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Comparison of hypotensive properties of dexmedetomedine versus nitroglycerine and their effectiveness to provide oligemic surgical field during Functional endoscopic sinus surgery : A randomized interventional study

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Abstract

Background: Induced hypotension is essential to provide better surgical field, to decrease blood loss and reduce the need for blood transfusion during surgery. Study was designed to compare the hypotensive properties of dexmedetomedine and nitroglycerine and to study their safety and effectiveness to provide oligemic surgical field during Functional endoscopic sinus surgery.

Material and Methods: 70 patients of ASA grade I and II scheduled for functional endoscopic sinus surgery were randomly assigned into 2 groups. Group A Patients received Inj.dexmedetomidine i.v. bolus 1µg/kg in 10ml of saline, over 10 minutes followed by an infusion of 1µg/kg/hr through infusion pump. Group B Patients received Inj.nitroglycerine 5 µg/kg/min through infusion pump.

Results : Both groups achieved the target mean arterial pressure(65-75 mmHg) with better hemodynamic stability with dexmedetomedine group (p value < 0.05). The quality of surgical field was comparable between both the groups. Emergence time, sedation score and time to first analgesic were significantly increased in dexmedetomedine group when compared to nitroglycerine group.

Conclusion: Dexmedetomidine provided better hemodynamic stability and comparable operative field visibility during FESS when compared to nitroglycerine. Both dexmedetomidine and nitroglycerine are safe agents for controlled hypotension and are effective in providing ideal surgical field during FESS.

Keywords: Dexmedetomidine, Onset, MAP.

Introduction

Controlled (deliberate/induced) hypotension is a technique where the arterial blood pressure is lowered in a deliberate but controllable manner to minimize surgical blood loss and enhance the operative field visibility.[1,2] The two main strategies for achieving hypotensive anaesthesia are (a) deep anaesthesia and heavy analgesia and (b) standard anaesthesia and administration of hypotensive drugs. By deepening the anaesthetic plane and using high doses of analgesics, such as opioids, the recovery time maybe prolonged. On the other hand, administering a hypotensive agent to a patient who is anaesthetized using a standard anaesthetic protocol may result in postoperative hypotension.[3]

Dexmedetomidine is highly selective (eight times more selective than clonidine),[4] specific and potent α2-adrenergic agonist having analgesic, sedative, antihypertensive, and anaesthetic sparing effects when used in the systemic route.[5] Prior administration of dexmedetomidine can also provide a hypotensive anesthesia and a better surgical field and finally an abbreviated operative duration.[6,7]

Nitroglycerine is a prototype of therapeutically active nitrates. Nitrates improve oxygen supply to the myocardium. Nitroglycerine has been medically used as a potent vasodilator to treat heart conditions such as angina and chronic heart failure. In patients with stable angina and those recovering from acute coronary syndromes and myocardial infarction are at a risk for coronary events and in these cases nitroglycerine may be required to treat acute symptoms of myocardial ischemia.[8]

With this background, this study was designed to compare the efficacy and safety of Dexmedetomidine versus Nitroglycerine as a hypotensive agent in FESS with attention on the quality of surgical field, emergence time, sedation score, VAS score, recovery profile and to evaluate the side effects, if any.

Material and methods

The study was conducted in the department of ENT, S.M.S. Medical College, Jaipur , With due permission from institutional ethics committee was obtained. Study design was hospital based randomized comparative interventional study. Sample size was calculated to be 34 subjects for each of two groups at an alpha error 0.05 and power 80% expecting minimum detectable difference in mean blood pressure in both groups to be 5±7.2 mmHg 5 min after intubation[12]. So, for study purpose, 35 cases were taken in each group. Sampling technique was **s**imple random technique through sealed envelope method.

After checking fasting status, informed written consent and PAC, intravenous access was secured. Inj. Ringer lactate infusion was started. Baseline haemodymanic parameters were recorded. Group A Patients received Inj.dexmedetomidine i.v. bolus 1µg/kg in 10ml of saline, over 10 minutes followed by an infusion of 1µg/kg/hr through infusion pump. Group B Patients received Inj.nitroglycerine 5 µg/kg/min through infusion pump. All the infusions were titrated to maintain a mean arterial blood pressure between 65-70 mmHg. Inj. Ranitidine 1mg/kg + Inj. Metoclopramide 0.1 mg/kg +Inj. Glycopyrrolate 0.004 mg/kg+ Inj. Midazolam 0.02 mg/kg + Inj. Fentanyl 2 µg/kg given in premedication.

After preoxygenation with 100% O_2, anaesthesia was induced with inj. thiopentone sodium 5 mg/kg intravenously slowly and intubation was facilitated with inj. succinylcholine 2mg/kg, then laryngoscopy and tracheal intubation were performed. Loading dose of inj. atracurium 0.5 mg/kg was given. Anaesthesia was

maintained with 40% O2+60% N2O and inj. atracurium 0.1 mg/kg and isoflurane 0.4 MAC. Intraoperative monitoring and vital parameters (HR, SBP, DBP, MAP, SPO_2) were recorded after every 10 minutes. Surgical site for bleeding and need of suctioning were checked after every 10 minutes and infusion of study drug was stopped 5 minutes before completion of surgery.

At end of surgery, patient was reversed with inj. neostigmine 0.05 mg/kg i.v. and inj. glycopyrrolate 0.01 mg/kg. Extubation was done when patient was fully awake. Hemodynamic parameters were recorded. Emergence time after surgery was recorded. VAS score was assessed every 15 minutes postoperatively. Inj. Diclofenac 75 mg i.v. was given as rescue analgesic on VAS score of 3 and the time to first analgesic request was noted. The post-operative sedation was assessed every 30 minutes upto 2 hours after surgery by using Ramsay Sedation Score. This was the end point of our study. Incidence of adverse effects like nausea, vomiting, shivering, dry mouth, bradycardia were recorded.

Results

There was no statistical significant difference in the demographic data between the 2 groups. The baseline hemodynamic parameters were also comparable with each other. Both the groups were comparable with regards to the hemodynamic parameters. (Table 1)

There was no statistically significant difference in mean heart rate between the two groups at baseline. There was significant difference in mean heart rate between the two groups after induction, after intubation and during the entire intra operative period. The mean heart rate was statistically significantly higher in group B as compared to group A (Table 2) . Both groups reached the desired MAP (65-70 mmHg) with intergroup significant differences after induction and one minute after intubation. In group A MAP was 67± 6.5, 67.2± 6.3, 65.9± 6.2, 66.4± 6.1, 69.8± 6.1, 70.7± 6.1, 70.0± 6.0, 69.9± 5.7, 70.8± 5.6 and 71.9± 5.7 mmHg after induction, 1 min after intubation, 5 min after intubation, 10 min, 20 min, 30 min, 40 min, 50mmin, 60 min and 70 min respectively. In group B MAP was 72.0± 6.7, 71.3± 6.9, 67.6± 6.2, 68.2± 6.4, 71.8± 6.0, 71.8± 6.2, 72.0± 6.3, 72.3± 6.8, 73.5± 7.4 and 75.9± 7.6 mmHg after induction, 1 min after intubation, 5 min after intubation, 10 min, 20 min, 30 min, 40 min, 50 min, 60 min and 70 min respectively. Throughout the intra operative period both groups provided hypotensive anaesthesia in a desirable manner (Table 3) .When both the groups were compared among themselves, the difference in mean change in heart rate and mean arterial pressure was found to be statistically significant. The quality of surgical field was comparable between the two groups. There was no statistically significant difference between the two groups in terms of mean estimated blood loss and average category scale.

Time for first rescue analgesia was significantly higher in dexmedetomidine (59.83 ± 6.92 minutes) than nitroglycerine group (30.71 ± 3.27 minutes) [Table 4] . Emergence time was significantly prolonged in dexmedetomidine group (6.8 ± 0.78 minutes) than nitroglycerine group (4.59 ± 0.55 minutes)[Table 5] . We found that sedation scores were significantly higher in dexmedetomidine group (3.60± 0.50, 3.43± 0.50, 2.94± 0.54, 2.43± 0.50, 2.0± 0.49) than nitroglycerine group (2.54± 0.56, 1.80± 0.47, 1.49± 0.51, 1.29± 0.46, 1.20±0.41) at 0, 30, 60, 90and 120 minutes after the surgery. Sedation was more pronounced and lasted for a longer period in dexmedetomidine group as compared to nitroglycerine group.(Table 6)

Table 1 : Demographic data

Variable	GROUP A MEAN±SD	GROUP B MEAN±SD	P VALUE
Age (years)	34.51 ± 7.23	33.74 ± 3.60	0.574(N.S.)
Gender(M/F)	23/12	21/14	0.805(N.S)
Weight (kg)	58.03 ± 3.93	58.53± 2.19	0.513 (N.S.)
ASA grade(1/2)	25/10	23/12	0.377(N.S)
Duration of surgery(min)	71.34 ± 6.19	69.66 ± 4.51	0.197 (N.S.)

Table 2 : Mean Heart rate

Time point	Group A	Intra group p value	Group B	Intra group p value	Inter group P value	Intergroup Significance
Baseline	75.97 ± 7.5	-	77.7 ± 6.6	-	0.369	N.S.
After loading	66.37 ± 3.1	<0.001*		-	-	
After induction	71.46 ± 14.8	0.113	108.1 ± 13.2	<0.001*	<0.001*	S
1 minute	76.1 ± 15.28	0.968	113.5 ± 13.1	<0.001*	<0.001*	S
5 minutes	72.77 ± 13.66	0.229	101.3 ± 10.7	<0.001*	<0.001*	S
10 minutes	70.83 ± 10.8	0.023	92.2 ± 8.50	<0.001*	<0.001*	S
20 minutes	72.6 ± 10.2	0.121	90.3 ± 8.1	<0.001*	<0.001*	S
30 minutes	71.66 ± 9.16	0.034*	88.4 ± 7.45	<0.001*	<0.001*	S
40 minutes	71.8 ± 8.45	0.032*	86.6 ± 6.8	<0.001*	<0.001*	S
50 minutes	72.8 ± 9.1	0.117	85.4 ± 7.25	0.0002*	<0.001*	S
60 minutes	70.6 ± 8.3	0.006	83.9 ± 7.3	0.002*	<0.001*	S
70 minutes	72.0 ± 7.07	0.026*	82.6 ± 7.7	0.018	<0.001*	S

*p value is significant

Table 3 : Mean arterial pressure

Time point	Group A	Intra group p value	Group B	Intra group p value	Inter group P value	Intergroup Significance
Baseline	95.1 ± 6.9	-	94.3 ± 5.7	-	0.593	N.S.
After loading	68.2 ± 7	<0.001*	-	-	-	-
After induction	67.9± 6.5	<0.001*	72.0 ± 6.7	<0.001*	0.011	S
1 minute	67.2 ± 6.3	<0.001*	71.3 ± 6.9	<0.001*	0.012	S
5 minutes	65.9 ± 6.2	<0.001*	67.6 ± 6.2	<0.001*	0.266	N.S.
10 minutes	66.4 ± 6.1	<0.001*	68.2 ± 6.4	<0.001*	0.238	N.S.
20 minutes	69.8 ± 6.1	<0.001*	71.8 ± 6.0	<0.001*	0.168	N.S.
30 minutes	70.7 ± 6.1	<0.001*	71.8 ± 6.2	<0.001*	0.443	N.S.
40 minutes	70.0 ± 6.0	<0.001*	72.0± 6.3	<0.001*	0.185	N.S.
50 minutes	69.9 ± 5.7	<0.001*	72.3 ± 6.8	<0.001*	0.117	N.S.
60 minutes	70.8 ± 5.6	<0.001*	73.5 ± 7.4	<0.001*	0.097	N.S.
70 minutes	71.9 ± 5.7	<0.001*	75.9 ± 7.6	<0.001*	0.015	N.S.

*p value is significant

Table 4 : Time to first rescue analgesic request

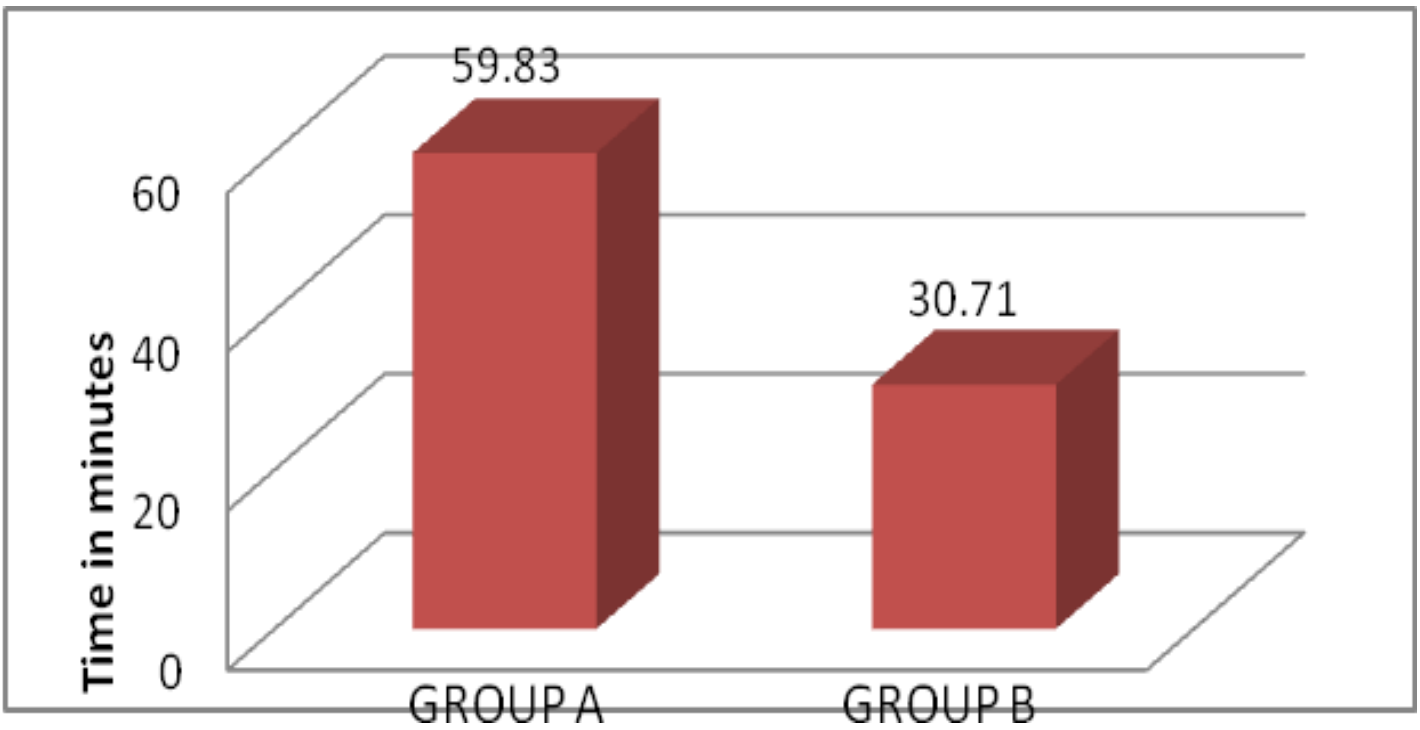


Table 5 : Mean emergence time

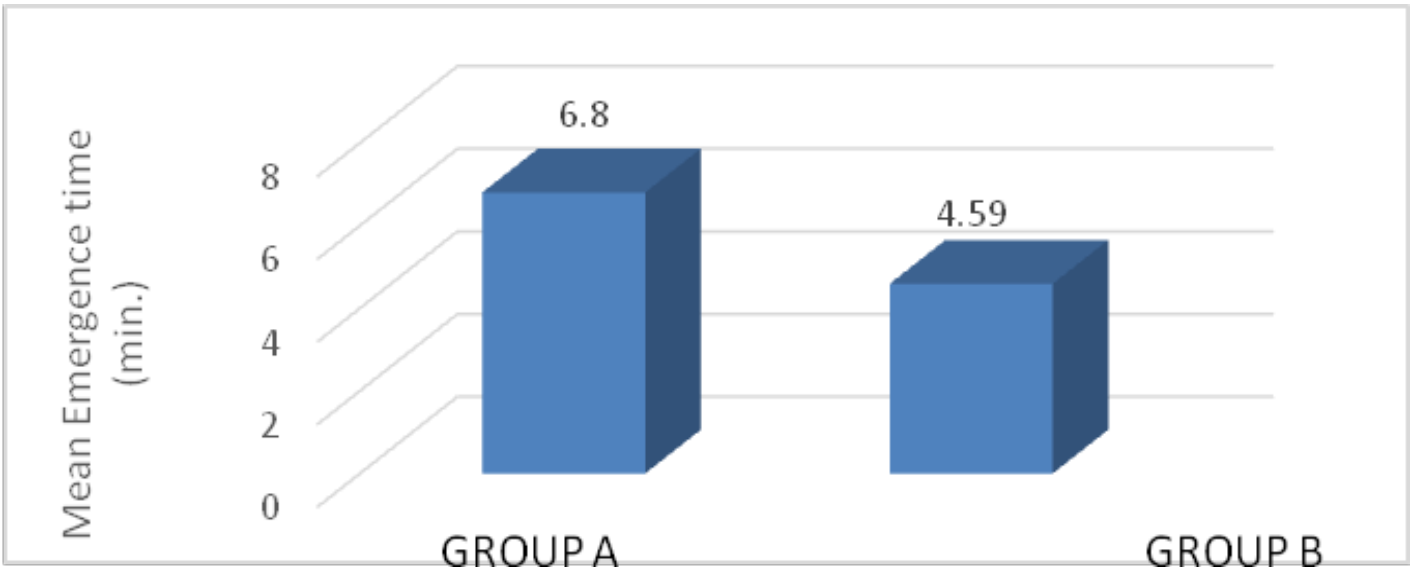


Table 6 : sedation score

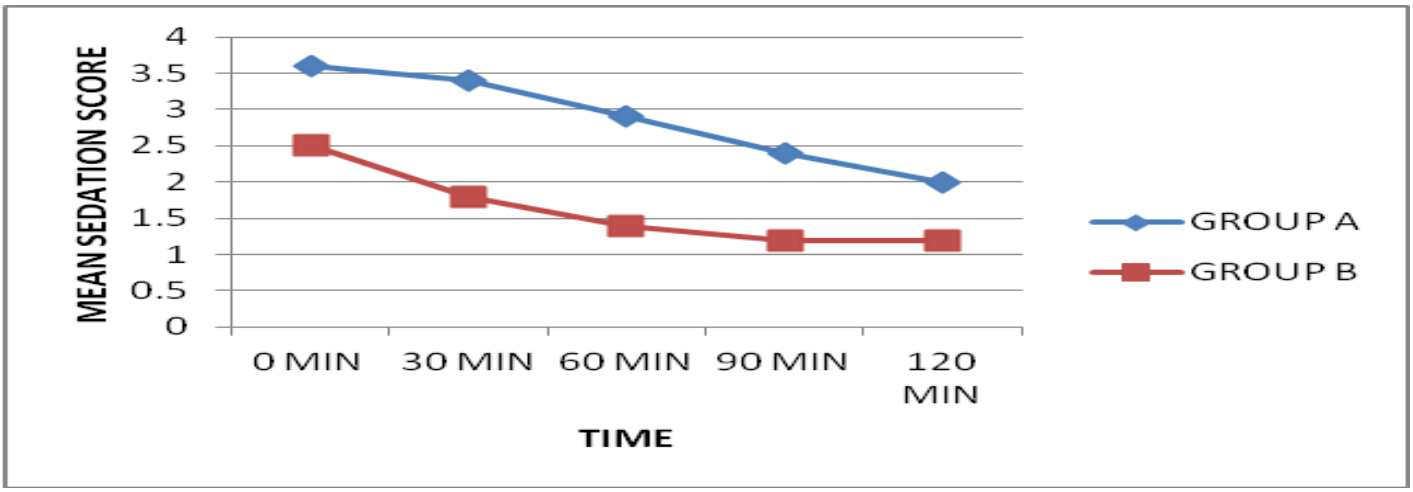
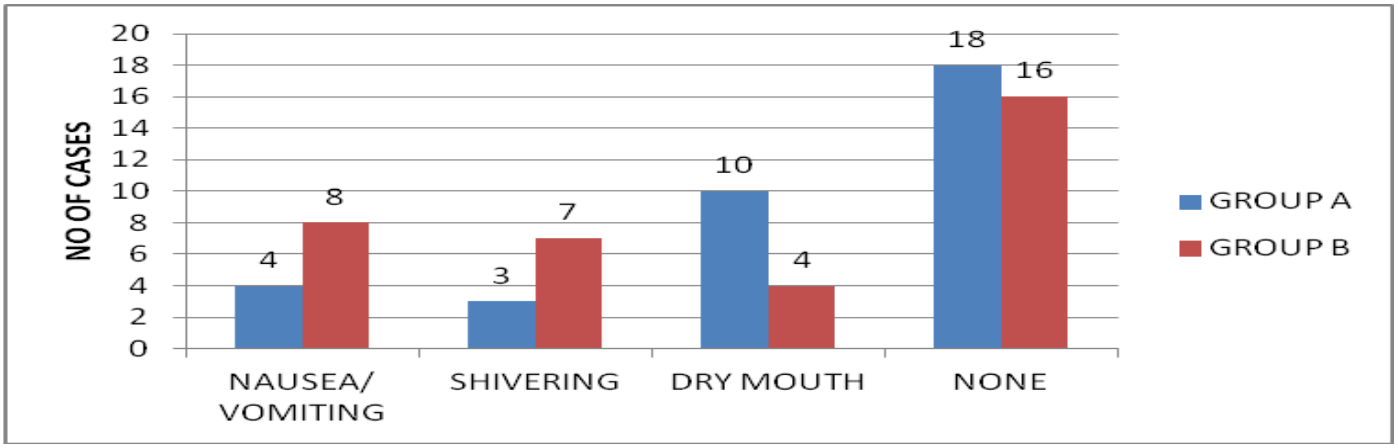


Table 7 : Post operative complications



Discussion

A lot of efforts have been done to optimize the surgical conditions for FESS. An important technique to reduce bleeding during the surgery is controlled reduction in blood pressure to such levels so that bleeding is minimal, but at the same time perfusion to the vital organs is well-maintained. This is the underlying concept for controlled hypotensive anesthesia.[9] In our study, the mean heart rate decreased in both the groups after loading of study drugs and was statistically significant throughout the surgery. The fall in heart rate in dexmedetomidine group is attributed to its central sympatholytic action. The mean heart rate was statistically significantly higher in group B. This observation was similar to those observed by Praveen D V et al,[10] and Patel DD et al, [11].

MAP was comparable with each other at baseline. The p value was significant after induction and 1 minute after intubation. It was statistically significantly higher (p value <0.05) in group B as compared to group A after stoppage of drug. This observation was similar to Bajwa et al[12] and also in Vineela Ch et al[13].

Mean emergence time in group A was 6.8 ± 0.78 minutes and in group B was 4.59 ± 0.55 minutes.There was statistically significant difference in mean emergence time between the study groups with p value <0.001. The result of this study is comparable with that of Praveen DV et al[10] and resemblance is also seen with Khalifa O and Awad O,[14] . In our study, post operative sedation score was assessed using Ramsay sedation score. We found that sedation scores were significantly higher in dexmedetomidine group than nitroglycerine group at 0, 30, 60, 90and 120 minutes after the surgery. Bajwa et al[12],and Cr patel et al.[15] had similar observations.

Conclusion

Dexmedetomidine provided better hemodynamic stability and comparable operative field visibility during FESS when compared to nitroglycerine. Both dexmedetomidine and nitroglycerine are safe agents for controlled hypotension and are effective in providing ideal surgical field during FESS. Dexmedetomidine provides an additional benefit of reducing the analgesic requirements and providing postoperative sedation.

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