

Preoperative amylmetacresol and dichlorobenzyl alcohol with lignocaine lozenge reduces postoperative sore throat following general anaesthesia using supraglottic airway devices: A double-blinded, randomised, placebo-controlled trial

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Submitted: 31-Aug-2021

Revised: 21-Mar-2022

Accepted: 05-Jul-2022

Published: 22-Jul-2022

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ABSTRACT

Background and Aims: Postoperative sore throat (POST) is an undesirable event reported in up to 62% of patients receiving general anaesthesia (GA). The incidence of POST following GA using a supraglottic airway device (SAD) is approximately 50%, with symptoms persisting up to 48 h. We examined the role of preoperative lozenges containing amylmetacresol and dichlorobenzyl alcohol (AMC/DCBA) with lignocaine (Strepsils[®] Max Plus) in reducing the incidence and intensity of POST following GA using SAD. **Methods:** We conducted a prospective, double-blinded, randomised, placebo-controlled trial involving 88 adults receiving GA for elective surgery using SAD not exceeding 2 h. Patients received either Strepsils Max Plus (Strepsils-LA group) or a placebo before induction of GA. The incidence and intensity of sore throat, dysphagia and dysphonia was measured using the Verbal Rating Scale at 30 min (early) and at 24 h (late) after removal of SAD. **Results:** Overall POST incidence was lower in the Strepsils-LA group (27.7% versus 56.8%, $P = 0.007$). Patients in the Strepsils-LA group reported a significantly lower incidence of early POST (14.9% versus 37.8%, $P = 0.016$) with a lower mean \pm standard deviation intensity score (0.17 ± 0.43 versus 0.49 ± 0.69 , $P = 0.016$). Although the overall incidence of dysphagia was lower (23.4% versus 48.6%, $P = 0.016$), more patients experienced dysphonia in the Strepsils-LA group. AMC/DCBA with lignocaine lozenges showed a relative risk reduction of 50% and a number needed to treat of 4 in reducing POST. **Conclusion:** AMC/DCBA with lignocaine lozenges administered before GA using SAD is a simple and safe method to reduce the incidence and severity of POST.

Key words: Anaesthesia, General; Benzyl Alcohol; Cresols, laryngeal masks, lidocaine, pharyngitis

Access this article online

Website: www.ijaweb.org

DOI: 10.4103/ija.ija_809_21

Quick response code



INTRODUCTION

The incidence of postoperative sore throat (POST) after general anaesthesia (GA) following the use of a supraglottic airway device (SAD) is as high as 49%, and symptoms can persist for up to 48 h.^[1,2] Although a minor complication, it is among the top undesirable events experienced after GA and has been implicated in the overall recovery of patients.^[3] The postulated mechanism of POST includes local tissue injury with subsequent inflammation.^[4]

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How to cite this article: Sundaraj S, Shariffuddin II, Chaw SH, Zakaria WA, Ng KW, Ruslan SR. Preoperative amylmetacresol and dichlorobenzyl alcohol with lignocaine lozenge reduces postoperative sore throat following general anaesthesia using supraglottic airway devices: A double-blinded, randomised, placebo-controlled trial. *Indian J Anaesth* 2022;66:523-9.

Several studies have shown that zinc tablets, nebulised dexmedetomidine, topical magnesium and benzydamine spray can produce a significant reduction in the incidence of POST following GA including with the use of SAD.^[5-9] However, the effect of lignocaine on POST has been equivocal.^[1] Amylmetacresol and dichlorobenzyl alcohol (AMC/DCBA), the active ingredients in the standard preparation of Strepsils® lozenges, have been shown to reduce the intensity of sore throat in non-anaesthetised subjects. Proposed mechanisms of action of AMC/DCBA are antiseptic (viricidal) as well as anaesthetic qualities.^[10] Currently, to the best of our knowledge, there is no study that evaluates the effect of AMC/DCBA with lignocaine in reducing POST following SAD insertion.

It was our hypothesis that AMC/DCBA combined with lignocaine would reduce the incidence and intensity of POST following SAD. Thus, the primary objective of this study was to evaluate the effect of AMC/DCBA with lignocaine lozenge in reducing the incidence and intensity of POST following SAD insertion. The secondary objectives were to measure the intensity of sore throat, dysphagia and dysphonia at 30 min and at 24 h.

METHODS

We obtained approval from the Institutional Review Board (ethics approval number: 201887-6582) before the study commencement, and written informed consent was obtained from all participating subjects. The trial was registered with ClinicalTrials.gov (NCT03944655) and adhered to the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines. The study was conducted from January 2019 to August 2019 at a tertiary hospital. The study followed all the principles of the Declaration of Helsinki.

Adult patients with American Society of Anesthesiologists (ASA) physical status class I or II, scheduled for elective surgical procedures under GA amenable to supraglottic airway insertion were recruited for the study. Exclusion criteria were patients with a body mass index (BMI) of more than 35 kg/m², a history of upper respiratory tract infection, sore throat, dysphagia or dysphonia within 2 weeks before surgery, presence of risk factors for regurgitation or aspiration, pregnant or nursing women, known allergies to the study drug and refusal to participate in the study. Patients were excluded from per protocol analysis if there was more than one attempt at SAD insertion, use

of airway adjuncts (e.g. laryngoscope, bougie) during SAD placement, insertion or presence of a gastric tube, total duration of SAD placement exceeding 120 min, failed SAD placement/performance tests, conversion of SAD to an endotracheal tube (ETT) intraoperatively or an intracuff pressure of more than 60 cmH₂O.

The patients were randomised using a computer-generated block randomisation method consisting of two intervention groups, that is, 'placebo' and 'Strepsils-LA', with a balanced ratio of 1:1 with 52 subjects in each group. The study drugs were placed in sequentially numbered, concealed, opaque envelopes. Both the perioperative anaesthesiologist and the observer were blinded to the group allotment of the patients.

Patients assigned to the group Strepsils-LA received one lozenge of Strepsils Max Plus [Reckitt Benckiser, Bangkok (Thailand)] containing the active ingredients AMC 0.6 mg, 2,4-DCBA 1.2 mg, lignocaine hydrochloride 10 mg, sucrose, glucose syrup, tartaric acid, flavourings, sodium saccharin, indigo carmine and quinoline yellow. The placebo group received identical-looking lozenges [Cavendish & Harvey, Kaltenkirchen (Germany)] containing glucose syrup, sugar and flavourings. Both lozenges were similar and not easily distinguishable with regards to appearance, colour, taste and smell.

Patients were positioned supine on the operating table, with the head resting on a head ring. Standard monitoring was applied before the induction of anaesthesia. The insertion of SAD was done based on the manufacturer's recommendation. SAD was deflated entirely, and a water-based lubricant was applied to the posterior part of the cuff and airway tube. The size of SAD was chosen following the manufacturer's recommendations.

After pre-oxygenation, anaesthesia was induced with fentanyl 1.5–2 µg/kg and propofol 2–3 mg/kg, and anaesthesia was maintained with sevoflurane (end-tidal concentration of 2%–3%) in 100% oxygen until the patient's jaw was considered relaxed, before insertion of SAD. The cuff of SAD was inflated with the recommended air volume, and the intracuff pressure was ensured to be less than 60 cmH₂O using a standardised handheld manometer [VBM Medizintechnik, Sulz am Neckar (Germany)].

The time of SAD insertion was taken when an effective airway (defined as the first square wave

capnograph trace) was recorded. A minimum of two placement tests (i.e. sternal notch test and bubble test) and one performance test (oral leak pharyngeal test) were performed to define successful insertion.^[11] Intraoperative analgesia was left to the discretion of the managing anaesthesiologist to achieve an adequate level of pain relief. At the end of surgery, SAD was removed, with the cuff not deflated, and the time recorded.

Data collected included patient characteristics, procedure details, operator details (level and years of experience) and anaesthesia details (SAD type and size, SAD duration). The number of attempts, aids used, ETT conversion, suction attempts, presence of blood on removal and intraoperative analgesia administered were noted. Any adverse events that occurred were also documented.

An independent observer assessed the patients for POST, dysphonia and dysphagia and their intensities 30 min (early) after arriving at the recovery bay. All the patients who were interviewed at 30 min had met the post-anaesthesia discharge criteria, indicating an adequate recovery of cognitive function. Reassessment was then done at 24 h (late) at the bedside (in-patient) or by phone call (day case surgery). Sore throat was defined as constant pain independent of swallowing, while dysphagia was defined as difficulty or pain provoked by swallowing and dysphonia as difficulty or pain on speaking.

The primary outcome measures were the incidence of sore throat at 30 min and at 24 h after SAD was removed. The secondary outcome measures included the intensity of sore throat and the incidence and intensity of dysphagia and dysphonia at 30 min and at 24 h. The intensity of symptoms was reported using the Verbal Rating Scale (VRS) and subsequently converted to grading scores represented as null = 0, mild = 1, moderate = 2 and severe = 3.

By using the primary and secondary outcome measures evaluated at 30 min and at 24 h, we also explored the overall POST incidence occurring within the first 24 h after removal of SAD. Presence of symptoms either at 30 min, or at 24 h, or both was considered as a single overall POST event.

Novel studies involving ETT using a standard preparation of Strepisils reported an incidence of POST up to 13.7% and overall incidence reduction

of 59%–77%.^[12,13] In order to detect a clinically significant POST reduction of 10%, and assuming a two-sided type I error protection of 0.05 and a power of 0.80, we calculated that a sample size of 52 patients was required. We initially aimed to recruit 60 patients, with 30 patients in each group to account for possible dropouts. However, we observed a higher than anticipated protocol deviation, and a revised sample size of 104 subjects with 52 patients in each intervention group was determined suitable to maintain adequate power of the study.

A complete intention-to-treat analysis was performed for all randomised patients when complete data was available and when there were missing data, an incomplete intention-to-treat analysis was performed. No imputation for missing data was undertaken. A per protocol analysis was subsequently performed after excluding protocol deviations. Data were expressed, where appropriate, as mean (standard deviation [SD]) in normally distributed continuous data, or median (interquartile range [IQR]) in non-normally distributed continuous data or frequency and percentages in categorical data. Chi-square test and Fisher's exact test were used where appropriate for categorical data, Student's *t*-test for parametric data and Mann-Whitney U test for non-parametric data. All comparisons were two sided, and a *P* value of less than 0.05 was determined to be statistically significant and required to exclude the null hypothesis. All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) Statistics, Version 22.0 (IBM Corp., Armonk, NY, USA).

RESULTS

We recruited and randomised 104 eligible patients. Subsequently, 88 patients received the allocated intervention [Figure 1]. The treatment groups had similar baseline demographics and clinical characteristics [Table 1]. There were no reports of adverse events in both the study groups.

The incidence of sore throat at 30 min was significantly lower in the Strepisils-LA group compared to the placebo group [14.9% versus (vs.) 37.8%, *P* = 0.016] [Table 2]. When re-evaluated at 24 h, the incidence of sore throat was similarly lower in the Strepisils-LA group, but this was not statistically significant (17.0% vs. 32.4%, *P* = 0.10).

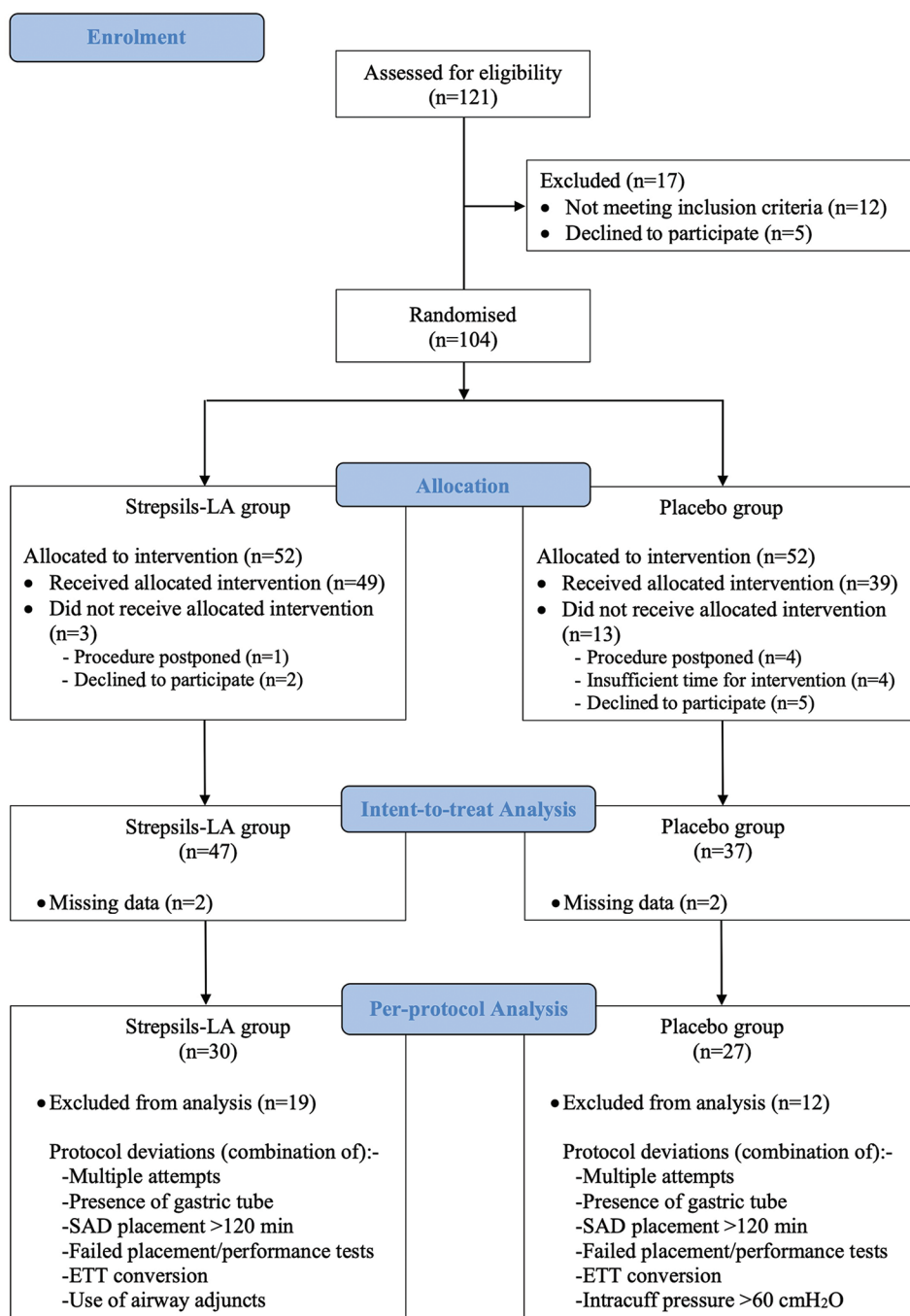


Figure 1: CONSORT 2010 flow diagram. CONSORT=Consolidated Standards of Reporting Trials, ETT=Endotracheal tube, SAD=Supraglottic airway device, n=number

Analysis of the secondary outcomes revealed lower incidences of dysphagia in the Strepsils-LA group at 30 min ($P = 0.10$) and at 24 h ($P = 0.17$), but the differences did not reach statistical significance. On the contrary, the incidence of early dysphonia was detected to be higher in the Strepsils-LA group (17.0% vs. 10.8%, $P = 0.42$).

The mean intensity scores for patients with sore throat and dysphagia were lower in the Strepsils-LA

group at both early and late assessments. Patients who developed early sore throat in the Strepsils-LA group had a significantly lower mean \pm SD intensity score (0.17 ± 0.43 vs. 0.49 ± 0.69 , $P = 0.016$). However, patients with dysphonia reported a higher mean intensity score in the Strepsils-LA group.

The overall incidence of sore throat and dysphagia was higher in both the treatment groups in the first

Table 1: Demographic and clinical characteristics

| Variable | Strepsils-LA (n=49) | Placebo (n=39) |
|--|---------------------|----------------|
| Age, years | 44.2 (16.2) | 47.8 (12.8) |
| Sex | | |
| Male | 15 [30.6%] | 8 [20.5%] |
| Female | 34 [69.4%] | 31 [79.5%] |
| BMI, kg/m ² | 25.0 (4.6) | 25.5 (4.4) |
| ASA physical status class | | |
| I | 26 [53.1%] | 17 [43.6%] |
| II | 23 [46.9%] | 22 [56.4%] |
| Admission type | | |
| In-patient | 18 [36.7%] | 14 [35.9%] |
| Day case | 31 [63.3%] | 25 [64.1%] |
| Surgery type | | |
| General surgery | 33 [67.3%] | 22 [56.4%] |
| Gynaecology | 5 [10.2%] | 10 [25.6%] |
| Orthopaedic | 6 [12.2%] | 3 [7.7%] |
| ENT | 1 [2.0%] | 1 [2.6%] |
| Urology | 3 [6.1%] | 3 [7.7%] |
| Others | 1 [2.0%] | 0 [0.0%] |
| Operator anaesthesia experience, years | 5 {4} | 5 {3} |
| Operator level of experience | | |
| Non-trainee | 1 [2.0%] | 1 [2.6%] |
| Trainee | 44 [89.8%] | 36 [92.3%] |
| Specialist | 4 [8.2%] | 2 [5.1%] |
| SAD type* | | |
| AMBU® AuraGain™ | 11 [22.4%] | 11 [28.9%] |
| LMA® Supreme™ | 35 [71.4%] | 23 [60.5%] |
| LMA® Proseal™ | 1 [2.0%] | 1 [2.6%] |
| LMA® Classic™ | 1 [2.0%] | 1 [2.6%] |
| Baska mask | 1 [2.0%] | 2 [5.3%] |
| SAD size* | | |
| Size 3 | 31 [63.3%] | 30 [78.9%] |
| Size 4 | 17 [34.7%] | 8 [21.1%] |
| Size 5 | 1 [2.0%] | 0 [0.0%] |
| Intraoperative analgesia | | |
| IV fentanyl, µg/kg | 1.67 (0.33) | 1.55 (0.38) |
| IV morphine, mg/kg | 0.07 (0.03) | 0.07 (0.04) |
| IV paracetamol, mg/kg | 16.59 (0.14) | 16.00 (3.04) |
| IV parecoxib, mg/kg | 0.66 (0.14) | 0.64 (0.11) |
| IV tramadol, mg/kg | 0.95 (0.31) | 0.83 (0.12) |
| Suction on SAD removal | 43 [87.8%] | 27 [69.2%] |
| Duration from intervention to SAD insertion, min | 75.0 {69} | 65.5 {40} |
| Duration of SAD (insertion to removal), min | 71.5 {53} | 60.0 {33} |

ASA=American Society of Anesthesiologists, BMI=body mass index, ENT=ear, nose and throat, IV=intravenous, LMA=laryngeal mask airway, SAD=supraglottic airway device. Data expressed as mean (standard deviation), median (interquartile range) or number [percentage]
*Missing data in placebo group=one case (failed SAD insertion)

24 h following SAD removal [Table 3]. The incidence was significantly lower in the Strepsils-LA group for sore throat (27.7% vs. 56.8%, $P = 0.007$) and dysphagia (23.4% vs. 48.6%, $P = 0.016$). There was higher incidence of dysphonia in the Strepsils-LA group compared to the placebo. Preoperative administration of Strepsils Max Plus was associated

with an absolute risk reduction of 29%, relative risk reduction of 50% and a number needed to treat of 4 in preventing POST in the first 24 h.

When per-protocol analysis was performed, there was a significantly reduced incidence of sore throat at 30 min in the Strepsils-LA group (10% vs. 37%, $P = 0.015$). All other subgroups yielded lower incidences of late sore throat, early and late dysphagia in the Strepsils-LA group, but higher incidence of early dysphonia in the same intervention group. The mean \pm SD intensity score of early sore throat was significantly lower in the Strepsils-LA group (0.10 ± 0.31 vs. 0.48 ± 0.70 , $P = 0.017$). The overall incidence of sore throat in the first 24 h was significantly lower in the Strepsils-LA group (26.7% vs. 55.6%, $P = 0.026$).

DISCUSSION

The overall incidence of sore throat and dysphagia of approximately 57% and 49%, respectively, detected in our study was comparable with other studies.^[1,14,15] Our study showed that the incidence and intensity of sore throat and dysphagia after GA using SAD can be reduced with the preoperative administration of AMC/DCBA with lignocaine lozenges (Strepsils Max Plus). These results are consistent with two studies that evaluated the effects of standard preparation Strepsils in GA using ETs.^[12,13] It is also consistent with a systematic review showing the beneficial results of lignocaine in the reduction of POST.^[16,17]

Sore throat following the use of SAD is postulated to be the result of direct injury to the pharyngeal mucosa in the supraglottic regions, with resulting inflammation caused by the process of airway instrumentation or the irritating effects of foreign airway objects.^[4] With the insertion of a SAD, the main force is applied to the end of the soft palate and the posterior pharyngeal wall.^[18] Subsequently, the final resting position of the rim of the SAD cuff lies just below the base of the tongue, with the sides of the cuff against the aryepiglottic folds and the tip of the cuff above the upper oesophageal sphincter.^[19] Therefore, we believe that the use of lubricants on the cuff of SAD will only exert its pharmacological action predominantly at the contact surface of the cuff and surrounding tissue while neglecting the area of main force applied during insertion, which then leads to sore throat. In comparison, a proportion of a spray/inhalation method is immediately swallowed after application, while gargles only deliver the active drug to the anterior oral cavity because of the gag reflex.^[10,20]

Table 2: Primary and secondary outcome measures (intention-to-treat analysis)

| Outcome measures | Incidence | | | Intensity scores | | |
|----------------------|----------------------|-----------------|--------------------------|----------------------|-----------------|--------------------------|
| | Strepsils-LA (n=47)* | Placebo (n=37)# | P | Strepsils-LA (n=47)* | Placebo (n=37)# | P |
| Sore throat – 30 min | 7 [14.9%] | 14 [37.8%] | 0.016^a | 0.17 (0.43) | 0.49 (0.69) | 0.016^b |
| Sore throat – 24 h | 8 [17.0%] | 12 [32.4%] | 0.10 ^a | 0.21 (0.51) | 0.32 (0.48) | 0.16 ^b |
| Dysphagia – 30 min | 8 [17.0%] | 12 [32.4%] | 0.10 ^a | 0.19 (0.45) | 0.41 (0.69) | 0.10 ^b |
| Dysphagia – 24 h | 6 [12.8%] | 9 [24.3%] | 0.17 ^a | 0.15 (0.42) | 0.24 (0.44) | 0.25 ^b |
| Dysphonia – 30 min | 8 [17.0%] | 4 [10.8%] | 0.42 ^a | 0.17 (0.38) | 0.14 (0.42) | 0.54 ^b |
| Dysphonia – 24 h | 1 [2.1%] | 0 | 1.00 ^c | 0.02 (0.15) | 0 | 1.00 ^b |

Data expressed as number [percentage] and mean (standard deviation) where appropriate. ^a χ^2 test; ^bMann–Whitney U test; ^cFisher's exact test. *Missing data=two cases; #missing data=two cases. The bold numbers represent a statistically significant value (i.e., $P < 0.05$)

Table 3: Overall incidence in the first 24 h (intention-to-treat analysis)

| Outcome measures | Strepsils-LA (n=47)* | Placebo (n=37)# | P |
|------------------|----------------------|-----------------|--------------------------|
| Sore throat | 13 [27.7%] | 21 [56.8%] | 0.007^a |
| Dysphagia | 11 [23.4%] | 18 [48.6%] | 0.016^a |
| Dysphonia | 9 [19.1%] | 4 [10.8%] | 0.29 ^a |

Data expressed as number [percentage]. ^a χ^2 test. *Missing data=two cases; #missing data=two cases. The bold numbers represent a statistically significant value (i.e., $P < 0.05$)

A lozenge formulation is a highly suitable method for drug delivery as it directly coats the pharyngeal mucous membranes, whereby it plays a reservoir-like role by slowly dissolving to release the active ingredients directly onto the irritated mucosal tissues.^[10] Through the flow of saliva and action of swallowing, the drug is further able to reach the supraglottic region and exert its effects. The patients who developed early sore throat in the Strepsils-LA group had a significantly lower mean \pm SD intensity score. This can be attributed to the long duration of action of AMC/DCBA, which was reported to be more than 2 h after administration.^[10]

Interestingly, our results revealed that the incidence of dysphonia at all time intervals was higher in the Strepsils-LA group, which is contrary to the results from another study investigating the role of a standard preparation of Strepsils.^[12] Dysphonia is partly due to injury of structures in the pharynx and larynx responsible for the articular production of speech, which are partly innervated by the glossopharyngeal and superior laryngeal nerves.^[21] The glossopharyngeal nerve can be blocked at the caudal aspect of the posterior tonsillar pillar, while the superior laryngeal nerve can be blocked in the piriform fossa where it runs just deep to the mucosa.^[22] *In vitro* studies have shown that the combination of AMC and DCBA possesses local anaesthetic-like action by blocking voltage-gated sodium channels, and in the presence of lignocaine, it further augments blocking of sodium channels.^[23] Hence, the combination of AMC/DCBA and lignocaine in the lozenges could be absorbed in

these areas and it subsequently leads to the blocking of the glossopharyngeal and superior laryngeal nerves, affecting speech articulation, which could manifest as difficulty or pain on speaking.

There are several limitations to our study. We did not enquire about the history of smoking, which is associated with POST.^[24] However, as a standard practice in our centre, all elective patients are required to stop smoking for a minimum of 24 h before surgery. There were also varying durations between study drug administration and SAD insertion, which could result in diminishing the pharmacological effect. However, the mean duration from intervention to SAD insertion was comparable in both the study groups.

CONCLUSION

In conclusion, the use of preoperative AMC/DCBA with lignocaine lozenges such as Strepsils Max Plus is a simple and safe method to reduce the incidence of POST in patients receiving GA using a SAD. Future studies on POST should evaluate the possible benefits of administering regular doses of Strepsils Max Plus postoperatively.

Acknowledgements

The authors are grateful to the nursing staff of the Department of Anaesthesiology, University Malaya Medical Centre for their invaluable role in the various aspects of this study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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