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Comparative Study of Effect of Preoperative Ketamine and Magnesium Sulphate Nebulization in Reducing the Incidence and Severity of Post Operative Sore Throat after Tracheal Intubation A Double Bind Randomized Control Study

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Abstract: ***Background: Routine tracheal intubation for elective surgical procedures can result in pathological changes, trauma and nerve damage which may also account for postoperative throat symptoms which is considered as a minor complication, but is a valid reason of dissatisfaction and morbidity among patients. We studied to evaluate the role of preoperative ketamine and MgSO4 nebulization on incidence and severity of postoperative sore throat. Material and methods: This study was conducted in 90 patients of either sex divided in three groups (Group k n=30, Group m n=30 and Group C n=30) was done. Group k patients were received ketamine nebulisation Group M received MgSO4 nebulization and Group C nebulized with normal saline Sore throat assessment and hemodynamic recording were done at pre - nebulisation, pre - induction and immediate after recovery 0 h, 2, 4, 6, 8, 12, 24 h post operatively. these groups was compared using one - way analysis of variance (ONE –WAY ANOVA) and difference between the groups compared using unpaired T - Test. Results: Ketamine nebulation prevent incidence of POST in comparison of MgSO4. Conclusion: We concluded that preoperative nebulization for prevention of POST with ketamine can be safe and effectively used for patients among undergoing general surgery under General Anaesthesia with tracheal intubation***

Keywords: Nebulisation, Ketamine, Mgso4

1. Introduction

Sore throat (ST), a common complaint of post operative period after tracheal intubation is being considered as a minor complication, but is a valid reason of dissatisfaction and morbidity among patients. [(1)] Routine tracheal intubation for elective surgical procedures can result in pathological changes, trauma and nerve damage which may also account for postoperative throat symptoms. It would appear, however, that high intracuff pressure is associated with nerve palsies due to neuropraxia and nerve compression. The use of smaller tubes has the distinct advantage of reducing the incidence of postoperative sore throat. The pharmacological methods used to reduce ST include use of become thasonegel, gargling with azulenesulphonate, ketamine, licorice, magnesiumsulphate, and topical preparations of benzylamine hydrochloride. It is usually administered by gargling, atomized spraying onto the ETT cuff or oral cavity and has been found to have therapeutic effects for postoperative sore throat. ([2, 3, 4)] N - methyl - D - aspartate (NMDA) have a proven role innociception and inflammation. ([5)] Ketamine and MgSO4 both are N - methyl - D - aspartate (NMDA) receptor antagonist.

The purpose of this study was to evaluate the role of preoperative ketamine and MgSO4 nebulization on incidence and severity of postoperative sore throat in patients undergoing tracheal intubation during General anesthesia.

2. Material and methods

After obtaining hospital ethical committee approval, 90 Patients of either gender, age 18 to 60 years belonging to American Society of Anesthesiologists physical status I to II scheduled for elective surgeries other than head, neck and oral surgeries under general anaesthesia were selected and written informed consent was obtained. Patient with Known allergy to the study medication, Respiratory or cardiac diseases and hepatic or renal impairment History of preoperative sore throat Systemic illness like diabetes mellitus and hypertension and taking medications for psychiatric diseases were excluded from the study. The procedure was explained to the patients during pre - anaesthetic visit. Continuous monitoring of heart rate, BP, respiratory rate and spo2 were done by a nurse in the preoperative room. The patients were randomly divided into 3 groups with 30 patients in each group, using computer generated random number. A total sample size of 90 cases divided in 3 groups (30 each). In **Group M (n=30)** patients were nebulised with MgSo4 (5 ml of 225 mg isotonic Magnesium Sulphate.) with nebuliser machine 10 mins prior

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to surgery for 15 mins, in **Group K (n=30)** patients were nebulised with ketamine solution (5 ml of 50mg ketamine) with nebuliser machine 10 mins prior to surgery for 15 mins and in **Group C (n=30)** these patients were nebulised with 5 ml NS. Then after shifted to operative room, vital parameter attached then after general anaesthesia patient were intubated with suitable size of endotracheal tube. After surgery patient were extubated and shift to post operative room.

Sore throat assessment and hemodynamic recording were done at pre - nebulisation (Baseline parameters before nebulisation of the patient), pre - induction (parameters after nebulisation) and in immediate after recovery 0 h, 2, 4, 6, 8, 12, 24 h post operatively. Pain intensity (throat pain) was assessed by verbal numerical rating scale at pre - nebulisation (Baseline parameters before nebulisation of the patient), pre - induction (parameters after nebulisation) and in immediate after recovery 0 h, 2, 4, 6, 8, 12, 24 h post operatively by a blinded interviewer.

Data were collected and computed using Microsoft Excel 2013 and analysed using SPSS version 28.0. Continuous variable was summarized as mean + SD (standard deviation). Categorical variables were actual number and percentage (%). For Numerical variable was compared between the three groups, ANOVA test was used and for Categorical Variable was compared with the Normal saline, magnesium sulphate and Ketamine nebulisation group, the variables were represented by both the tables and bar diagrams. For test of significance, chi - square test is used.

3. Results

The demographic data of the three studied groups are summarized in Table 1, statistical analysis revealed nonsignificant differences between the three groups as regards age, height and weight. No patients were excluded after inclusion to the study.

Table 1: Demographic Data

	Group K	Group M	Group C	P value
Age (Years)	**36.26±10.34**	**40.2±7.84**	**36.56±10.55**	0.240
Weight (Kg)	68.23±8.34	68.93±7.82	68.43±8.22	0.854
Sex N, (%) Male	20 (66.67)	18 (60)	19 (63.3)	0.866
Sex N, (%) Female	10 (33.3)	12 (40)	11 (36.7)	

Data are presented as mean±SD or ratio of patients. *P*>0.05 is considered statistically non significant. SD=Standard deviation.

The perioperative heart rate, Systolic Blood Pressure, Diastolic blood pressure and Mean arterial pressure distribution was comparable in all 3 groups. Though fall in heart rate, Systolic Blood Pressure, Diastolic blood pressure and Mean arterial pressure was observed during intra – operative period in all the groups but results were not statistically significant (P>0.05) over time intervals.

The Post Operative Sore Throat (POST) was assessed immediately after extubation till 24 hours. There was nil incidence of POST after 24 hours. The difference in the incidence of POST between ketamine group, Mgso4 and control group was statistically significant with lower incidence in ketamine group. At 2 hours comparable between groups and was statistically not significant between group K and group M (p value 0.090) and group M and group C (p value 0.738), but it was statistically significant between group K & group C (P value 0.044). At 4 hours comparable between groups and was statistically highly significant between group K and group M (p value 0.009) and group K and group C (p value 0.0002), but it was statistically not significant between group M & group C (P value 0.242). At 6 hours comparable between groups and was statistically highly significant between group K and group M (p value 0.009) and group K and group C (p value 0.0002), but it was statistically not significant between group M & group C (P value 0.259). At 8 hours comparable between groups and was statistically not significant between group K and group M (p value 0.052) and group M and group C (p value 0.184), but it was statistically highly significant between group K & group C (P value 0.001). At 12 hours comparable between groups and was statistically not significant between group K and group M (p value 0.687), group M and group C (p value 0.488), and group K & group C (P value 0.278). (Table 2)

Table 2: Post Operative Sore Throat Incidence

Time		Group K (n=30)	Group M (n=30)	Group C (n=30)	Chi – TEST	P Value	Group K V/S M	Group M V/S C	Group K V/S C
After Extubation	P	22 (73%)	26 (86%)	27 (90%)	3.36	0.186 (NS)	0.196 (NS)	0.687 (NS)	0.095 (NS)
	A	8 (27%)	4 (14%)	3 (10%)					
2 hr	P	18 (60%)	24 (80%)	25 (83%)	5.02	0.081 (NS)	0.090 (NS)	0.738 (NS)	0.044 (S)
	A	12 (40%)	6 (20%)	5 (17%)					
4hr	P	10 (33%)	20 (67%)	24 (80%)	14.44	0.00073 HS	0.009 (HS)	0.242 (NS)	0.0002 (HS)
	A	20 (67%)	10 (33%)	6 (20%)					
6hr	P	9 (30%)	19 (63%)	23 (76%)	14.11	0.00086 HS	0.009 (HS)	0.259 (NS)	0.0002 (HS)
	A	21 (70%)	11 (37%)	7 (24%)					
8hr	P	3 (10%)	9 (30%)	14 (46%)	9.84	0.007 (HS)	0.052 (NS)	0.184 (NS)	0.001 (HS)
	A	27 (90%)	21 (70%)	16 (54%)					
12hr	P	3 (10%)	4 (13%)	6 (20%)	2.699	0.260 (NS)	0.687 (NS)	0.488 (NS)	0.278 (NS)
	A	27 (90%)	26 (87%)	24 (80%					
24hr	P	0	0	0	…….	…….			
	A	30 (100%)	30 (100%)	30 (100%)					

The pain score was assessed using Verbal Numerical Rating Scale (VNRS) from extubation till 24 hours. VNRS score was 0 for all subjects at after 24 hours. the pain score was lower in ketamine group patients from at 4 hours, 6 hours and 8 hours after extubation compared to Mgso4 and controls groups and the difference was statistically

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significant. Inter - group the pain score was assessed using Verbal Numerical Rating Scale (VNRS) from extubation to till 24 hours. was comparable between groups and was statistically significant between group K and group M at 4 hours and 6 hours after extubation. And group K & group C at 4 hours, 6 hours and 8 hours after extubation as shown in table 3.

Table 3: Pain score (VNRS)

Time		Group K (n=30)	Group M (n=30)	Group C (n=30)	Chi - Test	P Value	Group K V/S Group M	Group K V/S Group C	Group M V/S Group C
After Extubation	P	20	24	25			0.242	0.136	0.738
	A	10	6	5	2.608	0.271			
2 hr	P	16	22	23	4.375	0.112	0.107	0.058	0.765
	A	14	8	7					
4hr	P	8	18	22	13.928	0.0009	0.009	0.0003	0.273
	A	22	12	8					
6hr	P	7	17	21	13.86	0.001	0.008	0.0002	0.283
	A	23	13	9					
8hr	P	5	9	14	6.324	0.042	0.222	0.012	0.184
	A	25	21	16					
12hr	P	3	4	5	0.576	0.749	0.687	0.447	0.717
	A	27	26	25					
24hr	P	0	0	0		…….			
	A	30	30	30					

No other complications occurred during and after surgery.

4. Discussion

Postoperative sore throat (POST) is a well - recognized side effect after endotracheal intubation. But the discomfort produced by sore throat makes it one of the most undesirable side effects in the post operative period.

Ketamine and Magnesium Sulphate both can blockN - methyl - D – as particacid (NMDA) receptor. Ketamine relaxes the tracheal muscle contraction through a mechanism independent of NMDA receptors. In addition, the decreased broncho motortone induced by Ketamine is probably due to its interference with Ca2+ (a required step necessary to maintain the contraction). In this sense, Magnesium Sulphate could probably block the Ca2+ entrance to tracheal muscle in a more effective manner. Recent reports of the incidence of postoperative sore throat following anesthesia have claimed that the incidence of postoperative sore throat does not necessarily reflect damage caused by the tracheal tube cuff but more of increased muscle contracture. By preventing central sensitization, pre - emptive analgesia along with intensive multimodal analgesic interventions could theoretically reduce postoperative sore throat incidence and severity. Hence in our study we compared pre - emptive ketamine nebulization with magnesium sulphate nebulization as a means to prevent post - operative sore throat. The use of cuffed tubes, **Jaensson M. et al (2010)** [6] showed a higher incidence of sore throat by larger size tube compared with smaller size, hence in our study we use 7.5 mm tube for female patients and 8.5mm tube for male patients in both the groups. Incidence of post operative sore throat has been found to be higher when tubes with high pressure low volume cuffs are used in comparison with tubes with high - volume low - pressure cuffs. Hence in our study we used portex tubes that have a high - volume low - pressure cuff in all patients.

In this study, we studied throat pain as a secondary outcome, and observed that the pain score using Verbal Numerical Rating Scale (VNRS) was less in Ketamine group at different time intervals which is Statistically significant ($p<0.05$). **Teymourian et al (2015)** [7], compared the effectiveness of Magnesium and Ketamine Gargle in alleviating the Postoperative Sore Throat and Pain and concluded that there was significant decrease in postoperative throat pain in magnesium sulphate and ketamine groups when compared with control group. **Shekhar S et al (2019)** [8]**,** observed better analgesia with ketamine nebulisation than control group which coincides with our study observing better analgesia with ketamine nebulization as VNRS - 0 was at 8 hrs in 83.33% patients.

Post operative sore throat incidence were more after extubation and up to 6 hours in most of patients but it was less with ketamine. Then it was in decreasing pattern and relieved in 24 hours in most of the patients. With respect to the route of administration, in our study, we chose nebulisation as the route of administration, because nebulisation is inexpensive, quick, convenient, and easy to administer also. **Rajan S et al (2017)** [9] found a statistically significant reduction in the incidence of sore throat in Group K and Group M2 at 0, 2, and 4 h after extubation as compared to the control group. Which coincides with our study, Although Group M1 also had decreased incidence, and the difference was not statistically significant. All the groups exhibited decreased incidence at 12 and 24 h but insignificant statistically. The maximum decrease in incidence was observed in Group K, followed by Group M2 and finally Group M1 Similar results also found with Ketamine nebulization by **Ranjana et al (2020)** [10], who compared the effectiveness of Ketamine with other drugs in alleviating Postoperative Sore Throat and observed that the maximum reduction in POST was with ketamine followed by magnesium sulphate and then lignocaine. Studies like **Thomas D et al (2018)** [(11),] **Kumar D et al (2021)** [(12),] also observed a similar reduction in incidence and severity of POST by using preoperative ketamine nebulisation. Which are consistent with our study results.

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There was no statistically significant difference in the intra/post - operative complications like hypertension, hypotension, bradycardia postoperative nausea and vomiting and sedation between different groups.

5. Future Scope

Ketamine with its lower incidence and severity of the Post Operative Sore Throat, reduced pain score and hemodynamic stability is preferred over magnesium sulphate. But further studies have to be done to precisely calculate the exact dose of ketamine required for minimal hemodynamic variations which occurred in our study in the ketamine group.

6. Conclusion

With the lower incidence and severity of the Post Operative Sore Throat, reduced pain score and hemodynamic stability, it is concluded that preoperative nebulization for prevention of POST with ketamine can be safe and effectively used for patients among undergoing general surgery under General Anaesthesia with tracheal intubation without any side effects.

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