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Original Article

Anaesthesia Section

# Comparison of Preoperative Magnesium Sulphate and Budesonide Nebulisation in Reducing the Incidence and Severity of Postoperative Sore Throat- A Randomised Controlled Study

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## ABSTRACT

**Introduction:** General anaesthesia with endotracheal intubation, being one of the most commonly performed procedures in clinical anaesthesiology, is not without adverse effects. Postoperative Sore Throat (POST) is one of the common adverse effects with a varying incidence. Prophylactic management of POST is recommended to improve the quality of postanaesthesia care and recovery.

**Aim:** To evaluate the effectiveness of preoperative nebulisation with magnesium sulphate and budesonide in reducing the incidence and severity of POST.

**Materials and Methods:** This randomised double-blinded control study was conducted in the Department of Anaesthesiology at Jawaharlal Nehru Institute of Medical Sciences, Imphal, Manipur, India, from September 2020 to December 2021. The study included 120 patients, of either sex, aged between 20-60 years with American Society of Anesthesiologists (ASA) grade I and II posted for elective surgery requiring general anaesthesia with endotracheal intubation. The patients were randomly divided into three groups of 40 patients each. Group M was nebulised with 250 mg magnesium sulphate, Group B with 250 mcg budesonide and Group S was nebulised with normal saline, 15 minutes prior to the induction of anaesthesia. Incidence and severity of POST was documented at 0 hr, 2 hrs, 24 hrs and 48 hrs postextubation on a 0-3 score. Data collected was analysed using Statistical Package for Social Sciences (SPSS) version 22.0 and the results were then statistically analysed using Analysis of Variance (ANOVA) and Chi-square test.

**Results:** The incidence of POST was more in saline group when compared with budesonide and magnesium sulphate group at all points of observation (0 hr, 2 hrs, 24 hrs and 48 hrs). The severity of POST was moderate in saline group while the other two groups experienced mild severity. This was statistically significant at 0 hr, 2 hrs and 24 hrs (p-value <0.05). But at 48 hrs severity of POST among the three groups was not significant.

**Conclusion:** Preoperative nebulisation with magnesium sulphate and budesonide significantly reduces the incidence and severity of postoperative sore throat.


**Keywords:** Endotracheal intubation, General anaesthesia, Prophylaxis

## INTRODUCTION

Postoperative Sore Throat (POST) is a common sequela after endotracheal intubation and is ranked as the 8th most undesirable outcome after general anaesthesia by the American Society of Anaesthesiologists (ASA) [1]. POST hampers patient's recovery from anaesthesia and delays the patient's return to normal routine activities. The primary aetiological factor implicated in this problem is the use of airway instrumentation which commonly includes direct laryngoscopy and the Endotracheal Tube (ETT). The process of airway instrumentation leads to mucosal injury causing inflammation of the airway, mucosal dehydration and mucosal oedema which gives rise to the various signs and symptoms of POST comprising of pain and discomfort in the throat, hoarseness, cough, difficulty in swallowing and even difficulty in breathing. Several studies have also identified certain risk factors for the development of POST which include age, female gender, smoking, prolonged duration of anaesthesia, large sized ETT, pre-existing upper respiratory tract infection, lack of humidified air in the anaesthesia delivery system, and use of high flow anaesthetic mixture [2,3].

Both pharmacological and non pharmacological methods have been studied for the prophylactic management of POST. The non pharmacological methods include use of smaller sized ETT, smooth and gentle laryngoscopy and intubation, gentle oropharyngeal suctioning, minimising intracuff pressure, intubation after full relaxation and extubation with fully deflated tracheal cuff [4]. Pharmacological methods include use of steroids like dexamethasone and betamethasone, local anaesthetics like lignocaine, Non Steroidal Anti-Inflammatory Drugs (NSAIDs), zinc lozenges, N-Methyl D-Aspartate (NMDA) antagonists like ketamine [5].

Experimental data have shown the role of NMDA receptors in central and peripheral nociception [6]. The role of NMDA receptor antagonists in reducing POST is gaining popularity. Magnesium sulphate, being an NMDA receptor antagonist, thus have a potential role in reducing POST. Steroids, by virtue of their anti-inflammatory action, have also been found to have a beneficial effect in reducing POST. Budesonide has potent local anti-inflammatory properties and its usefulness in prevention of POST has been investigated with promising results when administered before induction of anaesthesia through oxygen driven atomizing inhalation [7]. Effectiveness of preoperative inhaled magnesium sulphate versus inhaled budesonide for prevention of postoperative sore throat, cough and hoarseness of voice after oral endotracheal intubation studied by Kotb MM et al., concluded that preoperative budesonide and magnesium sulphate inhalation significantly decreased the incidence of POST. The study was, however, conducted among patients who were smokers [8].

As far as authors knowledge is concerned, there is no study which compared these drugs among normal patients for the prevention of POST. The hypothesis was that preoperative nebulisation with magnesium and budesonide will decrease the incidence and severity of POST as compared to placebo with normal saline. With the consideration, role of magnesium sulphate as an NMDA antagonist

and budesonide as a steroid in the prevention of POST, the present study aimed to compare the efficacy of preoperative nebulisation with magnesium sulphate and budesonide in reducing the incidence and severity of postoperative sore throat.

## MATERIALS AND METHODS

The randomised double-blinded control study was conducted in the Department of Anaesthesiology, Jawaharlal Nehru Institute of Medical Sciences, Imphal, Manipur, India, from September 2020 to December 2021. The ethical clearance was obtained from the Institute of Ethical Clearance {Letter No. Ac/06/IEC/JNIMS/2018 (PGT). CTRI/2021/03/032191}. A written informed consent was taken from all the participants and the procedure was fully explained.

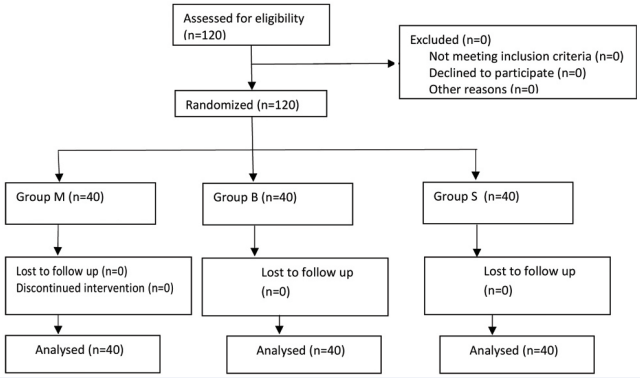
**Sample size calculation:** The sample size was calculated with alpha value of 0.05 and power of 80% and treatment effect size of 36.7% [5]. The calculated sample size was 35 per group. To accommodate any exclusion, 40 patients for each group were selected. So, a total of 120 patients were selected for the study.

**Inclusion criteria:** A total of 120 patients, aged between 20-60 years, of either sex, belonging to American Society of Anesthesiologists (ASA) grade I or II and undergoing elective surgery in supine position under general anaesthesia with endotracheal intubation were included for the study.

**Exclusion criteria:** Patients with pre-existing sore throat, upper respiratory tract infection, Chronic Obstructive Pulmonary Disease (COPD) or asthma, Mallampati score more than II, and those undergoing oral or nasal surgeries were excluded from the study. Patients requiring more than one attempt of intubation were also excluded from the study.

Patients enrolled for the study were randomised into three groups of 40 each, using computer-generated random number tables in opaque sealed envelopes prepared by other personnel not involved in the study [Table/Fig-1]. The envelopes were opened by a nurse not involved in the study. Preoperative nebulisation was given to the groups as follows:

- **Group M** received 0.5 mL (250 mg) of 50% w/v magnesium sulphate with 4.5 mL normal saline.
- **Group B** was given 1 mL (250 mcg) budesonide with 4 mL normal saline.
- **Group S** received 5 mL normal saline.




**[Table/Fig-1]:** Consolidated Standards of Reporting Trials (CONSORT) diagram.

### Study Procedure

The patients were nebulised with the study drugs 15 minutes prior to the induction of anaesthesia. After nebulisation, patient was shifted to the operating room and connected to standard ASA monitors {non invasive blood pressure, Electrocardiogram (ECG), Oxygen saturation ($SpO_2$) and End Tidal Carbon Dioxide ($EtCO_2$)}. After preoxygenation for three minutes and premedication with intravenous (i.v.) ondansetron (0.1 mg/kg) and i.v. fentanyl (2 mcg/kg), anaesthesia was induced with i.v. propofol (2 mg/kg). Tracheal intubation was facilitated with i.v. succinylcholine (2 mg/kg) using a sterile soft seal polyvinyl chloride endotracheal tube with internal diameter 7-7.5 mm in female and 7.5-8.0 mm in male patients. The tracheal cuff was inflated with air and the cuff pressure was maintained between 20-25 cm of $H_2O$ using a hand-held tracheal cuff pressure manometer. Anaesthesia was maintained using oxygen-nitrous oxide mixture with sevoflurane and i.v. vecuronium 0.08 mg/kg. On completion of surgery, neuromuscular blockade was reversed with i.v. glycopyrrolate 10 mcg/kg and i.v. neostigmine 50 mcg/kg. Extubation was done after fully deflating the tracheal cuff and gentle oropharyngeal suctioning. Patients were shifted to Postanaesthesia Care Unit (PACU) and assessed for incidence and severity of sore throat according to the scoring system [Table/Fig-2] [9]. Incidence of cough and hoarseness of voice were also evaluated in all the groups. The first observation at PACU was taken as 0 hr, then further assessed at 2 hrs, 24 hrs and 48 hrs. The scores were noted and compared among the three groups.

| Score | Criteria |
|---|---|
| 0 | No sore throat at any time since the operation. |
| 1 | Minimal- Patient answered in the affirmative when asked about sore throat. |
| 2 | Moderate- Patient complained of sore throat on his/her own. |
| 3 | Severe- Patient is in obvious distress. |

**[Table/Fig-2]:** Assessment of sore throat [9].

## STATISTICAL ANALYSIS

Data was analysed using Statistical Package for Social Sciences (SPSS) inc. Chicago 2, USA, window-based version 22.0. For continuous data, mean and standard deviation was calculated. Categorical data was described in frequency and percentage. Chi-square test, paired t test and Analysis of Variance (ANOVA) was used for comparison between groups. A p-value <0.05 was considered statistically significant.

## RESULTS

A total of 120 patients undergoing general anaesthesia with endotracheal intubation, with no losses to follow-up throughout the study. There was no significant difference regarding age, sex, Body Mass Index (BMI), ASA status and duration of anaesthesia among the study groups [Table/Fig-3].

| Variables | Group S | Group B | Group M | p-value |
|---|---|---|---|---|
| Age in years (Mean±SD) | 39.6±11.4 | 44.0±12.8 | 38.3±11.8 | 0.089 (ANOVA) |
| **Gender** | | | | |
| Male | 13 (32.5%) | 21 (52.5%) | 15 (37.5%) | 0.39 (Chi-square test) |
| Female | 7 (17.5%) | 19 (47.5%) | 25 (62.5%) | |
| BMI kg/m$^2$ (Mean±SD) | 25.4±4.5 | 26.1±5.6 | 25.4±5.0 | 0.789 (Chi-square test) |
| **American Society of Anaesthesiologists (ASA) grade** | | | | |
| I | 22 (55%) | 27 (67.5%) | 25 (62.5%) | 0.512 (Chi-square test) |
| II | 18 (45%) | 13 (32.5%) | 15 (37.5%) | |
| Duration of surgery in minutes (Mean±SD) | 65.8±15.9 | 66.8±16.8 | 72.6±20.3 | 0.183 (ANOVA) |

**[Table/Fig-3]:** Comparison of demographic profile of the three groups.
*p-value <0.05 was considered as statistically significant

The incidence of sore throat was highest just after extubation (0 hr). Patients in saline group recorded the highest incidence (65%). At other points of observation, the incidence of sore throat was also significantly higher in saline group as compared to the other two groups. However, the incidence of sore throat was comparable between magnesium sulphate and budesonide group [Table/Fig-4].

Regarding severity of sore throat, most patients in saline group had moderate sore throat, while patients in both magnesium sulphate and budesonide group had mild sore throat. This observation

| Time in hours | Group S n (%) | Group B n (%) | Group M n (%) | p-value Group S and B | p-value Group S and M | p-value Group B and M |
|---|---|---|---|---|---|---|
| 0 hr | 26 (65) | 15 (37.5) | 16 (40) | 0.01* | 0.04* | 0.81 |
| 2 hrs | 25 (62.5) | 14 (35) | 16 (40) | 0.01* | 0.04* | 0.64 |
| 24 hrs | 19 (47.5) | 2 (5) | 3 (7.5) | 0.000* | 0.000* | 0.644 |
| 48 hrs | 13 (32.5) | 1 (2.5) | 1(2.5) | 0.0004* | 0.0004* | 1 |

**[Table/Fig-4]:** Incidence of sore throat and comparison of p-value in the three groups.
*p-value <0.05 was considered as statistically significant; Chi-square test used

was statistically significant at 0 hr and 2 hrs between saline and magnesium sulphate group (p-value <0.05) while it was significant at 0 hr, 2 hrs and 24 hrs between saline and budesonide group. At 48 hrs, severity score among the three groups was not significant. Also, there was no statistically significant difference in severity of POST between budesonide and magnesium sulphate at all points of observation [Table/Fig-5].

The incidence of hoarseness was also highest at 0 hr in saline group (35%) compared to magnesium sulphate (10%) and budesonide (12.5%) groups. The difference was statistically significant at 0 hr, 2 hrs and 24 hrs (p-value <0.05). However, at 48 hrs, although the hoarseness was higher in saline group the difference among the three groups was not statistically significant. Magnesium sulphate and budesonide groups showed comparable incidence of hoarseness at all points of observation [Table/Fig-6].

The incidence of cough was highest in saline group (25%) compared to magnesium sulphate and budesonide groups. However, the difference was not statistically significant (p-value <0.05) [Table/Fig-7].

## DISCUSSION

Postoperative sore throat negatively affects patient's satisfaction during recovery in the postoperative period. Prophylaxis for POST is highly recommended to improve the quality of anaesthesia care. Various drugs and techniques have been tried to alleviate or minimise the occurrence of POST. Use of steroids and NMDA receptor antagonists have been found to have a beneficial effect in reducing the incidence and severity of POST [10]. The present study compared the effect of preoperative nebulisation with budesonide and magnesium sulphate on the incidence and severity of POST. Nebulisation technique was adopted for the ease of administration, better patient compliance, smaller volume requirement, reduced risk of adverse events compared with other methods such as intravenous, topical application, gargle. Inhalational route also has the advantage of less systemic side effects due to limited systemic absorption [11].

Female sex and younger age are identified as risk factors for the development of POST. Both Chen KT et al., and Biro P et al., noted a significant higher incidence of POST in females [12,13]. However, a study by Jaensson M et al., observed no significant gender difference regarding the occurrence of POST [14].

| Time interval (hrs) | Severity | Group S n (%) | Group B n (%) | Group M n (%) | p-value Group S and B | p-value Group S and M | p-value Group B and M |
|---|---|---|---|---|---|---|---|
| 0 hr | Mild | 6 (15) | 11 (27.5) | 11 (27.5) | <0.001 | 0.011* | 0.94 |
| | Moderate | 13 (32.5) | 3 (7.5) | 4 (10) | | | |
| | Severe | 7 (17.5) | 1 (2.5) | 1 (2.5) | | | |
| 2 hrs | Mild | 5 (12.5) | 10 (25) | 11 (27.5) | 0.006* | 0.007* | 0.187 |
| | Moderate | 14 (35) | 3 (7.5) | 4 (10) | | | |
| | Severe | 6 (15) | 1 (2.5) | 1 (2.5) | | | |
| 24 hrs | Mild | 4 (10) | 2 (5) | 1 (2.5) | 0.006* | 0.72 | 0.41 |
| | Moderate | 12 (30) | 1 (2.5) | 2 (5) | | | |
| | Severe | 3 (7.5) | - | - | | | |
| 48 hrs | Mild | 3 (7.5) | - | 1 (2.5) | 0.74 | 0.26 | 0.36 |
| | Moderate | 8 (20) | 1 (2.5) | - | | | |
| | Severe | 2 (5) | - | - | | | |

**[Table/Fig-5]:** Comparison of severity of sore throat in the three groups.
*p-value <0.05 was considered as statistically significant; Chi-square test used

| Time interval (hrs) | Group S n (%) | Group B n (%) | Group M n (%) | p-value Group S and B | p-value Group S and M | p-value Group B and M |
|---|---|---|---|---|---|---|
| 0 hr | 14 (35) | 5 (12.5) | 4 (10) | 0.01* | 0.007* | 0.72 |
| 2 hrs | 14 (35) | 4 (10) | 4 (10) | 0.007* | 0.007* | 1 |
| 24 hrs | 8 (20) | 2 (5) | 2 (5) | 0.04* | 0.04* | 1 |
| 48 hrs | 5 (12.5) | 1 (2.5) | 2 (5) | 0.08 | 0.23 | 0.55 |

**[Table/Fig-6]:** Incidence of hoarseness of voice in the three groups.
*p-value <0.05 was considered as statistically significant; Chi-square test used

| Time interval (hrs) | Group S n (%) | Group B n (%) | Group M n (%) | p-value Group S and B | p-value Group S and M | p-value Group B and M |
|---|---|---|---|---|---|---|
| 0 hr | 10 (25) | 4 (10) | 4 (10) | 0.07 | 0.07 | 1 |
| 2 hrs | 8 (20) | 3 (7.5) | 4 (10) | 0.104 | 0.21 | 0.69 |
| 24 hrs | 5 (12.5) | 1 (2.5) | 1 (2.5) | 0.08 | 0.08 | 1 |
| 48 hrs | 3 (7.5) | 1 (2.5) | 1 (2.5) | 0.30 | 0.30 | 1 |

**[Table/Fig-7]:** Incidence of cough in the three groups.
*p-value <0.05 was considered as statistically significant; Chi-square test used

One of the mechanisms involved in the development of POST is localised inflammation of pharyngo-laryngeal mucosa. Steroids, by virtue of its anti-inflammatory action, are believed to reduce the incidence and severity of POST. They can be used either locally, intravenously or in nebulised form. Ayoub MC et al., and Selvaraj T and Dhanpal R, showed that application of betamethasone gel on endotracheal tube significantly reduces the incidence of sore throat [15,16]. Thomas S et al., also found that intravenous dexamethasone reduced the incidence and severity of postoperative sore throat [17]. Budesonide inhalation suspension has been proven to be very effective and well tolerated in patients with asthma and rhinitis. The effectiveness of inhalational budesonide in reducing the incidence and severity of POST in patients undergoing thyroid surgery was reported by Chen YQ et al., [18]. In the present study also, the incidence and severity of sore throat was significantly lower in budesonide group compared to saline group at all points of observation. Similar result was also reported by Rajan S et al., [7].

It is widely accepted that NMDA receptors are located both in central and peripheral nervous system and play a role in nociception and inflammation. Recently, use of NMDA receptor antagonists like ketamine and magnesium sulphate to alleviate postoperative sore throat have gained the attention of many researchers. The peripheral analgesic and anti-inflammatory effects of ketamine in preventing POST have been documented in many clinical trials. Mostafa RH et al., reported that perioperative ketamine nebulisation was very effective in reducing the intensity of POST in paediatric patients [19]. The results of magnesium nebulisation have also been favourable in reducing POST. Borazan H et al., had concluded from their study that preoperative magnesium lozenges reduced the incidence and severity of POST [20]. Yadav M et al., also reported that preoperative magnesium sulphate nebulisation reduced the incidence of POST compared to normal saline [21]. The current study also noted a significant decrease in the incidence of sore throat in magnesium sulphate group compared to saline group at all points of observation. Studies by Padma T et al., and Kumar BG et al., also reported reduced incidence of sore throat with preoperative magnesium nebulisation [22,23].

In the present study the groups were comparable regarding age, sex, BMI, ASA status and duration of surgery. The incidence of POST was significantly lower in magnesium sulphate and budesonide group compared to normal saline group. However, it was comparable between magnesium sulphate and budesonide group. Two meta-analyses conducted by Kuriyama A et al., also concluded that aerosolized corticosteroids and topical administration of magnesium can be effective in preventing postoperative sore throat. The peak incidence of POST was recorded at 2-4 hour postoperatively in most studies. In the present study also the incidence of POST was maximum at 0 hrs and 2 hrs and least at 48 hrs in all the study groups [24,25].

Regarding the severity of sore throat, authors observed that sore throat was of mild type in both magnesium sulphate and budesonide group while saline group experienced moderate sore throat. The difference was statistically significant at 0 hr, 2 hrs, and 24 hrs. But at 48 hrs, the severity of sore throat among the three groups was not significant. This observation was similar to the finding of Sheikh SA et al., who found that less severe sore throat occurred in patients receiving magnesium sulphate or dexamethasone [26]. Teymourian H et al., also concluded that low dose magnesium gargle decreased the severity of sore throat more effective than ketamine [27].

The study by Kotb MM et al., also mentioned that preoperative budesonide inhalation significantly decreased the incidence of hoarseness of voice but magnesium sulphate nebulisation had no effect on cough and hoarseness. However, we observed that the incidence of hoarseness of voice was significantly decreased in both budesonide and magnesium sulphate group compared to control at 0 hr, 2 hrs and 24 hrs but the effect on cough was not significant [8]. Rajan S et al., also found that postoperative hoarseness of voice was significantly reduced at 12 hrs and 24 hrs after preoperative budesonide nebulisation. The incidence of cough was more in saline group than budesonide and magnesium sulphate group but the difference was not statistically significant. There were no adverse outcomes either local or systemic after nebulisation of the study drugs. This might be due to the use of relatively lower dosage of drugs [7].

### Limitation(s)

Factors like lack of humidification of anaesthetic gas mixture, use of systemic analgesic and different choices of analgesics in different patients could interfere in the interpretation of results. In addition, subjective assessment of POST and inter individual variation during endotracheal intubation were also other factors that could interfere in the assessment and interpretation of POST.

## CONCLUSION(S)

Preoperative nebulisation with budesonide and magnesium sulphate was significantly more effective in reducing the incidence and severity of postoperative sore throat in patients undergoing general anaesthesia with endotracheal intubation.

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