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FULL PAPER

Effectiveness of turmeric-based lozenges in reducing the postoperative sore throat and cough– A prospective randomized placebo-controlled study

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Common issues that often arise in the interval after extubation include postoperative sore throat (POST) and postoperative cough (POC). To avoid POC and POST, medicinal lozenges can be used before intubation. In this study, we looked at the effectiveness of turmeric lozenges in reducing POST and POC after orotracheal intubation in patients having elective procedures under general anaesthesia. This prospective, randomized, double-blinded, and placebo-controlled was conducted in 120 patients undergoing elective surgery requiring general anaesthesia with endotracheal intubation. They were split into four groups. Thirty minutes before intubation, Group A received a placebo lozenge, Group B received turmeric lozenges with menthol and eucalyptus; Group C received turmeric lozenges with tulsi; and Group D received orange-flavored turmeric lozenges. Groups were compared for their effectiveness in reducing POST and POC using Harding and Mcvey's scale at 0, 2, 4, 6, 12, and 24 hours following extubation. The POST occurrence differed significantly across the groups ($p < 0.05$) and same applied to the occurrence of POC also ($p < 0.01$). Group B was more effective in reducing the POST and POC followed by Group C, Group D, and Group A. Preoperatively administered turmeric based Lozenges before general anaesthesia with endotracheal intubation considerably decreased the occurrence and severity of postoperative sore throat and cough.

KEYWORDS

Postoperative; sore throat; cough; prevention; orotracheal intubation; general anaesthesia; turmeric; lozenges.

Introduction

Postoperative sore throat (POST) is one of the common undesirable outcomes in the postoperative period following tracheal intubation[1], with the incidence ranging from 21-65% [2,3]. POST occurs mainly by two mechanisms airway instrumentation causing mucosal injury and irritating effects of a foreign object in the trachea as well as in the upper airway resulting in inflammation. Post-operative cough (POC), which occurs at an incidence of 15 to 94% [4] and occurs after emergence from general anaesthesia and subsequently in the post-anaesthesia care unit.

Numerous clinical trials have investigated the effectiveness of various methods for lowering POST after endotracheal tube and laryngeal mask airway insertion (LMA) [5]. Many medications through different modes of administration have been tried and tested but still there is an unmet need for an efficacious, feasible, and safe alternative drug to combat POST and POC after general anaesthesia. One of the prophylactic methods to avoid POST and POC is to take medicated lozenges before surgery.

Literature search revealed that turmeric in the form of Lozenges aided to reduce the occurrence of POST with its antioxidant, anti-inflammatory, analgesic, and antimicrobial characteristics [6]. Therefore, we set out to determine if giving patients turmeric-based lozenges before surgery would lessen the frequency and intensity of POST after general anaesthesia with endotracheal intubation. Our trial was prospective, randomized, double-blinded, and placebo-controlled. We compared three different combinations of turmeric based lozenges with the placebo to determine which combination is effective in reducing the intensity and severity of POST and POC. The compared lozenges include turmeric with menthol oil and eucalyptus oil, turmeric with tulsi and orange flavoured turmeric.

Our primary objective was to assess the incidence of score "0" of POST in the 6th postoperative hour, and our secondary objectives were to measure the incidence and severity of POST and POC at different time periods in the first 24 hours postoperatively, Total amount of rescue analgesics and incidence of side effects. Previous research with turmeric-based lozenges in patients receiving general anaesthesia with LMA led us to the decision to evaluate at the 6th hour [6].

Methodology

After receiving approval from the institutional ethics committee, this research was carried out from July to December, 2023 at the Department of Anaesthesiology at a tertiary care hospital in the Kanchipuram district. This study was a randomized, double-blinded, and placebo-controlled trial. After thoroughly explaining the method, informed written consent was acquired from all study participants. The sample size was obtained from the below formula, with a CI of 95%, 80% power, and absolute precision of 0.2.

$$n = \frac{Z1^2\{P1(1-P1) + P2(1-P2)\}}{d^2}$$

The minimum sample size required to conduct the study was 30 in each group (TOTAL – 120 patients).

Inclusion criteria were as follow:

- Adults between age of 18 to 60 years;
- Patients belonging to American Society of Anaesthesiologists (ASA) physical status I or II; and
- Patients scheduled for elective surgeries under general anaesthesia with orotracheal intubation.

Exclusion criteria were as follow:

- Patient Refusal;
- Chronic Smokers;
- Pregnant Women;
- Patients with prior upper and lower respiratory tract infections;
- Patients undergoing surgeries of head, neck, and thorax;
- Patients with prior sore throat and cough;
- Patients requiring more than one attempt of endotracheal intubation;
- Patients with a body mass index (BMI) greater than 30 kilogram/square meter;
- Patients with gastro-esophageal reflux disease;
- Patients with severe cardio-respiratory diseases;
- Patients with severe impairment of renal or hepatic functions;
- Patients with an adverse reaction to

any of the study drugs (menthol, eucalyptus, turmeric, and orange);

- Patients requiring Intraoperative usage of drugs like steroids, non-steroidal anti-inflammatory drugs, anti-sialogogues, and nitrous oxide gas;
- Patients requiring Ryle's tube insertion;
- Patients requiring Nasopharyngeal or oropharyngeal packing; and
- Patients requiring Cricoid pressure.

An independent anesthetist prepared a sealed envelope containing the study medication and handed over to the attending anaesthetist. The attending anesthetist who was unaware of the group allocation provided the study drug from the sealed envelope to the patient in the preoperative room. The study's participants were randomly assigned to one of four groups, with 30 people in each, using random number tables created by computers.

The study groups allocated by the independent anesthetists were as follows;

1. Group A (n=30) - Placebo containing a Multivitamin drug.
2. Group B (n=30) - Turmeric lozenges containing Turmeric extract (Curcuma longa 100 mg), Menthol oil, and Eucalyptus oil (Turmgel metholyptus, Gelnova Laboratories, India Pvt. Ltd.)
3. Group C (n=30) - Turmeric lozenges containing Turmeric extract (Curcuma longa 100 mg) and Tulsi (Ocimum sanctum 10 mg) (Turmgel tulsi, Gelnova Laboratories, India Pvt. Ltd.)
4. Group D (n=30) - Turmeric lozenges with Orange flavour containing Turmeric extract (Curcuma longa 100 mg) with Orange oil (Turmgel, Gelnova Laboratories, India Pvt. Ltd.)

All patients who met the inclusion criteria were maintained empty stomach for solids and liquids for six hours on the night before surgery. The patients were administered with 150 mg of ranitidine and 0.25 mg of alprazolam orally the night before surgery, and 2 hours prior to the procedure. Patients were told to consume the lozenge thoroughly by chewing it 30 minutes prior to surgery in the preoperative area. Patients were asked to spit up any remaining lozenge before being sent to the surgery room.

The patients were shifted to the operating room and the attending anaesthesiologist administered general anesthesia to the patients with routine ASA standard monitoring. All the study participants received General anaesthesia with short-acting opioids (injection fentanyl 2 mcg/kg), induction agents (propofol 2 mg/kg), inhalational anaesthetics (sevoflurane/ isoflurane), non-depolarizing muscle relaxants (atracurium (0.5 mg/kg)/ vecuronium (0.1 mg/kg)), reversal agents (neostigmine (0.05 mg/kg) and glycopyrrolate (10 mcg/kg), and analgesic (paracetamol 15 mg/kg) according to the discretion of the attending anaesthesiologists.

A 7 mm endotracheal tube (ETT) was used for female patients and an 8 mm tube for male patients as a norm. Rigorous tracking of the initial endotracheal cuff pressures during the surgery, and we used a manometer to keep the intracuff pressure between 20 and 25 cm H_2O. One anaesthesiologist with more than two years of experience performed all of the intubations. If more than one attempt of intubation attempt was required, then the patient was excluded from the study and the attending anaesthetists decided upon the further anaesthesia care plan.

The patients were assessed for POST and POC immediately following extubation and transferred to the Post Anaesthesia Care Unit (PACU) and subsequently to ward where they underwent additional assessments at 0, 2, 4, 6, 12, and 24 hours. Figure 1 displays a 4-point scale from 0 to 3 to assess the severity of POST and POC, following the guidelines provided by Harding and McVey.

Sore throat	
	Score
No sore throat	0
Minimal sore throat (complaints only on asking)	1
Moderate sore throat (Complaints of soreness on his / her own)	2
Severe sore throat (Complaints of throat pain)	3
Cough	
	Score
No cough at any time since the operation	0
Minimal cough or scratchy throat (light or single episode of cough)	1
Moderate cough (more than one episode of non-sustained cough)	2
Severe cough (sustained and repetitive cough)	3

FIGURE 1 Harding and Mcvey scoring system

All the patients were given intravenous paracetamol (one gram) as a part of multimodal analgesia for the surgery. If the patient had further complaints of POST and POC, rescue analgesia of Inj. Tramadol 2 mg/kg was given. The enrollment, group allocation, analysis, and results were done according to the consort diagram, as depicted in Figure 2.

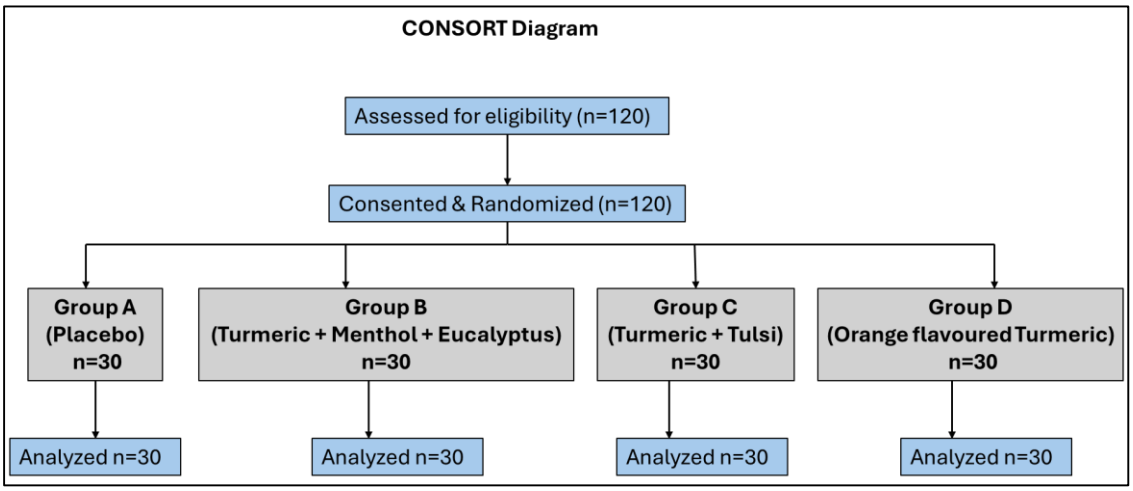

FIGURE 2 Consort diagram

Statistical analysis

The Excel spreadsheet was updated with the new data. Utilizing SPSS 22.0, descriptive statistics were computed, yielding the mean, standard deviation, and percentages. Frequency and percentage were used to characterize the categorical data. To compare the groups, we utilized paired t-tests, Analysis of Variance (ANOVA), and chi-square tests. It was deemed statistically significant if the p-value was less than 0.05.

Results

There was no loss of follow-up data for any of the 120 patients who were enrolled in our study. Demographic parameters were comparable as observed from Tables 1 and 2 across all groups.

TABLE 1 Demographic profile

Variables	A Mean± SD	B Mean± SD	C Mean± SD	D Mean± SD	*P*-value
Age	39.73±8.994	39.2±10.759	41.33±11.742	44.4±8.76	>0.05
Height	162.3±7.918	165.97±8.499	161.63±8.935	165.57±5.211	>0.05
Weight	66.97±8.189	64.67±8.347	60.17±7.625	66.07±6.883	>0.05
BMI	25.57±3.039	23.55±1.701	22.84±1.656	24.02±1.903	>0.05

TABLE 2 Gender data

Variables		A n (%)	B n (%)	C n (%)	D n (%)	*P*-value
Gender	**Male**	8(26.7)	16(53.3)	13(43.3)	16(53.3)	χ^2=5.779; p>0.05
	Female	22(73.3)	14(46.7)	17(56.7)	14(46.7)	

There was no significant difference in the time taken for intubation and duration of surgery among the four groups. At or before the 24-hour mark, no patient needed rescue analgesia. The POST incidence at first 24 postoperative hours with score 0, 1, and 2 were observed as depicted in Figures 3, 4, and 5, respectively. The primary objective of this study was the POST incidence at 6th postoperative hour. It was significantly least in Group B followed by Group D, Group C, and Group A ($p<0.05$).

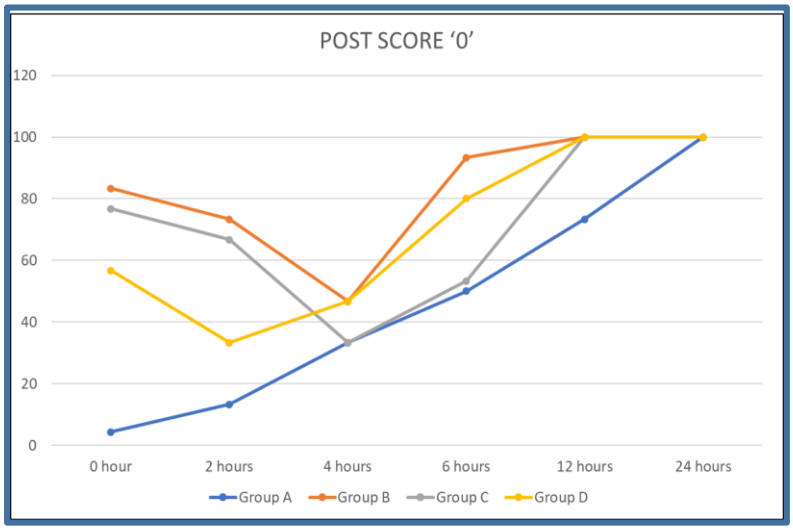

FIGURE 3 Incidence of POST score "0" among all groups in the first 24 postoperative hours

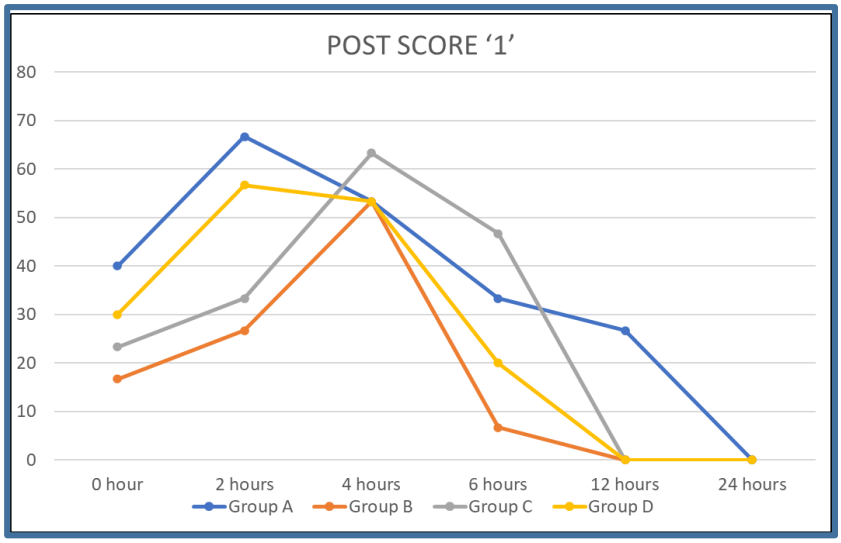

FIGURE 4 Incidence of POST score "1" among all groups in the first 24 postoperative hours

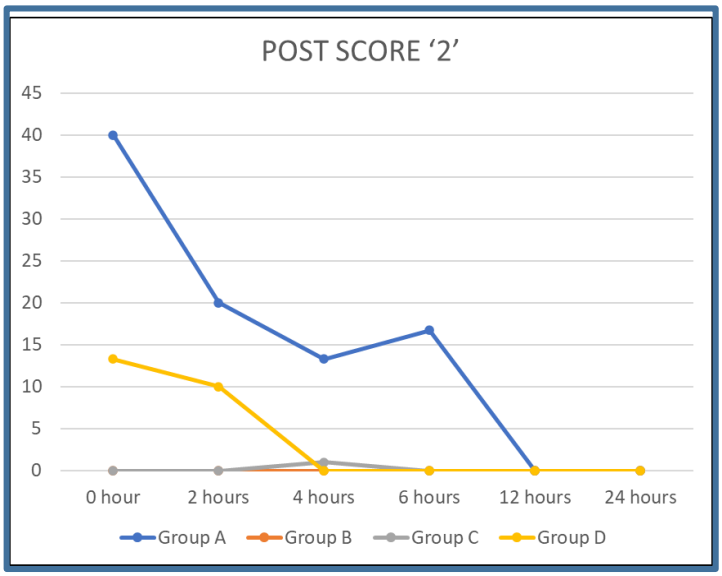

FIGURE 5 Incidence of POST score "2" among all groups in the first 24 postoperative hours

The POC incidence of at first 24 postoperative hours with score 0, 1, and 2 were observed as depicted in Figure 6, 7, and 8, respectively. At 6th postoperative hour, it was observed that the Groups C and B reduced POC at about the same rate followed by Group D when compared to Group A ($p<0.05$).

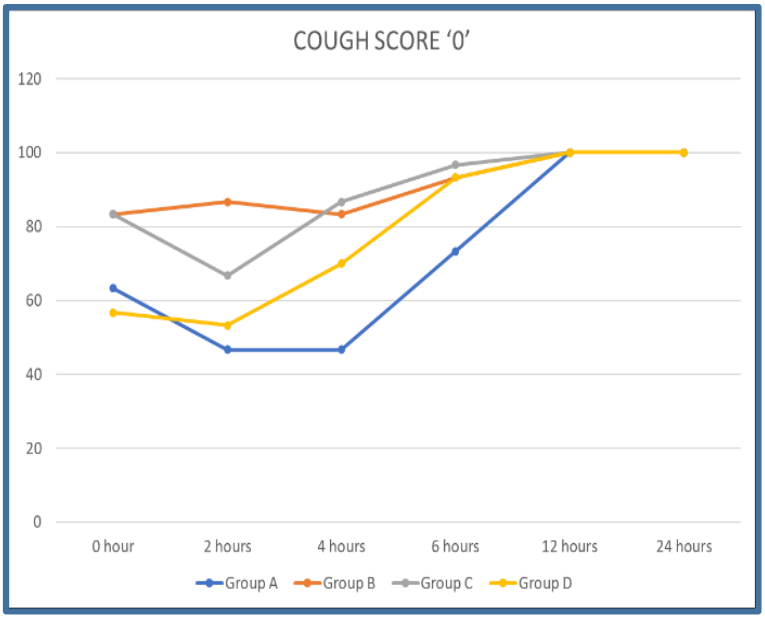

FIGURE 6 Incidence of POC score "0" across all the groups

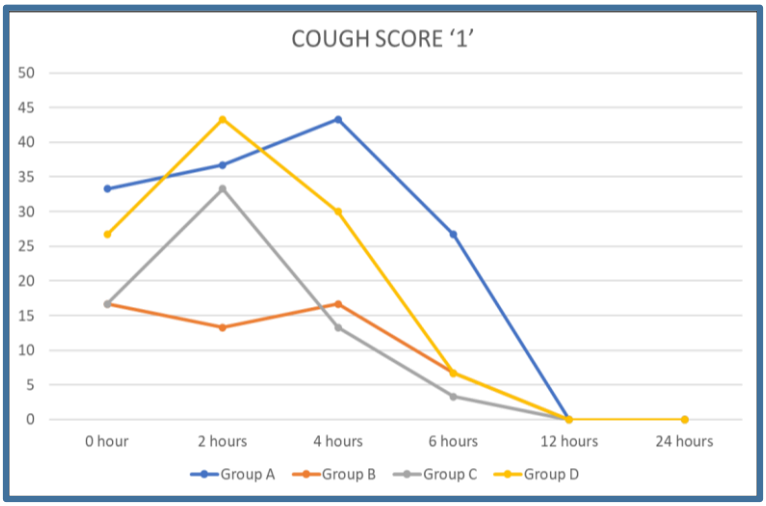

FIGURE 7 Incidence of POC score "1" across all the groups

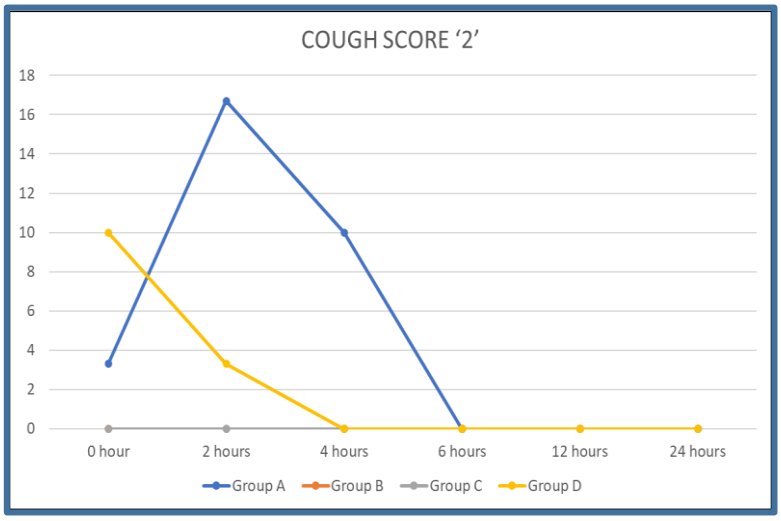

FIGURE 8 Incidence of POC score "2" across all the groups

The incidence of POST and POC at the 12th and 24th hour was zero in all the groups except Group A. None of the groups had an incidence of score 3 of POST or POC. To determine which group was more effective in lowering the incidence of POST and POC, statistical analysis was performed using two-factor ANOVA across the four groups and between hours. The percentage representation of POST values varied significantly between the groups, with a p-value less than 0.05 (Tables 3 and 4).

TABLE 3 ANOVA analysis of POST Score "0"

Summary	Counts	Summation	Mean	SD
A	4	136.7	34.2	15.49
B	4	296.7	74.2	20.07
C	4	230.0	57.5	18.73
D	4	216.7	54.2	19.70
0 Hour	4	256.7	64.2	19.70
2 Hour	4	186.7	46.7	28.28
4 Hour	4	160.0	40.0	7.70
6 Hour	4	276.7	69.2	20.97

TABLE 4 ANOVA analysis of POST

Source of variation	Sum of squares	Degrees of freedom	Mean squares	F value	*P*-value
Rows (Groups)	3233.3	3	1077.8	5.307	
				Significant	< 0.05
Columns (Hours)	2316.7	3	772.2	3.802	0.052

In Table 4, It was observed that the percentage (%) representation of POST values does not alter significantly across hours (p= 0.052).

TABLE 5 ANOVA analysis of POC Score "0"

SUMMARY	Counts	Summation	Average	Variance
A	4	230.1	57.5	13.2
B	4	346.7	86.7	4.7
C	4	333.3	83.3	12.5
D	4	280.1	70.0	17.0
0 Hour	4	293.4	73.4	11.5
2 Hour	4	253.4	63.4	17.6
4 Hour	4	286.7	71.7	18.2
6 Hour	4	356.7	89.2	10.7

TABLE 6 ANOVA analysis of POC

ANOVA					
Source of variation	**Sum of squares**	**Degrees of freedom**	**Mean squares**	**F value**	***P*-value**
Rows (Groups)	2138.1	3	712.71	12.263	
				Significant	< 0.01
Column(Hours)	1394.9	3	464.97	8.000	
				Significant	< 0.01

The percentage representation of POC values varied significantly across the Groups in different time periods ($p < 0.01$) (Tables 5 and 6).

Discussion

Lozenges contribute to the decrease of POST and POC related to airway instrumentation [6]. Several studies have been done on the use of different lozenges to reduce POST. As the incidence of POST and POC are higher, a formulation that is relatively cheap, easily available, and palatable with lesser side effects that can be easily administered is preferred to reduce it. Turmeric based lozenges has not been tested for incidence of POST and POC after orotracheal intubation with endotracheal tubes, yet. Hence, turmeric-based medicated lozenges were chosen in this study.

Individual properties of the contents in the turmeric-based lozenges are as follows: A natural cure for a sore throat, turmeric (Curcuma longa) has a long history of usage [6]. Buccal absorption allows the curcumin to enter the circulation without entering the digestive tract. It has inherent antimicrobial, antiseptic, antioxidant, anti-inflammatory, anticancer properties, and it is impermeable and very lipophilic. Various respiratory disorders, including coughs, colds, sore throats, and the common cold, have been treated with it [7].

In addition to its calming and analgesic effects, menthol is a local anesthetic. When a sore throat occurs, it is often prescribed. A mild agonistic activity on the kappa opioid receptor is seen. When used topically, menthol may alleviate pain on its own or be enhanced by adding other substances, such as eucalyptus oil, a natural decongestant. Extracting menthol from Mentha piperita leaves yields an active ingredient with cytotoxic, antioxidant, antiviral, antibacterial, and antiallergenic properties [8].

The leaf extracts of eucalyptus species, especially E. globulus have been extensively used in various therapies like aromatherapy, and phytotherapy, in treating the common cold for its biological effects. It has antibacterial, antihyperglycemic, and antioxidant activities [9,10].

Tulsi (Ocimum sanctum), commonly called holy basil has various therapeutic properties like adaptogenic, anti-microbial, anti-inflammatory, cardioprotective, and immunomodulatory effects. It also possesses decongestant action, helps in reducing phlegm and has smoothening effects on the throat [11].

Upon literature search, only one trial was deciphered that looked at the efficacy of a turmeric lozenge combination in decreasing POST after LMA placement. Lozenges containing a mixture of Turmeric, Menthol oil, and Eucalyptus oil at all intervals, had a lower incidence of POST. In contrast, Orange-flavored turmeric lozenges had a worsening of POST severity score. Turmeric with mentholyptus showed superior outcomes at the earliest time period (at 30 minutes after surgery), according to their research. Their investigation found that following LMA installation, the incidence of POST was significantly reduced with lozenges containing

turmeric extract, menthol, and eucalyptus oil when compared to orange flavor turmeric lozenges [6]. These findings are in concordance with our study. This signifies that turmeric with mentholyptus combination scores over rest of the combinations of turmeric. These findings may be obvious because of the symbiotic effect of all three ingredients of turmeric, Menthol and eucalytus over POST. After through literature search, No study has been identified which comments on incidence of POC after turmeric based lozenges.

Prospective research by Jaensson *et al.* on the effects of postoperative sore throat (POST) and hoarseness after endotracheal tube (ETT) or laryngoscopy (LMA) found that POST was more common in women after LMA, but no such difference when ETT was used for intubation [12]. Across all four categories, we did not find a statistically significant difference in the occurrence of POST or POC based on gender.

The effectiveness of topical magnesium, liquorice, and corticosteroids in preventing postoperative sore throat 24 hours after endotracheal intubation was found to be the most promising in a Bayesian network meta-analysis of topical agents for this purpose [13]. In our study apart from preventing post-operative sore throat, the turmeric-based lozenges also aided in preventing the postoperative cough 24 hours after endotracheal intubation

According to the literature, we did find studies with other lozenges like Magnesium, Zinc, Licorice, Amylmetacresol, dichlorobenzyl alcohol, etc. in reducing POST and POC. However, there has been no research on the effectiveness of turmeric lozenges in reducing the occurrence of POST and POC following endotracheal tube insertion. This study is the first of its kind.

This study was not devoid of limitations. Firstly, we chose a healthy population in the middle age group belonging to ASA 1 and 2. Secondly, lack of access to pharmacokinetic information on the local and systemic effects of oral turmeric lozenges, and the dosage and timing of administration solely relied on prior research. Thirdly, we have done this study in the south Indian population with a meagre number of patients in a single tertiary care center. In the Future, Multicentric studies can be performed on adults belonging to different ethnicities with higher sample sizes. Finally, further research is needed to determine if there is a correlation between the number of tries and manner of ETT intubation and the POST and postoperative cough.

Conclusion

We conclude that the incidence and severity of post-operative sore throat (POST) and post-operative cough (POC) was significantly reduced by turmeric based lozenges. The combination of turmeric, menthol, and eucalyptus was the most effective, followed by turmeric with tulsi, and orange flavored turmeric. Additional research is required to determine the relationship between the effects of number of attempts of intubation, techniques of endotracheal intubation, and critical plasma concentrations of turmeric and its combinations on the POST and POC.

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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

The authors declare that there is no conflict of interest in this study.

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