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Evolution of shockwave lithotripsy (SWL) technique: a 25-year single centre experience of >5000 patients

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Objective

To assess the impact of various treatment optimisation strategies in shockwave lithotripsy (SWL) used at a single centre over the last 25 years.

Patients and Methods

In all, 5017 patients treated between 1989 and 2013 were reviewed and divided into groups A, B, C and D for the treatment periods of 1989–1994 (1561 patients), 1995–2000 (1741), 2001–2006 (1039) and 2007–2013 (676), respectively. The Sonolith 3000 (A and B) and Dornier compact delta lithotripters (C and D) were used. Refinements included frequent re-localisation, limiting maximum shocks and booster therapy in group B and Hounsfield unit estimation, power ramping and improved coupling in group D. Parameters reviewed were annual SWL utilisation, stone and treatment data, retreatment, auxiliary procedures, complications and stone-free rate (SFR).

Results

The SFR with Dornier compact delta was significantly higher than that of the Sonolith 3000 ($P < 0.001$). The SFR improved significantly from 77.58%, 81.28%, 82.58% to 88.02% in groups A, B, C, and D, respectively ($P < 0.001$). There was a concomitant decrease in repeat SWL (re-treatment rate: A, 48.7%; B, 33.4%; C, 15.8%; and D, 10.1%; $P < 0.001$) and complication rates (A, 8%; B, 6.4%; C, 4.9%; and D, 1.6%; $P < 0.001$). This led to a rise in the efficiency quotient (EQ) in groups A–D from 50.41, 58.94, 68.78 to 77.06 ($P < 0.001$).The auxiliary procedure rates were similar in all groups ($P = 0.62$).

Conclusion

In conclusion, improvement in the EQ together with a concomitant decrease in complication rate can be achieved with optimum patient selection and use of various treatment optimising strategies.

Keywords

shockwave lithotripsy, urolithiasis, efficiency quotient, technique, treatment optimisation, experience

Introduction

Urolithiasis incidence is increasing globally [1,2]. Since its introduction in 1984, shockwave lithotripsy (SWL) has continued to be an efficient and safe method of treating urolithiasis. Before SWL, most urinary stones were removed by open surgery with its associated morbidity, higher incidence of complications and longer convalescence. SWL has become the preferred method of treatment for most urinary calculi. There has been a gradual change in the technology, selection criteria, methods of delivering shockwaves and treatment outcomes in the past three decades. Together with the improved mechanics of the newer machines, treatment strategies, experience and diligent cost-effectiveness assessments have played an important role in achieving the desired outcome. We report our single centre experience of treating >5000 patients with SWL over the past 25 years.

Patient and Methods

In all, 5017 patients consecutively treated with SWL at a single centre between 1 January1989 and 30 November 2013 were retrospectively evaluated. The aim of this study was to assess the impact of various treatment optimising strategies used at our centre over the years. Parameters reviewed were annual SWL treatment rate, patient demographics, stone and treatment data, re-treatment (repeat SWL), auxiliary procedures, complications and stone-free rate (SFR) during an arbitrary four phases of development since the introduction of SWL. Consequently, patients were divided in four groups: A,

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B, C and D during the treatment periods of 1989–1994, 1995–2000, 2001–2006 and 2007–2013, respectively.

Patients in all the four groups underwent an abdominal plain X-ray of the kidneys, ureters and bladder (KUB), ultrasound (US) KUB and routine IVU preoperatively. The varied treatment strategies during the respective treatment periods were as follows:

Group A: The first 1561 patients between 1989 and 1994 were treated on a Sonolith 3000 electrohydraulic machine (Technomed International, France). It had a six-way articulating US probe for localisation. The upper limit initially set for the number of shocks/sitting was 3000 according to the manufacturer's specifications. The frequency setting for renal and ureteric stones was 1 Hz (60/min).

Group B: Certain treatment optimisation strategies were applied with the Sonolith 3000 machine in the next 1741 patients from 1995 to 2000. These included: re-localisation of the calculus after every 200 shocks, restricting shocks to 1500/sitting for renal and 2000/sitting for ureteric stones, use of booster therapy (1500 maximum additional shocks) if required after 48 h (Fig. 1).

Group C: Dornier Compact Delta electromagnetic lithotripter (Dornier MedTech, Germany) replaced the Sonolith 3000 for the next 1039 patients between 2001 and 2006.The same optimisation strategies as used in group B were followed. Additionally, stones were localised with US and/or fluoroscopic guidance.

Group D: Further refinement occurred with the use of CT with IVU to determine the location, size and stone attenuation value in Hounsfield units (HU) before SWL. The last 676 patients, between 2007 and 2013, were treated on the same Dornier compact delta machine albeit with some changes in the protocol. These were: power ramping and improved acoustic coupling.

Patients were given i.v. sedoanalgesia, which provided optimum respiratory excursion with good pain relief without the need of full general anaesthesia. In general, patients with bleeding disorders, anatomical abnormalities, PUJ obstruction, ureteric strictures and diverticular stones were excluded. All patients were treated on an inpatient basis after obtaining informed consent and were discharged the next day if they were asymptomatic and a confirmatory X-ray showed good fragmentation. Patients were advised to come for follow up at 1 and 3 months for radiological confirmation of stone-free status and to determine any postoperative complications by X-ray and US. Data were recorded and entered prospectively in a Microsoft access database (Microsoft, Redmond, USA).

Treatment success was defined as complete stone-free status or residual fragments of <0.4 cm at the 3 month follow-up. The groups were compared using the efficiency quotient (EQ) as originally described by Denstedt et al. [3].

$$\mathrm{EQ} = [\%\ \text{Stone free}/(100\% + \%\ \text{Retreatment} + \%\ \text{Auxiliary procedures})] \times 100$$

Data are reported as the mean (standard deviation, SD) and number (percentage) in tabulated format in the results. Statistical analysis was done using SPSS statistical software. The Student's *t*-test was used for testing continuous variables and the chi-square test was used for categorical variables. A $P < 0.05$ was considered to indicate statistical significance.

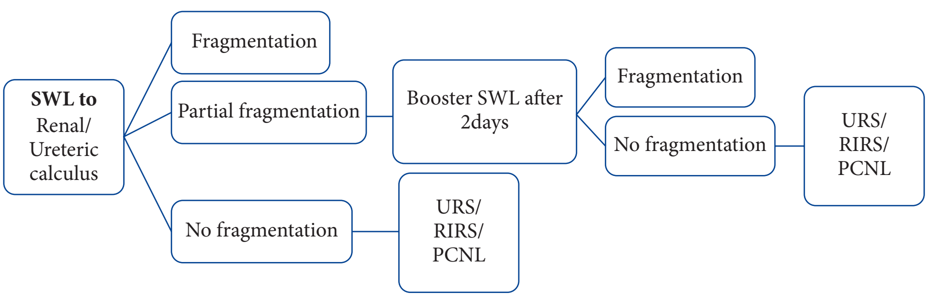
Results

In all, 5283 patients were treated during the 25-year study period from 1989 to 2013. In all, 266 (5.04%) patients were lost to follow-up and were excluded from the final analysis. Of the remaining 5017 patients, 4101 (81.74%) had renal and 916 (18.26%) ureteric stones. In all, 4079 patients were rendered stone free giving an overall SFR of 81.3%. The overall patient demographics and stone characteristics are shown in Table 1. The annual utilisation of SWL during the study period is as shown in Figure 2.

The SFR stratified according to stone size and stone location is given in Tables 2 and 3, respectively. In all, 572 patients (11.4%) patients required booster therapy during the same hospital admission. In all, 69% of patients required a single sitting of SWL for successful stone fragmentation.

SFR with the Dornier compact delta was significantly higher than with the Sonolith 3000, at 84.72% vs 79.53% ($P < 0.001$). The number of patients requiring multiple sittings of SWL

Fig. 1 Flowchart of management of stones by SWL, shock wave lithotripsy; PCNL, percutaneous nephrolithotomy; RIRS, retrograde intra-renal surgery.



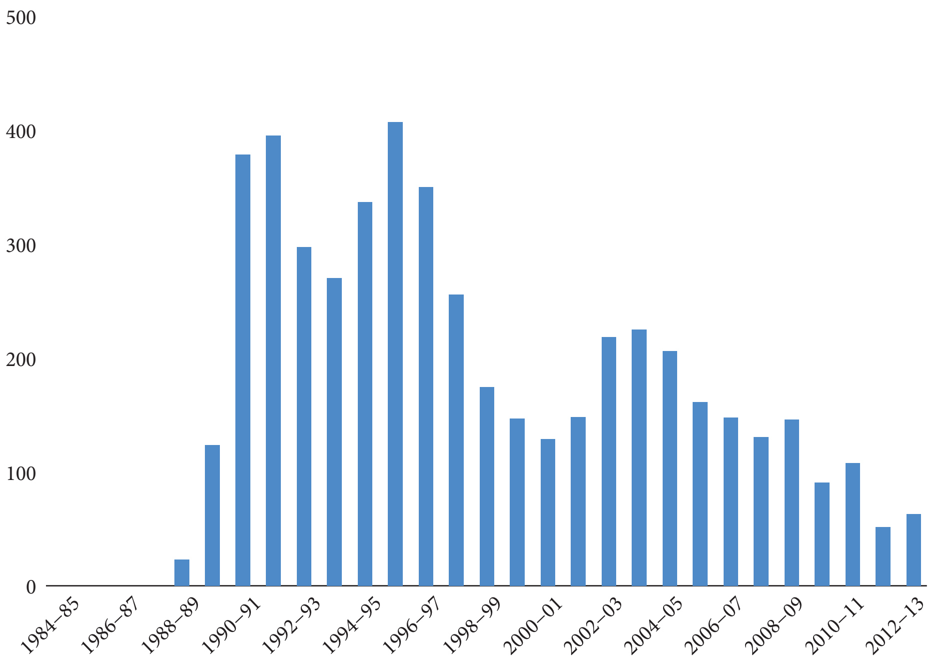


Fig. 2 Utilisation of SWL each year at our centre over the past 25 years.

Table 1 The patients' demographics and stone characteristics.

Characteristic	Value
Mean (SD) age, years	39.24 (14.29)
Gender (male: female, n)	2.68 : 1 (3652 : 1365)
Mean (SD) stone size, cm	1.29 (0.53)
Side (left : right, n)	0.98 : 1.00 (2488 : 2529)
Stone location, n (%)	
Pelvic	1972 (39.3)
Upper calyx	253 (5)
Middle calyx	326 (6.5)
Lower calyx	996 (19.9)
Upper ureter	886 (17.6)
Lower and mid ureter	8 (0.2)
Multiple	576 (11.5)
Mean (SD) stone attenuation value on CT (group D), HU	1153.4 (326.6)
Comorbidities, %	11.6

Table 2 Number of shocks and SFR according to size of stone.

Size of stone, cm	Number of patients, n (%)	Mean number of shocks	Stone free, n (%)
<0.5	123 (2.4)	1207	99 (80.5)
0.6–1.0	2018 (40.2)	1595	1671 (82.8)
1.1–2.0	2494 (49.7)	1905	2021 (81.0)
>2.0	382 (7.6)	2266	288 (75.4)
Total	5017	1794	4079 (81.3)

was significantly higher in the Sonolith 3000 group compared with the Dornier group, 40.6% vs 13.6% ($P < 0.001$).

Table 4 analyses the various treatment groups during the study period. There was a significant increase in SFR from 77.58% to 81.28% in the Sonolith group after introduction of optimisation steps. The SFR improved further to 82.58% and 88.02% in groups C and D, respectively with the Dornier machine. There was sequential improvement in the SFR over the study period ($P < 0.001$). There was a statistically significant decrease in repeat SWL (A, 48.7%; B, 33.4%; C, 15.8%; and D, 10.1%; $P < 0.001$) along with the total number of shocks required (A, 2153; B, 1817; C, 1528; and D, 1486; $P < 0.001$). The auxiliary procedure rates were similar in all groups (A, 5.2%; B, 4.5%; C, 4.3%; and D, 4.1% $P = 0.62$). Progressive increments in EQ were noted in the series (A, 50.41; B, 58.94; C, 68.78; and D, 77.06; $P < 0.001$). Complication rates reduced significantly during the study period from 8.0% (group A), 6.4% (B), 4.9% (C) to 1.6% (D), respectively ($P < 0.001$). Overall, complications occurred in 298 (5.94%) patients and are as listed in Table 5. Auxiliary procedures after SWL were required in 232 (4.62%) of the patients (Table 5). The complication and auxiliary procedure rates were consistent with those seen in literature and are

Table 3 SFR according to location of stone.

Site of stone	Number of patients, n (%)	Stone free, n (%)
Pelvic	1972 (39.3)	1686 (85.5)
Upper calyx	253 (5)	205 (81.0)
Middle calyx	326 (6)	265 (81.3)
Lower calyx	996 (19.9)	763 (76.6)
Upper ureter	886 (17.6)	719 (81.1)
Mid and lower ureter	8 (0.2)	7 (87.50)
Multiple	576 (11.5)	434 (75.35)
Total	5017	4079 (81.3)

Table 4 Comparison between the various periods of SWL.

Variable	A. Sonolith 3000 (1989–1994)	B. Sonolith 3000 (1995–2000)	C. Dornier compact delta (2001–2006)	D. Dornier compact delta (2007–2013)	P (A,B,C,D)
Mean (SD) stone size, cm	1.56 (0.62)	1.18 (0.38)	1.19 (0.47)	1.09 (0.43)	<0.001
SFR, % (n/N)	77.58 (1211/1561)	81.28 (1415/1741)	82.58 (858/1039)	88.02 (595/676)	<0.001
No of sittings, n (%)					
1	801 (51.3)	1160 (66.6)	874 (84.1)	608 (89.9)	
2	383 (24.5)	566 (32.5)	150 (14.4)	66 (9.8)	
3	180 (11.5)	15 (0.9)	15 (1.4)	2 (0.3)	
> 3	197 (12.6)	0	0	0	
Mean (SD) number of shocks	2153 (895.28)	1817.52 (1064.62)	1528.62 (767.10)	1486.61 (568.98)	<0.001
Repeat SWL (>1 sitting), n (%)	760 (48.7)	581 (33.4)	165 (15.8)	68 (10.1)	<0.001
Auxiliary procedures, n %)	81 (5.2)	78 (4.5)	45 (4.3)	28 (4.1)	0.62 (NS)
EQ	50.41	58.94	68.78	77.06	<0.001
Complication rate, n (%)	125 (8.0)	111 (6.4)	51 (4.9)	11 (1.6)	<0.001

Table 5 Complications after SWL and auxiliary procedures.

Variable	Number of patients (%)
Complications (Clavien-Dindo grade)	298 (5.94)
Grade 1	
Fever (antipyretics)	75 (1.49)
Renal colic (analgesics)	51 (1.02)
Grade 2	
Steinstrasse (medical management)	32 (0.64)
Perinephric hematoma (medical management)	24 (0.48)
Grade 3A	
Obstruction (relieved with percutaneous nephrostomy)	3 (0.06)
Grade 3B	
Obstruction (relieved by JJ stenting)	19 (0.38)
Steinstrasse (relieved by JJ stenting/URS)	66 (1.32)
Grade 4	
Urosepsis	28 (0.56)
Auxiliary (secondary) procedures:	232 (4.62)
JJ stent placement	85 (1.69)
Percutaneous nephrostomy placement	3 (0.06)
URS	82 (1.63)
Percutaneous nephrolithotomy	57 (1.14)
Open surgery	5 (0.10)

shown in Table 5. The overall EQ of the total SWL group was 59.79 in the present study population.

Discussion

The current European Association of Urology guidelines on urolithiasis recommend SWL as the first-line treatment in renal stones of <2.0 cm and upper ureteric stones of <1.0 cm [4]. Despite 30 years elapsing, newer lithotripters continue to be beleaguered by their inability to supersede the results obtained with the Dornier HM3 (Human Model 3), despite several benefits. This can be ascribed to the comparatively larger focal point and greater peak pressures in the case of the Dornier HM3. Since the initial report by Chaussy et al. [5], which reported a success rate as high as 70%, several other papers have also cited a SFR of >70% [6–8]. In a large series of 1840 patients in the United States Cooperative study, Drach et al. [6] reported an overall success rate of 77% with an EQ of 67. At our centre an overall success rate of 81.3% was achieved with an EQ of 59, which is consistent with EQs reported in other studies with EQs of 51–67 [6–9]. Although larger stones required more shocks/sitting and had a higher rate of repeat SWL, on analysing SFR based on size, we found similar success rates for all stone sizes ($P = 0.59$). This could be attributed to appropriate case selection, as most of the stones in the present study were in the <2.0 cm group (4635, 92.4%) with an average size of 1.29 cm. Stones of >2.0 cm are treated with percutaneous nephrolithotomy at our centre. Another point to note is that a sizeable number of stones were in the lower calyx (19.6%), which were also selected after considering the infundibular width, angle and length before selecting them for SWL [10]. There was a statistically significant difference in SFR according to the location of stone ($P < 0.001$), with the highest SFR for pelvic stones (85.5%) and lowest in multiple stone locations (75.35%) and lower calyx calculi (76.61%). We achieved excellent SFRs for upper ureteric stones but the non-inclusion of mid and lower ureteric stones for SWL precludes any statements of significance about its use for ureteric stones in general.

The EQ improved sequentially from groups A to D. There was a concomitant decrease in the stone burden selected for SWL over time (1.56 cm in group A to 1.09 cm in group D, $P < 0.001$). In the early 1990s, after the initial enthusiasm for this new technique with rising SWL utilisation rates (Fig. 2), we found that the 3-month SFR was low at 77.58%. Hence the use of SWL tapered off during the mid-1990s (Fig. 2). We brought about several changes in technique and were able to improve the outcomes with SWL in group B and achieved a SFR of 81.28%, with a consequent rise in SWL usage (Fig. 2). In group B, we started re-localising the stones after every 200 shocks to improve the efficiency of fragmentation and to decrease the chances of injury to the surrounding parenchyma. The total number of maximum shocks/sitting was decreased from 3000 to 1500 resulting in a decline in complication rates from 8% to 6.4% ($P < 0.001$). Earlier the cost of SWL was determined by the stone size being treated, which was skewing the charges and becoming financially unviable. To maintain the economic viability of SWL, we performed an internal audit and arrived at a cost/shock value. This helped us in reducing the financial burden to the patient, as lesser shocks to achieve fragmentation translated into reduced cost for the patient.

In early 2000, with the simultaneous improvement in other endourological methods, e.g. percutaneous nephrolithotomy and ureterorenoscopy (URS), SWL lagged in achieving similar success rates [11–14]. A sharp decline was witnessed in utilisation rates of SWL in early 2000 (Fig. 2). In order to attain a success rate similar to other endourological interventions we had to revise the selection criteria to exclude larger stones (>1.5 cm) for SWL in groups C and D, thereby leading to an overall decrease in stone sizes as compared to group A ($P < 0.001$).

The improved efficiency in the later groups (C and D) could also be attributed to the change of machine from the Sonolith 3000 to the Dornier compact delta. Accurate targeting and real-time simultaneous monitoring for optimum fragmentation was possible due to the integrated dual modalities of X-ray and US in the Dornier machine.

The last 6 years of group D was further challenged with the high SFR achieved with flexible URS for stones of <1.5 cm [15]. The precipitous fall in utilisation rates of SWL could be attributed to this (Fig. 2). Still there was a sizeable proportion of patients being treated with SWL at our centre (15%). Appropriate patient selection by using CT (excluding patients with hard stones: attenuation value of >1200 HU) helped us in improving the success rate further as seen in group D, as it plays a key role in prediction of stone breakage [16]. In our patient population almost 90% of the stones were calcium oxalate calculi with calcium oxalate monohydrate forming a major proportion (74.8%). With most of the stones in our patients having an attenuation value of >1000 HU it would make SWL a less preferred alternative if we were to strictly follow current guidelines [4]. But in a prospective study by Shah et al. [17] it was found that stones with attenuation values of <1200 HU and those of >1200 HU had SFRs which were not statistically different (88.1% vs 82.5%, $P = 0.35$). Although the group with stones with attenuation values of <1200 HU had a significantly better EQ with lower numbers and intensity of shock requirement when compared with stones of >1200 HU [17]. This aided us in selecting patients with stones attenuation values of <1200 HU for SWL.

Another important modification was in the sequence of shockwave delivery in group D. 'Step-wise power ramping' with a brief pause of ≈2–3 min after the initial 100 shocks at a low-power setting was used before increasing the power of the shocks further to a higher setting [18,19]. Several initial shocks given at a low setting are thought to induce vasoconstriction and thereby decrease renal injury and improve stone comminution, although the exact physiological basis is still being researched. But including a brief pause after pretreatment with low-intensity shocks has definitely being proven to be renoprotective in the porcine setting, with a decrease in the renal lesion size from 4% to 0.5% of functioning renal volume when it was included [20].

The Sonolith 3000 electrohydraulic machine had the disadvantage of requiring periodic manual adjustment, as generation of shockwaves caused the electrode to wear down progressively. Improvement of acoustic coupling with the modern dry head lithotripters, such as the Dornier compact delta, has helped. Minimising handling to decrease the air pockets at the coupling interface can improve the efficiency. Application of the gel directly from the wide mouth of the gel bottle instead of squeezing it out and allowing the inflation feature of the treatment head to smoothen out the gel was done to achieve optimum coupling [21].

More often than not it is claimed that results with newer machines are inferior to the unmodified HM3. In the case of the original HM3 comprehensive training was required before being allowed to operate the machine. Our group underwent extensive training in France before using the Sonolith 3000 machine. Lithotripter machines are often described as 'easy to use', often leading to a neglect of proper training. SWL is often shunted down to the most junior of residents or technicians in many centres who have received little or no mentoring in its use leading to poorer outcomes. At our centre all SWLs are performed by residents or junior fellows under the expert supervision of a consultant urologist or senior endourology fellow well versed with the technical nuances of performing SWL. Lithotripter manufacturers and hospitals should earmark time and resources to proper training for optimal results. This would result in improved success rates and less complications.

The present study has several limitations despite having a large number of subjects. Firstly, the study was retrospective in nature allowing for potential confounding factors. Secondly the imaging methods used in the follow-up included plain X-ray and US, both prone to observer bias. Ideally a plain CT would have better defined true stone-free status, albeit with an added cost burden as well as radiation exposure. The effect of CT stone attenuation values (HU) and stone composition on SFRs could not be assessed due to the availability of these in only a small proportion of the total number of patients. Also, the EQ as a means of objective assessment of lithotripters has been questioned earlier in other studies and its use as a comparative tool also has its own shortcomings.

In conclusion, SWL is highly effective in treating urolithiasis in properly selected patients with the added advantage of low complication rates. Newer generation lithotripters have been able to improve the EQ further by decreasing the number of additional sittings. The complications decreased with increasing experience and refinement in technique. With evolution of technique and a decrease in retreatment rates, SWL has emerged as a first-line option for managing small bulk urolithiasis (<1.5 cm). It is possible to further improve the efficacy and safety of SWL with the use of preoperative CT for patient selection and treatment planning.

Conflict of Interest

None.

Financial Disclosures

None.

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Abbreviations: EQ, efficiency quotient; HU, Hounsfield unit; KUB, kidneys, ureters and bladder; SFR, stone-free rate; SWL, shockwave lithotripsy; URS, ureterorenoscopy; US, ultrasound/ultrasonography.