BANGLADESH JOURNAL OF
UROLOGY
Bangladesh J. Urol. 2023; 26(1): 14-21
www.banglajol.info/index.php/BJU
DOI: https://doi.org/10.3329/bju.v26i1.70080

Original Article

ISSN : 2304 - 8514 (Print)
ISSN : 2304 - 8522 (Online)

Effect of Clean Intermittent Self-Catheterization by Frequency After Optical Internal Urethrotomy For Primary Bulbar Urethral Stricture

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Received: 01- 10 - 2022
Accepted: 04 - 11 - 2022
Conflicts of interest: None

Keywords: Primary bulbar stricture, OIU (Optical Internal Urethrotomy), CISC (Clean Intermittent Self-catheterization), Stricture recurrence, Frequency of CISC

Abstract

Background: *The concept of clean intermittent self-catheterization (CISC) after optical internal urethrotomy has been regarded as preventive management for bulbar urethral stricture recurrence. Starting date of CISC, total duration of CISC, catheter size and material, and lubricating preparations for the catheter of CISC after OIU have been investigated in several studies to correlate and modify stricture recurrence. But doing CISC by an optimal frequency is still an unsettled issue. Some studies recommended doing this preventive procedure more frequently and some preferred a less intense course of frequency. But patients may find it difficult to follow a daily self-catheterization frequency. Moreover, effect and complications of doing clean intermittent self-catheterization after optical internal urethrotomy has been investigated insufficiently for primary bulbar urethral stricture in existing literatures. So, this study investigated whether CISC biweekly was more beneficial than daily after OIU for primary bulbar urethral stricture.*

Objective: *To compare the effect of doing clean intermittent self-catheterization twice weekly and daily after optical internal urethrotomy for primary bulbar urethral stricture.*

Materials and methods: *This was a hospital based quasi-experimental study among study samples who were selected for optical internal urethrotomy with diagnosed primary bulbar urethral stricture of d"1.5 cm in length and conducted from November, 2020 to February, 2022 in the Department of Urology, Bangabandhu Sheikh Mujib Medical University. Fifty four study subjects were selected by purposive sampling. After first postoperative week of optical internal urethrotomy, patients attended to learn clean intermittent self-catheterization with a 14 Fr Nelaton Polyvinyl chloride catheter on outdoor basis. They were divided into two groups: Group-A did CISC twice weekly and Group-B practiced CISC daily. Both groups were instructed to do CISC for 6 months. Any patient reported complications associated with CISC (UTI, epididymo-orchitis, per-urethral bleeding, hematuria, urethral pain) were evaluated and treated during this period. After completion of 6 months, both groups had stopped doing CISC. Out-patient follow–*

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up had been performed in both groups at 3 and 7 months to compare International Prostate Symptom Score (IPSS), maximum urinary flow rate (Qmax) by uroflowmetry, post void residual urine (PVR) by ultrasonography and stricture recurrence by retrograde urethrography. Four patients were lost during follow up. Finally, 50 patients were analyzed for this study.

Results: *There was no statistically significant difference in mean age, stricture etiology, preoperative stricture length, preoperative IPSS, PVR, and Qmax between groups. There were statistically non-significant findings regarding IPSS and Qmax measured in the 3rd and 7th month but the change in PVR was significant (22.24±25.26 vs 41.13±48.11 ml, p=0.02). UTI occurred significantly higher in group B (23.1% vs 0%, p=0.01) during follow-up in 3rd month. There was no statistically significant difference regarding stricture recurrence between the two groups. A significantly higher proportion (50%) of patients had shown stricture recurrence with stricture length between 1.1-1.5 cm during follow-up.*

Conclusion: *CISC twice weekly after OIU is equally effective regarding stricture recurrence and complications in comparison to the patients doing CISC daily for short-segment stricture.*

Introduction

Urethral stricture disease is a complicated surgical problem for mankind since ancient times.[1] The prevalence of urethral stricture disease in the USA is estimated between approximately 200/100,000 in younger men to >600/100,000 in men older than 65.[2] In general, the term urethral stricture refers to anterior urethral disease, or a scarring process involving the spongy erectile tissue of the corpus spongiosum (spongiofibrosis).[3] Combined use of retrograde urethrogram and voiding cystourethrogram (VCUG) can better evaluate the length of bulbar stricture.[4]

Optical internal urethrotomy (OIU) has been used as the primary treatment of new as well as recurrent stricture.[5] Despite good immediate result, there is a considerable risk of recurrence between 10 to 50%.[6,7] Stricture recurrence is usually found within 3-18 months with a mean interval of 3 months after OIU.[8] To prevent this high rate of recurrence, the concept of clean intermittent self-catheterization (CISC) has been being utilized for decades which was first introduced by Lapides.[9]

The process of CISC prevents the urethral scar from contracting while it matures.[10] The concept of doing CISC following OIU has been popularized to delay the onset of symptoms and reduce the risk of stricture recurrence.[11] But higher stricture recurrences are still found in several studies in patients doing CISC after OIU. The median time to recurrence is found greater in men doing CISC (7 months) than in men who do not perform this procedure after OIU.[12] Along with many debatable aspects of clean intermittent self-catheterization, the frequency regimen of this adjunctive procedure is an unsettled issue due to a lack of prospective comparison.

The frequency of CISC in the existing literature varied widely from once daily to once in 30 days with the most common protocol being weekly or biweekly.[11, 13] There is no uniformly accepted method to follow up with patients doing CISC. Many studies have used RGU or cystoscopy routinely after OIU during follow up which is invasive and also costly. Using a maximum urinary flow rate of <15 ml/sec, Pansadoro and Emiliozzi showed that stricture recurrence could be diagnosed in 84% of patients.[14] Very few studies have investigated the effect of CISC on primary urethral stricture. But there is no known prospective study comparing the effect of doing CISC by different frequencies after optical internal urethrotomy.[15]

Pain, haematuria, symptomatic and asymptomatic bacteriuria, and epididymitis are frequently reported complications associated with CISC while UTI is the most common.[12, 16-18] Complication of doing CISC with different compositions of catheter has been reported by some studies.[10,19] But adverse effects of this procedure concerning the frequency of practice are not found in existing studies. To the best of knowledge, no previous study has addressed the comparative

effect of CISC by different frequencies after optical internal urethrotomy in Bangladeshi population. So, this Quasi-Experimental study compared the effect of post internal urethrotomy clean intermittent self-catheterization practiced either daily or biweekly for primary bulbar urethral stricture in Bangladeshi population.

Material and Method

This was a hospital-based quasi-experimental study conducted from November, 2020 to February, 2022 in the Department of Urology, Bangabandhu Sheikh Mujib Medical University, Dhaka. The study population was all the patients with a diagnosis of urethral stricture who attended in Department of Urology, BSMMU. Male patients of 18 to 60 years old with single, d"1.5 cm, primary bulbar urethral stricture who were selected for an optical internal urethrotomy (OIU) were the study subjects. Patients who were not able to perform CISC, had known carcinoma prostate and bladder malignancy, had known bleeding diathesis, having concomitant bladder outflow obstruction other than urethral stricture were excluded from the study.

Fifty-four study subjects were selected by purposive sampling. They were divided into two groups: Group-A did CISC twice weekly and Group B practiced CISC daily. Ethical clearance for the study was taken from the Institutional Review Board of BSMMU before the commencement of this study. The aim and objectives of the study along with its procedure, risks, and benefits of this study were explained to the study subjects in an easily understandable local language. Written informed consent was taken from all the study subjects without exploiting any of their weakness.

All patients were evaluated pre-operatively by detailed history, physical examination, urinalysis, and culture sensitivity, Ultrasonography of the Kidney, Ureter, and Urinary Bladder region with MCC and PVR, Uroflowmetry and Retrograde urethrogram (RGU). The length of stricture was measured as the maximum distance along a tangential straight line touching the edges of the normal urethra adjoining the stricture segment either above or below in a retrograde urethrogram (RGU) film.

Pre-operatively antibiotic Ceftriaxone 1gm was injected intravenously half an hour before OIU and spinal anesthesia was given to each patient. OIU was performed as day case surgery by a standard procedure using 22 Fr Karl Storz urethrotome and sache's cold knife. All patients who underwent OIU had a 16 Fr bi-channel indwelling Foley catheter for 7 days after completion of urethrotomy. After the first postoperative week, patients were asked to attend on an outdoor basis to remove the per-urethral catheter and learn CISC with a 14 Fr JMI Nelaton Polyvinyl Chloride (PVC) catheter.

Both groups were instructed to do CISC for 6 months. Patients were verbally instructed and taught the procedure of CISC in simple language. Both groups of patients had been provided with sufficient numbers of 14Fr JMI Nelaton catheters and Jasocaine 2% (Lignocaine) local anesthetic lubricant gel preparation to continue CISC at home for allocated duration. Patients were instructed to wash their hands, catheter and nozzle of tube containing local anesthetic gel with soap and water before starting CISC. Patients were told to put local anesthetic gel by inserting nozzle tip of tube into urethra and wait for 2 minutes compressing external urethral meatus. Then a 14 Fr Nelaton catheter was advanced through meatus into urethra slowly up to a point when urine comes out. Patients were told to do this procedure for 5 minutes in each session. After completion of doing CISC patients were requested to clean again catheter, nozzle of anesthetic tube with soap and water. Patients were told to preserve the Nelaton catheter in a clean plastic jar with a cover. Patients were advised to change the Nelaton catheter at an interval of 15 days. Any patient-reported complications associated with CISC (UTI, epididymo-orchitis, per-urethral bleeding, hematuria, and urethral pain) were evaluated and treated during this period. Patients having a significant number of pus cells (>5/HPF) in urinalysis and growth of bacteria (CFU>10^5) in the culture of urine were considered suffering from UTI. After the completion of 6 months, both groups stopped doing CISC. Out-patient follow–up had been performed at 3 and 7 months to assess and compare maximum urinary flow rate (Qmax), International prostate symptom score (IPSS), post-void residual urine (PVR), and stricture recurrence between groups.

Maximum urinary flow rate (Qmax in ml/second) was measured by uroflowmetry (MEDICA S.p.A., 2019) in Department of Urology, BSMMU. Post void residual urine (PVR in ml) was measured by ultrasonography of kidney, ureter and urinary bladder region (KUB; by Philips affinity 30 model) in Department of Radiology and Imaging, BSMMU. Routine urinalysis and culture

sensitivity tests were done in Department of Microbiology, BSMMU at each follow-up visit and also when patients presented with symptoms of urinary tract infection like fever, lower urinary tract symptoms (LUTS), and lower abdominal pain. A Patient was suspected to have a stricture recurrence if there was a symptomatic presentation (IPSS>10), deterioration of their flow rate (Qmax<15 ml/sec), and Ultrasound measured significant post-void residual urine (20% of Maximum Cystometric Capacity). All stricture recurrences were confirmed by urethrography (RGU with VCUG) which was performed in the Department of Radiology and Imaging, BSMMU. Recurrence of urethral stricture was defined as a reappearance of bulbar urethral stricture on retrograde urethrography in patients during follow-up.

Data were coded, entered, and analyzed on a computer. The statistical analysis was conducted using IBM SPSS (statistical package for social science) Windows version 20 statistical software. For statistical analysis, The Chi-Square Test and Fisher's Exact test were applied to compare categorical data. Student's unpaired t-test (for normally distributed numerical data) and Mann-Whitney U test (data in skewed distribution) were done to compare continuous data between two groups. P value <0.05 was considered statistically significant.

Results

Among 54 patients, 4 patients became 'drop out' during follow-up. Among them, 1 patient from group B did not attend a follow-up at 3 months. Two patients from group B and 1 patient from group A did not attend the final follow-up in the 7th month. Finally, 50 patients were analyzed for this study where group A comprised 26 patients (doing CISC biweekly) and group B comprised 24 patients (doing CISC daily). Among 50 study subjects, 2 patients developed (1 patient from each group) stricture recurrence after the first follow-up and the remaining 48 patients were assessed for final follow-up at 7 months.

There was no statistically significant difference in mean age (34.85 versus 34.48 years), mean stricture length (0.87 versus 0.94 cm), stricture etiology (p=0.34), mean pre-operative IPSS (22.70 versus 22.07), PVR (99.33 versus 104.52 ml) and Qmax (9.12 versus 8.99 ml/sec) between group A and B. In group A, 74.1% of patients had proximal bulbar strictures but 63% of patients in group B had distal bulbar strictures (p=0.01). There were statistically non-significant findings regarding IPSS and

Qmax measured in the 3rd and 7th months. From follow-up at the 7th month, the mean PVR was 22.24±25.26 ml in group A and 41.13±48.11 ml in group B which was significantly different (p=0.02). It was observed that 6 patients (23.1%) of group B had UTI but none of group A during follow-up at 3rd month (p=0.01). But the occurrence of complications between groups was found statistically non-significant. Four patients (16.7%) doing CISC daily and two patients (7.7%) doing CISC twice weekly had a recurrence of urethral stricture which was statistically non-significant (p=0.41). Three patients who had a documented UTI developed stricture recurrence which was statistically significant (p=0.03). It was observed that patients with preoperative stricture length between 1.1-1.5 cm developed a significantly higher proportion (50%) of recurrence.

Table-I : ***Patient characteristics and baseline data in the compared groups***

	Group-A	Group-B	Statistics
Patient age (Mean±SD)	34.85±10.97	34.48±12.19	0.82
Preoperative stricture length (cm)	0.87±0.38	0.94±0.32	0.49
Preoperative IPSS	22.70±5.22	22.07±5.42	0.67
Preoperative Qmax (ml/sec)	9.12±2.59	8.99±3.58	0.89
Preoperative PVR (ml)	99.33±28.89	104.52±22.02	0.46
Stricture location (%)Proximal bulbarDistal bulbar	74.125.9	3763	0.01
Stricture etiology (%)IdiopathicTraumaticInflammatory	59.3040.7	51.97.440.7	0.34

Table-II: *Recurrence of stricture in relation tolength of the stricture.*

Pre-operative stricture length (cm)	Group-A		Group-B		Total	p-value
	Participants	Recurrence	Participants	Recurrence	Recurrence	
0.1-0.5	12	0	7	1(14.29)	1(5.2)	
0.6-1.0	10	0	16	1 (6.25)	1(3.8)	0.001
1.1-1.5	5	2 (40)	4	2 (50)	4(44.44)	

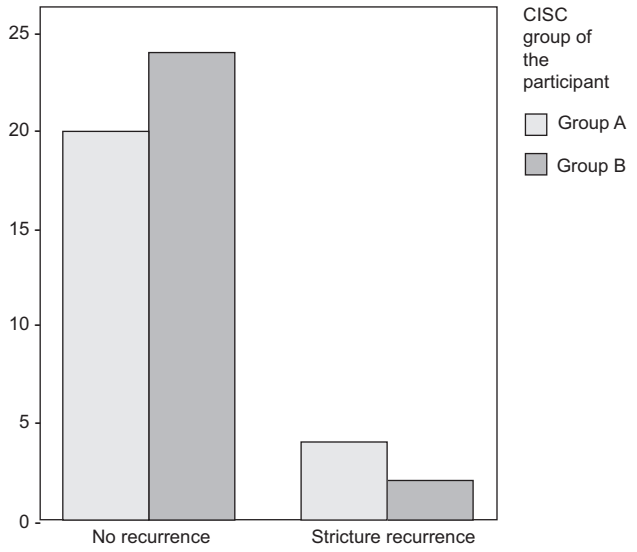

Figure-1: *Comparison of stricture recurrence*

Discussion

Many studies had showed the efficacy of clean intermittent self-catheterization (CISC) as a preventive strategy for urethral stricture recurrence after optical internal urethrotomy (OIU). Most of the available literature focused on the efficacy of CISC on recurrent stricture after urethrotomy. This study was conducted to assess the effect of CISC in terms of frequency of self-catheterization on primary bulbar stricture.

This study also compared the stricture recurrence and complications between groups doing CISC biweekly and daily.

In this study, relatively younger patients were the study subjects, similar to a study by Ahmed et al.[21] There was no statistically significant difference in stricture etiology, mean preoperative stricture length, preoperative IPSS, PVR, and Qmax between groups. In a study by Ahmed et al, it was reported that the majority of patients had a length of stricture <1 cm which coincided with the findings of the current study.[21] Rasool et al reported optical internal urethrotomy as a very successful procedure in highly selected patients with short bulbar strictures (1.0-1.5 cm).[26]

In this study, most of the patients had a urethral stricture of idiopathic etiology. This finding coincided with Chandra and Singh who showed that 54.1 % of their study subjects had stricture from the idiopathic cause.[22] Kjaegaard et al also showed similar findings that 56% of their participants had an idiopathic stricture[16]. But Khan et al in their study showed trauma as the most common etiology of stricture.[17]

The reason behind the higher proportion of idiopathic stricture in the present study was possibly due to unrecognized trauma and urinary tract infection by the atypical organism.

In this study, patients' IPSS and PVR had been measured pre and postoperatively. Most of the authors didn't report mean IPSS and PVR in their studies during the follow-up of their patients. In a prospective study by Heyns and Marais, it was reported that an IPSS of >10 or maximum urine flow <15 ml/second missed a clinically significant stricture only in 4.3% of patients.[23] Their findings concurred with the present study where most of the patients had higher IPSS during diagnosis of stricture recurrence.

Although difference in Qmax between groups found statistically non-significant during follow up, better Qmax in CISC biweekly group possibly due to relatively lower stricture recurrence in this group. Conversely, Newman et al observed significantly greater improvement in maximum urinary flow rate in patients doing more frequent CISC (CISC daily or even every other day).[25] However, the recurrence of stricture was not reported in their study.

The difference in PVR was statistically significant between two groups (p=0.02) in current study at final follow up. The cause of raised PVR in patients doing CISC daily is possibly due to the relatively greater

number of patients with stricture recurrence in this group who had high PVR during follow-up.In a study by Chandra and Singh on CISC, they mentioned the measurement of PVR during follow-up in their methodology but didn't show a comparison by the group in their results.[22]

It was observed that during follow up in present study by urinalysis and culture, 6 patients (23.1%) doing CISC daily had UTI (Urinary Tract Infection) but none of CISC biweekly group during follow up at 3rd month. More UTIs in CISC daily group in early follow-up might be due to more frequent insertion of the foreign body like Nelaton catheter and lack of proper hygiene. Similar to this finding, Lauritzen et al observed that ten out of 55 patients (18%) in the CISC group were treated for UTI after their initial internal urethrotomy.[13] A Similar occurrence of positive urine culture in the treatment group (CISC) was also observed by Kumar et al and Khan et al.[17,24]

UTI is the most commonly reported complication in this study. But the differences in complications between CISC groups were not statistically significant. The reason behind relatively higher complications in daily group possibly due to more frequent insertion of catheter in this group that resulted in trauma and infection. The most common complication observed by Roosen in the postoperative period was also a urinary tract infection followed by urethral bleeding [8]. However, Bodker et al reported urethral hemorrhage as a major complication in their study which differ from current study [12]. Matanhelia et al reported that no patient in the CISC arm of their trial developed UTI.[18] This was contradictory to findings of current study where total 9 patients from both groups suffered from UTI.

In this study, it was observed that 4 patients (16.7%) doing CISC daily and 2 patients (7.7%) doing CISC twice weekly had a recurrence of urethral stricture. Relatively higher stricture recurrence in patients performing self-catheterization daily was also observed by Lauritzen et al [13]. In their study, one out of four (25%) doing CISC 30 times per month had a recurrence. On the other hand, two of the 21 (10%) patients doing self-catheterization eight times per month had a recurrence. About 15% of patients doing CISC daily in a retrospective study by Trivedi had developed stricture recurrence [27]. Other studies did not report the effect of the frequency of doing CISC on stricture recurrence.

The reason behind no difference in stricture recurrence between CISC groups in current study possibly due to preventive beneficial effect of self-catheterization on stricture recurrence either done twice weekly or daily. No patient had clinical signs of recurrence during clean intermittent self-catheterization in a study with short follow up period by Bodker et al.[12] For this reason, an obligatory 1 month pause of doing CISC was instructed to all participants at 6 months in present study to reveal any difference of stricture recurrence between groups. Although patients doing CISC daily had more recurrence, it did not differ significantly from the biweekly group. A longer follow-up period and larger sample size might be required to observe any significant difference in stricture recurrence by different frequencies of CISC.

In the current study, it was observed that a relatively longer length of stricture had the most recurrence. This might be due to the lower success rate of OIU for bulbar stricture length more than 1cm. For that reason, CISC could not prevent stricture recurrence effectively in these study subjects. In a study by Afridi et al, it was reported that nine (50%) patients with stricture length >1.5 cm and 10 (41%) participants with stricture length <1.5cm in the CISC group had a recurrence [20]. But patients with bulbar stricture more than 1.5 cm were not included in current study.

This study revealed that doing CISC either twice weekly or daily after OIU was equally effective and there was no significant difference in stricture recurrence and complications.

Conclusion

Considering the findings of this study, it can be concluded that doing CISC twice weekly after OIU is equally effective and there is no significant difference in stricture recurrence and complications in comparison to the patients doing CISC daily for short segment stricture. Patients underwent OIU for short primary bulbar urethral stricture may be advised to do CISC less frequently to improve compliance.

Recommendation

Population based, multi-centric study with larger sample size and longer follow-up period is required to prove the efficacy of CISC by frequency.

Acknowledgement

We thanks to all our patients who consented to be included in this study and also all the Faculty members

Department of Urology, Bangabandhu Sheikh Mujib Medical University.

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