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Original Research Article

# Study between Fentanyl - Propofol versus Ketamine - Propofol Combination for Sedation and Recovery in ERCP Procedure

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**Abstract:**

**Background:** The gold standard diagnostic and therapeutic approach for pancreaticobiliary diseases is the ERCP, which is frequently carried out in daycare. It is necessary to have a sufficient depth of anaesthesia under sedation or Total Intravenous Anaesthesia (TIVA) for immobility, analgesia, and patient comfort. The ideal sedative–analgesic mixture ought to preserve a patient's hemodynamic status and ought to cause no breathing depression, a quick onset and reversal to initial values, and a small occurrence of postoperative nausea and vomiting. Several pharmacological agents including dexmedetomidine, fentanyl, ketamine, and propofol, are now widely accessible, taking into consideration short induction, rapid recovery, and lessening complications associated with using a single drug.

**Aims and Objectives:** To investigate the groups receiving Fentanyl-Propofol (FentP) versus Ketamine-Propofol (KetP) in ERCP in terms of sedation, rescue sedation requirement, and recovery scores during ERCP. To observe the procedure's hemodynamic changes, postoperative pain score and complications of ERCP. To observe the occurrence of any side effects and complications related to Fentanyl-Propofol (FentP) versus Ketamine-Propofol (KetP).

**Materials and Methods:** A study was carried out at Gandhi Medical College, Bhopal which included 30 adult patients between the age of 18-65 years of ASA Grade I, II and III who underwent ERCP after informed consent. Both groups received 1mg Midazolam and Inj Glycopyrrolate 0.2mg in the pre-anaesthesia area. Group A received Ketamine-Propofol (KetP) and Group B received Fentanyl-Propofol (FentP), each contain 15 patients. All patients are given a loading dose of Propofol 0.75 mg/kg and 75$\mu$g/kg/minute infusion was started. The group FentP received Fentanyl 2$\mu$g/kg and the group KetP received Ketamine 0.5mg/kg. Ramsay sedation scores, the necessity for rescue sedation, hemodynamics changes, complications during surgery and Modified Aldrete score are noted.

**Results:** Ramsay sedation scores at 0, 2, and 4 minute in group B (FentP) are significantly lower, suggesting patients in group A (KetP) experience early sedation (P value 0.00). However, the FentP group has significantly greater sedation scores at 8, 10, and 15 minutes (P value 0.05).There was no statistical difference between the two groups in terms of recovery time (P value > 0.05). There was a significantly reduced requirement of rescue sedation in group KetP (P value < 0.01). FentP caused slightly delayed recovery time and respiratory depression compared to KetP. MAP in group FentP was lower than baseline, this suggests KetP provides better hemodynamic stability than FentP.

**Conclusion:** KetP (Ketamine – Propofol) group offers greater sedation, need lesser rescue sedation dose of Propofol, faster recovery with better hemodynamics and fewer complications when compared to FentP (Fentanyl – Propofol) group. Ketamine and Propofol are advised in patients having higher risk of respiratory depression. Pain after ERCP is less in FentP group compared to KetP group.

**Keywords:** ERCP, Propofol, Ketamine, Fentanyl, sedation, analgesia, Modified Aldrete score.

## Introduction

Endoscopic Retrograde Cholangiopancreatography (ERCP) is a crucial diagnostic and therapeutic procedure used in the management of various hepatobiliary and pancreatic disorders. [1] The ideal sedative–analgesic mixture ought to preserve a patient's hemodynamic status and ought to cause no respiratory depression, a quick onset and reversal to initial values, and a small occurrence of postoperative nausea and vomiting. [2,3]

Several pharmacological agents including Dexmedetomidine, Fentanyl, Ketamine, and Propofol are now widely accessible, taking into consideration short induction, rapid recovery, and lessening complications associated with using a single drug. [4] Additional small doses of supplementary drugs example Ketamine and Fentanyl are recommended as Propofol, if administered in excess to deepen anaesthesia can have significant cardiac adverse effects. Ketamine (phencyclidine derivative), short-acting intravenous anaesthetic drug that causes dissociative anaesthesia. [5] It has acceptable analgesic and hypnotic effects, but also cause lower respiratory depression and fewer cardiac complications. Fentanyl, an opioid agonist has an adjuvant action with intravenous anaesthetics and produces analgesia, but may cause respiratory depression. The most commonly used IV anaesthetic is Propofol, an alkalyl phenol presently formulated in a lipid emulsion. Propofol provide as rapid onset and offset. [6,7] A unique action of propofol is its antiemetic effect, at concentrations less than those producing sedation. Hence present study was carried out to investigate the groups receiving fentanyl-propofol (FentP) versus ketamine-propofol (KetP) in ERCP in terms of sedation, rescue sedation requirement, and recovery scores during ERCP and to observe the procedure's hemodynamic changes, postoperative pain score and complications of ERCP. To observe the occurrence of any side effects and complications related to fentanyl-propofol (FentP) versus ketamine-propofol (KetP).

## Materials and Methods

A prospective observational hospital based study was performed at perating room of Gandhi Medical College, Bhopal.

| Inclusion criteria | Exclusion criteria |
|---|---|
| ASA Grade I, II and III | Patients refusal |
| Age between 18 – 65 years | Drug allergy |
| | Cardiac disease |
| | Respiratory distress |
| | Psychiatric disorders |
| | Pregnancy |

This study includes 30 patients who were undergone ERCP after informed and written consent. Both groups received Inj Midazolam 1mg and Inj Glycopyrrolate 0.2mg in the pre-operative area. Standard anaesthetic monitoring was done after shifting the patient to operating room.

Group A received Ketamine-Propofol (KetP), and Group B received Fentanyl-Propofol (FentP) each containing 15 patients. All patients were given a loading dose of Inj Propofol 0.75 mg/kg and 75$\mu$g/kg/minute was given for maintanence doses accordingly. The group FentP received Inj Fentanyl 2$\mu$g/kg and the group KetP received Ketamine 0.5mg/kg. Patient was made into prone position and oxygenated via nasal prongs. Inj Hyoscine 20mg and Inj Paracetamol 1gm were given to all the patients of both groups. Ramsay sedation scores, the necessity for rescue sedation, hemodynamics changes, complications during surgery and Modified Aldrete score were noted.

**Statistical Analysis:** All the data analysis were performed using IBM SPSS ver. 25 software. Quantitative data were expressed as mean and standard deviation whereas categorical variables were expressed as numbers. The statistical analysis was done using unpaired T test using Excel

## Results

**Table 1: Showing Gender distribution and baseline parameters between groups**

| Variables | | | Groups | |
|---|---|---|---|---|
| | | | Group A | Group B |
| | | | KetaP | FentP |
| Gender | Male | Total No | 9 | 10 |
| | | Percentage | 30.00% | 33% |
| | Female | Total No | 7 | 5 |
| | | Percentage | 23% | 17% |
| Baseline | MAP (Mean mmHg) | | 95.14 ± 20.94 | 91.05 ± 28.13 |
| | HR (Mean bpm) | | 85.02±15.15 | 84.1 ± 15.2 |

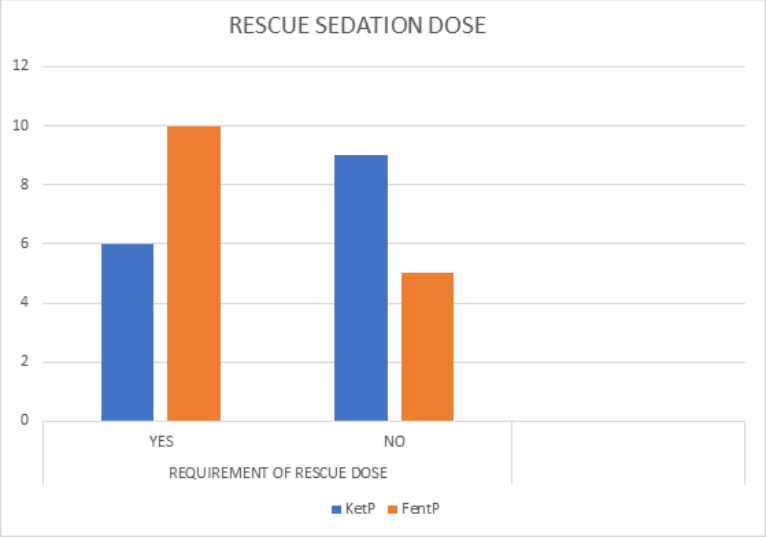


**Figure 1: Rescue Sedation score between both the groups**

**Table 2: Comparing Ramsey Score at different time points between groups**

| Time points | KetP | | | FentP | | |
|---|---|---|---|---|---|---|
| **Ramsey Score** | **N** | **Mean** | **SD** | **N** | **Mean** | **SD** |
| 0 min | 15 | 5.27 | 1.416 | 15 | 4.16 | 1.162 |
| 2 min | 15 | 5.69 | 0.66 | 15 | 4.90 | 0.53 |
| 4 min | 15 | 5.92 | 0.27 | 15 | 5.05 | 0.38 |
| 8min | 15 | 5.10 | 0.78 | 15 | 5.85 | 0.35 |
| 10 min | 15 | 5.53 | 0.93 | 15 | 5.84 | 0.37 |
| 15 min | 15 | 4.24 | 0.46 | 15 | 4.73 | 0.50 |
| 20 min | 15 | 4.61 | 0.82 | 15 | 4.70 | 0.55 |
| Recovery time | 15 | 14.14 | 1.93 | 15 | 14.40 | 2.03 |

Ramsay sedation scores at 0, 2, and 4 minute in group B (FentP) are significantly lower, suggesting patients in group A (KetP) experience early sedation (P value 0.00). However, the FentP group had significantly greater sedation scores at 8, 10, and 15 minutes (P value 0.05). There was no statistical difference between the two groups in terms of recovery time (P value > 0.05). There was a significantly reduced requirement of rescue sedation in group KetP (P value < 0.01). FentP caused slightly delayed recovery time and respiratory depression compared to KetP. MAP in group FentP was lower than baseline, this suggests KetP provides better hemodynamic stability than FentP.

## Discussion

For diagnostic and therapeutic ERCP, adequate patient sedation is required. Intravenous Propofol sedation is more effective and safe when administered under close patient monitoring, and it is associated with faster post-procedure recovery, however, it is well known that propofol alone is ineffective because it does not relieve pain.

KetP had a faster onset and higher level of sedation during the initial phase of the procedure (0-4 mins), while FentP had better sedative properties during the mid-phase (8-15 min). After 20 minutes, there was no noticeable difference. KetP was found to significantly minimize overall propofol use. Similar reports were revealed by previous studies. [8, 9]

KetP provided improved hemodynamic control since at 10 minutes after the procedure began, MAP in the FentP group was lower than the initial MAP. Pain following ERCP was less in the FentP group than in the KetP group at the time of recovery and discharge. Similar reports were revealed by previous studies. [10,11]

## Conclusion

KetP (Ketamine – Propofol) group offers greater sedation, need lesser rescue sedation dose of Propofol, faster recovery with better hemodynamics and fewer complications when compared to FentP (Fentanyl – Propofol) group.

Ketamine and Propofol are advised in patients having higher risk of respiratory depression. Pain after ERCP is less in FentP group compared to KetP group.

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