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Original Research Paper

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COMPARISON BETWEEN PROPOFOL AND DEXMEDETOMIDINE INFUSION FOR CONTROLLED HYPOTENSION DURING FUNCTIONAL ENDOSCOPIC SINUS SURGERY

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ABSTRACT Patients aged 18-60 years,ASA grade I, II, who had some middle ear pathology and scheduled to undergo middle ear surgery were included in the prospective, randomized, single blinded study. This study was done to evaluate the comparative efficacy of dexmedetomidine and propofol infusions in producing hypotensive anaesthesia as well as to determine the advantages and disadvantages in patients undergoing endoscopic sinus surgeries. Patients were enlisted for the study after obtaining informed risk consent and were randomly allocated into two groups, Group D (dexmedetomidine infusion receiving group) and Group P (propofol infusion receiving group) using a computer generated randomization chart. After induction, patients in Group D received dexmedetomidine maintenance infusion of 0.2-0.5 mcg/kg/hr . Patients in group P received propofol infusion at the rate of 50-150 mcg/kg/min. The target MAP was 60-70 mmHg or 30% below baseline value, whichever was greater. Oxygen saturation and end-tidal carbon dioxide were maintained throughout the surgery. Whether targets were achieved in terms of haemodynamics and other secondary parameters were compared in the two groups. It was found that targets were achieved in more number of cases in Group D than in Group P and there was significant difference in between the two groups.

KEYWORDS : controlled hypotension, dexmedetomidine, propofol

INTRODUCTION :

Sinusitis is an important cause of morbidity, loss of income and may exacerbate chest disease. Patients commonly seek advice on recurring symptoms of rhinorrhoea, nasal congestion, intermittent facial pain with postnasal drip. Objective of functional endoscopic sinus surgery (FESS) is to restore drainage and aeration of paranasal sinuses and seeks to preserve the normal anatomical structures and function. FESS can be achieved with the use of local anaesthesia with topically applied vasoconstrictors or general anaesthesia. Due to the nature of location that endoscopic sinus surgery is done, even a small amount of bleeding can leave a negative effect on vision of surgeon. Surgical bleeding during endoscopically[1] done sinus surgeries can markedly reduce the visibility of the operative field.[2] Increased bleeding makes surgery harder and longer. To reduce bleeding intraoperatively, maintaining deliberate hypotension (MAP 60 to 70 mmHg) and HR around 50 beats per minute has been a popular technique. This helps to improve the visibility of the surgical field, reduce blood loss and reduce the operating time. Propofol is an intravenous induction agent for general anaesthesia as well as maintenance sedative during general anaesthesia acting by GABA receptor interaction and also resulting in hypotension and bradycardia[3]. Propofol , with slight influence on the myocardium, dilates veins hence facilitating the outflow of blood from the surgical field. It decreases cardiac output by limiting the venous return, thereby reducing the inflow of blood to the surgical field. Propofol anaesthesia results in decreased density of capillaries within the oral mucous membranes.

Propofol infusion reduces blood pressure by 20%-30% compared to before that. Dexmedetomidine is a highly selective alpha 2 agonist which is known to produce sedation, analgesia, and also has sympatholytic[4,5,6], anaesthetic sparing and haemodynamic stabilising properties without significant respiratory depression. The direct vasoconstrictive effect is counterbalanced by alpha2 mediated anti ischaemic effect in perioperative period probably due to reduction in norepinephrine release, thus maintenance of a stable haemodynamics[7]. It reduces central sympathetic outflow leading to hypotension and bradycardia[8] by reducing norepinephrine release. Propofol and dexmedetomidine by infusion have been successfully used to produce hypotensive anaesthesia in endoscopic sinus surgeries to reduce intra operative blood loss and improve visualization of surgical field[9].

OBJECTIVES :

The objective of the study was to compare primarily intraoperative blood loss and operative blood visibility between the two groups and secondarily mean blood pressure, heart rate, oxygen saturation, end tidal carbon dioxide, cerebral oxygen saturation, serum lactate at the end of controlled hypotension, recovery profile and adverse effects if any.

METHODOLOGY :

Maintenance of relatively dry, bloodless field is favourable for surgeons during FESS as it produces better visibility , ease of surgery and reduces operating time. Randomly selected patients who underwent FESS under general anaesthesia in ENT OT in a tertiary care hospital and satisfying all inclusion and exclusion criteria were included in the study.

INCLUSION CRITERIA:

Randomly selected patients admitted in ENT ward with nasal pathology belonging to American Society of Anaesthe siologists (ASA)status I or II, aged from 18-60 years of either sex and had given written consent were included in the study.

EXCLUSION CRITERIA :

- pregnant and breast feeding women
- pre-existing cardiac disease ,renal disorder ,hepatic disease and psychiatric disorder
- patients who refused to participate
- history suggestive of any coagulation disorder, diabetes mellitus, alcoholism, neuromuscular/neurological disorder
- history of allergy to drugs
- any other contraindications for using propofol and dexmedetomidine

Sample size :

Sample size for the study was calculated on the basis of intraoperative blood loss as the primary outcome measure. It was calculated that 17 subjects would be required per group

(propofol and dexmedetomidine) in order to detect difference of 30 ml in intraoperative blood loss with 80% power and 5% probability of Type 1 error. This calculation assumed SD of 30 ml for the blood loss parameter (on the basis of earlier study) and two sided testing. Giving 15% margin for dropout, the recruitment target was kept at 20 subjects per group.

Methods of data collection :

In this single blinded RCT, 40 patients underwent FESS. Blood loss was assessed intraoperatively by determining suction volumes and gauze counting. The operative field visibility was rated according to a 6-point scale by Fromme et al and Boezart et al depending on the bleeding occurring at the operative site, where

0 = no bleeding
1 = slight bleeding , blood evacuation not necessary
2 = slight bleeding , some blood must be evacuated
3 = low bleeding, blood must be evacuated frequently as operative field is visible only briefly after evacuation
4 = average bleeding, blood must be evacuated often , as operative field is visible only immediately after evacuation
5 =heavy bleeding , constant blood evacuation needed, as bleeding often exceeds evacuation , rendering surgery nearly impossible.

BS (bleeding score) was assessed at ten minutes interval , starting from the time of incision and ending with closure of wound by asking the surgeon. The haemodynamic monitoring was recorded preoperatively, 5 minutes after intubation, at the start of the surgery, then every 10 minutes throughout the surgery, at extubation and finally at 1 and 5 minutes after extubation. All relevant laboratory investigations were done preoperatively.

Procedure :

After obtaining Institutional Ethical Committee approval and informed consent from each patient ,a parallel group single blind randomised controlled trial was conducted. After receiving the patients in the operating room, an intravenous line was established with an 18 G intravenous cannula and infusion of lactated ringer's solution was started. Intra operative heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), oxygen saturation (spo2), electrocardiogram(ECG) and capnogram (ETCO2) were monitored. Each patient after adequate preoxygenation received glycopyrrolate 4 mcg/kg and fentanyl 2 mcg/kg as premedication and thiopentone sodium 5 mg/kg as an induction agent and atracurium 0.5 mg/kg were administered to facilitate tracheal intubation. Anaesthesia was subsequently maintained with nitrous oxide, oxygen, isoflurane in titrated dose and appropriate boluses of atracurium (0.1 mg/kg) under controlled mechanical ventilation. After induction, patients in group D received dexmedetomidine maintenance infusion of 0.2- 0.5 mcg/kg/hr continuously. Patients in group P received propofol infusion at the rate of 50-150 mcg/kg/min. The target MAP was 60-70 mmHg or 30% below baseline value , whichever was greater. The drug infusion was stopped 5-8 minutes prior to the end of surgery. Blood loss was assessed intraoperatively using suction volumes and gauze counting. Haemodynamic parameters , duration of surgery, blood lactate level at the end of controlled hypotension, cerebral oxygen saturation and adverse effects were the secondary outcomes. Infusion of the study drug was stopped immediately if the patient developed bradycardia (HR less than 45 beats/min) or significant hypotension (MAP less than 30% of preoperative value). Atropine (0.01 mg/kg) and phenylephrine were used for treating bradycardia and significant hypotension respectively. All raw data was be entered into a Microsoft Excel spreadsheet and analysed. Missing values (haemodynamic parameters) were imputed by Last Observation Carry Forward strategy. On completion of each surgery , neostigmine 50 mcg/kg and glycopyrrolate 10 mcg/kg were given to antagonise neuromuscular blockade. Near-infrared spectroscopy (NIRS) cerebral oximetry allows continuous and non-invasive monitoring of regional cerebral oxygen saturation (rSO2). Cerebral oxygen saturation reflects the balance between cerebral oxygen supply and demand and it is affected by changes in blood oxygenation, CBF, haemoglobin (Hb) content, and cerebral metabolic rate of oxygen (CMRO2).

RESULT :

Forty patients, aged between 18-60 years, ASA grade I and II, scheduled to undergo FESS under general anaesthesia, were randomly divided into two groups. Patients in group D received dexmedetomidine maintenance infusion of 0.2- 0.5 mcg/kg/hr . Patients in group P received propofol infusion at the rate of 50-150 mcg/kg/min. All the data were analysed statistically and p-value <0.05 were considered statistically significant.

The duration of surgery was more in Group D. There were no significant differences in both the groups in SBP after the surgery had started but there is significant attenuation in SBP in Group D patients later intraoperatively. There was significant attenuation in DBP intraoperatively in both the groups. The decrease was more in the initial time points in case of Group P. Later, DBP is decreased more in Group D.

Table 1 Comparison of mean arterial pressure (mmHg) in the two groups during intra operative period

TIME POINT	GROUP P (MEDIAN I.Q.R)	GROUP D (MEDIAN I.Q.R)	p-VALUE
BASELINE	95.5	96	0.230
	91.5-101	93.75-102.25	
POST INTUBATION 5 MINUTES	86 80.5-94.25	91 86.5-99.5	0.048*
START OF SURGERY	87	89	0.051
	78-89.25	83.5-96	
10 MINUTE INTRAOPERATIVE	83.5 80.5-89	86 81.75-90	0.524
20 MINUTE INTRAOPERATIVE	83 78.75-89	86.5 81.75-89	0.103
30 MINUTE INTRAOPERATIVE	83.5 77.75-89.5	84 80.75-87	0.956
40 MINUTE INTRAOPERATIVE	82 76-88	85.5 80.75-90.25	0.269
50 MINUTE INTRAOPERATIVE	84 76.5-88	80.5 78-84	0.448
60 MINUTE INTRAOPERATIVE	82	82.5	0.448
	77.75-81.25	79-84.75	
70 MINUTE INTRAOPERATIVE	82.5 78.75-88	83.5 77.75-87	0.857
80 MINUTE INTRAOPERATIVE	83 77.5-88.25	80.5 78-83	0.148
90 MINUTE INTRAOPERATIVE	86.5 81-89.25	82 78.75-83	0.028*
100 MINUTE INTRAOPERATIVE	86.5 82.75-90	85 80.75-89	0.247
110 MINUTE INTRAOPERATIVE	87.5	84	0.071
	84-90	81-89	
120 MINUTE INTRAOPERATIVE	88 83.75-93	84.5 81-89.25	0.229
EXTUBATION	101	99.5	0.803
	97.75-105	96-104.25	
1 MINUTE AFTER EXTUBATION	101 95.25-104	98 93.75-104.25	0.967

5 MINUTES AFTER EXTUBATION	99 94.75-102.5	96 92-99.75	0.666

Student's unpaired t test was applied to determine any significant changes in mean arterial pressure at any time point. * denotes statistically significant changes in MAP when compared with baseline. Table 1 shows that MAP of Group D patients were lower as compared to Group P after about one hour after the surgery had started.

Table 2 Comparison of heart rate (bpm) in the two groups during intra operative period

TIME POINT	GROUP P (MEDIAN I.Q.R.)	GROUP D (MEDIAN I.Q.R.)	p-VALUE
BASELINE	80 78-85.5	78 67.25-98.75	0.875
POST INTUBATION 5 MINUTES	82 79-89	80 66-104.5	0.853
STARTOF SURGERY	80 71.75-85.5	78.5 64.25-96.75	0.862
10 MINUTE INTRAOPERATIVE	78.5 72-87	71.5 63.75-90	0.534
20 MINUTE INTRAOPERATIVE	76.5 70.75-89.25	72 63.75-87.75	0.464
30 MINUTE INTRAOPERATIVE	76 69.75-87.5	68.5 64-84.75	0.367
40 MINUTE INTRAOPERATIVE	72 68-81.25	69 60.75-80.75	0.475
50 MINUTE INTRAOPERATIVE	75 70-82	66.5 58-81.25	0.214
60 MINUTE INTRAOPERATIVE	76.5 70.5-82.75	64.5 58.75-78	0.058
70 MINUTE INTRAOPERATIVE	78 71.5-83.5	66.5 57.5-75.25	0.026*
80 MINUTE INTRAOPERATIVE	77.5 67.75-83.5	65.5 60-75.25	0.059
90 MINUTE INTRAOPERATIVE	78 71.5-83.5	69 64-78.25	0.125
100 MINUTE INTRAOPERATIVE	78.5 70.75-83.5	69.5 64-77.25	0.262
110 MINUTE INTRAOPERATIVE	79.5 71.5-83.5	70.5 66.25-82.5	0.213
120 MINUTE INTRAOPERATIVE	79.5 77.25-83.5	71.5 63.75-84	0.177
EXTUBATION	93.5 89.75-108	86.5 78.75-96.25	0.101
1 MINUTE AFTER EXTUBATION	90 85.5-112	81 73.25-87	0.050
5 MINUTES AFTER EXTUBATION	88 84-102	81.5 72-87	0.166

Student unpaired t-test was applied to determine any significant change in median heart rate at any point of time between groups. * denotes statistically significant changes in heart rate at the mentioned time points when compared with the baseline. In both the groups there is increase in HR following laryngoscopy and intubation and during extubation but this attenuation is much less in Group D. HR decreased more in Group D.

Table 3 : Comparison of Bleeding Score (BS) between Group P and D

TIME SCALE	GROUP P (MEDIAN I.Q.R.)	GROUP D (MEDIAN I.Q.R.)	p-VALUE
BS10min	1 1-1.25	1 1-2	0.284
BS20min	2 1-2	2 1-2	0.779
BS30min	2 1-2	2 1-2	0.332
BS40min	1 1-2	2 1-2	0.016*
BS50min	1 1-2	2 1.75-2	0.015*
BS60min	1 1-2	2 1-2	0.207
BS70min	1 1-2	1 1-2	0.423
BS80min	1 1-1.25	2 1-2	0.060
BS90min	1 1-2	1 1-2	0.541
BS100min	1.5 1-2	1 1-2	0.794
BS110min	1 1-2	1 1-2	0.992
BS120min	1 1-2	1 1-2	0.992

Comparison of median values done by applying Mann Whitney test showed higher BS in Groups D.

Table 4 Comparison of rso2 in between the groups at different points of time

TIME POINT	GROUP P (MEDIAN I.Q.R.)	GROUP D (MEDIAN I.Q.R.)	p-VALUE
BASELINE	68 65-69	65 62-67	0.007*
POST INTUBATION 5 MINUTES	55 52-56.5	53 52.75-56	0.787
STARTOF SURGERY	53 51.75-55.25	52 51-54	0.384
10 MINUTE INTRAOPERATIVE	52 51-54.25	51 50.75-52.25	0.267
20 MINUTE INTRAOPERATIVE	52 51-53	51 50-51.25	0.030*
30 MINUTE INTRAOPERATIVE	51 50-53	51 50-52	0.928
40 MINUTE INTRAOPERATIVE	51.5 49.75-52.25	51 49.75-52.25	0.667
50 MINUTE INTRAOPERATIVE	51.5 50-52.25	50.5 49-53	0.312
60 MINUTE INTRAOPERATIVE	52 50.75-53	50 48-50.25	0.001*
70 MINUTE INTRAOPERATIVE	53 51-53.5	50 49-51.25	0.000*
80 MINUTE INTRAOPERATIVE	53 52-54	50 49.5-52	0.003*
90 MINUTE INTRAOPERATIVE	53 52-55	51 50-52.25	0.023*
100 MINUTE INTRAOPERATIVE	53 52-55	51 50-53	0.034*
110 MINUTE INTRAOPERATIVE	53 52-55.25	51 50-53.25	0.023*
120 MINUTE INTRAOPERATIVE	53.5 52-55.25	52 51-53.25	0.051
EXTUBATION	59 58-60.25	57 55-58.25	0.005*
1 MINUTE AFTER EXTUBATION	64 62.5-65.5	61 56.75-63	0.006*
5 MINUTES AFTER EXTUBATION	68 65.75-69	63.5 59-65.25	0.000*

Statistically significant changes in rso2 are evident at the mentioned time points when compared with the baseline with lower values in Group D.

Table 5 Comparison of serum lactate level at the end of controlled hypotension between the two groups

GROUP	P	D	p-VALUE
LACTATE			0.039*
RANGE	2.02-5.1	2.9-5.6	
MEAN ±SD	3.94 ±0.977	4.53 ±0.705	

The Student's unpaired t-test revealed statistically significant difference between the groups (p-value 0.039), with more in Group D.

Table 6 Comparison of blood loss intraoperatively between the two groups

GROUP	P	D	p-VALUE
BLOOD LOSS (ml)			<0.001*
RANGE	50-400	250-1500	
MEAN ±SD	162 ±126.68	793 ±324.43	

Blood loss was more in Group D (p-value <0.001).

There was no significant statistical difference in recovery between the groups.

DISCUSSION :

Blood pressure usually increases following laryngoscopy, intubation and extubation of trachea, in light plane of anaesthesia, surgical stimuli, airway suctioning etc. This can cause excessive bleeding in the surgical field and worsen the operating condition for the surgeon. Coughing, straining or sudden head movement will lead to difficulty during endoscopy. In this study both dexmedetomidine and propofol were effective in reducing BP, HR, minimizing surgical site bleeding[4], improving quality of the surgical field, better visualization of the surgical field, and decreasing operative time without certain adverse effects. The average blood loss was less in Group P (162 ml) than in Group D (793 ml). Thus patients who received propofol, had less intraoperative blood loss and provided better surgical field visibility than patients who received dexmedetomidine. The duration of surgery was less in Group P (mean being 87 minutes) than in Group D (mean being 131.5 minutes). This might be attributable to less blood loss in propofol group. It was observed that intraoperative dexmedetomidine infusion decreases haemodynamic response to certain noxious stimuli like intubation ,extubation , skin incision and attenuated the haemodynamic response during emergence from anaesthesia. Cerebral oxygen saturation, however, was less in Group D than in Group P. The mean serum lactate level at the end of controlled hypotension was less in Group P (3.94 mmol/L) than in Group D (4.53 mmol/L). There have been certain adverse effects in these surgeries due to the two drug infusions like delayed recovery/reversal , prolonged sedation after extubation and bradycardia intraoperatively (less than 45 beats/min). Bradycardia was treated with intravenous atropine. No vasopressor support was required in any of the surgeries.

CONCLUSION :

From this study it may be concluded that both the drugs are effective in achieving controlled hypotension but dexmedetomidine produces better haemodynamics as compared to propofol and propofol reduces intraoperative bleeding more than dexmedetomidine, improves operative field visibility and increases surgeon's satisfaction in patients undergoing functional endoscopic sinus surgery.

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