Recent outcomes of retrograde intrarenal surgery for large renal stones: A comparison analysis with disposable and reusable ureteroscopes

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Research Article

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Abstract

The aim of this study is to evaluate the recent outcomes of retrograde intrarenal surgery (RIRS) with a disposable ureteroscope in comparison to RIRS with a reusable ureteroscope. One hundred thirty patients with renal stones of 15-40 mm were analyzed. The patient characteristics and surgical outcomes of 64 patients treated with a disposable ureteroscope LithoVue® (disposable-scope group) were compared with those of 66 patients treated with a reusable scope previously (reusable-scope group). In the disposable-scope group, the mean stone diameter (24.9 vs. 22.0 mm, p=0.01) and stone volume (2.8 vs. 1.8 cc, p<0.01) were significantly larger than those in the reusable-scope group. The stone-free rate after one session of the disposable-scope group was equivalent to that of the reusable-scope group (81.3% vs. 86.4%, p=0.43) without the increase of complications although it required longer operative time (111.0 vs. 90.2 min, p<0.01). Moreover, the stone-free rate of the disposable-scope group was correlated with stone volume [cut-off value 2.9 cc, area under the curve (AUC) 0.94] better than stone diameter (cut-off value 26.0 mm, AUC 0.76). After propensity-score matching, 37 patients from each group were included. Although the disposable-scope group tended to require longer operative time (100.5 vs. 89.2 min, p=0.06), the stone-free rates of both groups were the same (91.2%). In conclusion, we are now able to treat larger renal stones with a disposable ureteroscope although it requires longer operative time. The stone volume can predict the outcome of RIRS for large renal stones of 15-40 mm more accurately than stone diameter.

Introduction

Disposable digital flexible ureteroscopes are becoming widespread as an answer to the fragility issue with reusable flexible ureteroscopes,1–4 although there is currently no clear consensus on its cost-effectiveness.5–7 Since 2017, we have used disposable ureteroscopes for patients with large renal stones (≥15 mm). In this study, we evaluated the recent outcomes of retrograde intrarenal surgery (RIRS) for renal stones of 15–40 mm and in comparison to operations performed with a conventional reusable ureteroscope.

Methods

Patient selection and data collection

We managed 1610 consecutive cases of ureteroscopic lithotripsy between January 2008 and July 2021, including 879 renal stone cases. From 2017 to 2021, a total of 64 patients with large renal stones of 15–40 mm were treated by RIRS with a disposable ureteroscope. When a staged operation was performed, the clinical data of the initial operation were included. Patients with nephrostomy tubes were excluded due to the complexity of evaluating the treatment outcomes. Patient information, including age, sex, body mass index, underlying comorbidities, preoperative urine culture results, presence of a ureteral stent, was collected. Stone characteristics, such as the location and size, were determined by plain X-ray and non-contrast computed tomography (NCCT). The total stone diameter was defined as the sum of the maximum diameter of each stone, and the stone volume was automatically calculated using a SYNAPSE
VINCENT® volume analyzer (Fujifilm, Tokyo, Japan). We automatically extracted 3D images of the stones by setting the threshold value at 100 Hounsfield units. In cases with multiple stones, the total stone volume was measured. The stone composition groups were determined according to the most prominent crystal, except for cases of struvite calculi when any amount of struvite was identified. A positive preoperative urine culture result was defined as ≥ 10,000 colony-forming units/ml. Antibiotic sensitivity was also analyzed. Pathogen-specific antibiotic therapy was administered for an adequate duration by the treating urologists. In cases in which a ureteral stent had been in place for more than two months, the ureteral stent was replaced prior to surgery.

The outcomes of 64 patients treated with a disposable ureteroscope (disposable-scope group) were compared with those of 66 patients with renal stones of 15–40 mm who were treated with a reusable ureteroscope previously (reusable-scope group). All surgeries were performed with the same holmium:YAG (Yttrium Aluminum Garnet) laser by a total of eight surgeons under the supervision of one experienced surgeon (R.T.). To make the baseline conditions of the two groups equivalent, we performed a propensity-score matching analysis. This study was approved by the institutional ethics committee of Tokyo Metropolitan Ohtsuka Hospital (approval number 2019-81).

RIRS procedure

RIRS for renal stones was performed in the lithotomy position under general anesthesia. As a routine procedure, we checked the ureter with a semi-rigid ureteroscope (Fibre Uretero-Renoscope; Richard Wolf, Knittlingen, Germany) and inserted a ureteral access sheath (12/14 Fr or 10/12 Fr ReTrace®; Coloplast, Humlebaek, Denmark or 12/14 Fr or 10/12 Fr Biflex®; Rocamed, Monaco) in all cases. A disposable flexible ureteroscope (LithoVue®; Boston Scientific, Natick, MA, USA) or a reusable flexible fiberoptic ureteroscope (URF-P6®, URF-P7®; Olympus, Tokyo, Japan or Flex-X2s®; Karl Storz, Tuttlingen, Germany) was used. Stones were fragmented with a holmium:YAG laser (Litho®; Quanta system, Milan, Italy), which can modulate the pulse duration. The laser power was usually set to 9.6–15 W (1.2–1.5 J, 8–10 Hz, long-pulse mode). Stones were fragmented into the smallest chips possible and residual fragments were picked out using a nitinol stone retrieval basket (Escape®; Boston Scientific), when possible. A 6-Fr ureteral stent and a urethral catheter were placed at the end of the operations in all cases. The operative time was defined as the time from the insertion of the endoscope into the urethra to the completion of ureteral stent placement.

Follow-up

The urethral catheter was removed on postoperative day 1. Patients were usually discharged the following day. The ureteral stent was generally removed on postoperative day 7. A stone-free status was defined as no stones visible or residual fragments of < 4 mm on NCCT after 1–2 months of follow-up. An additional operation was planned if necessary.

Statistical analyses
Data were compared between the disposable-scope group and the reusable-scope group using the chi-squared test for categorical variables and Student’s t-test or the Mann-Whitney U test for continuous variables. Propensity-score matching (1:1) was used to adjust the difference in clinical variables between the two groups. Patients in both groups were matched based on the calculated propensity-scores by a regression model using age, sex, body mass index, stone diameter, stone volume, preoperative stented, preoperative urine culture results, presence of lower pole stone, size of the ureteral access sheath, and main stone composition as covariates. We further compared the surgical outcomes between the unmatched and matched groups. A logistic regression analysis was used to examine the correlation between a stone-free status after one RIRS session and the stone size (diameter and volume). Receiver operating characteristic (ROC) curves and the Youden index were used to calculate the optimal cut-off value of the stone size for predicting a stone-free status after one RIRS session. Two-sided p values of < 0.05 were considered to indicate statistical significance. Statistical analyses were performed using the JMP software program (version 14.0, SAS, Cary, NC, USA).

**Results**

**Clinical variables and surgical outcomes**

Table 1 shows the clinical variables and surgical outcomes of the study groups. A total of 130 patients were included in this study (64 patients in the disposable-scope group and 66 patients in the reusable-scope group). Before matching, there were significant differences between the two groups in some influential variables (mean stone diameter, stone volume, size of the access sheath, and main stone composition). In particular, the mean stone diameter and stone volume of the disposable-scope group were significantly larger than those of reusable-scope group (24.9 mm vs. 22.0 mm, p = 0.01, and 2.8 cc vs. 1.8 cc, p < 0.01). 12/14 Fr access sheaths were used more frequently in the disposable-scope group in comparison to the reusable-scope group. After matching, 37 patients from each group were included in the analysis, and there were no significant differences in the clinical variables of the matched groups. The mean stone diameter and stone volume of the matched two groups were equivalent (22.8 mm vs. 22.8 mm, p = 0.96, and 2.3 cc vs. 2.0 cc, p = 0.38). Furthermore, the rate of using a 12/14 Fr access sheath was equivalent in the matched two groups (75.7% vs. 78.4%, p = 0.78).
### Table 1
Clinical variables and surgical outcomes in the disposable-scope and reusable-scope groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Unmatched groups</th>
<th>Matched groups</th>
<th>P value</th>
<th>Unmatched groups</th>
<th>Matched groups</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All (n = 130)</td>
<td>Disposable (n = 64)</td>
<td>Reusable (n = 66)</td>
<td>P value</td>
<td>Disposable (n = 37)</td>
<td>Reusable (n = 37)</td>
</tr>
<tr>
<td><strong>Patient’s characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>82 (63.1)</td>
<td>45 (70.3)</td>
<td>37 (56.1)</td>
<td>0.09</td>
<td>22 (59.5)</td>
<td>26 (70.3)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>59.6 ± 14.1</td>
<td>57.3 ± 12.9</td>
<td>61.7 ± 14.9</td>
<td>0.08</td>
<td>56.8 ± 14.0</td>
<td>59.4 ± 13.1</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>24.2 ± 4.5</td>
<td>24.3 ± 4.2</td>
<td>24.1 ± 4.8</td>
<td>0.81</td>
<td>24.1 ± 4.8</td>
<td>24.4 ± 5.0</td>
</tr>
<tr>
<td>Pre-stented (%)</td>
<td>27 (21.1)</td>
<td>10 (15.6)</td>
<td>17 (26.6)</td>
<td>0.13</td>
<td>8 (21.6)</td>
<td>5 (13.5)</td>
</tr>
<tr>
<td>Positive urine culture (%)</td>
<td>59 (45.4)</td>
<td>26 (40.6)</td>
<td>33 (50.0)</td>
<td>0.28</td>
<td>19 (51.4)</td>
<td>15 (40.5)</td>
</tr>
<tr>
<td>Stone diameter (mm)</td>
<td>23.4 ± 6.5</td>
<td>24.9 ± 6.2</td>
<td>22.0 ± 6.5</td>
<td>0.01*</td>
<td>22.8 ± 6.2</td>
<td>22.8 ± 7.3</td>
</tr>
<tr>
<td>Stone volume (cc)</td>
<td>2.3 ± 1.5</td>
<td>2.8 ± 1.5</td>
<td>1.8 ± 1.4</td>
<td>&lt; 0.01*</td>
<td>2.3 ± 1.2</td>
<td>2.0 ± 1.5</td>
</tr>
<tr>
<td>Lower pole stone (%)</td>
<td>90 (69.2)</td>
<td>48 (75.0)</td>
<td>42 (63.6)</td>
<td>0.16</td>
<td>27 (73.0)</td>
<td>26 (70.3)</td>
</tr>
<tr>
<td>Access sheath size</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>12/14 Fr</td>
<td>94 (72.3)</td>
<td>54 (84.4)</td>
<td>40 (60.6)</td>
<td>&lt; 0.01*</td>
<td>28 (75.7)</td>
<td>29 (78.4)</td>
</tr>
<tr>
<td>10/12 Fr</td>
<td>36 (27.7)</td>
<td>10 (15.6)</td>
<td>26 (39.4)</td>
<td></td>
<td>9 (24.3)</td>
<td>8 (21.6)</td>
</tr>
<tr>
<td>Main stone composition</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Calcium oxalate (%)</td>
<td>95 (73.1)</td>
<td>49 (76.6)</td>
<td>46 (69.7)</td>
<td></td>
<td>30 (81.1)</td>
<td>30 (81.1)</td>
</tr>
<tr>
<td>Struvite (%)</td>
<td>11 (8.5)</td>
<td>2 (3.1)</td>
<td>9 (13.6)</td>
<td></td>
<td>2 (5.4)</td>
<td>1 (2.7)</td>
</tr>
<tr>
<td>Uric acid (%)</td>
<td>3 (2.3)</td>
<td>3 (4.7)</td>
<td>0 (0.0)</td>
<td></td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

Categorical variables are shown as the number of patients (%). Continuous variables are shown as the mean ± standard deviation. *P < 0.05
Before matching, the mean operative time of the disposable-scope group was significantly longer in comparison to the reusable-scope group (111.0 min vs. 90.2 min, p < 0.01). The stone-free rate (residual fragment < 4 mm) of the disposable-scope group was equivalent to that of the reusable-scope group (81.3 vs. 86.4%; p = 0.43). The additional treatment rates of the two groups did not differ to a statistically significant extent (15.6% vs. 10.6%, p = 0.40). After matching, the stone-free rates of the disposable-scope group and the reusable-scope group were the same (91.2%). The mean operative time of the disposable-scope group tended to be longer than that of the reusable-scope group (100.5 min vs. 89.2 min, p = 0.06). The complication rates of the two groups were equivalent.

### Cut-off value of stone size for predicting a stone-free status after one RIRS session

Figure 1 shows the logistic regression curves and ROC curves for predicting a stone-free status after one RIRS session based on the stone diameter and stone volume. In the reusable-scope group, a stone-free status after one RIRS session was not correlated with the stone diameter (p = 0.77) but was correlated with the stone volume (p < 0.01). The cut-off value was 1.9 cc, and the area under the curve (AUC) was...
0.79. In contrast, in the disposable-scope group, a stone-free status after one RIRS session was correlated with both the stone diameter and stone volume (p < 0.01). The cut-off values of the stone diameter and volume were 26.0 mm (AUC 0.76) and 2.9 cc (AUC 0.94), respectively.

Discussion

The use of disposable digital flexible ureteroscopes is becoming widespread in response to the fragility issue seen with flexible ureteroscopes. Their operability has been shown to be comparable to that of reusable ureteroscopes.\(^1\)\(^-\)\(^4\) However, due to differences in medical systems among countries, there is no consensus concerning their cost-effectiveness.\(^5\)\(^-\)\(^7\) In countries that have adopted a national health insurance system such as Japan, when using a disposable ureteroscope, it is necessary to calculate the scope's market price and the number of cases that are likely to require the scope at a hospital so that a deficit does not develop. A hybrid method is therefore applied, wherein a disposable ureteroscope is used for cases in which the scope might be easily broken, while a conventional reusable ureteroscope is used in other cases.\(^6\)

LithoVue® was launched in 2017 as the first disposable digital flexible ureteroscope in Japan. Since then, we have been using LithoVue® scopes in selected cases where the ureteroscope might be easily broken, including cases with large renal stones of \(\geq 15\) mm. Therefore, in this study, we divided patients with large renal stones of 15–40 mm in size who underwent RIRS into two groups: the reusable-scope group and the disposable-scope group; we then compared the surgical outcomes.

When the variables were compared between the two groups, the stone diameter and stone volume of the disposable-scope group were significantly larger in comparison to the reusable-scope group. The stone-free rates of the two groups were equivalent, although the mean operative time of the disposable-scope group was significantly longer as the stone size grew. After matching, the disposable-scope group was found to have the same stone-free rate as the reusable-scope group. Considering these results, a disposable ureteroscope performed comparably, not superior, to a current reusable ureteroscope. However, using a disposable ureteroscope, we were able to successfully treat larger renal stones than we previously treated using with a reusable ureteroscope. We think the advantages of a disposable ureteroscope influenced the results. The surgeons were freed from the anxieties about breaking the scope. Furthermore, surgeons were able to perform longer operations with less fatigue because of the light weight of the disposable ureteroscope.\(^8\) These advantages have increased the size of renal stones for which RIRS is indicated.

In this study, the mean operative time of the disposable-scope group tended to be longer than that of the reusable-scope group even after matching. This trend was also shown in a recently reported meta-analysis comparing disposable and reusable flexible ureteroscopes for RIRS.\(^9\) The benchtop and in-vivo studies have demonstrated that LithoVue® is not inferior to reusable ureteroscopes when comparing image quality and manoeuvrability.\(^10\),\(^11\) However, in clinical practice, the different image quality
associated with LithoVue® may be responsible for this longer operative time, although the time is closely linked with the experience of the surgeon.

Conventionally, percutaneous nephrolithotomy is the first treatment option for renal stones of >20 mm in size according to the guidelines. However, in clinical practice, many reports have suggested that ureteroscopy can be used to treat stones of up to 25 or 30 mm in size, including in two-stage operations. Indeed, in this study, the cut-off value of stone diameter for predicting a stone-free status after one RIRS session was 26.0 mm in the disposable-scope group, although we could not determine a significant cut-off value in the reusable-scope group.

Generally, the stone volume can be calculated by the conversion formula ($\pi/6 \times \text{length} \times \text{width} \times \text{height}$). However, when the stone size becomes quite large, the stone volume can no longer be calculated accurately by this formula. Some authors hold the opinion that the stone volume -rather than the stone diameter- should be used as a selection criterion for the treatment of large renal stones. We can now measure the stone volume accurately using a volume analyzer, even if the stone has a complicated shape. Indeed, in this study, we were able to determine more accurate cut-off values with the stone volume than with the stone diameter. Moreover, the cut-off value was 2.9 cc in the disposable-scope group, which was quite precise (AUC 0.94). In the future, the selection of treatments for large stones should be based on the stone volume rather than the stone diameter.

The present study was associated with several limitations. Firstly, this was a retrospective study, although we used a propensity-score matching to derive a result as close to a prospective study as possible. Secondly, several disposable ureteroscopes are currently available on the market. Although we do not have a case series using other disposable ureteroscopes, the LithoVue® is considered to be show excellent operability and durability. We have never experienced failure of a LithoVue® ureteroscope during surgery. Thirdly, there were differences in the experience of the surgeons, although all surgeries were performed under the supervision of one experienced surgeon. Conversely, this study showed the general advantages of using a disposable ureteroscope, irrespective of the surgeon's experience.

**Conclusion**

A disposable ureteroscope can perform comparably, not superior, to a current reusable ureteroscope. However, a disposable ureteroscope frees the surgeons from the issues of fragility associated with reusable ureteroscopes and helps to increase the stone size for which RIRS is indicated. We are now able to treat larger renal stones with a disposable ureteroscope without the increase of complications although it requires longer operative time. Furthermore, the stone volume can predict the outcome of RIRS for large renal stones of 15–40 mm more accurately than stone diameter. The ideal cut-off value of the stone volume for predicting a stone-free status after one RIRS session is approximately 3 cc.

**Declarations**
Acknowledgments

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Author contributions

R.T.: project development, data collection, data analysis, manuscript writing. Y.W.: data collection, manuscript editing. M.K., H.F, T.T.: data collection

Author disclosure statement

Conflict of interest: None declared.

Approval of the research protocol: The protocol for this research project has been approved by a suitably constituted Ethics Committee of Tokyo Metropolitan Ohtsuka Hospital (approval number 2019-81) and it conforms to the provisions of the Declaration of Helsinki.

Informed consent: Written informed consent was obtained from all the participants and/or their surrogates.

Registry: N/A

Animal studies: N/A

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References


Figures
Figure 1

Logistic regression curves and ROC curves for predicting a stone-free status after one RIRS session based on the stone diameter and stone volume.