

Effect of Music Therapy in Patients undergoing Surgery under General Anaesthesia: A Randomised Controlled Study

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ABSTRACT

Introduction: Surgical procedures are uncomfortable, stressful, and cause anxiety in patients. Preoperative anxiety affects haemodynamic parameters, reduces pain tolerance, and delays postoperative recovery. Music therapy is a non-pharmacologic, cost-effective intervention that can alleviate anxiety and improve patient satisfaction.

Aim: This study aims to evaluate the effects of music therapy in patients undergoing surgery under general anaesthesia.

Materials and Methods: This randomised controlled study included 60 patients aged >18 years with American Society of Anesthesiologists (ASA) physical status I-III scheduled for surgery under general anaesthesia, who were randomly allocated to Group M (music) or Group C (control), 30 in each group. In Group M, soothing (raga) music was played from 20 minutes preoperatively until the end of surgery. In Group C, no music was played. Both groups were analysed for the primary outcome (intensity of pain) and secondary outcomes {haemodynamic parameters, Bispectral Index (BIS) value, patient satisfaction, quality of recovery, and Postoperative

Nausea and Vomiting (PONV)}. The Student's t-test was used to compare continuous variables and the Chi-square test was used to compare categorical variables. A p-value <0.05 was considered statistically significant.

Results: No statistically significant difference was found in demographic data between the two groups. Intraoperative Mean Arterial Blood Pressure (MAP) was significantly different post-intubation for up to 60 minutes. BIS values were comparable and not significantly different. In Group M, the mean Visual Analog Scale (VAS) pain score at the 6th postoperative hour was lower than in Group C (2.24±0.43 vs. 3.90±1.01). The patient satisfaction score (Likert scale) was higher in Group M (3.13±0.34) than in Group C (3.00±0.00). Quality of recovery (Riker Scale) was 3.82±0.38 in Group M vs 4.56±0.67 in Group C, with a statistically significant difference. Regarding PONV, Group M scored better than Group C (0.21±0.41 vs 0.83±0.69; p<0.001).

Conclusion: Music interventions significantly reduce pain and PONV in surgical patients and improve overall patient satisfaction and quality of recovery.

Keywords: General, Haemodynamics, Pain, Patient satisfaction, Quality of recovery

INTRODUCTION

Music therapy is considered a therapeutic contribution as a non-pharmacological, inexpensive, and safe technique. Based on scientific data, the effects of music therapy include modulation of hormonal secretions and nociceptive reflexes [1,2]. Music has been shown to regulate mood, behaviour, and the psychology of patients, guiding them into a more positive frame of mind. Music is known to affect the limbic system, which controls deep emotions and many autonomic parameters. It decreases stress and anxiety through its relaxing effect. Anxiety can lower the pain threshold, amplify nociceptive signaling, and increase pain perception. Thus, anxiety and pain are correlated and can influence each other. Endogenous endorphin release has been implicated as a mechanism for decreasing pain and analgesic requirements in some studies [3]. Music therapy may induce the release of endogenous endorphins, thereby altering pain perception. Auditory pathways connecting with the hypothalamus, hippocampus, and the reticular activating system are thought to attenuate the release of excitatory neurotransmitters, thus providing relaxation and the sedative effects of music [4].

Surgery and anaesthesia are generally distressing experiences for patients and can be a source of stress and anxiety that hamper the desired therapeutic goal [5]. Despite the long history of music's therapeutic benefits, this harmless tool is not yet widely exploited in daily anaesthesia practice, reflecting a lack of recommendations. Hence, further research is needed to establish the clinical use of music therapy in patients undergoing surgery. The aim of the study was to evaluate the effects of music therapy in patients undergoing

surgery under general anaesthesia. The primary objective was to compare the intensity of pain in both groups, and the secondary objectives were to compare haemodynamic parameters, BIS values, intraoperative end-tidal concentration of inhalational agent, patient satisfaction scores, recovery quality, and PONV in both groups.

MATERIALS AND METHODS

This double-blind randomised controlled study was conducted at PDU Medical College, Rajkot, Gujarat, India, from October 2019 to December 2020 after Institutional Ethics Committee approval (Reg. no. PDU/MCR/IEC/4511/2020). Written informed consent was obtained from all study participants.

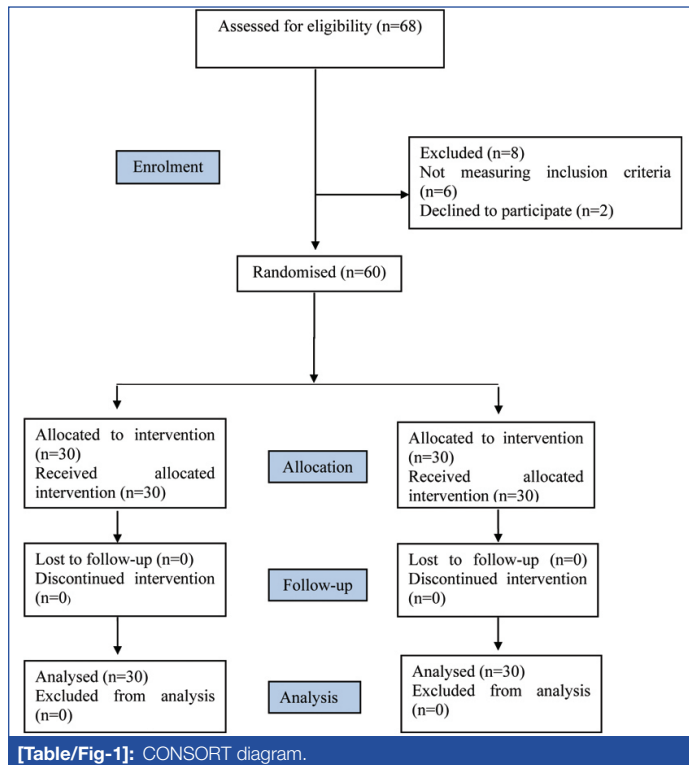
Inclusion criteria: Sixty participants aged >18 years of either sex, ASA grade I-III, who were scheduled for surgery under general anaesthesia, were included.

Exclusion criteria: Patients with cognitive, psychological, or memory disorders; hearing impairment or ear deformity; prolonged use of analgesics or drug addiction; cardiac, renal, respiratory, or hepatic impairment; neuromuscular or bleeding disorders; and haemodynamically unstable patients were excluded from the study.

Sample size calculation: Based on a previous study, the average VAS score for pain was 33.8±13.63 in the music group versus 45.1±16 in the control group. The mean difference (δ) in VAS score was 11.3 and the Standard Deviation (SD) was 13.63 [6]. The sample size was calculated using the formula $n=2(Z\alpha+Z\beta)^2 \times \sigma^2/\delta^2$, i.e., $n=2(1.96+0.84)^2 \times (13.63)^2/(11.3)^2$, assuming a significance level of 0.05 ($Z\alpha=1.96$) and 80% power ($\beta=0.84$). The calculated sample

size was approximately 23 per group. To increase the study power and enable parametric analyses, 30 participants were enrolled in each group.

The patients were randomly divided into two equal groups: music group (Group M, n=30) and control group (Group C, n=30). The CONSORT flow chart is presented in [Table/Fig-1]. We assessed 68 patients for eligibility and randomised 60 patients equally into the two study groups. Of these, eight patients were not randomised as they did not meet all eligibility criteria or declined to consent.



Study Procedure

This was a double-blind randomised controlled study conducted as follows. The enrolled patients were randomly allocated to one of the two groups in a 1:1 ratio using a computer-generated random number system generated by an independent physician [Table/Fig-1] with allocation concealed in sequentially numbered opaque sealed envelopes. After enrollment and baseline assessments, envelopes were opened and the intervention allocated to the patient.

Blinding and intervention: All participants were fitted with headphones by a single anaesthetist who was not involved in the study. The music group received music via headphones, while the control group wore headphones with no music to maintain blinding. After administration of the allocated therapy, the envelope containing the patient's details was affixed with a sticker and returned to the randomisation controller. To minimise bias, the anaesthesiologist blinded to group allocation recorded the study parameters throughout the study period.

Preoperative and intraoperative management: In the preoperative room, pulse, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Blood Oxygen Saturation (SpO₂) were recorded in patients undergoing surgery under general anaesthesia. Patients were provided with headphones connected to an MP3 player containing pre-recorded soothing (raga) music for 20 minutes in the preoperative room, and this music continued into the operating room. Standard monitoring {Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), End-tidal Carbon Dioxide (EtCO₂)} and Bispectral Index (BIS) monitoring were applied. An IV line was secured. Premedication consisted of glycopyrrolate 4 µg/kg, ondansetron 4 mg, ranitidine 50 mg, and midazolam 0.03 mg/kg. All patients were preoxygenated with 100% O₂ for three minutes.

General anaesthesia: Anaesthesia was induced with propofol 2-2.5 mg/kg, fentanyl 1.5 µg/kg, and to facilitate intubation with an appropriately sized cuffed endotracheal tube, vecuronium bromide 0.1 mg/kg was given. Anaesthesia was maintained with a mixture of 50% N₂O in O₂ and isoflurane (end-tidal concentration 0.3-1.5%) to maintain BIS 50-60. Fentanyl boluses of 2 µg/kg were given as required to maintain BIS. Haemodynamic parameters, BIS values, and end-tidal isoflurane concentration (vol%) were recorded every 15 minutes until the end of surgery. Neuromuscular blockade reversal was achieved with neostigmine 0.05 mg/kg and glycopyrrolate 0.04 mg/kg. Music was continued until the end of surgery (wound closure); after that, music was stopped and headphones removed.

Postoperative management: Postoperative pain was managed with rescue analgesia (intramuscular diclofenac sodium 1.5 mg/kg) in the recovery room when VAS >3. After extubation, patients were transferred to the recovery room and observed for PONV, pain, and other parameters as described. Rescue antiemetic (ondansetron 4 mg IV) was administered when PONV score >1.

Outcome measures: Quality of awakening was assessed by the Riker Sedation-Agitation Scale (RSAS) [7,8]. Pain on waking was assessed by the Visual Analog Scale (VAS), where 0 represents "No pain" and 10 represents "Unbearable pain." Patient satisfaction was assessed using a 5-point Likert scale where 1=very dissatisfied, 2=dissatisfied, 3=neutral, 4=satisfied, 5=very satisfied. PONV was assessed on a scale: 0=Retching, 1=Nausea, 2=Vomiting.

STATISTICAL ANALYSIS

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 22.0 (IBM Corp., Armonk, NY, USA) and included comparisons of primary and secondary variables between the two groups. Continuous variables are expressed as mean±SD, while categorical variables are presented as numbers and percentages. Data were checked for normality before analysis. The independent samples t-test was used to compare continuous variables (e.g., heart rate, blood pressure) that followed a normal distribution, and the Chi-square test was used to compare categorical variables. A p-value <0.05 was considered statistically significant.

RESULTS

No statistically significant differences were found in demographic parameters and surgical profiles between the two groups [Table/Fig-2]. The mean Heart Rate (HR), SpO₂, BIS value, and intraoperative end-tidal concentration of the inhalational agent were comparable between groups and not statistically significant (p>0.05) [Table/Fig-3]. Mean Arterial Pressure (MAP) differed significantly between groups from post-intubation up to 60 minutes [Table/Fig-3].

Parameters	Group-M (n=30) Mean±SD ^a	Group-C (n=30) Mean±SD ^a	p-value ^b
Age (years)	40.33±12.72	38.23±12.90	0.52 ^c
Sex*			
Male	15 (50%)	16 (53.3%)	-
Female	15 (50%)	14 (46.6%)	
ASA status*			
Grade-I	0	0	-
Grade-II	17 (56.6%)	4 (13.3%)	
Grade-III	13 (43.3%)	26 (86.6%)	
Duration of surgery (minute)	139.75±9.75	141.03±10.8	0.49 ^c

[Table/Fig-2]: Demographic data of study participants.

a- Values are represented as mean±SD except marked * which is expressed as number (%) of patients; b- p<0.05 was considered significant; c) Chi-square test; ASA: American society of anaesthesiologists; n: Number

Mean VAS scores at 6, 12, and 24 hours were 2.24, 3.96, 2.20 in Group M and 3.90, 2.46, 1.00 in Group C, respectively. These data indicate that VAS pain scores were lower at 6 hours in the music

Haemodynamic parameters	Group-M Mean±SD ^a	Group-C Mean±SD ^a	p-value ^b
Heart rate (minute)	82.96±5.17	82.67±5.27	0.4152 ^c
SpO ₂	99.93±0.25	99.83±0.37	0.2284 ^c
MBP just before induction (mm hg)	98.02±5.5	98.2±5.38	0.4492 ^c
MBP Post intubation (mm hg)	99.84±5.86	103.68±5.13	0.0071 ^c
MBP 30 minutes (mm hg)	90.49±7.08	95.23±4.83	0.0003 ^c
MBP 60 minutes (mm hg)	85.65±4.59	92.95±4.78	0.0001 ^c
MBP 120 minutes (mm hg)	97.09±3.73	95.56±3.28	0.0484 ^c
BIS value	53.63±2.39	54.36±2.32	0.1174 ^c
Dial conc. of inhalation agent	0.95±0.10	0.96±0.10	0.3499 ^c

[Table/Fig-3]: Perioperative parameters.

a) Values are represented as mean±SD except marked *which is expressed as number of patients; b) p<0.05 was considered significant; c) Chi-square test; MBP: Mean blood pressure

group compared with the non-music group, and the music group required less analgesia during the postoperative period [Table/Fig-4]. Patient satisfaction at 6 hours, assessed by a 5-point Likert scale, was higher in Group M (3.13±0.34) than in Group C (3.00±0.00), with statistical significance [Table/Fig-5]. Quality of recovery assessed by the Riker Sedation-Agitation Scale (RSAS) at 6 hours was 3.82 in Group M and 4.56 in Group C, a statistically significant difference [Table/Fig-5]. Regarding PONV, the music group scored better than the control group (0.21±0.41 vs 0.83±0.69; p<0.001) [Table/Fig-6].

Time	Group-M Mean±SD ^a	Group-C Mean±SD ^a	p-value ^b
0 minute	0.06±0.25	1.0±0.26	<0.001 ^c
2 hour	1.24±0.43	1.0±0.27	0.0005 ^c
6 hour	2.24±0.43	3.9±1.01	<0.0001 ^c
12 hour	3.96±1.01	2.46±0.57	<0.0001 ^c
24 hour	2.20±0.41	1.0±0.25	<0.0001 ^c

[Table/Fig-4]: VAS score.

a) Values are represented as mean±SD; b) p<0.05 was considered significant; c) Chi-square test

Parameters	Group-M Mean±SD ^a	Group-C Mean±SD ^a	p-value ^b
5 point Likert scale	3.13±0.34	3.0±0.0	0.0406 ^c
Riker scale	3.82±0.38	4.56±0.67	<0.0001 ^c

[Table/Fig-5]: 5 point Likert Scale and Riker Scale.

a) Values are represented as mean±SD; b) p<0.05 was considered significant; c) Chi-square test

Time	Group-M Mean±SD ^a	Group-C Mean±SD ^a	p-value ^b
6 hour	0.21±0.41	0.83±0.69	<0.0001 ^c
12 hour	0.00±0.00	0.86±0.56	<0.0001

[Table/Fig-6]: Postoperative nausea vomiting.

a) Values are represented as mean±SD; b) p<0.05 was considered significant; c) Chi-square test

DISCUSSION

Surgical procedures are uncomfortable and stressful and can provoke anxiety in patients. Preoperative anxiety affects haemodynamic vitals, decreases pain tolerance, and delays postoperative recovery. Reducing preoperative anxiety can lead to decreased pain, vomiting, shorter recovery time, and increased patient satisfaction [9]. Music therapy is increasingly used as a nonpharmacological intervention in the perioperative period to improve patient outcomes, reduce the need for multiple medications, and thereby reduce the physiological effects of stress such as anxiety, blood pressure, heart rate, and respiratory rate [10]. It is a safe, inexpensive, pain-free, and effective treatment without side effects.

In our study, we concluded that patients in the music therapy group had better awakening quality, a lower pain level according to the VAS, a higher patient satisfaction rate, and a lower incidence of PONV. There was a significant difference in MAP between the two groups post-intubation up to 60 minutes. We also deduced that

intraoperative awareness was lower in the music group but not statistically significant.

We observed that intraoperative music therapy reduced HR, but this was not statistically significant compared with the control group. With music therapy, MAP was significantly reduced post-intubation up to 60 minutes compared with the control group. A similar finding was reported by Steelman VM et al., who found that there was no reduction in HR, but a statistically significant fall in BP with music therapy [11]. Vazhakalayil SJ and Varma S also stated in their study that Systolic Blood Pressure (SBP) was reduced from five minutes to 30 minutes after induction in the music group, which was significant but not significant after 30 minutes, and there was no significant difference in HR throughout surgery [12].

In contrast to our results, Mohamed K et al., Binnis-Turner PG et al., and Wang J et al., showed a significant reduction in HR and MAP in the intervention group compared with the control group [13-15]. The positive effect on haemodynamics might be due to reduced anxiety by diverting the patient's attention to music. In contrast to our findings, Gökçek E and Kaydu A, Patil Kalyani N et al., and Saxena KN et al., studied that there were no statistically significant differences in HR and Mean Blood Pressure (MBP) with music therapy compared to the control group [7,10,16]. Previous studies have investigated the effects of preoperative, intraoperative, and postoperative music therapy on BP, and their findings suggest that music interventions may be most effective in reducing blood pressure if music is initiated preoperatively [6,7,10,13,14,17].

Guerrier G et al., showed that the reduction of pain is greatest when patients are allowed to choose the type of music [18]. In contrast to this study, some studies concluded that music selection by patients has no significant effects on pain scores [14,17,19]. In our study we used only raga music, which was pre-recorded and initiated preoperatively. Patient music selection did not have a profound effect on increasing patient satisfaction or the success of music therapy, but it did allow autonomy and control to patients and is a way to empower patients in an unfamiliar and stressful situation. It is the act of personal choice that determines the greatest effectiveness of the therapy at the individual level [20].

Few studies used a VAS score to measure pain at different stages during surgery and found that pain intensity during the recovery period was significantly reduced in the music group [6,16,20,21]. Tajbakhsh A et al., showed that mean pain intensity was significantly lower and the duration of analgesia was longer in the music group [22]. The mechanism of action of music therapy for pain relief is multifactorial, involving increased endorphin release, attenuation of conduction in the afferent fibers, and psychological factors [19]. In contrast to this finding, Vazhakalayil SJ and Varma S noted that there was no significant difference in VAS scores between the music and control groups at various time intervals throughout the study period [12].

We used the Riker Sedation-Agitation Scale (RSAS) to measure the level of awakening quality and concluded that recovery quality was better in the intervention group. Several studies evaluating music therapy's effect on recovery quality using RSAS have found that sedation scores were higher in the music group and there is a significant association between music therapy and qualitative recovery [6,11,16,23]. In contrast to this finding, Tajbakhsh A et al., assessed patients' level of calmness in the recovery room and found no significant association (p=0.164) [22]. From these results, we conclude that music therapy can reduce stress.

Our results showed a significant improvement in patient satisfaction in Group M, measured by a 5-point Likert scale. In other studies, questionnaires were used to measure patient satisfaction with surgical experiences; all studies showed higher satisfaction scores for the music group than the control group [20,24,25]. In studies published by Kahloul M et al., Gökçek E and Kaydu A, and Saxena

KN et al., they confirmed that the rate of satisfaction was higher using the Evan scale in the music group [6,7,16]. The relaxing quality of music therapy improves patient satisfaction and helps alleviate anxiety. In the present study, in the music group there was a significant reduction of postoperative nausea and vomiting. This finding is supported by a study in which there was no case of PONV in the music group and 24% of the control group suffered from mild nausea in recovery [22]. Our result differs from several studies that found music therapy did not reduce PONV [9,11].

In our study, there was no statistically significant difference in the intraoperative end-tidal concentration of the inhalational agent and in the intraoperative BIS value. Similar to our study, Szmuk P et al., showed that the end-tidal concentration of sevoflurane required to maintain BIS near 50 was identical in patients exposed to music or not [26]. Palmer B et al., stated that sedative requirements were not reduced according to BIS monitoring in the music therapy group [24]. In contrast, a study showed that mean propofol consumption was significantly lower to maintain a fixed BIS number in the music group [22].

Limitation(s)

There were several limitations in this study that must be acknowledged. We used only one pre-recorded music track for all patients. Providing patients with more selections from different types of music and allowing them to select music themselves might yield greater benefits. Also, the VAS score is recognised as a valid indicator and is widely used as a pain rating scale in clinical trials, but it remains highly subjective. To demonstrate the importance of this technique in the operating theatre, large-scale studies should be carried out.

CONCLUSION(S)

Our study results clearly show that music may have a definite role in improving postoperative outcomes—reduction of postoperative pain, improved patient satisfaction scores, better quality of recovery, and more stable haemodynamics in patients undergoing surgery under general anaesthesia. Music therapy is simple, nonpharmacological, inexpensive, time-efficient, enjoyable, and should be considered as an intraoperative option for surgery, as it is innovative and non invasive.

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AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Jan 27, 2025
- Manual Googling: May 13, 2025
- iThenticate Software: May 15, 2025 (8%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

Date of Submission: Jan 25, 2025
Date of Peer Review: Apr 15, 2025
Date of Acceptance: May 17, 2025
Date of Publishing: Jan 01, 2026