

## Does the Choice of Suture Material Affect the Incidence of Urethrocutaneous Fistulae After Hypospadias Repair? – A Comparison of Polyglactin 910 with Polydioxanone

Adnan Khalid<sup>1</sup>, Syed Hashim Zaidi<sup>2</sup>, Marvi Baloch<sup>3</sup> Fahad Saleem<sup>4\*</sup>

<sup>1</sup>Consultant General & Paediatric Surgeon, Combined Military Hospital, Quetta, Pakistan

<sup>2</sup>Consultant Paediatric Surgeon, Combined Military Hospital, Multan, Pakistan

<sup>3</sup>Department of Pharmacology, Faculty of Pharmacy & Health Sciences, University of Balochistan, Quetta

<sup>4</sup>Department of Pharmacy Practice, Faculty of Pharmacy & Health Sciences, University of Balochistan, Quetta

Available Online: 25<sup>th</sup> July, 2017

### ABSTRACT

**Background:** We aimed to assess the incidence of developing postoperative urethrocutaneous fistulae (UCF) while using either polyglactin 910 or polydioxanone for the repair of subcoronal hypospadias in paediatric patients. **Methods:** A multicenter, two-group posttest-only randomized experimental design was adopted for the study. The study was conducted at PNS Shifa Hospital Karachi, Combined Military Hospital Malir, Military Hospital Rawalpindi and Combined Military Hospital Multan from 2009 to 2016. Boys between the ages of 1 – 10 years with confirmed diagnosis of subcoronal hypospadias suitable for single stage repair with the Snodgrass technique and also completing a minimum follow up of 6 months were targeted for the study. The subjects were later randomized into PG group (those undergoing urethral repair with polyglactin 901) and PD group (those in whom polydioxanone was used). Both descriptive and inferential statistics were used for data analysis. SPSS v. 21.0 was used for data analysis with  $p < 0.05$  taken as significant value. **Results:** Two hundred patients with confirmed diagnosis of subcoronal hypospadias were recruited for the study in the proposed study period. Twenty-nine patients (29%) in the PG and 26 (26%) in the PD group developed UCF. There were seven (7%) cases of wound infection in the PG group compared to four cases (4%) in the PD Group; all eleven of the said were among those who developed UCF. Meatal stenosis was observed in six patients (6%) in the PG group and in nine patients (9%) of the PD group. No significant difference in the incidence of postoperative urethral fistula formation with the use of polyglactin 910 versus polydioxanone was however reported by the study findings. **Conclusion:** As there was no significant difference in the incidence UCF between Polyglactin 910 and Polydioxanone, the choice of suture material should be based on economical variations and availability of the two products.

**Keywords:** Hypospadias, Polyglactin 910, Polydioxanone, Urethrocutaneous Fistula.

### INTRODUCTION

Hypospadias is a common congenital anomaly affecting about 0.7% of newborn worldwide<sup>1,2</sup>. The fact that over 300 methods have been tried over the course of history for the repair of this anomaly, only serves to prove that search for the ideal method of repair is still being carried out<sup>2</sup>. For the past few decades, the most popular procedures have been the tubularized incised plate urethroplasty (Snodgrass technique) mainly employed for distal hypospadias and the 2-stage Bracka repair used for the proximal varieties<sup>3,4</sup>. Within this context, Urethrocutaneous fistula (UCF) continues to be a common and frustrating complication after hypospadias repair<sup>5</sup>. Reported incidence of fistula formation varies greatly from 0.48% to 44%<sup>6,7</sup>. However, in general practice, it is our personal observation that the incidence is more towards the higher side. Many factors are thought to contribute to fistula formation and amongst the various guidelines pertaining to the repair technique there is consensus regarding the gentle tissue handling,

precise hemostasis, use of magnification and meticulous subcuticular suturing without any tension<sup>8</sup>. There are, however, many controversies too, such as the use of stents, types of dressings and which suture material to use. We aimed to address the last question in this study and focused on the two most commonly used suture materials used worldwide, polyglactin 910 and polydioxanone. There are numerous studies about suture material and how they behave in living tissue or on exposure to human urine<sup>9,10</sup>. Some have compared different sutures used with different techniques<sup>11</sup>. We, however, did not find any study which compared different sutures whilst keeping all other variables, such as age, location of hypospadiac meatus, surgical technique, type of stents and dressing, almost identical in the two study groups. Therefore, we decided to compare two commonly employed absorbable suture materials (polyglactin 910 and polydioxanone), the former being multifilament and the latter monofilament.

Looking at the different qualities of the two sutures (Table 1), we believed that the monofilament would give better results when compared with the multifilament. Hence it was hypothesized that incidence of developing UCF will be significantly related to the use of polydioxanone when compared with polyglactin 910 for the repair of subcoronal hypospadias in paediatric patients attending various Armed Forces Hospitals of Pakistan.

## METHODS

### *Study design, settings and time frame*

The study was multicenter in nature and was designed as a two-group posttest-only randomized experiment. The study was carried out at four different tertiary hospitals of Pakistan Armed Forces between 2009 and 2016.

### *Study participants, randomization and inclusion criteria*

A total of 234 boys underwent the Snodgrass repair of subcoronal hypospadias during this period but only 200 completed the minimum follow up of six months. The 200 subjects were randomized into two groups using a coin toss method i.e., the PG group, those in which polyglactin 910 was used (n=100) and the PD group, in whom the hypospadias was repaired using polydioxanone (n=100). Subjects in the age range of 1-10 years, with confirmed diagnosis of Subcoronal hypospadias, having no chordee or only mild chordee, which was easily corrected by skin and dartos degloving of the penis, with hypospadiac morbid anatomy suitable for the Snodgrass repair technique and had no presurgical testosterone stimulation to enhance penile/glans size were included in the study. The patients were included if they were not operated upon previously and have undergone Snodgrass repair<sup>13</sup>. Subjects were excluded from the study if they had had prior hypospadias repairs, in whom presurgical testosterone stimulation had been used, had hypospadias other than subcoronal position and underwent hypospadias repair by a different surgical technique (other than the Snodgrass repair).

### *Surgical Technique*

Two experienced consultant paediatric surgeons (during their postings to different hospitals from 2009-2016) performed all repairs. The Snodgrass tabularized incised plate urethroplasty was used in all cases. Complete detail of the surgical technique is beyond the scope of this paper and the reader is referred to specialized text (4). The points of standardizing the technique however need to be mentioned.

The urethroplasty was done using interrupted subcuticular 6/0 sutures (polyglactin 910 in the PG group and polydioxanone in the PD group) and it was ensured that there was a minimum of tension on the repair. A middle layer of dorsal dartos fascia was buttonholed and placed on the ventral aspect between the urethral repair and the skin suture line. In all cases the skin was closed using interrupted 6/0 polyglactin 910 sutures inserted in a subcuticular manner so as to minimize the chances of epithelialized skin suture tracks.

A nasogastric feeding tube of appropriate size (usually between 6 to 8) was kept as a urethral stent until the seventh postoperative day. It was made sure that the tube fitted loosely in the neourethral lumen and did not exert

any tension on the urethral suture line. The stent was secured by a 4/0 polypropylene suture to the glans tip. Dressing was in the form of a layer of chloramphenicol eye ointment followed by paraffin gauze and a layer of cotton gauze secured in place by a "daisy" dressing made of sticking plaster.

### *Medication*

Antibiotic prophylaxis was started at the time of induction of anaesthesia with intravenous ampicillin 90 mg/kg per day in three divided doses plus amikacin 20 mg/kg per day in two divided doses. This was continued for three days after which oral co-amoxiclav and ciprofloxacin were continued until the removal of the stent on the seventh postoperative day. Oral oxybutynin (0.2 mg/kg per dose given 12 hourly) was also prescribed to prevent bladder spasms and was discontinued once the stent was removed.

### *Follow-up*

The patients were followed up at intervals up to a minimum of six months to report the outcomes; mainly the presence or absence UCF. Other complications such as wound infection and meatal stenosis were also noted.

### *Statistical analysis*

Data was collected via a pre-validated data collection form. The form was constructed by the research team and was validated prior to data collection. Data was coded and exported to SPSS v. 21.0 for data analysis. Both descriptive and inferential measures were employed with  $p < 0.05$  was taken as significant.

### *Ethical considerations*

The ethical committees of all four hospitals gave ethical approval.

## RESULTS

### *Demographic characteristics of the study participants*

Two hundred patients completed the study. Mean age of the subjects in the PG group was  $3.7 \pm 1.8$  years (range being 1.6 to 9.6 years) whilst in the PD group the mean age was  $3.6 \pm 1.6$  years (range being 1.8 to 8.9 years). Both groups were comparable in term of age ( $p > 0.05$ ).

### *Disease-related characteristics of the study participants*

Twenty-nine, out of the 100 boys (29%), in the PG group developed UCF, with mean age of  $3.3 \pm 1.4$  years. The mean time to the appearance of the fistulae was  $12.0 \pm 4.5$  post-operative days, the range being 7 to 20 days. In PD group twenty-six out of the 100 (26%) developed UCF; their mean age being  $3.5 \pm 1.4$  years and the mean time to appearance of the fistulae was  $10.6 \pm 4.3$  days, the range being 6 to 21 days. Wound infection was seen in seven patients (7%) in the PG group versus four (4%) in the PD group; all eleven boys with wound infection were among those who developed UCF. None of the boys developed more than one UCF and none of the fistulae seen in this study healed spontaneously at six months follow up. Meatal stenosis occurred in six of the PG and nine (9%) of the PD group. Both UCF and meatal stenosis were seen in two patients in the PG group and three in the PD group. In all cases the meatal stenosis was seen more than three weeks after the repair.

The Man Whitney U test was used to examine our study hypothesis. No significant association ( $> 0.05$ ) was

Table 1: Comparison of monofilament and multifilament absorbable sutures<sup>12</sup>.

	Monofilament e.g. Polydioxanone	Multifilament e.g. Polygalactin 910
Advantages	Minimal tissue drag and trauma (low friction)	More pliable and flexible
	Minimal capillarity	Better knot holding security
	No interstices that may harbor bacteria	
	Difficult handling and knotting	Higher capillarity
Disadvantages	Nicking or damaging the thread with forceps or needle holders may predispose to breakage	Rough surface with greater tissue drag and trauma

reported with the use of either of the sutures and the development of UCF. Additionally, there was no significant association observed between mean time to appearance of fistula, range of time to appearance of fistula, development of wound infection, meatal stenosis and UCF plus meatal stenosis as shown in Table 2 (see figure 1 and 2)

## DISCUSSION

Urethrocutaneous fistula is a very common complication after the repair of subcoronal and the more proximal forms of hypospadias with rates reported to range from 0.48 % to 44 % (6, 13). Many different techniques have been tried for fistula prevention. Since Retik *et al.* used the dartos flap as a covering layer between the neourethra and penile skin it has been the mainstay to avoid UCF in hypospadias repair<sup>14</sup>. The fistula rates in our study appear to be somewhat higher than reported in other local studies. Uzair and colleagues reported a 9.6% fistula rate with the use of interrupted 6/0 polyglactin 910 suture for urethral closure<sup>15</sup>. There is, however, a long learning curve and as highlighted in a major study by Khan and colleagues that the results tend to improve with time and experience<sup>16</sup>. They reported fistula rates of 38.8%, however, they have included all forms of hypospadias and specialists as well as residents had performed the operations. We corroborate these findings; however, we have not stratified our results as to what was the rate of UCF complications during the initial years of our study as compared to the results towards the end. Wound infection was seen more commonly in the PG group whilst meatal stenosis was more in the PD group. We do not believe that meatal stenosis was the reason for the UCF in these patients because in all cases the meatal stenosis was discovered after the fistula; furthermore, the UCF was seen in only one-third of the patients having meatal stenosis in both groups.

The study was initiated with the hypothesis that while keeping all other variables constant, there is a significant difference between the choice of sutures and development of UCF. A thorough literature review revealed paucity of information regarding the current study objective. However, Ulman and colleagues compared the complication rates following the use of polyglactin (Vicryl) and polydioxanone (PDS) sutures for hypospadias repair<sup>11</sup>. They reported a significant difference in the incidence of urethrocutaneous fistula with a rate of 16.6% in the Vicryl group and 4.9% in the PDS group. Their groups were, however, not identical. The Vicryl group comprised of 36 patients who underwent repair of the

urethra with continuous full-thickness 6/0 vicryl whilst in the PDS group of 61 patients this step was done using 7/0 continuous subcuticular closure. Furthermore, the skin flap closure in the two groups was also different; in the Vicryl group it was done using 5/0 standard Vicryl whilst in the PDS group 5/0 Rapide Vicryl was used. Only the type of repair was the same, i.e., the Mathieu repair.

Furthermore, a study comparing the structural and histological parameters of the penis and urethra and their changes using stereological methods after urethroplasty on incised rat urethrae using five different absorbable suture materials, sought to determine the best material based on better collagen deposition, larger lumen volume, vascularization and less inflammation<sup>14</sup>. The authors concluded that monofilament polyglycaprone 25 (Monocryl) was found to be associated with more vessel density and a wider lumen. In the polydioxanone group more urethral epithelium was observed compared to the polyglactin 910 group. The major drawbacks of this study were that it was done on previously intact rat urethrae, which have no histological resemblance to the hypospadiac human urethra<sup>10</sup>.

Moreover, Kerstein and colleagues studied the effects of human urine on tensile strengths of absorbable sutures used in hypospadias repair. They found that exposure to urine reduced the tensile and breaking strength of all the suture materials tested. Polydioxanone demonstrated the greatest resilience. Vicryl Rapide was the weakest suture and degraded completely by day 6. Polyglactin 910 and polyglycaprone 25 had similar degradation profiles, but the former retained more of its tensile strength for longer. The concluded that there is a balance to be struck between the duration that a suture material must remain in any surgical wound and the risk that it causes foreign body effects. The results of this study suggest that polyglactin 910 has the best characteristics for urethroplasty of the four suture materials tested<sup>9</sup>. Comparing to our study, we did not find any significant difference between the PG and PD group as regards to the complication of UC fistula formation. This would imply that the other factors of fistula prevention such as gentle tissue handling, the use of magnification and fine absorbable sutures along with a tension free repair remain the main surgical strategies against fistula prevention.

On the contrary to what is reported above, our groups were well matched for age at the time of hypospadias repair. Nevertheless, the mean ages of both groups were somewhat higher than the current recommendations of performing the repair between 6 and 18 months after

Table 2: Demographic &amp; Disease related information of the study respondents.

Characteristics	PG Group	PD Group	P-value*
Number of respondents	100	100	0.923
Mean age at repair (years)	3.7 ± 1.8	3.6 ± 1.6	0.237
Age range (years)	1.6 to 9.6	1.8 to 8.9	0.445
Development of UCF	29 (29%)	26 (26%)	0.345
Mean age of UCF patients (years)	3.3 ± 1.4	3.5 ± 1.4	N/A
Mean time to appearance of fistula (days)	12.0 ± 4.5	10.6 ± 4.3	0.776
Range of time to appearance of fistula (days)	7 - 20	6 - 21	0.455
Wound infection	7 (7%)	4 (4%)	0.089
Meatal stenosis	6 (6%)	9 (9%)	0.211
UCF plus Meatal stenosis	2 (2%)	3 (3%)	0.435

\*Man Whitney U test, N/A = Not applicable

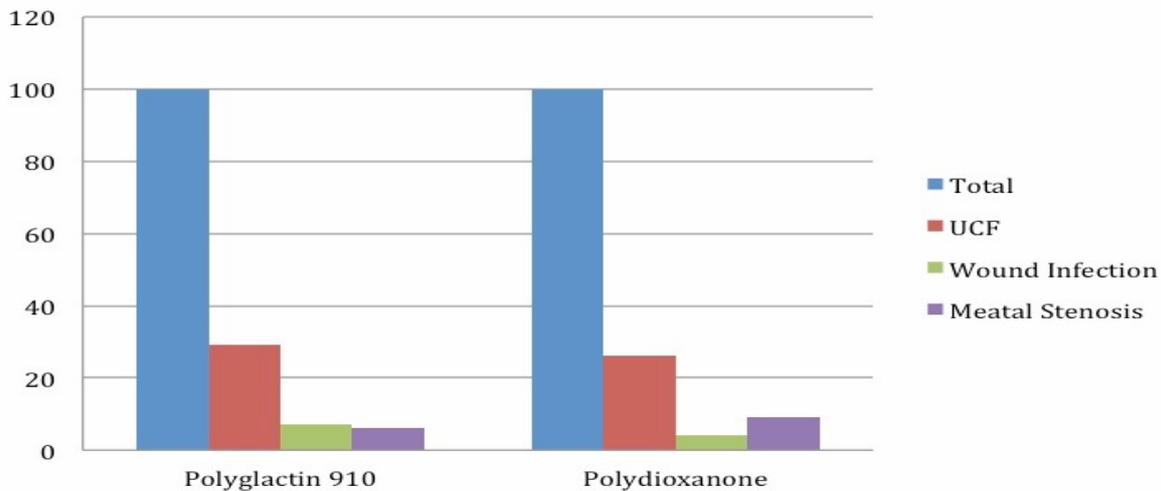


Figure 1: Bar chart showing number of Urethrocutaneous fistulae (UCF) and other complications.

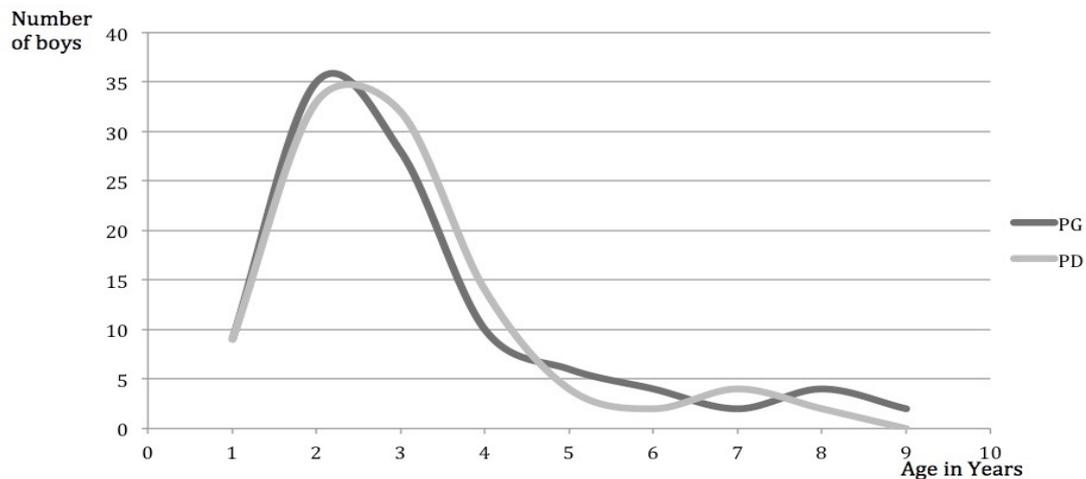


Figure 2: Age distribution of the two study groups – PG: Polyglactin 910, PD: Polydioxanone.

birth<sup>13,17</sup>. We had to operate on relatively older children, firstly, because majority of these patients were children of active servicemen in the armed forces and not all of them can be operated at the ideal age because of exigencies of service and logistic reasons and, secondly, in order to exclude boys with relatively small penises in whom presurgical testosterone had been used, we found suitable cases only in the older age range.

Exclusion of boys treated with presurgical testosterone was done so that all variables other than the suture materials could be kept identical, especially so because some workers have shown that use of presurgical testosterone stimulation may actually result in increased rates of healing complications as well as increasing the likelihood of overactive behavior and erections<sup>18,19</sup>. Oxybutynin was prescribed postoperatively in all children in order to prevent urinary bladder spasms due to trigonal

irritation by the indwelling urethral stent, which is not only be severely discomforting but may also predispose to fistula formation by forcing urine under pressure into to urethra outside of the stent. Oxybutynin tended to cause mild to moderate constipation that was managed by giving oral lactulose. Once again, to ensure standardization, oxybutynin was given to all children.

## CONCLUSION

Based on the study results, the null hypothesis is rejected and we conclude that there appears to be no significant difference between the incidences of UCF after hypospadias repairs done using polyglactin 910 or polydioxanone for the urethral closure. Other factors e.g. cost, availability etc should be considered before using either polyglactin 910 or polydioxanone for the urethral closure.

## DISCLOSURE

There is no conflict of interest to disclose. No funding was received for this study.

## REFERENCES

- Gallentine ML, Morey AF, Thompson IM. Hypospadias: a contemporary epidemiologic assessment. *Urology*. 2001;57(4):788-90.
- Cimador M, Vallasciani S, Manzoni G, Rigamonti W, De Grazia E, Castagnetti M. Failed hypospadias in paediatric patients. *Nature Reviews Urology*. 2013;10(11):657-66.
- Bracka A. The role of two-stage repair in modern hypospadiology. *Indian Journal of Urology*. 2008;24(2):210-8.
- Snodgrass W. Tubularized, incised plate urethroplasty for distal hypospadias. *The Journal of Urology*. 1994;151(2):464-5.
- Cimador M, Castagnetti M, De Grazia E. Urethrocutaneous fistula repair after hypospadias surgery. *BJU International*. 2003;92(6):621-3.
- Elder JS, Duckett JW. Complications of hypospadias repair. In: Smith RB, Ehrlich RM (eds). *Complications of Urologic Surgery*, 2nd edn. WB Saunders, Philadelphia, PA, 1990; 549-68.
- Kass E, Bolong D. Single stage hypospadias reconstruction without fistula. *The Journal of Urology*. 1990;144(2):520-2.
- Baskin LS. Hypospadias. In: Coran AG, Adzick NS, Krummel TM, Laberge JM, Shamberger RC, caldamone AA eds. *Pediatric Surgery – 7th ed.* WB Saunders, Philadelphia, PA, 2012; 1531-53.
- Kerstein RL, Sedaghati T, Seifalian AM, Kang N. Effect of human urine on the tensile strength of sutures used for hypospadias surgery. *Journal of Plastic, Reconstructive & Aesthetic Surgery*. 2013;66(6):835-8.
- Shirazi M, Noorafshan A, Serhan A. Effects of different suture materials used for the repair of hypospadias: a stereological study in a rat model. *Urologia Internationalis*. 2012;89(4):395-401.
- Ulman I, Erikci V, Avanoğlu A, Gökdemir A. The effect of suturing technique and material on complication rate following hypospadias repair. *European Journal of Pediatric Surgery*. 1997;7(3):156-7.
- Leaper DJ. Basic Surgical Skills and Anastomoses. In: Williams NS, Bulstrode CJK, O'Connell PR eds. *Baily & Love's Short Practice of Surgery 25th Edition*. Edward Arnold, London 2008; 236-39.
- Kass E, Kogan S, Manley C, Wacksman J, Klykylo W, Meza A, et al. Timing of elective surgery on the genitalia of male children with particular reference to the risks, benefits, and psychological effects of surgery and anesthesia. *Pediatrics*. 1996;97(4):590-4.
- Retik A, Mandell J, Bauer S, Atala A. Meatal based hypospadias repair with the use of a dorsal subcutaneous flap to prevent urethrocutaneous fistula. *The Journal of Urology*. 1994;152(4):1229-31.
- Uzair M, Ahmad M, Hussain M, Younus M, Khan K. Frequency of urethrocutaneous fistula following Snodgrass hypospadias repair in children. *Journal of Postgraduate Medical Institute*. 2012;27(1):74-7.
- Khan M, Majeed A, Hayat W, Ullah H, Naz S, Shah SA, et al. Hypospadias repair: a single centre experience. *Plastic Surgery International*. 2014;10.1155/2014/453039.
- Manzoni G, Bracka A, Palminteri E, Marrocco G. Hypospadias surgery: when, what and by whom? *BJU International*. 2004;94(8):1188-95.
- Gorduza DB, Gay C-L, Elisângela de Mattos ES, Demède D, Hameury F, Berthiller J, et al. Does androgen stimulation prior to hypospadias surgery increase the rate of healing complications?—A preliminary report. *Journal of Pediatric Urology*. 2011;7(2):158-61.
- Leung AK, Robson WL. Hypospadias: an update. *Asian journal of andrology*. 2007;9(1):16-22.