Comparison of the Effectiveness of Propofol-Remifentanil and Propofol-Fentanyl for Procedural Sedation During Endoscopic Retrograde Cholangiopancreatography

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ABSTRACT

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is a technically challenging procedure that demands effective procedural sedation for patient comfort and procedural success. This study aimed to compare the efficacy of propofol-remifentanil (Group R) and propofol-fentanyl (Group F) combinations for sedation during ERCP. **Methods & Materials:** This prospective, comparative study was conducted at Dhaka Medical College Hospital from April 2023 to October 2024. 50 adult patients (ASA I-II) who were undergoing elective ERCP were randomly divided into two groups of 25 patients. Both groups were given a loading dose of 1.5 mg/kg of propofol, with Group F being given a fentanyl 1 mcg/kg bolus and Group R being given a remifentanil infusion of 0.05 mcg/kg/min. Haemodynamic parameters, sedation (Ramsay Sedation Scale), pain (Facial Pain Rating Scale), drug requirements, recovery time, and adverse events were recorded. Data were entered and analyzed using IBM SPSS version 26. **Results:** Demographic and baseline characteristics were similar between the two groups. Heart rate and mean arterial pressure were significantly lower in group R in the procedural phases ($p<0.05$). Group R also had deeper sedation at T2 (RSS: 5.1 vs 3.1, $p=0.001$) and had significantly lower pain scores throughout ($p<0.05$). Total propofol consumption (180.5 vs 213.3 mg, $p=0.026$), rescue analgesia requirement (3.0 vs 15.0 mg, $p=0.013$), recovery time (8.9 vs 12.8 min, $p=0.001$), and time to discharge (65.7 vs 78.4 min, $p=0.002$) were significantly lower in Group R. Adverse event rates were similar between groups. **Conclusion:** Propofol-remifentanil combination is more effective and clinically useful for procedural sedation in ERCP, offering superior sedation quality, better analgesia, reduced propofol consumption, and faster recovery.

Keywords: *ERCP; propofol; remifentanil; fentanyl; procedural sedation; Ramsay Sedation Scale.*

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced endoscopy procedure performed for the diagnosis and treatment of biliary and pancreatic diseases such as choledocholithiasis, biliary strictures and pancreatitis. Effective procedural sedation is necessary for patient comfort, procedural success and safety because of the prolonged and invasive nature of the procedure [1]. Over the last decade, the need for good sedation during ERCP has increased greatly, and the search for the best combination of drugs with rapid onset, good analgesia and rapid recovery has begun [2]. Propofol has become a drug of choice for procedural sedation because of its quick onset of action, short duration of action, and good recovery profile. When administered alone, however, higher doses may be needed to provide sufficient sedation, which may lead to cardiorespiratory depression [3]. Propofol can be used in combination with opioids (e.g. fentanyl or remifentanil) to reduce the dose required due to the synergistic effect, and to improve the quality of sedation and analgesia [4]. Fentanyl is a common synthetic opioid that has proven to be safe and effective in procedural sedation. It has a relatively short duration of action and is widely used by clinicians as an adjunct to propofol in endoscopy procedures [5]. Remifentanil is an ultra-short acting opioid that is metabolized by non-specific plasma and tissue esterases and has a context-sensitive half-life of about 3 to 5 minutes, regardless of infusion time [6]. This distinctive pharmacokinetic profile enables precise titration of analgesia and allows for a rapid offset after prolonged infusions, especially during variable-duration procedures like ERCP [7]. Remifentanil has been assessed in several studies for its use in different procedures and has been shown to provide better intraoperative pain relief and more rapid recovery than longer-acting opioids [8]. The Ramsay Sedation Scale (RSS) is one of the most commonly used scales to assess depth of sedation in clinical practice. The goal of procedural sedation is to achieve patient immobility with spontaneous ventilation, typically a score greater than 3.A score greater than 3 is generally aimed for during procedural sedation to ensure patient immobility with spontaneous ventilation [9]. Likewise, the Facial Pain Rating Scale (F-PRS) is a validated tool for measuring pain intensity in patients with limited verbal communication during sedation [10]. They have been widely applied in the field of endoscopic sedation research to objectively assess the quality of sedation and the effectiveness of the analgesia. Comparative clinical evidence for remifentanil specifically for ERCP sedation is limited, especially from South Asian clinical settings, despite the theoretical benefits of remifentanil. Previous research has shown conflicting results for haemodynamic stability, sedation level, and recovery parameters between remifentanil and fentanyl sedation with propofol [11]. Clinically significant potential benefits of remifentanil in reducing total propofol consumption and minimizing post-procedural recovery time are especially relevant in high-volume endoscopy units where procedural efficiency is a key concern. The aim of this study was therefore to compare the efficacy of propofol-remifentanil with propofol-fentanyl for procedural sedation in ERCP, focusing on

haemodynamic parameters, sedation and pain scores, drug requirements, and recovery outcomes.

METHODS & MATERIALS

This prospective, comparative study was carried out at the Department of Anaesthesia, Pain, Palliative and Intensive Care, Dhaka Medical College Hospital, Dhaka, Bangladesh, from April 2023 to October 2024 in collaboration with the Department of Surgical Gastroenterology, Dhaka Medical College Hospital, Dhaka, Bangladesh. A total of 50 adult patients who were scheduled for elective ERCP were enrolled. Patients with American Society of Anesthesiologists (ASA) physical status I or II, Mallampati class I or II were included. Patients were excluded if they had a history of drug allergy, smoking, severe obesity, clinically significant cardiovascular, respiratory, hepatic, renal, neurological, or psychiatric illness, or were pregnant or lactating. The patients were randomly assigned to two groups of 25 by computer-generated randomisation. Group F (Fentanyl group) was given an intravenous bolus dose of fentanyl 1 mcg/kg followed by infusion of normal saline, while Group R (Remifentanil group) was given an intravenous bolus dose of distilled water followed by infusion of remifentanil at 0.05 mcg/kg/min during the procedure. The loading dose of propofol was 1.5 mg/kg for both groups, and additional doses of propofol 0.5 mg/kg were given as necessary to keep the Ramsay Sedation Scale (RSS) score above 3. If the Facial Pain Rating Scale (F-PRS) score was greater than 2, rescue analgesia was given as pethidine 25 mg. Independent variables were opioid adjunct (fentanyl or remifentanil), and dependent variables were haemodynamic parameters (heart rate, mean arterial pressure, and oxygen saturation), sedation score (RSS), pain score (F-PRS), total drug requirements, onset of sedation, procedure and recovery duration, and adverse events. The Modified Aldrete Score was used to assess recovery. Data were analyzed using IBM SPSS Statistics version 26. Quantitative variables were presented as mean ± SD, categorical variables were presented as frequency and percentage, and the comparison between groups was done by Student's t-test and ANOVA, and the value of $p<0.05$ was considered statistically significant. The time point in this study was shown as follows: T0 = Baseline (before administration of study drugs); T2 = 5 minutes after administration of study drugs (early procedural phase); T5 = 15 minutes after administration of study drugs (mid-procedural phase); T10 = 30 minutes after administration of study drugs (late procedural phase); After procedure = immediately after completion of ERCP.

RESULTS

The demographic profile of both groups is shown in Table I. The mean age of Group F was 40.40 ± 9.13 years and of Group R was 40.48 ± 9.28 years (p=0.975). Mean BMI was comparable (Group F: 23.5 ± 1.4; Group R: 23.2 ± 1.3 kg/m²; p=0.473). The female patients outnumbered the male patients in both groups (60% in Group F and 64% in Group R). The ASA status was more common in Group F (72%) than in Group R (56%) (*Table I*).

Table I
Demographic characteristics of the study population (*n*=50).

Variable	Group F (n=25)	Group R (n=25)	p-value
Age (years)	40.40 ± 9.13	40.48 ± 9.28	0.975
BMI (kg/m²)	23.5 ± 1.4	23.2 ± 1.3	0.473
Gender (Male)	10 (40.0%)	9 (36.0%)	0.773
Gender (Female)	15 (60.0%)	16 (64.0%)	0.773
ASA I	18 (72.0%)	14 (56.0%)	0.239
ASA II	7 (28.0%)	11 (44.0%)	0.237

The co-morbidity profile of the study participants is summarized in *Table II*. The most common co-morbidity was hypertension, which was seen in 28% of Group F and 40% of Group R patients.

Table II
Clinical characteristics and co-morbidities (*n*=50).

Variable	Group F (n=25)	Group R (n=25)	p-value
No co-morbidity	16 (64.0%)	14 (56.0%)	0.238
Diabetes mellitus	2 (8.0%)	1 (4.0%)	0.217
Hypertension	7 (28.0%)	10 (40.0%)	0.128

Haemodynamic and oxygenation parameters are shown in *Table III* at five time points. There were no differences in baseline heart rate and MAP between groups (p>0.05). Heart rates were significantly lower in Group R compared to Group F from T2 onwards (p<0.05) and at T10 (73.0 vs 84.6 beats/min). Similarly, MAP was significantly lower in Group R at all post-baseline time points (p<0.05). There was no statistically significant difference in oxygen saturation (SpO_2) between the groups at any time point (p>0.05).

Table III
Comparison of physiological parameters during ERCP (*n*=50).

Parameter	Time Point	Group F (n=25)	Group R (n=25)	p-value
Heart rate (beats/min)	T0	83.8±6.1	84.2±7.3	0.852
	T2	81.4±7.5	76.8±8.1	0.041
	T5	83.2±7.0	74.8±8.4	0.002
	T10	84.6±6.8	73.0±8.8	0.001
	After procedure	86.1±6.5	78.4±7.2	0.001
Mean arterial pressure (mmHg)	T0	96.7±5.6	94.4±4.1	0.110
	T2	90.3±4.9	85.7±5.1	0.006
	T5	87.8±4.3	82.9±4.8	0.001
	T10	85.2±3.6	80.4±4.0	0.001

	After procedure	89.6±4.8	84.9±5.0	0.002
SpO_2 (%)	T0	98.1±2.5	98.2±1.7	0.808
	T2	97.8±1.6	98.0±1.4	0.653
	T5	97.5±1.3	97.9±1.5	0.394
	T10	97.2±1.0	97.6±1.3	0.356
	After procedure	98.0±1.2	98.3±1.1	0.361

The sedation depth at procedural time points is shown in *Table IV*, based on the RSS. There was no difference between the two groups in baseline scores (p=0.085). At T2, Group R demonstrated significantly deeper sedation than Group F (5.1 ± 1.0 vs 3.1 ± 1.2; p=0.001). Sedation scores were also numerically higher in Group R at T5 and T10, but not statistically significant (p=0.148 and p=0.198, respectively). There were no differences in post-procedure RSS values between groups (p=0.472).

Table IV
Comparison of Ramsay Sedation Score (RSS) during ERCP (*n*=50).

Time Point	Group F (n=25)	Group R (n=25)	p-value
T0	1.8±0.4	2.0±0.2	0.085
T2	3.1±1.2	5.1±1.0	0.001
T5	3.2±1.5	3.8±1.2	0.148
T10	3.3±1.1	3.8±1.1	0.198
After procedure	2.1±0.5	2.0±0.4	0.472

The Facial Pain Rating Scale (FPRS) was used to assess pain at various stages of the procedure, and the results are presented in *Table V*. There was no difference between the baseline pain scores of both groups (p=0.611). From T2 onward, Group R consistently reported lower pain scores than Group F at all time points (T2: 0.72 vs 1.52, p=0.043; T5: 0.64 vs 1.40, p=0.030; T10: 0.30 vs 1.30, p=0.026; post-procedure: 0.90 vs 2.20, p=0.009), with statistically significant differences observed at all post-baseline assessments.

Table V
Comparison of F-PRS pain score during ERCP (*n*=50).

Time Point	Group F (n=25)	Group R (n=25)	p-value
T0	1.16±1.7	1.40±2.1	0.611
T2	1.52±1.66	0.72±0.97	0.043
T5	1.40±1.60	0.64±1.30	0.030
T10	1.30±1.60	0.30±0.70	0.026
After procedure	2.20±1.50	0.90±0.80	0.009

Data on drug utilization and procedural parameters are shown in *Table VI*. Patients in Group R had significantly fewer patients who required rescue opioids (20% vs 56%; p=0.019). The additional and total doses of propofol were significantly lower in Group R (77.0 vs 110.5 mg and 180.5 vs 213.3 mg, respectively; p<0.05). Total opioid requirement was higher in Group R (109.5 vs 69.3 mcg; p=0.001). Onset of sedation was faster in Group R (2.6 vs 4.2 min; p=0.002). The duration of procedure and sedation was similar between groups (p>0.05).

Table VI
Comparison of drug requirements and procedural characteristics (*n*=50).

Variable	Group F (n=25)	Group R (n=25)	p-value
Patients requiring rescue opioids	14 (56.0%)	5 (20.0%)	0.019
Propofol initial bolus (mg)	98.8±20.9	102.4±10.6	0.462
Additional propofol dose (mg)	110.5±30.1	77.0±17.3	0.001
Total propofol dose (mg)	213.3±40.4	180.5±22.5	0.026
Total opioid requirement (mcg)	69.3±7.08	109.5±20.6	0.001
Rescue analgesic requirement (mg)	15.0±21.5	3.0±8.2	0.013
Onset of sedation (min)	4.2±0.8	2.6±0.7	0.002
Duration of ERCP (min)	29.2±5.7	30.0±6.8	0.641
Duration of sedation (min)	40.6±6.0	39.9±7.0	0.696

Summary of recovery outcomes and adverse event profiles are presented in *Table VII*. Recovery time was significantly shorter in Group R (8.9 ± 2.8 vs 12.8 ± 3.6 min; p=0.001), and time to discharge was also significantly reduced (65.7 ± 10.2 vs 78.4 ± 12.5 min; p=0.002). Post-procedural pain was more common in Group F (40% vs 8%; p=0.009). The incidence of hypotension, bradycardia, restlessness, and desaturation was comparable between the two groups, with no significant difference between them [Table VII].

Table VII
Comparison of recovery outcomes and adverse events (*n*=50).

Variable	Group F (n=25)	Group R (n=25)	p-value
Recovery time (min)	12.8±3.6	8.9±2.8	0.001
Time to discharge (min)	78.4±12.5	65.7±10.2	0.002
Pain	10 (40.0%)	2 (8.0%)	0.009
Hypotension	3 (12.0%)	3 (12.0%)	1.000
Bradycardia	2 (8.0%)	3 (12.0%)	0.637
Restlessness	7 (28.0%)	2 (8.0%)	0.070
Desaturation	3 (12.0%)	1 (4.0%)	0.297

DISCUSSION

This study compared the efficacy of propofol-remifentanil sedation with propofol-fentanyl sedation in ERCP, a procedure that is technically complex and has a variable duration, requiring precise and titratable analgesia. The two groups were comparable in terms of age, sex, BMI, ASA classification, and co-morbidity profile, and any differences in clinical outcomes were due to the sedation regimen and not to patient-related confounders. One of the most notable results of this study was the significantly reduced heart rate and mean arterial pressure in Group R in the early procedural phase. This haemodynamic pattern is typical of the sympatholytic effect of remifentanil, which is more effective at reducing the physiological stress response to procedural stimulation than single-bolus fentanyl [12]. These differences were statistically significant, but not clinically significant in both groups, and the incidence of hypotension and bradycardia was comparable, indicating that the haemodynamic effects of remifentanil were well-tolerated and did not compromise patient safety [13]. Both regimens were safe, with oxygen saturation levels not dropping below 97% during the procedure, and no clinically significant desaturation events were observed [14]. The mean RSS for Group R was significantly lower at the early procedural phase (T2) than for Group F, 5.1 versus 3.1 (p=0.001). This disimilarity is due to the rapid onset of remifentanil infusion and its synergistic effect with propofol, which enabled earlier and deeper sedation without the need for additional propofol loading [15]. Remifentanil's rapid onset of action when the infusion is started may have minimized nociceptive input and arousal, which allowed for deeper sedation with lower doses of propofol compared to the slower equilibration of fentanyl to the effect site [16]. Sedation scores were similar between groups at mid and late procedural phases, possibly due to similar titration of propofol during steady state. At all post-baseline time points, including post-procedurally, Group R had significantly lower pain scores than Group F, with Group F patients reporting significantly higher pain (2.20 vs 0.90; p=0.009). The superior analgesic profile of remifentanil infusion over fentanyl bolus is documented by Bhatt et al., mainly due to the continuous receptor occupancy of remifentanil during the procedure, whereas the plasma concentration of fentanyl decreases over time [17]. This analgesic benefit was directly reflected in clinical outcomes with significantly fewer patients in Group R requiring rescue opioid analgesia (20% vs 56%; p=0.019), and significantly less rescue pethidine (3.0 vs 15.0 mg; p=0.013) [18]. The total and supplemental propofol consumption was significantly less in Group R (180.5 vs 213.3 mg and 77.0 vs 110.5 mg, respectively; p<0.05). The propofol-sparing effect of remifentanil infusion is a clinically relevant benefit, and lower doses of propofol have been shown to be associated with a decreased risk of respiratory depression, cardiovascular compromise, and prolonged recovery [19]. The rapid onset of sedation in Group R (2.6 vs 4.2 min; p=0.002) is in line with the rapid pharmacokinetics of remifentanil and probably due to its earlier effect on procedural arousal, which is mediated by the analgesic effect, and thus allows for faster attainment of target sedation depth [20]. The recovery time was significantly shorter in Group R (8.9 min vs 12.8 min; p=0.001), and the time to discharge was also significantly shorter (65.7 min vs 78.4 min; p=0.002). The results are directly related to the ultra-short context-sensitive half-life of remifentanil, which means that the opioid effect is rapidly offset, irrespective of the duration of infusion, while fentanyl has a longer elimination half-life, which may lead to residual sedation and delayed readiness for discharge [21]. Operational implications of faster turnover are important from an efficiency and resource utilization point of view in endoscopy units. Adverse event profiles were similar between groups, with hypotension, bradycardia, restlessness, and desaturation being the most common events, and both regimens were safe when administered by trained personnel with proper monitoring [22]. The analgesic benefits of remifentanil infusion were further confirmed by the higher incidence of post-procedural pain in Group F (40% vs 8%; p=0.009). These results indicate that propofol-remifentanil is a clinically superior sedation regimen for ERCP than propofol-fentanyl, with superior analgesia, lower drug consumption, and quicker recovery, without compromising safety.

LIMITATIONS

This study was performed in a single tertiary centre with a small number of patients (n=50) and may not be applicable to other populations and endoscopy settings. Furthermore, the study did not evaluate long-term pain results or satisfaction scores beyond the immediate recovery period.

CONCLUSION

In patients undergoing ERCP, the propofol-remifentanil combination provided better sedation, better intraoperative analgesia, and significantly lower pain scores compared to propofol-fentanyl. The pharmacodynamic interaction between remifentanil and propofol was favourable as Group R needed significantly less supplemental propofol and rescue analgesia. The time to sedation was shorter, and recovery times were significantly reduced in the remifentanil group, which also resulted in a reduction in time to discharge. Both treatments were haemodynamically stable and had similar adverse event rates, thus demonstrating the safety of remifentanil infusion as an adjunct to procedural sedation. The propofol-remifentanil combination is a more effective and clinically efficient approach to procedural sedation during ERCP, and may be a preferred sedation approach in appropriately monitored endoscopy settings, based on these findings.

RECOMMENDATIONS

These results should be confirmed by future multicenter, large-scale randomized controlled trials in different patient groups and in different levels of ERCP complexity. Patient satisfaction scores, cost-effectiveness analyses, and bispectral index monitoring should be included in further studies to better assess remifentanil-based sedation regimens in procedural endoscopy.

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CONFLICT OF INTEREST

None declared

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