Does Extracorporeal Shock Wave Lithotripsy Cause Hearing Impairment in Children?

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Abbreviations and Acronyms

HESW = high energy shock wave
SNR = signal-to-noise response
SPL = sound pressure level
SW = shock wave
SWL = extracorporeal shock wave lithotripsy
TEOAE = transient evoked otoacoustic emission

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Purpose: We evaluated the possible effects of noise created by high energy shock waves on the hearing function of children treated with extracorporeal shock wave lithotripsy.

Materials and Methods: A total of 65 children with normal hearing function were included in the study. Patients were divided into 3 groups, ie those becoming stone-free after 1 session of shock wave lithotripsy (group 1, 22 children), those requiring 3 sessions to achieve stone-free status (group 2, 21) and healthy children/controls (group 3, 22). Extracorporeal shock wave lithotripsy was applied with patients in the supine position with a 90-minute frequency and a total of 2,000 shock waves in each session (Compact Sigma, Dornier MedTech, Wessling, Germany). Second energy level was used with a maximum energy value of 58 joules per session in all patients. Hearing function and possible cochlear impairment were evaluated by transient evoked otoacoustic emissions test at 1.0, 1.4, 2.0, 2.8 and 4.0 kHz frequencies before the procedure, 2 hours later, and 1 month after completion of the first shock wave lithotripsy session in groups 1 and 2. In controls the same evaluation procedures were performed at the beginning of the study and 7 weeks later.

Results: Regarding transient evoked otoacoustic emissions data, in groups 1 and 2 there was no significant alteration in values obtained after shock wave lithotripsy compared to values obtained at the beginning of the study, similar to controls.

Conclusions: A well planned shock wave lithotripsy procedure is a safe and effective treatment in children with urinary stones and causes no detectable harmful effect on hearing function.

Key Words: child, hearing loss, high-energy shock waves, lithotripsy, urinary calculi

Since its clinical introduction in the early 1980s, extracorporeal shock wave lithotripsy has become the most popular therapy worldwide for treating patients with urinary calculi, yielding effective and safe results in the majority of adults and children with upper urinary stones.[1] The first successful results in children were reported by Newman et al in 1986.[2] Although extracorporeal shock wave lithotripsy has not yet been approved by the United States Food and Drug Administration in children, there are

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many studies showing its effectiveness and safety in pediatric patients.[3–7]

Despite the accumulated evidence indicating the highly successful and safe nature of extracorporeal shock wave lithotripsy in children, some complications have been reported, including hematuria, small subcapsular hematoma, petechiae on the skin, urinary tract infection, fever, renal colic and steinstrasse.[7,8] In addition to these well-known risks, another potential risk could originate from the noise produced by the high energy shock waves, with possible negative effects on the hearing function of treated patients.

Noise induced hearing loss is caused by repeated exposure to loud sounds for an extended period, exposure to loud impulse sound(s) or a combination of both. Exposure to continuous high intensity noise initiates a cascade of reactions at the cochlear level, leading to death by apoptosis of the outer hair cell of the organ of Corti.[9] TEOAE is a diagnostic method that has been widely used during the last decade to study cochlear function in a noninvasive and objective manner. Otoacoustic emission measurements are a sensitive indicator in evaluating peripheral hearing function. This method allows us to objectively monitor small changes in the cochlea and determine the cochlear component that is causing hearing loss, which cannot be determined using other audiology methods.[10,11] For these reasons we prefer TEOAE testing to assess cochlear function.

Although some contradictory data have been reported in the literature focusing on the possible effects of HESW induced noise on hearing status in adults,[10,12–16] to our knowledge no study has thus far evaluated the possible adverse effects of HESWs on the hearing function of children undergoing SWL. In this prospective controlled study we evaluated the possible effects of noise created by HESWs on the hearing function of children treated with SWL.

MATERIALS AND METHODS

This prospective controlled study included 43 pediatric patients with solitary renal stones referred to the urology clinic at Dr. Lutfi Kirdar Training and Research Hospital between December 2012 and March 2014. The study protocol was approved by the hospital ethics committee (No. 11, November 13, 2012). All steps of the study were planned and applied carefully according to the Helsinki Declaration.

Patients who had undergone SWL or ear surgery previously, or had hearing loss or tinnitus were excluded from the study. A total of 65 children (including controls) were divided into 3 groups, ie those who became stone-free after 1 session of SWL (group 1, 22 patients), those requiring 3 sessions to achieve stone-free status (group 2, 21) and healthy controls referred to the outpatient pediatric department (group 3, 22).

Routine biochemical tests, urinalysis, urine culture sensitivity test, bleeding and clotting times, and electrocardiography were performed before SWL in the majority of patients, as well as x-ray of the kidneys, ureters and bladder, and/or urinary system ultrasonography. Noncontrast abdominopelvic computerized tomography was performed when needed. Finally, all patients again underwent a hearing evaluation via otorhinolaryngological examination and TEOAE test.

SWL was applied using an electromagnetic shock wave generating system (Compact Sigma). General anesthesia was required for older children, and sedoanalgesia was used for younger children (0.5 to 1 mg/kg ketamine and 0.05 to 0.1 mg/kg midazolam). Opaque stones were localized by fluoroscopy, and lucent stones were localized by ultrasonography. SWL was applied with patients in the supine position with a frequency of 90 SWs per minute and a total of 2,000 SWs in each session. Second energy level was reached in the first 200 SWs, with a maximum energy value of 58 joules per session in all patients. All patients were evaluated 1 week after the first SWL session with x-ray of the kidneys, ureters and bladder, and/or urinary system ultrasonography to define stone fragmentation and obstruction (hydronephrosis) level. Up to 3 total SWL sessions were performed in study patients and were administered at 1-week intervals.

Regarding the hearing evaluation, TEOAE values were recorded in all cases. Frequencies tested were 1.0, 1.4, 2.0, 2.8 and 4.0 kHz using Echoport ILO288-I EZ-Screen 2 (Otodynamics Ltd, Hatfield, Herts, United Kingdom). A TEOAE response was considered positive and acceptable for analysis if 1) mean amplitude of the cochlear response was greater than the noise in the external canal, 2) reproducibility rate of the responses was greater than 50%, 3) rate of stimulus stability was greater than 75%, 4) stimulus amplitude was 75 dB SPL, 5) overall SNR was 3 dB SPL and 6) rate of SNR was 3 dB SPL for at least 2 of the tested frequencies.[17] All patients included in the study had normal TEOAE responses, indicating normal hearing. All SNR data obtained were comparatively evaluated before and after treatment in all groups. The sound produced by the lithotripter was recorded at the lithotripter SW generator head, at the patient ear and at the urologist station levels using a ST85A Mini Sound Level Meter (Standard Instruments Co, Ltd, Kowloon, Hong Kong).

In study patients the TEOAE test was applied before SWL, and then 2 hours after completion of the first or sole session (short term) and 1 month after completion of the final or sole session (long term). In controls the TEOAE test was administered at the beginning of the study and 7 weeks later, in accordance with the timing applied in study group 2. Children in groups 1 and 2 who could cooperate were asked about the presence of tinnitus and/or hearing loss after the procedure.

All data are given as mean $\pm$ SD and were evaluated with the Mann-Whitney U test, Kruskal-Wallis test and Wilcoxon signed rank test. Statistical analysis was performed using SPSS®, version 20.0 for Windows®. A p value of less than 0.05 was considered statistically significant.