institutions, 44 consecutive, nonrandomized patients with primary UPJ obstruction underwent percutaneous endopyeloplasty ( $n = 15$ ; group 1), percutaneous endopyelotomy ( $n = 15$ ; group 2), or laparoscopic dismembered pyeloplasty ( $n = 14$ ; group 3). The study inclusion criteria were short segment (less than 1 cm) stenosis, no prior surgery for UPJ obstruction, and no crossing vessels in groups 1 and 2. The mean patient age was 30.3, 38.6, and 38.9 years and the duration of symptoms was 5.5, 6, and 6.6 months in groups 1, 2, and 3, respectively. Postoperative success was evaluated by symptoms, intravenous urography, and/or diuretic renography.

**Results.** The mean operative time was 119 minutes in group 1, 52 minutes in group 2, and 243 minutes in group 3 ( $P < 0.001$ ). Complications occurred in 3 patients in group 1 (fever in 2 and fluid extravasation in 1), 2 patients in group 2 (bleeding in 1 and urinoma in 1), and no patients in group 3. The duration of double-J stent placement was 2, 4, and 6 weeks in groups 1, 2, and 3, respectively. A resolution of symptoms and unobstructed drainage on intravenous urography and/or diuretic renography was noted in 100% and 100% of patients in group 1 (mean follow-up 11.6 months), 93% and 88% of patients in group 2 (mean follow-up 31.4 months), and 93% and 100% of patients in group 3 (mean follow-up 20 months).

**Conclusions.** The results of this retrospective comparison of patients with primary UPJ obstruction suggest that percutaneous endopyeloplasty may have functional superiority over percutaneous endopyelotomy. The technical simplicity and shorter operative time of endopyeloplasty are advantages compared with laparoscopic pyeloplasty. Endopyeloplasty may be associated with a shorter duration of stenting compared with the other techniques. Longer term follow-up in a larger group of patients from multiple centers and a prospective randomized comparison among these various minimally invasive approaches are necessary to validate these preliminary results. UROLOGY 64: 16–21, 2004. © 2004 Elsevier Inc.

Currently, endopyelotomy remains the initial treatment of choice for most adults with primary ureteropelvic junction (UPJ) obstruction. Overall, endopyelotomy is associated with a 10%

to 15% failure rate.<sup>1</sup> This failure rate increases further in patients with severe hydronephrosis, poor renal function, or a crossing vessel.<sup>2,3</sup> Laparoscopic pyeloplasty has also been reported, with a success rate of 95% to 100%.<sup>4</sup> However, laparoscopic pyeloplasty is limited by the steep learning curve and technical challenges posed by intracorporeal laparoscopic suturing.

We recently developed a novel technique of percutaneous endopyeloplasty with the aim of improving the success rate of endopyelotomy. Endopyeloplasty consists of percutaneous horizontal suturing of a standard longitudinal endopyelotomy

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**TABLE I. Demographic data**

Characteristic	Endopyeloplasty (Group 1)	Endopyelotomy (Group 2)	P Value	Laparoscopic Pyeloplasty (Group 3)	P Value
Patients (n)	15	15	NS	14	NS
Mean age (yr)	30.3 ± 7.7 (18–42)	38.6 ± 16.3 (21–70)	0.04	38.9 ± 17 (12–73)	0.14
Male (n)	11	7	0.12	7	0.12
Side (n)					
Right	6	10	0.13	6	0.88
Left	9	5		8	
ASA class (n)					
I	15	13	0.13	3	<0.001
II	0	2	0.13	10	<0.001
III–IV	0	0	NS	1	0.30
Presenting symptoms (n)					
Pain	13	14	0.54	13	0.68
Urinary infection	1	2	0.13	0	NS
Incidental	2	1	0.54	1	0.72
Prior treatment (n)	0	0	NS	0	NS
Mean preoperative serum creatinine (mg/dL)	0.9 ± 0.1 (0.7–1.2)	0.9 ± 0.2 (0.7–1.3)	0.42	0.9 ± 0.5 (0.7–3.1)	0.12

Key: NS = not significant; ASA = American Society of Anesthesiologists. Data in parentheses are ranges.

incision in a Heineke-Mikulicz fashion using a nephroscope. After developing the technique and documenting its efficacy in the porcine model,<sup>5</sup> we reported our initial clinical experience.<sup>6</sup> In this report, in a two-center experience, we present a retrospective, nonrandomized comparison of the intermediate-term results of endopyeloplasty compared with percutaneous endopyelotomy and laparoscopic pyeloplasty in patients with primary UPJ obstruction.

## MATERIAL AND METHODS

From July 2001 through April 2002, percutaneous endopyeloplasty was performed in 15 patients (group 1) with primary UPJ obstruction. The data were compared with the data from 15 consecutive patients who underwent conventional percutaneous endopyelotomy from April 1998 through November 2001 (group 2) and the data from 14 patients who underwent dismembered retroperitoneal laparoscopic pyeloplasty from September 1998 through July 2002 (group 3). Endopyeloplasty (group 1) and endopyelotomy (group 2) were performed at the Muljibhai Patel Urological Hospital, and laparoscopic pyeloplasty (group 3) was performed during the same period at the Cleveland Clinic Foundation. Endopyeloplasty was performed after obtaining approval from the institutional review board of the institution and informed consent from the patient. The study inclusion criteria were short segment (less than 1 cm) UPJ stenosis, no prior surgery for UPJ obstruction, and no crossing vessels in group 1. The diagnosis of UPJ obstruction was typically based on intravenous urography (IVU), with diuretic renal scanning and/or three-dimensional computed tomography performed on an individual basis according to the surgeon's discretion. The mean patient age was 30.3 ± 7.7 years (range, 18 to 42), 38.6 ± 16.3 years (range, 21 to 70), and 38.9 ± 17 years (range, 12 to 73) and the duration of flank symptoms was 5.5 months (range, 2 to 12), 6 months (range, 3 to 14), and 6.6 months (range, 2 to 14) in

groups 1, 2, and 3, respectively (Table I). The degree of hydronephrosis was mild in 3, 5, and 1 patient, moderate in 9, 9, and 2 patients, and severe in 3, 1, and 11 patients in groups 1, 2, and 3, respectively. In group 3, 6 patients had an intraoperatively confirmed crossing vessel (Table II).

Our technique of percutaneous endopyeloplasty has been previously described in detail.<sup>5,6</sup> In brief, it entails retrograde ureteral catheterization, percutaneous renal access through an upper or middle calix, a conventional, laterally located, longitudinal endopyelotomy incision using a cone-tip Bugbee electrode and cutting current, mobilization of the distal ureter, percutaneous horizontal suturing of the vertical endopyelotomy incision, and antegrade placement of a 6F double-J ureteral stent and nephrostomy tube. Suturing was performed using a modified 5-mm laparoscopic suturing device (SewRight SR5, LSI Solutions, Victor, NY) inserted through the nephroscope working channel. The nephrostomy tube was removed after obtaining a nephrostogram at 48 hours.

Percutaneous endopyelotomy was performed using a Bugbee electrode and cutting current in a standard fashion, and a 14/7F endopyelotomy stent (Microvasive, Natick, Mass) was inserted antegradely. The nephrostomy tube was removed 48 hours postoperatively after obtaining a nephrostogram. Postoperatively, the endopyelotomy stent was left indwelling for 6 weeks.

Laparoscopic dismembered Anderson-Hynes pyeloplasty was performed using a three-port retroperitoneal approach. A 4.7F, 26-cm, double-J ureteral stent was cystoscopically placed at the outset in all patients. The ureter and pelvis were adequately spatulated, and a running ureteropelvic anastomosis was performed with two 4-0 Vicryl sutures on an RB-1 needle using freehand intracorporeal laparoscopic suturing and knot tying techniques. The ureteral stent was removed after 4 weeks in all 14 patients.

Postoperative assessment of success was determined from symptom evaluation (person and telephone interviews), IVU, and diuretic renal scanning. Statistical analysis between the parameters among the three groups was performed using the Student *t* test for continuous variables and Fisher's exact test for categorical variables. All results are reported as the mean ±

**TABLE II. UPJ characteristics**

Characteristic	Endopyeloplasty (Group 1; n = 15)	Endopyelotomy (Group 2; n = 15)	P Value	Laparoscopic Pyeloplasty (Group 3; n = 14)	P Value
Type of UPJ obstruction					
Primary	15	15	NS	14	NS
Secondary	0	0	NS	0	NS
Ureteral insertion					
Nondependent	11	13	0.36	NA	NS
Dependent	4	2	0.36	NA	NS
Renal pelvis					
Intrarenal	5	3	0.4	1	0.61
Extrarenal	10	12	0.4	13	0.61
Degree of hydronephrosis*					
Mild	2	5	0.4	1	0.03
Moderate	9	8	NS	2	0.004
Severe	4	1	0.27	11	<0.001
Crossing vessel					
Present	1 <sup>†</sup>	0	NS	6	<0.01
Absent	14	15	NS	8	<0.01

KEY: UPJ = ureteropyelvic junction; NS = not significant.

\* Grading of hydronephrosis based on radiologic appearance of calices on preoperative imaging: absent: normal calices; mild: blunting of caliceal fornices; moderate: flattening, convexity of the caliceal cup; severe: grossly blown out and dilated calix.

<sup>†</sup> In 1 patient undergoing endopyeloplasty, a crossing vessel missed on preoperative imaging was visualized intraoperatively.

**TABLE III. Intraoperative and postoperative data**

	Endopyeloplasty (Group 1; n = 15)	Endopyelotomy (Group 2; n = 15)	P Value	Laparoscopic Pyeloplasty (Group 3; n = 14)	P Value
Total operative time (min)	119.3 ± 28.8 (62–180)	52 ± 9.4 (40–70)	<0.001	242.9 ± 76 (145–420)	<0.001
Intraoperative complications (n)	1 (fluid extravasation)	1 (bleeding)	NS	0	0.3
Mean hospital stay (days)	3.2 ± 1.2 (2–6)	3.8 ± 0.6 (2–6)	0.12	1.3 ± 0.2 (7 hr to 2 days)	<0.0001
Postoperative complications (n)	2 (fever)	1 (urinoma)	0.54	0	0.13
Mean duration of nephrostomy drainage (days)	2	2	NS	NA	NS
Mean duration of ureteral stenting (wk)	2	6	NA	4	NA
Symptom free (%)	15 (100)	14 (93)	0.30	13 (93)	0.30
Improved on IVU/renal scan (%)	15 (100)	13 (87.6)	0.13	14 (100)	>0.99
Follow-up (mo)	11.6 ± 4.6 (4–16)	31.4 ± 12.6 (11–49)	<0.0001	20 ± 14 (2–49)	0.02

KEY: NS = not significant; NA = not assessed; IVU = intravenous urography.

Data in parentheses are ranges, unless otherwise noted.

standard deviation, with the range in parentheses. A P value of less than 0.05 was considered statistically significant.

## RESULTS

Percutaneous endopyeloplasty was technically successful in all 15 patients. The mean operative time was 119.3 ± 28.8 minutes (range, 62 to 180), and the mean suturing time was 28.6 minutes

(range, 14 to 62; Table III). Endopyeloplasty suturing involved placing a single suture in 1 kidney, 2 sutures in 2 kidneys, 3 sutures in 10 kidneys, and 4 sutures in 2 kidneys. The mean hospital stay was 3.2 ± 1.2 days (range, 2 to 6). The ureteral stent was removed after 2 weeks in 14 patients; 1 patient with severe hydronephrosis and preoperatively documented urinary infection had persistent post-

operative fever and the stent was kept in place for an additional 4 weeks. Complications included intraoperative mild irrigation fluid extravasation in 1 and postoperative pyrexia in 2 patients; all were successfully managed conservatively. During a mean follow-up of 11.6 months (range, 4 to 16), all 15 patients (100%) were symptom-free, with unobstructed urinary drainage on IVU (n = 15) and diuretic renal scan (n = 9).

Antegrade endopyelotomy was technically successful in all 15 patients, with a mean operative time of  $52 \pm 9.4$  minutes (range, 40 to 70,  $P < 0.001$ ). The mean hospital stay was  $3.8 \pm 0.6$  days (range, 2 to 6,  $P = 0.12$ ). The double-J stent was routinely removed at 6 weeks in all patients. Complications occurred in 2 patients: bleeding requiring transfusion in 1 and postoperative urinoma requiring percutaneous aspiration in 1 patient ( $P = 0.78$ ). During a mean follow-up of  $31.4 \pm 12.6$  months (range, 11 to 49), 14 patients (93%) were symptom free ( $P = 0.30$ ) and 13 patients (88%) had unobstructed drainage on IVU and/or diuretic renal scan ( $P = 0.13$ ). Endopyelotomy failed to relieve the obstruction in 2 patients; the failure was detected at 4 and 7 months postoperatively. Both patients with persistent obstruction after endopyelotomy underwent successful secondary open pyeloplasty. Intrinsic fibrotic restenosis at the endopyelotomy site was observed at exploration, which was confirmed by histologic examination of the excised UPJ.

Retroperitoneoscopic dismembered pyeloplasty was technically successful in all 14 patients. Reduction pyeloplasty was performed in 8 patients (57%). Crossing vessels were identified intraoperatively in 6 patients and were transposed in 5. The mean operative time was  $243 \pm 76$  minutes (range 145 to 270,  $P < 0.001$ ), and the hospital stay was  $1.3 \pm 0.2$  days (range 7 hours to 2 days,  $P < 0.0001$ ). The double-J stent was typically removed at 4 weeks after IVU. No intraoperative or postoperative complications occurred. During a mean follow-up of  $20 \pm 14$  months (range 2 to 49), 13 patients (93%) were symptom free ( $P = 0.30$ ), and all 14 patients (100%) had unobstructed drainage on IVU and/or diuretic renal scan ( $P > 0.99$ ).

## COMMENT

The ideal minimally invasive treatment for UPJ obstruction would be technically simple, would be efficacious in relieving obstruction in the long-term, and would have the ability to treat all anatomic types and causes of obstruction. Needless to say, such an ideal treatment has thus far been elusive. Recently, endopyelotomy, largely because of its technical simplicity and decreased morbidity, has supplanted open pyeloplasty as the initial treat-

ment option for most adults and older children with primary UPJ obstruction. Overall, endopyelotomy is associated with a 10% to 15% failure rate, clearly inferior to the success after open pyeloplasty.<sup>1</sup> This failure rate may increase to 46% to 50% in patients with severe hydronephrosis, poor renal function, or a crossing vessel.<sup>2,3</sup> In 1996, Oshinsky *et al.*<sup>7</sup> explored percutaneous endoscopic pyeloplasty in 8 patients with UPJ obstruction in an attempt to improve the results of endopyelotomy.

Laparoscopic pyeloplasty has been recently reported, with success rates in excess of 95%.<sup>4</sup> Moreover, laparoscopy can be applied in patients with significant hydronephrosis requiring pelvic reduction and in patients with a crossing vessel that may require ureteral-vascular transposition. However, the steep learning curve inherent to laparoscopic intracorporeal suturing may limit laparoscopic pyeloplasty to select centers proficient in reconstructive laparoscopy.

Our novel technique of percutaneous endopyeloplasty consists of horizontal suturing of a standard vertical endopyelotomy incision performed through the solitary percutaneous renal tract using a nephroscope in a Heineke-Mikulicz fashion, thereby essentially creating a Fenger-plasty. We developed the technique and evaluated its short-term efficacy in a survival chronic porcine model with 3 months of follow-up.<sup>5</sup> Specifically, two findings in our porcine study suggested a potential functional superiority of percutaneous endopyeloplasty over conventional endopyelotomy. First, the endopyeloplasty healed by primary intention in a full-thickness manner, resulting in a significantly wider caliber UPJ compared with that after endopyelotomy (13.8F versus 7.5F,  $P = 0.01$ ), which heals by secondary intention. Second, the precisely sutured endopyeloplasty incision resulted in significantly less contrast extravasation compared with after endopyelotomy, in which routine documentation of contrast extravasation is the intraoperative hallmark of technical success. Given the known detrimental effect of urinary extravasation on ureteral healing,<sup>8</sup> endopyeloplasty may provide a more optimal environment for primary full-thickness tissue healing compared with endopyelotomy.

Subsequent to these encouraging results in the porcine model, the initial clinical experience of percutaneous endopyeloplasty in 9 select patients with primary UPJ obstruction was reported.<sup>6</sup> In the present report, we present our updated experience with endopyeloplasty in 15 patients. The procedure was technically successful in all 15 patients, with a mean operative time of 119.3 minutes (range, 62 to 180) and mean endopyeloplasty suturing time of 28.6 minutes (range, 14 to 62), at-

testing to the consistent technical feasibility and simplicity of this procedure. Three minor complications occurred, all managed conservatively: intraoperative mild fluid extravasation in 1 and postoperative fever in 2 patients. No patient required readmission or an ancillary procedure. During a mean follow-up of 11.6 months, all 15 patients were symptom free with improved urinary drainage on IVU and/or diuretic renal scan. Although the duration of follow-up was shorter in the endopyeloplasty group, the trend is important, because most endourologic failures tend to be early. Importantly, 8 patients in the present series have each completed more than 1 year of follow-up, attesting to the durability of the initial success. Moreover, all 4 patients with severe hydronephrosis also showed improvement during a follow-up of 16 ( $n = 2$ ) and 6 ( $n = 2$ ) months. This suggests that, in contrast to endopyelotomy, percutaneous endopyeloplasty may be effective in treating UPJ obstruction in patients with significant hydronephrosis. However, additional experience in this particular subgroup of patients is needed.

Percutaneous endopyeloplasty was associated with a longer operative time compared with endopyelotomy (119.3 minutes versus 54.6 minutes,  $P < 0.001$ ). This approximately 60-minute longer operative time was due to the additional time required for suturing (mean 29 minutes) plus the time required for ureteral mobilization and instrument setup. Both techniques were comparable in terms of blood loss, complications, and hospital stay. Endopyeloplasty was associated with a trend toward higher functional success compared with endopyelotomy as determined by symptoms (100% versus 93%,  $P = 0.3$ ) and imaging findings (100% versus 88%,  $P = 0.13$ ) during a mean follow-up of 11.6 and 31.4 months, respectively.

The success rates of endopyeloplasty were similar to those of laparoscopic dismembered pyeloplasty (symptomatic improvement in 100% versus 93%,  $P = 0.76$ ; improvement on IVU/renography 100% versus 100%,  $P > 0.99$ ). However, retroperitoneoscopic pyeloplasty was associated with a significantly longer operative time (243 minutes versus 119 minutes,  $P < 0.001$ ), attesting to the technical complexity of intracorporeal laparoscopic suturing. We recognize, however, that the laparoscopic group had more patients with a crossing vessel (6 versus 0) and severe hydronephrosis (11 versus 4) than did the endopyeloplasty group.

Percutaneous endopyeloplasty has certain limitations. First, a definite learning curve is associated with the procedure in general and the use of the suturing device in particular. Second, extravasation of irrigation fluid may occur during the ureteral mobilization and suturing. We have attempted to minimize the clinical significance of

fluid extravasation by switching to normal saline from glycine after completing the UPJ incision and before suturing. As such, only 1 patient developed postoperative hyponatremia and responded to conservative treatment. Third, the current technique may not be suitable for patients with long-segment stenosis, crossing vessels, prior surgery for UPJ obstruction, or significant pelvic dilation requiring reduction. As such, we have recently performed a completely dismembered endopyeloplasty in the laboratory, which may be able to address the latter issue in the future.<sup>9</sup>

Certain limitations were present in the present study. Ours was a retrospective nonrandomized review. Surgeon and patient preference dictated the choice of the minimally invasive approach, although patients with a significant crossing vessel identified on preoperative imaging were preferentially treated with laparoscopic dismembered pyeloplasty. The postoperative hospital stay could not be truly compared among the groups because patients underwent surgery at two different institutions, one within and one outside the United States. Finally, the number of patients in each group was small, and longer follow-up is necessary.

We believe that endopyelotomy and laparoscopic pyeloplasty are complementary rather than competitive surgical approaches in the treatment of patients with UPJ obstruction. This initial retrospective comparison suggests that endopyeloplasty, with a somewhat greater functional success rate and shorter ureteral stenting time, may potentially present a superior endoscopic alternative to endopyelotomy in the management algorithm of primary UPJ obstruction. If these preliminary results are validated by multiple centers in a larger cohort of patients, in the future, endopyeloplasty and laparoscopic pyeloplasty could potentially cover the entire surgical spectrum of primary UPJ obstruction with improved efficacy. Such a multicenter trial is currently being planned.

## CONCLUSIONS

Percutaneous endopyeloplasty is a safe and effective procedure for the treatment of select patients with primary UPJ obstruction. The initial success was shown to be durable during a 1-year period of follow-up. Our retrospective comparison of consecutive patients suggests that percutaneous endopyeloplasty may have a functional superiority over antegrade endopyelotomy in select patients with primary UPJ obstruction. The technical simplicity and shorter operative time are advantages of our novel technique compared with laparoscopic pyeloplasty. Endopyeloplasty is associated with a shorter duration of stenting compared with the

other techniques. Longer term data in a larger group of patients from multiple centers and a prospective randomized comparison among these three approaches are necessary to determine the optimal minimally invasive treatment algorithm for primary UPJ obstruction.

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#### EDITORIAL COMMENT

Modern endourologic instrumentation and techniques have revolutionized the contemporary management of primary UPJ obstruction. The authors are to be congratulated for performing the first retrospective, nonrandomized trial comparing the functional outcomes of these three techniques. Percutaneous endopyeloplasty converts a vertical endopyelotomy incision to a horizontal closure by placing interrupted sutures through a nephrostomy tract in a Heineke-Mikulicz technique.

Several technical points for conducting a percutaneous endopyeloplasty have been identified to decrease the learning curve. With standard endopyelotomy, dilation of the UPJ to 16F is conducted before incising the tissue in the posterolateral location. This dilation step should be avoided before endopyeloplasty, because this step can thin the tissue and increase friability, resulting in sutures pulling through during knot tying. Preincision dilation may also lead to ureteral tears that cannot be incorporated into the suture line. Placement of the sutures needs to be perpendicular to the endopyelotomy incision to result in the widest caliber lumen. Furthermore, a generous distal ureteral flap must be created to provide a suf-

ficient amount of tissue to support the sutures. A ureteral balloon dilator placed in the proximal ureter may facilitate mobilization of an adequate distal ureteral flap. Needle placement on the distal and proximal ureteral segment should incorporate a significant tissue segment, because this is the crucial step to avoid having the suture tear through the tissue. Cutting the excess suture after extracorporeal knot tying can be challenging and may be facilitated by a custom cutting device (LSI Solutions, Victor, NY) or the use of thin endoscopic scissors.

Percutaneous endopyelotomy is a promising technique. Suture closure of the endopyelotomy incision may facilitate ureteral healing with decreased urinary extravasation, with the resulting advantage of a shorter duration of ureteral stenting. A direct, mucosa-to-mucosa closure can be achieved. However, the procedure does have a steep learning curve with significant technical expertise needed. The procedure does not address the issues of reduction of the renal pelvis or transposition of crossing vessels. In our experience with the procedure, dating back to 1996, the crucial step has always been to avoid tearing the ureteral mucosa during placement and tightening of the knot. Our experience with this device after working with it in the animal laboratory was a subsequent high clinical failure rate (50%, 3 of 6) assessed by both IVU/renal scan and patient symptoms. Laparoscopic pyeloplasty could be performed subsequently with the achievement of an Anderson-Hynes dismembered pyeloplasty. At the time of the procedure, crossing vessels were identified. Percutaneous endopyeloplasty is technically more difficult than endopyelotomy.

The authors purport the ideal minimally invasive treatment of UPJ obstruction would be technically simple, would be efficacious in relieving obstruction in the long term, and would have the ability to treat all anatomic types and causes of obstruction. We would add to the list the desire to have little need for highly specialized equipment, and, if there were such a need, that the equipment would be usable in other applications. We would also add that it would minimize the risk of postoperative urinary extravasation and, finally, that the ideal procedure for UPJ obstruction would eliminate the requirement for postprocedural stenting, or at least minimize its duration. The long-term success rates of endopyeloplasty will be defined by radiographic patency and the absence of symptoms to determine final efficacy.

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