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A COMPARISON OF INTRAVENOUS DEXMEDETOMIDINE AND INTRAVENOUS MAGNESIUM SULPHATE FOR CONTROLLED HYPOTENSION IN ENT SURGERY UNDER GENERAL ANAESTHESIA.

Anesthesiology

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ABSTRACT

Introduction: Controlled Hypotension has been used to reduce bleeding and provide a satisfactory surgical field. Our aim was to observe efficacy of dexmedetomidine and MgSO4 in ENT surgeries as controlled hypotensive agent, effect on surgical field and onset of action and recovery characteristics. **Method:** Thirty six patients of ASA 1 and 2 aged 18 to 60 years posted for ENT surgery divided in group D and group M(n=18).Group D received Inj. Dexmedetomidine 1µg/kg in 100 ml of 0.9% NS administered over 10 min as loading dose followed by infusion at 0.2 to 0.7µg/kg/h and Group M received Inj. MgSO4 40 mg/kg in 100 ml of 0.9% NS was given as loading dose over 10 min followed by an infusion at 10 to 15 mg/kg/h; half an hour before induction and continued till end of surgery. Baseline vitals noted. Drug according to the group started and standard monitoring was done from loading dose till end of surgery. Infusion titrated to keep MAP (mean arterial pressure) between 60 to 70 mm of Hg. Onset of action and Quality of surgical field assessment done using Average category scale (ACS) grading. Ramsay Sedation Score (RSS) used for assessment of sedation. **Result:** Dexmedetomidine is found to be superior to MgSO4 in lowering MAP earlier with low dose of infusion provides good surgical filed and lesser intra-operative bleeding. **Name of Statistical test:** Descriptive statistics, Independent t-test, Chi-square test.**Conclusion:** Dexmedetomidine is better alternative to MgSO4 for Controlled hypotensive agent in ENT surgery under general anaesthesia.

KEYWORDS

Controlled Hypotension, Dexmedetomidine, $MgSO_4$, ENT surgery.

INTRODUCTION

Intentional hypotension to limit intraoperative blood loss has dramatically improved surgical dissection during ENT surgery. A bloodless surgical field provides better visibility of the operative field, with reduced risk of injury to adjoining structures. [1] Numerous pharmacological agents have been used effectively for controlled hypotension by reducing the baseline mean arterial pressure (MAP) by 30% or maintaining MAP at 60–70 mmHg. Inhalational anaesthetics (isoflurane and sevoflurane); vasodilators (e.g., sodium nitroprusside and nitro glycerine); beta (β) -adrenoceptor blocker (e.g., esmolol); opioids (e.g., remifentanil); alpha 2 (α2) adrenergic agonists (clonidine and dexmedetomidine)and magnesium sulphate (MgSO4) are increasingly being used for controlled hypotension during general anaesthesia (GA).[2][3][4]

Ideally, a hypotensive agent should be easy to administer, has faster onset time, rapid elimination without toxic metabolites, should have negligible effects on vital organs and predictable dose dependent effect.[3] Dexmedetomidine, a highly selective α2 adrenoreceptor agonist has sedative, analgesic and anaesthesia sparing effects.

It has a dose dependant decrease in arterial blood pressure, heart rate (HR) and cardiac output because of central sympatholysis. [5] Magnesium sulphate has also been found to reduce the arterial pressure and HR by inhibiting the release of Norepinephrine. [6] Both the drugs have been studied previously, and they have proven efficacy as newer hypotensive agent, but the ideal hypotensive agent should have a shorter onset time.

MATERIALS AND METHODS

This prospective observational randomized study was conducted on Thirty six eligible ASA (American Society of Anaesthesiologist) class 1 and 2 patients of either sex and age between 18 to 60 years who were posted for ENT surgery, between January 2020 and March 2020. This study was conducted according to the Declaration of Helsinki and performed after clearance from Institutional ethical committee and a written informed consent from all the subjects were also obtained after informing them the nature of the study and complications.

Patients were divided into two groups, each group contained 18 patients:

Group D (Dexmedetomidine group)**-** Dexmedetomidine 1 µg/kg was diluted in 100 ml of 0.9% normal saline (NS) administered over 10 min as a loading dose followed by infusion at 0.2 to 0.7 µg/kg/h . For infusion, 100 µg (1 ampoule) of the drug was diluted in 100 ml of 0.9% normal saline to make a final volume of 100 ml and final concentration of 1 µg/ml

Group M (Magnesium Sulphate group)**-** $MgSO_4$ 40 mg/kg was diluted in 100 ml of 0.9% normal saline was given as loading dose over 10 min followed by an infusion at 10 to 15 mg/kg/h . For infusion 5 gm (5 ampoules i.e., 10 ml) was diluted in 90 ml of 0.9% NS to make a final volume of 100 ml and final concentration of 50 mg/ml.

The treatment group was selected by blinded manner. Patients were examined a day before surgery and a detailed history was obtained. Patients were assessed for any evidence of pallor, icterus, cyanosis, clubbing, blood pressure, heart rate, respiratory rate, temperature and airway patency preoperatively.

Patients below 18 years of age, who refused to take part in study, those having known hypersensitivity to study drugs, those who are hemodynamically unstable, with co morbid condition and patient with psychiatric illness were excluded from study.

Patients were kept NBM (nil by mouth) for 6-8 hours.

A day before surgery, consent for involvement in study & effect with purpose of using, either of the drug and their side-effects were explained to patients.

In operation theatre, Standard monitoring such as heart rate, respiratory rate, oxygen saturation(SpO2) ,Non invasive blood pressure (NIBP) and Electrocardiogram (ECG) were attached and monitored continuously thereafter till end of surgery. Aim was to maintain MAP between 60-70mm of Hg .

The time required to achieve target MAP was noted. Infusion was first started at minimum doses for both the drugs (0.2-0.4 µg/kg/hr and 10-15 mg/kg/hr for dexmedetomidine and $MgSO_4$ respectively). The infusion rate for both the drugs was adjusted according to MAP readings thought the surgery. The number of patients requiring the minimum or maximum doses of infusion were noted and recorded in both the groups.

Assessment of surgical field for bleeding was carried out by the surgeon. The bleeding score was assessed by the Average category scale (ACS) grading to assess Quality of Surgical field according to it surgeon satisfaction score was assessed by the surgeon at the end of surgery as 0/1 = Good 2/3 = Fair 4/5 = Poor . All infusions were stopped 5 min before end of surgery. Inj. Glycopyrolate kg 0.01 mg/kg with Neostigmine 0.05 mg/kg IV was used for reversal of neuromuscular blockade and patient was extubated .After extubation; all patients were transferred to the post-anaesthesia care unit (PACU). In PACU adverse events such as nausea, vomiting, anaphylactic reaction, bradycardia and hypotension if occurred were assessed, noted and treated accordingly. Patients were also observed for sedation postoperatively with RSS (1-6) [7].

Statistical Analysis:

Data were statistically described in terms of mean± standard deviation (SD), or frequencies (number of cases), and 95% confidence of interval mean, median and percentages when appropriate. Comparison of numerical variables between the study groups was done using the Student's t-test for independent samples. For comparing categorical data Chi-square test was performed. Alternatively, when the expected frequency was less than five, the exact test was used. P 0.05 was considered statistically significant. All statistical calculation was done using the SPSS software version (16) for Microsoft Windows.

OBSERVATION & RESULTS

Table 1: Comparison of Demographic data

Parameter	Group D	Group M	P value
Age(years)	38.23±14.42	37.74±17.74	0.864(NS)
Sex M/F	12.6	10.8	0.486(NS)
Weight	59.24±7.94	62.06±12.06	0.045(S)

Table 1: Both groups were comparable with respect to age gender and ASA classification. P value >0.005 not significant (NS), P value = 0.005 significant (S), P value < 0.005 highly significant (HS)

Table 2: Comparison of mean time (min) to achieve target MAP and duration of controlled hypotension between Group D and Group M.

Parameter	Group D	Group M	P value
Mean time (min) to achieve target MAP	10.45±2.12	23.36±4.58	<0.001(HS)
Duration of controlled hypotension	75.22±29.82	92.43±32.26	<0.001(HS)

Table 2: Comparison of mean time (min) to achieve target MAP And comparison of duration of controlled hypotension between Group D and Group M, which is highly significant between both groups.

Table 3: Comparison of dose of infusion and time taken to achieve target MAP between Group D and Group M

Variables	Range	Group D (n=18)	Group M (n=18)	Chi-square value	P value
Dose of infusion	Minimum Maximum	16 2	4 14	4.86	0.022(S)
Time taken to achieve target MAP	10 min or less > 10 min	12 6	4 14	3.68	0.05(HS)

Table 3: Comparison of dose of infusion between Group D and Group M, which is significant between both groups while comparison of time taken to achieve to target MAP between Group D and Group M, which is highly significant between both groups.

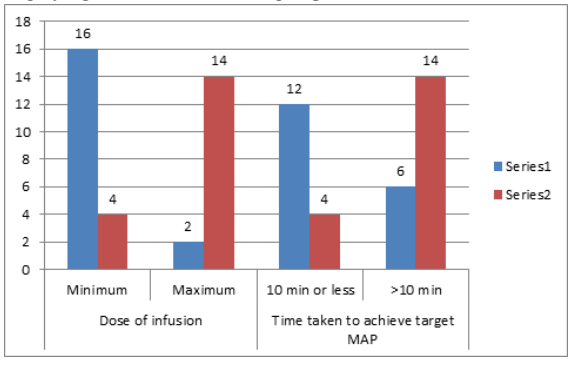


Table 4: Comparison of average Category Scale (ACS) grading to assess quality of surgical field between Group D and Group M

Variables	Range	Group D (n=18)	Group M (n=18)	Chi-square value	P value
Average Category Scale (ACS) grading to assess quality of surgical field	2 ≤ >2	14 4	2 16	34.84	<0.001(HS)

Table 4: comparison of Average Category Scale (ACS) grading to assess quality of surgical field between Group D and Group M, which is highly significant between both groups.

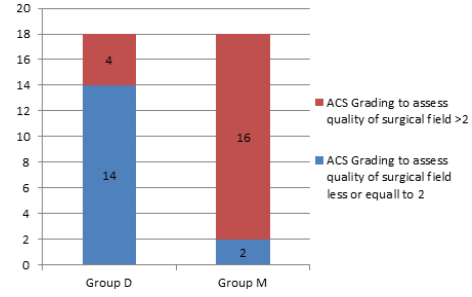


Table 5: Comparison of Ramsay Sedation Score (RSS) at 5 min, 15 min and 30 min between Group D and Group M

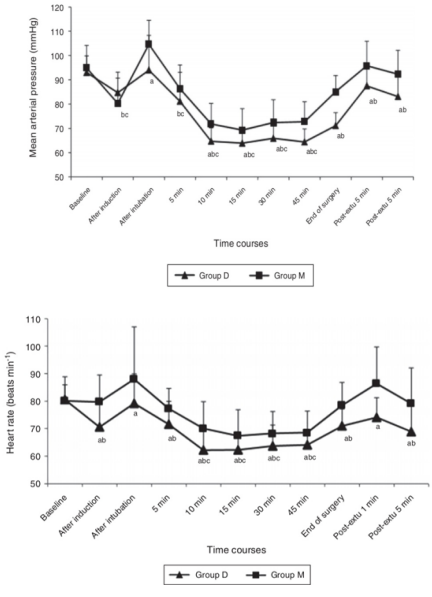
	Group D	Group M	P value
Ramsay Sedation Score (RSS)			
At 5 min	3.86±0.66	2.58±0.42	0.000(HS)
`15 min	2.43±0.48	2.04±0.36	0.000(HS)
30 min	1.46±0.50	1.46±0.50	1.000(HS)

Table 5: Comparison of Ramsay Sedation Score at 5 min and 15 min between Group D and Group M, which is highly significant between both groups. While comparison of Ramsay Sedation Score at 30 min in both groups were comparable.

Table 6: Comparison of side effects between Group D and Group M

	Group D	Group M	P value
Side Effects			
Nausea	4(22.22%)	6(33.33%)	0.26(NS)
Vomiting	2(11.11%)	4(22.22%)	0.422(NS)
Bradycardia and hypotension	1(5.55%)	3(16.66%)	0.306(NS)

Table 6: Comparison of side effects between Group D and Group M, which is not significant in both groups.



DISCUSSION

Controlled hypotension has a definitive role in ENT surgery as it reduces bleeding and improves visibility of the surgical field; hence it decreases the time taken for surgery and duration of general anaesthesia. We compared the efficacy of dexmedetomidine and MgSO4 for achieving controlled hypotension; Time to achieve target MAP and infusion dose to achieve MAP. The RSS (Ramsay Sedation Score), ACS (Average Category Scale) and adverse effects of two drugs were assessed and analysed statistically. The current study results suggest that controlled hypotension was achieved in both the groups but target MAP (60 to 70 mm hg) was achieved rapidly in group D (10.45±2.12 min) as compared with group M(23.36±4.58 min) ; P value of this comparison is <0.001 which is highly significant. Similarly, Khalifa et al. achieved a target MAP of 55-65 mmHg at 10 min following study drugs (dexmedetomidine, $MgSO_4$ and NTG) in functional endoscopic sinus surgery. **[8]** In study of Adnan Bayram et al, the hypotensive effects of dexmedetomidine administered in ENT surgery, it has been reported that surgeon satisfaction was increased. And concluded that dexmedetomidine provide controlled hypotension in a more effective and more stable manner in the patients undergoing FESS. **[10]** Secondary to decrease in the heart rate and blood pressure due to inhibiting effects of dexmedetomidine on central sympathetic stimulation and stimulation of the peripheral α-2 adreno receptors in vascular smooth muscle tissue is responsible for this. Shams et al**. [2]** In a study by Guven et al. Comparing hypotensive effects of dexmedetomidine and placebo agent, it was concluded that dexmedetomidine is a safe and effective agent in controlled hypotension. [**9]** In the current study, 16 patients in group D achieved the target MAP with a minimum infusion of study drug. Two patients in group D required maximum infusion of study drug; acute exacerbated disease condition in the ear could be the cause for the same. In our study, 14 patients in group M required maximum infusion of the study drug to achieve target MAP. Similarly Shams et al. Demonstrated that dexmedetomidine, administered as a 1 µg/kg i.v. Bolus and a 04 to 0.8 µg/kg/h i.v. Infusion, was safe for controlled hypotension and is effective in providing ideal surgical field during FESS. **[2]** In our study, we found that Average Category Scale (ACS) grading to assess quality of surgical field came with the range of MAP (55-65mmhg) were <=2 in 14 patients of group D compared to 2 patients in group M. In study of Adnan Bayram et al concluded that dexmedetomidine increased surgeon satisfaction and quality of surgical site, while not prolonging the recovery period. **[10]** These findings were also supported by Saritha Gohiya et al for use of intravenous dexmedetomidine in modified radical mastoidectomy under general anaesthesia. **[11]** Post extubation RSS was significantly low and patients were more sedated in group D at 5 and 15 min, but the RSS was comparable at 30 min in both the groups. These findings were supported by Faranak et al. study (in which patients in the dexmedetomidine group were more sedated at the PACU due to its sedative-sparing effects via central actions in the locus coreuleus and the time to reach modified Aldrete score >=9 was longer compared with those of the magnesium group) and other studies in which longer time of recovery and discharge from the PACU were recorded in patients who received dexmedetomidine. **[12][2]** Intra and post operative adverse effects were not significant in both the groups.

CONCLUSION

Intravenous Dexmedetomidine and intravenous magnesium sulphate are effective for induced hypotension during ENT surgery but Dexmedetomidine achieved target MAP earlier with low dose of infusion, satisfactory surgical field and less intra-operative bleeding.

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