

# Safety of Propofol in Patients Undergoing Endoscopy and Colonoscopy

Arslan Shahzad<sup>1</sup>, Faria Mumtaz<sup>1</sup>, Javaria Isram<sup>1</sup> and Muhammad Tahir<sup>2</sup>

Propofol in Patients Undergoing Endoscopy and Colonoscopy

## ABSTRACT

**Objective:** To evaluate the safety profile of propofol sedation in patients undergoing endoscopy and colonoscopy.

**Study Design:** A retrospective observational study

**Place and Duration of Study:** This study was conducted at the department of Medicine and Gastroenterology, PAF Hospital, Islamabad, from January 2019 and September 2024.

**Methods:** Inclusion criteria encompassed all adult patients ( $\geq 18$  years) who received propofol for sedation during endoscopy or colonoscopy. Patients with incomplete medical records, those who received sedation other than propofol, or those with contraindications to sedation were excluded. Data collection included demographic information, comorbidities, procedure details, sedation-related parameters, safety parameters evaluation, and procedural outcomes.

**Results:** In a total of 6220 patients, 4806 (77.3%) underwent upper endoscopy whereas 1414 (22.7%) had colonoscopy performed. There were 3492 (56.1%) male patients. The mean age was  $53.28 \pm 15.70$  years. The mean propofol induction dose was  $0.6 \pm 0.1$  mg/kg in patients undergoing upper endoscopy, and  $0.7 \pm 0.2$  mg/kg in those undergoing colonoscopy ( $p < 0.001$ ). The mean procedure duration in patients undergoing upper endoscopy, and colonoscopy were  $18.25 \pm 4.77$  minutes, and  $21.59 \pm 5.24$  minutes ( $p < 0.001$ ), respectively. Procedural complications were reported in 108 (1.7%) patients, and the most common complications were respiratory depression, and hypotension, noted in 37 (0.6%), and 30 (0.5%), patients, respectively. Procedural success was reported in 6189 (99.5%) patients. The mean recovery time was significantly higher in patients undergoing colonoscopy ( $32.1 \pm 6.1$  minutes vs.  $30.5 \pm 5.2$  minutes,  $p < 0.001$ ).

**Conclusion:** This study reaffirms the safety and efficacy of propofol sedation in gastrointestinal endoscopy. With high procedural success rates, minimal adverse events, and rapid recovery times, propofol remains the sedative of choice for endoscopic procedures.

**Key Words:** Colonoscopy, endoscopy, hypotension, propofol, respiratory depression, sedation.

**Citation of article:** Shahzad A, Mumtaz F, Isram J, Tahir M. Safety of Propofol in Patients Undergoing Endoscopy and Colonoscopy. *Med Forum* 2024;35(12):3-7.doi:10.60110/medforum.351201.

## INTRODUCTION

Endoscopy and colonoscopy are essential diagnostic and therapeutic procedures commonly performed in gastroenterology and medicine clinics globally. The estimates show that around 18 million endoscopic procedures are performed annually in the US.<sup>1</sup> The increasing utilization of endoscopy and colonoscopy for gastrointestinal evaluations necessitates effective sedation protocols to ensure patient's comfort, reduce anxiety, and improve procedural outcomes.<sup>2</sup>

<sup>1</sup>. Department of Gastroenterology / Medicine<sup>2</sup>, PAF Hospital, Islamabad, Pakistan.

Correspondence: Dr. Arslan Shahzad, Associated Professor, Department of Gastroenterology, PAF Hospital, Islamabad, Pakistan.

Contact No: 0300-8521111

Email: drarslanshahzad@hotmail.com

Received: October, 2024

Accepted: October, 2024

Printed: November, 2024

While endoscopy, and colonoscopy procedures are generally safe when performed by trained professionals, but these are not without risks.<sup>3</sup> Safety concerns arise due to the invasiveness of the procedures, the use of sedatives or anesthetics, and patient-specific factors such as comorbidities.<sup>4</sup> Identifying and addressing these safety issues is critical to ensuring patient safety, optimizing procedural outcomes, and reducing complications.<sup>5</sup>

Propofol, a short-acting sedative-hypnotic agent, has become a preferred choice due to its rapid onset, predictable recovery profile, and patient tolerability.<sup>6,7</sup> Propofol is a popular form sedation for endoscopic procedures worldwide due to its rapid action and favorable recovery profile.<sup>8</sup> Propofol, administered by trained professionals, provides deep sedation with minimal residual effects. While its efficacy is well-documented, concerns remain about potential adverse events such as respiratory depression, hypotension, and rare cardiac complications.<sup>9</sup>

Understanding the safety and outcomes of propofol sedation, especially in large-scale settings, is essential to inform clinical guidelines and improve patient outcomes.

This study aims to provide real-world evidence of propofol's safety profile, focusing on complications, and patient outcomes. By analyzing data from a large sample size, this study seeks to identify factors that may predispose patients to adverse events, thereby guiding future clinical practice. The objective of this study was to evaluate the safety profile of propofol sedation in patients undergoing endoscopy and colonoscopy, with a focus on identifying the incidence of adverse events, procedural success rates, and patient outcomes.

## METHODS

This retrospective observational study was conducted at the department of Medicine and Gastroenterology, PAF Hospital, Islamabad, Pakistan. The study included all patients who underwent endoscopic procedures between January 2019 and September 2024. A total of 6220 patients undergoing endoscopic evaluation were included in the analysis. The data were retrieved from the hospital's electronic medical records, ensuring strict confidentiality and adherence to ethical guidelines. Inclusion criteria encompassed all adult patients ( $\geq 18$  years) who received propofol for sedation during endoscopy or colonoscopy. Patients with incomplete medical records, those who received sedation other than propofol, or those with contraindications to sedation were excluded. Ethical approval was obtained from the institutional review board (letter number: 241211-B). Given the retrospective design, the need for informed consent was waived, as no interventions or direct patient contact were involved.

Data collection included demographic information (age, gender, and body mass index), comorbidities (e.g., cardiovascular or pulmonary diseases), procedure details (type of procedure, duration, and therapeutic interventions), and sedation-related parameters (total dose of propofol, complications, and recovery time). The sedation protocol was standardized for all procedures. Propofol was administered by an anesthesiologist. Propofol dosage was tailored to patient needs and procedural requirements. The induction dose ranged from 0.5–1.0 mg/kg, administered over 1–2 minutes, with lower doses (0.25–0.5 mg/kg) used for elderly or debilitated patients to minimize complications. For maintenance of sedation, intermittent boluses (10–20 mg) or a continuous infusion (25–75 mcg/kg/min) was used, adjusted based on the desired sedation level and patient response. Propofol was delivered via IV with slow administration to avoid oversedation or cardiorespiratory depression. Supplemental oxygen was provided to all patients, and vital signs, including oxygen saturation, blood pressure, heart rate, and respiratory rate, were continuously monitored. Emergency airway management equipment was available throughout the procedures. Pre-

procedural fasting was ensured in all patients in accordance with established guidelines to minimize the risk of aspiration. Safety parameters included the incidence of adverse events. Respiratory depression was labeled as oxygen saturation  $< 90\%$  for  $> 30$  seconds, apnea  $\geq 20$  seconds, or requiring assisted ventilation. Hypotension was defined as systolic BP  $< 90$  mmHg or  $> 20\%$  drop from baseline, requiring intervention. Bradycardia was deemed as heart rate  $< 50$  bpm or  $> 20\%$  drop from baseline, persisting  $\geq 30$  seconds, requiring treatment. Arrhythmia was named if there was any abnormal rhythm (e.g., AF, VT) requiring clinical intervention. Bleeding was labeled as blood loss during/after the procedure needing hemostatic intervention or transfusion. Perforation was defined as the full-thickness GI tract tear confirmed by imaging or clinical signs, requiring repair. Aspiration was termed as inhalation of contents causing respiratory distress, oxygen desaturation, or confirmed on imaging. Adverse events were categorized as minor (e.g., transient hypoxemia or mild hypotension) or major (e.g., severe hypoxemia requiring intervention, prolonged hypotension, or cardiac arrest). The severity and management of complications were documented. Outcome measures included the incidence of adverse events, successful procedure completion rates, and recovery time. Secondary outcomes included the identification of patient- and procedure-related factors associated with adverse events. Statistical analysis was performed using IBM-SPSS Statistics, version 26.0. Continuous variables were expressed as means and standard deviations, while categorical variables were presented as frequencies and percentages. Comparisons between groups were made using the chi-square test for categorical data and t-tests for continuous data. A p-value of  $< 0.05$  was considered statistically significant.

## RESULTS

In a total of 6220 patients, 4806 (77.3%) underwent upper endoscopy whereas 1414 (22.7%) had colonoscopy performed. There were 3492 (56.1%) male, and 2728 (43.9%) female patients. The mean age was  $53.28 \pm 15.70$  years. It was found that there were significantly more male patients who underwent colonoscopy (60.0% vs. 55.0%,  $p < 0.001$ ). Age of patients undergoing colonoscopy was significantly higher ( $54.92 \pm 16.81$  years vs.  $52.14 \pm 15.37$  years,  $p < 0.001$ ). The mean BMI was  $24.8 \pm 4.5$  kg/m<sup>2</sup> in patients undergoing upper endoscopy, while it was  $26.2 \pm 5.0$  in patients who had colonoscopy performed ( $p < 0.001$ ). Comorbidities were reported in 1574 (25.3%) patients and distinct patterns were identified in patients undergoing upper endoscopy, and colonoscopy. Table-1 is showing comparison of characteristics of patients undergoing upper endoscopy, and colonoscopy.

**Table No. 1: Characteristics of patients (N=6220)**

Characteristics		Total (N=6220)	Upper Endoscopy (n=4806)	Colonoscopy (n=1414)	P-value
Gender	Male	3492 (56.1%)	2644 (55.0%)	848 (60.0%)	<0.001
	Female	2728 (43.9%)	2162 (45.0%)	566 (40.0%)	
Age (years)		53.28±15.70	52.14±15.37	54.92±16.81	<0.001
Body mass index (kg/m <sup>2</sup> )	Underweight (<18.5)	593 (9.5%)	480 (10.0%)	113 (8.0%)	<0.001
	Normal (18.5-24.9)	2941 (47.3%)	2403 (50.0%)	538 (38.0%)	
	Overweight (25-29.9)	1949 (31.3%)	1442 (30.0%)	507 (35.9%)	
	Obese (≥30)	737 (11.9%)	481 (10.0%)	256 (18.1%)	
Comorbidities	Cardiovascular diseases	634 (10.2%)	424 (8.8%)	210 (14.9%)	<0.001
	Diabetes mellitus	476 (7.7%)	302 (6.3%)	174 (12.3%)	<0.001
	Pulmonary diseases	297 (4.8%)	184 (3.8%)	113 (8.0%)	<0.001
	Others	167 (2.7%)	104 (2.2%)	63 (4.5%)	<0.001

The mean propofol induction dose was 0.6±0.1 mg/kg in patients undergoing upper endoscopy, and 0.7±0.2 mg/kg in those undergoing colonoscopy (p<0.001). The mean maintenance dose was 35.1±5.5 mcg/kg/min in upper endoscopy patients while it was 38.4±6.8 mcg/kg/min in patients undergoing colonoscopy (p<0.001). The mean procedure duration in patients undergoing upper endoscopy, and colonoscopy were 18.25±4.77 minutes, and 21.59±5.24 minutes

(p<0.001), respectively. Procedural complications were reported in 108 (1.7%) patients, and the most common complications were respiratory depression, hypotension, bradycardia, arrhythmias, and bleeding, noted in 37 (0.6%), 30 (0.5%), 18 (0.3%), 15 (0.2%), and 8 (0.1%) patients, respectively. None of the patients reported perforation, or aspiration. Table-2 is showing details of safety parameters in patients undergoing endoscopic evaluation.

**Table No. 2: Safety parameters evaluation**

Safety parameters	Total (N=6220)	Upper Endoscopy (n=4806)	Colonoscopy (n=1414)	P-value
Respiratory depression	37 (0.6%)	26 (0.5%)	11 (0.8%)	0.308
Hypotension	30 (0.5%)	22 (0.5%)	8 (0.6%)	0.606
Bradycardia	18 (0.3%)	12 (0.2%)	6 (0.4%)	0.283
Arrhythmias	15 (0.2%)	11 (0.2%)	4 (0.3%)	0.716
Bleeding	8 (0.1%)	6 (0.1%)	2 (0.1%)	0.878

Procedural success was reported in 6189 (99.5%) patients. Procedural failure was reported in 20 (0.4%) upper endoscopies and 11 (0.8%) colonoscopies. In upper endoscopy, the most common reasons were patient intolerance or inability to cooperate (n=10), followed by obstructive lesions or anatomical challenges (n=5), equipment malfunction (n=3), and complications such as bleeding (n=2). For colonoscopy,

the primary reason was inadequate bowel preparation (n=6), with additional failures due to patient discomfort or refusal to continue (n=3) and anatomical variations or obstructive pathology (n=2). The mean recovery time was significantly higher in patients undergoing colonoscopy (32.1±6.1 minutes vs. 30.5±5.2 minutes, p<0.001), as shown in table-3.

**Table No. 3: Comparison of Outcomes**

Outcomes		Total (N=6220)	Upper Endoscopy (n=4806)	Colonoscopy (n=1414)	P-value
Procedural success	Yes	6189 (99.5%)	4786 (99.6%)	1403 (99.2%)	0.089
	No	31 (0.5%)	20 (0.4%)	11 (0.8%)	
Recovery time (minutes)		31.4±5.5	30.5±5.2	32.1±6.1	<0.001

**DISCUSSION**

This study demonstrated that propofol sedation is safe and effective, with high procedural success rates and

minimal complications. Our study reported a procedural success rate of 99.5%, with 99.6% success in upper endoscopy and 99.2% in colonoscopy. These rates align closely with those reported by Horiuchi et al., who

observed a 100% procedural success rate in their analysis of 2,101 outpatient colonoscopies under propofol sedation.<sup>10</sup> Sato et al., reported success rates exceeding 99% in their cohort of 32,550 colonoscopies and 117,661 esophagogastroduodenoscopies.<sup>11</sup> A recently study by Lu et al reported the sedation success rates of propofol as 98.3% in elderly outpatients undergoing GI endoscopy exhibiting its effectiveness.<sup>12</sup> The consistency across studies underscores propofol's efficacy in facilitating successful endoscopic procedures.

The low incidence of adverse events in our study corroborates findings from previous research. Respiratory depression, hypotension, bradycardia, arrhythmias, and bleeding were observed in 0.6%, 0.5%, 0.3%, 0.2%, and 0.1% of patients, respectively. In comparison, Heuss et al. reported transient oxygen desaturation (<90%) in 1.7% of low-risk patients (ASA I and II) and 3.6% of high-risk patients (ASA III and IV).<sup>13</sup> Sato et al. observed a 1.3% incidence of transient oxygen desaturation in their large-scale study.<sup>11</sup> These minor discrepancies may be attributed to differences in patient populations, sedation protocols, and monitoring techniques. The present study involved anesthesiologist-administered sedation, whereas many previous studies utilized nurse-administered protocols.<sup>14,15</sup>

The mean recovery time in our study was 31.4±5.5 minutes, with shorter times for upper endoscopy (30.5±5.2 minutes) compared to colonoscopy (32.1±6.1 minutes;  $p < 0.001$ ). Sipe et al. reported similar recovery times, with most patients standing unassisted within 10 minutes and being discharged within 37 minutes.<sup>16</sup> The rapid recovery associated with propofol reflects its favorable pharmacokinetic profile, characterized by a short half-life and rapid clearance.

The clinical implications of our findings are significant. Propofol sedation facilitates high procedural success rates, shortens recovery times, and maintains an excellent safety profile, even in resource-limited settings.<sup>17,18</sup> These advantages make propofol an ideal sedative for gastrointestinal endoscopy. The findings of this study support the continued use of propofol by trained anesthesiologists, particularly in settings where patient safety is paramount.<sup>19</sup> Notably, our study highlights the importance of individualized dosing with propofol.<sup>20</sup> The mean propofol induction dose was 0.6±0.1 mg/kg for upper endoscopy and 0.7±0.2 mg/kg for colonoscopy ( $p < 0.001$ ), reflecting procedural differences in sedation requirements. Maintenance doses were similarly tailored, with colonoscopy patients requiring higher doses (38.4±6.8 mcg/kg/min) compared to upper endoscopy patients (35.1±5.5 mcg/kg/min;  $p < 0.001$ ). These findings underscore the need for dose adjustments based on procedural complexity, patient factors, and desired sedation depth.<sup>21</sup> This study also highlights the role of robust

monitoring and preparation in minimizing adverse events. Pre-procedural fasting, continuous monitoring of vital signs, and the availability of emergency airway management equipment contributed to the low incidence of complications.<sup>22</sup> These measures should remain standard practice in endoscopic sedation protocols.

This study has several limitations. The retrospective design limits our ability to establish causality or control for unmeasured confounders. The single-center setting may limit the generalizability of our findings to other populations or healthcare systems. While we documented adverse events during the procedures, post-discharge complications were not assessed, potentially underestimating the true incidence of adverse events. Finally, our reliance on electronic medical records may have introduced reporting bias, as minor events might not have been consistently documented.

## CONCLUSION

This study reaffirms the safety and efficacy of propofol sedation in gastrointestinal endoscopy. With high procedural success rates, minimal adverse events, and rapid recovery times, propofol remains the sedative of choice for endoscopic procedures. The findings emphasize the importance of individualized dosing, robust monitoring, and adherence to sedation protocols to optimize patient outcomes.

### Author's Contribution:

Concept & Design or acquisition of analysis or interpretation of data:	Arslan Shahzad, Faria Mumtaz
Drafting or Revising Critically:	Javaria Isram, Muhammad Tahir
Final Approval of version:	All the above authors
Agreement to accountable for all aspects of work:	All the above authors

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

**Source of Funding:** None

**Ethical Approval:** No.241211-P dated 'nil'

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