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Prospective Observational Study to Assess Controlled Hypotension Using Dexmedetomidine and Magnesium Sulphate Among Patients Undergoing Functional Endoscopic Sinus Surgery(Fess) in Tertiary Care Hospital

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KEYWORDS
Fess, Dexmedetomidine, Magnesium Sulphate..

ABSTRACT:

AIM

Functional endoscopic sinus surgery (FESS) is done in closed space and bleeding becomes a major determinant for visibility. Stimulation of nasal mucosa and pharyngeal tissue causes a centrally mediated sympathetic reaction that results in hemodynamic response during the procedure. Aim of our study is to observe time taken to achieve 20 % decrease in MAP from baseline mean arterial pressure and to observe circulatory response to tracheal intubation and extubation.

MATERIALS AND METHODOLOGY:

A prospective randomized observational study conducted at our hospital for a period of 1 year from January 2023 onwards.

96 patients were selected for the study after applying inclusion and exclusion criteria. As per the deision of the consultant anesthetist patients received either Inj.Dexmeditomidine 1mcg/kg as loading dose in 100 ml NS over 10 mins before induction of anesthesia and maintenance dose of 0.5-1 mcg/kg administered after induction of anesthesia or Inj.Magnesium sulphate 40mg/kg as loading dose in 100ml NS over 10 mins before induction of anesthesia and maintenance dose of 10-15 mg/kg after induction of anesthesia. Hemodynamic status pre induction, post induction at 3 mins,5 mins,15 mins,45 mins and 5 mins post extubation was observed.

- **RESULTS:**

In this study involving 96 patient undergoing FESS. Dexmedetomidine was found to be a better hypotensive agent compared to magnesium sulphate by reducing heart rate and mean arterial pressure by 20%.

- **CONCLUSION**:

We concluded that dexmedetomidine when used in above mentioned doses produced early onset and sustained controlled hypotension that is more significant than magnesium sulphate in patients undergoing FESS. Dexmedetomidine is a better agent to blunt tracheal response than magnesium sulphate without causing pronounced complications.

INTRODUCTION:

Functional endoscopic sinus surgery (FESS) seems to be the most common surgical technique these days. This surgery is performed majorly as a treatment for Chronic Rhinosinusitis. FESS surgery is done in closed space and bleeding becomes a major determinant for visibility. Stress response during intubation may cause tachycardia and hypertension thereby increasing the cardiac load. Stimulation of nasal mucosa and pharyngeal tissue causes a centrally mediated sympathetic reaction that

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results in hemodynamic response during the procedure. Excessive bleeding can prolong the duration of surgery and may decrease blood pressure and may require transfusion associated with its own complications. Thus, controlled hypotension using pharmacological agents like dexmedetomidine and magnesium sulphate [1,2] are used to decrease bleeding and enhance visibility at surgical site. The term "hypotension" has no set definition. There are several definitions of hypotension in the literature, according to reports [3]. Controlled hypotension is defined as a 20% decrease from baseline mean arterial pressure (MAP) or a fall in systolic blood pressure to 80 – 90mm Hg or diastolic blood pressure 50 –65mm Hg. Additionally, studies show that drop in MAP of 10 –20% from baseline is sufficient to reduce blood loss. Techniques of producing controlled hypotension includes pharmacological therapy, Reverse Trendelenburg for head and neck surgeries, positive end expiratory pressure. Advantages of pharmacological therapy over other includes administration with ease, effect that is dose dependent and predictable, titrability, rapid clearance, minimal impact on essential organ blood flow.

Dexmedetomidine is an alpha 2 adrenergic receptor agonist. Structure of dexmedetomidine is 4(2, 3 dimethyl ephenyl) ethyl_1H -imidazole monohydrochloride. Empiricalformula- C13H16HC1.Clinically it can be used as premedication, sedation in ICU [4], Colonoscopy [5], vitreoretinal surgery [6], adjuvant in regional techniques. Dexmedetomidine acts as ideal hypotensive agent as it has less toxic side effects and maintain adequate perfusion to vital organs and can be easily administered and its predictability is also good. It also helps in attenuating response to tracheal intubation and extubation [7],blunt stress response during awake intubation[8],also produce postoperative analgesia. Alpha 2 receptor antagonist atipamezole has the ability to reverse the sedative and sympatholytic effects of dexmedetomidine in a dose-dependent manner [9]. Magnesium is fourth most cation after sodium, potassium, phosphorous. Normal range is 1. 4 - 2.2 mEq/L (0.7-1.1mmol/L) Magnesium acts by blocking N-methyl- D-aspartate receptor and Ca2 + channel [10]. Clinical application of magnesium includes : used in eclampsia for controlling seizures, as analgesia, accelerates action of nondepolarizing muscle relaxants, reduces shivering, attenuates tracheal response, controlled hypotension, anti-arrhythmic property, status asthmaticus as it has bronchodilator action, also used as tocolytics.

STUDY DESIGN:

Prospective, randomized, Double-blinded, Observational parallel study.

STUDY AREA:

ENT operative room complex at xxx Hospital.

STUDY POPULATION:

96 patients undergoing FESS under General anesthesia were included.

INCLUSION CRITERIA:

All patients undergoing FESS

1. ASA grade – I, II (Hypertensive patients excluded)
2. Age above 18 and below 65 years

EXCLUSION CRITERIA:

1. Known Hypertensive patients
2. ASA III, IV
3. Known Hyper sensitivity reactions to dexmedetomidine and magnesium sulphate
4. BMI > 35
5. Anticipated difficult airway
6. Patients intubated by means other than direct laryngoscopy
7. If laryngoscopy takes more than 20 seconds and need for more than one intubation attempts

STUDY TOOL:

Questionnaire, Patients' Medical records were used for collecting data

METHODOLOGY:

This was a prospective observational study of 96 patients subjected to elective FESS surgery between January 2023 to January 2024. The study was approved by ethical committee of the Institute and informed consent were obtained from the patients. Patient shifted to operating room, monitors were connected and baseline Mean arterial pressure and Heart rate were noted. Intravenous fluids were administered as per standard fluid chart. Patients were premedicated with intravenous Inj. Glycopyrrolate 0.2mg and Inj. Midazolam 1mg. Loading dose of Inj. Magnesium sulphate 40mg/kg in 100ml NS over 10 mins were given to patients in group M and 1mcg/ kg of Dexmedetomidine in100ml NS over 10 mins before induction of anesthesia for patients in group D. After 3 mins of preoxygenation, Patients

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induced with Inj. Fentanyl 2mcg/ kg and Inj. Propofol 1.5 -2.5mg/kg titrated till achieving loss of verbal command, Paralyzed with Inj. Atracurium 0.5mg/kg. Endotracheal tube of adequate size was selected for each patient, and intubated by direct laryngoscopy. Throat packing was done. Maintenance of anesthesia with O2 - N2O-sevoflurane and Inj. Atracurium 0.1mg/kg. Intraoperative analgesics with Inj. Tramadol 0.5mg/kg and INJ. Paracetamol 15mg/kg. Controlled mechanical ventilation done with targeted End tidal carbon-dioxide level of 35-40mm Hg. Maintenance dose of Inj. Magnesium sulphate 10 -15mg/kg was given to patients in Group M and 0.5-1 mcg/ kg of Inj. Dexmedetomidine were given to patients in Group D. A 20% drop in mean arterial pressure (MAP) from baseline was considered as controlled Hypotension. After the procedure, the infusion of dexmedetomidine and magnesium sulphate was terminated thirty minutes prior to extubation INJ. Ondansetron 0.1mg/kg was administered. Neostigmine 0.5mg/kg and glycopyrrolate 0.1 mg/kg injections were used to reverse once adequate respiratory efforts achieved and then patient extubated. After observation for 5 minutes patient then shifted to recovery room.

RESULTS AND OBSERVATION:

Table 1: Comparison of HR Between Groups by Independent Sample Test

HR	Groups	N	Mean	SD	t-value	p-value
Baseline	GroupD	48	88.8	11.5	2.837	0.006**
	GroupM	48	82.3	11.0		
Pre-Induction	GroupD	48	82.4	10.0	0.897	0.372#
	GroupM	48	80.5	10.7		
Post-Induction	GroupD	48	76.3	7.7	1.633	0.106#
	GroupM	48	79.3	10.5		
Intubation	GroupD	48	92.6	10.8	0.142	0.888#
	GroupM	48	92.9	9.3		
3Mins	GroupD	48	82.6	9.4	2.988	0.004**
	GroupM	48	87.9	8.0		
5Mins	GroupD	48	77.5	8.8	4.043	0.0005**
	GroupM	48	84.2	7.4		
15Mins	GroupD	48	71.3	7.4	7.810	0.0005**
	GroupM	48	82.5	6.7		
45Mins	GroupD	48	69.2	7.7	11.506	0.0005**
	GroupM	48	88.6	8.8		

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Extubation	GroupD	48	84.8	8.7	4.126	0.0005**
	GroupM	48	91.7	7.7		
5MinsPost Extubation	GroupD	48	78.6	7.4	5.054	0.0005**
	GroupM	48	86.8	8.2		
**Highly Significant at p<0.01and No Statistical Significance at p>0.05level						

Table 2: Comparison of MAP Between Groups by Independent Sample Test

MAP	Groups	N	Mean	SD	t-value	p-value
Baseline	GroupD	48	89.9	6.2	1.944	0.055#
	GroupM	48	87.2	7.2		
Pre-Induction	GroupD	48	85.9	6.5	1.494	0.139#
	GroupM	48	83.8	7.0		
Post-Induction	GroupD	48	88.0	7.2	1.154	0.252#
	GroupM	48	86.3	7.6		
Intubation	GroupD	48	82.2	5.8	8.186	0.0005**
	GroupM	48	93.7	7.9		
3Mins	GroupD	48	78.7	5.3	9.622	0.0005**
	GroupM	48	90.6	6.7		
5Mins	GroupD	48	71.9	5.5	10.951	0.0005**

Table 3: Comparison of Time Taken to Achieve 20% Reduction from Baseline of Map Between Groups by Pearson's Chi-square Test

			Groups		Total	χ^2-value	p-value
			Group D	Group M			
Timetakentoachieve20% Reduction from Baseline	0-5 Mins	Count	25	0	25	67.611	0.0005**
		%	52.1%	0.0%	26.0%		
	5-15 Mins	Count	17	2	19		
		%	35.4%	4.2%	19.8%		

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of MAP	>15 Mins	Count	6	46	52		
		%	12.5%	95.8%	54.2%		
Total		Count	48	48	96		
		%	100.0%	100.0%	100.0%		
**Highly Statistical Significance at p<0.01level							

The results were driven using independent test. Baseline Heartrate were comparable with the groups as there was no statistical difference noted in the former, [Table 1]. The statistical significance for HR was high for all the time durations except during Pre-Induction, Post-Induction and Intubation with p<0.01. There was no statistical significance in HR during Pre-Induction, Post-Induction and Intubation (p>0.05). Group -D has significant decrease in MAP when compared to Group-M at all time durations Baseline mean arterial pressure were comparable with the groups as there was no statistical difference noted in the former, [Table 2]. The statistical significance for MAP was high for all the time durations except Baseline, Pre-Induction, and Post-Induction with p<0.01. Dexmedetomidine produced desired 20% fall in the mean arterial pressure much earlier [Table 3] than magnesium sulphate which was found to have p value<0.05. Magnesium sulphate also produced sustained fall in mean arterial pressure after 15 mins of administering the maintenance dose.

DISCUSSION:

Here, we compared magnesium sulphate and dexmedetomidine with the aim of minimizing bleeding by establishing a controlled hypotension. In our study, no statistically significant difference was found in age, BMI, gender, ASA physical status, Baseline Heartrate and mean arterial pressure. Our study reveals dexmedetomidine is a better drug to significantly reduce mean arterial pressure compared to magnesium sulphate at all time durations.

About 90 % of patients in dexmedetomidine group has 20% reduction in MAP from baseline in less than 15 mins whereas in magnesium group only 4 % of patients experienced fall less than 15mins. This is suggestive that dexmedetomidine provided more hemodynamic stability than magnesium. Chhabra et al concluded that dexmedetomidine achieves 20% decrease in mean arterial pressure earlier than magnesium sulphate [11] similar to our study. Balata et al concluded that decrease in heart rate were comparable between two groups but statistically significant difference was seen in mean arterial pressure during intubation in dexmedetomidine group compared to magnesium sulphate group [12] in support with our study. Guler et al inferred that Dexmedetomidine group has less increase in heart rate and mean arterial pressure during extubation than magnesium [13].

CONCLUSION:

We concluded that dexmedetomidine when used in above mentioned doses produced early onset and sustained controlled hypotension that is more significant than magnesium sulphate in patients undergoing FESS. Dexmedetomidine is a better agent to blunt tracheal response than magnesium without causing pronounced complications. Thus, we suggest the use of Dexmedetomidine as an ideal agent to produce controlled hypotension, to reduce bleeding in patients undergoing Functional Endoscopic Sinus Surgery.

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