IS DEXMEDETOMIDINE A POOR SURROGATE TO PROPOFOL FOR PROCEDURAL SEDATION DURING ENDOSCOPIC RETROGRADE CHOLANGIO-PANCREATOGRAPHY (ERCP)

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ABSTRACT: BACKGROUND AND OBJECTIVES: ERCP is a routinely carried out diagnostic and/or therapeutic procedure. It is a distressing procedure in awake patients. These patients require sedation mainly to minimize their anxiety and analgesics to alleviate pain and discomfort thereby enhancing patient's cooperation throughout the procedure[1]. Propofol has been traditionally used. Dexmedetomidine, a novel selective α2 agonist is known to produce sedation without compromising hemodynamic stability or causing respiratory depression. Objective of this study was to compare Propofol-Fentanyl combination with Dexmedetomidine-Fentanyl combination for providing satisfactory procedural sedation during ERCP. **METHODS:** 70 patients undergoing elective ERCP were divided into 2 groups of 35 each. Dexmedetomidine group patients received Fentanyl 1μg/kg and a loading dose of Dexmedetomidine1μg/kg over 10 minutes followed by a maintenance dose of 0.5 μg/kg/hr intravenously. Propofol Group patients received Fentanyl 1μg/kg and a loading dose of Propofol infused at 0.5mg/kg over 10 min followed by a maintenance dose of 2 mg/kg/hr intravenously. If patients showed signs of insufficient sedation as measured by Richmond Agitation Sedation Scale (RASS) they were supplemented with rescue Propofol bolus doses of 0.5 mg/kg. Sedation score and vitals were assessed every 5 minutes till the end of the procedure and every 5 minutes for 15 minutes during recovery. **RESULTS:** At the end of 15 minutes (pre-procedure), RASS in Dexmedetomidine group was -2.89±0.71 and RASS in the Propofol group was -3.31±0.53. Propofol group achieved the desired targeted RASS of more than -3 at 15 minutes. 22% of patients in Dexmedetomidine group and 2.8% of the patients in the Propofol group did not achieve RASS of -3 even after 15 minutes of infusion. Mean RASS over entire ERCP in Dexmedetomidine group was -3.18±.41 and in the Propofol group was -3.31±.39. Mean RASS over entire ERCP in Dexmedetomidine group was lesser than Propofol but there was no statistically significant difference (p=0.134) **CONCLUSION:** The combination of Propofol with Fentanyl achieved better overall conditions for ERCP compared to the combination of Dexmedetomidine with Fentanyl.

KEYWORDS: Dexmedetomidine; Propofol; Endoscopic Retrograde cholangiopancreatography; procedural sedation.

INTRODUCTION: Endoscopic retrograde cholangiopancreatography (ERCP) is a technique that combines the use of endoscopy and fluoroscopy to diagnose and treat the problems of the biliary and/or pancreatic ductal systems. This includes gallstones, inflammatory strictures (scars), leaks (from trauma and surgery), and growths. These patients require sedation primarily to reduce anxiety and analgesics to alleviate pain and discomfort, thereby enhancing patient's cooperation during the procedure.[1]

Various drug regimens have been used to attain optimum sedation. Some of these regimens are combination of Propofol and Fentanyl[2], Midazolam and Pethidine[3], Ketamine and Propofol[4], Ketamine and Diazepam[5]etc. Droperidol alone has also been used for sedation.[6]

Propofol has been commonly used for induction and maintenance of sedation of patients undergoing ERCP[7, 8]. Dexmedetomidine provided comparable safe and effective depth of sedation and analgesia in post operative patients. It reduced Fentanyl requirement without causing respiratory depression[9, 10, 11].

This prospective randomized study was designed to compare the efficacy, safety, and tolerability of the combination of Dexmedetomidine with Fentanyl with the combination of Propofol and Fentanyl for sedation in patients undergoing ERCP. It was hypothesized that the unique property of lack of respiratory depression with Dexmedetomidine and therefore decreased hypoxic events during the procedure would facilitate acceptable and stable condition without compromising level of sedation.

METHODOLOGY: Following institution ethics committee's approval and after obtaining informed consent seventy ASA I,II and III, patients belonging to either gender, aged between 20 – 70 years, posted for elective ERCP and requiring procedural sedation were recruited. Patients undergoing emergency ERCP and patients with cardio respiratory co-morbidities were excluded from the study. A baseline demographic data of the patients (age, sex, weight, associated co morbid diseases) was collected. The patients were randomly assigned (computer generated number) into either of the two groups (35 in each group): Group D: Dexmedetomidine and Fentanyl and Group P: Propofol and Fentanyl.

Patients were kept NPO as per ASA guidelines and informed consent for the endoscopic procedure was obtained. All patients were premedicated with oral Pantoprazole 40 mg the previous night and on the morning of the procedure. Oral Ondansetron 4 mg was administered on the morning of the procedure. Glycopyrrolate 0.2 mg intramuscularly was administered 30 minutes (min) before the procedure. All patients were given 15 ml of 2% Xylocaine viscous and were instructed to gargle for 5 minutes before spitting it out.

In the Endoscopy room an intravenous line was secured and normal saline at the rate of 75 ml/hr was started. Standard monitoring consisting of heart rate (HR), electrocardiogram (ECG), non-invasive blood pressure (NIBP) and oxygen saturation (SpO_2) was instituted. All patients received oxygen at 4Lit/min through nasal cannula. Patients were positioned in either left lateral or semi prone as per endoscopist preference.

Separate infusion pumps containing Dexmedetomidine (2µg/ml) and Propofol 1 %(10 mg/ml) was setup. Baseline recordings of HR, ECG, NIBP, SpO2 and respiratory rate (RR) were recorded.

Group D patients received Fentanyl 1µg/kg bolus over 2(min) and a loading dose of Dexmedetomidine 1µg/kg over 10 min followed by a maintenance dose of 0.5µg/kg/hr.

Group P patients received Fentanyl 1µg/kg bolus over 2 min and a loading dose of Propofol infused at 0.5mg/kg over 10 min followed by a maintenance dose of 2 mg/kg/hr

Sedation assessment: Sedation score in accordance with Richmond Agitation sedation score (RASS: Table1) was assessed at the beginning of the procedure and again at the end of 10 minutes. The

desired targeted level of sedation was RASS of -3. If the desired targeted level of sedation was not attained, a Propofol bolus dose of 0.5 mg/kg was administered in both the groups. The introduction of the scope was allowed only after targeted sedation level (RASS -3) was attained.

Sedation levels were continuously assessed by RASS (0 to -5) every 5 minutes. Facial grimace, movement were taken as inadequate analgesia and sudden increase in HR and MAP >10% from baseline value and RAAS OF >-2 were considered to be manifestation of inadequate sedation.

If patients showed signs of insufficient sedation they were supplemented with Propofol bolus doses of 0.5 mg/kg and if they showed signs of insufficient analgesia they were supplemented with Fentanyl bolus doses of 0.5µg/kg. Infusion was stopped once the procedure was completed. Patients were shifted to recovery where vital signs and sedation level were monitored every 5 minutes for the next 15 minutes.

The total duration of the procedure and the total dose of Fentanyl, Propofol and Dexmedetomidine used in both the groups were recorded.

If the following events occurred during the procedure, it was regarded as complication of the procedure.

a) Hypoxaemia was defined as fall in oxygen saturation below 90%.
b) Hypotension was defined as fall in mean arterial pressure below 60 mmHg.
c) Bradycardia was defined as decrease in heart rate below 60 bpm.
   Hypoxemia was managed by increasing oxygen to 6-8L/min and/or jaw thrust. Hypotension was managed with intravenous ephedrine 3mg incremental doses. Bradycardia was managed with intravenous glycopyrrolate 0.2mg

Statistical analysis: Data was analyzed using Statistical Package for Social Sciences (SPSS) version 16.0. Descriptive statistics such as mean, median, standard deviation were employed to summarize the quantitative data such as age, BMI, Mean Arterial Pressure (MAP) .Chi-square test was employed to compare the proportions between the two comparison groups. Independent sample't' test was used for comparison of various parameters between the two groups. $P \leq 0.05$ was considered statistically significant.

RESULTS: Seventy patients undergoing ERCP were divided into two groups, Group D and Group P of 35 each. The demographic variables such as age, BMI, gender distribution, ASA physical status and pre-induction HR, MAP, and RR were comparable between both the groups (Table 2).

RASS: (Table3 and Graph 1): There was no statistically significant difference in sedation level based on RASS at 5 min (p=0.441) and 10 min (p=0.092) between the two groups. There was a statistically significant difference in RASS at 15 min (p=0.006). Dexmedetomidine group manifested lighter levels of sedation compared to the Propofol group. There was no significant difference in mean RASS over entire ERCP (p=0.174) and Post procedure at 5 minutes (p=0.353), 10 minutes (p=0.060) and 15 minutes (p=0.108).

In Dexmedetomidine group 20 patients required 0.5 mg/kg, 12 patients required 1 mg/kg and 2 patients required 1.5 mg/kg of Propofol supplementation to achieve the targeted RASS of - 3. One patient did not require Propofol to attain the sedation score of RASS of -3. Post procedure Dexmedetomidine group showed higher level of sedation (-0.74) compared to Propofol group (-

0.51) but it was not statistically significant (p = 0.108)

Mean Arterial Pressure: (Graph 2): There was a statistically significant difference in mean MAP at 15 minutes (p=0.016) and the mean over the entire duration of ERCP (p=0.004). Dexmedetomidine group showed lower mean MAP compared to the Propofol group. There was statistically no significant difference found in Post procedure MAP at 5 minutes (p=0405), 10 minutes (p=0.236) and 15 minutes (p=0.343).Two patients had an initial hypertensive response to the loading dose of Dexmedetomidine.

Heart Rate: (Graph 3): There was statistically no significant difference in mean HR between both the groups at 5 minutes (p=0.665) and 10 minutes (p=0.467). There was statistical significance at 15 minutes (p=0.003) and also over the entire ERCP (p=0.000). During the procedure Dexmedetomidine group had lower heart rate compared to the Propofol group.

Statistically no significant difference was found in mean HR at 5 minutes (p=0.166), 10 minutes (p=0.337) and 15 minutes (p=0.513) during recovery

Oxygen saturation: (Table 6): No statistically significant difference was found in oxygen saturation at 5 minutes (p=0.745).There was statistically significantly difference at 10 minutes (p=0.008), 15 minutes (p=0.001) and mean over entire ERCP (p=0.000). Propofol group showed lesser oxygen saturation compared to Dexmedetomidine group. There was a statistically significant difference in Post procedure SpO2 at 5 min, 10 min and 15 min (p=<0.05). Propofol group showed lower oxygen saturation compared to Dexmedetomidine group during recovery.

Respiratory Rate: (Graph 5): There was a statistically significant difference in RR at 5 minutes (p=0.005).Propofol group had lower RR compared to Dexmedetomidine group. There was no statistically significant difference at 10 min (p=0.150) and 15 min (p=0.109).There was statistically significant difference (p=0.028) in the mean RR over entire ERCP. Propofol group had lower RR compared to that of Propofol. There was no significant difference in the RR during recovery between both the groups at 5 min (p=0.112), 10 min (p=0.296) and 15 min (p=0.865).

Total dose of Fentanyl: (Table 4): Total dose of Fentanyl required in Dexmedetomidine group was 65.01±13.39 μg. The total dose of Fentanyl required in the Propofol group was73.66±17.40 μg. There was a statistically significant difference in the dose of Fentanyl requirement (p=0.015). Dexmedetomidine group required less Fentanyl compared to Propofol group.

Total dose of Propofol: (Table 4): Total dose of Propofol required in Dexmedetomidine group was 128.36±98.67 mg and in Propofol group was163.96±80.98 mg. There was no statistically significant difference between both the groups (p=0.26).

Complications during the procedure: (Table 5): Two patients in Dexmedetomidine group and three patients in Propofol group developed Hypoxaemia after Propofol bolus doses. Two patients in Dexmedetomidine group and four patients in Propofol group developed hypotension.

DISCUSSION: Sedation for ERCP should have rapid onset of action, adequate depth of sedation/analgesia to alleviate patient discomfort and a short duration of action [12]. Sedation for ERCP is more complex than other procedural sedation due to sharing of the upper airway and positioning of the patient in left lateral or semi prone position.

Propofol is a lipophilic intravenous anaesthetic agent with rapid distribution and short elimination half life without a cumulative effect after infusion (short context sensitive half life) and narrow therapeutic spectrum[13]. Propofol after evaluation in a variety of sedative regimens has been shown to provide superior quality sedation with the advantage of better patient cooperation and shorter recovery time[14, 15]. Specifically, studies for ERCP under deep sedation used Propofol alone or in combination with sedatives[1-4, 12-15].

Sedation with Dexmedetomidine in the ICU setting is promising with increased patient satisfaction, maintenance of natural sleep cycle and better tolerance of general procedures, including turning and suctioning[9-11]. There was shorter duration of ventilator support and quicker discharge. Dexmedetomidine has also been used for providing sedation in postoperative patients[9]. It also has anaesthetic and opioid sparing effect in general anaesthesia when used as an adjuvant[16]. The most important aspect of sedation with Dexmedetomidine is the quality of the cooperative sedation. Patients display a unique arousability, positive respiratory profile with the maintenance of adequate spontaneous respiration and patency of the upper airway and appropriate ventilatory response to hypoxia and hypercarbia[17].

In our study both Dexmedetomidine group and Propofol group did not achieve target level of RASS of -3 at the end of 10 minutes. (2.2±0.83 Vs -2.51±0.70) and had to be supplemented with Propofol bolus doses. In Dexmedetomidine group 22% of patients and 2.8% of the patients in the Propofol group did not achieve RASS of -3 even after 15 minutes of sedation. Dexmedetomidine has a slow onset of action when compared to Propofol. The patients in the Dexmedetomidine group did not achieve adequate RASS even after 15 minutes thereby delaying the introduction of the scope.

Propofol boluses were supplemented in both the groups when patient showed signs of insufficient sedation or became agitated. Patients in Dexmedetomidine group showed more incidences of inadequate sedation (-3.18±0.41) when compared to the Propofol group. Hence Dexmedetomidine would not be appropriate for blunting quick changes in the level of nociceptive or reflex stimuli that occur during ERCP. Higher doses would not be appropriate as it is a short duration procedure and increasing dosage will only prolong the post procedure sedation, prolonging the recovery .Muller et al[2] concluded that Dexmedetomidine alone was not as effective as Propofol combined with Fentanyl for providing conscious sedation during ERCP. Chowdary et al[5] compared the combination of ketamine and diazepam with the combination of Propofol and Fentanyl for sedation in ERCP and found that Propofol and Fentanyl combination provided safe and effective sedation during ERCP. Combination of Propofol and Fentanyl was found to provide more effective sedation for ERCP in our study also.

Post procedure Dexmedetomidine group showed higher level of sedation compared to Propofol group but it was not statistically significant. It is explained by its context sensitive half time ranging from 4 min after 10 min infusion to 250 minutes after 8 hour infusion where as Context sensitive half time of Propofol is less than 40 min even after prolonged infusion. Similar findings were shown in Muller et al[2] study.

Fentanyl requirement in Dexmedetomidine group (65.01±13.39 µg) was significantly less

compared to Propofol group (73.66±17.40 μg). This can be explained by opioid sparing effect of Dexmedetomidine 2, [17, 18] with the added advantage of lesser incidence of opioid related side effects.

MAP and mean HR at 15 min and also over entire ERCP were significantly lower in the Dexmedetomidine group compared to Propofol group. This can be explained by central presynaptic α2 agonistic action of Dexmedetomidine. Postoperatively MAP continued to be on the lower side in Dexmedetomidine group due to relatively longer context sensitive half time of Dexmedetomidine compared to that of Propofol [2, 18-20].

Mean oxygen saturation at 5 minutes in both the groups was comparable. Mean oxygen saturation at 10 minutes and 15 minutes and over entire ERCP was significantly lower in the Propofol group. In Propofol group 8.5% of the patients showed an episode of hypoxaemia compared to 5.7% in the Dexmedetomidine group and the hypoxaemia coincided with the administration of Propofol bolus doses in both the groups [5, 21, 22.] Propofol has a dose dependant depressive effect on respiration and transient hypoxia, which are usually recognized and managed appropriately without any untoward effect[2].

In our study, dose of dexmedetomidine used were not as high as the doses used in mechanically ventilated patients and use of target plasma concentration level could have been better option.

CONCLUSION: From our study we concluded that Dexmedetomidine group did not achieve desired targeted level of sedation required for ERCP and had to be supplemented with additional doses of Propofol. Dexmedetomidine group had lighter sedation levels compared to the Propofol group during the procedure, but during recovery Dexmedetomidine group showed deeper sedation than Propofol group. The combination of Propofol with Fentanyl achieved better conditions for ERCP when compared to the combination of Dexmedetomidine with Fentanyl.

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Score	Description
4	**Combative** - Overtly combative or violent; immediate danger to staff
3	**Very agitated** - Pulls on or removes tube(s) or catheter(s) or has aggressive behaviour towards staff.
2	**Agitated** - Frequent non purposeful movement or patient–ventilator dyssynchrony
1	**Restless** - Anxious or apprehensive but movements not aggressive or vigorous
0	**Alert and calm**
-1	**Drowsy** - Not fully alert, but arousable with eye contact for more than 10 secs to voice
-2	**Light sedation** - Briefly arousable with eye contact for less than 10 seconds to voice
-3	**Moderate sedation** - Any movement but no eye contact to voice
-4	**Deep sedation** - No response to voice, but any movement to physical stimulation
-5	**Unarousable** - No response to voice or physical stimulation

Table -1: Assessment of sedation using Richmond Agitation Sedation Scale

Characteristics	Group D	Group P	p value
Age* (years)	47.09±13.43	48.46±12.75	0.663
BMI*(kg/m^2)	22.94±3.54	22.13±3.30	0.328
Sex**			
Men	20 (57.1%)	23 (65.7%)	X2= 0.54, Df= 1, p=0.624
Women	15 (42.95%)	12 (34.3%)	
ASA status**			
I	15(42.9%)	15 (42.9%)	X2= 0.12 Df= 2 p=0.939
II	14(40%)	15 (42.9%)	
III	6 (17.1%)	5 (14.3%)	
HR (beats /min)	92.49± 14.54	90.29±12.69	0.502
MAP (mm of Hg)	100.11±11.09	98.77±10.12	0.599
RR (cycles/min)	17.66±4.30	17.06±2.70	0.487
Total	35 (100.0%)	35 (100. %)	-

Table -2: Baseline characteristics of the study population

* Mean ±SD

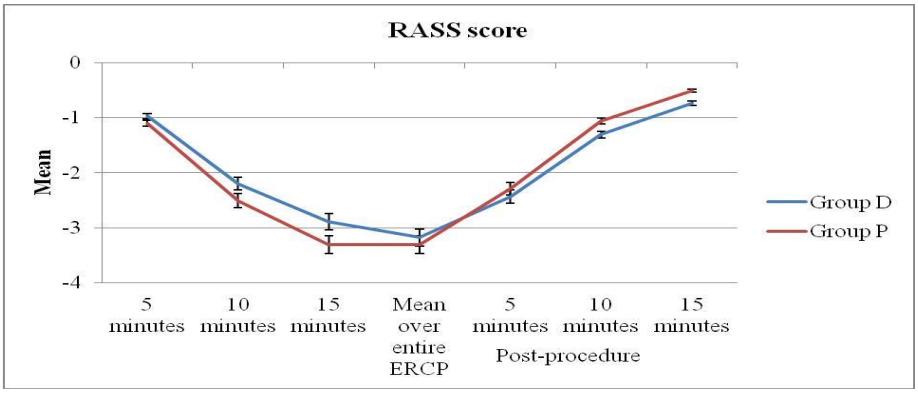
** n (%)

SEDATION LEVEL USING RICHMOND ALERTNESS SEDATION SCORE:

RASS	GROUP D	GROUP P	P VALUE
Pre-procedure			
05 min	-0.97 ± 0.82	-1.11 ± 0.71	0.441
10 min	-2.20 ± 0.83	-2.51 ± 0.70	0.092
15 min	-2.89 ± 0.71	-3.31 ± 0.53	0.006
Mean –entire ERCP	-3.18 ± 0.41	-3.31 ± 0.39	0.174

Post-procedure			
05 min	-2.43 ±0.69	-2.29 ± 0.57	0.053
10 min	-1.31 ± 0.67	-1.06 ± 0.41	0.060
15 min	-0.74 ± 0.65	-0.51 ± 0.50	0.108

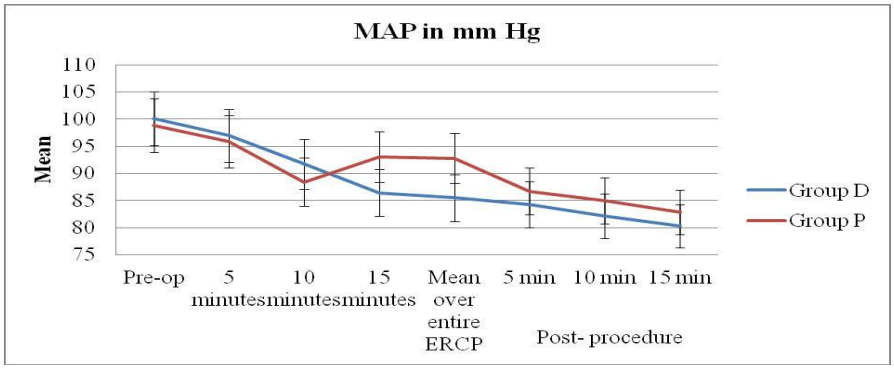
Table -3: Mean RASS comparison



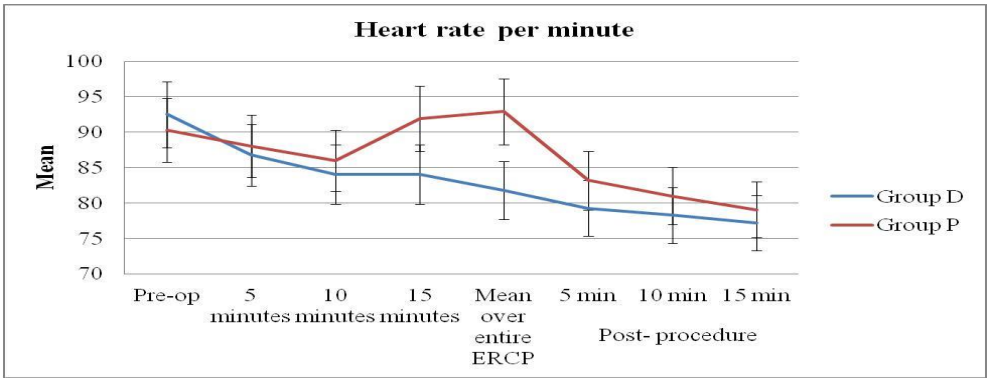
Graph 1: Comparison of sedation score

Parameter	Group D	Group P	P value
Total Duration Of Procedure (minutes)	37.23±17.74	37.14±18.64	0.608
Total Dose Of Fentanyl (µg)	65.01±13.39	73.66±17.40	0.015
Total Dose Of Propofol(mg)	128.36±98.67	163.96±80.98	0.206
Total Dose Of Dexmedetomidine (mg)	71.563	--	--

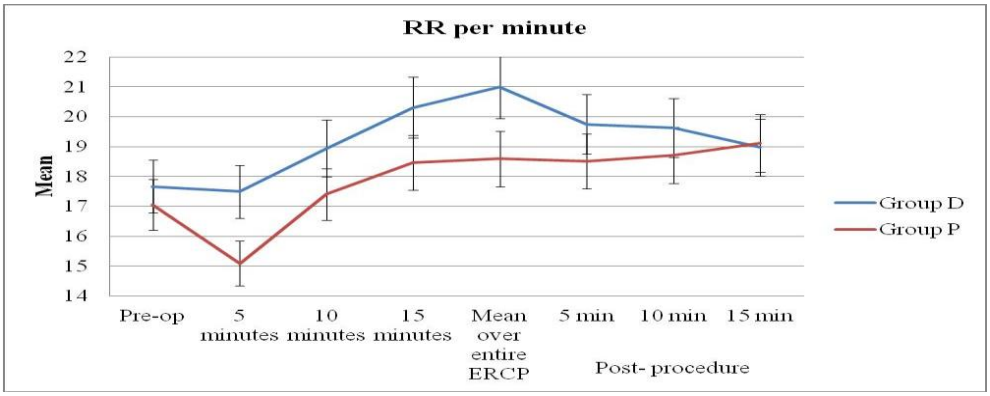
Table - 4: Comparison of mean duration and total dose of Fentanyl, Propofol and Dexmedetomidine between the two groups



Graph -2: Mean Arterial Pressure Comparison



Graph -3: Mean heart rate Comparison



Graph 4: Comparison of respiratory rate

SpO2 (%)	Group D	Group P	p value
During procedure			
5 minutes	98.29±2.88	98.09±2.20	0.745
10 minutes	98.49±3.15	96.34±3.40	0.008
15 minutes	97.94±3.27	95.29±3.08	0.001
Mean over entire ERCP	98.3±2.03	96.1±2.71	0.000
Post procedure			
5 minutes	98.43±2.53	96.97±1.96	0.009
10 minutes	99.29±1.12	97.63±1.78	0.000
15 minutes	99.6±.55	98.49±.78	0.000

Table - 5: Mean SpO2 comparison between the two groups

Complications	Group D	Group P
Hypoxaemia (SPO2 <90%)	2(5.7%)	3(08.5%)
Hypotension (MAP<60 mm Hg)	2(5.7%)	4(11.4%)

Table - 6: Comparison of complications between the two groups

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