

The Effects of Listening to Music on Anxiety, Pain, and Satisfaction during Urodynamic Study: A Randomized Controlled Trial

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Keywords

Music therapy · State-trait anxiety inventory · Satisfaction · Urodynamic study · Visual Analog Scale

Abstract

Introduction: To assess the influence of music therapy on perceived anxiety and pain during outpatient urodynamic study (UDS) in a prospective, randomized fashion. **Methods:** Between January and December 2018, a total of 70 patients were randomized to either have music therapy (study) or not have (control) in a 1:1 ratio. To the study group, Sufi music was delivered at low tempo. All participants performed the State-Trait Anxiety Inventory evaluation after the procedure and assessed their degree of pain, satisfaction, and willingness to undergo an additional or repeat procedure using the Visual Analog Scale. **Results:** Patient demographic and baseline characteristics were found to be similar between the 2 groups. Though music did not significantly alleviate pain (4.6 ± 1.2 vs. 4.4 ± 1.7 ; $p = 0.76$) and anxiety (47.7 ± 7.75 vs. 46.4 ± 6.5 ; $p = 0.36$), it had a positive impact on the patient's willingness to repeat UDS (3.4 ± 1.4 vs. 6.1 ± 1.3 ; $p = 0.005$) and provided overall satisfaction (4.6 ± 0.61 vs. 7.2 ± 1.33 ; $p = 0.004$). **Conclusions:** Music is a practical, harmless, and inexpensive non-pharmacological option that can be adopted

during medical and surgical procedures, although according to this present study, listening to music during UDS had no effect on pain and anxiety levels.

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Introduction

Urodynamic study (UDS) often enables urologists evaluate bladder and urethra function in outpatient clinics [1]. The reliability of UDS ensures accuracy in diagnosis, but it is accompanied by procedural discomforts and pain because it involves positioning catheters in the urethra, rectum, and bladder. Such invasive procedures in patients who are awake may demonstrate pain resulting in incomplete examinations and patient noncompliance [2, 3]. To overcome this pain and anxiety during UDS, various pharmacologic options, including lidocaine gel and catheter tip lubrication for urethral catheterization have been used, along with non-pharmacological methods, such as patient education, heating pad, music, distraction, and relaxation [4–6].

Music is a cheap, safe, and effective form of complementary medicine, which mitigates pain and anxiety in various urological procedures including cystoscopy, tran-

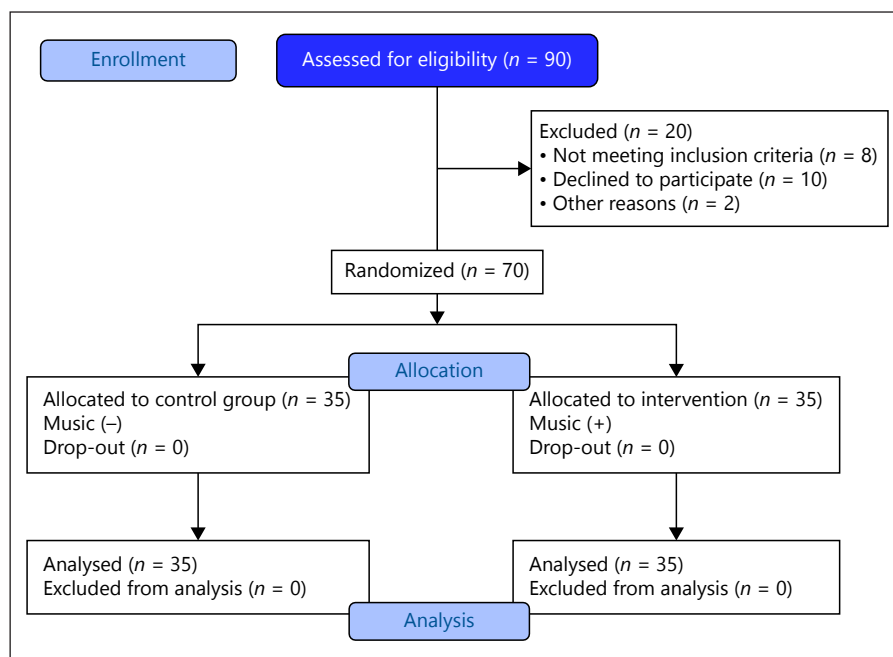


Fig. 1. Flowchart of the randomized controlled trial. Adopted from CONSORT 2010.

rectal prostate biopsy, and extracorporeal shock wave lithotripsy [7–10]. However, available literature presents limited and controversial data evaluating the influence of music on pain and anxiety from the patient's perspective during UDS. The aim of this study was, therefore, to assess the effect of music on patient satisfaction manifested as analgesic and anxiolytic effects during UDS.

Materials and Methods

Design and Setting

This was a prospective randomized controlled experimental study to determine the effect of music therapy on anxiety, pain, and stress level during UDS. The study was performed in Aksaray University Training and Research Hospital Urology polyclinic between January and October 2018.

Sample

A total of 90 patients were screened (Fig. 1) and their demographics were recorded. A sample size estimation was performed using NCSS and PASS (NCSS LLC., Kaysville, UT, USA) statistical package program, and a power analysis was based on a previous investigation on anxiety [4]. This required the enrollment of 33 patients in each group for a power of >95%, with 5% type 1 error. Exclusion criteria included paraplegia (not able to feel the catheter pain), hearing impairment, concomitant medications, including analgesic or anxiolytic drugs to suppress the symptoms of anxiety until 24 h prior to UDS, previous history of minor urological intervention such as UDS, cystoscopy and inability to understand or fulfill commands during UDS. The flowchart of the patients participating in the study is given in Figure 1.

Procedure

A total of 70 patients met the inclusion criteria. Using simple randomization, cards with letters C (control) and S (study) were placed in closed envelopes and the patients were asked to draw a random envelope. After the draw, 2 groups, that is, I (control patients) and II (study patients), were created in a 1:1 ratio. Group II patients were exposed to flute music therapy (Sufi musical recital, Huseyni mode) at low tempo (60–80 rhythm/min) with weak beats and calm rhythms about 10 min before UDS and until the procedure was completed. This music composition involved vocal and instrumental music performed on a reed flute called "Ney." A competent lecturer, specialized in music, recommended all the music compositions played during the therapy. Patients in the study group completed the State-Trait Anxiety Inventory (STAI) 15 min before the procedure and 10 min after UDS; STAI and Visual Analog Scale (VAS) were evaluated. Procedural anxiety (before and immediately after UDS) was assessed using the validated form of STAI [11, 12], which comprised 20 multiple-choice questions with 2 subscales with scores ranging from 20 to 80; higher scores indicating greater anxiety. Furthermore, patients' pain, satisfaction, and willingness to undergo a repeat session immediately after the UDS were measured using the (VAS, 0–10). Hemodynamic variables, including mean arterial pressure and heart rates, were assessed for pain and anxiety-related physiological outcomes. The trial was blinded for the data manager (a nurse who collected data) and statistician.

UDS and Measurements

International Continence Society guidelines that specified patient position, catheter placement, filling rate, and reporting sensations [13] were adopted to perform UDS in our outpatient clinic. To measure the vesical pressure a 7-Fr urinary catheter was placed followed by a 7-Fr rectal catheter to measure abdominal pressure.

Table 1. Patient demographics and baseline clinical characteristics

| | Group I (control) (n = 35) | Group II (study) (n = 35) | p value |
|---------------------------------|-------------------------------|------------------------------|---------|
| Age, years, mean ± SD | 59±12.4 | 58±10.9 | 0.67** |
| Gender, n (%) | | | |
| Male | 14 (40) | 16 (45.8) | 0.432* |
| Female | 21 (60) | 19 (54.2) | |
| Before UDS, mean ± SD | | | |
| SBP, mm Hg | 124.1±9.6 | 127±11 | 0.22** |
| DBP, mm Hg | 79.6±8 | 81.1±9 | 0.34** |
| Heart rate, bpm | 71.2±6.1 | 70.6±5.3 | 0.41** |
| Urinary incontinence (mixed), n | 20 | 18 | 0.672** |
| Urinary retention, n | 10 | 13 | |
| Overactive bladder (dry), n | 5 | 4 | |
| Duration of UDS, min, mean ± SD | 27.5±5.5 | 28.2±4.5 | |

* Chi-square test.
** Independent *t* test.
UDS, urodynamic study.

Lubricant gel with lidocaine was used in each patient during catheter placement. An experienced urodynamic nurse and urology doctor was present in the room during the procedure. Antibiotic prophylaxis was not administered to the patients.

Data Analysis

Analyses were performed using SPSS statistical software for Windows Version 21.0 (SPSS Inc., Chicago, IL, USA). The Shapiro-Wilk test was used to demonstrate whether data were normally distributed. Statistical significance was determined using an independent *t* test and Pearson's chi-squared test. Continuous variables were expressed as mean ± SD. Significance was assessed for $p < 0.05$.

Results

Demographics and baseline clinical characteristics of 70 patients are shown in Table 1. There were no significant differences in age, duration of UDS, vital signs, and hemodynamic variables between the study and control groups. Furthermore, there were no significant differences in terms of hemodynamic variables (Table 1).

In addition, there were no significant differences in the mean pre- and post-anxiety scores after UDS between groups I and II. The mean post-procedural pain score, pulse rates, SBP, and DBP were comparable between the 2 groups. However, patients in group II were significantly more satisfied after the procedure but more willing to experience a repeat procedure as compared to the control group (Table 2).

Discussion/Conclusion

Reports of physical (pain) and psychological (anxiety) discomfort experienced by patients during UDS have prompted the use of non-pharmacological approaches to mitigate pain. Among the former approaches, music therapy exerts positive effects on the nervous and endocrine systems and provides meaningful reactions in emotions and thoughts. The most important effect of music is relaxation and stress reduction. Music therapy has been demonstrated to reduce anxiety and pain in patients with several diseases. In this randomized controlled study, we evaluated the effect of listening to music on the level of anxiety and pain during UDS. The results of this study show that listening to music during UDS had no effect on anxiety and pain; however, there was greater patient-reported satisfaction with the procedure, such that patients were willing to undergo a repeat UDS.

Because of the highly invasive nature of the procedure, several patients experience pain and embarrassment during UDS. This is supported by a recent study showing that patients with a pain score of ≥ 3 comprised 50% of the patients undergoing UDS and pain scores were consistent with the level of anxiety. Therefore, patients as well as the urologists are generally concerned about the physical discomfort and physiological distress [14]. Moreover, the new International Continence Society good urodynamic practice guidelines do not present any strategy to reduce anxiety, except patient positioning during UDS [13]. Ac-

Table 2. Post-procedure vital signs and pain, satisfaction, and willingness to undergo repeat UDS

| | Group I (control) (<i>n</i> = 35), mean ± SD | Group II (study) (<i>n</i> = 35), mean ± SD | <i>p</i> value |
|--------------------------------|--|---|----------------|
| After UDS | | | |
| SBP, mm Hg | 124±8.5 | 126.8±10.8 | 0.24* |
| DBP, mm Hg | 80.2±8 | 80.8±8.7 | 0.33* |
| Heart rate, bpm | 70.9±6.2 | 70.8±5.5 | 0.40* |
| STAI score | 47.7±7.75 | 46.4±6.5 | 0.36* |
| VAS score | 4.6±1.2 | 4.4±1.7 | 0.76* |
| Satisfaction score | 4.6±0.61 | 7.2±1.33 | 0.004* |
| Willingness to have repeat UDS | 3.4±1.4 | 6.1±1.3 | 0.005* |

* Independent *t* test.

Values of *p* < 0.05 was accepted as significant and marked bold.

UDS, urodynamic study; STAI, State-Trait Anxiety Inventory; VAS, Visual Analog Scale.

cordingly, patients should undergo a UDS in their preferred position as they did in this trial.

Despite the use of several pharmacological agents, including lidocaine, to decrease anxiety and pain related to UDS [15], patients may still experience pain and anxiety during UDS. Alternative, non-pharmacological treatment modalities, such as heating and lubricants, have been adopted, although none of these have been validated [4, 15]. Indeed, Greenstein et al. [6] recommended that reading an information leaflet before the procedure can reduce anxiety induced by UDS, which was contradicted by another study [16].

Music is a potential non-pharmacological strategy to alleviate pain and anxiety in several medical and surgical conditions [17–21]. In a study evaluating the neural response of pain and its alleviation via music, it was demonstrated that music stimulates the mesolimbic system to release dopamine, which awakens the opioid pathway in the brain to adventitiously exert a diffuse analgesic effect [22]. Music therapy has been validated in several urologic procedures as a complementary approach that enables patients to experience less pain and anxiety [9, 10, 23, 24]. Sufi music includes both vocal and instrumental aspects [25]. In the literature, Sufi music is considered a relaxing music and can create relaxation and calmness in the individual by reducing blood pressure, and pulse and respiration rate. Reversing the harmful effects of stress response is another mechanism contributing its relaxation effect [25–27].

Today, only 2 studies have thus far evaluated the effect of music therapy in UDS. According to a recent meta-analysis, music therapy during UDS improves general satisfaction; however, its effect on pain and anxiety is ob-

scure [28]. In the first study by Shim et al. [23], anxiety scores were assessed by STAI and pain levels by VAS, but anxiety, pain, and stress were not alleviated with music therapy during UDS in either gender, which is similar with our outcomes. However, in this study, the outcome of willingness to repeat UDS was only based on inter-gender analysis [23]. Contrarily, Öztürk et al. [29] showed that there were significant differences in mean pain score on VAS and mean post-procedural STAI score between the 2 groups and they recommend music therapy as an effective method to reduce anxiety and pain during UDS.

The findings in the present study may be attributed to the age of the patients and the procedure itself. In a study that evaluated patients' perceptions of physical and emotional discomfort associated with UDS demonstrated that regardless of gender, UDS is generally a well-tolerated procedure. However, they found that older age was a predictor of less physical discomfort, which is evident in the average age of the current study (58.5 years) as well as that reported by Shim et al. [23] (58.35 years), both of which are higher than those reported by Öztürk et al. [29] (50 years). Despite being an invasive procedure, urodynamic catheters are relatively small (6 Fr) instruments when compared to instruments used in cystoscopy, bronchoscopy, and hysteroscopy, which are employed in other studies, where music has shown to alleviate anxiety and pain. In addition, the use of lubricant/lidocaine gels prior to the procedure can render UDS more tolerable.

There are some inherent limitations of this study. First, blinding of patients and clinicians was not possible with a therapeutic intervention of such a kind. Moreover, the lack of a standardized method to deliver music during UDS was a drawback because there was only one option

as the sound system. Patient preference may have been a factor in defining relaxing music because Sufi music has been confirmed as relaxing, but this was not chosen by the patients. Lastly, we did not evaluate gender differences to music therapy during UDS though it has been demonstrated that male patients demonstrate lower levels of pain, stress, and anxiety scores than female patients [23].

In conclusion, although music is considered to be a safe, cheap, and simple method to alleviate pain and anxiety during medical procedures, music therapy did not significantly alleviate pain, anxiety, or stress during UDS. Nevertheless, music therapy could be considered a complementary tool to improve patient satisfaction with the procedures and enhance their willingness for repeat UDS. Additional studies with larger samples and a variety of music genres are warranted to validate the efficacy of music therapy during UDS.

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Statement of Ethics

The study was performed according to the principles of the Helsinki Declaration. An Institutional Review Board approval was obtained prior to execution of the study (2018/182). Written informed consent was obtained from all patients. Anonymity and privacy were guaranteed. The study was reported in accordance with the Consolidated Standards of Reporting Trials statement and the trial was registered at clinicaltrials.gov (NCT03791177).

Disclosure Statement

The authors have no conflicts of interest to disclose.

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Author Contributions

M.G. and M.A.D.: protocol/project development; M.G. and F.C.: data collection or management; M.G. and F.C.: data analysis; M.G.: manuscript writing/editing.

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