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TO ASSESS THE QUALITY OF SURGICAL FIELD DURING FESS SURGERIES: A COMPARISON OF DEXMEDETOMIDINE WITH MAGNESIUM SULPHATE: A RANDOMISED PROSPECTIVE CLINICAL STUDY

Anaesthesiology

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ABSTRACT

Background And Aim Endoscopic sinus surgery has progressed from a limited surgical intervention for chronic sinus disease to a viable approach for diffuse sino-nasal polyposis, benign tumors, orbital lesions and rhino-mucormycosis. Deliberate hypotension for creating oligemic field achieved by various pharmacological agents viz. inhalational agent, vasodilators, ß blockers, opioids, □2 agonists and MgSO4 have been tried. We compared Dexmedetomidine and Magnesium Sulphate with increased doses to provide oligemic field during FESS surgeries keeping patient safety, surgeons satisfaction and post-operative recovery. **Methodology** This was a prospective randomized study among 60 patients divided in Dexmedetomidine group (n=30) - To receive Inj.Dexmedetomidine (Loading-dose of 1µg/kg in 50ml of 0.9% saline solution over 15min) before induction of anesthesia followed by continuous infusion @ 0.5µg/kg/hr and MgSO4 Group (n=30) Inj.Magnesium Sulphate (Loading-dose of 40 mg/kg in 50ml of 0.9% saline solution over 15min before induction of anesthesia followed by continuous infusion @20mg/kg/hr) for deliberate hypotension all throughout the surgery. Primary objective was providing better quality of the surgical field during FESS and its assessment, surgeons' satisfaction and patient stability. **Results** Both the groups had comparable demographics. The surgical field (Fromme-Boezaart scale) immediately after intubation till 75-90 minutes of surgery was found to be better with Dexmedetomidine ($p<0.05$) at all intervals as compared to MgSO4. The surgeons' satisfaction score was also better with Dexmedetomidine. Hemodynamically little difference was observed in pulse rate, MAP between two groups with no post-operative sedation or other known complications like delayed recovery in both the groups. **Conclusion** Inj.Dexmedetomidine in the prescribed dose for deliberate hypotension proved to be having edge over Inj. Magnesium Sulphate in achieving a better surgical field, hemodynamic stability and better safety profile in FESS surgeries despite of the escalated dose considered for Magnesium Sulphate.

KEYWORDS

FESS, Controlled Hypotension, Dexmedetomidine, Magnesium Sulphate, Mean Arterial Pressure, Surgical Field

INTRODUCTION:

Kennedy(1) stated that "endoscopic sinus surgery has progressed from a limited surgical intervention for chronic sinus disease to a viable approach for diffuse sino-nasal polyposis, benign tumors, skull base defects and orbital lesions"(2)(3). Nasal polypectomy, septoplasty, septo-rhinoplasty are the commonest ones being performed. In the COVID era, the incidence of Rhino-Mucormycosis(4) cases flared up and surgical excision of the lesion to prevent the central nervous spread was the need of the hours. Sino nasal area is highly vascular area being supplied by external and internal carotid vessels and intervening in this area can amount to substantial bleed.(5) Oligemia if created can substantiate a better surgical field and surgeons' satisfaction. Controlled or Deliberate hypotension helps to achieve both by reducing the blood loss improvises the area for surgery. Numerous pharmacological agents (inhalational agent, vasodilators, ß blockers, opioids, □2 agonists and $MgSO_4$) have been used effectively for controlled hypotension by reducing the baseline mean arterial pressure (MAP) by 30% or maintaining MAP at 60–70 mmHg.(6) Selective □2 adrenoceptor agonists (Dexmedetomidine) and Magnesium Sulphate $MGSO_4$ have been studied exclusively for use of deliberate hypotensive anaesthesia for FESS surgeries for Improvisation of surgical field, time to achieve this hypotensive field, surgeon and patient satisfaction. We conducted this study with use of Dexmedetomidine and MgSo4 for achieving controlled hypotension with increased dose during various FESS procedures (including rhinoplasty-mucormycosis(4,7,8)cases) to limit intraoperative blood loss and provide the best possible oligemic field, keeping in mind the patient safety and comfort at the end of surgery.

METHODOLOGY:

This study protocol, after approval by The Institutional Ethics Committee for Human Research- PG Research (IECHR-PGR) (IHEC/21/OUT/SRPG017) and CTRI (Clinical Trial Registry of India) Registration (CTRI/2022/04/042142), involved 60 adult patients fitting into inclusion criteria of either sex, between 20 to 60 years of age, belonging to ASA status I & II posted for FESS surgeries for various indications. Sample size calculation done with the use of formula $N = [(4\sigma^2)\ (Z_{(1-(\alpha/2))} + Z_{(1-\beta)})^2] \div E^2$, where N is total sample size, σ is SD taken as 2, $Z_{(1-(\alpha/2))}$ taken as 1.96 with accepted confidence level 95%, $Z_{(1-\beta)}$, 0.84 with power of the study 80%. E is expected difference in means, taken as 1.5. Comparing the distinctive surgical field score between the two groups was the parameter considered for sample size calculation (Akayya et al[5](9)). The patients were randomly allocated into two groups of 30 patients each using **sealed envelope method** in two groups:

Group D: To receive Inj. Dexmedetomidine - Loading dose of 1µg/kg in 50 ml of 0.9% saline solution over 15 min before induction of anesthesia followed by continuous infusion @ 0.5µg/kg/hr,

Group M: To receive Inj. Magnesium Sulphate - Loading dose of 40 mg/kg in 50 ml of 0.9% saline solution over 15 min before induction of anesthesia followed by continuous infusion @20mg/kg/hr,. Standard ASA monitoring to record baseline parameters, pre-medication with IV Glycopyrrolate 5µg/kg, IV Midazolam 0.05 mg/kg, IV, analgesia with IV Tramadol 2mg/kg and cottonoids soaked with epinephrine 1: 80,000 inserted into nasal passages for 10 minutes administered to all patients after the loading infusion of the study. The drugs infusions were prepared in the dose concentration that was to be infused at the same rate in ml/hr immediately after intubation till 15 minutes before the end of surgery through syringe infusion pump for both the groups. General Anesthesia administered with conventional drugs and controlled ventilation with nitrous oxide and oxygen(50%: 50%) keeping end tidal carbon dioxide ($EtCO_2$) pressure at 32–36 mmHg was pursued. Peroperatively, a MAP of 55-65 was targeted and maintained using the infusion drugs and supplemental Sevoflurane. Surgeon's satisfaction for the quality of surgical field achieved was noted via designated score.

The time needed to reach the target MAP with the infusion of the study drug was noted. Supplementation of Sevoflurane was used to keep the MAP at desired value. The surgeon was asked to estimate the quality of the surgical field using a predefined category scale adopted from Fromme et al (Table 1) after stabilization of the desired MAP values at various predefined intervals. The infusion of study drug was stopped 15 min before the end of surgery. Inj. Paracetamol (15mg/kg) was started once the infusion was stopped and the patient extubated at the end of surgery after fulfilment of extubation criteria. In the PACU, the patients were monitored for vitals, postoperative sedation score (Ramsay sedation score(10) – Table 2)) and recovery scores (modified Aldrete score(11)) which were observed and noted at 15 min, 30 min,

60 and 90 minutes after tracheal extubation. Patients were considered ready for discharge from the PACU when the Aldrete score was ≥9, and the time to achieve the same was noted. Master chart of the observed data and parameters was prepared in Microsoft excel sheet. Descriptive analysis was done for demographical details. The data was presented as mean ± SD and compared using unpaired t test. Other categorical outcomes like Bleeding, surgeons' satisfaction, sedation and demographic data (Sex, ASA physical grading, type of fracture) were compared between the groups using Chi square and Fischer Exact T test as applicable.

Table 1: Quality of Surgical Field on a numeric rating scale introduced by Fromme et al. and Boezzart et al.

SCORE	BLEEDING	SUCTION REQT.
0	No Bleeding.	Blood evacuation not necessary.
1	Slight Bleeding	Blood evacuation not necessary.
2	Slight Bleeding	Sometimes blood has to be evacuated.
3	Low Bleeding	Blood has to be often evacuated. Operative field is visible for some seconds after evacuation
4	Average Bleeding	Blood has to be often evacuated.
5	High Bleeding	Constant blood evacuation is needed. Sometimes bleeding exceeds evacuation. Surgery is hardly possible

Table 2: Recovery Scale (ramsay's Sedation Score) – At The End Of Surgery

AWAKE LEVELS	SCORE
Anxious, Agitated or both	1
Cooperative, Oriented and tranquil	2
Only responds to commands	3
ASLEEP LEVELS	
Brisk response	4
Sluggish response	5
No response	6

RESULTS

Total 66 patients were found to be eligible for our study, out of which, 60 patients underwent study interventions.(Figure 1) Demographic data in both the groups showed no difference. (Table 3)

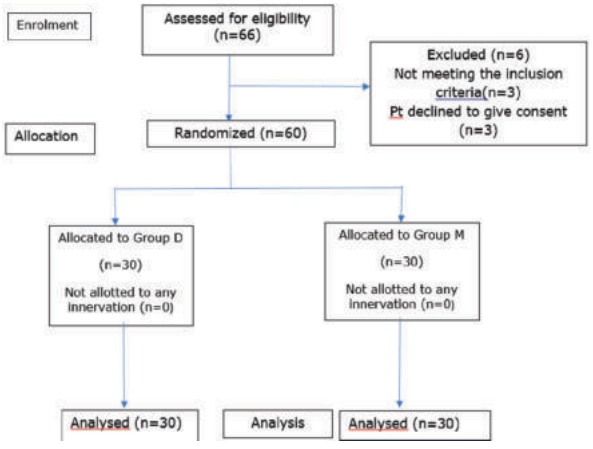

Figure 1: Consort Chart

Table:1 Inter-group Comparisons Of Means Of Baseline Demographic Characteristics

PARAMETERS	GROUP D Mean ± SD	GROUP M Mean ± SD	p-value
AGE (in years)	41 ± 13	32 ± 11	>0.05
SEX (Male: Female)	22:8	19:11	>0.05
Weight (in kgs)	63.5 ± 4.7	63.13 ± 5	>0.05
BMI (in kg/m2)	23 ± 0.3	23.38 ± 0.93	>0.05

Hemodynamic Parameters:

The pulse rates remained comparable between the two groups during pre-induction, post infusion, post intubation, 3- and 10-minutes post induction. (FIGURE 2) There was a significant difference in mean of pulse rate at 30 minutes between the two groups. Intra-group comparison suggested significant decrease from baseline, in mean pulse rate in both groups D and M, While the same in the post extubation period, showed a slight rise in the values which came to baseline values within 10-15 minutes, and stayed the same upto 90 mins. In the inter group comparison, The difference in mean pulse rate was significant post extubation, 15 min, 30 min, 60 min, 90 min were significantly lower in Group D as compared to Group M. (P-value <0.05 for all) (FIGURE 3)

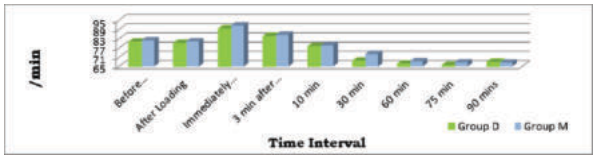

Figure 2: Inter-group Comparison Of Mean Heart Rate Per-operatively

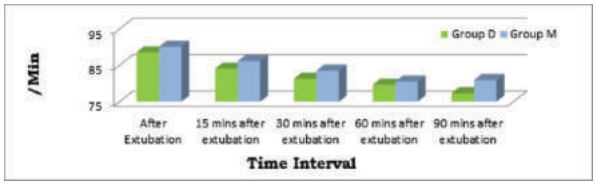

Figure 3: Intra Comparison Of Mean Heart Rate, Post Extubation

The difference in mean MAP at all these predetermined intervals (from intubation till the end) when compared with base line values were statistically significant at all intervals (FIGURE 4), Whereas for group M, statistically significant decrease in mean MAP occurred from 30mins to 75 mins. The mean MAP at 30 mins, 60 mins, 75 mins, were significantly lower in Group D as compared to Group M. (*p* value <0.05 for all). At extubation, Intra-group comparison suggested significant decrease in mean MAP in both groups D and M, from baseline i.e. at extubation, to various set points in time (15min, 30min, 60min, 90min). The mean MAP at various time intervals like extubation, 15 min, 30 min, 60 min, 90 min were significantly lower in Group D as compared to Group M. (*p*-value <0.05 for all) (FIGURE 5).

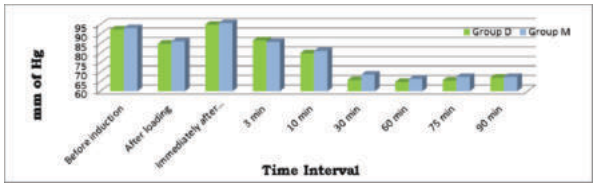

Figure 4: Intra-group Comparison Of Mean Arterial Pressure,

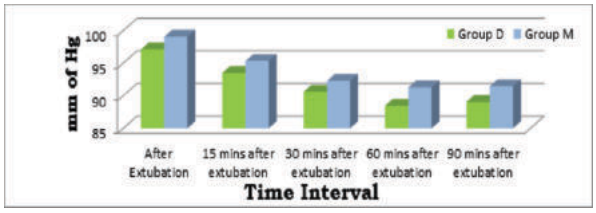

Figure 5: Inter-group Comparison Of Mean Arterial Pressure, Post Extubation

Surgical Field evaluation score (FIGURE 6) and Surgeon satisfaction score (TABLE 4) was measured in terms of bad, moderate, good and excellent, assessed by the Boezaart scale. Both scales showed group D provided better quality of surgical field when compared to Magnesium Sulphate group (p value < 0.05).

Table 4: Inter-group Evaluation Of Surgeon's Satisfaction Score At Various Time Intervals

Type of study drug	Surgeon Satisfaction Score					
	2	3	4	MEAN ± SD	Chi2	P-value
DEX(n=30)	3	18	9	3.20 ± 0.60	8.59	0.01 S
MGSO4(n=30)	13	12	5	2.73 ± 0.73		
DEX(n=30)	3	20	7	3.13 ± 0.56	6.10	0.04 S
MGSO4(n=30)	11	15	4	2.77 ± 0.67		
DEX(n=30)	1	22	7	3.20 ± 0.48	6.46	0.03 S
MGSO4(n=30)	8	16	6	2.93 ± 0.68		
DEX(n=15)	1	8	6	3.36 ± 0.61	6.43	0.04 S
MGSO4(n=16)	5	10	1	2.75 ± 0.56		

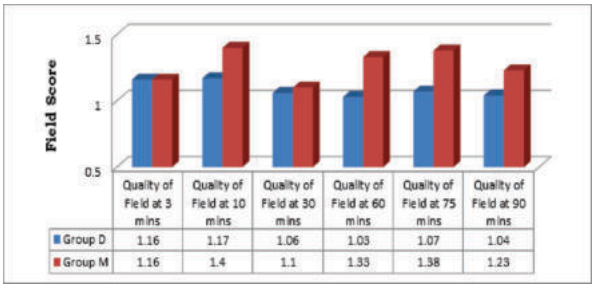

Figure 6: Inter-group Evaluation Of Surgical Field At Various Time Intervals

Sedation and Recovery (TABLE 5) in the post operative period showed 60% patients achieved Aldrete Score of 9 in Group D as compared to 83% in Group M at end of extubation. The total amount of bleeding calculated by number of gauze pieces used, amount of fluid in suction apparatus found statistical significance between the groups. (Table 6)

Table 5: Ramsay Sedation Score:

RAMSAY SCORE	TYPE OF STUDY DRUG	1	2	3	4	MEAN ± SD	t-value	p-value
At extubation	DEX	2	1	11	16	3.37 ± 0.84	9.7046	0.02
	MGSO4	1	10	10	9	2.9 ± 0.87		
15 min after surgery	DEX	2	3	14	11	3.13 ± 0.85	10.1333	0.01
	MGSO4	2	10	16	2	2.6 ± 0.7		
30 min after surgery	DEX	3	12	8	7	2.63 ± 0.95	9.6495	0.02
	MGSO4	1	23	5	1	2.2 ± 0.54		

Table 6: Average Blood Loss During Surgery

SURGERY	APPROX. BLOOD LOSS DURING SURGERY	AVERAGE BLOOD LOSS DURING SURGERY	
		GROUP-D	GROUP-M
FESS	60-75 ml	84.83 ±17.58ml	94.0 ±17.14 ml
SEPTOPLASTY	60-75 ml		
FESS + DEBRIDEMENT	90-120 ml		
FESS + SEPTOPLASTY	80-100 ml		
FESS + CONCHOPLASTY	75-100 ml		

DISCUSSION

It is the prime concern of every ENT surgeon to delineate the intricate vascular anatomy during Nasal surgeries and thus the need for a bloodless, clear operative field, which is obtained by induced systemic hypotension(12). Almost without exception, the techniques and agents used for controlled hypotension have arisen from an "accidental" finding. Deliberately induced hypotensive anaesthesia defined as a method to produce a controlled and safe reduction in the arterial blood pressure (BP) while preserving organ perfusion by reducing the BP of the patient by almost 20% by decreasing capillary ooze(13). In this study, the primary objective of bloodless field achieved with use of the study drugs revealed a surgical score of 1.17 ± 0.37 at 10 minutes in Group D, while in Group M, a score of 1.4 ± 0.49 with a *p*-value of 0.04. Similar significant findings were found at 30 and 60 minutes.

Similarly, In 2014, Akkaya et al(9) compared the effects With Boezaart scale score(14) at 2.6 ± 1 at 15 minutes in Mgso4 and 1.5 ± 0.8 minutes in Dex, at *p*-value of 0.005, results were highly significant. 30 minutes score results were similar. In 2018, Kamal et al(15) using Average Category Score. With score 1.19 in Dexmedetomidine group compared to score 2.03 at 15 and score 1.97 at 30 minutes for Magnesium Sulphate group, better oligemic field was observed in former (Dexmedetomidine). In 2013, A Cardesin et al(16) In their study also Fromme Boezaart score was used for assessing quality of surgical field. With score 1.91 ± 0.53 in Clonidine group as compared to 2.92 ± 0.79 in Opioid group suggesting supremacy of Alpha agonist in creation of surgical field. The loading dose of the Inj. Magsulph was increased to 40mg/kg as compared to above said studies, the purpose being to find out the maximum permissible dose which does not interact and synergise the action of Non depolarizing Muscle Relaxants used during the surgery and does not require frequent titration with inhalational agents to achieve the desired MAP. The sedation observed postoperatively was very less with Magnesium sulphate. (17)

The secondary objective of hemodynamic stability, post operative recovery revealed that significant decrease in mean MAP at 30 mins, 60 mins, 75 mins, were significantly lower in Group D as compared to Group M. (*p*-value<0.05 for all). In 2014, Akkaya et al(9), (MAP) analysis revealed that the blood pressure was lower for a short period of time in Group D at the 35th and 65th min. with *p*-values at the 35th and 65th min as 0.005 and 0.023, respectively. In 2017, Rokhtanak et al(18), MAP was achieved within the desired range in both groups. There was no significant difference between the 2 groups in terms of the mean baseline HR and MAP (Figure 1,2,3,&4) like our study. MAP and HR values at tracheal extubation and during the stay at PACU were higher in the Mg group, compared with those of the Dex group (*p* <0.001, respectively). In Group D, Ramsay's sedation (score of 3.37 ± 0.84 was observed at extubation, compared to Group M (2.9 ± 0.87), suggested that patients were more sedated with infusion of Group D drug as compared to Group M. Rokhtanak et al(18), Chhabra et al and Sahu et al(12) also observed similar findings.

Ours being a tertiary care teaching hospital, we were unable to measure the plasma drug concentrations of the study drugs. Inspite of methods to remove subjective bias like Likert Scale for the Surgeon Satisfaction Score for the clarity of the surgical field, it ultimately depends on the subjectivism of the operating surgeon. No objective parameters available.

CONCLUSION

In concurrence to the above results, we come to conclusion that Inj Dexmedetomidine in the prescribed dose for deliberate hypotension proved to be having edge over Inj. Magnesium Sulphate in achieving a better surgical field, hemodynamic stability and better safety profile in FESS surgeries despite of the escalated dose considered for Magnesium Sulphate.

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