Original

A Comparison of Two Routes of Magnesium Sulphate Administration for Prevention of Postoperative Sore Throat

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Abstract

Background: Postoperative sore throat (POST) is an undesirable complication after general anaesthesia involving use of endotracheal tubes (ETT). Pharmacological agents via different routes have been used for prevention. This study compared two routes of magnesium sulphate ($MgSO_4$) in reducing its incidence and severity.

Methods: This was a prospective, randomized, double-blind, placebo-controlled study in 84 patients undergoing abdominal surgery under general anaesthesia with tracheal intubation. Patients were randomly allocated into three groups. Group I (n=28) patients were nebulised with 3mls of normal saline (NS) and received 30mg/kg of IV $MgSO_4$ in 50mls of NS. Group II (n=28) patients were nebulised with 225mg (3mls) of isotonic $MgSO_4$ and infused with 50mls of NS. Patients in control group III (n=28) were nebulised with 3mls of NS and infused with 50mls of NS. Postoperatively, incidence and severity of POST were assessed at 0hour, 1hour, 4hours and 24hours using a four-point scale. ETT cuff pressure in all patients was maintained at 25cmH_2O. Descriptive and inferential analysis were conducted using SPSS v.22 and presented as frequencies and percentages.

Results: There were 84 patients with M:F ratio of 1:1.6 and mean age of 35.7±10.9years. Overall incidence of POST was 25(30.1%), but 3(11.1%), 7(25.0%), and 15(53.6%) in Groups I, II and III respectively. Severity was worse in the control group (p=0.002). No statistical difference occurred between nebulised and intravenous Groups (p = 0.324)

Conclusion: Intravenous and nebulised routes of $MgSO_4$ have comparable effects in reducing incidence and severity of POST.

Keywords: Tracheal Intubation, $MgSO_4$, Postoperative Sore Throat.

How to cite this article

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Introduction

Airway maintenance is a crucial part of general anaesthesia, and the period of unconsciousness and Postoperative Sore Throat (POST) is a recognised complication when tracheal tubes are utilised for airway maintenance. Its presence is known to affect the overall patient satisfaction with the anaesthetic experience[1]. POST was rated as the 8th most undesirable complication after general anaesthesia. Defined as pain or discomfort in the larynx or pharynx during the postoperative period, POST could be attributed to the local irritation, inflammation, mucosal dehydration and oedema associated with airway instrumentation and a reduction in the mucosal blood flow in trachea, leading to ischaemic damage.[2] It is commoner in prolonged surgeries and with over inflation of the tracheal tube cuff. Although POST resolves spontaneously, and may not require any treatment, its avoidance is of great importance to patients as it can be irritating and at times distressing. It could potentially increase duration of hospital stay and delay return to routine activities, thereby causing avoidable financial burden on patients. Its prevention is therefore of great importance.

The incidence of POST ranges between 14.4% and 72.5% and is lowest in patients who are managed using face mask and highest in patients with endotracheal intubation.[3]

This wide variation in the incidence of POST can be attributed to various factors including age, sex, surgical site, timing of surgery, choice of anaesthetics, endotracheal tube (ETT) size, ETT cuff design, ETT intracuff pressure, personnel experience, number of attempts at intubation, as well as the assessment tool and methods.[4]

Over the years, non-pharmacological and pharmacological means have been used to reduce the burden of POST. The non- pharmacological methods are simple and include the use of smaller sized tracheal tubes, gentle oropharyngeal suctioning, careful airway instrumentation, minimizing number of laryngoscopy and intubation attempts, intubation after a fully relaxed larynx and minimizing the intracuff pressure to less than 25cmH_2O.
Some of the pharmacological agents used include different forms and routes of lidocaine[4] steroids such as dexamethasone,[5] non-steroidal anti-inflammatory drugs (NSAIDs) such as benzylamine hydrochloride,[6.] N-methyl-D-aspartate (NMDA) receptor antagonists such as ketamine and magnesium sulphate.[7]

Some studies have been done to compare the effectiveness of different agents, but there is paucity of literature in our region that standardised endotracheal tube cuff pressure, analgesic regimen, etc. Different routes of administration of magnesium sulphate for prevention of POST have also not been objectively studied.

Magnesium sulphate is an N-methyl-D-aspartate (NMDA) receptor antagonists that acts on local NMDA receptors and significantly inhibits endotoxin-induced up-regulation of inflammatory molecules,[7] Systemic and local administration has been shown to effectively attenuate the occurrence of airway complications associated with tracheal intubation.[8,9] and This study therefore compared the effectiveness of intravenous and nebulised magnesium sulphate in reducing the incidence of POST and provides evidence-based recommendations on its prevention in our environment.

METHODS

Setting

This study was conducted in the operating theatres, recovery unit, surgical and gynaecology wards of the University of Port Harcourt Teaching Hospital. It is an 850-bedded tertiary centre that has sixteen (16) clinical departments providing both in-patient, out-patient and emergency services.

Design

This was a prospective, randomised, double-blind, placebo-controlled study.

Population/grouping/randomisation

Eighty-four adult patients in the American Society of Anaesthesiologists (ASA) Class I or II, who had abdominal surgery under general anaesthesia with tracheal intubation were studied.
Patients were randomised into three groups: Groups I, II, and III. Groups I & II were the intervention groups and Group III was the control. Each group consisted of 28 patients.
All medications were prepared and administered by a trained Research Assistant. Nebulised medication was administered using Omron nebuliser- NE C28P model prior to induction of anaesthesia, while intravenous medication was administered immediately after

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induction. Patients' randomisation was done by means of folded papers containing any of the three groups and placed in an opaque envelope. The theatre nurse who was not part of the study was asked to pick one of the folded papers, and the content of the paper picked determined which group the patient was allocated.

Sample size calculation
Based on the occurrence of POST in related studies, a sample size was calculated[10] and eighty-four patients (32 males and 52 females) aged 18 – 65 years, who met the inclusion criteria were randomly allocated into three groups using a simple randomisation technique.

Study variables
These included patients' demographic and clinical characteristics as well as the presence and severity of postoperative sore throat.

Intervention
Group I (n = 28) patients were nebulised with 3ml of normal saline **(placebo)** and infused with 30mg/Kg of IV $MgSO_4$ in 50ml of normal saline.
Group II (n = 28) patients were nebulised with 225mg (3ml) of isotonic $MgSO_4$ and infused with 50ml of normal saline (placebo).
Group III (n = 28) patients (control group) were nebulised with 3ml of normal saline (placebo) and infused with 50ml of normal saline (placebo).

Course of Anaesthesia.
Electrocardiography, non-invasive blood pressure, and pulse oximetry were recorded and continuously monitored in all patients throughout anaesthesia and surgery. Anaesthesia was induced with 2mg/kg of intravenous propofol plus 2µg/kg of fentanyl, and tracheal intubation was facilitated with intravenous suxamethonium, 2mg/kg. Females were intubated using size 7mm internal diameter endotracheal tube, while males were intubated using a size 8mm tube. All the endotracheal tubes were lubricated with chlorhexidine gel.[12] Direct laryngoscopy and intubation were performed by the same researcher Thereafter, the endotracheal tube cuff was inflated and maintained at 25cmH_2O using a hand-held cuff manometer (AMBU VBM CE0123 model). The cuff pressure was checked every 30 minutes to ensure a constant intra-cuff pressure.

Anaesthesia was maintained with infusion of 0.025 – 0.2mg/kg/min of propofol and muscle relaxation with 0.1mg/kg of intravenous pancuronium. Intraoperative analgesia was achieved with 0.5 - 1mg/kg of 0.5% plain bupivacaine via epidural catheter which was activated immediately after intubation.

At the end of surgery, the oropharynx was suctioned under direct vision, and anaesthetic agents were discontinued. Reversal of residual neuromuscular blockade was achieved using 10µg/kg of intravenous glycopyrrolate followed by 50µg/kg of intravenous neostigmine. With clinical evidence of adequate reversal and stable vital signs, endotracheal tube was fully deflated, and patient was extubated and subsequently transferred to the post anaesthesia care unit (PACU), where essential monitors were then attached for monitoring of non-invasive blood pressure, pulse rate and oxygen saturation.

Postoperatively, incidence and severity of POST were assessed at 0hour, 1hour, 4hour and 24hour, using a four-point scale proposed by Stout et al.[11] One patient was excluded from Group I (IV $MgSO_4$) because the surgery lasted beyond one hundred and eighty minutes unexpectedly.
The time of arrival in PACU (estimated at about 10minutes post-extubation) was recorded as 0hour and patients were interviewed using a scale of 0 to 3 to determine incidence and severity of POST as proposed by Stout et al.[11]
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 in voice or hoarseness, associated with throat pain).[11]

Data collection
Data was collected using the structured proforma with the study variables itemised in sections.

Data analysis
Data was analysed using Statistical Product and Service Solutions (SPSS) version 22 software. Tables and charts were used to present data as appropriate. Quantitative data such as incidence and duration of postoperative sore throat was presented as frequencies and

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proportions while means and standard deviation were used to summarize quantitative data like body mass index. The Chi-Square test or Fisher's Exact test was used to test for difference in proportions, while the independent t-test was used to test for difference in mean between any two groups. The differences in mean across the three groups was assessed using one-way analysis of variance (ANOVA) test and the Duncan multiple range test (DMRT). In addition to p-values, the effect size was estimated using Cramér's V to assess the strength of association for categorical variables.[13] A p-value of less than or equal to 0.05 was considered statistically significant.

Ethical considerations

Ethical approval was obtained from the research and ethical committee of the University of Port-Harcourt Teaching Hospital, Port Harcourt, Rivers State, and written informed consent was obtained from all the patients after detailed explanation of the study design, goals, and possible complications.

Results

Of the 84 patients recruited, 28 were allocated to each study group. However, 83 patients completed the study as one patient was excluded from Group I because the surgery lasted beyond one hundred and eighty minutes unexpectedly (Figure 1).

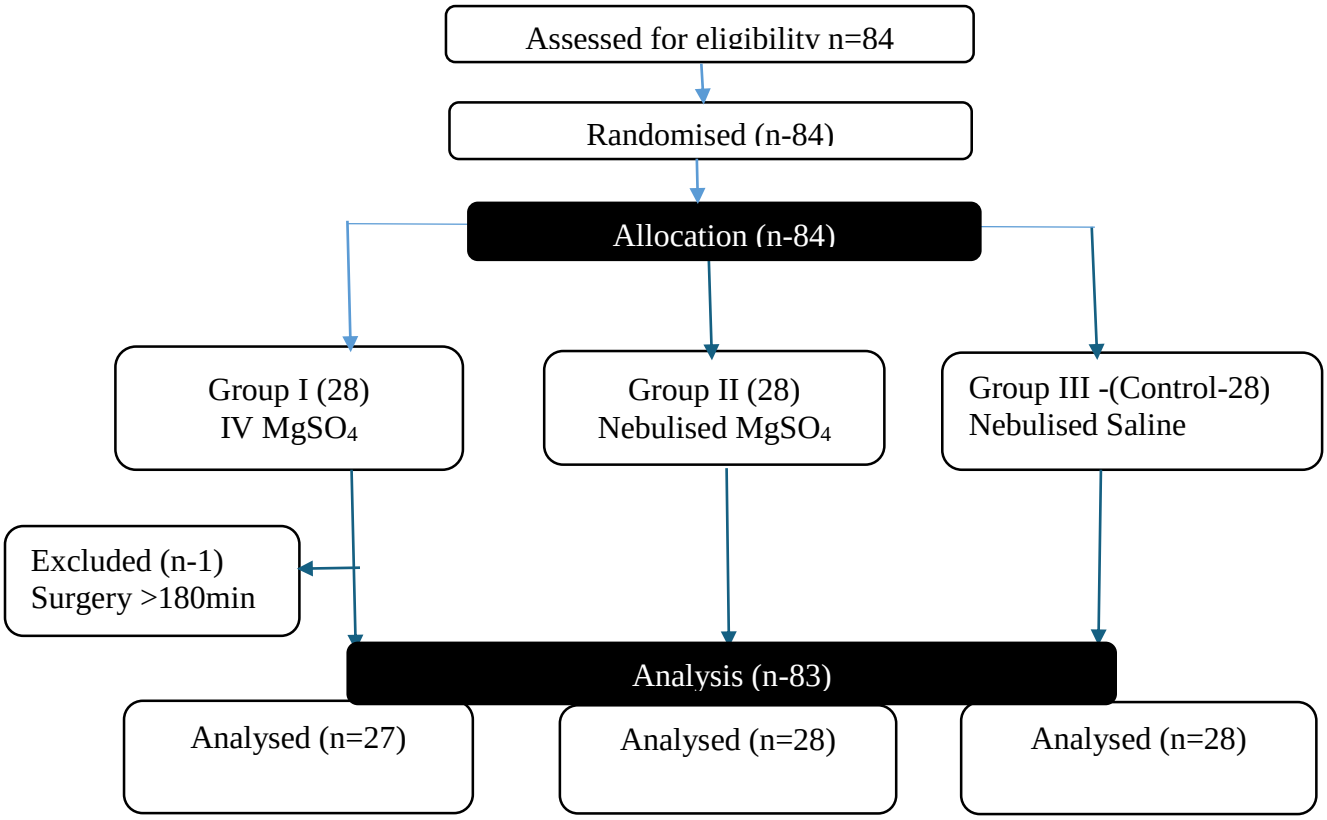

Figure 1: CONSORT Flow Chart of the study.

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The three groups were statistically similar in terms of age, weight, height, BMI, American Society of Anaesthesiologists' (ASA) physical status classification, duration of laryngoscopy, intubation attempts, and duration of surgery (Table 1 and Table 2).

Table 1: Patients Demographic and Clinical Characteristics across Study Groups

Variables	Group 1 (Intravenous) n=27	Group 2 (Nebulised) n=28	Group 3 (Control) n=28	χ^2/ANOVA	p-value
Age in years n(%)					
10-19	1 (3.7)	1 (3.6)	1 (3.6)		
20-29	8 (29.6)	7 (25.0)	12 (42.9)		
30-39	8 (29.6)	9 (32.1)	9 (32.1)	3.70	0.883
40-49	5 (18.5)	7 (25.0)	4 (14.3)		
≥50	5 (18.5)	4 (14.3)	2 (7.1)		
Mean (SD) [Range]	36.25±11.17 [12-54]	37.79±12.03 [19-67]	32.71±9.05 [12-52]	1.62β	0.205
Weight (kg)					
Mean (SD) [Range]	78.49±11.57 [59-105]	76.89±10.41 [58-95]	81.13±11.39 [61-107]	1.04β	0.360
Height (m)					
Mean (SD) [Range]	1.70±0.0412 [1.62-1.79]	1.70±0.036 [1.62-1.76]	1.69±0.048 [1.54-1.75]	0.83β	0.439
BMI					
Mean (SD) [Range]	26.99±3.642 [21.94-37.20]	26.23±2.93 [21.02-31.89]	28.37±4.298 [23.03-41.74]	2.47β	0.091
ASA class n (%)					
1	18 (66.7)	16 (57.1)	13 (46.4)	2.63	0.269
11	9 (33.3)	12 (42.9)	15 (53.6)		

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Table 2: Clinical Characteristics (intraoperative) across Study Groups

Variables	Group 1 (Intravenous) n=27	Group 2 (Nebulised) n=28	Group 3 (Control) n=28	χ^2/ANOVA	p-value
Duration of Laryngoscopy (secs)					
Mean (SD)	17.04±4.96	15.07±3.43	16.18±5.767	1.17$^{\beta}$	0.315
[Range]	[11-30]	[10-24]	[9-35]		
Intubation Attempts n (%)					
1	24 (88.9)	26 (92.9)	25 (89.3)		
2	2 (7.4)	2 (7.1)	3 (10.7)	2.33	0.675
3	1 (3.7)	0 (0.0)	0 (0.0)		
Mean (SD)	1.18±0.47	1.07±0.26	1.10±0.32	0.63$^{\beta}$	0.533
[Range]	[1-3]	[1-2]	[1-2]		
Duration of Surgery (mins)					
Mean (SD)	114.71±31.22	124.57±22.23	117.79±21.16	1.11$^{\beta}$	0.333
[Range]	[70-131]	[76-162]	[75-132]		
Complications n (%)					
Yes	0 (0)	0 (0)	0 (0)		
No	27 (100.0)	28 (100.0)	28 (100.0)		

**Statistically significant (p≤0.05), χ^2 = Ch-Square, Analysis of Variance = ANOVA Test$^{\beta}$*

The incidence of POST was found to be 25 (30.1%) (Table 3). The highest incidence was reported at the immediate postoperative period, where 20 (80.0%) were mild, while 3 (12.0%) and 2 (8.0%) were moderate and severe POST respectively. The incidence was highest in the control group and was found to be statistically significant (P<0.01). For the Relative Risk assessment, Patients who received IV $MgSO_4$ had about 79% lower risk of developing POST compared to controls (p=0.022). Those who received nebulized $MgSO_4$ had about 53% lower risk of POST compared to controls (p=0.045). Cramér's V was calculated to be 0.27, indicating a medium effect size and suggesting a meaningful association between treatment group and POST incidence.

By the 24th hour post extubation, only mild POST was reported in both intravenous and controlled groups with a combined incidence of 4 (4.8%) but no POST was recorded in the nebulized group. (Figure 2). Although there was higher occurrence of POST in the nebulized group compared to the intravenous group (7 vs 3), this was not statistically significant (p = 0.32). Patients who received nebulized $MgSO_4$ had approximately 2.25 times the risk of developing POST compared to those who received IV $MgSO_4$. However, the difference was not statistically significant (p = 0.345). Table 4.

Incidence of POST and BMI was not statistically significant (p = 0.09), with 7 (46.7%) of BMI >30Kg/m^2 (15), 11 (21.7%) of BMI 25.0–29.9Kg/m^2 (46) and 8 (36.4%) of BMI <25Kg/m^2 (22) developing some degree of POST (Figure 3).

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Table 3: Incidence of POST across Intravenous $MgSO_4$, Nebulized $MgSO_4$ and Placebo groups

	Incidence of POST		Total	Fisher's Exact P	Risk (Incidence)	RR (p-value)
	Yes - n (%)	No - n (%)				
Groups I (Intravenous)	3 (11.1)	24 (88.9)	27 (100.0)		3/27=0.111	IV/Ctr=0.21 **(0.022)***
Groups II (Nebulized)	7 (25.0)	21 (75.0)	28 (100.0)	**<0.001***	7/28=0.250	Neb/Ctr=0.47 **(0.045)***
Group III (Placebo)	15 (53.6)	13 (46.4)	28 (100.0)		15/28=0.536	-

**Statistically significant (p≤0.05)*

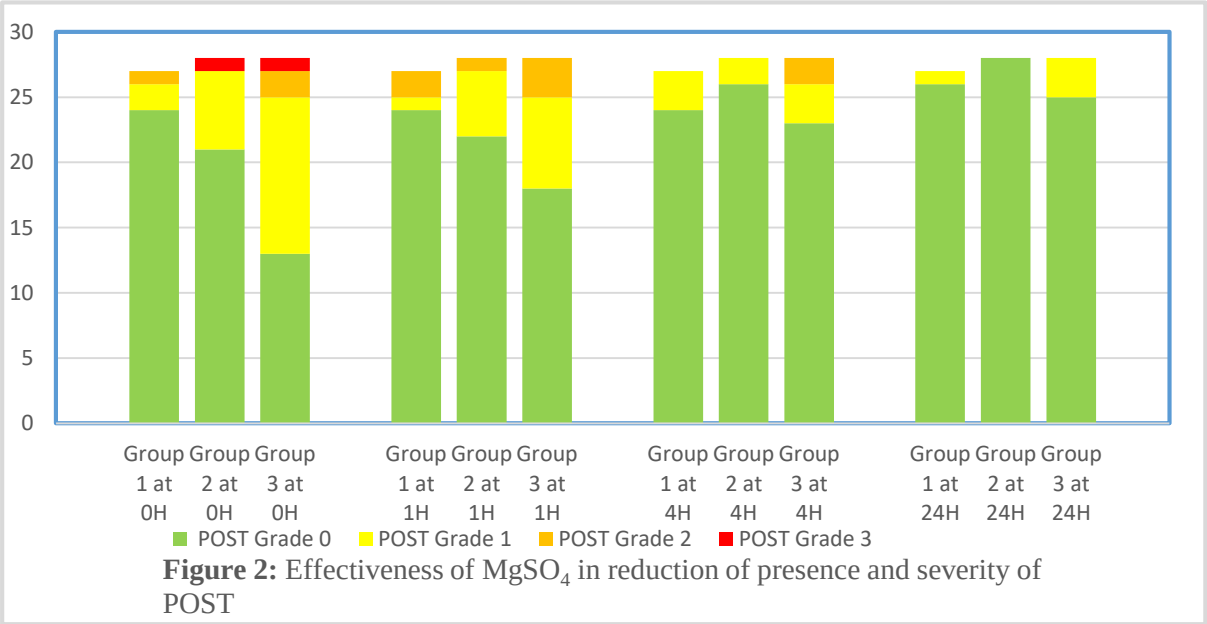

Figure 2: Effectiveness of $MgSO_4$ in reduction of presence and severity of POST

Table 4: Occurrence of POST across Groups 1 (Intravenous) and 2 (Nebulized)

	Incidence of POST		Total	Fisher's Exact P	Risk (Incidence)	RR (p-value)
	Yes - n (%)	No - n (%)				
Groups I (Intravenous)	3 (11.1)	24 (88.9)	27 (100.0)		3/27=0.111	0.250/0.111 =2.25
Groups II (Nebulized)	7 (25.0)	21 (75.0)	28 (100.0)	0.324	7/28=0.250	(0.345)

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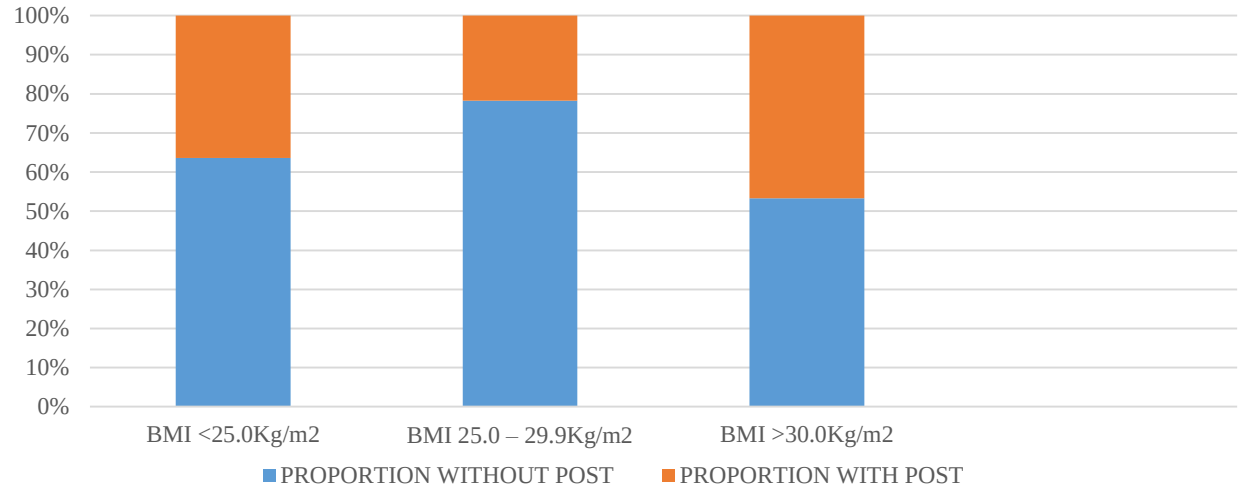

Figure 3: Incidence of POST based on BMI

Discussion

There were no statistically significant differences ($p > 0.05$) in the demographic and clinical parameters across all groups studied. However, magnesium sulphate whether administered intravenously or via nebulization, was shown to statistically reduce the incidence of POST. Similarly, a reduction of severity of POST in the intervention groups was also found.

This outcome supports the studies by Sheikh et al[5] and Chattopadhyay et al[14] which showed that local or intravenously administered magnesium sulphate significantly reduced the presence and severity of POST. Sheikh et al[5] observed that the number of patients who developed POST after receiving intravenous magnesium sulphate was significantly lower compared to those who received placebo (12% v 46% at 24h post extubation). This was higher than what was reported in the index study (3.7% v 10.7%). The routine use of gum elastic bougie for all patients in the study by Sheikh and colleagues could account for this difference. It was also seen in their study that about 50% of patients in the magnesium sulphate group had mild POST, whereas, about 80% of patients in the placebo group had moderate and severe POST. Chattopadhyay and colleagues compared the effect of preoperative gargle of magnesium sulphate and aspirin and found out that magnesium sulphate significantly reduced the incidence and severity of POST. Although,

IV $MgSO_4$ was more effective in reducing the occurrence of POST (RR 79% vs 53% for IV vs Nebulised respectively), no statistically significant difference was found. Therefore, magnesium sulphate via the nebulized and intravenous routes is effective in reducing both the incidence and severity of POST as shown in the present study; Cramér's V having been calculated to be 0.27. {Cramér's V values are interpreted as small effect size - 0.1; medium effect size -0.3; large effect size - ≥ 0.5}.

Systemic and peripherally administered N-methyl-D-aspartate (NMDA) receptor antagonists, like magnesium sulphate, are involved with anti-nociception and anti-inflammatory cascade, by reducing nuclear factor kappa-light-chain-enhancer of activated B-cells activity, and tumor necrosis factor alpha production. It diminishes the expression of inducible nitric oxide synthase, serum C-reactive protein, and interleukins 6 and 10.[15] Nebulisation has been documented as the preferred method of peripheral administration of magnesium sulphate as it ensures that the drug is equally and effectively distributed all over the

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pharynx and upper respiratory tract. It also prevents the user variability when the drug is gargled or administered as lozenges.[16]

The duration of POST reduced steadily across all groups in this study. By the 24th hour, complete resolution of POST was seen in nebulized group, whereas 66.6% resolution was observed in the intravenous group and 80% resolution was seen in the control group (Figure 2). This significant reduction of POST even among the placebo group could be because of maintaining the pilot balloon cuff pressure within the recommended range. This finding was like the report by Ganason et al[17] who compared the effect of pilot balloon cuff monitoring and incidence of POST. They found that 90.38% patients who had their endotracheal tube cuff pressure maintained at 25cmH_2O (like this study) had complete resolution of POST within 24 hours post extubation, and by 48 hours post extubation, no case of POST was reported.

Like the findings in our study, Fenta et al[18] found no direct relationship between BMI and POST even though the risk of throat complications was significantly increased following repeated attempts at intubation of patients with high BMI (Figure 3). Gemechu et al[19] also reported that the number of intubation attempts had a significant association with development of POST. They reported that patients who were intubated after the second attempt were about three times more likely to have POST compared to patients who were intubated at the first attempt. The high incidence of throat complications in obese patients could be due to potential difficult intubation among obese patients, which results in repeated attempts at intubation, and the use of airway adjuncts and intubation aids, thus increasing the risk of airway trauma. On the contrary, Edomwonyi et al[20] reported no significant difference in throat complications following repeated attempts at laryngoscopy, although no reference was made to the BMI of those studied.

Conclusion

This study has compared the effectiveness of magnesium sulphate administered via the intravenous and nebulized routes in reducing the incidence and severity of postoperative sore throat in patients who had general anesthesia with tracheal intubation. There was a statistically significant reduction in incidence of POST in the intervention groups compared to the control group. Although no statistically significant difference was observed between the intravenous and nebulized groups, incidence of POST was lower among the intravenous group. It has also been shown that when magnesium sulphate is administered intravenously or by nebulization, the severity of postoperative sore throat is reduced. It is therefore recommended for use in the prevention of POST.

Authors' Contribution: BA, OTA and UUJ all contributed to the conception and study design, while BA contributed to the data acquisition and analysis. BA and OTA drafted the manuscript, and all authors revised it critically for its intellectual content and approved the final version for publication.

Conflict of interest: *None*

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