Does Extracorporeal Shock Wave Lithotripsy Cause Hearing Impairment?

Murat Tuncer, Banu A. Erdogan, Ozgur Yazici, Cahit Sahin, Gokhan Altin, Gokhan Faydaci, Bilal Eryildirim, and Kemal Sarica

OBJECTIVE To evaluate the possible effects of extracorporeal shock wave lithotripsy (ESWL) on the hearing status of the patients in this prospective controlled study.

METHODS A total of 40 patients with normal hearing function were included to the study. We had 20 patients each in the study group and control group. The treatment parameters were standardized in all 3 sessions in which a total of 3000 shock waves with a rate of 90/min along with a total energy value of 126 J at the fourth energy level have been applied (Dornier Compact Sigma, Medtech, Germany). In addition to the testing of hearing functions and possible cochlear impairment by Transient Evoked Otoacoustic Emissions test at 1.0, 1.4, 2.0, 2.8, and 4.0 kHz frequencies, complications such as ear pain, tinnitus, and hearing loss have been well evaluated in each patient before the procedure and 2 hours and 1 month after the completion of the third session of ESWL in the study group. The same evaluation procedures were performed before the study and after 7-weeks in the control group.

RESULTS Regarding Transient Evoked Otoacoustic Emissions data obtained in study group and control group patients, there was no significant alteration in values obtained after ESWL when compared with the values before the procedure.

CONCLUSION A well-planned ESWL procedure is a safe and effective treatment in urinary stones and causes no detectable harmful effect on the hearing function of treated patients. UROLOGY ■: ■—■, 2014.

After its clinical introduction in the early 1980s, extracorporeal shock wave lithotripsy (ESWL) has become the most popular therapy for urinary calculi throughout the world with its effective and safe results in most upper urinary stones both in adults and children. However, despite its highly successful and minimal invasive nature, application of high-energy shock waves (HESW) with this system may cause some minor and major complications.[1] Complications of ESWL may depend on residual stone fragments, infection, and direct mechanical effects of HESW on tissues such as gastrointestinal, cardiovascular, genital, and reproductive system.[2,3] Concerning such possible harmful effects, in addition to these well-known reported risks, another potential risk could originate from the noise produced by the HESW on the hearing function of treated cases. It is well known and reported that acoustic energy generated by HESW during the disintegration of the stones causes noise depending on the energy level used. However, there are some contradictory reports published in the literature focusing on the possible effects of HESW-induced noise on the hearing status of human beings.[4-9]

In this present prospective controlled study, we aimed to evaluate the possible effects of noise created by HESW on the hearing function of the treated cases during short- and long-term follow-up.

MATERIALS AND METHODS

A total of 65 patients referring to urology department between December 2012 and March 2013 were included to this prospective controlled study. Study protocol was approved by Dr. Lutfi Kirdar Kartal Training and Research Hospital's Etic Committee (date: November 13, 2012; file number: 11). All the steps of the study were planned and applied suitably according to Helsinki Declaration.

Twenty-five patients in whom a complete stone fragmentation has been observed after 1 or 2 sessions were excluded from the study. In addition to the patients with previous ESWL history, patients with hearing loss, tinnitus, and previous ear surgery were all not included to the study program. A total of 40 patients were included and divided into 2 groups. Although 20 patients (14 men and 6 women) undergoing ESWL for unilateral kidney stones constituted study group, another 20 patients (15 men and 5 women) referring to the department for reasons other than urolithiasis were studied in the control group.

Financial Disclosure: *The authors declare that they have no relevant financial interests.*

From the Dr. Lutfi Kirdar Training and Research Hospital Urology Clinic, Istanbul, Turkey; the Dr. Lutfi Kirdar Training and Research Hospital Otorhinolaryngology Clinic, Istanbul, Turkey; and the Department of Otorhinolaryngology, Medipol University, Istanbul, Turkey

Reprint requests: Murat Tuncer, M.D., Altunizade mah., Atif bey sok., Gokdeniz sitesi E blok D:20 Kosuyolu, Istanbul, Turkey. E-mail: murattuncer77@hotmail.com

Submitted: October 2, 2013, accepted (with revisions): December 26, 2013

0090-4295/14/$36.00
http://dx.doi.org/10.1016/j.urology.2013.12.056

Before the ESWL, after the routine biochemical and urine tests, in addition to kidney-ureter-bladder and/or urinary system ultrasonography performed in most the cases, a noncontrast abdominopelvic computed tomography was applied when needed. Finally, all cases were again examined well at the otorhinolaryngology department for the actual status of hearing by performing otorhinolaryngologic examinations and Transient Evoked Otoacoustic Emissions (TEOAE) test.

All cases were treated with an electromagnetic shock wave (SW) generating system (Dornier Compact Sigma, Medtech, Germany), and ESWL procedure was applied at supine position with a 90\min frequency and total of 3000 SWs in each session. Fourth energy level was reached in first 500 waves, and total of 126 J energy was performed in all patients. A maximum number of 3 ESWL sessions were performed in all patients in the study group with a week period among each session.

Concerning the evaluation of the hearing system, TEOAE values were recorded in all cases. The frequencies were tested at 1.0, 1.4, 2.0, 2.8, and 4.0 kHz using Echoport OAE EZ-Screen 2 (Otodynamics ltd. 30-38, Beaconsfield Road Hatfield Herts AL10 8BB, United Kingdom). After each ESWL session, subjective symptoms such as tinnitus, pain in the ears, or any change in hearing were carefully noted. The sound produced by the lithotripter was recorded at both lithotriptor's SW generator head, at the patient's ear and the operators (urologist) station levels by using Sound Level Meter. (Mini, A Type - ST-85A).

In the study group cases, TEOAE test was applied first before the ESWL (B-ESWL) procedure and then 2 hours (A-2-hours) and 1 month after (A-1-month) the completion of third session. In the control group cases, however, TEOAE test was applied first B-ESWL and 7 weeks after (A-7-weeks) after the first session of ESWL in accordance with the timing in study group cases (1 month after 3 sessions).

All data were given as mean ± standard variation and evaluated with Mann Whitney *U* test, Kolmogorov Smirnov test, paired sample *t* test, and Wilcoxon test using SPSS v15.0 for windows. $P < .05$ was accepted as statistically significant.

RESULTS

Evaluation of our findings did reveal the following data: there was no significant difference with respect to the patient, stone (in the study group), and demographic characteristics in both groups ($P > 05$; Table 1).

Regarding the TEOAE values (including all frequency levels—1.0, 1.4, 2.0, 2.8, and 4.0 kHz) obtained in study group patients, there was no statistically significant alteration in values obtained before and after (A-2-hours and A-1-month) ESWL. Similar to these patients, again no significant difference could be demonstrated in control group cases both before and after (A-7-week) treatment. Values obtained from TEOAE values in both groups before and after ESWL are being demonstrated in Tables 2-4.

Evaluation of the sound level at various parts during the treatment namely at the head of the SW generator, the patient's ear and operator's (urologist) station level did show the values to be 65.2-71.5, 60.7-68.4, and 58.7-66.2 dB, respectively. During the treatment, the SW generator was fixed to an energy level of 4 during the course of all shock wave lithotripsy procedures in the study group.

Last but not least, none of the patients evaluated in both groups developed tinnitus, ear pain, or hearing loss after ESWL, which has been well assessed after each session.

Table 1. Demographic characteristics and mean stone size of the cases

Characteristics	Study Group (n: 20)	Control Group (n: 20)	*P*
Gender (male/female)	14/6	15/5	
Age (y)	39.75 ± 10.95 (25-58)	36.59 ± 11.18 (24-58)	.401
Stone size (m^2)	112.91 ± 64.45 (55.2-372.8)		

COMMENT

After its clinical introduction in 1982, ESWL became the preferred treatment modality in the management of urinary calculi with its successful results.[10] However, despite its highly successful and safe results, studies did clearly show that some certain side effects can occur after this procedure. The reported complications related with this subject namely gross hematuria, pain, and perinephritic hematoma are generally minor problems that could be treated in a conservative manner in most the cases.[11]

SWs used in ESWL may have effects not only on the treated kidneys but also on hearing function. Related with this subject, published studies did clearly show that HESW-related noise is impulsive in nature,[7] and all the possible side effects on hearing function were related to the number of HESW,[12] the level of discharge energy,[13] intensity of the sound produced by HESW, and time between impulses.[7]

Focusing on the possible harmful effects of HESW on hearing function of the treated cases, there are limited data reported in the published literature. Although odiometric tests were applied in first trials,[7,8] otoacoustic emission measurements proved to be the most sensitive test for the determination of the possible hazards of noise induced. It has been well shown that otoacoustic emission measurements have the ability to detect the earliest subtle changes reflecting the auditory function at the cellular level. Otoacoustic emissions as a potential applied test for cochlear function[14,15] have several advantages, including objectivity, noninvasiveness, and specificity for testing the biomechanical activity of the outer hair cells, the most fragile class of receptors of the organ of Corti.[16-18]

Evaluation of the recent literature did show some studies evaluating the possible effects of ESWL on hearing function using Transient Otoacoustic Emissions tests.[4-6,9] Because of the aforementioned advantages TEOAE test was also performed in this study to evaluate the status of hearing function in treated cases.