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Comparison of Dexmedetomidine with Ketamine (DEXKET) and Propofol with Ketamine (KETOFOL) During Endoscopic Retrograde Cholangi

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ABSTRACT

Background: Endoscopic retrograde cholangiopancreatography (ERCP) requires safe and effective sedation to maintain patient comfort and procedural safety. Ketamine-propofol (KetoFol) is commonly used, but risks of desaturation and delayed recovery remain. Dexmedetomidine combined with ketamine (Dexket) offers stable sedation with minimal respiratory depression. Comparative local evidence of these two combinations in ERCP patients is limited.

Methods: This randomized controlled trial was conducted at the Endoscopy Department, Patel Hospital, Karachi. A total of 110 patients aged 18–60 years undergoing ERCP were randomly allocated into two groups: Group A received KetoFol, and Group B received Dexket. Oxygen saturation (SpO_2), vital signs, and Ramsay sedation scores were recorded during the procedure and recovery. Data were analysed using appropriate statistical tests, with a p-value <0.05 considered significant.

Results: Group B (Dexket) demonstrated significantly higher mean SpO_2 compared to Group A (97.5% vs. 93.2%, p<0.001) with more stable hemodynamics. At 10 minutes, deeper sedation was observed in Group B (Ramsay score 5.18 vs. 3.35), while recovery was faster at 30 minutes (2.03 vs. 5.09).

Conclusion: Dexket provided superior oxygenation, more stable sedation, and quicker recovery compared to KetoFol during ERCP. This suggests Dexket as a safer and more effective alternative for procedural sedation. Further multicenter trials are recommended to confirm its wider clinical applicability

Keywords: Dexmedetomidine, Ketamine, Propofol, Sedation, Oxygen Saturation.

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INTRODUCTION

For upper GI procedures, patients often require anesthesia in the form of sedation, monitored anesthesia care (MAC), or general anesthesia. Over the last decade, there has been significant development in the mode of anesthesia practice for such cases[1]. There has been an ongoing debate on which mode of anesthesia is safer and superior to others. Most of the cases are performed under sedation or MAC; however, some procedures with a higher risk of aspiration or longer duration may require general anesthesia with an endotracheal tube[2].

Upper GI procedures used to be performed without sedation, but now the common practice is to either proceed with MAC or GA [3]. American Society of Gastrointestinal Endoscopy recommends that sedation for endoscopy is safer if provided by a trained anaesthetist rather than a sedation staff[4]. According to a study, 14% of the procedures had to be aborted due to inadequate sedation while performing ERCP[5]. Respiratory complications can occur during the procedure as well as postoperatively and can result in poor outcomes and delay in discharge from the hospital. Different drugs, which are synergistic in action, provide better outcomes with fewer unwanted effects. The multimodal approach seems to be very effective in the routine practice, as seen in the reduction of incidence of postoperative nausea and vomiting (PONV) and in pain management.

At many centres, agents that cause sedation, amnesia, analgesia, and quick recovery are used for such short procedures. Sedation helps in facilitating the operator and ensures that the patient cooperates and stays steady throughout [6]. Very often, a combination of ketamine and propofol (Ketofol) or a combination of ketamine and dexmedetomidine (dexket) is used to permit sedation, analgesia, and early recovery. Propofol is an IV anesthetic agent used for induction and maintenance of anesthesia, a good sedative agent, and an antiemetic, but it can cause significant respiratory depression.

Ketamine is a general anesthetic producing profound analgesia and dissociative anesthesia, a good bronchodilator, but can cause nausea, vomiting, and dizziness. Dexmedetomidine provides important postsurgical analgesia and appears to have no clinically important adverse effects on respiration in the surgical patient who requires intensive care[7]. Oxygen desaturation of 8.5% was observed with group ketamine-dexmedetomidine and 25.71% with group ketamine-propofol, as shown by Table 10 from our parent study[8].

In this study, we compared ketamine-propofol and dexmedetomidine-ketamine combination in sedation in endoscopic procedures in terms of efficacy and safety by measuring SpO2. We aimed to show that the dexmedetomidine-ketamine combination could have similar or superior safety and efficacy with the ketamine-propofol combination in terms of changes in oxygen saturation, avoiding hypoxia and hypoventilation. Sedation for endoscopic procedures is always a challenge for an anesthesiologist. literature showed that different combinations can aid in such procedures, but evidence showing a combination of Dexketoprofen or Ketofol is scanty, so the rationale of our study is to assess the change in saturation of oxygen (SpO2) in patients undergoing an endoscopic procedure with this combination of drugs.

METHODS

A double-blind randomized trial was conducted in the Endoscopy Department of Patel Hospital to compare oxygen saturation and sedation levels in patients undergoing ERCP under sedation using two different drug combinations. The study was approved by the hospital's ethics review committee, and written informed consent was obtained from all participants. The trial duration was set at a minimum of six months following the approval of the study protocol.

Patients included in the study were between 18 and 60 years of age, classified as ASA physical status I or II, and undergoing ERCP procedures lasting approximately forty minutes. The sampling technique used was non-probability consecutive sampling. Individuals were excluded if they had a BMI over 35 kg/m², a history of respiratory complications in prior surgeries, or underlying pulmonary conditions. Further exclusion criteria included upper or lower respiratory tract infections within two weeks before the procedure, a Mallampati score of 3 or 4, known cases of obstructive sleep apnea or use of CPAP/BIPAP, current use of sedative medications, craniofacial deformities or anticipated

difficult airway, active ischemic heart disease, or if sedation had to be escalated from monitored anesthesia care to general anesthesia.

The sample size was determined using data from a previous study comparing dexmedetomidine-ketamine with propofol-ketamine during upper GI endoscopy in hepatic patients. Based on mean oxygen saturation levels and a standard deviation of 1.14, the required total sample size was calculated to be 110 patients, with 55 in each group, using a standard sample size calculation formula.

After screening for eligibility, patients were randomly assigned into two groups using a block randomization method generated by computer software. Each block included two assignments (Group A and Group B) with four allocations per block. A coding grid was maintained for documentation using serial numbers without any identifying information to ensure participant confidentiality. Group A received a combination of ketamine and dexmedetomidine (referred to as DexKet), while Group B received ketamine and propofol (referred to as KetoFol). Blinding was ensured by having a technician uninvolved in the procedure wrap all syringes in aluminum foil, so the administering anesthesiologist was unaware of the drug allocation.

Standard monitoring including non-invasive blood pressure, ECG, and pulse oximetry was applied before the procedure. Each drug combination was prepared in identical 50 mL syringes using 0.9% saline as the diluent. The DexKet group received 200 mg ketamine and 200 µg dexmedetomidine in 50 mL of saline, while the KetoFol group received 200 mg each of ketamine and propofol in the same volume. Both groups were administered an IV loading dose of 0.5 mg/kg ketamine plus either 0.5 µg/kg dexmedetomidine or 0.5 mg/kg propofol, followed by maintenance doses of 0.1 mg/kg/hr for ketamine and 0.1 µg/kg/hr or mg/kg/hr for the accompanying drug depending on the group. If additional sedation was needed during the procedure, a 0.1 mg/kg bolus of ketamine (from a pre-prepared 100 mg/10 mL syringe) was given, repeatable after three minutes if patient movement persisted.

Oxygen saturation (SpO_2) was recorded at several time points: baseline, post-loading dose, at the time of endoscope insertion, and at 5, 10, and 15 minutes thereafter. Additionally, post-procedure sedation was assessed using the Ramsay Sedation Scale at 5, 10, and 15 minutes in the recovery area. Effect modifiers including age, BMI, and Mallampati score were considered in both groups and were recorded for further analysis.

All data were analyzed using SPSS version 26. Continuous variables such as age, BMI, infusion rates, oxygen saturation, pulse, blood pressure, and Ramsay sedation scores were summarized as means and standard deviations or medians with interquartile ranges, depending on the normality of distribution, assessed using the Shapiro–Wilk test. Categorical data, including gender, intervention groups, and supplemental oxygen requirement, were presented as frequencies and percentages. The independent sample t-tests or Mann–Whitney U tests were employed for comparing quantitative variables between the two groups, based on distribution characteristics. A p-value of less than 0.05 was considered statistically significant.

RESULTS

This randomized controlled trial included 110 patients split into two groups. Group A received ketamine-propofol (Ketofol), while Group B received dexmedetomidine-ketamine (Dexket). Patients in Group B were slightly older, with an average age of 43.0 years compared to 35.6 years in Group A. Most patients in Group A were between 18 and 40 years old, while Group B had a higher proportion of patients in the 41 to 60 age range. The gender distribution was similar across both groups.

Group B had a higher average BMI (28.7 kg/m²) compared to Group A (27.6 kg/m²). Notably, most participants in Group A had a BMI of 30 or less, while the majority in Group B were above that threshold.

Vital signs showed some key differences. Patients in Group B had a lower heart rate and diastolic pressure but slightly higher systolic pressure. More importantly, oxygen saturation was consistently better in the dexket group, averaging 97.5% versus 93.2% in the Ketofol group.

When comparing oxygen saturation over time, Group B maintained better levels at every checkpoint. From baseline through to 15 minutes, SpO_2 readings in Group B remained more stable and significantly higher, with p-values consistently at 0.00, indicating strong statistical significance.

Sedation scores also differed meaningfully. Group B showed deeper sedation early on, particularly at 10 minutes, where the Ramsay Sedation Score peaked at 5.18 compared to 3.35 in Group A. However, by 30 minutes, Group B patients were significantly more alert, with scores dropping to 2.03, while Group A remained more sedated at 5.09. This suggests that Dexket provided effective, controlled sedation with quicker recovery.

Table 1: Distribution of General Characteristics of The Patients Enrolled in This RCT

Variables	Group A (Ketamine-propofol) n (%)	Group B (Dexmedetomidine-ketamine) n (%)
Age (years)	35.6±12.01	43.0±9.34
BMI (kg/m2)	27.6±2.26	28.7±2.78
Age		
18 to 40 years	34 (61.8)	25 (45.5)
41 to 60 years	21 (38.2)	30 (54.5)
Gender		
Male	31 (56.4)	30 (54.5)
Female	24 (43.6)	25 (45.5)
BMI status		
<= 30Kg/m2	52 (94.5)	19 (34.5)
> 30Kg/m2	03 (5.5)	36 (65.5)

Table 2: Distribution of Mean Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, and Oxygen Saturation in Group A (Ketamine-Propofol) Versus Group B (Dexmedetomidine-Ketamine)

Outcomes	Group A (Ketamine-propofol) n (%)	Group B (Dexmedetomidine-ketamine) n (%)
Heart rate (beats/min)	83.7±10.87	77.8±11.65
Systolic blood pressure (mmHg)	128.8±21.90	130.8±19.06
Diastolic blood pressure (mmHg)	81.1±24.36	75.9±14.74
Oxygen saturation (%)	93.2±4.33	97.5±2.05

Table 3: Distribution of Percent Saturation in Group A (Ketamine-Propofol) Versus Group B (Dexmedetomidine-Ketamine)

Outcomes	Group A (Ketamine-propofol) n (%)	Group B (Dexmedetomidine-ketamine) n (%)	P-value
Percent saturation (Spo2)			
At baseline	95.2±4.41	97.8±1.47	0.001
After the loading dose	93.1±4.39	95.3±1.86	0.001
After insertion of the endoscope	92.2±6.19	93.4±1.53	0.001
At 5 minutes	93.4±5.18	93.7±1.66	0.001
At 10 minutes	94.9±4.22	94.2±0.79	0.001
At 15 minutes	95.2±4.82	96.5±1.17	0.001

Table 4: Distribution of Postoperative Ramsay Sedation Score in Group A (Ketamine-Propofol) Versus Group B (Dexmedetomidine-Ketamine)

Outcomes	Group A (Ketamine-propofol) n (%)	Group B (Dexmedetomidine-ketamine) n (%)	P value
Postoperative Ramsay Sedation Score (Spo2)			
At baseline	1.01±0.13	1.18±0.39	0.001
After induction	2.31±0.46	2.66±0.64	0.001
At 10 minutes	3.35±0.67	5.18±0.70	0.001
At 20 minutes	4.38±0.81	4.24±0.98	0.001
At 30 minutes	5.09±1.06	2.03±0.86	0.001

DISCUSSION

This study set out to compare the clinical performance of dexmedetomidine with ketamine (Dexket) and propofol with ketamine (Ketofol) during endoscopic retrograde cholangiopancreatography. The results clearly favored the dexket combination in terms of sedation quality, oxygen saturation, and overall physiological stability.

Patients in the dexket group maintained better oxygen saturation throughout the procedure. This supports earlier findings that dexmedetomidine preserves respiratory function more effectively than traditional sedatives like propofol or opioids[9]. Alongside this, the dexket group showed lower heart rates and diastolic blood pressure, likely due to the sympatholytic effect of dexmedetomidine[10]. In contrast, ketamine-propofol tends to create more variability, as the stimulatory nature of ketamine may override the dampening effects of propofol[11].

The sedation profile further highlights the clinical value of dexket. These patients achieved deeper sedation early on but also recovered more quickly. This rapid return to baseline makes dexket especially useful for short procedures where early discharge is a priority[12,13]. Faster recovery times reduce resource use and improve patient turnover in outpatient settings[14].

Despite having older patients and a higher proportion of individuals with elevated BMI, the dexket group still achieved more stable outcomes. That's important, as older or obese patients are generally at greater risk for sedation-related complications. The safety profile observed here aligns with other studies that highlight dexmedetomidine's value in vulnerable populations[15,16].

Finally, fewer rescue medications were needed in the dexket group, suggesting a more sustained analgesic effect. This mirrors results from previous research on dexmedetomidine-tramadol combinations, where enhanced pain control translated into reduced post-procedure intervention[17,18].

In summary, using bupivacaine with dexmedetomidine with ketamine (Dexket) provided better oxygenation, smoother sedation, and quicker recovery compared to ketamine-propofol (Ketofol). These advantages make it a compelling option, especially for higher-risk patients and outpatient procedures. Future studies should explore this combination further across diverse surgical contexts.

This study offers useful insight into the effectiveness of clinical performance of dexmedetomidine with ketamine (dexket) and propofol with ketamine (Ketofol) during endoscopic retrograde cholangiopancreatography, but it has a few limitations. Using non-probability consecutive sampling may have introduced selection bias, making it harder to apply these results to broader patient populations. Conducting the study at a single center also limits how widely the findings can be generalized.

We excluded patients with diabetes and metastatic disease, but didn't control for other factors that can affect pain perception, such as individual pain tolerance, psychological state, or the use of other medications. Pain was only assessed in the immediate postoperative period, so we couldn't evaluate longer-term outcomes like delayed discomfort or overall satisfaction. Although the sample size met statistical requirements, a larger, multicenter trial would help confirm these findings and strengthen the evidence for using tramadol as an adjuvant in local anesthesia.

CONCLUSION

Combining dexmedetomidine-ketamine provided more effective sedation and better oxygenation than the ketamine-propofol combination. Patients receiving dexket stayed more stable throughout the procedure, experienced deeper sedation when needed, and recovered faster. These results highlight dexmedetomidine-ketamine as a safer, more efficient option for procedural sedation and postoperative pain control. Future studies should explore its use across a wider range of surgical procedures.

LIST OF ABBREVIATIONS

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CONFLICT OF INTEREST

None

ETHICAL APPROVAL

The study was conducted after approval Patel Hospital Institution Review Board (Approval No. PH/IRB/2023/019).

AUTHORS' CONTRIBUTION

All authors contributed equally, as per the ICMJE guidelines.

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