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The effectiveness of Zaontz urethral stent in hypospadias treatment in terms of children comfort according to the Parents' Postoperative Pain Measurement (PPPM) scale: A retrospective study

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Abstract

Aim: Advances in the techniques and materials used in hypospadias surgery are aimed at improving cosmetic and functional results. In our study, we aimed to compare the impact of using Zaontz urethral stent (ZUS) on patient comfort in children undergoing hypospadias surgery, as opposed to feeding tubes.

Materials and Methods: A total of 178 patients who underwent distal hypospadias surgery were included in the study. Snodgrass technique was performed routinely in all cases. In all cases, 6 Fr, 8 Fr and 10 Fr urethral stents were used depending on the surgical situation. Patients were divided into two groups according to the catheterization method. While in Group 1, catheterization was performed with a feeding tube, ZUS was used in Group 2. Demographic data of the patients were analyzed. In the postoperative period, the groups were compared in terms of patient comfort according to the Parents' Postoperative Pain Measurement (PPPM) scale. This scale was evaluated three times a day during the hospitilation period. A score of at least 6 out of 15 was considered clinically significant pain.

Results: Age, catheterization size, operation and hospitalization time were similar between the groups ($p>0.05$). PPPM score in Group 2 was observed as 3.25, significantly lower than Group 1 ($p<0.001$).

Conclusion: As a result of our study, it was observed that ZUS would positively contribute to postoperative patient comfort in hypospadias repair.

Introduction

Hypospadias is an abnormal opening of the urethra at any point from the ventral part of the penis. Hypospadias is a common urethral defect in pediatric surgery practice and its incidence is approximately 1 in every 250-300 live male births [1]. Most of them are subjected to surgical repair, and urethral stents are used in the majority of repairs [1,2]. However, there is limited documentation about the material properties of urethral catheters and their impact on surgical complication [2]. The purpose of using a urethral stent is to immobilize the suture line, empty the bladder and reduce tissue reaction. The most common problems associated with urethral stent use are bladder spasms, obstruction, infection, and trauma during stent insertion and removal [3].

The Zaontz urethral stent (ZUS) is a thermoplastic elastomer with strong melting transitions above body temperature. The feeding tube is the stiffest, least extensible stent, which can be broken under significant tension. Cyclic deformation studies show that ZUS can flex and recover their shape better, suggesting that the amount of plastic deformation exhibited by this stent is lower compared to the feeding tube [3,4].

The aim of our study is to analyze the effect of ZUS on patient comfort in hypospadias repair compared to the use of a feeding tube.

Materials and Methods

A total of 178 patients who underwent primary distal hypospadias surgery between December 2017 and June 2021 were included in the study. Snodgrass technique was performed routinely by the same physician in all cases. In all cases, 6 Fr, 8 Fr and 10 Fr uretral stents were used de-

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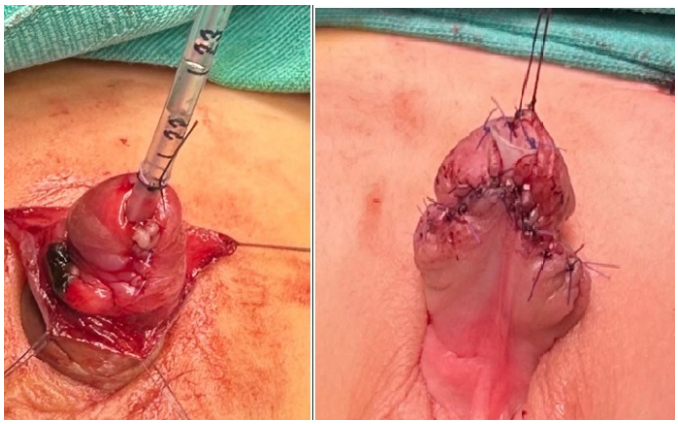

Figure 1. View of feeding tube, Zaontz urethral stent and its placement after hypospaias repair.

Table 1. Parents' Postoperative Pain Measurement (PPPM).

	Yes	No
1.Whine or complain more than usual?		
2. Cry more easily than usual?		
3. Play less than usual?		
4. Not do the things s/he normally does?		
5. Act more worried than usual?		
6. Act more quiet than usual?		
7. Have less energy than usual?		
8. Refuse to eat?		
9. Eat less than usual?		
10.Hold the sore part of his/her body?		
11.Try not to bump the sore part of his/her body?		
12. Groan or moan more than usual?		
13. Look more flushed than usual?		
14. Want to be close to you more than usual?		
15.Take medication when she/he normally refuses?		

pending on the surgical situation. Patients were analyzed in two groups according to the catheterization method. While in Group 1, catheterization was performed with a feeding tube, ZUS (Cook Medical) was used in Group 2. The feeding tube was placed within the bladder while the ZUS was placed just within the external sphincter and fixed with an absorbable suture to the glans penis (Figure 1). The choice of catheterization is determined based on the preference of the parents of the patient after informing them of the advantages and disadvantages of the different procedures. The patients' ages, operation and hospitalization times were analyzed. In the postoperative period, the groups were compared in terms of patient comfort according to the Parents' Postoperative Pain Measurement (PPPM) scale. This scale was evaluated three times a day during the hospitalization period. According to this scoring system, observation during the patient's stay with the urethral stent and the number of items that parents circled as "Yes" were summed for a total score out of 15 (Table 1). Parents were asked to complete the assessment within specific time intervals. A score of at least 6 out of 15 was considered clinically significant pain [5,6].

Patients were routinely hospitalized with a urethral catheter for 7 days. Patients with endocrinological pathologies such as Cushing's syndrome and diabetes mellitus, and patients with neurological problems such as spina bifida, multiple sclerosis and psychological disorders were excluded from the study.

The study was approved by Tokat Gaziosmanpasa University Local Ethics Committee (24-KAEK-166).

Statistical analysis

The statistical package MedCalc (version 20.009; Ostend, Belgium) was used to perform the analyses. The analysis application G*Power version 3.1.2 was utilized to determine the study's power. The Kolmogorov-Smirnov test was utilized in the data evaluation process to ascertain whether the groups adhered to a normal distribution. If the groups were normally distributed, the number was expressed as mean (with 95% confidence interval), SD (standard deviation). If the groups were not normally distributed, median (with 95% confidence interval) and interquartile distance values were used. Independent t-test was used to compare the groups for the groups fitting the normal distribution. Mann-Whitney U test was used for groups that did not fit the normal distribution. The groups were shown with box-whisker graphs. Significance level $p<0.05$ was taken for the interpretation of the results.

Results

A total of 90 patients were in Group 1. Age and hospitalization time were similar between the groups ($p>0.05$). All cases were hospitalized for a standard period of 7 days. Patients were catheterized with 6 Fr, 8 Fr and 10 Fr sizes, depending on the urethra and surgical situation. On the other hand, there is no difference in catheterization size, success and complications rates between the two groups ($p>0.05$). PPPM score in Group 2 was observed as 3.25, significantly lower than Group 1 ($p<0.001$).

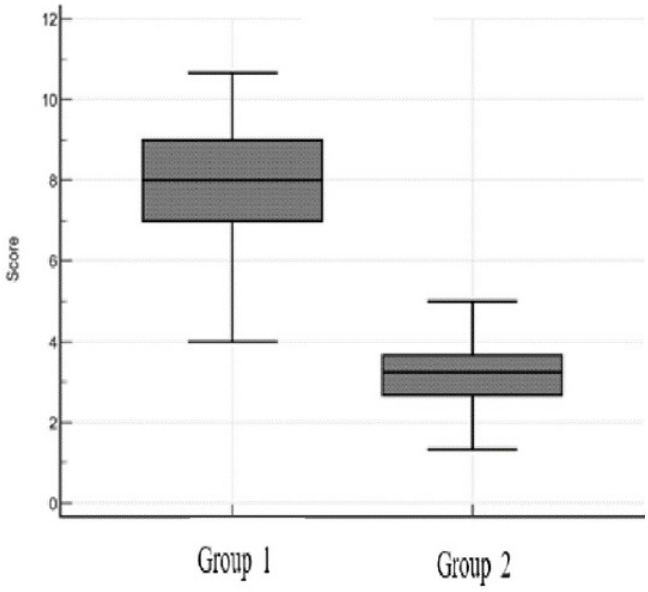

Figure 2. Box plot for comparison of Parents' Postoperative Pain Measurement (PPPM) in study groups.

Table 2. Age, operation time and PPPM score data of the groups.

	Group 1				Group 2				p-value
	N	Median	95% Confidence Interval	IQR	N	Median	95% Confidence Interval	IQR	
Age (year)	90	4.0	3.0-4.0	3.0	88	4.0	3.0-4.0	3.0	0.934
Operation time (min)	90	60.0	59.0-61.0	8.0	88	60.0	59.0-61.0	8.0	0.853
PPPM Score	90	8.0	8.0-8.13	2.0	88	3.25	3.0 -3.33	1.0	<0.001*

* Significant difference at <0.05 level according to Mann-Whitney U test IQR: Distance between quartiles.

In Group 2, none of patient had a PPPM score was above 5 (Figure 2) (Table 2).

Discussion

Anthyllis is known to have performed the first documented hypospadias surgery. Galen emphasized the importance of the cordi [7]. Today, the Snodgrass technique is widely and safely performed in many pediatric urology clinics in the treatment of cases with distal hypospadias. Urethral catheterization is quite common to reduce the rate of complications such as meatal stenosis, urethrocutaneous fistula and urethral stenosis due to hypospadias repair [8]. However, there are also authors who have published follow-up protocols without urethral stent after hypospadias repair [8,9]. The main reason for this situation is parental anxiety and patient discomfort due to catheterization [8]. Scientists are working intensively on the use of different catheter types to minimize pain, bladder spasm and trauma due to catheterization [3,8]. We believe that diversion and stent use remain necessary, and we routinely perform it in all hypospadias surgeries in our practice. However, we believe it is crucial to minimize the undesirable side effects associated with stent use. In this context, our study planned to analyze two commonly used catheter types in terms of patient comfort.

ZUS is a urethral stent designed to empty the bladder after epispadias and hypospadias surgery. The stents are designed in 6F, 8F and 10F diameters and 12 cm in length according to the width of the urethra. It is recommended to advance the stent to the external urethral meatus and fix it to the glans penis with an absorbable suture [3]. In our practices, the ZUS is fixed to the penis in 3 places with sutures and on the day of stent removal, the sutures are removed with a scalpel and the ZUS is removed. We think that this fixation method reduces the movement of the stent and reduces postoperative pain. The feeding tube is the least extensible type of stent and has a very high threshold for fracture with tension. On the other hand, due to the very high hardness of the feeding tube, it increases its tendency to traumatize the uroepithelium. However, feeding tubes are cheaper than other stents and provide a significant cost advantage [4]. Clinical trials show that the use of silicone catheters causes cuff formation and neo-urethral damage during catheter removal [10]. When the use of latex Foley catheters was compared with silicone catheters, it was observed to cause less cuff formation, but allergic reaction and obstruction occurred [10,11]. We observed that the ZUS and feeding tube used in our study did not cause cuff formation as they lacked balloons and reservoir. No allergic reaction occurred in any of the patients.

Pain is a multifaceted and complex experience that extends beyond the physiologic interpretation of a harmful stimulus and includes psychological, cognitive, sociocultural, and emotional factors [12]. Postoperative pain management is important in children; inadequate pain management leads to prolonged hospital stays, patient dissatisfaction and increased morbidity and mortality [13]. A wide variety of pain measurement methods and different assessment tools are available to evaluate pediatric pain [14]. Guidelines recommend that families of children undergoing surgery receive counseling on pain assessment, analgesic use and appropriate application of other methods [15]. PPPM is a scale developed by Chambers et al. in 1996 to enable parents to evaluate their children's postoperative pain [5]. The Turkish validity and reliability study of this international scale was performed [6]. The PPPM, includes a 15-item list of behaviors suitable for use by families, based on the evaluation of postoperative behaviors in children unable to express their pain [16,17]. During the patient's stay with the urethral stent and the number of items that parents circled as "Yes" were summed for a total score out of 15. Thus, in this study we used the internationally accepted PPPM scale to evaluate postoperative pain in children [6,7].

Ozcan et al. performed a non-blinded, clinical research compared the ZUS with the infant feeding tube. In their study, they reported that ZUS provides significant advantages regarding patient comfort according to the Face, Legs, Activity, Crying, Consolability (FLACC) scale, as it is shorter than the feeding tube and is located only within the external sphincter [3]. Although the cases in our study were evaluated according to the PPPM scale, they similarly observed that the comfort level of patients catheterized with ZUS improved statistically significantly. We believe the main reason for this situation is directly related to the fact that patients are happier because they continued to urinate physiologically. On the other hand, in our study, no discomfort was observed in any of the patients catheterized with ZUS.

Limitations

The small number of children and the retrospective nature of the analysis are the main limitations of our research. Our study needs to be developed prospectively, with a larger series and using different urethral stents.

Conclusion

We concluded that ZUS may have an advantage compared to the feeding tube in terms of patient comfort in hypospa-

dias surgery. ZUS would positively contribute to postoperative patient comfort in hypospadias repair.

Conflict of interest

No conflict of interest was declared by the authors.

Ethical approval

The study was approved by Tokat Gaziosmanpasa University Local Ethics Committee (24-KAEK-166).

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