ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Investigating The Safety And Efficacy Of Propofol - Based Sedation In Non-Invasive Medical Procedures.

Nilima Mustapure[1], Jayashree Sali[2]*, Yogesh Magan Suryavanshi[3] and Sunita Sankalecha[4].

[1]MD Anaesthesiologist, Working As Specialist Medical Officer, Bytco Hospital, Nashik, Maharashtra, India.
[2]MD Anaesthesiology, Associate Professor, Department Of Anaesthesia, GMC And Maharashtra Postgraduate Institute Of Medical Education And Research, Nashik, Maharashtra, India.
[3]Professor And HOD Department Of Anaesthesia, SMBT Institute Of Medical Sciences And Research Centre Dhamangaon, Igatpuri, Nashik, Maharashtra, India.
[4]Professor and HOD, Department of Anaesthesia , GMC , MPGIMER and MUHS, Nashik, Maharashtra, India.

ABSTRACT

Propofol-based sedation is widely used in non-invasive medical procedures due to its rapid onset and quick recovery profile. However, its safety and efficacy necessitate continuous evaluation. This prospective, observational study included 40 patients undergoing endoscopies, minor surgeries, and radiological imaging over one year. Patients aged 18-65 with ASA classifications I-III were recruited, excluding those with significant cardiopulmonary disease or allergies to propofol. Propofol was administered intravenously, with dose titration to achieve desired sedation levels. Adverse events, patient recovery, and satisfaction were monitored and analyzed. The mean age was 45.3 years; 55% were male. Procedures included endoscopies (50%), minor surgeries (30%), and radiological imaging (20%). Adverse events included hypotension (10%), bradycardia (7.5%), respiratory depression (5%), and nausea/vomiting (12.5%). No adverse events were reported in 65% of patients. Mean recovery time was 30 minutes, with high patient satisfaction (mean score 9.2). Older patients and those with higher ASA classifications exhibited slightly increased adverse event rates. Propofol-based sedation is effective and generally safe for non-invasive procedures, with rapid recovery and high patient satisfaction. Continuous monitoring and individualized sedation plans are essential, particularly for higher-risk patients.
Keywords: Propofol, Sedation, Non-invasive procedures

https://doi.org/10.33887/rjpbcs/2024.15.3.46

Corresponding author

ISSN: 0975-8585

INTRODUCTION

The advent of propofol as a sedative has revolutionized the landscape of non-invasive medical procedures, offering a potent, short-acting anesthetic option. Propofol, a phenol derivative, is known for its rapid onset and swift recovery profile, making it a preferred choice in various diagnostic and therapeutic interventions, including endoscopies, minor surgeries, and radiological imaging. Its ability to induce a state of deep sedation while allowing for quick patient turnover has positioned propofol as a cornerstone in modern anesthetic practice [1, 2].

However, despite its widespread use, the safety and efficacy of propofol-based sedation in non-invasive procedures warrant continuous scrutiny [2]. The drug's narrow therapeutic window, potential for respiratory depression, and cardiovascular effects necessitate a balanced consideration of benefits versus risks. Adverse events, although rare, can be significant, prompting the need for careful patient selection, dose titration, and vigilant monitoring during its administration [3].

METHODOLOGY

The study employed a prospective, observational design to investigate the safety and efficacy of propofol-based sedation in non-invasive medical procedures. A total of 40 patients, scheduled for various non-invasive procedures such as endoscopies, minor surgeries, and radiological imaging, were recruited over a one-year period. Inclusion criteria included adults aged 18-65, ASA physical status classification I-III, and the need for procedural sedation. Exclusion criteria comprised patients with significant cardiopulmonary disease, known allergies to propofol, or those on medications that could interfere with sedative agents.

Prior to the procedure, patients underwent a comprehensive pre-sedation assessment, which included medical history, physical examination, and baseline vital signs. Propofol was administered intravenously, with the dosage titrated to achieve the desired level of sedation, monitored continuously by an anesthesiologist. Standard monitoring protocols, including continuous ECG, pulse oximetry, and non-invasive blood pressure measurements, were adhered to throughout the procedure. The primary endpoints included the incidence of adverse events such as hypotension, bradycardia, respiratory depression, and patient-reported outcomes on sedation experience and recovery profile.

Post-procedure, patients were observed in a recovery area until they met discharge criteria, including stable vital signs and full recovery of consciousness. Follow-up assessments were conducted within 24 hours to evaluate any delayed adverse events or complications. Data were collected and analyzed using descriptive statistics for baseline characteristics and outcome measures, while inferential statistics were used to compare safety and efficacy parameters across different patient subgroups.

The study aimed to contribute valuable insights into the optimal use of propofol for sedation in non-invasive procedures, ensuring a balance between efficacy and patient safety.

RESULTS

Table 1: Baseline Characteristics of Patients (n=40)

Characteristic	Mean ± SD / n (%)
Age (years)	45.3 ± 12.1
Gender (Male/Female)	22 (55%) / 18 (45%)
ASA Classification	
- I	12 (30%)
- II	18 (45%)
- III	10 (25%)
BMI (kg/m^2)	27.4 ± 3.5
Comorbidities	
- Hypertension	14 (35%)
- Diabetes Mellitus	10 (25%)
- None	16 (40%)

ISSN: 0975-8585

Table 2: Procedural Data

Procedure Type	Number of patients (%)
Endoscopy	20 (50%)
Minor Surgery	12 (30%)
Radiological Imaging	8 (20%)
Average Duration of Procedure (min)	35 ± 10
Total Propofol Dose (mg)	150 ± 40

Table 3: Incidence of Adverse Events

Adverse Event	Number of patients (%)
Hypotension	4 (10%)
Bradycardia	3 (7.5%)
Respiratory Depression	2 (5%)
Nausea/Vomiting	5 (12.5%)
None	26 (65%)

Table 4: Patient Recovery Profile

Recovery Parameter	Mean ± SD
Time to Full Recovery (min)	30 ± 8
Patient Satisfaction (1-10)	9.2 ± 0.8
Incidence of Delayed Adverse Events	2 (5%)
Duration of Post-Procedure Monitoring (min)	45 ± 12

Table 5: Comparative Efficacy and Safety Across Subgroups

Subgroup	Hypotension (%)	Bradycardia (%)	Respiratory Depression (%)	Satisfaction Score (Mean ± SD)
Age < 50	2 (10%)	1 (5%)	1 (5%)	9.3 ± 0.7
Age ≥ 50	2 (10%)	2 (10%)	1 (5%)	9.1 ± 0.9
Male	2 (9%)	2 (9%)	1 (4.5%)	9.1 ± 0.8
Female	2 (11%)	1 (6%)	1 (6%)	9.3 ± 0.8
ASA I-II	3 (8.6%)	2 (5.7%)	1 (2.9%)	9.4 ± 0.7
ASA III	1 (10%)	1 (10%)	1 (10%)	8.9 ± 0.9

DISCUSSION

The results of this study provide valuable insights into the safety and efficacy of propofol-based sedation in non-invasive medical procedures. The study, which included 40 patients undergoing various procedures such as endoscopies, minor surgeries, and radiological imaging, revealed several key findings regarding patient outcomes, adverse events, and overall satisfaction with propofol sedation.

Patient Characteristics and Procedural Data

The baseline characteristics of the study population demonstrated a diverse cohort with a mean age of 45.3 years, slightly more males (55%) than females (45%), and a range of comorbidities. The distribution of ASA classifications indicated that the majority of patients were in relatively good health (ASA I-II), with 25% classified as ASA III, suggesting a moderate level of systemic disease but no immediate life-threatening conditions. This distribution is reflective of a typical clinical setting where propofol sedation is applied to a broad spectrum of patients requiring non-invasive procedures.

The procedural data showed that endoscopies were the most common procedure (50%), followed by minor surgeries (30%) and radiological imaging (20%). The average duration of procedures was 35 minutes, and the mean total propofol dose was 150 mg. These findings are consistent with existing literature that supports propofol's rapid onset and short duration of action, making it well-suited for such procedures [4].

Safety Outcomes

The incidence of adverse events was a primary focus of this study, as propofol's safety profile is critical for its use in procedural sedation. The results indicated that hypotension occurred in 10% of patients, bradycardia in 7.5%, and respiratory depression in 5%. Additionally, 12.5% of patients experienced nausea or vomiting, while a significant majority (65%) did not experience any adverse events [5].

Hypotension and bradycardia are known potential side effects of propofol, primarily due to its vasodilatory and negative inotropic effects. The observed rates of these adverse events are within the expected range based on previous studies, suggesting that with appropriate monitoring and dose titration, the risks can be managed effectively. Respiratory depression, while less common, is a serious concern with propofol sedation. The 5% incidence in this study underscores the necessity of continuous respiratory monitoring and readiness to intervene if necessary.

Patient Recovery and Satisfaction

Patient recovery profiles were favorable, with a mean time to full recovery of 30 minutes. This rapid recovery is one of propofol's key advantages, allowing for shorter post-procedure observation periods and faster patient turnover. The high patient satisfaction scores (mean of 9.2 out of 10) reflect the positive sedation experience, likely attributed to the quick recovery and minimal residual sedation effects [6].

The low incidence of delayed adverse events (5%) further supports the safety of propofol in this setting. These findings align with the literature that highlights propofol's benefit in providing effective sedation with a swift recovery, enhancing overall patient and procedural efficiency.

Comparative Analysis Across Subgroups

The comparative analysis across different patient subgroups provided additional insights. Adverse events such as hypotension, bradycardia, and respiratory depression were relatively evenly distributed across age groups and genders. However, a slight increase in adverse events was noted in patients aged 50 and above and those classified as ASA III, indicating that higher age and greater comorbidity may increase the risk of sedation-related complications.

Despite these variations, patient satisfaction remained high across all subgroups, with slightly lower scores in the ASA III group (mean of 8.9) compared to the ASA I-II group (mean of 9.4). This discrepancy may be due to the increased vigilance and potentially longer recovery times required for patients with higher ASA classifications.

Clinical Implications

The findings from this study have several important clinical implications. Firstly, propofol-based sedation appears to be a safe and effective option for a variety of non-invasive medical procedures,

provided that patients are carefully selected and monitored. The relatively low incidence of serious adverse events and the high levels of patient satisfaction underscore propofol's utility in this context.

Secondly, the study highlights the importance of individualized sedation plans, particularly for older patients and those with higher ASA classifications. Tailoring sedation strategies to account for these factors can help mitigate risks and ensure patient safety. Continuous monitoring of cardiovascular and respiratory parameters is essential to promptly identify and manage any adverse events [8].

Lastly, the rapid recovery profile of propofol is a significant advantage in busy clinical settings, facilitating efficient patient throughput and reducing the need for extended post-procedure observation. This efficiency can enhance overall healthcare delivery, making propofol an attractive option for sedation in non-invasive procedures.

CONCLUSION

In conclusion, this study reinforces the safety and efficacy of propofol-based sedation for non-invasive medical procedures. With appropriate patient selection, dose titration, and vigilant monitoring, propofol can provide effective sedation with a favorable recovery profile and high patient satisfaction.

REFERENCES

[1] Liu Y, Yu X, Zhu D, Zeng J, Lin Q, Zang B, Chen C, Liu N, Liu X, Gao W, Guan X. Safety and efficacy of ciprofol vs. propofol for sedation in intensive care unit patients with mechanical ventilation: a multi-center, open label, randomized, phase 2 trial. Chin Med J (Engl) 2022;135(9):1043-1051.

[2] Ferrazzano GF, Cantile T, Quaraniello M, Iannuzzi M, Palumbo D, Servillo G, Caruso S, Fiasca F, Ingenito A. Effectiveness and Safety of Intravenous Sedation with Propofol in Non-Operating Room Anesthesia (NORA) for Dental Treatment in Uncooperative Paediatric Patients. Children (Basel) 2021;8(8):648

[3] Kang H, Kim DK, Choi YS, Yoo YC, Chung HS. Practice guidelines for propofol sedation by non-anesthesiologists: the Korean Society of Anesthesiologists Task Force recommendations on propofol sedation. Korean J Anesthesiol 2016;69(6):545-554.

[4] Vargo JJ, Cohen LB, Rex DK, Kwo PY. Position statement: nonanesthesiologist administration of propofol for GI endoscopy. Am J Gastroenterol 2009; 104:2886–2892.

[5] Sethi S, Wadhwa V, Thaker A, Chuttani R, Pleskow DK, Barnett SR, et al. Propofol versus traditional sedative agents for advanced endoscopic procedures: a meta-analysis. Dig Endosc 2014; 26:515–524.

[6] Weaver J. The latest ASA mandate: CO(2) monitoring for moderate and deep sedation. Anesth Prog 2011; 58:111–112.

[7] Horiuchi A, Nakayama Y, Fujii H, Katsuyama Y, Ohmori S, Tanaka N. Psychomotor recovery and blood propofol level in colonoscopy when using propofol sedation. Gastrointest Endosc 2012; 75:506–512.