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Original article

Factors Associated with Complications in Sedation Administered by Non-Anesthesiologist Physicians During Outpatient Endoscopic Procedures

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Abstract

Objective: To identify clinical and sociodemographic factors associated with complications related to superficial sedation administered by non-anesthesiologist physicians during outpatient endoscopic procedures. **Materials and methods:** An analytical cross-sectional study was conducted, including 680 patients undergoing endoscopic procedures over a 32-day period. Clinical and demographic variables, type of procedure, sedative agents, need for additional dosing, and major and minor complications were evaluated. **Results:** The majority of patients were female (64%), with a mean age of 49.6 years. Esophagogastroduodenoscopy (EGD) was the most common procedure (62.6%). Most patients were classified as ASA I (58.2%), with hypertension and hypothyroidism being the most frequent chronic conditions. The average doses administered were 5.3 mg of midazolam and 83.9 µg of fentanyl; 36.3% of patients required additional doses. Minor complications occurred in 13% of patients, primarily hypotension and oxygen desaturation. No major complications were reported. In the bivariate analysis, minor complications were significantly associated with obesity (PR = 2.76; 95% CI: 1.333–5.739; p = 0.013), undergoing combined EGD and colonoscopy in a single session (PR = 1.53; 95% CI: 1.04–2.24; p = 0.028), colonoscopy alone (PR = 1.65; 95% CI: 1.05–2.58; p = 0.031), and fentanyl doses greater than 75 µg (PR = 2.13; 95% CI: 1.40–3.23; p < 0.001). **Conclusions:** A thorough medical history should be obtained prior to any procedure to identify relevant comorbidities. Sedative agents, particularly fentanyl, must be used with caution and appropriate dosing. Procedures of longer duration should be carefully planned to minimize the risk of complications.

Keywords

Conscious sedation, endoscopy, postoperative complications, endoscopic surgical procedures.

INTRODUCTION

Conscious sedation is characterized by a controlled reduction in alertness and pain perception while maintaining stable vital signs, airway protection, and spontaneous ventilation[(1)]. In Colombia, the Colombian Society of Anesthesiology and Resuscitation (SCARE) has issued recommendations for sedation and analgesia administered by non-anesthesiologist physicians, stating that outpatient endoscopic procedures under Grade I (anxiolysis) and Grade II (conscious sedation) sedation can be performed with a good safety profile[(2)]. This practice is permitted as long as patients are classified as ASA I or II and the personnel involved have the necessary academic training to carry out the procedure. The safety of this technique depends on careful patient selection, adequate staff training, and the implementation of appropriate safety policies and guidelines for the outpatient setting[(3,4)]. Although conscious sedation can be an effective, practical, and safe technique in outpatient care, it is important to consider the associated risks.

This study aims to identify potential complications related to conscious sedation and determine the factors

associated with their occurrence. The assessment seeks to guide the adoption of safe practices that help reduce the incidence of complications and adverse events related to sedation during endoscopic procedures.

MATERIALS AND METHODS

An analytical cross-sectional study was conducted on the clinical and sociodemographic factors associated with complications in sedation practices administered by non-anesthesiologist physicians in patients undergoing endoscopic procedures. The study was carried out at a specialized gastroenterology institute in Medellín from November 22 to December 23, 2023. Patients aged 13 to 75 scheduled primarily for upper and lower gastrointestinal endoscopy, classified as ASA I or II, and who provided informed consent for the procedure were included. These examinations were performed by a team of 11 gastroenterologists and 5 sedation physicians. Patients with predictors of difficult airways or those who did not receive sedative medications for the procedure were excluded. The variables analyzed included the patient's medical and demographic history, type of endoscopic procedure, sedative agents used, administered sedative doses, need for additional doses, and minor and major complications.

The following clinical conditions were considered minor complications: hypotension (a 30% decrease from baseline blood pressure), arrhythmias (heart rate >100 beats per minute [bpm] or a 20% drop from baseline heart rate), hypertension (systolic or diastolic blood pressure >180/110 mmHg), and desaturation (SpO_2 <90% for more than 15 seconds). Major complications were defined as those requiring orotracheal intubation, cardiopulmonary arrest, or death. The study was approved by the Institutional Ethics Committee and deemed risk-free since it did not involve any intentional intervention or modification of the biological, physiological, psychological, or social variables of the participants. The study also adheres to the fundamental principles of research ethics in accordance with the 2013 version of the Declaration of Helsinki[5] and Resolution 008430 of 1993 issued by the Colombian Ministry of Health[6].

Statistical Analysis

A database was created using clinical records in Excel 2013. Statistical analysis was performed using OpenEPI web and Jamovi version 2.2. Absolute and relative frequencies were calculated for qualitative variables, while measures of central tendency and dispersion were used for quantitative variables. Bivariate analysis was conducted using the chi-square test for dichotomous qualitative variables, with a *p*-value <0.05 considered statistically significant. The strength of the association was assessed using prevalence ratios.

RESULTS

Data were collected from 680 patients who underwent 924 endoscopic procedures. The results revealed a sex distribution of 64% female patients, with a mean age of 49.6 years.

Regarding procedures, esophagogastroduodenoscopy (EGD) was the most commonly performed, accounting for 62.6% of all procedures. ASA classification showed that 58.2% of patients were categorized as ASA I, while the remaining were ASA II. The most prevalent chronic conditions in the study population were hypertension (16.6%) and hypothyroidism (11.3%) (**Table 1**).

During the study, 13% of patients experienced sedation-related complications. Among these, hypotension (6.7%) and desaturation (3.4%) were the most common. Notably, all cases of arrhythmia (2.6%) were sinus-related, predominantly bradycardia (82.4%). No major complications were recorded. The distribution of complications is detailed in **Table 2**.

Regarding sedation medications, the average initial doses—regardless of the procedure—were as follows: midazolam 5.3 mg (range: 3–8 mg) and fentanyl 83.9 µg (range: 50–150 µg). A total of 36.3% of patients required additional medication during the procedure, either through titration of the initial drugs or the addition of ketamine.

Analysis of associations with medical history revealed that only obesity was significantly associated with complications (PR = 2.76, 95% CI: 1.333–5.739; *p*-value = 0.013). Additionally, a significant association was found between procedure type and complications: colonoscopy (PR = 1.65, 95% CI: 1.05–2.58; *p*-value = 0.031) and simultaneous EGD + colonoscopy (PR = 1.53, 95% CI: 1.04–2.24; *p*-value = 0.028). Conversely, patients undergoing EGD alone were less than half as likely (0.48 times) to experience sedation-related complications compared to those who did not undergo this procedure: PR = 0.48, 95% CI: 0.31-0.72, *p*-value <0.001.

No significant association was found between midazolam dose and minor complications, likely due to low variability in administered doses. In contrast, fentanyl doses >75 µg were associated with a higher risk of complications (PR = 2.13, 95% CI: 1.40–3.23; *p*-value < 0.001), whereas doses ≤75 µg had a protective effect (PR = 0.46, 95% CI: 0.30–0.70; *p*-value = 0.0003).

DISCUSSION

Over the past decade, there has been a notable increase in the use of non-anesthesiologist physicians to administer sedation during endoscopic procedures in gastroenterology,

Table 1. Summary of Demographic and Clinical Variables

Patient Characteristics	n = 680 (%)
Sex	
- Female	435 (64.0%)
- Male	245 (36.0%)
Age Group	
- 12 to 18	10 (1.5%)
- 19 to 26	36 (5.3%)
- 27 to 59	402 (59.1%)
- ≥60	232 (34.1%)
Procedure	
- Colonoscopy	343 (37.1%)
- Rectal echoendoscopy	2 (0.3%)
- Esophagogastroduodenoscopy	579 (62.6%)
ASA	
- I	396 (58.2%)
- II	284 (41.8%)
Medical History	**n = 680 (%)**
Hypertension	
- Yes	113 (16.6%)
- No	567 (83.4%)
Diabetes	
- Yes	40 (5.9%)
- No	640 (94.1%)
Obesity	
- Yes	14 (2.1%)
- No	666 (97.9%)
Respiratory Disease	
- Yes	13 (1.9%)
- No	667 (98.1%)
Hypothyroidism	
- Yes	77 (11.3%)
- No	603 (88.7%)
Psychiatric Disorders	
- Yes	34 (5.0%)
- No	646 (95.0%)

Table prepared by the authors.

Table 2. Frequency of Complications

Complications	n = 680 (%)
Presence of Complications	
- Yes	91 (13.4%)
- No	589 (86.6%)
Hypotension	
- Yes	46 (6.7%)
- No	634 (93.3%)
Hypertension	
- Yes	17 (2.5%)
- No	663 (97.5%)
Bronchospasm	
- No	680 (100.0%)
Laryngospasm	
- No	680 (100.0%)
Chest Rigidity	
- No	680 (100.0%)
Stridor	
- No	680 (100.0%)
Arrhythmia	
- Yes	18 (2.6%)
- No	662 (97.4%)
Desaturation	
- Yes	23 (3.4%)
- No	657 (96.6%)

Table prepared by the authors.

particularly in outpatient settings. This has sparked growing interest in understanding its impact on the safety, quality, and cost of such procedures. Internationally, various gastroenterology and anesthesiology societies—including the American Society for Gastrointestinal Endoscopy (ASGE), the European Society of Gastrointestinal Endoscopy (ESGE), the European Society of Anesthesiology, and the European Society of Gastroenterology—have published guidelines for procedures requiring sedation administered by non-anesthesiologists[7]. Questions have also arisen not only about who should administer sedation but also about the increasing use of medications previously restricted to deep sedation under an anesthesiologist's supervision, such as propofol[8-10].

In Colombia, the Colombian Society of Anesthesiology and Resuscitation (SCARE) recommends the use of medications for conscious sedation by non-anesthesiologist physicians, though some studies report the unregulated use of propofol[11,12]. This study did not include propofol due to the institution's adherence to current regulations regarding conscious sedation.

Complications associated with conscious sedation during endoscopic procedures include airway compromise (laryngospasm, bronchospasm) leading to desaturation or hypoxia, as well as hemodynamic events (hypotension, bradycardia), which in some cases may result in death[13]. This study recorded no major complications, consistent with findings from the multicenter *ProSed 2* study, which reported a major complication rate of 0.01% and a mortality rate of 0.005% in 368,206 procedures[14].

The incidence of minor complications varies in the literature, ranging from 5.3% in *ProSed 2* to 20% in a study conducted at Hospital San Martín in León, Argentina[15]. In the present study, it was 20%, aligning with previous research[16,17]. These complications were resolved with interventions such as Larson's maneuver, increased fraction of inspired oxygen (FiO_2), and anticholinergics like hyoscine for hypotension and bradycardia[18-20]. Obesity was identified as a significant risk factor for complications (p = 0.013; PR = 2.76; 95% CI: 1.333–5.739), highlighting the need for adjusted sedative dosing and close monitoring in these patients due to their higher risk of obstructive sleep apnea[21-24].

This study employed midazolam with fentanyl and, in some cases, ketamine as rescue medication for pain or anxiety. Doses exceeding 75 µg of fentanyl were associated with a significant increase in minor complications, underscoring the importance of careful administration (**Table 3**). No significant association was found between midazolam doses and complications, likely due to limited variability in its use.

Significant associations were observed between minor complications and combined procedures such as EGD/colonoscopy, while EGD alone showed lower risk, possibly due to its shorter duration and reduced sedative requirements[19].

CONCLUSIONS

Our study demonstrates that conscious sedation administered by non-anesthesiologist physicians during outpatient endoscopic procedures is safe, with a low incidence of minor complications and no major complications reported. Individualized planning of sedative medications—particularly fentanyl, which may affect respiratory and cardiovascular function depending on the dose—is crucial. Finally, prolonged procedures carry a higher risk of complications, emphasizing the need for effective time management during these interventions. These considerations are essential for classifying and preventing complications and determining whether patients should be referred for deep sedation under an anesthesiologist's care.

Table 3. Bivariate Analysis of Clinical and Demographic Factors in Patients Undergoing Conscious Sedation for Endoscopic Procedures

Characteristics	Complications		*p*-value
	Yes (%)	No (%)	
Sex			
- Female	58 (8.5%)	377 (55.4%)	0.96
- Male	33 (4.9%)	212 (31.2%)	
Age Group			
- 12 to 18	0 (0.0%)	10 (1.5%)	0.21
- 19 to 26	1 (0.1%)	35 (5.1%)	0.054
- 27 to 59	53 (7.8%)	349 (51.3%)	0.85
- ≥60	37 (5.4%)	195 (28.7%)	0.15
Procedure			
- Colonoscopy	20(2.9%)	79 (11.6%)	**0.031**
- EGD + COL	42 (6.2%)	202 (29.7%)	**0.028**
- Rectal echoendoscopy	0 (0.0%)	2 (0.3%)	0.57
- Esophagogastroduodenoscopy	29 (4.3%)	306 (45%)	**<0.001**
ASA			
- I	50 (7.4%)	346 (50.9%)	0.49
- II	41 (6%)	243 (35.7%)	
Medical History	**Complications**		***p*-value**
	Yes (%)	**No (%)**	
Hypertension			
- Yes	17 (2.5%)	96 (14%)	0.57
- No	74 (10.9%)	493 (72.5%)	
Diabetes			
- Yes	6 (0.9%)	34 (5%)	0.75
- No	85 (12.5%)	555 (81.6%)	
Obesity			
- Yes	5 (0.7%)	9 (1.3%)	**0.013**
- No	86 (12.6%)	580 (85.3%)	
Respiratory Disease			
- Yes	1 (0.1%)	12 (1.8%)	0.54
- No	90 (13.2%)	577 (84.9%)	
Hypothyroidism			
- Yes	6 (0.9%)	71 (10.4%)	0.12
- No	85 (12.5%)	518 (76.2%)	
Psychiatric Disorders			
- Yes	3 (0.4%)	31 (4.6%)	0.42
- No	88 (12.9%)	558 (82.1%)	
Midazolam Dose			
- ≤5 mg	71 (10.4%)	453 (66.6%)	0.81
- >5 mg	20(2.9%)	136 (20%)	
Fentanyl Dose			
- ≤75 µg	61 (9%)	275 (40.6%)	**<0.001**
- >75 µg	29 (4.3%)	312 (46.1%)	

ASA: American Society of Anesthesiologists classification; EGD + COL: Esophagogastroduodenoscopy and colonoscopy performed simultaneously. Table prepared by the authors.

REFERENCES

1. Green SM, Roback MG, Krauss BS, Miner JR, Schneider S, Kivela PD, et al. Unscheduled Procedural Sedation: A Multidisciplinary Consensus Practice Guideline. Ann Emerg Med. 2019;73(5):e51-65. https://doi.org/10.1016/j.annemergmed.2019.02.022
2. Ibarra P, Galindo M, Molano A, Niño C, Rubiano A, Echeverry P, et al. Recomendaciones para la sedación y la analgesia por médicos no anestesiólogos y odontólogos de pacientes mayores de 12 años. Rev Colomb Anestesiol. 2012;40(1):67-74. https://doi.org/10.1016/S0120-3347(12)70012-6
3. Arnal Velasco D, Romero García E, Martínez Palli G, Muñoz Corsini L, Rey Martínez M, Postigo Morales S. Recomendaciones de seguridad del paciente para sedaciones en procedimientos fuera del área quirúrgica. Revista Española de Anestesiología y Reanimación. 2016;63(10):577-87. https://doi.org/10.1016/j.redar.2016.07.006
4. Parra MJ, Badenes R. Monitorización en procesos de sedación. Revista Española de Anestesiología y Reanimación. 2023;70:S1-5. https://doi.org/10.1016/j.redar.2022.12.001
5. Asociación Médica Mundial. Declaración de Helsinki [Internet]. Asociación Médica Mundial; 2013 [citado el 22 de diciembre de 2023]. Disponible en: http://www.redsamid.net/archivos/201606/2013-declaracion-helsinki-brasil.pdf?1
6. Ministerio de Salud de Colombia. Resolución número 8430 de 1993, por la cual se establecen las normas científicas, técnicas y administrativas para la investigación en salud [Internet]. Ministerio de Salud de Colombia; 1993 [citado el 22 de diciembre de 2023]. Disponible en: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF
7. Dumonceau J, Riphaus A, Aparicio J, Beilenhoff U, Knape J, 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(11):960-74. https://doi.org/10.1055/s-0030-1255728
8. Vargo JJ, Cohen LB, Rex DK, Kwo PY, American Association for the Study of Liver Diseases, American College of Gasteroenterology, et al. Position statement: Nonanesthesiologist administration of propofol for GI endoscopy. Gastroenterology. 2009;137(6):2161-7. https://doi.org/10.1053/j.gastro.2009.09.050
9. Protopapas AA, Stournaras E, Neokosmidis G, Stogiannou D, Filippidis A, Protopapas AN. Endoscopic sedation practices of Greek gastroenterologists: a nationwide survey. Ann Gastroenterol. 2020;33(4):366-73. https://doi.org/10.20524/aog.2020.0494
10. Viazis N, Vlachogiannakos J, Apostolopoulos P, Mimidis K, Tzouvala M, Tsionis T, et al. Sedation during endoscopic procedures: a Hellenic Society of Gastroenterology Position Statement. Ann Gastroenterol. 2023;36(3):231-243. https://doi.org/10.20524/aog.2023.0789
11. Sepúlveda Copete M, Rojas Rojas NE, Herrera Lara EF, Sánchez Londoño S, Pérez JS, Castaño Casas JP, et al. Sedación administrada por médicos generales para procedimientos endoscópicos de baja complejidad: experiencia en una unidad de endoscopia de una clínica de alta complejidad en Cali. Rev Colomb Gastroenterol. 2022;37(3):276-81. https://doi.org/10.22516/25007440.836
12. Mulett-Vásquez E, Osorio Chica M, Arango Molano LA. Sedación con Propofol por no anestesiólogos para colonoscopia total. Rev Colomb Gastroenterol. 2019;34(4):345-9. https://doi.org/10.22516/25007440.302
13. Gaytán-Fernández B. Riesgos y complicaciones durante la sedación para endoscopía diagnóstica del tubo digestivo sin enfermedad concomitante. Revista Mexicana de Anestesiología. 2021;44(3):200-6. https://doi.org/10.35366/99667
14. Behrens A, Kreuzmayr A, Manner H, Koop H, Lorenz A, Schaefer C, et al. Acute sedation-associated complications in GI endoscopy (ProSed 2 Study): results from the prospective multicentre electronic registry of sedation-associated complications. Gut. 2019;68(3):445-52. https://doi.org/10.1136/gutjnl-2015-311037
15. Villarroel M. Complicaciones de la sedación moderada en un centro avanzado de entrenamiento en endoscopía digestiva. [Tesis de Grado]. La Plata: Universidad Nacional de La Plata; 2011 [consultado el 23 de diciembre de 2023]. Disponible en: https://sedici.unlp.edu.ar/handle/10915/5439
16. Baudet JS, Aguirre-Jaime A. Effect of conscious sedation with midazolam and fentanyl on the overall quality of colonoscopy: a prospective and randomized study. Rev Esp Enferm Dig. 2019;111(7):507-513. https://doi.org/10.17235/reed.2019.5735/2018
17. Finn RT, Boyd A, Lin L, Gellad ZF. Bolus Administration of Fentanyl and Midazolam for Colonoscopy Increases Endoscopy Unit Efficiency and Safety Compared With Titrated Sedation. Clin Gastroenterol Hepatol. 2017;15(9):1419-1426.e2. https://doi.org/10.1016/j.cgh.2017.03.030
18. Knigge S, Hahnenkamp K. Nonoperating room anesthesia for endoscopic procedures. Curr Op Anaesthesiol. 2017;30(6):652-7. https://doi.org/10.1097/ACO.0000000000000518
19. Jirapinyo P, Abu Dayyeh BK, Thompson CC. Conscious sedation for upper endoscopy in the gastric bypass patient: prevalence of cardiopulmonary adverse events and predictors of sedation requirement. Dig Dis Sci. 2014;59(9):2173-7. https://doi.org/10.1007/s10620-014-3140-4
20. Sidhu R, Turnbull D, Haboubi H, Leeds JS, Healey C, Hebbar S, et al. British Society of Gastroenterology guidelines on sedation in gastrointestinal endoscopy. Gut.

2024;73(2):219-45. https://doi.org/10.1136/gutjnl-2023-330396
21. Patel VA, Romain PSt, Sanchez J, Fisher DA, Schulteis RD. Obstructive Sleep Apnea Increases the Risk of Cardiopulmonary Adverse Events Associated with Ambulatory Colonoscopy Independent of Body Mass Index. Dig Dis Sci. 2017;62(10):2834-9. https://doi.org/10.1007/s10620-017-4731-7
22. Hernández C JJ. Sedación consciente para la colonoscopia ambulatoria. Rev Cuba Anestesiol Reanim. 2015;14(1):13-28.
23. Vargo JJ. Procedural sedation and obesity: waters left uncharted. Gastrointest Endosc. 2009;70(5):980-4. https://doi.org/10.1016/j.gie.2009.07.003
24. Early DS, Lightdale JR, Vargo JJ, Acosta RD, Chandrasekhara V, Chathadi KV, et al. Guidelines for sedation and anesthesia in GI endoscopy. Gastrointestinal Endoscopy. 2018;87(2):327-37. https://doi.org/10.1016/j.gie.2017.07.018