

Intravenous Sedation for Endoscopic Ultrasonography in Siriraj Hospital

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บทคัดย่อ : การให้ยาระงับความรู้สึกทางหลอดเลือดดำสำหรับการส่องกล้องระบบทางเดินอาหารแบบมีอัลตราซาวด์ในโรงพยาบาลศิริราช

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บทนำ : การส่องกล้องระบบทางเดินอาหารแบบมีอัลตราซาวด์เป็นหัตถการส่องกล้องชนิดหนึ่งเพื่อการวินิจฉัยและรักษาความผิดปกติของระบบทางเดินอาหารและอวัยวะใกล้เคียง ซึ่งเป็นหัตถการชนิดหนึ่งที่ต้องการยาระงับความรู้สึก โดยส่วนมากมักใช้ยาระงับความรู้สึกทางหลอดเลือดดำ **วัตถุประสงค์ :** เพื่อศึกษาประสิทธิภาพของการให้ยาระงับความรู้สึกทางหลอดเลือดดำในผู้ป่วยที่ได้รับการทำหัตถการส่องกล้องระบบทางเดินอาหารแบบมีอัลตราซาวด์ในโรงพยาบาลศิริราช **วิธีการศึกษา :** ศึกษาแบบย้อนหลังผู้ป่วยที่ได้รับการให้ยาระงับความรู้สึกสำหรับส่องกล้องระบบทางเดินอาหารแบบมีอัลตราซาวด์ตั้งแต่เดือนกันยายน พ.ศ. 2548 จนถึงเดือนกุมภาพันธ์ พ.ศ. 2552 รวบรวมข้อมูลทั่วไป ปัญหาก่อนการให้ยาระงับความรู้สึก ระยะเวลาการให้ยาระงับความรู้สึก ยาที่ใช้ และภาวะแทรกซ้อน ประมวลและสรุปผลโดยใช้สถิติเชิงพรรณนา **ผลการศึกษา :** ในช่วงระยะเวลาการศึกษามีผู้ป่วยทั้งหมด 521 คน ในจำนวนนี้มีผู้ป่วย 513 คน (มีตั้งแต่อายุ 19 ปี จนถึงอายุ 97 ปี)

อายุเฉลี่ย 55.2 ± 15.3 ปี ผู้ชาย 249 คน และผู้หญิง 264 คน มารับการส่องกล้องระบบทางเดินอาหารแบบมีอัลตราซาวด์โดยใช้ยาระงับความรู้สึกทางหลอดเลือดดำ ผู้ป่วยส่วนมากจะมี ASA class I หรือ II (43.6%, 47.4%) ระยะเวลาการทำหัตถการเฉลี่ย 52.3 ± 23.7 นาที (ตั้งแต่ 15 นาที จนถึง 225 นาที) เหตุที่ต้องมาทำหัตถการ ได้แก่ ความผิดปกติของตับอ่อน (38.4%) ความผิดปกติของกระเพาะอาหาร (19.5%) ความผิดปกติของตับและระบบทางเดินน้ำดี (14.4%) ปวดท้อง (10.1%) เนื้องอกของหลอดอาหาร (5.5%) ความผิดปกติของต่อมเหงื่อในท้อง (4.9%) ก้อนเนื้องอกในท้อง (2.1%) และอื่น ๆ (5.1%) ทั้งนี้พบว่าโรคความดันเลือดสูง (16.2%) โรคระบบเลือด (13.1%) และเบาหวาน (9.2%) เป็นปัญหาก่อนการให้ยาระงับความรู้สึกที่พบบ่อยสุดสามอันดับแรก ผู้ป่วยได้รับการส่องกล้องระบบทางเดินอาหารแบบมีอัลตราซาวด์เพื่อการวินิจฉัยเพียงอย่างเดียว 332 คน (64.7%) อวัยวะที่สงสัยว่ามีพยาธิสภาพส่วนมากคือ ตับอ่อน กระเพาะอาหาร ตับและระบบทางเดินน้ำดี ผู้ป่วยส่วนมากได้รับ

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ยา propofol, fentanyl และ midazolam และจะใช้ยาทั้งสามชนิดร่วมกันมากที่สุด โดยปริมาณยาเฉลี่ยของ propofol ในผู้ป่วยอายุน้อยกว่า 60 ปีใช้มากกว่าเมื่อเทียบกับผู้ป่วยกลุ่มอายุอื่น แต่ปริมาณยาเฉลี่ยของ fentanyl และ midazolam ไม่แตกต่างกัน พบภาวะแทรกซ้อนทั้งหมด 40.7% ส่วนใหญ่เป็นความดันเลือดต่ำ แต่ภาวะแทรกซ้อนที่เกิดขึ้นไม่แตกต่างกันเมื่อเปรียบเทียบในแง่ของอายุ ระดับของ ASA และการใช้ยาระงับความรู้สึกทางหลอดเลือดดำร่วมกัน *สรุป* : การให้ยาระงับความรู้สึกทางหลอดเลือดดำในผู้ป่วยที่มารับการส่องกล้องระบบทางเดิน

อาหารแบบมีอัลตราซาวด์โดยบุคลากรทางด้านวิสัญญีมีความปลอดภัยค่อนข้างมากและมีประสิทธิภาพ ภาวะแทรกซ้อนที่รุนแรงพบน้อยมาก

คำสำคัญ : การให้ยาระงับความรู้สึกทางหลอดเลือดดำ การทำอัลตราซาวด์ระบบทางเดินอาหารผ่านการส่องกล้อง ประสิทธิภาพทางคลินิก

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Endoscopic ultrasonography (EUS) is a combination of endoscopy and intraluminal ultrasonography. It is used to image suspected pathology in the gastrointestinal tract and in the adjacent organs.¹⁻⁵ Improved accuracy and cost-effectiveness has been established in comparison with other imaging techniques. For example, many studies recommend that EUS is superior to computer tomography (CT) for tumor and lymph node staging of luminal and pancreatobiliary malignancies.^{6,7}

In practice, however, most EUS procedures are performed in the endoscopy room or operating room. Patients undergoing EUS usually receive some forms of anesthesia. The type of anesthesia used is chosen according to the patient's medical condition and the anesthesiologist's preference. Many centers use intravenous sedation (IVS) for this procedure because of its obvious advantages.⁸⁻¹⁰ Little data is available concerning the advantages and the disadvantages for IVS for patients undergoing EUS, especially in developing countries.

The aim of this study was to evaluate the clinical efficacy of IVS for EUS procedure in Siriraj Hospital.

Materials and Methods

This retrospective study was approved by the Institutional Review Board of the Faculty of Medicine Siriraj Hospital, Mahidol University. Data of all patients

referred to Siriraj GI Endoscopy Center at Siriraj Hospital, a tertiary care referral center between September 2005 and February 2009, were collected prospectively. All endoscopies were performed by staff endoscopists. The following data were obtained : age, gender, weight, ASA physical status, indications for EUS, pre-sedation problems, procedural time and agents, as well as adverse events : hypotension (decrease by 20% from baseline and below normal for age), hypertension (increase by 20% from baseline and above normal for age), bradycardia (decrease in heart rate by 30% from baseline and below normal for age) and desaturation ($SpO_2 < 90\%$). The efficacy of sedation was defined as the successful completion of the entire procedure.

Monitorings during the procedures were measurement of blood pressure, electrocardiogram, respiratory rate and oxygen saturation. No premedication was administered before the procedure. All patients were oxygenated via nasal canula and sedated by well trained anesthetic personnel directly supervised by a staff anesthesiologist in the endoscopy room. Anesthetic personnel included residents in anesthesiology and nurse anesthetists. The patients were sedated to either moderate (conscious) or deep sedation level according to guideline of the American Society of Anesthesiologists.¹¹

Results were presented as mean (SD) or percentage (%), when appropriate. Comparisons of sedative

agents used, combination of sedative drugs and incidence of sedation related adverse events among the different age groups as well as the incidence of sedation related adverse events between the different ASA physical status and the particular combination of sedative agents groups were done with one-way ANOVA F-test. The statistical software package SPSS for Windows version 11 (SPSS Inc., Chicago, IL) was used to analyze the data. A significant level of 0.05 was used throughout the study.

Results

During the study period, a total of 521 EUS procedures were reviewed. Of these, 513 patients (249 male and 264 female ; mean age 55.2 ± 15.3 years) were anesthetized by using IVS technique. The range in age was from 17 to 97 years. Of these, 332 patients (64.7%) were outpatients. All outpatient cases were utilized only for diagnostic EUS but not for fine needle aspiration (FNA) and other interventions. Of 513 patients, 273 patients (53.2%) were also topicalized with lidocaine viscous and/or lidocaine spray before the endoscopy.

Table 1 showed the patient characteristics, mean sedation time and the indications for EUS. The mean sedation time was 52.3 minutes (SD 23.7 minutes ; range 15-225 minutes).

The endoscopy characteristics and pre-sedation problems were presented in Table 2. Three hundred and thirty two procedures (64.7%) were only used for diagnostic EUS and 158 procedures (30.8%) were utilized with EUS and fine needle aspiration (FNA). Moreover, 23 procedures (4.5%) were employed with EUS and other interventions such as pancreatic pseudocyst drainage and celiac plexus block. Most of the target organs of these procedures were pancreas, stomach and hepatobiliary tract. The majority of pre-sedation medical problems involved mainly hypertension (16.2%), hematologic diseases including anemia (13.1%), diabetes mellitus (9.2%), as well as electrolyte imbalance (7.4%) and cardiovascular diseases (7.0%). Other problems were

liver diseases and dyslipidemia.

Sedative agents used and the combination of sedative drugs categorized by age were shown in Table 3. Of the total of 513 intravenous sedations, propofol, fentanyl and midazolam were the most common sedative drugs. Most of them were used in combination with two, three or four other agents. All cases were concluded with the satisfactory completion of the procedure.

According to age, the mean dose of propofol and midazolam in age < 60 years old group was statistically significantly higher than the other groups ($p < 0.001$ and $p = 0.002$, respectively). However, the mean dose of fentanyl, pethidine and ketamine was not significantly different among the three aged groups. The combination of propofol, midazolam and fentanyl was the most common combination of sedative agents used in all aged groups. However, there was a high number of the combination of propofol and midazolam in patients aged > 80 years old ($p = 0.006$).

Table 4 showed the incidence of sedation related adverse events categorized by age and ASA physical status. Varying according to the patient's age, cardiovascular adverse events consisted mainly of hypotension which was the most common adverse event in all age groups. Respiratory adverse events were rare. However, all adverse events were not statistically significantly different among the three aged groups ($p = 0.989$). Varying according to the patient's ASA physical status, cardiovascular adverse events consisted mainly of hypotension which was also the most common adverse event in all ASA groups. Additionally, all adverse events were also not different among the three ASA groups ($p = 0.512$).

The incidence of sedation related adverse events categorized by combination of sedative agents was presented in Table 5. A cardiovascular adverse event which consisted mainly of hypotension was also the most common adverse event in all combination groups. Consequently, all adverse events were also not different

Table 1 Patient characteristics, sedation time and indications for procedure

Variable	Result (n = 513)
Age (yr) (mean, SD ; min-max)	55.3 (15.3) ; 17 - 97
Gender (Male/Female ; n, %)	249/264 (48.5/51.5)
Weight (kg) (mean, SD ; min-max)	55.0 (8.7) ; 27 - 94
ASA physical status (I, II, III, IV ; n, %)	224/243/45/1 (43.6/47.4/8.8/0.2)
Sedation time (min) (mean, SD ; min-max)	52.3 (23.7) ; 15 - 225
Indications (n, %)	
Pancreatic abnormality	197 (38.4)
Gastric abnormality	100 (19.5)
Hepatobiliary abnormality	74 (14.4)
Abdominal pain	52 (10.1)
Esophageal tumor	28 (5.5)
Abdominal lymphadenopathy	25 (4.9)
Abdominal mass	11 (2.1)
Miscellaneous	26 (5.1)

among all combination groups. All adverse events were under the care of an anesthesiologist. No serious complications were occurred.

Discussion

We presented data derived from a retrospective data analysis examining EUS sedation in a tertiary academic hospital. The data showed that in the hands of anesthetic personnel, IVS for the EUS procedure is reliable, relatively safe and much appreciated by both endoscopists and patients. In Siriraj Hospital, these procedures that required some forms of anesthesia are performed on about 1.0% of all GIE procedures.¹² The majority of them (98.5%) were performed under IVS technique.

EUS was introduced into gastroenterological diagnostics for more than 20 years ago. Since then, it 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. In addition, it has been used for other endoscopic interventions such as EUS-guided drainage of pancreatic cyst,^{13,14} bile duct¹⁵⁻¹⁸ and pancreatic duct.¹⁹⁻²¹ Other endoscopic interventions were EUS-guided celiac plexus neurolysis or block,^{22,23} fine needle tattooing,^{24,25} anti-tumor injection therapy,²⁶⁻²⁸ and brachytherapy and radio-frequency ablation.^{29,30} Many physicians now consider EUS to be the method of choice for diagnosis of pancreatic mass and mediastinal adenopathy when other techniques have failed, as well as for other lesions that are poorly seen by or inaccessible to biopsy by other imaging modalities.

EUS is an essential procedure among GI abnormality diagnoses and treatments, even in our institution, where we observe an increase in the number of these procedures every year. Therefore, it is mandatory to standardize a safe, easy and well tolerated anesthetic procedure which is feasible in the GI endoscopy unit.

Table 2 Endoscopy characteristics and pre-sedation problems

	Number (%)
Type of EUS	
Diagnostic EUS	332 (64.7)
EUS and FNA	158 (30.8)
EUS and other interventions	23 (4.5)
Target organ suspected	
Pancreas	201 (39.2)
Stomach	101 (19.7)
Hepatobiliary tract	74 (14.4)
Abdominal lymph node	25 (4.9)
Esophagus	22 (4.3)
Duodenum	8 (1.6)
Celiac plexus	7 (1.4)
Colon and rectum	5 (1.0)
Unknown	70 (13.6)
Pre-sedation problems	
Hypertension	83 (16.2)
Hematologic disease	67 (13.1)
Diabetes mellitus	47 (9.2)
Electrolyte imbalance	38 (7.4)
Cardiovascular disease	36 (7.0)
Liver disease	28 (5.5)
Dyslipidemia	14 (2.7)
Others	12 (2.3)

EUS : Endoscopic ultrasonography, FNA : Fine needle aspiration

In our previous experiences,^{31,32} we have noted that topical anesthesia alone is not sufficient for pain-free procedures. In contrast, general anesthesia, which may be of benefit for the patient and endoscopist comforts, may be difficult to administer, especially in co-morbidity patients. In addition, the lack of experience in anesthesia care among endoscopy personnel might increase the risk of complications.

Managing sedated patients requires an under-

standing of the level of sedation that can be achieved.³³⁻³⁶ Moderate (conscious) sedation refers to a controlled state of diminished consciousness wherein protective reflexes, the ability to respond to moderate physical or verbal stimuli and the ability to maintain a patent airway are retained. In contrast, deep sedation refers to a controlled state of depressed consciousness from which the patient is not easily aroused, with likely loss of protective airway reflexes and the ability to maintain a patent airway.^{36,37}

Table 3 Sedative agents used [n (%); mean (SD), mg/kg/hr] and combination of sedative drugs [n (%)] categorical by age

Agents	All (513)	< 60 year (304)	60-80 year (193)	> 80 year (16)	p value
Propofol	505 (98.4), 5.4 (2.0)	301 (99.0), 5.7 (1.8)	188 (97.4), 4.9 (1.9)	16 (100.0), 5.4 (3.0)	< 0.001*
Fentanyl	477 (93.0), 0.001 (0.001)	283 (93.1), 0.001 (0.001)	180 (93.3), 0.001 (0.001)	14 (87.5), 0.001 (0.000)	0.788
Midazolam	460 (89.7), 0.034 (0.016)	273 (89.8), 0.036 (0.016)	172 (89.1), 0.031 (0.015)	15 (93.8), 0.031 (0.011)	0.002*
Pethidine	25 (4.9), 0.6 (0.3)	17 (5.6), 0.6 (0.3)	8 (4.1), 0.6 (0.2)	0	0.570
Ketamine	5 (1.0), 1.2 (0.7)	1 (0.3), 0.5	4 (2.1), 1.4 (0.7)	0	0.277
Combination					
MF	8 (1.6)	3 (1.0)	5 (2.6)	0	0.326
PF	50 (9.7)	29 (9.5)	20 (10.4)	1 (6.3)	0.852
PM	10 (1.9)	6 (2.0)	2 (1.0)	2 (12.5)	0.006*
PPe	3 (0.6)	2 (0.7)	1 (0.5)	0	0.934
PMF	416 (81.1)	249 (81.9)	154 (79.8)	13 (81.3)	0.842
PMPe	21 (4.1)	14 (4.6)	7 (3.6)	0	0.609
PMK	3 (0.6)	0	3 (1.6)	0	0.082
PMFK	2 (0.4)	1 (0.3)	1 (0.5)	0	0.917

M : Midazolam, F : Fentanyl, P : Propofol, Pe : Pethidine, K : Ketamine

* Considered to be statistically significant

Table 4 Incidence of sedation related adverse events categorized by age and ASA physical status (n, %)

Adverse events	< 60 yr (304)	60-80 yr (193)	> 80 yr (16)	p value	ASA I (224)	ASA II (243)	ASA III (45)	p value
Overall	120 (39.5)	81 (42.0)	8 (50.0)	0.989	88 (39.3)	100 (41.2)	20 (44.4)	0.512
Cardiovascular								
Hypotension	109 (35.9)	75 (38.9)	8 (50.0)	0.456	83 (37.1)	89 (36.6)	19 (42.2)	0.535
Bradycardia	6 (2.0)	4 (2.1)	0	0.846	3 (1.3)	6 (2.5)	1 (2.2)	0.670
Respiratory								
Hypoxia (SpO ₂ < 90%)	2 (0.7)	1 (0.5)	0	0.934	1 (0.4)	2 (0.8)	0	0.899
Upper airway obstruction	3 (1.0)	1 (0.5)	0	0.793	1 (0.4)	3 (1.2)	0	0.717

Table 5 Incidence of sedation related adverse events categorized by combination of sedative agents (n, %)

Adverse events	MF (8)	PF (50)	PM (10)	PMF (416)	PMPe (21)	Other (8)	p value
Overall	3 (37.5)	22 (44.0)	0	170 (40.9)	10 (47.6)	4 (50.0)	0.866
Cardiovascular							
Hypotension	3 (37.5)	19 (38.0)	0	157 (37.7)	9 (42.9)	4 (50.0)	0.235
Bradycardia	0	3 (6.0)	0	7 (1.7)	0	0	0.371
Respiratory							
Hypoxia (SpO ₂ < 90%)	0	0	0	2 (0.5)	1 (4.8)	0	0.234
Upper airway obstruction	0	0	0	4 (1.0)	0	0	0.967

MF : Midazolam-fentanyl, PF : Propofol-fentanyl, PM : Propofol-midazolam, PMF : Propofol-midazolam-fentanyl, PMPe : Propofol-midazolam-pethidine

Propofol has also been gaining wide acceptance and has an excellent safety profile, with more than 20,000 adult patients reported in the literature.^{35,36,38} Propofol may be administered alone but in clinical practice it is commonly administered in combination. Propofol, combined with short acting benzodiazepine, with or without fentanyl, has already been used in several GI endoscopic procedures.³⁹ In this study, we have shown that sedation

with low dose propofol and midazolam, as well as with low dose fentanyl is safe and well tolerated by the patient. However, the amount of sedation required depends on the patient's physical status.

A systematic review and meta-analysis of randomized, controlled trials of moderate sedation for routine endoscopic procedures showed that moderate sedation provided a high level of physician and patient

satisfaction and a low risk of serious adverse events when administered with all currently available agents. Midazolam-based regimens had longer sedation and recovery times than did propofol.⁹

In this study, we detected a relatively high overall rate of adverse events in 40.7% of procedures. This rate is higher than that commonly reported because we used very strict criteria in defining adverse events. If only significant respiratory adverse events, such as prolonged desaturation or apnea are counted, the adverse event rate is only 1.4%. Surprisingly, these adverse events were not statistically significantly different in any group designated, categorized according to age, ASA physical status and combination of sedative agents. Arrhythmias have been underreported because not all patients were monitored with electrocardiography. In general, complication rates for GI endoscopy may be procedure and sedation-related, and have been reported in the range 0.2-0.35%. Mortality rates attributable to this procedure have been reported between 0.004% for outpatients and 0.01% for inpatients.³⁷

Limitations of the present study exist. First, there is the wide range in age of the patients in our study. Drug requirements, recovery time and side effects can be related to patient's age. Second, this is a retrospective study and inaccurate and incomplete documentation of certain measures, as with many chart reviews, also occurred in this study. Third, the limitation of monitoring such as that of end-tidal carbon dioxide would result in a lower rate of adverse events. Fourth, many anesthesiologists define complications differently. Finally, because serious complications in our series were low in number, further studies in larger prospective groups of patients are therefore needed.

Conclusion

We report the performance from Siriraj Hospital of clinical efficacy of IVS for EUS procedure in a unit outside the OR. The findings of the present study showed

that EUS sedation performed by anesthetic personnel is relatively safe and effective. There is no need for special techniques or drugs in sedation. Serious complications are rare.

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Intravenous Sedation for Endoscopic Ultrasonography in Siriraj Hospital

Abstract

Background : Endoscopic ultrasonography (EUS) is a procedure for diagnosis and treatment in patients with abnormality of gastrointestinal tract and adjacent organs. It commonly performed under intravenous sedation. The efficacy by which a patient is sedated remains controversial. **Objective :** To evaluate the clinical efficacy of intravenous sedation for the EUS procedure in Siriraj Hospital. **Methods :** The patients on whom EUS had been performed by using intravenous sedation (IVS) during the period of September, 2005 to February, 2009 at Siriraj GI Endoscopy Center were retrospective analyzed. The patients' characteristics, pre-sedation problems, sedative agents, time and complications were assessed. **Results :** During the study period, a total of 521 EUS procedures were reviewed. Of these, 513 patients (249 male and 264 female ; mean age 55.2 ± 15.3 years and ranged from 17 year to 97 years) were performed under IVS technique. Most patients were classified in ASA class I or II (43.6%, 47.4%). Mean sedation time was 52.3 ± 23.7 minutes and ranged from 15 to 225 minutes. Indications for EUS were pancreatic abnormality (38.4%), gastric abnormality (19.5%), hepatobiliary abnormality (14.4%), abdominal pain (10.1%), esophageal tumor (5.5%), abdominal lymphadenopathy (4.9%), abdominal mass (2.1%) and others (5.1%). Preanesthetic problems were hypertension (16.2%), hematalogic diseases (13.1%) and diabetes mellitus (9.2%). Of 513 patients, 332 procedures (64.7%) were performed only for diagnosis. Pancreas, stomach and hepatobiliary tract were the main target organs. The main sedative agents used were propofol, fentanyl and midazolam. Mean dose of propofol in patients aged < 60 years was significantly higher than in the other aged groups. However, the mean dose of fentanyl and midazolam was not significantly different. The combination of propofol, fentanyl and midazolam was commonly used. Overall complication rate was 40.7%. Cardiovascular adverse event including hypotension was the most frequent sedative complication. By comparison according to age, ASA physical status and combination of sedative agents, all adverse events were not significantly different. **Conclusion :** IVS performed by anesthetic personnel for EUS procedure is relatively safe and effective. Serious adverse events are rare.

Keywords : *Intravenous sedation, Endoscopic ultrasonography, Clinical efficacy*
