

Impact Of Ketamine Versus Dexmedetomidine Soaked Pharyngeal Packing On Postoperative Sore Throat In Functional Endoscopic Sinus Surgery: A Randomized Controlled Trial

Running title: Impact of ketamine versus dexmedetomidine soaked pharyngeal packing on post-operative sore throat in functional Endoscopic Sinus Surgery

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Abstract

Background:

The postoperative sore throat (POST) and post-extubation cough (PEC) frequently follow the insertion of an endotracheal tube in general anesthesia, which makes postoperative morbidity higher. We aimed to assess the efficacy of the dexmedetomidine-soaked pharyngeal pack in alleviating POST versus Ketamine among patients with functional endoscopic sinus surgery (FESS).

Methods:

One hundred twenty patients were randomized into three groups, each containing 40 patients. Following anesthesia induction and intubation, the placement of pharyngeal packs in either saline (group C), Ketamine (group K), or dexmedetomidine (group D) in the posterior pharyngeal wall was done under clear vision. The primary outcome was the incidence of POST at six hours following surgery. The secondary outcomes were the incidence of POST at 0, 12, and 24 hours, at 0, 30, 60, 90, and 120 minutes, and the Postoperative Nausea and Vomiting (PONV) score at 1, 2, and 6 hours.

Results:

None of the patients of Group D experienced a POST at 6 hours post-operatively, and this was significantly lower when compared to the ketamine group (67.5%) and control group (87.5%) with a p-value (<0.001). At 6 hours post-operatively, group K experienced considerably fewer POST episodes than group C. Group D showed a lower cough incidence than other groups at 60 minutes. PONV was significantly higher in group K at 2 hours post-operatively.

Conclusions:

Pharyngeal-soaked dexmedetomidine effectively prevented postoperative airway complications, especially POST, in patients after the FESS procedure.

Keywords:

Cough; Dexmedetomidine; Endoscopic sinus surgery; Ketamine; Sore throat.

Introduction

Postoperative sore throat (POST) and post-extubation cough (PEC) are frequent, well-known sequelae following the insertion of an endotracheal tube in general anesthesia, raising postoperative discomfort. Studies demonstrate a wide range in the occurrence of postoperative airway problems, from 20%

to as high as 100% for POST and 30-50% for PEC. (1)

Several contributing factors include the size of the endotracheal tube, the cuff's construction, the procedure's length, etc. In functional endoscopic sinus surgery (FESS), packing the oropharynx and nostrils increases the risk of POST and postoperative mouth breathing.

Regardless of the source, the primary mechanism proposed includes airway irritation and inflammation. (2) With varying degrees of efficacy, a few pharmaceutical and non-medicinal interventions have been demonstrated to decrease the frequency of airway complaints, including magnesium sulfate, steroids, and lidocaine, which were evaluated with varying degrees of success rate. (2-4) Each of the analgesic and anti-inflammatory properties of Ketamine and dexmedetomidine contributes to reducing POST (5, 6).

We compared the ability of Ketamine versus dexmedetomidine to reduce the incidence of sore throats after post-sinus surgery. We hypothesized that soaking pharyngeal packs with these medications improves the quality of recovery, decreases the risk of postoperative sore throat, and increases patients' satisfaction more than placebo.

Patients And Methods

The Medical Ethics Committee of the Faculty of Medicine, Assiut University, Assiut, Egypt, approved this study, IRB: 17101486, with clinical trials registration ID: NCT 04955158. The study started in February 2021 and ended in February 2023. Participants signed an informed consent. The study included patients with the following criteria: age 18–65 years, males and females, ASA physical status I-III scheduled for elective FESS in Ear, Nose, and Throat operative theatre in the Main Assiut University Hospital. Patients who had previously experienced a sore throat before surgery, an upper respiratory infection, a potentially difficult airway, a history of digestive, respiratory, or neck pathology, were regular smokers, had used steroids within the previous 48 hours, or were pregnant, were all excluded from the study.

One hundred twenty patients were included in the study, and according to a random number of sequences, patients were allocated into one of three groups (40 patients each). Group assignments were kept in a well-sealed opaque envelope, which was opened after patient recruitment by the nurse

who prepared the pharyngeal packs as follows: 20x 10 cm² sterile gauze was used for packing, and 20 ml of 0.9 % saline was added to dilute the test drugs ketamine (50 mg) group K or dexmedetomidine (75 µg) Group D. In the controlled group C, the pack was only impregnated in 20 ml of 0.9% saline.

In the operating theater, the patient's monitoring was done according to the anesthesia protocol standardized by the American Society of Anesthesiologists (ASA). Lidocaine (0.5 mg kg⁻¹), propofol (3mg kg⁻¹), fentanyl (1µ kg⁻¹), and rocuronium (0.8 mg kg⁻¹) were used for general anesthesia induction. Female patients were intubated with a 6.5 mm endotracheal tube, while a 7 mm tube was used for males, and the cuff was lubricated with lidocaine jelly 2%. Initial endotracheal cuff pressures were recorded, then intra-cuff pressures were maintained at 20–22 cmH₂O throughout the anesthetic using a manometer. Following anesthesia and tracheal tube insertion, direct visualization of the patient's throat by the surgeon (who was blind to the research groups) for placement of a pack saturated with either saline, Ketamine, or dexmedetomidine was done. For maintenance of anesthesia, sevoflurane was used in a mixture of oxygen and air. During surgery, intravenous fluid was maintained at an infusion rate of 3 mL/kg/h.

Before extubation, patients were given 1gm paracetamol for postoperative analgesia. Essentially, all anesthetists participating in the study should have at least five years of experience in intubation to diminish operator bias. Documentation of the operative time. Recording of oropharyngeal bleeding when visualized during emergence. Post-operatively, suctioning of the oropharynx under vision, removal of pharyngeal pack, ensuring that the patient is fully conscious, hemodynamically stable, and fulfilling other routine extubation criteria, and removing the tracheal tube was done. Then, the patients were transferred to the Post-Anesthesia Care Unit (PACU). The anesthetist who recorded the intraoperative and postoperative data was blinded to the patient group.

The primary outcome of this study was to determine the incidence of POST at six hours following surgery. The secondary outcomes were the incidence of POST at 0, 12, and 24 hours, cough score at 0, 30, 60, 90, and 120 minutes, Postoperative Nausea and Vomiting (PONV) score at 1, 2, and 6 hours, postoperative Visual Analogue Scale (VAS) pain score at 0, 1, 2, 4, 6, 12, 24 hours and postoperative fentanyl consumption.

Assessment using a standardized scale for sore throat (time 0 hours) was done. POST seriousness was classified as 0 when there was no sore throat, 1 for mild sore throat, 2 when discomfort was moderate, and 3 for severe sore throat associated with hoarseness. (5) Severity assessment was done at 0, 6, 12, and 24 hours.

The cough was evaluated as follows: absence of cough since the surgery was regarded as 0, mild cough or throat scratching was regarded as 1, intermediate cough was considered 2, and intense cough was considered 3. The assessment was done at 0-time PACU, 30, 60, 90, and 120 minutes after surgery. (7)

PONV was evaluated and recorded by the PACU nurses, with a verbal descriptive score that correlated with a visual analogue nausea scale allowing objective evaluation of severity where 0 was given for absent nausea and vomiting after surgery, 1 represented slight postoperative nausea without vomiting or need for antiemetics, 2 represented moderate nausea after surgery requiring antiemetic therapy, and 3 for post-surgical nausea and vomiting (8). The record was taken at 1 hour, 2 hours, and 6 hours after PACU arrival; 4 mg IV ondansetron for nausea and vomiting. Postoperative pain was assessed at 0, 1, 2, 4, 6, 12, and 24 hours using a 0-10 cm VAS, where 0 meant the absence of any pain, and 10 represented the most severe pain ever experienced by the patient (9). Fentanyl was used to alleviate pain of a severity ≥ 4 on VAS through a bolus of 0.5 $\mu\text{g}/\text{kg}$. To assess patients discharged from the hospital before 24 hours, the investigator contacted them at home.

Statistical Analyses:

Calculation of Sample Size:

According to the study of Rudra A et al. (5), where the incidence of POST following intubation during the 24 hours following the operation was 50 %, 35 patients were required in each of the three study groups to find out 25% variation in the incidence at 5% significance level and 90 % power of the study. Forty patients were enrolled in each group to compensate for dropouts during the research.

Data Analysis:

Data analysis was done using SPSS, version 22. The normality of data was tested using the χ^2 test. Quantitative variables were represented as mean \pm standard deviation, and qualitative variables were represented as frequencies (n) and percentages (%). As for continuous parametric variables, the ANOVA test was used to compare different groups. For univariate analysis of qualitative data, the χ^2 test was applied. Statistical significance was considered when p-values were less than 0.05.

Results

In our clinical trial, 143 patients were evaluated to see if they were eligible to participate, and 23 patients were excluded (18 were unsuitable, and 5 were unwilling to participate). Only 120 patients were included and randomly allocated into three groups (40 patients each). All 120 participants completed the study (**figure 1**). The patient's clinical and demographic characteristics did not significantly differ within the three groups (**Table 1**).

The incidence of the POST dexmedetomidine group was the least at the four postoperative times of the study. At 6,12, and 24 hours post-operatively, no patient in the dexmedetomidine group suffered from POST, while at the immediate postoperative time, 11 patients suffered from POST. On the other hand, the incidence of POST at the immediate postoperative time was 36 patients in each of the control and ketamine groups. At 6 hours postoperative, 35 patients in the control group and 27 patients in the ketamine

group suffered from POST. The incidence of POST decreased after 12 hours in the above groups to 28 patients in the control group and 18 patients in the ketamine group and dropped again after 24 hours into 17 patients in the control group and 11 patients in the ketamine group (**Table 2**).

A post-hoc test showed that the cough score was significantly higher in the ketamine group in the immediate postoperative time and after 30 minutes. After 60 minutes, the post-hoc test showed a significantly low cough score in the dexmedetomidine group (**Table 3**).

PONV was significantly higher in the ketamine group at 2 hours postoperative, while after 1 hour postoperative, there was no significant difference between the three groups (**Figure 2**).

VAS for pain measurements was constantly higher in the first 12 hours in the control group compared to the ketamine and dexmedetomidine groups. After 24 hours, no difference was found between all groups. The total amount of fentanyl consumed in the 1st 24 hours of postoperative analgesia ($175.4 \pm 30.7 \mu\text{g}$) was significantly higher among the control group (P-value < 0.001) (**Table 4**).

Legend of Tables

Table 1: Patient demographic and clinical data among the three groups

	Group C (n = 40)	Group K (n = 40)	Group D (n = 40)	P- value
Age (years)	33.2 ± 9.7	35.3 ± 11.06	33.7 ± 9.85	0.653
Gender (male/female)	23/17	23/17	18/22	0.433
Body Mass Index	26.80 ± 3.45	25.64 ± 2.32	26.19 ± 2.85	0.212
ASA physical status (I/II)	37/3	33/7	38/2	0.143
Duration of anesthesia (hours)	2.4 ± 0.61	2.6 ± 0.77	2.4 ± 0.58	0.362
Duration of surgery (hours)	2.3 ± 1.41	2.2 ± 0.74	2 ± 0.47	0.254

Data are presented as mean ±SD and number.

ASA: American Society of Anesthesiologists.

Table 2: POST measurements among the three groups

Table 2: Incidence of postoperative sore throat in the three groups

	Group C (n = 40)	Group K (n = 40)	Group D (n = 40)	P value
Immediate postoperative	36 (90%)	36 (90%)	11 (27.5%) [#]	<0.001*
After 6 hours	35 (87.5%)	27 (67.5%)	0 [#]	<0.001*
After 12 hours	28 (70%)	18 (45%)	0 [#]	<0.001*
After 24 hours	17 (42.5%)	11 (27.5%)	0 [#]	<0.001*

Data are presented as frequency (percentage),

* significant at p-value <0.05 using Chi-square test,

[#] This group is statistically significant from other groups using Bonferroni correction post-hoc test

Table 3: Cough score among the three groups

	Group C (n = 40)	Group K (n = 40)	Group D (n = 40)	P-value
Immediate postoperative	0 (0-2)	0 (0-2) [#]	0 (0-1)	0.002*
After 30 minutes	0 (0-2)	0 (0-2) [#]	0 (0-1)	0.002*
After 60 minutes	0 (0-2)	0 (0-1)	0 (0-1) [#]	0.010*
After 90 minutes	0 (0-2)	0 (0-1)	0 (0-0)	0.083
After 120 minutes	0 (0-1)	0 (0-1)	0 (0-0)	0.119

Data are presented as median (range),

*: significant at p-value <0.05 using Kruskal-Wallis test

[#] This group is statistically significant from other groups using the Bonferroni correction post-hoc test

Table 4: VAS measurements among the three groups

Table 4: VAS measurements and total fentanyl consumption among the three groups

	Group C (n = 40)	Group K (n = 40)	Group D (n = 40)	P-value
Immediate postoperative	6.5 (5-8) [#]	4 (4-6)	4 (3-6)	<0.001*
After 1 hour	6.5 (5-8) [#]	4 (3-5)	4 (3-5)	<0.001*
After 2 hours	6 (4-8) [#]	3 (2-5)	3 (2-4)	<0.001*
After 4 hours	5 (4-7) [#]	2 (0-3)	2 (1-3)	<0.001*
After 6 hours	4 (3-5) [#]	1 (0-3)	1 (0-2)	<0.001*
After 12 hours	2 (1-3) [#]	0 (0-2)	0 (0-2)	<0.001*
After 24 hours	0 (0-1)	0 (0-2)	0 (0-1)	0.165
Total fentanyl consumption (µg)	175.4 ± 30.7 [#]	70 ± 22.6	61.5 ± 27.3	<0.001*

Data are presented as median (IQR), VAS: Visual analog scale,

* significant as p-value <0.05 using Kruskal-Wallis test

[#] This group is statistically significant from other groups using Bonferroni correction post-hoc test

Legend of Figures

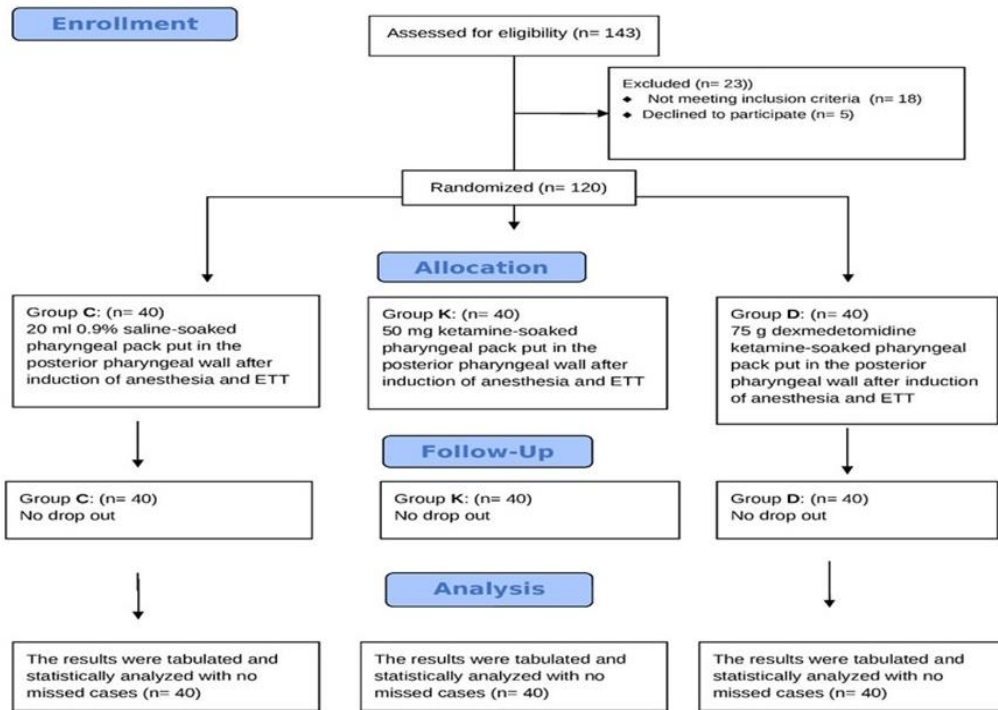


Figure 1: Consort Flow Chart

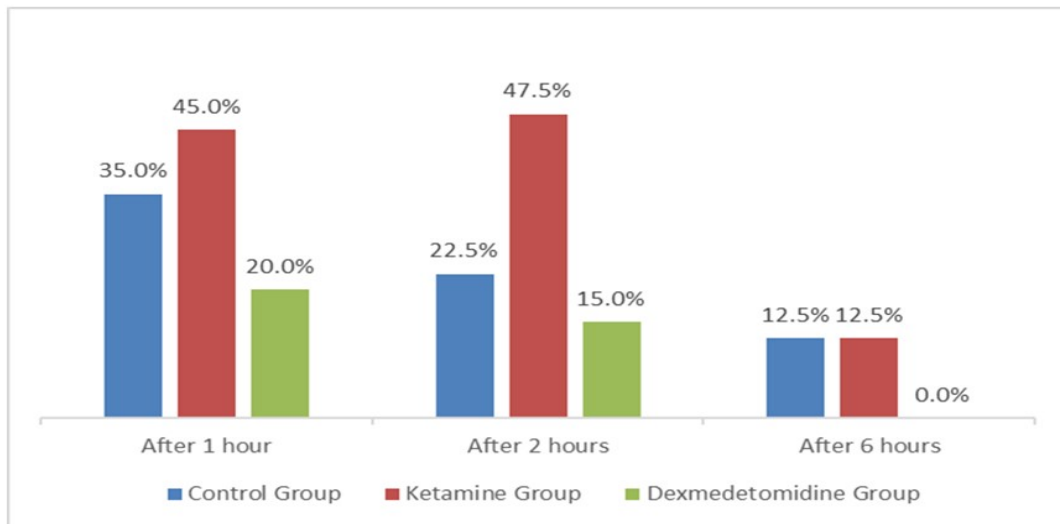


Figure 2: PONV measurements among the three groups

Data are presented as percentage of patients

Chi square test is significant between groups only after 2 hours.

Ketamine group is the source of significant after 2 hours using Bonferroni post-hoc test

Discussion

An endotracheal tube may cause discomfort and pain. Tube cuff irritation causes airway secretions to increase, cough to get worse, and causes additional pain. Sore throat after endotracheal intubation is the second most common side effect of anesthesia, after nausea and vomiting (6). POST may result in lower patient satisfaction while necessitating more adjunct pain management in the recovery unit after anesthesia. (10)

In this study, we found that none of the patients of the dexmedetomidine group developed POST (0%) compared to the ketamine and control group at 6h post-operatively (67.5%, 87.5%, respectively). Cough was significantly higher in the ketamine group at immediate and 30 minutes postoperative. In contrast, it was significantly lower in the dexmedetomidine group at 60 minutes postoperative. PONV was significantly higher in the ketamine group compared to other groups up to one hour postoperative. Total opioid consumption was significantly higher in the control group ($175.4 \pm 30.7 \mu\text{g}$) (P-value < 0.001). One of the most unfavorable intubation-related consequences, POST, with an estimated prevalence of 14.5% to 65%, is produced by temporary tracheal or throat mucosa irritability (11). Since its inception in the United States in 1985, FESS has become the most widely used surgical procedure for treating chronic rhinosinusitis (12). Ketamine, an N-methyl-D-aspartate (NMDA) receptor antagonist, was utilized in a nebulized form to reduce (POST) because of its analgesic and anti-inflammatory properties (13). Dexmedetomidine is a selective α -adrenergic receptor agonist (with about eight times more affinity than clonidine) with minimal depressive effects but has a dose-dependent sedative impact on respiration. Additionally, it reduces inflammation and blocks pain signals (14).

In agreement with our findings, Choi EK *et al.* (15) studied the effect of intravenous infusion of dexmedetomidine or remifentanyl in 98 patients undergoing spine surgeries.

The Dexmedetomidine group showed a significant decrease in POST than the remifentanyl group. In the first hour following the surgery, nausea was significantly lower with dexmedetomidine. Also, Kim *et al.* (16) observed similar effects in thyroidectomy patients, and Niu *et al.* (17) assessed the impact of intratracheal dexmedetomidine either alone or with ropivacaine before anesthesia on POST in patients scheduled for spine surgery. Using a mixture of dexmedetomidine and ropivacaine significantly reduced POST and intraoperative anesthetics consumption.

Our results revealed a lower incidence of POST in the ketamine group compared to the saline group. In concordance with our results, Ahuja V *et al.* (18) recruited 50 patients undergoing elective surgery under general anesthesia into two groups. Each group was nebulized either with Ketamine or saline before anesthesia. Ketamine significantly diminished the frequency and intensity of early POST. Similarly, Goti and Sojitra (19) reported that the incidence of POST was considerably lower with nebulized Ketamine than with nebulized saline 2,4 hours post-operatively.

On the other hand, Thomas *et al.* (20) studied 100 patients for elective thyroid surgery. Patients were randomly assigned into two groups. Each group was given either Ketamine 50mg or dexmedetomidine 50 μg mixed 4mL of saline and nebulized for 15 minutes. They reported that there were no appreciable differences in POST in both groups, and both drugs effectively decreased POST. Also, Dehkordy *et al.* (6) studied the effect of Ketamine or dexmedetomidine diluted with 100 ml water gargled preoperatively in emergency abdominal surgeries. Both were efficient in reducing POST. The dexmedetomidine group experienced a more significant effect on hemodynamic and oxygen saturation than the ketamine group.

Tekeli *et al.* compared intravenous infusion of Ketamine or dexmedetomidine combined with propofol in patients undergoing upper gastrointestinal endoscopy

(21). ketamine significantly increased the rate of coughing. Chen et al. (22) studied the effect of intraoperative infusions of three different drugs, Ketamine, dexmedetomidine, and placebo, in patients who underwent elective strabismus surgery. The dexmedetomidine group experienced a significantly decreased incidence of postoperative vomiting (POV) compared to the placebo and ketamine groups.

Similar to our results, Xu et al. (23) found that dexmedetomidine significantly reduced postoperative pain scores in FESS patients markedly more than the control group. Also, Sonawane et al. (19) noted that the median VAS score during the 48 hours significantly decreased in the dexmedetomidine group than in the ketamine group. Kaur et al. (24) studied patients assigned to FESS. Drip infusion of intra-operative dexmedetomidine significantly reduced anesthetic and analgesic consumption compared to saline. Additionally, it was observed that throat packs devoid of medication did not appear to benefit from reducing postoperative nausea

and vomiting (PONV) or soreness during procedures involving the upper airway or head and neck (25-27).

Our study limitations: First, no plasma dexmedetomidine or ketamine levels were measured. As a result, we cannot wholly exclude the role of the systemic effect. Second, we did not examine the impact of inflammatory factors on the therapeutic advantages of dexmedetomidine and Ketamine in lowering POST, which calls for additional research. Finally, rather than administering medication per kilogram to each patient, we employed a set dose across the board.

We recommend using a dexmedetomidine-soaked pharyngeal pack to prevent POST in FESS and other surgeries requiring the placement of an oropharyngeal pack or an endotracheal tube insertion.

We concluded that soaked pharyngeal packing with dexmedetomidine reduced POST in patients undergoing FESS procedures.

Conflict of interest:

There is nothing to declare.

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