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Primary female epispadias: Perineal approach or Kelly repair?

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Summary

Objectives
Primary female epispadias encompasses a spectrum of disease, presenting with a variable degree of incontinence. We hypothesized that although perineal urethrocervicoplasty can be a successful first-line procedure in patients with normal bladder, a more radical reconstruction was necessary to achieve continence in cases lying at the most severe end of the spectrum. Our aim was to assess the results of a surgical management using perineal approach in girls with normal bladder capacity, and Kelly radical soft-tissue mobilization (RSTM) in patients with inadequate bladder, based on the assumption that bladder capacity (BC) is a reliable marker of epispadias severity.

Study design
Prospective inclusion of incontinent girls with female epispadias referred to a single institution. Patients with normal BC were treated with perineal urethrocervicoplasty (PUCP, group 1). Patients with small bladder underwent RSTM (group 2). Follow-up was at 1, 3, 6, and 12 months postoperatively, then annually, including physical examination, renal ultrasound at each visit, continence status, and estimation of functional/maximal BC. The main study outcome was continence status at the age of 5 years or later, if postoperative follow-up was >12 months.

Results
From 2006 to 2017, 16 consecutive children were prospectively included in this study, at a median age of 39 months (5–102 months). Seven girls were included in group 1 and underwent PUCP; at the last follow-up, five out of seven were dry by day (4/5 day and night), although three out of five required bladder-neck injection after perineal reconstruction due to stress incontinence. Two patients with persistent incontinence and absence of BC increase after PUCP subsequently underwent RSTM. Eleven patients with low BC (56% [10–94%] of expected BC) were included in group 2 (9 without prior surgery, 2 after PUCP failure). Among the eight evaluable patients, eight out of eight achieved diurnal continence, and 3/8 were fully continent. One girl with obstructive micturition required clean intermittent catheterization.

Discussion
The traditional approach of female epispadias based on staged reconstruction (urethroplasty followed by bladder-neck reconstruction) raised concerns regarding the risk of non-physiological obstructive micturition. The perineal approach was suggested as an alternative, with reported diurnal continence rates of 60–80%, but less than 50% of nocturnal continence, presumably in relation with limited bladder capacity. In cases selected within the most severe end of the epispadias spectrum, the Kelly RSTM seems to offer excellent continence rates.

Conclusion
A tailored approach to female epispadias, based on perineal reconstruction in favorable cases, and radical soft-tissue mobilization in severe cases, seems to yield good continence outcomes in the long term.

Table Quantitative data expressed as median (range).

	Perineal reconstruction	Kelly repair
n	7	11
Age at diagnosis (months)	28 (11–102)	39 (5–70)
Bladder capacity at diagnosis (%)[a]	116 (92–143)	56 (10–94)
Age at surgery (months)	32 (14–102)	42 (8–93)
Evaluable	7	8
Continence status *n* (%)[b]		
Dry day/night	4 (57)	3 (38)
Dry by day	5 (71)	8 (100)
Still wearing protections	2 (29)	–
Bladder capacity at final evaluation (%)[a]	82 (56–102)	87% (25–103)
Emptying with CIC	0	1
Additional procedure		
BN injection	3	0
Bladder augmentation	0	0

CIC = clean intermittent catheterization.
[a] Percentage of expected Bladder capacity for age.
[b] Assessed at 5 years or later, after follow-up > 12 months.

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Introduction

Primary female epispadias is a rare congenital malformation that forms part of the bladder exstrophy—epispadias complex, occurring with an estimated prevalence of 1:160,000 to 1:480,000 live births [1,2]. Associated anomalies include wide and short urethra, incompetent bladder neck, bifid clitoris, variable pubic bone diastasis, midline depression on the mons pubis, and ill-defined labia minora. Primary female epispadias in itself is a spectrum of disease, with a wide range of severity in terms of bladder neck deficiency and bladder development, although virtually all affected girls will present with some degree of urinary incontinence [2]. Traditional approach consisted of combination of urethroplasty and bladder neck reconstruction (BNR) [3,4]. An alternative technique described a single-stage perineal approach with urethral lengthening [5], and bladder neck tailoring to reinforce bladder outlet resistances [6—8]. The radical soft-tissue mobilization (RSTM) described by Kelly [9,10] has also the potential to allow anatomical reconstruction within the whole spectrum of bladder exstrophy—epispadias complex, and can be applied for both male and female primary epispadias.

Although it has been shown that at least the mild forms of female epispadias could achieve satisfactory continence results through a limited perineal approach [7,11], it is unknown whether the most severe cases of the spectrum would benefit from this technique. We hypothesized that surgical management of primary female epispadias could be tailored according to the severity of the malformation, with a strategy based on the perineal approach in moderate cases and the Kelly procedure in the most severe, using bladder capacity as a surrogate marker of the degree of severity.

Patients and methods

From 2006 to 2017, all girls referred to a single institution for primary female epispadias management, as part of a supraregional healthcare referral program aiming at centralization of patients with bladder exstrophy and primary epispadias, were prospectively included in the present study after informed consent was obtained.

This study complied with the principles of the Declaration of Helsinki (1964), and received approval from the Institutional Ethical and Clinical Research (Centre d'Investigation Clinique) review board (Nantes, 2006).

Preoperative assessment protocol

All patients underwent evaluation including physical examination, renal assessment (renal ultrasound, serum electrolytes), and urethrocystoscopy with cystography under general anesthesia prior to surgical reconstruction.

Parameters analyzed at preoperative assessment were the width of pubic diastasis, the length of urethra and endoscopic aspect of the bladder neck, bladder capacity, the presence of vesicoureteral reflux (VUR), and intravesical pressure variations during bladder filling.

Normal bladder capacity (mL) adjusted for age was calculated according to the Hjälmas formula: $37.4 + [age_{yrs} \times 22.6]$ in infants girls, and $30 \times (age_{yrs} + 1)$ after 24 months of age [12].

Maximal bladder capacity and bladder compliance were calculated based on the increase in pressure during slow filling to the maximum capacity, with a balloon catheter blocked at the bladder neck to prevent urine leakage.

Bladder status was determined using a combination of these factors, resulting in allocation to two groups: children with adequate bladder (normal bladder capacity, normal compliance, moderate incontinence, normal looking bladder neck, no pubic diastasis, low grade VUR, all criteria present, group 1), and children with inadequate bladder (small bladder or impaired compliance, group 2).

Inclusion criteria were female patients presenting with incontinent primary epispadias, with or without a previous attempt at surgical reconstruction. Patients were allocated to two surgical techniques according to their bladder status: girls with normal bladder were treated with perineal urethrocervicoplasty (group 1), and those with inadequate bladder underwent RSTM (group 2).

Surgical techniques

Perineal urethrocervicoplasty (PUCP) was performed as initially described by Manzoni and Ransley [5], then later modified to include bladder neck tailoring [6,7], and recently detailed by Macedo et al. [13]. A diamond-shape incision allowed excision of the glabrous skin of the mons, pre-pubic abnormal tissue, and the anterior roof of the abnormal urethra up to the bladder neck. The lower bladder neck and the urethral plate were tubularized over an 8—10F catheter, and muscular fibers of the urogenital diaphragm were incised laterally to the urethra and re-approximated on the midline after urethral reconstruction. An indwelling transurethral catheter was left for 8 days postoperatively.

RSTM was performed using a combined pelvic and perineal approach, as described in boys for bladder exstrophy and epispadias repair by Kelly [9,10]. Technical details of this technique can be found at Supplementary material. Through a short transpubic midline incision, the lateral faces of the bladder were exposed, giving access to the superior aspect of the pelvic floor. The most anterior fibers of the levator ani muscle were incised at the level of their insertion on the internal obturator muscle fascia, providing exposure of the ischiorectal fat and the urogenital diaphragm. Initial incision was then extended perineally on both sides. Perineal dissection allowed adequate exposure of the corpora cavernosa, and the use of a muscle stimulator facilitated identification of the bulbospongiosus, ischiocavernosus, and transverse perineal muscles. The periosteum of the ischiopubic rami was peeled away from the branch to allow mobilization of both corpora cavernosa, until the neurovascular pedicle exiting from the Alcock's canal was identified. All striated muscular structures, part of the urogenital diaphragm, linking the urogenital complex to the anterior pelvic ring, were detached from the bone. Further dissection, on the medial aspect of the corpora, allowed separation of the corpora from the urethral plate, which eventually allowed repositioning the bladder neck deeper into the pelvic cavity. Reconstruction included ureteral submucosal cranial reimplantation if necessary,

bladder neck funneling reconstruction after excision of external full thickness triangles, and urethral reconstruction with tubularization over an 8–10F catheter. Muscular fibers detached from the pelvis and fibers of the bulbospongiosum muscle were wrapped around the bladder neck and the upper urethra whenever possible. A corporoplasty was performed by approximating both corpora cavernosa ventrally to the neo-urethra on the midline, and both glans and clitoris were covered by a common clitoral hood. Postoperative drainage relied on ureteric stents for 8–10 days, and a transurethral and suprapubic catheter for 21 days.

Supplementary video related to this article can be found at https://doi.org/10.1016/j.jpurol.2017.08.017.

Postoperative protocol

All patients were prospectively scheduled for assessment at 1, 3, 6, and 12 months postoperatively, then annually until at least the age of 5 years. Assessment included bladder and renal ultrasound at each visit. After toilet-training age, uroflowmetry, post-void residual, and parental standardized evaluation of maximum and functional bladder capacity were systematically performed for each appointment. In case of persistent incontinence, cystomanometry and assessment under general anesthesia including urethrocystoscopy and cystography were performed at the ages of 3 and 5 years.

The main outcome was the continence status at the age of 5 years or later, based on a standardized urinary continence score (Table 1) if postoperative follow-up $>$ 12 months was achieved. Secondary parameters included dryness intervals, onset of upper-tract dilatation, episodes of urinary tract infections (UTIs), indications of obstructive micturition (uroflow, post-void residual, high voiding pressure), functional and maximum bladder capacity, bladder overactivity requiring anticholinergic medications, and need for additional surgical procedures.

Quantitative data were expressed as median (range). Bladder capacity was expressed either in milliliters, or as percentage of the expected bladder capacity adjusted for age. Quantitative data were compared using the Wilcoxon rank sum test whenever necessary.

Results

From 2006 to 2017, 16 consecutive girls with primary female epispadias were referred to our institution and prospectively included in this protocol. A flowchart of these 16 patients is summarized in Fig. 1.

Accurate diagnosis was made at birth or during the first weeks of life (n = 9), or after toilet-training age for chronic wetting (n = 7), at a median age of 54 months (35–102 months).

Table 1 Urinary continence score.

Grade	
0	Complete incontinence
1	Able to retain urine with dry intervals; some "control" but still wearing protections
2	Sufficient dry intervals by day: in underwear, not needing protection; wet at night
3	Dry by day and night: in underwear, no protection

Adapted from Cuckow-P *et al.*
ESPU annual meeting. 2014. Innsbrück, Austria.

Preoperative assessment

Initial evaluation performed at a median age of 39 months (5–102 months) revealed a median maximum bladder capacity (BC) of 79% (0–143%) of expected BC for age (Fig. 2). Uni- or bilateral vesicoureteral reflux was observed in nine out of 16 cases (56%).

Seven girls were eligible for inclusion in group 1, with normal bladder capacity, normal compliance, no or minimal VUR, and minimal pubic diastasis. Their BC was 116% (92–143%) of expected bladder capacity. None of them had undergone previous surgery. They were allocated to group 1 and underwent primary PUCP at a median age of 32 months (14–102 months).

Nine girls with small capacity or poorly compliant bladders were allocated to group 2 (BC 56% [10–94%], VUR 7/9) and underwent primary Kelly RSTM. In addition, two girls from group 1 with failure of PUCP and inadequate bladder growth underwent secondary Kelly repair 52 and 74 months after PUCP, respectively. These two girls were kept in the intention-to-treat for group 1 analysis, but they have also been included in the group 2 results as they met inclusion criteria. Hence, a total of 11 Kelly repair procedures were performed at a median age of 42 months (8–93 months), of which eight (7 primary, 1 secondary) had reached the age and follow-up criteria for analysis. There was no difference in age at presentation or surgery between the two groups.

Therefore, we report the results of seven PUCP procedures and eight Kelly repairs (primary or secondary) that have met the end-point criteria.

Outcome

The 15 reported cases are described after a follow-up of 57 months (15–132 months), at a median age of 8.5 years (5–14.5 years). In an overall analysis (Table 2), 13 out of 15 girls (87%) and eight out of 15 (53%) demonstrated grade 2 or 3 continence, respectively, at the age of 5 years. Two patients (13%) presented with a variable degree of postoperative infravesical obstruction, of whom one required clean intermittent catheterization (CIC).

In group 1 (perineal approach), four out of seven patients (57%) were fully dry days and nights (grade 3) at last follow-up, and one out of seven achieved diurnal continence (grade 2) with persistent night wetting due to limited bladder capacity (82% of expected max BC at 6 years). None of the patients in this group developed upper-tract dilatation or experienced febrile UTIs. However, among these five patients, three out of five with residual stress incontinence after initial surgery required subsequent bladder neck injection of a bulking agent to achieve acceptable dryness, and four out of five showed urge incontinence related to significant bladder overactivity on cystomanometry, and required prolonged anticholinergic therapy. In contrast,

Table 2 Surgical procedures and continence outcomes.

No.	Age at surgery (years)	Need for additional procedure	Further procedure	Obstruction	BC at last follow-up	Age at last follow-up (years)	Final continence score
Perineal approach							
1	3	—	—	Mild	89%	14.0	3
2	1.2	Stress/urge incontinence	BN deflux injection	—	102%	7.8	3
3	8.5	Urge incontinence		—	86%	14.6	3
4	5.3	Stress/urge incontinence	BN deflux injection	—	76%	9.9	3
5	2.7	Stress incontinence	BN deflux injection	—	82%	6.1	2
6[a]	1.6	Yes	Kelly RSTM	—	59%	5.8	1
7	1.2	Yes	Kelly RSTM	—	56%	5.0	1
Kelly RSTM							
1[a]	7.8	—		—	97%	13.4	3
2	1	—		—	100%	9.0	3
3	4.1	—	CIC	Severe	92%	9.8	3
4[b]	3.5	—		—	—	5.8	2
5	4.5	—	May need bladder augmentation	—	34%	8.7	2
6	2.5	—		—	87%	5.5	2
7	2.6	—		—	103%	5.5	2
8	5.8	—		—	25%	7.1	2

BN = bladder neck; CIC = clean intermittent catheterization; RSTM = radical soft-tissue mobilization ; BC = bladder capacity (% of expected BC for age).

[a] Patient no. 6 (group 1) underwent secondary RSTM (no. 1 group 2) after failure of primary perineal approach.

[b] Patient lost for follow—up at the age of 5.8 years, 27 months after surgery.

one out of five showed transient symptoms of mild infravesical obstruction (obstructed uroflows with normal upper tract, without post-void residuals or UTI) and remains under close monitoring after a follow-up of 11 years. Two girls with initially acceptable bladders didn't achieve daytime continence due to poorly growing bladders: at last follow-up after PUCP (5 and 6 years of age), bladder capacity was estimated at 100 and 120 mL (55% and 58% of expected BC, respectively). They underwent a secondary RSTM procedure, and are subsequently reported in group 2.

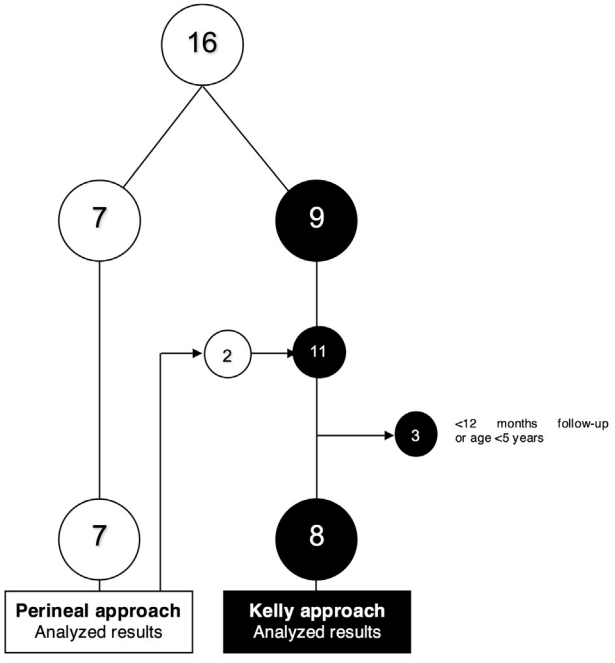

Figure 1 Patient flowchart.

In group 2 (Kelly RSTM procedure), eight out of 11 girls were eligible for final analysis (age < 5 years, $n = 1$; follow-up < 12 months, $n = 2$). Among these eight patients, all were dry by day at 5 years or later (grade 2 continence), and three out of eight were dry day and night (grade 3); seven out of eight showed normal bell-shape uroflow curves, normal detrusor voiding pressures, and no post-void residuals. One girl with an obstructive uroflow pattern, high voiding pressures, and dilating upper tract required intermittent catheterization. As yet, none of the patients have required bladder augmentation, although limited bladder capacity was clearly accountable for nocturnal incontinence in two patients who may eventually require augmentation. It seemed that bladder growth was the main factor allowing night continence to be achieved: patients with grade 2 continence still showed insufficient bladder capacity (49% of expected BC; 25—87%), as opposed to those dry by nights (92% of expected BC; 69—100%). Improvement of continence score and bladder capacity was observed in parallel with time after surgery: grade 3 continence was recorded in girls at 69 months (67—96 months) of follow-up after reconstruction compared with 34 months (15—49 months) for grade 2 ($p = 0.03$).

Discussion

Achievement of satisfactory urinary continence while preserving the upper urinary tract remains a major challenge in

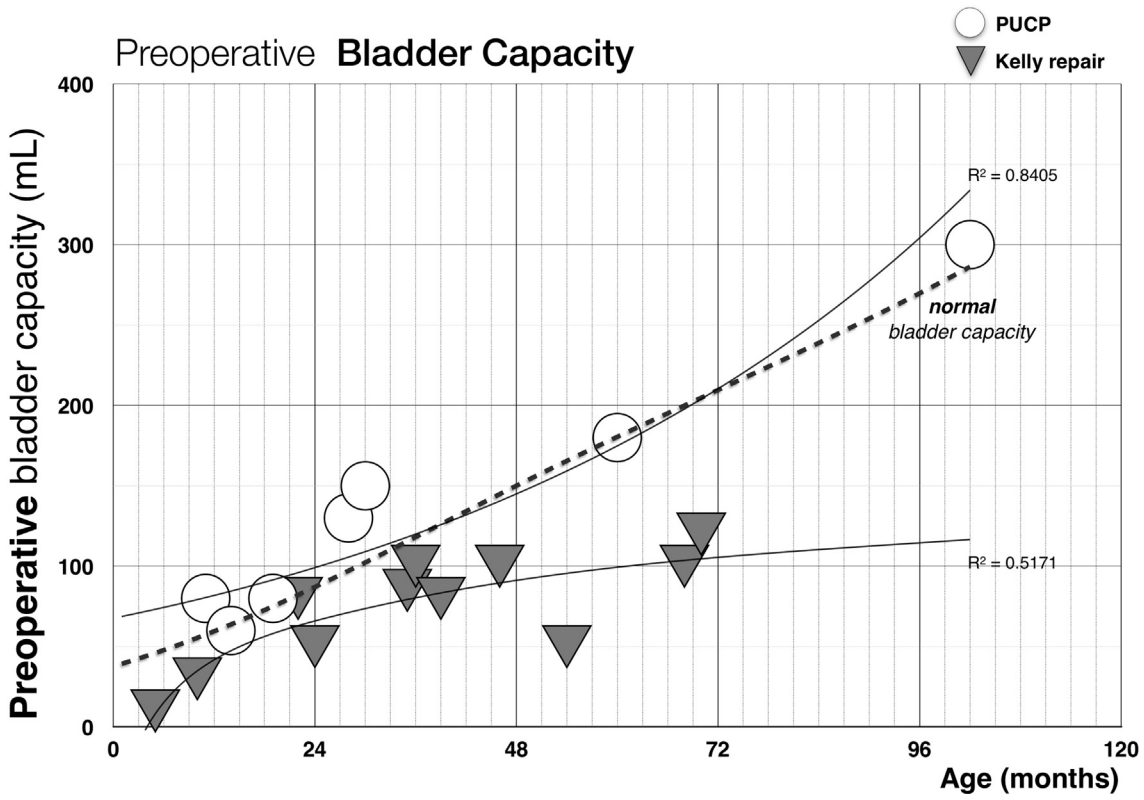

Figure 2 Preoperative bladder capacity (mL) at initial evaluation. PUCP = perineal urethrocervicoplasty (group 1); Kelly repair = radical soft-tissue mobilization (group 2).

female children with primary epispadias. The current study showed that within the whole spectrum of female epispadias, 87% of children could achieve daytime continence and 53% full continence at 5 years, with volitional voiding in the vast majority, with a tailored surgical strategy based on the degree of severity of the malformation. To the best of our knowledge, this is the first report on the results of the Kelly repair in primary female epispadias.

Incontinence in these children results from a variable combination of low urethral resistances, incompetent bladder neck, and small bladder capacity. Female epispadias has been classified into vestibular, subsymphyseal, and retrosymphyseal subtypes depending on the severity [14]. In the most distal vestibular forms, the urethral meatus can be merely patulous in girls with stress incontinence but normal bladder and spontaneous long dry intervals. At the most severe end of the spectrum, large retrosymphyseal epispadias may present with bladder prolapse [15], very low bladder capacity, and full incontinence.

We used bladder capacity as a surrogate marker of the severity of epispadias, as it is certainly the key parameter for continence outcome.

The traditional surgical approach of incontinent epispadias based on a classical Young—Dees—Leadbetter BNR showed satisfactory results when performed with genital reconstruction in one stage [16,17]. The main factor for successful BNR remains the bladder capacity, and it has long been recognized that a small incontinent and refluxing bladder at the time of BNR considerably reduces the chances of attaining continence [4,18]; therefore, Gearhart and co-workers [3,4] in Baltimore developed a strategy of staged reconstruction, with urethral and genital reconstruction performed at the age of 12—18 months, followed by BNR at the age of 5—6 years based on the assumption that urethral lengthening may trigger an increase in bladder capacity as a result of bladder adaptation to increased outlet resistances. They reported favorable continence results, although conclusions regarding bladder capacity may be limited, since it was not calculated as a percentage of the expected bladder capacity [19]. It is however believed that bladders in primary epispadias cases would respond more favorably to increased resistances than exstrophy bladders, as a large majority seemed to reach capacity suitable for BNR [3]. Several publications have raised concerns that bladder neck surgery could be responsible for impaired detrusor function, especially when it involves extensive trigonal dissection, with deterioration of compliance and bladder stability [20], uninhibited contractions [21], or hypocontractility [19,21]. A major concern in these patients is the high prevalence of inefficient emptying and abnormal voiding dynamics in patients considered to show "good results" of the BNR procedure [22,23], with recurrent UTIs, bladder stones, upper-tract dilatation, and ultimately a high-risk of renal damage. Bladder outlet resistances created by surgery remains a passive and static obstruction, intermittently forced by increasing bladder pressure, and it is doubtful BNR provides any dynamic control of these resistances [23]. As a consequence, we believe that a formal bladder-neck tightening

procedure should be associated with a continent catheterizable channel, and be reserved for failures of other reconstructive strategies.

In 2009, Manzoni and Ransley [5] presented an alternative single-stage technique based on urethral retubularization via a limited perineal approach, similar to the first urethral stage described by Gearhart et al., in 1993 [4]; this technique was then modified into a urethrocervicoplasty [6—8], with reported diurnal continence rates from 60% to 85% with volitional voiding [6,7,11], but dropping below 50% of cases when considering night-time continence. Unfortunately, none of these publications precisely analyzed the results of the perineal approach in regard to the preoperative bladder capacity parameter. It is likely that bladder capacity was, in these publications, the main limiting factor to achieve nocturnal continence; in our selected population of girls with normal preoperative capacity, we obtained 60% of full time continence, but the three patients with persistent wetting were those in whom the bladder failed to develop.

Independently of bladder capacity, perineal urethroplasty may fail to provide sufficient bladder outlet resistance in a significant number of cases [24], although additional procedures such as bulking agent injections may improve continence outcome, as in our experience.

It was our hypothesis that the perineal approach could be insufficient for patients at the most severe end of the spectrum of female epispadias who might benefit from a more radical reconstruction. The Kelly radical soft-tissue mobilization is deemed to allow anatomical reconstruction, based on the assumption that muscular structures allowing potential physiological micturition are present, but need to be detached from the abnormal pelvic ring and replaced in an anatomical position [25]. Of note, this procedure doesn't involve any extensive trigonal surgery similar to what is performed in BNR, but is limited to a funneling cervicoplasty as initially described by Young [26]. The technique also offers the advantage to enable ureteric reimplantation whenever necessary, compared with pure perineal approach. The detachment of all striated muscular structures, and reapproximation around the mid-urethra allows a unique way of re-establishing "normal" anatomy for bladder outlet resistances [27]. In our limited experience, the Kelly repair seemed to offer promising results, with 100% of patients with diurnal continence and 37% full continence obtained at 5 years, even in cases selected from the worst end of the female epispadias spectrum. Interestingly, seven out of our patients seemed to have physiological micturition, and only one required CIC. Whether RSTM truly has the potential to trigger bladder growth more efficiently than the perineal approach in these severe cases remains to be investigated.

The age at which the epispadias is diagnosed and BC estimation is performed obviously has an important impact on decision-making: when normal bladder capacity is ascertained after toilet training age, it gives robust indications on the reservoir growth potential. In contrast, observing a purported "normal bladder" at birth doesn't give insurance that growth will occur, especially with a perineal reconstruction, which is the explanation of the two failures in our PUCP subgroup. One might draw the conclusion that reserving PUCP to grown-up children, diagnosed late with proven normal bladder at toilet training age, would be a reasonable option.

Limitations of the present study clearly include the small number of patients, inevitable in this extremely rare condition. The two groups analyzed were intentionally not similar, as we hypothesized that the children presenting with the most severe forms of primary epispadias required a more radical approach than simple perineal tubularization. To ascertain the true benefit of RSTM over the perineal approach in terms of bladder catch-up growth will require longer follow-up.

Conclusion

Surgical strategy based on the preoperative bladder capacity yields promising results in primary female epispadias repair. In girls with normal bladders, we confirmed that the single perineal approach achieved up to 60% of day and night continence, provided the bladder remains normal and enlarges concurrently with statural growth. At the most severe end of the spectrum, the radical soft-tissue mobilization seemed to offer diurnal continence in most children, and night-time continence in at least a third of them, while preserving normal volitional voiding.

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Conflict of interest

None.

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