The Efficacy and Safety of Extracorporeal Shock Wave Lithotripsy in Children

Çocuklarda Beden Dışı Şok Dalga Litotripsinin Etkinliği ve Güvenilirliği

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Abstract

Technological advances in the design of shock wave lithotriptors have precipitated important changes in the management of urolithiasis in children. New generation lithotriptors have reduced the need for anesthesia, lowered hospitalization duration, and resulted in better fluoroscopic targeting reducing radiation exposure. Currently, shock wave lithotripsy (SWL) has become standard first line treatment for most renal and ureteral calculi in children. Herein, the literature and assess success rates, re-treatment rates, preoperative stenting, anesthesia requirements, side effects, and complications of SWL were reviewed. As a result, we aimed to demonstrate that SWL is safe for the treatment of pediatric urolithiasis.

Keywords: Children, Efficacy, Safety, Shock wave lithotripsy

Anahtar Kelimeler: Çocuk, Etkinlik, Güvenilirlik, Şok dalga litotripsı
pediatric urolithiasis is a rare entity. Although the incidence of urolithiasis in children is only 2 to 3% in developed countries, it occurs more commonly in underdeveloped countries [1]. In an epidemiological report from Turkey, it was documented that urolithiasis is considered an endemic disease in children younger than 14 years old [2]. Because children with urolithiasis begin forming stones earlier in life than adults, their cumulative likelihood of stone recurrences may be higher. Thus, with continuing advances in technology, stone management has evolved from invasive procedures such as open surgery to less invasive techniques such as extracorporeal shock wave lithotripsy (SWL), ureteroscopy and percutaneous nephrolithotomy (PCNL) [3]. SWL was first introduced into clinical practice in 1980 by Chaussy and associates [4]. The first report of successful SWL on children was presented by Newman et al. [5] in 1986.

Since then, acceptable success rates, a high safety profile and minimal morbidity have made SWL the preferred first line treatment choice for pediatric urolithiasis [6,7]. Currently, SWL is being widely applied in clinical use for pediatric stone disease. The advent of second- and third- generation lithotriptors, including dry head lithotriptors and those equipped with advanced imaging systems, has made visualization, especially of ureteral stones, much easier. Additionally, the use of acoustic membranes and advanced lens systems has resulted in repetitive shock waves of moderate intensity. As a result, SWL, using newer generation lithotriptors, with minimal anesthesia is possible for a majority of pediatric patients with a high treatment rate [6-8]. It is mandatory to evaluate every child with urolithiasis prior to SWL with a complete metabolic evaluation and urinary tract imaging looking for congenital anomalies such as ureteropelvic junction (UPJ) obstruction and obstructive megaureter. Indications for SWL in pediatric patients with urolithiasis that have been established are similar to those for adults and include pain, hematuria, infection, obstruction, or potential for obstruction [1,9,10]. Previously, many children were referred for SWL only after a failed open surgery. Currently, SWL is the first-line treatment for most urinary tract stones [9]. Despite numerous successful reports and increasing experience, guidelines for SWL in children still have not been fully determined and SWL has not been approved by the US Food and Drug Administration (FDA) in this population.

**Comparison of Lithotriptors in Pediatric Lithotripsy:**

The lack of clinical agreement about treatment outcomes of lithotripsy (i.e., stone-free vs. residual fragments of various sizes) restricts appropriate comparison between various lithotriptors. There is a general consensus that re-treatment rates are an appropriate indicator of lithotripter effectiveness. According to this definition, the unmodified HM-3 lithotriptor remains the gold standard for SWL [9]. Although there have been several comparative trials of lithotriptors reported in adult population [11-14], few have been published with regards to children [15-17]. Comparisons of results achieved with various lithotripsy units at various institutions are difficult, chiefly due to the variability in patient selection, the definition of success, follow-up methodology, and reported auxiliary measures. Prospective randomized controlled trials comparing different lithotriptors are scarce [13]. The first prospective randomized study comparing electrohydraulic (Dornier MPL 5000) and electromagnetic lithotriptors (Dornier Lithostar Modularis S) at a single center was published by Sheir et al. [13] in 2003. They reported that the electromagnetic lithotriptor had significant clinical advantages over the electrohydraulic lithotriptor in terms of treatment time, re-treatment rate and success rate. In a recently published study, Raza et al. [16] reported results of a comparison between the Dornier MPL 9000 and Siemens Lithostar Modularis lithotriptor in children with upper tract urolithiasis and found that the electrohydraulic machine resulted in a higher stone-free rate and complication rate than the electromagnetic machine. In our comparative study [17] using the same lithotriptors, we showed that there were no significant differences in success rates except for with lower ureteral stones. We speculated that the higher success rate with the Siemens Lithostar Modularis in distal ureteral calculi is related to better high-resolution fluoroscopic targeting rather than stone burden.

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<td>MFL 5000</td>
<td>MFL 9000</td>
<td>Lithostar Modularis</td>
<td>Lithostar Modularis</td>
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<tr>
<td>No. of patients</td>
<td>102</td>
<td>40</td>
<td>50</td>
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<td>87</td>
<td>95</td>
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<td>Complication</td>
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<td>1/40</td>
<td>8/50</td>
<td>4/40</td>
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<td>Re-treatment/patient</td>
<td>1.8</td>
<td>2.3</td>
<td>1.7</td>
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**Factors Affecting the Success Rate of SWL:**

Lower infundibulopelvic angle (LIPA), complex calyceal pattern, anatomical abnormalities, a narrow infundibulum diameter and a long infundibulum are generally accepted as the most adverse prognostic factors for stone clearance, however, this point is under debate. Tan et al. [18] concluded that SWL is a good initial option for treatment of most renal calculi less than 2 cm, except in the presence of unfavorable lower calyceal anatomy. Additionally, multiple factors such as increased stone burden, multiple stones, staghorn calculi, narrow LIPA and a long lower infundibulum adversely affect the clearance rate. Some studies suggested that an influence on disintegrate clearance by the collecting system anatomy is possible, but this is of minor clinical importance. Onal et al. [19] suggest that calyceal pelvic anatomy in pediatric lower pole stones has no significant impact on stone clearance after SWL. We reported that the transverse diameter of the stone was the only significant factor affecting stone-free rate following SWL treatment [6]. For larger stones, the probability of complete clearance following a single SWL session decreases. Several authors have reported that stones up to 15 mm are easily fragmented and cleared [3,6,7,15,17,20]. Younger children have better stone-free rates than older children [6]. More recently formed urinary stones in small children may be more fragile than...
SWL Series in Pediatric Urolithiasis:

SWL has been successfully used in pediatric renal and ureteral calculi management [20-26]. Studies in the lithotripsy experience in children are seen in Table 2.

SWL has been shown to provide good results, ranging from 68% to 97.6%, in the management of pediatric urolithiasis. The definitions of children, duration of follow-up, success (such as stone-free and clinically insignificant residual fragments), and treatment parameters differ among studies [9]. The majority of these reports used stone-free rate as the definition for treatment success. However, a limited number of studies used Efficiency Quotient (EQ) as a definition of success [3,16,17,26-31]. EQ is calculated as stone-free percentage x 100/ (100% + re-treatment rate percentage + auxiliary procedure percentage) as previously described [32]. Calculating the EQ is important because it takes into consideration factors that increase patient’s morbidity, re-treatment rate and the rate of auxiliary procedures [30]. SWL for vesical calculi management is reported on rarely in the literature. Muslumanoglu et al. [3] treated 16 children with bladder calculi, and while they achieved 100% stone-free rates for bladder stones smaller than 1 cm, this success diminished 50% in stones larger than 2 cm. Rizvi and colleagues [33] reported a success rate of 45.5% using SWL for bladder stones smaller than 1 cm.

Although SWL is a highly popular and accepted modality for treating renal stones, the optimal treatment choice for distal ureteral calculi remains controversial. Recent technological developments have yielded smaller endoscopic instruments and more efficient intracorporeal lithotripsy sources, including the holmium YAG laser. For this reason, there is still controversy over the use of ureteroscopy and SWL for the treatment of distal ureteral calculi in children [34–38].

SWL provides good results ranging from 76% to 90.1% in pediatric distal ureteral calculi (Table 3). Nabi et al. [39] reported that stones up to 10 mm were easily fragmented and the clearance rate was found to be 90%. In the our study [26], the success rate was 86.2%, comparable to rates reported in other pediatric series.

Anesthesia during Lithotripsy:

Several anesthetic techniques have been used in pediatric SWL series including general anesthesia, regional anesthesia or intravenous sedation. Commonly, general anesthesia is re-
quired for first-generation lithotriptors, whereas intravenous sedation is generally sufficient for most second- and third-generation machines [9,40]. Technical developments of third-generation lithotriptors have resulted in a reduction in the need for anesthesia [9]. Recent developments of new anesthetic techniques, adaptable to SWL, have greatly influenced treatment protocol. Short-acting agents such as alfentanil hydrochloride, midazolam and propofol have been used in various combinations allowing most SWL treatments to be performed on an outpatient basis [9]. We treated 81 children (62.7% of our patient population) with the MPL-9000, using general anesthesia. The remaining patients (37.3%) were sedated with midazolam, fentanyl or ketamine [6]. In contrast, in our recently published study, we treated all patients (90 children) with sedoanalgesia using the Lithostar Modularis machine [17]. Demirkesen et al. [7] using the Lithostar lithotriptor, treated 87% of their patients with sedation. Netto et al. [22] used the Lithostar Plus machine and general anesthesia was required in only 15.1% of 86 children. Commonly, general anesthesia is required for first-generation and some second-generation lithotriptors, whereas sedoanalgesia suffices when using most second- and third-generation lithotriptors [6,7,9,22].

Stent Requirements for SWL Treatment:
The issue of ureteral stent placement before SWL has become more and more controversial [41,42]. The use of internal stents is currently not been recommended in children undergoing SWL, because stone debris is rapidly eliminated in younger children easier than in older children and adults [43]. Some authors insert a double J stent in children who have a significant stone burden (greater than 625 mm²), solitary kidney, anatomical abnormality, or difficult stone visualization such as radiolucent stones [3,6,18]. Shukla et al. [44] does not recommend the use of ureteral stent in preterm infants. Lottmann et al. [21] speculated that double J stent insertion was not beneficial, particularly in boys, in whom there is a potential risk of urethral stricture and require additional general anesthesia to remove the stent. We believe that ureteral stents reduce post SWL morbidity in children with larger stones (greater than 25 mm), especially in patients coming from rural areas.

Outcome and Management of Small Residual Stone Fragments Post-SWL:
The success of SWL is sometimes defined as clinically insignificant residual fragments (CIRF) less than 4 to 5 mm in adult populations, but this definition may not hold true for pediatric patients [45]. Residual fragments are associated with a higher risk of new stone formation. Thus, residual fragments after SWL are still a dilemma. In Afshar’s series the incidence of growth in size of residual fragments was 34.5% after a mean follow-up of 2 years, and they stressed small residual fragments increase the
Complications After SWL Treatment:
SWL has been shown to be safe in pediatric patients and infants [5,47]. However, its safety for the renal parenchyma, especially in very young children whose kidneys are actively growing, has not yet been fully confirmed. In the literature, complications following SWL are minor and relatively infrequent [1-47]. There are no reports of severe, acute renal damage due to SWL in children [47]. Thomas et al. [48] suggested that there might be some reduction in overall functional growth in the post-SWL kidney, but there appears to be no statistically significant long-term effect on renal function or renal growth after SWL. Lottmann et al. [47] reported that after several treatment sessions in kidneys with scars of infant, SWL did not appear to be harmful to the renal parenchyma. The most frequently observed complications are hematuria, steinstrasse, ureteral obstruction, and urinary tract infection with or without fever [42]. Cutaneous petechiae at the shock wave entry site and gross hematuria typically resolved 24 to 48 hours after treatment. Many recent publications do not mention the occurrence of post-treatment skin bruising or hematuria, likely because they do not consider these as complications [9]. Major complications such as subcapsular, intrarenal and perirenal hematomas were also reported [6,9,42]. Goel and colleagues [49] reported that hematomas (4% intrarenal, 6% perirenal and 2% subcapsular) after lithotripsy were seen in 50 treated children. Our percentage of subcapsular hematomas, in a series consisting of 263 children, was only 0.4% [17]. Several studies in children following SWL treatment found no significant or permanent variation in differential renal function [47-50,51]. Additionally, experimental and clinical studies mostly agree that SWL is safe with regards to scar formation, ovarian reserve, number of pregnancies, fetal numbers and weight, and epiphysial damage [48,52,53]. Consequently, in several pediatric SWL reports, major complications occurred rarely and most post-lithotripsy complications were minor (Table 4).

The use of fluoroscopic targeting during SWL in children is associated with exposure of x-ray [9]. Kroovand et al. [54] carefully monitored radiation exposure during SWL treatment and estimated that average exposure of radiation during this procedure was the same of other diagnostic abdominal procedures such as a barium enema or voiding cystourethrogram.

Conflicts of interest statement The authors declare that they have no conflict of interest to the publication of this article.

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Contraindications of SWL:
SWL is contraindicated in patients with coagulopathy, urinary tract infection, non-functioning kidney, severe congenital skeletal abnormalities, uncontrolled hypertension, obstruction distal to the stone such as UPJ obstruction, obstructive megaureter, a second distal stone and urethral stricture [8,9].

Discussion:
More than 25 years have passed since the use of SWL began in the pediatric population, and guidelines for SWL in children still have not been fully determined. However, experimental and clinical studies have demonstrated that SWL is a safe procedure in kidneys and adjacent organs [1,48,52,53].

Because children with urolithiasis are at risk for a longer time period than adults, their cumulative likelihood of stone recurrences may be higher. Thus, postoperative medical treatment in order to prevent stone recurrence is very important [1,9,46]. SWL is minimally invasive, effective and safe for the management of pediatric urolithiasis [1-55]. Small residual fragments after lithotripsy in children are clinically significant, because they increase the chance of adverse clinical outcomes [45]. Additionally, residual fragments are associated with a higher risk of new stone formation. Therefore, these children require close follow-up and convenient medical treatment, especially in the presence of a predisposing metabolic and/or anatomical disorder.

Preoperative ureteral stent placement should be reserved for selected situations such as solitary kidney, staghorn calculi and significant stone bulk (greater than 25 mm diameter). The incidence of device insertion in the children treated with SWL was 9.2% among 1584 children (Table 4).

In pediatric SWL reports, most complications were minor, and major complications occurred rarely. The complication rate in the pediatric lithotripsy series was 11.9% among 1584 patients. The more frequent complications observed are steinstrasse, colic pain and UTI (Table 4). Major complications reported only in 4 cases among 1584 children.

In conclusion, SWL is a minimally invasive, effective, and safe procedure for the management of pediatric urolithiasis. Compared with invasive treatments, SWL offers many advantages including minimal anesthesia, shorter hospitalization, more rapid recovery, lower complication rates, less renal injury, and easier intervention.