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# COMPARISON OF EFFICACY OF TWO TYPES OF MUSIC PLAYED INTRA-OPERATIVELY AS AN ADJUNCT TO SPINAL ANESTHESIA FOR BETTER PERI-OPERATIVE EXPERIENCE OF THE PATIENT: A RANDOMISED CONTROL STUDY

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**Keywords:**

Anesthesia, Perioperative anxiety, Non-pharmacological methods, Music therapy, Post-operative pain

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**ABSTRACT: Aim:** To compare the effects of two types of music (meditation and devotional) played intra-operatively and control (no music) as an adjunct to spinal anaesthesia for better and holistic approach to perioperative care of the patient. **Methodology:** A prospective, randomised control study was conducted at a tertiary care hospital with 60 patients. The patients were randomly allocated into three groups with 20 members in each group as group A with meditation music, group B with devotional music and group C with no music. Informed consent was obtained from the patients and the following parameters were observed – intra-operative hemodynamic profile, post-operative anxiety, post-operative nausea & vomiting and overall patient satisfaction. After intervention data was collected and statistically analyzed. **Results:** The patients in the intra-operative music groups showed statistically significant reduction in post-operative anxiety and pain and better hemodynamic profile. The patients in the meditation group showed statistically significant reduction in the same parameters when compared with the patients in the devotional group. Overall patient satisfaction was more significant in devotional group as compared to medication group and control group. **Conclusion:** We showed that music played intraoperatively is good adjunct to spinal anaesthesia and has potential to enrich patients' perioperative experience by reducing intra-operative and post-operative anxiety, improving hemodynamic profile and increasing overall patient satisfaction.

**INTRODUCTION:** The incidence of pre-operative anxiety has been determined to be between 32% to 61% [1, 2, 3, 4] depending on gender, setting of surgery, motives of surgery and other factors. Perioperative anxiety has been described as a vague, uneasy feeling, the source of which is often nonspecific and unknown to the individual. Three distinct dimensions of preoperative anxiety are known: fear of the unknown, fear of feeling ill, and fear for life [5].

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The loss of autonomy during surgery and anaesthesia and the fear of resulting complications, incapacitation, death results in distressing anxiety in the perioperative scenario [6]. Anxiety can lead to abnormal hemodynamics as a result of stress response and stimulation of the autonomic and neuro-endocrine systems.

Several studies have descried mechanisms such as excessive cortisol production with insulin resistance and sympathetic and vagal disturbances [7, 8, 9]. One study postulated that elevated cortisol levels as a response of excessive anxiety may suppress the immune system precipitating post-operative infectious complications [10]. This leads to a stressful and unpleasant experience for the patient requiring surgery and leads to difficulties in managing the perioperative period for the

anaesthesiologist [2]. Different individuals react differently to anxiety and stressful situations. Their response is determined by their mental framework and adaptability to a stressful situation [2]. Significant predictors of perioperative anxiety are age, gender, availability of family support and type of surgery [11]. Pre-operative anxiety has shown to increase post-operative anxiety [12], increased analgesic requirements and prolonged recovery and hospital stay [13, 14]. Induction of anaesthesia and patient recovery is adversely affected by anxiety [15]. The overall experience of the patient is unsatisfactory and leads to increased anxiety to further surgical procedures if warranted.

There is increased interest in obtaining solutions to reduce perioperative anxiety and enable a holistic, pleasant perioperative experience for the patient. Both pharmacological and non-pharmacological methods have been researched to reduce perioperative anxiety. Amongst the available solutions, music is an economical, non-invasive and non-pharmacological technique that has shown to reduce anxiety and enhance the holistic perioperative experience of the patient [16, 17].

S Leardi *et al* have shown that music reduces the stress response to day surgery [18]. The ambient noises in operation room include the sounds from the monitors and other equipment and the conversations between the staff. This can elevate anxiety levels in patients, especially those undergoing anaesthesia by regional techniques [19].

Studies have shown that playing music in the intra-operative period showed reduction in anxiety, pain [5, 16, 19] and ensured a more pleasant perioperative experience. Nilsson showed that listening to music reduced serum cortisol levels in post cardiac surgery patients [20]. Music of a relaxing tempo and soothing melody are being used as part of relaxation techniques and spa treatments. Though different genre of music is available, many studies have shown that mediational music of relaxing, nature sounds has the most impact on reducing stress and anxiety. One study showed that when the choice of music was given to the individual, the neuro-hormonal stress response was significantly reduced [18]. Another study showed that music of patients' choice resulted in lower anxiety levels and better satisfaction scores [21].

We determined to compare the effect of meditational music with soothing nature melodies and devotional music of the patients' choice on hemodynamics, anxiety, pain and overall satisfaction on the perioperative experience.

**METHODOLOGY:** A prospective, randomized-control study was conducted from January 2021 to July 2021 at a tertiary care hospital on 60 patients undergoing surgery under spinal anaesthesia after obtaining approval from the institutional review board (SMC/IEC/2021/03/299) and Clinical Trials Registry – India (CTRI/2022/07/043802). Written informed consent was obtained from the participants. The inclusion criteria included surgical patients who were willing to participate in the study and had signed the informed written consent form with the American Society of Anesthesiologists (ASA) physical status Classes I and II. The exclusion criteria were patients with hearing defects or any ear abnormalities, patients with psychiatric disorders and patients who were not willing to participate. We assumed an arbitrary sample size of 60 with 20 patients in each group due to the high reported prevalence of perioperative anxiety and reduced case load due to COVID-19 pandemic.

Our primary objective was to assess the effectiveness of two types of intraoperative music – meditation music and devotional music, on the holistic well-being and perioperative experience of patients and compare the same with patients in the control group. The second was to compare the effectiveness of the above two types of intraoperative music with control (no music) in reducing postoperative pain, anxiety and the severity of postoperative nausea vomiting at 1, 6, and 24 h.

Patients were randomly allotted into three groups of 20 patients; two intervention groups – meditation music group or group A and devotional music group or group B and the control group or group C, where no music was played. Randomization was done using a random number generator. The randomization into three groups was done, just before taking the patient to the operation theatre. Music was played from an MP3 player or mobile phone through bilateral headphones that covered the whole ear, so that no other sounds from

the operation room would interfere in the study. The patients who belonged Group A listened to meditation music adjudged to be calming and soothing and those who belonged Group B listened to devotional music of their choice. The patient who was assigned to Group C listened to no music and in essence heard the ambient operating room noises including monitors and conversations. Under aseptic precautions, spinal anaesthesia was given and the headphones were then applied to patients in Groups A and B and music was played according to the patient's group and continued until skin closure and dressing. No sedatives or anxiolytics were administered to the patient in any group. Intraoperative hemodynamics – heart rate and blood pressure were recorded. More than 20% fall in blood pressure was treated with Inj. Ephedrine 6mg bolus intravenously. Post-operatively, anxiety and pain were recorded using the visual analogue scale at the 1 hr, 6 hr and 24 hr marks. The intensity of pain was estimated by the Visual Analogue Pain Scale (VAPS) and the intensity of anxiety by using the Visual Analogue Anxiety Scale (VAAS) where – 0 is the minimum and 10 is the maximum possible pain and anxiety respectively that the patient can experience. Post-operative rescue analgesia was administered if the VAPS score was more than 3 or the patient requested for analgesia. Inj. Tramadol 50 mg intra-muscularly was administered as rescue analgesia. Post-operative nausea and vomiting (PONV) impact scale score was used to determine nausea and vomiting at the 1 hr, 6 hr and 24 hr mark. Overall satisfaction score was assessed using a numerical rating scale (NRS) from 0-10, where 0 indicated extreme dissatisfaction and 10 indicated complete satisfaction. Data collected was statistically analyzed.

Statistical analysis was done using SPSS software and MS Excel software. Student t-test, chi-square test and ANOVA test were used to determine statistical significance. $P<0.05$ was taken to indicate a statistically significant difference.

## RESULTS:

**Demographic Profile:** The mean age, gender and comorbidities were comparable among the study participants **Table 1**. Pregnant patients have been included under ASA 2; Group A had 4 patients, Group B had 3 patients and Group C had 5 patients.

**TABLE 1: DEMOGRAPHIC PROFILE OF THE STUDY PARTICIPANTS**

| Variable | Group A Devotional | Group B Meditation | Group C Control | P value |
|---|---|---|---|---|
| Age (mean years) | 32.75 (13.6) | 35.95(11.3) | 40.75(18.5) | 0.331 |
| Gender (%) | | | | |
| Male | 7 (35) | 7 (35) | 6 (30) | |
| Female | 13 (65) | 13 (65) | 14 (70) | 0.928 |
| BMI (mean kg/$m^2$) | 26.8(2.2) | 27.2(2.5) | 27.2(3.4) | 0.574 |
| Comorbidities (%) | | | | |
| Anemia | 1 (5) | 0 | 0 | |
| Diabetes | 1 (5) | 3 (15) | 1(5) | |
| Hypothyroidism | 0 | 0 | 1(5) | |
| Nil | 18 (90) | 17 (85) | 18(90) | 0.317 |
| ASA (%) | | | | |
| 1 | 7(35) | 4(20) | 5(25) | |
| 2 | 13(65) | 16(80) | 15(75) | 0.551 |

**Hemodynamic Profile Analysis:** We calculated the statistical significance for heart rate using one way ANOVA test. We used 60 minutes of surgery as cut-off as the maximum number of cases in each group finished by 60 minutes of surgery (devotional – 8, meditation – 10, control -10). We have shown that there is significant reduction in anxiety between the interventional and control groups **Table 2.** We also used a paired T test to determine the significance of heart rate changes within each group at 5, 10, 15, 20, 25, 30, 45 and 60 minutes. We found that there was statistically significant reduction in heart rate from the 10 minute mark in the devotional group and 15 minute mark in the meditation group. There was no significant change in heart rate in the control group except at the 60 minute mark **Table 3**. There was no statistical difference in blood pressure between the three groups.

**TABLE 2: HEART RATE ANALYSIS BETWEEN THE THREE GROUPS**

| Heart rate | Devotional Mean + SD | Meditation Mean + SD | Control Mean + SD | P value (one way ANOVA) |
|---|---|---|---|---|
| 5 min | 85.05 + 9.07 | 90.65 +14.61 | 91.3 + 15.86 | 0.195 |
| 10 min | 83.45 + 9.43 | 90.55 +13.94 | 90.05 + 14.87 | 0.106 |
| 15 min | 81.7 + 9.52 | 87.5 +13.3 | 91.65 + 13.09 | 0.023 |
| 20 min | 80.05 + 9.83 | 85.3 +10.88 | 90.4 + 11.51 | 0.014 |
| 25 min | 78.6 + 9.73 | 82.1 +11.22 | 89.2 + 10.89 | 0.008 |
| 30 min | 79.25 + 7.81 | 81.1 +10.76 | 88.65 + 11.97 | 0.008 |
| 45 min | 78.5 + 7.03 | 80.1 +9.41 | 87.35 + 10.94 | 0.004 |
| 60 min | 76.75 + 7.56 | 77.6 +9.02 | 86.75 + 10.81 | 0.0003 |

**TABLE 3: HEART RATE ANALYSIS WITHIN EACH GROUP**

| Paired T test | Devotional | Meditation | Control |
|---|---|---|---|
| 0 v 5 min | 0.322 | 0.033 | 0.072 |
| 0 v 10 min | 0.027 | 0.056 | 0.073 |
| 0 v 15 min | 0.002 | 0.00014 | 0.275 |
| 0 v 20 min | 0.004 | 0.00001 | 0.149 |
| 0 v 25 min | 0.001 | 0.0000012 | 0.084 |
| 0 v 30 min | 0.003 | 0.0000018 | 0.081 |
| 0 v 45 min | 0.0009 | 0.0000013 | 0.064 |
| 0 v 60 min | 0.0005 | 0.0000012 | 0.01 |

**VAAS Scores Analysis:** Desirable value of VAAS score was taken as less than 4 on the VAAS scale. Chi square ($\chi^2$) test done between the number of people who had desirable values of VAAS score in each of the groups. Unpaired T test was done between the means of each group.

There was significant reduction in the mean VAAS score at 1 hour and 6 hours after surgery between the interventional groups and the control group. $\chi^2$ test showed significant reduction of anxiety in both the devotional and medication groups when compared with the control group.

$\chi^2$ test between the two interventional groups showed comparable reduction in anxiety. T test showed a significant reduction in mean VAAS score between the interventional and control groups. T test also showed a significant difference between the two interventional groups, with meditation group showing lower mean VAAS scores **Table 4.** At 1 hour after surgery, the number of subjects with desirable VAAS scores (<4) in each group, the mean and the most frequent VAAS score (mode) given by the subjects are follows: devotional group – 14, mean – 3, mode – 3; meditation group – 18, mean – 2.1, mode – 2; control – 6, mean – 4.5, mode – 5.

At 6 hours after surgery, the number of subjects with desirable VAAS scores (<4) in each group, the mean and the most frequent VAAS score (mode) given by the subjects are follows: devotional group – 16, mean – 2.55, mode – 3; meditation group – 18, mean – 1.55, mode – 1; control – 9, mean – 3.45, mode – 4.

At 24 hours after surgery, there was no significant difference in VAAS scores between the three groups. At 24 hours after surgery, the number of subjects with desirable VAAS scores (<4) in each group, the mean and the most frequent VAAS score (mode) given by the subjects are follows: devotional group – 8, mean – 3.65, mode – 4; meditation group – 10, mean – 3, mode – 4; control – 7, mean – 3.6, mode – 4.

**TABLE 4: VAAS SCORE ANALYSIS BETWEEN THE THREE GROUPS**

| | | Devotional vs Control | Meditation vs control | Devotional vs Meditation |
|---|---|---|---|---|
| VAAS @ 1 hr. | $\chi^2$ test - p value | 0.0114 | 0.00011 | 0.114 |
| | T test - p value | 0.00002 | 0.00000001 | 0.004 |
| VAAS @ 6hrs. | $\chi^2$ test - p value | 0.0222 | 0.002 | 0.376 |
| | T test - p value | 0.0156 | 0.0000024 | 0.003 |
| VAAS @ 24hrs. | $\chi^2$ test - p value | 0.744 | 0.337 | 0.525 |
| | T test - p value | 0.883 | 0.123 | 0.112 |

**VAPS Scores Analysis:** The desirable value of VAPS score was taken as less than 4. A one way ANOVA test was done on the VAPS scores between the three groups at the 1 hr, 6 hr and 24 hr. mark after surgery. There was statistically significant difference (p value 0.0206) between the three groups at the 1 hour mark **Table 5**. An unpaired T test was done between 2 groups at a time to identify which group had statistically significant reduction in VAPS scores. The T test showed that the meditation group had statistically significant lower VAPS scores as compared to the devotional (p value 0.01) and control group (p value 0.021).

At 1 hour after surgery, the number of subjects with desirable VAPS scores (<4) in each group, the mean and the most frequent VAPS score (mode) given by the subjects are follows: devotional group – 19, mean – 2.6, mode – 3; meditation group – 20, mean – 2.05, mode – 2; control – 16, mean – 2.65, mode – 2.

At 6 hours after surgery, the number of subjects with desirable VAAS scores (<4) in each group, the mean and the most frequent VAPS score (mode) given by the subjects are follows: devotional group – 15, mean – 2.9, mode – 3; meditation group – 15, mean – 2.75, mode – 2; control – 13, mean – 3.05, mode – 3.

At 24 hours after surgery, there was no significant difference in VAPS scores between the three groups. At 24 hours after surgery, the number of subjects with desirable VAPS scores (<4) in each group, the mean and the most frequent VAPS score (mode) given by the subjects are follows: devotional group – 8, mean – 3.8, mode – 5; meditation group – 16, mean – 3.9, mode – 4; control – 7, mean – 3.8, mode – 4.

**TABLE 5: VAPS SCORE BETWEEN THE THREE GROUPS**

| VAPS | Devotional Mean ± SD | Meditation Mean ±SD | Control Mean ± SD | P value (one way ANOVA) |
|---|---|---|---|---|
| @ 1 hr. | 2.6 ± 0.598 | 2.05 ± 0.686 | 2.65 ± 0.875 | 0.0206 |
| @ 6 hrs. | 2.9 ± 0.788 | 2.75 ± 0.911 | 3.05 ± 0.826 | 0.560 |
| @ 24 hrs. | 3.8 ± 1.005 | 3.9 ± 0.852 | 3.8 ± 0.952 | 0.906 |

**PONV Analysis:** The one way ANOVA test did not show statistically significant difference between the three groups.

**Overall Satisfaction Scores Analysis:** The mean score was highest in the devotional group at 8.5, followed by the meditation group at 7.95 and the control group at 6.45. The most frequent score (mode) in each group is as follows: devotional – 9, meditation – 7, control – 6. The one way ANOVA test done on the overall patient satisfaction scores showed a significant difference (p value 0.00001) between the two groups. Hence an unpaired T test was done between the groups **Table 6**. The subjects in the devotional group had statistically significant higher satisfaction scores when compared to the other two groups.

**TABLE 6: OVERALL SATISFACTION SCORE BETWEEN THE THREE GROUPS**

| | Devotional vs Control | Meditation vs control | Devotional vs Meditation |
|---|---|---|---|
| Overall patient satisfaction score | 0.000000006 | 0.000008 | 0.042 |

**DISCUSSION:** Spinal anaesthesia is a regional anaesthesia technique involving injection of the local anaestheticinto the subarachnoid space which extends from foramen magnum to S2 in adults and S3 in children. It is commonly administered for surgeries of the lower limb, perineum, abdomen and pelvis. During this the patient is either awake or mildly sedated. The patient is vulnerable to sounds in the operation theatre and conversations between the operating staff. This leads to increases stress, anxiety and fear. Anxiety induces a stress response that can adversely affect the patient and increase the anaesthetic and analgesic requirements [2]. The stimulation of the autonomic nervous system and the neuro-humoral system leads to a worse physiological and psychological response in the surgical patient. Many studies are being conducted to identify suitable adjuncts to anaesthesia that help reduce the anxiety and stress response. Non-pharmacological modalities such as education, behavioral techniques, complementary and alternative medicine techniques have shown to be effective in reducing perioperative anxiety [22]. Complementary and alternative medicine

techniques comprise of music, hypnosis, acupuncture, acupressure [22]. Music is one such adjunct being evaluated for its effect on anxiety and stress response. One study compared music therapy and virtual reality therapy with a control group and found significantly reduced anxiety and pain scores in the interventional groups [23, 24]. Music therapy is easy to use, inexpensive and significantly reduces perioperative pain and anxiety and increases patient satisfaction [25, 26, 27, 28, 29, 30]. Music therapy also improves general well-being of patients [31, 32] and the operating room staff [31].

Music therapy produced significantly lower anxiety scores when compared to intra-operative midazolam [33, 34] but did not reduce sedation requirements [35] or opioid use [36]. Casarin*et al* found that music therapy significantly reduced the pre-operative anxiety and had no effect on anxiety in the early and late post-operative periods [37]. Deng *et al* evaluated the effect of perioperative aromatherapy, music therapy and combination (aroma and music) therapy in women with breast cancer.

They found that combination therapy had the lowest scores of pain and anxiety and lowest levels of IL-6 and HMGB-1. Music therapy and aromatherapy had similar scores and the usual care group had the highest scores [38]. Auricular-point pressure with personalized music therapy reduced stress response in primiparas [39]. Personalized music therapy reduced anxiety and helped parturients bond better with the newborns [40]. Music therapy was found to reduce anxiety in children and their caregivers [41]. Patient selected music was more effective than prefixed music therapy in reducing perioperative anxiety [42].

**Music Therapy can be Passive:**
**Listening to Recorded Music or Active:** playing a preferred instrument. Both have shown to reduce perioperative anxiety [43]. Different genres of music are available and many studies have evaluated the effect on various genres on anxiety and stress relief. To note, classical music, jazz music and meditational music have found to be more soothing and relaxing. These genres of music have found to have a positive effect on the neuro-humoral activity and emotional responses of the individuals [44, 45]. In a clinical setting, music can be used in one of two ways: as a masking agent to prevent ambient sounds in the operating room and hospital; and as a distraction agent to remove focus from stressful situations [44]. Studies have shown that music is effective as a masking agent and not as efficacious as a distracting agent [46, 47]. Patients also prefer to be given a choice in the distracting agent, be it the genre of music or an audiovisual agent such as imagery or reading a book [47]. Meditation music has shown to have the property of reducing negative emotions such as anxiety and sadness and improve the positive emotions such as joy and beauty [48]. One study has shown that meditating with devotional music caused a decrease in theta brain waves that led to lower stress and anxiety levels[49].

In this study we compared the efficacy of two types of music played intraoperatively (meditation & devotional) and standard care (no music) as an adjunct to spinal anaesthesia for hemodynamic stability, reduced post-operative anxiety, pain, nausea & vomiting and overall patient satisfaction. The demographics were comparable between the three groups with near equal distribution of genders.

There was no statistical difference between the mean ages and the ASA grades in each group. Since we did not confine our study to a particular type of surgery, we limited our analyses of the hemodynamic profile to the first 1 hour of surgery. Maximum number of surgeries finished at the 1 hour mark after induction of spinal anaesthesia. We found that there was a statistically significant reduction in heart rate from the 10 minute mark in the devotional group and 15 minute mark in the meditation group. There was no significant change in heart rate in the control group except at the 60 minute mark.

We attribute this to the fact that most surgeries finished at the 1 hour mark and the surgical patient experienced relief as the procedure went well. We did not elicit any significant change in blood pressure between the three groups. Binns-Turner *et al* showed non-significant chances in heart rate in both groups. They found significant decrease in mean arterial pressure and blood pressure in their interventional group [50]. The postoperative anxiety was much lower in music groups than control group in our study.

There was significant reduction in the mean VAAS score at 1 hour and 6 hours after completion of surgery between the interventional groups and the control group. The T test showed that the meditation group had statistically significant lower VAAS scores as compared to the devotional and control group at 1hour and 6 hours after completion of surgery. Many studies have shown a decrease in post-operative anxiety in surgical patients who listened to music [19, 50, 51, 52]. Our study is in concurrence with the above cited studies.

In our study, there was significant decrease in the post-operative pain at 1 hour after completion of surgery. The T test showed that the meditation group had statistically significant lower VAPS scores as compared to the devotional and control group at 1hour after completion of surgery. Dale VH showed that the postoperative pain relief was much evident due to the use of intraoperative music therapy [53]. Our findings were concurrent with this study.

There was no significant reduction in post-operative nausea and vomiting between the groups. Cetinkaya showed that there were statistically significant difference in severity of post-operative nausea & vomiting among the groups [54]. We were unable to replicate the same finding in our study.

Overall satisfaction scores were significantly higher among the devotional music group than meditation music group and the control group. Studies have suggested that there was better compliance and lesser anxiety when the choice of music was offered to the individual [18, 21, 24].

Patients in the devotional groups had the opportunity to choose the type of devotional music they preferred and were able to chant or sing along with their preferred music. The Indian population, in general is more spiritual with faith in God. The choice of chanting or singing along with the devotional music has reflected on the higher satisfaction scores in the devotional group.

We also postulate that the autonomy of choice of music in a situation with very minimal autonomy *i.e.,* the surgical procedure has shown higher satisfaction scores in our study. Hence patients can be given a choice of music which they would like to listen to and this will definitely have more optimistic results in reducing anxiety and ensuring higher overall patient satisfaction and a holistic perioperative experience. We acknowledge several limitations of our study.

Our sample size is small even though we had a comparable demographic profile. We did not record the pre-operative anxiety for comparison within each group. We also did not account for previous exposure to a surgical procedure and knowledge of the same. Our study subjects ranged through a variety of surgical specialties from obstetrics to urology. The duration of each surgery varied and so the volume of anaesthetic drug given as subarachnoid block varied. Though we used the visual analogue scale, we did not take into consideration the education of our study subjects. Nevertheless, we have shown that music played intraoperatively has a positive effect on the surgical patients' anxiety. We have also shown that this holistic approach to the surgical patient results in a better overall satisfaction of the patient.

**CONCLUSION:** The findings of our study are in concurrence with many studies and have shown that music is an economical, easy to use, convenient, adaptable adjunct to reducing perioperative anxiety for a better holistic perioperative experience for the surgical patient.

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