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Evaluation of Role of Nebulized Magnesium Sulphate on the Incidence of Sore Throat in Patients Intubated with Cuffed Endotracheal Tube - A Prospective Double Blinded Study

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Abstract: ***Background and aims: Postoperative sore throat (POST) is a well - recognized complication after general anaesthesia (GA). Numerous nonpharmacological and pharmacological measures have been used for attenuating POST with variable success. The present study was conducted to compare the efficiency of preoperative nebulization of magnesium sulphate and normal saline in reducing the incidence of POST, POC (post operative cough), POH (post operative hoarseness of voice) following GA. Study design: This study was a prospective randomized, double - blinded study. Materials and Methods: Following institutional ethical committee approval and written informed consent, a prospective randomized double blinded study was conducted in 100 cases divided in to two equal groups. Patients included in the study were of either gender belonging to American Society of Anaesthesiologist (ASA) status 1 or 2 undergoing elective surgery for less than 2 hours duration requiring tracheal intubation. Patients in Group 1 were nebulized with 3ml solution containing 250 mg of magnesium sulphate and Group 2 were nebulized with 3ml of normal saline for 15 mins, 5 mins before induction of anaesthesia. The incidence Post operative sore throat (POST), post operative cough (POC), post operative hoarseness of voice (POH) were evaluated at 0, 4, 8, 12, 24 hours in the post operative period. Results and discussion: The findings of this study showed that preoperative nebulization with magnesium sulfate had decreased the incidence of sore throat compared to the control group at 0hrs ($p<0.002759$); at 4hrs ($p<0.00001$); 8hrs ($p<0.00001$); 12hrs ($p<0.00001$) and at 24hrs ($p<0.00001$). There was significant reduction in POC at 0hr ($p=0.009244$) after nebulization with magnesium sulfate than in the normal saline group. The incidence of hoarseness was significantly reduced with the use of magnesium sulfate compared to normal saline at 8^{th} hours. Conclusion: Preoperative magnesium sulfate nebulization is considered to be effective in reducing post operative sore throat compared to normal saline. Magnesium sulfate nebulization in the pre operative period has reduced the incidence of post operative cough at 0hrs and post operative hoarseness at 8hrs.***

Keywords: Magnesium sulphate, Nebulization, Post operative sore throat, Post operative cough, Post operative hoarseness of voice

1. Introduction

Sore throat is a common complication in post operative period after tracheal intubation, and one of the most common undesirable anaesthesia associated problems. The incidence of post operative sore throat (POST) has been found to be as high as 21% - 65%. The factors known for post operative sore throat include age, sex, type as well as duration of surgery, size of endo - tracheal tubes, intracuff pressures, mechanical injury during laryngoscopy and intubation.

Various measures have been attempted to reduce the incidence of POST (post operative sore throat), some among these are non - pharmacological and some are pharmacological. Awareness and knowledge about the potential risk factors and precautions may thereby help to reduce this complication.

It is an established fact that NMDA receptors (N - methyl D - aspartate) play a role in nociception and inflammation and these receptors are known to be present in central and peripheral nervous system. NMDA antagonists such as magnesium sulfate and ketamine work on peripheral nerve endings in the mucosal lining of the upper airway which in turn may reduce the incidence of sore throat. Moreover, magnesium sulfate being an antagonist to NMDA receptors further prevents sensitization to the peripheral pain stimulus.

Various studies have used magnesium sulfate in the form of nebulization in various doses and also in form of gargles or lozenges to reduce the incidence of POST but nebulization is considered better than other methods as it is easy to administer, smaller volume of drugs with low systemic adverse effects are delivered and better acceptance for patients may be achieved.

With this background the present study is planned to evaluate the efficacy of preoperative magnesium sulfate nebulization to reduce the incidence of post operative sore throat in patients undergoing elective surgeries with general anaesthesia with endotracheal intubation.

2. Material and Methods

Following institutional ethical committee approval and written informed consent, the prospective randomized double - blinded study was conducted in 100 cases. To accommodate any exclusion, 50 patients from each group were selected.

Patients included in study were of either gender, aged between 18 and 60 years belonging to American Society of Anaesthesiologist (ASA) 1 or 2 status undergoing elective surgery of less than 2 hours duration requiring tracheal intubation. Pregnant patient, patients having allergy or hypersensitivity with magnesium sulphate, emergency

surgery cases, patients having pre operative sore throat, cough, hoarseness of voice, having anticipated difficult airway, procedures lasting for more than 2 hours duration were excluded from the study. Patients were allocated randomly to two groups, Group 1 and Group 2. Simple randomization was done using SPSS software.

Group 1 received nebulization with 3ml of 250mg of magnesium sulfate and those allocated to Group 2 received 3ml of 0.9% normal saline nebulization in the pre operative period. Recruitment was continued till there was equal number of study participants in both the groups meeting the desired sample size, i. e., 50 participants in each group. Once the patient arrived at the OT complex patient's identity was confirmed, written informed consent was checked and an IV access was secured and intravenous fluid normal saline as per protocol were started. Patient was then shifted to the pre operative room where the monitor (ECG, NIBP and SpO2) was connected.

Both, patients in each group and observer i. e. anaesthesiologist who were anaesthetizing the cases and recording the scores blinded for the study. Anaesthesiologist not associated with the management of the case and not participating in the study prepared the study drug and nebulized the patient in preoperative area. In case of Group 1, magnesium sulfate was prepared for nebulization. Patients were pre oxygenated for 3 - 5minutes. Patients were given Glycopyrrolate at 0.01mg/kg. Induction was done with propofol at 2mg/kg. After ensuring bag mask ventilation, neuromuscular blockade was facilitated by succinylcholine at 1.5mg/kg. Laryngoscopy was done using laryngoscope blade size 3 or 4 as per patient. Endotracheal intubation was done by anaesthesiologist who was blinded for the study. The patient intubated with endotracheal tube (ETT) was connected to the ventilator with tidal volume as per body weight, respiratory rate and I: E ratio set as per patient. The trachea was intubated with cuffed soft seal sterile polyvinyl chloride tracheal tube of adequate size. The tracheal tube cuff was inflated till the point where no leakage was obtained with assisted mechanical ventilation. Thereafter, cuff pressure was checked with airway pressure gauge and targeted to be kept below 20mm Hg. Endotracheal tube cuff pressure was monitored at interval of every 15minutes and was kept below the targeted value. GA was maintained with oxygen and air in a ratio of 50% each and an inhalation anaesthetic agent isoflurane along with intermittent doses of non - depolarizing muscle relaxant vecuronium every 20 min. The last dose of non - depolarizing muscle relaxant vecuronium was given 20 min prior to extubation. Residual neuromuscular blockade was reversed with IV neostigmine 0.05mg/kg and glycopyrrolate 0.01mg/kg. Extubation was done on return of spontaneous ventilation and when patient starts responding to commands. Analgesia was maintained with multimodal analgesia. Patients were then shifted to post anaesthesia care unit.

Patients were assessed just after shifting to the post operative care unit by the primary investigator. This was considered as 0 hours. Scores of post - operative sore throat (POST); post operative cough (POC) and post operative hoarseness (POH) was documented based on the severity scoring (score 0, 1, 2, 3) as described in post operative assessment grades. The same primary investigator documented the grades of severity at 4hours, 8hours, 12hours, 24 hours for POST, POC and POH in the ward.

Post Operative Assessment - Severity [10]	Grade
POST OPERATIVE SORE THROAT	
No sore throat at any time since the operation	0
Mild –patient answered in the affirmative when asked about sore throat	1
Moderate - patient complained of sore throat on his/her own	2
Severe - patient is in distress	3
POST OPERATIVE COUGH	
No cough at any time since the operation	0
Minimal	1
Moderate	2
Severe	3
POST OPERATIVE HOARSENESS OF VOICE	
No hoarseness any time since the operation	0
Mild - minimal change in quality of speech. Patient answers in affirmative only when enquired about	1
Moderate - moderate change in quality of speech of which the patient complains on his/her own	2
Severe - gross change in the quality of voice perceived by the observer	3

3. Result

Study was conducted in 100 patients where 50 patients were in Group 1 where magnesium sulfate was used for nebulization. In this group, 19 patients were males and 31 were females (19+31=50). In the remaining 50 patients who were in Group 2, where normal saline was used for nebulization, 18 patients were male and 32 females (18+32=50).

Demographic characteristic of the study population has been represented in Table 1, 2 and 3.

Demographic and Clinical Characteristics of Study Population:

Table 1: Age in Years

Sex	Mean ± SD	
	Group 1: Magnesium Sulfate	Group 2: Normal Saline
Male	40.89 ± 8.19	38.72 ± 9.34
Female	37.51 ± 8.29	39.59 ± 7.94

Table 2: Weight in Kg

Sex	Mean ± SD	
	Group 1: Magnesium Sulfate	Group 2: Normal Saline
Male	72.84 ± 6.04	75.91 ± 6.89
Female	59.87 ± 5.23	63.1 ± 6.92

Table 3

	Mean ± SD		p Value
	Group 1: Magnesium Sulfate	Group 2: Normal Saline	
Age (Years)	38.8 ± 8.33	39.28 ± 8.91	0.7808
Weight (Kg)	64.80 ± 8.40	67.71 ± 9.24	0.0691

Table 4: Comparison of Post Operative Sore Throat between the Magnesium Sulphate (Group1) and Normal Saline (Group 2) at 0 HRS, 4HRS, 8HRS, 12HRS, 24HRS:

Post Operative Sore Throat	Score 0	Score 1	Score 2	Score 3	Chi square	P value	P<0.05
Group 1 (0 hours) $MgSO_4$	21 (42%)	25 (50%)	4 (8%)	0 (0.00%)	14.1025	<0.002759	Significant at p<0.05
Group 2 (0 hours) NS	5 (10%)	36 (72%)	8 (16%)	1 (2%)			
Group 1 (4 hours) $MgSO_4$	7 (14%)	36 (72%)	7 (14%)	0 (0.00%)	40.1067	<0.00001	Significant at p<0.05
Group 2 (4 hours) NS	0 (0.00%)	12 (24%)	37 (74%)	1 (2%)			
Group 1 (8 hours) $MgSO_4$	8 (16%)	32 (64%)	10 (20%)	0 (0.00%)	60.3514	<0.00001	Significant at p<0.05
Group 2 (8 hours) NS	0 (0.00%)	2 (4%)	48 (96%)	0 (0.00%)			
Group 1 (12hrs) $MgSO_4$	14 (28%)	28 (56%)	8 (16%)	0 (0.00%)	45.548	<0.00001	Significant at p<0.05
Group 2 (12hours) NS	0 (0%)	9 (18%)	41 (82%)	0 (0%)			
Group 1 (24 hours) $MgSO_4$	25 (50%)	24 (48%)	1 (2%)	0 (0.00%)	34.1375	<0.00001	Significant at p<0.05
Group 2 (24 hours) NS	0 (0.00%)	36 (72%)	14 (28%)	0 (0.00%)			

Table 5: Comparison of Post Operative Cough between Magnesium Sulphate (Group 1) and Normal Saline (Group 2) at 0HR, 4HRS, 8HRS, 12HRS, 24HRS:

Post Operative Cough	Score 0	Score 1	Score 2	Score 3	Chi Square	P value	P<0.05
Group 1 (0 hours) $MgSO_4$	46 (92%)	4 (8%)	0 (0%)	0 (0%)	6.7751	0.009244	Significant at p<0.05
Group 2 (0 hours) NS	36 (72%)	14 (28%)	0 (0%)	0 (0%)			
Group 1 (4 hours) $MgSO_4$	48 (96%)	2 (4%)	0 (0%)	0 (0%)	3.0525	0.80613	Not Significant at p<0.05
Group 2 (4 hours) NS	43 (86%)	7 (14%)	0 (0%)	0 (0%)			
Group 1 (8 hours) $MgSO_4$	50 (100%)	0 (0%)	0 (0%)	0 (0%)			
Group 2 (8 hours) NS	50 (100%)	0 (0%)	0 (0%)	0 (0%)			
Group 1 (12 hours) $MgSO_4$	50 (100%)	0 (0%)	0 (0%)	0 (0%)			
Group 2 (12 hours) NS	50 (100%)	0 (0%)	0 (0%)	0 (0%)			
Group 1 (24 hours) $MgSO_4$	50 (100%)	0 (0%)	0 (0%)	0 (0%)			
Group 2 (24 hours) NS	50 (100%)	0 (0%)	0 (0%)	0 (0%)			

Table 6: Comparison of Post Operative Hoarseness of Voice Between Magnesium Sulfate (Group1) and Normal Saline (Group 2) aT 0hrs, 4hrs, 8hrs, 12hrs, 24hrs:

Post Operative Hoarseness	Score 0	Score 1	Score 2	Score 3	Chi Square	P value	P<0.05
Group 1 (0 hour) $MgSO_4$	18 (36%)	32 (64%)	0 (0%)	0 (0%)	5.1529	0.07603	Not Significant at p<0.05
Group 2 (0 hour) NS	9 (18%)	37 (74%)	4 (8%)	0 (0%)			
Group 1 (4 hours) $MgSO_4$	21 (42%)	29 (58%)	0 (0%)	0 (0%)	2.4058	0.30032	Not Significant at p<0.05
Group 2 (4 hours) NS	13 (26%)	35 (70%)	2 (4%)	0 (0%)			
Group 1 (8 hours) $MgSO_4$	47 (94%)	3 (6%)	0 (0%)	0 (0%)	6.00775	0.0478	Significant at p<0.05
Group 2 (8 hours) NS	39 (78%)	10 (20%)	1 (2%)	0 (0%)			
Group 1 (12hours) $MgSO_4$	49 (98%)	1 (2%)	0(0%)	0 (0%)	3.8402	0.05004	Not significant at p<0.05
Group 2 (12hours) NS	44 (88%)	6 (12%)	0 (0%)	0 (0%)			
Group 1 (24hours) $MgSO_4$	49 (98%)	1 (2%)	0 (0%)	0 (0%)	1.0417	0.3074	Not significant at p<0.05
Group 2 (24hours) NS	47 (94%)	3 (6%)	0 (0%)	0 (0%)			

4. Discussion

Post operative sore throat (POST); cough (POC) and hoarseness (POH) of voice are common; may be self - resolving after tracheal intubation. Despite being self - resolving, it results in discomfort to the patient, hence undesirable. Patients who are undergoing large abdominal or thoracic surgeries, sore throat may cause hinderance in clearing and coughing out of secretions.

In the present study, the effect of preoperative nebulization with magnesium sulfate (3ml of 250mg) and normal saline (3ml of 0.9%) to decrease the incidence of post operative sore throat (POST), post operative cough (POC) and post operative hoarseness (POH) for ASA grade 1 and 2 patients between 18 to 60years of age of either gender undergoing surgeries for less than 2hrs duration were compared. The findings of this study showed that preoperative nebulization with magnesium sulfate had decreased the incidence of sore throat compared to the control group at 0hrs ($p<0.002759$); at 4hrs ($p<0.00001$); 8hrs ($p<0.00001$); 12hrs ($p<0.00001$) and at 24hrs ($p<0.00001$).

Kumar BG et al conducted a study to compare the efficiency of preoperative nebulization of normal saline and magnesium sulphate in reducing the incidence of POST following GA. They found that MgSO4 significantly reduced the incidence of POST compared to normal saline.

Brindha R et al conducted a study to assess the efficacy of magnesium sulphate nebulization in reducing the incidence of postoperative sore throat by comparing preoperative nebulization with 3ml normal saline and 3ml solution containing 50mg/ml of $MgSO_4$. They concluded that the use of magnesium sulfate in the form of nebulization as a pre - medication agent significantly reduced the incidence of POST compared to normal saline.

Kamel AAF, Amin OAI et al conducted study on effect of preoperative nebulized magnesium sulphate and lidocaine on the prevention of post operative sore throat. They found that Preoperative 250 mg nebulized magnesium sulfate had more protection against post - intubation sore throat than 100 mg nebulized lidocaine.

The above study results were similar to the present analytical study which documented that preoperative magnesium sulphate nebulization decreases the incidence of POST and thereby patients do not experience the discomfortness for next 24hrs.

Incidence of post operative cough (POC) and post operative hoarseness (POH) following pre operative nebulization with magnesium sulfate were the secondary outcomes which were evaluated in this study. It was observed that there was significant reduction in POC at 0hr (p=0.009244) after nebulization with magnesium sulphate, the study drug, than in the normal saline group. At 4th hour incidence of POC decreased in both groups but the difference was not significant (p=0.80613). None of the patients in both the groups had any evidence of POC from 8th hrs.

Ashwini H et al however had found that no patients had cough with the use of dexamethasone nebulization and only 1 patient had cough at 4th and 8th hour with use of magnesium sulfate nebulization.

The incidence of cough reduced with time as inflammatory effects subsides. However, one case was reported at 4th and 8th hour, as documented in the above referred study. This difference with magnesium sulphate with our study, with no incidence of cough, may be due to strict maintenance of cuff pressure below 20mm Hg.

Incidence of post operative hoarseness to voice was also evaluated between the two groups. Change in the incidence of hoarseness of voice in the patients receiving the study drug, that is, magnesium sulphate, and normal saline was found to be not significant at 0 hour (p=0.07603), at 4 hours (p=0.30032), at 12 hours (0.05004) and at 24 hours (p=0.3704). However, the incidence of hoarseness was significantly reduced with the use of magnesium sulfate compared to normal saline at 8th hour (p=0.478). Further evaluation showed that only score 0 at 8th hour for hoarseness to voice, when compared between the two groups, was significant (Z value=2.0174) when magnesium sulfate was used.

In the present study, cough from 8th hour and hoarseness from the 12th hour had similar prevalence in both the groups and was of mild severity. This was based on the findings that from 8th hours in cough and from 12th hours in hoarseness, maximum patients had a score 0 in both the study drug and normal saline groups.

Study done by **Ashwini et al** had also evaluated hoarseness of voice. None of the patients in their study; either with the use of dexamethasone or magnesium sulfate had hoarseness of voice.

Study done by **Rajan S et al** had taken into consideration the incidence of post operative hoarseness along with post operative cough. They concluded a reduction in the severity of both post operative sore throat and hoarseness with the use of 50mg of ketamine and 500mg of magnesium sulphate.

The above study results were similar to the present study result, from which it was inferred that preoperative magnesium sulphate nebulization was effective in reducing incidence of post operative hoarseness of voice.

5. Limitations of the Study

There are some limitations of this study which are:

- The serum magnesium level was not evaluated. The effect of plasma concentration of serum magnesium on post operative sore throat (POST), post operative cough (POC), post operative hoarseness of voice (POH) may be a contributing factor for these above conditions which could have been optimized with the dose of magnesium sulphate.
- The result may be variable in a bigger sample. This study was conducted in ASA 1 and 2. The effect of magnesium sulphate in ASA 3 and above with cardiopulmonary comorbidity was not evaluated which might have lot of implications with magnesium sulphate nebulization.
- The dose of magnesium sulfate nebulization has not been decided, as it is arbitrarily obtained from the previous studies.
- Magnesium sulphate was used in the form of nebulization. The drug absorption by this route has been shown to be variable and low (10%). [46]
- Absence of adverse events may be due to relatively low dose of study drug.

6. Conclusion

On the basis of the findings of the present study it is concluded that nebulization with 3ml of 250mg of magnesium sulfate (MgSO4) in the preoperative period is an effective drug for reducing the incidence of post operative sore throat for 24 hours following extubation.

Use of magnesium sulfate nebulization has reduced the incidence of post operative cough at 0 hour and post operative hoarseness at 8thhours.

Magnesium sulfate in the form of nebulization is easy to be administered and large doses may be avoided. This fact is supported by the studies where magnesium sulfate has been used by nebulization for treatment of acute asthma. No systemic or local adverse effects were noted. The literatures reviewed and the findings of the present study has shown that use of magnesium sulfate in various forms in the preoperative period has been found to be effective measure in reducing post operative sore throat.

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Conflicts of interest
There are no conflicts of interest.

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