



## **Original Article**



# Effect of Music on Pain, Anxiety and Physiological Parameters among Postoperative Sternotomy Patients: A Randomized Controlled Trial

Prabu Ganesan<sup>10</sup>, Kumari Jayaram Manjini<sup>1\*0</sup>, Sai Chandran Bathala Vedagiri<sup>20</sup>

<sup>1</sup>Department of Medical Surgical Nursing, College of Nursing, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India

### **Article Info**

## **Article History:**

Received: 21 May 2021 Accepted: 10 Mar. 2022 e-Published: 20 July 2022

#### **Keywords:**

Music therapy, Pain, Anxiety, Sternotomy, Heart rate, Blood pressure

#### \*Corresponding Author:

Kumari Jayaram Manjini, Email: kumari\_mj@ymail.com

#### **Abstract**

**Introduction:** Music is a non-invasive, inexpensive and non-pharmacological nursing intervention that has no side effects and can be effective when provided alongside the routine care in cardiothoracic and vascular surgery (CTVS) ward and intensive care unit (ICU). The objective of the study was to assess the effect of music on pain, anxiety and physiological parameters among the post-operative sternotomy patients from CTVS ward and ICU in Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India.

**Methods:** A randomized controlled trial research design was used to conduct the study among 70 post-operative sternotomy patients. The pain score, and anxiety level were recorded using Numerical Pain Rating Scale (NPRS) and post-operative anxiety scale, with the physiological parameters recorded for both groups before the music intervention, after the first post-operative day, and after the intervention on seventh post-operative day. Data were analyzed by SPSS software version 23.

**Results:** There was a marked reduction in the mean score of pain, anxiety, systolic and diastolic blood pressure (SBP & DBP), heart rate and respiratory rate in the study group as compared to the control group. There was a significant difference between the mean score of pain, anxiety, SBP, DBP, heart rate, respiratory rate and oxygen saturation in both groups after the intervention. **Conclusion:** Music was found to be effective on pain, anxiety, diastolic blood pressure, heart rate and oxygen saturation among post-operative sternotomy patients. Thus, it is essential to include music as a tool in post-operative care.

## Introduction

World Health Organization (WHO) reports that cardiovascular diseases (CVDs) are the leading cause of death globally. In 2019, an estimated 17.9 million people died from CVDs, it representing 32% of all global deaths.<sup>1</sup> WHO said that India accounts for one-fifth of these deaths worldwide especially in younger population.<sup>2</sup> According to the Global Burden of Disease, nearly a quarter (24.8%) of all deaths in India is due to CVDs. Longitudinal Aging Study conducted in India on self-reported prevalence of diagnosed CVDs among older adults (45-59) & elderly age (>60), data on 2020 was released by the Union Ministry of Family and Health Welfare. It stated that in Puducherry union territory, 23.9% patients were belonging 45-59 age group, 45.2% were above 60-year elderly group, 31.9% were male and 35.2% were female; in Tamilnadu, 21.2 % patients were belonging to 45-59 years, 36.8% were above 60 years, 28.7% were male and 28.2% were female.<sup>3</sup> These statistical report shows there is a high prevalence of CVDs in Puducherry and Tamilnadu. There are many different ways of managing and treating CVD. Surgical treatment provides long-term benefit for certain subgroups of patients with combined coronary artery and peripheral arterial vascular disease. Most cardiothoracic surgeons preferred the median sternotomy because it provides optimal exposure and access to the entire heart.<sup>4</sup> It is the only viable approach for those undergoing concomitant bypass grafting; it provides direct access to all important cardiovascular structures, and valve exposure is usually excellent.<sup>5</sup>

Worldwide, it is estimated that over 2 million people undergo median sternotomy for heart surgery each year.<sup>6</sup> In the immediate post-operative period after sternotomy, most of the patients suffering severe pain. It makes negative impact on patients' recovery in post-operative period. The pain without proper treatment may lead to adverse hemodynamic consequences like tachycardia, arrhythmias and hypertension; it also can lead to sleep, mode and behavioral changes. All of these consequences

<sup>&</sup>lt;sup>2</sup>Department of CTVS, JIPMER, Puducherry, India

of pain end results are increased hospital stay, readmission, and prolonged recovery and negatively affect quality of life.7

Music intervention may be used as complementary forms to manage patients' symptoms such as anxiety and pain. Numerous studies have shown that music interventions can improve patient symptoms such as anxiety, pain, and relaxation.8 Research study supporting the use of music therapy that it is readily available, low risk, inexpensive, and does not require intense training by staff. It may reduce the need for moderate sedation and improve the overall patient experience, nursing staff gained a greater appreciation of evidence-based practice. Because 87% of the music therapy participants reported that music helps in reducing pain and anxiety during painful procedures.9 Many studies reports that music is health for mind to relax by hearing slower music. Music directly affects brain waves. It reduces stress, anxiety and lowers blood pressure.10

Music also increases the relaxation by reducing the release of stress hormones and weakening arousal of the pituitary-adrenal stress axis.11 Reduction of the stress hormones by music was done by the down-regulation of hypothalamic-pituitary-adrenal axis activity, which can be seen in reduction of serum concentrations of cortisol. Brain has a nice correlation with music evoked emotions. Music also has impact on down regulation of autonomic nervous system activity which results in lowering both blood pressure and heart rate.12 Luis et al conducted a study to assess the effect of live oud music on physiological and psychological parameters in twelve cardiac surgery patients who was randomly allocated in either intervention group or control group were given customized live oud music for 20 minutes before and after surgery while patients in the control group heard the normal hospital sounds. Anxiety scores were measured preoperatively, vital signs and pain scores were monitored postoperatively together with serum levels of cortisol, which was indicator of the stress response. In the intervention group, listening to music helped in reducing the pain scores and respiratory rates (P values of 0.04 and 0.03 respectively) with the positive effect. Additionally, patients who listened to music has borderline reduction in heart rates, anxiety scores and serum cortisol levels in the music group than in the control group.<sup>13</sup> Bojorquez et al conducted study to find the approach for managing pain and anxiety using music therapy for surgical patients in the inpatient setting. Music was evaluated by paired t-test and Wilcoxon signed-rank score was used with using Numerical Pain Rating Scale (NPRS) and the patient reported outcome measurement information system anxiety short form before and after the music intervention encounter. Among patients who received music intervention (n = 42), there was a high difference in mean score reduction in both pain (pre = 6.07, post = 3.45, t=7.04,  $P \le 0.001$ ) and anxiety (pre=56.47, post=46.52, t=7.78,  $P \le 0.001$ ). The reduction in pain and anxiety

was clinically significant.14 Music has the power to soothe, inspire, energize, and uplift for people who are living with chronic pain which can be offered by many pain centers and cancer centres.<sup>15</sup> Music has a cultural implication and insufficient studies are published on using the western and classical music and only minimum number of studies done in finding the effect of music on pain, anxiety and physiological parameter among post-operative sternotomy patients in Indian setup.<sup>16</sup> Music intervention is widely accepted, practiced and used to increase patient comfort. Even though, there is a positive result in many previous studies, in the study setting not practiced to apply the music intervention to reduce the pain among sternotomy patients. There is a gap between music intervention and pain management in the postoperative wards and intensive care units (ICUs). Hence, the researcher interest to implement the music intervention with evidence-based practice so they did the study under randomized control trial. This study is useful for staffs in handling and managing the post-operative pain, coping with their anxiety and improving the quality of patients' care.

The study objective was to assess the effect of music intervention on level of pain, anxiety and physiological parameters of heart rate, respiratory rate, and oxygen saturation, systolic and diastolic blood pressure among the post-operative sternotomy patients by compare with routine hospital management in control group before and after the music intervention. The study hypothesis was music intervention is effective in reducing the level of pain, anxiety, and in physiological parameter showed positive changes in heart rate, respiratory rate, and oxygen saturation, systolic and diastolic blood pressure had better effect among the sternotomy in study group after received music intervention than the patient who did not received music intervention.

## **Material and Methods**

The researcher was obtained prior permission from the Nursing Research Monitoring Committee (NRMC) and Institute Ethics Committee (IEC-JIPMER) Reg. No. JIP/ IEC/2019/049 to protect the human subjects from risk. Confidentiality of the data, right to withdraw from the study and the anonymity of the participants were clearly explained before data collection to the participants. Written informed consent was obtained from the participants before they were enrolled in the study Good Clinical Practice guidelines of Indian Council of Medical Research were followed. Participant's data were stored confidentially. The participants were explained that participation of the study on voluntary and free to withdraw at any time without giving any reason, and without affect the routine hospital medical care.

A randomized controlled trial study conducted in the cardiothoracic and vascular surgery intensive care unit (CTVS ICU) and CTVS ward at tertiary care hospital,

Puducherry, India from August 2019 to March 2020. The patients who were first time undergone non-emergency sternotomy procedure only recruited for the study. Total sample size for the study was 70 patients, 35 in the study group and 35 in the control group was determined by using the sample size estimation formula of comparing two independent means. The minimum expected differences in mean level of pain between two groups was one (1) unit in NPRS with a standard deviation of 1.5, with level of significance at 0.05 and power of 0.8. Sampling technique randomization was done using block randomization method. Block randomization list generated through computer was used to randomize the patients into the study and control groups through opaque open label sealed envelope by the researcher. Inclusion criteria of the study was patient's age over 18 years, elective and first-time sternotomy patients, patients recovered from anesthesia and weaned off from ventilator, patients with the signs of stable hemodynamic (systolic blood pressure≥90 mm Hg, heart rate=60-120 beats per minute, absence of any abnormal dysrhythmias), and ability to follow verbal orders. Exclusion criteria was patient on continuous infusion of sedatives and analgesic and muscle relaxants drugs after 6 to 8 hours after surgery, patients with hearing problems, and patients who were undergone cardiopulmonary resuscitation procedure in operating room or postoperative ICU were excluded from the study.

Operational definitions in this study, "Effect" refers to the change which is result or consequence of an action or other cause of a particular intervention done on the patient by the investigator. "Music" refers to the instrumental sounds that are five different type's music without lyrics that includes melodies type of western and Indian music with a sustained melodic quality with a rate of 60-80 beats per minute and absence of strong rhymes. These music is mild, melodic with soft rhymes. "Pain" refers to the highly unpleasant physical sensation caused by the postoperative sternotomy wound for the open sternotomy patients that is measured in the first day of post-operative. "Anxiety" refers to the feeling of worry, nervousness or unease about something with an uncertain outcome of the open sternotomy surgery that the patient underwent. "Physiological parameters" refers to the heart rate, oxygen saturation, systolic and diastolic blood pressure. "Postoperative sternotomy patient" refers to the patients who underwent open sternotomy procedure for coronary artery bypass graft and valvular surgery and in the first post-operative day when they are conscious and oriented and verbally expressive of their pain and anxiety. The conceptual framework adopted for the present study was Betty Neuman's System Model. This model emphasizes the individual's relationship to stressors, the reaction to it and levels of intervention.17

The tool used to do data collection which consists of socio-demographic and clinical variables includes age,

gender, marital history, educational status, occupation, alcohol use, smoking, music listening frequency, type of surgery, co-morbidities, patient's duration of surgery, types of sedatives used, patient's number of days in ICU stay, type of analgesia used and any post-operative complication. NPRS visual analogue scale used to measure level of pain is rated between 0 to 10 in which pain level was ranged from no (0), mild (1-3), moderate (4-6), severe (7-10) pain. The level of anxiety was measured by using Post-Operative Anxiety scale (I am feeling the surroundings calm, I am unable to concentrate, I am feeling homely, I am feeling nervous, I am worrying of thoughts arising in my mind, I feel my heart palpitation, I am feeling happy, My breathing is rapid, I had good sleep, I am feeling refreshed, I am feeling of inadequacy, I am feeling confused, My mind is peaceful now, I don't have fear of complications), which is a self-structured tool has totally 14 statements. All the statements are scored as yes /no. The anxiety level was ranged as no (0), mild (1-4) moderate (5-8) and Severe (9-14). The reliability of postoperative anxiety scale was checked by using Guttman split-half coefficient method with 'r' value of 0.82 was found to be reliable for usage in this study. Validity and reliability of the demographic data questionnaire was prepared after reviewing the works of literature and tool content obtained from CTVS expert, nursing experts, their suggestions were incorporated in the tool. NPRS is a standardized scale with test-retest reliability (intraclass correlation coefficient=0.81) done by Pathak et al.18 The physiological parameters that includes heart rate, respiratory rate, oxygen saturation, diastolic and systolic blood pressure which was measured by using the available cardiac monitor in the CTVS ICU and CTVS wards named as STAR 55, Larson and Turbo medical equipment were used in the study with accuracy of pulse rate range of 20 to 230 bpm ± 3 bpm (± standard deviation), pulse oximetry accuracy of 100 to 70% (±2 digits), 0 to 69% (unspecified) (± standard deviation) Noninvasive blood pressure monitor with accuracy of ±3 mm Hg.19

Patients who met the inclusion criteria were selected in the study. Informed written consent was obtained from the participants. The pre-test was done for pain, anxiety, and physiological parameters (heart rate, respiratory rate, and oxygen saturation, systolic and diastolic blood pressure) before the intervention in both groups by the researcher in the CTVS ICU and CTVS wards on first post-operative day.

The researcher was discussed and consulted with the music expert, as per their guidance the music intervention was delivered in the study group. Music intervention was given a way of music frame with five different types of music without lyrics that includes melodies type of western and Indian music with a sustained melodic quality with a rate of 60-80 beats per minute and absence of strong rhymes. All the four forms of standardized western music are used with permission.20

The five types of music in the music frame include five melodic music's which was played for 10 seconds in each, to know the preferred music by the patients in study group. After the patient was chosen the preferred music within the given music frame, the same was played by noise cancellation head phones for 15-20 minutes' duration with four hours of gap during the day time at the convenience of the patient in CTVS ICU and ward. Changing volume was controlled by the patient. This music intervention was given from first to seventh post-operative days along with the routine management. The study participants had not listened music from their mobile phone and television during the intervention period.

The control group participants were given noise cancellation headphones without music with routine management. All the patients in the both the groups were provided with the standard pre- operative and post-operative care according to the protocol developed by the cardiovascular surgeon and nurses. The study independent variables were provided preferred music selected from the music frame which has included music of piano, guitar, flute, and saxophone. The outcome variables including pain, anxiety and physiological parameters was assessed in post-test after seventh days of music intervention in the study group and after routine care in the control group at the same period. There was no unintended effect has happened in both groups. Figure 1 shows CONSORT diagram.

The participants' age, gender, marital status,

educational level, alcohol use, smoking, music listening frequency, type of surgery, co-morbidities and postoperative complication data had analyzed in frequency and percentage. The continuous variables of age, level of pain, anxiety and physiological parameters were explored in mean with standard deviation. Compare the level of pain, anxiety and physiological parameter between groups were carried out by independent student t test or the alternative non-parametric tests like Mann-Whitney U test were used. Comparison between the before and after intervention scores was analyze by using paired t test or the alternative non-parametric tests. The independent factor associated with the level of pain, anxiety and physiological parameters explored by using regression analysis. Various other tests like chi-square test and Fisher's exact test were used to analyze the categorical variables and to rule out for the presence of association between the variables. Data were analyzed using SPSS Statistics for Windows, version 23 (SPSS Inc., Chicago, Ill., USA).

#### Results

A sum of 70 patients was eligible for the study, 35 in each group and there were no drop-outs. Table 1 shows the socio-demographic variables and clinical variables of 70 postoperative sternotomy patients in study and control groups, mean (SD) age was 49.17 (13.55) in control group and 48.77 (13.62) in study group, *P* was 0.90. Duration of surgery mean (SD) in minutes was 245.8 (58.68) in

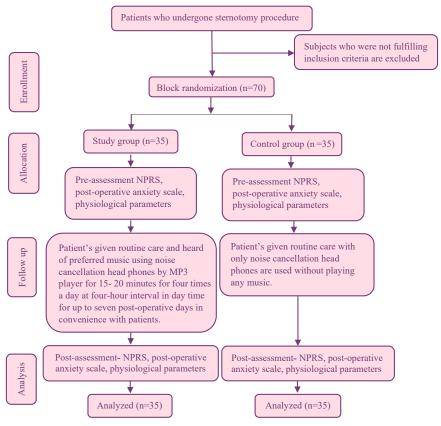


Figure 1. CONSORT diagram of the study

**Table 1.** Distribution of socio-demographic and clinical variables among postoperative sternotomy patients in control and study groups

Variable	Study group (n=35)	Control group (n=35)	P value <sup>a</sup>	
Age (y)				
18-29	4 (11.43)	6 (17.14)		
30-44	7 (20)	1 (2.86)	0.45	
45-59	17 (48.57)	21 (60)	0.15	
≥60	7 (20)	7 (20)		
Gender				
Male	22 (62.86)	19 (54.29)	0.46	
Female	13 (37.14)	16 (45.71)		
Marital status				
Single	0 (0)	1 (2.86)		
Married	35 (100)	34 (97.14)	0.31	
Educational level				
Illiterate	3 (8.57)	3 (8.57)		
Elementary school	4 (11.43)	6 (17.14)		
Below high	7 (20)	7 (20)		
High school	16 (45.72)	13 (37.14)	0.76	
Diploma	2 (5.71)	4 (11.43)		
UG	3 (8.57)	1 (2.86)		
PG	0 (0)	1 (2.86)		
Alcohol use	- (-)			
Yes	9 (25.71)	11 (31.43)		
No	26 (74.29)	24 (68.57)	0.59	
Smoking				
Yes	10 (28.57)	9 (25.71)		
No	25 (71.43	26 (74.29)	0.78	
Music listening frequency				
Everyday	4 (11.43)	6 (17.14)		
Sometimes	13 (37.14)	11 (31.43)		
Occasionally	8 (22.86)	8 (22.86)	0.82	
Rarely	8 (22.86)	6 (17.14)	0.02	
Never	2 (5.71)	4 (11.43)		
Type of surgery	2 (3.71)	1 (11.73)		
Valve replacement	18 (51.43)	16 (45.71)		
Coronary artery bypass grafting	17 (48.57)	19 (54.29)	0.63	
Co-morbidities	17 (40.37)	19 (34.23)		
Nil	18 (51 42)	15 (42.86)		
	18 (51.43)			
Hypertension	9 (25.71)	8 (22.86)	0.17	
Diabetes mellitus	7 (20)	7 (20)	0.17	
Bronchial asthma	1 (2.86)	0 (0)		
Hypertension and diabetes	0 (0)	5 (14.28)		
Post- operative complication				
No	34 (97.14)	35 (100)	0.31	
Yes Chi square test was used.	1 (2.86)	0 (0)		

<sup>&</sup>lt;sup>a</sup> Chi square test was used.

control group and 242.4 (52.71) was in study group, *P* was 0.79. Number of days stayed in ICU mean (SD) was 3.57

(0.60) in control group and 3.46 (0.65) in study group, P was 0.45. All patients had undergone general anesthesia in both groups.

Table 2 reveals that in post assessment majority of the patients (71.4%) had mild pain in study group whereas 20% of the patient only had mild pain in control group.

Table 3 compares the level of pain among postoperative sternotomy patients within the study group (music intervention with routine care) and control groups (routine care only) in pre- and post-assessment. It shows that, the calculated paired t test value of t = 24.80 shows statistically highly significant with high mean difference between the pre-assessment and post- assessment of the level of pain among postoperative sternotomy patients in study group while compare with the control group the calculated paired t test value of t = 20.14. It shows the mean reduction of pain (mean difference 5.657 in study and 3.829 in control group) was high in study group than the control group. Hence, compare the level of pain between the study and control groups shows that, the calculated independent t test value of t = 1.52 shows statistically no significant difference in control and study groups in pre-assessment. In post-assessment the mean (SD) score of pain in the study group was 2.91(1.04) and the mean score in the control group was 4.34 (1.30). The calculated independent t test value of t = -5.06 shows statistically highly significant difference between comparison of the level of pain among postoperative sternotomy patients in study and control groups in post-test respectively.

Table 4 reveals that in post assessment majority of the patients (68.6%) had mild anxiety in study group after music intervention whereas 11.4% of the patient only had mild anxiety in control group after routine intervention without music.

Table 5 compares the level of anxiety among postoperative sternotomy patients within the study group (music intervention with routine care) and control groups (routine care only) in pre- and post-assessment. It shows that the calculated paired t test value of t = 15.33 show the mean reduction of anxiety after received intervention in study group. The calculated paired t-test value of t = 6.79shows that there was statistically highly significant with high mean difference value was nine in study group and 2.51 in control group in between the pre-assessment and post- assessment of anxiety level. There was statistically highly significant with low mean difference between the pre-assessment and post- assessment of the anxiety in control groups. Hence, compare the level of anxiety between the study and control groups shows that, the calculated independent t test value of t = 0.96 shows statistically no significant difference in pre-assessment in both groups. But, in post-assessment the calculated independent t test value of t = -8.82 shows statistically highly significant difference while compare of the level of anxiety among postoperative sternotomy patients in control and study groups.

**Table 2.** Level of pain among postoperative sternotomy patients in pre and post assessment

	No. (%)				
Level of pain	Study group (n=35)		Control group (n=35)		
	Pre- assessment	Post- assessment	Pre- assessment	Post- assessment	
No pain	0 (0)	0 (0)	0 (0)	0 (0)	
Mild	0 (0)	25 (71.4)	0 (0)	7 (20)	
Moderate	0 (0)	10 (28.6)	4 (11.4)	28 (80)	
Severe	35 (100)	0 (0)	31 (88.6)	0 (0)	

**Table 3.** Compare the mean and standard deviation of pain among postoperative sternotomy patients within groups in pre and post-assessment

Assessment	Mean (SD)	P value <sup>a</sup>
Study group (n=35)		
Pre-assessment	8.57 (0.91)	0.001*
Post-assessment	2.91 (1.04)	0.001
Control group (n=35)		
Pre-assessment	8.17 (1.24)	0.001*
Post-assessment	4.34 (1.30)	0.001*

<sup>&</sup>lt;sup>a</sup> Paired t test, \*Statistically significant.

**Table 4.** Level of anxiety among post-operative sternotomy patients in study and control groups

Level of anxiety	No. (%)				
	Study group (n=35)		Control group (n=35)		
	Pre- assessment	Post- assessment	Pre- assessment	Post- assessment	
No anxiety	0 (0)	9 (25.7)	0 (0)	2 (5.71)	
Mild	0 (0)	24 (68.6)	2 (5.71)	4 (11.43)	
Moderate	6 (17.1)	2 (5.7)	9 (25.72)	13 (37.2)	
Severe	29 (82.9)	0 (0)	24 (68.57)	16 (45.7)	

**Table 5.** Comparison of the mean and standard deviation of anxiety among postoperative sternotomy patients within the study and control groups in preand post-assessment

Assessment	Mean (SD)	P value <sup>a</sup>		
Study group (n=35)				
Pre-assessment	10.94 (2.84)	0.001*		
Post-assessment	1.94 (1.79)	0.001*		
Control group (n=35)				
Pre-assessment	10.23 (3.31)	0.001*		
Post-assessment	7.71 (3.42)	0.001*		

<sup>&</sup>lt;sup>a</sup> Paired *t* test, \*Statistically significant.

Table 6 shows compare the physiological parameters among postoperative sternotomy patients within the study group (music intervention with routine care) and control groups (routine care only) in pre and post-assessment.

In study group, there was a significance changes in the physiological parameters with mean difference value of systolic blood pressure was 17.11, diastolic blood pressure was 9.82, heart rate was 20.48, respiratory rate was 7.85, oxygen saturation was -3.31. At the same

time, in control group mean (SD) of the physiological parameters with mean difference was systolic blood pressure 10.37, diastolic blood pressure 7.02, heart rate 13.62, respiratory rate 5.97 and by evident in paired *t* test had statistically highly significant and oxygen saturation -1.54 is statistically significant in control group with the lower mean differences than the study group respectively.

Hence, compare the physiological parameter between the study and control groups reports that the physiological parameters by evident in independent t test had statistically significant in study and control groups in pre- assessment respectively. The calculated independent t test value of t=-2.03 for diastolic blood pressure, t=-2.38 for heart rate and t=4.40 for oxygen saturation had statistically significant in study and control groups in post- assessment respectively.

Post-operative complication had shown statistically significant association with pretest level of anxiety among postoperative sternotomy patients in study groups with chi-square value of ( $\chi^2$ =4.97, df=1) at P<0.05 level respectively. The other demographic and clinical variables had not shown statistically significant association with pretest level of anxiety among postoperative sternotomy patients in study groups respectively.

#### Discussion

The study objective was to assess the effect of music on pain, anxiety and physiological parameters among postoperative sternotomy patients in study and control groups. The study result reports there is higher mean difference in the study group than the control group in pain, anxiety level and physiological parameters shows the positive influence of music intervention on the study group on controlling the pain, anxiety and regulating physiological parameters, there was statistically significant (P=0.001). These findings clearly say the positive impact of music on relief of post-operative pain, post-operative anxiety and regulating the physiological parameters. So the study hypothesis was accepted that music is effective in reducing the level of pain, anxiety and positive effect on physiological parameters in the study group than the control group.

The level of pain in study groups, there is marked reduction in the mean score of pain from 8.57 to 2.91 with higher mean difference and with statistically highly significant difference ( $t=24.80,\ P=0.001$ ) between comparison of the pre-test and post-test of the level of pain among postoperative sternotomy patients in study group. These findings are supported by de Andrade et al done a randomized controlled trial on effect of listening to music on anxiety, pain, and cardiorespiratory parameters in cardiac surgery. The study results may contribute to the implementation of non-pharmacological interventions in health services, highlighting the protocols for listening to music, to minimize anxiety and pain in cardiac surgery.  $^{21}$ 

The level of pain in the control group, there is

**Table 6.** Comparison of the effect of music on physiological parameters among postoperative sternotomy patients in control and study groups

	Si	Study group (n=35)			ntrol group (n=35)	
Physiological parameters	Mean (SD)		n de	Mean (SD)		D 1 .
	Pre-assessment	Post-assessment	P value <sup>a</sup>	Pre-assessment	Post-assessment	- P value <sup>a</sup>
Systolic blood pressure (mm Hg)	139.7(10.17)	122.6 (7.19)	0.001*	134.8 (9.11)	124.4 (6.27)	0.001*
Diastolic blood pressure (mm Hg)	90.34(6.63)	80.51 (5.68)	0.001*	90.74 (8.28)	83.71 (7.37)	0.001*
Heart rate (beats/min)	100.4(12.59)	80 (9.72)	0.001*	100.2 (14.29)	86.57 (13.11)	0.001*
Respiratory rate (Breathes/minute)	23.94(3.75)	16.09 (1.96)	0.001*	22.86 (4.22)	16.89 (1.89)	0.001*
Oxygen saturation (%)	95.54(1.77)	98.86 (0.69)	0.001*	96.11 (3.38)	97.66 (1.45)	0.001*

<sup>&</sup>lt;sup>a</sup> Paired t test, \* Statistically significant.

reduction in the mean score of pain from 8.17 to 4.34 with minimum mean difference of 2.51 and with statistically highly significant difference (t = 20.14, P = 0.001) between comparison of the pre-test and post-test of the level of pain among postoperative sternotomy patients in control group. The above findings are inconsistent with the study conducted by Shabandokht-Zarmi et al conducted study on the effect of self-selected soothing music on fistula puncture-related pain in 114 dialysis patients by nonrandom, convenience sampling with in three groups of music, headphone and control. The fistula puncturerelated pain was monitored within a minute after venepuncture procedure for all the three groups. This study showed a reduced mean pain score between the music and control groups, and the music and headphone groups after the intervention. But there is no change in mean pain score between the headphone and control groups after the intervention.<sup>22</sup>

The level of anxiety in study groups, there is marked reduction in the mean score of anxiety from 10.94 to 1.94 with higher mean difference of 9 and with statistically highly significant difference (t = 15.33, P = 0.001) between comparison of the pre-test and post-test of the level of anxiety among postoperative sternotomy patients in study groups. The above results go parallel with the study findings conducted by Jawaharani et al on the effect of music therapy in critically ill 120 patients admitted to the ICU of a tertiary care center. The study finding reveals that statistically significant reduction in Glasgow Coma Scale, heart rate, blood pressure, and Hamilton anxiety scale rating on day 1 versus day 5 and in comparison to the control group as well. The patients were also noted to have a lesser duration of hospital stay and lesser mean morbidity in the ICU compared to controls. The study concluded that music therapy can be a crucial adjuvant to protocol-based management that already exists across critical care settings, and strongly feel that further studies, including a greater number of patients and follow-up evaluations, are needed to confirm promising results observed in this study.<sup>23</sup>

The level of anxiety in control group, there is reduction in the mean score of anxiety from 10.23 to 7.71 with lower mean difference of 2.51 and with statistically significant difference (t=6.79, P=0.001) between comparison of

the pre-test and post-test of the level of anxiety among postoperative sternotomy patients in control group. This finding goes inconsistent with Kavak Akelma et al conducted a randomized, prospective, single-blinded, controlled trial study on, the impact of favourite music on surgical anxiety and pain, 11 patients of elective herniation surgery randomly allotted in two groups, music cluster (group M) and management cluster (group C). The results show that there is reduction mean surgical STAI scores for the patients in music group than in cluster C score (39) [range 35-43] vs. 41 [range 37-43], P<0.05). The mean STAI score was statistically significant in cluster M than the cluster C (P<0.05). The change in of hemodynamic was also significant in cluster M than in cluster C (P=0.001). The Numerical Rating Scale (NRS) scores were same between the teams. The patient satisfaction score was found to be higher in cluster M (P = 0.01) there's reduction in anxiety, regulated hemodynamic parameters, and improved surgical patient satisfaction can be achieved by providing patient-preferred music preoperatively.24

The level of physiological parameters of systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate in study group has marked reduction in the mean score and improved mean score of oxygen saturation with higher mean difference and with statistically highly significant difference (P=0.001) between before and after intervention in the level of physiological parameters among postoperative sternotomy patients in study group.

The level of physiological parameters in control groups, there is reduction in the mean score of physiological parameters with lower mean difference and with statistically significant difference (P=0.001) between before and after routine care in the level of physiological parameters among postoperative sternotomy patients in control groups. The above findings goes consistent with the results of Shokati Ahmadabad et al done a randomized controlled clinical trial among 50 patients on effect of listening to preferred music on intensity of pain and physiologic parameters in patients undergoing coronary artery bypass grafting surgery. Patients in group "A" received usual care after surgery. In addition to usual care, patients in group "B" listen their preferred music (music played by MP4 player with special headphones for 30 minutes two times per day). Patients' pain and

physiologic parameters (heart rate, respiratory rate, diastolic and systolic blood pressure) were measured with using NRS and standard apparatus immediately before and 30 minutes after intervention. The study found that the mean (SD) score of pain intensity before and after intervention in patients in group "B" was 4.18 (2.68) and 3.13 (2.55) respectively. Among physiologic parameters, heart rate and respiratory rate decreased significantly in patients in group "B" (P > 0.05). The study concludes music should be considered by clinicians as a nonpharmacological, non-invasive, simple, cheap, safe, and effective method for pain management after coronary artery bypass graft surgery. Music also has not negative effect of patient's physiologic parameters.<sup>25</sup> The patient's anxiety affects by the post-operative complications which need to considered to be one of the important factors among the demographic and clinical variables. It is clearly indicated that there is a strong relationship between the post-operative complications in a patient is directly related with the patient's anxiety level. About limitation, current study was conducted in only one ICU of CTVS specialty.

Recommendation for future study may be conducted qualitative approach on effectiveness of music on pain and anxiety can also study.

#### Conclusion

Music intervention was highly effective in reducing in the level of pain, anxiety, diastolic blood pressure, heart rate and respiratory rate among post-operative sternotomy patients. It may be considered to play a mild music in wards and ICUs will help to improve the patients' physiological parameters, reduce the pain, anxiety, elevated oxygen saturation and patients feel comfort while listen their favorite music.

## Acknowledgments

We acknowledge all the participants for their kind cooperation in the study and JIPMER Institute Intramural fund committee for sanctioned the fund for the study.

## **Authors' Contributions**

KJM: Project administration, concepts, design, definition of intellectual content, clinical search, data analysis, statistical analysis, manuscript preparation, manuscript editing, manuscript review and guarantor. PG: Concept design, data collection, data analysis and data handling. SBV: Concept design and definition of intellectual content.

#### **Conflict of Interests**

There is no conflict of interest in this study.

## **Data Accessibility**

The datasets are available from the corresponding author on reasonable request.

## **Ethical Issues**

The study was also registered under Clinical Trial Registry of India (CTRI) with the Reg. No: CTRI/2019/11/022112. The researcher was obtained prior permission from the Nursing Research Monitoring Committee (NRMC) and Institute Ethics Committee (IEC-JIPMER)

## **Research Highlights**

## What is the current knowledge?

 Music is not using to reduce the pain, anxiety and regulating the physiological parameters in postoperative cardiovascular surgery ward in study setting.

#### What is new here?

• These findings clearly say the positive impact of music on relief of post-operative pain, postoperative anxiety and regulating the physiological parameters (heart rate, respiratory rate, and oxygen saturation, systolic and diastolic blood pressure). Based on the above results of this study, music has significantly reduced the pain, anxiety and physiological parameters among postoperative sternotomy patients compare with the routine hospital care. The present study findings help to implement evidence based practice in the study setting.

Reg. No. JIP/IEC/2019/049 to protect the human subjects from risk.

#### Funding

The study received Intramural Fund from JIPMER, Puducherry, India vide @ Memorandum No.JIP/Dean(R)/Intramural/Phs 1/2019-20.

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