ORIGINAL RESEARCH PAPER
Volume - 15 | Issue - 02 | February - 2026 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

BISPECTRAL INDEX-GUIDED SEDATION FOR ERCP: A RANDOMIZED CONTROLLED TRIAL COMPARING PROPOFOL-KETAMINE VERSUS DEXMEDETOMIDINE-KETAMINE

Anaesthesiology

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ABSTRACT

Background: Endoscopic Retrograde Cholangiopancreatography (ERCP) requires optimal sedation balancing patient comfort with respiratory safety. This study compares propofol- ketamine versus dexmedetomidine-ketamine combinations under Bispectral Index (BIS) guidance. **Methods:** A prospective, randomized, double-blind controlled trial was conducted with 90 patients (ASA I-II, aged 18-65 years) undergoing ERCP. Patients were randomized into propofol- ketamine (PK, n=45) or dexmedetomidine-ketamine (DK, n=45) groups. Primary outcome was sedation depth via BIS monitoring. Secondary outcomes included hemodynamic stability, recovery profile, and satisfaction scores. **Results:** Both groups achieved comparable initial sedation depths (BIS ~58). The PK group demonstrated significantly higher systolic (148 vs 127 mmHg, p<0.001) and diastolic (91 vs 83 mmHg, p<0.001) blood pressures during peak procedure time. Heart rate was consistently lower in the DK group (68 vs 89 bpm, p<0.01). Deeper sedation occurred in the PK group (Ramsay score 5 vs 3, p<0.001), with faster recovery (BIS 93 vs 85 at 5 minutes post-procedure, p<0.001). Oxygen saturation remained stable (98-99%) in both groups. Surgeon and anesthesiologist satisfaction scores were comparable. **Conclusions:** Both sedation protocols provided safe and effective sedation for ERCP. Dexmedetomidine-ketamine offered superior hemodynamic stability, while propofol-ketamine provided deeper sedation with faster recovery. BIS monitoring enabled precise sedation management in both protocols.

KEYWORDS

ERCP, Sedation, Propofol, Ketamine, Dexmedetomidine, Bispectral Index, Hemodynamic Stability

INTRODUCTION

Endoscopic Retrograde Cholangiopancreatography (ERCP) has evolved from a diagnostic modality introduced by McCune and colleagues in 1968[1] to a complex therapeutic intervention for biliary and pancreatic disorders[2]. Modern therapeutic ERCP procedures have increased in complexity and duration, with mean procedure times extending from 15-30 minutes for diagnostic procedures to 30-90 minutes for therapeutic interventions[3]. This evolution has necessitated more sophisticated sedation approaches to ensure patient comfort and procedural success.

ERCP presents unique sedation challenges including prone positioning that limits airway access, prolonged duration, and fluctuating stimulation levels requiring patient immobility during critical phases such as sphincterotomy[4]. Traditional moderate sedation with benzodiazepines and opioids has been associated with variable sedation quality and suboptimal procedural conditions[5]. Consequently, there has been a paradigm shift toward deeper sedation administered by anesthesia professionals, demonstrating improved procedural success rates and patient satisfaction[6].

Propofol, despite its favorable pharmacokinetic profile, is associated with dose-dependent respiratory depression and hypotension[7]. Ketamine provides dissociative anesthesia with preserved respiratory drive but may cause emergence phenomena[8]. Dexmedetomidine offers conscious sedation with maintained respiratory function but may cause bradycardia and hypotension[9]. Combination approaches leverage complementary properties while minimizing individual limitations. "Ketofol" (propofol-ketamine) counterbalances propofol-induced respiratory depression[10], while dexmedetomidine-ketamine combinations may provide hemodynamic stability with excellent analgesia[11].

Bispectral Index (BIS) monitoring represents an objective method to assess sedation depth through processed electroencephalogram analysis, with values of 65-85 indicating moderate sedation and 50-65 indicating deep sedation[12]. BIS-guided sedation allows precise titration to specific targets, potentially reducing oversedation risks while ensuring adequate procedural depth[13].

This study compares propofol-ketamine versus dexmedetomidine-ketamine combinations under BIS guidance for ERCP sedation, evaluating efficacy, safety, and recovery profiles to identify the optimal sedation approach.Materials and Methods Study Design and Ethics

This hospital-based, prospective, randomized, double-blind controlled trial was conducted between March 2023 and August 2024. The study protocol was approved by the institutional ethics committee, and written informed consent was obtained from all participants.

Sample Size and Randomization

A total of 90 patients were enrolled, assuming 90% power with 5% alpha error and 10% standard deviation. Patients were randomly allocated using computer-generated random number tables into two equal groups (n=45 each):

- Group PK: Propofol-ketamine combination
- Group DK: Dexmedetomidine-ketamine combination

Inclusion and Exclusion Criteria

Inclusion Criteria:

- ASA physical status I-II
- Age 18-65 years
- Scheduled for ERCP
- All genders

Exclusion Criteria:

- Preexisting cardiac disease
- Severe renal dysfunction
- Pregnancy or lactation
- Known drug allergies
- Hypertension
- Increased intracranial pressure

Anesthetic Protocol

Standard monitoring included electrocardiogram, pulse oximetry, non-invasive blood pressure, and BIS monitoring. Patients were positioned prone with oxygen supplementation (2 L/min via nasal prongs). Premedication included midazolam 0.003 mg/kg and fentanyl 2 µg/kg.Induction was performed with propofol 1.5-2.5 mg/kg titrated to achieve BIS 55±5. Lidocaine 0.5 mg/kg was administered before propofol to minimize injection pain.

Drug Preparation:
- Propofol: 10 mg/ml (1%)
- Dexmedetomidine: 2 µg/ml (diluted in normal saline)
- Ketamine: 2 mg/ml (diluted in normal saline)

Infusion Rates:
- Propofol: 4 mg/kg/hr
- Dexmedetomidine: 0.5 µg/kg/hr
- Ketamine: 2 mg/kg/hr

Data Collection
Vital parameters (heart rate, blood pressure, oxygen saturation, respiratory rate, end-tidal CO_2, BIS values) were recorded at baseline, pre-induction, and at 5, 10, 15, 20, 30, 45, 60, 75, 90, 105, and 120 minutes during the procedure, plus 5, 10, 15, 20, and 30 minutes post-procedure.

Additional assessments included:
- Ramsay Sedation Score (5-minute intervals)
- Modified Aldrete Score for recovery assessment
- Time to achieve BIS 50±5 and recovery to BIS ≥90
- Total drug consumption
- Satisfaction scores (patient, surgeon, anesthesiologist using Likert 5-point scale)
- Complications

Blinding
Double-blind methodology was maintained with medications prepared and coded by an independent observer not involved in other aspects of the study.

Statistical Analysis
Data was analyzed using appropriate statistical tests with significance set at $p \leq 0.05$. Mann- Whitney U test was used for continuous variables, and chi-square test for categorical variables.

RESULTS

Demographic and Baseline Characteristics
A total of 90 patients were enrolled and randomized into two equal groups of 45 patients each. The demographic distribution showed that the largest proportion of participants (36.67%) fell within the 41-50 years age group, with an overall median age of 43.5 years (IQR 33.25-50.0 years). The PK group exhibited a more uniform age distribution across all categories, while the DK group showed a concentration in the 41-50 years category (48.89%). Despite these observable differences, the age distribution was not statistically significant between groups ($\chi^2 = 6.764$, $p = 0.07$) (Table 1).

Body Mass Index distribution was comparable between the two groups, with no statistically significant difference ($\chi^2 = 6.013$, $p = 0.198$). The median BMI values were remarkably similar, with 22.15 kg/m² (IQR 18.17-27.17) in the PK group and 21.77 kg/m² (IQR 16.98-27.14) in the DK group. Across the entire study population, underweight patients comprised the largest proportion (31.11%) (Table 2). Blood pressure categories showed no significant difference between groups ($\chi^2 = 1.573$, $p = 0.665$), with hypertension Stage 1 being the most prevalent condition (33.33%) across the cohort (Table 3).

Baseline Physiological Parameters
Baseline vital parameters revealed significant differences in three parameters between the groups (Table 4). The PK group demonstrated higher diastolic blood pressure (82.33 vs 74 mmHg, $p = 0.015$) and mean arterial pressure (97 vs 91 mmHg, $p = 0.031$). End-tidal CO_2 was also significantly higher in the PK group (40 vs 36 mmHg, $p = 0.043$). Other parameters including heart rate, systolic blood pressure, oxygen saturation, and respiratory rate showed no significant differences between groups.

Pre-induction measurements showed similar patterns, with most vital parameters being comparable between groups except for $ETCO_2$, which remained significantly different (36 vs 40 mmHg, $p = 0.034$), maintaining the pattern observed in baseline measurements (Table 5).

Hemodynamic Response During Procedure
The hemodynamic profiles revealed distinct differences between the two sedation protocols throughout the procedure. Heart rate measurements demonstrated significant differences at all intraoperative time points ($p < 0.01$). The DK group consistently showed lower heart rates compared to the PK group, with notable differences at 20 minutes (98 vs 82 bpm), 45 minutes (89 vs 68 bpm), and 60 minutes (92 vs 71 bpm). This pattern continued into the postoperative phase at most time points (Table 6, Figure 6).

Systolic blood pressure showed even more pronounced differences during the intraoperative phase, with the PK group demonstrating significantly higher values at all time points ($p < 0.001$). Peak differences occurred at 20-30 minutes, with the PK group reaching 148-149 mmHg compared to127-133 mmHg in the DK group. Remarkably, these differences resolved completely during the postoperative phase, with nearly identical values between groups (Table 7, Figure 7).

Diastolic blood pressure patterns mirrored the systolic findings, with the PK group showing consistently higher values during the intraoperative phase from 10 minutes onwards ($p < 0.001$). The most pronounced difference occurred at 20-30 minutes (91 vs 83 mmHg). Similar to systolic pressure, these differences completely resolved postoperatively (Table 8, Figure 8).

Mean blood pressure remained relatively stable throughout most time points, with only one statistically significant difference observed at 60 minutes, where the PK group showed higher values (97 vs 88 mmHg, $p = 0.015$) (Table 9, Figure 9).

Respiratory Parameters
Oxygen saturation remained remarkably stable throughout the procedure in both groups, with median values consistently between 98-99% and no statistically significant differences at any time point. The narrow interquartile ranges (2-3 percentage points) indicated minimal variability within and between groups (Table 10).

Respiratory rate measurements revealed a more complex pattern with significant differences at specific time points. At 20 minutes, 45 minutes, and 60 minutes intraoperatively, as well as at 5 and 15 minutes postoperatively, the PK group demonstrated lower respiratory rates compared to the DK group ($p < 0.001$). The most notable difference occurred at 45 minutes, with the PK group showing 9 breaths/minute compared to 13 breaths/minute in the DK group (Table 11, Figure 10).

End-tidal CO_2 measurements showed statistically significant differences at pre-induction, 20- minute, and 30-minute marks. The PK group generally demonstrated higher $ETCO_2$ values during these time points, with values ranging between 36-39 mmHg compared to 35-40 mmHg in the DK group (Table 12).

Sedation Depth and Neurophysiological Monitoring
Bispectral Index monitoring provided objective assessment of sedation depth throughout the procedure. Both groups achieved comparable initial sedation levels, with median BIS values dropping from 97 to approximately 58 during the early procedural phase. Significant differences emerged at later time points, with the PK group showing deeper sedation at 45 minutes (52 vs 58, $p < 0.001$) and 60 minutes (61 vs 68, $p < 0.001$). During recovery, the PK group demonstrated faster emergence, with significantly higher BIS values at 5 and 15 minutes postoperatively (93 vs 85, $p < 0.001$) (Table 13, Figure 11).

Clinical Assessment and Satisfaction Scores
The Modified Aldrete Score showed no significant difference between groups, with both achieving a median score of 10, indicating comparable recovery readiness. However, the Ramsay Sedation Score revealed a statistically significant difference ($p < 0.001$), with the PK group demonstratingdeeper sedation (median score 5) compared to the DK group (median score 3). Surgeon satisfaction scores were identical between groups (median score 5), while anesthesiologist satisfaction scores showed no significant difference, with the PK group scoring 5 and the DK group scoring 4 (Table 14).

The comprehensive physiological monitoring throughout the procedure demonstrated that both sedation protocols provided effective sedation for ERCP procedures, with distinct pharmacodynamic profiles. The propofol-ketamine combination was characterized by more pronounced hemodynamic fluctuations and deeper sedation levels, while the dexmedetomidine- ketamine combination offered greater hemodynamic stability with lighter sedation levels. Both protocols maintained excellent respiratory safety profiles, with consistent oxygen saturation levels throughout the procedures.

DISCUSSION

This prospective, randomized, double-blind controlled trial provides comprehensive evidence comparing propofol-ketamine and dexmedetomidine-ketamine combinations under BIS guidance for ERCP sedation. The study demonstrates that both protocols offer safe and effective sedation while exhibiting distinct pharmacodynamic profiles that may influence clinical decision-making based on individual patient characteristics and procedural requirements.

The most striking finding was the significant difference in hemodynamic responses between the two sedation protocols. The propofol-ketamine group demonstrated consistently higher systolic and diastolic blood pressures throughout the intraoperative phase, with peak values reaching 148- 149 mmHg systolic and 91 mmHg diastolic. This pronounced cardiovascular stimulation aligns with ketamine's well-documented sympathomimetic properties, which appear to predominate over propofol's hypotensive tendencies in this combination[14]. These findings are consistent with previous studies by Goyal et al., who reported similar hemodynamic patterns with ketamine- containing regimens[11].

In contrast, the dexmedetomidine-ketamine group exhibited more stable hemodynamic parameters, likely due to dexmedetomidine's sympatholytic effects counterbalancing ketamine's cardiovascular stimulation. This interaction has been previously described in the literature, where dexmedetomidine's alpha-2 agonist properties effectively moderate the sympathetic response induced by ketamine[15]. The clinical implications of these hemodynamic differences are significant, particularly for patients with cardiovascular comorbidities, hypertension, or conditions where blood pressure surges could pose risks.

The heart rate patterns further supported these hemodynamic differences, with the dexmedetomidine-ketamine group consistently showing lower heart rates throughout the procedure. This bradycardic tendency, while generally well-tolerated in our study population, warrants careful consideration in patients with pre-existing conduction disorders or those receiving concurrent medications that may further depress heart rate[16].

Sedation Depth and Neurophysiological Assessment

The implementation of BIS monitoring provided objective insights into the neurophysiological differences between the two sedation protocols. Both groups achieved comparable initial sedation depths, confirming the effectiveness of the standardized induction protocol targeting BIS 55±5. However, subtle but significant differences emerged during the maintenance phase, with the propofol-ketamine group demonstrating slightly deeper sedation at 45 and 60 minutes[17].

The deeper sedation levels in the propofol-ketamine group were corroborated by the significantly higher Ramsay Sedation Scores (5 vs 3), indicating a more profound sedative state. This finding aligns with the known pharmacological properties of propofol as a potent GABA-ergic agentproducing dose-dependent central nervous system depression[18]. The clinical significance of this deeper sedation may be advantageous for complex or prolonged ERCP procedures where patient immobility is crucial, but it may also increase the risk of respiratory depression in susceptible patients.

Interestingly, despite achieving deeper intraoperative sedation, the propofol-ketamine group demonstrated faster recovery, as evidenced by higher BIS values at 5 and 15 minutes post- procedure. This rapid emergence likely reflects propofol's favorable pharmacokinetic profile with its short context-sensitive half-time, even after prolonged administration[19]. This characteristic may facilitate faster patient turnover and earlier discharge readiness, particularly relevant in busy endoscopy units.

Respiratory Safety Profile

One of the most reassuring findings was the consistent maintenance of oxygen saturation levels (98-99%) across both groups throughout the procedure. This excellent respiratory safety profile contradicts concerns about respiratory depression with deeper sedation levels and supports the safety of both combination approaches for ERCP sedation[20]. The preservation of respiratory function likely reflects the beneficial effects of ketamine in both combinations, as ketamine uniquely maintains respiratory drive and airway reflexes even at anesthetic doses[21].

The respiratory rate patterns revealed more nuanced differences, with the propofol-ketamine group showing lower respiratory rates at specific time points. While statistically significant, these differences remained within clinically acceptable ranges and did not translate into oxygen desaturation events. The end-tidal CO_2 measurements further supported adequate ventilation in both groups, with values remaining within normal physiological ranges[22].

Clinical Performance and Satisfaction

The comparable surgeon and anesthesiologist satisfaction scores between groups indicate that both sedation protocols provided adequate procedural conditions. This finding is clinically significant, as it suggests that the choice between protocols can be individualized based on patient factors rather than concerns about procedural interference. The identical surgeon satisfaction scores (median 5) confirm that both protocols facilitated optimal working conditions for the endoscopist[23].

The Modified Aldrete Scores demonstrated equivalent recovery readiness between groups, suggesting that despite the deeper intraoperative sedation in the propofol-ketamine group, both protocols allow for safe and timely recovery. This finding supports the clinical viability of both approaches for outpatient ERCP procedures.

Clinical Implications and Protocol Selection

The results suggest that sedation protocol selection should be individualized based on patient- specific factors and procedural requirements. The dexmedetomidine-ketamine combination maybe preferable for patients with cardiovascular risk factors, hypertension, or conditions where hemodynamic stability is paramount. The more stable blood pressure and heart rate profile observed with this combination could reduce the need for additional interventions and monitoring[24].

Conversely, the propofol-ketamine combination may be advantageous for cases requiring deeper sedation levels, such as prolonged or technically challenging procedures where patient immobility is critical. The faster recovery profile associated with this combination could also benefit high- volume endoscopy units where rapid patient turnover is desired[25].

Study Strengths and Limitations

The study's methodological strengths include its randomized, double-blind design, objective BIS monitoring, and comprehensive physiological assessment. The use of standardized protocols and experienced anesthesia providers minimizes confounding variables and enhances the validity of the findings.

However, several limitations warrant consideration. The study population was limited to ASA I-II patients aged 18-65 years, which may limit generalizability to higher-risk populations commonly undergoing ERCP. The single-center design and relatively modest sample size (n=90) may also restrict the external validity of findings. Additionally, the study focused on immediate procedural and early recovery outcomes without long-term follow-up.

Future Research Directions

Future research should investigate these sedation combinations in higher-risk patient populations, including elderly patients and those with significant cardiovascular or respiratory comorbidities. Long-term outcome studies examining patient satisfaction, quality of recovery, and cost- effectiveness would provide valuable additional insights. Additionally, investigation of optimal BIS targets for different combination regimens could further refine sedation protocols.

CONCLUSION

Both propofol-ketamine and dexmedetomidine-ketamine combinations provide safe and effective sedation for ERCP procedures under BIS guidance. The choice between protocols should be individualized, with dexmedetomidine-ketamine offering superior hemodynamic stability and propofol-ketamine providing deeper sedation with faster recovery. The integration of BIS monitoring enables precise sedation management and enhances the safety profile of both combination approaches.

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