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Original Research Article

A Prospective Study Comparing Dexmeditomidine-Propofol and Fentanyl-Propofol Combinations in Terms of Poropofol Dose, Safety, Recovery Profile and Post-Operative Analgesic Requirement in Patients Undergoing Functional Endoscopic Sinus Surgery

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Conflict of interest: Nil

Abstract

Aim: The Aim of the study is to compare Dexmedetomidine-Propofol and Fentanyl-Propofol on Propofol consumption, perioperative haemodynamics, Fentanyl requirements and post-operative recovery profile in patients undergoing functional endoscopic sinus surgery (FESS).

Primary Objective: To compare dexmedetomidine-propofol with fentanyl-propofol combination on propofol consumption during induction and maintenance Secondary objective: To compare intraoperative hemodynamics, additional fentanyl requirements, recovery profile, side effects, post-operative analgesia

Method: The study was conducted in ENT operation theatre at Thanjavur Medical College after obtaining approval from the Institutional Ethical Committee. Written informed consent was taken from all study participants before conduct of the study. Pre-anaesthesia assessment was done in PAC clinic. On the day of surgery standard monitoring was applied, two IV line were secured with 18G IV cannula. GROUP DP-patients who received Dexmedetomidine 1 µg/kg as IV infusion in 100ml normal saline 10 minutes prior to induction. GROUP FP --patients who received Fentanyl 2 µg/kg as IV infusion in 100ml normal saline 10 minutes prior to induction. All the collected data were entered in Microsoft Excel worksheet and double checked for any clerical errors. The variables with normal distribution were expressed as mean with standard deviation. The variables that were not normally distributed were expressed as median with range. Frequencies are expressed in percentage. Proportions were reported with 95% confidence intervals.

Conclusion: From our study we conclude that Dexmedetomidine and Propofol combination resulted in reduced intraoperative Propofol consumption during induction and maintenance, provided improved hemodynamic stability, reduced intraoperative Fentanyl requirements, early recovery and prolonged postoperative analgesia when compared to Fentanyl and Propofol combination in patients undergoing FESS with no significant side effects in both the groups.

Keywords: Dexmedetomidine, Propofol, Fentanyl, Hemodynamics, Recovery.

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Introduction

Total Intravenous Anesthesia (TIVA) is a general anaesthesia technique in which intravenous drugs are used to produce temporary loss of consciousness and sensation.

TIVA has various advantages over standard volatile techniques, including better surgical field visibility, significant reduction in the intraoperative blood loss, a superior recovery profile with a lower risk of postoperative nausea and vomiting, the ability to promote intraoperative wake-up while maintaining amnesia, preserving cerebral autoregulation, and no operating room pollution. TIVA can be performed with syringe pumps or with Target-controlled infusion (TCI). According to a meta-analysis, TIVA has the potential to offer improved surgical field visibility and minimize intraoperative blood loss than inhalational anesthesia in FESS. Impaired sinonasal visibility due to mucosal bleeding may be problematic in cases of chronic rhinosinusitis (CRS) with high-grade inflammatory illness, implying a role for TIVA in that disease subgroup.

This study compared the effects of dexmedetomidine-propofol and fentanyl-propofol on, propofol requirements, perioperative hemodynamics, fentanyl requirements and post-operative recovery profiles in patients undergoing functional endoscopic sinus surgeries.

Aim: The Aim of the study is to compare Dexmedetomidine-Propofol and Fentanyl-Propofol on Propofol consumption, perioperative haemodynamics, Fentanyl requirements and post-operative recovery profile in patients undergoing functional endoscopic sinus surgery (FESS).

Primary Objective: To compare dexmeditomidine-propofol with fentanyl-propofol combination on propofol consumption during induction and maintenance

Secondary Objective: To compare intraoperative hemodynamics, additional fentanyl requirements, recovery profile, side effects, post-operative analgesia

Materials and Methods

Study Design: The study was designed as a Prospective Randomized Double Blind study.

Study Setting: The study was conducted in the Department of Anaesthesiology, Thanjavur Medical College and Hospital. This study was conducted for a period of 1 year from January2023 to December2023.

Population: Patients posted for Functional endoscopic sinus surgery under General anaesthesia in Thanjavur Medical College Hospital depending upon the inclusion and exclusion criteria.

Sample Size: The statistically calculated sample size was 18 in each group. Considering the dropout rate as 10%, this was rounded to 20 in each group. The total sample size was 40.

Inclusion Criteria: Elective FESS, ASA physical status 1&2, Age 25 to 65 years.

Exclusion Criteria: Patient refusal, allergic to the drugs used in the study, patients with cardiovascular diseases, cerebrovascular insufficiency, liver disease, renal dysfunction and pregnancy.

Methodology

The study was conducted in ENT operation theatre at Thanjavur Medical College after obtaining approval from the Institutional Ethical Committee. Written informed consent was taken from all study participants before conduct of the study. Pre-anaesthesia assessment was done in PAC clinic. On the day of surgery standard monitoring was applied, two IV line were secured with 18G iv cannula.

Group DP- patients who received Dexmedetomidine 1 µg/kg as iv infusion in 100ml normal saline 10 minutes prior to induction.

Group FP - patients who received Fentanyl 2 µg/kg as iv infusion in 100ml normal saline 10 minutes prior to induction.

Premedication with inj.Glycopyrolate 0.01mg/kg and inj.Midazolam 2mg was given to both the groups.

Before induction of anesthesia the study drugs were prepared as the following:

1. **Propofol infusion:** Propofol in the dose of 10mg/ml in 50ml syringe
2. **Dexmedetomidine infusion:** Dexmedetomidine in the dose of 1µg/ml in 50ml normal saline in 50 ml syringe.
3. **Fentanyl infusion:** Fentanyl in the dose of 2 µg/ml in 50ml normal saline in 50 ml syringe.

Induction was done with inj. Propofol in 20 mg aliquots until the Bispectral Index (BIS) value reached below 60. Succinyl choline 1mg/kg was used to facilitate endotracheal intubation. A suitable sized cuffed endotracheal tube was used for intubation. Controlled mechanical ventilation was instituted with air and O_2 mixture. Capnography was connected and mechanical ventilation was adjusted to maintain $EtCO_2$ at 30–35 mmHg. Infusion of one of the study drugs either Dexmedetomidine 0.5µg/kg/h or Fentanyl 1µg/kg/h was started immediately after intubation and continued along with Propofol infusion 3–6 mg/kg/h to maintain BIS around 40–60. Inj.Vecuronium 0.1mg/kg iv was used to provide muscle relaxation and bolus doses of Fentanyl 0.5 mcg/kg was given whenever there was an increase in HR or MABP >20% of baseline. At the end of the surgery the study drugs were discontinued, residual neuromuscular blockade was reversed with inj. Neostigmine 50µ/kg and inj. Glycopyrolate 10µ/kg and extubation done. After extubation patients were assessed for sedation level using Ramsay sedation scale. Post operatively,

Patients were monitored in PACU till modified Aldrete Score is greater or equal to. 9 Patients were observed for 24 hrs after completion of the surgery for any adverse events. Inj.Tramadol 1.5mg/kg was given for post op analgesia when needed using Visual Analogue Scale for pain when the score was more than 4.

Parameters Recorded

1. Intra-operative Propofol consumption during induction and maintenance
2. Hemodynamic parameters - HR, SBP, DBP, MABP, SPO2 at induction, at intubation, 5 mints, 15 mints, 30 mints, 45 mints, 60 mints & at extubation.

3. Additional doses of Fentanyl
4. Time from discontinuation of Dexmedetomidine-Propofol or Fenatnyl-Propofol infusion at the end of surgery to extubation.
5. Time from extubation to achieve a Ramsay sedation score -2.
6. Time from end of surgery to the first post-operative analgesic request.
7. Side effects like bradycardia, PONV, hypotension, hypertension

Statistical Analysis: All the collected data were entered in Microsoft Excel worksheet and double checked for any clerical errors.

The variables with normal distribution were expressed as mean with standard deviation. The variables that were not normally distributed were expressed as median with range. Frequencies are expressed in percentage. Proportions were reported with 95% confidence intervals.

Table 1: Comparison of intraoperative Propofol requirements between studies groups (D-P & F-P):

Variable	Group D-P (n=20)	Group F-P (n=20)	P-value
Total amount of propofol consumption during induction (mg/kg)	1.31 ± 0.13	1.58 ± 0.16	**0.001**
Total amount of propofol consumption during maintenance (mg/kg/h)	3.40 ± 0.17	4.61 ± 0.58	**0.001**

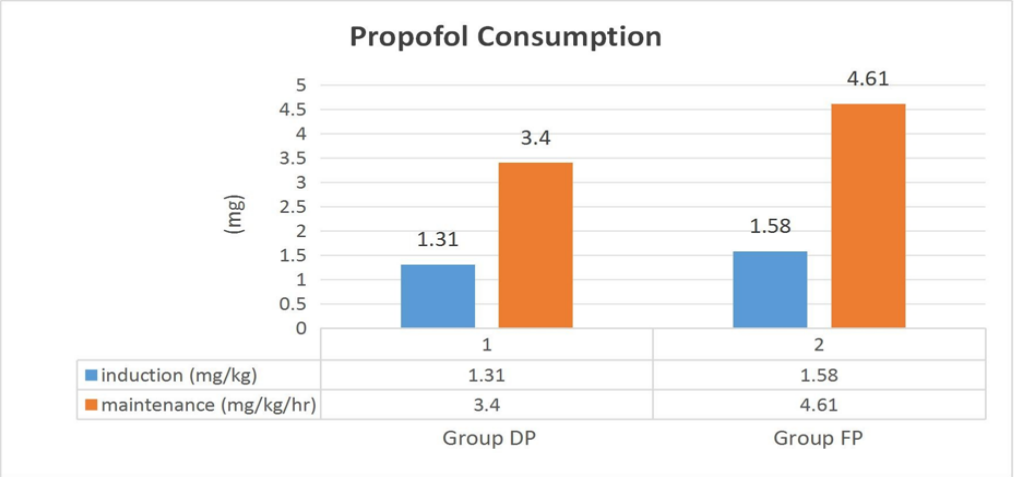

Figure 1: Propofol Consumption

Table 2: Comparison of Mean arterial blood pressure between the studies groups (D-P & F-P):

Mean arterial BP (mm/Hg)	Study group	Mean	Standard deviation	95 % Confidence interval for mean		Minimum	Maximum	P-value
				Lower limit	Upper limit			
Baseline	D-P (n=20)	90.30	7.49	90.79	97.81	80	110	
	F-P (n=20)	88.95	6.32	85.99	91.91	80	100	0.258
Before induction	D-P (n=20)	89.35	7.36	92.67	100.73	84	113	
	F-P (n=20)	87.70	8.62	87.15	93.55	83	112	0.318
Before intubation	D-P (n=20)	86.55	7.15	86.20	92.90	77	105	
	F-P (n=20)	84.90	7.22	80.52	87.28	73	105	0.392
At 5 mins	D-P (n=20)	91.45	5.25	91.99	96.91	87	107	
	F-P (n=20)	89.20	5.18	89.77	94.63	83	103	0.181
At 15 mins	D-P (n=20)	91.65	3.62	90.30	93.70	87	99	
	F-P (n=20)	88.30	4.21	87.33	91.27	81	100	0.287
At 30 mins	D-P (n=20)	90.95	4.22	88.97	92.93	86	104	
	F-P (n=20)	90.15	2.99	88.75	91.55	84	95	0.494
At 45 mins	D-P (n=20)	89.30	4.46	87.21	91.39	83	97	
	F-P (n=20)	91.25	6.82	88.06	94.44	80	109	0.291
At 60 mins	D-P (n=20)	88.85	2.99	87.45	90.25	84	94	
	F-P (n=20)	90.05	3.37	88.47	91.63	84	96	0.242
During extubation	D-P (n=20)	92.00	3.71	92.26	95.74	88	101	
	F-P (n=20)	93.65	5.54	92.05	97.25	84	105	0.666

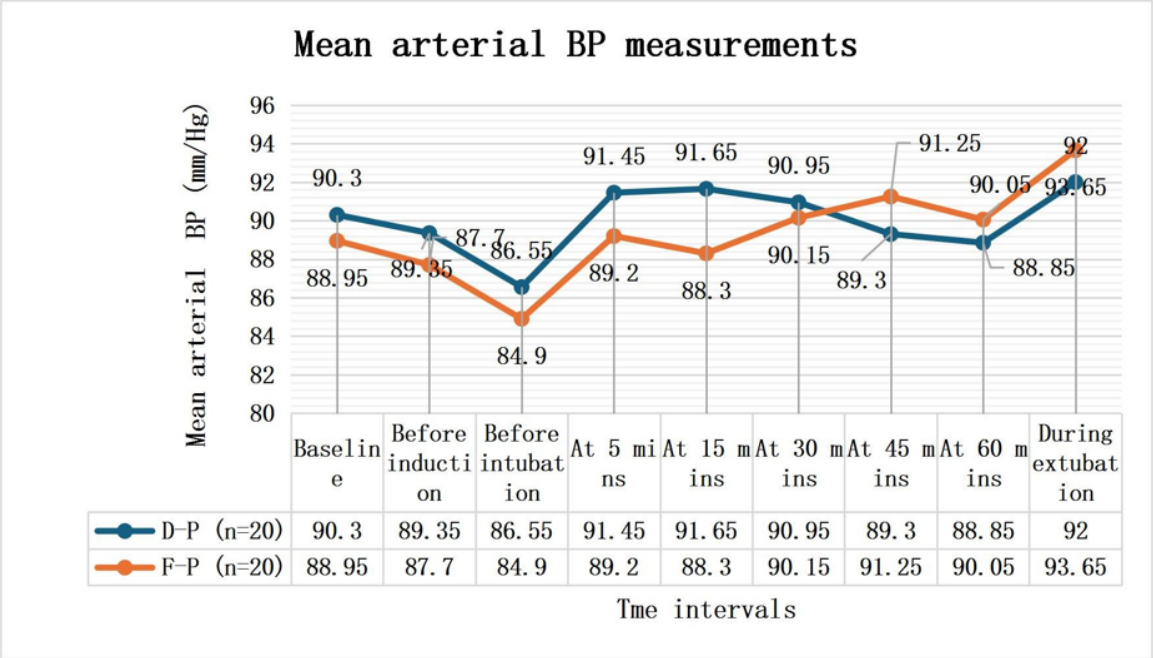

Figure 2: Mean arterial BP measurements

Table 3: Comparison of heart rate between the studies groups (D-P & F-P)

Heart rate (beats/min)	Study group	Mean	Standard deviation	95 % Confidence interval for mean		Minimum	Maximum	P-value
				Lower limit	Upper limit			
Baseline	D-P (n=20)	79.30	7.435	75.82	82.78	68	92	
	F-P (n=20)	84.70	7.378	81.25	88.15	68	102	0.276
Before induction	D-P (n=20)	78.90	7.383	75.44	82.36	68	94	
	F-P (n=20)	88.90	7.504	85.39	92.41	76	107	**0.001**
Before intubation	D-P (n=20)	73.50	5.835	70.77	76.23	64	86	
	F-P (n=20)	85.55	12.866	79.53	91.57	74	130	**0.001**
At 5 mins	D-P (n=20)	76.45	5.643	73.81	79.09	68	92	
	F-P (n=20)	91.30	10.367	86.45	96.15	76	122	**0.001**
At 15 mins	D-P (n=20)	72.20	7.281	68.79	75.61	64	92	
	F-P (n=20)	86.60	6.676	83.48	89.72	72	99	**0.001**
At 30 mins	D-P (n=20)	71.20	6.818	68.01	74.39	60	84	
	F-P (n=20)	85.80	7.757	82.17	89.43	74	106	**0.001**
At 45 mins	D-P (n=20)	68.45	6.211	65.54	71.36	60	86	
	F-P (n=20)	88.05	9.006	83.84	92.26	72	110	**0.001**
At 60 mins	D-P (n=20)	66.50	4.936	64.19	68.81	56	76	
	F-P (n=20)	86.75	5.830	84.02	89.48	74	94	**0.001**
During extubation	D-P (n=20)	74.05	6.278	71.11	76.99	66	88	**0.001**

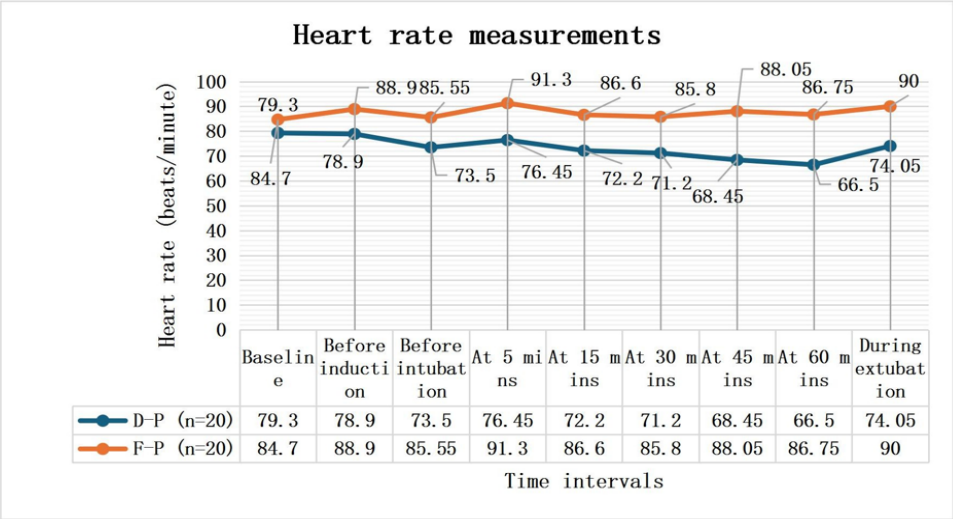

Figure 3: Heart rate measurements

Table 4. Comparison of intraoperative Fentanyl requirements between studies groups (D-P & F-P):

Variable		Group D-P (n=20)	Group F-P (n=20)	P-value
No. of additional doses of fentanyl required	**0**	19	15	
	1	1	5	0.080
	2	0	0	

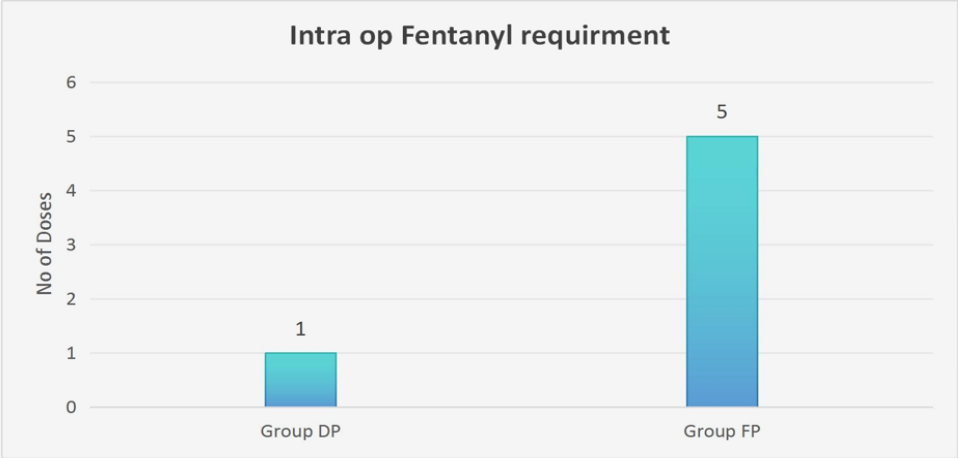

Figure 4: Intra op Fentanyl requirment

Table 5: Comparison of post-operative recovery profile between study groups:

Variables	Group D-P (n=20)	Group F-P (n=20)	P-value
Time since anaesthetic discontinuation to tracheal extubation (min)	6.00 ± 1.07	9.85 ± 2.96	**0.001**
Time from extubation to Ramsay sedation score of 2 (min)	4.05 ± 0.82	6.10 ± 1.58	**0.001**

Table 6: Comparison of adverse events between groups:

Adverse events		Group D-P (n=20)	Group F-P (n=20)	P-value
Bradycardia	**Yes**	1	1	
	No	19	19	
PONV	**Yes**	0	5	0.091
	No	20	15	
Hypotension	**Yes**	0	0	
	No	20	20	
Hypertension	**Yes**	0	0	
	No	20	20	

Table 7: Comparison of post-operative analgesic requirement between groups:

Variables	Group D-P (n=20)	Group F-P (n=20)	P-value
Time from extubation to first post-operative analgesic requirement (hours)	6.37 ± 1.53	4.22 ± 1.56	**0.001**

Discussion

The results obtained in our study were similar to the results in the study done by Jasmita et al. They conducted a prospective randomised double-blind study in 60 patients undergoing elective abdominal surgeries in the year 2021 in which they compared Dexmedetomedine and Fentanyl on haemodynamics, propofol consumption and post-operative recovery profile. The study results showed that there was a decrement in the heart rate in Dexmedetomedine-Propofol (D-P) group when compared to Fentanyl-Propofol (F-P) group. In our study the decrement in heart rate was statistically significant (p-0.001) at all time intervals when compared to F-P group. In their study there was a significant reduction in Propofol consumption during induction (p-0.033) in D-P group (1.105±0.30) than F-P group (1.281±0.32). In our study we also observed a statistically significant reduction in Propofol consumption during induction (p-0.001) in D-P group (1.31

± 0.13) than F-P group(1.58 ± 0.16).The maintenance dose of Propofol was lower in D-P group (3.787±1.29)in their study when campared to F-P group(4.403±1.37).In our study also the Propofol consumption during maintenance was lower in D-P group(3.40 ± 0.17) than F-P group(4.61 ± 0.58) and is statistically significant(p-0.001). Similar to their study in our study we observed that the intra operative Fentanyl requirement was less in D-P group than F-P group. In their study the time required from the discontinuation of the study drugs to extubation was found to be less in D-P group (12.43±3.10) than F-P group (15.93±4.25) and is statistically significant(p-0.001). In our study also D-P group (6.00 ± 1.07) required less time for extubation than F-P group (9.85±2.96) and is statistically significant (p-0.001).

In their study D-P group (7.63±3.68) required less time than F-P group(10.40±5.43) to achieve a Ramsay sedation score of 2 after extubation and is statistically significant(p-0.025).Likewise in our study D-P group(4.05 ± 0.82)required less time to achieve Ramsay sedation score of 2 after extubation than F-P group(6.10 ± 1.58) and is statistically significant(p-0.001).In their study there was a statistically significant(p-0.001) delay in the first postoperative analgesic requirement in D-P group (39.10±22.18 mints) when compared to F-P group(22.10±12.59 mints).Similarly in our study also D-P group(6.37 ± 1.53 hours) required statistically significant(p-0.001) delay in the first postoperative analgesic requirment than F-P group(4.22 ± 1.56 hours). In our study, there was a statistically significant (p-0.001) decrease in the induction dose of Propofol in the D-P group when compared to F-P-group. Dexmedetomidine's hypnotic action, which is brought on by the hyperpolarization of noradrenergic locus coeruleus neurons rather than Propofol's agonism of GABA, could be the cause of this. Similar results were obtained by Khare A et al where they compared Dexmedetomidine with normal saline on intraoperative haemodynamics and Propofol requirement in 40 patients undergoing laparoscopic cholecystectomy. In our study Fentanyl 2µg/kg was used replacing normal saline and we also observed that D-P group (1.31 ± 0.13 mg/kg) required statistically significant(p-0.001) less Propofol consumption during induction compared to Group F-P (1.58 ± 0.16 mg/kg).

In our study, we observed a statically significant (p-0.001) reduction in the maintenance dose of propofol in D-P group (3.40 ± 0.17mg/kg/h) when compared to Group F-P (4.61 ± 0.58mg/kg/h). Similar results were obtained in a study by Sen, et al in patients undergoing elective spine surgery. They compared loading dose of Dexmedetomidine 1µg/kg over 10 min and Dexemedetomidine infusion at a rate of 0.2 µg/kg/h with the same volume of 0.9% normal saline solution as placebo. The results were that the mean requirement of Propofol was found to be decreased by 48.08% and 61.87% for induction and maintenance of anaesthesia respectively while using Dexmedetomidine.

They concluded that administration of Dexmedetomidine significantly reduces the requirement of Propofol while maintaining desired depth of anaesthesia without any significant complication. In our study we used 0.5µg/kg/h of Dexmedetomidine for maintenance instead of 0.2 µg/kg/h.In the above study there was no significant difference between the two groups with respect to intraoperative haemodynamics. In our study there was a significant decremenent in heart rate in Dexmedetomidine group throughout the procedure when compared to Fentanyl group. This fall in heart rate could be due to the higher dose of Dexmedetomidine we used for maintenance in our study but all the patients were hemodynamically stable throughout the procedure.

In our study, there was a statistically significant decrease in HR in Dexmedetomidine group at all time when compared to Fentanyl group. But there

was a slight increase in HR along with SBP, DBP, MABP post intubation in D-P group. This increase in HR was significantly lower when compared to the increase in HR post intubation in F-P group. In a study by Laha a et al where they conducted a randomised double-blind study in patient's undegoing major elective surgery. They administered Dexmedetomidine 1µg/kg in 10ml normal saline in one group and 10ml normal saline in the other group before induction. The result showed that Dexmedetomidine 1 ug/kg attenuated but did not totally abolish the cardiovascular and catecholamine responses to tracheal intubation after induction of anesthesia. HR, SBP, DBP all increased after intubation at 1, 2, 3 and 5 min in both the groups, but the rise was significantly less in the Dexmedetomidine group. Requirement of propofol was significantly less in the Dexmedetomidine group. They concluded that preoperative administration of a single dose of Dexmedetomidine blunted the hemodynamic responses during laryngoscopy and reduced anesthetic requirements.

In another study by Solanki NM al, where they studied the effect of dexmedetomidine in attenuating the pressor response of laryngoscopy and intubation and perioperative haemodynamic stability and opined that Dexmedetomidine decreases plasma epinephrine and norepinephrine levels peri- operatively. They observed a decrease in HR in the Dexmedetomidine group from the baseline at all time points till extubation similar to our study. In our study also there was a statistically significant decrease in HR in Dexmedetomidine group at all time when compared to Fentanyl group. In the Dexmedetomidine group patients in our trial, we also observed a statistically significant (p-0.001) reduction in HR at all time points.

In a study by M.W. Abdalla et al where they compared Dexmedetomidine and Propofol with Ketamine and Propofol in patients scheduled for ERCP. They used loading dose of Dexmedetomidine 1 µg/kg over 15 min then maintained by a 0.5 µg/kg/h and Ketamine 1 mg/kg over15 min then maintained by 0.5 mg/kg/h. They observed that postprocedural recovery time was significantly shorter in DP than KP group and they concluded that Dexmedetomidine–propofol combination as TIVA during ERCP showed better intra and post-procedural hemodynamic stability, less PONV, less postoperative cognitive dysfunctions and shorter recovery time when compared with Ketamine–Propofol combination.

In our study we used Fentanyl 2 µg/kg as a loading dose and then maintained with Fentanyl infusion 1µg/kg/hr instead of ketamine .We also observed that DP group(n=20) showed no PONV and better recovery profile (p-0.001)when compared to FP group. In our study there was a delayed post-operative analgesic requirement in D-P group (6.37 ± 1.53 hrs vs 4.22 ± 1.56 hrs) than in F-P group (P = 0.001). This result is similar to the study by Gurbet A et al in 50 females undergoing TAH. They found that an intraoperative loading dose of Dexmedetomidine 1 µg/kg followed by Dexmedetomidine infusion at the rate of 0.5 µg/kg/h vs Placebo normal saline provided adequate analgesia for at least 48 h after surgery .They concluded that continuous iv Dexmedetomidine during abdominal surgery provides effective postoperative analgesia, and reduces postoperative morphine requirements without increasing the incidence of side effects... The extended analgesic effects of Dexmedetomidine following surgery may be attributed to the thymoanaleptic and anxiolytic effects of alpha-2 agonists, which target the psychological component of pain following surgery. There was also a significant decrement in the intra-operative Fentanyl consumption by the Dexmedetomidine group when compared to placebo group in the above study. In our study also there was less intraoperative Fentanyl requirement in the Dexmedetomidine group.

In a study by Shama t et al in patients undergoing FESS, they compared Dexmedetomidine 1 µg/Kg over 10 min before induction of anesthesia and Dexmedetomidine 0.4-0.8 µg/Kg/h infusion during maintenance (DEX group) with Esmolol, loading dose 1mg/kg followed by 0.4-0.8 mg/kg/h infusion during maintenance (E group). In that study the time to first analgesic request was significantly longer in DEX group when compared to E group. In our study also there was a statistically significant (p-0.001) delay in the first post op analgesic request in D-P group (6.37 ± 1.53) than F-P group (4.22 ± 1.56).

In our study One patient in D-P group had bradycardia (HR<60) intra operatively, but no intervention was done as the patient had stable hemodynamics. The patient recovered spontaneously and had no further episodes of bradycardia throughout the postoperative period. In F-P group five patients had post-operative vomiting. One patient had bradycardia along with vomiting postoperatively. As the patient's hemodynamics were stable the patient was observed who then recovered spontaneously without any interventions and had an uneventful post-operative period.

In our study BIS monitoring was used for evaluating the depth of anaesthesia and sedation. Chen Zhang et al conducted a prospective, randomized, double-blinded study in Patients (≥ 18 years of age) undergoing TIVA and they concluded that BIS-guided TIVA (BIS was recommended to maintain between 40 - 60) decreased the risk of awareness compared with routine TIVA. In our

study the intra operative BIS was maintained between 40 - 60.

Conclusion

From our study we conclude that Dexmedetomidine and Propofol combination resulted in reduced intraoperative Propofol consumption during induction and maintenance, provided improved hemodynamic stability, reduced intraoperative Fentanyl requirements, early recovery and prolonged postoperative analgesia when compared to Fentanyl and Propofol combination in patients undergoing FESS with no significant side effects in both the groups.

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