Does Radial Extracorporeal Shockwave Therapy Impair Hearing Function in Patients with Plantar Fasciitis?

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Abstract

Background: Radial extracorporeal shock wave therapy (r-ESWT) is commonly used for the treatment of chronic plantar fasciitis. Previously in the urology literature, some studies reported hearing impairment after extracorporeal shock wave lithotripsy. However, there is no study that evaluates the possible side effects of r-ESWT on the hearing function of patients. The aim of this study was to investigate the effects of r-ESWT on the pure tone audiometry of the patients on whom r-ESWT was applied for chronic plantar fasciitis.

Material and Methods: Patients with the diagnosis of plantar fasciitis who were treated with r-ESWT were included in this prospective case-control study. Before and after the r-ESWT application, all patients were consulted to our otolaryngology department for pure tone audiometric examination to detect any hearing impairment before and after the treatment. A control group was also constructed that consisted of patients who were admitted to our department for any complaint. Results: A total of 67 patients participated in the study. Radial ESWT group consisted of 47 patients (39 female, 8 male) with the mean age of 44.1 years. The control group consisted of 20 patients (12 female, 8 male) with the mean age of 36.9 years. We observed a 20-dB threshold shift at 8000Hz in 1 patient who had no clinical symptom. This patient had no threshold shift at the 1-month control audiometric measurement.

Conclusion: According to the results acquired from this study, we can consider that r-ESWT treatment in patients with chronic plantar fasciitis has no markedly detrimental effect on the hearing function.

Keywords: Audiometry, complications, ESWT, hearing loss, plantar fasciitis

INTRODUCTION

Plantar fasciitis (PF) is the most common reason for inferior heel pain, resulting in activity limitations for the affected adult population.[1] Its etiology is not well understood and likely multifactorial.[2] This foot disorder is thought to be caused by biomechanical overstress of the plantar fascia.[3] Degenerative changes are associated with an increased tension of the plantar fascia in both stance and gait phases. [3] Diagnosis can be made depending on the patient’s history and results of physical examination. Patients may complain about the most serious heel pain during the first few steps in the morning or after a period of rest.[4] Additional to these clinical signs, there is localized tenderness during palpation at the insertion of the fascia during physical examination.[5] Extracorporeal shock wave therapy (ESWT) is a safe, effective treatment and it is commonly used in patients with PF who don’t have pain relief with conservative treatments that include insoles, shoe modification, physical therapy, stretching exercises, night splints and nonsteroidal anti-inflammatory drugs.[6]

There is a paucity of studies in the literature explaining the specific mechanisms of ESWT in treating tendon diseases. ESWT can destroy sensory unmyelinated nerve fibers and stimulate revascularization and collagen synthesis in

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degenerative tissues. ESWT is defined as a sequence of sonic pulses characterized by high peak pressure with fast pressure rise and a short life cycle. Shock waves differ from sound waves in that the wave front, where compression takes place, is a region of the sudden change in stress and density. Radial extracorporeal shock wave therapy (r-ESWT) is the application of high-energy acoustic shock waves. When applying r-ESWT several important variables such as the number of shockwaves given, the number of treatment sessions and in-between intervals and energy flux density should be taken into account. However, despite its highly successful and minimally invasive nature, the application of high-energy shock waves rarely may cause some minor and major complications reported as follows: fascia ruptures, osteonecrosis of the humeral head, acute myocardial infarction and damage to nerves or other structures. On the other hand, another potential risk could originate from the noise produced by the high-energy acoustic shock waves with possible negative effects on the hearing function of treated cases. Auditory functions may be deteriorated by repeated exposure to loud sound over an extended period of time, exposure to very loud impulse sound(s), or a combination of both. To our knowledge, in the literature, there is a scarcity of studies that evaluate the possible side effects of r-ESWT on hearing function of patients with PF. We hypothesized that hearing impairment may occur due to noise produced by the device during ESWT sessions as previously reported after ESWT in the literature. The aim of this study was to investigate the effects of r-ESWT on the pure tone audiometry of the patients on whom r-ESWT was applied for PF.

**PATIENTS AND METHODS**

**Study population**

This prospective case-control study was approved by our institution’s Ethical Review Board (ID: 33216249-604.01.02-E.13618, Date: 15.03.2018) and performed in accordance with the “Declaration of Helsinki”. Between April 2018 and September 2018, r-ESWT was applied to 50 patients with the diagnosis of chronic PF. Radial extracorporeal shockwave therapy was applied for patients with chronic PF with persistent symptoms over 6 months that were not alleviated despite performing all conservative treatment modalities (rest, shoe insert, drug therapy, stretching, and corticosteroid injection). Before and after the r-ESWT application, all patients were consulted to our otolaryngology department for pure tone audiometric examination to detect any hearing impairment before and after the treatment. Patients with previous ESWT history, tinnitus, hearing loss and those who refused to participate in the study were excluded. The study group consisted of 47 patients who underwent audiometric evaluation before and after r-ESWT treatment. A control group consisted of 20 patients who were admitted to our department for any complaint.

**Radial ESWT procedure**

All 47 patients with chronic PF were treated with an electronic shock wave generating system device (Swiss Dolorclast Master Touch, Electro Medical Systems, Nyon, Switzerland). Radial ESWT was applied while the patient was lying at the supine position. Each patient received two sessions of R-ESWT 1 week apart, with 2,000 impulses per session (air pressure of the device set at 3.5 bar; [EFD = 0.16 ml/mm2]; impulses applied with the 15 mm applicator at a frequency of 8 Hz). The gel was used between the cap and skin during the applications for ensuring conductivity. The sound produced by the device was measured by a decibel meter.

**Audiometric evaluation**

A baseline pure tone audiometric evaluation was performed by an audiometrist who was blinded to the study groups. The audiometric evaluation was performed before and after r-ESWT procedure. Audiometric evaluation was also performed for the control group twice with a 1-month interval. Test frequencies included from 500 Hz to 8000 Hz in octave intervals. Pure tone thresholds were determined using MADSEN Astera 2 clinical audiometer (Otometrics A/S, Taastrup, Denmark). Any threshold shift ≥ 20 dB at any frequency was defined as hearing loss. Tinnitus was also recorded for all patients if detected.

**Statistical analysis**

Continuous data were given as mean and standard deviation, categorical data were given as frequency and percentages. SPSS 20 (SPSS Inc., IBM, NY, USA) was used for statistical analysis. The comparison of means was performed by either Mann Whitney U test or t-test in accordance to Kolmogorov Smirnov normality analysis. Frequencies were compared by Fisher’s exact test. P value lower than 0.05 was considered as statistically significant.

**Theory/calculation**

We hypothesized that hearing impairment may occur due to noise produced by the device during ESWT sessions as previously reported after ESWT in the literature.

**RESULTS**

A total of 67 patients participated in this prospective case-control study. Radial ESWT group consisted of 47 patients (39 female, 8 male) with the mean age of 44.1 ± 11.4 years (ranges, 20 to 67 years). The control group consisted of 20 patients (12 female, 8 male) with the mean age of 36.9 ± 9.2 years (ranges, 27 to 57 years). The control group was significantly younger than r-ESWT group (P = 0.008) whereas the genders of the groups did not significantly differ (P = 0.061).

Mean decibel (dB) measured in the operation room during r-ESWT sessions was 88 dB. We observed a 20-dB threshold
shift at 8000Hz in 1 patient who had no clinical symptom. This patient had no threshold shift at the 1-month control audiometric measurement. No patients had any tinnitus after r-ESWT sessions. The comparison of groups in terms of measured audiometric frequencies in each octave intervals was demonstrated in Table 1. There were no significant differences between groups in frequencies measured in each octave intervals. No other complication occurred during the follow-up of the patients.

### DISCUSSION

This is the first prospective controlled study that evaluated hazardous effects on auditory functions of patients with recalcitrant PF treated with r-ESWT. The high energy shock wave is impulse noise which may have harmful effects on the cochlear function depends on the level of discharge energy, the number of exposures, sound intensity and time between impulses. [16]

Noise intensity is measured in decibels of sound pressure level. The peak sound pressure produced by the extracorporeal shock wave generating system device in the operation room was found to be 90 dB at the maximum energy output of the machine as applied in this study. Terlecki et al. [17] recorded 88–90 dB sound pressure levels and found no ototoxicity similar to our study; whereas, Naguib et al. [18] found that extracorporeal shock wave has a potentially hazardous effect on hearing although they measured lower sound intensity (between 75.6 and 87.2 dB).

The type of sound exposure can be constant or in the form of impulse noise. The ear protects itself from constant loud noises by acoustic reflex which is a feedback loop that starts in the cochlea, goes through the spinal cord and back out to the stapedius muscle. Contraction of the stapedius muscle impedes the mobility of the ossiculum chain and, therefore, dampens the sound transmitted to the cochlea. [16,19,20] Although this protective mechanism is not as effective for impulse noise because the reflex is initiated after exposure to the sound, patients in our study who received an average of 2,000 pulses per treatment didn’t have any impairment of auditory function. Tuncer et al. [21] applied 3,000 shock waves in each session in their study and showed that shock wave therapy had no side effects on hearing function. A case report study of Kraus and Weinder [22] showed that a urologist who administered extracorporeal shockwave lithotripsy (ESWL) five sessions per week, an average of 3000 shocks waves noted hearing loss, particularly at high frequencies. [22] There is a debate about the effect of time of being exposed to shock waves in literature. Naguib et al. [18] investigated the effect of exposure time to the shock wave by measuring the hearing levels of the patient and staff before and after the procedure and they found that staff members experienced more hearing loss because they were exposed to noise for longer periods of time. On the contrary, Dawson et al. [23] found no evidence that single or repeated exposure to the noise produced by ESWL was associated with hearing loss. In this study, the interval between the two impulses was half a second and every session took 15 minutes, total time 45 minutes and we didn’t find permanent hearing loss in any of our patients.

The main limitation of our study was that pure tone audiometry is a subjective test and the specificity of ototoxicity detection is low. However, this study is the first in the literature reporting the temporary hearing loss at high frequency. Physicians should be aware of this complication which may occur even with two sessions of r-ESWT application. Further prospective randomized

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**Table 1: Comparison of audiometric evaluations between groups**

| Frequency | Audimetric evaluation | Side     | rESWT group (n = 47) | Control group (n = 20) | P values |
|-----------|-----------------------|----------|----------------------|------------------------|----------|
| 500 Hz    | 1st audiometry        | Left ear | 10.2 ± 4.7           | 9.5 ± 3.5              | 0.552    |
|           | 2nd audiometry        | Left ear | 10.2 ± 4.7           | 9.5 ± 3.5              | 0.552    |
|           | 2nd audiometry        | Right ear| 11 ± 5.3             | 9.5 ± 3.5              | 0.233    |
|           | 2nd audiometry        | Right ear| 10.6 ± 4.8           | 9.5 ± 3.5              | 0.349    |
| 1000 Hz   | 1st audiometry        | Left ear | 10.4 ± 4.7           | 9.5 ± 3.5              | 0.439    |
|           | 2nd audiometry        | Left ear | 10.3 ± 4.8           | 9.5 ± 3.5              | 0.498    |
|           | 2nd audiometry        | Right ear| 11 ± 5.3             | 9.5 ± 3.5              | 0.233    |
|           | 2nd audiometry        | Right ear| 10.5 ± 5.3           | 9.5 ± 3.5              | 0.433    |
| 2000 Hz   | 1st audiometry        | Left ear | 11.9 ± 6.2           | 10 ± 3.9               | 0.209    |
|           | 2nd audiometry        | Left ear | 11.8 ± 5             | 10.5 ± 3.5             | 0.298    |
|           | 2nd audiometry        | Right ear| 11.5 ± 6.1           | 10 ± 3.9               | 0.292    |
|           | 2nd audiometry        | Right ear| 11.8 ± 5.4           | 10.5 ± 3.5             | 0.329    |
| 4000 Hz   | 1st audiometry        | Left ear | 15.5 ± 6.3           | 15.5 ± 4.2             | 0.984    |
|           | 2nd audiometry        | Left ear | 15.8 ± 5.9           | 15 ± 3.9               | 0.559    |
|           | 2nd audiometry        | Right ear| 14.8 ± 6.2           | 15.5 ± 4.2             | 0.692    |
|           | 2nd audiometry        | Right ear| 15.4 ± 6             | 15 ± 3.9               | 0.774    |
| 8000 Hz   | 1st audiometry        | Left ear | 17.1 ± 5.6           | 15 ± 3.9               | 0.133    |
|           | 2nd audiometry        | Left ear | 17.6 ± 6.6           | 17.5 ± 4.7             | 0.923    |
|           | 2nd audiometry        | Right ear| 17.7 ± 6.4           | 15 ± 3.9               | 0.079    |
|           | 2nd audiometry        | Right ear| 18.1 ± 6.2           | 17.5 ± 4.7             | 0.661    |

rESWT = radial extracorporal shock wave therapy
well-controlled studies are needed to reach a higher level of evidence about the evaluation of the hazardous effect of ESWT on hearing functions.

CONCLUSION

According to the results acquired from this study, we can consider that r-ESWT treatment in patients with chronic PF has no markedly detrimental effect on the hearing function.

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Conflict of Interest Statement

All authors declare that there is no conflict of interest.

REFERENCES

1. Ibrahim MI, Donatelli RA, Schmitz C, Hellman MA, Buxbaum F. Chronic plantar fasciitis treated with two sessions of radial extracorporeal shock wave therapy. Foot Ankle Int 2010;31:391-7. https://doi.org/10.3113/FAI.2010.0391
2. Wearing SC, Smeathers JE, Urry SR, Hennig EM, Hills AP. The pathomechanics of plantar fasciitis. Sports Med 2006;36:585-611. https://doi.org/10.2165/00007256-200636070-00004
3. Yin MC, Ye J, Yao M, Cui XL, Xia Y, Shen QX, Tong ZY, Wu XQ, Ma JM, Mo W. Is extracorporeal shock wave therapy clinical efficacy for relief of chronic, recalcitrant plantar fasciitis? A systematic review and meta-analysis of randomized placebo or active-treatment controlled trials. Arch Phys Med Rehabil 2014;95:1585-93. https://doi.org/10.1016/j.apmr.2014.01.033
4. Sun J, Gao F, Wang Y, Sun W, Jiang B, Li Z. Extracorporeal shock wave therapy is effective in treating chronic plantar fasciitis: A meta-analysis of RCTs. Medicine (Baltimore) 2017;96:e6621. https://doi.org/10.1097/MD.0000000000006621
5. Almekinders LC, Temple JD. Etiology, diagnosis, and treatment of tendinitis: an analysis of the literature. Med Sci Sports Exerc 1998;30:1183-90. Review.
6. Purcell RL, Schroeder IG, Keeling LE, Formby PM, Eckel TT, Shawen SB. Clinical outcomes after extracorporeal shock wave therapy for chronic plantar fasciitis in a predominantly active duty population. J Foot Ankle Surg 2018;57:854-7. https://doi.org/10.1016/j.jfas.2017.11.030
7. Hsu RW, Hsu WH, Tai CL, et al. Effect of shock-wave therapy on patellar tendinopathy in a rabbit model. J Orthop Res 2004;22:221-7. https://doi.org/10.1016/S0736-0266(03)00138-4
8. Ueberle F. Extracorporeal Shock Waves in Orthopaedics. 1. In: Siebert W, Bach M, editor. Shock wave technology, Berlin: Springer 1998. pp. 59-87.
9. Schmitz C, Császár NB, Rompe JD, Chaves H, Furia JP. Treatment of chronic plantar fasciopathy with extracorporeal shock waves (review). J Orthop Surg Res 2013;8:31. https://doi.org/10.1186/1749-799X-8-31
10. Nikolij-Dimitrova ED, Gjerakaroska-Savevska C, Koevska V, Mitrovska B, Gocevska M, Manoleva M, Kalchovska-Ivanovska B. The effectiveness of radial extracorporeal shock wave therapy for chronic Achilles tendinopathy: a case report with 18 months follow-up. Open Access Maced J Med Sci 2018;6: 523-7. https://doi.org/10.3889/oamjms.2018.134
11. Speed C. A systematic review of shockwave therapies in soft tissue conditions: focusing on the evidence. Br J Sports Med 2014;48:1538-42. https://doi.org/10.1136/bjsports-2012-091961
12. Roerink RL, Dietvorst M, van der Zwaard B, van der Worp H, Zwerver J. Complications of extracorporeal shockwave therapy in plantar fasciitis: Systematic review. Int J Surg 2017;46:133-45. https://doi.org/10.1016/j.ijsu.2017.08.587
13. Perouansky M, Pizov R. Acute myocardial infarction after extracorporeal shock-wave lithotripsy: a dilemma of management. Isr J Med Sci 1997;33:71-4.
14. Liu HM, Chao CM, Hsieh YJ, Jiang CC. Humeral head osteonecrosis after extracorporeal shock-wave treatment for rotator cuff tendinopathy. A case report. J Bone Joint Surg Am 2006;88:1353-6. https://doi.org/10.2106/JBJS.E.00868
15. Durst HB, Blatter G, Kuster MS. Osteonecrosis of the humeral head after extracorporeal shock-wave lithotripsy. J Bone Joint Surg Br 2002;84:744-6.
16. Lusk RP, Tyler RS. Hazardous sound levels produced by extracorporeal shock wave lithotripsy. J Urol 1987;137:1113-4.
17. Terlecki RP, Triest JA. A Contemporary evaluation of the auditory hazard of extracorporeal shock wave lithotripsy. Urology 2007; 70:898-9. https://doi.org/10.1016/j.urology.2007.06.1151
18. Naguib MB, Badrl-El Din M, Madian YT, Iskander NM. Identification of the auditory hazards of extracorporeal shock wave lithotripsy. J Laryngol Otol 2002;116:1-5.
19. Snooorenburg CF. Damage risk criteria for impulse noise. In: Hamernik RP, Henderson Salve R, Edited by. New Perspectives on Noise-Induced Hearing Loss. New York: Raven Press, 1982.
20. Kryter KD. Impairment to hearing from exposure to noise. J Acoust Soc Am 1973;53:1211-34.
21. Tuncer M, Erdogan BA, Yazici O, Sahin C, Altin G, Faydaci G, Eryildirim B, Sarica K. Does extracorporeal shock wave lithotripsy cause hearing impairment? Urology 2014;84:12-5. https://doi.org/10.1016/j.urology.2013.12.056
22. Kraus S, Weidner W. Prolonged exposure to extracorporeal shock wave lithotripsy and noise induced hearing damage. J Urol 2001;165:1984.
23. Dawson C, Chilcott-Jones A, Corry DA, Cohen NP, Williams HO, Nockler IB, Whitfield HN. Does lithotripsy cause hearing loss? Br J Urol 1994;73:129-35.