



CONCIOUS SEDATION FOR ENDOSCOPIC RETROGRADE CHOLANGIO PANCREATOGRAPHY USING DEXMEDETOMIDINE AND PROPOFOL: A COMPARITIVE STUDY

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ABSTRACT

Objectives: This comparative study was carried out between Propofol and Dexmedetomidine in patients undergoing Endoscopic Retrograde Cholangio Pancreatography using conscious sedation to evaluate hemodynamic profile and sedation score .

Materials and Methods: 40 patients of either sex in the age group of 20 to 60 years in ASA I and ASA II were randomly selected and assigned into two groups for the study. Group D received an initial infusion of Inj Dexmedetomidine 1mcg/kg/min for 10 min followed by an infusion of 0.2- 0.6mcg/kg/min titrated to Ramsey sedation score of 3-4. Group P received an initial bolus of 1mg/kg Propofol followed by intermittent bolus of 10mg titrated to Ramsey sedation score of 3 to 4. Patients systolic and diastolic pressures, heart rate and pain was also measured.

Results: Patients receiving Dexmedetomidine (Group D) had lower heart rate starting 25 min and at 30,35,40 min ($p < 0.05$). No significant difference was observed in the Mean arterial pressure (MAP) between both groups. 5 patients from Group P and 2 patients from Group D had gag reflex. 08 patients from Group P had coughing and nausea while 02 patients from Group D had the same. When patient and physician satisfaction were compared between both the groups patients receiving Dexmedetomidine showed higher satisfaction levels.

Conclusion: Use of Dexmedetomidine for conscious sedation in patients undergoing ERCP may be a better alternative. However in view of lower heart rate associated with the use of Dexmedetomidine further research into its usefulness may be required.

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INTRODUCTION

Endoscopic Retrograde Cholangiopancreatography (ERCP) is a procedure to diagnose and treat conditions of bile duct, gallbladder, liver, pancreas (1). Among the various techniques used for providing sedation and analgesia to patients undergoing Conscious sedation remains a popular choice(2). Different anesthetic agents like Propofol, Midazolam and Ketamine have been used to provide conscious sedation of which Propofol is a very popular choice due to its high clearance, early recovery, relative cardiovascular stability and low incidence of Post op nausea and vomiting (PONV)(3).

With the expanding use of selective alpha 2 agonists, Dexmedetomidine has gained popularity as a newer drug for providing conscious sedation in these patients due to its unique characteristics of providing sedation and analgesia with minimal cardiovascular and respiratory depression and early recovery of cognitive functions(4).

The main objective of this study was to compare the effects of Propofol and Dexmedetomidine during ERCP on the hemodynamic, respiratory parameters and sedation. The

secondary objectives was the patient comfort and ease of procedure by the physician.

MATERIALS AND METHODS

This study was carried out in 40 patients of either using a prospective randomised comparative method. Informed consent was obtained from all patients. The study population of either sex were in the age group 20 to 60 years and in American Society of Anaesthesiologist (ASA) grade I and II. All patients were evaluated at Pre Anaesthetic clinic and subjects with Hypertension, Coronary Artery Disease, Br Asthma, COPD, Diabetes, hepatic, renal and hepatic disease, Psychiatric illness, drug allergy and difficulty in communication were excluded from the study. All patients were admitted to the hospital one day prior to the procedure.

Patient heart rate (HR), Systolic Blood pressure (SP), Diastolic blood pressure(DP), Mean arterial pressure(MAP), Oxygen saturation(SpO₂), respiratory rate(RR) and patient demographics were noted. The Ramsay sedation scale(5) was used to assess sedation. Modified Aldrete score (MAS) (6) was used to assess recovery at 5min and 10 min and Wong

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baker face scale(7) was used to assess pain. Likert Scale was used to measure patient satisfaction

All patients were premedicated using Tab Alprazolam 0.25mg and Pantoperazole 40mg the night before the procedure. All patients received Inj Fentanyl 1mcg/kg 5 min before start of the procedure. The patients in Propofol group (Group P) were administered Inj Propofol 1mg/kg followed by 10mg increment to achieve a RSS of 3-4. The patients in Dexmedetomidine group were administered Inj Dexmedetomidine 1mcg/kg/min for 10 min followed by continued infusion of 0.3-0.6mcg/kg/min to achieve a RSS of 3-4. Oxygen supplementation was given by nasal prongs 4lit/min to all subjects. All patients were monitored using SpO₂, 12 lead ECG, Heart rate, NIBP. All parameters were noted at intervals of min starting with loading dose of Fentanyl.

A SpO₂ recording of 90% or less was considered as desaturation. Heart rate of less than 50/min or more than 110/min or a baseline deviation of 20 ±% was considered as Bradycardia and tachycardia respectively. Mean Arterial Pressure (MAP) of less than 60mmHg or more than 150mmHg or a base line variation of more than 20% was considered as hypotension and hypertension respectively. Patient comfort parameters such as gagging, coughing and nausea and vomiting were assessed.

The collected data was tabulated and statistically analysed using “MedCalc”. The data was analyzed by appropriate statistical tools. Data was presented as mean with standard deviation or proportions as appropriate. Mean, median, standard deviation and variance were calculated and following statistical significance tests were applied. T-test was used to compare the two independent data groups. Chi-square test was used to compare categorical data. T-test was used to compare the difference between two means. Test of significance was performed for analyzing difference of proportions. 2x2 diagnostic table was used for sensitivity, specificity, positive predictive value. The calculated value was compared with the tabulated value at particular degree of freedom and find the level of significance. A “p-value of p< 0.05 was considered to be significant

OBSERVATIONS AND RESULTS

When the two study groups were compared there was no difference in the demographic data between the two groups (Table 1). The heart rate between both groups were however significantly different starting at 25 minutes and at 30,35 and 40 min (p< 0.05) (Fig 1). In both the groups bradycardia or tachycardia requiring clinical intervention was not observed in any patient. No significant differences in MAP were observed between both Group D and Group P and within the group (Fig 2). No clinical intervention was required for management of blood pressure in both groups.

08 patients from Group P had coughing and nausea while 02 patients from Group D had the same. Gag reflex was present in 6 patients in Group P and 4 patient in Group D When patient and physician satisfaction were compared between both the groups, patients receiving Dexmedetomidine showed higher satisfaction levels (Table 2).

In the Post anaesthesia care unit MAS was applied at 5min and 10 min. 16 patients in group D and 6 patients of Group P reached a MAS of 10 in 5 min. At 10 min 12 patients Group P

and 18 patients of Group D had achieved a MAS of 10. Recovery scores were statistically significant between Group P and Group D(p<0.001 and p<0.05 respectively)

Table 1(Demographic Data)

Parameters	Group P	Group D
Sex (Male/Female)	8/12	9/11
Age(years)	47±13	48±12
Weight (Kg)	66±13	68±10

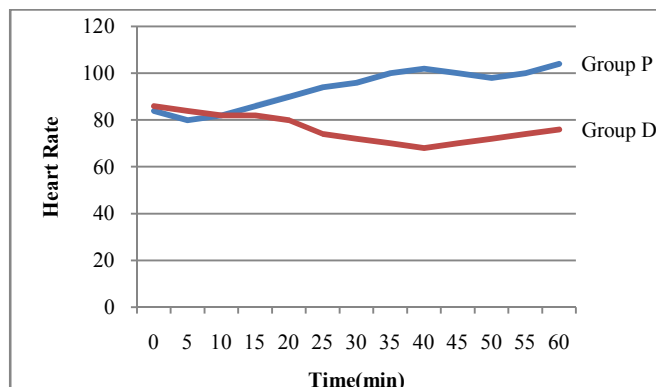


Fig 1 Heart Rate (Mean± SD)

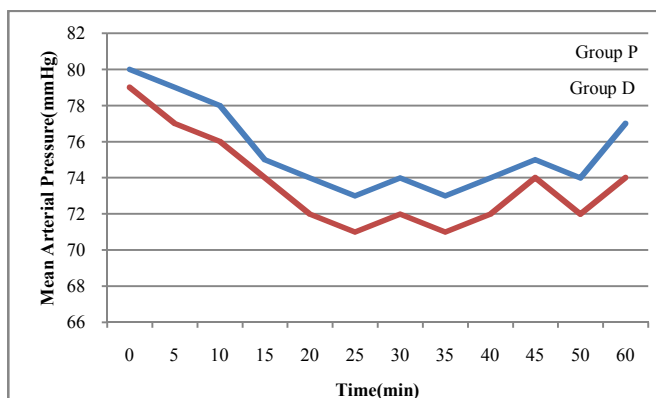


Fig 2 Mean Arterial Pressure (Mean ±SD)

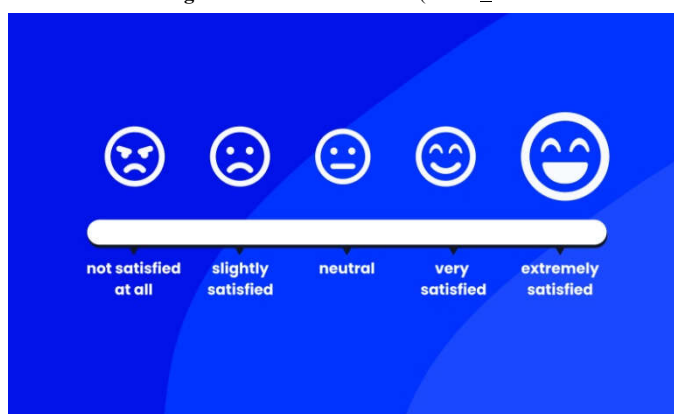


Figure 3 (Likert Scale for Satisfaction)

Table 2 (Patient and Physician satisfaction)

Patient Satisfaction	Likert Scale				
	Not Satisfied	Slightly Satisfied	Neutral	Very Satisfied	Extremely Satisfied
Group P	1	Nil	Nil	9	15
Group D	Nil	Nil	Nil	6	19
Physician Satisfaction					
	Not Satisfied	Slightly Satisfied	Neutral	Very Satisfied	Extremely Satisfied
Group P	Nil	1	Nil	7	17
Group D	Nil	Nil	Nil	4	21

Table (MAS score 10 comparison between groups)

	5min	10 min
Group P	6	12
Group D	16	18

DISCUSSION

Conscious sedation refers to a variety of technique by which different diagnostic and therapeutic procedures can be carried out without resorting to General Anaesthesia. The advantages of conscious sedation include reduction in pain, anxiety and procedural discomfort while maintaining airway reflexes, spontaneous respiration and hemodynamic stability(8). ERCP is a frequent and popular procedure used for the diagnosis of hepatobiliary procedures. It however causes a lot of patient discomfort and along with retching, nausea and vomiting if the patient is not adequately sedated. In our study we used conscious sedation to provide optimum condition for endoscopy with a immobile patient with adequate sedation, analgesia and hemodynamic stability.

Propofol has been in use for many years as a standard agent for providing sedation for endoscopic procedures has a rapid onset and recovery times, lack of active metabolites and decreased incidence of post operative nausea and vomiting(9). Dexmedetomidine is a selective alpha 2 agonist which is being increasingly used to provide procedural sedation in ICU, operation theatre and endoscopic suites(10). It has a unique analgesic property in addition to its short duration of action and cardiostable properties (11) making it suitable to be used for procedural sedation.

The dose regime used in our study to provide conscious sedation was adequate to provide a optimum degree of patient comfort, operator satisfaction, adequate analgesia with preservation of protective reflexes and sufficient level of hemodynamic stability. Different studies have used varying doses of Propofol for procedural sedation. Karanth *et al* in their study used a loading dose of propofol of 2-3mg/kg over 10 min followed by an infusion of 25-100mcg/kg/min till the end of procedure(12). Miner *et all* used 1mg/kg of Propofol followed by 0.5mg/kg every 3 min(13).

Dexmedetomidine has been studied for conscious sedation as a alternative drug in various studies. Arain *et al* evaluated the cardio respiratory effects of Dexmedetomidine using a regime of 1mcg/kg/min as a loading followed with a maintainance of 0.4-0.7mcg/kg/min(14). Kaygusuz *et al* used Dexmedetomidine in a dose of 6mcg/kg/min over 10 min followed by 0.2mcg/kg/min for Extracorporeal shockwave lithtripsy(15).

In our trial we used Dexmdetomidine in a loading dose of 1mcg/kg/min over 10 min followed by infusion of 0.3-0.6mcg/kg/min. While the level of patient comfort was adequate and cardio respiratory stability was maintained there was a significant fall in heart rare between 15min to 40 min. This however did not require any intervention. A fall in Blood pressure was also noticed in both groups however between both groups no significant difference was noticed and did not require any treatment. Overall patient satisfaction was better with the Dexmedetomidine group. In conclusion our study brought out that Dexmedetomidine could be a superior alternate drug for conscious sedation in patients undergoing endoscopic procedures or procedures under local or regional anaesthesia.

However due to a significant fall in heart rate further evaluation of the drug should be carried out.

Conflict of Interest

There is no conflict of interest

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