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Music versus midazolam to alleviate anxiety and physiological responses in patients receiving spinal anesthesia: A prospective randomized controlled study

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Abstract

This study aimed to evaluate the anxiety levels and physiological responses between music listening and given intravenous midazolam for perioperative anxiolytics in patients who receiving spinal anesthesia (SA). This prospective, randomized, controlled trial was conducted in adult patients undergoing elective surgery under SA. Participants were randomly assigned to either the music group (Mu group) or the midazolam group (Mi group). The Mu group listened to their preferred music, while the Mi group received an intravenous midazolam. Anxiety levels were assessed using State-Trait Anxiety Inventory (STAI) questionnaire, and physiological parameters were recorded pre- and postoperatively. The primary outcome was the change in STAI score from pre- to postoperative assessment. Secondary outcomes included the changes of physiological parameters, incidence of complications, and patient satisfaction. A total of 72 patients completed the study, 38 patients in Mu group and 34 patients in Mi group. The mean change in STAI score was -2.9 (SD 8.0) in the Mu group and -5.7 (SD 6.6) in the Mi group, with a mean difference of 2.78 (95% CI -0.7 to 6.3, $p = 0.114$). There were no significant differences in physiological parameters or complication rate between groups. Patient’s satisfaction scores were high in both groups. These finding suggest that music may be a viable alternative to midazolam for intraoperative anxiolysis in patients undergoing SA.

Keywords: Music, Midazolam, Anxiety, Spinal Anesthesia

1. Introduction

Spinal anesthesia (SA) is commonly preferred for surgeries below the umbilicus due to its low cost, effectiveness, and favorable safety profile [1]. SA has been shown to reduce acute and chronic pain, postoperative nausea and vomiting, and pulmonary complications in certain surgical procedures [2]. However, patients remain fully conscious during surgery under SA and are able to perceive the operative environment and hear various sounds, which can provoke anxiety. Uncontrolled anxiety and stress during surgery may negatively impact both physical and mental health and hinder early postoperative recovery [3,4], making minimizing such anxiety a key priority. Sedation has been shown to improve patient satisfaction during SA and may enhance acceptance of SA techniques among surgical patients [5]. Midazolam, a commonly used anxiolytic, is preferred for sedation due to its rapid onset and offset, as well as its amnestic and anxiolytic properties, which effectively reduce intraoperative anxiety [6]. However, midazolam is associated with adverse effects, including respiratory depression, nausea, vomiting, headache, and agitation [7]. Additionally, some studies have identified midazolam as a contributing factor to postoperative delirium [8,9].

Interestingly, music is a non-pharmacologic intervention that has been shown to reduce stress, as evidenced by lower cortisol levels ($p < 0.05$), and to decrease sedative requirements, including reduced propofol consumption ($p < 0.01$), compared with control group in patients undergoing surgery under regional anesthesia [10]. In patients SA, listening to music significantly lowered state-trait anxiety inventory (STAI) scores compared with ambient noise [11]. One study comparing midazolam and music listening during preoperative nerve blocks found no significant difference in STAI scores between the two groups (mean difference −2.5; 95% CI, −5.9 to 0.9; p = 0.1) [12]. Another study that evaluated the effects of midazolam versus music listening prior to SA reported significantly lower postoperative anxiety in the music group, with mean STAI scores of 28.1 and 34.7, respectively (p = 0.01) [13]. In addition to being a safe and cost-effective method for reducing perioperative anxiety, listening to music during surgery has also been shown to improve patient satisfaction [11–13]. However, to date, no study has directly compared the effects of intraoperative midazolam with music therapy in patients undergoing surgery under SA. Therefore, the aim of this study was to evaluate the effects of intraoperative midazolam infusion versus music listening as anxiolytic interventions in patients receiving SA.

2. Materials and methods

2.1 Design and participants

This prospective, randomized, controlled trial was conducted from October 2021 to January 2022 at Srinagarind Hospital, Khon Kaen University, in patients undergoing elective surgery under SA. Eligible participants were those aged 18–65 years with an American Society of Anesthesiologists physical status (ASA PS) classification of I–III. Exclusion criteria included alcohol dependence, end-stage renal disease, benzodiazepine use within 24 hr prior to surgery, visual or hearing impairment, pregnancy, lactation, psychiatric disorders, and known hypersensitivity to midazolam.

2.2 Study definition

2.2.1 Spielberger State-Trait Anxiety Inventory (STAI)

The STAI is a self-reported questionnaire consisting of 20 items rated on a 4-point Likert scale to assess the respondent's current level of anxiety. Responses are scored as follows: 1 = not at all, 2 = slightly, 3 = moderately so, and 4 = very much so. Total scores range from 20 to 80, with scores of 20–40 indicating low anxiety, 41–60 indicating moderate anxiety, and 61–80 indicating high anxiety [14]. This study used the Thai version of the STAI, translated by Kotchabhakdi N. et al., which demonstrated strong validity and reliability, with a Cronbach's alpha of 0.95 and a content validity index of 0.94 [15].

2.2.2. Sedation score

In 1998, Ready et al developed the original sedation score [16]. A modified version, used at our hospital, assigns four levels: 0 = alert, 1 = occasionally drowsy, 2 = consistently drowsy but easily arousable, and 3 = somnolent and difficult to arouse [17]. A score of 3 indicates over-sedation.

2.3 Procedure

P Patients undergoing elective surgery under SA were assessed for eligibility and provided with information about the study's purpose, procedures, and safety considerations before enrollment. Written informed consent was obtained from all participants. Eligible patients were randomly assigned to either the music (Mu) group or the midazolam (Mi) group using a computer-generated block-of-four randomization list. Group assignments were concealed in opaque envelopes.

One day prior to surgery, participants were evaluated for baseline measures, including (1) anxiety using the Thai version of the STAI questionnaire and (2) physiological parameters, including heart rate (HR), respiratory rate (RR), and systolic and diastolic blood pressure (SBP and DBP). On the day of surgery, the allocation sequence was opened shortly before the SA was conducted. Patients in the Mu group were asked to prepare their preferred music. If their preferred music was unavailable, the researcher provided nature-inspired music, such as sounds of rain, wind, sea, or forest. All participants underwent surgery with standard anesthesia care under SA. Due to the distinct nature of the interventions, patient blinding was not feasible. Following a successful SA, patients received the assigned anxiety-reducing intervention. Patients in the Mi group received intravenous (IV) midazolam at a dose of 0.04 mg/kg (maximum 2.5 mg), followed by an IV infusion at 0.02 mg/kg/hr (maximum 2 mg/hr). Patients in the Mu group listened to their preferred music through noise-cancelling headphones during surgery. Patients were withdrawn from the study if SA failed and conversion to general anesthesia was required. Intervention-related complications observed during surgery included paradoxical agitation, nausea/vomiting, sedation score, communication difficulties, and tourniquet pain.

If a patient became overly sedated, the anesthesiologist discontinued midazolam, ensured airway patency, and administered oxygen to maintain oxygen saturation above 94 %. In cases of paradoxical agitation from midazolam, the infusion was stopped, and 0.2 mg of IV flumazenil was administered every minute until symptoms resolved.

If a patient in the Mu group experienced anxiety and requested sedation with midazolam, the drug was administered, and the patient was withdrawn from the study. Following surgery, patients remained in the post-anesthesia care unit (PACU) for one hr. Once fully awake (sedation score = 0), a member of the research team—blinded to group assignment—assessed the postoperative STAI score, physiological parameters, and patient satisfaction with the anxiolytic intervention using a numerical rating scale (NRS) from 0 to 10.

2.4 Outcome measures

The primary outcome was the difference between preoperative and postoperative STAI scores. Secondary outcomes included changes in physiological parameters (SBP, DBP, HR, and RR), complications (paradoxical agitation, nausea or vomiting, over-sedation, communication difficulties, and tourniquet pain), and patient satisfaction scores.

2.5 Sample size calculation

The sample size was calculated based on the hypothesis that the two anxiolytic interventions would be equivalent, using the difference in post- to preoperative STAI scores of −1.6 (SD 10.7) in the Mu group and −4.2 (SD 11) in the Mi group [12]. A beta error of 0.20 (80% power), an alpha error of 0.05, and a clinically meaningful difference in STAI score of 10 points were assumed. As a result, a minimum of 34 patients was required per group. Accounting for a 10% expected dropout rate, the final estimated sample size was 38 patients per group.

2.6 Statistical analysis

Data were analyzed using STATA for Windows, version 18 (Stata Corp LP, College Station, TX, USA). Categorical variables were presented as numbers and percentages and compared using the Pearson Chi-square test or Fisher exact test, as appropriate. Continuous variables were expressed as mean ± standard deviation (SD) for normally distributed data or median and interquartile range (IQR) for non-normally distributed data. Between-group comparisons of continuous variables were performed using the independent t-test or Mann-Whitney U test, depending on data distribution. Within-group comparisons of pre- and postoperative values were analyzed using the paired t-test. A per-protocol analysis was performed. Statistical significance was defined as a $p < 0.05$.

3. Result

Between October 2021 and January 2022, 78 patients were screened and invited to participate: two declined. Seventy-six patients were then randomly allocated to either the music (Mu) group or the midazolam (Mi) group, with 38 patients in each. Four patients in the Mi group did not receive the allocated intervention: three were converted to general anesthesia due to inadequate SA, and one declined to follow the study protocol. In total, 72 patients completed the study 38 in the Mu group and 34 in the Mi group (Figure 1).

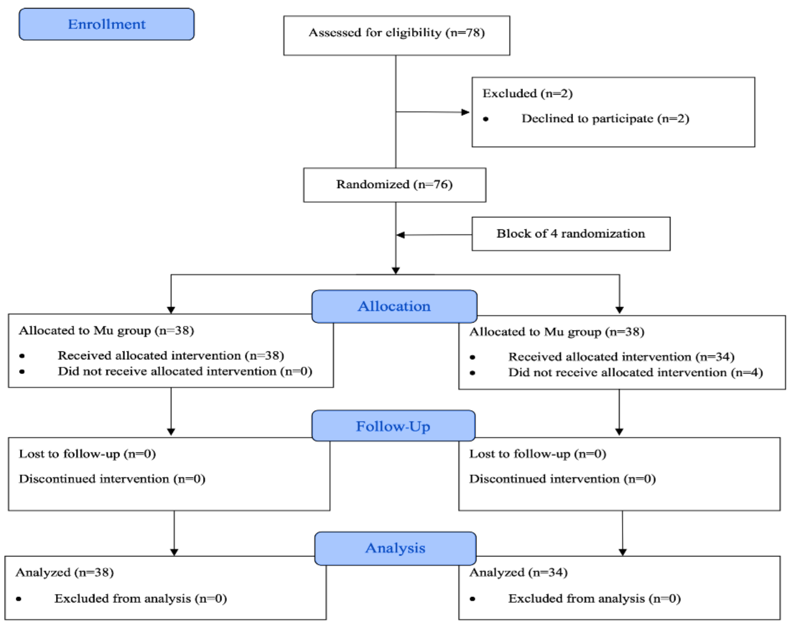

Figure 1 CONSORT flow diagram illustrating patient selection, randomization, and study completion.

The median age of the study population was 45 years. Most participants were classified as ASA PS I (72.2%), and 63.9% were male. The majority underwent orthopedic (48.6%) or rectal (44.4%) procedures. There were no statistically significant differences between the two groups in terms of gender, age, weight, height, ASA PS classification, type of surgery, operative time, or education level (Table 1).

Table 1 Baseline characteristics of patients undergoing spinal anesthesia, stratified by anxiolytic intervention: music (Mu) versus midazolam (Mi) (n=72).

Variables	Mu group (n=38)	Mi group (n=34)	*p*-value
Male gender	23 (60.5)	23 (67.7)	0.530
Age (years); mean (SD)	42.7 (14.2)	43.1 (16.4)	0.919
Weight (kg); mean (SD)	68.8 (13.7)	67.2 (11.6)	0.588
Height (cm); mean (SD)	165.3 (8.9)	165.9 (9.3)	0.773
ASA PS classification			0.292
I	25 (65.8)	27 (79.4)	
II	12 (31.6)	7 (20.6)	
III	1 (2.63)	0 (0)	
Type of surgery			0.825
Orthopedic	20 (52.6)	15 (44.1)	
Rectal	16 (42.1)	16 (47.1)	
Trauma	1 (2.6)	2 (5.9)	
Urological	1 (2.6)	1 (2.9)	
Operative time (min); median (min, max)	60 (30, 130)	60 (50, 90)	0.910
Patient's education			0.053
Primary school	5 (13.2)	9 (26.5)	
High school	15 (39.5)	13 (38.2)	
Bachelor's degree	9 (23.9)	11 (32.4)	
Higher bachelor's degree	9 (23.9)	1 (2.9)	

Data presented as number (%) unless indicated otherwise; ASA = American society of Anesthesiologists.

Table 2 displays the STAI scores and physiological parameters comparing the Mu and Mi groups. There were no statistically significant differences in preoperative STAI scores or physiological parameters between the groups. The baseline STAI scores were 37.7 (SD 7.4) in the Mu group and 40.8 (SD 8.1) in the Mi group (p = 0.093). Similarly, postoperative STAI scores and physiological parameters did not differ significantly between groups. The postoperative STAI scores were 34.7 (SD 7.5) in the Mu group and 35.1 (SD 6.7) in the Mi group (p = 0.849).

Table 2 Comparison of state-trait anxiety inventory (STAI) score and physiological parameters between the music (Mu) and midazolam (Mi) groups in patients undergoing spinal anesthesia (n=72).

Variables	Mu group (n=38)	Mi group (n=34)	*p*-value
Preoperative (baseline)			
STAI score (points)	37.7 (7.4)	40.8 (8.1)	0.093
Heart rate (bpm)	77.2 (12.4)	77.5 (9.7)	0.914
Respiratory rate (tpm)	15.6 (1.7)	15.6 (1.7)	0.691
Systolic BP (mmHg)	133.3 (14.9)	129.0 (16.3)	0.247
Diastolic BP (mmHg)	80.7 (9.2)	76.5 (10.9)	0.076
Postoperative			
STAI score (points)	34.7 (7.5)	35.1 (6.7)	0.849
Heart rate (bpm)	67.2 (10.8)	70.7 (12.0)	0.207
Respiratory rate (tpm)	15.3 (2.8)	15.9 (2.8)	0.566
Systolic BP (mmHg)	117.4 (23.4)	123.0 (16.6)	0.436
Diastolic BP (mmHg)	72.3 (9.3)	71.5 (10.6)	0.728

Data presented as mean (SD); STAI = State-Trait Anxiety Inventory; respiratory rate; tpm = times per min; BP = blood pressure

The differences in post- to pre-operative STAI scores and physiological parameters are presented in Table 3. The reduction in STAI score was greater in the Mi group (−5.7 [SD 6.6]) compared to the Mu group (−2.9 [SD 8.0]), but this difference was not statistically significant (mean difference 2.8; 95% CI −0.7 to 6.3; p = 0.114). Changes in physiological parameters—including SBP, DBP, HR, and RR—were similar between groups.

Table 3 Change in state-trait anxiety inventory (STAI) scores and physiological parameters from pre- to postoperative in the music (Mu) and midazolam (Mi) groups (n=72).

Variables	Mu group (n=38)	Mi group (n=34)	Mean Difference (95%CI)	*p*-value
STAI score (points)	-2.9 (8.0)	-5.7 (6.6)	2.8 (-0.7, 6.3)	0.114
HR (bpm)	-10.0 (13.6)	-6.9 (13.3)	-3.1 (-9.5, 3.3)	0.333
RR (tpm)	-0.3 (3.2)	0.2 (3.1)	-0.5 (-1.9, 1.0)	0.533
Systolic BP (mmHg)	-15.9 (25.2)	-6.0 (14.6)	-8 (-17, 1.0)	0.072
Diastolic BP (mmHg)	-8.4 (11.0)	-5.0 (11.4)	-3.5 (-8.7, 1.8)	0.195

Data presented as mean (SD); STAI = State-Trait Anxiety Inventory; HR = heart rate; RR = respiratory rate; BP = blood pressure; tpm = times per min.

Following the anxiolytic intervention, both the Mu and Mi groups demonstrated a significant reduction in STAI scores. The difference between post- and preoperative STAI scores was −2.9 (95% CI, −5.5 to −0.3; p = 0.030) in the Mu group and −5.7 (95% CI, −8.0 to −3.4; p < 0.001) in the Mi group. Regarding changes in physiological parameters from pre- to postoperative baseline within each group, both groups showed similar trends. Postoperative HR, SBP, and DBP significantly decreased, while RR remained unchanged.

Patients in the Mi group received an average midazolam dose of 3.1 mg (SD 1.0). No cases of paradoxical agitation or excessive sedation were observed. One patient in the Mi group reported difficulty communicating after midazolam administration. Tourniquets were applied in 12 patients in the Mu group and 13 in the Mi group; only one patient in the Mu group reported tourniquet-related pain, which resolved shortly after tourniquet deflation and did not require sedation. Therefore, there was no patients in Mu group needed sedation. One patient in each group experienced nausea and vomiting.

The median patient satisfaction score in the Mi group was 10 (IQR 9–10), which was significantly higher than the Mu group's score of 9.5 (IQR 9–10) (p = 0.046). However, both groups reported extremely high satisfaction overall.

4. Discussions

Music therapy has been used for anxiolysis and analgesia in surgical patients during the preoperative [12,13], intraoperative [11], and postoperative [18] periods. Its anxiolytic effect is thought to be mediated by a reduction in cortisol levels, reflecting a stress-reducing response [10,19]. Additionally, music may reduce pain perception by decreasing muscle tension and promoting the release of endogenous opioids [20]. Prasad et al. found that patients who listened to their preferred music experienced greater anxiety reduction compared to those who listened to pre-selected recordings chosen by medical staff [13]. Based on this evidence, our protocol allowed patients to listen to their preferred music.

This study examined the effects of music listening versus intraoperative midazolam administration in patients undergoing SA. We found that the reduction in anxiety levels, as measured by the change in STAI scores from pre- to post-operation, was comparable between the two interventions. Our findings align with a study by Graff et al., which assessed the effects of IV midazolam and music listening prior to ultrasound-guided peripheral nerve block and reported similar reductions in STAI anxiety scores in both groups [12]. Additionally, research by Koelsch et al. comparing instrumental music to a non-musical placebo during surgery under SA demonstrated that patients in the music group required lower doses of propofol (2.2 vs. 2.7 mg/kg/hr) and had lower bispectral index values, suggesting deeper sedation despite reduced medication use [10]. Together, these findings support the use of music as a viable non-pharmacologic alternative to sedative medications for reducing perioperative anxiety.

Our results contrast those reported by Prasad et al., who used a 10-point visual analogue scale (VAS) to assess anxiety and found that music listening reduced anxiety scores significantly more than midazolam [13]. This discrepancy may be attributed to differences in protocol; in our study, midazolam was administered as a continuous IV infusion throughout the operation, while in their study, it was given as a single dose 10 min prior to spinal block. Similarly, Giordano et al. reported that preoperative music therapy reduced postoperative anxiety more effectively than midazolam in patients undergoing stomatology surgery under general anesthesia [21].

Notably, in their study, music was delivered by a certified music therapist, which may have enhanced its therapeutic effect. However, it is important to consider that the 10-point VAS used in both studies is not a validated instrument for assessing anxiety.

The baseline STAI scores in our study population were 37.7 in the Mu group and 40.8 in the Mi group, indicating a low level of anxiety prior to surgery. Following the anxiolytic intervention, both groups showed a significant reduction in postoperative STAI scores compared to their preoperative scores, suggesting that both midazolam and music effectively reduced perioperative anxiety during SA. Similarly, Lee WP et al. reported that patients who listened to music for 30 min in the PACU following spinal anesthesia experienced a significant reduction in STAI scores—from 59.0 to 31.2 [18].

Similar findings have been reported in surgical patients receiving SA, with studies showing lower anxiety scores in music-listening groups compared to non-music controls [18,22,23]. Abdul Hamid MR et al. found that intraoperative music during total knee arthroplasty (TKA) under SA significantly reduced anxiety, with a greater reduction in 10-point VAS scores (3.38 vs 2.29) and lower mean STAI scores (48.9 vs 54.0) [22]. Kukreja P et al. studied patients undergoing TKA under SA with preoperative adductor canal block, all of whom received 1 mg midazolam and 50 mcg fentanyl for sedation during the block. Postoperative STAI scores were significantly lower in the music group (28.1) compared to the non-music group (34.71) [23].

Regarding changes in physiological parameters, which can serve as indicators of stress, our findings showed that HR, SBP, and DBP significantly decreased following intervention in both the music and midazolam groups. Similar outcomes have been reported in previous studies on music listening [18,22,24]. This effect may be attributed to music's ability to reduce pain and both physiological and psychological stress, thereby dampening the autonomic response [20,25]. Additionally, music has been shown to directly activate the dopaminergic mesolimbic reward system [26].

Consistent with the findings of Graff V. et al., patient satisfaction was statistically higher in the midazolam group [12]. However, given that both groups reported high satisfaction scores (median >9/10), the difference is unlikely to be clinically meaningful.

This study has several limitations. First, postoperative anxiety was assessed shortly after surgery, which may have been influenced by residual sedation from midazolam. However, we mitigated this by ensuring patients were fully awake (sedation score = 0) before administering the STAI questionnaire. Second, we did not measure cortisol levels, which could have provided objective evidence of stress reduction. Additionally, the short follow-up period did not allow for assessment of postoperative delirium or cognitive function. Future studies should consider including patients with higher baseline anxiety to better evaluate the comparative effectiveness of music and pharmacologic interventions. Incorporating objective biomarkers, such as serum cortisol, could provide greater insight into physiological effects. Long-term outcomes and comparisons across different types of music interventions should also be explored to optimize perioperative anxiety management.

5. Conclusions

Music intervention alleviates anxiety in patients undergoing SA comparably to midazolam, without associated complications, and with high levels of patient satisfaction, suggesting that music listening may be considered a viable alternative to intraoperative midazolam.

6. Ethical approval

The study protocol was registered with the Thai Clinical Trials Registry (TCTR20220323006) and approved by the Khon Kaen University Ethics Committee for Human Research, in accordance with the Helsinki Declaration and ICH good clinical guidelines (HE641384).

7. Acknowledgements

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8. Conflicts of interest

The authors declare that we have no conflict of interest.

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