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Music from Noise-Canceling Headphones Is Beneficial against Anxiety in Male Bladder Cancer Patients Undergoing Follow-Up Cystoscopy: A Prospective Randomized Trial

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Abstract
Introduction: Bladder cancer, with a greater incidence in males than in females, requires frequent cystoscopies. We aimed to evaluate the effect of music played through noise-canceling headphones on male bladder cancer patients during follow-up cystoscopy. ***Methods:*** A total of 160 male bladder cancer patients undergoing follow-up flexible cystoscopy were randomly divided into the noise-canceling headphones without music group and the noise-canceling headphones with music group (groups 1 and 2, respectively; $n = 80$ per group). The patients' clinical characteristics were examined, and objective and subjective measurements were compared before and after cystoscopy. The primary outcomes that were evaluated included the visual analog scale (VAS, 0–10) and the state-trait anxiety inventory (STAI, 20–80). Other outcomes, including vital signs and scores for assessing satisfaction and the willingness to repeat the procedure, were also examined. ***Results:*** The characteristics of the patients in groups 1 and 2, and their pre-cystoscopy status, did not differ significantly. Although post-cystoscopy vital signs for the objective parameters and VAS pain scores were similar between the groups, subjective parameters were not. When compared with group 1, post-cystoscopy STAI-state scores were significantly lower in group 2, whereas patients' satisfaction scores and the willingness to repeat the procedure were significantly higher in group 2 ($p = 0.002$, 0.001, and 0.001, respectively). Additionally, in group 2, STAI-state scores changed significantly after the procedure when compared with before the procedure ($p = 0.002$). ***Conclusion:*** Providing music to male bladder cancer patients through noise-canceling headphones was found to reduce anxiety during cystoscopy and to improve patient satisfaction and willingness to undergo repeat cystoscopy.

Introduction

Music is thought to reduce pain, anxiety, and stress by diverting the patient's attention away from negative stimuli, thereby helping them to feel more comfortable [1]. Therefore, music therapy has been used as an adjuvant during cancer treatment in various clinical settings [2]. Noise-canceling headphones, which are designed to exclude external noise, are very effective at reducing

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external sounds [3]. They therefore make the wearer comfortable and increase their focus on the music being transmitted from the headphones [4].

Bladder cancer, which has a 4-fold higher incidence in males than in females, requires frequent cystoscopy because of its high risk of recurrence and progression [5]. However, long-term regular follow-up cystoscopy can negatively impact the patient's quality of life [6]. When compared with female patients, male patients with bladder cancer may experience greater discomfort because of the anatomic differences in the urethra [7, 8]. Despite the recent introduction of flexible cystoscopy, male patients still experience anxiety- and pain-associated discomfort during the procedure [9]. In this study, we hypothesized that playing music through noise-canceling headphones might positively affect male patients during flexible cystoscopy and evaluated how music from noise-canceling headphones affects feelings of anxiety and pain in male bladder cancer patients during follow-up cystoscopy.

Materials and Methods

Patients

This study involved 160 male bladder cancer patients who underwent follow-up using flexible cystoscopy from January 2022 to May 2022. Using computer-based block randomization (block size of four), the patients were placed into the no music group or the music group (groups 1 and 2, respectively; $n = 80$ per group). The study's inclusion criteria were being male, having bladder cancer, being >20 years old, intending to have the first follow-up cystoscopy, and having been previously diagnosed with non-muscle invasive bladder cancer after transurethral resection of bladder tumors (TURB). Patients meeting the following criteria were excluded from the study: being allergic to lidocaine, having a urinary tract infection, having anatomical problems involving the urethra or prostate, use of an analgesic 24 h before the procedure, having a history of anxiety disorder or other psychiatric diseases, having hearing loss, not being able to complete cystoscopy, and not being to complete questionnaires because of language impairment. Patient characteristics, including age, body mass index, medical history, cancer history, international prostate symptom score (IPSS), international index of erectile function (IIEF-5) score, prostate-specific antigen level, serum testosterone level, maximal flow rate, and post-void residual urine volume, were measured.

Assessment of Objective and Subjective Parameters Pre- and Post-Cystoscopy

Objective parameters, including systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, and arterial oxygen saturation, were measured before and after cystoscopy. Subjective parameters, including the pre-cystoscopy state-trait anxiety inventory (STAI)-state and STAI-trait scores, were measured within 1 week before the procedure. Post-cystoscopy STAI-state scores were measured immediately after cystoscopy without knowledge of their results. Patient anxiety was assessed using STAI, a self-reported anxiety inventory that uses two separate, 20-item multiple-choice subscales to measure trait (baseline) and state (situational) anxiety. Its overall scores range from 20 to 80, with higher scores indicating higher anxiety [10]. A visual analog scale (VAS) was used to assess pain level on a scale of 0–10, with 0 indicating "no pain" and 10 indicating "the worst pain imaginable." The post-procedure questionnaire included the assessment of overall satisfaction with the cystoscopy and the willingness to undergo the procedure again if needed (both on a scale of 0–10).

The primary outcome was how the two groups differed after cystoscopy, based on pain levels (VAS) and anxiety (STAI). The differences between the two groups in their satisfaction and willingness to undergo repeat cystoscopy (based on the VAS) were assessed as secondary outcomes.

Cystoscopy

An experienced physician (H.-J.C.) performed all cystoscopies. First, the patients were placed in a lithotomy position with no further interventions, such as biopsies. Next, the genitals and the surrounding area were disinfected using povidone-iodine. Fifteen minutes before the procedure, 11 mL of 2% lidocaine jelly was injected into the urethra. An Olympus 16F flexible cystoscope, with gravity-fed irrigation fluid, was used for cystoscopy.

Providing Music with Noise-Canceling Headphones

The music offered to the patients was chosen within 1 week of the cystoscopy based on the patients' preferred music genre and volume. The patients were given noise-canceling headphones (Bose QuietComfort 35 II Wireless Bluetooth Headphones, Bose, Framingham, MA, USA) in the procedure room, before the cystoscopy. After the procedure and randomization, the assistant checked whether music had been provided, as well as whether the preferred music genre and volume had been provided to the patients in the music group. The urologist performing cystoscopy was blinded to whether music was provided or not. Music was provided at the time of lidocaine administration and continued until after the procedure and patient transfer from the cystoscopy room.

Statistical Analyses

The appropriate sample size was calculated to be at least 128 patients (64 per group, $p < 0.05$, power: 80%). The criteria used for sample size calculation assumed VAS minimal clinical important mean difference of 1 and standard deviations of 2 for the intervention and control groups, respectively [11]. A total of 160 patients were included in the study to allow for possible dropouts (80 patients in each group). All statistical analyses were performed on SPSS version 20.0 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean ± standard deviation. Categorical variables are presented as frequencies (%). Differences between the two groups were compared using χ^2 tests for categorical data or independent t tests for continuous data. $p < 0.05$ indicates statistically significant differences.

Results

Table 1 summarizes the demographic data and preoperative characteristics of the enrolled patients. Patients were divided into group 1 (no music with noise-canceling headphones, $n = 80$) and group 2 (music from noise-canceling headphones, $n = 80$). All 160 patients

Table 1. Patients' characteristics and pre-cystoscopy status comparisons between the two groups (n = 160)

	Total	Group 1 (n = 80)	Group 2 (n = 80)	p value
Age, years	69.2±11.2	69.2±12.6	69.3±9.7	0.950
Body mass index, kg/m^2	23.8±2.8	23.7±2.8	24.0±2.9	0.615
Hypertension, n (%)	78 (48.8)	36 (45.0)	42 (52.8)	0.343
Cardiovascular disease, n (%)	13 (8.1)	5 (6.3)	8 (10.0)	0.385
Diabetes mellitus, n (%)	35 (21.9)	14 (17.5)	21 (26.3)	0.181
Other cancer history, n (%)	26 (16.3)	11 (13.8)	15 (18.8)	0.391
Prostate-specific antigen, ng/mL	1.8±1.9	1.7±1.4	1.9±2.2	0.371
Testosterone, ng/mL	3.1±1.2	3.1±1.1	3.2±1.3	0.770
Total IPSS score	11.4±7.1	11.9±7.5	10.9±6.7	0.377
Voiding symptom	6.0±4.8	6.2±5.1	5.8±4.5	0.612
Storage symptom	5.4±3.3	5.7±3.5	5.1±3.2	0.248
Maximal flow rate, mL/s	15.8±6.8	15.2±6.4	16.4±7.1	0.268
Post-void residual urine, mL	48.0±53.8	49.2±48.1	46.8±59.2	0.782
IIEF-5 score	8.8±7.8	8.5±7.5	9.0±8.0	0.663
Objective parameters				
Systolic BP, mm Hg	137.4±18.7	135.7±18.9	139.1±18.4	0.263
Diastolic BP, mm Hg	74.9±10.2	74.4±10.4	75.4±10.0	0.530
Heart rate, beats/min	80.2±13.4	80.2±14.9	80.2±11.8	0.991
Respiratory rate, breaths/min	19.9±0.1	19.9±0.2	19.9±0.2	0.652
Arterial oxygen saturation, %	96.8±1.4	96.8±1.4	96.9±1.4	0.492
Subjective parameters				
STAI-state score	42.5±8.9	41.7±9.0	43.2±8.7	0.270
STAI-trait score	39.2±8.0	38.7±8.3	39.8±7.8	0.388
Procedure time, min	3.2±0.3	3.2±0.3	3.2±0.2	0.486
Bladder mass detection, n (%)	31 (19.4)	16 (20.0)	15 (18.8)	0.841

IPSS, international prostate symptom score; IIEF, international index of erectile function; BP, blood pressure; STAI, state-trait anxiety inventory.

completed the study (Fig. 1). The patients had a mean age of 69.2 ± 11.2 years and a mean body mass index of 23.8 ± 2.8 kg/m^2. The number of patients with a history of hypertension, cardiovascular disease, diabetes mellitus, benign prostate hypertrophy, or other cancers was 78 (48.8%), 13 (8.1%), 35 (21.9%), 113 (70.6%), and 26 (16.3%), respectively. Other cancers included urologic cancers (kidney and prostate cancers) and non-urologic cancers (including colon, gastric, lung, skin, and thyroid cancers). The patients' mean IPSS and IIEF-5 scores were 11.4 ± 7.1 and 8.8 ± 7.8, respectively. The mean serum prostate-specific antigen and mean serum testosterone levels were 1.8 ± 1.9 ng/mL and 3.1 ± 1.2 ng/mL, respectively. The mean duration of the cystoscopy was 3.2 ± 0.3 min. Bladder masses were detected in 31 cases (19.4%). The patient characteristics, including objective and subjective pre-cystoscopy parameters, did not differ significantly between the two groups. The patients had no post-cystoscopy complications. After cystoscopy, patients with suspected bladder cancer recurrence underwent reTURB for confirmation.

Table 2 summarizes the post-cystoscopy objective and subjective parameters of the two groups. Objective post-cystoscopy parameters did not differ significantly between the two groups. In both groups, systolic BP, diastolic BP, and heart rate were elevated after cystoscopy when compared with before the procedure, but they were not significantly different between the two groups (p = 0.105, 0.435, and 0.189, respectively). However, post-cystoscopy subjective parameters differed significantly between the groups (online suppl. Fig. 1; for all online suppl. material, see https://doi.org/10.1159/000539312). The mean scores for STAI-state, VAS, satisfaction, and willingness to repeat cystoscopy (post-

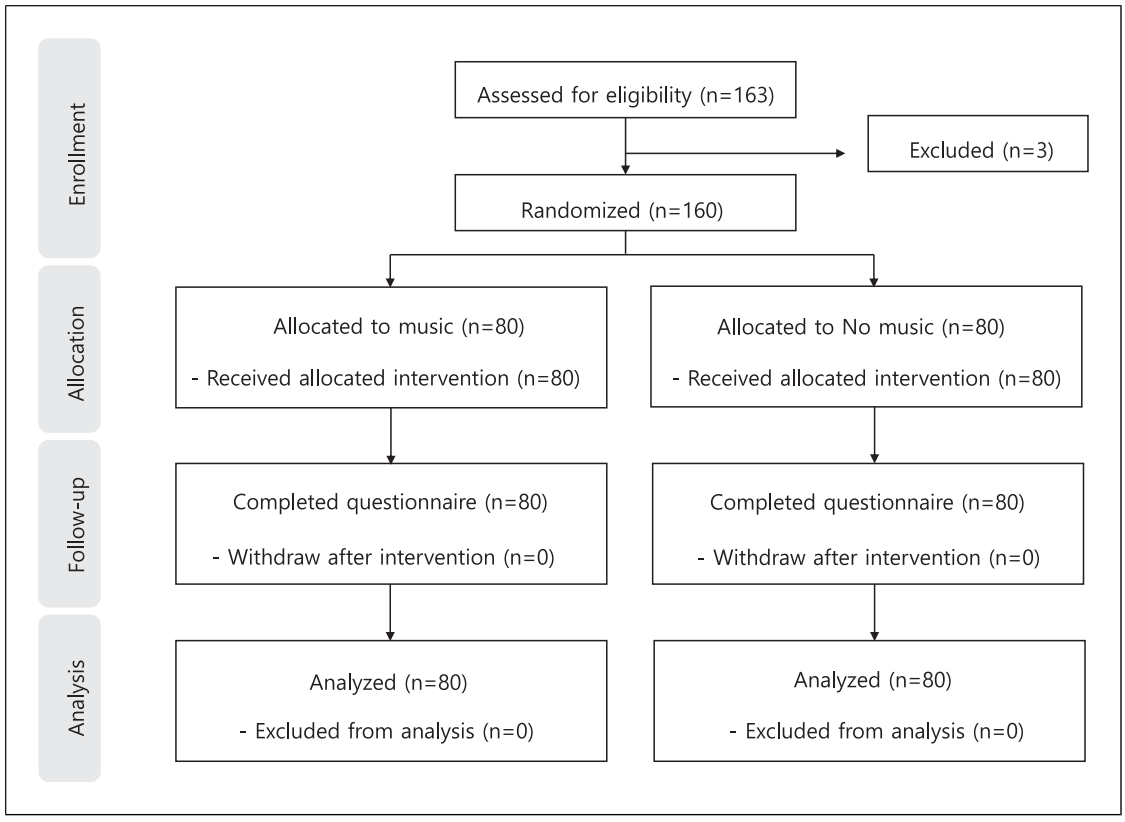

Fig. 1. Flowchart of the study.

Table 2. Comparisons of the post-cystoscopy parameters between the two groups (n = 160)

	Total	Group 1 (n = 80)	Group 2 (n = 80)	p value
Objective parameters				
Systolic BP, mm Hg	143.3±18.3	143.5±18.5	143.2±18.1	0.928
Post-cystoscopy change	5.9±13.9	7.7±15.0	4.2±12.7	0.105
Diastolic BP, mm Hg	77.1±13.4	77.2±14.3	76.9±12.5	0.920
Post-cystoscopy change	2.2±9.9	2.9±10.1	1.6±9.7	0.435
Heart rate, beats/min	82.6±12.2	83.6±13.3	81.7±11.1	0.321
Post-cystoscopy change	2.4±9.1	3.3±11.0	1.4±6.8	0.189
Respiratory rate, breaths/min	20.0±0.0	20.0±0.0	20.0±0.0	1.000
Post-cystoscopy change	0.0±0.2	0.0±0.2	0.0±0.2	0.652
Arterial oxygen saturation, %	96.3±2.6	96.0±3.0	96.6±2.1	0.103
Post-cystoscopy change	−0.5±2.9	−0.8±3.3	−0.3±2.5	0.271
Subjective parameters				
STAI-state score	41.0±6.7	42.7±6.7	39.4±6.4	0.002
Post-cystoscopy change	−1.4±10.2	1.0±10.0	−3.9±9.8	0.002
VAS score	5.1±1.8	5.3±1.8	4.8±1.8	0.054
Satisfaction	5.8±1.8	5.2±1.6	6.5±1.8	0.001
Willing to repeat cystoscopy	5.8±2.6	5.0±2.5	6.6±2.4	0.001

BP, blood pressure; STAI, state-trait anxiety inventory; VAS, visual analog scale.

cystoscopy subjective parameters) were 41.0 ± 6.7, 5.1 ± 1.8, 5.8 ± 1.8, and 5.8 ± 2.6, respectively. The post-cystoscopy STAI-state score was significantly lower in group 2 when compared with group 1 ($p = 0.002$). In both groups, the pre- and post-cystoscopy STAI-state scores differed significantly ($p = 0.002$). When compared with group 1, the post-cystoscopy VAS scores for patient satisfaction and their willingness to repeat the procedure were higher in group 2 ($p = 0.001$ and 0.001, respectively), whereas the mean post-cystoscopy VAS score for pain was lower in group 2, although the difference was not statistically significant.

Discussion

Because of the high risk of bladder cancer recurrence, patients require rigorous cystoscopy-based surveillance, which can negatively impact the patient's quality of life [2]. Although pain scores did not differ between the groups, we observed that in male bladder cancer patients, music played through noise-canceling headphones had positive effects on anxiety, satisfaction, and the willingness to undergo repeat flexible cystoscopy.

Because the urethra differs anatomically between sexes [7], male patients who undergo cystoscopy complain of anxiety and pain more than female patients [12]. Several studies have reported that lidocaine jelly, increased irrigation flow rate, analgesic drugs, stress balls, hand holding, and a flexible cystoscope help relieve patients' discomfort during cystoscopy [6, 13, 14]. However, regular long-term follow-up of bladder cancer patients using cystoscopy still poses a significant burden to patients not only because of pain and cystoscopy-associated anxiety but also because of the anxiety associated with the risk of cancer recurrence and progression [15].

Cancer diagnosis causes anxiety and negatively impacts the patient's mental health and quality of life [16]. Thus, clinicians should be concerned about the anxiety caused by routine clinical appointments and provide psychosocial support to the patients [2]. The biological mechanisms underlying the relationship between the physiological effects of anxiety and pain perception are well known [17]. In a recent study, music therapy reportedly modulated pain perception via at least two different mechanisms involving changes of activity in the delta and gamma bands at different stages of the pain processing system [18].

By playing music, the dosage of sedatives and analgesics can be reduced because music may reduce the perception of discomfort by activating the cingulo-frontal cortex, a brain area associated with pain control [19]. A systematic review found that in adults with cancer when compared with standard care, music interventions may have beneficial effects on anxiety, pain, depression, hope, and fatigue [20]. Several studies have demonstrated the advantages of providing music to patients as an additional treatment option during urologic clinical procedures, including prostate biopsies, urodynamic studies, rigid/flexible cystoscopy, and extracorporeal shock wave lithotripsy [12, 21–23].

Based on several parameters, two studies have described the effects of music on patients undergoing rigid cystoscopy, including positive effects on pain and anxiety [12, 20]. However, flexible cystoscopy is now the gold standard for bladder exploration because it causes less discomfort to the patients, and the equipment is easier to prepare and maintain [24]. Three studies have reported the beneficial effects of music on patients undergoing their first flexible cystoscopy [9, 12]. A study by Zhang et al. [25], in which patients listened to classical/Chinese folk/foreign music, suggested that listening to preferred room music during cystoscopy is an easy way of improving comfort and reducing anxiety in male patients. A study by Raheem et al. [26], in which male and female patients listened to the same excerpt of classical music during flexible cystoscopy, showed that listening to room music decreased anxiety and pain. A recent study has suggested that in male patients, listening to pure binaural beats or classical music through headphones may effectively reduce the anxiety levels and pain scores associated with diagnostic cystoscopy and ureteral stent removal [27]. However, another recent study found no difference in the effect of music on patients during flexible cystoscopy [9], although that study involved an ethnically heterogeneous group and cystoscopy was performed by three clinicians under the same room music. Moreover, these four studies involving flexible cystoscopy were performed on non-cancer patients. Furthermore, each of these studies had at least one of the following limitations, which may have affected their findings: (1) by providing room music, the physicians were not blinded to the study conditions, (2) music selection was not based on the patients' preferences, and (3) the procedure was performed by multiple physicians.

To minimize these limitations, our study used noise-canceling headphones to direct the music to the patients only. Providing music through noise-canceling headphones may exclude interfering noises, allowing users to better understand and focus on the sound coming through the headphones in a quiet environment [28]. Moreover, we allowed the patients to pick their preferred music genre and volume before the procedure. All study participants wore noise-canceling headphones, and to minimize possible bias, all cystoscopy was performed by the same physician (H.-J.C.), who was blinded to the experimental conditions. In our study, the vital signs of the objective parameters did not

differ between the music and the no music groups, which is consistent with previous studies. Additionally, VAS scores for pain during the procedure did not differ significantly between the groups, and this may have been influenced by the experience of the physician and the flexible cystoscope. However, other subjective parameters revealed the beneficial effects of providing music to the patients through noise-canceling headphones.

This study has some limitations. First, it is a single-center study involving a patient population from one region, and pain sensitivity may vary by region and race [29]. Hence, larger studies involving multiple regions are needed to validate our findings. Because the patients involved in this study had been diagnosed with bladder cancer and were having their first follow-up cystoscopy, the results of this study might have been influenced by previous cystoscopy in cases where the procedure had been performed before cancer diagnosis. Additionally, the pain and discomfort caused by the movement of the flexible cystoscope may vary depending on the course of the procedure, and data could not be collected at each step. Thus, in future studies, devices are needed to immediately and accurately estimate the patients' state, as well as to confirm the influence of music. In order to increase their focus on the music and help them feel more comfortable, patients were prompted to choose their preferred music genre and volume. Notably, however, the study results could still have been affected by different music genres and volumes. Finally, to blind the physician during the procedure, all patients wore headphones, which limited our ability to assess the effects of noise-canceling headphones without music. Nonetheless, our study is important because it is the first to demonstrate the positive effects of playing music through noise-canceling headphones during flexible cystoscopy in male bladder cancer patients.

Conclusion

In male bladder cancer patients, music from noise-canceling headphones could have reduced anxiety and improved satisfaction and the willingness to repeat cystoscopy. These findings improve our understanding of the effects playing music through noise-canceling headphones has on cancer patients and have potential application in the reduction of discomfort during cystoscopy in bladder cancer patients.

Statement of Ethics

The study adhered to the Declaration of Helsinki guidelines and the Ethical Guidelines for Clinical Studies. The study protocol was approved by the Institutional Review Board of the Chonnam National University Hwasun Hospital (approval number: CNUHH-2021-060). All participants gave written informed consent.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Concept and design: Ho Seok Chung. Data acquisition, analysis, and interpretation: Hyun-Jin Cho, Eu Chang Hwang, and Seung Il Jung. Funding acquisition: Ho Seok Chung. Drafting of the manuscript: Ho Seok Chung and Hyun-Jin Cho. Critical revision of the manuscript for important intellectual content: Eu Chang Hwang, Darshan P. Patel, Tung-Chin Hsieh, Dongdeuk Kwon, and Kwangsung Park. Supervision: Ho Seok Chung, Darshan P. Patel, and Tung-Chin Hsieh. Approval of the final manuscript: all authors.

Data Availability Statement

All data generated or analyzed during this study are included in this manuscript and its online supplementary material. Further inquiries can be directed to the corresponding author, if needed.

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