

Effect of Different Musical Types on Patient's Relaxation, Anxiety and Pain Perception during Shock Wave Lithotripsy: A Randomized Controlled Study

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Purpose: The aim of this study was to investigate the effects of listening to different music types during extracorporeal shock wave lithotripsy (SWL) on the patients' pain control, anxiety level, and satisfaction.

Materials and Methods: This study was a prospective single-blinded, parallel-group randomized clinical trial with balanced randomization [1:1]. A total of 150 patients who underwent first-session SWL were included in the study. The patients were randomly divided into five groups (30 participants in each group) as follows: headphones were not put on and no music was played in Group 1 (control group); headphones were put on but no music was played in Group 2; Turkish art music was listened to with headphones in Group 3; Western classical music was listened to with headphones in Group 4; the type of music the patient liked was listened to with headphones in Group 5. Demographic data related to patients and procedure, State-Trait Anxiety Inventory-State Anxiety (STAI-SA), Visual Analog Scale (VAS) scores, willingness to repeat procedure (0: never 4: happily), and patient satisfaction rates (0: poor 4: excellent) were recorded immediately after the procedure.

Results: There was a statistically significant difference between groups in terms of median VAS scores (7, 6, 4.5, 5, and 4, respectively, $P < .001$), whereas the VAS scores in Groups 3, 4, and 5 were significantly lower than those in Group 1 and 2 ($P < .001$). The median STAI-SA scores between the groups were significantly different (45, 45, 42, 45, and 40, respectively, $P < .001$), while the anxiety levels in Groups 3, 4, and 5 were significantly lower than those in Group 1 ($P = .008$, $P = .018$, and $P < .001$, respectively). Moreover, there were statistically significant differences between the groups in terms of willingness to repeat the procedure and patient satisfaction rates ($P < .001$).

Conclusion: Music therapy during SWL reduced the patients' pain and anxiety scores, moreover listening to the patient's preferred music type provided greater satisfaction. Listening to the patient's preferred music type could be standardized and routinely used during SWL.

Keywords: anxiety; music; nephrolithiasis; pain; shockwave lithotripsy

INTRODUCTION

Extracorporeal shock wave lithotripsy (SWL) has been used extensively in the treatment of urinary tract stones since the 1980s due to its low morbidity and high efficacy.⁽¹⁾ The most common complaints of the patients undergoing SWL are pain and anxiety. Despite pain reduction with new generation SWL devices, severe pain was still reported in 30% of all patients when treated without undergoing analgesia.⁽²⁾

It is important that patients are kept at the lowest levels of pain and anxiety to ensure their compliance with the SWL procedure. Therefore, many complementary therapies have been reported.⁽³⁾ One of these therapies is music which is a non-pharmacological and non-chemical method and used in addition to traditional care and medical treatment for postoperative pain treatment.⁽⁴⁾ Moreover, it is a source of pleasure for many people and has been used throughout history to alleviate sickness and pain.⁽⁵⁾

In the literature, there are several studies related to listening to music during SWL.⁽⁶⁻¹²⁾ These studies have shown that music has positive effects on pain and anxiety during SWL. Individuals' musical preferences are influenced by age, gender, culture, mood, and previous

musical experience. Different types of music have been shown to affect heart rate, blood pressure, and the frequency and depth of breathing.⁽¹³⁾ It is important to consider the musical preferences of individuals, as these preferences contribute to the therapeutic effect.⁽¹⁴⁾

In this study, patients with upper urinary tract stones undergoing SWL without any medication were assessed for their pain and anxiety scores after listening to different music types during the procedure. To our knowledge, this is the first study in the literature investigating the effect of different music types on the pain and anxiety scores of patients during SWL.

MATERIALS AND METHODS

Study population

This prospective randomized study was completed with the permission of the presidency Clinical Research Ethics Committee in Adiyaman University (2016/5-5) between July 2016 and November 2017. Informed consent was obtained, and the patients participated voluntarily in the study.

Inclusion criteria were presence of a radiopaque stone 10-20 mm in diameter localized in the renal pelvis or ureteropelvic (UP) junction, not having a ureteral stent,

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Table 1. Demographic and clinical characteristics

	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	Group 4 (n=30)	Group 5 (n=30)	p-value
Age (years)	38.4 ± 13.9	39.2 ± 12.1	37.7 ± 10.9	36.3 ± 10.6	36.4 ± 10.2	.883†
Gender					.081‡	
Male	16 (53.3%)	17 (56.7%)	25 (83.3%)	21 (70.0%)	22 (73.3%)	
Female	14 (46.7%)	13 (43.3%)	5 (16.7%)	9 (30.0%)	8 (26.7%)	
Body mass index (kg/m ²)	26.3 ± 3.3	26.1 ± 2.3	25.6 ± 2.7	26.0 ± 2.3	26.4 ± 1.4	.748†
Stone location			.963‡			
Pelvis	21 (70.0%)	19 (63.3%)	20 (66.7%)	21 (70.0%)	19 (63.3%)	
Ureteropelvic (up) junction	9 (30.0%)	11 (36.7%)	10 (33.3%)	9 (30.0%)	11 (36.7%)	
Stone laterality			.983‡			
Right	11 (36.7%)	12 (40.0%)	11 (36.7%)	12 (40.0%)	10 (33.3%)	
Left	19 (63.3%)	18 (60.0%)	19 (63.3%)	18 (60.0%)	20 (66.7%)	
Stone size (mm)	11.5 (10.0-13.0)	12.0 (11.0-14.0) ^{a,b}	10.0 (10.0-12.0) ^a	10.0 (10.0-12.0) ^b	12.0 (10.0-12.25)	.007¶
SWL duration (min)	30.0 (25.0-30.0)	28.5 (25.0-30.0)	30.0 (28.75-30.0)	25.0 (25.0-30.0)	27.5 (25.0-30.0)	.185¶
SWL total energy (joule)	80.0 (74.75-92.5)	85.0 (65.0-93.25)	92.0 (82.0-101.25)	90.0 (64.25-103.5)	94.0 (79.75-96.25)	.159¶
Total number of shockwaves	2700 (2500-2900)	2725 (2500-2900)	2851.5 (2685.7-3000.0)	2842.5 (2437.2-2958.7)	2800 (2500-2925)	.473¶

† One-Way ANOVA, data shown as mean ± SD, ‡ Pearson's Chi-square test, data presented as number of cases and percentages, ¶ Kruskal–Wallis test, descriptive statistics given as median (Q1 – Q3), a: Group 2 vs Group 3 (*P* < .001), b: Group 2 vs Group 4 (*P* = .002).

age over 18 years, and absence of renal colic before the procedure. Exclusion criteria were previous SWL history, presence of ureteral stent, hearing deficit, uncontrolled hypertension and antidepressant drug usage. Patients' enrollment algorithm has been illustrated in **Figure 1**.

Before SWL, the size and localization of the kidney stones were evaluated by plain films (KUB radiography), ultrasonography and computed tomography. Study design

This study was a prospective single-blinded, parallel-group randomized clinical trial with balanced randomization [1:1]. Sample size was calculated considering a .30 effect size with One-Way ANOVA expected difference among study groups in the primary outcome of interest. Considering type I error of .05 and type II error of .20, at least 28 cases were needed for each

Therefore 30 cases were decided to be enrolled in each arm of the study. Sample size estimation was performed using G*Power 3.0.10. (Franz Faul, Universität Kiel, Kiel, Germany) statistical package.

Patients were randomly assigned to one of the five study groups (30 patients in each group). Randomization was carried out using computerized random numbers. The allocated treatment for each patient was recorded in concealed envelopes. All study personnel were blinded to treatment assignment. The procedure of simple randomization was followed therefore no restriction we had such as stratifying or blocking. After achieving eligibility criteria and patient's agreement on participation, the concealed envelopes were opened by one of the staff who was working at the clinic and unaware of the study.

The study was completed by a senior urologist and a staff lithotripsy technician. The patients were randomly divided into five groups as follows: headphones were not put on and no music was played in Group 1 (control group); headphones were put on but no music was played in Group 2; Turkish art music was listened to with headphones in Group 3; Western classical music was listened to with headphones in Group 4; the type of music the patient liked was listened to with headphones in Group 5.

The headphones were Sony MDR ZX100. Medication was not administered to any patient in any group before or during the procedure. A total of 150 patients (30 in each group) who underwent first-session SWL were included in the study. The demographic data related to the patient and procedure, pain and anxiety scores, willingness to repeat procedure (0: never 4: happily), and patient satisfaction rates (0: poor 4: excellent) were recorded. Hemodynamic parameters were also recorded before and after the SWL procedure.

Outcome assessment

Anxiety assessment was performed by using the State-Trait Anxiety Inventory-State Anxiety Scores (STAI-SA) form. The anxiety score was calculated as follows: Questions 1, 2, 5, 8, 10, 11, 15, 16, 19, and 20 of the 20 questions on the form had opposite statement. The total scores obtained from the reverse statements were subtracted from those of the remaining direct statements. 50 points were added in order to calcu-

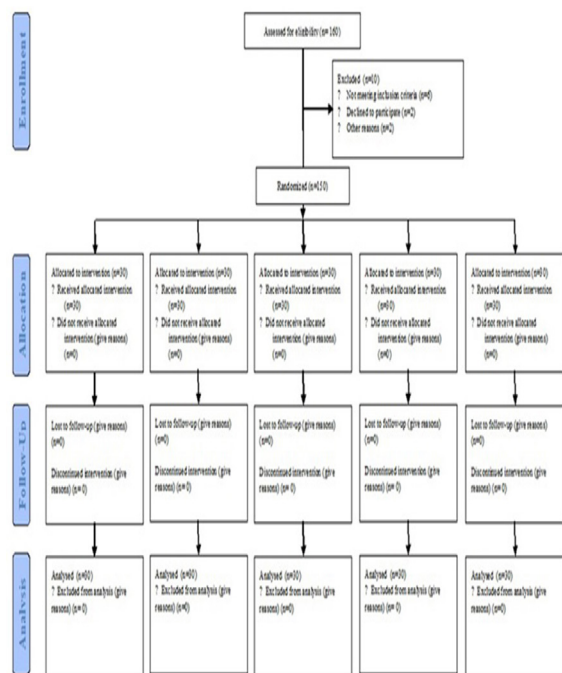


Figure 1. Patients' enrollment algorithm.

Table 2. Clinical outcomes

Group 5 (n=30)	p-value	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	Group 4 (n=30)	
Patient satisfaction rate 0=poor to 4=excellent	1 (1 - 2) ^{b,c}	2 (1 - 2) ^{d,e,f}	2 (1 - 3) ^{a,d,g}	2 (1 - 3) ^{b,e,h}	3 (2.75 - 3) ^{c,f,g,h}	<.001†
Willingness to repeat procedure 0=never to 4 happily	1 (1 - 2) ^{b,c}	2 (1 - 2) ^{d,e,f}	2.5 (1 - 3) ^{a,d,g}	2 (2 - 3) ^{b,e,h}	3 (3 - 3.25) ^{c,f,g,h}	<.001†
Visual analog scale (VAS) 0=no pain to 10=unbearable pain	7 (6 - 7.25) ^{a,b,c}	6 (5 - 7.25) ^{d,e,f}	4.5 (4 - 6) ^{a,d}	5 (3 - 5.25) ^{b,e}	4 (3 - 5) ^{c,f}	<.001†
STAI-State Anxiety Score min=20 to max=80	45 (42 - 54) ^{a,b,c}	45 (40 - 48.25) ^f	42 (37.75 - 45) ^a	45 (32.75 - 45.5) ^b	40 (31.75 - 45) ^{c,f}	<.001†
Stone-free rate	15 (50.0%)	16 (53.3%)	16 (53.3%)	16 (53.3%)	17 (56.7%)	.992‡

† Kruskal–Wallis test, descriptive statistics given as median (Q1 – Q3), ‡ Pearson's Chi-square test, data presented as number of cases and percentages, a: Group 1 vs Group 3 ($P < .01$), b: Group 1 vs Group 4 ($P < .05$), c: Group 1 vs Group 5 ($P < .001$), d: Group 2 vs Group 3 ($P < .05$), e: Group 2 vs Group 4 ($P < .05$), f: Group 2 vs Group 5 ($P < .001$), g: Group 3 vs Group 5 ($P < .05$), h: Group 4 vs Group 5 ($P < .01$).

late the anxiety score (constant value). This score was a minimum value of 20 and a maximum value of 80. Higher scores indicate greater anxiety. Visual analog scale (VAS pain: 0-10) was used to evaluate pain. (16) The zero value was defined as "no pain", while the value 10 was defined as "unbearable pain". The patient was asked to indicate the degree of pain. In all patients, VAS and STAI scores were recorded immediately after the SWL procedure.

Treatment success defined as the absence of stone fragments or the presence of clinically insignificant fragments smaller than 4 mm in diameter and being stone-free was assessed by KUB radiography and ultrasonography on the 15th day of SWL. All recorded parameters were compared between the five groups.

SWL technique

SWL was performed using a ModularisVario lithotripter (ModularisVario; Siemens, AG Healthcare, Munich, Germany). ModularisVario is a mobile, fully integrated, next-generation lithotripter with an electromagnetic shock wave source and fully integrated fluoroscopic guided device. The energy levels start with E0.1 and progressively increase to a maximum of E8.0 in 38 steps. The average energy level, the maximum energy level, and the total energy delivered were automatically displayed at the end of each session.

The patients were treated in the supine position. Fluoroscopy was used to localize the stone. Lubricating gel was applied to the area where SWL was to be administered in all patients. For the Kidney: Number of shock waves = 3000-3500, Energy level (max) = 3-4, Starting: 100 shock waves with Level 0.1-1 Afterwards, maximal level: Pelvis: 4.0 with Frequency SW/min = 60. The number of shock waves, their intensity, and their energy were recorded for patients in all groups.

Statistical Analysis

Normality of continuous variables was determined using Kolmogorov–Smirnov test. Levene test was used for the evaluation of homogeneity of variances. Descriptive statistics for continuous variables were shown as mean±SD or median (Q1-Q3), as appropriate. Number of cases and percentages were used for categorical data. The mean differences among groups for normally distributed data were compared by One-Way ANOVA, while Kruskal–Wallis test was applied for the comparisons of variables that were not normally distributed or the variance homogeneity assumption was not met. When the p-values from Kruskal–Wallis test statistics were statistically significant, Conover's multiple com-

parison test was used to determine which group(s) differed from the others.

Categorical data were analyzed using Pearson's Chi-square test. Data analysis was performed by using IBM SPSS Statistics version 17.0 software (IBM Corporation, Armonk, NY, USA). A p-value less than 0.05 was considered as statistically significant.

RESULTS

There were no statistically significant differences between the groups in terms of age, mean body mass index, stone localization ($P = .883$, $P = .748$, $P = .963$, respectively). There were no statistically significant differences between groups in terms of SWL duration, total SWL energy, or total number of shock waves among the groups ($P > .05$ for all comparison). Demographic and clinical characteristics and SWL variables for the study groups are presented in **Table 1**. There was a statistically significant difference between the groups in terms of median VAS scores (7, 6, 4.5, 5, and 4, respectively), $P < .001$, while the VAS scores in Groups 3, 4, and 5 were significantly lower than those in Groups 1 and 2 ($P < .001$). There was not a statistically significant difference between Groups 1 and 2, Groups 3 and 4, Groups 3 and 5, or Groups 4 and 5 in terms of VAS scores ($P = .386$, $P = .956$, $P = .112$ and $P = .100$, respectively) (**Table 2**). There was a statistically significant difference between groups in terms of median STAI scores (45, 45, 42, 45, and 40, respectively), $P < .001$, while the anxiety levels in Groups 3, 4 and 5 were statistically lower than that in Group 1 ($P = .008$, $P = .018$ and $P < .001$, respectively). In addition, the anxiety level in Group 5 was statistically lower than Group 2 ($P < .001$). There was not a statistically significant difference between Groups 1 and 2, Groups 2 and 3, Groups 2 and 4, Groups 3 and 4, Groups 3 and 5, or Groups 4 and 5 in terms of anxiety levels ($P = .442$, $P = .059$, $P = .107$, $P = .780$, $P = .145$ and $P = .083$, respectively) (**Table 2**). In addition, there were statistically significant differences between the groups in terms of willingness to repeat the procedure and patient satisfaction rates ($P < .001$), whereas these parameters were significantly higher in Groups 3, 4, and 5 than in Group 1 ($P < .001$). In addition, the willingness to repeat the procedure and patient satisfaction rates in Group 5 were significantly higher than those in Groups 3 and 4 ($P = .005$ and $P < .001$), ($P = .007$ and $P = .003$), respectively) (**Table 2**). The stone-free rates were statistically similar between the groups ($P = .992$) (**Table 2**).

DISCUSSION

There are many interventions that can be performed in outpatients without anesthesia. One of them is SWL therapy, which has revolutionized the treatment of urinary tract calculi because of its cost effectiveness and low morbidity. For these reasons, it remains one of the first choice in the treatment of renal stones up to 20 mm.⁽¹⁷⁾

Patients should be immobile for a while in certain procedures like SWL, Magnetic Resonance Imaging (MRI), and colonoscopy. Disturbing noise and beats from the SWL device can cause the patient to feel pain and anxiety, and to move.⁽⁶⁾ Both pain and anxiety can reduce the patient's tolerance, which can lead to difficulty in targeting the stone, preventing maximal energy delivery. Therefore, fragmentation of the stone may fail during the procedure, and patients may refuse additional SWL sessions due to pain and anxiety.⁽⁷⁾

The success of SWL is closely related to factors such as the patient's compliance with the procedure, the experience of the person using the device, the localization of the stone, urinary system anatomy, and composition of the stone.⁽¹⁸⁾ The patient's pain and anxiety should be kept to a minimal level to provide compliance with the SWL procedure and achieve the highest possible success rates.

Local anesthetic drugs such as EMLA (2.5% lidocaine and 2.5% prilocaine), NSAIDs (diclofenac, ketorolac, and piroxicam), opioids (morphine, fentanyl, and pethidine), and anxiolytics (midazolam) can be used before the SWL procedure for these purposes. According to the Urolithiasis Guideline prepared by the European Urology Association, the recommendation level for pain control is C and the level of evidence is 4.⁽¹⁹⁾ However, side effects such as respiratory depression, hypotension, tachycardia, bradycardia, transient cognitive dysfunction, nausea-vomiting, and allergic reactions may occur due to these drugs.⁽¹³⁾ Therefore, complementary treatments are becoming increasingly popular in order to reduce pain and anxiety during SWL. These treatments include music, transcutaneous electrical nerve stimulation, acupuncture, and auricular acupressure.

Music therapy has been shown to reduce pain by activating the cingulofrontal cortex.^(20,21) It is also suggested that music has anxiolytic effects and should be used as therapy in stressful interventions. In the literature, there are a few studies about the approach of listening to music during SWL.

Koch et al. reported that listening to music during SWL significantly reduced the requirement for alfentanil.⁽²²⁾ Moreover, Cepeda et al. argued that music did not reduce the requirement for alfentanil when using patient-controlled analgesia during SWL. Limitations of this study include the limited number of patients and the use of morphine and ketorolac in addition to pre-procedural alfentanil.⁽²³⁾

In another study using music or midazolam during SWL, music was found to be at least as effective as midazolam and had similar STAI-SA and VAS scores.⁽⁹⁾ In addition, the common feature of these three studies was the administration of analgesics and anxiolytics to the control group. Patients in our study did not any receive medication. Therefore, our study differs from these studies.

In these studies, patients completed SWL sessions by using NSAIDs or drugs such as alfentanil and midazolam before the procedure; as a result anxiety scores were found to be lower. Since we did not use any analgesics or anxiolytics in our study, our pain and anxiety scores may be slightly higher than those reported in the literature.

Akbaş et al. reported in their prospective study that there were lower anxiety and pain scores during SWL sessions in which the patient listened to music. In addition, patients were asked to complete more SWL therapy while listening to music, and patients were more satisfied.⁽⁶⁾ One of the limitations of this study was that the stone-free rates were not compared between the first and second sessions, while the other limitation was that there was not a third group using only noise-canceling headphones.

In a prospective randomized trial by Karalar et al., it was reported that music therapy during SWL reduced pain and anxiety, and that music therapy with active noise-canceling headphones (NCHs) was more effective for pain and anxiety reduction.⁽⁷⁾

In the present study, we used active non-noise canceling headphones. Patients receiving music therapy (Groups 3, 4, 5) were found to have lower pain scores than those who did not (Groups 1, 2). When we compared Groups 3, 4, and 5 in terms of music types, there was not a statistically significant difference in terms of VAS scores.

In addition, when we compared Groups 1 and 2, there was not a statistically significant difference in terms of VAS scores. The anxiety scores of the patients who received music therapy in our study (Groups 3, 4, 5) were lower than those who did not receive music therapy (Groups 1, 2).

We found that anxiety scores were lower in Group 5 than those in Groups 1 and 2. In addition, when the groups that listened to music were evaluated among themselves in this study, we also found that the approach in which the patient listened to his/her favorite music during SWL had more positive results than the patients listening to other types of music in terms of the willingness to repeat the procedure and satisfaction rates.

One limitation in this study was the absence of analgesic groups.

CONCLUSIONS

Our results suggest that music therapy during SWL reduces the level of pain and anxiety. When we compared the groups in terms of music types, it was determined that willingness to repeat the procedure and patient satisfaction rates were better when the patients listened to the music types they liked. Music therapy during SWL is a noninvasive, inexpensive, simple, and non-pharmacological method. Allowing the patients to listen to the music they like using headphones allows SWL to be better tolerated. Thus, patients are protected from unwanted side effects of drugs. Furthermore during the SWL procedures, listening to the patient's preferred music type could become standardised.

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CONFLICT ON INTEREST

The authors report no conflict of interest.

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