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Comparative Study of Outcome between Customized Suture Stent and Traditional Double J Stent Following Ureteroscopy and Intracorporeal Pneumatic Lithotripsy

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A B S T R A C T

***Background*:** Double J (DJ) stents are used post-ureteroscopy to maintain ureteral patency and prevent strictures, but can cause significant morbidity. Removal with an extraction suture avoids cystoscopy, though data on effectiveness and discomfort is limited. ***Objective*:** To evaluate the outcomes of using a customized suture stent compared to a conventional DJ stent, focusing on complications and patient comfort. ***Method*:** This quasi-experimental study was conducted at the Department of Urology, Dhaka Medical College Hospital, from May 2021 to April 2022. Ninety-one patients with lower and mid ureteric stones were enrolled using purposive sampling. Patients were alternately assigned to either the traditional DJ stent group (6 Fr DJ stent) or the customized suture stent group (6 Fr customized DJ suture stent). Urinary symptoms were assessed, and pain during stent removal was measured using the Visual Analogue Scale (VAS). Urinary tract infections were detected through urine routine microscopy examination (RME) and culture/sensitivity (C/S). Adverse effects, including stent migration, were recorded. ***Results*:** The mean ages were 32.4 (±13.0) years in the customized suture stent group and 37.1 (±13.7) years in the traditional DJ stent group. Males comprised 71.1% of the customized suture stent group and 52.2% of the traditional DJ stent group. The traditional DJ stent group had a significantly longer stent duration (p=0.015). Median VAS scores were 1.0 (1.0-2.0) for the customized suture stent group and 3.0 (3.0-5.0) for the traditional DJ stent group (p<0.001). There were no significant differences between groups regarding urine RME, C/S, frequency, dysuria, hematuria, incontinence, and urgency. ***Conclusion*:** The VAS score during stent removal was significantly higher in the traditional DJ stent group compared to the customized suture stent group, which enabled early self-removal 4 to 7 days post-ureteroscopy. No significant differences were observed between groups regarding urinary complications.

Keywords: Double J stent, Customized suture stent, Ureteroscopy, Postoperative morbidity.

INTRODUCTION

Ureteral stents are routinely used after ureteroscopy (URS) to ensure drainage of the upper urinary tract, particularly when obstruction of the ureter is present or anticipated [1]. The primary advantage of stent placement is the prevention of ureteric obstruction due to edema caused by the manipulation during URS. Double J (DJ) stents are commonly used for this purpose and are typically removed two weeks after URS [2]. Despite their benefits, DJ stents are often associated with significant postoperative morbidity, including urgency, frequency, urinary incontinence, hematuria, and pain. Studies have reported that approximately 78% of patients with a DJ stent develop stent-related urinary symptoms (SRS), with more than 80% experiencing pain that affects their daily lives. Furthermore, about 58% of patients report reduced workability, and 32% experience sexual dysfunction [3].

The negative impact of ureteral stents on quality of life is significant, often causing urgency, discomfort, and complications such as infection and encrustation. Consequently, minimizing the dwell time of these stents is a major concern [4]. Typically, stent removal involves a return visit to the clinic or hospital, where the stent is removed using a cystoscope in a procedure room or operating theater. This adds to the patient's burden in terms of additional costs and trips to the hospital associated with their ureteroscopy [5]. Cystoscopic stent removal can also lead to post-procedural infections. Previous studies have shown that 57% of patients experience moderate to severe pain during cystoscopic removal, with 23% reporting delayed severe pain and 9% requiring emergency care [6]. An alternative method, removing a ureteral stent using an extraction suture, has been suggested to avoid general anesthesia and unnecessary urethral instrumentation, particularly in pediatric patients [7].

Studies indicate no significant difference in post-procedure events between ureteral stents with extraction sutures and conventional DJ stents [8]. However, there were significant differences between the suture stent and non-suture stent groups regarding dysuria (2.96 vs. 2.36, p=0.03) and difficulties with heavy physical activity (2.77 vs. 2.18, p=0.04). Moreover, patients report less pain when removing extraction suture stents than flexible cystoscopic stent removal [9]. Despite these advantages, some surgeons hesitate to use customized suture stents due to concerns about inadvertent removal and increased stent-related discomfort or complications. Additionally, there is a lack of strong evidence regarding the safety and tolerability of this method [10]. However, the technique is advantageous as it can eliminate the need for an invasive cystoscopic procedure (Kim *et al*., 2015). The objective of this study is to evaluate the outcomes of using an extraction suture for stent removal at home, which may reduce costs by eliminating the need for cystoscopic removal and/or clinic visits, and to prevent retrograde stent migration, which occurs in up to 8% of patients [11].

Thus, this study was designed to compare the outcomes between customized suture stents and traditional DJ stents, focusing on complications and patient comfort. By investigating these outcomes, we aim to provide clearer evidence regarding the effectiveness and safety of customized suture stents, potentially offering a less invasive and more cost-effective alternative to traditional stent removal methods.

OBJECTIVES

General objective

- To determine the outcome of using a customized suture stent and to compare complications with a conventional D-J stent.

Specific Objectives

- To assess pain during stent removal by visual analogous scale (VAS).
- To detect urinary tract infection by urine RME and urine C/S study.
- To assess and compare urinary symptoms (Frequency, urgency, haematuria, dysuria, and incontinence)

MATERIALS AND METHODS

Study design

This study was designed as a quasi-experimental investigation conducted at the Department of Urology, Dhaka Medical College Hospital, from May 2021 to April 2022. The study compared the outcomes of using a customized suture stent versus a traditional Double J (DJ) stent in patients with lower and mid-ureteric stones. A total of 91 patients were included and selected using purposive sampling. Participants were assigned to either the traditional DJ stent group or the customized suture stent group. Data on urinary symptoms, pain during stent removal, urinary tract infections, and adverse effects were collected.

Inclusion criteria

- Age:18 to 60 years
- Patient with lower and mid ureteric stone
- Stone size < 1 cm requires treatment with URS and intracorporal pneumatic lithotripsy.
- Complete clearance of stone

Exclusion criteria

- Obstructive voiding symptoms
- Patients who were taking an alpha-blocker or anti-cholinergic agent to treat lower urinary tract symptoms or who were taking analgesics for chronic pain were also excluded to rule out any influence of the drugs on the symptom.
- Any history of previous ureteric stone surgery.
- The pre-operative indwelling of D-J stent.

- Solitary kidney
- Ureteral abnormalities
- Intra-procedural complications (e.g- ureteral damage, significant bleeding)

Data Collection

Data were collected from 91 patients alternately assigned to either the traditional DJ stent group or the customized suture stent group. Patient demographics, urinary symptoms, and pain levels during stent removal were documented. Pain was assessed using the Visual Analogue Scale (VAS). Urinary tract infections were identified through urine routine microscopy examination (RME) and culture/sensitivity (C/S). Adverse effects, including stent migration, were also recorded. Follow-up evaluations were conducted to monitor any complications or changes in urinary symptoms. All data were systematically recorded and analyzed to compare outcomes between the two stent groups.

Data analysis

Data analysis was performed using SPSS version 26. Continuous variables were expressed as mean ± standard deviation and categorical variables as frequencies and percentages. The t-test was used to compare continuous variables between the two groups, while the Chi-square test was employed for categorical variables. A p-value of <0.05 was considered statistically significant. The primary outcome, pain during stent removal, was analyzed using the Visual Analogue Scale (VAS) scores. Secondary outcomes, including urinary symptoms and incidence of urinary tract infections, were also analyzed to assess the differences between the traditional DJ stent and customized suture stent groups.

Ethical Consideration

The Ethical Review Committee of Dhaka Medical College Hospital approved the study protocol. Written informed consent was obtained from all participants before their inclusion. Participants were assured of confidentiality, and their right to withdraw from the study without any consequences to their medical treatment was emphasized. The study adhered to ethical guidelines to ensure all participants' safety, rights, and well-being throughout the research.

RESULTS

Table 1: Distribution of patients by age (n=91)

Age Group (years)	Total (n=91)	Customized Suture Stent (n=45)	Traditional DJ Stent (n=46)
<30	50 (54.9%)	27 (60.4%)	23 (50.0%)
31-40	12 (13.2%)	8 (17.8%)	4 (8.7%)
41-50	19 (20.9%)	5 (11.1%)	14 (30.4%)
51-60	10 (11.0%)	5 (11.1%)	5 (10.9%)
Mean ± SD	34.7 ± 13.5	32.4 ± 13.0	37.1 ± 13.7

The mean age of the patients in the customized suture stent and traditional DJ stent groups were 32.4 (±13.0) and 37.1 (±13.7) years, respectively. In the customized suture stent group, 32 (71.1%) were male, while 24 (52.2%) were male in the traditional DJ stent group. The traditional DJ stent group had a significantly longer duration of stent placement compared to the customized suture stent group ($p=0.015$). The median VAS score for pain during stent removal was 1.0 (1.0-2.0) in the customized suture stent group and 3.0 (3.0-5.0) in the traditional DJ stent group, with the latter showing significantly higher VAS scores ($p<0.001$). There were no significant differences between the groups regarding urine RME ($p=0.999$), CS ($p=0.999$), frequency ($p=0.710$), dysuria ($p=0.635$), hematuria ($p=0.999$), incontinence ($p=0.434$), and urgency ($p=0.857$).

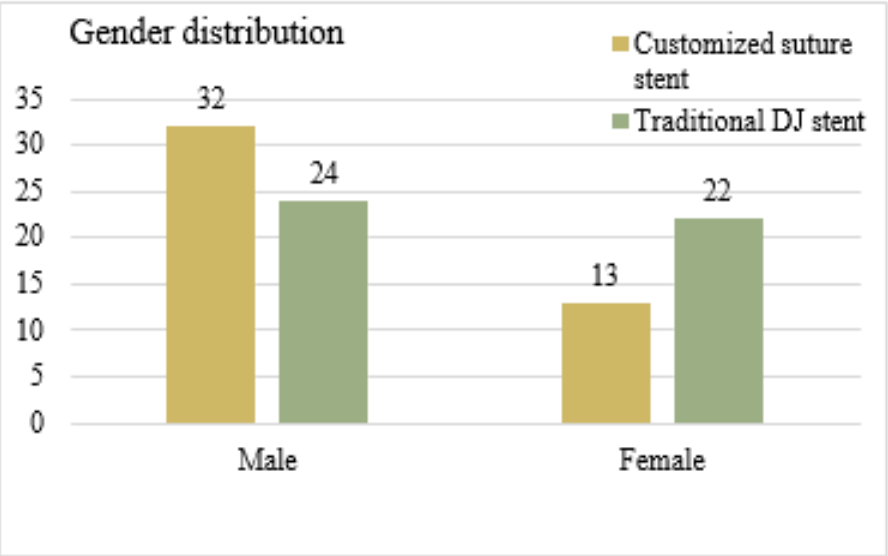

Figure 1: Distribution of patients by gender

In the customized suture stent group, 32 (71.1%) were male, compared to 24 (52.2%) in the traditional DJ stent group.

Table 2: Distribution of patients by size of the stone and side involvement (n=91)

Criteria	Customized Suture Stent (n=45)	Traditional DJ Stent (n=46)
Size of stone (Mean ± SD) (cm)	0.88 ± 0.12	0.85 ± 0.08
Right	27 (60.0%)	24 (52.2%)
Left	18 (40.0%)	22 (47.8%)

The mean size of the stone was 0.88 (±0.12) cm in the customized suture stent group and 0.85 (±0.08) cm in the traditional DJ stent group. Most patients had stones on the right side.

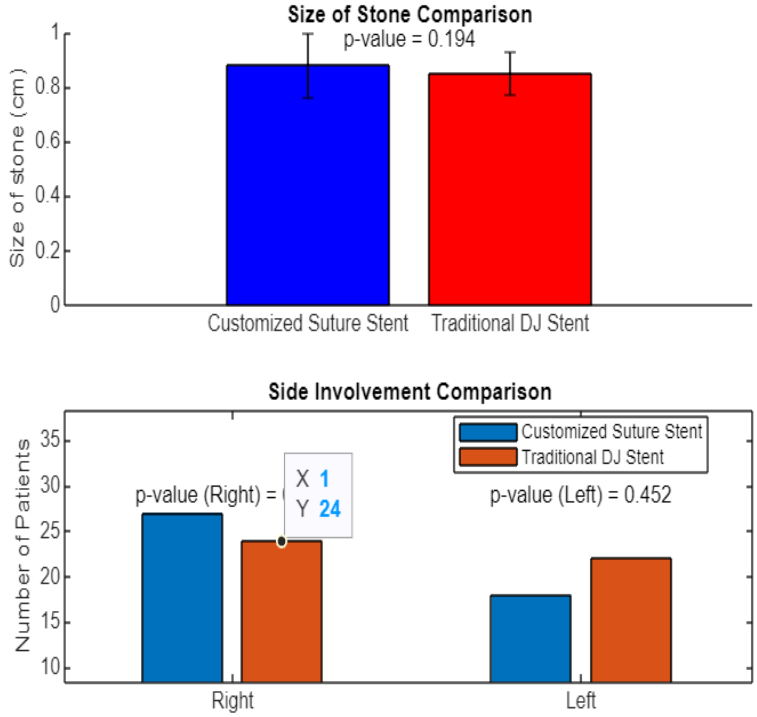

Figure 2: Comparison of patients by size of the stone and side involvement (n=91)

Shows no significant difference between the customized suture stent and traditional DJ stent groups regarding the mean size of stones (0.88 ± 0.12 cm vs. 0.85 ± 0.08 cm, p=0.194). Side involvement was also similar, with 60.0% right and 40.0% left in the customized suture stent group versus 52.2% right and 47.8% left in the traditional DJ stent group (p=0.452). These findings indicate comparable baseline stone size and location characteristics across both groups.

Table 3: Distribution of patients by stent duration (n=91)

Stent Duration (days)	Customized Suture Stent (n=45)	Traditional DJ Stent (n=46)	p-value
4 to 5	43 (95.6%)	36 (78.3%)	0.015a
6 to 7	2 (4.4%)	10 (21.7%)	
Mean ± SD	5.7 ± 2.8	8.1 ± 3.2	<0.001b

a = Chi-square test, b = Unpaired t-test

Double J stents are typically removed 3 to 6 weeks after URS. In the customized suture stent group, 43 (95.6%) patients had stents for 4-5 days, and 2 (4.4%) had stents for 6-7 days. In the traditional DJ stent group, 36 (78.3%) had stents for 4-5 days, and 10 (21.7%) had stents for 6-7 days. The traditional DJ stent group had a significantly longer stent duration (p=0.015).

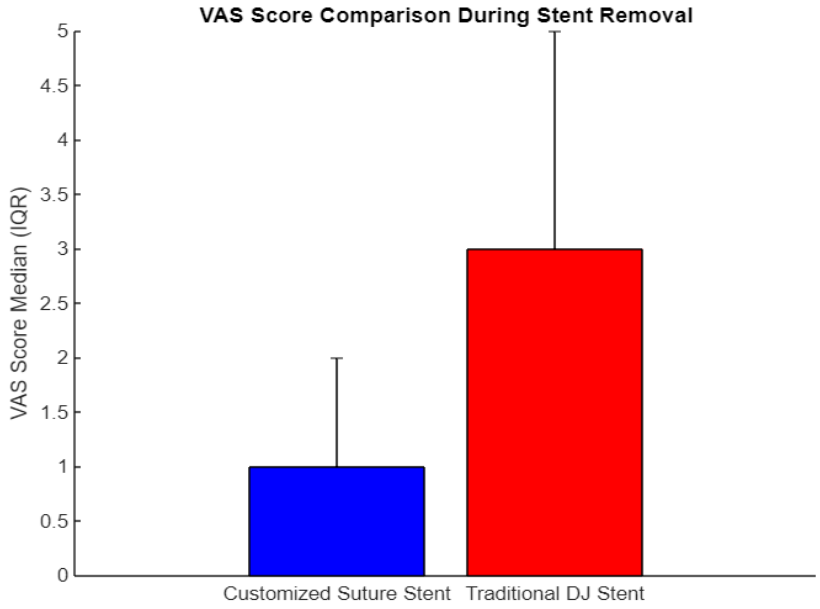

Figure 3: Comparison of patients by pain during stent removal in VAS score (n=91)

Shows a significant difference in pain levels during stent removal between the groups. The median VAS score for the customized suture stent group is 1.0 (IQR 1.0-2.0), while for the traditional DJ stent group, it is 3.0 (IQR 3.0-5.0), with a p-value of <0.001. This indicates that patients with the customized suture stent experienced significantly less pain during stent removal compared to those with the traditional DJ stent.

Table 4: Comparison of UTI or pyelonephritis by urine RME and CS (n=91)

Criteria	Customized Suture Stent (n=45)	Traditional DJ Stent (n=46)	p-value
Urine for RME			
Pus cell >10/HPF	2 (4.4%)	3 (6.5%)	0.999a
Pus cell <10/HPF	43 (95.6%)	43 (93.5%)	
Urine for CS			
Growth (positive)	0 (0.0%)	1 (2.2%)	0.999a
No growth	45 (100.0%)	45 (97.8%)	

a = Fisher Exact test

In the customized suture stent group, 2 (4.4%) patients had UTI based on urine RME, compared to 3 (6.5%) in the traditional DJ stent group. No patients in the customized suture stent group had positive CS, while 1 (2.2%) in the traditional DJ stent group did. There was no significant difference between the groups (p>0.05).

Table 5: Comparison of patients by stent in situ-related symptoms or complications (n=91)

Criteria	Customized Suture Stent (n=45)	Traditional DJ Stent (n=46)	p-value
Frequency	14 (31.1%)	16 (34.8%)	
Dysuria	8 (17.8%)	10 (21.7%)	
Haematuria	2 (4.4%)	3 (6.5%)	
Incontinence	4 (8.9%)	2 (4.3%)	
Urgency	11 (24.4%)	12 (26.1%)	0.857a
Stent migration	0 (0.0%)	0 (0.0%)	
Accidental removal	0 (0.0%)	0 (0.0%)	

a = Chi-square test, b = Fisher Exact test

In the customized suture stent group, 14 (31.1%) patients had frequency, 8 (17.8%) had dysuria, 2 (4.4%) had hematuria, 4 (8.9%) had incontinence, and 11 (24.4%) had urgency. In the traditional DJ stent group, 16 (34.8%) had frequency, 10 (21.7%) had dysuria, 3 (6.5%) had hematuria, 2 (4.3%) had incontinence, and 12 (26.1%) had urgency. There were no significant differences between the groups regarding these symptoms ($p>0.05$). No stent migration or accidental removal occurred in either group.

DISCUSSION

Ureteric stent placement is indicated to avoid post-ureteroscopic complications such as mucosal edema and subsequent obstruction, clot or fragment colic, and delayed inflammation-related stricture development [12, 13]. However, a significant proportion of patients treated with an indwelling ureteric stent experience lower urinary tract symptoms. The present study aimed to determine and compare the outcomes of a customized suture stent with a conventional DJ stent. Most patients in this study were younger than 30 years, with mean ages of 32.4 (±13.0) years in the customized suture stent group and 37.1 (±13.7) years in the traditional DJ stent group. No significant statistical difference was observed between the groups regarding age, which aligns with the findings.

The study also found a predominance of male patients, consistent with other research. Rove *et al*., reported 72.4% male patients and found 72.5% male patients in their studies [14]. Similarly, it was reported that more than 51.0% of their study participants were male. Regarding stent duration, 95.6% of patients in the customized suture stent group had their stents for 4 to 5 days, compared to 78.3% in the traditional DJ stent group. The duration of stent placement was significantly less in the customized suture stent group ($p=0.015$). Pietropaolo*et al*., also reported lower overall stent dwell time in patients who had their stents removed via extraction suture [15].

Other studies corroborate these findings, showing that the durations of stents left in situ were significantly less in the suture stent group [16]. For traditional stent removal, patients required scheduling from the hospital, often leading to delays. Many patients, coming from distant districts, depended on attendants for help. Conversely, removing the customized suture stent did not require hospital scheduling, saving patients time and travel costs. The median VAS score for pain during stent removal was significantly lower in the customized suture stent group (1.0, IQR 1.0-2.0) compared to the traditional DJ stent group (3.0, IQR 3.0-5.0) ($p<0.001$). Previous studies report a wide range of VAS scores for cystoscopic stent removal, from 1.8 to 8.0, possibly due to variations in settings, such as the use of rigid or flexible cystoscopes and adjunctive medications or local anesthesia.

Al Demour*et al*., found that ureteral stent removal by extraction suture after ureteroscopy resulted in significantly less pain than cystoscopic removal for male patients [17]. A systematic review revealed lower VAS scores following extraction suture removal compared to traditional cystoscopic methods (mean difference 0.14, $p < 0.00001$). Despite using topical anesthesia, patients in the traditional DJ stent group experienced more pain, potentially due to anxiety and the use of a rigid cystoscope (21 Fr). Additionally, the local anesthesia used may not have been sufficient, given the inadequate time for its action. In contrast, the customized suture stent group experienced less pain, likely due to reduced anxiety and the absence of stretching caused by the thin extraction suture (3/0 polypropylene) or DJ stent (6 Fr).

This study found no significant statistical difference between the groups regarding urine RME and CS, consistent with. reported a total urinary tract infection rate of 6.4%, with no significant difference between the two groups (7.9% vs. 5.6%, $p = 0.49$). Although there is a risk of ascending infection after placing an extraction suture, no patient in this study developed a UTI, possibly due to strict personal hygiene and the use of antimicrobial agents pre-and post-operatively. The short duration of indwelling suture stents might also contribute to the low infection rate. Stent-related symptoms significantly impact patients' daily lives, reported in 92% of cases [18]. Dysuria was present in 17.8% of the customized suture stent group and 21.7% of the traditional DJ stent group, showing no significant difference ($p=0.635$). This finding aligns with, although significantly higher dysuria scores were reported in the customized suture stent group ($p=0.030$).

In this study, 4.4% of patients in the customized suture stent group and 6.5% in the traditional DJ stent group experienced hematuria (p=0.999). Reported significantly higher hematuria rates in the cystoscopic stent removal groups ($p < 0.001$), likely due to the shorter dwell times provided by string removal. There was no significant statistical difference between the groups regarding frequency (p=0.509), dysuria (p=0.635), hematuria (p=0.999), incontinence (p=0.434), and urgency (p=0.485), consistent with findings by [19]. Complication rates in the study were similar between the suture stent group (12.8%) and DJ stent group (14.0%) (p=0.867), possibly due to the reduced dwell time of the DJ stent.

While stents with sutures carry a risk of accidental removal, no such incidents occurred in this study due to clear patient instructions. However, reported that 10% of patients experienced stent dislodgement with extraction sutures. Higher incidences of stent dislodgement with extraction strings were also reported [20]. In this study, no patient in either group experienced stent migration, likely due to thorough pre-operative education and careful placement of the stent. The extraction suture was secured with micropore tape to prevent accidental removal. Although some patients experienced detachment of the tape, there was no stent migration, possibly due to the proper placement of the stent and the presence of coils at both ends preventing migration.

The customized suture stent was cost-effective and did not require staffing, equipment, or maintenance costs. Removing the stent at home saved travel costs for patients and their attendants. The customized suture stent offers significant advantages over traditional DJ stents, including reduced removal pain, shorter dwell time, and cost savings. These benefits, coupled with the absence of significant differences in complications, suggest that the customized suture stent is a viable alternative to traditional stent removal methods. Further studies with larger sample sizes and long-term follow-up are warranted to confirm these findings.

CONCLUSION

The visual analog scale (VAS) score during stent removal in the traditional DJ stent group is significantly higher than that of the customized suture stent group, which had early self-removal after 4 to 7 days of ureteroscopy. There was no significant statistical difference between the groups regarding urine RME and C/S, frequency, dysuria, hematuria, incontinence, and urgency.

RECOMMENDATIONS

Prospective randomized trials are needed to determine the benefits and disadvantages of ureteric stents with customized suture stents.

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