

Single-J versus double-J stents after ureterorenoscopy for renal stones: A randomized comparison of safety and tolerability

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Introduction Ureteral stents are generally used after ureterorenoscopy (URS) procedures, even in uncomplicated ones. We aimed to compare the safety and tolerability of single-J (SJ) stents and double-J (DJ) stents in patients submitted to flexible URS for renal stones.

Material and methods This prospective, randomized, unblinded, single-center study was conducted between July 2022 and May 2024, involving patients undergoing flexible URS with holmium laser lithotripsy for renal stones. Patients were randomized to either SJ stents (removed within 24 hours) or DJ stents (removed 2-4 weeks post-surgery). Primary endpoints included emergency department admissions, postoperative complications, and reintervention rates. Secondary endpoints included stent tolerability and surgery efficacy. A symptom questionnaire was applied at postoperative weeks 1 (W1) and 4 (W4).

Results We included 125 patients (60 in group SJ and 65 in group DJ), with comparable baseline characteristics. Emergency department admissions were similar (18.3% vs 16.9%, $p = 0.84$), as were complications (18.3% vs 21.5%, $p = 0.65$) and reintervention rates (1.7% vs 3.1%, $p = 1.0$). SJ stents showed better tolerability, with lower scores for lower urinary tract symptoms (LUTS) and pain at both time points.

Conclusions SJ stents placed for less than 24 hours after complete flexible URS are comparable to DJ stents regarding safety and are better tolerated, particularly 4 weeks after the surgery. SJ stents should be prioritized, reducing costs and hospital visits for stent removal.

Key Words: urolithiasis <> urinary catheters <> ureteroscopy <> lithotripsy <> laser <> patient safety

INTRODUCTION

Ureteral stenting after ureterorenoscopy (URS) is frequently used worldwide, even though major guidelines suggest it is optional for uncomplicated procedures [1, 2]. Studies with large samples have shown that ureteral stenting is performed at the end of over 80% of the surgeries [3, 4]. This can be attributed to several factors, including the surgeon's personal convictions, hospital logistical reasons, and accessibility to emergency services. Although findings of a systematic-review suggested that stenting

reduced the number of emergency department visits, the investigators alerted to the uncertainty of the data behind those results, as most studies were small and retrospective [5]. Despite the widespread use of ureteral catheters, stent-related symptoms, like hematuria or urinary frequency, remain a significant problem, as extensively studied in the literature [5, 6]. Some stents, such as the Polaris™, are specifically designed to mitigate these symptoms [7].

Even when the surgeon has decided to use a ureteral stent, there is limited literature to guide the decision on which catheter to use. Therefore, our aim was

to provide good quality evidence on this subject. With this prospective randomized unblinded study, our objective was to compare the safety and tolerability of the 2 most common ureteral catheter types used in our hospital, the single-J loop (SJ) stents and the double-J loop (DJ) stents.

MATERIAL AND METHODS

Study design and participants

This randomized unblinded prospective study was carried out at Hospital de Braga, between July 2022 and May 2024. Patients submitted to flexible ureteroscopy with holmium laser lithotripsy of renal stones without ureteral access sheath use were randomized to ureteral catheterization with SJ stents (Coloplast Vortek® single loop ureteral stent, with 6Fr diameter; group SJ) or DJ stents (Coloplast Biosoft® duo double loop ureteral stent, with 6Fr diameter and 24–26 cm length; group DJ). SJ stents had an early removal less than 24 hours after the surgery, before hospital discharge, while DJ stents were removed in a subsequent appointment, 2–4 weeks after surgery.

For logistical reasons, randomization was conducted weekly (starting on Monday), alternating between group SJ and group DJ. The catheter group for the first week was randomly selected using a computer program. The surgeons were not informed of the randomization strategy; they were only informed of the group the patients were allocated to on the day of the surgery. Deviations from randomization were permitted only in cases of stent unavailability, not based on the surgeon's decision.

Written informed consent was obtained from all participants before enrolment. Exclusion criteria were concomitant bladder or ureteral stones, urinary tract alterations (congenital malformations, previous reconstructive procedures, or history of urothelial cancer), bilateral procedures, and inability/impossibility to answer questionnaires.

Outcomes

The primary endpoints, evaluated in the first postoperative month, were admission to the emergency department, postoperative complications, and reintervention rate. Secondary endpoints were stent tolerability and surgery efficacy.

Data collection

Patients' charts were reviewed frequently to monitor complications. Tolerability was studied with

a simple phone symptom questionnaire at postoperative weeks 1 and 4. This questionnaire included 2 numeric pain scales (0–10 points, with 10 being the most extreme pain ever experienced) for lumbar and supra-pubic pain, and 5 questions focused on lower urinary tract symptoms (LUTS) – dysuria, hematuria, urinary incontinence, urgency, and urinary frequency; patients rated the frequency of the symptoms on a scale from zero (never) to five (almost always), and the total score for the LUTS questions was 25. It was based on the validated ureteral stent symptom questionnaire by Joshi et al. [8].

Efficacy was also evaluated by the stone-free rate (SFR), which was defined by the absence of residual stones >4 mm in imaging postoperative examination (computed tomography). We also included a secondary SFR that considered patients who underwent a postoperative ultrasound (US) or were assessed through the surgeon's clinical evaluation when no radiographic examination was performed.

Postoperative follow-up encompassed the first month after surgery. Complications were reported according to the Clavien-Dindo classification [9].

The sample size for this study was calculated using the application G*Power® V3.1.9.7, and a minimum of 82 patients should be included. After achieving the necessary number, study termination was decided for a specific date (end of May 2024).

Statistical analysis

Statistical analysis was performed using IBM® SPSS® Statistics Software (version 28). Descriptive analysis included representation of categorical variables by frequencies (n) and proportions (%), while continuous variables were described by means (M) and standard deviations (SD), or medians (Mdn) and interquartile ranges (IQR), when applicable. Comparison between groups was performed using a χ^2 test or Fisher's exact test for categorical variables (depending on the expected cell counts), the independent t-test for standard distribution variables, and the Mann-Whitney U test as a non-parametric alternative. As-treated and intention-to-treat (ITT) analyses were both performed.

A $p < 0.05$ was considered statistically significant with a 95% confidence interval (CI).

Bioethical standards

The study was approved by the Ethics Committee of the Hospital de Braga and University of Minho in Braga, Portugal (approval number: CEHB_64_2024).

RESULTS

We included 125 patients (60 in group SJ and 65 in group DJ). Twelve patients (10%) did not receive the allocated stent due to stent unavailability at the date. Of these, 7 (58%) received SJ stents and 5 (42%) received DJ stents, despite being randomized to the opposite group. Both As-treated and ITT analyses were performed with similar results. The following results were obtained with the As-treated analysis; we included the ITT analysis of primary and secondary outcomes in the Suppl. Tables 1 and 2.

Baseline characteristics were comparable between groups, as illustrated in Table 1.

Primary outcomes – safety

Twenty-two patients (17.6%) were admitted to the emergency department. The reasons were: pain (n = 15, 12.0%), fever (n = 3, 2.4%), hematuria (n = 2, 1.6%), nausea (n = 1, 0.8%), and skin rash (n = 1, 0.8%).

Twenty-five patients (20.0%) suffered complications, 11 (18.3%) in group SJ and 14 (21.5%) in group DJ (p = 0.65). Complications were mostly grade I (pain requiring analgesics or bleeding) or grade II (steinstrasse treated with analgesics and α -blockers or pyelonephritis needing antibiotics).

Reintervention rate was low and not statistically different between groups. The motive for reintervention was an obstructive pyelonephritis needing stenting in a patient from group SJ and 2 incrustated stents in patients from group DJ.

Group-specific results are shown in Table 2.

Complications were more frequent in non-pre-stented patients (26.8% vs 11.1%, p = 0.03). Nevertheless, even in the non-pre-stented subgroup (n = 71), complications were comparable between Group SJ and Group DJ (29.4% vs 24.3%, respectively; p = 0.63); the reintervention rate was also similar (0% vs 2.7%, p = 1.0).

There were no reported intraoperative complications.

Table 1. Patient demographic and surgical characteristics

| | Sample (n = 125) | Group SJ (n = 60) | Group DJ (n = 65) | p |
|--|------------------------|--------------------------|------------------------|------|
| Demographic characteristics | | | | |
| Sex, n (%) Male | 70.0 (56.0%) | 31.0 (51.7%) | 39 (60.0%) | 0.35 |
| Age (years), M ±SD | 57.2 ±12.2 | 56.8 ±12.0 | 57.5 ±12.4 | 0.60 |
| BMI (kg/m²), Mdn (IQR) | 27.4 (24.8–31.2) | 26.4 (24.5–30.1) | 27.8 (25.0–32.4) | 0.10 |
| Comorbidities | | | | |
| Previous urolithiasis, n (%) | 86.0 (68.8%) | 44.0 (73.3%) | 42.0 (64.6%) | 0.29 |
| Previous urolithiasis surgery, n (%) | 80.0 (64.0%) | 40.0 (66.7%) | 40.0 (61.5%) | 0.55 |
| Arterial Hypertension, n (%) | 52.0 (41.6%) | 26.0 (43.3%) | 26.0 (40.0%) | 0.71 |
| Diabetes mellitus, n (%) | 25.0 (20.0%) | 10.0 (16.7%) | 15.0 (23.1%) | 0.37 |
| Depression, n (%) | 16.0 (12.8%) | 9.0 (15.0%) | 7 (10.8%) | 0.48 |
| ASA Score, n (%) | | | | 0.97 |
| ASA I | 13 (10.4%) | 6 (10.0%) | 7 (10.8%) | |
| ASA II | 90 (72.0%) | 43 (71.7%) | 47 (72.3%) | |
| ASA III | 22 (17.6%) | 11 (18.3%) | 11 (16.9%) | |
| Lithiasis and surgery data | | | | |
| Side, n (%) Left | 72 (57.6) | 39 (65.0) | 33 (50.8) | 0.11 |
| Stone number, n (%) One Multiple | 87 (69.6) 38 (30.4) | 36 (60.0) 24 (40.0) | 51 (78.5) 14 (21.9) | 0.03 |
| Stone maximum diameter (mm), Mdn (IQR) | 11.0 (9.0–14.0) | 10.0 (9.0–13.0) | 12.0 (9.0–15.0) | 0.06 |
| Stone density (HU), Mdn (IQR) | 980.0 (525.0–1343.3) | 1,060.0 (525.0 – 1363.0) | 900.0 (500.0–1341.0) | 0.63 |
| Pre-stenting – ureteral stent in place at the time of surgery, n (%) | 54 (43.2) | 26 (43.3) | 28 (43.1) | 0.98 |
| Surgery duration (min), Mdn (IQR) | 27.0 (20.5–34.5) | 27.0 (21.0–34.0) | 27.0 (20.0–36.0) | 0.84 |

ASA – American Society of Anesthesiologists; HU – Hounsfield units; IQR – interquartile range; M – Mean; Mdn – Median; SD – standard deviation

Secondary outcomes – tolerability

Nine patients from group SJ and 12 from group DJ (15.0% vs 18.5%, $p = 0.61$) did not complete at least one of the questionnaires and were excluded from the tolerability assessment.

The main results from the questionnaire assessment are described in Table 3.

The most frequently reported LUT symptom was urinary frequency for both groups at both time-points. Detailed answers to each LUTS question can be found in Suppl. Tables 3 and 4.

Regarding therapeutic regimens, at W1, no statistically significant differences were demonstrated between groups in analgesic medication (60.8% in group SJ and 60.4% in group DJ, $p = 0.97$) or α -blockers (76.5% in group SJ and 64.2% in group DJ, $p = 0.17$), but antispasmodics like trospium chloride or mirabegron were more frequently used by DJ stent patients (7.8% in group SJ and 34.0% in group DJ, $p = 0.001$). At W4, less patients were taking medication, and only antispasmodics showed a statistically significant difference between groups (0.0% in group SJ and 13.5% in group DJ, $p = 0.03$). Twenty-one (39.6%) patients from group DJ had the stent removed before answering the W4 questionnaire. DJ stents were removed after a median of 29 days (IQR: 21.5–44.5).

Table 2. Primary outcomes

| | Group SJ (n = 60) | Group DJ (n = 65) | p |
|---------------------------------|----------------------|----------------------|------|
| Safety – n (%) | | | |
| Emergency department admissions | 11 (18.3%) | 11 (16.9%) | 0.84 |
| Total complications | 11 (18.3%) | 14 (21.5%) | 0.65 |
| Grade I–II | 10 (16.7%) | 12 (18.5%) | |
| Grade ≥III | 1 (1.7%) | 2 (3.1%) | 0.93 |
| Reintervention rate | 1 (1.7%) | 2 (3.1%) | 1.00 |

Table 3. Secondary outcomes

| | | Group SJ (n = 51) | Group DJ (n = 53) | p |
|--|----|----------------------|----------------------|--------|
| Tolerability / Symptom Questionnaire – Mdn (IQR) | | | | |
| LUTS – Symptom Score Total | W1 | 6 (3–9) | 10 (5–13) | 0.01 |
| | W4 | 2 (0–5) | 7 (2.5–13.5) | <0.001 |
| Lumbar Pain | W1 | 1 (0–4) | 3 (0–5) | 0.14 |
| | W4 | 0 (0–1) | 1 (0–5) | 0.02 |
| Supra-pubic Pain | W1 | 1 (0–4) | 3 (0–6) | 0.002 |
| | W4 | 0 (0–0) | 1 (0–5) | <0.001 |

IQR – interquartile range; Mdn – median; W1 – postoperative week 1; W4 – postoperative week 4

Secondary outcomes – procedure efficacy

Only 29.6% of the patients had a control image within 30 days of the surgery: 32 with CT and 4 with US. Considering only the patients reviewed by CT, the global stone-free rate was 75.0% (82.4% in group SJ and 66.7% in group DJ, $p = 0.42$). Ten patients had no stone (31.3%), 4 patients had fragments smaller than 2 mm (12.5%), and 10 patients had residual fragments with 2.1–4 mm (31.3%). A secondary SFR including all patients revealed that only 6.4% had confirmed residual stones >4 mm, corresponding to a global 93.6% stone-free rate (95.0% in group SJ and 92.3% in group DJ, $p = 0.72$).

DISCUSSION

Ureteral stents are generally used after URS procedures, even in uncomplicated ones. However, there is still limited evidence on the optimal type and duration of stent usage. To our knowledge, this is the first randomized study comparing SJ vs DJ stents after flexible URS. The FaST studies also compared these stents in different settings, but none included solely flexible URS, and their focus was specifically urinary symptoms related to both stents [10, 11]. There is also a previous retrospective study comparing these stents after treatment of ureteral stones [12].

The baseline characteristics of our two groups were generally comparable. However, there was a statistically significant difference in the number of stones, with multiple stones being more frequent in group SJ. Additionally, there was a trend towards slightly larger stones in group DJ.

Our main objective was to compare the safety of both stents in terms of emergency department admission, overall complications, and reintervention rate. This study's complication rate of 20% was higher than global studies, like the ones by the Clinical Research Office of the Endourological Society (CROES) [4, 13], but similar to the comparative studies between these two stents [10–12]. Most complications were minor, and no patients experienced severe complications (Clavien-Dindo's grade >III).

Notably, the complication rate was not statistically different between group SJ and DJ, and the most frequent complication was pain requiring analgesics in both groups. Reintervention rate was 1.7% in group SJ and 3.1% in group DJ, which was lower than reported by previous studies [10, 11]. In contrast to the findings of FAST 3 [11], which was terminated early due to an unexpectedly high reintervention rate when SJ stents were placed, the reintervention rate in group SJ was rare, even

when considering only primary URS (without pre-stenting). Therefore, our findings suggest SJ stents are at least as safe as DJ stents.

As demonstrated by the questionnaire results, LUTS were significantly less frequent in group SJ at both time points. Although lumbar pain was not significantly more intense in group DJ at W1, it became more severe after 4 weeks. Additionally, suprapubic pain was greater in group DJ at both W1 and W4. These findings corroborate those of the FAST trial [10].

Regarding questionnaire results at W4, nearly 40% of the group DJ patients had already removed their stents before answering the questionnaire, potentially underestimating differences between groups. Conversely, the observed differences at W4 might be attributable solely to the earlier removal of SJ stents rather than the stent type itself. Regardless, given the easier removal and less associated costs with SJ stents, they offer advantages over early removed DJ stents; however, this study was not designed to compare early removal of DJ stents, so this question remains to be answered, and should be addressed in future trials.

Lastly, SFR was also concordant with the literature [4, 6], although only a few patients had a postoperative imaging study.

One of the main limitations of this study is the unblinding of both surgeons and patients, with its inherent biases – the randomization process intended to reduce surgeon bias, as each surgeon placed both types of stents. Additionally, patients were scheduled by an external urologist who was unaware of the randomization process and did not perform the surgeries, ensuring that case characteristics did not influence patient selection. It is also important to note that deviations from randomization were only permitted if the randomized stent was not available at the time; to further control this limitation, both as-treated and ITT analyses were performed and presented.

While not formally validated, the questionnaire used was derived from the USSQ [8] and was abbreviated to include only the urinary domain symptoms deemed most relevant by the investigators. Another limitation is the absence of a baseline assessment of LUTS and pain. This prevents us from determining whether the groups differed in their initial symptoms or if pre-existing symptoms were influenced by stent placement. Although we believe these limitations do not significantly impact our results, acknowledging them is essential for the design of future studies.

CONCLUSIONS

Our study demonstrates that SJ stents placed for less than 24 hours after complete flexible URS are comparable to DJ stents regarding emergency department admission, complications, and reintervention rates. Furthermore, SJ stents were better tolerated, particularly at 4 weeks post-surgery. Consequently, urologists should prioritize SJ stents, reducing costs and hospital visits for stent removal. Additional randomized trials with larger sample sizes are needed to reinforce this practice.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest.

FUNDING

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ETHICS APPROVAL STATEMENT

The study was approved by the Ethics Committee of the Hospital of Braga and University of Minho in Braga, Portugal (approval number: CEHB_64_2024).

SUPPLEMENTARY MATERIALS

Suppl. Table 1. Primary outcomes – intention to treat analysis

| | Group SJ (n = 58) | Group DJ (n = 67) | p |
|---------------------------------|----------------------|----------------------|------|
| Safety, n (%) | | | |
| Emergency department admissions | 13 (22.4%) | 9 (13.4%) | 0.19 |
| Total complications | 13 (22.4%) | 12 (17.9%) | 0.53 |
| Grade I–II | 12 (20.7%) | 10 (14.9%) | |
| Grade ≥III | 1 (1.7%) | 2 (3.1%) | 0.61 |
| Reintervention rate | 1 (1.7%) | 2 (3.1%) | 1.00 |

Suppl. Table 2. Secondary outcomes – intention to treat analysis

| | | Group SJ (n = 48) | Group DJ (n = 56) | p |
|--|----|----------------------|----------------------|-------|
| Tolerability / Symptom Questionnaire – Mdn (IQR) | | | | |
| LUTS Symptom Score Total | W1 | 6.5 (3–10) | 9 (5–12.75) | 0.080 |
| | W4 | 3 (0–6.75) | 6 (2–10) | 0.005 |
| Lumbar Pain | W1 | 2 (0–4.75) | 2.5 (0–5) | 0.510 |
| | W4 | 0 (0–1) | 1 (0–5) | 0.008 |
| Supra-pubic Pain | W1 | 2 (0–4) | 3 (0–5) | 0.210 |
| | W4 | 0 (0–0.75) | 1 (0–4) | 0.004 |
| Efficacy, n (%) | | | | |
| | | Group SJ (n = 17) | Group DJ (n = 15) | p |
| Stone-free rate | | 13 (76.5) | 11 (73.3) | 0.840 |

IQR – interquartile range; Mdn – median; W1 – postoperative week 1;
W4 – postoperative week 4

Suppl. Table 3. LUTS Questionnaire answers at week 1

| Question | Group SJ (n = 51) | Group DJ (n = 53) | p |
|-----------------------------|----------------------|----------------------|--------|
| Dysuria, n (%) | | | |
| Never | 29 (56.9) | 16 (30.2) | <0.001 |
| Very rarely | 8 (15.7) | 6 (11.3) | |
| Rarely | 8 (15.7) | 4 (7.5) | |
| Sometimes | 5 (9.8) | 12 (22.6) | |
| More than half of the times | 0 (0.0) | 4 (7.5) | |
| Almost always | 1 (2.0) | 11 (20.8) | |
| Hematuria, n (%) | | | |
| Never | 27 (52.9) | 31 (58.5) | 0.64 |
| Very rarely | 8 (15.7) | 8 (15.1) | |
| Rarely | 9 (17.6) | 6 (11.3) | |
| Sometimes | 5 (9.8) | 4 (7.5) | |
| More than half of the times | 1 (2.0) | 0 (0) | |
| Almost always | 1 (2.0) | 4 (7.5) | |
| Urinary incontinence, n (%) | | | |
| Never | 40 (78.4) | 45 (84.9) | 0.58 |
| Very rarely | 2 (3.9) | 0 (0) | |
| Rarely | 5 (9.8) | 3 (5.7) | |
| Sometimes | 2 (3.9) | 3 (5.7) | |
| More than half of the times | 2 (3.9) | 1 (1.9) | |
| Almost always | 0 (0) | 1 (1.9) | |
| Urinary frequency, n (%) | | | |
| Never | 10 (19.6) | 7 (13.2) | 0.04 |
| Very rarely | 2 (3.9) | 5 (9.4) | |
| Rarely | 7 (13.7) | 3 (5.7) | |
| Sometimes | 21 (41.2) | 12 (22.6) | |
| More than half of the times | 8 (15.7) | 19 (35.8) | |
| Almost always | 3 (5.9) | 7 (13.2) | |
| Urinary urgency, n (%) | | | |
| Never | 20 (39.2) | 15 (28.3) | 0.02 |
| Very rarely | 2 (3.9) | 5 (9.4) | |
| Rarely | 10 (19.6) | 9 (17.0) | |
| Sometimes | 11 (21.6) | 4 (7.5) | |
| More than half of the times | 6 (11.8) | 7 (13.2) | |
| Almost always | 2 (3.9) | 13 (24.5) | |
| Total LUTS Score, Mdn (IQR) | 6 (3–9) | 10 (5–13) | 0.01 |

IQR – interquartile range; LUTS – lower urinary tract symptoms; Mdn = Median

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