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Original Article

Mucosa grafts urethroplasty in hypospadias-associated urethral stricture: critical factors for treatment selection

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Abstract: This research aimed to identify factors affecting outcomes of hypospadias-associated urethral stricture repair, and to find the best surgical method for overweight and obese patients. There were 188 patients who were admitted in this study. Multivariable analysis was performed by logistic regression with the success rate as the dependent variable. Multivariate linear regression was performed, and the spearman value was used to evaluate the linear regression. Stratified analysis was adopted depending on BMI (Body mass index) status. The Mantel-Haenszel (M-H) test and Breslow-Day (B-D) test were used to test the homogeneity of OR (Odds ratio). Kaplan-Meier (K-M) curves were plotted. The BMI status (OR=0.233, 95% CI=0.090-0.600, P=0.003) and the number of previous operations (OR=0.140, 95% CI=0.056-0.351, P=0.000) were independently associated with success rate. A two-stage method had higher success rate than one-stage in the overweightness & obesity group (OR=4.911, 95% CI=1.504-16.036, *P*=0.004). There was a significant difference in homogeneity (M-H test, P=0.029; B-D test, P=0.026). "Treatment (P=0.007)" in overweight & obese group, "BMI (P=0.000)", "numbers of previous operations (P=0.000)" were associated with unsuccessful-free survival rates. This research suggested that a two-stage method had a higher success rate for overweight and obese patients while both one- and two-stage achieved satisfied outcomes in BMI-normal patients.

Keywords: Hypospadias, urethral stricture, two-stage repair, risk factor, one-stage repair

Introduction

Hypospadias is one of the most common congenital urological conditions, affecting about 1 in every 200 males [1]. The location of the urethral meatus range can be anywhere: within the glans, at the corona, the shaft of the penis, the scrotum, or the perineum. Hypospadias repair aims to create a straight penis, an adequate-caliber neo-urethra, and a meatus at/or near the tip of the glans penis. The goal is to achieve normal voiding and good penile cosmesis with minimal complications. Although related surgical techniques have been improved dramatically in recent decades, there is still a high complication rate: 10% of distal [2], and 17% [3] to >50% [4, 5] of proximal repairs.

Hypospadias-associated urethral stricture (HAUS) is defined as a urethral stricture after hypospadias repair and has been regarded as one of the most common causes of urethral stricture for men aged below 45 years [6]. The most popular repairs for HAUS are single-stage dorsal inlay graft and 2-stage mucosa replacement urethroplasty [7, 8]. There is a considerable variation of the success rates in different literature. For example, Myers et al [9] reported an initial success rate of 36% for two-stage repairs, whereas Meeks et al [10] reported a success rate of 86%. It should be taken into account that such variation might be caused by some risk factors such as patient heterogeneity [11]. Among them, body mass index (BMI) was regarded as an important factor of treatment failure. Thereby, our aim was to identify factors that affect outcomes of HAUS repair, and to find the best surgical method for overweight and obese patients.

Materials and methods

Study design and patients

A total of 232 patients were treated at the Plastic Surgery Hospital, Chinese Academy of Me-

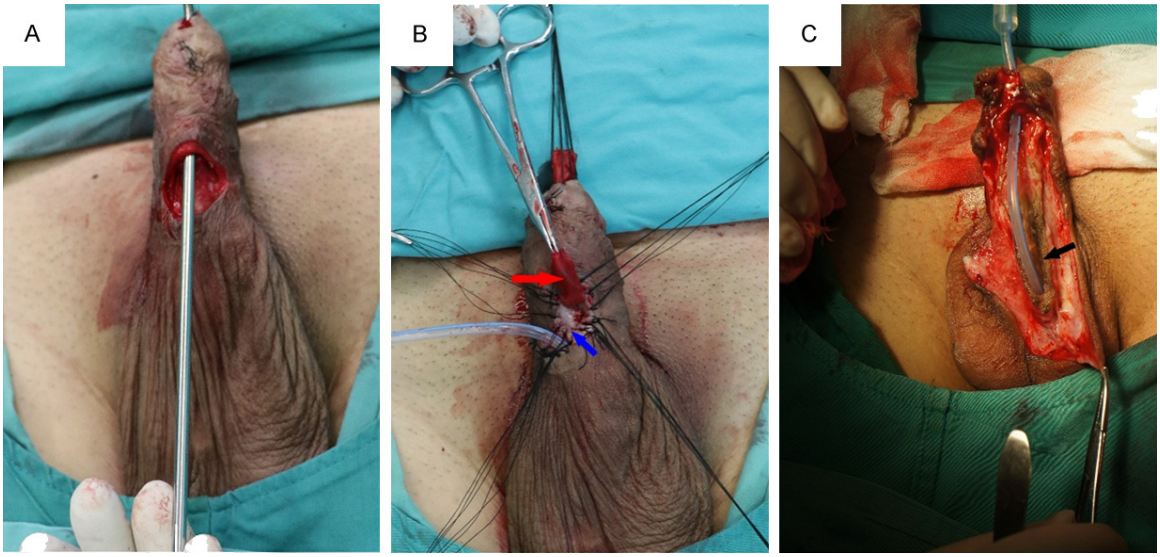

Figure 1. The key procedures of the two-stage method. A. We used surrounding prepuce flap to form a tunnel. B. The fabricated urethra indicated by red arrow was inserted into the tunnel. The blue arrow indicated the proximal part of the fabricated tissue which was grafted and sutured with the distal meatus of normal urethra. C. The black arrow indicated the proximal part of the fabricated tissue which was grafted and sutured before. It was tubularized and sutured longitudinally around the catheter to form the proximal part of neourethra.

dical Sciences (CAMS) and Peking Union Medical College (PUMC) between January 1st, 2000, and October 1st, 2019. Among them, 188 were included in this study and 44 patients were excluded due to loss of follow-up. Urethra stricture was diagnosed due to symptoms, including stranguria, urinary retention, and urinary tract infection. Urethral ultrasound was also adopted to identify the stricture.

The inclusion criteria were: (1) diagnosed with HAUS; (2) without other urethra-related congenital malformation; (3) patients were at least 18 years old when diagnosed. The success of treatment was defined as: (1) no stricture-related symptoms, such as stranguria, urinary retention, and urinary tract infection; (2) the absence of fistula; (3) the aesthetic outcome is acceptable by both patients and surgeons. We defined prevalence of overweightness and obesity by the World Health Organization standard categorization according to which BMI ≥25 to <30 kg/m^2 was defined as overweightness and BMI ≥30 kg/m^2 as obese.

Surgical technique

Two methods were adopted in our study: one-stage prepuce flap method and modified two-stage buccal mucosa graft (BMG) group.

One-stage treatment: We used the single-stage on lay method first described by Elder et al [12]. This method was only applied in the following patients: first, patients who refused a two-stage operation; second, patients without severe scaring in the prepuce; third, patients with enough prepuce tissue to form a neourethra.

Two-stage treatment: This method was first reported by our colleges Zhao et al [13]. The surgeons were divided into two teams: the oral team and the penis team. Two mucosal strips were obtained and sutured longitudinally. The mucosa strips covered a gauze roll to form a mucosal tube. The surgeons in the penis team opened the strict urethra and removed it, leaving a wide meatus proximally to void through. We also formed a ventral tunnel by the surrounding penile tissue (**Figure 1A**). The tunnel was placed between the subcutaneous and tunica albuginea and extended from the normal urethral meatus to the distal urethral meatus. The mucosal tube was inserted into the tube (**Figure 1B**). An outer dressing was used to provide stress to adhere to the mucosal tube into the tunnel wall. The gauze roll was removed one month from surgery. The second surgery was carried out 6-12 months later. The residual mucosa was tubularized to form the urethra

between the two meatus (**Figure 1C**). The septal scrotal flap described by Liu [14] was used to form additional waterproof layer. The second stage was performed at least 6 months after the first stage.

Observation parameters

Clinical data were collected from institutional medical records.

Follow-up

All patients were followed for 41 months after surgery. Urethral-related symptom and cosmetic evaluation were performed every six months. Patients with stricture-related symptoms received urethral ultrasound.

Statistical analysis

Stata/SE 15.1 (Stata Corp., College Station, TX, USA) was used for statistical analysis. Continuous variables were presented as means ± standard deviations, or as medians and interquartile ranges according to their distribution. Categorical variables were reported as the frequency with percentage. Two-sided *p*-values <0.05 were considered statistically significant. First, univariate and multivariable analysis was performed by logistic regression with success rate as the dependent variable. Odds ratio (OR) and 95% confidence intervals (CI) were calculated. Second, stratified analysis was adopted depending on BMI status. The Mantel-Haenszel (M-H) test and Breslow-Day (B-D) test was used to test the homogeneity of ORs. Next, Kaplan-Meier (K-M) curves were plotted to explore the unsuccessful-free survival rates, according to the stratified analysis and multivariable analysis. Log-rank test was used to test K-M curves. Finally, multivariate linear regression was performed, and spearman values were used to evaluate the linear regression.

Results

Basic information

A total of 188 patients aging from 18 to 49 years (median =25y, p25=21y, p75=28.5y) were included. The baseline information was shown in **Table 1**. All patients were diagnosed with HAUS. One hundred and twenty six (67.0%) patients were in the normal-BMI group and 62 (33.0%) in overweight & obese group. Seventy-two patients (38.3%) were treated by the one-stage method and 156 (83.0%) by the two-stage method. There were 136 (72.3%) patients whose stenosis length were less than 3 cm and 52 (38.2%) patients over 3 cm.

Therapeutic effect

Thirty-nine (20.74%) patients had failed outcomes after our treatment and needed further operations. Among them, 30 patients had complications (**Table 2**): 4 with urethral diverticulum, 17 with fistula, 9 for urethral stricture. Nine patients were had cosmetic un-satisfaction.

Multivariable analyses

In univariate analyses, age, the age at initial treatment, BMI status, treatment method, the number of previous treatments and stricture length were related to success rate (**Table 1**).

In the multivariable analyses, only BMI and the number of previous operations were independently associated with success rate (**Table 3**). Patients with normal BMI had a higher success rate than overweight and obese patients (OR= 0.233, 95% CI=0.090-0.600, P=0.003). Success rate decreased as the number of previous operations increased: for patients with two or more operations, the success rate was only 0.14-fold greater than those only with hypospadias repair (OR=0.140, 95% CI=0.056-0.351, P=0.000).

The method of treatment was not associated with the success of urethroplasty (OR=1.804, 95% CI=0.712-4.571, P=0.214) in multivariable analysis. Interestingly, in the further stratified analysis (**Table 4**), the two-stage method had higher success rate than one-stage method in overweight & obese group (OR=4.911, 95% CI=1.50407-16.03585, P=0.004). Combined M-H OR was 2.149 (95% CI=1.000-4.672, P=0.048). There was a statistical significance in homogeneity (M-H test, P=0.0287; B-D test, P=0.0257).

The Kaplan-Meier curves for unsuccessful-free survival showed that “Treatment (P=0.007)” in overweight & obese group, “BMI (P=0.000)”, “numbers of previous operations (P=0.000)” were associated with unsuccessful-free survival rates (**Figure 2**).

Table 1. Summary of characteristics of patients and univariate analyses according to success rate

	Non-successful	Success	*p* value*
Age (median [p25, p75])	25 (23, 32)	25 (20, 28)	0.020**
Age at initial hypospadias repair (median [p25, p75])	20 (17, 23)	18 (16, 21)	0.023**
Hypospadias severity at birth (n [%])			0.884
Forme fruste of hypospadias	7 (17.9)	26 (17.4)	
Distal urethral location***	2 (5.1)	12 (8.1)	
Proximal urethral location****	10 (25.6)	45 (30.2)	
Severe with an abnormally small glans	14 (35.9)	35 (23.5)	
Other variants*****	6 (15.4)	31 (20.8)	
BMI (n [%])			0.000**
Normal	13 (33.3)	113 (75.8)	
Overweightness & obesity	26 (66.7)	36 (24,2)	
Smoking (n [%])			0.435
No	5 (12.8)	27 (18.1)	
Current or former	34 (87.2)	122 (81.9)	
Treatment (n [%])			0.027**
One-stage	20 (51.3)	52 (48.7)	
Two-stage	19 (34.9)	97 (65.1)	
Number of previous urethra-related operations (n [%])			0.000**
1	11 (28.2)	118 (79.2)	
≥2	28 (71.8)	31 (20.8)	
Surgical technique of initial treatment for hypospadias (n [%])			0.958
Tubularizing the urethral plate (TIP) method	23 (59.0)	90 (60.4)	
Two-stage buccal mucosa grafts method	10 (25.7)	35 (23.5)	
Onlay method	6 (15.4)	24 (16.1)	
Site of stenosis (n [%])			0.746
Urithral meatus	16 (41.0)	57 (38.3)	
Anastomosis	14 (35.9)	68 (45.6)	
Others	9 (23.1)	24 (16.1)	
Length of stenosis (n [%])			0.000*
<3	19 (48.7)	117 (78.5)	
≥3	20 (51.3)	32 (21.5)	

*: univariate logistic regression according to success rate. **: positive value. ***: on glans or coronal margin. ****: on penile shaft, at the penoscrotal junction, or within the scrotum. *****: including chordee without hypospadias and megameatus with a normal appearing foreskin.

Table 2. The distribution of unsuccessful patients

Reason for non-success	One-stage	Two-stage
Cosmetic unsatisfaction (n [%])	4 (19.0)	5 (27.8)
Urethral diverticulum (n [%])	4 (19.0)	0 (0)
Urethrocutaneous fistula (n [%])	11 (52.4)	6 (33.3)
Severe urethral stricture (n [%])	2 (9.5)	7 (38.9)
Total	21	18

Linear regression

BMI had a linear relationship with the length of operation in both the one- and two-stage groups (**Table 5**). In the two-stage group, BMI was associated with the length of operation in stage one alone (Spearman value =0.715). The adjusted $R^2 \geq 0.4$ indicated a well-fit effect.

Discussion

How to manage and treat HAUS in patients has always been a challenge. In the present study, we aimed to find a most suitable treatment and the predictors of treatment failure.

First, there seemed to be no significant difference regarding the treatment method of HAUS. It was in line with previous literature. Aldamanhori et al [11] reported a series of 79 cases

Table 3. Multivariable analysis according to the success

Characteristics	Multivariable analysis			
	OR	95% CI		p
Age	1.036	0.945	1.135	0.456
Age at initial hypospadias repair	0.915	0.836	1.002	0.056
Hypospadias severity at birth (Forme fruste of hypospadias as reference)				
Distal urethral location**	2.061	0.285	14.896	0.474
Proximal urethral location***	1.271	0.337	4.796	0.723
Severe with an abnormally small glans	0.968	0.255	3.673	0.962
Other variants****	1.620	0.357	7.347	0.532
BMI status (Normal as reference)				
Overweight & obese	0.233	0.090	0.600	0.003*
Smoking (No as reference)				
Current or former	0.754	0.194	2.923	0.683
Treatment (one-stage as reference)				
Two-stage	1.804	0.712	4.571	0.214
Number of previous urethra-related operations (one as reference)				
≥2	0.140	0.056	0.351	0.000*
Surgical technique of initial treatment for hypospadias (TIP***** as reference)				
Two-stage buccal mucosa graft method	1.966	0.642	6.024	0.237
Onlay method	1.586	0.431	5.832	0.487
Site of stenosis (urethral meatus as reference)				
Anastomosis	0.654	0.236	1.816	0.415
Others	0.510	0.131	1.979	0.330
Length of stenosis (<3 as reference)				
≥3	0.536	0.200	1.437	0.215

*: positive result. **: on glans or coronal margin. ***: on penile shaft, at the penoscrotal junction, or within the scrotum. ****: including chordee without hypospadias and megameatus with a normal appearing foreskin. *****: Tubularizing the urethral plate.

Table 4. Stratified analysis according to BIM status

Treatment method	Unsuccessful	Success	*p* value	OR (95% CI)
BMI: Normal				
One-stage method (n)	4	41	0.695	0.780 (0.225-2.709)
Two-stage method (n)	9	72		
BMI: Overweight & obese				
One-stage method (n)	17	10	0.004	4.911 (1.504-16.036)
Two-stage method (n)	9	26		

Mantel-Haenszel OR=2.149, 95% CI=1.000-4.672, P=0.0478. Test of homogeneity: Mantel-Haenszel test, P=0.0287; Breslow-Day test, P=0.0257.

with re-do hypospadias treated by one- or two stage operations: 80.7% in one-stage and 79.2% in two-stage were successful. Talab et al [15] reported their experience of 62 cases, showing that 87.1% in the one-stage group and 90.4% in the two-stage group were successful. Previous studies ignored the difference of BMI status which is critical for treatment success. In the further stratified analyses, a two-stage method had a higher success rate in overweight & obese group, while in the BMI-normal group there was no significant difference between two methods. The reason is unknown. We come up with a hypothesis that it might be related to inadequate surgical exposure and long operation time. First, in our study, the value of BMI was also associated with the length of operation as obesity might impair the surgical exposure and positioning. Besides, a one-stage method needed more procedures and operative time. Therefore, inadequate surgical exposure and longer surgical time might be the reasons why a two-stage method had a higher success rate in the overweight & obese group.

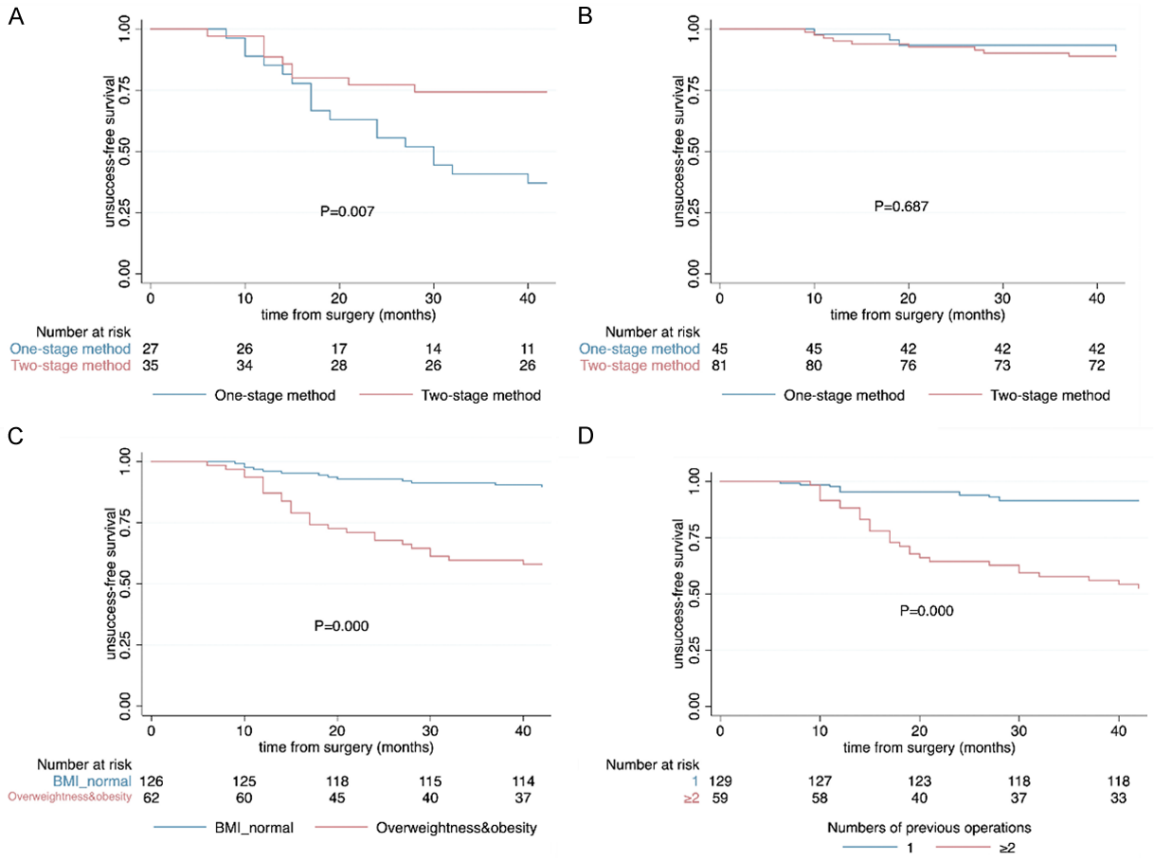

Figure 2. Kaplan-Meier curve of unsuccessful-free survival rate. A. Kaplan-Meier curve depicting unsuccessful-free survival rate according to the treatment in the overweight & obese group. B. Kaplan-Meier curve depicting unsuccessful-free survival rate according to the treatment in BMI-normal group. C. Kaplan-Meier curve depicting unsuccessful-free survival rate according to BMI status. D. Kaplan-Meier curve depicting unsuccessful-free survival rate according to the numbers of previous operations.

Table 5. Linear regression analysis of factors affecting the length of operation

	Coefficient	*P* value	Spearman value (*P* value)	Adjust R^2
One-stage Group				
BMI value (kg/m^2)	3.856792	0.000	0.845 (P=0.000)	0.6693
Period of smoke (years)	0.1028295	0.758	0.0922 (P=0.499)	-0.0167
Two-stage Group: the first stage				
BMI value (kg/m^2)	3.223466	0.000	0.715 (P=0.000)	0.4572
Period of smoke (years)	-0.2450199	0.459	-0.0937 (P=0.354)	-0.0045
Two-stage Group: the second stage				
BMI value (kg/m^2)	0.1814247	0.642	0.034 (P=0.717)	-0.0069
Period of smoke (years)	0.3906608	0.180	0.0775 (P=0.444)	0.0083

Second, the initial treatment method for hypospadias is not associated with treatment outcomes. Traditionally, the initial treatment was thought to be a critical factor for the success of sequent urethra-related operations. However, new techniques (tubularized incised plate repair, 2-stage BMG repairs) and precise operative procedures may protect the blood supply better, which decreases the failure risk in sequent treatments. Barbagli et al [16] reported on 408 cases which showed that the number of previous operations was not associated with the risk of treatment failure. However, the current levels of evidence are limited, highlight-

ing the need for more large sets of data to evaluate the different techniques [17].

Third, it is known that obesity contributes to a myriad of complications [18]. Breyer et al [19] demonstrated that overweight and obese patients had higher risk of urethroplasty failure. We are careful to make a conclusion as Buschemeyer et al [20] thought there exists a bias that comorbidities in overweight and obese patients might confound the multivariate results.

Finally, the length of stricture was not associated with the success of treatment, which was not in line with other literature [21]. That might be a product of patient heterogeneity: in both groups, surgeons would remove the stricture urethra totally and reconstructed the neo-urethral by prepuce flap or oral mucosa. Therefore, the length of stenosis is not a critical factor.

Tobacco use was not associated with treatment success in the present study, which contradicted prior published studies: patients who consumed tobacco had less successful outcomes (58.3% vs. 94.4%, P=0.008) [22] and higher rate of donor site morbidity [23]. In our research, most patients were young adults, which might be the result. Nevertheless, it still should be advocated for all patients preoperatively that smoking cessation at least 1 month prior to all surgeries significantly decreased wound and overall complication rates [18].

Most patients in our study received initial hypospadias repair when they were over 18 years old, which was unusual in western countries. In Asia it is common, especially in low-income rural area. Even though age was not a risk factor, we still advocate that hypospadias patients need to receive surgery before 1 year of age.

The limitations of the present study are having a small number of patients and it's a retrospective study. Second, we need longer follow-up times to know the long-term outcomes. In addition, due to the broad spectrum of associated symptoms and abnormalities associated with adult hypospadias, there is still no universal opinion about the success criteria of surgical treatment. A universal opinion is necessary for the comparison of different literature.

In conclusion, BMI and the number of previous operations were independently associated with success rate. A two-stage method had a higher success rates for overweight and obese patients while both one- and two-stage surgeries achieved satisfied outcomes in BMI-normal patients. The value of BMI is associated closely with operative time.

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Disclosure of conflict of interest

None.

Abbreviations

HAUS, Hypospadias-associated urethral stricture; BMI, Body mass index; BMG, Buccal mucosa graft; OR, Odds ratio; CI, Confidence intervals; M-H, Mantel-Haenszel; B-D, Breslow-Day; K-M, Kaplan-Meier.

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