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Original Article

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Efficacy of Different Doses of Magnesium Sulphate Nebulization in Preventing Postoperative Sore Throat: A Comparative Study

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ABSTRACT

Introduction: Postoperative sore throat (POST) is one of the most common complications in patients undergoing endotracheal intubation for general anaesthesia. Magnesium sulphate nebulization helps in providing equal and effective distribution of the drug throughout the pharynx and upper respiratory tract. In this study, we have compared three different strengths of magnesium sulphate (125 mg,250 mg and 500 mg) pre-operatively to prevent POST.

Methodology: A prospective randomized, comparative study of 90 physical status ASA Class I and II patients scheduled for surgeries under general anaesthesia requiring endotracheal intubation was conducted at a tertiary care hospital.

After institutional ethical committee clearance, informed written consent was obtained from all patients who met the inclusion criteria. Patients were randomized into group A (125mg MgSO4), group B (250 mg MgSO4) and group C (500mg MgSO4) according to sealed envelope method.

Patients included in the study were nebulized with respective doses of magnesium sulphate for 15 minutes before induction of anaesthesia. After the completion of surgery, patients were shifted to post operative anaesthesia care unit and incidence of postoperative sore throat at rest and on swallowing was assessed at 0, 2, 4 ,12 and 24 hours postoperatively.

Results: Incidence of POST at rest and swallowing was high in group A(125mg) at all time points. There was a statistically significant difference at rest between group A(125mg) and group C(500mg) at 0 hours (p= 0.015), 2 hours (p= 0.013), 4hrs (p=0.006),12hrs(p=0.005) & 24hrs(p=0.023).

No incidence of POST at rest was observed at 24hrs with Group C (500mg).

Incidence of POST at swallowing observed was statistically significant between group A(150mg) and group C(500mg) at all time points.

No significant difference was observed at both rest and swallowing between group B(250mg) and C(500mg) at all time points.

Conclusion: We conclude that 500mg MgSO4 nebulization administered pre-operatively is superior in attenuating the incidence of POST when compared to 250mg and 125mg.

Key Words: *Postoperative sore throat (POST), Magnesium sulphate nebulization, Endotracheal intubation, General anaesthesia, Pre-operative prophylaxis*

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INTRODUCTION

Postoperative sore throat (POST) is one of the most common complications in patients undergoing endotracheal intubation for general anaesthesia. The incidence of sore throat after tracheal intubation varies from 6.6 – 90%. Avoiding POST is a priority as it contributes to patient satisfaction. [1-4]

Factors attributing to POST are size of the endotracheal tube, lateral wall pressure, hypotension and inadvertent trauma to the airway during endotracheal intubation. The pressure exerted by the cuff of the tracheal tube on the lateral wall of trachea should not exceed the mean mucosal capillary perfusion pressure that is around 30 cm of water. [5]

Various pharmacological and non- pharmacological measures have been used for attenuating POST pre-emptively. Non- pharmacological measures include using smaller sized tracheal tube, cautious airway instrumentation, reducing the number of laryngoscopy attempts, intubation after complete relaxation of the larynx, minimal oropharyngeal suctioning, maintaining tracheal cuff pressures at 20 mm Hg and extubation when the tracheal cuff is completely deflated. Pharmacological measures for attenuating POST are nebulization of beclomethasone, fluticasone, ketamine, lignocaine and magnesium sulphate, benzydamine hydrochloride local spray and intracuff administration of alkalinized

lignocaine.[6-9]

In the past, several studies have been done using different doses of magnesium sulphate nebulization pre- operatively to attenuate POST in comparison with ketamine, lignocaine and corticosteroids. [4-6,11,13]

The current study was undertaken to find the effective nebulized dose of magnesium sulphate in preventing POST.

AIM OF THE STUDY

To compare the efficacy of three doses of preoperative magnesium sulphate nebulization in preventing postoperative sore throat following endotracheal intubation.

OBJECTIVE

To determine the occurrence of postoperative sore throat at rest and on swallowing at 0,2,4,12 and 24 hours with three doses (125mg, 250mg, 500mg) of preoperative magnesium sulphate nebulization.

MATERIALS &METHODS

SOURCE OF DATA:

The study was conducted as a prospective randomized, comparative study of 90 physical status ASA Class I and II patients scheduled for surgeries under general anaesthesia requiring endotracheal intubation. The study was conducted between the period of August 2022 to July 2023 after approval by the ethics committee of the institution and informed consent.

- **STUDY DESIGN**: Randomized prospective comparative Study
- **STUDY AREA**: The Oxford Medical College Hospital and Research Centre, Bangalore
- **DURATION OF STUDY**: One year
- **STUDY POPULATION**: Patients undergoing elective surgery requiring endotracheal intubation

SAMPLE SIZE:

Sample size is calculated by using the comparison of proportion formula

Where p1= 27. %5 and p2=57.5% (add formula)

n=84, to accommodate any exclusion, 90 patients were selected, so from each group 30 patients were selected.

$$p = \frac{p_1 + rp_2}{1+r}$$

$$n = \frac{\left[Z_{1-\alpha/2}\sqrt{(r+1)p(1-p)} + Z_{1-\beta}\sqrt{rp_1(1-p_1)+p_2(1-p_2)} \right]^2}{r(p_2-p_1)^2}$$

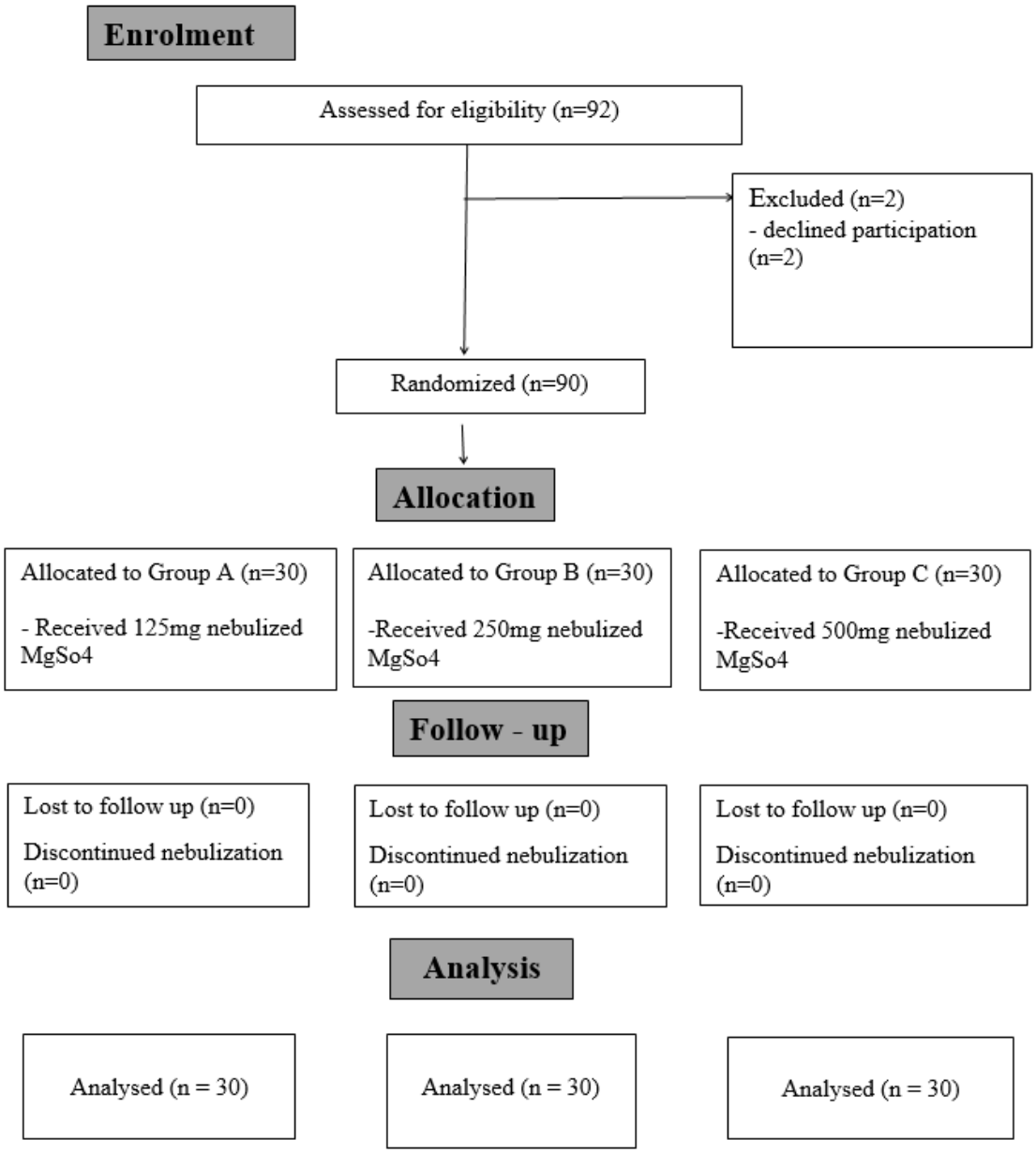
INCLUSION CRITERIA:

- Patients undergoing elective surgery of approximately 2 hours duration requiring endotracheal intubation.
- Age: 18 years and above
- ASA physical status I and II
- Patients giving valid written informed consent

EXCLUSION CRITERIA:

- Patients having anticipated difficult intubation
- Emergency surgery
- Patients having neuromuscular disease.
- Patients undergoing laparoscopic surgeries and neck surgeries.
- Patients who will require post-operative ventilation.
- Patients having allergy and hypersensitivity to the study drug.

CONSORT FLOW CHART



METHODOLOGY

After institutional ethical committee clearance, informed written consent was obtained from all patients who met the inclusion criteria. Patients were randomized into group A (125mg MgSO4), group B(250 mg MgSO4) and group C (500mg MgSO4) according to sealed envelope method . Demographic data like age, sex, height and weight were recorded. All patients were premedicated with Tab Alprazolam0.25mg and tab Ranitidine150mg on night before surgery and on the morning of surgery. Routine nil per oral guidelines were followed.

Group “A”-Patients in group A were nebulized with 125 mg isotonic magnesium sulphate (0.5ml of 25% MgSo4 and 4.5ml normal saline).

Group “B”-Patients in group B were nebulized with 250 mg isotonic magnesium sulphate (1ml of 25% MgSo4 and 4 ml of normal saline).

Group "C"- Patients in group C were nebulized with 500mg isotonic magnesium sulphate (2ml of 25%MgSo4 and 3ml of normal saline).

In the preoperative room, ECG, pulse oximeter and non-invasive BP monitor were connected and with strict asepsis IV access was secured.

Patients included in the study were nebulized with respective doses of magnesium sulphate for 15 minutes before induction of anaesthesia. Upon arrival in the operation theatre, standard monitors like ECG, pulseoximeter,non-invasive BP monitor were connected. Patients were premedicated with inj glycopyrollate 3mcg/kg, inj ondansetron 0.08 mg/kg and inj midazolam 20 mcg/ kg. Anaesthesia was induced with inj.fentanyl 2mcg/kg and inj.propofol 2mg/kg. Endotracheal intubation was facilitated by vecuronium 0.1mg/kg,trachea was intubated with soft seal cuffed sterile polyvinyl chloride endotracheal tube (Portex Limited CT 21, 6JL, UK) 7 mm inner diameter for female and 8 mm for male patients. The tracheal tube cuff was inflated with air till audible leak was absent. The cuff pressure was checked after intubation using hand held endotracheal cuff pressure monitor (Portex Cuff Inflator/Pressure Gauge, SIMS Portex, Hythe, Kent, and UK) and then every 30min till end of surgery and pressure was maintained at 20 cm of H2O.

Anaesthesia was maintained with oxygen: air (2:1) with 1% of isoflurane, intermittent doses of vecuronium and fentanyl as required. Last dose of vecuronium was given 40 minutes prior to extubation. At the end of surgery, the muscle relaxation was reversed with a combination of Neostigmine 0.05 mg/kg and Glycopyrrolate 0.01 mg/kg. Patients were extubated after meeting regular extubation criteria. Tracheal extubation was done following gentle suctioning of oral secretions by a 14F soft suction catheter and patients were shifted to post operative anaesthesia care unit and incidence of postoperative sore throat at rest and on swallowing was assessed at 0, 2, 4 ,12 and 24 hours postoperatively. In the postoperative ward, patients were also monitored for any drug related side effects. The patient and the investigator were blinded towards the study drug.

Statistical Methods:

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. The following assumptions on data is made, Assumptions: 1. Dependent variables should be normally distributed, 2. Samples drawn from the population should be random, Cases of the samples should be independent

The one-way analysis of variance (ANOVA) is employed to determine whether there are any statistically significant differences between the means of three or more independent (unrelated) groups. The one-way ANOVA compares the means between the groups you are interested in and determines whether any of those means are statistically significantly different from each other. Specifically, it tests the null hypothesis:

$$H_0: \mu_1 = \mu_2 = \mu_3 = \cdots = \mu_k$$

where μ = group mean and k = number of groups. If, however, the one-way ANOVA returns a statistically significant result, we accept the alternative hypothesis (H_A), which is that there are at least two group means that are statistically significantly different from each other.

Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small.

Significant figures

+ Suggestive significance (P value: 0.05<P<0.10)
* Moderately significant (P value:0.01<P ≤ 0.05)
** Strongly significant (P value: P≤0.01)

Statistical software:

The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc**.**

RESULTS:

Table 1: Demographic data.

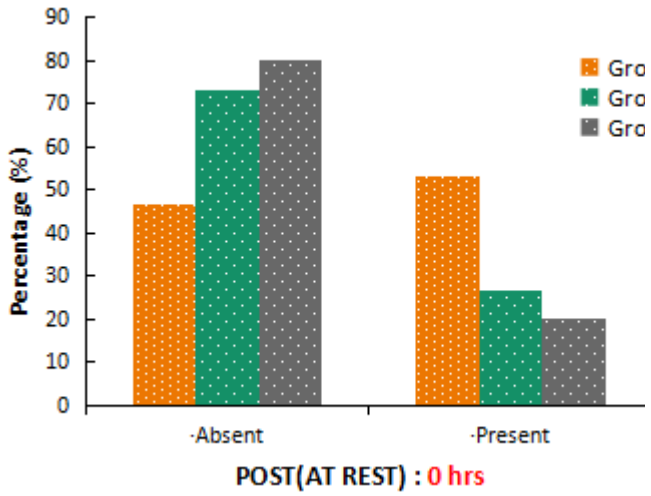
Variables	**Group A**	**Group B**	**Group C**	**P Value**	**Statistical test applied**
Age (years)(mean +/- SD)	37.47+/-11.49	34.83+/-12.14	36.87+/-10.2	0.641	ANOVA
Gender (M/F)	13/17	16/14	11/19	0.425	Chi Square
BMI(Kg/m^2)(mean +/- SD)	23.9+/-2.34	22.57+/-2.37	23.33+/-2.37	0.096	Student t
Duration of surgery (Mins) (Mean +/- SD)	155.67+/-22.2	154.67+/-25.83	160.33+/-21.25	0.602	Student t

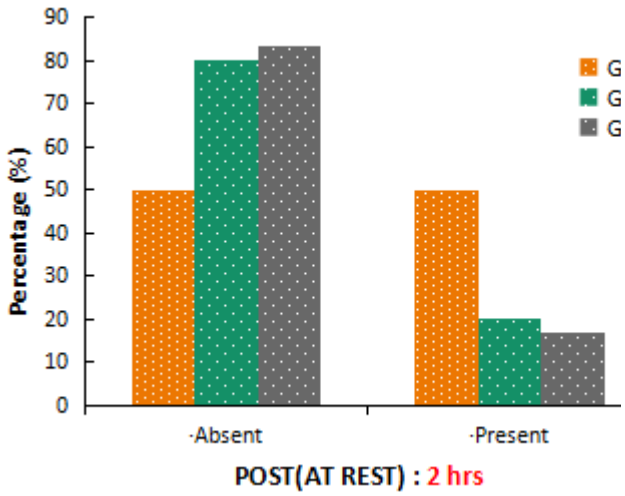
The demographic variables like age, gender and body mass index were comparable among all the three groups. With respect to duration of surgery there was no significant difference among all the three groups.

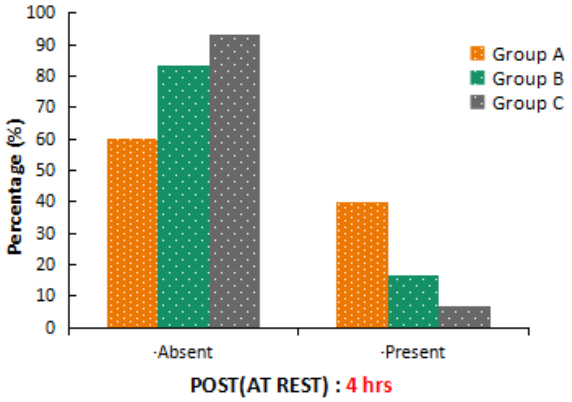
Table 2: Postoperative sore throat "at rest"

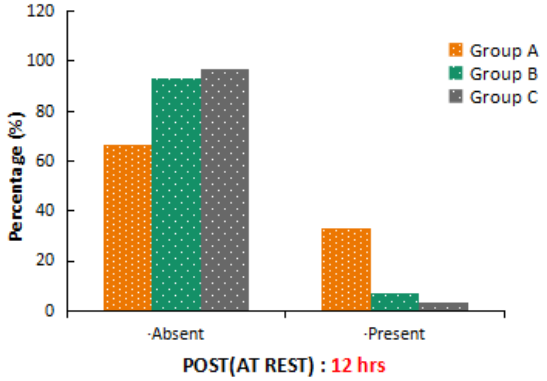
POST(AT REST)	RESULTS			SIGNIFICANCE		
	Group A	Group B	Group C	A vs B	A vs C	B vs C
0 hrs						
Absent	14(46.7%)	22(73.3%)	24(80%)	0.065+	0.015*	0.764
Present	16(53.3%)	8(26.7%)	6(20%)			
2 hrs						
Absent	15(50%)	24(80%)	25(83.3%)	0.030*	0.013*	1.000
Present	15(50%)	6(20%)	5(16.7%)			
4hrs						
Absent	18(60%)	25(83.3%)	28(93.3%)	0.080+	0.006**	0.423
Present	12(40%)	5(16.7%)	2(6.7%)			
12 hrs						
Absent	20(66.7%)	28(93.3%)	29(96.7%)	0.021*	0.005**	1.000
Present	10(33.3%)	2(6.7%)	1(3.3%)			
24hrs						
Absent	24(80%)	28(93.3%)	30(100%)	0.254	0.023*	0.491
Present	6(20%)	2(6.7%)	0(0%)			
Total	30(100%)	30(100%)	30(100%)			

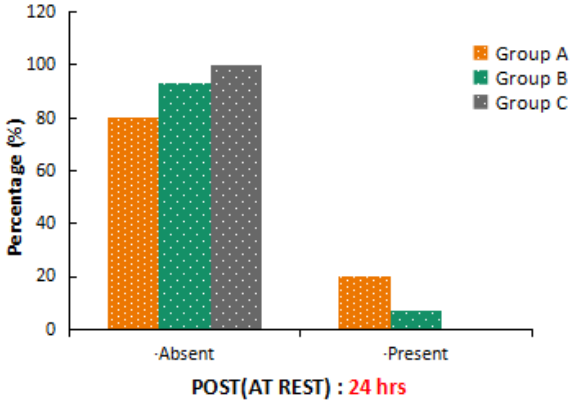
Chi-Square Test/Fisher Exact Test











Incidence of POST at rest was high in group A at all time points.

There was a statistically significant difference between group A and group B at 2 hours(p= 0.030) and 12 hours(p= 0.021).

Between group A and group C, significant difference was observed at all time points.

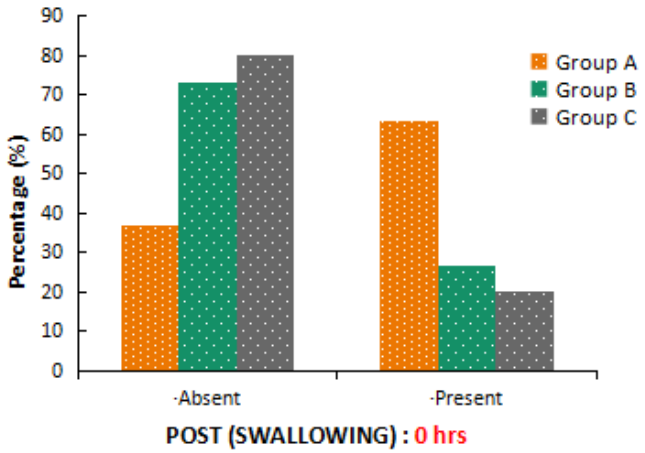
No significant difference was observed in group B and group C at all time points.

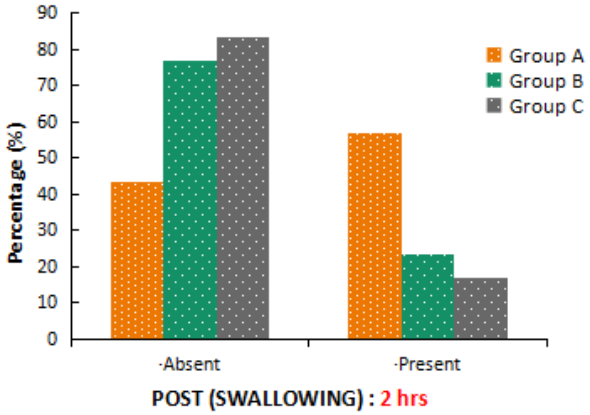
Table 3: Postoperative sore throat "on swallowing "

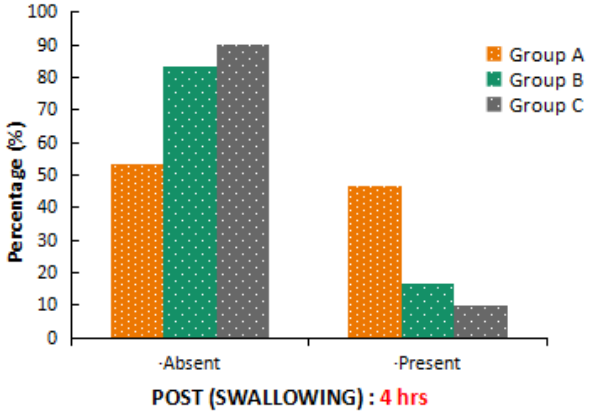
POST (SWALLOWING)	Group A	Group B	Group C	SIGNIFICANCE		
				A vs B	A vs C	B vs C
0 hrs						
Absent	11(36.7%)	22(73.3%)	24(80%)	0.009**	<0.001**	0.764
Present	19(63.3%)	8(26.7%)	6(20%)			
2 hrs						
Absent	13(43.3%)	23(76.7%)	25(83.3%)	0.017*	0.003**	0.751
Present	17(56.7%)	7(23.3%)	5(16.7%)			
4hrs						

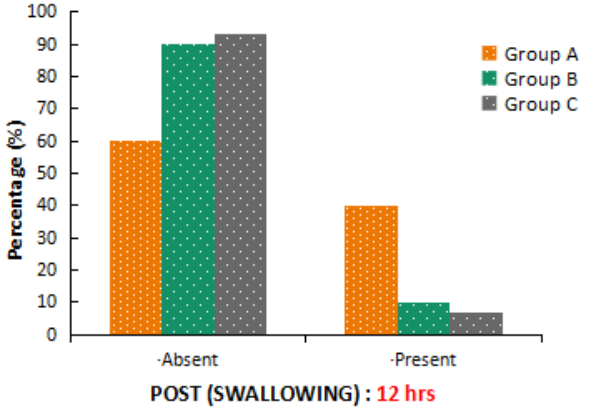
Absent	16(53.3%)	25(83.3%)	27(90%)	0.026*	0.004**	0.706
Present	14(46.7%)	5(16.7%)	3(10%)			
12 hrs						
Absent	18(60%)	27(90%)	28(93.3%)	0.008**	0.004**	1.000
Present	12(40%)	3(10%)	2(6.7%)			
24hrs						
Absent	22(73.3%)	28(93.3%)	29(96.7%)	0.079+	0.025*	1.000
Present	8(26.7%)	2(6.7%)	1(3.3%)			
Total	30(100%)	30(100%)	30(100%)			

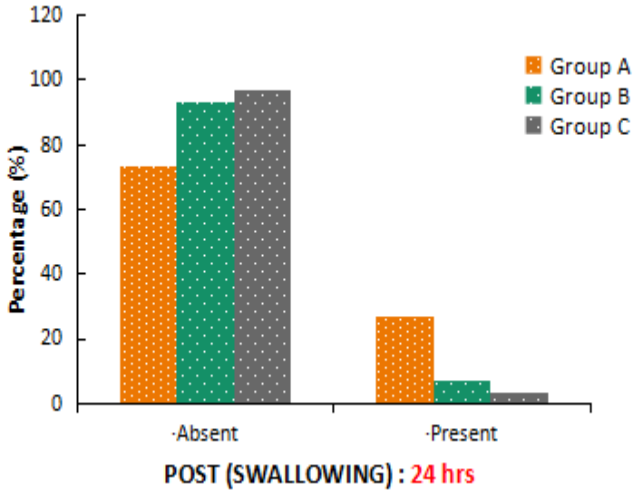
Chi-Square Test/Fisher Exact Test











Incidence of post at swallowing was high in group A at all time points.
There was a statistically significant difference observed between group A and B at 0,2,4 and 12 hours.
Between group A and group C, there was a significant difference observed at all time points.
No significant difference was observed between group
B and group C at all time points.

DISCUSSION

Magnesium sulphate is a N- Methyl- D-Aspartate (NMDA) receptor antagonist with local analgesic and anti-inflammatory properties. [5] NMDA receptors are present in central and peripheral nervous system. [10] Magnesium sulphate is administered as gargle, lozenges or nebulization before surgery for attenuating POST.

In many studies gargle has been the preferred route of drug administration, but it has its own limitations with patient variability and taste of the medication being the major confounding factor. Magnesium sulphate nebulization helps in providing equal and effective distribution of the drug throughout the pharynx and upper respiratory tract [11]. This route of administration is preferred as it is simple, economical, better patient adherence and the effective volume of drug required is less. [12]

In this study, we have compared three different strengths of magnesium sulphate (125 mg,250 mg and 500 mg) pre-operatively to prevent POST.

We observed that, the incidence of POST at rest and swallowing was lower in group C (500mg MgSO4) at all time points when compared to group A (125mg MgSO4) and group B (250 mg MgSO4). No incidence of POST at rest was observed at 24 hours with group C.

Despite the fact that group B had decreased incidence of POST at all time points, it was not statistically significant when compared to group C.

Similar results were seen the study conducted by Rajan et al [11]

Kamel et al and Mostafa et al concluded that 250 mg MgSO4 nebulization pre-operatively reduced the incidence and severity of POST. [13,14]

In our study there was no adverse effects seen due to MgSO4 as the amount of drug absorbed systemically is minimal. [15]

Conclusion

We conclude that 500mg MgSO4 nebulization administered pre-operatively is superior in attenuating the incidence of POST when compared to 250mg and 125mg.

Limitation

The drawback of our study is that the serum magnesium levels were not measured.

REFERENCES:

1. Sumathi PA, Shenoy T, Ambareesha M, Krishna HM(2008). Controlled comparison between betamethasone gel and lidocaine jelly applied over tracheal tube to reduce postoperative sore throat, cough, and hoarseness of voice. Br J Anaesth 2008; 100:215-8.
2. Christensen AM, Willemoes-Larsen H, Lundby L, Jakobsen KB(1994). Postoperative throat complaints after tracheal intubation. Br J Anaesth; 73:786–7.
3. McHardy FE, Chung F(1999). Postoperative sore throat; cause, and treatment. Anaesthesia; 54: 444-53.
4. Padma T, Raju B, Raviraj GS(2020). The Effect of Nebulized Magnesium Sulphate on The Incidence of Postoperative Sorethroat. Anesthesia. Acad. Anesthesiol. Int; 5(1):185-190.
5. Dr Kumar et al(2020). The Effect of Nebulised Magnesium Sulphate on the Incidence of Post Operative Sore Throat. JMSCR; vol 08, Issue 08: 190-196.
6. Patel N, Dhuliya S, Shah D(2022), Comparative evaluation of incidence of post operative sore throat after nebulization with ketamine and magnesium sulfate in patients undergoing general anaesthesia requiring endotracheal intubation. *Indian J Clin Anaesth*; 9(2):227-232
7. Canbay O, Celebi N, Sahin A, Celiker V, Ozgen S, Aypar U(2008). Ketamine gargle for attenuating postoperative sore throat. *Br J Anaesth*; 100(4):490–3.
8. Al-Qahtani AS, Messahel FM(2005). Quality improvement in anesthetic practice–incidence of sore throat after using small tracheal tube. *Middle East J Anesthesiol*; 18(1):179–83.
9. Agarwal A, Nath SS, Goswami D, Gupta D, Dhiraaj S, Singh PK(2006). An evaluation of the efficacy of aspirin and benzydamine hydrochloride gargle for attenuating postoperative sore throat: A prospective, randomized, single-blind study. *Anesth Analg*; 103(4):1001–3.
10. Lin CY, Tsai PS, Hung YC et al(2010). L-type calcium channels are involved in mediating the anti-inflammatory effects of magnesium sulphate. Br J Anaesth., 104(9):44–51.a
11. Rajan S, Malayil GJ, Varghese R, Kumar L. Comparison of Usefulness of Ketamine and Magnesium Sulfate Nebulizations for Attenuating Postoperative Sore Throat, Hoarseness of Voice, and Cough. Anesth Essays Res. 2017 Apr-Jun;11(2):287-293.
12. Yu J, Ren L, Min S, Yang Y, Lv F (2020) Nebulized pharmacological agents for preventing postoperative sore throat: A systematic review and network meta-analysis. PLoS ONE 15(8): e0237174.
13. Mostafa, E., Abdel Rahman, A., Mahmoud, M(2018). Magnesium Sulfate Nebulizer versus Ketamine Nebulizer in Decreasing Incidence and Severity of Post Operative Sore Throat with Endotracheal Intubation in Adults. *The Egyptian Journal of Hospital Medicine*; 73(8): 7244-7250.
14. Kamel AAF, Medhat MM, Salem DAE, Naby SMA(2022). Effect of perioperative magnesium sulfate and labetalol infusion on peripheral perfusion and postoperative pain in nasal surgery: a randomized controlled trial. Patient Saf Surg; 16(1):27.
15. Hess DR(2000). Nebulizers: Principles and performance. Respir Care; 45:609-22.