

# Efficacy and safety during endoscopic retrograde cholangiopancreatography (ERCP) under total intravenous anesthesia – propofol alone versus propofol supplemented with dexketa, a comparative study in medical college, Kolkata



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## ABSTRACT

**Background:** Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive procedure and, hence, is distressing for awake patients, requiring an adequate level of anesthesia. Recent advancements have encouraged the use of monitored anesthesia care, that allows the patient to tolerate unpleasant experiences during procedures while maintaining cardio-respiratory function. Usually, propofol-based anesthesia is given in ERCP. The main aim of this study is to compare the effect of propofol alone and propofol with ketamine and dexmedetomidine on the hemodynamics during ERCP, recovery profile, and side effects (if any). **Aims and Objectives:** (1) To compare efficacy in terms of hemodynamic stability and desaturation events. (2) Recovery and quality of recovery. (3) Pain score. (4) Incidence of post-operative nausea and vomiting. **Materials and Methods:** This is a comparative double-blinded study. Adult patients from the age group of 18–70 years belonging to the American Society of Anesthesiologists (ASA-I) and ASA-II who had undergone ERCP under total intravenous anesthesia were taken and randomly assigned to either of the two groups. Both groups received 0.01 mg/kg glycopyrrolate, 0.1 mg/kg ondansetron, 0.05 mg/kg midazolam, 50 mcg fentanyl, and 40 mg hyoscine. Group A patients received 30 mg propofol as a bolus dose and then repeated according to requirements. Group B patients received 0.5 mcg/kg dexmedetomidine as a loading dose and 0.3 mcg/kg/h as a maintenance infusion dose. 30 mg propofol was given before negotiating scope and then 1 mL (1:1) mixture of propofol and ketamine was repeated according to requirements. Total propofol consumption, hemodynamics, quality of recovery, and side effects (if any) were recorded at regular intervals. **Results:** The study showed significant cases in Group A had episodes of hypotension and apneic events, whereas there were very few hemodynamic instability and almost no apneic events in Group B patients. The requirement of propofol was much higher in Group A patients. **Conclusion:** Dexmedetomidine when used along with propofol and ketamine in ERCP patients reduced the dose requirement of propofol and maintained hemodynamic stability without causing any apneic events.

**Key words:** Dexmedetomidine; Propofol; Ketamine; Endoscopic retrograde cholangiopancreatography; Total intravenous anesthesia

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## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) used for hepatobiliary stones and strictures causing obstructive jaundice and hyperbilirubinemia has a therapeutic as well as palliative role in advanced end-stage diseases and reduces the necessity of major surgical interventions and avoids morbidity and mortality.<sup>1,2</sup>

Advanced obstructive conditions with high bilirubin and enzyme levels alter drug mechanics and interactions, enhancing the chances of toxicity and adverse effects of individual drugs.<sup>3</sup> Hence, different drugs, when combined and used in the lowest possible doses, have beneficial effects.

Propofol has been widely used in hospital, office-based, and outdoor-based scenarios worldwide in most cases to achieve an adequate level of depth, sedation, and analgesia.<sup>4,5</sup> When used alone, it is used in supraoptimal doses in most cases.

Most complications in ERCP are related to anesthesia, including cardiopulmonary events such as hypoxemia, hypoventilation, airway obstruction, apnea, arrhythmia, hypotension, and vasovagal episodes.<sup>3</sup>

With the emerging use of different intravenous anesthetic agents, the adverse effects of a single agent in supraoptimal dose during the procedure can be avoided.<sup>6</sup> Introducing dexmedetomidine and ketamine as additives to propofol is expected to dramatically decrease the dose requirements of propofol, using quality sedation of dexmedetomidine and excellent analgesia of ketamine, whereas their mutual antagonistic effects in some properties nullify their side effect.<sup>7-10</sup>

### Aims and objectives

#### Aims

Our study aims to examine the combination drug effect of the mentioned intravenous anesthetic.<sup>11-14</sup>

#### Objectives of this study

1. To compare efficacy in terms of hemodynamic stability
2. To compare efficacy in terms of desaturation events
3. Recovery and quality of recovery (measured in terms of Modified Aldrete's score)
4. Pain score (in terms of faces pain scale) measured at regular intervals up to 2 h after the end of the procedure
5. Incidence of post-operative nausea and vomiting (PONV) up to 4 h after the end of the procedure and gaining clear consciousness.

## MATERIALS AND METHODS

This is a comparative, double-blinded observational study. After taking approval from the Institutional Ethics Committee and written informed consent, a total of 66 adult patients scheduled for therapeutic ERCP in the Gastromedicine Department of Medical College and Hospital, Kolkata, during May 2023–August 2023, were enrolled in the study. All patients aged between 18 and 70 years were in the American Society of Anesthesiologists (ASA I) and ASA II physical status classification having no anticipated difficult airway. Patients with acute kidney injury, chronic kidney disease, low ejection fraction, other heart diseases, morbid obesity, undergoing the emergency procedure, with a difficult airway, having known allergy to drugs to be used in the study, previous bleeding disorder or coagulopathy, and duration of a procedure if more than 60 min were excluded from our study. The study took place in the ERCP operation theater of the super specialty block of Medical College and Hospital, Kolkata. However, out of 66 patients, two cases had to be aborted. The procedures followed were in accordance with the ethical guidelines laid down by the Declaration of Helsinki, 1975 (as revised in 1983) for biomedical research involving human subjects.

- Group A: Patients were getting injection of propofol
- Group B: Patients were getting injection propofol + injection ketamine + injection dexmedetomidine.

First, we did intravenous cannulation of the patients of the two groups and secured it properly. Pre-loading was done with intravenous fluid ringer lactate 10–15 mL/kg over 30 min. Non-invasive blood pressure cuff, oxygen saturation probe, and electrocardiogram (ECG) leads were attached. Moist oxygen at 2 L/min was given to all patients through the nasal cannula.

The patient was made to lie in a prone position on the operating table and all monitors were attached. 0.01 mg/kg injection of glycopyrrolate, 0.1 mg/kg injection of ondansetron, and 0.05 mg/kg injection of midazolam was given slow IV to both groups of patients as pre-medications. Now, Group A patients were given only injection of propofol and Group B patients were given injection of propofol with injection of ketamine and injection of dexmedetomidine.

To Group A patients, 100 mL 0.9% normal saline (NS) infusion was given slowly IV over 10 min (for blinding purposes). Then, a 30 mg injection of propofol was given a slow IV as a bolus dose in running fluid. After 3 min, a mouth gag was placed. While negotiating scope, a 50 mcg injection of fentanyl and injection of propofol were given

a slow IV as per need. By this time, 50 mL NS was started as an infusion dose slowly IV through a syringe pump (for blinding purposes). Then, the injection of propofol was repeated slowly IV according to requirements. NS infusion was stopped after stone retrieval.

To Group B patients, 0.5 mcg/kg body weight injection dexmedetomidine in 100 mL NS was given as a loading dose over 10 min IV. Then, a 30 mg injection of propofol was given in a slow IV as a bolus dose in running fluid. After 3 min, a mouth gag was placed. While negotiating scope, a 50 mcg injection of fentanyl was given a slow IV. By this time, injection of dexmedetomidine was started as an infusion dose of 0.3 mcg/kg/h IV through a syringe pump. The scope was then negotiated. A (1:1) mixture of injection propofol and injection ketamine was prepared beforehand by taking a 10 mL syringe, in which 5 mL injection propofol, 1 mL injection of ketamine, and the rest 4 mL 0.9% injection NS was taken. Then each ml of this mixture would contain 5 mg of injection propofol and 5 mg injection ketamine. After the scope was negotiated, 1 mL of this (1:1) mixture of injection propofol and injection ketamine was given a slow IV according to requirements. Infusion of injection dexmedetomidine was stopped after stone retrieval.

Injection of buscopan (40 mg) was given a slow IV after negotiating scope and before sphincterotomy to patients of both groups.

ECG, blood pressure, heart rate (HR), and oxygen saturation were monitored throughout the operative procedure and recorded every 5 min till the end of the procedure. The patient and the 3<sup>rd</sup> person recording the data were blinded about the procedure. Intravenous fluid was administered according to the hemodynamic status of the patient. Vasopressors and vasodilators were kept for emergency use. After the procedure, all patients were sent to the post-operative care unit and were monitored for pain, PONV, and quality of recovery.

Pain assessment (measured in terms of face pain scale) was measured at the end of the procedure and then at 15 min intervals up to 2 h. Recovery and quality of recovery were measured in terms of Modified Aldrete's Score. Incidence of PONV was monitored up to 4 h after the end of the procedure and gaining clear consciousness.

In the case of bradycardia (HR <50 beat/min), hypotension (i.e., mean arterial pressure [MAP] <65 mm Hg), or desaturation (SPO<sub>2</sub> <92%), adequate therapeutic applications were carried out in each situation (atropine 0.5 mg for bradycardia, vasopressors such as injection

mephentermine 6 mg or injection of phenylephrine 100 mcg for hypotension). In case of desaturation, oxygen through the nasal cannula was increased to 4–6 L/min. Post-operative pain was assessed by visual analog scale (VAS), if VAS >3, pain was treated by 10–15 mg/kg paracetamol IV infusion. PONV was treated by giving 4 mg injection of ondansetron slow IV. Patients were discharged from the recovery room when a Modified Aldrete's score ≥9 was obtained.

## RESULTS

Categorical variables were expressed as number of patients and percentage of patients and compared, if required, using Pearson's Chi-square test for independence of attributes/Fisher's exact test as appropriate.

Continuous variables were expressed as Mean ± standard deviation and compared using unpaired t-test/One-Way analysis of variance if the data follows normal distribution or median and interquartile range, and compared using Mann–Whitney U test if the data does not follow normal distribution.

The statistical software Statistical Package for the Social Sciences version 22 was used for the analysis.

An alpha level of 5% has been taken, i.e., if any P<0.05, it was considered significant.

Demographic parameters such as age and sex, time for recovery, Modified Aldrete's Score, and post-operative nausea vomiting had no significant difference between the two groups.

Parameters are analyzed using Student's unpaired t-test except categorical data, which are analyzed using Chi-square test. P<0.05 indicates that the difference is statistically significant.

The demographic parameters, time for recovery, Modified Aldrete's score, and post-operative nausea vomiting were comparable between the two groups (Table 1).

Intergroup analysis, Student's unpaired t-test, P<0.05 indicates that the difference is statistically significant. Group A, patients receiving only propofol, Group B, patients receiving propofol + dexketa mixture.

The mean HR at 0 min, 5 min, 10 min, 15 min, 20 min, 25 min, 30 min, 35 min, 40 min, and 45 min were considerably lower with the use of propofol + dexketa mixture in comparison with the use of propofol alone (Table 2).

**Table 1: Demographic characteristics, time for recovery, modified Aldrete’s score, and post-operative nausea vomiting comparison between two groups**

Parameters	Group A	Group B	P-value	Significance
Age (mean)	49.69	44.42	0.106	NS
Sex	Female=20 Male=13	Female=19 Male=14	0.802	NS
Time for recovery (mean±SD)	8.55±1.03	9.30±1.69	0.066	NS
Modified Aldrete’s score (mean±SD)	8.70±0.77	8.45±0.62	0.345	NS
PONV	No=30 Yes=3	No=31 Yes=2	0.642	NS

NS: Nonsignificant, SD: Standard deviation, PONV: Post-operative nausea and vomiting

**Table 2: Comparison of heart rate at different points of time between the 2 groups**

Parameter	Group A			Group B			P-value	Significance
	Mean	Median	SD	Mean	Median	SD		
HR_0	108.85	111.00	15.02	92.36	90.00	15.57	<0.001	Significant
HR_5	110.42	109.00	12.46	98.21	92.00	13.49	<0.001	Significant
HR_10	110.09	113.00	11.88	91.61	96.00	7.29	<0.001	Significant
HR_15	114.45	112.00	8.21	91.79	90.00	4.68	<0.001	Significant
HR_20	108.00	107.00	8.84	94.73	90.00	15.68	0.001	Significant
HR_25	104.62	100.00	12.11	92.22	87.00	13.55	0.001	Significant
HR_30	107.43	111.00	13.34	83.00	83.00	0.00	<0.001	Significant
HR_35	97.67	94.00	18.88	77.82	81.00	4.43	0.001	Significant
HR_40	96.87	91.00	22.55	78.94	80.00	1.48	0.021	Significant
HR_45	115.73	113.00	4.56	74.00	74.00	0.00	<0.001	Significant
HR_50	106.73	109.00	15.01				NA	NA
HR_55	104.00	104.00	0.00				NA	NA

SD: Standard deviation, NA: Not available

Intergroup analysis, Student’s unpaired t-test, P<0.05 indicates that the difference is statistically significant. Group A, patients receiving only propofol, Group B, patients receiving propofol + dexketa mixture.

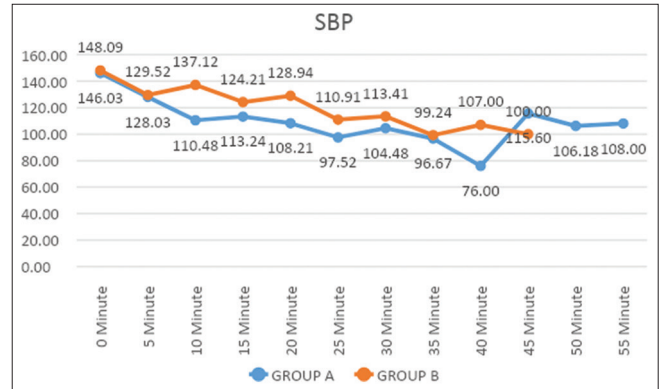
The mean SBP at 10 min, 15 min, 20 min, 25 min, and 40 min were considerably lower in the case of using propofol alone in comparison with using propofol + dexketa mixture (Graph 1).

Intergroup analysis, Student’s unpaired t-test, P<0.05 indicates that the difference is statistically significant. Group A, patients receiving only propofol, Group B, patients receiving propofol + dexketa mixture.

The mean diastolic blood pressure (DBP) at 10 min, 20 min, 25 min, 30 min, and 40 min was considerably lower with the use of propofol alone in comparison with using propofol + dexketa mixture (Graph 2).

Intergroup analysis, Student’s unpaired t-test, P<0.05 indicates that the difference is statistically significant. Group A, patients receiving only propofol, Group B, patients receiving propofol + dexketa mixture.

The mean MAP at 10 min, 20 min, 25 min, and 40 min were considerably lower in the group using only propofol as

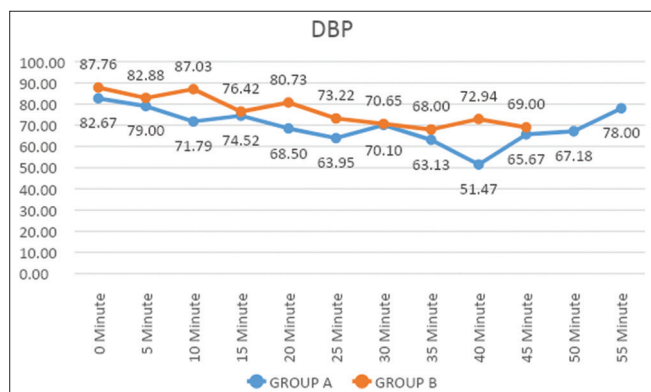


**Graph 1:** Comparison of systolic blood pressure (SBP) at different points of time between the two groups

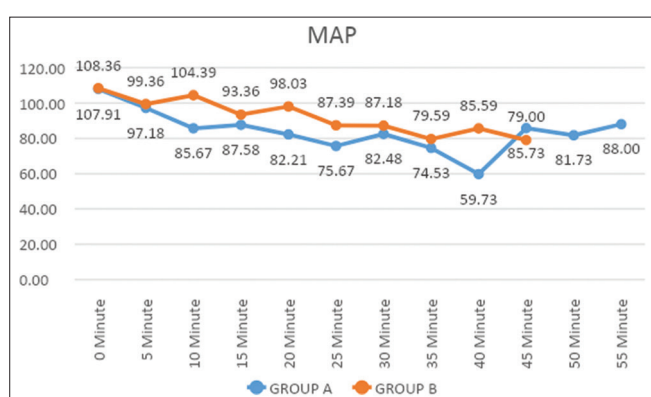
compared to the group using propofol + dexketa mixture (Graph 3).

Intergroup analysis, Student’s unpaired t-test, P<0.05 indicates that the difference is statistically significant. Group A, patients receiving only propofol, Group B, patients receiving propofol + dexketa mixture.

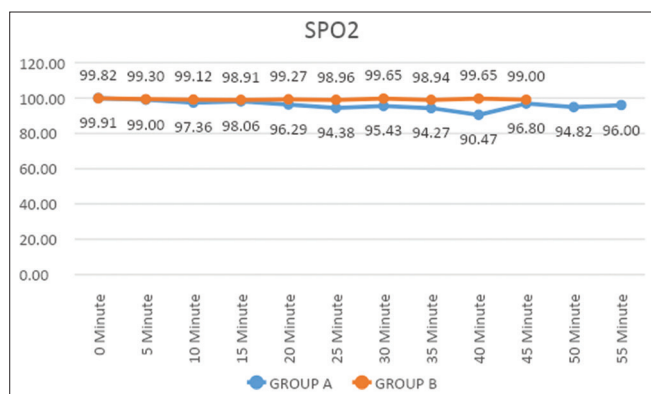
The mean SPO<sub>2</sub> at 10 min, 15 min, 20 min, 25 min, 30 min, 35 min, and 40 min were considerably lower in the case of using propofol alone in comparison with the use of propofol + dexketa mixture (Graph 4).



**Graph 2:** Comparison of diastolic blood pressure at different points of time between the two groups



**Graph 3:** Comparison of mean arterial pressure at different points of time between the two groups



**Graph 4:** Comparison of oxygen saturation at different points of time between the two groups

Intergroup analysis, Student’s unpaired t-test,  $P < 0.05$  indicates that the difference is statistically significant. Group A, patients receiving only propofol, Group B, patients receiving propofol + dexketa mixture.

The mean requirement of vasopressor was considerably much lower in the group receiving propofol + dexketa mixture than in the group receiving only propofol (Table 3).

Intergroup analysis, Student’s unpaired t-test,  $P < 0.05$  indicates that the difference is statistically significant. Group A, patients receiving only propofol, Group B, patients receiving propofol + dexketa mixture.

The mean pain score was considerably lower in the group receiving propofol + dexketa mixture than in the group receiving only propofol (Table 4).

Intergroup analysis, Student’s unpaired t-test,  $P < 0.05$  indicates that the difference is statistically significant. Group A, patients receiving only propofol, Group B, patients receiving propofol + dexketa mixture.

The mean propofol consumption was considerably much lower in the group receiving propofol + dexketa mixture than in the group receiving only propofol (Table 5).

Intergroup analysis, Pearson’s Chi-square test,  $P < 0.05$  indicates that the difference is statistically significant. Group A, patients receiving only propofol, Group B, patients receiving propofol + dexketa mixture.

The endoscopists were more satisfied with the performance of patients receiving propofol + dexketa mixture than those receiving only propofol (Table 6).

## DISCUSSION

When the HRs were compared between the two groups, Group B patients showed lower HR as compared to Group A patients. The mean HRs of Group B patients ranged from 77/min to 98/min whereas that of Group A patients ranged from 96/min to 115/min. Thus the HRs between the two groups were found to be statistically significant. Thus, the use of dexmedetomidine resulted in a lowering of the HR.<sup>15-17</sup>

On comparing the systolic blood pressure, DBP, and MAP between the two groups, we found that Group A patients had episodes of hypotension as compared to Group B patients. This was statistically significant. Thus, Group A patients also required the use of vasopressors to correct the hypotension. The requirement of vasopressors was also found to be statistically significant between the two groups.<sup>18</sup> Thus the sole use of propofol causes significant episodes of hypotension whereas propofol when combined with ketamine and dexmedetomidine did not cause such episodes as ketamine has been found to cause an increase in blood pressure.

**Table 3: Comparison of requirement of vasopressor between the two groups**

Parameter	Group A			Group B			P-value	Significance
	Mean	Median	Std. deviation	Mean	Median	Std. deviation		
Requirement of vasopressor	60.67	18.00	67.17	6.00	6.00	0.00	0.003	Significant

**Table 4: Comparison of pain score between the 2 groups**

Parameter	Group A			Group B			P-value	Significance
	Mean	Median	SD	Mean	Median	SD		
Pain score	4.06	4.00	1.27	3.03	4.00	1.02	0.001	Significant

SD: Standard deviation

**Table 5: Comparison of propofol consumption between the two groups**

Parameter	Group A			Group B			P-value	Significance
	Mean	Median	SD	Mean	Median	SD		
Propofol consumption	147.88	140.00	50.36	38.48	30.00	11.21	<0.001	Significant

**Table 6: Comparison of endoscopist's satisfaction between the 2 groups**

Parameter	Group A	Group B	P-value	Significance
Endoscopist's satisfaction (%)	25	75	0.001	Significant

A comparison of the oxygen saturation between the two groups showed there were more desaturation (apneic) events in patients of Group A as compared to patients of Group B. The mean oxygen saturation of Group A patients ranged from 90% to 99% whereas that of Group B patients ranged from 98% to 99%. The P-values were found to be statistically significant. An episode of apnea in one patient was corrected by making the patient supine and ventilating with a bag and mask.<sup>19</sup>

The mean propofol consumption in Group A patients was between 100 and 150 mg whereas the mean propofol consumption in Group B patients was between 30 and 40 mg. In comparison, the P-values were found to be statistically significant. Thus, propofol when combined with ketamine and dexmedetomidine lowers its consumption to a great extent.<sup>14-19</sup>

On comparing the time for recovery between the two groups, Group A patients had a mean recovery time of 8.5 min whereas the mean recovery time in the case of Group B patients was found to be 9.3 min. The Group B patients had a slightly delayed recovery as compared to Group A patients but the P-values when compared were not found to be statistically significant. This shows that the use of dexmedetomidine causes a slight delay in recovery

but it is almost nearly equal to the recovery time in cases where propofol is used as the sole agent.

The pain score when compared between the two groups showed that the Group A patients had more pain as compared to Group B patients. The P-values when compared were found to be statistically significant.<sup>20</sup> Propofol, when used as the sole agent, caused more pain than when it was combined with ketamine and dexmedetomidine. This is because of the excellent analgesic properties of ketamine and also of dexmedetomidine. 50 mcg injection of fentanyl was given to patients of both groups before the start of the procedure.<sup>21</sup>

PONV when compared between the two groups showed that such incidence was comparable in both groups. Propofol being an excellent anti-emetic agent caused almost no post-operative nausea or vomiting in both the groups. On comparing, the P-values were not found to be statistically significant.

Endoscopist's satisfaction index showed that they were more satisfied with the performance of patients belonging to Group B as compared to Group A and this was statistically significant.

#### Limitations of the study

1. ET/CO<sub>2</sub> could not be monitored in this study
2. BIS (Bi Spectral Index) could not be monitored in either dexmedetomidine or ketamine usage
3. In this study, we did not find out the effect of hyperbilirubinemia or altered hepatic function on the drug dose requirements

4. Patients who were critically ill or already intubated were not included in this study.

## CONCLUSION

K (ketamine): P (propofol): D (dexmedetomidine) mixture, when combined and used in ERCP patients, reduced the dose requirement of propofol, decreased pain, and maintained hemodynamic stability without causing any hypoxic events than when propofol was used alone.

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**Authors Contribution:**

**DG**- Definition of intellectual content, Literature survey, Prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, manuscript preparation and submission of article. **DR**- Concept, design, clinical protocol, manuscript preparation, editing, and manuscript revision. **DD**- Design of study, statistical analysis and interpretation. **AGDB**- Review manuscript, literature survey and preparation of figures. **SK**- Coordination and manuscript revision.

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