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Comparison Of Effect of Preoperative Nebulization with Magnesium Sulfate and Postoperative Nebulization with Magnesium Sulfate in Prevention of Postoperative Sore Throat in Anticipated Difficult Intubation Patients.

Dr.K.Sannihita[1], Dr.Prameela VS[2], Dr.Avinash Munirathna[3]
[1]Junior Resident, [2] Professor, Department of Anaesthesiology, Akash Institute of Medical Sciences and Research Centre, [3]Assistant Professor,Akash Institute of Medical Sciences and Research Centre.

ABSTRACT
Background:
Postoperative sore throat (POST) is a frequent complaint after endotracheal intubation, resulting in significant anguish and discomfort to the patient.Various non-pharmacological and pharmacological methods have been studied extensively for decreasing POST with varying results. Magnesium can block N-methyl-D-Aspartic acid (NMDA) receptors. However, there are not enough studies on their direct local analgesic effect .This study evaluates and compares the efficacy of preoperative nebulization with Magnesium Sulfate versus postoperative nebulization with Magnesium Sulfate in preventing the incidence and severity of postoperative sore throat (POST) in patients with anticipated difficult intubations.
Objective:
To evaluate and compare the efficacy of preoperative nebulization with Magnesium Sulfate versus postoperative nebulization with Magnesium Sulfate in preventing the incidence and severity of postoperative sore throat (POST).To evaluate side effects including hemodynamic changes, nausea, vomiting, cough, hoarseness of voice and dry mouth in both groups
Methods: *Patients in both groups received nebulization with 250 mg Magnesium Sulfate (0.5 mL) diluted in 4.5 mL saline. All selected patients were premedicated with 1 mg Midazolam. Group A received nebulization in the preoperative room for 15 minutes, starting 5 minutes before surgery. They were then taken to the operating room for general anaesthesia and endotracheal intubation, performed under ASA monitoring by a trained anaesthesiologist. After surgery, neuromuscular blockade was reversed, and patients were extubated upon meeting extubation criteria. Group B received the same nebulization protocol in the PACU, 5 minutes after arrival.The observed parameters were–number of attempts at intubation,vital signs during surgery(heart rate,NIBP,ECG,SpO_2, $ETCO_2$),duration of anaesthesia and assessment of POST.They were graded for severity of POST [grade 0- no sore throat ,grade 1-mild sore throat ,complains only on asking, grade 2-moderate sore throat,complains of sore throat by themselves, grade 3- severe sore throat,change of voice or hoarseness] every 2 hours till 24 hours.*
Results: *No significant difference was found between the two groups in terms of the number of intubation attempts ($p = 0.45$). No significant difference was found between the two groups in terms of the duration of anesthesia ($p = 0.2$).Group A (preoperative nebulization) showed significantly better control of heart rate ($p = 0.03$) and borderline better control of blood pressure ($p = 0.05$) compared to Group B(postoperative nebulization).*
Conclusion: *Both preoperative and postoperative nebulization with Magnesium Sulfate have roles in managing POST in patients with anticipated difficult intubation. Preoperative nebulization might offer more preventive benefits, whereas postoperative nebulization can be effective in managing symptoms that develop despite preventive measures.*

Keywords
Postoperative sore throat (POST), Magnesium Sulfate nebulization, airway inflammation

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I. INTRODUCTION

One of the most common complications after endotracheal intubation is sore throat. It represents 18–65% of all post-operative endotracheal intubation complications, and usually lasts 12–24 h after surgery. [1]

Although the symptoms resolve spontaneously without any treatment, prophylactic management for decreasing its frequency, and severity is desirable. [2]

There are various causative factor for post-operative sore throat (POST) which include mucosal trauma, erosion and inflammation due to endotracheal intubation, lack of airway humidity, suctioning of airway and surgical manipulation of tissue adjacent to airway. [3]

The pharmacological methods used to reduce POST includes use of Beclomethasone gel, gargling with Azulene Sulphonate, Ketamine and Licorice.[4]

The problem with gargle or lozenges is the bitter taste of the drug and the risk of aspiration while gargling which may lead to serious complications. Hence, the administration of the drug through aerosol route gained popularity. [5]

The nebulized route ensures equivalent and effectual distribution all over the pharynx till the beginning of the upper respiratory tract.[1]

It is known that N-methyl-D-aspartate (NMDA) receptors have a role in nociception and inflammation. NMDA receptors are found not only in the central nervous system but also in the peripheral nervous system and spinal cord.[5]

The antinociceptive and the anti-inflammatory properties of Magnesium Sulfate with the available data suggest it has a potential role in reducing POST.[5]

We therefore decided to compare the effect of pre-operative nebulizations and post-operative nebulizations with Magnesium Sulfate in prevention of POST in anticipated difficult intubation patients as these patients are more prone for POST.

II. METHODOLOGY

Study Design and Population

A Prospective, randomised hospital based study was conducted from April-June 2023, in the Department of Anaesthesiology, Akash Institute of Medical Sciences, after obtaining approval from instituitional ethics committee and patient informed consent.

Based on a similar study by M Reddy[6], the sample size was calculated as 60 (Group A-30, Group B-30).

A total of 60 patients with anticipated difficult intubation posted for general anaesthesia were included.

Inclusion Criteria

- ASA PS I-II
- Age 18-65 years
- Patients with anticipated difficult intubation during pre anaesthesia checkup- Mallampatti class III and IV, neck circumference >43cm, BMI >30kg/m^2, buck teeth, mouth opening < 3 cm incisor distance
- Surgeries done under GA requiring endotracheal intubation for a duration of more than 1 hour

Exclusion Criteria

- History of preoperative sore throat
- Upper respiratory tract infections
- Known allergy to the study drug
- Pregnancy
- Patients undergoing oral, nasal or throat surgeries

Anesthetic Technique

Patients subserving the above inclusion and exclusion criteria were divided into 2 groups by a randomized computer generated sampling as Group A (pre-operative nebulization) and Group B (post-operative nebulization). Both the groups receive 250mg of Magnesium Sulfate diluted to a total volume of 5mL using normal saline.

Group A received nebulization in the preoperative room for 15 minutes and were induced within 5 minutes of nebulization.

Patients were shifted to the operating room and induced within 5 minutes of nebulization. General anaesthesia (GA) was administered with standard ASA monitoring (SpO_2, HR, ECG, SBP, DBP, and $ETCO_2$). Induction was achieved using intravenous Injection Fentanyl (2 mcg/kg), Injection Propofol (2–3 mg/kg) and Injection Vecuronium (0.1 mg/kg) to facilitate endotracheal intubation. No Lignocaine gel or spray was used during intubation. KY lubricating gel was used instead of Lignocaine gel for the lubrication of the endotracheal tube. Patients were intubated by an experienced anaesthesiologist using an appropriately sized soft seal sterile high volume, low pressure cuff endotracheal tubes. Following successful intubation, bilateral equal air entry was confirmed by auscultation, and the endotracheal tube was secured. The number of intubation attempts was documented. Anaesthesia was maintained with a mixture of Oxygen, Air, and Isoflurane, with supplemental doses of Injection Vecuronium (1 mg) administered every 45 minutes or earlier as clinically indicated. Endotracheal cuff pressure was maintained between 20 cmH_2O and 25 cmH_2O throughout the procedure.

In both the groups, surgery was conducted with vital signs charting (SpO_2, HR, ECG, SBP, DBP, and $ETCO_2$). At the conclusion of the surgery, all the patients were reversed with Injection Neostigmine 2.5 mg and Injection Glycopyrrolate 0.5 mg and extubated once they started breathing spontaneously and responded to verbal commands while ensuring they did not buck or cough on the tube.
Group B received the same nebulization protocol in the PACU for 15minutes, 5 minutes after arrival.

Outcomes Measured

- Blood pressure and heart rate monitoring
- POST score at 2 hourly intervals till 24 hours according to 4-point grading scale.

0= no sore throat
1=mild sore throat (complains of sore throat on asking)
2=moderate sore throat (complains of sore throat on his/her own)
3=severe sore throat (change of voice or hoarseness, associated with pain)

- Side effects such as nausea, vomiting, dry mouth, cough.

III. RESULTS

Demographics

A total of 60 patients undergoing surgeries done under GA requiring endotracheal intubation for a duration of more than 1 hour were enrolled and randomized equally into two groups: Group A and Group B. Analysis revealed no statistically significant differences observed between the groups in terms of the distribution of study subjects.

Table-1

Characteristic	Group A (pre-operative nebulization, n=30)	Group B (post-operative nebulization, n=30)	p-value
Age (years, mean ± SD)	43.8 ± 13.38	38.36 ± 11.94	0.10
Gender (Female/Male)	19/11	20/ 10	0.50
ASA Grade I / II	20 / 10	21 / 09	0.793

Number of attempts at intubation, time taken for intubation and endotracheal cuff pressure
No statistical significance was observed in terms of intubation time, number of intubation attempts and endotracheal cuff pressure in both the groups, with p values of 0.18, 0.45 and 0.34 respectively.

Table-2

Mean	A	B	p value
Time taken for intubation (minutes)	1.12 ± 0.38	1.50 ± 1.48	0.18
Number of attempts	2.3±0.7	2.6 ± 0.8	0.45
Endotracheal cuff pressure	21.46 ± 1.16	21.20 ± 0.99	0.34

Duration of surgery
Analysis of variation of duration of anaesthesia among group A and B using independent t test showed insignificant difference, with a p value of 0.2. Group A had a mean of 180± 20 minutes and Group B had a mean of 185 ± 22 minutes.

Table-3

	A	B	p value
Duration of anaesthesia (minutes)	180 ± 20	185 ± 22	0.2

Hemodynamic changes
Analysis of variation of heart rate and blood indicated Group A (preoperative nebulization) showed significantly better control of heart rate (p = 0.03) and borderline better control of blood pressure (p = 0.05) compared to Group B (postoperative nebulization).

Table-4

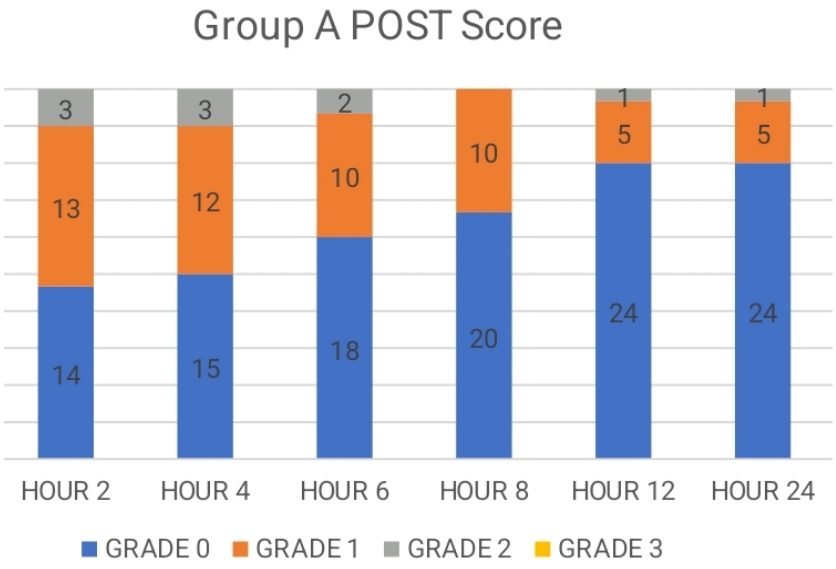
	A (Mean ± SD)	B (Mean ± SD)	p value
HR bpm	76 ± 8	80 ± 10	0.03
BP mmHg	120/80 ± 10	125/85 ± 12	0.05

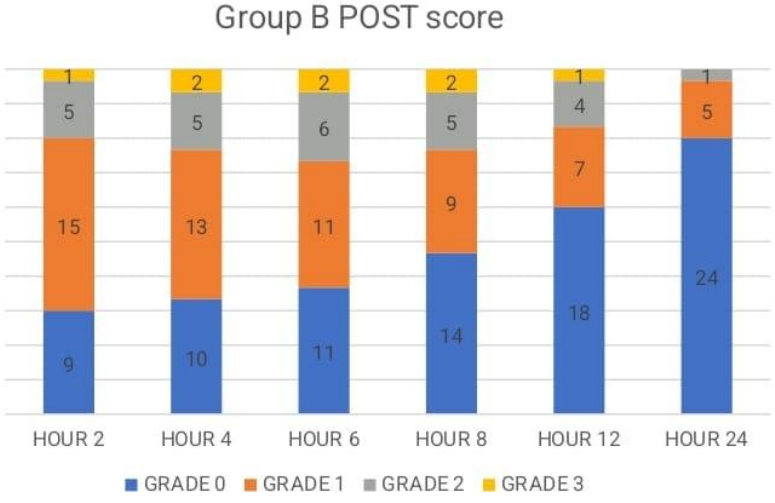
POST score
Group A consistently shows a higher percentage of patients with Grade 0 POST (no sore throat) at all time points, compared to Group B. Conversely, Group B tends to have higher percentages in Grades 1–3, indicating more discomfort.

Statistical significance (p-values) is observed at earlier time points 2 hours (p = 0.04), 4 hours (p = 0.05), and 6 hours (p = 0.02) suggesting a significant difference between the groups in early postoperative sore throat severity. However, this difference diminishes over time, as seen with non-significant p-values at 8, 12, and 24 hours.

Table-5

	2		4		6		8		12		24	
	A N(%)	B N(%)	A N(%)	B N(%)	A N(%)	B N(%)	A N(%)	B N(%)	A N(%)	B N(%)	A N(%)	B N(%)
Grade 0	14 (46.7)	9 (30.0)	15 (50.0)	10 (33.3)	18 (60.0)	11 (36.7)	20 (66.7)	14 (46.7)	24 (80.0)	18 (60.0)	25 (83.3)	24 (80.0)
Grade 1	13 (43.3)	15 (50.0)	12 (40.0)	13 (43.3)	10 (33.3)	11 (36.7)	10 (33.3)	9 (30.0)	5 (16.7)	7 (23.3)	4 (13.3)	5 (16.7)
Grade 2	3 (10.0)	5 (16.7)	3 (10.0)	5 (16.7)	2 (6.7)	6 (20.0)	0	5 (16.7)	1 (3.3)	4 (13.3)	1 (3.3)	1 (3.3)
Grade 3	0	1 (3.3)	0	2 (6.7)	0	2 (6.7)	0	2 (6.7)	0	1 (3.3)	0	0
p value	0.04		0.05		0.02		0.06		0.07		0.08	





Adverse effects
The incidence of adverse effects in our study was nil, with no reported cases of nausea, vomiting, dry mouth, cough.

IV. DISCUSSION

Widespread recognition of the undertreatment of sore throat by clinicians has led to the development of preemptive strategies for its alleviation.[7]

Although many preventive protocols have been offered, none has gained much attention.[7]

Increasing amounts of experimental data show that NMDA receptors are found not only in the central nervous system but also in the peripheral nerves. Peripherally administered NMDA receptor antagonists are involved with antinociception and anti-inflammatory cascade.[8]

Magnesium has a non-competitive antagonistic action on NMDA receptors. It has antinociceptive effects that are primarily based on the inhibition of calcium entry into the cell. Magnesium exerts its antiinflammatory effect by decreasing the release of inflammatory mediators such as histamine, thromboxanes, and leukotrienes, and is useful in controlling inflammation.[9]

Yadav M et al in 2016 conducted a study to compare the efficiency of preoperative nebulization of normal saline and Magnesium Sulfate in reducing the incidence of POST. 100 patients were divided into 2 equal groups. Group A were nebulized with 3mL of normal saline and Group B were nebulized with 3mL of 225mg Magnesium Sulfate for 15 minutes. It was concluded that Magnesium Sulfate significantly reduces the incidence of POST compared to normal saline.[7]

Teymourian et al in 2014 conducted a study to compare the effects of Magnesium Sulfate and Ketamine gargle on the incidence and severity of POST in 100 patients, divided into 2 groups. Ketamine group received gargle (0.5mg/kg) and Magnesium Sulfate group received gargle (20mg/kg) 15 minutes before operation. It was concluded that the number of patients with POST was significantly lower in Magnesium Sulfate group compared to Ketamine.[10]

Brinda et al in 2020 conducted a study to analyse the effect of Magnesium Sulfate on the incidence of POST, A total of 100 patients with ASA grade 1 &2 ,posted for elective surgeries lasting for the duration of 2hrs or more and requiring tracheal intubation were divided into two groups.Group A received nebulisation with 3ml of normal saline for 15 minutes, 5 minutes before induction of anaesthesia and similarly patients in group B were nebulised with 3ml of solution containing 50 mg/mL of Magnesium Sulfate. Presence of sore throat was assessed at rest and at swallowing on immediate extubation, and at 2, 4 hours and 24 hours post extubation. It was concluded that the use of Magnesium Sulfate in the form of nebulization significantly reduces the incidence of POST compared to normal saline.[11]

In agreement with the above studies, we have given preoperative nebulization to one group and postoperative nebulization to the other with Magnesium Sulfate 250mg (0.5mL) with 4.5mL saline and have found useful reduction in POST. Preoperative nebulization with magnesium sulfate (Group A) resulted in a significantly lower incidence and severity of postoperative sore throat (POST) compared to postoperative nebulization (Group B), particularly in the early postoperative period. A higher proportion of patients in Group A reported no sore throat (Grade 0) at all time intervals. Statistically significant differences were observed at 2, 4, and 6 hours postoperatively, indicating a clear early benefit. However, this difference diminished over time, with no statistically significant differences observed at 8, 12, and 24 hours.

V. LIMITATION

- Sample size of our study is small, it may limit the generalizability of the findings to the broader population.
- The dose we used was a fixed and the least effective dose is not known.
- We did not measure the serum levels of magnesium to monitor the drug levels
- Laryngoscopy was done by different anaesthesiologists.

VI. CONCLUSION

Both preoperative and postoperative nebulization with Magnesium Sulfate have roles in managing POST in patients with anticipated difficult intubation. Preoperative nebulization might offer more preventive benefits, whereas postoperative nebulization can be effective in managing symptoms that develop despite preventive measures.

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