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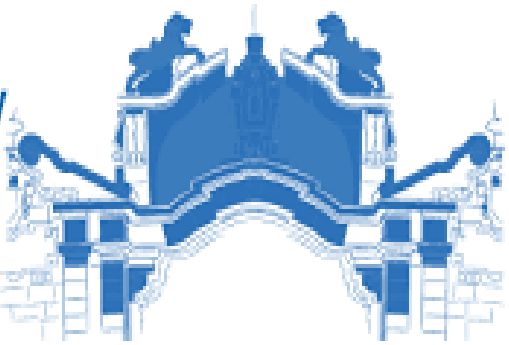

SEEK WISDOM, ELEVATE YOUR INTELLECT AND SERVE HUMANITY !

ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCE

SCHOOL OF MEDICINE

DEPARTMENT OF ANESTHESIA

EFFECTS OF INTRAVENOUS LIDOCAINE AND DEXAMETHASONE ON THE INCIDENCE AND SEVERITY OF POSTOPERATIVE SORE THROAT IN ADULT SURGICAL PATIENTS AT TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA, 2023; A PROSPECTIVE COHORT STUDY

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A THESIS SUBMITTED TO ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCE DEPARTMENT OF ANESTHESIA IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN ADVANCED CLINICAL ANESTHESIA.

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ADDIS ABABA, ETHIOPIA

Addis Ababa University

College of Health Science

School of Medicine

Department of Anesthesia

A thesis submitted to Addis Ababa University College of Health Science Department of Anesthesia in partial fulfillment of the requirements for the degree of master of science in advanced clinical anesthesia.

Name of investigator	Samuel Belay Ayalew
Name of advisors	Tinbite Daniel and Hirbo Samuel
Full title of the research project	Effects of intravenous lidocaine and dexamethasone on the incidence and severity of postoperative sore throat in adult surgical patients at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia, 2023; a prospective cohort study
Duration of project	January 1 to March 30, 2023 G.C.
Study area	Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia
Total cost of the project	24,825 birr
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June, 2023

Addis Ababa, Ethiopia

Declaration

I, the undersigned, declare that this thesis is my original work in partial fulfillment of the requirements for the MSc in Anaesthesia. I understand that plagiarism will not be tolerated, and all directly quoted materials have been appropriately referenced.

Name: Samuel Belay

Signature _____

Submission to: MSc tutor, Department of Anesthesia, Addis Ababa University

Date of submission _____

This thesis work has been submitted for examination with our approval as advisors and tutors on the MSc in Advanced Clinical Anesthesia course.

Approval of the advisors:

	Name	Signature	Date
1.	_____	_____	_____
2.	_____	_____	_____

Approval

This is to certify that the thesis prepared by Samuel Belay, entitled: Effects of intravenous lidocaine and dexamethasone on the incidence and severity of postoperative sore throat in adult surgical patients at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia, 2023, in partial fulfillment of the requirements for the degree of Master's of Science in Advanced Clinical Anesthesia, complies with the regulations of the university and meets the accepted standards with respect to originality and quality.

Signed by the Examining Committee:

External examiner Name	Signature	Date
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Finally, I would like to say thanks to my friends for their guidance in this research.

Abstruct

Background: Sore throat is the common postoperative complaint and uncomfortable side effect in patients receiving general anesthesia with endotracheal intubation. Drugs with analgesic and anti-inflammatory properties, like steroids and local anesthetics, are the best options for postoperative sore throat prophylaxis.

Objective: The objective of this study was to compare the effects of intravenous lidocaine and dexamethasone on the incidence and severity of postoperative sore throat following endotracheal extubation in adult surgical patients at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia, from January 1 to March 30, 2023 G.C.

Methods: A prospective cohort study was carried out at TASH. Data from 50 patients in the lidocaine, 50 in the dexamethasone, and 49 in the control groups were analyzed. The data were collected using observation based on structured questionnaires. A systematic random sampling technique was applied to select respondents. The data were entered into EpiData version 4.6.0.6 and transferred to STATA version 17 statistical software for analysis. A Comparison of continuous data among the groups were performed using a one-way ANOVA test for parametric data. The Kruskal-Wallis rank test was used for non-parametric data. Associations between variables were tested using chi-squared test, Fisher's exact test, and binary logistic regression. Bivariable and multivariable logistic regression was used to determine degree of association.

Result: The incidence of POST was 40%, 32%, and 57.1% in the lidocaine, dexamethasone, and control groups, respectively (P = .0356). Dexamethasone reduced the incidence of POST (AOR: 0.374, 95% CI: 0.149–0.939). However, no difference was observed in the severity of POST at 3 hours (p =0.130), 6 hours (p= 0.096), 12 hours (p =0.313), and 24 hours (p =.0.525) of the post-extubation period among the three groups. IV lidocaine did not effectively reduce the incidence and severity of POST at different time intervals.

Conclusion and recommendation: Intravenous dexamethasone is more effective than intravenous lidocaine in reducing the incidence of POST among the groups. Based on these findings, intravenous dexamethasone is recommended to decrease the incidence of POST.

Key words: postoperative sore throat, endotracheal extubation, dexamethasone, lidocaine

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Acronyms and Abbreviations

AAU	Addis Ababa University
ANOVA	Analysis of Variance
AOR	Adjusted Odds Ratio
ASA	American Society of Anesthesiologists
BMI	Body Mass Index
BSc	Bachelor of science
COR	Crude Odds Ratio
ETI	Endotracheal Intubation
ETT	Endotracheal Tube
GA	General Anesthesia
IV	Intravenous
MSc	Master of Science
PACU	Post Anesthesia Care Unit
PI	Principal Investigator
POST	Postoperative Sore Throat
RR	Risk Ratio
SD	Standard Deviation
SMD	Standardized Mean Difference
STATA	Statistics and Data
TASH	Tikur Anbessa Specialized Hospital

URTI	Upper Respiratory Tract Infection

Chapter One: Introduction

1.1 Background information

Postoperative sore throat (POST) is the nociceptive pain caused by an injury to the throat and tracheal mucosa after general anesthesia (GA) with endotracheal intubation (ETI) (1). It results in discomfort and pain following extubation and surgery, hoarseness of voice, coughing, and sleep disterbances, makes them have more trouble swallowing and speaking as well as it extends hospital stay, which may cause patients to postpone returning to their regular routine activities (1–3). It ranks as the sixth most unfavorable postoperative incident (4).

The incidence of POST and hoarseness is as high as 30% to 70% (4,5). The high variability of POST incidence is caused by a vast variety of parameters involved in POST, including the kind of airway device, size of endotracheal tube (ETT), insertion technique and number of attempts, use or type of lubricant, ETT cuff pressure, duration of ETI, type of anesthetic drug provided, and patient factors (1,6–13). The likelihood of developing a POST within 24 hours of surgery in Ethiopia's general and referral hospitals was 48.8% and 45.6%, respectively (6,14).

POST is seen as a more typical adverse event after GA with ETT than when either a supraglottic airway device or a facemask is used (9). The mechanistic basis for POST is believed to be mucosal dehydration, trauma during intubation, and airway irritation and inflammation brought on by pressure from the endotracheal tube cuff on the tracheal wall. The precise anatomical site of a sore throat is still unknown (4,9,14).

Numerous non-pharmacological or pharmaceutical techniques such as using the right size and type of ETT, tracheal tube lubrication, checking cuff pressure during surgery, benzydamine hydrochloride gargles, aspirin, lignocaine spray or injection, dexamethasone, magnesium sulfate, ketamine gargling, and stellate ganglion blocking have been introduced to reduce the frequency and severity of POST (2,15–18).

The prophylactic use of steroids during recovery was observed to lower the frequency of throat pain and cough, likely through modulating the inflammatory response brought on by tissue injury. This anti-inflammatory response includes preventing leukocyte migration to the site of inflammation, preventing cytokine release likely by maintaining cellular integrity, and inhibiting fibroblast proliferation (19–21).

Due to its analgesic and anti-inflammatory effects, lidocaine, an aminoamide local anesthetic, has also been frequently used to suppress airway reflexes, minimize bronchial hyper-reactivity, and attenuate hemodynamic responses following intubation (2,5). There is uncertainty regarding the precise mechanism by which lidocaine reduces postoperative airway discomfort. The fact that IV lidocaine inhibits the stimulation of airway sensory C fibers and the production of sensory neuropeptides may be the one proposed mechanism (2,18,22,23). This would lessen throat inflammation and irritation, which would improve patient satisfaction and hasten the recovery process in the post-anesthesia recovery area (24).

Prophylactic use of IV dexamethasone and lidocaine is more efficacious than a placebo to decrease the frequency and intensity POST following surgery (4,5,18,25). However, there is a discrepancy in the the effects of IV lidocaine and dexamethasone to decrease the incidence of POST after ETI (17,26).

1.2 statement of the problem

Postoperative sore throat is a typical, painful, unpleasant, and upsetting complication that follows GA with ETI and that results in patient morbidity and dissatisfaction in the postoperative period (4,5). A POST could affect 0.51 million to 1.2 million patients per year who undergo surgery under GA with ETT (5). A recent systematic review and meta-analysis in Ethiopia showed the pooled incidence of POST was 40.48%, which is very high (27).

A POST following endotracheal extubation may develop for a variety of reasons, and its incidence varies depending on the technique used to control the airway. It occurs more frequently when certain surgical and anesthetic-related factors are present, including: patients with an unanticipated difficult airway, prolonged duration of ETI, unexperienced anesthetists; annoying impact of unhumidified gases, larger ETT size, high ETT cuff inflation pressure; and bleeding on the tip of the ETT or laryngoscope (4,8,28–31).

It has noticeable consequences for surgical and anesthesia outcomes; like debilitating throat pain following surgery, patient dissatisfaction and discomfort after surgery, inability to swallow for several days, bad memories of symptoms, delayed patients return to normal routine activities, delayed discharge from the hospital, insomnia, and memory impairment. All these results in poor postoperative outcomes and an increased economic burden. Furthermore, anesthesia care providers may not be aware of the incidence of sore throat in their practice area as many patients may not seek medical advice for POST (13,32).

Various practice modification methods and preemptive medications are being tried to prevent the incidence and severity of post extubation sore throat. They comprise careful laryngoscopy and ETI, lubricating the cuff of the ETT with a water-soluble jelly, utilizing the suitable ETT cuff pressure, gentle oropharynx suctioning before extubation, extubation after total deflation of the ETT cuff, and applying drugs that have analgesic and anti-inflammatory properties like lignocaine and steroids with different routes (2,16,17). Most of these methods are limited in low-income countries like our country, Ethiopia, and are not well practiced. However, administration of IV dexamethasone and Lidocaine is simple, effective, easily available, and practicable in the operating room (29,33).

Awareness of the prophylactic effects of IV Lidocaine and dexamethasone to decrease the incidence and severity of POST following GA with ETI will allow health care providers to use these drugs to reduce postoperative morbidity and patient dissatisfaction, and improve a patient's anesthesia experience. Therefore, this study aims to compare the effects of prophylactic IV lidocaine and dexamethasone on the incidence and severity of POST at TASH.

1.3 Justification of the study

There are a lot of studies that suggest the use of IV dexamethasone and lidocaine to reduce the incidence and severity of POST following endotracheal extubation. The incidence of POST has been found to vary with different patient and hospital characteristics, such as different pain threshold levels among different populations, different airway management techniques and interventions. Our patients' pleasure and the delivery of high-quality care are of utmost significance. As a result, the study will contribute to potential strategies for lowering the incidence and severity of POST in our settings. It will also help clinicians use evidence-based prevention of POST to improve postoperative outcomes and decrease the economic burden.

The results of this study will also help anesthesia care providers use their efforts to reduce the incidence and severity of POST following endotracheal extubation in TASH. It will also help the anesthesia department head and hospital pharmaceutical provisions to work further on the availability of intravenous dexamethasone and lidocaine in the surgical room.

To the best of my search, published research could not be found in our country, Ethiopia, which will make this study serve as a baseline data for other scholars.

Chapter Two: Literature Review

Postoperative sore throat is a well-recognized complication after GA with ETT. After surgery, it may result in dissatisfaction and discomfort and hinder the patient's return to normal routine activities (34). A number of factors are thought to contribute to the development of POST following ETI, but the presence of an ETT in the trachea and a localized inflammatory response of the airway mucosa in response to the intubation technique both play a crucial role (35).

Certain practice adjustments should be used to decrease the prevalence of POST. In addition to this, different literature supports the proactive use of drugs with anti-inflammatory effects for the prevention of POST. Lidocaine and steroids like dexamethasone are the main components of those drugs that have a significant role in analgesic and anti-inflammatory activities (3,4,24).

2.1 Causes of postoperative sore throat following endotracheal extubation

The causes of postoperative sore throat following endotracheal extubation include mucosal corrosion by the endotracheal tube's cuff, trauma during intubation, and mucosal drought. When a patient is under general anesthesia, the tracheal mucosa and the endotracheal tube might rub against each other, which can lead to mucosal corrosion (29). Laryngoscopy or repositioning the tube may excite sensory C fibers and cause subaltern neuroplasticity, which is associated with postoperative sore throat (1).

Other factors that could contribute to postoperative sore throat include the uncomfortable effects of unhumidified gases, the use of throat packs, female gender, the size of the endotracheal tube, the degree of difficulty in intubation, and duration of the surgery or anesthesia (36).

According to a study done in north-central Ethiopia, female patients who underwent general surgery with ETT had a substantial association with POST (AOR: 2.576, 95% CI: 1.134,5.85) (6). Another similar studies conducted in Gondar, Ethiopia, and south Ethiopia also suggests being female is a risk factor for POST following endotracheal extubation (7,27).

However, a study conducted in Nepal found that female sex did not show a significant association with postoperative sore throat (AOR=1.34, 95% CI: 0.69, 2.58) (4).

In a study done in Korea, the position of the patient can influence the likelihood of postoperative sore throat by moving the endotracheal tube. This study looked into the preventive role of dexamethasone during prone-position surgery (25).

A study that was conducted in Dharan, Nepal, shows that the duration of endotracheal intubation was an independent risk factor for postoperative sore throat in patients who underwent elective surgery under general anesthesia with ETI (AOR, 1, CI: 1.002-1.01, P =0.006) (4).

According to research done in the University of Gondar Teaching Hospital, Northwest Ethiopia, the risk factors that had an association with postoperative throat pain after GA with ETI were female sex (AOR =3.3, 95% CI: 1.07, 10.375), the use of a nasogastric tube (AOR =0.41, 95% CI: 0.174, 0.965), and the number of attempts to ETI (AOR =3.291, 95% CI: 1.658, 6.531) (7).

2.2 Incidence of postoperative sore throat following endotracheal extubation

In a systematic review and meta-analysis that was conducted in Japan and Canada, the incidence of POST was 30% to 70%, and 62%, respectively following GA with ETT (5,17). In a study conducted at Dharan, Nepal, the incidence of a sore throat following surgery with ETT among dexamethasone, lidocaine and placebo groups was 36%, 43% and 56% respectively (P = .02) (4).

As per studies conducted in Tanzania, found that the prophylactic use of IV dexamethasone at a dose of 0.1 mg/kg has significantly lowered the incidence of POST by 36.9%, 73.9% and 65.2% at 1 hour, 6 hours and 24 hours of post-extubation period respectively (37).

According to Institution-based cross-sectional studies carried out in TASH, SPHMMC, Debre Tabor General Hospital and Ethiopian teaching hospitals, Ethiopia, the incidence of POST among adult surgical patients under GA with ETT was 45.6%, 48.5%, 48.8% and 56.6%, respectively (6,13,14,28).

2.3 Severity of postoperative sore throat following endotracheal extubation

As per studies carried out in Fukui, Japan, and Beijing, China, IV dexamethasone was associated with a reduced severity (standardized mean difference (SMD), - 1.06; 95% CI, - 1.80 to - 0.33) and (SMD =-1.15; 95 % CI, -1.86 to -0.45; P = 0.002; heterogeneity test, I^2 = 91.7 %) of POST following surgery under GA with ETT (20,38).

A randomized controlled trial study in Pakistan found that patients with sore throat were mild (25%), moderate (28%), and severe (12%) in the dexamethasone group and mild (25%), moderate (28%), severe (14%) in the lidocaine group which had not significant differences among groups (31).

In Muhimbili National Hospital, Tanzania, a study showed that the severity of POST was lower in patients who was taken IV dexamethasone than those who taken the placebo group, with a statistically significant lower proportion of patients experiencing a moderate sore throat at 1 hour in the dexamethasone group (37).

Studies conducted in Jimma University Teaching Hospital, Ethiopia, showed that sore throat complaint was mild in 25.9%, moderate in 18.9%, and severe in 11.8% (28).

2.4 Effects of intravenous dexamethasone and lidocaine on postoperative sore throat

As per randomized controlled trials carried out in Iran and Pakistan, studies demonstrate that prophylactic intravenous (IV) dexamethasone and lidocaine can both lessen the incidence and intensity of POST in individuals undergoing GA with ETI in the first 24 hours following extubation and can be used safely in picky patients (18,31). A comprehensive analysis conducted by John Wiley & Sons indicated that systemic lidocaine administration lowers the likelihood of POST significantly among surgical patients with ETI (RR 0.64, 0.48 to 0.85) (5).

According to Yang et al. administering IV dexamethasone 10mg before induction of anesthesia decreased the frequency and intensity of postoperative throat pain within 24 hours of a thyroidectomy (39). The results of a study in Azad Kashmir demonstrate that prophylactic IV dexamethasone reduces the incidence of POST in the first 24 hours following endotracheal extubation compared to the control group with normal saline ((16.4% Vs 54.5%) ($p < 0.01$) (40).

The results of a study conducted in Indea, IV dexamethasone had a statistically significant reduction in the incidence and severity of sore throat after GA with ETI compared to the placebo group (18% Vs 54%) (41). A systematic review and meta-analysis conducted in Japan indicate that preoperative IV dexamethasone administration was associated with a decreased incidence and severity of POST compared with non-analgesic controls in adults who are having elective surgery under GA with ETI (38).

A meta-analysis done in Beijing, China, showed that IV dexamethasone greater than 0.1 mg/kg decreased the frequency and intensity of sore throat at 24 hours after surgery (RR 0.68 and SD-1.15) (20). In 2016, a study conducted by Sang Lee described that administering prophylactic IV Dexamethasone in prone surgery lowers the incidence of POST, and 0.2 mg/kg reduces the frequency of postoperative hoarseness (25).

In a study conducted at North Bengal Medical College, India, demonstrated that prophylactic intravenous dexamethasone in a dose of 0.2 mg/kg can reduce the incidence of POST at 1 hour of the post-extubation period by 30%, with an efficacy of 60% (21).

A study done by Thomas et al. demonstrates the prevalence of POST was lower in the dexamethasone group (20%) compared to the control group (56.3%) during the first 24 hours after surgery ($p < .01$). In this similar study, the severity of POST at 1 hour, 3 hours, 6 hours, 12 hours, and 24 hours following surgery was less in the dexamethasone group compared to the control group ($p < .01$) at correlating time interval (42).

However, in a study carried out in Thailand found that there was no statistically significant difference between the incidence of sore throat at 1hour/24 hours of the postoperative period in the normal saline group (48.6/48.6%), 4mg dexamethasone group (54.3/28.6%), and 8mg dexamethasone group (54.3/42.9) (26).

According to findings of a study that was carried out in Fauji Foundation Hospital, Pakistan, the frequency and severity of POST in patients undergoing GA with ETI among the dexamethasone and Lidocaine group were 40% and 42% ($p = 0.998$) respectively, a difference that was not statistically significant (31).

The results of a study conducted by Fayed found that there was a significant difference in the effects of prophylactic intravenous dexamethasone (17.6%) and lidocaine (21.4%) in patients who underwent laparoscopic cholecystectomy to decrease the incidence of POST, hoarseness and cough within 24 hours of surgery ($p = .001$) (29).

A systematic review and meta-analysis conducted in China revealed that dexamethasone, with or without concurrent medications, significantly reduced the incidence of POST (OR 0.44, 95% CI 0.33-0.58, $P < 0.00001$) compared with placebo (43). Research conducted in Iran showed that IV lidocaine (1-1.5mg/kg) reduced the likelihood and intensity of POST resulting from ETI (44).

According to a study done in Iran, both IV lidocaine and dexamethasone groups had considerably lower rates of sore throats than the placebo group within 30 minutes after extubation (p 0.05). Although IV lidocaine is more effective than dexamethasone injection at times 1, 6, and 24 hours following endotracheal extubation, this difference was not statistically significant in reducing post-operative sore throat (18).

A meta-analysis conducted by the Cochrane Collaboration reviewed 19 studies recommends that topical and systemic lidocaine therapy appeared to reduce the risk of POST (RR 0.64, 95% CI 0.48–0.85); however, when only the studies rated as being of high quality were analyzed, this benefit was no longer observed (RR 0.71, 95% CI 0.47–1.09) (5). As per a study conducted in Canada, IV lidocaine significantly decreased POST at 1 hour (RR: 0.46; 95% CI: 0.32-0.67) when compared to placebo or no therapy (23).

In a three-year randomized, double-blind study conducted in India surgical patients who had endotracheal tubes, prophylaxis IV dexamethasone (8 mg) significantly reduced the risk of POST (OR, 0.44; 95% CI, 0.24–0.82; P <.01). However, patients who received prophylactic lidocaine (1.5 mg/kg) did not significantly decrease in POST frequency (OR, 0.62; 95% CI, 0.33–1.14; P = .12). And the results of this study show no difference was observed in the severity of a sore throat among the groups (4).

In a study done in Muhimbili National Hospital, Tanzania; the incidence of patients developing sore throat postoperatively in patients who received dexamethasone exhibited statistically significant lower incidences compared to the group of patients who received placebo (58.7% Vs 95.6%, p <.001; 21.7% vs. 95.6%, p <.001; 4.4% vs. 69.6%, p <.001) at 1, 6, and 24 hours, respectively, with a reduction of 36.9% during the first hour (37).

2.5 Conceptual framework

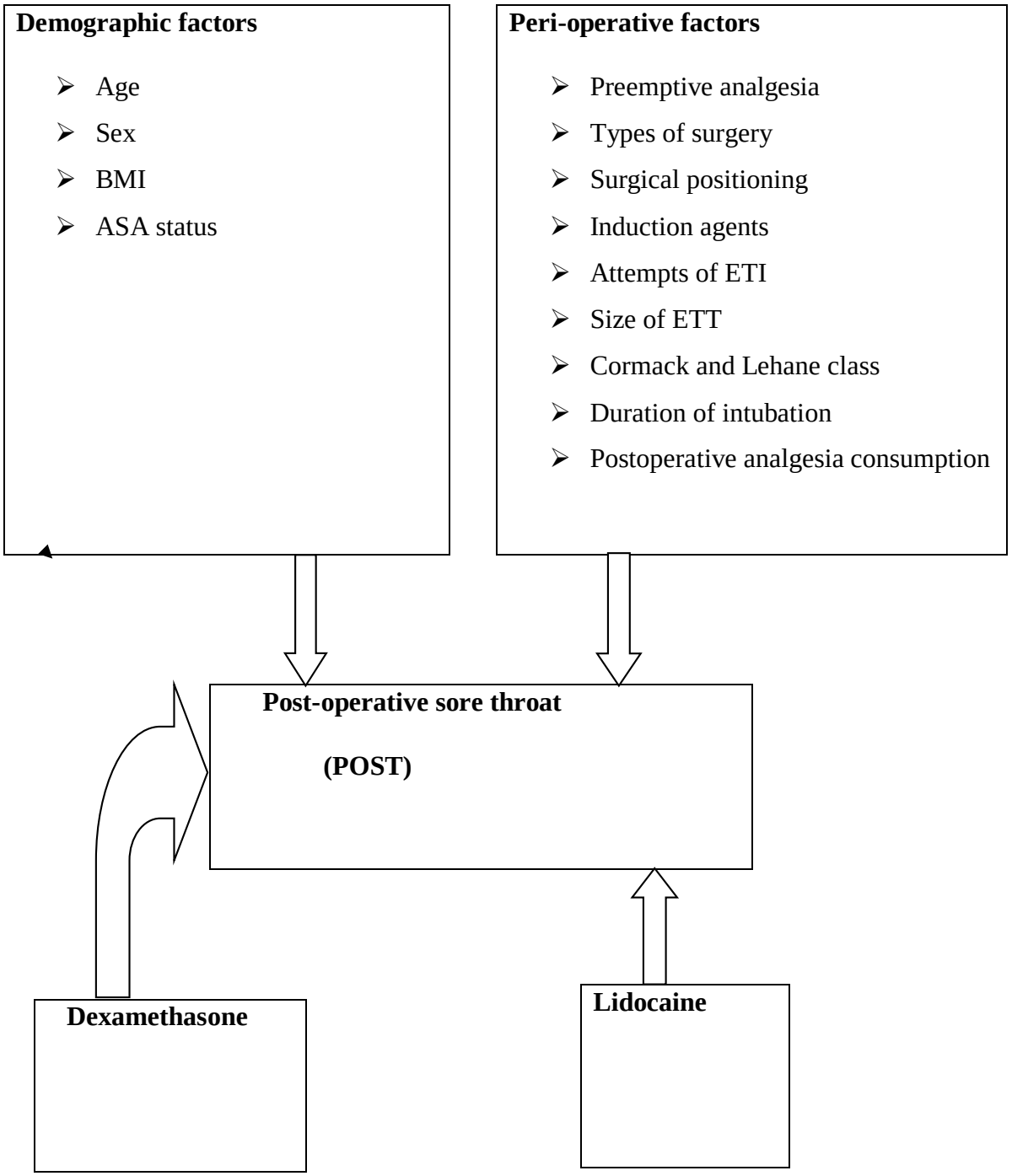

Figure 1: Conceptual frame work that shows factors or exposures that affect the incidence and severity of POST: from a review of the literatures(4,5,37,38)

2.6 Research hypothesis

The incidence and severity of POST after endotracheal tube extubation among patients who received IV lidocaine or IV dexamethasone and who didn't receive both exposures were hypothesized as follows:

1. **Null hypothesis (HO):** The population centers between the incidence of POST among the three groups were equal.

   Alternative hypothesis (HA): At least one of the population tends to exhibit different values than the other populations between the incidence of POST among the three groups.
2. **Null hypothesis (HO):** The population centers between the severity of POST among the three groups were equal.
3. **Alternative hypothesis (HA):** At least one of the population tends to exhibit different values than the other populations between the severity of POST among the three groups.

Chapter Three: Objectives

3.1 General objective

- ✓ To assess the prophylactic effects of intravenous lidocaine and dexamethasone on the incidence and severity of POST following endotracheal extubation in adult surgical patients at TASH, Addis Ababa, Ethiopia, from January 1 to March 30, 2023 G.C.

3.2 Specific objectives

- ✓ To compare the prophylactic effects of intravenous lidocaine and dexamethasone on the incidence of POST following endotracheal extubation in adult surgical patients
- ✓ To compare the prophylactic effects of intravenous lidocaine and dexamethasone on the severity of POST following endotracheal extubation in adult surgical patients
- ✓ To assess the perioperative clinical characterstics contributing to the incidence of POST following endotracheal extubation in adult surgical patients as a secondary objective

Chapter Four: Methods

4.1 Study design and period

A hospital-based prospective cohort study was conducted from January 1 to March 30, 2023.

4.2 study area

The study was conducted at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia. This hospital is one of the largest tertiary referral hospital in the country. It was founded in 1972 E.C. and serves as a teaching hospital for Addis Ababa University College of Health Sciences and School of Medicine. It offers a wide range of specialties and subspecialties. It serves roughly 500,000 patients each year as outpatients and inpatients and has a total bed capacity of about 800. The hospital now has 17 operating rooms, of which 12 are for elective procedures and 5 are for emergency procedures.

4.3 Population

4.3.1 Source population

All adult patients who underwent elective surgery under GA with ETI at Tikur Anbessa Specialized Hospital during the study period.

4.3.2 Study population

All eligible adult patients who met the inclusion criteria during the study period as exposed and non-exposed group.

4.4 Variables

4.4.1 Dependent variable

- Postoperative sore throat: Yes/No
- Postoperative sore throat severity

4.4.2 Independent variables

- Demographic characterstics (Age, Sex, BMI, ASA physical status)
- Preemptive analgesia
- Types of surgery
- Surgical positioning
- Exposure status: non-exposed group, Dexamethasone group, and Lidocaine group
- Induction agents
- Cormach-Lehane grading scheme for laryngoscopy
- Attempts of ETI

- Size of ETT
- Duration of endotracheal intubation

4.5 Eligibility criteria

4.5.1 Inclusion criteria

- Patients who undergoing elective surgery under GA with ETT without the study drugs as the non-exposed group, patients who received either IV lidocaine (1.5mg/kg) or dexamethasone (8mg) before 5-10 minutes of anesthesia induction as the exposed group, Patients age from 18-65 years, and ASA physical status I and II were included.

4.5.2 Exclusion criteria

- Patients with recent or ongoing URTI
- Patients who had a preoperative sore throat
- Smoker
- Patients who undergo surgeries on the oral cavity or oropharynx
- Obstetrics surgery
- Patients who had anticipated difficult intubation
- Patients who had taken combined lidocaine and dexamethasone or other steroid agents
- Intubation attempts >2
- Unpredicted long duration of surgeries (>4 hours)
- Patients were transferred to the intensive care unit with ETT in situ.

4.6. Sample size determination and sampling techniques

4.6.1. Sample size determination

A pilot study was conducted from November 28 to December 27, 2022, at TASH, using 10% of the sample size from the prior study that was carried out in Dharan, Nepal, which enrolled 180 patients and was used to determine the sample size for this study because there had not previously been a published study on the same topic in the study area (4). The sample size was calculated using a priori power analysis (g*power version 3.1.9.7 statistical software) after obtaining the sample mean and standard deviation of POST among the groups from the pilot study. Mean of group-1 (lidocaine group)= 1.4, mean of group-2 (dexamethasone group) = 1.3, mean of group-3 (control group) = 1.6 and Standard deviation with in each group = 0.471.

An error probability of 5%, a power (1-error probability) of 80%, the calculated effect size (0.267), and a 10% attrition rate were used to calculate the sample size.

Therefore, the sample size was 141 and adding a 10% attrition rate. 10% of 141=14.1≈15. The final estimation of the total sample size was 141+15 = 156. Subjects were selected for the study in an equal ratio to the groups (1:1:1 ratio), which was determined by dividing the total sample size by the number of study groups (156/3 = 52). Therefore, 52 patients were observed in each group.

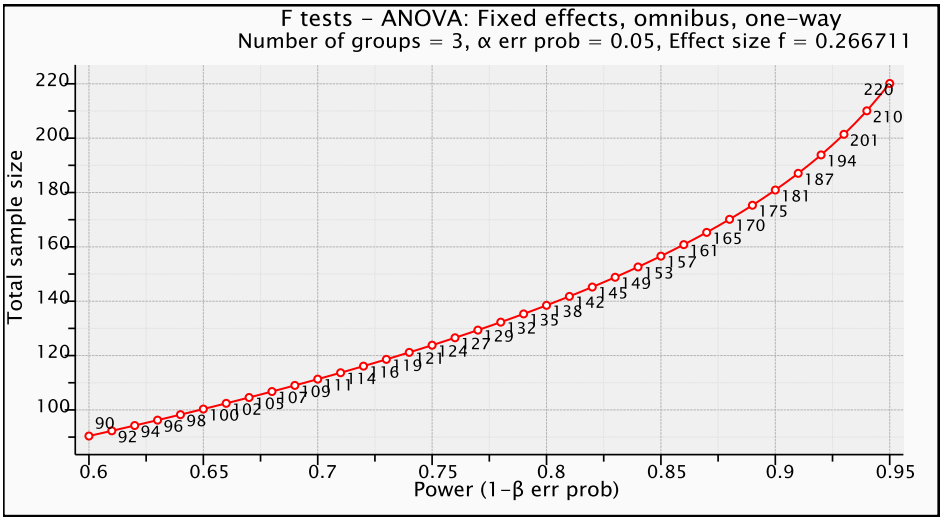

Figure 2: Sample size determination using g*power software

4.6.2. Sampling techniques and procedures

Tikur Anbessa Specialized Hospital was selected because it is the largest tertiary referral hospital in the country and receives a diverse set of patients from all around Ethiopia, and the study drugs are practiced in day to day activity for indicated surgical patients. The data were collected using observation based on structured questionnaires. The study subjects were chosen through a systematic random sampling method. As a sampling frame, the daily operation schedule list was employed. According to the situational analysis at TASH, 260 patients who meet the inclusion criteria had surgery from September 3 to November 2, as determined by surgical log book registrations. Therefore, the sample was collected using a sample interval (k) =156/260. K value was determined to be 3/5 from this sampling fraction, and data collection was conducted on three

patients for every five patients who undergo surgery under GA with ETT. The study's first patient was randomly selected, and the subsequent patients were arranged in the order in which they were admitted to the PACU. Based on groupings, the first three patients admitted to the PACU were included in the study, while the final two patients admitted to the PACU were excluded. Up until the necessary sample size was obtained, this sampling procedure was used.

The required number of samples for each group was identified as follows (Figure 3).

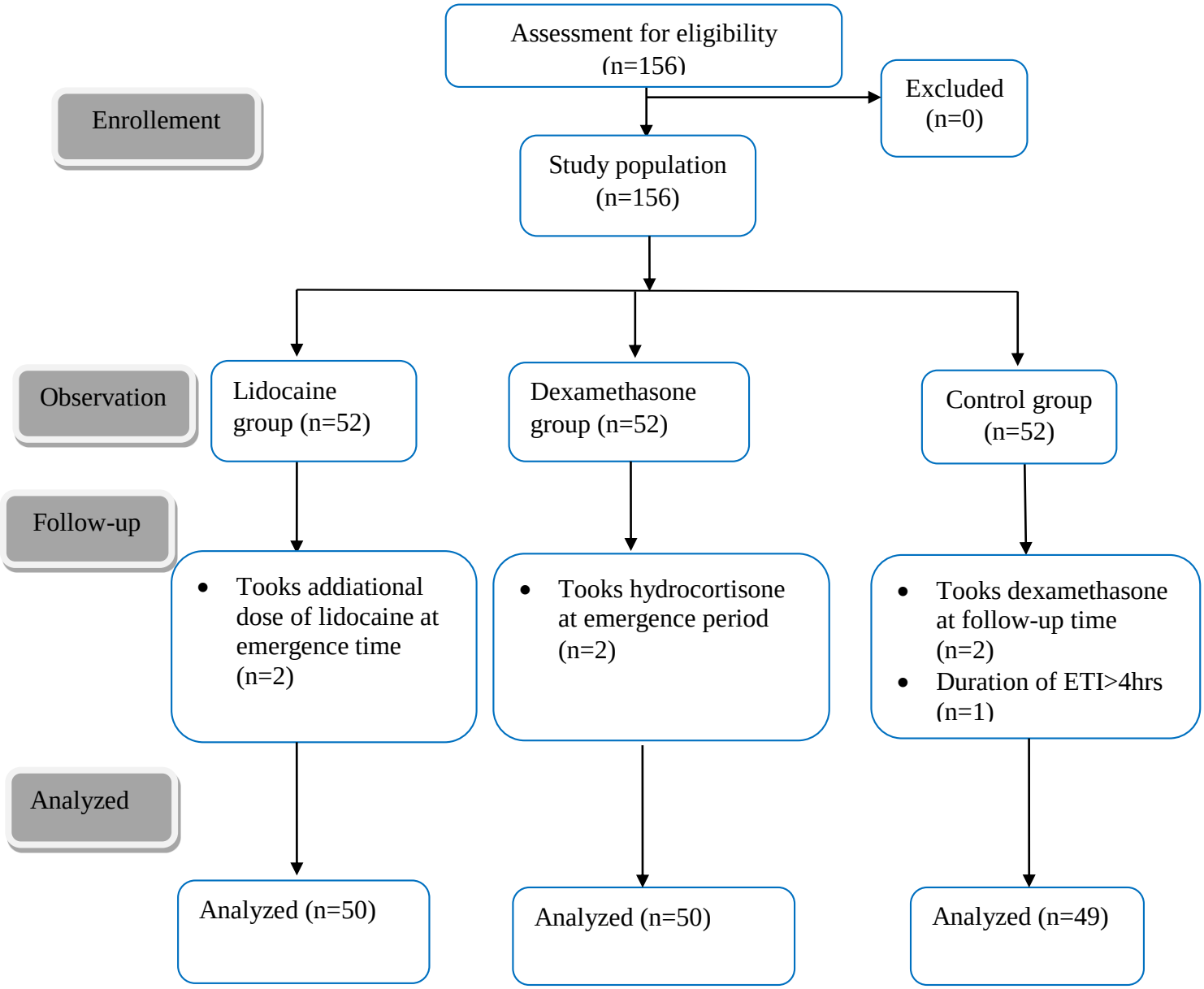

Figure 3: A flowchart of the study

4.7. Data collection techniques, Quality control and Analysis

4.7.1. Data collection process and patient handling techniques

Based on data from a chart review and patient interview, all patients who were scheduled for elective surgery under GA with ETT and met the inclusion criteria were selected at the preoperative period. All patients were managed with standard perioperative monitorings by MSc anesthetists and anesthesiologists. Data about the demographic, surgical, and perioperative anesthesia profiles; including age, gender, BMI, ASA physical status, types of surgery, preemptive analgesia, surgical positioning, induction agents, laryngoscopic grades, number of attempts of ETI, size of ETT, and duration of ETI, were observed and filled out by anesthetist data collectors. Surgical patients who received 8 mg dexamethasone or 1.5 mg/kg lidocaine intravenously before 5-to-10 minutes of anesthesia induction as the exposed group and those who did not receive both IV lidocaine and dexamethasone as the non-exposed group (but taken other anesthesia and surgical treatments as an exposed groups) were recorded by the responsible anesthetist data collectors. All the study subjects were induced with IV induction agents and relaxed with 2 mg/kg of succinylcholine during ETI. In the intraoperative period, all patients were ventilated with oxygen and maintained anesthesia with inhalational anesthetic drugs and 0.1 mg/kg of vecuronium for relaxants. At the end of surgery, muscle relaxation was reversed by 0.05 mg/kg neostigmine and 0.02 mg/kg atropine. The patients were extubated after fulfilling the extubation criteria and transferred to the PACU and then to the ward.

A data extraction checklist was prepared in English by reviewing literatures. Two BSc and four MSc anesthesia students collected the data under the supervision of the principal investigator at Tikur Anbessa specialized hospital. The data collector trained each study subject on techniques to report the incidence and severity of postoperative sore throat.

The accountable data collector, who was not informed of the group allocation by using codes to represent the groups, gathered the postoperative data. Postoperative follow-up and data collection on the incidence and severity of POST and postoperative analgesia consumption were collected at the surgical ward for 24 hours. Data collection was started at 3 hours after being transferred to PACU, then continued at 6 hours, 12 hours, and 24 hours. The postoperative sore throat was assessed in all groups using sore throat assessment scales that were applied before in different studies. On a four-point scale, each patient was asked to describe their throat pain verbally.

4.7.2. Data quality control and assurance

The data collectors (two BSc and four MSc anesthesia students) received training in order to obtain relevant and quality data, and a pre-test was conducted on 5% of the total sample size at Menelik II referral hospital. The data was collected and properly filled out in the pre-designed format. The principal investigator (PI) and the supervisor cross-checked the completed forms for clarity, accuracy, consistency, and completeness. Any ambiguity or incompleteness was corrected by the investigator every day.

4.7.3. Data processing and analysis

The data were manually reviewed for completeness and then coded and entered into EpiData version 4.6.0.6 and transferred to STATA version 17 statistical software for analysis. The Shapiro-Wilk test and histogram were used to determine the normality of the data distribution for continuous data. Multicollinearity was checked using variance inflation factors (VIF) with a tolerance of 10% to describe categorical variables. Goodness of fit test was also checked using Hosmer and Lemeshow test. A comparison of parametric data among the groups such as age and duration of ETI was performed using a one-way ANOVA test. The Kruskal-wallis rank test was applied for non-parametric data such as BMI. Associations between independent and dependent variables were tested by using chi-squared test, Fisher's exact test, and binary logistic regression. Bivariable and multivariable logistic regression was used to determine degree of association. The findings of continuous variables were expressed as mean ± SD, and categorical variables has been presented as frequencies and percentages. Finally, the variables that have a significant association with the outcome variable was expressed using odds ratio, 95% CI, and p-value of less than 0.05 was considered as statistically significant.

4.8 Operational definitions

Postoperative sore throat: considered present if the patient complains of pain, scratchiness, or irritation of the throat at the postoperative period. Therefore, the data was recorded as yes if POST occurred within 24 hours of post-extubation period and no if it was not occurred with in the mentioned time range. The patients graded the severity of a sore throat using the scoring system as described previously (45,46) which can be stated verbally. The degree of sore throat is represented by the following pain assessment tool.

0 = No sore throat

1 = Minimal sore throat (complaints of sore throat only on asking)

2 = Moderate sore throat (complaints of sore throat on his/her own)

3 = Severe sore throat (change in voice or hoarseness, associated with throat pain) over 24 hours.

Endotracheal tube: a flexible plastic tube that is placed through the mouth or nose into the trachea to help the patient to breath.

Endotracheal intubation: a technique used for airway maintenance by which a tube was inserted to the trachea.

ASA classification: a method used to assess the fitness of patients before surgery and communicate a patients pre-anesthesia medical co-morbidities.

4.9 Ethical consideration

Permission for the study was obtained from Addis Ababa University, College of Health Sciences. The respondent's verbal informed agreement was obtained after they had been informed about the study. The confidentiality of the patients was respected, they were anonymous, and their identities were not disclosed.

4.10 Dissemination of Results

The study result will be presented for research defense at Addis Ababa University, College of Health Science, Department of Anesthesia, and copies of the final thesis output will be distributed to the College of Health Science, Department of Anesthesia, and the student research office at Addis Ababa University. It will then be sent for publication in national and international journals.

Chapter Five: Results

5.1 Demographic and perioperative characteristics related to the three groups

Among a sample of 156 patients enrolled in this study, 149 were included in the final analysis. Seven patients were excluded from the analysis: two had received an additional dose of lidocaine at the time of emergence, two had received hydrocortisone at the time of emergence, two had received dexamethasone at the time of follow-up, and one patient had a prolonged duration of surgery (>4 hours). The results indicate that there is no significant difference among the three groups in both demographic data, surgical characteristics, and perioperative profiles of the patient (Tables 1 and 2).

Table 1: Demographic and surgical profiles of the study subject

Characterstics		Lidocaine group (n=50)	Dexametasone group (n=50)	Control group (n=49)	p-value
Age (yr)*		40.78± 8.087	40.48±10.124	40.59±9.246	.986
Gender $	Male	25(50%)	20(40%)	23(47%)	.589
	Female	25(50%)	30(60%)	26(53%)	
BMI (kg/m^2)**		20.6(4.1)	19.85(4.5)	20.9(4.1)	.1287
ASA physical status $					.683
	ASA I	20 (40%)	24(48%)	23(47%)	
	ASA II	30(60%)	26(52%)	26(53%)	
Types of surgery $					.284
Abdominal		9(18%)	7(14%)	4(8.2%)	
Urology		11(22%)	12(24%)	8(16.3%)	
Endocrine		10(20%)	12(24%)	12(24.5%)	
Vascular		8(16%)	3(6%)	4(8.2%)	
Orthopedics		7(14%)	7(14%)	16(32.6%)	
Gynecology		5(10%)	9(18%)	5(10.2%)	
Surgical positioning $					.407
Supine		30(60%)	35(70%)	33(67.3%)	
"Supine with head tilt"		11(22%)	5(10%)	5(10.2%)	
Lateral		9(18%)	10(20%)	11(22.5%)	

*= mean ± SD, tested by one-way ANOVA. **=median (IQR), tested by the Kruskal-Wallis rank test. $= number (%), tested by the chi-square test and Fisher's exact test. BMI, body mass index; ASA, American Society of Anesthesiologist; SD, standard deviation; IQR, Interquartile range; yr, year; kg/m^2, kilogram per meter square.

Table 2: Perioperative profiles of the study subject among lidocaine, dexamethasone and control groups

Characterstics	Lidocaine group (n=50)	Dexametasone group (n=50)	Control group (n=49)	P-value
"Preemptive analgesia" $				.486
Fentanyl	37(74%)	43(86%)	35(71.4%)	
Morphine	9(18%)	6(12%)	8(16.3%)	
Tramadol	2(2%)	1(2%)	4(8.2%)	
Diclofenac	2(4%)	0(0%)	2(4.1%)	
Induction agents $				.347
Ketamine	4(8%)	3(6%)	1(2%)	
Propofol	32(64%)	31(62%)	34(69.4%)	
Ketofole	8(16%)	12(24%)	5(10.2%)	
Thiopentone	6(12%)	4(8%)	9(18.4%)	
Laryngoscope grade $				.355
Grade-1	36(72%)	40(80%)	33(67.3%)	
Grade-2	14(28%)	10(20%)	16(32.7%)	
Attemts of ETI $				.285
One-attempt	49(98%)	49(98%)	45(91.8%)	
Two-attempts	1(2%)	1(2%)	4(8.2%)	
Size of ETT(mmID) $				.376
6.0	10(20%)	15(30%)	8(16.3%)	
6.5	14(28%)	16(32%)	20(40.8%)	
7.0	20(40%)	15(30%)	13(26.6%)	
7.5	6(12%)	4(8%)	8(16.3%)	
Duration of ETI(min) *	161±33	154±35	151±28	.328
"Post-op analgesia consumption" $				.166
Diclofenac	4(8%)	3(6%)	11(22.5%)	
Tramadol	6(12%)	2(4%)	3(6.1%)	
"Diclofenac +tramadol"	36(72%)	42(84%)	31(63.3%)	
Morphine	2(4%)	1(2%)	3(6.1%)	
Paracitamol	2(45)	2(4%)	1(2%)	

*= mean ± SD, tested by one-way ANOVA. $= number (%), tested by the chi-square test and Fisher's exact test. ETT, endotracheal tube; ETI, endotracheal intubation; Post-op, postoperative, SD, standard deviation; mmID, millimeter internal diameter; min, minute.

5.2 Clinical parametrs and its association with the incidence of POST

The mean age between patients who develop POST following tracheal extubation was 40.89 ± 9.05 and those patients who do not develop POST were 40.41 ± 9.23. The median and IQR of BMI in patients who underwent elective surgery and developed POST versus those who did not develop POST were 21.05 (4.35) and 20.4 (4.2), respectively. The mean duration of ETI in patients who developed POST was 161.95 ± 32.24, compared to 150.65 ± 31.16 in patients who did not develop POST (table 3).

Table 3: Perioperative Continuous independent variables among elective surgical patients under general anesthesia with ETT

Variables	Incidence of POST	
	Yes	No
Age (yr)*	40.89 ± 9.05	40.41 ±9.23
BMI (kg/m^2)**	21.05 (4.35)	20.4 (4.2)
Duration of ETI (min)*	161.95 ±32.24	150.65 ± 31.16

*= presented as Mean ±SD. **=presented as median (IQR). POST, postoperative sore throat; BMI, body mass index; yr, year; kg/m^2 , kilogram per meter square; min, minute.

Among the categorical perioperative variables, gender and surgical positioning shows an association with the incidence of POST with p-value of (p =0.017 and 0.006, respectively) table 4).

Table 4: Perioperative clinical characterstics and its association with the incidence of POST among elective surgical patients under general anesthesia with ETT

Variables	Categories	Incidence of POST		P-value
		Yes	No	
Gender	Male	22	46	0.017*
	Female	42	39	
ASA physical status	ASA I	25	42	0.290
	ASA II	39	43	
Types of surgery	Abdominal	9	11	0.786
	Urology	12	19	
	Endocrine	16	18	
	Vascular	7	8	
	Orthopedics	10	20	
	Gynecology	10	9	

Preemptive analgesia	Fentanyl Morphine Tramadol Diclofenac	47 9 5 3	68 14 2 1	0.226
Surgical positioning	Supine Supine with head tilt Lateral	34 15 15	64 6 15	0.006*
Size of ETT	6mmID 6.5mmID 7mmID 7.5mmID	11 24 19 10	22 26 29 8	0.368
Induction agents	Ketamine Propofol Ketofole Thiopentone	2 42 9 11	6 55 16 8	0.240
Laryngoscopic grades	Grade 1 Grade 2	46 18	63 22	0.760
Attempts of ETT	One-attempt Two-attempt	60 4	83 2	0.218
Postoperative-analgesia consumption	Diclofenac Tramadol Diclofenac + tramadol Morphine Paracitamol	10 11 108 6 5	9 5 66 3 2	0.590

Presented as number, tested by the chi-square test and Fisher's exact test. P-value <0.05 to be statistically significant, and a p-value <0.25 were candidates for multivariable logistic regression. POST, Postoperative sore throat; ASA, American Society of Anesthesiologist; mmID, millimeter internal diameter.

5.3 Incidence and severity of postoperative sore throat among lidocaine, dexamethasone and control groups

The incidence of POST within 24 hours of the post-extubation period in the Lidocaine, Dexamethasone, and Control groups was 40%, 32%, and 57.1%, respectively. It shows an association between lidocaine, dexamethasone, and control groups relating to the incidence of POST following tracheal extubation (p =0.036) (table 5).

Table 5: Incidence of POST during 24 hours of post-extubation period among the three groups

Variable	Lidocaine	Dexamethasone	Control	p-value
incidence of POST				0.036
Yes	20 (40%)	16 (32%)	28 (57.1%)	
No	30 (60%)	34 (68%)	21 (42.9%)	

Presented as number (%), tested by the chi-square test POST, Postoperative sore throat.

Based on chi square and Fisher's exact test analysis, there is no association between lidocaine, dexamethasone, and control groups relating to the severity of POST at different time intervals during 24 hours of post extubation perids (p =0.130, 0.096, 0.313, and 0.525 at 3 hours, 6 hours, 12 hours, and 24 hours respectively) (table 6).

Table 6: Severity of postoperative sore throat among the three groups

Severity of POST at different time intervals	Scales of POST	Lidocaine group (n=50)	Dexametasone group (n=50)	Control group (n=49)	p-value
Severity of POST at 3 hrs	No POST	30(60%)	34(68%)	21(42.9%)	.130
	Minimal POST	15(30%)	12(24%)	17(34.7%)	
	Moderate POST	5(10%)	3(6%)	8(16.3%)	
	Sever POST	0(0%)	1(2%)	3(6.1%)	
Severity of POST at 6 hrs	No POST	30(60%)	35(70%)	21(42.9%)	.096
	Minimal POST	16(32%)	11(22%)	18(36.7%)	
	Moderate POST	4(8%)	3(6%)	7(14.3%)	
	Sever POST	0(0%)	1(2%)	3(6.1%)	
Severity of POST at 12 hrs	No POST	37(74%)	38(76%)	28(57.2%)	.313
	Minimal POST	11(22%)	9(18%)	15(30.6%)	
	Moderate POST	2(4%)	3(6%)	5(10.2%)	
	Sever POST	0(0%)	0(0%)	1(2%)	
Severity of POST at 24 hrs	No POST	41(82%)	42(84%)	34(69.4%)	.525
	Minimal POST	8(16%)	7(14%)	11(22.5%)	
	Moderate POST	1(2%)	1(2%)	3(6.1%)	
	Sever POST	0(0%)	0(0%)	1(2%)	

*= number (%), tested by the chi-square test and Fisher's exact test. POST, Postoperative sore throat; hrs, hours.

The incidence of POST within 24 hours hours of the post-extubation period and the scales of sore throat after endotracheal extubation at different time intervals are shown in Figures 4 and 5.

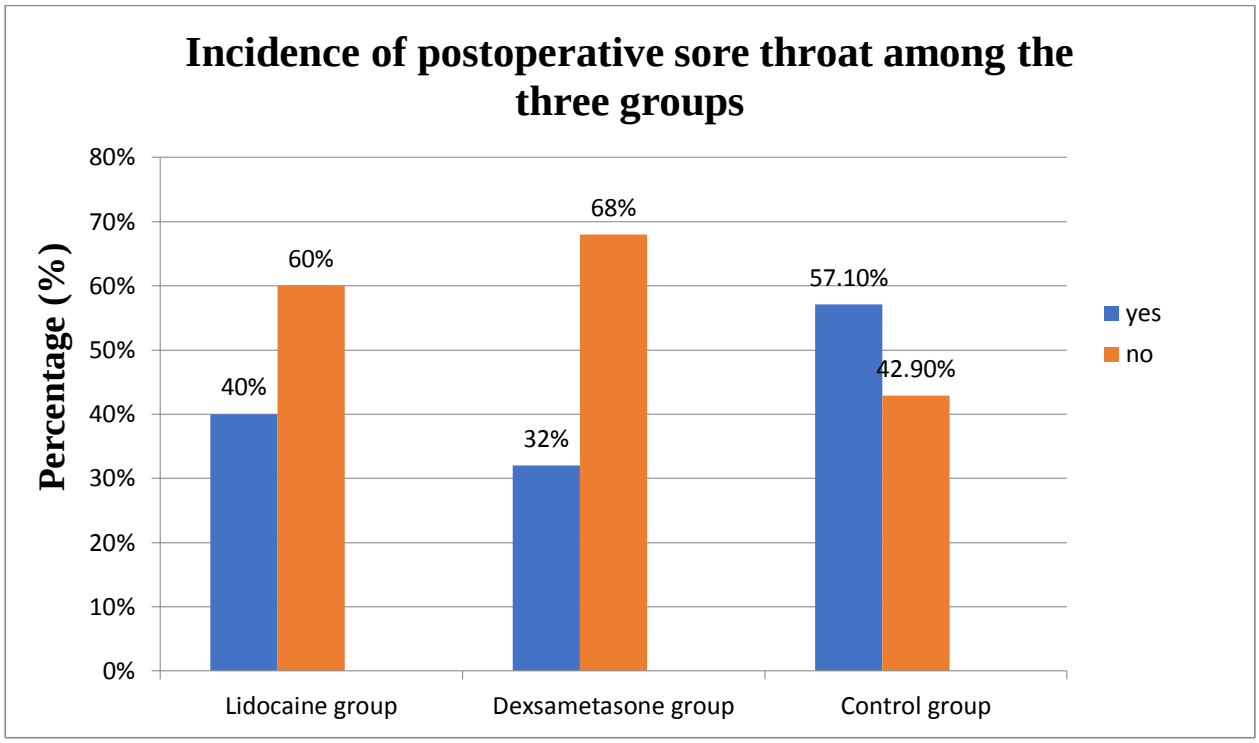

Figure 4: Incidence of POST within 24 hours of post-extubation period among the three groups

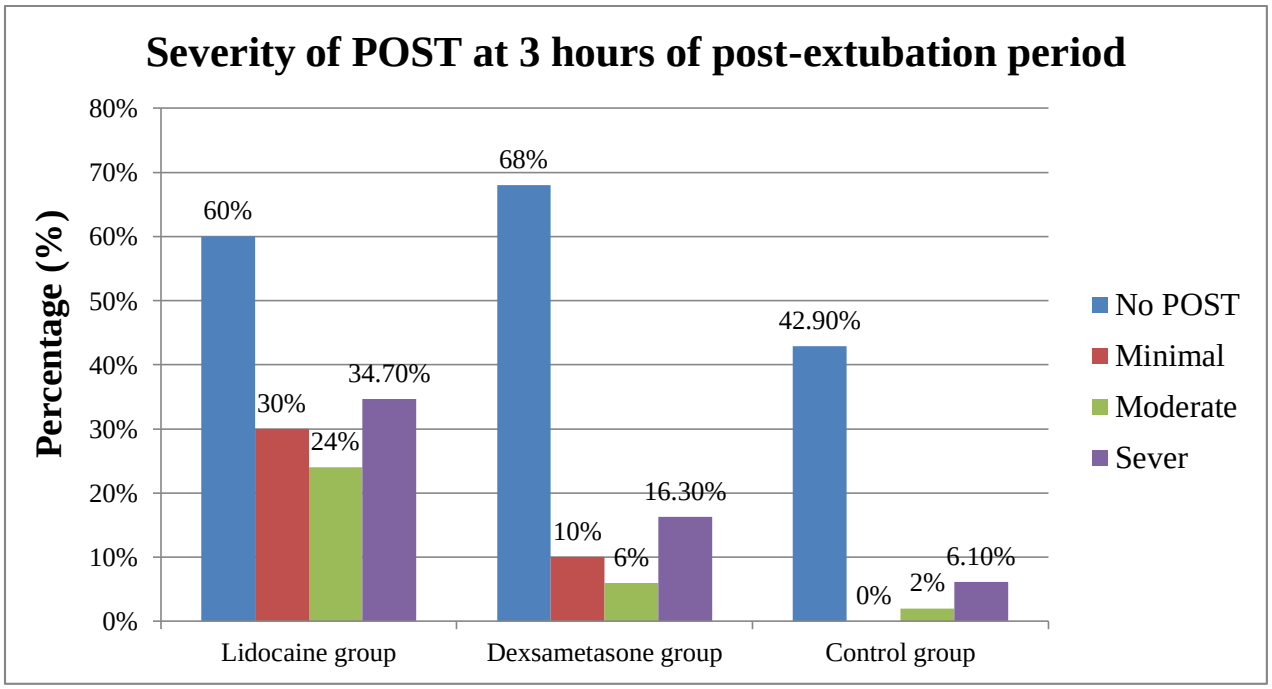

Figure 5: Scales of POST at 3 hours of post-extubation period among the three groups

5.4 Interpretation of Multivariable logistic regression interms of Adjusted Odds Ratio

In a bivariable study, gender, preemptive analgesia, surgical positioning, induction agents, attempts at ETI, duration of ETI, lidocaine, and dexamethasone groups were found to be positively associated with the incidence of POST with a p-value of less than 0.25 and were candidates for multivariable logistic regression.

In multivariate logistic regression, the incidence of POST in elective adult surgical patients following endotracheal extubation was significantly associated with gender, surgical positioning, and dexamethasone group.

Patients of female gender were 2.7 times (AOR: 2.69, 95% CI: 1.26, 5.73) more likely to develop POST than males. The odds of developing POST were 5 times (AOR: 5.03, 95% CI: 1.66–15.26) more in patients who underwent surgery using supine with head tilt positioning than those patients who underwent surgery with supine and lateral positions. Dexamethasone group had a marked reduction in the incidence of POST by 63% (AOR: 0.37, 95% CI: 0.15–0.94) (table 7).

Table 7: Bivariable and Multivariable binary logistic regression-showing factors associated with the incidence of POST among elective surgical patients at TASH

Variables	Categories	Incidence of POST		COR(95% CI)	AOR(95% CI)	P-value
		Yes (n=64)	No (n=85)			
Gender	Male	22	46	1	1	
	Female	42	39	2.25(1.15-4.34)	2.69(1.26-5.73)	0.010*
Preemptive analgesia	Fentanyl	47	68	1	1	
	Morphine	9	14	0.93(0.37-2.33)	0.86(0.30-2.50)	0.787
	Tramadol	5	2	3.62(0.67-19.44)	3.72(0.59-23.71)	0.164
	Diclofenac	3	1	4.34(0.44-43.01)	4.80(0.39-5.96)	0.223
Surgical positioning	Supine	34	64	1	1	

	Supine with head tilt	15	6	4.71(1.67-13.24)	5.03(1.66-15.26)	0.004*
	Lateral	15	15	1.88(0.82-4.31)	2.13(0.84-5.41)	0.111
Induction agents	Ketamine	2	6	1	1	
	Propofol	42	55	2.29(0.44-11.93)	1.01(0.18-5.80)	0.987
	Ketofole	9	16	1.69(0.28-10.17)	0.92(0.14-6.15)	0.931
	Thiopentone	11	8	4.13(0.65-26.01)	1.66(0.24-11.55)	0.611
Attempts of ETT	One attempt	60	83	1	1	
	Two attempt	4	2	2.77(0.49-15.60)	3.09(0.43-22.21)	0.262
Groups of drugs	Lidocaine	20	30	0.50(0.23-1.11)	0.45(0.18-1.11)	0.084
	Dexamethasone	16	34	0.035(0.16-0.80)	0.37(0.15-0.94)	0.036*
	Control	28	21	1	1	

*=Significant in the Multivariable binary logistic regression (p-value < 0.05). COR, crude odds ratio; AOR, adjusted odds ratio; CI confidence interval; 1, Reference.

Chapter Six: Discussion

This study compared the effects of IV lidocaine and dexamethasone on the incidence and severity of POST in patients undergoing elective surgery under GA with ETT. The incidence of POST during the first 24 hours was 32%, 40%, and 57.1% in the dexamethasone, lidocaine, and control groups, respectively. This finding has been consistent with a study done by Subedi et al. that showed the incidence of POST in patients requiring GA with ETT was 36%, 43%, and 56% in the dexamethasone, lidocaine, and normal saline groups, respectively (4).

This present study demonstrates that the incidence of POST within the first 24 hours of post-extubation period was lower in the dexamethasone group than the control group by 63% (AOR: 0.37, 95% CI: 0.15–0.94). This result is consistent with studies carried out in Iran, Palestine, and India that found IV dexamethasone was effective in reducing the incidence of POST in patients requiring ETI (4,18,29).

The possible reasons are due to its anti-inflammatory and immunosuppressive properties, which are explained by central inhibition of prostaglandin synthesis, decreased central nervous system serotonin turnover, and modulation of the systemic inflammatory response in favor of its anti-inflammatory mediators (37,42).

Similar to this present study, a double-blind randomized trial conducted in Korea and Tanzania found that patients who received IV dexamethasone prior to induction of anesthesia experienced significantly lower rates of POST and hoarseness than those who received placebo at 1, 6, and 24 hours after tracheal extubation (25,37).

This study were also comparable to a meta-analysis of randomized controlled trials conducted in Ireland by Sun L. et al., which showed that a single dose of intravenous dexamethasone reduced the incidence of POST within 24 hours of surgery (20).

However, research conducted by Ruangsin et al. revealed that there was no significant difference in the effectiveness of two different doses of prophylactic IV dexamethasone (4 mg and 8 mg) against POST following ETI (26). This contradictory finding is probably due to the relatively small sample size (35 in each group) and different analytic models; they used the unpaired Student’s t-test and Mann-Whitney U test for the analysis of continuous data among the three groups (4 mg dexamethasone group, 8 mg dexamethasone group, and 2 ml normal saline group).

In this present study, prophylactic IV lidocaine (1.5 mg/kg) did not significantly decrease the incidence of POST after endotracheal extubation in patients who underwent elective surgery under GA with ETT. This is comparable to a randomized controlled trial conducted in India and Palestine that revealed that IV lidocaine alone was ineffective in reducing POST following surgery (4, 29).

However, a randomized controlled trials in Iran contradicts this study by suggesting that the use of IV lidocaine prior to ETI reduces the frequency of POST and would improve patient outcomes (44). A study conducted by Yang SS. et al. revealed that IV lidocaine significantly decreased POST at 1 hour when compared to placebo or no therapy (23).

On contrary to this study, a meta-analysis of systematic reviews conducted by Tanaka et al. in 2015 revealed that lidocaine administered topically and intravenously significantly decreased the risk of sore throat after surgery. However, a subgroup analysis of high-quality studies shows that there are no statistically significant differences in preventing POST related to IV lidocaine (5).

According to the results of the current study, we found that giving prophylactic IV dexamethasone or lidocaine to patients undergoing elective surgery under GA with ETT can't have an association with the severity of POST at different time intervals (3 hours, 6 hours, 12 hours and 24 hours) after endotracheal tube extubation.

This result is supported by a study conducted in India, which suggested that there were no statistically significant differences in the severity of POST among the groups at 12 and 24 hours following surgery (4). Similar findings have been observed in studies conducted by Yang C. et al. showed that IV injection of prophylactic 10 mg dexamethasone did not have a significant effect on the severity of POST at rest or while swallowing in the first 6 hours after endotracheal extubation (39).

However, studies conducted by Mohan et al. and Thomas et al. that show the administration of prophylactic IV dexamethasone before surgery decreases the severity of POST after endotracheal tube extubation at 1 hour, 3 hours, and 6 hours following surgery (41,42). This finding is also contrary to a study done by Nandi et al., which found that prophylactic IV dexamethasone reduces the severity of sore throat after ETI at 1 hour and 6 hours after surgery (37). This difference is probably due to using of different methodologie and different target populations.

Contrary to this study, Yang C. et al. demonstrated that administration of prophylactic IV dexamethasone (10 mg) reduces the severity of POST during swallowing at 24 hours following surgery (39). This discrepancy is most likely the result of the use of various airway management techniques and different methodologies, including different study designs and the application of controlled ETT cuff pressures.

According to the findings of this study, the variables significantly associated with the incidence of POST were female gender and supine with head tilt surgical positioning. The duration of ETI also has a difference in the mean time between patients who developed POST and those who did not developed POST.

Female patients were 2.69 times more likely to develop POST than males. This finding is in line with studies conducted in Debre Tabor General Hospital, north-central Ethiopia showed that female patients were significantly associated to POST with an odds of 2.58 times more risky than males (6). Another similar studies conducted in Gondar, Ethiopia and south Ethiopia also supports the findings of this research (7,27). One of the causes of this diference is that due to reporting bias because womens are more likely to report such postoperative side effects (47).

In contrary to this study, a research conducted at Nepal found that there were no significant association between sex and postoperative sore throat following tracheal extubation (4).

In this current study, the odds of developing a postoperative sore throat after surgery in supine with head tilt surgical positioning were 5 times greater than those of patients who underwent surgery in supine and lateral positions. But I can't get research conducted with this variable for comparisons. The probable mechanism could be that the endotracheal tube may move according to the patient's position, which may have an impact on the frequency of POST (25).

In this present study, the mean duration of ETI in patients who developed POST was 161.95 ± 32.24, compared to 150.65 ± 31.16 in patients who did not develop POST. This finding is in line with a study conducted in Nepal and Canada that found the duration of ETI was associated with POST in patients who underwent elective surgery under GA with ETI (4,17). This could be explained by the possibility that a tracheal tube left in place for an extended period of time caused vocal cord or tracheal mucosa irritation (48).

Chapter Seven: Strengths and limitations

7.1 Strengths

Baseline variables, including demographic, surgical, and perioperative characteristics, were homogeneous.

It provides insights and clues about the effects of IV dexamethasone and lidocaine on the incidence and severity of POST following tracheal extubation among patients who underwent elective surgery under GA with ETT for other scholars; since published research could not be found in our country, Ethiopia.

7.2 Limitations

Tracheal cuff pressures were not monitored in this present study due to lack of equipment; hence, sore throat may develop as a result of high cuff pressures during anesthesia by causing mucosal ischemia (8).

As it is an observational study, certain confounding factors could not be controlled.

Exclusions may limit generalizability.

Another limitation is that the geographic regions only covered a single centere, therefore, our results are limited generalizability to the regions.

Chapter Eight: Conclusion and recommendation

8.1 Conclusion

Intravenous dexamethasone (8 mg) decreased the incidence of POST during the first 24 hours of the post-extubation period in patients who underwent elective surgery under GA with ETI. However, no difference was observed in the severity of POST at different time intervals (3hours, 6 hours, 12 hours and 24 hours of post-extubation period) among lidocaine, dexamethasone and control groups. Intravenous lidocaine (1.5 mg/kg) could not have significantly reduced the incidence and severity of POST at different time intervals. Female gender, supine with head tilt surgical positioning and duration of ETI were the variables significantly associated with the incidence of POST.

8.2 Recommendations

The incidence and severity of postoperative sore throat is high, we suggest prophylactic intravenous dexamethasone be given to patients who underwent elective surgery under GA with ETT to decrease the incidence of POST.

We also advise researchers to conduct large sample size with multicenter study designs.

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ANNEXES

Annex I: Information Sheet and Informed Consent Form

Addis Ababa University, College of Health Science, School of Medicine, Department of Anesthesia

Greetings, my name is…….I am a data collector on behalf of **Samuel Belay** for the study entitled "Effects of intravenous Lidocaine and dexamethasone on the incidence and severity of postoperative sore throat after endotracheal tube extubation in adult surgical patients at TASH, Addis Ababa, Ethiopia, 2023; A prospective cohort study". The purpose of this study is to compare the effects of intravenous Lidocaine and dexamethasone on the incidence and severity of postoperative sore throat.

You have been selected to participate in this study. There will be no direct incentive paid for participating in this study since the study is not linked to any financial aid. But in the future, the information gathered by this study will help programmers, researchers, and policy makers to give appropriate attention to issues of interest and treatment options. Being a part of this study will not have any negative impacts. Your participation is not obligatory; it is based on your willingness, and you can stop answering any single question at any time you want. The information you provide- your name and address, or any information that identifies you- will be kept confidential by using only code numbers and locking the data. Your legitimate participation is very important for the success of this project. Therefore, you are kindly requested to participate in this study based on your willingness.

If you need any further information or explanation regarding the study, you can use this address to contact the investigator:

Name: ***Samuel Belay*** Tel- ***+251-919430145***

Do you agree to participate in the study? A. Yes ☐ B. No ☐

Questionnaire code……

Thank you for your participation!

Annex II: Questionnaire

A data collection format for adult patients who underwent elective surgery at TASH, Addis Ababa, Ethiopia. Fill in the blank space provided, encircle the alternatives when necessary, and finally check the questions for completeness.

1. Demographic data

101	Patient code number	…….(please write this code number on the patient's card)
102	Age	..……..…years
103	Gender	1. Male 2. Female
104	Weight	……kg
105	BMI	……kg/m^2
106	ASA physical status	1. I 2. II

2. Preoperative and intraoperative anesthesia and surgical interventions

201	Types of surgery	1. Abdominal 2. Urology 3. Endocrine	4. Vascular 5. Orthopedic 6. Gynecology
202	Preemptive Analgesia given (You can answer more than one alternative)	1. Fentanyl……..mcg 2. Pethidine…….mg 3. Morphine…….mg 4. Tramadol…….mg	5. Non-opioid analgesia (specify with dose)……. 6. Not premedicated
203	Surgical positioning of the patient	1. Supine 2. Trendelenburg 3. Reverse trendelenburg	4. Lateral 5. Prone 6. Lithotomy
204	Groups (which pre-medication agent is taken	1. Lidocaine……..……mg IV 2. Dexamethasone…….mg IV 3. Neither of the two (control group)	

	to decrease postoperative sore throat?)	4. Combined Lidocaine & dexamethasone	
205	Induction agents	1. Ketamine 2. Propofol	3. Ketofole 4. Thiopentone
206	Cormack-Lehane grading scheme for laryngoscopy	1. I 2. II	3. III 4. IV
207	Attempts of Endotracheal Tube Intubation	1. 1 2. 2 3. >2	
208	Size of ETT	…….mmID	
209	Types of ETT cuffs	1. High-volume, low-pressure 2. High-pressure, low-volume	
210	Does the patient take additional lidocaine before extubation?	1. Yes (specify the dose)……..mg 2. No	
211	Does the patient take additional dexamethasone before extubation?	1. Yes (specify the dose)……..mg 2. No	
212	Duration of intubation	……in minute	
213	Is the patient extubated in the operation theater?	1. Yes 2. No	

3. Postoperative sore throat characterstics

301	Do you have sore throat at 3-hours of the postoperative period?	1. No sore throat (0) 2. Minimal sore throat (1) 3. Moderate sore throat (2) 4. Sever sore throat (3)

302	Do you have sore throat at 6-hours of the postoperative period?	1. No sore throat (0) 2. Minimal sore throat (1) 3. Moderate sore throat (2) 4. Sever sore throat (3)
303	Do you have sore throat at 12-hours of the postoperative period?	1. No sore throat (0) 2. Minimal sore throat (1) 3. Moderate sore throat (2) 4. Sever sore throat (3)
304	Do you have sore throat at 24-hours of the postoperative period?	1. No sore throat (0) 2. Minimal sore throat (1) 3. Moderate sore throat (2) 4. Sever sore throat (3)
305	Postoperative total analgesia consumption	Specify……..

Postoperative sore throat assessment tools

A. The scale was taken four times during 24 hours of the post-extubation period following surgery.

B. Patients were asked the following questions to rate the severity of their sore throat:

1. What number on a 0 to 10 scale would you give your sore throat right now?
2. When the explanation suggested above is not sufficient for the patient, further explanation of the scale is done:

    0 = No sore throat

    1 = Minimal sore throat (complaints of sore throat only on asking)

    2 = Moderate sore throat (complaints of sore throat on his/her own)

    3 = Severe sore throat (change in voice or hoarseness, associated with throat pain)

Annex III: Assumption Models

Table 8: Assumptions of Multicollinearity for logistic regresions

Variables	Collinearity Statistics	
	Tolerance	VIF
Age	.687	1.456
gender of the patient	.774	1.291
BMI of the patient	.633	1.579
ASA physical status of the patient	.927	1.078
types of surgery	.919	1.088
analgesia premedication	.927	1.079
surgical positioning of the patient	.884	1.131
induction agents	.919	1.088
cormach-lehane grading scheme for laryngoscopy	.715	1.399
attempts of endotracheal intubation	.798	1.254
size of ETT	.675	1.482
Duration of ETI	.620	1.612
Postoperative analgesia consumption	.627	1.594
Groups of drugs	.454	2.200

Tolerance >0.1 and VIF <10 were acceptable. VIF, variance inflation factors

Table 9: Assumptions of normality for continuous variables: Shapiro–Wilk test

Variable	z	P-value
Age	-0.551	0.70912
BMI	4.269	0.00001
Duration of ETI	1.007	0.15706

p-value >0.05 considerred to be normally distributed