The Efficiency of Different Adjunct Techniques for Regional Anesthesia

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In the present prospective, randomized controlled trial, 110 unpremedicated patients undergoing orthopedic surgery under regional anesthesia were randomly divided into 5 groups, with 22 patients in each. During the operation, group 1 listened to a pre-recorded explanation and music, group 2 listened to a subliminal sound, group 3 received propofol by patient-controlled sedation (PCS), group 4 received intravenous midazolam, and group 5 was the control group. Patients in the midazolam group were significantly more sedated than the control group at 1 hr. into the operation. The group that listened to an explanation and music were significantly less satisfied than the propofol group at the end of the operation and 30 min. postoperatively. An incremental cost-effectiveness ratio showed that if explanation and music are used instead of propofol it would save 299.53 baht per patient, but the patient satisfaction score will be 17.26 points lower than if the more expensive drug is used.

Keywords: *Regional anesthesia, Adjunct technique, Subliminal sound, Music, Patient-controlled sedation*

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Regional anesthesia is a safe technique for surgery below the diaphragm. It provides analgesia with muscle relaxation, which facilitates surgical exposure and reduces the stress response. However, while remaining awake during a surgical procedure, the patient may have perioperative anxiety and fear due to an unfamiliar environment, and exposure to multiple anxiety-provoking visual and auditory stimuli[1]. Sedation during regional anesthesia is often desirable to diminish the anxiety and fear associated with the operating room activity and surgical preparation. A wide variety of centrally active drugs are used to provide sedation, anxiolysis, and amnesia. Midazolam and propofol are rapid-acting sedative-hypnotic drugs which can be used for these purposes. However, there are several disadvantages related to the use of these drugs such as respiratory and cardiovascular depression, airway obstruction and their high cost[2,3].

Kane, in 1914, was the first person to provide intraoperative music to distract patients from "the horror of surgery"[4]. Music is widely used to help individuals relax and divert their attention from an unpleasant and stressful situation. It is also reduces sedative and analgesic requirement during an operation[1,5,6].

The objectives of the present study were to compare whether different adjunct techniques (explanation and music, subliminal audiotape, propofol patient-controlled sedation, and conventional sedation with midazolam) could decrease anxiety and increase satisfaction in patients undergoing orthopedic surgery under regional anesthesia. The cost-effectiveness of each technique was also analyzed.

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Material and Method

This was a prospective, randomized, controlled trial. It was conducted after approval by the Ethics

Committee of Siriraj Hospital. The investigator enrolled 110 adult patients, with an ASA rating of I or II who were scheduled to undergo total knee replacement or open reduction with internal fixation for fractured lower extremities under regional anesthesia and who gave written informed consent the evening before surgery. Patients with mental illness or with documented hearing loss and those having any contraindication to regional anesthesia were excluded. The patients were given an explanation of the study protocol and all were unpremedicated before going to the operating room. On the day of the operation, demographic data were obtained, and baseline sedation score was determined using an Alertness/sedation scale (Table 1)[7]. Patients were also asked to evaluate their anxiety level on a verbal analogue score (VAS 0-100), ranging from 0 (complete relaxation) to 100 (the worst feeling of anxiety possible).

In the operating room, noninvasive arterial blood pressure, electrocardiograph and pulse oximetry values were noted every 5 min until the end of surgery. An attending anesthesiologist performed lumbar spinal or epidural anesthesia. After an adequate dermatomal level of anesthesia for the particular procedure was confirmed and cardiorespiratory stability was ensured, the patients were randomly divided using a random number table in an opaque envelope into 5 groups, 22 in each as follows:

Group I Explanation and music: Patients listened to music and an explanation about the benefits and care during regional anesthesia via an earphone during the perioperative period. The explanation took 2 minutes and was repeated twice after which there was music. The volume of the music was set by the patients.

Group II Subliminal audiotape: Patients listened to music with a subliminal message. The message contained suggestions related to 6 different areas of well being prepared by one of the investigators (PP). The volume of the music was set by the patients.

Group III Propofol patient-controlled sedation (PCS): Patients were instructed how to use the PCS device and were given an explanation about the sedation properties of its content. The PCS was set to deliver propofol 0.3 mg/kg PCS dose for the patients older than 60 years and 0.6 mg/kg PCS dose for the patients in a younger age group with a 3-minute lock out interval.

Group IV Midazolam: Patients received midazolam 0.05 mg/kg bolus. If the patient complained of discomfort or anxiety after the first dose of midazolam, midazolam 0.02 mg/kg or narcotics could be given.

Table 1. Alertness/sedation scale*

Response	Score level
Completely awake	5
Awake but lethargic response to name spoken in normal tone	4
Asleep but responds to loud verbal command	3
Asleep but responds to shaking	2
Does not respond to shaking	1
Does not respond to noxious stimuli	0

* from Gan TJ, et al

Group V Control: Patients received no adjunct techniques. Anxiolytic or analgesic drugs could be given by the attending anesthesiologist if the patient complained of being anxious.

The sedation score and anxiety VAS were obtained 1 hour into the operation and at the end of the operation. Sedation scores were also obtained at 10 min, 15 min, and 24 hr postoperatively.

Satisfaction score was determined using a verbal analogue score (VAS 0-100), with 0 meaning totally unsatisfied and 100 the highest satisfaction that is possible at the end of operation, 30 min, and 24-36 hr. postoperatively by the nurse anesthetists who were blinded to the adjunct technique the patients received.

Complications included hemodynamic instability, which defined hypotension as a systolic BP < 30% of baseline value, hypertension as a systolic BP > 30% of baseline values, bradycardia as a heart rate < 60 beats/min, tachycardia as a heart rate > 120 beats/min, hypoxemia as O2 Sat < 92% for more than 5 sec. The attending anesthesiologist treated these complications by giving vasopressors, sedatives, analgesics, or sympatholytic drug intravenously or administering oxygen via a face mask as indicated. The costs of each adjunct technique were calculated as follows:

1. Labor and material costs were calculated using salary and fringe benefit per minute multiplied by duration of adjunct techniques. Cheevawattana S[8] reported the labor cost of an anesthesiologist working at Siriraj Hospital at that time (1998) to be 2.28 baht/min. The authors inflated the cost up 5% per year so the labor costs were estimated as 2.64 baht/min for the year 2002. The depreciation cost for the monitoring equipment was 0.33 baht/min. Assuming the

life span of the equipment to be 5 years. So the labor costs plus material costs were 2.97 baht/min.

2. Cost of adjunct techniques

2.1 Group I: The cost of the earphones was 150 baht and the recorded tape cassette was 50 baht. This material and equipment can be used 50 times so the cost per each application was 4 baht.

2.2 Group II: The cost of the earphones was 150 baht and the content recorded was estimated to be 110 baht. This material and equipment can be used 50 times so the cost per each application was 5.2 baht.

2.3 Group III: The cost of the PCS equipment (Graseby 3300) reported by Sanansilp V[9] was 178.51 baht/case. The mean dose of propofol given was 168.11 mg/case and this cost 161.38 baht. Therefore, the overall cost of this adjunct technique was 339.89 baht/case

2.4 Group IV: The cost of midazolam was 27.38 baht/case

2.5 Group V: The control group had no extra cost.

3. The cost of rescue drugs such as sedatives, analgesics, vasopressors were calculated using the dose in milligrams given multiplied by the cost per milligram.

Discrete (ordinal) variables such as sedation score were analyzed using the Kruskal-Wallis test and Mann-Whitney U test while continuous variables such as anxiety and satisfaction VAS were analyzed with a Repeated measure ANOVA test. The incidence of complications was analyzed using Chi-squared test. Statistical significance was assumed for $p < 0.05$.

Results

There was no statistically significant difference among the 5 groups with regard to demographic characteristics, duration of adjunct technique, type of operation (Table 2) method of regional anesthesia (Table 3), or drugs received in each group (Table 4). Anxiety scores were not statistically different at any time among the 5 groups (Table 5). The sedation score in the midazolam group was significantly lower than the control group at 1 hour into the operation. The satisfaction score in the explanation and music group was significantly lower than the propofol group at the end of the operation and at 30 min postoperatively (Table 5). Eight patients in the propofol group and five patients in the midazolam group became hypoxemic and were treated with oxygen via facemask and 3 patients in each group needed airway adjuncts to maintain the airway patency (Table 6).

The cost of each adjunct technique is shown in Table 7. The cheapest technique was explanation and music. When an incremental cost-effectiveness ratio was calculated using the ratio between the difference of the cost divided by the difference of

Table 2. The demographic and clinical characteristics

Group	Explanation and music (n = 22)	Subliminal Sound (n = 22)	Propofol (n = 22)	Midazolam (n = 22)	Control (n = 22)	p
Age (yr)*	38.9±18.5	49.1±22.1	43.9±18.1	45.9±21.7	48.9±21.8	0.461
Body weight (kg)	62.6±12.9	58.6±9.8	64.3±10.5	58.3±18.4	68.3±18.4	0.10
Gender (Male:Female)	13:9	10:12	12:10	12:10	12:10	0.928
ASA (I:II)	15:7	12:10	15:7	16:6	16:6	0.694
Operation (TKR:Fx)	10:12	10:12	10:12	10:12	10:12	1.0
Previous regional anesthesia	8	2	6	9	8	0.150
Previous similar operation	9	1	4	7	6	0.058
Duration of adjunct technique (min)	98.8±33.5	111.3±40.0	110.01±35.3	123.1±49.7	122.7±43.2	0.25

TKR = Total knee replacement, Fx = Fracture treatment

Table 3. The regional anesthetic technique that the patients received

Group	Explanationand music (n = 22)	Subliminal Sound (n = 22)	Propofol (n = 22)	Midazolam (n = 22)	Control (n = 22)	p
Regional anesthesia:						
Spinal	10	6	7	8	11	0.368
Epidural	5	10	7	6	5	
Spinal with morphine	7	6	8	8	6	

Table 4. Number of patients who received rescue drugs during anesthesia (%)

Group	Explanation and music	Subliminal sound	Propofol	Midazolam	Control	p
No drug	12 (54.5)	9 (40.9)	15 (68.2)	13 (59.1)	14 (63.6)	0.414
Received drugs:	10 (45.5)	13 (59.1)	7 (31.8)	9 (40.9)	8 (36.4)	
Ephedrine or aramine	4 (18.2)	4 (18.2)	4 (18.2)	4 (18.2)	1 (4.5)	
Atropine	1 (4.5)	-	2 (9.1)	-	1 (4.5)	
Narcotics	5 (22.7)	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	
Sedatives	-	1 (4.5)	-	-	2 (9.1)	
Sedatives and narcotics	-	1 (4.5)	-	2 (9.1)	1 (4.5)	
Ephedrine and atropine	-	-	-	-	2 (9.1)	
Ephedrine and narcotics	-	2 (9.1)	-	-	-	
Ephedrine and sedatives	-	2 (9.1)	-	1 (4.5)	-	
Atropine and narcotics	-	-	-	1 (4.5)	-	

Table 5. Sedation scores, anxiety scores and satisfaction scores of the 5 groups. Sedation scores are shown as median (min,max) and anxiety,satisfaction scores are shown as mean ± SD

Group	Explanation and music	Subliminal sound	Propofol	Midazolam	Control	p
Sedation baseline	5 (5,5)	5 (5,5)	5 (5,5)	5 (5,5)	5 (5,5)	1.000
Sedation at 1 hr into the operation	5 (4,5)	5 (4,5)	5 (2,5)	4 (2,5)*	5 (4,5)*	0.000
Sedation at end of the operation	5 (4,5)	5 (3,5)	5 (4,5)	5 (2,5)	5 (4,5)	0.066
Sedation at 10 min	5 (5,5)	5 (4,5)	5 (5,5)	5 (4,5)	5 (4,5)	0.204
Sedation at 15 min	5 (5,5)	5 (4,5)	5 (4,5)	5 (4,5)	5 (4,5)	0.654
Sedation at 24 hr	5 (5,5)	5 (5,5)	5 (5,5)	5 (5,5)	5 (5,5)	1.000
Anxiety at premed	43.64 ±40.65	31.36±31.82	33.86 ±31.24	29.98±34.35	34.09±35.84	0.725
Anxiety at 1 hr into the operation	13.18 ±23.38	14.77±22.60	13.64 ±29.53	12.91±26.50	17.05±28.23	0.985
Anxiety at end of the operation	4.09 ±11.82	10.45±29.35	12.27 ±30.38	4.09±12.21	9.09±23.89	0.676
Satisfaction at end of the operation	79.56*±22.57	83.64±21.72	96.82*±7.16	92.27±11.93	88.18±18.16	0.012
Satisfaction at 30 min postoperatively	81.36*±20.31	82.73±19.32	96.36*±7.27	93.14±11.68	88.64±18.07	0.009
Satisfaction at 24-36 hr postoperatively	81.59 ±18.73	87.73±15.72	86.82 ±13.93	86.82±16.37	86.36±21.34	0.785

Table 6. The complications in each group

Group	Explanation and music (n = 22)	Subliminal Sound (n = 22)	Propofol (n = 22)	Midazolam (n = 22)	Control (n = 22)	p
Hypoxia	0	2	8	5	1	0.002
Airway obstruction	0	0	3	3	0	0.049
Bradycardia	2	4	5	1	6	0.2
Hypotension	5	7	3	7	5	0.6

Table 7. Costs per case (baht) of different adjunct techniques

Cost	Explanation and music	Subliminal sound	Propofol	Midazolam	Control
Labor and material	98 x 2.97 = 291.06	111 x 2.97 = 329.67	110 x 2.97 = 326.7	123 x 2.97 = 365.31	122 x 2.97 = 362.34
Adjuncttechnique	4	5.20	339.89	27.38	-
Rescue drug	90	256	18	165	147
Total (baht)	385.06	590.87	684.59	557.69	509.34

effectiveness, the cost per patient of explanation and music group was 299.53 baht lower than the propofol group. However, the satisfaction score was 17.26 lower in the explanation and music group. This means that if propofol to explanation and music in 100 patients is prefered, 29,953 baht more is needed and will be able to increase the satisfaction score from 79.6 to 96.8 at the end of the operation and from 81.4 to 96.4 at 30 min after the operation. However, this will not increase satisfaction at 24-36 hr postoperatively.

Discussion

Perioperative anxiety is directly related to fear of the surroundings, an unfamiliar environment, loss of control, and death and disfigurement. Auditory input is a known modulator of the human response to stress and music and may have a therapeutic role in medicine. It is also an attractive option from an economic standpoint. The present study found that anxiety scores were high before the operation and decreased more than 50% in all groups at 1 hr into the operation and were even lower at the end of the operation. Lepage et al[5] reported the preoperative anxiety level of 4.2 ± 2.7 and 3.7 ± 2.5 (VAS 0-10) which was reduced to 1.1 and 1.0 in the postoperative period in the group that listened to music and the group that did not respectively. Patients in both groups of this study received midazolam PCS and the dose of midazolam used was significantly lower in the music group for the same anxiety level. The present study, however, could not show a reduction in the anxiety score with music. This may be because of the habits and cultural characteristics of Thai patients with an optimistic point of view, which resulted in a low anxiety score in all groups. The sample size of the present study may be too small to show a significant difference in anxiety among the groups. For it to contribute to anxiety reduction, the music selected should exhibit certain specific characteristics. It should be chosen by the patient, because personally selected music seems more likely to reduce autonomic reactivity, as opposed to an investigator's selection[10,11]. Tracks should be mixed to convey a continuous and homogeneous ambience. Some patients in the present study also asked for their favorite music but the authors only provided them the type of music that had been prepared.

The sedation scores in the present study were low in the midazolam group and respiratory complications were high in the midazolam and propofol PCS group so vigilance with regard to airway patency is needed when using these techniques with regional anesthesia.

Satisfaction scores were high in all groups of the present study. Even though the score was statistically higher in the propofol group, it may not have clinical significance. The potential benefit also disappeared at 24 hr after the operation. Most available scales designed for measuring it during the perioperative period were inadequate because they did not allow for control of confounding variables, such as social desirability[12].

Numerous studies have reported the use of patient-controlled sedation (PCS) during surgical procedures under regional anesthesia[2,13,14]. PCS provides sedation, anxiolysis and amnesia using the sedative drugs given as the patient's demand with the lock out interval so that the patient would not receive the drug to prevent drug overdose. Elderly patients are more susceptible to drug induced complications (oversedation, respiratory depression, confusion, etc.) so the authors used a dose of 0.3 mg/kg in the propofol PCS for patients older than 60 years and 0.6 mg/kg for patients in the younger age group.

Pooviboonsuk P, et al[15] reported that subliminal audiotape provide relaxation and improvement in the personal well being of volunteers even after the first listening session. Four different aspects of well being those subjects rated to be improved were relaxation, life enjoyment, strong-mindedness, and self-esteem. There has been no study showing that subliminal audiotape influences anxiety or sedation requirement in the perioperative period.

Thailand is a developing country with a limited budget for health care. Techniques should be used, which provide highly efficient, good quality anesthesia. In the present study, the authors compared 3 major techniques, a listening technique (which was composed of explanation and music and subliminal audiotape group), an intravenous sedative technique (which was composed of propofol PCS and midazolam group), and a control group. The authors expected that the lowest cost technique would be the listening technique but it was found that our patients in the subliminal audiotape group needed more rescue drugs compared to other groups so the cost of this technique was higher compare to the explanation and music group. When calculating the cost/effectiveness ratio, the authors found that if propofol is prefered to explanation and music in 100 patients it costs 29,953 baht more to make the satisfaction score statistically significantly higher with a questionable clinically

significant difference. The cost/effectiveness ratio helps the policy planner to make an explicit choice of how the majority of patients should be treated. The authors recommend using the explanation and music technique as the adjunct technique for the patient undergoing orthopedic procedures under regional anesthesia as it is a cost-effective technique.

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การใช้เทคนิคเสริมในผู้ป่วยที่มารับการระงับความรู้สึกเฉพาะส่วน

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ผู้ป่วยที่มารับรับการผ่าตัดทางออร์โธปิดิกส์ ภายใต้เทคนิคการระงับความรู้สึกเฉพาะส่วน 110 คน ถูกแบ่งโดยสุ่มออกเป็น 5 กลุ่ม ๆ ละ 22 คน ระหว่างการผ่าตัด ผู้ป่วยในกลุ่มที่ 1 ฟังเพลงบรรเลงร่วมกับการอธิบายถึงเทคนิคการระงับความรู้สึกได้รับทางหูฟัง กลุ่มที่ 2 ฟังเสียงระดับจิตใต้สำนึก กลุ่มที่ 3 ได้รับยา Propofol เข้าหลอดเลือดดำ โดยผู้ป่วยควบคุมยาด้วยตนเอง กลุ่มที่ 4 ได้รับยา midazdam เข้าหลอดเลือดดำ โดยวิสัญญีแพทย์ กลุ่มที่ 5 เป็นกลุ่มควบคุม ผลการศึกษาพบว่าผู้ป่วยที่ได้รับยา midazdam มีอาการง่วงซึมมากกว่ากลุ่มควบคุมในระยะ 1 ชั่วโมงหลังเริ่มผ่าตัด ผู้ป่วยกลุ่มที่ฟังเพลงบรรเลงร่วมกับคำอธิบายมีความพอใจในช่วงเสร็จผ่าตัดและช่วง 30 นาทีหลังผ่าตัดน้อยกว่ากลุ่มที่ได้รับยา propofol การคำนวณประสิทธิภาพและราคาพบว่าเมื่อให้ผู้ป่วยฟังเพลงบรรเลงร่วมกับการอธิบายแทนการใช้ยา propofol จะสามารถประหยัดเงินได้ถึง 299.53 บาทต่อผู้ป่วย 1 คน แต่ความพึงพอใจของผู้ป่วยจะลดลง 17.26 คะแนน