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Periprostatic Block Alone is not Superior to Music Therapy and TENS for Pain and Anxiety During Transrectal Prostate Biopsy: A Single-center Prospective Randomized Study

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

Transrectal ultrasound-guided prostate biopsy is known to be a painful invasive procedure. Various methods have been described to make the procedure painless. However, care is taken not to increase the complication rates. In this study, it is seen that listening to music during the procedure, produses an analgesic effect similar to transcutaneous electrical nerve stimulation and periprostatic block application without increasing complication rates.

Abstract

Objective: This study aimed to compare the effects of transcutaneous electrical nerve stimulation (TENS) and music therapy on pain and anxiety in male patients undergoing transrectal ultrasound-guided prostate biopsy (TRUSPB).

Materials and Methods: Between March 2022 and March 2023, TRUSPB was applied prospectively to 150 eligible patients who were randomly divided into five equal groups at the Urology Department of Zonguldak Bülent Ecevit University, Turkiye. In group L, the procedure was performed with periprostatic block (PB) only. In group LT, the procedure was performed with PB+TENS; in group LM, the procedure was performed with PB+music; in group M, the procedure was performed with music only; and in group T, the procedure was performed with TENS only. The anxiety and pain levels were compared between the groups using objective and subjective parameters.

Results: Pain scores at the beginning, in the middle and at the end of the TRUSPB procedure did not reach a statistical differences (p=0.05, p=0.363, p=0.329, respectively). The procedure-related anxiety score differences among the groups were the same (p=0.058). The procedure time was highest in group LT and lowest in group M (p=0.000).

Conclusion: The effects of music and TENS on pain and anxiety scores during TRUSPB were similar to those of PB. Performing the procedure with music is preferable because it shortens the procedure time and requires fewer needle insertions without increasing the complication rate.

Keywords: Transrectal, prostate biopsy, transcutaneous electrical stimulation, pain, music therapy

Introduction

Transrectal ultrasound-guided prostate biopsy (TRUSPB) remains the accepted method for the diagnosis of prostate cancer (1). However, it remains a painful and uncomfortable procedure for most patients (2). Techniques such as intrarectal lidocaine, periprostatic nerve block, sedation, and nitrous oxide inhalation are used to address this issue (3,4). However, considering the possible side effects of systemic drug administration or the additional stress burden of nerve block, the search for a simple approach has continued.

Today, music is a method used in many medical fields to address patient experiences of pain and anxiety (5). Studies have shown its use as a non-pharmacological method that aims to take the patient's attention away from the procedure and the perception of pain (6,7).

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In transcutaneous electrical nerve stimulation (TENS), the electric current and frequency are adjusted according to the individual, creating sensory intensity without motor contraction and increasing the opioid release (8). With this feature, TENS is an easy, effective, and safe method that can be used to mitigate many types of pain, which can vary in terms of neurologic and mechanical origin (9).

Several studies have investigated the effect of TENS and music therapy on TRUSPB-related pain and anxiety (9-11). However, no study has yet compared music practice with TENS. To close this gap, we aimed to compare the effects of TENS and music therapy on pain and anxiety in men who underwent TRUSPB.

Materials and Methods

This prospective, randomized controlled study was conducted between March 2022 and March 2023 at the urology clinic of Zonguldak Bülent Ecevit University's (ZBEU) Faculty of Medicine after obtaining approval from the ZBEU's Local Ethics Committee (meeting date: 23/02/2022, protocol no: 2022/04-15). (ClinicalTrials number for the study is NCT05358223). Written informed consent was obtained from all participants prior to the procedure. All biopsies were performed by the same surgeon (RG).

Patient Selection and Evaluation

The number of patients who met the inclusion criteria and applied to the clinic within the defined time period was 175. After applying the exclusion criteria, 150 men were included in the study (Figure 1). Patients were randomly assigned to five balanced groups by the clinic physician (OÖ). For randomization a computer program was used (the 3rd generator program was selected at http://www.randomization.com). The program generated a randomly numbered list in blocks of 5. The list was kept secret from the surgeon (RG) who performed the biopsy throughout the study and was not disclosed until the last patient was at the final follow-up. After the list was determined by (OÖ), the service nurse included the patients in the relevant group starting from the first number according to the list created. According to the study design, the patients and physicians were not blinded. Only the outcome assessor was blinded during data processing.

The inclusion criteria were patients with elevated prostate specific antigen (PSA) according to the NCCN guideline basic evaluation and risk group classification (12), abnormal prostate examination, and the presence of type 4 and 5 lesions according to The Prostate Imaging-Reporting and Data System in multiparametric prostatic magnetic resonance imaging (mpMRI). The exclusion criteria included patients with acute prostatitis, neutropenia, bleeding diathesis, the use of pacemakers or defibrillators, the use of electronic devices for the central nervous system, mental and organic defects that prevent participation, epilepsy under treatment, alcohol and narcotics abuse, skin lesions on the electrode attachment sites, anorectal pathology, and a lack of agreement to participate in the study.

Demographic data, comorbidities, total (t) and free (f) PSA, f/t PSA ratio, total testosterone, hemogram, urea, creatinine, international prostate symptom score, international erectile function index score, findings of digital rectal examinations, and prostate volumes were acquired.

The cognitive biopsy was performed under the illumination of MpMRI findings. Participants in the groups were given ceftibuten 400 mg (Wincef® 400 mg, Celtis İlaç, İstanbul, Turkiye) once a day starting a day before the procedure and continued for three days orally and a single dose of gentamicin 160 mg (Genthaver

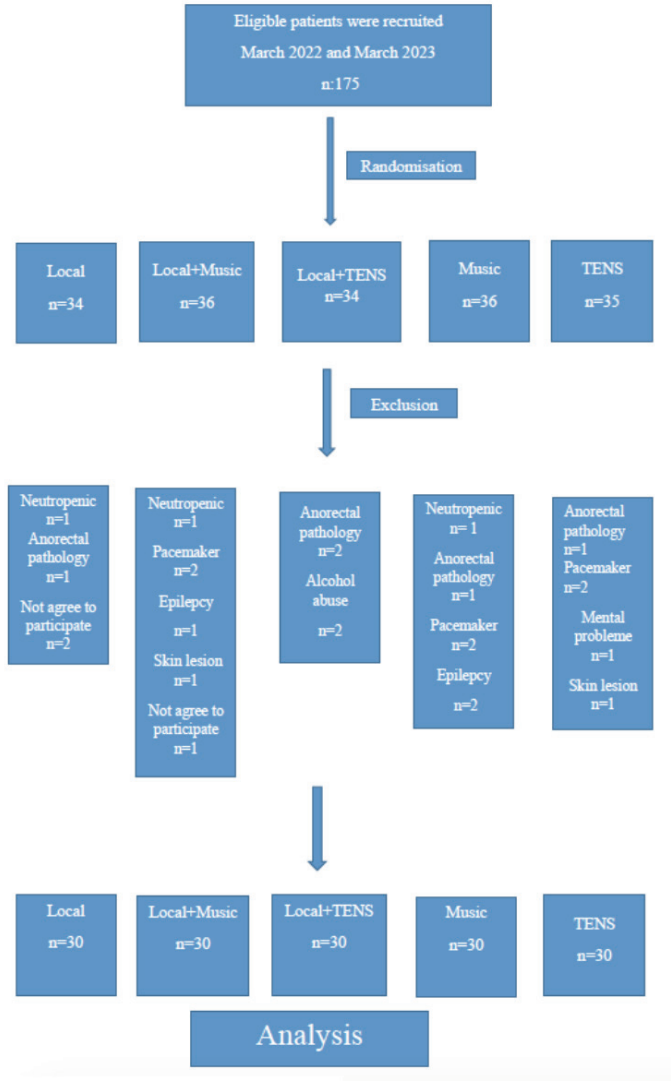

Figure 1. Flowchart of the study

160 mg/2 mL, Osel Ilac, Turkiye) intramuscularly before the procedure. For patients receiving anticoagulant therapy, medication was discontinued before the procedure according to the half-life of the anticoagulant type. Platelet antagonists and new-generation antithrombotic drugs were discontinued 5 days before the procedure.

The primary outcome of the study was to define the difference in the effect of music, TENS, and local anesthesia on the perception of pain and anxiety resulting from transrectal prostate biopsy.

Objective [blood pressure (BP), heart rate (HR), partial oxygen saturation (SpO_2)] and subjective measures were used to assess pain and anxiety levels. Complications within 1 week were recorded when patients visited the clinic or by telephone call.

In all groups, BP, HR and SpO_2 values of the patients were measured at the beginning, middle, and end of the procedure and recorded. The middle stage of the process refers to the period immediately after half of the total number of cores to be taken.

The pain level of the patients was evaluated three times for each procedure using the visual analog scale (VAS). The first evaluation was performed immediately after the probe insertion; the second evaluation was performed at the middle of the prosedure; and the third evaluation was performed 15 minutes after the procedure was completed. The VAS is a scale that scores the severity of pain between 0 and 10 (0 represents no pain, 10 represents the most severe pain state). Anxiety levels were calculated using the Turkish version of the state-trait anxiety inventory (STAI) (13), which was given to all patient groups the day before the procedure. After the prostate biopsy was completed, this scale was given to the patients again, and their anxiety status was re-evaluated after they had fully recovered from the procedure. The STAI comprises 20-item scales to assess individual situational anxiety. Each question consists of a four-point Likert scale and is scored between 20 and 80 in total. High scores indicate increased anxiety.

In all groups, the procedure was performed in a room that was comfortable and free from external stimuli, with the patient positioned in the left lateral decubitus position. Intrarectal 2 g of lidocaine gel (Lubragel® 11 mL, İstem Med, Ankara, Turkiye) was squeezed just before inserting the ultrasound probe. Prostatic volume was calculated automatically using the formula height × width × length × π/6, and possible suspicious areas were recorded after 6.5-MHz rectal prob insertion. An automatic biopsy gun (18G × 25 cm, Maxicore, Geotek Healthcare Products, Turkiye) was used to perform a standard 12-core systematic prostate biopsy. An additional 2 core per-lesion were taken from the pathological areas obtained on mpMRI.

In the first group (L), after probe insertion, an additional infiltration of 5 mL of 2% prilocaine (2% Priloc®, vemilac, Turkiye) was applied to each prostate–seminal vesicle junction using a 7-inch, 22-gauge spinal needle in the sagittal axis. To prevent intravascular injection, the syringe was aspirated before injection. The total biopsy time in this group was defined as the sum of the local anesthetic infiltration 2-3 min before the biopsy plus the time to take the biopsy in seconds.

In the second group (LM), standard slow music with no lyrics, chosen randomly by our team from the youtube.com website (https://www.youtube.com/watch?v=WLWJy1eXX2c&t=1980s), was started immediately before patient arrival to the office and played until after patient departure. The music was played through an external cellular device, and the volume was controlled at a comfortable level according to the patient's preference. After placing the patient in the lateral decubitus position and probe insertion, an additional infiltration of 5 mL of 2% prilocaine (2% Priloc®, vemilac, Turkiye) was applied to each prostate-seminal vesicle junction using a 7-inch, 22-gauge spinal needle in the sagittal axis. To prevent intravascular injection, the syringe was aspirated before injection. In this group, the total biopsy time was defined as the sum of local anesthetic infiltration 2-3 min before the biopsy plus the time to take the biopsy in seconds.

In the third group (LT), we used a two-channel TENStem eco basic device with two electrodes on both sides (Pierenkemper GmbH, Hoernsheimer Eck 19, 35,578 Wetzlar, Germany) (Figure 2a). For this study, before the transrectal ultrasound probe was inserted, we attached one of the adhesive electrodes connected to the first channel to the right anterior suprapubic skin surface and the corresponding electrode to the right posterior presacral skin surface. Similarly, one of the electrodes connected to the second channel was attached to the left anterior suprapubic skin surface, and the corresponding electrode was attached to the left posterior presacral skin surface, as shown in Figure 2b, c. At least 3-6 min before the biopsy, bipolar stimulation (TENS stimulation) was started at a lower energy and then increased to 60 mA with a 100-Hz frequency and 150 μs pulse width. The amplitude was set to a level that each patient could tolerate. After placing the patient in the lateral decubitus position and probe insertion, an additional infiltration of 5 mL of 2% prilocaine (2% Priloc®, vemilac, Turkiye) was applied to each prostate-seminal vesicle junction using a 7-inch, 22-gauge spinal needle in the sagittal axis. To prevent intravascular injection, the syringe was aspirated before injection. For this group, the total biopsy time was defined as the sum of the placement of the TENS electrodes and the local anesthetic infiltration 2-3 min before the biopsy plus the time to take the biopsy in seconds.

In the fourth group (M), music was played throughout the procedure without the application of any periprostatic infiltration prior to biopsy. The total biopsy time was counted at the initiation of the intrarectal probe insertion.

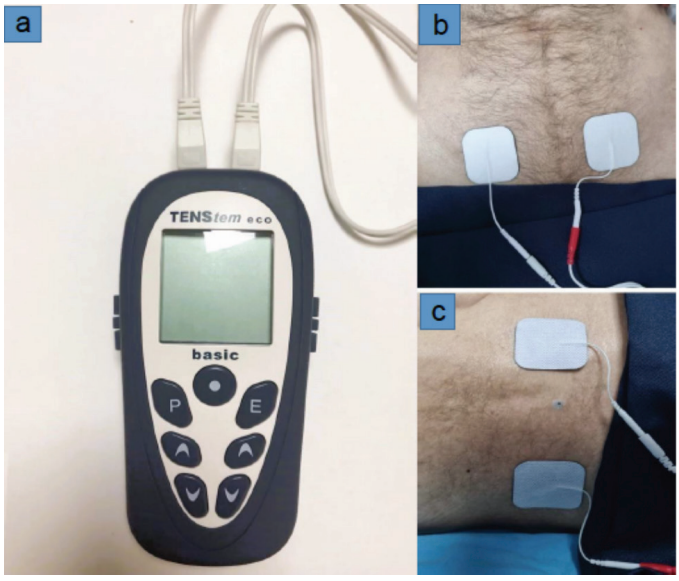

Figure 2. a: TENS device, b: TENS electrode placement right and left suprapubik skin, c: TENS electrode placement right and left presacral skin

TENS: Transcutaneous electrical nerve stimulation

In the fifth group (T), TENS device electrodes were attached to the patient as described. No periprostatic infiltration was performed prior to the biopsy procedure. The total biopsy time was calculated as the sum of the placement of the TENS electrodes plus the time to biopsy in seconds.

Statistical Analysis

The nominal and ordinal data were defined using frequency distributions, and the measurement data were defined using means. The chi-square similarity ratio, chi-square tests, Kolmogorov-Smirnov test, One-Way ANOVA, and Kruskal-Wallis test were used for the analysis of parameters. All analyses were performed at a 95% confidence interval using the SPSS 25.0 (SPSS Inc., Chicago, IL, USA) program and a 0.05 significance level.

The sample size was calculated using G*power 3.1.9.2 (design by Franz, Universitat Kiel, Germany). The minimum number of patients to be recruited with a 95% confidence interval and a 0.05 margin of error was 67 for the sum of all groups based on the study closest to our study (9).

Results

All demographic variables are emphasized in Table 1. The mean ages, mean body mass indexes, and mean prostate volumes of the participants were similar between the groups (p=0.950, p=0.886, p=0.854, respectively). Pathological results, including prostate cancer, were similar between groups (p=0.515). No significant difference was observed between the groups in terms of complication rates requiring hospitalization (p=0.325).

No statistically significant difference was observed between the groups in terms of pain and anxiety scores measured at the beginning, middle, and end of the procedure; however, the mean biopsy times were higher in the LT group and lower in the M group (p=0.00). All objective and subjective variables of the patients correlated with the procedure are summarized in Table 2.

Discussion

TRUSPB is a painful procedure, with up to 20% of patients experiencing severe pain that requires intervention (14). Although various methods have been tried for pain palliation, periprostatic blockade is currently the preferred method today (15). In the study of Cho and Choi (10) adding music to the periprostatic block application had a positive effect on procedure-related pain scores. Similarly, in the study of Lee et al. (11), a positive effect of performing the biopsy procedure with music on patient pain scores was reported. The periprostatic block procedure was not performed in this patient, but IV sedation was performed. In a study by Tsivian et al. (16), pain scores were found to be lower in the music group. In this study, there were three patient groups, each with 30 patients. Each group underwent a periprostatic block, with one group used as the control, one group given noise-canceling headphones, and the other group given headphones with music (16). Similarly, in our study, we observed that performing the TRUSPB procedure with music only had a similar effect on pain scores as performing the procedure with periprostatic block. On the other hand, in a recent study by Packiam et al. (17), the positive effects of music practice were not demonstrated. However, the fact that anxiety levels were not evaluated before the procedure was considered a limitation of this study (17). In the study of Bolat et al. (9), the effect of applying the TRUSPB procedure with TENS or periprostatic block on patient pain scores was compared, and no difference was found. As a result of two recent meta-analyses in the literature, it has been interpreted that TENS application is effective in pain palliation, and it has been suggested that it can be used as an additional method alongside the main treatment in this context (18,19).

When we evaluated the data of our study, TENS application had a similar effect to periprostatic block only and music application on pain scores related to the TRUSPB procedure. We believe that the fact that the patients were motivated by pain before the procedure may have kept the results below expectations, indicating that the algologic measurements may not be objective enough.

The physiological connections between anxiety and pain perception are well-known today (11). Sympathetic activity

Table 1. Demographic data of patients						
Groups	**Group L (n=30)**	**Group LM (n=30)**	**Group LT (n=30)**	**Group M (n=30)**	**Group T (n=30)**	**p**
Age, (mean ± SD, years)	64.63±8.08	65.50±5.87	64.97±6.92	65.43±5.59	64.27±7.48	0.950[a]
BMI, (mean ± SD, kg/m²)	27.83±2.87	27.02±3.49	27.58±2.84	27.42±3.56	27.29±2.78	0.886[a]
Diabetes mellitus, n (%)	6 (20.0)	5 (16.7)	7 (23.3)	8 (26.7)	5 (16.7)	0.847[c]
Hypertension, n (%)	9 (30.0)	10 (33.3)	13 (43.3)	12 (40.0)	8 (26.7)	0.639[c]
Usage of anticoagulant medication, n (%)	9 (30.0)	10 (33.3)	9 (30.0)	9 (30.0)	8 (26.7)	0.989[c]
Reason for clinical application, n (%)						
LUTS	7 (23.3)	11 (36.7)	6 (20.0)	4 (13.3)	6 (20.0)	0.567[b]
High level of PSA	12 (40.0)	9 (30.0)	9 (30.0)	15 (50.0)	12 (40.0)	
Routine control	-	-	-	1 (3.3)	-	
LUTS + high level of PSA	11 (36.7)	10 (33.3)	15 (50.0)	10 (33.3)	12 (40.0)	
IPSS, mean ± SD	18.30±5.29	18.60±5.90	18.00±7.02	18.50±5.05	18.03±6.61	0.981[d]
IEFF, mean ± SD	13.03±4.97	12.80±5.19	13.87±6.10	13.37±5.21	13.13±4.34	0.954[d]
DRE, n (%)						
Adenoma	23 (76.7)	21 (70.0)	23 (76.7)	21 (70.0)	19 (63.3)	0.784[b]
Right side hard/nodule	4 (13.3)	3 (10.0)	2 (6.7)	7 (23.3)	6 (20.0)	
Left side hard/nodule	1 (3.3)	3 (10.0)	2 (6.7)	1 (3.3)	3 (10.0)	
Diffuse hard	2 (6.7)	3 (10.0)	3 (10.0)	1 (3.3)	2 (6.7)	
MP-MRI, n (%)	13 (43.3)	11 (36.7)	12 (40.0)	12 (40.0)	11 (36.7)	0.983[c]
Prostate volume, (mean ± SD, mL)	54.00±22.13	50.07±17.76	51.83±23.16	53.67±23.95	48.93±20.56	0.854[d]
Number of cores taken (mean ± SD)	12.80±1.21	12.77±1.14	12.77±1.17	12.77±1.07	12.50±0.90	0.873[d]
TENStem preset energy level						
Right side, (mean ± SD)			15.40±4.21		15.43±4.16	0.928[e]
Left side, (mean ± SD)			13.07±4.58		13.33±4.53	0.817[e]
Total PSA, (mean ± SD, ng/mL)	10.45±6.49	12.47±5.68	10.50±5.21	10.30±4.03	11.07±7.32	0.314[d]
Free PSA, (mean ± SD, ng/mL)	1.91±1.10	1.98±1.02	1.80±1.13	1.92±1.31	1.77±1.28	0.659[d]
Free/total PSA, (mean ± SD, ng/mL)	0.20±0.09	0.17±0.06	0.17±0.07	0.18±0.08	0.17±0.09	0.511[a]
PSA density, (mean ± SD)	0.23±0.22	0.28±0.17	0.24±0.14	0.22±0.10	0.24±0.17	0.572[d]
Total testesterone, (mean ± SD, ng/mL)	4.22±1.38	4.23±1.41	4.17±1.45	4.23±1.68	4.21±1.20	0.980[d]
Q_{max}, (mean ± SD, mL/s)	11.53±5.72	12.59±8.27	12.05±5.51	12.44±7.27	12.73±6.76	0.954[d]
Q_{median}, (mean ± SD, mL/s)	5.86±2.32	6.12±3.67	6.06±2.64	6.18±3.74	6.32±3.47	0.992[d]
Voided volume, (mean ± SD, mL)	254.63±122.08	291.63±141.51	234.50±109.29	263.17±129.72	228.23±115.50	0.398[d]
Voiding time, (mean ± SD, s)	45.20±17.29	49.00±23.23	41.77±12.16	42.63±14.87	39.27±11.33	0.675[d]
Post void residue, (mean ± SD, mL)	121.33±94.81	111.07±121.87	128.67±119.31	123.27±139.77	122.50±66.88	0.587[d]
Pathology, n (%)						
BPH	19 (63.3)	14 (46.7)	12 (40.0)	10 (33.3)	16 (53.3)	0.515[b]
PCA	9 (30.0)	11 (36.7)	12 (40.0)	11 (36.7)	11 (36.7)	
ASAP	1 (3.3)	3 (10.0)	4 (13.3)	6 (20.0)	1 (3.3)	
HGPIN	1 (3.3)	2 (6.7)	2 (6.7)	3 (10.0)	3 (6.7)	
Complications, n (%)						
Hematuria, n (%)	7 (23.3)	8 (26.7)	6 (20.0)	6 (20.0)	6 (20.0)	0.961[c]
Hematospermia, n (%)	14 (46.7)	13 (43.3)	17 (56.7)	12 (40.0)	15 (50.0)	0.740[c]
Rectal bleeding, n (%)	6 (20.0)	2 (6.7)	5 (16.7)	4 (13.3)	5 (16.7)	0.606[b]
Fever, <2 day, n (%)	1 (3.3)	3 (10.0)	5 (16.7)	5 (16.7)	3 (10.0)	0.382[b]
Sepsis, n (%)	-	1 (3.3)	-	2 (6.7)	1 (3.3)	0.325[b]
Retention, n (%)	3 (10.0)	2 (6.7)	5 (16.7)	3 (10.0)	3 (10.0)	0.808[b]

[a]: One-Way ANOVA, [b]: Chi-square similarity ratio, [c]: Chi-square, [d]: Kruskal-Wallis, [e]: Mann-Whitney U, SD: Standard deviation, BMI: Body mass index, LUTS: Lower urinary trackt symptoms, PSA: Prostate spesific antigens, ASAP: Atypical small acinar proliferation, HPGIN: High grade prostatic intraepitaliel neoplasia, BPH: Benign prostate hyperplasia, IEFF: International erectil function form, IPSS: International prostate symptom score, MRI: Magnetic resonance imaging, DRE: Digital rectal examination

Table 2. Comparison of objective and subjective parameters of the groups

		Group L (n=30)	Group LM (n=30)	Group LT (n=30)	Group M (n=30)	Group T (n=30)	p
Systolic blood pressure (mmHg)	Pre-test	140.53±16.05	131.17±15.54	133.40±14.99	132.87±13.39	135.20±14.51	0.217[a]
	Test	142.48±14.66	137.20±15.59	137.43±16.23	134.77±16.61	138.62±16.84	0.424[a]
	Post-test	144.43±14.61	139.23±16.04	135.23±12.08	137.30±16.43	134.20±16.39	0.054[a]
Diastolic blood pressure (mmhg)	Pre-test	76.67±10.68	76.33±11.05	79.23±14.43	75.10±8.64	74.30±7.97	0.786[a]
	Test	78.42±8.23	75.30±9.58	81.90±25.01	75.60±9.49	76.43±11.28	0.539[a]
	Post-test	80.17±8.79	80.80±12.56	80.73±10.61	81.47±12.26	75.33±12.24	0.261[a]
Heart rate (beats/min)	Pre-test	82.13±8.20	76.57±9.36	79.07±10.69	83.83±8.56	79.63±14.29	0.057[a]
	Test	83.85±7.94	82.70±7.72	82.87±9.71	88.40±9.15	84.00±13.96	0.074[a]
	Post-test	85.57±9.33	85.50±9.71	80.73±12.96	88.00±9.47	83.50±14.97	0.180[b]
Partial oxygen saturation (%)	Pre-test	96.76±1.18	96.77±2.03	97.10±1.32	96.47±2.06	96.77±2.46	0.548[a]
	Test	96.20±1.15	96.43±1.52	96.57±1.63	95.67±2.73	96.07±3.52	0.353[a]
	Post-test	96.33±1.60	96.37±2.19	96.67±1.65	96.17±2.63	96.07±4.74	0.482[a]
VAS_1 (mean ± SD)		1.03±1.33	1.73±1.86	2.03±1.79	2.40±2.25	2.57±2.51	0.050[a]
VAS_2 (mean ± SD)		2.90±2.31	2.67±1.84	2.63±2.13	3.37±2.20	3.70±2.67	0.363[a]
VAS_3 (mean ± SD)		2.87±2.67	3.03±2.01	2.40±2.94	3.40±2.61	3.37±2.91	0.329[a]
Pre-prosedure STAI (mean ± SD)		47.77±6.39	47.77±7.44	47.07±6.68	47.93±6.97	47.07±7.43	0.980[b]
Post-prosedure STAI (mean ± SD)		49.23±9.03	51.03±9.29	49.77±10.16	53.03±10.02	46.37±6.78	0.132[a]
STAI (Δ) (mean ± SD)		1.47±7.32	3.27±7.31	2.70±6.84	5.10±6.30	-0.70±4.98	0.058[a]
Biopsy time (mean ± SD)[c]		466.77±75.68	462.57±74.66	820.00±77.26	338.03±81.32	672.73±82.11	**0.000[a]**

[a]: Kruskal-Wallis test, [b]: One-Way ANOVA test, [c]. P: Group L-LM: 0.900, Group L-LT: 0.000, Group L-M: 0.000, Group L-T:, 0.000, Group LM-LT: 0.000, Group LM-M: 0.000, Group LM-T: 0.000, Group LT-M: 0.000, Group LT-T: 0.000, Group M-T: 0.000
VAS_1: After prob insertion, VAS_2: During prosedure, VAS_3: 15 minute after prosedure, SD: Standard deviation, VAS: Visual analog scale

triggered by anxiety increases the perception of pain (20). Therefore, it is also important to combat procedural anxiety. In the literature, the only study in which TENS-guided TRUSPB was applied was that by Bolat et al. (9), in which the effect on pain rather than anxiety level was evaluated and no difference was observed. The effect of TENS application on anxiety scores was similar to that of other methods. The effect of TENS application is also seen without periprostatic block application. In many studies on music, it has been reported that listening to music reduces the level of anxiety related to the TRUSPB process (10,11,21). In a study by Tsivian et al., on the contrary, it was reported that listening to music did not affect the anxiety levels of patients (16). A similar result was reported by Packiam et al. (17). In our study, the effect of music application on anxiety levels was similar to that of TENS and periprostatic block. In a meta-analysis by Hole et al. (22), music was suggested as a method that can be used in surgical procedures. Although a positive effect was observed particularly when patients listened to music of their choice, no clear conclusion was reached on the effect of the duration of the music, the method of listening, and the music's volume (22).

In addition to subjective parameters, objective parameters are used to evaluate pain and anxiety. Vital parameters recorded during the procedure are used for monitoring. The body's response to pain is increasing BP, HR, and SpO_2. In this context, in our study, BP, HR, and partial oxygen pressure were monitored before, during, and after the procedure. However, we did not observe any significant differences in the vital signs between the groups. This result was consistent with the subjective parameters.

In our study, patients were evaluated into 5 groups. The subjective and objective values of the groups in which only music and TENS were applied were similar to those of the groups in which periprostatic block was applied. We believe that this situation can be interpreted as periprostatic block being sufficiently effective or as music and TENS being as effective as periprostatic block.

In a meta-analysis published by Richman et al. (23), it was reported that periprostatic block application was the most appropriate anesthesia application based on the 16 articles examined. Ingber et al. (24) supported this in their study, in which they used lidocaine for periprostatic block in one group and physiological saline in the other group. In their study evaluating four different methods, Kravchick et al. (25) found that periprostatic blockade was only effective during the biopsy procedure and was ineffective during probe insertion. In contrast, the authors reported that intrarectal 40% dimethylsulfoxide mixed with lidocaine was the most effective drug (25). Since it has been reported in the literature that transrectal prostate biopsy is a painful procedure that requires analgesics, we did not create a control group that underwent TRUSPB without any additional procedures.

Study Limitations

There are some limitations to our study. First, this was a single-center study with a small number of patients in each group. Second, since the biopsy procedure is decided on a patient-by-patient basis, it is not possible to establish a certain standard. This may complicate the assessment. Third, in our study, no group underwent the procedure without any additional intervention. Therefore, we lacked a control group to compare the additional interventions. Fourt, the fact that the music selection was predetermined by our team -i.e., it was not left to the patient's choice- and the fact that headphones were not used shows that different studies are needed to make generalizations about music because it has been shown that different results can be obtained. Fifth, awareness of the patient and operator of the procedure may have affected the results; however, due to the nature of the procedure, overcoming this limitation may not have been possible. Sixth, after the procedure, we did not ask the patients questions such as "Are you satisfied with the procedure?" or "Would you like the procedure to be repeated in the same way?". Despite these limitations, the strength of our study is the absence of similar studies on this subject in the literature.

Conclusion

In conclusion, the addition of music and TENS during TRUSPB may be as effective as periprostatic block for pain and stress management. On the other hand, TENS application has a negative effect on procedure time without any increase in complication rates. In this context, listening to music during the procedure seems to be preferable, without any increase in the procedure time, without affecting the complication rates, and with a lower number of needle insertions.

Ethics

Ethics Committee Approval: Zonguldak Bülent Ecevit University's Local Ethics Committee approved the study (meeting date: 23/02/2022, protocol no: 2022/04-15).

Informed Consent: Written informed consent was obtained from the participants before the procedure.

Footnotes

Authorship Contributions

Surgical and Medical Practices: R.G., Concept: R.G., O.Ö., Design: R.G., Data Collection or Processing: O.Ö., Literature Search: R.G., O.Ö., Writing: R.G.

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

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