The Safety of Propofol Infusion Compared to Midazolam and Meperidine Intravenous Bolus for Patients Undergoing Double Balloon Enteroscopy

Sombat Treeprasertsuk MD, PhD*, Rungsun Rerknimitr MD*,
Phonthep Angsuwatcharakon MD, MSc**, Wiriyaporn Ridtitid MD, MSc*, Kessarin Thanapirom MD*,
Pradermchai Kongkam MD, MSc*, Yuwadee Ponuthai RN**, Vichai Viriyautsahakul MD, MSc***

** Division of Gastroenterology, Faculty of Medicine, Chulalongkortn University, Bangkok, Thailand*
*** Department of Anatomy, Faculty of Medicine, Chulalongkortn University, Bangkok, Thailand*
**** Department of Medicine, King Chulalongkorn Memorial Hospital, Thai Red Cross Society, Bangkok, Thailand*

Objective: *The double balloon enteroscopy (DBE) procedure is long and requires moderate sedation. We aim to determine whether the administration of propofol infusion is safe by comparing it to intravenous midazolam/meperidine in patients undergoing DBE.*

Material and Method: *A prospective study with 48 patients was conducted at King Chulalongkorn Hospital randomizing (block of four) patients into two groups. In group 1, 28 patients were enrolled for intravenous midazolam/meperidine, and one patient was dropped out before underwent DBE due to hemodynamic instability. Therefore, 27 (n = 27) participants were included in Group 1. In group 2, 28 patients were enrolled for propofol infusion, and seven patients were dropped out before underwent DBE, five due to hemodynamic instability (n = 5), and two refused treatment (n = 2). Therefore, 21 (n = 21) participants were included in Group 2. Vital signs and oxygen saturation were regularly monitored.*

Results: *Mean ± SD age of patients was 56.8±9.2 years, and 41.7% of patients were male. There was no difference in demographic data between the groups. For the safety profile, 25.9% of the midazolam/meperidine group and 33.3% of the propofol group developed hypotension and/or desaturation (p = 0.45). The patients' satisfaction of group 1 and group 2 were 86.7±6.5% and 86.3±8.1%, respectively, and presented no significant difference (p = 0.89).*

Conclusion: *Propofol infusion is safe and shows no difference in outcome from the midazolam and meperidine sedation for the DBE procedure.*

Keywords: *Safety, Sedation, Propofol infusion, Double balloon enteroscopy (DBE), midazolam, meperidine*

J Med Assoc Thai 2014; 97 (5): 483-9
Full text. e-Journal: *http://www.jmatonline.com*

Conscious sedation is routinely used by trained gastroenterologists, especially for standard gastrointestinal (GI) endoscopy in the outpatient setting. Normally, endoscopy requires adequate short and safe sedation. Propofol (2, 6-diisopropyl phenol) is an intravenous (IV) sedative medication used for the induction and maintenance of conscious sedation. The pharmacokinetic profile of propofol makes it suitable for conscious sedation during GI endoscopy[1]. Its major advantage is rapid onset of action, with the onset of sedation occurring only 30 to 60 seconds after injection[2]. The plasma half-life ranges from 1.3 to 4.1 minutes[3]. The rapid hepatic clearance after an IV bolus dose[4] and the rapid offset of sedation with quick recovery times are an outstanding advantage[5]. High-risk patients, including patients with cardiac dysfunction or elderly patients with comorbidities classified by the American Society of Anesthesiologists (ASA) as grade 3-4, also showed good sedation results with propofol[6]. These high-risk patients require particularly careful monitoring and a dose reduction average of 10 to 20% less than minimal risk patients[6]. The most common side effects are vital signs instability including hypoxia, hypotension, and cardiac arrhythmia, while severe respiratory depression requiring intervention is found in less than 0.3% of patients[6,7]. Moderate sedation is the accepted level of sedation for diagnostic, uncomplicated therapeutic upper endoscopy and long duration GI procedures[8]. Propofol has been proven to have similar efficacy as other sedative agents when used for esophagogastroduodenoscopy (EGD), colonoscopy, endoscopic retrograde cholangiopancreatography

Correspondence to:
Treeprasertsuk S, Division of Gastroenterology, Department of Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok 10330, Thailand.
Phone: 0-2256-4265, Fax: 0-2252-7839
E-mail: battan5410@yahoo.com

(ERCP), and endoscopic ultrasonography (EUS). However, it has not been studied in patients undergoing double balloon endoscopy (DBE). DBE is a new method of enteroscopy developed by using a balloon assistant system to improve access to the small intestine[9]. DBE is accepted as an important tool for patients with suspected small bowel GI bleeding or obscured GI bleeding[9,10]. Because there are no data on the safety and outcome of propofol infusion compared to midazolam/meperidine intravenous bolus for these groups of patients, we conducted a prospective study to determine whether the administration of propofol infusion to be as safe and effective as midazolam/meperidine for patients undergoing DBE procedure.

Material and Method

A prospective randomized study was undertaken to evaluate the efficacy and safety of sedation by comparing the use of propofol infusion to conventional sedation (midazolam/meperidine). All eligible patients undergoing DBE were recruited. Exclusion criteria were an age of less than 20 years, a previous history of propofol or other sedative medication allergy, a soy bean allergy, pregnancy, an ASA physical status greater than 3, and vital sign instability within 12 hours prior to the DBE procedure. Associated medical illnesses were recorded and graded according to patient ASA status[11]. Forty-eight consecutive DBE patients were enrolled between July 1, 2006 and December 31, 2007, at the Division of Gastroenterology, King Chulalongkorn Memorial Hospital. During the enrollment period, all eligible patients were randomized (block of four) into two groups. Group 1 included 28 patients recruited to underwent sedation by using IV midazolam/meperidine, one patient was dropped out before underwent DBE due to hemodynamic instability (n = 27). Group 2, 28 patients were enrolled for propofol IV infusion, seven patients were dropped out before underwent DBE, five due to hemodynamic instability and two refused treatment (n = 21). For group 1, the initial dose of sedation started with 25 mg of meperidine (Abbott Laboratories, North Chicago, IL) plus 2.5 mg of midazolam (Ben Venue Laboratories, Bedford, OH) by IV bolus. Sedation was subsequently maintained by intermittent IV bolus doses of meperidine (12.5-50 mg/each dose) or midazolam (0.5-2.5 mg/each dose). For group 2, 1% propofol emulsion (Baxter Healthcare Corp., Irvine, CA) was started with the initial dose of 0.5 mg/kg IV bolus, and then continuously dripped at a rate of 0.25-1 mg/kg/hr, titrating for a moderate level of sedation. An automated infusion pump (Terufusion syringe pump TE-331, Terumo Cooperation, Tokyo, Japan) was used for propofol infusion. All sedative agents were administered by registered endoscopy nurses (RN) and were supervised by GI endoscopists.

Monitoring, safety and outcome measurement

The aim of moderate sedation is to maintain a patient's sedation level during the GI endoscopy procedure where a patient can respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation[5]. For safety purposes, vital signs and oxygen saturation were monitored during the examination[12,13]. If the systolic blood pressure (SBP) fell below 90 mmHg or ≥20% reduction from baseline, an intravenous isotonic fluid hydration was administered and adjusted until vital signs became stable. Heart rate and oxygen saturation were regularly monitored. If oxygen saturation fell below 90% or desaturation occurred, an oxygen supplement by nasal cannula with a flow rate of 2 to 5 L/min was promptly administered. GI endoscopic rooms were well equipped with a bag-valve ventilation mask, an endotracheal tube, and materials and drugs for cardiopulmonary resuscitation. All medical demographic data were recorded on specific DBE case record forms including patient's age, sex, body weight, height, route of endoscopic insertion, indication for DBE, type of therapeutic DBE procedures, total dose of each sedative drug and recovery time.

For outcome measurements, the diagnostic yields and the duration of DBE procedure were also recorded. Patients' satisfaction level was recorded using a score range (0 = poor to 100 = excellent). The assessment of safety was recorded as follows: whether oxygen saturation fell below 90%, whether blood pressure was lower than 90 mmHg, and the occurrence of serious adverse events, including cardiac arrhythmia requiring medical therapy and severe respiratory depression requiring intervention. Written informed consent was obtained from all enrolled patients.

Statistical analysis

To obtain reasonable estimation for the primary end-point of patients' safety, we used the difference of the percentage of desaturation as our primary parameter. The desaturation rate in the midazolam/meperidine group and the propofol group were 3% and 19%, respectively[4]. For a two-sided test

of two proportions with a baseline proportion of 0.03 and a difference of proportion to detect of 15%, the sample size was calculated based on an alpha of 0.05 and 80% power in at least 20 patients per group.

Continuous data were expressed as the mean ± standard deviation (SD) or medians, and interquartile range (IQR) as appropriate. Categorical data were expressed as the number of subjects (and percentage) with a specified condition or clinical variable. Comparisons between the two treatment groups were performed using the independent t-test if data were normally distributed or the Wilcoxon rank-sum test if the data were non-normally distributed. Categorical data were presented as numbers (percentage) and compared using Fisher's exact test or the Chi-square test where appropriate. All tests were two-sided, with $p<0.05$ as the chosen level of significance.

Results

Forty-eight patients underwent the DBE procedure with a male to female ratio of 0.7/1. The mean ± SD age was 56.8±19.3 years (range 20-91 years). The mean sedative doses of midazolam/meperidine were 6.3±2.5 and 57.4±27.6 mg, respectively, and the mean dose of propofol was 348.8±209.3 mg. There was no significant difference between the groups regarding demographic data (Table 1). The overall proportion of elderly patients aged ≥70 years was 33.3%. Two-thirds of patients from the groups were classified at ASA status grade 3 due to comorbidity conditions including coronary heart disease, anemia, GI bleeding and/or elderly patients. For laboratory tests, the mean hematocrit of all patients was 29.2±7.9%.

Efficacy, safety, and adverse events

There was no statistical significant difference in the efficacy and safety of the patients received midazolam/meperidine compared to those received propofol group as demonstrated in Table 2. In addition, there was no difference in the major indication, route, or duration of the DBE procedure (oral/anal) between the two groups. During the procedure, 25.9% of patients in the midazolam/meperidine group and 33.3% of patients in the propofol group developed hypotension and/or desaturation with no statistically significant difference ($p = 0.45$). Transient desaturation and hypotension events were normalized within few minutes of oxygen supplementation and tactile stimulation with verbal commands. No assisted ventilation was required. After procedures, all patients' general conditions were fully recovered. Patient's satisfaction was high, at 86.4±7.3% in both groups. There were no serious adverse events such as cardiac arrhythmia or severe respiratory depression requiring intervention in the present study.

The comparison of patients with an ASA status grade 1-2 (n = 14) to an ASA status grade 3-4 (n = 34), demographic data in terms of the proportion of male gender, baseline SBP, body mass index (BMI), and the number of patients having transient desaturation and/or hypotension showed no statistically significant differences between the two groups. However, a higher mean age and a lower mean hemoglobin (Hb) level were found in patients with ASA status grade 3-4 compared to patients with ASA status grade 1-2 [Age; 64.2±16.9 years vs. 38.9±11.3 years ($p<0.01$) and Hb level; 8.9±2.6 g/dl vs. 11.7±2.4 g/dl ($p = 0.03$)]. Regarding the route of the DBE procedure, the demographic data showed no statistically significant

Table 1. Demographic and clinical data of 48 patients with DBE procedures

Variables	Total (n = 48)	Group 1 midazolam/ meperidine (n = 27)	Group 2 propofol (n = 21)	*p*-value
Age (years), mean ± SD	56.8±19.2	60.3±17.6	52.4±20.9	0.16
Male (%)	20 (41.7%)	11 (40.7%)	9 (42.8%)	0.88
Age ≥70 years (%)	16 (33.3%)	10 (37.0%)	6 (28.6%)	0.54
ASA grade 3-4 (%)	34 (70.8%)	19 (70.4%)	15 (71.4%)	0.94
Baseline SBP (mmHg), mean ± SD	135.9±28.4	136.1±28.1	135.9±29.4	0.99
Body weight (kg), mean ± SD	58.5±16.4	56.5±17.6	60.2±15.9	0.64
BMI (kg/m^2), mean ± SD	20.7±3.6	19.4±3.3	21.1±3.9	0.59
Hematocrit (%), mean ± SD	29.2±7.9	28.5±7.7	30.3±8.6	0.57

ASA = the American Society of Anesthesiologist; BMI = body mass index; DBE = double balloon enteroscopy; SBP = systemic blood pressure

Table 2. Efficacy and Safety of propofol compared to midazolam and meperidine intraoperative and post operative data for DBE procedure

Intraoperative and postoperative data	Total (n = 48)	Group 1 midazolam/ meperidine (n = 27)	Group 2 propofol (n = 21)	*p*-value
Indication; OGIB or anemia	30 (62.5%)	17 (62.9%)	13 (61.9%)	0.94
Route of DBE; oral	23 (47.9%)	12 (44.4%)	11 (52.4%)	0.58
Positive small bowel lesion (%)	29 (60.4%)	14 (51.8%)	15 (71.4%)	0.17
DBE procedural time (min), mean ± SD	56.0±20.6	53.8±18.9	59.6±23.1	0.38
Length of insertion (cm), mean ± SD	322.1±156.4	333.2±129.3	305.9±192.7	0.58
Therapeutic DBE (%)	13 (27.1%)	6 (22.2%)	7 (33.3%)	0.39
O_2 saturation <90% (%)	9 (18.7%)	4 (14.8%)	5 (23.8%)	0.88
SBP <90 mmHg (%)	5 (10.4%)	3 (11.1%)	2 (9.5%)	0.39
Recovery time (minute), mean ± SD	4.5±5.1	7.0±9.5	3.4±1.9	0.58
Patient satisfaction (%), mean ± SD	86.4±7.3	86.7±6.5	86.3±8.1	0.89

DBE = double balloon enteroscopy; OGIB = obscure GI bleeding; SBP = systemic blood pressure

difference between the oral route (n = 23) and the anal route (n = 25). The mean duration of the DBE procedure by the oral route (53.0±17.6 min) showed no difference from the anal route (59.3±23.4 min) (p = 0.32). Comparing the therapeutic DBE (n = 13) to the diagnostic DBE procedure (n = 35), the mean duration of therapeutic DBE (72.7±26.1 min) was significantly longer than that of diagnostic DBE (49.4±13.3 min) (p = 0.01).

Discussion

DBE procedure is a new GI endoscopy procedure to visualize of the entire small bowel. The entire procedure usually requires a mean time of two hours for both the oral and anal route[14,15]. According to the Consensus Report of the Second International Conference on DBE, there is a wide range of sedative options[10]. However, there have been no studies showing difference in the outcome of different sedative medications. Since then, DBE has presented more evidence of improvements in diagnostic yield of patients with small intestinal diseases[16]. Therefore, several efforts to promote the success of the DBE procedure were implemented, including developments in equipment and sedative techniques[10]. Recently, propofol has emerged for outpatient use in many standard GI procedures including EGD and colonoscopy[17-20]. The major advantages of propofol sedation are the convenience of drug administration and required less health personnel per procedure. Kulling and colleagues reported that the safe administration of propofol sedation in a practice setting of EGD or colonoscopy required only one GI endoscopist and one endoscopy nurse and no additional staff needed[18].

The present study was the first to confirm the safety profile of propofol infusion in the DBE procedure. We found that patients receiving propofol infusion for sedation experienced no difference in the rate of complication, including hypotension and desaturation, from the standard sedation with midazolam and meperidine. However, the side effects of both sedative medications for the DBE procedure seemed to be higher than those reported in other GI procedures including EGD, colonoscopy, and ERCP, as shown in Table 3[4,18,21,22]. The higher incidence of complications in patients undergoing the DBE procedure may be explained by the longer duration of the procedure and the higher accumulation of the dosage of sedative drugs. In addition, most patients were in the high-risk category, with history of recent GI bleeding or anemia or elderly patients. These co-morbidities may be important factors contributing to the occurrence of desaturation and hypotension. None of our patients developed serious complications. Interestingly, most patients had high satisfaction at the final evaluation.

The strength of the present study is that it is the first prospective study with randomization to evaluate the safety and efficacy of propofol infusion for the DBE procedure compared to standard sedation. We used an automated infusion pump technique for propofol administration, which is more accurate for dose adjustment and may play an essential role in the

Table 3. Different GI endoscopic procedures and propofol doses used

Author, year, procedure, (number of patients)	Dose of propofol, mg (mean ± SD)	Duration of procedure, min (mean ± SD)	SaO_2 <90% (%)	SBP <90 mmHg (%)
Kulling D, 2007[18]				
EGD (n = 14,856)	61 (50-650)	No data	2.3	No data
Colonoscopy (n = 12,205)	116 (30-500)			
Koshy G, 2000[4]				
EGD (n = 78)	40 (20-120)	12.0±9.9	7.3	24
Colonoscopy (n = 72)		25.2±12.4		
Ong WC, 2007[22]				
ERCP (n = 104)	192.4±87.9	17.1±10.2	4.8	0
Agostoni M, 2007[21]				
EUS (n = 54): combined of propofol and fentanyl	119.7 mg and 106 micro-gm	23.0±11.0	0	0

EGD = esophagogastroduodenoscopy; EUS = endoscopic ultrasonography; ERCP = endoscopic retrograde cholangiopancreatography; SaO_2 = saturation of oxygenation, SBP = systemic blood pressure

constant level of moderate sedation[23]. Our study did have certain limitations; first, the duration of the therapeutic DBE procedure, which was longer than the diagnostic DBE, was not controlled. However, it was not the primary objective of our study. Second, the wide range of patients' age was also of concern. On this basis, the safety of the DBE procedure using propofol could not be implemented in all GI endoscopic units. Currently, the topic of non-anesthesiologist administration of propofol (NAAP), related to gastrointestinal endoscopy has been published more frequently. The results of NAAP-studies showed that NAAP is safe, convenient to use to attain moderate sedation with higher patients' satisfaction[24,25]. Recently, the European Society of Gastrointestinal Endoscopy (ESGE), the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) and the European Society of Anesthesiology (ESA) have endorsed the guideline of non-anesthesiologist administration of propofol for GI endoscopy[25]. This guideline does not mention the patients selection for propofol use. However, it points out the advantage of propofol-based sedation that includes the higher post-procedure patient satisfaction for most endoscopic procedures, the reduced time to sedation, and reduced recovery time with the similar rate of complications comparing to the traditional sedation[25]. Propofol-based sedation may increase the quality of endoscopic examination, however, there are no cost-effectiveness data directly comparing the NAAP with the traditional sedation[25]. Interestingly, there was a study focusing on cirrhotic patients underwent gastroscopy or colonoscopy with moderate sedation, that the liver condition may impair the metabolism of sedative drugs, which may cause hepatic encephalopathy[26]. It showed that propofol based regimen had shorter sedation times and recovery times than midazolam-based regimens with similar complication rate[19,26].

Conclusion

Propofol infusion is safe and demonstrates no difference in outcome from the standard sedation with midazolam and meperidine for the DBE procedure. The propofol infusion technique may be considered as an alternative technique to be used with caution for a long-duration GI endoscopic procedure like DBE.

Acknowledgments

The present study was supported by the 2007-2008 Research Grant of Division of Gastroenterology, Faculty of Medicine, Chulalongkorn University, Thailand.

Potential conflicts of interest

None.

References

1. Gepts E, Claeys MA, Camu F, Smekens L. Infusion of propofol ('Diprivan') as sedative technique for colonoscopies. Postgrad Med J 1985; 61 (Suppl 3): 120-6.
2. Faigel DO, Baron TH, Goldstein JL, Hirota WK, Jacobson BC, Johanson JF, Leighton JA, et al. Guidelines for the use of deep sedation and anesthesia for GI endoscopy. Gastrointest

Endosc 2002; 56: 613-7.
3. Vargo JJ. Propofol: a gastroenterologist's perspective. Gastrointest Endosc Clin N Am 2004; 14: 313-23.
4. Koshy G, Nair S, Norkus EP, Hertan HI, Pitchumoni CS. Propofol versus midazolam and meperidine for conscious sedation in GI endoscopy. Am J Gastroenterol 2000; 95: 1476-9.
5. Rex DK. Review article: moderate sedation for endoscopy: sedation regimens for non-anaesthesiologists. Aliment Pharmacol Ther 2006; 24: 163-71.
6. Heuss LT, Schnieper P, Drewe J, Pflimlin E, Beglinger C. Safety of propofol for conscious sedation during endoscopic procedures in high-risk patients-a prospective, controlled study. Am J Gastroenterol 2003; 98: 1751-7.
7. Qadeer MA, Vargo JJ, Khandwala F, Lopez R, Zuccaro G. Propofol versus traditional sedative agents for gastrointestinal endoscopy: a meta-analysis. Clin Gastroenterol Hepatol 2005; 3: 1049-56.
8. Rex DK. The science and politics of propofol. Am J Gastroenterol 2004; 99: 2080-3.
9. Yamamoto H, Sekine Y, Sato Y, Higashizawa T, Miyata T, Iino S, et al. Total enteroscopy with a nonsurgical steerable double-balloon method. Gastrointest Endosc 2001; 53: 216-20.
10. Pohl J, Blancas JM, Cave D, Choi KY, Delvaux M, Ell C, et al. Consensus report of the 2nd International Conference on double balloon endoscopy. Endoscopy 2008; 40: 156-60.
11. Keats AS. The ASA classification of physical status--a recapitulation. Anesthesiology 1978; 49: 233-6.
12. Heuss LT, Froehlich F, Beglinger C. Changing patterns of sedation and monitoring practice during endoscopy: results of a nationwide survey in Switzerland. Endoscopy 2005; 37: 161-6.
13. Radaelli F, Terruzzi V, Minoli G. Extended/advanced monitoring techniques in gastrointestinal endoscopy. Gastrointest Endosc Clin N Am 2004; 14: 335-52.
14. Haruta H, Yamamoto H, Mizuta K, Kita Y, Uno T, Egami S, et al. A case of successful enteroscopic balloon dilation for late anastomotic stricture of choledochojejunostomy after living donor liver transplantation. Liver Transpl 2005; 11: 1608-10.
15. Hayashi Y, Yamamoto H, Kita H, Sunada K, Sato H, Yano T, et al. Non-steroidal anti-inflammatory drug-induced small bowel injuries identified by double-balloon endoscopy. World J Gastroenterol 2005; 11: 4861-4.
16. Fukumoto A, Tanaka S, Yamamoto H, Yao T, Matsui T, Iida M, et al. Diagnosis and treatment of small-bowel stricture by double balloon endoscopy. Gastrointest Endosc 2007; 66 (3 Suppl): S108-12.
17. Byrne MF, Chiba N, Singh H, Sadowski DC. Propofol use for sedation during endoscopy in adults: a Canadian Association of Gastroenterology position statement. Can J Gastroenterol 2008; 22: 457-9.
18. Kulling D, Orlandi M, Inauen W. Propofol sedation during endoscopic procedures: how much staff and monitoring are necessary? Gastrointest Endosc 2007; 66: 443-9.
19. McQuaid KR, Laine L. A systematic review and meta-analysis of randomized, controlled trials of moderate sedation for routine endoscopic procedures. Gastrointest Endosc 2008; 67: 910-23.
20. Zippi M, Traversa G, De Felici I, Febbraro I, Mattei E, Pietranico B, et al. Sedation with propofol in endoscopic retrograde cholangiopancreatography: personal experience. Clin Ter 2008; 159: 19-22.
21. Agostoni M, Fanti L, Arcidiacono PG, Gemma M, Strini G, Torri G, et al. Midazolam and pethidine versus propofol and fentanyl patient controlled sedation/analgesia for upper gastrointestinal tract ultrasound endoscopy: a prospective randomized controlled trial. Dig Liver Dis 2007; 39: 1024-9.
22. Ong WC, Santosh D, Lakhtakia S, Reddy DN. A randomized controlled trial on use of propofol alone versus propofol with midazolam, ketamine, and pentazocine "sedato-analgesic cocktail" for sedation during ERCP. Endoscopy 2007; 39: 807-12.
23. Kongkam P, Rerknimitr R, Punyathavorn S, Sitthi-Amorn C, Ponauthai Y, Prempracha N, et al. Propofol infusion versus intermittent meperidine and midazolam injection for conscious sedation in ERCP. J Gastrointestin Liver Dis 2008; 17: 291-7.
24. Fanti L, Gemma M, Agostoni M, Testoni PA. A much sought-after drug--propofol sedation for GI endoscopy: always better but who cares? Dig Dis Sci 2012;57:1980-2.
25. Dumonceau JM, Riphaus A, Aparicio JR, Beilenhoff U, Knape JT, Ortmann M, et al. European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy Nurses and Associates, and the European Society of Anaesthesiology Guideline:

Non-anesthesiologist administration of propofol for GI endoscopy. Endoscopy 2010; 42: 960-74.
26. Correia LM, Bonilha DQ, Gomes GF, Brito JR, Nakao FS, Lenz L, et al. Sedation during upper GI endoscopy in cirrhotic outpatients: a randomized, controlled trial comparing propofol and fentanyl with midazolam and fentanyl. Gastrointest Endosc 2011;73:45-51, 51.e1.

การศึกษาเปรียบเทียบความปลอดภัยของการใช้ยาทำให้สงบกลุ่มโพรโพฟอลกับยามาตรฐานกลุ่มมิดาโซแลมและเมพเพอร์ริดีนในผู้ป่วยที่รับการตรวจส่องกล้องลำไส้เล็ก

สมบัติ ตรีประเสริฐสุข, รังสรรค์ ฤกษ์นิมิตร, พรเทพ อังศุวัชรากรณ์, วิริยาพร ฤทธิทิศ, เกศรินทร์ ถานะภิรมย์, ประเดิมชัย คงคำ, ยุวดี พลอุทัย, วิชัย วิริยะอุตสาหกุล

ภูมิหลัง: *การตรวจส่องกล้องลำไส้เล็กแบบใหม่ที่ใช้หลักการของบอลลูนสองตัวในการยึดผนังลำไส้เป็นหัตถการที่ใช้เวลานานและต้องทำให้ผู้ป่วยสงบในระดับปานกลาง และยาทำให้สงบกลุ่มโพรโพฟอลเริ่มเป็นที่นิยมใช้มากขึ้นเพราะมีประสิทธิภาพในการทำให้ผู้ป่วยสงบและฟื้นได้เร็วเมื่อเทียบกับยามาตรฐานกลุ่มมิดาโซแลมและเมพเพอร์ริดีน*

วัตถุประสงค์: *เพื่อศึกษาถึงความปลอดภัยและผลลัพธ์ของการใช้ยาทำให้สงบกลุ่มโพรโพฟอลกับยามาตรฐานกลุ่มมิดาโซแลมและเมพเพอร์ริดีนในผู้ป่วยที่รับการตรวจส่องกล้องลำไส้เล็กแบบใหม่ที่ใช้หลักการของบอลลูนสองตัว*

วัสดุและวิธีการ: *ศึกษาเปรียบเทียบผู้ป่วยที่จำเป็นต้องได้รับการตรวจส่องกล้องลำไส้เล็กแบบใหม่ที่ใช้หลักการของบอลลูนสองตัวที่เข้าร่วมการศึกษานี้จำนวน 48 ราย ตั้งแต่เดือนกรกฎาคม พ.ศ. 2549 ถึง เดือนธันวาคม พ.ศ. 2550 ที่โรงพยาบาลจุฬาลงกรณ์ โดยแบ่งผู้ป่วยเป็น 2 กลุ่ม โดยวิธีการสุ่ม ๆ กลุ่มละ 28 ราย โดยจัดแบบบล็อกละ 4 ราย กลุ่มแรกได้เข้าร่วมการศึกษาจริงจำนวน 27 ราย ที่ได้รับยามาตรฐานกลุ่มมิดาโซแลมและเมพเพอร์ริดีน โดยมี 1 ราย หลังถูกจัดกลุ่มแต่ไม่ได้รับการตรวจส่องกล้องลำไส้เล็กแบบใหม่ที่ใช้หลักการของบอลลูนสองตัวเพราะมีสัญญาณชีพไม่คงตัว และกลุ่มที่สอง 21 ราย ที่ได้รับยากลุ่มโพรโพฟอล โดยมี 7 ราย หลังถูกจัดกลุ่มแต่ไม่ได้รับการตรวจส่องกล้องลำไส้เล็กแบบใหม่ที่ใช้หลักการของบอลลูนสองตัวเพราะมีสัญญาณชีพไม่คงตัว 5 ราย และปฏิเสธการรักษา 2 ราย ผู้ป่วยที่เข้าร่วมการศึกษาจะได้รับการเฝ้าติดตามสัญญาณชีพและวัดระดับออกซิเจนที่ปลายนิ้วอย่างสม่ำเสมอ*

ผลการศึกษา: *ค่าเฉลี่ยและส่วนเบี่ยงเบนมาตรฐานของอายุผู้ป่วยคือ 56.8±19.2 ปี และร้อยละ 41.7 ของผู้ป่วยเป็นเพศชาย พบว่าข้อมูลพื้นฐานของทั้งสองกลุ่มไม่มีความแตกต่างกัน ส่วนในด้านความปลอดภัยและผลลัพธ์ของการใช้ยาสลบพบว่า ร้อยละ 25.9 ของกลุ่มที่ได้ยามาตรฐานกลุ่มมิดาโซแลมและเมพเพอร์ริดีน และร้อยละ 33.3 ของกลุ่มที่ได้ยากลุ่มโพรโพฟอลมีระดับความดันต่ำหรือมีระดับออกซิเจนในเลือดต่ำลง แต่ไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ ในด้านความพึงพอใจของผู้ป่วยที่ได้รับยาทำให้สงบพบว่า ร้อยละ 86.7±6.5 ของผู้ป่วยกลุ่มที่หนึ่ง และร้อยละ 86.3±8.1 ของผู้ป่วยกลุ่มที่สองมีความพอใจโดยไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ (p = 0.89)*

สรุป: *การให้ยาทำให้สงบทั้งสองกลุ่มคือกลุ่มโพรโพฟอลกับยามาตรฐานกลุ่มมิดาโซแลมและเมพเพอร์ริดีนในผู้ป่วยที่รับการตรวจส่องกล้องลำไส้เล็กแบบใหม่ที่ใช้หลักการของบอลลูนสองตัวมีความปลอดภัยและมีผลลัพธ์ของการใช้ยาทำให้สงบไม่แตกต่างกัน*