



ADDIS ABABA UNIVERSITY
COLLAGE OF HEALTH SCIENCE
SCHOOL OF MEDICINE
DEPARTMENT OF ANAESTHESIA

Prophylactic effect of sub hypnotic dose of propofol in the prevention of Intraoperative post-delivery nausea and vomiting in mothers undergoing elective caesarean section under spinal anaesthesia at ALERT referral hospital, Addis Ababa, Ethiopia, 2020, a prospective cohort study.

PRINCIPAL INVESTIGATOR: - Adane Bayisa (BSC)

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June, 2020

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Declaration

I, the undersigned declare that the research Prophylactic effect of sub hypnotic dose of propofol in the prevention of Intraoperative post-delivery nausea and vomiting in mothers undergoing elective caesarean section under spinal anaesthesia at ALERT referral hospital, Addis Ababa, Ethiopia. Institutional based prospective cohort study is my original work in partial fulfilment of the requirements of Master's science degree in Anaesthesia. I understand that plagiarism is not tolerated and all directly quoted material has been appropriately referenced.

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Abstract

Background: Post-delivery Nausea and vomiting is one of the most common and unpleasant events affecting parturients undergoing caesarean delivery under spinal anaesthesia. It causes

Parturient discomfort, it interferes with surgery, elevates the risk of bleeding as well as increasing the risk of pulmonary aspiration.

Objective: To assess the prophylactic effects of sub hypnotic dose of propofol in preventing the occurrence and severity of post-delivery nausea and vomiting in parturients who underwent elective Caesarean Section under Spinal Anaesthesia

Methods: A prospective cohort study was done at Alert Referral hospital on 62 Parturients who came for elective caesarean section under spinal anaesthesia by using systematic random sampling method. Incidence of nausea and vomiting, severity of nausea and use of rescue anti emetic were assessed. Distribution of numerical data analysed using Shapiro Wilk test. Independent t-test and Mann Whitney U test were used to compare symmetric and asymmetric data, respectively. Categorical variable between two groups were analysed using Chi Square or fisher exact test as appropriate. P value <0.05 was considered as statistically significant.

Result: The incidence of PDNV was significantly lower in the propofol group when compared to non-propofol group the first 10 minutes post-delivery period (41.9% vs.74.2%) ($P = 0.01$). The severity of nausea was statistically greater in the non propofol group compared to propofol group (32.3% in non propofol group experienced moderate nausea versus 3.2% in the propofol group ($p=0.006$) and severe nausea was (0% Vs 22.7%, $p=0.11$) Less Intraoperative rescue antiemetic metoclopramide consumption was observed in sub hypnotic propofol group compared to non-propofol group. The median rescue ant emetic consumption was 10 mg in non-propofol group and 0 mg in propofol group ($p<0.001$).

Conclusion and recommendations: Administration of prophylactic sub hypnotic dose of propofol (20 mg IV bolus) after delivery of the baby and clamping of the umbilical cord was effective in the prevention and immediate treatment of post-delivery nausea and vomiting and reduce need for Intraoperative rescue antiemetic for parturients undergoing elective caesarean section under spinal anaesthesia.

The researcher recommend the use of prophylactic intravenous sub hypnotic dose of propofol (20 mg) for parturients undergoing elective caesarean section under spinal anaesthesia for the prevention of Intraoperative post-delivery nausea and vomiting.

Key words: caesarean section, spinal anaesthesia, nausea vomiting

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List of abbreviation and acronyms

ASA	American Society of Anaesthesiologists
ALERT	ALL Africa Leprosy Rehabilitation and Training centres
BMI	Body Mass Index
BPM	Beat per Minute
CS	Caesarean Section
GA	General Anaesthesia
DBP	Diastolic Blood Pressure
VRS	Verbal Rating Score of Nausea
SBP	Systolic Blood Pressure
SA	Spinal Anaesthesia
PONV	Postoperative Nausea and Vomiting
IONV	Intra Operative Nausea and Vomiting
PDNV	Post Delivery Nausea and Vomiting
Mg	Milligram
MAP	Mean Arterial Pressure
IV	Intravenous
µG	Microgram
NSAIDS	Non-Steroidal Anti-Inflammatory Drugs
PR	Pulse Rate
RR	Respiratory Rate
SPO ₂	Arterial Blood Saturation
W H O	World Health Organization

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Chapter 1: Introduction

1.1 Background

It is well known fact that many women in the world face critical challenges of giving birth through the normal way during delivery Thus, one of the widely used means that health professionals employ to help women not able to deliver through the normal means is caesarean section.

Over the years, Caesarean section (C-section) has remained to be a crucial obstetric intervention for saving lives of women and their newborns from pregnancy and childbirth induced complications.(1)

According to World Health Organization, the rate of Caesarean section (C/S)lies between 10% and 15 % but most recent studies portray it is a little higher around 19% and Ethiopian national Caesarean section rate is around 2% but the rate is considered to vary widely among different administrative regions .in Addis Ababa rate of caesarean section is 24.4% (2,3) .

Regarding the anaesthetics technique used, both general and regional anaesthesia (spinal, epidural or combined spinal and epidural anaesthesia) are acceptable for use during Caesarean section. Regional anaesthesia is used in 95% of deliveries, with spinal and combined spinal and epidural anaesthesia being the most commonly used regional techniques in scheduled caesarean section(3, 4).

Regional anaesthesia is preferred as it allows the mother to be conscious during the procedure and interact with her baby immediately afterwards. Moreover, compared to general anaesthesia, regional anaesthesia is better at preventing persistent postoperative pain that can last up to eight hours after the procedure. Other advantages of regional anaesthesia include, elimination of typical risks associated with general anaesthesia such as pulmonary aspiration of gastric contents and oesophageal intubation (3, 4, 5).

Nausea and vomiting during and or after spinal anaesthesia for elective Caesareans delivery is a common finding that may occur in up to 66% of patients. The injected local anaesthetics do not only specifically block the bundle of pain fibers but also lead to a vessel dilatation by affecting sympathetic efferences.

As a result of the induced temporary sympathicolysis, blood pressure fluctuations, particularly presenting as significant hypotension can occur. On top of that, the increased vagal tone entails bradycardia, which is often accompanied by nausea and vomiting. Hence, the expected blood loss increases by several hundreds of millimetres within a short period of time. This can lead to a major bleeding. Depending on the parturients cardiac output and other circulatory variables, compensating huge blood loss quickly can be challenging and usually take several minutes(6).

Meanwhile, the blood pressure may further decrease. These serious of events cause a reduced per-fusion of the brain. Consequently, this ischemia may activate the vomiting centers in the medulla oblongata. As a result, parturients can be forced to entertain nausea and – in worst case – vomiting. In addition to that, the unavoidable manipulation of the uterus and peritoneum as well as the externalization of the uterus during the procedure can cause nausea and vomiting by activating afferent vagal efferences. (7,8)

Consulting Apfel's predictive postoperative nausea and vomiting PONV score that consists of four ascertained risk factors (female, non-smoker, opioids use, previous PONV events or motion sickness), parturients often fulfill at least two of these criteria with their gender and the non-smoker status. (9, 10, 11)

In view of such unprecedented incidence of Intraoperative and post delivery nausea and vomiting, several studies have made an effort to design both pharmaceutical (ondansetron, metolclopromide, droperidol and ginger) and non-pharmaceutical therapies (acupressure and acupuncture). Although these treatment options have been proved to reduce the incidence of nausea and vomiting, many of these drugs are standard treatment for postoperative nausea and vomiting but not specific solutions for parturients. Sub hypnotic dose of propofol is thought to be an effective anti emetic and therefore very useful to decrease the incidence of PONV. (12, 13, 14).

Propofol is an intravenous general anaesthetic and sedation drug used for induction and maintenance of anaesthesia and sedation. Propofol is thought to produce its sedative or anaesthetic effects by the positive modulation of the inhibitory function of the neurotransmitter GABA. Propofol possesses antiemetic properties when administered in sub-hypnotic doses. However, the exact mechanism by which Propofol acts as an antiemetic remains unclear. It has been postulated that its antiemetic effects may be due to an antagonist at the 5-HT3 receptor (15).

1.2 Statement of the Problem

Intraoperative Post-delivery nausea and vomiting that occurs in women undergoing caesarean section under regional anaesthesia is a vital clinical problem since these techniques are used widely. Nausea and vomiting during regional anaesthesia for caesarean section is very common and yet unpleasant event. Apart from causing patient discomfort, it interferes with surgery and increases procedure time, enhanced intra- and post-operative pain, elevates the risk of bleeding, inadvertent surgical trauma as well as increasing the risk of pulmonary aspiration of gastric contents. Furthermore, it can result in hospitalization or later re-admission, thus increasing both health care costs and the psychological burden on the patient. The incidence of post delivery nausea and vomiting during caesarean section under regional anaesthesia is estimated to be 50%–80% without administration of prophylactic drugs. (12, 16, 17)

It has multiple and complex etiologies and risk factors, which includes hypotension due to sympathectomy, vagal hyperactivity, visceral pain, IV opioids supplementation, stimulation during surgery such as push on the abdomen for fetus delivery, uterine agents and visceral manipulation (9-12)

Therefore, use of prophylactic anti-emetics in these patients is logical. Many researches have been conducted to study the pattern and counteract these problems. Currently used anti-emetics may induce undesirable side effects, such as extra pyramidal symptoms (dopamine receptor antagonists), excessive sedation and tachycardia (antihistamine drugs). Recent researches are focused on finding an effective and well tolerated anti emetic agents, which lacks the aforementioned adverse effects. As a result, sub hypnotic dose of propofol is found to be useful in alleviating nausea and vomiting in mothers undergoing caesarean section under spinal anaesthesia for caesarean section more efficiently than droperidol and metoclopramide without causing undesirable side effects.. (13, 18,27)

1.3 Justification of the study

On the basis of such high incidence of intra operative and post delivery nausea and vomiting, several studies have made an effort to design both pharmaceutical and non-pharmaceutical remedies, such as ondansetron, metoclopramide, droperidol, ginger, acupuncture and acupressure. Although these treatments have been proved to reduce the incidence of nausea and vomiting, many of these drugs have been used as a standard treatment for post-operative

nausea and vomiting (PONV) rather than particularly for the parturient (6, 13, 14, 19, and 20). Additionally, the existing drugs used for prevention or treatment of this problem have adverse effect such as intense sedation, dystonic reactions, restlessness, and extra pyramidal symptoms.

Ideally, one would prefer a more specific, safe, accessible, cheap and effective prophylaxis and immediate treatment of post-delivery nausea and vomiting occurrence for parturient. The direct and indirect anti emetic effects of propofol are well known and it has been acknowledged to manifest profound anti emetic properties at sub hypnotic (15)

There is a controversy regarding the effectiveness and optimum doses of prophylactic sub-hypnotic doses of propofol in the prevention and treatment of the occurrence and severity of postoperative nausea and vomiting in parturient undergoing caesarean section under spinal anaesthetics (18-28).

As far as the authors' knowledge, there is no previous study done in our country to assess the prophylactic effects of sub hypnotic dose of propofol in the prevention and immediate treatment of post-delivery nausea and vomiting (PDNV) for caesarean section after spinal anaesthesia despite it has been studied in different part of the world.

Additionally since the researches have been done in different hospital set up and different facilities from our country, I want to study the prophylactic effect of sub hypnotic dose of propofol in our society.

Besides, this research may contribute in the improvement of both pre service and in-service training and education. It could also contribute in giving insight for practitioners and researchers to do further research on the issue.

Therefore, the objective of the present study was to assess the prophylactic effects of sub hypnotic dose of propofol on the occurrence and severity of PONV in parturients undergoing caesarean section under spinal anaesthesia

1.4 Hypothesis

HO1: There is no difference in the incidence of nausea between groups

HA1: There is difference in the incidence of nausea between groups

HO2: There is no difference in the incidence of vomiting between groups.

HA2: There is difference in the incidence of vomiting between groups

HO3: There is no difference in the severity of nausea between groups

HA3: There is difference in severity of nausea between groups

HO4: There is no difference in rescue anti emetic requirements between groups

HA4: There is difference in rescue anti emetic requirement between groups

Chapter Two

2. Literature review

Nausea and vomiting during regional anaesthesia for caesarean section are very common and yet unpleasant events. They cause significant distress to the patients and interfere with surgical procedure. Moreover, they can lead to medical side effects such as aspiration of gastric content, enhanced intra- and post operative pain, increased hospital stay and readmission, exploit hospital's and parturients resources and even bleeding or surgical trauma. (12)

Sub-hypnotic doses of Propofol have been associated with a lower incidence of PONV compared with placebo (18, 20, 23, 24, 26, and 27), midazolam (25) and metoclopramide, droperidol and placebo (28) for parturient undergoing caesarean section under spinal anaesthetics without any significant side effects. However, studies conducted by Shi JJ et al. (19) and Caba F et al. (4) found no significant differences in the incidence and severity of post-operative nausea and vomiting between sub hypnotic dose propofol versus none propofol group on those mothers taking spinal anaesthesia for elective C-section.

It has been used at dose range of 0.5 mg/kg/h to 1.5 mg/kg/h for the prevention and treatment of PONV in parturient undergoing caesarean section under spinal anaesthesia (23,27,28). Prophylaxis with sub hypnotic intravenous bolus dose of 20 mg propofol [25] and 20 mg sub hypnotic intravenous bolus dose plus 0.1 mg/kg/hr. propofol (18) has been shown effective in reducing the incidence of PONV without any significant side effects. However, Shi JJ et al. [19] reported no reduction in emesis in patients with a bolus injection of low dose (10 mg) propofol in patients undergoing caesarean delivery under spinal anaesthesia

A randomized, double-blind, and placebo-controlled clinical trial conducted in Iran by Rasooli S. et al. (2014); in 90 parturient age 20-30 years who undergone spinal anaesthesia for caesarean section were randomly allocated (n=30 in each group) to one of three groups receiving propofol 20 mg bolus and 1 mg/kg/hr., midazolam 1mg bolus and 1mg/kg/hr and placebo immediately after umbilical cord clamping. The researcher found incidence of nausea and vomiting was significantly higher in the control group compared to propofol and midazolam groups. In both sub hypnotic propofol and midazolam group incidence of nausea and vomiting decreased significantly ($p < 0.001$). Similarly Intraoperative metoclopramide consumption was significantly high in control group with p value < 0.001 (18)

Randomized controlled double blind study done on patients taking spinal anaesthesia for elective C- section in Taiwan by Je-Jang Shi, Yong-Ping Wang (1994) shows statistically insignificant difference on the incident of nausea (24% vs. 40%) and vomiting (16% vs.20%) in the group exposed to sub hypnotic dose of propofol (10mg) and groups that had received placebo, respectively. The researcher concluded that low dose propofol (10 mg) administered during spinal anaesthesia for caesarean section failed to reduce the incidence of emesis (19)

Differently in a research done by Kun Niu (2018) et al, in china, using randomized prospective study on Eighty ASA 1 or 2 women undergoing elective caesarean delivery under spinal anaesthesia, forty patients each were included in the propofol (20mg bolus+1mg/kg) and placebo group didn't found significant difference between the groups in terms of vomiting and retching p value>0.05 but incidence of post delivery nausea significantly low in propofol group (incidence of nausea in propofol 25% and 60% in control group P<0.001) finally the researchers recommend the use of sub hypnotic dose of propofol is important in the management of nausea without causes respiratory depression but not for vomiting and retching.(20).

On another hand Randomized Controlled double blind study on those mothers taking spinal anaesthesia for elective C-section in Spain by Caba, F(1997) et al, shows no significant differences in the incidence and severity of intra operative nausea and vomiting between two groups (22.5% sub hypnotic propofol versus none propofol group 23%) (21) the researchers finally conclude 10mg propofol is not effective in prevention of nausea and vomiting.

A. Rudra and his colleagues in India (2004) performed prospective randomized control trial to assess the efficacy of propofol in prevention of emesis (PONV) on Sixty ASA 1 and ASA 2 women undergoing elective C-section with spinal bupivacain by categorizing 30 parturient on each of the exposed (propofol 1mg/kg/hr.) and non-exposed group (placebo interlipid) immediately after clamping of the umbilical cord.. The researcher found that 86% with propofol group and 40% with placebo did not develop nausea and is clinically significant with P <0.05 and the severity of nausea was less in patients who had received propofol 1.0 mgkg-1hr-1 than in those who had received placebo (P < 0.05). The researchers concluded that propofol, given at sub hypnotic dose (1 mg/kg/hr.) significantly decreases the incidence and severity of emetic episodes in patients undergoing caesarean delivery under spinal anaesthesia without causing clinically important adverse effect (23).

Another prospective, randomized, double blind, placebo controlled study conducted by S Mukherjee et al. in India (2006) in eighty parturient undergoing elective C-section by categorizing into three propofol taking group (0.5mg/kg/hr, 1mg/kg/hr, 1.5mg/kg/hr) and placebo in order to know the optimum dose of propofol to treat post-operative nausea and vomiting immediately after the clamping of the umbilical cord. The study yielded the incident of patients without nausea and vomiting (emetic episodes) intra operatively post-delivery period was 45% for 0.5 mg/kg/hr with p value(<0.05), 85% with 1mg/kg/hr ($P<0.01$), and 85% for 1.5mg/kg/hr with p value <0.001 compared with placebo (40%) and the researchers conclude propofol 1mg/kg/hr is optimum dose for reducing emetic symptoms during caesarean delivery and no need to use 1.5 mg/kg of propofol. The researchers found that number of emesis free patients were greater in the propofol groups compared to placebo ($P < 0.01$) and the severity of nausea was greater in patients receiving placebo than in those receiving propofol ($P < 0.05$) (24).

Comparative randomized controlled double blind trial conducted to compare the antiemetic effects of sub hypnotic dose of propofol and midazolam in 42 ASA 1and ASA 2 aged between 15 and 35 parturient undergoing elective caesarean section under spinal anaesthesia by Zabetian H et al. in Iran (2016) showed significant difference in the incidence of postoperative nausea and vomiting between the groups. In their conclusion they recommend to use sup hypnotic dose of propofol (20mg) immediately after spinal anaesthesia in preventing post-delivery nausea and vomiting (25).

In another double-blinded placebo controlled trial study conducted by S. Samimi et.al in Iran (2018) in 114 ASA physical status I and II parturient 18-40 years old undergoing elective C-section under spinal anaesthesia, the incidence of nausea and vomiting was significantly lower in midazolam (1mg bolus and 2 mg/hr infusion) and propofol groups (20 mg bolus, 1mg/kg/hr. infusion) compared with saline group (nausea: 19%, 15.8% versus 57.9%), vomiting (7.9%, 5% versus 34.2%). Sub hypnotic dose of propofol administer after clamping of the umbilical cord was effective for preventing of postoperative nausea and vomiting in parturients undergoing caesarean section under spinal anaesthesia (26).

On the other hand, a prospective randomized placebo-controlled study done by M. Numazaki and Y. Fujii in Japan on sixty patients who underwent C-section under spinal anaesthesia showed the incidence of patients who were emesis free in the intra operative and postoperative period was 37% with placebo and 77% with propofol ($P=0.001$). The

researchers concluded that sub hypnotic dose of propofol (1mg/kg/hr) is effective for preventing nausea and vomiting in parturient undergoing elective caesarean section (27).

Another randomized double-blinded placebo-controlled study done by M. Numazaki et.al in Japan (2003) to compare the effectiveness in prevention of post-operative nausea and vomiting by giving sub hypnotic dose of propofol, metoclopramide, droperidol and placebo (intralipid) found 80% of sub hypnotic dose of propofol group were emetic free while 78% from metoclopramide and droperidol groups compared with placebo (40%) demonstrated to be free from emesis. The researchers concluded prophylactic anti emetic efficacy of propofol at sub hypnotic dose (1mg/kg/hr.), droperidol 1.25 mg and metoclopramide 10mg is comparable in prevention of severe nausea on parturient undergoing c/s but sub hypnotic dose of propofol to be more effective (28).

Chapter Three

3. Objective

3.1. General Objectives

To assess the prophylactic effect of sub hypnotic dose of propofol in preventing the occurrence and severity of Post Delivery Nausea and Vomiting in parturient who undergo elective Caesarean Section under Spinal Anaesthesia at ALERT Referral Hospital, Addis Ababa, Ethiopia from December 2,2019 to March2,2020.

3.2. Specific objectives

- To compare the incidence of nausea between the sub hypnotic dose of propofol and non-propofol groups.
- To compare the incidence of vomiting between the sub hypnotic dose of propofol and non-propofol groups.
- To compare the severity of post-delivery nausea between the sub hypnotic dose of propofol and non-propofol groups
- To compare rescue anti-emetic requirement between the sub hypnotic dose of propofol and non-propofol groups.

Chapter Four

4. Methodology

4.1. Study Area

This particular study was conducted at ALERT hospital, which is one of the thirteen government hospitals found in Addis Ababa, capital city of Ethiopia Administered under ministry of health. ALERT is primarily established for leprosy and tuberculosis rehabilitation and training. Now it has a lot of catchment area, health centres from where different complicated cases are referred. It has so many departments of specialties beneath it. The acronyms of ALERT stand for All Africa leprosy rehabilitation and training centres. Currently it is a 268-bed hospital, which provides dermatology, Trauma centres, ophthalmology, general surgery, obstetrics and orthopaedics service. ALERT hospital has eight major operation tables among these two of them are used for gynaecological and obstetric service. These units serve on average 4446 per year (370 per month) from these around 2500 parturients undergoes caesarean section annually.

4.2. Study Design and Period

An Institutional based prospective observational cohort study was Employed from December 2, 2019 to March2, 2020.

4.3. Source and Study Population

4.3.1. Source population

All Parturient underwent caesarean section under spinal anaesthesia at ALERT hospital.

4.3.2. Study population

Selected parturient who were undergoing Elective caesarean section under spinal anaesthesia and fulfilled inclusion criteria during the study period at ALERT hospital were included.

4.4. Study variables

4.4.1. Dependent variables

- Incidence of nausea
- Incidence of vomiting
- Severity of nausea measured by verbal rating scale (VRS)
- Total rescue anti emetic consumption intraoperatively

4.4.2. Independent variable

- Socio demographic characteristics: age; ASA status
- Hemodynamic variables: blood pressure, heart rate, respiratory rate , arterial oxygen saturation (Spo₂)
- Verbal rating scale
- Use of uteronic medications

- Exposure variable: sub hypnotic dose of propofol group and non-propofol group

4.5. Inclusion and exclusion criteria

4.5.1. Inclusion criteria

ASA II mothers who were scheduled for elective caesarean section who underwent caesarean section under spinal anaesthesia that were received 20 mg sub hypnotic dose of propofol or not.

4.5.2. Exclusion criteria

- Patients who had smoking habit
- patients who had history of motion sickness
- Administration of anti emetic medication in the previous 24 hours,
- Mothers with known Allergy to propofol
- Mothers who use intra operative opioids were excluded.

4.6. operational Definition

ASA status: is a surgical risk stratifications validated by American Society of Anaesthesiologist

ASA II: A patient with mild systemic disease only without substantive functional limitation. Example (include but not limited to) current smoker, pregnancy, obesity $30 < \text{BMI} < 40$, well controlled medical condition, mild lung disease.

Spinal anaesthesia- It a type of regional anaesthesia in which local anaesthetic Agents is administered in subarachnoid space for mothers underwent caesarean section.

Effectiveness: the ability of sub hypnotic dose of propofol to produce intended or expected result or outcome

Sub hypnotic dose propofol group parturient who received 20 mg propofol under spinal anaesthesia during caesarean section after the baby delivered and umbilical cord is clamped.

No Sub hypnotic dose propofol group: parturient who did not received 20 mg propofol under spinal anaesthesia during caesarean section.

Nausea: a subjective sensation suggesting that a patient desires to vomit.(30)

Vomiting: a forceful expulsion of gastric contents from the mouth (30)

Hypotension: The decrease in mean arterial blood pressure (more than 20% from baseline value) after spinal injection defined as hypotension.

Verbal Rating Score (VRS) for nausea: is a valid nausea intensity assessment tool that involves asking a patient to rate her nausea from 0-10(11-point scale) with the understanding that 0 is equal to no nausea and 10 equal to the worst possible nausea. Any score more than zero was considered as nausea. (20)

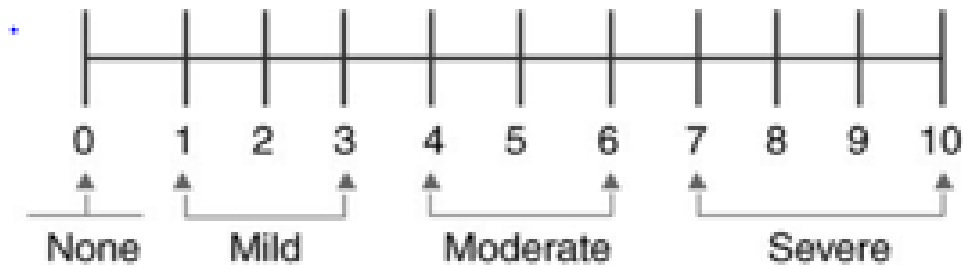


Figure 1: VRS nausea intensity assessment tool adapted from semanted scholars

4.7. Sample Size and Sampling technique

4.7.1. Sample size

Comparison of two proportions with equal sample size formula for independent study with incidence of nausea was used to calculate the sample size .Having no previous study done in the study area, the result adopted from literature from china (2018) has been used to calculate the sample size based on the two-outcome variables and the largest sample size was used for recruiting study subjects. The study shows the incidence of nausea is significantly decreased which is reported as (25% versus 60%, $P < 0.001$).⁽²⁰⁾

$$n = \frac{(Z1 + Z2)^2 2P(1 - P)}{(P2 - P1)^2}$$

Where

n = Sample size in each group

z1 = 1.96 for 95% confidence level= 1.64 for 95% power

z2 = 0.84 for 80% power

p1 = proportion in propofol group=25%=0.25

p2 = proportion in control group=60%=0.6

$$P = \frac{P1+P2}{2} = 0.425 \quad 1-P=0.575$$

$$n = \frac{(1.96 + 0.84)^2 * 2 * 0.425(1 - 0.425)}{(0.6 - 0.25)^2}$$

$$= 31$$

So that using 1:1 ration between groups and adding 10% contingency 68 patients were required.

Systematic random sampling was used to select study participants. The daily elective caesarean section schedule list was used as a sampling frame.

The situational analysis showed that 11 mothers who fulfilled our inclusion criteria were operated in alert referral Hospital per week that got from surgery logbook record, according to this data, we had 132 parturients in our study period, and we collected data from 68 parturients. So sample interval (k) was calculated as $K=132/68$, approximately 2.

The first participant was selected randomly using lottery method. Then every two parturients were included in this study from the daily operation schedule list until the required sample size was met.

n=total sample population

N=total study population

K=skip interval

4.7.2. Data Collection Technique and Study populations(patients)

Four anaesthetists were given training by the principal investigator about how to collect the data. In ALERT hospital, some anaesthetists give 20 mg of propofol intravenously as a prophylaxis for the prevention and immediate treatment of post-delivery nausea, vomiting in parturient undergoing caesarean section under spinal anaesthesia after the umbilical cord is clamped, and baby is delivered.

The Parturients were grouped based on their exposure to prophylactic sub hypnotic dose of propofol based on the responsible anaesthetists' independent decision to give 20 mg of 1% propofol; i.e. if the anaesthetist decides to give propofol, that parturient has been followed under the propofol group; if not, the parturient has been grouped under non propofol group after the delivery of baby and clamping of the umbilical cord and followed until the end of surgery.

Parturients who were scheduled for Elective caesarean section under spinal anaesthesia who fulfilled inclusion criteria and volunteered to take part in the study were instructed on how to self-report nausea using the eleven-point verbal rating scale (VRS) score and intra

operatively trained anaesthetists filled structured questionnaires every 10 Minutes till the end of procedures.

Intra operatively after the umbilical cord clamp 20 mg propofol was administered by the responsible anaesthetist and trained anaesthetists collect data on the incidence of nausea, incidence of vomiting and severity of nausea using VRS at the 10th, 20th and 30th minutes after the umbilical cord is clamped and the baby is delivered and total requirement (consumption) for anti-emetics was documented for 30 minutes intraoperatively.

4.8. Data quality control

A structured questionnaire was prepared in English for data collection and informed consent was prepared in English and translated to Amharic by language expert.

Pre-test was done for two days (November 4 and 5) at Yekatit 12 hospital with 5% of total sample size, which were not included in the actual study. Collected data were checked for completeness, accuracy and clarity. Based on the findings of the pre-testing, appropriate amendments and revisions were made before the final administration of the questionnaire for actual data collection. There was a discussion on any kind of problem the data collectors was face during the data collection process and Regular supervision was done during data collection by principal investigator.

4.9. Data processing and analysis

Data were cleaned, entered, coded and analysed by using SPSS version 20. Data distribution was tested for normality using Shapiro Wilk test and presented in terms of mean \pm SD for symmetric data like age, baseline heart rate, and baseline respiratory rate baseline mean arterial pressure, fasting hours, and baseline oxygen saturation, blood loose, duration of surgery and after drug administration mean arterial blood pressure, heart rate, and respiratory rate.

Median (Interquartile range) was used for asymmetric numeric data like, baseline verbal rating scale and intra operative metolclopromide and Dexamitasone used. Homogeneity of variance was assessed using Levene's test for equality of variance.

Comparison of numerical variables between study groups were done using independent t- test for normally distributed numerical data (age, baseline heart rate, baseline respiratory rate baseline mean arterial pressure, fasting hours, and baseline oxygen saturation)

Mann Whitney U test for non-parametric data (baseline verbal rating scale and intra operative metoclopramide and Dexamitasonone used). Frequency and percentage were used to describe categorical variable (diagnosis, episode of nausea and vomiting, severity of nausea, intra operative complications) and statistical difference between groups were tested using Chi square and fisher's exact test. A p value <0.05 considered statistically significant.

4.10. Ethical consideration

Ethical clearance and approval to conduct the research was obtained from the university ethical clearance and review committee before the start of the study. The importance of the study was explained & verbal informed consent was obtained from each participant by the data collectors. The consent form was in line with the ethical principle of “autonomy” was involve a sentence says their decision to participate or not to participate will have no effect on their ability and right to receive services at the health centre. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify parturients.

4.11. Dissemination of the study results

The results of the study will be presented to the department of anaesthesia as part of M.Sc. in advanced clinical anaesthesia thesis and it will be submitted to College of Health Sciences, Department of anaesthesia and a copy of this material will be given to ALERT, Addis Ababa University student research office. After presentation on workshops and seminars, hopefully it will be published in peer reviewed reputable journals. It also serves as a reference material to researchers, experts and policy makers for intervention.

Chapter five

5. Result and Discussion

5.1. Results

5.1.1. Demographic and hemodynamic characteristics of patients

Data was collected from 68 parturients; six samples were excluded since they met exclusion criteria. 62 patients (31 patients in each group) were finally involved for analysis based on whether they received 20mg of propofol as sub hypnotic propofol group or not received as non-propofol group.

Table 1: Demographic and hemodynamic characteristics of parturients who underwent elective C-Section under spinal anaesthesia at ALERT hospital, Addis Ababa Ethiopia, 2019/2020 (n=62)

Variables	Sub hypnotic propofol group(n=31)	No sub hypnotic propofol group(n=31)	P value
Age(years)	28.35 ±3.77	27.26±4.12	0.279
NPO time(hours)	8±1.24	8±1.32	1.00
Parity n (%)			0.263
Prim gravid	7(38.9%)	11(61.1%)	
Multi gravid	24(54.5%)	20(45.5%)	
Baseline MAP	92.53±8.27	92.41±6.7	0.948
MAP after drug administration	72.58±8.69	72.07±6.93	0.80
Baseline verbal rating scale	0.00(0-2)**	0.00(0-2)**	0.704
Baseline HR(BPM)	90.16±11.43	92.87 ±12.64	0.38
HR after drug administration	89.1±11.44	90.87±12.64	0.564
Baseline RR	15.16±1.46	14.87 ±1.54	0.45
RR after drug administration	14.23±1.36	13.97±1.38	0.461
Base line SPO2	97.16±2.02	96.58±1.63	0.217
SPO2 after drug administration	97.97±1.82	97.58±1.67	0.380
Duration of surgery	38.71±4.2	38.94±3.8	0.825
Estimated blood loos(ml)	979.03±41.9	987.10±38.9	0.419

*Hint: Values are presented as mean ± SD, **= Median (IQR), and n (%) = number and percentage. Median (IQR); Mann Whitney test used; Mean± standard deviation, independent t-test used; n (%) = number (proportion); Chi square test used. p-value < 0.05 considered statistically significant*

No statistical significant differences were found between the groups with respect to demographic characteristics and hemodynamic characteristics of parturients were comparable pre and post propofol administration between groups (table-1). Additionally all mothers were given oxytocins as uterine agent thus we did not perform analysis since it is constant between groups.

5.1.2. Incidence and severity of Intraoperative Post Delivery Nausea and Vomiting

The overall incidence of Post Delivery Nausea and Vomiting in the first 10 minutes postoperatively was significantly lower in the propofol group than that of non-propofol group (41.9% and 74.2% respectively).

The incidence of nausea during the first 10 minutes post-delivery time was significantly lower in parturients who received propofol (41.9%) when compared to non-propofol group (74.2%) ($P = 0.01$). Similarly, the incidence of vomiting was significantly lower in parturients who received propofol in the first 10 minutes post-delivery time when compared to non-propofol group (19.4% and 45.2%, respectively).

At the end of caesarean section (30 minutes), three parturients from non-sub hypnotic propofol group and one parturient from sub hypnotic propofol group complain nausea and one parturient from non-sub hypnotic propofol group experienced vomiting, while no mother from sub hypnotic propofol group. However, there were no statistically significant differences in the incidence of nausea and vomiting at 10-20 minutes and 20-30 minutes (table 2).

Table 2 incidence of nausea and vomiting in parturients who underwent elective caesarean section under spinal anaesthesia at ALERT hospital, Addis Ababa Ethiopia, 2019/2020

Time intervals	Variables		Sub hypnotic propofol group (n=31)	Non propofol group(n=31)	P value
0-10 minute	Nausea	Yes	13 (41.9%)	23 (74.2%)	0.01**
		No	18 (58.1%)	8(25.8%)	
	Vomiting	Yes	6 (19.4%)	14 (45.2%)	0.03**
		No	25 (80.6%)	17 (54.8%)	
10-20 minute	Nausea	Yes	4 (12.9%)	10 (32.3%)	0.068*
		No	27 (87.1%)	21 (67.7%)	
	Vomiting	Yes	1 (3.2%)	3 (9.7%)	0.612#
		No	30 (96.8%)	28 (90.3%)	
20 -30minute	Nausea	Yes	1 (3.2%)	3 (9.7%)	0.612#
		No	30 (96.8%)	28 (93%)	
	Vomiting	Yes	0(0%)	1(3.2%)	1.0#
		No	31(100%)	30(96.8%)	

Hint: values are expressed in number (proportion); Chi square test used, statistically significant**, # fishers exact test used*

The severity of nausea was statistically greater in the non propofol group compared to propofol group; 9 patients (32.3%) in non propofol group experienced moderate nausea versus 1 patient (3.2%) in the propofol group (p=0.006). seven patients (22.6%) in non propofol group experienced severe nausea versus no episodes in the propofol group which was statistically significant(p=0.011).

Three parturients from sub hypnotic propofol group and eight parturients from non-sub hypnotic propofol group complain mild nausea and one parturient from sub hypnotic propofol group and two parturients from non-sub hypnotic propofol complain moderate nausea at 10-20; one parturient from sub hypnotic propofol group and three parturients from non-sub hypnotic propofol develop mild nausea at and 20-30 minutes .

However, there were no statistically significant differences in the severity of nausea at 10-20 minutes and 20-30 minutes (table 3).

Table 3 severity of nausea in parturients who underwent elective caesarean section under spinal anaesthesia at ALERT hospital, Addis Ababa Ethiopia, 2019/2020

Time intervals	Variables	Sub hypnotic propofol group (n=31)	Non propofol group(n=31)	P value
0-10 minute	Mild	12 (38.7%)	7 (22.6)	0.168*
	Moderate	1 (3.2%)	9 (32.3%)	0.006**
	Severe	0 (0%)	7(22.6%)	0.011##
10-20 minute	Mild	3 (9.7%)	8 (25.8%)	0.96*
	Moderate	1 (3.2%)	2 (6.5%)	1.0#
	Severe	0 (0%)	0 (0%)	
20 minute-30minutes	Mild	1 (3.2%)	3 (9.7%)	0.612#
	Moderate	0 (0%)	0 (0%)	
	Severe	0 (0%)	0 (0%)	

Hint: values are expressed in number (proportion); Chi square test used, statistically significant **, #Fishers exact test was used,## statistically significant*

5.1.3. Comparison of rescue antiemetic consumption between groups

The median rescue ant emetic consumption in non-propofol group was 10 mg and 0 mg in propofol group with statistically significant difference (p<0.001).

Intraoperative rescue anti emetics metoclopramide consumption in no sub hypnotic propofol group analysed using Mann Whitney test is statically significant compared with sub hypnotic propofol group with p value <0.001, however, there was no significance difference in Dexamitasone consumption between the two groups (table 4)

Table 4 Intraoperative rescue anti emetic consumption of metolclopromide and Dexamitasone in parturients who underwent elective caesarean section under spinal anaesthesia at ALERT hospital, Addis Ababa Ethiopia, 2019/2020

Variables	Sub hypnotic propofol group	No Sub hypnotic Propofol group	P value
Metolclopromide (milligram)	0.00(0-10)	10.00(0-10)	<0.001*
Dexamitasone (milligram)	0.00(0)	0.00(0-4)	0.096

Hint: ## = Median (IQR); Mann Whitney test used, statistical significant*

5.1.4. Complication between Groups

Between the groups, the occurrence of Intraoperative complication was observed on 16 (51.7%) parturients of in the sub hypnotic propofol group while it was 22 (71.0 %) of parturients for the non-sub hypnotic propofol group but it was not statically significant p value 0.118. (Table 5)

Table 5: intra operative complications of parturients underwent elective caesarean section under spinal anaesthesia at ALERT hospital, Addis Ababa Ethiopia, 2019/2020

	Variable	Sub hypnotic propofol group	No sub hypnotic propofol group	P- value
Intraoperative complications	Hypotension(yes)	10 (32.3%)	17 (54.8%)	0.73*
	Shivering(yes)	1 (3.2%)	0 (0%)	1.000#
	Sedation(yes)	3 (9.7%)	1 (3.2%)	0.238#
	Headache(yes)	2 (6.5%)	4 (12.9)	0.390

*Hint: number (proportion); Chi square test used*chi square were used, fishers exact test used.*

5.2. Discussion

Spinal anaesthesia in Caesarean section is associated with high incidence of nausea and vomiting and the reported incidence of nausea and vomiting in parturients during and immediately after caesarean section under spinal anaesthesia ranges from 50% to 80% when no prophylactic antiemetic is given (12, 16, and 17).

The focus of this study was to assess the prophylactic effect of sub hypnotic dose of propofol in preventing the occurrences of nausea, vomiting, severity of nausea and need for rescue antiemetic consumption at ALERT referral hospital, Addis Ababa, Ethiopia.

The result showed statistically significant difference in terms of incidence and severity of nausea, incidence of vomiting and metolclopromide consumption when sub hypnotic dose of propofol is used compared to no sub hypnotic dose of propofol group.

The present study demonstrates post-delivery sub hypnotic dose propofol (20mg) administration in parturients undergoing caesarean section under spinal anaesthesia after umbilical cord clamped resulted in statistically significant reduction in incidence (occurrence) of Intraoperative post-delivery nausea and vomiting in propofol group compared with the non-propofol group in the first 10 minutes. This finding is consistent with other studies that demonstrated a reduction in the incidence of PONV (18, 20, 25, 26).

The current study demonstrates post delivery sub hypnotic dose propofol (20mg) administration after umbilical cord clamped resulted statistically significant lower incidence (occurrence) nausea, vomiting and severity of nausea in sub hypnotic propofol group compared with the no sub hypnotic propofol group in 0-10 minutes.

In this study, the incidence of nausea alone was significantly lower in the propofol group than non-propofol groups (41.9% and 74.2% respectively) ($p=0.01$). This finding was highly comparable with Kun Niu et al. (20) and A. Rudra et al. (23) studies which found incidence of post-delivery nausea was significantly low in propofol at sub hypnotic doses (1 mg/kg/hr) group compared to placebo (saline) (25% vs. 60%) and (14% vs. 60), respectively) in women undergoing caesarean delivery under spinal anaesthesia.

The current study is also comparable with a study done by Samimi Sade et al. (26) which found the incidence of nausea was significantly lower in propofol group (20 mg bolus, 1mg/kg/hr. infusion) compared with saline group (15.8% versus 57.9%). But, the actual

figures (incidence) of post-delivery nausea in these studies were lower when compared with our study. The differences might be due to differences in the study design, difference in patient follow up for postoperative nausea and vomiting, in the route of propofol administration; they were administering propofol in infusion (1 ml/kg/hr.).

However, the result of present study is inconsistent with a study done in Taiwan by Shi JJ. et al. (19) and in Spain by Caba F et al. (21) found no significant differences in the incidence of post-operative nausea between sub hypnotic dose propofol versus non-propofol group on those mothers taking spinal anaesthesia for elective C-section. This difference might be due to the difference in the dose of propofol administered, which was 10mg.

The current study also showed that the incidence of vomiting alone in propofol group was significantly lower than that of non-propofol group (6 (19.4%) versus 16 (45.2%) ($p=0.03$). the present study is consistent with a study by Rudra and his colleagues (23) found that propofol at sub hypnotic doses (1 mg/kg/hr.) in women undergoing caesarean delivery under spinal anaesthesia resulted a significant decreases in the incidence and severity of emetic episodes in the Intraoperative or post-delivery period and a study done by Samimi Sade et al. (26) which found the incidence of vomiting was significantly lower in propofol group (20 mg bolus, 1mg/kg/hr. infusion) compared with saline group (5% versus 34.2%).

The result of current study is also in line with study done in Japan by M. Numazaki and Y. Fujii (27) and M. Numazaki et al. (28) which found a statistical significant reduction in the incidence of patients who were emesis free in the propofol group (1mg/kg/hr.) compared to placebo (77% vs. 37%, 80 % vs. 40%; respectively) in the intra operative and postoperative period in mothers who underwent C-section under spinal anaesthesia ($P=0.001$).

The result of present study is inconsistent with a study done in Taiwan by Shi JJ. et al. (19) and in Spain by Caba F et al. (21) found no significant differences in the incidence of post-operative vomiting between sub hypnotic dose propofol versus none propofol group. This is might be due to the use of insufficient dose of propofol in their study, which was 10 mg.

In contrary to current study, study conducted by Kun Niu et al.in China (20) also didn't found significant difference in the incidence of vomiting and retching between propofol (1mg/kg/hr.) and placebo (saline) groups in women undergoing elective caesarean delivery under spinal anaesthesia. The possible explanation for the difference might be due to the

administration of propofol (20 mg bolus IV) as rescue anti-emetics every 5 minute when patients complaining nausea or developed vomiting until symptoms were considered to have ceased in their study in both groups, which has antiemetic property (15).

In this study, the severity of nausea, which was measured by verbal rating scale, was significantly low in propofol group compared to non-propofol group. Moderate nausea was reported by 9 patients (32.3%) in non propofol group versus 1 patient (3.2%) in the propofol group.

During the first 10 minute after delivery of the baby and clamping of the umbilical cord, no patients experienced severe nausea in the propofol group, while seven patients (22.6%) in non propofol group experienced ($p=0.011$). The result of current study is in line with a study by A. Rudra and his colleagues (23), S Mukherjee et al. in India (24) and M. Numazaki et.al. (28) In which the researchers found that propofol given at sub hypnotic dose (1 mg/kg/hr.) significantly decreases severity of emetic episodes in patients undergoing caesarean delivery under spinal anaesthesia without causing clinically important adverse effects.

In contrary to this study, study conducted by Shi JJ. et al (19), Caba et al. (21), found no significant differences in severity of intra operative nausea and vomiting between two groups.

In this study, less Intraoperative rescue antiemetic metoclopramide consumption was observed in sub hypnotic propofol group compared to non-propofol group. The median rescue ant emetic consumption was 10 mg in non-propofol group and 0 mg in propofol group ($p<0.001$).

A study conducted in Iran by Rasooli S. et al. (18) reported that patients given propofol had significantly less rescue antiemetic metoclopramide requirements than those in a control group (2(6.7%) in propofol group versus 12(40%) in control group) during and after caesarean section with spinal anaesthesia p value <0.001 .

In contrary to this study, study conducted by Kun Niu et al.in China (20) didn't found significant difference in Intraoperative rescue antiemetic consumption between propofol (1mg/kg/hr.) and placebo (saline) groups in women undergoing elective caesarean delivery under spinal anaesthesia. The possible explanation for the difference might be due to the administration of propofol (20 mg bolus IV) as rescue anti-emetics every 5 minute when patients complaining nausea or developed vomiting and Ondansetron 4 mg was administered

intravenously if two rescue anti-emetic doses of propofol, 20 mg each, failed to control nausea and vomiting in both groups which have antiemetic properties (15).

Postoperative nausea and vomiting in parturients undergoing caesarean section under spinal anaesthesia has multiple and complex etiologies and risk factors, which includes hypotension due to sympathectomy, maternal demographics, operative procedure and anaesthetic technique (9-12). But, in our study, all parturients were homogenous and all groups were identical regarding the demographic characteristics, operation and their anaesthetic management.

In the current study, we found no statistical significant Intraoperative complications such as hypotension, sedation or respiratory depression between the propofol and non-propofol groups in mothers who underwent caesarean section under spinal anaesthesia in the Intraoperative period. The present finding is in line with and can be explained by Gann TG and colleagues study which reported that the plasma concentration of propofol to have antiemetic property (343 ng/ml) was much lower when compared to the concentration associated with sedation(1-3 mcg/ml (29). Our result was also comparable with other studies regarding clinically important adverse effects (20, 23, 24, 25)

Chapter Six

6. Strength and Limitation

6.1. Strength of the Study

All homogenous study participants were included in the study

6.2. Limitation of the Study

- Lack of standard nausea and vomiting management protocol in the study hospital
- Lack of adequate comparable cohort study for comparison
- There was no follow up after 30 minutes of operation; we only followed patients for the first 30 minutes after delivery of the baby and clamping of umbilical cord intraoperatively and total antiemetic consumption was not reported after the end of caesarean section in the recovery room and ward as well.

Chapter Seven

7 Conclusion and Recommendation

7.1 Conclusion

Administration of prophylactic sub hypnotic dose of propofol (20 mg IV bolus) after delivery of the baby and clamping of the umbilical cord was effective in reducing PONV, the prevention and immediate treatment of post-delivery nausea and vomiting and reduce need for Intraoperative rescue antiemetic for parturients undergoing elective caesarean section under spinal anaesthesia.

7.2 Recommendation

Based on the findings of the present study, the following recommendations forwarded

- **For ALERT Hospital, all Anaesthesia staff** : we recommend the use of prophylactic intravenous sub hypnotic dose of propofol (20 mg) for parturients undergoing elective caesarean section under spinal anaesthesia for the prevention of Intraoperative post-delivery nausea and vomiting.
- **For Ethiopian society of Anaesthetists:** we recommend to give an update for every anaesthetists country wide on the use of sub hypnotic dose of propofol for elective caesarean section in terms of decreasing incidence of nausea, vomiting, severity of nausea and rescue anti emetic consumption..
- **For researchers:** considering this study as a baseline, we strongly recommend a further long-term multicenter study and randomized controlled trial studies.

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ANNEX I

Dear participant

This study is planned to assess the prophylactic effect of sub hypnotic dose of propofol in preventing the occurrence and severity of Post Delivery Nausea and Vomiting in parturient who undergo elective Caesarean Section under Spinal Anaesthesia. By chance, you are admitted to participate in the study if you are willing. Therefore, we kindly request your participation in the study and honest response to achieve the objective of the study. Your responses are completely confidential and you have full right either to refuse a single question or leave the study. Thanks for taking part in the study.

Are you willing to participate in the study, please?

A) YES

B) NO

For further question, ask the Investigator-----Adane Bayisa

Tell. +251912416506

E-mail-adanebayisasa@gmail.com

ANNEX II

ውድ የዚህ ጥናት ተሳታፊዎች

ይህ ጥናት ታስቦ የተዘጋጀው በቀዶ ጥገና ለመውለድ በሚሰጥ ግማሽ ማዳንዘዣ(Spinal Anaesthesia) አማካኝነት የሚከሰት ማቅለሽለሽ እና ማስታወክ ፕሮፖፎል በሚባል መድኃኒት በምን ያህል እንደሚቀን ስለማወቅ ነው። እርሶም እንደእድል ሆኖ በዚህ ጥናት እንዲሳተፉት መርጠዋለ።

የዚህ ጥናት ጥቅም እርስዎ በሚሰጡት ምላሽ መሰረት መረጃዎችን በማማላት በሚገኘው ወጤት መሰረት መረጃዎችን በማጠናቀር ወጤቱን እየተሰራበት ካለው ጋር ለማገናዘብ እንዲቻል ነው።

ጥናቱ በትክክል አላማውን እንዲመታ የእርሶዎን ድጋፍ እንጠይቃለን። የማንኛውም

ግለሰብ ስም እንዲሁም ሀሳቡ ሙሉ በሙሉ በሚስጥር የተጠበቀ ነው። በጥናቱ መሳተፍ አለመሳተፍ የራስዎ ምርጫ ብቻ ነው። ግልፅ የሆነ ምላሽን እንዲሰጡን በአክብሮት እንጠይቃለን።

ለመሳተፍ ፈቃደኝነዎት ሀ/ አዎ ፊርማ _____

ለ/ አይደለሁም

ለመሳተፍ ፈቃደኛ ስለሆኑ እናመሰግናለን!!!!!!

ለበለጠ መረጃ በዚህ ስልክ ይደውሉ፡....0912416506 ...አዳነ ባይሳ

ANNEXIII

Addis Ababa University College of health science department of anaesthesia questionnaire for data collection on prophylactic effect of sub hypnotic dose of propofol in the prevention of post-delivery nausea and vomiting in mothers undergoing elective caesarean section under spinal anaesthesia.

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

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

Ser.no.	Question	Response
1	Age (yrs)	
2	ASA	A.II
3	Baseline Heart rate	
4	Heart rate after drug administration	
5	Baseline Blood pressure with MAP	
6	MAP after drug administration	
7	Base line RR & spo2	
8	RR & spo2 after drug administration	
9	Baseline VRS	
10	NPO Times	_____hrs
11	Does the patient has history of coexisting disease	A. Yes B. No
12	If yes specify	
13	Parity	A.Primigravid B.maltigravid

Section III: Data during Intra-operative period

S.NO.	Questions	Response
14	Administered sub hypnotic dose of propofol.	A. YES B.NO

Se.N O	Episode of nausea and-vomiting	Response				
		10 th minutes	20 th minutes	30 th minutes	40 th minutes	At the end of surgery
15	Does the patient feeling Nausea	A. Yes B. No	A. Yes B. No	A. Yes B. No	A. Yes B. No	A. Yes B. No
16	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	A. Mild B. Moderate C. Severe	A. Mild B .Moderate C. Severe
17	Does the patient Vomited	A. Yes B. No	A. Yes B. No	A. Yes B. No	C. Yes D. No	A. Yes B. No
18	Does the patient received additional ant emetics	A. Yes B. No	A. Yes B. No	A. Yes B. No	A. Yes B. No	A. Yes B. No
19	If Q.20 yes (Specify) If NO. Skip to next .Questions					
20	Types of intra operative anti emetic administered	A.Metoclopro mide B. Dexamitasol	C.Ondanstron D. Cimetidene	E, others (specify)		

21. Complication observed intra operatively (with in 30 minutes)

A. Hypotension

B. headache

C. sedation

D. Others (specify)

E. None

22. Duration of surgery (in minutes)_____

23. Estimated blood loss (in ml)_____

24 Total and type of rescue anti emetic consumed intraoperatively_____

25. Types of uteronic medication used_____

26. Types of uteronic medication used_____

Date_____Data collector name____

signature_____

Appendix 1 አማርኛ ትርጉም

በቁጥር አምሳያ መለኪያ (Verbal Rating Scale)



1. ይህ መለኪያ በመጀመሪያው 1ሰከት 4 ጊዜ የሚወሰድ ሲሆን.
 - a. በሽተኛው የሚጠየቃቸው ጥያቄዎች
 - i. አሁን የሚሰማዎት ማቅለሽለሽ በየትኛው ቁጥር ይወክሉታል ;
 - ii. ከዜሮ እስከ አስር ካሉት ቁጥሮች አሁን የሚሰማዎት ማቅለሽለሽ የትኛው ቁጥር ይገልፀዋል
2. ከላይ የተሰጠው ማብራሪያ በቂ ሳይሆን ሲቀር፣ ለበሽተኛው የበለጠ መረጃ መስጠት አስፈላጊ ሆኖ ይገኛል
 - a. 0- ምንም ማቅለሽለሽ የለም
 - b. 1-3 - ትንሽ ማቅለሽለሽ አለ
 - c. 4-6 - መካከለኛ ማቅለሽለሽ አለ
 - d. 7-10 - ከባድ ማቅለሽለሽ አለ