

# Success Rate of Sedation in Esophagogastroduodenoscopy using Fentanyl and Midazolam in Combination with Topical Lidocaine

Saipin Muangman MD\*, Somchai Amornytin MD\*,  
Peerachatra Mangmeesri MD\*, Saowapark Chumpathong MD\*,  
Nonthalee Pausawasdi MD\*\*, Watcharasak Chotiwaputta MD\*\*, Julajak Limsrivilai MD\*\*,  
Oranee Svastdi-xuto BNS\*, Tassanee Jaiyen BNS\*, Choopong Luansritisakul MD\*

\* Department of Anesthesiology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand  
\*\* Division of Gastroenterology, Department of Medicine, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand

**Objective:** To evaluate the success rate of moderate sedation with fentanyl and midazolam combined with topical lidocaine in esophagogastroduodenoscopy (EGD), relative to level of patients and endoscopists' satisfaction, time to recovery, and associated complications.

**Material and Method:** Patients undergoing EGD were given topical lidocaine at the pharyngeal area and intravenous sedation with a combination of fentanyl 1 mcg/kg and midazolam 20 mcg/kg. In patients who could not tolerate EGD, an additional dose of fentanyl 0.5 mcg/kg and midazolam 10 mcg/kg was administered. Patients who continued to demonstrate intolerance to EGD were given a bolus dose of propofol 1 mg/kg, followed by propofol infusion 2 to 5 mg/kg/hr. Success was defined as completion of EGD procedure using fentanyl and midazolam sedation only, with no observation of patient intolerance. After the procedure, patients and endoscopists' satisfaction was evaluated.

**Results:** Eighty-two patients were enrolled in this study. Success rate of the studied sedation protocol was 100%, but two patients required an additional dose of fentanyl and midazolam. Seventy-six participants (92.7%) were satisfied with the sedation technique, and 100% of endoscopists reported being either satisfied or very satisfied. The average time to following verbal commands after completion of the procedure was 1.4 minutes. Desaturation was observed in one patient, which was corrected by jaw-thrust maneuver and increased oxygen flow.

**Conclusion:** Intravenous fentanyl and midazolam combined with topical lidocaine in EGD yielded good results and a high level of satisfaction among both patients and endoscopists with some acceptable complications.

**Keywords:** Esophagogastroduodenoscopy, Intravenous sedation, success rate, Fentanyl, midazolam, Topical lidocaine

**J Med Assoc Thai 2017; 100 (Suppl. 7): S195-S201**

**Full text. e-Journal:** <http://www.jmatonline.com>

Esophagogastroduodenoscopy (EGD) is an increasingly performed procedure. Feelings of discomfort and regurgitation can occur in patients at the time that the scope passes through the throat and into the esophagus. Anesthesia plays an important role in alleviating this issue, ranging from topical local anesthetic agents to general anesthesia.

Survey data from the United States suggests that more than 98% of EGDs and colonoscopies are performed under sedation. By contrast, non-sedated

endoscopy is performed in many European countries<sup>(1)</sup>. At Siriraj Hospital, Thailand's largest university-based tertiary referral center, topical local anesthesia is the most common technique used during EGDs. Discomfort is sometimes observed among patients, which can make it difficult for the endoscopist to pass the scope into the esophagus.

Moderate sedation provides a high level of physician and patient satisfaction and a low risk of serious adverse events with all currently available agents<sup>(1)</sup>. Deeply sedated patients may have inadequate spontaneous ventilation and require assistance to maintain a patent airway. Level of sedation should be titrated to achieve a safe, comfortable, and technically successful endoscopic procedure<sup>(2)</sup>. Fentanyl and midazolam are the two drugs commonly

**Correspondence to:**

Luansritisakul C, Department of Anesthesiology, Faculty of Medicine Siriraj Hospital, Mahidol University, 2 Wanglang Road, Bangkoknoi, Bangkok 10700, Thailand.  
Phone: +66-2-4197978, Fax: +66-2-4113256  
E-mail: choopong.lun@mahidol.ac.th

used, as a result of their combined synergistic effect. Combined with a topical local anesthetic, sedation dose can be reduced resulting in less complications and an effective anesthesia method for the EGD procedure.

The objective of this study was to evaluate the success rate of moderate sedation with fentanyl and midazolam combined with topical lidocaine in esophagogastroduodenoscopy, relative to level of patients and endoscopists' satisfaction with the procedure, time to recovery, and associated complications.

### Material and Method

This study design was approved by the Institutional Review Board (Si 306/2013). The study was conducted at Siriraj Hospital, Bangkok, Thailand during June 2013 to June 2014. Ambulatory patients aged 18 to 75 years with American Society of Anesthesiologists (ASA) physical status classification I-III who were scheduled to undergo EGD were enrolled. Written informed consent was obtained from all patients before they underwent the EGD procedure. Patients were excluded for any one or more of the following reasons including having risk of aspiration such as massive gastrointestinal hemorrhage; expected difficult airway; undergoing simultaneous EGD and colonoscopy (given that colonoscopy patients are routinely sedated with infusion agents); history of allergy to any studied drugs; vulnerable subject; and/or, refusal to participate in the study.

After written informed consent was obtained, patient baseline information and vital signs were recorded. Each patient was orally topicalized two times with 2% lidocaine viscous solution, and then sprayed with 10% lidocaine at the oropharynx and tonsil pillar. Patients were then tested for adequacy of topical anesthesia using a tongue depressor. The topical anesthesia procedure was performed by a single anesthesiologist (SM) throughout the study to ensure the quality and consistency of the topical technique. Patients were given isotonic crystalloid solution at a maintenance rate and nasal cannula with oxygen flow of 3 L/min. Five minutes prior to EGD, fentanyl 1 mcg/kg and midazolam 20 mcg/kg were given intravenously via bolus injection. Vital signs (noninvasive blood pressure, heart rate, and oxygen saturation) were recorded every minute during sedation until conclusion of the procedure. Esophagogastroduodenoscopy procedures in this study were performed by the endoscopists having clinical experience more than one year.

During performing EGD, patient tolerance and complications were observed by the attending anesthesiologist. In cases where patients were unable to tolerate EGD, an additional dose of fentanyl 0.5 mcg/kg and midazolam 10 mcg/kg was administered intravenously. Five minutes were allowed for onset of the additional drugs before proceeding to endoscopy. According to protocol and in cases where patients could still not tolerate the procedure after receiving the second dose of fentanyl and midazolam, a bolus dose of propofol 1 mg/kg, followed by propofol infusion 2 to 5 mg/kg/hr would be given. Patients with unstable vital signs were carefully observed and had appropriated management.

Patient demographic data, indications for undergoing EGD, procedural time, time to response after sedation, complications, and patients and endoscopists' satisfaction with the procedure were collected and recorded. Vital signs (blood pressure, heart rate, and oxygen saturation) were recorded every minute after sedation until the procedure was concluded, then every five minutes during the recovery period.

**Table 1.** Patient demographic and clinical characteristics

Patient characteristics	Total (n = 82)
Gender	
Male	30 (36.6)
Female	52 (63.4)
Age	51.7±12.7
ASA classification	
I	31 (37.8)
II	48 (58.5)
III	3 (3.7)
Indications for EGD	
Dyspepsia	40 (48.8)
Surveillance of esophageal varices	14 (14.7)
Gastritis	10 (12.2)
Gastrointestinal bleeding	9 (11.0)
GERD	3 (3.7)
Check-up	3 (3.7)
Unexplained weight loss	1 (1.2)
Irritable bowel syndrome	1 (1.2)
Malignancy	1 (1.2)

Data presented as mean ± standard deviation or number and percentage, unless otherwise specified.

ASA = American Society of Anesthesiologists; SD = standard deviation; EGD = esophagogastroduodenoscopy; GERD = gastroesophageal reflux disease

Types of patient intolerance included gagging that delayed endoscope insertion for more than thirty seconds, gagging after passing the endoscope into the esophagus, and significant patient movement. Patients were observed for complications, including aspiration, airway obstruction, respiratory apnea, perforation of visceral organ, and iatrogenic hemorrhage. Hypertension and hypotension were defined as change in any blood pressure more than 20% from baseline. Tachycardia was defined as elevation of heart rate more than 120 bpm, with bradycardia defined as heart rate less than 60 bpm. Desaturation was defined as oxygen saturation less than 92%. Any event or complication that occurred would be treated by an experienced anesthesiologist and the event would be recorded.

After completion of the EGD procedure, endoscopists were asked to verbally rate their satisfaction with the anesthesia protocol into the following 4 classifications: very satisfied, satisfied, neutral, or unsatisfied. The research team recorded the time from withdrawal of the endoscope to the time patients were able to correctly respond to the verbal command to open their eyes and tell their name correctly. Once able to correctly respond to postoperative

commands, patients would be sent to the recovery room where vital signs were routinely monitored every five minutes. Patient sedation score, PACU score (Modified Aldrete score), and side effects were also recorded. When patients had fully regained consciousness, patient satisfaction was evaluated verbally by using classification categories of very satisfied, satisfied, neutral, or unsatisfied.

#### Statistical analysis

This study was piloted in ten patients during March 2013, with sedation performed by one of authors. The result showed successful sedation in seven out of ten patients. The other three patients were continued with propofol infusion. Using an expected primary endpoint of 70% (from the pilot study) and a Type I error of 0.05, a group size of 82 subjects was calculated. Data are summarized using descriptive statistics, including number and percentage or mean and standard deviation. Data were analyzed using PASW Statistics for Windows, 18.0 Chicago: SPSS Inc.

#### Results

Of the 82 patients evaluated for efficacy of

**Table 2.** Level of satisfaction with combination fentanyl, midazolam, and topical lidocaine in Esophagogastroduodenoscopy among patients and endoscopists

Level of satisfaction	Patients (n = 82)	Endoscopists (n = 82)
Very satisfied	60 (73.2)	70 (85.4)
Satisfied	16 (19.5)	12 (14.6)
Neutral	4 (4.9)	0 (0)
Unsatisfied	2 (2.4)	0 (0)

**Table 3.** Patient complications that developed during Esophagogastroduodenoscopy and in the recovery room after Esophagogastroduodenoscopy

Complications	During EGD Patients (n = 82)	Recovery room Patients (n = 82)
No complications	48 (58.5)	46 (56.1)
Bradycardia	14 (17.1)	19 (23.2)
Tachycardia	10 (12.2)	6 (7.3)
Hypertension	3 (3.7)	5 (6.1)
Hypotension	3 (3.7)	4 (4.9)
Desaturation	1 (1.2)	0 (0)
Hypertension and tachycardia	1 (1.2)	0 (0)
Hypertension and bradycardia	1 (1.2)	0 (0)
Hypotension and bradycardia	1 (1.2)	1 (1.2)
Nausea/vomiting	0 (0)	0 (0)
Hypertension and nausea/vomiting	0 (0)	1 (1.2)

topical lidocaine combined with sedation using combined fentanyl 1 mcg/kg and midazolam 20 mcg/kg in EGD, 100% of patients were successfully sedated and 100% of procedures were successfully performed without the need for conversion to propofol. Two patients (2.4%) required an additional dose of fentanyl 0.5 mcg/kg and midazolam 10 mcg/kg in order to tolerate the procedure. Mean duration of EGD was 11.1 minutes (range: 2 to 31). After EGD, 49 patients (59.8%) regained consciousness immediately after scope removal and were able to open their eyes and tell their name correctly following commands to do so. Average time to correct response to verbal command was  $1.46 \pm 2.42$  minutes, with a maximum response time of 10 minutes after removal of endoscope.

Ninety-two percent of patients described being either satisfied or very satisfied with the studied sedation technique. Two patients reported being unsatisfied, as follows: one patient said that she expected to have a deeper sleep while having the procedure, and the other complained of having a sore throat after EGD. Regarding endoscopists' satisfaction, 100% of endoscopists reported being either satisfied or very satisfied with this sedation technique, with some commenting that manipulation of the scope into the esophagus was easier and less clinically eventful. None of the endoscopists reported a neutral or unsatisfied level of satisfaction regarding the studied sedation technique.

Some complications were observed following sedation during the EGD procedure. Bradycardia had the highest incidence, occurring in 19.5% of patients in the EGD suite and 23.2% of patients in the recovery room. Among the 23 patients who developed bradycardia, 16 had a heart rate lower than 65 prior to sedation. Tachycardia was found in ten patients (12.2%) during the procedure and in six patients (7.3%) in the recovery room. Hypotension was seen in three patients (3.7%) during the procedure and intravenous fluid bolus was given. One dose of antihypertensive drug was given to one patient that developed hypertension during the procedure. No cases in this study had to be rescued with a resuscitation drug, such as vasopressor or atropine.

The most serious complication observed in this series was desaturation (lowest oxygen saturation at 89%) in one patient (1.2%) during the EGD procedure. Airway was maintained with jaw thrust and increased oxygen flow via nasal cannula, with improvement in oxygen saturation being observed within one minute. No airway equipment was used in any case and none

of the EGD procedures had to be stopped for any reason once the procedure began. One patient had nausea and vomiting in the recovery room, but her symptoms were mild and were improved with antiemetic drug.

## Discussion

The authors selected sedative agents that are effective and that are known to produce the least number of complications. In the present study, sedation with fentanyl and midazolam combined with topical lidocaine was used because these agents synergistically produce sedation and analgesia, with minimal hemodynamic and respiration-related complications. Our regimen resulted in a high level of satisfaction among most patients and endoscopists. This result was consistent with the results of a systematic review by McQuaid et al<sup>(1)</sup>.

The success rate of sedation in this study was 100%, which is higher than the 70% success rate observed in the pilot study. This difference in findings may be due to uncertain criteria regarding patient intolerance to EGD and/or variability in or an unexperienced topical anesthesia technique, which resulted in a higher sedation requirement in the pilot study. However, a higher success rate in the pilot study would have resulted in a lower sample size calculation for this study. As such, the high rates of success and satisfaction are even more meaningful and more strongly support the efficacy of this sedation protocol. Regarding the dose of midazolam, high dose of this agent (more than 5 mg) had been used in several previous studies<sup>(3-5)</sup>. However, this can result in increased side effects, such as hypoxia, hypotension, as well as delayed sedative effect. Campo et al<sup>(6)</sup> found that the patients receiving low-dose midazolam (35 mcg/kg) exhibited better response to the examination than the patients in placebo group and had fewer adverse effects than those in high-dose group. Several studies also supported that low-dose midazolam (30 to 35 mcg/kg) allowed good condition for endoscopy<sup>(7-12)</sup>. This decreased dose of midazolam reduces incidence of adverse events and accelerates the recovery period, both of which result in a faster cycle time of patients through the endoscopy unit.

Conversely, in the clinical setting, the use of low dose of midazolam might lead to patient dissatisfaction due to being uncomfortable and having an unpleasant memory of the endoscopy procedure. Yi et al<sup>(13)</sup> had conducted research to assess the appropriate dose of midazolam for upper gastrointestinal endoscopy. They proposed a

recommended dose of midazolam of 0.06 mg/kg. However, in present study, the authors found that with a combination to fentanyl and topical lidocaine, the dose of midazolam can be reduced to 0.02 mg/kg producing an effective level of sedation. Previous studies reported that opioids had synergistic interaction with midazolam<sup>(14,15)</sup>. Ristikankare et al also found that intravenous midazolam and topical pharyngeal anesthesia alleviated hemodynamic response during gastroscopy<sup>(16)</sup>.

Several medications have been shown to be effective in sedation for upper gastrointestinal endoscopy. Amornyothin et al<sup>(17)</sup> reported that sedation with propofol can increase both patients and endoscopists' satisfaction. Moreover, several studies showed that sedation with propofol was superior to standard sedation using midazolam and opioids<sup>(18-23)</sup>. The higher level of patient satisfaction for propofol is likely due to the fact that propofol produces deeper sedation. However, deeply sedated patients may have inadequate spontaneous ventilation and may require assistance to maintain a patent airway<sup>(1)</sup>, thus increasing the probability of unexpected complications. Amornyothin et al<sup>(17)</sup> did not report adverse events in his study. From the endoscopist's perspective, too deep sedation may be disadvantageous, as it may cause loss of muscle tone and increase the chance of visceral organ perforation. Furthermore, our sedation regimen may be superior to propofol, because it produces an adequate level of sedation for successful passing of the endoscope, but it does not compromise patient hemodynamics which propofol can.

Recently, several studies have demonstrated that dexmedetomidine is a safe and effective sedative agent for gastrointestinal endoscopy<sup>(24,25)</sup>. However, since dexmedetomidine is still a branded medication and has a significant acquisition cost, the use of dexmedetomidine is a less favourable strategy than the use of midazolam, in terms of cost-effectiveness.

Limitations of this study include inadequate assessment of pre-procedural anxiety in EGD patients and a failure to identify patients who had previously undergone EGD. Pre-procedure knowledge of either of these two factors could possibly have influenced level of EGD success. In addition, this study was conducted in ambulatory outpatients. As such, the results of our study may not apply to hospital inpatients who may have more serious conditions that may cause or somehow associate with a higher rate of complications. Based on the results of this study, sedation with low-dose fentanyl and midazolam combined with topical

lidocaine is safe and effective in EGD. The adverse events observed in this study were not clinically relevant, except for hypoxia in one patient (1.2%).

The authors recommend this sedation technique for use in routine practice in selected cases of gastro enteroscopy to increase patient comfort and willingness and to facilitate a faster and less eventful procedure for the endoscopist. This protocol should include continuous oxygen saturation monitoring. Skilled airway management and resuscitation personnel should always be on-hand or available to quickly and competently manage desaturation and unforeseen events. Although this sedation protocol was shown to be effective, sedation-associated risk counselling should always be conducted with the patient by written informed consent for sedation.

### Conclusion

Intravenous fentanyl and midazolam combined with topical lidocaine in esophagogastroduodenoscopy (EGD) yielded good results and a high level of satisfaction among both patients and endoscopists with some acceptable complications. This method may be safely used in routine gastro duodenoscopy in selected patients being treated by an endoscopic team with skilled airway management.

### What is already known on this topic?

Feelings of discomfort and regurgitation during esophagogastroduodenoscopy (EGD) can occur in patients at the time the scope passes through the throat and into the esophagus, leading to a failure of the procedure and patient dissatisfaction.

### What this study adds?

This study demonstrated the efficacy of sedation regimen for esophagogastroduodenoscopy using midazolam and fentanyl combined with topical lidocaine.

### Potential conflicts of interest

None.

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อัตราความสำเร็จของการระงับความรู้สึกสำหรับการส่องกล้องทางเดินอาหารส่วนบนด้วยยา Fentanyl, Midazolam ร่วมกับการพ่นยาชาเฉพาะที่ Lidocaine

สายพิณ เมืองแมน, สมชาย อมรโยธิน, พีรฉัตร มั่งมีศรี, เสาวภาลัย จำปาทอง, นนทลี เผ่าสวัสดิ์, วัชรศักดิ์ โชติยะปุตตะ, จุลจักร ลิ้มศรีวิไล, อรณี สวัสดิ์-ชูโต, ทศนีย์ ใจเย็น, ชุพงศ์ ล้วนศรีติสกุล

วัตถุประสงค์: เพื่อประเมินอัตราความสำเร็จของการให้ยาเพื่อให้เกิดความสงบระดับปานกลางด้วยยา fentanyl, midazolam ร่วมกับการพ่นยาชาเฉพาะที่ lidocaine ในการส่องกล้องทางเดินอาหารส่วนบน ร่วมกับประเมิน ความพึงพอใจของผู้ป่วย แพทย์ผู้ส่องกล้อง ระยะเวลา การฟื้นตัวและภาวะแทรกซ้อน วัสดุและวิธีการ: ผู้ป่วยที่เข้ารับการส่องกล้องทางเดินอาหารส่วนบนทุกรายจะได้รับการพ่นยาชา lidocaine ที่บริเวณคอหอยร่วมกับได้รับยา fentanyl 1 mcg/kg และ midazolam 20 mcg/kg ทางหลอดเลือดดำ ผู้ป่วยที่ไม่สามารถทนการส่องกล้องได้จะได้รับยาครั้งที่สองคือ fentanyl 0.5 mcg/kg และ midazolam 10 mcg/kg ถ้ายังไม่สามารถทนการส่องกล้องได้อีกจะได้รับยา propofol 1 mg/kg ทางหลอดเลือดดำและหยุดต่อด้วยอัตรา 2-5mg/kg/hour นิยามของอัตราความสำเร็จของการระงับความรู้สึกคือ ผู้ป่วยทนการส่องกล้องโดยได้รับเฉพาะยา fentanyl และ midazolam เท่านั้น ผู้ป่วยและแพทย์ผู้ส่องกล้องจะได้รับการประเมินความพึงพอใจหลังการส่องกล้องเสร็จสิ้น

ผลการศึกษา: การศึกษานี้มีผู้ป่วยที่เข้ารับการศึกษานี้ 82 คน โดยมีอัตราความสำเร็จของการระงับความรู้สึกด้วยวิธีนี้ 100% โดยมีผู้ป่วยเพียง 2 รายที่ได้รับยา fentanyl และ midazolam ครั้งที่สอง ผู้ป่วย 76 ราย (ร้อยละ 92.7) พึงพอใจ เทคนิคนี้ และ 100% ของแพทย์ผู้ส่องกล้องให้ระดับความพึงพอใจในระดับพึงพอใจหรือพึงพอใจมาก หลังเสร็จสิ้นการส่องกล้อง เวลาเฉลี่ยที่ผู้ป่วยสามารถทำตามคำสั่งด้วยเสียงได้คือ 1.4 นาที และมีผู้ป่วยเพียง 1 ราย ที่มีภาวะความเข้มข้นของออกซิเจนต่ำ ซึ่งแก้ไขได้ด้วยการเปิดทางเดินหายใจด้วยวิธี jaw-thrust และเพิ่มอัตราการไหลของออกซิเจนผ่าน nasal cannula

สรุป: การให้ยา fentanyl, midazolam ร่วมกับการพ่นยาชาเฉพาะที่ lidocaine ในการส่องกล้องทางเดินอาหารส่วนบนมีอัตราความสำเร็จสูง และได้รับความพึงพอใจจากผู้ป่วยและแพทย์ผู้ส่องกล้องสูงโดยมีภาวะแทรกซ้อนต่ำ

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