A Study on Comparison between Dexmedetomidine and Magnesium Sulphate in Controlled Hypotension during Functional Endoscopic Sinus Surgery under General Anaesthesia

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ABSTRACT

Introduction: Induced hypotension to minimize bleeding during functional endoscopic sinus surgery (FESS) is of vital importance to the surgeon and anesthetist to decrease the risk of complications as well as procedural failure. The aim and objective of the study was to compare the efficacy of Dexmedetomidine and Magnesium Sulphate for controlled hypotension during functional endoscopic sinus surgeries.

Material and Methods: Sixty-two patients were studied, randomized into two groups of 31 each. Patients were allocated into two groups: Group A (n= 31): Patients receiving Dexmedetomidine, Group B (n= 31): Patients receiving Magnesium Sulphate.

Results: Average Category Scores were better with Dexmedetomidine than Magnesium Sulphate. Hemodynamic parameters during intraoperative and postoperative period were better with Dexmedetomidine than Magnesium Sulphate. Emergence time and recovery was little prolonged in dexmedetomidine group. Post-operative analgesic duration and analgesic request was similar and comparable in both the groups.

Conclusion: Dexmedetomidine is effective in providing induced hypotension during Functional Endoscopic Sinus Surgery than Magnesium Sulphate.

Keywords: Controlled Hypotension, Dexmedetomidine, Functional Endoscopic Sinus Surgery, Magnesium Sulfate

INTRODUCTION

Controlled hypotension or induced hypotension is a technique to reduce the blood loss and the necessity of blood transfusion during surgery by improving the visibility of the surgical site and decreasing the arterial blood pressure until hypotension is reached.[1] Functional Endoscopic Sinus Surgery (FESS) is the primary surgical treatment for chronic rhinosinusitis. Visibility of surgical site is diminished by intraoperative bleeding leading to increased rate of complications. Therefore, the important concern for anaesthesiologist here is to improve the visibility of the surgical site by reducing bleeding during functional endoscopic sinus surgeries.[2] An ideal agent for inducing controlled hypotension cannot be asserted. The ideal agent used for induced or controlled hypotension must have certain properties and characteristic features are ease of administration, shorter onset of time, rapid elimination from the body with negligible toxic metabolites, negligible impact on vital organs, predictable and dose-dependent effects.[1,3] Intraoperative bleeding during functional endoscopic sinus surgery can be controlled by various methods such as packing adrenalin soaked gauze into the nasal mucosa, reverse Trendelenburg position during surgery and hypotensive anaesthesia.[4] Drugs such as beta-blockers, arterial and venous dilators, calcium channel blockers, alpha-1-agonist and anesthetic agents like propofol, opioids, autonomic ganglionic blockers and inhalational agents are being used to achieve induced hypotension.[1] Functional Endoscopic Sinus Surgeries is usually done under general anesthesia which has the following advantages like an immobile surgical field, effective protection of airway, adequate analgesia, and ventilation. The only limitation of general anesthesia is intense intraoperative bleeding than local anaesthesia.[5] Dexmedetomidine is a centrally acting, highly selective, specific, and most potent alpha-2-adrenergic agonist having analgesic, sedative, antihypertensive, anesthetic-sparing effects, anxiolytic, hypnotic and sympatholytic effects.[6] Magnesium Sulphate is a good drug for controlled hypotension, as it stabilizes the cell membrane and intracytoplasmic organelles by activation of Na+-K+ ATPase and Ca2+ ATPase enzymes, which play an important role in transmembrane ion exchange during depolarisation and repolarisation phases.[7] Magnesium Sulphate also inhibits the release of norepinephrine by blocking N-type Ca2+ channels at nerve endings, and this leads to decreased blood pressure13. Magnesium Sulphate reduces the analgesic needs as it is a N-Methyl-D-Aspartate receptor antagonist.[8] It also produces a vasodilatory effect by increasing the synthesis of prostacyclin and inhibiting angiotensin converting enzyme activity by limiting the outflow of calcium from sarcoplasmic reticulum.[9] This study is designed to compare the efficacy and safety of

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Dexmedetomidine and Magnesium Sulphate as hypotensive agents in Functional Endoscopic Sinus Surgeries. The quality of the surgical field, satisfaction of surgeon, recovery profile and postoperative analgesia also compared.

The aim and objective of the study were to compare the efficacy of Dexmedetomidine and Magnesium Sulphate for controlled hypotension during functional endoscopic sinus surgeries.

MATERIAL AND METHODS

The study was conducted in the ENT Departments of Government Kilpauk Medical College Hospital and Government Royapettah Hospital, Chennai after obtaining Institutional Ethics Committee approval.

Sixty-two patients were studied, randomized into two groups of 31 each.

Patients were allocated into two groups:

Group A (n= 31): Patients receiving Dexmedetomidine

Group B (n= 31): Patients receiving Magnesium Sulphate

The surgeon who performed the surgery was blinded to the study drug. The surgeon was asked to provide scores for the quality of the surgical field using a predefined category scale and duration of surgery.

Inclusion Criteria

1. Age 18 - 60 yrs
2. ASA I and II patients
3. Males and females
4. Valid written informed consent
5. Posted for elective FESS surgery

Exclusion Criteria

1. Patient refusal
2. ASA grade III and IV
3. Known allergy to study drug
4. Recurrent sinus surgery
5. Systemic hypertension
6. Diabetes mellitus
7. Patients with coagulopathies or receiving drugs influencing blood coagulation
8. Coronary Artery Disease
9. Renal, Hepatic or Cerebral insufficiency
10. Patients on adrenergic blocking drugs
11. Any type of A-V block on electrocardiogram (ECG), heart failure, severe bradycardia
12. Current psychiatric disorder or any respiratory disorders.
13. Impaired ability to communicate (e.g., confusion, poor hearing or language barrier)
14. Pregnant patients.

The patients were assessed preoperatively, and they were explained about the purpose of the study, the procedure of the study and about the possible adverse events that can occur due to the study drug, and written informed consent was obtained from those patients who were willing to take part in the study.

On arrival of the patient in the operating room, monitors to be connected - Pulse oximeter, Non-Invasive Blood Pressure (NIBP) and ECG were connected, and baseline values were recorded. Two 18G intravenous cannulas was inserted, one for infusion of the study drug and the other for the administration of fluids and other anesthetic drugs. In both groups, a cotton swab soaked in a solution containing 20 mg/ml Lidocaine hydrochloride with 0.005 mg/ ml Epinephrine (1 in 1000 dilution) is packed to the nostril on both the medial and lateral conchae for 10 minutes. All patients were pre-medicated with IV Glycopyrrolate 5µg/kg, IV Midazolam 0.05 mg/kg, IV Fentanyl 2µg/kg. In Group A, patients received the loading dose of 1 µg/kg Dexmedetomidine IV diluted in 100 ml 0.9% normal saline infused over 10 min, before induction of anesthesia, followed by continuous infusion of 0.5 - 1 µg/kg/hr. In Group B, patients received Magnesium Sulphate IV diluted in 100 ml o.9% normal saline with a loading dose 40 mg/kg, infused over 10 min, before induction of anesthesia, followed by continuous infusion of 10 - 15 mg/kg/hr. Induction was done with IV Propofol 2 mg/kg. Endotracheal intubation was facilitated with IV Atracurium 0.5 mg/kg with the suitable sized cuffed endotracheal tube. Anesthesia was maintained with Desflurane 2-6%. All patients were mechanically ventilated with Nitrous oxide and Oxygen (50%: 50%). IV Fentanyl was given for intraoperative analgesia. Patients received lactated Ringer's solution IV according to Holliday Segar formula. Patients were placed in 15° reverse Trendelenburg position which helps to improve venous drainage.

Hemodynamic parameters such as Pulse Rate, Non-invasive blood pressure (Systolic Blood Pressure, Diastolic Blood Pressure and Mean Arterial Pressure), and SPO2 were recorded every 5 minutes during the 1st 15 minutes and every 15 minutes after that, until the end of surgery. For statistical purpose, they were documented at 0, 5, 10, 15, 30, 45 minutes depending on the duration of surgery, and at 0 and 5minutes after stoppage of study drug. Intraoperatively, the Mean Arterial Pressure (MAP) was maintained in the range of 60 - 70 mmHg, by adjusting the dose of the study drug within the specified dose earlier. If the MAP were higher than the desired range even with the maximum dose of the study drug, the MAP would be reduced by increasing the Desflurane concentration. If this measure fails to reduce the Mean Arterial Pressure (MAP) intraoperatively, Nitroglycerine (NTG) infusion was started to reduce MAP within the desired range. If the MAP dropped below 60 mmHg, the blood pressure was raised by reducing the dose of the study drug and maintaining inhalational agent to the lowest dose mentioned earlier. If this measure fails to raise the blood pressure intraoperatively, graded doses of Inj. Ephedrine 6 mg to be used. If the heart rate falls below 50 beats/minute, Inj. Atropine 0.6 mg would be used to correct it. When the MAP reached the desired range (60 - 70 mmHg) and was maintained for at least 10 minutes, the surgeon is asked to estimate the quality of the surgical field using a predefined category scale adopted from that of Fromme et al. Infusion of the study drug was stopped five minutes before the anticipated end of surgery. Desflurane was stopped at the end of the surgery. The residual neuromuscular blockade was reversed with Inj. Neostigmine (0.05 mg/kg) IV and Inj.

Glycopyrrolate (0.01 mg/kg) IV. Emergence time, defined as the time interval between discontinuation of anesthetics and eye-opening in response to the verbal command, is noted.

Surgeon satisfaction was scored by the surgeon who performed the surgery which was blind regarding drugs used and assessed with a 4-point scale: 1 = bad, 2 = moderate, 3 = good, 4 = excellent. Postoperative recovery was evaluated using a Modified Aldrete Score (0-10), and time needed to achieve ≥9 was noted

Once the Modified Aldrete Score was attained ≥9, patients will be shifted to post-operative ward. The intensity of post-operative pain can be measured by NRS scale –Numeric Rating Scale.

When NRS > 4, patients were treated with Inj. Tramadol 100 mg IM.

Patients were monitored in the postoperative ward for any complications including nausea, vomiting, bradycardia or tachycardia, hypotension or hypertension, etc. during the first 24 hours following surgery and were managed accordingly.

RESULTS

There was no statistical difference between the demographic characters between the two groups. The two groups were matched according to the duration of surgery and found that there was significant difference between them and the above values shows that duration of surgery was decreased significantly in Dexmedetomidine group when compared to Magnesium Sulphate group (figure-1).

The pulse rates remained comparable between the two groups during pre-induction, post induction, 5 minutes and 10 minutes post induction. There was a significant difference in pulse rate at 15 minutes (63.77±0.90 vs 66.45±0.84, p value- 0.033), 30 minutes (64.06±1.01 vs 66.84±0.77 p value- 0.034), at stoppage of drug (64.19±0.86 vs 67.39±0.79 p value- 0.008) and 5 minutes after stoppage of drug (64.87±0.87 vs 71.26±0.82 p value-0.0001), which shows that pulse rate was significantly lower in Dexmedetomidine

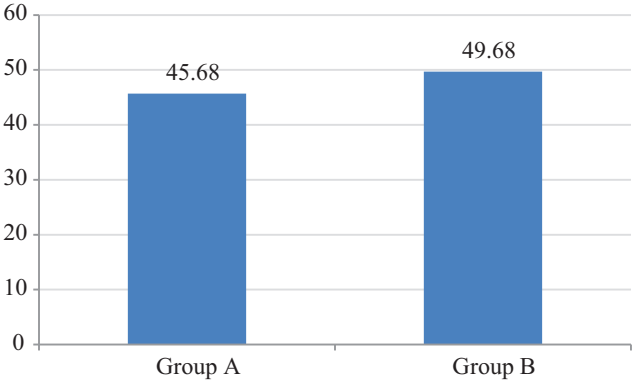

Figure-1: Duration of Surgery (minutes)

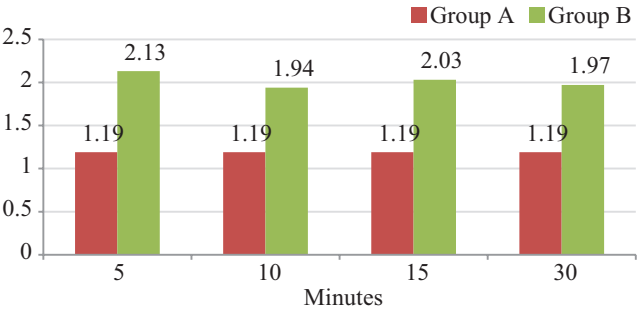

Figure-2: Average category score

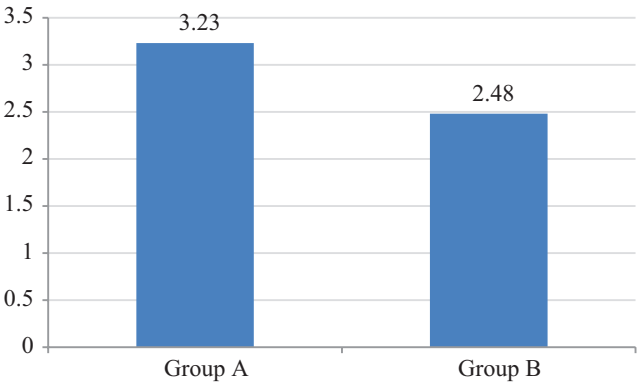

Figure-3: Surgeon satisfaction score

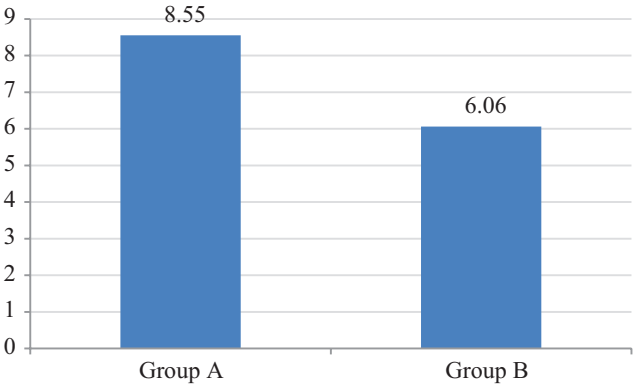

Figure-4: Emergence time

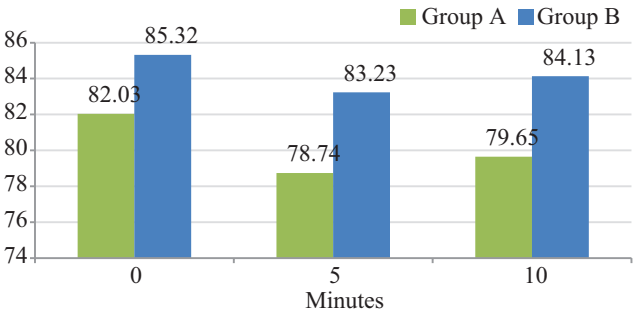

Figure-5: Post-Operative Mean Arterial Pressure (MAP in mmHg)

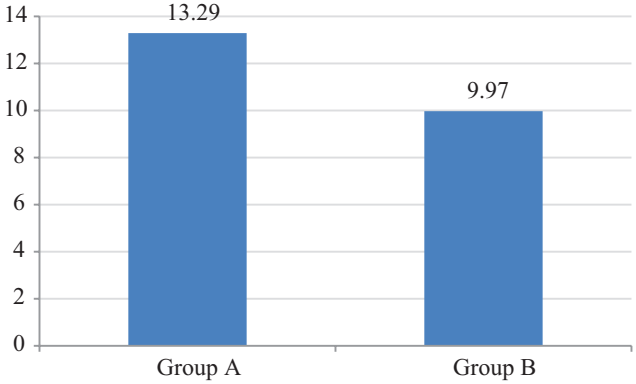

Figure-6: Time to attain modified aldrete score ≥9

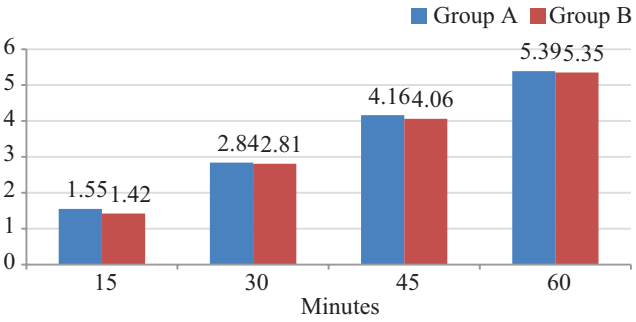

Figure-7: Numeric Pain Rating Scale

group than Magnesium Sulphate group.

Intraoperative Systolic Blood Pressure was significantly lower in Dexmedetomidine group than Magnesium Sulphate group (p value <0.05) except during the stoppage of drug where little increase in systolic pressure in Dexmedetomidine group.

Intraoperative Diastolic Blood Pressure was significantly lower in Dexmedetomidine group than Magnesium Sulphate group (p value <0.05) except during post induction and stoppage of drug.

Mean Arterial Pressure (MAP) was significantly lower in Dexmedetomidine group throughout the intraoperative period (p value <0.05) except during the stoppage of drug.

Intraoperative saturation of oxygen (SpO_2) remains comparable in both the groups and there was no significant difference between them.

The Average Category Score to assess the quality of surgical field in terms of bleeding during intraoperative period shows that Dexmedetomidine group provides better quality of surgical field when compared to Magnesium Sulphate group (p value < 0.05) (figure-2).

Surgeon satisfaction score was measured in terms of bad, moderate, good and excellent and it was observed that surgeon had an excellent operating condition and satisfaction in Dexmedetomidine group when compared to Magnesium Sulphate group (3.23±0.09 vs 2.28±0.09, p value- 0.0001) (figure-3).

Emergence time was significantly increased in Dexmedetomidine group when compared to Magnesium Sulphate group (8.55±0.17 vs 6.06±0.19, p value- 0.0001) (figure-4).

The Pulse Rate were significantly higher in the Magnesium Sulphate group during the postoperative period, compared to the Dexmedetomidine group (p value- 0.0001).

Post extubation Systolic Blood Pressure was significantly lower in Dexmedetomidine group when compared to Magnesium Sulphate group (p value- 0.008).

The post-operative Diastolic Blood Pressures were significantly lower in the Dexmedetomidine group compared to the Magnesium Sulphate group (p value <0.05).

The Mean Arterial Pressure in the post-operative period were significantly lower in the Dexmedetomidine group compared to Magnesium Sulphate group (p value <0.05).

Post-operative oxygen saturation was comparable between the two groups (figure-5).

The time to attain Modified Aldrete Score ≥9 is significantly lower in the Magnesium Sulphate group compared to Dexmedetomidine group (13.29±0.21 vs 9.97±0.22, p value- 0.0001) (figure-6).

The Numeric Pain Rating Scale was comparable between two groups and there was no significant difference noted.

Nitroglycerine necessity during intra-operative period was significantly increased in Magnesium Sulphate group compared to Dexmedetomidine group (p value- 0.008) (figure-7).

DISCUSSION

Several studies have revealed that controlled hypotension is beneficial during Functional Endoscopic Sinus Surgeries in terms of improved surgical field visibility and thereby shorter duration of surgery and better outcome. Various drugs have been tried to induce hypotension during surgery. These include ù-blockers, vasodilators, calcium channel blockers, and anaesthetic drugs like propofol, opioids and inhalational agents. Many studies were conducted comparing these agents with regard to hemodynamic stability, patient tolerance, quality of the surgical field, etc.[10] Many studies have been conducted regarding the efficacy of Dexmedetomidine as a hypotensive agent. Dexmedetomidine has the added advantages of analgesic and sedative and anesthetic-sparing effects.[11] Recently several studies were conducted regarding the analgesic and anesthetic-sparing effects of Magnesium Sulphate in addition to its use as a hypotensive agent.[12] In our study, Dexmedetomidine is compared with Magnesium Sulphate with regards to efficacy as a hypotensive agent, recovery profile, and post-operative pain relief. In our study, we observed that there was a significant fall in heart rate and blood pressure following induction in both the groups. Both the drugs were effective in maintaining the intraoperative Mean Arterial Pressure (MAP) within the target pressure of 60 – 70 mm of Hg. Another additional drug of Nitroglycerine was needed to maintain the Mean Arterial Pressure (MAP) significantly in Magnesium Sulphate group (p-value- 0.008). The hemodynamic parameters such as heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure was significantly lower in the Dexmedetomidine group compared to Magnesium Sulphate group during the intraoperative period till the stoppage of the study drug.[12-14] The Average Category Score to assess the quality of the surgical field in terms of bleeding during the intraoperative period measured at 5 minutes, 10 minutes, 15 minutes and 30 minutes shows that Dexmedetomidine group provides a better quality of surgical field when compared to Magnesium Sulphate group (p-value < 0.05). Surgeon satisfaction score was measured in terms of bad, moderate, good and excellent with the score of 1, 2, 3 and 4 and, it was observed that surgeon had an excellent satisfaction in Dexmedetomidine group when compared to Magnesium Sulphate group (3.23±0.09 vs. 2.28±0.09, p-value- 0.0001). It was found that duration of surgery was decreased significantly in Dexmedetomidine group when compared to Magnesium Sulphate group (45.68±0.91 vs. 49.68±0.88; p-value (0.002). Systolic blood

pressure, diastolic blood pressure and mean arterial pressure (MAP) were lower in the Dexmedetomidine group at the time of stoppage of the study drug, but not significant, and all the parameters were significantly lower in Dexmedetomidine group after 5 minutes of stoppage of the drug. Emergence time, measured as the time between stoppage of anesthetic agents to respond to commands, was significantly longer in the Dexmedetomidine group (8.55±0.17 vs. 6.06±0.19, p-value- 0.0001), showing that the Dexmedetomidine group had a delayed recovery compared to the Magnesium Sulphate group. The time to reach Modified Aldrete Score of ≥9 was significantly longer in the Dexmedetomidine group. In the postoperative period, the pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure of the patients belonging to the Magnesium Sulphate group were significantly higher than those in Dexmedetomidine group. The Numeric Pain Rating Scale was comparable between the two groups, and there was no significant difference noted and both the drugs have similar analgesic potency post-operatively. Thus we have observed in our study that Dexmedetomidine is effective in providing good quality of surgical fields, better haemodynamic stability, but recovery was faster with Magnesium sulphate, whereas both Dexmedetomidine and Magnesium Sulphate had the advantage of prolonged postoperative analgesia.[15]

CONCLUSION

We conclude that dexmedetomidine used in our study provided controlled hypotension more effectively and stably with better hemodynamic stability in patients undergoing Functional Endoscopic Sinus Surgery, and also increased surgeon satisfaction by achieving better surgical field.

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