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High-pressure balloon dilatation for the treatment of primary obstructive megaureter: is it the first line of treatment in children and infants?

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Summary

AIMS OF THE STUDY: To evaluate the efficacy of high-pressure balloon dilatation (HPBD) as treatment of primary obstructive megaureter (POM) in paediatric patients, we analysed the data of our institute from June 2018 to September 2019.

METHODS: 14 patients, aged 5 months to 5 years, with POM were treated with HPBD. All patients had a distal ureter dilatation greater than 7 mm associated with obstructive features on a mercaptoacetyl triglycine-3 diuretic renogram scan, and a voiding cystourethrogram without vesicoureteral reflux. HPBD was performed in 12 patients, whereas 2 patients (14%), aged 5 and 6 months, required open surgical treatment because of failure to pass the balloon catheter through the vesicoureteral junction. The procedure was performed with a 5 Fr balloon catheter for two cycles of 5 minutes each at 17 atm. A double-J stent and a urinary catheter were inserted at the end of procedure in all patients.

RESULTS: No operative complications or symptoms or recurrence were recorded in our series. The patients were generally discharged 24 hours after surgery. All the patients showed an improvement on ultrasonography at the postoperative follow-up, with no evidence of obstruction. During the procedure a clear stenotic ring was identified in 10 of the 12 patients, which disappeared in all 10 cases after the HPBD technique.

CONCLUSIONS: Based on our experience, HPBD may be considered the first-line surgical approach in the treatment of POM in children, avoiding bladder surgery in most cases.

Introduction

Megaureter is defined as a congenital dilated ureter larger than 7 mm [1]. Smith classified megaureters into four categories – obstructive, refluxing, refluxing and obstructive, or nonrefluxing and nonobstructive – later subdivided into primary and secondary by King [2, 3]. Primary obstructive megaureter (POM) is due to abnormal peristalsis of the distal ureter, which creates a functional obstruction; this condition resolves spontaneously in approximately 80% of those patients diagnosed prenatally, and that is why conservative management is initially safe [4]. There are some scenarios in which surgical management is indicated: progressive increase of megaureter size, impairment of differential renal function, or the presence of symptoms (recurrent urinary tract infections, abdominal pain, stones or haematuria). Traditionally, the surgical management of POM consists of reimplantation with or without ureteral remodelling [5, 6]. Ureteral reimplantation has good results, with a success rate of 90–96%. On the other hand, this technique is difficult in very young children (<1 years of age) and it is not free of complications [7, 8]. In fact, for these patients some authors have proposed a temporary urinary derivation in the first year of life, either external (cutaneous ureterostomy) [5, 9] or internal, such as endoscopic or open insertion of a double-J stent [10–12]. With the advent of minimally invasive surgery, alternatives for treating these patients have been sought. Endoscopic dilatation or endoureterotomy of the vesicoureteral junction have also been described as valid treatments [13, 14]. Endoscopic treatment with high-pressure balloon dilatation (HPBD) was described by Angulo in 1998 [15]; since then several publications have shown that HPBD is a feasible, safe and minimally invasive procedure, even for patients less than 1 year of age [16–22]. The aim of this study was to describe our experience and the outcomes of the HPBD technique, which, starting from 2018, in our institute has become the first line of treatment for patients with POM.

ABBREVIATIONS:

HPBD	high-pressure balloon dilatation
MAG-3	mercaptoacetyl triglycine-3
POM	primary obstructive megaureter
UTI	urinary tract infection
VUJ	vesicoureteral junction
VCUG	voiding cystourethrogram

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Material and methods

We retrospectively analysed a total of 14 patients affected by POM and treated from June 2018 to September 2019 at our institute with HPBD technique.

The inclusion criteria for our study were megaureter in a single renal system associated with an obstructive pattern on mercaptoacetyl triglycine-3 (MAG-3) diuretic renogram scan (fig. 1), absence of ectopic obstructed ureter, orthotopic ureterocele and vesicoureteral reflux on voiding cystourethrogram (VCUG).

An ultrasonographic scan was used to measure the diameter of the pelvis, calyces and distal ureter, and the characteristics of renal parenchyma. A normal drainage curve at 30 minutes after injection of MAG-3 was evaluated as no obstruction; if an obstructed curve was shown, a diuretic test with intravenous furosemide (1 mg/kg) was performed and total urinary drainage was measured at 20 minutes after the furosemide injection. Washout halftime ($T_{½}$) >20 minutes after furosemide injection was considered an obstructive pattern. Orthostatism and post-micturition imaging were involved in the analysis of the results. The indications for surgical treatment in our patients were (table 1): break-through febrile urinary tract infection (UTI) despite antibiotic prophylaxis; progressive worsening of megaureter diameter with renal parenchyma thinning; impaired renal function (split renal function <40% at diagnosis or decreasing more than 10% during follow-up). Antibiotic prophylaxis was administered postoperatively until removal of the ureteral double-J stent placed after the pneumatic dilatation in the same procedure.

Clinical data, ultrasound imaging and scintigraphy results preoperatively and postoperatively were evaluated. Intraoperative and postoperative complications were analysed. Follow-up consisted of ultrasonographic scans at 1 and 3 months after double-J stent removal and MAG-3 renography 4–6 months after HPBD. Urine analysis was performed every month for 6 months. Statistical analysis was a non-parametric paired test (Wilcoxon test).

Surgical technique

During general anaesthesia and under antibiotic prophylaxis (usually cefazoline 50 mg/kg), cystoscopy with a 9.5 Fr Wolf cystoscope was performed. A hydrophilic guidewire (0.18 inches) was introduced through the vesicoureteral junction (VUJ), which was calibrated by a 3 Fr Pollak catheter and then dilated with a 5 Fr balloon catheter for two cycles of 5 minutes. The balloon length was 4 cm, and the filled balloon diameter was 5 mm (fig. 2). When the balloon was placed at the VUJ, it was inflated with ra-

Figure 1: Obstructive pattern on preoperative mercaptoacetyl triglycine-3 (MAG-3) renal scans.

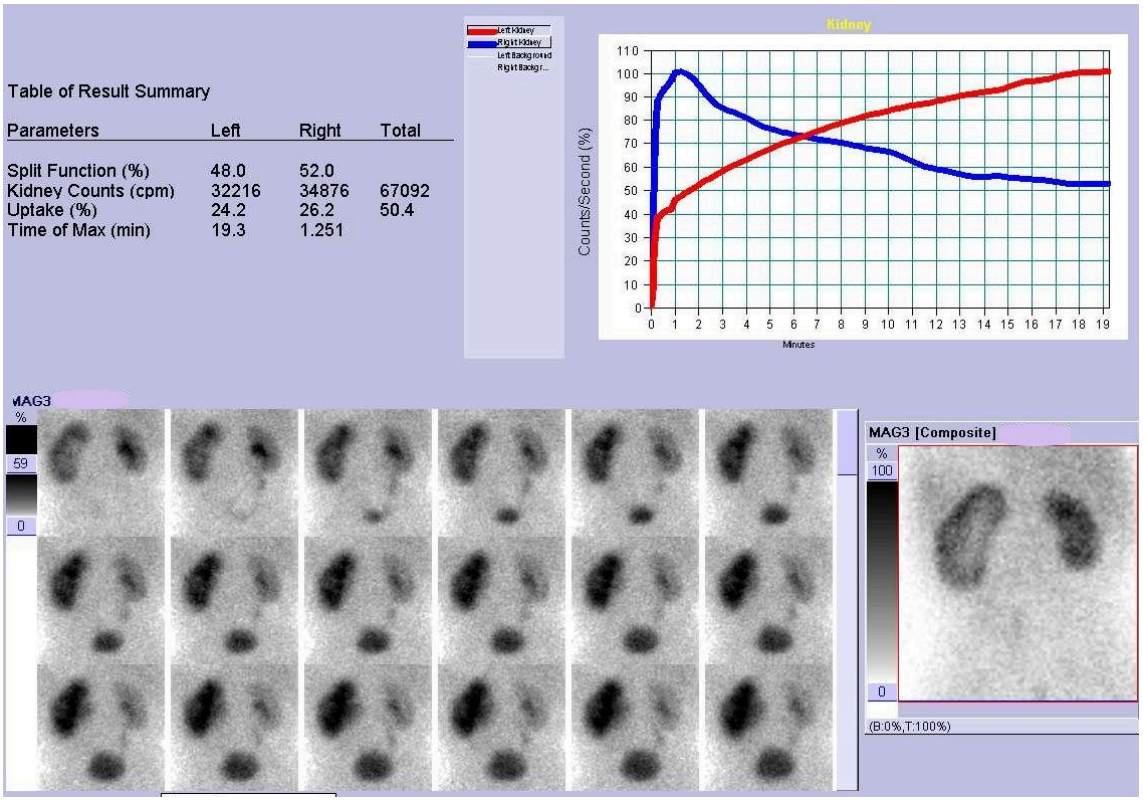


Table 1: Indications for surgical treatment (high-pressure balloon dilatation).

Clinical presentation	Number of cases
UTI	6 (50%)
UHN worsening + renal parenchymal thinning	5 (41.7%)
UHN worsening + UTI+ impairment of DRF	1 (8.3%)
Total	**12**

DRF = differential renal function; UTI = urinary tract infection; UHN = ureterohydronephrosis

diological contrast to 17 atm pressure under fluoroscopic visualisation until the disappearance of the stenosis. Dilatation was judged effective when the stenotic ring completely disappeared, and the balloon catheter was then extracted (fig. 3). A double-J stent was left *in situ* after the balloon dilatation: in the first year of life we placed a 3.7 Fr stent, in children between 1and 3 years old a 4 Fr stent was inserted and over 3 years a 4.8 Fr stent was used. At the end of the procedure a bladder catheter was left for 24 hours. Double-J stents were removed 6–8 weeks after the HPBD via endoscopy.

Results

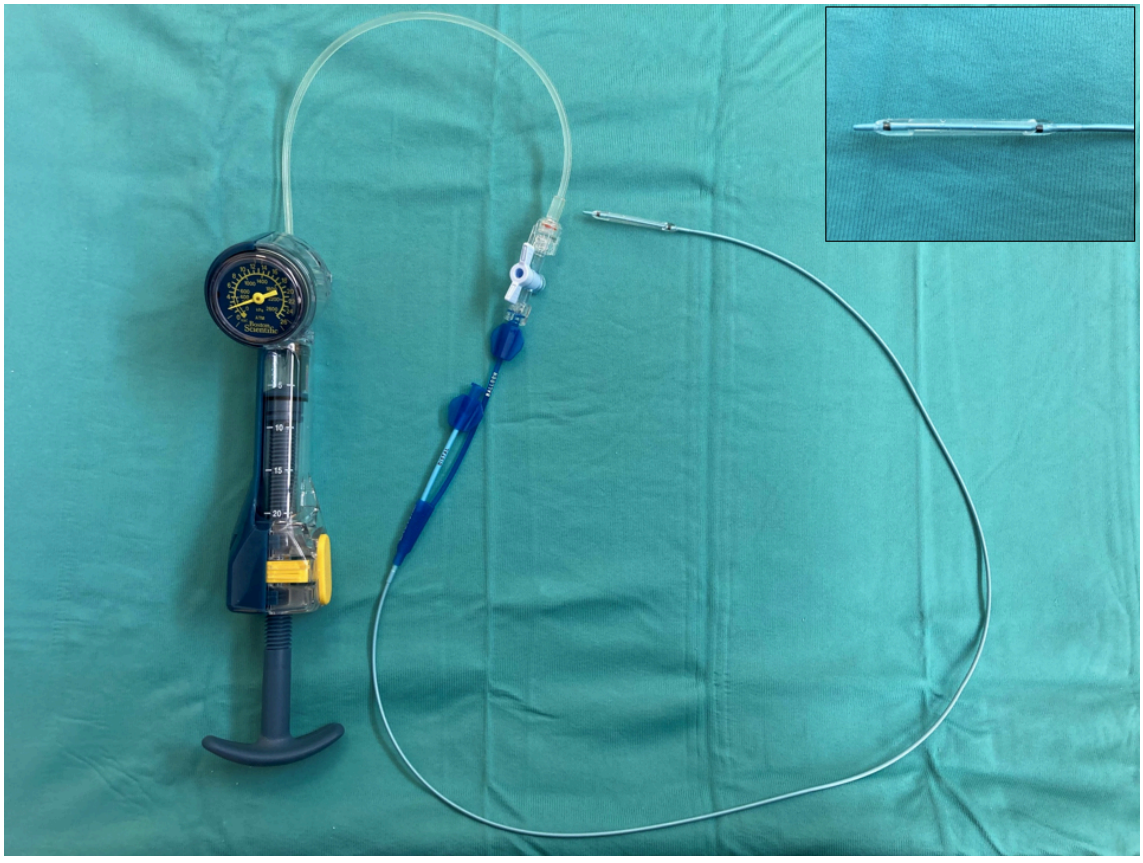
We reviewed the data from patients who underwent surgical treatment of POM with HPBD from June 2018 to September 2019 at our institute. Of 14 patients affected by unilateral POM, the HPBD technique was used in 12 (86%), whereas 2/14 (14%), males, aged 5 and 6 months, required open surgical treatment because of failure to pass the balloon catheter through the VUJ. Finally, we analysed a total of 12 patients (8 boys and 4 girls) affected by unilateral POM, left-sided in 9 patients (75%) and right-sided in 3 patients (25%). Median age at surgery was 14.5 months (range 5–61), and the median weight was 12.2 kg (range 5.4–16). Eight of the12 patients (66.6%) were diagnosed by antenatal ultrasound.

During the procedure, a clear stenotic ring was identified in 10 of the 12 patients (83% of cases) and it disappeared in all 10 cases after the HPBD technique. In two patients (16% of cases), no evidence of ureteral stenosis was observed during the balloon dilatation. There were no intraoperative complications in our series. The median operative time was 40 minutes (range 20–60) and discharge was generally 24 hours after surgery (range 24–72 hours). After a median follow-up of 16.5 months (range 15–30) no postoperative complications or symptoms or recurrence were recorded. The postoperative ultrasound scan at 3 months after the double-J removal showed a significant improvement of ureteral dilatation in all patients after the HPBD technique (Wilcoxon test, $p = 0.0005$). In fact, the median pretreatment ureteral diameter was 15.5 mm (9–22), and the median posttreatment ureteral diameter was 7 mm (range 0–11) (table 2). No evidence of obstruction was seen after HPBD treatment in any patient on MAG-3 renal scans with furosemide performed 4–6 months postoperatively (fig.4), and there was no subsequent deterioration in renal function in any case.

Discussion

The treatment of POM in infants is quite controversial. A conservative approach is indicated in most cases since POM heals spontaneously without any consequences for renal function. Nevertheless, there are cases of POM with an obstructive pattern on renography associated with increasing dilatation and/or decreased renal function, in which there is a clear indication for surgery to avoid renal damage. The standard surgical management of POM consists of ureteral reimplantation with or without ureteric remodelling, which is associated with reported success rates of 90–96%. However, complications and morbidity may occur, especially during the first year of life; in fact, reimplantation of a dilated ureter in a small bladder (patient <1

Figure 2: The 5 Fr balloon catheter with inflation device.



year of age) can be challenging and leads to potential complications such as secondary obstruction, and VUR and bladder dysfunction in the long term [4, 6, 23, 24]. For these reasons, many authors have performed during the first year of life a temporary ureteral diversion, such as cutaneous ureterostomy, to preserve renal function and allow reduction of the megaureter diameter in an attempt to avoid ureter remodelling at definitive surgery. This chose is not

Figure 3: The inflated balloon shows the ring-like stenotic portion of the vesicoureteral junction that disappears after high-pressure balloon dilatation.

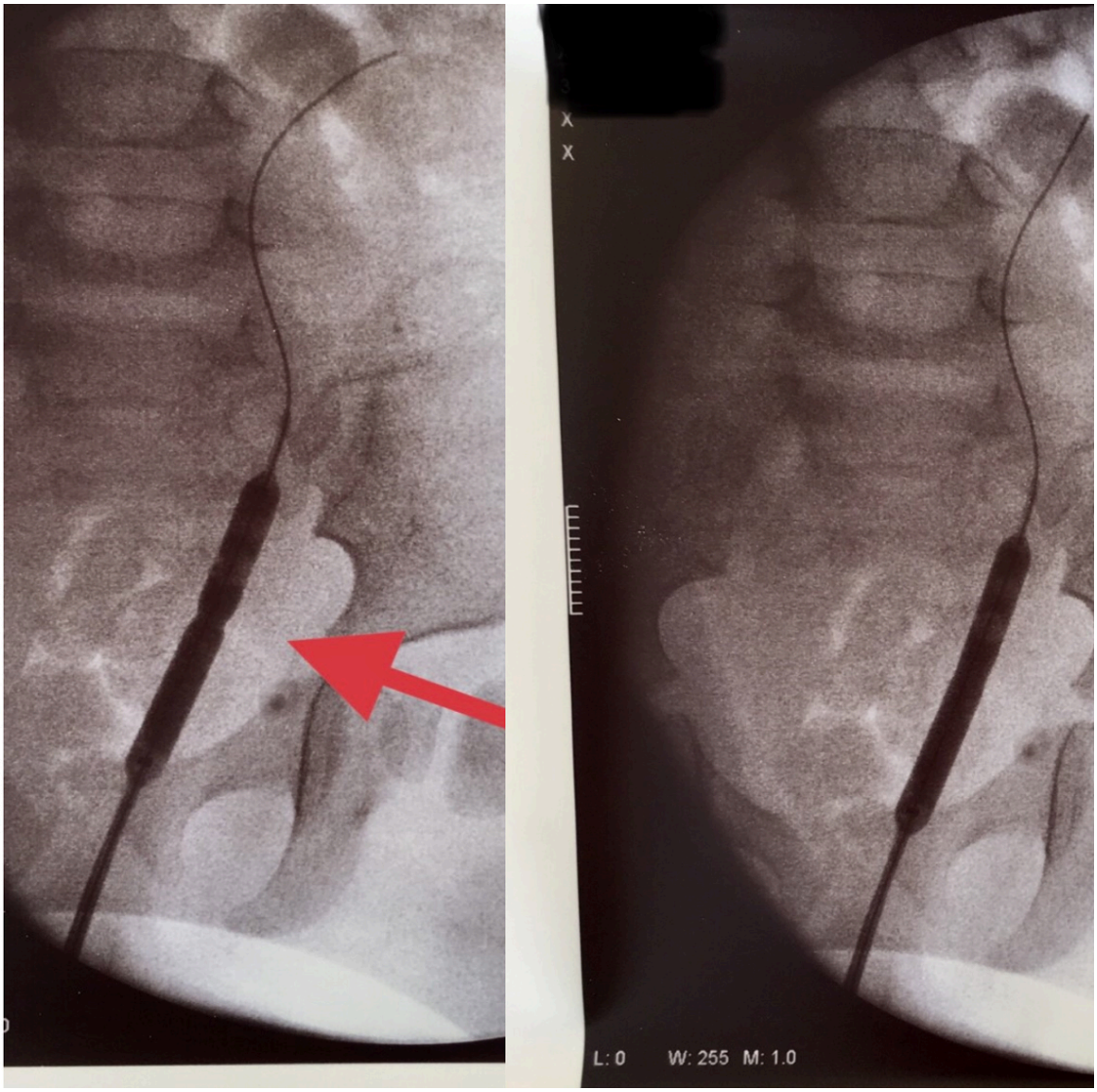


Table 2: Characteristics and outcomes of the patients.

Patient	Sex	Side affected	Age at surgery (months)	Preoperative VCGU	Pre-operative MAG-3 diuretic renography*	Last preoperative ultrasound (DUD)	Postoperative MAG-3 renography	Postoperative ultrasound (DUD)
1	M	L	7	No reflux	Obstruction	11 mm	No obstruction	7 mm
2	M	L	17	No reflux	Obstruction	15 mm	No obstruction	10 mm
3	M	L	6	No reflux	Obstruction	18 mm	No obstruction	7 mm
4	M	R	11	No reflux	Obstruction	11 mm	No obstruction	9 mm
5	M	R	12	No reflux	Obstruction	20 mm	No obstruction	7 mm
6	M	L	36	No reflux	Obstruction	22 mm	No obstruction	8 mm
7	F	L	39	No reflux	Obstruction	22 mm	No obstruction	10 mm
8	M	L	5	No reflux	Obstruction	9 mm	No obstruction	5 mm
9	F	L	61	No reflux	Obstruction	14.5 mm	No obstruction	7 mm
10	F	R	53	No reflux	Obstruction	20 mm	No obstruction	11 mm
11	F	L	28	No reflux	Obstruction	16 mm	No obstruction	No dilatation
12	M	L	7	No reflux	Obstruction	12 mm	No obstruction	4.5 mm

DUD = distal ureteral diameter; MAG-3 = mercaptoacetyl triglycine-3; VCUG = voiding cystourethrogram * Obstruction: $T_{½}$ >20 minutes after furosemide during renography; no obstruction: a normal drainage curve at 30 minutes after injection of MAG-3 without administration of furosemide

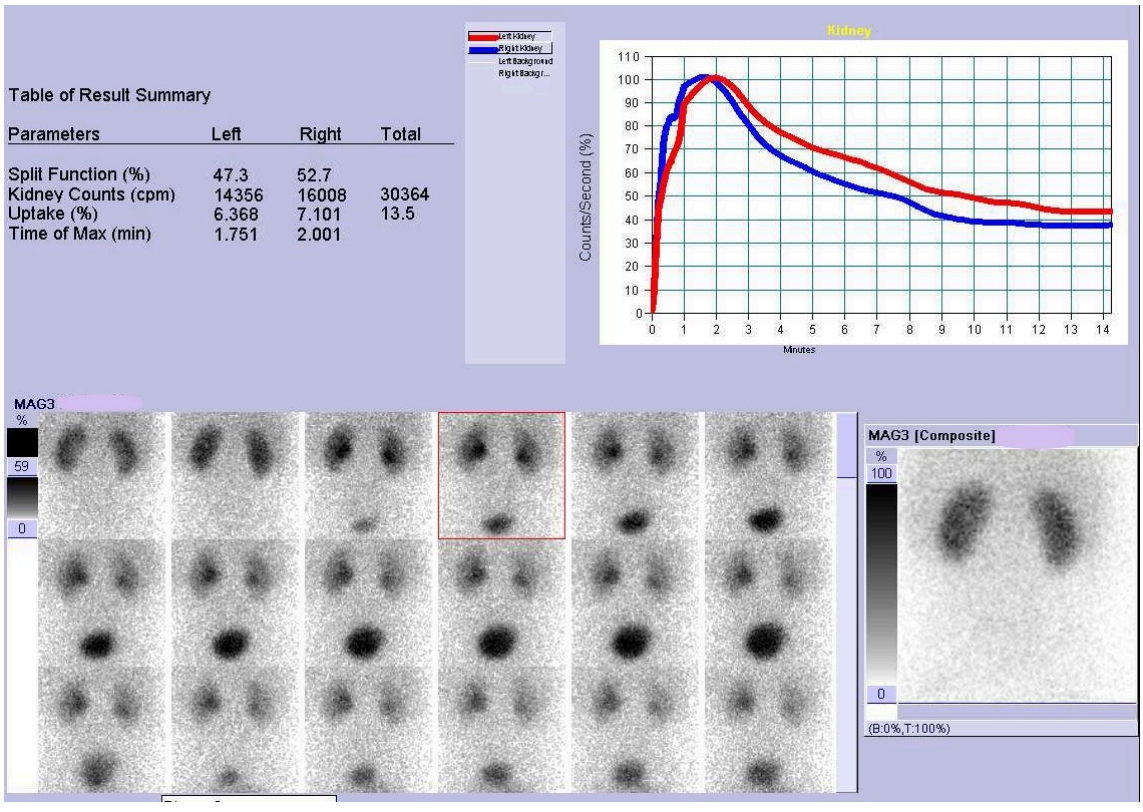
free of complications. External ureterostomy is a temporary solution, and it may have complications such as urinary infections, skin irritation, prolapse and stenosis [25, 26].

Many authors have described the placement of a double-J ureteral stent as a temporary solution for the initial treatment of POM. Castagnetti et al. reported effective ureteral drainage after double-J stent placement, avoiding the following ureteral reimplantation [10]. However, open surgery was used for the 50% of double-J stent placements, and more than half of the patients required ureteral reimplantation. Carrol et al. analysed 31 cases of POM managed by endoscopic placement of double-J ureteral stent [12]. Urinary dilatation improved in almost all patients and in 15 of them the obstruction was resolved without further surgical procedures. Nevertheless, 50% of the cases developed renal damage and 35% of the patients were finally submitted to ureteral reimplantation. The J-J stent remained for long period of time (6 months), causing secondary complications such as urinary infections, stent migration and obstruction. Farrugia et al. reported the outcome of 16 cases of POM treated with a J-J stent, showing that urinary dilatation improved in 56% of patients, but was associated with comorbidity in 30% (UTIs, lithiasis, migration of J-J stent); ureteral reimplantation was required in 6 (37.5%) cases and nephrectomy in 2 (12.5%) owing to loss of renal function [11].

In recent years, the development of minimally invasive techniques in paediatrics have led to non-aggressive procedures for the surgical management of POM, such as laparoscopic, robotic, or endourological approaches [10–14]. HPBD was first described by Angulo et al. in 1998 as initial treatment for children with POM [15]. Since then some reports with few cases and short follow-up showed that HPBD using either the original technique or variations of it was a feasible, safe and effective procedure for the treatment of POM, even for children less than 1 year of age. Torino et al. described five cases below 1 year of age treated with HPBD, with disappearance of the obstruction (on MAG-3 scan, after a mean follow-up of 23.8 months) in all patients and absence of complications [16]. In 2007, Angerri et al. reported their initial experience with six patients in whom urinary obstruction disappeared after HPBD without associated complications after a median follow-up of 31 months [17]. In 2012, Christman et al. described the disappearance of urinary dilatation in 71% of patients after follow-up of 3.2 years [18]. García-Aparicio et al. presented a series of 13 cases treated by HPBD with a success rate of 84.6% (11 of 13) at medium follow-up and a secondary VUR in two patients (one case of secondary VUR underwent ureteral reimplantation and the other was conservatively treated) [19]. Recent reports have focused on establishing long-term effectiveness of HPBD as definitive treatment of POM, showing good outcomes with little associated morbidity. In 2014, Romero et al. described their experience of 29 patients with a median age of 4 months at treatment [27]; it was concluded that 84% of the patients remained asymptomatic with disappearance of the ureterohydronephrosis and effective urinary drainage after a median postoperative follow-up of 47 months. Five patients had secondary VUR and three of them were successfully managed by endoscopic treatment.

Ortiz et al. reported in 2018 their experience of 79 patients submitted to HPBD (median age at surgery 4 months) [28], with an 87.3% success rate after a follow-up of 6.4 years, and a VUR incidence post HPBD of 21.5% (76.4%

Figure 4: Resolution of the obstructive pattern on postoperative mercaptoacetyl triglycine-3 (MAG-3) renal scans.



of these were treated endoscopically).Technical modifications of Angulo's procedure have been accomplished with encouraging results. Capozza et al. described dilation of the VUJ with a cutting-balloon in three patients with persistence of the stenotic ring during a previous HPBD, obtaining a complete resolution of the stenosis after a mean follow-up of 10 months [22].

Despite the advantages of the HPBD technique, the endourological management of POM remains controversial. The debatable aspects remain recurrence, secondary VUR and the requirement for X-rays in patients less than 1 year old. Moreover, it is difficult to evaluate HPBD as a definitive treatment of POM based on the limited series described in the literature. The potential *de novo* onset of VUR in the dilated ureter may be the source of some controversy. In the literature the incidence of postoperative VUR (after HPBD) varies between 5% and 27% [21, 29], but it was endoscopically treated with good results.

In our series we have not found clinical evidence of secondary VUR during follow-up after HPBD; in our practice, in accordance with literature, we do not systematically perform a VCUG in the absence of symptoms because it is an invasive investigation. HPBD treatment was successful in our 12 patients and not performed (unable to pass the balloon catheter through the VUJ) in 2 patients who required open surgical treatment; both patients (aged 5 and 6 months) underwent temporary ureterocutaneostomy at the time of the failed endoscopic procedure and, subsequently, they were definitively treated with Cohen ureteral reimplantation after 1 year of age. No patient developed recurrence during our follow-up. Based on our experience, and after an analysis of the literature, we consider HPBD of the VUJ a minimally invasive technique with a short learning curve associated with high success rates and a low rate of complications; in any case, its result depends on the selection of adequate endoscopic material. The choice of the balloon catheter size in relation to the patient's age is very important for the success of the HPBD. In our series, this technique failed in two patients who were the smallest, 5 and 6 months old. Our balloon catheter (5 Fr diameter) was probably too large for these patients and the use of a smaller balloon catheter (less than 5 Fr diameter) could make HPBD feasible also in patients less than 1 year old.

POM is described by literature as a congenital dilatation of the ureter due to an adynamic segment at its terminal portion as the result of a disturbed development of the prevesical portion of the ureter [20]; for this reason, the aetiopathogenesis of POM has always been based on a functional defect. In our series we found, during the HPBD, a stenotic ring at the VUJ in 10 (83%) patients, the same result found by Torino in 2013 and Capozza in 2014 (80% and 83% of patients, respectively, with a stenotic ring during HPBD) [16, 22].The HPBD technique is described as effective when the ring at the VUJ disappears during the procedure [17, 20, 21, 28], and for some authors the patients who have a ring that disappears during the procedure have a better result at follow-up [16, 22].The presence of the ring and its disappearance during HPBD indicates an anatomical cause of the POM rather than a functional cause as described in the literature; for this reason, we suggest a new aetiopathogenetic hypothesis of POM based on an anatomical stricture of the VUJ.

HPBD proved to be a safe, feasible and minimally invasive technique to treat POM with surgical criteria, even under 1 year of age. In comparison with standard surgery, HPBD has the advantages of being a less invasive procedure with no patient-age limitations. In our opinion, the HPBD may be utilised as first-line treatment in the management of POM in children, avoiding unnecessary bladder surgery in most cases. In any case, this technique does not influence conventional surgery in the case of failure.

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