Cost-effectiveness of using stone cone, balloon dilator, stone basket, and entrapment device in ureteroscopic laser lithotripsy for ureteric stones

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Abstract
Objective: To evaluate the costs and stone-free rates of ureteroscopic laser lithotripsy (ULL) performed with and without auxiliary equipment and to compare first-time ULL with total treatment.

Methods: One hundred patients who underwent first-time ULL without the use of auxiliary equipment because its unavailability comprised the no-device ULL (ndULL) group. Additionally, 100 patients who underwent first-time ULL with the use of auxiliary equipment when necessary comprised the device ULL (dULL) group.

Results: In the ndULL and dULL groups, the stone-free rates after first-time ULL were 72% and 94% and the mean cost was US $1037 ± 15.10 and US $1452 ± 19.80 per case, respectively, with a statistically significant difference. The stone-free rates at the end of treatment were 98% and 99%, respectively, without a statistically significant difference. When secondary treatment costs were added to the first ULL costs after failed treatment, the mean total cost was US $1625 ± 12.60 in the ndULL group and US $1566 ± 11.01 in the dULL group without a statistically significant difference.

Conclusions: The stone-free rates and costs after first-time ULL were significantly different between the groups. However, after total treatment, there was no statistically significant difference between the two groups.
Introduction

Ureteroscopic laser lithotripsy (ULL) is usually the first treatment option for ureteral stones. Semi-rigid ureteroscopy has become a standard procedure for the management of urinary stones. However, semi-rigid ureteroscopy is safe even for proximal ureteral stones.1,2

The success rate of ureteral stone treatment does not depend only on the ureteroscope; the energy source used is also important. Electrohydraulic, pneumatic, ultrasound, and laser energy sources can be used. Laser therapy, especially that using the holmium:yttrium-aluminum-garnet (Ho:YAG) laser, is the most efficient technique for lithotripsy at all anatomic locations3 and is the gold standard for rigid and flexible ureteroscopy.4

Proximal migration of the stone is common in ULL, but it can be prevented by using stone retrieval devices.5,6 A ureteral balloon dilator can be used when the ureter calibration is narrow and the ureteroscope cannot pass through the ureteral orifice.7

Because using auxiliary equipment in first-time ULL (fULL) increases the cost, such equipment is not used in many urology clinics. However, avoidance of using this equipment decreases effectiveness6 and increases the likelihood of needing a secondary procedure such as extracorporeal shock wave lithotripsy (ESWL) or flexible ULL because of stone migration to the kidney, repeat ULL (reULL) for residual stones or in patients who underwent double J stent placement for passive dilation, or postoperative double J stent removal. These secondary treatments increase the cost of ULL. Many cost-effectiveness studies for fULL have been performed.8,9 However, the cost-effectiveness of the total treatment (TT) of ULL has not been thoroughly researched. Such a study would provide useful cost-related information and may also serve as a baseline for further studies regarding this topic.

Therefore, the present study was designed to investigate the cost-effectiveness of using a stone cone, balloon dilator, stone basket, and entrapment device in TT of ULL while taking into account the aforementioned relative cost increase.

Methods

This study adhered to the tenets of the Helsinki Declaration of the World Medical Association, and it was fully approved by the local ethics committee of the University of Health Sciences Derince Training and Research Hospital (approval no. 2020-153). Because this was a retrospective study involving a medical record review, the requirement for verbal or written informed consent was waived.

Inclusion and exclusion criteria

This study involved a review of ULL operations (no changes from semi-rigid to flexible ureteroscopy) performed in 4 separate hospitals by a single surgeon (K.C.) with
experience involving 320 cases who worked during separate time periods in all hospitals from 2010 to 2020. The four hospitals differed from one another in terms of providing auxiliary equipment.

The inclusion criteria were primary ureteric stones (proximal/middle/distal), stone diameter of 6 to 15 mm, and age of >18 to <75 years. The exclusion criteria were residual stones from previous ULL procedures, bilateral stones, horseshoe kidney, ectopic kidney, duplex collecting system, sequelae such as stenosis due to previous surgeries, follow-up for <1 year, and missing file data.

**Study population**

The medical records of 137 patients treated with auxiliary equipment and 197 patients treated with no auxiliary equipment were available in the hospital’s archives and retrospectively analyzed. Of these 334 patients, 134 were excluded based on the above-mentioned study criteria.

The remaining 200 patients were divided into a no-device ULL (ndULL) group and a device ULL (dULL) group. The 100 patients in the ndULL group underwent fULL when no auxiliary devices (stone cone, balloon dilator, stone basket, or entrapment device) were available in the hospital’s operating room and were therefore not used during surgery. Similarly, the 100 patients in the dULL group underwent fULL when all of the auxiliary devices (stone cone, balloon dilator, stone basket, and entrapment device) were available in the hospital’s operating room and were therefore used when necessary during surgery.

The following patient characteristics were recorded: age, sex, stone location (proximal, middle, or distal ureter), surgery time, duration of hospitalization, and stone size (calculated by measuring the length and width of the stone in millimeters on imaging examinations, mostly computed tomography, according to European Association of Urology guidelines).1

For each patient, the following costs were determined: the costs of preoperative urological examination and biochemical tests, computed tomography and other imaging costs, costs of surgical procedures (ULL, flexible ULL, double J stent removal, reULL, or open surgery) and ESWL, hospital bed fees for the period of hospitalization, costs of complications and medical treatments performed in addition to surgical procedures, costs of auxiliary equipment used (stone cone, entrapment device, stone basket, ureteral balloon dilator, or double J stent), and costs of the urological examinations and imaging tests conducted during postoperative follow-up. The costs were standardized based on the price table for private hospitals determined by the Republic of Turkey Social Security Institution according to the Communiqué on Health Practices of the package fee for surgeries (each procedure fee was calculated by adding Turkish Lira (TRY ₺) + 200% difference). The average United States dollar (US $)/TRY exchange rate was determined for the years 2010 to 2019, and the costs were standardized such that US $1 = TRY 3.73. Medical procedures other than the surgery package (e.g., ESWL, hospital bed fees for the period of hospitalization, costs of complications) were added to this price.

In the first stage, the fULL costs and stone-free rates were determined and compared between the two study groups. In the second stage, the secondary treatments performed until an effective treatment (based on a 98% stone-free rate in the ndULL group) was provided were determined. The costs of these secondary treatments were calculated and added to the costs of fULL for recalculation and comparison of the total effectiveness and costs. The reporting
of this study conforms to the STROBE statement.10

Statistical analyses

Results are given as mean ± standard deviation. Data were analyzed using IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Armonk, NY, USA). The means of continuous variables were analyzed with Student’s t test and one-way analysis of variance, followed by Tukey’s test for cost ratio in terms of the device used. Categorical variables were analyzed using the chi-square test, and a probability level of \( P < 0.01 \) was considered statistically significant.

Results

ULL was performed with an Ho:YAG energy source in all patients. Semi-rigid ureteroscopes with a proximal end of 8.5 Fr (Richard Wolf, Knittlingen, Germany), 10 Fr, 9 Fr, and 9.5 Fr (Karl Storz, Tuttingen, Germany) were used in 38% and 62% of patients in the ndULL group and in 44% and 56% of patients in the dULL group, respectively.

Age, sex, stone location, stone size, operation, and duration of hospitalization were similar between the ndULL and dULL groups, with no statistically significant differences. Table 1 shows the characteristics of the patients and stones in each study group.

None of the auxiliary equipment included in the study (stone cone, balloon dilator, stone basket, or entrapment device) was used in the ndULL group. A double J stent was available in the hospital during surgeries in both groups and was used in 73% of patients in the ndULL group (passive dilation was required in 8% of patients) and in 31% of patients in the dULL group, with a statistically significant difference between the two groups (\( P = 0.002 \)).

In the dULL group, a stone cone (Boston Scientific, Natick, MA, USA) or entrapment device (Cook Urological, Bloomington, IN, USA) was routinely placed in each patient after the ureter was entered and a stone was seen, and the ULL procedure was then performed. For impacted stones, this device was placed after the stone was slightly broken off and/or minimally pushed. Residual stones larger than 2mm were collected with stone baskets (Plasti-med, Istanbul, Turkey) when necessary. In 11% of patients with difficult access to the ureter, a ureteral balloon dilator (Plasti-med) was used, the ureter was

| Table 1. Demographic and clinical characteristics of patients and stones in each study group. |
|---------------------------------|--------------|--------------|-----------|
| Patient and stone characteristics | ndULL        | dULL        | \( P \) value |
| Number of patients              | 100          | 100         |            |
| Age, years                      | 39.79 ± 12.1 | 39.15 ± 11.1| 0.38       |
| Male:female ratio               | 62%:38%      | 60%:40%     | 0.56       |
| Stone size, mm\(^2\)            | 88.72 ± 34.18| 91.12 ± 22.12| 0.63       |
| Stone location                  |              |             | 0.54       |
| Proximal                        | 22%          | 20%         |            |
| Middle                          | 30%          | 28%         |            |
| Distal                          | 48%          | 52%         |            |
| Operation time, minutes         | 23.08 ± 10.33| 28.09 ± 11.67| 0.24       |
| Duration of hospitalization, days | 1.20 ± 2.16 | 1.09 ± 1.27 | 0.36       |

Data are presented as n, %, or mean ± standard deviation.

ndULL, no-device ureteroscopic laser lithotripsy; dULL, device ureteroscopic laser lithotripsy.
dilated, and the procedure was continued. The auxiliary equipment used in the ndULL and dULL groups as well as their rates are given in Table 2.

The stone-free rates after fULL were 72% and 94% in the ndULL and dULL groups, respectively, with a statistically significant difference ($P = 0.001$). The rate of migration to the kidney was 8% and 3%, respectively, in the ndULL and dULL groups. When reULL, ESWL, flexible ULL, or open surgery procedures performed as secondary treatments were included for patients whose treatment failed, the stone-free rate of TT was 98% and 99% in the two groups with no significant difference. A stone-free state could not be achieved in 2% of patients in the ndULL group and 1% of patients in the dULL group as a result of secondary treatments, and residual stones of 5 mm were left for follow-up.

In the ndULL group, 1% of patients developed stenosis in the lower ureter, and no secondary surgical procedure with a double J stent was required during follow-up. In the dULL group, 2% of patients developed complications due to the balloon dilator (laceration at the lower end of the ureter). Ureteroneocystostomy was performed by open surgery in one of these patients, and the other underwent placement of a double J stent. The complication rates were similar between the two groups, with no statistically significant difference. Table 3 shows the fULL stone-free rates and the secondary treatment rates in both groups.

The mean cost of fULL for each case was calculated as US $1037 ± 15.10 in the

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**Table 2. Devices used in the present study.**

| Devices           | ndULL | dULL | $P$ value | Cost (US $)   |
|-------------------|-------|------|-----------|--------------|
| Double J stent    | 73%   | 31%  | 0.002     | 23.05 ± 11.72 |
| Stone cone        | 0%    | 76%  | 0.001     | 208.05 ± 18.53|
| Entrapment device | 0%    | 24%  | 0.001     | 459.33 ± 22.31|
| Stone basket      | 0%    | 10%  | 0.002     | 97.56 ± 15.33 |
| Balloon dilator   | 0%    | 11%  | 0.002     | 450.27 ± 27.17|

Data are presented as % or mean ± standard deviation.
ndULL, no-device ureteroscopic laser lithotripsy; dULL, device ureteroscopic laser lithotripsy.

**Table 3. fULL stone-free rates and secondary treatment rates in both groups.**

| Treatments            | ndULL | dULL | $P$ value | Cost (US $)   |
|-----------------------|-------|------|-----------|--------------|
| fULL stone-free rate  | 72%   | 94%  | 0.001     | 1037 ± 15.1/1452 ± 19.8 |
| TT stone-free rate    | 98%   | 99%  | 0.31      | 1625±12.6/1566 ± 11.1 |
| reULL rate            | 20%   | 2%   | 0.002     | 1102.44 ± 74.14 |
| ESWL                  | 8%    | 3%   | 0.23      | 795.13 ± 52.12 |
| Open surgery          | 0%    | 1%   | 0.44      | 1187 ± 00.00 |
| Double J stent removal| 70%   | 28%  | 0.001     | 461.30 ± 95.23 |
| Flexible ULL rate     | 2%    | 1%   | 0.51      | 2735.53 ± 92.32 |

Data are presented as % or mean ± standard deviation.
ndULL, no-device ureteroscopic laser lithotripsy; dULL, device ureteroscopic laser lithotripsy; fULL, first-time ureteroscopic laser lithotripsy; TT, total treatment; reULL: repeat ureteroscopic laser lithotripsy; ESWL, extracorporeal shock wave lithotripsy.
ndULL group and US $1452 ± 19.80 in the dULL group, with a statistically significant difference ($P = 0.002$). In line with the purpose of the study, when the reULL, flexible ULL, ESWL, open surgery, and double J stent removal procedures performed until an effective treatment was provided were added to the costs of fULL and the relative cost was calculated in patients whose treatment failed or who developed complications, the mean effective treatment cost for a patient in the ndULL group was US $1625 ± 12.60 and that of a patient in the dULL group was US $1566 ± 11.01, with no statistically significant difference. The stone-free and cost data for fULL and TT of both groups are shown in Figure 1.

Discussion

Economic evaluation methods such as assessment of cost-effectiveness can be used to efficiently distribute healthcare resources and ensure a balance between good patient care and reasonable cost control. To assess the cost-effectiveness of a new modality, the new modality must be compared with at least one other modality, and two estimates must be made: extra cost and extra effect. Cost-effectiveness aids this decision by estimating the additional cost per unit of the additional benefit.

Although treatment success rates have increased with the introduction of lasers to ureteroscopic lithotripsy, the effectiveness of this surgery remains low because of stone migration, residual fragments, or an inability to enter difficult ureters with narrow calibration on the first attempt. The increase in costs due to the performance of secondary treatments after unsuccessful surgical procedures is an important problem.

Although auxiliary equipment such as a stone cone, stone basket, or entrapment device can be used to increase the effectiveness of treatment by preventing stone migration and collecting residual stones, they are often avoided because they increase the cost of surgery. In 1998, Knispel et al. reported a 40% migration

Figure 1. Cost-effectiveness of stone-free fULL and TT in the present study. fULL, first-time ureteroscopic laser lithotripsy; TT, total treatment; ndULL, no-device ureteroscopic laser lithotripsy; dULL, device ureteroscopic laser lithotripsy.
rate of proximal ureteral stones in ULL. The use of pneumatic energy in that study reduced the effectiveness of the surgery. Allameh et al.\textsuperscript{13} reported that the proximal ureteral stone-free rate as a result of using a stone cone or entrapment device together with a Ho:YAG laser was 83.3\% and 90.9\%, respectively, whereas it was 55.0\% in patients in whom a stone cone or stone basket was not used. In the present study, an average of 21\% of the stones in both groups were also found in the proximal ureter. This played a role in lowering the fULL stone-free rate in the ndULL group (72\%) due to migration to the kidney (8\%). Eisner and Dretler\textsuperscript{14} reported that the stone migration rate was 3.8\% after using a stone cone; in the present study, this rate was 3\% in the dULL group in which a stone cone and entrapment device were used. In addition, in the study by Eisner and Dretler,\textsuperscript{14} this rate was 1.5\% and 0.0\% for middle and distal ureteral stones, respectively. In the present study, the rate of stone migration of middle and distal ureteral stones was 0\%, and a stone cone or entrapment device was found to be very effective in the dULL group. Giulianelli et al.\textsuperscript{15} reported a stone-free rate of 84.1\% in ULL regardless of the location of the ureteral stones and did not use a stone cone, entrapment device, stone basket, or ureteral balloon dilator in their study. In the present study, this rate was 72\% in the ndULL group. The significantly lower number of stones in the proximal ureter in their study than in the present study likely played a role in the higher success rate found in their study of 658 patients. In another similar study, this rate was 57\% to 76\% regardless of location,\textsuperscript{16} which is largely consistent with the present study.

In the present study, a stone cone or entrapment device was used in all patients in the dULL group, and the treatment success rate was 94\%; however, the average cost of fULL significantly increased by approximately US $268.36. This shows that the use of a stone cone or entrapment device increases the cost of fULL along with its effectiveness.

Another factor affecting failure of ULL is the impossibility of the initial entry in difficult ureters. In ULL, the rate of failure of the initial entry to the ureter reportedly ranges from 8\% to 10\%. With the use of a ureteral balloon dilator, this failure rate falls to 1\% to 2\%, and the rate of complications is low when the procedure is safely performed by experienced surgeons.\textsuperscript{17} Kuntz et al.\textsuperscript{18} reported that the use of a ureteral balloon dilator increases the cost along with the effectiveness, and the rate of complications is less than 1\% when the procedure is safely performed. In the present study, a ureteral balloon dilator was used in 11\% of patients in the dULL group as needed, which increased the average cost of fULL by approximately US $49.53. In addition, 2\% of patients in this group developed a ureteral injury, but this rate was not significantly different from that in the ndULL group. Ureteroneocystostomy was performed in one patient, and the average TT cost increased by US $11.87.

For ureters that are difficult to treat, a double J stent can be placed for passive dilation as an alternative to ureteral balloon dilation. However, this will necessitate a subsequent secondary treatment. Giulianelli et al.\textsuperscript{15} reported that 32.3\% of the patients in their study required placement of a double J stent for passive dilation, and the authors placed a double J stent after fULL in 23.2\% of these patients. In contrast, Cetti et al.\textsuperscript{7} showed that ureteral balloon dilation was required at a rate of 8.4\% and passive dilation at a rate of 11\%. In the present study, passive dilation was required in 8\% of patients in the ndULL group, and when other reasons were added, a double J stent was placed in 73\% patients in total. This occurred in 31\% of
patients in the dULL group, with a statistically significant difference. The use of a stone cone or entrapment device in the dULL group prevented stone migration and facilitated an effective breaking procedure, decreasing the requirement for double J stent placement. Additionally, in 10% of patients in this group, collection of >2-mm stone fragments using a stone basket reduced the need for placement of a double J stent. Conversely, the use of a balloon dilator eliminated the need for passive dilation in 11 patients and helped reduce the number of double J stents. Consequently, in the ndULL group, the increased costs due to the high number of double J stent placements and subsequent removal procedures increased the average cost of TT by US $193.75, with a statistically significant difference.

The diameter of the rigid ureteroscope used in ULL also plays a role in treatment efficiency.19 Because rigid ureteroscopes of different diameters were used in different centers in the present study, this variable could not be standardized, and costs are often widely variable among countries. This is a limitation of the present study.

To achieve a stone-free state in TT for stone migration to the kidney, ESWL was performed as a secondary procedure in 8% of patients in the ndULL group and 3% of patients in the dULL group. This increased the average cost of TT by US $39.79 in the ndULL group relative to the dULL group. Flexible ULL was performed as secondary treatment to achieve stone-free TT in 2% of patients in the ndULL group and 1% of patients in the dULL group in whom ESWL failed. Although there was no statistically significant difference, this increased the average cost of stone-free TT in the ndULL group by US $27.31 compared with the dULL group.

The reULL surgeries performed to provide effective treatment after an unsuccessful fULL significantly increased the average cost of stone-free TT. In the ndULL and dULL groups, 20% and 2% of patients underwent reULL, respectively, and an additional 18 reULL procedures were needed in the ndULL group. This difference of 18 patients increased the average cost of stone-free TT by approximately US $198.44 in the ndULL group.

In the present study, the average cost of fULL was significantly higher in the dULL group than in the ndULL group (US $1452 vs. $1037, respectively). A substantial part of this increase in cost was due to the use of a stone cone, entrapment device, stone basket, or balloon dilator in the dULL group, as expected. In line with the purpose of the present study, when the calculated costs were added to fULL and TT cost-effectiveness analyses were performed, there was no statistically significant difference in the TT effectiveness (98%/99%) and TT cost (US $1625/$1556) between the two groups. Secondary procedures (ESWL, reULL, double J stent removal, and flexible ULL) performed to achieve a stone-free state in TT increased the average TT cost by US $588 in the ndULL group and by US $114 in the dULL group. Consequently, a statistically significant difference was found in the cost-effectiveness analysis for fULL between the two groups, but when the cost-effectiveness was calculated for TT, there was no statistically significant difference.

Because of the surgeon’s preference and patients’ expectations of high treatment efficacy, a stone cone or entrapment device was used in all patients of the dULL group. Notably, 52% of patients in the dULL group had lower ureteral stones, and devices are not usually required for such stones.20 This might explain the significant TT cost difference between the two groups.

Although the auxiliary equipment used in ULL seems to increase both the effectiveness and cost of surgery at first glance, the cost and effectiveness of treatment decrease
when this auxiliary equipment is not used, and there is an increased need for double J stent placement. Therefore, as a result of the added relative cost of secondary procedures (ESWL, reULL, and flexible ULL) and the double J stent removal procedure performed in patients with failed treatment, the TT costs increase and the difference with the other group no longer exists.

Conclusions

It initially appeared that the stone-free rates and costs after fULL were significantly different between the ndULL and dULL groups; after TT, however, there were no significant differences between the two groups. Surgeons should have a stone cone, entrapment device, basket, and ureteral balloon dilator available in the operating room while performing ULL and should use them when necessary without worrying about increased costs.

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