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A comparative study of dexmedetomidine and propofol infusion during monitored anesthesia care (MAC) in endoscopic retrograde cholangiopancreatography (ERCP): a randomized controlled trial

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Abstract

Background: Endoscopic retrograde cholangio-pancreatography (ERCP) is an invasive procedure and hence is distressing for awake patients, requiring adequate level of sedation and analgesia. Recent advancements have encouraged use of monitored anesthesia care (MAC), that allows the patient to tolerate unpleasant procedures while maintaining cardio-respiratory function. The main aim is to compare the effect of dexmedetomidine and propofol on the hemodynamics during ERCP, quality of sedation, recovery profile, and any side effects. A total of 100 patients were randomized by a computer-generated random number table into two groups of 30 patients each. The group P received continuous propofol infusion at a rate of 25-75 mcg/kg/min to achieve a Ramsay sedation scale (RSS) of 3-4 before starting the procedure. Group D received dexmedetomidine at loading dose of 1 μg/kg i.v. over 10 min followed by 0.5 μg/kg/h infusion until RSS reached 3-4.

Results: The present study shows significant decrease in heart rate in group D (65.27 ± 4. 3 vs.77.27 ± 9.3) with more stable blood pressure values throughout than group P. There were episodes of transient desaturation in few patients in group P while no patient showed any signs of respiratory depression or desaturation in group D. The time to achieve Ramsay sedation score (RSS) 3-4 is significantly more in group D (11.4 ± 1.37 vs. 7.93 ± 1.32) with increased tendency to use rescue drug but shows better and early recovery.

Conclusion: Dexmedetomidine is a better substitute to propofol for patients undergoing ERCP; however, use of adjunct may be necessary to decrease the need for rescue drug.

Keywords: Dexmedetomidine, Propofol, Monitored anesthesia care (MAC), Endoscopic retrograde cholangiopancreatography (ERCP)

Background

Endoscopic retrograde cholangio-pancreatography (ERCP) is an invasive procedure, and hence is distressing for awake patients, that necessitates adequate level of sedation and analgesia (Chen et al. 2005). The choices of sedation vary between moderate or conscious sedation, deep sedation, and complete general anesthesia (Kapoor 2011). Failure rate and complications were found to be high with light sedation. General anesthesia though found to be safe and successful, is associated with increased use of resources, time, and overall cost. The examination, usually, lasts for about 20 min with very low complication rate (Samson et al. 2014). In fact, most complications in GI endoscopy are related to sedation,

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including cardiopulmonary events such as hypoxemia, hypoventilation, airway obstruction, apnea, arrythmia, hypotension, and vasovagal episodes; hence, the need for judicious use of sedation is warranted (Beeton 2011). Recent advancements have encouraged use of monitored anesthesia care (MAC), which is a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function (American Society of Anesthesiologists 2004). Propofol is non-opioid, non-barbiturate, popular sedative, hypnotic agent with rapid onset, and short duration of action. Propofol also provides antiemetic properties, high-quality sedation, and rapid onset and recovery. Additionally, a consistent target effect site concentration can be maintained without overdose of the drugs (Aantaa et al. 1991). In recent years, dexmedetomidine has become of the frequently used drugs in anesthetic armamentarium, along with routine anesthetic drugs, due to its hemodynamic, sedative, anxiolytic, analgesic, neuroprotective, and anesthetic sparing effects. Other claimed advantages include minimal respiratory depression with cardiac protection, neuroprotection, and renoprotection; thus, making it useful at various situations including offsite procedures (Panzer et al. 2009). In this study, an attempt has been made to compare the effect of dexmedetomidine and propofol on the hemodynamics during ERCP, quality of sedation as assessed by patient and endoscopist satisfaction score, recovery profile, and any side effects during or after the procedure.

Methods

This was a prospective single-blinded randomized controlled study conducted in a tertiary care hospital and research center for a period of 18 months between June 2018 and November 2019, after obtaining the approval from the institutional ethical committee (IEC No. 79/17). A written informed consent was taken from all the patients.

Inclusion criteria

Patients of either sex scheduled for diagnostic and therapeutic ERCP aged between 18 and 60 years of ASA physical status I and II and were included.

Exclusion criteria

Patients with consent refusal, age less than 18 years or more than 60 years, baseline $SpO_2 < 90\%$, mechanically ventilated patients, history of allergy to the drugs used, drug abuse or opioid dependence, psychiatric illness, patients with diabetes mellitus, hypertension, visual and hearing impairment, and pregnancy or morbid obesity.

This study was enrolled in clinical trial registry (CTRI/2019/08/020705) and followed the ethical principles for medical research involving human subjects according to Helsinki Declaration 2013.

Sample size

In a previous study, the heart rate 5 min after injecting propofol was found to be 78 with SD of 11 (Moshari et al. 2017). Hypothesizing a minimum of 10% difference in heart rate following injection dexmedetomidine, sample size was determined to be 30 in each group to be able to reject the null hypothesis that the hemodynamic vitals in both these groups are equal with a probability (power) of 0.80.The type 1 error probability associated with this null hypothesis is 0.05. We included 30 patients in each group.

Randomization

Randomization sequence was drawn using a computer-generated random number table. The patients were randomized into the study arm (group D) and control arm (group P) using this random number table.

Blinding

Allocation concealment (blinding) was done using sequentially numbered opaque envelopes (SNOPES). The names of patients fulfilling inclusion/exclusion criteria and consenting for participation in the study were sequentially entered on the cover of the opaque envelope and after that the envelope was opened to reveal the study arm for the patient. The patient was blind regarding his/her allocation of study arm (Fig. 1).

1. Group P: 30 patients who received continuous propofol infusion at a rate of 25-75 mcg/kg/min to achieve a Ramsey sedation scale (RSS) of 3-4 at the beginning.
2. Group D: 30 patients who received dexmedetomidine at loading dose of 1 mcg/kg i.v. over 10 min followed by 0.5 μg/kg/h infusion until RSS reached 3-4.

The groups were also similar in respect to time of intervention by endoscopist, i.e., after achievement of RSS 3-4. Before starting sedation, patients in both groups received an intravenous injection of 1 mcg/kg fentanyl. Depth of sedation was measured by using RSS by anesthesiologist.

The following parameters were monitored and recorded by anesthesiologist at 5 min intervals during the procedure: (1) time to achieve RSS of 3-4; (2) hemodynamic parameters like heart rate (HR), mean arterial pressure (MAP), and the pulse oxygen saturation (SpO_2); (3) the facial pain scale (FPS) 0-10 to evaluate

Fig. 1 Consort-2010 flow diagram
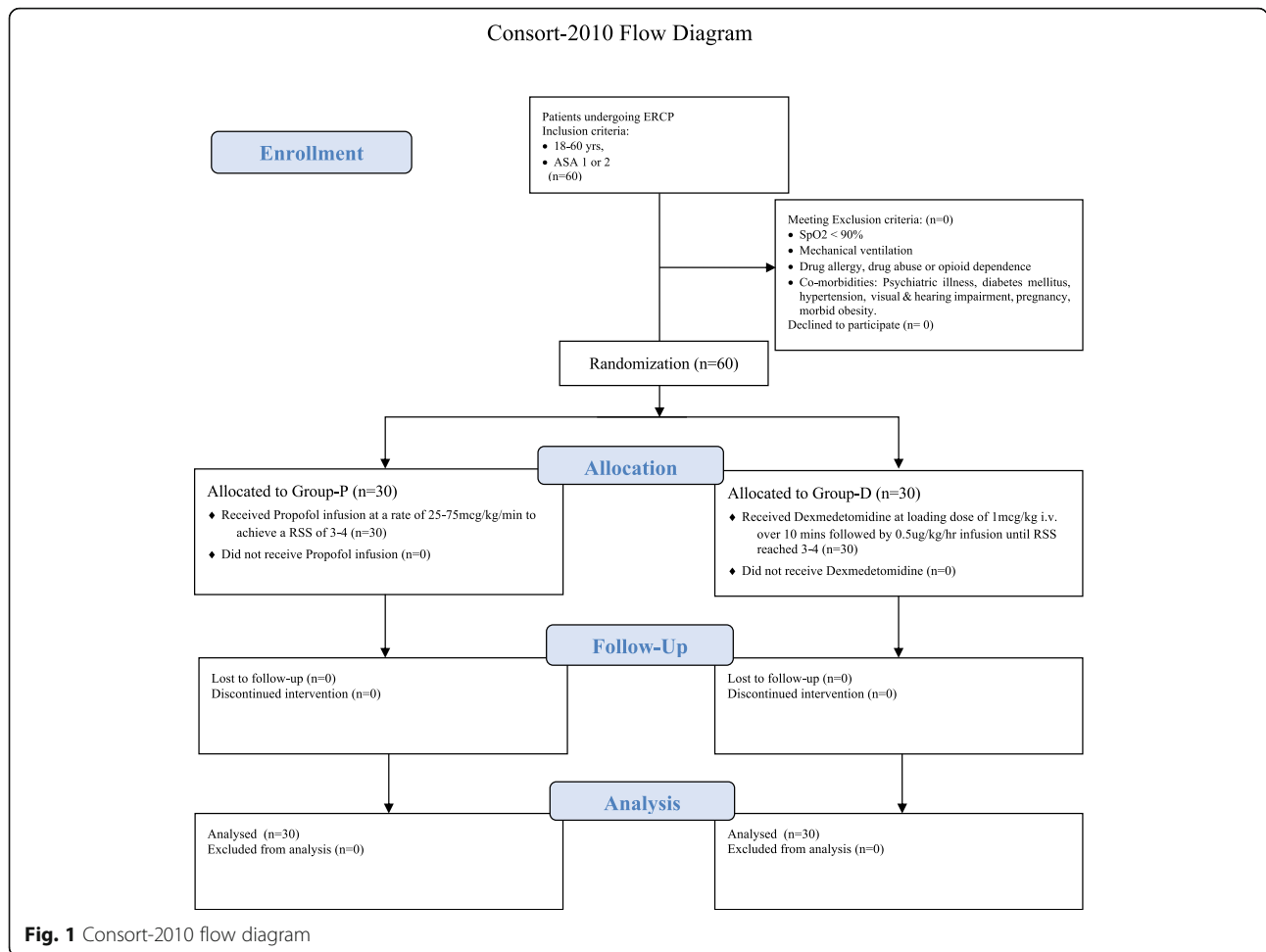
pain (Talu 2007) (Fig. 2). During the procedure if patient required more than three episodes of personal restraint by the assistant or if either patient or endoscopist was uncomfortable, the rescue IV sedation was provided with propofol in top up incremental dose of 10 mg until patient reached RSS 3-4 and the requirement of rescue sedative drug was recorded. During procedure, complications were observed, recorded, and treated accordingly. Oxygen desaturation was considered when SpO_2 level dropped below 92% for more than 10 s. A heart rate under 50 beats/min or a 20% decrease from the baseline was labeled as bradycardia, whereas a HR over 110 or an increase of more than 20% from the baseline level was considered as tachycardia. Mean arterial pressure lower than 60 mmHg or 20% less than the baseline was regarded as hypotension and a MAP value of over 150 mmHg or a 20% increase from the baseline was regarded as hypertension. Possible complications, such as respiratory depression, allergies, coughing, gagging, shivering, nausea, and vomiting, were recorded. After the procedure, the satisfaction of the surgeon and patients were assessed using satisfaction scores as Excellent

= 4, Good = 3, Fair = 2, and Poor = 1 (Sethi et al. 2014). In the recovery room, patient FPS, vital parameters were recorded every 5 min by anesthesiologist till Modified Aldrete score (MAS) of 9-10 reached, along with any adverse effects. Patients were discharged on achieving a MAS of 9-10.

Statistics

Descriptive statistics were used to describe the baseline characteristics. Dichotomous outcomes were compared by chi-square test with continuity correction or Fisher's exact test as applicable. Numerical variables were compared by the Student's t test or Mann-Whitney U test, depending on the distribution. Analysis was performed using SPSS version 22. The results were considered significant if $P < 0.05$.

Results

There was no significant difference in demographic variables in both the groups. The amount of fentanyl used was also similar in both the groups (Table 1). The total amount of intervention drug used in group P (propofol)
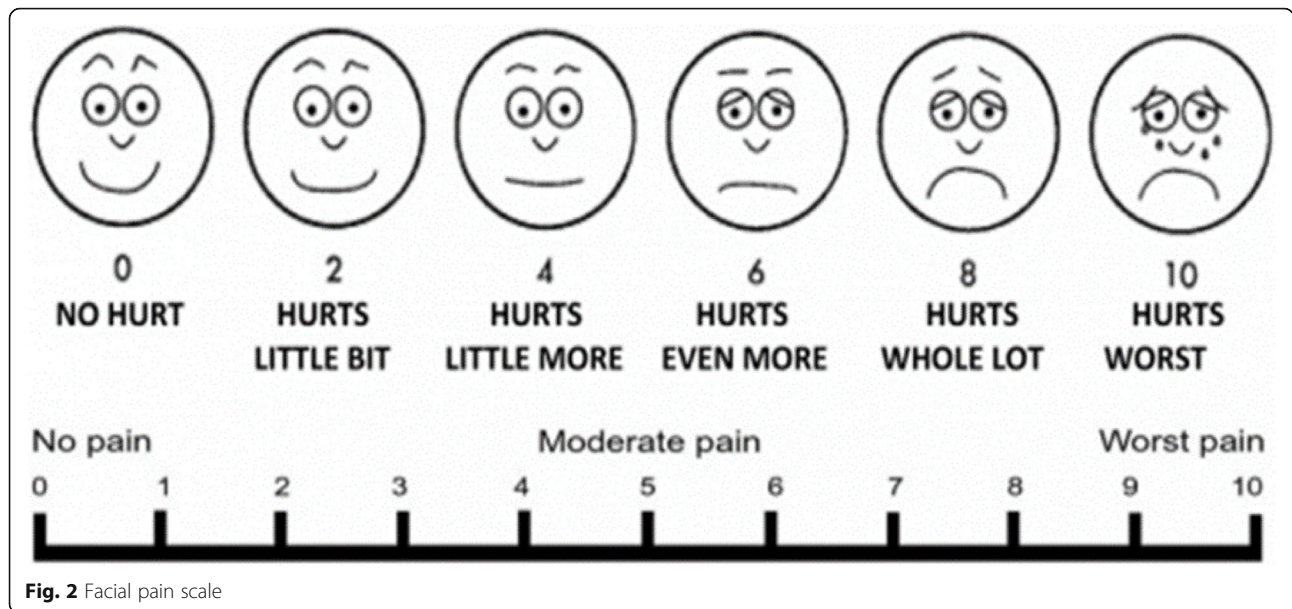
Fig. 2 Facial pain scale

varied from 90-140 mg with a mean ± SE of 114.6 ± 16.5 mg and the total amount of intervention drug used in group D varied from 58-85 mcg with a mean (± SE) of 72.6 ± 10.2 mcg. There was no difference in baseline values of heart rate in both the groups. After loading, there is a significant decrease in heart rate in group D as compared to group P (P = <0.001).The mean heart rate in group P is comparable throughout the procedure and during recovery, while in group D there is a significant decrease in heart rate on post loading as well as through the procedure. There was significant difference in HR between both the groups at 5, 10, 15, and 20 min. In the recovery period, the difference is statistically significant at 5 and 10 min between both the groups but becomes insignificant at 15 min (Fig. 3). At baseline, there was no significant difference among the two groups for MAP (p = 0.447).There was no significant difference in MAP after loading at 5 min and 10 min but significantly reduced in group P at 15 min (p = 0.028) and 20 min (p = 0.001). This significant reduction was also extended in the recovery period at 5 min (p = 0.035) but became non-significant at 10 and 15 min (Fig. 4). The oxygen saturation showed significant reduction (not

desaturation) in group P than group D (p < 0.05), after loading throughout the procedure that became non-significant during recovery (Fig. 5). Time to achieve Ramsay sedation score of 3-4 showed significant difference between the groups (7.93 ± 1.32 in group P vs. 11.4 ± 1.37 in group D) (Table 2) with an increasing trend of using the rescue drug in group D, the amount of rescue drug used did not vary significantly between the groups (p = 0.486) (Table 3). The complications (desaturation, restlessness coughing gagging, and vomiting) in both the groups showed no statistical difference though it was slightly higher in group P (Fig. 6). In our study, achievement of MAS 9-10 during recovery was significantly faster in group D at 5 min (87% vs. 0%) and at 10 min (100% vs. 13%) (Table 4). In our study, we compared patient and endoscopist satisfaction by a scoring system which showed no statistical difference between both groups. However, the endoscopist score in group D was slightly less due to increased tendency to use rescue drug (propofol bolus) because of restlessness (Table 5). The FPS score also showed no significant difference at any time period during the procedure or recovery.

Discussion

Summary of key findings: The present study was conducted to compare the effects of injection dexmedetomidine and injection propofol as a conscious sedative agent used in short procedure of ERCP. All variables were comparable in the two groups.

Dexmedetomidine usage is associated with a greater decrease in HR, in part because of its sympatholytic effect due to its action on α_2 adrenoreceptor, and also because of a vagal mimetic effect. In this study also, after
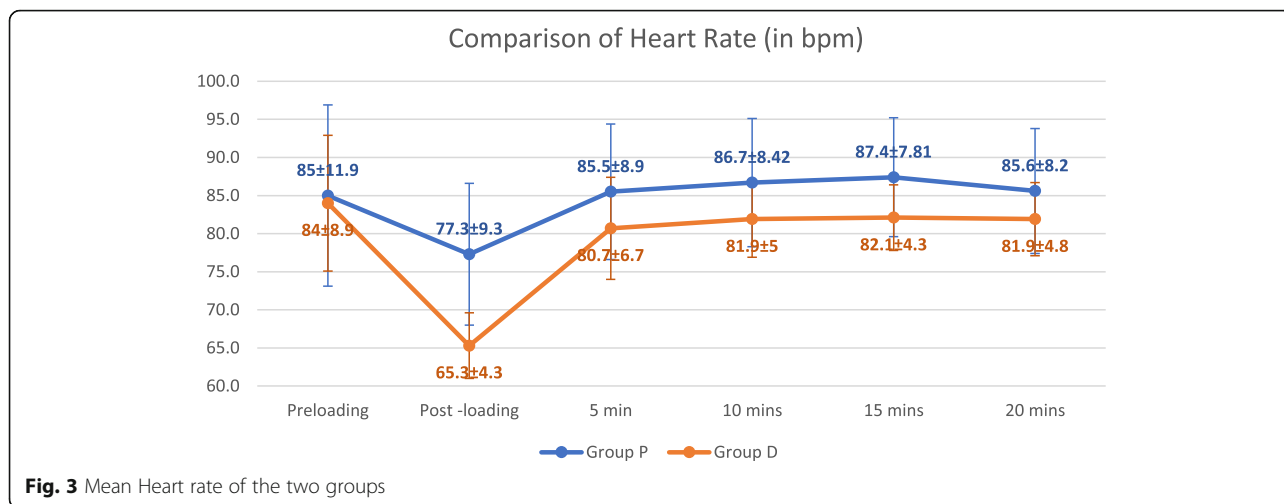
Table 1 Description of baseline characteristics in two group

Baseline characteristics	Group P (n = 30)	Group D (n = 30)	p value*
Age (years)	46.1 ± 11.4	48.6 ± 10.5	0.394
Weight (kg)	65.9 ± 11.3	63.1 ± 8.7	0.288
Male (%)	16 (53.33)	20 (66.67)	0.292
Total fentanyl used (μg)	65.8 ± 11.3	63 ± 8.7	0.288

Data are mean±SD and proportion. No significant difference P > .05. SD standard deviation

Fig. 3 Mean Heart rate of the two groups

loading, there is a significant decrease in heart rate in group D as compared to group P (p = <0.001) with the mean heart rate being 77.27 ± 9.3 vs. 65.27 ± 4.3. Within the group, it is comparable throughout the procedure and recovery in group P, but a significant decrease in heart rate throughout the procedure post loading and during recovery at 5 to 10 min in group D. These results are in accordance with the studies done by Sethi et al. (Sethi et al. 2014), Kilic et al. (Kilic et al. 2011), and Inatomi et al. (Inatomi et al. 2018) where they also found statistically significant lower HRs in dexmedetomidine group.

A significant decrease in MAP is noted in group P after loading at 15 min (p = 0.028) with mean MAP of 83.6 ± 13.4 vs. 90.0 ± 7.8 and at 20 min (p = 0.001) with mean MAP of 80.4 ± 14.4 vs. 90.0 ± 7.6, because the most significant cardiovascular effect of propofol during the induction of anesthesia is a drop in the blood pressure which is explained by the powerful inhibitory effect of propofol on the sympathetic nervous system. Dexmedetomidine is also known to decrease sympathetic

outflow and circulating catecholamine levels and would therefore be expected to attenuate the hemodynamic response to endoscopy which is shown by decrease in MAP post loading throughout the procedure; however, these parameters remained comparatively stable in dexmedetomidine group than in propofol group. This probably indicates the analgesic properties of dexmedetomidine along with fentanyl, and the findings suggest that dexmedetomidine has clinical advantages over propofol with regard to controlling hemodynamic variability. This was supported by the studies of Coté et al. (Coté et al. 2010) and Arian et al. (Arain and Ebert 2002) who also reported significant hypotension in the propofol group. In their study, Tsai et al. (Tsai et al. 2010) evaluated dexmedetomidine hemodynamic stability in comparison to propofol in sedation for fibreoptic naso-tracheal intubation in 40 patients with anticipated difficult airway undergoing elective surgery and agreed upon the intraoperative hemodynamic stability of dexmedetomidine as the current study. Intra-procedural hemodynamic stability was also supported by another
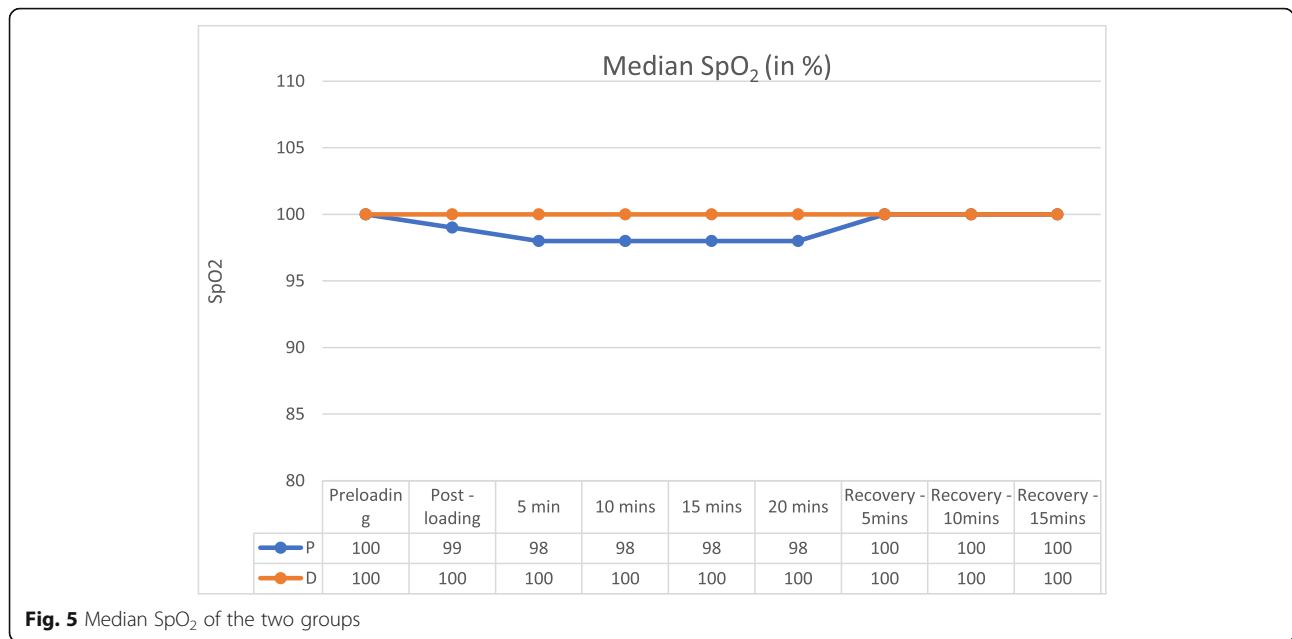

Fig. 4 Mean arterial pressure of the two groups
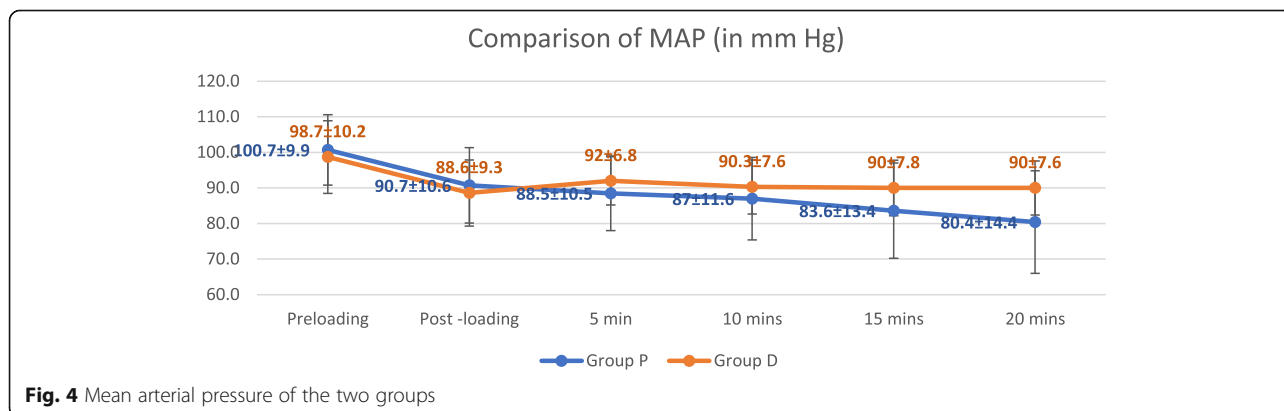
Fig. 5 Median SpO$_2$ of the two groups

study performed by Sethi et al. (Sethi et al. 2014) who studied dexmedetomidine versus midazolam for conscious sedation in ERCP. They observed decreased HR and comparatively stable MAP values in dexmedetomidine group. Contrary to this, Muller et al. (Muller et al. 2008) reported intra-procedural hemodynamic instability of dexmedetomidine as they studied dexmedetomidine alone against propofol–fentanyl for conscious sedation during ERCP. This might be explained by the lighter level of sedation in dexmedetomidine group; they administered dexmedetomidine in loading dose 1μg/kg infused over 10 min then maintained by 0.2 μg/kg/h so requiring additional sedatives.

The oxygen saturation showed significant difference between the groups after loading throughout the procedure that became non-significant during recovery but there was no deterioration in respiratory parameters (respiratory rate, desaturation) as observed by Demiraran et al (Demiraran et al. 2007) for dexmedetomidine group in their study.

The time to achieve Ramsay sedation score of 3-4 showed significant difference ($p < 0.001$) between the groups with 7.93 ± 1.3 vs. 11.4 ± 1.37 in group P and D respectively.

The complications in both the groups showed no statistical difference; however, it was slightly higher in group P. Four patients in group P developed desaturation while there was no such episode in group D. The desaturation in all the patients in group P was transient and was spontaneously reverted without any intervention. This observation is probably explained by the use of infusion for propofol administration, maintaining a constant therapeutic level which would not exceed the therapeutic window. Jang SY et al. (Jang et al. 2012) in their study confirmed that if we achieved the desired level of sedation using a minimal dose of propofol with BIS monitoring, then the risk of respiratory depression is reduced.

Both the groups did not show any significant complications in the recovery period. Similarly Abdellatif et al. (Abdellatif et al. 2012) and Arain-Ebert (Arain and Ebert 2002) reported no intraoperative or post-operative adverse effects in dexmedetomidine group in their study, but Coté et al. (Coté et al. 2010) in their prospective study of 799 patients undergoing endoscopy (ERCP, EUS, and small bowel enteroscopy) procedures under propofol sedation found a hypoxemia rate of 12.8%,

Table 2 Time to achieve desired RSS of 3-4

Time (in min)	Group P (n = 30)	Group D (n = 30)	p value*
To achieve desired RSS of 3-4 (in min)	7.93 ± 1.31	11.4 ± 1.37	< 0.001

Data are mean±SD. Significant difference P < .05, RSS Ramsay sedation score

Table 3 Rescue drug used

Rescue drug used (Inj. propofol bolus)	Group P (n = 30)	Group D (n = 30)	p value*
No. of patients required rescue drug	2 (6.7%)	8 (26.7%)	< 0.001
Total dosage (mg)	80	280	< 0.001
Dose/patient (mg)	40 ± 14.1	35 ± 7.6	0.486

Data are mean±SD and proportion. No significant difference P > .05, SD standard deviation

Fig. 6 Comparison of complications between the groups
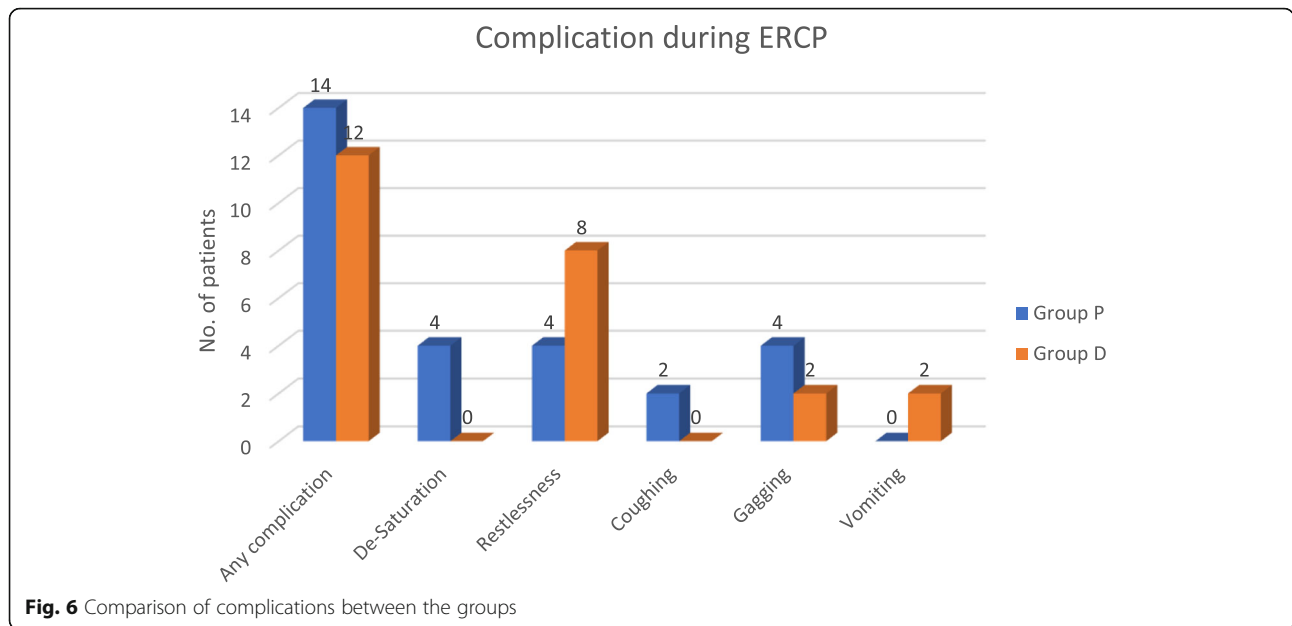
hypotension rate of 0.8%, airway maneuvres were required in 14.4%, and premature termination rate of 0.6% patients. This is probably due to difference in the drug administration.

In our study, MAS was significantly different between two groups at 5 and 10 min during recovery. MAS 9-10 at 5 min was achieved by 87% in group D and none in group P. By 10 min, all patients in group D achieved MAS value of 10 while only 13% of group P patients achieved it. Kilic et al. (Kilic et al. 2011) in their study observed that 80% in Group D reached a MAS value of 10 over 5 min and 96% by 10th min. and Sethi et al. (Sethi et al. 2014) supported this finding as they reported shorter recovery time for dexmedetomidine group in patients undergoing ERCP under conscious sedation, as 90% of patients received dexmedetomidine achieved Aldrete score 9–10 within 5 min.

The present study compared patient and endoscopist satisfaction by a scoring system which showed no statistical difference between both groups, although the endoscopist score in group D was slightly lower due to increased restlessness in patients of this group. This is the reason behind the more use of rescue drug (propofol bolus) in group D.

The FPS score showed no significant difference at all time periods during the procedure and recovery. Pain control is mediated by μ receptors with fentanyl while effect on locus coeruleus is responsible for action of dexmedetomidine. Dexmedetomidine provides analgesia with a ceiling effect at doses > 0.5 μg/kg. Previous study detected that opioid requirements in the intraoperative period and in the post-anesthetic care unit (PACU) are reduced by dexmedetomidine (Arain and Ebert 2002).

Strength and limitation of study

The advantage of the present study is that there is better hemodynamic stability in group D; however, in group P also, there are no major derangements in hemodynamics and respiratory parameters as seen with previous studies, apart from the expected effects of propofol in respect to decrease in blood pressure and oxygen saturation. There is better patient and endoscopist satisfaction score, better pain control, lesser incidence of complications, and better recovery profile with dexmedetomidine. However, the only concern was an increase in tendency to use a rescue drug in dexmedetomidine group. The potential limitations in the current study are its small sample size.

Table 4 Modified Aldrete score (MAS) of 9-10 at 5 min during recovery

Achievement of MAS of 9-10 at 5 min during recovery	Group P (*n* = 30)	Group D (*n* = 30)	*p* value*
Number of patients achieved (%)	0 (0%)	26 (86.67%)	< 0.001

Data are proportion, significant difference *P* < .05

Table 5 Comparison of patient's and endoscopist satisfaction

Scores	Group P (*n* = 30)	Group D (*n* = 30)	*p* value*
Doctor's satisfaction (median, IQR)	4 (3, 4)	3 (3, 4)	0.305
Patient's satisfaction (median, IQR)	4 (3, 4)	4 (3, 4)	0.595

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Conclusion

This study concludes that dexmedetomidine is a better substitute to propofol for patients undergoing ERCP; however, a need for adjunct may be necessary to decrease the need for rescue drug.

Direction for future research

There is always a need for further multicentric RCT to confirm the findings as only a small number of studies are published regarding use of dexmedetomidine for MAC in ERCP.

Abbreviations
ERCP: Endoscopic retrograde cholangio-pancreatography; MAC: Monitored anesthesia care; RSS: Ramsay sedation score; IEC: Institutional ethical committee; CTRI: Clinical trial registry of India; HR: Heart rate; MAP: Mean arterial pressure; MAS: Modified Aldrete score; RCT: Randomized controlled trial; PACU: Post-anesthetic care unit; FPS: Facial pain scale; SNOPES: Sequentially numbered opaque envelopes

CTRI number
CTRI/2019/08/020705 [Registered on 14/08/2019], CTRI Website URL—http://ctri.nic.in.

Authors' contributions
NS and MH has major role in conceptualizing/designing the study; SR and MT have made substantial contributions to acquisition, analysis, and interpretation of data; SK and DM have major contribution in writing the manuscript along with NS. All authors contributed in substantively revising the manuscript. The manuscript has been read and approved by all the authors, and the requirements for authorship as stated earlier in this document have been met, and each author believes that the manuscript represents honest work.

Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study was conducted after obtaining the approval from the institutional ethical committee of Dr. Ram Manohar Lohia Institute of Medical Sciences Lucknow with IEC No. 79/17 dated 04/06/2018. A written informed consent was taken from all the patients.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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