

# Office-Based Ureteral Stenting Using a Single-Use Flexible Cystoscope Under Local Anesthesia: A Two-Center Prospective Study on Feasibility and Patient Experience

Federico Zorzi, MD,<sup>1</sup> Fabio Traunero, MD,<sup>2</sup> Victoria Jahrreiss, MD,<sup>3,4</sup> Giulio Rossin, MD,<sup>1</sup> Andrea Piasentin, MD,<sup>1</sup> Tommaso Cai, MD,<sup>5</sup> Paolo Umari, MD,<sup>1</sup> Giovanni Liguori, PhD,<sup>1</sup> Bhaskar Somani, PhD,<sup>4</sup> Amelia Pietropaolo, MD,<sup>4,6,\*</sup> and Michele Rizzo, PhD<sup>1,\*</sup>

## Abstract

**Introduction:** To evaluate the feasibility, safety, and patient satisfaction of Double-J (DJ) ureteral stenting using a flexible cystoscope under local anesthesia (LA).

**Materials and Methods:** We analyzed prospectively collected data from all patients who underwent DJ stent insertion or replacement using flexible single-use cystoscope under LA between February 2022 and September 2024 at two tertiary referral centers. Failure was defined as the inability to effectively complete the scheduled stent insertion or replacement. Pain was assessed using the Visual Analog Scale, whereas overall patient satisfaction and willingness to undergo future ureteral stenting under LA were also recorded.

**Results:** A total of 189 consecutive procedures were performed, including 131 (69.3%) unilateral and 31 (16.5%) bilateral DJ replacements and 22 (11.6%) unilateral and 5 (2.6%) bilateral DJ insertions. The median patient age was 76 years (interquartile range [IQR] 66–80), the median Charlson Comorbidity Index was 8 (IQR 6–12), and the median hospital stay was 0 days (0–0.25). Technical failure occurred in 13 cases (7.3%). Causes of failure were DJ encrustation, urethral stricture, or inability to identify the ureteral orifice (9 cases, 69.2%). These cases were effectively managed by percutaneous nephrostomy (PNS) or stent placement under sedation. Four (30.8%) procedures were interrupted because of pain felt by patients. Complications included one case of stent migration necessitating ureteroscopy, three cases necessitating PNS placement, and 10 grade 2 complications (5.6%). Overall, 170 patients (89.9%) expressed willingness to undergo the same procedure under LA in the future.

**Conclusion:** These results demonstrate that DJ stenting using a flexible cystoscope under LA in an outpatient setting is a feasible, safe, and well-tolerated procedure. It offers a high success rate with a low incidence of minor complications.

**Keywords:** ureteral stenting, Double-J stent, flexible cystoscopy, disposable cystoscope, local anesthesia, office-based procedures

## Introduction

Since their introduction in the 1970s, Double-J (DJ) ureteral stents have become fundamental tools in urologic practice,

widely used for managing upper urinary tract obstructions, facilitating postoperative drainage after ureterorenoscopy, and providing relief in cases of acute and chronic upper urinary obstruction secondary to intrinsic or extrinsic ureteral

<sup>1</sup>Department of Urology, University of Trieste, Trieste, Italy.

<sup>2</sup>Department of Urology, University of Udine, Udine, Italy.

<sup>3</sup>Department of Urology, Comprehensive Cancer Center, Medical University of Vienna, Vienna, Austria.

<sup>4</sup>University Hospital Southampton NHS Trust, Southampton, UK.

<sup>5</sup>Department of Urology, University of Trento, Trento, Italy.

<sup>6</sup>EAU Young Academic Urologists (YAU) Urolithiasis and Endourology Working Group Arnhem, Arnhem, The Netherlands.

\*Contributed equally to this work as senior authors.



blockage.<sup>1,2</sup> If left untreated, obstructive uropathy can lead to severe complications, including urinary tract infections, urosepsis, and irreversible renal damage, necessitating urgent decompression. Drainage is needed to preserve renal function and prevent life-threatening conditions such as sepsis and septic shock.<sup>3,4</sup> In this context, ureteral stenting represents a less invasive alternative to percutaneous nephrostomy (PNS), offering a long-term option for urinary drainage in selected patients.<sup>5</sup>

Traditionally, placement and replacement of ureteral stents are performed in the operating room (OR) using rigid cystoscopy under fluoroscopic guidance. This approach often necessitates either general anesthesia (GA) or conscious sedation to ensure patient comfort and the correct delivery of the procedure.<sup>6</sup> Although GA remains the standard for many urologic interventions, its use is not without risks, particularly in elderly or comorbid patients who may experience perioperative complications such as cardiovascular or pulmonary events, postoperative cognitive dysfunction, and prolonged hospital stays.<sup>7</sup>

Most patients in our cohort were either not suitable for a more definitive solution for their ureteral obstruction or chose to have a ureteral stent for it. As such, routine ureteral stent exchange is essential to ensure adequate renal drainage and to maintain quality of life. Delays in definitive surgical management often because of backlogs on GA waiting lists can result in overdue stents, which are at increased risk of blockage or calcification. Stent encrustation is a well-recognized complication of prolonged indwelling stents and may necessitate complex, combined endourologic procedures for removal.<sup>8–10</sup> Encrustation is believed to be associated with bacterial colonization of the stent surface, with the likelihood of this complication increasing with longer indwelling times.<sup>11</sup> Furthermore, reliance on OR-based procedures places significant strain on health care resources, increasing hospital costs and limiting the availability of surgical suites for other high-priority interventions.<sup>12</sup>

In recent years, advances in endoscopic technology have facilitated the development of flexible cystoscopes, which have demonstrated superior patient tolerability compared with rigid cystoscopes for various diagnostic and therapeutic procedures, including ureteral stent removal.<sup>13</sup> More recently, the advent of single-use (disposable) flexible cystoscopes (disposable cystoscopes [DCs]) has introduced a promising alternative, potentially reducing the risk of cross-contamination, eliminating the need for costly reprocessing, and increasing procedural efficiency.<sup>14,15</sup> The devices are connected to portable wireless monitors, eliminating the need for bulky and heavy stack systems. This setup helps keep the cystoscopy suite available for other diagnostic procedures, thereby minimizing delays in the cancer diagnostic pathway and reducing potential costs associated with rescheduling or missed procedural slots.<sup>16,17</sup> Although these devices have been validated for diagnostic cystoscopy and stent removal, their application for ureteral stent placement remains underexplored.

This study aims to evaluate the efficacy and safety of ureteral stenting using DC in an elective setting at two high-volume endourologic referral centers. By assessing procedural success rates, patient tolerability, and health care resource utilization, this investigation seeks to determine whether this technique represents a viable cost-effective alternative to traditional OR-based ureteral stenting,

particularly in frail patient populations where anesthesia-related risks should be minimized.

## Materials and Methods

### *Setting of the procedures*

The procedures were carried out under local anesthesia (LA) either in the cystoscopy suite equipped with image intensification or in an interventional radiology suite. All procedures were performed in one of two hospital-based settings using a standardized technique agreed upon by both centers. This ensured consistency in patient selection, procedural execution, and outcome assessment. Informed consent was obtained from all patients using a uniform protocol. Anesthesiologic support was not utilized during these procedures. Vital signs were continuously monitored throughout each procedure. Patients independently positioned themselves on the operating table, with their legs placed in the lithotomy position. Locoregional antisepsis was performed using an iodopovidone solution, and a sterile field was prepared. LA consisted of instilling 1% lidocaine jelly into the distal urethra approximately 3 to 5 minutes before cystoscopy insertion.

The digital Ambu<sup>®</sup> aScope<sup>™</sup> 4 Cysto (Ambu A/S, Baltorbakken 13, Ballerup, Denmark) DC with its portable monitor (full HD portable aView 2<sup>™</sup> Advance, Ambu A/S) was utilized for all procedures. We used two types of guidewires during the procedures. The primary choice was the 0.035-inch Sensor<sup>™</sup> PTFE-Nitinol Guidewire (Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA, USA) for its features of sliding and maneuverability.<sup>18</sup> In more challenging cases, such as those involving ureteral tortuosity or significant narrowing, we also used the Terumo<sup>®</sup> Radifocus Guide Wire M Non-Vascular (Terumo Corporation, 2–44-1 Hatagaya, Shibuya-ku, Tokyo, Japan) with completely hydrophilic Mcoat<sup>™</sup>.

### *Ureteral stenting technique*

The DC was introduced in the patient's urethra and used to identify the ureteral orifices. A hydrophilic guidewire was then passed under direct vision into the ureteral orifice. Under fluoroscopic guidance, the guidewire was advanced as much as the pyelocaliceal area. The cystoscope was removed, and a ureteral catheter was advanced along the guidewire to perform retrograde pyelography. Subsequently, the DJ was inserted over a hydrophilic or hybrid guidewire using the dedicated release device attached to its distal end. Under fluoroscopic guidance, the stent was advanced into the renal pelvicaliceal system. The guidewire was then gradually withdrawn to allow observation of the proximal loop forming within the renal pelvis. To confirm appropriate distal positioning, the fluoroscopic collimator was adjusted to view the pubic symphysis. Once the distal tip of the stent reached this anatomical landmark, the guidewire was fully withdrawn, allowing the distal loop to form within the bladder, which was also checked cystoscopically, thus completing stent deployment.

In cases of ureteral substenosis causing resistance to stent advancement, a 4F ureteral catheter with a straight open tip was advanced over the guidewire and under fluoroscopic guidance through the working channel of the cystoscope until it reached the narrowed segment. It was then used to help negotiate the stenosis with the guidewire.

In case of DJ substitution, the existing stent was exteriorized from the urethral meatus using a grasper, and the guidewire was inserted coaxially into the stent lumen. A new stent was then placed after the previously described technique. The same procedure was repeated contralaterally if bilateral stenting was indicated. At the end of the procedure, the bladder was emptied through the working channel of the cystoscope or the patient is encouraged to void spontaneously.

### Study design

Data were prospectively collected from all patients who underwent retrograde ureteral stent placement or exchange using a flexible cystoscope under LA at two tertiary referral centers in Italy and the United Kingdom between February 25, 2022, and September 30, 2024. For patients undergoing multiple procedures, each intervention was recorded as an independent event. Four types of procedures were included as follows: bilateral stent placement, unilateral stent placement, unilateral stent exchange, and bilateral stent exchange.

If a preprocedural urine culture (UC) was positive, patients received targeted antibiotics based on culture sensitivity, and a follow-up test was performed to confirm UC negativization before the intervention. In cases of negative or nondiagnostic UC without urinary symptoms, standard antimicrobial prophylaxis was administered. Conversely, patients with a nondiagnostic analysis and suspected urinary tract infection repeated the UC before the procedure to rule out possible infections. Antimicrobial prophylaxis consisted of a single dose of a third-generation cephalosporin or intramuscular gentamicin, administered on the day of the procedure according to patient body weight.

Informed consent was obtained from all patients, who agreed to undergo the procedure without GA or locoregional sedation. All patients received preprocedural counseling about the potential risk of technical failure and the possibility of requiring a repeat procedure. In the event of failure, the procedure would be interrupted and rescheduled under GA in an OR setting.

Institutional approval for data analysis was granted by the Ethics Committee of the University of Trieste (Protocol No. 60565, approved on 09/04/2024), and the project was registered as a clinical audit at University Hospital Southampton (Audit Number: QI/0093).

### Study outcomes

The primary outcome was the effective completion of the procedure using the single-use flexible cystoscope. Technical failure was defined as the inability to complete the ureteral stent placement or replacement using the proposed technique.

Secondary outcomes included patient-reported discomfort during the procedure, the need for anesthesiologist intervention, intensive care unit (ICU) admission, and postoperative complications. Additional data collected comprised procedure duration, fluoroscopy time and radiation dose, use of retrograde pyelography, intraoperative complications, length of hospital stay, and 30-day readmission rates.

Postoperative complications were classified according to the Clavien–Dindo (CD) system,<sup>19</sup> and they were defined as adverse events arising as a consequence of the procedure that necessitated further treatment. Procedures were

considered unsuccessful if they could not be completed for the intended indication and necessitated additional interventions to manage the issue encountered.

Renal function was assessed by calculating the estimated glomerular filtration rate (eGFR) before and after the procedure using the Chronic Kidney Disease Epidemiology Collaboration formula. Pain experienced during the procedure was assessed using the Visual Analog Scale (VAS) score. After the procedure, patients were asked to rate their overall satisfaction on a 5-point scale, with 1 representing the worst health care-related experience. Patients were also invited to express whether they would be willing to undergo the same procedure under similar conditions in the future, based on their level of satisfaction.

### Statistical analyses

Categorical variables were reported as absolute numbers and percentages and described using frequencies and proportions. Continuous variables were expressed as medians with interquartile ranges (IQRs). Outcomes were compared between effective and unsuccessful procedures. Depending on the distribution, continuous variables were analyzed using either the Student's *t* test or the Mann–Whitney *U* test. Categorical variables were compared using the Chi-square test. A *p*-value <0.05 was considered statistically significant, indicating a meaningful difference between the two groups for the variables assessed. Statistical analyses were performed using SPSS version 23 (SPSS Inc., Chicago, IL, USA).

### Results

During the study period, a total of 189 procedures involving bilateral and unilateral ureteral stent insertion and replacement were prospectively collected, recorded, and analyzed. Comprehensive clinical data were available for all the candidate patients. The underlying causes of upper urinary tract obstruction in the study population differed. The most common pathology analysis was extrinsic ureteral compression because of cancer metastases, observed in 66 patients (34.9%). Pyeloureteral junction obstruction and untreated ureteral lithiasis were responsible for obstruction in 41 (21.7%) and 18 (9.5%) patients, respectively. Iatrogenic ureteral strictures were identified in 26 cases (13.8%), whereas retroperitoneal fibrosis was present in 22 patients (11.6%). An additional 10 patients (5.3%) had other causes of obstruction, including rare or mixed etiologies (Table 1).

Overall, 162 procedures (85.7%) were DJ stent replacements, whereas 27 (14.3%) were primary stent insertions. A total of 176 procedures (93.1%) were effectively completed, with technical failure occurring in 13 cases (6.9%). The median age of patients was 76 years (IQR 64–80), and the median Charlson Comorbidity Index (CCI) was 8 (IQR 6–12). Preprocedural UC was positive in 74 cases (47.4%), necessitating preoperative antibiotic treatment. Cultures were negative in 90 cases, whereas 25 were nondiagnostic. The median change in eGFR was 0.5 mL/min. No significant difference was noted between unilateral and bilateral procedures impacting the success or failure of the procedures (*p* = 0.26) (Tables 2, 3 and 4). Reported degree of VAS score felt during the procedure was minimal, with a median of 2 (IQR 1–3) and no significant differences between the analyzed

TABLE 1. CAUSES OF UPPER URINARY TRACT OBSTRUCTION

|  | Total 189<br>(100%) |
|--|---------------------|
| Ureteral ab extrinsic compression by tumor of known origin   | 66 (34.9%)          |
| Anal carcinoma   | 8 (4.2%)            |
| Ovarian cancer   | 14 (7.4%)           |
| Colorectal cancer  | 7 (3.7%)            |
| Prostate cancer  | 23 (12.2%)          |
| Uterine cancer   | 11 (5.8%)           |
| Breast cancer  | 2 (1.1%)            |
| Renal cell carcinoma   | 1 (0.5%)            |
| Ureteral ab extrinsic compression by tumor of unknown origin | 1 (0.5%)            |
| Urolithiasis   | 18 (9.5%)           |
| PUJ syndrome   | 41 (21.7%)          |
| Iatrogenic ureteral stenosis                                 | 26 (13.8%)          |
| Retroperitoneal fibrosis                                     | 22 (11.6%)          |
| Pelvic fibrosis after RT                                     | 10 (5.3%)           |
| Uterine prolapse   | 3 (1.6%)            |
| Chronic granulomatous prostatitis                            | 1 (0.5%)            |
| Dysplastic kidney  | 1 (0.5%)            |

PUJ syndrome = pyeloureteral junction syndrome; RT = radiation therapy.

groups of effective vs failed procedures ( $p = 0.09$ ). Likewise, overall satisfaction with the procedure was consistently high (median score 5, IQR 5–5), and 170 patients out of 189 (89.9%) reported the willingness to undergo the same procedure in LA. Median duration of the procedure was 22 minutes (15, 30), while almost all the patients were discharged on the same day of the procedure (median 0, IQR 0–1).

### Complications

Complications (Table 5) included 1 case of stent migration necessitating ureteroscopy for repositioning (CD grade IIIb), 3 cases necessitating PNS placement (CD grade IIIa), and 10 CD grade II complications (5.6%). Of them, six patients developed transient fever after the procedure that resolved with oral antibiotics (CD II) and 4 patients developed urosepsis, which was managed on the ward with intravenous broad-spectrum antibiotics (CD II). In three cases, postprocedural placement of a PNS was required because of either persistent or newly developed hydronephrosis accompanied by colicky pain, unresponsive to DJ stent drainage. In these cases, the ureteral stents were subsequently removed via flexible cystoscopy. Overall, 89.9% ( $n = 170$ ) of patients expressed willingness to undergo the same procedure under LA in the future.

### Unsuccessful procedures

Among the 13 unsuccessful procedures (6.9%) (Supplementary Table S1), six cases involved calcification of the distal loop of the DJ stent, which were subsequently managed effectively in the OR under GA after laser lithotripsy of the calcifications. In two cases, stent insertion failed because of the inability to identify or cannulate the ureteral meatus; both patients were subsequently referred for PNS. In one case, the DC could not traverse a urethral stricture, whereas in another case involving bilateral

stent substitution, the procedure was suspended because of severe pain reported by the patient. In the remaining three cases, the procedures were interrupted because of patient-reported high-grade pain, and the patients were referred to the OR for the procedure to be completed under sedation.

### Discussion

The study analyzes the procedural success and satisfaction outcomes of a large cohort of highly comorbid patients undergoing endoscopic ureteral DJ insertion or replacement under LA. To the best of our knowledge, with a total study population of 189 patients, this represents one of the largest reported series of ureteral stenting procedures performed using a DC in an outpatient setting.

The transition to an office-based approach was grounded in shared decision-making rather than logistical necessity. All patients were thoroughly counseled on the available options, including the potential for performing the procedure under GA in an OR setting. The in-office procedure was not positioned as a substitute driven by resource constraints, but rather as an alternative supported by clinical evidence and tailored to patient preferences. Most patients expressed a strong preference for avoiding anesthesia and hospital admission, particularly when informed of the high success rates, low discomfort levels, and rapid recovery associated with the outpatient technique. The process of shared decision-making played a key role in optimizing patient satisfaction and aligning procedural choices with individual health status and values.

Patients requiring periodic ureteral stent replacement because of chronic upper urinary tract obstruction typically undergo multiple stent changes over their lifetime, often at least every 6 months. Our findings highlight that, in a group of highly comorbid patients, the use of LA effectively mitigates risks associated with GA or sedation and shortens hospital stays reducing the likelihood of hospital-acquired infections. Notably, half of the study population was over 77 years old and had a CCI greater than 10. Given that frailty and advanced age significantly elevate anesthetic risks, many of these patients would otherwise require postoperative in-hospital stay or intensive care support after GA.<sup>20</sup>

By minimizing the need for anesthetic interventions, OR occupancy, and hospital admissions, substantial economic savings can be achieved, potentially offsetting the costs of disposable instruments.<sup>21</sup> Patients with chronic upper urinary tract obstruction require either a PNS or a DJ ureteral stent to preserve renal function. Although indwelling ureteral stents can cause bothersome lower urinary tract symptoms,<sup>22</sup> internal drainage is generally preferred by most patients. Although no major clinical differences have been consistently demonstrated between PNS tubes and ureteral stents, the latter eliminates the need for an external drainage bag, thereby reducing the risk of urinary tract infections and accidental dislodgment associated with improper handling of external devices.<sup>23</sup>

All procedures were conducted using a DC, which offers high technical performance in terms of tip deflection and imaging resolution.<sup>15,24</sup> This advantage translates into shorter diagnostic times and increased procedural efficiency. Single-use instruments might appear to have a reduced environmental impact compared with reusable alternatives; however, further high-quality, comparative life-cycle analyses

TABLE 2. DEMOGRAPHIC FEATURES AND PROCEDURE CHARACTERISTICS

|   | Total N = 189<br>(100%) | Success N = 176<br>(93.1%) | Failure N = 13<br>(6.9%) | p-Value |
|---|-------------------------|----------------------------|--------------------------|---------|
| Age at the procedure, median (IQR)                                | 76 (66, 80)             | 76 (66, 80)                | 80 (70, 82)              | 0.61    |
| Male, number (%)  | 68 (36%)                | 61 (34.7%)                 | 7 (53.8%)                | 0.16    |
| Female, number (%)  | 121 (64%)               | 115 (65.3%)                | 6 (46.2%)                |         |
| Charlson Comorbidity index, median (IQR)                          | 8 (6, 12)               | 8 (7, 12.2)                | 8 (6, 12)                | 0.96    |
| Preprocedure eGFR (mL/min), median (IQR)                          | 73.8 (56.9, 89)         | 73.9 (58.2, 89.8)          | 66.9 (56.2, 82.6)        | 0.67    |
| Postprocedure eGFR (mL/min), median (IQR)                         | 74.3 (56.4, 93.1)       | 75.6 (56.4, 93.6)          | 63.1 (58.6, 76.2)        | 0.7     |
| Delta eGFR (mL/min), median (IQR)                                 | 0.5 (-1.9, 3.3)         | 0.5 (-1.9, 3.3)            | 1.9 (-2.7, 7.3)          | 0.33    |
| Preprocedural urine culture                                       |                         |                            |                          | 0.96    |
| Positive preprocedural urine culture, n (%)                       | 74 (39.2%)              | 68 (38.6%)                 | 6 (46.2%)                |         |
| Negative preprocedural urine culture, n (%)                       | 90 (47.6%)              | 85 (48.3%)                 | 5 (38.5%)                |         |
| Nondiagnostic urine culture, n (%)                                | 25 (13.2%)              | 23 (13.1%)                 | 2 (15.3%)                |         |
| Type of procedure   |                         |                            |                          | 0.26    |
| Unilateral stent change, n (%)                                    | 131 (69.3%)             | 124 (70.4%)                | 7 (53.8%)                |         |
| Bilateral stent change, n (%)                                     | 31 (16.5%)              | 27 (15.4%)                 | 4 (30.8%)                |         |
| Unilateral stent insertion, n (%)                                 | 22 (11.6%)              | 21 (11.9%)                 | 1 (7.7%)                 |         |
| Bilateral stent insertion, n (%)                                  | 5 (2.6%)                | 4 (2.3%)                   | 1 (7.7%)                 |         |
| Retrograde pyelography performed, n (%)                           | 134 (71.2%)             | 131 (74.4%)                | 3 (23.1%)                | <0.01   |
| Postoperative complication (Clavien–Dindo classification)         |                         |                            |                          | 0.92    |
| Grade 0 and I, n (%)  | 175 (92.6%)             | 162 (92%)                  | 13 (100%)                |         |
| Grade II, n (%)   | 10 (5.3%)               | 10 (5.7%)                  | 0 (0%)                   |         |
| Grade IIIa, n (%)   | 3 (1.6%)                | 3 (1.7%)                   | 0 (0%)                   |         |
| Grade IIIb, n (%)   | 1 (0.5%)                | 1 (0.6%)                   | 0 (0%)                   |         |
| Pain assessment VAS, median (IQR)                                 | 2 (1, 3)                | 2 (1, 3)                   | 3 (2, 5)                 | 0.09    |
| Patients' VAS score ≤3, n (%)                                     | 145 (76.7%)             | 136 (77.3%)                | 9 (69.2%)                |         |
| Patients' VAS score >3, n (%)                                     | 44 (23.3%)              | 40 (22.7%)                 | 4 (30.8%)                |         |
| Overall satisfaction with the procedure (scale 1–5), median (IQR) | 5 (4, 5)                | 5 (4, 5)                   | 3 (3, 4)                 | <0.01   |
| Preference: Would do it all over again, n (%)                     |                         |                            |                          | <0.01   |
| Yes   | 170 (89.9%)             | 166 (94.3%)                | 4 (30.8%)                |         |
| Uncertain   | 16 (8.5%)               | 8 (4.5%)                   | 8 (61.5%)                |         |
| No  | 3 (1.6%)                | 2 (1.1%)                   | 1 (7.7%)                 |         |
| Duration of the procedure (minutes), median (IQR)                 | 22 (15, 30)             | 20 (15, 30)                | 40 (25, 60)              | <0.01   |
| Length of Hospital stay (days), median (IQR)                      | 0 (0, 1)                | 0 (0, 1)                   | 1 (0, 3)                 | 0.09    |
| Time of fluoroscopy (minutes:seconds), median (IQR)               | 1:04 (0:28; 4:09)       | 1:04 (0:27; 2:01)          | 2:59 (0:42; 4:5)         | 0.86    |
| Total energy delivered (μGy·m <sup>2</sup> ), median (IQR)        | 39.01 (19.8; 81.38)     | 32.49 (16.15, 71.62)       | 100.6 (65.63, 332.64)    | <0.01   |

eGFR = estimated glomerular filtration rate; IQR = interquartile range; VAS = Visual Analog Scale.

are needed to draw definitive conclusions.<sup>25</sup> DCs are routinely used in procedures such as stent removal, demonstrating favorable outcomes in terms of patient safety and cost-effectiveness. Their portability further enhances their utility, allowing procedures to be performed at the bedside, in ORs,

or in interventional radiology suites, thereby optimizing hospital resource allocation.<sup>17</sup>

Several studies support the feasibility of in-office DJ procedures. In 2015, Nourparvar and coworkers performed 42 bedside stent placements in the emergency department under

TABLE 3. FLUOROSCOPY TIME, RADIATION EXPOSURE, AND PROCEDURAL DURATION FOR UNILATERAL AND BILATERAL URETERAL STENT POSITIONING PROCEDURES, STRATIFIED BY PROCEDURAL SUCCESS OR FAILURE

|  | Unilateral stent positioning<br>(successes, n = 21) | Unilateral stent positioning<br>(failures, n = 1) | Bilateral stent positioning<br>(successes, n = 4) | Bilateral stent positioning<br>(failures, n = 1) |
|--|---|---|---|--|
| Time of fluoroscopy (minutes:seconds), median (IQR)        | 2:05 (1:21, 3:17)                                   | 2:50  | 1:47 (1:03, 4:32)                                 | 1:58   |
| Total energy delivered (μGy·m <sup>2</sup> ), median (IQR) | 43.25 (27.89; 58.62)                                | 54.63   | 46.4 (25.5, 79.45)                                | 76.13  |
| Duration of the procedure (minutes:seconds), median (IQR)  | 25:00 (20:00, 33:00)                                | 40:00   | 25:00 (23:45, 34:45)                              | 70:00  |

TABLE 4. COMPARISON OF RADIATION-RELATED FEATURES AND PATIENT-REPORTED OUTCOMES FOR UNILATERAL AND BILATERAL URETERAL STENT POSITIONING, STRATIFIED BY PATIENT SEX

|   | <i>Unilateral stent positioning (males, n = 8)</i> | <i>Unilateral stent positioning (females, n = 14)</i> | <i>Bilateral stent positioning (males, n = 1)</i> | <i>Bilateral stent positioning (females, n = 4)</i> |
|---|--|---|---|---|
| Total energy delivered ( $\mu\text{Gy}\cdot\text{m}^2$ ), <i>median (IQR)</i> | 47.25 (40.29, 56.7)                                | 85.45 (60.21, 98.2)                                   | 121.5   | 46.4 (25.5, 68.08)                                  |
| Time of fluoroscopy (minutes: seconds), <i>median (IQR)</i>                   | 01:41 (01:10, 02:36)                               | 2:50 (2:00, 03:18)                                    | 3:50  | 01:47 (01:03, 01:53)                                |
| Duration of the procedure (minutes: seconds), <i>median (IQR)</i>             | 22:30 (12:45, 31:15)                               | 27:30 (25:00, 38:15)                                  | 44:00   | 25:00 (23:45, 28:45)                                |
| VAS score, <i>median (IQR)</i>  | 3.5 (2, 6)   | 2 (1, 2.75)   | 2   | 1.5 (1, 2)  |
| Preference Would do it all over again, <i>n (%)</i>                           | 4.75 (4, 5)  | 5 (4, 5)  | 5   | 5 (4, 5)  |

LA without fluoroscopic guidance, reaching a 71% success rate. Although this study lacked procedural radiologic support and did not include patient selection criteria, it highlights the practicality of this approach.<sup>26</sup> Some of the earliest reports on bedside ureteral stenting focused primarily on critically ill patients. As early as 1986, Clayman and colleagues effectively performed bedside ureteral stenting in five ICU patients using a 15F flexible fiber-optic choledochoscope, demonstrating the feasibility of the technique in a high-risk setting.<sup>27</sup> Adeyoju and associates in 2001 performed similar work on 20 patients in an outpatient setup, with excellent success rates.<sup>28</sup> The largest case series on this subject, published by McFarlane and coworkers in 2001, involved 723 procedures in 472 patients, with a technical success rate of 89%. Among the patients surveyed, 94% (282 of 300) reported the procedure to be tolerable.<sup>29</sup>

Some more recent studies on the subject have been published by Sivalingam and associates in 2013 and Carrion and colleagues in 2017, and both studies have confirmed that ureteral stent placement can be safely and effectively performed under LA in the office.<sup>30,31</sup> Similar conclusions were drawn in a study published by Sinha and coworkers in 2018, in which a total of 316 procedures were performed with an overall success rate of 85.4%.<sup>32</sup>

The shift from a traditional surgical procedure to an office-based intervention under LA represents a significant advancement, benefiting both patients and the health care system. Our findings using the DC align with existing

literature, demonstrating the clear advantages of this approach, including rapid symptom relief, avoidance of GA, reduced hospitalization, and substantial cost savings. The evolution of endourologic technology has facilitated reduction in procedural invasiveness, creating a mutually beneficial scenario for both patients and health care providers.

Although this technique is generally considered feasible, particularly in female patients, elective DJ stenting is still routinely performed in most centers in the OR under GA or sedation. Our findings highlight the potential to shift these procedures from the OR to a dedicated interventional suite equipped with fluoroscopic imaging. To optimize safety and procedural success, we recommend scheduling stent exchanges every 4 to 6 months to reduce the risk of encrustation and biofilm formation, which were common causes of technical failure in our cohort. Based on our experience, office-based stent placement using a DC is best suited for elective cases in which patients have minimal stent encrustation, no significant anatomic distortion, and are able to tolerate positioning and LA. Careful preprocedural evaluation, including imaging and review of prior stent characteristics, can help identify patients most likely to benefit from this approach.

For more complex cases, such as those involving stent encrustation, bladder anatomical abnormalities, mucosal changes because of tumors, or prior pelvic radiotherapy, rigid cystoscopy with anesthetic support in the OR still remains the preferred and safer option. As this was the first

TABLE 5. DESCRIPTION OF COMPLICATIONS GRADED  $\geq 2$  ACCORDING TO THE CLAVIEN–DINDO CLASSIFICATION ( $N = 14$ )

| <i>CD classification</i> | <i>Number of patients</i> | <i>Cause</i>   | <i>Management</i>   |
|--------------------------|---------------------------|--|---|
| Grade II                 | 6                         | Transient postprocedural fever; patients underwent laboratory tests and urine culture                | Oral antibiotic administration and conservative management (antipyretics)   |
| Grade II                 | 4                         | Postprocedural fever and development of urosepsis  | Broad-spectrum antibiotic therapy   |
| Grade IIIa               | 3                         | Recurrent flank pain and persistent hydronephrosis despite correct positioning of the Double-J stent | Percutaneous nephrostomy insertion  |
| Grade IIIb               | 1                         | Migration of the distal loop of the Double-J stent into the ureter                                   | Retrieval of the distal end using forceps during semirigid ureterorenoscopy |

CD = Clavien–Dindo.

prospective series evaluating the use of DC for ureteral stent placement under LA, no predefined fluoroscopy or procedural time thresholds for early termination were established. The longer procedural durations observed in unsuccessful cases likely reflect a combination of procedural complexity, anatomical challenges, and operator unfamiliarity during the early adoption phase of the technique. We acknowledge the potential value of implementing time-based discontinuation criteria, such as a fluoroscopy time exceeding 5 minutes or a total procedure duration beyond 30 to 40 minutes, as objective safety and efficiency benchmarks. Development and validation of such thresholds will be a focus of future protocol refinement, with the aim of minimizing patient discomfort, radiation exposure, and procedural inefficiency in office-based settings.

The main limitation of this study is its observational design, although data were collected prospectively. Furthermore, individuals who declined the procedure were not included in the analysis, potentially introducing a selection bias. Nevertheless, patient satisfaction was consistently high, supporting the safety and patients' tolerance of the proposed procedure.

Interestingly, ambient interventions such as the use of calming music and mood lighting during the procedure have been shown to enhance patient relaxation, increase pain tolerance, and reduce overall discomfort and procedure-related anxiety.<sup>33,34</sup> Although a recent systematic review shows that the overall effect on environment from single-use scopes is positive, further life cycle and cost-effectiveness analyses are needed to draw definitive conclusions about sustainability and long-term value.<sup>35</sup> Future studies also need to have dedicated cost-effectiveness comparison and quality of life between single-use and reusable flexible cystoscopes. These additional outcomes will be critical to establishing the broader value proposition of single-use devices in outpatient endourology.

## Conclusions

The results of our study support the safety and feasibility of ureteral stenting using a DC in an office-based setting, particularly for patients with significant comorbidities. This approach reduces procedural risks and enhances resource efficiency, offering a valuable alternative to both traditional OR-based interventions and the use of reusable cystoscopes. A more in-depth evaluation of patient experience and resource savings, conducted through standardized prospective protocols, will be essential to improve the reproducibility and scalability of this technique.

## Authors' Contributions

All authors contributed to the study. Conceptualization: M.R., B.S., and A. Pietropaolo. Methodology: A. Piasentin, V.J., and G.R. Formal analysis and investigation: F.Z., T.C., and P.U. Writing—original draft preparation: F.T., F.Z., V.J., and G.R. Writing—review and editing: F.Z., B.S., A. Pietropaolo, and P.U. Funding acquisition: M.R., G.L., A. Piasentin, and T.C. Supervision: A. Pietropaolo, A. Piasentin, and G.L.

## Declaration

F.Z. has full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

## Author Disclosure Statement

The authors declare no conflicts of interest.

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## Supplementary Material

Supplementary Table S1

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Address correspondence to:  
*Federico Zorzi, MD*  
*Department of Urology*  
*University of Trieste*  
*34126 Trieste*  
*Italy*

*E-mail: federicozorzi94@gmail.com*

#### Abbreviations Used

CCI = Charlson Comorbidity Index  
 CD = Clavien–Dindo  
 DC = disposable cystoscope

**Abbreviations Used (Cont.)**

DJ = Double-J  
eGFR = estimated glomerular filtration rate  
GA = general anesthesia  
ICU = intensive care unit  
IQR = interquartile range  
LA = local anesthesia

OR = operating room  
PNS = percutaneous nephrostomy  
PUJ = pyeloureteral junction  
RT = radiation therapy  
SPSS = Statistical Package for the Social Sciences  
UC = urine culture  
VAS = Visual Analog Scale