Integrative Anesthesiology

RESEARCH ARTICLE

Ketamine versus Dexmedetomidine as Adjunct Agent to Propofol for Sedation during Endoscopic Retrograde Cholangiopancreatography (ERCP)

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Abstract

Introduction and Objectives: ERCP procedure is used for diagnosis and management of several biliary and pancreatic disorders. As it is a lengthy and uncomfortable procedure, adequate sedation is required to assure patient cooperation and increase success rate of the procedure. Many agents are available to provide conscious sedation and Propofol is the most commonly used agent. Dexmedetomidine -a selective α 2 adrenergic receptor agonist- is used recently for conscious sedation with analgesic effect also Ketamine has many effects such as; amnesia, analgesia and maintains spontaneous breathing.

Our aim was to compare efficacy and safety of Dexmedetomidine versus Ketamine as an adjunct drug to propofol for sedation during ERCP procedures.

Methods: This randomized clinical trial was carried out on 48 patients aged 21-70 years old of either sex, undergoing ERCP (diagnostic or therapeutic), with ASA II (- III). Patients were randomly assigned into two groups, (24 Patients each).

Group D; Sedation started by dexmedetomidine 0.5µg/kg plus propofol 50 mg as loading followed by of dexmedetomidine 0.4 µg/kg plus propofol 1 mg/kg/h infusion.

Group K; Sedation started by a mixture of 8 mg propofol plus 2 mg ketamine administered as following; 5 ml loading then infusion titrated till targeted RSS score of 5.

ERCP was carried out in the standard manner for all patients, then patients were discharged to PACU after achieving score of 9-10 of an Aldrete Recovery Scale and time taken to achieve this score was recorded.

The patient's HR, MAP, Respiratory complications, NRS score for pain measurement, PONV, Any other side effects and level of satisfaction of both surgeon and patients were recorded.

Results: Demographic data and baseline vital signs were comparable between the two groups. There was significant decrease in HR, MAP, respiration rate (RR) and SpO_2 in (group D) during the procedure and early post-operative (P. value 0.000**). But after that no significant difference was found. Mean time to, achieve RSS 3-4 was 8 (±0.6) min in group K versus 6 (±1.1) min in group D (P<0.001) and to achieve an Aldrete Recovery Scale Score of 9– 10 was 8 (±0.6) min in group K versus 6 (±1.1) min in group D (P<0.001) also, the total propofol requirement during the procedure was statistically decreased the Group D (P. value 0.000**). Comparable reduction in NRS pain scores was found in both group, but side effects as; hallucinations, agitation, nausea and vomiting were significantly increased in (group K).

Conclusion: Both combinations; dexmedetomidine plus propofol and Ketofol were effective for sedation and analgesia during ERCP procedures, but dexmedetomidine plus propofol resulted in better recovery, lesser side effects, higher levels of analgesia and lower propofol requirements than Ketofol.

Keywords: Dexmedetomidine- Sedation- Propofol- ERCP- Ketamine

Introduction and Objectives

Endoscopic retrograde cholangiopancreatography (ERCP) procedure is used for diagnosis and management of several biliary and pancreatic disorders and its indications have increased enormously recently **[1]**.

It is a complex, lengthy and uncomfortable procedure that require adequate sedation and analgesia, to decrease incidence of agitation and discomfort that have been reported to be among factors causing ERCP failure **[2,3]**.

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So sedation is meant to enhance the comfort level of the patients and allay their anxiety associated with the procedure. Sedation facilitates patient cooperation and comfort level during the procedure. An ideal sedative agent should act rapidly, have a predictable clinical effect and should be easily titrable **[4]**.

Many agents are available to provide conscious sedation including benzodiazepines **[5]** (midazolam and diazepam) with an opioid **[6]** (fentanyl or remifentanil), with or without propofol **[7].**

Propofol -the most commonly used agent for sedation during ERCP procedures- is a potent hypnotic agent with rapid onset of action and rapid recovery. Dose dependent cardiac and respiratory depression with inadequate analgesic action; represent the common adverse effects observed with it **[8]**.

Dexmedetomidine (DEX) -imidazole compound- is a pharmacologically active selective α 2-adrenergic receptor agonist. It acts on the presynaptic receptor and regulates the release of norepinephrine through a negative feedback mechanism. It was introduced in the year 1999, when the FDA approved it in the intensive care unit (ICU) for sedation and analgesia for the short duration (less than 24 hours) **[9].**

Ketamine -NMDA receptor antagonist- binds to opioid receptors and sigma receptors, leads to a special condition called ‘‘dissociative anesthesia’’ **[10]**. It has many effects such as; amnesia, analgesia and maintains spontaneous breathing **[11].**

Our aim was to compare efficacy and safety of Dexmedetomidine versus Ketamine as an adjunct drug to propofol for sedation during ERCP procedures.

Patients and Methods

After local ethical committee approval of the faculty of medicine Assiut University and written informed consent from patients, this randomized clinical trial was carried out on 48 patients aged 21-70 years old of either sex, classified as American Society of Anaesthesiologist (ASA) Grade II – III, undergoing ERCP diagnostic or therapeutic.

We excluded patients who had (ASA) Grade VI, baseline SpO_2 <90%, patients with difficulty in communication, who refused the study , patients allergic to the studied medications, morbidly obese patients, patients with chronic obstructive pulmonary disease, complicated airway and pregnant patients.

One day before surgery, preoperative evaluation was done including; medical, history, physical examination and routine laboratory investigations. On the arrival of patient to ERCP unit, venous access was inserted and secured by and Ringer Lactate infusion was started. Vital signs such as (HR, mean arterial pressure MAP and oxygen saturation SPO_2) were recorded and thereafter, every 5 min until the completion of the ERCP.

Patients were randomly assigned into two groups, (24 patients each) and method of randomization was as following; opaque sealed envelopes containing randomization schedule (computer generated); the opaque envelopes were sequentially numbered and were opened just immediately before starting of ERCP.

Group D; Sedation was induced by dexmedetomidine 0.5 µg/kg plus propofol 50 mg as loading followed by infusion of dexmedetomidine 0.4 µg/kg plus propofol 1 mg/kg/h.

Group K; Sedation was induced by a mixture of (ketamine: propofol concentration 1:4) prepared in 50 ml syringe containing DW 5% (each ml contained 8 mg propofol and 2 mg ketamine), administered as following; 5 ml of Ketofol as loading then infusion titrated till targeted RSS score.

ERCP was carried out in the usual standard manner for all patients in prone position and after routine preparations.

The level of sedation was assessed at 2 min intervals and the infusion rate was titrated to achieve a Ramsay Sedation Scale (RSS) score of 5 (Table 1) **[12]**. Infusion was discontinued at the end of the procedure and the total propofol consumption was recorded. Recovery time was calculated as the time from discontinuation of drug infusion till achievement of RSS score of 5 then patients were discharged to PACU after achieving score of 9-10 of an Aldrete Recovery Scale (Table 2) **[13]**. Time taken to achieve this score was also recorded.

Sedation Level	Description
1	Patient is anxious, agitated or restless or both.
2	Patient is cooperative, oriented and tranquil.
3	Patient responds only to commands.
4	Patient responds to light glabellar tap or loud auditory stimulus.
5	Patient has a sluggish response to light glabellar tap or loud auditory stimulus.
6	No response.

Table 1: Ramsay Sedation Scale.

Activity: able to move voluntarily or on command	
4 Extremities	2
2 Extremities	1
0 Extremities	0
Respiration	
Able to deep breath and cough freely	2
Dyspnea shallow or limited breathing	1
Apneic	0
Circulation	
BP ± 20 mm of preanesthetic level	2
BP ± 20-50 mm of preanesthesia level	1
BP ± 50 mm of preanesthesia level	0
Consciousness	
Fully awake	2
Arousable on calling	1
Not responding	0
O_2 Saturation	
Able to maintain O_2 saturation > 92% on room air	2
Needs O_2 inhalation to maintain O_2 saturation > 90%	1
O_2 saturation < 90% even with O_2 supplemetation	0

Table 2: The Modified Aldrete Scoring System.

Any respiratory depression as –desaturation (SpO_2 <90%) or apnea (for more than 15 seconds) -were recorded and treated by supporting the airway and/or assisting ventilation.

Hypotension (systolic blood pressure <85 mmHg) was managed by IV fluid plus IV ephedrine 0.1 mg/kg. Bradycardia (HR less than 50 beats /min) and was managed by IV atropine 0.01 mg/kg.

All patients were followed up for 24 hours in PACU by the following parameters;

-NRS score for pain measurement, which was recorded at 1, 2, 6, 12 and 24 hours.

-Postoperative nausea and vomiting (PONV)

-Any other adverse events (e.g., hallucinations, agitation, shivering and hiccough) were recorded and were managed accordingly.

-The patient's vital signs were assessed at regular intervals.

-The satisfaction of the surgeon and patients was assessed using satisfaction score (Table 3).

Statistical Analysis

Data analysis: Statistical analysis was carried out using SPSS ® version 21 software. Normality distribution of continuous data was tested. Data were expressed as number, percentage, mean and standard deviation. Chi-square test was used in order to compare qualitative variable among studied groups. Independent t- test was used to compare quantitative variables between the two studied groups. P Value < 0.05 was considered statistically significant.

Sample size estimation: It was determined to detect a 20% improvement in Achievement of modified Aldrete score of 9-10 (average standard deviation 0.8 cm) with a power of 0.8. To account for the multiple outcomes and dropouts we increased the sample size to 24 patients per group.

Criteria	Score
Excellent	4
Good	3
Fair	2
Poor	1

Table 3: Satisfaction score.

Results

This study involved two groups of patients who underwent diagnostic and therapeutic ERCP, Group D (n=24) and the Group K (n=24).

The demographic data, the patient's characteristics and baseline vital signs between the two groups were statistically insignificant (Table 4).

There was significant decrease in HR, MAP, respiration rate (RR) and SpO_2 in (group D) during the procedure and early post-operative (P. value 0.000**). (Figures 1-3), but during the remaining of post-operative periods (HR and MAP) were comparable (Table 5).

Mean time to achieve RSS 3-4 was 8 (±0.6) min in group K versus 6 (±1.1) min in group D (P<0.001) and to achieve an Aldrete Recovery Scale Score of 9-10 was 8 (±0.6) min in group K versus 6 (±1.1) min in group D (P<0.001) also, the total propofol requirement during the procedure was

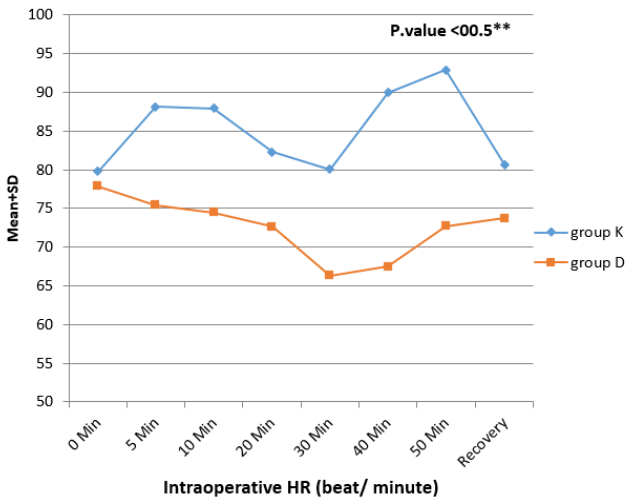

Figure 1: Intra-operative heart rate (HR) (beat/min).

Data expressed as (Mean ± SD) and number (%) **Group D:** Dexmedetomidine group **Group K:** Ketamine group.

	Group D (n=24)	Group K (n=24)	P. value
Age: mean ± SD	48.73 ± 5.61 (38-70)	46.73 ± 6.07 (42-74)	0.191
Gender, M/F	10/14	11/13	0.592
BMI, kg/m²: mean ± SD	18.1 ±3.3	20.9 ±1.5	0.066
ASA, n (%)			
II	16 (66%)	18 (75 %)	0.501
III	8 (33.3 %)	6 (25 %)	
ERCP duration (minutes), **(mean ± SD)**	38.64 ± 0.7(31. - 57)	34.1 ± 0.68 (30 - 60)	0.196
Aim of ERCP:			
-Diagnostic	2 (8.33 %)	1 (4.2. %)	0.795
-Therapeutic	22 (91.66 %)	23 (95.8%)	0.998

Table 4: Demographic data of the studied groups.

Data expressed as (Mean ± SD) and number (%) **Group D:** Dexmedetomidine group; **Group K:** Ketamine group.

statistically decreased in the Group D (P. value 0.000**) (Table 6).

We found reduction in NRS pain scores in both group in comparable manner at all measured time points (Table 7). Finally; complications (hallucinations, agitation, nausea and vomiting) was significantly increased in (group K) (Figure 4).

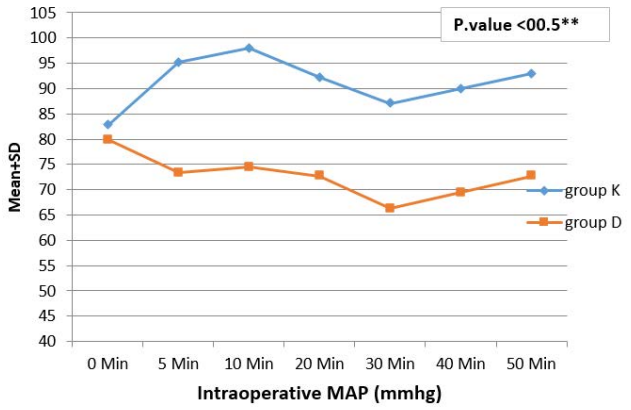

Figure 2: Intra-operative mean arterial pressure (MAP) mm/Hg.

Data expressed as (Mean ± SD) and number (%) **Group D:** Dexmedetomidine group **Group K:** Ketamine group.

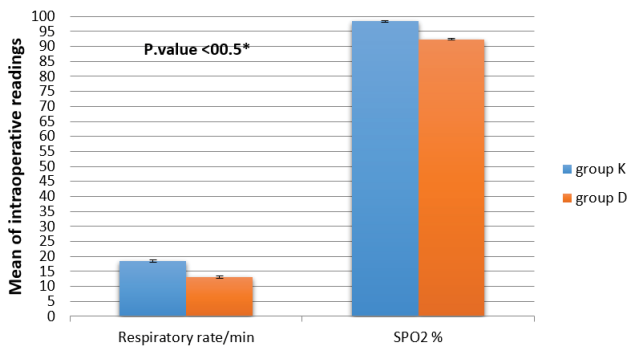

Figure 3: Intra-operative respiratory rate and saturation O_2.

Data expressed as (Mean ± SD) and number (%) **Group D:** Dexmedetomidine group **Group K:** Ketamine group.

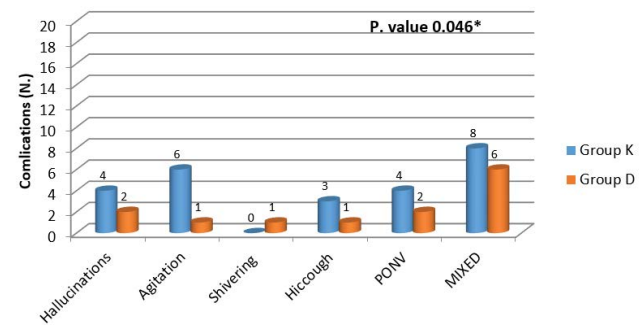

Figure 4: Post ERCP complications.

Data are expressed as numbers, P. value < 0.05 considered statistically significant. **Group D:** Dexmedetomidine group **Group K:** Ketamine group. There was significant difference between the two groups.

Discussion

Both sedation and analgesia allow patient to tolerate unpleasant procedure such as ERCP by reliving discomfort or pain and also can expedite the conduct of procedure and avoid complications such as duodenal perforation, pancreatitis that results from poor patient cooperation **[14].**

This prospective randomized controlled trial aimed to compare the efficacy and safety of IV dexmedetomidine versus ketamine as adjuvant to propofol, for conscious sedation during ERCP. The dose regimens of both drugs used in our study were similar to that used by many previous studies **[15-17]**. Continuous infusion technique was used in our study to maintain a steady state sedation level. The RSS score has been used to assess the level of sedation.

We found that, dexmedetomidine added to propofol provides better safety profile, earlier recovery and significant satisfaction of both doctors and patients with significant decreased in hemodynamic parameters.

Propofol, a phenol derivative, is a short-acting intravenously

MAP (mm/hg)	**Group K (n=24)**	**Group D (n=24)**	**P. value**
1 h	79.67 ± 12.12(62 - 98)	65.07 ± 7(52 - 77)	0.001*
2 h	82.47 ± 10.04(62 - 100)	64.53 ± 10.02(56 - 90)	0.002*
4 h	77.9±10.6(58 - 94)	78.5±9.3(68 - 95)	0.117
6 h	73.73 ± 11.79(60 - 100)	69.67 ± 7.32(60 - 82)	0.120
12 h	77.2 ± 13.43(62 - 108)	73.2 ± 8.35(59 - 86)	0.218
24 h	73.13 ± 8.86(62 - 98)	72.93 ± 4.95(65 - 82)	0.914
HR (bpm)			
1 h	81.93 ± 18.02(56 - 120)	66.47 ± 14.43(57 – 110)	0.001*
2 h	84.13 ± 10.37(65 - 98)	62.4 ± 7.16(65 - 89)	0.005*
4 h	74.8±11.0(56 - 94)	77.9±14.0(57 - 97)	0.326
6 h	83.27 ± 13.96(58 - 110)	78.67 ± 11.81(56 - 108)	0.212
12 h	79.07 ± 14.14(59 - 108)	75.33 ± 11.57(50 - 98)	0.161
24 h	73.93 ± 12.34(55 - 100)	72.73 ± 13.05(55 - 100)	0.952

Table 5: Post-operative MAP and HR.

Data are expressed as mean ± SD. At 1 and 2, hours MAP= mean arterial pressure (mmhg), HR=heart rate (beat per minutes). h=hour interval **Group D:** Dexmedetomidine group; **Group K:** Ketamine group P. value < 0.05 considered statistically significant. There was significant difference in early post operative periods being decreased in group D in comparison to group K.

NRS scores	Group K (n=24)	Group D (n=24)	p value
1 h	3 (1-4)	2 (2-4)	0.822
2 h	2 (1-3)	2 (1-4)	0.512
4 h	2 (1-3)	1.5 (1-3)	0.946
8 h	1 (1-2)	1.5 (1-2)	0.354
12 h	1 (1-2)	1 (1-2)	0.734
24 h	2.5 (2-3)	2.2 (2:3)	0.126

Table 6: Pain NRS scores during the postoperative 24 hours.

Data are expressed as median (range) NRS=numerical rating scale, h=hour. P. value < 0.05 considered statistically significant. **Group D:** Dexmedetomidine group; **Group K:** Ketamine group P. value < 0.05 considered statistically significant. There was no significant difference between the two groups.

	Group K (n=24) Mean ± SD	Group D (n=24) Mean ± SD	P. value
Time to achieve desired RSS of 3-4	8 (±1.6)	6 (±1.1)	0.005*
Time to achieve an Aldrete Recovery Scale Score of 9– 10	8 (±0.6)	6 (±1.1)	0.209
Total propofol requirement	50.6 ± 12.5	32.3 ±12.43	0.000**
Doctors satisfaction (median/interquartile range)	2 (1.75-2)	3 (3-3.25)	0.004*
Patients satisfaction (median/interquartile range)	3 (2-3)	4 (4-4)	0.003*

Table 7: Time to achieve; desired RSS of 3-4, an Aldrete Recovery Scale Score of 9– 10 and Total propofol requirement.

Data are expressed as mean ± SD, P. value < 0.05 considered statistically significant. **Group D:** Dexmedetomidine group; **Group K:** Ketamine group. There was significant difference between the two groups.

administered sedative and hypnotic agent. It has been used frequently over the past two decades as a sedative agent for endoscopic procedures. However, propofol can cause deep sedation or even dangerous side effects that need cardiopulmonary support **[18]**.

And using dexmedetomidine as a sole agent for conscious sedation during ERCP resulted in less satisfactory sedation than propofol, as most of the patients needed additional sedatives to achieve a sufficient sedation level. However this may be attributed to the use of dexmedetomidine as a sole agent with a relatively small dose similar to those employed in intensive care for sedation and in anesthesia as an adjunct agent. In spite of that, patients received dexmedetomidine needed less fentanyl and had a longer recovery period during which they were more sedated than patients received propofol **[19-20]**.

Confirming that, a study compared dexmedetomidine and propofol during electrophysiology study and demonstrated comparable sedation level with either drug. Mean arterial blood pressure values were significantly higher at 5, 15 min in dexmedetomidine group. RR values were significantly lower in dexmedetomidine group than in propofol group **[21].**

In our study, we can explain the higher incidence of hypotension, bradycardia, apnea and desaturation has been observed in group dexmedetomidine – propofol because of is a potent hypnotic drug and dexmedetomidine is a highly selective α-2 adrenergic agonist with sedative and analgesic properties. It causes sympatholysis and affects hemodynamic stability **[22].**

But With the use of dexmedetomidine, hemodynamics was less affected by the stressful periods during the procedure. That is considered beneficial especially for the elderly patients undergoing ERCP who could be potentially hypertensive or ischemic **[23].**

And the analgesic effects are mediated by α2 - alpha 2 adrenergic receptors present on the neurons of superficial dorsal horn in lamina II, by inhibiting the release of nociceptive transmitters, namely substance P and glutamate and by hyperpolarization of spinal interneurons **[24].**

Sympatholysis occurs due to the activation of postsynaptic α2 adrenergic receptors that results in hypotension and bradycardia thus helps in attenuating the stress response leading to ideal sedation **[25].**

So adding dexmedetomidine to propofol to get these benefits and this resulted in a reduction in amount of propofol used. This may provide respiratory safety **[26]**.

Ketamine causes amnesia, analgesia and maintains spontaneous breathing **[27]**. But its use as a single sedative agent has been limited by its propensity to cause vivid and frightening emergent reactions **[25]**, sympathomimetic effects and vomiting when given in sedating doses **[28].**

Ketamine–propofol combinations in different ratios have been used by many authors before. This combination revealed hemodynamic stability. Akin and colleagues found better maintenance of MAP without prolonging recovery in the ketamine–propofol (1:3) combination group than in the propofol monotherapy group **[29–32].**

In a previous study by Akin et al. who compared propofol (1.5 mg/kg) to propofol (1.5 mg/kg) and ketamine (0.5 mg/kg) in a ratio of 3:1 and reported no cases of desaturation with ketofol, but with propofol 4/30 had desaturation and 6/30 had apnea, blood pressure and heart rate were significantly lower with propofol than ketofol and reported that the addition of low dose ketamine to propofol reduced the risk of respiratory depression and the need for repeat medication administration. **[33]**

Another study by Hasanein and El-Sayed, they compared two techniques of sedation for obese patients undergoing ERCP, using either ketofol or fentanyl–propofol as regards propofol consumption, recovery time, patients' satisfaction and sedation-related adverse events and they concluded that; Ketamine/propofol combination 1:4 provided better sedation quality than fentanyl/ propofol combination with less side

effects and can be safely used for sedating obese patients undergoing ERCP **[15]**.

Although there is a higher incidence of emergence agitation and PONV in the ketofol group compared with the fentanyl–propofol group, this incidence rate is much lower than the usual incidence rate of ketamine alone. Emergence reactions and vomiting are significant adverse effects of ketamine usage, occurring more in adults than in children **[34]**.

In our study, we compared patients and endoscopist satisfaction by a scoring system and there was statistically significant difference between two groups (P<0.001). Group D had higher satisfaction scores both for patients and endoscopist. Our findings were similar to findings of Erdurmus et al. **[35]** and Karaaslan et al. **[36].**

Conclusion

Both combinations; dexmedetomidine plus propofol and Ketofol were effective for sedation and anlgesia during ERCP procedures, but dexmedetomidine plus propofol resulted in better recovery, lesser side effects, higher levels of analgesia and lower propofol requirements than Ketofol.

Study Limitations

Our study has many limitations. First, the study was not double blind. Second; sample size was small. Finally, we should include patients with ASA physical status classes > III.

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