Journal of Pediatric Urology (xxxx) xxx xxx

# Endoscopic balloon dilatation of primary obstructive megaureter: An effective first line management in children

Olugbenga Awolaran [a], Ijeoma Nwachukwu [a], Anu Paul [a], Massimo Garriboli [a], Arash Taghizadeh [a], Sara Lobo [a], Karim Awad [b,c], Kate Burns [b], Mohamed Shalaby [b], Mark Woodward [b], Pankaj Mishra [a,*]

[a]Paediatric Urology Department, Evelina London Children's Hospital, St Thomas' Hospital, Westminster Bridge Road, London SE1 7EH, United Kingdom

[b]Paediatric Urology Department, Bristol Royal Hospital for Children, Paul O'Gorman Building, Upper Maudlin Street, Bristol BS2 8BJ, United Kingdom

[c]Department of Pediatric Surgery, Children's Hospital, Ain Shams University Hospitals, Cairo, Egypt

* Correspondence to: Pankaj Mishra, Paediatric urology department, Evelina London Children's Hospital, St Thomas' Hospital, Westminster Bridge Road, London SE1 7EH, United Kingdom
pankaj.mishra@gstt.nhs.uk (P. Mishra)

**Keywords**
Endoscopic; Balloon; Dilatation; Megaureters; Children

Received 29 May 2024
Revised 6 September 2024
Accepted 10 September 2024
Available online xxx

## Summary

### Aim
This study evaluates outcomes of endoscopic balloon dilatation (EBD) in the management of primary obstructive megaureter (POM) in children.

### Methods
Retrospective data between 2013 and 2023 from two tertiary paediatric surgical centres in the UK were reviewed. Pre and post-operative clinical and imaging parameters of children managed with EBD were assessed. Failure of procedure was defined as requiring further intervention due to persistent/recurrent symptoms, upper tract dilatation and/or obstruction on MAG3 over the follow up period.

### Results
55 children with 61 renal units were evaluated. Median age at treatment was 18 months with a median follow up of 24 months. There was significant reduction in upper tract ultrasound measurements following balloon dilatation but there was no significant difference between the pre and post-operative renal function on MAG3. No significance difference was demonstrated when the outcomes of cutting and non-cutting balloons were compared. No significant difference was shown when outcomes after EBD were compared between infants vs older children as well as ureteric dilatation less than or over 25 mm ($p = 0.841$). 87% were successfully treated with a single dilatation and this increased to 95% after second dilatation. The remaining 5% had ureteric re-implantation.

### Discussion
Although a retrospective study, the patient population is relatively large. 87% success rate shown after EBD is comparable to similar studies. It has been suggested that children less than 12months and those with severe ureteric dilatation (>25 mm) may not be suitable for EBD. No significant difference was demonstrated when the outcomes of these categories of children were compared to other children with POM. All of the patients that had repeat balloon dilatation required no further intervention, a finding that has so far not been well evaluated in available literature.

### Conclusions
This study demonstrates 87% success rate after single EBD in children with POM and this outcome increased to 95% following a second dilatation. EBD is shown to be an effective definitive surgical management option of POM. It can be safely offered as first line management in all patient groups and repeated if no initial response.

https://doi.org/10.1016/j.jpurol.2024.09.007


Please cite this article as: Awolaran O et al., Endoscopic balloon dilatation of primary obstructive megaureter: An effective first line management in children, Journal of Pediatric Urology, https://doi.org/10.1016/j.jpurol.2024.09.007

**Summary table**

| | | P-value |
|---|---|---|
| Outcomes based on age (median post-op APD) | | |
| - <12months | 20 units (13 mm) | 0.433 |
| - >/ = 12mo | 41 units (13 mm) | |
| Outcomes based on severity of DUD diameter (median post-op DUD) | | |
| - <25 mm | 87% (11 mm) | 0.701 |
| - >/ = 25 mm | 13% (7 mm) | |
| Further interventions (10 children) | | |
| - Repeat balloon dilatation | 5 | |
| - Ureteric re-implantation | 3 | |
| - Ureteroscopy + laser for stent encrustation | 1 | |
| - Endoscopic treatment of VUR | 1 | |
| Procedure related complications (5 children) | | |
| - Post-op VUR | 2 | |
| - Stent encrustation | 1 | |
| - Stent migration | 1 | |
| - Failure to cannulate ureteric orifice | 1 | |
| - Post-op UTI | 1 | |

## Introduction

Over 80% of megaureters secondary to vesicoureteric junction (VUJ) hold-up in children can be managed conservatively as they tend to resolve spontaneously or remain stable without symptoms [1,2]. Surgical intervention is needed for those with clinical and/or radiological deterioration. This include break through urinary tract infections (UTI), worsening upper tract dilatation and initial differential renal function (DRF) below 40% or a drop in DRF of >/ = 10% on serial scans [1,3].

Endoscopic intervention is increasingly being used in the management of primary obstructive megaureter (POM) [4]. This was initially used as a temporising procedure especially in infants where the traditional re-implantation procedure was avoided. Endourological treatment options include ureteric stenting alone, high pressure balloon dilation (HPBD) and cutting balloon ureterotomy (CBU) [5].

Although improvement in upper tract dilatation has been shown with double J stenting alone, about 30—70% requirement for further surgical intervention in form of re-implantation is reported [5—7]. Furthermore, a high rate of stent related complications (40—70%) is reported in children managed with stenting alone [6,7], and a significant number of children required stents in situ for prolonged period [5]. Angulo first described balloon dilatation as a temporary measure particularly for infants [8]. Endoscopic balloon dilatation (EBD) is increasingly being employed as definitive management and it has been used in children of all age groups [9—12]. Evidence of its long-term effectiveness is however still emerging.

Cutting balloon ureterotomy (CBU), in addition to dilating the obstructed vesicoureteric junction, achieves an ureterotomy in a controlled way. Its use was initially described in the management of ureteric strictures and pelviureteric junction obstruction [13,14]. CBU is being employed in endoscopic management of children with POM either as primary technique or as an adjunct when result with HPBD is not satisfactory [15]. Evidence about the superiority of either of these 2 techniques over the other in children is lacking.

This study reviews the outcomes of endoscopic balloon dilatation of POM in children over a 10 year period from 2 centres. Overall results of its use are evaluated and the outcomes observed in HPBD are compared with that of CBU. The characteristics of those that required further intervention are described.

## Material and methods

Data was retrospectively collected for children with POM managed with endoscopic balloon dilatation at two tertiary paediatric surgical centres in the United Kingdom between 2013 and 2023. Information extracted included patient demographics, indication for intervention, pre-and post-operative parameters on imaging and complications. Outcomes of both HPBD and CBU were compared.

All children that presented with POM that required intervention over the 10-year period were treated with endoscopic balloon dilatation (EBD). Children with distal ureteric dilatation >15 mm or/and symptoms (UTI) or/and function <40% on MAG3 with obstructive curve or drop of function >10% on serial MAG3 scans were included.

EBD was performed under general anaesthesia (GA). A single dose of prophylactic intravenous antibiotics was given at induction. Using a paediatric offset (straight working channel) cystoscope, the VUJ was accessed with Stryker® Synchro-14 0.014 inch × 200 cm (M00313010) guidewire with hydrophilic coating. These wires are very flimsy, hence a 3fr ureteric catheter is used to stabilise and manipulate it in a controlled manner. The same catheter is advanced across the VUJ to perform a retrograde study to delineate the point of narrowing and outline the dilated ureter.

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**Table 1** Patient characteristics.

| | |
|---|---|
| 55 children, 61 renal units | |
| M:F | 40:15 |
| Median age at surgery | 18 months (2 months—17yrs) |
| Age | |
| <12months | 20 renal units (33%) |
| >/ = 12months | 41 renal units (67%) |
| Laterality | |
| - Left | 32 (58%) |
| - Right | 16 (29%) |
| - Bilateral | 7 (13%) |
| Indications for surgery | |
| - Increasing upper tract dilatation | 27 (44%) |
| - Decreased renal function | 18 (30%) |
| - UTI | 12 (20%) |
| - Pain | 4 (6%) |

**Table 2** Pre and post op imaging findings.

| | Pre-op | Post op | P-values |
|---|---|---|---|
| APD (mm) | 21 (3—55) | 13 (0—65) | **0.00004** |
| DUD (mm) | 16 (10—48) | 9.5 (0—33) | **0.00002** |
| MAG 3 (%) | 44.5 (13—62) | 47.5 (25—63) | 0.291 |

Bold numbers are statisticaly significant.

HPBD was performed with 4Fr, 6 mm × 4 mm Cook Medical balloon dilator device passed over the guidewire and VUJ dilated to a pressure of 4—13 atm under direct cystoscopic and fluoroscopic vision. Boston scientific small peripheral cutting balloon MONORAIL® 3.0 mm (M001BPM3015140F0) or WOLVERINE™ cutting balloon were used in those that had CBU. The VUJ was stretched and incised by see-saw motion after inflating the balloon and activating the blades under cystoscopic fluoroscopic vision. This procedure is repeated a few times to ensure adequate dilation. Adequate dilatation was defined as resolution of 'waisting' of the VUJ seen on fluoroscopy.

4.7Fr double J stent was placed in all cases and removed under GA about 6—8 weeks after the procedure. Follow up ultrasound was done after 6 weeks and repeated based on clinical judgement. Mercaptoacetyltriglycine (MAG3) scans were performed between 6 and 12months to evaluate the outcome of the procedure.

Primary outcome studied was need for further intervention following a single EBD. Failure of initial procedure was defined as requiring further intervention due to persistent/recurrent symptoms, upper tract dilatation and/or obstruction on MAG3 over the follow up period. Those who failed had repeat EBD or progressed to reimplantation. Statistical analysis for significance was calculated electronically with Chi-square and Mann—Whitney U tests using a p-value of less than 0.05 as significant.

## Results

55 children with 61 renal units were managed over the 10-year period. The median age at treatment was 18months (2 month—17 years). 32 children (58%) had left POM. The commonest indications for intervention were increasing upper tract dilatation (44%), reduced or decreasing renal function (30%), and urinary tract infection (20%). Further details of patient demographic characteristics are shown in Table 1. Median follow up after treatment was 24months (2—122). 42/55 (76%) had 12 months or more follow up.

**Table 3** Outcome comparison between CBU and HPBD.

| | HPBD (n = 23) | CBU (n = 38) | p-value |
|---|---|---|---|
| Age at procedure (months) | 18 (2—165) | 17.5 (2—211) | 0.610 |
| **Resolution after dilatation** | | | |
| Median difference between pre and post- op ARPD (mm) | 7.6 (0—27) | 6 (0—39) | 0.449 |
| Median difference between pre and post -op DUD (mm) | 4.8 (0—21) | 5 (0—48) | 0.586 |
| Further intervention | 3 (13%) | 5 (13%) | 0.989 |

**Table 4** Outcomes after endoscopic balloon dilatation.

| | | P-value |
|---|---|---|
| Overall success rate after single dilatation | 87% | |
| Outcomes based on age (median post-op APD) | | |
| - <12months | 20 units (13 mm) | 0.433 |
| - >/ = 12mo | 41 units (13 mm) | |
| Outcomes based on severity of DUD diameter (median post-op DUD) | | |
| - <25 mm | 87% (11 mm) | 0.701 |
| - >/ = 25 mm | 13% (7 mm) | |
| Total further interventions (10 children) | | |
| - Repeat balloon dilatation | 5 | |
| - Ureteric re-implantation | 3 | |
| - Ureteroscopy + laser for stent encrustation | 1 | |
| - Endoscopic treatment of VUR | 1 | |
| Further procedures for POM (8 children) | | |
| Median pre-operative APD | | |
| - No further intervention | 22 mm | 0.19 |
| - Further intervention | 33 mm | |
| Median Post-op APD | | |
| - No further intervention | 11.5 mm | **0.022** |
| - Further intervention | 30.5 mm | |
| Procedure related complications (5 children) | | |
| - Post-op VUR | 2 | |
| - Stent encrustation | 1 | |
| - Stent migration | 1 | |
| - Failure to cannulate ureteric orifice | 1 | |
| - Post-op UTI | 1 | |

Bold numbers are statisticaly significant.

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The median pre-operative anteroposterior pelvic diameter (APD) and distal ureteric diameter (DUD) were 21 mm and 16 mm respectively. The median renal function on MAG3 at intervention was 44%. Further details of pre and post-operative upper tract measurements and MAG3 functions are shown in Table 2. There was significant reduction in renal pelvis ($p < 0.001$) and ureteric ($p < 0.001$) measurements following balloon dilatation. Post-operative MAG 3 function was available in 54% (33/61). There was no significant difference between the pre and post-operative renal function ($p = 0.291$), however, improvement in drainage was observed in those that were successful.

Cutting balloon was used in 36 renal units as the primary technique and non-cutting HPBD in 23 units. 2 units had their procedure started with HPBD but changed to CBU due to lack of satisfactory dilatation of the VUJ as evidenced by failure of resolution of 'waisting' on fluoroscopy. There was no significant difference in the degree of resolution of upper tract dilatation when pre and post-operative measurements between cutting and non-cutting balloons were compared as shown in Table 3. 20/61 (33%) of the renal units were in infants (<12months) and 8(13%) had severe pre-operative distal ureteric dilatation of 25 mm or more. No significant difference in the degree of post-operative hydroureteronephrosis resolution was demonstrated between infants vs older children ($p = 0.433$) as well as under vs over 25 mm DUD ($p = 0.841$).

5 children (9%) experienced 6 procedure related complications. These included post-operative vesicoureteral reflux (VUR) in 2 patients (1 required endoscopic treatment), 2 stent complications, 1 post-operative UTI and there was failure to cannulate the ureteric orifice in 1 patient in which case the VUJ was accessed antegrade (Table 4). 8 of the 61 renal units (13%) had further procedures to treat persistent/recurrent POM. 5/8 had repeat balloon dilatation following which they all required nothing further. The remaining 3 had ureteric re-implantation as the next step following poor response to the 1st dilatation. 2 procedures were performed for other complications (Table 4). Hence, 87% were successfully treated with a single dilatation, 95% success after 2 dilatations and the overall re-implantation rate in this cohort was 5%.

Lack of change in or worsening post-operative upper tract dilatation measurements on ultrasound or/and MAG3 drainage curve were the main indications for further procedures. There was no statistically significant difference in the median pre-operative APD ($p = 0.19$) and DUD ($p = 0.752$) between those that required further procedures and those that did not. Similarly, there was no significant difference in the pre and post-operative MAG3 function between both groups ($p = 0.867$). Having further procedures had no significant statistical relationship with type of balloon used ($p = 0.99$), age under or over 12months ($p = 0.551$), and DUD over 25 mm ($p = 0.70$).

## Discussion

Endoscopic balloon dilatation is increasingly being used in the management of POM as a definitive procedure. 87% of the patients in our cohort were successfully managed with a single dilatation and they required no further intervention after a median follow up period of 2-years. Over 80% success rate has been reported by other studies [9,10,16]. This observation demonstrates a huge shift from historical practice where ureteric re-implantation was the only surgical intervention offered and this was performed in up to 89% of children [17]. EBD can therefore be safely regarded as a definitive management and should be offered as first line given its effectiveness and significantly low morbidity compared to open surgical procedures.

EBD for POM has been considered to be unsuitable or less effective in certain categories of patients. Ureteric dilatation of >25 mm has been suggested as an indication for primary re-implantation [18]. Beloy et al. excluded these patients from management with HPBD [10]. 13% of the patients in this study had pre-operative ureteric dilatation of >/ = 25 mm. There was no significant difference found in the degree of upper tract dilatation resolution and need for further intervention when compared to the group that had pre-operative DUD of <25 mm. Doudt et al. in a systematic review found endoscopic management of POM in <12months less successful than in older children [4]. Another systematic review by Ripatti et al. on the contrary demonstrated no difference [19]. This study found no significant difference in outcomes with EBD in <12 months, which constituted 33% of the study population, compared to older children. EBD is therefore shown to be an effective treatment of POM in infants and older children as well as in those with severe ureteric dilatation.

Endo-ureterotomy using a cutting balloon is a recognised option for VUJ dilatation and it is being increasingly used [15]. Very little evidence is however available on how CBU compares with simple HPBD in terms of effectiveness in the management of POM in children. Cutting balloon was used as the primary method of VUJ dilation in 59% of the cases presented. There was no significant difference in the degree of resolution of both APD and DUD measurements when cutting and non-cutting balloon were compared. Capoozza et all recommended using a cutting balloon when satisfactory dilatation as demonstrated by resolution of 'waisting' on fluoroscopy is not achieved with simple balloon [20]. This approach was employed in 2 patients in this cohort. Both devices offer comparable outcomes and may be effectively used individually or in combination to achieve optimal dilatation.

13% had re-intervention for persistent POM. No pre-operative predictor of response to EBD could be identified as there were no significant differences in the pre-operative upper tract measurements and MAG3 function when those that needed further procedures were compared to those that responded. Second balloon dilatation was successful in all of the cases where it was attempted with no further requirement for intervention during the follow up period. The 3 cases that had ureteric re-implantation had it after a single failed EBD. Our observation is that re-implantation procedures after single EBD attempt tend to be performed at the early stage of surgeons' experience with EBD. Willingness to repeat EBD seemed to increase as more experience with its use was gained. Repeating EBD is therefore shown to be effective and is worth attempting before proceeding to ureteric reimplantation.

Failure to pass guidewire or balloon into the VUJ has been reported in about 10–25% of EBD attempts for POM

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[4,21,22]. This was an indication to abandon the procedure and proceed to ureteric re-implantation in some reports [22—24]. Thicker guide wires were often used in these cases. This difficulty was experienced in only 1 (1.8%) of the cases in this study. Based on our experience, we found the use of fine and flexible guide wire (0.014inch) to be key to successful cannulation of the usually tiny VUJ in these patients. A useful technique to help stabilise and control the manipulation of the flimsy guide wire, is to pass it inside a 3fr ureteric catheter. Once the guide wire is in the ureter, the 3Fr ureteric catheter is passed over it to facilitate a retrograde study. Once position is confirmed, the ureteric catheter is replaced by the balloon catheter which is advanced over the guide wire and VUJ is dilated under both cystoscopic and radiological guidance. The small guidewire is replaced with a stiffer 0.035-inch guide wire and used to place a double J stent. Using the appropriate kit could make a significant difference and prevent avoidable more invasive surgical interventions.

## Conclusions

Endoscopic balloon dilatation is shown to be an effective definitive surgical management option of POM with 87% requiring no further intervention after a single dilatation following 2 years median follow up. Success rate increased to 95% after 2 dilatations. Optimal response to EBD as demonstrated is not limited by degree of ureteric dilatation or age. It can therefore be safely offered as first line management in all patient groups. Second balloon dilatation was successful in all of the cases where it was attempted. We recommend attempting a repeat dilatation before proceeding to reimplantation in those with poor response to the first dilatation. No difference in outcome was demonstrated between cutting and non-cutting balloon. The 2 devices can be used in combination to achieve optimal result.

## Funding source

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

## Ethical approval

Ethical approval was not required.

## Conflict of interest

The authors declare no conflict of interest.

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