VOLUME - 10, ISSUE - 11, NOVEMBER - 2021 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Anaesthesiology

EFFECT OF NEBULIZED KETAMINE AND MAGNESIUM SULPHATE ON INCIDENCE OF POSTOPERATIVE SORETHROAT – A COMPARATIVE STUDY

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ABSTRACT

BACKGROUND: Post-operative sorethroat(POST) following endotracheal intubation is a well-known complication, several methods have been tried to reduce this incidence. We are comparing the effects of nebulized ketamine & Magnesium Sulphate to reduce this.

AIMS AND OBJECTIVES: To compare the efficacy of nebulized ketamine and magnesium sulfate in reducing the incidence of POST.

MATERIALS AND METHODS: After obtaining Ethical clearance and patient consent, 40 Patients undergoing surgery under general anesthesia were randomized in to two groups. Five minutes prior to the induction of anesthesia, patients were nebulized with Group K = 1 ml of ketamine [50 mg] +4 ml normal saline, Group M = 0.5 ml of Magnesium Sulphate [250 mg] +4.5 normal saline, and Group S – 5 ml normal saline.

RESULTS: There is moderate significant difference between both the groups at 0 hr.
No significant difference between two groups at 2,6,12 and 24 hrs.

CONCLUSION: Ketamineand Magnesium sulfate reduce the incidence of POST, are almost similar in their effects.

KEYWORDS : Hoarseness of voice, ketamine, magnesium sulfate, nebulization, postoperative sore throat.

INTRODUCTION:

Post-operative Sore throat (POST) can be a side effect of general anesthesia with anendotracheal tube or a Supraglottic airway[1]. POST can cause considerable patientdiscomfort and in certain surgical procedures may lead to post-operative surgicalcomplication.

Sore throat and hoarseness were among the most common complications ofendotracheal intubation, in the first 24 hours after the procedure [2,3] .Several methods have been tried pre-operatively to reduce the incidence of post-operative sore throat (POST) with variable results.To reduce POST variousnon-pharmacological and pharmacological methods have been used.

Thepharmacological methods Include aspirin gargles, lignocaine 10%spray, IVdexamethasone, ketamine gargling ,betamethasone gel on tracheal tube, magnesiumsulfate lozenges,nebulized ketamine and magnesium Sulphate[4]. Because of bitter taste with gargle or lozenges is and the risk of aspiration while gargling which may lead to serious complications, administration of the drug through aerosol route gained popularity with good acceptance from the patients.

N-methyl-D-aspartate (NMDA) receptors are found not only in the central nervous system but also in the peripheral nervous system and spinal cord and they have a role in nociception and inflammation.[9,10]The antinociceptive and the anti-inflammatory properties of ketamine[5,6] and magnesium sulfate[9,10,11,12,13] and the available data suggests that both these drugs have a potential role in reducing POST.

Hence, in our study we aimed at using the aerosol route of magnesium sulfate and ketamine and to find their effectiveness in preventing POST.

Materials And Methods

Settings And Design:

This is a prospective, randomized, anddouble-blind study.After obtaining Ethical clearance and patient consent, Patients ofAmerican Society of Anesthesiologists physical status Classes I and II, inthe age group of 18–60 years, of either sex, undergoing surgery undergeneral anesthesia were randomized in to two groups.

Exclusion Criteria:

History of prior sore throat ;Patients using steroids or NSAIDS;Patients with COPD, asthma ;

Mallampati grade >2 ;Patients with >2 attempts of intubation .Patients were nebulized with 5 ml solution (Group K – 1 ml of ketamine [50 mg] +4 ml normal saline, Group M – 0.5 ml of Magnesium Sulphate [250 mg] +4.5 normal saline, and Group S – 5 ml normal saline).

Preoperative, intraoperative and postoperative hemodynamic monitoring was done. The POST monitoring was done at 2, 4, 8,12, and 24 hr.

Postoperatively and graded on a four-point scale (0-3).

1. 0=no sore throat
2. 1=mild sore throat (complain of sore throat on asking)
3. 2=moderate sore throat (complain of sore throat on his/her own)
4. 3=severe sore throat (change in voice or hoarseness associated with throat pain)
5. All patients were kept fasting overnight and premedicated with oral alprazolam 0.5 mg and ranitidine 150 mg on night before surgery and on the morning of surgery.

Five minutes prior to the induction of anesthesia, patients in Group k were nebulized with Group K – 1 ml of ketamine [50 mg] +4 ml normal saline, Group M – 0.5 ml of Magnesium

Sulphate [250 mg] +4.5 normal saline, and Group S – 5 ml normal saline. The solution for nebulization was administered by an anesthesiologist not associated with the management of the case. Theanesthesiologist anesthetizing the case and those recording the scores was blinded to it.

In the operation theater, after connecting the patient to standard monitoring intravenous access was secured. Anesthesia was induced with fentanyl 2 mcg/kg and thiopentone 5 mg/kg. Tracheal

Intubation was facilitated by Vecuronium 0.1 mg/kg, and the trachea intubated with soft seal cuffed sterile polyvinyl chloride tracheal tube of 7 mm inner diameter in female and 8 mm in male patients.

The tracheal tube cuff was inflated with air. Immediately after intubation, the tracheal tube cuff was inflateduntil no air leakage can be heard with a stethoscope placed over thetrachea externally, at peak airway pressure of 20 cm H2O. Ventilation was controlled, and no nasogastric tube inserted.

Anesthesia maintained with 66% nitrous oxide in oxygen with 1% ofisoflurane and intermittent doses of Vecuronium and fentanyl as required. At the end of surgery, the muscle relaxation will be reversed with a combination of neostigmine 0.05 mg/kg and Glycopyrrolate 0.01 mg/kg. The trachea was extubated.After extubation criteria were met, and the patients were shifted to post anesthesia care unit.Presence of sore throat was noted at rest and on swallowing immediately after extubation, and 2 h, 4 h, and 24 h postoperatively. In the postoperative ward, patients were monitored for any drug-related side effects.

Analysis And Statistical Methods

Study Design: A Comparative two group's clinical study Samples are gender matched with P=0.185 and are age matched with P=0.898,(Student t test)

Table 1: Mp Grade- Frequency Distribution In Two Groups Of Patients Studied

MP Grade	Group K	Group M	Total
1	7(35%)	10(50%)	17(42.5%)
2	13(65%)	10(50%)	23(57.5%)
Total	20(100%)	20(100%)	40(100%)

P=0.337, Not Significant, Chi-Square Test

Table 2: Duration Of Surgery-frequency Distribution In Two Groups Of Patients Studied

Duration of Surgery (hrs)	Group K	Group M	Total
1	0(0%)	0(0%)	0(0%)
2	2(10%)	17(85%)	19(47.5%)
3	14(70%)	3(15%)	17(42.5%)
4	4(20%)	0(0%)	4(10%)
Total	20(100%)	20(100%)	40(100%)
Mean ± SD	3.10±0.55	2.15±0.37	2.63±0.67

P<0.001**, Significant, Student t test

Table 3: Pulse Rate (bpm)-comparison In Two Groups Of Patients Studied

Pulse Rate (bpm)	Group K	Group M	Total	P value
Pre induction vitals	78.55±2.06	80.55±2.17	79.55±1.49	0.508
0 hour	83.20±2.04	87.00±2.01	85.10±1.45	0.193
2nd hour	79.45±1.73	83.20±1.76	81.33±1.25	0.137
6th hour	75.25±1.33	79.00±1.72	77.13±1.11	0.093+
12th hour	72.30±0.95	76.85±1.73	74.58±1.04	0.027*
24th hour	72.15±0.85	76.60±1.61	74.38±0.97	0.019*

* Moderately significant (P value:0.01<P 0.05)

Table 4: Map (mm Hg)-comparison In Two Groups Of Patients Studied

MAP (mm Hg)	Group K	Group M	Total	P value
Pre induction vitals	74.55±1.60	69.45±0.73	72.00±0.96	0.006**
0 hour	77.45±1.72	73.90±0.71	75.68±0.96	0.064+
2nd hour	73.20±1.21	70.40±0.48	71.80±0.68	0.038*
6th hour	71.00±0.80	68.30±0.63	69.65±0.55	0.012*
12th hour	69.25±0.68	67.95±0.57	68.60±0.45	0.151
24th hour	69.00±0.72	68.60±0.60	68.80±0.46	0.671

+ Suggestive significance (P value: 0.05<P<0.10)
* Moderately significant (P value:0.01<P 0.05)
** Strongly significant (P value : P0.01)

Table 5: Spo2 %-comparison In Two Groups Of Patients Studied

SPO2 %	Group K	Group M	Total	P value
Pre induction vitals	99.85±0.08	99.50±0.14	99.68±0.08	0.033*
0 hour	99.90±0.10	99.50±0.20	99.70±0.11	0.080+
2nd hour	99.50±0.21	98.30±0.27	98.90±0.20	0.001**
6th hour	99.30±0.22	98.55±0.29	98.93±0.19	0.048*
12th hour	99.25±0.22	98.60±0.28	98.93±0.18	0.071+
24th hour	99.15±0.20	98.55±0.29	98.85±0.18	0.091+

+ Suggestive significance (P value: 0.05<P<0.10)
* Moderately significant (P value:0.01<P 0.05)
** Strongly significant (P value : P0.01)

Table 6: Post Grading-frequency Distribution In Two Groups Of Patients Studied

Post grading	Group K (n=20)	Group M (n=20)	Total (n=40)	P value
0 Hour				
• 0	6(30%)	0(0%)	6(15%)	0.015*
• 1	7(35%)	7(35%)	14(35%)	
• 2	7(35%)	13(65%)	20(50%)	
2nd Hour				
• 0	17(85%)	12(60%)	29(72.5%)	0.155
• 1	3(15%)	8(40%)	11(27.5%)	
• 2	0(0%)	0(0%)	0(0%)	
6th Hour				
• 0	19(95%)	19(95%)	38(95%)	1.000
• 1	1(5%)	1(5%)	2(5%)	
• 2	0(0%)	0(0%)	0(0%)	
12th Hour				
• 0	20(100%)	20(100%)	40(100%)	1.000
• 1	0(0%)	0(0%)	0(0%)	
• 2	0(0%)	0(0%)	0(0%)	
24th Hour				
• 0	20(100%)	20(100%)	40(100%)	1.000
• 1	0(0%)	0(0%)	0(0%)	
• 2	0(0%)	0(0%)	0(0%)	

Chi-Square/Fisher Exact Test

30%of the patients in group K had no sore throat, 35% in each group experienced mild sore throat , 35% in group K and 65% in group M experienced moderate sore throat in the immediate postoperative period at 0 h. In Group K, 85% patients and in Group B,60% patients had no sore throat remaining experienced mild sore throat in both the groups at 2 h but not statistically significant (P = 0.155). At 6 h, 95%of patients in each groups had not experienced any sore throat and 5% of patients in each groups complained of mild sore throat and it was not statistically significant (P = 1.000). At 12 and 24hrs, none of the patients complained of sore throat, and it was not statistically significant (P = 1.000).

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

Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven`s test for homogeneity of variance has been performed to assess the homogeneity of variance. A t-test is a statistical test that is used to compare the means of two groups. It is often used in hypothesis testing to determine whether a process or treatment actually has an effect on the population of interest, or whether two groups are different from one anotherwith the null hypothesis (H_0) is that the true difference between these group means is zero and the alternate hypothesis (H_a) is that the true difference is different from zero.

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 : P0.01)

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**.**

DISCUSSION:

Post-Operative Sore throat (POST), a common complaint after tracheal intubation is being considered as a minor complication, but is a valid reason of dissatisfaction and morbidity among patient. The incidence of ST is 21–65% in patients receiving general anaesthesia (GA) with tracheal intubation[1]. Various non-pharmacological and pharmaco logical trials have been used for attenuating POST . The pharmacological methods used to reduce ST include use of beclomethasone gel, gargling with azulene sulphonate, ketamine, licorice, magnesium Sulphate, etc.

The anti-inflammatory and antinociceptive properties of magnesium sulfate is thought to be by reducing the release of inflammatory mediators such as histamine, leukotrienes, and thromboxanes.[13] Magnesium also antagonizes NMDA receptors. It is also noted that the effect of magnesium was due to the direct contact of magnesium ions with the pharyngeal wall. Ketamine being NMDA receptor antagonist produces profound antinociceptive and anti-inflammatory action by acting on peripheral NMDA receptors on the pharyngeal wall because the systemic administration of ketamine does not produce the same desired effect.[16]

A study done by Ahuja *et al*. [7] evaluated the effectiveness of nebulized ketamine on the severity of POST and concluded that ketamine nebulization significantly reduced the severity of POST at 4 h. A similar study also conducted by Aditya *et al*. [14] and found that ketamine nebulization significantly reduced the incidence and severity of POST in immediate postoperative period.

Yadav *et al*. [8]evaluated the effect of magnesium sulfate nebulization on POST at rest and swallowing and found that it significantly decreased the incidence of POST at 4 and 24 h.

Borazan *et al*. [13] also conducted a similar study with magnesium sulfate lozenges and found that it significantly reduced the incidence and severity of POST.

Jain and Barasker[15] also conducted a similar study comparing ketamine and magnesium sulfate nebulization on POST and found that both decreased the incidence of POST when compared to control group but no significant difference between the ketamine and magnesium sulfate group.

Segaran s *et al.* concluded that nebulization with ketamine 50 mg before endotracheal intubation is more effective in preventing POST at 4 and 6 h than nebulization with magnesium sulfate 250 mg.

In our study we observed that there was minimal comparision between ketamine and magnesium sulfate at 0hr in which ketamine showed better results which was moderately significant statistically(p-0.015).we have not observed any statistically significant change between both the drugs at 2,6,12 and 24 hrs.The hemodynamic parameters such as HR, MAP showed no statistically significant change in both the groups.

CONCLUSION

Ketamine and Magnesium sulfate reduce the incidence of POST, are almost similar in their effects.

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