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*Review Article*

# Endoscopic balloon dilation vs ureteral reimplantation for the treatment of primary obstructive megaureter: a meta-analysis of case series studies

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**Abstract:** Objective: This essay is to evaluate the clinical efficacy and complication rates of endoscopic balloon dilation (EBD) vs ureteral reimplantation (UR) in the treatment of primary obstructive megaureter (POM) based on the current status of the literature. Materials and methods: A systematic literature search through PubMed, Science Direct, the Cochrane Library was performed. The inclusion criteria were: 1) patients with POM, 2) use of EBD or UR as the first treatment, 3) each case series study not less than one patient, 4) the clinical efficacy was reported. The complication rates were also quantified from the available studies. Any study with incomplete data or repeat data was excluded. A proportional meta-analysis was performed on both outcomes by a random-effect model. Results: Forty-three studies (10 studies for EBD, 33 studies for UR) were included. The pooled proportion of clinical efficacy was 92% in EBD therapy from a total 169 of POMs. There was significant heterogeneity ($I^2$ = 54.9%) between the studies showing the inconsistency of clinical and methodological aspects. The pooled proportion of clinical efficacy was 92% in UR therapy from a total 631 POMs. There was no heterogeneity ($I^2$ = 24.5%) between the studies. The complication rate of UR seemed lower than that of EBD (6.1% vs 12.0%), but with no statistically significant difference. Conclusions: This meta-analysis shows that both EBD and UR have similar efficacy for POM. However, random controlled clinical trials are urgently needed to determine which procedure is the most suitable for the treatment of POM.

**Keywords:** Endoscopic balloon dilation, ureteral reimplantation, primary obstructive megaureter, meta-analysis

## Introduction

Megaureter is defined as a congenial condition which may be classified as obstructive, refluxing, refluxing and obstructive, or non-refluxing and non-obstructive by King in 1980 [1]. Primary obstructive megaureter (POM) is caused by abnormal peristalsis of the distal ureter that resulting in a functional obstruction. Almost 80% of POM are diagnosed prenatally and relieve spontaneously. That is why the conservative management is required for majority of megaureter [2-4]. The followings are the key indications for surgical management: recurrent urinary tract infections (UTI), progress of hydroureteronephrosis and impairment of differential renal function.

Traditionally, the main surgical management for POM is ureteral reimplantation (UR) with or without ureteral tapering which has a success rate of 90-96% [5]. It can be performed by open, laparoscopic or robotic approach. But UR is difficult in newborns or young children, and it is not the most minimally invasive surgery. With the development of minimally invasive surgery, alternative management for treating POM have been sought. In 1998, Angulo firstly reported endoscopic balloon dilation (EBD) for POM [6]. It is usually performed by an endoscopic high-pressure balloon to dilate the stenosed ureter. Since then, some studies about EBD have been reported. Sometimes, holmium laser or cutting balloon may be performed to cut narrow ring of ureter combining with EBD. These studies conclude that EBD is a safe, feasible and minimally invasive procedure whose success rate ranges from 85% to 100%. Especially for the young patients, EBD may be a less invasive alternative.

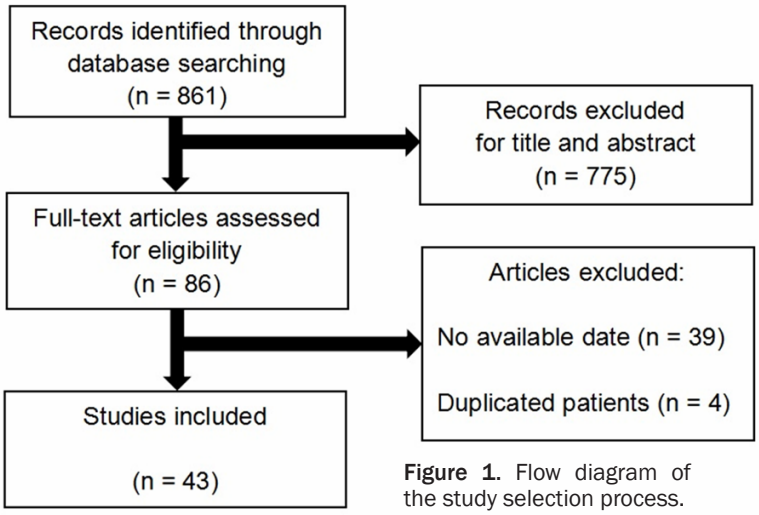


**Figure 1.** Flow diagram of the study selection process.

In spite of several series of EBD and UR for the treatment of POM, there is still no randomized controlled trial comparing the two procedures. Therefore, to clear up which is the superior procedure, we perform a proportional meta-analysis of case-series studies to evaluate the clinical efficacy and complication rates of EBD and UR [7, 8].

## Materials and methods

### *Inclusion and exclusion criteria*

The included studies should include the following criteria: 1) patients with POM, 2) use of EBD or UR as the first treatment, 3) case series studies (number of reported patients in each study not less than one, 4) the clinical efficacy was measured by the specified follow-up imaging. The clinical efficacy was defined as the percentage of megaureters treated successfully by EBD or UR. The successful treatment of POM was defined as no recurrent obstruction, no reflux and no symptoms. We also quantified the complication rates from the available studies. Any study with incomplete data or repeat data was excluded.

### *Study selection and data extraction*

A systematic literature search through PubMed, Science Direct, the Cochrane Library was performed up to November, 2015. The search terms were as follows: (megaureter OR primary obstructive megaureter OR primary megaureter OR ureteropelvic junction obstruction) OR (endoscopic balloon dilation OR endoscopic dilation OR high-pressure balloon dilation OR endoscopic OR balloon) OR (ureteral reimplantation OR ureteroneocystostomy OR reimplantation). The reference lists of the related articles were also searched for any additional included studies.

Two independent reviewers based on the title and abstract complete the initial screen. Then, data were extracted from the identified articles by a reviewer and checked by another reviewer. The following information was obtained from each article: first author's name, publication year, country, study type, number of patients, number of megaureters, patients' characteristics, complications, follow-up outcomes. If there were repeat outcomes published from the same group, we extracted the data from the most recent or most complete article. The mean age and mean follow-up time calculated in this study were based on the mean age and mean follow-up time from included studies.

### *Statistical analysis*

The clinical efficacy and complications rates were regarded as the dichotomous variable with their respectively 95% confidence interval (CI). A proportional meta-analysis was performed by a random-effect model resulting from the clear differences among the included studies and several uncontrolled variables. Significant heterogeneity across studies was denoted by an $I^2 > 50\%$ or $P < 0.05$. The STATSDIRECT software was used to plot the included studies into a meta-analysis.

We used forest plots to summarize the data. The solid black square represents the effect estimate of each study and the length of each horizontal line on forest plot corresponds to a 95% CI of the corresponding studies' effect estimate. The size of the black square represents the weight of each study. At the bottom of the forest plot, an unfilled diamond was displayed as the pooled estimate. A horizontal line through the diamond corresponds to CI of pooled estimates [7].

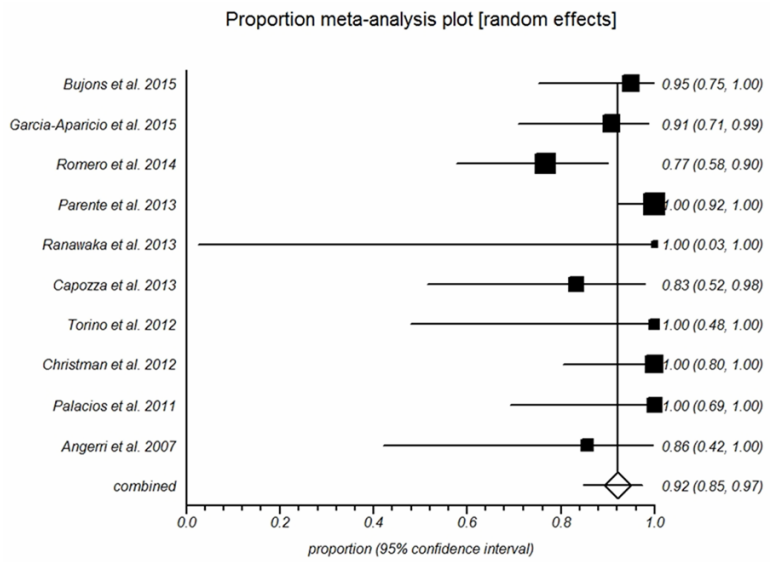


**Figure 2.** Proportional meta-analysis of EBD studies regarding clinical efficacy.

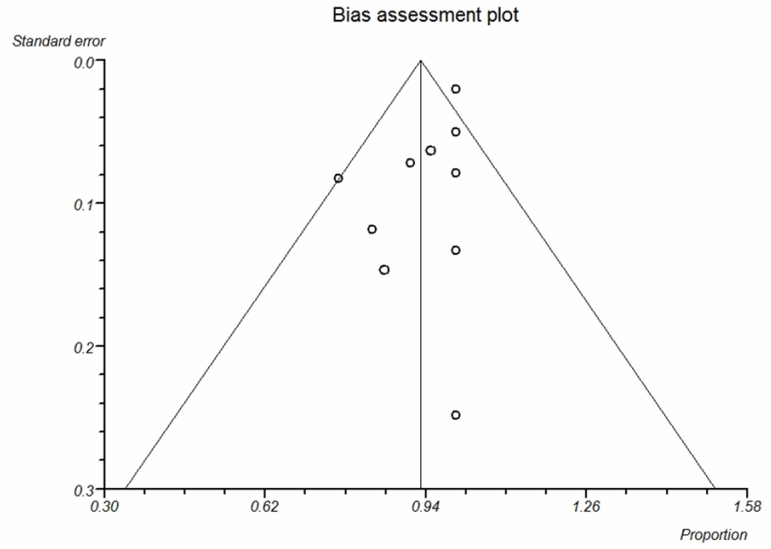


**Figure 3.** Funnel plot of EBD studies regarding clinical efficacy by Egger test.

The possibility of publication bias was assessed by funnel plots using Egger tests. The significant statistical difference between two procedures was defined if their combined 95% CIs did not overlap. A $P < 0.05$ was regarded as significant for the calculation of heterogeneity [7].

## Results

We finally identified 43 studies (10 studies for EBD [9-18] and 33 studies [12, 19-50] for UR) that met our inclusion criteria and were included in the meta-analysis (**Figure 1**). All included studies were designed retrospectively. None of the studies was randomized. Of these studies, EBD was performed in 169 POMs (163 patients), compared with 631 POMs (600 megaureters for 569 patients, but 31 megaureters for unknown the number of patients) underwent UR. Not all of included studies provided the data of the mean age and the mean follow-up time of patients, so we could not calculate out the accurate date.

The pooled proportion of clinical efficacy was 92% (95% CI = 0.85 to 0.97) in EBD therapy from 10 studies with a total of 169 POMs. There was significant heterogeneity ($I^2$ = 54.9%, P = 0.018) between the studies included in the meta-analysis which showing the inconsistency of clinical and methodological aspects (**Figure 2**).

**Figure 3** displays a symmetric funnel plot regarding the clinical efficacy of the EBD case series by Egger test (95% CI = -2.09 to 0.11, P = 0.07), which means publication bias is unlikely to occur.

The pooled proportion of clinical efficacy was 92% (95% CI = 0.89 to 0.95) in UR therapy from 33 studies with a total of 631 POMs. There was no heterogeneity ($I^2$ = 24.5%, P = 0.104) between the studies included in the meta-analysis (**Figure 4**).

**Figure 5** presents the results of an asymmetric funnel plot regarding the clinical efficacy of UR case series by Egger test (95% CI = -1.14 to -0.16, P = 0.011) which suggests the possible bias of publication.

The pooled proportion of complication rate for EBD was 12.0% (95% CI = 0.05 to 0.22) from

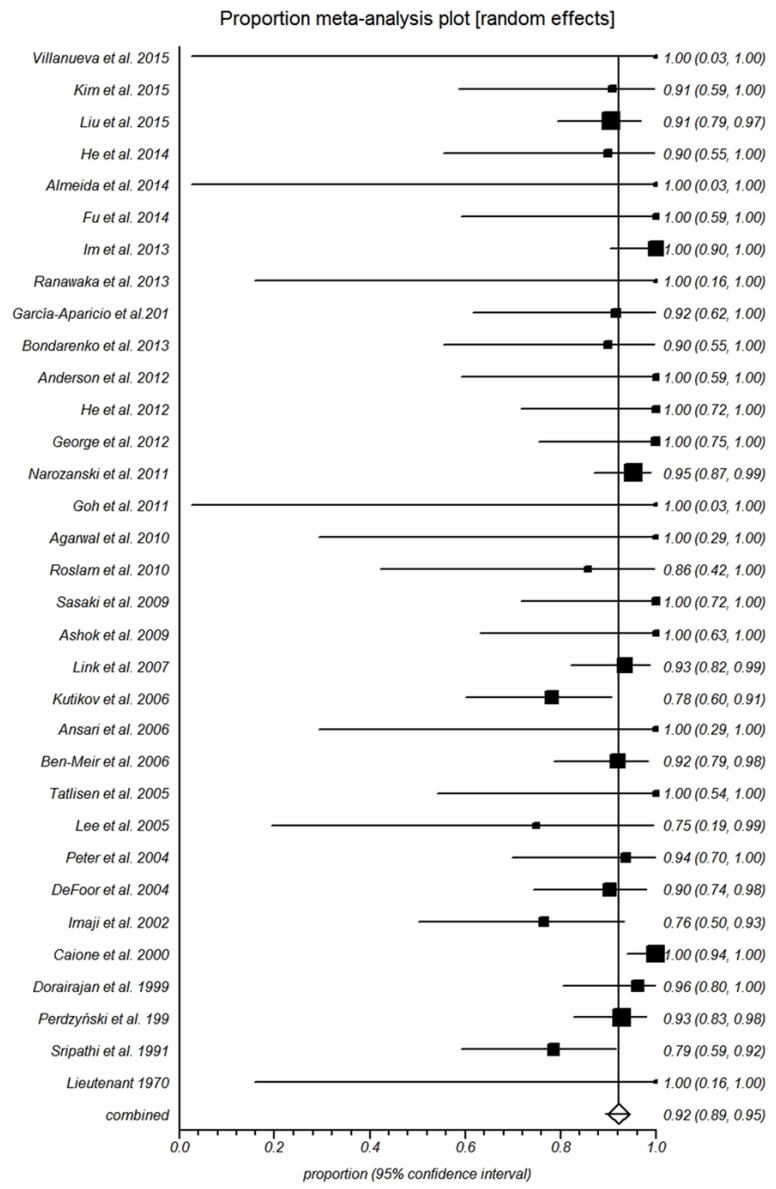


**Figure 4.** Proportional meta-analysis of UR studies regarding clinical efficacy.

10 studies with a total of 163 POMs. There was significant heterogeneity ($I^2$ = 64.2%, P = 0.003) (**Figure 6**).

The pooled proportion of complication rate for UR was 6.9% (95% CI = 0.04 to 0.11) from 31 studies with a total of 536 POMs. There was significance regarding heterogeneity for this outcome ($I^2$ = 51%, P < 0.001) (**Figure 7**).

The complications in patients treated with UR included recurrent urinary tract infection, moderate or severe reflux, recurrent obstruction, urinary leakage. The complications in patients treated with EBD included recurrent urinary tract infection, acute abdominal pain immediately after surgery, ureteral calculi, double-J catheter falling into bladder, recurrent obstruction needing ureteral implantation.

We could find that both EBD and UR had almost equally clinical efficacy, and the complication rate of UR looked like lower than the complication rate of EBD (6.1% vs 12.0%). However, there was no significant difference regarding both clinical efficacy and complication rates between EBD and UR treatment as their CIs overlapped (**Figures 2**, **4**, **6** and **7**).

## Discussion

The term "megaureter" was firstly described by Caulk in 1923 [51] which is used to describe dilated ureters because of congenital anomalies of the vesicoureteral junction. But the definition of a dilated ureter is still not established in previous literature. In 2014, British Association of Pediatric Urologists (BAPU) defined that a prenatal ureteral diameter over 7 mm is abnormal and should be investigated postnatally, and a postnatally ureteric dilatation > 10 mm is indication for a MAG-3 scan to look for the vesicoureteral obstruction after bladder outlet obstruction and vesicoureteral reflux are both excluded [52]. The recognized indications for surgery in POMs are worsening of the differential renal function (< 40%), progressive hydroureteronephrosis, high grade reflux without improvement and failure of conservative management (recurrent febrile UTI, durative pain) [52].

Because the recognition for the etiology of POM is abnormal peristalsis of the distal ureter causes a functional obstruction [53]. The ure-

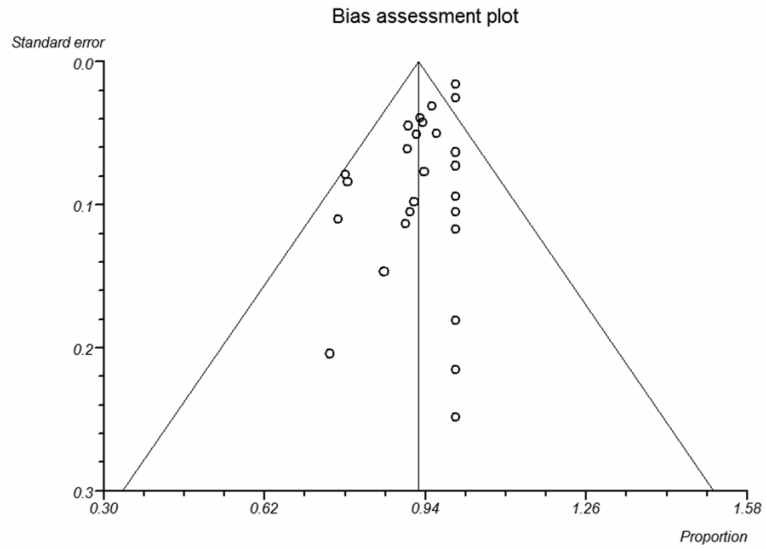


**Figure 5.** Funnel plot of UR studies regarding clinical efficacy by Egger test.

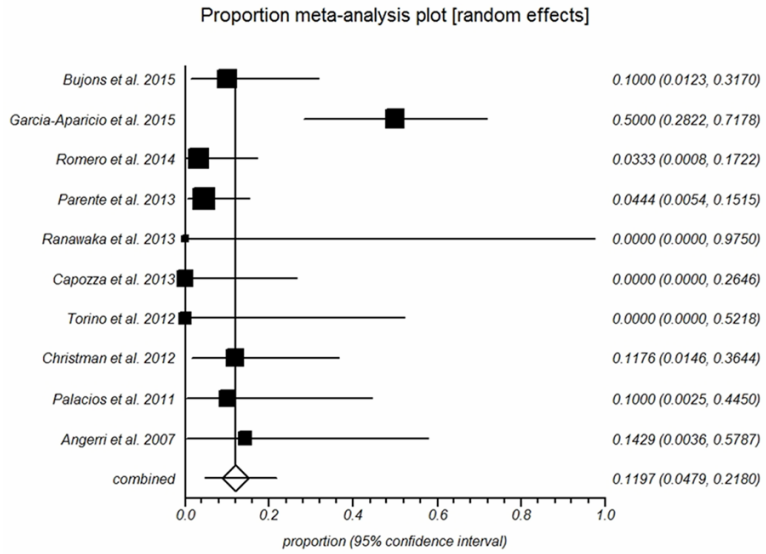


**Figure 6.** Proportional meta-analysis of EBD studies regarding complication rate.

teral reimplantation is regarded as standard surgical management for POM which can achieve the excision of abnormally distal segment of dilated ureter. The reported success rates of UR were more than 90% [9], but complications and morbidity maystill occur. Especially for young patients aged ≤ 2 year and bladder capacity < 130 ml, the surgery is complicated and challenged for surgeons [54]. The complication rates for open UR and laparoscopic UR were 14.7% and 8.3%, respectively [55].

Gradually, in the past three decades, the surgical management of POMs has evolved from primary ureteral reimplantation to initial conservative management because of high rate of spontaneous relief at long-term follow-up time [56, 57]. In addition, minimally invasive procedures have provided the patients with a variety of surgical options, including endoscopic, laparoscopic, robotic procedures. Of the endoscopic procedures, EBD is an interesting procedure for POM that avoids unnecessary open surgery. It was believed to be a safe, feasible, less invasive and effective method. The advantages of EBD over UR are that the distal ureteral blood supply is protected intactly, no invasion of the bladder and abdomen, no drainage tube, allowing for a quick recovery and very short hospitalization. Patients can discharge usually 1 to 2 days after EBD, even they can go home the same day of operation. But the hospitalization may be 3 to 6 days after UR. The learning curve of EBD is also low and it is easy to reproduce by surgeons. However, there is still no randomized and controlled studies comparing EBD with UR. For this reason, a proportional meta-analysis of uncontrolled studies was performed.

In our meta-analysis, significant heterogeneity exists in EBD clinical efficacy ($I^2$ = 54.9%) and complications ($I^2$ = 64.2%) (**Figures 2** and **6**). The reason for heterogeneity might be both methodological and clinical. There were differences in patient selection, severity of disease, dilated techniques, and duration of follow-up in 10 included studies. But a symmetric funnel plot for EBD series suggests publication bias is unlikely to occur.

Our analysis shows that there is no heterogeneity ($I^2$ = 24.5%) (**Figure 4**) in UR clinical efficacy, but significant heterogeneity in UR complications ($I^2$ = 51%) (**Figure 7**). This might suggest

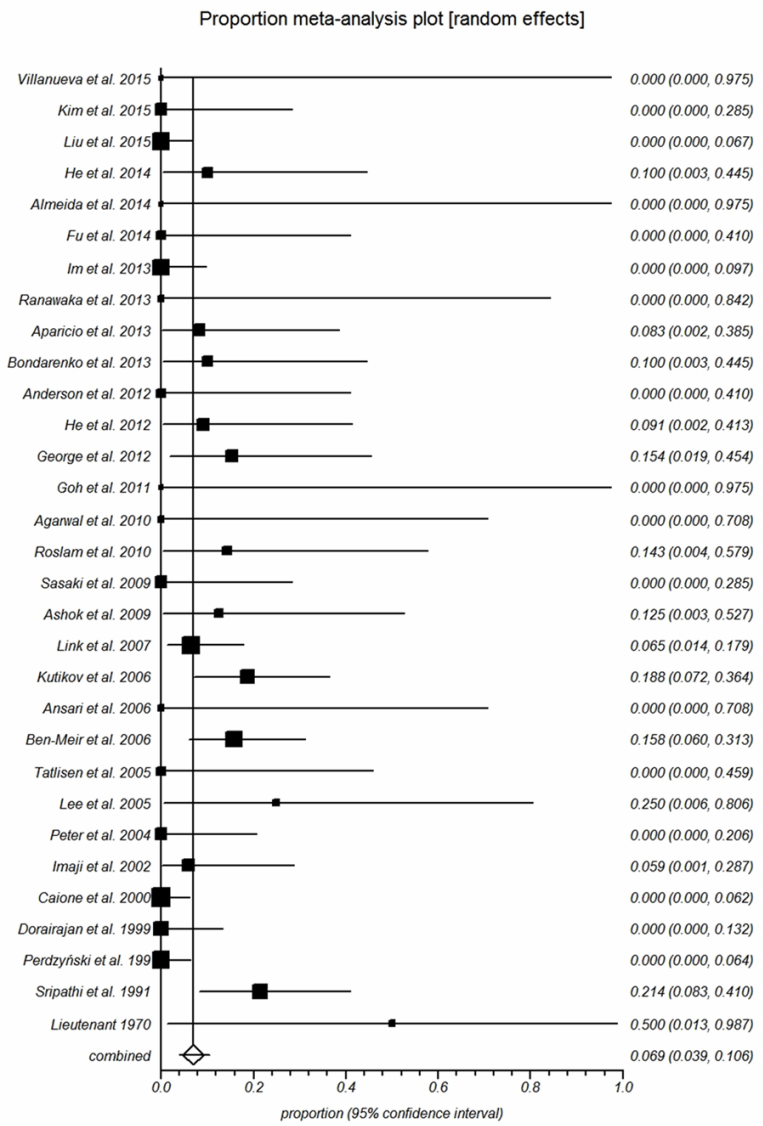


**Figure 7.** Proportional meta-analysis of UR studies regarding complication rate.

that UR series were less consistent in the way they reported complications. An asymmetric funnel plot for the UR series suggests the possibility of publication bias. Actually, we have try our best to collect all the published and unpublished studies about UR for POMs in different languages.

Not all included studies reported the mean age and mean follow-up time of patients, so we could not calculate the accurately mean age and mean follow-up time. We try calculating with the reported data of two series, we found that the mean follow-up time was 44.9 months in EBD group and 44.2 months in UR group, and the mean age of EBD series was younger than that of UR series (20.5 vs 106.3 months). This may suggest us that EBD is more popular in young patients aged < 2 years.

Furthermore, if an EBD approach fail after a long-term follow-up, a UR surgery can be performed. However, no articles about young POM patients reported their outcomes after these young patients became adults.

Although BAPU thought that there was very limited experience with EBD, we still could find that both EBD and UR had almost equally success rate (92%) after a long-term follow-up. The analysis showed that the complication rate of UR looked like lower than that EBD. This might be the reason of less number of EBD patients.

In conclusion, this proportional meta-analysis shows that both EBD and UR seem to achieve equally satisfied outcomes in patients with POM after a long-term follow-up. However, rigorously randomized and controlled studies are needed to determine the exact role of EBD and UR in the treatment of POM.

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## Disclosure of conflict of interest

None.

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