

# High-pressure balloon dilatation in children: our results in 30 patients with POM and the implications of the cystoscopic evaluation

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## Abstract

Primary Obstructive Megaureter (POM) is a common cause of hydronephrosis in children with spontaneous resolution in most cases. High-Pressure Balloon Dilatation (HPBD) has been proposed as a minimally invasive procedure for POM correction in selected patients. The aim of the paper is to review our experience with HPBD in patients with POM. We performed a retrospective study in a single Centre collecting data on patients' demographics, diagnostic modalities, surgical details, results and follow-up. In particular, the endoscopic aspect of the orifice permitted the identification of 3 patterns: adynamic ureteral segment, stenotic ureteric ring and pseudoureterocelic orifice. We performed HPBD in 30 patients over 6 years. We had 23 patients with adynamic distal ureteral segment (type 1), 4 with stenotic ring (type 2) and 3 with ureterocelic orifice (type 3). In 3 patients (10%) the guidewire did not easily pass into the ureter requiring ureteral stenting or papillotomy. Post-operative course was uneventful. Five patients (3 pseudoureterocelic) required open surgery during follow-up. HPBD for the treatment of POM is a safe and feasible procedure and it can be a definitive treatment of POM. Complications are mainly due to double J stent and none of our patients had symptoms related to vesico-ureteral reflux. The aspect of the orifice, identified during cystoscopy, seems to correlate with the efficacy of the dilatation: type 1 and 2 are associated with good and excellent results respectively; type 3 do not permit

dilatation in almost all cases requiring papillotomy. HPBD can be performed in selected patients of all paediatric ages as first therapeutic line. The presence of a pseudoureterocelic orifice or long stenosis might interfere with the ureteral stenting and seems associated with worse outcomes.

## Introduction

Primary Obstructive Megaureter (POM) refers to a dilated ureter (diameter larger than > 5 mm) from an intrinsic congenital pre-vesical obstruction that is mostly functional rather than an anatomical narrowing.<sup>1,2</sup>

In almost 80% of cases POM spontaneously resolves during the first years of age without consequences on the renal function.<sup>3-6</sup>

According to 2016 EAU Guidelines on Paediatric Urology, an intervention is required in case of symptomatic children, if there is a drop-in function in conservative follow-up and when hydroureteronephrosis is increasing with parenchyma thinning.<sup>7</sup>

Surgery has been classically relied on ureteral reimplantation with or without ureteral remodelling with a reported success rate of 90%.<sup>3</sup> However, the procedure is complex in patients younger than 6 months of age with high morbidity and not negligible re-intervention risk (12% in patients < 12 months).<sup>3</sup> For these reasons, less-invasive procedures have been proposed, initially as bridge strategies (urinary diversions, ureteral stents, endoureterotomy, ureteral dilatation).<sup>1</sup>

We report our experience in the use of High-Pressure Balloon Dilatation (HPBD) for the treatment of POM in children. We also described the cystoscopic appearance of the ureteric orifice in our series: distal adynamic ureteral segment, intramural stenotic ring and ureterocelic.

## Materials and Methods

We performed a retrospective study over a period of 6 years (January 2012 – January 2018) collecting data of patients treated by HPBD at a single Centre.

The diagnosis of POM was performed in case of ureteral diameter larger than 10 mm with an obstructive pattern on MAG3 renogram scan and without vesico-ureteral reflux on voiding cystourethrography.

Operative management was required in patients with POM and at least one of the following elements: i) Febrile urinary tract infections despite prophylaxis; ii) Differential renal function < 40% or DRF reduction > 10%; iii) Progressive worsening of dilatation in two consecutive US studies.

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HPBD was the technique of choice except for neonates with huge urinary tract dilations or severely reduced renal function who underwent prevesical bypass.

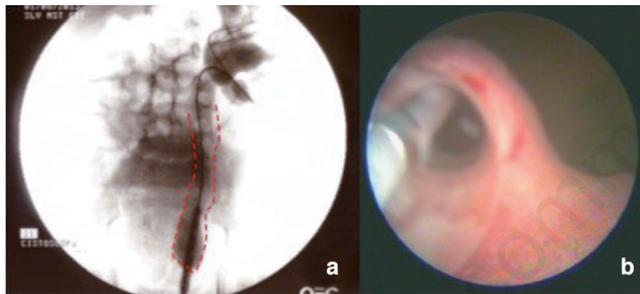
The cystoscopy was performed by an 8,5-11 F device with a working channel. Most of the procedures were performed by the compact 9.5 ch paediatric cystoureteroscope (Karl Storz – Endoskope) with an operative channel of 6 ch for instruments of 5 ch). After retrograde pyelography, a hydrophilic 0.18-0.35” Terumo flexible guidewire was passed into the ureter. Then the balloon catheter (6 ch; length 4 cm; diameter 5 mm) was inserted. In smaller children this placement was performed under radiological guidance (not through the operating channel of the cystoscope) with the cystoscope being inserted in parallel. The uretero-vesical junction was dilated at 20 Atm (that is the nominal pressure of the balloon device) for 2 minutes (maximum four times). The procedure was performed under fluoroscopy and with x-ray control. Initially the filling of the balloon with contrast medium helped in the identification of the ureteric aspect. After dilatation, a 4,8 ch double J stent was inserted into the ureter in children > 12 months (up to 28 cm of length for the risk of ascension in folded megaueters); a smaller stent (3 ch, 8 – 14 cm) was used for infants < 12 months of age. The stent was withdrawn with cystoscopy under general anaesthesia after 3 months. The decision to keep a ureteral stent was based on the will to avoid acute obstructive complications related to an oedema of the papilla and to give patients an additional chance of success. Follow-up consisted of clinical evaluation, US scans at 1, 3, 6 and 12 months and MAG3 renogram 3

months after stent removal. We judged the results of the treatment on the base of reduction in dilatation, change of the drainage curve from obstructed to a non-obstructed pattern and percentage of retained tracer at the end of the test.

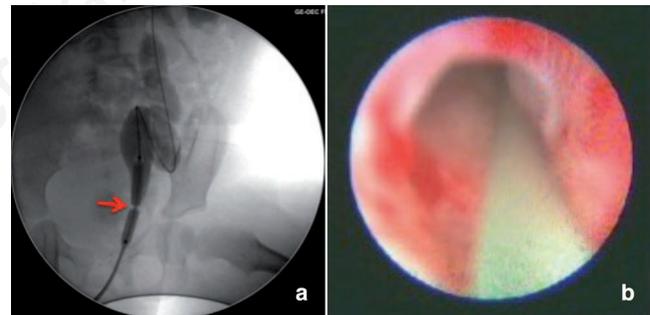
On the base of the appearance of the ureteral orifice during the cystoscopy and fluoroscopic evaluation, we identified three settings (Figure 1): i) distal adynamic ureteral segment (Figure 1): the distal ureter has lost the propulsive motion; in other words, the distal ureter is altered and appears as a motionless tube. The remaining proximal tracts of the ureter are normal of even hypertrophic in an attempt to win the low obstacle; ii) intramural stenotic ring (Figure 2): a concentric stenosis was well evident in a limited medial tract of the intramural ureter; iii) ureterocelic orifice (Figure 3): the orifice appeared exuberant causing a proximal ureteral folding.

## Results

Thirty patients underwent HPBD during the study period (9 females and 21 males). Twenty-five patients (83,4%) came to our attention after prenatal identification of hydroureteronephrosis and 5/30 (16,6%) after birth for recurrent UTI (n=3) or incidental diagnosis (n=2). The left side was involved in 20 patients and 1 case was bilateral. Surgical indications included: UTI (n=8), worsening of dilatation (n=10), altered renal function (n=4), and thinned renal



**Figure 1.** Intraoperative retrograde pyelography during HPBD (a): there is not any evident narrowing when the ureter is filled with contrast solution (the hedges of the ureter are marked with two red interrupted lines). During dilatation (b) the distal adynamic ureteral segment has a sort of cracking despite the absence of a well-defined ring (b).



**Figure 2.** HPBD in case of intramural stenotic ring: the ring is well evident during fluoroscopy creating the typical hourglass figure [red arrow (a)]. The simultaneous endoscopic view during HPBD permits to appreciate the cracking of the ring (b).



**Figure 3.** The orifice bulges into the bladder with an “ureterocelic” aspect (a); the orifice is first cut (b), and the dilatation is performed thereafter (c).

parenchyma (n=8). Endoscopy was performed at a mean age of 3.6 years (range 0.4-12.2). Nine patients were younger than 12 months of age at time of endoscopic treatment. Table 1 compares results in infants (< 1 year of age) and in older children. The statistical analysis (p-value modified by Yates for small numbers) showed no significant difference between the two groups.

HPBD together with JJ stent placement was the most common procedure (27/30 cases). In 3/30 patients (10%) we had difficulties in inserting the guidewire into the ureter: HPBD was preceded by papillotomy in two cases while a stent alone was left for one month in the remaining patient. After one month, we managed to perform a HPBD but the Terumo guidewire was accidentally removed soon after the dilatation and we decided not to place the JJ stent. We did not have any intraoperative complications. During follow-up (mean 3,3 years) an open ureteral reimplantation was performed in 5/30 patients (16%). Three of them were the patients with difficult ureteral stenting, younger than 12 months of age. The remaining 2/5 patients were older children (respectively of 4.4 and 4.6 years of age). One of them had contralateral renal hypoplasia and surgery was performed for persisting dilatation despite improved MAG3 pattern (absence of obstruction). The other patient had flank pain two days after stent removal and sudden increased ureteral dilation. The boy was hospitalized for further investigations and eventually we decided for surgery.

One out of 30 patients (3%) had transient haematuria and 1/30 (3%) had urinary tract infection and subsequent stent removal. None of the patients developed vesicoureteral reflux. Mean pre-operative ureteral diameter was 16 mm [range 10-25] and mean post-operative ureteral diameter was 7,9 mm [range 2-15].

The statistical analysis applied to pre-and post-operative ureteral diameters showed statistically significant differences (p-value = 0.0009).

Considering the cystoscopic appearance of the orifice: 23/30 patients had a distal adynamic ureteral segment; 4/30 had a stenotic ring and 3/30 an ureterocelic orifice that made the guidewire insertion difficult.

## Discussion

HPBD as primary treatment for children with POM gives satisfactory results.<sup>8</sup> The technique has been shown to be safe, feasible and minimally invasive.<sup>2,6,9</sup> Described HPBD advantages include the preservation of the ureteral vascular supply avoiding

the violation of the bladder and the possibility to perform an open ureteral reimplant surgery in case of failure.<sup>6</sup> The reported morbidity rate is between 7 and 15% and it is related to ureteral stents in most cases.<sup>6</sup>

Despite the fact that the indication of the Literature is to perform HPBD as an early procedure in young patients,<sup>1,2,8,10-13</sup> we had positive results also in children older than 24 months. In fact, comparing the group of infants treated in the first year of age with older children we had comparable results. However, the *ureterocelic orifice* was only observed in infants and might explain the severity of the picture and the need of a more aggressive treatment. We are also aware of the possibility to redo the dilatation in case of failure. Ortiz *et al.* reported on a series of 92 patients treated by HPBD and they had 12.2% of re-stenosis (9 cases). A new EBD was done with good long-term outcome in 8 cases (88.9%). Only 1 patient developed recurrent re-stenosis and finally required ureteral reimplantation. At our Institution, the current approach is to avoid multiple HPBD procedures as non-responders benefit more from an early open surgery (less anaesthesia, reduced endoscopic complication rate, reduced time to stent removal).<sup>14</sup>

Regarding post-procedure complications, we recorded 2 cases (7%) of patients with haematuria and UTI, both related to the presence of the stent confirming that the ureteral stent might be the cause of unpleasant symptoms after surgery. In one of them (UTI) the stent was removed shortly after the diagnosis of infection. The use of ureteral stents after HPBD is advocated to avoid obstructive oedema-related complications but some aspects, such as the time to remove the stent, are still unclear.<sup>13,15</sup>

Another topic of current discussion is the incidence of post-operative Vesicoureteral Reflux (VUR). The reported incidence varies widely in different series, being 5% according to Doudt<sup>1</sup> and reaching 27% in the experience of Garcia-Aparicio.<sup>15</sup> Most authors agree on the fact that VUR might be a transient condition without huge clinical implications.<sup>15,16</sup> We do not routinely perform Micturating Cystourethrogram (MCUG) after HPBD except for symptomatic cases and none of our patients developed symptoms requiring MCUG after surgery.

HPBD has a reported success of 80-90%.<sup>5,15</sup> The efficacy of the dilatation seems to be related to the characteristics of the orifice / stenosis that are defined during cystoscopy. Christman *et al.* reported a series of 17 patients younger than 3 years treated by HPBD with or without laser-incision.<sup>13</sup> They found that patients with long stenosis (5 cases with stenosis between 2 and 3 cm) did not achieve satisfactory improvements after surgery.

Observing the aspect of the ureteric orifice both during cys-

Table 1.

	Infants (< 12 months of age)	Children (> 12 months of age)	p-value (Yates mod)
Number of patients	9	21	
M:F	5:4	16:5	0.486
Prenatal diagnosis (number)	9	16	0.285
Side	Left 4; Right 4; Bilateral 1	Left 16; Right 5	
Mean age at HPBD	7.4 months	5.3 years	
Cystoscopic appearance	- distal adynamic ureteral segment = 2 - stenotic ring = 4 - ureterocelic orifice = 3	- distal adynamic ureteral segment = 2	
Procedure	- HPBD alone = 1 - Papillotomy = 2 - HPBD + stent = 6	- HPBD + stent = 21	
Redo open	3	2	0.285

toscopy and the balloon dilatation, we identified three patterns: excluding pseudo ureterocele these aspects are only visible looking through the inflated balloon. Moreover, the diagnosis is confirmed by the fluoroscopic appearance of the obstructing segment (e.g. hourglass appearance when there is a stenotic ring).

In our series, the most common endoscopic picture was that of a distal adynamic ureter, identified in 23 patients (77%). The adynamic tract leads to proximal ureteral dilatation and folding. In these cases, it is important to choose a stent of appropriate length and to be careful to its possible twisting inside the ureter. With these technical precautions the dilatation is possible and quite simple. We could discuss over the real need of a dilatation in patients without a well evident stenotic ring. However, we had the impression that there is always a sort of *cracking* during HPBD in cases with distal adynamic ureter. The endoscopic manoeuvre together with the placement of the ureteral stent favour the correction of the lower obstruction and lead to positive results. We cannot say if these patients would have benefit in the same way from stent placement alone.

Four patients (13%) had a stenotic intramural ureter: the stenotic ring was well evident when the balloon was filled as well as its prompt disappearance during the dilatation. HPBD gives the best results in patients with the stenotic ring, as previously reported.<sup>10</sup>

In rare cases (3/30 in our series, 10%) the orifice resembles an ureterocele with the stenotic ureteral meatus located at the top of the bulging. This peculiar conformation makes the placement of the guidewire difficult. There have been reports in Literature showing the impossibility to insert a ureteral wire although a detailed description of the aspect of the orifice is often lacking.<sup>1</sup> A recent metanalysis considering 12 studies (11 retrospective) and a total of 237 obstructed renal units reported that in 10% of cases the ureter was not stented.<sup>1</sup> The impossibility to place a stent makes the dilatation not practicable. We could speculate over the possible role of papillotomy in such complex cases. Unfortunately, we do not have a significant experience as we performed papillotomy only in 2 patients and in one of them an open surgery was required during long-term follow-up.

Capozza *et al.* described a success of 83% when HPBD was performed alone or together with Cutting-Balloon™ Ureterotomy (CBU).<sup>10</sup> CBU was required in 3/12 patients and it resulted a valid alternative when the stenotic ring persisted after dilatation. Unlike the experience of Capozza and other reports, we never had problems with the dilatation once we managed to access the ureter with the guidewire.<sup>13</sup> Bujons *et al.* came to the same conclusion and they consider HPBD as a safe, feasible and effective procedure.<sup>4</sup> Endoureterotomy was performed at 6 and 12 o'clock (the latter involving only the mucosa) by Bapat *et al.* with the aim of increasing the success rate reducing the risk of VUR.<sup>17</sup>

Some authors<sup>8,9</sup> suggest attempting a second dilatation after a few weeks when the placement of a double J stent is possible but the access through the VUJ cannot be achieved.

Our overall failure rate is comparable with that reported in literature and the procedure was successful in 84% of cases.<sup>1</sup> Considering our 5 patients that required redo open surgery, 3/5 had an ureterocelic orifice and were treated before 12 months of age. The presence of an ureterocelic orifice makes the dilatation alone not possible but it probable correlates with worse outcomes, as well. Additionally, we should also consider the age factor with all the three patients being under 12 months of age at the time of endoscopy.

Therefore, the endoscopic aspect of the orifice seems to predict the feasibility and success of HPBD. Distal adynamic ureters (type 1) permit to perform HPBD but ureteral stenting seems essential to obtain good results. The presence of intramural stenotic rings (type

2) is associated with excellent response to dilatation. The HPBD is difficult and often not possible when there is an ureterocelic orifice (type 3). In these cases, papillotomy might be the best choice.

The limits of the current study are the retrospective nature and the small number of patients but we should consider that the overall percentage of patients requiring surgery for POM is small.

## Conclusions

High-pressure balloon dilatation is a valid alternative to classic reimplantation in case of primary obstructive megaureter. This minimally invasive approach can be performed in selected patients of all paediatric ages as first therapeutic line. The dilatation seems possible in all cases in which the ureter can be stented. However, the impossibility to proceed should be considered in cases with a pseudoureterocelic orifice or long stenosis identified during cystoscopy. Ureteral stenting alone might be chosen in case of distal adynamic ureter but more data are required to draw definitive conclusions.

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