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ORIGINAL ARTICLE

Comparing extracorporeal shock wave lithotripsy and ureteroscopy laser lithotripsy for treatment of urinary stones smaller than 2 cm: a cost-utility analysis in the Spanish clinical setting

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Abstract

Purpose To analyze the efficiency and cost-utility profile of ureteroscopy versus shock wave lithotripsy for treatment of reno-ureteral stones smaller than 2 cm.

Methods Patients treated for urinary stones smaller than 2 cm were included in this study (n = 750) and divided into two groups based on technique of treatment. To assess the cost-utility profile a sample of 48 patients (50% of each group) was evaluated. Quality of life survey (Euroqol 5QD-3L) before–after treatment was applied, Markov model was designed to calculate quality of life in each status of the patients (stone or stone-free with and without double-J stent) and to estimate the incremental cost-utility. Monte carlo simulation was conducted for a probabilistic sensitivity analysis. Chi-square was used for comparing qualitative variables and *T* student's for continuous variables.

Results Shock wave lithotripsy group had 408 (54.4%) and ureteroscopy group had 342 (45.6%) patients. Of them, 56.3% were treated for renal stones and 43.7% for ureteral stones. Ureteroscopy produced slightly higher overall quality of patients' life, but produced a significant higher overall cost per quality-adjusted life year (QALY) than shock wave lithotripsy, exceeding the cost-utility threshold (20,000€/QALY). Sensitivity analysis confirmed results in 93.65% of cases. Difference was maintained in subgroup analysis (ureteral vs renal stones).

Conclusions Results suggest that in our clinical setting shock wave lithotripsy has better cost-utility profile than ureteroscopy for treatment of reno-ureteral stones less than 2 cm, but excluding waiting times, in ideal clinical setting, ureteroscopy would have better cost-utility profile than shock wave lithotripsy.

Keywords Lithotripsy · Quality-adjusted life years · Quality of life · Ureteroscopy · Urinary calculi

Introduction

Urinary lithiasis has prevalence from 1 to 13% showing great variability around the world [1]. In Spain, its prevalence is 5.06% (2,233,214 patients) and its incidence is 325,079 cases per year [2]. The high recurrence rate (40% and 60% at 5 and 9 year, respectively) [3] leads to several treatments, admissions, high impact on quality of life and decrease in productivity, generating an estimated burden of $ 4.5 billion/year for healthcare system, and losses of $775 million by indirect costs in USA [4].

Regarding the surgical treatment of urinary stones smaller than 2 cm, the most widely used techniques are extracorporeal shock wave lithotripsy (SWL) and ureteroscopy with Holmium-YAG laser lithotripsy (URS/RIRS). The choice of one or the other depends on anatomical factors, stone characteristics and safety profile of each technique [5].

Despite several investigations have showed that URS/RIRS has better cost-effectiveness profile [6–8], in Spanish medical setting SWL seems to be superior in terms of direct and indirect cost [6–10]. However, another factor as patient's quality of life (QOL) has been less evaluated, showing so far

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a slightly dominance of SWL over URS/RIRS in patient's QOL [6, 11–13].

This study belongs to a bigger research project started in 2012 and still going on to evaluate our own cost-effectiveness and cost-utility profile in all possible scenarios of stone treatment. The objective of this research is to analyze which treatment technique for reno-ureteral stones smaller than 2 cm has a better cost-utility profile.

Materials and methods

A total of 750 patients treated for urinary stones smaller than 2 cm from 2012 to 2015 were included consecutively in this prospective study. Patients were divided into two groups: patients treated with ureteroscopy with Holmium-YAG laser lithotripsy as initial technique (URS/RIRS group) versus, patients treated with up to four SWL as initial technique (SWL group). Patients younger than 14 years, stones higher than 2 cm, multiple stones, pregnancy, blood disorders or uncontrolled urinary tract infection were excluded. Demographic parameters, stone size, localization, treatment-related variables, hospital stay, per-operative complications, and medical costs were analyzed and compared between both groups.

Spain has a public healthcare system that guarantees universal coverage for all residents. The hospital's economic model is based on ABC model (activity-based costing) and top-down method to calculate the costs by process care activity [14]. Following this method hospitalization and surgery costs were calculated, based on each diagnosis-related groups weight (DRGs).

To evaluate the procedure outcome X-ray and ultrasound were performed 1 month after each treatment session. In uncertain cases a CT was performed. Stone-free rate (SFR) was defined by lithiasis absence or clinically insignificant residual fragments (smaller than 4 mm) [15]. The final SFR was determined 6 months after the first treatment. Determination of first treatment modality relied on discussion between surgeons and patients following the current clinical guidelines and recommendations. This study was approved by the ethical committee of our institution.

SWL technique

Extracorporeal shock wave lithotripsy was performed using a third-generation electromagnetic lithotripter (Siemens Lithoskop, shockwave system Pulso). The procedure was performed in supine position. Stone localization during the procedure was performed by X-ray. Patients were under intravenous analgesia with meperidine and midazolam. The shock frequency used was 2 Hz (120). The mean of total number of shock waves applied was 5424.02 waves (SD 1741.7), the mean of voltage, maximum voltage and total energy applied per session was 2.82 kV (SD 0.72), 4.19 kV (SD 0.76) and 210.21 J (SD 151.84), respectively.

In case of unsuccessful treatment, patients underwent a second SWL procedure, with a maximum of four according to our institutional protocol. If residual stones persisted, a ureteroscopy was performed.

URS/RIRS technique

All procedures were performed under general anaesthesia and inpatient regime. A 6.5 Fr semi-rigid ureteroscopy (Karl Storz GmbH) was employed. The fragmentation source was Stonelight® Holmium Laser System by AMS Inc, with 550 µm fiber. In the caliceal stones treatment, a flexible ureteroscope was employed (Flex-XTM 7.5 Fr × 600 mm, Karl Storz GmbH) with a 275 µm fiber and a 10–12 Fr ureteral access sheath. Stones were fragmented (1–1.2 J and 8 Hz) and fragments were removed with a nitinol basket. An open double-J stent and Foley catheter were placed after the procedure in all patients. The urethral catheter was removed 24 h later, and double-J stent was removed 10–15 days after procedure.

In patients with significant residual fragments in a maximum of four weeks after the first procedure, a rescue ureteroscopy was performed.

Cost utility analysis

Cost utility analysis (CUA) is an economic evaluation when the outcomes of alternative procedures are expressed in terms of a "utility based" unit of measurement. The most used is the quality adjusted life year (QALY) [6, 16]. The evaluating period was 6 months, (time needed to treat the lithiasis) thus, the obtained QALYs were divided by twelve to obtain the equivalence per month. Finally, they were added to obtain the total QALYs in that 6-month period.

To assess the cost-utility profile, 48 patients of the sample were included to evaluate their quality of life, 24 of them undergoing URS/RIRS and 24 treated with SWL from January to December 2016. The QALYs were determined through Euroqol-5D-3L quality of life questionnaire [17, 18].

The questionnaire was applied to the patients the day before the procedure and once the stone treatment was completed. A Markov model comparing both techniques was designed to calculate quality of life in each status of the patients (urinary stone with and without JJ stent, and stone-free patients with and without JJ stent). This was compared with the respective costs to perform a cost-utility analysis.

Two different situations were analysed. First, our actual situation, with a median of 5 months (3.5–8) of surgical waiting list to perform any procedure under general anaesthesia, and with a median of 2 weeks (1–4) of waiting time to perform a SWL. On the other hand, an ideal situation, performing both procedures within the first month. In both cases, a subgroup analysis was performed with renal and ureteral stones.

The probabilities of success of each technique were obtained from a decision tree elaborated with the main sample of patients. A Monte carlo simulation was conducted for a probabilistic sensitivity analysis [19]. It is explained in detail in supplementary material.

To assess the cost of each procedure, the hospitalization cost was calculated, including procedure cost, supplies, hospital stay, complications, additional procedures, etc. In addition, the postoperative visits and examinations' costs were also recorded.

For statistical analysis, categorical variables were resumed as frequency and percentage. Continuous variables were resumed using the average and 95% standard deviation (SD). Chi-squared test was used for comparing qualitative variables and a *T* Student's test for continuous variables. A statistical significance of 0.05 was considered ($p < 0.05$).

Results

Of 750 patients, 408 (54.4%) were in the SWL group, of them 242 (59.3%) and 166 (40.7%) had renal and ureteral stones, respectively. The remaining 342 patients (45.6%) were in the URS/RIRS group, of them 180 (52.6%) and 162 (47.4%) had renal and ureteral stones, respectively. Both groups were comparable with respect to BMI, stone size, side and location. Otherwise, statistically significant difference was found regarding patients age, gender and the antecedents of previous urinary drainage and previous stone treatment (Table 1).

Overall success for SWL and URS/RIRS were 77.1% and 90.7%, respectively, with statistical differences ($p < 0.001$). When it was stratified to stone location, the success rates for SWL and URS/RIRS were 76.8% and 86.7% ($p = 0.015$) for renal stones, and 77.6% and 95% (p 0.015) for ureteral stones, respectively. Average SWL sessions needed were 2.29 (SD 1.27). A total of 163 (40%) cases were resolved with a single procedure.

Otherwise, SWL showed higher complication rate (112 patients; 27.5%) than URS/RIRS (50 patients; 15.1%). Chi-square test revealed significant difference between complication rate in both techniques ($p < 0.001$). Adverse events were evaluated separately. Intra-operative complications and postoperative adverse events in both techniques are shown in supplementary materials.

Regarding cost-effectiveness analysis, in all cases, URS was more expensive and less effective than SWL. The overall cost of SWL was 1524.781€, with an effectiveness of 0.99. The overall cost of URS was 1738.329€, with an effectiveness of 0.97. The incremental Cost-Effectiveness ratio (ICER) was − 12,739.5805, being favourable the SWL. When the subgroup analysis (kidney stones vs ureteral stones) was performed, no differences were found, maintaining SWL as a favourable technique. The sensitivity analysis accepted SWL as favourable alternative in 90.35% of simulated cases.

Table 1 Sociodemographic distribution of patients

Variable	SWL mean (SD)	URS mean (SD)	*p* value
Age	53.02 (12.58)	55.68 (13.96)	0.006*
BMI	26.99 (4.33)	27.41 (5.47)	0.38*
Stone size			
Maximum diameter (mm)	11.19 (5.85)	10.93 (6.35)	0.57*
	n (%)	*n* (%)	
Gender			
Male	253 (62)	172 (50.3)	0.001^
Female	155 (38)	170 (49.7)	
Stone side			
Right	187 (45.8)	153 (45.4)	0.94^
Left	221 (54.2)	184 (54.6)	
Stone size			
< 1 cm	220 (54.7)	61 (48.5)	0.1^
> 1 cm	182 (45.3)	171 (51.5)	
Stone location			
Renal	242 (59.3)	180 (52.6)	0.07^
Ureteral	166 (40.7)	162 (47.4)	
None	328 (80.4)	222 (66.5)	< 0.001^
Previous drainage			
Double-J stent	76 (18.6)	104 (31.1)	
Nephrostomy tube	3 (0.7)	7 (2.1)	
Both	1 (0.2)	1 (0.3)	
None	403 (98.8)	188 (55.8)	< 0.001^
Previous treatment			
ESWL	4 (1)	122 (36.2)	
URS	0 (0)	22 (6.5)	
PCNL	1 (0.2)	6 (0.8)	

*Student's test

^Chi-square test

Results of CUA are shown in Table 2. In the first scene, conducting incremental cost-utility ratio (ICUR) at 5th month of waiting list, the Monte carlo sensitivity analysis supports SWL dominance in 93.65% of cases in global analysis, 62.05% of cases in ureteral stones and 87.7% of cases in renal stones. When both techniques are performed within the first month, sensitivity analysis maintained URS/RIRS as dominating alternative in 77.3% of cases in global

Table 2 Cost-utility analysis results

URS at 5th month of waiting list					
	Cost (€)	Utility (QALYS)	Δ Cost (€)	Δ Utility (QALYS)	ICUR (Δ €/Δ QALYS)
Global analysis					
SWL	1524.781	0.51832600	213.547	0.00020155	1059,482.3
URS	1738.329	0.51852756			
Ureteral stones					
SWL	1545.507	0.52217306	95.343	0.00321224	29,681.404
URS	1640.851	0.52538530			
Renal stones					
SWL	1508.906	0.51537932	334.821	−0.00426669	−78,473.316
URS	1843.728	0.51111263			
URS and SWL performed at the same time					
	Cost (€)	Utility (QALYS)	Δ Cost (€)	Δ Utility (QALYS)	ICUR (Δ €/Δ QALYS)
Global analysis					
SWL	1524.781	0.51832601	213.547	0.0222	9608.890
URS	1738.329	0.54054999			
Ureteral stones					
SWL	1545.507	0.52217306	95.343	0.0214	4445.842
URS	1640.851	0.54361868			
Renal stones					
SWL	1508.906	0.51537932	334.821	0.0219	15,321.769
URS	1843.728	0.53723198			

analysis, 81.15% of cases in ureteral stones and 53.65% of cases in renal stones.

Discussion

Two of the main minimally invasive treatments for renal and ureteral stones are SWL and ureteroscopy. The choice of one or another depends on numerous factors, but costs have been increasingly considered leading to the development of cost-effectiveness analysis by several groups and, in some cases, changing the decision tree in their daily practice.

Another factor, maybe less studied, considers the patient's QOL (CUA) before-after treatment. Quality of life is an estimate of freedom from impairment. When it includes psychosocial, physical and emotional status as well as patient autonomy, we can talk about health-related quality of life (HRQOL) [20]. Patients with urinary stones have been described as an ideal sample for evaluation of HRQOL due to its prevalence, recurrence, moderate to severe symptoms and presence in adult and productive population [11]. Although some investigations about QOL in patients with urinary stones have been carried out, the evidence comparing directly SWL vs URS/RIRS from a cost-utility approach is scarce.

According to our results, if both techniques are conducted within the first month, URS/RIRS shows as a more expensive technique, but also with higher improvement in HRQOL after treatment. Overall, URS/RIRS shows dominance over SWL with an ICUR of 9608.89 €/QALY. This trend was maintained in subgroup analysis, but with a higher dominance of URS/RIRS over SWL in ureteral stones (ICUR 4445.84) than renal stones (ICUR 15,321.76).

Interestingly, when both techniques were analyzed according to our daily practice considering URS/RIRS and SWL waiting list, SWL showed a better cost-utility profile. Thus, when SWL is carried out within the first month and URS/RIRS is performed from the 5th month, shows an overall ICUR of 1,059,482.3 €/QALY, and a ureteral ICUR of 29,681.40/QALY, above the established cost-utility threshold (20,000€/QALY) [21, 22]. For renal stones, URS/RIRS resulted more expensive and got less QALYs, obtaining an ICUR of −78,473.31 €/QALY.

Multiple factors may explain these differences. The longer waiting list penalizes URS/RIRS due to the known direct relationship between time suffering any disease and the impact in HRQOL. Besides, 38.1% of patients waiting for URS/RIRS had JJ stent, that could affect the results decreasing HRQOL, although these variables were taken into account through the Markov model and patients with JJ stent usually have priority on our waiting list. Similar result was described by Bensalah, who found indwelling catheters as a negative factor for HRQOL [23].

Izamin et al. performed an interesting prospective and comparative analysis between SWL (30 patients) and URS (37 patients) as treatment for proximal ureteric stones regarding effectiveness, cost and QOL. They found similar SFR, but higher total cost for SWL vs URS (930.02RM vs 621.95RM). However, the SWL group had a larger median size of the stones which may limit its effectiveness, and its higher cost may be explained by the equipment price: 666.14RM for SWL and 51.57RM for URS [6]. To assess QOL, the SF-36 questionnaire was applied. When both techniques were compared there was a slightly higher QOL score for URS, but did not reach statistical significance. Regarding the cost-utility analysis URS seemed to have a favourable profile, with a total cost per increment in QOL of 86.18RM vs 247.02RM for SWL [6]. However, waiting list for each technique is not mentioned, and the high SWL equipment cost could explain the difference compared to our results.

Otherwise, Arafa and Rabah compared 275 patients with urinary stones after lithotripsy matched with 275 healthy volunteers. They recorded the results on SF-36 questionnaire 3–15 months after treatment. Surprisingly they found that lithotripsy cases had significantly higher scores in most of the questionnaire subscales, being overcome by volunteers scores only in body pain subscale. Their results may be explained by the so-called response shift: the improvement in HRQOL can be a result of an accommodation process that involves changing internal standards and values. Among the types of treatments, SWL seemed to be superior to URS/RIRS and PCNL regarding HRQOL [11].

Finally, similar results were reported by Kurahashi in Japanese population, with no significant differences in SF-36 scores for any scale between lithotripsy patients and healthy volunteers after an observation period of 3–78 months. However in his experience, SWL was superior to URS/RIRS and PCNL only in general health, with no differences in the other seven subscales [24]. Although these results are similar to ours, direct comparisons should be made with caution since HRQOL assessment should be based on QALY, a measure not provided by the SF-36 questionnaire.

Our report has several strengths. Cost-effectiveness analysis was performed using a large number of patients, and several variables have been considered. It is the first study, to our knowledge, with a direct comparison between URS/RIRS and SWL from a cost-utility point of view, using a validated HRQOL questionnaire and a Markov model to explore all the possible status of our patients before, during and after treatment. This study will allow us to make decisions considering not only the effectiveness of the technique, so we will be able to inform the patients considering other important outcomes. Another strength is the prospective evaluation of QOL, because stone disease has a significant memory bias that occurs when HRQOL is retrospectively assessed.

The main limitation of our study is the small sample of patients in whom HRQOL was assessed. That could explain the variation in Monte carlo sensitivity analysis when subgroup analysis was performed. On the other hand, we applied the EQ-5D questionnaire, a generic HRQOL assess tool, not specific for urinary stone patients. It would be interesting to develop a specific HRQOL questionnaire. Finally, it is difficult to extrapolate our results to other clinical units, since there are a lot of variables which influences on cost-utility analysis.

Conclusion

Our results show that in an ideal clinical setting, URS/RIRS seems to have a better cost-utility profile than SWL. However, in our situation, due to longer waiting list of URS/RIRS, SWL showed a better cost-utility profile for the treatment of small-moderated-sized urinary stones. We encourage urologists to consider their patients' HRQOL, as well as the clinical and economic outcomes as it could improve the assistance quality and contribute to the sustainability of the healthcare system.

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Code availability Microsoft Office, IBM SPSS v21.

Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to declare.

Ethics approval This research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The study protocol was approved by our institute's committee on human research.

Consent for publication All authors declare their consent for publication.

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