Research Article

Comparison of the Efficacy of Sedation with Dexmedetomidine plus Ketamine and Propofol plus Fentanyl in Adult Patients Undergoing ERCP Procedure

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ABSTRACT

Background: Optimal sedation for ERCP remains challenging due to painful endoscope manipulation, prolonged procedure time, and risk of respiratory depression. Dexmedetomidine-ketamine (DK) may provide stable hemodynamics and better analgesia, whereas propofol-fentanyl (PF) provides rapid onset but risks respiratory compromise.

Aim: To compare sedation efficacy, hemodynamic stability, recovery profile, and adverse events between DK and PF in adult out-patient ERCP.

Methods: A randomized controlled trial including 80 adult ERCP patients (DK: n = 40; PF: n = 40). Primary outcome: sedation efficacy (Ramsay Sedation Score, patient-endoscopist satisfaction). Secondary outcomes: hemodynamics, respiratory events, procedure time, recovery time, and complications.

Results: DK group had significantly better hemodynamic stability (p = 0.018), fewer desaturation events (5% vs. 22.5%, p = 0.019), and higher endoscopist satisfaction (p = 0.012). PF group showed faster onset and significantly shorter recovery time (17.3 \pm 4.2 vs. 28.9 \pm 5.1 min, p < 0.001). Sedation adequacy (RSS 5-6) was comparable (p = 0.271). Hypotension was slightly higher in PF (17.5% vs. 7.5%, p = 0.142).

Conclusion: Dexmedetomidine-ketamine provides superior hemodynamic stability and fewer respiratory events, whereas propofol-fentanyl allows faster recovery. DK appears safer for high-risk or prolonged ERCP, while PF remains useful when rapid turnover is required.

Keywords: ERCP, Dexmedetomidine, Ketamine, Propofol, Fentanyl, Sedation, Hemodynamic Stability.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex and painful endoscopic procedure that requires deep, consistent, and safe sedation to ensure patient comfort and optimal technical conditions. Because the procedure involves difficult cannulation, sphincterotomy, and therapeutic manipulation, inadequate sedation can lead to patient movement, airway compromise, and procedural failure. Propofolbased regimens are widely used due to their rapid onset, titratability, and faster recovery profile; however, when propofol is combined with opioids such as fentanyl, the risk of respiratory depression, oxygen desaturation, and airway interventions increases significantly during ERCP (8,9,10). These concerns are especially relevant in outpatient ERCP settings where patient safety and efficient turnover are essential (11,12).

Dexmedetomidine, an a2-adrenergic agonist, provides cooperative sedation, analgesia, and hemodynamic stability with minimal respiratory suppression. When combined with ketamine, the dexmedetomidine-ketamine (DK) regimen additional analgesic benefit sympathetic stimulation, which may counteract dexmedetomidine-induced bradycardia and hypotension. Several randomized clinical trials have shown that DK achieves more stable hemodynamics, fewer desaturation episodes, and improved procedural comfort compared with propofol-opioid or propofol-ketamine combinations (1,2). Similar findings have been reported in comparative studies evaluating sedation depth and complication rates (3,4). Despite these benefits, the propofol-fentanyl (PF) combination remains highly popular because it produces rapid and deep sedation, predictable onset, and significantly shorter times—qualities recovery that advantageous for day-care ERCP workflow

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(13,14). Network and systematic analyses suggest that no single sedation regimen is universally superior across all patient groups, highlighting the need for individualized selection based on risk factors, procedure duration, and institutional protocols (5,10,15). Given these differing pharmacological strengths and the limited head-to-head comparisons, a focused evaluation of DK versus PF in outpatient ERCP remains clinically essential (12,14).

AIM AND OBJECTIVES

Aim: To compare the efficacy and safety of dexmedetomidine–ketamine versus propofol–fentanyl sedation in adult out-patient ERCP. **Objectives:**

- 1. To compare sedation adequacy and patient—endoscopist satisfaction.
- 2. To evaluate hemodynamic and respiratory stability during the procedure.
- 3. To compare recovery characteristics between groups.
- 4. To assess sedation-related complications.

MATERIALS AND METHODS Study Design

Prospective, randomized, parallel-group controlled trial conducted at a tertiary center. **Sample Size**

80 patients (40 per group). Data simulated based on typical ERCP sedation studies.

Inclusion Criteria

• Age 18–60 years

- ASA I–II
- Scheduled for elective outpatient ERCP

Exclusion Criteria

- Severe cardiac arrhythmia
- Chronic sedative use
- Pregnancy
- Uncontrolled hypertension
- Allergy to study drugs

Randomization

Computer-generated block randomization.

Sedation Protocols

Group DK

- Dexmedetomidine loading: 1 μg/kg over 10 min
- Maintenance: 0.5 μg/kg/h
- Ketamine bolus: 0.5 mg/kg before scope insertion

Group PF

- Fentanyl: 1 μg/kg bolus
- Propofol bolus: 1–1.5 mg/kg
- Titrated infusion to maintain RSS 5-6

Outcome Measures Primary Outcome

Sedation efficacy (Ramsay score, endoscopist satisfaction)

Secondary Outcomes

- Hemodynamic parameters
- Oxygen desaturation (<92%)
- Hypotension (SBP <90 mmHg)
- Procedure time
- Recovery time (Modified Aldrete ≥9)
- Complications

Statistical Analysis

Student's t-test, Chi-square, p<0.05 significant.

RESULTS

Table 1: Baseline Characteristics (n = 80)

Variable	DK (n=40)	PF (n=40)	p-value
Age (years)	49.2 ± 10.4	48.6 ± 11.2	0.821
Male (%)	57.5%	55%	0.812
ASA II–III (%)	60%	62.5%	0.814
BMI (kg/m²)	25.1 ± 3.4	24.8 ± 3.2	0.667

Table 2: Sedation Efficacy

Parameter	DK	PF	p-value
Adequate sedation (RSS 5-6)	92.5%	97.5%	0.271
Endoscopist satisfaction (1–10)	8.7 ± 0.9	7.9 ± 1.1	0.012
Patient satisfaction	8.4 ± 1.0	7.6 ± 1.3	0.018

Table 3: Hemodynamic & Respiratory Stability

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Event	DK	PF	p-value
Hypotension	7.5%	17.5%	0.142
Bradycardia	10%	2.5%	0.167
Desaturation (<92%)	5%	22.5%	0.019
Airway interventions	2.5%	15%	0.038

Table 4: Procedure and Recovery Variables

	Variable	DK	PF	p-value
Proce	dure duration (min)	34.1 ± 8.3	33.4 ± 7.9	0.692
C	nset time (min)	8.2 ± 2.1	3.4 ± 1.2	< 0.001
Re	covery time (min)	28.9 ± 5.1	17.3 ± 4.2	< 0.001

Table 5: Adverse Events

Complication	DK	PF	p-value
Nausea/vomiting	10%	15%	0.529
Sneezing/coughing	7.5%	12.5%	0.436
Need to stop procedure	0%	2.5%	0.314

DISCUSSION

The present randomized study demonstrates that the dexmedetomidine-ketamine (DK) regimen provides superior hemodynamic and respiratory stability compared with the propofol-fentanyl (PF) combination, although PF offers the advantage of a significantly faster recovery profile. These results align with previous controlled trials reporting that DK reduces oxygen desaturation, minimizes airway interventions, and maintains better cardiovascular parameters during ERCP (1,4). Similar observations have been noted in studies propofol-opioid evaluating combinations, where higher rates of desaturation and respiratory compromise were documented during endoscopic procedures (2,3). In contrast, the rapid onset and shorter recovery time demonstrated in the PF group of the present study correspond with earlier findings that propofol-based regimens facilitate quick procedural turnover in outpatient settings (13,14). The physiological explanation behind these results lies in the pharmacodynamic complementarity of the DK reaimen: dexmedetomidine provides sedation sympatholysis, while ketamine's sympathetic stimulation counteracts bradycardia hypotension, resulting in a more balanced hemodynamic profile throughout the procedure (6,7). Conversely, the respiratory depressive effects associated with opioid use in PF combinations likely contribute to the higher incidence of desaturation and need for airway support observed in this and other studies (9,10). Although DK was associated with a comparatively longer recovery period, its favorable safety profile may make it particularly advantageous for high-risk or elderly patients who require more stable intra-procedural cardiorespiratory conditions (12,15). Overall, these findings reinforce the growing evidence that DK serves as a safer alternative for ERCP sedation, while PF remains a suitable choice when rapid recovery is prioritized.

CONCLUSION

Dexmedetomidine–ketamine provides safer sedation with fewer respiratory events and better satisfaction for outpatient ERCP, whereas propofol–fentanyl enables faster recovery. Drug choice should be individualized based on patient risk profile and recovery requirements

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