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ORIGINAL PAPER

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Comparison of success rates and financial cost of extracorporeal shock-wave lithotripsy in situ and after manipulation for proximal ureteral stones

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Abstract Our aim was to compare the stone free rate and the financial cost between in situ and after manipulation shock wave lithotripsy (SWL) for proximal ureteral stones. A total of 130 patients with proximal ureteral stones were prospectively randomized into two groups. Sixty-five patients (group 1) underwent SWL in situ and 65 patients (group 2) underwent SWL after an attempt was made to push back the stone into the kidney with the help of a ureteral catheter. The mean per person financial cost of both techniques was estimated after a follow up period of 3 months. The stone free rate 1 month post treatment was 83% (54/65 patients) for group 1 and 95% (62/65) for group 2. The higher success rate at 1 month for the pushback group was statistically significant ($P = 0.04$) but was correlated with a higher cost (€852 vs €1,008.5). Fifteen additional sessions of SWL and follow up visits were needed in group 1, therefore making the final costs of the two therapeutic pathways almost equal (€1,050.9 vs €1,088.9), with no great difference in the overall fragmentation rates at 3 months between groups (94% and 97%, respectively). Stone manipulation offers higher stone free rates faster than in situ extracorporeal SWL, but is more expensive. This disparity in cost is diminished when costs are corrected for follow-ups and treatment of complications.

Keywords ESWL · In-situ manipulation · Proximal ureteral stone

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Introduction

Cost effectiveness is a very important factor when dealing with health care issues which often dictates therapeutic approaches in some countries. Ureteroscopy is cheaper and has challenged extracorporeal shock-wave lithotripsy (ESWL) in the treatment of upper ureteral stones. Despite its very high success rate, most patients do not select it as a first therapeutic option. ESWL is the therapy preferred as initial management for such stones in Greece due to its non-invasiveness.

A stone in the proximal ureter can be treated successfully by in situ ESWL [1, 6, 7, 8, 14, 17]. Nevertheless, the fact that the stone can fragment more easily when there is space around it has lead some urologists to attempt to push the stone back into the renal pelvis where more space is available, and then perform the ESWL session. Results comparing the two methods are conflicting [3, 12, 15, 22, 23, 24, 25].

A prospective randomized study was designed in order to compare the effectiveness of ESWL with and without manipulation. The cost of both therapeutic approaches was also calculated in order for cost-effectiveness to help us choose between the two pathways.

Material and methods

In this randomized prospective study, 130 patients treated from January 1999 to February 2001 for a single proximal ureteral stone were divided into two groups. Group 1 included 65 patients who were managed with SWL in situ while group 2 included 65 patients who underwent SWL after ureteral manipulation of the stone. The Scientific Council of our hospital approved the study and each patient provided informed consent.

All of the patients included in the study had normal renal function and sterile urine before therapy. They were all submitted to intravenous urography to assess stone position and the degree of obstruction. We excluded patients with systemic diseases, such as diabetes and hypertension, as well as those patients with stones less than 0.5 cm or more than 2 cm. Patients with stones smaller than 5 mm were excluded because of their high probability of spontaneous expulsion while those with stones larger than 2 cm were not

included because ESWL is not very efficient in the treatment of these stones [14]. Stone volume was assessed with the PICA 88 computer programme [7]. Patients with severe dilatation of the renal pelvis and calyces were also excluded. The degree of obstruction was subjectively evaluated as grade 1 or 2 (grade 1: no dilatation, grade 2: mild dilatation of the pelvis).

All patients underwent stone shock wave treatment in a supine position. In case of discomfort or pain, 0.025 mg of fentanyl citrate was intravenously administered. In the second group of patients, the stone was pushed back into the kidney with the help of a 6 F ureteral catheter using local anesthesia (transurethral application of 10 cc lidocaine jelly 2%) before the SWL procedure. The procedure was performed under fluoroscopic guidance and antibiotic prophylaxis was administered. Saline was flushed through the catheter on several occasions in order to facilitate manipulation. If the push back manipulation was not possible, an attempt was made to bypass the stone with the ureteral catheter or to place its tip immediately below the calculus. In the latter case, saline irrigation was used during shock wave treatment. The ureteral catheter was removed immediately after SWL in all of the above cases. All procedures in both groups of patients were performed on an outpatient basis.

A Dornier lithotriptor (DL-50) was used and a maximum number of up to 2,500 shock waves was delivered to every patient of both groups. The procedure was performed under periodic fluoroscopic guidance. Shock wave lithotripsy was occasionally terminated early when total destruction of the stone was evident.

All patients were evaluated monthly for a period of 3 months with a KUB and a renal ultrasound to assess the results of treatment. Treatment was considered successful when the patients were stone free.

Statistical analysis was performed using the χ^2-test with Yates correction when the values in the contingency tables were very small.

The financial cost for the treatment of each group was estimated using the following economic parameters: (1) cost of the SWL session (including the cost for lithotriptor maintenance), (2) cost of manipulation (including the expense of an outpatient endoscopic-operation room), (3) cost of the ureteral catheter used, (4) cost of medications used during the procedures, (5) cost of follow-up visits, and (6) cost of emergency room visits. The estimations were based on prices dictated by the National Health System Medical Care Value Tables, as these prices are equal for all public hospitals. Confirmation of billed services was done in consultation with the Hospital Accountant's Office. Cost of treatment modality was estimated for each patient separately until he was either stone free or reached the 3 month period, as determined in the initial study planning. The mean cost of each therapeutic modality was calculated by dividing overall cost by the number of patients in each group.

Results

Both groups were comparable for gender, age, stone site, size and initial degree of obstruction (Table 1). The stone was pushed back into the renal pelvis successfully in 55 out of 65 patients (84.6%). In nine cases, stone manipulation failed and the ureteral catheter bypassed the stone. In the remaining patient, the ureteral catheter was placed and remained underneath the calculus during SWL. The mean number of shock waves used in groups 1 and 2 was 1,844 and 1,350, respectively, while the mean power per session was 78% vs 72%.

Stone free rates overall and 1 and 2 months are listed in Table 2. Patients with residual lithiasis at 1 and 2 months needing an additional procedure are listed in Table 3. At 3 months, no change of residual fragment status was observed. Therefore, final success rates for SWL in situ and after manipulation were 94% and 97%, respectively. In total, 80 SWL sessions were performed in-group 1 and 65 in group 2. No statistical difference was found between the two groups in terms of the final outcome of stone treatment. However, there was a statistical difference noted after initial treatment at 1 month in favor of the ESWL after manipulation group ($P = 0.04$).

Table 1 Patient characteristics

	In situ SWL group	SWL after manipulation group
Mean age (range)	43 (20–62)	51 (22–65)
Gender		
Men	50	48
Women	15	17
Stone location		
Right side	25	28
Left side	40	37
Mean stone size (mm)	9.4	11.2
Grade of obstruction		
Grade 1	15	17
Grade 2	50	48

Table 2 Stone free rates

Stone free (%)	In situ group	Manipulation group	*P*
At 1 month	54/65 (83%)	62/65 (92%)	0.04
At 2 months	61/65 (94%)	63/65 (97%)	0.68
Overall after 3 months	61/65 (94%)	63/65 (97%)	0.68

For each grade of obstruction and stone size, the data on the number of shock waves and the number of patients stone free at 3 months are given in Table 4. There was a correlation between the size of stone and the number of shock waves needed for complete disintegration, with bigger stones needing more shock waves for fragmentation. Bigger stones, as expected, had lower success rates in both groups, while they were more effectively treated after manipulation (57% vs 86%). Differences between groups were not statistically significant.

The complications presented in both groups were renal colic due to residual fragments and urinary tract infections. Twenty and 15 patients had a renal colic post treatment in the in situ and after manipulation groups respectively ($P = 0.429$), while urinary tract infections were seen in five and eight patients from groups 1 and 2, respectively ($P = 0.56$). Renal ultrasound revealed a moderate dilation of the renal pelvis and calyces in patients with colic pain. Since no evidence of infection was present, patients were treated as outpatients and remained for a short stay in the emergency room until the pain subsided. They were invited for another ultrasound a week later, which showed mild or no dilation at all in all patients. No double J stent or needle nephrostomy was needed. Patients with signs of urinary tract

Table 3 Patients with residual fragments

Need for additional procedure	In situ group	Stone size	Manipulation group	Stone size
At 1 month				
Yes	11	> 8 mm	0	
No	0		3	< 5 mm
At 2 months				
Yes	4	> 7 mm	0	
No	0		2	< 5 mm
At 3 months				
Yes	4	> 5 mm	0	
No	0		2	< 5 mm

Table 4 ESWL session's characteristics and stone free rates according to stone burden and grade of obstruction

	No. of shock waves (mean ± SD)		Final no. of stone free patients (%)		
	SWL In situ group	SWL manipulation group	SWL in situ group	SWL manipulation group	*P*
Stone burden (cm^3)					
< 0.15	1,760 ± 371	1,226 ± 245	40/40(100%)	36/36(100%)	
0.15–0.25	1,960 ± 401	1,420 ± 252	17/18(94%)	21/22(95%)	0.88
0.25–0.45	2,021 ± 440	1,631 ± 338	4/7(57%)	6/7(86%)	0.26
Obstruction grade					
Grade 1	1,756 ± 437	1,176 ± 235	15/15	16/17	0.33
Grade 2	1,902 ± 302	1,522 ± 277	46/50	45/46	0.36

infections in urine specimens performed after low-grade fever were treated conservatively with antibiotic coverage without the need for hospitalization or the placement of a double J stent, since no dilatation of the collecting system was observed.

Table 5 lists the cost of the procedures, consumables and overall therapies. Since a patient stopped seeing his doctor only when found stone free, there were more follow-up appointments per patient in group 1, thus increasing the follow up cost. Overall, 80 follow-up visits were done in group 1 and 70 in group 2, making a total follow-up cost of €1,200 in group 1 and €1,125 in group 2. There were no severe complications such as ureteral perforation, urinomas or sepsis requiring hospitalization. Thirty patients from group 1 and 23 from group 2 visited the emergency room and therefore the overall cost of emergency visits was higher in group 1 (€150 vs €115).

At the end of the first therapy for all of the patients, cost per patient was more in the manipulation group (Table 5). However, when the costs for additional sessions of SWL, follow up and emergency visits were calculated, the cost for both groups was almost equal (€1,050.9 vs €1,088.9)

Table 5 Cost of procedures, consumables and overall therapies in Euro

Service/consumable	Cost (Euro)
SWL session (+lithotriptor maintenance)	822 + 15
Manipulation procedure using the day case operation room	153
Ureteral catheter	3.5
Follow up visit with KUB and renal US	15
Emergency room visit	5
Mean (per person) cost of therapy after first treatment	
In situ SWL	852
SWL after manipulation	1,008.5
Overall mean (per person) cost of therapy	
In situ SWL	1,050.9
SWL after manipulation	1,088.9

Discussion

ESWL still remains the treatment of choice for proximal ureteral stones, despite the appearance of new, smaller caliber ureteroscopes and laser technology that present an attractive alternative for the therapy of these stones [16, 23].

Stones can be more effectively broken when there is more space around them in which they can expand when absorbing the energy from the shock waves [19]. Therefore, many urologists opt to manipulate a proximal stone by pushing it back to the more spacious renal pelvis. On the other hand, there is always the risk of injuring the ureter during manipulation with a ureteral catheter and therefore many prefer performing SWL in situ for these stones.

Results on the efficacy of these two methods are conflicting. Favorable outcomes with stone manipulation before ESWL have been reported beginning in the late 1980s [17]. Stone manipulation in a Medline review by Wang et al. [25] was found to be more efficient overall and rates ranged from 73% to 96% [3, 15, 22]. Nevertheless, numerous other reports from in situ ESWL have

been equally good with success rates between 50% and 97% [1, 6, 7, 8, 12, 14, 15, 20, 24].

A prospective randomized study was designed in order to assess the need to manipulate a proximal ureteral stone before ESWL using a latest generation lithotriptor. This was combined with an effort to estimate cost effectiveness for each treatment modality and evaluate whether this could help us choose between the two therapeutic pathways.

The rate of successful manipulation of the stone was 84.6%, which is similar to the successful pushback rates in other studies [9, 11]. A final stone free rate of 94% was accomplished when in situ SWL was applied. When the stone was pushed back the success rate was 97%. These results are similar to those reported by others [8, 15, 22, 24]. Overall, stone free rates between the two groups were not found to be statistically different, but when evaluating the results at 1 month after therapy, ESWL with stone manipulation was more effective than ESWL in situ, with success rates being 95% vs 83%, respectively ($P = 0.04$).

Another interesting finding is that larger stones are more efficiently treated following manipulation (86% vs 57%, Table 4). It has been shown experimentally that in vitro changes in the environment around the stone offer higher rates of fragmentation [19]. Manipulation and push back procedures induce similar changes in vivo by creating more space around the stones and therefore it seems that manipulation plays a more important role in larger stones, which seem to need the space for expansion more than the smaller ones.

Given the high success rates for both treatment modalities, therapy decision making must also take into consideration parameters like possible complications and overall cost. Ureteral catheterization is an invasive procedure which may lead to infection, perforation, urine extravasation, and late ureteral stricture [5]. Apart from several urinary tract infections, which could also be attributed to stone fragmentation, we did not experience any ureteral perforations with subsequent extravasation. No late ureteral strictures were seen but our follow up was too short to be conclusive on this matter.

Ureteroscopy is cheaper [10, 13, 18, 21] but more invasive than ESWL and when patients opt for this kind of management they usually have the quickest way to resolve their problem in mind. Therefore, the question raised is whether stone manipulation could decrease the overall cost of ESWL by offering a faster, stone free status by being less invasive than ureteroscopy.

In most studies, the initial purchase cost of the lithotriptor contributes significantly to treatment cost [2, 18]. The overall cost of an ESWL session seems to be low in our study. This could be attributed in part to the fact that the cost of lithotriptor purchase was not included when calculating the final session cost, since our institution is a reference center treating a large volume of stone patients every year, and therefore the lithotriptor has already been financially discounted. In any case, it would influence the cost in both groups equally and therefore play a minor role in the cost variation between the two groups. In an effort to diminish costs, push back procedures were performed on an outpatient basis in all cases. For many years now in our institution, ESWL sessions have also been performed on an outpatient basis unless medically otherwise indicated. This contributes to cost containment as well.

Cost-effectiveness analysis is a useful tool for comparing different treatment options, especially if these techniques show similar therapeutic results [4]. Stone manipulation was €156.5 more expensive compared with in situ lithotripsy when only one treatment without complications and secondary therapy was calculated. Although at first sight it is obvious that stone manipulation would be more expensive because of the simple ureteral stent placement needed, when considering the overall costs of a method, all additional therapeutic procedures and hospital visits should also be included. Therefore, second and third ESWL sessions, additional emergency room and follow-up visits, as well as additional examinations, must be incorporated in the final cost. This makes the cost difference between the two methods only €33 with the manipulation group still being slightly more expensive (€1,050.9 vs €1,088.9). When a patient became stone free, he was not invited to the next follow-up visit. In group 1, more patients had residual fragments and therefore needed more follow-up visits. Similarly, more emergency visits were noted in group 1 during the whole follow-up period (30 vs 23). Emergency visits were due to complications and were treated conservatively in all cases.

Initial treatment with stone manipulation was more expensive (€1,008.5 vs €852) but also more efficient (95% vs 83%). Therefore, more patients became stone free and returned to their jobs sooner. Although a ureteral stone is not a life threatening situation and can be asymptomatic for a long period, the fear of renal colic can put a patient into a state of continuing mental stress due to the sudden onset and intensity of symptoms. The cost of working hours lost due to residual fragments can not be estimated, since it is different for each patient and might refer to avoidance of physical straining, postponement of business travel, or other job related activities, which are different for each occupational category. In some professions, such as pilots [26], higher stone free rates in a short time, even at higher financial cost, is desired.

The selection of optimal treatment is still institution dependent. Treatment strategy depends on factors like stone size and location, degree of hydronephrosis, treatment cost, patient preference, technological background and the doctor's skill [18].

ESWL after stone manipulation in this study presented higher stone free rates in a shorter period of time with a slightly higher financial cost. Therefore, management planning must take into consideration the fact that some patients are willing to take the risks of placing a ureteral catheter and manipulating the stone before SWL in order to be able to return to full activity sooner. In situ SWL provides similar final stone free outcomes

but could also imply more therapeutic sessions, and should be used when a high stone free rate in a short time is not the main goal of the treatment.

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