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ORIGINAL PAPER

Is shock wave lithotripsy efficient for the elderly stone formers? Results of a matched-pair analysis

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Abstract The aim of the study was to evaluate the impact of age on the efficacy of extracorporeal shock wave lithotripsy (SWL), in a comparative study based on the principles of matched-pair analysis. Over a period of 4 years, 2,311 patients were treated with SWL in a tertiary referral center. Patient and stone data were recorded in a prospective electronic database. Among these patients, 115 (4.97%) were older than 70 years of age and fulfilled the criteria for inclusion in the study (Group A). For the purposes of the comparative analysis, Group A patients were matched for gender and stone parameters (side, location of stone, and diameter ±2 mm) with a control group of patients under the age of 70 (Group B). Following matching, the patients' electronic medical records were reviewed, to identify SWL success rates at 3 months and McNemar's test was used to compare the efficacy of SWL between the two groups. Matching was possible in all cases. The results indicate that there were no statistically significant differences in the mean number of SWL sessions or in the mean number of impulses per session between the two groups. The overall stone clearance rate achieved by SWL alone was 71.3% for Group A and 73.9% for group B. Discordant pairs were found in 37 cases (in 17 pairs only patients in Group A became stone-free, while in 20 pairs only patients in Group B became stone-free). By using McNemar's test, the difference in stone clearance rates between the two groups was not found to be statistically significant ($p = 0.742$). A total of 22 patients (19.1%) in Group A and 17 patients (14.7%) in Group B underwent an adjuvant procedure to achieve stone clearance. McNemar's test also revealed the absence of any statistically significant difference in SWL success rates between older and younger patients in the subgroups of patients presenting with either ureteric or renal stones ($p = 0.727$ and $p = 0.571$, respectively). In conclusion, SWL is still considered one of the first-line tools for geriatric patients suffering from urolithiasis, as increased age alone does not seem to adversely affect the efficacy of SWL.

Keywords Elderly · Shockwave lithotripsy · Stones · Matched-pair

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Introduction

Extracorporeal shock wave lithotripsy (SWL) is considered one of the first-line tools for treating urolithiasis [1]. The major technological improvements and expanding experience in the use of the technique have added to its safety, but also highlighted its limitations. In particular, the role of SWL in the management of stone formers of extreme age remains to be clarified [2]. Longer life expectancy, the tendency for pro-active management of stone disease, and high-recurrence rates will lead to an increase in the number of elderly stone patients referred for interventional management in the years to come. Issues of relevance for this population have been identified in the past and contribute to the notion that geriatric stone patients should not be considered a mere extension of the younger lithiasis population [3, 4]. Previous studies focusing on the effect of age on the success rates of SWL have led to conflicting results [5–11], and the issue of SWL efficacy in the elderly stone population remains to be clarified.

In this study, we aim to evaluate the effect of age on the outcome of SWL, through the comparison of success rates in two groups of patients (aged >70 and <70 years), based on the principles of matched-pair analysis.

Patients and methods

Between September 2005 and August 2009, 2,311 patients were treated by SWL in a tertiary referral center and their demographic and clinical parameters were recorded in a prospectively created electronic database.

The management protocol for stone patients who presented as potential candidates for the SWL treatment was kept constant during the study period. The diagnosis of urolithiasis was confirmed by either intravenous urography or non-contrast spiral computed tomography. Patient's informed consent was obtained prior to treatment and the indications for SWL were set in accordance with the current guidelines [1].

All patients were treated on a Siemens Lithostar Multiline® (Siemens Erlangen/Germany). The absence of urinary infection was confirmed prior to the procedure by a negative urine dipstick. Standard pre-medication with 100 mg of Diclofenac per rectum (±Pethidine 75 mg IM and 12.5 mg Prochlorperazine IM if needed) was administered 30 min prior to the SWL session. Patients with renal and proximal ureteric stones were placed in the supine position, while prone positioning was necessary for distal ureteric stones. The SWL protocol included administration of shockwaves under fluoroscopic guidance at a rate of 90 shockwaves per min. The first 100 shocks were administered at an energy level of 0.1, with the intention to administer a total of 5,000 shockwaves up to an energy level of 9 for ureteric stones and 4,000 shockwaves up to an energy level of 4 for renal stones, according to the manufacturer's recommendations. Except those in-patients returning to the ward, patients were observed in the short-stay unit for 4 h and discharged if clinically stable. The patients were routinely reviewed 2 weeks after the procedure with a combination of plain abdominal X-ray and renal ultrasonography. If the absence of stone fragmentation was noted, the patients underwent a second SWL session. All patients were reviewed 3 months after the final SWL session with a combination of plain abdominal X-ray and renal ultrasonography. Success was defined as no additional intervention and the absence of fragments of any size on the plain abdominal film at 3 months.

Patients with staghorn calculi, who underwent SWL in combination with percutaneous nephrolithotripsy (PCNL) as part of a planned combined management scheme, as well as patients with unknown follow-up status, patients with ureteric stents in situ, underlying anatomic abnormalities and patients with radiolucent stones or stones with a maximum diameter of more than 20 mm were excluded from the study. Adult patients with a solitary, radiopaque, renal or ureteric stone <20 mm in diameter were considered for further analysis. A total of 115 patients (4.97%) over 70 years of age were identified as fulfilling the inclusion criteria and included in Group A.

To achieve some degrees of comparison between the younger and older patients, we used matched-pair analysis of similar cohorts in terms of stone parameters, with age being the only difference between the two groups. The 115 patients of Group A were matched to 115 patients younger than 70 years (Group B). The patients were exactly matched for gender (male/female), side (left/right), location of stone and size (maximum stone diameter ±2 mm). If the diameter was not matched exactly, the size criterion was extended to ±1 and ±2 mm. When more than one match was identified, random selection through the use of computer software was performed.

Following matching, the patients' electronic medical records and imaging reports were reviewed, to determine the success of SWL. The two groups were compared in terms of treatment efficacy, by using McNemar's Chi-square test and each pair was assigned in one of the four categories (both patients of the pair became stone-free or both SWL failures or one patient stone-free and the other failure or vice versa). The first two categories were the concordant pairs, while the latter two categories represented the discordant pairs. The discordant pairs were taken into account in the calculations by Chi-square distribution with one degree of freedom. The data were summarized as the means for continuous variables and in frequency tables for categorical variables. Comparison of non-parametric numerical data (such as stone size and age) was performed by using the Mann–Whitney U test. Statistical analysis was done with the SPSS software package (SPSS 13.0 Inc., Chicago, IL, USA).

Results

The patients' mean age was 75.9 years (range 70–88) for Group A and 47.3 years (range 18–66) for Group B ($p < 0.001$). In total, 35 pairs involved stones located in the ureter (30.4%) and 80 stones located in the kidney (69.6%). The pre-treatment patient demographic parameters and stone characteristics are summarized in Table 1. Stone location was further sub-classified into four groups (distal ureter, proximal ureter, pelvis/upper calyx/mid calyx and lower calyx) and the distribution is also presented in Table 1.

Table 2 summarizes the comparison of SWL treatment parameters between the two groups and the overall results of SWL, in terms of treatment success. Matching was achieved in all 115 cases (100%). There was no statistically

Table 1 Patients' demographic parameters and clinical characteristics of stone disease

		Group A		Group B	*p* value
Total number of patients		115		115	
No. side (%)					
Left		61 (53)		61 (53)	
Right		54 (47)		54 (47)	
Male		87 (75.7%)		87 (75.7%)	
Female		28 (24.3%)		28 (24.3%)	
Patients' mean age (years) (SD)		75.9 (4.5)		47.3 (11.3)	<0.001
Mean (SD) stone diameter (mm)		8.98 (3.23)		8.89 (3.23)	0.256
Distribution of stone location	Number (%)	Mean stone diameter in mm (SD)	Number (%)	Mean stone diameter in mm (SD)	
Distal ureter	14 (12.2)	7.7 (2.9)	14 (12.2)	7.6 (2.9)	0.818
Proximal ureter	21 (18.3)	9.6 (3.7)	21 (18.3)	9.3 (3.5)	0.204
Pelvis, upper or mid calyx	45 (39.1)	9.1 (2.9)	45 (39.1)	9.0 (2.8)	0.719
Lower calyx	35 (30.4)	9.0 (3.5)	35 (30.4)	9.1 (3.7)	0.676

Table 2 The parameters of treatment in the matched-pair analysis groups and the results of SWL

	Group A (age > 70 years)	Group B (age < 70 years)	*p* value
Number of patients	115	115	
Mean (SD) stone diameter (mm)	8.98 (3.23)	8.89 (3.23)	0.256
Mean SWL sessions	1.62	1.56	0.101
Mean number of impulses per session	3,689 ± 594.2	3,632 ± 665.9	0.284
SWL success	82/115 (71.3%)	85/115 (73.9%)	0.742
Single treatment SWL success	71/115 (61.7%)	75/115 (65.2%)	0.219

Table 3 Outcomes of SWL and need for adjuvant interventions

	Group A	Group B	*p* value
Stone-free by SWL	82/115 (71.3%)	85/115 (73.9%)	0.742*
Adjuvant procedures in total	22 (19.1%)	17 (14.7%)	0.379**
Ureteroscopy/laser fragmentation	15	9	
Laparoscopic ureterolithotomy	1	–	
PCNL	6	8	
Declined adjuvant procedure or considered poor candidates for adjuvant procedures	2	–	
Residual fragments <3 mm	9	13	

* McNemar's test

** Chi-square test

significant difference in the mean number of SWL sessions or in the mean number of impulses per session between the two groups. Stone-free rates were 2.6% higher for Group B patients (stone-free rates were 71.3% for group A vs. 73.9% for group B). Discordant pairs were found in 37 cases. In particular, in 17 pairs only patients in Group A became stone-free, while in 20 pairs only patients in Group B became stone-free. By using McNemar's test, the difference in stone clearance rates between the two groups was not found to be statistically significant ($p = 0.742$). The success rates and the need for adjuvant invasive procedures in the two patient groups are outlined in Table 3. In the group of older patients, the overall stone-free rate achieved by SWL alone was 71.3%, while 22 patients underwent an adjuvant invasive stone procedure to achieve stone clearance (compared with 17 younger patients, $p = 0.379$, Chi-square test). Two patients in Group A were initially offered an adjuvant procedure (PCNL), but did not undergo further surgery and they were managed by watchful waiting. One of these patients declined further proactive treatment for urolithiasis, while the second patient was considered of high-surgical risk, due to progression of underlying coronary heart disease while awaiting surgery.

In order to clarify whether treatment outcomes were different for calculi located in the kidney compared with those located in the ureter, a similar matched-pair analysis approach was employed (Table 4). This sub-classification allowed the identification of 35 pairs of patients with ureteric calculi and 80 pairs of patients with renal calculi. The results of the McNemar's test for both subgroups revealed the absence of any statistically significant difference in stone clearance between the older and younger patients ($p = 0.727$ for the subgroup with ureteric stones and $p = 0.571$ for the subgroup with renal stones). The same principles were applied to compare the single treatment SWL

Table 4 Matched-pair analysis of outcomes in two patient subgroups (ureteric and renal stones)

	Group A	Group B	*p* value
Ureteric stones (35 pairs)			
Number of patients	35	35	
Mean stone diameter (mm) (SD) (%)	8.8 (3.5)	8.5 (3.2)	0.086
Stone clearance (%)	27/35 (80)	26/35 (74.3)	0.727
Renal stones (80 pairs)			
Number of patients	80	80	
Mean stone diameter (mm) (SD) (%)	9.1 (3.1)	9.1 (3.3)	1.00
Stone clearance (%)	55/80 (68.7)	59/80 (73.8)	0.571

success rates between the two cohorts. Single treatment success rates were 61.7% for Group A and 65.2% for Group B. By using McNemar's test, the difference in single treatment stone clearance rates between the two groups was not found to be statistically significant ($p = 0.219$).

In total, 23 patients (20%) over 60 years old were included in Group B. The two groups were compared in terms of co-morbidities (Table 5). Exact case-by-case matching for co-morbidities was not possible. In order to limit the cofounding factor of co-morbidities, we applied the principles of matched-pair analysis in a sub-group of younger patients aged 20–40 years old. We identified 38 patients aged between 20 and 40 years in Group B and matched them to 38 patients aged over 70 years. The results of the McNemar's test for this subgroup revealed the absence of any statistically significant difference in stone clearance between patients over 70 years and patients aged 20–40 years ($p = 0.664$).

No severe SWL-related complications (such as clinically significant perinephric hematomas requiring admission or intervention, urosepsis, acute coronary events or arrhythmias) were noted in either of the two groups. The ultrasound studies performed 2 weeks post-SWL did not identify any cases of asymptomatic perinephric hematoma in either of the two cohorts. In Group A, however, three cases of post-SWL ureteric obstructions due to steinstrasse occurred (2.6%). These cases involved patients with a significant stone burden (median diameter of stone 14.5 mm) and were successfully managed by ureteroscopy. Only one case of ureteric obstruction after SWL was noted in Group B (0.9%). The case involved a 34-year-old patient who presented with a 13-mm proximal ureteric stone and was managed by ureteroscopy.

Table 5 Comparison of co-morbidities between the two groups

Underlying condition	Number of patients (%)		*p* value
	Group A (>70 years)	Group B (<70 years)	
Hypertension	34 (29.6)	21 (18.3)	0.044*
Diabetes mellitus	23 (20.0)	15 (13)	0.155*
Coronary heart disease	35 (30.4)	13 (11.3)	<0.001*
History of malignancy	11 (9.6)	6 (5.2)	0.208*
Aspirin treatment	40 (34.8)	19 (16.5)	0.002*
Oral anticoagulant treatment	8 (6.9)	4 (3.5)	0.236*
Chronic kidney disease	18 (15.7)	11 (9.6)	0.164*
Abdominal aortic aneurysm	5 (4.3)	2 (1.7)	0.722**
Cardiac pacemaker	3 (2.6)	2 (1.7)	0.999**
Inflammatory bowel disease	5 (4.3)	4 (3.5)	0.999**

* Chi-square test

** Fisher's exact test

Discussion

Urolithiasis is mainly considered a disease of the middle age and only a few reports focus on the epidemiology and special considerations of this common entity in the geriatric population. Yet, the elderly stone formers (age >65 years) comprise 9.6–12% of all stone patients [3, 4] and usually experience the first symptomatic stone-related episode later in life [3]. Their metabolic profile may also differ [3]. These significant differences support the notion that elderly stone formers do not represent a mere extension of the younger stone population [2].

This statement has significant implications in the management of older patients with stone disease. Early reports regarding the use of SWL in this patient group have considered the method as safe and effective [5], and these results have been reproduced by more recent papers [6, 7]. However, the issue of the method's efficacy (particularly in terms of stone-free rates, SFR) has not been clarified. The question whether age adversely affects the efficacy of SWL has led to contradictory results (Table 6). An early report referring to the use of HM-3 lithotripter revealed lower SFRs among older patients presenting with renal calculi [8]. Abdel-Khalek et al. [9], in a study that included 2,954 patients with renal stones treated by SWL, demonstrated on multivariate analysis that patient age above 40 years was a predictor of SWL failure. These findings were not reproduced by newer reports for stones located in the ureter [10, 11]. Age was not included in a preoperative nomogram for predicting stone clearance after SWL [12], since it did not represent an independent predictor for fragmentation on multivariate logistic regression analysis. According to the findings of a retrospective study, clearance of renal

Table 6 A summary of the results of contemporary studies regarding the impact of age on SWL efficacy

References	Study objectives and design	Conclusions and comments
Sighinolfi et al. [6]	Retrospective observational study	SWL represents the treatment of choice for urolithiasis in the geriatric population
		Continuous ECG and U/S monitoring advisable
Halachmi et al. [7]	Retrospective comparative study	Age itself has no effect on the success rate of SWL for ureteric stones
Ackermann et al. [8]	Retrospective study, multivariate logistic analysis	Regarding renal stones, age is a significant prognostic factor for SWL outcome
Abdel-Khalek et al. [9]	Retrospective study, multivariate logistic analysis	Patient age is a prognostic factor for renal stone clearance after SWL
Gomha et al. [10]	Retrospective study	Regarding ureteric stones, patient age does not represent a prognostic factor for SWL outcome
	Multivariate logistic analysis and artificial neural network analysis	
Delakas et al. [11]	Retrospective study, multivariate logistic analysis	Regarding ureteric stones, patient age does not represent a prognostic factor for SWL outcome
Ikegaya et al. [23]	Retrospective comparative study	Age may have a negative impact on stone fragmentation
Kanao et al. [12]	Retrospective study	Age was not included in a preoperative nomogram for predicting stone clearance after SWL
	Multivariate analysis, using a logistic regression model	
Ng et al. [13]	Retrospective study	SFR in older patients was significantly lower for renal, but not for ureteric stones
	Multivariate analysis	

stones, but not ureteric stones, was affected by age [13]. In fact, Ng et al. [14] proposed a hypothesis that age-related changes in the acoustic impedance of the kidneys due to underlying glomerulosclerosis may have an impact on the effectiveness of shockwave transmission to renal stones, but not for ureteric stones. This phenomenon may explain both the increased echogenicity of the kidneys during ultrasonography and the lower SFR for renal stones in older patients [13]. On the other hand, the motility of the renal pelvis and ureter may be affected by aging, leading to decreased expulsion of stone fragments after SWL. Age, however, does not seem to have an impact on the drainage of contrast material (as seen in IVU studies) or radioisotopes (in dynamic renograms) [13]. These two concepts (i.e., age-related changes in renal acoustic impedance and upper urinary tract motility) represent the fields of potential future research.

In order to achieve some form of comparison, we selected the matched-pair analysis as a way to determine whether age affects the efficacy of SWL. This approach allows the demonstration of a significant difference by comparing smaller groups of patients than in randomized studies [15]. This study design was first used in the field of SWL by Portis et al. [16], to achieve an accurate determination of the effectiveness of new SWL technology with a relatively small clinical study group. The same principles were employed in a number of studies, in an attempt to compare the SWL and ureteroscopy [17, 18] and to assess the effect of ureteric stents on the success rates of SWL [19]. In our study, no statistically significant difference in stone clearance rates was noted when a cohort of patients older than 70 years old was compared with a group of younger patients matched for gender, stone side, size, and location. The absence of statistically significant difference was also noted when the principles of matched-pair analysis were employed to compare the stone clearance rates within the two subgroups of matched-pair patients (ureteric and renal stones).

One major limitation in our study is the fact that it does not incorporate more parameters (such as body mass index and stone chemical composition) in the context of matched-pair analysis, since these data were not available for all patients. These factors are considered to be of particular importance for predicting the success of SWL [8–11]. However, we achieved exact matching in all patients in as many parameters as possible (sex, side, and stone location). Matching in terms of exact size was possible in 59.1% (81/137) of cases, while 100% matching was possible when stone size of ± 2 mm was considered. The major limitation for matched-pair analysis is selection bias, while observational bias is limited by the fact that our department has employed the same SWL technique and post-SWL follow-up protocol over the whole period of the study.

SWL-related morbidity in the elderly is not well elucidated in the current literature. However, age is considered an independent predictor of subcapsular or perinephric hematoma formation following electromagnetic SWL [20]. In our series, no clinically significant subcapsular or perirenal hematomas requiring admission or intervention were noted, but this finding is limited by the

fact that our follow-up imaging protocol included a renal ultrasonography 2 weeks after the SWL session. Symptomatic intrarenal, subcapsular or perirenal hematomas are rare and occur in <1% of patients who undergo SWL [20–22]. This rate, however, increases to 20–25% when CT or MRI is routinely performed after each SWL session [20]. On the other hand, in our study factors such as hypertension, treatment with medication that affect the coagulation cascade and other co-morbidity, as well as anesthetic risk were not included in the matching criteria. This limitation does not allow valid conclusions regarding the impact of age per se on SWL-related morbidity and further studies are needed to clarify the safety of this modality in the elderly.

In conclusion, SWL should still be considered as one of the first-line tools for geriatric patients presenting with urolithiasis. Increased age alone does not seem to adversely affect the outcome of SWL, in terms of stone clearance rates. The lack of valid data regarding the impact of age on SWL-related morbidity represents an issue that still needs to be clarified, to provide valid patient counseling prior to any invasive treatment for urolithiasis.

Conflict of interest None.

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