Evaluating the Effectiveness of Intracuff Dexmedetomidine versus alkalinized lidocaine in Preventing Postoperative Sore Throat Following Prolonged Prone Surgery.

IRB: HP-01-R079

Date: 15/04/2025

Introduction:

Tracheal intubation is performed under general anesthesia to secure the airway and is often associated with varying degrees of trauma. One of the most common consequences of intubation is postoperative sore throat (POST), which affects approximately 30% to 65% of patients. Additionally, hoarseness of voice occurs in about 16% to 55% of cases (1,2). POST is considered one of the most undesirable outcomes of the postoperative period, as it significantly negatively impacts the overall surgical experience and the hospital stay. It can adversely affect patient satisfaction and daily activities even after discharge from the hospital (2).

POST is caused by various factors, including vocal cord damage, nerve compression, congestive blood loss, and injury to the epithelium and mucosal cells resulting from airway secretions and prolonged anesthesia (3).

Recently, studies have indicated that several factors contribute to POST, including the shape of tracheal tubes, cuff size, cuff pressure, duration of tube placement, number of suctioning attempts, the time and manipulations required for tube insertion, and the use of inhalation anesthesia (3).

The position change from supine to prone can make a change in endotracheal tube (ETT) cuff pressure and endotracheal tube displacement. The change in cuff pressure and tube displacement can affect the incidence of POST, hoarseness, and cough (4,5). The improper placement of a patient in prone position caused the neck muscles to cramp, put pressure on the vocal cords causing hoarseness (6).

To decrease the incidence of POST, various interventions can be implemented. Among non-pharmacological approaches, choosing the appropriate tracheal tube size is critical for minimizing POST and ensuring effective airway management during intubation. The

recommended sizes are 6.0 to 7.5 mm for females and 7.0 to 8.0 mm for males. Excessive cuff pressure can cause mucosal trauma and pressure-related injuries, thereby raising the likelihood of developing POST. To reduce these effects, a prospective randomized controlled trial found that maintaining cuff pressure at 20-25 mmHg was linked to a lower incidence of POST. Additional strategies included using video laryngoscopy during intubation, topically applying non-steroidal anti-inflammatory drugs (NSAIDs), administering steroids during surgery, and utilizing various gargles (such as magnesium and ketamine) during the procedure (7,8).

Use of various pharmacological agents have been advocated in the literature to reduce the incidence of POST, hoarseness and dysphagia such as the topical administration of nonsteroidal anti-inflammatory drugs, lidocaine, steroids and ketamine in various modalities like inhalation, nebulization, gargling and Intravenous routes through various mechanisms of action, according to systematic reviews (9).

Intracuff use of saline and lignocaine is recently being reviewed for the effectiveness in preventing coughing, POST, and postoperative hoarseness (10). Increasing the alkalinity of the local anaesthetic using sodium bicarbonate ($NaHCO_3$) increases the pH of the solution and can predictably increase the percentage of the non-ionized fraction of the drug, thus dramatically increasing its diffusion through the ETT cuff (11).

Dexmedetomidine, a selective alpha-2 receptor agonist, is administered for short-term sedation with a specificity and an affinity are up to eight times higher than clonidine (12). Recent reports revealed that a single dose of gargled Dexmedetomidine (0.5 μg/kg) has the same effect as the intravenous administration, on reducing cough rate and postoperative pain score with no complications or significant side effects (13). Intratracheal dexmedetomidine given 15 minutes prior to end of surgery was more effective at reducing cough reflex, facilitating a smooth

extubation, and encouraging a balanced anesthetic recovery more than intratracheal lidocaine (14).

Aim of the work:

The purpose of the present study will be to evaluate the effectiveness of intracuff dexmedetomidine versus alkalinized lidocaine in preventing postoperative sore throat following prolonged prone surgery.

Patients and methods:

One hundred patients aged between 18 to 75 years, American Society of Anesthesiologists (ASA) physical status I and II patients of either sex, undergoing lumbar spine surgery in prone position under general anesthesia with endotracheal intubation will be prospectively investigated. Patients with a history of recent respiratory tract infection, prior medication with analgesics or corticosteroids will be excluded. Other Exclusion criteria will include patients who have preoperative sore throat, hoarseness and cough, have a nasogastric tube, patients with Mallampati class > 2 and who required more than one attempt for tracheal intubation or patients had a duration of tracheal intubation of < 60 min or > 300 min and patients not willing to provide their voluntary written informed consent.

Using a computer-generated random number table, the patients will be randomly allocated into **Group A**, ETT cuff will be filled with dexmedetomidine (n = 50) or **Group B**, ETT cuff will be filled with alkalinized lidocaine (n = 50). An anesthetic nurse, who will not be taking part in postoperative patient interview and assessment, will prepare the study solution and ETT.

In group A, ETT cuff will be filled with 4 ml of dexmedetomidine 4 mcg/ml. While in group B, lidocaine 2%, 2 ml will be initially injected into the cuff, and then a supplementary volume of 2 ml of sodium bicarbonate ($NaHCO_3$) 8.4% will be added to obtain the minimal occlusive

volume. Patients will be premeditated with IV glycopyrrolate 0.2 mg and IV midazolam 0.03 mg/kg. Non-invasive blood pressure, electrocardiography, pulse oximetry, and patient state index (PSI) using a sedation monitor (SedLine, Masimo Corp, Irvine, CA 92618) will be applied when the patients arrived in the operating room. Anesthesia will be induced with fentanyl 2 μg /kg, propofol 2 mg/kg and cisatracurium 0.2 mg/kg. We will ventilate all patients with 100% oxygen via a facial mask. We will perform tracheal intubation after confirming adequate muscle relaxation (the absence of movement and jaw relaxation). Endotracheal intubation will be performed with tubes having an internal diameter of 8.0 Or 7.5 mm for male patients, and 7.5 or 7.0 mm for female patients.

One experienced anesthesiologist, blinded of experimental protocol, will perform endotracheal intubation and anaesthesia in all patients during the study. Another anesthesiologist, who was not blinded to study protocol, though excluded from the data collection, carefully will inflate cuffs in all patients. The cuff pressure will be inflated at the minimal occlusive volume i.e., no air leak around the tube cuff when positive pressure was administered at 20 cm. of water.

Patient's position will be changed from supine to prone for surgery, and patient's head will be positioned on the sponge face pillow without head rotation. After position change from supine to prone, we will re-adjust the cuff pressure. Anesthesia will be maintained with 1.5−2.5 vol% sevoflurane and 50% in air. The end-tidal CO2 will be kept between 35 and 40 mmHg. The depth of anesthesia will be monitored and kept between 25 to 50 (PSI Index). unit. Oral airway devices will not be used intraoperatively. Once the surgery is completed and the patient is fully awake (with TOF greater than 0.7 and PSI greater than 80), they will be extubated followed by gentle oropharyngeal suction.

The primary outcome will be the incidence and severity of POST, hoarseness, cough will be assessed for 1st, 6th, 12th and 24th hour after extubation. The assessment will be done by the on-call anesthesiology resident who was blinded of the study group. The severity of POST, hoarseness, and cough will be graded using a 4-point scale (0: no, 1: minimal, 2: moderate, 3: severe) (Table 1) (15). Any patient will develop post-operative sore throat will be given dexamethasone 8 mg IV stat and advised warm normal saline gargles.

Postoperative visual analog scale scores (0 = no pain to 10 = the most severe pain). Fentanyl will be used to alleviate pain of a severity ≥5 on VAS through a bolus of 0.5 μg/kg. Episodes of nausea will be also assessed at each time point. Cricoid compression, duration of tracheal intubation, duration of prone position, duration of anesthetic time, and incidence of cough during extubation will be recorded.

The secondary objective will focus on monitoring hemodynamic parameters such as blood pressure, heart rate, and oxygen saturation. Measurements will be taken at multiple time points, including 5 minutes before anesthesia, baseline reading before tracheal intubation, 5 minutes post-intubation, every 15 minutes during surgery, and at 2, 12, and 24 hours following the procedure.

Table 1. Scoring System for Assessment of Sore Throat, Hoarseness and Cough

Severity score	Description
Sore throat	
0	No sore throat at any time since the operation
1	Minimal sore throat
2	Moderate sore throat
3	Severe sore throat
Hoarseness	
0	No complaint of hoarseness
1	Minimal change in quality of speech. (minimal hoarseness)
2	Moderate change in quality of speech. (moderate hoarseness)
3	Gross change in the quality of speech. (severe hoarseness)
Cough	
0	No cough at any time since the operation
1	Minimal cough
2	Moderate cough
3	Severe cough

Results and statistics

The sample size was estimated from preliminary data obtained from 40 patients, And the assumption that a 20% reduction in the incidence of POST Would be clinically relevant.

The Power analysis suggested that a minimum of 44 patients in each group would be needed for a $\beta = 0.2$, $\alpha = 0.05$, (adjusted Bonferroni's p-value). To Compensate for potential dropouts (drop Rate = 10%), 50 patients will be enrolled in each group.

Data were analyzed using SPSS version 16.0 (SPSS Inc, USA) and will be presented as mean and standard deviation (SD) or frequencies (%). A parametric test (independent sample t-test) will be used for determining any difference between the means of two groups for a particular

variable. Repeated measures analysis of variance (ANOVA) will be used to determine any difference in the basic monitoring profile and amount of drug required at different time intervals of individuals in both groups. A p-value <0.05 will be considered as statistically significant, and a p-value <0.001 as highly significant.

Discussion

The data obtained will be compared with similar study.

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