Original Article

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Urology Section

Early versus Late Per-urethral Catheter Removal Following Anterior Anastomotic and Buccal Mucosal Onlay Urethroplasty: A Randomised Controlled Trial

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ABSTRACT

Introduction: The postoperative catheter duration after urethroplasty has been less studied, and available literature is variable. The Duration of Catheterisation (DUC) in the literature ranges from as early as three days to as late as 21 days.

Aim: To determine the ideal DUC after both anastomotic and Buccal Mucosal Graft (BMG) urethroplasty.

Materials and Methods: The present randomised controlled study was done from June 2023 to May 2024 at IPGME&R-SSKM hospital (Institute of Postgraduate Medical Education and Research- Seth Sukhlal Karnani Memorial), Kolkata, West Bengal, India. A total of 30 patients of anastomotic and 30 patients of BMG urethroplasty were studied. Thirty patients of anastomotic urethroplasty were divided into group A (Early PUG done on Day 7) (n=15) and group B (Late PUG done on Day 14) (n=15). Thirty patients of BMG urethroplasty were divided into group I (Early PUG on Day 14) (n=15) and group II (Late PUG on Day 21) (n=15). Extravasation was assessed by performing a Pericatheter Urethrogram (PUG) and was compared by a Chi-square test. Patients without extravasation had their catheter removed immediately and patients with extravasation were kept on catheter for seven more days. The Urinary Tract Infection (UTI) and recurrence rates were compared by Fisher's-Exact test.

Results: Anastomotic urethroplasty patients had extravasation in 9/15 patients (60%) on Postoperative Day-7 (POD-7) (group A) and 2/15 patients (13.3%) on POD-14 (group B). BMG Urethroplasty patients had extravasation in 6/15 patients (40%) on POD-14 (group I) and 2/15 patients (13.3%) on POD-21 (group II). Among anastomotic urethroplasty, 3/15 patients (20%) had UTI in group A and 2/15 patient (13.3%) had UTI in group B. About 2/15 patients (13.3%) had recurrences in group A and no recurrences in group B. In BMG urethroplasty, UTI occurred in 3/15 patients (20%) in group-I and 2/15 patients (13.3%) in group II. One patient in each group I and group II (6.7%) showed recurrence of stricture.

Conclusion: In conclusion, early catheter removal cannot be considered safe in all patients but should be individualised.

Keywords: Pericatheter retrograde urethrogram, Urethra, Urethral stricture, Urinary catheterisation

INTRODUCTION

Urethral stricture is more prevalent in non-industrialised countries, particularly in urban areas [1]. The concept of the reconstructive ladder in the management of urethral stricture has become less common, and open reconstructive urethroplasty is now considered the gold standard of management [2]. Anastomotic urethroplasty and substitution urethroplasty are the two primary methods of reconstruction. The indications and techniques for urethroplasty have been widely agreed upon by clinicians worldwide [3]. A temporary urethral catheter is required postoperatively to prevent urine extravasation and allow the wound to heal. However, the DUC after urethroplasty is variable in the literature, ranging from 3 to 28 days [3-7]. The DUC should be kept as short as possible for several reasons: to reduce patient discomfort, minimise inactivity, decrease the incidence of Urinary Tract Infections (UTIs), and lower the risk of recurrence of stricture [8,9]. However, the optimal DUC remains less studied. Within this wide range, the ideal DUC- one that balances healing with extravasation and prevents complications associated with prolonged catheterisation- needs to be determined. The time of catheter removal after anterior anastomotic urethroplasty traditionally ranged from 7 to 14 days with low extravasation rates [3-5]. In BMG urethroplasty, catheter removal ranged from 7 to 28 days [10,11] with a study demonstrating lower extravasation rates with early removal [6]. These studies have the limitation of no randomisation. There is no study which was done prospectively with a control group. The aim of this study was to compare the extravasation rates, UTI rates, and recurrence rates between early and late urethrograms, to determine ideal DUC.

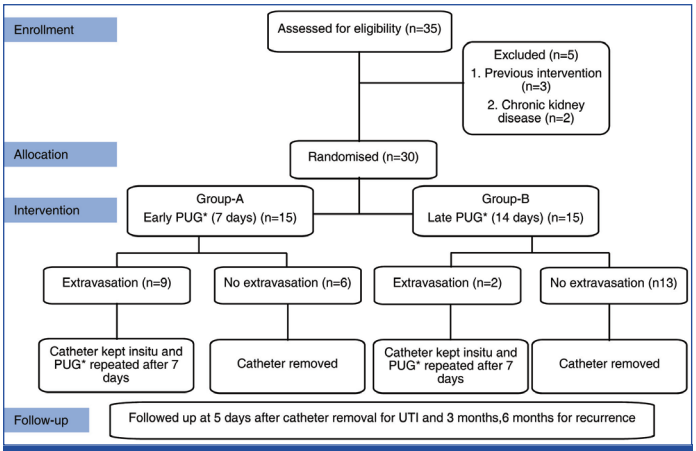
MATERIALS AND METHODS

The present randomised controlled study (CTRI registration Number - CTRI/2024/12/078061) was done in the Department of Urology at the Institute of Postgraduate Medical Education and Research - Seth Sukhlal Karnani Memorial Hospital, Kolkata, West Bengal, India, from June 2023 to May 2024. Institutional Ethics Committee (Memo No-IPGME&R/IEC/2023/486) approval was obtained. Informed written consent was obtained from the participants.

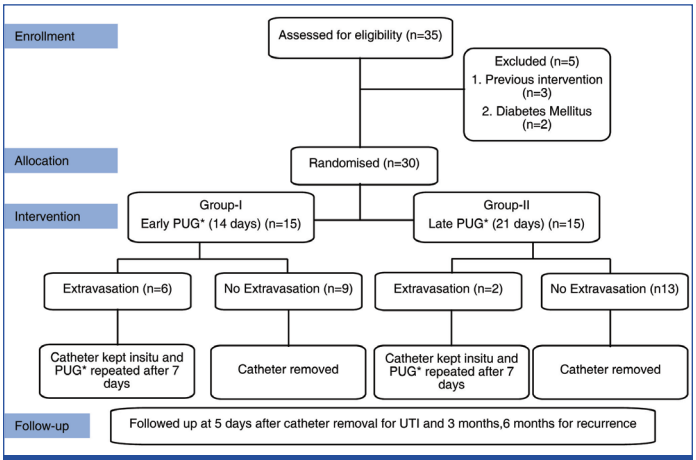
Sample size calculation: The sample size was calculated using the formula $n=Z^2 1-\alpha/2x \cdot p(1-p)/d^{2,}$ where p (anticipated proportion of extravasation according to previous study) [12] =0.15, d (desired precision) =12.5%. The sample size was 30 per group, so a total of 60 patients were included.

Inclusion and Exclusion criteria: Inclusion criteria were patients who were operated for anterior anastomotic urethroplasty or BMG urethroplasty (Dorsal Onlay technique). Exclusion criteria were patients with a history of previous urethral stricture surgery, chronic kidney disease, uncontrolled diabetes mellitus, and those who had received radiotherapy.

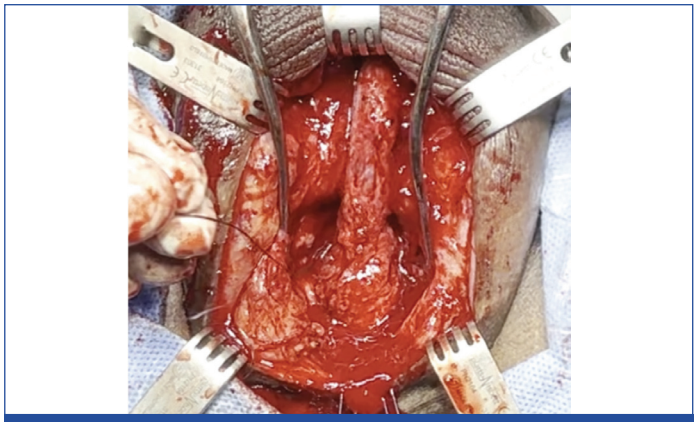
The type of urethral reconstruction was determined before the start of the study based on the aetiology of the stricture, its length, and the degree of obliteration. The study included 30 cases of each anastomotic and BMG reconstruction as shown in the CONSORT flowchart [Table/Fig-1,2].



[Table/Fig-1]: CONSORT flow chart for anastomotic urethroplasty.
PUG*: Pericatheter urethrogram



[Table/Fig-2: CONSORT flow chart for Buccal Mucosal Graft Onlay Urethroplasty.
PUG*: Pericatheter urethrogram



[Table/Fig-3: Intraoperative picture after anastomotic urethroplasty.

[Table/Fig-4: Pericatheter Urethrogram (PUG) showing extravasation.

Study Procedure

Anastomotic Urethroplasty: All patients (n=30) underwent surgery with sterile urine cultures, and injection ceftriaxone 1 gm was administered for five days postoperatively, followed by oral Levofloxacin 500 mg during the DUC. A 16Fr silicone catheter was placed, and antiseptic dressing was changed on POD 2. In patients with suprapubic cystostomy, it was kept open for drainage, and the PUC was clamped during discharge [Table/Fig-3]. These patients were divided into two groups (parallel arms) based on a computer-generated sequence generated by a paramedical staff unrelated to the study and stored on a password protected computer in a 1:1 ratio and allocated based on the sequence by nursing staff and the investigators were unaware. Group A (n=15) consisted of patients in whom a PUG was done on the 7th POD, while group B (n=15) consisted of patients in whom PUG was done on the 14th POD. Blinding was not done. A 5 Fr infant feeding tube was inserted alongside the Foley catheter for 3-4 cm, and 5 mL of urograffin-76% mixed with 5 mL of normal saline was injected to check for extravasation. The catheter was removed only if there was no or minimal extravasation of contrast. If significant extravasation [Table/Fig-4] occurred, the catheter was left in place for another seven days, and PUG was repeated. Uroflowmetry was performed after catheter removal, and urine culture was done five days post-catheter removal. Patients were followed up at three months and six months after surgery. If patients showed symptoms of urethral stricture such as poor flow, straining, they were evaluated with uroflowmetry and Retrograde Urethrogram (RGU) or urethroscopy if needed. Extravasation rates, UTI rates, and recurrence rates were analysed for group A and group B.

BMG Urethroplasty: A similar methodology was followed for the BMG urethroplasty group, but postoperative dressing was changed on day 5. Patients were divided into two groups (parallel arms) based on a computer-generated sequence generated by a paramedical staff unrelated to the study and stored on a password protected computer in a 1:1 ratio and allocated based on the sequence by nursing staff and the investigators were unaware: Group I (n=15) consisted of patients in whom PUG was performed on the 14th POD, while group II (n=15) consisted of patients in whom PUG was done on the 21st POD. Blinding was not done. Extravasation rates, UTI rates, and recurrence rates were analysed for group I and group II.

STATISTICAL ANALYSIS

The Statistical Package for Social Sciences (SPSS) v23 (IBM corp.) was used for data analysis. Descriptive statistics were elaborated in the form of means/standard deviations and medians/IQRs for continuous variables, and frequencies and percentages for categorical variables. Group comparisons for continuously distributed data were made using an independent sample t-test when comparing two groups. In non-normally distributed data, appropriate non-parametric tests in the form of the Wilcoxon Kruskal-Wallis Test were used. Chi-squared test was used for group comparisons for categorical data. In case the expected frequency in the contingency tables was found to be <5 for >20% of the cells, Fisher's-Exact test was used instead. Statistical significance was kept at $p<0.05$.

RESULTS

Anastomotic Urethroplasty: The age, aetiology, stricture location, and stricture length did not vary significantly between groups. When PUG was performed early (POD-7, group A), anastomotic urethroplasty patients had an extravasation in 9/15 patients (60%) on POD-7 compared to 2/15 patients (13.3%) when PUG was performed later (POD-14, group B). The remaining nine patients in group A, who exhibited extravasation, retained their catheter for an additional seven days. Among these nine patients, 2 (22.2%) showed extravasation on POD 14, and PUG was repeated around

POD 21. Their catheters were subsequently removed. In group A, two patients (13.3%) experienced recurrence. These recurrences occurred in patients whose catheters were removed on POD 7 and POD 14, respectively [Table/Fig-5].

BMG Urethroplasty: The age, aetiology, stricture location, and stricture length did not vary significantly between both the groups. When PUG was performed early (POD 14, group I), there was extravasation in 6/15 patients (40%) on POD-14 compared to 2/15 patients (13.3%) when PUG was performed later (POD 21, group II). Out of the 15 patients in group I, nine had their catheter removed early (before POD 14), while the remaining six patients who experienced extravasation kept their catheter in situ for an additional seven days. By POD 21, no extravasation was observed in these patients. Two patients (13.3%) experienced recurrence, one from each group (group I and group II) [Table/Fig-6].

Parameters	Group A (n=15)	Group B (n=15)	p-value
Age (Years)	40.47±14.97	35.73±19.79	0.467[2]
Aetiology	0.533[1]		
Trauma	11 (73.3%)	13 (86.7%)	
Inflammatory	2 (13.3%)	0 (0.0%)	
Idiopathic	2 (13.3%)	2 (13.3%)	
Iatrogenic	0 (0.0%)	0 (0.0%)	
Supra pubic cystostomy (Yes)	14 (93.3%)	15 (100.0%)	1.000[1]
Intraop finding (stricture location)	0.658[1]		
Bulbar urethra	12 (80%)	10 (66.7%)	
Bulbo-membranous Junction (BMJ)	3 (20.0%)	5 (33.4%)	
Penobulbar	0 (0%)	0 (0%)	
Stricture length (cm)	1.77±0.46	1.83±0.45	0.434[3]
Technique	1.000[1]		
EPA†	14 (93.3%)	14 (93.3%)	
PPU‡	1 (6.7%)	1 (6.7%)	
PUG*result (First) (Extravasation Rate) ***	0.008[4]		
Extravasation	9 (60.0%)	2 (13.3%)	
No Extravasation	6 (40.0%)	13 (86.7%)	
PUG*result (Second)	1.000[1]		
Extravasation	2 (22.2%)	0 (0.0%)	
No Extravasation	7 (77.8%)	2 (100.0%)	
PUG*result (Third) No Extravasation	2 (100.0%)	0 (NaN%)	
Duration of catheterisation (Days)	12.6±5.44	15.3±2.61	0.116[2]
UTI	3 (20.0%)	2 (13.3%)	0.330[1]
Recurrence	2 (13.3%)	0 (0.0%)	0.483[1]

[Table/Fig-5]: Comparison of parameters among anastomotic – early (A) vs late (B) PUG*
PUG*: Pericatheter urethrogram; EPA†: Excision and primary anastomosis; PPU‡: Progressive perineal urethroplasty,
***Significant at p<0.05, 1: Fisher's-Exact test, 2: t-test, 3: Wilcoxon-Mann-Whitney U Test, 4: Chi-Squared test

Parameters	Group I (n=15)	Group II (n=15)	p-value
Age (Years)	44.87±11.47	39.13±14.79	0.246[2]
Etiology	0.635[1]		
Trauma	4 (26.7%)	2 (13.3%)	
Inflammatory	7 (46.7%)	8 (53.3%)	
Idiopathic	2 (13.3%)	1 (6.7%)	
Iatrogenic	2 (13.3%)	4 (26.7%)	
Supra Pubic Cystostomy (Yes)	13 (86.7%)	15 (100.0%)	0.483[1]
Intraop Finding (Stricture Location)	0.027[1]		
Bulbar urethra	8 (53.3%)	4 (26.6%)	
Penile	4 (26.6%)	10 (66.7%)	
Bulbo-membranous Junction (BMJ)	1 (6.7%)	0	
Penobulbar	2 (13.3%)	1 (6.7%)	
Stricture Length (cm)	2.40±0.63	2.67±0.79	0.318[3]
Technique			0.224[1]
Dorsal Onlay	15 (100.0%)	15 (100.0%)	
PUG* result (First) (Extravasation Rate)	0.215[1]		
Extravasation	6 (40.0%)	2 (13.3%)	
No Extravasation	9 (60.0%)	13 (86.7%)	
PUG*Result (Second)	1.000[4]		
Extravasation	0 (0.0%)	0 (0.0%)	
No Extravasation	6 (100.0%)	2 (100.0%)	
Duration of Catheterisation (DUC) (Days)	16.1±3.73	21.9±2.46	0.035[2]
UTI	3 (20.0%)	2 (13.3%)	1.000[1]
Recurrence	1 (6.7%)	1 (6.7%)	1.000[1]

[Table/Fig-6]: Comparison of parameters among BMG urethroplasty - early (I) vs late. (II) PUG*
PUG*: Pericatheter Urethrogram
***Significant at p<0.05, 1: Fisher's-Exact Test, 2: t-test, 3: Wilcoxon-Mann-Whitney U Test, 4: Chi-squared Test

DISCUSSION

Early catheter removal has been advocated after various surgeries due to its potential to accelerate early recovery of patients. For example, after robotic radical prostatectomy, early catheter removal has been recommended even though vesicourethral anastomosis has been performed [13,14]. The present evidence regarding the optimum DUC after urethroplasty is limited, and available evidence shows variable time periods [15,16]. Wound healing process is different in anastomotic and substitution urethroplasties and therefore there is need for appropriate protocol to be followed in each of them.

In the literature some authors prefer Voiding Cystourethrogram (VCUG) by removing the catheter to check for extravasation [6]. In the present study PUG was done to avoid the risk of injury to operated site associated with removing and re inserting the catheter. However, it is important to note that PUG is less physiological and causes high pressure which may increase the risk of UTI.

In the present study, in both anastomotic and BMG urethroplasty, attempt of early removal of catheter did not give the best results and delaying it for seven more days showed better results.

Granieri MA et al., published the largest series including 407 patients who underwent bulbar urethroplasty. About 232 patients had excision and primary anastomosis among which extravasation rate was 5.6% when 1st PUG was done after a mean duration of 16.12 days which is lower than the extravasation rate in the present study for group B (13.3%). In the same study 25 patients had onlay urethroplasty which showed 4% extravasation rate at a mean DUC of 22.16 days which in The present study is comparable to group II (PUG done on POD-21) which had an extravasation rate of 13.3%. This study recommends routine removal of catheter after three weeks without the use of PUG as extravasation rates dropped to less than 1% at this time which validates the current study [17].

Solanki S et al., performed a study in India in which 28 patients underwent anastomotic urethroplasty for less than 2 cm urethral strictures. The extravasation rate was 64.3% when PUG was done around 14 days which is high compared to the current study (group B - 13.3%) and extravasation rate dropped to 11.11% after 21 days. The high extravasation rate was attributed to post traumatic aetiology of strictures [18].

The present study is one of the few prospective studies in the literature exploring the feasibility of early removal of catheter to determine the

optimum DUC. Based on the present study findings, the optimum duration for catheter removal appears to be around 14 days for anastomotic urethroplasty and 21 days for BMG urethroplasty. This study contributes valuable evidence to the ongoing debate regarding catheter management after urethroplasty and provides a framework for decision making with the understanding that early removal strategy is not safe for all patients.

Limitation(s)

The present study had a small sample size for both the anastomotic and BMG urethroplasty groups. All the surgeries were not done by a single surgeon. Lichen sclerosis, spongiofibrosis, and urethral mucosa vascularity were not taken into consideration. The duration of follow-up was only six months after surgery, and the recurrence of stricture might be underestimated.

CONCLUSION(S)

Early catheter removal cannot be considered safe in all patients and should be individualised. Studies with a larger sample size and long-term follow-up are required to study the optimum duration for catheter removal after anastomotic and BMG urethroplasty and validate these findings.

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