Received: 06 February 2024 | Revised: 18 March 2024 | Accepted: 28 March 2024
DOI: 10.48309/JMPCR.2024.446078.1136
Journal of Medicinal and Pharmaceutical Chemistry Research
SAMI

FULL PAPER

Efficacy of preoperative prophylactic low dose zinc lozenge in reducing post-operative sore throat in adults scheduled for elective surgeries under general anaesthesia with orotracheal intubation: A prospective randomized double blinded trial

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Postoperative sore throat (POST) often occurs succeeding tracheal intubation. It is hypothesized that preoperatively administered prophylactic low dose oral zinc lozenges help in attenuating the POST occurrence due to its anti-inflammatory effect while promoting healing of tissues. This study was done to evaluate its efficacy in preventing POST in adult patients undergoing tracheal intubation as a part of general anaesthesia. 220 Patients posted for surgery with tracheal intubation as a part of general anaesthesia were included into this prospective randomized double blinded study. Those included were randomized into two groups Group Z or Group P and received either zinc or lozenge containing placebo, respectively, 30 minutes preoperatively. Assessment of incidence and severity of POST was done using a 4-point scale of 0-3 at particular time intervals. 102 Patients and 97 patients were taken up for analysis in Group Z and Group P respectively. The comparison of demographic and intraoperative variables in both the groups were comparable. The lower occurrence of POST was statistically significant after preoperative use of zinc lozenge at intervals 0, 2 and 4 hours (p=<0.001**) except at 24 hours. The POST severity was mild in Group Z at 0, 2, and 4 hours in comparison with the placebo group. However, at 24 hours, both the groups were comparable. A prophylactic low dose of 18.75 mg zinc lozenge given 30 minutes before surgery is efficacious in reducing the occurrence of POST in the post-operative period in patients undergoing tracheal intubation as a part of general anesthesia.

KEYWORDS

Anti-inflammatory; intubation; lozenge; sore throat; zinc.

Introduction

General anaesthesia (GA) usually involves tracheal intubation for administration of anaesthetic gases and for ventilation. Usually tracheal intubation is associated with an inflamed trachea, manifesting as Postoperative sore throat (POST) [1].

Although the severity and intensity of POST differ from an individual, it has been estimated that up to 90% of people who are administered GA, experience it [2]. The POST incidence with larger endotracheal tubes (ET) was 48%, and with the smaller tubes, was lower at 22% [3]. No specific treatment has proven to be particularly successful for POST, and the symptoms typically improve on their own within 72 hours without medication [4].

In smaller ET, lubricating with jelly which is water soluble, atraumatic intubation and maintaining a lower pressure in ET cuff are examples of non-pharmacological ways to alleviate POST [5]. Whereas several pharmacologic measures have shown significant change in reducing the POST incidence, like using preoperative gargles with Lidocaine and also Aspirin and Ketamine, beclomethasone, or fluticasone inhalation and liquorice gargle or lozenges containing Magnesium 30 min before induction of anaesthesia. [6-8]. Zinc has an anti-inflammatory effect, improved wound healing and healthy epithelial tissue [5]. In addition to promote re-epithelialization, zinc also lowers bacterial activity [9]. According to a study done on cancer therapy, zinc lozenges were shown to have benefited patients receiving high-dose chemotherapy, which demonstrated a significantly lower analgesic requirement for oral pain [10]. Lozenge form was used due to its local effects on the mucosal lining along with the systemic effects [6].

Upper respiratory tract infections and sore throats have been treated with zinc lozenges, which are readily available in the western world and similarly priced to magnesium lozenges. These lozenges are not commonly found in India and hence there is limited data on the effect of zinc lozenges on POST for Indian population. Among the available literature evidence, lozenges containing zinc acetate with 40 mg of elemental zinc have been used and studied for POST and found to be effective [6].

There is no literature available evaluating whether low dose of 18.75 mg of elemental zinc in the form of zinc acetate lozenges reduced the incidence of POST in Indian population. Hence, we decided to evaluate the effectiveness of low dose oral zinc acetate lozenges (18.75 mg of elemental zinc) given 30 minutes before intubation in lowering POST until 24 hours following extubation in patients undergoing elective tracheal intubation in Indian population.

Methodology

After getting approval and clearance from the Institutional Ethical committee (SMC/IEC/2021/12/004) and the Clinical Trial Registry of India (CTRI/2022/07/044328), this prospective, double-blinded randomized controlled study was performed over two months from July to September 2022 at Saveetha Medical College and Hospital, Tamil Nadu, India. Farhang *et al.* [6], found the proportion of POST with zinc and placebo group at 4 hours to be 7% and 29% respectively and the calculated risk difference was -22%. According to two proportion hypotheses and by setting the power of the study at 99% and alpha error of 1, the sample size required was calculated to be 188.

Concerning a chance of attrition due to obvious reasons, we chose a much larger sample size of 220 patients for the study. Study sampling was done using simple random sampling until the desired sample size was achieved. Patients over 18 years of age and with American Society of Anesthesiologists (ASA) physical status grading of between I and III who were posted to undergo elective tracheal intubation as a part of general anesthesia lasting between 1 to 6 hours. This minimum and the maximum duration was decided with the help of prior research, to make sure that the ET did not stay in situ for > 6 hours to prevent irritation of the oro-pharyngeal mucosa [11]. Exclusion

criteria included those with a symptoms of throat inflammation, upper airway infections, immune-compromised states, longstanding smokers, pregnant women, those undergoing surgery involving head and neck, history of difficult airway, use of supraglottic airway devices, or being allergic to zinc. Intraoperative use of steroids, non-steroidal anti-inflammatory drugs, anti-sialagogues and nitrous oxide gas were not included.

The enrolled subjects were randomized using computer generating random number allocation using online software and assigned to two different groups- Group Z (those who received Zinc lozenges) and Group P (those who receive placebo lozenges) and sealed envelope method. Each of the subject's demographic data (age, gender, body weight, and height) was collected using face to face interview method.

An envelope containing the appropriate Lozenge was sealed close by an anesthesiologist who was not involved in the study. After obtaining informed consent, the sealed envelope with the study lozenge (zinc acetate containing 18.75 mg of elemental zinc, life extension enhanced zinc lozenges) or a placebo lozenge was given to the patient by a blinded operating room anesthesiologist with more than 2 years of experience. It was ensured that the lozenge completely dissolved in the patient's mouth 30 minutes before induction of anesthesia. The patient was then induced as per standard protocol (Fentanyl, Propofol, and Atracurium according to body weight) and intubated atraumatically with 7mm ET for females and 8 mm for males [12]. After securing the tube, a cuff pressure monitor was used maintain pressures between 20 to 22 cm H2O. A record was kept of the Intubation time (duration from laryngoscope insertion into the mouth to successful insertion of ET confirmed by bilateral chest rise during ventilation), the number of intubation attempts, Cormack-Lehane grade, and the trauma possibility during intubation. Anaesthesia was maintained till the end of surgery with a total fresh gas flow of 6 liters (50:50-oxygen: medical air) and sevoflurane with a target MAC of 1. The total duration of surgery and anaesthesia was recorded.

The patient was asked for symptoms of POST immediately post removal of ET after adequate reversal, (time 0 hours). The patient was then shifted to PACU and further evaluation was done at 2, 4, and 24 hours, respectively (ward visit). A standardized 4-point scale from 0 to 3 is used to assess the severity of POST; 0 indicates no soreness, 1 indicates minimal soreness (complaints on being asked), 2 indicates some soreness (complaints spontaneously), and 3 indicates severe soreness of the throat (voice change, change in voice timbre, and throat pain). Side effects such as nausea, vomiting, diarrhea and metallic taste were recorded. Post-operative parameters were recorded by a postgraduate resident who was blinded as to which group the patient belonged to.If the patients had Moderate sore throat, they were given reassurance that the POST will resolve eventually by itself in the next 48 hours. If the patients had severe sore throat, rescue measures like intravenous Injection dexamethasone 8 milligram and injection ketorolac 30 milligram was given twice daily for the next 48 hours along with reassurance.

The enrollment, group allocation, and analysis as well as results were done according to the consort diagram, as depicted in Figure 1.

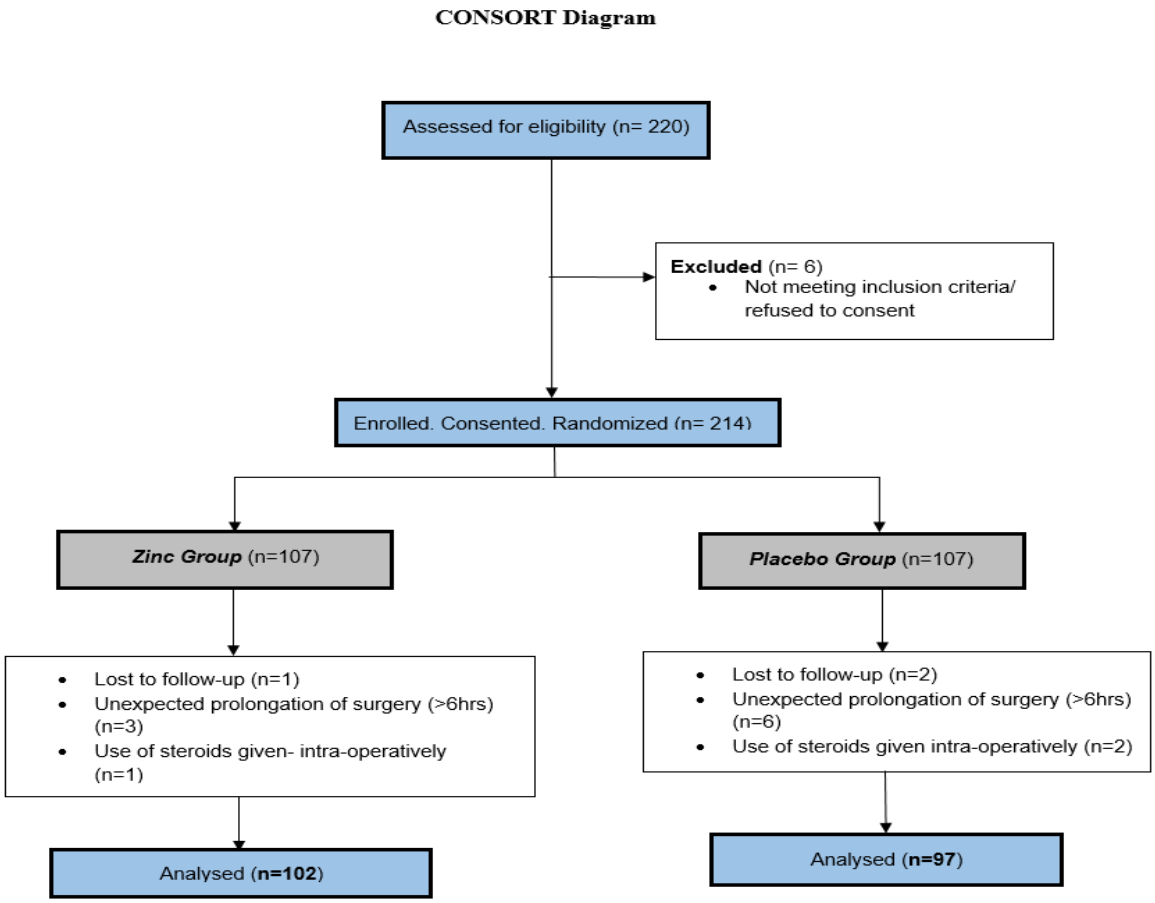

FIGURE 1 Consort diagram

IBM SPSS statistics version 23.0 was used for statistical analysis. Categorical variables were analyzed using descriptive statistics and expressed in frequencies, whereas mean and standard deviation was done for continuous variables. Chi-Square test was used for determining statistical significance. Unpaired sample t-test was used to look for any statistical significance between the bivariate samples in the independent groups. A p-value of less than 0.05 is considered a significant level.

Results

220 Study subjects met the inclusion criteria out of which only 214 gave consent and were randomly allocated to two groups – Group Z (zinc) and Group P (placebo). Among them, five from Group Z and ten patients from Group P were excluded due to loss of follow-up, surgery lasting for > 6 hours and intra-operative administration of steroid injection as mentioned in the consort diagram (Figure 1). Hence, 102 and 97 patients in the zinc group and placebo group were analyzed.

TABLE 1 Demographic profile (BMI: Body Mass Index; MMP: Modified Mallampati Grade; ASA: American Society of Anaesthesiology Physical Status)

Variables	Group Z (n=102)	Group P (n=97)	*P*-value
Mean age (years)	44.55+/-15.34	42.78+/-15.56	0.42(NS)
Gender (Male/Female)	51/51 50.0%/50%	46/51 47.4%/52.6%	0.82(NS)
Weight (kgs)	65.39+/-9.99	65.72+/-8.54	0.80(NS)
Height (cms)	162.47+/-7.17	163.57+/-7.26	0.29(NS)
BMI	25.94+/-3.26	26.05+/-2.78	0.79(NS)
MMP Grade (1/2)	65/37 63.7%/36.2%	58/39 59.7%/40.2%	0.64(NS)
ASA (1/2)	73/29 71.6%/28.4%	76/21 78.3%/21.6%	0.68 (NS)

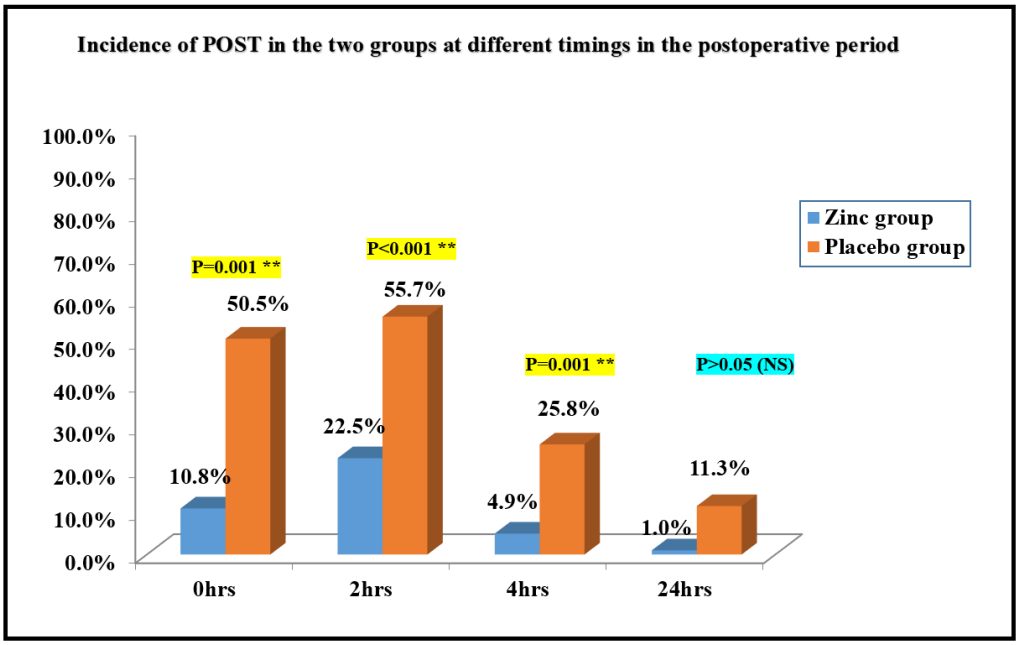

FIGURE 2 Incidence of POST between zinc and placebo group at different timings (0, 2, 4, and 24) hours. [p-value < 0.05 is considered significant (highlighted in yellow**)]

The POST occurrence between the two groups at 0, 2, 4, and 24 h is depicted in Figure 2. Statistical difference was found at 0 hours (p-value =0.001**), 2 hours (p-value <0.001**), and 4 hours (p-value = 0.001**). At 24 hours, the occurrence of POST, though lower in the Group Z than in Group P was found to be statistically insignificant (p-value > 0.05).

TABLE 2 Intraoperative data (CL Grading: Cormack Lehane Grading)

Groups	Zinc Group (n=102)	Placebo Group (n=97)	*P*-value
Mean duration of laryngoscopy (sec)	14.08+/- 3.22	14.37+/-2.89	0.841 (NS)
Mean attempts at laryngoscopy(1/2/3)	93/8/1 91.2%/7.8%/1.0	92/5/0 94.8%/5.2%/0	0.45 (NS)
CL Grading* (I,II,III,IV)	80/18/4/0 78.4%/17.6%/3.9%/0	71/21/5/0 73.1%/21.6%/5.1%/ 0	0.81 (NS)
Mean duration of anaesthesia (min)	172.4+/-58.20	181.12+/-55.42	0.99 (NS)
Mean duration of surgery (min)	150.3+/-63.11	165.18+/-61.25	0.084 (NS)
Side Effects Yes/No	1/101 (1%/99%)	5/92 (5.2%/94.8%)	0.085 (NS)

The patient's demographic profile and intra-operative data (Tables 1 and 2) was found comparable with p-value > 0.05.

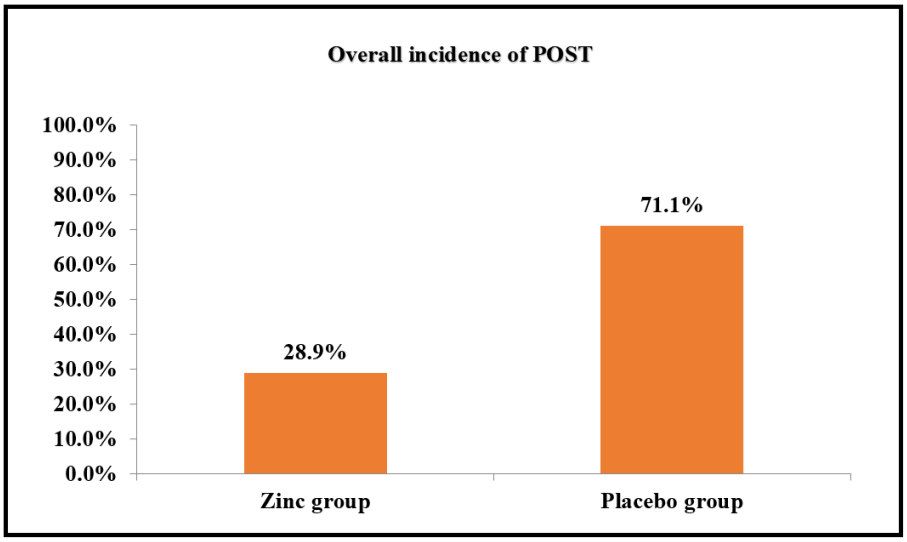

FIGURE 3 Comparison of incidence of POST in Group Z and Group P (p= <0.001**)

There was an higher occurrence of POST in Group P when compared to Group Z as depicted in Figure 3 which was statistically significant (p=<0.001***).

TABLE 3 Comparison of degree of POST between Group Z and Group P
[POST- degree of severity was much lesser in Group Z at 0, 2, and 4 hours which was statistically significant with P- value <0.05 (Highlighted in yellow**)]

Variables	Minimal POST Mild POST	Some POST Moderate POST	Severe POST Severe POST
0 hours			
Zinc Group	10.8%	0%	0%
Placebo Group	47.4%	3%	0%
p- value		0.001*	
2 hours			
Zinc Group	22.5%	0%	0%
Placebo Group	49.5%	5.2%	1%
p- value		<0.001**	
4 hours			
Zinc Group	4.9%	0%	0%
Placebo Group	25.8%	0%	0%
p- value		<0.001**	
24 hours			
Zinc Group	11.8%	2.9%	0%
Placebo Group	11.3%	8.2%	3.1%
p- value		>0.05 (NS)	

The severity (mild, moderate, and severe) of POST between zinc and placebo groups is provided in Table 3. The patients in group Z developed lower grade of POST (minimal) in the time interval 0 hr (p=001**), 2 hrs (p<001**), and 4 hrs (p<001**) hours when compared to the placebo group. At 24 hrs, the POST severity among both the groups was comparable. There was no statistically significant difference between those who developed moderate and severe POST in both the groups at all times.

Concerning the side effects, one and three patients in the zinc and placebo group experienced nausea. Two other patients also developed gastrointestinal irritation in the Group P. there was no statistical significance with respect to occurrence of adverse effects in Group Z and Group P.

Discussion

POST can be caused by several factors such as gender, age, type of surgery, anesthesia technique, the size of the ET tube, cuff pressure, mucosal injury due to laryngoscopy and trauma while inserting ETT and the length of the procedure [14-16]. In our study, we found all these factors to be comparable in this regard. Keeping this in mind, the ET tube used and the cuff pressure was standardized for all cases.

It was proven earlier that POST can be due to pharyngeal, laryngeal and tracheal irritation leading to inflammation but it can also occur without intubation. Since the exact mechanism of POST is multifactorial, it was assumed that drugs such as non-steroidal anti-inflammatory drugs and steroids can influence the incidence of POST and thus its use was excluded from the study.

Recently, lozenges containing magnesium have been used to mitigate the occurrence of POST, similar to our finding with zinc lozenges. This is mostly due to the minerals anti-inflammatory property and healing effect on the mucosa. A study was done by Kim *et al.* [22] which indicated that the inhibition of release of cytokine, reduction of reactive oxygen species, and subsequent reductions in cyclooxygenase-2 (COX-2) production and prostaglandin-E2 (PGE-2) release are responsible for the group zinc's decreased incidence of POST. Zinc is also known to be used in the treatment of various conditions involving mucosal irritation [9]. Sarkar *et al.* [19] found that a zinc dispersible tablet given 30 min before intubation reduced the occurrence and degree of POST for up to 4 h post-operatively. Zinc was found to be equally effective in treating mucosal lesions when used either as a lozenge or systemically [23]. However, its use in the context of POST has not been studied extensively [21].

Our study shows that giving low dose of zinc lozenge (18.75 mg) 30 minutes preoperatively results in reduced occurrence and degree of POST at the evaluation times of 0 hours, 2 hours, and 4 hours post-operatively. Likewise, mild POST was more common in the group P than the group Z at all-time points (0 hours, 2 hours, and 4 hours) except 24 hours post extubation. Moderate and severe POST was not different among both the groups in different time intervals and none in the two groups had a higher degree of POST in Zinc group. According to data from prior research, it might be caused by zinc's anti-inflammatory activity, which can start anywhere between 30 minutes and 4-6 hours after administration [4]. This anti-inflammatory reaction can be a result of reduced local inflammatory reaction as a result of decreased levels of reactive oxygen species which in turn causes decreased COX-2 expression and PGE-2 production. Farhang *et al.* observed that the occurrence of mild POST was significantly higher in group P than group Z and they also noted that the occurrence of Moderate POST at 4th hour period as well as severe POST at the 24th postoperative hour were significantly higher in placebo group and Moderate and severe POST at other time intervals were comparable [6].

We observed that the overall occurrence of POST was more among the group P (71.1%) than group Z (28.9%) ($p<0.01^{***}$). Our data demonstrates that, in comparison to other trials, the occurrence of POST was lower [6,19].

There is weak evidence on the natural history of POST and the duration. Since POST is worse immediately post extubation and then decreases, there are no standard guidelines for POST evaluation time. It also known that POST extending beyond 24 hours might be due to some other reason such as direct injury.

There were a lot of studies which has shown the effect of 40 mg oral zinc lozenges on the decreased incidence of POST [6,18,19], but our study which is the first known study, has shown the same efficacy with low dose of 18.75 mg elemental zinc lozenges. The results

of our study are well comparable to those of an earlier research by Farhang *et al.* using zinc lozenges, which further supports the potential of zinc in the lozenge form for POST prophylaxis [6]. The zinc lozenges did not have any notable side effects.

To enumerate the limitations of the study, it was initially done in one medical facility. Secondly, we chose a healthy population in the middle age group belonging to ASA 1 and 2 without any anticipated difficulty in laryngoscopy or intubation. Thirdly, we lacked access to pharmacokinetic information on the local effects of oral zinc lozenges, and the dosage and timing of administration solely relied on prior research (Farhang et al. [6] ; Sarkar and Mandal [19]). Fourthly, we did not analyze the serum zinc level after administration of lozenges and compare the pharmacological effect on postoperative sore throat.

Conclusion

The occurrence of POST at 0, 2, 4, and 24 hours following general anaesthesia with tracheal intubation can be reduced significantly by administration of a single prophylactic low dosage of elemental zinc (18.75 mg) in the form of lozenges, 30 minutes before intubation in the preoperative period. To determine the minimum effective dose, most effective combinations of drugs required, when to use, and how often to use, more research with bigger sample size is required. In addition, more research comparing our dosage and formulation with other treatments that have been proven effective in lowering POST are warranted.

Acknowledgements

None

Funding

None.

Authors' Contributions

All authors contributed to data analysis, drafting,and revising of the paper and agreed to be responsible for all the aspects of this work.

Conflict of Interest

There is no conflict of interest in this study.

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How to cite this article: Tasneem Fathima Ahmed, Kaaviya. R, Priya. H, Sanjana Venkata Lakshmana, Surya. R, V.S.G. Yachendra, Efficacy of preoperative prophylactic low dose zinc lozenge in reducing post-operative sore throat in adults scheduled for elective surgeries under general anaesthesia with orotracheal intubation: a prospective randomized double blinded trial. *Journal of Medicinal and Pharmaceutical Chemistry Research*, 2024, 6(8), 1188-1198. **Link:** https://jmpcr.samipubco.com/article_193293.html