Effect of targeting and generator type on efficacy of extracorporeal shock wave lithotripsy

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Objective. Analysis of the effect of technical factors, i.e. the type of stone targeting and shock wave generator, on ESWL efficacy. Evaluation of secondary outcomes to determine an optimal strategy for performing the procedure.

Patients and Method. In the period from 01/2016 to 07/2021, we analyzed data from patients indicated for ESWL for nephrolithiasis and proximal or distal ureterolithiasis. This was a tricenter retrospective study to evaluate stone-free rates (SFR) while taking into account the number of ESWL sessions in four selected groups of patients with comparable characteristics. A patient is considered stone-free in the absence of residual lithiasis or with an asymptomatic residue of up to 2 mm. The real-time ultrasound-guided (USG) arm consisted of a group of 120 patients on the electromagnetic STORZ SLK lithotripter in the period from 02/2017 to 02/2020. A total of three comparison arms with x-ray guidance were created: A: 68 patients between 01/2016 and 03/2017 on the Medilit 7 electrohydraulic lithotripter. B: 72 patients from 04/2017 to 10/2017 on the Sonolith i-sys electroconductive lithotripter (EDAP). C: 120 patients from 03/2018 to 07/2021 on the STORZ SLK electromagnetic lithotripter. By comparing the US and x-ray guidance using the STORZ SLK lithotripter, the effect of targeting when using an identical device (electromagnetic generator) was evaluated. By comparing the arms A, B, and C, the efficacy in different types of generators – electromagnetic, electroconductive, electrohydraulic – was assessed when the same type of targeting (fluoroscopy) was used. The secondary parameters that were monitored included: the rate of use of auxiliary techniques in stone management; radiation exposure for the patient and/or operator; analgesic consumption; and the time required to perform the procedure.

Results. When US versus x-ray guidance was compared in an electromagnetic lithotripter, SFRs of 90% vs. 85% (P=0.329), i.e. statistically comparable results, were obtained. By comparing electromagnetic, electroconductive, and electrohydraulic generators with fluoroscopy, SFRs of 85%, 88.9%, and 88.2% were obtained, respectively (P=0.727). When the degree of need for intraoperative analgesic administration was assessed, the electromagnetic generator was found to have a significantly lower consumption (20.8% vs. 30.6% vs. 48.5%) (P=0.0005). Values less than 1095 HU and 108.5 mm were shown to be optimal cut-off values for stone density and skin-to-stone distance, respectively.

Conclusion. Based on our comparative analysis, the noninferiority of US stone targeting was demonstrated compared to fluoroscopic targeting. No significant differences in ESWL efficacy were found using electrohydraulic, electroconductive or electromagnetic shock wave generators. With the electromagnetic lithotripter, there was a significantly lower analgesic consumption than with the electrohydraulic type.

Key words: efficacy, extracorporeal shock wave lithotripsy, radiation exposure, ultrasound, urolithiasis

Received: March 15, 2022; Revised: June 7, 2022; Accepted: June 13, 2022; Available online: June 27, 2022
https://doi.org/10.5507/bp.2022.029

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INTRODUCTION

In the era of customized treatment, the correct indication and therapeutic considerations remain crucial in the management of urolithiasis along with a thorough evaluation of all factors related to the patient, the stone, technical possibilities, and surgeon expertise.

The aim of the present study was to provide an insight into the current level of ESWL efficacy, while taking into account the progressive development and refinement of stone targeting and comparing the technical aspects of the procedure. Currently, most centers use perioperative skiascopy for stone targeting. Less frequently, ultrasound targeting alone is used, which primarily depends on the operational capacity and the degree of expertise of particular centers. Ultrasound guidance is generally preferred when efforts are made to minimize radiation exposure, which is particularly emphasized in pediatric and young patients of childbearing age, all the more so in those with a diagnosis of recurrent nephrolithiasis due to a genetically determined metabolic disease (e.g., Dent disease, hyperoxaluria), as well as in persons with a history of actinotherapy for a malignancy. Due to the technical improvement of ultrasound guidance systems that allows precise real-time stone targeting throughout the procedure, operators can respond more quickly and adequately to the evolution of stone fragmentation or change of position. Also non-negligible is the radiation exposure for the attending medical personnel given the fact that not all units operating ESWL technology harbor an operational part with an x-ray arm separated from the control station.

The purpose of our study was to show whether the two methods of stone targeting are equal and whether ultrasound guidance achieves comparable results in terms of stone-free rate (SFR) by observing the effect of skiascopy and ultrasound guidance on the same lithotripter. In addition, we assessed the efficacy of individual types of shock wave generators by comparing three models of lithotripters with the same fluoroscopy guidance system. Last but not least, we focused on the need to use analgesia as part of premedication or perioperatively when a pain response developed as well as on the degree of radiation exposure in the study arms.

METHODS

The study was aimed at patients indicated for extracorporeal lithotripsy, with this method being the primary intervention for their stone disease. All cases involved radiopaque nephrolithiasis and proximal or distal ureterolithiasis. The stone size ranged from 6 to 13.5 mm (Table 1,3) in accordance with the European Association of Urology (EAU) guidelines[1].

The present study was initiated by a retrospective analysis of data from 120 patients who, from 2017 to 2020, underwent outpatient ESWL therapy at Dr. Christian Türk's practice in Vienna on the electromagnetic STORZ – Modulith SLK lithotripter using in-line ultrasound guidance only.

For comparative analysis, in the first step, we used the results of the study which was conducted at the Department of Urology, University Hospital Olomouc in 2017. It focused on the comparison of efficacy of two generations of lithotripters: the modern Sonolith i-sys by the EDAP-TMS company with an electroconductive shock wave generator and its predecessor Medilit 7 with a classic electrohydraulic generator. In the next step of comparison, data were used from a retrospective study carried out at the Department of Urology of the Hanusch Hospital in Vienna for the period 2018–2021. The efficacy of the electromagnetic STORZ – Modulith SLK lithotripter was assessed. This group of patients as well as that of those treated with the Sonolith i-sys and Medilit lithotripters was targeted under skiascopy guidance.

Each enrolled patient underwent non-contrast spiral CT of the urinary tract to assess the baseline CT parameters of urolithiasis as follows: size (in millimeters); location (in a particular calyx in the case of nephrolithiasis or proximal/distal ureterolithiasis); evaluation of skin-to-stone distance; and CT scan to estimate stone density. Radiopaqueness was verified using a scout scan (a reconstructive CT scan) or noncontrast nephrogram. This nephrogram was also used to confirm stone-free status as part of monitoring of the effect of lithotripsy or as an indication for another phase of lithotripsy treatment and/or a change in treatment strategy. Patient enrollment was done in order for all study groups to be balanced.

The operators in all centers had many years of experience and expertise in performing ESWL; however, in the US guidance arm, the operator was a methodology expert.

We focused primarily on the following parameters: SFR and the number of interventions needed to achieve a stone-free situation. One of the study objectives was to confirm the hypothesis that the results obtained with ultrasound targeting were not inferior (in terms of SFR) compared to fluoroscopic targeting. To confirm the statistical difference, the value of the difference in SFR was determined to be greater than 10%. Another objective was to ascertain whether the type of generator had an effect on efficacy. In addition to ESWL efficacy, we focused on the need to use analgesia as part of premedication or perioperatively when a pain response developed, radiation exposure, and the rate of need for a change in treatment strategy (DJ stent placement / RIRS / PCNL).

Data were analyzed using IBM SPSS Statistics for Windows statistical software, Version 23.0. Armonk, NY: IBM Corp. The cut-off value for the dependent variables of skin-to-stone distance and stone density was determined by statistical processing.

RESULTS

Statistics

Quantitative variables are presented as means and standard deviation (SD), minimum and maximum values, and medians. The Shapiro-Wilk normality test confirmed that the data were not normally distributed and the Kruskal-Wallis and the Mann-Whitney U tests were used to compare three and two independent samples, respectively.

Qualitative variables were expressed as absolute and relative frequencies. The groups were compared using Fisher's exact test. All tests were performed at the P=0.05 level of significance and are indicated red. In this case, post-hoc tests using the Bonferroni correction were carried out.

Comparison of the USG vs. x-ray guidance using the STORZ SLK electromagnetic lithotripter

Balanced group characteristics for this comparison are presented in Table 1. No statistically significant difference in ESWL efficacy and analgesics consumption was found between USG-Storz and RTG-Storz group, P>0.05 (Table 2). USG targeting isn't inferior to the fluoroscopic.

Comparison of three types of generators – electromagnetic, electroconductive, and electrohydraulic using fluoroscopic targeting

This analysis is based on balanced group characteristics too (Table 3). A statistically significant difference in ESWL efficacy wasn't found among the three types of generators. There are statistically significant differences only for the analgesics variable (Table 4). Most painful

Table 1. Group characteristics.

	Group										
	RTG-Storz (n=120)					USG-Storz (n=120)					*P*
	Mean	SD	Min	Median	Max	Mean	SD	Min	Median	Max	
StSD (mm)	99.7	10.6	80.0	99.0	129.0	101.0	12.1	80.0	99.0	129.0	0.508[a]
SD (HU)	1044.2	165.1	672.0	1013.0	1569.0	1022.9	168.1	672.0	1006.5	1412.0	0.388[a]
Size (mm)	7.9	1.8	6.0	7.3	13.5	7.8	1.8	6.0	7.0	13.0	0.381[a]

Position	Count	%	Count	%	*P*
Upper pole	20.0	16.7	20.0	16.7	0.096[b]
Lower pole	35.0	29.2	35.0	29.2	
Mid pole	20.0	16.7	20.0	16.7	
Pelvilithiasis	24.0	20	19.0	15.8	
Proximal ureter	19.0	15.8	15.0	12.5	
Distal ureter	2.0	1.7	11.0	9.2	

[a]Mann-Whitney U test; [b]Fisher's Exact Test; SD (HU), Stone Density (Hounsfield unit); StSD, Skin-to-stone density.

Table 2. Statistical evaluation of ESWL efficacy and rate of need for analgesics administration.

		Group				
		RTG-Storz (n=120)		USG-Storz (n=120)		
		Count	%	Count	%	*P*
Stone free	no	18.0	15	12.0	10	0.329[b]
	yes	102.0	85	108.0	90	
ESWL No.	1	69.0	57.5	81.0	67.5	0.058[a]
	2	41.0	34.2	37.0	30.8	
	3	9.0	7.5	2.0	1.7	
	4	1.0	0.8	0.0	0.0	
Analgesics	no	95.0	79.2	106.0	88.3	0.079[b]
	yes	25.0	20.8	14.0	11.7	

[a]Mann-Whitney U test; [b]Fisher's Exact Test; SD (HU).

Table 3. Group characteristics.

	Group															
	RTG.Storz (n=120)					EDAP (n=72)					Medilit (n=68)					
	Mean	SD	Min	Median	Max	Mean	SD	Min	Median	Max	Mean	SD	Min	Median	Max	*P*
StSD (mm)	99.7	10.6	80	99	129	99.3	12.4	79.0	97.5	129	100.9	11.7	77	98.0	129	0.677[c]
SD (HU)	1044.2	165.1	672	1013	1569	1002.2	171.8	672	996	1304	1010.6	154.2	746	999.5	1340	0.220[c]
Size (mm)	7.9	1.8	6.0	7.3	13.5	8.0	1.8	6.0	8.0	12.5	8.1	1.9	6.0	7.0	13.0	0.903[c]

Position	Count	%	Count	%	Count	%	*P*
Upper pole	20.0	16.7	10.0	13.9	10.0	14.7	0.501[b]
Lower pole	35.0	29.2	28.0	38.9	23.0	33.8	
Mid pole	20.0	16.7	10.0	13.9	10.0	14.7	
Pelvilithiasis	24.0	20	9.0	12.5	10.0	14.7	
Proximal ureter	19.0	15.8	10.0	13.9	10.0	14.7	
Distal ureter	2.0	1.7	5.0	6.9	5.0	7.4	

[b]Fisher's Exact Test; [c]Kruskal-Wallis Test; SD (HU), Stone Density (Hounsfield unit); StSD, Skin-to-stone density.

ESWL procedure is using the electrohydraulic generator. Post-hoc tests with Bonferroni correction for analgesics:

Groups 1 vs. 2 *P*=0.495
Groups 1 vs. 3 *P*=0.0004
Groups 2 vs. 3 *P*=0.114

There is a significant difference only between the RTG STORZ and Medilit Groups; in the Medilit Group, there is a significantly higher proportion of analgesics (in 49%) than with the RTG Storz Group (21%), *P*=0.0004.

To find the **optimal cut-off value for CT stone density and skin-to-stone distance** (Table 5), Youden's J statistic (max SE+ SP) was used, which maximizes the distance to the diagonal line, see the Fig. 1.

The cumulative radiation exposure of the patients in the US arm ranged from 178 mGy/cm^2 to 329 mGy/cm^2. This

Table 4. Statistical evaluation of ESWL efficacy and rate of need for analgesics administration.

		Group						
		RTG Storz		EDAP		Medilit		
		Count	%	Count	%	Count	%	*P*
Stone free	no	18.0	15	8.0	11.1	8.0	11.8	0.727[b]
	yes	102.0	85	64.0	88.9	60.0	88.2	
ESWL No.	1	69.0	57.5	44.0	61.1	39.0	57.4	0.799[c]
	2	41.0	34.2	24	33.3	23.0	33.8	
	3	9.0	7.5	4.0	5.6	5.0	7.4	
	4	1.0	0.8	0.0	0.0	1.0	1.5	
Analgesics	no	95.0	79.2	50.0	69.4	35.0	51.5	0.0005[b]
	yes	25.0	20.8	22.0	30.6	33.0	48.5	

[b]Fisher's Exact Test; [c]Kruskal-Wallis Test.

Table 5. Statistical evaluation of CT parameters of stone density and skin-to-stone distance.

	AUC	95% confidence interval	Sensitivity (SE)	Specificity (SP)	Optimal cut-off
Stone density (HU)	0.852	0.797-0.907	0.818	0.747	≤ 1095
Skin-to-stone distance (mm)	0.804	0.727-0.881	0.705	0.813	≤ 108.5

AUC, Area under curve.

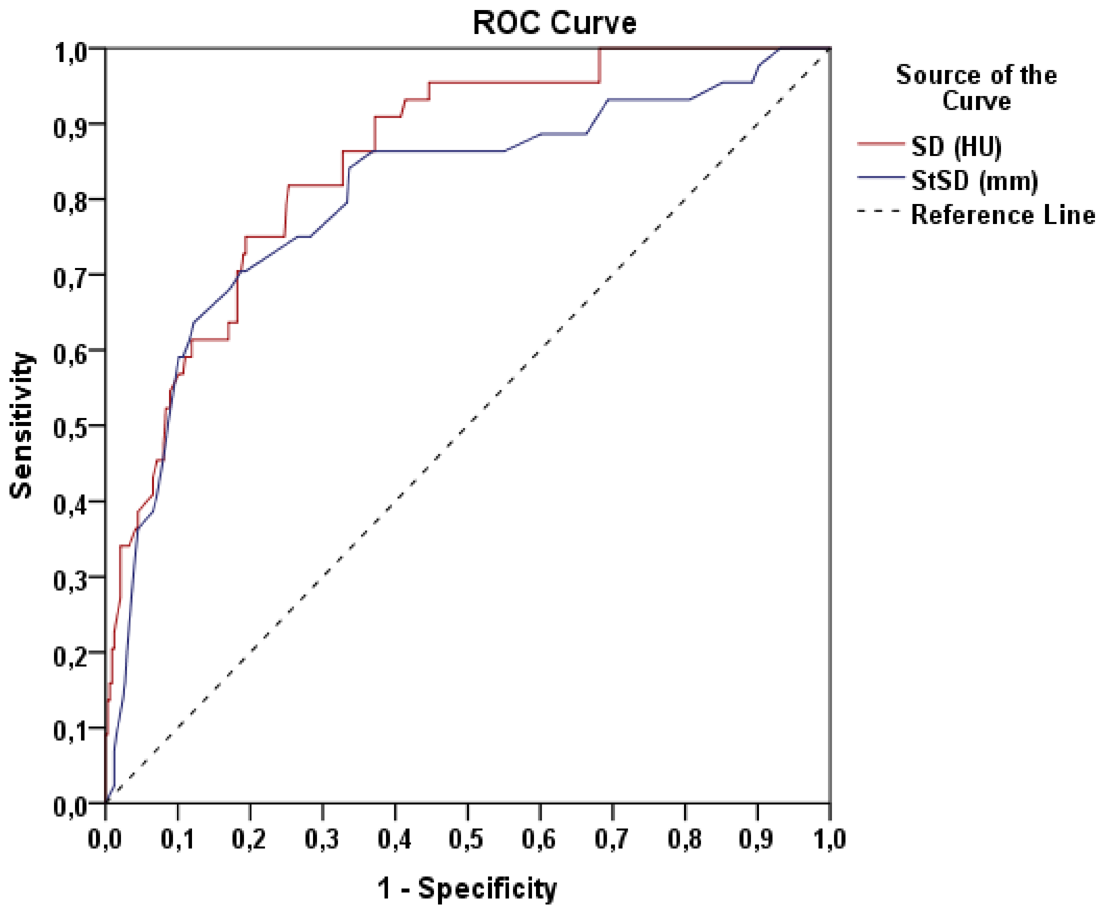

Fig. 1. ROC analysis. According to ROC analysis, the optimal cut off for skin-to-stone distance (StSD) is ≤ 108.5 mm and optimal cut off for stone density (SD) is ≤ 1095 Hountfield units (HU).

is the sum of doses received from low-dose noncontrast abdominal CT, follow-up noncontrast nephrograms, and/or skiagraphy as part of auxiliary procedures. In the case of fluoroscopy guidance, the values measured ranged from 2,723 mGy/cm^2 to 28,376 mGy/cm^2.

The duration of one ESWL session was comparable: the US arm 32–53 mins and the x-ray guidance arm 33–64 min. There was a difference in the presence of the operator when the procedure itself was performed: US vs. x-ray = 80% vs. 56%. In addition, in the x-ray guidance

Table 6. Overview of the available studies focused on equivalence of flouoscopic and USG targeting.

Author	Year of the study	n (patients)	SFR (USG vs. Fluoro)	*P* (USG vs. Fluoro)
Smith, GB	2016	94	60 vs. 45%	0.18
Van Besien, Belgium	2017	114	79 vs. 70%	0.28
Motolova CZ/AT	2022	240	90 vs. 85%	0.329

arms, there was a difference in the radiation exposure for the attending personnel: in the Medilit and Edap arms, there was no radiation exposure for the operator since the center utilizes a remote-control station. In the Storz arm, targeting was done at the bedside in which, despite the use of standard protective equipment, it was not possible, given the relevant physical principles, to completely eliminate the reflected radiation.

Auxiliary procedures were most often performed in the case of x-ray guidance on an electromagnetic lithotripter, but the difference was statistically insignificant; P=0.329.

The nature and rate of ESWL complications were comparable in all the groups analyzed.

Complications were rated as grade 2 and lower according to the Clavien-Dindo classification.

DISCUSSION

The introduction of extracorporeal shock wave lithotripsy (ESWL) into clinical practice was a milestone in treating urolithiasis, ending the era of invasiveness of open surgical approaches. Modern treatment for urolithiasis is based on three cornerstones: ESWL and two endourology techniques – percutaneous nephrolitholapaxy (PCNL/miniPCNL) and ureterorenoscopy (URS) or retrograde intrarenal surgery (RIRS). The development of both endourology techniques is more progressive, which is reflected in the direct comparison of treatment efficacy, to the disadvantage of ESWL. However, ESWL boasts the lowest level of invasiveness, no need for anesthesia, and performance on an outpatient basis.

The very heart of the lithotripter is a shock wave generator. Currently, electromagnetic, electrohydraulic/electroconductive, and piezoelectric generators are used. It has been 40 years since the introduction of first-generation Dornier electrohydraulic lithotripters in clinical practice and, because of their high efficacy, they still serve as a reference model for comparative studies of the latest devices. Despite innovations in their development, it has not been possible to precisely define the key technical aspect of efficacy. The primary parameters considered, i.e. excitation energy intensity and focal zone, were not shown to be crucial. So far, the mechanism of action of the shock wave in stone disintegration has not been fully elucidated. Adaptive modulation of the nature of the generated waves might be an interesting perspective in device development.

Thus, to develop the methodology and improve the efficacy of ESWL, it is necessary to focus on optimizing the intraprocedural steps. Among them, precise stone targeting is of utmost importance.

Stone targeting can be performed by means of fluoroscopy, ultrasonography, or in combination. While no significant development can be expected in skiagraphy, ultrasound imaging boasts increasingly high resolution and accessories to facilitate the implementation of continuous real-time stone monitoring. A major advantage of ultrasonography is the absence of radiation exposure and the related elimination of the risk of producing stochastic biological effects for both the patient and the attending staff. The recurrence rate of urolithiasis in the first year is around 10%. In the case of multiple stones, the doses of radiation exposure at one-year follow-up reach 54,850 mGy/cm^2 (ref.[2]). US-guided ESWL can be performed even in the case of non-contrast lithiasis, when there is insufficiency or dissolution therapy is contraindicated.

US targeting of ureterolithiasis in the proximal and distal ureter is largely trouble-free; stones in the mid-portion of the ureter are typically not possible to be targeted. It is the in-situ emergency ESWL in which fluoroscopy remains the targeting method of choice. Combined guidance systems of modern devices are thus a convenient choice, even in terms of their use as part of a possible acute auxiliary intervention. State-of-the-art guidance systems are equipped with acoustic stone targeting technology or with a highly sophisticated stone tracking software that automatically adjusts lithotripter targeting, while taking into account the patient's diaphragmatic excursions[3].

The first-generation Dornier HM-3 lithotripter which, with fluoroscopy guidance, achieved an average SFR of 73% in an unselected group of patients has held its strong position as a reference model for evaluating the efficacy of novel devices. The pioneering work conducted on modern lithotripters with US guidance reports an SFR of 68.5% (ref.[3-5]). Only a few studies have addressed the issue of equivalence of these two targeting techniques in recent years, the most recent being an English study published in 2016 (ref.[4]) and one from Belgium published in 2017 (ref.[5]). The primary outcomes of interest have been shown to be uniform. Our present analysis attempted to overcome their two most fundamental limitations. It was conducted in a larger group of patients (Table 6).

Balanced cohort characteristics were achieved by a strict selection of probands.

The higher, though insignificantly, SFR outcome in the US arm with the use of an identical shock wave generator is presumed to result from better stone targeting in real time in which a more accurate monitoring of the signs of disintegration enables to more optimally control shock wave intensity and frequency, resulting in a positive effect on efficacy and reduced analgesic consumption.

A possible limitation of the study is on the part of the operator: although all the centers have a high level of expertise, US targeting was performed by a single operator who was a methodology expert; in the other two centers, two different operators were responsible for fluoroscopic targeting.

Patient positioning and stone targeting require a greater operator involvement when performing ESWL with US guidance, which is not uncommonly the reason for preferring fluoroscopy guidance. Mastering the right technique of US-guided stone targeting requires more time, with the presence of an experienced ESWL operator always being an excellent opportunity to mentor new generations of urologists.

No significant differences in efficacy were demonstrated with the use of an electrohydraulic, electroconductive, and electromagnetic lithotripter, which is in agreement with the results of several studies[6-7]. However, a significant difference was observed when analgesic consumption was compared: it was significantly higher in the electrohydraulic type than in the electromagnetic generator type with fluoroscopy guidance. When pain symptoms were reported, diclofenac was the drug of choice with a sufficient effect.

Electromagnetic lithotripters have smaller foci compared to electrohydraulic ones – a more exact focal zone with a high density of effect. The cavitation effect is one of the mechanisms of stone disintegration in ESWL. On the basis of a numerical analysis of the development of cavitation effects during transmission of the shock wave to the focus, a higher production and longer action of cavitation bubbles were found in electrohydraulic lithotripters compared to electromagnetic ones. This is because the electromagnetic lithotripter generates a secondary compression pulse that causes a significant reduction in the number of cavitation bubbles, thus weakening this important fragmentation mechanism[8].

In addition to the above-mentioned differences in US and fluoroscopic targeting, the issue of radiation hygiene is of great importance. We compared operator´s radiation exposure during ESWL procedure targeted from remote-control station (Fig. 2) vs. bedside tareting (Fig. 3). Despite the use of protective equipment, the exposure was significantly higher during bedside targeting (during targeting from the radiation-shielded control station, the radiation exposure was close to zero)

Fig. 2. Remote - control station.

Fig. 3. Bedside targeting.

CONCLUSION

For years, ESWL has been a well-established treatment modality for urolithiasis approved by urology guidelines, with modern lithotripters being standard equipment at urology centers around the world; therefore, it is important to make the most of the potential of these devices with a high purchase price, but a long-term operability at an acceptable cost.

A thorough evaluation of important characteristics of the patient and the stone is crucial for the correct indication for ESWL.

No statistically significant differences in efficacy were found for different types of latest-generation lithotripters. Ultrasonography should be the preferred method for stone targeting with regard to the effort to eliminate both patient and operator radiation exposure, as it is at least equivalent to fluoroscopic targeting.

The dominant position of ESWL in the treatment of childhood urolithiasis also obliges us to make further efforts in the technical development of shock wave generators. Only when the physics of the shock wave has been explained perfectly will we be able to intervene precisely in the modulation of its effect in the biological environment in order to achieve a painless and highly effective treatment without injury to adjacent tissue[9-10].

Acknowledgement: This work was supported by the IGA_LF_2020_044 grant of the Faculty of Medicine and Dentistry, Palacký University in Olomouc.

Author contributions: MM: study conception and design, data acquisition, data analysis and interpretation, drafting of the manuscript; MK: Data analysis and interpretation, critical revision of the manuscript for important intellectual content.

Conflict of interest statement: None declared.

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