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Risk factors for adverse reactions to nurse-administered propofol during outpatient endoscopy: a cross-sectional study

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Abstract

Background Endoscopic procedures are essential for diagnosing and managing gastrointestinal conditions, often requiring sedation for patient comfort. Propofol is a common choice for outpatient sedation due to its rapid onset and predictable recovery time. Although propofol has an established safety profile, adverse drug reactions (ADRs) can still occur. This study investigated the prevalence and risk factors associated with ADRs related to nurse-administered propofol sedation during outpatient endoscopic procedures at a private hospital in Peru.

Method We conducted a retrospective study. The clinical records of 919 Peruvian patients who underwent endoscopic interventions under propofol sedation were reviewed. This study included patients between the ages of 18 and 69 years who had American Society of Anesthesiologists (ASA) physical status classification scores of I–III and who were hemodynamically stable with an oxygen saturation (SO2) > 90% before the procedure. Sedation was nurse-administered using standardized protocols. ADR data, including severity and causality assessment data, were collected. Data were collected and analyzed by SPSS, Inc., and the statistical significance was calculated at the $p < 0.05$ level.

Results A total of 693 patients were included in the study, 30.9% of whom experienced at least one ADR, predominantly cardiovascular or respiratory events such as hypotension and hypoxia, with causality scores classified as probable or definitive. Among the ADRs, 35.8% ($n = 87$) were moderately severe, and 64.2% ($n = 143$) were mildly severe. There were no reports of any serious adverse events. An ASA class III status ($p = 0.048$, PR adjusted (PRa) = 1.73, 95% CI: 1.01–2.99) and a procedure time of more than 20 min ($p < 0.0001$, PRa = 2.05, 95% CI: 1.53–2.73) were significant risk factors for ADR occurrence. Patients with ADRs had longer recovery times than did those without ADRs (22 min ± 22.5 vs. 14 min ± 8, respectively; $p < 0.001$).

Conclusion In our work, moderate propofol sedation administered by trained nursing staff to outpatients undergoing interventional endoscopic procedures was generally safe but not free from risks. Vital parameters should be monitored regularly during long-term interventions and when patients are classified as ASA III.

Keywords Propofol, Adverse drug reactions, Endoscopic procedures, Nurse, Peru

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Introduction

Gastrointestinal endoscopy is a routine procedure employed for both diagnostic and therapeutic purposes. It involves the insertion of a flexible tube equipped with a camera and light source into the gastrointestinal tract, aiming to visualize and assess the lining of the esophagus, stomach, and intestines. To ensure patient comfort and cooperation throughout this process, sedation is frequently administered [1].

Propofol, a short-acting intravenous anesthetic agent, is increasingly utilized for sedation due to its rapid onset and predictable recovery profile in endoscopic procedures [2]. In outpatient settings, where rapid turnover and patient satisfaction are paramount, sedation with nurse-administered propofol has emerged as a convenient and cost-effective alternative to traditional anesthesia delivery models [3].

Sedation with propofol has several advantages; however, it is not free from risk and can potentially lead to adverse drug reactions (ADRs), which can be defined as harmful and unintended responses to medications at normal therapeutic doses [4]. These ADRs can affect the central nervous, cardiovascular, and respiratory systems [5–7], ranging from mild respiratory depression to life-threatening events such as hypoxia and cardiovascular complications [8]. Sedative-related adverse events are a critical concern in this context.

Despite the wide use of propofol sedation in outpatient endoscopy, there are fewer available publications concerning the profile safety of nurse-administered propofol sedation in comparison to propofol sedation administered by anesthesiologists, especially in nonclinical trial design studies or in populations from low-income countries [9–11].

Although some studies have shown that non-anaesthesiologists' propofol sedation can be administered safely [10, 11] and represents a significant reduction in the financial burden of personnel costs [12, 13], some developing countries can resist implementing this type of sedation due to the lack of evidence of the effectiveness and safety of this procedure in their specific populations. In countries with marked differences in access to the healthcare system, the implementation of this type of procedure might improve access to essential diagnostic and therapeutic services. By reducing costs, expanding access, and maintaining high standards of care through proper training and protocols, this approach could significantly benefit healthcare systems and patient populations in these regions.

Therefore, we conducted a cross-sectional study to investigate the prevalence and identify the risk factors associated with ADRs related to moderate sedation with nurse-administered propofol during outpatient endoscopic procedures in a low-income country.

Methods

Study design and population

We conducted a single-center retrospective study in a private tertiary care hospital in Peru. We reviewed medical records from a database of 919 outpatients who received an endoscopic intervention performed under sedation with propofol from January 2021 to July 2022. Patients who were between 18 and 69 years old, who had American Society of Anesthesiologists (ASA) physical status classification scores of I–III, and who were hemodynamically stable with oxygen saturation (SO_2) > 90% before the procedure were included. Patients who received endoscopic procedures requiring deep sedation, who were pregnant, or who had a medical history of allergy to propofol were excluded.

Procedures and sedation

The endoscopic procedures were performed at the Ambulatory Endoscopic Center by experienced physicians (with advanced cardiovascular resuscitation certification), nurses, and researchers using standard techniques. For this study, sedation was carried out by three trained nurses. The nurses received 4 weeks of training in the Anesthesiology Department, which included hands-on experience with dosing, intervals, and administration of propofol using boluses and pumps during procedures in the operating room. After completing the full training, the three nurses participated in the study. The physicians were responsible for performing the endoscopic procedures and ensuring patient safety.

Propofol was initially administered with a loading dose of 10 to 60 mg, adjusted according to the patient's age, weight, and comorbidities, and followed by a repeated bolus of 10 to 20 mg of this drug to maintain an adequate sedation level for the patient. Adequate sedation was assessed based on a subtle drop in blood pressure (approximately 10 mmHg) or heart rate (5 beats per minute), alongside the absence of a neurologic response to verbal stimulation, such as calling the patient's name. Propofol was always administered intravenously. No other drugs for sedation were used.

Continuous monitoring of heart rate, SO_2, and respiratory rate was performed. Blood pressure was measured automatically before drug administration and then at 5-minute intervals. Vital signs and oxygenation were recorded at baseline, 5 min before the procedure, at the beginning, at the end of the procedure, and 5 min after the end of the procedure.

Oxygen was not used routinely. If the $SO_{2\ concentration}$ fell below 90%, a chin-lift maneuver was performed. If the $SO_{2\ concentration}$ remained less than 90% for 30 s despite the maneuvers, supplemental oxygen was administered via a binasal cannula at 4 l/m.

Variables and data collection

In this study, ADRs were defined as any adverse response to a medication or medicinal product that is both "noxious and unintended" and that occurs at doses utilized in humans for preventive, diagnostic, or therapeutic purposes or for the alteration of physiological function. In addition, serious adverse events (SAEs) are considered any medical incident that, regardless of dosage, has the potential to lead to death, necessitate hospitalization or prolongation of hospitalization, cause persistent or significant disability/incapacity, or result in a congenital anomaly/birth defect [4].

Furthermore, cardiovascular adverse events included hypotension (systolic blood pressure < 90 mmHg), bradycardia (heart rate < 40 beats/minute), tachycardia (heart rate > 100 beats/minute), tachypnea (breathing > 20 breaths/minute). Additionally, hypoxia was defined as SO_2 < 90%.

Two independent researchers collected ADRs documented in the medical records from the beginning of the endoscopic intervention until patient recovery. In addition, a research pharmacist used the adapted Naranjo algorithm to establish causality between ADRs and and the drug administered [14, 15]. Only probable and definitive events were considered to determine severity, and other analyses were performed.

The severity of ADRs was measured using Hartwig´s Severity Assessment Scale [16]. This scale categorizes the severity of ADRs into seven levels: levels 1 and 2 as mild (those that were self-limiting and able to resolve over time without treatment), levels 3 and 4 as moderate (those that required treatment or an increased length of stay by at least one day) and levels 5–7 as severe (those that were life-threatening or caused permanent harm or death).

The frequencies of ADRs were classified as follows: very common ≥ 1/10 (≥ 10%), common ≥ 1/100 and < 1/10 (≥ 1 and < 10%), uncommon ≥ 1/1000 and < 1/100 (≥ 0.1 and < 1%), rare ≥ 1/10.000 and < 1/1.000 (≥ 0.01% and < 0.1%), very rare < 1/10.000 (< 0.01%) and unknown (described in package inserts as ADRs observed at the post commercialization stage but not during drug trials) [17].

Other variables were collected through a data collection sheet (DCS) designed with the Google Form tool. The DCS included basal characteristics (sex and age), unhealthy habits (alcohol use and smoking), and clinical profiles (ASA classification, Mallampati score [18] to evaluate the intubation difficulty, type of procedure, body mass index (BMI) categories regarding the World Health Organization's classification [19], total dose used, procedure time, airway support measures and recovery time). The recovery time was defined as the time spent in the recovery area after procedural sedation until safe discharge (Aldrete score ≥ 10).

Statistical analysis

Quantitative variables are described as medians and interquartile ranges, and categorical variables are described as frequencies and percentages. We explored the association between the presence of ADRs and potential risk factors using the chi-square test. All variables were included in this analysis except for airway support measures and recovery time. In addition, some variables (ASA classification, BMI categories, type of procedure, and Mallampati classification) were recategorized to maintain a proper number of patients in each cell for this statistical test. For the next step, variables with $p < 0.20$ (ASA classification, procedure time, and total dose) were included in the multivariable analysis with a robust Poisson regression model. We verified that excluding nonsignificant variables did not make an important contribution to the multivariate analysis in the presence of other variables according to the recommendations of Bursac et al. [20]. The degree of association was represented by the prevalence ratio (PR) with its respective 95% confidence interval (95% CI). Furthermore, we compared the recovery time after endoscopic intervention between patients with or without ADRs to propofol using the Mann–Whitney U test. Values of $p < 0.05$ were considered significant. Data analysis was performed using IBM SPSS Statistics for Windows (version 24.0, RRID: SCR_016479).

Ethical considerations

This research was approved by the Institutional Research Ethics Committee of San Juan Bautista Private University (Registry No. 1277–2022– CIEI-UPSJB).

Results

Sociodemographic characteristics of the patients

According to the selection criteria, a total of 693 participants were included in this study. The patient selection process is described in Fig. 1.

The median age of the patients was 48 ± 18 years (range: 18–69 years). Additionally, 37.7% ($n = 261$) were males. The basal characteristics, unhealthy habits and clinical profiles of the patients are detailed in Table 1.

Adverse drug reactions to propofol

Of the total sample, 214 patients (30.9%) had at least one possible ADR. According to the causality score obtained via the Naranjo algorithm, all the events related to propofol administration were classified as probable or definitive.

In total, 230 ADRs related to the cardiovascular or respiratory system were reported. We did not find any SAEs in this study. The prevalence, frequency, and severity of each ADR are explained in Fig. 2.

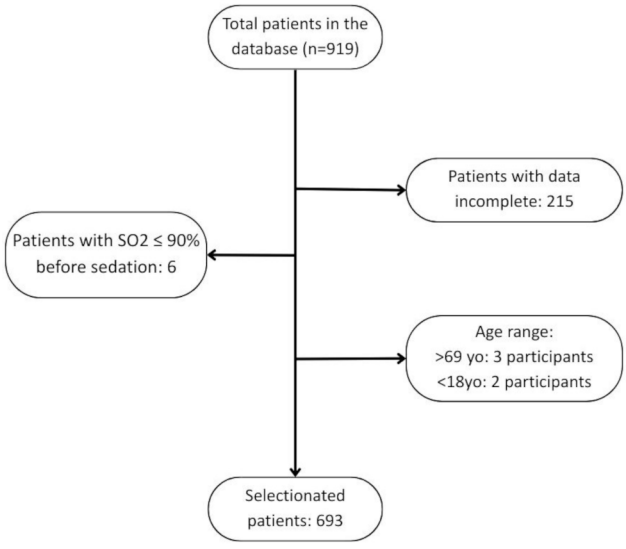

Fig. 1 The selection process for patients who received endoscopic intervention under moderate sedation with propofol

Factors associated with adverse drug reactions related to propofol use

We found that only two variables were significantly associated with the presence of ADRs related to propofol use. An ASA class III status ($p = 0.048$, PR adjusted (PRa) = 1.73, 95% CI: 1.01–2.99) and a procedure time of more than 20 min ($p > 0.0001$, PRa = 2.05, and 95% CI: 1.53–2.73) were risk factors for the occurrence of ADRs among patients who had received propofol. These analyses are described in detail in Table 2.

Recovery time among patients with or without adverse drug reactions related to propofol use

Finally, we found that patients with ADRs related to propofol use had longer recovery times than patients without these ADRs did (median ± interquartile range: 22 min ± 22.25 vs. 14 min ± 19.0, respectively; $p < 0.0001$) (Fig. 3).

Bars represent the median ± interquartile range of each group. $^{***}p < 0.0001$.

Discussion

Propofol has been widely utilized for sedation during endoscopic procedures in the last decade. Its safety profile, when administered by properly trained health professionals, is comparable to or even superior to that of other frequently employed sedatives such as meperidine, fentanyl, and benzodiazepines such as midazolam [7, 9].

We performed a retrospective study to assess the safety of propofol administered via boluses by nurses who were appropriately trained in the drug administration process and patient monitoring during endoscopic procedures.

Table 1 Basal characteristics, unhealthy habits and clinical profiles of patients who received endoscopic intervention under sedation with Propofol

Characteristics	*n*	%
Basal characteristics		
Sex		
Female	432	62.3%
Male	261	37.7%
Age groups		
18–35	131	18.9%
36–53	319	46.0%
54–69	243	35.0%
Unhealthy habits		
Alcohol use		
Yes	28	4.1%
No	665	95.9%
Smoking		
Yes	20	2.9%
No	673	97.1%
Clinical profile		
ASA classification		
I	519	74.9%
II	163	23.5%
III	11	1.6%
Type of procedure		
Upper endoscopy	160	23.0%
Colonoscopy	198	28.6%
Upper endoscopy + colonoscopy	324	46.8%
Echoendoscopy or Endoscopic ultrasound	7	1.0%
ERCP	4	0.6%
Propofol total dose	170 ± 120*	
BMI (kg/m2) categories	26.3 ± 5.5*	
UW (< 18.5)	4	0.6%
HW (18.5–24.9)	225	32.5%
OW (25-29.9)	282	40.7%
O (≥ 30)	130	18.8%
No reported	52	7.5%
Mallampati Classification		
1	211	30.5%
2	414	59.7%
3	66	9.5%
4	2	0.3%
Procedure time		
≤ 20 min	423	61.1%
> 20 min	270	38.9%
Airway support measures		
Chin-lift maneuver	21	3.0%
Supplemental oxygen administration	82	11.8%
Recovery time (min)	15 ± 21*	

*median ± interquartile range. ERCP: endoscopic retrograde cholangiopancreatography. BMI: Body mass index. HW: Healthy weight. UW: Underweight. OW: Overweight. O: Obesity

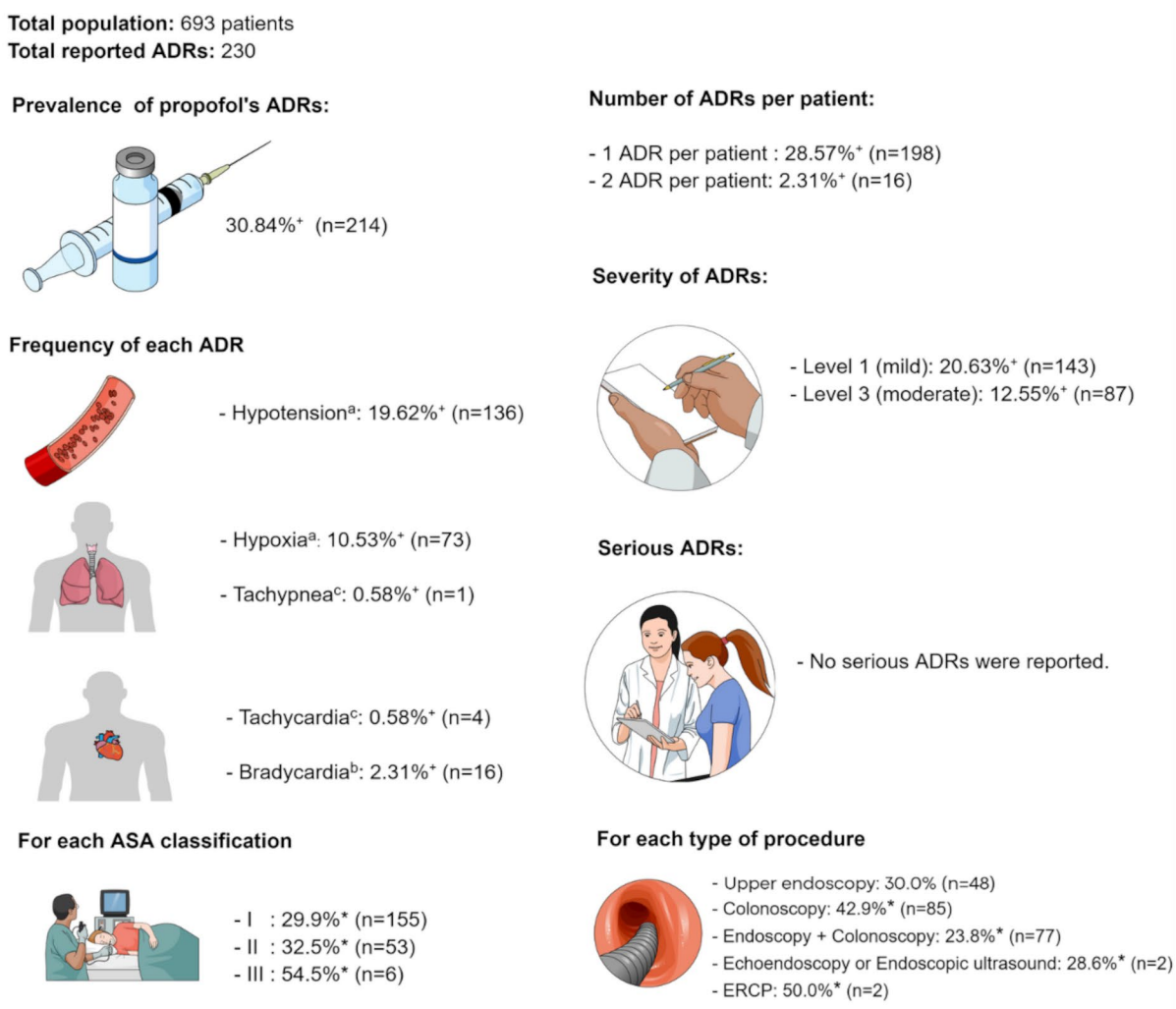

Fig. 2 Prevalence, frequency, and severity of adverse drug reactions reported in patients who received an endoscopic intervention performed under sedation with propofol

[+]These frequencies were calculated based on the total population ($n=693$). * These frequencies were calculated for each subpopulation of each ASA classification and type of procedure. [a]Very common (≥ 10%), [b]Common (≥ 1 and < 10%), and [c]Uncommon (≥ 0.1 and < 1%). ADR: adverse drug reaction; ERCP: endoscopic retrograde cholangiopancreatography

They play a critical role in maintaining the quality and safety of endoscopic procedures. There were few patients who required airway support measures (including the chin-lift maneuver and supplemental oxygen administration), and there was no need for further respiratory assistance in any patient. Similar to other works [3, 21], in our study, nurse-administered propofol sedation was safe and practical for outpatient gastrointestinal endoscopy.

In this study, we comprehensively documented every event that may be linked to an ADR, even if it was short-lived and appropriately resolved. We reported that 30.8% of the patients experienced at least one ADR during endoscopic intervention. The percentages of almost all the ADRs were consistent with the findings reported by Guzzo et al. [22], except for hypoxia, which was lower in our study. This difference could be attributed to our use of a smaller total propofol dose and our decision not to employ additional drugs during the endoscopic procedures [23].

All the ADRs we found were of mild or moderate severity. We did not encounter any SAEs in our study. It is possible that the lack of SAEs may be imputed to our sample size. Duprey et al. [7] reported serious cardiovascular adverse events (SCAEs) of intravenous sedative drugs over an 8-year period. In the case of propofol ($n=1596$), the percentages of patients with one or more SCAE events and the incidence of each SCAE event were 17% and 7 (10^6 days of sedative exposure), respectively. However, the authors included all reported events for propofol, not limited solely to endoscopic procedures. In another study, Wehrmann and Riphaus [24] showed that in a 6-year observation period of patients who received

Table 2 Bivariate and logistic regression analyses of adverse drug reactions to Propofol and other variables in patients who received endoscopic intervention under sedation with this drug

	Propofol's Adverse Drug Reaction				*p* value	PRc	95% CI	*p* value	PRa	95% CI
	No		Yes							
	n	%	*n*	%						
Sex										
Male	183	70.1	78	29.9		Ref.				
Female	296	68.5	136	31.5	0.659	1.05	[0.83–1.32]			
Age groups										
18–35	96	73.3	35	26.7		Ref.				
36–53	222	69.6	97	30.4	0.362	1.26	[0.90–1.76]			
54–69	161	66.3	82	33.7		1.13	[0.81–1.58]			
Alcohol use										
No	459	69	206	31		Ref.				
Yes	20	71.4	8	28.6	0.787	0.92	[0.50–1.67]			
Smoking										
No	463	68.8	210	31.2		Ref.				
Yes	16	80	4	20	0.324	0.64	[0.26–1.55]			
ASA Classification										
I y II	474	69.5	208	30.5		Ref.			Ref.	
III	5	45.5	6	54.5	**0.039**	**1.78**	**[1.03–3.10]**	**0.048**	**1.73**	**[1.01–2.99]**
Type of procedure										
Nonadvanced endoscopic procedure†	472	69.2	210	30.8		Ref.				
Advanced endoscopic procedure††	7	63.6	4	36.4	0.692	1.18	[0.53–2.60]			
Mallampati Classification										
1 and 2	429	68.6	196	31.4		Ref.				
3 and 4	50	73.5	18	26.5	0.421	0.84	[0.55–1.27]			
Procedure time										
≤ 20 min	323	76.4	100	23.6		Ref.			Ref.	
> 20 min	156	57.8	114	42.2	**< 0.0001**	**1.78**	**[1.43–2.23]**	**< 0.0001**	**2.05**	**[1.53–2.73]**
Total dose		160 ± 110*		190 ± 130*	**0.012**	**1.01**	**[1.00-1.02]**	0.145	0.99	[0.98-1.00]
BMI categories										
Non-O	345	67.5	166	32.5		Ref.				
O	91	70.0	39	30.0	0.592	1.08	0.81–1.44			

†Nonadvanced endoscopic procedures include upper endoscopy, colonoscopy, and upper endoscopy + colonoscopy. ††Advanced endoscopic procedures include echo-endoscopy or endoscopic ultrasound and endoscopic retrograde cholangiopancreatography (ERCP). BMI: body mass index. Non-O: Non-obesity (includes healthy weight, underweight, and overweight patients). O: Obesity. *Median ± interquartile range. PRc: prevalence ratio crude. PRa: prevalence ratio adjusted. Ref.: reference. 95% CI: 95% confidence interval

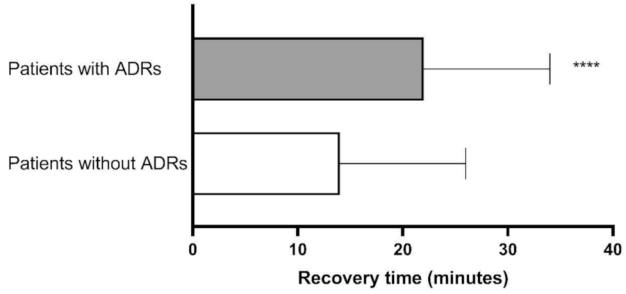

Fig. 3 Differences in recovery time after endoscopic intervention between patients with or without adverse drug reactions (ADRs) related to propofol use

propofol sedation for interventional endoscopic procedures ($n = 9547$), assisted ventilation was required for 40 patients (0.4%), endotracheal intubation was necessary for 9 patients (0.09%), 28 patients required additional monitoring in the intensive care unit (ICU) (0.3%), and 3 patients likely died due to sedation-related side effects (mortality rate, 0.03%).

Furthermore, we detailed the frequency of ADRs for each ASA classification and type of procedure. Compared to another study [25] with a similar context but performing sedation by an anesthesiologist, the ADR rate among ASA III class patients in our study was higher. This difference may be attributable to the expertise of the anesthesiologist in sedation management compared with a nurse. Similarly, the frequency of ADRs in patients under colonoscopy and endoscopy procedures was higher in our work than the findings reported by Sato et al. [3], which may relate to differences in the sedation propofol protocol. Nonetheless, these differences need to be confirmed with a larger sample size.

Multivariate analyses revealed that an ASA class III was associated with the occurrence of ADRs in patients receiving propofol sedation. However, due to the small number of participants with this ASA classification in our study, this result should still be confirmed. Other studies have documented both significant [24, 26] and nonsignificant [22, 25] associations between these variables. These disparities could be explained by differences in the study design, procedure complexity, and type of sedation administered.

A procedure time of more than 20 min was another independent risk factor in our study. Gemma et al. [26] reported an association between procedure duration and respiratory and cardiovascular adverse events in patients under propofol sedation during endoscopic interventions. This is possibly because prolonged procedures extend the exposure to the occurrence of ADRs in these patients.

In contrast with previous literature [22, 27], our findings showed that obesity was not a significant risk factor for propofol-related ADRs. This may be explained by the heterogeneity of obesity [28], as obese individuals with normal metabolic health (e.g., normal insulin sensitivity and blood pressure) may have a lower risk of complications [29]. Additionally, nurses administering propofol may have been more cautious with obese patients, reducing the risk of ADRs in this group. However, this result should be interpreted cautiously, and further research with larger sample sizes is necessary to confirm these observations and refine risk assessments for obese patients.

On the other hand, the overall recovery time in our study (15 min ± 21) was lower than that in other studies [22, 30]. Although it is difficult to make a direct comparison among these results without a comprehensive understanding of the recovery criteria used in each study, the longer stays observed in the other studies may be related to the use of benzodiazepines [30] and higher propofol doses during the process of sedation [7]. In addition, we showed that patients who experienced ADRs had longer recovery times than patients who did not experience these events.

This study has several limitations. First, the study primarily involved nonadvanced endoscopic procedures (upper endoscopy, colonoscopy, and upper endoscopy + colonoscopy), with the majority of patients having an ASA classification of I-II. Consequently, these findings were predominantly obtained within a low-risk context. Second, due to the unavailability of a suitable and accessible ADR data source in Peru [31], as well as the Food and Drug Administration's MedWatch Adverse Event Reporting System in the United States, we could not conduct a study with a large population. Third, this study could only show correlations and not establish causality among these variables. As strengths, this is the first study to evaluate the postmarketing safety profile of the use of propofol in endoscopic procedures in Peru, a low-income country, and it is one of the few such studies carried out in Latin America. This work highlights the importance of multidisciplinary collaboration among doctors, researchers, nurses, and pharmacists to investigate the safety profile of medications. Finally, although we included mainly a low-risk population, they constitute the majority of individuals receiving daily medical care in our country's hospitals.

Conclusion

This study showed that nurse-administered propofol sedation for endoscopic procedures was generally safe, but some risks were involved, such as increased adverse events in patients with higher ASA classification or longer procedures. These findings address a critical gap in understanding the safety of propofol when given by trained nurses, especially in outpatient settings. Further research is needed to evaluate the safety of propofol

sedation, particularly in higher-risk populations and for advanced endoscopic procedures.

Abbreviations

ADR	Adverse Drug Reaction
ASA	American Society of Anesthesiologists
CI	Confidence Interval
DCS	Data Collection Sheet
ERCP	Endoscopic Retrograde Cholangiopancreatography
PR	Prevalence Ratio
PRc	Prevalence Ratio Crude
PRa	Prevalence Ratio Adjusted

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Author contributions
JSC, AZ, and FS conceived and designed the study and drafted the manuscript. RI, JFS, and AZ analyzed and interpreted the study data. All authors acquired study data, revised the manuscript critically for important intellectual content, read and approved the final version of the manuscript, and agreed to its submission for publication. The corresponding author (JSC) and FS had full access to all the study data. All authors ensure the accuracy of the manuscript and agree to take personal responsibility for their contributions.

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Data availability
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This research was approved by the Institutional Research Ethics Committee of San Juan Bautista Private University (Registry No. 1277–2022 - CIEI-UPSJB). Because of retrospective study, informed consent was waived.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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