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Stricture Free Survival after Urethroplasty: A 6-Year Malaysian Referral Centre Experience

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Abstract

Background: Urethroplasty is the gold standard for treatment for urethral strictures. We describe our results of urethroplasty and analyse the risk factors associated with stricture recurrence and stricture-free survival. **Methods**: A retrospective review of urethroplasty surgery carried out from 2016-2022. Patient records were analysed to obtain demographics, clinical, pathological and outcome data. Success of surgery is defined as postoperative Q_{max} > 15 ml/s or absence of any instrumentation of urethra such as urethral dilatation, after removal of urethral indwelling catheter. **Results**: A total of 66 patients who fulfilled the inclusion criteria were selected. Mean age was 43.8. Mean follow up was 27.2 ± 21.8 months. Stricture recurred in 18 patients (27.3%). Estimated stricture free survival time was 59.6 months (95% CI: 50.87 - 68.37). Previous surgical history for stricture was found to be predictive of stricture recurrence. After adjusting for age, BMI, aetiology of stricture and stricture length, previous surgical history had a risk of stricture recurrence approximately three times higher compared to those without. **Conclusion**: Previous surgical intervention for urethral stricture was found to be the most significant factor for stricture recurrence. We strongly advocate that the first curative surgery done for urethral strictures should be done in high volume centres and by experienced reconstructive urologists.

Keywords

Urethroplasty, Urethra, Stricture, Recurrence, Factors, Survival, Reconstructive, Urology

1. Background

Male adult urethral strictures is a common disease with an incidence as high as

0.6% in susceptible populations [1]. Urethral strictures can be divided anatomically to anterior or posterior strictures with anterior urethra being most commonly affected (92.2%) [2]. Urethral stricture remains a heterogenous clinical entity with multiple aetiologies and treatment options. Treatment of urethral strictures vary from bedside urethral dilatation, endoscopic procedures such as internal urethrotomy and various open reconstructive surgeries. As there are too many clinical factors to consider such as patient preference, aetiology, stricture length, surgeon experience and patient expectation, it is difficult to determine which is the best treatment option to offer our patients. Urethroplasty remains the gold standard for treatment of urethral strictures with durable long term success [3]. As there is a lack of high quality evidence from randomised control trials, there are conflicting evidence in literature regarding the potential risk factors for stricture recurrence. Some authors have reported preoperative urinary flow rates, smoking, prior urethrotomy or urethroplasty and lichen sclerosus as significant factors for stricture recurrence whereas others have reported stricture length to be a factor [4]-[7]. Although urethroplasty has been performed in Malaysia for a long time, there is a lack of published data from Malaysia regarding urethral stricture diseases. The aim of this study was to analyse the data in our centre to determine risk factors for stricture recurrence in our local population.

2. Methods

A retrospective review was carried out looking into all urethroplasties performed by a single consultant at a single institution (Hospital Tengku Ampuan Afzan) from 2016 to 2022. This study was registered in the National Medical Research Register (NMMR) and approved by the Medical Research Ethics Committee (MREC). The reason why we chose 6 years to be the duration of our study was that after being kept for 7 years, medical records are disposed and it will be impossible to obtain data beyond this duration. As this is a retrospective study, we reviewed all the cases of urethroplasty performed during this period and selected patients without exclusion criteria. Exclusion criteria were patients who had previous surgery done for hypospadias and patients who had a history of pelvic radiotherapy. A total of 72 patients were found, 5 patients were excluded as medical records were missing, another 1 patient was excluded as he had surgical correction done for hypospadias before. A total of 66 patients fulfilled the inclusion criteria and were selected in the study.

Patient's demographics such as age and body mass index (BMI) were recorded. Comorbidities such as hypertension, hyperlipidaemia, diabetes mellitus and coronary artery disease were identified and recorded. Previous surgical history done for urethral stricture were also recorded such as previous internal urethrotomies, urethral dilatation or previous urethroplasty. Clinical and pathological factors such as peak urinary flow rate (Q_{max}), stricture location and length, and aetiology of stricture were recorded. Surgical approaches for urethroplasty were divided into two types, the first being excision and primary anastomotic

urethroplasty (EPA) and the second is augmentation urethroplasty using buccal mucosa graft (BMG). Following surgery, patients were kept on urethral indwelling catheter and a suprapubic catheter for 21 days after EPA and 28 days after BMG augmentation urethroplasty respectively. Peri catheter urethrogram was performed to assess for patency of anastomosis and the urethral and suprapubic catheters were removed if there was no evidence of contrast leak. In the case where there was contrast leak during peri catheter urethrogram, the catheters were changed and kept for another week. No patients were kept on catheters longer than that. Patients were followed up usually on the 1st month, 3rd month and 6 monthly thereafter. Assessment during follow up consisted of patient's history, physical examination, uroflowmetry and post void residual volume (PVR) assessment. During follow up, a Q_{max} of <15 mls/s would trigger further evaluation with cystoscopy. If urethral calibre is more than 16-Fr on cystoscopy, these patients are classified as recurrence free and those with urethral calibre less than 16-Fr on cystoscopy were classified as recurrent strictures irrespective of subsequent interventions.

The data underwent analysis using SPSS statistics software version 23.0. Continuous data were presented as mean ± standard deviation, while categorical data were expressed as frequency and percentage. To assess stricture-free survival, we employed the Kaplan-Meier survival curve. Patient data were censored either at the last follow-up or in the event of urethroplasty failure. Univariate Cox proportional hazards regression analysis was utilized to identify predictors for recurrence post-surgery. Furthermore, multiple Cox regression analysis was conducted to determine the primary predictor factor after adjusting for other independent variables. Statistical significance was set at $p < 0.05$.

3. Results

Between 2016 and 2022, a total of 66 patients underwent urethroplasty at Hospital Tengku Ampuan Afzan. The mean patient age was 43.8 ± 19.3 years. The average BMI was 27.2 kg/m^2, indicating that patients generally fell into the overweight category. Mean duration of follow up post urethroplasty for this group of patients was 27.2 ± 21.8 months. Among the patients, 36.4% were smokers. Notably, 42.4% had comorbidities, and 22.7% had a history of previous surgeries.

The surgical techniques employed were as follows: 75.8% underwent EPA, while 24.2% received BMG treatment. The mean stricture length was 2.8 ± 2.5 cm. 71.2% patients had strictures less than 3 cm, while 28.8% had strictures of 3 cm or more.

Encouragingly, 72.7% of patients achieved a stricture-free outcome post-urethroplasty. One patient had a recurrence within 1.8 months post urethroplasty. The mean preoperative Q_{max} was 1.8 mL/s, which significantly improved to 20.7 mL/s postoperatively. Complications were observed in only 12.1% of patients.

The demographic and clinical characteristics of the patients who underwent urethroplasty are presented in Table 1.

Table 1. Demographic and clinical characteristics of patients who underwent urethroplasty.

	N = 66
Age (mean ± SD)	43.8 ± 19.3
BMI (kg/m^2) (mean ± SD)	27.2 ± 5.2
Duration of follow up post urethroplasty(months) (mean ± SD)	27.2 ± 21.8
The presence of comorbidity n (%)	28 (42.4)
Past medical history n (%)	
Yes	28 (42.4)
No	38 (57.6)
Previous surgical intervention	
Yes	15 (22.7)
No	51 (77.3)
Technique	
BMG	16 (24.2)
EPA	50 (75.8)
Aetiology of stricture n (%)	
Trauma	41 (62.1)
Infection/Inflammation	11 (16.7)
Iatrogenic	14 (21.2)
Stricture length (cm) (mean ± SD)	2.8 ± 2.5
Stricture length n (%)	
<3 cm	47 (71.2)
≥3 cm	19 (28.8)
Smoking	
Yes	24 (36.4)
No	42 (63.6)
Complication Post Procedure	
Yes	8 (12.1)
No	58 (87.9）
Stricture free n(%)	
Yes	48 (72.7)
No	18 (27.3)
Mean preoperative Q_{max} (mL/s) (mean ± SD)	1.8 ± 2.1
Mean postoperative Q_{max} (mL/s) (mean ± SD)	20.7 ± 9.7

SD: standard deviation, *BMI*: body mass index, BMG: buccal mucosal graft, EPA: excision and primary anastomosis, Q_{max} :Peak urinary flow rate.

The Kaplan Meier survival analysis indicated that 25% of the patients experienced recurrence within 16.2 months. Stricture recurrence plateaued at 22.5

months (Figure 1). The mean stricture-free survival time of the patients was 59.6 months (95% CI: 50.87 - 68.37).

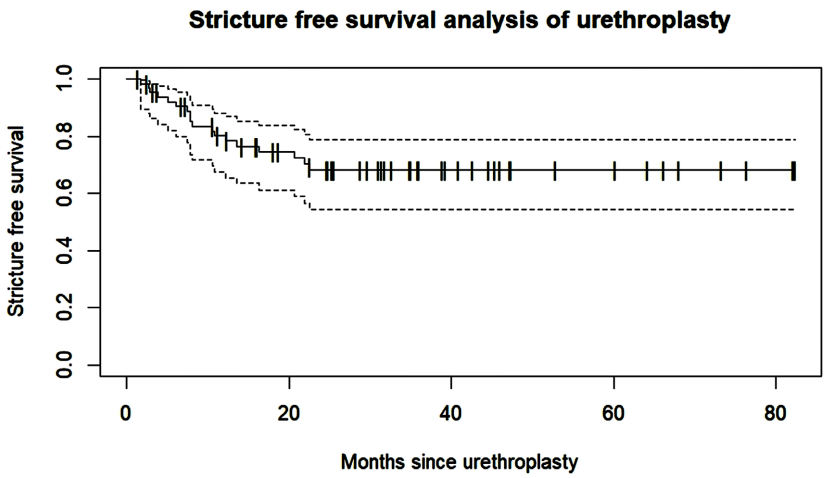

Figure 1. Kaplan-Meier survival plot depicting the stricture-free survival analysis of urethroplasty.

In patients with a history of previous surgery, the Kaplan-Meier survival analysis revealed a statistically significant increase in stricture recurrence ($p < 0.05$). Figure 2 illustrates that the median stricture-free survival time for these patients was 16.2 months, with a mean stricture-free survival time of 22.0 months (95% CI: 13.55 - 30.46). In contrast, patients without a surgical history exhibited a significantly longer mean stricture-free survival time of 65.98 months (95% CI: 13.55 - 30.46). By 22.5 months, 77.2% of patients without a surgical history had achieved stricture-free status, whereas only 37.5% of those with a surgical history had reached this milestone by 28.7 months.

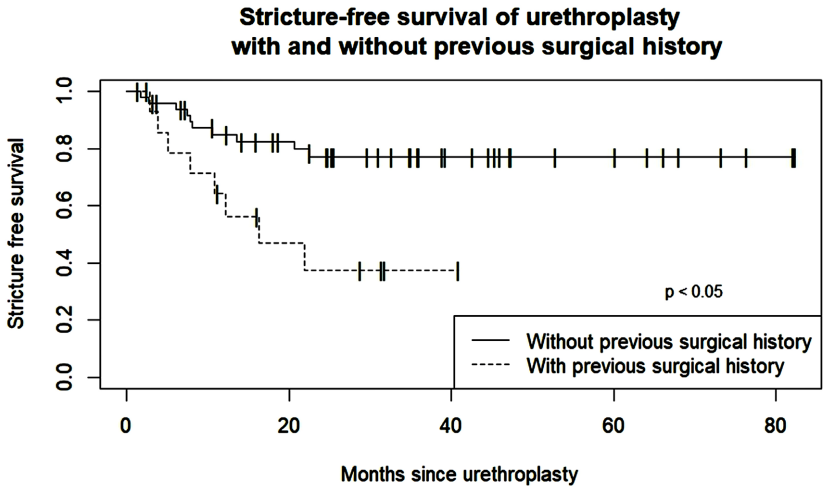

Figure 2. Kaplan-Meier survival plot depicting the stricture-free survival analysis of urethroplasty with and without previous surgical history.

Table 2 presents the results of univariate and multivariate cox regression

models analysing potential prognostic factors for stricture-free survival. In univariate analysis, age (HR 0.99; 95% CI 0.96 - 1.01), BMI (HR 0.90; 95% CI 0.81 - 1.01) and the presence of comorbidities (HR 0.67; 95% CI 0.25 - 1.79) are not significant predictors. For the aetiology of stricture, using trauma as the reference group, infection or inflammation (HR 2.37; 95% CI 0.86 - 6.52) and iatrogenic causes (HR 0.67; 95% CI 0.15 - 3.06) do not show statistical significance. In terms of technique used, BMG (HR 1.17; 95% CI 0.38 - 3.54) compared to EPA (reference) is not significant. Stricture length less than 3 cm (HR 0.85; 95% CI 0.32 - 2.26), complications post procedure (HR 0.99; 95% CI 0.23 - 4.30), and smoking (HR 1.38; 95% CI 0.54 - 3.50) are also not significant predictors. Notably, the univariate analysis revealed that only previous surgical intervention significantly increased stricture recurrence (HR 3.41; 95% CI 1.34 - 8.68; p = 0.01).

Table 2. Univariate and multivariate analysis of potential prognostic factors for stricture-free survival.

Variable		Crude HR (95% CI)		p value	Adjusted HR (95% CI)		p value
Age		0.99	(0.96 - 1.01)	0.243	0.97	(0.94 - 1.01)	0.156
BMI		0.9	(0.81 - 1.01)	0.081	0.92	(0.81 - 1.04)	0.183
Comorbidity	Yes	0.67	(0.25 - 1.79)	0.428			
	No	1					
Previous surgical history	Yes	3.41	(1.34 - 8.68)	0.01	3.75	(1.31 - 10.78)	0.014
	No	1			1		
Aetiology of stricture	Trauma	1			1		
	Infection or Inflammation	2.37	(0.86 - 6.52)	0.096	3.19	(0.90-11.26)	0.072
	Iatrogenic	0.67	(0.15 - 3.06)	0.605	1.10	(0.17-7.01)	0.920
Technique	BMG	1.17	(0.38 - 3.54)	0.787			
	EPA	1					
Stricture length	<3	0.85	(0.32 - 2.26)	0.742	1.16	(0.37 - 3.65)	0.800
	≥3	1			1		
Complication post procedure	Yes	0.99	(0.23 - 4.30)	0.987			
	No	1					
Smoking	Yes	1.38	(0.54 - 3.50)	0.498			
	No	1					

Furthermore, a multiple cox regression model was employed to comprehensively assess the combined effects of these factors on the success rate of urethroplasty. Following adjustments for age, BMI, aetiology of stricture, and stricture

length, the data indicated that a previous surgical history presented approximately a threefold higher risk of stricture recurrence compared to those without a previous surgical history (adjusted HR = 3.75, 95% CI = 1.31 - 10.78). These results underscore the critical impact of previous surgical interventions on stricture recurrence and the necessity for further research to enhance surgical outcomes.

4. Discussion

Existing literature highlights various risk factors linked to stricture recurrences following urethroplasty, although the available data remains inconclusive. From our study, we have found that previous surgical interventions such as internal urethrotomy, urethral dilatation and urethroplasty are significant risk factors for stricture recurrence as these are essentially revisional surgeries from previous failed attempts at treatment of a urethral stricture (p = 0.01). As mentioned by Calvacanti, urethral stricture forms when the normal urethral tissue is replaced by collagenous tissue and extracellular matrix changes after an insult [8]. Due to repeated insults to the urethra and its surrounding tissues, more and more collagenous tissues and fibrosis occurs, thus making subsequent urethroplasty more challenging. Other authors have noted that even a single or repeated transurethral manipulation or treatment can increase stricture length, complexity and ultimately delays curative urethroplasty [9]-[11]. Another study in Ghana had similar findings as they found a poorer success rate of urethroplasty in patients who underwent multiple procedures [12]. We were not able to study whether the exact number of prior endoscopic interventions influences urethroplasty outcomes as a majority of our cases were referred from other centres and it was difficult to obtain accurate data. In a study by the famous urethroplasty surgeon Barbagli *et al.*, they found that four or more prior internal urethrotomies were a risk factor for poor outcomes in urethroplasty [13].

In some studies, presence of comorbidities and obesity are significant factors for stricture recurrence. If a patient is obese, the entire perioperative process is significantly more complex with a multitude of factors to take into consideration. Preoperative hygiene might be poor leading to higher risk of surgical site infections, giving anaesthesia to obese patients are also more challenging. During surgery, surgical field exposure will be more difficult, and the proximal urethra can be very difficult to access, making an already complex surgery such as urethroplasty more challenging. Obese patients might have biological factors that impair wound healing such as relative vascular insufficiency, chronic inflammation, impaired collagen synthesis and micro and macromolecular deficiency [14]. Despite Malaysia having an obese population, we did not find it to be a significant factor for stricture recurrence.

Patient's comorbidities such as diabetes and smoking history have been reported to be associated with stricture recurrences [4] [15]. We however did not find these to be statistically significant. Smoking and diabetes are well known to negatively affect tissue vasculature and wound healing. Regardless of whether

smoking is associated with stricture recurrence or not, cessation of smoking prior to surgery is strongly advocated to reduce complication rates [16].

Stricture length is one of the main reported factors associated with stricture recurrence after urethroplasty. A systematic review done by Meeks *et al.*, showed a statistically significant difference in failure rate of 12.4% vs. 16.6%, favouring strictures shorter than 5 cm. In that study, they had an average stricture length of 4.8 cm [17]. We have chosen 3 cm to be our cut-off for statistical analysis because the mean stricture length in our study was 2.8 cm. Based on this cut-off, we did not find stricture length to be a statistically significant factor for stricture recurrence. The likely reason for stricture length to influence urethroplasty outcomes is that different stricture lengths usually determine the type of reconstructive surgery done. Based on the European Association of Urology 2023 guidelines, for shorter strictures up to 2 cm, excision and primary anastomosis is the most common surgical technique. As for strictures longer than 2 cm, various methods of free graft urethroplasty are commonly used. As there is a larger segment of damaged tissue in longer strictures, tissue healing, blood supply and graft uptake might be affected and these might be the reason why longer strictures have higher recurrence rates [18] [19].

Many authors have found stricture aetiology such as infective, iatrogenic and lichen sclerosus to be significant predictors of stricture recurrence post urethroplasty [20]. In infective strictures, significant inflammation, necrosis and fibrosis may occur and these factors impair tissue vascularity and healing, which leads to stricture recurrence [21]. In our study, most of the cases were due to trauma. Almost all of the patients with traumatic aetiology had strictures located at the bulbar or bulbomembranous urethra. We performed delayed urethroplasty for all our patients. This is to allow injured tissues to stabilize before embarking on curative surgery. The majority of mechanisms of injury were pelvic fractures and saddle injury. There were only two patients who had traumatic urethral injury with their stricture located in the anterior urethra. The first was a patient who was attacked by a buffalo and suffered a severe perineal trauma and the other a sports related blunt injury.

We found in our study that urethroplasty failures occurred within two years and subsequently plateaus. This is consistent with literature citing that stricture recurrences usually occur within the first 2 years post operatively [4] [20] [22]. Although our study showed that strictures stabilize within 2 years, late recurrences beyond 2 years do occur and have been reported by multiple authors before, and they can occur as late as 87 months [15] [22] [23]. Barbagli *et al.* published their long term follow up results and found that although there is always a theoretical possibility of late stricture recurrences, they stabilize after 5 years with a success rate of 73.8%. He also suggested that patients should be considered to be cured after 7 years of follow up and further follow up should be at the clinician's discretion.

In our study, a total of 9 patients developed complications. 2 of them were Clavien-Dindo 3 and above, and the other 7 were Clavien-Dindo 1 to 2. Out of

the 2 patients with significant complications post-surgery, one of them had intraoperative rectal injury requiring repair and colostomy creation. As for the other patient, unfortunately, he had a hospital acquired pneumonia which required care in the intensive care unit. There was no mortality reported in our study. A total of 18 out of 66 patients had stricture recurrence and this corresponded to a 72% success rate. Our success rate is comparable to those reported in literature, ranging around 70% - 90% [4] [11] [15] [17]-[19].

For those patients who developed recurrent strictures during follow up, flexible urethroscopy was mandatory to assess the nature of the recurrence. Of the 18 patients who had recurrence, 10 were treated with urethral dilatation as there was a thin and flimsy stricture membrane. 4 were satisfied as they were able to void despite a poor urinary flow and refused any further intervention. All 4 patients were on suprapubic catheter prior to surgery. 4 patients were planned for delayed revision urethroplasty to allow the previous surgical wound to completely heal.

Going forward, it is imperative to manage patients with urethral stricture disease holistically. It is not only necessary to correct the stricture disease itself surgically, but we must also take into consideration patient's views and integrate patient-reported outcome measures (PROMs) to judge success of treatment [24]. A PROM such as the urethral stricture surgery patient-reported outcome measure (USS-PROM) needs to be validated in our multilingual country. A successful surgery viewed by the surgeon, might not be the same for the patient. For example, one of our patients who had a complete stricture was not able to father a child due to this disease. Although he was one of the patients who developed stricture recurrence, he was able to father a child and was immensely satisfied with our role in addressing his concerns. Because of this, his slow urinary flow was not concerning to him at all. The reason why we chose Q_{max} of 15 mls/s as a trigger for further workup for stricture recurrence is because at this peak flow rate, majority of patients will be satisfied with their urinary flow [25].

The limitations of our study include its retrospective nature, single institution and surgeon series, small sample size and not all patients were followed up for the same duration of time.

Although we routinely perform uroflowmetry during our follow up, not every patient had a uroflowmetry done during each follow up. We were not able to separately analyse surgical techniques and assess their individual success rates due to the low number of patients. There is also a need to have a proper consensus on the definition of stricture recurrence after urethroplasty.

5. Conclusion

We can conclude from this study that we should consider urethroplasty as the first line of treatment for urethral strictures as it is a definitive surgery with good and durable results in experienced hands. Other forms of endourological management for urethral strictures such as urethral dilatation or internal urethrotomies are inferior to urethroplasty and should only be considered in special situa-

tions and probably as a temporizing measure. Examples of these are strictures which are thin and flimsy and also if patients are in rural areas where there is a lack of urological services. We also recommend setting up centralized regional urethroplasty centres to have a larger number of patients and increase surgical experience and training. A high number of cases will also help to improve surgical outcomes for our patients.

Ethics Approval and Consent to Participate

This study was registered in the National Medical Research Register (NMRR) and approved by the Medical Research Ethics Committee (MREC) with NMRR ID-23-00861-1N5.

Consent for Publication

The authors would like to thank the Director General of Health Malaysia for the permission to publish this paper.

Availability of Data and Materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Conflicts of Interest

The authors declare that they have no competing interests.

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List of Abbreviations

BMI	Body Mass Index
EPA	Excision and primary anastomotic urethroplasty
BMG	Buccal mucosa graft
Q_{max}	Peak urinary flow rate
NMMR	National Medical Research Register
MREC	Medical Research Ethics Committee
PROM	Patient-Reported Outcome Measure
USS-PROM	Urethral Stricture Surgery Patient-Reported Outcome Measure