

Shock Wave Lithotripsy Using Fluoroscopic Versus Ultrasonic Localization for Paediatric Renal Stones: Prospective Randomized Comparative Study

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Abstract

Background: Shock wave lithotripsy (SWL) is a well-known technique used in the treatment of kidney stones since the early eighties. For successful SWL, accurate visualization of the shock waves is performed by ultrasound (US) or fluoroscope (FS) to fully focus the shock waves on the stone.

Aim of Study : The aim of the study was to evaluate the outcome of ultrasonic localization in SWL treatment of paediatric renal stones on complications and treatment success.

Patients and Methods: This study was conducted in Urology Department, Qena University Hospital from January 2021 to June 2022. This study was conducted on 50 children (2-16) years of age.

Results: Regarding Stones free rate, our results revealed that SWL using ultrasonic localization is an effective primary treatment option for Paediatric Renal stones located in renal pelvis range from 10-20mm in size.

Conclusion: The success rate of SWL using ultrasonic localization and complications. Therefore, we consider that ionizing radiation is not necessary in the pediatric age group. Not using ionizing radiation is an important advantage of ultrasonic focusing.

Key Words: Shockwave – Lithotripsy – Focus – Ultrasonic – Kidney stone.

Introduction

EPIDEMIOLOGICAL studies have shown a progressive increase in the incidence of paediatric urolithiasis over the past few decades [1].

Paediatric stone disease is considered endemic in developing nations including Turkey, Pakistan and eastern countries [2]. The introduction of SWL by Chaussy et al., in the early 1980s revolutionized the management of upper urinary tract calculus disease.

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Reports of successful SWL in children were first published in 1986 [3]; then several reports showed safety, and stone-free rates comparable with those of adults. For successful SWL, accurate localization of the shock waves is performed by ultrasound (US) or fluoroscope (FS) to fully focus the shock waves on the stone.

Patients and Methods

This study: Done at Urology Department, Qena University Hospital.

Inclusion criteria: Children (2-16) years of age with radiopaque renal pelvic stones less than 20mm.

Exclusion criteria: Previous percutaneous nephrolithotripsy at the same side, previous renal exploration for stones at the same side, positive urinary culture and calyceal stones.

Sample size calculation: 50 children (2-16) years of age who were treated with SWL using ultrasonic focusing were included in the study.

Demographic data, SWL parameters and success rates were recorded.

Methods:

All of patients were subjected to the following:

Complete history taking: Personal history: Age, sex, history of chronic diseases including diabetes mellitus and cardiac diseases and history of previous surgeries.

Clinical examination: Vital signs (Blood pressure, Temperature, Heart rate, Respiratory rate) and signs of (Pallor, Cyanosis, Jaundice, and Lymph node enlargement) and pre-operative urine analysis, KUB, C.T was done.

Renal CT scan: The coverage area for the CT scan extended from the upper pole of both kidneys to the base of the urinary bladder. CT images at a slice thickness of 5mm complimented with 3mm coronal/sagittal reformatted image were acquired.

ESWL was performed at our hospital using electromagnetic lithotripter Dornier Gemini lithotripter® is a fully integrated, new generation lithotripter with an electromagnetic shockwave source, and fully integrated fluoroscopic and ultrasonic guidance. We started with E1 (the lowest level which equals 16.0mJ) then increase gradually until we reached to energy level E5 (which equals 41.0mJ). We started session slowly as cooking the rice on quite fire to get the best results without exceeding 75J. ESWL session was usually started at E1 for firstly 250 shocks, and then moving to next level for the next 250 shocks and the voltage was then gradually increased up to a maximum of E 5. The shock waves were delivered at a rate of 70 shocks /min. The number and energy of shock waves used were modified until adequate fragmentation was achieved or the maximum number of shocks was reached. A maximum of 2600 shocks were planned for each session or 75J energy of shock waves.

SWL using ultrasonic focus: Shock wave lithotripsy was applied using the Lithoscope under general anaesthesia as outpatient procedure. All procedures were performed by using ultrasonic localization in a supine position. Before the SWL procedure, ketamine 3-5mg/kg and fentanyl 0.5-1 mg/kg were administered intravenously to all patients for sedation. Follow-up schedule: Visit every 4 weeks up to 3 months to evaluate postoperative outcome parameters: Primary (main): Stone-free rates, complications and Secondary (subsidiary): Compilations.

Ethical considerations and consent form: The protocol was applied for approval of Research Ethics Committee. Informed consent was obtained from the patients before enrolment of the study.

Data management and analysis: Data was analysed using Statistical Package for Social Sciences (SPSS) software program (version 2.0). Qualitative variable was recorded as frequencies and percentages and will be compared by chi-square test. Regression analysis and correlation between different variable will be test by Ben Ferroni test as indicated. *p*-value <0.05 is significant.

Results

Table (1): Demographic characteristics.

(n=50)	
<i>Age (years):</i>	
Mean ± SD	9.21±3.93
Range	2-16
<i>Gender:</i>	
Male	23 (46%)
Female	27 (54%)
<i>Residence:</i>	
Rural	30 (60%)
Urban	20 (40%)
<i>BMI (kg/m²):</i>	
Mean ± SD	24.11±2.79

Table (2): Stone characteristics.

(n=50)	
<i>Density (HU):</i>	
Mean ± SD	519±207.73
<i>Size (mm):</i>	
Mean ± SD	13.88±1.75

Table (3): Session characteristics between the studied groups.

Group I (n=50)	
<i>Number of sessions:</i>	
Mean ± SD	2.91±0.073
<i>Shocks per session:</i>	
Mean ± SD	2396.8±473.5

Table (4): Complication grade I-II between the studied groups.

(n=50)	
Transient Hematuria I	1 (2%)
Fever I	2 (4%)
UTI II	2 (4%)

Table (5): Stones free rate.

	Group I (n=50)	
	N	%
1 st day	20	40
One month	38	76

Table (6): Success rate.

	Group I (n=50)	
	N	%
Successful	46	92
Failed	4	8

Discussion

A correct focusing of the stone is done through ultrasonography (US) or fluoroscopy (FS) for a successful SWL. Radio-opaque stones in the kidney or at the ureteropelvic (UP) junction may usually be imaged both with US and FS. To the best of our knowledge, limited studies are available in the literature comparing the ultrasonic and fluoroscopic methods in the treatment of kidney stones with SWL in the pediatric age group.

This study was conducted in Urology Department, Qena University Hospital from June 2021 to June 2022. This study was conducted on 50 children (2-16) years of age who were treated with SWL using ultrasonic focusing.

As well, the current study was supported by Ozkaya, [4] aimed to investigate the effect of US and FS methods used for focusing on stone in SWL treatment of renal stones in pediatric patients on side effect and treatment success. The study enrolled 495 children under 16 years of age who were treated with SWL using ultrasonic and fluoroscopic focusing.

In addition, a single center retrospective cohort study by Smith et al., [5] aimed to compare stone free rates (SFR) using fluoroscopy or ultrasound (US). The study enrolled 95 patients with renal calculi undergoing first SWL treatment with localization using US (48 patients) and fluoroscopy (47 patients). There was no significant difference between the demographic data.

Furthermore, Goren et al., [6] aimed to evaluate the outcomes and ionizing radiation (IR) exposure of children with cystine stones (CS) using different shockwave lithotripsy (SWL) guidance modalities.

The related studies were not mentioned the clinical presentations in their studied patients.

Also, the study by Van Besien et al., [7] revealed that there was no significant difference between the studied groups regarding stone size, Stone density, Stone position and Stone composition.

Furthermore, the study by Goren et al., [6] revealed that there no significant difference between the studied groups regarding stone size, and Stone area.

Regarding Session characteristics between the studied groups, the present study showed that that there no significant difference between the groups regarding number of sessions and number of shock waves per session.

The study by Ozkaya, [4] reported that the mean number of shock waves varied between 60-80 beats per minute and the total number of beats was on average 2530.5 beats during the procedure. The number of sessions that were performed with 2-3 week of intervals was 1-3. The shock wave frequency, the shock wave number and the energy protocol were the same in both groups due to the standard study protocol in SWL procedures applied to pediatric patients in their clinic.

Furthermore, the study by Goren et al., [6] reported that the median number of SWL sessions was significantly lower in the US guided group than the FL-guided group. The mean number of shockwaves and applied energy levels were similar between groups.

Regarding Complication grade I-II between the studied groups, we found that the major complication was UTI in both groups. However, no significant difference was found between the two groups regarding complications.

However, the study by Chang et al., [8] reported that Significant lower retreatment (USa 14.8% vs. FS 35.6%, $p < 0.001$) and complication rates (USa 1.9% vs. FS 5.5%, $p = 0.031$) were noted in the USa group compared with the FS group. The most common complication was post-SWL-related flank pain (Clavien-Dindo grade I), which occurred in 1 (0.5%) USa group patient and 11 (5.1%) FS group patients, however no cases required hospitalization. In all cases symptoms were controlled with intravenous/intramuscular or oral non-steroidal anti-inflammatory drugs (NSAIDs).

Our results were supported by Ozkaya, [4] as they reported that the complication rate was 0.2% (1 patient) and 0.4% (2 patients) in Group 1 and 2, respectively, and there was no statistically significant difference between the groups ($p = 0.495$).

Smith et al., [5] reported that there were fewer re admissions in the US group of four patients, two requiring intervention with ureteric stenting under general or regional anesthesia (ClavienDindo Grade 3), and two managed conservatively with analgesics (ClavienDindo Grade 2). The fluoroscopy group had eight re admissions with three requiring intervention (ClavienDindo Grade 3), five managed conservatively (ClavienDindo Grade 2). No patients had serious complications.

Regarding Stones free rate between the two groups, our results revealed that Stones free rate was significantly higher in group II compared to group I in the first^{1st} day, while there is no signif-

icant between the two groups regarding one month stone rate. Our results also showed that disintegrate rate was significantly higher in group II compared to group I.

However, the study by Chang et al., [8] reported that the overall stone free rate was significantly better in the USa group compared with the FS group (USa 43.5% vs. FS 28.2%, $p < 0.001$), and the overall stone disintegration rates were significantly higher (USa 85.6% vs. FS 64.3%, $p < 0.001$).

In agreement with the present results the study by Van Besien et al., [7] demonstrated similar results, with the USa SWL stone-free rate not being inferior to the FS SWL, but with no need for ionizing radiation.

The study by Goren et al., [6] revealed that SWL failed in 10 (19.6%) patients. Two patients were treated with percutaneous nephrolithotomy, and one was treated with micro-percutaneous nephrolithotomy. All patients were stone free post-operatively. Postoperative stone analyses yielded cystine stones. The remaining patients had clinically insignificant residual fragments and these patients were followed-up.

However, the study by Chang et al., [8] reported that the overall outcome was significantly better in the US group than the FS group.

In agreement with the current results Ozkaya, [4] reported that the success rate was 90.5% in Group 1, it was 92.3% in Group 2 and no statistically significant difference was observed between the groups ($p = 0.474$).

While the study by Van Besien et al., [7] reported that the success rate was estimated to be 10% (confidence interval 7.8% to 28.2%) higher for the US-guided group compared to the FS-guided group.

Conclusion:

We consider that ionizing radiation is not necessary in the pediatric age group. Not using ionizing radiation is an important advantage of

ultrasonic focusing. We recommend the use of the ultrasonic focusing method in the pediatric age group, which has similar success rates, and provides an additional advantage by avoiding radiation, instead of the fluoroscopic focusing method, which uses ionizing radiation for SWL.

Author Consent and Conflict of interest:

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

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نتائج تفتيت حصوات الكلى فى الأطفال عن طريق الموجات التصادمية باستخدام الموجات فوق الصوتية (السونار)، خبراتنا فى مستشفى قنا الجامعى

مقدمة : مرض حصوات الجهاز البولى هو حالة نادرة فى الطفولة. المرض أكثر شيوعاً فى البلدان النامية والمتخلفة. تم الإبلاغ عن زيادة انتشار مرض حصوات الجهاز البولى فى الأطفال الذين تقل أعمارهم عن ١٥ عاماً. تميل إجراءات التنظير الداخلى طفيفة التوغل مثل تنظير الحالب أو استئصال حصوات الكلى عن طريق الجلد إلى استخدامها لعلاج حصوات الكلى أو الحوض. من ناحية أخرى، لا يزال تفتيت الحصوات بموجة الصدمة أحد خيارات العلاج لحصى الكلى.

كان الهدف الرئيسى من هذه الدراسة : هو تقييم نتائج توطين الموجات فوق الصوتية مقابل التنظير الفلورى فى علاج تفتيت الحصوات بموجة الصدمة لحصى الكلى لدى الأطفال على المضاعفات ونجاح العلاج.

أجريت هذه الدراسة المقارنة العشوائية فى قسم المسالك البولية بمستشفى قنا الجامعى فى الفترة من يناير ٢٠٢١ إلى يونيو ٢٠٢١. وقد أجريت هذه الدراسة على ١٠٠ طفل (٢-١٦) عاماً فى مجموعتين تم علاجهم باستخدام تفتيت الحصوات بموجة الصدمة باستخدام الموجات فوق الصوتية مقابل التركيز التنظيرى التآلى. المدرجة فى الدراسة. تم تصنيف المرضى الذين يعانون من تركيز التنظير الشعاعى على أنهم مجموعة (١) وتم تصنيف المرضى الذين يعانون من تركيز الموجات فوق الصوتية على أنهم مجموعة (٢).

أظهرت النتائج الرئيسية للدراسة ما يلى :

- فيما يتعلق بخصائص الجلسة بين المجموعات المدروسة، أظهرت الدراسة الحالية أنه لا يوجد فرق كبير بين المجموعات فيما يتعلق بعدد الجلسات وعدد موجات الصدمة فى الجلسة.
- فيما يتعلق بوظيفة الكلى قبل الجراحة بين المجموعات المدروسة، أظهرت نتائجنا أنه لا يوجد فرق معنوى بين المجموعتين فيما يتعلق بالكرياتينين والتهاب الكلية.
- فيما يتعلق بمعدل النجاح بين المجموعتين، أظهرت الدراسة الحالية أن معدل النجاح لم يكن أعلى بشكل ملحوظ فى المجموعة الثانية مقارنة بالمجموعة الأولى.

بناءً على النتائج التى توصلنا إليها، نوصى باستخدام طريقة التركيز بالموجات فوق الصوتية فى الفئة العمرية للأطفال، والتى لها معدلات نجاح مماثلة، وتوفر ميزة إضافية عن طريق تجنب الإشعاع، بدلاً من طريقة التركيز التنظيرية، التى تستخدم الإشعاع المؤين لتفتيت الحصوات بموجة الصدمة.