EFFECT OF PERIOPERATIVE MUSIC ON RECOVERY PROFILE IN PATIENTS UNDERGOING ABDOMINAL SURGERIES UNDER GENERAL ANAESTHESIA: A RANDOMIZED CONTROL TRIAL

THESIS

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DOCTOR OF MEDICINE (MD)

ANAESTHESIOLOGY AND CRITICAL CARE

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DECLARATION

I hereby declare that the thesis titled **"EFFECT OF PERIOPERATIVE MUSIC ON RECOVERY PROFILE IN PATIENTS UNDERGOING ABDOMINAL SURGERIES UNDER GENERAL ANAESTHESIA: A RANDOMIZED CONTROL TRIAL"** embodies the original work carried out by me at All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE FROM THE SUPERVISORS

This is to certify that the thesis titled **"EFFECT OF PERIOPERATIVE MUSIC ON RECOVERY PROFILE IN PATIENTS UNDERGOING ABDOMINAL SURGERIES UNDER GENERAL ANAESTHESIA: A RANDOMIZED CONTROL TRIAL"** is the bonafide work of **Dr. Muhammed Shahid Fasal** carried out under our guidance and supervision, at Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences, Jodhpur.

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The root of all goodness lies in the soil of appreciation of the goodness

- Dalai lama

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A true teacher would never tell you what to do. But, would give you the knowledge with which you could decide what would be best for you to do', said Christopher Pike. My guide, Dr Priyanka Sethi is the paradigm of these words. I take this opportunity to express my immense gratitude to her resourcefulness and patience in walking me through every step and for simplifying this arduous task.

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Dr. MUHAMMED SHAHID FASAL

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LIST OF ABBREVIATIONS

TIVA – Total intravenous anaesthesia

ASA – American society of anesthesiologists

GA – General Anaesthesia

PACU – Post Anaesthetic Care Unit

VAS – Visual Analog Scale

RASS – Richmond Agitation Sedation Scale

RCT – Randomized Control Trial

BIS – Bispectral Index

PONV – Postoperative Nausea and Vomiting

IQR – Interquartile Range

SD – Standard Deviation

HR – Heart rate

SPo2 – Peripheral oxygen saturation

NIBP – Non-invasive Blood Pressure

ECG – Electrocardiography

MAP – Mean Arterial Pressure

Mins – Minutes

PTSD – Post Traumatic Stress Disorder

Inj - Injection

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SUMMARY

Background: Music is a non-pharmacologic intervention that is virtually harmless, relatively cost effective and has been shown to significantly decrease preoperative anxiety and probably may affect overall outcome of perioperative patients. Literature is scarce about role of perioperative music on patients undergoing surgery under general anesthesia. Biaural tone music is less explored form of music. We aimed to evaluate role of binaural tone music on postoperative recovery profile of patients posted for laparoscopic abdominal surgeries under total intravenous anaesthesia.

Methods: Total 70 patients of American Society of Anesthesiologists (ASA) physical status grade I and II, aged between 18 to 60 years were enrolled. After informed consent, patients were randomized in two groups, group A and group B. Group A patients will listen to Binaural tone music throughout the perioperative period from preoperative period to 30 minutes in postoperative period. Group B patients will not listen to music at all. Quality of recovery from general anaesthesia (using Richmond agitation sedation scoring), total amount of intraoperative propofol consumption, postoperative visual analogue scale (VAS) pain score and time of first rescue analgesia was recorded in both the groups.

Results: Patients in binaural tone music had numerically better recovery profile, though the difference was not statically significant. Propofol consumption and postoperative pain scores were lower in binaural tone music group when compared to control group.

Conclusion: Binaural tone music under general anaesthesia can help in providing better recovery with calm patients in postoperative period, lesser anaesthetic requirement, reduced postoperative pain and lesser post-operative analgesic requirement. Patients were overall more satisfied in binaural tone music group at 24 hours postoperatively.

INTRODUCTION

INTRODUCTION

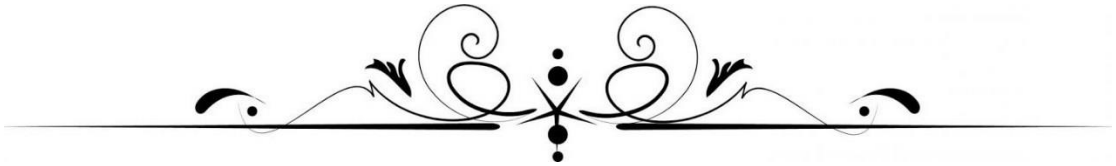
Music is a very old and effective method to deal with stress. Being an inexpensive, safe and easily accessible tool, music is widely used for therapeutic purposes to maintain or enhance a person's social, mental, and physical abilities[1]. Numerous neurophysiology research on the subject of the impacts of music established some data, particularly on the impact of music on hormonal secretions and nociceptive reflexes[1,2].

Preoperative anxiety is prevalent and can have a deleterious impact on the perioperative course by increasing stress indicators, causing hemodynamic fluctuations, and hindering postoperative recovery [4,5]. Surgery and anaesthesia are generally unpleasant for patients, and they can cause stress and fear that might prevent them from attaining their therapeutic goals[6,7]. There is evidence that listening to music can have a positive impact on stress-related physiological[35-37], cognitive[38], and emotional[39-41] processes.

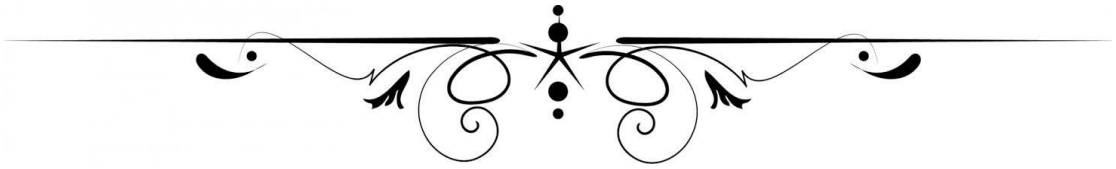
Listening to music in stressful conditions has been associated with to significant reduction or lesser increase in stress hormones as cortisol.[42-44] Various studies have evaluated the effect of music in improving the quality of perioperative care[5]. The use of acute analgesic medications may be decreased, patients may feel more relaxed, and patient satisfaction may increase by listening to music throughout the perioperative phase[7].

Binaural beat music is a newer form of music therapy. These are artifacts of auditory processing, whose perception is brought on by distinct physical stimuli in the brain. These special sounds are heard when each ear is exposed to two auditory inputs with different frequencies50. When sine waves within a close range are transmitted to each ear separately, binaural beats are produced. For example, when the 240 Hz tone is offered to the right ear and the 200 Hz tone to the left, a 40 Hz rhythm is experienced, which is regarded as being "within" the head. Only when the carrier frequency was below 1000 Hz were the binaural beats discernible65.Brain combines the two impulses received from the two different sounds heard in the opposing ears to create a third "beat" or sound. The distinctions between the "beats" fade in and out, creating a wavering, mesmerizing rhythm that is thought to alter inner consciousness. Brain immediately induces a hypnotic trance state by mimicking the variations in the sounds, which helps to sleep, relax, focus, practice meditation, and other relaxing activities. However, literature is scarce about use of binaural tone music in general anesthesia.

Anxiolysis is an important part of enhanced recovery after surgery (ERAS) protocol. Anti-anxiety effect of music can further help in following components of ERAS protocol in a better way. So, the use of non-pharmacological, easy, inexpensive method such as music for the enhanced recovery, can prove to be an important part of our anesthesia practice. Literature is scarce, for role of music especially binaural tone music, under general anesthesia. We aimed to evaluate effect of binaural tone music on perioperative profile of patients posted for abdominal laparoscopic surgeries. We hypothesise that perioperative binaural tone music provides better post-operative recovery with improved perioperative profile.



REVIEW OF LITERATURE



REVIEW OF LITERATURE

1. **Hole J et al**[7] published in 2015 a systematic review and meta-analysis on music as an aid for postoperative recovery in adults. They included randomized controlled trials (RCTs) of adult patients undergoing surgical procedures, excluding those involving the central nervous system or head and neck. They identified 4261 titles and abstracts, and included 73 RCTs in the systematic review, with size varying between 20 and 458 participants. Choice of music, timing, and duration varied. Comparators included routine care, headphones with no music, white noise, and undisturbed bed rest. 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]). They concluded that music could be offered to help patients in reducing pain and anxiety during the postoperative period.

2. **Leodoro J et al**[8] published a study in 2014 to know influence of music on preoperative anxiety and physiologic parameters in women undergoing gynecologic surgery. They recruited 97 women undergoing gynecological surgeries and divided into 2 groups with music therapy and placebo. They compared Preoperative anxiety using the State Trait Anxiety Inventory (STAI) and also patients' physiologic parameters (blood pressure [BP], pulse [P], and respiration [R]) at two time periods. Women allocated in the experimental group showed 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. They found significant reduction in preoperative anxiety in musical therapy group. They concluded, the use of music during the preoperative period helps in reducing anxiety and unpleasant symptoms in women undergoing gynecologic surgery.

3. **Kahloul M et al**[9] published a study in 2016 on effect of music therapy under general anaesthesia for patients undergoing abdominal surgery. One hundred and forty patients were included and allocated into 2 groups with and without music therapy. They used patient selected music and on those who doesn't have any preference were provided with instrumental music. Hemodynamic parameters, quality of arousal, pain experienced, patient's satisfaction, and awareness incidence during anesthesia were recorded. Results showed more stable hemodynamic profile in music group (group M) for systolic arterial

blood pressure, calm recovery in group M (77.1% versus 44%, p < 10-3) and lower average Visual Analog Scale (VAS) score in the intervention group (33.8 ± 13.63 versus 45.1 ± 16.2; p < 10-3). The satisfaction rate was significantly higher among the experimental group (81.4% versus 51.4%; p < 10-3). The incidence of intraoperative awareness was higher in control group (8 cases versus 3 cases) but the difference was not statistically significant.

4. **Patil Kalyani N et al[10]** published a study in 2015 on impact of intraoperative music therapy on the anaesthetic requirement and stress response in laparoscopic surgeries under general anaesthesia. 60 ASA 1 patients in music and no music groups were included in this study. In the music group, classical instrumental music was played after the induction of anesthesia until the skin closure. In the no-music group, patients wore headphones but no music was played. Anaesthetic requirement in the form of Bi Spectral index, end tidal isoflurane concentration and haemodynamic changes, was compared. There was no statistically significant difference in the intraoperative hemodynamics between the two groups. The Bispectral (BIS) value, end-tidal isoflurane concentration, and fentanyl requirement were comparable in the two groups. Thus, they could not demonstrate the beneficial effects of intraoperative music as a nonpharmacological intervention under general anesthesia on stress response and anesthetic requirement.

5. **U. Nilsson et al[11]** did a double-blind randomised controlled trial in 2001 on improved recovery after music and therapeutic suggestions during general anaesthesia. Ninety women, ASA I–II, scheduled for an elective abdominal hysterectomy via a lower abdominal incision under general anaesthesia were studied in music (M), and music combined with therapeutic suggestions (M/TS), and the control group. They concluded, patients exposed to music in combination with therapeutic suggestions required less rescue analgesic compared with the controls and patients in the music group experienced more effective analgesia the first day after surgery and was mobilised earlier after the operation. No differences were noted in nausea, emesis, bowel function, well-being or length of hospital stay between the groups.

6. **Arslan S et al[12]** published a study in 2017 on the effect of music on preoperative anxiety in men undergoing urogenital surgery. They had taken 64 patients of aged between 18 and 65 and measured pre and post-test anxiety using the State Trait Anxiety Inventory (STAI).

Their result showed anxiety score averages between the groups following the music therapy were statistically significant ($p<0.001$); 33.68 (SD=8.03) for the experimental group and 44.43(SD=10.42) for the control group. They concluded that listening to self-selected music during the preoperative period could effectively reduce anxiety levels.

7. **Bringman H et al[13]** published an RCT in 2009 on use of music as pre-medication before surgery. They recruited 372 subjects and made 2 group as midazolam group and music group. They showed that 177 patients who completed the music protocol, the mean (standard deviation) STAI-stat 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. They concluded that relaxing music decreases the level of anxiety in a pre-operative setting largely than orally administrated midazolam.

8. **Forooghy et al[14]** published a study in 2015, RCT on effect of music therapy on patients' anxiety and hemodynamic parameters during percutaneous transluminal coronary angioplasty. They had taken 64 patients and 20 to 40-minute music therapy (light instrumental music albums by Johann Sebastian Bach and Mariko Makino) as intervention. They found that differences between the two groups, regarding hemodynamic parameters, were not significant after the intervention ($P > 0.05$) but post-intervention anxiety in the experimental group was significantly lower than the control group (32.06 ± 8.57 and 38.97 ± 12.77, respectively; $P = 0.014$). They concluded that music therapy can significantly alleviate patients' anxiety during coronary angioplasty.

9. **Bechtold ML et al[15]** published a meta-analysis in 2009 on effect of music on patients undergoing colonoscopy: a meta-analysis of randomized controlled trials. Randomized controlled trials (RCTs) that compared music versus no music for adults (aged 18 years or over) who underwent colonoscopy were included. They compared total procedure time, dose of sedative medications, patients' pain scores, patients' experience, and willingness to repeat the procedure in the future. The type of music used in the interventions varied between studies and included classical, radio station, easy-listening or patient-directed selections. Music was played preoperatively or during procedure only. Sedation used during procedures included midazolam and meperidine. Validity was assessed using Jadad criteria (maximum score 5 points). Eight RCTs (n=712) were included in the review. Two

RCTs scored a maximum of 5 points for study validity, three RCTs scored 3 points and three RCTs scored 2 points. Sample sizes ranged from 29 to 166. Scores for patients' overall experience were significantly improved with music (SMD -0.65, 95% CI -1.01 to -0.28, p=0.0006; four RCTs). No statistically significant differences between music and no music groups were found for patients' pain scores, doses of midazolam or meperidine, or willingness to have a repeat procedure in the future. Music was associated with a trend toward shorter procedure times, but this was not statistically significant. They concluded music played during colonoscopy improved patients' overall experience, but did not alter requirement for sedative pain medication, procedure times, patients' pain or patients' willingness to repeat the procedure in the future.

10. **Jayaraman L et al[16]** in 2006 studied effect of intraoperative music therapy or positive therapeutic suggestions during general anaesthesia on the postoperative outcome. One hundred and eleven patients undergoing laparoscopic cholecystectomy included and were randomly allocated to three groups; two intervention groups, Music (M), Music combined with therapeutic suggestions (MTS) and the control group exposed to operation room sounds(C). Patients in the M group listened to music from a CD player judged to be relaxing and calming. Patients on the MTS group listened to the same music as in the M group accompanied by relaxing and encouraging suggestions recorded in a female voice by a person with experience in hypnotherapy. In various parameters such as pain, fatigue, psychological wellbeing and postoperative nausea, vomiting at 1 hour after surgery, the intervention groups (M and MTS) group scored much better than the control group. There was no significant difference between the music group and MTS group as p value >0.05. They concluded that there was no definite advantage of therapeutic suggestions as compared to the music alone.

11. **Kühlmann R et al[17]** in 2015 conducted a RCT to understand the effect of music interventions in pediatric surgery (The Music Under Surgery in Children Study). Study was conducted in children of 0–3 years of age admitted for orchidopexy, hypospadias, or inguinal hernia repair. They were assigned to a preoperative music group, pre- and intraoperative music group, or no music group (control). The outcomes measured were the postoperative level of distress (assessed with the COMFORT-Behavior scale), preoperative level of distress, preoperative anxiety, and physiological measurements such as heart rate and blood pressure. One hundred ninety-five infants with median age 6.9

months (interquartile range, 3.3–11.1) were randomized. A nonsignificant difference in COMFORT-Behavior scale scores between the pre- and intraoperative music intervention group and control group at 4 hours after surgery was found (mean difference, −1.22; 95% CI, 2.60–0.17; *P* = .085). The differences in HR among the 3 study arms at all time points were not statistically significant (*P* = .069). They concluded music interventions do not seem to benefit all young children undergoing surgery.

12. **Ortega A et al[18]** in 2018 conducted a RCT to assess the effect of music therapy for pain and anxiety in patients posted for nasal bone fracture reduction. 36 patients posted for closed reduction of the nasal fracture under local anaesthesia were recruited and randomized into 2 groups: 17 received the music intervention, and 19 patients received no intervention and acted as controls. The music group heard music through headphones during the pre-, intra-, and postprocedural periods of the intervention. Physiological variables (blood pressure and heart rate) were measured. An anxiety survey (State-Trait Anxiety Inventory) and the visual analog scale for measuring pain were also applied. They concluded that the music group exhibited significantly lower levels of systolic blood pressure (P = .0001), anxiety (P =00.0001), and pain (P = .0004) than the control group.

13. **Kühlmann A Y R et al[19]** in 2017 conducted a systemic review and meta-analysis evaluating music interventions for anxiety and pain in surgery. Eleven electronic databases were searched for full-text publications of RCTs investigating the effect of music interventions on anxiety and pain during invasive surgery published between 1 January 1980 and 20 October 2016. Ninety-two RCTs (7385 patients) were included in the systematic review, of which 81 were included in the meta-analysis. Music interventions significantly decreased anxiety (MD –0·69, 95 per cent CI –0·88 to –0·50; *P*<0·001) and pain (MD –0·50, –0·66 to –0·34; *P*<0·001) compared with controls, equivalent to a decrease of 21mm for anxiety and 10mm for pain on a 100-mm visual analogue scale. Changes in outcome corrected for baseline were even larger: MD –1·41 (–1·89 to –0·94; *P*<0·001) for anxiety and –0·54 (–0·93 to –0·15; *P*=0·006) for pain. They proved interventions during general anaesthesia significantly decreased pain compared with that in controls (MD –0·41, –0·64 to –0·18; *P*<0·001). Meta-regression analysis found no significant association between the effect of music interventions and age, sex, choice and

timing of music, and type of anaesthesia. They concluded music interventions significantly reduce anxiety and pain in adult surgical patients.

14. **Palmer J B et al[20]** in 2015 conducted a RCT on effects of music therapy on anaesthesia requirements and anxiety in women undergoing ambulatory breast surgery for cancer diagnosis and treatment. 207 female patients undergoing surgery for breast cancer were randomly assigned to receive either patient-selected live music (LM) preoperatively with therapist-selected recorded music intraoperatively (n=69), patient-selected recorded music (RM) preoperatively with therapist-selected recorded music intraoperatively (n=70), or usual care (UC) preoperatively with noise-blocking earmuffs intraoperatively (n=68). Their results showed LM and the RM groups did not differ significantly from the UC group in the amount of propofol required to reach moderate sedation. Compared with the UC group, both the LM and the RM groups had greater reductions (P<.001) in anxiety scores preoperatively (mean changes [and standard deviation: -30.9 [36.3], -26.8 [29.3], and 0.0 [22.7]), respectively. The LM and RM groups did not differ from the UC group with respect to recovery time; however, the LM group had a shorter recovery time compared with the RM group (a difference of 12.4 minutes; 95% CI, 2.2 to 22.5; P=.018). Satisfaction scores for the LM and RM groups did not differ from those of the UC group**.** They concluded including music therapy as a complementary modality with cancer surgery may help manage preoperative anxiety in a way that is safe, effective, time-efficient, and enjoyable.

15. **Gökcek E et al[21]** published a randomized, controlled, prospective study with 120 patients in 2 groups (60 each in both groups), undergoing septorhinoplasty within a 2 months period. They evaluated the effect of music therapy on intraoperative awareness, recovery, patient satisfaction, awakening pain and waking quality. 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; $p < 0.001$) which means that the patients with music therapy had better awakening quality. 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. Patient satisfaction rate was significantly higher in the music group (73.3% vs. 36.6%) than the control group ($p < 0.001$). The incidence of intraoperative awareness was higher in the control group (4 cases vs. 9 cases), but the difference was not statistically significant ($p = 0.14$).

16. **Liu Y et al**[22] in 2015 conducted a study on effects of music therapy on pain, anxiety, and vital signs in patients after thoracic surgery. It was a randomized controlled clinical trial conducted in the thoracic surgery department of two tertiary hospitals in Wuhan, China. 112 patients were recruited and randomly assigned to either experimental (n=56) or control (n=56) group. The experimental group received standard care and a 30-min soft music intervention for 3 days, while the control group received only standard care. Pain, anxiety, vital signs (blood pressure, heart rate and respiratory rate), patient-controlled analgesia, and diclofenac sodium suppository use was noted. The experimental group showed statistically significant decrease in pain, anxiety, systolic blood pressure and heart rate over time compared to the control group, but no significant difference were identified in diastolic blood pressure, respiratory rate, patient-controlled analgesia and diclofenac sodium suppository use. Thus, they concluded music therapy helps to reduce postoperative pain and anxiety, and lower systolic blood pressure and heart rate in patients after thoracic surgery.

17. **Chlan L**[23] studied effectiveness of a music therapy intervention on relaxation and anxiety for patients receiving ventilatory assistance. Study had two-group, pretest-posttest experimental design with repeated measures. Subjects were randomized to either a 30-minute music condition or a rest period. They included fifty-four alert, non-sedated patients receiving mechanical ventilation in four urban midwestern intensive care units. State anxiety (pretest and posttest), heart rate, and respiratory rate was recorded every 5 minutes for 30 minutes. Results showed subjects who received music therapy reported significantly less anxiety posttest (10.1) than those subjects in the control group (16.2). Heart rate and respiratory rate decreased over time for those subjects in the music group as compared with the control group subjects. They concluded single music therapy session was found to be effective for decreasing anxiety and promoting relaxation, as indicated by decreases in heart rate and respiratory rate over the intervention period with this sample of patients receiving ventilatory assistance.

18. **Migneault B et al**[24] studied the effect of music on the neurohormonal stress response to surgery under general anesthesia as measured by epinephrine, norepinephrine, cortisol, and adrenocorticotropic hormone (ACTH) blood levels. Thirty female patients scheduled for abdominal gynecological procedures were enrolled and randomly divided into two groups: group NM (no music) and group M (music after the induction of anesthesia until

the end of surgery). They established three sample times for hormonal dosage during the procedure and one in the recovery room. Hemodynamic data were recorded at all times, and postoperative consumption of morphine in the first 24 h was noted. There was no group difference at any sample time or in the postoperative period in terms of mean arterial blood pressure, heart rate, isoflurane end-tidal concentration, time of the day at which the surgery was performed, Bispectral index (BIS) value, doses of fentanyl, or consumption of postoperative morphine. There was no difference between the two groups on plasmatic levels of norepinephrine, epinephrine, cortisol, or ACTH at any sample time (although the blood level of these hormones significantly increased in each group with surgical stimulation). In conclusion, they could not demonstrate a significant effect of intraoperative music on surgical stress when used under general anesthesia.

19. **Mimi et al**[25] studied the effect of music therapy on postoperative pain, heart rate, systolic blood pressure and analgesic use after nasal surgery. Fifty-seven patients (24 females, 33 males; mean ± SD age 39.9 ± 14.35 years [range 15 to 69 years] were matched for age and sex and then non selectively assigned to either an experimental (n = 27) or a control (n = 30) group. Music was played intermittently to members of the experimental group during the first 24-hour postoperative period. Pain intensity was measured using the pain verbal rating scales (VRS). They found significant decreases in pain intensity over time in the experimental group compared to the control group ($p < 0.0001$). In addition, the experimental group had lower systolic blood pressure and heart rate, and took fewer oral analgesics for pain. They concluded that music therapy is an effective nonpharmacologic approach for postoperative pain management.

20. **Kiviniemi K**[26] wrote an article on conscious awareness and memory during general anaesthesia. Implicit and explicit memory and factors associated with awareness were discussed. Overhearing negative stimuli may affect patient outcome, because learning and language comprehension can occur during what appears to be clinically adequate anesthesia. Strategies to block threatening auditory stimuli include use of earphones, music tapes, white noise, reassuring statements, or positive suggestion. Behavioral anesthesia decreases patient stress to enhance recovery. They suggested that the evidence of patient benefit resulting from therapeutic suggestion is inconclusive.

21. **Binns-Turner PG et al**[27] in 2010 studied on perioperative music and its effects on anxiety, hemodynamics, and pain in women undergoing mastectomy. They used a quasi-experimental design to evaluate the effects of a perioperative music intervention (provided continuously throughout the preoperative, intraoperative, and postoperative periods) on changes in mean arterial pressure (MAP), heart rate, anxiety, and pain in women with a diagnosis of breast cancer undergoing mastectomy. A total of 30 women were assigned randomly to a control group or to the music intervention group. Findings indicated that women in the intervention group had a greater decrease in MAP and anxiety with less pain from the preoperative period to the time of discharge from the recovery room compared with women in the control group. They concluded perioperative music can reduce MAP, anxiety, and pain among women undergoing mastectomy for breast cancer.

22. **Li XM et al**[28] in 2010 conducted a RCT on effects of music therapy on pain among female breast cancer patients after radical mastectomy. A total of 120 breast cancer patients who received personal controlled analgesia (PCA) following surgery (mastectomy) were randomly allocated to two groups, an intervention group, and a control group (60 patients in each group). The intervention group accepted music therapy from the first day after radical mastectomy to the third admission to hospital for chemotherapy in addition to the routine nursing care and control group received only routine nursing care. Pain scores were measured at baseline and three post-tests using the general questionnaire and Chinese version of short-form of McGill pain questionnaire. Music therapy was found to reduce the pain rating index (PRI-total) score in the intervention group significantly compared with the control group with a mean difference (95% CI) of -2.38 (-2.80, -1.95), -2.41 (-2.85, -1.96), and -1.87 (-2.33, -1.42) for the 1st, 2nd, and 3rd post-tests, respectively. Similar results were found for visual analogue scale (VAS) and present pain intensity (PPI) scores. They concluded that music therapy has both short- and long-term positive effects on alleviating pain in breast cancer patients following radical mastectomy.

23. **Xiao Y et al**[29] in 2018 studied the effects of aroma therapy and music intervention on pain and anxiety for breast cancer patients in the perioperative period. 100 breast cancer patients who received surgical treatment were recruited and assigned randomly into a control group, an aroma therapy group, a music intervention group, and a joint-therapy group (n=25 per group). Patients in the control group received regular post-surgical nursery and patients from other groups received aroma therapy, music intervention, or

both in addition to the regular nursery. The scale of anxiety and pain were measured. The measurements were at three time points, namely 30 min before the surgery (T1), 30 min after the recovery period of anesthesia (T2), and 4 hours after the removal of anesthesia tubing (T3). The scale of pain was significantly increased at the post-operation (T2, T3) compared to pre-surgery (T1). The therapeutic group showed significant decrease in pain at post-operation (T3) comparing with the control group ($P<0.05$). The scale of anxiety was the highest at pre-surgery (T1). During anaesthesia recovery, the anxiety of patients at post-operation T2 and T3 in the therapeutic groups significantly decreased compared with the control group ($P<0.05$). They concluded that both the aroma therapy and the music therapy can decrease the stress-responsive anxiety and pain for the breast cancer patients in the perioperative period.

24. **Casarin J et al**[30] in 2021 conducted a RCT on effect of music therapy for preoperative anxiety reduction in women undergoing total laparoscopic hysterectomy. One hundred patients undergoing total laparoscopic hysterectomy (TLH) with nononcologic indications were taken for study with 30 and 70 in the music and control arms, respectively. Anxiety was evaluated with the state-trait anxiety inventory y form (STAI-Y) at baseline and during preoperative, early postoperative, and late postoperative periods. Pathologic anxiety was defined as STAI-Y state >45. Postoperative pain was registered using the visual analog scale. Their study showed women in the music arm experienced lower anxiety levels (median STAI-Y scores 38.0 vs 41.0; p = .002) during the preoperative period. STAI-Y scores did not vary significantly by intervention at each subsequent time point. A significant difference between the groups (music vs control) was found in the proportion of women with pathologic anxiety during the preoperative (16.7% vs 37.2%; p = .04) and early postoperative periods (0% vs 12.9%; p = .04), whereas no significant difference between the groups was registered during the late postoperative period (6.6% vs 7.1%; p = .93). Postoperative pain intensity did not significantly differ between the groups at 1, 3, and 6 hours after surgery. They concluded music therapy might be a viable complementary modality to usual surgical care in the gynecologic setting for its ability to significantly decrease preoperative anxiety in women undergoing TLH for benign conditions.

25. **Wiwatwongwana et al**[49] in 2016 studied on the effect of music with and without binaural beat audio on operative anxiety in patients undergoing cataract surgery: a randomized

controlled trial. This prospective RCT included 141 patients undergoing cataract surgery under local anesthesia. The patients were randomized into three groups; the binaural beat music group (BB), the plain music intervention group (MI), and a control group (ear phones with no music). Blood pressure (BP) and heart rate were measured on admission, at the beginning of and 20 min after the start of the operation. Peri-operative anxiety level was assessed using the State-Trait Anxiety Inventory questionnaire (STAI). The BB and MI groups comprised 44 patients each and the control group 47. Patients in the MI group and BB group 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).

26. **Peter Szmuk et al**[51] in 2008 tested the hypothesis that intraoperative exposure to soothing music reduces the end-tidal concentration of sevoflurane (ETSevo) necessary to maintain Bispectral index (BIS) near 50 during laparoscopic surgery. Forty patients, aged 40 – 60 yrs, ASA I and II, undergoing laparoscopic hernias or cholecystectomy under general anesthesia were studied. Results showed the ETSevo necessary to maintain a BIS near 50 was virtually identical in patients who listened to music (1.29, 0.33%) and those who did not (1.27, 0.33%, P 0.84). Patients who listened to music reported slightly less pain, but the difference was not statistically significant. Mean arterial blood pressure was slightly higher in patients who listened to music (101 11 mm Hg) than in those who did not (94 10 mm Hg, P 0.040). Thus, they concluded the end-tidal concentration of sevoflurane required to maintain BIS near 50 during laparoscopic cholecystectomy was virtually identical in patients exposed to music or not.

27. **Ling Jiunn Loong et al**[52] in 2022 did a randomized control trial on the effect of Binaural Beat Audio on Operative Pain and Anxiety in Cataract Surgery under Topical Anaesthesia. They studied on 61 patients undergoing cataract surgery under topical anaesthesia and were divided into two research conditions; the binaural beat audio group, and a sham-control grou*p* (ear phones with no music). Patients completed the state-trait anxiety inventory questionnaire (STAI), and their blood pressure (BP) and heart rate (HR) was

measured pre- and post-intervention. Intraoperative pain levels were ascertained using a visual analog scale (VAS). They concluded that the binaural beat group had significantly lower pain scores ($p < 0.001$), HR ($p < 0.001$), diastolic BP ($p = 0.003$), mean arterial pressure ($p = 0.007$) and anxiety ($p = 0.009$) than the control group. Within the binaural beat group, subjects experienced a statistically significant reduction in HR ($p = 0.004$) and anxiety ($p < 0.001$) levels compared to baseline values, while all parameters, except anxiety, increased significantly in the control group. They concluded binaural beat audio may also have additional benefits in modulating the tachycardic response to stress.

28. **Mahmut Taha Ölçücü et al[53]** in 2021 conducted a RCT on the effects of listening to binaural beats on anxiety levels and pain scores in male patients undergoing cystoscopy and ureteral stent removal. Their objective was to investigate 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. Patients in the DC group (DCG) and USR group (USRG) were divided into three subgroups according to interventions applied; DCG-1 and USRG-1, patients listened to binaural beats; DCG-2 and USRG-2, patients listened to classical music; and DCG-3 and USRG-3, patients wore headphones, but were not exposed to audio (control group). The State-Trait Anxiety Inventory (STAI) and Visual Analog Scale (VAS) were used for measuring anxiety and pain scores, respectively. Demographic data, initial STAI, tolerance rate of interventions, terminal STAI (STAI-T), differences of STAI (delta STAI, STAI-D), and VAS scores were compared. Between July 2019 and March 2020, a total of 252 and 159 eligible male patients for DCG and USRG were included, respectively. The tolerance rate in binaural beat groups was significantly lower than in other groups ($p < 0.05$ for all). There were significant decreases in terms of STAI-T when DCG-1 and DCG-2 were compared with DCG-3 and USRG-1 and USRG-2 were compared with USRG-3 ($p < 0.05$ for all). There were significant decreases in STAI-D scores when DCG-1 and DCG-2 were compared with DCG-3 and when USRG-1 and USRG-2 were compared with USRG-3 ($p < 0.001$ for all). Binaural beat 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).

29. **Alessandro Tani et al[54]** in 2021 conducted a prospective randomized control trial on effect of binaural beats to reduce postoperative morphine consumption in older adults after

total knee replacement surgery. Study included 40 patients undergoing TKR under spinal anaesthesia and divided into 2 groups (n = 20 each), one receiving BBs stimulation with frequencies of 256 Hz in one ear and 260 Hz in the opposite ear producing a BB of 4 Hz (intervention group), and the other receiving acoustical stimulation at 256 Hz in both ears (control group). BBs, or acoustical stimulation, were administered before the surgical procedure. Both acoustical stimuli, generated with the gnaural program, were delivered through stereo headphones connected to a laptop in the preoperative holding area. Patients who received the intervention, consumed almost half of the dosage of morphine during the first postoperative day when compared with the control group's consumption. They concluded that BB stimulation before surgery can be successfully used as a nonpharmacological treatment to reduce morphine consumption in older adults who undergo knee replacement. The use of a noninvasive, safe, and inexpensive BB intervention can result in a positive effect on patients' postoperative recovery.

30. **Caroline Lepage et al**[55] in 2001 did a prospective study on whether music can influence anxiety and perioperative sedative requirements in outpatients undergoing surgery with spinal anesthesia. They evaluated the correlation between two anxiety measures, the State-Trait Anxiety Inventory test (STAI) and the visual analog scale (VAS 0–10), with 0 meaning complete relaxation and 10 the worst feeling of anxiety possible. Fifty un-premedicated patients were randomly assigned to listen to music of their choice via headset during the perioperative period (Group I) or to have no music (Group II). All participants used patient-controlled IV midazolam sedation and underwent repeated evaluations of their anxiety level with the STAI and the VAS 0–10. Midazolam requirements during surgery (Group I, 0.6+- 0.7 versus Group II, 1.3 +- 1.1 mg; P 0.05) and for the whole perioperative period (Group I, 1.2+_ 1.3 versus Group II, 2.5 +_ 2.0 mg; P 0.05) were smaller in patients listening to music. Anxiety levels, measured with STAI or VAS 0–10, were similar in both groups. They concluded that patients listening to music require less midazolam to achieve a similar degree of relaxation as controls and that measures of anxiety obtained from the STAI and the VAS 0–10 are positively, but only moderately, correlated.

31. **Ayse Mizrak et al**[56] in 2022 studied the effects of high level of noise on the consumption of anesthetic agents during total intravenous anesthesia (TIVA) and the satisfaction of patient and surgeon. 90 patients who would undergo cholecystectomy surgery were

randomized in 3 groups in this study planned as a double blind, prospective, randomized clinical trial. Propofol and remifentanil infusion was started to obtain BIS values between 40- 60 for all patients. The patients in Group N (n=30) were subjected to noise of normal operating room, Group S (n=30) were subjected to noise between 80-85 Db with headphone and for patients in Group Q subjection to noise of the operating room was prevented by covering the ears with headphones (n=30). Intraoperative total remifentanil and propofol consumption of the patients, postoperative patient and physician satisfaction, postoperative side effects was recorded. Total remifentanil and propofol used during surgery were significantly lower in Group Q than in Group N and Group S (p=0,0001, p=0,04). Postoperative patient satisfaction in Group Q was statistically higher than in Group N and Group S (p=0.001). Surgeon satisfaction in Group Q was also higher than in Group N and Group S (p=0.01). They concluded that High noise level for patients who undergo cholecystectomy surgery under TIVA increases total remifentanil and propofol consumption during operation and it decreases patient and surgeon satisfaction.

32. **Victor X. Fu MD et al**[57] in 2021 did a systematic review and metanalysis on perception of auditory stimuli during general anaesthesia and its effects on patient outcomes. They performed systematic literature search of Embase, Ovid Medline, and Cochrane Central from inception date until 15 October 2020. Fifty-three (4,200 patients) of 5,859 identified articles were included. There was evidence of implicit memory formation in seven out of 17 studies (41%) when assessed using perceptual priming tasks. Mixed results were observed on postoperative behavioral and motor response after intraoperative suggestions. Intraoperative music significantly reduced postoperative pain (standardized mean difference [SMD], -0.84; 95% confidence interval [CI], -1.1 to -0.57; $P < 0.001$; $I2 = 0$; $n = 226$) and opioid requirements (SMD, -0.29; 95% CI, -0.57 to -0.015; $P = 0.039$; $I2 = 36$; $n = 336$), while positive therapeutic suggestions did not. They concluded that intraoperative auditory stimuli can be perceived and processed during clinically adequate, general anesthesia irrespective of surgical procedure severity, leading to implicit memory formation without explicit awareness. Intraoperative music can exert significant beneficial effects on postoperative pain and opioid requirements. Whether the employed intraoperative anesthesia regimen is of influence is not yet clear.

33. **Nidhi Yadav et al**[58] in 2020 studied on the effect of music on preoperative anxiety in patients undergoing laparoscopic cholecystectomy. in this randomized controlled study,

104 patients posted for laparoscopic cholecystectomy were studied. Patients in both groups received oral alprazolam 0.25 mg on the night before surgery. In addition, patients in Group II were also exposed to 30 min of soft, soothing music, 1 h before the surgery. Vitals of patients, including heart rate (HR), blood pressure, and respiratory rate, in both the groups along with the general anxiety – visual analog scale (GA-VAS), were recorded and compared. On comparing T30 vitals between the two groups, a statistically significant difference was seen in all the monitored parameters, with vitals in Group II being lower than in Group I. T60 vitals in Group II were found to be lower than Group I in all the monitored parameters, except for HR (P = 0.051). The GA-VAS scores in Group II were lower compared to Group I (P = 0.008). They concluded exposure to music (as an addition to alprazolam 0.25 mg) in the preoperative period for patients who underwent laparoscopic cholecystectomy reduces the patient's anxiety compared to alprazolam alone.

34. **Bahman Aghaie et al[59]** studied the effect of nature-based sound therapy on agitation and anxiety in coronary artery bypass graft patients during the weaning of mechanical ventilation: A randomised clinical trial. 120 coronary artery bypass graft patients aged 45–65 years undergoing weaning from mechanical ventilation were randomly assigned to intervention and control groups. Patients in the intervention group listened to nature-based sounds through headphones; the control group had headphones with no sound. Hemodynamic variables, anxiety levels and agitation were assessed using the faces anxiety scale and Richmond agitation sedation scale, respectively. Patients in both groups had vital signs recorded after the first trigger, at 20 min intervals throughout the procedure, immediately after the procedure, 20 min after extubation, and 30 min after extubation. Data were collected over 5 months from December 2012 to April 2013. The intervention group had significantly lower anxiety and agitation levels than the control group. They concluded nature-based sound can provide an effective method of decreasing potential adverse hemodynamic responses arising from anxiety and agitation in weaning from mechanical ventilation in coronary artery bypass graft patients.

35. **Vahid Saadatmand et al[60]** in 2012 conducted a RCT on the effect of nature-based sounds' intervention on agitation, anxiety, and stress in patients under mechanical ventilator support. A total of 60 patients aged 18–65 years under mechanical ventilation support in an intensive care unit were randomly assigned to the control and experimental groups. The effect of nature-based sounds (N-BS) on agitation, anxiety level and physiological signs

of stress in patients under mechanical ventilator support was studied. The patients in the intervention group received 90 min of N-BS. Pleasant nature sounds were played to the patients using media players and headphones. Patient's physiological signs were taken immediately before the intervention and at the 30th, 60th, 90th minutes and 30 min after the procedure had finished. Data were collected over eight months from Oct 2011 to June 2012. Anxiety levels and agitation were assessed using the Faces Anxiety Scale and Richmond Agitation Sedation Scale, respectively. The experimental group had significantly lower systolic blood pressure, diastolic blood pressure, anxiety, and agitation levels than the control group. These reductions increased progressively in the 30th, 60th, 90th minutes, and 30 min after the procedure had finished indicating a cumulative dose effect.

36. **Fatma Dursun Ergezen et al[61]** published a systematic review on the effectiveness of music intervention on postoperative nausea and vomiting. There were 576 patients in the seven studies who met the inclusion criteria. Music was implemented in postoperative, intraoperative, and perioperative periods. Meta-analyses revealed that music interventions significantly reduced postoperative vomiting (95% CI: 0.01 to 0.63, Z = 2.07, $P < 0.05$, Hedge's g = 0.32), and had no statistical significant effect on postoperative nausea (95% CI: −0.13 to 0.70, Z = 1.34, $P > 0.05$, Hedge's g = 0.28).

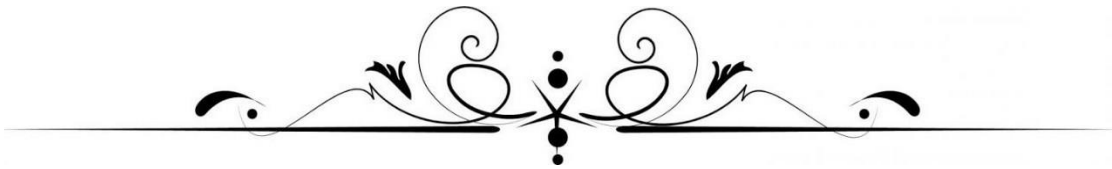
37. **G. Mahran et al[62]** studied on the effect of music on preventing intraoperative awareness in paediatric patients undergoing open-heart surgery. It was a prospective, randomized double blind study, patients were randomized into two equal groups; In C group (n = 25) patients acted as the control and did not listening to music, while in music group (n = 25) patients listening to music. In both groups, auditory evoked potentials index electrodes connected before induction of anesthesia at operative room to detect depth of anesthesia and occurrence of intraoperative awareness. An interview with the patients and their parents to evaluate occurrence of awareness by using a semi-structured in-depth questionnaire. The results showed there was statistically significant decrease in occurrence of awareness in music group versus the control group (P value =0.000***). Thus, they concluded that the application of music was highly effective in reducing intraoperative awareness.

38. **S Jaber et al**[63] studied the effects of music therapy in intensive care unit without sedation in weaning patients versus non-ventilated patients in 2006. Thirty patients were studied (intubated group n = 15, non-intubated group n = 15). Patients were randomized to receive either 20 minutes of uninterrupted rest or then 20 minutes of music therapy or the music therapy first and then the uninterrupted rest period. Patients selected a relaxing music of their choice from a selection including different types of music. They concluded music significantly decreased HR (88+/-15 vs 82+/-15, P<0.05), SAP (137+/-17 vs 128+/-14, P<0.05), RR (25+/-3 vs 22+/-4, P<0.05), BIS (94+/-5 vs 81+/-10, P<0.01), RASS (+0.1+/-0.7 vs -0.7+/-0.9, P<0.05) and NRS (4.4+/-1.7 vs 1.9+/-1.3, P<0.01) in both intubated and non-intubated groups whereas no significant change was observed during the rest period.

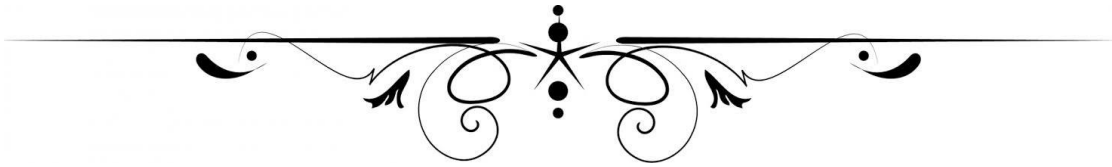
39. **R. Padmanabhan et al**[64] in 2005 did a prospective, randomised, controlled study examining binaural beat audio and pre-operative anxiety in patients undergoing general anaesthesia for day case surgery. They recruited 108 patients scheduled to undergo general anaesthesia for elective surgery at the day surgery unit at Sunderland royal hospital. They measured anxiety with the state-trait anxiety inventory questionnaire and compared binaural beat audio (binaural Group) with an identical soundtrack but without these added tones (audio Group) and with a third group who received no specific intervention (no Intervention Group). Results showed that mean 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. They concluded binaural beat audio has the potential to decrease acute pre-operative anxiety significantly.

40. **Dabu-Bondoc et al**[65] conducted a RCT to evaluate the effect of hemispheric synchronized sounds and intraoperative anesthetic requirements. They randomized subjects undergoing general anesthesia and outpatient surgery into two groups: the treatment group received hemispheric synchronized sounds (n = 31), and the control group received a blank cassette tape (n = 29). Both groups received the intervention in the preoperative area and during the surgical procedure. Subjects underwent a propofol-based anesthetic regimen, and propofol doses required for the induction and maintenance of anesthesia was noted. Bispectral index monitor was used to ensure that the hypnotic component of the anesthetic state was the same in all patients. They found no differences in the amount of propofol

used during the induction of anesthesia (2.49 ± 0.59 mg/kg versus 2.60 ± 0.59 mg/kg; P = 0.48) or the maintenance of anesthesia (0.141 ± 0.02 mg · kg−1 · min−1 versus 0.146 ± 0.04 mg · kg−1 · min−1; P = 0.62) between the Hemisync® and control groups. We also found no differences between the group and the control group for participants with high state anxiety (P = not significant). They concluded that hemispheric synchronized sounds do not reduce the hypnotic component of the anesthetic state of patients undergoing general anesthesia and surgery.



AIMS & OBJECTIVES



AIMS AND OBJECTIVES

- Primary Outcome:

To compare recovery profile postoperatively in both the groups using Richmond Agitation Sedation score (RASS).

- Secondary Outcome:

1. To know and compare total anaesthetic requirement in both the groups.
2. To know time of first rescue analgesic in both the groups
3. To know and compare patient satisfaction score in both the groups.
4. To know about any intraoperative or postoperative complications.
5. To compare postoperative VAS scores for pain in both the groups.

- **HYPOTHESIS**

  - Perioperative music reduces total intraoperative anaesthesia consumption along with good post-operative recovery.

MATERIALS & METHODS

MATERIAL AND METHODS

STUDY SETTING: This Randomized control trial was conducted in Department of Anaesthesiology & Critical Care**,** AIIMS Jodhpur after getting approval from Institutional Ethics Committee (IEC Ref.No: **AIIMS/IEC/2021/3501**) and registration in CTRI (Reg.No: **CTRI/2021/09/036451**). Written informed consent were taken from all patients participating in the study.

STUDY DESIGN: Randomized control trial.

STUDY PARTICIPANTS:

Patients of American Society of Anesthesiologists (ASA) physical status grade I and II, aged between 18 to 60years, scheduled to undergo laparoscopic abdominal surgery (expected duration of less than 3 hours) in general anesthesia were enrolled after exercising the following exclusion criteria:

Exclusion Criteria:

1. Patient refusal
2. History of psychiatric illness and hearing impairment.
3. History of opioid and alcohol addiction
4. If patient is not extubated and is shifted being intubated.
5. Preoperative hypotension (Mean arterial blood pressure < 50 mmHg), preoperative bradycardia (Heart rate < 45 beats/min) and preoperative dysrhythmia.

An attending anesthesiologist examined the patient during the preoperative visit, one day prior to surgery. Informed consent for general anesthesia along with consent for participation was taken preoperatively. Fasting status of patients was confirmed prior to surgery.

Patients were allocated in two groups, intervention group A and control group B by computer generated algorithm. Simple random sequence was generated from the computer. The group allocation numbers were concealed in sealed opaque envelopes. All the patients included in study wear headphones with noise reduction in preoperative area. At this point, a staff member not involved with the patient at any time, opened the sealed envelope containing the randomized treatment like binaural tone music (Group A) or control (Group B). Group A

patients listened to binaural tone music from preoperative period, and patient of Group B didn't listen to any music during the study period. .

All baseline vitals were recorded in preoperative area. A staff member fitted earphones into the patient's ears and play the binaural tone music in intervention group while no music was played in control group. The headphones were kept on the patients in control group for blinding of staff member who was monitoring the patient. The patients in intervention group continued listening to the same binaural tone, from preoperative area to post-operative area. The volume will be adjusted on the smart phone according to patient's comfort.

Ten minutes after applying headphones, in preoperative area, patient was wheeled in the operating room with the headphones and music.

A**naesthesia Technique:** In the operating room, routine monitoring including continuous electrocardiography (ECG), non-invasive blood pressure (NIBP), peripheral oxygen saturation (SpO_2) and Bispectral index (BIS) monitors were attached and baseline vitals were recorded.

Midazolam was given for anxiolysis. Anaesthesia was induced with Inj Fentanyl 2mcg/kg, Inj propofol 2mg/kg and Inj rocuronium 0.6mg/kg. The anaesthesia was maintained with Inj Propofol and oxygen + air 50:50%. The target BIS value is kept between 40 – 60.

Patient in group A continued to receive intervention throughout the surgery till 30 minutes post operatively as per allocated group. After proper painting and draping surgery started. Heart rate (HR), SpO2 and blood pressure were continuously monitored throughout the surgery. Baseline vitals were recorded for any other significant deviation. Significant hypotension or bradycardia were defined as 20% reduction from the baseline value, and were 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. Inj Paracetamol 1gm was given as an analgesic to all patients. Surgical wound infiltration was done with 0.25% of bupivacaine.

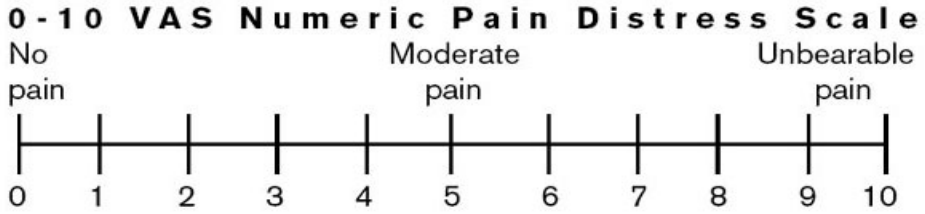
Total intraoperative propofol used, was noted for both the groups. Patients was extubated after adequate neuromuscular recovery at the end of surgery and shifted to recovery unit. The quality of recovery from anaesthesia was assessed using Richmond agitation sedation score immediately after extubation and in PACU at 10mins interval for next 30 minutes. Pain was assessed using visual analog score (VAS) with its 0-10 scale (0=no pain and 10=worst

imaginable pain) immediate postoperative, at 30 minutes for next 2 hours then at 6 hours by an independent observer. Time to first rescue analgesia was also recorded.

Any intraoperative or postoperative complications as hypotension, respiratory depression, post-operative nausea and vomiting (PONV), shivering, headache and dizziness was 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.

Scales to be used in study:

VAS – Visual Analog Scale (pain)



Richmond Agitation Sedation scale:

Richmond Agitation-Sedation Scale

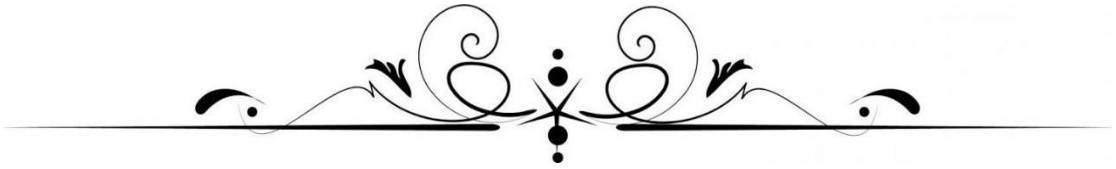
	Target RASS Value	RASS Description
+4	Combative	Combative, violent, immediate danger to staff
+3	Very Agitated	Pulls or removes tube(s) or catheter(s); aggressive
+2	Agitated	Frequent non-purposeful movement, fights ventilator
+1	Restless	Anxious, apprehensive but movements are not aggressive or vigorous
0	Alert and Calm	
-1	Drowsy	Not fully alert, but has sustained awakening to voice (eye opening & contact **greater** than 10 seconds)
-2	Light Sedation	Briefly awakens to voice (eye opening & contact **less** than 10 seconds)
-3	Moderate Sedation	Movements or eye opening to voice (but **NO** eye contact)
-4	Deep Sedation	No response to voice, but has movement or eye opening to physical stimulation
-5	Unarousable	No response to voice or physical stimulation

STATISTICAL ANALYSIS

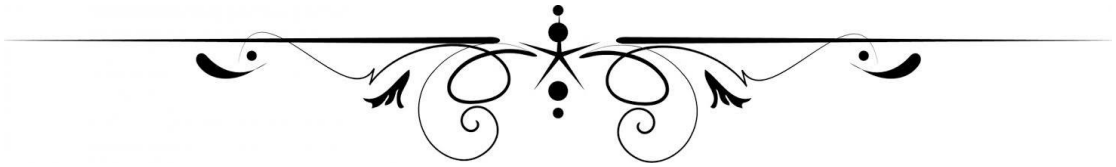
Data collected was tabulated in excel spread sheet and was analyzed using SPSS IBM software version 22 (IBM SPSS Advanced statistics, Chicago, IL, USA). Results of the categorical measurements was presented in numbers or ratio and results of quantitative variables are presented as median (IQR) or mean (SD). Chi square test was applied for comparing qualitative data. Unpaired Student's t test was applied for comparing normally distributed quantitative data. Mann Whitney U test for skewed and ordinal data. The difference was considered significant if $P < 0.05$ will be obtained.

SAMPLE SIZE

Sample size was calculated using Open Epi software. Using data from Kahloul M et al (9) baseline incidence of calm recovery in control arm was 44% and in intervention arm was 77%. Sample size was calculated assuming power of study as 80%, alpha error as 5% with 95% confidence interval. Final sample size came out to be 35 patients in each group. Total 70 patients are needed in this study.



OBSEVATION & RESULTS



OBSERVATION AND RESULTS

This prospective randomized control trial was conducted in the Department of Anaesthesiology and Critical care, AIIMS Jodhpur. Seventy patients belonging to American Society of Anesthesiologists (ASA) physical status grade I and II, aged 18 to 60years, scheduled to undergo laparoscopic abdominal surgery in general anesthesia were included in the study. They were randomly divided into two groups, Group A and Group B using a computer-generated random number table. Group A listened to binaural tone music throughout the perioperative period starting from preoperative area to the postoperative area, while Group B was taken as control without any musical intervention.

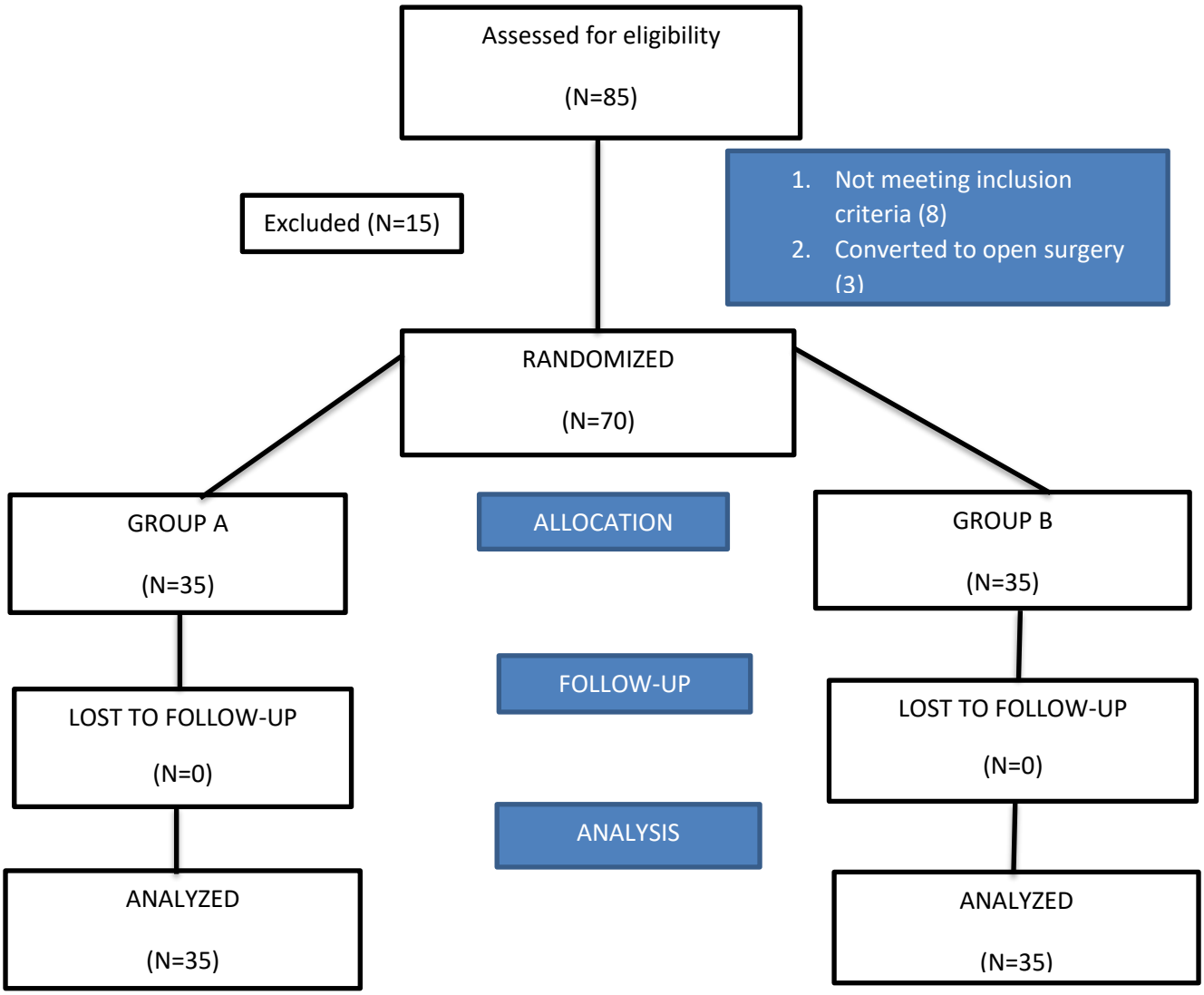


Figure 1: Consort flow diagram

Table 1: Type of surgeries

CASES	GROUP A	GROUP B
LAP CHOLECYSTECTOMY	19	17
TAPP	5	7
TEP	2	3
LAP CYSTECTOMY	2	2
LAP CYST DEROOFING	2	1
TLH	1	3
OTHERS	4	2
TOTAL	**35**	**35**

Majority of cases in both groups were laparoscopic cholecystectomy (19 vs 17). Other cases were transabdominal preperitoneal repair (TAPP), totally extraperitoneal repair (TEP), laparoscopic cystectomy, laparoscopic cyst deroofing, total laparoscopic hysterectomy, laparoscopic salpingo-oophrectomy, laparoscopic appendix, laparoscopic total abdominal hysterectomy + bilateral salpingo-oophrectomy (TAH + BSO) and laparoscopic gastrojejunostomy. Others in group A include 2 TAH + BSO, 1 laparoscopic salpingo-oophrectomy and 1 laparoscopic appendicectomy, while in group B include 1 laparoscopic salpingo-oophrectomy and 1 laparoscopic gastrojejunostomy.

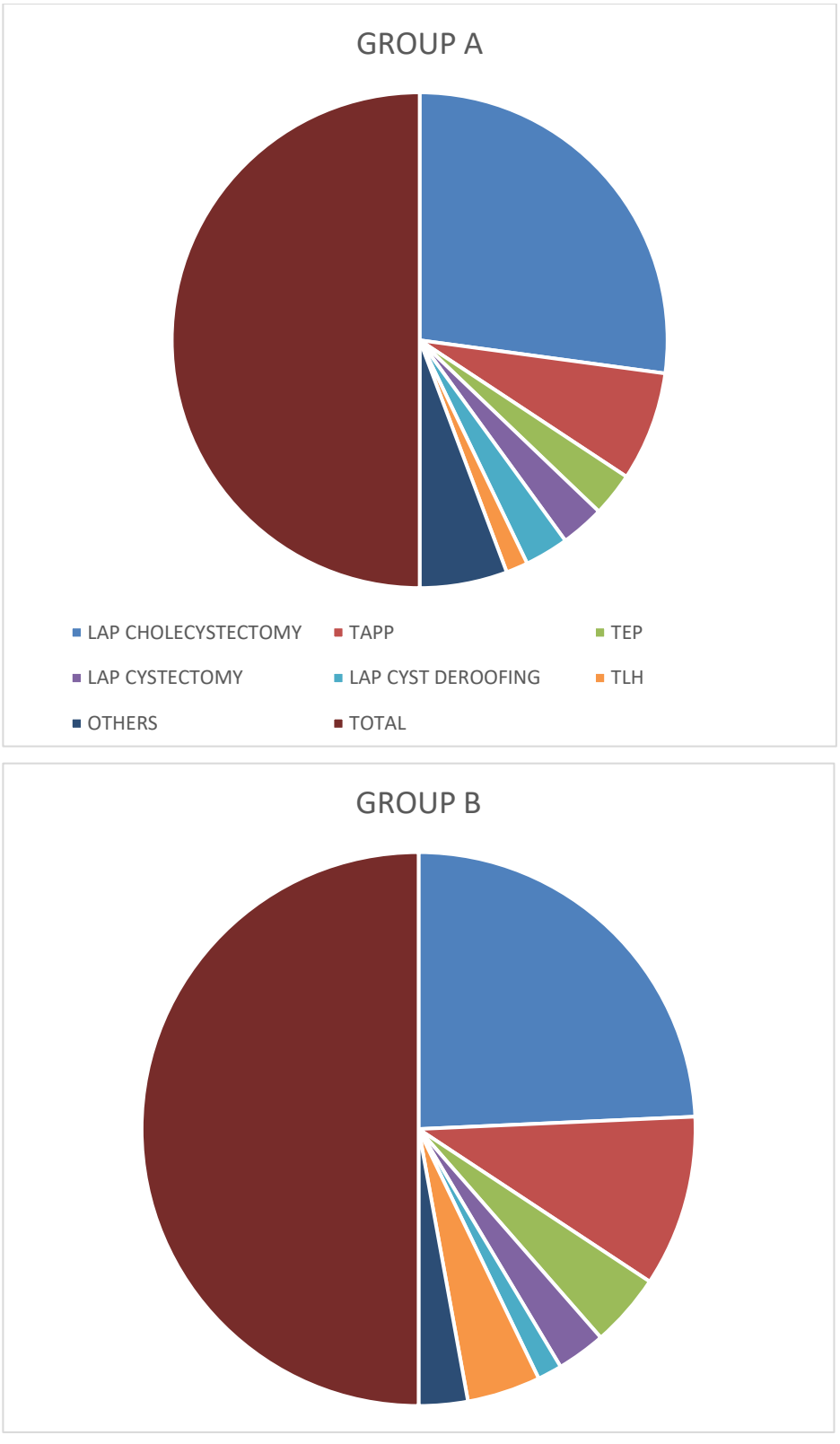


Figure 2: Pie chart showing distribution of cases in both groups.

Table 2: Comparison of age distribution between two groups

Age (years)	Group A		Group B	
	No.	%	No.	%
20-30 yrs	11	31.43	5	14.28
31-40 yrs	8	22.86	10	28.57
41-50 yrs	9	25.71	12	34.28
>50 yrs	7	20.00	8	22.85
Total	35	100.00	35	100.00
Mean±SD	38.77±13.28		41.29±10.05	
Result (p value)	0.539**			

*Significant; **non-significant

The study consists of 35 patients of age group 18-60 years in both groups. The mean age in Group A was 38.77±13.28 and for Group B was 41.29±10.05. The distribution of people in each group based on age is comparable(P=0.539).

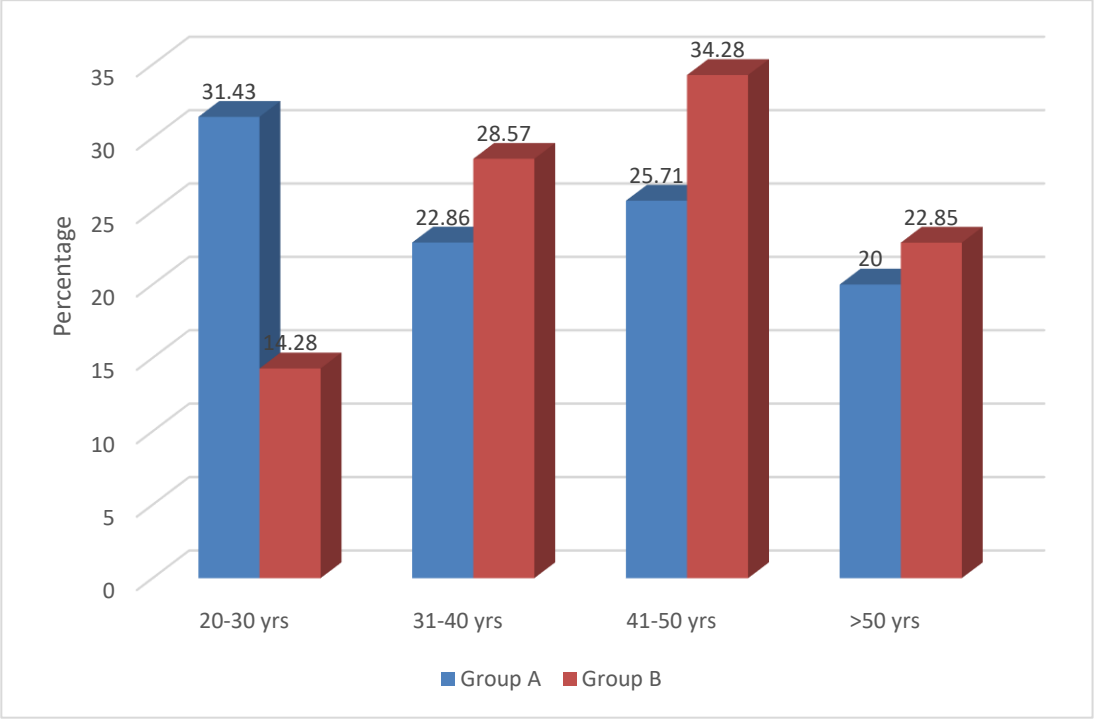


Figure 3: Comparison of age distribution between two groups

Table 3: Comparison of gender distribution between two groups

SEX	Group A		Group B	
	No.	%	No.	%
Male	15	42.86	13	37.14
Female	20	57.14	22	62.85
Total	35	100.00	35	100.00
Result (p value)	0.807**			

*significant; **non-significant

In Group A, 15 (42.9%) patients were males and 20 (57.1%) patients were females. In Group B, 13 (37%) patients were males, and 22 (62.8%) patients were females. Gender of both groups is comparable.

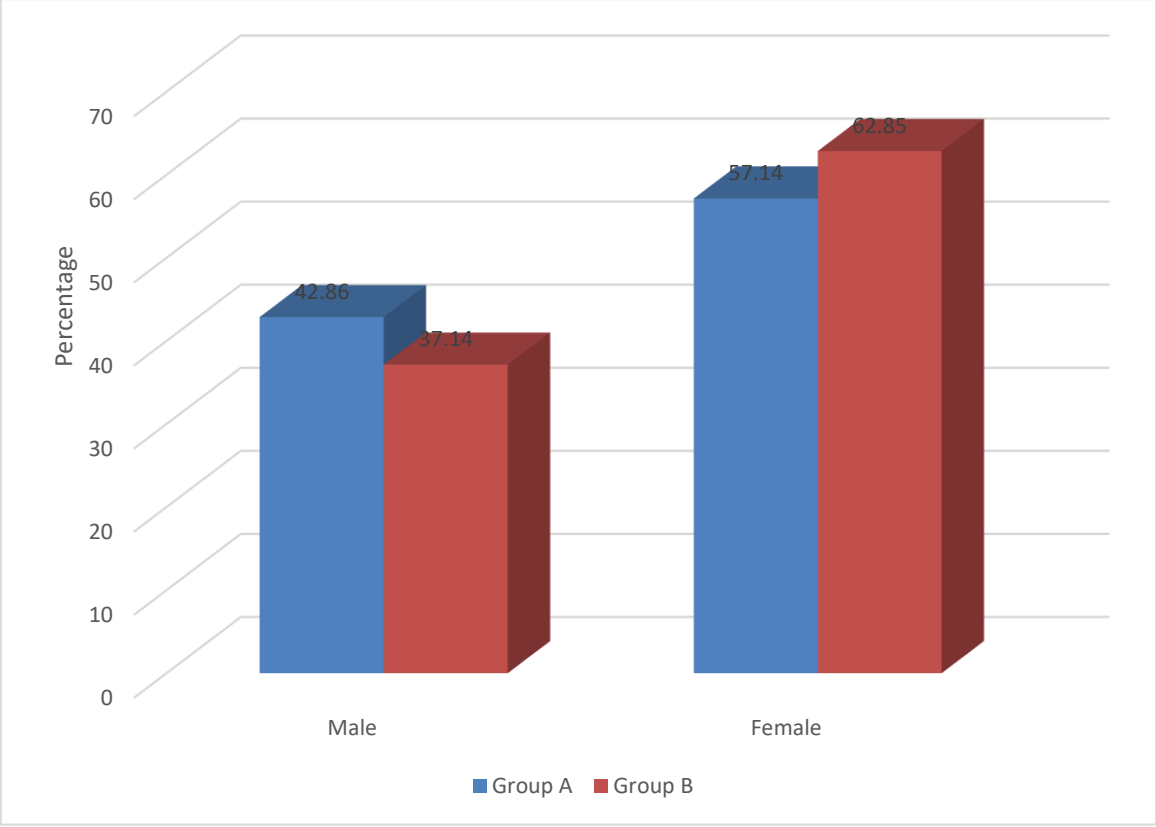


Figure 4: Comparison of gender distribution between two groups

Table 4: Distribution of patient's weight (in kilogram) in study population

Weight	Group A		Group B	
	Mean	SD	Mean	SD
Mean weight (kg)	64.43	9.59	61.31	11.98
Result (p value)	0.234**			

*Significant; **non-significant

Mean age of group A was 64.43 +_9.59 kg and that of group B was 61.31+_11.98 kg. Weight of patients on both groups was comparable (p=0.234).

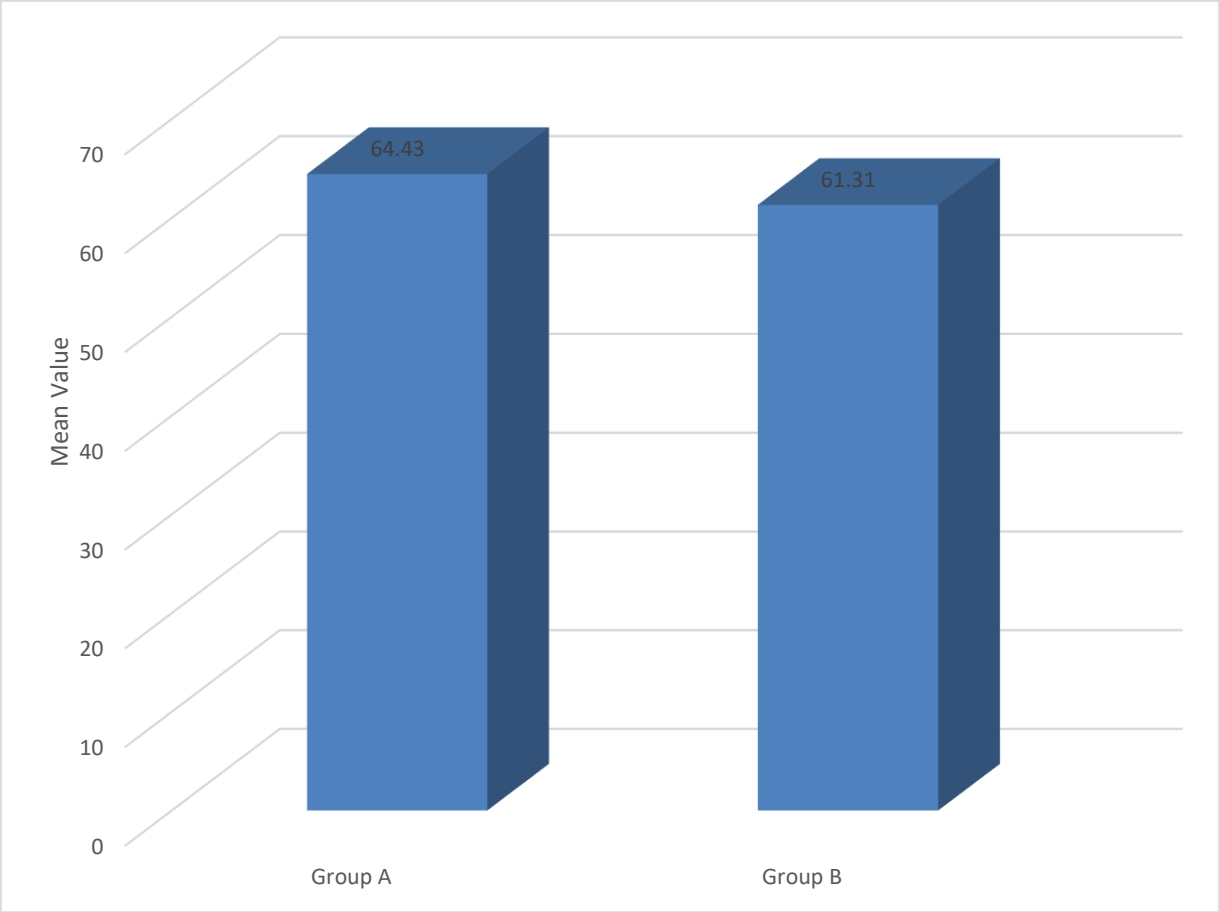


Figure 5: Comparison of patient's weight between two groups

Table 5: Comparison of ASA grade between two groups

ASA grade	Group A		Group B	
	No.	%	No.	%
ASA I	24	68.57	19	54.28
ASA II	11	31.42	16	45.71
Total	35	100.00	35	100.00
Result (p value)	0.326**			

*significant; **non-significant

In group A, ASA I and ASA II patients was 24 (68.57%) and 11 (31.42%) respectively. Group B had 19 (54.28%) patients of ASA I and 16(45.71%) patients of ASA II.

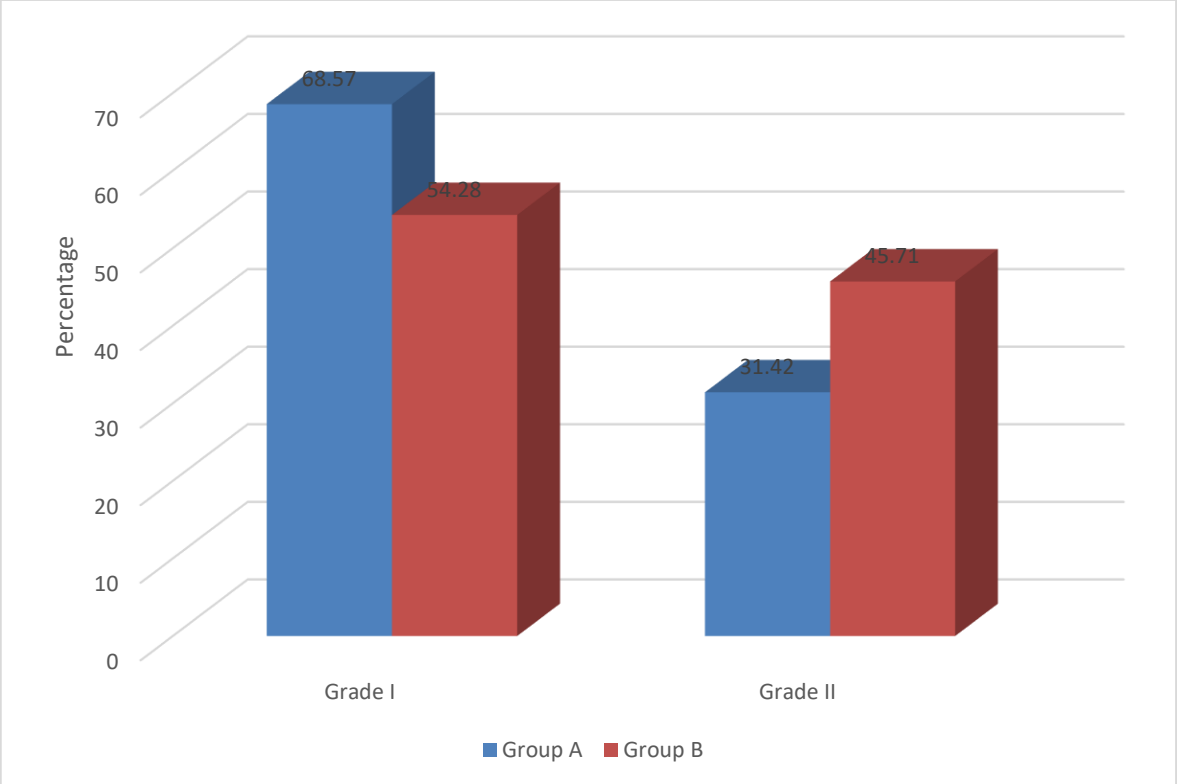


Figure 6: Comparison of ASA grade between two groups

Table 6: Comparison of intraoperative mean blood pressure (mm of hg) between two groups at various time intervals

Mean blood pressure (mm of Hg)	Group A		Group B		Result (p value)
	Mean	SD	Mean	SD	
Baseline (before induction)	97.37	4.22	95.94	5.97	0.251**
5 minutes after induction	79.29	7.46	84.43	9.30	0.012*
10 minutes after induction	73.09	6.08	76.57	9.80	0.078**
15 minutes after induction	75.29	8.20	79.94	9.91	0.035*
30 minutes after induction	78.46	8.78	82.00	9.91	0.117**
60 minutes after induction	79.97	7.62	83.46	8.67	0.078**
90minutes after induction	83.28	7.59	86.14	8.77	0.171**
120 minutes after induction	84.15	7.32	86.87	12.45	0.497**

*significant; **non-significant

Above table shows comparison of mean blood pressure (mm of Hg) between the two groups. The mean blood pressure was calculated at baseline, 5minutes, 10minutes, 15minutes, 30minutes, 60minutes, 90minutes, 120minutes, 180minutes in both the groups. The numerical values of mean blood pressure are lower in music group compared to control group but not statistically significant except at 5 minutes post induction.

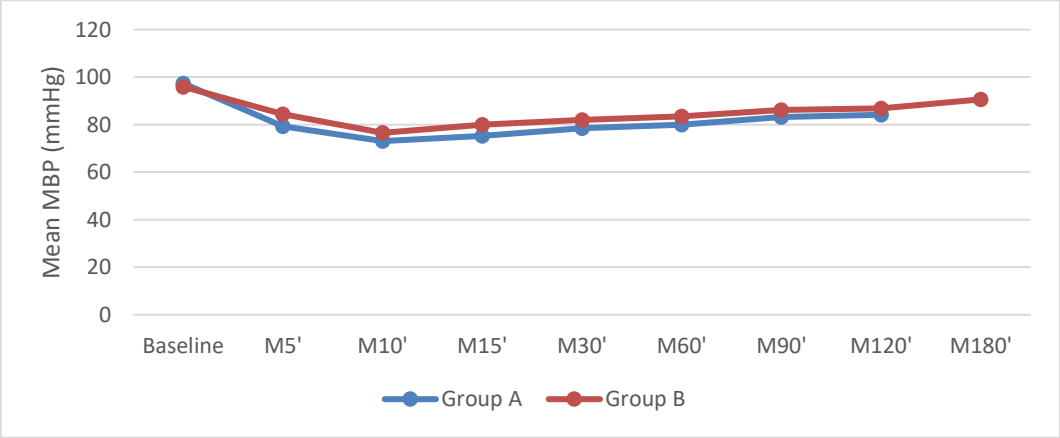


Figure 7: Comparison of mean blood pressure (mm of hg) between two groups at different time intervals

Table 7: Comparison of pulse rate (per minute) between two groups at different time intervals

PULSE RATE (per minutes)	Group A		Group B		Result (p value)
	Mean	SD	Mean	SD	
Baseline (before induction)	88.37	8.07	89.11	9.35	0.723**
5 minutes after induction	79.54	7.25	85.54	12.00	0.017*
10 minutes after induction	76.63	8.14	84.26	12.33	0.003*
15 minutes after induction	76.51	7.37	83.49	12.17	0.005*
30 minutes after induction	78.63	8.20	81.94	10.19	0.138**
60 minutes after induction	79.54	7.53	80.69	10.68	0.606**
90 minutes after induction	78.14	7.16	80.09	9.16	0.361**
120 minutes after induction	79.27	8.11	81.41	7.83	0.453**

*significant; **non-significant

Above table shows comparison of pulse rate (per minute) between the two groups. The pulse rate was calculated at baseline, 5minutes, 10minutes, 15minutes, 30minutes, 60minutes, 90minutes, 120minutes, 180minutes in both the groups. The numerical values of pulse rate were lower in music group as compared to control group, but it was statistically significant till 15 minutes post induction only.

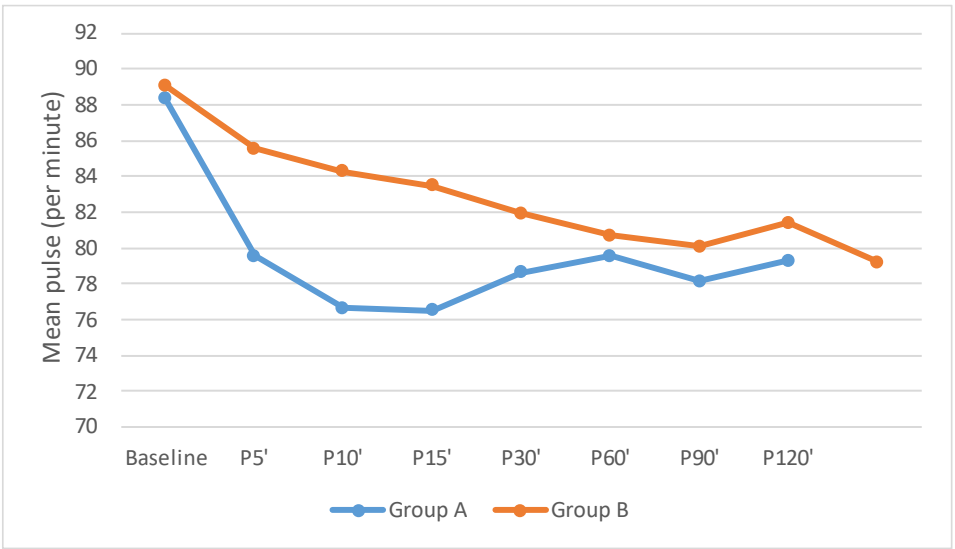


Figure 8: Comparison of pulse rate (per minute) between two groups at different time intervals

Table 8: Comparison of total propofol consumption between two groups

	Group A		Group B	
	Mean	SD	Mean	SD
Total Propofol Consumption (mg)	690.9	12.33	945.1	12.17
Result (p value)	p<0.001*			

*significant; **non-significant

There was a statistically significant difference in total propofol consumption between two groups with a p-value of <0.001. Mean total propofol consumption in Group A is 690.9mg and of Group B is 945.1mg.

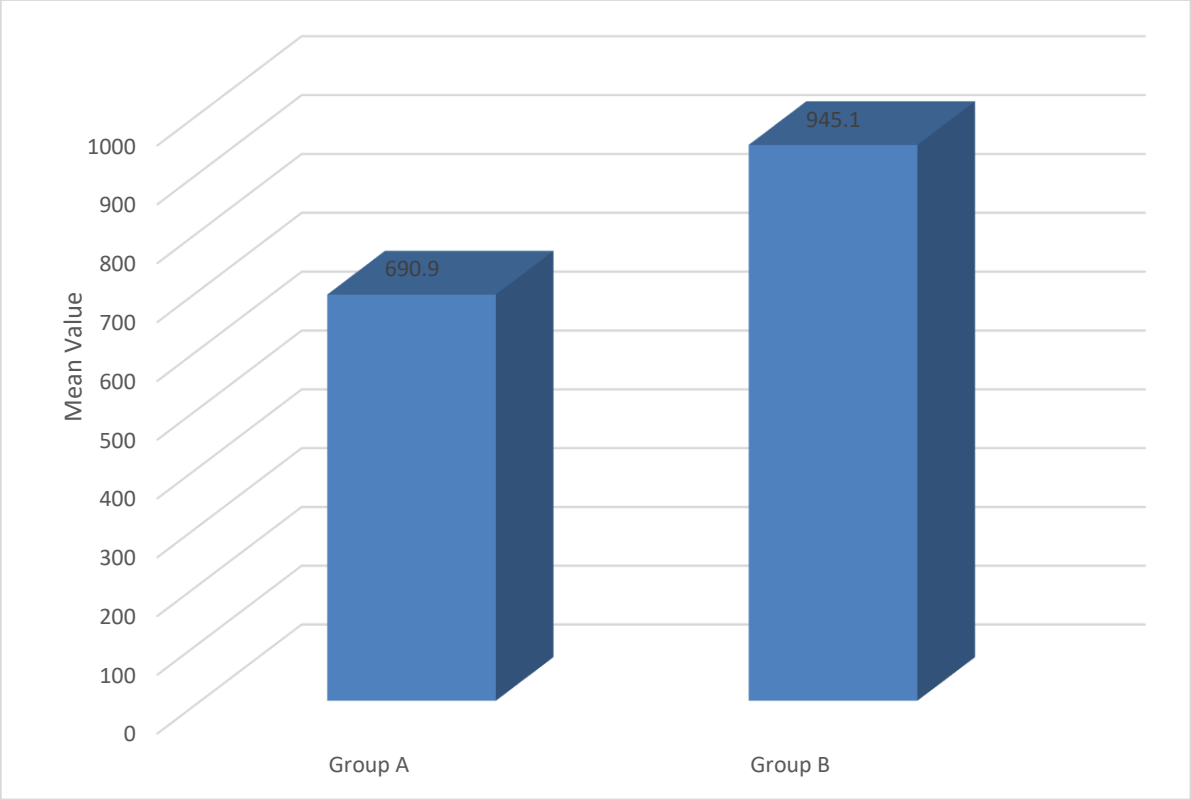


Figure 9: Comparison total propofol consumption (mg) between two groups

Table 9: Comparison of duration of surgery in both groups

	Group A		Group B	
	Mean	SD	Mean	SD
Duration of surgery	1.42	0.43	1.51	0.43
Result (p value)	0.361**			

*significant; **non-significant

There was no statistically significant relation in duration of surgery in both groups with a p-value of 0.361, which shows the duration of surgery in both groups were comparable.

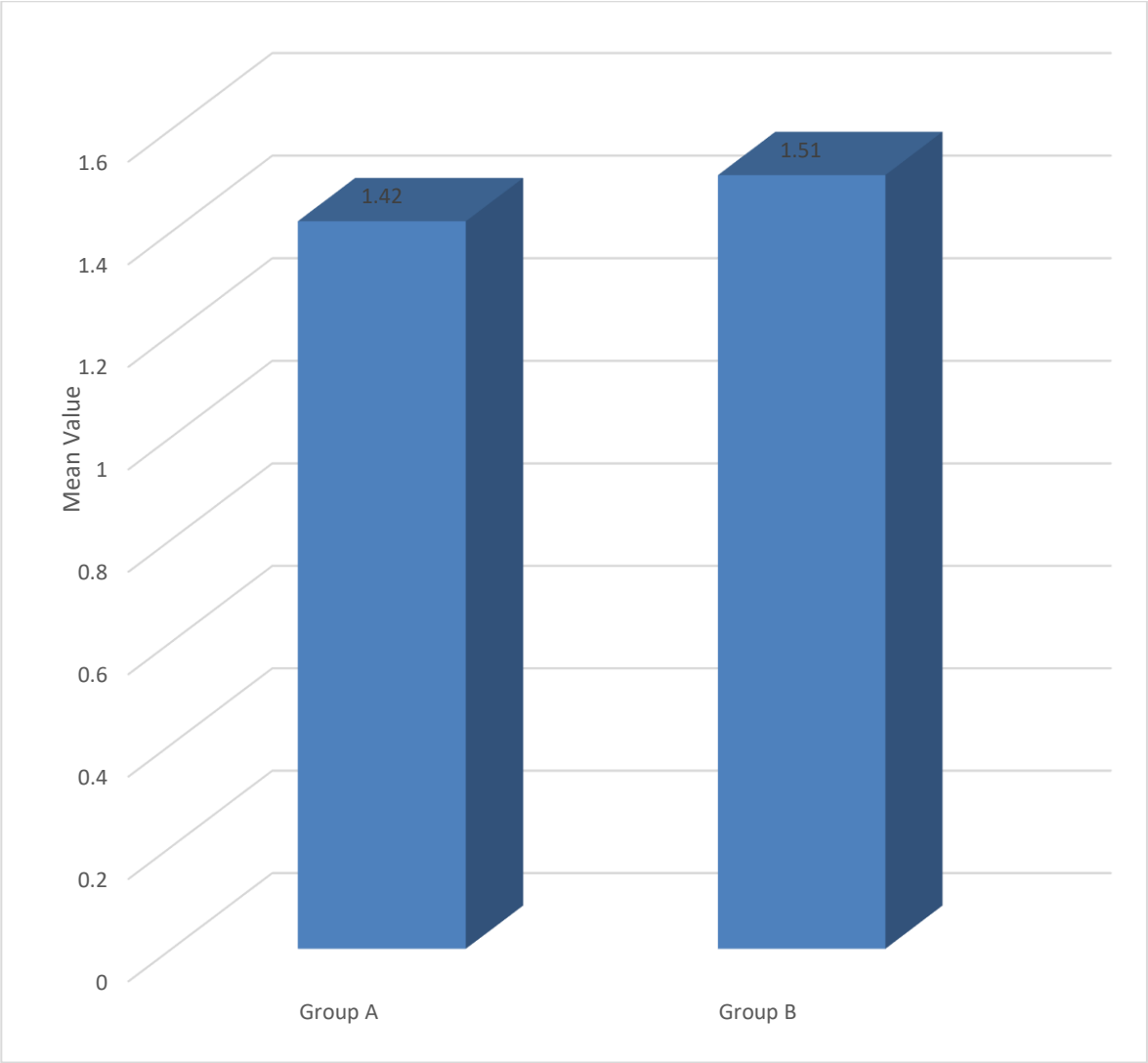


Figure 10: Comparison of duration of surgery in both groups

Table 10: Comparison of time of first rescue analgesia between two groups

	Group A		Group B	
	Mean	SD	Mean	SD
TIME OF FIRST RESCUE ANALGESIA	3.32	1.21	4.02	6.41
Result (p value)	0.531**			

*significant; **non-significant

There was no statistically significant relation in time of first rescue analgesia in both groups with a p-value of 0.531.

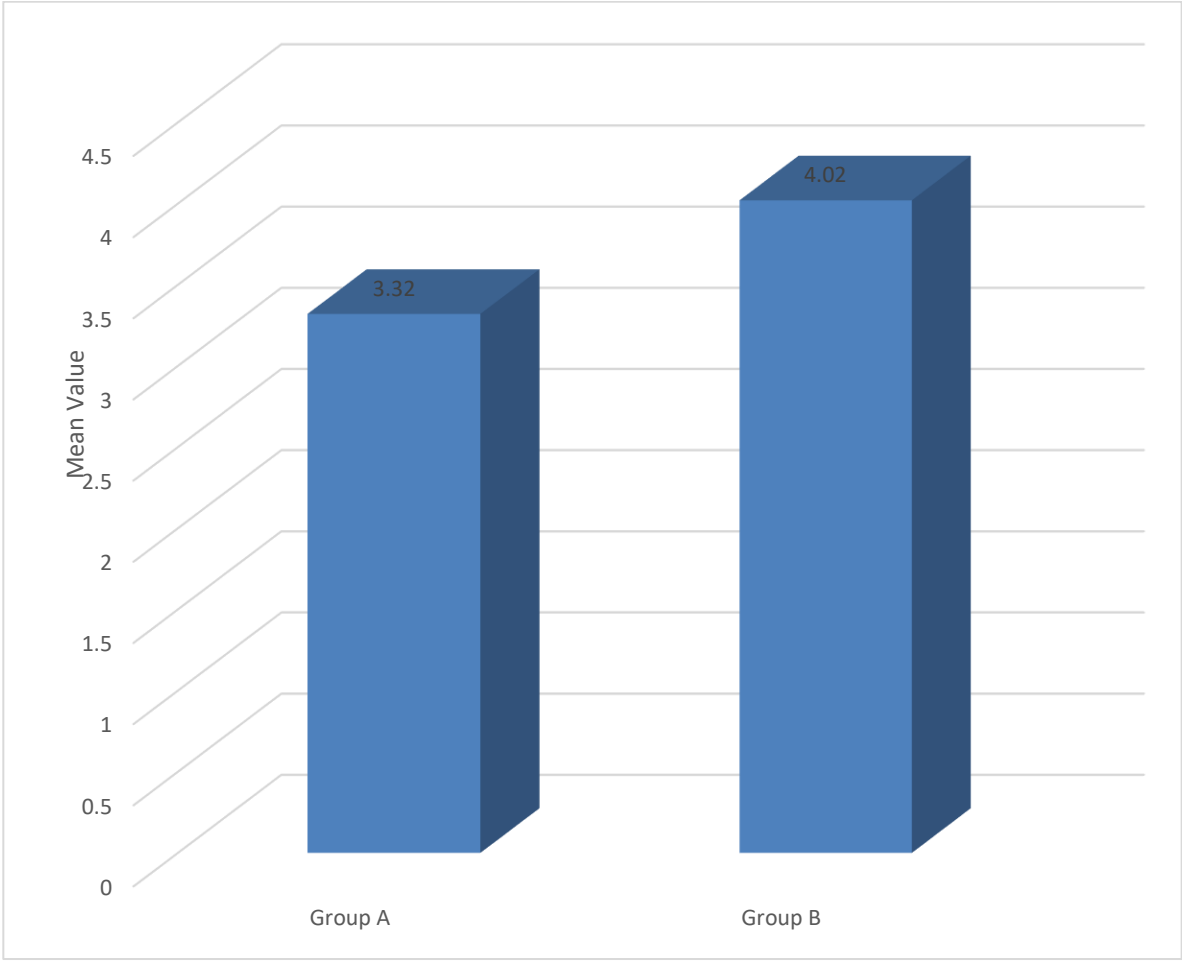


Figure 11: Comparison of time of first rescue analgesia between two groups

Table 11: Comparison of Richmond agitation sedation scale (RASS) between two groups at different time intervals post operatively

Timings	Group A				Group B				Result (p value)
	Mean	SD	Median	IQR	Mean	SD	Median	IQR	
RASS At extubation	-1.69	0.80	-2.00	1.00	-1.46	0.82	-1.00	1.00	0.239**
RASS 10 minutes	-0.89	0.68	-1.00	1.00	-0.83	0.71	-1.00	1.00	0.730**
RASS 20 minutes'	-0.26	0.56	0.00	0.50	-0.17	0.57	0.00	0.00	0.527**
RASS 30 minutes'	0.09	0.45	0.00	0.00	0.17	0.38	0.00	0.00	0.390**

*significant; **non-significant

The quality of recovery from anaesthesia was assessed using Richmond sedation – agitation score (RASS) immediately after extubation and in PACU at 10minutes interval for 30 minutes. There was no statistically significant difference in RASS scoring in both groups (p>0.05).

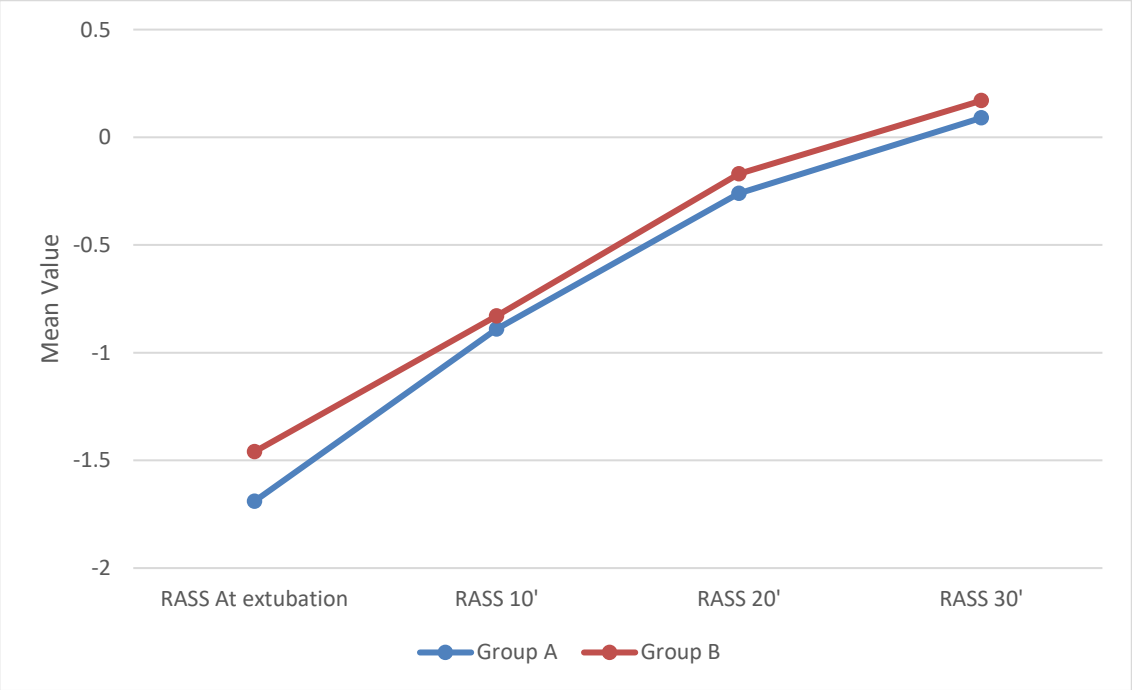


Figure 12: Comparison of Richmond agitation sedation scale (RASS) between two groups at different time intervals post extubation

Table 12: Comparison of mean blood pressure (mm of hg) between two groups at different time intervals post extubation

Mean blood pressure (MBP)	Group A		Group B		Result (p value)
	Mean	SD	Mean	SD	
AT EXTUBATION	95.03	5.81	93.14	6.73	0.213**
MBP AT 10 MINUTES	93.51	5.62	93.06	7.36	0.771**
MBP AT 20 MINUTES	93.77	5.57	91.23	6.16	0.074**
MBP AT 30 MINUTES	93.26	6.94	90.63	6.17	0.098**

*significant; **non-significant

Above table shows comparison of mean blood pressure (mm of Hg) between the two groups. The mean blood pressure was calculated at extubation, 10minutes, 20minutes, 30minutes in both the groups. There is no statistical significance between both groups in Mean BP post extubation and is comparable.

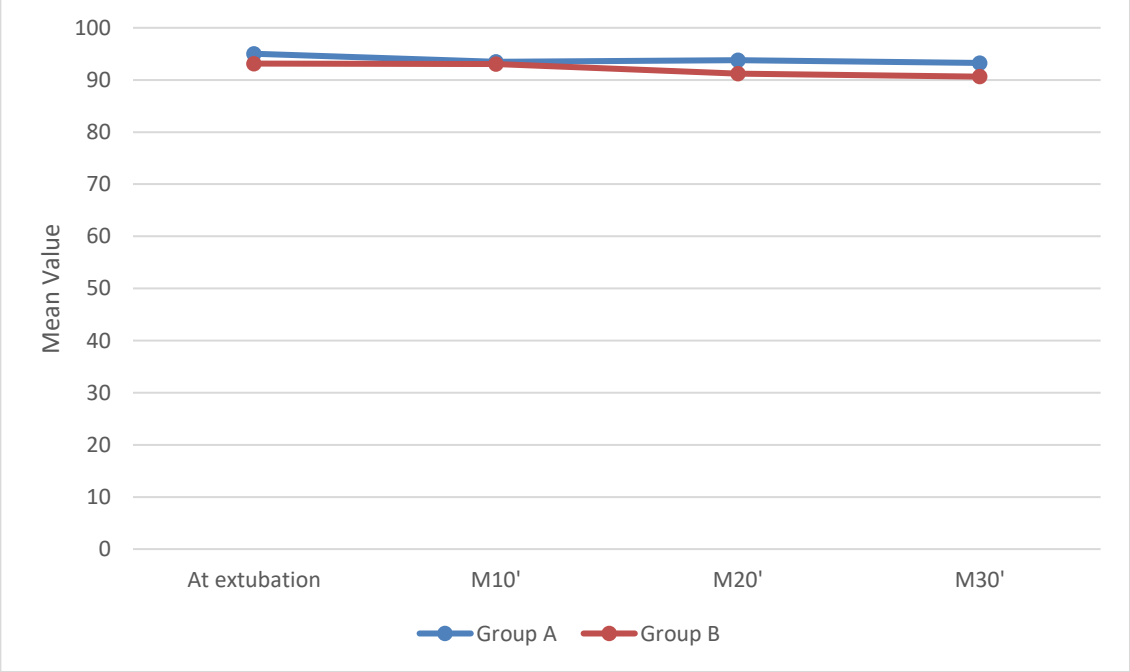


Figure 13: Comparison of mean blood pressure (mm of hg) between two groups at different time intervals post extubation

Table 13: Comparison of pulse rate (per minute) between two groups at different time intervals post extubation

PULSE RATE (PER MINUTE)	Group A		Group B		Result (p value)
	Mean	SD	Mean	SD	
At extubation	90.26	8.28	91.89	10.25	0.467**
Pulse rate at 10 minutes	88.23	7.70	88.43	8.22	0.916**
Pulse rate at 20 minutes	84.71	7.11	86.37	7.80	0.356**
Pulse rate at 30 minutes	84.00	6.14	86.20	6.65	0.756**

*significant; **non-significant

Above table shows comparison of pulse rate (per minute) between the two groups. The pulse rate was calculated at extubation, 10min, 20min, 30min in both the groups. It was comparable at all the time points

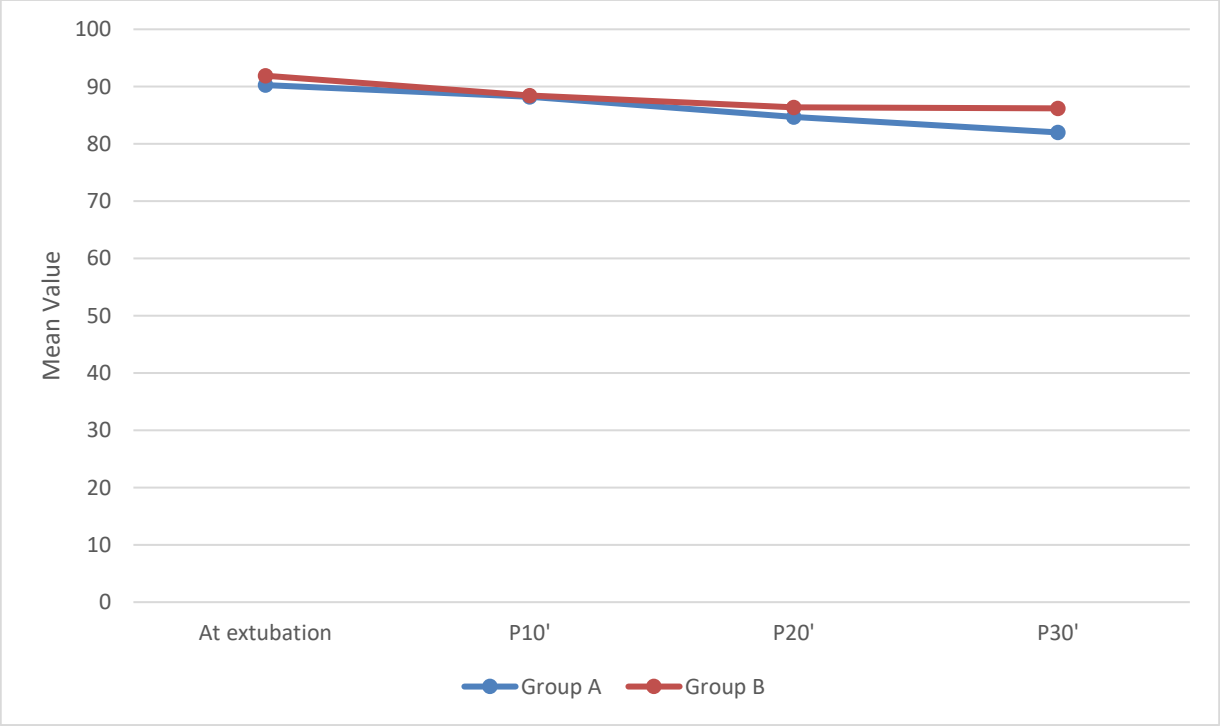


Figure 14: Comparison of pulse rate (per minute) between two groups at different time intervals post extubation

Table 14: Comparison of VAS score (R) between two groups at different time intervals post extubation

TIMINGS	Group A		Group B		Result (p value)
	Mean	SD	Mean	SD	
VAS (R) AT 30 minutes	3.80	0.63	3.46	0.74	0.041*
VAS (R) AT 60 minutes	2.74	0.70	3.86	0.60	p<0.001*
VAS (R) AT 90 minutes	2.54	0.70	3.69	0.72	p<0.001*
VAS (R) AT 120 minutes	2.26	0.51	3.17	0.75	p<0.001*
VAS (R) AT 6 HOURS	1.40	0.74	2.20	0.68	p<0.001*

*significant; **non-significant

Above table shows comparison of VAS SCORE at rest between the two groups. It was measured at 30min, 60min, 90min, 120min and at 6hours and difference was found to be statistically significant at all the time points.

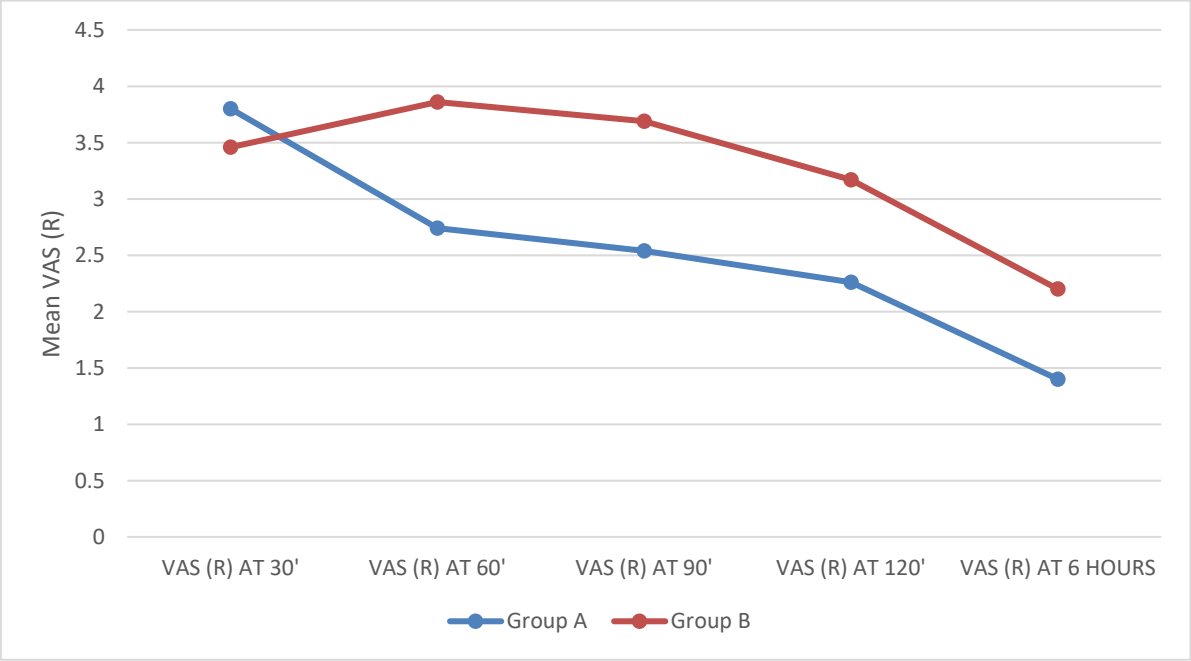


Figure 15: Comparison of VAS score (R) between two groups at different time intervals post extubation

Table 15: Comparison of VAS score (M) between two groups at different time intervals post extubation

TIMINGS	Group A		Group B		Result (p value)
	Mean	SD	Mean	SD	
VAS (M) AT 30 minutes	3.77	0.69	4.34	0.80	0.002*
VAS M) AT 60 minutes	3.77	0.65	4.74	0.74	p<0.001*
VAS (M) AT 90 minutes	3.69	0.72	4.66	0.76	p<0.001*
VAS (M) AT 120 minutes	3.37	0.55	4.20	0.76	p<0.001*
VAS (M) AT 6 HOURS	2.74	0.56	3.46	0.70	p<0.001*

*significant; **non-significant

Above table shows comparison of VAS SCORE at movement between the two groups. It was measured at 30min, 60min, 90min, 120min and at 6hours and result was found to be statistically significant at all the timepoints.

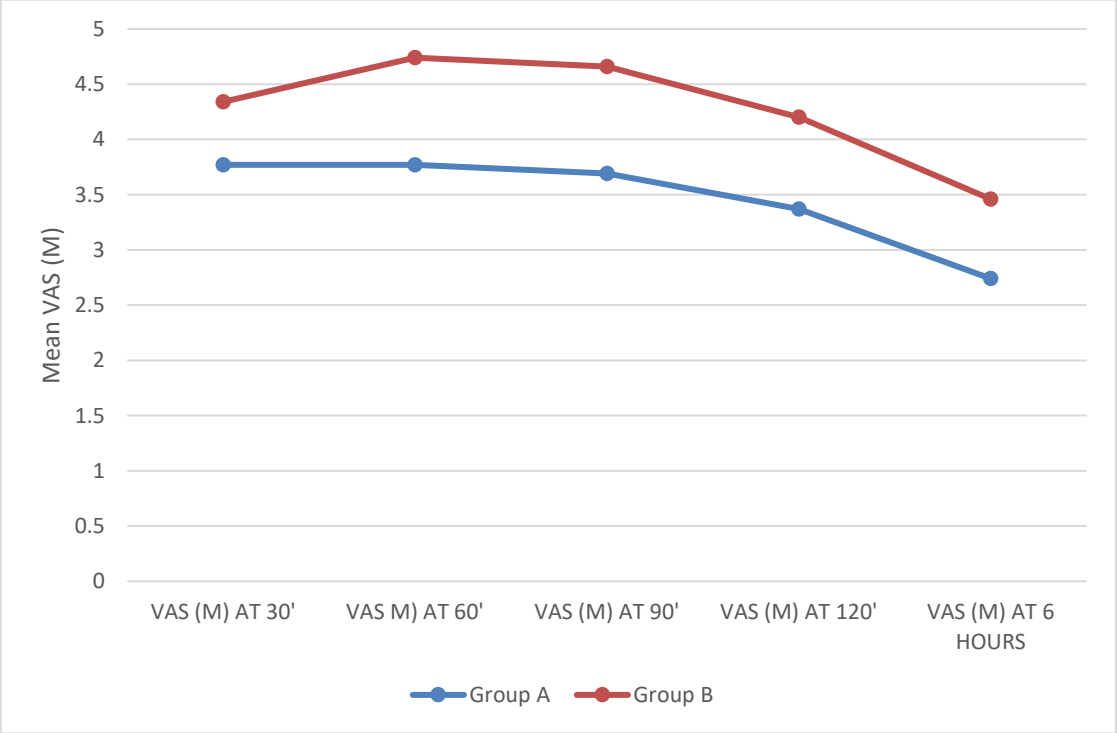


Figure 16: Comparison of VAS score (M) between two groups at different time intervals post extubation

Table 16: Comparison of post-operative complication between two groups

	Group A		Group B	
	No.	%	No.	%
Yes	2	5.71	6	17.14
No	33	94.28	29	82.85
Total	35	100.00	35	100.00
Result (p value)	0.260**			

*significant; **non-significant

There is no statistically significant difference in post-op complications between both the groups (p>0.05). Total of 6 patients in control group B had postoperative complications (4 had PONV and 2 had shivering); while in experimental group A, 2 had complications. (1 had PONV and other shivering).

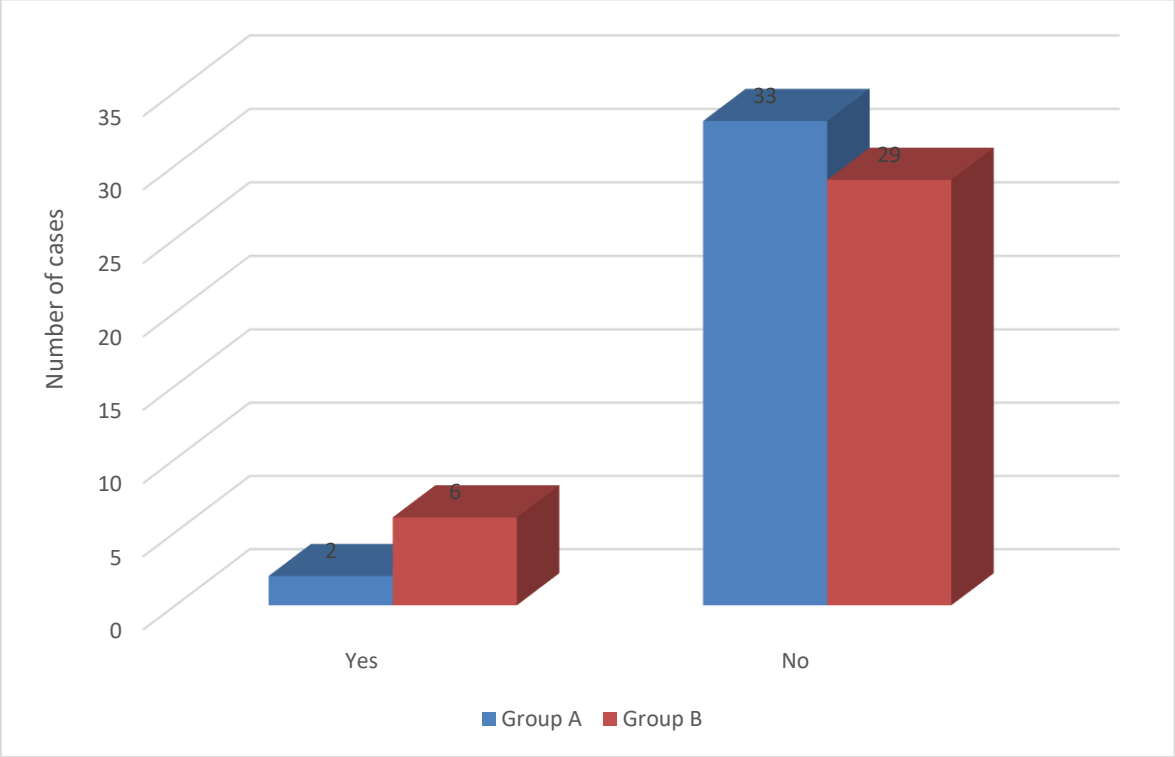


Figure 17: Comparison of post-operative complication between two groups

Table 17: Comparison of patient satisfaction score between two groups

	Group A		Group B	
	No.	%	No.	%
Excellent	2	5.71	0	0.00
Fair	19	54.29	29	82.86
Good	14	40.00	5	14.29
Poor	0	0.00	1	2.86
Total	35	100.00	35	100.00
Result (p value)	0.032*			

*significant; **non-significant

Above table shows comparison of patient satisfaction score between the two groups and shows statistically significant association with p value of 0.032. Majority of patients marked fair in both groups. Two patients in group A marked excellent and one in group B marked poor.

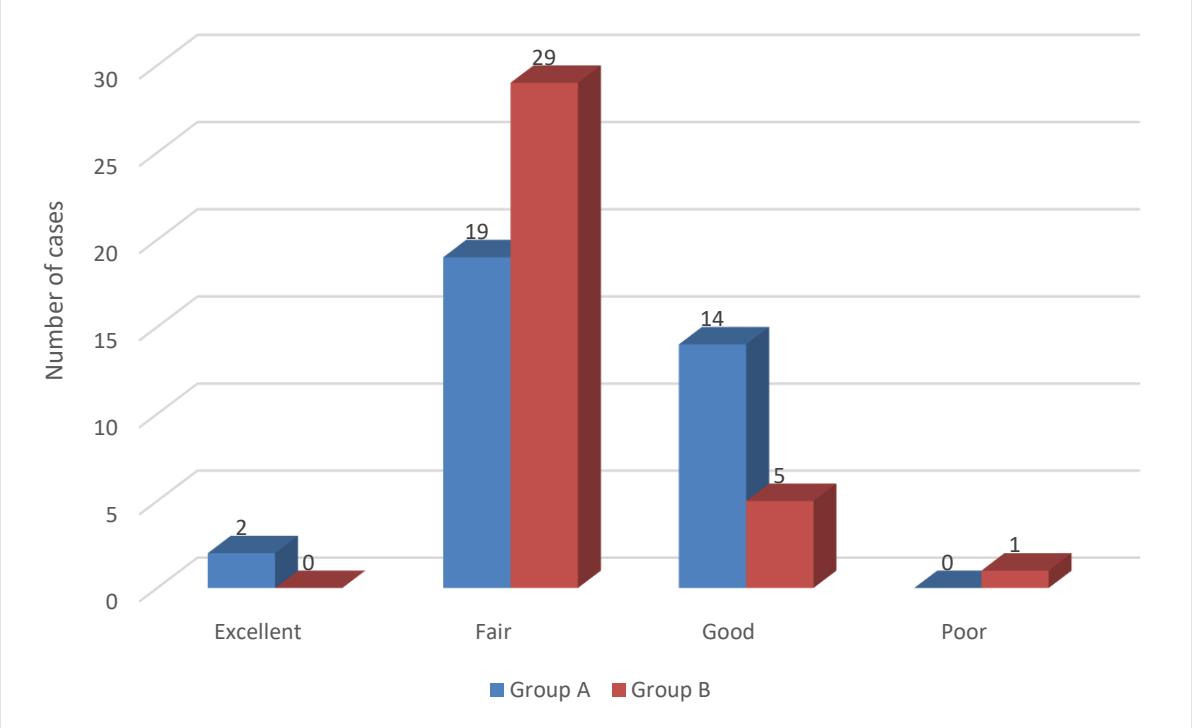


Figure 18: Comparison of patient satisfaction score between two groups

Table 18: Comparison of patient satisfaction score between two groups (Median, IQR)

	Group A [Median (IQR)]	Group B [Median (IQR)]
PATIENT SATISFATION SCORE	2 (2,3)	2 (2,2)
Result (p value)	0.015*	

*significant; **non-significant

Median of patient satisfaction score for both groups was 2. There was a higher patient satisfaction score on Group A as compared to Group B ($p<0.05$).

DISCUSSION

DISCUSSION

Surgery and anaesthesia are generally unpleasant experiences for patients can lead to stress and anxiety, which can interfere with the intended therapeutic outcome. Preoperative anxiety is prevalent and can have a deleterious impact on the perioperative course by increasing stress indices, promoting hemodynamic fluctuations, and hindering postoperative recovery. This could be avoided with perioperative music to some extent and can even replace the pharmacological agents. Listening to music during surgery has been associated with significant positive changes in cortisol levels (decreases and lower increases in cortisol)[42-44] as well as after such interventions (higher reductions in cortisol)[45]. There is evidence that listening to music can have a positive impact on stress-related physiological[35-37], cognitive[38], and emotional[39-41] processes. Literature[57] has come up mentioning the effect and perception of auditory stimuli during general anaesthesia and its role in patient outcomes. Evidence suggests that regardless of the complexity of the surgical technique, intraoperative auditory stimuli can be received and processed during clinically sufficient general anaesthesia, resulting in implicit memory development without explicit awareness. Intraoperative music may significantly reduce postoperative pain and the need for opioids. So, we planned this study to assess effect of binaural tone music under general anesthesia.

We enrolled 70 patients (35 in each group), posted for elective laparoscopic abdominal surgeries under TIVA with comparable age groups (mean age 38.77±13.28 vs 41.29±10.05; p = 0.539) and gender (p = 0.807). Duration of the surgery in both groups was also similar. We tried to evaluate effect of perioperative binaural tone on perioperative outcome. Freely available version of binaural tone music was used.

INTRAOPERATIVE HAEMODYNAMICS

Our study had two groups, Binaural tone music was played in intervention group A and control group was without music. Patients in intervention group (group A) had less numerical value of mean blood pressure and pulse as compared to group B but difference was not statistically significant. This was in accordance with study done by **Kahloul M et al[9], they assessed effect of perioperative** patient selected music and **their patients also had** more stable hemodynamic profile in music group. **Binns-Turner PG et al[27]** conducted a trial on 30 patients posted for mastectomy and concluded that women in the intervention group (perioperative music) had a greater decrease in MAP. **Patil Kalyani N et al[10]** enrolled sixty, ASA 1 patients and proved that classical instrumental music showed no statistically significant difference in the

intraoperative hemodynamics between both groups. **Migneault B et al[24] conducted a** study on 30 patients posted for abdominal gynecological procedures in 2 groups as with music (during intraoperative period) and without music. Patients in both groups were asked to select a CD from a list of four that they felt would be calming (classical, jazz, new-age, and popular piano music). They came to the conclusion that there was no group difference in mean arterial blood pressure or heart rate throughout any sample time or during the postoperative period. **Peter Szmuk et al[51]** studied effect of smoothening music in laparoscopic surgery and concluded there was no significant effect on MAP.

There are not many studies comparing intraoperative hemodynamics using binaural tone music in patients undergoing surgery under general anesthesia. Many studies used patient selected music which had more significant results in intraoperative hemodynamics. Overall literature suggests mixed effect of different types of music on hemodynamics, this may be due to different effect of various music form on neurohumoral response of body. Music can also reduce patient's anxiety regarding surgery, redirect patient's attention towards music and can also enhance a feeling of wellbeing. These all can have a positive impact on intraoperative hemodynamics.

RECOVERY PROFILE (RASS)

Primary objective of our study was to compare recovery profile postoperatively in both the groups using Richmond Agitation Sedation score (RASS). Binaural tone music group showed smooth recovery, numerically lower values than control group but difference was not statstically significant between 2 groups ($p>0.005$). As per our best knowledge, no study till date has compared the effect of binaural tone music on recovery from general anesthesia. However, few studies have tried to explore effect of different forms of music on postoperative recovery.

Gökcek E et al[21] conducted a study on the effects of music therapy in patients undergoing septorhinoplasty surgery under general anaesthesia. They included 120 patients in 2 groups (60 each in both groups). All the patients in the music group listened to relaxing indigenous and foreign music according to their preferences. Classical music was played for those who did not have any preference. They came to the conclusion that patients receiving music treatment experienced improved awakening qualities because their sedation agitation ratings were lower in the music group than in the control group at the postoperative period (3.76 ± 1.64 vs. 5.11 ± 2.13; $p < 0.001$). **Kahloul M et al[9]** in 2016 studied the effect of music therapy under general anaesthesia for patients undergoing abdominal surgery. One hundred and forty patients were

included and allocated into 2 groups with and without music therapy. Patients' choice of music was selected and those without a choice were played with instrumental music. Their results showed calm recovery in group M (77.1% versus 44%, p < 10-3). Both studies (**Gökcek E et al[21]** and **Kahloul M et al[9]**) used patient's choice of music and concluded having a better awakening quality. This might be due to better reduction in stress hormones by the patients selected music than binaural tone music.

An evaluation of the effects of nature-based sound treatment on agitation and anxiety in coronary artery bypass graft patients during the weaning of artificial ventilation was done by **Bahman Aghaie et al[59]** in a randomized control trial. 120 patients with coronary artery bypass grafts undergoing weaning from mechanical ventilation and were between the ages of 45 and 65 were randomly assigned to the intervention and control groups. Patients in the intervention group wore headphones with nature sounds playing while those in the control group wore headphones silent. They came to the conclusion that nature-based sound can be a useful tool for reducing potentially harmful hemodynamic reactions brought on by agitation and anxiety in patients with coronary artery bypass grafts who are weaning from mechanical breathing**.**

Another randomized controlled trial on the effects of nature-based sounds on agitation, anxiety, and stress in patients receiving mechanical ventilator support was carried out by **Vahid Saadatmand et al[60]** in 2012. The control and experimental groups were randomly allocated to a total of 60 patients in an intensive care unit who were receiving mechanical ventilation support and were between the ages of 18 and 65. They concluded that the experimental group (which listened to nature-based sounds) displayed noticeably less agitation than the control group.

Jaber et al.[63] gathered 30 intensive care unit patients and separated them into two groups for a study on the effects of music therapy in weaning patients without sedation versus non-ventilated patients. 15 non-intubated patients who did not meet any criteria for neurological or respiratory distress made comprised the first group. During the weaning from mechanical ventilation, 15 intubated patients made up the second group. Using the Richmond scale (RASS 5 to +4), they assessed the impact of music therapy on agitation-sedation and concluded that music therapy had a significant negative impact on both groups' RASS levels.

Music has been shown to help postoperative recovery in adults, according to a comprehensive review and meta-analysis by **Hole J et al[7]**. They found 4261 titles and abstracts, and 73 RCTs with sample sizes ranging from 20 to 458 participants were included in the systematic review. The type of music, the timing, and the length differed across research. They concluded that music may be used to help patients cope with pain and anxiety after surgery.

Music can be offered as a choice for better awakening quality from general anesthesia. Our study showed smooth recovery from general anesthesia in music group compared to control group, but the difference wasn't statistically significant. Many studies which used patient's choice of music could demonstrate a statistically significant better awakening quality in patients from general anesthesia. This could be due to more stable neurohormonal response among the music group due to the patient's choice of music.

ANAESTHETIC REQUIREMENT

Our study showed there was a statistically significant reduction in propofol consumption in music group($p<0.005$). There is not much literature available on the effect of music on anaesthetic requirement, and none of available study has evaluated effect of binaural tone music on anaesthesia requirement. We calculated the total propofol requirement (mg) on patients undergoing laparoscopic abdominal surgeries under TIVA. Intervention group in our study had lower propofol consumption when compared to control group.

Music can mask patients from the OT room noises and can decrease the stress hormone release, this can in turn help in reduction of hypnotic and analgesic dosage. **Ayse Mizrak et al[56]** studied 90 patients who underwent cholecystectomy surgery in 3 groups. Patients in Group N (n=30) were exposed to operating room noise; those in Group S (n=30) were exposed to noise between 80 and 85 Db with headphones; and those in Group Q were shielded from operating room noise by wearing headphones (n=30). They came to the conclusion that patients who have cholecystectomy surgery under TIVA experience excessive noise levels, which affects both patient and surgeon satisfaction and increases total remifentanil and propofol consumption during operation.

Peter Szmuk et al[51] conducted a study on forty patients undergoing laparoscopic hernias or cholecystectomy under general anaesthesia. They used patients' choice of music within any of classical, pop-rock, or Israeli music. They found that the end-tidal concentration of sevoflurane needed to keep BIS near 50 was almost the same in both patient groups.

In a study by **Palmer J. B. et al.[20]**, 207 female patients with breast cancer underwent surgery and were randomly assigned to receive either usual care (UC) preoperatively with noise-blocking earmuffs intraoperatively (n=68), patient-selected recorded music (RM) preoperatively with therapist-selected recorded music intraoperatively (n=69), or patient-selected recorded music (LM) preoperatively with live music and recorded music, respectively. They were unable to identify any measurable effects of intraoperative music on the need for propofol**.**

60 ASA I patients were randomly assigned to the music group or the no-music group for the **Patil Kalyani N et al.**[10] study. After the onset of anaesthesia until the skin was closed, classical instrumental music was played in the music group. Patients in the no-music group wore headphones, but there was no music played. They were unable to prove that using intraoperative music as a non-pharmacological intervention during general anaesthesia improved patients' stress responses and reduced their need for anaesthesia (end tidal isoflurane concentration).

Migneault B et al[24] studied on thirty female patients scheduled for abdominal gynecological procedures in 2 groups. The patients in both groups were invited to select a CD from a list of four suggested CDs during their preoperative visit that they found to be calming (classical, jazz, new-age, and popular piano music). They came to the conclusion that there was no correlation between music and BIS value or end tidal isoflurane concentration.

Dabu-Bondoc et al[65] studied the effect of Hemispheric Synchronized Sounds and Intraoperative Anesthetic Requirements**.** They came to the conclusion that the hypnotic component of the anaesthetic state experienced by patients undergoing general anaesthesia and surgery is not diminished by hemispheric synchronized noises. Their result was similar to our study.

All these studies by **Peter Szmuk et al**[51]**, Palmer J B et al**[20]**, Patil Kalyani N et al**[10]**, Migneault B et al**[24]**, Dabu-Bondoc et al**[65] couldn't demonstrate any decrease in anesthetic requirement by music. **Peter Szmuk et al**[51]**, Patil Kalyani N et al**[10] and **Migneault B et al**[24] studied anaesthetic requirement using inhalational anaesthesia as end-tidal anaesthetic requirement. None of these studies used binaural tone music; only patients' choice of music or instrumental music were used.

Music can also reduce patient's anxiety regarding surgery, redirect patient's attention towards music and can also enhance a feeling of wellbeing. Using music at patient's comfort sound level can help in masking from OT noises and have an smoothening effect. Thus, it may help for better hemodynamics, calm recovery and decreased anaesthestic requirement.

TIME OF FIRST RESCUE ANALGESIA

There was no statistically significant difference in time of first rescue analgesia between both groups in study (3.32±1.2 v/s 4.02 ± 6.041, p = 0.531).

Music has been shown to help postoperative recovery in adults, according to a comprehensive review and meta-analysis by **Hole J et al**[7]. They concluded that music improved patient

satisfaction (109 [051 to 168]) and decreased postoperative pain (SMD -077 [95% CI -099 to -056]), anxiety (-068 [-095 to -041]), and analgesic use.

A double-blind randomised controlled trial on improved recovery following music and therapeutic suggestions during general anaesthesia was conducted by **U. Nilsson et al.**[11] in 2001. Ninety women, ASA I–II, scheduled for an elective abdominal hysterectomy through a lower abdominal incision under general anaesthesia were divided into three groups: the control group, the music group, and the music group with therapeutic suggestions (M/TS). They concluded that patients exposed to music together with therapeutic suggestions needed less rescue analgesic than the controls and that patients in the music group had better effective analgesia on the first postoperative day and was mobilised earlier after the operation.

Alessandro Tani et al[54] demonstrated using binaural beat stimulation prior to surgery as a non-pharmacological treatment to lower morphine use in elderly patients having knee replacements is effective. **Li XM et al**[28] revealed after a radical mastectomy, music therapy had both short- and long-term beneficial benefits on reducing pain in breast cancer patients. Eventhough, there wasn't any statistically significant difference between two groups for the time of first rescue analgesia; there was significant difference on postoperative VAS scores and thus analgesic requirement.

POSTOPERATIVE PAIN (VAS SCORE)

Postoperative pain using Visual Analog Score (VAS score) was also assessed in both the groups and difference was found to be statistically significant ($p<0.005$) . Group A (Binaural tone music group) was found to have lower VAS score compared to other. There have been several studies to assess the effect of music on post-operative pain using VAS score. However, there are no studies comparing effect of binaural tone music with general anesthesia for postoperative analgesia. Most of the studies used patient selected music or instrumental music. Almost all the studies are in accordance with our study, proving role of music induced analgesia in the post-operative period.

Hole J et al[7] conducted a systematic review and metanalysis on improved recovery following music and concluded that music improved patient satisfaction (109 [051 to 168]) and decreased postoperative pain (SMD -077 [95% CI -099 to -056]), anxiety (-068 [-095 to -041]), and analgesic use. **Kahloul M et al**[9] studied the effect of music therapy under general anaesthesia for patients undergoing abdominal surgery and concluded there were lower average Visual Analog Scale (VAS) score in the intervention group (33.8 ± 13.63 versus 45.1 ± 16.2; $p < 10-3$). **Alessandro Tani et al**[54] demonstrated using binaural beat stimulation prior to surgery as a

non-pharmacological treatment to lower morphine use in elderly patients having knee replacements is effective. **U. Nilsson et al[11]** did a randomised controlled trial on Improved recovery after music and therapeutic suggestions during general anaesthesia and concluded patients exposed to music and therapeutic suggestions had reduced need for rescue analgesics. Additionally, patients in the music group had more effective analgesia on the first postoperative day and were able to leave the hospital sooner. **Ortega A et al[18]** studied effect of music therapy for pain and anxiety in management of nasal bone fracture reduction and concluded that the music group had significantly lower systolic blood pressure (P =.0001), anxiety (P = 00.0001), and pain (P =.0004) levels. **Kühlmann A Y R et al[19]** in 2017 conducted a systemic review and meta-analysis evaluating music interventions for anxiety and pain in surgery and found that music interventions significantly reduced anxiety and pain (MD -069, 95 percent CI -088 to -050; P 001), which is comparable to a decrease of 21mm for anxiety and 10mm for pain on a 100-mm visual analogue scale. **Mimi et al[25]** concluded music therapy is an effective nonpharmacologic approach for postoperative pain management. **Li XM et al[28]** revealed after a radical mastectomy, music therapy had both short- and long-term beneficial benefits on reducing pain in breast cancer patients. Eventhough, there wasn't any statistically significant difference between two groups for the time of first rescue analgesia; there was significant difference on postoperative VAS scores and thus analgesic requirement. Perioperative music, according to **Binns-Turner PG et al[27]**, can lessen discomfort, anxiety, and MAP in breast cancer mastectomy patients.

All these studies supported our result that perioperative music helps in reducing the post-operative VAS score and thus analgesic requirement. The process by which music therapy reduces pain is multifaceted and includes mnemonic encoding, activation of endorphin production, reduction of conduction in afferent fibers, and impact on psychomotility [(7)]. Thus, using binaural tone music during intraoperative period helps significantly to reduce the pain intensity during recovery period.

POSTOPERATIVE COMPLICATIONS

Even though the incidence of postoperative complications such as hypotension, post-operative nausea and vomiting (PONV), shivering and pain was more in control Group B as compared to intervention Group A but, there wasn't a statistically significant difference between both groups. Total of 6 patients in control group B had postoperative complications (4 had PONV and 2 had shivering); while in experimental group A, 2 had complications. (1 had PONV and other shivering).

No differences were discovered between the groups in terms of nausea, emesis, bowel function, overall wellbeing, or length of hospital stay by **U. Nilsson et al**. Effectiveness of Music Intervention on Postoperative Nausea and Vomiting was examined by **Fatma Dursun Ergezen et al**[61] (A Systematic Review and Meta-analysis). According to meta-analyses, music treatments had no statistically significant impact on postoperative nausea (95% CI: 0.13 to 0.70, Z = 1.34, P > 0.05, Hedge's g = 0.28), but significantly decreased postoperative vomiting (95% CI: 0.01 to 0.63, Z = 2.07, P 0.05, Hedge's g = 0.32).

So, probably perioperative binaural tone music has no role in causation or prevention of postoperative complications.

PATIENT SATISFACTION SCORE

Patients' satisfaction was assessed using a numerical satisfaction score (4= excellent, 3=good, 2=fair, 1=poor) 24 hours after surgery. Most of the patient in both groups marked fair. 2 patients in intervention group marked excellent while 1 patient in control marked poor. There was a statistically significant difference in both the groups, showing better patient satisfaction scores in binaural tone music group.

In their comprehensive review and meta-analysis on the use of music in adult postoperative recovery, **Hole J et al**[7] found that the music groups had higher patient satisfaction (109 [051 to 168]). According to **Kahloul M. et al**[9]'s study, the music therapy group's satisfaction rate was significantly greater (81.4% versus 51.4%; p 10-3). According to **Gökcek E. et al**[21], the patient satisfaction rate was considerably higher in the music group than the control group (73.3% vs. 36.6%; p 0.001). All these three studies results were concurrent with our study.

Music stimulates neurohumoral responses in our body, decreases overall stress and increases feeling of well-being, these all factors can combinedly affect overall satisfaction scores of patients.

Music being a non-pharmacological, low cost, low maintenance adjuvant therapy has many positive effects on patients posted for surgery under general anesthesia. No such study has been published till date on effect of binaural tone music on perioperative profile and outcome. This study may provide some insight about perioperative use of binaural tone music for surgeries under general anesthesia.

CONCLUSION & LIMITATION

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CONCLUSION

Perioperative binaural tone music under general anaesthesia can help in providing better recovery with calm patients in postoperative period, with lesser intraoperative anaesthestic requirement, reduced postoperative pain and lesser post-operative analgesic requirement. Patients were overall more satisfied in binaural tone music group at 24 hours postoperatively. Music affects neurohormonal responses, reducing overall stress response of body. It masks patient from operating room noises, provides a soothing effect and relaxation, which can further help in providing better hemodynamics, calm recovery, lesser anaesthestic requirement and decreasing post-operative pain when used in patients under general anaesthesia. Thus, we recommend more frequent usage of perioperative music therapy. Perioperative binaural tone music can be considered as add on therapy for better hemodynamics and good postoperative recovery in patients posted under general anaesthesia. Randomized control trials with larger sample sizes are further needed to establish our findings.

LIMITATIONS

1. We could have used perioperative EEG to correctly identify type of brain wave developing as a result of perioperative binaural tone music.
2. Freely available version of binaural tone music was used which might be not much reliable.
3. Our study was done in patients posted for laparoscopic abdominal surgery of less than 3 hours duration. More studies are needed in patients posted for major and longer duration surgeries to further assess the effect of binaural tone music under general anaesthesia.
4. Intraoperative awareness can occur during general anaesthesia and can lead to severe complications such as post-traumatic stress disorder (PTSD). We have not assessed intraoperative awareness in our patients. This could have been done, however we monitored depth of anaesthesia using BIS monitor.
5. Neuro hormonal assessment could have been done to substantiate the results and further increase their applicability. Perioperative, intraoperative and postoperative stress hormone (ACTH, cortisol, epinephrine, norepinephrine) levels could not be measured due to limited resources.

6. We could have measured baseline preoperative anxiety in both the groups and then further assess effect of binaural tone music under general anaesthesia on intraoperative propofol consumption, postoperative recovery and postoperative anxiety. We did not explored effect of preoperative anxiety, which could be a potential confounder.

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ANNEXURES

ANNEXURES

ANNEXURE 1

INSTITUTE'S ETHICAL COMMITTEE APPROVAL CERTIFICATE

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/2501 **Date: 12/03/2021**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3336**

Project title: **"Effect of perioperative music on recovery profile in patients undergoing abdominal surgeries under general anaesthesia: A randomized control trial"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.D. Dissertation**
Student Name:	**Dr. Muhammed Shahid Fasal**
Guide:	**Dr. Priyanka Sethi**
Co-Guide:	**Dr. Pradeep Kumar Bhatia, Dr. Ankur Sharma, Dr. Kamlesh Kumari & Dr. Darshana Rathod**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation. If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Basni Phase-2, Jodhpur, Rajasthan-342005; **Website:** www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

ANNEXURE 2

All India Institute of Medical Sciences, Jodhpur, Rajasthan.

Informed Consent Form

Title of the Project: EFFECT OF PERIOPERATIVE MUSIC ON RECOVERY PROFILE IN PATIENTS UNDERGOING ABDOMINAL SURGERIES UNDER GENERAL ANAESTHESIA: A RANDOMIZED CONTROL TRIAL

Name of the Principal Investigator: Dr Muhammed Shahid Fasal

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 recovery profile in patients undergoing abdominal surgeries under general anaesthesia: 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 and place: _____

Signature of Principal Investigator

1. Witness 1 2. Witness 2

Signature Signature

ANNEXURE 3

ऑल इंडिया इंस्टिट्यूट ऑफ मैडिकल साईंसिस,जोधपुर,राजस्थान

सूचित सहमति

अध्ययन का विषय: पेट की सर्जरी से गुजर रहे रोगियों में सामान्य संज्ञाहरण से ठीक होने पर संगीत दवा का प्रभाव - रैंडमआइस्ड कण्ट्रोल ट्रायल

प्रधानअन्वेषककानाम: डॉ मुहम्मद शाहिद फज़ल

रोगी /स्वयं सेवक पहचान संख्या:

मैं _____ S/o or D/o

_____ R/o

_____

अध्ययन "पेट की सर्जरी से गुजर रहे रोगियों में सामान्य संज्ञाहरण से ठीक होने पर संगीत दवा 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 4

PARTICIPANT INFORMATION SHEET (PIS)

Title of the Project: Effect of perioperative music on recovery profile in patients undergoing abdominal surgeries under general anaesthesia: A Randomized Control Trial

Name of the Principal Investigator: Dr Muhammed Shahid Fasal

Telephone Number: 8113985315

I have been explained in my own understanding language by the principal investigator that they are doing this study to see the effect of music medicine on recovery profile in patients undergoing abdominal surgeries under general anaesthesia

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 5

अखिल भारतीय आयुर्विज्ञानसंस्थान, जोधपुर, राजस्थान

प्रतिभागी सूचनापत्रक

पेट की सर्जरी से गुजर रहे रोगियों में सामान्य संज्ञाहरण से ठीक होने पर संगीत दवा का प्रभाव - रैंडमआइस्ड कण्ट्रोल ट्रायल

प्रधान अन्वेषक का नाम: डॉ मुहम्मद शाहिद फज़ल Tel. No.: 8113985315

मुझे मुख्य अन्वेषक द्वारा अपनी समझकी भाषा में समझाया गया है कि पेट की सर्जरी से गुजर रहे रोगियों में सामान्य संज्ञाहरण से ठीक होने पर संगीत दवा का प्रभाव 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 6

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

Department of Anaesthesiology &Critical Care

PROFORMA

PATIENT ID Age/Sex-

ASA- Diagnosis- Surgery-

Baseline (before Music)	Mean BP	Pulse

Intraoperative Hemodynamics:

Time (minutes):	5	10	15	30	60	90	120	180	210
MBP									
Pulse									

Total propofol consumption	**Duration of surgery**	**Time of rescue analgesic**

Post-operative:

Time	**RAAS scoring**	**MBP**	**Pulse**
At extubation			
10 (minutes)			
20 (minutes)			
30 (minutes)			

Time	30 mins	60mins	90mins	120mins	6 hours
VAS (PAIN) score					

24 hours postoperatively:

Any complication	**Patient Satisfaction Score:**	4-Excellent 3-Good 2-Fair 1-Poor (scoring)

ANNEXURE 7

MASTER CHART

	PATIENT ID	AGE (year)	SEX	ASA GRADE	WEIGHT	DIAGNOSIS	SURGERY	BASELINE MBP (mm of hg)	BASELINE PULSE (per minute)	M5'	M10'	M15'	M30'	M60'	M90'	M120'	M180'	M210'	P5'	P10'	P15'	P30'	P60'	P90'	P120'	P180'	P210'
1	AIIMS/JDH/2021/07/000847	50	F	1	50KG	Cholelithiasis	Lap Cholecystectomy	94	84	80	72	68	68	76	86	90			82	80	76	78	72	74	76		
2	AIIMS/JDH/2021/12/007558	58	F	2	58KG	Cholelithiasis	Lap Cholecystectomy	96	92	82	72	70	74	68	76	84			82	78	72	74	78	80	82		
3	AIIMS/JDH/2021/08/002882	23	M	1	74KG	Inguinal Hernia [L]	TEP (L)	100	88	72	68	74	78	84	88	92			78	76	74	76	78	74	82		
4	AIIMS/JDH/2021/06/000258	41	F	1	48kg	Ovarian cyst [L]	Laparoscopic cystectomy	94	94	84	76	88	84	86					82	80	78	84	86				
5	AIIMS/JDH/2022/01/035812	20	M	1	76KG	Splenic cyst	Lap Cyst Deroofing	96	78	82	74	72	76	76	82				82	78	74	78	86	88			
6	AIIMS/JDH/2022/02/017434	34	M	1	74KG	Cholelithiasis	Lap Cholecystectomy	98	85	88	74	80	78	82	86				86	90	88	82	78	76			
7	AIIMS/JDH/2021/09/007727	32	M	1	78KG	Cholelithiasis	Lap Cholecystectomy	96	86	86	72	72	70	76	78				80	82	84	78	86	86			
8	AIIMS/JDH/2021/09/003551	28	M	1	72kg	Inguinal Hernia [R]	TEP [R]	96	90	76	64	66	65	68	70	72			54	56	58	64	66	62	78		
9	AIIMS/JDH/2022/03/000301	28	M	1	68KG	Inguinal Hernia [L]	TAPP[L]	98	94	84	74	70	72	80					82	84	80	78	80				
10	AIIMS/JDH/2021/03/002532	60	F	2	68kg	Cholelithiasis	Lap Cholecystectomy	102	92	64	72	70	72	84	86				78	76	81	78	76	88			
11	AIIMS/JDH/2021/08/011408	50	M	2	76kg	Cholelithiasis	Lap Cholecystectomy	98	92	74	70	68	68	72	70				86	80	72	74	78				
12	AIIMS/JDH/2021/09/009242	54	M	1	72KG	GB Polyp	Lap Cholecystectomy	98	90	70	72	70	64	64					68	70	68	102	92				
13	AIIMS/JDH/2021/08/000419	58	F	1	58KG	AUB	Lap TAH + BSO	94	70	74	80	98	102	100	98	100			62	66	68	64	64	66	64		
14	AIIMS/JDH/2021/04/006788	50	F	2	60kg	Cholelithiasis	Lap Cholecystectomy	94	101	88	70	94	92	92	94				90	86	84	86	84	82			
15	AIIMS/JDH/2021/03/002098	21	F	1	48kg	Cholelithiasis	Lap Cholecystectomy	102	100	70	62	75	80	85	88				82	66	63	74	90	70	74		
16	AIIMS/JDH/2021/07/007261	45	F	1	64kg	Cholelithiasis	Lap Cholecystectomy	94	82	85	90	86	86	80	90				82	84	86	86	86	78	98		
17	AIIMS/JDH/2021/07/017745	45	F	1	58KG	AUB	Lap TAH + BSO	96	92	86	74	82	76	70	74	82			78	62	64	68	70	68	78		
18	AIIMS/JDH/2021/09/005660	31	F	1	54kg	Cholelithiasis	Lap Cholecystectomy	94	92	76	78	68	76	82	80	78			90	82	84	86	82	84	80		
19	AIIMS/JDH/2020/12/003349	33	F	1	58kg	AUB-L	Lap TLH	96	102	94	80	76	84	84	78	80			92	82	74	70	76	70	70		
20	AIIMS/JDH/2021/10/001590	43	F	2	62KG	Cholelithiasis	Lap Cholecystectomy	88	96	78	66	70	74	80	78	76			80	76	70	72	74	72	74		
21	AIIMS/JDH/2021/09/013600	60	F	1	57KG	Cholelithiasis	Lap Cholecystectomy	88	86	72	70	64	68	70					76	72	70	74	70				
22	AIIMS/JDH/2020/08/008273	34	M	1	72kg	Inguinal Hernia [L]	TAPP [L]	96	82	80	72	76	74	72	77	82			78	78	76	80	76	74	77		
23	AIIMS/JDH/2021/08/018218	55	F	1	64KG	Cholelithiasis	Lap Cholecystectomy	98	79	98	84	80	82	78	78	86			68	66	78	76	68	76	80		
24	AIIMS/JDH/2022/02/000967	33	F	1	58kg	AUB with ovarian cyst	Lap Cystectomy	102	106	80	84	86	99	96	102				92	94	86	82	88	86			
25	AIIMS/JDH/2022/01/035812	20	M	1	76kg	Splenic Cyst	Laparoscopic cyst deroofing	104	84	82	68	70	76	84	90				70	76	78	86	90	86			
26	AIIMS/JDH/2022/03/007096	21	M	1	74kg	Inguinal Hernia [L]	TAPP[L]	102	68	78	66	70	76	84	80				68	66	80	68	70	76			
27	AIIMS/JDH/2015/04/001006	60	M	2	70KG	Inguinal Hernia [L]	TAPP (L)	108	88	80	74	70	86	84					84	78	86	80	82				
28	AIIMS/JDH/2018/09/011037	34	M	1	80KG	Cholelithiasis	Lap Cholecystectomy	102	92	88	82	78	80	84	86	84			82	78	74	76	86	80	86		
29	AIIMS/JDH/2022/02/013204	31	F	1	56KG	Ovarian mass [R]	Lap Right Salpingooophorectomy	96	84	74	68	72	74	76	78	88			76	70	78	88	86	80	90		
30	AIIMS/JDH/2022/04/012447	49	M	1	76kg	Cholelithiasis	Lap Cholecystectomy	104	88	82	78	88	92	82	88				78	68	78	88	94	86			
31	AIIMS/JDH/2022/02/016367	28	F	1	55KG	Cholelithiasis	Lap Cholecystectomy	100	92	76	70	68	84	78	80				76	80	78	86	80	88			
32	AIIMS/JDH/2022/03/007047	20	M	1	74KG	Inguinal hernia [L]	TAPP [L]	102	82	78	76	68	74	78					84	76	72	68	76				
33	AIIMS/JDH/2021/11/007935	30	F	1	60kg	Cholelithiasis	Lap Cholecystectomy	98	82	78	70	80	84	78	80				84	76	74	78	76	76			
34	AIIMS/JDH/2017/03/004607	30	F	1	52kg	Acute appendicitis	Lap appendicectomy	96	88	70	68	72	76	80	86				88	82	90	76	80	84			
35	AIIMS/JDH/2021/09/011893	48	F	2	55kg	Symptomatic cholelithiasis	Lap Cholecystectomy	102	92	66	68	76	82	86	88				84	88	82	94	80	78			

	TOTAL PROPOFOL CONSUMPTION	DURATION OF SURGERY	RESCUE ANALGESIC	RAAS AT EXTUBATION	RAAS 10'	RAAS 20'	RAAS 30'	MBP AT EXTUBATION	M 10'	M20'	M30'	PULSE AT EXTUBATION	P 10'	P 20'	P 30'	VAS (R) AT 30'	VAS (M) AT 30'	VAS (R) AT 60'	VAS (M) AT 60'	VAS (R) AT 90'	VAS (M) AT 90'	VAS (R) AT 120'	VAS (M) AT 120'	VAS (R) AT 6 HOURS	VAS (M) AT 6 HOURS	POST-OP COMPLICATION	PATIENT SATISFATION SCORE
1	680mg	1 hour 15 minutes	4 hour	-2	-1	-1	0	88	94	90	88	90	82	80	74	3	3	2	3	3	4	2	3	2	3	NA	3-GOOD
2	700mg	1 hour 15minutes	4 hour	-2	-1	0	0	96	92	94	90	86	84	80	76	3	3	2	3	2	3	2	3	2	3	NA	3-GOOD
3	720mg	1hour	4 hour	-2	-1	0	0	96	90	92	88	86	90	82	86	3	3	2	3	2	3	2	3	1	2	NA	3-GOOD
4	600mg	1hour	4 hour	-3	-2	0	1	98	93	100	100	82	88	71	72	3	3	3	4	2	3	2	3	1	2	NA	4-EXCELLENT
5	780mg	1hour 30minutes	4 hour	-2	-1	0	0	92	90	88	88	92	82	84	86	3	3	2	3	3	4	2	3	2	3	NA	3-GOOD
6	680mg	1hour 15minutes	4 hour	-2	-1	-1	0	90	92	90	88	86	90	84	86	3	3	3	4	2	3	2	3	1	2	NA	3-GOOD
7	720mg	1hour 30minutes	2 hour	-2	-1	0	0	96	96	92	94	88	90	82	80	4	4	3	4	2	3	3	4	2	3	NA	2-FAIR
8	1000mg	2hours 20minutes	4 hour	-3	-2	-1	-1	94	92	88	82	98	94	86	78	4	4	3	4	2	3	2	3	1	3	NA	2-FAIR
9	580mg	1hour	4 hour	-2	-1	-1	0	98	96	92	94	88	90	82	80	3	3	2	3	2	3	2	4	2	3	NA	3-GOOD
10	650mg	1hour 30minutes	2 hour	-2	-1	0	0	82	86	84	80	90	88	86	84	4	4	3	4	2	3	3	4	2	3	NA	2-FAIR
11	680mg	1hour	30minutes	-1	0	0	0	96	90	94	90	86	78	80	82	3	3	2	3	3	4	2	3	3	4	NA	2-FAIR
12	500mg	1hour	2 hour	0	0	0	0	100	106	102	96	90	96	86	86	4	4	4	5	3	4	2	3	2	3	NA	2-FAIR
13	560mg	1hour 40minutes	4 hour	0	0	0	0	92	92	100	102	60	58	59	60	4	4	3	4	2	4	2	3	2	3	NA	2-FAIR
14	600mg	1 hour 30minutes	4 hour	-2	-1	0	0	92	90	90	92	84	86	82	80	4	4	2	3	3	5	2	3	1	3	Shivering	2-FAIR
15	800mg	2hour 15minutes	4 hour	-2	-1	1	2	80	76	76	75	102	98	95	90	3	2	2	3	2	3	2	4	1	2	NA	3-GOOD
16	800mg	1hour 45minutes	1 hour	-1	0	0	0	86	90	92	91	102	96	98	90	4	4	3	4	4	5	4	5	3	3	NA	2-FAIR
17	820mg	2hour 30minutes	2 hour	-3	-2	-1	0	100	92	90	90	98	94	88	86	4	4	4	5	4	5	2	3	1	3	NA	2-FAIR
18	560mg	1hour 30minutes	4 hour	-3	-2	-2	0	90	92	94	94	88	90	86	84	4	4	2	3	2	3	3	4	2	4	NA	2-FAIR
19	740mg	2 hour 20minutes	2 hour	-2	-1	0	0	88	90	88	86	86	84	82	80	4	4	4	5	3	4	3	4	2	3	NA	2-FAIR
20	680mg	2hour	4 hour	-1	0	0	0	90	86	88	82	84	78	82	78	5	5	3	4	4	5	2	3	2	3	NA	3-GOOD
21	500mg	1hour	2 hour	-1	0	0	0	94	90	94	96	82	86	80	78	5	5	3	4	4	5	2	3	2	3	NA	2-FAIR
22	850mg	2hour 15minutes	4 hour	-2	-1	0	0	94	90	92	94	90	88	88	86	4	4	3	4	2	4	3	4	2	3	NA	2-FAIR
23	1000mg	2hour 30minutes	4 hour	0	0	0	0	92	88	94	92	82	84	80	82	4	4	2	3	3	4	2	3	1	3	NA	2-FAIR
24	840mg	1hour 30minutes	2 hour	-1	0	0	0	100	94	96	100	85	88	90	76	5	5	4	4	3	4	2	3	1	3	PONV	2- FAIR
25	640mg	1hour 30minutes	4 hour	-2	-1	0	0	102	98	100	98	94	90	88	82	4	4	2	3	2	3	3	4	1	3	NA	3-GOOD
26	720mg	1hour 30minutes	4 hour	-2	-2	-1	0	96	98	96	96	100	98	88	86	5	5	2	4	2	4	2	3	1	2	NA	4-EXCELLENT
27	500mg	1hour	4 hour	-1	-1	0	0	102	100	98	98	86	84	80	86	4	4	3	4	3	4	2	4	1	3	NA	2-FAIR
28	800mg	1hour 30minutes	5 hour	-1	0	0	1	100	98	102	104	96	92	88	90	4	4	2	3	2	3	2	3	0	2	NA	3-GOOD
29	700mg	2hours	2 hour	-2	-1	0	0	104	98	100	98	96	98	88	90	4	4	4	5	2	3	2	3	1	3	NA	2-FAIR
30	700mg	1hour 30minutes	5 hour	-2	-2	-1	0	102	104	98	100	92	90	94	86	4	4	3	4	3	4	2	4	1	2	NA	3-GOOD
31	640mg	1hour 30minutes	4 hour	-2	-1	0	0	100	96	98	96	92	86	84	78	4	4	3	4	3	4	2	3	0	2	NA	3-GOOD
32	580mg	1hour	5 hour	-1	0	0	0	100	98	96	96	96	100	94	86	4	4	2	4	2	3	2	3	1	2	NA	2-FAIR
33	560mg	1hour 15minutes	2 hour	-2	-1	-1	0	98	100	102	100	98	96	96	88	4	4	3	4	2	4	2	3	0	2	NA	3-GOOD
34	660mg	1hour 30minutes	4 hour	-2	-1	0	0	102	98	96	102	98	88	84	78	3	3	3	4	2	3	2	3	1	2	NA	3-GOOD
35	640mg	1hour 30minutes	2 hour	-1	-1	0	0	96	98	96	104	106	84	88	80	3	3	3	4	2	3	3	4	1	3	NA	2-FAIR

Sr. No.	PATIENT ID	AGE (years)	SEX	ASA GRADE	WEIGHT	DIAGNOSIS	SURGERY	BASELINE MBP (mm of hg)	BASELINE PULSE (per minute)	M5'	M10'	M15'	M30'	M60'	M90'	M120'	M180'	M210'	P5'	P10'	P15'	P30'	P60'	P90'	P120'	P180'	P210'
1	AIIMS/JDH/2021/08/012926	44	F	2	58KG	Ovarian cyst	Lap Cystectomy	96	98	70	66	84	68	66	70	72			76	76	72	70	72	74	82		
2	AIIMS/JDH/2021/04/002602	54	M	2	76kg	Inguinal hernia [R] with varicocele	Lap hernioplasty with varicocelectomy	96	82	68	69	78	82	84	88	68			65	62	68	70	67	68	82		
3	AIIMS/JDH/2021/08/011408	50	M	2	75kg	Cholelithiasis	Lap Cholecystectomy	102	84	68	70	74	80	84	80				64	68	68	72	68	68			
4	AIIMS/JDH/2021/09/012235	31	F	1	50kg	AUB	TLH	94	88	92	86	84	84	78	86				100	96	94	92	94	82			
5	AIIMS/JDH/2021/09/001686	39	F	1	44kg	Cholelithiasis	Lap Cholecystectomy	86	92	86	78	76	84	80	90				82	84	84	82	84	88			
6	AIIMS/JDH/2021/08/004990	21	F	1	45kg	Cholelithiasis	Lap Cholecystectomy	88	88	88	86	84	81	88	91				82	84	84	89	87	80			
7	AIIMS/JDH/2021/11/007935	30	F	1	48kg	Cholelithiasis	Lap Cholecystectomy	96	98	90	84	70	74	78	88				100	92	88	86	84	84			
8	AIIMS/JDH/2021/06/010487	51	F	1	60kg	Cholelithiasis	Lap Cholecystectomy	100	92	94	80	84	100	100	105	104			64	66	61	64	64	69	72	72	
9	AIIMS/JDH/2021/08/011778	54	F	2	54kg	Cholelithiasis	Lap Cholecystectomy	92	70	90	66	63	68	72	70				76	62	72	74	62	64			
10	AIIMS/JDH/2021/07/015875	48	M	1	78kg	Inguinal hernia [Bilateral]	B/L TEP	96	82	94	92	86	84	86	86	86			90	80	78	82	84	78	82		
11	AIIMS/JDH/2021/09/012235	31	F	1	50kg	Cholelithiasis	Lap Cholecystectomy	76	111	65	71	80	80	70	71	65			121	120	120	94	91	94	94		
12	AIIMS/JDH/2021/10/005154	43	F	1	54KG	Cholelithiasis	Lap Cholecystectomy	90	68	100	102	104	107	99	87				68	80	80	86	70	68			
13	AIIMS/JDH/2021/03/000505	44	F	1	56kg	Ovarian mass [L] Serous cystadenoma	Laparoscopic salpingo-oophorectomy	96	90	96	90	92	86	90	88	90	86		86	80	74	65	58	60	62	80	
14	AIIMS/JDH/2022/02/015622	36	F	1	42kg	Cholelithiasis	Lap Cholecystectomy	90	98	82	78	70	72	84	88				90	92	88	86	88	86			
15	AIIMS/JDH/2022/02/016367	28	F	1	46kg	Cholelithiasis	Lap Cholecystectomy	96	100	86	78	74	76	80	90	92			96	88	86	90	88	90	92		
16	AIIMS/JDH/2021/07/001928	51	M	2	72kg	Inguinal hernia [R]	TAPP (R)	94	72	66	64	68	66	68	66				76	71	70	72	74	76	78	82	
17	AIIMS/JDH/2021/10/002019	49	M	1	70KG	Inguinal hernia [Bilateral]	B/L TEP	104	82	78	70	65	74	76	84				76	70	72	70	74	76			
18	AIIMS/JDH/2021/07/015440	20	F	1	50KG	Endometrioma [R]	Lap Cystectomy	94	98	92	88	82	78	80	82				98	92	90	82	84	80	84		
19	AIIMS/JDH/2021/06/004551	45	M	2	68KG	Recurrent inguinal hernia [R]	TAPP [R]	92	84	96	90	86	88	90	94	96	94		82	84	84	82	74	76	78	82	
20	AIIMS/JDH/2021/09/009856	35	M	1	74kg	Inguinal hernia [L]	TAPP (L)	96	96	94	96	90	86	88	88	94	92		80	82	84	84	84	76	78	80	
21	AIIMS/JDH/2021/10/001590	43	F	2	56kg	AUB	TLH	96	100	78	74	82	78	84	86	90			94	92	84	88	90	86	88		
22	AIIMS/JDH/2020/11/000856	36	M	2	78kg	Cholelithiasis	Lap Cholecystectomy	90	96	78	72	80	82	88	90	86			88	84	86	78	74	78	88		
23	AIIMS/JDH/2021/10/005154	43	F	2	58kg	AUB	TLH	96	92	78	70	68	78	82	84	86			84	88	78	72	70	72	84		
24	AIIMS/JDH/2021/07/012318	60	F	2	64kg	Inguinal hernia [L]	TAPP (L)	100	96	92	82	78	74	84	88	98			96	94	92	88	90	86	86		
25	AIIMS/JDH/2021/06/010487	51	F	1	58KG	Cholelithiasis	Lap Cholecystectomy	100	80	94	80	84	100	100	105	104			74	66	61	64	69	72	72		
26	AIIMS/JDH/2021/09/017630	26	M	1	74KG	Inguinal Hernia [L]	TAPP (L)	94	86	82	76	72	76	88	86				84	76	88	94	96	88			
27	AIIMS/JDH/2017/11/014615	44	F	2	50KG	Cholelithiasis	Lap Cholecystectomy	92	94	82	70	72	76	84	88				90	96	94	96	90	88			
28	AIIMS/JDH/2022/01/031767	38	M	1	80KG	Cholelithiasis	Lap Cholecystectomy	104	86	84	72	70	84	82	84				92	88	94	88	90	86			
29	AIIMS/JDH/2013/09/001031	47	F	2	56KG	Cholelithiasis	Lap Cholecystectomy	100	82	82	66	68	70	72	86				88	94	84	78	76	80			
30	AIIMS/JDH/2022/02/012006	31	F	1	50KG	Cholelithiasis	Lap Cholecystectomy	96	98	90	68	96	92	88	94				96	102	98	104	96	94			
31	AIIMS/JDH/2022/02/017466	36	M	1	76KG	Inguinal Hernia [L]	TAPP [L]	96	78	78	70	86	90	94	96				86	96	104	96	94	98			
32	AIIMS/JDH/2022/02/005025	46	M	2	80kg	Inguinal Hernia[L]	TAPP (L)	98	82	82	68	88	96	94	96				90	84	86	84	88	90			
33	AIIMS/JDH/2022/03/005861	55	F	2	62kg	Cholelithiasis	Lap Cholecystectomy	102	92	90	76	102	98	82	84				96	90	88	86	90	88			
34	AIIMS/JDH/2021/12/006978	51	M	2	76KG	Corrosive pyloric stricture	Lap Gastrojejunostomy	102	94	90	66	74	86	88	86				90	94	96	90	88	86			
35	AIIMS/JDH/2022/02/010097	34	F	2	58KG	Recurrent hydatid cyst	Lap Deroofing	96	90	80	66	84	72	70	70	72			76	76	72	70	72	74	82		

Sr. No.	TOTAL PROPOFOL CONSUMPTION	DURATION OF SURGERY	TIME OF FIRST RESCUE ANALGESIA	RAAS AT EXTUBATION	RAAS 10'	RAAS 20'	RAAS 30'	MBP AT EXTUBATION	M 10'	M20'	M30'	PULSE AT EXTUBATION	P 10'	P 20'	P 30'	VAS (R) AT 30'	VAS (M) AT 30'	VAS (R) AT 60'	VAS (M) AT 60'	VAS (R) AT 90'	VAS (M) AT 90'	VAS (R) AT 120'	VAS (M) AT 120'	VAS (R) AT 6 HOURS	VAS (M) AT 6HOURS	POST-OP COMPLICATION	PATIENT SATISFATION SCORE
1	1000mg	2 hours	4 hour	-2	-1	0	1	92	94	88	90	98	92	78	80	3	3	4	3	4	4	3	5	2	3	NA	2-FAIR
2	960mg	2 hours	4 hour	-2	-1	0	0	82	81	86	84	98	70	70	72	3	4	3	3	2	3	3	4	2	3	NA	2-FAIR
3	960mg	1 hour 30 min	2 hour	-2	-1	0	0	94	92	90	88	96	94	90	86	3	4	3	4	2	3	3	4	3	4	NA	2-FAIR
4	900mg	1 hour 30 minutes	2 hour	-1	-1	0	1	96	94	96	96	100	98	96	90	4	3	4	4	4	5	4	5	3	4	Shivering	2-FAIR
5	800mg	1 hour 30 minutes	2 hour	-2	-2	-1	0	88	92	92	90	86	90	92	86	4	5	3	4	4	5	3	4	3	4	NA	2-FAIR
6	800mg	1 hour 30 minutes	4 hour	-3	-2	-2	0	100	94	94	92	100	90	94	86	3	4	4	5	4	5	3	4	2	3	NA	2-FAIR
7	800mg	1 hour 15 minutes	4 hour	-1	0	1	1	98	92	94	96	102	100	88	90	4	5	4	5	4	5	4	5	2	3	NA	2-FAIR
8	1020mg	2 hours 30 minutes	4 hour	-2	1	0	0	84	84	82	80	78	72	74	76	3	4	4	5	4	5	2	3	2	3	NA	2-FAIR
9	850mg	1 hour 30 minutes	4 hour	-3	-2	-1	0	96	88	98	96	88	90	94	90	3	4	4	5	5	6	3	4	2	4	NA	2-FAIR
10	1060mg	2 hours 30 minutes	2 hour	-2	-2	-1	0	96	100	96	94	90	92	88	96	6	7	5	6	5	6	5	6	3	4	PONV	1-POOR
11	860mg	2 hours	30minutes	-3	-2	-1	0	70	68	68	68	121	91	94	100	5	6	6	7	4	5	4	5	3	4	NA	2-FAIR
12	1050mg	1 hour 30 minutes	2 hour	-1	0	0	0	82	80	83	80	77	76	75	77	3	4	4	5	4	5	4	5	2	3	NA	2-FAIR
13	1000mg	2 hours 30 minutes	4 hour	1	-1	-1	0	100	96	94	94	74	70	68	70	3	4	3	4	3	4	3	4	2	4	NA	2-FAIR
14	800mg	1 hour 15 minutes	1 hour	-1	-1	0	0	96	94	90	90	94	86	90	88	3	4	3	4	4	5	3	4	2	3	PONV	2-FAIR
15	920mg	1 hour 30 minutes	4 hour	-1	0	1	1	98	92	94	94	96	88	90	90	3	4	3	4	2	3	2	3	2	3	NA	2-FAIR
16	1200mg	1 hour 30 minutes	4 hour	-2	-1	0	0	80	82	84	86	72	80	78	82	3	4	4	5	4	5	3	4	2	4	NA	3-GOOD
17	800mg	1 hour 30 minutes	4 hours	-1	-1	0	0	94	96	94	92	92	88	88	90	3	4	4	5	4	5	3	4	0	2	NA	2-FAIR
18	750mg	1 hour	4 hour	-1	0	0	0	96	94	92	88	90	86	86	84	3	4	4	5	4	5	3	4	1	3	NA	2-FAIR
19	1100mg	2 hours	2 hour	-1	-1	0	0	96	94	98	94	90	88	90	84	4	5	3	4	3	3	3	4	2	3	NA	2-FAIR
20	1120mg	2 hours	2 hour	-2	-1	0	0	92	90	90	94	80	78	82	82	4	4	4	5	3	5	4	5	3	4	NA	2-FAIR
21	960mg	1 hour 30 minutes	2 hour	-1	-1	0	0	92	94	94	92	96	88	90	84	4	5	4	5	3	4	4	5	3	4	PONV	2-FAIR
22	900mg	1 hour 15 minutes	2 hour	-1	0	0	1	94	90	88	92	100	98	88	92	4	5	4	5	3	4	3	4	2	4	NA	2-FAIR
23	960mg	1 hour 30 minutes	1 hour	-1	0	0	0	94	96	92	90	98	94	86	94	3	4	4	5	4	5	4	5	3	3	Shivering	2-FAIR
24	1000mg	1 hour 45 minutes	1 hour	-1	-1	0	0	100	102	96	94	110	98	90	92	4	5	4	5	3	4	4	5	2	3	NA	2-FAIR
25	1020mg	2hours 30 minutes	2 hour	-2	-1	0	0	86	88	82	80	78	72	74	76	3	4	4	5	4	5	2	3	2	3	NA	2- FAIR
26	860mg	1hour 15 minutes	5hour	-1	0	0	0	94	100	94	96	90	92	90	86	3	4	3	4	3	4	3	4	2	3	NA	3-GOOD
27	880mg	1hour 30minutes	4 hour	-1	-1	0	0	94	96	96	90	96	90	88	90	3	4	4	5	4	5	3	4	2	3	NA	2-FAIR
28	940mg	1 hour 30 minutes	5hour	-1	-1	0	0	96	94	90	92	96	92	86	88	3	4	4	5	4	5	3	4	2	3	NA	3-GOOD
29	800mg	1hour 15minutes	4 hour	-1	-1	0	0	96	98	88	90	94	88	90	86	3	4	4	5	4	5	3	4	2	3	NA	2-FAIR
30	900mg	1hour 15minutes	2 hour	-1	0	0	0	98	100	96	94	96	94	100	90	3	4	4	5	4	5	4	5	2	3	NA	3-GOOD
31	920mg	1hour 30minutes	4 hour	-1	0	0	0	98	102	96	94	98	96	100	94	3	4	4	5	4	5	2	3	2	3	NA	3-GOOD
32	940mg	1hour 15minutes	5hour	-1	-1	0	0	98	102	94	96	96	94	84	86	3	4	4	5	4	5	2	3	2	3	NA	2- FAIR
33	1050mg	1hour 30minutes	4 hour	-1	-1	0	0	102	104	98	100	96	94	88	92	3	4	4	5	4	5	2	3	2	3	NA	2-FAIR
34	1300mg	2hour 30 minutes	30minutes	-2	-1	-1	0	96	100	98	96	96	94	86	88	5	6	4	5	4	5	4	5	4	5	PONV	2-FAIR
35	900mg	1hour 45minutes	4 hour	-2	-1	0	1	92	94	88	90	98	92	78	80	4	5	4	5	4	5	3	4	2	3	NA	2-FAIR