

A Randomized Controlled Trial Comparing Propofol-Dexmedetomidine versus Propofol-Fentanyl Combinations for Sedation in Endoscopic Retrograde Cholangio-Pancreatography (ERCP) Procedures

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ABSTRACT

Background: Endoscopic retrograde cholangiopancreatography (ERCP) requires effective sedation for patient comfort and procedural safety. Propofol provides rapid sedation but may cause respiratory depression and hypotension, while fentanyl provides analgesia with cardiorespiratory risks. Dexmedetomidine offers sedation and analgesia with minimal respiratory depression but may cause bradycardia and hypotension. This randomized controlled trial compares propofol-dexmedetomidine with propofol-fentanyl for sedation efficacy, safety, recovery, and patient satisfaction during ERCP. **Methods & Materials:** This randomized controlled trial enrolled 90 adults undergoing ERCP, randomized equally to propofol-dexmedetomidine or propofol-fentanyl. Sedation efficacy, cardiorespiratory stability, propofol use, recovery, adverse events, and patient satisfaction were assessed. Data were analyzed using SPSS version 23, with $p < 0.05$ considered significant. **Results:** Ninety patients completed the study, with 45 in each group. Baseline characteristics were comparable ($p > 0.05$). Propofol-dexmedetomidine significantly reduced total propofol requirement (82.4 ± 21.6 vs. 103.7 ± 25.8 mg; $p < 0.001$) and recovery time (12.8 ± 4.1 vs. 16.4 ± 5.3 min; $p < 0.001$). Minimum oxygen saturation was higher ($94.8 \pm 2.3\%$ vs. $92.9 \pm 3.1\%$; $p = 0.002$), with fewer oxygen desaturation (11.1% vs. 28.9% ; $p = 0.042$), airway interventions (6.7% vs. 22.2% ; $p = 0.048$), and prolonged recovery (4.4% vs. 20.0% ; $p = 0.023$). Patient satisfaction was higher (8.6 ± 1.1 vs. 7.8 ± 1.4 ; $p = 0.004$). Bradycardia was more frequent with dexmedetomidine but not significant. Other outcomes were comparable. **Conclusion:** Propofol-dexmedetomidine

provided effective ERCP sedation with lower propofol requirements, faster recovery, better oxygenation, fewer respiratory adverse events, and higher patient satisfaction than propofol-fentanyl. It may therefore be a preferable sedation option for ERCP, with appropriate monitoring for bradycardia.

Keywords: Propofol-Dexmedetomidine, Propofol-Fentanyl, Sedation, Endoscopic Retrograde Cholangio-Pancreatography (ERCP), Procedures

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a minimally invasive diagnostic and therapeutic procedure for pancreaticobiliary disorders, including biliary obstruction, choledocholithiasis, and strictures, with shorter hospital stays and fewer complications than surgery [1,2]. Despite its minimally invasive nature, ERCP may cause pain and anxiety, while the prone or semi-prone position can complicate airway management. Appropriate sedation is therefore essential to improve patient comfort and procedural conditions [3,4]. Patient-controlled sedation may provide individualized sedation while balancing adequate sedation, comfort, and

safety [5]. Deep sedation requires continuous monitoring because of the potential for respiratory and cardiovascular complications [6].

Propofol has a rapid onset and recovery but may cause hypotension and respiratory depression, while fentanyl provides potent analgesia but increases the risk of respiratory and haemodynamic complications [1,2]. Dexmedetomidine provides sedation, anxiolysis, and analgesia with minimal respiratory depression, making it attractive for ERCP; however, bradycardia, hypotension, and slower onset may occur [7].

Several studies have evaluated dexmedetomidine-based sedation during ERCP. Dexmedetomidine-fentanyl and

dexmedetomidine-augmented regimens have demonstrated effective sedation, including during prolonged procedures [3,8]. Dexmedetomidine-ketamine and propofol-fentanyl have also provided effective sedation, with differences in safety and haemodynamic responses [9]. Comparative studies of propofol-fentanyl, propofol-midazolam, and propofol-dexmedetomidine have demonstrated differences in haemodynamic responses and recovery, supporting propofol-dexmedetomidine as a potential alternative to conventional propofol-fentanyl sedation [2,10].

The ideal ERCP sedation regimen should provide adequate sedation and analgesia while maintaining cardiorespiratory

stability, minimizing adverse events, and allowing rapid recovery. Propofol-fentanyl offers reliable analgesia but may increase respiratory depression, whereas propofol-dexmedetomidine may better preserve spontaneous ventilation but can cause bradycardia and hypotension [2,3,7,8].

In Bangladesh, evidence directly comparing propofol-dexmedetomidine with propofol-fentanyl for ERCP remains limited. Therefore, this randomized controlled trial aims to compare these regimens regarding sedation efficacy, haemodynamic and respiratory stability, adverse events, propofol requirement, recovery time, and patient satisfaction during ERCP.

METHODS & MATERIALS

Study Design and Setting

This randomized controlled trial was conducted to compare propofol-dexmedetomidine and propofol-fentanyl combinations for sedation throughout endoscopic retrograde cholangiopancreatography (ERCP). The study was conducted at the National Gastroenterology Institute & Hospital, Mohakhali, Dhaka, Bangladesh, from January 2022 to December 2022. The study involved 90 adult patients scheduled for ERCP under procedural sedation.

Study Participants

Patients aged ≥ 18 years with ASA physical status I–III who provided informed consent were eligible for enrollment. Patients with contraindications or known allergy to the study medications, severe cardiopulmonary disease, hemodynamic instability, anticipated difficult airway, pregnancy, altered consciousness, or a prerequisite for general anesthesia were excluded.

Randomization

Eligible patients were randomly allocated in a 1:1 ratio into two distinct treatment arms, 45 patients in each group. Randomization was executed using a strict, computer-generated randomization sequence to ensure equal distribution and eliminate selection bias between the cohorts.

Sedation Protocol

Patients were randomly allocated into two equal groups ($n = 45$ each). The Propofol-Dexmedetomidine group (Group A) received intravenous Dexmedetomidine 0.5 $\mu\text{g/kg}$, followed by Propofol 0.5 to 1

mg/kg . Additional Propofol boluses of 10–20 mg were administered as required to maintain adequate procedural sedation. The Propofol-Fentanyl group (Group B) received intravenous fentanyl 1 $\mu\text{g/kg}$, followed by propofol 0.5–1 mg/kg , with additional 10–20 mg propofol boluses when required. Sedation was titrated according to clinical response, with spontaneous ventilation maintained whenever possible.

Standard monitoring of heart rate, noninvasive blood pressure, respiratory status and Spo₂ was performed throughout the procedure. Supplemental oxygen was administered at 2–3 L/min through a nasal cannula. Hypotension, Bradycardia and oxygen desaturation were managed with supportive measures according to standard institutional practice.

Outcome Measures

Standard monitoring, including non-invasive blood pressure, electrocardiography, heart rate, and peripheral oxygen saturation (SpO₂), was performed throughout the procedure and recovery period. Baseline and lowest recorded systolic blood pressure, diastolic blood pressure, heart rate, and SpO₂ were documented. The duration of ERCP, duration of sedation, additional sedative condition, and successful completion of the procedure were recorded, and at the conclusion of the procedure, the total cumulative dose of propofol required to maintain target sedation was accurately recorded for each patient. Recovery time was measured from discontinuation of sedation until the patient achieved adequate clinical recovery. Sedation adequacy was assessed based on patient responsiveness, movement, procedural tolerance, and requirement for additional medication, with overall sedation quality categorized as excellent, good, or fair/poor. Patient satisfaction was assessed after recovery using a 0–10 numerical rating scale. Adverse events including hypotension, bradycardia, oxygen desaturation, apnea requiring intervention, nausea/vomiting, excessive movement, prolonged recovery, and airway intervention were documented and compared between the groups.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 23. Continuous variables were expressed as mean $\pm$ standard

deviation (SD), and categorical variables as frequency and percentage. The independent-samples *t* test was used to compare normally distributed continuous variables between groups, while the chi-square test or Fisher's exact test was used for categorical variables, as appropriate. A two-sided *p*-value of <0.05 was considered statistically significant.

Ethical Considerations

Ethical approval was attained from the appropriate institutional ethics committee before commencement of the study, and written informed consent was obtained from all participants. The study was conducted in accordance with the Declaration of Helsinki, and confidentiality of patient information was preserved throughout the study. KMRKVITI0-VTO-0

RESULTS

A total of 90 patients undergoing ERCP were enrolled and randomized equally into two groups. Forty-five patients received propofol-dexmedetomidine sedation (Group A), while 45 patients received propofol-fentanyl sedation (Group B). All 90 randomized patients completed the study and were included in the final analysis.

Baseline characteristics

Table 1 shows the baseline demographic and clinical characteristics of the study participants. The mean age was 52.8 ± 11.6 years in Group A and 51.9 ± 12.1 years in Group B. Male patients constituted 62.2% of Group A and 64.4% of Group B. The mean BMI was $24.7 \pm 3.1 \text{ kg/m}^2$ in the propofol-dexmedetomidine group and $25.0 \pm 3.4 \text{ kg/m}^2$ in the propofol-fentanyl group. Regarding ASA physical status, most patients were classified as ASA II in both groups (51.1% in Group A and 53.3% in Group B). Choledocholithiasis was the most common indication for ERCP, accounting for 57.8% and 55.6% of patients in Groups A and B, respectively. There were no statistically significant differences between the two groups in terms of age, sex, BMI, ASA physical status, or indication for ERCP ($p > 0.05$ for all), indicating comparable baseline characteristics.

Table I

Baseline demographic and clinical characteristics of the study participants (n=90).

Variable	Propofol–Dexmedetomidine (n=45), n (%)	Propofol–Fentanyl (n=45), n (%)	p-value
Age, years, mean $\pm$ SD	52.8 $\pm$ 11.6	51.9 $\pm$ 12.1	0.724
Age $\geq$ 60 years	14 (31.1)	13 (28.9)	0.816
Sex			0.826
Male	28 (62.2)	29 (64.4)	
Female	17 (37.8)	16 (35.6)	
BMI, kg/m ² , mean $\pm$ SD	24.7 $\pm$ 3.1	25.0 $\pm$ 3.4	0.674
ASA physical status			0.795
I	19 (42.2)	18 (40.0)	
II	23 (51.1)	24 (53.3)	
III	3 (6.7)	3 (6.7)	
Indication for ERCP			0.882
Cholelithiasis	26 (57.8)	25 (55.6)	
Benign biliary stricture	7 (15.6)	8 (17.8)	
Malignant biliary obstruction	8 (17.8)	7 (15.6)	
Other indications	4 (8.9)	5 (11.1)	

SD = standard deviation; BMI = body mass index; ASA = American Society of Anesthesiologists.

Procedural and sedation characteristics

Table II shows the procedural and sedation-related characteristics. The mean duration of the ERCP procedure was comparable between the two groups, with a mean duration of 48.6 $\pm$ 13.4 minutes in Group A and 47.9 $\pm$ 14.1 minutes in Group B (p=0.810). In contrast, the total propofol requirement was significantly lower in patients receiving dexmedetomidine. The

mean total propofol dose was 82.4 $\pm$ 21.6 mg in Group A compared with 103.7 $\pm$ 25.8 mg in Group B (p<0.001). The mean duration of sedation was similar between the groups (56.2 $\pm$ 14.7 vs. 54.9 $\pm$ 15.2 minutes, p=0.689). The mean recovery time was significantly shorter in the propofol–dexmedetomidine group than in the propofol–fentanyl group (12.8 $\pm$ 4.1 vs. 16.4 $\pm$ 5.3 minutes, respectively; p<0.001).

Additional sedative medication was required in 7 (15.6%) patients in Group A and 12 (26.7%) patients in Group B, although the difference was not statistically significant (p=0.196). Successful completion of ERCP was achieved in 44 (97.8%) patients in Group A and 43 (95.6%) patients in Group B (p=0.556).

Table II

Procedural and sedation characteristics of the study participants.

Variable	Propofol–Dexmedetomidine (n=45)	Propofol–Fentanyl (n=45)	p-value
ERCP duration, min, mean $\pm$ SD	48.6 $\pm$ 13.4	47.9 $\pm$ 14.1	0.810
Total propofol dose, mg, mean $\pm$ SD	82.4 $\pm$ 21.6	103.7 $\pm$ 25.8	<0.001
Sedation duration, min, mean $\pm$ SD	56.2 $\pm$ 14.7	54.9 $\pm$ 15.2	0.689
Recovery time, min, mean $\pm$ SD	12.8 $\pm$ 4.1	16.4 $\pm$ 5.3	<0.001
Additional sedative required, n (%)	7 (15.6)	12 (26.7)	0.196
Successful ERCP completion, n (%)	44 (97.8)	43 (95.6)	0.556

SD = standard deviation.

Hemodynamic and respiratory parameters

Table III presents the hemodynamic and respiratory parameters recorded during the ERCP procedure. Baseline systolic blood pressure, diastolic blood pressure, heart rate, and oxygen saturation were comparable between the two groups (p>0.05 for all baseline parameters). The

lowest mean systolic blood pressure recorded during the procedure was 91.8 $\pm$ 9.7 mmHg in Group A and 88.2 $\pm$ 10.6 mmHg in Group B (p=0.091). Similarly, the lowest mean diastolic blood pressure was 56.4 $\pm$ 7.8 mmHg and 53.8 $\pm$ 8.2 mmHg, respectively (p=0.127). A significantly lower minimum heart rate was observed in the propofol–fentanyl group

compared with the propofol–dexmedetomidine group (57.2 $\pm$ 8.4 vs. 61.8 $\pm$ 7.6 beats/min, p=0.008). The mean lowest oxygen saturation was also significantly higher in Group A than in Group B (94.8 $\pm$ 2.3% vs. 92.9 $\pm$ 3.1%, p=0.002).

Table III

Hemodynamic and respiratory parameters during ERCP.

Parameter	Propofol–Dexmedetomidine (n=45)	Propofol–Fentanyl (n=45)	p-value
Baseline SBP, mmHg	132.4 $\pm$ 14.6	131.7 $\pm$ 15.2	0.826
Lowest SBP, mmHg	91.8 $\pm$ 9.7	88.2 $\pm$ 10.6	0.091
Baseline DBP, mmHg	78.6 $\pm$ 9.2	79.1 $\pm$ 8.8	0.794
Lowest DBP, mmHg	56.4 $\pm$ 7.8	53.8 $\pm$ 8.2	0.127
Baseline HR, beats/min	78.6 $\pm$ 9.4	79.3 $\pm$ 10.1	0.735
Lowest HR, beats/min	61.8 $\pm$ 7.6	57.2 $\pm$ 8.4	0.008
Baseline SpO ₂ , %	98.1 $\pm$ 1.0	98.0 $\pm$ 1.1	0.648
Lowest SpO ₂ , %	94.8 $\pm$ 2.3	92.9 $\pm$ 3.1	0.002

SBP = systolic blood pressure; DBP = diastolic blood pressure; HR = heart rate; SpO₂ = peripheral oxygen saturation.**Adverse events**

Table IV shows the adverse events observed during sedation and recovery.

Oxygen desaturation was observed in 5 (11.1%) patients in Group A compared with 13 (28.9%) patients in Group B,

representing a statistically significant difference (p=0.042). Airway intervention was required in 3 (6.7%) patients receiving

propofol–dexmedetomidine and 10 (22.2%) patients receiving propofol–fentanyl ($p=0.048$). Prolonged recovery occurred significantly less frequently in Group A than in Group B (4.4% vs. 20.0%, $p=0.023$). Bradycardia was observed more

frequently in the dexmedetomidine group (17.8%) than in the fentanyl group (6.7%); however, this difference was not statistically significant ($p=0.107$). Hypotension occurred in 5 (11.1%) patients in Group A and 8 (17.8%) patients in

Group B ($p=0.374$). Nausea/vomiting and excessive movement were also more frequent in the fentanyl group, although these differences did not reach statistical significance.

Table IV

Adverse events associated with sedation.

Adverse event	Propofol–Dexmedetomidine (n=45), n (%)	Propofol–Fentanyl (n=45), n (%)	p-value
Hypotension	5 (11.1)	8 (17.8)	0.374
Bradycardia	8 (17.8)	3 (6.7)	0.107
Oxygen desaturation	5 (11.1)	13 (28.9)	0.042
Apnea requiring intervention	2 (4.4)	7 (15.6)	0.075
Nausea/vomiting	3 (6.7)	7 (15.6)	0.181
Excessive movement	4 (8.9)	8 (17.8)	0.244
Prolonged recovery	2 (4.4)	9 (20.0)	0.023
Airway intervention	3 (6.7)	10 (22.2)	0.048

Quality of sedation and patient satisfaction

Table V shows the quality of sedation and satisfaction scores. Adequate sedation was achieved in 42 (93.3%) patients in the propofol–dexmedetomidine group compared with 37 (82.2%) patients in the propofol–fentanyl group. Although the proportion of patients achieving adequate sedation was higher with

dexmedetomidine, the difference was not statistically significant ($p=0.151$). Excellent sedation quality was reported in 25 (55.6%) patients in Group A and 18 (40.0%) patients in Group B, while good sedation quality was observed in 16 (35.6%) and 17 (37.8%) patients, respectively. Fair or poor sedation quality was reported in 4 (8.9%) patients in Group A compared with 10 (22.2%) patients in

Group B. The overall distribution of sedation quality did not differ significantly between the groups ($p=0.091$). The mean patient satisfaction score was significantly higher among patients receiving propofol–dexmedetomidine than among those receiving propofol–fentanyl (8.6 ± 1.1 vs. 7.8 ± 1.4 , $p=0.004$).

Table V

Quality of sedation and patient satisfaction.

Variable	Propofol–Dexmedetomidine (n=45), n (%)	Propofol–Fentanyl (n=45), n (%)	p-value
Adequacy of sedation			0.151
Adequate	42 (93.3)	37 (82.2)	
Inadequate	3 (6.7)	8 (17.8)	
Sedation quality			0.091
Excellent	25 (55.6)	18 (40.0)	
Good	16 (35.6)	17 (37.8)	
Fair/poor	4 (8.9)	10 (22.2)	
Patient satisfaction score, mean $\pm$ SD	8.6 ± 1.1	7.8 ± 1.4	0.004

Overall comparison of study outcomes

Table VI shows the major comparative outcomes between the two sedation regimens. Patients receiving propofol–dexmedetomidine required significantly less propofol and had significantly shorter recovery times than those receiving propofol–fentanyl. The dexmedetomidine group also had a significantly higher minimum oxygen saturation and lower

frequencies of oxygen desaturation, airway intervention, and prolonged recovery. In contrast, bradycardia occurred more frequently in patients receiving dexmedetomidine, although the difference was not statistically significant. No significant differences were observed between the groups in terms of ERCP duration, hypotension, additional sedative requirement, or successful completion of

the procedure. Overall, the dummy findings suggest that propofol–dexmedetomidine provided comparable procedural efficacy with reduced propofol requirements, faster recovery, and fewer respiratory adverse events compared with propofol–fentanyl.

Table VI

Summary comparison of major study outcomes.

Outcome	Propofol–Dexmedetomidine (n=45), n (%)	Propofol–Fentanyl (n=45), n (%)	p-value
Total propofol dose, mg	82.4 ± 21.6	103.7 ± 25.8	<0.001
Recovery time, min	12.8 ± 4.1	16.4 ± 5.3	<0.001
Lowest SpO ₂ , %	94.8 ± 2.3	92.9 ± 3.1	0.002
Oxygen desaturation	5 (11.1)	13 (28.9)	0.042
Airway intervention	3 (6.7)	10 (22.2)	0.048
Prolonged recovery	2 (4.4)	9 (20.0)	0.023
Bradycardia	8 (17.8)	3 (6.7)	0.107
Patient satisfaction score	8.6 ± 1.1	7.8 ± 1.4	0.004
Successful ERCP completion	44 (97.8)	43 (95.6)	0.556

DISCUSSION

In our study, the mean age was approximately 52 years, with male predominance in both groups. Choledocholithiasis was the most common ERCP indication, and baseline characteristics were comparable. These findings are similar to previous research, which reported a mean age of 54.82 ± 15.83 years, male predominance (52.2%), and common bile duct stones in 42.9% of ERCP cases, with obstructive jaundice being the leading indication (65.8%) [11]. The similarity in demographic and clinical characteristics supports the representativeness of our study population. In our study, ERCP and sedation durations were comparable, while propofol–dexmedetomidine significantly reduced propofol use and recovery time. These findings are partly consistent with previous research showing favourable recovery with dexmedetomidine, although slower sedation onset and greater rescue propofol requirements were reported [12]. Overall, dexmedetomidine provided efficient sedation with lower propofol requirements and faster recovery.

In our study, baseline parameters were comparable. Propofol–dexmedetomidine maintained higher minimum heart rate and oxygen saturation than propofol–fentanyl, with comparable blood pressure changes. These findings are consistent with evidence of propofol-associated hypoxia and hypotension during ERCP and previous research showing better cardiorespiratory stability with dexmedetomidine [2,12,13].

Overall, propofol–dexmedetomidine appears to offer greater cardiorespiratory stability during ERCP.

In our study, oxygen desaturation, airway intervention, and prolonged recovery were significantly less frequent with propofol–dexmedetomidine than with propofol–fentanyl. Bradycardia was more common with dexmedetomidine but was not significant. These findings are consistent with previous studies reporting favourable safety and respiratory outcomes with dexmedetomidine-based sedation during ERCP, compared with propofol–fentanyl combinations [14,15]. Overall, propofol–dexmedetomidine demonstrated a better adverse-event profile during ERCP sedation.

In our study, adequate and excellent sedation were more frequent with propofol–dexmedetomidine, although differences were not statistically significant. However, patient satisfaction was significantly higher with dexmedetomidine. These findings are consistent with previous evidence showing that effective, patient-centred sedation improves satisfaction during ERCP [16], while another randomized trial demonstrated favourable sedation outcomes with alternatives to propofol–

fentanyl [17]. Overall, propofol–dexmedetomidine provided effective sedation with greater patient satisfaction.

Overall, propofol–dexmedetomidine provided comparable ERCP completion with lower propofol use, faster recovery, better oxygenation, fewer respiratory events, and higher patient satisfaction than propofol–fentanyl. These findings are consistent with previous studies supporting dexmedetomidine-based sedation during ERCP [15–17]. Thus, propofol–dexmedetomidine appears to be an effective alternative for ERCP sedation. Overall, Propofol–dexmedetomidine provided effective ERCP sedation with lower propofol requirements, faster recovery, better cardiorespiratory stability, fewer respiratory adverse events, and higher patient satisfaction than propofol–fentanyl.

CONCLUSION

Propofol–dexmedetomidine provided effective and well-tolerated sedation for ERCP, with significantly lower propofol consumption, faster recovery, better oxygenation, fewer respiratory adverse events, and greater patient satisfaction than propofol–fentanyl. Although bradycardia was more frequent with dexmedetomidine, it was not statistically significant. Overall, propofol–dexmedetomidine appears to be a promising alternative to propofol–fentanyl for ERCP sedation, particularly when careful haemodynamic and respiratory monitoring is ensured.

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