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**ORIGINAL RESEARCH**

# A comparative observational study on the effect of music therapy on perioperative anxiety, sedative requirements and hemodynamic parameters in patients undergoing gynaecological surgery under regional anaesthesia

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## ABSTRACT

**Background:** Perioperative anxiety is a significant concern affecting patient outcomes and satisfaction, and approximately 60% to 80% of adult patients encounter perioperative anxiety. This study was conducted to evaluate effect of music therapy on perioperative anxiety, sedative requirements and hemodynamic parameters in patients undergoing gynaecological surgery under regional anaesthesia. **Materials and Methods:** This prospective observational study was conducted from July 2023 to June 2024. Study included 67 patients aged 18-60 years, with ASA CLASS I, II and III, scheduled for gynecological surgery under regional anesthesia. Patients were distributed into Group M (patients who opted for listening music during surgical procedure) and Group C (patients who did not opt for music therapy). Validated tools like State trait anxiety inventory score (STAI) and visual analogue scale- anxiety (VAS- A) were utilised to assess perioperative anxiety, and intraoperative sedative requirement was titrated using ramsay sedation score (RSS). Patient's hemodynamic parameters, RSS and need for midazolam for maintenance of sedation were recorded every 15 minutes intraoperatively. Data thus collected was subjected to statistical analysis and results were drawn. **Results:** Intra-group comparison showed that in post-operative period, STAI-SA and VAS-A scores were significantly lower compared to pre-operative period in both groups ($p<0.05$). Inter-group comparison showed that post-operative STAI-SA and VAS-A scores, as well as dose of Midazolam required to maintain RSS of $\geq 3$ were significantly lower in Group M as compared to Group C ($p<0.05$). **Conclusion:** Music therapy demonstrates promise as an adjunctive therapeutic modality for managing perioperative anxiety during gynaecological surgery.

**Keywords:** Anesthesia, Anxiety; Hemodynamic; Music; Sedation



## INTRODUCTION

Humans are complex creatures, navigating a wide spectrum of emotions in their daily lives. Among these, anxiety stands out as a potent force, casting a shadow of uncertainty over the future. Defined as a diffuse, unsettling apprehension often accompanied by autonomic symptoms, anxiety manifests in both physical sensations and psychological turmoil.[1] The interplay between emotional well-being and physiological equilibrium is profound, with substantial implications for various facets of human existence. Pharmacotherapy remains a cornerstone of anxiety management, however, still there exists a complementary realm of non-pharmacological modalities that merit exploration. Techniques rooted in cognitive-behavioural therapy, music therapy, aromatherapy, hypnosis and imagery relaxation therapy offer promising avenues for alleviating anxiety, circumventing the potential adverse effects associated with high doses of pharmacological agents.[2] Given the rich cultural heritage of India, characterized by a profound appreciation for the arts and music, leveraging these traditional modalities emerges as a compelling and cost-effective strategy for fostering positive psychological shifts in individuals grappling with anxiety.[3] Perioperative

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anxiety, characterized by apprehension and fear before, during, or after surgical procedures, presents a multifaceted challenge for healthcare providers. Emerging literature suggests that music can positively impact patients' levels of anxiety and hemodynamic parameters during the perioperative period.[4] Some of our esteemed consultants advocate for the integration of music therapy as part of perioperative care. So, we planned this observational study to evaluate the effect of music therapy on perioperative anxiety, sedative requirements and hemodynamic parameters in patients undergoing gynaecological surgery under regional anaesthesia.

## MATERIALS AND METHODS

This prospective observational study was conducted at a tertiary care centre from July 2023 to June 2024, after obtaining approval from the Institutional ethical committee with reference number GMCS/STU/ETHICS-3/Approval/7549/23. This study was registered in the Clinical Trials Registry - India (www.ctri.nic. in, vide registration number CTRI/2023/06/053421). Study included 67 patients aged 18-60 years, with ASA CLASS I, II and III, scheduled for planned gynecological surgery under regional anesthesia. Patients with mental impairment, hearing loss, those taking illicit antidepressant or anxiolytic drugs, or pregnant patients were excluded from the study. Written informed consent was obtained from each patient prior to their enrollment in the study. On the day of surgery, in the preanesthetic room, patient's vital parameters were recorded and patient's anxiety was assessed with State Trait Anxiety Index-State Anxiety [STAI-SA][5] and VAS-A[6,7] score for anxiety. Patients were also counselled by the attending consultant about music therapy and those who choose to listen to music constituted Group M (music group, n=33), while those who did not opted for music therapy constituted the Group C (control group, n=34). Then all the patients were premedicated with inj. Midazolam 0.02 mg/kg iv as per departmental protocol. After shifting patient to OT, regional anaesthesia was given as per departmental protocol. Some patients received spinal anaesthesia with Inj. Bupivacaine heavy (0.5%) at a dose of 0.3-0.5mg/kg with Inj. Dexmeditomedine 5 mcg as adjuvant. For some patients, combined spinal epidural anaesthesia was given for intraoperative anaesthesia and post operative analgesia. After establishment of effect of regional anaesthesia and final position for surgery was given. Patients in Group M were given a pair of headphones and music was played till the end of procedure, based on their choice (soft melodies, Bollywood, religious songs, folk music) at comfortable volume level. We used validated tools, State trait anxiety inventory score (STAI) and visual analogue scale- anxiety (VAS- A), to assess perioperative anxiety. Study parameters including Ramsey sedation score (RSS)[8-10], requirement of midazolam to keep patient's Ramsey sedation score 3, heart rate (HR), systolic blood pressure (SBP), Diastolic blood pressure (DBP), mean arterial pressure (MAP), respiratory rate (RR), SpO2, and EtCO2, were recorded every 15 minutes intraoperatively. We targeted a Ramsey Sedation Score of 3 or above intraoperatively and patients with a score less than 3 were supplemented with Inj. Midazolam 0.01 mg/kg iv. After surgery patients were shifted to post operative room for observation for at least 30 minutes as per departmental protocol. In recovery room, when patient became fully awake, they were again assessed with state trait anxiety index [STAI-SA] and VAS-A score for anxiety. Once patient became fully awake and hemodynamically stable, patients were shifted to ward. Data thus collected was subjected to statistical analysis and results were drawn.

### Statistical Analysis

The statistical analysis was done using EPI software version 2.3 using the student's t-test. The paired 't' test for comparison within the groups and unpaired 't' test for intergroup comparison. The difference was considered to be statistically significant when p value $<0.05$, highly significant when $p<0.001$ and extremely significant when $p\leq0.0001$.

## RESULTS

The mean age of patient in Group M was 44.81±8.05 years and Group C was 43.91±10.09 years. There was no significant difference in the mean age, weight, and height of patients between the two study groups ($p>0.05$). Although there was statistically significant difference in mean BMI between the study groups ($p<0.05$), it was within normal range in both the groups. (Table 1)

**Table 1: Characteristics of Study Patients**

| Patient Characteristics | | Group M (N=33) | Group C (N=34) | p value | |
|---|---|---|---|---|---|
| **Mean Age (years)** | | 44.81 ± 8.05 | 43.91 ±10.09 | 0.9102 | >0.05 |
| **Mean Weight (kg)** | | 56.75 ± 9.99 | 53.17 ± 8.35 | 0.1531 | >0.05 |
| **Mean Height (cm)** | | 154.54 ± 5.88 | 155.35 ±5.30 | 0.3437 | >0.05 |
| **Mean BMI (kg/m$^2$)** | | 23.87 ± 3.68 | 21.91 ± 2.41 | 0.0208 | <0.05 |
| **ASA Class** | **I/II** | 19 (57.57%) | 21 (61.76%) | | |
| | **III** | 14 (42.43%) | 13 (38.23%) | | |

We had to exclude 3 patients from group M and 4 participants from group C as general anaesthesia was supplemented to them. Thus, in further statistical analysis our sample size was 60 with 30 patients in each

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group. There was no significant difference in the mean hemodynamic parameters between the two study groups (p>0.05). Total duration of surgery in Group M was 122±29.93 minutes and Group C was 136±31.98 minutes, but the difference was not statistically significant. (p>0.05). (Table 2)

**Table 2: Comparison of Intra-operative Parameters between Study Groups**

| Intra-operative Parameters | Group M (N=30) | Group C (N=30) | p value | |
|---|---|---|---|---|
| **Pulse rate** | 86.6±10.26 | 86.46±10.47 | 0.9604 | >0.05 |
| **SBP** | 120±10.82 | 116.66±11.24 | 0.2469 | >0.05 |
| **DBP** | 77±07.39 | 75.33±07.3 | 0.2963 | >0.05 |
| **MAP** | 87.86±12.03 | 88.23±8.98 | 0.8940 | >0.05 |
| **Total duration of surgery** | 122±29.93 | 136 ±31.98 | 0.0829 | >0.05 |

Pre-operative STAI-SA and VAS-A scores were comparable between Group M and Group C. Intra-group comparison showed that in post-operative period, STAI-SA and VAS-A scores were significantly lower compared to pre-operative period in both groups (p<0.05). Inter-group comparison showed that post-operative STAI-SA and VAS-A scores were significantly lower in Group M as compared to Group C (p<0.05). Similarly, the dose of Midazolam required in Group M (0.26 ± 0.40 mg) was significantly lower than Group C (0.85 ± 0.77 mg) (p<0.001). (Table 3)

**Table 3: Comparison of Study Parameters between Study Groups**

| Scores | Group M (N=30) | Group C (N=30) | p value | |
|---|---|---|---|---|
| **Pre-op STAI-SA** | 53 ± 4.97 | 52.06 ± 6.38 | 0.4174 | >0.05 |
| **Post-op STAI-SA** | 43.83 ± 3.86 | 47.16 ± 5.47 | 0.0134 | <0.05 |
| **Pre-op VAS-A** | 5.9 ± 1.47 | 5.73 ± 1.31 | 0.5648 | >0.05 |
| **Post-op VAS-A** | 2.03 ± 0.76 | 2.93 ± 0.90 | 0.0001 | <0.001 |
| **Dose of Midazolam (mg)** | 0.26 ± 0.40 | 0.85 ± 0.77 | 0.0005 | <0.001 |

Out of 60 participants, most participants had moderate anxiety during all the points of assessment. We observed that anxiety scores were towards the upper range during pre-op period in both groups, while anxiety scores were towards the lower range during post-op period in both groups. (Table 4)

**Table 4: Degree of anxiety using STAI score classification (N=60)**

| | Low anxiety (20-39) | | Moderate anxiety (40-59) | | High anxiety (60-80) | |
|---|---|---|---|---|---|---|
| | **Group M (N=30)** | **Group C (N=30)** | **Group M (N=30)** | **Group C (N=30)** | **Group M (N=30)** | **Group C (N=30)** |
| **Pre op STAI-SA** | 0 (0%) | 0 (0%) | 29 (96.66%) | 26 (86.66%) | 1 (3.33%) | 4 (13.33%) |
| **Post op STAI-SA** | 3 (10%) | 4 (13.33%) | 27 (90%) | 26 (86.66%) | 0 (0%) | 0 (0%) |

## DISCUSSION

Perioperative anxiety is a significant concern affecting patient outcomes and satisfaction. Alleviating perioperative anxiety poses a formidable challenge for anaesthesiologists, given its emotional nature and the concomitant activation of the autonomic nervous system, leading to various pathophysiological alterations. Studies indicate that approximately 60 to 80% of adult patients encounter perioperative anxiety.[11] Effective management of perioperative anxiety involves multimodal interventions targeting various aspects of patients' emotional and psychological well-being.[12] Emerging literature suggests that music can positively impact patients' levels of anxiety and hemodynamic parameters during the perioperative period. This observational study was undertaken to evaluate the effect of music therapy on reducing anxiety during perioperative period in patients undergoing gynaecological surgery under regional anaesthesia at our tertiary care hospital. According to literature, females are more susceptible to perioperative anxiety compared to males.[13] Therefore, we selected female patients as our participants.

As anxiety is a subjective feeling, in our research, we employed subjective tools to evaluate anxiety levels. Literature advocates for the adoption of quantitative anxiety assessments for more effective patient care.[14] We utilized the State-Trait Anxiety Inventory (STAI) and the Visual Analog Scale – Anxiety (VAS-A) to assess patients' peri-operative anxiety. The STAI is a valuable tool for assessing anxiety in adults, offering separate scales to measure both temporary states and enduring traits of anxiety. Its robust psychometric properties, coupled with its versatility and ease of administration, have cemented its status as a gold standard measure in the field of anxiety assessment. The STAI scale employed in our study offered a quantitative evaluation of anxiety, featuring distinct questionnaire sections for assessing

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basal anxiety and peri-operative anxiety of participants.

VAS- A scale is validated for assessment of perioperative anxiety which takes <1 minute to complete, also is more sensitive to small changes and STAI scale which quantified peri-operative anxiety. Both scales are simple, easy to use and analyse. However, responses on the STAI may be influenced by subjective interpretation, social desirability bias, or mood fluctuations at the time of assessment. Also, some items in the STAI may overlap with symptoms of depression or other psychological conditions, potentially confounding interpretation. Previous studies have also used STAI, VAS or both in patient assessment.[15-19] During the intraoperative period, our goal was to maintain a Ramsay Sedation Score of 3 or higher. Therefore, we assessed all patients every 15 minutes for their sedation level using the Ramsay Sedation Score and administered intermittent injections of Midazolam (0.01 mg/kg) to achieve and sustain this score. Similarly, Ramsay Sedation Score was used to assess sedation level in previous studies by Rex DK et al[8] [26], Kress JP et al[9], Cheung CW et al[10] (2015), Ligree N et al[19].

Prior to surgery, both Group M and Group C exhibited comparable levels of anxiety, as indicated by State Trait Anxiety Index-State Anxiety (STAI-SA) scores and Visual Analog Scale for Anxiety (VAS-A) scores. Similar observations were made by Lee WP et al[20] and Wu PY et al[21] and in their respective studies. Following surgery, Group M showed significantly lower STAI-SA and VAS-A scores compared to Group C ($p < 0.05$). This indicates that music therapy was effective in reducing postoperative anxiety levels highlighting the clinical relevance of music therapy as an adjunct to managing postoperative anxiety. Similarly, significant reductions in anxiety levels were observed in music group as compared to control group in the study by Wu PY et al[21]. Lee WP et al[20], in a similar study, observed that music listening for 30 minutes in post-anaesthesia care unit significantly decreased anxiety level, improved hemodynamic stability and maintained normal respiratory rate. In another similar study, Kurdi MS et al[22] noted that meditation music group experienced significantly less postoperative pain and anxiety compared to the control group in cesarean section patients under spinal anaesthesia. These observations are in agreement with previous literature suggesting that music therapy decreases perioperative anxiety.[18,23-25]

In our study, both the groups experienced a reduction in anxiety scores from the pre-operative to post-operative periods. This reduction can be attributed to the dissolution of perioperative anxiety, which stems from uncertainty about the surgical process, potential complications, and anaesthesia. However, Group M exhibited a more pronounced reduction in anxiety compared to Group C. This suggests that music therapy helped to mitigate the increase in anxiety associated with surgery. In a similar study, Kukreja P et al[17] observed that anxiety levels decreased in both music and control groups post-operatively, however, the music group continued to show lower anxiety scores, albeit not reaching statistical significance.

In our study, intraoperatively, Group M required significantly less midazolam compared to Group C ($p < 0.001$) to maintain adequate sedation levels (Ramsey Sedation Score $\geq 3$), which is in accordance with the findings of the studies by Ebrahimi R et al[26] and Chandak A et al[27]. This finding underscores the potential of music therapy to reduce the need for pharmacological sedatives during surgery, thereby potentially lowering the risk of sedation-related complications and promoting a more favorable recovery profile. Giordano F et al[25] observed preoperative music therapy to be as effective as intravenous midazolam in reducing anxiety and promoting sedation before stomatology surgery under general anaesthesia.

In our study, both groups demonstrated stable intraoperative hemodynamic parameters throughout the study period, with no statistically significant differences between Group M and Group C, which is consistent with the findings of the study by Shukla A et al[24]. This indicates that music therapy did not adversely affect hemodynamic stability during surgery. Additionally, both groups showed a significant decrease in these parameters compared to baseline values, which is consistent with the expected physiological response to anaesthesia. Kahloula M et al[28] noted that patients exposed to music during abdominal surgery under general anaesthesia demonstrated enhanced hemodynamic stability, particularly in SBP. However, several studies have observed that hemodynamic parameters were lower in music group than control group.[18,19,21] The findings of our study underscore the potential of music therapy as a non-invasive and cost-effective intervention to alleviate perioperative anxiety and enhance patient satisfaction in gynaecological surgeries. Single centre study and smaller sample size were two limitations of this study.

## CONCLUSION

Music therapy demonstrates promise as an adjunctive therapeutic modality for managing perioperative anxiety during gynaecological surgery. By reducing anxiety and sedative requirements while maintaining hemodynamic stability, music therapy offers a holistic approach to enhancing patient-centred care. Moreover, the reduced need for midazolam in the music therapy group suggests potential cost savings and improved patient safety.

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