ผลของการป้องกันเสียงด้วยวัสดุอุดหูต่อความต้องการยาโปรโพฟอล ในการระงับความรู้สึกขณะสลายนิ่ว

นางสุภาภรณ์ ธาราหิรัญโชติ

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
ปีการศึกษา 2553

EFFECT OF NOISE BLOCK USING EARPLUGS ON PROPOFOL SEDATION REQUIREMENT DURING EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY

Mrs. Supaporn Tharahirunchot

A Thesis Submitted in Partial Fulfillment of the Requirements

for the Degree of Master of Science Program in Health Development

Faculty of Medicine

Chulalongkorn University

Academic Year 2010

Thesis Title	EFFECT OF NOISE BLOCK USING EARPLUGS ON PROPOFOL SEDATION REQUIREMENT DURING EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY
By	Mrs. Supaporn Tharahirunchot
Field of Study	Health Development
Thesis Advisor	Associate Professor Ketchada Uerpairojkit, M.D.

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สุภาภรณ์ ธาราหิรัญโชติ : ผลของการป้องกันเสียงด้วยวัสดุอุดหูต่อความต้องการยาโปรโพฟอลในการระงับความรู้สึกขณะสลายนิ่ว. (EFFECT OF NOISE BLOCK USING EARPLUGS ON PROPOFOL SEDATION REQUIREMENT DURING EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY)
อ.ที่ปรึกษาวิทยานิพนธ์หลัก : รศ.พญ.เกศชาดา เอื้อไพโรจน์กิจ, 43 หน้า.

วัตถุประสงค์ : เพื่อศึกษาว่าการป้องกันเสียงด้วยวัสดุอุดหูสามารถลดปริมาณของโปรโพฟอลที่ใช้เพื่อคงระดับของค่า bispectral index ให้คงที่ ในผู้ป่วยที่มาสลายนิ่ว (ESWL) ได้หรือไม่

รูปแบบการวิจัย : การศึกษาเชิงทดลองแบบสุ่มปกปิดสองทาง

วิธีการศึกษา : 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 โดยควบคุมระดับยาที่ให้ด้วย target controlled infusion เริ่มที่ 1.2 มคก/มล. และปรับขนาดยาครั้งละ 0.2 มคก/มล. ทุก 5 นาที เพื่อคงระดับค่า bispectral index ที่ 75-80 จนกระทั่งเสร็จสิ้นการสลายนิ่ว

การวัดค่าตัวแปร : ปริมาณโปรโพฟอล (มก.), ค่า BIS index (%), ระดับเสียงในห้องผ่าตัด (เดซิเบล), ระดับความพึงพอใจ (1-5)

ผลการศึกษา : ปริมาณโปรโพฟอลที่ใช้เพื่อคงระดับค่า BIS index ให้คงที่ในผู้ป่วยที่มาสลายนิ่ว (ESWL) ในกลุ่มป้องกันเสียงด้วยวัสดุอุดหูน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (6.91±2.05 และ 8.23±2.16 มก/กก/$ม^2$/ชม., p = 0.021, 95%CI = 0.21-2.42) ระดับความพึงพอใจของผู้ป่วยทั้ง 2 กลุ่ม ไม่มีความแตกต่างกัน (4[1] และ 4[1], p = 0.929)

สรุป : การป้องกันเสียงในห้องผ่าตัด สามารถลดปริมาณโปรโพฟอลที่ใช้ในการสงบประสาทในระดับตื้น ขณะทำการสลายนิ่ว (ESWL) ได้

สาขาวิชาการพัฒนาสุขภาพ ลายมือชื่อนิสิต.....
ปีการศึกษา 2553 ลายมือชื่อ อ.ที่ปรึกษาวิทยานิพนธ์หลัก.....

5275060630 : MAJOR HEALTH DEVELOPMENT
KEYWORDS : NOISE / BISPECTRAL INDEX / OPERATING ROOM NOISE / ESWL / SEDATION / PROPOFOL

SUPAPORN THARAHIRUNCHOT : EFFECT OF NOISE BLOCK USING EARPLUGS ON PROPOFOL SEDATION REQUIREMENT DURING EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY. THESIS ADVISOR : ASSOC. PROF. KETCHADA UERPAIROJKIT, M.D., 43 pp.

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).

Design: Randomized double- blinded controlled trial.

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 ± 2.05 vs 8.23 ± 2.16 mg/kg/m^2/hr, p=0.021, 95%CI=0.21-2.42).Patient satisfaction was similar in both groups (4[1] vs 4[1], p=0.929).

Conclusion: Noise elimination in ambient operating room can reduce the amount of propofol needed to maintain light sedation during ESWL.

Field of Study: Health Development Student's Signature: Supaporn Tharahirunchot

Academic Year: 2010 Advisor's Signature: Ketchada Uerpairojkit

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Finally I would like to acknowledge the patients who participate to this study.

CONTENTS

Page

CONTENTS (CONT.)

Page

LIST OF TABLES

Page

LIST OF FIGURES

Page

CHAPTER I
INTRODUCTION

Background and Rationale

Noise levels in the operating room range from 55 to 86 dB, depending on the type of surgery being performed [1]. Orthopedic surgery was found to have the highest average equivalent sound level. Neurosurgery, urology, cardiology and gastrointestinal surgery followed closely. For neurosurgery and orthopedic surgery, peak levels exceeded 100 dB over 40% of the time [2].

Noise can cause increases in heart rate, vascular resistance, and blood pressure [3]. The sound levels which measured exceed the 70 dB(A) threshold for noise induced peripheral vasoconstriction and hypertension, and noise-induced corticosteroid release [4]. Previous study showed that premedication did not reduce noise-induced distress in patients, so the emphasis should be on reducing sound levels to reduce that component of anxiety that is noise induced, rather than relying on premedication [5]. Furthermore, noise in the operating room may interfere with the ability of anesthesia providers to achieve a stable level of sedation for patients undergoing surgical procedures with local anesthesia and intravenous sedation as part of a monitored anesthesia care (MAC) technique [6].

Extracorporeal shock wave lithotripsy (ESWL) has been used widely and effectively in the treatment of urolithiasis since the 1980s. It provides a noninvasive, effective means of treatment, usually with no requirement of general anesthesia. Patient sedation can simplify the toleration of ESWL [7]. Patients with anxiety have more pain during ESWL, and it has been reported that using analgesic agents with sedation increases the efficacy of lithotripsy [7]. Furthermore shock wave sounds have been found to be disturbing to patients [8]. When sedation-analgesia procedures are used and the patient is awake during the procedure, pain sensation, staying still in the same position for a long time, being in a different condition, and discomfort from visual and

auditory stimuli increase the stress and anxiety of the patient [9]. Sound, pain, and position are important stress factors for patients who undergo ESWL [10].

Music is widely used to help persons relax and divert their attention from unpleasant and stressful situations. Intraoperative music may benefit awake patients undergoing urologic procedures during spinal anesthesia and patients undergoing lithotripsy. However, subsequent investigations are necessary to determine whether the decrease in sedative requirements results from intraoperative music or the elimination of ambient operating room noise [11].

A wide variety of objective clinical scoring systems has been developed to provide a more consistent method for monitoring temporal changes in the level of sedation during MAC. The most common neurophysiologic techniques for monitoring the depth of sedation involve the use of electroencephalogram (EEG), a noninvasive, objective, and continuous measure of brain function that has been shown to correlate with the depth of sedation [12]. Interpretation of EEG changes can be difficult when drug combinations are used because sedative and analgesic drugs alter the EEG in a drug-specific fashion [12, 13]. Recent studies with the EEG-BIS index suggest that the BIS value correlates best with the depth of sedation [14], and correlates with the depth of both midazolam- and propofol-induced sedation [15,16].

So this study is done to evaluate whether the elimination of ambient operating room noise can reduce the amount of propofol needed to maintain light sedation during extracorporeal shock wave lithotripsy. Bispectral index values will be applied for monitoring the level of sedation. If the elimination of ambient operating room noise can reduce the amount of propofol needed, the side effects of propofol infusion (e.g. hypotension, bradycardia) may reduce. Furthermore, most of patients undergo ESWL are out-patient cases, if the amount of propofol infusion decreases, the patients may be discharged to home more rapidly.

CHAPTER II
LITERATUR REVIEW

Pubmed database was searched and the search terms were “music AND anesthesia ANS BIS”. 7 articles were found. I considered that the article of Peter Szmuk et al. related to the background and rationale of this study.

Peter Szmuk et al. demonstrated that the end-tidal concentration of sevoflurane required to maintain BIS near 50 during laparoscopic cholecystectomy was virtually identical in patients exposed to music or not. This may be explained that explicit memory of auditory stimuli, such as words, stories, poems, and music, is rare during general anesthesia. In addition, implicit memory testing is much more complicated, and results vary widely depending on the test and anesthesia method used [17]. Some studies showed that 0.4-0.45 MAC isoflurane abolishes both explicit and implicit memory [18]. So listening to music during general anesthesia can not reduce the sevoflurane concentration needed to maintain a constant bispectral index.

Later, Pubmed database was searched again and the search terms were “noise AND anesthesia AND BIS”. 7 articles were found and I considered that the articles of Dae Woo Kim et al. and Jin Gu Kang et al. related to the background and rationale of this study.

Dae Woo Kim et al. evaluated the effect of noise on the bispectral index (BIS) value during propofol sedation by randomized, crossover protocol study. The target concentration of propofol target-controlled infusion (TCI) was adjusted to maintain the targeted BIS value at 80 (BIS 80 group) or at 75 (BIS 75 group). External experimental sound at level of 50, 80, 110, and 120 dB was applied to patients. In the BIS 80 group, the BIS values at 80, 110, and 120 dB were significantly increased compared with the value at 50 dB. Additionally, the BIS values at 110 and 120 dB were significantly increased compared with the value at 80 dB in the BIS 80 group. In contrast, the BIS values were not significantly increased with increasing noise levels from 50 to 120 dB in the BIS 75 group. So the authors concluded that experimental noise can alter the EEG-

BIS value during MAC sedation with propofol, although this effect was only apparent at lighter levels of propofol-induced sedation [19].

Jin Gu Kang et al.'s prospective, randomized,single-blinded study demonstrated 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 [20].

CHAPTER III
RESEARCH DESIGN

Research question

Can noise block using earplugs reduce the amount of propofol infusion needed to maintain a constant bispectral index (BIS) values in patients undergo extracorporeal shock wave lithotripsy (ESWL)?

Research objective

To determine whether noise block using earplugs can reduce the amount of propofol infusion needed to maintain a constant bispectral index (BIS) values in patients undergo extracorporeal shock wave lithotripsy (ESWL)

Research hypothesis

There is the difference in the amount of propofol infusion needed to maintain a constant bispectral index (BIS) values between the patients undergoing extracorporeal shock wave lithotripsy (ESWL) with noise block and those with ambient noise.

Statistical hypothesis

Null hypothesis

The amount of propofol infusion needed to maintain a constant bispectral index (BIS) value in patients undergoing extracorporeal shock wave lithotripsy with noise block is not different from those with ambient noise.

Alternative hypothesis

The amount of propofol infusion needed to maintain a constant bispectral index (BIS) value in patients undergoing extracorporeal shock wave lithotripsy with noise block is different from those with ambient noise.

Key words

Noise, bispectral index, operating room noise, extracorporeal shock wave

lithotripsy (ESWL), sedation, propofol

Preliminary agreement

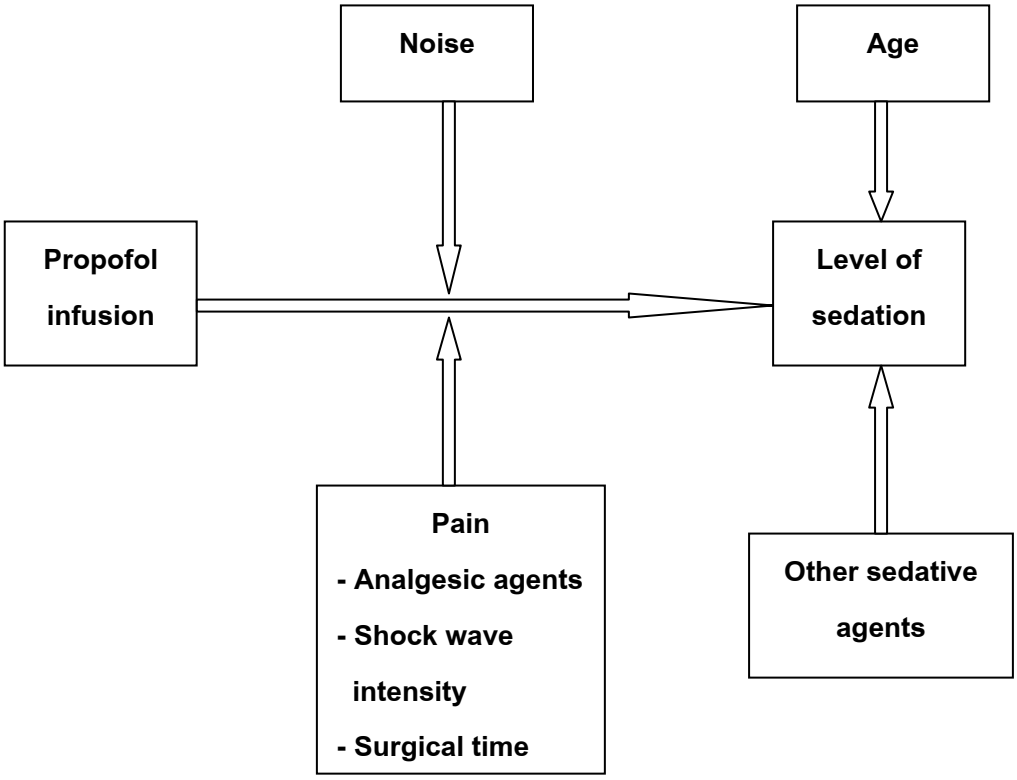
Shock wave lithotripter which be applied in this study is Dornier Compact Delta (therapy head without FarSight transducer). This lithotripter can generate various energy levels which each level has maximal pressure and effective focus energy (12 mm) as following:

Energy Levels	Max. Pressure P+[MPa]	Energy E(12mm)[mJ]
A	8	4.1
B	11	6.7
C	16	11.0
1	27	16.0
2	38	22.0
3	45	30.0
4	48	40.0
5	50	50.0
6	51	61.0

Willis (2006) reported a practical way to protect the treated kidney from the predicted lesion induced by a clinical dose of shockwaves. Before the administration of a clinical dose of 2000 shocks at 24 kV with an unmodified HM3 lithotripter, a pretreatment dose of 100 to 500 shockwaves at 12 kV is administered, followed by the full clinical dose to the same site. Under these conditions, the normal lesion of approximately 6% is reduced to approximately 0.3%, a highly significant change. One hypothesis of a possible mechanism of this outcome is that the pre-dose of shockwaves induces a significant vasoconstrictive event that prevents an incoming stress from shearing the vessel wall or perhaps prevents or reduces the number of cavitation events [21].

Basically, at Rajavithi Hospital, patients receive a pretreatment dose of shock wave at low levels (level A, B, C, 1, 2) before the administration of a clinical dose. Generally, they receive a pretreatment dose of 800-1,000 shocks at level-2. In this study, the investigators assign that all studied patients will equally received 1,000 shocks (rate of 80 shocks per minute) at energy level-2 for comparing the amount of propofol infusion between two groups in the same shock wave intensity. For another energy levels each patient will receive various dose of shockwaves and various maximal level of shockwave intensity , depending on destruction of stones.

Conceptual framework



Operational definitions

1. **American Society of Anesthesiologists (ASA) physical status** is a classification of patients preoperatively according to their health [22].

Class I	Healthy patient
Class II	Mild systemic disease – no functional limitation
Class III	Severe systemic disease – definite functional limitation
Class IV	Severe systemic disease that is a constant threat to life
Class V	Moribund patient unlikely to survive 24 hours with, or without operation

2. **Patient's satisfaction** was classified by Likert scale as

1 = Extremely not satisfied

2 = Not satisfied

3 = Fair

4 = Satisfied

5 = Extremely satisfied

Research design

Randomized double-blinded controlled trial

The investigators who assessed the outcomes and the participants did not know group allocation. The patients in noise block group were inserted earplugs into both ears after the administration of fentanyl and propofol intravenously, so the patients already slept and did not know their group allocation. For the investigators who assessed the outcomes, they were outside the operating room while ear plugs were inserted.

CHAPTER IV
RESEARCH METHODOLOGY

Population and sample

Target population

The patients who had nephrolithiasis and undergoing extracorporeal shock wave lithotripsy (ESWL) at Rajavithi Hospital.

Sample population

Sample population was the patients who had nephrolithiasis, scheduled for extracorporeal shock wave lithotripsy (ESWL) at Rajavithi Hospital and met the eligible criteria. Sampling method used in this study was consecutive sampling.

Method of recruitment of study population

All the patients who had all of the inclusion criteria and none of the exclusion criteria were recruited for the study.

Inclusion criteria

1. Age 18-65 years old
2. ASA physical status I or II
3. Patients have nephrolithiasis
4. Patients have not impacted cerumen by ear examination and have normal hearing function by audiometry
5. Patients provided written informed consent

Exclusion criteria

1. Patients who are allergic to propofol, fentanyl or eggs
2. Patients who had a history of chronic psychiatric drug use
3. Patients who have uncontrolled psychiatric disorder
4. Patients who have disorientation to time, place or person
5. Patients who were known alcoholics or users of illicit drugs

6. Patients with
    a. poor renal function – serum creatinine > 1.5 mg/dl
    b. poor liver function – serum albumin < 3 mg/dl or INR > 1.5
    c. cardiopulmonary disease
        i. FC III or IV, arrhythmia or history of myocardial infarction
        ii. Abnormal chest film
7. Uncooperated patients
8. Patients with airway difficulty
9. Patients who have obstructive sleep apnea (OSA)

Sample size determination

Primary outcome of this study is total amount of propofol infusion (mg/BMI/hr) needed to maintain a constant bispectral index (BIS) values. It was shown as mean of total amount of propofol infusion (mg/kg/m^2/hr). Mean of total amount of propofol infusion in noise blocked group compared to control group. Sample size was estimated from:

Test of difference in 2 independent means

$H_0 : \mu_1 - \mu_2 = 0$

$H_1 : \mu_1 - \mu_2 \neq 0$

$$n/\text{group} = 2[(z_{\alpha/2} + z_{\beta})\sigma/\Delta]^2$$

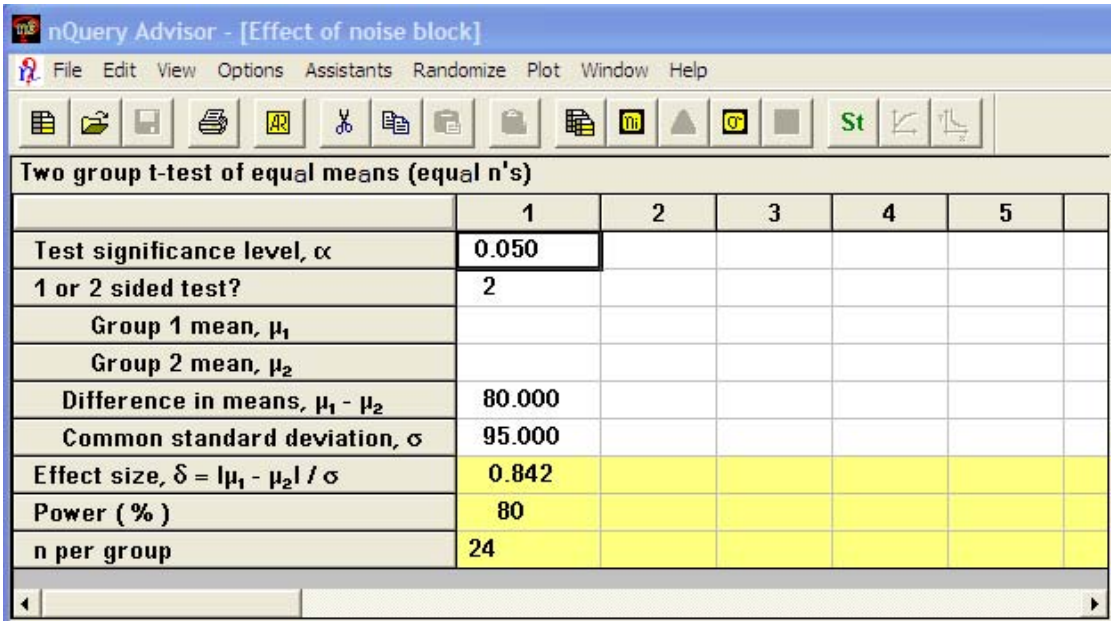
where α = Probability of type I error

β = Probability of type II error

σ = Common standard deviation of intraoperative requirements of propofol in group 1, 2

Δ = Difference in mean of intraoperative requirements of propofol between 2 groups = $\mu_1 - \mu_2$

Using nQuery Advisor program, two-sample Student's t-test (equal variances), the calculation of sample size based on the following assumptions concerning two sided test, intraoperative requirements of propofol, which resulted from the study of Zhang XW et al.[23], common standard deviation of 95 and difference in mean total amount of propofol of 80 mg (the most common side effect of propofol is hypotension which is dose-dependent side effect), type I error = 0.05, type II error = 0.2; the calculated sample size was 24 subjects per group. When calculated 20% of subjects added to cover dropout, the sample size would be 29 subjects per group, overall of 58 subjects.

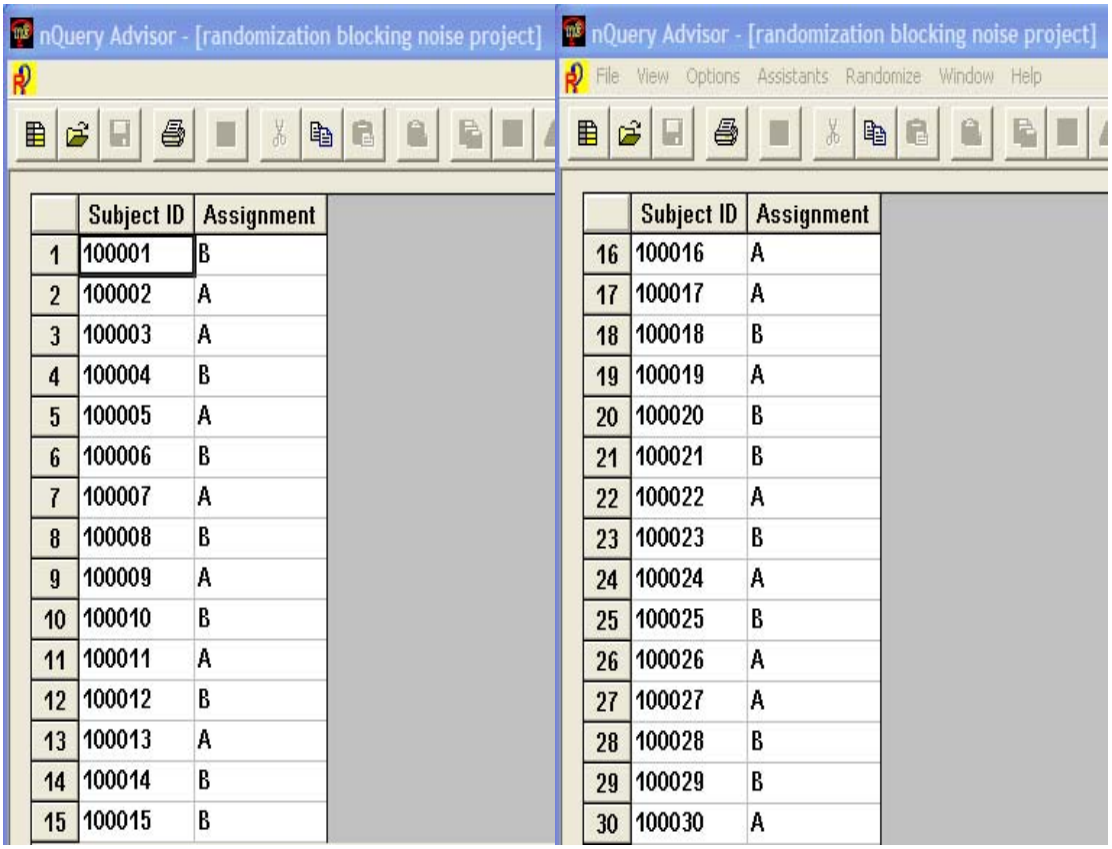


	1	2	3	4	5
Test significance level, α	0.050				
1 or 2 sided test?	2				
Group 1 mean, μ_1					
Group 2 mean, μ_2					
Difference in means, $\mu_1 - \mu_2$	80.000				
Common standard deviation, σ	95.000				
Effect size, $\delta = \lvert\mu_1 - \mu_2\rvert / \sigma$	0.842				
Power (%)	80				
n per group	24				

Figure 1 Sample size calculation

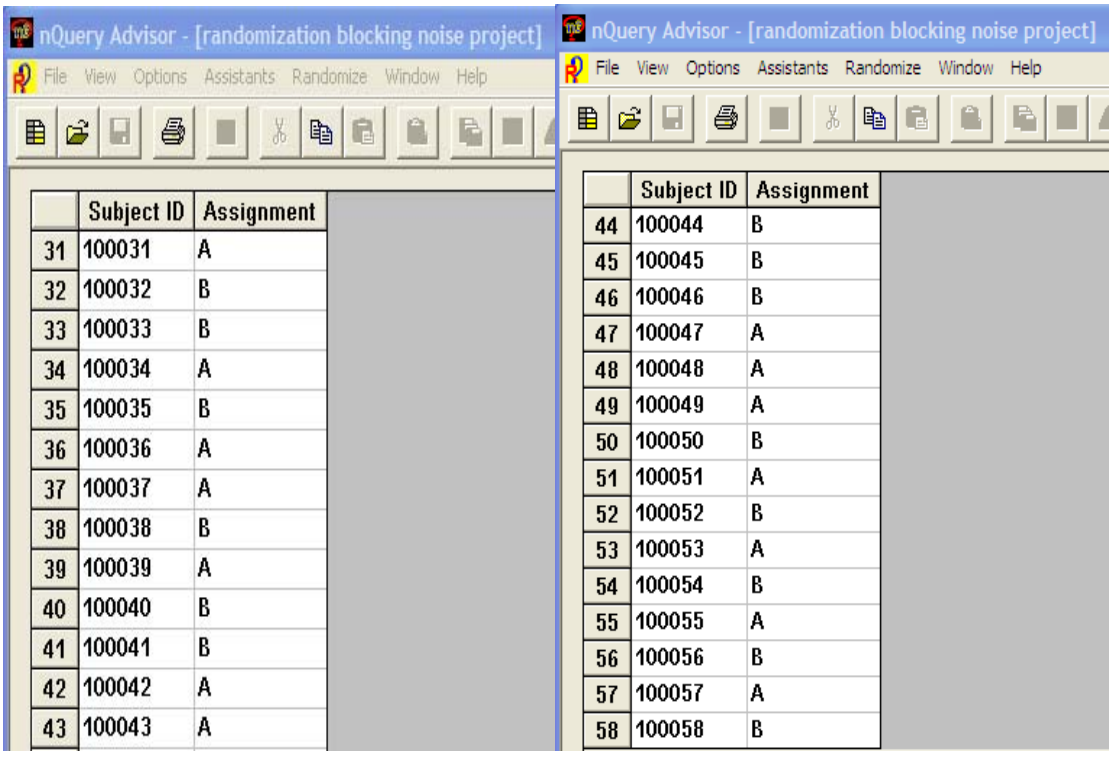
Randomization and allocation concealment

Patients were randomly allocated to either group. Simple randomization was obtained for all subjects to achieve assignment by computer generated randomization using nQuery Advisor program.



	Subject ID	Assignment
1	100001	B
2	100002	A
3	100003	A
4	100004	B
5	100005	A
6	100006	B
7	100007	A
8	100008	B
9	100009	A
10	100010	B
11	100011	A
12	100012	B
13	100013	A
14	100014	B
15	100015	B

	Subject ID	Assignment
16	100016	A
17	100017	A
18	100018	B
19	100019	A
20	100020	B
21	100021	B
22	100022	A
23	100023	B
24	100024	A
25	100025	B
26	100026	A
27	100027	A
28	100028	B
29	100029	B
30	100030	A



	Subject ID	Assignment
31	100031	A
32	100032	B
33	100033	B
34	100034	A
35	100035	B
36	100036	A
37	100037	A
38	100038	B
39	100039	A
40	100040	B
41	100041	B
42	100042	A
43	100043	A

	Subject ID	Assignment
44	100044	B
45	100045	B
46	100046	B
47	100047	A
48	100048	A
49	100049	A
50	100050	B
51	100051	A
52	100052	B
53	100053	A
54	100054	B
55	100055	A
56	100056	B
57	100057	A
58	100058	B

Figure 2 Computer generated simple randomization

The code was concealed in a sealed opaque envelop. The investigators were blinded to this assignment.

Intervention

The patients who were planned for extracorporeal shock wave lithotripsy (ESWL), had all of the inclusion criteria and none of the exclusion criteria signed the consent form after clear understanding about the study. They got auditory examination and undergo pure tone audiometry at outpatient department. In the day of extracorporeal shock wave lithotripsy (ESWL), the electroencephalograph signal was acquired using BIS monitor and BIS sensor electrodes were applied to the forehead and temple. Patients were randomized allocated to two groups:

Control group – Ear plugs were not inserted

Noise blocked group – Ear plugs were inserted into both ears

Ear plugs be used in this study were foam ear plugs 3M® 1100. Noise Reduction Rating (NRR) which be specified by ANSI S3.19/74 is 29 dB. Technique of inserting the ear plugs is described as following

1. roll earplugs
2. insert earplugs into both ears
3. hold for 10 seconds

The anesthesia nurses who inserted earplugs would be instructed about using these earplugs as above.

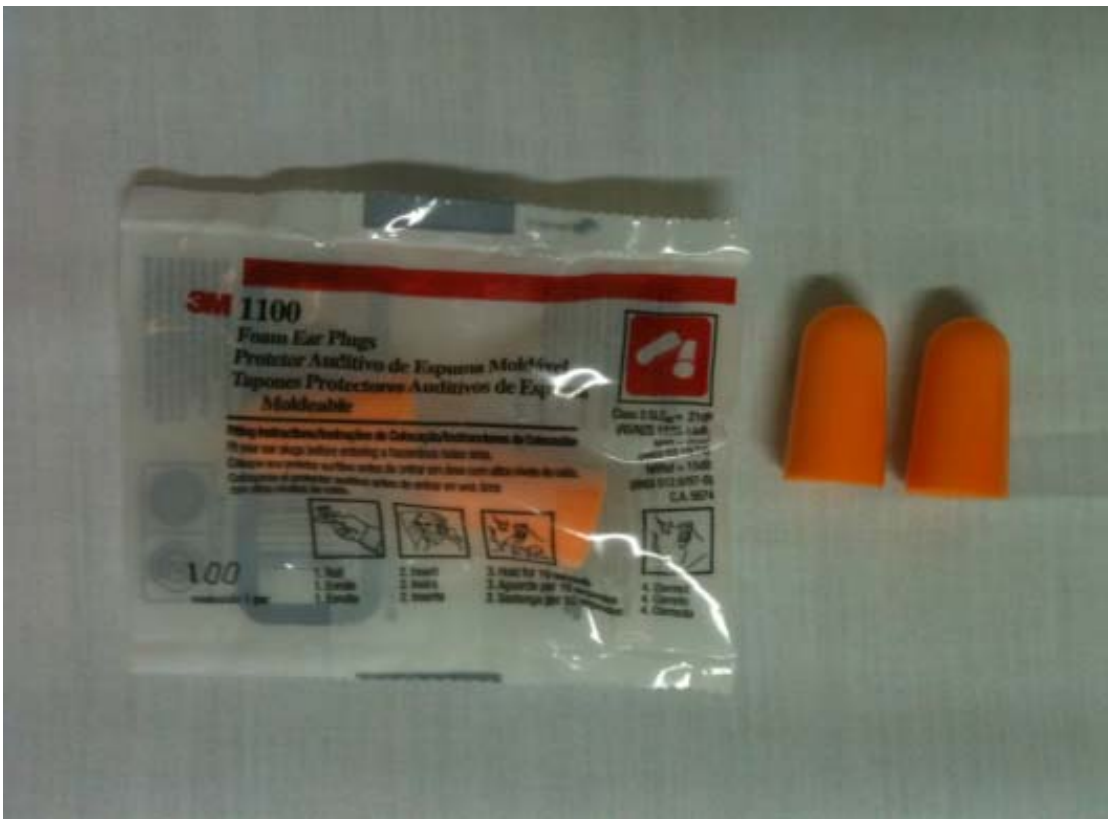


Figure 3 Foam ear plugs 3M® 1100

In the operating room, all patients were monitored with standard monitoring. They included noninvasive blood pressure, electrocardiogram and pulse oximeter. All patients received oxygen supplement with oxygen canula 4 litres/min. Before starting ESWL, anesthesia was administered with fentanyl 1 mcg/kg and target controlled infusion pump was set to deliver a propofol target concentration of 1.2 mcg/ml intravenously, based on Schnider's pharmacokinetic-pharmacodynamic (PK-PD) model. Then ear plugs were inserted into both ears of patients and checked correct position in noise blocked group and the surgical caps were put in all patients for covering their both ears. The investigators who assess the outcomes were not in the operating room while ear plugs were inserted, so the investigators did not know group allocation. Propofol TCI rate was adjusted gradually by 0.2 mcg/ml every 5 minute intraoperatively to achieve and maintain bispectral index (BIS) values at 75-80. They were maintained until the procedure finished. If patients moved until affecting to procedures, the investigators would immediately increase TCI rate 0.2 mcg/ml. The investigators would

decrease TCI rate 0.2 mcg/ml when pulse oximeter was less than 95%, noninvasive blood pressure reduced more than 30% of baseline or heart rate was less than 50 beats/min. Levels of shock wave energy (level A, B, C, 1-6) used in each patient were gradually increased until the renal stones were already broken. However, in this study, each patient would receive the same dose of shockwaves at energy level-2. The investigators assigned that all studied patients equally received 1,000 shocks (rate of 80 shocks per minute) at energy level-2. For the different energy levels, each patient received various doses of shockwave and various maximal level of shockwave intensity, depending on destruction of stones.

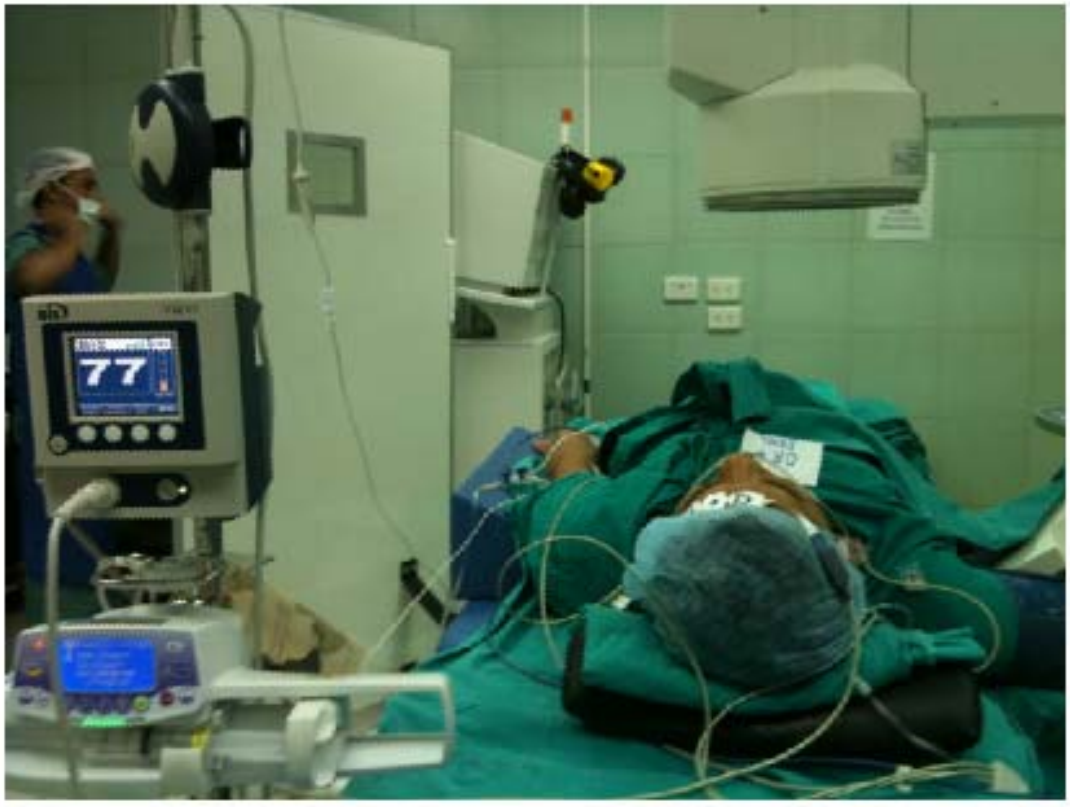


Figure 4 Patient and the environment during the procedure

In the operating room, these data were recorded;

- BIS index values before propofol infusion and every 5 minutes during propofol infusion

- TCI propofol rate every 5 minutes
- Total amount of propofol
- Ambient noise level before starting ESWL, every 5 minutes after starting ESWL and at the end of ESWL
- Amount of propofol used during energy level-2 period
- Maximal level of shock wave energy used
- Adverse events

In the postanesthetic care unit, the investigators interviewed ability of patients to remember the bad events during procedure and assessed patients' satisfaction.

Outcome measurement

1. The primary outcome was mean total amount of propofol in unit of mg., mg/BMI/h.,and mg/kg/h.
2. The secondary outcomes were
    i. Mean amount of propofol used during energy level-2 period in unit of mg., mg/BMI/h.,and mg/kg/h.
    ii. Number of patients which remember the bad events during procedure
    iii. Level of patient satisfaction

Data collection

Case record form was generated for each individual patient, which included:

1. Patient's characteristic and baseline data : age, sex, body weight, height, BMI, surgical time, anesthesia time
2. Ambient noise level at various times:
    - Before starting ESWL
    - Every 5 min after starting ESWL
    - At the end of ESWL
3. BIS index values every 5 minutes
4. Maximal level of shock wave energy used

5. Patient's outcome measurement:
   - Total amount of propofol (mg)
   - Milligrams of propofol used during energy level-2 period
   - Number of patients who remembered the bad events during procedure
   - Level of patient satisfaction
   - Number of patients which had adverse events e.g. hypotension, arrhythmia, desaturation

Data analysis

The patient's data would be statistically analyzed to compare the outcomes between two groups. They were summarized in this table.

Table 1 Statistical analysis

Outcome measurement	Statistical analysis
Primary outcome:	
- Mean total milligrams of propofol	Unpaired Student's *t*-test
Secondary outcomes:	
- Mean of milligrams of propofol used during energy level 2 period	Unpaired Student's *t*-test
- Number of patients to remember the bad events during procedure	Chi-square test
- Level of patient satisfaction	Mann-Whitney U test

Demographic data such as age, body weight, body mass index (BMI), surgical time, ambient noise level at various times and bispectral index values of each group were shown as mean $\pm$ S.D. Maximal level of shock wave energy used in each group was shown as median, interquartile range. Finally, the result showed the sex of the patients in each group.

The data were analyzed using SPSS version 13.0

Ethical considerations

This study protocol was reviewed and approved by the Institutional Review Board of Rajavithi Hospital. The patients were informed about objectives, methods, outcomes and risks of this study.

The patients had the right to refuse participation in this study or to withdraw from the study at any time without affecting to their proper medical care. A signed informed consent was obtained from the patient without enforcement. Data of the participants would be kept confidential.

In common practice for ESWL in Rajavithi Hospital, the patients had not been inserted earplugs. The greatest level of noise exposure was found to be at the head of the patient, with an average reading of 89 dB. The readings at the lithotripter technician's station averaged 84 dB. The anesthetist and urologist were exposed to average sound levels of 81 and 79 dB, respectively. All readings at each evaluated station evidenced a level of exposure considered safe by Occupational Safety and Health Administration (OSHA) standards, which permit 8 hours of exposure to 90 dB per day [24]. The intervention for this study was the patients who were allocated into experimental group were inserted with earplugs into both ears. These intervention and assessment were less harm to patients. Finally, the patients in experimental group received the same medical treatment and care as patients in control group.

Expected benefit and application

Noise block with ear plugs insertion is less harm and simple intervention. Most of patients undergoing extracorporeal shock wave lithotripsy (ESWL) are out-patient cases. If noise block can reduce sedative drugs needed to maintain appropriate sedation, the side effects which cause by sedative drugs may be decreased and the patients may be discharged to home more rapidly.

This study performed in the patients who scheduled for extracorporeal shock wave lithotripsy (ESWL). This procedure just causes mild to moderate pain and only needs light sedation. Result of this study may be generalized to patients who just need

light sedation during procedures (e.g. already regional anesthetized) and operation rooms are noisy (e.g. orthopedic operation rooms).

Administration and time schedule

Activity	**Expected time period of execution (month)**											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Project development	✓	✓										
Recruitment of subjects			✓	✓								
Data collection					✓	✓	✓	✓	✓	✓		
Cleaning data											✓	
Analysis and writing												✓

Budget (supported by Rajavithi Hospital)

- Payment for data collection (Package)	5,000	Baht
- Audiometry examination (200 Baht x 64)	12,800	Baht
- Audiometry examination fee	1,280	Baht
- BIS electrode (1,000 Baht x 20)	20,000	Baht
- Foam ear plugs 3M® 1100 (15 Baht x 29)	435	Baht
- Payment for report printing	2,500	Baht
- Office materials	500	Baht
- Total	**42,515**	**Baht**

CHAPTER V
RESULTS OF THE STUDY

64 patients got ear examination by otolaryngologists and were examined by pure tone audiometry at the outpatient department. There were 6 patients who were diagnosed to have neurosensory hearing loss from pure tone audiometry, another patients had normal hearing function. So remain 58 patients who fulfilled all of the inclusion criteria and none of the exclusion criteria were enrolled for this study. All 58 patients could complete the study protocol. Patient characteristics (sex, age, weight, height, and body mass index), surgical time and anesthesia time were similar in the both groups (Table 2).

Table 2 Patient characteristics, surgical and anesthesia time

	Noise blocked (n =29)	Control (n = 29)
Sex (M/F)	14 / 15	18 / 11
Age (yr)	44.17 $\pm$ 12.47	47.45 $\pm$ 11.38
Weight (kg)	63.62 $\pm$ 13.31	63.97 $\pm$ 11.79
Height (cm)	155.86 $\pm$ 28.16	162.21 $\pm$ 8.43
Body mass index (kg/m^2)	24.54 $\pm$ 4.33	24.16 $\pm$ 3.17
Surgical time (min)	57.59 $\pm$ 11.92	55.86 $\pm$ 13.96
Anesthesia time (min)	62.59 $\pm$ 11.92	60.86 $\pm$ 13.96

Values are represented as numbers, means $\pm$ S.D.

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 3).

Table 3 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 ± S.D, median (interquartile ranges).

Noise levels were similar in both groups for any times (Figure 5). In noise blocked group, maximal and minimal noise levels during ESWL were 82.4 dB and 65.0 dB, respectively. In control group, maximal noise level was 79.6 dB and minimal noise level during ESWL was 67.5 dB. Noises levels in the same group were rather stable during ESWL procedure, and seemed not depend on level of shock wave intensity.

TCI rate in noise blocked group appeared lower than TCI rate in control group in any times except at 55 minutes (Figure 6).

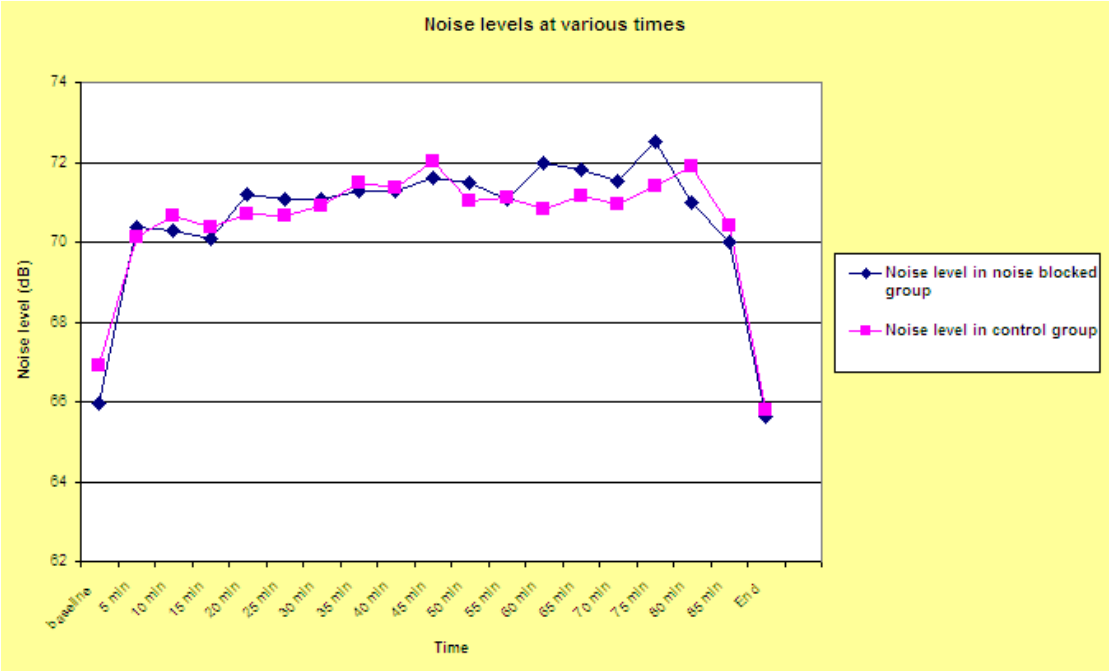


Figure 5 Noise levels at various times

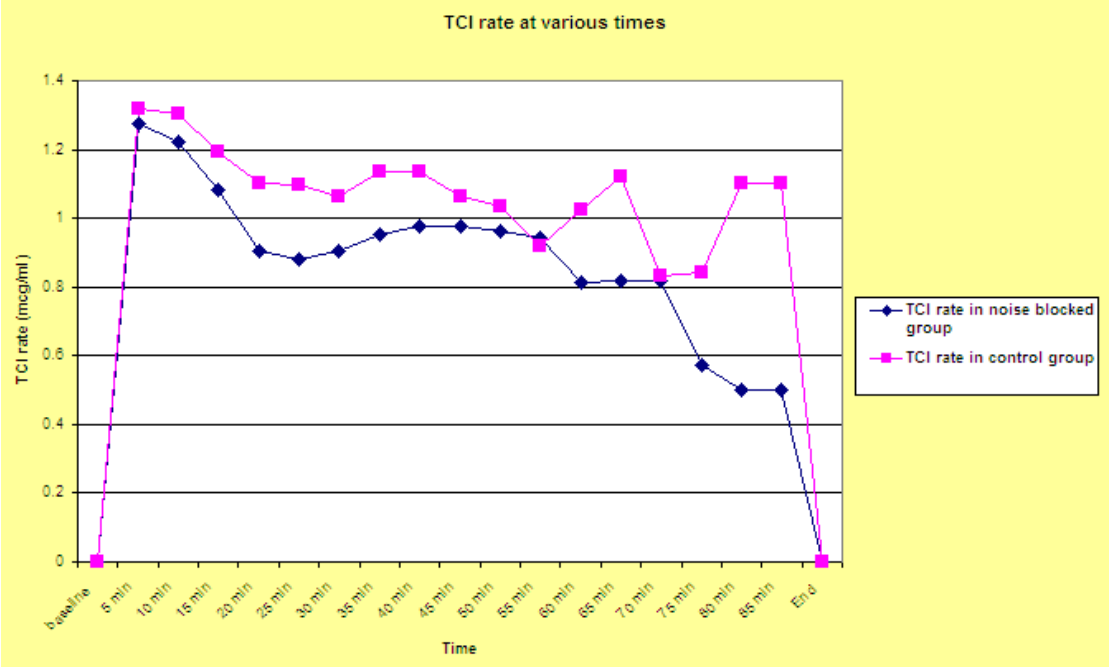


Figure 6 TCI rate at various times

Figure 7 and 8 show the histogram of total propofol amount (mg) in noise blocked and control group respectively. Moreover, figure 9 and 10 show the histogram of the propofol amount during energy level-2 period (mg) in noise blocked group and control group respectively.

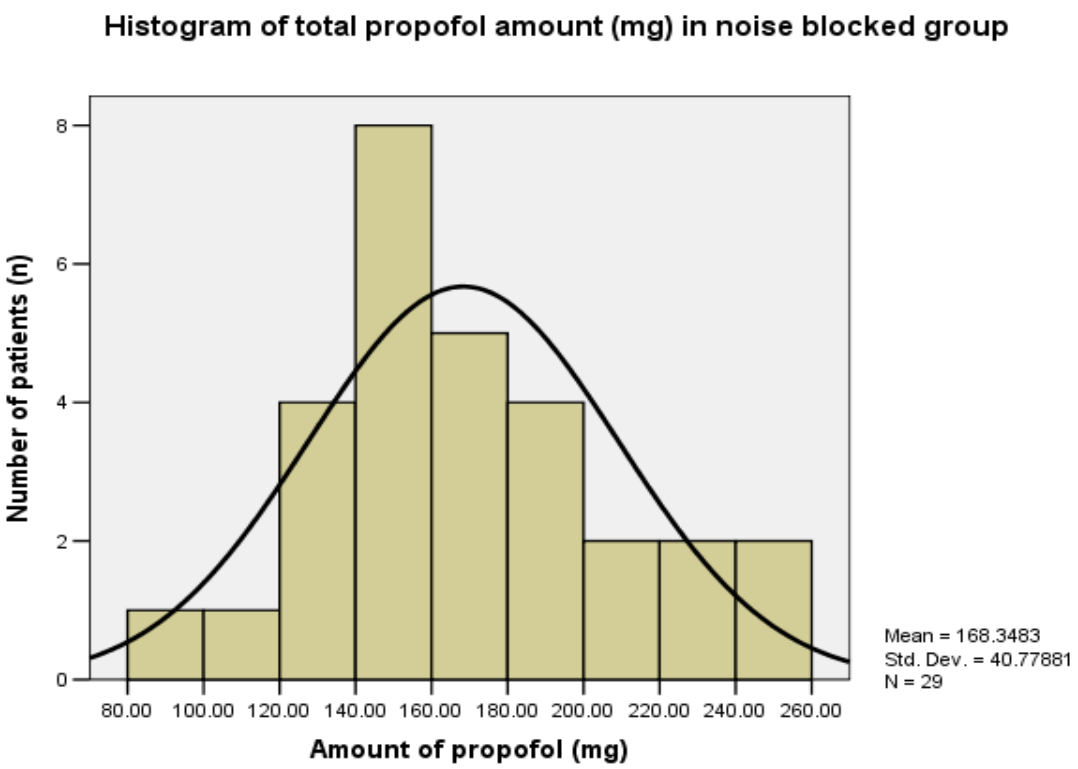


Figure 7 Histogram of total propofol amount (mg) in noise blocked group

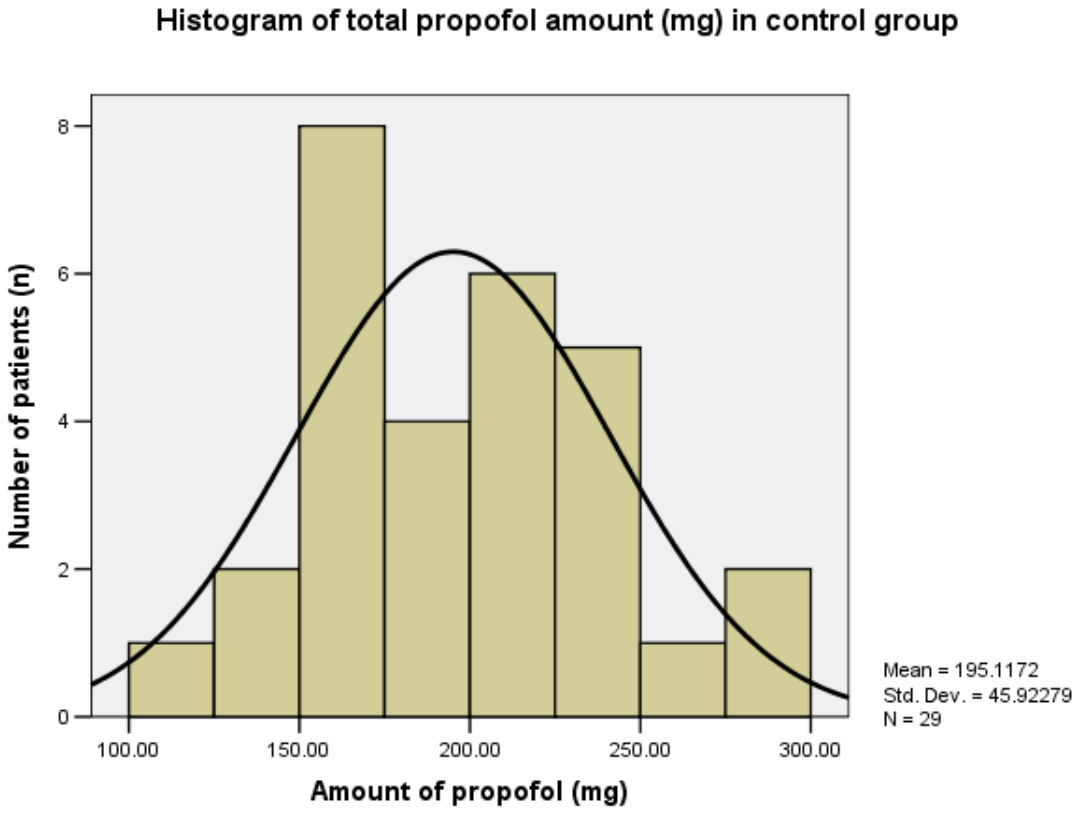


Figure 8 Histogram of total propofol amount (mg) in control group

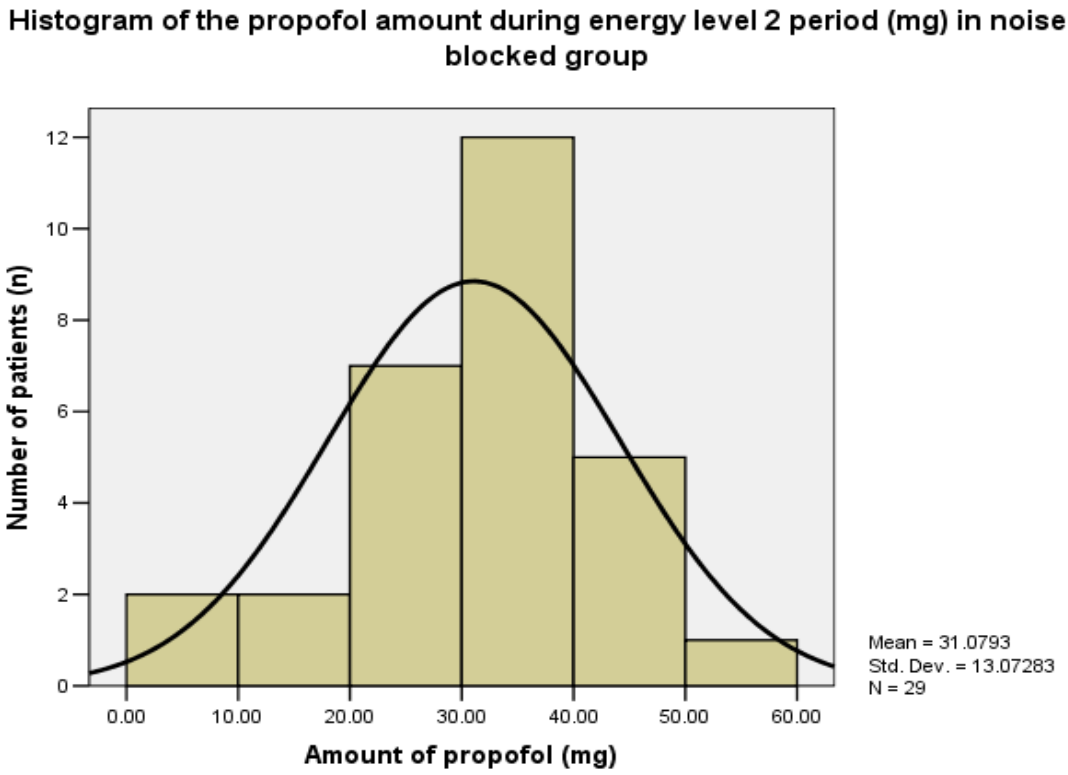


Figure 9 Histogram of propofol amount during energy level-2 period (mg) in noise blocked group

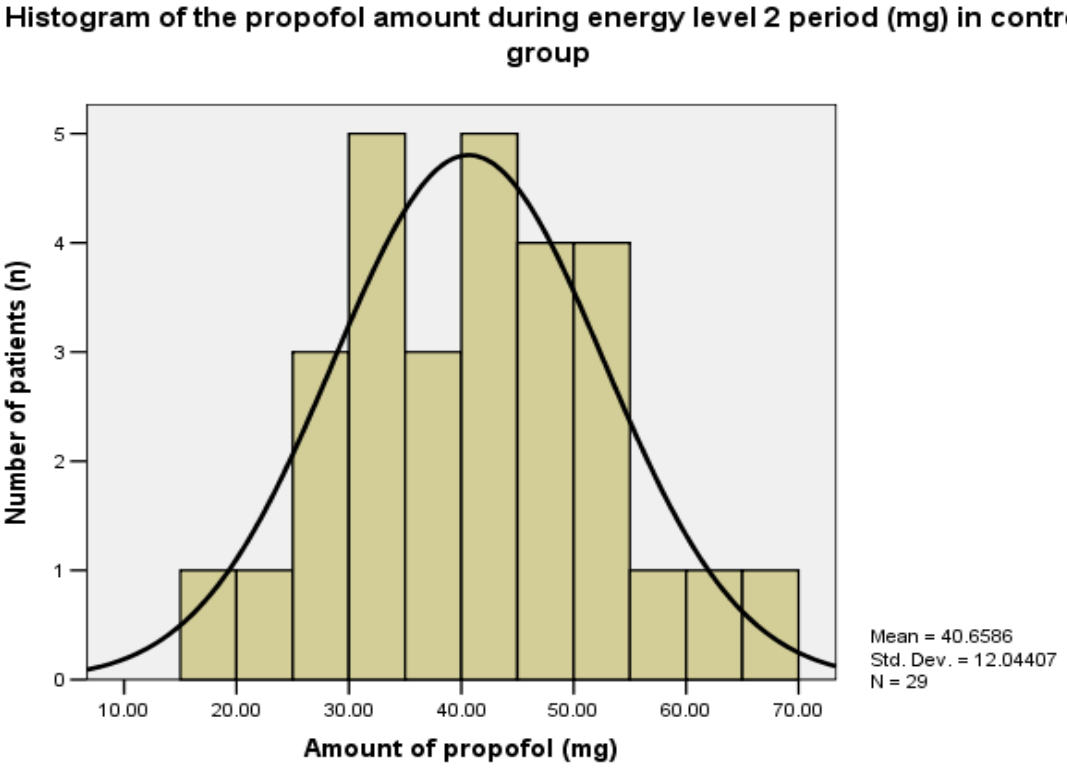


Figure 10 Histogram of propofol amount during energy level-2 period (mg) in control group

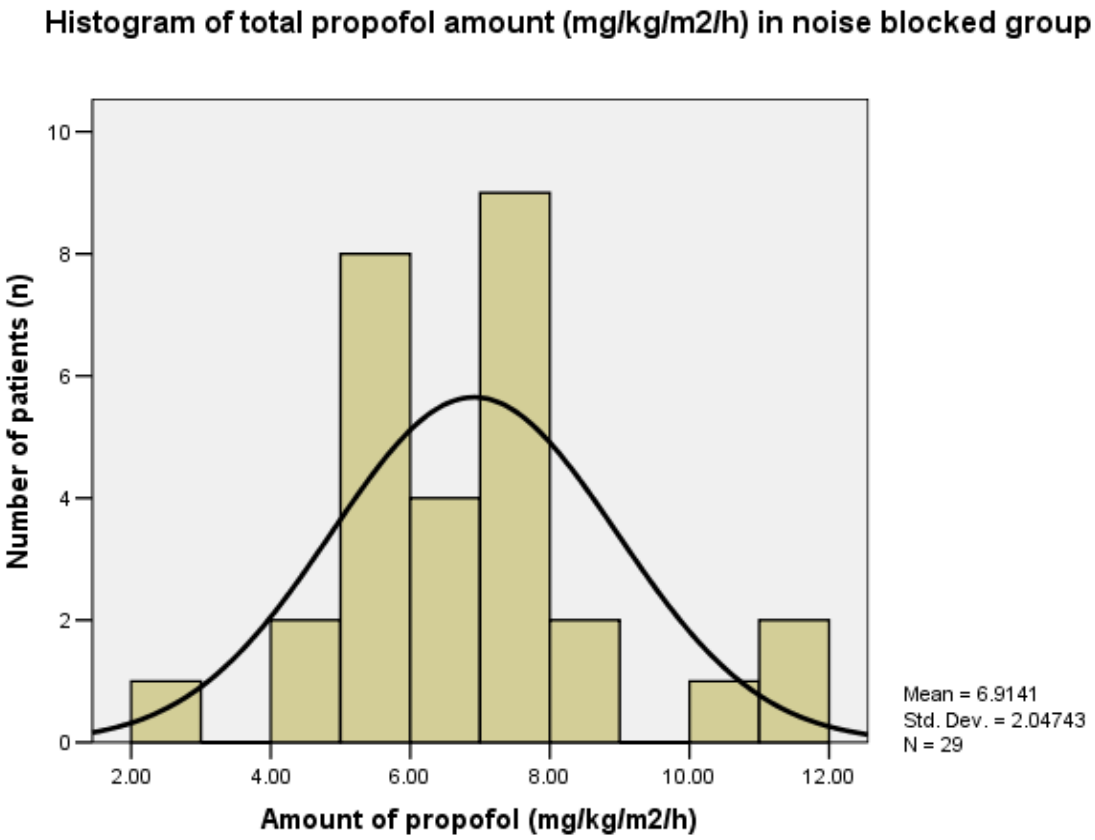


Figure 11 Histogram of total propofol amount (mg/kg/m^2/h)) in noise blocked group

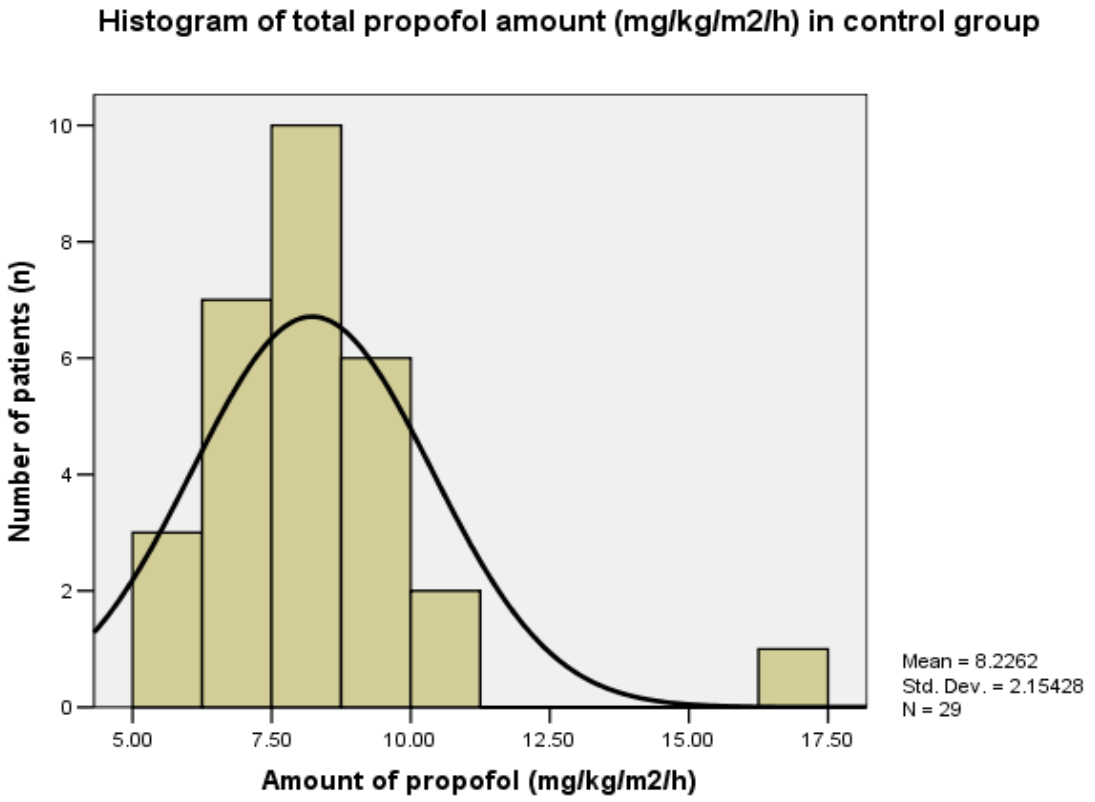


Figure 12 Histogram of total propofol amount (mg/kg/m^2/h)) in control group

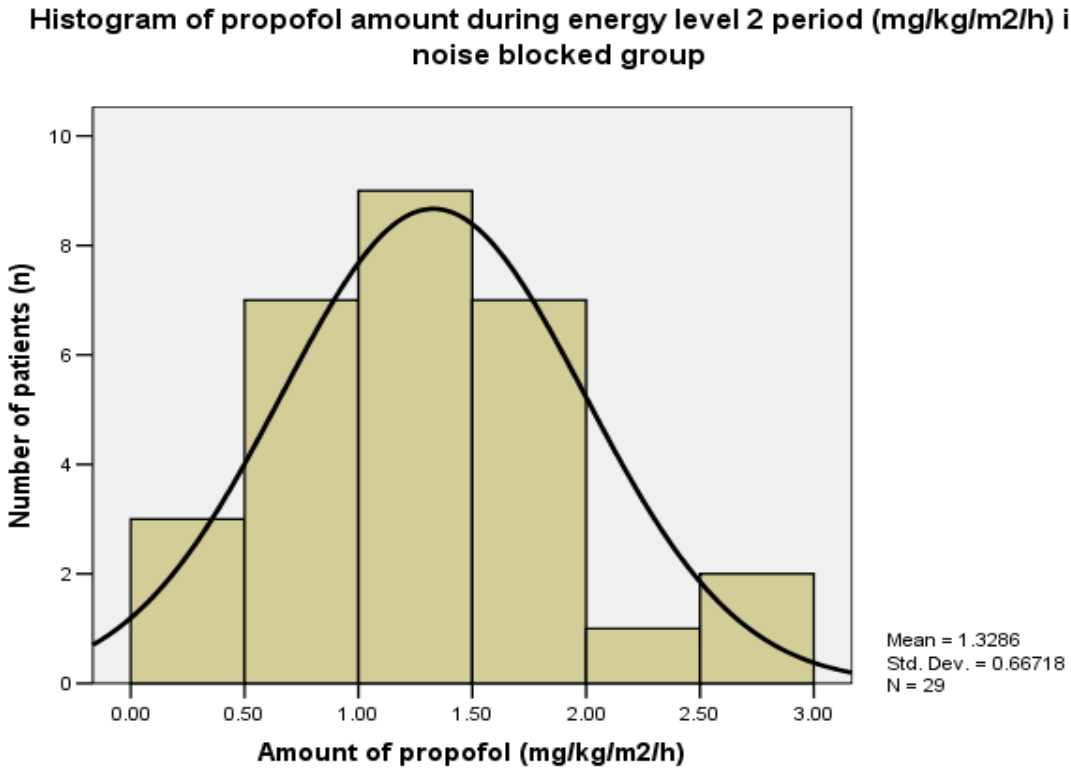


Figure 13 Histogram of propofol amount during energy level-2 period (mg/kg/m^2/h) in noise blocked group

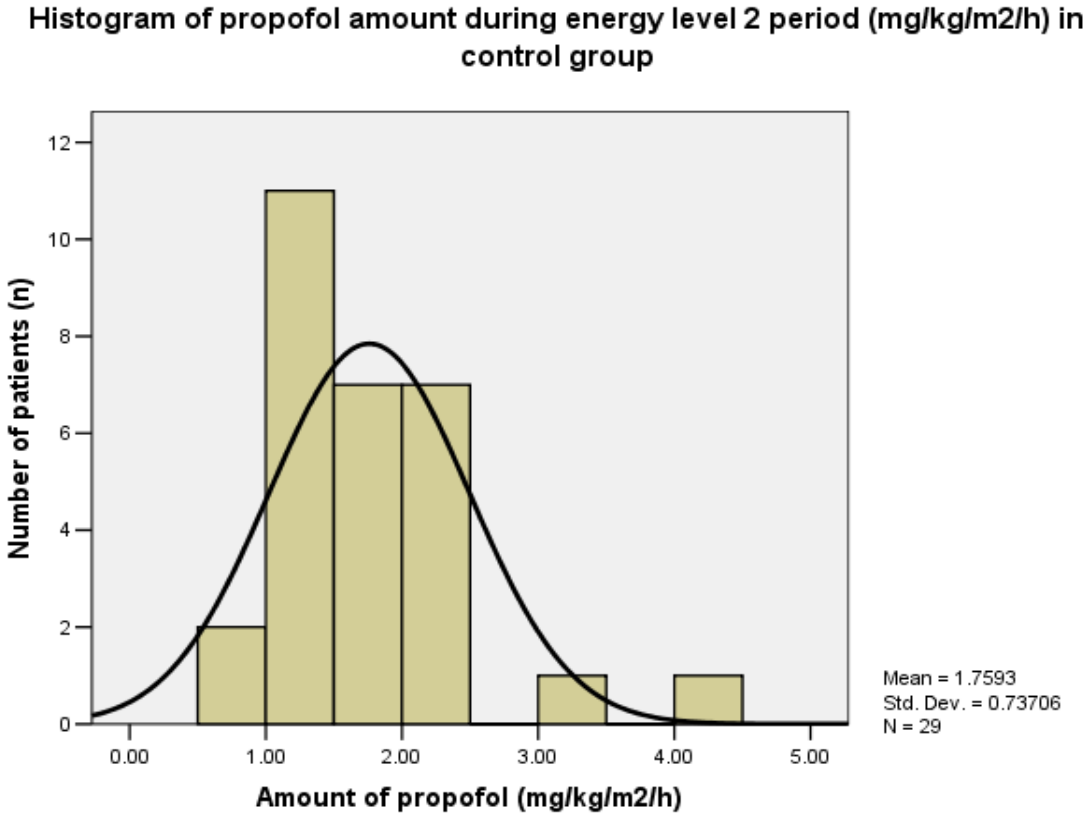


Figure 14 Histogram of propofol amount during energy level-2 period (mg/kg/m^2/h) in control group

Figure 11 and 12 show histogram of total propofol amount (mg/kg/m^2/h) in noise blocked and control group respectively. Then Figure 13 and 14 show histogram of the propofol amount during energy level-2 period (mg/kg/m^2/h) in noise blocked group and control group respectively.

All histograms showed fairly normal distribution.

The major outcomes of the study were shown in Table 4. 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 (both milligrams of propofol used and milligrams per BMI per hour of propofol) in the noise blocked group was significantly lower than that used in the control group. But when the data were analyzed by using unit of milligrams per weight per hour (mg/kg/h), the result showed that total propofol requirement and propofol requirement during level 2 of energy were not statistically different between two groups. There was one patient in control group, 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.

Table 4 Propofol requirements for sedation

	Noise blocked (n = 29)	Control (n = 29)	p-value	95% CI	Mean Difference
Total propofol amount (mg)	168.35 ± 40.78	195.12 ± 45.92	0.022	3.92-49.61	26.77
During energy level 2 period (mg)	31.08 ± 13.07	40.66 ± 12.04	0.005	2.97-16.19	9.58
Total propofol amount (mg/kg/m^2/h)	6.91 ± 2.05	8.23 ± 2.16	0.021	0.21-2.42	1.31
During energy level 2 period (mg/kg/m^2/h)	1.33 ± 0.67	1.76 ± 0.74	0.023	0.06-0.80	0.43
Total propofol amount (mg/kg/h)	2.71 ± 0.90	3.13 ± 0.78	0.062	-0.02-0.86	0.42
During energy level 2 period (mg/kg/h)	0.53 ± 0.28	0.66 ± 0.26	0.057	-0.004-0.28	0.14

Values are represented as means ± S.D.

Table 5 The amount of propofol used in various period of shock wave energy

	Pre-level-2 period	Level-2 period (same duration at 12.5 minutes)	Post-level-2 period
Propofol amount in noise blocked group (mg)	56.50 ± 20.98	31.08 ± 13.07	78.69 ± 36.16
Propofol amount in control group (mg)	62.99 ± 21.86	40.66 ± 12.04	93.00 ± 38.07
p-value	0.253	0.005	0.148
95% CI	-4.78-17.76	2.97-16.19	-5.22-33.84

Values are represented as means ± S.D.

The amount of propofol used either during pre-level-2 period or post-level-2 period of shock wave energy was not significantly different between two groups. Only the amount of propofol used during level-2 period was significantly different between noise blocked group and control group (Table 5).

Table 6 Patient satisfaction

	Noise blocked (n = 29)	Control (n = 29)	P
Patient satisfaction	4 [1]	4 [1]	0.929
Level of satisfaction			
Level 1 - Extremely dissatisfied	0 (0)	0 (0)	
Level 2 - Dissatisfied	0 (0)	0 (0)	
Level 3 - Fair	3 (10.3)	1 (3.4)	
Level 4 - Satisfied	15 (51.7)	18 (62.1)	
Level 5 – Extremely satisfied	11 (37.9)	10 (34.5)	

Values are represented as median [interquartile ranges], n (%)

Patient satisfaction in the two groups was similar (Table 6). Level of patient satisfaction in both groups was rather high. No one was dissatisfied in this study.

CHAPTER VI
DISCUSSION AND CONCLUSION

Discussion

This study showed that 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 (both milligrams of propofol used and milligrams per BMI per hour of propofol) in the noise blocked group was significantly lower than that used in the control group. But when the data were analyzed over the body weight only (mg/kg/h), the result showed that total propofol requirement and propofol requirement during this level were lower but not statistically different between two groups. Pharmacokinetic-pharmacodynamic (PK-PD) model of target control infusion in this study was based on Schnider's PK-PD model. The Schnider's model was developed during combined pharmacokinetic–pharmacodynamic modelling studies [25]. His model parameters included volume of distribution (V) which be composed of central (V_1), rapid peripheral (V_2), and slow peripheral (V_3) and clearance (Cl) which be composed of metabolic (Cl_1), rapid peripheral (Cl_2), and slow peripheral (Cl_3). The model includes age as a covariate of V_2 (rapid peripheral volume) and Cl_2 (rapid peripheral clearance) and weight, height, lean body mass (LBM), and gender as covariates of Cl_1 (metabolic clearance). Lean body mass was calculated from gender, weight (in kilograms), and height (in centimeters) [26,27]. So analyzing data by using unit of milligrams per weight per hour (mg/kg/h), not included height, was inappropriate for target controlled infusion which based on Schnider's PK-PD model.

Consistent with the study by Kang et al [20], 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 [17] 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 [19] demonstrated that experimental noise can alter the EEG-BIS value during MAC sedation with propofol. Furthermore, Kang et al [20] 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 [9, 10]. 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 profound sensory blockade [28]. 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.

Stone fragmentation may effect on pain intensity and total propofol requirement. Factors which effect on stone fragmentation were described as following [29]:

1. Experience of technicians - Increasing experience with ESWL allowed for increasingly accurate predictions relative to the number of shocks necessary to fragment a stone.

2. Small calculi lodged in the ureter or sequestered in a calyx may need second treatment, not because of volume, but because the fragments can not separate.
3. Size of stones
4. Some stones are harder and more difficult to fragment than others. For example, calcium oxalate dihydrate calculi fragment into crumbs while calcium oxalate monohydrate is less fragile and often breaks in small chunks. Struvite is soft and easily fragmented while cystine calculi are unable to be adequately treated by ESWL. The harder calculi require more shocks and higher kilovoltage to complete fragmentation than do the more fragile calculi.

In this study, we only included the patients with renal calculi, not ureteric calculi. Moreover, ESWL procedures in every patient were operated by the same technician. But we did not record the size and composition of the calculi. Some arguments may be made on the different power to break the different calculi, which may have an effect on pain during lithotripsy. The study has shown the randomization of patient allocation and controlled the equal period and intensity of the shocked power at the level-2. Then the comparisons were also made on the milligrams of propofol between the two groups at this period and showed that the requirements of the sedatives were reduced in the noised block group.

The most prominent effect of propofol is a decrease in arterial blood pressure, due to vasodilation, and perhaps the direct myocardial depressant effects. Clinically, the myocardial depressant effect and the vasodilation seem to be dose-dependent and plasma concentration-dependent. Moreover, propofol may cause apnea. The incidence and duration of which appear to be dependent on the dose, speed of injection, and concomitant premedication [30]. From the results of this study, noise block could reduce a dose of propofol needed to maintain appropriate sedation, so dose-dependent cardiovascular effects (myocardial depressant effect and vasodilation) and respiratory effects (apnea) may be decreased.

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, maximal noise level was 82.4 dB, and minimal noise level was 65.0 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. In addition, the reduction of the propofol requirement to maintain appropriate sedation may shorten discharge time, but this study did not investigate about discharge time of the patients. Further studies are needed to confirm this effectiveness of noise block on sedation during other procedures or different levels of ambient noise, and investigate about discharge time of the patients.

Conclusion

The elimination of ambient noise in the operating room with creating noise around 65-82 decibel with simple ear plugs (noise reduction rating (NRR) is 29 dB.) can reduce the amount of propofol needed to maintain light sedation during ESWL.

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APPENDICES

APPENDIX A

Case Record Form

Sequence No…….. Code……..

Date……..……..

Age…….years

Sex O male O female

Body weight…….kg. Height……..cm.

Body mass index……..kg/m^2

Surgical time…….min. Anesthesia time……..min

Time	Base line	5 min	10 min	15 Min	20 min	25 min	30 min	35 min	40 min	45 min	50 min	55 min	60 min	65 min
Ambient noise														
BIS values														
TCI rate propofol														

Time	70 min	75 min	80 min	85 min	90 min	95 min	100 min	105 min	110 min	115 min	120 min	125 min	130 min	end
Ambient noise														
BIS values														
TCI rate propofol														

Amount of propofol used during pre-energy level2 period……mg

Amount of propofol used at the end of energy level 2 period…….. mg

Amount of propofol used during energy level 2 period……..mg

Maximal level of shock wave energy used…….

Average ambient noise……dB

Average BIS index value…….....

Average propofol TCI rate……...mcg/ml

Total amount of propofol……..mg

Adverse events O hypotension O arrhythmia

O desaturation O other…….

Remember the bad events during procedure

O not remember O remember……

Patient satisfaction

O 1. Extremely dissatisfied

O 2. Dissatisfied

O 3. Fair

O 4. Satisfied

O 5. Extremely satisfied

APPENDIX B

เอกสารชี้แจงข้อมูลสำหรับผู้เข้าร่วมโครงการ (Patient Information Sheet)

ในเอกสารนี้ อาจมีข้อความที่ท่านอ่านแล้วยังไม่เข้าใจ โปรดสอบถามหัวหน้าโครงการวิจัย หรือผู้แทนให้ช่วยอธิบายจนกว่าจะเข้าใจดี ท่านอาจจะขอเอกสารนี้กลับไปอ่านที่บ้านเพื่อปรึกษาหารือกับญาติพี่น้อง เพื่อนสนิท แพทย์ประจำตัวของท่าน หรือแพทย์ท่านอื่น เพื่อช่วยในการตัดสินใจเข้าร่วมการวิจัย

ชื่อโครงการ ผลของการอุดหูต่อความต้องการยาโปรโพฟอลในการระงับความรู้สึกขณะสลาย นิ่ว **ชื่อผู้วิจัย** พ.ญ.สุภาภรณ์ ธาราหิรัญโชติ กลุ่มงานวิสัญญีวิทยา **สถานที่วิจัย** โรงพยาบาลราชวิถี **ผู้ให้ทุน** โรงพยาบาลราชวิถี **วัตถุประสงค์ของการวิจัย** โครงการวิจัยนี้ทำขึ้นเพื่อทดสอบว่าการอุดหูสามารถลดจำนวนของยาโปรโพฟอลในการระงับความรู้สึกขณะสลายนิ่วได้หรือไม่ ซึ่งมีประโยชน์ที่คาดว่าจะได้รับคือ ถ้าการอุดหูสามารถลดจำนวนของยาโปรโพฟอลในการระงับความรู้สึกขณะสลายนิ่วได้ ผลข้างเคียงที่อาจจะเกิดจากยาดังกล่าวอาจจะลดลง และผู้ป่วยอาจจะสามารถกลับบ้านได้เร็วขึ้น ท่านได้รับเชิญให้เข้าร่วมการวิจัยนี้เพราะ ท่านมีนิ่วที่ไตและได้รับการนัดหมายให้มาสลายนิ่ว โดยจะมีผู้เข้าร่วมการวิจัยนี้ทั้งสิ้นประมาณ 58 คน ระยะเวลาที่จะทำการวิจัยทั้งสิ้น ประมาณ 1 ปี

ขั้นตอนการปฏิบัติตัวหากท่านเข้าร่วมโครงการวิจัย

เมื่อท่านเข้าร่วมการวิจัยแล้ว ท่านจะได้รับการตรวจหูโดยแพทย์ และส่งตรวจการได้ยินโดยไม่มีค่าใช้จ่าย ถ้าท่านมีความผิดปกติในการได้ยิน ท่านจะถูกคัดออกจากการวิจัยนี้ ในวันที่ท่านมาสลายนิ่ว ท่านจะได้รับการดูแลรักษาตามปกติ ท่านจะได้รับการแบ่งกลุ่มเป็น 2 กลุ่ม คือ กลุ่มอุดหู กับกลุ่มไม่อุดหู โดยก่อนทำการสลายนิ่ว ท่านจะได้รับยานอนหลับ และยาแก้ปวด ซึ่งผู้ป่วยที่มาสลายนิ่วจะได้รับยานอนหลับ และยาแก้ปวด อยู่แล้ว หลังจากนั้น ท่านอาจจะได้รับการอุดหู หรือไม่ได้รับการอุดหูตามการแบ่งกลุ่มข้างต้น โดยที่ท่านจะไม่ทราบว่าท่านอยู่กลุ่มใด การอุดหูใช้ที่อุดหู 3M®1100 ซึ่งมีผลข้างเคียงจากการใช้อุปกรณ์ชนิดนี้น้อยมาก

การเข้าร่วมโครงการวิจัยของท่านต้องเป็นไปด้วยความสมัครใจ

หากท่านไม่เข้าร่วมในโครงการวิจัยนี้ จะไม่มีผลกระทบใดๆทั้งในปัจจุบัน และอนาคตในด้านการรักษาพยาบาลของท่าน โดยท่านจะได้รับการตรวจเพื่อการวินิจฉัย และรักษาโรคของท่านตามวิธีการที่เป็นมาตรฐาน หากมีข้อข้องใจที่จะสอบถามเกี่ยวข้องกับการวิจัย สามารถติดต่อ พ.ญ.สุภาภรณ์ ธาราหิรัญโชติ กลุ่มงานวิสัญญีวิทยา โรงพยาบาลราชวิถี กรุงเทพฯ โทร. 081-3254795

ข้อมูลส่วนตัวของท่านจะถูกเก็บรักษาไว้ ไม่เปิดเผยต่อสาธารณะเป็นรายบุคคล แต่จะรายงานผลการวิจัยเป็นข้อมูลส่วนรวม ข้อมูลของผู้ร่วมการวิจัยเป็นรายบุคคล อาจมีคณะบุคคลบางกลุ่มเข้ามาตรวจสอบได้ เช่น ผู้ให้ทุนวิจัย สถาบัน หรือองค์กรของรัฐที่มีหน้าที่ตรวจสอบคณะกรรมการจริยธรรมฯ เป็นต้น

APPENDIX C

หนังสือแสดงเจตนายินยอมเข้าร่วมการวิจัย (Consent Form)

การวิจัยเรื่อง ผลของการอุดหูต่อความต้องการยาโปรโพฟอลในการระงับความรู้สึกขณะสลายนิ่ว

วันที่ให้ความยินยอม วันที่.....เดือน.....พ.ศ.....

ก่อนที่ลงนามในใบยินยอมให้ทำการวิจัยนี้ ข้าพเจ้าได้รับการอธิบายจากผู้วิจัย ถึงวัตถุประสงค์ของการวิจัย วิธีการวิจัย อันตราย หรืออาการที่อาจจะเกิดขึ้นจากการวิจัย หรือจากยาที่ใช้ รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียด และเข้าใจดีแล้ว

ผู้วิจัยรับรองว่าจะตอบคำถามต่างๆที่ข้าพเจ้าสงสัยด้วยความเต็มใจ ไม่ปิดบัง ซ่อนเร้น จนข้าพเจ้าพอใจ ข้าพเจ้ามีสิทธิ์ที่จะบอกเลิกการเข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ และเข้าร่วมโครงการวิจัยด้วยความสมัครใจ และการบอกเลิกการเข้าร่วมการวิจัย จะไม่มีผลต่อการรักษาโรคที่ข้าพเจ้าพึงได้รับต่อไป

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเกี่ยวกับตัวข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปของการสรุปผลการวิจัย หรือเปิดเผยเฉพาะต่อผู้มีหน้าที่เกี่ยวข้องกับการสนับสนุนและกำกับดูแลการวิจัย

ผู้วิจัยรับรองว่าหากเกิดอันตรายใดๆ จากการวิจัยดังกล่าว ข้าพเจ้าจะได้รับการรักษาพยาบาลโดยไม่คิดมูลค่า และจะได้รับการชดเชยรายได้ที่สูญเสียไประหว่างการรักษาพยาบาลดังกล่าว โดยบุคคลที่รับผิดชอบเรื่องนี้คือ พ.ญ.สุภาภรณ์ ธาราหิรัญโชติ กลุ่มงานวิสัญญีวิทยา โรงพยาบาลราชวิถี โทร. 081-3254795

ข้าพเจ้าได้อ่านข้อความข้างต้น และมีความเข้าใจดีทุกประการ และได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม.....ผู้ยินยอม

(.....)

ลงนาม.....พยาน

(.....)

ลงนาม.....พยาน

(.....)

VITAE

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