

# A randomised, double-blind, comparative study of preoperative magnesium sulphate versus zinc sulphate gargle for prevention of postoperative sore throat following endotracheal intubation

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## ABSTRACT

**Background and Aims:** Magnesium sulphate and zinc sulphate have been reported to attenuate postoperative sore throat (POST). The study aims to compare the effect of preoperative magnesium sulphate and zinc sulphate gargle on the incidence and severity of POST following endotracheal intubation within 24 h. **Methods:** After ethics committee approval, 132 patients were randomly allocated to three groups (M, Z and D). Fifteen minutes before laryngoscopy and tracheal intubation, patients assigned to groups M and Z received a solution for gargle containing magnesium sulphate 20 mg/kg and zinc sulphate containing 40 mg of elemental zinc dissolved in 20 ml of 5% dextrose solution, respectively. Group D received 20 ml of 5% dextrose solution. Incidence and severity of POST (4-point score: Grade 0- no sore throat, Grade 1- mild sore throat, Grade 2- moderate sore throat, Grade 3- severe sore throat) was assessed for 24 h after extubation. Statistica, Version 8.0 (StatSoft, Inc., Tulsa, Oklahoma, USA) was used for analysing the data. **Results:** The lowest incidence of POST in group M was 13.6% (95% confidence interval [CI] 3.5–23.7) compared to 0% in group Z, whereas the highest incidence recorded in group M was 25% (95% CI 12.2–37.7) in contrast to 13.6% (95% CI 3.5–23.7) in group Z during the first 24 h after operation. It was observed that the incidence of mild POST (POST score 1) was significantly lower ( $P < 0.05$ ) in group Z compared to group M in the first 4 h postoperatively. **Conclusion:** Zinc sulphate gargle before laryngoscopy and tracheal intubation is more effective for reducing the incidence of POST than magnesium sulphate gargle.

**Keywords:** Anaesthesia, general, intratracheal, intubation, laryngoscopy, magnesium, postoperative sore throat, zinc

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## INTRODUCTION

There has been a significant improvement in tracheal intubation techniques over the last few decades, but sore throat after endotracheal intubation is still a concern. In a recent study, postoperative sore throat (POST) was the second most common minor problem after general anaesthesia (GA). The incidence of POST following endotracheal intubation ranges from 20% to 74%.<sup>[1]</sup>

Magnesium sulphate is an N-methyl-d-aspartate (NMDA) receptor antagonist with anti-inflammatory and local analgesic effects. Magnesium sulphate in

the dose range of 225 mg to more than 1 g has been administered as gargles or lozenges before tracheal intubation to attenuate the incidence of POST.<sup>[2]</sup> Recently, zinc sulphate lozenges and tablets containing

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elemental zinc 40 mg have succeeded in decreasing the incidence of POST because of their effect on wound healing and epithelial tissue health.<sup>[3,4]</sup> There is no study to date comparing these two agents.

In the present study, we have compared the efficacy of preoperative magnesium sulphate (20 mg/kg) and zinc sulphate (containing 40 mg of elemental zinc) gargling to prevent POST. We hypothesised that there is no difference in the incidence of POST with magnesium sulphate and zinc sulphate gargle. The study's primary objective was to compare the incidence of POST following preoperative gargle with magnesium and zinc sulphate. The secondary objective was to compare the severity of POST.

## METHODS

After obtaining approval from the institutional ethical committee (vide approval number MMC/IEC-2019/193 dated 28 January 2019) and trial registration at Clinical Trials Registry-India (CTRI/2019/04/018724, www.ctri.nic.in), enrolment of patients for the study was started. Written informed consent was obtained from patients to participate in the study and use the patient data for research and educational purposes. This randomised, double-blinded, controlled study was conducted over 12 months (from July 2019 to June 2020) in accordance with the principles of the Declaration of Helsinki, 2013.

Patients of both genders with American Society of Anesthesiologists (ASA) physical status I and II, aged between 18 and 65 years, undergoing elective laparoscopic cholecystectomy under general anaesthesia (GA) with endotracheal intubation, were enrolled in the study. Patients having a chronic cough, sore throat or allergy to the study drugs were not included in the present study. Patients requiring introduction of nasogastric or orogastric tube or throat pack in the perioperative period (within 24 h of surgery), having a history of difficult intubation, and with difficult intubation requiring more than one attempt and presence of a blood-stained tracheal tube on extubation were excluded from the study. Patients with a duration of anaesthesia exceeding 2 h, body mass index (BMI) >30 kg/m<sup>2</sup>, and pregnant and lactating mothers were also excluded.

Randomisation was done using the software randomizer.org. The allocation concealment was ensured using 132 sequentially numbered, opaque,

sealed envelopes containing numbers 1–132. The patient was allocated to the group according to the envelope number.

Patients in group M received magnesium sulphate solution (20 mg/kg dissolved in 20 ml of 5% dextrose solution). Those in group Z received zinc sulphate solution (containing 40 mg of elemental zinc dissolved in 20 ml of 5% dextrose solution), and group D patients were given 20 ml of 5% dextrose. An additional 5 g of anhydrous dextrose (a simple carbohydrate purified and crystallised D-glucose) was added to all solutions to make the taste similar. Patients were asked to gargle with this mixture for 30 s, 15 min before induction of anaesthesia. Preparation of solution according to the group to which the patient belongs was done by an anaesthesiologist who was not involved in the study. The solution for gargling was prepared in a disposable transparent glass wrapped with coloured, non-transparent paper to ensure blinding. Monitoring of patients and data collection was done by an anaesthesiologist who needed to be made unaware of the patient allocation in the study groups to ensure double-blinding.

Standard intraoperative monitors were attached in the operative room, and baseline parameters were recorded. Pre-oxygenation with 100% oxygen for 5 min was done. Intravenous (IV) fentanyl (2 µg/kg) and glycopyrrolate (4 µg/kg) were administered 3 min before induction of anaesthesia. Anaesthesia was induced with IV propofol 2 mg/kg, and IV atracurium 0.5 mg/kg was administered to facilitate endotracheal intubation. Three minutes after administration of atracurium, ensuring maximum neuromuscular blocking effect by a train-of-four (TOF) guard count zero, laryngoscopy was done by a Macintosh laryngoscope and the trachea was intubated. A soft seal cuffed, sterile polyvinyl chloride endotracheal tube (ETT) (Romsons Prime Pvt. Ltd., Delhi, India), made of thermosensitive material with polyurethane cuff conforming to F29 standards, was used for intubation with an internal diameter of 7 mm for female and 8 mm for male. ETT cuff was inflated with sterile water till no air leakage could be heard with a peak airway pressure of 20 cm H<sub>2</sub>O. All the patients received IV paracetamol 1 g 10 min after endotracheal intubation. Maintenance of anaesthesia was done with inhalational isoflurane 0.8% and nitrous oxide: oxygen (60:40) with a fresh gas flow of 6 l/min using a circle system and fresh soda lime. Respiratory rate (RR) and tidal volume were adjusted to keep end-tidal carbon dioxide (EtCO<sub>2</sub>) within the acceptable range (30–40 mmHg). IV atracurium

boluses of 0.1 mg/kg were repeated when the TOF count was two or more.

An experienced anaesthesiologist with at least 3 years of experience after post-graduation performed laryngoscopy and tracheal intubation. The duration of laryngoscopy was described as the time from laryngoscope insertion into the oral cavity to the time when ETT was inserted into the trachea. Electrocardiogram (lead II), heart rate (HR), oxygen saturation (SpO<sub>2</sub>), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), EtCO<sub>2</sub>, RR and temperature were recorded throughout the operative procedure. Routine intraoperative nasogastric or orogastric tube was not inserted.

After completion of the surgery, the residual neuromuscular blockade was reversed with IV neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg, and the trachea was extubated after establishing adequate spontaneous ventilation (more than 6 ml/kg), return of airway reflexes and observing TOF count of four. Oropharyngeal suctioning was done gently with direct superficial laryngoscopy to avoid tissue injury before extubation. Duration of surgery was defined as the time from induction of anaesthesia with propofol to the time of tracheal extubation. In the postoperative period, all patients received ondansetron 4 mg IV every 8 h after extubation. Patients complaining of visual analogue scale (VAS) score  $\geq 4$  received IV paracetamol 1 g.

POST was graded on a 4-point scale (0–3) as follows: Grade 0- no sore throat, Grade 1- mild sore throat (complains only when asked), Grade 2- moderate sore throat (complains on their own without asking), Grade 3- severe sore throat (voice change, hoarseness or throat pain).<sup>[3]</sup> The patients were enquired about POST on arrival to the post-anaesthesia care unit (0 h) and then at half-hour intervals for 2 h by an anaesthesiologist (blinded investigator) unaware of the group allocation. After 2h, the POST score was assessed at 4 h, 6 h, 12 h and 24 h. HR, SBP, DBP, MAP, SpO<sub>2</sub> and RR were recorded simultaneously. Postoperative pain was also recorded by VAS (0–10 cm; 0 cm = no pain, 10 cm = worst pain imaginable) at the time of assessment of POST. The patient's sedation was also recorded using the Ramsay Sedation Scale simultaneously. Other side effects in the postoperative period, like postoperative nausea and vomiting (PONV), were also noted.

The sample size was calculated assuming a POST incidence of 60% (P1).<sup>[1]</sup> No previous study has compared zinc sulphate with magnesium sulphate, and earlier studies on magnesium sulphate for reduction of POST documented variation in the result, so a pilot study was conducted on nine patients. A decrease of 20% at 6 h after extubation (P2) in the incidence of POST was accepted to be significant to reject the null hypothesis. Assuming type I error of 5% (0.05) and the power of the study to be 95%, in each group, the sample size was calculated using the formula  $n = 2 (Z\alpha + Z [1-\beta])^2 \times p \times q/d^2$ .<sup>[5]</sup> In this formula, P1 = 60%, P2 = 20%, effect size (d) = 40%. Average of P1 and P2 was  $p = P1 + P2/2$ ,  $60 + 20/2 = 40$ .  $q = 1 - p = 1-40 = 60\%$ . Sample size  $n = 2 (1.96 + 1.64)^2 \times 40 \times 60/(40)^2 = 39$ . The number of patients required in each group was estimated to be 40. Assuming a 10% possible loss to follow-up, the sample size in each group was calculated to be 44 patients per group.

For statistical analysis, data were entered in a Microsoft Excel chart. Statistica, Version 8.0 (StatSoft, Inc., Tulsa, Oklahoma, USA) and GraphPad Prism version 5 (San Diego, California, USA) were used for analysing the data. When three groups were compared, one way analysis of variance test was used for age, weight, sex, duration of laryngoscopy, duration of anaesthesia and incidence of POST at different times. Chi-square test was applied to compare the POST incidence between two groups. The difference between the groups was considered statistically significant when the *P* value was less than 0.05.

## RESULTS

One hundred and fifty patients were screened for eligibility for the study; 132 patients were recruited after exclusion of patients who were not found to be eligible for the study [Figure 1]. The groups were comparable in terms of weight, height, age, duration of laryngoscopy and anaesthesia ( $P > 0.05$ ) [Table 1].

In 24 h, the lowest incidence of POST recorded in group Z was 0% compared to 13.6% (95% confidence interval [CI] 3.5–23.7) in group M, whereas the highest incidence of POST in group Z was 13.6% (95% CI 3.5–23.7) in contrast to 25% (95% CI 12.2–37.7) in group M during the first 24 h after the operation. The incidence of POST was significantly lower in group Z compared to group M in the first 12 h postoperatively ( $P < 0.05$ ). The highest and lowest

incidences of POST recorded in group D were 56.8% (95% CI 42.1–71.5) and 40.9% (95% CI 26.3–55.4), respectively. The POST incidence was significantly higher throughout the study period in group D compared to the other two groups ( $P < 0.05$ ) [Table 2].

The incidence of mild POST (POST score 1) was significantly lower ( $P < 0.05$ ) in group Z compared to group M and group D in the first 4 h [Table 3]. However, when moderate cases of POST (POST score 2) were compared, it was observed that there was no significant difference between groups Z and M throughout the study period ( $P > 0.05$ ). The incidence of moderate POST (POST score 2) was significantly higher in group D compared to other groups ( $P < 0.05$ ) [Table 3]. No severe POST was recorded in groups M and Z, but four cases of severe POST were reported in group D.

No significant difference was detected among the study groups regarding HR, SBP, DBP, MAP, RR and SpO<sub>2</sub> during the study period ( $P > 0.05$ ). Ramsay

sedation score ( $P = 0.371$ ), VAS score ( $P = 0.35$ ) and the incidence of PONV ( $P = 0.38$ ) were comparable among the groups. Consumption of analgesic (paracetamol) was comparable among the groups ( $P = 0.78$ ). No other severe adverse effect was recorded in any patient.

## DISCUSSION

In the present study, the incidence of POST was significantly less in the zinc sulphate group compared to the magnesium sulphate group in the first 24 h. The incidence of mild POST (POST score 1) was also

Table 1: Demographic profile

	Group M (n=44)	Group Z (n=44)	Group D (n=44)
Age (years)	37.4 (12.4)	34.5 (12.5)	35.4 (12.8)
Weight (kg)	60.6 (8.2)	58.8 (6.9)	59.7 (7.4)
Gender (Male/Female)	21/23	20/24	21/23
Duration of laryngoscopy (s)	12.7 (0.9)	12.8 (0.8)	12.9 (0.9)
Duration of anaesthesia (min)	87.2 (16.6)	89.0 (15.8)	88.6 (15.7)

Data are expressed as mean (standard deviation) or numbers. Group M=magnesium sulphate gargle, Group Z=zinc sulphate gargle, Group D=5% dextrose gargle

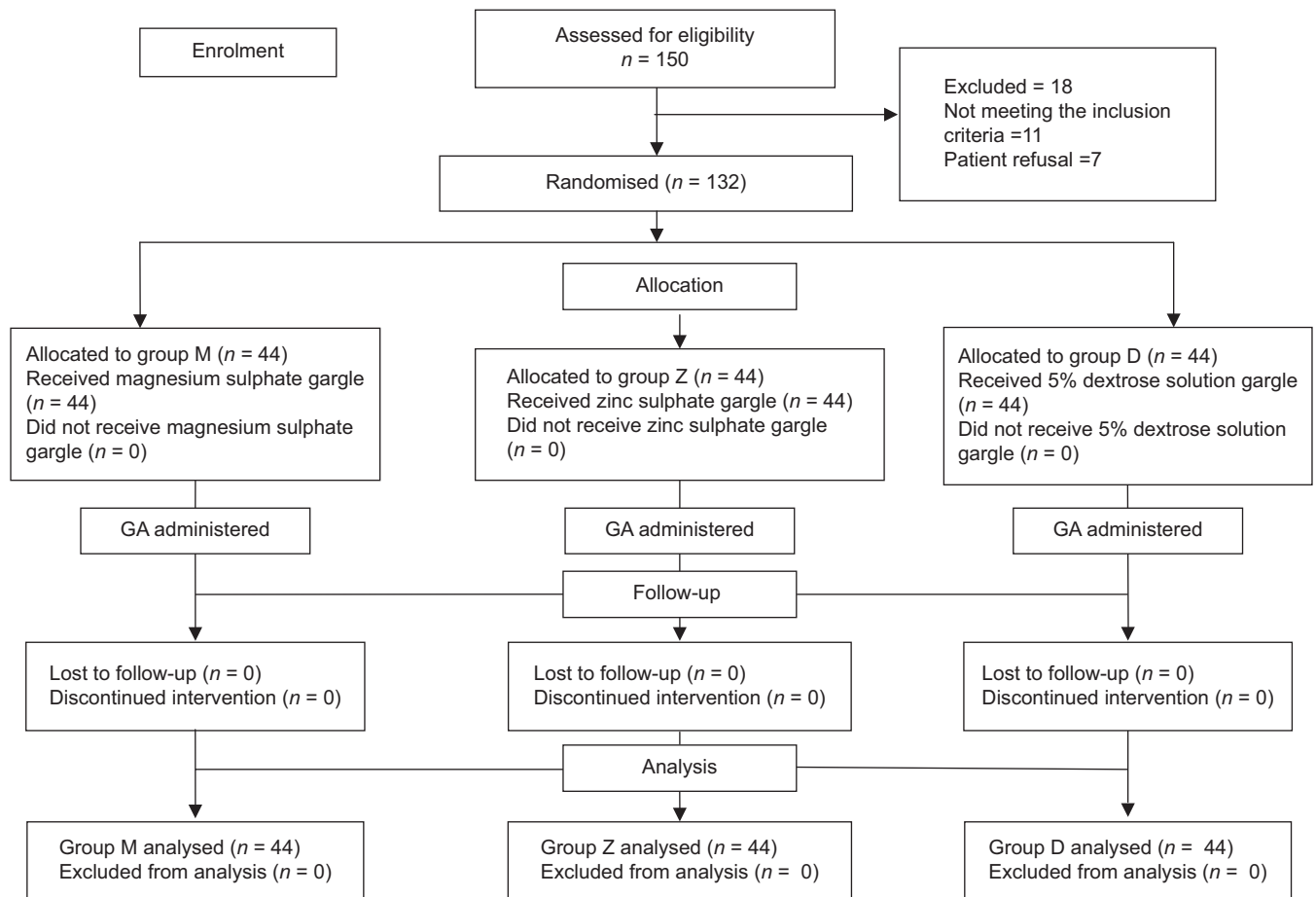


Figure 1: CONSORT 2010 flow diagram showing patient disposal in the study. Group M = magnesium sulphate gargle, Group Z = zinc sulphate gargle, Group D = 5% dextrose gargle. CONSORT = Consolidated Standards of Reporting Trials, GA = general anaesthesia

Table 2: Incidence of POST at different time intervals

Time (h after extubation)	Group M % (95%CI)	Group Z % (95%CI)	Group D % (95%CI)	P
0	13.6 (3.5–23.7)	0	56.8 (42.1–71.5)	0.001*
0.5	15.9 (5.1–26.7)	0	54.5 (39.8–69.2)	0.001*
1	15.9 (5.1–26.7)	0	54.5 (39.8–69.2)	0.001*
1.5	20.5 (8.5–32.3)	0	56.8 (42.1–71.5)	0.001*
2	25 (12.2–37.7)	4.5 (0–10.7)	54.5 (39.8–69.2)	0.001*
4	25 (12.2–37.7)	6.8 (0–14.2)	50 (35.2–64.7)	0.001*
6	22.7 (10.3–35.1)	6.8 (0–14.2)	52.3 (37.5–67)	0.001*
12	22.7 (10.3–35.1)	9.1 (0.6–17.5)	47.7 (32.9–62.4)	0.001*
24	18.2 (6.7–29.5)	13.6 (3.5–23.7)	40.9 (26.3–55.4)	0.001* 0.249#

Group M=magnesium sulphate gargle, Group Z=zinc sulphate gargle, Group D=5% dextrose gargle. \*One-way ANOVA. #Chi-square value, group M versus Z. ANOVA=analysis of variance, CI=confidence interval, POST=postoperative sore throat

Table 3: Comparison of mild and moderate POST among the groups

Time (h after extubation)	Group M % (95%CI)	Group Z % (95%CI)	Group D % (95%CI)	P
<b>Mild POST (POST score 1)</b>				
0	1.4 (1.9–20.7)	0	29.5 (16–43)	0.03*
0.5	13.6 (3.5–23.7)	0	29.5 (16–43)	0.01*
1	13.6 (3.5–23.7)	0	27.3 (14.1–40.4)	0.01*
1.5	15.9 (5.1–26.7)	0	27.3 (14.1–40.4)	0.009*
2	18.2 (6.7–29.5)	4.5 (0–10.7)	31.8 (18–45.5)	0.04*
4	18.2 (6.7–29.5)	4.5 (0–10.7)	25 (12.2–37.7)	0.04*
6	15.9 (5.1–26.7)	4.5 (0–10.7)	25 (12.2–37.7)	0.07*
12	20.5 (8.5–32.3)	9.1 (0.6–17.5)	22.7 (10.3–35.1)	0.07* 0.11#
24	18.2 (6.7–29.5)	13.6 (3.5–23.7)	20.5 (8.5–32.3)	0.38*
<b>Moderate POST (POST score 2)</b>				
0	2.27 (0–6.6)	0	18.18 (6.7–29.5)	0.004* 0.49@
0.5	2.27 (0–6.6)	0	15.9 (5.1–26.7)	0.009* 0.49@
1	2.27 (0–6.6)	0	18.2 (6.7–29.5)	0.004* 0.49@
1.5	4.54 (0–10.7)	0	20.5 (8.5–32.3)	0.001* 0.23@
2	6.81 (0–14.2)	0	15.9 (5.1–26.7)	0.009* 0.12@
4	6.81 (0–14.2)	2.3 (0–6.6)	18.9 (6.7–29.5)	0.01* 0.12@
6	6.81 (0–14.2)	2.3 (0–6.6)	20.5 (8.5–32.3)	0.009* 0.12@
12	2.3 (0–6.6)	0	20.5 (8.5–32.3)	0.009* 0.49@
24	0	0	20.5 (8.5–32.3)	0.001*

Group M=magnesium sulphate gargle, Group Z=zinc sulphate gargle, Group D=5% dextrose gargle. \*One way-ANOVA. @Chi-square test value group M versus D. @Chi-square test group M versus Z. ANOVA=analysis of variance, CI=confidence interval, POST=postoperative sore throat

substantially lower in the zinc group in the first 4 h compared to the magnesium group. Regarding moderate POST (POST score 2), no significant difference was observed between the zinc and magnesium groups in the first 24 h. The incidence of mild, moderate and severe POST was significantly less in the zinc and magnesium groups than in the placebo group.

Our observation with magnesium sulphate gargle was similar to previous studies with magnesium lozenges, gargle and nebulisation, compared to the control group.<sup>[2]</sup> Farhang and Grondin<sup>[3]</sup> and Sarkar and Mandal<sup>[4]</sup> observed a 2%–9% incidence of mild POST with zinc sulphate, comparable to the present study. The incidence of mild POST at 24 h in our study was



13%, compared to 12% and 15% reported in previous studies with zinc sulphate.<sup>[3,4]</sup> Moderate POST after zinc sulphate gargle between the second and fourth hours in the present study was 2%, compared to 2%–6% in previous studies.<sup>[3,4]</sup> Previous studies have not recorded any incidence of moderate POST at 24 h after using zinc sulphate, similar to the present study.<sup>[3,4]</sup> In the present study, mild and moderate POST incidence in the control group was similar to that reported in previous studies.<sup>[2-4]</sup>

POST may cause mild discomfort to pharyngitis, laryngitis and tracheitis, leading to hoarseness of voice, cough or dysphagia.<sup>[1]</sup> Though the POST mechanism is still unclear, it seems logical that it results from the injury to mucosa due to airway instrumentation, ultimately leading to inflammation. Vigorous oropharyngeal suctioning and tracheal ischaemia due to the pressure of the ETT cuff may also lead to mucosal dehydration or oedema. Mucosal injury from the friction between ETT and tissue may be another factor contributing to POST.<sup>[6]</sup>

Multiple pharmacological and non-pharmacological methods have been tried to reduce the incidence of POST, but with unpredictable success.<sup>[6]</sup> The smaller diameter of ETT, lubrication with water-soluble jelly, design of the cuff and reduced cuff pressure effectively lower POST. Gentle laryngoscopy, intubation and gentle oropharyngeal suctioning have been reported to lower the occurrence of POST.<sup>[6]</sup> Extubation, when the ETT cuff is completely deflated, is also effective in preventing POST.<sup>[6,7]</sup> Various pharmacological agents such as local anaesthetics, steroids, opioids, nonsteroidal anti-inflammatory drugs, ketamine and  $\alpha_2$  agonists were used to reduce the incidence of POST following GA.<sup>[8-10]</sup>

Inhibition of calcium entry into the cell and blockade of N-methyl-D-aspartate-type glutamate receptors are primarily responsible for the anti-nociceptive effect of magnesium. Anti-inflammatory and anti-nociceptive actions of magnesium after local application were reported from previous studies, and existing data suggest that magnesium may have a strong potential in the reduction of POST.<sup>[11]</sup> Zinc, as a topical agent to promote epithelial health and recovery after injury, has been reported for a long time. There are several studies on the action of zinc on wound healing and improving the health of epithelial tissue.<sup>[12]</sup> It is observed that zinc increases re-epithelialisation and decreases bacterial activity, resulting in rapid wound healing.<sup>[4]</sup>

We used a zinc sulphate tablet containing 40 mg of elemental zinc in the present study. Previous studies by Farhang and Grondin<sup>[3]</sup> and Sarkar and Mandal<sup>[4]</sup> have also used the same amount of elemental zinc as mouth-dispersible tablet 30 min before operation. A meta-analysis shows previous studies have used a 20 mg/kg magnesium sulphate solution for gargling, similar to our research.<sup>[2]</sup> Several studies with magnesium have used nebulisation. However, nebulisers may only be available in some setups, and lozenges are yet to be marketed, so we have opted for the feasible gargling method in all setups.<sup>[2]</sup>

ETT cuff pressure is one of the major determinant factors contributing to POST. Evidence suggests that limiting the ETT cuff pressures will decrease the incidence of POST.<sup>[1,6]</sup> So, we modified our study to use sterile water instead of air to inflate the cuff of ETT since diffusion of nitrous oxide into the cuff leads to a rise in cuff pressure and may increase the incidence of POST.

The present study has limitations. Here, the equivalent dose of zinc sulphate and magnesium sulphate was unknown, a cuff pressure monitor was not used, and a fixed dose of zinc was used in the zinc sulphate group. The application of our findings in difficult airway situations needs to be verified by future studies. Results may differ with a different preparation of study drugs (lozenges or nebulisation) or in other study populations (e.g. paediatric, geriatric, airway surgery, etc.) excluded in the current study.

## CONCLUSION

The incidence of POST was significantly less in the first 12 h after preoperative gargle with zinc sulphate than with magnesium sulphate. The incidence of mild POST was less in the zinc sulphate group compared to the magnesium sulphate group.

### Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared upon request.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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