Effect of Noise Block Using Earplugs on Propofol Sedation Requirement during Extracorporeal Shock Wave Lithotripsy

Supaporn Tharahirunchot MD*,
Suwanna Tatiyapongpinij BN*, Ketchada Uerpairojkit MD**

** Department of Anesthesiology, Rajavithi Hospital, College of Medicine, Rangsit University, Bangkok, Thailand*
*** Department of Anesthesia, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand*

Objective: *To determine effect of noise block using earplugs on reducing propofol infusion needed to maintain a constant bispectral index (BIS) values in patients undergoing extracorporeal shock wave lithotripsy (ESWL).*
Material and Method: *Fifty-eight patients (18-65 years) with nephrolithiasis undergoing ESWL, having ASA physical status I or II and have normal hearing function tested by audiometry were enrolled in this randomized, double-blind, controlled trial. Patients were randomized and allocated into two groups: noise blocked group (earplugs inserted into both ears) and control group (earplugs not inserted). Sedation by target-controlled infusion was started with 1.2 mcg/mL of propofol and propofol target concentration was adjusted gradually by 0.2 mcg/ml every 5 minutes intraoperatively to achieve and maintain bispectral index (BIS) values within 75-80% until the procedure finished. Total amount of propofol (mg), BIS values (%), ambient noise level (dB) and patient satisfaction (1-5) were measured.*
Results: *The amount of propofol infusion needed to maintain a constant BIS index value in patients undergoing ESWL in the noise blocked group was significantly lower than that in the control group (6.91 $\pm$ 2.05 vs. 8.23 $\pm$ 2.16 mg/kg/m^2/hr, p = 0.021). Patient satisfaction was similar in both groups (4 [1] vs. 4 [1], p = 0.929).*
Conclusion: *Noise diminution in ambient operating room can reduce the amount of propofol needed to maintain light sedation during ESWL.*

Keywords: *Noise, Bispectral index, Operating room noise, ESWL, Sedation, Propofol*

J Med Assoc Thai 2011; 94 (Suppl. 2): S103-S107
Full text. e-Journal: *http://www.mat.or.th/journal*

Generally, noise level in the operating room ranges from 55 to 86 dB, depending on the types of surgery being performed[1]. Auditory stimulation from this noise induces autonomic response and increases heart rate, vascular resistance, and blood pressure[2]. Previous study showed that premedication did not reduce noise-induced distress in patients, so the emphasis should be on reducing sound level to decrease noise-induced anxiety, rather than relying on premedication[3]. Furthermore, noise in the operating room may interfere anesthetic process to achieve a stable level of sedation in patients undergoing surgical procedures with local anesthesia and intravenous sedation as part of a monitored anesthesia care (MAC) technique[4]. Extracorporeal shock wave lithotripsy (ESWL) has been widely and effectively used in the treatment of urolithiasis, but during a long noisy procedure, patients may become restless, bored or uncomfortable. In addition to anxiety, patients may have more pain during ESWL. Using analgesic agents with sedation allows patients to rest and relax and this increases the efficacy of lithotripsy[5]. Sound, pain, and uncomfortable position are important stressful factors occurring with patients who undergo ESWL[6,7]. Some previous studies showed that intraoperative music may be beneficial in sedated patients undergoing urologic procedures during spinal anesthesia and patients undergoing lithotripsy. However, subsequent investigation is necessary to determine whether decrease in sedative requirements results from intraoperative music or the elimination of ambient noise in the operating room[8]. The aim of this study was to

Correspondence to:
Tharahirunchot S, Department of Anesthesiology, Department of Medicine, Rajavithi Hospital, 2 Phyathai Road, Ratchathewi, Bangkok 10400, Thailand.
Phone: 08-1325-4795
E-mail: supabura@windowslive.com

evaluate the effect of ambient noise elimination in operating room on reduction of propofol in maintaining the level of conscious sedation during ESWL.

Material and Method

After Institutional review board approval and obtaining patients' informed consent, fifty-eight patients were enrolled in this randomized, double-blind, controlled trial. Patients with age at 18-65 years, ASA Physical Status I and II, having nephrolithiasis and undergoing extracorporeal shock wave lithotripsy (ESWL) were included. Preoperative ear examination and audiometry were performed. Those patients with abnormal auditory function were excluded from the study. Patients with known uncontrolled psychiatric disorder, disorientation to time, place or person, known alcoholics, users of illicit drugs or chronic psychiatric drug, allergic to studied agents as well as those with significant renal, hepatic, cardiopulmonary diseases, airway difficulty or obstructive sleep apnea, were excluded from the study. Patients were randomly allocated into two groups (noise blocked, n = 29; and control, n = 29). Computer-generated simple randomization was obtained to assign for all subjects. The code was concealed in a sealed opaque envelope. The investigators were blinded to this assignment. After arrival in the operating room, the electroencephalograph signal was acquired using BIS monitor and BIS sensor electrodes applied to the forehead and temple. Noninvasive blood pressure, electrocardiogram and pulse oximeter in all patients were monitored with standard monitoring equipment. All patients were received oxygen supplement with oxygen canula 4 liters/min. Before starting ESWL, anesthesia was administered with fentanyl 1 mcg/kg and target controlled infusion pump was set to deliver propofol at a target concentration of 1.2 mcg/ml. After loss of conciousness, the foam ear plugs (3M®1100) were inserted into both ears of patients in the noise blocked group and the correct position were checked by an anesthesia nurse. The specification of noise reduction rating (NRR) specified by ANSI S3.19/74 showed 29 dB of noise reduction in this group. For the control group, the ear plugs were not inserted into their ears. The surgical caps were put in all patients for covering their both ears and all the investigators could not identify the patient groups. Then propofol TCI rate was adjusted gradually by 0.2 mcg/ml every 5 minutes intraoperatively to achieve and maintain bispectral index (BIS) values at 75-80 until the procedure finished. If the patients moved until the procedures were affected the investigators would immediately increase TCI rate 0.2 mcg/ml. The target concentration was reduced to be 0.2 mcg/ml when the oxygen saturation was less than 95%, or noninvasive blood pressure reduced more than 30% of baseline or heart rate was less than 50 beats/min. Each patient would equally receive 1,000 shocks (rate of 80 shocks per minute) at shock wave energy level 2. Levels of shock wave energy (level A, B, C, 1-6) being used in each patient were gradually increased individually (except level 2) until the renal stones were already broken. In the postanesthetic care unit, the unsatisfied experience during the procedure and patient satisfaction to the procedure were recorded by Likert scale 1-5:1 was extremely dissatisfied and 5 was extremely satisfied. Total propofol amount and the propofol amount during energy level 2 periods were recorded. BIS values and operating room noise level were recorded at the time before sedation when patients were prepared for ESWL and every 5 minutes until the end of the procedure. Otherwise, the maximal level of shock wave energy being used and adverse events were also recorded. Sample size calculation was based on the following assumptions concerning two sided test and performed to detect any difference in the total propofol requirement of 80 mg, common standard deviation of propofol requirements intraoperatively of 95[9], type I error = 0.05, type II error = 0.2. The calculated sample size was 24 subjects per group. When calculating 20% of subjects added to cover dropout, the sample size will be 29 subjects in each group. Unpaired Student's t-test was used to compare the total propofol amount and the amount used during energy level 2 period between the two groups. The patient satisfaction was compared using Mann-Whitney U test. Data are presented as means $\pm$ SD for continuous data, median (interquartile range) for ordinal data and counts for categorical data. P-values < 0.05 were considered statistically significant.

Results

All 58 patients could complete the study protocol. Patient characteristics, surgical time and anesthesia time were similar in the both groups (Table 1). No significant difference was detected between two groups regarding baseline operating room noise and BIS level intraoperative operating room noise and BIS level and maximal level of shock wave energy (Table 2). The major outcomes of the study are shown in Table 3. Comparing the sedation during ESWL procedure between the two groups, either during level 2 of the shockwave energy or when comparing the total requirement at the end of procedure, total propofol requirement in the noise blocked group was significantly lower than that used in the control group. Patient satisfaction was similar in the two groups. There was one patient whose peripheral oxygen saturation (SpO_2) was less than 90%, and was corrected well by nasal airway insertion. Finally, no patient recalled the bad events during the procedure.

Discussion

Consistent with the study by Kang et al[10], our study demonstrated that noise block using earplugs can reduce the amount of propofol infusion needed to maintain light sedation (BIS 75-80) in patients undergoing ESWL. Szmuk, et al[11] demonstrated that listening to music during general anesthesia (BIS near 50) can not reduce the sevoflurane concentration needed to maintain a constant Bispectral index. They explained that explicit memory of auditory stimuli is rare during general anesthesia. But at the lighter levels of anesthesia, Kim et al[12] demonstrated that experimental noise can alter the EEG-BIS value during MAC sedation with propofol. Furthermore, Kang et al[10] showed that blocking noise is more effective than playing music in reducing BIS scores during propofol sedation in patients undergoing total knee replacement with combined spinal-epidural anesthesia. These previous studies supported the results of our study which maintained a constant BIS values during the period of light sedation. Auditory stimuli in addition to pain perception, discomfort position for a long period and uncomfortable environment during the procedure increase the stress and anxiety of the patient[7,13]. When auditory stimuli are impeded, the stress and anxiety of the patient propably decrease, then the propofol sedation requirement becomes lower.

The reticular activating system (RAS) is an area of the brain responsible for regulating arousal and sleep-wake transitions. Previous study showed a decrease in the dose of sedative/hypnotic agents needed to ablate responses to nociceptive stimuli when the patient has received neuraxial blockade. It has been postulated that the reason for this phenomenon is decreased sensory input to the RAS as a result of the

Table 1. Patient characteristics, surgical and anesthesia time

	Noise blocked (n = 29)	Control (n = 29)
Sex (M/F)	14/15	18/11
Age (yr)	44.17 ± 12.47	47.45 ± 11.38
Weight (kg)	63.62 ± 13.31	63.97 ± 11.79
Body mass index (kg/m^2)	24.54 ± 4.33	24.16 ± 3.17
Surgical time (min)	57.59 ± 11.92	55.86 ± 13.96
Anesthesia time (min)	62.59 ± 11.92	60.86 ± 13.96

Values are represented as numbers, means ± SD

Table 2. Operating room noise level, BIS values and maximal level of shock wave energy

	Noise blocked (n = 29)	Control (n = 29)
Noise level (dB)		
Before ESWL	65.5 ± 1.0	66.0 ± 1.3
During ESWL	71.1 ± 0.9	71.1 ± 1.3
End of ESWL	65.6 ± 0.5	65.8 ± 0.8
BIS values (%)		
Before ESWL	96.3 ± 1.7	95.9 ± 2.5
During ESWL	77.4 ± 1.2	77.1 ± 1.2
End of ESWL	80.1 ± 1.3	80.4 ± 1.5
Maximal level of energy	4 (2)	4 (2)

Values are represented as means ± SD, median (interquartile ranges)

Table 3. Major results

	Noise blocked (n = 29)	Control (n = 29)	p	95% CI
Total propofol amount ($mg/kg/m^2/h$)	6.91 ± 2.05	8.23 ± 2.16	0.021	0.21-2.42
Propofol amount during energy level 2 period ($mg/kg/m^2/h$)	1.33 ± 0.67	1.76 ± 0.74	0.023	0.06-0.80
Patient satisfaction	4 (1)	4 (1)	0.929	

Values are represented as means ± SD, median (interquartile ranges) profound sensory blockade[14]. For our study, auditory sensory input to the RAS is diminished by earplugs. So this may explain the reason for our results. Regarding to the variation of the required energy levels of shockwaves in each patient, it may induce pain and stress differently. As a consequence this may influence to the propofol requirement of patients. In our study, we assigned all patients to equally receive 1,000 shocks (rate of 80 shocks per minute) at energy level 2, and we found the same result that noise block reduces the propofol requirement for sedation. However, we did not measure the plasma concentration of the agent.

Noise block with ear plugs is a simple technique with minimal risk and does not affect patient satisfaction. Therefore, we recommend this technique for patients who undergo ESWL. As our environmental noise level was approximately 71 dB, this result might be limited in other ambient noise levels, since we did not study the effective decibel range which can be protected by these simple ear plugs. Further studies are needed to confirm this effectiveness of noise block on sedation during other procedures or different levels of ambient noise.

In conclusion, the elimination of ambient noise in the operating room can reduce the amount of propofol needed to maintain light sedation during ESWL.

Acknowledgements

We are grateful to Professor John Kavanagh for his advice on methodology of this study. Furthermore we are indebted to the nursing staff of Department of Anesthesiology, otolaryngologists and audiologists of Department of Otolaryngology, as well as nursing staffs of urologic clinic, Department of Urology, Rajavithi hospital for their assistance.

Potential conflicts of interest

None.

References

1. Shapiro RA, Berland T. Noise in the operating room. N Engl J Med 1972; 287: 1236-8.
2. Kam PC, Kam AC, Thompson JF. Noise pollution in the anaesthetic and intensive care environment. Anaesthesia 1994; 49: 982-6.
3. Liu EH, Tan S. Patients' perception of sound levels in the surgical suite. J Clin Anesth 2000; 12: 298-302.
4. Sa Rego MM, Watcha MF, White PF. The changing role of monitored anesthesia care in the ambulatory setting. Anesth Analg 1997; 85: 1020-36.
5. Salinas AS, Lorenzo-Romero J, Segura M, Calero MR, Hernandez-Millan I, Martinez-Martin M, et al. Factors determining analgesic and sedative drug requirements during extracorporeal shock wave lithotripsy. Urol Int 1999; 63: 92-101.
6. Dawson C, Chilcott-Jones A, Corry DA, Cohen NP, Williams HO, Nockler IB, et al. Does lithotripsy cause hearing loss? Br J Urol 1994; 73: 129-35.
7. Cepeda MS, Diaz JE, Hernandez V, Daza E, Carr DB. Music does not reduce alfentanil requirement during patient-controlled analgesia (PCA) use in extracorporeal shock wave lithotripsy for renal stones. J Pain Symptom Manage 1998; 16: 382-7.
8. Koch ME, Kain ZN, Ayoub C, Rosenbaum SH. The sedative and analgesic sparing effect of music. Anesthesiology 1998; 89: 300-6.
9. Zhang XW, Fan Y, Manyande A, Tian YK, Yin P. Effects of music on target-controlled infusion of propofol requirements during combined spinal-epidural anaesthesia. Anaesthesia 2005; 60: 990-4.
10. Kang JG, Lee JJ, Kim dM, Kim JA, Kim CS, Hahm TS, et al. Blocking noise but not music lowers bispectral index scores during sedation in noisy operating rooms. J Clin Anesth 2008; 20: 12-6.
11. Szmuk P, Aroyo N, Ezri T, Muzikant G, Weisenberg M, Sessler DI. Listening to music during anesthesia does not reduce the sevoflurane concentration needed to maintain a constant bispectral index. Anesth Analg 2008; 107: 77-80.
12. Kim DW, Kil HY, White PF. The effect of noise on the bispectral index during propofol sedation. Anesth Analg 2001; 93: 1170-3.
13. Knight WE, Rickard PhD NS. Relaxing music prevents stress-induced increases in subjective anxiety, systolic blood pressure, and heart rate in healthy males and females. J Music Ther 2001; 38: 254-72.
14. Tverskoy M, Shagal M, Finger J, Kissin I. Subarachnoid bupivacaine blockade decreases midazolam and thiopental hypnotic requirements. J Clin Anesth 1994; 6: 487-90.

ผลของการป้องกันเสียงด้วยวัสดุอุดหูต่อความต้องการยาโปรโพฟอลในการระงับความรู้สึกขณะสลายนิ่ว

สุภาภรณ์ ธาราหิรัญโชติ, สุวรรณา ตติยพงศ์พินิจ, เกศชาดา เอื้อไพโรจน์กิจ

วัตถุประสงค์: *เพื่อศึกษาว่าการป้องกันเสียงด้วยวัสดุอุดหูสามารถลดปริมาณของโปรโพฟอล (propofol) ที่ใช้เพื่อคงระดับของค่า bispectral index ให้คงที่ ในผู้ป่วยที่มาสลายนิ่ว (ESWL) ได้หรือไม่*

วัสดุและวิธีการ: *ทำการศึกษาในผู้ป่วย 58 คน ที่เป็นนิ่วในไต มารับการสลายนิ่ว (ESWL) อายุตั้งแต่ 18-65 ปี ASA physical status ระดับ 1 หรือ 2 และมีการได้ยินปกติ โดยได้รับการตรวจด้วย audiometry แบ่งผู้ป่วยออกเป็น 2 กลุ่ม โดยวิธีการสุ่ม เป็น กลุ่มป้องกันเสียง (ได้รับการใส่วัสดุอุดหูในหูทั้ง 2 ข้าง) และกลุ่มควบคุม (ไม่ได้รับการใส่วัสดุอุดหู) หลังจากนั้น ผู้ป่วยได้รับยาสงบประสาทด้วย โปรโพฟอล (propofol) โดยควบคุมระดับยาที่ให้ด้วย target controlled infusion เริ่มที่ 1.2 ไมโครกรัม/มิลลิลิตร และปรับขนาดยาครั้งละ 0.2 ไมโครกรัม/มิลลิลิตร ทุก 5 นาที เพื่อคงระดับค่า bispectral index ที่ 75-80 จนกระทั่งเสร็จสิ้นการสลายนิ่ว การวัดค่าตัวแปร: ปริมาณโปรโพฟอล (propofol), ค่า BIS index, ระดับเสียงในห้องผ่าตัด, ระดับความพึงพอใจ*

ผลการศึกษา: *ปริมาณโปรโพฟอล (propofol) ที่ใช้เพื่อคงระดับค่า BIS index ให้คงที่ในผู้ป่วยที่มาสลายนิ่ว (ESWL) ในกลุ่มป้องกันเสียงด้วยวัสดุอุดหูน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (p = 0.021) ระดับความพึงพอใจของผู้ป่วยทั้ง 2 กลุ่ม ไม่มีความแตกต่างกัน*

สรุป: *การป้องกันเสียงในห้องผ่าตัดสามารถลดปริมาณโปรโพฟอล (propofol) ที่ใช้ในการสงบประสาทในระดับตื้นขณะทำการสลายนิ่ว (ESWL) ได้*