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COMPARISON OF NEBULIZED KETAMINE VERSUS NEBULIZED MAGNESIUM SULFATE FOR PREVENTION OF POST OPERATIVE SORE THROAT IN PATIENTS UNDERGOING GENERAL ANESTHESIA REQUIRING ENDOTRACHEAL INTUBATION: A DOUBLE BLIND RANDOMIZED CONTROL TRIAL

Anaesthesiology

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KEYWORDS

Postoperative sore throat, Ketamine, Magnesium sulfate, NMDA Receptor Antagoniost, Endotracheal Intubation

INTRODUCTION

Postoperative sore throat (POST) is a common undesirable outcome of tracheal intubation, with prevalence ranging from 21% to 65%. This is influenced by factors such as mechanical trauma during intubation, tracheal tube cuff pressure causing mucosal erosion, inflammation, and dehydration [1,2]. Prolonged intubation can lead to serious consequences, while even a short tracheal intubation period of one hour can cause extensive damage to the tracheal and laryngeal epithelium. Although POST is usually a self-limiting condition that resolves within 12-24 hours, its prevention is important to reduce hospital stay and improve patient satisfaction.[3]

Although considered a minor complication, POST can lead to significant patient morbidity and prolong the length of hospital stay. Several pharmacological and nonpharmacological methods have been employed to reduce the incidence of POST, with varying success rates. Some of these methods include using magnesium sulfate gargle, ketamine gargle, ketamine nebulization, magnesium sulfate nebulization, lidocaine spray using smaller size endotracheal tubes, and minimizing cuff pressure to <20 mmHg and minimizing laryngoscopy attempts.[5-12]

Pre-induction administration of topical anti-nociceptive and anti-inflammatory agents attenuate POST by counteracting the inflammation or nociception induced by mucosal injury.[13-15] Magnesium and Ketamine are N-methyl-D-aspartate receptor antagonist, possesses anti-nociceptive and anti-inflammatory properties. It has been proposed as a preventive measure for POST[16,22] The peripheral nerves in the airway subserving nociception contain N-methyl D-Aspartate receptors (NMDAR).[17] Antagonists to NMDAR are considered anti-nociceptive and have been investigated for POST in the forms of gargle, lozenge and nebulization with varied outcomes.[18-20]

Some studies compared these agents but still there is some need to do more research in this matter. We decided to undertake this study to test and compare the efficacies of pre-induction nebulized Magnesium and Ketamine for POST attenuation within 24 hours following general anaesthesia with endotracheal intubation.

MATERIAL AND METHOD

After receiving approval from the institutional ethics committee, a randomized double blind study was conducted on 120 patients between the ages of 18 and 65, who were classified as ASA I-II and undergoing general anesthesia requiring endotracheal intubation with surgery lasting up to 180 minutes. Patients with a history of preoperative sore throat or recent upper respiratory tract infection, allergy to any of the study drugs, oral or neck surgeries (such as thyroid surgery), chronic airway disease, anticipated difficult airway. and those requiring more than three attempts at intubation were excluded from the study.

The sample size was determined based on the mean incidence of postoperative sore throat, according to the existing literature, with 80% power and a 95% confidence interval, resulting in a minimum of 60 patients in each of the two groups. Patients were randomly assigned to either Group K (ketamine 50 mg) or Group M (magnesium sulfate 500 mg) using computer generated table of random number. Before entering the Operative room, a large bore intravenous (IV) cannula was secured, and standard vital parameters such as pulse rate (PR), mean arterial pressure (MAP), and SpO2 were recorded. The nebulization with oxygen source at 10L/min along with study drug in 5ml NS was done before 20 minutes of administrating general anaesthesia. Premedication was given with Inj. Glycopyrrolate 0.005 mg/kg iv, and 2ug/kg Fentanyl before induction.

In the operating room, a multipara monitor was used, including electrocardiogram, pulse oximetry, and noninvasive blood pressure monitoring. All vital parameters were recorded. The standard technique for general anesthesia was employed, including preoxygenation with 100% oxygen for 3 minutes and induction with Inj. Propofol 2 mg/kg iv., Inj. succinylcholine chloride 1.5 mg/kg i.v. Intubation was done with appropriate size endotracheal tube after direct laryngoscopy. General anesthesia was maintained using oxygen, nitrous oxide, and inhalation agents such as isoflurane or sevoflurane. The neuromuscular blockade was achieved using a non-depolarizing muscle relaxant, Inj. Atracurium 0.5 mg/kg IV, and maintained with Inj. Atracurium 0.1 mg/kg. Intraoperative standard hemodynamic monitoring was recorded at the time of laryngoscopy and then at 5 min, 10 min, 15 min, 30 min, 60 min, and every hour thereafter until the end of surgery. After the surgery, neuromuscular blockade was reversed with Inj. Glycopyrrolate 0.01mg/kg and Inj. Neostigmine 0.05 mg/kg IV. Extubation was performed after ensuring adequate tidal volume, respiratory rate, and reflex reversal. The patient was transferred to the recovery room, where humidified O2 was given at a flow rate of 5 L/min via ventimask, and vital signs were recorded. The patient was asked about sore throat, hoarseness of voice, and postoperative cough using a questionnaire at 0, 2, 4, 6, 12, and 24 h, and the responses were recorded by a four point scale.[3](0–3) as follows:

0 = no sore throat
1 = mild sore throat (complains of sore throat only 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 throat pain).

Consequently, the incidence and severity at 2, 4, 6, 12 and 24 hours were also assessed. The rescue therapy for post-operative sore throat, especially in patients with a grade 3 score, was with the use of a dispersible aspirin 75 mg gargle, which was repeated as needed until the patient got relief from the symptoms. Data collection and analysis were performed using a pre-structured proforma.

The collected data was entered in MS excel and analysed using SPSS software. The results were analyzed using mean, SD, and percentage in the form of tables, diagrams, and test of significance (independent t-test for intergroup comparison, Chi-square test for demographic data).

RESULT

Demographic data like age, weight and sex between the two groups was comparable, and there were no significant differences. The duration of laryngoscopy, time taken to intubate and the duration of surgery were 22.45 ± 9.28 s, 27.352 ± 9.04 s, and 123.8± 43.8min in Group A and 22.69 ± 9.05 s, 27.68 ± 9.23 s, and 125.64± 49.min in Group B, respectively. In Group A, 53 patients were intubated in the first attempt and 7 patients in the second attempt, while in Group B, 56 patients in the first attempt and 4 patients in the second attempt. These

values were comparable between the groups and it was not statistically significant ($P > 0.05$).

Baseline characteristics		Group K	Group M	P value
Mean± SD	Age(years)	39.27± 8.47	41.64± 9.23	0.145
	Height(cm)	167.27± 6.32	165.22± 5.36	0.135
	Weight(Kg)	62.74± 6.45	61.48± 7.48	0.083
ASA Grade	Grade 1	48	50	0.636
	Grade 2	12	10	
Gender	Male	38	32	0.266
	Female	22	28	

The pulse rate and MAP measurements before and after nebulization within group K and within group M were comparable and showed no statistically significant difference ($p > 0.05$). The intraoperative mean heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were also comparable between the two groups, but again, no statistically significant difference was observed ($p > 0.05$). Additionally, the oxygen saturation levels before and after nebulization, as well as during the surgery, were comparable in both groups.

The overall incidence of sore throat was found to be 42(35%) while among group K and group M were found to be 15(25%) and 27(45%) respectively. None of the patients in both the group complained of sore throat immediately (0 hours) after surgery. In group K who received ketamine, 6(10%) patients had grade 1 sore throat and 1(1.67%) patients had grade 2 sore throat during 2 hour assessment. Where as In group M who received magnesium sulphate, 6(10%) patients had grade 1 Sore throat while 5(8.37%) had moderate sore throat during 2 hour assessment. In spite of these difference between the groups, the statistical significance was not obtained. While taking into account the 4th hour assessment In group K 11(18.33%) patients had grade 1 sore throat and 4(6.67%) patients had grade 2 sore throat. Where as In group M who received magnesium sulphate, 18(30%) patients had grade1 Sore throat while 9(15%) had moderate sore throat. This difference was statistically significant.

During 6 hrs assessment in group K 5(8.37%) patients had grade 1 and 3(5%) patients had grade 2 sore throat during 6 hrs assessment. Whereas In group M 12(20%)had grade 1 and patients 4(6.67%)had grade 2 sore throat. It was not statistically significant difference. In group K 7(11.67%) patients had grade 1 sore throat during 12 hrs assessment. While In group M 9(15%)had grade 1 sore throat during 12 hrs assessment and It was not statistically significant. During 24 hrs assessment in group K 3(5%) patients had only grade 1 sore throat and In group M 5(8.37%) had only grade 1 sore throat These results were not statistically significant.

Time	Severity Grade	Group K	Group M	P value
0 h	0	0	0	
2 h	Grade 0	0	0	0.22
	Grade 1	6	6	
	Grade 2	1	5	
	Grade 3	0	0	
4 h	Grade 0	0	0	0.O21
	Grade 1	11	18	
	Grade 2	4	9	
	Grade 3	0	0	
6 h	Grade 0	0	0	0.068
	Grade 1	5	12	
	Grade 2	3	4	
	Grade 3	0	0	
12 h	Grade 0	0	0	0.591
	Grade 1	7	9	
	Grade 2	0	0	
	Grade 3	0	0	
24 h	Grade 0	0	0	0.464
	Grade 1	3	5	
	Grade 2	0	0	
	Grade 3	0	0	

DISCUSSION

Although postoperative sore throat (POST) is a well-known complication that can arise following general anesthesia with endotracheal intubation, it remains an important concern for surgical patients. Nebulization has been found to be an inexpensive, quick, convenient and easy-to-administer method, making it a popular choice. In our study, we aimed to compare the effectiveness of ketamine and magnesium sulfate nebulization in preventing POST.[1,2,3]

POST occurs following noxious stimulation provoked by inflammation that results from mucosal injuries. Excitatory amino acids such as glutamate and inflammatory mediators are released after such mucosal injuries or following stretch of pharyngeal muscles by instrumentation. Prior occupation of NMDAR by Ketamine or Magnesium molecules prevents glutamate mediated central sensitization and sensation of POST.[22] Peripherally administered NMDA receptor antagonists are involved with antinociception and anti-inflammatory cascade by reducing NFκβ activity, TNF-α (tumor necrosis factor α) production, expression of inducible nitric oxide synthase, serum C-reactive protein, IL-6 and IL-10. Ketamine and Magnesium both act on NMDA receptor and antagonize it.[23]

In our study, All demoghraphic parameter like age, sex and weight, intubation attempts, ASA physical status and mean duration of surgery were comparable between both groups and statistically insignificant which was in agreement with many previous studies. Our study also showed no significant difference in hemodynamic parameters between the two groups, which is consistent with the findings of study by Houman Teymourian.[5], R. Preethi.[21], Neepa patel[23].

The incidence of sore throat was assessed at 0hr, 2hr, 4hr, 6hr,12hr, and 24hrs in PACU. There was statistically significant reduction in sore throat was seen in group K compare to group M at 4hr ($p=<0.021$) only. Same result was found by Ahuja et al.[9]who 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. So we found that ketamine was more effective in reducing sore throat compared to magnesium sulphate. which is consistent with the findings of study by Sivakumar Segaran [3] Preethi.[21], Neepa patel[23]. However, Sunil Rajan et al. found that both ketamine and 500mg of magnesium sulphate showed a significant effect in reducing sore throat. There is evidence to suggest that increasing the dose of magnesium sulfate could improve its effectiveness in this regard. In fact, a study found that 500mg of magnesium sulfate was more effective than ketamine in controlling sore throats among patients.[5] It can be due to the method of administration of Ketamine and magnesium. He administered drug by gargle while in our study we used nebulization.

CONCLUSION

In our study it was seen that aerosol 50 mg ketamine plays a better role in reduction of sore throat compared to 500mg magnesium sulphate.

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