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**Research Article** 

# The Effect of Binaural Beat Music on Reducing Anxiety and Pain and Increasing Satisfaction of Ophthalmic Ambulatory Surgery Patients

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#### Abstract

**Background:** Preoperative anxiety can reduce the quality of anesthesia and increase the need for anesthetic medications, which can inadvertently increase the length of anesthesia and delay awakening, which results in more complications of anesthesia and surgery.

**Objectives:** The purpose of this study is to investigate the effect of binaural beat music (BBM) on anxiety, pain and satisfaction of patients with eye surgery.

**Methods:** This clinical trial enrolled sixty patients presenting to the surgical unit of Imam Khomeini Hospital in Kermanshah who were randomly assigned to two groups of binaural beat music group (n = 30) and control group (n = 30). Midazolam and propofol (if needed) were used in the conventional opioid group, while binaural beat music was played from 5 minutes before to the end of the surgery in addition to fentanyl (1 cc). Scores of state and trait anxiety (measured by STAI), pain score (measured by VAS), hemodynamic changes before and after surgery, patient satisfaction and surgeon satisfaction were recorded and compared between the two groups.

**Results:** State anxiety after surgery was significantly lower in the BBM group than that in the control group (P < 0.05). There was no significant difference between the two groups regarding trait anxiety symptoms and postoperative pain (P > 0.05). The level of state anxiety, trait anxiety and pain decreased significantly in the BBM group after surgery (P < 0.05). Furthermore, state anxiety and trait anxiety decreased significantly in the control group after surgery (P < 0.05). However, no significant difference was observed between the amount of pain before and after surgery in the control group (P > 0.05). There was no significant difference between systolic blood pressure, heart rate, SPO<sub>2</sub> after surgery in the two groups (P > 0.05). There was no significant difference between patient satisfaction and surgeon satisfaction in the two groups (P > 0.05).

**Conclusions:** Binaural beat music is effective in reducing anxiety and pain, controlling hemodynamic changes, and increasing the satisfaction of patients undergoing eye surgery, and can be a suitable alternative for opioid and sedative medications in anesthetized patients undergoing eye surgery.

*Keywords:* State Anxiety, Trait Anxiety, Binaural Beat Music (BBM)

#### 1. Background

Surgery is a usual treatment modality in many hospitals, with unwanted complications such as pain and anxiety (1). Surgery can provoke psychological reactions such as anxiety, and physical reactions like changes in physiological functions of the body including hypertension and tachycardia. A total of 23 million people undergo surgery annually in the United States alone, most of whom experience preoperative anxiety (2). Like pain, anxiety adversely affects recovery and tissue repair. In addition, too much psychological and physical strain induced by anxiety and pain can cause fatigue and a series of biochemical activities in patients that stimulate autonomic system, muscular tension, and increased production of corticosteroids (3). Retaining energy is necessary for tissue recovery and repair, and strategies to alleviate physical and psychological symptoms justify the use of non-pharmacological therapies such as massage therapy, oil therapy and music therapy in nursing care (4). The tendency to use nonpharmacological techniques to relieve pain and anxiety is currently increasing. One of these techniques is using

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pleasant sound stimuli, referred to as music therapy (5). Music has long been used as a means to evoke enthusiasm and motivation, as well as a therapeutic tool. Egyptians used music for treating women's infertility, and the relics suggest that Iranians used the sound of the lute to cure many patients (6). In Zoroastrian era, physicians used Persian music to treat their patients, and in the Sassanid court, music was among a physician's tools when women gave birth (7). About understanding music, Avicenna asserts: Music therapy and listening to music has a long history as a curing and healing factor (8). Moreover, music relieves pain and anxiety of the patient by distracting their attention and focus from anxiety-inducing stimuli (9). Relaxation is among psychological effects of music, which reduces heart rate, respiratory rate, and metabolism (10), and some studies have reported that music stabilizes blood pressure and heart rate after surgery (11). In a number of studies, music has been effective in reducing the amount of sedatives needed during surgery (12). The results of experimental studies conducted in western countries, Thailand, China, and Japan on the effects of music suggested that music alleviates pain and anxiety. The results of a study conducted on a specific type of folklore music in Java-Indonesia also showed reduced pain and anxiety in patients (13). Each kind of music can have specific and different effects on the person. A kind of music that can induce psychological and physiological effects similar to a particular medication will be highly valuable. The present study investigates the effect of a specific type of music called Binaural Beat Music (BBM) on anesthesia in patients undergoing eye surgery. BBM is currently regarded as auditory and digital opioid with a particular frequency that is claimed to create feelings equivalent to those of using some drugs. The fact that not many studies have investigated this type of music makes it necessary to conduct this study.

Moreover, not using medication and reducing complications of anesthesia in outpatient surgeries are the results of using BBM. In an experimental study by Hojjati et al. titled "The effect of music therapy on pulse and blood pressure variations in patients undergoing cesarean section" in Hakim Jorjani Hospital in Gorgan, on case (30 patients) and control (30 patients) groups, 15 - 20 minutes of light music was played for mothers in the case group. The results showed that music therapy before entering operating room reduced postoperative hemodynamic variations in mothers undergoing cesarean section and shortened the patient recovery period. Thus, music therapy should be considered by physicians, nurses, and medical team (14). In a prospective study by Atari et al. titled "The effect of sound of Quran on reducing anxiety and stabilizing patients' vital signs before inducing anesthesia" in two hospitals affiliated to Isfahan University of Medical Sciences", the results showed less mean anxiety changes, and also less mean heart rate changes compared to the study group. No significant difference was found between the two groups in systolic and diastolic blood pressure and respiratory rate. Given the effectiveness of the sound of Quran in reducing anxiety and cardiovascular stabilization, and considering benefits such as less time, lower costs, and safety, this method can be recommended for reducing patients' preoperative anxiety (15). In a randomized controlled clinical trial conducted by Nilsson on 42 patients, the analgesic and anxiolytic effects of music on the incidence of various systemic symptoms were investigated. Their results showed that music significantly reduces heart rate in 27% of cases, pain in 59%, and anxiety in 50% (16). Cruise et al. found that music has no effect on reducing anxiety of older patients undergoing cataract surgery. But, their systolic blood pressure, pulse rate and respiratory rate reduced after intervention (17). In a study by Wiwatwongwana et al. on 141 patients undergoing cataract surgery with local anesthesia, patients were randomly divided into three groups: patients receiving BBM, patients receiving plain music as intervention group (MI), and a control group (with headphone playing no music). Blood pressure and heart rate were measured at admission and 20 minutes into the operation. Anxiety caused by surgery was measured using State-Trait Anxiety Inventory (STAI). The results showed a greater reduction in heart rate in patients receiving BBM (18). In a study in China, Angela et al. examined 64 randomly selected patients, who received 30 minutes of music therapy. Anxiety, physiological indicators and patients' behavior during relaxation in two groups were recorded before and after the study. The patient satisfaction with music after listening to music was also recorded. The results showed that patients under mechanical ventilation who had listened to 30 minutes of music showed more calmness in the form of reduced physiological indicators and increased relaxation (19).

# 2. Objectives

The present study was conducted to collect comprehensive and accurate data on the effect of BBM on the quality of eye surgery anesthesia. If this modality if proved effective, it can be recommended as an alternative or in conjunction with other modalities to be integrated in plans and policies needed to prevent anxiety, pain, etc., as well as to pave the way for future studies.

### 3. Methods

In the present randomized clinical trial, the study population consisted of patients attending Imam Khomeini Teaching Hospital in Kermanshah. Those who met the study inclusion criteria were selected by convenience sampling method and signed informed consent. The study sample size of 60 patients was randomly divided into two groups of 30 patients. According to mean and standard deviation of vital signs in similar studies and using mean comparison equation, with 95% confidence interval and 80% power, sample size was determined 30 patients per group. These 60 patients were selected non-randomly, and then randomly divided into two 30-patient groups. Patients were initially selected non-randomly and in accordance with the study inclusion criteria. The two groups matched in terms of age and gender. STAI (to assess anxiety) and VAS (for pain score) were completed by both groups of patients. After entering the operating room, target patients were connected to the monitor and made ready for surgery with anesthesia by an anesthesia technician. Before the intervention, patients' vital signs including systolic and diastolic blood pressure, and pulse rate and respiratory rate were measured and recorded, and then in addition to using opioid (1 cc of fentanyl), instrumental BBM was played for patients by an MP3 player through disposable Samsung stereo headphones from five minutes before surgery until the end. Music was played five minutes before surgery until patient transfer to recovery ward (PACU), and then immediately afterwards, the patient's vital signs were measured and recorded again. Before entering the operating room, the control group completed the above questionnaires, were connected to the monitor and made ready for the eye surgery by an anesthesia technician, and received opioid (1 cc of fentanyl) with topical anesthesia; and were injected with midazolam and propofol if required and at discretion of the anesthesiologist. Vital signs were assessed by one of the anesthesia technicians. Data were collected using a questionnaire containing the patients' demographic and medical details such as age, gender, vital signs including pulse rate, respiratory rate, and systolic and diastolic blood pressure. These signs were assessed before intervention, every five minutes during intervention and immediately and 30 minutes after intervention by Data Scope Pasport-2 Monitoring Device. After completion of the checklist, data were entered into the computer and analyzed in SPSS. Spielberger State-Trait Anxiety Inventory (STAI) whose validity and reliability has been assessed in Iranian studies and reported 87% and 90% was prepared. The study inclusion criteria were patient's willingness to take part, elective surgery, age range of 18 to 70 years, no history of eye surgery, hemodynamic stability (90 mmHg < systolic blood pressure < 140 mmHg), no serious dysrhythmias, and heart rate between 60 and 100 beats per minute. The study exclusion criteria were seizure, history of neurological diseases or space occupying lesions, history of neuropsychiatric diseases, history of chronic pains, impaired hearing, non-outpatient surgery, less than 18 years of age, older than 70 years of age or senility, uncontrolled hypertension, pregnancy (in women), drug or alcohol addiction, history of chronic pains, use of opioids four hours before intervention, and history of playing a musical instrument. Furthermore, patients with complications during surgery and anesthesia, and those unwilling to continue were also excluded.

The patients' severity of pain was assessed by VAS. Patients were asked to identify their severity of pain on a 10cm ruler, which was a number between 0 and 10, where 0 indicated no pain and 10 the worst pain. Zero indicates no pain, 1 to 3 mild pain, 4 to 6 moderate pain, and 7 and higher shows severe pain (20).

#### 3.1. Data Analysis

Descriptive and analytical statistics (mean, median, and standard deviation) were used for quantitative variables, and frequency and relative frequency for qualitative variables in the form of one-dimensional and multidimensional tables. Variables were first assessed in terms of normal distribution using Kolmogorov-Smirnov test, and then analyzed using *t* and paired *t* tests. U Mann-Whitney and Wilcoxon tests were used instead of the above tests for non-normally distributed variables. Data were analyzed in SPSS at a significance level of 0.05.

# 4. Results

The present study was conducted on 60 patients undergoing eye surgery in Imam Khomeini Hospital in Kermanshah in 2017 if they met the inclusion criteria, of whom, 30 patients (50%) were assigned to BBM group and 30 (50%) to conventional group. Table 1 presents descriptive details and comparison of age and gender of patients undergoing eye surgery in BBM and conventional groups.

The results presented in Table 1 show no significant difference between BBM and conventional groups in terms of age and gender of patients undergoing eye surgery (P > 0.05).

# 4.1. Comparison of State Anxiety in Two Groups of Patients Undergoing Eye Surgery

The two groups were compared before and after surgery using U Mann-Whitney test. The levels of state

Feature	Group		PValue
feature	BBM	Conventional	i vulue
Age, y (mean $\pm$ SD)	$57.46 \pm 4.26$	$57.56 \pm 6.03$	0.941
Gender, No. (%)			0.606
Female	14 (46.7)	17 (56.7)	
Male	16 (53.3)	13 (43.3)	

 
 Table 1. Descriptive Details and Comparison of Age and Gender of Patients Undergoing Eye Surgery in BBM and Conventional Groups

anxiety before and after surgery in BBM and conventional groups were compared using paired t and Wilcoxon tests.

Table 2 presents descriptive details and comparison of state anxiety before and after surgery in patients undergoing eye surgery in BBM and conventional groups.

The intergroup comparison results presented in Table 2 show no significant difference between the two groups in terms of state anxiety before surgery (P > 0.05), but this difference was significant after surgery (P < 0.05).

The intragroup comparison showed that state anxiety in BBM group significantly reduced after surgery compared to before (P < 0.05). Moreover, state anxiety in conventional group also significantly reduced after surgery compared to before (P < 0.05).

# 4.2. Comparison of Trait Anxiety in Two Groups of Patients Undergoing Eye Surgery

The two groups were compared in terms of trait anxiety before and after surgery using U Mann-Whitney test. The levels of trait anxiety before and after surgery in BBM and conventional groups were compared using paired t and Wilcoxon tests.

Table 3 presents descriptive details and comparison of trait anxiety before and after surgery in patients undergoing eye surgery in BBM and conventional groups.

The intergroup comparison results presented in Table 3 show no significant difference between the two groups in terms of trait anxiety before surgery (P > 0.05), and also no significant difference between them after surgery (P > 0.05).

The intragroup comparison showed that trait anxiety in BBM group significantly reduced after surgery compared to before (P < 0.05). Moreover, trait anxiety in conventional group also significantly reduced after surgery compared to before (P < 0.05).

# 4.3. Comparison of Pain Levels in Two Groups of Patients Undergoing Eye Surgery

The two groups were compared in terms of pain levels before and after surgery using U Mann-Whitney test. The

pain levels before and after surgery in BBM and conventional groups were compared using paired t and Wilcoxon tests.

Table 4 presents descriptive details and comparison of pain levels before and after surgery in patients undergoing eye surgery in BBM and conventional groups.

The intergroup comparison results presented in Table 4 show no significant difference between the two groups in terms of pain levels before surgery (P > 0.05), and also no significant difference between them after surgery (P > 0.05).

The intragroup comparison showed that pain levels in BBM group significantly reduced after surgery compared to before (P < 0.05). But, no significant reduction was observed in pain level in conventional group after surgery compared to before (P > 0.05).

### 4.4. Comparison of Systolic Blood Pressure in Two Groups of Patients Undergoing Eye Surgery

The two groups were compared in terms of systolic blood pressure before and after surgery using U Mann-Whitney test. The systolic blood pressure before and after surgery in BBM and conventional groups were compared using paired t and Wilcoxon tests.

Table 5 presents descriptive details and comparison of systolic blood pressure before and after surgery in patients undergoing eye surgery in BBM and conventional groups.

The intergroup comparison results presented in Table 5 show no significant difference between the two groups in terms of systolic blood pressure before surgery (P > 0.05), and no significant difference between them after surgery (P > 0.05).

The intragroup comparison showed that systolic blood pressure in BBM group significantly reduced after surgery compared to before (P < 0.05). Moreover, systolic blood pressure in conventional group also significantly reduced after surgery compared to before (P < 0.05).

# 4.5. Comparison of Diastolic Blood Pressure in Two Groups of Patients Undergoing Eye Surgery

The two groups were compared in terms of diastolic blood pressure before and after surgery using independent t test. The diastolic blood pressure before and after surgery in BBM and conventional groups were compared using paired t and Wilcoxon tests.

Table 6 presents descriptive details and comparison of diastolic blood pressure before and after surgery in patients undergoing eye surgery in BBM and conventional groups.

The intergroup comparison results presented in Table 6 show no significant difference between the two groups in

Fable 2. Descriptive Details and Comparison of Stat	e Anxiety Before and Afte	er Surgery in Patients Ur	ndergoing Eye Surgery in	Study Groups
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Measurement Occasion	(	Group Intergroup Compar		Comparison
	BBM, Mean $\pm$ SD	Conventional, Mean $\pm$ SD	Test stat	P <sub>1</sub> Value
Before surgery	$42.66 \pm 8.18$	$42.56\pm8.6$	0.134	0.894
After surgery	$29.93 \pm 5.64$	$35.76\pm8.52$	2.91	0.004
Intragroup comparison				
Test stat	4.78	10.55		
P <sub>2</sub> value	< 0.001	< 0.001		

Table 3. Descriptive Details and Comparison of Trait Anxiety Before and After Surgery in Patients Undergoing Eye Surgery in Study Groups

(	Group Intergroup Con		Comparison
BBM, Mean $\pm$ SD	Conventional, Mean $\pm$ SD	Test Stat	P <sub>1</sub> Value
36.93±6.87	36.03±6.15	0.461	0.645
29±4.87	31.46±5.84	1.47	0.139
4.71	4.8		
< 0.001	< 0.001		
	BBM, Mean ± SD         36.93±6.87           29±4.87         4.71           4.71         < 0.001	Group           BBM, Mean ± SD         Conventional, Mean ± SD           36.93 ± 6.87         36.03 ± 6.15           29 ± 4.87         31.46 ± 5.84           4.71         4.8           < 0.001         < 0.001	Group         Intergroup           BBM, Mean ± SD         Conventional, Mean ± SD         Test Stat           36.93 ± 6.87         36.03 ± 6.15         0.461           29 ± 4.87         31.46 ± 5.84         1.47           4.71         4.8            < 0.001         < 0.001

Table 4. Descriptive Details and Comparison of Pain Levels Before and After Surgery in Two Groups of Patients Undergoing Eye Surgery

Measurement Occasion -	(	Group Interg		roup Comparison	
	BBM, Mean $\pm$ SD	Conventional, Mean $\pm$ SD	Test Stat	P <sub>1</sub> Value	
Before surgery	$1.23\pm1.4$	$1 \pm 1.61$	1.1	0.27	
After surgery	$0.66\pm0.95$	$0.46 \pm 1.16$	1.46	0.143	
Intragroup comparison					
Test stat	2.04	10.8			
P <sub>2</sub> value	0.041	0.071			

Table 5. Descriptive Details and Comparison of Systolic Blood Pressure Before and After Surgery in Two Groups of Patients Undergoing Eye Surgery

Measurement Occasion	(	Group Intergroup Com		Comparison
	BBM, Mean $\pm$ SD	Conventional, Mean $\pm$ SD	Test Stat	P <sub>1</sub> Value
Before surgery	$141.13 \pm 16.25$	$138.93 \pm 16.87$	0.516	0.608
After surgery	$130.63\pm26.72$	$134.23 \pm 14.88$	0	1
Intragroup comparison				
Test stat	4.78	2.6		
P <sub>2</sub> value	< 0.001	0.014		

terms of diastolic blood pressure before surgery (P> 0.05), but a significant difference was observed between them after surgery (P< 0.05).

The intragroup comparison showed that diastolic blood pressure in BBM group significantly reduced after surgery compared to before (P < 0.05). But, no significant reduction was observed in diastolic blood pressure in conventional group after surgery compared to before (P >

#### 0.05).

# 4.6. Comparison of Heart Rate in Two Groups of Patients Undergoing Eye Surgery

The two groups were compared in terms of heart rate before and after surgery using independent t test. Heart rate before and after surgery in BBM and conventional groups were compared using paired t and Wilcoxon tests.

Measurement Occasion	(	Group Intergroup Compar		Comparison
	BBM, Mean $\pm$ SD	Conventional, Mean $\pm$ SD	Test Stat	P1 Value
Before surgery	$83.76\pm8.32$	$86.4\pm7.52$	1.28	0.204
After surgery	$80.6\pm7.36$	$84.36\pm7.1$	2.01	0.048
Intragroup comparison				
Test stat	3.95	1.67		
P2 value	< 0.001	0.105		

Table 6. Descriptive Details and Comparison of Diastolic Blood Pressure Before and After Surgery in Two Groups of Patients Undergoing Eye Surgery

Table 7 presents descriptive details and comparison of heart rates before and after surgery in patients undergoing eye surgery in BBM and conventional groups.

The intergroup comparison results presented in Table 7 show no significant difference between the two groups in terms of heart rates before surgery (P > 0.05), and no significant difference between them after surgery (P > 0.05).

The intragroup comparison showed that heart rate in BBM group significantly reduced after surgery compared to before (P < 0.05). Moreover, heart rate in conventional group also significantly reduced after surgery compared to before (P < 0.05).

# 4.7. Comparison of SPO2 in Two Groups of Patients Undergoing Eye Surgery

The two groups were compared in terms of SPO<sub>2</sub> before and after surgery using U Mann-Whitney test. The SPO<sub>2</sub> before and after surgery in BBM and conventional groups were compared using Wilcoxon test.

Table 8 presents descriptive details and comparison of SPO<sub>2</sub> before and after surgery in patients undergoing eye surgery in BBM and conventional groups.

The intergroup comparison results presented in Table 8 show no significant difference between the two groups in terms of SPO<sub>2</sub> before surgery (P > 0.05), and no significant difference between them after surgery (P > 0.05).

The intragroup comparison showed no significant difference in SPO<sub>2</sub> before and after surgery in BBM group (P > 0.05), and no significant difference in SPO<sub>2</sub> before and after surgery in conventional group (P > 0.05).

4.8. Comparison of Satisfaction in Two Groups of Patients Undergoing Eye Surgery

The two groups were compared in terms of satisfaction using chi-square test.

Table 9 presents descriptive details and comparison of satisfaction in two groups of patients undergoing eye surgery.

The intergroup comparison results presented in Table 9 show no significant difference between the two groups in

terms of satisfaction of patients undergoing eye surgery (P > 0.05).

4.9. Comparison of Satisfaction of Surgeon of Two Groups of Patients Undergoing Eye Surgery

The surgeon's satisfaction levels with eye surgery of two groups of patients were compared using chi-square test.

Table 10 presents descriptive details and comparison of surgeon's satisfaction levels in two groups of patients undergoing eye surgery.

The results presented in Table 10 show no significant difference in surgeon's satisfaction with two groups of patients undergoing eye surgery (P > 0.05).

#### 5. Discussion

The present study results showed no significant difference between the two groups of patients undergoing eye surgery in terms of age and gender. Hence, randomization process was carried out well, and age and gender variables could not affect the difference between the two groups in treatment outcomes as confounding factors.

According to the most important results, state anxiety level after surgery was lower in BBM group than that in conventional group. No difference was observed between the two groups undergoing eye surgery in state anxiety and pain after surgery. State and trait anxiety levels decreased after surgery compared to before in both BBM and conventional groups. Moreover, pain level reduced after surgery compared to before in BBM group, but no difference was observed between pain levels before and after surgery in conventional group. Therefore, using BBM can be said to be as effective as opioids in anesthesia in reducing state and trait anxiety and pain levels. Some studies have recently recommended the use of BBM for reducing anxiety and pain in patients undergoing various surgeries (11, 18, 20, 21). In agreement with the present study results, Wiwatwongwana et al. (18) realized that using BBM

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Measurement Occasion –	(	Group Intergroup Compar		Comparison
	BBM, Mean $\pm$ SD	Conventional, Mean $\pm$ SD	Test Stat	P <sub>1</sub> Value
Before surgery	$79.06 \pm 13.22$	$79 \pm 13.2$	0.02	0.984
After surgery	$75.2\pm11.28$	$75.26\pm10.67$	0.024	0.981
Intragroup comparison				
Test stat	4.53	2.84		
P <sub>2</sub> value	< 0.001	0.008		

Table 7. Descriptive Details and Comparison of Heart Rates Before and After Surgery in Two Groups of Patients Undergoing Eye Surgery

Table 8. Descriptive Details and Comparison of SPO<sub>2</sub> Before and After Surgery in Two Groups of Patients Undergoing Eye Surgery

Measurement Occasion		Group Intergroup Comparis		Comparison
	BBM, Mean $\pm$ SD	Conventional, Mean $\pm$ SD	Test Stat	P <sub>1</sub> Value
Before surgery	$98.63 \pm 1.73$	99.1 ± 1.06	0.6	0.549
After surgery	$98.96 \pm 1.29$	$99.06 \pm 1.17$	0.255	0.799
Intragroup comparison				
Test stat	1.28	0.105		
P <sub>2</sub> value	0.199	0.916		

Table 9. Descriptive Details and Comparison of Satisfaction in Two Groups of Patients Undergoing Eye Surgery

Patient Satisfaction —	G	Group Test Stat		P. Value	
	BBM	Conventional		1 <sub>1</sub> value	
With	28 (93.3%)	28 (93.3%)	0	1	
Without	2 (6.7%)	2 (6.7%)	0	1	
Table 10. Descriptive Details and Compari	ison of Surgeon's Satisfaction Levels in Tw	vo Groups of Patients Undergoing Eye Sur	gery		

Surgeon Satisfaction	Gro	Group Test Stat		P. Value
	BBM	Conventional	rest stat	1] vinue
With	30 (100%)	30 (100%)	0	1
Without	0 (0%)	0 (0%)	0	1

and easy music compared to no music group led to reduced anxiety after intervention (based on SATI scale) in patients undergoing cataract surgery. However, no difference was found between BBM and plain music groups in terms of anxiety level. In agreement with the present study results, Chuter et al. (21) found that anxiety (based on VAS scale) reduced further in patients receiving BBM compared to plain music after elective surgeries (22). In agreement with the present study results, Padmanabhan et al. (11) found that using BBM and plain music compared to no music group led to reduced anxiety after intervention (based on SATI scale) by 26.3%, 11.1%, and 3.4% respectively in patients undergoing elective surgery. Hence, BBM has a significant potential for reducing acute preoperative anxiety. Weiland et al. (23) compared different types of music and listening methods in emergency patients with anxiety, and found that BBM reduced anxiety most (based on SATI) in these patients. The mechanism of action of BBM in reducing anxiety of patients undergoing eye surgery can be attributed to the sedative and anxiolytic effects of betaendorphin and serotonin neurotransmitters and inhibition of dopamine's anxiety effects. The results obtained by Jemmer showed that at beta and gamma frequencies, stimulation of brain waves leads to increased dopamine, and at alpha and theta leads to increased serotonin in the brain (24). The results obtained by Wahbeh et al. showed that adjusting brain waves at theta frequency leads to depletion of dopamine neurotransmitter in the brain (25). The results of a study by Peniston and Kulkosky showed that alpha/theta protocol leads to increased beta-endorphin in the brain, and the mechanism of this effect is revealed by the fact that beta-endorphin and serotonin neurotransmitters have a key role in sedation and control of anxiety, and that dopamine is known as the key factor in most anxiety disorders. Hence, mitigating anxiety by adjusting brain waves can be considered to be due to changes in the level of neurotransmitters (26). The results of a study conducted by Kienast et al. showed that dopamine release under stress leads to storage of this neurotransmitter in the amygdala and increased dopamine reserves in the amygdala is a factor for the person's anxious mood. Thus, reduced dopamine level due to adjustment of brain waves can lead to reduced dopamine reserves in the amygdala, resulting in reduced trait anxiety in the person (27). Comparison of hemodynamic changes in the present study revealed that postoperative diastolic blood pressure was lower in BBM compared to conventional group. However, no difference was observed between the two groups in postoperative systolic blood pressure, heart rate, and SPO<sub>2</sub>. But, systolic and diastolic blood pressure, and heart rate in BBM group reduced after surgery compared to before. Moreover, systolic blood pressure and heart rate in conventional group decreased after surgery compared to before. But, no difference was found in systolic blood pressure between before and after surgery in conventional group, and no significant difference was observed between before and after surgery SPO<sub>2</sub> level in both BBM and conventional groups. Therefore, using BBM appears to be as effective as opioids and sedatives in controlling hemodynamic changes in patients undergoing eye surgery. In agreement with the present study results, Wiwatwongwana et al. (18) found that using BBM and plain music compared to no music group leads to reduced systolic blood pressure in patients undergoing cataract surgery. However, only heart rate reduced in BBM group compared to no music group. No difference was found in systolic blood pressure before and after surgery in all three groups. The present study results showed no difference between BBM and conventional groups in satisfaction levels of patients and surgeons.

Being a clinical trial was among strong points of the present study. However, it had some limitations. First, we could not compare our results with other studies because there were only few similar studies. Thus, it is recommended that similar studies be conducted in future. Second, our sample size was small, which may have resulted in finding no significant differences between the two groups. Thus, it is recommended that future studies be designed with larger sample sizes. Finally, given the present and previous studies results, using BBM appears to be effective in reducing state and trait anxiety and pain, controlling hemodynamic changes, and increasing satisfaction of patients undergoing eye surgery, and can be an appropriate alternative to opioids and sedatives in anesthesia of patients undergoing eye surgery.

#### 5.1. Conclusions

According to the present study results, BBM appears to be effective in reducing state and trait anxiety and pain, controlling hemodynamic changes, and increasing satisfaction of patients undergoing eye surgery, and can be an appropriate alternative to opioids and sedatives in anesthesia of patients undergoing eye surgery. Physicians are recommended to utilize BBM as a useful and new approach to reducing anxiety and pain. It is recommended that future studies be designed with lower or zero dosage of opioids. It is further recommended that future studies be designed using BBM approach in other surgeries.

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#### Footnotes

**Clinical Trial Registration Code:** The present study was registered in IRCT under code: IRCT20130812014333N8. **Conflict of Interests:** The authors declared no conflict of interests.

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