

The effect of eye mask and selected music on the level of anxiety and hemodynamic parameters in patients undergoing cardiac angiography

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Abstract

Context: Anxiety is common among patients undergoing coronary angiography.

Aims: The aim of this study was to examine the comparative effects of eye masks and music on anxiety levels and hemodynamic indices of patients undergoing coronary angiography.

Setting and Design: This is a single-blind randomized clinical trial conducted on 300 patients undergoing coronary angiography.

Materials and Methods: Patients were recruited using convenience sampling and then randomly allocated to one of the four groups. Ten minutes before the coronary angiography, baseline anxiety levels were measured using the state-trait anxiety inventory. Patients' hemodynamic indices were also measured and recorded immediately before they entered the cath-lab operating room, as soon as, they were in bed in the cath-lab operating room, 5 min after the start of coronary angiography, and immediately and 20 min after the completion of coronary angiography. Anxiety levels were measured again 20 min after coronary angiography. **Statistical Analysis Used:** All statistical analyses were conducted using SPSS 22 Software. Mean and SD indices were used. The normality of both overt and covert anxiety variables was confirmed using Kolmogorov–Smirnov test. The presence of intervening variables was examined using analysis of variance, the final analysis was performed using analysis of covariance. For all analyses, a $P < 0.05$ was considered to be statistically significant.

Results: The mean scores on overt and covert anxiety decreased after intervention. A statistically significant difference was observed among the four groups on overt and covert anxiety ($P < 0.001$). Compared to before coronary angiography ($P < 0.001$) and routine care only group ($P < 0.001$), hemodynamic indices had a decreasing trend during coronary angiography in the intervention groups.

Conclusion: The results of the present study revealed that nonverbal, relaxing, and classical music significantly reduced anxiety and hemodynamic indices of patients undergoing coronary angiography. Future studies should examine the effectiveness of other music genres on anxiety and hemodynamic indices in patients undergoing coronary angiography.

Keywords: Angiography, Anxiety, Eye mask, Hemodynamic indices, Music

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INTRODUCTION

Cardiovascular disease is the main cause of death globally. It is also the third leading cause of disability in Iran with a mortality rate of 40%–45%.^[1] Coronary angiography is the most commonly used diagnostic technique to determine the severity and extent of coronary artery disease.^[2,3] More than 2,60,000 coronary angiography procedures are performed every year in Iran.^[4] Coronary angiography can also cause moderate to high anxiety,^[5,6] and 82% of patients experience anxiety before coronary angiography.^[6] Waiting time before angiography, worrying about the procedure, unfavorable clinical findings, possibility of hospitalization,^[7,8] operating room equipment, and environments, noise within the operating room^[9] can cause anxiety in most patients undergoing coronary angiography.

Anxiety is an emotional state characterized by symptoms of the activation of autonomous nervous system, including shortness of breath, rapid heart rate, high blood pressure, excess production of epinephrine and norepinephrine,^[10] and increased myocardial oxygen demand.^[11,12] There are a number of pharmacological options for the management of anxiety. Benzodiazepines are the most widely used medications to treat anxiety.^[13] The role of music in medical treatment has a long history, and it has been known for its healing power since ancient times.^[14] Music has a significant effect on human emotions. Inspiring music is energizing, while soft music is relaxing. Relaxing music has 60–80 beats/min.^[14,15] Eye mask is another nonpharmacological intervention used to manage anxiety. Eye mask reduces eyes' exposure to light, thereby promoting increased melatonin production.^[16,17] Melatonin, or sleep hormone, is primarily released by the brain in response to darkness and helps regulate the body's sleep-wake cycle.^[18] To the best of our knowledge, no study has been conducted and published on the comparative effects of eye masks and music on anxiety levels and hemodynamic indices of patients undergoing coronary angiography. The present study was thus conducted to examine the comparative effects of eye masks and music on anxiety levels and hemodynamic indices of patients undergoing coronary angiography.

MATERIALS AND METHODS

Study design

This is a single-blind randomized clinical trial with four parallel groups conducted in two hospitals.

Sample and sampling method

In this study, 300 coronary angiography candidates were examined in three intervention groups and one control group (routine care only). The sample size was calculated to be 360 patients (four groups of 90 patients each) based on a study by Arab *et al.*^[19] and using the mean and standard deviation (SD) of anxiety, Type 1 error (α) of 5%, Type 2 error (β) of 10%, and dropout probability of 20%.

Patients were recruited using convenience sampling and then assigned into four equal groups with block randomization (block size of four). Group A, Group B, Group C, and Group D received eye mask, music, music + eye mask, and routine care only, respectively.

Inclusion and exclusion criteria

Patients were eligible for the study if they were aged 18 years and older, willing to participate in the study, scheduled for coronary angiography, being able to communicate verbally and visually, having (Spielberger state-trait anxiety inventory [STAI]) scores of >32 and <73, willing to listen to music and close their eyes during coronary angiography, not administered narcotics 4 h before coronary angiography, not administered sedatives within 1 h before coronary angiography, not taking antipsychotics, not cognitively impaired, and not having visual and hearing impairments. Patients were excluded from the study if they were pregnant, suffering from acute pain, illiterate, having a history of coronary angiography, admitted for urgent coronary angiography, a member of healthcare team, and not allowed to listen to music during the coronary angiography, and In addition, the withdrawal criteria were as follows: Unwillingness to continue participating in the study, need for urgent coronary angioplasty or coronary artery bypass graft surgery, eye mask or headphone removed during coronary angiography, additional catheter procedures at the same time, total examination time no more than 20 min, and need for emergency medical treatment during the coronary angiography.

Measurement instruments

Measurement instruments used to collect data included a socio-demographic questionnaire (including age, gender, weight, height, body mass index, place of residence, level of education, marital status, occupation, and financial status), a questionnaire recording clinical details (including heart disease-related variables, prior history of hospitalization, type of vascular access, and drug addiction), and the STAI.

The STAI has 40 questions. Its first 20 questions measure the overt anxiety and its second 20 questions measure the covert anxiety. Overt anxiety refers to a person's

feelings in response to a particular situation, and covert anxiety is defined as a person's usual feelings in most situations.^[15] Each question is rated on a 4-point Likert intensity scale (1 = not at all; 2 = somewhat; 3 = moderately so; 4 = very much so). The anxiety score ranges from a minimum of 20 to a maximum of 80. According to the STAI, a score of 20–31 is considered as mild anxiety, a score of 32–42 is considered as moderate to low anxiety, a score of 43–52 as moderate to high anxiety, a score of 53–62 is considered as almost severe anxiety, and a score of 63–72 is considered as severe anxiety, and a score of 73 and above is considered as very severe anxiety. The reliability of the Persian version of the STAI was reported by Safara *et al.*^[20]

Interventions

Ten minutes before the coronary angiography, baseline anxiety levels were measured, and patients' socio-demographic/clinical characteristics were collected. Patients were routinely prepared for coronary angiography by Post Cath Ward staff. Patients' hemodynamic indices were measured and recorded immediately before they entered the cath-lab operating room, as soon as they were in bed in the cath-lab operating room, 5 min after the start of coronary angiography, and immediately and 20 min after the completion of coronary angiography. Respiratory rate per 1 min, blood pressure (right hand lying on the back), and pulse were measured and recorded through a monitor. Patients' anxiety was measured again 20 min after coronary angiography. It should be noted that the socio-demographic/clinical information was collected, and anxiety was measured by a single assessor and unaware of the study protocol and the way of random allocation of the patients to control and experimental groups. One hour before the angiography, the patients of music were instructed on the way of playing music through wireless headphones (Beats Studio 3 Wireless Headphones, made in China) during the procedure. The music started from the beginning of the angiography and continued throughout the procedure. Selected music included 10 classical nonverbal relaxing songs by Johann Sebastian Bach from *The Most Relaxing Bach Album in the World. Ever!* for a total duration of 20 min.

Venabili Metronome version 1.2.1 software (Nokia, Finland) was used to control the beat of the music. For the eye mask group, sleep eye mask (Feb-o-Sanat Co., Iran) was used. It consists of two thin layers, the inner part of which is made of soft cotton fabric to prevent damage to the eye, and the outer part is also made of linen fabric that prevents from any light entering the eye. This eye mask is closed with two straps on its outer sides behind the head and kept fixed on the face. Before participants entered the cath-lab operating

room, the eye mask was placed on their eyes and it was kept on his or her eyes throughout the angiography period. As soon as the patient left the cath-lab operating room and entered the recovery room, it was removed from the patient's eyes. In the eye mask plus music group, eye mask and music were used simultaneously. In this group, the eye mask was placed on the patient's eyes before the patient entering the cath-lab operating room and it was kept on the patient's eyes throughout the angiography period. As soon as the patient left the cath-lab operating room and entered the recovery room, the eye mask was removed from the patient's eyes. In addition, this group (eye mask + music) listened to music using headphone throughout the angiography procedure. To prevent transmission of the infection, the headphones were disinfected with alcohol after each use. The control group received routine care only.

Statistical analysis

All statistical analyses were conducted using SPSS 22 software. In the descriptive section, mean and SD indices were used. Furthermore, the normality of both overt and covert anxiety variables was confirmed using Kolmogorov–Smirnov test. Then, the presence of intervening variables was examined using analysis of variance, and finally, due to the presence of intervening variables, the final analysis was performed using analysis of covariance. For all analyses, a $P < 0.05$ was considered to be statistically significant.

Ethical considerations

This trial was approved by the Bioethics Committee of Mazandaran University of Medical Sciences, Sari, Iran (IR.MAZUMS.REC.1397.3096) and is registered with the Iranian Registry of Clinical Trials, IRCT20190328043132N1. The approval of the participating hospitals was also obtained. All participants were informed of the confidentiality of the data, and they were assured that they would have complete freedom to withdraw from the study at any time for any reason without unfavorable effects on the received care. All participants signed an informed consent form in which the research procedures and their rights had been explained.

RESULTS

The mean age of the participants was 58.83 ± 11.21 years, their mean height was 169.69 ± 10.64 cm, and their mean weight was 83.28 ± 14.64 kg. Table 1 shows the information about the education level variable separately for different groups. As observed, there was no statistically significant difference between the groups. Table 2 shows information about the status and type of occupation in patients undergoing angiography. As observed, there

was no statistically significant difference between the groups. Table 3 shows information about the income of patients undergoing angiography. As observed, there was no statistically significant difference between the groups. Table 4 shows the information on risk factors in patients undergoing angiography. As observed, there was no statistically significant difference between the groups. Table 5 shows overt and covert anxiety separately for treatment groups before the start of the study. As seen before coronary angiography, the level of overt and covert anxiety varies between groups ($P < 0.001$). Thus, in this study, overt and covert anxiety before the intervention is considered as intervening variable. Therefore, analysis of covariance was used to analyze the data [Table 5].

The results of Table 5 show that the effect of overt anxiety before intervention was different among the groups. It means that this variable is an intervening variable, so statistical analysis is performed to compare the means of overt anxiety after the intervention, after moderating the overt anxiety variable before the intervention. The results showed that after moderating the overt anxiety variable before the intervention, there was a significant difference between the means of overt anxiety at the end of the study. A similar analysis was performed on covert anxiety that similar results were obtained. Statistical analysis showed that after moderating the confounding variable of covert anxiety at the beginning of the study, there was a statistically significant difference between the means of covert anxiety

Table 1: Frequency distribution of education level variables of each group in patients undergoing cardiac angiography

Variable Frequency	Groups				Test	P
	<Diploma, n (%)	Diploma, n (%)	BSc, n (%)	≥MSc, n (%)		
Eye mask	11 (14.7)	34 (45.3)	28 (37.3)	2 (3.7)	17.3	0.29
Music	10 (13.3)	33 (44)	27 (36)	4 (6.6)		
Music + eye mask	12 (16)	24 (32)	29 (38.6)	10 (13.3)		
Routine care only	13 (17.3)	36 (48)	23 (30.6)	3 (4)		
Total	46 (15.3)	127 (42.3)	107 (35.7)	19 (6.6)		

Table 2: Frequency distribution of employment status in each group in patients undergoing cardiac angiography

Variable frequency	Groups						Test	P
	Employee, n (%)	Self-employed, n (%)	Retired, n (%)	Housewife, n (%)	Farmer, n (%)	Other, n (%)		
Eye mask	14 (18.7)	15 (20)	29 (38.7)	16 (21.3)	1 (1.3)	0	41.7	0.8
Music	14 (18.7)	19 (25.3)	20 (26.7)	15 (20)	6 (8)	1 (1.3)		
Music + eye mask	21 (28)	9 (12)	18 (24)	8 (10.7)	12 (16)	7 (9.3)		
Routine care only	9 (12)	16 (21.3)	24 (32)	17 (22.7)	9 (12)	0		
Total	58 (19.3)	59 (19.7)	91 (30.3)	56 (18.7)	28 (9.3)	8 (2.7)		

Table 3: Frequency distribution of financial status of each group in patients undergoing coronary angiography

Financial status	Groups					Test	P
	Music, n (%)	Eye mask, n (%)	Both, n (%)	Control, n (%)	Total, n (%)		
Enough	59 (78)	56 (74.7)	61 (81.7)	52 (69.3)	228 (75.9)	1.2	0.9
Low	16 (22)	19 (25.3)	14 (18.3)	23 (30.7)	72 (24)		

Table 4: Data on risk factors in patients undergoing angiography separately for study groups

Variable	Groups				P
	Eye mask (n=75), n (%)	Music (n=75), n (%)	Music + eye mask (n=75), n (%)	Routine care only (n=75), n (%)	
Hypertension					0.228
Yes	42 (56)	33 (44)	30 (40)	37 (49.3)	
No	33 (44)	42 (56)	45 (60)	38 (50.7)	
History of hypertension					0.219
Yes	40 (53.3)	42 (56)	30 (40)	38 (50.7)	
No	35 (46.7)	33 (44)	45 (60)	37 (49.3)	
Hyperlipidemia					0.334
Yes	37 (62.7)	45 (60)	40 (53.3)	37 (49.3)	
No	28 (37.3)	30 (40)	35 (46.7)	38 (50.7)	
Alcohol consumption					0.626
Yes	17 (21.3)	16 (21.3)	15 (20)	11 (14.7)	
No	58 (77.3)	59 (78.7)	60 (80)	64 (85.3)	
Diabetes					0.407
Yes	34 (35.3)	29 (38.7)	36 (48)	27 (36)	
No	41 (54.7)	46 (61.3)	39 (52)	48 (64)	

at the end of the study [Table 5]. The results showed that the headphone (music) group had the lowest level of overt and covert anxiety.

Patients' hemodynamic parameters were also measured in five-time intervals (immediately before entering the angiography room, as soon as they were in the angiography bed, 5 min after the start of the angiography, immediately after the completion of physician work in the angiography room, and 20 min after the intervention) and were recorded. Systolic and diastolic blood pressure, heart rate, and respiration rate in the selected music group compared to other groups increased 5 min after the start of angiography compared to immediately before entering the angiography room and as soon as they were placed in the angiography bed.

All hemodynamic parameters in the eye mask group increased compared to the selected music group and selected music plus eye mask group but decreased compared to the control group. Furthermore, the mentioned indicators in the selected music plus eye mask group did not decrease compared to the selected music group but had a decreasing trend compared to the control group. In general, hemodynamic parameters in the selected music group had a more decreasing trend than other groups [Figures 1-4]. The analysis also showed that systolic and diastolic blood pressure, heart rate, and respiration rate were higher in the control group than other groups. It indicates that all three types of interventions have a positive effect, but among these interventions, the selected music group showed the highest effect.

DISCUSSION

This study was intended to examine the comparative effects of eye masks and music on anxiety levels and hemodynamic indices of patients undergoing coronary angiography. In a randomized clinical trial, Rejeh *et al.* examined the effect of listening to nature pleasant sound on anxiety and physiological indices in patients undergoing coronary angiography. The experimental group listened to nature through headphones for 20 min 30 min before

angiography. The control group also received only routine hospital care. The results showed that the mean scores of anxiety and physiological indices of the experimental group were significantly different from those of the control group.^[21] Also, the results of the present study showed that the mean scores of overt and covert anxiety before the intervention compared to after the intervention in the experimental groups compared to the control group were statistically significant. In this regard, a meta-analysis study investigated the effect of music on the level of anxiety in patients undergoing cardiac catheterization, and its results showed that music could be used as a safe and convenient intervention to reduce anxiety in patients undergoing cardiac catheterization.^[22]

The results of the present study also revealed that music during coronary angiography reduced systolic blood pressure, diastolic blood pressure, heart rate, and respiration rate. Emami Zeydi *et al.* achieved similar results in the study on the effect of music on vital signs and oxyhemoglobin saturation in patients after open-heart surgery. Music may reduce heart rate, systolic blood pressure, and mean arterial pressure and increase oxyhemoglobin but has no effect on respiration rate or diastolic blood pressure.^[14] On the other hand, the results of a meta-analysis study entitled “The effect of music therapy on anxiety and physiological parameters of angiography” showed that music significantly reduced anxiety in patients undergoing coronary angiography, but

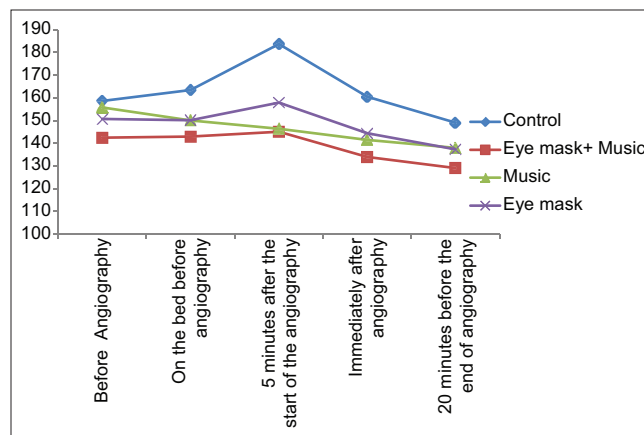


Figure 1: Ratio of systolic blood pressure to time

Table 5: Comparison of overt and covert anxiety before and after angiography

Groups	Time				P
	Before		After		
	Overt anxiety	Covert anxiety	Overt anxiety	Covert anxiety	
Eye mask	5.64±58.92	6.02±53.87	7.58±39.57	8.71±38.15	0.001
Music	58.49±5.69	54.31±7.91	34.71±6.70	35.55±6.62	0.001
Music + eye mask	56.80±6.10	50.55±6.21	35.13±7.28	35.19±7.57	0.001
Routine care only	54.73±6.11	55.77±5.90	45.40±6.37	46.24±6.83	0.001
Significance level	0.001	0.001	0.001	0.001	0.001

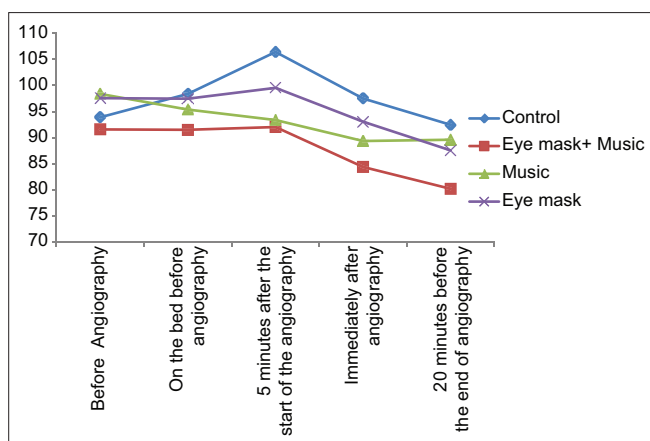


Figure 2: The ratio of diastolic blood pressure to time

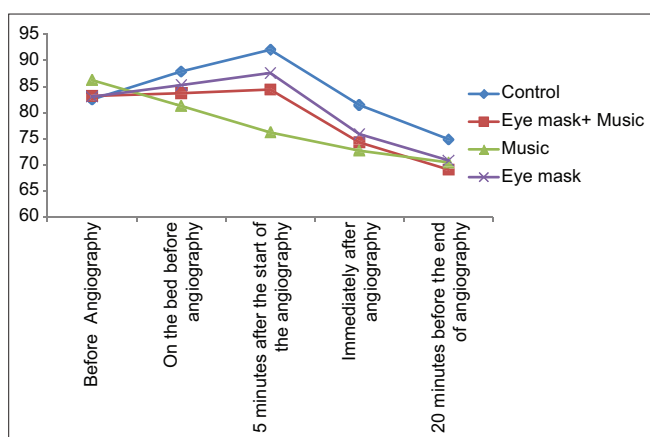


Figure 3: Ratio of heart rate to time

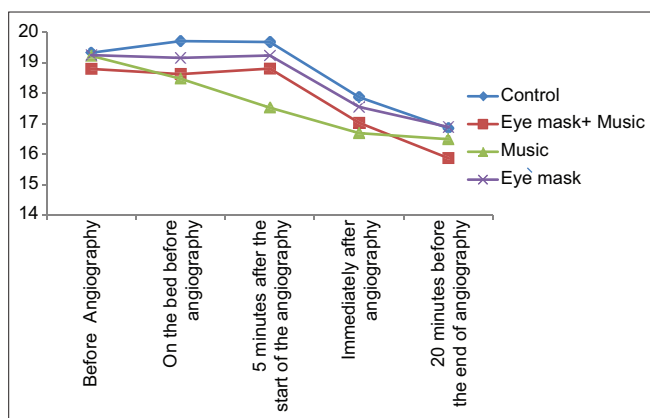


Figure 4: Ratio of respiration rate to time

it had no effect on physiological parameters of heart rate and blood pressure.^[23] Arab *et al.* also investigated the effect of music on anxiety and vital signs in patients with acute coronary syndrome and concluded that music had no effect on patients' vital signs.^[19]

The reason for the discrepancy in the results might be due to the type of music used and even the music playing time.

It may be due to the effect of preangiographic training. In the study conducted by Emami Zeydi *et al.*, the music was selected by the patients and played to them after the intervention. In the study conducted by Rejeh *et al.*, the used music was sounds of nature that were played to patients for 20 min before coronary angiography, but in the study conducted by Arab *et al.*, classical nonverbal Iranian music entitled "Gol-e Ney" was played to patients for 2 days for 20 min each time. However, in the present study, classical, nonverbal, and relaxing music (by Sebastian Bach) was used, as Arvand *et al.* in their study on the control of urethritis and Irritable bowel syndrome^[24] and Roohy *et al.* to control patients' anxiety before abdominal surgery used this style of music (Sebastian Bach classical and nonverbal music).^[25]

In the present study, music was played throughout the angiography period, while a search of available databases showed that music had not been played throughout the angiography period in any of the studies. In the present study, eye mask was used as a tool to prevent viewing of the angiography site as a potential cause of anxiety. The results of the present study revealed that eye masks could reduce anxiety and hemodynamic indices of patients during coronary angiography compared to the control group, but it had less effect compared to the music. In other studies, eye masks were used to improve patients' quality of sleep, including the studies conducted by Obanor *et al.*^[26] and Hu *et al.*^[27] Hu *et al.* investigated the effect of simultaneously use of earplug, eye mask, and relaxing music on sleep quality, melatonin levels, and cortisol levels in intensive care unit patients and concluded that the simultaneous use of earplug, eye mask, and relaxing music improved sleep and increased melatonin levels and decreased cortisol in patients.^[27] However, therapeutic interventions in cardiovascular disease, similar to other chronic diseases, cause problems such as anxiety, sleep disturbance, and depression in patients, and it is necessary to take care of these patients.^[28] The present study suffers some potential limitations. One of these limitations is the selection of music by researchers. In addition, covering the patients' eyes and depriving the patient of visual, auditory, and verbal communication with people around them and the environment may increase patients' anxiety and fear. Another limitation of the study is the level of patients' awareness of the treatment process that can affect the level of anxiety before and after the intervention, which was not measured in this study. This issue can be considered in future studies

CONCLUSION

The results of the present study revealed that nonverbal, relaxing, and classical music significantly reduced anxiety

and hemodynamic indices of patients undergoing coronary angiography. Future studies should examine the effectiveness of other music genres on anxiety and hemodynamic indices in patients undergoing coronary angiography.

Conflicts of interest

There are no conflicts of interest.

Authors' contribution

All authors contributed to this research.

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