Original Article

# Effect of steroid-soaked throat pack on postoperative throat complications following major oral and maxillofacial surgery


## ABSTRACT

**Background:** Postoperative throat complications (POTCs) are common and distressing to patients; consensus on their optimum treatment is unclear.

**Aim:** The aim of the study was to determine the efficacy of a steroid-soaked throat pack on POTCs following oral and maxillofacial surgery.

**Materials and Methods:** This was a randomized, triple-blinded, controlled clinical study design on all consecutive patients who had endotracheal intubation and pharyngeal throat packs following major oral and maxillofacial surgery. They were randomized into experimental (steroid) and control (normal saline) groups. The experimental group had their throat packs soaked with 10 ml aqueous solution of 100 mg hydrocortisone, while the control group had their throat pack soaked with 10 ml of 0.9% normal saline. The data were clinicodemographic, type of throat pack, postoperative sore throat, dysphagia, hoarseness, and cough. Both descriptive and inferential statistics were performed. *P* values < 0.05 were considered significant.

**Results:** A total of 48 patients comprising 24 in each group participated fully in the study. The mean age and the age range of the participants were 37.3 ± 15.6 years and 18–65 years, respectively. There was no significant difference between the two groups in the demographic and surgical characteristics studied ($P > 0.05$). There was a significantly higher prevalence of postoperative sore throat and dysphagia among the normal saline group compared to the steroid group ($P < 0.05$). There was no significant difference in the prevalence of postoperative cough and hoarseness between the steroid and normal saline groups ($P > 0.05$).

**Conclusion:** The use of a steroid-soaked throat pack was found to be more efficacious in the reduction of the prevalence of postoperative sore throat and dysphagia but did not affect the prevalence of postoperative cough and hoarseness among patients that had major oral and maxillofacial surgical procedures.



**Keywords:** Postoperative throat complication, steroid, normal saline, throat pack


## INTRODUCTION

Major oral and maxillofacial surgical procedures are still common in developing countries, probably due to late presentations and financial constraints.[1,2] Complications can arise following these procedures that are performed under general anesthesia.[3] Postoperative throat complications (POTCs) such as sore throat, dysphagia, cough, and hoarseness of voice are common and frequently complained about health burdens that affect the quality of life of patients following endotracheal intubation.[4] POTCs have been described as one of the most undesirable outcomes of


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the postoperative period because they adversely affect the satisfaction and activities of the patients even after discharge from the hospital.[5] A wide range of incidences of 30–100% have been reported following endotracheal intubations.[6,7] Many interventions were reported to decrease the incidence of POTCs. These include the use of smaller endotracheal tube size,[8] video laryngoscopy in the intubation process[9] reduction of endotracheal cuff pressure,[10] perioperative use of steroids (intravenous,[11] topical,[12] or inhaled[13]) use of topical non-steroidal anti-inflammatory drugs (NSAIDs),[14] and the use of different gargles (magnesium and ketamine).[15,16] The role, types, and methods of application of steroids in the relief of POTCs are well studied.[17–20] The method of administration of steroids ranges from topical to systemic application.[11–14] Though several studies[12,21] have reported the impregnation of steroid gel on the endotracheal tubes to relieve POTCs, however, they were reported to irritate the airway. Steroid-soaked throat packs are easily available, more cost-effective, easier to prepare and apply, easier to soak, and have better adaptability to the pharyngeal walls. Another advantage of a steroid-soaked throat pack is good retention of the solution compared to steroid-impregnated endotracheal tubes. Although several routes[17–23] of application of steroids in the relief of postoperative complications have been well documented, the optimum route of administration is still under debate, as it appears that no study has reported the role of throat packs soaked in steroid solution. This study aims to determine the efficacy of steroid-soaked throat packs on POTCs among patients undergoing oral and maxillofacial surgery.

## MATERIALS AND METHODS

### Study design

This is a parallel, two-arm, randomized, triple-blind, controlled clinical trial. The study protocol was prepared and implemented in accordance with the CONSORT statement (http://www.consort-statement.org/) [Figure 1] and was Ethical clearance was obtained from University of Benin Teaching Hospital Institutional Ethical Committee with reference no ADM/22/A/VOL.V11/14831289, dated 2021. Written informed consent was obtained from all drawn consecutive patients who had major oral and maxillofacial surgery under endotracheal intubation. Excluded from the study were those younger than 17 years, those with pre-existing throat infections or tumors, those on steroids or NSAIDs, and those who were medically compromised. Also excluded were those with a surgical duration longer than 240 minutes and difficult intubation.

### Sample size determination

In computing the required sample size for the study, we used the formula for comparison of proportions.[24] Based on the prevalence (i.e., 8% vs. 25.3%) in POTCs of previous studies,[12] 95% confidence interval (CI), a desired power of 80% (0.80), and a 10% non-response rate, a sample size of 24 per arm was derived and it was adjudged to have sufficient power to address the objectives of the study.

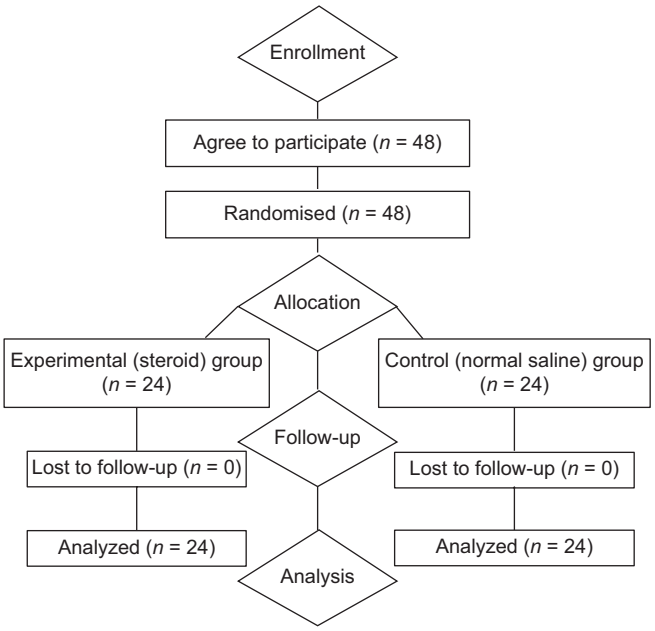


**Figure 1: The consort flow diagram of the study enrollment**

### Enrollment, randomization, and blinding

Forty-eight participants were enrolled in the study by the researcher. An independent observer randomized them using computer-aided block randomization into two groups of the same size: steroid (experimental; n = 24) and normal saline (control; n = 24). The patients and assessors were blinded in this study using Sequentially Numbered Opaque Sealed Envelope (SNOSE). The steroid group received 100 mg hydrocortisone constituted with 10 ml sterile water-impregnated gauze throat packs, while the normal saline group got 0.9% normal saline-impregnated gauze throat packs.

### The anesthetic procedure

This was performed by an experienced anesthesiologist who was blinded to the study protocol using a direct laryngoscopy. For the experimental (steroid) group, the throat packs were impregnated with 100 mg hydrocortisone (hydrocort, SmithKline Beecham, London, UK) dissolved in 10 ml of sterile water. For the control (normal saline) group, the throat packs were impregnated with 10 ml of 0.9% normal saline. The throat packs were placed in a standardized fashion.

### Surgical procedures

All consecutive major oral and maxillofacial procedures that met the selection criteria were performed under general

anesthesia with endotracheal intubation. The duration of the surgical procedure was measured and recorded. All patients had the same analgesic (pentazocine) and antibiotics (Augmentin). No patients received systemic corticosteroids or anti-edematous medications as a result of the study.

### Outcome assessment

This was performed by the researcher blinded to the intervention protocol 24 hours after surgery in the ward. The method used in the measurement of sore throat, dysphagia, cough, and hoarseness was adopted from a previous study.[25] It was asked with a direct questionnaire survey, "Do you have a sore throat, dysphagia, cough or/and hoarseness after surgery?." They were recorded as either "yes" or "no." A sore throat was defined as pain at the larynx or pharynx.[25] A cough was defined as a sudden, strong abdominal contraction.[25] Hoarseness was defined as a harsh or stained voice.[25] They were checked twice after the initial assessment after 24 hours post-surgery at six-hour intervals. Even a single cough was recorded as "yes." Patients with sore throats were placed on warm, saline mouth baths and analgesics by the attendant oral and maxillofacial surgeon.

### Data analysis

The variables measured were sociodemographic and surgical characteristics. The sociodemographic characteristics were age, gender, ethnicity, religion, and marital status. Other sociodemographic characteristics were the level of education, occupational status, and place of residence. The surgical characteristics were the type of oral and maxillofacial condition, types of surgery, duration of surgery, type of throat pack impregnations, and POTCs (sore throat, dysphagia, cough, and hoarseness). The continuous data were tested for normality with the Shapiro-Wilk test and summarized as ranges, means, and standard deviations, while the categorical data were summarized as frequency and percentages. The continuous variables were tested with an independent *t*-test, while the categorical variables was done with a Chi-square test or Fisher's test as appropriate. The results were presented in prose, tables, and charts. The 95% CI was used and statistical significance was set at the *P* value of ≤0.05. All data were analyzed using version 24 of Statistical Package for Social Science (IBM, Armonk, NY, USA).

## RESULT

A total of 48 patients that comprise 24 in each group were studied. Figure 1 shows the consort flow diagram of the study enrollment. The continuous data of the steroid ($P = 0.65$) and normal saline ($P = 0.78$) groups were normally distributed. The mean age and the age range of the participants were 37.3 ± 15.6 years and 18–65 years, respectively. There were 32 (66.7%) males and 16 (33.3%) females. Table 1 shows the sociodemographic characteristics of the study participants. There was no statistical difference between the two groups as regards the sociodemographic characteristics ($P > 0.05$). The clinical characteristics of the study participants are shown in Table 2. The clinical characteristics of the two groups did not differ statistically ($P > 0.05$). The prevalence of sore throat as well as dysphagia was significantly higher in the control group than in the experimental group [Table 3]. There was no statistical difference between the two groups as regards hoarseness and cough [Table 3].

## DISCUSSION

This two-arm, randomized controlled study assessed the efficacy of a steroid-soaked throat pack on POTCs among patients undergoing major oral and maxillofacial surgery.

**Table 1: Sociodemographic characteristics of the participants**

| Characteristic | Group I (*n*=24)[1] | Group II (*n*=24)[1] | *P*[2] |
|---|---|---|---|
| Age | 35.6 (13.8) | 39.0 (17.4) | 0.460 |
| Sex | | | |
| Male | 16 (66.7%) | 16 (66.7%) | 1.000 |
| Female | 8 (33.3%) | 8 (33.3%) | |
| Ethnicity | | | 0.389 |
| Ibo | 4 (16.7%) | 3 (12.5%) | |
| Hausa | 2 (8.3%) | 0 (0.0%) | |
| Yoruba | 0 (0.0%) | 0 (0.0%) | |
| Other | 18 (75.0%) | 21 (87.5%) | |
| Religion | | | 0.359 |
| Christianity | 21 (87.5%) | 23 (95.8%) | |
| Muslim | 2 (8.3%) | 0 (0.0%) | |
| Traditional | 1 (4.2%) | 0 (0.0%) | |
| Other | 0 (0.0%) | 1 (4.2%) | |
| Level of education | | | 0.690 |
| Primary | 3 (12.5%) | 2 (8.3%) | |
| Secondary | 12 (50.0%) | 14 (58.4%) | |
| Tertiary | 7 (29.2%) | 8 (33.3%) | |
| None | 2 (8.3%) | 0 (0.0%) | |
| Marital status* | | | 1.000 |
| Married | 13 (54.2%) | 14 (58.3%) | |
| Single | 10 (41.6%) | 9 (37.5%) | |
| Widow | 1 (4.2%) | 1 (4.2%) | |
| Occupational status | | | 0.818 |
| Employed | 16 (66.6%) | 17 (70.8%) | |
| Unemployed | 4 (16.7%) | 2 (8.4%) | |
| Dependent | 4 (16.7%) | 5 (20.8%) | |
| Place of residence | | | 1.000 |
| Urban | 21 (87.5%) | 21 (87.5%) | |
| Rural | 3 (12.5%) | 3 (12.5%) | |

[1]Mean (SD), *n* (%), [2]independent-samples *t*-test, Pearson's Chi-squared test, Fisher's exact test, *there were no widowers, divorced, or separated participants among the participants, group I=experimental (steroid) group, group II=control (normal saline) group, SD=standard deviation

**Table 2: Clinical characteristics of the participants**

| Characteristic | Group I (*n*=24) | Group II (*n*=24) | *P*[1] |
|---|---|---|---|
| Type of major surgery (*n* (%)) | | | |
| ORIF | 9 (37.5) | 8 (33.4) | |
| Parotidectomy | 6 (25.0) | 3 (12.5) | 0.925 |
| Submandibular gland excision | 1 (4.2) | 2 (8.3) | |
| Maxillectomy | 2 (8.3) | 3 (12.5) | |
| Mandibulectomy | 4 (16.7) | 6 (25.0) | |
| Soft tissue excisions | 2 (8.3) | 2 (8.3) | |
| Duration of surgery (minutes) | | | |
| Mean±SD | 171.6±67.4 | 180.2±91.1 | 1.016 |

[1]Pearson's Chi-squared test, group I=experimental (steroid) group, group II=control (normal saline) group, SD=standard deviation

**Table 3: Bivariate analysis of the study variables**

| Variables | Group I (*n*=24) | Group II (*n*=24) | *P*[1] |
|---|---|---|---|
| Sore throat (*n* (%)) | | | |
| Yes | 4 (16.7%) | 12 (50.0) | 0.014 |
| No | 20 (83.3) | 12 (50.0) | |
| Dysphagia (*n* (%)) | | | |
| Yes | 5 (20.8) | 13 (54.2) | 0.017 |
| No | 19 (79.2) | 11 (45.8) | |
| Hoarseness (*n* (%)) | | | |
| Yes | 6 (25.0) | 6 (25.0) | 1.000 |
| No | 18 (75.0) | 18 (75.0) | |
| Cough (*n* (%)) | | | |
| Yes | 5 (20.8) | 6 (25.0) | 0.731 |
| No | 19 (79.2) | 18 (75.0) | |

[1]Pearson's Chi-squared test, group I=experimental (steroid) group, group II=control (normal saline) group

It was hypothesized that a steroid-soaked throat pack would be superior to a normal saline-soaked throat pack in the reduction of the prevalence of postoperative sore throat, dysphagia, hoarseness, and cough in patients who had endotracheal intubation following oral and maxillofacial surgery. Normal saline-soaked throat packs are routinely used to prevent the inflow of fluids/secretions into the lower respiratory system and prevent pulmonary complications. While cuffed endotracheal intubation helps with ventilation during maxillofacial surgery complications such as postoperative sore throat, dysphagia, cough, and hoarseness are common complaints that may occur.[19] These outcomes are undesirable because they adversely affect the satisfaction and activities of the patients even after discharge from the hospital.[8]

The prevalence of postoperative sore throat was significantly higher in the control group than in the experimental group. This finding is comparable to that reported by Sumathi *et al*.[12] that lower pain scores among the steroid groups than the K-Y(Kentucky) gel groups. The overall prevalence of sore throat was 66.7%. Similarly, studies have shown that the prevalence rate of postoperative sore throat is as high as 30–100% in patients who are intubated.[17–23] However, there have been reports of reduced impact due to the use of anti-inflammatory agents such as steroids.[18] Postoperative sore throat is an inflammatory condition that can be caused by local irritation and traumatization of the airway during intubation.[12] Corticosteroids reduce the production of chemicals that cause inflammation[20] and also prevent the formation of the end products of potent inflammatory mediators. The steroid reduces the synthesis of inflammatory mediators by inhibiting cyclooxygenase-2 during inflammation. This could be the reason for the reduced prevalence in the experimental group. Therefore, the reduced prevalence of sore throat in the experiment group can be attributed to the impact of steroids.

The overall prevalence of dysphagia was 75.0%. This value is higher than the 25.9% reported by Sherif *et al*.,[19] who compared the effects of steroid gel and K-Y jelly-impregnated throat packs. This study also found a lower prevalence of dysphagia among the steroid group like the present study. However, the finding in the previous study[20] was not statistically significant, unlike the present study, which was statistically significant. Concerning the prevalence of postoperative dysphagia among study subjects, the control group was 2.6 times more likely to develop postoperative dysphagia relative to the experimental group. Similar to postoperative sore throats, difficulty swallowing after surgery can be attributed to structural, anatomical, or neuromuscular abnormalities[23] due to the irritation of the oropharyngeal mucosa and cuff-induced pressure of the mucosa causing an aseptic inflammation process. The reduced prevalence in the experimental group may be attributed to the fact that steroids produced anti-inflammatory effects hindering the metabolism of arachidonic acid, inhibiting the release of cytokines, and repressing the proliferation of fibroblasts.

In terms of hoarseness, the overall prevalence of hoarseness among the studied subjects was 50.0%, which differs from the 7.4% reported by Sherif *et al*.[19] Both the experimental and control groups were likely to develop hoarseness, as there was no association between the distribution of hoarseness and the type of throat pack used. The present study and that of Sherif *et al*.[19] did not find a statistically significant difference between the steroid and the control groups as regards the hoarseness of voice. Voice changes (whether in pitch or volume) due to the use of an endotracheal tube or laryngeal mask airways are not inflammatory. Therefore, the impact of the steroid-soaked throat pack was little to nothing. The relative risk of developing hoarseness was approximately one indicating that both groups were equally likely to develop hoarseness after maxillofacial surgery.

The overall incidence of cough was 45.8% and a lower incidence was also reported in previous studies.[12,20] This is an indication that cough is an infrequent symptom of endotracheal intubation. In this study, the control group had a slightly higher risk of developing a cough but this did not reach statistical significance. The distribution of cough was not related to the type of throat pack used. This is also probably due to the nature of cough being an involuntary respiratory response rather than an inflammation due to irritation of the throat. This study had a few limitations. The sample size could be relatively small, and it is also a single-center study, so its findings need precaution in generalization.

## CONCLUSION

The use of a steroid-soaked throat pack was found to be more efficacious in the reduction of the prevalence of postoperative sore throat and dysphagia but did not affect the prevalence of postoperative cough and hoarseness among patients who had major oral and maxillofacial surgical procedures.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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