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LAPAROSCOPIC URETEROLITHOTOMY; AN EQUALLY EFFECTIVE AND A SENSIBLE ALTERNATIVE TO FLEXIBLE URETERORENOSCOPY IN THE MANAGEMENT OF LARGE URETERAL STONES IN TERMS OF EFFECTIVITY AND COST

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Summary.- *OBJECTIVES: We aimed to understand whether laparoscopic ureterolithotomy (LU) is a good alternative to flexible ureterorenoscopic lithotripsy (FURS) by comparing these techniques concerning cost-effectiveness.*

METHODS: We analysed 79 patients with upper ureteral stones larger than 1.5 cm underwent FURS or LU concerning cost-effectiveness analysis. The data including age, body mass index (BMI), stone size, operation time, hospitalisation time, complications and stone-free rates of 15th day and 3rd months. We audited the costs of FURS and LU and compared them concerning cost-effectiveness.

RESULTS: There was not any statistically significant difference between the two groups with regard to age, BMI, stone size, stone-free rates at the 3rd month, and complication rates, (p>0.05).

The operation times were statistically lower in the FURS than in the LU (61.5±24.3 min and 140.9±49.1 min, respectively, p<0.05). The stone-free rate at the 15th day was lower in the FURS group than in the LU group (31 (81.6%) and 41 (100%), respectively, p<0.05) (Table I).

However, this statistical difference disappears at 3 months (p>0.05). The mean costs of FURS and LU were $194.2±12.4 and $179.2±58.5, respectively (p<0.001).

CONCLUSION: FURS is equally effective to LU in terms of stone-free rates. The cost of FURS is higher statistically than LU. FURS is shown as the first choice for the upper ureteral stones larger than 10 mm in size, if the laparoscopic experience is in high-level situations in that clinic, LU may be a suitable alternative to FURS, especially for challenging cases.

Keywords: *Flexible ureterorenoscopy. Laparoscopic ureterolitotomy. Cost-effectiveness. Lithotripsy.*

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Resumen.- *OBJETIVOS: El objetivo es determinar si la ureterolitectomia laparoscópica (UL) es una buena alternativa a la ureterorenoscopia flexible con litotricia (URSF) a través de la comparación de ambas técnicas en lo que a coste y efectividad radica.*

MÉTODOS: Analizamos 79 pacientes con litiasis ureterales proximales de más de 1,5 cm que recibieron URSF o UL en relación a coste-efectividad. Los datos recogidos incluyeron edad, IMC, tamaño de la litiasis, tiempo de la cirugía, tiempo de hospitalización, complicaciones y tasa libres de litiasis a los 15 días y 3 meses de la cirugía. Auditamos los costes de las URSF y UL y se compararon en relación a coste-efectividad.

RESULTADOS: No hubo diferencias estadísticamente significativas entre los grupos en relación a la edad, IMC, tamaño de la litiasis, tasa libre de litiasis a los 3 meses y complicaciones (p>0,05).

Los tiempos quirúrgicos fueron estadísticamente menores en URSF en comparación a UL (61,5±24,3 min y 140,9±49,1 min, respectivamente, p<0,05). La tasa libre de litiasis a los 15 días fue mas baja en el grupo de URSF que UL (31 (81,6%) y 41 (100%), respectivamente, p<0,05] (Tabla I).

Aunque la diferencia estadística desaparece a los 3 meses (p>0,05). El coste medio de URSF y UL fue de $194,2 ± 12,4 y $ 179,2 ± 58,5, respectivamente (p<0,001).

CONCLUSIÓN: URSF es igualmente efectiva que UL en términos de tasa libre de litiasis. Los costes de URSF es más alto que UL. URSF es la primera opción en el tratamiento de litiasis de más de 1 cm en uréter proximal. En caso de experiencia laparoscópica de alto nivel, UL puede sustituir a URSF, especialmente en casos difíciles.

Palabras clave: *Ureterorenoscopia flexible. Ureterolitotomia laparoscópica. Coste-efectividad. Litotripsia.*

INTRODUCTION

Currently, the prevalence rates for urinary stones vary from 1% to 20% (1). Although various treatment modalities have been used for ureteral stones including shock-wave lithotripsy (SWL), semi-rigid ureteroscopic lithotripsy (URS), flexible ureterorenoscopy (FURS), percutaneous nephrolithotomy (PNL), laparoscopic ureterolithotomy (LU) and open ureterolithotomy (2), because of technical improvements including endoscope miniaturisation, improved deflection mechanism, enhanced optical quality and tools, and introduction of disposables have led to an increased use of FURS for the upper ureteral stones greater than 10 mm (1). Nevertheless, as each of these treatment modalities has its' own pros and cons, the optimal choice of treatment is still controversial (3).

According to EAU-2019 guideline on urolithiasis, although URS (ante-or retrograde) is recommended as the first option for upper ureteral stones greater than 10 mm, and laparoscopic surgery may be a valid treatment option for challenging cases (1), the LU option can be compared with the others (4) especially in the experienced clinic for laparoscopic and endoscopic surgery.

It is typically expected to choose the cheapest and most effective one when deciding between different treatment modalities in medicine, and this reality is also valid for the treatment of upper ureteral stones. In the literature, FURS and LU had been compared with regard to clinical outcomes. According to our observation depends on our laparoscopic experience of our department, LU is as effective as FURS in terms of stone-free, as of the 3rd month results.

In this study, we aimed to understand whether LU will be a good alternative to FURS by comparing these techniques in terms of the cost-effectiveness analysis (CEA) as a high-volume clinic in which laparoscopic and endoscopic surgery was performed. To our knowledge, this is the first cost-effectiveness study in the literature comparing these techniques.

MATERIALS AND METHODS

Our study design was approved by the local ethics committee of our institution with the number of 2019-16/20. Informed consent was obtained by all subjects when they were enrolled. We performed a retrospective analysis of 79 patients with urolithiasis symptoms who established upper ureteral stones larger than 1.5 cm on their computerised tomography (CT). Upper ureteral stones were defined as the stones located in the part of ureter between upper borderline of the sacroiliac joint and ureteropelvic junction according to the CT.

Excluding Criteria

Patients with multiple ureteral stones with different localised and those accompanying renal stone larger than 5 mm were excluded from the study. The treatment methods, including SWL with pros and cons were discussed with the patients, and the patients themselves decided the management method and those preferred SWL were also excluded.

The demographic and clinical data including age, body mass index (BMI), stone size (mm^2), operation time (minute), hospitalisation time (day), complications according to the Clavien's classification and

stone-free rates on both 15th day and 3rd months were evaluated with direct x-ray for opaque stones, and CT for non-opaque ones were collected. When the residual fragments were measured less than 4 mm, it was accepted as stone-free. The longest axis of the stone was measured using non-contrast CT. The data were grouped according to the treatment modality (FURS versus LU) and analysed.

In addition, analgesic use and quality of life scores were assessed by a simple questionnaire, similar to International Prostate Symptoms Scores (IPSS).

Also, we audited the costs of FURS and LU in the United States (US) Dollars ($) and compared them in terms of cost-effectiveness. *The costs of disposable devices, hotel service during patient's hospitalisation period and second procedures in case of requiring were calculated and added to the cost of each procedure*. The expense of the same used items in both operations like foley catheter, double j stent and its removal operation, antibiotics, analgesics, anaesthetic drugs, fee of the doctor, price of endovision and additionally the prices of laser lithotriptor, and semi-rigid ureterorenoscope for FURS group and price of insufflator and laparoscopic needle holder for LU group were not added for the statistical analysis because of their using in the other surgical procedures.

Some calculation methods

• Flexible ureterorenoscope cost for each case

The cost of the flexible ureterorenoscope was $12500 and while auditing the cost of the flexible ureterorenoscope for each case, the all procedures including the kidney stones that performed by the same flexible ureterorenoscope were included as it was divided by a total of 91 cases. We have made this calculation, considering that it is more accurate to calculate by including all stone surgeries (including intrarenal lithotripsy) using one device until it broke. In this context, we have realised 91 RIRS including intrarenal stones in the study period. For that reason, we diveded the cost of the FURS into 91 cases in order to calculate the cost of FURS per case.

• Laser prob cost for each case

A laser prob cost of $1071 was divided by 70 the total case number in the FURS group in order to understand the cost of the laser prob per each case. In order to calculate the cost of the laser fiber per case, we calculated the financial cost of a laser fiber by dividing it by the total number of cases done with that laser fiber. For this study period, we performed 70 lithotripsy with the same laser fiber.

Table I. The demographic characteristics of the patients and some operative outcomes.

	FURS n=38 Mean±sd	**LU n=41 Mean±sd**	**p**
Age	54.7±11.9	48.8±13.5	0.36
BMI	28.1±4.6	27.2±4.8	0.291
Stone size (longest axis)	19.4±5.5	20.3±3.2	0.06
Operation time (min)	61.5±24.3	140.9±49.1	0.000
Hospitalisation time (day)	2.2±0.6	4.2±3.9	0.000
Stone-free rates (15th day) (n) (%)	31 (81.6%)	41 (100%)	0.004
Stone-free rates (3rd month) (n) (%)	35 (92.1%)	41 (100%)	0.107
Complications (n) (%)	1 (2.6%)	4 (9.8%)	0.194
Analgesic use	none:23 (60.5%)	none:21 (21.2%)	0.402
	non-NSAI:13 (34.2%)	non-NSAI:17 (41.4%)	
	NSAI:2 (5.2%)	NSAI:3 (7.3%)	
Quality of life scores	delighted (n:14)	delighted (n:14)	0.804
	pleased (n:22)	pleased (n:27)	

**FURS: Flexible ureterorenoscopy, LU:Laparoscopic ureterolithotomy, BMI: Body mass index, min: Minute, NSAI: Non-steroidal anti inflammatory drug.*

• Some disposable items costs calculation for LU

The trocars, harmonic scalpels, endoscissors, endograspers, veress needles, and cother cable costs were divided by 3, 4, 2, 5, 5, and 100, respectively because of their usage number.

Statistical analysis

Results are given as mean ± standard deviation (SD) and median with minimum and maximum. Data were analysed using SPSS-22 for Windows (SPSS, Inc., Chicago, IL) software. Statistical analyses of the means of continuous variables were performed with Student's t-test and a Mann-Whitney U test in the case of non-homogenic distribution. Qualitative variables were compared with Fisher's Exact test. A value of $p<0.05$ was accepted as statistically significant.

Surgical Technique for FURS

A semi-rigid ureteroscopy was performed to cannulate the ureteric orifice with 2 safety guidewire (Microvasive, Boston Scientific Corp, Natick, MA, USA) and to perform active dilatation under fluoroscopy. The ureteral access sheath was not used. FURS was pushed forward up to the ureteral stone over one of the guidewire. Upon reaching the stone, a 272-μ laser fibre (SureFlex™, 272 lithotripsy Fibers, American Medical Systems, San Jose, CA, USA) and laser lithotriptor machine (Stonelight™ 30, Cool Touch Branded Products, New Star Laser INC. Roseville, CA, USA) were used. At the end of the procedure, a JJ stent was inserted into the ureter, and small stone fragments were left in place for spontaneous passage. Ureteral double J stent was removed at three weeks later.

Surgical Technique for LU

Transperitoneal LU was performed according to the situation of the case. Having established pneumoperitoneum with veress needle, total of 4 trocars were used, 3 of them were 10 mm and 1 of them 5 mm trocar in both approaches. Having exposed the ureter, a longitudinal ureterolithotomy was made over the stone by the laparoscopic scalpel or scissors. Stone was extracted with a laparoscopic grasper, and then ureterolithotomy incision was closed with 4/0 vicryl after insertion of double J stent into the ureter. Ureteral double J stent was removed at 4-6 weeks later.

RESULTS

The number of patients in the FURS and LU groups was 38 and 41, respectively. The demographic characteristics of the patients in both groups are shown in Table I. There was not any statistically significant difference between the two groups with regard to age, BMI, stone size, stone-free rates at the 3rd month, and complication rates, ($p>0.05$) (Table I).

The operation time (min), and hospitalisation time (day) were statistically lower in the FURS group than in the LU group ((for operation time (min): 61.5±24.3 and 140.9±49.1, respectively, $p<0.05$) and for hospitalisation time (day): 2.2±0.6 and 4.2±3.9, respectively, $p<0.000$, (Table 1)).

The stone-free rate at the 15th day was lower in the FURS group than in the LU group (31 (81.6%) and 41 (100%), respectively, $p<0.05$) (Table I). However, this statistical difference disappears at three months ($p>0.05$, Table I).

Table II. The costs per one case for FURS.

Items	Cost per a case ($)	Number of usage
Flexible ureterorenoscope	12500/91=137.3	Used in 91 cases
Laser fiber	1071/70=15.3	Used in 70 cases
Guide wire	14/5=2.8	Used in 5 cases
Irrigation cost	2	Per case
Y tur setting	3	Per case
Hospital stay, per a day	15	Per day
The cost of second procedure in case of requiring	40	in only 4 cases
The mean cost for FURS (without hospital stay)	161.9	

**FURS: Flexible ureterorenoscopy.*

There was no statistically significant difference between the two groups in terms of analgesic use and quality of life scores (Table I). The cost per procedure is shown in Tables II and III. The mean costs of FURS and LU were $194.2 ± 12.4 and $ 179.2 ± 58.5, respectively (p<0.001, Table IV).

In 4 cases which FURS could not be applied in the first session due to ureteral stenosis, double J stent was inserted, and lithotripsy was achieved by FURS in the second session.

The complications for FURS

The double J stent push-backed into ureter in only one case (Clavien 3a).

The complications for LU

LU was converted to open surgery due to push-back of the stone into the renal pelvis. The nephrostomy tube was inserted due to increased drainage in only one case (Clavien 3a). Prolonged hospitalisation due to urosepsis and post-operative fever in 2 cases (Clavien 2).

DISCUSSION

In the last decade, the economic burden of surgical procedures started to gain more attention because of the economic downturn worldwide. This downturn has affected the decision-making process related to the most suitable surgical procedure for the patient (5-6). The cost of a surgical procedure and its clinical utility affect both the patients' and the physicians' choices (7). Moreover, this is more true for procedures requiring equipment dependent on advanced technology like the ones used in minimally invasive surgery. For that reason, urologists should become more aware of the economics of healthcare and should consider the true total costs and efficiency of different treatment modalities.

The approach to the upper ureter stones is a complex issue and may vary according to the stone size, the exact location, patients' factors and armamentarium of the clinics. Although the first two options treatment methods for the upper ureteral stones larger than 10 mm in size is ureteroscopic lithotripsy and SWL, respectively, according to the EAU-2019 guidelines on urolithiasis (1), management modalities consist of a huge spectrum including like FURS, SWL, PNL, laparoscopic surgery, mini-PNL, and open surgery (8).

We believe that the treatment decision will depend on the case in which the clinic is most experienced among the treatment modalities in many alternative situations. In this context, since we are a high-volume department in terms of laparoscopic surgery, we deemed it is necessary to investigate the

Table III. The costs per one case for LU.

Items	Cost per a case ($)	Number of usage
Trocar, 10mm	12/3=4	Used in 3 cases
Trocar, 5mm	27/3=9	Used in 3 cases
Harmonic scalpel	267/4=66.7	Used in 4 cases
Harmonic Cable	1070/100=10.7	Used in 100 cases
Endoscissors	23/2=11.5	Used in 2 cases
Endograsper	40/5=8	Used in 5 cases
Hemovac drain	1	Per a case
Vicryl	1	Per case
CO_2 gas	1	Per a case
Veress needle	5/5=1	Used in 5 cases
Coter cable	115/100=1.15	Used in 100 cases
Hospital stay, per a day	15	Per day
The mean cost for LU (without hospital stay)	116.1	

**LU: Laparoscopic ureterolithotomy.*

cost-effectiveness analysis between FURS and LU in order to use economic resources correctly.

Economic assessment methods, such as cost-effectiveness analysis (CEA), can be utilised to provide the most efficient distribution of scarce healthcare resources (9). The aim of the economic assessment in healthcare is to determine the value for money between different treatment modalities. There are 4 possibilities when comparing different modalities in regard to CEA: (1) more expensive and more effective, (2) more expensive and less effective, (3) less expensive and less effective, (4) less expensive and more effective (9-10). The modalities which fall into the fourth category are considered dominant and offer health gains at a lower cost (11).

While comparing different modalities concerning CEA, operation time that is one of the important factors that should be taken into consideration. The operation time of the preferred modality is expected to be shorter than the others, so that the operating room and operating room healthcare staff can be used more efficiently. However, this situation affects CEA as an invisible form. Our operation time for FURS is similar to those of Bagcioglu et al. and Pan et al. (73.07±13.5 min and 55.62±19.62 min, respectively) (10,12). The operation time for FURS that depends on the surgical technique and the experience of the clinic have been similar results, mostly in literature. According to our study, our mean operation time was lower in the FURS group than in the LU group (61.5±24.3 min and 140.9±49.1 min for FURS and LU, respectively, p<0.001, Table I). This difference is not only due to the operation time but also due to the difference in the preliminary preparation (such as positioning the patient and equipment) in the operating room. Regardless, FURS seems to be more advantageous in terms of operating room usage efficiency.

Hospitalisation time is another important factor that affects CEA results as an invisible form. However, it can prolong due to different reasons such as complication or pain feeling. As shown in our results, the hospitalisation time in the FURS group was significantly lower than in the LU group (2.2±0.6 days and 4.2±3.9 days for FURS and LU, respectively, p<0.001, Table I). Although there is no statistical difference in terms of complication rates between groups, the complication rate in the LU group was a bit higher than in the FURS group. According to our results, the invisible effect on CEA concerning with the loss of workforce is almost twice as high in LU group, but may not be meaningful for retired patients because no statistically significant difference was found in the quality of life scores of both groups in our study. According to our stone-free rates results at the 15th day, as expected, the stone-free rates for the LU group was significantly higher than the FURS group (81.6% and 100% for FURS and LU, respectively, p<0.004, Table I). However, this state of superiority becomes statistically insignificant at 3-month checks (92.1% and 100% for FURS and LU, respectively, p=0.107, Table I). Stone-free results for FURS are comparable to this SWL in the literature. Currently, SWL may be considered as one of the least invasive method for treatment of proximal ureteral stones, and because of this, it may be the first choice for most of the urologists. However, Khaladkar et al. reported 39% stone clearance rate after SWL procedure performed for large ureteral stones (>1.5 cm) (13). Also, worse cost-effectiveness was reported related to SWL when compared to ureterorenoscopy (14). Moreover, with larger stone size there is a higher risk of stone-street, which in turn may lead to re-intervention and may cause complications such as obstruction and urinary tract infection (15). Indeed, with its low stone-free rates and non-negligible complications, SWL does not seem to be attractive as a first-line treatment modality.

To our cost results revealed that the mean cost per procedure for FURS is significantly higher about $15 than the LU group (194.2±12.4 and 179.2±58.5 for FURS and LU, respectively, p<0.001, Table IV). These results contained the fee of the hospitalisation. When it is ignored hospital stay and its cost, similarly, our results showed that the FURS cost is higher about $48.1 than the LU group (164.2±12.4 and 116.1±10 for FURS and LU, respectively, p<0.001, Table IV). This statistical difference is largely due to the high cost of flexible ureterorenoscope itself. When it was analysed the effect of the hospitalisation time on these results, although the difference between two

Table IV. The mean costs of overall procedure.

COSTS ($)	FURS	LU	p
The mean cost per procedure	194.2 ± 12.4	179.2 ± 58.5	0.001
The mean cost without hospital stay	164.2 ± 12.4	116.1± 00	0.001

**FURS: Flexible Ureterorenoscopy, LU: Laparoscopic ureterolithotomy.*

groups is reduced because of the prolonged hospitalisation in LU group, the difference between groups is still significantly higher on behalf of the FURS group, but the amount of difference is about $15. The fee of the hospitalisation that affects this result can change from hospital to hospital depending on the quality of hospital services. However, at a future time, if the cost of the flexible ureterorenoscope can be reduced thanks to the improvements of technology, it may become more advantageous in CEA by equalising this difference between these two treatment modalities.

According to the effectiveness model described by Hoch et al. (11), our study falls into the second category; more expensive and less effective for the first 15 day but, then at the 3rd month more expensive and equally effective. CEA helps with this decision by estimating the additional cost per unit of additional gain.

Limitations of study

The first limitation of our study; the results of CEA studies in this area may vary from hospital to hospital, from country to country due to the difference in economic standards.

The second limitation of our study; the cost of the flexible ureterorenoscope per a case depends on the experience of that clinic, the more experience, the more prolonged survival of the flexible ureterorenoscope and as a result the more case means. The third limitation of our study; although one of the authors (AD) has studied about healthcare management and administration, no formal cost analysis by a chartered accountant was done in this study.

CONCLUSION

It seems that usage of FURS is equally effective to LU in terms of stone-free rates at the third month for larger than 1.5 cm in size for upper ureteral stones. The cost of FURS is statistically higher than LU. However, the difference in cost can change according to the hospitalisation time and the fee of the hospitalisation. Although according to EAU-2019 guidelines on urolithiasis, FURS is shown as the first choice for the upper ureteral stones larger than 10 mm in size, if the laparoscopic experience is in high-level situations, LU may be a suitable alternative to FURS.

ETHICS STATEMENT

The present study protocol was reviewed and approved by the institutional review board of Uludağ University. Approval number: 2019-16/20.

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