The Future of SWL: A Global Perspective

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Abstract. The future relevance of shock wave lithotripsy (SWL) to the treatment of urinary stones has been questioned by some. This paper reviews recent developments with an aim to predict the level of usefulness of SWL for the future. The incidence of urolithiasis is increasing throughout the world, and existing metaphylaxis is not widely effective. This results in an increasing need for active stone removal. SWL was and is a well established treatment modality for urolithiasis in the upper urinary tract. For most stone situations there will remain a reasonable choice between SWL versus endoscopic procedures, and it is unlikely that endoscopic procedures will displace SWL completely in general practice. In conclusion, SWL will continue to play an established, if slightly reduced, role in stone treatment in the future.

Keywords: kidney stones, lithotripsy, ureteroscopy, percutaneous nephrolithotomy
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A perspective on the future of SWL can only be developed from the extrapolation of the past and an analysis from the present. This includes not only evidence from the actual literature but also some subjective estimations by the author.

HISTORICAL DEVELOPMENT OF SWL

Within a very short time period after the first clinical treatment of a patient with a kidney stone in February 1980 using the prototype lithotripter Dornier HM1, the first serial-type HM3 was installed in Germany (in 1983) and thereafter distributed all over the world. The revolution of SWL was so successful that this treatment option shortly was accepted as a reasonable alternative to surgical procedures [1,2]. Already five years after its introduction, SWL was the first-choice treatment for nearly all calculi located in the upper urinary tract. Despite the necessity of general anesthesia, the low morbidity for the patient with this non-invasive procedure justified re-treatment when the stone was not completely disintegrated by the first session. Therefore SWL was applied for almost all renal and ureteral stones, excepting staghorn stones, diverticular stones, asymptomatic stones, and nephrocalcinosis. The parallel development of the endoscopic techniques of percutaneous (PCNL) and transureteral (URS) lithotripsy was significantly slower. Only after the availability of highly effective intracorporeal lithotripters and baskets was their range of indications increased. Certainly the short learning curve for SWL compared to endoscopic procedures has been an important reason for the fast spread of shock wave lithotripters. The application of shock waves was possible after a short training period for young urologists and has sometimes been
performed successfully by medical technicians. This is explained by the low risk of severe complications in SWL, even when it is mishandled.

In the first phase of its introduction, SWL seemed to cause no adverse side effects [1] but with time and the arrival of CT and MRI the risk for the kidney became apparent [3,4]. The rate of hematoma has been calculated to be around 0.5%.

The further development of lithotripters was intended to improve stone disintegration and to reduce side effects [5]. Concerning the side effects, on the one hand the trauma to the kidney and adjacent organs should be reduced. On the other hand pain during shock wave application had to be reduced to avoid general anesthesia. Both effects were thought to be reached by concentrating the shock wave energy to a smaller focal area. Under this intention the electrohydraulic shock wave generator has been modified, but also electromagnetic and piezoelectric sources were developed. The development was successful since pain was limited and SWL without anesthesia became possible [6].

Improvement of the disintegrative efficacy was not so prosperous. Some in vitro and ex vivo studies seemed to prove an advantage in stone comminution by the modern shock wave machines. But no clinical, prospective randomized trial could confirm a benefit compared with the unmodified Dornier HM3.

Nevertheless, some further improvements were gained:

- Stone localization by X-ray and/or sonography enabled the treatment of stones with weak or no radiodensity. Additionally, ultrasound localization reduced X-ray exposure to the patient. But sonographic localization did not become widely accepted since this procedure is more time consuming and ureteral stones usually are not detectable by ultrasound. In the US, urologists usually are not so experienced using sonography. All this has argued against the expensive addition of ultrasound.

- The optimal medium for transmission of acoustic shock waves is degassed water. In the Dornier HM3 the patient was immersed in a large water basin. This was also technically elaborate and costly. Therefore the basin was reduced to a water cushion to be coupled by a membrane and jelly between the water and the skin surface. On the downside, it has been shown that this coupling method reduces shock wave energy and can impair disintegration efficacy significantly.

- The upgrading of lithotripters to a multifunctional workstation or the integration of the shock wave generator into a urological workstation necessitated compromises. But this was driven by economic demands to enable the acquisition of a lithotripter by smaller hospitals. Therefore modular systems were developed with the possibility to use different parts of the workstation (e.g., the C-arm) separately from the lithotripsy system or to upgrade a urologic table by addition of a shock wave generator.
THE ACTUAL SITUATION OF SWL

Today there is a large variety of lithotripter systems, from expensive high-end devices down to low-budget machines. In a lot of cases financial limits influence the choice of the lithotripter significantly. Beyond that, there are no hard criteria for selecting the “best” lithotripter. In the following listing, some essential details of lithotripters are discussed from the present point of view as a basis for developing optimized units for the future:

- The configuration of the optimal pressure and energy distribution in the focus area for the most efficient disintegration and lowest side effects is still not known. The reason for that is that the parameters that control the different effects (disintegration and trauma) specifically are not defined. A larger focal zone with a higher energy density seems to increase stone comminution but also aggravate pain (and thus the need for anesthesia) and tissue damage. A machine with a small focal point, despite having a very high peak pressure, can be applied without narcotics, but the higher re-treatment rate of such systems indicates their lower clinical success.

- Additionally it is not clear what is the ideal system for generating shock waves: electrohydraulic, electromagnetic or piezoelectric. Several lithotripter manufacturers now offer a flexible focal zone (large and small focus), and that is possible now with all three technologies. Moreover, it is beneficial to provide a homogeneous shock wave and low maintenance costs, which is possible especially by electromagnetic and piezoelectric systems.

- Coupling of the shock wave from the generator to the body surface is an essential factor in lithotripsy. The best shock wave is not successful when it doesn’t reach the stone undisturbed. Concerning this, the Dornier HM3 provided the optimal way by immersing the patient in a water tub. In this design there is no interface to alter the shock wave. Most present-day lithotripters couple to the patient using water cushions, which is technically and practically easier to handle. But the addition of a silicon layer and the potential of adherent air bubbles (probably a frequent reason for poor SWL results in clinical practice) can decrease the shock wave energy significantly. The way back to the tub could be the future for ensuring optimal coupling, but that is not compatible with integration into a urological workstation.

- To localize the stone, fluoroscopy is the standard. Here the rotatable x-ray tube mounted on a C-arm is less expensive and more practical compared to the two fixed tubes of the HM3. For the option of ultrasound localization we should expect that in-line localization is more precise as compared with off-line.

Since there is no ideal lithotripter we have to choose between the different options, making technical and economic compromises.
THE DEVELOPMENT OF COMPETITIVE PROCEDURES: URS AND PCNL

While SWL showed a continuous increase in usage up to its culmination in the early 1990’s, endoscopic procedures have since that time been continuously progressing in technical precision and clinical application [7,8]. By means of miniaturization, more effective devices can be passed through to the stone (e.g., 6-8 French ureteroscopes, holmium laser, etc.) by URS [9] or PCNL [10]. By using flexible endoscopes (together with access sheaths and nitinol baskets) all parts of the upper urinary tract can be accessed. The crucial advantage of endoscopy compared to SWL is the potential for immediate removal of the concretions. Even optimal fragmentation by SWL is followed by a time period for the clearing of the fragments, with the associated risk of colic and obstruction. Particular for kidney stones the time for fragment clearance is unpredictable. But nowadays patients are less willing to accept a course of treatment with unpredictable outcomes. This disadvantage of SWL has to be balanced against the risks of complications of endoscopic methods, which are higher than for SWL.

CHANGES IN INDICATIONS FOR SWL

After the first application of SWL to kidney stones, the indications were expanded rapidly to nearly all stone situations. After the development of lithotripters with the possibility of ventral coupling, stones in the mid ureter could also be treated. “Soft” struvite stones were disintegrated just as were hard cystine or brushite stones. Therefore SWL was the first-choice treatment for all these stones, except for complex staghorn stones, in the early 1990’s. At that time some studies appeared which indicated limitations of SWL efficiency [11]. For stones larger than 2 cm and for staghorn calculi the re-treatment rate, auxiliary measures and complications are too frequent (http://www.auanet.org/guidelines/staghorn calculi05.cfm). For stones located in the lower pole the clearance of fragments can be reduced. Therefore for this stone position the indication for SWL is restricted to a stone size of less than 2 cm in case of a narrow, long and steep calyceal neck [12,13]. In the ureter, URS and SWL seem to be equally effective for stones up to 1 cm in size. For larger stones endoscopic procedures are preferred (http://www.auanet.org/guidelines/main_reports/UreStnMain8_16.pdf). For large ureteral or pelvic stones, laparoscopic procedures are increasingly used.

THE FUTURE ROLE OF SWL

Technical development of shock wave lithotripsy

The “mechanisms of shock wave action and strategies for improved SWL” have been presented excellently in this symposium (session 7). Meanwhile there are some important results for the clinical routine to be respected for an more effective and safer
SWL. With respect to this the frequency of shock wave application should be restricted to around 90 SW/min [14,15]. Furthermore, during the SWL session the shock wave energy should be increased progressively [16]. In this manner the initial atraumatic low energy induces vasoconstriction to protect the kidney when the energy is raised. Respecting this, the efficacy of the available lithotripters could be optimized. But the difficult challenge is to surpass that which was already achieved and is still the gold standard since more than 25 years ago.

Because the historical development of a smaller focal zone with high peak pressure was accompanied by loss of disintegrative capacity [17] the tendency is now toward a flexible shock wave generator providing different configurations of the focal zone.

The temporal and spatial pressure distribution of the shock wave determines its disintegrative efficacy on the stone and its traumatizing capacity in the tissue. The induction of cavitation plays a crucial role for both effects [18-21]. But, there may be a conformation of the shock wave that can allow both results; that is, it has been hypothesized that stone disintegration can be improved while tissue trauma is diminished by manipulating the dynamic of cavitation activity [22-24]. Since the possibilities are limited for changing the relevant parameters specifically using a single source, studies have also been performed by combining different generators. One of the first devices used clinically was a “Twin-Head” lithotripter. In this design two identical electrohydraulic sources are integrated to have the same focal point but the shockwave axes are perpendicular to each other [25]. Another option is the double-layer piezoelectric element in which two layers are activated with a short delay and with different energy parameter [26]. Both of these innovative lithotripters have not been shown to be superior to conventional machines with respect to disintegration and trauma. A very new and promising unit is the combination of an electrohydraulic with a piezoelectric generator. With this design a variety of parameters can be controlled specifically to evaluate the ideal pulse profile and shock wave sequence. For in vitro application the optimization was successful but this has to be confirmed in vivo and in the clinical setting [27].

As already mentioned, coupling and changes of the shock wave parameter during the intracorporeal path is a critical point in SWL [28,29]. These challenges may explain in part why it has been so difficult to improve SWL.

**Adverse side effects of SWL**

Just recently, reports about long-term side effects of SWL were published and were discussed intensively in this symposium [30] (session 7). Even though the author of this article speculates that the observation that SWL induces significant diabetes won’t be confirmed by further studies, we still have to await the definite results. For the moment we draw the conclusion that the side effects of SWL may not be disregarded in the discussion on changing and improving shock wave generators. And we are encouraged to search after the factors and parameters to distinguish between disintegration and side effects [22,31,32].
Stone localization and positioning

Besides shock wave generation and coupling the precise localization of the stone and its positioning in the focal point is essential for SWL success [33]. There are efforts to enable automatic positioning and continuous observation of stone location. The complete protection of the patient from x-rays can only be realized by using ultrasound imaging, and the first study to attempt to use ultrasound to track and target stones is promising [34]. But, automatic adjustment of localization of therapeutic energy in an actual patient is likely to be more difficult than in experimental models.

DEVELOPMENT OF COMPETITIVE ENDOSCOPIC TECHNIQUES

The next stage of progress in endoscopy technology will happen in the field of video imaging. The diameter of the endoscope can be reduced when the light and video-transmission channel requires a smaller part of the instrument cross section. Additional space for improved irrigation flow to improve the view will be achieved by smaller tools (laser fiber, baskets, grasper). The working channel cannot be reduced even more, since otherwise removal of stones and therefore the advantage of the endoscopic technique would be reduced. The reduction of the diameter in ureteroscopy will enable the elimination of postoperative stenting and therefore significantly reduce morbidity and avoid re-intervention for stent removal. PCNL has the advantage that a 26F access can be used without significant trauma to the kidney, when inserted properly. Mini-PCNL will become the alternative for smaller kidney stones and will fill the gap between flexible URS up to 1 cm kidney stones and 2 cm stones to be treated by conventional PCNL. Therefore there are reasonable endoscopic options for all urinary stones. If PCNL clears the stone definitively, a postoperative nephrostomy can be avoided in some cases to reduce morbidity even more.

PREDICTION OF SUCCESS

Different stone materials vary in their susceptibility to fragmentation by SWL. Therefore efforts are being made to predict the stone composition in situ especially using CT scans. Hounsfield units have been correlated with disintegration by SWL [35], but there are problems with this (see Williams et al. in this volume). Additionally, such measurements are not yet standardized and the correlations that have been reported are not specific enough to be used in clinical cases. One reason for this is that other parameters of the stone situation also affect the efficacy of SWL. This multifactorial situation may be able to be analyzed and predicted by “artificial neural networks” [36]. This approach can include not only stone composition but also size, location and other specifications of the stone. These computer programs can be trained and continue to learn with new data. The intention of this is to provide an electronic version of the physician’s experience. But in medicine we are far from the situation that human expertise based on knowledge and experience can be exceeded by
computers. One critical point is usually not considered: The personal preference of the surgeon founded in operating experience is an essential predictive factor for success. But according to “Evidence Based Medicine” this preference factor has to be discounted. Evidence-based medicine, what it is and what it isn’t: It’s about integrating individual clinical expertise and the best external evidence [37].

**TREATMENT PHILOSOPHY: SWL VS. ENDOUROLOGY**

For most of the calculi in the upper urinary tract different options are offered as reasonable and successful treatments. The physician’s experience is the next essential factor. But the final decision is set by the patient’s preference. In general, patients have to decide among three different strategies (Table 1).

**Table 1. The three strategies for treating stones in the upper urinary tract.**

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Advantage</th>
<th>Disadvantage</th>
</tr>
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<tbody>
<tr>
<td>SWL without anesthesia</td>
<td>o No anesthesia</td>
<td>o Lower stone clearance rate</td>
</tr>
<tr>
<td></td>
<td>o Low complication rate by procedure</td>
<td>o Longer follow-up to stone clearance</td>
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<tr>
<td></td>
<td>o Low treatment costs</td>
<td>o Risk of complication during passage of residual fragments</td>
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<tr>
<td></td>
<td>o No drainage (stent, PCNL)</td>
<td>o Higher costs in follow-up</td>
</tr>
<tr>
<td>SWL under anesthesia</td>
<td>o Better disintegration rate</td>
<td>o Moderate duration up to stone clearance</td>
</tr>
<tr>
<td></td>
<td>o Low complication rate by procedure</td>
<td>o Risk of complication during passage of residual fragments</td>
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<tr>
<td></td>
<td>o Moderate treatment costs</td>
<td>o Moderate costs in follow-up</td>
</tr>
<tr>
<td></td>
<td>o No drainage (stent, PCNL)</td>
<td></td>
</tr>
<tr>
<td>Endourology under anesthesia</td>
<td>o Highest immediate stone clearance rate</td>
<td>o Risk for severe complications</td>
</tr>
<tr>
<td></td>
<td>o Shortest treatment time</td>
<td>o Anesthesia</td>
</tr>
<tr>
<td></td>
<td>o Shortest and least expensive follow-up</td>
<td>o Drainage (stent, PCNL) re-intervention for removal of drainage</td>
</tr>
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</table>

In Europe the advantage of SWL being able to be used without anesthesia is highly appreciated [38]. Therefore the second generation lithotripters were favored even if they had limited efficacy compared to the HM3 under analgesia. In contrast, in the USA the application of general or spinal anesthesia for a comfortable shock wave treatment is not assessed as an disadvantage. Under anesthesia maximal energy can be applied with the intention to reach the highest rate of stone disintegration independently of the induced pain. The solitary limit is the tissue trauma.

The difference in using anesthesia has resulted in a bias in the competition for the nomination of the “gold standard” lithotripter. Until now the unmodified Dornier HM3 is seen to provide the highest disintegrative efficacy and is usually run under anesthesia. The high-end second or third generation lithotripters (Storz Modulith, Siemens Lithostar, Wolf Piezolith etc.) did not exceed this, but treatment was usually applied usually under analgesia-sedation. Studies should be conducted to compare all these machines (including the flexible focal zones of the latest machines) under the
same conditions (general anesthesia) with respect to disintegration and trauma. The results would then provide a basis for the next comparison against the endoscopic procedures.

ADDITIONAL PARAMETERS INFLUENCING THE FUTURE OF SWL

Epidemiology

Urologists should not fear that the occurrence of urinary stones will decline. In fact, the worldwide prevalence, incidence and number of treatments for urinary stones is growing continuously in industrialized nations. For example the prevalence and incidence rose from 4 to 7% and from 0.54 to 1.47 in Germany between 1979 and 2001 [39-44]. A primary reason for this could well be prosperity, which is also evidenced by the spread of the “metabolic syndrome” correlated with body mass index [45,46], diabetes mellitus [47,48] and gout [49-51] as independent risk factors (see also Session 1 from this Symposium).

Metabolic evaluation and metaphylaxis

The highest risk for the future of SWL would be the successful medical treatment of calcium oxalate stones. There are many new insights into the pathogenesis of urinary stones (sessions 1, 3, 5, 6 of this Symposium). We are waiting for a “Viagra-solution” for urinary stones. But the stone surgeons can be confident of keeping their employment, since only a few patients will pay so much money and side effects to avoid the occasional case of renal colic. Because of that, the pharmaceutical industry has limited interest in this field.

Economic factors

There is no doubt that economic factors play a distinct role in deciding between different treatment options [52]. Multiple trials have tried to calculate costs and remuneration for SWL and endourologic procedures, but have not been able to present consistent results. In some studies SWL was more cost effective [53] and in others URS [54-56]. Remuneration is determined by the health system and therefore differs significantly with the country [57]. The consequence is that cost-effectiveness cannot be calculated generally. Therefore a major factor in decision making is locally specific, but there is a general tendency toward endoscopy.

SUMMARY OF THE GLOBAL PERSPECTIVE

- The incidence of urolithiasis is continuously increasing along with the metabolic syndrome, which is correlated with prosperity.
Efficient metaphylaxis is missing due to low effectiveness, low acceptance and compliance by the patient or due to costs.

Knowledge about pathogenesis of urolithiasis is growing dramatically. Therefore the possibility to develop a sufficient medical treatment is imminent. But that would primarily reduce the prevalence, since treatment is not likely to be started until the first stone episode happens.

All this results in an increasing need for active stone removal.

SWL was and already is a well-established treatment modality for urolithiasis in the upper urinary tract.

For most stone situations there will remain a reasonable choice between SWL versus endoscopic procedures.

Concerning their efficiency, lithotripter development seems to have reached a peak level in recent years. A further increase is not to be expected. But attention should be paid to the clinical results of the “tailored shock wave configuration” using new generator concepts.

The evolution of tools for endoscopic stone removal is proceeding. The major point is to keep the advantage of immediate clearance of all concretions by maximal disintegration and removal via a sufficient working channel in the endoscope.

Adverse side effects of both treatment concepts are minimized. Reactivated discussions will show the harmlessness even in long term follow up.

Patients can expect a nearly 100% success rate. But additionally they expect more and more a very comfortable treatment. Therefore the tendency is to be treated under general anesthesia even for SWL to ensure pain-free and rapid (by using highly effective shock waves) therapy. Also for general anesthesia the morbidity could be reduced significantly as compared to the past.

Facing the choice between medically reasonable options, two other points will crucially influence the decision: expertise of the surgeon and costs. Parameters with respect to this in the calculation of efficiency have to be established.

In conclusion SWL will continue to play an established, if slightly reduced, role in stone treatment in the future.

REFERENCES