

The Effectiveness of Intravenous Sedation in Diagnostic Upper Gastrointestinal Endoscopy

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Background: Topical pharyngeal anesthesia is required to perform a technically adequate esophago-gastroduodenoscopy (EGD), but does not improve patient satisfaction, comfort, and willingness to repeat, particularly in the elderly and those with increased pharyngeal sensitivity. The comparative effectiveness of intravenous sedation versus no sedation remains poorly characterized.

Objective: To compare the effectiveness of diagnostic EGD with and without intravenous sedation in an adult Thai population.

Material and Method: A randomized controlled trial assigned patients into two groups, group C (topical pharyngeal anesthesia alone) and group I (intravenous sedation and topical pharyngeal anesthesia). All patients were topicalized with lidocaine viscous and spray. The patients in group I were sedated with midazolam 0.035 mg. kg⁻¹ and maintained with continuous propofol infusion. The ease of procedure and patient tolerance were evaluated. Secondary outcomes included patient and endoscopist satisfaction, total time to awake, and willingness to repeat the procedure.

Results: One hundred and seventy patients (mean age 50.5, 41.2% male) were randomized (group C = 85 and group I = 85; intervention) into two groups. Among patients of the two groups, 100% of the procedures were "successful". In group C, 98.8% were satisfied with their level of tolerance (comfort) while the group I had 100%. The willingness to repeat was 6.2 ± 1.6 in group C while group I had 9.4 ± 0.8. Patient and endoscopist satisfaction in group I was more satisfied than in group C (90.6% vs 35.3% and 81.2% vs 40.0% respectively) ($p < 0.001$). In group I, total amount of propofol was 91.6 ± 45.5 mg and total time to awake was 8.2 ± 4.2 min. The use of sedation was the major determinant of patient satisfaction, but contributed to an increased recovery room time. Hypertension and tachycardia were the most complications in group C, and hypotension was the most complication in group I.

Conclusion: In the average Thai adult population, sedated diagnostic EGD is a good strategy to increase endoscopist satisfaction and willingness to repeat.

Keywords: Effectiveness, Intravenous sedation, Upper gastrointestinal endoscopy

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Diagnostic upper gastrointestinal endoscopy is carried out for a multitude of clinical indications. It is the most commonly performed endoscopic procedure with an incidence of 8.6 per thousand population⁽¹⁾. In Siriraj Hospital, it represents 57.1% of all gastrointestinal (GI) endoscopic procedures.

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In most centers, patients undergoing diagnostic upper GI endoscopy are given the choice of topical pharyngeal anesthesia or being sedated during the procedure. GI endoscopy has generally been avoided in many patients owing to severe nausea and pain. Accordingly, sedative endoscopic examination using sedative medication has been undertaken to induce conscious sedation for comfortable and painless endoscopy⁽²⁾. The use of conscious sedation has

resulted in the widespread diffusion and acceptance of this technology among physicians and patients alike⁽³⁾. Improved patient tolerance and satisfaction afforded by parenteral sedation must be weighed against the risk of adverse cardiopulmonary events and the unit cost. It is estimated that sedation and related issues are responsible for up to 40% of total endoscopic cost including overhead costs and indirect costs⁽⁴⁾.

The authors designed a prospective, randomized study of upper gastrointestinal endoscopy to compare the effectiveness between intravenous sedation plus topical pharyngeal anesthesia and topical pharyngeal anesthesia alone in patients who had undergone upper gastrointestinal endoscopy.

Material and Method

The present prospective, randomized study was undertaken in 170 consecutive patients undergoing endoscopic examination. Patients who may have had problems during the test or had severe cardiovascular disease, pulmonary disease, a chronic alcohol history, drug abuse, or were pregnant or lactating were not included in the present study. There were 85 patients in the topical anesthesia alone (control) group (group C) and 85 patients in the sedation (intervention) group (group I). In each group, the patients were divided into two subgroups: Group A; patients who had undergone a previous endoscopy, Group B; patients who were undergoing an endoscopy for the first time. All patients had topicalized pharynx with 2% lidocaine viscous and 10% lidocaine spray and oxygenation via nasal cannula. In the control group, the patients received topical pharyngeal anesthesia alone. If the subsequent endoscopy was unsuccessful due to patient intolerance, patients were given a titrated dose of propofol. In the intervention group, the patients were administered 0.035 mg.kg⁻¹ of midazolam and titrated intravenous dose of propofol according to the patient's tolerance and clinical status. The dose administered was determined by the individual anesthesiologist and recorded for each patient. All procedures were performed by experienced endoscopists in a standardized environment using the same type of videoendoscopy equipment. Blood pressure, pulse, respiration rate, arterial oxygen saturation, and the cardiogram were monitored continuously. These parameters were checked just before, at the initiation of endoscopy and at 2 min intervals during the procedure.

The total duration of the procedure and the number of histological examinations were recorded.

The ease of procedure was evaluated using four categories as follows: 1, effortless; 2, easy; 3, fair; and 4, poor. The patient tolerance was divided into four categories as follows: 1, did not feel the thing; 2, well, 3, fair; 4, poor. The endoscopist and patient satisfaction were divided into four categories as follows: 1, very satisfied; 2, satisfied; 3, neutral; and 4, unsatisfied.

The comfort during the entire endoscopy was assessed. The present endoscopy comparing with the previous endoscopy without sedation and the willingness to repeat the same endoscopic procedure were asked. Scores were based on a 10 mm. visual analog scale of 0-10, where 0 is unbearable and 10 is excellent. Systolic and diastolic blood pressure, pulse, arterial oxygen saturation, and complication were recorded.

Statistical analysis

Results were reported as mean, standard deviation (SD) or percentage (%) where appropriate. Statistical analysis was done using Chi's square and Student's t-test. Results were considered significant at $p < 0.05$.

Results

Patients in both groups were similar with regard to demographic data (age, weight, height, and sex) and endoscopic procedure (duration and previous endoscopy). In ASA classification, ASA I in the control group was higher than the intervention group, significantly, as indicated in Table 1. According to the endoscopists, there was significant difference between two groups in terms of the ease of the procedure during intubation and for the overall period of endoscopy (Table 2).

The level of endoscopist satisfaction was significantly different between the two groups (40.0% and 81.2% respectively, $p < 0.05$) as shown in Table 3. The level of patient tolerance during the procedure was significantly different between the control and intervention group (21.2% and 63.6% respectively, $p < 0.05$) as shown in Table 4. The number of patients who had undergone a previous endoscopy, and were undergoing an endoscopy for the first time in group C and I were 16,69 and 32,53 respectively. The level of patient satisfaction during the procedure was significantly different between the two groups 5.1 ± 1.5 and 9.5 ± 0.6 respectively, $p < 0.05$ for subgroup A, and 6.8 ± 1.6 and 9.2 ± 0.8 respectively, $p < 0.05$ for subgroup B. Compared with conventional previous endoscopy performed without any sedation, the level of satisfaction was significantly different between group C and I (6.1

Table 1. Patient characteristics

	Group C (n = 85)	Group I (n = 85)	p-value
Age (yr) mean \pm SD	49.0 \pm 16.3	52.0 \pm 16.5	0.20
Sex			
Male	37 (43.5%)	33 (38.8%)	0.53
Female	48 (56.5%)	52 (61.2%)	
Weight (kg) mean \pm SD	56.3 \pm 11.0	56.7 \pm 10.8	0.84
Height (cm) mean \pm SD	158.7 \pm 7.7	156.2 \pm 18.4	0.25
ASA			
I	62 (72.9%)	37 (43.5%)	<0.05
II	23 (27.1%)	43 (50.6%)	
III	0	5 (5.9%)	
Duration of endoscopy (min) mean \pm SD	7.4 \pm 3.1	8.5 \pm 4.7	0.06

Group C = topical pharyngeal anesthesia alone

Group I = intravenous sedation and topical pharyngeal anesthesia

Table 2. Ease of endoscopy, as assessed by the endoscopists

	Group C	Group I	p-value
Effortless	19 (22.4%)	53 (62.4%)	<0.05
Easy	58 (68.2%)	29 (34.1%)	
Fair	8 (9.4%)	3 (3.5%)	
Poor	0	0	

Group C = topical pharyngeal anesthesia alone

Group I = intravenous sedation and topical pharyngeal anesthesia

Table 3. Endoscopist satisfaction

	Group C	Group I	p-value
Very satisfied	34 (40.0%)	69 (81.2%)	<0.05
Satisfied	44 (51.8%)	12 (14.1%)	
Neutral	7 (8.2%)	4 (4.7%)	
Unsatisfied	0	0	

Group C = topical pharyngeal anesthesia alone

Group I = intravenous sedation and topical pharyngeal anesthesia

Table 4. Patient tolerance

	Group C	Group I	p-value
Did not feel the thing	18 (21.2%)	54 (63.6%)	<0.05
Well	50 (58.8%)	28 (32.9%)	
Fair	16 (18.8%)	3 (3.5%)	
Poor	1 (1.2%)	0	

Group C = topical pharyngeal anesthesia alone

Group I = intravenous sedation and topical pharyngeal anesthesia

± 2.5 and 8.8 ± 1.2 respectively, $p < 0.05$). The same results were obtained when patients were asked whether they would undergo the same endoscopic procedure, as they had this time, in future endoscopies (6.2 ± 1.6 and 9.4 ± 0.8 respectively, $p < 0.05$). Overall satisfaction in group I was significantly higher than group C. However, the combination of satisfaction and very satisfactory was not significantly different between the two groups as shown in Table 5. Changes in systolic and diastolic blood pressure and pulse during the endoscopic procedure were significantly reduced in group I compared with group C. Arterial oxygen saturation was not clearly different between the two groups. In all patients, oxygen saturation was maintained over 95% during the procedure. Overall complications were not different between the two groups. Hypertension and tachycardia were the most common complications in group C, while hypotension was the most complication in group I.

Discussion

Upper gastrointestinal endoscopy is a common and essential examination to detect early gastric cancer. However, endoscopy is generally avoided because of anxiety and severe discomfort. The technology of endoscopy has improved over the past 20 years and the methods of premedication have changed as well. Sedative premedication has been used to settle patient anxiety and can reduce the discomfort and unpleasantness during the insertion of the endoscope. Moreover, this premedication can reduce the fear of the test by inducing amnesia so that the patients can undergo the endoscopy in a comfortable state. The most frequently used sedative drugs are midazolam and propofol.

Table 5. Patient satisfaction

	Group C	Group I	p-value
Felt comfortable during the entire endoscopy*			
Group A**	5.1 ± 1.5	9.5 ± 0.6	<0.05
Group B**	6.8 ± 1.6	9.2 ± 0.8	<0.05
Present endoscopy was more comfortable than previous endoscopy without sedation*	6.1 ± 2.5	8.8 ± 1.2	<0.05
Will undergo future endoscopies like the present endoscopy*	6.2 ± 1.6	9.4 ± 0.8	<0.05
Overall satisfaction (%)			
Very satisfied	35.3	90.6	<0.05
Satisfied	56.5	9.4	
Neutral	7.0	0	
Unsatisfied	1.2	0	

Group C = topical pharyngeal anesthesia alone

Group I = intravenous sedation and topical pharyngeal anesthesia

* Score were based on a 10 mm. visual analog scale of 0-10, where 0 is unbearable and 10 is excellent

** Group A, patients who had undergone a previous endoscopy

Group B, patients who were undergoing an endoscopy for the first time

The standard use of sedation to facilitate the performance of esophagogastroduodenoscopy (EGD) was initially established with the use of rigid and semi-rigid endoscopes. This trend has continued despite the evolution of flexible endoscopy, such as now in the United States⁽⁵⁾.

Data from Canada⁽⁶⁾, Scandinavia^(3,7), Britain⁽⁸⁾, and Iraq⁽⁹⁾ confirm that in some subsets of the adult ambulatory population, it is possible to perform a comfortable and technically adequate unsedated diagnostic EGD. This is supported by a recently published retrospective study from the UK that demonstrates a 54% decline in the use of parenteral sedation for diagnostic EGD, over a 10-yr period from 1989 to 1998⁽¹⁰⁾.

The present study has some important strengths that distinguish it from the existing literature. All potential patients were approached during the specified time frame for inclusion in the present study. There were very few exclusion criteria. Independent observers were responsible for data collection and patients themselves rated their satisfaction as opposed to the use of a physician surrogate assessment^(9,11). The post procedure patient centered outcomes were assessed following recovery from sedation.

Several limitations are also noteworthy. The authors were unable to guarantee blinding of the endoscopist to randomization group in all cases, in that some endoscopists could perhaps predict which patient had been sedated by the patients' behavior. The present study was conducted at an academic tertiary

center. This may influence the possibility of generalizing of the present findings to nontertiary settings. In addition, cultural and societal influence is likely an important (though difficult to measure) modifier of a patient's satisfaction and willingness to undergo an unsedated endoscopy. Wayne recently noted the prevalent use of sedation in North America and South America (72%) compared to Europe (56%) and Asia (44%)⁽¹²⁾.

Yacavone R, et al studied 559 patients with prior endoscopic experience to identify and prioritize the elements inherent in the prediction of patient satisfaction, they found that the patients' perceived satisfaction with their comfort during the procedure was an important predictor of patient satisfaction. In the absence of an accepted biometric tool, the authors chose to use a constructed variable based on a 4-point scale with demonstrated face validity and sensitivity to change. However, the authors remain cognizant of the risk of possible ceiling and floor effects inherent in the presented scale, which may limit its discriminant ability⁽¹³⁾.

Consistent with previous clinical observations of Abraham NS et al⁽⁶⁾, age was an important predictor of successful endoscopy. The presence of pharyngeal sensitivity decreased the odds of a successful endoscopy (OR = 0.66; 95% CI 0.44-1.08), however, this observation was limited by a small number of patients with significant pharyngeal sensitivity (n = 98). The high technical adequacy rate (98%) showed no compromise by the absence of sedation⁽⁶⁾.

Unsedated upper gastrointestinal endoscopy avoids dangers and costs associated with the use of sedative drugs, requires less postprocedural nursing care, allows immediate post procedural conversation, and faster throughout the patients in endoscopy units^(2,10). Olithselvan et al⁽¹⁴⁾ confirmed that a large proportion of patients can have diagnostic upper gastrointestinal endoscopy without sedation and that men are more likely than women to accept unsedated endoscopy.

Clearly, it is advantageous to identify the factors that might encourage patients to undergo upper gastrointestinal endoscopy without sedation^(6,15). A patient's choice may be influenced by fear of experiencing gagging or pain during the procedure, fear of being sedated, need to remain unsedated to drive later, personal experiences of previous procedures, or the reports of other patients' experiences. Furthermore, expectations about sedation for endoscopic procedures vary in different countries. Given the equivalent technical adequacy in both arms, the true determinant of successful endoscopy appears to be a patient's satisfaction with their self-perceived level of comfort during the procedure.

Conclusion

The effectiveness of intravenous sedation and topical pharyngeal anesthesia is higher than topical pharyngeal anesthesia alone in patients who have undergone upper gastrointestinal endoscopy. For the primary outcome of successful endoscopy, it remains the most efficacious strategy by increasing clinical efficacy.

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ประสิทธิภาพของการให้ยาระงับประสาททางหลอดเลือดดำในผู้ป่วยที่มารับการส่องกล้องตรวจวินิจฉัยระบบทางเดินอาหารส่วนต้น

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บทนำ: การให้ยาระงับความรู้สึกบริเวณช่องปาก และลำคอจำเป็นต้องทำก่อนการส่องกล้องตรวจวินิจฉัยระบบทางเดินอาหารส่วนต้น แต่เนื่องจากการระงับความรู้สึกวิธีนี้ทำให้ผู้ป่วยไม่สะดวกสบาย ไม่พึงพอใจ และไม่ยอมใช้วิธีนี้ในการตรวจครั้งต่อไป การศึกษาประสิทธิภาพของการให้ยาระงับประสาททางหลอดเลือดดำร่วมกับยาชาเฉพาะที่เปรียบเทียบกับการให้ยาชาเฉพาะที่เพียงอย่างเดียวจึงไม่มีการศึกษาอย่างละเอียด

วัตถุประสงค์: เปรียบเทียบประสิทธิภาพของการให้ยาระงับประสาททางหลอดเลือดดำร่วมกับยาชาเฉพาะที่และการให้ยาชาเฉพาะที่เพียงอย่างเดียวในผู้ป่วยไทยที่มารับการส่องกล้องตรวจวินิจฉัยระบบทางเดินอาหารส่วนต้น

วัสดุและวิธีการ: แบ่งผู้ป่วยแบบสุ่มออกเป็น 2 กลุ่ม; กลุ่ม C (ยาชาเฉพาะที่) และกลุ่ม I (ยาระงับประสาทร่วมกับยาชาเฉพาะที่) ผู้ป่วยทุกคนจะได้รับการให้ยาชาบริเวณช่องปากและลำคอ แต่กลุ่ม I จะได้รับ midazolam 0.035 มก./กก. และ propofol หยดแบบต่อเนื่องทางหลอดเลือดดำร่วมด้วย ประเมินความง่ายของการส่องกล้อง และความสะดวกสบายของผู้ป่วย นอกจากนี้จะประเมินความพึงพอใจของผู้ป่วยและแพทย์ผู้ทำการส่องกล้อง บันทึกจำนวน propofol ทั้งหมด, ระยะเวลาที่ผู้ป่วยฟื้นจากการให้ยาระงับประสาท, ภาวะแทรกซ้อนและความสมัครใจในการเลือกวิธีการให้ยาระงับความรู้สึกครั้งต่อไป

ผลการศึกษา: ผู้ป่วยทั้งหมด 170 คน (กลุ่มละ 85 คน) อายุเฉลี่ย 50.5 ปี เป็นผู้ชาย 41.2% สามารถทำการส่องกล้องได้สำเร็จทุกคน ผู้ป่วยกลุ่ม I มีความสะดวกสบาย 100% เทียบกับกลุ่ม C 98.8% นอกจากนี้ผู้ป่วยกลุ่ม I, 9.4 ± 0.8 สมัครใจเลือกใช้วิธีการให้ยาระงับความรู้สึกแบบเดิมอีกเทียบกับ 6.2 ± 1.6 ในกลุ่ม C ความพึงพอใจมากของผู้ป่วยและแพทย์ผู้ทำการส่องกล้องกลุ่ม I มากกว่ากลุ่ม C อย่างมีนัยสำคัญทางสถิติ (90.6% vs 35.3 % และ 81.2% vs 40.0 %) ปริมาณ propofol ทั้งหมดที่ใช้ 91.6 ± 45.5 มก. และเวลาที่ผู้ป่วยฟื้นจากการให้ยาระงับประสาทในกลุ่ม I เฉลี่ย 8.2 ± 4.2 นาที ความดันเลือดสูง และชีพจรเต้นเร็วเป็นภาวะแทรกซ้อนที่พบบ่อยที่สุดในกลุ่ม C แต่พบความดันเลือดต่ำในกลุ่ม I มากที่สุด

สรุป: การให้ยาระงับประสาทร่วมกับการใช้ยาชาเฉพาะที่ในผู้ป่วยไทยที่มารับการส่องกล้องตรวจวินิจฉัยความผิดปกติของระบบทางเดินอาหารส่วนต้น มีประสิทธิภาพดีเพิ่มความพึงพอใจของผู้ป่วยและแพทย์ผู้ส่องกล้อง นอกจากนี้ยังเพิ่มความสมัครใจให้ผู้ป่วยเลือกใช้วิธีการให้ยาระงับความรู้สึกแบบเดิมนี้อีกในครั้งต่อไป
