# THE EFFECT OF PREOPERATIVE VOLUME LOADING ON THE INCIDENCE OF POSTOPERATIVE NAUSEA AND VOMITING AT KENYATTA NATIONAL HOSPITAL

# A DISSERTATION PRESENTED IN PART FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN ANAESTHESIOLOGY UNIVERSITY OF NAIROBI

BY

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# **DEDICATION**

To my parents, my dear son, Eric, and my best friend and husband, Shem, who have inspired me and offered endless support and love.

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# LIST OF ABBREVIATIONS

ASA	American Society of Anesthesiologist
CTZ	Chemoreceptor Trigger Zone
GA	General anesthesia
hCG	human chorionic gonadotropic
hormone	
5HT <sub>3</sub>	5-hydroxytryptamine receptor 3
HCO <sub>3</sub> <sup>-</sup>	Bicarbonate
IV	Intravenous
RL	Ringers' Lactate
KNH	Kenyatta National Hospital
VAS	Visual Analogue Scale
MAP	Mean Arterial Pressure
Ng	Nanogram
N <sub>2</sub>	Nitrogen
N <sub>2</sub> O	Nitrous Oxide
NIBP	Non-Invasive Blood Pressure
HR	Heart Rate
O <sub>2</sub>	Oxygen
PACU	Post Anesthesia Care Unit
PONV	Postoperative Nausea and Vomiting
SPSS	Statistical Package for the Social
Sciences	

# **IMPORTANT DEFINITIONS**

# American Society of Anesthesiologists (ASA) Physical Status Classification

DISEASE STATE
No organic, physiologic, biochemical, or psychiatric disturbance
Mild to moderate systemic disturbance that may not be related to the reason for surgery
Severe systemic disturbance that may or may not be related to the reason
for surgery Severe systemic disturbance that is life threatening with or without
surgery
Moribund patient who has little chance of survival but is submitted to surgery as a last resort (resuscitative effort)
Any patient in whom an emergency operation is required

From information in American Society of Anesthesiologists: New classification of physical status. Anesthesiology 24:111, 1963.

The 4-2-1 formula: the Holliday-Segard normogram<sup>1</sup> approximates daily fluid loss, and therefore the daily fluid requirements, as follows:

100ml/kg/24hrs= 4ml/kg/hr for first 10kg body weight

50ml/kg/24hrs= 2ml/kg/hr for the next 10kg body weight

20ml/kg/24hrs= 1ml/kg/hr for the remaining body weight

# The Visual Analogue scale for Nausea:



How often since yesterday have you suffered from these complaints?





How greatly since yesterday were you restricted by these complaints?

#### ABSTRACT

*Background:* Nausea and vomiting in the postoperative period occurs in 20% to 30% of patients and together are the second most common complaints reported (pain is the most common). While the experience of PONV is self-limiting, postoperative vomiting /retching (POV/R) can lead to rare but serious medical complications, such as aspiration of gastric contents, wound dehiscence, esophageal rupture and pneumothorax.<sup>2,3</sup> PONV may delay patient discharge from Post Anaesthesia Care Units (PACUs) and can be the leading cause of unexpected/unplanned hospital admission after ambulatory surgery.<sup>4</sup>

*Objective:* To determine whether preoperative volume loading with a balanced salt solution would decrease the incidence of PONV in patients at increased risk of developing these symptoms

*Methodology:* This was a prospective randomized controlled clinical trial in which 60 adult female patients undergoing gynecological surgery, ASA class 1 and 2 were included in the study. A total of sixty (60) patients were randomly assigned preoperatively to an experimental group (group 1) and to a control group (group 2). The experimental group received preoperative intravenous fluid bolus of Ringers' Lactate (RL) solution of up to 1000ml using the 4-2-1 formula,<sup>1,5</sup> 1hour before induction of anaesthesia. The control group did not receive preoperative fluid, intraoperative fluid administration in both groups was determined by the anaesthetist. Both groups received prophylactic antiemetics at induction of anaesthesia. All patients were assessed for PONV by nurses blinded to patient group assignment in the PACU and post-surgical wards at 12hours and 24hours postoperatively.

*Results:* This clinical trial included 30 patients in the experimental and 30 patients in the control group. There was no difference in the distribution of age, weight, fasting time and the amount of blood loss in the 2 groups. The mean preoperative fluid volume administered to the experimental group was 853mls. Overall the mean DBP and HR tended to be higher in the experimental group than in the control group reaching statistical significance at 45 and 60 minutes intraoperatively for DBP. The overall incidence of PONV in this study was 36.7%. The incidence of PONV in the experimental group was 30.0% while it was 43.3% in the control group, and 30% of patients in the experimental group required rescue antiemetics postoperatively while 43.3% of patients in control group required postoperative antiemetics.

*Conclusion*: The incidence of PONV and the need for additional antiemetics was significantly reduced in the experimental group compared to the control group.

*Recommendation:* Preoperative fluid administration is a simple and cost-effective method of preventing dehydration, should be considered as routine preoperative therapy by anaesthetists.

# **INTRODUCTION**

Postoperative nausea and vomiting (PONV) are undesirable complications after operative procedures requiring general anesthesia. PONV may prolong recovery time, cause patient discomfort and dissatisfaction, increase morbidity and mortality, delay discharge and increase healthcare costs. The overall incidence of PONV for all surgeries has been estimated to be 25% to 30% and up to 70% in high risk groups. In a prospective interview-based study of the incidence of PONV, the highest incidence of emetic sequelae was observed in gynecological patients.<sup>6</sup> In KNH, a prospective study of the incidence of postoperative nausea and vomiting in patients undergoing elective ENT surgery, the overall incidence of PONV was 39.8%.<sup>7</sup>

to the incidence of PONV.<sup>8-11</sup> Preoperative dehydration can result in hypotension with greater than 35% reduction in systolic blood pressure at induction of anaesthesia and an increase in incidence of PONV.<sup>9</sup>

Several studies have been done on the prevention of postoperative nausea and vomiting. However, only limited work has been done to determine the correlation between preoperative fluid therapy and the well being of patients in the postoperative period.

#### LITERATURE REVIEW

Preoperative dehydration is common in surgical patients and is primarily due to a prolonged fasting period and bowel preparation without adequate preoperative fluid replacement. In KNH, adult patients undergoing elective surgery routinely fast from midnight of the day of surgery regardless of the time surgery begins. Preoperative fasting of 12 hours or more may result in a fluid deficit of about 1 liter, consisting primarily of free water and electrolytes.<sup>12</sup> Symptoms of preoperative fluid deficit are not clearly defined, but may include thirst,

drowsiness and dizziness.<sup>13</sup> Symptoms of mild dehydration may contribute to prolonged hospital stay after minor surgical procedures, as demonstrated in a large review by Chung. et.al, where postoperative dizziness and drowsiness were independent predictors of prolonged hospital stay after ambulatory surgery.<sup>14</sup>

The risk of dehydration is greater in patients who receive preoperative bowel preparation, patients with ascites, burns, trauma, bowel obstruction, peritonitis, the elderly, children and those who undergo surgery later in the day.<sup>15</sup>

Preoperative bowel preparation is not routinely done to all surgical patients in KNH, it is determined by the type of surgery.

Studies have shown that perioperative fluid administration decreases the incidence of PONV caused by relative hypovolemia.<sup>13</sup> It is known that both preoperative and intraoperative fluid replacement in high volumes prevents hypovolemia caused by preoperative fasting and decreases the incidence of PONV.<sup>16-18</sup>

Magner et.al.<sup>17</sup> compared the effect of intravenous infusion of 30ml/kg versus 10ml/kg given intraoperatively to 2 groups, each consisting of 35 patients undergoing gynecologic laparoscopic surgery. An independent *t test* demonstrated that the occurrence of postoperative vomiting was less in the group that received 30ml/kg than in the group receiving 10ml/kg (8.6% versus 25.7%; p=0.1).

Monti, et. al. (2000) in randomized controlled trial, 90 adult female patients undergoing gynaecological laparoscopy and all fasted from midnight, administered 1000ml normal saline preoperatively (duration before surgery not specified) to the experimental group and standard fluid regimen to the control group. Prevalence of PONV was significantly reduced with supplemental crystalloids.<sup>19</sup>

In another randomized controlled trial, Lambert et.al (2009), included 46 female patients (ASA 1 and 2), into 2 groups of 23 each. Both groups were given enema the evening before surgery and fasted from midnight. RL was given to the experimental group using the 4-2-1

formula up to 1Liter (if the formula required additional fluid it was given intraoperatively to avoid large volume side effects) 1hour before surgery, the control group received the routine intraoperative fluids. In their conclusion, the prevalence of PONV was significantly reduced with preoperative supplemental crystalloids.<sup>5</sup> Prophylactic antiemetic not given and duration of fasting not controlled in both studies.

In a prospective, double-blind, randomized controlled trial, Ali and colleagues studied the effects of pre-operative fluid load on post-operative nausea and vomiting. Eighty patients undergoing laparoscopic cholecystectomy/gynaecological surgery were randomly allocated to receive 2 ml.kg<sup>-1</sup> (conservative) or 15 ml.kg<sup>-1</sup> (supplemental) RL solution intravenously, shortly before induction of anaesthesia. The prevalence of PONV was significantly reduced with supplementalcrystalloids.<sup>18</sup>

During surgical procedures there are many avenues of fluid loss: blood loss, urine, loss of other body fluids (ascites, gastrointestinal contents), unhumidified anaesthetic gases, perspiration and evaporation are among the most common causes of loss. The impact of preoperative fluid status on clinical outcomes and incidences of thirst, drowsiness, and dizziness have been found to be significantly lower in patients who receive high infusion rates (up to 20ml/kg) of isotonic electrolytespreoperatively.<sup>13</sup>

Extensive literature search using CENTRAL, MEDLINE, EMBASE, CINAHL, and Web of Science, including prospective randomized controlled trials that reported PONV event rates in patients receiving supplemental IV crystalloids or a conservative fluid regimen after elective surgery under general anaesthesia suggest that providing supplemental fluids improved PONV outcomes compared with restricted fluid regimens.<sup>20</sup>

Trials investigating the effect of preoperative volume loading on the intraoperative blood pressure variability and postoperative nausea and vomiting have shown that preoperative volume loading is associated with lower variability of blood pressure and heart rate during operative period and also reduces the severity and incidence of postoperative nausea and vomiting.<sup>21-23</sup>

The actual mechanism of the beneficial effects of pre-operative hydration on PONV is not known. It is postulated that perioperative hypovolemia can cause hypoperfusion of gut mucosa and consequent ischemia leading to release of serotonin a potent trigger for nausea and vomiting.<sup>13,22</sup> Therefore, supplemental fluid load before induction of anaesthesia decreases volume deficit promoting euvolemia, a positive effect on splanchnic perfusion and may inhibit impending gut ischemia.

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#### **Physiology of Nausea and Vomiting**

Vomiting is the means by which the upper gastrointestinal tract rids itself of its contents when almost any part of the upper tract becomes excessively irritated or over-distended or over-excitable. Nausea and vomiting derive from centrally mediated reflexes and pathways. The sensory signals that initiate vomiting originate mainly from the pharynx, esophagus, stomach and upper portions of the small intestine, and direct stimulation of the Chemoreceptor Trigger Zone (CTZ). Nerve impulses are transmitted by both vagus and sympathetic afferent nerve fibers to multiple nuclei distributed in the brainstem, together forming the "vomiting center." Efferent fibers are transmitted via the 5<sup>th</sup>, 7<sup>th</sup>, 9<sup>th</sup>, 10<sup>th</sup> and 12<sup>th</sup> cranial nerves to the upper gastrointestinal tract, through vagal and sympathetic fibers to the lower tract, and through spinal nerves to the diaphragm and abdominal muscles.

Nausea is the subjective sensation of the need to vomit, most often caused by irritative stimulus from the gastrointestinal tract, lower brain impulses associated with motion sickness and impulses from the cerebral cortex. Vomiting occasionally occurs without the prodromal sensation of nausea, indicating that only certain portions of the vomiting center are associated with the sensation of nausea.

#### **Etiology of Nausea and Vomiting**

Nausea and vomiting may be induced through different pathways:

*Toxic materials in the gastrointestinal lumen*: results in the release of serotonin from enterochromaffin cells in close proximity to afferent vagal nerve endings of the gut wall.

*Absorbed toxins and drugs:* circulating in the blood causes nausea and vomiting via direct stimulation of the CTZ which has an abundance of receptors whose stimulation sends emetogenic triggers to the brainstem's vomiting center to activate the vomiting reflex.

*Stimulation of the vestibular system:* The vestibular nucleus is the relay point for spatial and motion input, and through its action on the CTZ it mediates the nausea and vomiting of "motion sickness" or "sea sickness" which is triggered via CN VIII by bursts of acceleration and deceleration action on the inner ear.

#### **Risk Factors and Independent Predictors**

The recognition of risk factors plays a critical role in making diagnostic and therapeutic decisions in medicine. PONV is multifactorial in its origin, as a consequence of emetogenic agents applied to susceptible patients.

#### **Patient-Related Independent Predictors**

Female Gender

Most prospective cohort studies have identified the female gender (in adults) as the strongest independent predictor for postoperative nausea,<sup>24</sup> vomiting,<sup>25,26</sup> use of antiemetic rescue treatment,<sup>27</sup> and overall PONV independent of anesthetic technique. Women have three times the risk of PONV compared to men. The reason for increased female susceptibility to nausea and vomiting is unclear but persists well after menopause and most of the rest of a woman's life.<sup>28</sup>

*Smoking:* Cohen and associates found that nonsmokers were 1.8 times more likely than smokers to have PONV.<sup>24</sup> These findings were subsequently confirmed by several large-scale studies.<sup>6,29,30</sup>

*History of PONV, Motion Sickness, or Migraine:* Susceptibility to emetogenic stimuli varies among individuals according to history of PONV,<sup>6,30-32</sup> history of motion sickness,<sup>6,30,32</sup> and history of migraine.<sup>6</sup>

*Age :* In adults, although the incidence of PONV decreases with age, it is not always a strong risk factor.<sup>24-27,31,32</sup> In children , however, Elberhart and coworkers have shown that an age of 3 years or older is associated with an increased risk for PONV.<sup>33</sup>

## **Anesthesia-Related Independent Predictors**

## **Opioids**

Regardless of whether opioids are used intraoperatively or postoperatively, the available evidence suggests that the dose of opioid, rather than type, is one of the main predictors (or causes) of PONV.<sup>34</sup> Most large studies using multivariate analysis demonstrate that the use of post-operative opioids doubles the risk for PONV.<sup>6,29,30,35</sup> As a consequence, opioids sparing strategies should reduce the incidence of PONV.

## Inhaled Anesthetic Agents, Nitrous Oxide and Propofol

Studies have demonstrated a lower incidence of nausea and vomiting with propofol compared with inhaled anesthetics. The inhaled anesthetics are strongly emetogenic. Their emetogenicity is dose related. The emetogenic effects of nitrous oxide and volatile anesthetics are additive.<sup>35</sup>

# Duration of Anesthesia

A number of studies have described the effect of duration of anesthesia on PONV.<sup>6,30,35</sup> Longer and more invasive surgeries are associated with more PONV.

#### **Surgery-Related Independent Predictors**

Many surgeries are associated with a high incidence of PONV. However, in many instances, these incidences may often be a reflection of other underlying factors, e.g. prolonged exposure to emetogenic volatile anesthetics, large doses of opioids. Therefore, risk assessment should also be based on the underlying independent predictors rather than the type of surgery alone.<sup>34</sup> Surgeries that have been shown to be independent predictors for PONV include laparoscopic cholecystectomy, hysterectomy, and strabismus surgery in children.<sup>25,36,37</sup>

#### **Risk Scoring for PONV**

For a long time prediction of PONV was assumed to be difficult, if not impossible, as it was believed to be influenced by too many factors. However, there is now sufficient evidence that the risk for emetic sequelae after balanced anaesthesia in adults can be determined by a simple model attributed to large defining studies on risk stratification.<sup>29</sup>

# Table 1: Predicting the risk of PONV by Apfel et.al

Apfel et al (Anaesthesiology 1999; 91:693 – 700<sup>29</sup>

RISK FACTOR	SCORE		SCODE(No. rick factors)		
	1	0	SCORE(INU. TISK Idelois)		
GENDER	FEMALE	MALE	0	10	
SMOKING STATUS	NON-SMOKER	SMOKER	1	21	
HISTORY OF PONV +	YES	NO	2	39	
	YES	NO	3	61	
OPIOIDS			4	78	

In a prospective interview-based survey on the incidence of postoperative nausea and vomiting, Koivuranta et.al.<sup>6</sup> found that the most important predictive factors associated with increased

risk of nausea and vomiting were female gender, previous history of postoperative sickness, a longer duration of surgery, nonsmoking and a history of motion sickness. Based on these five

items, they constructed a simple score predicting the risk of nausea and vomiting (as shown on the table below).

Characteristics	Points
Duration of surgery >60mins	1
Female sex	1
History of motion sickness	1
History of PONV	1
Nonsmoker	1
Total	5

# Table 2: Predicting the risk of PONV (Koivuranta et.al)

Non-selective routine antiemetic prophylactic treatment may not improve patient outcome when applied to all patients, the use of a risk- adapted prophylactic strategy is the most rational approach.

# Preoperative states Predisposing to Nausea and Vomiting

Hormonal, neural imbalances, central nervous system diseases and gastrointestinal disturbances can lead to nausea and vomiting. When present in the preoperative state they increase the risk of PONV. Specific conditions that increase the risk of PONV include:

*Diabetes mellitus:* Impaired gastric motility as a result of autonomic neuropathy increases the risk of nausea and vomiting in diabetic patients.

*Uremia* : The elevated level of vasopressin found in uremic patients thought to stimulate the CTZ.

*Intracranial Hypertension:* This typically occurs in the morning, without preceding nausea, and may be projectile. It results from direct pressure on the vomiting center and may arise from the high levels of vasopressin.

*Pregnancy*: Nausea and vomiting in pregnancy is associated with high levels of HCG also seen in the 3<sup>rd</sup> to 4<sup>th</sup> week of the menstrual cycle, molar pregnancy and multiple pregnancy. Hyperemesis gravidarum may result in significant fluid and electrolyte imbalance requiring hospitalization.

Abdominal disorders: Irritation and distension of viscera can lead to vomiting seen in multiple abdominal disorders including peritonitis, bowel and gastric outlet obstruction and

viral gastroenteritis. Obstruction of the ureter, testicular pain and cervical dilatation also induces nausea.

*Motion sickness:* A history of motion sickness increases the likelihood of PONV, with a high incidence in children contributing to their propensity to PONV. PONV from motion sickness commonly occurs during transport out of recovery room, and in ambulatory patients on arising from the stretcher or during the ride home.

*Perioperative pain:* Clinical studies have shown that pain is a stimulus to nausea and vomiting and that pain relief, regardless of analgesic used, can decrease nausea and vomiting. *Medications:* There are numerous pathways through which medications may affect nausea and vomiting. Two of the most important medicines encountered in preoperative patients are the opiates and cytotoxic agents. Others include: L-dopa, bromocryptine, cardiac glycosides, NSAIDs, and antibiotics. Opioids are widely used perioperatively and stimulate receptors in the CTZ to cause nausea and vomiting as well as sensitize the vestibular system to motion and delay gastric emptying.

#### General Management of Postoperative Nausea and Vomiting

Prevention of PONV is obviously desirable and begins in the preoperative period. There has been *No absolute consensus on how to manage PONV*. Risk stratification is important in order to identify and focus more attention on patients with moderate to high risk of PONV.

A number of published studies have detailed the development of risk stratification scoring systems and strategies that may help reduce the baseline risk of PONV including:

Minimizing positive pressure mask ventilation, avoiding pharyngeal irritation during emergence from anaesthesia, minimizing movement in the recovery period, opioids sparing strategies,

adequate anxiolysis, perioperative hydration, pain and glycemic control, prevention of hypoxia and use of regional anaesthesia (where possible) as opposed to GA.

Use of prophylactic antiemetics is determined by the risk of PONV in each specific patient, type of surgery, efficacy and side effects of the chosen agent. In high risk patients, combination antiemetic therapy is more effective than monotherapy.

# STUDY JUSTIFICATION

Despite greater understanding of the physiology of nausea and vomiting and despite advances in surgical techniques and introduction of less emetogenic anaesthetic techniques and drugs, certain operations and risk factors are still associated with an unacceptably high incidence of PONV. In a study of 'incidence and risk factors for PONV in ENT surgical patients in KNH, Dr. Betty Owure found the incidence of PONV to be 39.8%.<sup>7</sup> Current approaches to prevention and treatment of PONV remain limited, and >25% of patients continue to experience PONV within 24 hours of surgery. Universal pharmacologic PONV prophylaxis is not cost effective and is associated with increased side effects.

Nausea and vomiting are one of the most common reasons for poor patient satisfaction-rating, in the postoperative period.<sup>37</sup> It is estimated that an episode of vomiting prolongs Post Anesthetic Care Unit (PACU) stay by about 25 minutes,<sup>38</sup> resulting in an increase in the workload of the nursing staff and increased overall health care costs. The optimal approach to management of PONV remains unclear. There remains a need to develop cost-effective, ideally non-pharmacologic strategies to decrease the incidence of PONV, especially in high risk patients.

Several studies have been done on the prevention of nausea and vomiting. However, only limited work has been done to determine the correlation between preoperative fluid therapy and the well being of patients in the postoperative period.

# **RESEARCH QUESTION**

Does preoperative volume loading with a balanced salt solution decrease the incidence of PONV in patients at increased risk of developing these symptoms?

# NULL HYPOTHESIS

Preoperative volume loading does not decrease the incidence of PONV in patients at high risk.

# **GENERAL OBJECTIVE**

To determine whether preoperative volume loading with a balanced salt solution would decrease the incidence of PONV in patients at increased risk of developing these symptoms.

# **SPECIFIC OBJECTIVES**

To determine the incidence of PONV among the patients in both the control and experimental groups and identify differences if any.

To determine whether preoperative volume loading decreases postoperative additional antiemetic drug requirements

To investigate the effect of preoperative volume loading on the intra-operative blood pressure and heart rate variability among the experimental and control group

To determine the average duration of preoperative fasting time among the experimental group and the control group undergoing elective gynecologic surgery at KNH

# MATERIALS AND METHODS

#### **Study Design**

This was a prospective randomized controlled single blind trial in which patients undergoing elective gynaecological surgery were randomized into the experimental and control groups.

#### **Study Area**

The study took place at Kenyatta National Hospitals' gynecology theatre, PACU and postsurgical gynecology wards.

#### **Study Population**

Adult female patients undergoing elective gynecological surgery who met the inclusion criteria.

#### **Eligibility Criteria**

Inclusion Criteria

Patients who gave informed consent to participate in the study

Female patients who were scheduled for elective gynecologic surgery under general anaesthesia at KNH

Age – 18 to 55yrs

ASA class 1 & 2

Exclusion Criteria

Patients who did not consent to participate in the study.

History of PONV/ motion sickness, and those who had vomited or received antiemetic in the last 24 hours preoperatively.

Patients who were pregnant, prisoners

Patients who had history of hypertension, diabetes, heart disease, epilepsy or mental disability Patients who were undergoing Emergency gynecologic procedures or undergoing regional anaesthesia

Patients who were known smokers

Patients who developed hypotension or significant blood loss (requiring blood transfusion) intra-operatively

Patients who were given enema as bowel preparation before surgery

#### **Sample Size Determination**

Sample size was calculated using OpenEpi software, version 3, in which Fleiss formulae for randomized control study was applied to determine the appropriate sample size for a power of 0.8 and significance level of 0.05. The minimum sample size was 60 patients, 30 patients in each group.

Formulae:

$$n = C \frac{p_c q_c + p_e q_e}{d^2} + \frac{2}{d} + 2,$$
  
Pc = rc/Nc; Pe = re/Ne

Where  $r_c$  and  $r_e$  is the number of events in the control group and experimental group respectively and  $N_c$  is the total number of people in control group, and  $N_e$  for the experimental group. Pc is the proportion of the control group and Pe is the proportion of the experimental group. (Fleiss 1981) where qc = 1 - pc; qe = 1 - pe; and d = |Pc - Pe|. *d* is the difference between *pc* and *pe*, expressed as a positive quantity. C is a constant that depends on the values chosen for  $\alpha$  and  $\beta^{39}$ .

#### **Study Methodology**

All patients underwent preoperative assessment by the anaesthetist and were requested to fast from midnight of the day of surgery. During the pre-operative visit in the ward, the principal investigator included and excluded patients in the study in accordance with the criteria stated above. Patients who met the inclusion criteria were informed of the study and familiarized with the visual analogue scale (VAS)<sup>18,40</sup> of 0-10 for PONV. On this scale, score 0 means no nausea while score 10 means worst imaginable nausea or occurrence of vomiting. Nausea is defined as awareness of the tendency to vomit. Vomiting is defined as forceful expulsion of gastric contents through the mouth. Patients scheduled for elective gynaecological surgeries in KNH routinely undergo bowel preparation consisting of Ducolax oral tablets starting 3 days prior to surgery, a few selected patients are given enema on the night before surgery, for the purpose of this study all patients who received enema before surgery were excluded.

#### **Consenting process of randomization**

Written patient informed consent was obtained during the preoperative visit by the principal investigator. Using computer generated table of random numbers, consenting patients were randomly assigned to one of two groups; control group (group 1, who received routine fluid administration during surgery) or experimental group (group 2, who received preoperative volume loading of RL solution).

#### **Blinding process**

Study participants, the anaesthetist, PACU nurses and post-surgical ward nurses were unaware of the group assignments.

#### Role of providers involved in the study

The anaesthetist was informed of the study and requested to use the standard anaesthesia protocol provided by the principal investigator. The anaesthetist determined the amount of intravenous fluids given intraoperatively and post operatively in both groups and this was recorded. PACU and Post surgical ward nurses were familiarized with the visual analogue scale (VAS) for PONV by the investigator and were requested to record in the provided data collection sheet every episode of nausea or vomiting reported by the patients. They were requested to give intravenous ondansetron 4mg to patients who had nausea scale  $\geq 5$  or vomited.

#### Preoperative receiving area

The baseline Non Invasive Blood Pressure (NIBP), Heart Rate (HR) were recorded in both groups. Intravenous access was secured using gauge 18 cannula in all the study participants by the principal investigator. Group 2 was given RL solution as a preoperative fluid bolus 1hour before induction of anaesthesia. The amount of fluid administered was calculated on the basis of interval since the last oral intake (fasting time) using the 4-2-1 formula,<sup>1,5</sup> up to 1Liter and the amount of fluid administered was recorded (if the formula required more than 11iter of fluid replacement, the remaining amount was given intraoperatively to avoid large volume side effects).<sup>5</sup>

#### **Operating Room**

Continuous monitoring of oxygen saturation, ECG, HR, NIBP and capnogram was done. A standard anaesthesia protocol was used in both groups with consent from the anaesthetist. All patients received prophylactic antiemetic medication at induction of anaesthesia. Anaesthesia was induced using sodium thiopentone (3-5 mg/kg) and fentanyl (1-2µg/kg) and neuromuscular blockade achieved using atracurium 0.5mg/kg. After tracheal intubation anaesthesia was maintained using isoflurane at the minimum alveolar concentration and 50% nitrous oxide 50% oxygen. NIBP and HR were recorded before induction of anaesthesia, 5 minutes after induction and every 15 minutes intraoperatively until 5 minutes after extubation in both groups. Intravenous perfalgan 1gm and per rectal diclofenac at 1.5mg/kg was administered, local infiltration of 0.25% bupivacaine along the surgical incision site was done. At the end of surgery, 100% oxygen was administered and neuromuscular blockade antagonized using neostigmine (0.04mg/kg) and atropine (0.02mg/kg). Total amount of fluid administered preoperatively and intraoperatively, duration of anaesthesia, total dose of antiemetics and analgesics administered were recorded. The duration of anaesthesia was defined as time from induction of anaesthesia to extubation of the trachea.

#### PACU

Patients were given oxygen by mask 10L/min to maintain oxygen saturations at 100%. They were evaluated by the nurses for the presence or absence of postoperative nausea and vomiting. Rescue antiemetics, defined as any additional intervention provided for the treatment of established PONV, ondansetron at 4mg IV was administered if nausea scale was  $\geq 5$  or if vomiting occurred and was recorded.<sup>18</sup> The nurses in PACU and post-surgical wards were instructed not to make suggestions to patients about the feeling of nausea but to record patients' report if they complained of nausea. All episodes of nausea and vomiting were recorded on a data collection sheet.

#### **Post-surgical ward**

Observations for signs of nausea and vomiting continued and episodes recorded up to 24 hours postoperatively. All episodes of postoperative nausea and vomiting were recorded on a data collection sheet

#### **Post Exposure Monitoring**

Participants in both groups were monitored using standard anaesthesia monitoring technique, ECG,  $O_2$  saturation and BP in the operating room and in PACU. The investigator visited participants in the post-surgical ward on the evening of surgery and the following morning post surgery. During these visits BP and HR were measured, none of the participants developed signs of fluid overload during the study period.

#### **Data Management**

The patients initials, hospital number, age, weight, fasting time, duration of anaesthesia, total amount of fluids administered preoperatively and intraoperatively, BP and HR before, during and after surgery were recorded in the data collection sheet provided in the operating room by the investigator. The data collection sheet was handed over to PACU and post surgical ward nurses who recorded any episode of nausea or vomiting for 24hrs. The investigator collected all the data collection sheets from the surgical ward and entered the information into the computer SPSS version 20 for analysis. The analysed data was represented in form of tables, charts and graphs.

#### **Study Limitations**

Inability to control surgery starting time Busy personnel Routine use of prophylactic antiemetic at induction by the anaesthetists

#### **Bias Minimization**

Selection bias: Standardized criteria for enrolling patients to both groups was used Interviewer bias: nurses in PACU and post-surgical wards were blinded to the patients' group Recall bias: being a prospective study, the occurrence of the events (nausea and vomiting) were recorded as they happened.

#### **Ethical Considerations**

Approval to carry out the study was obtained from the KNH/UoN Ethics and Research Committee.

Written informed consent was obtained from each participant

The study respected the right of the patients to decline participation

There was no additional cost or incentive for participating in the study

There was no penalty for refusal to participate in this study, and the standard of care was the same for both study participants and non-participants.

IV RL, a balanced salt solution was administered in amounts that did not cause any harm to the participants.

The information obtained from each participant was treated with utmost confidentiality

No individual staff member was victimized in view of the results obtained from the research.

#### RESULTS

This study was conducted over a period of 3 months at Kenyatta National Hospital, a teaching and referral hospital with bed capacity of 2000 patients. A total of 60 female patients scheduled for gynaecological surgery were included and randomly divided into 2 groups. All patients included in the study underwent bowel preparation consisting of ducolax oral tablets 2 days prior to the day of surgery as is routinely done in the gynaecology wards, none of the patients received enema. Patients ranged in age from 18 to 65 years, figures 1 and 2 shows the distribution of age in control and experimental groups respectively. There was no difference in the mean age of the two groups.



#### Figure 1: The distribution of age (years) in the control

The youngest patient in the control group was 19years and the oldest patient was 64years, mean age 39years. Figure 2 below shows the age distribution in the experimental group, youngest patient was 18years while the oldest patient was 65years, mean age 39.03.

#### Age: Control group

# Figure 2: The distribution of age (years) in the experimental group



Age : Experimental group

Types of gynaecologic surgeries done included total abdominal hysterectomy (46.67%), diagnostic laparoscopies (28.33%), myomectomies (15%) and the remaining 10% consisted of total vaginal hysterectomy, vulvectomy and open ovarian mass excisions (Figure 3).



Figure 3: Distribution of types of surgeries in both groups, the most frequently done surgery was total abdominal hysterectomy

Comparing the distribution of surgery between the 2 groups in terms of open laparatomy versus laparoscopy, 21 patients in the control group underwent open laparatomy compared to 19 in experimental group, 7 patients in control group underwent laparoscopic surgeries compared with 10 in experimental group, 2 patients in control group underwent vaginal surgery compared with 1 in case group (figures 4 and 5). There was no significant difference in the types of surgeries done between the 2 groups.



Figure 4: Distribution of types of surgeries done in the control group

The most frequently performed surgery in the control group was open laparatomy (70%)



Figure 5: Distribution of types of surgeries in the experimental group

As shown in figure 5 the most frequently performed surgery in the experimental group was open laparatomy (63%).

Characteristic	Control group	Experimental	p-value
		group	
Age (yrs)	39±11.34	39.03±11.33	0.5
Weight (kg)	62.3±16.2	63.5±9.3	0.4
Fasting time (hrs)	10.3±2.04	10.7±2.74	0.52
Duration of anaesthesia (mins)	110.2±47.1	88.5±29,5	0.03
Amount of blood loss(mls)	429.3±232.1	335.7±200.4	0.112

Table 3: Patients' characteristics expressed in Mean ± SD

**Table 3:** shows that the patients were comparable in regards to the age, weight and fasting time. The minimum duration of fasting in all the patients was 8hours and the maximum duration was 15hours, with an average duration of fasting of 10.5hours. The amount of intraoperative blood loss was also comparable between the 2 groups (table 3) with minimum loss of 50mls and a maximum blood loss of 900mls, none of the patients in this study

developed intraoperative hypotension requiring blood transfusion. Duration of anaesthesia was significantly longer in the control group than in the experimental group as shown above.

	Control group	Experimental	p- value
		group	
Fluids:			
Preoperative IV fluids(mls)	0	853.3±136.6	
Intraoperative IV fluids(mls)	2089.3±681.14	1844.8±568.57	0.146
Patients requiring antiemetics-Number (%)	13(43.3%)	9(30%)	
Additional intraoperative Tramadol 100mg %	60%	40%	

Table 4: Fluid and medications requirements in both groups

The amount of intraoperative fluids administered ranged from a minimum of 1000mls to a maximum of 4500mls, the average amount administered to the experimental group was 1844mls and to the control group was 2089mls (table 4). There was no significant difference in the amount of fluid administered intraoperatively in both groups.

As regards changes in blood pressure, the pre-induction mean SBP, DBP and HR were comparable in the 2 groups. On induction of anaesthesia, there was a drop in the mean SBP in both groups, however, the drop was significant in the control group.

Table 5: Pre-induction systolic and diastolic blood pressures and hea	rt
rates in control and experimental groups	

Pre-induction systolic BP					
Control and	Minimum	Maximum	Mean	SD	p-value
experimental					
Control	105	156	130.2	13.63	0.385
Experimental	112	149	132.87	9.62	
Pre-induction diastolic BP					
Control	55	95	77.03	11.47	0.11
Experimental	65	95	81.37	9.04	
Pre-induction HR					
Control	60	117	83.37	12.07	0.432
Experimental	65	105	85.07	11.33	

BP=blood pressure, SD=standard deviation

There was no significant difference between the 2 groups in blood pressure and heart rate at pre-induction of anaesthesia as shown in table 5.

		Experimental	Control	
Intraoperative record		(Mean)	(Mean)	P-value
	SBP	118.33	109.77	0.059
	DBP	68.05	63.53	0.104
5 minutes after intubation	Heart rate	80.87	78.73	0.478
	SBP	118.17	108.97	0.052
	DBP	68.23	65.93	0.328
15 minutes	Heart rate	80.90	75.63	0.107
	SBP	123.40	112.67	0.001
	DBP	71.47	71.43	0.994
30 minutes	Heart rate	81.03	76.33	0.124
	SBP	126.77	113.41	0.073
	DBP	74.03	67.39	0.011
45 minutes	Heart rate	81.77	77.72	0.163
	SBP	127.56	114.82	0.042
	DBP	74.19	67.82	0.015
60 minutes	Heart rate	81.78	79.46	0.461
	SBP	130.06	116.96	0.062
	DBP	76.06	68.36	0.053
75 minutes	Heart rate	83.00	81.42	0.668
	SBP	135.08	112.10	0.062
	DBP	78.67	73.60	0.121
90 minutes	Heart rate	84.67	80.10	0.531

# Table 6: Intraoperative Blood Pressure and Heart rate Variability incontrol and experimental groups

SBP=systolic blood pressure, DBP=diastolic blood pressure, HR=heart rate

There was a significant reduction in the SBP in the control group compared to the experimental group after induction of anaesthesia. The drop in the mean SBP was 16% in control group compared with 10.01% drop in the experimental group on induction of anaesthesia (table 6). There was no significant change in the mean DBP and HR in both groups at induction of anaesthesia. At 30 and 60 minutes intraoperatively, the SDP in the control group was significantly less than in the experimental group. Over all the mean DBP and HR tended to be higher in the experimental group than in the control group reaching statistical significance at 45 and 60 minutes intraoperatively for DBP (figure 6). The incidence of PONV in PACU was 3.33%, at 12hrs was 30% and 24hrs was 10% (n=30), the incidence of PONV in the control group was 43.3% and 30% in the experimental group. The overall incidence of PONV in this study was 36.67%.

Time	Nausea		Vomiting		None	
	Experimenta	Contro	Experimenta	Contro	Experimenta	Contro
	l group	1	l group	1	l group	1
		Group		Group		Group
PAC	1	0	0	1	29	29
U						
12	6	5	2	3	22	22
hours						
24	0	3	0	1	21	17
hours						

**Table 7: Postoperative Occurrence of Nausea and Vomiting** 

Regarding the incidence of PONV, 8 patients in the control group experienced significant nausea while 5 patients had vomiting, whereas in experimental group 7 patients experienced significant nausea and 2 patients had vomiting (table 7). The overall incidence of PONV in PACU at 0-6hrs was 3.33%, at 6-12hrs was 30% and at 12-24hrs was 10% (n=30). Postoperative antiemetic requirement was higher in the control group than in experimental group, 30% of patients in experimental group required rescue antiemetics postoperatively while 43.3% of patients in control group required postoperative



**Figure 6: Postoperative Antiemetic Requirement** 

# Table 8: Shows the percentage of the patients who received rescueantiemetics postoperatively, ondansetron 4mg IV

group	Antiemetic requirement		
	Yes	No	p-value
Control	43.3%	56.7%	0.229
Experimental	30.0%	70%	

Sixty (60%) of the patients in the control group required additional intraoperative analgesia (Tramadol 100mg IV) whereas 40% of the patients in the experimental group required additional analgesia (Tramadol 100mg IV).

#### DISCUSSION

The purpose of this study was to determine the effect of preoperative volume loading with RL solution on the incidence of PONV in female patients undergoing gynaecologic surgery. There was a difference in the rate of PONV between the control and the experimental groups in this study. The incidence of PONV in the control group was a 43.3% and 30% incidence in the experimental group. This is consistent with the findings in several studies which concluded that preoperative administration of intravenous fluid bolus to replace the fluid deficit caused by preoperative fasting.<sup>5,12,13,17,18,19,22</sup> significantly decreased the incidence of PONV.

The presence of preoperative dehydration coupled with the high risk of hypotension at induction of anaesthesia due to anaesthetic agents causes splanchnic hypoperfusion which triggers the release of potent emetogenic agents. The overall incidence of PONV in this study was 36.67%, which is comparable to a study in 2007 at KNH, in which the incidence of PONV in patients undergoing ENT surgery was 39.8%,<sup>7</sup> and also comparable to similar studies which reported the incidence of PONV from ranging from 20 to 92%.<sup>23</sup>

The null hypothesis was that preoperative volume loading does not decrease the incidence of PONV in patients at high risk. The patients in experimental group experienced lower incidences of postoperative nausea and vomiting, thus the null hypothesis was rejected.

Studies on the effect of preoperative volume loading on the incidence of PONV have not evaluated simultaneously its effect on the variation in intraoperative blood pressure and also its effect on the later PONV. In the present study the effect of preoperative volume loading on the variation in blood pressure was evident on induction of anaesthesia in which there was a higher drop (16%) in the mean systolic BP in the control group than in the experimental group (10%). Throughout surgery, there was a significant difference in the mean systolic BP between the two groups, being higher and more stable in the experimental group than in the control group. Pusch et al.<sup>10</sup> showed that a large fall in systolic blood pressure during induction of general anaesthesia is associated with increased incidence of PONV.

Heidari et.al showed that variation in the intraoperative blood pressure and heart rate is strongly associated with increasing levels of postoperative nausea.<sup>23</sup>

Fasting before general anaesthesia aims to reduce the volume and acidity of stomach contents during surgery, thus reducing the risk of regurgitation/aspiration. The updated ASA guidelines on Preoperative Fasting, largely based on scientific evidence, published in 2011 states that for elective surgeries, intake of clear fluids is allowed up to two hours before induction of anaesthesia, breast milk is permissible up to four hours prior and intake of solids and infant formula should cease six hours before induction of anesthesia.

At KNH, all adult patients undergoing elective surgical procedures are routinely requested to fast (nil by mouth) from midnight of the day of surgery, for some patients surgery begins at 8am while for others surgery begins at 3pm giving a fasting duration range from 8hrs to 15hrs. In this study, the average duration of fasting in both the control group and experimental groups was 10.5hrs.

There is no evidence to suggest a shortened fluid fast results in an increased risk of aspiration, regurgitation or related morbidity compared with the standard 'nil by mouth from midnight' fasting policy, permitting patients to drink water preoperatively resulted in significantly lower gastric volumes.<sup>41</sup> Clinicians are encouraged to appraise this evidence and when necessary adjust any standard fasting policies (e.g. nil-by-mouth from midnight) for patients that are not considered 'at-risk' during anaesthesia.

Adanir at.al, was able to demonstrate that postoperative antiemetic requirement was significantly higher in the group that was not given preoperative fluids as compared to the group whose fluid deficit was covered preoperatively (64.42% and 48.11% respectively). This study confirms that administration of preoperative volume to cover the fluid deficit decreases postoperative antiemetics requirement.

Metoclopramide was given in all the patients at induction of anaesthesia as is routinely done by the anaesthetists, this may have influenced the results of this study, it is therefore, suggested that similar future studies omit the routine administration of antiemetics at induction of anaesthesia as done by other similar studies elsewhere.<sup>5,18,22,23</sup>

The exact mechanism of how preoperative volume loading decreases PONV remains unclear. Preoperative hydration to cover fluid deficit is simple, cost effective, devoid of side effects and a non-time consuming means of preventing the occurrence of postoperative nausea and vomiting thus enabling patients a more comfortable and faster postoperative recovery period with a shorter hospital stay.

# **Conclusions:**

Preoperative volume loading to replace the fluid deficit effectively reduces the incidence of PONV and consequently antiemetic requirement in high risk patients.

All patients are given preoperative antiemetic prophylaxis routinely at induction of anaesthesia without assessment of the risk of PONV at KNH.

Preoperative volume replacement of fluid deficit is associated with less hypotension at induction of anaesthesia and a more stable systolic blood pressure during surgery

Preoperative fasting at KNH ('nil by mouth from midnight') is not in keeping with the updated ASA fasting guidelines 2011, placing patients at a high risk of dehydration, higher risk of developing intraoperative hypotension and consequently high risk of PONV with a prolonged hospital stay.

# **Recommendations:**

Preoperative fluid administration is simple and cost-effective method of preventing dehydration, should be considered as routine therapy by KNH

The updated ASA Fasting guidelines should be adopted by the hospital to protect patients who undergo surgery later in the day from preoperative dehydration.

The unwarranted routine administration of prophylactic antiemetics at induction of anaesthesia is not evidence based, other non-pharmacologic measures to prevent postoperative nausea and vomiting should be adopted

The hospital should adopt patient-specific guidelines on perioperative rehydration so that patients unable to take orally can have IV rehydration commence preoperatively while awaits surgery

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# **APPENDIX I:**

# QUESTIONNAIRE

# Data Sheet:

Patient No.	Initials
Sex M F	
Age — years	
Weight kg	
Diagnosis	
Type of surgery	_
Bowel preparation Yes N	lo
If yes, name the type	
Premedication	
Fasting time — hours	
mmHg HR	beats/minute
Amount of preoperative IV fluids	mls
Duration between preoperative fluid le minutes	bading and induction of anaesthesia
Pre-induction NIBP mmHg	HR beats/minute

Induction agent:			
Sodium thiopentone		mgs	
Fentanyl	µgs		
Atracurium —		mgs	
Maintenance agents:			
Isoflurane	%	Nitrous oxide	L/min
Prophylactic antiemetics: Metoclopramide		mgs	
Intraoperative IV fluids:			
Ringers lactate		mls	
Normal saline		_ mls	
Total ——		– mls	

Intraoperative record of NIBP and HR every 15mins:

Time (mins)	NIBP	HR
5 after intubation		
15		
30		
45		
60		
75		
90		

Amount of blood loss \_\_\_\_\_ mls

Presence of ascites/hemoperitoneum Yes No

If yes above, how much? m	ls
Duration of anaesthesia — minutes	
Postoperative rescue antiemetics? NO	Ye
If yes above, Name the antiemetic used	Dose
Post operative analgesia:	
Diclofenac mg suppository	
Perfalgan g	
Bupivacaine skin infiltration 0.25% m	ls
Any other analgesic used NO	Yes
If yes, name the drug used Name	Dose mg

# **APPENDIX II**

## THE INFORMED CONSENT

Principal investigator: Dr Angela OnyandoInstitution: University of NairobiSponsor: SelfProposal: The Effect of preoperative volume loading on the incidence of post-operative nausea and vomiting.

# CONSENT FOR THE PATIENT

# **Consent** Explanation

My names are Dr. Angela Onyando, currently pursuing a postgraduate degree in Anesthesia and Critical Care.

I am conducting a study to find out if adequate pre-operative rehydration with a balanced intravenous salt solution would reduce the incidence of post-operative nausea and vomiting in female patients at high risk of these symptoms. I therefore, kindly invite you to participate in the study.

#### Study purpose

Post-operative nausea and vomiting is a common problem after surgery under general anesthesia. Several drugs that prevent vomiting are available but they have adverse effects and some are not effective. The reason am doing this research is to find out if pre-operative intravenous rehydration, an affordable method with no adverse effects, would reduce the incidence of post-operative nausea and vomiting.

#### Study procedure

This study will involve placing the participants into two groups. The groups are selected by chance, as if by tossing a coin. Participants in group 1 will be given a calculated amount of intravenous fluid while in theatre waiting room.

Participants in the group 2 will be given the IV fluid in the operating room. For both groups the surgical procedure will not change. I do not anticipate any risks arising from the amount of fluid you will be given before, during and after surgery.

During the study the healthcare workers will be looking after you very carefully. In case you develop nausea and vomiting or any problem after surgery you should report it to the healthcare worker taking care of you and treatment will be given.

The study will take place on the day of surgery and last 24hours after you leave the operating room.

## Voluntary

Your participation in this study is entirely voluntary. Whether you participate or not, all the services you receive in this hospital will continue and nothing will change. You will not be given any money or gifts to participate in this research. There may not be any benefits to you, but your participation will help us find an answer to the research question. You may change your mind at any time and stop participating even if you had agreed earlier.

# Study approval

This study is being conducted with the approval of the KNH/UON's Ethics and Research Committee.

# Confidentiality

Information about you collected during the study will not be identified by your name but by a number, known only to the researcher, it will not be shared with or given to anyone.

## Contact

If there is anything you are concerned about or that is bothering you about the study please feel free to ask me at any time. You may contact me on 0724485614.

Thank you

# **Consent form for the Patient**

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care.

Name of Participant\_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_

Day/month/year

# Maelezo ya kibali ya mgonjwa

Jina langu ni Angela Onyando. Mimi ni mwanafunzi katika chuo kikuu cha Nairobi. Ninasomea masomo ya udaktari. Ninafanya utafiti ya kujua kama kumpa mgonjwa maji kwenye mshipa ya damu kabla ya upasuaji inaweza kuzuia kutokea kwa kusikia kutapika na kutapika baada ya upasuaji kwa wagonjwa wanawake ambao wako na athari kubwa ya kutapika baada ya upasuaji. Ninawaalika kushiriki katika utafiti huu. Nia yangu kufanya huu utafiti ni kujua kama kumpa mgonjwa maji

#### Nia ya utafiti

Kutapika baada ya upasuaji ni shida kubwa sana. Kuna madawa mingi za kuzuia kutapika lakini zinaweza kuleta shida zingine. Sababu ya utafiti huu ni kuangalia kama tunaweza zuia kutapika kwa kuwapa wagonjwa maji kwenye mshipa kabla ya upasuaji, njia ambayo ni ya bei nafuu na haina athari kwa mgonjwa.

#### Kujumuishwa kwako

Kujumuishwa kwako katika utafiti huu ni kwa hiari yako na unaweza kujitoa wakati wowote bila kuingilia matibabu yako kwa vyovvyote vile. Utafiti huu hautakugharimu pesa zozote, haitaongeza ada yako ya hospitali na hautapewa marupurupu yoyote.

Idhini ya utafiti

Utafiti huu umeidhinishwa na KNH/UON Ethics and Research Committee

Siri

Majina yako, ugonjwa unaougua na mambo yote tutakayojua kukuhusu yatabaki siri.

Kuwasiliana nami

Kwa maelezo zaidi au malalamishi yoyote, wasiliana name kwa nambari ya simu 0724485614. Asante

# Kibali cha mgonjwa

Nimesoma/nimesomewa maelezo ya utafiti. Nimepewa fursa ya kuuliza maswali na nimejibiwa kikamilifu. Nimekubali kwa hiari yangu kushiriki katika utafiti huu. Ninaelewa kwamba niko na haki ya kujitoa kwa utafiti huu wakati wowote bila kupoteza haki yangu ya matibabu.

Jina la mshiriki \_\_\_\_\_

Sahihi ya mshiriki

Tarehe \_\_\_\_\_

# CONSENT FOR THE ANAESTHETIST

# **Consent explanation**

My names are Dr. Angela Onyando, currently pursuing a postgraduate degree in Anesthesia and Critical Care.

# The Study

I am conducting a study to determine if preoperative iv volume loading with a balanced salt solution reduces the incidence of PONV in female patients undergoing gynecological surgery. The patients will be randomly divided into group 1 and 2. Group 1 will receive a calculated amount of Lactated ringers' solution at the receiving area. Group 2 will not receive this regimen. You are kindly requested to use the provided standardized anesthesia technique in all the patients enrolled in the study.

# Participation in the study

Your participation in this study will be voluntary and you may decide to withdraw from it at any stage without any penalty.

# Study approval

This study will be conducted with the approval of The Kenyatta National Hospital/University of Nairobi Ethics and Research Committee.

# Confidentiality

Your identity will be protected with utmost confidentiality during the study and your personal details will not be recorded in the data collection tool.

## Contacts

For any clarifications or queries you may contact me on the telephone number 0724485614. Thank you

# **Consent Form for the Anaesthetist**

I.....(initials only) have read and understood the explanation of this study.

I have freely chosen to participate in the study and understand that whether or not I participate, the care I give patients will not be compromised in any way whatsoever.

I understand that I may choose to withdraw from the study at any stage without any penalty.

Signed......(Anaesthetist)

Signed ...... (Principal Investigator)