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COMPARATIVE STUDY OF MAGNESIUM SULPHATE NEBULIZATION AND LIGNOCAINE NEBULIZATION IN PREVENTION OF POSTOPERATIVE SORE THROAT (POST)

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ABSTRACT

Background: General anaesthesia (GA) includes intubation a necessary step to provide adequate ventilation in patients under anaesthesia along with protection of airway from regurgitation and aspiration. Postoperative sore throat (POST), hoarseness of voice, cough are common sequelae. The present study compares the efficiency of preoperative nebulization of lignocaine hydrochloride and magnesium sulphate for reducing the incidence of POST in patients under GA. **Methods**: The study conducted in GMC Kota and attached hospitals on 100 patients of surgery duration one hour to three hours. Patients were randomly allocated in two groups Lignocaine group and Magnesium group. **Results:** The majority of patients belonged to the age between 40 and 70 years. There was no significant difference in the mean pulse rate, SBP, mean SpO_2. Comparison of sore throat in both the groups at rest, just after extubation, 2 hours, 8 hours, 24 hours and 48 hours showed incidence more common in lignocaine group than magnesium group but no significant difference (P>0.05). Hoarsness after extubation reduced within 24 hours in Magnesium group in comparison to Lignocaine group where it persists till 48 hrs. **Conclusion:** Incidence of sore throat, hoarseness of voice and cough was more common in lignocaine group and more in female patients. Both drugs can be used for prevention of postoperative sore throat, but magnesium sulphate has better results.

INTRODUCTION

General anaesthesia is an integral part of anaesthesiology and intubation is a necessary step for protecting the airway from regurgitation and aspiration. Tracheal intubation can result in the introduction of oral organisms (minor local infection), abrasion of the tracheal mucosa (direct injury), reaction to the tube

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material, tracheal irritation caused by ETT cuff pressure, dehydration of upper respiratory tract mucosa, postoperative sore throat, hoarseness of voice, cough[1]. Mucosal injury caused by airway instrumentation is distressful to patients especially in abdominal incision [2]. Edomwonyi and colleagues [3] reported that 63% of the general adult surgical population had postoperative throat complications.

A higher incidence (72.5%) of postoperative airway complications was reported among obstetric and gynecological population by Coalhole and Ishaq [4]. Red rubber tube having low residual volume, high pressure cuff creates more pressure on the trachea than thin walled, low-pressure, high-volume cuff tubes. Blood flow do not cease until intracuff pressure of tube must be kept in the range of 80-120mmHg [5].

The various factors causing the above complication are more common in younger age and in females as compare to adults. It might be due to tighter fitting of tube in females. Incidence reported more during spring and winter season because of latent inflammation of the throat [6]**.**

No significant association found between intubation attempts and postoperative sore throat occurrences [7]. Higher incidence was in patients whom intubation lasted 2 hours or more and with large tube [8]**.** Nordin U et al. [9] studied blood flow in the rabbit tracheal mucosa during normal conditions and during tracheal intubation. They found that irritation of the tracheal mucosa by an endotracheal tube causes sudden rise in blood flow and relaxation of the arterioles with release of histamine like substances.

They also observed that low residual volume, high pressure cuff tubes exert high pressure on mucosa and cease the blood flow. While a thin walled, low-pressure, high-volume cuff tube does not harm until intracuff pressure kept in the range of 80-120 mm Hg (reason more even distribution of pressure over the mucosa). Lubrication of endotracheal tube cuff with jelly containing local anaesthetic causes more incidences of sore throat [10]**.**

Incidence is more in head and neck surgery because on the operation table head is extended and tip of the tube might be moving during surgery. Patients given suxamethonium either as a bolus or by infusion had a significantly higher incidence of sore throat, hoarseness and myalgia postoperatively [11]. According to Higgins PP et al patients with POST had a 14 minute longer stay in the post anaesthesia care unit and a 25 minute longer stay in the ambulatory care unit, and were discharged 51 minutes later from the facility compared with those who did not complain of POST [12].

Measures to reduce POST [13] are use of smaller size endotracheal tube, careful and gentle airway instrumentation, minimizing the duration and number of laryngoscopy attempts, intubation after the full relaxation of the larynx., gentle oropharyngeal suctioning, filling the cuff with an anaesthetic gas mixture, minimizing intracuff pressure<20mmhg.

Pharmacological measures include nebulisation with beclomethasone and fluticasone, gargling with azulene sulfonate, aspirin, ketamine [14], magnesium, benzydamine, green tea [15], hydrochloride and licorice etc, local spray of benzydamine hydrochloride, intracuff administration of alkalized lignocaine [16], steroid gel application on endotracheal tube. Extubation should be done when the tracheal tube is fully deflated with use of video laryngoscope blade [17].

Topical use of dexpanthenol, Amyl-m-cresol lozenges, magnesium lozenges [18] were also beneficial in POST while in severe cases of pain and dysphasia benzydamine hydrochloride is approved for the symptomatic relief [19,20].

Role of aerosolized drugs [21] is more lucrative as they have quick onset of action, low incidence of systemic adverse effects, delivery typically does not cause pain to the patient and require less patient coordination for optimum drug delivery.

Disadvantages of aerosol medications are specific breathing devices required, lower percentage of drug delivered to the site of action plus loss of some drug to the environment. In addition, certain drugs are only available in solution form and cannot be given through a metered-dose or dry powder inhaler.

The present study was conducted to compare the efficiency of preoperative nebulization of magnesium sulphate or lignocaine hydrochloride for reducing the incidence of POST in patients undergoing surgeries under GA. Lignocaine being local anaesthetic may reduce the local nerve irritation and magnesium sulphate being NMDA receptor antagonist was tried as cost-effective method to decrease POST.

METHODS

This was a prospective, randomized, double blinded, case control study entitled as "**Comparative study of Magnesium sulphate nebulization and Lignocaine nebulization in prevention of postoperative sore throat (POST)"** conducted in the department of Anaesthesiology, Government Medical College (GMC), Kota. 100 patients scheduled to undergo elective surgery lasting more than 1 hour but less than three hours under GA requiring tracheal intubation within the age group 40-70 years, of both sexes were randomly allocated in two groups by simple randomization using computer generated numbers. The study was carried out with the approval of hospital research and ethical committee, after obtaining informed consent from patient and their relatives.

The study remains free from being biased as neither the Patients nor the anaesthesiologist who nebulized as well as who anaesthetize and recorded the finding knows about the drug group.

Group A: 50 patients received nebulized magnesium sulphate 4 ml. (6.25%)
Group B: 50 patients received nebulized lignocaine 4 ml. (2%)
Inclusion criteria were Adult normotensive patients, age between 40 to 70 years of both sex undergoing surgery under general anesthesia with tracheal intubation, Mallampatti class 1 and 2, ASA grade I and II.

Exclusion Criteria were Patients allergic to any drugs, ASA grade III & IV, compromising renal function, severe neuromuscular disease, head, neck, or laparoscopic surgery, pts having any upper respiratory tract infection, pts with nasogastric tube or any nasal/throat packs require intraoperatively, pts with anticipated difficult intubation, requiring prone or lithotomy position during surgery, and pt's in whom more than 2 attempts of laryngoscopy were done.

Pre-anaesthesia evaluation included detailed history and physical examination to rule out any systemic diseases like respiratory disease, cardiovascular diseases, neuromuscular diseases, thyroid disease, liver or kidney disease and to know contraindications to drugs and techniques.

The following investigations were done in all the patients as Haemoglobin estimation, Urine examination for albumin, sugar and microscopy, Standard 12-lead electrocardiogram, X-ray chest/Screening of chest, Bl. sugar, Bl. urea, Serum creatinine, Co-agulation profile.

All patients were kept fasting overnight and pre-medicated with oral alprazolam 0.5 mg and ranitidine 150 mg on night before surgery and in the morning of surgery 30 minute prior to the induction of anesthesia, patients in Group A were nebulized with 4 ml of 250 mg isotonic nebulized magnesium sulfate (6.25% solution) for 15 min and Group B were nebulized with 4 ml of 2% lignocaine. Patients nebulized in sitting position through piston type compressor nebulizer. Patients were refrained from eating or drinking during that period, educated to spit out the secretions and advised to take deep inspiration by open mouth.

On arrival of the patient in the operating room after establishing intravenous line with 18-gauge intravenous cannula ringer lactate infusion was started. The patient's head was placed on a soft pillow of 10 cm height with the neck flexed and head extended. The patients were connected to multiparameter monitor to record heart rate, non-invasive SBP, DBP, MAP, $ETCO_2$, continuous ECG tracing and oxygen saturation. After recording baseline parameters, the patient was premedicated with injection midazolam 0.02 mg/kg body weight and oxygenated with 100% oxygen for 3 minutes via a face mask with Bain's circuit.

Anaesthesia was induced with fentanyl 2 mcg/kg and propofol 2 mg/kg. Once an adequate depth of anaesthesia was achieved, patient was paralyzed by giving intravenous succinylcholine 1.5 mg/kg body weight. Intermittent positive pressure ventilation was given with 100% oxygen for 1 minute with tidal volume of 6-8 ml/kg body weight. One minute after mask ventilation, gentle laryngoscopy and intubation was performed by an experienced anaesthesiologist.

Patients requiring intubation for more than 30 second or two attempts for intubation were excluded from the study. Trachea intubated with soft seal cuffed sterile polyvinyl chloride tracheal tube (Sterimed) of 7 to 7.5 mm inner diameter in female with Mcintosh 3 no. blade and 8 to 8.5 mm in male patients with Mcintosh 4 no. blade. The tracheal tube cuff was inflated with air (till slight leakage of air is observed on positive pressure on bag). Proper placement of endotracheal tube was confirmed by bilateral symmetrical chest movements, bilateral equal air entry

on auscultation, square waveform on capnograph, normal end tidal CO_2. The endotracheal tube was secured with adhesive tape.

After assuring the proper placement of endotracheal tube, anaesthesia was maintained with 1% isoflurane and vecuronium bromide 0.08 mg/kg body weight. Ventilation was controlled using Bain's circuit or closed circuit with soda lime in circle absorber using ventilator. The hemodynamic parameters were monitored in the following time interval Basal before premedication, just after intubation, 5 min, and 10 min after intubation and just after extubation.

On completion of surgery, anaesthetic agents were discontinued allowing smooth recovery of consciousness. The muscle relaxation was 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 (immediately after recovery of respiration), and the patients were shifted to post anesthesia care unit.

The primary aim of this study was to evaluate the postoperative sore throat both at rest and on swallowing. The secondary aim was to identify other laryngeal complaints, such as cough, hoarseness of voice, dysphonia and dysphagia. These symptoms were scored by nursing staff not knowing results of study. Sore throat was defined as pain at the larynx or pharynx.

It was asked about any throat pain after operation? Presence of sore throat was noted at rest and on swallowing. Cough was defined as a sudden, strong abdominal contraction while hoarseness as a harsh or stained voice of patients different from his/her normal voice. Presence of sore throat, hoarseness and cough was noted immediately after extubation, 2 hr, 8 hr, and 24 hrs, 48 hrs postoperatively.

In the postoperative ward, patients were also monitored for any drug-related side effects like nausea, vomiting, hypotension, respiratory depression etc.

All recorded data were expressed as mean ± S.D. Unpaired t test was used for numerical data to compare two group. Test of normality (Kolmogorov-Smirnov, Shapiro-Wilk) was done for continuous variables (height, weight, age). Categorical data (gender) was expressed as frequency of occurrence. Comparisons of categorical data between groups were done using Pearson Chi-square, continuity correction, likelihood ratio, ($P< 0.05$) and considered statistically significant. IBM SPSS-21 was used for statistical analysis.

RESULTS

With the level of significance [alpha] = 0.05 and power of 80%, sample size required was 50 per group so 100 patients were taken in two groups. The patients in both the groups were comparable with respect to the distribution of age, height, weight and American Society of Anesthesiologists' physical status. The mean age was 47±7.8 and 47.9±7.8 in group A and group B respectively Majority of patients were male i.e. 54% and 56% in magnesium group and lignocaine group respectively The pre procedural parameters (Mean±SD) of patients of both groups shows that average Pulse Rate, Systolic BP, Diastolic BP, SpO_2 was comparable in both groups and there was no significant difference ($P>0.05$).

On study we found intragroup comparison incidence of POST was more just after extubation in both groups. On intergroup comparison incidence of sore throat was more common in lignocaine group as compared to magnesium group but there was no significant difference in both groups ($P>0.05$).Similar results were obtained on comparison of sore throat on swallowing, hoarseness of voice and cough. Sore throat incidence decreased with time and after 48 hr no symptoms found.Hemodynamic parameter changes were least affected during intubation and extubation in both groups and comparatively better recovery from symptoms of POST in magnesium group.

In magnesium group 2 patients (4%) developed nausea while in lignocaine group 2 patients (4%) developed sedation. We conclude that the side effect profile of the both groups was quite similar and none of the patient had any additional morbidity.

Table 1 showing mean age of patients is 47±7.8 and 47.9±7.8 in group A and group B respectively. Both groups are similar with respect to age distribution ($P>0.05$) and majority are males. Data is analyzed statistically and results are comparable with no significant difference ($P>0.05$). Comparison of mean pulse rate, SBP, DBP in both groups reflect increase more in lignocaine group as compared to magnesium group just after intubation and extubation. There is no significant difference and both groups are similar with respect to mean SpO_2 ($P>0.05$).

Table 1:

TIME		Group A		Group B		P Value	Statistical Significance
		Mean	SD	Mean	SD		
Pulse rate							
Preoperative		81.2	9.25	79	9.4	0.2167	
Intraoperative	1 Min	87.1	8.84	89	9.7	0.2614	P value>0.05
	5 Min	85	11	85	10	0.9770	NS
	10 Min	86	8.8	86	9	0.9463	
Postoperative just after extubation		89.1	8.94	91	8.7	0.3093	
Systolic Blood Pressure (SBP)							
Preoperative		126	7.9	128	7.6	0.1309	
Intraoperative	1 Min	131	6.93	134	7.26	0.0514	P-value>0.05
	5 Min	127	7.3	129	7.7	0.1130	NS
	10 Min	126	6.1	129	6.6	0.0721	
Postoperative just after extubation		129	6.87	132	6.78	0.0819	
Diastolic Blood Pressure (DBP)							
Preoperative		84	7.2	85	10	0.5766	
Intraoperative	1 Min	86.84	7.06	90	9	0.0627	P- value>0.05
	5 Min	82	9	83	8.5	0.6530	NS
	10 Min	82	7.3	83	8.2	0.5222	
Postoperative just after extubation		86.5	8.65	89	8.9	0.1290	
SpO_2 (Saturation of blood) percentage							
Preoperative		98.7	0.93	98	1	0.13	
Intraoperative	1 Min	99.9	0.27	99.9	0.27	0.73	P-value>0.05
	5 Min	99.9	0.27	99.9	0.27	0.73	NS
	10 Min	99.9	0.27	99.9	0.27	0.55	
Postoperative just after extubation		98	0.7	99	1	0.29	

Table 2 shows comparison of sore throat at rest and on swallowing with time interval of just after extubation, 2 hours, 8 hours, 24 hours and 48 hours in both the groups. On intragroup comparison incidence of sore throat was more just after extubation, decreased with time and after 48 hrs no symptom. There was no significant difference in both groups (P>0.05). Comparison of hoarseness of voice and cough in both the groups has similar results with no significant difference (P>0.05).

As shown in table 3 in magnesium group 2 patients (4%) developed nausea, and 2 patients (4%) developed sedation in lignocaine group. We conclude that the side effect profile is quite similar as none of the patient had profound deep sedation or respiratory depression and no additional morbidity. Incidence of side effects is comparable (P >0.05) in both the groups.

DISCUSSION

Post operative sore throat (POST), cough and hoarseness of voice is common, uncomfortable, distressing sequelae after tracheal intubation under GA. It impacts the wellbeing of patients after surgical procedures and leaves the patients with unpleasant memories of surgery. Our study correlated with the study of Herlevsen P et al. (1992) [7] who tested effect of the laryngotracheal lignocaine spray on POST. Various pharmacological and non-pharmacological measures tried in past for attenuating POST like smaller sized tracheal tubes, careful airway instrumentation, minimizing the laryngoscopy attempts and duration, intubation after the full relaxation of the larynx, gentle oropharyngeal suctioning, filling the cuff with an anaesthetic gas mixture, minimizing intracuff pressure <20 mm Hg, extubation when tracheal tube is fully deflated, inhalation

of beclomethasone and fluticasone, gargling with azulene sulfonate, aspirin, ketamine, benzydamine hydrochloride & licorice, local spray of benzydamine hydrochloride, and intracuff administration of alkalized lignocaine.

Table 2:

TIME	Group A		Group B		P-value	Significance
	No. of pts.	Percentage	No.of pts.	Percentage		
Sore throat on Rest						
after extubation	7	14	9	18	0.770	
2hrs	4	8	6	12	0.505	
8 hrs	2	4	5	10	0.239	
24hrs	1	2	2	4	0.557	P value>0.05
48 hrs	0	0	0	0		
Sore throat on swallowing						
after extubation	9	18	12	24	0.624	
2 hrs	5	10	9	18	0.249	
8hrs	3	6	7	14	0.182	
24hrs	2	4	3	6	0.646	P value>0.05
48hrs	0	0	0	0		
Hoarseness of voice						
after extubation	4	8	7	14	0.337	
2 hrs	3	6	6	12	0.294	
8hrs	2	4	3	6	0.646	P-value>0.05
24hrs	0	0	1	2	0.314	
48hrs	0	0	0	0		
Cough						
after extubation	7	14	5	10	0.538	
2 hrs	3	6	4	8	0.695	
8hrs	2	4	3	6	0.646	P-value>0.05
24hrs	1	2	2	4	0.557	
48hrs	0	0	0	0		

Table: 3 Complication and side effect

S. No	Complication	Group A	Group B	Treatment
1.	Hypotension	0	0	NR
2.	Hypertension	0	0	NR
3.	Respiratory Depression	0	0	NR
4.	Oligourea	0	0	NR
5.	Cardiac Arrhythmia	0	0	NR
6.	Flushing/Redness of Skin	0	0	NR
7.	Seizure	0	0	NR
8.	Loss of Deep Tendon Reflex	0	0	NR
9.	Nausea	2	0	Inj.ondansetron 4 mg I.V. stat
10.	Transient Neuropathic Symptoms	0	0	NR
11.	Sedation	0	2	NR
12.	Slurred Speech/Confusion	0	0	NR

David M. Kali et al (2014) [18] used nonsteroidal, local anaesthetic, topical pharmacologic interventions preoperatively to decrease the incidence of POST in adults. They used ketamine, aspirin, azulene, benzydamine gargle or oral spray, dexpanthenol pastilles, and lozenges containing amyl-m-cresol or magnesium and concluded that all the medications decreased the incidence and the severity of POST but ketamine and aspirin gargle are the most effective. Our findings are also comparable to study done by Gupta S. K., Tharwani S. et al (2012) [22]. In their study they concluded severity of POST at rest and on swallowing reduced with magnesium sulphate nebulization.

In our study we used magnesium sulphate nebulization and lignocaine nebulization for reducing postoperative throat complaints. Magnesium acts as a NMDA antagonist and its receptor has role in nociception and inflammation. Lignocaine acts by anti-inflammatory action and reduce local nerve irritation. Both are easily available, cost effective, less side effects and have no long-term residual effects.

We used soft seal cuffed sterile polyvinyl chloride tracheal tube (Sterimed) of 7 to 7.5 mm inner diameter in female and 8 to 8.5 mm in male patients. The incidence of sore throat at rest, on swallowing, hoarseness of voice and cough were more in lignocaine group as compare to magnesium group and more common in female patients. On intragroup comparison incidence decrease with time and 48 hr after extubation there was no complain in both groups and were similar with respect to cough incidence ($P>0.05$)

Endotracheal intubation is associated with presser response and haemodynamic variation. The following hemodynamic parameters were recorded in all patients like heart rate [HR], systolic blood pressure [SBP], diastolic blood pressure [DBP], oxygen saturation [SpO_2] Basal (before premedication) and with time interval of just after intubation, 5 min., 10 min. interval and just after extubation.

Mean pulse rate increased as compared to basal value in both groups but increase was much more in lignocaine group and remained high as compared to magnesium group and remained high up to just after extubation. None of the patients in either groups required any treatment for tachycardia or arrhythmia (pulse rate was never less than 60 bpm). Results suggest that increase in parameters was due to intubation response. Mean oxygen saturation remained constant.

As shown in table 3 in magnesium group 2 (4%) patients developed nausea, and 2 (4%) patients developed sedation in lignocaine group. Hypotension, hypertension, oligourea, seizure, arrhythmias, respiratory depression, flushing of skin, loss of deep tendon reflex, slurring of speech and any other complications were not observed in any patient of either group. Our results indicate that the side effect profile was quite similar as none of the patient in both groups had profound deep sedation or respiratory depression and any additional morbidity.

Besides reducing POST other advantage was stable haemodynamic parameter during endotracheal intubation and extubation in magnesium group. In our study we didn't measure blood concentration of magnesium and lignocaine, to know their systemic side effects and toxicity level.

CONCLUSION

This study compared the nebulization of magnesium sulphate and lignocaine hydrochloride preoperatively to reduce the incidence of postoperative sore throat (POST) following GA. Both drugs can be used for prevention but magnesium sulphate is better than lignocaine. However further study required with large study group and monitoring of blood concentration of drugs.

FINANCIAL ASSISTANCE

Nil

CONFLICT OF INTEREST

The authors declare no conflict of interest

AUTHOR CONTRIBUTION

Gopal Sharma was involved in designing, Conceptualizing, literature search, data acquisition, manuscript editing, and review. Kumar Asnani contributed in literature search and data interpreting. Sanjay Kalyani and Mohit Kumar contributed in manuscript editing and review. The manuscript has been read and approved by all the authors.

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