Original Article นิพนธ์ต้นฉบับ

Efficacy of Music Therapy to Reduce Pain and Anxiety of Patients during Spinal Anesthesia: a Prospective Randomized Controlled Trial

Thanyarat Prommahachai[1], Nampetch Tongsiri[2], Akom Prommahachai[3]

[1] *Division of Anesthesiology, Udon Thani Hospital, Udon Thani, Thailand.*

[2] *Division of Anesthetic nurse, Udon Thani Hospital, Udon Thani, Thailand.*

[3] *Division of Orthopedics, Udon Thani Hospital, Udon Thani, Thailand.*

Abstract

Introduction: Spinal anesthesia is a highly effective for many surgeries. However, the procedure itself causes pain, anxiety and dissatisfaction to the patients. Music has been used to relieve pain and anxiety to patients having various types of operations but it has been lacked of evidence of its benefits during receiving spinal anesthesia. The purpose of this study was to evaluate the impact of music during spinal anesthesia on pain, anxiety and patient's satisfaction.

Methods: This prospective randomized, double-blinded, controlled trial was conducted from 5 September 2024 to 20th November 2024. Participant aged ≥18 years were randomly allocated to receive either music through in-ear headphones with noise cancelling technology connected to MP-3 player or no music by wearing the headphones in silent mode during undergoing spinal anesthesia. Spinal anesthesia was performed by an anesthesiologist without local anesthetic infiltration before spinal needle insertion then two assessment forms for pain and anxiety levels were completed by the patient and the anesthesiologist immediately following the procedure. Outcomes were assessed by rating visual analog scale regarding pain, anxiety, satisfaction and anesthesiologist's perception of the difficulty.

Results: The study included 60 participants. Baseline characteristics did not differ between the groups. Overall pain scores were similar in both groups. Nevertheless, patient's anxiety levels were lower and satisfaction scores were higher in the music group with statistically significant difference. The difficulty score of the procedure by the anesthesiologist shows no significant between the groups.

Conclusion: Patients who listened to music during undergoing spinal anesthesia reported lower anxiety and greater satisfaction. However, there were no differences in pain and physician-perceived procedure difficulty scores between the two groups.

Key words: anxiety, music, pain, spinal anesthesia

Correspondence to: Thanyarat Prommahachai, E-mail: pthanya17@gmail.com

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Introduction

Spinal anesthesia is a highly effective, safe and it is a widely used method for providing pain relief to patients before undergoing various types of surgery, especially lower extremities or lower body parts.[1] However, one of common problems in the patients undergoing the procedure is pain at the procedural site while inserting the needle. A previous study reported that 15.9% of patients were dissatisfied with the procedure due to pain during needle insertion. The etiology of the pain can be caused by many factors, such as the procedural technique, needle size used, worrisome and anxiety while receiving the procedure.[2] Mingir and colleagues [3] found that the procedure resulted a moderate level of anxiety.

There have been several measures proposed to reduce the pain, for instance, cold application[4] or using topical medications such as anti-inflammatory substance[5] to the needle insertion site before the procedure. Those techniques may reduce pain but their effects on reducing anxiety are unclear. Another method currently being used that has been found to be easy, safe and may help relieve pain and anxiety in patients undergoing various medical procedures is music therapy. The patients listening to music during undergoing skeletal traction significantly reduced anxiety.[6] In addition, many studies have found that the patient listening to music intraoperatively during various surgical types after spinal anesthesia demonstrated better vital sign status than the patients who did not listen to music, and those patients listening to music were more satisfied with the treatment.[7,8] However, there has been lack of evidence of benefits of music therapy during receiving spinal block procedure to date. The purpose of this study was to evaluate the effect of listening to music during undergoing spinal anesthesia in terms of procedural pain reduction, anxiety alleviation including an increase in patient's satisfaction. We hypothesized the giving music to a patient during the procedure would provide a better pain control, anxiety and satisfaction. The second aim of the study was to assess an anesthesiologist opinion about difficulty of the procedure regarding using music therapy during spinal anesthesia.

Methods

This study was a single center randomized controlled trial. The trial was conducted at Udon Thani Hospital, Udon Thani, Thailand from 5th September to 20th November 2024. The study protocol was approved by Udon Thani Hospital ethic committee (registration number UDH REC No.138/2567). The study was registered in Thai Clinical Trials Registry (TCTR20250718002). The inclusion criteria were male or female patients with age of 18 years old or older and receiving spinal anesthesia. The participants had to be fully conscious, well cooperative and normal auditory perception. Patients who were blinded, illiterate and also not welling to participate in the study were excluded from the study. Written informed consent was obtained from all participants. Patients were randomized 1:1 ratio into either the music therapy group or the control group. The allocation sequence was generated by using a web-based system to

achieve a sequence with block sizes of 4.[9] The random number allocation sequence was secured in a sealed envelope. Once a patient consented to enter the trial the envelope was opened by the research assistant (N.T.) who was not involved in outcome assessment and the patient was then offered the allocated treatment regimen.

Every participant was given a pair of in-ear headphones (the same model for all participants) connected to the MP-3 player with noise canceling technology to cut out sounding noise. Such headphones were not reused. Once the research assistant (N.T) opened the random envelope, in the treatment group, the MP-3 player wound be turned on a preloaded classical piano slow-paced music. In the control group, the MP-3 player would turn off for the patients, but the patients would wear in-ear headphones in silent mode at all times to reduce noise in the anesthetic room during the procedure. The spinal block procedure was performed by the principal investigator (T.P) on all patients. The principal investigator (T.P) was blinded to the group allocation. The principal investigator used a gauge 27 spinal needle for the procedure. No local anesthetic agent infiltration was used before spinal needle insertion. The participants were administered the same type of analgesia (0.5% bupivacaine) according to the body weight of each patient. After the procedure, the research assistant (N.T) removed the headphones and the music player. Then the principal investigator and the patients were given one assessment form which contained the patient's visual analog scale for pain, anxiety and satisfaction and the physician's visual analog scale for difficulty of the procedure and procedure successfulness evaluation.

Baseline information was collected from the participants consisting of age, gender, BMI, primary diagnosis, underlying medical conditions, operation, previous history of substance drug use and previous pain medications for the last one week before enrollment into the study such as morphine tramadol or non-steroidal anti-inflammatory drugs. The primary outcome was patient's pain score while undergoing spinal anesthesia by marking cross sign on visual analog scale with a 10 cm in length of linear line on the paper (0-10). 0 represents no pain during the procedure whereas 10 represents the worst pain that the patient ever experiences. Other outcomes were patient's anxiety and satisfaction level on the same visual analog scale during the procedure. Anxiety level was defined 0 as complete relaxation and 10 as the worst feeling of anxiety possible. Patient's satisfaction determines 0 as no satisfaction and 10 as the most satisfied experience. Similarly, a questionnaire with 0-10 visual analog scale for assessing the anesthesiologist (T.P.)'s perception of the difficulty of the spinal anesthesia was evaluated. The difficulty was rated from 0 (very easy) to 10 (the most difficult). The success of spinal anesthesia was justified by an anesthesiologist who was the principal investigator. After collecting data from all participants, the blinded assessor (A.P) was the one who measured on 10 cm linear line of VAS for all four outcomes before final statistical analysis

Statistical analysis

Sample size was calculated after a pilot study was conduct, and identified 3.21 as the standard deviation of visual analog score for pain in pilot population. The effect size of 1.8 was used regarding minimally clinical important difference of visual analog scale for pain score defined by Charoenpol and colleagues.[10] 25 patients per group (total 50 patients) were required to the study in order to obtain 80% of power and 5% of alpha error. 20% of data loss was determined and overall, at least 30 patients/group were recruited in our study. Categorical data were analyzed with Chi-square or Fisher Exact test. Distribution of continuous variables were examined with Shapiro-Wilk test. Normal distributed continuous data were analyzed with unpaired Student-t test. Mann-Whitney U test would be used for non-parametric statistical test if the requirement of normal distribution for the t test is not met. Multiple linear regression analysis would be performed to find correlation between patient-reported experience outcomes and predefined factors (age, gender, BMI, substance-drug usage, previous pain medications during the last one week before spinal anesthesia, and music) included in our multivariable model. Due to no missing data or a drop-out patient, handling missing values procedure was not performed. Multiple comparisons of four end-points (three of patient-reported outcomes and one of anesthesiologist-experience outcome) were analyzed by using Bonferroni procedure of multiplicity correction to reduce inflation of error. All analyses were carried out using SPSS version 26.

Results

During the study period, we screened 504 patients for eligibility. 429 patients were excluded because they were received spinal anesthesia from other anesthesiologists who were not participating in our trial. One patient declined consent. One had language barrier and communication problems. 3 patients were illiterate. Of the 60 patients who were randomly assigned to two groups, 30 were assigned to receive music therapy during spinal anesthesia and 30 were assigned to receive silent mode. (Figure 1) Mean age of the participants was 37.1 years old and mean BMI was 24.61 kg/m^2. Most patient (66.7%) were non-smoker or non-substances user. 33.3% of the patients used at least one kind of pain medications for the last seven days before participating in the present study. Majority of operations were orthopedic surgery, followed by obstetric surgery, and general surgery. Baseline characteristics comparing between the two groups were indicated no difference and represented in table 1.

In terms of primary outcomes analysis, the present study found that during the spinal anesthesia, the mean pain score in the music group was similar to the mean of control group, with no statistically significant difference. In contrast, the average patient's anxiety score was 3.02 in the music group and 5.09 in the control group, which shows statistically significant difference with a *P*-value of 0.002 (mean difference of -2.07 (95% CI -3.33 to -0.82). Additionally, the patients who received music therapy reported higher patient's satisfaction

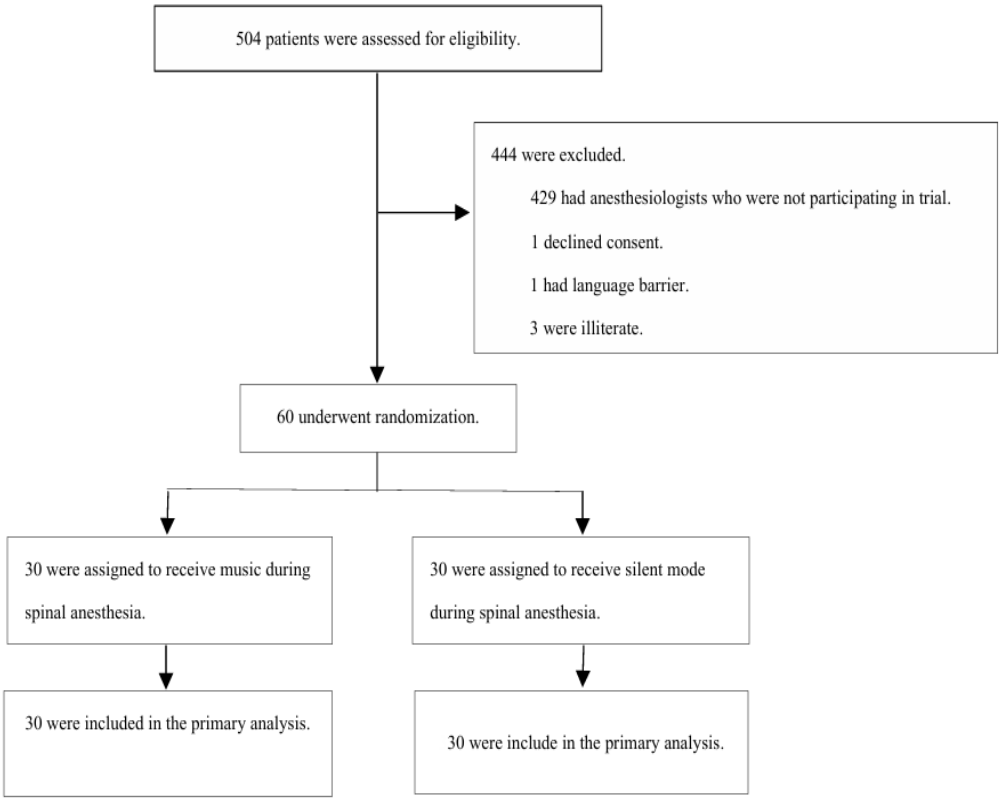


Figure 1 CONSORT diagram

Table 1 Baseline characteristics

	Music (n=30)	Control (n=30)	*P*-value
Age (yr), mean (range)	33.6 (18-71)	40.6 (21-67)	0.570
Gender, n (%)			
Male	16 (53.3)	12 (40.0)	0.301
Female	14 (46.7)	18 (60.0)	
Body mass index (kg/m^2), mean (range)	23.6 (15.6-32.5)	25.6 (18.0-35.3)	0.110
Types of operation, n (%)			0.674
General surgery	3 (10.0)	4 (13.3)	
Gynecological surgery	1 (3.3)	4 (13.3)	
Obstetric surgery	7 (23.3)	7 (23.3)	
Orthopedic surgery	17 (56.7)	13 (43.3)	
Urological surgery	2 (6.7)	2 (6.7)	
Smoking or substance use, n (%)	11 (36.7)	9 (30.0)	0.584
Previous pain medications, n (%)	8 (26.7)	12 (40.0)	0.273

scores during the procedure compared to those who were in the control group ($P < 0.001$).

Regarding the spinal anesthetic procedure, the anesthesiologist rated similar score of the difficulty of the procedure in the two groups (P=0.080) which favors to the music group (the lower score, the easier procedure) but no statistically significant difference. (Table 2) Spinal anesthesia was done successfully in all participants and there was no complication related to music devices nor the spinal procedure during the study.

In the multiple linear regression analysis of 60 participants, providing music to the patient was the only statistically significant predictor of lower anxiety score (P=0.004). Other predefined variables denied statistically significantly predicted patient anxiety. Additionally, music therapy was also the significant predictor to increase patient satisfaction visual analog scores, with score being 1.632 higher (P<0.001). (Table 3)

Discussion

The current prospective randomized controlled trial study demonstrates that providing music therapy to the patients while undergoing spinal anesthesia could decrease patient's anxiety and increase patient's satisfaction. However, patient's pain perception and physician-reported difficulty experience during the procedure showed no statistically significant difference between the two compared groups.

Music has been used as a distractive method during various invasive procedures recently to reduce perioperative pain. Several studies reveal music benefits to decrease pain score during some operations. Bürlukkara and colleagues reported opening music during retrograde intrarenal surgery under spinal anesthesia for renal or ureteral calculi reduced pain score with statistical significance.[11] Zengin and coworkers also indicated music reduced visual analog scale of pain with statistical significance in the participants undergoing port catheter placement to use chemotherapy and nutrition for the oncological patients.[12] The results from previous trials and the present study indicated that music therapy was not effective to reduce perioperative pain. Goel and colleagues reported that there were no statistical differences of pain reduction comparing between music-based intervention and control group in the patients received a

Table 2 Visual analog scale of pain, anxiety, satisfaction and difficulty of procedure

Visual analog scale	Music (mean ± S.D.)	Control (mean ± S.D.)	Mean difference (95% CI)	*P*-value
Pain	2.96 ± 2.01	2.91± 2.60	0.04 (-1.16 to 1.25)	0.941
Anxiety	3.02 ± 2.46	5.09 ± 2.41	-2.07 (-3.33 to -0.82)	0.002*
Satisfaction	9.57 ± 0.88	7.97 ± 1.31	1.60 (0.29 to 1.02)	<0.001*
Difficulty of procedure	0.89 ± 1.09	1.45 ± 1.32	-0.56 (-1.19 to 0.07)	0.080

* Statistically significant difference

Table 3 Multiple regression analysis of prediction on pain and anxiety (n=60)

	Unstandardized Beta[#]	95% CI	Standardized Beta	*P*-value
Prediction of anxiety				
Music therapy	-1.984 (0.649)	-3.286 to -0.682	-0.380	0.004
Age	-0.039 (0.023)	-0.086 to 0.007	-0.213	0.095
Body mass index	-0.023 (0.077)	-0.176 to 0.130	-0.043	0.746
Gender	1.396 (0.754)	-0.116 to 2.908	0.267	0.070
Type of operation	-0.104 (0.290)	-0.686 to 0.478	-0.044	0.721
Smoking or substance use	-0.245 (0.842)	-1.933 to 1.444	-0.044	0.772
Use of recent pain medication	1.001 (0.739)	-0.480 to 2.483	0.181	0.181
Prediction of satisfaction				
Music therapy	1.632 (0.305)	1.020 to 2.244	0.602	<0.001
Age	0.005 (0.011)	-0.017 to 0.027	0.054	0.635
Body mass index	0.016 (0.040)	-0.063 to 0.095	0.057	0.688
Gender	-0.097 (0.354)	-0.807 to 0.614	-0.036	0.786
Type of operation	-0.122 (0.136)	-0.395 to 0.151	-0.099	0.374
Smoking or substance use	-0.310 (0.396)	-1.103 to 0.483	-0.108	0.437
Use of recent pain medication	-0.366 (0.347)	-1.062 to 0.330	-0.127	0.296

[#] Data are shown as the beta coefficient with the standard error in parentheses.

single nerve block and underwent either general anesthesia or monitored anesthesia care in same-day surgery including breast surgeries, open inguinal hernia repairs, and laparoscopic or robotic surgeries.[13] Bechtold and colleagues[14] provided the same result as our study that music played during routine colonoscopy under low-dose conscious sedation in adult patients was no effective to reduce pain. A systematic review of 7 randomized controlled trials indicated that music during colonoscopy provided a small treatment effect.[15] We hypothesized that procedural pain is a somatic pain which is intense and music cannot modify or change significantly the pain pathway in the patients.

Our study reveals that the music group has a 2.07-point lower patient's anxiety score than the control group with statistical significance. The finding is similar to a previous study that music could reduce anxiety in most of the patients undergoing a laparoscopic procedure.[16] Patients undergoing outpatient colonoscopy also benefit from music to reduce anxiety during the operation according to Bechtold's study.[14] Patients' satisfaction in our study showed a better satisfaction in the patient provided with music therapy which is consistent with several studies. A recent study of 95 female patients who were undergoing elective minor gynecological surgeries and received music on Apple iPod Touch™ devices containing playlists of selected music genres and noise-cancelling earphones found that 97.6% of the patients

were satisfied (rate "excellent" and "good" on verbal rating scale) in preoperative period and 98.8% of the patient were still satisfied in postoperative period.[17]

A randomized controlled trial evaluating satisfaction in elective cystoscopy patients reported significantly higher visual analog scale of patient satisfaction in both two music groups (group one of listening to standardized classical music and group two of listening to music according to the patient's choice) comparing to the control group.[18] However, a randomized controlled study by Drzymalski and coworkers showed no statistical difference in maternal satisfaction scale for caesarian section comparing between music and control groups, which is contrary to our study result.[19]

Regarding the procedural difficulty perception score, anesthesiologist-reported procedure difficulty score was not found to increase the score with the use of music and there was not statistically different between the two compared groups in the present study. This finding is comparable to the study of Albersheim and colleagues that the surgeon who performed skeletal traction of proximal tibia procedure rated similar overall procedure difficulty scores in both two compared groups.[6] Such a finding might indicate music for the patient does not influence the surgeon performance.

Our study had several strengths. This study is a randomized controlled trial that using audio music to patients during the anesthesiologist performing spinal anesthesia in order to decrease patient's anxiety and improve patient's satisfaction. Our study design, which is prospective double blinded (physician and assessor) randomized trial. There was also an adequate pre-specified calculated recruited participants that allowed for analysis and ability to detect statistically significant findings. However, this study has also some limitations. The physician-perceived difficulty could be influenced and varied by the level of anesthesiologist's experiences. In our study, the procedure was only performed by the primary investigator. This physician skill may not be generalized to the different level experience of anesthesiologists. Another drawback of our study is that the patients were not blinded to the intervention. This weakness would result confirmation bias, which may have affected the validity of the survey responses from the patients.

Conclusion

The present study evaluated the effect of music therapy during a spinal anesthetic procedure on pain, anxiety and satisfaction. The results reveal that the patients reported lower anxiety and greater satisfaction while listening to music during the procedure compared with the control group. This technique is safe, effective and low cost which could improve patient's clinical outcomes. Nevertheless, there was no statistically significant difference detected in pain and physician-perceived procedure difficulty score between the two groups.

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