Soaking oro-pharyngeal pack with triamcinolone acetonide lowers discomfort in functional endoscopic sinus surgeries

Pack orofaringeo con triamcinolone disminuye molestias luego de cirugía endoscópica sinusal

Sherif S Sultan¹, Nouran Mohsen Ahmed Fahmy¹, Mohamed Ibrahim Hassan¹, Dalia Fahmy Emam¹

Abstract

Background: Postoperative sore throat (POST) is defined as pain or discomfort in the throat following general anesthesia. Throat packs are used by many surgical subspecialties for different benefits; however, they may increase the incidence of POST. Many interventions can be used to decrease incidence of POST. Triamcinolone acetonide (TA) is a moderately potent topical corticosteroid preparation. In this study, we hypothesized that soaking the throat pack with TA may decrease POST.

Methods and Material: This prospective interventional comparative study was performed on 54 patients planned for Functional Endoscopic Sinus Surgeries (FEES) surgery. After endotracheal intubation, a standard length of oro-pharyngeal pack was placed, then patients were randomly allocated into: Group I: Oro-pharyngeal packs were soaked with 15 mg Triamcinolone acetonide 0.1% and Group II: packs were soaked with the same volume of lubricating gel (K-Y gel®). The patients were postoperatively asked about: sore throat, dysphagia, hoarseness of voice and nausea and vomiting.

Results: Thirty minutes and 24 hours after extubation, Group I patients showed lower but statistically insignificant sore throat scores. Two to six hours after extubation, Group I showed a statistically significant reduction in sore throat scores. Six patients suffered dysphagia in group I compared with 8 patients in group II. Hoarseness of voice occurred in 1 patient in group I and 3 patients in group II. No patient complained of nausea or vomiting.

Conclusion: Soaking oropharyngeal pack with triamcinolone acetonide in ora-base gel was able to decrease POST in FESS patients.

Key words: Postoperative sore throat, oro-pharyngeal pack, triamcinolone acetonide, Functional Endoscopic Sinus Surgeries (FESS)

¹ Department of anesthesia, intensive care and pain management, faculty of medicine, Ain Shams University. Cairo, Egypt.

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ORCID
https://orcid.org/0000-0003-0681-186X

Contact Author:
Dalia Fahmy Emam
rady2002200276@gmail.com
Introduction

Postoperative sore throat (POST) is defined as pain, discomfort, scratchiness or irritation in the throat following general anesthesia that always worsens with swallowing. It may be due to pharyngitis or laryngitis. Highest incidence is after tracheal intubation (14.4%-64%)[1,2] followed by after insertion of laryngeal mask airway (LMA) (4.1%-34%) [3,4]. It is believed to occur even after general anesthesia based on face mask application[5]. Insertion of simple airway devices e.g. oropharyngeal or nasopharyngeal airway may also share its occurrence and increase its severity[6].

Throat packs are used by many surgical subspecialties for different reasons. They collect blood, secretions, bony and cartilaginous debris intraoperatively. This is claimed to decrease their inhalation and swallowing postoperatively and therefore decrease the incidence of postoperative complications e.g. postoperative nausea and vomiting[7]. Whatever were the benefits behind the insertion of throat packs they still have their side effects. Between these side effects is increasing the incidence of POST[8].

Many interventions can be used to decrease incidence of POST. These include using smaller endotracheal tube size[9] including video laryngoscopy in intubation process[10], limiting endotracheal cuff pressure[11], perioperative use of steroids (intravenous)[12], topical[13] or inhaled[14]), the use of topical non-steroidal anti-inflammatory drugs (NSAIDs) [15] and the use of different gargles (magnesium and ketamine[16].

Triamcinolone acetonide (TA) is a moderately potent corticosteroid preparation that is commonly used in wide range of oral mucosal lesions. These include different inflammatory and immunological lesions such as recurrent aphthous stomatitis[17] and oral lichen planus[18]. It has been used successfully to decrease throat discomfort - Sherif S. Sultan et al. in wide range of oral mucosal lesions. These include different inflammatory and immunological lesions such as recurrent aphthous stomatitis[17] and oral lichen planus[18]. It has been used successfully to decrease POST when applied along the length of the ETT[13]. Considering that application of throat pack may increase the incidence of POST, we hypothesized that the use of TA when added as an ora-base gel to the throat pack may decrease POST.

Methods

This prospective interventional comparative study was performed after approval of Research Ethics Committee, Faculty of Medicine, Ain Shams University, and Cairo, Egypt (FMASU M S 49/2019) and registered at Pan African Clinical Trial Registry (www. pactr.org, PACTR201909823246718). The study was performed at Ain Shams Universities Hospitals, Cairo, Egypt. Written informed consent was obtained from all patients prior to performing the procedure.

Patients undergoing Functional Endoscopic Sinus Surgeries (FESS) where enrolled in this double-blinded, randomized, controlled trial. Inclusion criteria included patient's age between 18 and 60 years, American Society of Anesthesiologists (ASA) physical status classification system class I and II, modified Mallampatti classification I and II, with no significant preexisting laryngotracheal diseases other than the indication of surgery. Patients included were presumed to undergo an easy intubation and a duration of surgery of less than 3 hours. Exclusion criteria included pharyngeal infection or ulceration, smokers, patients on corticosteroids or NSAIDs.

After arrival to the operating theatre, patients were attached to the monitors as per standard protocols. The same standardized anesthesia technique was used for all patients which included induction with fentanyl (1 μg/kg), propofol (2 mg/kg) and atracurium (0.5 mg/kg) and maintenance with 1.5-2% isoflurane in O2/Air mixture. Another booster dose of fentanyl (1 μg/kg) was given at start of surgery and top-up doses of atracurium were used according to the attending anesthesiologist. Endotracheal intubation was performed using disposable, well-lubricated tubes with an internal diameter of 7 mm for females and 7.5 mm for males. Endotracheal tube cuffs were inflated with air to reach a pressure of 25 mmHg. Patients requiring more than one attempt for passage of the tube were excluded from the study.

A standard length of oro-pharyngeal pack 120 cm and a width of 7.5 cm was placed under direct vision using Magill forceps and positioned in the oropharynx, thus isolating the nasal passage in order to allow suctioning of blood and debris from the operative field and prevent soiling of the pharynx, oesophagus and tracheal contamination. A label on the patient's forehead or the airway device was applied, and the time of insertion and removal of the oral pack was recorded on the operating room white board and the anesthetic sheet to avoid the risk of leaving the pack accidentally in place after extubation.

At this point, patients were randomly allocated into one of two groups utilizing computer generated list for allocation; Group I “Study Group”: Oro-pharyngeal packs were soaked with addition of 15 mg Triamcinolone acetonide 0.1% (Kenacort Orabase gel, SmithKline Beecham, London, UK) or Group II “Control Group”: Oro-pharyngeal packs were soaked with addition of the same volume of lubricating gel.
(K-Y gel®) for blinding. The soaked pack was positioned by residents blinded to the gel used to moisten the throat pack.

Patients were placed in a head-up position in order to provide optimum conditions for the surgery. If hypotensive anesthesia was needed, glyceryl trinitrate was used avoiding use of opioids, propranolol or increasing the concentration of inhaled anesthetic. At the end of operation, oro-pharyngeal pack was removed, and IV paracetamol (1 gm) was given. The nose was closed by a small nasal packing. Oropharyngeal suction before extubation was done under direct vision with a suction catheter, confirming that secretion clearance was complete. After completion of surgical procedure duration of surgery was recorded.

The patients were interviewed postoperatively (30 min after extubation)

Postoperatively, patients who were unaware of which gel had been used, were interviewed by a blinded investigator and asked about 4 complaints; sore throat, difficulty in swallowing (dysphagia), hoarseness of voice and postoperative nausea and vomiting. For sore throat, it was determined at the following intervals: 30 min after extubation, 2-6 hours after extubation and 24 hours after extubation. It was categorized based on visual analogue scale. The other 3 complaints were categorized as yes or no 24 h after extubation. All patients received oral paracetamol (500 mg/6 hours) postoperatively.

Sample size was calculated according to Chandak et al. study (2017) in which 0.1% triamcinolone acetonide paste succeeded in decreasing pain secondary to aphthous stomatitis from 3.60 ± 1.502 to 2.13 ± 1.302 in 24 h. Therefore, 16 patients per group would be sufficient to give 80% power at a 5% significance level. We enrolled 27 patients in each group.

Data were analyzed using Statistical Package for Social Science (SPSS Inc., Chicago, IL, USA, version 23.0 for windows). The quantitative parametric data were presented as mean, standard deviations (SD) and ranges then compared using independent t-test. The quantitative nonparametric data were presented as median, inter-quartile range (IQR) then compared using Mann-Whitney U-test. Qualitative variables were presented as number and percentages then compared with Chi-square test. The confidence interval was set to 95% and the margin of error accepted was set to 5%. Accordingly, the p-value was considered statistically significant when < 0.05.

Results

Fifty-four patients were included in the study equally divided into two groups. No significant differences were detected between the two groups concerning age, sex and duration of surgery (Table 1). Median scores of sore throat are shown in Table 2. Thirty minutes and 24 hours after extubation, Group I patients showed lower sore throat scores but that were statistically insignificant. Two to six hours after extubation, Group I showed a statistically significant reduction in sore throat scores compared to Group II (control group). This is shown in Figure 1.

A total of 6 patients suffered dysphagia in group I compared with 8 patients in group II with statisti-

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**Table 1. Comparison between the two groups regarding age, sex and duration of surgery**

|                      | Group I   | Group II  | P-value |
|----------------------|-----------|-----------|---------|
| Age in years (Mean ± SD) | 29.81 ± 5.53 | 30.81 ± 6.87 | 0.558   |
| Sex (Female/male)     | 13/14     | 7/20      | 0.091   |
| Duration of surgery (hours) (Mean ± SD) | 2.21 ± 0.15 | 2.21 ± 0.15 | 0.929   |

**Table 2. Comparison between the two groups regarding sore throat at 30 mins, 2-6 h and 24 h post-extubation. Data are presented as median (IQR)**

| Sore throat | Group I  | Group II | P-value |
|-------------|----------|----------|---------|
| 30 min      | 4 (4 - 5) | 5 (4 - 6) | 0.360   |
| 2-6 h       | 3 (3 - 4) | 4 (3 - 4) | 0.028   |
| 24 h        | 1 (1 - 2) | 2 (1 - 2) | 0.306   |
cally insignificant difference. Hoarseness of voice was a complaint of 1 patient in group I and 3 patients in group II with a statistically insignificant result. No patient complained of nausea or vomiting in our study (Table 3).

**Discussion**

Postoperative sore throat is a common anesthetic complication that is considered by many anesthesiologists as a minor complication. However, it may be the first complaint for some patients immediately after getting their conscious back even before they may complain of the incisional/operative pain. It should be avoided and prevented better than treating it. Prevention of POST is expected to improve the patient satisfaction and comfort postoperatively. Moreover, prevention is expected to reduce the patient stay in PACU and the overall hospital stay[19] dislodgement or (partial especially in day-surgery cases.

The use of oropharyngeal pack is a common practice asked by surgeons of different surgical sub-specialties. These include dental, oral and maxillofacial surgeries, a wide variety of rhino-pharyngo-laryngeal surgeries and neurosurgical surgeries that involve nasal route. It is well known that the use of pharyngeal packs adds to the postoperative discomfort and pain [20][8]. The mechanism behind POST caused by oropharyngeal packs is not very well-understood. An oropharyngeal pack may induce POST by the process of packing itself. Packing may include pharyngeal instrumentation (using laryngoscopy and/or Magill forceps) and passage of the hard, abrasive fibers (especially if not fully soaked) of cotton texture in its way from the incisors to its destination in oro-pharynx. This passage is performed through the oral cavity which is considered a pit tight canal that differs from person to person. Insertion of the oro-pharyngeal pack may induce dryness of the adjacent tissues through suction of water and body fluids by this dry piece of texture. This dryness may induce an area that is ready for inflammation. It is well-known that manipulation of abdominal towels containing cotton is associated with development of peritoneal adhesions[21]. Accordingly, it is not very strange that cotton fibers itself may induce inflammatory process for an adjacent mucosal surface.

In the current study, duration of surgery was 2.2 hours. Accordingly, it may be concluded that asking the patient about POST 30 minutes after extubation is about 3 hours after inserting the oro-pharyngeal pack. It is not known exactly the onset of action of topical steroids. Pharmacokinetics of topical steroids (including that in Ora-base forms) are affected by potency of the preparation, amount applied, nature of area applied to (thick skin, thin skin or mucosa) and condition of area applied to (normal, ulcerated or inflamed)[22]. It seems that 3 hours were not enough for triamcinolone acetonide to have its full effects that can decrease throat pain secondary to throat pack immediately postoperatively. The causative factors for POST after 30 mins other than throat packs may have been prevalent at that time. These factors may include lack of airway humidity, trauma during airway insertion, suctioning, high anesthetic gas flow rates and surgical manipulation of airway and adjacent tissue[23]. These factors may be the cause that

| Table 3. Comparison between the two groups regarding dysphagia, hoarseness and nausea and vomiting. Data are presented as number of patients |
|---------------------------------------------------------------|
| **Group I** | **Group II** | **P-value** |
| Dysphagia (No/Yes) | 21/6 | 19/8 | 0.535 |
| Hoarseness (No/Yes) | 26/1 | 24/3 | 0.299 |
| Nausea and vomiting (No/Yes) | 27/0 | 27/0 | — |
our results showed decrease in POST 30 minutes after extubation but failed to reach statistical significance. However, 2-6 hours postoperatively, effects of triamcinolone acetonide in decreasing POST due to oro-pharyngeal pack were evident. During this time, pain scores were significantly lower in study group compared to control group. This may be attributed to reaching the maximum available effect of topical triamcinolone acetonide applied. Triamcinolone acetonide is able to decrease number and functions of different inflammatory cells at site of inflammation including T and B lymphocytes, neutrophils, monocytes and eosinophils. Moreover, production of cytokines, chemokines, eicosanoids is markedly inhibited while the production of macrophage migration inhibitory factor is markedly enhanced[24].

After 24 hours, POST declines progressively to the degree that it is difficult to elicit the effect of the study drugs except, perhaps, if we have a bigger sample size. This generally goes with the usual noticed nature of behavior of POST that it usually subsides in most of patients by the end of the first postoperative day even without any extra analgesic more that the usually used postoperative analgesics[25]. An exception is the rough airway manipulation during a difficult intubation scenario.

The use of corticosteroids in prophylaxis against or treatment of POST is previously documented. A meta-analysis performed by[26] recommended that IV dexamethasone should be used in reduction of POST, hoarseness and PONV as grade 1A of evidence in a dose > 0.2 mg/kg in patients who are not pregnant, diabetic or have contraindications to corticosteroids. Moreover, gargling preoperatively with 0.05% dexamethasone decrease POST incidence from 63% to 33% when compared with gargling with normal saline[27].

The current study proved no statistically different results between the study group and the control group concerning dysphagia and hoarseness of voice. Dysphagia and hoarseness of voice were reported in the current study 24 hours after extubation. At that time, POST were not statistically different between the groups. As mentioned above, TA effects may have been faded away. Results in the current study concerning PONV go in line with other studies who proved no association between pharyngeal packs and PONV[28],[8],[20]. Adding to this is that topically applied TA is not expected to affect this kind of postoperative complication.

There are few limitations of this current study. First is that the sample size is low and if a bigger sample size was used the effects of topically applied triamcinolone acetonide may have a statistically significant results 30 minutes and 24 hours after extubation. Second is that the current study ignored the possible effects of systemically absorbed triamcinolone acetonide. This comes in concern when studies prove that systemically applied corticosteroids can decrease severity of POST[27]. However, Ramadas et al. proved that no systemic absorption is expected from topically TA applied to oral mucosa reflecting its safety profile[18].

In conclusion, soaking oropharyngeal pack with triamcinolone acetonide in ora-base gel was able to decrease POST in FESS patients.

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