

**ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCE
DEPERTMENT OF ANESTHESIA**



**COMPARING EFFECTIVNESS OF METOCLOPAMIDE ALONE VERSUS ITS
COMBINTION WITH DEXAMETHASONE FOR PREVENTION OF
POSTOPERATE NAUSEA AND VOMITING AFTER THYROIDECTOMY AT
MENELIK II HOSPITAL, ADDIS ABABA, ETHIOPIA 2018: COHORT STUDY.**

M.S.C THESIS

BY

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COMPARING EFFECTIVENESS OF METOCLOPAMIDE ALONE VERSUS ITS COMBINATION WITH DEXAMETHASONE FOR PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITTING AFTER THYROIDECTOMY AT MENELIK II HOSPITAL, ADDIS ABABA, ETHIOPIA 2018. FROM DECEMBER 1, 2017 TO FEBRUARY 30, 2018 G.C

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ADDIS ABABA UNIVERSITY

Declaration

I, the undersigned, declare that this thesis is my 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 and all directly quoted material has been appropriately referenced

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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

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3. _____	Signature _____	date_____

Dedication

This thesis is dedicated to all those who are contributing to development and progression of human knowledge. To my parents and my wife who supported and encouraged me when I confronted setbacks, felt hesitant and depressed. It is their patience; unconditional love and support that helped me go through the difficult periods of my life journey, follow my interests and fulfill my dreams.

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Abstract

Background: Postoperative nausea and vomiting (PONV) is a common post-operative unpleasant experience and also common following thyroidectomy that may cause for hematoma and post-operative airway obstruction. Several agents have been tried to reduce severity and incidence PONV. This study intended to compare effectiveness of Metoclopramide alone and its combination with Dexamethasone for prevention of PONV after thyroidectomy at Menelik II Hospital.

Method: Prospective cohort study was conducted on 76 American Society of Anesthesiologist (ASA) class I and II, adult patients undergone thyroidectomy. A systematic random sampling was applied to identify sample population through skip interval till required sample size was achieved. Study participants were grouped as Group = M (Metoclopramide alone) and Group = MD (Metoclopramide plus Dexamethasone). Following study participant received either 10 mg Metoclopramide or 5mg Metoclopramide plus 4mg Dexamethasone, PONV was recorded at 6, 12 and 24 hours post operatively. Continuous variables were expressed as mean $\pm$ SD or median-IQR as appropriate. Analysis was done by independent two sample t test, Mann Whitney U test and χ^2 or Fisher exact test. P-Value <0.05 was considered as statistically significant.

Result: The overall incidence of PONV within the first 24 hours was significantly higher in Group M as compared to Group MD, 24(63.15%) versus 9 (23.68 %) respectively with a P-value of $< .01$. Although difference was insignificant, severity of nausea at 6th, 12th and 24th was still higher in Group M. From side effects, Sedation was significantly lower in Group MD 6 (15.79%) versus 15 (39.47%) with a P-value of $< .05$. Despite difference was insignificant headache was found higher in Group M 10 (26.31) vs. 6 (10.52) respectively with P-value of $> .05$.

Conclusion: 5mg Metoclopramide combined with 4mg Dexamethasone has significant effects for prophylaxis of post-operative nausea and vomiting after thyroidectomy. Some side effects of drugs were also significantly reduced in combination group.

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Acronym and Lists of abbreviation

ASA	American Association of Anesthesiologist
BGL	Blood glucose levels
BMI	Body mass index
BP	Blood pressure
CI	Confidence interval
EAA	Ethiopian Anesthetists Association
GA	General Anesthesia
IQR	Inter quartile range
IRB	Institutional Review Board
IV	Intravenous
NPO	None Per-Ose
NRS	Numerical rating scale
PACU	Post anesthesia care unite
PONV	Postoperative Nausea and Vomiting
RCT	Randomized Control Trial
SD	Standard deviation
UK	United Kingdom

1. Introduction

1.1. Background

Thyroidectomy is a very common procedure. The indications for surgery are uncertainty about the nature of a thyroid mass, large goiter causing compressive symptoms, thyroid cancer, and thyrotoxicosis. Airway obstruction may occur after thyroidectomy due to airway edema or hematoma (1). Review of operated cases of thyroid surgery in Tikur Anbessa hospital showed that 472 patients underwent thyroidectomy from 1997 to 2000 (2). Thyroidectomy is commonly done under general anesthesia and related with high rate of PONV as high as 65 -84 % (3).

Postoperative nausea and vomiting (PONV) are development of episodes of nausea and emesis following surgical procedure before hospital discharge. Nausea is a subjective abdominal discomfort associated with an urge to vomit. Vomiting consists of forced ejection of gastric content by the neuromuscular complex with voluntary and involuntary components(4).

Preoperative factors (being female, history of motion sickness, nonsmoking), intraoperative factors (duration of surgery and anesthesia) and post-operative factors (Pain, Opioids, Hypoglycemia, Hypoxemia, Oral intake) have a role for PONV(5).

Despite modern anesthetic and surgical techniques, the incidence of PONV remains high which needs prevention and treatment before patients suffer from complications like severe dehydration, acid base and electrolyte imbalance, aspiration pneumonia wound dehiscence, bleeding and fatal air way obstruction due to hematoma after thyroidectomy (6, 7).

A number of agents have been tried to decrease the incidence and severity of PONV. Although, their cost is expensive, recently serotonin antagonist such as ondansetron are the most popular agent used for prevention and treatment of PONV. Other cost effective antiemetic such as Metoclopramide and Dexamethasone have also been shown to be an effective anti-emetic drug used for prevention of PONV in patients undergoing surgery(8). Even though the effective minimum safe dose has been controversial, a combination of metoclopramide and dexamethasone may have better antiemetic effect (9).

1.2. Statement of the Problem

Postoperative nausea and vomiting (PONV) is one of the most commonly reported undesired effects of anesthesia and patients with zero known risk factors carry a 10% risk of PONV(10). Post-operative nausea and vomiting after thyroidectomy is common, with the incidence rate of 60% to 84 % (11).

Post-operative nausea and vomiting is a devastating morbidity that may have severe consequences directly such as dehydration, electrolyte imbalance, wound dehiscence, and post-surgical hemorrhage and indirectly such as delayed discharge from PACU, unintended hospital admissions after day case surgery, extended hospital stay for inpatients and raise cost of the operation (6). After thyroid surgery PONV is a challenging problems for anesthetists due to surgical wound dehiscence and hematoma-induced upper airway obstruction following the procedure(12).

Several antiemetic have been studied for the prevention and treatment of PONV for patients scheduled for surgery. Among those antiemetic, Metoclopramide and Dexamethasone are one of them used for prophylaxis of PONV. However they have been reported to cause side effects such as excessive sedation , cardiac dysrhythmia and delayed wound healing, and wound infection, decreased serum cortisol levels, increased blood glucose levels (BGLs) respectively even after a single injection that may worsen by increased dose (13, 14). Using combination of low dose Metoclopramide with Dexamethasone may be better than a single high dose Metoclopramide alone or Dexamethasone for prevention of PONV(8, 9).

The newest anti-emetic serotonin receptor antagonists such as ondansetron are also available. Despite the fact serotonin receptor antagonists are highly effective in the prevention and treatment of PONV compared to Metoclopramide and Dexamethasone, their usages are limited because of their high cost and unavailability specially in most governmental hospitals (15).

1.3. Justification of the Study

Although Metoclopramide and dexamethasone as higher dose are effective with low cost, they are not risk free. Most effective anti-emetics, such as Ondansetron are also available for prevention and treatment of PONV however their uses are limited by their high price and unavailability in most hospitals of developing country like Ethiopia. Certain studies have showed that a combination of Metoclopramide with Dexamethasone may be better than a single high dose Metoclopramide alone for prevention of PONV.

Since PONV is influenced with various factors such as duration of surgery and anesthesia, types of surgery and anesthesia, analgesic drugs (opioids), heredities and ethnicity, finding in others country may not tailored with our populations. As I had tried to search such studies in our country, there have been no published researches that indicated, whether the combination is effective or not for prophylaxis of PONV. Alongside of improving the clinical practice, the result of this study become base line for further strong study such RCT in our country.

2. Literature Review

Postoperative nausea and vomiting are one of the main complications related to general anesthesia. (7). A prospective study done in Tanzania (2015) demonstrate that among the total of 348 patients the incidence of PONV was 41.4%. Age group 21-30, female gender, history of PONV, general anesthesia and intraoperative pethidine were the main predictors of PONV (16).

A cross-sectional study done Ethiopia found that the prevalence of PONV was 36.2% within 24 hours after operation and factors that associated with PONV were history of motion sickness, previous history of PONV, long duration of anesthesia and major operation(17).

The risk factors that affect the incidence of post-operative nausea and vomiting are multifactorial in origin such as being female, patients with previous history of motion sickness, nonsmoker, laparoscopic cholecystectomy increasing duration of surgery and anesthesia, Postoperative opioids and head and neck surgeries (5, 18).

Thyroidectomy is related with high rate of PONV as 65 -84 %. Apart from the distressing effects, the muscular effort accompanying PONV may contribute to medical complication such as aspiration pneumonia, wound dehiscence, bleeding, hematoma and even wound infection (3, 7).

Metoclopramide is a substituted benzamide used for its prokinetic and antiemetic properties. It has parasympathomimetic activity as well as being a dopamine-receptor (D2) antagonist with a direct effect on the chemoreceptor trigger zone and it also has serotonin-receptor (5-HT3) antagonist properties (13).

A prospective RCT study done in Iran (2014) on 151 patients , the incidence of nausea and vomiting was significantly higher in the metoclopramide group when compared with generic granisetron group with p-value <0.001 at 0-6 and 6-24 hours post-operative (19)

A prospective double blind RCT done in Indian in 2015 on 300 patients who received ,10mg IV Metoclopramide , 4mg IV Ondansetron and a combination of 4mg IV Ondansetron plus 8mg IV Dexamethasone. Highest incidence of PONV (49.37%) was observed in metoclopramide Group. While it was only 17.72% in ondansetron-dexamethasone Group (20)

A prospective study done in Portugal in 2017 on 2115 patients, grouped in two who received droperidol (0.625 mg) and droperidol-dexamethasone group received 5 mg Iv dexamethasone

found that a lower incidence of POV in dexamethasone- droperidol administered group patients ($p = 0.001$) (21).

Previous studies have found that prophylactic dexamethasone has anti-emetic effect for preventing the nausea and vomiting following cancer chemotherapy and patients undergoing tonsillectomy, thyroidectomy and abdominal hysterectomy (22). Dexamethasone may exert its anti-emetic actions through central inhibition of prostaglandin synthesis, by decreasing serotonin turnover in the central nervous system, and by influencing the systemic inflammatory response in favor of anti-inflammatory mediators (23).

A randomized blinded postoperative controlled trial done in 2017 in UK on 1350 patients, who grouped in to dexamethasone and standard care group, Vomiting within 24 hours of surgery occurred in 172 (25.5%) in the dexamethasone group and 223 (33.0%) standard care group . Additional postoperative antiemetic were given to 265 (39.3%) in dexamethasone group and 351 (51.9%) standard care group (24).

A two-arm, double-blind RCT done in Italy on 102 thyroidectomy patients demonstrate dexamethasone has been found to be effective in preventing PON .The severity of nausea and the need for antiemetic drugs were reduced in patients receiving dexamethasone with p value of $< .01$ (11).

The meta-analysis done in 2014 in china on 2,180 patients, demonstrated a significant decrease in the incidence of PONV P value of <0.001 , the need for rescue anti-emetics P value < 0.001 in patients receiving dexamethasone compared to placebo, with or without concomitant antiemetic. Dexamethasone 8–10 mg had a significantly greater effect for reducing the incidence of PONV than dexamethasone 1.25–5 mg. A significantly higher level of blood glucose during the immediate post-operative period in patients receiving dexamethasone compared to controls was the only adverse event (23).

A prospective study done in in Pakistan in 20011 on 150 patients undergoing “Laparoscopic Cholecystectomy showed that the incidence of PONV in the metoclopramide group was 20% after 0-4 hours, 50% after 4-24 hours and 70% after 0-24 hours of surgery as compared to in dexamethasone group 16% after 0-4 hours, 12% after 4-24 hours and 28% after 0-24 hour’s surgery. Significant difference was observed in both groups with a p -value < 0.001 (25).

A quantitative systematic review of randomized, placebo-controlled studies done in 1999 in Switzerland, evaluate higher doses of metoclopramide are clearly needed to establish the optimal dose of metoclopramide for the prevention of PONV. Sedation or drowsiness was felt sedated or drowsy with metoclopramide 10–20 mg (26).

A Single blinded RCT done in Pakistan in 2012 on 100 patients, in first 24 hours post-operative period the incidence of PONV was significantly less. Only 13(26%) patients experienced nausea or vomiting in metoclopramide plus dexamethasone as compared to 31(62%) in metoclopramide group (8).

A double-blind, randomized controlled trial done in Thailand (2015) on fifty eligible patients, the combination of dexamethasone and metoclopramide indicate a greater antiemetic effect with significant difference with p value of 0.001. The postoperative hospital stay in the combined group was lower with p value of 0.01) and there was no postoperative complications occurred in both groups(9).

A double blind placebo-controlled study done in Croatia on a total of 160 patients who were randomly as-signed to 4 groups (n = 40 each): group 1 consisting of control patients administered 0.9% NaCl; group 2 patients received metoclopramide 10 mg just before the end of anesthesia; group 3 patients received dexamethasone 8 mg after the induction of anesthesia; and group4 patients received dexamethasone 8 mg after the induction of anesthesia and metoclopramide 10 mg be-fore the end of anesthesia, demonstrate that the total incidence of PONV was 45% in Metoclopramide alone while 13% which is significantly lower in the combination of dexamethasone plus metoclopramide (27).

3. Objectives

3.1. General Objective

- To compare the effectiveness of Metoclopramide alone versus combined with Dexamethasone for prevention of PONV after thyroidectomy at Menelik II hospital.

3.2. Specific Objective

- To compare the incidence of PONV between the two groups.
- To compare the severity of PONV between the two groups.
- To compare the side effects between the two groups.

4. Methods and Materials

4.1. Study Area

The study was conducted at Menelik II Hospital which is earlier and historical public hospital found in a capital city of Ethiopia, Addis Ababa in Yeka kifle ketema. The hospital has catchment population of about 1.6 million people. This hospital has providing all general, urological, gynecological, orthopedics and emergency surgeries. Surgery department is major one which has three separated female and male wards in each referral clinics. Generally there are three functional operating tables in the operation room and one PACU nearby the operation room.

4.2. Study Design and Period

Hospital based prospective cohort study was employed from December 1, 2017 to February 30, 2018 G.C

4.3. Population

4.3.1. Source of Population:

All surgical patients who was scheduled for thyroidectomy under General Anesthesia at Menelik II hospital.

4.3.2. Study population:

Patients who were scheduled to undergone elective thyroidectomy and took either 10 mg IV Metoclopramide alone or 5 mg Metoclopramide plus 4mg Dexamethasone 10-20 minutes before induction of anesthesia.

4.3.3. Study unit: patients selected to participate in the study

4.4. Eligibility criteria

4.4.1. Inclusion criteria:

- Female patients who received, either 10 mg IV Metoclopramide alone or 5 mg Metoclopramide combined with 4 mg Dexamethasone as an anti-emetic prophylaxis 10-20 minutes before induction of anesthesia for elective thyroidectomy with in the study period.
- ASA I and II
- Adult patient

4.4.2. Exclusion criteria

- Patients who received other antiemetic prophylaxis before induction of anesthesia
- Patients who received other Steroid
- Patients who had motion sickness
- Patients who took extra anti-emetics during intra-operative period
- Patients who was induced with propofol
- Post-operative hypotension
- Post-operative hypoxia
- Post-operative hypoglycemia

4.5. Study Variables

4.5.1. Dependent variable

- Post-operative nausea and vomiting (PONV)
- Side effects of Metoclopramide alone and Metoclopramide plus Dexamethasone

4.5.2. Independent variable

- Socio-demographic variables: Age, Sex, BMI, ASA class and Smoking status
- Exposure variable: Metoclopramide alone, Metoclopramide plus Dexamethasone

Anesthesia related:

- Duration of anesthesia
- Induction agents
- Analgesic agents (opioids)
- NPO time

Surgery related: Duration of surgery

- Post-operative factors:
- Pain
- Hypotension
- Hypoxia

4.6. Operational Definitions

1. PONV is occurrence of episodes of nausea and vomiting after a surgical procedure and before 24 hrs.
2. Nausea is abdominal discomfort and urge to vomit
3. Vomiting is a forced ejection of gastric content
4. Grading of nausea by using VAS score
 - 0 = No nausea
 - 1-3 = Mild nausea.
 - 4- 6 = Moderate nausea
 - 7-10 = Severe nausea
5. Grading of vomiting
 - 0 = No Vomiting
 - < 2 episode vomiting
 - 2 episode vomiting
 - 2 episode vomiting
6. Duration of anesthesia time is interval from loss of consciousness to spontaneous recovery of consciousness in minutes after surgical procedure.
7. Duration of surgery time interval from skin incision to closure in minutes
8. NRS: is a valid pain intensity assessment tool that involves asking a patient to rate his or her pain from 0-10(11 point scale) with the understanding that 0 is equal to no pain and 10 equal to the worst possible pain
9. Grading of post-operative pain by using numeric rating scale
 - 0 = No pain
 - 1-3 = Mild pain
 - 4-6 = Moderate pain
 - 7-10 = Severe pain
10. NPO time; is from the last meal to time of induction of anesthesia in hours
11. Hypotension; low blood pressure (systolic BP < 90mmhg), with 24 hours

12. Hypoxia is inadequate oxygen supply with saturation reading below 90% within 24 hours.
15. Sedation; is a state between relaxed consciousness and very sleepy within 24 hours
16. Headache; the symptom of pain anywhere in the region of head within 24 hours
- 17 Anti-emetic request; if patients ask anti-emetic drugs any time within 24 hours post operatively when they feel nausea or vomiting.

Sample Size Determination and Sampling Technique

4.6.1. Sample size determination

Comparison of two proportions with equal sample size formula for independent cohort study

$$n1 = \frac{[za\sqrt{(1+\frac{1}{h})p^-q^-}]^2}{(p1-p2)^2} + \frac{[z\beta\sqrt{\frac{p1q1}{h}+p2q2}]^2}{(p1-p2)^2}$$
 where p1 and p2 are the probability of postoperative nausea and vomiting from Metoclopramide alone and Metoclopramide plus Dexamethasone group respectively. n1=sample for Metoclopramide, n2 =sample for Metoclopramide plus dexamethasone. $n2=n1, \lambda=n2/n1$.

Previous study done in Pakistan in 2011 showed that 64% from Metoclopramide group and 26% from Metoclopramide plus Dexamethasone group complained of postoperative nausea and vomiting(8).

$P1=0.64, q1=0.36, q^- \text{ (change)} = 1 - p^- = 0.55, P2=0.26, q2=0.74, p^- \text{ (change)} = (p1+\lambda p2)/(1+\lambda) = 0.45$.
 Having plan to get 90% chance of power and then the sample size becomes n1=34 and n2=34 patient. By adding 10% contingency, a total of 76 patients were participated in this study.

4.6.2. Sampling technique

A Systematic random sampling technique was applied to achieve the required sample size during the study period. From my situational analysis, at Menelik II hospital, on average two elective thyroidectomies were done in every working day. Therefore during my study period there were a total of 132 goiter patients. Using the skip interval ($k=N/n, 132/76 = 2$), where N= number of patients during the study period, n = sample size, k = interval. From the two the patients, one patient was taken following the first patient was selected through lottery method. Study participant

patients were grouped subsequently as Anesthetists provided either 10 mg Metoclopramide alone as Group M or 5mg Metoclopramide with 4mg Dexamethasone as Group MD.

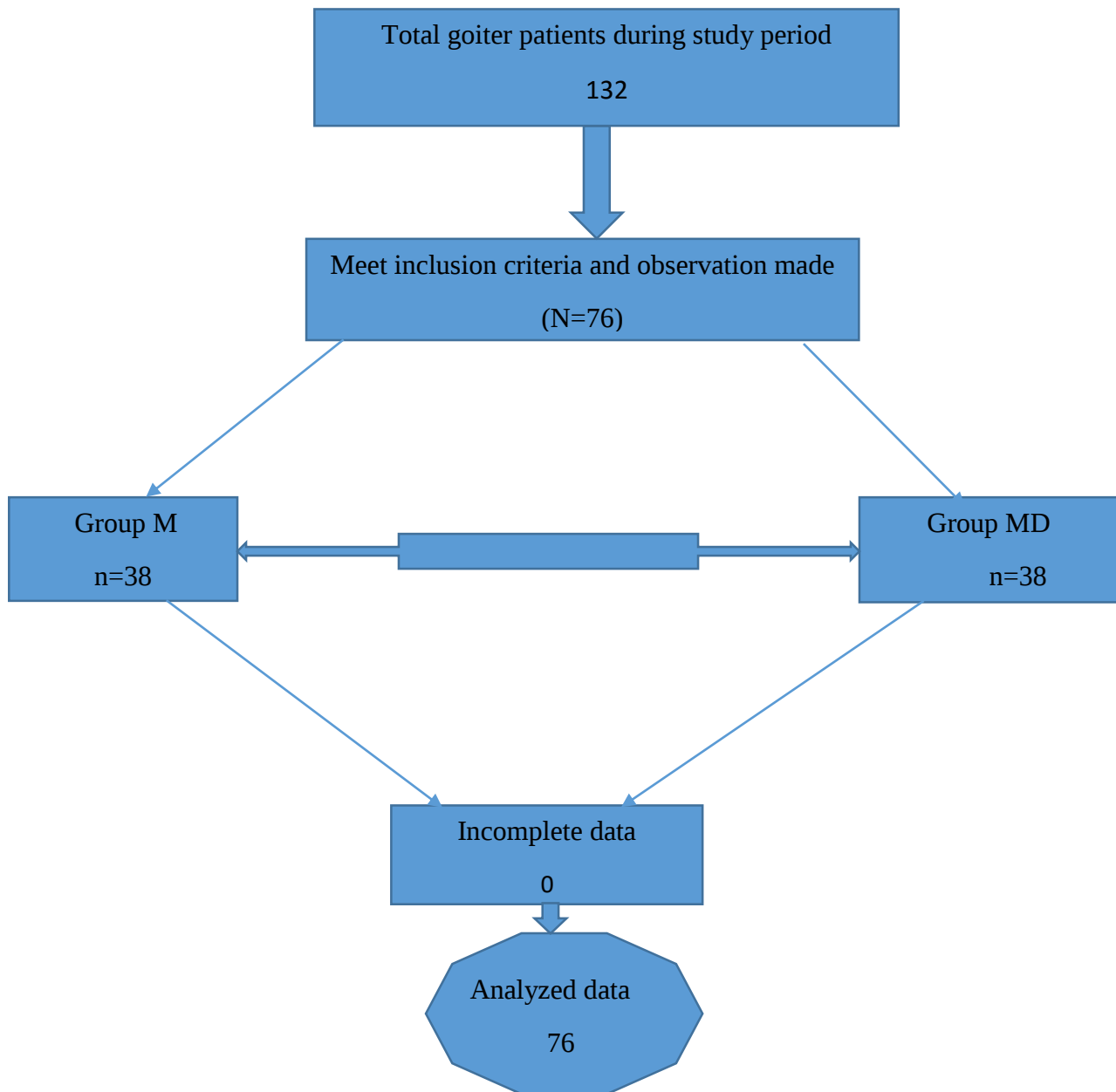


Figure 1: Enrollment chart for elective goiter patients scheduled at Menelik II hospital

All patients who were scheduled for elective thyroidectomy who fulfill inclusion criteria and volunteer to take part in the study were demonstrated on how to report nausea and vomiting using the NRS score for nausea and number of episode for vomiting during post-operative period at PACU and ward with the help of trained nurse.

Anti-emetic prophylaxis provision in the study hospital has been varied from Anesthetist to Anesthetist depending in their experience. Some Anesthetists have provided 10 mg IV Metoclopramide alone while others have provided 5mg Metoclopramide with 4mg Dexamethasone 10-20 minutes before induction of anesthesia commonly by thiopental for patients who undergo elective thyroidectomy. I used this opportunity to group study participant in either group. Patients who received 10 mg Metoclopramide alone were grouped as Group= M while patients who received 5 mg Metoclopramide with 4 mg Dexamethasone were grouped as Group MD.

4.7. Data collection Tools and Technique

Questionnaire and checklist was prepared in English language which contained socio demographic status, ASA classes NPO time, duration of surgery, duration of anesthesia, analgesic drug and complications of tested drugs. Patients were asked to report nausea and vomiting at PACU as soon as they fully respond to verbal command. Then PONV and other variables were recorded by one PACU and two ward nurses at 6th, 12th and 24th hours at PACU and wards.

4.8. Data Quality Control and Assurance

Data collectors were trained by principal investigators. Pretest was done for 5 % of sample size at Zewditu Memorial hospital. During data collection, regular supervision and follow up was made appropriately and principal investigator cross checked for completeness and consistency of data every day. All materials used for data collection was arrange sequentially and stored in safe and secure place.

4.9. Data Processing and Analysis

Data was checked manually for completeness and then coded and entered in to EPI info version 7. Then data was transferred to SPSS version 20 computer program for analysis. To display the result, descriptive statistics were computed and summarized through using tables and figures. Continuous variables (age and body mass index) were expressed as mean $\pm$ SD for normally distribute data and median $\pm$ IQR (duration of surgery and anesthesia, NPO time, dose of Tramadol, Fentanyl and Diclofenac) for skewed data. Frequency and cross tabulation was conducted to describe relevant variables in relation to the outcome variables and after checking for the normality assumption, analysis was done by independent sample t test for comparing means of two

independent samples of continuous variables (Age and BMI). Comparisons between different categories (incidence and severity of PONV and side effects of Metoclopramide alone and Metoclopramide with Dexamethasone) were evaluated using χ^2 and Fisher's exact test as appropriate. Non-normally distributed variables (duration of surgery and anesthesia, dose of analgesic) were analyzed using the Mann–Whitney *U*-test. P-value <0.05 was considered as statistically significant.

4.10. Dissemination and utilization of results

The results of current study will be presented to the department of anesthesia as part of M.S.C. in advanced clinical anesthesia thesis, communicated through annual students and staff research conference, annual national conference of Ethiopian Anesthetists Association (EAA) and effort will made to send to journals for publishing.

4.11. Ethical considerations

Before conducting the study, ethical clearance was obtained from Department of Anesthesia ethical review committee (ERC). Then formal letter detailing the objective of study was given to the hospital administrators. Following permission was gotten from the hospital managers, data collectors took informed consent from each study participant patient to gather data. During data collection process norms, values and morals of patients was respected by all data collectors.

5. Result and Discussion

5.1. Result

5.1.1. Demographic and Perioperative Characteristics

Seventy six ASA class I and II female adult goiter patients were included in the study based on whether they had received Metoclopramide alone and Metoclopramide with Dexamethasone as an anti-emetic prophylaxis 10-20 minute before induction of anesthesia for prevention of PONV. All the Study participant patients were females and there was no significant difference between the two groups regarding age, BMI, NPO time or ASA class with a p value of $>.05$ as show on in

Table 1: Socio-demographic and preoperative characteristics data computed by t-test and chi-square of elective goiter patient in Menelik II hospital from December 1, 2017 to February 30, 2018 G.C

	Group M (n=38)	Group MD (n=38)	P-value
Age in year (Mean $\pm$ SD)	40.47 $\pm$ 10.205	37.74 $\pm$ 8.847	.17
ASA class			
I (%)	32 (84.21)	29 (76.32)	
II (%)	6 (15.79)	9 (23.68)	.38
BMI in kg/m ² (Mean $\pm$ SD)	22.0341 $\pm$ 1.95	21.8432 $\pm$ 1.734	.26
NPO time in hours (IQR)	10 (10-11)	10 (9.75-11)	.66

n(%)=number(percent), BMI = body mass index, NPO= None Per-Ose = Mean $\pm$ SD= mean and standard deviation, Group M= metoclopramide alone, Group MD= Metoclopramide plus Dexamethasone, n (%), IQR= interquartile range, microgram, kg/m²= kilogram per meter square

The current study also revealed that there was no significant difference between the two groups regarding both intra operative and post-operative analgesia taken , and severity of post-operative pain , and duration of surgery and anesthesia with a p value of $>.05$ as shown in Table 2.

Table 2: Intraoperative and Postoperative characteristics data computed by Man Whitney U test and chi-square of elective goiter patients in Menelik II hospital from December 1, 2017 to February 30, 2018 G.C

	Group M (n=38)	Group MD (n=38)	P-value
Induction agent; Thiopental mg (median, IQR)	300 (250-350)	300 (250-350)	.16
Halothane (%)	22 (57.89)	26 (68.42)	
Isoflorane (%)	16 (42.11)	12 (31.58)	.342
Intraoperative Tramadol mg(IQR)	100 (50-100)	100 (50-100)	.50
Intraoperative Fentanyl μ m(IQR)	25 (0-50)	25 (0-25)	.35
Intraoperative Diclofenac mg(IQR)	75 (56.25-75)	75 (0-75)	.45
Surgical time in minutes(IQR)	75 (60-91.25)	73 (65-90)	.95
Anesthesia time in minute (IQR)	85 (73.75-110)	86 (77.25-101.25)	.90
Post-operative Tramadol mg(IQR)	50 (0-100)	50 (0-75)	.33
Post-operative Diclofenac mg(IQR)	75 (0-75)	75 (0-75)	.86
Post-operative pain			
Mild	16 (42.1)	11(28.94)	
Moderate	8 (21.05)	5 (13.16)	.19

n (%) = number (percent), Mean $\pm$ SD= mean and standard deviation, Group M= metoclopramide alone, Group MD= metoclopramide plus Dexamethasone, IQR= interquartile range, mg= milligram, μ m= microgram,

5.1.2. Comparison of incidence of PONV with in first 24 hours during post-operative period.

Post-operative nausea, vomiting and PONV was taken at 6th, 12th and 24th hours post operatively. As shown in table 3 below, Post-operative nausea and vomiting were lower in Group MD and significant difference was found at 6th hours of post-operative period.

Table 3: Incidence of postoperative nausea, vomiting and PONV computed by chi-square with in first 24 hours post operatively in Menelik II hospital from December 1, 2017 to February 30, 2018 G.C

	Group M (n=38)	Group MD (n=38)	P-value
Hours			
0-6hr			
Nausea	11(28.94)	4 (10.52)	.044*
Vomiting	4 (10.52)	0 (0)	.042*
PONV	15 (39.47)	4 (10.52)	.004*
7-12hr			
Nausea	7 (18.42)	5 (13.15)	.529
Vomiting	3 (7.89)	2 (5.26)	.644
PONV	10 (26.31)	7 (18.42)	.409
13-24hr			
Nausea	2 (5.26)	1(2.63)	.78
Vomiting	1 (2.63)	1(2.63)	1
PONV	3 (7.89)	2 (5.26)	.644
Overall PONV	24 (63.15)	9 (23.68)	.001*

n (%) = number (percent), Group M=Metoclopramide alone, Group MD= Metoclopramide plus Dexamethasone, PONV= post-operative nausea and vomiting, *= statistical significant

5.1.3. Comparison of overall incidence of PONV in first 24 hours of post-operative period.

The overall incidence of PONV in the first 24 hours was significantly lower in Group M with a p-value of <.01

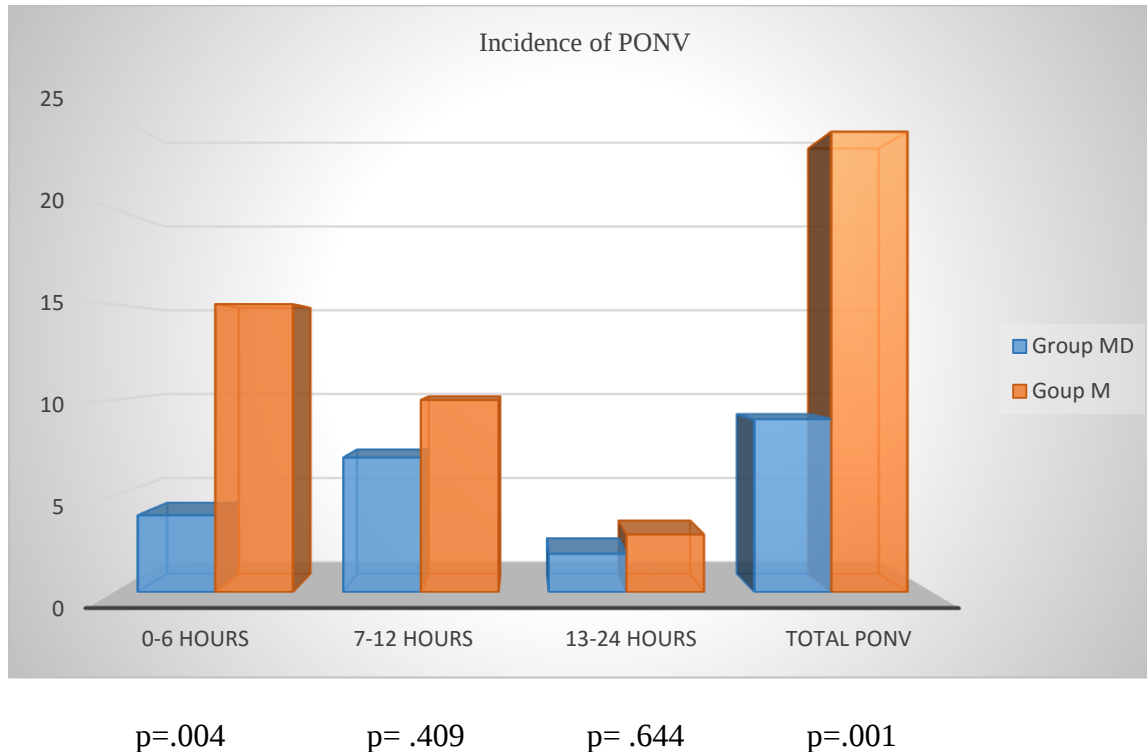


Figure 2: Incidence of PONV in each group at 6th, 12th, 24th hours and the overall incidence of PONV in first 24 hours in Menelik II hospital from December 1, 2017 to February 30, 2018 G.C

5.1.4. Comparison of severity of post-operative nausea and vomiting at Menelik II hospital.

The severity of post-operative nausea was lower in the MD group although there was no significant difference at all time interval of first 24 hours of post-operative period as shown in next page in Table 4 below. There were no study participant patients had more than one episodes of vomiting during the first 24 hours of post-operative period.

Table 4: Severity of postoperative nausea and anti-emetic request in Menelik II hospital from December 1, 2017 to February 30, 2018 G.C

Hours	Group M (n=38)	Group MD (n=38)	P-value
0-6hr			
Mild (%)	2 (5.26)	1 (2.63)	
Moderate (%)	5 (13.15)	2 (5.26)	.285
Severe (%)	4 (10.52)	1 (2.63)	
7-12hrs			
Mild (%)	3 (7.89)	1(2.63)	
Moderate (%)	1(2.63)	1(2.63)	.843
Severe (%)	3 (7.89)	3(7.89)	
13-24hrs			
Mild (%)	0 (0)	1(2.63)	
Moderate (%)	1(2.63)	0 (0)	1
Severe (%)	1(2.63)	1(2.63)	
Anti-emetic request at 24 hours (%)	7(10.52)	2 (2.63)	.15

n(%) = number(percent), Group M=Metoclopramide alone, Group MD= Metoclopramide plus Dexamethasone

5.1.5. Comparison of side effects of Group M and Group MD at Menelik II hospital.

The frequent side effects reported in the current study were headache and sedation. On comparison sedation is found significantly higher in Group M with p-value of .03. Regarding to headache there was no significant difference between the two groups with p-value of .23

5.2. Discussion

In our study the demographic status and peri-operative data including post-operative analgesia were comparable between the two groups with p value greater than 0.05. From the study participants all patients were female might be due to the highest incidence of goiter in females. Therefore the difference of outcome between the two groups to be expected will be caused by success of drugs investigated for prevention of PONV.

Metoclopramide is a central dopaminergic D2 receptor antagonist and prokinetic drug that increases gastric emptying and shortens bowel transit time and well known as sole anti-emetic agents for prevention and treatment of PONV (28). Dexamethasone has been used as an antiemetic with some degree of side effects and could decrease PONV when it combined with Metoclopramide and others anti-emetics. Mechanism of antiemetic effects of Dexamethasone is unclear till yet but it may involve central inhibition of prostaglandin and reduces 5-hydroxytryptophan in the neural tissue(23).

In this study it is found that the overall incidence of PONV was significantly higher in Group M as compared to Group MD 24 (63.15%) versus 9 (23.68 %) respectively with a p-value of <.01. The current study result was consistent with study done in Pakistan (8) demonstrated that PONV was higher in Metoclopramide alone group as compared to Metoclopramide plus Dexamethasone group, 31(62%) versus 13 (26%) respectively with a P – value of <.05. Another study in Croatia (27) also demonstrated that PONV also higher in Metoclopramide alone group as compare to Metoclopramide plus Dexamethasone group, 18 (45%) versus 5 (13%) respectively with a p value of <. 05.

Our study revealed that the incidence of PONV was significantly lower in Group MD in comparison to Group M 4 (10.52 %) versus 15 (39.47%) respectively with a p-value of <.05) at 6th hours post-operative period. Our finding was in line with previous study done in Thailand (9) which demonstrated that the incidence of PONV was 9 (18%) in combined group and 22 (44%) in Metoclopramide alone group at 6th hours with p-value of < 0.01. In our current study PONV was lower at 12th and 24th post-operative period and the difference was not significant with P-value of >.05. The current result was contradicted with previous study demonstrated that PONV was 10 (20%) versus 26 (52 %) at 12th hours and 0 (0%) versus 14 (28 %) at 24th hours respectively with significant difference with p-value of <.05. The reason of variation of these result might be

due to the time of drugs administration in our study the anti-emetic drugs was given 10-20 min before induction of anesthesia preoperatively while in previous study the drug was given just before end of anesthesia intra operatively. Types of procedure might be the reason as in our study after thyroidectomy while in previous study after laparoscopic cholecystectomy. In addition to those above reasons population difference and anesthesia practice may have a role for such difference.

We also found that severity of nausea at 6th, 12th and 24th were higher in Group M even though the difference was not significant with p – value of > .05. In contrary to the current finding, study done in Palestine (29) demonstrate that severity of nausea was lower in combination group as compared with Metoclopramide alone group with p-value of 0.01 regarding intensity of nausea. The likely reason for this alteration might be because of dose and time of drug administration, types of procedure, population variation and anesthesia practice.

The improvement of prevention of PONV in a combination groups can be clarified by the fact that Dexamethasone itself is an antiemetic drug that act via different mechanism in preventing PONV. Mechanism of antiemetic action of Dexamethasone is may be involved in central inhibition of prostaglandin and could reduce the level of 5- hydroxytryptophan in neural tissue by depleting its precursor tryptophan (24). So that diverse mechanisms working at the same time in a combination group for PONV may be responsible for this superior results.

The predominant side effects reported in our study were headache and sedation. Among those side effects sedation was found significantly higher in Group M, 15(39.47) versus 6(15.79) respectively with p-value of < .05. The higher score of sedation might be triggered by increase dose and additive interaction with other sedative agents such as opioids and induction agent that administered during surgery. This finding was in line with study done in Thailand (9) as sedation was 29 (58% in metoclopramide alone versus 9 (18%) in combination group with p value of <0.01.

In contrary to the our study another study done in Croatia demonstrated that sedation was 3 (8%) and 3 (8%) in both group respectively demonstrated difference was not significant (27). The reason for this difference might be due to variation in population, trends of pain management (opioids) and anesthesia practice.

The finding of this study also showed that headache was higher in Group M, 10 (26.31) versus 6 (10.52). However the difference between two groups was not significant with p-value of >.05. The

current study was in line with study done in Palestine (29) demonstrate that headache was 9 (30%) versus 9 (30%) with p of value of $> .05$ which was not significant difference.

On comparison of anti-emetic request, in the present study only two patients of Group MD asked antiemetic as compared to seven patients in Group M with a p-value of $> .05$. This result was contradicted with study done in Croatia (27) demonstrated that four patients from the Metoclopramide alone group and none of the patients from the Metoclopramide plus Dexamethasone group required antiemetic request with p-value of < 0.05 which was significant. The possible reason could be due to lack of similar standard for provision of anti-emetic medication once the patients complain nausea and vomiting, and request anti-emetics.

6. Strength and Limitation

6.1. Strength

Even though the study was observational, fortunately factors were comparable between the two groups.

6.2. Limitation of the Study

The study design was observational that made difficult to set standard for intervention.

7. Conclusion and Recommendation

7.1. Conclusion

The result of our study demonstrate intravenous injection of 5mg Metoclopramide combined with 4mg Dexamethasone is effective and safe for anti-emetic prophylaxis of PONV than 10mg Metoclopramide alone after thyroidectomy.

7.2. Recommendation

We recommend that better to provide 5mg IV Metoclopramide with 4mg Dexamethasone 10-20 minute before induction of anesthesia for prevention of PONV after thyroidectomy.

We recommend that Anesthetists and other health professionals better to use 5gg Metoclopramide with 4mg Dexamethasone for prevention of PONV after thyroidectomy.

We also recommend additional more strong study such as randomized controlled study.

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Annex

Annex I

Information sheet to get permission for the research

Introduction; this information sheet is prepared to explain the research project that you are asked to join by a group of research investigators. The research team includes MSc students, one senior advisor from AAU and three Nurses for data collection from Menelik II Hospital.

Name of Principal investigator: - Tamiru Tilahun (M.S.C Student in Anesthesia)

Advisor's name: - Mr.:- Adugna Aregawi, Mr. Feseha Fente and Senaite Awake

Name of sponsor: - AAU

Name of organization: - AAU, Health science college, Anesthesia department

This information sheet is prepared by the above mentioned investigator.

Risk; There is no any risk or harm that you will face by participating in this research. Any personal information recorded will not be copied and transferred to other bodies. No need of writing participants' name but by a code. Every piece of information will be kept confidentially.

Benefits; There is no incentive or payment to be gained by taking part in this project. The information collected from this research project will be kept confidential and only accessed the researcher and research assistant only. This research project will be reviewed and approved by ethical committee of the AAU. If you want to know more information, you can contact the committee.

Annex II

Consent form

Dear participant:

This is a research designed to compare the effectiveness of Metoclopramide alone versus Metoclopramide plus Dexamethasone for Prevention of Postoperative Nausea and Vomiting after thyroidectomy at Menelik II hospital as an anti-emetic prophylaxis for prevention of post-operative nausea and vomiting after thyroidectomy under General anesthesia. As a chance you are 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. So, we are requesting you to give honest response and keep participation.

Would you willing to participate in the study please? YES/No, Yes signature -----

Thanks for taking part in the study!!!!

For further question ask investigator

Tel: - +251964052613

E-mail:ttilahun14@gmail.com

Annex III

የመጠይቅ ፈቃድ

የተከበራችሁ የጥናቱ ተከፋዮች የዚህ ጥናት ዋና አላማ በ አድስ አበባ ጤና ቢሮ ስር በሚገኘው የዳግማዊ ሚኒልክ መታሰቢያ ሆስፒታል ኦፕራሲዮን ክፍል ለአንገት እጢ እብጠት ቀዶ ህክምና ለሚደረግላቸው ህሙማን ከጠቅላላ አነስቴዝያ በኋላ ለሚከሰት ማቅለሽለሽ እና ማስታወክ ፡ በአጋጣሚ እርስዎም በዚህ ጥናት እንዲሳተፉ ተመርጠዋል። የዚህ ጥናት ጥቅም እርስዎ በሚሰጡት ምላሽ መሰረት መረጃዎችን በማመልከት በሚገኘው ዉጤት መሰረት መረጃዎችን በማጠናቀር ውጤቱን እየተሰራበት ካለው ጋር ለማገናዘብ እንዲቻል ነዉ። ጥናቱ በትክክል አላማውን እንዲመታ የእርሶዎን ድጋፋ እንጠይቃለን። የማንኛውም ግለሰብ ስም አይመዘገብም እንዲሁም ሀሳቡ ብቻውን ይፋ እንዲዎጥ አይደረግም። ሙሉ በሙሉ በሚስጥር የተጠበቀ ነው። በጥናቱ መሳተፍ አለመሳተፍ የራስዎ መብት ብቻ ነዉ። ግልፅ የሆነ ምላሽንና ከልብ የመነጨ ተሳትፎዎን እንዲሰጡን

በአክብሮት እንጠይቃለን።

ለመሳተፍ ፈቃደኛ ነዎት ሀ/ አዎ ፊርማ ----- ለ/ አይደለሁም

ለመሳተፍ ፈቃደኛ ስለሆኑ እናመሰግናለን።

Annex IV

Part I: Identification, Anti-emetic prophylaxis given and NPO time

S. No	QUESTIONS	RESPONSE	CODE
1	Card No	-	
2	Age in years	-	
3	Sex:	A. M B. F	
4	ASA status:	A. I B. II	
5	Weigh in Kg	-	
6	Height in CM	-	
7	BMI kg/m ²	-	
8	NPO time in hrs.	-	
9	Anti-emetic prophylaxis given:	A. 10mg metoclopramide B. 5mg metoclopramide +4mg dexamethasone	

Part II. Intra operative data that would be filled

S. No	Question	Response	code
1	Induction agent in dose mg	A. ketamine-----mg B. Thiopental -----mg C .propofol -----mg	
2	Inhalational agent:	A. Halothane B. Isoflurane	
3	Intra operative Analgesia given	A. Tramadol -----mg B. Pethidine-----mg C. Fentanyl ----- μg D. Morphine -----mg F. Diclofenac--- -----mg	

Part III. Post-operative data

S. No	Question	Response
1	Duration of surgery and anesthesia	A. Surgery ----- minutes B. Anesthesia -----minutes
2	Post-operative Analgesia given	A. Tramadol -----mg B. Pethidine-----mg C. Fentanyl ----- µg D. Morphine-----mg F. Diclofenac--- ---mg.

Part IV: Episode of post-operative nausea and vomiting after anti-emetic prophylaxis

Episode of nausea	no	yes	Mild	Moderate	Severe
At 6 hours					
At 12 hour					
At 24 hours					
Episode of vomiting			Number of episodes		
At 6 hours					
At 12 hours					
At 24 hours					

VI. Side effects observed after antiemetic prophylaxis within 24 hours

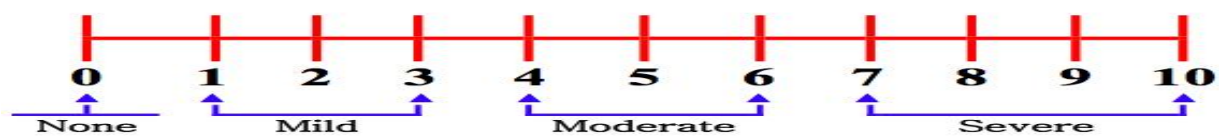
Side effects	no	yes
Headache		
Sedation		
Abdominal cramp		
Hypotension		
Others		

VII. Dose the patient has post-operative pain within 24 hours? If yes

A. Mild B. moderate C. severe

VII. Dose the patient ask anti-emetic drugs within 24 hours post operatively? A. no B. yes

Appendix



Numeric rating scale of severity of pain and nausea adopted from AAGBI.