ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 07 | July - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A PROSPECTIVE RANDOMIZED CONTROL STUDY ON MAGNESEUM SULFATE VERSUS KETAMINE NEBULIZATION ON THE EFFICACY IN THE IN PREVENTION OF INCIDENCE OF POSTOPERATIVE SORE THROAT

Anaesthesiology

Dr. Shraddha Pujari* Registrar, DNB, Department of Anesthesiology, Yashoda Hospitals, Secunderabad, Telangana. *Corresponding Author

Dr. Manne Manisha DNB, Department of Anesthesiology, Yashoda Hospitals, Secunderabad, Telangana.

Dr. M. Naga Sahitya DNB, Department of Anesthesiology, Yashoda Hospitals, Secunderabad, Telangana.

Dr. Gajanan Fultambkar Consultant, Anesthesiologist, Department of Anesthesiology, Yashoda Hospitals, Secunderabad, Telangana.

ABSTRACT

Background: Anaesthesia's main purpose is to control the airways, and endotracheal intubation, an essential part of the procedure. After extubation, ET (endotracheal tubes) may cause local irritation and inflammation, which can lead to the development of Post Operative Sore Throat (POST). **Material And Methods:** Total 102 patients of ASA Grade 1, Grade 2 were randomized into two groups of 51 each, Group K received nebulization with 50 mg ketamine (1 ml with 2 ml of normal saline) and Group M were nebulized with 3ml of 225 mg isotonic magnesium sulfate. Patients were nebulized 10 minutes prior to induction. Statistical analysis was conducted using SPSS Version 21.0, with significance defined as $P < 0.05$. **Results:** Current results show that, the age, sex and hemodynamic changes did not significantly differ between the two groups. The magnesium sulfate group had 43.1% Post Operative Sore Throat (POST) incidence while the ketamine group had 9.8% incidence. **Conclusion:** In the current study, it was found that the magnesium sulphate group experienced a higher incidence of Post Operative Sore Throat (POST) compared to the ketamine group. Hemodynamic variables, the time required for rescue analgesia, and adverse reactions were not significantly different. Thus, Ketamine nebulization should be preferred over MgSO4 nebulization in the prevention of development of POST.

KEYWORDS

Ketamine, Magnesium Sulphate, Post Operative Sore Throat (POST), ASA Grade 1, Grade 2.

INTRODUCTION

One of the most frequent postoperative issues that cause patients to become dissatisfied is a sore throat following trachealis. The likelihood of an endotracheal tube causing a sore throat varies depending on the type of tube, size, and pressure of the cuff [1]. In fact, it is in sixth place among the top 10 side effects of general anaesthesia and between 30% to 70% of patients encounter this [2]. The three mechanistic causes of Postoperative Sore Throat (POST) include trauma during intubation, mucosal dehydration and irritation and inflammation of the airway caused by the pressure from the endotracheal tube (ETT) [3].

Even though the majority of clinicians view it as a minor complication, the patient may experience significant distress. Coughing caused by sore throat after surgery puts strain on the suture site, which makes the surgical site more painful and increases the patient's discomfort and dissatisfaction [4]. Moreover, it increases patient morbidity and causes the postoperative phase to stick in the patient's memory. The patient may experience mild hoarseness or complete aphonia as a result of endotracheal intubation [5]. N-methyl D-aspartate receptors (NMDAR) are found in the peripheral nerves in the airway that support nociception [6]. NMDAR antagonists are considered to be anti-nociceptive and have been studied for Postoperative Sore Throat (POST) through nebulization, lozenge, and gargle, with varying degrees of success [7]. However, nebulization has the distinct advantage of uniform distribution over all areas subjected to instrumentation and mucosal damage, whereas lozenge and gargle forms are limited to the supraglottic region and exhibit significant inter-patient variability when administered [8].

Magnesium and Ketamine are commonly available N-methyl D-aspartate receptors (NMDAR) antagonists with anti- inflammatory properties [9] . Ketamine has been used as a gargle for reducing the incidence and severity of sore throat (ST) due to its anti-nociceptive and anti-inflammatory effects [10]. Nebulization has also been employed as a means of preventing sore throat (ST). Magnesium comes in powder, paste, or solution form and functions as an antagonist of the N-methyl D-aspartate (NMDA) receptor ion channel [11].

Numerous research studies that have been published in the past have used pharmaceutical or non-pharmacological methods to reduce voice hoarseness and Postoperative Sore Throat (POST). An appropriate-sized endotracheal tube, a cuff or not, and airway adjuncts like bougies or stylets are used in non-pharmacological techniques [12]. Whereas, medication such as magnesium sulfate, aspirin, lignocaine, ketamine, and dexamethasone will be administered either intravenously, topically, or locally in pharmacological techniques [13]. These agents were compared to a placebo in earlier studies using varying doses and application patterns.

The current study aimed to assess and compare the effectiveness of ketamine and pre-induction nebulized magnesium for Postoperative Sore Throat (POST) attenuation within the first 24 hours of endotracheal intubation and general anesthesia.

MATERIAL AND METHODS

Study Design:

A prospective, randomized, controlled study.

Study Sample:

This prospective study included 102 American Society of Anesthesiologists (ASA) Grade I and Grade II patients regardless of sex, between the ages 20 and 60 years who were undergoing elective surgeries under general anesthesia. The computerized random table was used to randomly assign 51 patients of any sex to the Magnesium Sulphate Group (Group M) or Ketamine Group (Group K).

Inclusion Criteria:

This study includes patients with similar diagnosis, between 20 years to 60 years of age and American Society of Anesthesiologists (ASA) Grade I and II patients, who have given written informed consent undergoing elective surgeries in supine position under general anesthesia and whose surgeries lasting for approximately two hours.

Exclusion Criteria:

This study excludes patients, refused to participate in the study, anticipated difficult intubation, with neuromuscular disease, allergy or hypersensitivity to the drugs, with a history of pre-operative sore throat, history of oral, head and neck surgeries, on non-steroidal anti-inflammatory drug medication, chronic obstructive pulmonary disease, history of smoking and patients who required more than one attempt at intubation.

Study Site:

The current study is a single-centre, hospital-based investigation conducted from February 2022 to September 2022 in the Department of Anaesthesia, Yashoda Hospital, Secunderabad, which is accredited by the NABH and NABL.

Patients were randomized into two groups by an anesthesiologist who is not involved in the study by using computer-generated random number tables. Group M were nebulized with 3ml of 225 mg isotonic Magnesium Sulphate. Group K were nebulized with 50 mg Ketamine (1 ml with 2 ml of normal saline). All the patients were nebulized 10 minutes prior to induction.

Throughout the anesthesia, routine non-invasive monitoring was carried out. After preoxygenation, the patient received intravenous glycopyrrolate (0.004 mg/kg), midazolam (0.02 mg/kg), and fentanyl (2 mg/kg). Intravenous injections of propofol (2 mg/kg) and atracurium (0.5 mg/kg) were used to induce anesthesia. Following a duration of two minutes for mask ventilation, the patient was intubated using a sterile, soft-seal cuffed polyvinyl chloride tracheal tube measuring 7-7.5mm for women and 8-8.5mm for men. Following intubation, the tracheal tube cuff was inflated to the point where a stethoscope recording at peak airway pressure of 20 cm of water revealed no air leakage.

To prevent muscle paralysis, anesthesia was maintained with an intravenous injection of atracurium (0.01 mg/kg) and 50% oxygen and nitrogen oxide, as well as sevoflurane 1-1.5 minimum alveolar concentration (MAC) at a fresh gas flow rate of 3 liters per minute. A volume control ventilation mode was selected and the patient was placed on a ventilator. After the surgery, the patient was sufficiently sedated, the oropharynx was carefully suctioned, and the sevoflurane was then turned off. The concentration of inspiratory oxygen was raised to 100%. After the completion of surgery, residual neuromuscular block was treated with intravenous neostigmine (0.05 mg/kg) and intravenous glycopyrrolate (0.01 mg/kg). After fully deflating the cuff, the patient's trachea was extubated when the patient resumed spontaneous breathing and became cognizant. Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) were among the basic parameters that were measured prior to and following nebulization, before the laryngoscopy and intubation, and then one, three, five minutes after intubation, and for every fifteen minutes until the procedure was finished.

Pre-nebulization (baseline parameters), post-nebulization, pre-induction, and immediate recovery were all assessed for sore throats at 0 hours, 2, 4, 6, 12, and 24 hours after surgery. Postoperative sore throat (POST) was graded on a four-point scale (0-3) as, Grade 0 - no sore throat, Grade 1 - mild sore throat (complains of sore throat only on asking), Grade 2 - moderate sore throat (complains of sore throat on his/her own) and Grade 3 - severe sore throat (change of voice or hoarseness, associated with throat pain)

Statistical Analysis

The statistical analysis was performed using IBM SPSS V21. Mean ± SD was used to present the quantitative data, Mann-Whitney test was used if the data failed the "Normality test," and the unpaired t-test was used if the data passed. Number (%) was used to present the results of categorical measurements. Fisher's exact test and the Chi-Square test with continuity correction were used to evaluate the associations between the qualitative variables in all two-by-two tables. A p-value of less than 0.05 was deemed significant for statistical significance.

RESULTS

Table 1 shows that the current study group's mean age distribution was 36.76±7.84 years and there was no significant difference between the study groups (p = 0.54). Out of the total 102 cases, 43.1% were females while 56.9% were males with no significant difference between two study groups (p=0.31). Results also shows that, a total of 70.6% cases were in ASA grade I while 29.4% were in ASA grade II with no significant difference between the study groups (p=0.41). The incidence of hypotension and bradycardia was considerably higher in those treated with group M (5.9%, 5.9%) than group K (0%, 0%). Results also show that the values recorded for PONV was differ in both the groups group K (2.0%), group M (9.8%) which is also statistically insignificant (p=0.20). Overall incidence of significant post-operative sore throat (POST) was 43.1% in magnesium group (Group M) as compared to 9.8% in the ketamine group (Group k) (p<0.01).

Table 2 explains that the mean heart rate and systolic blood pressure at baseline also during the study was comparable between Group K and Group M (p>0.05). The group that received Magnesium Sulphate (Group M) had a lower mean heart rate and systolic blood pressure during the surgical operation than the group that received Ketamine (Group K); however, difference was not statistically significant (p>0.05). At 60 min of post intubation, the heart rate and systolic blood pressure is maximum and least was recorded at 15min, in both the groups.

Table 3 explains that the diastolic blood pressure and mean arterial pressure at baseline during the study was comparable between Group K and Group M (p>0.05). The group that received Magnesium Sulfate had a lower diastolic blood pressure and mean arterial pressure during the surgical operation than the group that received Ketamine; however, this difference was not statistically significant (*p*>0.05) At 60 min of post intubation, the heart rate and systolic blood pressure is maximum and least was recorded at 15min, in both the groups.

Table 1: Age, Gender And Asa Grade, Maximum Sensory Block And Adverse Reactions Comparison Among Study Groups

Characteristics	Group		Total	P-value
	Group K	Group M		
Age (Mean±SD)	36.27±7.44	37.24±8.25	102	0.54
Female	19(37.3%)	25(49.0%)	44(43.1%)	0.31
Male	32(67.7%)	26(51.0%)	58(56.9%)	
Total	51(100.0%)	51(100.0%)	102(100.0%)	
ASA grade				
Grade 1	37(72.5%)	35(68.6%)	72(70.6%)	0.41
Grade 2	14(27.5%)	16(31.4%)	30(29.4%)	
Total	51(100.0%)	51(100.0%)	102(100.0%)	
Adverse reactions				
Bradycardia	0(0.0%)	3(5.9%)	3(2.9%)	0.24
Hypotension	0(0.0%)	3(5.9%)	3(2.9%)	0.24
PONV	1(2.0%)	5(9.8%)	6(5.9%)	0.20
Over all incidence of post-operative sore throat (POST) (Gr >=2)				
No	46(90.2%)	29(56.9%)	75(73.5%)	< 0.01
Yes	5(9.8%)	22(43.1%)	27(26.5%)	
Total	51(100.0%)	51(100.0%)	102(100.0%)	

Table 2 : Comparison Of Changes In Heart Rate And Systolic Blood Pressure Among Study Groups

Characteristics	Heart rate		P-value	Systolic blood pressure		P-value
	Group K (Mean±SD)	Group M (Mean±SD)		Group K (Mean±SD)	Group M (Mean±SD)	
Base line	80.69±7.06	80.35±7.12	0.81	127.80±6.04	127.59±5.79	0.85
After Nebulization	77.15±6.20	76.68±5.80	0.69	123.27±7.00	123.23±6.99	0.97
Post-Induction	69.45±10.85	69.71±11.38	0.9	111.96±10.47	111.06±9.67	0.65
Post Intubation						
1 min	73.61±12.19	73.00±11.91	0.79	118.73±12.58	118.86±13.14	0.96

3 min	66.12±18.01	66.25±18.90	0.97	110.92±18.98	110.84±19.72	0.98
5 min	66.47±16.44	65.47±15.52	0.75	110.51±19.63	109.31±18.90	0.75
15 min	63.14±11.26	62.82±11.31	0.89	110.86±14.25	110.73±14.70	0.97
30 min	63.80±12.08	63.35±11.99	0.85	110.79±15.04	110.44±15.31	0.91
45 min	70.12±13.20	69.64±13.12	0.84	121.88±16.46	121.52±16.77	0.02
60 min	76.50±14.41	75.97±14.31	0.81	132.96±17.96	132.56±18.30	0.91

Table 3: Comparison Of Changes In Diastolic Pressure And Mean Arterial Pressure Among Study Groups

Characteristics	Diastolic blood pressure		p-value	Mean arterial pressure		p-value
	Group K (Mean±SD)	Group M (Mean±SD)		Group K (Mean±SD)	Group M (Mean±SD)	
Base line	80.96±6.28	81.69±6.09	0.55	96.61±5.97	97.04±5.79	0.72
After Nebulization	77.85±5.97	78.46±6.61	0.62	92.99±6.07	93.41±6.55	0.74
Post-Induction	67.53±6.55	67.80±7.33	0.84	82.27±7.49	82.22±7.82	0.97
Post Intubation						
1 min	74.75±10.42	75.24±11.25	0.82	89.37±10.82	89.78±11.60	0.85
3 min	67.61±13.87	67.55±14.64	0.98	82.06±15.43	81.98±16.16	0.98
5 min	66.88±13.73	66.24±13.49	0.81	81.41±15.60	80.57±15.19	0.78
15 min	64.29±12.46	64.20±13.02	0.97	79.84±12.72	79.73±13.28	0.96
30 min	64.81±12.59	64.60±12.96	0.93	80.16±13.18	79.89±13.54	0.92
45 min	71.24±13.83	71.02±14.26	0.94	88.14±14.45	87.87±14.87	0.93
60 min	77.72±15.09	77.48±15.55	0.94	96.16±15.77	95.86±16.22	0.93

Table 4 : Comparison Of Study Groups As Per Incidence Of Post-operative Sore Throat (POST)

Grades of POST	2 hr		4 hr		6 hr		12 hr		24 hr	
	K	M	K	M	K	M	K	M	K	M
0	14 (27.5%)	12 (23.5%)	34 (66.7%)	13 (25.5%)	45 (88.2%)	22 (43.1%)	50 (98.0%)	28 (54.9%)	50 (98.0%)	35 (68.6%)
1	32 (62.7%)	17 (33.3%)	16 (31.4%)	21 (41.2%)	6 (11.8%)	22 (43.1%)	1 (2.0%)	19 (37.3%)	1 (2.0%)	16 (31.4%)
2	5 (9.8%)	17 (33.3%)	1 (2.0%)	16 (31.4%)	0 (0.0%)	6 (11.8%)	0 (0.0%)	4 (7.8%)	0 (0.0%)	0 (0.0%)
3	0 (0.0%)	5 (9.8%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	51 (100%)	51 (100%)	51 (100%)	51 (100%)	51 (100%)	51 (100%)	51 (100%)	51 (100%)	51 (100%)	51 (100%)
p-value	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01

Table 4 explains that maximum patients (9.8%) in the Magnesium group (M Group) had significant post-operative sore throats by the second hour (p<0.01) whereas in Ketamine Group (K Group) no patient has post operative sore throat till 24hours. Moderate post operative sore throat has observed in 33.3% of patients during second hour in M Group with 9.8% patients in K Group. During the post-operative follow-up period, the Magnesium group (M Group) experienced a significantly higher incidence of sore throat (p<0.01).

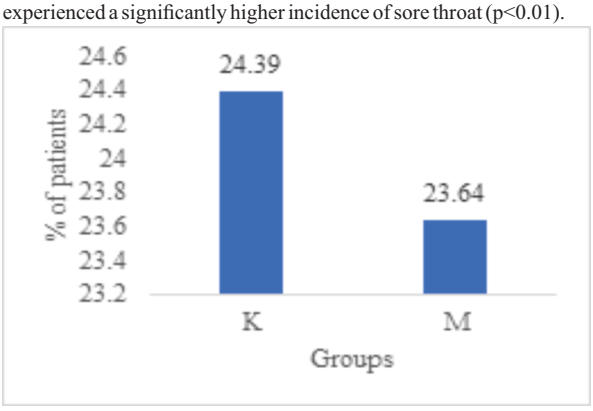

Fig 1: Comparison Of Study Groups As Per Mean Time For Rescue Analgesia

Figure 1 explains that mean time for rescue analgesia was similar between the study groups. The proportion of patients requiring rescue analgesia was higher among Group K as compared to Group M (24.39% v/s 23.64%, *p*=0.65). Difference in rescue analgesics among patients in both the groups was found to be statistically in significant.

DISCUSSION

Following general anaesthesia, postoperative sore throat is frequently experienced by the patients. While physicians typically consider it to be a relatively minor complication, patients believe that, the prevention is crucial. An intrinsic risk factor for the emergence of this frequent sore throat complication is, endotracheal intubation [14] . The study group's mean age was below 40 years, with a higher proportion of men than women. The majority of the study's cases were ASA Grade I cases, which were followed by ASA Grade II cases. There was no difference in the ASA Grade of cases, gender, or age between the study groups (p>0.05).

In a comparative study on preoperative Ketamine and MgSO4 nebulization for incidence of post operative sore throat after endotracheal intubation it was found that, the magnesium and ketamine group's hemodynamic response to laryngoscopy was significantly attenuated (p>0.05) [15]. In our study the mean heart rate was comparable between the study groups at baseline and also during the study procedure (p>0.05). Similarly, mean systolic, diastolic and arterial blood pressure was comparable between the study groups at baseline and also during the study procedure (p>0.05). In a randomised control trial on comparison of incidence of postoperative sore throat after nebulization with Ketamine, Lignocaine and Magnesium Sulphate it was observed that there were no significant differences in the hemodynamic profile between magnesium and ketamine [16]. Preoperative nebulization utilizing ketamine, magnesium sulphate, and lignocaine is a straightforward and efficient method to lower the frequency of Sore Throat (ST) in patients receiving general anaesthesia (GA) during tracheal intubations. However, Ketamine has the greatest reduction in POST, followed by magnesium sulfate and lignocaine[17].

Our study shows that, in comparison to the ketamine group, the magnesium group experienced a significantly higher number of cases of sore throats by the second hour of the post-operative period (p<0.01). During the entire post-operative follow-up period, up to 24 hours, this significant difference was observed (p<0.01). Studies on the incidence of sore throat in the postoperative period up to 24 hours following nebulization with MgSO4 and ketamine it was observed that magnesium group experienced higher number of patients with sore throat [18]. In a study on three nebulized medications for the prevention of postoperative sore throat in the pediatric population at 4-hour postoperative mark it was observed that, patients in the Ketamine group had the significant (*p*=0.003) lowest incidence of postoperative sore throat (POST) when compared to patients in the Magnesium and Dexamethasone groups [19]. On comparison of nebulized ketamine with nebulized magnesium sulfate, the ketamine group at 4 and 6 hours,

shown a significant decrease in the incidence and severity of sore throats than magnesium sulfate group [20]. Preventive application of topical magnesium prior to the initiation of general anesthesia appears to be a successful strategy in reducing the occurrence of postoperative sore throat (POST)[21].

Current study shows that mean pain score was comparable between the study groups and in comparison, to magnesium sulphate, preoperative nebulized ketamine relieves throat pain earlier in the first 24 hours following endotracheal intubation. In the studies that compare magnesium and ketamine for post-operative pain, magnesium at low doses reduces sore throat and pain intensity more effectively [22].

CONCLUSION

The hemodynamic response to laryngoscopy was significantly lower in both the groups and they also had comparable rates of post-operative analgesia and other adverse reactions. In conclusion, to reduce sore throat after surgery, ketamine nebulization should be preferred over magnesium sulphate in patients undergoing endotracheal intubation for procedures done under general anesthesia.

Acknowledgements:
Authors would like to thank Management Yashoda Hospitals for the continuous support and special thanks to Dr.Amidyala Lingaiah (Director of Medical Services Yashoda Hospitals).

Declarations
Funding: No funding sources
Conflict Of Interest: None declared
Ethical Approval: Not required

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