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Original article

Sedation Administered by General Practitioners for Low Complexity Endoscopic Procedures: Experience in an Endoscopy Unit of a Tertiary Referral Hospital in Cali

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Abstract

Objectives: in Colombia, sedation by non-anesthesiologists for endoscopic procedures outside the operating room has been implemented. A description of an experience in the gastroenterology unit of a tertiary referral hospital in Cali, Colombia, was conducted. **Materials and methods**: an analytical cohort observational study to describe the frequency and type of adverse events associated with sedation procedures performed by general practitioners and evaluate the factors related to their occurrence in patients who attended the endoscopy unit of Fundación Valle del Lili for endoscopic studies under intravenous sedation. Between November 2018 and June 2019, non-anesthesiologist physicians performed this procedure due to the minimal risk implied. A descriptive analysis was completed, and the median and interquartile range were calculated for numerical variables and frequencies for qualitative variables. **Results**: There were 1506 participants, 59.4% ASA I and 40.6% ASA II in this study. On average, the starting dose of propofol was 60 mg, and the total dose was 140 mg. Forty-six patients (3.05%) reported non-severe adverse events; the most common occurrence was transient desaturation (80.4%). No patients experienced severe adverse events. The average initial Aldrete scale score was 8, while at discharge, the average score was 10. **Conclusions:** sedation for endoscopic procedures performed by non-anesthesiologists is safe provided that it is performed by trained personnel conducting a correct assessment of the patient's (cardiovascular, gastrointestinal, and neurological) history and risk factors within the framework of the current institutional guidelines.

Keywords

Endoscopy, colonoscopy, sedation, general practitioner, safety, experience.

INTRODUCTION

Sedation is the level of consciousness decrease induced by drugs, intending to improve patients' tolerance to invasive and non-invasive medical procedures. Using sedation administered by trained general practitioners offers greater opportunity for procedures with a low risk of complication, either diagnostic or therapeutic.

Since 2015, low-risk patients at the endoscopy unit of Fundación Valle del Lili have been undergoing sedation by non-anesthesiologists. These general practitioners have previously received complete theoretical and practical training in sedation provided by the institution's anesthesiologists. We intend to share this experience to learn about procedural safety, describe drug regimens and doses used, and identify the incidence and type of adverse events and the risk factors for these events.

MATERIALS AND METHODS

An observational, analytical cohort-type study was conducted to describe the frequency and type of adverse events related to sedation procedures performed by general practitioners and to assess the factors associated with their occurrence. Before data collection, pre-endoscopic assessment, intraprocedural adverse events reporting, and recovery formats were designed and implemented during the study. We prospectively included male and female patients over 18 who came to the unit to undergo an endoscopic study under intravenous sedation. Given its low risk, the sedation was performed by a non-anesthesiologist. However, the endoscopist did perform the procedure. Patients classified as ASA PS I and II were considered low-risk patients according to the American Society of Anesthesiologists criteria (ASA)[1].

Patient demographic variables such as gender, age, and medical history were recorded at the time of the procedure. We included information on difficult airway determinants: the Mallampati scale[2], dentures, cervical spine range of motion, thyromental distance, and a known difficult airway. The patient's vital signs were recorded before entering the procedure room (cannulation), at the beginning of the procedure, during the procedure, and upon admission to the recovery room.

Before the procedure, vital signs are monitored and the patient is pre-oxygenated with a nasal cannula. The institutional protocol regarding propofol use establishes the use of sedation with a single agent (monotherapy). The ideal agent for this procedure is propofol, and the instruction is to use it titrated, starting with a 0.5–1 mg/kg dose. Midazolam in low doses (< 0.05 mg/kg) may be used as an adjuvant medicinal product in the following cases: high doses of propofol and patients with high anxiety levels. Regarding non-anesthesiologists using propofol, the institutional guide and the Ministry of Health and Social Protection of Colombia established, according to Resolution 1441 of 2013, that trained non-anesthesiologists can perform sedation.

The initial and total doses of the drugs used to sedate the patient were recorded during the procedure. Likewise, adverse events are classified as follows: none, serious (admission to the intensive care unit [ICU], intubation, need for resuscitation, and death) or non-serious (paradoxical anxiety, oxygen saturation (SaO_2) < 90% for more than 10 seconds, more than 25% drop of systolic blood pressure, laryngospasm, heart rate (HR) drop exceeding 20% or HR greater than 100 beats per minute [bpm]). Two anesthesiologists are constantly offering support in the endoscopy unit.

Eventually, the patient's final destination after recovery was recorded (outpatient, hospitalization, ICU, morgue, other), and recovery from sedation was assessed with the Aldrete score[3] upon arrival at the recovery room and before discharge from the endoscopy unit. The work was approved and submitted by the ethics committee. Based on current legislation for procedures requiring sedation, we used the informed consent document from the institution.

A descriptive analysis of the data recorded in the recording formats was performed. Median and interquartile ranges (IQR) were calculated for numerical variables, while qualitative variables were described with frequencies. The Shapiro-Wilk statistical test was applied for quantitative data. Where relevant, bivariate and multivariate analyses were conducted to explore possible associations between exposure and outcome variables. Complications were measured for the frequency calculations obtained for all patients, so the estimates obtained are reliable. In addition, they are highly accurate due to the number of patients included and analyzed.

RESULTS

Between November 2018 and June 2019, we included 1506 patients in this study. The patients' median age was 53 (95% IQR: 40–62), 63.6% were women, and 36.4% were men. The average body mass index (BMI) was 25.5 (95% IQR: 23.1–28), and the average weight was 68.7 kg (95% IQR: 61–78). The medical history and clinical characteristics of patients are summarized in **Table 1**. The most frequent indications for the procedures were dyspepsia (25.7%), regular check-ups or monitoring (14.4%), abdominal pain (13.7%), and gastroesophageal reflux (6%). Outpatients accounted for 88.4% and 11.6% were inpatient. Regarding the type of procedure, 51.2% were upper digestive endoscopies, 19.7% were colonoscopies, and 29.1% were upper endoscopy plus colonoscopy.

Patients classified as ASA I: 59.4% and 40.6% as ASA II. Seven (0.46%) patients had a history of difficult airways. On average, an initial dose of propofol of 60 mg (95% IQR: 40-80 mg) and a total dose of 140 mg (95% IQR: 100-200 mg) were used during endoscopic procedures. The average dose used for midazolam was 2 mg (95% IQR: 2-3 mg) (**Table 2**).

Regarding vital signs monitoring, the mean arterial pressure (MAP) at the beginning of the procedure averaged 89 mm Hg (IQR 95%: 80–98 mm Hg), HR was 71 bpm (IQR 95%: 64–80 bpm), and SaO_2 was 99% (95% IQR: 99–100). At the end of the procedure, the MAP was 83 mm Hg (95% IQR: 75–93 mm Hg) on average; HR, 69 bpm (IQR 95%: 62–77 bpm), and SaO_2, 99% (IQR 95%: 98–100). In the recovery room, the average MAP was 68 mm Hg (95% IQR: 61–77 mm Hg); HR, 67 bpm (IQR 95%: 59–75 bpm), and SaO_2, 98% (IQR 95%: 96–99). The initial average Aldrete score was 8, while at discharge, the average score was 10.

Table 1. Clinical characteristics of the population

Characteristics	n = 1506	%
Gender, n (%)		
- Female	958	63.6
- Male	548	36.4
Origin, n (%)		
- Outpatient	1331	88.4
- Inpatient	175	11.6
Past medical history, n (%)		
- Neurological[a]	41	2.7
- Respiratory[b]	35	2.3
- Cardiovascular[c]	335	22.2
- Hematologic[d]	52	3.5
- Endocrine[e]	299	19.9
- Renal[f]	43	2.9
- Gastrointestinal[g]	249	16.5
- Allergies	165	11.0
- Total	1219	80.9
ASA PS classification, n (%)		
- I (a normal healthy patient)	896	59.4
- II (mild systemic disease)	610	40.6

Most commonly known past medical history reported:
[a] Psychiatric disorder (14), stroke (4), malignant hyperthermia (4), and migraine (4).
[b] Asthma (20), smoking (6), COPD (5), sleep apnea (3).
[c] High blood pressure (323), arrhythmias (10), heart attack (4), heart failure (2).
[d] Antiaggregation (23), anemia (12), anticoagulation (10).
[e] Thyroid diseases (192), diabetes mellitus (72), obesity (31), dyslipidemia (13).
[f] Chronic kidney disease (35), kidney stones (4).
[g] Dyspepsia (29), gastroesophageal reflux (21), neoplasia (17), peptic ulcer (8), inflammatory bowel disease (9), gastrointestinal bleeding (2).
COPD: chronic obstructive pulmonary disease

Non-serious adverse events were recorded in 46 patients (3.05%), of whom 80.4% had desaturation, 6.5% laryngospasm, 6.5% cough, and 4.3% bradycardia. No patients experienced serious adverse events. A relationship between the occurrence of adverse events in patients with a neurological ($p = 0.049$), cardiovascular ($p = 0.003$), and gastrointestinal ($p = 0.006$) medical history was found. Likewise, a

Table 2. Drug regimens used for sedation

Drugs	Doses (IQR 95%)[a]
Propofol	
- Initial dose	60 mg (40-80 mg)
- Total dose	140 mg (100-200 mg)
Midazolam	
- Initial dose	2 mg (1-3 mg)
- Total dose	2 mg (2-3 mg)
Lidocaine	
- Single dose	30 mg (20-40 mg)

relationship was found in patients with ASA PS II anesthetic risk classification ($p = 0.002$) (**Table 3**). There was no statistically significant relationship between medication use and adverse events. The average time of endoscopy was 8 minutes, and 13 minutes for colonoscopy.

DISCUSSION

The general practitioner model for sedation outside the operating room has been implemented in different countries worldwide with good results[4]. Since the publication of the Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, first adopted by the ASA in 1995, the involvement of anesthesiologists in digestive endoscopy has been declining to allow trained physicians and nurses to take over. In the United States, although almost 100% of digestive endoscopies are performed under sedation[5], only 17.2% of colonoscopies involve an anesthesiologist's presence, which has reduced the costs of the procedures by approximately 20%[6,7]. Thus, the sedation process performed by general practitioners has similar safety and effectiveness levels to sedation administered by anesthesiologists in low-risk patients[4,8], as long as physicians are trained for this purpose[9]. The above mentioned per the institutional protocols, which emphasize that physicians must undergo a complete theoretical and practical training. On the other hand, patients with ASA PS classification between III and V are 5 and 7 times more at risk of complications than low-risk patients; therefore, they should be evaluated and treated by an anesthesiologist[10-12].

This system has been implemented in Colombia since 2012, as shown in the recommendations for sedation and analgesia by non-anesthesiologists and dentists of patients

Table 3. Relationship between adverse events and patients' characteristics

Characteristics	Adverse events		*p*[a]
	No (n = 1460)	Yes (n = 46)	
Age	52 (39 - 62)	64 (54 - 72)	0
Gender			
- Female	927	31	0.39
- Male	533	15	
BMI	25.45	27.3	0.0011
Procedure type			
- Endoscopy	746	27	
- Colonoscopy	294	3	0.064
- Endoscopy and colonoscopy	420	16	
Origin			
- Outpatient	1292	39	NC[b]
- Inpatient	168	7	NC[b]
Past medical history			
- Neurologic	28	4	0.049
- Respiratory	20	1	0.609
- Cardiovascular	214	18	0.003
- Hematologic	32	2	0.654
- Endocrine	189	12	0.243
- Renal	26	0	0.625
- Gastrointestinal	154	15	0.006
ASA PS classification			
- I	882	15	0.002
- II	579	31	
Mallampati score			
- I	898	16	
- II	450	21	0.002
- III	105	8	
- IV	7	1	
Dentures			
- Denies	1347	42	
- Fixed	42	2	0.202
- Removable	71	2	
Thyromental distance			
- Greater than 3 fingerbreadths	1381	38	0.003
- Less than 3 fingerbreadths	79	8	0.234

[a]A $p < 0.05$ value was considered statistically significant. [b]CN: not calculated.

over 12 years, published by the Colombian Society of Anesthesiology and Resuscitation[11,13]. There was no report on the results of this practice in our country until recently. In 2019, Mullet-Vásquez *et al* published a study evaluating the evolution of colonoscopies in which propofol sedation was applied to low-risk patients. Even in our local context, they found that sedation performed by non-anesthesiologists is a safe procedure[14].

The use of intravenous (IV) sedation during endoscopic procedures ranges from 20% to 98%, depending on the country[5]. Using a benzodiazepine with an opioid is the most common method, although endoscopists reported better results using propofol for conscious sedation[15]. A recent meta-analysis showed that, overall, propofol had been associated with a 39% reduction in complications (hypoxemia, hypotension, or arrhythmias) during a low-complexity digestive endoscopy compared to other agents. However, this difference is not evident in patients undergoing advanced endoscopy[16]. Fortunately, preventing many sedation complications with proper staff training and standardization of associated processes is possible[11]. In addition, non-anesthesiologists administering propofol is associated with better sedation, increased patient cooperation, and shorter recovery discharge periods[8]. Propofol was used in our population because it is safe and we used it with average total doses of 140 mg and maximum doses of 200 mg. Propofol administration triggers pain at the puncture site, although chemical phlebitis is rare, and this uncomfortable effect can be controlled or avoided with the concomitant administration of lidocaine. The average dose of lidocaine used in our study was 30 mg.

Diagnostic digestive endoscopy has a 0.02% to 0.54% complication rate. In cases where sedation is applied, it accounts for 50% of complications[17]. In a prospective multicenter study documenting acute complications associated with endoscopy sedation between 2011 and 2014, the major complications rate (ICU admission, intubation, need for resuscitation, and death) accounted for 0.01%; mortality, 0.005%, and minor complication rate (paradoxical anxiety, SaO_2 < 90% for more than 10 seconds, more than 25% drop in systolic pressure, HR drop higher than 20%, or HR higher than 100 bpm) accounted for 0,3%, with a ratio directly proportional to the ASA PS class, the type and duration of the procedure[18]. Other less common complications include arrhythmias or bronchoaspiration.

In our study, the adverse event rate was 3.05 %, higher than the rate reported in the literature. In a paper by Sharma *et al,* reviewing data from 324,737 endoscopic procedures under sedation, cardiopulmonary adverse events were reported in 0.9% of procedures[19]. A higher rate in our study could be explained by a higher number of reported transient oxygen

desaturation episodes. The most common adverse event was desaturation, closely related to respiratory depression triggered by propofol or benzodiazepines, as appropriate. All desaturation cases were self-limiting or subsided with oxygen titration through a nasal cannula, routinely used in all procedures under sedation. The relationship of the ASA PS class with the occurrence of adverse events in our study was expected and consistent with the one reported in the literature. Notably, no relationship was found between predictors of difficult airways and the incidence of adverse events. However, in an event requiring securing the airway, it is advisable to inform the anesthesiologist of the presence of these factors and provide a rapid response system or code blue should major complications arise.

Monitoring should continue until the patient is wide awake, hemodynamically stable, has a permeable airway, and has adequate airway and respiratory reflexes during recovery[20,21]. The Aldrete scale has been used for more than 30 years to assess the clinical condition of patients after anesthesia and their gradual course towards recovery afterward. The scale assesses limb activity, respiratory function, circulatory status, oxygenation, and consciousness. Additionally, its modified version for outpatient surgery includes criteria for patient readiness to go home[3]. The average score of patients on admission to recovery was 8 and on discharge was 10, demonstrating satisfactory post-procedural recovery and probably indicative of close surveillance that could contribute to favorable outcomes.

CONCLUSION

In recent years, the Clínica Fundación Valle del Lili's gastroenterology service has implemented sedation administered by non-anesthesiologists in the endoscopy unit with extensive experience. In this issue, we have summarized our experience on this topic. Therefore, this practice seems safe as long as it is performed by medical personnel trained within the current institutional guidelines. However, necessary resources and an anesthesiologist for the service where the procedure is to be performed should always be available should an event occur. Finally, more studies are required to verify the cost-effectiveness of this practice in Colombia.

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