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ARTICLE

Is extracorporeal shockwave lithotripsy (SWL) still suitable for >1.5 cm intrarenal stones? Data analysis of 1902 SWLs

Wilmar Azal Neto[a]*, Enzo Morales[b]*, Marina Joseane Pachecco[b], Renato Nardi Pedro[c]* and Leonardo O. Reis[a]*

[a]UroScience, University of Campinas and Pontifical Catholic University of Campinas, Campinas, Brazil; [b]Medicine, Faculdade São Leopoldo Mandic, Campinas, Brazil; [c]Endourology Section, University of Campinas and AME/SBO Lithotripsy Center – UNICAMP, Campinas, Brazil

ABSTRACT

Purpose: According to the American Urological Association and European Association of Urology guidelines, shockwave lithotripsy (SWL) is the least-invasive treatment option for kidney stones smaller than 2 cm. However, it is well known that SWL stone-free rates (SFR) decline as stone size increases. We sought to evaluate whether the size limit of 1.5 cm could be a better predictor of success after a single SWL session than current recommendations.

Methods: Data from an SWL-dedicated center were prospectively scrutinized according to stone locations and sizes. Information on patients' demography, lithotripsy parameters, and outcomes was evaluated by multivariate analysis among 1902 SWLs.

Results: The overall SFR was 70.8% (1347/1902). SFRs according to stone size were <1 cm: 73.8% (825/1118), 1–1.5 cm: 70.4% (401/569) and >1.5 cm: 56.2% (121/215); and according to calculi location were lower pole (LP) 64.4% (398/618), mid pole 73.8% (339/459), upper pole 73.8% (273/370) and renal pelvis 74.1% (337/455). Multivariate analysis revealed better SFR independent better SFR in <1.5 cm ($p < 0.01$), and non-LP stones ($p < 0.01$).

Conclusion: SWL is an effective treatment modality for kidney stones. The single session reached up to 74.8% SFRs (range 70.8%–74.8%) when indicated for intrarenal non LP stones smaller than 1.5 cm. Patients with stones >1.5 cm or >1 cm located in the LP should be counseled on the lower SFRs after a single SWL session.

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Introduction

Urolithiasis is a prevalent disease around the globe. Its incidence is increasing over time, and it has been estimated that up to 8.8% of the United States of America's population will be affected by this condition [1]. Currently, kidney stones are treated by minimally invasive surgical modalities such as extracorporeal shockwave lithotripsy (SWL), flexible ureteroscopy (FURS) and percutaneous nephrolithotomy (PCNL). According to the American Urological Association (AUA) and European Association of Urology (EAU) guidelines, SWL is the least-invasive procedure and it can be an option for kidney calculi smaller than 2 cm [1,2]. However, it is well known that SWL stone-free rates (SFRs) decline as stone size increases, making endourological approaches more suitable for bigger lithiasis burden [1–3].

Success rates for SWL depend on several patient and stone characteristics, with lower SFRs reported for calculi located in the lower pole, long stone-to-skin distance (SSD), hard stones and big stone burden [3]. Nevertheless, stone size is one of the most traditionally used features to choose between surgical treatment modalities [4].

In an era of profound advancements in minimally invasive endoscopic approaches of the upper urinary tract providing high treatment success, it is important to gather as much scientific evidence as possible to counsel our patients on the best option for their stones in particular. In the present study, we sought to evaluate whether the size limit of 1.5 cm could be a better predictor of success after a single SWL session than the current recommendation. For this purpose, we report data from an SWL-dedicated center, where every procedure follows its best procedure clinical practice standards.

Methods

From December 2009 to December 2018 a total of 4130 SWL were performed at an outpatient Lithotripsy Center with a devoted operating room and staff in the interior of São Paulo State, Brazil. The center is a referral for more than 16 counties, and all patients referred to it had been seen by the respective county's general urologist and had undergone laboratory and image workup with kidney, ureter and bladder (KUB) radiography and urinary tract ultrasound (US). A

CONTACT Leonardo O. Reis reisleo.l@gmail.com UroScience, University of Campinas and Pontifical Catholic University of Campinas, Av. John Boyd Dunlop - Jardim Ipaussurama, Campinas, 13034-685, SP, Brazil.
*Authors contributed equally.

dedicated radiologist performed and reported the US and KUB stone size by the largest diameter.

All data regarding every patient and the SWL performed were prospectively tabulated (Microsoft Excell®) according to the patient's information, stone size and location, SWL procedure parameters and its outcomes. SWL outcome was based on a KUB and/or US, which were checked by the SWL center urologist 4 weeks after the procedure, at the follow-up visit.

SWL procedure description

According to the lithotripsy center protocol, all procedures were done under intravenous sedation with fentanyl, midazolam and propofol that was carried out by the SWL-dedicated anesthesiology team. The lithotripter machine used in all cases was a Siemens® Modularis Variostar (Erlanger, Germany) that has an electromagnetic energy source (joules) with a penetration depth of 14 cm. Patient positioning, stone identification and targeting, shockwave delivery and energy setting were carried out by only one SWL-trained urologist, also responsible for checking on the follow-up visits.

Intraoperative stone localization was determined in all patients with ultrasound (Siemens® G20, Erlanger, Germany) and, if necessary, fluoroscopy (Siemens® Arcadis, Erlanger, Germany). Shockwave impulses were guided in real time by ultrasound (targeting) and increased in a stepwise manner (ramping) at a frequency of 1.5 Hz (90 shocks/min) in every case. Intrarenal calculi fragmentation was assessed in real-time with US, whereas pure fluoroscopic evaluation was limited for cases with difficulty in stone targeting, such as anatomical abnormalities suspected during the real-time US.

Patients were discharged on the same day from the center to their counties after a full recovery from intravenous sedation. Painkillers and a non-steroidal anti-inflammatory were prescribed in case of post-SWL pain. None of the patients were put on alpha-blockers trying to aid fragment clearance.

Study population

Inclusion criteria: (a) a single intrarenal stone smaller than 2 cm, (b) first SWL session, (c) available 4-week postoperative image follow-up, (d) performed by a single SWL-trained urologist.

Exclusion criteria: (a) ureteral stones, (b) congenital kidney abnormalities, (c) presence of double J catheter ipsilateral to the treatment unit, (d) repeated SWL.

The study population was evaluated based on the collection of the following information: (a) stone size, (b) stone location, (c) stone-free rates, (d) SWL settings (including the number of shocks, maximal energy, mean energy), (e) demographics (age and gender).

Outcomes

SWL success (stone-free) was considered in patients with no fragments or a fragment up to 4 mm at the KUB radiography or US presented in the 4-week post-SWL consult. SFR and <4 mm residual fragment rate were evaluated according to stone size and location.

Data analysis was performed with Microsoft Excel® (version 16.32 – 2019) using mean and standard deviation, student *t*-test and multivariate analysis, where $p < 0.05$ was considered significant. For comparison, the stone size was categorized as <1 cm, 1–1.5 cm, and >1.5 cm and location as lower pole (LP), mid pole (MP), upper pole (UP) and pelvis.

Results

There were 1902 consecutive eligible SWLs, 45.6% were male (868) and 54.4% were female (1034), mean age was 45.8 ± 13.8 years, mean stone size was 0.89 cm ± 0.4, the mean number of shocks was 1997 ± 534, mean maximum energy (Emax) was 2.96 ± 0.44 J, mean mid energy (Emed) was 1.78 ± 0.52 J and overall SFR was 70.8% (1347/1902).

The total number of procedures that met the exclusion criteria was 2228: 55.2% ($n = 1230$) other urologists or multiple stones; 21.5% ($n = 479$) repeated SWL procedure; 13.8% ($n = 307$) ureteral stones; 9% ($n = 200$) double J catheter and 0.5% kidney abnormalities ($n = 12$).

The percentage of patients with stones located at LP, MP, UP and pelvis were, respectively, 32.4% (618), 24.1% (459), 19.4% (370) and 23.9% (455). Additionally, according to the size, calculi <1 cm, 1–1.5 cm and >1.5 cm, were, respectively, 58.7% (1118), 29.9% (569) and 11.3% (215) (Figure 1). There was no significant difference in stone size between UP/MP/LP stones ($p = 0.11$); however, pelvis location was more associated with >1.5 cm stones ($p = 0.0000045$).

Table 1 shows the study population characteristics and results.

SFRs of UP (73.8%), MP (73.8%) and pelvis (74.1%) stones were significantly better than LP (64.4%) stones ($p = 0.001$, $p = 0.00008$ and, $p = 0.00005$, respectively). Also, all non-LP calculi (UP, MP, pelvis) when compared with LP stones showed significantly better SFRs ($p = 0.004$). There was no significant difference in the SFRs between UP, MP and pelvis stones ($p = 0.94$).

Patients with kidney calculi <1 cm and 1–1.5 cm had significantly better SFRs (73.7%, $p = 0.000001$; 70.4%, $p = 0.0003$,

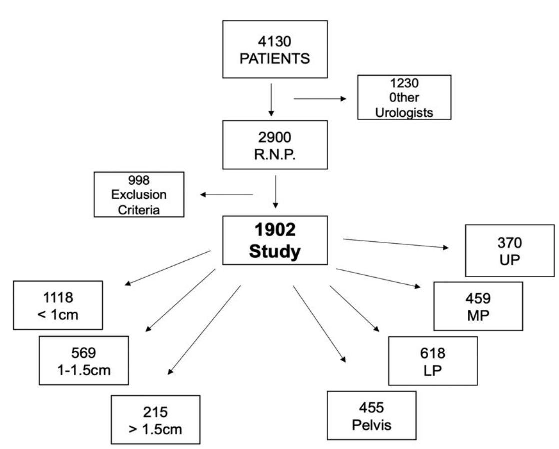

Figure 1. Study design. Lithotripsy Center 4130 SWL from 2009 to 2018.

Table 1. Study population characteristics and results.

Variables	<1 cm	1–1.5 cm	>1.5 cm	Lower pole	Mid pole	Upper pole	Pelvis	Total
Demography								
N	1118	569	215	618	459	370	455	1902
Male/ female (%)	44/56	49/51	43/57	49/51	46/54	43/57	44/56	46/54
Mean age (years)	44.9 (±13.6)	46.4 (±14.4)	48.7 (±13.2)	45.7 (±- 13.1)	43.9 (±14.3)	44.8 (±14.0)	48.4 (±13.8)	45.8 (±13.8)
4-week image follow-up								
SFR (%)	73.7	70.4	**56.2***	**64.4***	73.8	73.8	74.1	70.8
SFR <4 mm Frag (%)	6.3	25.9	40.4	13.3	5.9	16.1	10.7	11.3
SWL parameters								
Mean no. shocks	1847 (±475)	2102 (±502)	**2504* (±535)**	1978 (±517)	1880 (±449)	1975 (±597)	2161 (±546)	1997 (±535)
Mean Emax (joule)	2.85 (±0.39)	3.30 (±0.37)	3.29 (±0.44)	2.90 (±0.35)	2.80 (±0.40)	2.90 (±0.41)	3.20 (±0.54)	2.96 (±0.44)
Mean Emed (joule)	1.61 (±0.49)	2.09 (±0.47)	2.22 (±0.51)	1.70 (±0.47)	1.70 (±0.48)	1.70 (±0.56)	2.00 (±0.55)	1.78 (±0.52)

*$p < 0.05$.

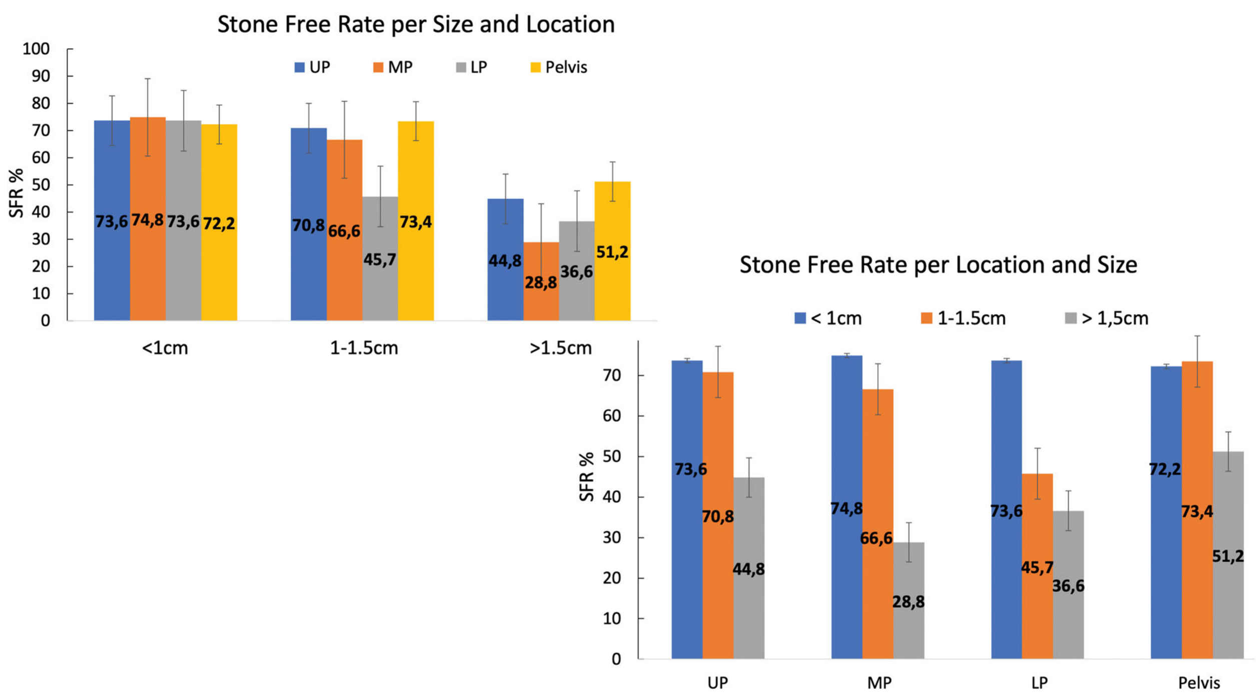

Figure 2. Stone free rates according to size and location.

respectively) than >1.5 cm stones (56.2%), whereas there was no difference in SFRs between <1 cm and 1–1.5 cm stones ($p = 0.1$).

Multivariate analysis revealed an independent better SFR in <1.5 cm ($p < 0.01$) and non-LP stones ($p < 0.01$). Figure 2 illustrates the SFRs according to stone size and location.

Figure 3 illustrates the shockwaves number and energy (joules) per stone size and location. Bigger stones underwent a higher number and energy of shocks, $p < 0.05$ for stones >1.5 cm.

Discussion

According to the most recent 2021 update of the EAU Urolithiasis Guideline [2] and also 2016 AUA Kidney Stones Surgical Management [1], SWL is considered a first-line treatment modality for stones smaller than 2 cm, not only for its competitive results but also for being the least-invasive treatment option.

In the present study, the overall SWL SFR after a single session was 70.8%, which goes along with data published in other centers that advocate the best-known SWL practices, which include general anesthesia [5], ultrasound targeting [6], stepwise energy adjustment (ramping) [7], electromagnetic lithotripter and an SWL-trained urologist [8]. Most of our SWLs were ultrasound-guided, decreasing radiation exposure – as recommended by the ALARA (As Low As Reasonably Achievable) X-Ray policy, and it allowed a more accurate real-time stone localization.

However, SWL SFRs are known to decrease in certain circumstances such as (a) lower pole stones, (b) high-density lithiasis, (c) long SSD and (d) large calculi burden [3]. Khalil

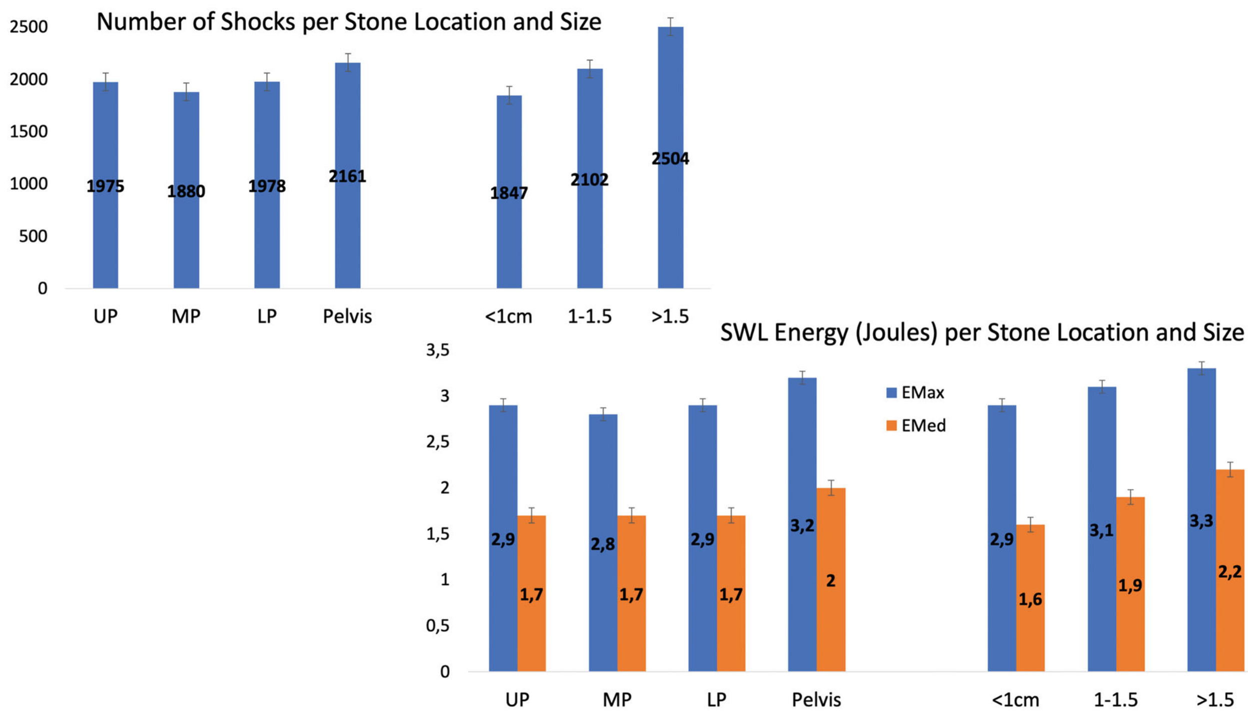

Figure 3. Shockwaves number and energy (joules) per stone size and location.

et al. suggested that stone burden is more important than location in predicting SFRs [9]. The authors stated that SFRs of stones of 1 cm, 1.1–2 cm and >2 cm was 50.2%, 39.6% and 10.2%, whereas SFRs for stones in the renal pelvis, lower, middle and upper calyces were 72.4%, 56%, 55.6% and 69%, respectively. The present study also showed that stone size is a major predictor of outcome. Stones >1.5 cm have lower SWL SFRs after a single session (56.2%, $p < 0.05$); however, the stone location did play an important role in predicting SFRs. Lower pole stones were associated with poor SFRs after a single SWL session (64.4%, $p < 0.05$). Nevertheless, apart from these two specific situations, the study's single-session SWL SFRs reached up to 74.8% (range 70.8%–74.8%) when indicated for intrarenal non-LP stones smaller than 1.5 cm.

Recently, comparison of SWL versus endourological approaches (FURS and PCNL) for stones >1.5 cm has shown better SFRs for the endoscopic counterpart [9–12]. Due to the increase in safety of the endoscopic procedures and also to their competitive SFRs, the role of SWL for bigger stones has been questioned, although it is worth noting that most studies looked at lower pole stones, where SWL has a well-known disadvantage.

The present study reported SFRs for 1–1.5 cm and >1.5 cm LP stones after a single SWL session of 45.7% and 36.6%, respectively. Both recent literature and the present study presents discouraging SWL SFRs for 1–1.5 cm and >1.5 cm LP stones after a single session. On the other hand, Kim et al. showed that SWL for >1 cm LP stone is indeed efficient in rendering patients stone-free after a mean of 3.8 SWL sessions [13]. And our study's modest findings on >1 cm LP SFRs were not consistent for <1 cm LP stones, which achieved as high as 73.6% SFR after a single SWL session. The results displayed in the present study are related to a single SWL procedure for a practical comparison with other treatment modalities that usually require a single patient admission.

Interestingly, the number of shockwaves and energy delivered to stones >1.5 cm were higher ($p < 0.05$), translating the clinical efforts in fragmenting these stones to optimize SFRs. The present study demonstrated that as stone size increases the SWL energy settings increase accordingly. This was not seen with regards to stone location, where SWL energy settings did not present significant difference, except for a tendency for higher SWL energy and the number of shocks in the pelvis; however, the pelvis had a higher percentage of stones >1.5 cm (23%, $p < 0.05$) compared with other locations.

Also, it is important to note that more shockwaves mean more procedural time and more energy delivered to the kidney, meaning more risk of adverse events and tissue injury [14]. Moreover, the <4 mm residual fragment rate also increased as stone sizes increased, as foreseen due to more fragments generated during SWL for a bigger stone burden.

Therefore, for the two above-mentioned situations (kidney stones >1 cm in the lower pole and calculi >1.5 cm) where SWL SFRs could be jeopardized, the endoscopic approach seems to be a better option. And they make clear the impact of technology in the endourology field, frequently launching better endoscopic tools, promoting training skills laboratories and fostering more attractive physician reimbursement. SWL has not been subjected to technological advances at a rate close to its endoscopic counterparts, and also new urologists are not getting well trained on it. The impact of lack of practice on the SWL outcomes is substantial [8] once SWL-trained teams are highly efficient in resulting in competitive SFRs [15]. The results published in the present study not only reiterate the essential role of SWL in the active treatment of kidney stones but also highlights the importance of case selection and personnel training for achieving excellent treatment outcomes.

Regarding the SWL 'outcome', while most fragments are cleared within a short period after the procedure, some may take up to 3 months to be eliminated [16]. As also defined by other studies [17,18], our endpoint follow-up, unfortunately, was at 4 weeks – at this point, the patient returned to their county, even though we are aware that this might have underestimated the real SFR.

It is important to mention that the present study has limitations. First, it has not evaluated information on SSD and lithiasis density, once the patients were referred to our center with a basic preoperative workup done in their districts – that means, no computerized tomography (CT), which is the gold standard exam. Second, our SWL center is an Ambulatorial Surgical Unit and is not equipped with a CT as well, and so even though some studies measure their results by using KUB alone [18–21] or KUB plus US [22,23], a post-procedure CT would have been more accurate to analyze SFRs. Lastly, all post-SWL events were assisted by the referring urologist at the patients' counties, and therefore no information on complications was included in the paper.

Conclusion

SWL is an effective treatment modality for kidney stones. The single session reached up to 74.8% SFRs (range 70.8%–74.8%) when indicated for intrarenal non-LP stones smaller than 1.5 cm. Patients with stones >1.5 cm anywhere in the kidney or >1 cm located in the lower pole should be counseled on the lower SFRs after a single SWL session.

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Ethical approval

Research involving Human Participants: The authors certify that the study was performed under the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Author contributions

All authors have made a substantial contribution to the information or material submitted for publication. All authors have read and approved the final manuscript. No author has direct or indirect commercial or financial incentives associated with the publishing of this manuscript. There was no extra-institutional funding for this project. The manuscript, or portions thereof, is not under consideration for publication by any other journal or electronic publication and has not been published previously.

Disclosure statement

No potential conflict of interest was reported by the author(s).

ORCID

Leonardo O. Reis http://orcid.org/0000-0003-2092-414X

References

[1] Assimos D, Krambeck A, Miller NL, et al. Surgical management of stones: American Urological Association/Endourological Society Guideline, PART I. J Urol. 2016;196(4):1153–1160.
[2] Türk C, Petřík A, Sarica K, et al. EAU guidelines on interventional treatment for urolithiasis. Eur Urol. 2016;69(3):475–482.
[3] El-Nahas AR, El-Assmy AM, Mansour O, et al. A prospective multivariate analysis of factors predicting stone disintegration by extracorporeal shock wave lithotripsy: the value of high-resolution non-contrast computed tomography. Eur Urol. 2007;51(6): 1688–1693.
[4] Weaver J, Monga M. Extracorporeal shockwave lithotripsy for upper tract urolithiasis. Curr Opin Urol. 2014;24(2):168–172.
[5] Sorensen C, Chandhoke P, Moore M, et al. Comparison of intravenous sedation versus general anesthesia on the efficacy of the Doli 50 lithotriptor. J Urol. 2002;168(1):35–37.
[6] Van Besien J, Uvin P, Hermie I, et al. Ultrasonography is not inferior to fluoroscopy to guide extracorporeal shock waves during treatment of renal and upper ureteric calculi: a randomized prospective study. Biomed Res Int. 2017;2017:7802672.
[7] Skuginna V, Nguyen DP, Seiler R, et al. Does stepwise voltage ramping protect the kidney from injury during extracorporeal shockwave lithotripsy? Results of a prospective randomized trial. Eur Urol. 2016;69(2):267–273.
[8] Okada A, Yasui T, Taguchi K, et al. Impact of official technical training for urologists on the efficacy of shock wave lithotripsy. Urolithiasis. 2013;41(6):487–492.
[9] Khalil MM. Which is more important in predicting the outcome of extracorporeal shockwave lithotripsy of solitary renal stones: stone location or stone burden? J Endourol. 2012;26(5):535–539.
[10] Torricelli FC, Marchini GS, Yamauchi FI, et al. Impact of renal anatomy on shock wave lithotripsy outcomes for lower pole kidney stones: results of a prospective multifactorial analysis controlled by computerized tomography. J Urol. 2015;193(6):2002–2007.
[11] El-Nahas AR, Ibrahim HM, Youssef RF, et al. Flexible ureterorenoscopy versus extracorporeal shock wave lithotripsy for treatment of lower pole stones of 10-20 mm. BJU Int. 2012;110(6):898–902.
[12] Ghani KR, Sammon JD, Karakiewicz PI, et al. Trends in surgery for upper urinary tract calculi in the USA using the Nationwide Inpatient Sample: 1999–2009. BJU Int. 2013;112(2):224–230.
[13] Kim TB, Lee SC, Kim KH, et al. The feasibility of shockwave lithotripsy for treating solitary, lower calyceal stones over 1 cm in size. Can Urol Assoc J. 2013;7(3–4):E156–E160.
[14] Hadj-Moussa M, Brown JA. Effect of high shock number on acute complication development after extracorporeal shockwave lithotripsy. J Endourol. 2013;27(8):1015–1019.
[15] Lee C, Best SL, Ugarte R, et al. Impact of learning curve on efficacy of shock wave lithotripsy. Radiol Technol. 2008;80(1):20–24.
[16] Azal Neto W, Reis LO, Pedro RN. Prediction of stone-free rates following extracorporeal shockwave lithotripsy in a contemporary cohort of patients with stone densities exceeding 1000 HU. Scand J Urol. 2020;54(4):344–348.
[17] Ouzaid I, Al-Qahtani S, Dominique S, et al. A 970 Hounsfield units (HU) threshold of kidney stone density on non-contrast computed tomography (NCCT) improves patients' selection for extracorporeal shockwave lithotripsy (ESWL): evidence from a prospective study. BJU Int. 2012;110(11b):E438–E442.
[18] Elkoushy MA, Hassan JA, Morehouse DD, et al. Factors determining stone-free rate in shock wave lithotripsy using standard focus of Storz Modulith SLX-F2 lithotripter. Urology. 2011;78(4): 759–763.

[19] Pareek G, Armenakas NA, Panagopoulos G, et al. Extracorporeal shock wave lithotripsy success based on body mass index and Hounsfield units. Urology. 2005;65(1):33–36.
[20] Joseph P, Mandal AK, Singh SK, et al. Computerized tomography attenuation value of renal calculus: can it predict successful fragmentation of the calculus by extracorporeal shock wave lithotripsy? A preliminary study. J Urol. 2002;167(5):1968–1971.
[21] Buchholz NP, Rhabar MH, Talati J. Is measurement of stone surface area necessary for SWL treatment of nonstaghorn calculi? J Endourol. 2002;16(4):215–220.
[22] Abdelhamid M, Mosharafa AA, Ibrahim H, et al. A prospective evaluation of high-resolution CT parameters in predicting extracorporeal shockwave lithotripsy success for upper urinary tract calculi. J Endourol. 2016;30(11):1227–1232.
[23] Mi Y, Ren K, Pan H, et al. Flexible ureterorenoscopy (F-URS) with holmium laser versus extracorporeal shock wave lithotripsy (ESWL) for treatment of renal stone $<$2cm: a meta-analysis. Urolithiasis. 2016;44(4):353–365.