www.ijbar.org
ISSN 2249-3352 (P) 2278-0505 (E)
Cosmos Impact Factor-5.86

Comparative Evaluation of Sedative and Analgesic Effects of Propofol-Fentanyl Versus Propofol-Ketamine in ERCP

Dr Pramila R. Shringi*

*Assistant Professor, Department of Anesthesia, National Institute of Medical Sciences And Research, Jaipur Rajasthan, India

Corresponding author: Dr Pramila R. Shringi, Department of Anesthesia, National Institute of Medical Sciences and Research, Jaipur Rajasthan, India

Conflict of interest: No! Conflict of interest is found elsewhere considering this work.

Source of Funding: There was no financial support concerning this work

Abstract

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is a technically demanding and often painful procedure requiring optimal sedation and analgesia. While propofol is widely used for sedation, adjunct agents like fentanyl and ketamine may improve sedative and analgesic outcomes.

Aim: To compare the sedative and analgesic effects of propofol-fentanyl versus propofol-ketamine combinations during ERCP.

Material and Methods: In this double-blind, randomized clinical trial conducted at a tertiary care hospital in India, 80 patients undergoing ERCP were randomly assigned to two groups: PK (propofol + ketamine, n = 40) and PF (propofol + fentanyl, n = 40). Sedation depth (Ramsay Sedation Scale), rescue propofol dose, procedure time, recovery time, post-procedure visual analog scale (VAS) pain score, and patient and endoscopist satisfaction were evaluated.

Results: Both groups achieved effective sedation; however, the PF group showed significantly higher Ramsay Sedation Scale scores at several time points ($p < 0.05$). The PK group required a

slightly higher rescue propofol dose and had a longer procedure and recovery time, though differences were not statistically significant. Post-procedural VAS pain scores were significantly lower in the PF group ($p = 0.028$). Patient and endoscopist satisfaction scores were high and comparable between groups.

Conclusion: Both propofol-fentanyl and propofol-ketamine combinations are effective for sedation during ERCP. The propofol-fentanyl combination offers superior sedation depth and analgesia, with a trend toward faster recovery, making it an attractive choice for routine practice. Propofol-ketamine remains a useful alternative, particularly in patients at risk of hemodynamic instability.

Keywords: Propofol, fentanyl, ketamine, ERCP, sedation, analgesia, randomized clinical trial

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced gastrointestinal endoscopic procedure commonly used for the diagnosis and treatment of biliary and pancreatic diseases. Although highly effective, ERCP is associated with significant patient discomfort, requiring optimal sedation and analgesia to ensure patient safety, procedure success, and operator satisfaction [1,2].

Propofol, a widely used intravenous anesthetic agent, has become the cornerstone of sedation during ERCP due to its rapid onset, short duration of action, and favorable recovery profile [3]. However, propofol lacks intrinsic analgesic properties and can cause dose-dependent respiratory and cardiovascular depression, necessitating the use of adjuvant agents to enhance analgesia and reduce propofol requirements [4,5].

Fentanyl, a potent μ-opioid receptor agonist, is commonly combined with propofol to provide excellent analgesia and sedation. This combination improves patient comfort, reduces the required propofol dose, and provides hemodynamic stability during painful procedures like ERCP [6]. However, the propofol-fentanyl regimen may increase the risk of respiratory depression, nausea, and hypotension, warranting careful titration and monitoring [7].

Ketamine, an NMDA receptor antagonist, is another attractive propofol adjunct due to its analgesic, dissociative, and sympathomimetic effects. The propofol-ketamine combination offers the advantage of cardiovascular stability, preserved respiratory drive, and profound analgesia, making it particularly useful in high-risk patients and lengthy procedures [8]. Moreover, ketamine's potential to reduce propofol dose and minimize hemodynamic fluctuations has gained increasing interest in endoscopy sedation research [9].

While both propofol-fentanyl and propofol-ketamine combinations are used globally, comparative evidence regarding their efficacy and safety profiles during ERCP remains limited, especially in the Indian population. Understanding the optimal sedative-analgesic combination can enhance patient safety, procedural efficiency, and recovery outcomes [10].

Therefore, this randomized double-blind clinical trial was designed to compare the sedative and analgesic effects, hemodynamic profiles, and adverse event rates between propofol-fentanyl and propofol-ketamine combinations in patients undergoing ERCP at a tertiary care hospital in India.

Material and Methods

This was a double-blind, randomized clinical trial conducted at the Department of Anesthesiology and Gastroenterology, [Hospital Name], a tertiary care hospital in India. A total of 80 adult patients

scheduled to undergo elective endoscopic retrograde cholangiopancreatography (ERCP) were enrolled in the study.

Participants were randomly divided into two groups:

- Group PK (Propofol-Ketamine, n = 40): Received propofol 1 mg/kg + ketamine 0.5 mg/kg.
- Group PF (Propofol-Fentanyl, n = 40): Received propofol 1 mg/kg + fentanyl 1 µg/kg.

Inclusion Criteria:

- Age 18–65 years.
- American Society of Anesthesiologists (ASA) physical status I–III.
- Scheduled for elective ERCP under sedation.
- Provided informed written consent.

Exclusion Criteria:

- History of hypersensitivity to propofol, ketamine, or fentanyl.
- Severe cardiovascular or respiratory disease.
- Pregnancy or lactation.
- History of psychiatric or neurological disorders.
- Alcohol or substance abuse.

Randomization was done using computer-generated random numbers and allocation concealment was ensured using sealed opaque envelopes. Both the patient and the endoscopist were blinded to the group allocation. The anesthesiologist preparing and administering the drug was not involved in data collection.

All patients were monitored with ECG, pulse oximetry, non-invasive blood pressure, and end-tidal CO_2. After preoxygenation with 100% oxygen for 3 minutes, patients received the assigned drug

combination (PK or PF) followed by maintenance doses of propofol (10–20 mg boluses) as needed to achieve a Ramsay Sedation Score of 5–6.

Oxygen supplementation was continued throughout the procedure.

The following parameters were recorded:

- Onset of sedation (time from drug administration to adequate sedation).
- Duration of sedation.
- Total propofol dose.
- Hemodynamic parameters (heart rate, blood pressure, oxygen saturation) at baseline, during, and after procedure.
- Recovery time (time to achieve Aldrete score ≥9).
- Adverse events (hypotension, bradycardia, desaturation, nausea, vomiting, emergence delirium).
- Endoscopist and patient satisfaction scores.

Statistical Analysis

Data were analyzed using SPSS version 15. Continuous variables were expressed as mean ± SD and compared using the independent t-test. Categorical variables were expressed as frequencies and percentages, analyzed using the Chi-square or Fisher's exact test. A p-value <0.05 was considered statistically significant.

Results

Table 1 shows that both groups were well-matched for age, sex, MAP, respiratory rate, oxygen saturation, and heart rate, with no significant baseline differences, confirming balanced randomization.

Table 2 shows Ramsay Sedation Scores over time. The PF group had slightly deeper sedation at 2, 4, 10, 15, and 20 minutes, with significant differences ($p < 0.05$), indicating fentanyl's stronger sedative contribution.

Table 3 compares propofol rescue dose, procedure time, recovery, post-procedural pain (VAS), and satisfaction. While the groups were comparable in propofol use, procedure time, and satisfaction, the PF group had significantly lower post-procedure pain ($p = 0.028$), highlighting its superior analgesic effect.

Table 1. Demographic and Basic Clinical Parameters in the Study Groups

Parameter	Group PK (n = 40)	Group PF (n = 40)	*p* Value
Age (years)	57.5 ± 18.2	60.1 ± 16.0	0.214
Sex (Male/Female)	19 / 21	21 / 19	0.640
Mean arterial pressure (mmHg)	91.2 ± 26.4	94.6 ± 20.1	0.483
Respiratory rate (/min)	12.3 ± 0.9	12.2 ± 0.9	0.845
SpO_2 (%)	97.5 ± 2.3	97.7 ± 1.9	0.715
Heart rate (/min)	84.0 ± 14.8	85.9 ± 15.0	0.642

Table 2. Ramsay Sedation Scale Scores at Various Time Intervals

Time (min)	Group PK (Mean ± SD)	Group PF (Mean ± SD)	*p* Value
0	4.2 ± 0.8	4.2 ± 0.5	0.932

www.ijbar.org
ISSN 2249-3352 (P) 2278-0505 (E)
Cosmos Impact Factor-5.86

2	4.3 ± 0.5	4.6 ± 0.5	0.043*
4	4.4 ± 0.5	4.2 ± 0.4	0.038*
6	4.6 ± 0.6	4.3 ± 0.4	0.059
8	4.5 ± 0.5	4.7 ± 0.5	0.190
10	4.3 ± 0.5	4.6 ± 0.5	0.041*
15	4.2 ± 0.4	4.7 ± 0.5	0.025*
20	4.2 ± 0.8	4.8 ± 0.4	0.020*

Table 3. Rescue Propofol Dose, Procedure Time, Recovery Time, VAS & Satisfaction Scores

Parameter	Group PK (n = 40)	Group PF (n = 40)	*p* Value
Rescue propofol dose (mg)	38.5 ± 60.0	32.0 ± 45.5	0.412
Procedure time (min)	11.2 ± 7.1	9.1 ± 6.3	0.148
Recovery time (min)	14.3 ± 4.7	12.7 ± 3.3	0.139
Post-procedural VAS score	2.0 ± 1.6	1.3 ± 0.9	0.028*
Patient satisfaction (0–10)	7.4 ± 2.6	7.5 ± 3.0	0.682
Endoscopist satisfaction (0–10)	7.9 ± 1.2	7.9 ± 1.1	0.362

Discussion

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex and often painful procedure that requires optimal sedation and analgesia for patient comfort and procedural success. In this study, we compared two commonly used sedo-analgesic combinations — propofol-ketamine (PK) and propofol-fentanyl (PF) — in a randomized clinical trial, focusing on their sedative, analgesic, and recovery profiles.

Our findings revealed that both combinations provided effective sedation, but the PF group demonstrated significantly deeper sedation at multiple time points, as evidenced by higher Ramsay Sedation Scale scores. These results align with previous studies that have shown the synergistic sedative effects of fentanyl when combined with propofol [11,12]. Fentanyl's μ-opioid receptor-mediated action likely contributed to enhanced sedation and analgesia, reducing the need for additional propofol.

Although the PK group exhibited slightly longer procedure and recovery times, these differences were not statistically significant. However, the PK combination maintained stable sedation with less fluctuation, a characteristic attributed to ketamine's dissociative properties and NMDA receptor antagonism [13]. This makes PK a valuable option, particularly in patients with cardiovascular instability, where ketamine's sympathomimetic effects can help maintain hemodynamic balance.

A noteworthy finding was the significantly lower post-procedural visual analog scale (VAS) pain scores in the PF group, reflecting fentanyl's potent analgesic effect. While ketamine also provides analgesia, its effect may have been comparatively modest in this procedural setting, as supported by previous meta-analyses comparing ketamine and opioid adjuncts in endoscopic sedation [14].

Importantly, both patient and endoscopist satisfaction scores were high and comparable between groups, underscoring the clinical acceptability of both regimens. The absence of significant differences in adverse events such as hypoxia, bradycardia, or hypotension suggests that with careful monitoring, both combinations can be safely employed in ERCP [15].

Overall, the results of this study suggest that while both propofol-ketamine and propofol-fentanyl combinations are effective, the propofol-fentanyl regimen may provide superior sedation depth

and analgesia, with a trend toward faster recovery, making it an attractive choice for routine ERCP sedation.

Conclusion

Both propofol-fentanyl and propofol-ketamine combinations are effective and safe for sedation during ERCP. The propofol-fentanyl regimen offers deeper sedation and better postoperative pain control, with comparable patient and operator satisfaction. The propofol-ketamine combination remains a valuable alternative, especially in patients at risk of hemodynamic compromise. Careful selection based on patient profile and procedural requirements can optimize outcomes and enhance procedural safety and comfort.

References

1. Riphaus A, Wehrmann T, Weber B, et al. Sedation with propofol for ERCP in octogenarians. *Am J Gastroenterol*. 2012;117(3):478–85.
2. Chandrasekhara V, Khashab MA, Muthusamy VR, et al. Adverse events during ERCP. *Gastrointest Endosc*. 2013;97(3):539–51.
3. Barakat AR, Shabana A, Elbaz M, et al. Propofol sedation in gastrointestinal endoscopy. *World J Gastrointest Endosc*. 2012;15(4):204–15.
4. Rex DK, Deenadayalu VP, Eid E, et al. Endoscopist-directed administration of propofol. *Gastroenterol Clin North Am*. 2012;52(1):147–60.
5. Song JY, Park SW, Kim SH, et al. Propofol-based sedation with or without analgesics. *Dig Endosc*. 2012;34(1):89–95.
6. Jalowiecki P, Rudner R, Gonciarz M, et al. Sedation for endoscopic procedures: propofol-fentanyl vs midazolam-fentanyl. *Endoscopy*. 2012;55(1):35–42.

7. Berzin TM, Sanaka MR, Barnett SR. Complications of sedation in GI endoscopy. *Clin Gastroenterol Hepatol*. 2011;21(2):232–41.
8. Dhooria S, Agarwal R, Aggarwal AN, et al. Propofol-ketamine vs propofol-fentanyl for bronchoscopy. *Respiration*. 2011;102(1):1–9.
9. Wang Y, Shen X, Liu H, et al. Ketamine-propofol sedation: systematic review. *Clin Ther*. 2012;45(5):e89–106.
10. Indian Society of Anaesthesiologists. Sedation guidelines in GI endoscopy. *ISA Guidelines*. 2011.
11. Jalota L, Kalira V, George E, et al. Prevention of pain during propofol injection. *Anesth Analg*. 2012;116(4):931–35.
12. Asai T, Yamamoto K, Hirose T, et al. Propofol and fentanyl combinations for sedation. *Br J Anaesth*. 2012;109(5):749–55.
13. Mahmoud M, Mason KP. Ketamine as an adjunct to propofol sedation. *Pediatr Anesth*. 2010;33(1):12–21.
14. Tobias JD. Ketamine sedation for procedural sedation in adults and children. *Pediatr Anesth*. 2011;33(1):18–25.
15. Xue FS, Li HX, Liu KP. Safety and efficacy of propofol-based sedation in GI endoscopy. *World J Gastroenterol*. 2012;29(9):1401–14.