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A randomized controlled study to compare the efficacy of amyl meta cresol-2, 4-dichlorobenzyl alcohol lozenges Vs warm saline gargles Vs control in the prevention and treatment of post-operative sore throat after endotracheal intubation

Munira A Dilawer[1], Sandeep Mutha[1], Ajit Gaikwad[1], Deepak Phalgune[2,*]

[1]*Dept. of Anaesthesiology, Poona Hospital & Research Centre, Pune, Maharashtra, India*
[2]*Dept. of Research, Poona Hospital & Research Centre, Pune, Maharashtra, India*

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ABSTRACT

Introduction: The incidence of a post-operative sore throat (POST) varied from 21%–100% in intubated patients. Numerous non-pharmacological and pharmacological measures have been used for attenuating POST with variable success. The aim of the present study was to compare the efficacy of amyl meta cresol-2,4-dichlorobenzyl alcohol (AMC-2,4-DCBA) lozenges against warm normal saline (0.9%) gargles versus control in preventing and treating POST after extubation of the patients who have undergone surgical procedures under general anaesthesia.

Materials and Methods: This single-blind randomised controlled study was conducted in 120 patients. Group S patients received one honey and lemon-flavoured AMC-2,4-DCBA lozenge. Group G and Group C patients received warm normal saline and distilled water for gargling respectively. Assessment of POST was carried out at 1 h, 12 h and 24 h. The primary outcome measure was to compare the degree of sore throat whereas secondary outcome measure was to compare patient comfort in terms of relief of symptoms. Comparison of quantitative and qualitative variables was done using analysis of variance test and chi-square test/Fisher's exact test respectively.

Results: There was no statistically significant difference between Group S, Group G and Group C in relation to Ramsay sedation score, supplemental analgesics given, three-point assessment score at 1 h, 12 h, and 24 h. AMC-2,4-DCBA lozenges offered the maximum benefit in terms of patient comfort of POST symptoms at the end of 24 h post-surgically.

Conclusions: Amyl meta cresol-2,4-dichlorobenzyl alcohol lozenges and warm normal saline gargles did not show a significant benefit in relieving post-operative sore throat in the post-surgical period as compared to the placebo.

1. Introduction

The incidence of a post-operative sore throat (POST) varied from 21%–100% in intubated patients.[1–3] Numerous non-pharmacological and pharmacological measures have been used for attenuating POST with variable success.[4–9] Non-pharmacological methods, such as endotracheal tube smaller in size, using water-soluble jelly for lubricating endotracheal tube, careful airway instrumentation, intubation after full relaxation, gentle oropharyngeal suctioning, reducing intracuff pressure and extubation when the tracheal tube cuff is fully deflated have been reported to decrease the incidence of POST.[3]

* *Corresponding author*.
E-mail address: dphalgune@gmail.com (D. Phalgune).

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Pharmacological measures such as beclomethasone inhalation and gargling with azulene sulfonate have been reported to decrease the incidence of POST.[8] Tenoxicam (a hydrophilic non-steroidal anti-inflammatory drug) from an impregnated gauze pack has been shown to be effective in reducing moderate or severe POST.[10] Pre-emptive topical benzydamine hydrochloride has been reported to decrease the incidence of sore throat resulting from laryngeal mask airway use.[11] Ketamine and magnesium sulphate (both N-methyl-D-aspartate receptor antagonists) have been used as gargles and nebulisation to reduce the incidence of POST.[6,12–17]

The present study was aimed at comparing the efficacy of Amyl meta cresol-2,4-dichlorobenzyl alcohol (AMC-2,4-DCBA) lozenges against warm normal saline (0.9%) gargles versus control in preventing and treating POST after extubation of patients who have undergone surgical procedures under general anaesthesia.

2. Materials and Methods

This randomised single-blind controlled study was conducted between May 2018 and October 2019 in operation theatre, post-operative care unit (PACU) and wards. After approval from the scientific advisory committee (RECH/SAC/2018-19/198) and institutional ethics committee (RECH/EC/2018-19/243), written informed consent was obtained from all the patients prior to enrolment explaining the risks and benefits of the procedure.

Patients aged ≥ 18 years posted for surgeries under general anaesthesia with a minimal surgical duration of 1 h - 4 h, with Cormack-Lehane grade I-III, and falling into American Society of Anaesthesiologist (ASA) grades I-III were included. Patients with a history of sore throat seven days prior to surgery, patients with oral pathology, patients undergoing oral or maxillofacial surgeries, patients with a history of allergic asthma, rhinitis, pharyngitis, patients with a history of severe gastro-oesophageal reflux disease were excluded. Patients with more than one attempt for intubation were also excluded.

Out of 150 patients assessed for eligibility, after exclusion, 120 patients were randomly divided into three equal groups of 40 each with the help of www.randomizer.org (Figure 1). The program was known as research randomizer. The program produced three sets of random numbers out of the range of numbers provided (for e.g. 1-120) by taking user input on having uniqueness of the numbers to be generated. For the present study, the program produced three sets of 40 unique numbers per set. The sheet of the random numbers was ready before the study was started. Group S patients received one honey and lemon-flavoured AMC-2,4-DCBA lozenge (containing 2,4-DCBA 1.2 mg, AMC 0.6 mg, sucrose, glucose syrup, honey, tartaric acid, peppermint oil, terpene less lemon oil and quinolone yellow). Group G patients received warm normal saline (0.9%) 50 mL for gargling for one min. The normal saline was heated to keep a temperature between 27^0 and 30^0 Celsius. Group C patients received distilled water for gargling for one min. All the patients received lozenges/ warm normal saline/ distilled water 10 min after they arrived in PACU. The consciousness level of all the patients was assessed by Ramsay sedation scale (a score of two was considered appropriate.) prior to the administration of any modality.[18] The assessment was carried out at 1 h, 12 h and 24 h intervals on a three-point scoring system for severity of POST and patient's comfort in terms of relief of symptoms. This assessment was done by the same resident, who was blinded to the interventional modality the patient received.

The detailed pre-anaesthesia check-up was conducted for fitness along with an elaborate airway assessment as mentioned in the study proforma to look for any signs of difficult intubation, which could contribute as an independent risk factor for the POST. The Mallampati score for each individual was noted.[19] In the operation theatre, adequate intravenous (IV) access was ensured and minimum mandatory monitoring including blood pressure (BP), pulse oximeter, electrocardiogram (ECG), end-tidal CO_2 ($ETCO_2$) was initiated. Surgery was performed under standard general anaesthesia protocols. The night before surgery, all the patients received tablet lansoprazole 30 mg and tablet lorazepam 2 mg orally. All the patients also received 15 mL of 0.2% chlorhexidine gluconate mouth rinse after meals one day prior to surgery. Before the induction of anaesthesia, all the patients received IV palonosetron 250 μg and IV pantoprazole 40 mg. Induction was carried out with Inj. propofol 2mg/kg and Inj. fentanyl 2 μg/kg. Inj. rocuronium bromide 1 mg/kg was administered as a non-depolarising neuromuscular blocker prior to intubation and graded doses at intervals were used for maintenance of the neuromuscular blockade during the surgery. Atraumatic Portex endotracheal tube was placed after direct laryngoscopy under vision. During direct laryngoscopy, visualisation of the glottis with vocal cords for placement of the endotracheal tube was graded using the Cormack-Lehane classification system.[20] Confirmation of the endotracheal tube placement was carried out by auscultation of the chest, chest rise after ventilation and capnography monitoring. The cuff pressure for the endotracheal tube was maintained between 25 and 30 cm of H_2O as per the standard guidelines to prevent any peri-cuff leak and prevent excess mucosal injury to the trachea. Anaesthesia was maintained with Oxygen: Nitrous oxide: 50:50 and sevoflurane, with the end-tidal concentration of the inhalational anaesthetic maintained between 1.5% - 1.8% (adjusted according to hemodynamic parameters) with controlled ventilation. $ETCO_2$ was maintained between 30 mm and 35 mm of Hg. Inj. rocuronium in supplemental doses of 0.2 mg/kg was used for muscle relaxation

if required. After the surgery, patients were reversed with IV neostigmine 0.04 mg/kg and IV glycopyrrolate 0.008 mg/kg. Nasopharyngeal and oropharyngeal suction was performed with soft tip suction catheter of 14 French gauge. The endotracheal tube was removed during inspiration. Extubation was performed maintaining the end-tidal inhalational anaesthetic concentration at 0.2% - 0.3%, when the patients were taking adequate spontaneous breaths suggesting good ventilation, yet were not coughing or bucking on the endotracheal tube. Patients who coughed or bucked on the tube were excluded from the study group. After patients were fully awake and able to follow commands, they were wheeled into the PACU area with oxygenation being maintained for an additional 15-20 minutes by Hudson's face mask. Immediately in the PACU, patients were randomly assigned to receive any one intervention after ten min of post-operative observation. Patients were assessed at the end of ten min by the Ramsay sedation scale for their level of consciousness, where a score of two or three was considered appropriate indicating the patient was co-operative, oriented and tranquil or can respond to commands.

Ramsay Sedation scale:[18]

Awake levels

1. Patient anxious or agitated or both.
2. Patient is cooperative, oriented and tranquil.
3. Patient responds to commands only.

Asleep levels

1. A brisk response to a light glabellar tap.
2. A sluggish response to a light glabellar tap.
3. No response.

The first dose of the intervention was given in PACU and the remaining two doses were given in wards. Group S patients received one honey and lemon-flavoured AMC-2,4-DCBA lozenge. Group G patients received warm normal saline (0.9%) 50 mL for gargling for one min. Group C patients received distilled water for gargling for one min. These interventions were done post-operatively at 8 and 16 hours. Assessment for the sore throat was done using a three-point scoring system at 3 different intervals – 1 h post-operatively in the PACU, 12 h after surgery and 24 h after surgery in the wards.

The three-point scoring system was as follows:

Score 1 – no symptoms or mild throat discomfort while talking or swallowing

Score 2 – throat pain while talking or swallowing or hoarseness of voice

Score 3 – Aphonia

During the pre-operative visit, all the patients were explained regarding the three point scoring system of reporting symptoms of sore throat and were told that they will have to indicate post-operative throat discomfort in this manner. For analgesia, patients received Inj. diclofenac 75 mg intramuscularly intra-operatively, and/or IV paracetamol 1 gm. Demographic data, airway assessment parameters, intra-operative Cormack-Lehane grading during direct laryngoscopy, the total duration of anaesthesia and requirement of any supplemental analgesics were recorded.

The primary outcome measure was to compare the degree of the sore throat whereas secondary outcome measure was to compare patient comfort in terms of relief of symptoms (reduction in the degree of the sore throat after each modality). On the basis of a previously published study,[21] a sample size of 22 patients in each group was calculated by formula[22] with 80% power and 5% probability of Type I error to reject the null hypothesis. We included 40 patients in each group to validate the results.

2.1. Statistical analysis

Data collected were entered in Excel 2007 and analysis of data was done using Statistical Package for Social Sciences for Windows, Version 20.0 from IBM Corporation Armonk, NY, USA. The data on categorical variables are shown as n (% of cases) and the data on continuous variables are presented as mean and standard deviation (SD). Comparison of the distribution of categorical variables such as gender, ASA grade, Mallampati score, Cormack-Lehane grade, Ramsay sedation score, supplemental analgesics given and three-point assessment score was done using Chi-Square or Fisher's exact test. Comparison of continuous variables such as mean age, mean body mass index (BMI) and mean duration of anaesthesia was done using analysis of variance (ANOVA) test. The underlying normality assumption was tested before subjecting the study variables to ANOVA test. McNemar's test was used to compare patient relief in terms of sore throat symptoms. The confidence limit for significance was fixed at 95% level with a p-value < 0.05.

3. Results

Of 150 patients assessed for eligibility, 30 were excluded because patients were chronic smokers (10), a history of sore throat 7 days prior to surgery (5), refusal to participate (3), patients' with Cormack-Lehane grade IV (2), a patient who required more than one attempt at intubation (4), patients who required bougie for intubation (1) and patients who coughed or bucked on extubation (5) (Figure 1)

There was no statistically significant difference between Group S, Group G and Group C in relation to mean age, gender, mean BMI, ASA grades, Mallampati score, Cormack-Lehane grade and mean duration of anaesthesia (Table 1). There was no statistically significant difference between Group S, Group G and Group C in relation Ramsay sedation score, supplemental analgesics given, three-point assessment score at 1 h, 12 h and 24 h (Table 2). As evident from Table 3, at the end of 12 h assessment, none of the

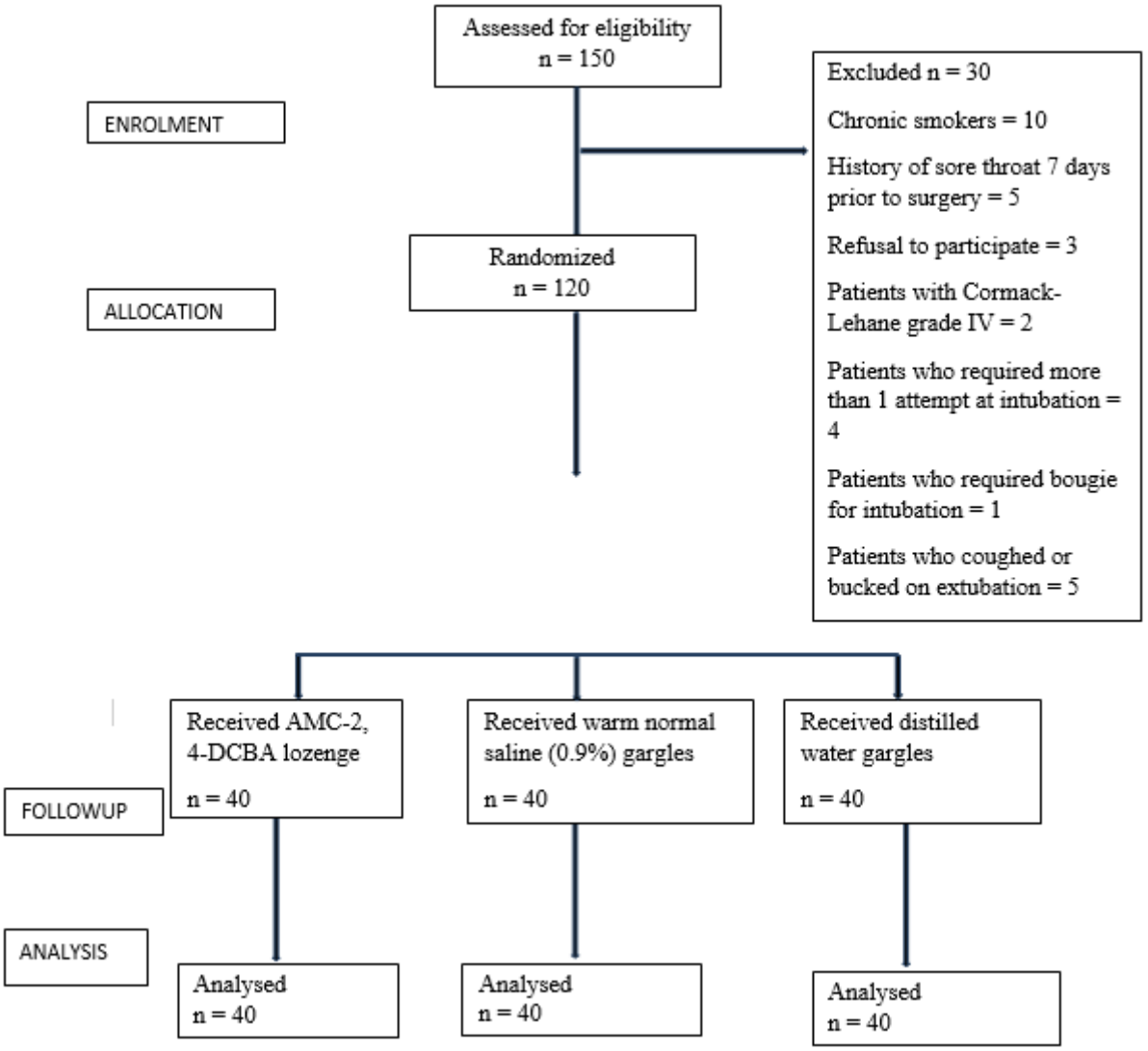

Fig. 1: Consort flow diagram

modalities showed any statistically significant difference in relieving sore throat symptoms amounting to overall patient comfort (p-value > 0.05). As depicted in Table 4, at the end of 24 h assessment, AMC-2,4-DCBA lozenges were superior in terms of patient comfort of relief of sore throat symptoms over the other two groups (p-value = 0.004 for the lozenges group, p- value > 0.05 for the other two groups).

4. Discussion

The present study was conducted to compare the efficacy of AMC-2,4-DCBA lozenges against warm normal saline (0.9%) gargles versus control in preventing and treating POST after extubation of patients who have undergone surgical procedures under general anaesthesia. There is not a single study reported in the literature comparing these three modalities for the alleviation of symptoms of POST. Some studies have compared various other pharmacologic agents for the alleviation and reduction of incidence of POST.

In the present study, there was no statistically significant difference between Group S, Group G and Group C in relation Ramsay sedation score, supplemental analgesics given, three-point pain assessment score at 1 h, 12 h and 24 h.

Ebneshahidi A and Mohseni M conducted a randomized double-blind placebo-controlled study to evaluate the efficacy of Strepsils honey and a lemon lozenge containing the active ingredients 2,4-DCBA 1.2 mg, AMC 0.6 mg, sucrose, glucose syrup, honey, tartaric acid, peppermint oil, terpeneless lemon oil and quinoline yellow on the incidence and severity of POST and hoarseness of voice.Participants were randomly allocated to receive either Strepsils, or identical-looking placebo tablets immediately before arrival

Table 1: Baseline characteristics

Characteristics	AMC-2,4-DCBA Lozenge (Group S) N = 40	Normal Saline Gargles (Group G) N = 40	Distilled Water Gargles (Group C) N =40	P-value
Mean age in years ± SD	40.4 ± 12.3	39.0 ± 13.5	39.5 ± 14.8	0.888*
Gender (%)				
Male	21 (52.5)	21 (52.5)	21 (52.5)	0.301**
Female	19 (47.5)	19 (47.5)	19 (47.5)	
Mean BMI in Kg/m^2 ± SD	22.9 ± 2.4	22.5 ± 2.9	22.7 ± 2.5	0.792*
ASA grade (%)				
Grade I	29 (72.5)	25 (62.5)	32 (80.0)	
Grade II	9 (22.5)	14 (35.0)	7 (17.5)	0.411***
Grade III	2 (5.0)	1 (2.5)	1 (2.5)	
Mallampati Score (%)				
Grade I	26 (65.0)	28 (70.0)	33 (82.5)	
Grade II	13 (32.5)	10 (25.0)	5 (12.5)	0.309***
Grade III	1 (2.5)	2 (5.0)	2 (5.0)	
Cormack-Lehane Grade (%)				
1	36 (90.0)	32 (80.0)	34 (85.0)	
2a	3 (7.5)	5 (12.5)	4 (10.0)	0.897***
2b	1 (2.5)	2 (5.0)	1 (2.5)	
3	0 (0.0)	1 (2.5)	1 (2.5)	
Mean duration of anaesthesia in h ± SD	2.6 ± 0.7	2.4 ± 0.5	2.4 ± 0.6	0.150*

*Analysis of Variance (ANOVA) test was used
**Chi square test was used
*** Fisher's exact test was used
BMI- Body mass index
ASA - American Society of Anaesthesiologist
SD- Standard deviation

Table 2: Comparison of post-operative characteristics

Characteristics	AMC-2,4-DCBA Lozenge (Group S) N = 40	Normal Saline Gargles (Group G) N = 40	Distilled Water Gargles (Group C) N =40	P-value
Ramsay Sedation Score (%)				
2	21 (52.5)	21 (52.5)	18 (45.0)	0.741*
3	19 (47.5)	19 (47.5)	22 (55.0)	
Supplemental Analgesics given (%)				
Yes	36 (90.0)	34 (85.0)	34 (85.0)	0.749**
No	4 (10.0)	6 (15.0)	6 (15.0)	
Three-point assessment score at 1 h (%)				
1	30 (75.0)	33 (82.5)	32 (80.0)	
2	9 (22.5)	7 (17.5)	8 (20.0)	0.663**
3	1 (2.5)	0 (0.0)	0 (0.0)	
Three-point assessment score at 12 h (%)				
1	36 (90.0)	34 (85.0)	34 (85.0)	
2	4 (10.0)	6 (15.0)	6 (15.0)	0.749**
3	0 (0.0)	0 (0.0)	0 (0.0)	
Three-point assessment score at 24 h (%)				
1	39 (97.5)	38 (95.0)	36 (90.0)	
2	1 (2.5)	2 (5.0)	4 (10.0)	0.346**
3	0 (0.0)	0 (0.0)	0 (0.0)	

*Chi square test was used **Fisher's exact test was used

Table 3: Comparison of patient relief in terms of sore throat symptoms (reduction in degree of sore throat) at the end of 12 hours

Group				At 12h post-operative		Total	P-value
				Score 1	Score 2,3		
AMC-2,4-DCBA lozenges (Group S)	At 1 h post-operative	Score 1	n (%)	29 (96.7)	1 (3.3)	30 (100.0)	0.070
		Score 2,3	n (%)	7 (70.0)	3 (30.0)	10 (100.0)	
		Total	n (%)	36 (90.0)	4 (10.0)	40 (100.0)	
Normal saline gargles (Group G)	At 1 h post-operative	Score 1	n (%)	32 (97.0)	1 (3.0)	33 (100.0)	1.000
		Score 2,3	n (%)	2 (28.6)	5 (71.4)	7 (100.0)	
		Total	n (%)	34 (85.0)	6 (15.0)	40 (100.0)	
Distilled water gargles (Group C)	At 1 h post-operative	Score 1	n (%)	31 (96.9)	1 (3.1)	32 (100.0)	0.625
		Score 2,3	n (%)	3 (37.5)	5 (62.5)	8 (100.0)	
		Total	n (%)	34 (85.0)	6 (15.0)	40 (100.0)	

McNemar Test was used

Table 4: Comparison of patient relief in terms of sore throat symptoms (reduction in degree of sore throat) at the end of 24 hours

Group				At 24h post-operative		Total	P-value
				Score 1	Score 2,3		
AMC-2,4-DCBA lozenges (Group S)	At 1 h post-operative	Score 1	n (%)	30 (100.0)	0 (0.0)	30 (100.0)	0.004
		Score 2,3	n (%)	9 (90.0)	1 (10.0)	10 (100.0)	
		Total	n (%)	39 (97.5)	1 (2.5)	40 (100.0)	
Normal saline gargles (Group G)	At 1 h post-operative	Score 1	n (%)	33 (100.0)	0 (0.0)	33 (100.0)	0.063
		Score 2,3	n (%)	5 (71.4)	2 (28.6)	7 (100.0)	
		Total	n (%)	38 (95.0)	2 (5.0)	40 (100.0)	
Distilled water gargles (Group C)	At 1 h post-operative	Score 1	n (%)	31 (96.9)	1 (3.1)	32 (100.0)	0.219
		Score 2,3	n (%)	5 (62.5)	3 (37.5)	8 (100.0)	
		Total	n (%)	36 (90.0)	4 (10.0)	40 (100.0)	

McNemar Test was used

to the operating room (45 min before induction of anaesthesia on an average). The incidence of POST in patients who received Strepsils honey and lemon lozenges was about one-third as compared with the placebo group (p-value = 0.003). The hoarseness was reported less frequently in the Strepsils honey and lemon lozenge group than the placebo group (p-value = 0.04). The incidence of both sore throat and hoarseness decreased at the 24 h assessment after surgery, but the differences between the two groups remained statistically significant (p-value = 0.04). The mean ± SD of severity scores of the early sore throat (0.52 ± 0.85 vs 0.20 ± 0.57), late sore throat (0.22 ± 0.50 vs 0.08 ± 0.32), early hoarseness (0.36 ± 0.65 vs 0.16 ± 0.47) and late hoarseness (0.22 ± 0.45 vs 0.08 ± 0.27) in the placebo group were significantly higher than in the Strepsils honey and lemon lozenge group (p-value < 0.05).[23]

Titinchi F et al. conducted a randomized study in relieving POST symptoms in patients undergoing surgical removal of third molars under general anaesthesia. Group 1 formed the control group and did not receive any palliative medication. Group 2 was administered 200 mL tea with honey and lemon juice (5 mL of honey and 5 mL of lemon juice added to unsweetened English tea). Group 3 was administered honey and lemon-flavoured Strepsils® (Boots, Nottingham, UK) containing 2,4-DCBA 1.2 mg, AMC 0.6 mg, sucrose, glucose syrup, honey, tartaric acid, peppermint oil, terpeneless lemon oil and quinolone yellow. The score of POST immediately after surgery and prior to administering any medication was comparable in all the three groups. However, the score of POST after administration of the first dose of medication differed among the three groups. For Group 1 (control group), the score of POST was unchanged (p-value > 0.05) while for Group 2 the POST score was significantly lower after administration of the first dose (p-value < 0.01), and that for Group 3 also, it was significantly lower after administration of the first dosage (p-value < 0.001) as compared to the baseline POST score. The severity of POST significantly decreased 24 h after surgery for all the three groups (p-value < 0.05). A comparison of POST scores between the control group and the honey and lemon in the tea group showed no statistically significant differences (P > 0.05). However, when the honey and lemon-flavoured Strepsils lozenges group was compared to the control group, a statistically significant (p-value < 0.02) difference was found between the POST scores, indicating the high efficacy of honey and lemon-flavoured Strepsils lozenges in relieving post-operative throat symptoms.[24]

Rudra A et al. conducted a randomized single-blind placebo-controlled study to compare the effectiveness of ketamine gargles in preventing POST after endotracheal intubation. The study included 20 patients in each group. The control group received 30 mL of water for gargling, whereas the study group received 1 mL of ketamine 50 mg

in 29 mL of water (total 30 mL) for gargling.The study reported that the severity of POST was significantly lower in the ketamine group than in the control group (p-value < 0.05). The study further stated that the percentage of patients in the control group had a significantly higher incidence of POST at 4 h, 8 h and 24 h (85%, 75%, and 60%) as compared to patients in ketamine group (40%, 35% and 25%) [p-value < 0.05].[25]

Yadav M and Gopinath R conducted a randomized double-blind study to evaluate the efficacy of ketamine, tramadol, 1.5% saline and normal saline gargle on POST after endotracheal intubation. The gargling was done 5 min before giving anaesthesia. There was no significant difference in POST at 0 h, 4 h and 24 h amongst the four groups. The incidence of POST at 0 h and at 2 h was significantly lower in the ketamine group.[26] In our study, the incidence of the sore throat and its severity did not differ significantly amongst the three groups at 1 h, 12 h and 24 h post-operatively.

Studies conducted by Rudra A et al. and Yadav M and Gopinath R did not use lozenges or warm saline gargles to compare POST after endotracheal intubation. However, in the present study, lozenges/warm normal saline/distilled water were used to compare POST after endotracheal intubation.

5. Limitations

Potential limitations of the study merit consideration. Responsiveness of patients in the immediate post-operative period may be questioned. Fentanyl, or sevoflurane still circulating in the bloodstream immediately after surgery could have affected their ability to accurately perceive throat symptoms. At the time of extubation, patients who coughed or bucked on the tube were excluded. These patients may have a greater incidence of the sore throat. There might be a lot of user variability associated with gargling. The exact duration of gargling in each case at a particular given time could not be calculated and compared. None of the modalities was administered pre-operatively prior to induction. Multicentric study with a large sample size is needed to substantiate the research findings described in this paper.

6. Conclusions

Amyl meta cresol-2,4-dichlorobenzyl alcohol lozenges and warm normal saline gargles did not show a significant benefit in relieving post-operative sore throat at 1 h, 12 h and 24 h in the postsurgical period as compared to the placebo. Amyl meta cresol-2,4-dichlorobenzyl alcoho lozenges offered the maximum benefit in terms of patient comfort of post-operative sore throat symptoms at the end of 24 h post-surgically.

7. Source of Funding

None.

8. Conflict of Interest

The authors declare no conflict of interest.

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Author biography

Munira A Dilawer, Senior Resident

Sandeep Mutha, Consultant Anaesthesiologist

Ajit Gaikwad, Consultant Anaesthesiologist

Deepak Phalgune, Research Consultant https://orcid.org/0000-0003-4225-8010

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