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# Pre-Operative, Prophylactic Use of Oral Zinc Tablet in the Management of Post-Operative Sore Throat

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## ABSTRACT

**Background:** Postoperative sore throat (POST) is considered to be quite common complaint. Its symptoms tend to improve with time, but use of oral zinc lozenge has been shown to reduce the incidence and severity of POST. The aim of the present study was to find the efficacy of oral zinc sulfate, given 30 min preoperatively, in reducing POST, primarily caused by endotracheal intubation, till 24 hours after surgery.

**Method:** A prospective, randomized, double-blinded, placebo-control-trial study was conducted on 80 patients, further divided into two groups of 40 patients each, between the age group of 18-60 years, of either gender, in Super Specialty Hospital, GMC Jammu, over a period of 6-months. The two groups received either dispersible zinc tablet or a placebo. The severity of POST was graded on a 4-point scale ranging from 0 to 3 and evaluation was repeated at 30 min, 2, 4, and 24 hour, postoperatively.

**Results:** The difference in severity of sore throat was found to be statistically significant at all evaluation time intervals, except at 24 hours, which was quite lower in Zinc group. The overall incidence of POST in Zinc group was 26.3%, which was significantly higher at 50% in placebo group.

**Conclusion:** A dose 40 mg zinc dispersible tablet, equivalent to 40 mg elemental zinc, given 30 min before surgery, effectively reduced the incidence and severity of POST.

***Key Words:*** Post Operative Sore Throat, Oral Zinc Lozenge, Endotracheal Intubation

## INTRODUCTION

Common issues and complaints of patients receiving general anaesthesia include: nausea and vomiting, sore throat or hoarseness, dry mouth, shivering or chills, sleepiness, muscle aches, difficulty urinating, ileus etc. Postoperative sore throat (POST) is considered to be quite common complaint.[1,2] Itimproves with time, however any intervention to prevent it may improve patient satisfaction and may impact discharge from hospital. Several of such pharmacological and non-pharmacological remedies have been tried over the time, with varying degree of success.[3,4] Use of oral zinc lozenge has been shown to reduce the incidence and severity of POST.[5]

Zinc as a micronutrient, is known to promote growth and tissue repair. Zinc is also helpful in modulating immune system. It has been used for prevention of oral mucositis in patients receiving high dose chemotherapy. [6,7] Prophylactic use of topical magnesium also has been shown to prevent POST due to its anti-inflammatory properties.[8]

There is minimum literature and studies available pertaining to the effects of zinc on POST in Indian population, therefore, the aim of the present study was to find the efficacy of oral zinc sulfate, given 30 minutes preoperatively, in reducing POST, primarily caused by endotracheal intubation, till 24 hours after surgery. The dispersible tablet form of zinc was preferred due to its easy availability and known effect on oropharyngeal mucosa.

## MATERIALS AND METHODS

A prospective, randomized, double-blinded, placebo-control-trial study was conducted on a total of 80 patients, in Super Specialty Hospital, GMC Jammu, over a period of 6-months. The study group was further divided into two groups with age and gender-matched 40 patients each. A written informed consent was obtained from all participants. Ethical approval was duly obtained from institutional ethical committee. Randomization, for selection, was achieved using computer-generated random code number and sealed envelope method to create separate two groups to receive either dispersible zinc tablet or a placebo. The code was maintained till the completion of study.

***Inclusion Criteria:***

Patients between the age group of 18 to 60 years were included.

Patients with ASA Physical Status of I and II, posted for low to moderate risk surgeries of duration greater than 1 h and less than 6-h duration, were included in the study.

***Exclusion Criteria:***

Smokers, pregnant patients, patients with a recent history of sore throat or upper respiratory tract infection, Mallampati grade (MPG) greater than II and patients with allergy to zinc were excluded from the study.

A specific surgical duration was chosen to ensure that the patient was intubated long enough to cause irritation of oropharyngeal mucosa.

After written informed consent, a sealed and coded envelope with either zinc or placebo tablets was given to the patient, with instruction to dissolve the tablet in mouth 30 min prior to surgery. The zinc group received zinc sulfate tablets, equivalent to 40 mg elemental zinc, as was commercially available. The control group received placebo tablets with no active ingredient but was indistinguishable in appearance and taste from the one containing zinc. The investigators and the patients alike were blinded about the content of the envelope and the code was maintained until the completion of the study.

Till the patient was sucking on the provided dispersible tablet, all kinds of sedative medications were held back. Premedication included injection ranitidine (50 mg iv), inj. ondansetron (4 mg iv). After 3 min of preoxygenation, anaesthetic induction was commenced with intravenous tramadol 1mg/kg and propofol 2mg/kg followed by orotracheal intubation facilitated by atracurium0.5 mg/kg.

Laryngoscopies were performed on both groups and laryngoscopic view of glottis was classified using Cormack–Lehane classification. Duration of laryngoscopy (time from opening mouth to the placement of the endotracheal tube) and the intubation time (the interval between the insertion of the laryngoscope blade into the mouth to the inflation of the endotracheal tube cuff) was recorded in all patients. The cuff pressure of the endotracheal tube was adjusted every 30 min, using a handheld pressure gauge and maintained between 20 and 22 cm of H2O.

Anesthesia was maintained with 1.1% isoflurane in 60% N2O and 40% O2 mixture, intermittent fentanyl and atracurium at0.15 mg/kg was used when required. The use of steroids and anti-inflammatory drugs was recorded. The patients were extubated upon completion of surgery following careful suctioning of the oropharynx and were transferred to the Post Anesthesia Care Unit (PACU).

During emergence from anesthesia, any coughing or bucking was duly noted. On arrival at PACU, immediate evaluation for presence and severity sore throat was done (time = 0), using a standardized scale. Side effects such as nausea, vomiting, metallic taste, and diarrhea were also noted.

The severity of POST was graded on a 4-point scale ranging from 0 to 3; 0 being no sore throat, 1 being mild discomfort (complaints only upon questioning),2 being moderate sore throat (complains of his/her

own), and 3 being severe sore throat (change in voice, hoarseness and throat pain). The evaluation was repeated at 30 min, 2, 4, and 24 h.

Based upon previous studies,[9,10] the incidence of POST was presumed to be 65%, power at 80%, alpha error at 0.05; only 36 patients in each group were required to detect a 50% reduction in the incidence of POST. Assuming drop out at 10%, 40 patients in each group were included, making the total sample size 80.

***Statistical Methods:*** Data was analyzed using Microsoft Excel-2010 software. All categorical variables were expressed as number and percentage, whereas the continuous variables were expressed as mean ± standard deviation. Patient demographics and the incidence of POST between groups were compared using the Chi-square test. The P value < 0.01 was considered significant.

## RESULTS

A total of 80 patients who gave consent were enrolled and were randomly allocated, 40 to zinc group and 40 to placebo group. Two patients each in zinc group and placebo group required more than one attempt at intubation and were excluded from the study. Thus, data from 76 patients were available for analysis: 38 from zinc group and 38 from placebo group. Both groups were found be comparable in regards of demographic variables. (Tables 1)

**Table 1: Demographic Characteristics of Patients**

| | **Zinc group (n=38)** | **Placebo group (n=38)** | **p-value** |
|---|---|---|---|
| Age (years) (mean ± SD) | 38.23 ± 9.66 | 38.80 ± 9.72 | 0.767 |
| Weight (kg) (mean ± SD) | 66.58 ± 7.96 | 67.08 ± 8.12 | 0.252 |
| Gender Ratio (male/female) n | 21/17 | 20/18 | 0.831 |
| % | (55%/45%) | (53%/47%) | |
| ASA PS* (I/II) n | 27/11 | 25/13 | 0.132 |
| % | (71%/29%) | (66%/34%) | |

**ASA PS – American Society of Anesthesiologists Physical Status.*

**Table 2: Incidence of POST at different evaluation times**

| **Evaluation time** | **Incidence in Zinc group (n=38)** | **Incidence in Placebo group (n=38)** | **p-value** |
|---|---|---|---|
| At 0 min | 2 (5.3%) | 9 (23.7%) | 0.0071* |
| At 30 min | 4 (10.5%) | 12 (31.6%) | 0.0034* |
| At 2 hours | 3 (7.9%) | 13 (34.2%) | 0.0006** |
| At 4 hours | 3 (7.9%) | 12 (31.6%) | 0.0012* |
| At 24 hours | 10 (26.3%) | 12 (31.6%) | 0.088 |

**P<0.01 = significant. **P<0.001 = highly significant*

**Table 3: Severity of POST at different evaluation times**

| **Evaluation Time** | **Zinc group (n=38)** | | | **Placebo group (n=38)** | | | **p-value** |
|---|---|---|---|---|---|---|---|
| | Mild | Moderate | Severe | Mild | Moderate | Severe | |
| **At 0 min** | 2 (5.3%) | 0 | 0 | 7 (18.4%) | 2 (5.3%) | 0 | 0.0072* |
| **At 30 min** | 4 (10.5%) | 0 | 0 | 10 (26.3%) | 2 (5.3%) | 0 | 0.0039* |
| **At 2 hours** | 3 (7.9%) | 0 | 0 | 8 (21.1%) | 4 (10.5%) | 1 (2.6%) | 0.0007** |
| **At 4 hours** | 1 (2.6%) | 2 (5.3%) | 0 | 3 (4.5%) | 6 (15.8%) | 3 (7.9%) | 0.0011* |
| **At 24 hours** | 7 (18.4%) | 3 (7.9%) | 0 | 7 (18.4%) | 3 (7.9%) | 2 (5.3%) | 0.1304 |

**P<0.01 = significant. **P<0.001 = highly significant*

**Table 4: Overall incidence with respect to severity of POST**

| | Zinc group (n=38) | Placebo group (n=38) | p-value |
|---|---|---|---|
| Mild POST | 7 (18.4%) | 6 (15.8%) | .873 |
| Moderate POST | 3 (7.9%) | 10 (26.3%) | 0.026* |
| Severe POST | 0 (0%) | 3 (7.9%) | 0.241 |
| Overall Incidence | 10(26.3%) | 19 (50%) | 0.015* |

**P<0.05 was considered significant*

The incidence of POST between groups was found to be statistically significant at all evaluation time intervals, except at 24 hours. (Table 2)

The severity of POST was also found significantly lower in Zinc group than Placebo group. No statistically significant difference was found in severity of POST between groups at 24 h, however two patients in placebo group still complained of severe POST, while there was none such case in Zinc group. (Table 3)

When comparing overall severity of POST between groups, the incidence of moderate POST was found to be statistically significant ($p<0.05$), however the overall incidence of POST in Zinc group was 26.3%, which was significantly higher at 50% in placebo group. (Table 4)

## DISCUSSION

Postoperative sore throat (POST) has a reported incidence of up to 62% following general anaesthesia. Adults undergoing tracheal intubation, females, young children, pre-existing lung disease and prolonged duration of anesthesia are considered to be greatest risk factors. Tracheal intubation without neuromuscular blockade, use of double-lumen tubes, as well as high tracheal tube cuff pressures may also increase the risk of postoperative sore throat.[11] Pharyngeal, laryngeal, or tracheal irritation leading to inflammation may be the reason for POST, but it may also occur in absence of tracheal intubation. In the absence of any clearly established single mechanism which leads to POST, treatment with anti-inflammatory agents (e.g., steroids and NSAIDs) to some extent help reduce its symptoms.

In the present study, administration of dispersible zinc tablet orally, 30 min before intubation showed lower incidence and less severity of POST at 0, 30 min, 2 hour, and 4 hour evaluation time. It may be due to the onset of anti-inflammatory action by dispersible zinc tablet which may range from 30 min to 4–6 hours based on the available data from previous studies.[4-6,12] A statistically significant difference was found between groups in our primary outcome (incidence of POST at 4 h) with a $p = 0.0012$ (highly significant).The overall incidence of POST was also lower in Zinc group. This was quite similar to the outcome of the study by Sarkar et. al. [13] and Farhang et al.[5] This lower incidence of POST in the zinc group can be attributed to the prevention of cytokine release, decrease in reactive oxygen species, and a subsequent decrease in cyclooxygenase-2 (COX-2) expression, and prostaglandin-E2 (PGE-2) release.[14]

On comparing overall severity of POST between groups and observing the overall incidence of POST in placebo group (at 50%) and that of Zinc group (at 26.3%), it can be shown that almost 23.7% of patients were possibly saved by the Zinc dosage at an appropriate time pre-operatively, which is significant. In absence of studies in context of natural history and duration of POST, it can be assumed that sore throat extending up-to 24 h and beyond, may have mechanism as that of injury, and is therefore treated as such.

The duration of action of zinc locally is not well established; for upper respiratory therapy it is recommended every 4 h; whereas in oncologic studies, mouth washes are given every 6–12 hours. Topically applied zinc in the form of a suspension, or in the lozenge form, have been shown to be as effective as systemic therapy in prevention of mucositis and oral pain associated with chemotherapy.[7,15] But in terms of side effects, no difference in incidences of postoperative nausea, vomiting and diarrhea between the two groups, particular to this study, was observed.

This study may carry some limitations, like small sample size and that it pertained to a shorter span of time in a single healthcare unit. Further, no pharmacokinetic data on local effects of oral dispersible zinc tablets was available to us and the dosage and time of administration time was based on previous studies only. Dispersible zinc tablets were used, because they were easily available.

## CONCLUSION

A dose 40 mg zinc dispersible tablet, equivalent to 40 mg elemental zinc, given 30 min before surgery, effectively reduced the incidence and severity of POST, during first 4 h after extubation. This study further validated the potential of zinc in prevention of POST, but more such studies will be needed with larger sample size to ascertain

the exact dosage, combinations of micronutrients, timings and frequency of administration.

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**Ethical Approval:** Approved

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