



ORIGINAL RESEARCH PAPER

Surgery

MULTIVARIATE ANALYSIS OF FACTORS ASSOCIATED WITH FAILURE OF TUBULARIZED INCISED PLATE URETHROPLASTY REPAIR FOR HYOSPADIAS: A PROSPECTIVE STUDY

KEY WORDS: Complications, congenital anomalies, surgical flaps, spongiosum, urologic surgical procedures

Saran Rama Kishan	Associate Professor, Department of Surgery, Dr.S.N.Medical College, Jodhpur, Rajasthan, India
Mirdha Kiran*	Senior Specialist, Umaid Hospital, Dr.S.N.Medical College, Jodhpur, Rajasthan, India, *Corresponding Author
Saran Sanya	Geetangali Medical College & Hospital, Udaipur, India,
Takhar Rajendra Prasad	Assistant Professor, Govt. Medical College, Kota, Rajasthan, India.

ABSTRACT

INTRODUCTION: The tubularized incised plate urethroplasty (TIPU) is a standard technique widely used for the management of hypospadias.

AIM: To evaluate the role of patients' age and local penile factors affecting the outcomes of TIPU repair for hypospadias.

MATERIALS AND METHODS: This was a prospective study conducted between April 2009 and October 2011. Patients with hypospadias who underwent TIPU were included in the study. The study variables were age, severity of hypospadias, degree of curvature and torsion, size of penis and glans, width of urethral plate, development of spongiosum and complication rate. The patients were followed up for 10 months to 2 years (mean: 20 months). Chi square test was used to compare between categorical variables.

RESULTS: A total of 125 patients with mean age 8.8 years (range: 6 months to 26 years) were studied. The complication rate between patients with >15 years and <5 years was 20% and 3.6% (p=0.08), respectively. Patients with proximal penile hypospadias had 30% of complications. The complication rate was significantly (p=0.001) associated with the degree of curvature, 35.7%, 30.8%, and 3.6% in severe, moderate and mild curvature, respectively. Complications were higher in patients with poor spongiosum and higher age (p=0.001) and in patients with narrow urethral plate (p=0.0001). Urethral fistula and stricture were the most commonly reported complications. The development of urethral plate and spongiosum is directly proportional to the complication rate.

CONCLUSION: Results showed that age of child, type of hypospadias, degree of curvature, quality of spongiosum and width of urethral plate are important factors associated with the TIPU outcomes. Patients with >5 years of age, proximal hypospadias, poor spongiosum and narrow urethral plate have higher rate of complications.

Introduction

Hypospadias is a congenital anomaly found in males and characterized by abnormal urethral opening. The tubularized incised plate urethroplasty (TIPU), also known as Thiersch-Duplay procedure, is a standard technique widely used for surgical management of hypospadias. Various other techniques are also used such as Mathieu urethroplasty (flip-flap technique) or vascularized island flap [1]. There are several complications reported after TIPU. Various risk factors like age of correction, type of hypospadias, degree of curvature, degree of torsion, length of penis, glans size, width of urethral plate, quality of corpus spongiosum, and preputial reconstruction have been associated with the outcome of TIPU repair. Surgical skill and suture material also influence the outcome of hypospadias repair [2-5].

The most common complications of hypospadias correction with the TIPU failure are residual curvature, urethral breakdown, fistula formation, urethral stricture and meatal stenosis [5]. To our knowledge these no such prospective study which evaluated results hypospadias with reference to these factors. The aim of this study was to evaluate the role of various factors associated with the failure of hypospadias.

Materials and Methods

A prospective study was conducted in a tertiary care teaching hospital between April 2009 and October 2011, in male patients presenting with hypospadias and its variants, who underwent TIPU repair. Patients requiring flap urethroplasty or in case intra-operative decision was made for flap urethroplasty, redo cases and patients with lost to follow-up were excluded from the study. A written informed consent or assent in case of pediatric patients was obtained before participation of the study.

The eligible patients underwent a thorough clinical examination and following data was collected regarding the location of the external meatus, assessment of degree ventral chordee and

torsion, the size of penis and glans, status of prepuce, and intra-operative assessment of the width of the urethral plate and the quality of development of the corpus spongiosum.

The penile size was determined as mentioned in the literature [6]. The standard glans size was considered by measuring the width in 10 patients aged between 1 and 15 years admitted for non-urologic conditions. The mean (SD) was taken as the criterion for small glans size in the corresponding age groups. The size of glans was classified based on its diameter from I to V grades, <8.0, <11.3, <12.6, <13.9, and <21.5, respectively. The degree of ventral curvature and torsion were measured on the operation table before penile de-gloving using a sterile protractor.

The intra-operative appearance of the corpus spongiosum was assessed and classified into three types: Type 1: Poorly developed, with deficient spongiosal tissue and low vascularity [Table/Fig-1], Type 2: Moderately developed, with normal size and thickness of spongiosal tissue and normal vascularity [Table/Fig-2], Type 3: Well Developed, Robust thick Spongiosum with good vascularity [Table/Fig-3] [6].

In wide type, the tubularization was performed easily without any incision, over the largest sized catheter or infant feeding tube (IFT) accommodated into the normal proximal urethra. Whereas, in average and narrow urethral plate, a superficial and deep incision is required for tubularization over the catheter or IFT, respectively.

Surgical technique

A U-shaped incision was made encircling the meatus up to the corona, preserving the urethral plate, and extending circumferentially around the corona followed by the mobilization of the urethral plate and corpus spongiosum. A V shaped incision was given in cases with no chordee or torsion, and preputioplasty was needed. Penile de-gloving was performed in cases like ventral curvature followed by Gittes test to assess chordee correction.

After every step of chordee correction, methods like mobilization of urethral plate and spongiosum is needed, proximally, the urethra with spongiosum was mobilized up to the bulbar urethra and dorsal plication. Glanular chordee was improved by mobilizing the urethral plate into the glans. This stepwise approach also corrects the torsion.

The urethral plate was then tubularized without or with a deep incision through the spongiosum in the midline with 7/0 PDS continuous sutures, irrespective of the age. Spongioplasty and glansplasty was performed to complete the procedure with 6/0 vicryl interrupted sutures, and a 6 Fr to 10 Fr urethral catheter, which were smaller than the catheter over which urethral plate was tubularized, depending on patient age, left in situ.

Preputioplasty was performed only in cases where prepuce is of an adequate size and the parents or patients wished to retain it. Dorsal dartos wrap was not used in any case. Pressure dressing was performed in all patients and urethral catheter was removed on postoperative day 7 to 10. Patients were followed at 1 month, 3 months, 6 months, 12 months and then yearly for cosmesis, fistula, meatal stenosis and any other complications. At follow up visits, patients or parents were asked to void for visualizing the stream and any leakage other than the meatus (suggestive of a fistula).

Post-operative complications and results in each group were recorded and compared with different age groups and other variables. Chi square test was used to compare between categorical variables. A p value of <0.05 was considered to be statistically significant. The statistical analysis was done using SPSS statistical software (version 20).

Results

A total of 154 patients were screened, of which 125 were included in the study. According to different age groups, patients were divided into five groups consisting of group I; n=30 aged <2 years, group II; n=28 aged 2-4 years, group III; n=22 aged 5-10 years, group IV; n=20 aged 10-15 years, and group V; n=25 aged >15 years. The mean age of all patients ranged from 6 months to 26 years was 8.8 years. The follow up period ranged from 10-24 months (mean 16 months).

Age

Most of the complications of TIPU repair were seen in group III, IV and V with patients aged >5 years. Patients aged >15 years had the highest number (n=5) of complications followed by patients aged 5-10 years and 10-15 years group with three complications including one case of urethral fistula in each group. Only one complication was recorded in patients <2 years within one year of the procedure. The complications in all the five groups were statistically significant (p=0.001) [Table/Fig-4].

Type of hypospadias

The degree of hypospadias was associated with the location of meatus. The majority of patients had distal penile (n=87), followed by proximal penile (n=20) and mid penile hypospadias (n=18). The location of hypospadias was significantly (p=0.001) associated with the rate of complications. Patients with proximal penile hypospadias had 30% of complications followed by mid penile hypospadias (11%) and distal penile hypospadias (6%) [Table/Fig-4].

Complications regarding the severity of hypospadias considering degree of curvature, width of urethral plate and development of spongiosum were also evaluated and found to be statistically significant. The number of complications were associated with the severity and age of the patients with hypospadias. The patients between 5-15 years of age (n=42) had, 14% of complication rate (0.0017) [Table/Fig-5].

Ventral curvature

Of 125 patients, 55 patients had ventral curvature ranged from 30 to 115 degrees. The degree of curvature was classified as mild (<30 degrees), moderate (30-60 degrees) and severe (>60 degrees). The majority of the patients (n=70) had nil ventral curvature. Of 55 patients having ventral curvature, 28 had mild degree of curvature,

followed by 14 severe degree and 13 moderate degree of curvature. The complication rates were significantly (p=0.0004) associated with the degree of curvature. The majority (n=5) of the complications were seen in patients with severe degree of curvature, followed by moderate (n=4), nil (n=3) and mild (n=1) degree of curvature [Table/Fig-6].

Quality of spongiosum

The spongiosum was well developed in 66 number of patients (53%), moderately developed in 48 (38%) and poorly developed in 11 (9%) number of patients. Of 11 poorly developed patients, 4 were more than 15 years old. The quality of spongiosum was significantly (p=0.0001) associated with the number of complications. The majority (n=7) of the complications were recorded in patients with poorly developed spongiosum, followed by patients with well and moderately developed spongiosum (n=3 each) [Table/Fig-5].

Width of urethral plate

The urethral plate was wide in 60 patients (48%), average in 48 (38%) and narrow in 17 (14%) patients. The width of the urethral plate was significantly (p=0.0018) correlated with rate of complications. Higher rate (41%) of complications were recorded in patients with narrow urethral plate, followed by average (8%) and wide (3) [Table/Fig-5].

Penile torsion

Penile torsion was classified as mild (<45 degrees), moderate (45-90 degrees) and severe (>90 degrees). The degree of penile torsion ranged from 30 to 180 degrees in 12.8% (n=16) cases. Correction by penile de-gloving was possible in 4 cases, 7 cases required mobilization of the urethral plate, and mobilization of urethral plate into glans was required in 5 cases. Severe torsion was seen more frequently in patients with distal hypospadias. However, none of the patients with severe torsion had any complication. The most (n=7) of the complications were noted in patients with mild degree of torsion (p=0.0001) [Table/Fig-5].

Size of penis and glans

Size of the penis and glans was normal in 96% (n=120) and 95% (n=119) of patients, respectively. There was no significant association between size of penis (p=0.43), glans (p=0.39) and complication rate of TIPU repair. Of patients with average size of penis and glans, 13 had complications. None of them had complications with small sized of penis and glans [Table/Fig-5].

Preputioplasty

Preputioplasty was done in 38.4% (n=48) of cases and surgical outcomes after TIPU were not affected. The overall incidence of complications was 10.4% (13/125). [Table/Fig-6] summarizes the complication in each patient and [Table/Fig-7] shows the complication rates with respect to risk factors in these patients. Out of these 13 patients, six (46.15%) had proximal hypospadias, five of 13 had either torsion (n=3) or severe chordee (n=2), one with either moderately or poorly developed spongiosum. None of the patients had wide urethral plate. Three patients of urethral fistula and one of urethral disruption had good results after the second surgery (i.e., results were 100% after the second surgery).

Discussion

This prospective study was aimed to evaluate the role of various factors which may contribute to the failure of hypospadias. Overall, it was observed that age of child, type of hypospadias, degree of curvature, quality of spongiosum and width of urethral plate are important factors associated with the TIPU repair.

In the present study, of the 125 patients evaluated, 20% (n=25) of the patients were more than 15 years of age, this could be due to the poor financial status, ignorance, feeling of shame, lack of correct guidance and proper healthcare facilities in the rural areas of the region.

In this study cohort, complication rates showed an increasing trend with the increasing age. There was substantial difference in complication rates (20% vs 3.3%) between adult patients >15 years and the patient groups <2 years (6 months to 2 years)

showing as compared to the age group 2-5 years i.e., 20% versus 3.6%. Age was an important factor in hypospadias patients with more than 5 years. Higher complication rates in older children with hypospadias repair were also reported in several studies (18.7% to 54%) [2,7,8].

Hensle et al. reported 52.3% of complications in patients with hypospadias repair [2].

The long-term complications may be due to various reasons including post-operative erections, differences in vascularity and wound healing characteristics, susceptibility to infections in the form of different skin and hair flora that may introduce infection [2,7-10].

Histopathological examination of prepuceal skin of older children and neonates showed higher expression of the pro-inflammatory cytokines in the 15 samples of foreskin from boys, authors demonstrated higher production of pro-inflammatory cytokines IL-6, IL-8, TNF- α and TGF- β 1 at baseline and after stimulation with PDGF, in older children compared to neonates, the degree of scarring and complications related to wound healing was proposed to be roughly proportional with the degree of inflammation and levels of IL-6, IL-8, TGF- β 1 and TNF- α [11].

However, some studies do not report age as an independent predictive factor for post-operative complications. Patients (n=13) with TIPU as a primary repair, aged from 18 to 26 years with a good urethral plate of adequate width, and minimum chordee had no greater incidence of complications [10,12,13].

In the present study, the location of hypospadias was again found to be a significant factor affecting the results. The complication rates were statistically significant ($p=0.001$) showing 30%, 11% and 6% in proximal, mid and distal penile hypospadias, respectively. Complications in the younger age group were associated with the severity of hypospadias as evidenced by the statistically significant association in 16% patients (n=20) in the age group of 10-15 years ($p=0.024$). In the age group of 5-15 years comprising 33.6% cases with 42 patients, this correlation was also significant ($p=0.0017$).

In patients > 15 years, the complications were higher irrespective of the severity of hypospadias. Although initially the age and type of hypospadias both affect complication rates; as the age increases, the complications are higher irrespective of the type of hypospadias, making age as an independent risk factor for the occurrence of complications.

In a study, 551 consecutive patients underwent distal TIPU repairs, with a mean age of 17 months and mean follow up of 8.2 months had only 4% (n=19) complication rate [14].

Snodgrass WT, et al. also reported a complication rate of 11% (3 out of 27 patients) in patients aged 6 months to 3 years with mid shaft and penoscrotal hypospadias [15]. More proximal is the hypospadias, more is the complications (30% in proximal vs 5.7% in distal). Same were also reported in the literature i.e. 22% in proximal and 9% in distal [11,12].

In this study there were 55 cases with varying degree of chordee, of which 36% complications had severe degree of chordee, followed by 31% having moderate and 3.6% having mild degree of chordee ($p=0.0001$). In the present study the degree of curvature was associated with the severity of hypospadias with up to 45% cases of proximal hypospadias having severe curvature. In our study, Chordee is associated with more complication rate (with-18% Vs without 4.2%). Similar results also reported in the literature i.e. 25% [3].

Well-developed corpus spongiosum is needed to reduce the severity of hypospadias [8]. Poorly developed corpus spongiosum was associated with increased number of complications. Reconstruction with spongioplasty proved to reduce the complications [16].

In this study most of the complication were found in poorly developed spongiosum as compared to well and moderately developed spongiosum.

Aboutaleb H, et al. effect of urethral plate characteristics on outcome of TIPU. Urethral plates were flat, cleft and deeply grooved, also some have >8mm or <8mm urethral plate width. Patients with <8mm urethral plate width had significantly higher fistula rate ($p=0.004$) and failed 8Fr calibrations as compared to >8mm width. These findings were also similar with flat urethral plate. Thus, adequate urethral plate width is needed for the success of hypospadias treatment [17].

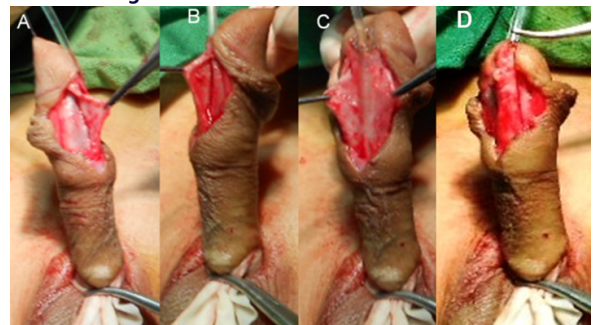
In Holland et al, of 46 patients, urethral fistula developed in six patients with <8mm width of urethral plate. Of the 15 boys with shall urethral groove, six had neourethral caliber of 6Fr [18]. However, in some studies there was no significant in results associated with plate configuration or width [18-20]. In this study, complications were commonly reported in narrow urethral plate as compared to wide. Mosharafa AA, et al. also showed similar findings [21].

In this study, 4.8% of patients with distal hypospadias reported small penis and glans size, but, none of them showed any correlation with outcomes of TIPU repair. No significant association of higher rate of glans dehiscence was reported in patients with proximal hypospadias, though such findings have been reported [21,22]. However, another study reported glans dehiscence in 20 of 520 distal, one of 47 mid-shafts, and 11 of 74 proximal tubularized incised plate repairs. Glans dehiscence was 3.6 times higher in patients with proximal and distal meatal location, and patients underwent revision surgery had 4.7 increase risk of glans dehiscence [23]. In a round table discussion, one patient reported he had no fistula after 4 years of hypospadias repair, but most common complication reported was glans dehiscence [22]. Another prospective study with 490 boys and glans size <14mm reported small glans size, reoperations and mid/proximal meatus were independent risk factor for urethroplasty complications [24].

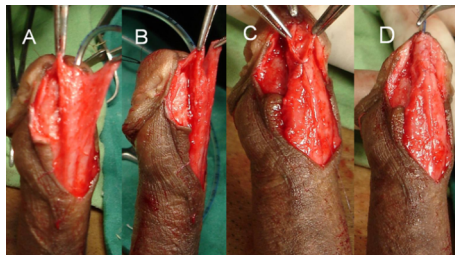
CONCLUSION

We conclude that the important factors associated with the TIPU repair were age of child, type of hypospadias, degree of curvature and quality of spongiosum and width of urethral plate. Patients with >5 years of age, proximal hypospadias, poor spongiosum and narrow urethral plate have higher rate of complications. Patient having >3 risk factors have higher chances of complications, precaution is needed to be taken by surgeons for better results. The overall evaluation of risk factors in hypospadias patients will help new surgeons for appropriate case selection and referring the high-risk group patients to more experienced surgeons. These patients or parents should be informed beforehand regarding the patient's condition and outcome after surgery.

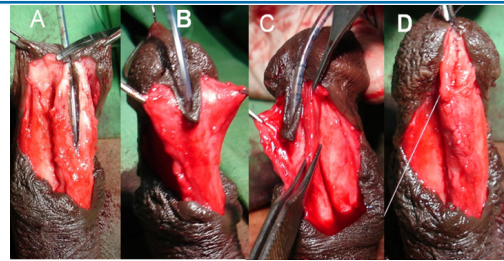
Tables and Figures:



[Table/Fig-1]: Showing poorly developed corpus spongiosum. (A) Mobilized spongiosum on left side with minimal spongiosum tissue, (B) Mobilized spongiosum on right with minimal spongiosum tissue, (C) Hypoplastic urethra and both side mobilized spongiosum with minimal spongiosum tissue, and (D) Neourethral diameter less than proximal healthy urethra after spongioplasty.



[Table/Fig-2]: Showing moderately developed corpus spongiosum. (A and B) Both side mobilized spongiosum with moderate spongiosum tissue, (C and D) Spongioplasty of mobilized spongiosum - neourethral diameter almost equal to the proximal healthy urethra after spongioplasty.



[Table/Fig-3]: Showing well developed corpus spongiosum. (A, B, and C) Both side mobilized spongiosum with robust healthy spongiosum tissue. (D) Spongioplasty of mobilized spongiosum - neourethral diameter more than proximal healthy urethra after Spongioplasty.

[Table/Fig-4]: Patient groups with variables, complications and statistical significance

Variables	Group I 30 (24)	Group II 28 (22)	Group III 22 (18)	Group IV 20 (16)	Group V 25 (20)	Total 125 (100)	Complications	P value
Complications	1 (3.3)	1 (3.6)	3 (13.6)	3 (15)	5 (20)	13 (100)	-	0.001
Degree of hypospadias								0.001
Distal penile	20 (67)	18 (64)	15 (68)	15 (75)	19 (76)	87 (70)	5 (6)	
Mid penile	4 (13)	6 (21)	3 (14)	2 (10)	3 (12)	18 (14)	2 (11)	
Proximal	6 (20)	4 (14)	4 (18)	3 (15)	3 (12)	20 (16)	6 (30)	
Penile chordee 55/125 (44%) mean = 300								0.0001
Nil	17 (57)	13 (46)	10 (46)	14 (70)	16 (64)	70 (56)	3 (4)	
Mild	6 (20)	8 (29)	8 (36)	2 (10)	4 (16)	28 (22)	1 (4)	
Moderate	4 (13)	4 (14)	2 (9)	2 (10)	1 (4)	13 (10)	4 (31)	
Severe	3 (10)	3 (11)	2 (9)	2 (10)	4 (16)	14 (11)	5 (36)	
Quality of spongiosum								0.0001
Well developed	8 (27)	18 (64)	13 (59)	11 (55)	16 (64)	66 (53)	3 (5)	
Mod. developed	20 (67)	8 (29)	8 (36)	7 (35)	5 (20)	48 (38)	3 (6)	
Poorly developed	2 (7)	2 (7)	1 (5)	2 (10)	4 (16)	11 (9)	7 (63)	
Urethral plate								
Wide	13 (43)	18 (64)	10 (46)	10 (50)	9 (36)	60 (48)	2 (3)	
Average	15 (50)	8 (29)	8 (36)	7 (35)	10 (40)	48 (38)	4 (8)	
Narrow	2 (7)	2 (7)	4 (18)	3 (15)	6 (24)	17 (14)	7 (41)	
Penile torsion 25/125 (20%) mean = 180								0.0001
Nil	15 (50)	15 (54)	11 (50)	9 (45)	10 (40)	60 (48)	3 (5)	
Mild	12 (40)	10 (36)	8 (36)	9 (45)	10 (40)	49 (39)	7 (14)	
Moderate	2 (7)	2 (7)	2 (9)	1 (5)	3 (12)	10 (8)	3 (30)	
Severe	1 (3)	1 (4)	1 (5)	1 (5)	2 (8)	6 (5)	0 (0)	
Size of penis in cm (small penis-length of penis GI <3.5, GII <4.5, GIII <5, GIV <5.5, GV <11.5)¹⁰								0.43
Average	28 (93)	27 (96)	20 (91)	20 (100)	25 (100)	120 (96)	13 (11)	
Small	2 (7)	1 (4)	2 (9)	0	0	5 (4)	0 (0)	
Size of glans in mm (small glans diameter GI <8.0, GII <11.3, GIII <12.6, GIV <13.9, GV <21.5)								0.39
Average	27 (90)	27 (96)	20 (91)	20 (100)	25 (100)	119 (95)	13 (11)	
Small (GI)	3 (10)	1 (4)	2 (9)	0	0	6 (5)	0 (0)	

Data presented as number (percentage). G, grade.

[Table/Fig-5]: Correlation of variables with the type of hypospadias

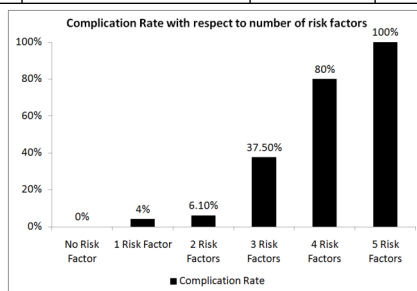
Variables	Type of hypospadias			Complications	P value
	Distal	Mild penile	Proximal		
Age of patients					
Group I (6months-2 years)	20	4	6	1	0.126
Group II (2-5 years)	18	6	4	1	0.149
Group III (5-10 years)	15	3	4	3	0.064
Group IV (10-15 years)	15	2	3	3	0.024
Group III and IV (combine)	30	5	7	6	0.0017
Group V (>15 years)	19	3	3	5	0.645
Quality of spongiosum					
Well developed	49	12	5	3	0.0001
Moderately developed	32	7	9	3	
Poorly developed	6	0	5	7	
Width of urethral plate					
Wide	41	11	8	2	0.0018
Average	35	8	5	4	
Narrow	11	0	6	7	

Penile torsion					
Mild (<45)	12	2	2	6	0.823
Moderate (45-90)	4	2	1	3	
Severe (>90)	2	0	0	0	
Degree of penile curvature					
Mild (<30)	24	3	1	2	0.0004
Moderate (30-60)	6	3	4	3	
Severe (>90)	3	2	9	5	
Size of penis					
Average	84	17	19	13	0.929
Small	3	1	1	0	
Size of glans					
Average	83	17	19	13	0.876
Small	4	1	1	0	

Data presented as number of patients.

[Table/Fig-6]: Details of complications in each case

Case No.	Complications	Age (years)	Type of hypospadias	Chordee indegree (°)	Urethral plate	Spongiosum	No. of risk factors
1	Fistula	1.5	Peno-scrotal	70	Narrow	Poor	4
2	Fistula	3	Mid Penile	35	Average	Well	1
3	Fistula	5.6	Peno-scrotal	40	Narrow	Moderate	4
4	Superficial skin necrosis	8	Proximal penile	90	Average	Well	3
5	Meatal Stenosis	9	Distal	Nil	Wide	Well	1
6	Meatal Stenosis	12	Distal penile	Nil	Narrow	Moderate	2
7	Stricture	13	Proximal	65	Wide	Poor	4
8	Fistula	15	Peno-scrotal	95	Narrow	Poor	5
9	Stricture	18	Distal penile	35	Narrow	Poor	4
10	Fistula	18	Mid penile	10	Average	Moderate	2
11	Fistula	20	Peno-Scrotal	70	Narrow	Poor	5
12	Meatal stenosis	22	Distal penile	25	Average	Poor	3
13	Disruption of urethra	23	Distal penile	Nil	Narrow	Poor	3
Total	13	Mean = 12.9	-	Mean = 41.1	N = 8 A = 4 W = 1	Poor = 7 Mod = 3 Well = 3	<3F = 4 3F = 3 4F = 4 5F = 2



[Table/Fig-7]: Summary of complication rate

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