EFFECT OF MUSIC ON ANXIETY AND PHYSIOLOGIC PARAMETERS IN PATIENTS POSTED FOR SURGERY UNDER REGIONAL ANAESTHESIA: A RANDOMISED CONTROLLED TRIAL

Thesis Submitted to

All India Institute of Medical Sciences, Jodhpur

In partial fulfilment of the requirement for the degree of

DOCTOR OF MEDICINE (MD)

(ANAESTHESIOLOGY AND CRITICAL CARE)

MAY, 2022 **DR. MARKANDEY PRASAD**

AIIMS, JODHPUR

DECLARATION

I here declare that thesis titled "**Effect of music on anxiety and physiologic parameters in patients posted for surgery under regional anaesthesia: A randomised controlled trial**" is a bonafide and original research work carried out in partial fulfilment of the requirements for the Degree Of Masters under supervision and guidance, in the Department of Anaesthesiology and Critical care, All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE FROM THE SUPERVISORS

Certified that the submitted thesis titled **"EFFECT OF MUSIC ON ANXIETY AND PHYSIOLOGIC PARAMETERS IN PATIENTS POSTED FOR SURGERY UNDER REGIONAL ANAESTHESIA: A RANDOMISED CONTROLLED TRIAL"** is a record of the research work undertaken by **Dr Markandey Prasad** in partial fulfilment of the requirements for the award of the degree of **"Doctor of Medicine (MD) Anaesthesiology"** under my guidance and supervision.

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CERTIFICATE FROM THE HEAD OF THE DEPARTMENT

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ETHICAL CLEARANCE CERTIFICATE

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To,
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Subject: Effect of music on anxiety and physiologic parameters in patients posted for surgery under regional anaesthesia: A randomized control trial

Dear Dr. Sethi,

This has reference to your above mentioned **M.D. Thesis Protocol of Dr. Markanday Prasad**. The project was discussed in the Ethics Committee online meeting held on 23-12-2019 and revised on 17.09.2021 the following members of the Ethics Committee attended the meeting:

1.	Dr. F.S.K Barar, Former Professor & Head, Pharmacology, SMS Medical College	Chairman
2.	Justice N.N. Mathur, Former Vice Chancellor, National Law University, Jodhpur	Member
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8.	Dr. Abhinav Dixit, Professor, Dept. of Physiology, AIIMS, Jodhpur	Member
9.	Dr. Tanuj Kanchan, Professor, Dept. of Forensic Medicine, AIIMS, Jodhpur	Member
10.	Dr. Praveen Sharma, Professor, Dept. of Biochemistry, AIIMS, Jodhpur.	Member Secretary

The Project has been approved with effect from 17.09.2021 subject to the following conditions:

- The approval is valid for the period of the conduct of study according to this protocol under the responsibility of Principal Investigator: Dr. Priyanka Sethi, Co-Investigators: Dr. Pradeep Kumar Bhatia, Dr. Ankur Sharma and Dr. Kamlesh Chaudhary.
- No significant changes to the research protocol could be made and implemented without prior consent of the IEC and any changes/deviations from the protocol which increase the risk for the subjects should be submitted to the IEC and approved by it prior to implementation.
- It is confirmed that the Ethics Committee of AIIMS, Jodhpur is composed of and functions as per ICH GCP and other applications regulatory guidelines.
- It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.
- The study progress report should be made available to the IEC for review annually.

With Warm regards.

Yours Sincerely,

Dr. Praveen Sharma
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

ACKNOWLEDGEMENT

"The beautiful thing about learning is that no one can take away it from you"

-B.B. king

First and foremost, I express my thankfulness to The Almighty God for his blessing on my thesis project completion. Nothing is possible without good teachers' guidance. With these words, I'd like to express my heartfelt gratitude to **Dr. Priyanka Sethi**, my MD thesis guide and Associate Professor, Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences, Jodhpur, for her unwavering trust and support. I am very delighted and appreciative for the chance to experience under her tutelage.

Dr. Pradeep Kumar Bhatia, Professor and HOD of the Department of Anaesthesiology and Critical Care,

Dr. Ankur Sharma, Associate Professor of the Department of Anaesthesiology and Critical Care, and

Dr. Kamlesh Kumari, Assistant Professor of the Department of Anaesthesiology and Critical Care AIIMS Jodhpur, are also my co-guides. Their continual coaching and step-by-step support have been crucial in developing the environment of success and requirements that must be met for a dissertation from our prestigious institute.

I'd want to show my thankfulness to all of the faculty members of the Department of Anaesthesiology and Critical Care at the All-India Institute of Medical Sciences in Jodhpur for their unwavering support. I hope I've been a close friend to **Dr. Anas V P, Dr. Prem kumar, Dr. Anjana Ramachandran, Dr. Shipra Roy, Dr. Priyadarshan, and Dr. Somya Goel,** and I appreciate their support.

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- DR. MARKANDEY PRASAD

LIST OF ABBREVIATIONS

IV	Intra Venous
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
PR	Pulse rate
VAS	Visual analogue score
MOV	Movement
NIBP	Non-invasive blood pressure
MAP	Mean arterial blood pressure
STAI	Strait Trait Anxiety Inventory
ECG	Electrocardiogram
RCT	Randomized controlled trial
EEG	Electroencephalogram
PONV	Postoperative nausea and vomiting
PACU	Post Anaesthetic Care Unit
HR	Heart rate
ASA	American Society of Anaesthesiologist
OT	Operation Theatre

CONTENTS

LIST OF TABLES

LIST OF FIGURES

FINAL DISCUSSION

By: KAMLESH KUMARI

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The aim of this study is to investigate and compare the anxiety-reducing effect of music (self-selected and investigator selected) with midazolam, played preoperatively from 10 min prior to the administration of regional anesthesia till 30 minutes post operatively. The primary outcome of our study will was be to compare the change in visual analogue anxiety scale (VAS- A) before and after placement of regional anesthesia in between the three study groups (as per the group allotment). The secondary outcome will bewere: Tto assess and compare intra-group and inter-group VAS-A score in all the three groups at various time points which includes: preoperatively, after 10 minutes of intervention, after block placement, at 60 minutes intraoperatively, at the time of skin suture and 30 minutes after completion of surgery, Tto evaluate differences in patient satisfaction scores and physician satisfaction scores of their experience during the procedure, physician satisfaction scores of their experience while conducting the procedure, Dduration of analgesia (time to use first rescue analgesic), vital signs including mean arterial pressure and heart rate and any complication. Formatted: Font: 14 pt, Font color: Red Commented [1]: Copy exactly you mentioned in your plan. Otherwise they will reject and you need to reprint it. 43|Page S = Significant ; NS = Non Significant S = Significant ; NS = Non Significant S = Significant ; NS = Non Significant Statistical analysis In gGeneral anaesthesia, induction and emergence are the two crucial steps because, as the body is susceptible to a variety of stress and hemodynamic changes.

Preoperative anxiety is can adversely affect a patient's perioperative course by elevating stress markers along with **promoting fluctuations in** hemodynamic **and** further **negatively impacting on postoperative recovery. Preoperative anxiety is routinely treated with** drugs **such as short-acting benzodiazepines** 6

. Music is a non-invasive, safe and economical intervention that requires no special skill. It has positive effect on pain and anxiety. .[28] Our brain accepts it very well, as people like to listen music repeatedly . Effectiveness of music has been established in treatment of physical and mental stress. It further helps in managing the physical, emotional and social needs of patients. [29,30,31,32] Music modulates the mood, behaviour and psychology of the patient. It reduces anxiety and have a favourable impact on hemodynamics. [33,34,35]. Music reduces individual's perception of pain by releasing endogenous opioid and reducing muscle tension and interfering with nerve conduction. It also acts by reducing the transmission of a pain signal and anxiety.[(36]). In our study we divided patient into 3 groups which include: - 44|Page ? Group A: Where patients received search-selected music (binaural tone) via noise- canceling headphones. ? Group B: Patients received intravenous midazolam minimum of 1 mg to 2 mg maximum as per clinical judgement. ? Group C: Patients were made to listen, patient preferred music via noise-canceling headphones. Binaural beats or tone is

oscillating sound, produced when two different sounds with different frequencies are listened by individual's right and left ear separately but simultaneously.

For instance, when the left ear is listening **a tone of** 300 **Hz and the right ear a tone of** 320 **Hz, the** individual **will perceive a tone that oscillates at a frequency of** 20 **Hz (i.e** .,20 **beats per second** 5

). Binaural tones impact by increasing neural synchronization. [(37]) The binaural beat produced

if the frequency of each tone is less than 1000 Hz and the difference between the two is less than 35 Hz 1

.

When each ear hears a tone at a slightly different frequency, your brain tries to compensate by creating the perception of a third sound. This creation of a third sound is caused by the same part of the brain that helps you determine the location of a sound. Binaural 1

beats are created at different frequencies. Each frequency corresponds to different levels of activity.

Gamma (γ) pattern: Gamma waves are the highest frequency of brain activity between 30 Hz and 50 Hz 1

. It is associated with alertness, concentration and problem solving.

People listening to binaural beats at gamma frequencies of 40 Hz experience better **memory, cognition and even mood. Beta (β) pattern: Beta waves range between 13 Hz and 30 Hz** 1

. They are associated with an active and alert mind. Higher levels of beta waves may be associated with anxiety. Beta wave pattern has been shown to improve mood and task performance while listening. Alpha (α) pattern: Ranging between 8 Hz and 13 Hz, these waves indicate a relaxed and restful mind. This wave can increase creativity in few listeners. 45|Page Theta (θ) pattern: During stage one

of sleep, brain produces theta waves of frequency between 4 Hz and 8 Hz . They are associated with drowsiness and meditation . Literature shows that listening to binaural beats at 6 Hz frequency can induce a meditative state. Delta (δ) pattern: The slowest brain waves are delta waves. These waves have a frequency between 0.5 Hz and 4 Hz . With transition into deeper sleep stages, brain switches from theta waves to delta waves. Dreaming can occur. Binaural beats at delta frequencies can help in better sleep 1

. [14] Evidence establishes that

preoperative anxiety starts as soon as the procedure is planned and reaches peak on the day of surgery ; further confirmed by other physical changes , as increased hormones and acute phase's protein release , hypertension, tachycardia episodes 2

, fluid and electrolyte imbalances, rise in body temperature

and longer wound healing . It can affect the surgical outcome and the postoperative recovery . It leads to increase in the dosage of anaesthetics and sedatives given 2

perioperatively

with a consequent higher risk of adverse events. Patients with anxiety have a longer hospital stay with decreased postoperative satisfaction and are less compliant with rehabilitation and occupational therapy . [(11]). In the 2

present study, the difference in the mean age and sex among these groups were statistically non-significant (P value >0.05), hence these groups were comparable with respect to age and sex. Visual Assessment Score -Anxiety Score In our study we measured VAS A score to measure anxiety at different time periods (Baseline, after 10 minutes in the operation theatre, before block placement, after block placement and after 60 minutes of block placement) among the study groups. We found that the VAS A score was significantly lower in the patient selected music group (Group C) after 10 minutes in the operation theatre (p value- 0.005), before block placement (0.004) and 60 minutes after block placement (p value- 0.038). Conversely after the block placement the VAS A score was comparatively lower in group A but it was not statistically significant (p value- 0.618). We have also compared VAS A score between Group A and B, Group B and C and Group C and A at the above specified time intervals. We found that on comparison between Group B and Group C, VAS A score was lower in Group C which was statistically significant at the following points of measurement (after 10 minutes in the operation theatre (p value- <0.001), 46|Page before block placement (p value-

0.0002) and 60 minutes after block placement (p value- <0.001)). Similarly, during comparison of VASof VAS A score between Group A and Group C the VAS A score was significantly lower in Group C at the following points of measurement (after 10 minutes in the operation theatre (p value- 0.007) and after 60 minutes of block placement (p value- 0.001).This). We also compared mean difference of VAS anxiety score between before and after block. There was a statistically significant difference in group A and C. This may be probably because music of patient's choice has better anxiolysis effect than midazolam and binaural tone music. Patient is more distracted from thought of surgery by listening to music especially, if it's of patient choice. Further studies are needed to compare effect of different music types on perioperative anxiety. We alsoWe also compared anxietycompared anxiety during skin closure and 30 minutes after skin closure between the study groups. We found that VAS A score was lower in Group C at all points of measurement which was statistically significant (p value <0.001). We have also compared VAS A score post operatively between Group A and B, Group B and C and Group C and A at various time periods time intervals and found that during comparison of VAS A score between Group B and Group C, VAS A score was lower at the above specified points of measurement but was significantly lower after 30 minutes of skin closure (p value <0.001). Also, VAS A score was significantly lower during the comparison between Group A and Group C (p value of <0.001) at the above specified points of measurement. Our findings were consistent with a study done by Ugras G A et al[47], in which they used STAI-S score instead if VAS score as in our study and found that there was a statistically significant reduction in STAI-S score in the post-music group. Our findings were also similar to a study done by ghezeljeh T N et al [45], in which they found that with music therapy during intervention there was a statistically significant decrease the pain (VAS) and anxiety scores and increase in relaxation scores. In our study binaural music therapy shows significant less anxiety and pain than patient selected music and only midazolam. Our results were supported by study of Kukreja P et al (2020) [27] , they also observed less anxiety and pain with music therapy. Labrague LJ et al (2016) [22] and Lee and Kim's [38] also observed similar result as in our study. Our findings are also consistent with a study done in which they found statistically significant reduction in anxiety level in binaural music group. Our study results were also in 47|Page aceeptanceacceptance with a study done by Mahumut Taha et al [42] in which they notice lListening to pure binaural beats may a simple and effective method to reduce anxiety level and pain. Visual Analogue score for pain: At Rest: In our study we also measured VAS R for measuring postoperative pain at different time intervals (10,30,60,90,120,180 minutes postoperatively) was compared among the study groups. We found that the VAS R score was significantly lower in the patient selected music group (Group C) which was statistically significant at all time points of measurement. We have also compared VAS R score between Group A and B, Group B and C and Group C and A at the above specified time intervals. We found that on comparison between Group B and Group C, painC, pain scores were lower in Group C which was statistically significant at the following points of measurement ; (10 minutes (p value- 0.0006), 30 minutes (p value -0.003), 90 minutes (p value- 0.008) and), 180 minutes (p value- 0.007). Similarly, during comparison of VAS R score between Group A and Group C, VAS R score was significantly lower in Group C at all the above specified points of measurement. Similarly, during comparison of VAS R score between Group A and Group B, the VAS R score was significantly lower in Group B at all the above specified points of measurement but was statistically significant at 120 minutes (p value- 0.029) and at 180 minutes (p value – 0.009). At Movement: In our study, we also measured VAS duringVAS during movement at different time intervals (10, 30,60,90,120,180 minutes postoperatively) among the study groups. We found that the VAS M score was significantly lower in the patient selected music group (Group C) which was statistically significant at all time points of measurement. We have also compared VAS M score between Group A and B, Group B and C and Group C and A at the above specified time intervals. We found that on

comparison between Group B and Group C, VAS A score was lower in Group C which was statistically significant at the following points of measurement ;(10 minutes (p value-0.003), 30 minutes (p value -0.003), 90 minutes (p value- 0.046) and , 180 minutes (p value- 0.005). Similarly, during comparison of VAS M score between Group A and Group C the VAS M score was significantly lower in Group C at following points of measurement (30 minutes p value-0.001),60 minutes (p value -0.005), 90 minutes (p value- 48 | P a g e <0.001),120 minutes (p value-0.003). Similarly, during comparison of VAS M score between Group A and Group B the VAS M score was significantly lower in Group B at all the above specified points of measurement but was statistically significant at all points of measurement. Both during rest and movement, patients in group C (patient(patient selected music) had lower pain scores followedscores followed by midazolam group then binaural tone music. We could not find any literature supporting our findings. These findings may be because patient in preference selected music group were more distracted and anxiety free then other groups. This might reduce some factors especially psychological which leads to enhanced perception of pain in perioperative period. Music therapy may also release some endorphins which results in reduced pain perception.[43] None of the patients included in this study have received intraoperative and postoperative dexmedetomidine infusion. Blood Pressure: On comparing intraoperative mean arterial pressure between GroupGroup A and Group B the mean arterial pressure was significantly lower in group A (binaural tone music) at 10,15, 30,60,90,120 minutes. On comparing the intraoperative BP between Group B and C, the mean arterial bp was statistically significant lower in Group C at 10, 15,30, 90, 120 and 180 minutes respectively. This decrease in mean bp could be attributablebe attributable to greater relaxation and anxiolysis achieved due to music therapy (both binaural tone and patient choice music). Similarly on comparison of intraoperative mean BPbp between Group A and Group C, the mean arterial BP was significantly lower in Group A at 30,60,90 minutes respectively. It was comparable to other studies like that conducted by Kahloul M et al(24) where they found that there was more stability in mean systolic blood pressure among the music group when compared with control group. In a study published in 2007, Jaber et al(44), found that systolic arterial blood pressure (137 ± 17 versus 128 ± 14 mm Hg, p < 0.05). Our findings are contradictory to the findings done by Reynaud D et a[48] in which they found that the hemodynamic parameters were stable in self-selected music group when compared to selected music group. In study conducted by Veena Graff [26] also there was no significant difference between the mean arterial pressure trend throughout the nerve block among the music and midazolam groups. This discrepancy has been attributable to the selection of predetermined music and the timing of its introduction. 49 | P a g e Pulse Rate: On comparing intraoperative pPulse rate between Group A, Group B and Group C the mean pPulse rRate was significantly lower in group A and Group C (binaural tone music) at 10, 15, 30,60,90,120 minutes. This decrease in mMean pPulse rRate could be attributable to greater relaxation and anxiolysis achieved due to music therapy (both binaural tone and patient choice music). In the postoperative period on comparing the pPulse rate between Group A,B,C the mean pPulse rRate was lower in Group A and Group C (both binaural tone and patient choice music). Our findings are contradictory to the findings done by Reynaud D et al[48] in which they found that the hemodynamic parameters were considerable low and stable in self-selected music group as compared to predetermined music group. This discrepancy has been attributable to the selection of predetermined music. Our results supported by Jaber et al(44))where they

found that music therapy provides a significant reduction in heart rate (88 ± 15 versus 82 ± 15 bpm, p < 0.05 3

) among the music group and the control group. In a study conducted by Gökçek et al(27) they found heart rate (78.56+ 9.66 v/s 79.63 + 13.84) and mean arterial blood pressures (85.13+ 10.43 v/s 86.66 + 10.78) were lower among the music group and the control, but results were not statistically significant. Time of Rescue Analgesia: In our study time of rRescue aAnalgesia was 6.96±1.61 hours in Group A, 7.21±01.60 hours in group B and 6.81±1.33 hours in Group C. The difference in time of rRescue aAnalgesia between these groups was non-significant (P =0.267). Mishra R et al 39 in their study proved that music has no effect on time of rescue anlagesicanalgesic. Patient satisfactory score (at 24 hrs postoperatively): In Group A, 59 (78.67%) patient shows excellent satisfactory score, 16 (21.33%) patient shows good satisfactory score. In Group B, 63 (84%) patient shows excellent satisfactory score, 12 (16.33%) patient shows good satisfactory score. In Group C, 72 (96%) patient shows excellent 50|Page satisfactory score, 3 (4%) patient shows good satisfactory score. The difference in satisfactory score of these was statically significant. (P=0.007) Patients in group C (self-selected music) seems to be maximally satisfied with excellent satisfaction followed by midazolam group then binaural tone group patients. In our study, music therapy patients showed better satisfactory score than midazolam group which is supported by Jayaraman et al. [40]. They also advocated positive effects of music therapy on patient satisfaction. This effect is more evident when the music is chosen by the patient [40]. Similar results were found by Bechtold et al [46] , they enrolled patients posted

for colonoscopy under general anaesthesia (85 patients treatment group versus 81 patients control group). The frequency of patients preferred **music in subsequent colonoscopy was significantly higher in the intervention group (96.3% versus 56.1%; p < 0. 0001** 4

). They showed that satisfaction was significantly greater in the intervention group.

Music therapy improves patient **satisfaction directly by its relaxing effect, and indirectly** by **its effects on** various **factors such as perioperative pain** , stress **and** postoperative nausea **and vomiting** 3

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INTRODUCTION

INTRODUCTION

Preoperative anxiety is can adversely affect perioperative course by increasing stress markers, promoting fluctuations in hemodynamic and negatively affecting postoperative recovery. [1,2] Most patients posted for surgery have anxiety and accepted as an expected response. It is an unpleasant state of uneasiness or stress, associated with abnormal hemodynamic probably because of sympathetic, parasympathetic and endocrine stimulation. Effect of anxiety depends depends on various factors. These are age, gender, type, proposed surgery, previous surgical experience, and personality.

Preoperative anxiety is routinely treated with drugs as short-acting benzodiazepines. Benzodiazepines are known to associated with various side effects such as respiratory depression, hemodynamic changes and paradoxical effects as aggression, hostility, and psychomotor irritability. [3,4] A recent Cochrane review showed that there is low quality of evidence about effect of midazolam in reducing pre-procedural anxiety compared with placebo[5]. Music is a non-pharmacologic intervention which can probably significantly decrease peri operative anxiety. [6] It is harmless and inexpensive. It can be used as an adjunct or replacement for drugs used to manage preoperative anxiety. [7-8]

Music has different types of pitch, rhythm, and tone. Different types of music can have different effects on stress. Effects of music depends on one's personal experience with his/her cultural and religious beliefs. Listening to favourite music can lead to increase in secretion of ß endorphin, pleasant emotions and reduced pain. Literature has proved that high-pitched music can elicit stress, conversely low-pitched, slow paced, harmonious music and music beats similar to a human heartbeat (60–80 beat/min) left people feeling relaxed and with good therapeutic effects when listening for at least 30 min. [14] Volume up to 60 dB helped to relax and relieve stress. [8]

"A binaural beat is an illusion created by the brain when two tones with slightly different frequencies are listened simultaneously. [13]

Binaural beats are a sound perception created by brain. If person listens to two tones, with different frequency with each in a different ear, brain creates an additional tone. This third tone is called a binaural beat.

When binaural beats are sustained over a time, they can synchronize with brain waves. So, can alter your brain wave activity along with levels of arousal.

In the preoperative setting, binaural tone music can be used either as an adjuvant or replacement anxiolytics. If patient is undergoing surgery under undergoing conscious sedation and/or regional anesthesia it can reduce patient's overall drug used for sedation and/or analgesia along with improving patient's comfort and satisfaction. [11,12] Patients sometime may refuse regional anaesthesia because they do not want to "hear" their surroundings. In this scenario, a simple solution to minimize a patient's fear would be to place a pair of headphones and allow the patient to listen to music during the intraoperative setting. The aim of this study is to investigate and compare the anxiety-reducing effect of music (self-selected and investigator selected) with midazolam, played preoperatively from 10 min prior to the administration of regional anaesthesia till 30 minutes post operatively.

AIM & OBJECTIVES

AIM AND OBJECTIVES

Aim:-

The aim of this study was to investigate and compare the anxiety-reducing effect of music (self-selected and investigator selected) with midazolam, played preoperatively from 10 min prior to the administration of regional anaesthesia till 30 minutes post operatively.

Objectives:-

i. The primary outcome: To compare the change in visual analogue anxiety scale (VAS- A) before and after placement of regional anaesthesia in between the three study groups (as per the group allotment).

ii. The secondary outcome:

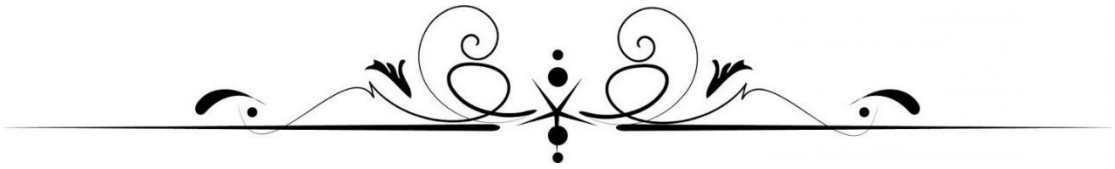
   a. To assess and compare intra-group and inter-group VAS-A score in all the three groups preoperatively, after 10 minutes of intervention, after block placement, at 60 minutes intraoperatively, at the time of skin suture and 30 minutes after completion of surgery.

   b. To evaluate differences in patient satisfaction scores of their experience during the procedure, physician satisfaction scores of their experience while conducting the procedure.

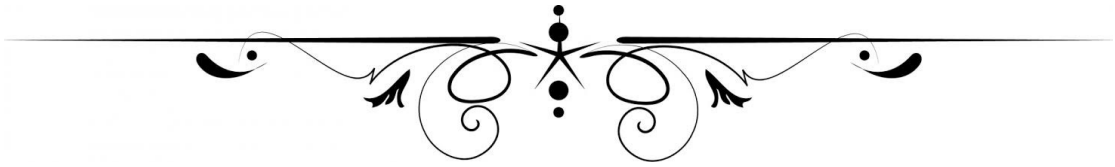
   c. Duration of analgesia (time to use first rescue analgesic).

   d. Vital signs including mean arterial pressure and heart rate.

   e. Complications.



REVIEW OF LITERATURE



REVIEW OF LITERATURE

Preoperative anxiety can adversely affect a patient's perioperative course by elevating stress markers, promoting fluctuations in hemodynamic and negatively impacting on postoperative recovery. Preoperative anxiety is routinely treated with short-acting benzodiazepines as midazolam. Listening to music is a non-invasive, safe and economical non-pharmacological intervention that requires no special skill to administer and also has a positive effect on pain and anxiety.

Esther Mok RN et al (2003). [15] investigated role of music as a method of reducing patients' anxiety during minor surgery with local anesthesia. They assessed the effectiveness of music as a relaxation modality by measuring patients' vital signs and self-reported anxiety before and after surgery. Their results showed that patients who listened to their choice of music during surgery experienced significantly lower anxiety levels, heart rates and blood pressure than patients who did not listen to music.

Martha D et al (2006). [16] conducted a randomized controlled trial of 170 patients, to determine effect of 15 minutes of self-selected music on pre-procedure anxiety. The State Trait Anxiety Inventory was used to measure patients' anxiety. One-hundred sixty-six men and 4 women comprised the sample with an average age of 66.8 years (SD 9.95, range 37 to 85 years). 170 patients were enrolled patients who listened to music (n=89) reduced their anxiety score from 38.57 (SD 10.46) to 35.2 (SD 9.7), while those who did not listen to music (n=81) reduced their anxiety score from 36.23 (SD 10.54) to 35.1 (SD 10.59); the difference between the groups was statistically significant (t=1.95, df 161, p=0.05). They recommended that music has a in reducing the anxiety.

Arslan S (2008). [17] conducted with a total of 64 patients; aged between 18 and 65. The control group received routine preoperative care while the experimental group listened to their choice of music for 30 minutes in their room while they awaited surgery. Main outcome measures pre and post-test anxiety were measured using the State Trait Anxiety Inventory (STAI) to assess anxiety before and after listening to the music preferred by the patient. Anxiety score averages between the groups following the music therapy were statistically significant 33.68 (SD=8.03) for the experimental group and 44.43(SD=10.42) for the control group. Their findings support the use of music as an independent nursing intervention to manage preoperative anxiety in patients undergoing urogenital surgery. They recommended

that listening to self-selected music during the preoperative period can effectively reduce anxiety levels and should be a useful tool for preoperative nursing.

Bringman H et al (2009). [18] conducted on three hundred and seventy-two patients scheduled for elective surgery they randomized patients to receive pre-operative 0.05-0.1 mg/kg of midazolam orally or by relaxing music. The main outcome measure was the State Trait Anxiety Inventory (STAI X-1), which was completed by the patients just before and after the intervention. Of the 177 patients who completed the music protocol, the mean and (SD) STAI-state anxiety scores were 34 (8) before and 30 (7) after the intervention. The corresponding scores for the 150 patients in the midazolam group were 36 (8) before and 34 (7) after the intervention. The decline in the STAI-state anxiety score was significantly greater in the music group compared with the midazolam group (P<0.001, 95% confidence interval range -3.8 to -1.8). Relaxing music decreases the level of anxiety in a pre-operative setting to a greater extent than orally administrated midazolam. They suggested that higher effectiveness and absence of apparent adverse effects makes pre-operative relaxing music a useful alternative to midazolam for pre-medication.

Pi-Chu Lin et al (2011). [19] recruited sixty patients to evaluate effect of perioperative music on anxiety. The study group listened to selected music from the evening before surgery to the second day after surgery. The control group did not listen to music. Patients' levels of anxiety and pain were measured with visual analogue scales (VAS). Physiological measures, including heart rate, blood pressure and 24-hour urinalysis were performed. The mean VAS score for degree of anxiety in the study group was 0·8–2·0, compared with 2·1–5·1 in the control group. The mean VAS score for degree of pain in the study group was 1·7–3·0, compared with 4·4–6·0 in the control group. The differences between the two groups in VAS scores for both anxiety.The average age of the 60 patients was 62·18 (SD 18·76) *p*= 0·018–0·001) and pain (*p*= 0·001) were statistically significant. One hour after surgery, the mean blood pressure was significantly lower in the study group than in the control group (*p*= 0·014), but no significant differences were found between the two groups in urine cortisol (*p*=0·145–0·495), norepinephrine (*p*=0·228–0·626) or epinephrine values (*p*- 0·074–0·619). They showed that music therapy has some positive effects on levels of anxiety and pain in patients undergoing spinal surgery.

Bradt J et al (2013). [20] conducted a systemic review they included 26 trials (2051 participants). All studies they included used to listen to pre-recorded music. The results

suggested that music listening may have a beneficial effect on preoperative anxiety. Specifically, music listening resulted, on average, in an anxiety reduction that was 5.72 units greater (95% CI -7.27 to -4.17, P < 0.00001) than that in the standard care group as measured by the strait-Trait Anxiety Inventory (STAI-S), and -0.60 standardized units (95% CI -0.90 to -0.31, P < 0.0001) on other anxiety scales. Their results also suggested a small effect on heart rate and diastolic blood pressure, but no support was found for reductions in systolic blood pressure, respiratory rate and skin temperature. Most trials were assessed to be at high risk of bias because of lack of blinding. Blinding of outcome assessors is often impossible in music therapy and music medicine studies that use subjective outcomes, unless in studies in which the music intervention is compared to another treatment intervention. They, we concluded that music interventions may provide a viable alternative to sedatives and anti-anxiety drugs for reducing preoperative anxiety.

Hole J et al (2015). [21] conducted a review and included RCTs in which any form of music initiated before, during, or after surgery was compared with standard care or other non-drug interventions. They found that music reduced postoperative pain (SMD -0·77 [95% CI -0·99 to -0·56]), anxiety (-0·68 [-0·95 to -0·41]) and analgesia use (-0·37 [-0·54 to -0·20]) and increased patient satisfaction (1·09 [0·51 to 1·68]), but length of stay did not differ (SMD -0·11 [-0·35 to 0·12]). Subgroup analyses in their review showed that choice of music and timing of delivery made little difference to outcomes. Music could be offered as a way to help patients reduce pain and anxiety during the postoperative period.

Forooghy M et al (2015). [22] conducted a randomized controlled trial, conducted in the catheterization laboratory Unit of Baqiyatallah Hospital, in Tehran, Iran. A sample of 64 patients, who were planned to undergo coronary angioplasty, were recruited. Patients were randomly allocated to either the control or the experimental groups. In the experimental group, patients received a 20 to 40-minute music therapy intervention, consisting of light instrumental music. Patients in the control group received the routine care of the study setting, which consisted of no music therapy intervention. Before the intervention, the study groups did not differ significantly in terms of anxiety level and hemodynamic parameters. Moreover, the differences between the two groups, regarding hemodynamic parameters, were not significant after the intervention (P > 0.05). However, the level of post-intervention anxiety in the experimental group was significantly lower than the control group (32.06 ± 8.57 and 38.97 ± 12.77, respectively; P = 0.014). Compared with the baseline readings, the

level of anxiety in the control group did not change significantly after the study (41.91 ± 9.88 vs. 38.97 ± 12.77; P = 0.101); however, in the experimental group, the level of post-intervention anxiety was significantly lower than the pretest readings (32.06 ± 8.57 vs. 41.16 ± 10.6; P = 0.001). They concluded that music therapy is a safe, simple, inexpensive, and non-invasive nursing intervention, which can significantly alleviate patients' anxiety during coronary angioplasty

Labrague LJ et al (2016). [23] conducted a study and employed a pre- and post-test experimental design with non-random assignment. Ninety-seven women undergoing gynaecologic surgery were included in the study, where 49 were allocated to the control group (no music group) and 48 were assigned to the experimental group (music group). Preoperative anxiety was measured using the State Trait Anxiety Inventory (STAI) while non-invasive instruments were used in measuring the patients' physiologic parameters (blood pressure [BP], pulse [P], and respiration [R]) at two time periods. Women allocated in the experimental group had lower STAI scores ($t = 17.41$, $p < .05$), systolic ($t = 6.45$, $p < .05$) and diastolic ($t = 2.80$, $p < .006$) BP, and P rate (PR; $t = 7.32$, $p < .05$) than in the control group. This study provides empirical evidence to support the use of music during the preoperative period in reducing anxiety and unpleasant symptoms in women undergoing gynaecologic surgery.

Wen-Ping Leea et al (2017). [24] A study to evaluate the effect of music in pain .The experimental group received 30 min of musical intervention and routine nursing care in the Post-Anaesthesia Care Unit (PACU) while the control group received only routine nursing care. The study found significant differences in both anxiety and physiological indices between the two groups. The mean score of the State-Trait Anxiety Inventory (STAI) in the study group decreased from a pre-test score of 59.0 to a post-test score of 31.20 ($t = 28.63$, $p < 0.001$). Physiological indices such as heart rate ($t = 2.61$, $p = 0.012$), respiration rate ($t = 2.29$, $p = 0.026$), systolic blood pressure ($t = 2.30$, $p = 0.026$), and diastolic blood pressure ($t = 3.02$, $p = 0.004$) decreased significantly as well. Control group was not seeing significant changes from pre-op values. Listening to music while in the recovery room may decrease the level of anxiety in surgical patients receiving spinal anesthesia. The results of this study can serve as a reference for PACU nurses in utilizing music listening programs to achieve the goal of holistic care

Veena Graff et al (2018)[25] conducted RCT on music versus midazolam during preoperative nerve block placements. They compared IV midazolam (1–2 mg) with noise-cancelling headphone delivered music medicine on patients received a preoperative usg-guided single-injection peripheral nerve block as primary regional anaesthetic. The change in the State Trait Anxiety Inventory-6 (STAI-6) anxiety scores from after to before the procedure was similar in both groups but patient satisfaction scores were higher in the midazolam. They concluded that music therapy can be given as alternative to midazolam for anxiety reliever in those who undergone peripheral nerve block.

Gokcek E et al (2020).[26] conducted a randomized, controlled, prospective study with 120 patients undergoing septo-rhinoplasty in 2 months period. The patients were randomly selected and divided into two groups: group music (music during surgery) and control group (without music during surgery). All patients underwent standard general anaesthesia. Patients aged 18-70 years who would undergo a planned surgery under general anaesthesia were included. In the music group, sedation agitation scores were lower than those in the control group at the postoperative period (3.76±1.64 vs. 5.11±2.13; $p<0.001$). In addition; in patients of the music group, the pain level (2.73±1.28 vs. 3.61±1.40) was lower ($p<0.001$), requiring fewer analgesic drugs intake. Music therapy, which is a nonpharmacologic intervention, is an effective method, without side effects, leading to positive effects in the awakening, hemodynamic parameters and analgesic requirements in the postoperative period. They concluded that music therapy is also effective in reducing the anxiety and intraoperative awareness episodes of surgical patients.

Kukreja P et al (2020). [27] conducted a randomized controlled study; to compare the effect of music therapy in patients ≥ 18 years old. Patients were randomized in a 1:1 ratio for either the "music" or "control" group. Both groups were compared for sedation requirements, preoperative and postoperative anxiety levels, and patient satisfaction. Subjects in the music group had a statistically significantly lower than average State-Trait Anxiety Inventory (STAI)-State baseline score as compared to the control group (music group 31.00 (standard deviation (SD) 1.44), control group 38.04 (SD 2.35); $p = 0.01$). Postoperative STAI-State-Trait Anxiety Inventory (STAI)-State scores for the music group were lower for the music group than the control group (music group 28.34 (SD 1.64), control group 32.21 (SD 1.56), $p= 0.09$). STAI-Trait scores were similar preoperatively, but significantly less post-operatively in the music group (28.14 SD 1.0) as compared to the control group (34.71 SD

2.31); p = 0.01. Propofol dose per kilogram per surgical minute was similar between the two groups (music group 0.05, control group 0.06; p= 0.264). Patient satisfaction scores with their perioperative experience were higher in the music group (p= 0.009). They concluded that music therapy may be offered as an alternative to traditional anxiolytics intra-operatively. However further studies are warranted to evaluate whether or not music therapy can decrease sedation and anxiolytic medications during surgery.

Ölçücü MT et al. [42] investigated the effects of pure binaural beats on anxiety and pain scores in male patients undergoing diagnostic cystoscopy (DC) and ureteral stent removal (USR) under local anesthesia. a total of 252 and 159 eligible male patients for DC Group and USR Group were included, respectively. After exclusions, remaining patients were; DCG-1, n = 61; DCG-2, n = 73; DCG-3, n = 75; USRG-1, n = 41; USRG-2, n = 50; and USRG-3, n = 52. The tolerance rate in binaural beats groups was significantly lower than in other groups (p< 0.001 for all). Binaural beats groups had significantly lower VAS scores than other groups and classical music groups had significantly lower VAS scores than control groups (p<0.05 for all). According to this study listening to pure binaural beats may be a simple and effective method to reduce anxiety levels and pain scores associated with the DC and USR procedures in males.

Padmanaban etal . [40] conducted prospective, randomized, controlled study examining binaural beat audio and pre-operative anxiety in patients undergoing general anaesthesia for day case surgery on 104 patients found that mean [95% CI] decreases in anxiety scores were 26.3% [19– 33%] in the Binaural Group (p = 0.001 vs. Audio Group, p < 0.0001 vs. No Intervention Group), 11.1% [6–16%] in the Audio Group (p = 0.15 vs. No Intervention Group) and 3.8% [0–7%] in the no Intervention Group. Binaural beat audio has the potential to decrease acute pre-operative anxiety significantly.

D Wiwatwongwana etal [43] in their study on the effect of music with and without binaural beat audio on operative anxiety in patients undergoing cataract surgery on 141 patients showed significant reduction of STAI state scores after music intervention compared with the control group (P<0.001) but the difference was not significant between the MI and BB group (STAI-S score MI group −7.0, BB group − 9.0, P = 0.085). Systolic BP was significantly lower in both MI (P = 0.043) and BB (0.040) groups although there was no difference between the two groups (P = 1.000). A significant reduction in heart rate was seen only in the BB group (BB vs control P = 0.004, BB vs MI P = 0.050, MI vs control P = 0.303).

MATERIAL & METHODS

MATERIAL AND METHODS

Inclusion Criteria:

Patients belonging to American Society of Anaesthesiologists (ASA) physical status grade I and II, aged between 18 to 60 years, scheduled to undergo surgery under regional anaesthesia were enrolled.

Exclusion Criteria:

1. Patient refusal
2. History of psychiatric illness and pre-existing neurological deficits
3. Patients who were extremely anxious (scores ≥ 8 on VAS-A)
4. Pre-existing infection at block site
5. Coagulation Disorder
6. Patient with morbid obesity BMI >40 kg/ m2
7. Pregnant and breast-feeding patients
8. Decreased pulmonary reserve, cardiac disorders and renal dysfunctions
9. Known allergy to midazolam
10. Presence of any preoperative pain or history of chronic pain
11. History of regular analgesic use
12. Preoperative hypotension (Mean arterial blood pressure < 50 mmHg), preoperative bradycardia (Heart rate < 45 beats/min) and preoperative dysrhythmia.

All the patients were examined during the preoperative visit, one day prior to surgery by the attending anaesthesiologist. Informed consent for regional anaesthesia along with consent for participation was taken in preoperative period. Fasting status of patients was confirmed prior to surgery.

Patients were randomly allocated in a one-to-one fashion using a computer-generated algorithm into three groups. Simple random sequence was generated from the computer. The group allocation numbers were concealed in sealed opaque envelopes which were opened just before the start of the planned regional block. Group A patients received search-selected music (binaural tone) via noise-cancelling headphones, Group B received intravenous midazolam minimum of 1 mg to 2 mg maximum as per clinical judgement, and Group C

patients were made to listen to patient preferred music via noise-cancelling headphones. Subjects were given the freedom to adjust and readjust the volume of music during the entire listening experience. A staff member not involved with the patient at any time opened the sealed envelope containing the randomized treatment, research selected music, self-selected music or control (no sound but intravenous midazolam). The same staff member was also made to fit the in-ear earphones (Flying Tiger, Copenhagen, Denmark) into the patient's ears and adjust the volume on the smart phone. All patients, including the control group, wore earphones during the procedure, to ensure blinding of the staff. The patients were not blinded. VAS-A scores was assessed by an independent observer. Intra operatively VAS-A was assessed at 60 minutes intra operatively. If VAS- A > 8, any time after intervention as per group allocated then that patient was not included in study and infusion of dexmedetomidine (0.2 to 0.5mcg/kg/hr) was started.

In preoperative area, the research assistant administered the VAS- A scoring tool. Then patients were randomized to one of the three study groups. In the operating room, routine monitoring including continuous electrocardiography (ECG), non-invasive blood pressure (NIBP) and peripheral oxygen saturation (SpO_2) were attached. Baseline vitals were recorded. At this point, patients received either intravenous midazolam or start listening to music, based on their group assignment. 10 min were allowed to pass, followed by assessment of VAS-A score, after that regional anaesthesia was given, then again VAS -A anxiety scores were assessed. Patient was observed further 10 minutes for successful block placement, if pin prick sensation in desired dermatomes did not decrease in this time, then it is considered as block failure and patient was not enrolled in study. We have included all patients undergoing surgery in spinal anaesthesia only. Patient listened to music throughout the surgery, intra operatively VAS-A was again assessed at 60 minutes then at skin closure. In post-operative period, VAS-A was again assessed at 30 minutes of duration.

Anaesthetic Technique: After arrival in the operation theatre, routine monitoring was continued. Patient continued to receive intervention throughout the surgery till 30 minutes post operatively as per allocated group. Heart rate (HR), SpO2 and blood pressure were continuously monitored throughout the surgery. Baseline vitals were recorded, and any other significant deviation was noted. Significant hypotension or bradycardia was defined as 20% reduction from the baseline value and was also recorded. Bradycardia was treated with IV

atropine 10 µg/kg and significant hypotension was managed with intravenous fluid administration and boluses of IV ephedrine 3mg. VAS- A was assessed as mentioned earlier. Postoperative pain was assessed using visual analogue score (VAS) with its 0-10 scale (0=no pain and 10=worst imaginable pain) at immediate postoperative, at 30 minutes for next 2 hours by an independent observer. Time to first rescue analgesia was also recorded. Procedure related and postoperative complications as hypotension, respiratory depression, post-operative nausea, and vomiting (PONV), shivering, headache, dizziness & failure rate were recorded. At 24 hours after surgery, satisfaction of the patients was assessed using a numerical satisfaction score as 4= excellent, 3=good, 2=fair, 1=poor.

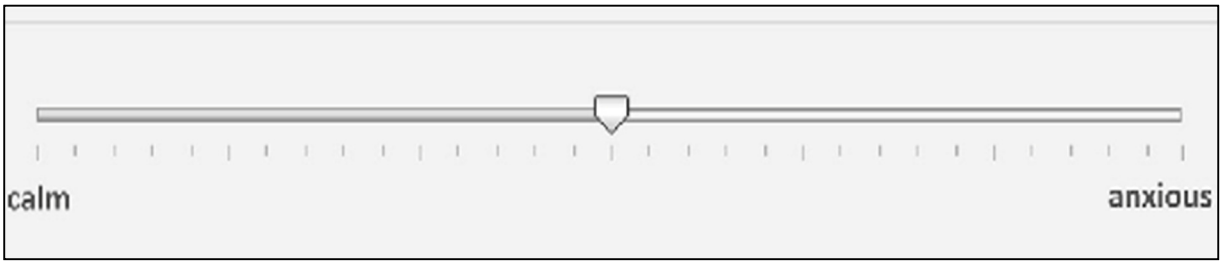
Type of music used in study: Patients made to choose their music of preference when they were allotted to that group. The characteristics that were common to relaxing music are non-lyrical, tempo ranges of 60-80 beats per minute and non-percussive sounds without too many fluctuations in the melody.

We used patients' choice music and preselected music (binaural tone).

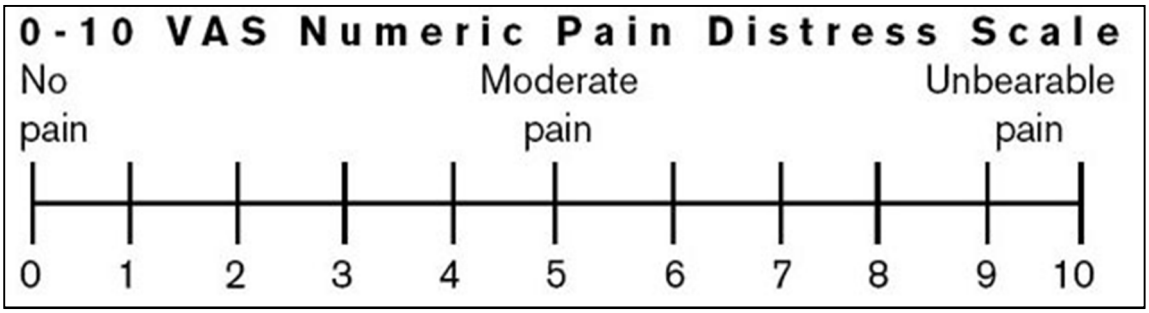
Binaural beats were developed when two different tones were played at the same time through both ears. Binaural infused music is a recommended style of music that is known to be soothing and relaxing, the difference in the frequencies from these tones form a rhythm produced within the brain and can produce a particular electroencephalography (EEG)-associated state. For example, if there is a tone playing at 410 Hz in the right ear and another tone playing at 400 Hz in the left ear, the difference of the two tones i.e 10 Hz and can simulate an alpha-wave EEG pattern, a waveform known to occur in the relaxed state. There are numerous styles of binaural beat infused music options that can simulate the alpha, theta, and delta EEG wave-forms and can be found on common music applications.
We used binaural tone music freely available on internet. https://you.be/jNUHb5ZzqLQ.

Scales used in study:
The **visual analogue anxiety score (VAS-A)** comprises a 10 cm line, on which the participant marks her current degree of anxiety with the left end of the line being labelled "no anxiety" or calm and the right end being labelled "maximum anxiety". For analysis the marking is then measured in mm from the left end.

VAS (Numeric anxiety scale 0-10)



VAS – Visual Analog Scale(pain)



Sample Size

Erhan G et al [49] have reported the post intervention mean (SD) VAS scores as 2.73(1.28) in the music group and 3.61 (1.4) in control group. Considering this for effect size calculation, we estimated a sample size of 75 per group at 95% confidence interval ,95% power and 20% contingency.

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2 / \kappa)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

$$n_2 = \frac{(\kappa * \sigma_1^2 + \sigma_2^2)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

The notation for the formulae are:

n_1 = sample size of Group 1

n_2 = sample size of Group 2

σ_1 = standard deviation of Group 1

σ_2 = standard deviation of Group 2

Δ = difference in group means

κ = ratio = n_2/n_1

$Z_{1-\alpha/2}$ = two-sided Z value (eg. Z=1.96 for 95% confidence interval).

$Z_{1-\beta}$ = power

Reference:

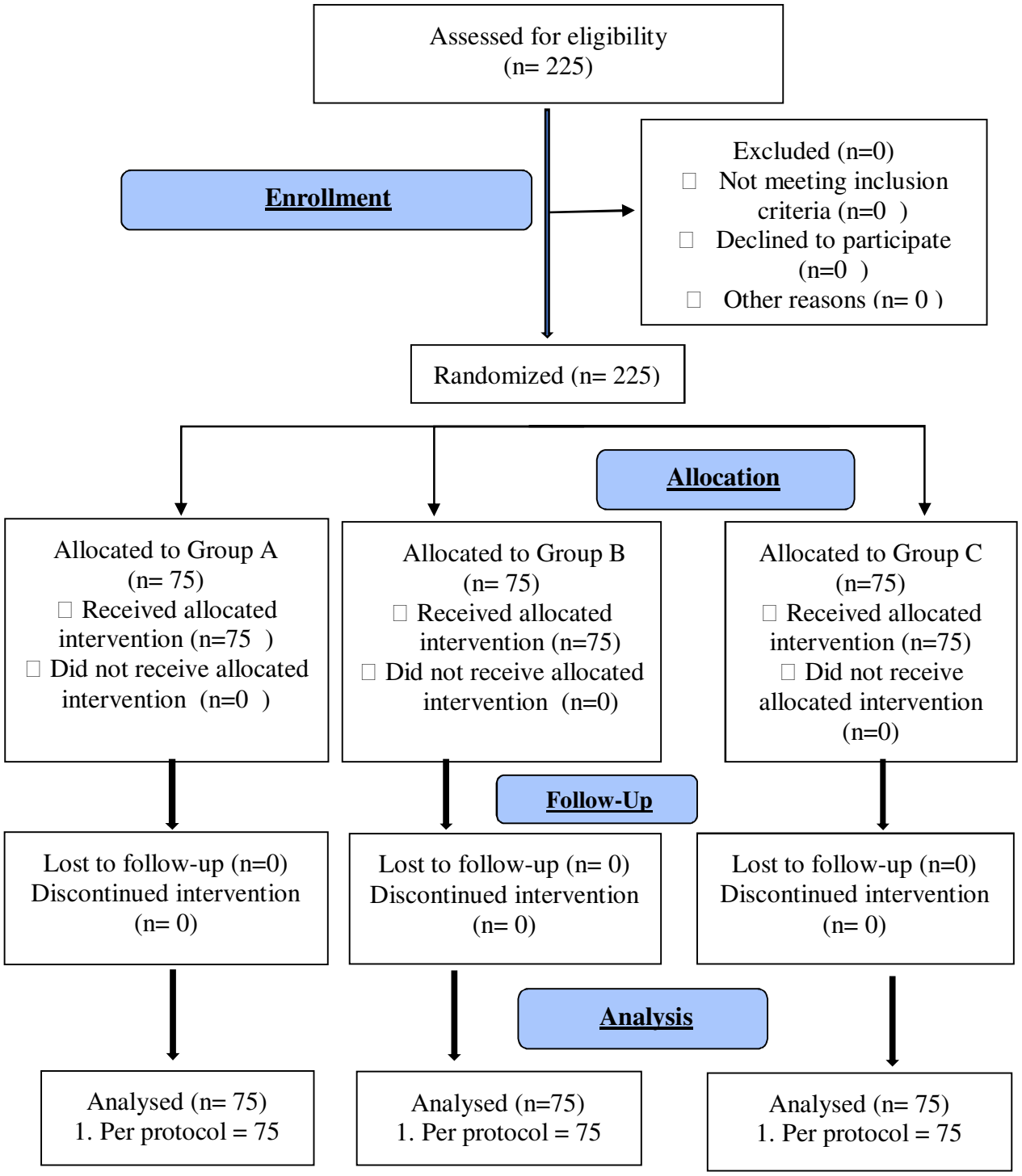
Bernard Rosner. Fundamentals of Biostatistics (5th edition). (based on equation 8.27)

Statistical analysis

All the data were entered on Excel sheet M.S. Office Excel and analyzed statistically using SPSS Statistical software (version. 26.0.0)

All the quantitative data were summarized in the form of Mean+ Sd. The difference between mean value of the groups was analyzed using ANOVA with post-hoc tests. All the qualitative data were summarized in the form of proportions. The difference between proportions were analyzed using Chi square test. Probability was considered significant if it is less than 0.05.

CONSORT STUDY CHART



RESULTS

RESULTS

In this study, total 225 patients were enrolled and randomised in three groups. These groups were namely group A : Binaural tone music group , group B: Midazolam group and group C: patient's choice music group. They were compared for effect of perioperative intervention on patient's anxiety at different time points.

Age wise distribution of the study population:

Table 1: Age wise distribution of the study population

	Group A		**Group B**		**Group C**	
	No.	%	No.	%	No.	%
18-50	60	80.00	61	81.33	61	81.33
51-60	15	20.00	14	18.67	14	18.67
Total	75	100.00	75	100.00	75	100.00
Mean±SD	37.68±12.33		35.65±12.27		34.75±12.39	
Result (P value)	0.972 (NS)					

S = Significant; NS = non-Significant

Above mentioned table shows age wise distribution of the study population.

In group A out of 75 cases 60 (80%) were in age group of 18-50 years, 15 cases (20%) were in age group of 51-60 years.

In group B out of 75 cases 61 (81.33%) were in age group of 18-50 years, 14 cases (18.67%) were in age group of 51-60 years.

In group C out of 75 cases 61 (81.33%) were in age group of 18-50 years, 14 cases (18.67%) were in age group of 51-60 years.

There was no statistically significant difference among groups. (P value = 0.972)

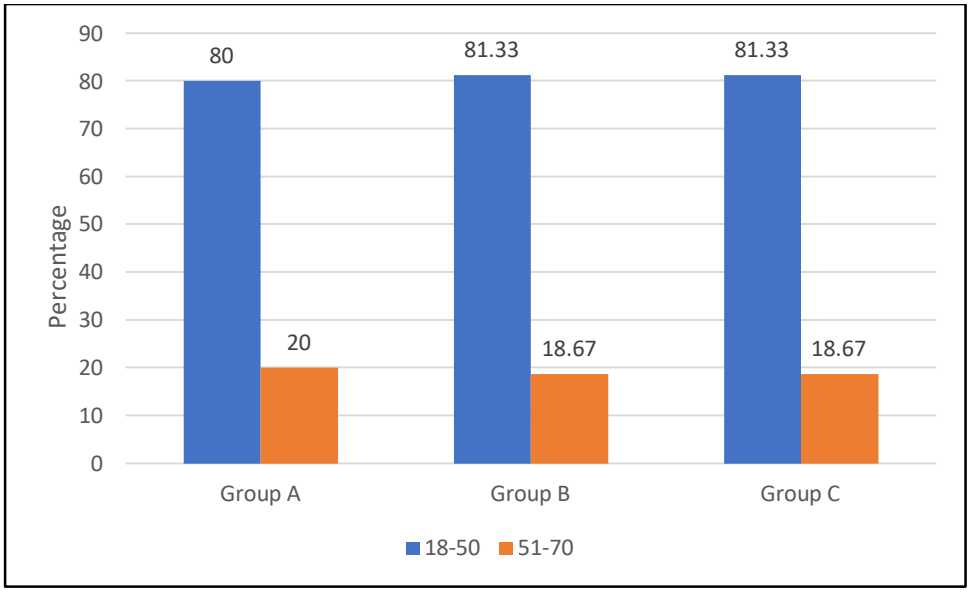


Figure 1: Age wise distribution of the study population:

Sex wise distribution of the study group

Table 2: Sex wise distribution of the study group

	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Male	49	65.33	58	77.33	59	78.67
Female	26	34.67	17	22.67	16	21.33
Total	75	100.00	75	100.00	75	100.00
Result (P value)	0.124 (NS)					

S = Significant; NS = non-Significant

In present study, 65.33% patients were male and 34.67% patients were female in group-A. 73.33% patients were male and 22.67% patients were female group in group-B. 78.67% patients were male and 21.33% patients were female group in group-C. The gender difference among groups was statistically insignificant.

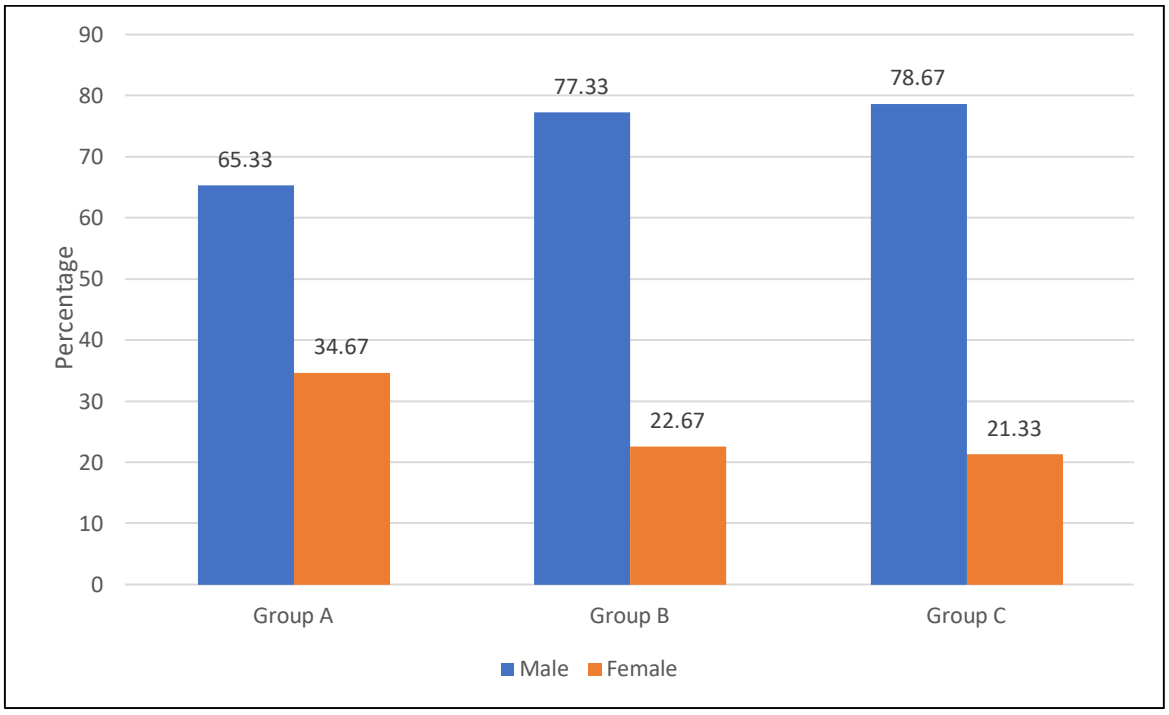


Figure 2: Sex wise distribution of the study group

Comparison of VAS A among the study group:

Table 3: Comparison of VAS A among the study group

	Group A		Group B		Group C		Result (P value)
	Mean	SD	Mean	SD	Mean	SD	
Baseline	4.72	1.36	4.75	1.13	4.44	1.05	0.218 (NS)
After 10 Mint	4.35	1.36	4.53	1.07	3.80	1.08	0.0005(S)
Before Block Placement	4.00	1.23	4.28	0.88	3.71	1.00	0.004(S)
After Block Placement	3.31	1.30	3.40	0.97	3.48	0.94	0.618(NS)
At 60 Min.	3.20	1.14	3.00	0.82	2.25	0.74	0.038 (S)

In present study, baselines anxiety score was comparable in all the groups. There was statistically significant difference between the mean VAS scores after 10 minutes, before block placement and at 60 minutes after the block placement in all the three groups. There was no significant difference in VAS A after block placement in the three groups..

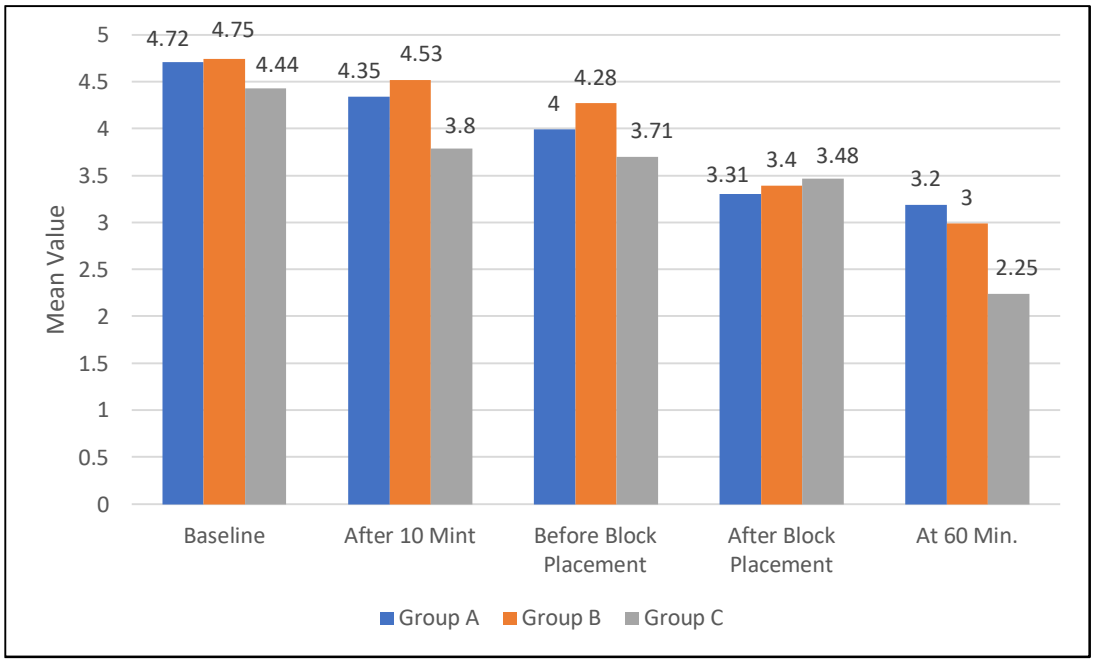


Figure 3: Comparison of VAS A among the study group

Comparison of VAS A between Group A and Group B:

Table 4: Comparison of VAS A between Group A and Group B

	Group A		Group B		Result (P value)
	Mean	SD	Mean	SD	
Baseline	4.72	1.36	4.75	1.13	0.896 (NS)
After 10 Mint	4.35	1.36	4.53	1.07	0.351 (NS)
Before Block Placement	4.00	1.23	4.28	0.88	0.110 (NS)
After Block Placement	3.31	1.30	3.40	0.97	0.620 (NS)
At 60 Min.	3.20	1.14	3.00	0.82	0.219 (NS)

There was no statistically significant difference at various time interval among group A and group B.

Comparison of VAS A between Group B and Group C:

Table 5: Comparison of VAS A between Group B and Group C

	Group B		Group C		Result (P value)
	Mean	SD	Mean	SD	
Baseline	4.75	1.13	4.44	1.05	0.087 (NS)
After 10 Mint	4.53	1.07	3.80	1.08	p<0.001(S)
Before Block Placement	4.28	0.88	3.71	1.00	0.0002(S)
After Block Placement	3.40	0.97	3.48	0.94	0.608 (NS)
At 60 Min.	3.00	0.82	2.25	0.74	p<0.001(S)

Mean VAS A score were comparable at baseline and after block placement. There was statistically significant difference at various time interval (10 minutes after the block, before block placement and after 60. minutes of block placement) between groups.

Comparison of VAS A between Group A and Group C:

Table 6: Comparison of VAS A between Group A and Group C

	Group A		Group C		Result (P value)
	Mean	SD	Mean	SD	
Baseline	4.72	1.36	4.44	1.05	0.161 (NS)
After 10 Mint	4.35	1.36	3.80	1.08	0.007 (S)
Before Block Placement	4.00	1.23	3.71	1.00	0.110 (NS)
After Block Placement	3.31	1.30	3.48	0.94	0.351 (NS)
At 60 Min.	3.20	1.14	2.25	0.74	p<0.001 (S)

Baseline anxiety scores were comparable in both the groups. There was statistical significant difference in anxiety scores after 10 minutes from the baseline and at 60 minutes after block placement.

Intragroup Comparison of VAS Anxiety:

Comparison of mean change of VAS A scores (Baseline- skin closure) between the study groups:

Table 7: Comparison of mean change of VAS A scores (Baseline- skin closure) between the study groups

Time	Group A		Group B		Group C	
	Mean	SD	Mean	SD	Mean	SD
Baseline	4.72	1.36	4.75	1.13	4.44	1.05
Skin closure	3.24	1.22	3.04	0.86	2.47	0.91
Mean Difference	1.48	1.32	1.71	1.16	1.97	1.42
Result (P value)	0.070 (NS)					

Mean difference in VAS anxiety score (Baseline -skin closure) was calculated for all the three groups and one way anova was applied to compare the difference in mean change, which came out to be statistically non-significant. (p value= 0.070)

Comparison of Mean change of VAS A scores (before and after administration of the block) between the study groups:

Table 8: Comparison of Mean change of VAS A scores (before and after administration of the block) between the study groups

	Group A		Group B		Group C	
	Mean	SD	Mean	SD	Mean	SD
Before Block	4.00	1.23	4.28	0.88	3.71	1.00
After block	3.30	1.30	3.40	0.97	3.48	0.94
Mean Difference	0.69	0.90	0.88	0.93	0.23	0.58
Result (P value)	p<0.001 (S)					

Mean difference in VAS anxiety score (before and after administration of the block)) was calculated in all the three groups and one way anova was applied to compare the difference in mean change, which came out to be statistically significant. (p value <0.001).

Comparing mean VAS-A scores (before and after administration of the block) among groups A and B:

Table 9: Comparing mean VAS-A scores (before and after administration of the block) among groups A and B

	Group A		Group B		Result (P value)
	Mean	SD	Mean	SD	
Mean Difference (before and after administration of the block)	0.693	0.90	0.88	0.93	0.213 (NS)

Comparing mean VAS-A scores before and after administration of the block among groups B and C:

Table 10: Comparing mean VAS-A scores before and after administration of the block among groups B and C

	Group B		**Group C**		**Result (P value)**
	Mean	SD	Mean	SD	
Mean Difference (before and after administration of the block)	0.88	0.93	0.23	0.58	0.79 (NS)

Comparing mean VAS-A scores before and after administration of the block among groups A and C:

Table 11: Comparing mean VAS-A scores before and after administration of the block among groups A and C

	Group A		**Group C**		**Result (P value)**
	Mean	SD	Mean	SD	
Mean Difference (**before and after administration of the block)**	0.69	0.90	0.23	0.58	<0.001 (S)

On Post Hoc test we found that there was significant difference between mean VAS-A scores among the groups A and C (p-value; two-tailed = 0.0001). It was found that mean difference among group B was lesser than that of the group A.

There was statistically significant difference in mean difference (before and after administration of the block) in group A and Group C. Mean fall of anxiety was more in Group A when compared to group C.

Comparison of mean arterial pressure (mmHg) among the study group:

Table 12: Comparison of mean arterial pressure (mmHg) among the study group

	Group A		Group B		Group C		Result (P value)
	Mean	SD	Mean	SD	Mean	SD	
5 m	79.31	12.70	79.55	6.96	80.04	6.43	0.882 (NS)
10 m	79.40	11.13	82.89	7.32	80.41	6.13	0.035 (S)
15 m	79.85	11.17	83.47	5.38	80.41	6.20	0.012 (S)
30 m	77.49	10.75	83.61	6.99	81.36	6.61	p<0.001 (S)
60 m	78.79	10.39	85.43	7.34	84.21	6.85	p<0.001 (S)
90 m	78.28	9.19	84.97	6.76	81.36	7.91	p<0.001 (S)
120 m	79.30	10.26	84.68	8.45	80.89	6.76	0.001 (S)
180 m	82.93	11.51	84.02	7.23	81.32	6.14	0.178 (NS)

The above table shows the comparison of mean arterial pressure (mmHg) at different time interval in three groups. There was statistical significant difference at various time interval except after 5 minutes from baseline and at 180 minutes.

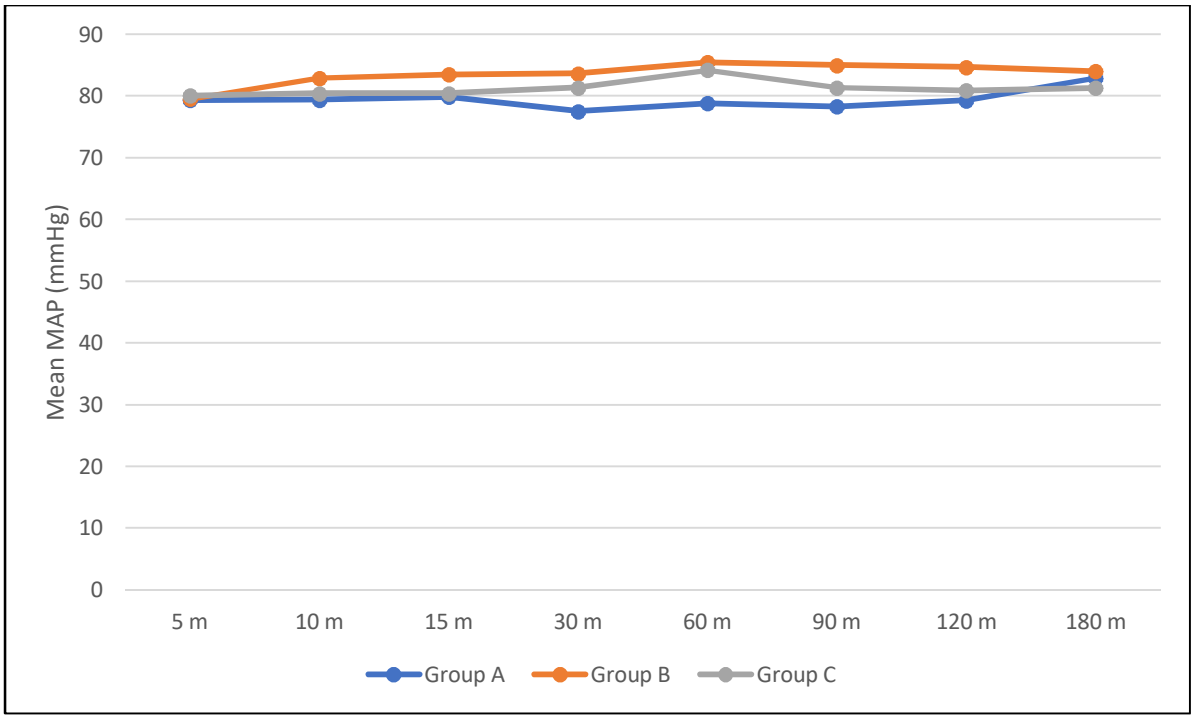


Figure 4: Comparison of mean arterial pressure (mmHg) among the study group

Comparison of mean arterial pressure (mmHg) between group A and Group B

Table 13: Comparison of mean arterial pressure (mmHg) between group A and GroupB

	Group A		**Group B**		**Result (P value)**
	Mean	SD	Mean	SD	
5 m	79.31	12.70	79.55	6.96	0.886 (NS)
10 m	79.40	11.13	82.89	7.32	0.024 (S)
15 m	79.85	11.17	83.47	5.38	0.012 (S)
30 m	77.49	10.75	83.61	6.99	p<0.001 (S)
60 m	78.79	10.39	85.43	7.34	p<0.001 (S)
90 m	78.28	9.19	84.97	6.76	p<0.001 (S)
120 m	79.30	10.26	84.68	8.45	0.001 (S)
180 m	82.93	11.51	84.02	7.23	0.534 (NS)

The above table shows the comparison of mean arterial pressure (mmHg) at different time interval between groups. There was statistically significant difference at various time interval except 5 minutes. and 180 minutes.

Comparison of mean arterial pressure (mmHg) between group B and Group C:

Table 14: Comparison of mean arterial pressure (mmHg) between groupB and groupC

	Group B		Group C		Result (P value)
	Mean	SD	Mean	SD	
5 m	79.55	6.96	80.04	6.43	0.652 (NS)
10 m	82.89	7.32	80.41	6.13	0.025 (S)
15 m	83.47	5.38	80.41	6.20	0.001 (S)
30 m	83.61	6.99	81.36	6.61	0.044 (S)
60 m	85.43	7.34	84.21	6.85	0.297 (NS)
90 m	84.97	6.76	81.36	7.91	0.003 (S)
120 m	84.68	8.45	80.89	6.76	0.003 (S)
180 m	84.02	7.23	81.32	6.14	0.022 (S)

This table shows the comparison of mean arterial pressure (mmHg) at different time interval between groups. There was statistically significant difference at various time interval between group except 5 minutes and 60 minutes.

Comparison of mean arterial pressure (mmHg) between group A and Group C:

Table 15: Comparison of mean arterial pressure (mmHg) between group A and C

	Group A		Group C		Result (P value)
	Mean	SD	Mean	SD	
5 m	79.31	12.70	80.04	6.43	0.656 (NS)
10 m	79.40	11.13	80.41	6.13	0.490 (NS)
15 m	79.85	11.17	80.41	6.20	0.704 (NS)
30 m	77.49	10.75	81.36	6.61	0.008 (S)
60 m	78.79	10.39	84.21	6.85	0.0002 (S)
90 m	78.28	9.19	81.36	7.91	0.033 (S)
120 m	79.30	10.26	80.89	6.76	0.280 (NS)
180 m	82.93	11.51	81.32	6.14	0.322 (NS)

This table shows the comparison of mean arterial pressure (mmHg) at different time interval between groups. Mean BP was comparable at 5,10,15, 120 and 180 minutes. There was a statistically significant difference at 30 and 60 minutes.

Intra Op Comparison of PR (bpm) among the study group:

Table 16: Intra Op Comparison of PR (bpm) among the study group

	Group A		Group B		Group C		Result (P value)
	Mean	SD	Mean	SD	Mean	SD	
5 m	79.30	12.70	79.55	6.96	80.04	6.43	0.882 (NS)
10 m	79.40	11.13	82.89	7.32	80.41	6.13	0.035 (S)
15 m	79.85	11.16	83.47	5.38	80.41	6.20	0.012 (S)
30 m	77.49	10.75	83.61	6.99	81.36	6.61	p<0.001(S)
60 m	78.79	10.39	85.43	7.34	84.21	6.86	p<0.001(S)
90 m	78.28	9.18	84.97	6.76	81.36	7.91	p<0.001(S)
120 m	79.30	10.25	84.68	8.45	80.89	6.76	0.001 (S)
180 m	82.92	11.50	84.02	7.23	81.33	6.15	0.178(NS)

This table shows the comparison of pulse rate at different time interval between groups. Mean pulse rate was comparable at 5 and 180 minutes. There was a statistically significant difference at 10,15.30,60,90 and 120 minutes in all the three groups.

Comparison of mean VAS A among study group:

Table 17: Comparison of mean VAS A among study group

	Group A		Group B		Group C		Result (P value)
	Mean	SD	Mean	SD	Mean	SD	
Skin Closure	3.24	1.22	3.04	0.86	2.47	0.91	p<0.001
After 30 M	3.16	1.26	2.76	0.73	2.21	0.70	p<0.001

The above table shows that there was a statistically significant difference in the mean VAS score during skin closure and 30 minutes postoperatively in all the three groups.

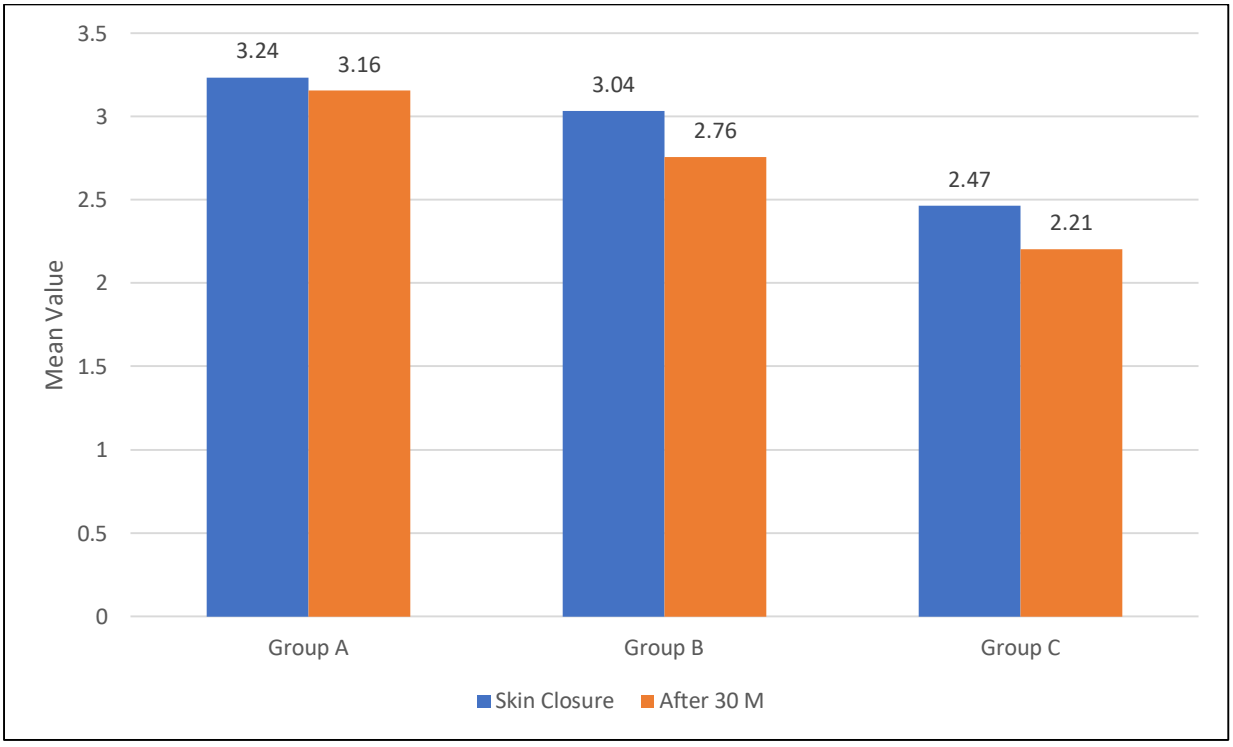


Figure 5: Comparison of mean VAS A among study group

Comparison of mean VAS A between Group A and Group B:

Table 18: Comparison of mean VAS A between Group A and Group B

	Group A		**Group B**		**Result (P value)**
	Mean	SD	Mean	SD	
Skin Closure	3.24	1.22	3.04	0.86	0.247 (NS)
After 30 M	3.16	1.26	2.76	0.73	0.018(S)

This table shows that the mean VAS A score was comparable in both the groups during skin closure but there was statistically significant difference at 30 minutes postoperatively.

Comparison of mean VAS A between Group B and Group C:

Table 19: Comparison of mean VAS A between Group B and Group C

	Group B		**Group C**		**Result (P value)**
	Mean	SD	Mean	SD	
Skin Closure	3.04	0.86	2.47	0.91	0.0001(S)
After 30 M	2.76	0.73	2.21	0.70	p<0.001(S)

This table shows the mean VAS A score was significantly different in group B and C at skin closure and 30 minutes postoperatively.

Comparison of mean VAS A between Group A and Group C:

Figure 20: Comparison of mean VAS A between Group A and Group C

	Group A		**Group C**		**Result (P value)**
	Mean	SD	Mean	SD	
Skin Closure	3.24	1.22	2.47	0.91	p<0.001(S)
After 30 M	3.16	1.26	2.21	0.70	p<0.01(S)

This table shows the mean VAS A score was significantly different in group B and C at skin closure and 30 minutes postoperatively.

Comparison of mean time of rescue analgesia among the study group:

Table 21: Comparison of mean time of rescue analgesia among the study group

	Group A		Group B		Group C	
	Mean	SD	Mean	SD	Mean	SD
Time of rescue analgesia (in hours)	6.96	1.61	7.21	1.60	6.81	1.33
Result (P value)	0.267 (NS)					

In present study, mean time of rescue analgesia (hours) in group-A was 6.96±1.61, in group-B was 7.21±1.60, and in group C was 6.81±1.33. There was no significant difference in all the three groups.

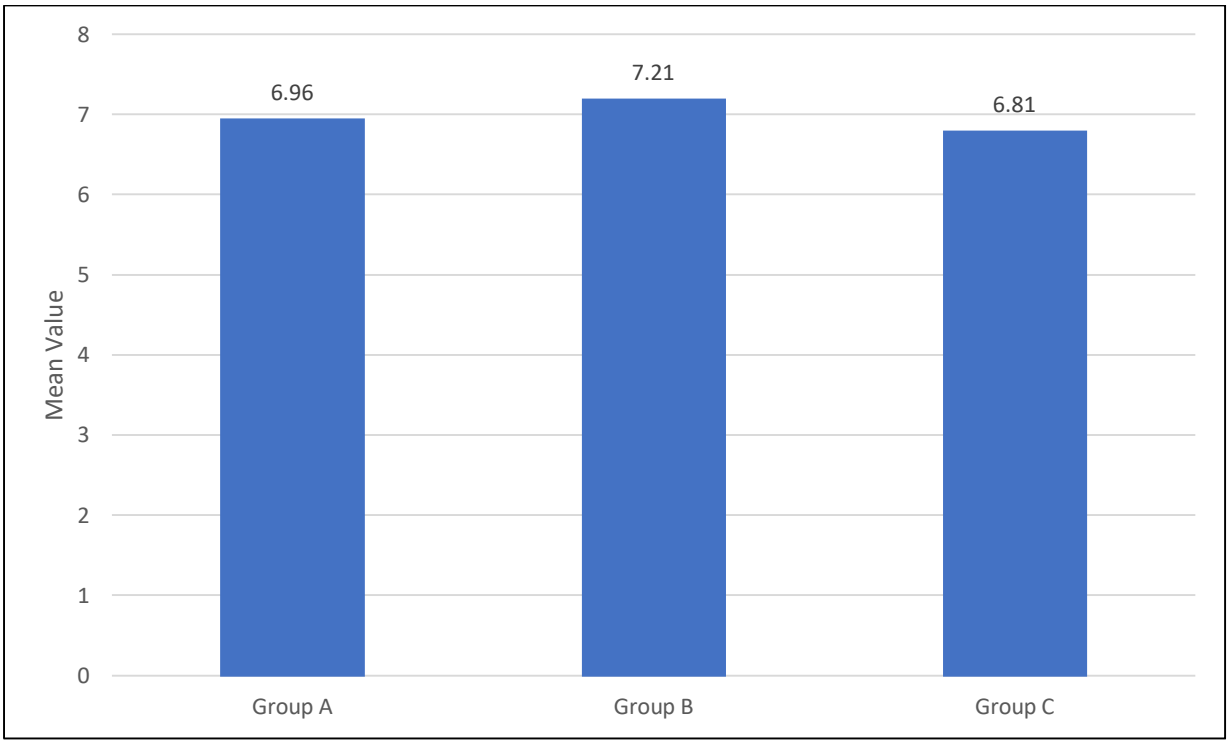


Figure 6: Comparison of mean time of rescue analgesia among the study group

VAS SCORE (Pain)

Comparison of mean VAS score at rest among the study group:

Table 22: Comparison of mean VAS score at rest among the study group

	Group A		Group B		Group C		Result (P value)
	Mean	SD	Mean	SD	Mean	SD	
10 M	3.08	1.12	3.04	0.89	2.59	0.68	0.001 (S)
30 M	2.77	0.98	2.73	0.68	2.41	0.59	0.008 (S)
60 M	2.19	1.02	1.93	0.66	1.77	0.53	0.004 (S)
90 M	1.65	0.81	1.49	0.53	1.28	0.45	0.001 (S)
120 M	1.07	0.84	0.81	0.54	0.68	0.50	0.001 (S)
180 M	0.43	0.68	0.19	0.43	0.04	0.20	p<0.001 (S)

In present study, there was a statistically significant difference in mean VAS scores for pain in all the 3 groups.

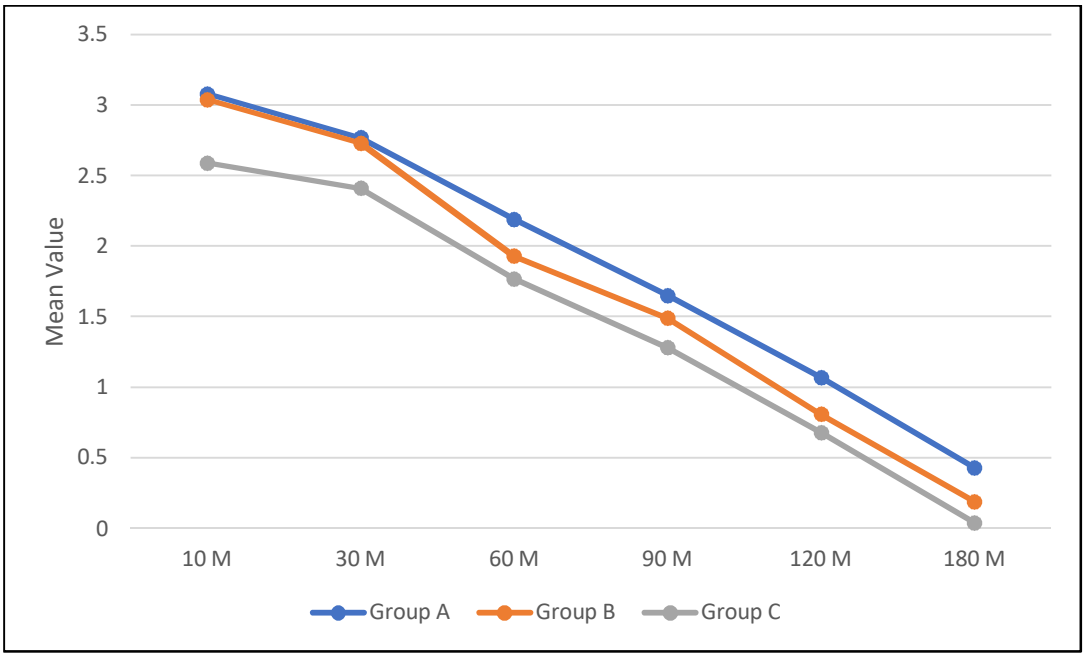


Figure 7: Comparison of mean VAS score at rest among the study group

Comparison of mean VAS score at rest between group A and group B:

Table 23: Comparison of mean VAS score at rest between group A and group B

	Group A		**Group B**		**Result (P value)**
	Mean	SD	Mean	SD	
10 M	3.08	1.12	3.04	0.89	0.809(NS)
30 M	2.77	0.98	2.73	0.68	0.772(NS)
60 M	2.19	1.02	1.93	0.66	0.074(NS)
90 M	1.65	0.81	1.49	0.53	0.155(NS)
120 M	1.07	0.84	0.81	0.54	0.029(S)
180 M	0.43	0.68	0.19	0.43	0.009(S)

The mean VAS score for pain at rest was comparable in group A and group B till 90 minutes postoperatively. There was significant difference at 120 and 180 minutes, in both the groups.

Comparison of mean VAS score at rest between group B and group C:

Table 24: Comparison of mean VAS score at rest between group B and group C

	Group B		Group C		Result (P value)
	Mean	SD	Mean	SD	
10 M	3.04	0.89	2.59	0.68	0.0006 (S)
30 M	2.73	0.68	2.41	0.59	0.002 (S)
60 M	1.93	0.66	1.77	0.53	0.106 (NS)
90 M	1.49	0.53	1.28	0.45	0.008 (S)
120 M	0.81	0.54	0.68	0.50	0.117(NS)
180 M	0.19	0.43	0.04	0.20	0.007 (S)

The mean VAS score for pain at rest was not comparable in both the groups except at 90 and 180 minutes. .

Comparison of mean VAS score at rest between group A and group C

Table 25: Comparison of mean VAS score at rest between group A and group C

	Group A		**Group C**		**Result (P value)**
	Mean	SD	Mean	SD	
10 M	3.08	1.12	2.59	0.68	0.001 (S)
30 M	2.77	0.98	2.41	0.59	0.007 (S)
60 M	2.19	1.02	1.77	0.53	0.002 (S)
90 M	1.65	0.81	1.28	0.45	0.0006 (S)
120 M	1.07	0.84	0.68	0.50	0.0008 (S)
180 M	0.43	0.68	0.04	0.20	p<0.001 (S)

The mean VAS at rest was significantly different in group A and Group C at different time points.

Comparison of mean VAS score at movement among the study group

Table 26: Comparison of mean VAS score at movement among the study group

	Group A		Group B		Group C		Result (P value)
	Mean	SD	Mean	SD	Mean	SD	
10 M	3.51	0.84	4.04	0.89	3.57	0.70	0.0001 (S)
30 M	3.08	0.67	3.71	0.71	3.41	0.59	p<0.001 (S)
60 M	2.49	0.69	2.88	0.72	2.77	0.53	0.001 (S)
90 M	1.85	0.67	2.44	0.58	2.28	0.45	p<0.001 (S)
120 M	1.35	0.58	1.79	0.53	1.63	0.56	p<0.001 (S)
180 M	1.07	0.25	1.16	0.37	1.03	0.16	0.010 (S)

The mean VAS at rest was significantly different in group A and Group C at different time points

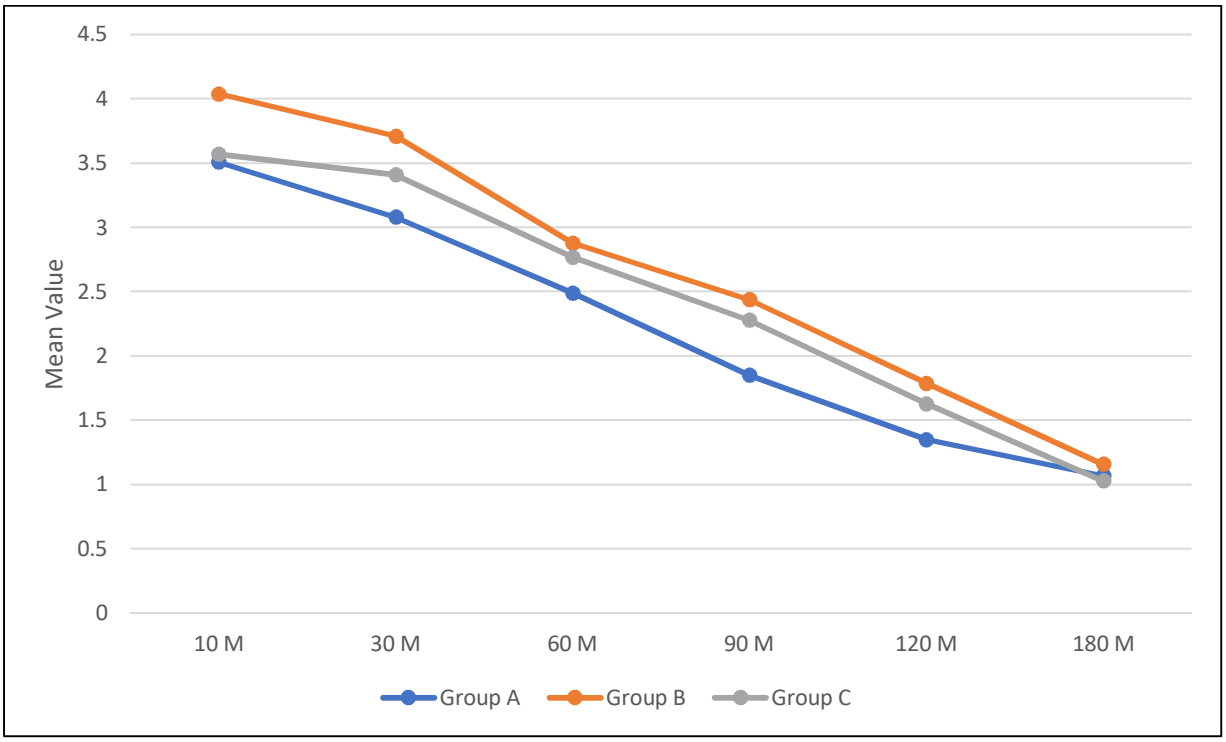


Figure 8: Comparison of mean VAS score at movement among the study group

Comparison of mean VAS score at movement between group A and Group B:

Table 27: Comparison of mean VAS score at movement between Group A and Group B

	Group A		**Group B**		**Result (P value)**
	Mean	SD	Mean	SD	
10 M	3.51	0.84	4.04	0.89	0.0002
30 M	3.08	0.67	3.71	0.71	p<0.001
60 M	2.49	0.69	2.88	0.72	0.0009
90 M	1.85	0.67	2.44	0.58	p<0.001
120 M	1.35	0.58	1.79	0.53	p<0.001
180 M	1.07	0.25	1.16	0.37	0.076

There was significant difference in mean VAS scores for pain at movement in group A and group B at different time points as shown in table.

Comparison of mean VAS score at movement between group B and Group C:

Table 28: Comparison of mean VAS score at movement between group B and Group C

	Group B		Group C		Result (P value)
	Mean	SD	Mean	SD	
10 M	4.04	0.89	3.57	0.70	0.003 (S)
30 M	3.71	0.71	3.41	0.59	0.003 (S)
60 M	2.88	0.72	2.77	0.53	0.209 (NS)
90 M	2.44	0.58	2.28	0.45	0.046 (S)
120 M	1.79	0.53	1.63	0.56	0.067 (NS)
180 M	1.16	0.37	1.03	0.16	0.005 (S)

There was significant difference in mean VAS scores for pain at movement in group A and group B at different time points as shown in table.

Comparison of mean VAS score at movement between group A and Group C:

Table 29: Comparison of mean VAS score at movement between group A and Group C

	Group A		**Group C**		**Result (P value)**
	Mean	SD	Mean	SD	
10 M	3.51	0.84	3.57	0.70	0.599 (NS)
30 M	3.08	0.67	3.41	0.59	0.001 (S)
60 M	2.49	0.69	2.77	0.53	0.005 (S)
90 M	1.85	0.67	2.28	0.45	p<0.001 (S)
120 M	1.35	0.58	1.63	0.56	0.003 (S)
180 M	1.07	0.25	1.03	0.16	0.240 (NS)

There was significant difference in mean VAS scores for pain at movement in group A and group B at different time points as shown in table.

Distribution of cases according to patient satisfaction score (24 hrs postoperatively):

Table 30: Distribution of cases according to patient satisfaction score (24 hrs postoperatively)

	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Excellent	59	78.67	63	84.00	72	96.00
Good	16	21.33	12	16.00	3	4.00
Fair	0	0.00	0	0.00	0	0.00
Poor	0	0.00	0	0.00	0	0.00
Total	75	100.00	75	100.00	75	100.00
Result (P value)	0.007 (S)					

S = Significant; NS = non-Significant

This table shows that Group –A, there was no fair, no poor in any case in this group, it showed excellent in 78.67% cases and good in 21.33% cases at 24 hrs. post operatively. In group-B there was no fair, no poor postoperatively in any case in this group. it showed excellent in 84% cases and good in 16% cases. In group-C there was no fair, no poor postoperatively in any case in this group. it showed excellent in 96% cases and good in 4% cases.

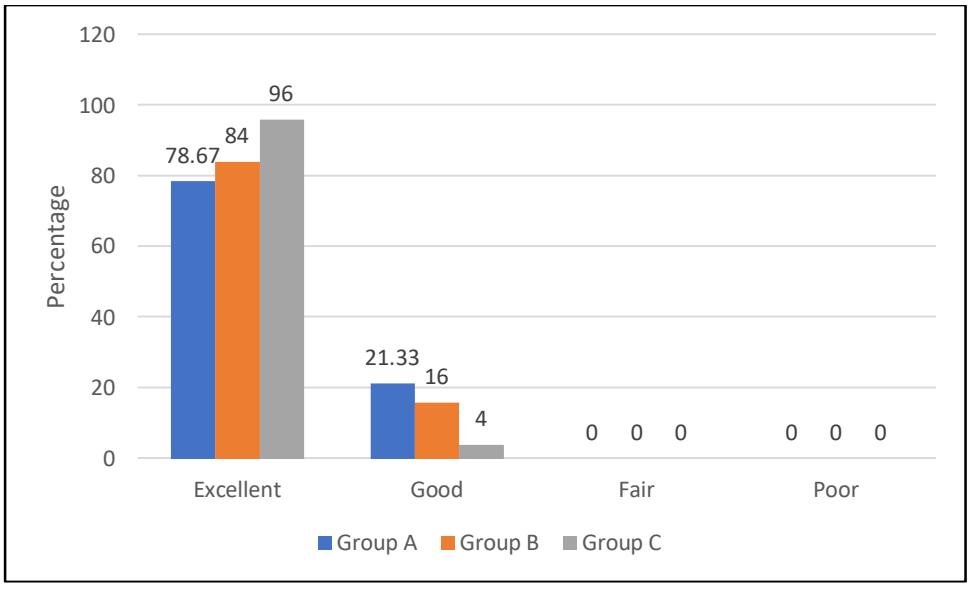


Figure 9: Distribution of cases according to patient satisfaction score (24 hrs postoperatively)

ANY OTHER COMPLICATIONS

Table 31: Any other complications

	Group A		Group B		Group C		Result (P value)
	Yes	No	Yes	No	Yes	No	
Hypotension	5	70	0	75	0	75	0.006 (S)
Respiratory Depression	0	75	0	75	0	75	-
Shivering	0	75	0	75	0	75	-
Headache	0	75	0	75	0	75	-

This table shows that there was no respiratory depression, no shivering and no headache in any case among the study group, it showed hypotension in 5 cases of group A, no hypotension was observed in group B and Group C.

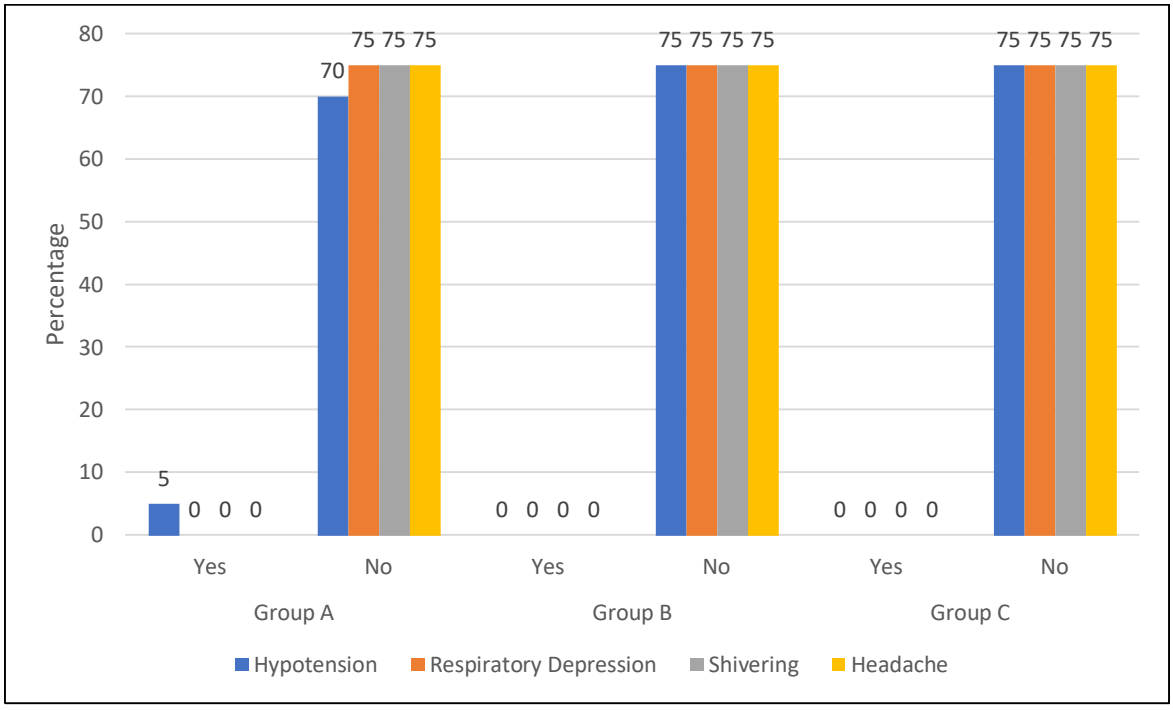


Figure 10: Any other complications

DISCUSSION

DISSCCUSION

In general anaesthesia, induction and emergence from anaesthesia are the two most crucial steps because, during this period, the body is susceptible to a variety of stress and hemodynamic changes. Preoperative anxiety is common and can adversely affect a patient's perioperative course by elevating stress markers, promoting fluctuations in hemodynamic and negatively impacting on postoperative recovery. Preoperative anxiety is routinely treated with pharmacologic agents such as short-acting benzodiazepines.

Listening to music is a non-invasive, safe and economical non-pharmacological intervention that requires no special skill to administer. It has a positive effect on pain and anxiety and also has minimal lethal and ethical concerns. [28] Music therapy is a structured, organized therapeutic intervention. Our brain accepts it very well, as we like and enjoy listening to music over and over again. Music is a very old therapeutic mean, the effectiveness of which has been essentially proven in the treatment of physical and mental stress related to certain neuropsychiatric disorders. It also helps in addressing the physical, emotional, cognitive and social needs of patients. [29,30,31,32]

Listening to music has been shown to modulate the mood, behaviour and the psychology of the patient into a 'more positive frame of mind'. It has been shown to reduce the state of anxiety while having a favourable impact on hemodynamic variables. [33,34,35]. Music was able to reduce an individual's perception of pain by inducing the release of endogenous opioid and reducing muscle tension and by interfering with nerve conduction. It acts by reducing the transmission of a pain signal as well as anxiety, helplessness and powerlessness.[36].

In our study we divided patient into 3 groups which include: -

- Group A: Where patients received search-selected music (binaural tone) via noise-canceling headphones.
- Group B: Patients received intravenous midazolam minimum of 1 mg to 2 mg maximum as per clinical judgement.
- Group C: Patients were made to listen, patient preferred music via noise-canceling headphones.

Binaural beats or tone is the oscillating sound that is produced when two different sounds with varying frequencies presented to individual's right and left ear separately at the same time. For instance, when the left ear is presented with a tone of 300 Hz and the right ear with a tone of 320 Hz, the individual will perceive a tone that oscillates at a frequency of 20 Hz (i.e.,20 beats per second). These binaural tones impact processing of information by increasing the neural synchronization. [37]

The binaural beat can be heard if the frequency of each tone in your ears is less than 1000 Hz and the difference between the two tones is less than 35 Hz.

When each ear hears a tone at a slightly different frequency, your brain tries to compensate by creating the perception of a third sound. This creation of a third sound is caused by the same part of the brain that helps you determine the location of a sound.

Binaural beats can be created at different frequencies. Each frequency is associated with outcomes that correspond to different levels of activity.

Gamma (γ) pattern: Gamma waves are the highest frequency of brain activity between 30 Hz and 50 Hz. This type of brain activity is associated with alertness, concentration and problem solving. A small study found that people listening to binaural beats at gamma frequencies of 40 Hz experienced improved memory, cognition and even mood.

Beta (β) pattern**:** Beta waves range between 13 Hz and 30 Hz. These waves in the brain are linked to an active and alert mind. Higher levels of beta waves are also associated with anxiety. Listening to binaural beats in the beta wave pattern has been shown to improve mood and task performance.

Alpha (α) pattern: Ranging between 8 Hz and 13 Hz, alpha waves indicate a relaxed and restful mind. Research shows that binaural beat stimulation in the alpha range can increase creativity in some listeners.

Theta (θ) pattern: During stage one of sleep, which is the lightest stage of sleep, your brain produces theta waves at a frequency between 4 Hz and 8 Hz. Theta waves are also associated with drowsiness and meditation. Studies show that listening to binaural beats at 6 Hz frequency can induce a meditative state.

Delta (δ) pattern: The slowest brain waves are delta waves. These waves have a frequency between 0.5 Hz and 4 Hz. As you transition into deeper sleep stages, your brain switches from theta waves to delta waves. Dreaming can occur. Listening to binaural beats at delta frequencies can help you sleep. [14]

Emerging pieces of evidence show how preoperative anxiety starts as soon as the procedure is planned and reaches its peak on the day of surgery ; this is further confirmed by associated physical changes , such as increased hormones and acute phase's protein release, tachycardia episodes, hypertension, rise in body temperature , fluid and electrolyte imbalances, diminished immune responses and longer wound healing , which can affect the surgical outcome and the postoperative recovery and lead to the increase of the dosage of anaesthetics and sedatives given on the day of surgery with a consequent higher risk of adverse events and interactions. Likewise, patients with anxiety tend to have a longer hospital stay, a decreased postoperative satisfaction, and to be less compliant with rehabilitation and occupational therapy. [11]

In the present study, the difference in the mean age and sex among these groups were statistically non-significant (*P value >0.05*), hence these groups were comparable with respect to age and sex.

Visual Assessment Score -Anxiety Score

In our study we measured VAS A score to measure anxiety at different time periods (Baseline, after 10 minutes in the operation theatre, before block placement, after block placement and after 60 minutes of block placement) among the study groups. We found that the VAS A score was significantly lower in the patient selected music group (Group C) after 10 minutes in the operation theatre (p value- 0.005), before block placement (0.004) and 60 minutes after block placement (p value- 0.038). Conversely after the block placement the VAS A score was comparatively lower in group A but it was not statistically significant (p value- 0.618). We have also compared VAS A score between Group A and B, Group B and C and Group C and A at the above specified time intervals. We found that on comparison between Group B and Group C, VAS A score was lower in Group C which was statistically significant at the following points of measurement (after 10 minutes in the operation theatre (p value- <0.001), before block placement (p value- 0.0002) and 60 minutes after block

placement (p value- <0.001)). Similarly, during comparison of VAS A score between Group A and Group C the VAS A score was significantly lower in Group C at the following points of measurement (after 10 minutes in the operation theatre (p value- 0.007) and after 60 minutes of block placement (p value- 0.001).

We also compared mean difference of VAS anxiety score between before and after block. There was a statistically significant difference in group A and C.

This may be probably because music of patient's choice has better anxiolysis effect than midazolam and binaural tone music. Patient is more distracted from thought of surgery by listening to music especially, if it's of patient choice. Further studies are needed to compare effect of different music types on perioperative anxiety.

We also compared anxiety during skin closure and 30 minutes after skin closure between the study groups. We found that VAS A score was lower in Group C at all points of measurement which was statistically significant (p value <0.001). We have also compared VAS A score post operatively between Group A and B, Group B and C and Group C and A at various time periods time intervals and found that during comparison of VAS A score between Group B and Group C, VAS A score was lower at the above specified points of measurement but was significantly lower after 30 minutes of skin closure (p value <0.001). Also, VAS A score was significantly lower during the comparison between Group A and Group C (p value of <0.001) at the above specified points of measurement.

Our findings were consistent with a study done by Ugras G A et al[47], in which they used STAI-S score instead if VAS score as in our study and found that there was a statistically significant reduction in STAI-S score in the post-music group. Our findings were also similar to a study done by ghezeljeh T N et al [45], in which they found that with music therapy during intervention there was a statistically significant decrease the pain (VAS) and anxiety scores and increase in relaxation scores. In our study binaural music therapy shows significant less anxiety and pain than patient selected music and only midazolam. Our results were supported by study of Kukreja P et al (2020) [27] , they also observed less anxiety and pain with music therapy. Labrague LJ et al (2016) [22] and Lee and Kim's [38] also observed similar result as in our study. Our findings are also consistent with a study done in which they found statistically significant reduction in anxiety level in binaural music group. Our study results were also in

acceptance with a study done by Mahumut Taha et al [42] in which they notice listening to pure binaural beats may a simple and effective method to reduce anxiety level and pain.

Visual Analogue score for pain:

At Rest:

In our study we also measured VAS R for measuring postoperative pain at different time intervals (10,30,60,90,120,180 minutes postoperatively) was compared among the study groups. We found that the VAS R score was significantly lower in the patient selected music group (Group C) which was statistically significant at all time points of measurement. We have also compared VAS R score between Group A and B, Group B and C and Group C and A at the above specified time intervals. We found that on comparison between Group B and Group C, pain scores were lower in Group C which was statistically significant at the following points of measurement ; 10 minutes (p value-0.0006), 30 minutes (p value -0.003), 90 minutes (p value- 0.008) and 180 minutes (p value- 0.007). Similarly, during comparison of VAS R score between Group A and Group C, VAS R score was significantly lower in Group C at all the above specified points of measurement. Similarly, during comparison of VAS R score between Group A and Group B, the VAS R score was significantly lower in Group B at all the above specified points of measurement but was statistically significant at 120 minutes (p value- 0.029) and at 180 minutes (p value – 0.009).

At Movement:

In our study, we also measured VAS during movement at different time intervals (10, 30,60,90,120,180 minutes postoperatively) among the study groups. We found that the VAS M score was significantly lower in the patient selected music group (Group C) which was statistically significant at all time points of measurement. We have also compared VAS M score between Group A and B, Group B and C and Group C and A at the above specified time intervals. We found that on comparison between Group B and Group C, VAS A score was lower in Group C which was statistically significant at the following points of measurement ;10 minutes (p value-0.003), 30 minutes (p value -0.003), 90 minutes (p value-0.046) and 180 minutes (p value- 0.005). Similarly, during comparison of VAS M score between Group A and Group C the VAS M score was significantly lower in Group C at following points of measurement (30 minutes p value-0.001),60 minutes (p value -0.005), 90

minutes (p value-<0.001),120 minutes (p value-0.003). Similarly, during comparison of VAS M score between Group A and Group B the VAS M score was significantly lower in Group B at all the above specified points of measurement but was statistically significant at all points of measurement.

Both during rest and movement, patients in group C (patient selected music) had lower pain scores followed by midazolam group then binaural tone music. We could not find any literature supporting our findings. These findings may be because patient in preference selected music group were more distracted and anxiety free then other groups. This might reduce some factors especially psychological which leads to enhanced perception of pain in perioperative period.

Music therapy may also release some endorphins which results in reduced pain perception.[43] None of the patients included in this study have received intraoperative and postoperative dexmedetomidine infusion.

Blood Pressure:

On comparing intraoperative mean arterial pressure between Group A and Group B the mean arterial pressure was significantly lower in group A (binaural tone music) at 10,15, 30,60,90,120 minutes. On comparing the intraoperative BP between Group B and C, the mean arterial bp was statistically significant lower in Group C at 10, 15,30, 90, 120 and 180 minutes respectively. This decrease in mean bp could be attributable to greater relaxation and anxiolysis achieved due to music therapy (both binaural tone and patient choice music). Similarly on comparison of intraoperative mean BP between Group A and Group C, the mean arterial BP was significantly lower in Group A at 30,60,90 minutes respectively. It was comparable to other studies like that conducted by Kahloul M et al(24) where they found that there was more stability in mean systolic blood pressure among the music group when compared with control group. In a study published in 2007, Jaber et al(44), found that systolic arterial blood pressure (137 ± 17 versus 128 ± 14 mm Hg, $p < 0.05$). Our findings are contradictory to the findings done by Reynaud D et a[48] in which they found that the hemodynamic parameters were considerable low and stable in self-selected music group as compared to predetermined music group. In study conducted by Veena Graff [26] also there was no significant difference between the mean arterial pressure trend throughout the nerve

block among the music and midazolam groups. This discrepancy has been attributable to the selection of predetermined music and the timing of its introduction.

Pulse Rate:

On comparing intraoperative pulse rate between Group A, Group B and Group C the mean pulse rate was significantly lower in group A and Group C (binaural tone music) at 10, 15, 30,60,90,120 minutes. This decrease in mean pulse rate could be attributable to greater relaxation and anxiolysis achieved due to music therapy (both binaural tone and patient choice music). In the postoperative period on comparing the pulse rate between Group A,B,C the mean pulse rate was lower in Group A and Group C (both binaural tone and patient choice music). Our findings are contradictory to the findings done by Reynaud D et al[48] in which they found that the hemodynamic parameters were considerable low and stable in self-selected music group as compared to predetermined music group. This discrepancy has been attributable to the selection of predetermined music.

Our results supported by Jaber et al(44) where they found that music therapy provides a significant reduction in heart rate (88 ± 15 versus 82 ± 15 bpm, $p < 0.05$) among the music group and the control group.

In a study conducted by Gökçek et al(27) they found lower heart rate (78.56± 9.66 v/s 79.63 ± 13.84) and mean arterial blood pressures (85.13± 10.43 v/s 86.66 ± 10.78) among the music group and the control, but these results were not statistically significant.

Time of Rescue Analgesia:

In our study time of rescue analgesia was 6.96±1.61 hours in Group A, 7.21±01.60 hours in group B and 6.81±1.33 hours in Group C. The difference in time of rescue analgesia between these groups was non-significant (P =0.267). Mishra R et al [39] in their study proved that music does not make any change in time of rescue analgesic.

Patient satisfactory score (at 24 hrs postoperatively):

In Group A, 59 (78.67%) patient shows excellent satisfactory score, 16 (21.33%) patient shows good satisfactory score. In Group B, 63 (84%) patient shows excellent satisfactory

score, 12 (16.33%) patient shows good satisfactory score. In Group C, 72 (96%) patient shows excellent satisfactory score, 3 (4%) patient shows good satisfactory score. The difference in satisfactory score of these was statically significant. (P=0.007)

Patients in group C (self-selected music) seems to be maximally satisfied with excellent satisfaction followed by midazolam group then binaural tone group patients.

In our study, music therapy patients showed better satisfactory score than midazolam group which is supported by Jayaraman et al. [40]. They also confirmed the beneficial effects of music therapy on patient satisfaction. This effect is seen essentially when the music used is chosen by the patient [40]. Similar results were found by Bechtold et al [46] in a study enrolling patients intended for colonoscopy under general anaesthesia (85 patients treatment group versus 81 patients control group). The frequency of patients claiming music in subsequent colonoscopy was significantly higher in the intervention group (96.3% versus 56.1%; $p < 0.0001$. In a meta-analysis published by on 8 randomized trials including 712 patients who underwent colonoscopy under general anaesthesia with or without music therapy, satisfaction was significantly greater in the intervention group.

Music therapy improves satisfaction directly by its relaxing effect, and indirectly through its effects on other dissatisfaction factors such as perioperative pain and stress and postoperative nausea and vomiting.

DISSCCUSION

In general anaesthesia, induction and emergence are the two crucial steps because, as the body is susceptible to a variety of stress and hemodynamic changes. Preoperative anxiety is can adversely affect a patient's perioperative course by elevating stress markers along with promoting fluctuations in hemodynamic and further negatively impacting on postoperative recovery. Preoperative anxiety is routinely treated with drugs such as short-acting benzodiazepines.

Music is a non-invasive, safe and economical intervention that requires no special skill. It has positive effect on pain and anxiety. [28] Our brain accepts it very well, as people like to listen music repeatedly . Effectiveness of music has been established in treatment of physical and mental stress. It further helps in managing the physical, emotional and social needs of patients. [29,30,31,32]

Music modulates the mood, behaviour and psychology of the patient. It reduces anxiety and have a favourable impact on hemodynamics. [33,34,35]. Music reduces individual's perception of pain by releasing endogenous opioid and reducing muscle tension and interfering with nerve conduction. It also acts by reducing the transmission of a pain signal and anxiety.[36].

In our study we divided patient into 3 groups which include: -

- Group A: Where patients received search-selected music (binaural tone) via noise-canceling headphones.
- Group B: Patients received intravenous midazolam minimum of 1 mg to 2 mg maximum as per clinical judgement.
- Group C: Patients were made to listen, patient preferred music via noise-canceling headphones.

Binaural beats or tone is oscillating sound, produced when two different sounds with different frequencies are listened by individual's right and left ear separately but simultaneously. For instance, when the left ear is listening a tone of 300 Hz and the right ear a tone of 320 Hz, the individual will perceive a tone that oscillates at a frequency of 20 Hz (i.e.,20 beats per second). Binaural tones impact by increasing neural synchronization. [37]

The binaural beat produced if the frequency of each tone is less than 1000 Hz and the difference between the two is less than 35 Hz.

When each ear hears a tone at a slightly different frequency, your brain tries to compensate by creating the perception of a third sound. This creation of a third sound is caused by the same part of the brain that helps you determine the location of a sound.

Binaural beats are created at different frequencies. Each frequency corresponds to different levels of activity.

Gamma (γ) pattern: Gamma waves are the highest frequency of brain activity between 30 Hz and 50 Hz. It is associated with alertness, concentration and problem solving. People listening to binaural beats at gamma frequencies of 40 Hz experience better memory, cognition and even mood.

Beta (β) pattern**:** Beta waves range between 13 Hz and 30 Hz. They are associated with an active and alert mind. Higher levels of beta waves may be associated with anxiety. Beta wave pattern has been shown to improve mood and task performance while listening.

Alpha (α) pattern: Ranging between 8 Hz and 13 Hz, these waves indicate a relaxed and restful mind. This wave can increase creativity in few listeners.

Theta (θ) pattern: During stage one of sleep, brain produces theta waves of frequency between 4 Hz and 8 Hz. They are associated with drowsiness and meditation. Literature shows that listening to binaural beats at 6 Hz frequency can induce a meditative state.

Delta (δ) pattern: The slowest brain waves are delta waves. These waves have a frequency between 0.5 Hz and 4 Hz. With transition into deeper sleep stages, brain switches from theta waves to delta waves. Dreaming can occur. Binaural beats at delta frequencies can help in better sleep. [14]

Evidence establishes that preoperative anxiety starts as soon as the procedure is planned and reaches peak on the day of surgery ; further confirmed by other physical changes , as increased hormones and acute phase's protein release, hypertension, tachycardia episodes, fluid and electrolyte imbalances, rise in body temperature and longer wound healing. It can affect the surgical outcome and the postoperative recovery. It leads to increase in the dosage of anaesthetics and sedatives given perioperatively with a consequent higher risk of adverse

events. Patients with anxiety have a longer hospital stay with decreased postoperative satisfaction and are less compliant with rehabilitation and occupational therapy. [11]

In the present study, the difference in the mean age and sex among these groups were statistically non-significant (*P value >0.05*), hence these groups were comparable with respect to age and sex.

Visual Assessment Score -Anxiety Score

In our study we measured VAS A score to measure anxiety at different time periods (Baseline, after 10 minutes in the operation theatre, before block placement, after block placement and after 60 minutes of block placement) among the study groups. We found that the VAS A score was significantly lower in the patient selected music group (Group C) after 10 minutes in the operation theatre (p value- 0.005), before block placement (0.004) and 60 minutes after block placement (p value- 0.038). Conversely after the block placement the VAS A score was comparatively lower in group A but it was not statistically significant (p value- 0.618). We have also compared VAS A score between Group A and B, Group B and C and Group C and A at the above specified time intervals. We found that on comparison between Group B and Group C, VAS A score was lower in Group C which was statistically significant at the following points of measurement (after 10 minutes in the operation theatre (p value- <0.001), before block placement (p value- 0.0002) and 60 minutes after block placement (p value- <0.001)). Similarly, during comparison of VAS A score between Group A and Group C the VAS A score was significantly lower in Group C at the following points of measurement (after 10 minutes in the operation theatre (p value- 0.007) and after 60 minutes of block placement (p value- 0.001).

We also compared mean difference of VAS anxiety score between before and after block. There was a statistically significant difference in group A and C.

This may be probably because music of patient's choice has better anxiolysis effect than midazolam and binaural tone music. Patient is more distracted from thought of surgery by listening to music especially, if it's of patient choice. Further studies are needed to compare effect of different music types on perioperative anxiety.

We also compared anxiety during skin closure and 30 minutes after skin closure between the study groups. We found that VAS A score was lower in Group C at all points of measurement which was statistically significant (p value <0.001). We have also compared VAS A score

post operatively between Group A and B, Group B and C and Group C and A at various time periods time intervals and found that during comparison of VAS A score between Group B and Group C, VAS A score was lower at the above specified points of measurement but was significantly lower after 30 minutes of skin closure (p value <0.001). Also, VAS A score was significantly lower during the comparison between Group A and Group C (p value of <0.001) at the above specified points of measurement.

Our findings were consistent with a study done by Ugras G A et al[47], in which they used STAI-S score instead if VAS score as in our study and found that there was a statistically significant reduction in STAI-S score in the post-music group. Our findings were also similar to a study done by ghezeljeh T N et al [45], in which they found that with music therapy during intervention there was a statistically significant decrease the pain (VAS) and anxiety scores and increase in relaxation scores. In our study binaural music therapy shows significant less anxiety and pain than patient selected music and only midazolam. Our results were supported by study of Kukreja P et al (2020) [27] , they also observed less anxiety and pain with music therapy. Labrague LJ et al (2016) [22] and Lee and Kim's [38] also observed similar result as in our study. Our findings are also consistent with a study done in which they found statistically significant reduction in anxiety level in binaural music group. Our study results were also in acceptance with a study done by Mahumut Taha et al [42] in which they notice listening to pure binaural beats may a simple and effective method to reduce anxiety level and pain.

Visual Analogue score for pain:

At Rest:

In our study we also measured VAS R for measuring postoperative pain at different time intervals (10,30,60,90,120,180 minutes postoperatively) was compared among the study groups. We found that the VAS R score was significantly lower in the patient selected music group (Group C) which was statistically significant at all time points of measurement. We have also compared VAS R score between Group A and B, Group B and C and Group C and A at the above specified time intervals. We found that on comparison between Group B and Group C, pain scores were lower in Group C which was statistically significant at the following points of measurement ; 10 minutes (p value-0.0006), 30 minutes (p value -0.003), 90 minutes (p value- 0.008) and 180 minutes (p value- 0.007). Similarly, during comparison of VAS R score between Group A and Group C, VAS R score was significantly lower in

Group C at all the above specified points of measurement. Similarly, during comparison of VAS R score between Group A and Group B, the VAS R score was significantly lower in Group B at all the above specified points of measurement but was statistically significant at 120 minutes (p value- 0.029) and at 180 minutes (p value – 0.009).

At Movement:

In our study, we also measured VAS during movement at different time intervals (10, 30,60,90,120,180 minutes postoperatively) among the study groups. We found that the VAS M score was significantly lower in the patient selected music group (Group C) which was statistically significant at all time points of measurement. We have also compared VAS M score between Group A and B, Group B and C and Group C and A at the above specified time intervals. We found that on comparison between Group B and Group C, VAS A score was lower in Group C which was statistically significant at the following points of measurement ;10 minutes (p value-0.003), 30 minutes (p value -0.003), 90 minutes (p value-0.046) and 180 minutes (p value- 0.005). Similarly, during comparison of VAS M score between Group A and Group C the VAS M score was significantly lower in Group C at following points of measurement (30 minutes p value-0.001),60 minutes (p value -0.005), 90 minutes (p value-<0.001),120 minutes (p value-0.003). Similarly, during comparison of VAS M score between Group A and Group B the VAS M score was significantly lower in Group B at all the above specified points of measurement but was statistically significant at all points of measurement.

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Music therapy may also release some endorphins which results in reduced pain perception.[43] None of the patients included in this study have received intraoperative and postoperative dexmedetomidine infusion.

Blood Pressure:

On comparing intraoperative mean arterial pressure between Group A and Group B the mean arterial pressure was significantly lower in group A (binaural tone music) at 10,15, 30,60,90,120 minutes. On comparing the intraoperative BP between Group B and C, the mean arterial bp was statistically significant lower in Group C at 10, 15,30, 90, 120 and 180 minutes respectively. This decrease in mean bp could be attributable to greater relaxation and anxiolysis achieved due to music therapy (both binaural tone and patient choice music). Similarly on comparison of intraoperative mean BP between Group A and Group C, the mean arterial BP was significantly lower in Group A at 30,60,90 minutes respectively. It was comparable to other studies like that conducted by Kahloul M et al[24] where they found that there was more stability in mean systolic blood pressure among the music group when compared with control group. In a study published in 2007, Jaber et al[44], found that systolic arterial blood pressure (137 ± 17 versus 128 ± 14 mm Hg, $p < 0.05$). Our findings are contradictory to the findings done by Reynaud D et a[48] in which they found that the hemodynamic parameters were stable in self-selected music group when compared to selected music group. In study conducted by Veena Graff [26] also there was no significant difference between the mean arterial pressure trend throughout the nerve block among the music and midazolam groups. This discrepancy has been attributable to the selection of predetermined music and the timing of its introduction.

Pulse Rate:

On comparing intraoperative pulse rate between Group A, Group B and Group C the mean pulse rate was significantly lower in group A and Group C (binaural tone music) at 10, 15, 30,60,90,120 minutes. This decrease in mean pulse rate could be attributable to greater relaxation and anxiolysis achieved due to music therapy (both binaural tone and patient choice music). In the postoperative period on comparing the pulse rate between Group A,B,C the mean pulse rate was lower in Group A and Group C (both binaural tone and patient choice music). Our findings are contradictory to the findings done by Reynaud D et al[48] in which they found that the hemodynamic parameters were considerable low and stable in self-selected music group as compared to predetermined music group. This discrepancy has been attributable to the selection of predetermined music.

Our results supported by Jaber et al[44] where they found that music therapy provides a significant reduction in heart rate (88 ± 15 versus 82 ± 15 bpm, $p < 0.05$) among the music group and the control group.

In a study conducted by Gökçek et al[27] they found heart rate (78.56± 9.66 v/s 79.63 ± 13.84) and mean arterial blood pressures (85.13± 10.43 v/s 86.66 ± 10.78) were lower among the music group and the control, but results were not statistically significant.

Time of Rescue Analgesia:

In our study time of rescue analgesia was 6.96±1.61 hours in Group A, 7.21±01.60 hours in group B and 6.81±1.33 hours in Group C. The difference in time of rescue analgesia between these groups was non-significant (P =0.267). Mishra R et al [39] in their study proved that music has no effect on time of rescue analgesic.

Patient satisfactory score (at 24 hrs postoperatively):

In Group A, 59 (78.67%) patient shows excellent satisfactory score, 16 (21.33%) patient shows good satisfactory score. In Group B, 63 (84%) patient shows excellent satisfactory score, 12 (16.33%) patient shows good satisfactory score. In Group C, 72 (96%) patient shows excellent satisfactory score, 3 (4%) patient shows good satisfactory score. The difference in satisfactory score of these was statically significant. (P=0.007)

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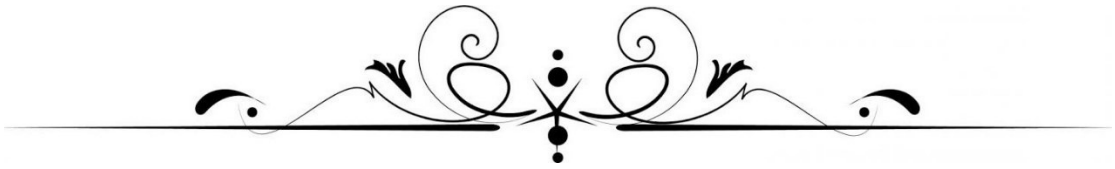
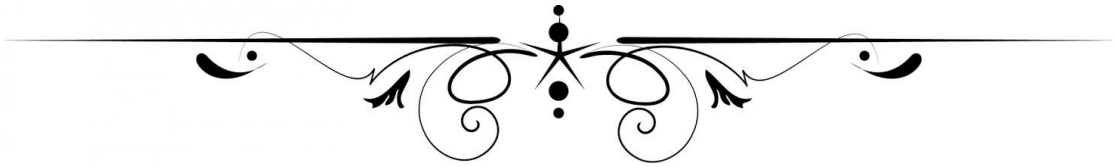
In our study, music therapy patients showed better satisfactory score than midazolam group which is supported by Jayaraman et al. [40]. They also advocated positive effects of music therapy on patient satisfaction. This effect is more evident when the music is chosen by the patient [40]. Similar results were found by Bechtold et al [46] , they enrolled patients posted for colonoscopy under general anaesthesia (85 patients treatment group versus 81 patients control group). The frequency of patients preferred music in subsequent colonoscopy was significantly higher in the intervention group (96.3% versus 56.1%; $p < 0.0001$). They showed that satisfaction was significantly greater in the intervention group.

Music therapy improves patient satisfaction directly by its relaxing effect, and indirectly by its effects on various factors such as perioperative pain, stress and postoperative nausea and vomiting.



STRENGTH & LIMITATION



STRENGTH OF STUDY

Being a randomized control trial, it generates highest level of evidence.

Music therapy is non-invasive, free of cost therapy which can add a new dimension to the perioperative anxiety management of the patients.

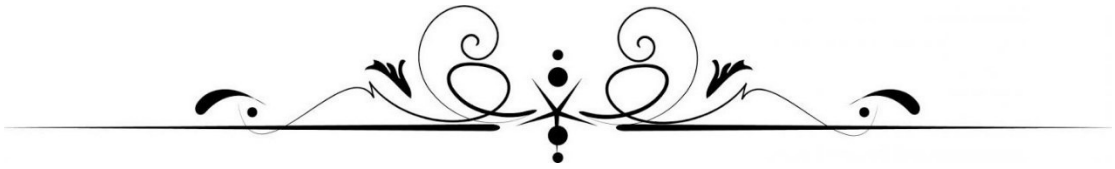
Binaural tone is antianxiety music, less explored for perioperative use. This study has added to the literature about its use for perioperative anxiety.

LIMITATIONS OF STUDY

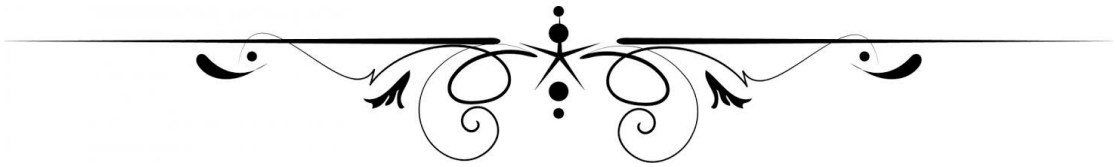
Visual analogue scale is a subjective scoring system, we could have added more objective scales as STAT scoring scales, to generalize the results.

We blinded the assessors, but patients were not blinded in this study.

We only involve patients with spinal anesthesia in our study, if we could involve patients with all types of regional anesthesia in this study, results would have been more generalized with more applicability.



CONCLUSION

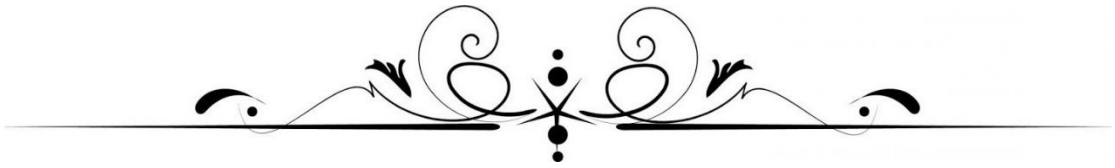


CONCLUSION

This study concluded that music therapy can be an easy, safe, and low-cost, non-pharmacological intervention for managing perioperative anxiety. Binaural tone is a dual tone music which also has a role in managing anxiety. This study has proved that patient selected music has better anxiety effect than midazolam and binaural tone music therapy patients.

Music therapy can be recommended to take a place in the routine care of patients. It can be easily implemented by healthcare workers in hospitals, as it is an effective method for managing the subjective feeling of patients like pain and anxiety in painful procedures.

There is not much literature about perioperative use of binaural tone music, and studies comparing it with patients preferred music and midazolam. More randomized control trials with larger sample size are needed to further establish results of our study.



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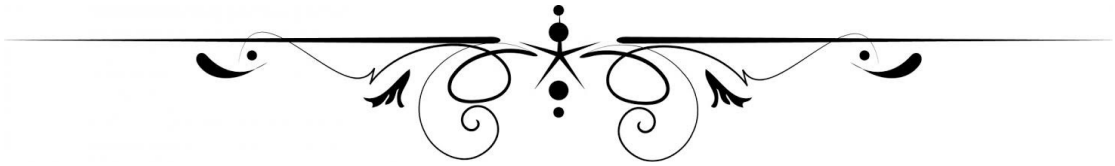

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ANNEXURES

ANNEXURE – 1

All India Institute of Medical Sciences, Jodhpur, Rajasthan.

Informed Consent Form

Title of the Project: **Effect of music on anxiety and physiologic parameters in patients posted for surgery under regional anaesthesia: A randomized control trial.**

Name of the Principal Investigator:

Patient/Volunteer Identification No:

I, _____S/o or D/o _____ R/o _____ give my full, free, voluntary consent to be a part of the study "Effect of music on anxiety and physiologic parameters in trauma patients posted for nerve block surgery: Randomized control trial", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from **AIIMS Jodhpur** (Company Name) or from regulatory authorities. I give permission for these individuals to have access to my records.

Date : _____

Place : _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date : _____ Place: _____

Signature of Principal Investigator

1. Witness 1
   Signature

2. Witness 2
   Signature

ANNEXURE - 2

ऑल इंडिया इंस्टिट्यूट ऑफ मैडिकल साईंसिस,जोधपुर,राजस्थान

सूचित सहमति प्रपत्र

परियोजना का शीर्षक: नर्व ब्लॉक के तहत सर्जरी के लिए पोस्ट रोगियों में चिंता और शारीरिक मापदंडों पर संगीत का प्रभाव - रैंडमआइस्ड कण्ट्रोल ट्रायल

प्रधानअन्वेषककानाम:

रोगी /स्वयं सेवक पहचान संख्या:

मैं_____ S/o or D/o _____

R/o_____

अध्ययन "नर्व ब्लॉक के तहत सर्जरी के लिए पोस्ट रोगियों में चिंता और शारीरिक मापदंडों पर संगीत का प्रभाव - रैंडमआइस्ड कण्ट्रोल ट्रायल "का एक हिस्सा होने के लिए मेरी पूरी,स्वैच्छिक सहमति दे रहा हू, इसके परीक्षण प्रक्रिया और प्रकृति के बारे में मुझे मेरी अपनी भाषा में समझाया गया है . मैं पुष्टि करता हूं कि मुझे सवाल पूछने का अवसर मिला है।

मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और बिना किसी कारण के किसी भी समय अध्ययन से बाहर निकलने के मेरे अधिकार से अवगत हूं।

तारीख : _____ _____

जगह: _____ **हस्ताक्षर / बाएं अंगूठे का निशान**

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है।

तारीख : _____ _____

स्थान: _____ **प्रमुख अन्वेषक के हस्ताक्षर**

1. **गवाह** 1 _____ 2. **गवाह** 2 _____

ANNEXURE – 3

PARTICIPANT INFORMATION SHEET (PIS)

Title of the Project: Effect of music on anxiety and physiologic parameters in patients posted for surgery under regional nerve blocks: A randomized control trial

Name of the Principal Investigator: Dr.Markandey Prasad Tel. No :7668931624

I have been explained in my own understanding language by the principal investigator that they

are doing this study to compare effect of music on anxiety and physiologic parameters in trauma

patient posted for regional nerve block surgery: Randomized control trial.

I have been informed that I can withdraw myself from study at any time.

The data obtained from me will be used for the purpose of the study only. All my records will be kept confidential.

Patient name and registration id:

ANNEXURE – 4

अखिल भारतीय आयुर्विज्ञानसंस्थान , जोधपुर, राजस्थान।

प्रतिभागी सूचनापत्रक:

तंत्रिकाब्लॉक के तहत सर्जरीके लिए तैनात रोगियों में चिंता और शारीरिक मापदंडों पर संगीत का प्रभाव यादृच्छिक नियंत्रण परीक्षण

प्रधान अन्वेषक का नाम:डॉ. मार्कण्डेय प्रसाद Tel. No. :7668931624

मुझे मुख्य अन्वेषक द्वारा अपनी समझकी भाषा में समझाया गया है कि वतंत्रिका ब्लॉक के तहत सर्जरी के लिए तैनात आघात के रोगियों में चिंता और शारीरिक मापदंडों पर संगीत के प्रभाव की तुलना करने के लिए यह अध्ययन कर रहे हैं

मुझे सूचित किया गया है कि मैं किसी भी समय अपने आपको अध्ययन से हटा सकता हूं।

मुझ से प्राप्त आंकड़ों का उपयोग केवल अध्ययन के उद्देश्य के लिए किया जाएगा। मेरे सभी रिकॉर्ड गोपनीय रखे जाएंगे।

रोगी का नाम रपंजीकरणआईडी:

हस्ताक्षर:

ANNEXURE – 5

All India Institute of Medical Sciences (AIIMS), Jodhpur.

Department of Anaesthesiology &Critical Care

PROFORMA

PATIENT ID

Group:

Baseline: VAS A score: SBP: DBP: P

After 10 min: VAS A score: SBP: DBP: P:

Before block placement: VAS A score: SBP: DBP: P

After block placement: VAS A score: SBP: DBP: P:

Assessment after 15 minutes: success/failure

Intra operative: (Haemodynamics)

Time	**5 min**	**10min**	**15min**	**30min**	**60min**	**90min**	**120min**	**180min**
SBP								
DBP								
P								

Intraoperatively: VAS A at 60 minutes

Postoperatively:

Skin closure VAS A score: SBP: DBP: P:

After 30 minutes: VAS A score: SBP: DBP: P:

Time of first rescue analgesia:

VAS SCORE

TIME		**10min**	**30min**	**60min**	**90min**	**120min**	**180min**
REST							
MOVEMENT							

SATISFACTION SCORE: (at 24 hours postoperatively): Patient Doctor

4-Excellent

3-Good

2-Fair

1-Poor

ANY OTHER COMPLAINTS:

Hypotension	Yes	No
Respiratory depression	Yes	No
Shivering	Yes	No
Headache	Yes	No