

ORIGINAL ARTICLE

Music Harmonizes Extracorporeal Shockwave Lithotripsy Experience by Reducing Anxiety and Pain – A Randomized Control Trial

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ABSTRACT

Aim: To find out the role of listening to music during extracorporeal shockwave lithotripsy to reduce pain and anxiety during the procedure.

Design: A randomised controlled trial.

Place and Duration of Study: Lithotripsy department at The Kidney Centre Postgraduate Training Institute, Karachi, from January to July 2021.

Methodology: One hundred ten patients were randomly assigned into two groups of fifty-five patients each; Group-M (first session of ESWL with music and second session without music) and Group-X (first session of ESWL without music and second session with music). Patients with the music group were provided headphones with soothing music throughout their procedure. Routine analgesic (intravenous nalbuphine 0.1mg/kg) was administered to patients as per treatment guidelines. Each patient received a total of 4000 shockwaves with energy levels varying from 11.45 to 13.1 kilovolts and frequency ranging between 2 to 3 Hertz. Patients filled out two questionnaires, Visual Analogue Scale (VAS) and State-Trait Anxiety Inventory (STAI). Baseline data for all patients was calculated and compared between the two groups. Data were analysed using IBM SPSS ver. 20.

Results: Ninety-eight were males while twelve were females. Gender distribution between groups does not differ significantly ($p = 0.862$). The mean age in Group-M was 36.22 ± 9.78 while in Group-X was 36.13 ± 9.89 without any significant difference between groups ($p = 0.422$). BMI of Group-M patients (25.34 ± 4.64) was not significantly different from Group-X (25.41 ± 4.80) ($p = 0.327$).

Median stone size of Group-M was 1.0 ; 0.30 while that of Group-X was 1.1; 0.40 ($p=0.997$). Stone laterality was not significantly different among the two groups ($p = 0.961$). The distribution of stone location among both groups was not significantly different from each other ($p=0.949$). In Group-M, first session patients (with music) had significantly lower median VAS score (2; 1) as compared to second session patients without music (4; 2), ($p < 0.001$). In Group-X, first session patients (without music) had significantly higher median VAS score (6; 1) as compared to second session patients with music (4; 2), ($p < 0.001$).

Conclusion: Music therapy during ESWL sessions reduces both pain and anxiety and also improves overall compliance of stone disease patients by eradicating the fear of the procedure.

Keywords: ESWL, Lithotripsy, Visual Analogue Scale, Renal calculi.

INTRODUCTION

Extracorporeal shockwave lithotripsy (ESWL) has been the most widely used option for the outpatient management of the renal stone disease for many years now¹. This procedure has been used safely and effectively since the 1980s². The hallmark of this treatment modality is its noninvasiveness, low morbidity and high efficacy³. The factors contributing to the success of this technique are the experience of the medical staff conducting the procedure, localization of stone, urinary tract anatomy, stone composition and patient compliance⁴. The first lithotripter was introduced by Chaussy et al. in 1983; since then, new generation ESWL machines have reduced pain to many degrees. However, 30% of all patients still report severe pain during the ESWL procedure without analgesia⁵. Both pain and anxiety cause reduced tolerance and erratic respiration in patients during ESWL, leading to difficulty targeting the stone and preventing maximal energy delivery⁶.

To mitigate the effects of pain analgesic drugs are used before and during the ESWL procedure, which include NSAIDs (diclofenac, ketorolac and piroxicam), opioids (nalbuphine, morphine, fentanyl and pethidine), anxiolytics (midazolam), and local anaesthetic agents like lidocaine and prilocaine⁷. These drugs increase the overall procedural costs, lengthen the treatment process, and have different adverse effects⁸.

Therefore, the use of music to promote relaxation and alleviate perceived pain has been considered beneficial for a long time⁹⁻¹¹. Listening to music has been practised in the operating room due to its highly favourable tranquillizing effect since 1914¹². Shock wave sounds generated during ESWL are disturbing to patients, and a music piece listened to by way of a headset seems to be a reasonable alternative to it¹³. The published literature

proves the notion that music has a positive influence in reducing pain and anxiety during ESWL¹⁴⁻¹⁸.

However, the music is cultural and this study aims to strengthen the evidence further in this perspective so that institutional practices and future guidelines might be shaped and innovated accordingly.

METHODOLOGY

After getting ethical review board approval and taking informed consent, patients meeting the inclusion criteria that was defined as patients from the age 16 years to 65 years age, including all genders came for the first session of ESWL having stone size less than one centimeter on ultrasound or X-ray were randomly assigned using a simple randomization method²⁶ to either Group-M (first session of ESWL with music and second session without music) or Group-X (first session of ESWL without music and second session with music). The sample size was estimated using a comparison of the mean. Nonprobability consecutive sampling was used as a sampling technique. These sampling methods and sampling estimations followed previous published study¹⁶ that yield a sample size of one hundred ten, among which fifty-five patients have received ESWL with music initially, and the remaining fifty-five have received ESWL without music in their first session. Patients in ESWL with a music group were provided headphones with a soothing piece of music throughout their procedure. Routine institutional analgesic (intravenous nalbuphine 0.1mg/kg) was administered to patients of both groups during the procedure. A total of 4000 shockwaves with energy levels varying from 70 to 80 (11.45 to 13.1 kilovolts) and frequencies ranging between 2 to 3 Hertz were delivered via Storz Modulith® SLK lithotripter to patients in both groups depending upon the stone size and hardness.

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All patients filled out two questionnaires at the end of the procedure; Visual Analogue Scale (VAS) and State-Trait Anxiety Inventory (STAI) form Y1. The anxiety scores were calculated as given: questions 1, 2, 5, 8, 10, 11, 15, 16, 19, and 20 were REVERSE statements, while the remaining questions were DIRECT statements. All the points obtained from the reverse statements were subtracted from the total points of the remaining direct statements, followed by, the addition of the figure of 50 (fixed value) to this resultant number to yield a minimum of 20 and a maximum of 80. Scores show the anxiety levels, higher scores mean significantly higher anxiety. The score methods are already published and validated in a previously published similar study¹⁷.

Data analysis: Descriptive analyses of variables were presented in terms of frequencies and percentages. Mean and standard deviation was computed for normal continuous variables (like Age, BMI, Number and frequency of shockwaves). At the same time, median with interquartile range (IQR) was taken for skewed continuous variables (like Stone size, Shockwave power, VAS score and STAI score). The Shapiro-Wilk test was applied to check the normality of data using $p = 0.05$ as a significant difference value. A t-test was applied for normally distributed continuous variables to observe the difference between the two groups, while the Kruskal-Wallis test was used for continuous asymmetric variables. To detect the association between two categorical variables (like Gender, Stone side and Stone location), the Chi-square test was executed with a level of significance of ≤ 0.05 (p -value). All data analysis was performed by IBM SPSS version 20.

Table 1: Baseline demographics and clinical characteristics

	Group-M (Lithotripsy with Music First)	Group-X (Lithotripsy without Music First)	P-Value (p)
Male (n number)	48	50	$p = 0.862$
Female (n number)	07	05	
Mean	36.22	36.13	$p = 0.422$
Standard Deviation	+9.78	+9.89	
Mean	25.34	25.41	$p = 0.327$
Standard Deviation	+4.64	+4.80	
Median	1.0	1.1	$p = 0.997$
Interquartile Range	0.30	0.40	
Right	25	23	$p = 0.961$
Left	30	32	
Upper Calyx	16	12	$P = 0.949$
Middle Calyx	28	24	
Lower Calyx	40	36	
Pelvis	26	38	

Table 2: Procedural parameters for Group-M (Lithotripsy With Music First)

	First Session (Without Music)	Second Session (With Music)	-Value (p)
Mean	4000	4000	$p = 1.00$
Standard Deviation	+0	+0	
Median	11.45	11.45	$p = 1.00$
Interquartile Range	1.65	1.65	
Mean	3	3	$p = 1.00$
Standard Deviation	+0	+0	
Median	2	4	$p < 0.001$
Interquartile Range	1	2	
Median	27	70	$p < 0.001$
Interquartile Range	2	5	

Table 3: Procedural parameters for group-x (lithotripsy without music first)

	First Session (Without Music)	Second Session (With Music)	-Value (p)
Mean	4000	4000	$p = 1.00$
Standard Deviation	+0	+0	
Median	13.1	13.1	$p = 1.00$
Interquartile Range	1.65	1.65	
Mean	3	3	$p = 1.00$
Standard Deviation	+0	+0	
Median	27	69	$p < 0.001$
Interquartile Range	2	5	

RESULTS

Of all one hundred ten patients, ninety-eight were males while twelve were females, and gender distribution between the two groups does not differ significantly ($p = 0.862$). The mean age of patients in Group-M was 36.22 ± 9.78 , while Group-X was 36.13 ± 9.89 , without any significant difference between the two groups ($p = 0.422$). The BMI of Group-M patients (25.34 ± 4.64) was not significantly different from that of Group-X (25.41 ± 4.80) ($p = 0.327$).

The median stone size of Group-M patients was 1.0 ± 0.30 while that of Group-X was 1.1 ± 0.40 ($p = 0.997$). Stone laterality was not significantly different among the two groups ($p = 0.961$), with Group-M having twenty-five patients with right-sided and thirty patients having left-sided stones. In contrast, Group-X had twenty-three patients with right-sided and thirty-two patients having left sided stones. Sixteen and twelve patients had upper calyceal stones in Group-M and X, respectively. Twenty-eight and twenty-four patients had middle calyceal stones in Group-M and X, respectively. Forty and thirty-six patients had lower calyceal stones in Group-M and X, respectively. Twenty-six and thirty-eight patients had renal pelvic stones in Group-M and X, respectively. The distribution of stone location among both groups was not significant ($p = 0.949$).

Each patients received 4000 shockwaves in every lithotripsy session with a frequency of three Hertz. Group-M patients received the same shockwaves energy in kilovolts (11.45 ± 1.65) each session (with and without music). Group-X patients also received the same shockwaves energy in kilovolts (13.1 ± 1.65) each session (with and without music). Shockwave energy delivered was not significantly different between the two groups ($p = 0.571$).

In Group-M, first session patients (with music) had a lower median VAS score (2; 1) while the second session patients (without music) had a higher median VAS score (4; 2), demonstrating a significant difference between the two sessions ($p < 0.001$).

In Group-X, first session patients (without music) had a higher median VAS score (6; 1) while the second session patients (with music) had a lower median VAS score (4; 2), demonstrating a significant difference between the two sessions ($p < 0.001$).

DISCUSSION

Anxiety is one of the most common emotions, especially when encountering anything unknown, like undergoing any surgical procedure. To mitigate the effects of anxiety different drugs were introduced and different alternative manoeuvres have also been used. However, music has been one of them and is considered an important tool¹⁹.

Erdal Yilmaz *et al.*, in 2003, emphasised that music has a sedative and anxiolytic effect and found STAI-TA scoring to be substantially reduced in a group with music as compared to a group with no music. Due to this, the ESWL procedure became possible with little distress & anxiety and also resulted in smooth post-procedure recovery and reduced analgesics needed later²⁰.

A meta-analysis was done at the Department of Urology, West China Hospital, Chengdu, China, by Zhenghao Wang in 2020, comprising 5 RCTs published between 2016 and 2020 with a total sample size of 580. This meta-analysis was based on a pain and anxiety comparison among patients undergoing ESWL. The mean difference of pain scores between the music and control group in the 5 RCTs was 0.90, 0.50, 0.60, 2.00 & 2.00 (all showing significant reduction in pain with music). Similarly mean difference of anxiety scores between the music and control group in these RCTs was 3.30, 4.20, 4.20, 2.70 & 3.31 (again showing reduced anxiety with the use of music)²¹.

Mustafa Karalar *et al.* found in a study from 2016 that Noise-Cancelling Headphones (NCH) seem to cancel the distracting sounds of ESWL machines and shockwave sounds after coupling. Thus inclusion of music along with this new technique in the

procedure has proved to be very beneficial in reducing pain, stress and anxiety. VAS scores were distinctly different across the three groups (Group 1: Controls, Group 2: ESWL with NCH, Group 3: ESWL without NCH) of his study (5.1, 3.6 and 4.5, respectively, $p < 0.001$), with Group 1 having the maximum VAS score, while Group 2 having the least²².

Similar results were published by *Alpaslan Akbas et al.* in 2015, where data was collected for 400 patients from different hospitals in Turkey. The results compiled were in favour of the benefits of using music along with the ESWL procedure. In their study, EMLA cream was used before the procedure, and music in one group and without music in the other. According to the results, their patients preferred music during the procedures being performed, with anxiety scores falling from 48.1 to 40.2 ($p < 0.001$) and VAS score regressing from 6.3 to 2.6 among patient groups without music and those with music,²³.

Successful use of music is not just limited to ESWL procedures; in fact, researchers have found that music application is feasible in many medical and surgical procedures. Nowadays, different medical procedures are being conducted using music, most prominent is Flexible Cystoscopy which is a standard procedure in the surveillance of bladder cancer. A recent study from 2021 by *Gauba A et al.*, conducted in 3 different continents comprising countries like the USA, China, and Italy, established that music minimises the pain and anxiety in most patients undergoing cystoscopy²⁴.

ESRD (end-stage renal disease) is one of the most common morbidities of the modern era. Such patients need renal transplantation as the best possible treatment for lifelong disease-free survival. However, the most challenging part of the treatment is finding a donor. Such patients are on hemodialysis until renal transplantation, for which an (AVF) Arterio-venous fistula is created surgically, through which many dialysis sessions can be done until the transplantation is successful. *Sanem Guler Cimen et al.* demonstrated in a recent study from 2021 that AVF surgery which is generally performed under Local Anesthesia, can be augmented with the use of music, thereby substantially reducing pain and anxiety during the procedure, which was evident by normal pulse and blood pressure during surgery, making music a successful and essential adjunct to this procedure²⁵.

CONCLUSION

Attention diversion during the uneasy and painful procedure of lithotripsy can be eased out with the help of simultaneous music therapy during the session, which reduces both pain and anxiety and improves overall compliance of stone disease patients by eradicating the fear of the procedure.

Conflict of interest: Authors declare no conflict of interest.

Funding: The study has not received any funding.

Patient consent: All patients were informed about the procedure, and protocols of the trial and informed consent were taken from all patients after explaining the procedure, its adverse effects, outcomes and alternative procedures. The consent form was available in English and Urdu (native language).

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