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The Effects of Listening to Music Embedded Binaural Beats on Anxiety Levels and Pain Scores in Male Patients Undergoing Prostate Biopsy: A Randomized Placebo-controlled Study

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What's known on the subject? and What does the study add?

Listening to binaural beats is a different distraction method to reduce anxiety and pain scores of the patients who underwent in daily medical procedures. In this study, we found listening to music embedded binaural beats can be used to reduce anxiety and pain scores of the patients who underwent prostate biopsy.

Abstract

Objective: To investigate the effects of binaural beats (BB) embedded with music on pain and anxiety scores in patients who underwent transrectal ultrasound-guided prostate biopsy with the suspicion of prostate cancer under local anesthesia.

Materials and Methods: This was a prospective, randomized, placebo-controlled study. Patients were divided into three groups; binaural beat group (BBG), music group (MG), and control group (CG). Anxiety assessment was made with the State-Trait Anxiety Inventory (STAI) form. The initial anxiety scores of the patients were recorded as STAI initial (STAI-I) before the procedure. Post-procedure anxiety scores of the patients were recorded as STAI-T terminal (STAI-T). The difference between STAI-I and STAI-T was recorded as STAI delta (STAI-D). A visual analog scale (VAS) was used for post-procedural pain scores. Demographic data, STAI-I, STAI-T, STAI-D, and VAS scores were compared.

Results: A total of 270 patients who met the study criteria, 90 in each group, were included in the study. When STAI-T and STAI-D were evaluated, there was a significant decrease in BBG and MG compared with CG. When the VAS during the procedure was evaluated, there was a significant difference between the BBG, MG, and CG groups. When the BBG vs MG, BBG vs CG, and BBG and MG groups were compared separately in terms of VAS, $p<0.001$, $p<0.001$ and $p=0.04$, respectively.

Conclusion: As a result, music embedded BB may be an effective, safe, well-tolerated and inexpensive method in reducing anxiety and pain scores in male patients who will undergo prostate biopsy.

Keywords: Biopsy, prostate, anxiety, binaural beats, pain

Introduction

According to the latest studies, prostate cancer is the 2nd most common cancer and the 5th most common cause of death (1,2). Transrectal ultrasound-guided prostate biopsy (TRUS-PBX) is the standard method in the diagnosing of prostate cancer (3,4). Intrarectal and periprostatic nerve blockade are frequently used methods for reducing pain in TRUS-PBX (5,6). Between 19% and 30% of patients experience pain during TRUS-PBX (7,8). Various methods have been attempted to reduce pain and anxiety. Some of these have been shown in studies with medical methods and some with non-medical methods such as music (8,9).

Binaural beats (BB), first described in detail by Oster (10), are based on giving the same intensity but different frequencies to the ear (11). BB cause the brain to produce vibrations of the

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same amplitude and localization as perceived sounds. Studies reported BB reduces pain and anxiety as a distraction method (12-14).

In this study, we investigated the effects of music embedded BB on pain and anxiety scores in patients who underwent TRUS-PBX with the suspicion of prostate cancer. We hypothesized that BB embedded music would significantly reduce pain and anxiety scores in patients who underwent TRUS-PBX.

Materials and Methods

Participants Selection and Ethics Statements

The study was initiated after the approval of the ethics committee number 2019-096. Male patients with at least formal schooling (1-8 years of education), who underwent TRUS-PBX for the first time because of clinical suspicion of prostate cancer, were included in the study. Those patients with hearing and vision problems and/or mental retardation, neurological deficits, a history of chronic pelvic pain syndrome and anorectal diseases, analgesia use 24 hours before the procedure, use of transcylisers or antidepressants, declined to participate in the study, failed to complete questionnaires, failure to tolerate intervention were excluded from the study. The study and its aim were explained to all the patients. Informed consent was provided from all patients who wanted participated in the study. The age and body mass index (BMI) of the patients included in the study were recorded.

Randomization and Sample Size

The study was conducted in a prospective randomized, unblinded, and placebo-controlled manner. Patients were equally divided into three groups 1:1:1 by computer-generated block randomization; binaural beat group (BBG), music group (MG), and control group (CG). The block randomization method was used when the patients were allocated to the groups. A power analysis indicated minimum 267 patients were required for statistical comparison that has a power (1-β) of 0.80 at an alpha value of 0.05, with an effect size of 0.25 (G*Power 3.1, (Kiel, Germany) (15).

Preparation of Patients, Measurement of Anxiety Levels and Pain Scores

In this study, an Anxiety assessment was made with the State-Trait Anxiety Inventory (STAI) form. STAI is a form developed to determine the anxiety level of patients (16). The total score ranges from 20 to 80; higher scores indicate higher levels of anxiety. The Turkish version was translated by Öner and LeCompte (17). The initial anxiety scores of the patients were recorded as STAI initial (STAI-I) before the procedure.

Music embedded BB was listened to the BBG group of the patients. BB were produced with a software (artisan Spirit Inc. Binaural Beat version1.0.15) with an alpha wave frequency of 10 Hz (180 Hz for the right ear and 190 Hz for the left ear) and embedded in the music. During MG, patients were listened to the type of music they wanted. All audio types were listened with wireless stereo headphones (Sony WH-CH510; Sony Corporation, U.S.).

Local anesthesia was provided with periprostatic lidocaine injection after intrarectal injection of 2% lidocaine gel after cleaning the perianal region of the patients. Prostate biopsies were obtained by biplanar transrectal ultrasound (Mindray CB10-4, China) as 12 cores. Listening was continued during the procedure. The procedure time was recorded as the entry and exit of the TRUS probe from the anal region.

Post-procedure anxiety scores of the patients were recorded as STAI-T terminal (STAI-T). The difference between STAI-I and STAI-T was recorded as STAI delta (STAI-D).

The visual analog scale (VAS) is a common instrument in which patients score their pain levels between 0 and 10 (18). We used the VAS I to evaluate the patients' pain scores after the procedure.

Statistical Analysis

The statistical analysis was performed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY). The assumptions of normality were evaluated using the Shapiro-Wilk test. According to Shapiro-Wilk test the variables of the study have non-normally (non-parametric) distrubiton. Kruskal-Wallis test was used for non-parametric variables to determine differences between groups, Bonferroni-Dunn test was used as a Post-hoc test for significant cases. A p-value of <0.05 was considered statistically significant.

Results

A total of 382 male patients who underwent prostate biopsy between the December 2019 and February 2021 were admitted to our clinic. Patients who did not meet the study criteria were excluded. A total of 270 patients, 90 in each group, were included in the study. The flow diagram of the study is shown in the figure (Figure 1).

The mean ages of BG, MG, CG were 66 (47-75), 66.5 (45-77), 66 (47-77), respectively, and there was no significant difference between the groups ($p>0.05$). The mean BMI was 26.48 (19.03-43.09), 27.31 (17.51-37.92), 26.45 (18.87-37.34), respectively, and there was no significant difference between the groups in terms of BMI ($p>0.05$) (Table 1).

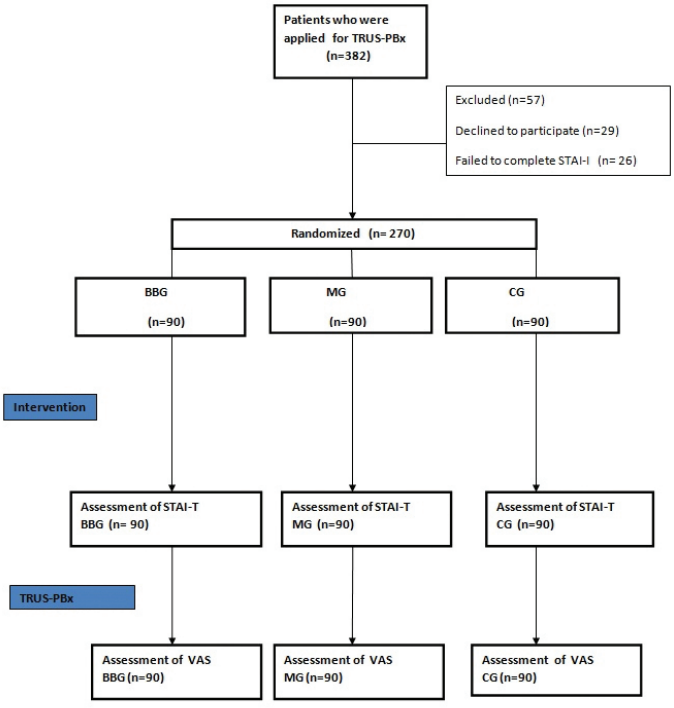

Figure 1. Flowchart diagram of participants who underwent transrectal ultrasound-guided prostate biopsy

TRUS-PBx: Transrectal ultrasound-guided prostate biopsy, BBG: Binaural beat group, MG: Music group, CG: control group, STAI-T: State-Trait Anxiety Inventory-terminal, VAS: Visual analog scale

There was no significant difference between the groups in terms of STAI-I (p>0.05). When STAI-T and STAI-D were evaluated, it was observed that there was a significant decrease in BBG and MG compared with the CG (p=0.003 and p<0.001, respectively). However, there was no significant difference between BBG and MG in terms of STAI-I and STAI-T (p=0.388 and p=0.571, respectively). There was no significant difference between the groups in terms of TRUS-PBX procedure time (p>0.05). When the VAS during the procedure was compared, it was observed that there was a significant difference between the BBG, MG, and CG groups (p<0.001) (Table 2). Separate comparisons of BBG vs MG, BBG vs CG, MG vs CG in terms of VAS were p<0.001, p<0.001 and p=0.04, respectively.

Discussion

In this study, we observed that music embedded BB significantly reduces anxiety and pain scores in men who underwent TRUS-PBx. Although there was no significant difference between were seen between BB and music in terms of anxiety score, it was seen that BB was significantly superior to music in terms of pain score.

Table 1. Patient demographics details

Variables	Binaural beat group (n=90)	Music group (n=90)	Control group (n=90)	p-value
Age (year, mean ± SD, range) (median, min-max)	63.86±7.15 66 (47-75)	63.76±7.85 66.5 (45-77)	64.61±6.58 66 (47-77)	0.838
BMI (mean ± SD, range) (median, min-max)	26.82±4.18 26.48 (19.03-43.09)	27.47±3.69 27.31 (17.51-37.92)	26.64±3.65 26.45 (18.87-37.34)	0.155
PSA (ng/mL), (median, min-max)	9.6 (5.7-15.8)	8.72 (2.7-18.5)	8.17 (3.1-16.7)	0.093
ASA score, n (%)				
1	29 (32.3)	25 (27.8)	27 (30)	0.376
2	53 (58.8)	56 (62.2)	53 (58.8)	
3	8 (8.9)	9 (10)	10 (11.2)	
PV (g, mean ± SD, range)	47.53 (33-92)	50.25 (29-85)	46.92 (35-85)	0.243

SD: Standard deviation, BMI: Body mass index, PSA: Prostate spesific antigen, ASA: American Society of Anesthesiologists, min: Minimum, max: Maximum

Table 2. Comparison of patients STAI-I, STAI-T, STAI-D, VAS scores and duration between the groups

Variables	Binaural beat group (n=90)	Music group (n=90)	Control group (n=90)	p-value
STAI-I (median, min-max)	39 (27-58)	42 (27-57)	40 (24-59)	0.817
STAI-T (median, min-max)	32 (23-58)[a]	37 (21-53)[a]	39.5 (24-59)[b]	**0.003***
STAI-D (median, min-max)	5 (0-16)[a]	5 (1-14)[a]	1 (-2-2)[b]	**<0.001***
Duration (minute, median, min-max)	4.5 (3.5-6)	4.5 (3.5-6.5)	4.5 (3.5-6)	0.89
VAS score (median, range)	1 (0-10)[a]	3 (0-10)[b]	4 (0-10)[c]	**<0.001***

STAI-D: State-Trait Anxiety Inventory-Delta, STAI-I: State-Trait Anxiety Inventory-Initial, STAI-T: State-Trait Anxiety Inventory-Terminal, VAS: Visual analog scale, [a, b, c]: Different lowercases denote statistically significant differences, *bolded values are significant p values between groups, min: Minimum, max: Maximum

Many studies have been conducted to reduce pre-procedural anxiety and pain during the procedure in male patients before prostate biopsy. Some of these include medical treatments, whereas others include distraction-based studies. The most common distraction methods used to reduce pain and anxiety in the prostate biopsy are visual and auditory. Auditory methods are used more frequently because they are easier to apply and are thought to be more effective.

It has been shown in studies and meta-analyses that listening to music before prostate biopsy significantly reduces pain and anxiety scores (9,19). In contrast, there are studies in the literature reporting that listening to music is not effective in reducing anxiety and pain (20). Music is effective in reducing anxiety and pain not only in prostate biopsy but also in other procedures that are frequently performed locally in urology practice (21-23).

There have been many studies showing that binaural music embedded in pure or music reduces anxiety and pain scores in surgical procedures. The mechanism of these effects of BB has not been fully elucidated. It has been suggested that this effect is due to the brain changing the dominant wave frequency toward the frequency of external stimuli to synchronize the neural activity with stimuli from binaural concerts (11). Alpha waves (8-13 Hz) in brain activity are associated with relaxation (14,24). It has been shown in various studies that BB are effective in this wave range, providing relaxation and reducing pain (12,14,24).

Isik et al. (12) conducted a randomized study that includes 60 patients who underwent dental intervention. They divided groups into two equal group. They used pure BBs in their study. As a result they reported that BB significantly reduces anxiety and pain scores in patients who underwent dental intervention. Padmanabhan et al. (24) reported that BB and music significantly reduced anxiety scores in patients who would undergo surgical intervention under general anesthesia. They found these results in a randomized study that included 108 patients. Similar results were obtained by Wiwatwongwana et al. (14). They observed patients while they were undergoing cataract surgery under local anesthesia. He also stated that BB significantly reduced pre-procedural HR and systolic blood pressure in patients compared with other groups (14). In both studies, it was reported that there was no significant difference between BB and music in terms of their effect on anxiety.

Studies have been conducted showing that BB reduce intraoperative pain and therefore reduce the need for analgesics (25-27). Debaouc reported that BB reduced the postoperative analgesic requirement and also shortens the length of hospital stay (25). According to Ölçücü et al. (13) showed that listening to pure BB significantly reduced pain and anxiety scores in patients who underwent cystoscopy and ureteral stent removal under local anesthesia. They stated that there was no difference between pure BB and music in terms of anxiety scores, they also reported that pure BB significantly reduced pain scores compared to music. They also stated that the tolerance rate of pure BB music was significantly lower compared to the MG and CG, and some patients stated that BB was meaningless and disturbing (13). However, in our study we music embedded BBs was used and there was no patient who could not tolerate it.

Study Limitations

This study has some limitations. The most important limitation is that the study was not blinded. The fact that it is single-centered can be considered a limitation. Another limitation is that different people perform prostate biopsy procedures. But since TRUS-PBX is a simple and easy procedure, we think that there can be no big differences between urologists. If blood pressure and pulse change were monitored in the study, it would have increased the power of the study.

Conclusion

As a result, music embedded BB may be an effective, safe, well-tolerated and inexpensive method in reducing anxiety and pain scores in male patients who will undergo prostate biopsy. To confirm our results, it would be more appropriate to conduct double-blind multicenter studies with a larger number of patients.

Ethics

Ethics Committee Approval: The study was initiated after the approval of the ethics committee number 2019-096, approval date: 16/05/2019.

Informed Consent: Informed consent was provided from all patients who wanted participated in the study.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: M.Ö., K.Y., Concept: M.Ö., K.Y., Design: M.T.Ö., Data Collection or Processing: K.Y., Analysis or Interpretation: K.Y., M.T.Ö., Literature Search: M.T.Ö., Writing: K.Y.

Conflict of Interest: No conflict of interest was declared by the authors.

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