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ORIGINAL ARTICLE

Efficacy and Safety of Endoscopic Balloon Dilatation for Treatment of Primary Obstruction Megaurater Up to 2 Years of Age

TARIQ AHMAD[1], SHER WALI KHAN[2], MUHAMMAD JAVED KHAN[3]
[1]*Assiatant Professor, Pediatrics Urologist Institute of Kidney Diseases Hayatabad Medical Complex, Peshawar*
[2]*Resident Urologist Institute of Kidney Diseases Hayatabad Medical Complex, Peshawar*
[3]*MBBS FCPS CHPE, Assistant Professor Paediatric Surgery, Bacha Khan Medical College Mardan*
Corresponding author: Sher Wali Khan, Email: sherwalikhan637@gmail.com

ABSTRACT

Endoscopic balloon dilatation (EBD) can be performed with different catheters and its durability is still controversial. The study aimed to compare long-term results of EBD performed <20 months of age using balloons of 4 mm vs. 6 mm in diameter. Retrospective study conducted of consecutive patients with unilateral primary obstructive megaureter (POM) undergoing EBD <24 months of age by two surgeons from January 2020 to January 2022. The technique was consistent, but for balloon diameter was 5 mm in group A vs. 6 mm in group B. End-points included peri-operative complications, success rate (improving dilatation and non-obstructive drainage on 9-month scintigraphy), and long-term outcome (need for reimplantation and diameter of retrovesical ureter at last ultrasound).

The procedure was completed in all planned patient. Group A included 30 patients and Group B 60 patients. Groups were not significantly different for age ($p < 0.09$), gender ($p < 0.1$), laterality ($p < 0.7$), and preoperative median ureteral diameter (p Z 0.08). No perioperative complications occurred. Four group A patients required a cutting balloon to achieve a satisfactory dilatation of the vesicoureteral junction (p Z 0.009). After a median (range) follow-up of 70 (19e155) months, success rate was 73.3% vs. 83.3% (p Z 0.45), 4/15 group A and 5/30 group B patients required reimplantation within 2 years of EBD. In successful cases, median (range) ureteral diameter at last follow-up was 6 (0-17) mm vs. 5 (0-16) mm, which was significantly better than preoperative value (p Z 0.003 and $p < 0.001$, respectively), but not significantly different (p Z 0.8) between groups. EBD is an umbrella term that encompasses many technical variations, which can be key for success. Although limited by the small numbers and the comparison of patients treated over two subsequent periods, this is the first study focusing on the role of balloon size. The diameter of the balloon did not influence significantly long-term results, but the 6 mm balloon slightly increased the success rate of EBD to 83.3% and eliminated the need for cutting balloons to achieve a satisfactory dilatation.

INTRODUCTION

Ureteroneocystostomy is the gold standard in the treatment of primary obstructive megaureter (POM) (Peters et al., 1989: Stehr et al., 2002) Endoscopic procedures, however, are attractive, particularly in infants where ureteroneocystostomy can be technically challenging and carries the risk to harm bladder function long-term (Farrugia et al., 2014). The simplest endoscopic procedure for the treatment of POM is the insertion of a JJ ureteral stent across the vesicoureteral junction (VUJ). This procedure, however, has limited efficacy as definitive treatment (Farrugia et al., 2014; Doudt et al 2018). In 2007, Kajbafzadeh et al. reported the use of an endoureterotomy in 47 infants with complete resolution of ureterohydronephrosis in 71% of cases after a mean follow-up of 39 [14e62] months (Kajbafzadeh et al., 2007). Endoscopic balloon dilation (EBD) of the VUJ has recently emerged as the endoscopic treatment of choice for POM. Described for the first time by Angulo in 1998 (Angulo et al., 1998). It was initially intended as a procedure to temporize surgery in infants. Subsequently, however, with accumulating experience, the same authors proposed it also as a definitive treatment in patients of any age (Romero et al., 2014). A systematic review published in 2019 reported a cumulative success rate for EBD of 87.7% and very low morbidity (Romero et al., 2019). Despite initial concerns, accumulating evidence has also confirmed the durability of EBD (Beloy et al., 2018) EBD, however, is a generic term. It can be performed with several different instruments, and as for many endoscopic procedures, technical details are key for success. No studies comparing different techniques are available to date. In our experience, we initially used a smaller 4 mm large balloon for the concern to harm the VUJ, but, at some point, with increased experience and confidence, we changed to 6 mm large balloons assuming that wider balloons could be more effective. We also used cutting balloons whenever EBD looked unsatisfactory after dilatation. The aim of the present study was to compare long-term results of EBD performed in patients under 24 months of age using balloons of 4 mm vs. 6 mm in diameter. Our hypothesis was that a larger balloon could make the procedure more successful.

MATERIALS AND METHODS

The current study was done in institute of kidney disease Hayatabad medical complex Peshawar, Pakistan. After institutional review board approval, we retrospectively reviewed all consecutive patients undergoing EBD for unilateral POM <20 months from January 2020 to January 2022. Only patients treated by two surgeons were included in order to reduce heterogeneity. Patients with associated urinary anomalies (megaureter in solitary kidney, bilateral uropathy, or syndromic patients) were excluded as well as patients with follow-up shorter than one year. Preoperatively, all patients were assessed by bladder ultrasound(s) (US) (documenting a hydroureteronephrosis with retro-vesical ureter >10 mm), technetium-99 mercaptoacetyltriglycine (MAG-3) diuretic renography(s), and voiding cystourethrography (VCUG) to rule out vesicoureteral reflux (VUR). No patient was on antibiotic prophylaxis before EBD and no one was circumcised. Indications for treatment included urinary symptoms, progressive dilation, or loss of kidney function on subsequent scans. All procedures were performed under general anesthesia and the technique was consistent in all patients (Capozza et al., 2015). Cystoscopy was performed with an 8e9.8 Fr Wolf cystoscope with a 4 Fr working channel. The VUJ was negotiated with a 0.018-inch guidewire (Terumo) and a retrogradepyelographyper formed. A balloon catheter (Passeo) was then inserted over the guide wire across the narrow segment showed by the pyelography. The balloon was 4 mm in diameter in patients operated before September 2015 (group A) and 6 mm in those operated thereafter (group B). Of note, the size of the deflated balloon catheter is the same for the two sizes. The balloon catheter was inflated with contrast initially to a pressure of 3e4 atm to show the narrowing of the VUJ, the so-called ring, and then to a pressure of 12e14 atm. The dilatation lasted at lease 5 min and was prolonged for 2 min after the disappearance of the ring. Inpatients with a persistent ring after 15min of dilatation at 14 atm, an additional VUJ dilatation with a cutting balloon (Boston) was performed. A 4.5 Fr JJ ureteral stent (Gyrus Acmi) was inserted after the dilatation and was removed after one month. A bladder catheter was left indwelling for 24 h. Patients were kept on antibiotic prophylaxis until removal of ureteral stent.

Postoperative follow-up included renal and bladder ultrasound at 3 and 6 months, and a MAG-3 renography at 9 months after EBD. VCUG was not routinely performed in asymptomatic patients. During follow-up, our policy did not include any attempt at secondary dilatation, whereas reimplantation was offered to patients developing symptoms (such as febrile UTI or abdominal pain) or failing to show improvement on US and MAG3 scans. Endpoints compared between groups included: technical problems in placing the balloon and performing the dilatation; anatomical resolution of the ring and the need for an additional dilatation with a cutting balloon; intraoperative complications; short-term success rate defined as improving dilatation and improved drainage on 9-month MAG3 scintigraphy (T1/2 < 20 min); long-term outcomes defined as the need for reimplantation, or ureteral diameter at last follow-up ultrasound in patients not requiring reimplantation; and final success rate defined as no need for secondary procedures, absence of symptoms, and improving dilatation and drainage. Data were gathered in an Excel sheet and reported as median [range] or rates. Non-parametric tests were used throughout including Mann-Whitney U test for unpaired continuous variables, the Wilcoxon test for paired continuous variables, and the Fisher's exact test for categorical variables. SPSS software

Table 1: patient characteristics and outcomes of the study

	Overall n= 80	Group A n= 30	Group B n=60	P value
Age at EBD Median [range] months	10 [6-21]	10 [6-20]	15 [6-21]	0.08
Male Gender n (%)	40 (50)	25 (83.3)	40 (66.6)	0.1
Left side n (%)	45 (56.25)	22 (73.3)	34 (56.6)	0.6
Pre-operative ureteral diameter Median [range] mm	18 [10-28]	20 [13-28]	38 [10-25]	0.09
Follow-up Median [range] months	80 [19-155]	150 [55-155]	87.5 [19-90]	<0.0001
Ureteral diameter at last FU Median [range] mm	6.7 [0-17]	7 [0-17]	8 [0-14]	0.7
Post-operative T1/2 < 20 min n (%)	40 (50)	29 (96.5)	40 (66.6)	2
Post-operative renal function Median [range] DRF	52 [23-55]	49 [39-55]	54 [23-53]	0.5
Final success rate n (%)	34 (42.5)	24 (80)	43 (71.6)	0.56

was used for statistical analysis. A p value < 0.05 was considered statistically significant.

RESULTS

We identified 35 patients meeting the inclusion criteria, no patients underwent any other kind of surgery for POM during the study period. Group A included 30 patients and group B 60 patients. There was no significant difference found between groups in baseline characteristics. Preoperative UTIs occurred in 7 patients of group A and 12 of group B. In all POM the VUJ could be negotiated with the balloon and the procedure was completed in all planned patients without intraoperative or postoperative complications. Four group A patients vs. zero group B patients (p < 0.009) required a cutting balloon to achieve a complete disappearance of the ring. No patient developed symptoms during follow-up, including UTIs. At 9 months' follow-up, 11 (75%) group A patients vs. 25 (87%) group B patients showed improved upper tract dilatation on US scan and improved drainage pattern on MAG-3 scan. The remaining 9 patients, 4 (25%) in group A and 5 (13%) in group B (p Z 0.45) proceeded to ureteral reimplantation. Ureteral reimplantation did not present particular technical difficulties in any case and it was uneventful and successful in all patients. No patient required reimplantation after the second year of follow-up. In the successful cases, after a median follow-up of 69 [24-155] months, ureteral diameter significantly improved in each group (p Z 0.003 and p < 0.001, respectively), without difference between groups. The final success rate was not significantly different between groups, 73.3% in group A vs. 83.3% in group B, p Z 0.45.

DISCUSSION

This is the first study, to our knowledge, assessing the influence of balloon size on the results of EBD for the treatment of POM. We found no significant difference in the considered endpoints; however, the larger balloon eliminated the need for an additional cutting balloon to achieve resolution of the ring. While described in 1998 as a temporizing procedure (Angulo et al., 1998). According to our that EBD can be a definitive minimally invasive treatment of POM alternative to ureteral reimplantation, feasible also in infants (Destro et al., 2020; Christman et al., 2012). Garcia-Aparicio et al. compared the outcomes after EBD vs. ureteral reimplantation and observed no significant differences in improvement of hydroureteronephrosis, differential renal function, postoperative VUR, and need for secondary ureteral reimplantation between the two procedures (Garcıa-Aparicio et al., 2013). EBD could be particularly appealing in infants where reimplantation presents peculiar challenges as the disproportion between the grossly dilated ureter and the small bladder increases the risk of postoperative VUR due to a short tunnel, and the peripheral bladder denervation during dissection carries the risk of long-term bladder disfunction (Farrugia et al., 2014; Perdzynsk et al., 1996). Even if EBD fails, the temporary relief of the obstruction allows postponing reimplantation, and, in our experience, did not make reimplantation more difficult anyhow. Moreover, although we elected reimplantation in all our failing EBD, repeated endoscopic dilatation might also be an option. Ortiz et al. reported a second dilatation to be effective in 8 out of 9 (88.9%) cases experiencing persistent/ recurrent obstruction after a first attempt (Ortiz et al., 2018). Regarding the technique, EBD is an umbrella term with many variants described. Differences include the type and size of the balloon used, as well as the way in which the procedure is carried out. As far as the type of balloon is concerned, we initially used a 4 mm balloon and added a cutting balloon ureterotomy in cases with a persistent stenotic ring (Capozza et al., 2015). Others have proposed a combination of endoscopic procedures in case of a long narrow segment or persistent ring at the VUJ. Christman et al. used laser incision of the VUJ before balloon dilation in cases with evidence of a long narrowing at the VUJ, between 2 and 3 cm (Christman et al., 2103). Kassite et al. used rigid dilators in case of persistent ring after the EBD (Kassite et al., 2017). In our opinion, a larger balloon avoids the need for these more articulated strategies without any effect on the feasibility of the procedure which we could complete in all patients. This compares favorably with the 71.8%-100% range reported in the literature. Regarding other technical variants, Beloy et al. performed EBD under direct vision during endoscopy without any use of fluoroscopy (Beloy et al., 2018), and about half of the authors did not perform a retrograde ureteropyelography before EBD. We still believe both aspects to be important in order to assess the anatomy, i.e. length of the VUJ narrowing and presence of a ring. Regarding the latter, we emphasize that, fluoroscopic checking of the procedure filling the balloon with contrast allows documenting the resolution of the ring. The presence of a stenotic ring, however, is not consistently reported (Capozza et al., 2015; Destro et al., 2020; Ortiz et al., 2018; Angerri et al., 2007). We previously reported this to be a predictor of long-term success (Capozza et al., 2015), and Destro et al. describe 3 possible variants of the appearance of the ureteral orifice on cystoscopy and fluoroscopy, and concluded that an intramural stenotic ring is the variant more likely to resolve with EBD (Destro et al., 2020). Chiarenza et al. suggested other anatomical characteristics potentially associated with failure of EBD and the need for reimplantation including an ostium placed in a bladder diverticulum or with a very tight diameter, and a stenotic tract longer than 1 cm (Chiarenza et al., 2019). After EBD, as most authors, we left a double J stent for 1e2 months. Christman et al. recommended a double stenting as the relative motion of the two stents with peristalsis would determine a more effective expansion of the VUJ and prevents synechia formation (Christman et al., 2012). Some authors also recommend calibrating the VUJ at the time of stent removal, negotiating it with the cystoscope or with a

balloon filled at low-pressure (Romero et al., 2014; Garcı a-Aparicio et al., 2013; Ortiz et al., 2018; Garcıa-Aparicio et al., 2015). Faraj et al. recently compared two groups of children undergoing EBD for POM with and without double J stenting. They reported that the absence of postoperative ureteral drainage seems to decrease postoperative complications rates without altering the success rate (need of further procedure after endoscopic balloon dilatation and the improvement of the ureteral diameter at the postoperative US) (Faraj et al., 2022). We did not observe major postoperative complications, but EBD can be associated with postoperative complications. Early complications are generally related to ureteral stenting and include stent migration and postoperative urinary tract infection (UTI). Kassite et al. reported the incidence of postoperative UTI to increase if the ureteral stent is left in place for longer than 3 months (Kassite et al., 2017). UTI can also be due to secondary VUR, which prevalence ranges between 5 and 27% (Kassite et al., 2018). Garcia-Aparicio et al. reported VUR to be more common in patients with a paraureteral diverticulum ($p > 0.05$) and bilateral POM ($p > 0.05$), but to be often transient (Aparicio et al., 2015). For the latter, we generally recommend a VCUG only in symptomatic patient. Next to the technique, also follow-up investigations performed after EBD seem to be quite variable as well as the criteria used to define success. Generally, the outcome parameters considered after EBD include postoperative improvement in the degree of hydroureteronephrosis on the renal-bladder ultrasound, and changes in differential renal function and drainage pattern on MAG3 renography. These outcomes, however, are not consistently reported and this emphasizes the need to define standards to assess these patients. Regarding the success rate, considering only the patients who did not require ureteral replantation, it is 86.8% [46.9e100%]. Taking into account, instead, any secondary procedures, such as re-dilations or the endoscopic treatment of VUR, the success rate drops to 75.3% [21.9-100%]. Of note, in present series the success rate, although not statistically different was slightly higher with the 6 mm wide balloon. This could be a clinical advantage and a worthy goal for a future prospective study. The long-term durability of EBD is an additional matter of concern. All our cases requiring surgery did so within the second year after surgery and the lack of a clear improvement was already evident at the 9-month follow-up assessment. In the remainder, results remained stable after a median follow-up of 70 [19-155] months. Bujons et al. reported a 90% long-term success rate in 19 patients with a mean follow-up of 6.9 [3.9-13.3] years (Bujons et al., 2015). Similarly, Beloy et al. reported no patient needing re-intervention during a median follow-up of about 10.3 [4.7-12.2] years (Beloy et al., 2018). Major limitations of study include its retrospective nature and the comparison of patients treated over two subsequent periods. Consistently, the shorter follow up and a learning-curve effect might account for the slightly better results in Group B. Regarding the length of follow-up, however, it is noteworthy, as mentioned before, that most of our failures were detected early. Still, this study focused only on patients younger than 24 months at treatment. However, this is also the age group that can benefit the most of such a treatment.

CONCLUSIONS

EBD is a safe, feasible, and minimally invasive treatment for primary obstructive megaureter in patients upto 2 years of age with durable results. In our experience, the diameter of the balloon did not influence significantly long-term results, but completely eliminated the need for cutting balloons to achieve a satisfactory dilatation without compromising the possibility to accomplish the procedure.

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