Recovery Time and Complications of Propofol-Based Deep Sedation for Endoscopic Ultrasonography: A Comparison between With and Without Topical Pharyngeal Anesthesia

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Objective: *The study is aimed to compare the recovery time and sedation-related complication in propofol-based deep sedation (PBDS) with and without topical pharyngeal anesthesia for EUS procedures in adult Thai population.*
Material and Method: *Thirty-two adult patients undergoing EUS procedures were equally randomly assigned to receive pharyngeal topicalized either with lidocaine spray (Group L) or normal saline (Group N). All patients were premedicated with 1 mcg/kg of fentanyl and 0.02 mg/kg of midazolam. PBDS was maintained with continuous propofol infusion. Recovery time using postanesthetic recovery score and discharge score as well as sedation-related complications were evaluated. Total doses of propofol, fentanyl and midazolam as well as arterial blood pressure values were also recorded.*
Results: *All EUS procedures were completely successful. There were no significant differences in gender, age, body mass index, ASA physical status, duration of procedure and indications of procedure between the two groups. The recovery time, respiratory-related complications, and total doses of propofol, fentanyl and midazolam in both groups were not significantly different. Hypotension in group L was significantly greater than in group N. In addition, hypertension in group L was significantly lower than in group N. However, these complications were transient and easily treated.*
Conclusion: *Addition of topical pharyngeal anesthesia in PBDS technique did not promote the recovery time and not increase the complication rate during and after EUS procedure. PBDS in both regimens provided effective and safe for EUS. No serious complications were noted.*

Keywords: *Recovery time, Complication, Propofol, Endoscopic Ultrasonography, Topical pharyngeal anesthesia*

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Endoscopic ultrasonography (EUS) is a combination of endoscopy and intraluminal ultrasonography. It is used to image the suspected pathology in the gastrointestinal tract and in the adjacent organs[1-3]. Improved accuracy and cost-effectiveness has been recognized in comparison with other imaging techniques. In practice, most EUS procedures are performed in the endoscopy room or in the operating room. EUS is an invasive and prolonged endoscopic procedure. It creates pain and requires some sedation and/or anesthesia during the procedure[4]. The type of anesthesia is according to the patient's medical condition and the anesthesiologist's preference.

Previous studies of non-sedated esophago-gastroduodenoscopy (EGD) demonstrated that the use of topical pharyngeal anesthesia increased the patients' satisfaction[5,6]. Another study of patients undergoing EGD with propofol sedation indicated that topical pharyngeal anesthesia was safe for EGD procedure but did not decrease the necessary dose of propofol or improve the anesthesiologist's or endoscopist's satisfaction[7]. To date, several centers commonly use propofol sedation for EUS procedure because of its obvious advantages[8-10]. Routine administration of sedative and analgesic drugs is widely provided for this procedure. In our center, the combination of propofol and sedoanalgesic drugs used for endoscopic procedures is the most common practice[8,10,11]. However, its use is not without risk, such as cardiorespiratory

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depression.

We hypothesized that the additional topical pharyngeal anesthesia with propofol-based deep sedation (PBDS) could improve the recovery profile and complications for EUS procedures. Therefore, we conducted a prospective, randomized, double-blind, controlled study to determine whether there is any difference in the recovery time and the complication rate between patients who received PBDS with and without topical pharyngeal anesthesia in an endoscopic unit outside the operating room in Thailand.

Material and Method

Patients

The study was approved by International Review Board (Si 153/2015). Data were conducted at a large tertiary care referral center, Siriraj Hospital, Bangkok, Thailand. Patients with age between 18 and 65 years who presented for EUS procedures were eligible for the study. Exclusion criteria included patients with American Society of Anesthesiologists (ASA) physical status class IV or V, severe cardiorespiratory instabilities, severe hypertension, psychological abnormality, end staged renal disease, any clinical evidence of hepatic encephalopathy, pregnancy, and refusal to participate in the study. A total of 32 consecutive patients were eligible and randomized for the study. The study was approved by the Institutional Review Board of the Faculty of Medicine Siriraj Hospital. All patients provided written informed consent for the study and the procedure.

Study design

The study is a prospective, randomized, double-blinded, controlled study. Patients were randomized into either pharyngeal topicalized with lidocaine spray (Group L) or pharyngeal topicalized with normal saline (Group N) by using computerized generated randomization numbers and sealed in envelopes. The endoscopists and the patients were blinded to the randomization procedure. Randomization took place in the preprocedural room, separated from the procedural room and the recovery room. PBDS and pharyngeal topicalization were performed in the preprocedural room by the anesthetic personnel and PBDS was conducted in the procedural room by the blinded anesthetist. Additionally, the blinded research assistant was presented in the recovery room to collect procedural data and other research data. Recovery time was the primary outcome. Recovery time included postanesthetic recovery time and discharge time. The secondary outcome variables were sedation-related complications and total doses of propofol, fentanyl and midazolam as well as arterial blood pressure values. All EUS procedures were performed using an Olympus video endoscope compatible with the type of endoscopy (GF-UE160-AL5 or GFUC140P-AL5 Olympus Corporation, Tokyo, Japan). After completion of the EUS procedures, admission into the inpatient hospital service was arranged to rule out post-EUS complications. The EUS procedure was performed by three senior endoscopists with more than 10 years of experience.

PBDS and topical pharyngeal techniques

Each patient was monitored in standard manner for noninvasive blood pressure, heart rate, heart rhythm with single channel electrocardiogram, and oxygen saturation with pulse oximetry. All patients were premedicated with 1 mcg/kg of fentanyl and 0.02 mg/kg of midazolam. PBDS was induced with 0.5 to 1 mg/kg of propofol and was maintained only with 5 mg/kg/hr of continuous propofol infusion. All sedation was administered by the nurse anesthetist or anesthesiology resident supervised by the staff anesthesiologist in the procedural room. The targeted depth of sedation level was deep sedation. The level of sedation during the procedure was assessed with the Observer's Assessment of Alertness/Sedation score[12] (5 = respond readily to name call in normal tone, 4 = lethargic response to name call in normal tone, 3 = respond only after loud and/or repeated name call, 2 = respond only after mild prodding or shaking, 1 = not respond to mild prodding or shaking). The depth of sedation level was observed and maintained at the score of 1 throughout the procedure. If the depth of sedation level was deeper or lighter than the targeted depth, the rate of propofol infusion would decrease or increase respectively. For topical pharyngeal technique, all patients were topicalized at posterior pharynx for twice and at each tonsillar pillar with 10% lidocaine spray in group L and with normal saline in group N, respectively. In group L, the anesthesia was tested by using tongue depressor. If the gag reflex was presented, another twice of 10% lidocaine spray was supplemented.

Recovery time and complication

Recovery times including postanesthetic recovery time and discharge time were evaluated every 5 min after the procedure. Postanesthetic recovery time defined as the time from the end of propofol infusion to the postanesthetic recovery score at least 9 of 10

(Consciousness: 2 = alert and oriented, 1=arousable and calling, 0 = no response to noxious stimuli; Respiration: 2 = deeply breathe and cough, 1 = dyspnea or shallow breathing, 0 = apnea; Oxygen saturation: 2 ≥95% in room air, 1 = 90 to 95% in room air; 0 ≤90% in oxygen supplementation; Arterial blood pressure: 2 = ±20 mmHg of baseline, 1 = ±20 to 50 mmHg of baseline, 0 = ±50 mmHg of baseline; Movement: 2 = moving four extremities, 1 = moving two extremities, 0 = no movement). Discharge time defined as the time from the end of propofol infusion to the discharge score at least 3 of 5 criteria (no nausea/vomiting, no postural hypotension, orientation to time/place/person, walking five meters without ataxic gait, no dizziness/vertigo). Alteration in hemodynamic parameters was considered as the complication if any of the following was observed: hypertension or hypotension (increase or decrease in mean arterial blood pressure at least 20% from baseline), tachycardia or bradycardia (increase or decrease in heart rate at least 20% from baseline), and oxygen desaturation (SpO_2 <90%). In addition, other symptoms such as dizziness, abdominal pain, nausea, or vomiting were also recorded as sedation-related complications. However, our study did not directly evaluate the procedure-related complications.

Statistical analysis

The study was designed to test the null hypothesis that PBDS with the combination of topical pharyngeal anesthesia would offer better recovery time than PBDS technique alone for EUS procedure. The sample size was calculated from a reduction of the recovery time from 84 to 60 minutes[14]. A sample size of 32 subjects was needed and the power of the test was 0.8. Additionally, α was set to 0.05 for all comparisons. Results were expressed as mean ± SD or percentage (%) as appropriate. Comparisons between PBDS with and without topical pharyngeal anesthesia groups were compared by using with Chi-square test (for categorical variables), Chi-square test for trend (for ordinal variables), and two-sample independent t-test (for continuous variables). The statistical software package PASW Statistics for Windows, 18.0, Chicago: SPSS Inc. was used to analyze the data. All statistical comparisons were made at the two-sided 5% level of significance.

Results

Of the total 32 patients, 16 patients were randomized to group L while 16 patients were randomized to group N and no one dropped out from the study as the consort flow diagram (Fig. 1). All EUS procedures were successfully completed. There were no significant differences in gender, age, body mass index (BMI), ASA physical status, duration of procedure and indications of procedure between the

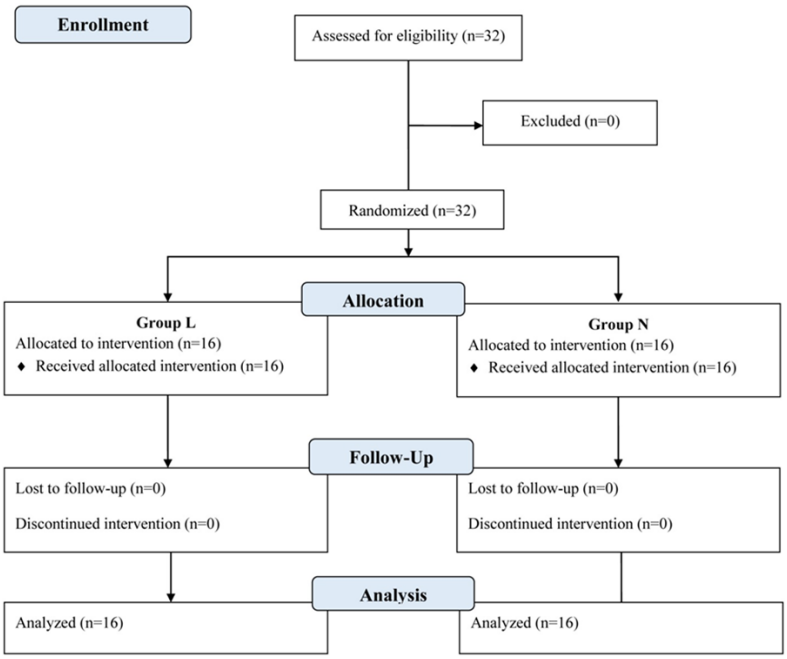

Fig. 1 Consort patient flow.

two groups (Table 1).

Patients in Group L had shorter time between end of sedation to the postanesthetic recovery score at least 9 of 10 than those in Group N which was nearly statistically significant (16.6±6.0 vs. 22.2±9.1 minutes, $p = 0.05$) (Table 2). Though mean time between end of sedation and discharge time in Group L was also shorter than in Group N (26.6±9.9 vs. 33.8±13.7 minutes, $p = 0.10$), which showed no statistically significant. There were statistically significant differences between the two groups in terms of drugs usage and perioperative complications. Table 2 demonstrated the recovery time, sedation-related complications and sedoanalgesic drugs use in this procedure. The recovery time using postanesthetic recovery score and discharge score in both groups was not significantly different. However, the recovery time in group L was relatively shorter than in group N. The complication rate in both groups was

Table 1. Demographic and operative data

Variables	Group L (n = 16)	Group N (n = 16)
Gender: Male	8 (50.0)	5 (31.3)
Age (yr)	57.5±11.8	58.9±8.6
Body mass index (kg/m^2)	22.7±3.9	26.4±4.5
ASA physical status		
I	5 (31.3)	2 (12.5)
II	9 (56.3)	12 (75.0)
III	2 (12.5)	2 (12.5)
Duration of procedure (min)	40.6±14.0	38.4±13.8
Indications of procedure		
Pancreatic tumor	12 (75.0)	9 (56.3)
Gall stone	1 (6.3)	3 (18.8)
Pancreatitis	1 (6.3)	0
Chronic abdominal pain	2 (12.5)	4 (25.0)

Data presented as mean±SD or n (%).
Group L = PBDS and pharyngeal topicalized with lidocaine spray; Group N = PBDS and pharyngeal topicalized with normal saline.

Table 2. Recovery time, sedation-related complications and sedoanalgesic drugs

Variables	Group L (n = 16)	Group N (n = 16)	*p*-value
Recovery time (min)			
Post-anesthetic recovery score≥9	16.6±6.0	22.2±9.1	0.05
Discharge criteria 3 out of 5 criteria	26.6±9.9	33.8±13.7	0.10
Sedation-related complications			
Respiratory-related			
Pulmonary aspiration	0	1 (6.3)	0.31
Upper airway obstruction	7 (43.8)	7 (43.8)	1.00
Oxygen desaturation	0	2 (12.5)	0.14
Cardiovascular-related			
Hypotension	10 (62.5)	3 (18.8)	0.01
Hypertension	0	5 (31.3)	0.02
Tachycardia	1 (6.3)	0	0.31
Sedoanalgesic drugs			
Propofol (mg)	237.7±120.3	224.7±65.1	0.88
Fentanyl (mcg)	55.8±7.3	68.9±15.5	0.80
Midazolam (mg)	1.2±0.4	1.4±0.4	0.98

Data presented as mean±SD or n (%)

not significantly different. Most of the complications were cardiorespiratory-related complications including hypotension and upper airway obstruction. Hypotension in group L was significantly greater than in group N. In addition, hypertension in group L was significantly lower than in group N. However, these complications were transient and easily treated with no adverse sequelae. Although, one patient in group N was suspected pulmonary aspiration, no significant interventions were needed. No serious complications were observed. Moreover, the alteration of mean arterial blood pressure was shown in Fig. 2.

Discussion

EUS has gained wide acceptance as a safe and efficient method for imaging within gastrointestinal tumor and for the diagnosis of submucosal lesions and common bile duct stones[1-3]. In our endoscopic center, intravenous sedation is usually utilized for EUS procedure[14]. Many physicians have noted that topical anesthesia alone is not sufficient for pain-free procedures. The combination of topical anesthesia and intravenous anesthesia may improve the efficacy. The primary objective of the study was aimed to compare the recovery time and sedation-related complication in PBDS with and without topical pharyngeal anesthesia for EUS procedure in adult Thai population. This study showed that both regimens provided effective and safe for this procedure. Addition of topical pharyngeal anesthesia in PBDS technique did not promote the recovery time and reduce complication during and immediately after EUS procedure.

In our study, there were not significantly different in the recovery time. Although the present study was conducted for EUS procedure, the result was comparable with our previous study[15]. One possible explanation of this finding is that the efficacy of PBDS is adequate for EUS procedure. The depth of sedation level in all patients was deep. Our previous study prospectively identified the pattern of home-readiness, the persistent symptoms after procedure and the factors that delay discharge after satisfied home-readiness criteria, in 369 patients undergoing ambulatory endoscopic procedures. The result showed that the majority of patients would accomplish a satisfactory score at or before one hour after procedure. The time to home-readiness by objective evaluation was associated with the type of endoscopic procedure. Most delays after satisfied home-readiness scores, were due to non-medical reasons such as waiting for the relatives[15].

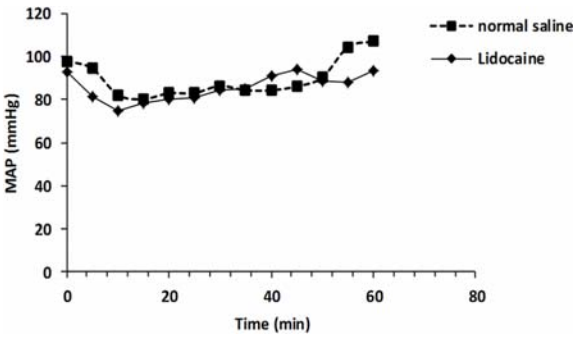

Fig. 2 Mean arterial blood pressure during the procedure.

The risk factors of sedation-related complications include the type, dose and mode of administration of sedative agents, as well as the patients' age and underlying medical diseases[16]. Consequently, these complications in both groups were not significantly different. However, sedation-related complications in this present study were relatively greater than in the other studies. In addition, the result of the study also demonstrated that the complication rate should be correlated to the depth of PBDS technique directly. The present study used only standard monitoring, including an assessment of blood pressure, pulse rate, respiratory rate and pulse oximetry, as well as electrocardiogram[17]. We detected a relatively high overall complication rate in both groups, and there might be several explanations. We used these criteria in defining adverse events: hypotension/hypertension and bradycardia/tachycardia as the changes of mean arterial blood pressure and heart rate of more than 20% of baseline values. Hypoxia was defined as oxygen saturation <90%. Interestingly, we found that all sedation-related complications were cardiorespiratory-related.

Although our study did not directly evaluate the procedure-related complications, we did not observe any serious complications during or after the procedures. Our previous study also confirmed that colonoscopy[18] and percutaneous endoscopic gastrostomy[19] under propofol-based sedation did not increase the perforation rate. Serious complications are uncommon. Furthermore, PBDS for endoscopic retrograde cholangiopancreatography (ERCP) in sick elderly patients by trained anesthetic personnel with appropriate monitoring was safe and effective. The clinical efficacy of this technique in sick elderly patients was not different or worse than in general elderly patients[20].

Deep sedation is commonly used for invasive

endoscopic procedures including ERCP and EUS. The combination of propofol, fentanyl and midazolam has already been used in these procedures. This technique is well accepted by endoscopists[21]. Patients breathed spontaneously; however, oxygen saturation was always over 95%, and age, ASA physical status, BMI as well as the combination of sedoanalgesic agents did not negatively influence this parameter. Generally, sedation was accomplished to ensure the patient safety, to minimize physical discomfort or pain, to provide analgesia and procedural amnesia, as well as to control behavior during the procedure. The amount of sedoanalgesic drugs in both groups did not significantly different.

There are several limitations in this study. First, the sample size of the study was relatively small. Second, the design of our study aimed to the target of deep sedation level. It could not be applied to the other levels of sedation. Third, all participants were Thai populations. The result of the study might not be applied in other populations. Fourth, all procedures were both diagnostic and therapeutic. We did not analyze these procedures separately. Fifth, the capnometry did not utilize in this procedure. The sedation-related complication rate might be underreported. Overall, despite these limitations, we are confident that these findings are generalizable to the practice of EUS under the use of PBDS technique. However, the indications of procedures in this study were diagnostic and therapeutic procedures. If we perform only diagnostic EUS procedures, moderate sedation could apply for these. However, further randomized control studies need to be evaluated.

In conclusion, the findings of the present study showed that PBDS for EUS procedure was relatively safe and effective when performed by experienced endoscopists. Serious complications were none. However, PBDS with topical pharyngeal anesthesia did not improve the recovery time and complications during EUS procedures.

What is already known on this topic?

EUS requires some forms of anesthesia. PBDS for this procedure is relatively safe and effective when performed by anesthetic personnel. Cardiorespiratory-related complication is the most frequent anesthetic complication.

What this study adds?

This study shows the performance of PBDS with and without topical pharyngeal anesthesia utilizing anesthetic personnel in proper patients with appropriate assessment and preparation as well as adequate monitoring in an endoscopy unit outside the operating room in a developing country.

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Trial registration

Clinicaltrials.in.th: TCTR20170526001.

Potential conflicts of interest

None.

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ระยะเวลาการฟื้นตัวและภาวะแทรกซ้อนของการทำให้ผู้ป่วยหลับลึกโดยใช้ยาโพรโพฟอลเป็นหลักสำหรับหัตถการส่องกล้องด้วยอัลตร้าซาวด์: การเปรียบเทียบระหว่างการให้และไม่ให้ยาชาเฉพาะที่ร่วมด้วย

นฤนาท โลมะรัตน์, ทศพร ศิลปเดช, สายพิณ เมืองแมน, วารุณี บัวแย้ม, ขนิษฐา ไกรประสิทธิ์, ปฐมพร บุณนาค, สมชาย อมรโยธิน

วัตถุประสงค์: ศึกษาเปรียบเทียบระยะเวลาการฟื้นตัวและภาวะแทรกซ้อนระหว่างการทำให้ผู้ป่วยหลับลึก โดยใช้ยาโพรโพฟอลเป็นหลักร่วมกับยาชาเฉพาะที่กับการทำให้ผู้ป่วยหลับลึกโดยใช้ยาโพรโพฟอลเป็นหลักอย่างเดียว สำหรับหัตถการส่องกล้องด้วยอัลตร้าซาวด์ในประชากรไทย

วัสดุและวิธีการ: ผู้ป่วยทั้งหมด 32 คน มารับการส่องกล้องแบบมีอัลตร้าซาวด์แบบสุ่มออกเป็น 2 กลุ่ม กลุ่มละ 16 คน คือ กลุ่มทำให้ผู้ป่วยหลับลึกโดยใช้ยาโพรโพฟอลเป็นหลักร่วมกับพ่นคอด้วยไลโดเคนชนิดพ่น (กลุ่ม L) และ กลุ่มทำให้ผู้ป่วยหลับลึกโดยใช้ยาโพรโพฟอล เป็นหลักร่วมกับพ่นคอด้วยน้ำเกลือนอร์มัล (กลุ่ม N) ผู้ป่วยทุกคนได้รับยา เฟนตานิลขนาด 1 มคก./กก. และ ยาไมด้าโซแลมขนาด 0.02 มก./กก. หลังจากนั้นจะได้รับยาโพรโพฟอล ทางหลอดเลือดดำหยดแบบต่อเนื่อง บันทึกระยะเวลาการฟื้นตัวและภาวะแทรกซ้อน บันทึกปริมาณยาโพรโพฟอล เฟนตานิล และยาไมด้าโซแลมที่ใช้ รวมทั้งค่าความดันเลือดแดงเฉลี่ย

ผลการศึกษา: การทำหัตถการทั้งหมดประสบผลสำเร็จ ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติของเพศ อายุ ดัชนีมวลกาย ASA physical status ระยะเวลาทำหัตถการ และ ข้อบ่งชี้สำหรับทำหัตถการระหว่างสองกลุ่ม นอกจากนี้ยังไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติ ของระยะเวลาการฟื้นตัว ภาวะแทรกซ้อนที่สัมพันธ์กับ ระบบการหายใจ และปริมาณยาโพรโพฟอล และ ยาไมด้าโซแลมที่ใช้ ระหว่างสองกลุ่ม ภาวะความดันเลือดต่ำในกลุ่ม L พบได้มากกว่ากลุ่ม N อย่างมีนัยสำคัญทางสถิติ นอกจากนี้ภาวะความดันเลือดสูงในกลุ่ม L พบได้น้อยกว่ากลุ่ม N อย่างมีนัยสำคัญทางสถิติ อย่างไรก็ตาม ภาวะแทรกซ้อนเหล่านี้เกิดขึ้นชั่วคราวและแก้ไขได้ง่าย

สรุป: การบริหารยาชาเฉพาะที่ร่วมกับการทำให้ผู้ป่วยหลับลึกโดยใช้ยาโพรโพฟอล เป็นหลักสำหรับหัตถการ ส่องกล้องด้วยอัลตร้าซาวด์ไม่สามารถช่วยลดระยะเวลาการฟื้นตัวและภาวะแทรกซ้อนได้ การทำให้ผู้ป่วยหลับลึก โดยใช้ยาโพรโพฟอล เป็นหลักทั้งสองวิธีมีประสิทธิภาพ และปลอดภัยสำหรับหัตถการส่องกล้องด้วยอัลตร้าซาวด์ โดยไม่พบภาวะแทรกซ้อนที่รุนแรง