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EFFICACY OF INTRAVENOUS DEXMEDETOMIDINE VERSUS MAGNESIUM SULPHATE FOR CONTROLLED HYPOTENSION IN FUNCTIONAL ENDOSCOPIC SINUS SURGERY: A RANDOMIZED DOUBLE-BLIND STUDY.

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ABSTRACT **Background & Aim:** Controlled hypotension is an anaesthestic technique in which there is deliberate reduction of systemic blood pressure during general anaesthesia. The aim of our study was to compare the efficacy of intravenous dexmedetomidine and magnesium sulphate for controlled hypotension in functional endoscopic sinus surgery. **Method:** A randomized, prospective, and double-blind study was carried out, which included 92 patients of either sex of ASA grade I & II who underwent elective FESS. Patients were randomly assigned to two groups: Group D, patients received dexmedetomidine 1 µg/kg infused over 10 minutes before induction of anesthesia, followed by continuous infusion of 0.4-0.8µg/kg/hr. Group M, Patients received intravenous MgSO4 40 mg/kg infused over 10 minutes before induction of anesthesia, followed by continuous infusion of 10 to 15 mg/Kg/hr. **Results:** There was no significant difference in MAP and HR between both the groups. Average category scale was lower ($p<0.001$) and surgeon's satisfaction score was higher ($p<0.001$) in group D when its compared group M. Blood loss was less in group D than group M. Incidence of Bradycardia & Hypotension in group D was 15.22% & 36.96% while in group M was 2.17% & 13.04%. The difference in incidence of Bradycardia & Hypotension in both the groups was statistically significant. **Conclusion:** Both dexmedetomidine and MgSO4 provide satisfactory controlled hypotension in FESS. However, dexmedetomidine is found to be more effective in terms of good surgical field, less blood loss, better surgeon satisfaction score.

KEYWORDS : controlled Hypotension, Dexmedetomidine, MgSO4, Functional Endoscopic sinus surgery.

INTRODUCTION

Hypotensive anaesthesia has been used to control blood pressure thereby reducing blood flow to surgical area leading to reduced blood loss and improved visualization of the surgical field.

Functional endoscopic sinus surgery (FESS) has been widely considered as the surgery of choice for chronic sinusitis. The confined space and rich vascularity leading to continuous bleeding are significant problems in surgery. Various methods have been used to improve the surgical field, such as patient positioning in reverse Trendelenburg position, decongestion of the nose, infiltration of the lateral nasal wall with lidocaine and epinephrine, or using hypotensive anaesthesia technique.

Controlled hypotension or deliberate hypotension is a technique where reduction of systolic blood pressure to 80 to 90 mm hg, or reduction of mean arterial pressure (MAP) to 60-70 mm Hg or a 30% reduction from baseline MAP. Appropriate patient evaluation and selection, proper positioning, and monitoring are essential before employing controlled hypotension. The deliberate or induced hypotension by using various drugs could be due to a reduction of cardiac output or blood pressure or a combination of both. There are various pharmacological agents that produce deliberate hypotension such as vasodilators (sodium nitroprusside, nicardipine & nitroglycerine), adrenergic beta-blockers (propranolol, esmolol, labetalol, metoprolol), magnesium sulphate, inhalational anaesthetic agents (isoflurane, sevoflurane, desflurane), intravenous alpha 2 agonists like dexmedetomidine, clonidine, and short-acting opioids like fentanyl or remifentanil. TIVA (Total Intravenous Anaesthesia) with propofol is also gaining popularity to facilitate controlled hypotension.

Dexmedetomidine is a highly selective and potent α-2 adrenoreceptor agonist, with unique properties, like giving sedation and analgesia without respiratory depression. Alpha 2 receptor agonists act on G-protein coupled alpha 2 receptors (3 subtypes – α2A, α2B, α2C) and produce different pharmacological effects. These receptor subtypes are found in central, peripheral, and autonomic nervous systems, vital organs, and blood vessels. It has a sympatholytic effect due to reduction in norepinephrine concentration, which in turn decreases the heart rate and blood pressure. The presynaptic site of action of α-2 receptor modulates the release of norepinephrine through a negative feedback mechanism. Magnesium sulphate stabilizes the cell membrane and intracytoplasmic organelles by mediating the activation of Na^{+}-k^{+} ATPase & Ca^{++} ATPase enzymes, which play a role in transmembrane ion exchange during the depolarization & repolarization phases. In addition, magnesium inhibits the release of norepinephrine by blocking the N-type Ca^{++} channels at nerve endings and thus decreasing blood pressure. Magnesium is a N-methyl-D-aspartate (NMDA) receptor antagonist reducing the need for analgesics and sedatives, and competes with calcium in the neural canals, thereby inhibiting the release of acetylcholine (ACh) at the motor end plate. It also acts as a vasodilator by increasing prostacyclin synthesis and by inhibiting the angiotensin-converting enzyme (ACE), and being widely used in patients with preeclampsia and pheochromocytoma.

Dexmedetomidine and magnesium sulphate have been used in anaesthetic practice to achieve controlled hypotension. Both the drugs have been compared with other hypotensive agents for controlled hypotension but there are limited studies available comparing these two drugs. Hence this study was undertaken to evaluate the safety and efficacy of dexmedetomidine as a hypotensive agent in comparison to magnesium sulphate in FESS with respect to the quality of the surgical field, amount of blood loss, surgeon's satisfaction, side effects, and complications in adult patients.

MATERIALS AND METHOD

Materials and Method

After approval of Institutional Scientific & Ethics Committee and Clinical Trials Registry of India CTRI/2022/05/042615 registration, the study was conducted as per consort guidelines and followed ethical guidelines of the Declaration of Helsinki. This was a prospective, randomized double-blind study. 92 patients aged 18-60 years belonging to ASA I-II, and undergoing functional endoscopic sinus surgery, Weight 55-85kg, Height 135-180cm were included in the study. Any patient refusing to give consent, Hypersensitivity to study drugs, Patients with recurrent sinus surgery, Anemia (hemoglobin concentration < 8gm/dl), Patients with coagulopathies, Systemic hypertension, Sinus bradycardia, Cardiovascular diseases, Renal diseases, Central nervous system diseases, and Hepatic diseases, novel corona virus positive patients were excluded from the study.

PAC was done a day before surgery. Written & informed consent was

taken. Patients were kept nil per oral for 6 hours prior to the surgery. Patient's identification, consent form, diagnosis was rechecked and confirmed on the day of surgery. On arrival at the operation theatre, the patient was positioned in supine position. Routine multipara monitors were attached & baseline heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2) & electrocardiogram (ECG) were recorded. In the operating room, two intravenous cannulas (18 G cannula) were inserted, one for infusion of dexmedetomidine or magnesium sulphate and the other for the administration of fluids and other drugs.

All the selected patients were randomized into two groups D & M by sequentially numbered opaque sealed envelope (SNOSE) technique. The envelope was opened by the anaesthesiologist (primary investigator), before the administration of GA the drugs for bolus & infusions were prepared by him/her according to the group allotted to the patient. Another anaesthesiologist (secondary investigator) performing the GA was unaware of the constituent of the drug and infusion and the allotted group. The secondary investigator recorded the data throughout the perioperative period.

In group D, patients received a loading dose of 1µg/kg dexmedetomidine diluted in 100 ml 0.9% normal saline infused over 10 minutes before induction of anaesthesia, followed by continuous infusion of 0.4-0.8µg/kg/hr. In group M, patients received 40mg/kg of magnesium sulphate diluted in 100ml 0.9% normal saline infused over 10 minutes before induction of anesthesia intravenously which was followed by continuous infusion of 10 to 15 mg/kg/hr.

All patients were premedicated with intravenous (i.v) midazolam (0.02mg/kg), ondansetron (0.1mg/kg), glycopyrrolate (0.1mg/kg), and fentanyl (1µg/kg). After pre-oxygenation with 100% oxygen, patients were induced with 2 mg/kg of propofol in titrated doses followed by atracurium 0.6mg/kg to facilitate endotracheal intubation. Trachea was intubated with the appropriate size of a cuffed endotracheal tube. The oropharynx was packed with a saline-soaked throat pack. Anaesthesia was maintained with O_2/N_2O (50:50), sevoflurane (1-3%), and fentanyl. Intermittent boluses of inj.atracurium was used for muscle relaxation. All patients were given a 15° reverse Trendelenburg position to improve venous drainage.

The mean arterial pressure (MAP) was maintained between 60-70mm Hg throughout the surgery. The time needed to reach the target mean arterial pressure with the infusion of the study drug was noted. Infusions were first started at minimum doses for both drugs (0.2-0.4 µg/kg/hr and 10-12 mg/kg/hr for dexmedetomidine and magnesium sulphate respectively. If the mean arterial pressure was >70 mm Hg, the infusion of the study drug was gradually increased to maximum doses (0.4-0.7 µg/kg/hr and 12-15 mg/kg/hr for dexmedetomidine and magnesium sulphate, respectively). The infusion rate for both drugs was adjusted according to the mean arterial pressure readings throughout the surgery. If mean arterial pressure was not achieved in the target range even after the maximum infusion rate, the concentration of sevoflurane was increased.

MAP< 60 mm Hg was taken as hypotension. MAP< 60 mm Hg was managed with rapid i.v fluids (250-500 ml) and i.v mephentermine 5-10 mg, and the rate of infusion and sevoflurane dial concentration lowered immediately. If there was sinus bradycardia i.e., HR<50 beats/min, it was treated with atropine (0.02 mg/kg) i.v.

Vital parameters namely, blood pressure (systolic blood pressure, diastolic blood pressure, and mean arterial pressure), pulse rate, oxygen saturation, and $EtCO_2$ were monitored and measured at 5 min intervals from the time of intervention till shifting to the ward. All the infusions and sevoflurane were stopped 5 mins before the end of surgery. All patients were reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg i.v at the end of surgery. Extubation was done when patients started breathing spontaneously and were able to obey commands. Oropharyngeal suctioning was done before extubation. After extubation, 100% oxygen was given via facemask during the recovery period, and then patient was shifted to the recovery room for further observation.

The surgeons graded the surgical field at the end of the procedure using an average category scale (Boezaart scale), a clear surgical field without requirement of suctioning was defined as a 'bloodless' field.

Average category scale for assessment of intraoperative surgical field (measured at 5, 10, 15, 30, 45, 60, 75, & 90 mins)

- 0-No bleeding.
- 1-Slight bleeding; no suctioning of blood required.
- 2-Slight bleeding; occasional suctioning required; surgical field not threatened
- 3- Slight bleeding; frequent suctioning required; bleeding threatened the surgical field a few seconds after suction was removed.
- 4-Moderate bleeding; frequent suctioning required; bleeding threatened the surgical field immediately after suction was removed
- 5-Severe bleeding; constant suctioning required; bleeding appeared faster than could be removed by suction; surgical field severely threatened and surgery notpossible.

Blood loss was estimated by measuring the volume in the suction bottle and the number of swabs soaked in blood accounting for any saline flush used during the procedure.

Surgeon satisfaction score was assessed using 4 point scale by the surgeon who performed the surgery who was blinded regarding drugs used

1. Poor
2. Moderate
3. Good
4. Excellent

Average category scale and surgeon satisfaction score were noted. Aldrete's recovery score (time to reach Aldrete score ≥ 9) were measured in the recovery room.

Sedation was evaluated using Ramsay sedation score (measured at 5, 30, 60 mins after tracheal extubation)

Any adverse events (e.g., Hypotension, Bradycardia, Fall in SpO_2, Sedation, Dryness of mouth, Shivering, Nausea and vomiting, Delayed recovery were observed and recorded in post operative ward.) Data was entered in Microsoft Excel & analyzed using SPSS (Statistical Package for Social Sciences), version 25. And expressed as mean & standard deviation. Student unpaired t test was used to compare the mean values of different parameters. p value<0.05 was considered as statistically significant.

RESULTS

Table-1 Demographic profile

	Group D (n=46)	Group M (n=46)	p value
	(mean±SD)		
Age	33.39±11.49	36.59±13.66	0.21
Sex (M:F)	32:14	30:16	0.65
Weight (kg)	56.15±8.77	58.13±13.25	0.32
Height (cm)	158.89±7.54	158.97±7.07	0.95
ASA physical status Grade I : Grade II	33:13	26:20	0.15

TABLE- 2 Average category score

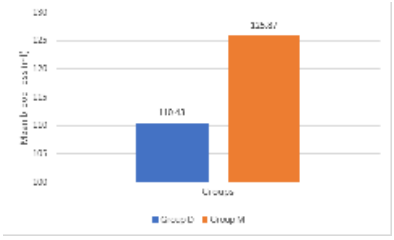
Average category score	Grade I			Grade II			Grade III		
	Group D n (%)	Group M n (%)	P value	Group D n (%)	Group M n (%)	P value	Group D n (%)	Group M n (%)	P value
5 mins	41(89.13%)	38(82.61%)	0.63	5(10.87%)	8(17.39%)	0.23	0	0	-
10 mins	18(39.13%)	13(28.26%)	0.20	28(60.87%)	33(71.74%)	0.36	0	0	-
15 mins	4(8.7%)	4(8.7%)	1	41(89.13%)	37(80.43%)	0.52	1(2.17%)	5(10.87%)	0.02
30 mins	1(2.33%)	0(0%)	0.15	35(81.4%)	29(72.5%)	0.28	7(16.28%)	11(27.5%)	0.18
45 mins	7(17.07%)	3(8.82%)	0.07	32(78.05%)	20(58.82%)	0.018	2(4.88%)	11(32.35%)	0.00042
60 mins	10(40%)	9(42.86%)	0.74	13(52%)	7(33.33%)	0.057	2(8%)	5(23.81%)	0.10

75 mins	1(12.5 %)	1(20%)	1	6(75%)	3(60%)	0.15	1(12.5%)	1(20 %)	1
90 mins	0(0%)	0(0%)	-	1(100 %)	2(100 %)	0.41	0	0	-

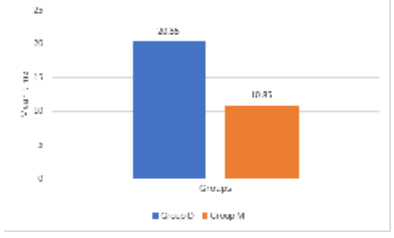
Table-3 Comparison of surgeon's satisfaction score

	Group D		Group M		P value
Surgeon's satisfaction score	N	%	N	%	
Poor (1)	0	0	0	0	-
Moderate (2)	5	10.87	31	67.39	<0.001 HS
Good (3)	33	71.74	15	32.61	<0.001 HS
Very good (4)	8	17.39	0	0	0.003 HS
Total	46	100	46	100	

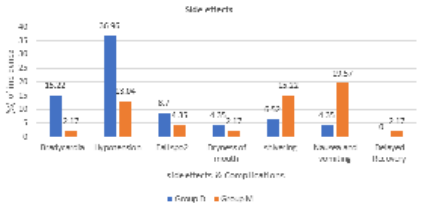
Graph- 1 Comparison of mean amount of blood loss



Graph-2
Mean Time to reach Aldrete score >9



Graph-3 Side effects & Complications



Demographic variables like age, sex, Weight, Height and ASA physical status were statistically comparable between the two groups (table-1).

MAP was achieved within the desired range in both groups. There was no significant difference between the two groups in terms of the mean baseline HR and MAP.

Differences in Mean Heart rate during 15,20,25 minutes were statistically significant, during post-induction, 5 minutes, 10 minutes, 30 minutes, and 45 minutes were statistically not significant. Differences in mean arterial blood pressure during 10, 15, 20, and 25 minutes were statistically significant, during post-induction, 5, 30, 45, 50, 55, 60, 65, 70, 75, 80, 85, and 90 minutes were not statistically significant.

Average Category Score was evaluated at 15 min and was observed to be 2.17% (ACS-3) in group D and 10.87% (ACS-3) in group M (p=0.02), 8.6% (ACS- 3) in group D and 2.15% in group M (ACS-3) (p=0.010) at 30 mins, and 4.8% (ACS-3) in group D and 3.35% (ACS-3) in group M (p=0.004) at 45 mins showing that Average Category Score was found to be statistically significant in group D as compared to group M (table-2).

Mean amount of blood loss was 110.43±37.77 ml in group D, while in group M, it was 125.87±30.08 ml. Difference in amount of blood loss were statistically significant among both the groups (p =0.033) (graph-1). The difference in surgeon satisfaction score among both the groups was statistically significant (p < 0.001) (table-3).

Mean time to reach aldrete score >9 was 20.35±3.9 mins in group D, while in group M, it was 10.85±2.86 mins. mean time to reach aldrete score >9 were statistiscally significant between group D & group M (p<0.001) (graph-2).

Incidence of Bradycardia & Hypotension in group D was 15.22% & 36.96% while in Group M was 2.17% & 13.04%, respectively which was statistically significant.

The difference in incidence of Bradycardia & Hypotension in both groups were statistically significant. (p- 0.026) (p-0.008). Incidence of fall SpO_2, dryness of mouth, shivering, nausea and vomiting, & delayed recovery in group D was 8.7%, 4.35%, 6.52%, 4.35%, 0% while in Group M was 4.35%, 2.17%, 15.22%, 19.57%, 2.17%. The difference in incidence of Fall in SpO_2, dryness of mouth, shivering, & delayed recovery were not statistically significant (p>0.05). But nausea & vomiting was statistically significant (graph-3).

DISCUSSION

A lot of efforts have been done to optimize the surgical conditions for FESS. Controlled hypotension has been widely advocated to control bleeding during FESS to improve the quality of surgical field. In our prospective randomized study of dexmedetomidine or $MgSO_4$ in combination with sevoflurane we planned to provide this optimal surgical field. Both drugs were effective in achieving MAP of 60 to 70 mmHg and lowering the heart rate ensured good surgical condition and providing dry surgical field during FESS.

The mean HR in group D & group M was comparable at baseline. Differences in HR during 15,20,25 minutes were statistically significant. Differences in heart rate during post-induction, 5 minutes, 10 minutes, 30 minutes, and 45 minutes were statistically not significant.

Mean arterial blood pressure in group D & group M was comparable at baseline. Differences in mean arterial blood pressure during 10, 15, 20, and 25 minutes were statistically significant. Differences in mean arterial blood pressure during post-induction, 5, 30, 45, 50, 55, 60, 65, 70, 75, 80, 85, and 90 minutes were not statistically significant.

Bayram A et al[3] investigated the effect of single dose of dexmedetomidine 0.5mcg/kg administration 10 min before induction of anesthesia and reported significant reduction in MAP and HR. Surgical site visibility was evaluated by the surgeon and communicated to the observer by accessing the 6 point scale of Average Category Score. In our study, the Average Category Score was evaluated at 15 min and was observed to be 2.17% (ACS-3) in group D and 10.87 % (ACS-3) in group M (p=0.02), 8.6% (ACS- 3) in group D and 2.15% in group M (ACS-3) (p=0.010) at 30 mins, and 4.8% (ACS-3) in group D and 3.35% (ACS-3) in group M (p=0.004) at 45 mins showing that Average Category Score was found to be statistically significant in group D as compared to group M. Chhabra A et al[6]. Observed that the maximum number of patients in group dexmedetomidine had a bleeding score of 2 or less (n=26) as compared with Group $MgSO_4$ where most of the patients had a bleeding score >2 (n=32) (p=0.85). Their results are similar to our study as we also used dexmedetomidine and $MgSO_4$ with the same drug dosages and timing of administration. Though Mean amount of blood loss was 110.43±37.77 ml in group D, while in group M, it was 125.87±30.08 ml. The difference in the amount of blood loss was statistically significant among both groups (p value=0.033). Group D had lower blood loss when compared with group M. Teki S et al[17] compared dexmedetomidine with esmolol and found that the average blood loss in group dexmedetomidine was 104.15ml and 113.24ml in the esmolol group, which was significantly low in dexmedetomidine group like our study. The difference in surgeon's satisfaction score among both groups was statistically significant. (p-value 0.001). Group D had a higher surgeon satisfaction score than group M. Chhabra A et al[6]. compared dexmedetomidine with $MgSO_4$ and found that the surgeon's satisfaction score in the dexmedetomidine group was better than $MgSO_4$ (p<0.001). Their results are similar to our study because both the average category score and blood loss were lesser in group D due to

same dose of dexmedetomidine and time of administration in our study also.The mean time to reach modified Aldrete score >9 was 20.35±3.9 mins in group D, while in group M, it was 10.85±2.86 mins. mean time to reach Aldrete score >9 was statistically significant in both Group D & Group M ($p<0.001$).**Bayram A et al[3].** compared dexmedetomidine with $MgSO_4$ and found that the mean duration of reaching an Aldrete score ≥9 was significantly higher in Group dexmedetomidine ($p=0.01$). The incidence of Bradycardia & Hypotension in group D was 15.22% & 36.96% while in group M was 2.17% & 13.04%. The difference in the incidence of Bradycardia & Hypotension in both groups was statistically significant. (p- 0.026, p-0.008). The differences in the modified Ramsay sedation scale among the 2 groups were statistically significant. RSS was significantly higher and patients were more sedated in group dexmedetomidine at 5, 15, and 60 min ($p<0.001$). Incidence of Fall SPO_2, dryness of mouth, shivering, Nausea, vomiting, & Delayed recovery in group D was 8.7%, 4.35%, 6.52%, 4.35%, 0% while in group M was 4.35%, 2.17%, 15.22%, 19.57%, 2.17%. The difference in the incidence of Fall SPO_2, dryness of mouth, shivering, Nausea, vomiting & Delayed recovery was not statistically significant. **Bayram A et al**[3] observed side effects there was no significant difference between the two groups in terms of bradycardia in group D (13.3%) group M (3.3%), hypotension group D (13.3%) group M (6.6%), vomiting group D (3.3%) group M (13.3%), shivering group D (3.3%) group M (10%). The results were comparable to our study this could be due to same dose of dexmedetomidine & magnesium sulphate used and time of administration.

LIMITATIONS

Though $MgSO_4$ is known to cause potentiation of the muscle relaxant and delayed recovery, we did not use peripheral nerve stimulation to monitor neuromuscular block and Bispectral index to monitor depth of anaesthesia in our study as our goal was to achieve controlled hypotension which provides optimum surgical field conditions Post operative non-measurement of serum magnesium sulfate and calcium level.

We did not use a control group because it would have been unethical not to try to control bleeding in FESS where surgical field visibility may be compromised due to bleeding.

Invasive monitoring of blood pressure can also be done in hypotensive anaesthesia, Which we did not use but recent studies concluded that it does not aid in achieving lower target blood pressure.

CONCLUSION

In our study we concluded that both dexmedetomidine and MgS04 provide satisfactory controlled hypotension in FESS. However, dexmedetomidine is found to be more effective in terms of good surgical field, less blood loss, better surgeon satisfaction score, with minimal sedation.

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