A Comparison of Clinical Outcomes of Operating Room Versus Office-based Ureteral Stenting With the Novel Use of Nitrous Oxide Sedation


OBJECTIVES
To examine the safety and effectiveness of placing ureteral stents in an office-based setting vs in the operating room (OR).

METHODS
A retrospective chart review was performed to examine outcomes, specifically complication rate, unanticipated hospitalizations, and stent failures, when patients received JJ stents in the clinic procedure suite, using local analgesia and/or nitrous oxide gas analgesia, compared to patients who had ureteral stents placed in the OR, typically with general anesthesia. Additionally, multivariable analysis was performed to determine predictors of complications.

RESULTS
Around 565 procedures were performed in the clinic and 179 were performed in the OR. The complication rate for the clinic group was 4.1%, compared to 7.8% in the OR group. Unplanned admissions to the hospital occurred after 3.0% of clinic procedures and 9.5% of OR procedures. Stent placements failed in 1.1% of clinic procedures and 0.56% of OR procedures. Clinic procedure time was 10 minutes vs 12 minutes in the OR ($P < 0.01$). Clinic vs OR setting was not predictive of complications ($P = 0.99$). We did not identify factors that impacted complication rate in ureteral stent placement in the clinic vs OR setting. Notably, the procedure time for a clinic stent placement was significantly shorter than the OR stent placement.

CONCLUSIONS
This study demonstrates excellent outcomes with a novel approach to a standard procedure, with shorter procedure time and no difference in complication rates. UROLOGY 132: 37–42, 2019. © 2019 Elsevier Inc.

Urinary obstruction is a problem commonly managed by urologists. A variety of etiologies can result in urinary obstruction, including urinary tract stones, strictures, retroperitoneal fibrosis, external compression, and cancers. In managing urinary obstruction, urgent decompression of the urinary tract is important to prevent serious life-threatening complications. Urolithiasis must be managed urgently in a variety of situations, including urinary obstruction, infections of urinary tract, impending renal deterioration, intractable pain or vomiting, solitary kidney, and anuria. Methods to relieve obstruction include using percutaneous nephrostomy or insertion of a Double-J ureteral stent.

Placing a ureteral stent is a relatively short procedure. However, because of the invasive nature of stent placement, it is generally performed in the operating room (OR). If the OR is unavailable, delays can result in prolonged patient discomfort, progression to urosepsis, and compromised renal function. Additionally, there are overhead costs that are associated with performing a procedure in the OR. OR costs are estimated to be roughly $20 per minute for basic surgical procedures and fixed overhead costs represent roughly half of this figure. These costs depend not only on the supplies and medical staff, but also anesthesia costs, hospital overhead, and administrative costs. Thus, limiting OR use is a potential cost-saving measure. Furthermore, diminishing OR use frees up the OR for more urgent cases. Therefore, given the extra cost to the hospital and the patient to perform stent placements in the OR, as well as the need for stent procedures
be completed quickly, it is logical to look for alternative venues to complete these procedures.

When stents are performed in the OR, general anesthesia (GA) can be used for pain control, although monitored sedation with benzodiazepine sedatives, such as midazolam, can also be used in this setting. Risks of GA include tracheal intubation complications, cardiovascular and cerebrovascular complications, and adverse reactions such as malignant hyperthermia. Others have attempted to avoid GA during stent placement, however none with large sample size or utilizing precisely the approach that we outline here. Even so, other studies have demonstrated that it is possible, and likely cost-effective, to avoid GA for stent placement, paving the way for the present study.

This study compares patients who had ureteral stents placed in a clinic procedure suite with nitrous oxide (N₂O) and/or local analgesia (LA) for analgesia versus patients whose stents were placed in an OR, typically with GA. We aim to compare the safety and efficacy of performing ureteral stent placement in a clinic/outpatient setting compared to the OR setting.

**METHODS**

**Patients**

After Institutional Review Board (IRB) approval, a retrospective chart review was performed of patients requiring urgent management with a Double-J ureteral stent, either in the clinic or in the OR setting at a single institution from February 2014 to March 2018. Determination of whether to place the stent in the clinic or the OR was determined by several factors, including the time of the patient’s presentation, the urgency of the need for stent placement, nil per os status, physician’s preference, and OR availability. Inclusion criteria included urgent stent placement in either the procedure suite or the OR for any indication, age over 18 years, ability to provide consent, and, in the clinic stent group, those expressing a willingness to have their stent placed in the clinic. Exclusion criteria were patients who did not require a stent, patients under 18 years of age, mentally incapacitated patients, patients with signs of sepsis preoperatively, and patients with unstable vital signs. Patients had stents placed for a variety of reasons, including stones. Among these patients, need for stent placement was determined based upon guideline criteria. These indications include obstruction compromising kidney function, infected urine, and uncontrollable pain. Other indications are shown in Table 1.

**Clinic Procedure Suite Description**

The urology clinic is in a building attached to the hospital. An image of a procedure suites is shown in Figure 1. Equipment in the room includes a setup for administering N₂O and dedicated fluoroscopy. The clinic is open roughly 8 AM to roughly 5 PM on nonholiday weekdays, during which time stent placements are preferentially performed in the clinic suite if possible.

**Clinic Stent Procedure**

Patients were brought to directly to the clinic suite after presenting to the hospital or clinic with signs and symptoms of obstructive uropathy. Patients were monitored with a pulse oximeter and intermittent blood pressure determination with a blood pressure cuff. The patient was prepped and draped. For LA, patients received lidocaine jelly applied to the urethra. Patients received

### Table 1. Patient descriptions

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Clinic Stent Group</th>
<th>Operating Room Stent Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>463</td>
<td>161</td>
</tr>
<tr>
<td>Age (y), Median (Range)</td>
<td>565 57 (18-95)</td>
<td>179 57 (18-93)</td>
</tr>
<tr>
<td>Sex (% Male)</td>
<td>565 41</td>
<td>179 48</td>
</tr>
<tr>
<td>Charlson score (median [range])</td>
<td>565 3 (0-14)</td>
<td>179 3 (0-12)</td>
</tr>
<tr>
<td>Primary or exchange (% primary)</td>
<td>565 76</td>
<td>178 79.2</td>
</tr>
<tr>
<td>Renal units addressed (% single)</td>
<td>565 90.4</td>
<td>176 75.6</td>
</tr>
<tr>
<td>Indications (% of total procedures)</td>
<td>565</td>
<td>179</td>
</tr>
<tr>
<td>Stone</td>
<td>67.2</td>
<td>72.1</td>
</tr>
<tr>
<td>Malignancy</td>
<td>14.9</td>
<td>10.1</td>
</tr>
<tr>
<td>Stricture</td>
<td>6.5</td>
<td>6.1</td>
</tr>
<tr>
<td>UPJO</td>
<td>4.4</td>
<td>1.1</td>
</tr>
<tr>
<td>Retroperitoneal fibrosis</td>
<td>2.5</td>
<td>0.56</td>
</tr>
<tr>
<td>Other</td>
<td>5.3</td>
<td>10.6</td>
</tr>
<tr>
<td>Mean size of largest stone (mm, median [range])</td>
<td>380 7 (2-30)</td>
<td>77 6 (2-130)</td>
</tr>
<tr>
<td>Stone location (% of procedures for stones)</td>
<td>380</td>
<td>110 1</td>
</tr>
<tr>
<td>Kidney</td>
<td>12.9</td>
<td>6.4</td>
</tr>
<tr>
<td>Proximal ureter</td>
<td>54.7</td>
<td>50.9</td>
</tr>
<tr>
<td>Distal ureter</td>
<td>37.6</td>
<td>34.5</td>
</tr>
<tr>
<td>Hydronephrosis (% of total procedures)</td>
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<td>160</td>
</tr>
<tr>
<td>Any hydronephrosis</td>
<td>66.6</td>
<td>93.2</td>
</tr>
<tr>
<td>Bilateral</td>
<td>6.8</td>
<td>20.6</td>
</tr>
</tbody>
</table>

* p<0.05.
LA, with or without N₂O based upon physician preference. A 16 Fr flexible cystoscope was used in males and a 22 Fr rigid cystoscope was used in females. The cystoscope was introduced into the bladder and the affected ureteral orifice was identified. Fluoroscopic guidance was used to deploy a Glidewire into the ureter. A retrograde pyelogram was done, and a Double-J stent was passed over the Glidewire. Next, the Glidewire was removed, and fluoroscopy was again used to demonstrate good curl in the kidney and ureter. In pregnant patients, the minimum necessary fluoroscopy was used, with lead apron is placed above the abdomen. Following the procedure, the patient recovered from N₂O on the clinic procedure suite table, which typically took less than 1 minute.

Procedure for the Use of N₂O
N₂O is administered in a 50/50 mixture with oxygen via a face mask. The mask is held in place by the patient themselves with a nurse monitoring the patient throughout the procedure. The patient is evaluated with a continuous pulse oximeter and intermittent blood pressure monitoring. No special credentialing is required for physicians to administer N₂O at our institution.

Operating Room Stent Procedure
Patients were brought to the OR and anesthesia was administered by anesthesia staff. Patients were then prepped and draped in standard fashion. In patients receiving N₂O, the anesthesia staff administered N₂O via a mask, like the setup in the clinic. The cystoscopy and stent placement were then performed similarly as in the clinic. After the procedure, patients recovered in the postanesthesia care unit with some patients transferred directly to the intensive care unit due to signs of sepsis postoperatively. Length of recovery depended on the type of anesthesia received.

Data Analysis
The study design was a retrospective chart review concerning patients undergoing procedures meeting the inclusion criteria. Clinic and OR stent groups were compared using Fisher’s Exact test and the Mann-Whitney U test, where appropriate. Additionally, a multivariable analysis was performed to identify contributors to complication rates. Variables analyzed included: patient age, gender, Charlson score, whether the stent was placed in the clinic or the OR, new stent vs exchange, number of renal units were addressed, presence of urolithiasis, stone size, procedure time, whether nitrous oxide was used, whether the stone was in the kidney or the ureter, and presence of hydronephrosis.

RESULTS
Patient Demographics
Results were analyzed from 565 stent procedures placed in 463 patients in the clinic and these were compared to 179 stents placed in 161 patients in the OR. Demographic data for both groups are shown in Table 1. Of note, procedures performed in the OR were more likely to involve 2 renal units with 90.4% of clinic procedures and only 75.6% of OR stent procedures addressing 1 renal unit (P = .0001). Additionally, patients in the OR group were more likely to have an obstructing stone in their kidney or have bilateral hydronephrosis. Other demographics, such as age, patient sex, whether the procedure was a primary stent or a stent exchange, indications for the procedure, and stone size were similar between groups. Of the 509 procedures performed for stone management, 380 were performed in the clinic and 129 in the OR.
Procedure data is shown in Supplementary Table 1. In 77.9% of clinic procedures, N₂O anesthesia was used, compared to 2.7% of OR procedures (P < 0.0001). N₂O time was shorter in the clinic group. However, the data were not statistically significant, likely due to the low number of patients who received N₂O in the OR group. Importantly, the procedure length was shorter in the clinic group, with procedures lasting a median of 10 minutes, compared to 12 minutes in the OR group (P < 0.0097).

**Outcomes**

Outcomes are shown in Table 2. The complication rate for the clinic group was 4.1%, compared to 7.8% in the OR group. Complications in the clinic and OR groups are listed in Supplementary Table 2. The most common complication in both groups was urinary tract infections (UTIs), which occurred at similar rates. Urinary retention, incorrect stent deployment, sepsis/bacteremia, and nausea/vomiting occurred more frequently in the clinic stent group, while the OR group had stent failure, stent migration, and desaturation during anesthesia as its more frequent complications. Unplanned admissions to the hospital occurred after 3.0% of clinic procedures and 9.5% of OR procedures. Stent placements failed in 1.1% of clinic procedures and 0.56% of procedures performed in the OR. Among stone patients, 3% of individuals had complications with 2.6% of the clinic stent group and 2.8% in the OR stent group experiencing adverse events.

Stent failures occurred following none of the clinic and 6 of OR procedures. In all patients in whom stents failed, symptoms continued after placement resulting in reevaluation. Symptoms included creatinine elevation, pain, or hydronephrosis on repeat imaging. One of these procedures was performed for retroperitoneal fibrosis, 3 for stricture disease, 2 for distal ureteral stones. The patient with retroperitoneal fibrosis was managed with stent replacement. In the ureteral strictures, a second set of stents was placed beside the first set, resulting in adequate flow. Both stone patients had percutaneous nephrostomy tubes used for management of their obstructive uropathy.

Tolerability was not directly assessed in the database. However, 72 patients underwent repeat stent placements. Of these patients, 59 patients underwent a stent placement in the clinic followed by at least 1 other stent placement procedure. Of the patients undergoing a procedure after their initial procedure in the clinic, 54 had their additional procedures in the clinic, and only 5 had their subsequent procedures in the OR. In the patients who underwent further procedures in the OR, the change to the OR was due either to patient condition or to a lack of availability of the clinic suite.

**Analysis for Predictors of Complications**

To determine the predictors of complications in our dataset, we performed a logistic regression analysis. Predictors of complications demonstrated in our univariable analysis included the number of renal units addressed, whether a procedure was performed for a stone or a different indication, and the procedure length. We then used multivariable analysis to determine predictors of complications. Notably, we did not identify any factors that significantly impacted the complication rate in ureteral stent placement in clinic vs OR setting in the multivariable analysis (Table 3). A separate analysis was conducted to examine complication risks in the patients having their procedures for stones (Supplementary Table 3). No factors were demonstrated to increase the complication risk in either the univariable or the multivariable analysis of this subset of patients.

**CONCLUSIONS**

In managing urinary obstruction, urgent decompression of the urinary tract is important to prevent pressure built up in the urinary system from causing irreversible renal
damage or urosepsis and to alleviate pain.\textsuperscript{4,5} Urgent ureteral stent placement remains a common and important procedure in managing stones and other obstructive pathologies in the urinary tract.

Finding strategies to safely reduce costs for patients could greatly improve health care delivery. OR costs, which are estimated to be roughly $20 per minute, represent up to 40\% of a hospital’s total resource costs. Thus, methods for performing procedures outside the OR may represent a significant source of cost savings as well minimizing risks of general anesthesia for the patient.\textsuperscript{15} Stent placement in the clinic, instead of in the OR, using N\textsubscript{2}O or LA is an attractive strategy for reducing costs\textsuperscript{12-14} According to Carrouget et al, LA use during stent placement in the OR led to increased operative time but shorter total OR time, which saved OR costs.\textsuperscript{13} Sivaligam et al, based out of Wisconsin in the United States (US), showed that when stents were placed under LA, costs were only $11,037, compared to the $30,741 in charges for stent placements with GA.\textsuperscript{14} Another study, performed in Massachusetts in the US, demonstrated that stents, on average, cost about $600 when placed in the clinic, compared to roughly $2,300 for stents placed in the OR, based on Medicare cost data.\textsuperscript{16} Furthermore, after accounting added costs from repeat procedures, average savings in this study for performing procedures in the clinic came to roughly $1,551 per procedure. Thus, others have shown that avoiding the OR saves significant amounts of money for both the hospital and the patient. The strategy employed in our study, stent placement in the clinic with LA or N\textsubscript{2}O, combines the approaches of avoiding the OR and avoiding GA to further reduce costs.

In addition to the OR-related expenses, OR unavailability and access can also delay the performance of these relatively short procedures. OR-related delays, which can be caused by previously scheduled surgeries, staffing availability, and aspiration risks due to nil per os status, have the potential to prolong patient discomfort and have been shown in some studies increase the likelihood of poor outcomes.\textsuperscript{17-19} Furthermore, OR delays can even increase hospital costs related to a procedure.\textsuperscript{17} Thus, avoiding delays in the OR with the quick availability of a clinic procedure suite can be a strategy for improving stent placement. Additionally, in this study, stent placements in the clinic were a median of 2 minutes faster than in the OR. While 2 minutes may seem insignificant, given the frequency with which stents are placed, this could represent a significant time savings for the medical team involved in placing stents. Furthermore, this figure includes only the procedure itself, not the time required for preparation of the OR, patient transport, anesthesia induction, or recovery.

Further cost savings might be possible by avoiding GA. One commonly used strategy, moderate sedation with midazolam or other benzodiazepine medications, is commonly used for cystoscopy with stent placement.\textsuperscript{10,11} In another approach, Carrouget et al found that ureteral stent placement under LA in women avoids the unnecessary risks and costs associated with GA.\textsuperscript{13} Sivaligam et al reported the feasibility of office-based stent placement under LA with rigid cystoscopy with comparable success and complication rate.\textsuperscript{14} Nourparvar et al also demonstrated that bedside stent placement with LA is feasible and effective without introducing a risk for substantial complications.\textsuperscript{12}

However, there are also limitations to LA. In one study, half of individuals who had stents placed under LA would not choose that approach again due to pain and discomfort.\textsuperscript{13} While the current study did not directly address procedure tolerability, anecdotally, the procedure appeared well-tolerated and pain control was not generally a problem after the procedure. Furthermore, only 1 patient in the clinic group required operative intervention for pain, which consisted of stent removal and replacement. Additionally, of the 59 patients who underwent repeat procedures, 54 of these individuals were willing to undergo multiple procedures in the clinic. For the 5 patients who had their repeat procedures in the OR, the reason for this choice was dependent on patient condition and clinic availability, not patient preference. Most of our clinic group patients received N\textsubscript{2}O anesthesia, which improved the tolerability of the procedure, and did not introduce any complications. Thus, the approach discussed in this study is likely effective in controlling pain without introducing the complications associated with GA.

The use of N\textsubscript{2}O has been shown to be safe as a component of anesthesia in the OR, for minor emergency department or inpatient procedures, and in office settings.\textsuperscript{20-24} N\textsubscript{2}O is commonly used, along with other agents, for analgesia during office-based dental procedures in the US, with few adverse events and a high degree of patient satisfaction.\textsuperscript{20,22} N\textsubscript{2}O is easy to administer, requiring limited added personnel and minimal further training, which varies state to state in the US. Thus, this approach is easy to employ and well-tolerated.

In this study, placing stents in the clinic, compared to the OR, did not increase the rate of complications. While it may appear to be more difficult to place a stent in an awake patient, only about 1\% of stent placements attempted could not be completed in the clinic. Additionally, we only noted failures of stents in the OR group. It is unclear why these only occurred in this group; it may be that these patients were selected for procedures in the OR due to the severity of their condition and were thus at a greater risk of stent failure. In our multivariable analysis, there were no risk factors associated with an increased risk of complications. The most common complication in both groups was new UTIs. However, it is important to consider that these infections may have already been present in the patients and masked by the symptoms of obstructive uropathy. Thus, the rate of new UTIs may be inflated. Therefore, it appears that the clinic setting is a safe and effective venue for performing stent placement procedures.
Strengths of this study include the large clinic stent group and the novel approach of using N2O anesthesia. Limitations include the retrospective nature of the study, the smaller OR stent group, a lack of assessment of subject pain and comfort, and the heterogeneity of stent indications in both groups. Overall, this study demonstrates excellent outcomes with a novel approach to a common procedure. More studies are needed to determine the best combination of operative setting and anesthetic and analgesic management to optimize stent placement while reducing costs. However, the approach outlined here, stent placement using LA and N2O in the clinic setting, is likely a viable and safe strategy that warrants further exploration and adoption.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2019.07.010.

References