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Urethrocutaneous Fistula After Hypospadias Repair in children: Analysis of Risk Factors – Re-visit

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ABSTRACT

Background: Urethrocutaneous fistulas following hypospadias correction are one of the most prevalent hypospadias surgical complications. Hypospadias is one of the most frequent congenital malformations, with an almost universal upward trend over time.
Aim of the study: Study aimed to review the rate of urethrocutaneous fistula (UCF) formation after the repair of hypospadias in children and try to analyze the possible risk factors for its formation.
Patients and Methods: A total of 316 cases who underwent hypospadias surgery between February 2015 and December 2020 were included in this retrospective research. 246 children were followed up on for more than 6 months in our report. The child's age at the time of the hypospadias operation, the location of the hypospadias, the presence of chordae, the type of operation, the type of sutures and techniques, the approaches and period of catheter use after hypospadias operation, splint size, the level of experience of the participating surgeon, post-operative complications, presentation time of the fistula, size of fistula, the fistulae number, and the position of fistula were all potential risk factors.
Results: Following hypospadias surgery, 49 children out of 246 developed urethrocutaneous fistulae (19.8%, 49/246). The type of hypospadias
(P-0.006) and the nature of hypospadias operation (P-0.766) were found associated with the formation of the fistula in the univariate analysis. The hypospadias site only was a significant risk factor in the formation of fistulae after the surgery of hypospadias in the multivariate analysis ($p < 0.001$).
Conclusion: After hypospadias correction, the likelihood of urethrocutaneous fistula formation is related to the site of hypospadias (greater in the proximal hypospadias). The type of hypospadias procedure, the suture utilized, and the method used were not linked to the formation of fistulae.
Keywords: *Fistula; Hypospadias; Risk factors; children.*

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INTRODUCTION

Urethrocutaneous fistulas following hypospadias correction are one of the most prevalent hypospadias surgical complications. The rate at which it forms varies by country [1].

Hypospadias is one of the most frequent congenital malformations, with an almost universal upward trend over time [2].

This developing trend has led to advancements in hypospadias surgical treatment, including the tubularized incised plate, Mathieu repair, MAGPI operation, Inlay grafts, Preputial Island flaps, and two-staged hypospadias surgery, despite these developments, complications still rise [1].

In terms of the child's quality of life, it's essential to reduce the possibility of complications following

surgery. Many studies have been conducted in the past to investigate possible risk factors, with varying findings. As a result, further research aimed at identifying them would always be advantageous [3].

By collecting and analyzing data from our institutes, we want to discover the risk variables linked to urethrocutaneous fistula post-hypospadias correction operation. Several analyzed risk factors might be linked to the incidence of urethrocutaneous fistula following the repair operation, according to our hypothesis.

We aim to review the rate of UCF formation after the repair of hypospadias in children and try to analyze the possible risk factors for its formation.

PATIENTS AND METHODS

A retrospective study of children with hypospadias was done at two hospitals affiliated with our institution. A number of 316 individuals had hypospadias correction at our urologic clinic between January 2016 and December 2020, a 5-year span, according to the data obtained.

This research involved 246 of the 316 patients who had been followed up for more than 6 months. Cases who did not attend the clinic on a regular basis were surveyed by telephones. The children were allocated into two groups: the group A, which had urethrocutaneous fistula after hypospadias correction included 49 cases (19.9%), and group B, which had no urethrocutaneous fistula post hypospadias correction included 197 cases (80.08%).

Patients' ages at the time of hypospadias repair, hypospadias location (distal, middle, or proximal), presence of chordae, the type of hypospadias correction, material of suturing and techniques, means and period of catheterization post hypospadias correction, splint size, level of experience of involved surgeon, post-operative incidence, timing of presentation of UCF, number of fistulae, size of fistulae, and site of fistulae were all investigated retrospective.

Hypospadias is classified as distal (glandular, coronal, sub coronal), middle (penile), or proximal (penoscrotal, scrotal, perineal) depending on the abnormal position of the meatus. Tubularized incised plate (TIP) urethroplasty, Duckets, meatal advancement and glanduloplasty (MAGPI), and transverse preputial island flap (TPIF) urethroplasty were all used to treat hypospadias.

Statistical methods

IBM SPSS Statistics version 23.0 was used to gather and analyse the data (IBM Co., USA). We used the chi-square or Fisher's exact tests for categorical data. The continuous variables were examined using the Student's t test. For multivariate analysis, binary logistic regression is utilised. The significance level was set at $p < 0.05$.

RESULTS

After hypospadias correction, 49 of the 246 children (19.91 %) developed urethrocutaneous fistulas. The incidence of additional congenital urologic abnormalities, the mean follow-up lengths, and the mean age of the patients at the time of follow-up were all mentioned. There is many congenital urological disorders associated with hypospadias as cryptorchidism, penile curvature and inguinal hernia. Our study revealed that 4 (1.6%) patients had associated congenital disorders with non-significant impact on developing UCF (Table 1).

Demographic data	**Total patients (n=246)**
Age (years)	
Mean±SD	5.11±4.63
Range	0.5-17
<2 year	61 (24.8%)
2-4 years	43 (17.5%)
>4 years	142 (57.7%)
Follow-up period (months)	
Mean±SD	34.35±7.91
Range	23-43
No. of other congenital urologic disorders (%)	
No	242 (98.4%)
Yes	4 (1.6%)

Table 1: Description of the age distribution of total study population.

The two groups were comparable in age with the mean±SD in each of Group A and Group B was 5.06±3.69 compared to 5.37±3.68 respectively, as there is no statistically significant difference between the Group A and Group B with p-value (p=0.632) (Table 2).

For coronal, subcoronal, distal, middle, and proximal hypospadias, the occurrence rates of fistulas were 13.8 % (34), 42.7 % (105), 24 % (59), 9.8 % (24) and 9.8 % (24) respectively. As for the genior among surgeon it was 122 patients (49.6%) were enior and 124 patients (50.4%). For the level of experience of the surgeon, in group A there were 23 patients (46.9%) Senior and 26 patients (53.1%) Genior compared to group B were 99 patients (50.3%) Senior and 98 patients (49.7%) Genior, there is no statistically significant difference between the groups (Table 3, 4).

Polyglactin (Vicryl) and polydioxanone (PDS) sutures were utilized in hypospadias correction. The frequency rates of fistulas were 65.3 % and 34.7 %, respectively. Corresponding to suturing technique I (Interrupted or Continuous), the frequency rates of fistulas were 61.8 % and 38.2 % in the interrupted and continuous suturing procedures, respectively. Suture technique II (Full-thickness or Subcuticular) rates for full thickness and sub cuticular suture methods were 73.6 % and 26.4 %, respectively, for full-thickness and subcuticular suturing procedures. The frequency rates of fistulas formation were not significantly different depending on the materials of suturing or the method (p=0.920, p=0.812, and p=0.732, respectively).

Fistula development was significantly associated to hypospadias site and hypospadias operation type in the univariate analysis. Only the site of hypospadias was a significant risk factor for fistulas formation following hypospadias operation in the multivariate analysis with stratification by hypospadias location (Tables 4, 5).

All cases were catheterized with urethral stenting. In groups A and B, the average period of urethral stent

was 11.53±2.33 and 11.88±2.41 days, respectively (Table 6).

There were no definitive post operative complications after hypospadias surgery in our cases.

For splint size there were in group A 25 patients (51.0%) were 6 fr, 15 patients (30.6%) were 8 fr and 9 patients (18.4%) were 10 fr compared to group B were 69 patients (35.0%) were 6 fr, 78 patients (39.6%) were 8 fr and 50 patients (25.4%) were 10 fr, there is no statistically significant difference between the groups with p-value (p=0.118).

Most of the children (79.6%) had only one fistula, and none had more than three. 24 individuals (49%) of 49 cases who developed fistula following hypospadias surgery did so within two years. The shortest time between hypospadias correction and urethrocutaneous fistula formation was 6 months. The longest time between hypospadias correction and urethrocutaneous fistula formation was 6 years which interpreted as most patients came when they were already at the age of more than 4 years old. This age demographics shows that early awareness of the disease is still low. (Table 8).

Demographic data	Group A (n=49)	Group B(n=197)	Total (n=246)	Test value	p-value	Sig.
Age (years)						
Mean±SD	5.06±3.69	5.37±3.68	5.11±4.63	t=0.271	0.632	NS
Range	0.5-13	1-17	0.5-17			
Age group						
<2 year	11 (22.4%)	49 (24.9%)	61 (24.8%)			
2-4 years	9 (18.4%)	32 (16.2%)	43 (17.5%)	x2=0.201	0.904	NS
>4 years	29 (59.2%)	116 (58.9%)	142 (57.7%)			

Table 2: Comparison between group A and group B according to age.

Primary hypospadias repair	Group A		Group B		Total		Test value	p-value	Sig.
	No.	%	No.	%	No.	%			
Site of hypospadias									
Coronal	6	12.2%	28	14.2%	34	13.8%			
Distal Shaft	13	26.5%	46	23.4%	59	24.0%			
Mid Shaft	9	18.4%	15	7.6%	24	9.8%	14.322	0.006*	Sig.
Proximal Shaft	9	18.4%	15	7.6%	24	9.8%			
Subcoronal	12	24.5%	93	47.2%	105	42.7%			
Chordae									
No Chordae	37	75.5%	122	61.9%	159	64.6%	3.166	0.075	Ns.
Present	12	24.5%	75	38.1%	87	35.4%			
Type of repair									
Duckets	6	12.2%	18	9.1%	24	9.8%			
MAGPI	12	24.5%	41	20.8%	53	21.5%	1.145	0.766	Ns.
TPIF	3	6.1%	18	9.1%	21	8.5%			
TIP	28	57.1%	120	60.9%	148	60.2%			
Suture material									
PDS	17	34.7%	66	33.5%	83	33.7%	0.010	0.920	Ns.
Vicryl	32	65.3%	131	66.5%	163	66.3%			
Suture technique l									
Continous	18	36.7%	76	38.6%	94	38.2%	0.057	0.812	Ns.
Interrupted	31	63.3%	121	61.4%	152	61.8%			
Suture technique ll									
Full Thickness	37	75.5%	144	73.1%	181	73.6%	0.118	0.732	Ns.
Subcuticular	12	24.5%	53	26.9%	65	26.4%			
Surgeon									
Senior	23	46.9%	99	50.3%	122	49.6%	0.065	0.798	Ns.
Genior	26	53.1%	98	49.7%	124	50.4%			

Table 3: Comparison between group A and group B according to primary hypospadias repair. (TIP) tubularized incised plate urethroplasty; (TPIF) transverse preputial island flap; (MAGPI) meatal advancement and glanduloplasty.

Primary hypospadias repair	Group A (n=49) No. %		Group B (n=197) No. %		Odds ratio (95% C.I.)	p-value
Age (years)	5.06±3.69		5.37±3.68		1.68 (1.26-2.14)	0.217
Site of hypospadias						
Distal Shaft	13	26.5%	46	23.4%		
Coronal	6	12.2%	28	14.2%	0.76 (0.26-2.22)	
Mid Shaft	9	18.4%	15	7.6%	2.12 (0.76-5.59)	<0.001
Proximal Shaft	9	18.4%	15	7.6%	2.12 (0.76-5.59)	
Subcoronal	12	24.5%	93	47.2%	0.46 (0.19-1.08)	
Suture material						
Vicryl	32	65.3%	131	66.5%	1.05 (0.55-2.04)	0.455
PDS	17	34.7%	66	33.5%		
Suture technique I						
Interrupted	31	63.3%	121	61.4%	0.92 (0.48-1.77)	0.391
Continous	18	36.7%	76	38.6%		
Suture technique II						
Full Thickness	37	75.5%	144	73.1%	0.88 (0.43-1.82)	0.362
Subcuticular	12	24.5%	53	26.9%		

Table 4: Multivariate analysis of risk factors for urethrocutaneous fistula formation after hypospadias operation. (PDS) polydioxanone.

Primary hypospadias repair	Coronal (n=34)					Distal Shaft (n=59)					Mid Shaft (n=24)					Proximal Shaft (n=24)					Subcoronal (n=105)				
	Group A (n=6) No. %		Group B (n=28) No. %		p-value	Group A (n=13) No. %		Group B (n=46) No. %		p-value	Group A (n=9) No. %		Group B (n=15) No. %		p-value	Group A (n=9) No. %		Group B (n=15) No. %		p-value	Group A (n=12) No. %		Group B (n=93) No. %		p-value
Age (years)	5.57±4.06		5.91±4.05		0.512	4.77±3.48		5.06±3.47		0.185	5.02±3.66		5.33±3.65		0.367	4.53±3.31		4.81±3.30		0.280	5.29±3.86		5.61±3.85		0.263
No. of other congenital urologic disorders (%)																									
No	6	100.0%	26	92.9%	0.440	13	100.0%	46	100.0%	1.000	9	100.0%	15	100.0%	1.000	8	88.9%	15	100.0%	0.164	12	100.0%	92	98.9%	0.631
Yes	0	0.0%	2	7.1%		0	0.0%	0	0.0%		0	0.0%	0	0.0%		1	11.1%	0	0.0%		0	0.0%	1	1.1%	
Chordae																									
No Chordae	6	100.0%	25	89.3%	0.352	10	76.9%	29	63.0%	0.309	6	66.7%	6	40.0%	0.181	6	66.7%	6	40.0%	0.181	9	75.0%	56	60.2%	0.282
Present	0	0.0%	3	10.7%		3	23.1%	17	37.0%		3	33.3%	9	60.0%		3	33.3%	9	60.0%		3	25.0%	37	39.8%	
Type of repair																									
Duckets	0	0.0%	0	0.0%		0	0.0%	6	13.0%		3	33.3%	6	40.0%		1	11.1%	2	13.3%		1	8.3%	5	5.4%	
MAGPI	0	0.0%	3	10.7%	0.403	6	46.2%	22	47.8%	0.252	0	0.0%	0	0.0%	0.232	0	0.0%	0	0.0%	0.854	3	25.0%	19	20.4%	0.556
PIF	0	0.0%	3	10.7%		0	0.0%	3	6.5%		0	0.0%	3	20.0%		1	11.1%	2	13.3%		2	16.7%	7	7.5%	
TIP	6	100.0%	22	78.6%		7	53.8%	15	32.6%		6	66.7%	6	40.0%		7	77.8%	11	73.3%		6	50.0%	62	66.7%	
Suture material																									
PDS	3	50.0%	17	25.0%	0.339	3	23.1%	21	45.7%	0.222	3	33.3%	3	20.0%	0.710	5	55.6%	7	46.7%	0.774	3	25.0%	18	19.4%	0.214
Vicryl	3	50.0%	11	39.3%		10	76.9%	25	54.3%		6	66.7%	12	80.0%		4	44.4%	8	53.3%		9	75.0%	75	80.6%	
Suture technique l																									
Continuous	3	50.0%	10	35.7%	0.451	6	46.2%	22	47.8%	0.804	3	33.3%	3	20.0%	0.409	4	44.4%	5	33.3%	0.803	6	50.0%	32	34.4%	0.255
Interrupted	3	50.0%	18	64.3%		7	53.8%	24	52.2%		6	66.7%	12	80.0%		5	55.6%	10	66.7%		6	50.0%	61	65.6%	
Suture technique ll																									
Full Thickness	3	50.0%	20	71.4%	0.272	7	53.8%	35	76.1%	0.104	7	77.8%	14	93.3%	0.556	7	77.8%	8	53.3%	0.392	9	75.0%	71	76.3%	0.701
Subcuticular	3	50.0%	8	28.6%		6	46.2%	11	23.9%		2	22.2%	1	6.7%		2	22.2%	7	46.7%		3	25.0%	22	23.7%	
Surgeon																									
Senior	4	66.7%	15	53.6%	0.490	6	46.2%	29	63.0%	0.241	5	55.6%	10	66.7%	0.803	2	22.2%	9	60.0%	0.063	6	50.0%	36	38.7%	0.581
Genior	2	33.3%	13	46.4%		7	53.8%	17	37.0%		4	44.4%	5	33.3%		7	77.8%	6	40.0%		6	50.0%	57	61.3%	

Table 5: Multivariate analysis of risk factors for urethrocutaneous fistula formation after hypospadias operation according to hypospadias site.

`	Group A (n=49)	Group B (n=197)	Total (n=246)	Test value	p-value	Sig.
Mean±SD	11.53±2.33	11.88±2.43	11.81±2.41	-0.904	0.367	NS
Range	10-15	10-15	10-15			

Table 6: Comparison between group A and group B according to duration of catheter "days".

Urethral splint size:	Group A (n=49)		Group B (n=197)		Total (n=246)		Test value	p-value	Sig.
	No.	%	No.	%	No.	%			
6 fr	25	51.0%	69	35.0%	94	38.2%			
8 fr	15	30.6%	78	39.6%	93	37.8%	4.269	0.118	Ns.
10 fr	9	18.4%	50	25.4%	59	24.0%			

Table 7: Comparison between group A and group B according to urethral splint size. (Fr) french**.**

urethrocutaneous fistulas Characteristics and properties	No.	%
Timing of presentation (years)		
Less than 2 years	24	49.0%
2- 4 years	12	24.5%
More than 4 years	13	26.5%
Timing of repair of urethrocutaneous fistula (months)		
<12 months	28	57.1%
>12 months	21	42.9%
Size of fistula		
Pinpoint (<2mm)	16	32.7%
Small (>2-4mm)	27	55.1%
Large (>4mm)	6	12.2%
Site of UCF		
Distal Shaft	18	36.7%
Mid Shaft	6	12.2%
Proximal Shaft	16	32.7%
Subcoronal	9	18.4%
Number of UCF		
1.00	39	79.6%
2.00	10	20.4%

Table 8: Characteristics and properties of urethrocutaneous fistulas distribution among study group (n=49) (UCF) urethrocutaneous fistula..

DISCUSSION

Low complication rates are anticipated with an optimal hypospadias repair, resulting in a normal penis in terms of aesthetics and function, both urination and sexually [4,5]. The issue of postoperative sequelae of hypospadias surgery and related risk factors has long been a fascinating topic for pediatric urologist to research and debate [6]. One of the most prevalent after repair of hypospadias consequences, urethrocutaneous fistula, is a huge problem for both the surgeon and the children [7].

After the correction, 19.9% of the patients in this research had urethrocutaneous fistula.The incidence rate is in the middle of prior research estimates, which range from 6.2% to 38.8%. [7–9]

According to research published by The American Academy of Pediatrics, paediatric genital operations should be accomplished between the ages of six and eighteen months [10].

By the age of six months, most newborns have developed a decent tolerance for anesthesia and surgery. They are potty trained and aware of their genitalia by the age of 18 months. Some urologists have a preference to operate the child at four months for hypospadias treatment due to the short time of healing, less scar, and the assumption that it is at ease for the newborns to overcome the operation stress [11].

Because of ignorance, illiteracy, and financial constraints, the average age of hospital admission in underdeveloped nations is greater than in rich countries. As a result, whenever the patients are taken to the hospital, which is normally after the age of four years, they are operated on [12].

AS patients less than two years old who underwent primary repair 11 (22.4%) patient developed UCF, the age group between 2-4 years old 9 (18.4%) developed UCF and the age group more than 4 yeaes old 29 (59.2%) developed UCF . This data revealed that the age is non significant factor for developing fistula (P-0.904) which correlates to Chung et al.[3]

(P-0.299).In contrast Duarsa [13] showed that the age is a significant factor fro developing UCF (P-0.015). Also Sheng [17] discovered that the age is non significant factor for developing fistula.

Of the 49 patient who developed UCF post repair, 24 patient (49%) developed fistula within 2 years. Chung et al.[3] reported that 47 (74.6%) developed fistula within 1 month. Opposite to expectations our study revealed that 13 (26.5%) patient developed fistula after 4 years which interpreted as most patients came when they were already at the age of more than 4 years old. This age demographics shows that early awareness of the disease is still low.

The incidence rate is in the middle of prior research estimates, which range from 6.2% to 38.8%. [7–9] After the correction, 19.9% of the patients in this research had urethrocutaneous fistula. The frequency of fistulas differs from surgeon to surgeon., Kass and Bolong [14] stated just one patient (0.48 %) developing a fistula in 206 patients of hypospadias operations. Sarhan [4] discovered 47 cases (9.4%) with fistulae development out of 500 hypospadias procedures. As shown in Korean research, out of 212 hypospadias procedures, [15] it was reported that 42 cases (19.8%) with fistulas formation, whereas Hwang [16] stated that 16 cases (31.4%) with fistulas formation out of 51 hypospadias procedures. Chung et al.[3] revealed that 63 patients (21.4%) out of 294 developed fistula. Sheng [17] discovered 39 patients (32.5%) with fistulae out of 120 hypospadias procedures. Recently, Duarsa [13] reported that 15.27% of patients developed urethrocutaneous fistula after the repair.

In the univariate analysis, the type of hypospadias had a statistically significant impact on the result (P-0.006). So, each hypospadias site was studied separately, and the results indicated that no other factors had a major impact on the surgery's outcome in multivariate analysis (P<0.001).The types of hypospadias in this study are significantly correlated to the development of fistula as in Chung et al.'s [3] study which shows that distal hypospadias have better outcome and lower risk of fistula compared to proximal cases (P<0.001). On the contrary, Duarsa [13] shows type of hypospadias is not significant factor (P-0.102).Sheng [17] did not take the site of hypospadias into cosideration as a risk factor for developing urethrocutaneous fistula.

There is no single procedure which is suitable for all patients. .With the advancement of surgical techniques, it is unsurprising that the urethroplasty technique is not significantly linked to the risk of developing fistula. In the univariate analysis, the method of correction had a statistically significant impact on the result (P-0.766), however, in multivariate analysis the method of correction was not significant for developing fistula (P-0.556). Duarsa [13] showed that the type of hypospadias repair was not significantly linked to the development of fistula (P-0.102) in contrast to Chung et al.'s [3] study which revealed that distal hypospadias have lower risk of fistula compared to proximal cases

(P-0.006), while Sheng [17] did not depend on method of correction as a risk factor for developing fistula.

For splint size there is no statistically significant difference between the groups with p-value (p-0.118) in this study as opposed to Duarsa [13] who claimed that splint size is a significant risk factor for developing fistula (P-0.023), and it is possible that a larger splint size, would increase the risk of post operative hematoma and wound infection. Chung et al. [3] & Sheng [17] did no mention splint size as a risk factor.

Sheng [17] discovered that the chance of development fistulas following hypospadias correction is linked to the length of the urethral defects and previous urethral operations. However, an analysis of the length of the urethral defects and previous urethral operations as a possible risk has never been discussed previously in any research, thus further researches on the relation of the length of the urethral defects and previous urethral operations should be implemented in the future.

So, our results indicated that only site of hypospadias had a major impact on the surgery's outcome.The types of hypospadias in this study are significantly correlated to the development of fistula as in Chung et al.'s [3] study which shows that distal hypospadias have better outcome and lower risk of fistula compared to proximal cases. On the contrary, Duarsa [13] shows type of hypospadias is not significant factor while age and splint size are. Sheng [17] discovered that the chance of development fistulae following hypospadias correction is linked to the length of the urethral defects and previous urethra operations, but not to age, surgical technique, kind of surgical intervention, chordae extent, or other variables.

It's unclear why some individuals get urethrocutaneous fistula while others don't. A crucial element is assumed to be surgical technique, while a regional deficiency in the growth hormones might have a role [18].

Hormonal treatment has been advocated to minimise the formation of fistulas, although the outcomes have been variable. Additionally, several aspects of postoperative care, such as the usage of specific kinds of dressings and operative materials, wound condition, and the antibiotic, should be deemed [16].

These postoperative characteristics were of limited data in our analysis but might be substantial hazard factors; thus, we wish to include them in our follow up investigations. Because there were so many variables to examine and the analysis is so challenging, there were only some researches on peri-operative risk factors for the formation of the fistulas. Even though our research study had shortcomings and drawbacks, it may be beneficial to physician considering hypospadias correction. To corroborate our preliminary findings in this comparatively small case study, more research with various study designs will be required.

CONCLUSION

After hypospadias correction, the likelihood of urethrocutaneous fistula formation is related to the site of hypospadias (greater in the proximal hypospadias). The type of hypospadias procedure, the suture utilized, and the method used were not linked to the formation of fistulas.

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