Outcome of stented versus unstented mid-shaft to distal hypospadias repair

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Abstract Aims: We compared the outcomes of unstented repair (UR) versus stented repair (SR) in patients with mid-shaft to coronal hypospadias (HS) to elucidate if SR has any advantage over the UR.

Materials and Methods: We retrospectively studied our mid-shaft to coronal HS repair patients between January 2013 and January 2018. We recorded variables such as degree of HS, age at repair, surgeon, type of repair, suture used, stent usage, and standard early and late complications. Relative risk (RR) was calculated and P < 0.05 was considered significant.

Results: We included 120 patients (63 UR, 57 SR). There was no statistically significant difference in any parameters in both the groups. All had either tubularized incised plate or Thiersch–Duplay procedure. Urethroplasty was done with PDS 6/0 in all cases. Trainees performed two-third of the repairs under variable supervision. Early complications included one UR patient having urinary retention needing insertion of urethral catheter, five SR patients having bleeding/swelling, and three UR having dysuria. All were managed conservatively. For late complications, 98 patients were available (UR: 51, SR: 47) with fistula in 17 (17.3%), UR 8 (15.6%) versus SR 9 (19.1%) (P = 0.5, RR = 1.2) meatal stenosis in 3, UR 3 versus SR 0 (P = 0.06, RR = 6.4) and glanular dehiscence 6, UR 4 versus SR 2 (P = 0.25, RR = 1.8).

Conclusion: There were no statistically significant differences in the short-term complications between UR and SR for HS. In the long term, RR for meatal stenosis is higher in UR.

Keywords: Hypospadias repair, stented repair, unstented repair

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Received: 21.10.2020, Accepted: 21.12.2020, Published: 15.02.2022.

INTRODUCTION

Majority of surgeons use bladder drainage post hypospadias (HS) repair to protect the repair and prevent complications such as hemorrhage, meatal stenosis, fistula, and urinary retention.^[1-4] Stents are known to cause bladder

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	DOI: 10.4103/UA.UA_168_20				

spasms, hematuria, accidental dislodgement, blockage, migration, kinking, need for a second visit for removal, and parental anxiety.^[3,4] Unstented HS unstented repair (UR) repair seems a very logical option to avoid all these adverse events.^[4] Despite a continual debate on the subject, the issue remains unresolved.^[3]

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How to cite this article: Burki T, Al Hams AW, Nazer A, Mojallid A, Abasher A, Jamalalail Y, *et al.* Outcome of stented versus unstented mid-shaft to distal hypospadias repair. Urol Ann 2022;14:147-51.

We started UR in 2010. We intend to ascertain if UR has any higher complications rate as compared to stented repair (SR).

MATERIALS AND METHODS

After approval by the ethical committee, we retrospectively looked into our record of all the boys between ages 6 months to 14 years, who underwent HS repair for mid-shaft to coronal HS from January 2013 to January 2018. All the cases with glanular HS, mega meatus intact prepuce, more proximal HS, fistula repair, redo repair, HS with severe chordee needing Nesbit/Baskin procedure, and two-staged procedure were excluded from the study. The patients were divided into two groups: unstented HS repair and stented HS repair, depending on the usage of urethral stent postoperatively. All the patients received caudal block and antibiotics at induction of anesthesia. All underwent either Snodgrass/tabularized incised plate (TIP) or Thiersch-Duplay (TD) repair. PDS 6/0 was used for urethroplasty in all cases using continuous technique. Glans was repaired with 6/0 PDS as well. Spongioplasty and use of waterproofing layer were decided by individual surgeons. Decision to leave a stent was also left at the discretion of the surgeon. If a stent was used, it was either Zaontz or NG tube size 8F. At the end of the procedure, Tegaderm dressing was applied in all the cases. Oxybutynin was not routinely prescribed. All the procedures were done as a day case. In SR, all the children were seen in the clinic a week after surgery for the removal of the stent. The UR group parents were instructed sitz bath after 48 h till the dressing came off. Follow-up was arranged after 3-6 months. The children who had attained full urine control were seen at least 6 months postoperatively for delayed complications before discharge. The children who had not attained full urine control were seen every 6 months till they achieved full control before being discharged. The complications were divided into early complications, i.e., in the day unit before discharge or revisit to an emergency within 28 days of surgery or late complications which were recorded during their planned outpatients' visit. All the patients had insurance coverage with our hospital only so if there were any complication, we were the only hospital they could visit. The early complications included difficultly in passing urine, significant pain needing extra analgesia, bleeding, bladder spasm, and catheter-related issues such as blockage, kinking, or falling off before time, needing unscheduled hospital visits. The late complications included fistula, stricture, meatal stenosis, or dehiscence. Relative risk (RR) was calculated for major complications and Fisher's Exact test was used to calculate the significance between the two groups with P < 0.05 considered to be significant.

RESULTS

There were a total of 120 patients (UR 63, SR 57). There was no statistically significant difference between the severity of HS, age at repair, type of repair, use of antibiotics, and length of follow-up between the two groups [Table 1]. Two-third of the cases were operated by trainee fellows under variable levels of supervision. The second (waterproofing) layer was used in 81 patients (UR 39, SR 42). All of these were local ventral flaps. Spongioplasty was not done in any case.

Postoperatively in the recovery room, three UR patients had issues. One had bleeding needing pressure dressing for 1 h, one needed a bit longer observation in the recovery for difficulty in passing urine, but eventually, he passed urine and was discharged the same day. One 5-year old boy went into urinary retention. He was unable to pass urine in the day unit, had pain, and palpable bladder. He did not respond to conservative measures. Eventually, he had insertion of urethral catheter under general anesthesia (GA). After discharge, seven patients revisited emergency (UR: 2, SR: 5). In the SR group, stent-related issues were found only in two patients, one had bladder spasms needing oxybutynin and one had stuck catheter needing GA to remove it. The rest of the three attended emergency for bruises/swelling of the penis, all managed conservatively. In the UR group, one patient came to the emergency twice for dysuria, on day 1 and 2 postoperatively, managed with observation alone on both the occasions and sent back to home from the emergency. None of the patients in the SR group had any other stent-related issues such as hematuria, blockage, and migration.

In the long-term follow-up, only 98 patients were available (UR 51, SR 47). The rest had either short follow-up or lost to follow-up. Among these, fistula was reported in 17 (17.3%), which included UR (8, 15.5%) versus SR (9, 19.1%) (P = 0.5; RR = 1.2). Meatal stenosis needing surgery was recorded in three, all were from UR (P = 0.06, RR = 6.4). Glanular dehiscence was seen in 6, UR: 4 (7.8%) versus SR: 2 (4.25%) (P = 0.25, RR 1.8). None of the patients had urethral stricture [Table 2]. Twenty-two

Table 1: Demographics unstented repair versus stented repair

	Total=120	UR 63	SR 57
Median age at repair (months)		22 (5-144)	27 (7-120)
Follow up median (months)		14	13
Median age at last		48	47
follow-up (months)			
Hypospadias type			
Coronal	69	39	30
Subcoronal	32	17	15
Mid-shaft	19	17	11

UR: Unstented repair, SR: Stented repair

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Complications	Total=98, n (%)	UR 51, <i>n</i> (%)	SR 47, <i>n</i> (%)	P (RR)
Fistula	17/98 (17.3)	8/51 (15.5)	9/47 (19.1)	0.5 (1.2)
Meatal stenosis	3 (2.9)	3/51 (5.8)	0/47	0.06 (6.8)
Glanular dehiscence	6 (5.8)	4/51 (7.8)	2/47 (4.2)	0.25 (1.8)
Urethral stricture	0	0	0	0`´

Table	2: Comparison o	f long-term	outcomes	between	unstented	repai	r versus stente	d repair
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UR: Unstented repair, SR: Stented repair, RR: Relative risk

of these patients have undergone corrective surgery for these complications and five are on the waiting list.

DISCUSSION

With an incidence of HS of 1 in 200–300, HS repair remains one of the most common operations done by pediatric urologists.^[5] Currently, for single-stage HS repair, TIP urethroplasty is the most popular technique used worldwide.^[6] There are many unresolved issues pertaining to HS repair and the use of postoperative stent, especially after distal HS repair, remains one of these issues.

Duckett proposed that stenting after HS repair helps in maintaining a water-tight anastomosis during healing and decreases patient's discomfort.^[7] Studies have shown that stenting promotes healing, especially after TIP repair, and prevents stricture formation by letting the epithelialization happens from the edges of the incised plate rather than healing in concentric rings.^[8-10] Uncontrolled animal model studies have shown no scarring and normal epithelialization from the edges after the TIP procedure with a stent.^[9,10] However, Hafeez et al. have shown in their animal model study that the use of urethral stent is not necessary to keep the edges apart till re-epithelialization happens, as regular voiding similarly keeps the edges apart for long enough for normal epithelialization.^[11] They also observed in the same study that unstented TIP repair has similarly excellent healing, indicating that indwelling catheters are unnecessary postoperatively for the normal epithelialization.^[11] It has also been argued that apart from inflammation caused by the stent, it may cause bladder spasm and the urine may bypass the catheter at high pressure through the neo-urethra promoting fistula formation.^[3]

Urinary retention remains one of the most feared complications of stentless HS repair. In an uncontrolled study of 89 infants by Chalmers *et al.*, who underwent distal HS repair without a stent, and using various techniques of repair, only one patient developed urinary retention, needing urethral catheterization in the immediate postoperative period.^[4] In two smaller uncontrolled studies, using the TIP repair technique without a stent for distal HS, no incidence of urinary retention was reported postoperatively.^[12,13] In a larger noncomparative study by Leclair *et al.*, 161 children underwent TIP repair for mid-shaft to distal HS, four children developed urinary retention needing supra-pubic catheter (SPC). Two of these had SPC in the early postoperative period and the other two needed SPC on D6 postoperatively for chronic retention. However, urinary retention did not put these children into higher complications later on like fistula or Stenosis.^[14] In another larger comparative study of 254 patients (UR: 151, SR: 103) who underwent TIP procedure, six patients developed urinary retention, but it was not statistically significant (P = 0.084). On the contrary, they found a statistically significant rate of UTIs and bladder spasms in the stented group.^[15] In contrast, El-Sherbiny has reported very high complications rates in his comparison of stented and unstented TIP repair in children with full urine control, with a median age of 6 years at repair (range: 2–17 years).^[16] He found urinary retention in 34% versus 0% and urinary extravasation in 17% versus 0% in unstended and SR groups, respectively. In this study, they used only penile block to avoid urinary retention postoperative. The definition of urinary retention, dysuria, and extravasation is not very clear in this study. Other studies have not shown any correlation between urinary retention and age at surgery.^[14,17]

Stentless repair has also been reported using the Mathieu technique. A large study including 336 patients failed to demonstrate any significant different in postoperative urinary retention between stented and unstented groups^[17] though in a smaller uncontrolled study by Buson *et al.*, the urinary retention rate in unstented HS repair was 19%.^[18] Impact of caudal block or penile block on urinary retention has shown to be of no significance.^[4,12,16-18]

Our experience has been similar to the authors where the urinary retention has not been recorded as a significant problem irrespective of age and caudal versus penile block.^[4,12-15] It could be because of smaller sample as the larger studies have shown higher incidences of urinary retention between 2.5% and 4% needing intervention compared to ours of 1.5%. Other possible explanations include appropriate use of postoperative analgesia, definition of urinary retention, management of impending urinary retention, discharge criteria, and ease of access to hospital.

The reported fistula rates for all types of HS repair are between 6% and 40% depending on the severity of HS

and technique used.^[19] The mean acceptable fistula rate for distal TIP repair from large centers has been <8%.^[20] In the comparative studies of TIP procedure, the incidence of fistula and meatal stenosis has been low in both UR and SR groups with no statistically significant difference between the two groups.^[15,16] In the uncontrolled studies of UR, the fistula rate has also been reported well below the acceptable rate of 8.^[12-14] In unstented Mathieu repair, except for Buson et al. who has reported a 14% fistula rate, the rest of the studies have shown no significantly high rates of either fistula formation or meatal stenosis rates.^[17,18,21,22] On the contrary in a systematic review by Wilkinson et al., the use of urethral stent in Mathieu HS repair was found to significantly increase the chances of both fistula formation (RR 7.45, P < 0.001) as well as meatal stenosis (RR 1.8, P < 0.31) when compared to UR.^[23]

Our overall fistula rate has been high. The possible causes which may have contributed to it were felt to be lack of experience of the trainees (learning curve), variable supervision of the trainees, lack of dorsal sub-dartous flap, and spongioplasty which has been suggested by others as a possible contributor to higher fistula rates.^[14,20,23-25] All of our fellows come from adult urology backgrounds and none of them have any significant experience of HS repair before starting training with us. To decrease the incidence of fistula, we decided to have a better supervision of the trainees, use of second dorsal dartos flap, and if possible to do spongioplasty. We will re-audit in the next few years to check its impact on the outcome.

Our study has shown a high RR of 6.8 for meatal stenosis in UR cases though it did not reach statistical significance. Chalmers *et al.* have also reported a similar 4.7% meatal stenosis rate.^[4] In the systematic review by Wilkinson *et al.*, the meatal stenosis rate has been between 0.5% and 17% for UR using TIP technique.^[23] It appears that many other unknown factors are responsible for such a variable rate of meatal stenosis in these different series.

The limitations of our study include the retrospective nature of the study. Our study is also underpowered. Our study required 203 patients (80% with alpha = 0.05 - Type I error). One reason for small number is that we did not include glanular HS and mega meatus intact prepuce repair, which if included may have biased the study in favor of UR, as nearly all of these cases were UR, with much lower complications. Including a smaller number of mid-shafts, HS repair appears to create a nonhomogeneous study group, but we intentionally included it to give a message that even in these cases, urinary retention or other complications are not a significant problem. There could have been some

element of bias in selection in the two groups with easier cases selected for UR. This could have been an issue in the earlier time when we started the UR in 2010. With more experience, we are doing more and more cases of UR which would have eliminated the element of bias and that is one of the reasons for including patients after 2014. We appreciate that we have a much higher rate of fistula than generally expected for which we have put mechanisms in place to reduce it. Although we had only one case of urinary retention in the UR group, we do not know how many children had some or significant issues with passing urine while at home in UR or catheter-related bladder spasms and difficulty in passing urine after removing the catheter in SR group. We could not document outcomes in 22 patients (18.3%) in the long-term follow-up which may have resulted a bias in our study.

We did not calculate the cost of second visit to the outpatient in stented group in terms of loss of working hours for parents and cost of transport or stay in hotels. Many of our patients come from very far-off places and we do not know if they stayed locally or went home and came back for removal of the stent a week later. If known, this may become a strong factor in decision-making to choose the type of surgery for the most cost-effective treatment and for convenience of patients.

CONCLUSION

There are no significant short-term or long-term differences in the complications of unstented mid-shaft to distal HS repair when compared to stented HS repair, except for high RR for meatal stenosis in UR s. The use of urethral stent appears to be of no significant advantage. Future studies should look into economic impact of use of stents for HS repair.

Financial support and sponsorship Nil.

Conflicts of interest

There are no conflicts of interest.

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