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Original Article – Urolithiasis

Impact of Extracorporeal Shock Wave Lithotripsy on Quality of Life in Pediatric Urinary Stone Patients

Ekstrakorporeal Şok Dalga Litotripsi'nin Pediatrik Üriner Taşı Olan Hastalarda Yaşam Kalitesi Üzerindeki Etkisi

Short Title: Impact of Pediatric SWL on QoL (Pediatrik SWL'nin Yaşam Kalitesi Üzerindeki Etkisi)

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Abstract

Objective: This study aimed to evaluate the impact of extracorporeal shock wave lithotripsy (SWL), a commonly used treatment for pediatric urinary stone disease, on children's quality of life (QoL) using a validated and reliable QoL instrument (PedsQL™ 4.0).

Materials and Methods: In this prospective study, patients under the age of 18 who were scheduled for SWL due to kidney or ureteral stones between March 2018 and March 2020 were included. The age-appropriate PedsQL™ 4.0 questionnaire was administered before SWL, and on days 3 and 14 post-treatment. The relationship between QoL scores and parameters such as stone-free status, age, gender, stone location, and stone size was statistically analyzed.

Results: A total of 36 children (21 males and 15 females) were included. The stone-free rate after the first SWL session was 63.9%. QoL scores significantly decreased on day 3 post-SWL ($p=0.031$) but significantly improved by the second week compared to baseline ($p=0.001$). Notably, children aged 2–7 years, those with lower calyceal stones, stone size <1 cm, and stone-free status had significantly better QoL scores.

Conclusion: Although pediatric SWL may temporarily reduce QoL in the early postoperative period, it significantly improves QoL by the second week. Age, stone location, stone size, and achieving a stone-free status are important factors influencing QoL outcomes.

Keywords: extracorporeal shock wave lithotripsy, quality of life, pediatric, urinary system stone disease

Özet

Amaç: Bu çalışmada, çocukluk çağı üriner sistem taş hastalığında yaygın olarak kullanılan ekstrakorporeal şok dalga litotripsi (ESWL) tedavisinin çocukların yaşam kalitesi üzerindeki etkisinin, geçerli ve güvenilir bir yaşam kalitesi ölçeği (PedsQL™ 4.0) kullanılarak değerlendirilmesi amaçlandı.

Gereçler ve Yöntemler: Mart 2018 - Mart 2020 tarihleri arasında böbrek veya üreter taşı nedeniyle ESWL planlanan 18 yaş altı hastalar prospektif olarak çalışmaya dahil edildi. Tüm hastalara tedavi öncesi, tedaviden 3 gün sonra ve 14 gün sonra yaşa uygun PedsQL™ 4.0 ölçeği uygulandı. Taşsızlık oranı, yaş, cinsiyet, taş lokalizasyonu ve taş boyutu gibi parametrelerle yaşam kalitesi skorları arasındaki ilişki istatistiksel olarak değerlendirildi.

Bulgular: Çalışmaya 36 çocuk (21 erkek, 15 kız) dahil edildi. İlk ESWL seansı sonrası taşsızlık oranı %63.9 idi. Tedavinin üçüncü gününde yaşam kalitesi puanlarında anlamlı bir düşüş görülürken (p=0.031), ikinci haftada yaşam kalitesi puanlarında anlamlı bir artış tespit edildi (p=0.001). Özellikle 2-7 yaş arası, alt kaliks taşları, <1 cm taş boyutu ve taşsız olan hastalarda yaşam kalitesi skorları belirgin olarak daha yüksekti.

Sonuç: Pediatrik ESWL tedavisi kısa dönemde yaşam kalitesini olumsuz etkileyebilse de, ikinci hafta itibariyle yaşam kalitesinde belirgin bir iyileşme sağlamaktadır. Yaş, taş lokalizasyonu, taş boyutu ve taşsızlık durumu yaşam kalitesini etkileyen önemli faktörlerdir.

Anahtar kelimeler: ekstrakorporeal şok dalga litotripsi, pediatrik, ürolityazis, yaşam kalitesi

Introduction

Urinary system stone disease; is a common health problem prevalence ranging from 1-20%. The prevalence of urolithiasis is increasing and children are more likely to experience recurrence [1,2]. Although endourological treatments are becoming widespread with the miniaturization of endoscopic instruments, extracorporeal shock wave lithotripsy (SWL) is widely used in the treatment of pediatric urinary stone disease. SWL is a noninvasive, effective and reliable method [3]. It is easier for children to reduce shock wave transmission due to the smaller body volume, shorter ureter length and high ureter compliance facilitating spontaneous disposal of stone fragments [4]. According to the European Urology Association; SWL is the first-choice method in children with renal and ureteral stones up to 20 millimeters [5].

In pediatric patients with urinary stone disease, the stone-free rate of SWL has been reported as 67-93% in the short term and 57-92% in long-term follow-up studies [6]. However, the complication rates of SWL are very low [7]. Pediatric SWL is a painful procedure. It is often performed under sedation or general anesthesia to reduce pain and ensure patient immobility. Both the SWL procedure itself and the anesthesia administered may affect the quality of life (QoL) of the child. Although there are many studies on the efficacy and safety of pediatric SWL, to the best of our knowledge, no published studies have explored the association between SWL and QoL in pediatric patients.

Assessing QoL in children is critical, as it impacts their physical, emotional, and social development, as well as family dynamics. In this study, we aimed to determine the relationship between pediatric SWL and patients' QoL using a validated QoL scale.

Materials and Methods

After obtaining institutional ethics committee approval (No:48670771-514.10), patients under 18 years of age with kidney or ureteral stones scheduled for SWL were included between March 2018 and March 2020 in this prospective study. The research was conducted according to the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects." A priori power analysis was conducted using an effect size of 0.8, alpha of 0.05, and power of 0.80 for a paired t-test design. The analysis revealed that a minimum of 14 participants would be required.

All patients were evaluated by ultrasonography (USG), and kidney, ureter, and bladder (KUB) radiography, with computed tomography (CT) employed in cases of diagnostic uncertainty. Patients with anomalies of urinary tract, internal and external diversion, coagulopathy, chronic or other acute active disease were excluded from the study. Patients with multiple stones, known cystine stone disease, non-opaque stones were excluded to ensure homogeneity in stone characteristics and imaging accuracy. Pre-SWL workups included urinalysis, urine culture, complete blood count, creatinine levels and coagulation tests. Stone size was measured as the longest diameter on USG, KUB or CT imaging. All patients were requested to complete the validated age matched QoL scale at baseline, and at 3 and 14 day after SWL.

QoL Measurements

Pediatric Quality of Life Inventory™ 4.0 (PedsQL™ 4.0) was used as a health-related QoL instrument. This scale has been developed and validated as a valid and reliable tool that can be used for self-reports and proxy-reports in children under the age of 18 [8-11]. Studies have shown that there is no difference between the completion of the PedsQL scoring system by the child and the parent. In order to ensure homogeneity, the forms of all patients were filled by their parents in our study.

PedsQL ™ 4.0 is a five-point Likert scale, consisting of five different forms by different ages; under 2 years of age, for 2-4, 5-7, 8-12 and 13-18 years of age. Each form consists of a total of 23 items, which are physical functioning (eight items), emotional functioning (five items), social functioning (five items) and school/cognititve functioning (five items). The sum of the emotional, social and school/cognitive functionality subgroups forms the psychosocial subgroup. There are five options in each item; never (100 point), rarely (75 point), sometimes (50 point), often (25 point) and almost always (0 point). The total score is calculated by dividing

the number of items. Thus, a PedsQL score between 0-100 is obtained. A higher score indicates better QoL.

SWL Technique

SWL was performed by a single experienced urologist using the Dornier Compact Sigma lithotripter (Dornier MedTech, Wessling, Germany) under intravenous sedation or general anesthesia. All patients received standardized intravenous sedation or general anesthesia based on age and clinical needs. Both fluoroscopy and USG imaging were used to locate stones. The procedure was started with a low voltage of 13 kV and was gradually increased to 20 kV. SWL session was terminated when full stone fragmentation was achieved, or 2000 shock wave counts were reached. KUB graphy and USG was done at the first week after SWL for follow-up. If a complete stone clearance was obtained, the patients were considered as stone-free. If stone-free was not achieved, a second SWL session was planned.

Statistical Analysis

Independent t test was used to compare independent groups, pearson correlation test to examine the relationship between variables and pearson chi-square, chi-square and fisher exact tests were used to compare categorical data. A paired sample t-test or Wilcoxon test was used to compare the dependent groups. Quantitative data were expressed as mean ± standard deviation values on tables. Categorical data are expressed as n (frequency) and percentages (%). Data were analyzed at 95% confidence level and it was considered significant when p value was less than 0.05.

Results

The study included a total of 36 children, comprising 21 males and 15 females. The mean age of the participants was 70.1 months, and the mean stone size measured 10.2 mm. Following the initial session of SWL, the stone-free rate was 63.9%, corresponding to 23 patients **(Table 1)**.

Upon comparing baseline and postoperative PedsQL scores and subscores, it was observed that the PedsQL scores on the third postoperative day were significantly lower than the baseline scores (85.2 and 83.9, respectively, p= 0.031). Conversely, the PedsQL scores in the second postoperative week were significantly higher than the baseline scores (91.9 and 83.9, respectively, p= 0.001) **(Table 2)**.

When the baseline QoL values of the patients were compared, it was found that there was no difference between the male and female patients, between the age groups, according to the location of the stone and the stone size ($p > 0.05$) **(Table 3)**.

Table 3 shows comparison of PedsQL scores baseline and after SWL according to gender, age, stone location, stone size and stone-free rate. On day 3 after SWL; PedsQL scores were found to be significantly lower in patients 2-4 years age, 8-12 years age, ≥ 1 cm stone size and stone-free patients ($p < 0.05$). However, 2 weeks after SWL; the PedsQL scores were significantly higher in both female and male patients, 2-7 years of age, lower calyceal stones, less than 1 cm of stone size and stone-free patients ($p < 0.05$) **(Table 3)**.

There was no complication during SWL. In the first 2 weeks follow-up, urinary tract infection (UTI) was observed in 2 patients. The patients were treated with appropriate antibiotic treatment.

Discussion

Urinary stone disease is a chronic condition that adversely impacts QoL due to its propensity for recurrence and the necessity for surgical interventions. According to Hall et al., the recurrence rate of urinary stone disease ranges from 10% to 48% [12]. Similar to other chronic conditions, there is an association between urinary stone disease and psychological factors such as stress, depression, and other mental health disorders. Patients experiencing recurrent urinary stone disease exhibit elevated stress levels compared to healthy individuals [13]. Miyaoka et al. reported that stress levels were significantly heightened during episodes of painful renal colic [14].

In quality of life assessments, patients with urinary stone disease exhibited significantly poorer scores in pain, physical functioning, social functioning, and general health compared to healthy individuals [15,16]. While existing studies on the QoL in urinary stone patients have focused exclusively on adults, there is a notable absence of research concerning pediatric patients with urinary stones [17]. To the best of our knowledge, our study represents the first investigation into the QoL in pediatric patients undergoing SWL.

In a study conducted by Penniston et al., it was observed that the QoL scores for men and women with urinary stone disease were comparable [16]. Bensalah et al. identified obesity, age, and surgical history as factors influencing the QoL in patients with urinary stones [15]. In

our study, no significant association was found between QoL and variables such as gender, age, stone size, and stone location.

SWL is widely used as an effective and reliable method in patients with pediatric urinary stone disease. In pediatric patients, the stone-free rate of SWL ranges from 50% to 90% [18,19]. Factors affecting the success of SWL include age, stone size, location and composition, patient habits and lithotriptor activity [20]. The most important factor affecting the success of SWL is the stone size. According to the study by Dogan et al, stone-free rates in pediatric SWL; for stones <1 cm, 1-2 cm and> 2 cm, it is about 90%, 80% and 60% respectively [21].

Kurahashi et al. conducted an examination of patients who had undergone SWL at least three months prior due to urinary stone disease. The study found no significant difference in QoL between these patients and the general population. In this investigation, SWL was compared with percutaneous nephrolithotomy (PNL) and ureterorenoscopy (URS), with SWL demonstrating a higher overall health score than the other treatment methods [22]. Similarly, Arafa et al. assessed patients who had undergone SWL at least three months earlier for urinary stone disease. The QoL scores of these patients were found to be superior to those of the general population. In the same study, when SWL was compared to PNL and URS, SWL's QoL score was higher than those of the other treatment methods [23].

In our study, on the third day following SWL, the physical and overall QoL metrics were significantly lower than the preoperative values. This outcome may be attributed to the impact of SWL on the body, as well as the effect of renal colic-induced fragments post-SWL. However, by the second week after SWL, all QoL metrics were significantly higher than the preoperative values. This finding suggests that SWL can enhance QoL even in the early stages by effectively treating urinary stone disease.

Regrettably, research concerning the parameters influencing the QoL—such as age, gender, and stone location—in patients undergoing SWL remains insufficient. Sahin et al. identified that patients with stones exceeding 2 cm in size experienced a diminished QoL and had a higher frequency of emergency room visits [24]. In alignment with these findings, our study determined that the QoL was notably improved in patients with stones measuring less than 1 cm.

The limitations of this study include the small sample size and the absence of a control group. It is imperative to conduct further studies with larger sample sizes and the inclusion of control groups. This would enable the provision of comprehensive information to parents

regarding the potential impact of SWL on their child's QoL. As PedsQL scores were reported by parents, the results may reflect parental perceptions rather than the child's direct experience, which could introduce bias. Additionally, the evaluation of only the initial SWL session may present a limitation.

Conclusion

Pediatric SWL may temporarily reduce QoL in the early postoperative period, likely attributable to the reduction in stone fragments. However, by the second week post-SWL, there is a notable improvement in the child's quality of life. Factors influencing this quality of life include age range of 2-7 years, presence of lower calyceal stones, stone size less than 1 cm, and achieving a stone-free status. Future research should explore long-term QoL outcomes and the impact of repeated SWL sessions in pediatric patients.

Ethics Committee Approval: Ethical approval for this study was obtained from University of Health Sciences, Okmeydanı Training and Research Hospital Clinical Research Ethics Committee (Approval number and date: 48670771-514.10 and 01.08.2018).
Informed Consent: An informed consent was obtained from all the patients.
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Table 1. Demographic characteristics of the patients

Gender	
Female	15 (41.7%)
Male	21 (58.3%)
Age* (month)	70.1 ± 48.1
Operation side (right/left)	20/16
Stone location	
Upper calyx	3 (8.3%)
Middle calyx	8 (22.2%)
Lower calyx	11 (30.6%)
Renal pelvis	9 (25.0%)
Proximal ureter	5 (13.9%)
Stone size* (mm)	10.2 ± 3.9
Stone free rate	23 (63.9%)

*: mean ± standard deviation

Table 2. Comparison of PedsQL subscores

	Baseline	**Post-op 3rd day**	**p^{α}**	**Post-op 14th day**	**p^{β}**
Physical*	85.5 ± 15.1	80.3 ± 15.8	**0.001**	92.0 ± 10.4	**0.003**
Emotional*	84.4 ± 21.0	83.6 ± 21.1	1.000	92.0 ± 13.0	**0.007**
Social*	92.8 ± 14.7	93.1 ± 14.7	0.317	97.3 ± 8.2	**0.012**
Cognitive/School *	84.3 ± 15.2	84.1 ± 15.8	0.833	89.4 ± 13.8	**0.015**
Psychosocial *	87.3 ± 14.2	87.0 ± 14.2	0.674	93.0 ± 9.4	**0.001**
Total*	85.2 ± 13.7	83.9 ± 13.5	0.031	91.9 ± 9.7	**0.001**

*: mean ± standard deviation, PedsQL: Pediatric quality of life inventory
α: Postoperative 3rd day vs baseline, β: Postoperative 14th day vs baseline

Table 3. The effect of variables on PedsQL score

	Baseline	**p**	**Postoperative 3rd day**	**p$^{\alpha}$**	**Postoperative 14th day**	**p$^{\beta}$**
Gender						
Female	87.3 ± 13.4	0.303	85.5 ± 13.4	0.123	91.9 ± 11.1	**0.004**
Male	82.4 ± 14.1		81.7 ± 13.8	0.108	91.8 ± 7.7	**0.011**
Age						
<2 years	77.6 ± 18.9	0.672	78.6 ± 19.3	1.000	87.6 ± 8.6	0.144
2-4 years	90.6 ± 7.8		88.9 ± 8.1	**0.026**	97.5 ± 2.1	**0.008**
5-7 years	83.9 ± 18.2		83.6 ± 18.7	0.317	89.9 ± 14.0	**0.043**
8-12 years	87.4 ± 11.7		82.2 ± 11.8	**0.042**	92.0 ± 8.5	0.107
13-18 years	80.2 ± 11.9		82.0 ± 10.3	0.655	85.9 ± 13.8	0.655
Stone location						
Upper calyx	86.2 ± 12.3	0.228	84.7 ± 12.0	0.317	86.4 ± 9.6	0.655
Middle calyx	76.8 ± 14.9		78.1 ± 15.3	0.916	85.8 ± 12.2	0.075
Lower calyx	88.6 ± 9.9		87.7 ± 10.2	0.068	93.9 ± 9.9	**0.017**
Renal pelvis	86.3 ± 16.3		84.9 ± 15.5	0.066	95.3 ± 3.8	**0.050**
Proximal ureter	88.7 ± 14.5		82.6 ± 16.3	0.180	94.1 ± 10.1	0.068
Stone size						
<1 cm	84.2 ± 15.1	0.590	84.6 ± 14.8	0.511	91.2 ± 11.4	**0.001**
≥1 cm	86.8 ± 11.6		82.8 ± 11.7	**0.012**	92.9 ± 6.4	0.075
Success						
Stone Free	84.9 ± 15.1	0.912	83.1 ± 15.1	**0.027**	94.8 ± 7.9	**0.001**
Not Stone Free	85.8 ± 11.5		85.3 ± 10.7	0.500	86.8 ± 10.8	0.612

*: mean ± standard deviation, PedsQL: Pediatric Quality of Life Inventory
α: Postoperative 3rd day vs baseline, β: Postoperative 14th day vs baseline