



**THE EFFECTIVENESS OF PROPOFOL VERSUS DEXAMETHASONE
ADMINISTRATION FOR PREVENTION OF POSTOPERATIVE NAUSEA AND
VOMITING IN PATIENTS WHO UNDERWENT EAR, NOSE AND THROAT
SURGERY AT, TIKUR ANBESSA SPECIALIZED, AND YKETIT 12 HOSPITAL,
ADDIS ABABA, ETHIOPIA, 2018**

By: Sintayehu Mulugeta (Masters anesthesia students)

**Advisors: Mr. wosenyele. A. (Bsc, Msc in anesthesia)
Sr. Lemlem (Bsc, Msc in anesthesia)
Sr. Tinbt (Bsc, Msc in anesthesia)**

**A RESEARCH PAPER TO BE SUBMITTED TO ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES DEPARTMENT OF ANAESTHESIA FOR
PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE MASTERS OF
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Name of Investigator	Sintayehu Mulugeta
Name of advisor(s)	Mr. wosenyele.A, Sr. Lemlem and Sr. Tinbt
Full title of the research project	The effectiveness of Propofol versus Dexamethasone administration for prevention postoperative nausea and vomiting in patients underwent ENT surgery
Duration of project	December 20- March 20, 2017/18.
Study area	Tikur Anbessa and yketit Hospital ,Addis Ababa University
Address of investigator	E-mail:smulugeta17@gmail.com

Declaration

I hereby declare the research paper title effectiveness of propofol vs dexamethasone in prevention of PONV submitted by me is based on actual and original work in partial fulfillment of the requirements for the degree of MSc in Advanced Clinical Anesthesia. I understand that plagiarism will not be tolerated, any reference to work done from other source have been duly cited and referenced.

Name: _____

Signature: _____

Submission to MSc Tutor, Department of Anesthesia, Addis Ababa University.

Date of Submission: _____

This thesis work has been submitted for examination with my/our approval as Advisors and Tutors on the MSc in Advanced Clinical Anesthesia course

Name Signature

1. _____

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Abstract

Background: *Postoperative nausea and vomiting is a common postoperative unpleasant and distressefull experience with high incidence among Ear, Nose and Throat surgery primarily occurs with 24 hours can lead to significant morbidity. Several studies have shown that small dose of Propofol has direct ant emetics effect as well as Dexamethasone is effective in prevention of Post operative nausea and vomiting with no significant complications in various types of surgery.*

Objectives: *The aim of the study is to Compare the effectiveness of Propofol vs Dexamethasone administration for prevention of postoperative nausea and vomiting in patients underwent Ear, Nose and Throat surgery at Tikur Anbessa Specialized and Yketit 12 Hospital.*

Methods: *Institutional based Prospective cohort study was conducted at Tikur Anbessa Specialized and yketit 12 Hospital from December 20- March 20, 2017/18. This study was conducted on 80 ASA I and II patients aged 18-65 years. Data was analyzed by using computer software SPSS version 20. Independent t-test were used for Comparison of symmetric numerical and mannwhitney for asymmetric data between groups. Categorical data were analyzed with the Chi-Square test and P- Value of less than 0.05 were considered as level of the signficancy.*

Result: *The incidences of PONV in overall 24 hours period were 35% in propofol and 25% in Dexamethasone group. There was statistically significant difference was found in the incidence of PONV and use of antiemetic (5% VS 0%) in Propofol and Dexamethasone at 12–24hours periods (22.5% vs. 0%) respectively. In overall period 27.5% of patients in propofol, 22.5% of patients were felt mild nausea in Dexamethasone group while 12.5% of patients in Propofol and 5% of patients in Dexamethasone were felt moderate nausea.*

Conclusion and Recommendation: *Dexamethasone administration at end of operation was found effective in prevention of postoperative nausea- vomiting and reduction of rescue ant emetics requirement in patients underwent Ear, Nose and Throat surgery. we recommend to use Dexamethasone as prophylaxis of Postoperative nausea and vomiting in Ear, Nose and Throat surgery*

KEYWORDS: Anesthesia, postoperative nausea and vomiting, propofol , dexamethasone

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List of Acronyms

ASA-American Society of Anesthesiology

BMI-Body Mass Index

ENT-Ear, nose, throat

5HT₃- Five Hydroxytryptamine receptors

ICU-Intensive care unit

NRS – Numeric rating score of nausea

PONV-postoperative nausea and vomiting

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CHAPTER ONE

1.1. Background

Ear, nose and throat surgery is one of commonly performed surgery under general anaesthesia in developing countries. Postoperative nausea and vomiting (PONV) is the most common complications after surgery and anesthesia. It is defined as nausea and vomiting occurring within 24 hours after surgery (1).

Overall it affecting more than 30% of ASA(American society of anesthesiologist) I and II patients, but for ASA III and above patients(among high-risk patients)it can be as high as 70–80% and are reported by patients to be two of the five most undesirable outcomes (1).

The complex act of vomiting involves the co-ordination of respiratory, gastrointestinal and abdominal musculature and is controlled by the emetic centre. This area is situated in the lateral reticular formation close to the tractus solitarius in the brain stem and is thought to be emetic centre. Electrical stimulation of the emetic centre and tractus solitarius will cause immediate vomiting (2).

Propofol is a novel total intravenous anesthetic that has been shown to possess antiemetic properties when administered in sub-hypnotic doses as part of combination therapy. However, the exact mechanism by which Propofol acts as an antiemetic remains unclear. It has been postulated that its antiemetic effects may be as an antagonist at the 5-HT₃ receptor. It is widely believed that Propofol based Anaesthesia reduces post operative nausea (3).

Several studies have shown that dexamethasone, a corticosteroid, is an effective antiemetic for PONV prophylaxis in various types of surgery and in improving surgical outcomes (4).

Although reports on propofol and steroid therapy are available in different country, no evidence was covered regarding comparing the effects of Propofol VS Dexamethasone for the prevention of PONV in Ethiopia. So, Updating the health professional with new and alternative agent to reduce incidence of post operative nausea and vomiting a necessary option especially in ENT surgical patients. Hence this study will aim to compare effectiveness of dexamethasone with sub hypnotic dose of propofol for prevention of PONV.

1.2. Statement of the problem

Postoperative nausea and vomiting (PONV) is a long-standing and multi-factorial problem for anesthesia practitioners with a significant and the most distressing morbidities, associated with surgery and anesthesia that has been repeatedly investigated in surveys of incidence (5).

PONV develops as a complication after anesthesia, and surgery, if not prevented, recovery and hospitalization time can be prolonged, leading to unpleasant hospital experiences and increased health care costs (6). Prolonged vomiting may result in electrolyte imbalance (hypocalcemia, hypochloremia, hyponatremic metabolic alkalosis) and dehydration, Mallory-Weis tears, Esophageal rupture, Aspiration, increases the risk of postoperative bleeding, and airway obstruction specially in patients undergoing ENT surgery (7).

In the absence of antiemetic treatment, currently, the overall incidence of PONV is estimated to be 28 to 80%, with severe, intractable PONV estimated to occur in approximately 18% for all surgical interventions and patient population (1).

In a study done in Australia overall 37.7% of patients experienced nausea-vomiting as most frequently recorded complications in the first 24 hours (8). From Africa, a prospective study done in Nigeria found the incidence of nausea and vomiting 24 hours after surgery is 41.6 % (9). The overall incidence of PONV in our country is reported to be 36.2 % as study done in Gondar (10).

The pathophysiology of PONV is multifactorial; multiple pathways, neurotransmitters and risk factors are involved, therefore a multimodal approach is the optimal strategy for management of PONV. However, whether prophylaxis or treatment is more effective in reducing the incidence remains controversial (11). PONV is associated with several risk factors including age, gender, history of previous PONV or motion sickness, smoking, obesity, surgical and Anaesthetic related factors, patient and parental anxiety (12).

Ear, Nose and Throat is one of specialty involving head and neck surgery which is associated with an appreciably high rate of postoperative nausea and vomiting (30–70%) in relative to other surgery when no prophylaxis is done (13-15). Research has shown that the use of several different antiemetic medications can reduce the occurrence of PONV from over 52% to less than 30% in certain populations (16). In an attempt to decrease the incidence of nausea-vomiting, a number of antiemetics have been studied. However, Most of ant emetics used is ant histamine, butryphenones (droperidol) and dopamine antagonist (metochlopramide) to prevent PONV,

however they may have undesirable adverse effect such as excessive sedation, hypotension , dysphoria, dry mouth, restlessness and extra pyramidal symptoms. The condition remains a challenge for anesthesiologists. The selective serotonin receptor–antagonist are highly effective in prevention of PONV, But it is highly cost (4). Dexamethasone is a glucocorticoid and has been used as an antiemetic drug in patients receiving chemotherapy for more than 25 years. Several prospective studies have shown that severity of PONV associated with LC is reduced by dexamethasone (17, 18). Many study shows that IV low dose of Propofol (0.5mg/kg) is as effective drug for prevention of PONV with no significant complication (5); even though it has been used by a number of anesthesiologists it is still under investigate (17). As far as knowledge and search of author no published study on this area.

Hence, the aim of this study is to comparing effectiveness sub hypnotic dose of propofol versus dexamethasone for as PONV Prophylaxis in Ethiopia.

1.3 Significance of the study

Postoperative nausea and vomiting (PONV) is still one of the most widely arising complications even with numerous advances in medicine (6).

Even though PONV is a major cause of morbidity following surgery and anesthesia, attention is not given for the incidence of this problem.

To maintain the efficacy and cost-saving benefit of surgery, effective antiemetic administration and prophylaxis for certain patients undergoing surgery would be desirable. Less time recovering in the post anesthesia care unit and in the hospital not only equates to less cost to the patient and healthcare facility but also to an increase in patient satisfaction. In order to provide economical effective care for surgical patients, interventions must be geared towards reducing the occurrence of postoperative complications.

The managements of PONV vary between different studies. This is attributed to difference in the incidence of PONV among different population. Differences in the patient characteristics, clinical setup and skill of the anesthetists or other practitioners can also influence the management of PONV.

Use of Propofol and dexamethasone as prophylaxis of PONV is inexpensive and effective, with minimal adverse effects after single-dose administration (19).

It has been studied in different part of the world, But As far as my knowledge goes, there is no previous study done in our country on comparing the effectiveness of dexamethasone vs. sub hypnotic dose of propofol as PONV prophylaxis. Evidence based local or national data on effectiveness of dexamethasone vs propofol as prophylaxis of PONV will help anesthetists and other practitioner to improve quality of anesthesia care, patient comfort and reduce incidence of PONV. The study will provide the advanced and alternative clinical knowledge for prevention of PONV in ENT surgical patients. It can also be used as a base line data for further multicenter studies and for the development of guidelines for PONV Prevention .The purpose of this study is therefore, to provide evidence based information to the anesthetists and other concerned professionals on comparing effectiveness of dexamethasone vs. sub hypnotic dose of propofol as PONV Prophylaxis in selected Hospital.

CHAPTER TWO

Literature review

Postoperative nausea and vomiting (PONV) is a common postoperative unpleasant and distressful experience with high incidence among ENT surgery (20).

Its occurrence is miserable for the patient and both troubling and perplexing to the provider. It is not surprising that a staggering number of publications have been dedicated to the prevention and management of this complication. Unfortunately, its pathophysiology is incompletely understood, and the many contributing factors have rendered the majority of the publications inconclusive (21).

DEFINITIONS AND PHYSIOLOGY

Nausea and vomiting are distinct entities that may occur at any point during or after a clinical procedure. Vomiting or emesis, which is the actual oral expulsion of gastrointestinal contents, is the result of contractions of the gut and the thoraco abdominal wall musculature. Nausea refers to a subjective feeling of the need to vomit (21).

The vomiting center lies in the medulla oblongata and comprises the reticular formation and the nucleus of the tractus solitarius. When activated, motor pathways descend from this center and trigger vomiting. These efferent pathways travel within the 5th, 7th, 9th, 10th, and 12th cranial nerves to the upper gastrointestinal tract, within vagal and sympathetic nerves to the lower tract, and within spinal nerves to the diaphragm and abdominal muscles. The vomiting center can be activated directly by irritants or indirectly following input from 4 principal areas: gastrointestinal tract, cerebral cortex and thalamus, vestibular region, and chemoreceptor trigger zone (CRTZ) (21).

Possible mechanism of action of dexamethasone in PONV Prevention

At present, the mechanism of action of dexamethasone in PONV prevention is still not fully understood. Dexamethasone is a synthetic form of adrenocorticoid, and acts mainly as a glucocorticoid receptor with almost no mineral corticoid receptor functions. Some glucocorticoid receptors are related to the physiological conduction path for vomiting (22). The glucocorticoid receptors exist in the part of the brain stem where the nucleus of solitary tract and area postrema reside (23). Recent animal experiments have proved that glucocorticoid receptors on both sides

of the nucleus of the solitary tract, not area postrema, in the brain stem act to conduct the main antiemetic effect of dexamethasone (24, 25). Other possible explanations for dexamethasone preventing PONV include central inhibition of prostaglandin synthesis, reduction of central serotonin activity, and change of permeability of blood-brain barrier to plasma proteins. Dexamethasone can effectively reduce local inflammatory reactions after surgery; this may reduce the inflammation triggered by afferent stimulation of parasympathetic nervous system to the vomiting center, thereby reducing PONV (26).

Dosage and timing of administration of dexamethasone

As randomized placebo control study done at ,oxford university, London demonstrate that the recommended intravenous dose of dexamethasone for prevention of PONV in adults is 2.5-10 mg is also effective in patients under went tonsillectomy and strabismus surgery (18, 27).

A 2008 Study done at Geneva, Switzerland shows that At 24 hours, 24 of 54 participants who received placebo (44%; 95% confidence interval [CI],31%-59%) had experienced PONV compared with 20 of 53 (38%;95% CI, 25%-52%), 13 of 54 (24%; 95% CI, 13%-38%), and 6 of 52 (12%; 95% CI, 4%-23%) who received dexamethasone at 0.05, 0.15, and 0.5 mg/kg, respectively (P0.001 for linear trend) (28). As a result, different optimal doses of dexamethasone are used to treat nausea and vomiting caused by various emetic factors. The timing of administration of dexamethasone is crucial for preventing PONV. Intravenous dexamethasone generally requires a longer period of time to take effect and a time lag of 12-24hours to achieve the maximal result and its physiological effect in the body can remain for 36-72 hours (29). In terms of these pharmacological properties, the characteristic of dexamethasone is clearly a drug with the slow onset time and long duration of action. Studies have showed that the antiemetic effect of dexamethasone begins approximately 2 hours after intravenous injection (25).

Chemotherapy patients have also reported that dexamethasone is effective in preventing a late onset of vomiting (30, 31). In preventing an early onset of PONV (nausea and vomiting occurring 0-6 hours after surgery is considered an early onset of PONV; nausea and vomiting occurring after 6-24 hours is considered to be a late onset of PONV). However, no studies have touched the duration of antiemetic effect of dexamethasone, but a duration of up to 24 hours after surgery is generally accepted as a fact(32, 33).

As randomized study conducted in Taiwan on patient underwent laparoscopic cholecystectomy showed that 5mg of dexamethesone is effective in prevention of PONV(P<.01) (18). Two double

randomized studies on meta analysis on compared two doses of dexamethasone and concluded that doses of 8 to 10 mg were significantly more effective at reducing the overall incidence of PONV than doses of 4–5 mg (RR 0.54, 95% CI 0.34–0.88) (34).

The effect of Dexamethasone for the prevention of PONV

As the preventive effect of Dexamethasone against chemotherapy induced nausea and vomiting was real, many studies on Dexamethasone in preventing PONV in various surgical procedures have discovered that the results are generally quite favorable. These procedures have included laparoscopic cholecystectomy, laparoscopic tubal ligation, hysterectomy, thyroidectomy, ENT surgery, total knee replacement and strabismus surgery (12, 32, 33).

The potential adverse effects of using Dexamethasone

Adverse effects from using large amounts of dexamethasone may include difficulty in controlling blood sugar levels, wound infections, delayed wound healing, gastric ulcers, and a vascular necrosis. These are potential adverse effects of long-term use of dexamethasone (32, 33, 35). Recent studies have shown that although a single use of a low-dose of dexamethasone is effective in preventing PONV (36). Furthermore, in numerous studies on prevention of PONV with Dexamethasone, no fatal outcomes have been reported (28, 35). Therefore, Dexamethasone is generally considered a safe antiemetic.

Possible mechanism of action of propofol in PONV Prevention

The antiemetic mechanism of propofol is not clearly known. But there is some vague theoretical mechanism of ant emetics effect of propofol includes direct depression action on chemoreceptor trigger zone, vagal nuclei or modulation of subcortical pathway and possibly due to its weak serotonin antagonist effect (37). Randomized Clinical trial study conducted at Zurich, Switzerland by Borgeat et al. demonstrated that propofol in subhypnotic doses (10mg) possesses direct antiemetic properties in the context of minor elective surgery (17).

Dosage and timing of administration of propofol in prevention of PONV

The dosage of propofol that needs to be administered to have antiemetic effect has always been a challenge. Various studies have tried to identify appropriate doses for the antiemetic effect of propofol. According to randomized control study done by Borgeat et al reported use of 17ug/kg/min propofol infusion in a group of patients receiving cisplatin chemotherapy (11). A case report by Schulman et al indicates that the plasma concentration of propofol to treat refractory PONV is 197ng/ml (38). Moreover, Borgeat et al administered a bolus of propofol in

the dose of 10-20mg, for the treatment of PONV (11). In another study, Kim et al found that 0.5mg/kg of propofol is effective preventing in PONV (13, 39).

Song et al have shown that intravenous (IV) administration of 0.5 mg/kg propofol, a low dose, at the end of surgery was effective in preventing nausea and vomiting after Laparoscopic cholecystectomy (11). Time of administration of propofol for prevention of PONV is still controversial (40).

The effect of propofol for the prevention of PONV

Furthermore, the use of propofol for maintenance of anesthesia has a positive effect on PONV reduction (41).

According to a 1999 to double blind randomized comparison study of small dose of propofol vs placebo by American anesthesiology society Propofol as an induction and maintenance agent has been associated with a lower incidence of PONV (42). More recently, propofol in subhypnotic doses has been shown to be effective against chemotherapy-induced nausea and vomiting (11).

A 2001 Double blind randomized comparative study of efficacy of propofol versus metoclopramide conducted in Japan Toride kayto hospital, conclude that small dose of propofol has better ant emetic effect than metochlopramide a patient underwent middle ear surgery (43).

Another double-blind, randomized Comparison of sub hypnotic doses of thiopentone vs propofol on the incidence of postoperative nausea and vomiting following middle ear surgery at Helsinki University Central Hospital Haartmaninkatu ,Helsinki Finland Conclude that the patients in the propofol group did not suffer from retching and vomiting (R&V) during the first 6 hrs and less ant emetics requirement during the first 24 hrs (44).

Recent observational cohort study done in Gondar, Ethiopia, on comparison of propofol and usual care conclude that Administration of a sub hypnotic intravenous dose of propofol was effective in reducing the incidence and severity of PONV, and the need for rescue anti-emetic during the first six postoperative hours in patients undergoing open abdominal surgery under general anaesthesia (45).

The effect of dexamethasone versus propofol for the prevention of PONV

A 2015 randomized clinical trial study done in Turkey at Ataturk University comparing Subhypnotic of Propofol versus Dexamethasone in Prevention of Postoperative Nausea and Vomiting Related to Laparoscopic Cholecystectomy (46). In 0–24 hours, the incidence of PONV

was significantly lower in the dexamethasone group and Propofol group compared with Control group (37.5%, 40%, and 72.5%, respectively). There was no significant difference in the incidence of PONV and use of anti-emetics between the groups. The study concludes that subhypnotic dose of propofol 1mg/kg is as effective as dexamethasone for the prevention of PONV during the first 24 hours after anesthesia in patients undergoing Laparoscopic Cholecystectomy (45).

A 2011 Randomized, Double-Blind Study done at Gazi University Faculty of Dentistry, Ankara, Turkey on comparing the effectiveness of subhypnotic dose of propofol vs dexamethasone on laparoscopic cholecystectomy concludes that the total PONV rates up to 24 hours post anesthesia were 20% and 50% for dexamethasone group and propofol group, respectively. There were no significant differences between the values at 4 to 12 hours and at 12 to 24 hours. The studies were conducted in different countries and most of them come up to a conclusion that incidence of PONV is significantly lower in dexamethasone than in subhypnotic dose of propofol (47).

A 2015 study conducted in India on Study of efficacy of Propofol, Ondansetron and Dexamethasone in prevention of PONV following thyroidectomy concludes that overall incidence of PONV in the first 24 hour period was 35% in propofol group, 25% in ondansetron group and 20% in dexamethasone group (48).

However, still there is a conflict among the literature on timing of either propofol or dexamethasone administration for PONV and till now these studies lack literature in our country so this study will focus on comparing the effectiveness of dexamethasone VS subhypnotic dose of propofol for postoperative nausea and vomiting prevention among ENT surgical patients at Tikur Anbessa Specialized and Yekatit 12 Hospital to fill this gap.

Conceptual Framework

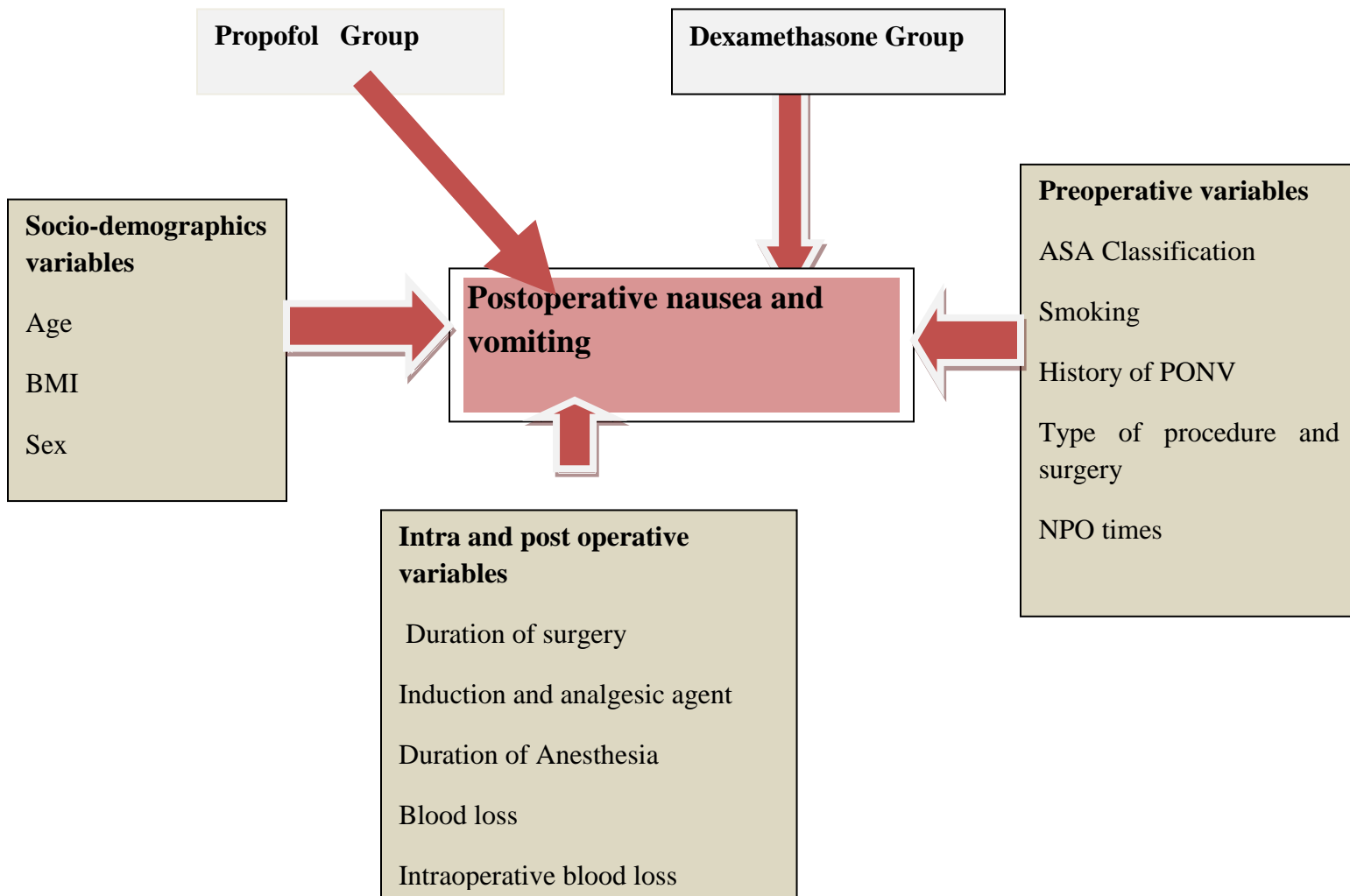


Figure 1: schematic presentation conceptual Frame work.

Hypothesis Test

H0: The effect of sub hypnotic dose of Propofol is not significantly comparable with Dexamethasone in prevention of post operative nausea vomiting for 24 hours.

H1: The effect of sub hypnotic dose of Propofol is significantly comparable with Dexamethasone in prevention of post operative nausea vomiting for 24 hours.

H0: There is not significant difference in severity of post-operative nausea between Propofol group and Dexamethasone group during 24hours.

H1: There is significant difference in severity of post-operative nausea between Propofol group and Dexamethasone group during 24hours.

H0: There is no significant difference in requirement of rescue ant emetic between propofol group and Dexamethasone group during 24hours.

H1: There is significant difference in requirement of rescue ant emetic between Propofol group and Dexamethasone group during 24hours.

CHAPTOR THREE:

Objectives of the Study

3.1. General objective

To compare the effectiveness dexamethasone and propofol in prevention of post operative nausea and vomiting in patients undergoing ENT surgery at Tikur Anbessa Specialized and yketit 12 Hospital ,Addis Ababa, December 20- march 20, 2017/18.

3.2. Specific objectives

1. To compare the incidence of post operative nausea and vomiting between Propofol and Dexamethasone group in patients undergoing ENT surgery.
2. To compare severity nausea between propofol and dexamethasone group in patients undergoing ENT surgery.
3. To compare post operative ant -emetics needs between two groups in patients undergoing ENT surgery.

CHAPTER FOUR: Methodology

4.1. Study area and period

The study was conducted in Addis Ababa University, college of health sciences, TikurAnbessa Specialized Teaching and Yketit Hospital. The Tikur Anbessa hospital is located in the heart of Addis Ababa and it is the largest teaching hospital in Ethiopia having about 800 beds and 17 well equipped operation room, recovery with 13 beds, Adult, neonatal and pediatric ICU and other specialty units. It provides diagnosis and treatment for 370,000- 400,000 patients per year and approximately 7000– 9000 patients undergo surgery in a year. The Hospital is also used as a teaching hospital and research center for the College of Health Sciences, Addis Ababa University. It has above 150 specialists, in various areas of medical ,pediatric, gynecology and surgical specializations and fairly adequate numbers of all the other health professionals constituting the health care team. Currently the hospital provides surgical service from Monday to Friday including general surgery, neuro, orthopedics, ENT, cardiothoracic and gynecological procedure based on proposed schedule. Yketit 12 hospital is also one of Referral Hospital providing comprehensive medical service under the management of Addis Ababa Health Bureau. The data was collected from December 20- March 20, 2017/18.

4.2. Study Design

Institutional based Prospective observational cohort study was conducted in patients undergoing ENT surgery at operation room, recovery or wards in the first 24hours of post operative day.

4.3. Population

4.3.1. Source population: All elective ENT patients who were scheduled for surgery in Tikur Anbessa specialized Hospital and Yketit 12 Hospital

4.3.2. Study population: All patients who were met inclusion criteria and underwent elective ENT surgeries under anesthesia during study time.

4.4. Sample size determination and sampling Techniques

4.4.1. Sample Size Determination

Double proportion sample sized based on proportion of nausea and vomiting between two groups was used to calculate sample size for each group. Since there is no previous study done in the study area, result adopted from literature has been used to calculate sample size based on the two outcome variable and the largest sample size was used for recruiting study subjects. From recent study in India, the proportion of patients experienced PONV with propofol group and dexamethasone group were 50% and 20% respectively (50, 51)

The required sample size to show with 95% likelihood that the proportion N/V within 24 hours is equal between two groups was calculated as

$$n_1 = n_2 = \frac{\left(z_{\alpha/2} \sqrt{2\bar{p}\bar{q}} + z_{\beta} \sqrt{p_1q_1 + p_2q_2} \right)^2}{\Delta^2}$$

Where

$$\bar{p} = \frac{p_1 + p_2}{2} \quad \bar{q} = 1 - \bar{p}.$$

$\Delta = p_1 - p_2$

Where n = the sample size in each of the groups

as:

n1= number of patients taken propofol

n2 = number of patients taken dexamethasone

Z= 95% confidence interval =1.96

$f(\beta) =$ the power function at 80% = 0.84

P1–proportion of ponv in propofol group

P2- proportion of ponv in dexamethasone group

From the literature of the proportion N/V, P1=0.5 in Propofol group P2= 0.2 in dexamethasone group

Substituting variables =

$$\frac{(1.96\sqrt{2 \times 0.64 \times 0.36} + 0.84\sqrt{0.5 \times 0.5 + 0.2 \times 0.8})^2}{(0.5 - 0.2)^2} = 38$$

n = 42 considering non respondent rate of 10%. using 1:1 ratio between groups and a total of 84 patients will be required.

4.4.2. Sampling Technique

Systematic random sampling was used to select study participants on daily operation schedule list. Based on average values of the previous surgery over 3 months on the log book, 166 patients were underwent ENT Surgery. The patients were Selected every K^{th} unit as on log book data at study area 166 were underwent ENT surgery. The sampling interval K was calculated using formula: $K = N/n = 2$. Eighty participants were enrolled with the chance of 50%. Patients were ordered by listing of patients underwent ENT surgery consecutives. The first patient was selected by lottery method. Finally data collection was made every 2 consecutive patients underwent surgery in both groups until required sample size was reached.

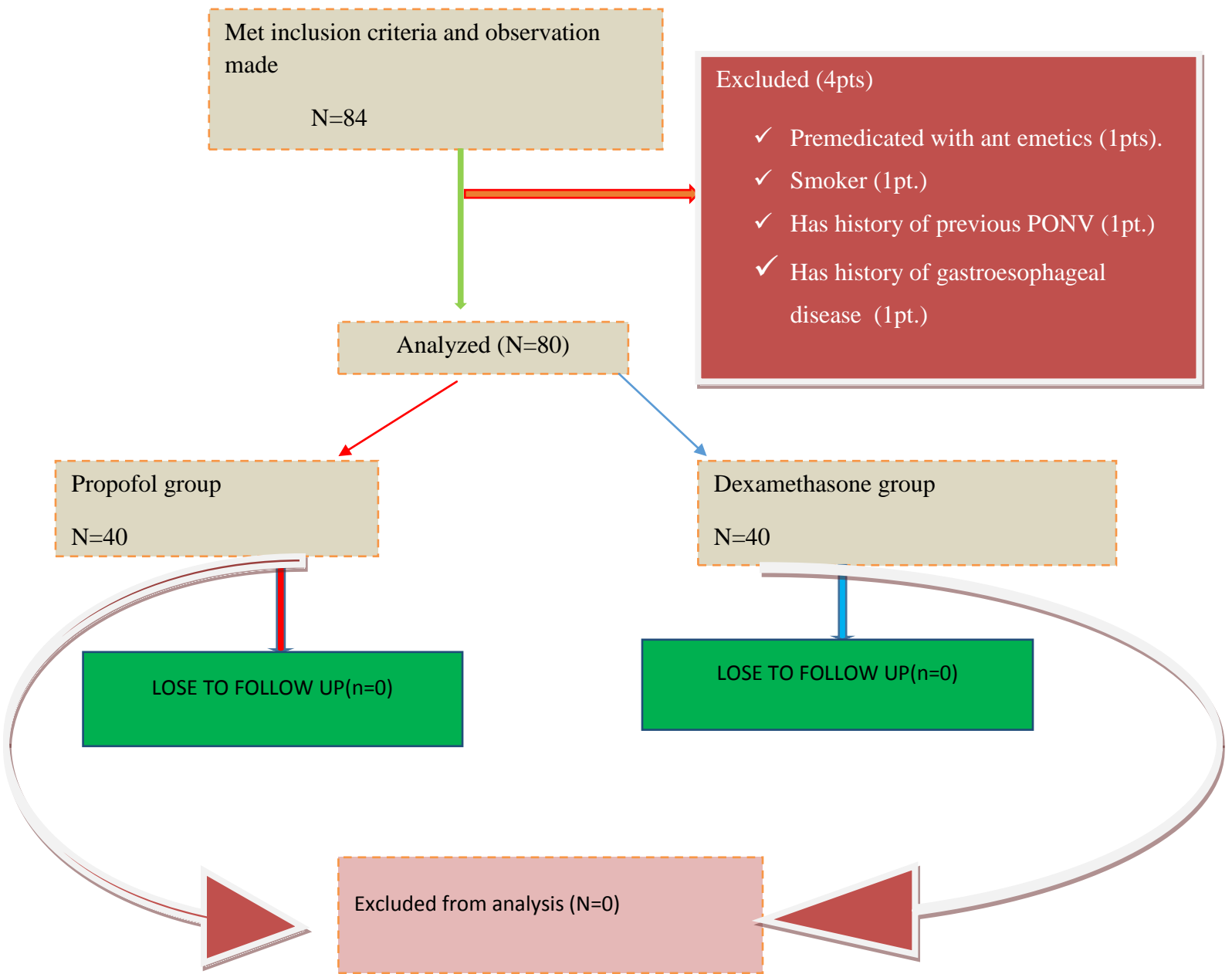


Figure 2: Enrollment chart for elective ENT patients scheduled at Tikur Anbessa and Yketit 12 Hospital.

4.5. Eligibility criteria

4.5.1. Inclusion criteria

ASA I and II Patients

Patients aged 18-65years underwent surgery under general Anesthesia. ⁽²⁾

4.5.2. Exclusion criteria

Hypersensitivity to drugs

Emergency patients

All subjects requiring admission to the intensive care unit or mechanical ventilation.

Ant emetics premedication.

Smoker

History of nausea vomiting

Hypotension

Gastro esophageal reflex disorder

Insulin dependent Diabetics

4.6. Study Variables

4.6.1. Independent variables

Sociodemographics variables

Age

Sex

ASA classification

NPO times

Intraoperative variables

Propofol

Dexamethasone

Type of surgery

Duration of surgery and anesthesia

Intra operative blood loss

Induction and analgesic agent

4.6.2. Dependent variables

Postoperative Nausea and Vomiting

Rescue ant emetics

4.7. Data Collection Technique

4.7.1. Data Collection tool and procedure

Data collection was carried out by structured and pretested questionnaire which consisting of general patient characteristics information and which was prepared in English. The response was circled or written with pen in provided space. The data was collected by two Anesthetists and two nurses, just after brief training on the topic and how to collect the data was given. All Patients who met the inclusion criteria and underwent ENT surgery was recruited into the study during specified period at Recovery room or ward.

4.7.2. Data processing

After verbal consent was obtained from respondent, approval letter from concerned body received and the questionnaire was filled by data collectors. Finally the filled questionnaire was collected by principal investigator. Data collected for outcome measurement was included the administration, timing, and dosage of a rescue antiemetic due to an incidence or complaint of nausea and/or vomiting, as well as readmission to the hospital within 24 hours following a surgical procedure due to a complaint of PONV. All patients who were scheduled for elective ENT surgery and who fulfill inclusion criteria and volunteer to take part in the study were instructed on how to self-report nausea using the eleven point NRS score 0 to 10 in the morning of operation day at ward with trained data collectors. Induction of anesthesia was done with thiopentone or ketamine and maintenance with halothane. The Anesthetists were routinely using subhypnotic dose of propofol or Dexamethasone based on their experience as prophylaxis of PONV prevention. The data collectors were assigning the patients as the ant emetic prophylaxis were given based on their practice. Almost all of M.Sc or Bsc anesthesia professionals including M.Sc. anesthesia student were provide the prophylaxis drug at the time of skin incision closure. All patient were extubated and transferred to recovery room after widely awake where patients were stay for minimum of one hour and transferd to ward. The degree of postoperative nausea were scored using NRS of nausea. The occurrence of nausea, its severity and vomiting as well as

additional anti emetics administration were recorded at immediate post operative, 6th hour, 12th hour and 24th hour at recovery or wards after the end of surgery. In addition, associated adverse effects were also documented within 24 hours.

4.7.3. Data Analysis and Interpretation

Data was checked manually for completeness, coded and entered in to Epi info version 7 computer software for cleaning and then exported to SPSS Version 20 for analysis. Descriptive statistics was used to explore the socio-demographic characteristics of patients or data was presented as mean± Standard deviation for normal distributed and median and interquartile range for asymmetric data. Plot, skewness and kurtosis, curve with histogram Shapiro Wilk test was used to test for distributions of data while homogeneity of equal variance was assessed using Levene's test. Comparison of numerical data between groups was evaluated using Independent t-test and Mann Whitney test based for symmetric and asymmetric data respectively. Categorical data was analyzed with the Chi-Square test or Fisher exact test as needed and P- Value of less than 0.05 and power of analysis 80% was considered as significantly associated with outcome variable. Frequency and percentage were used to describe categorical variable and statistical difference between groups were tested using Chi square test.

4.8. Data Quality control measure

4.8.1 Pre test

Pretest was carried out to test the quality and effectiveness of the questionnaires on 5 % of the study subject, to assess clarity, understanding ability, flow and consistency, and was revised prior to the actual data collection. Pretest was done at Minillik II hospital on 4(5% of sample) respondents 2 in Propofol group and 2 in Dexamethasone group who underwent ENT surgery under General anesthesia and were not included in the main study.

4.8.2 Quality control

During the data collection supervision of data collectors was undertaken by the principal investigator throughout. Data collectors and supervisor were trained on each item included in the study tools, objective of study, rights of respondents, confidentiality of information obtained. During data collection, regular supervision and follow-up was made. Investigator was cross-checked for completeness, ambiguous suspicions, impossible variables filled and consistency of data on a daily basis. Once the data was collected and checked for completeness, consistency and accuracy, it was sorted, categorized and summarized.

4.9. Dissemination of Result

The result of the study will be disseminated to the authority of college of health science and school of medicine/departments of anaesthesia, Tikur Anbessa specialized and Yketit 12 hospital, Addis Ababa University student research office, Ethiopian Anesthetist Association and national or international journal for publication.

4.10. Ethical Consideration

Ethical clearance was obtained from the university ethical clearance committee after reviewing the proposal by the ethical committee of the college before the start of the study. Then after official letter for permission was requested from college of public health and medicine, which was given to Tikur Anbessa specialized and Yketit 12 Hospital clinical director office. The objective of the study was explained & verbal informed consent was obtained from each participant by the data collector. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients.

4.11. Operational definition

Anesthesia: pharmacology induce loss of conscious, reflex, sensation, memory and free from pain.

ASA status: is a surgical risk stratification validated by American Society of Anesthesiologists; described as follows:

ASA I: a healthy patient with no organic/physiological/psychiatric problems

ASA II: controlled medical conditions with mild systemic effect and no limitation of functional ability

ASA III: medical condition with severe systemic effect, limitation in functional capacity

ASA IV: poorly controlled medical conditions associated with significant impairment in functional ability that is potential threat to life

ASA V: critical condition, little chance of survival without surgical procedure

ASA VI: brain dead patient undergoing organ donation

Elective surgery: is surgery done before on set (appearance) of any complication that might constitute urgent indication.

Early post-operative time: the time when the patient reaches to post Anesthesia care unit n to six hours.

Late post-operative time: time considered from six hours of patient reached to post Anesthesia care unit to twenty four hours.

Nausea: is an unpleasant sensation associated with the urge to vomit, which is the forceful ejection of liquid **or** semisolid stomach contents.

Numeric rating score: is a valid nausea/vomiting intensity assessment tool that involves asking a patient to rate his or her nausea intensity from 0-10(11 point scale) with the understanding that 0 is equal to no nausea and 10 equal to the worst possible nausea (49).

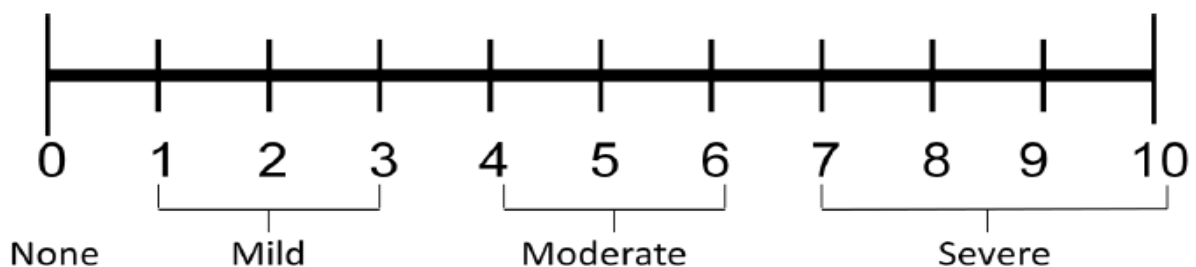


Figure 3: 0-10 point NRS of nausea scoring scale .⁽⁴⁹⁾

Post operative nausea and vomiting: any nausea, retching or vomitus occurring in the first 24 hours after surgery

Retching- labored spasmodic, rhythmic contraction of the respiratory muscles without the expulsion of gastric contents

Sub hypnotic dose of propofol-ant emetic dose of propofol (0.5mg/kg).

Vomiting: forceful expulsion of gastric or intestinal contents through the mouth.

CHAPTER FIVE: Results and Discussion

5.1. Results

5.1.1. Sociodemographics and preoperative characteristics

A total of 80 ASA I and II adult (18-65 Yrs) patients underwent ENT surgery under general anesthesia were included in the study. They were divided into two response rate of 100%. The majority of patients were ASA I (82.5%) and females (51.25%). There were no statistically significant difference between the two groups in terms of age, oral intake time's, sex, BMI, type of surgery, ASA classification, duration of anesthesia, and surgery (**Table 1**).

Table 1: sociodemographics and preoperative characteristics of patients underwent ENT surgery Tikur Anbesa Specialized and Yketit 12 Hospital , Addis Ababa University, Ethiopia, December 20- March 20, 2017/18.

Variables	Propofol group N=40	Dexamethasone group N=40	Total	P value
Age (mean \pm SD)	33.57 \pm 10.9	32.9 \pm 10.6	32.94 \pm 10.64	0.595
Sex (Female /male n%)	55%/45%	47.5%/52.5%	51.2%/48.8%	0.655
ASA(I/ II n%)	80% /20%	87.5% /12.5%	82.5% /17.5%	0.544
BMI (median and IQR)	20.5(19-22.4)	20.7(19.5-21.6)	41.2(19.6-21.9)	0.897
NPO times(hrs) (median andIQR)	10(9-10.5)	10(9-10)	20 (9-11)	0.817
Type of surgery				
middle ear surgery	18(45%)	17(42.5%)	35(43.75%)	0.34
nasal surgery	9(22.5%)	8(20%)	17(21.25%)	0.489
throat surgery	13(32.5%)	15(37.5%)	28(35%)	0.241
Total	40	40	80	

Hint -n (%) =number and percentage

The value are given as mean \pm SD for age, Interquartile range (IQR)and median for BMI and number of patients or frequency for the rest.

5.1.2. Intraoperative characteristics

Most of the patient were induced with thiopentone(55%). tramadol and diclofnac(48.75%) were the most commonly used analgesic agents. There were no statistically significant difference in the intraoperative variables between the two groups(**Table2**).

Table2 :Intraoperative characteristics of operated patient at Tikur Anbesa Specialized and yketit 12 Hospital , Addis Ababa University, Ethiopia, December 20- March 20, 2017/18.

Variables	Propofol group N=40	Dexamethasone group N=40	P value
duration of surgery(min) (Median and IQR)	65(45-110)	57(50-80)	0.354
duration of anesthesia(min) Median and IQR	80(57.5-120)	65(60-85)	0.268
estimated intra operative blood loss (ml) Median and IQR	150(100-300)	150(100-250)	0.996
Total fluid replaced(ml) Median and IQR	800(500-1000)	700(525-1000)	0.294
Induction agents			
Ketamine	20(50%)	16(40%)	0.5
Thiopentone	20(50%)	24(60%)	0.354
Intraop analgesia			
Fentanyl	5(12.5%)	6(15%)	0.64
Morphine	10(25%)	6(15%)	0.274
pethidine	6(15%)	8(20%)	0.655
Tramadol and diclofnac	19(47.5%)	20(50%)	0.705

Hint -n (%) =number and percentage

Primary outcome variables

5.1.3. Incidence of PONV and ant emetic Requirement

There was significant association in the incidence of PONV and requirement of rescue ant emetics in the 12-24 hours of postoperative day (22.5% vs 0%), in propofol and dexamethasone group respectively ($\chi^2=10.14$, $p=0.002$, 95% CI (0.09-0.36)) (**Table 3**).

Table 3: Incidence of PONV at Tikur Anbessa Specialized and yketit 12 Hospital during 24 hours, Addis Ababa University, Ethiopia, December 20- March 20, 2017/18.

Scale of PONV	Propofol group (N=40)	Dexamethasone group (N=40)	X ²	P value
0–6 hours				
None (n%)	33(82.5%)	33(80%)		
Nausea (n%)	5(12.5%)	6(15%)	.105	0.745
Vomiting (n%)	2(5%)	1(2.5%)	.346	0.553
Rescue antiemetic (n%)	1(2.5%)	1(2.5%)	0.000	1.000
Total PONV (n, %)	7(17.5%)	7(17.5%)	0.000	1.000
6-12 hours				
None (n%)	31(77.5%)	34(85%)		
Nausea (n%)	6(15%)	4(10%)	.457	0.499
Vomiting (n%)	3(7.5%)	2(5%)	0.000	1.000
Rescue antiemetic (n %)	3(7.5%)	0%	.384	0.241
Total PONV (n, %)	9(22.5%)	6(15%)	.738	0.39
12-24 hours				
None (n%)	31(82.5%)	40(100%)		
Nausea (n%)	6(15%)	0%	6.486	0.026*
Vomiting (n%)	3(7.5%)	0%	4.276	0.039*
Rescue antiemetic (n%)	2(5%)	0(0%)	5.356	0.021*
Total PONV (n, %)	9(22.5%)	0%	8.01	0.002*

n (%) =number and percentage * =statistically significant

The overall incidence of PONV at 0-24 hour were (95%CI (0.2-0.5) 35% vs. 25% 95% CI(0.11-0.39) in propofol and dexamethasone group respectively ($X^2=.952$, $p=0.329$).

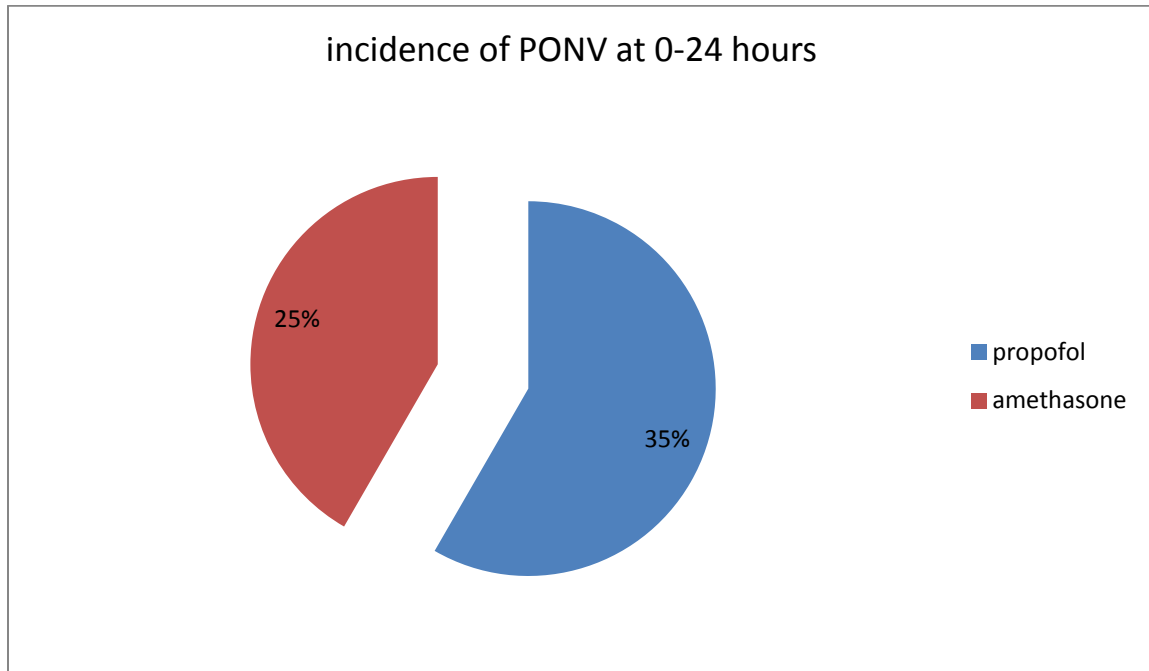


Figure 3: Overall Incidence of PONV at Tikur Anbessa Specialized and yketit 12 Hospital during 24 hours, Addis Ababa University, Ethiopia, December 20- March 20, 2017/18.

Secondary outcome

5.1.4. Severity of nausea

Totally (27.5% vs 22.5%) of patients were felt mild and (15% vs 5%) of patients were felt moderate nausea in Propofol and Dexamethasone group respectively in overall period. where as statistically significant association was found in the 12-24hrs. ($p=0.012$) (**Figure 3**).

Table 4: Comparison of postoperative nausea severity using 11 point NRS score (0-10) at Tikur Anbesa Specialized and Yekatit 12 Hospital, Addis Ababa University, Ethiopia, December 20-March 20, 2017/18

Severity of nausea	Propofol groups (N=40)	Dexamethasone Group (N=40)	P Value
0-6 hours			
No	33(82.5%)	32(80%)	0.812
mild	5(12.5%)	7(17.5%)	
moderate	2(5%)	1(2.5%)	
severe	0(0%)	0(0%)	
6-12hours			
No	31(77.5%)	35(87.5%)	0.253
mild	7(17.5%)	4(10%)	
moderate	2(5%)	1(2.5%)	
severe	0(0%)	0(0%)	
12-24 hours			
No	33(82.5%)	40 (100%)	0.012
mild	5(12.5%)	0%	
moderate	2(5%)	0%	
severe	0(0%)	0%	
0-24 hours			
Mild	11(27.5%)	9(22.5%)	0.342
Moderate	6(15%)	2(5%)	0.256

5.1.4.1. Rescue ant emetics

Five patients in Propofol group and 2 patients in Dexamethasone group required antiemetic in the overall period but statistically significant association was found in the 12-24 hour period ($p < 0.05$). (Table 5).

Table 5: Rescue ant emetic administered during 24 hours of post operative day at Tikur Anbesa Specialized and Yekatit 12 Hospital, Addis Ababa University, Ethiopia, December 20- March 20, 2017/18.

Rescue ant emetics	Propofol group N =40	Dexamethasone group N=40	P value
0-6 hours			
Metoclopramide (n)%	1(2.5%)	1(2.5%)	1.000
Cimetidine (n)%	0%	0%	
6-12 hours			
Metoclopramide (n)%	2(5%)	1(2.5%)	0.411
Cimetidine (n)%	1(2.5%)	0%	
12-24 hours			
Metoclopramide (n)%	2(5%)	0%	0.044*
Cimetidine (n)%	0%	0%	
0-24 hours			
Metoclopramide (n)%	5(12.5%)	2(5%)	0.230
Cimetidine (n)%	1 (2.5%)	0%	

Hint: n (%) =number and percentage * =statistically significant

5.1.5. Associated side effect

In overall period 2.5% of patient in propofol group and 5% patents in Dexamethasone group were complain dizziness (p=0.646).(Figure 4).

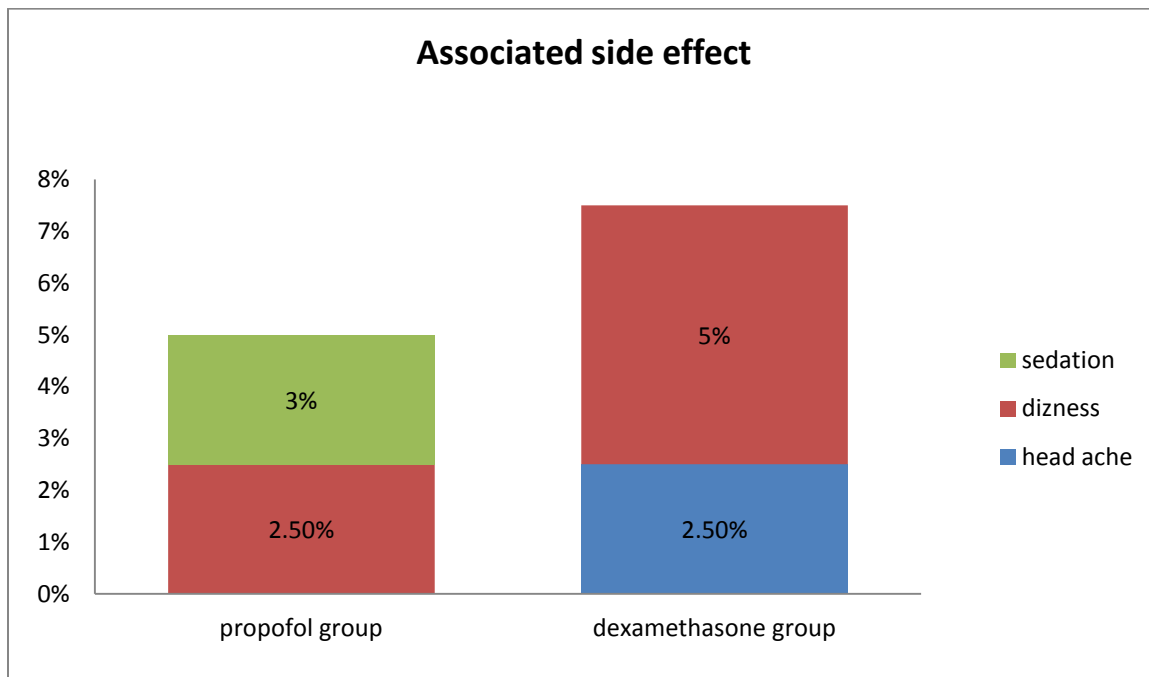


Figure 4: Associated Side effect observed within 24 hours after administered ant emetics at Tikur Anbesa Specialized and yketit 12 Hospital , Addis Ababa University, Ethiopia, December –Feb,2017/8.

5.2. Discussion

Ear, Nose and throat surgery has been associated with high incidence of PONV, Published articles show a great discrepancy in the incidence of PONV ranging from 30% to 70 % in patient did not took prophylaxis (15).

In present study we found a significantly lower incidence of PONV and proportion of rescue antiemetic administered in the Dexamethasone group than in the Propofol group (22.5% vs 0%) respectively at 12-24 hours period ($p < 0.05$).

Our study is comparable with study done in Turkey by Mine Celik, et al. in 2014 shows that incidence of PONV (10% vs 20%, $p < 0.05$) in Dexamethasone and Propofol group respectively. According to this study there was also significant difference in anti emetic requirement (46). possible justification is Intravenous dexamethasone generally requires a longer period of time to take effect and a time lag of 12-24 hours to achieve the maximal result and its physiological effect in the body can remain for 36-72 hours, even though half live of propofol is 2-24 hours, its clinical effect is shorter (29).

In contrary to our study a randomized controlled trail done in Turkey in 2012 shows there was no statistically significant difference between the two groups. The study shows that the incidence of PONV in Propofol and Dexamethasone is comparable at 12-24 hours (50). the possible reason for the difference is the former was used additional dose of dexamethasone in propofol group which has prolonged anti emetics effect in combination.

secondary outcome of this study was to assess the severity of nausea, using a categorical numerical scale. No patients experienced severe nausea in both groups over 24 hours period.

In 12-24 hours With regard to severity of nausea our study shows that significant difference between the two groups, 12.5% mild, 5% moderate in propofol group and no in dexamethasone group ($p = 0.012$). Our study shows comparable result with study done in Turkey in 2017 by Özgür Özmen et al. mild 6.7% in dexamethasone group and 20% mild, 3.3% moderate in propofol group. in this study NRS score in dexamethasone is significantly less than propofol group. ($p < 0.05$) (51). These results are similar to those reported by previous studies (50, 52) even though the assessment tool used and definition of severity of nausea differs between studies. This finding was comparable with our study, however, the small discrepancy in terms of the actual figure and duration might be explained by difference of perioperative patient management, study method and population.

In our study the total incidence of postoperative nausea and vomiting were (35% v25%) in Propofol and Dexamethasone group respectively in overall 24 hours period (P=0.329) as measured by the occurrence of nausea and vomiting, and the need for rescue anti-emetics.) and in overall period 27.5% of patients in propofol group and 22.5% of patients in Dexamethasone were felt mild nausea. our result is comparable with Randomized control study conducted in Turkey in overall period 37.5% vs. 40% in Propofol and Dexamethasone group (50).our study was also comparable with study done in India in 2015 shows that Overall incidence of PONV in the first 24 hour period was 35% in Propofol group and 20% in Dexamethasone group no Statically significant difference in the incidence of PONV was noted between the groups (48).

In contrary to Our results Fujii et al shows that the incidence of PONV is significantly higher in propofol than dexamethasone group in the 0- 24 hours period. 33% with propofol (P = 0.003), 15% dexamethasone (P = 0.001) (53). This difference may be explained by the addition of propofol to dexamethasone group and the fact that dexamethasone generally requires a longer period of time to take effect and a time lag of 12-24hours to achieve the maximal result.

In our study sub-hypnotic dose of propofol and 8mg of dexamethasone administered at the end of ENT surgery shows that the incidence of PONV at 0-6hours were comparable in dexamethasone (17.5%) and propofol (17.5%) group (p>0.05).

Our study is in line with Study done by song et al. on Sub hypnotic dose of Propofol and 8mg of dexamethasone administration at the end of surgery is effectively reduce incidence of early PONV (0–6 h) (4, 22).Our study was also comparable with Randomized control trial study conducted in 2014 in Turkey by Mine Celik, et al. shows that the incidence of early PONV(0-6hrs) is 30% in propofol group and 30% in dexamethasone group (p>0.05). However, the incidence of PONV was comparatively high in this study than our study. This difference could be explained by the small sample size in the Turkey study. This study also in line with our study in terms of requirement of ant emetics is same between the two groups Our results were also comparable with prospective randomized clinical trial study done in 2011 in India (5%vs 10%) in propofol and Dexamethasone group (p>0.05) (48). (46).

Contrary to our results, small dose of propofol was significantly effective than dexamethasone at 0-6hours in thyroidectomy in trials of Ewalenko et al (1996) (11). Possible explanation of the difference may be the former used 1mg/kg of propofol, our dose of propofol 0.5 mg/kg.

In our study the incidence of PONV at 6-12 hrs, were 22.5% in propofol group and 15% in Dexamethasone group ($p>0.05$), 7.5% of patients required anti emetic in propofol group while no requirement of anti emetic is observed in dexamethasone group($p>0.05$). Our study also shows comparable result with study done in Turkey in 2017. In this study incidence of PONV is 20% in dexamethasone group and 25% in propofol group ($p>0.05$). In this study anti emetics requirement 7.5% in propofol and 2.5% in dexamethasone group ($p>0.05$) (52). The likely explanation for the similarity between two studies is the similarity of dose and time of drug administration.

In contrary to our study a randomized controlled trial done in India in 2011 shows that there is significant difference between the two groups with regard to proportion of PONV(48). The possible explanation for this contradictory result is difference in study design, and nausea management practice in study set up.

The Comparable Mild to moderate nausea was reported in Propofol and Dexamethasone group at 0-6hrs, 12.5% mild, 5% moderate in Propofol and in Dexamethasone group 17.5% mild, 2.5% moderate, whereas in 6-12hours, 17.5% mild, 5% moderate, in propofol group and 10% mild, 2.5% moderate in dexamethasone group($p>0.05$).

Randomized double blind study conducted by 2017 in Turkey shows severity of nausea based on NRS score is comparable between the two groups in early 0-6hrs (52).

In our study there were no statistically significant difference between the two groups in requirement of rescue anti emetic at 0-6hrs, and 6-12hrs of post operative day. During 12-24 hrs, the requirement of rescue antiemetic in the propofol group was found significantly different from the groups ($p<0.05$).

Our study demonstrates the total post-operative metoclopramide requirement over 24 hours were lower in Dexamethasone group than in propofol group (12.5% vs 5%), but it is not statistically significant. Our result is comparable with study done in Turkey in 2011 even though different drugs were used, study reveals total rescue anti emetic consumption in propofol is higher than dexamethasone group during 24 hours (50).

Our study shows the proportion of patients that need rescue anti-emetic (metoclopramide or cimetidine) was comparable in the propofol and dexamethasone group during 0- 6 hours of Postoperative day. Two (5%) of patients in propofol and 1 (2.5%) patient in Dexamethasone group were required metoclopramide at 6-12 hours period ($p=0.411$).our finding is comparable with a 2015 study conducted at Asarwa, Ahmedabad in India shows that 2(10%) vs. 1(5%) of patients require additional ant emetics in propofol and dexamethasone at 8-12 hours respectively ($p>0.05$).

During 12-24 hours metoclopramide requirment is significantly higher in propofol than dexamethasone group ($p=0.044$).we found out propofol is less effective than Dexamethasone in reduction of rescue anti emetic requirement at 12-24hours.

A 2011 Study in Turkey reported that patients rescue antiemetic requirements in propofol and dexamethasone is comparable at 0-12hour. This finding is also similar to those reported by previous studies (48, 50, 52) even though the consumed rescue ant emetic differs between studies. We lack similar finding for comparison since most studies are using odansentrol as rescue ant emetics protocol. Thus, lack of standard PONV management protocol in the study hospital.

6.1 Limitation of the Study

Since Randomized Clinical trial was not yet allowed in our university, the patients were not randomized. In our study since we were only comparing dexamethasone and propofol we fail to compare with control group.

Almost all of our literature is from abroad as no literature on same topic in our country.

6.2 Strength

Study participant were homogenous between the propofol and dexamethasone group.

7. Conclusion and recommendation

7.1. Conclusion

Dexamethasone administration at end of operation was found effective in prevention of postoperative nausea- vomiting and reduction of rescue ant emetics requirement in patients underwent Ear, Nose and Throat surgery.

7.2. Recommendation

For professional

We recommend to use Dexamethasone as prophylaxis of Postoperative nausea and vomiting in Ear, Nose and Throat surgery.

For researcher

We also recommend additional randomized controlled study.

Reference

1. G. T. Risk factors for postoperative nausea and vomiting *Anesthesia and Analgesia*; 2006; 102::1884-98.
2. Mehernoor FW PF. Postoperative Nausea and Vomiting: Its Etiology, Treatment, and Prevention. *Anesthesiology*. 1992 77(1):162-84.
3. D. Song CWW, P.F. White, et al. .Antiemetic activity of propofol after sevoflurane and desflurane anesthesia for outpatient laparoscopic cholecystectomy *Anesthesiology Clin*. (1998) , 89:838-43.
4. Watcha MF WP. postoperative nausea and vomiting:etiology, treatment and prevention *anesthesiology Clin*. 1992;77:162-84.
5. Apfel CC LE KM, Greim CA, Roewer N. . A simplified risk score for predicting postoperative nausea and vomiting: conclusions from cross validations between two centers. . *Anesthesiology Clin*. 1999;91:693-700.
6. AL K. Prevention and treatment of postoperative nausea and vomiting. *Drugs*,. 2000;59:213-43.
7. Unal Y OO, Arslan M, et al. comparison of the efficacy of propofol and metoclopramide in preventing postoperative nausea and vomiting after middle ear surgery. *Saudi Med J*. 2009;30:778 -82.
8. Zeitz K, H. McCutcheon, and A. Albrecht. Postoperative complications in the first 24 hours general surgery audit. *Journal of Advanced Nursing*. 2004;46(6):633-40.
9. Soyannwo OA, Ajuwon A.J., Amanor-Boadu S.D., and Ajao, O.G. Postoperative nausea and vomiting in Nigerians. *East Afr Med J*. 1998;75(4):243-5.
10. Hoyle J RD, Melkie TB. Prevalence and factors associated with postoperative nausea and vomiting at the university of gondar teaching hospital,northwest Ethiopia, 2012.
11. Borgeat A W-SO, Saiah M, Rifat K Subhypnotic doses of propofol possess direct antiemetic properties. *Anesth Analg* 1992;74:539-41 PubMedCrossRefGoogle Scholar.
12. Apfel C. C. KP, Eberhart L. H Comparison of surgical site and patient's history with a simplified risk score for the prediction of postoperative nausea and vomiting. *Anaesthesia*. 2004;59:1078-82 [PubMed].
13. Apfel CC HF, Jukar-Rao S, Etal. evidence based analysis of risk factors for Post operative nausea and vomiting. *Br J Anaesth*. 2012;357:742-53.

14. Ewalenko P JS, Dejonckheere M, Andry G, Wyns C. Antiemetic effect of sub hypnotic doses of propofol after thyroidectomy. *Br J Anaesth* 1996;77:463-7.
15. C. L. Burlacu DH, D. J. Buggy et al. "Continuous gastric decompression for postoperative nausea and vomiting after coronary revascularization surgery,". *Anesthesia & Analgesia*. 2005;100(2):321-6.
16. Chatterjee S, Rudra, A., & Sengupta, S. . Current concepts in the management of postoperative nausea and vomiting. . *Anesthesiology Research and Practice*. 2011;11:1-10.
17. A. Borgeat OHGW-S, M. Saiah, and K. Rifat,. Subhypnotic doses of propofol possess direct antiemetic properties. *Anesthesia & Analgesia*, . ,1992.;74(4):539-41
18. Wang JJ HS, Lee SC, Liu YC, Ho CM. The use of dexamethasone for preventing postoperative nausea and vomiting in females undergoing thyroidectomy a dose-ranging study. *Anesth Analg*. 2000;91:1404-7.
19. T. Bisgaard BK, H. Kehlet, et al. Preoperative dexamethasone improves surgical outcome after laparoscopic cholecystectomy. *Ann Surg*. 2003; 238: 651-60.
20. P H. Effect of ondansetron on nausea and vomiting after middle ear surgery during general anesthesia. *Br J Anaesth* . 1996;76:316-8.
21. Guyton A. C. HJE. *Textbook of Medical Physiology* 11th ed. ed. Philadelphia,Pa: Elsevier; 2006. 823-4 p.
22. Bountra C GJ, Gardner CJ, Jordan CC, Kilpatrick GJ, Twissell DJ, et al., *Oncology*. Towards understanding the aetiology and pathophysiology of the emetic reflex: novel approaches to antiemetic drugs. 1996;53:102-9.
23. Morimoto M MN, Ozawa H, Yokoyama K, Kawata M. Distribution of glucocorticoid receptor immunoreactivity and mRNA in the rat brain: an immunohistochemical and in situ hybridization study. *Neurosci Res*. 1996;26:235-69.
24. Topal A GN. Effect of dexamethasone, metoclopramide or acepromazine on emesis in cats sedated with xylazine hydrochloride. *Acta Vet Brno* 2006;75:299-303.

25. Ho CM HS, Wang JJ, Tsai SK, Chai CY.. . Dexamethasone has a central antiemetic mechanism in decerebrated cats. *Anesth Analg.* 2004;99:734-9.
26. Holte K KH. Perioperative single-dose glucocorticoid administration: Pathophysiologic effects and clinical implications. *J Am Coll Surg.* 2002;195: 694-712.
27. Liu K HC, Chia YY. The effect of dose of dexamethasone for antiemesis after major gynecological surgery. *Anesth Analg.* 1999;89:1316-8.
28. Christoph Czarnetzki M, MBA Nadia Elia, MD, MSc ,Christopher Lysakowski, MD Lionel Dumont, MD,e tal. Dexamethasone and Risk of Nausea and Vomiting and Postoperative Bleeding After Tonsillectomy in Children. *American Medical Association.* 2008;300(22):2621-30.
29. 14. Holte K KH. Perioperative single-dose glucocorticoid administration: pathophysiologic effects and clinical implications. *J Am Coll Surg* 2002;195:694-712.
30. Ho ST WJ, Tzeng JI, Liu HS, Ger LP, Liaw WJ. . Dexamethasone for preventing nausea and vomiting associated with epidural morphine: a doseranging study. *Anesth Analg.* 2001; 92:745-8.
31. Thangaswamy CR RV, Trikha A, Dehran M, Chandralekha Dexamethasone before total laparoscopic hysterectomy: a randomized controlled doseresponse study. . *J Anesth.* 2010;24:24-30.
32. Henzi I WB, Tramer MR. Dexamethasone for the prevention of postoperative nausea and vomiting: a quantitative systematic review. *Anesth Analg.* 2000;90:184-94.
33. Karanicolas PJ SS, Kanbur B, Davies E, Guyatt GH. The impact of prophylactic dexamethasone on nausea and vomiting after laparoscopic cholecystectomy: a systematic review and meta-analysis. *Ann Surg.* 2008;248:751-62.
34. Chen C-C, Chen T-L, Tam K-W, Siddiqui FJ, Chan ES-Y. Dexamethasone for Prevention of Postoperative Nausea and Vomiting in Patients Undergoing Thyroidectomy. *World Journal of Surgery.* 2012;36:: 61–8.
35. Holte K KH. Perioperative single-dose glucocorticoid administration: pathophysiologic effects and clinical implications. *J Am Coll Surg* 2002;195:694-712.
36. Eberhart LH GJ, Morin AM, Stief T, Kalder M, Lattermann R, et al. . Randomised controlled trial of the effect of oral premedication with dexamethasone on hyperglycaemic response to abdominal hysterectomy. *Eur J Anaesthesiol.* 2011;28:195-201.

37. Hammas B HA, Thorn S-E, Wattwil M. Effects of propofol on ipecacuanha-induced nausea and vomiting. *Acta Anaesthesiol Scand* 1998;42: 447-51PubMedCrossRefGoogle Scholar.
38. Shulman SR RC, Canada AT, Glass PS. Long-term propofol infusion for refractory postoperative nausea: a case report with quantitative propofol analysis. *Anesth Anlg* 1995;80:636-7.
39. Kim E-G PH, Kang H, Choi J, Lee HJ. Antiemetic effect of propofol administered at the end of surgery in laparoscopic assisted vaginal hysterectomy. *Korean J Anaesthesiol*. 2014;66(3):210-5.
40. D. F. Cechetto TD, C. J. Gibson, and A. W. Gelb. The effects of propofol in the area postrema of rats. *Anesthesia and Analgesia*. 2001;92,(4).
41. J. R. Sneyd AC, W. D. Byrom, and A. J. T. Bilski, s, . A meta-analysis of nausea and vomiting following maintenance of anaesthesia with propofol or inhalational agent. *European Journal of Anaesthesiology*,. 1998;15(4):433-45.
42. Watcha MF SR, White PF, Stevens JL. Effect of propofol on the incidence of postoperative vomiting after strabismus surgery in pediatric outpatients. *Anesthesiology* 1991;75:204-9.
43. Yoshitaka Fuj M, HIROYOSH Tanake, MD, Noriaki kobayshi, MD. comparing small dose of propofol vs metchlorpromide. *arch otololarngology head and neck surgery*. 2001;27:25-8.
44. P. Honkavaara, Saarnivaara L. Comparison of subhypnotic doses of thiopentone vs propofol on the incidence of postoperative nausea and vomiting following middle ear surgery. *Acta Anaesthesiologica Scandinavica* February 1998;42(2):211-5.
45. Hailu Yimer a, Nugusu Ayalew b, Zewditu Abdisa a, Adugna Aregawi. Effect of sub-hypnotic dose of propofol on prevention of postoperative nausea and vomiting as part of multimodal antiemetic in patients undergoing open abdominal surgery. *International Journal of Surgery Open*. 2018;10:15-20.
46. Mine Celik AD, 1 Mehmet Aksoy,, Ilker Ince AA, Mehmet Comez,and Ali Fuat Erdem3. Infusion of Subhypnotic Propofol as Effective as Dexamethasone in Prevention of Postoperative Nausea and Vomiting Related to Laparoscopic Cholecystectomy. *BioMed Research International*. 2015:5.
47. ARMUSDKNSAK Y. Nausea and vomiting after ENT surgeries: A comparison between ondansetron, metoclopramide and small dose of propofol. *Indian J Otolaryngol Head Neck Surg*. March 2010;62(1):29-31.

48. P M Patel* MAB, K N Vadhia, D T Dave, B M Patel. Study of efficacy of Propofol, Ondansetron and Dexamethasone in prevention of post operative nausea & vomiting (PONV) following thyroidectomy. *Asian Pac J Health Sci.* 2015;2(4):65-72.
49. R.Wengritzky PSMa. simplified post operative nausea and vomiting impact scale. *Br J Anaesth.* 2012;108(3):423-29.
50. Arslan M DM. prevention of post operative nausea and vomiting with small dose of propofol and dexamethasone in a patient undergoing ENT surgery. *Bratisl Lek Listy.* 2011;12(6):332-6.
51. Mine Celik AD, Mehmet Aksoy, Ilker Ince, Ali Ahiskalioglu, Mehmet Comez, and Ali Fuat Erdem. is Infusion of Subhypnotic Propofol as Effective as Dexamethasone in Prevention of Postoperative Nausea and Vomiting Related to Laparoscopic Cholecystectomy? *BioMed Research International.* July 2014;1(1):1-6.
52. Özgür ÖZMEN¹ FB, Zakir ARslAn³. The effects of dexamethasone vs low doses of propofol on postoperative nausea and vomiting in tympanoplasty surgery. *Medeniyet Medical Journal* 7. july 2014;32(2):85-90.
53. Fujii Y NMCT. Prevention of PONV with a small dose of propofol alone and combined with dexamethasone in patients undergoing laparoscopic cholecystectomy. 2004;8.:1286-91.

Annex I Consent form
INFORMED CONSENT

Greetings:

Hello, how are you?

This research proposal is designed to compare effectiveness of propofol vs dexamethasone as prevention of postoperative nausea and vomiting for patient underwent ENT surgery. As a chance you will be included in the study. So, we kindly request your involvement in the study and honest response to achieve the objective of the study. Your response completely confidential and you have full right either to refuse a single question or leave the study. However, your honest response to those question will help us to asses and understand the effect.

Would you willing to participate in the study please?

YES-----NO -----

My name is ----- . I am currently patient at Tikur Anbesa specialized hospital at surgical ward (recovery) that iam scheduled to be operated. I would understand the risk- benefit of anesthesia and surgery, as well as the aim of this study as I have told by data collector anesthetist and surgeon about risk- benefits surgery and decide to take surgery and provide necessary information for data collectors after surgery if needed. So iam agree and accept to give them necessary information as needed and make sure with my signature as follow

Sign.....

date.....

Thanks for taking part in the study!!!!

For further question ask investigator

Tel: - +251910121583

E-mail: smulugeta17@gmail.com

Annex II Questionnaire

Addis Ababa University College of health science department of anesthesia questionnaire for data collection on effectiveness of propofol vs dexamethasone in prevention of postoperative nausea and vomiting

Instruction: read the following sentences care full, observe and review cards or asking patients if needed write or tick the response on the space provided (additional information can be referred from the card or anaesthesia note)

Part I Socio-demographic and preoperative characteristics of patients at Tikur Anbesa specialized hospital , Addis Ababa University, Ethiopia, dec -feb, 2018

MRN_____ Bed no. ----- DX-----

Ser.no.	Question	Response
10	Age (yrs)	
11	ASA	A.I B. II
13	Sex	A. F B. M
14	BMI _____(height____/weight_____)	
15	NPO Times	_____hrs
16	Is He/she has history of anesthesia and surgery	A. Yes B. NO
17	If yes Type of anesthesia	General_____ Regional_____
18	Does the patient has history of smoking	Yes_____NO_____
19	Does the patient has history of motion sickness	Yes____ No_____
20	Does the patient has Previous history of post operative nausea and vomiting	A. Yes B. No
21	Does the patient has premeditated with ant emetics?	A. Yes B. No If yes specify-----
	Does the patient has history of coexisting disease	A. Yes B. No
	If yes specify	-----

Part II Intraoperative characteristics of patient operated at Tikur Anbesa specialized hospital ,
Addis Ababa University, Ethiopia, December -feb, 2018

Ser.no	Question	Response	Code
33	Induction agent	A. Propofol B. Ketamine C. thiopetone d. others	
34	Maintenance of anesthesia	A. Inhalational (specifiy)_____ C, opioid B. Iv anesthesia (specifiy)_____ D others	
35	Type of procedure	A. Tonsillectomy B. Tympanoplasty C.Mastedioctomy D. Others specify_--	
36	Duration of surgery in minute	_____minute	
37	Estimated Intra operative blood loss	-----ML	
39	Total fluid replaced	-----ML	
40	Duration of anesthesia	_____MINUTE	

Part III: postoperative characteristics of patient operated at Tikur Anbesa specialized hospital ,
Addis Ababa University, Ethiopia, Decem -feb, 2018

S.NO.	Questions	Response
41	Administered ant emetic	A. 0.5 mg/Kg of propofol IV B. 8 mg of dexamethasone

Se.N O	Episode of nausea -vomiting	Response			Code
		6 th hours	12 th hours	24 th hours	
42	Does the patient feeling Nausea	A. YES B. NO	A.YES B. NO	A.YES B. NO	

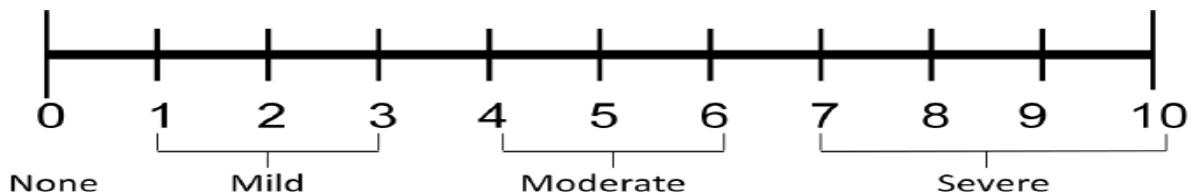
43	If yes how is severity of nausea according to numeric rate of nausea score	A. Mild B. Moderate C. Severe	A. Mild B. Moderate C. Severe	A. Mild B. Moderate C. Severe	
44	Does the patient Vomited	A. Yes B. No	A. Yes B. No No	A. Yes B. No	
45	Does the patient feeling Retching	A. Yes B. No	A. Yes B. No	A. Yes B. No	
46	Does the patient received additional ant emetics	A. Yes B. No	A. Yes B. No	A. Yes B. No	
47	If Q.46 yes (Specify) If NO. Skip to next .Questions	(drug type____ dose----	(drug type____ dose----	(drug type____ dose----	
48	Type of Post operative analgesia administered	A. Pethidine B. Tramadol	C. Diclofnac (specify)_____	E. Others	

IV. Complication observed within 24 hrs

A. Hypotension b. head ache C. sedation D. Others (specify) E. None

VI. Total and type of anti emetic consumed with 24 Hours _____

Numeric rate of severity of nausea



Date _____ Data collector
name _____ signiture _____