EFFECT OF PLETHYSMOGRAPHY VARIABILITY INDEX BASED FLUID THERAPY IN ENHANCING RECOVERY AFTERMAJOR ABDOMINAL-PELVICSURGERY

A THESIS SUBMITTED TO THE UNIVERSITY OF NAIROBI IN FULFILLMENT OF THE MASTER'S DEGREE IN ANAESTHESIA

BY

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H58/87395/2016

DECLARATION

I certify that this dissertation is my original work. It has not been presented for the award of a degree in any other institution.

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DEDICATION

I dedicate this thesis to my late Dad (Shem) and Mother (Margret) who have been my biggest supporters and for their unwavering support and encouragement.

ACKNOWLEDMENT

I would like to acknowledge my supervisors Dr. Gatheru and Dr. Chikophe for their guidance and support during development and writing of the thesis.

My deepest gratitude to Surgilabs who provided the Radical 7 pulse oximeter and adhesive SPO2 sensors that was used to monitor PVI intraoperatively.

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LIST OF ABBREVIATIONS

ASA	American Society of Anesthesiologists physical status classification
ATP	Adenosine Triphosphate
CI	Cardiac Index
CFM	Conventional Fluid Management
CO	Cardiac Output
CVP	Central Venous Pressure
DO2	Oxygen delivery
EDM	Esophageal Doppler Monitoring
ERAS	Enhanced Recovery after Surgery
esCC	Estimated continuous cardiac index
GDFM	Goal Directed Fluid Management
HR	Heart rate
LOS	Length of Stay
MAP	Mean Arterial Pressure
PAC	Pulmonary Artery Catheter
PACU	Post Anesthesia Care Unit
PAOP	Pulmonary Artery Occlusion Pressures
PONV	Post-operative nausea and vomiting
PGDT	Perioperative Goal Directed Therapy
PI	Perfusion Index
POD	Post-Operative Day

PPV	Pulse Pressure Variation
PVI	Plethysmography Variability Index
SV	Stroke Volume
SVV	Stroke volume variation
U/O	Urine Output
VO2	Oxygen consumption

OPERATIONAL DEFINITIONS

Major abdominal-pelvic surgery- Procedures expected to last more than two hours with an anticipated blood loss of more than 500 or significant fluid shifts.

ABSTRACT

STUDY BACKGROUND:

Intra-operative fluid management based on Heart Rate (HR), Mean arterial pressure (MAP), Central Venous Pressure (CVP), urine output (U/O), replacing perioperative fluid deficits, insensible losses and ongoing fluid losses defines today's approach to perioperative fluid paradigm. However, these parameters may be insensitive indicators of hypovolemia or changes in cardiac index (CI). Plethysmography variability index (PVI has been shown to have the ability to predict if patients will respond to additional fluids non-invasively under mechanical ventilation and has also been shown to improve patient outcomes however we don't have local data.

Main Objective:

To compare the effectiveness of PVI Guided Fluid Therapy (GDT) with the conventional fluid therapy in terms of intra-operative fluid management, incidence of Post-Operative Nausea and Vomiting (PONV), time to start oral feeds and incidence of post-operative complications.

Methods:

The study was a quasi-experimental post-test only non-equivalent group design. 90 American Society of Anesthesiologists physical status classification (ASA)1 and 2 patients, more than 18years, with no cardiopulmonary disease undergoing major abdominal-pelvic surgery were recruited and assigned to either conventional or PVI group. The study was carried out in Kenyatta National Hospital (KNH) main theaters, Main theatre Post-anesthesia care unit (PACU) and the general wards post-operatively. In the conventional group fluids were administered based on HR, MAP, CVP, U/O. The PVI group, fluid was administered guided by the PVI measurements maintaining PVI> 10 and MAP> 65mmhg.

Results;

There was no difference in the amount of intraoperative crystalloid fluid and total fluids infused between the PVI and conventional group (P=0.26 P=0.7). No significant nausea and vomiting in both the PVI and conventional groups. There was no difference in oral intake between the two

groups with a P value of 0.99. None of the patients developed postoperative complications during the follow up period of the study.

Conclusion

There was no difference in the amount of crystalloids and total fluids given between the conventional and total fluids infused. There was low incidence of PONV in both groups and postoperative complications were not observed during the study period.

1.0 CHAPTER ONE

INTRODUCTION

Intra operative fluid management based on HR, MAP, CVP, urine output, replacing perioperative fluid deficits, insensible losses and ongoing fluid losses defines today's approach to perioperative fluid paradigm. However, these parameters remain relatively unchanged despite decreasing blood flow and may be insensitive indicators of hypovolemia or changes in cardiac index. Perioperative fluid deficits differ amongst individual patients in different surgical settings. This may result in unfavorable outcomes; insufficient fluid or excess fluid administration.

Perioperative goal directed therapy (PGDT) is one of the strategies used in Enhanced Recovery after Surgery (ERAS) and is based on individualized fluid status and cardiac output optimization. PGDT ensures adequate hydration, maintains euvolemia, avoids hypervolemia/hypovolemia and maintains adequate oxygen supply (1). PGDT reduces complications including nausea, vomiting, incidence of ileus or intestinal obstruction while allowing taking food earlier, becoming more alert, mobile and ultimately reducing hospital length of stay (LOS) (2).

Several cardiac output monitoring devices have been used to study PGDT however none has been approved for routine use. Selection of cardiac output (CO) monitoring device depends on several factors such as the hospital system, equipment related, cost, practicality, and type of surgery, intervention, extent of invasiveness, safety, and personal preference. Newer technologies of PGDT are easier to implement because they require less training and easily understood by a clinician.

In this study we look at the effects of PVI a non-invasive monitor that uses a pulse oximetry plethysmography waveform that is automatic and a continuous calculation of the respiratory variations in mechanically ventilated patients to guide fluid therapy. Studies have shown that PVI guided fluid therapy has shown to improve outcomes in patients undergoing major abdominal surgeries; however, there is no local data. In this study we will assess the effectiveness of current fluid management in our set up. We will also assess the effectiveness of additional PVI monitor to guide fluid therapy in enhancing recovery of patients.

2.0 CHAPTER TWO

LITERATURE REVIEW

To achieve excellent outcomes appropriate intravascular volume is important. The challenge has been determining the right volume to give. Fluids should be administered in according to individual requirements. Intravascular volume status and comorbidities before the surgery, chosen anesthetic technique and severity of surgery are some of the factors that influence perioperative fluid requirements.

2.1 FACTORS AFFECTING INTRAVASCULAR VOLUME DERANGEMENTS

2.1.1 Pre-Operative

Fasting overnight does not significantly reduce intravascular volume significantly, however perioperative dehydration can be reduced by allowing clear oral fluids up to two hours before surgery (3,4). Gastrointestinal fluid loss as a result of mechanical bowel preparation may contribute to preoperative volume depletion. Inflammation and interstitial edema caused by bowel obstruction and pancreatitis may also contribute to intravascular volume depletion Finally Hemorrhage requiring surgical hemostasis in order to allow adequate volume repletion

2.1.2 Anesthesia Related Factors

Most anesthetic drugs used during induction and maintenance cause hypotension by dose dependent vasodilation and myocardial depression (5). In addition, Sympathetic blockade during subarachnoid block can cause relative hypovolemia due to increased venous capacitance and dilatation of arteriolar resistant vessels.

2.1.3 Surgery Related Factors

Surgery related factors such as hemorrhage, coagulopathy due to hemodilution which aggravates blood loss, positive pressure ventilation, use of high Positive End Expiratory Pressure (PEEP) and large tidal volumes during mechanical ventilation. Also prolonged operative time particularly with an open abdominal cavity may lead to increased bowel edema and sequestration of fluid.

2.2 EFFECTS OF FLUID IMBALANCE

2.2.1 Hypovolemia

Perioperative dehydration and vasodilation as a result of anesthetic drugs and surgical bleeding results in absolute or relative hypovolemia. If left untreated patients will develop decreased peripheral perfusion with ischemic injury to vital organs leading to multisystem organ failure. At a cellular level, circulatory inadequacy will result in decrease in oxygen concentration with corresponding decrease in Adenosine Triphosphate (ATP) for metabolic process; anaerobic metabolism ensues with production of acidosis (6). Renal hypo perfusion may cause pre- renal and renal failure (7) and lastly low oxygen tension in surgical incisions may impair wound healing. (8)

2.2.2 Hypervolemia

The most common cause of perioperative hypervolemia is retention of fluid administered during surgery. Increased morbidity, mortality and increased duration of stay in the Intensive Care Unit (ICU) has been correlated with clinically significant post-operative fluid retention (weight gain > 10% above pre-operative baseline. (9) Excess fluid during surgery may cause starling myocardial performance curve to shift to the right, increasing requirements of cardiac function which may possibly increase cardiac morbidity postoperatively. Excess lung fluid may also cause acute respiratory failure as a result impaired gas exchange (10). In the gastrointestinal system, hypervolemia can lead to gastrointestinal edema, decreased bowel motility and ileus (11). In patients undergoing bowel surgery, anastomotic dehiscence may occur as a result of increased tension at the bowel anastomoses sites (12).

2.3 ASSESSING FLUID RESPONSIVENESS

Fluid responsiveness is a strategy used to select patients who will benefit from additional fluid administration. (13). A fluid responsive patient will have an increase in Stroke Volume (SV)and Cardiac Output (CO) when additional fluid is given because they have a preload reserve. Additional fluids should only be given to patients who will be fluid responsive by increasing the SV and CO. Fluid responsiveness is best evaluated by using the Frank–Starling curve, where small increments in preload will result in an increase in SV(14). The initial indices which were used in assessing patient's response to fluid were static measures such as CVP and Pulmonary artery occlusion pressures (PAOP). Over time these measures are proving to be inaccurate (15 16). Recently dynamic indices such as Pulse Pressure Variation (PPV), Stroke Volume Variation (SVV) and PVI were developed to assess patient's response to fluid administration and can be accurately used in mechanically ventilated patients based

on cardio-pulmonary interactions. Dynamic parameters have been shown to give a better judgment of response to a fluid challenge compared with traditional static parameters (17).

2.4 PERIOPERATIVE GOAL DIRECTED FLUID THERAPY

PGDT is defined as the hemodynamic optimization during perioperative care to predefined hemodynamic targets by titrating fluids, vasopressors and inotropes. The main goal of PGDT is to provide adequate organ and tissue perfusion by maintaining or restoring sufficient oxygen delivery. PGDT was first described by Shoemaker et al. He did a study on the effects of supraphysiologic systemic oxygen delivery on outcome in high risk surgery. Pulmonary artery catheter (PAC) measurements were used to guide crystalloids, colloids, vasoactive drugs and supplemental oxygen. Patients in the PGDT had lesser days in intensive care, ventilator days, post- operative complications and post-operative deaths. (18). Boyd and colleagues also showed decline in post-operative complications and post-operative deaths in high risk patients. Perioperative optimization of CI and DO2 guided by PAC measurements was used to administer fluids, oxygen and dopexamine. The GDT group spent less time in intensive care and shorter hospital stay. Not every PGDT using PAC showed clinical benefit (19). Gattinoni and colleagues were unable to clearly show the difference in mortality organ dysfunction or length of stay between the protocol and the control groups (20). The disadvantage of using PAC for guiding fluid therapy is that it is invasive, has high rate of complications and not useful for routine perioperative setting.

Esophageal Doppler monitoring guided fluid therapy has also shown improved outcomes. Mythen and Ebb did a study on PGDT using esophageal monitoring focusing on the intracellular gastric mucosa PH as index of microcirculatory perfusion. The study demonstrated lower incidence of gut mucosal hypoperfusion, post- operative complication, number of ICU and hospital days in the GDT group (21). Gan et al also conducted a study in non-cardiac surgical patients undergoing major surgery. 100 patients were randomized into routine care or Esophageal Doppler Monitoring (EDM) PGDT. Significant improvement in SV and CO in the PGDT group was observed. PGDT group demonstrated reduced hospital days (5 vs. 7 days) and lesser time to eat solid food (3 vs. 5 days, $p < 0.05$) (22). Arterial waveform has been used to derive dynamic parameters such as PPV, SPV and SVV.

2.5 PLETHYSMOGRAPHY VARIABILITY INDEX (PVI)

Plethysmography variability index is a non-invasive monitor that provides a numerical value automatically and continuously. PVI uses a pulse oximeter sensor that automatically calculates variations in respirations in the plethysmograph waveform. PVI calculation measures changes in Perfusion Index (PI) which shows the amplitude of pulse oximeter waveform calculated as the pulsatile (AC) signal indexed against the non-pulsatile (DC) signal. PI= AC/DC × 100

PVI is calculated as a percentage (PVI= [PImax- PImin/PImax] X 100). There is less variability over the respiratory cycle when the PVI is low, while patients will respond to additional fluid when the PVI value is higher increasing the SV and CO. PVI measurement is more accurate in patients who are mechanically ventilated with a sinus rhythm because it relies on heart-lung interactions. However, Keller et al demonstrated PVI can detect changes in patients who are breathing spontaneously but is a weak predictor of fluid responsiveness (23). Common sites of measurements include the forehead, ear and finger. Studies looking at the different sites of measurement and their accuracy have been done. Fischer et al concluded cephalic sites that is the forehead and ear were less insensitive to increase in vasomotor tone (24). Desranges and colleagues also compared the forehead, ear and finger. Measurements from the finger, ear and forehead predicted fluid responsiveness with the forehead being the best; however, it was not statistically significant (25). Finger is the most common site because of its simplicity in operation.

Studies have shown PVI monitoring can predict fluid responsiveness similar to other invasive monitoring techniques. A study done by Cannesson et al in patients undergoing coronary artery bypass. The study demonstrated increases in MAP and CVP using PVI to guide additional fluid boluses. Decreases in PPV, Pulse oximeter waveform amplitude (ΔPOP) and PVI without change in the PI and the association between PVI and POP before and after fluid boluses ($r= 0.65$, $P< 0.01$) was demonstrated. Responders and non-responders were identified by a PVI value of > 14% before volume expansion with 81% sensitivity and 100% specificity (26).

Zimmerman et al did a study in patients undergoing elective abdominal surgery. He noted that PVI and SVV, can be indicators of fluid responsiveness in major and high-risk surgeries under general anesthesia. In major surgeries and critically ill patients, PVI monitoring has been demonstrated to function similar to more expensive and invasive dynamic techniques (27).

PVI monitoring has reduced accuracy if a patient has arrhythmias, heart failure, breathing spontaneously, or using low tidal volume (< 8ml/kg) similar to SVV and PPV.

2.6 EVIDENCE OF GOAL DIRECTED THERAPY USING PVI

2.6.1 Fluid Administration

Fluid therapy intraoperatively and post-operatively at the right time and amount is of great importance. Forget et al conducted a study on GDT management using pulse oximeter derived PVI. After the induction, the PVI group received a crystalloid bolus of 500ml, after which a crystalloid infusion of 2ml/kg/h was given. Colloids of 250ml bolus were administered if PVI> 13. Vasoactive drug support was given to achieve a MAP of 65mmhg. In the control group, an infusion of 500ml crystalloid bolus was given followed by fluid therapy on the basis of fluid challenges and their effect on the MAP and CVP. The study concluded that the PVI group had lower intraoperative crystalloids and total volume of fluids infused and lower lactate levels intraoperatively and postoperatively (28).

Another study done by Sevim Cesur et al conducted a study in ASA I and II (Appendix III) patients going through elective colorectal surgery. Goal directed group, received 0.9% Normal saline at 2ml/kg/hr. Gelofusine 250ml was given when PVI was more than 13% and ephedrine 5mg was given when needed to achieve MAP> 65mmhg.In the CFM group amount of crystalloid administered and urine output were statistically higher intraoperatively ($p < 0.001$, p: 0.018) while fluid balance was lower in the GDFM at the end of the surgery (29).

Yinan et al conducted a study on PVI GDT in ASA I and II patients under combined general and epidural anesthesia. In the PVI group crystalloid fluid infusion of 2ml/kg/h was maintained and colloid or crystalloid boluses were infused once PVI>13. In the control group crystalloid fluid infusion of 4-8ml/kg/hr was maintained and crystalloid infusion was quickly initiated if MAP was <65 mmHg. Norepinephrine was given as needed in both groups to maintain MAP>65 in small doses. The study demonstrated in the PVI guided fluid therapy the amount of fluid was lower than the amount of fluid given in the control group 1,918 ± 437 mL vs 2,327 ± 463 mL with a $P < 0.05$. The study also showed the PVI group received less crystalloid than the control group with a $P< 0.05$ (30).

2.7 GASTROINTESTINAL COMPLICATIONS

To ensure early postoperative feeding, normal gastrointestinal function is essential. Ability to tolerate to oral diet after abdominal surgery is an essential prerequisite before hospital discharge. Gut hypo perfusion plays a key role in gastrointestinal complications. Routine monitoring cannot determine gastrointestinal tract hypoperfusion and the gastrointestinal may be damaged during prolonged periods of hypoperfusion. Gastrointestinal complications have been shown to be less when GDT is used to guide fluid given intraoperatively.

Rizk et al in 2014 did a study on Goal directed fluid optimization using PVI in laparoscopic bariatric obese patients compared with liberal fluid regimen. In the GDT group, lactate level and volumes of infused Ringer's lactate and hydroxyl ethyl starch were less in the GDT group with a $P < 0.001$ intraoperatively. U/O was also lower in the GDT group ($P < 0.001$). Postoperatively, the group that received GDT showed lower urine output, $P < 0.001$ and shorter duration to recovery ($P < 0.001$), first bowel movement ($P < 0.001$) and resume solid diet ($P < 0.001$). In group that received liberal fluid regimen, hypoxemia, diuresis, fatigue was more frequent. No differences were shown in other postoperative complications (31)

Sevim Cesur et al demonstrated the time to pass stool was longer in the CFM group when compared with the GDFM ($p = 0.016$) after elective colorectal surgery (29).

Chompunut Nethan et al did a study on effects of totally noninvasive guided perioperative fluid optimization for enhanced recovery after surgery in major abdominal surgery. In the GDT group, fluid optimization protocol aimed PVI<20 and esCCI>2.5L/min/m2. The returning of bowel sound and starting of soft diet was faster in the PGDT group (P<0.001, P<0.001respectively). The overall cost of treatment was significantly lower (P= 0.023) and the hospital stay was shorter in the PGDT (P=0.003). However, the changes in blood lactate level immediately after surgery of both groups were not different (32)

GDT suggested by Gan et al where fluid was administered to maximize stroke volume using esophageal doppler. The results showed lower incidence of PONV, earlier return of bowel function and decrease in the length of post-operative hospital stay (22).

2.8 JUSTIFICATION

Major surgery predisposes patients to the effects of anesthesia, blood loss, fluid shifts inflammation and surgical trauma which result in overall substantial increase in oxygen demand. This response is met by an increase in CO and oxygen extraction. An imbalance in tissue oxygen delivery and demand may occur predisposing patients to post-operative complications. To achieve optimal outcomes, perioperative maintenance of adequate intravascular is important. Currently there is no hemodynamic tool that has been accepted to guide fluid therapy. The traditional use of BP, MAP, HR and CVP has been shown to be insensitive markers in guiding fluid administration. While hemodynamic tools like pulmonary artery catheter, esophageal echocardiogram have been shown to reduce post-operative complications and enhance recovery however they are invasive, associated with complications, expensive and require extensive training. Dynamic indices have been shown to provide a superior assessment to fluid challenge compared with static traditional parameters. Recently PVI monitoring has been shown to be more effective dynamic indicator of fluid responsiveness similar to invasive monitors. PVI is simple and cost effective compared to cardiac output or oxygen delivery monitoring techniques and has a potential for widespread application. Studies have shown that PVI guided fluid therapy is effective in enhancing recovery however locally there is no data to support this. This study will enable us have local data which will assess our current fluid management which will help formulating recommendations on intra-operative fluid management.

2.9 RESEARCH QUESTION

Is plethysmography variability index-based fluid therapy more effective than conventional fluid therapy in patients undergoing major abdominal-pelvic surgery?

2.10 BROAD OBJECTIVE

To compare the effectiveness of PVI guided fluid therapy with conventional fluid therapy in enhancing recovery after major abdominal pelvic surgery.

2.11 SPECIFIC OBJECTIVES

a) To compare the volume of crystalloid and total fluid infused intraoperatively in PVI based fluid therapy with volume infused in the conventional fluid therapy.

b) To compare the incidence of PONV in PVI based fluid therapy with the conventional fluid therapy.

c) To determine time to start of oral feeds in patients with PVI based fluid therapy compared with the conventional fluid therapy.

d) To compare the incidence of post-operative complications in PVI based fluid therapy with conventional fluid therapy.

2.12 HYPOTHESIS

2.12.1 Null Hypothesis

Goal directed fluid optimization using PVI is not effective in enhancing recovery after surgery.

2.12.2 Alternative Hypothesis

Goal directed fluid optimization using PVI is effective in enhancing recovery after major abdominal-pelvic surgery

3.0 CHAPTER THREE

METHODOLOGY

3.1 RESEARCH METHODOLOGY

The study was a quasi-experiment post-test only non-equivalent group design. There were two groups of participants; the conventional and interventional group. Convenience sampling for each group was done. Non- random allocation using alternate participants was used to assign participants to either conventional or intervention group. In the conventional group, participants undergoing major abdominal- pelvic surgery under general anesthesia were administered fluid therapy based on BP, MAP, HR, U/O, replacing fluid deficits and ongoing losses which is the common practice currently at KNH. The PVI group participants undergoing major abdominal pelvic surgery under general anesthesia were administered fluid therapy based on the PVI measurements in addition to the standard monitoring.

3.2 STUDY POPULATION

The study was conducted on ASA 1 and 2 patients greater than 18 years undergoing Major abdominal-pelvic surgery under general anesthesia. Major abdominal- pelvic surgeries included general surgery, gynecology and urology surgeries.

3.3STUDY SITE

The study site was KNH main theatre, PACU and Wards. KNH is the largest referral and teaching hospital in the country with bed capacity of 1800 with referrals from all over the country for specialized care. KNH main theatre has a total of 12 operating rooms.

3.4SAMPLE SIZE

In this study the sample size sufficient to detect a difference between the mean volumes of crystalloids, sample size formula for comparing two means was used as denoted below;

$$\boldsymbol{n = 2 * \left(Z_{\alpha/2} + Z_{1-\beta}\right)^2 * \frac{\sigma^2}{d^2}}$$

Where$Z_{\alpha/2}$, is the level of significance, $Z_{1-\beta}$ is the power of the test with β=20%, σ is the variance of the difference, and d is the expected mean difference of the measurement between conventional and

intervention (PVI) values. The following values were assumed in the calculation of the sample size $Z_{\alpha/2}$=1.96, $Z_{1-\beta}$=0.842, $\sigma = 730$, and d =409, the average total fluid administered in the PVI group was 1918 while the conventional group received 2327 yielding a sample size of 50 in each arm and 60 after adjusting for non-response rate of 20%. The estimates were based on a similar study(30)

3.5 ELIGIBILITY

3.5.1 Inclusion Criteria

a) Adults > 18years

b) ASA 1 and 2 patients

c) Patients undergoing major abdominal-pelvic surgeries, i.e. general surgery, urology and gynecology surgeries

d) Patients with a normal sinus rhythm

e) Patients with no lung pathology

3.5.2 Exclusion Criteria

a) Patients who failed to give consent

b) Patients with cardiac or pulmonary disease

c) Patients undergoing laparoscopic surgery

3.6 SAMPLING

Convenience sampling technique was used to select participants for conventional and PVI group. Theatre lists were used as a master frame from which selection of participants was done. Matching was done using demographic data and type of surgery to ensure groups are similar to prevent selection bias.

3.7 STUDY PROTOCOL

Patients were assessed for the suitability of surgery on the day before the surgery and informed consent was taken before surgery. In the operating room, intravenous access was secured. Standard monitoring for both groups with ECG, BP, SPO_2, HR, end tidal carbon dioxide ($ETCO_2$) and catheterization was done to monitor urine output. General anesthesia and intubation was done using Fentanyl 1-2mcg/kg, Propofol 2-3mg/kg and Neuromuscular blockade with Suxamethionium, Cis-atracurium, Atracurium or Rocuronium. Rapid sequence induction was preferred method of intubation with Suxamethionium or Rocuronium after the Covid 19 pandemic. Anesthesia was maintained using mixture of nitrous oxide, oxygen and Isoflurane. Patients were ventilated with a tidal volume of 6-8ml/kg. Multimodal analgesia with Morphine, Paracetamol and Ketesse was given and some had local infiltration with Bupivacaine. Anti-emetic which was given during the study was Ondansetron in addition to dexamethasone. Simplified PONV impact scale was used to assess the clinically significant PONV because it is simple to use and measure intensity of significant PONV(33).

3.8 CONVENTIONAL GROUP

Fluid therapy was administered based on vitals (BP, MAP, HR), replacing fluid deficits based on the duration of pre-operative fasting, replacing estimated blood loss, urine output and replacing insensible losses.

3.9 INTERVENTION GROUP

Pulse oximeter sensor was placed in the index finger. BP cuff was placed on the contralateral hand to ensure there was no interference with the signal. Masimo Radical 7 monitor with a PVI software was connected to the pulse oximeter sensor. PI changes over a duration of time sufficient to include one or more complete respiratory cycle using inbuilt algorithm was used to calculate PVI. Baseline PVI was recorded and monitored continuously.

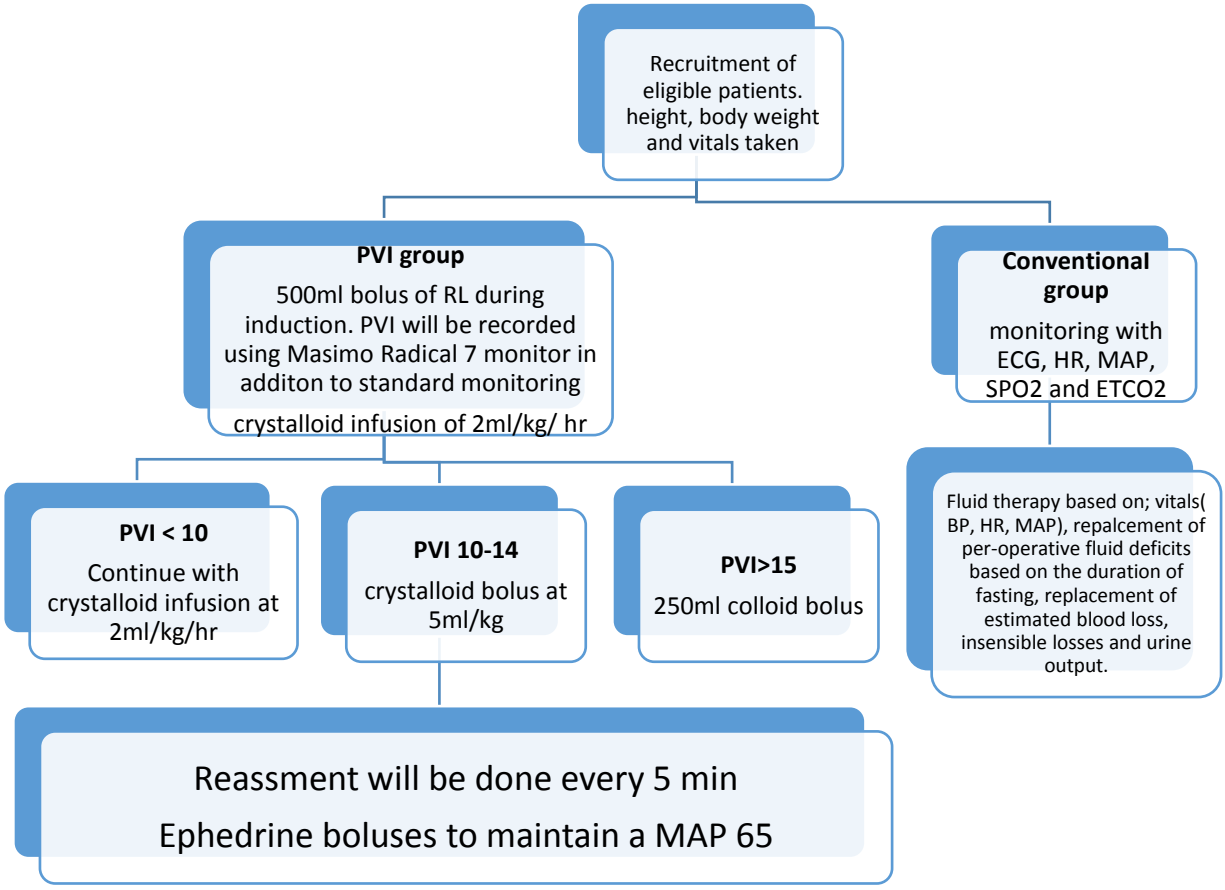

FIG 1; FLOW CHART DEMONSTRATING STUDY PROTOCOL

3.10 OUTCOME MEASURES

a) Amount of fluids given intraoperatively

b) Vasopressor use

c) Post- operative nausea and vomiting

d) Time to start and tolerate oral diet

e) Post-operative complications; Post- operative ileus, wound dehiscence, Reduced urine output, Need for repeat surgery.

3.11 RESEARCH TOOLS

3.11.1 Data Collection Procedure

Data collection was commenced after approval from research and ethics committee at KNH-UON and the KNH administration. Research assistant was recruited and trained to aid data collection. The research assistant was provided with adequate personal protection equipment was provided and also trained on the covid 19 prevention guidelines. Informed consent was obtained from eligible patients.

Demographic data, weight and height measurements were taken. After induction intraoperative data was recorded for the duration of the operation. Patients were followed up in PACU and the wards for 72 hours

3.11.1.1 Data management

All participants had a study number assigned to them. All data obtained was clearly and appropriately labeled and then stored in a locked cabinet which is only accessible by the principle investigator for data analysis. Data was then transferred to the principle investigator's laptop which will be password protected.

3.11.1.2 Data Analysis

Continuous data was explored for normality using Shapiro-wilk test and summarized using mean (SD) or median. The group comparison where continuous data are involved was compared using independent t-test or Mann-Whitney test in case of skewed distributions. The categorical data was compared using two sample test of proportion using chi-square test or Fisher's exact for smaller cell counts. All the analysis was done using RStudio version 1.3.959 and p-value<0.05 was significant.

3.12 ETHICAL CONSIDERATION

Ethical approval from the research and ethics committee at KNH- UON and KNH administration was done prior to commencing the study. The study was conducted according to the prevailing ethical guidelines of the University. Informed consent was obtained from participants prior to enrolling in any aspect of the study. Those who declined or withdrew from the study at any point received the same quality of care. The identity of all participants was kept confidential by assigning a unique study number to all respondents. Personal information was only be obtained by the principal investigator and the research assistant. The study had no harmful effects on the participants and did not entail any invasive procedures. The data collected from the study was entered in a protected computer database that was password secured that which the principal investigator and supervisors could only access. Data of participants who wish to withdraw will be handled in the same manner, however forms will be marked and will be excluded from the study and data analysis.

4.0 CHAPTER 4

RESULTS

96 patients were evaluated for eligibility. However, 3 cases were cancelled because of lack of theatre space and 2 cases were cancelled for lack of crosshatched blood. Therefore 91 patients who fulfilled the criteria were enrolled in the study. 45 in the conventional group and 46 in the interventional group. 1 patient in the conventional group was eliminated as she turned out to have an inoperable condition.

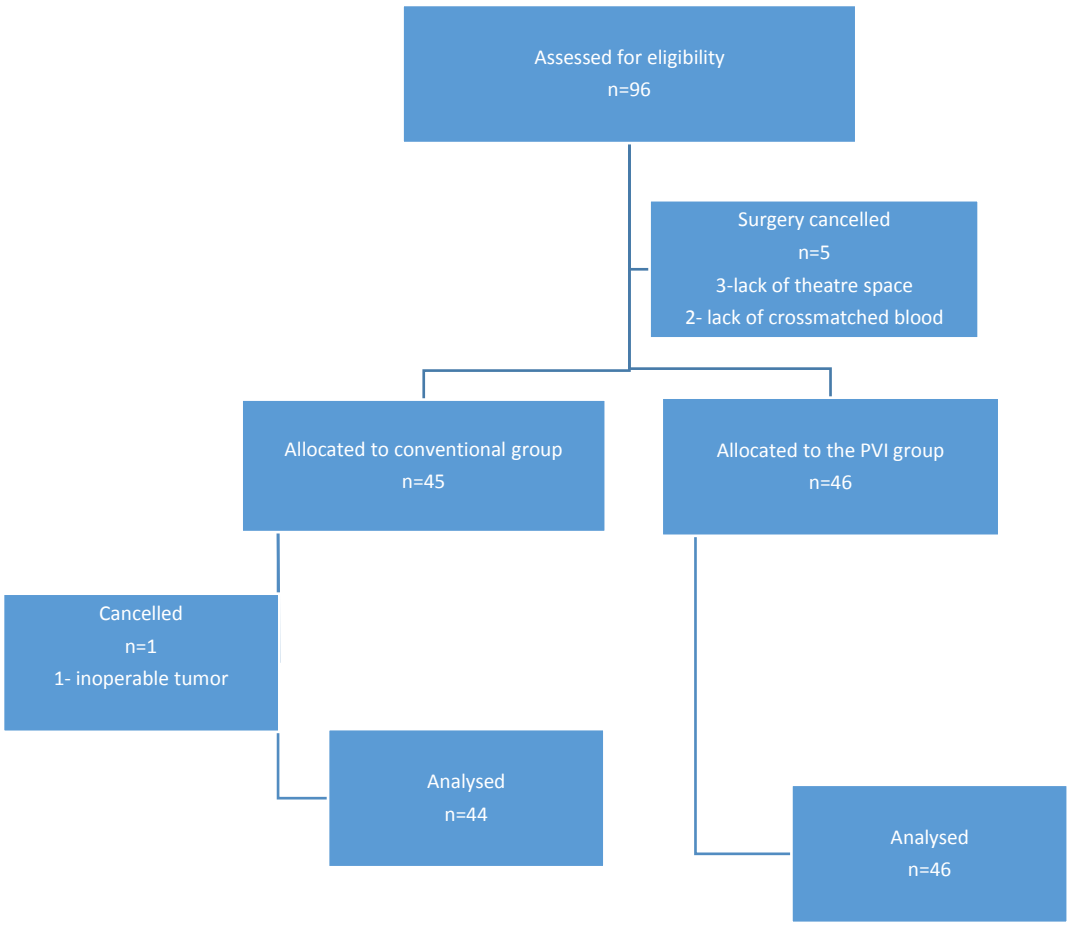

FIG 2: FLOW CHART OF PARTICIPANT ENROLLMENT PROCESS

4.1 DEMOGRAPHIC DATA

The demographic characteristics are presented in Table 1. Most of the patients were female and were distributed almost equally between the cases and controls. Patients undergoing elective gynecology surgeries were more eligible for the study compared to urology and general surgery during the study period thus recruiting more females. The intervention group had more ASA 1 patients while the patients in the control group were predominantly ASAII as demonstrated in the table 1. Non-random allocation of participants using alternate participants explains the unequal representation of ASA classes between the groups. There was no statistically significant difference in age and weight between the two groups.

Table 1; Demographic data

Characteristics	**All N=90**	**Conventional N= 44**	**Intervention N=46**	**P value**
Age	40.5(35-49)	41(34.8-49.0)	40.5(35.3-50.3)	0.84
Gender			39(84.8)	
Female	76(84.4)	37(84.1)	7(15.2)	0.999
Male	14(15.6)	7(15.9)		
Weight	65(58-72)	62(56.8-70.5)	65(58.5-73.5)	0.66
ASA Class				
ASA I	47(52.2)	15(34.1)	32(69.6)	**0.0016**
ASA II	43(47.8)	29(65.9)	14(30.4)	

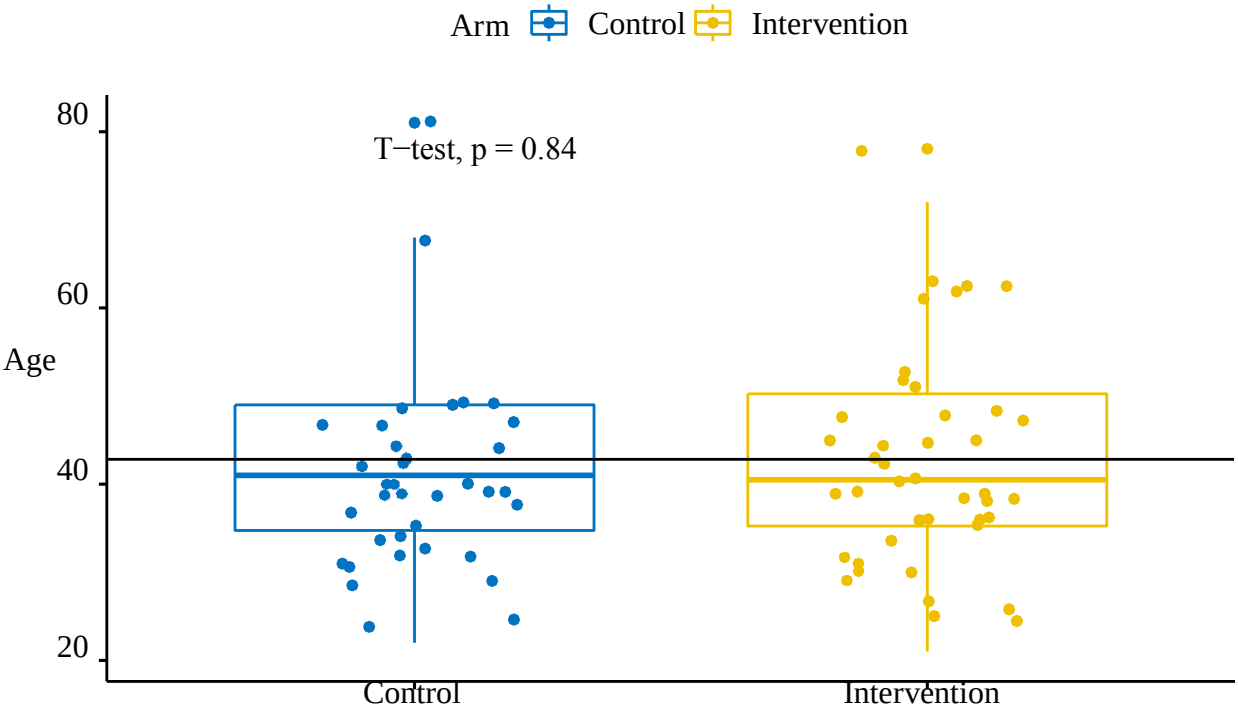

FIG 3: COMPARISONOF THE TWO ARMS BY MEAN AGE

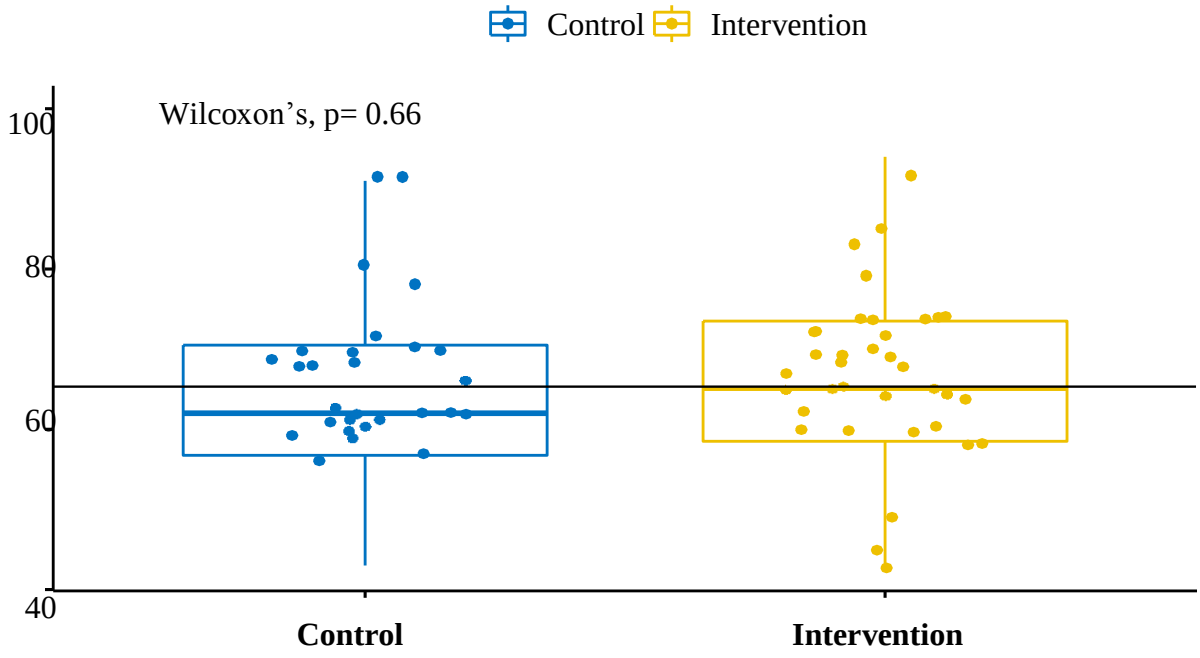

FIG 4: COMPARISON OF THE TWO ARMS BY MEAN WEIGHT.

4.2 TYPE OPERATION

91.1% of the operations were gynecology, 4.4% were urology and General surgery were 4.4%. Convenience sampling was used to select patients, thus resulting in unequal representation of participants who were qualified for the study. The specific surgeries done are illustrated in the table 2 below and there was no statistically significant difference between the conventional and the intervention group.

Table 2; Type of operation

OPERATION	CONVENTIONAL	INTERVENTION	P-VALUE
Myomectomy	7	9	
Nephrectomy	3	1	
Radical Hysterectomy	1	1	
Radical Vulvectomy	2	2	**0.9298**
Hemicolectomy	1	1	
Total abdominal hysterectomy	17	19	
X-lap	13	13	
	44	46	

4.3 DURATION OF SURGERY

Median duration of surgery was 150 minutes with an interquartile range of 135-170minutes. There was no statistically significant difference in the duration of surgery between the two groups with a p value of 0.86

Normal Distribution, Median = 150, Min = 85, Max= 270

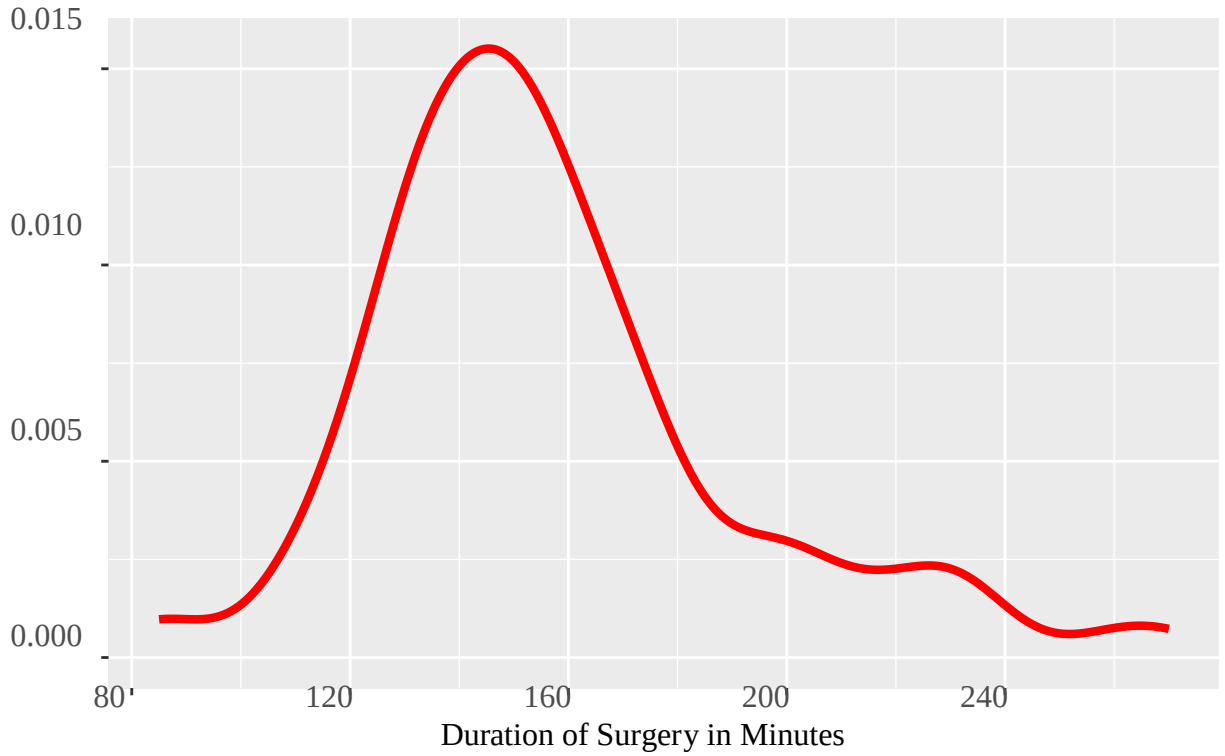

FIG 5: DENSITY PLOT FOR DURATION OF SURGERY

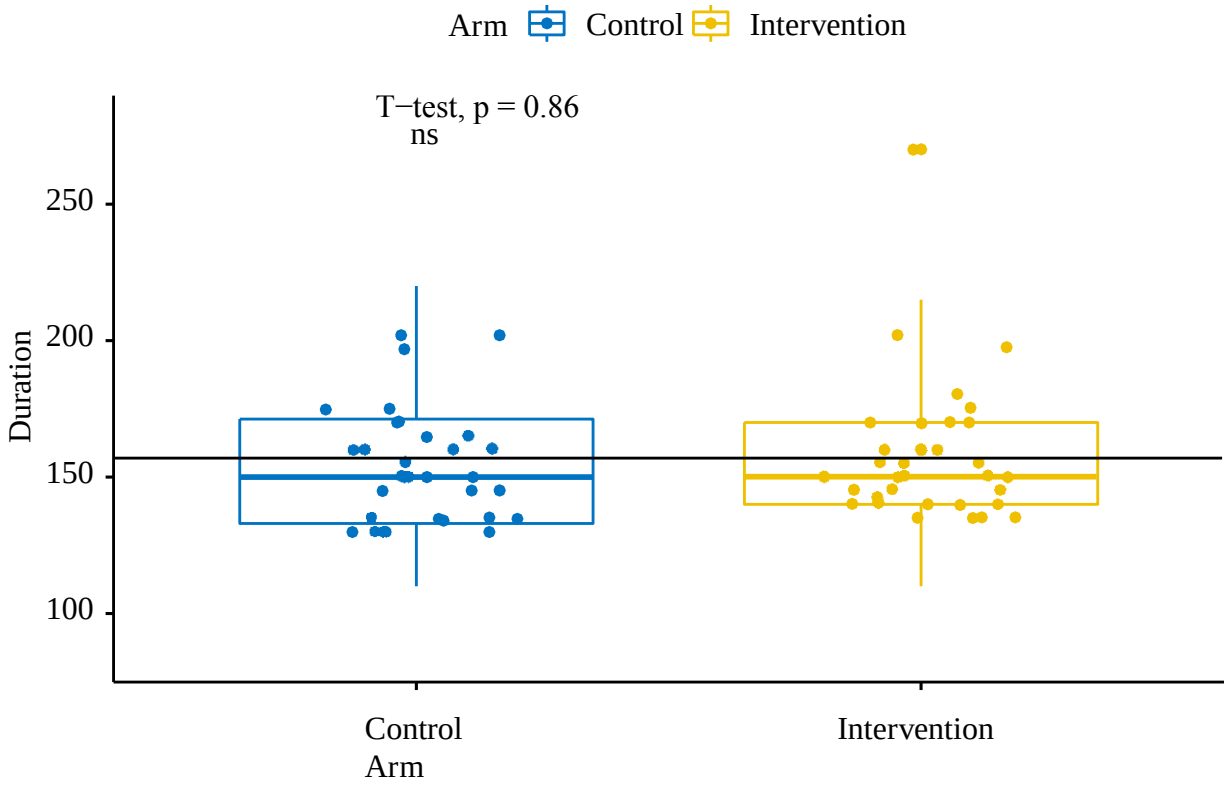

FIG 6: COMPARISON OF THE TWO ARMS BY MEAN DURATION OF SURGERY

4.5 MECHANICAL VENTILATION

Mode of ventilation for all patients was volume control. Flow waveform time analysis was monitored to ensure there was no auto peep. The median tidal volume was 7.7ml/PBW (7.1-8.0ml/PBW). There was no statistical significance between the two groups with regards to the tidal volume given with a P value of 0.48.

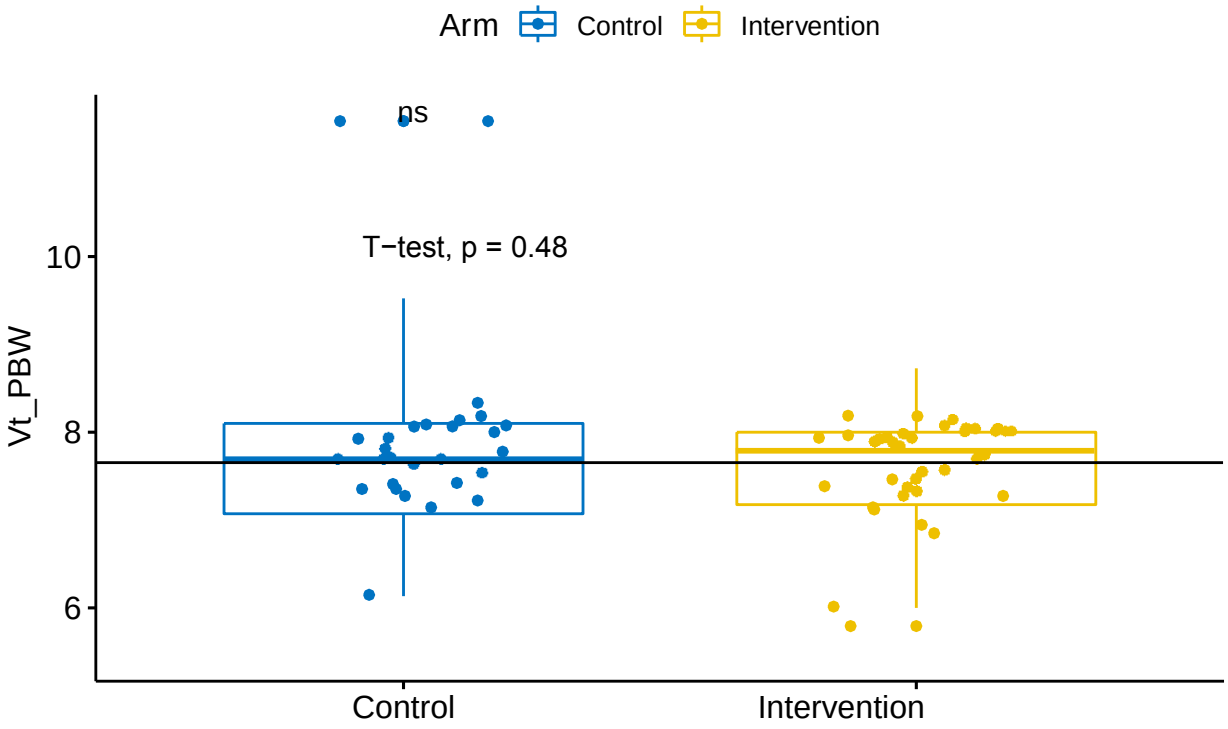

FIG 7: COMPARISON OF THE TWO ARMS BY MEAN TIDAL VOLUME/PBW

4.6 INTRAOPERATIVE FLUID ADMNISTRATION

The median amount of crystalloid fluids given throughout surgery was 11ml/kg /hr (9.3-13ml/kg/hr. The conventional group was infused a larger amount of crystalloids compared to the PVI group but was no statistically significant difference between the two groups. (12.2ml/kg/hr vs 11.1ml/kg/hr P= 0.26). However, the mean total colloids administered was significantly less in the conventional (139.5; SD=274.4) than in the intervention (460.2; SD=295.0), p-value<0.001.

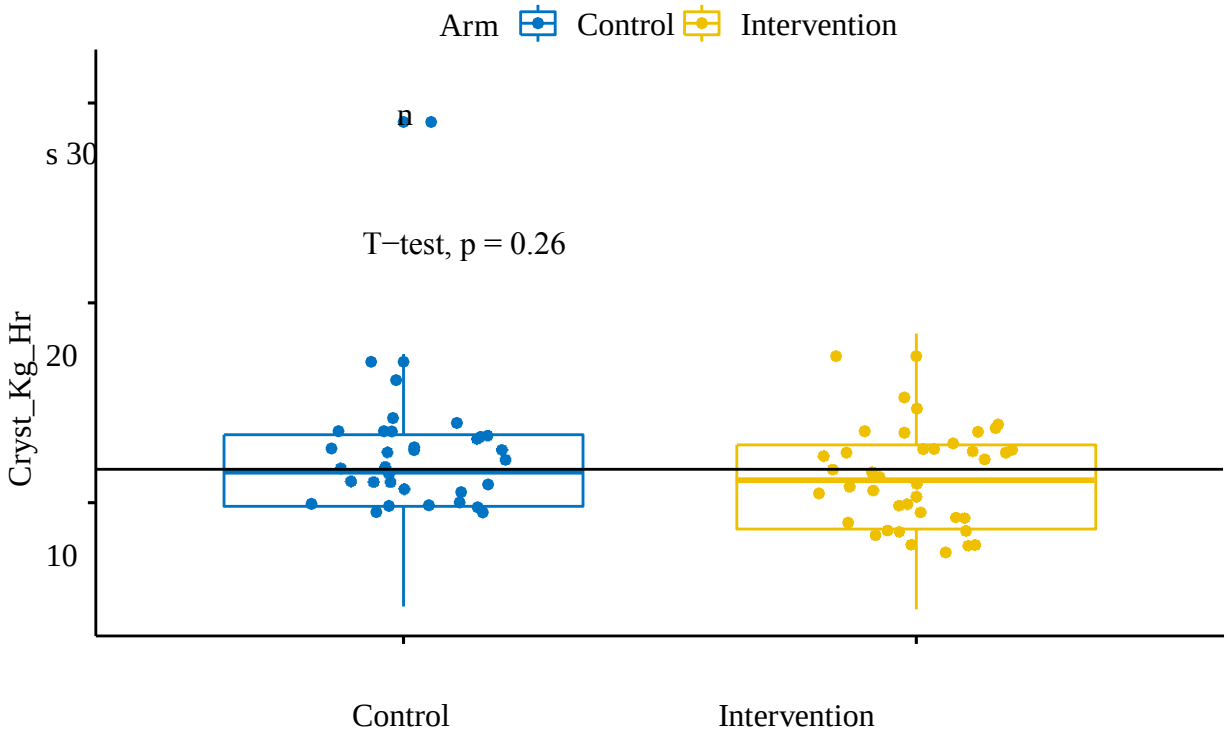

FIG 8: COMPARISON OF THE TWO ARMS BY MEAN DOSE OF CRYSTALLOID INFUSED

4.7 TOTAL FLUID

Median cumulative total fluid given throughout the surgery was 13.99ml/kg/hr (10.9-16.9ml/kg/hr). The conventional group received less total fluid compared to the PVI group however there was no statistically significant difference. (14.1ml/kg/hr vs 14.7ml/kg/hr P=0.7)

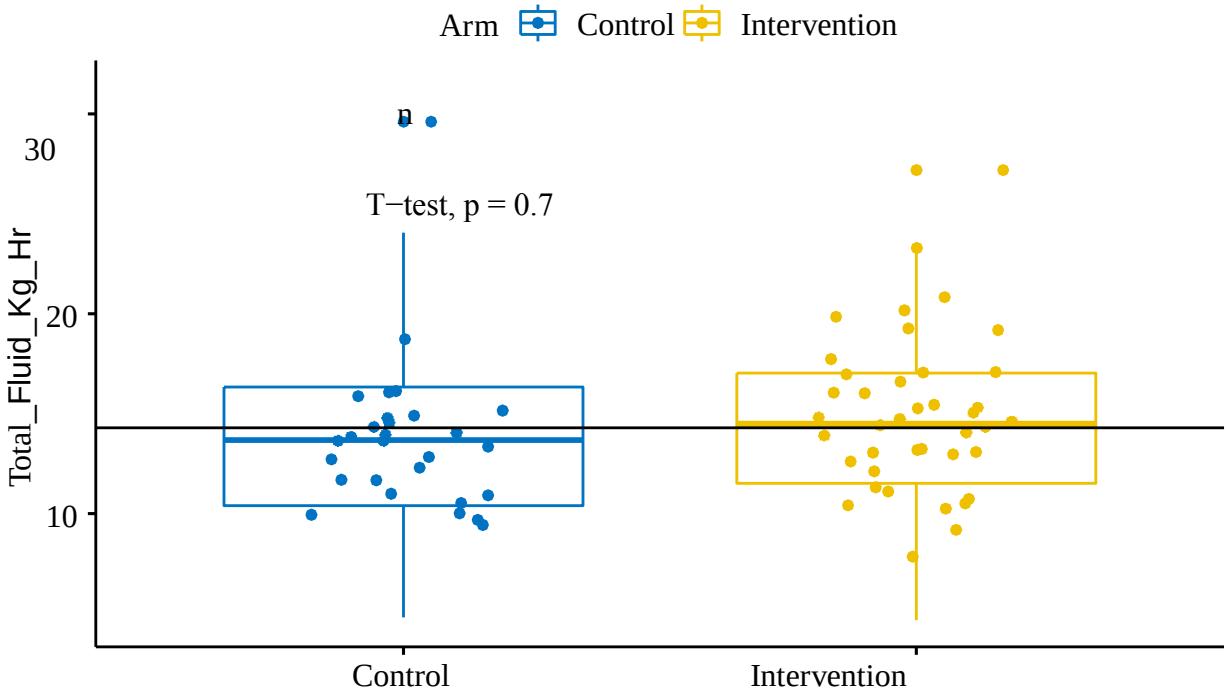

FIG 9: COMPARISON OF THE TWO ARMS BY MEAN DOSE OF TOTAL FLUID INFUSED

4.8 VASOPRESSOR USE

Table 3; Vasopressor use

	All N=90	Conventional N=44	Intervention N=46	P- Value
Vasopressor use	15(16.6)	4(9)	11(23.9)	0.108

Vasopressors were used for 11(23.9%) patients in the PVI group and 4(9%) patients in the conventional group. Vasopressor used was Ephedrine. There was no statistically significant difference in the rate of vasopressor use between the two groups with P value of 0.108. Similar study by M. Fischer et al on individualized fluid therapy using PVI, vasopressors were used both in the PVI (54%) and control group (59%) with p value of 0.326. Common vasopressor used was ephedrine but also Norepinephrine was used in 4% of patients in each group . Contrary O. Azimaragh et al demonstrated no patient required any vasoactive drug both in the PVI and control group (34).

4.9 PACU HEMODYNAMIC DATA

In both groups patients were hemodynamically stable. SBP, DBP,HR, and MAP data were collected at 4 different time points 10 minutes apart (10,20,30,40 minutes) at changes recorded at each time point. Among the cases, the median SBP at time 10 and 20 minutes were the same, a decline was observed at time 30 minutes. The DBP however increased

.

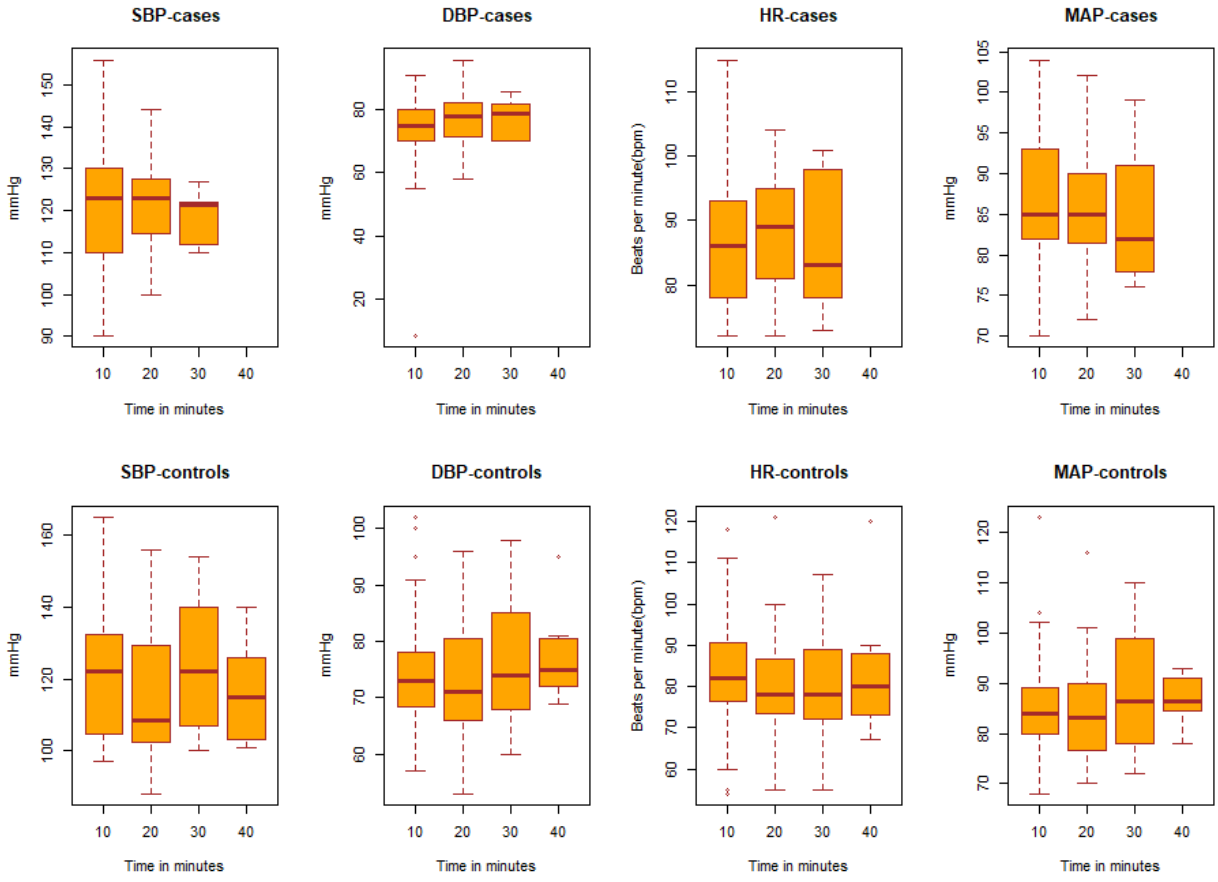

Fig10: PACU hemodynamic data

4.10 PONV

PONV was assessed using PONV impact scale. A score of > 5 signified clinically important PONV. Patients were assessed for PONV in PACU and in the wards for 72hrs. PONV impact scale ranged from 0-3, in overall, majority of the patients scored 0 and the number of patients decreased with the increase in the scale. In PACU there was a statistically significant difference in those who had mild symptoms of PONV with a P value of 0.05. In the wards there was no statistically significant difference in those who had mild symptoms between the conventional and intervention groups.

Table 4: PONV SCALE AT PACU

PONV IMPACT SCALE	Type			
	All N=90	**Conventional n=44**	**Intervention n=46**	**P-value**
0	61(67.8)	22(50.0)	39(67.8)	
1	25(27.8)	19(43.2)	6(13.0)	**0.005**
2	3(3.3)	2(4.5)	1(2.2)	
3	1(1.1)	1(2.3)	0(0.0)	

On follow up for 72 hours none of the patients had significant nausea and vomiting. Majority of the patients scored 0 at 24, 48 and 72hrs and the number decreased as the scale increased. There was no statistically significant difference between the two groups at 24, 48 and 72 hours as demonstrated in table 5, 6 and 7.

TABLE 5; PONV IMPACT SCALE AT 24HRS

PONV IMPACT SCALE	Type			
	All N=90	Conventional n=44	Intervention n=46	P-value
0	51(56.7)	20(45.5)	31(67.4)	
1	28(31.1)	16(36.4)	12(26.1)	**0.1586**
2	7(7.8)	5(11.4)	2(4.3)	
3	4(4.4)	3(6.8)	1(2.2)	

TABLE 6; PONV IMPACT SCALE AT 48HRS

PONV IMPACT SCALE	Type			
	All N=90	Conventional n=44	Intervention n=46	P-value
0	64(71.1)	26(59.1)	38(82.6)	
1	15(16.7)	10(22.7)	5(10.9)	**0.1019**
2	8(8.9)	6(13.6)	2(4.3)	
3	3(3.3)	2(4.5)	1(2.2)	

TABLE 7; PONV IMPACT SCALE AT 72HRS

PONV IMPACT SCALE	Type			
	All N=90	Conventional n=44	Intervention n=46	P-value
0	60(66.7)	25(56.8)	35(76.1)	
1	16(17.8)	10(22.7)	6(13.0)	**0.1749**
2	12(13.3)	7(15.9)	5(10.9)	
3	2(2.2)	2(4.5)	1(2.2)	

4.11 ORAL INTAKE

The number patients given oral fluids were 71(87.9%), 84(93.3%), and 87(96.7%) at 24, 48, and 72 hours respectively. There was a statistically significant difference between intervention and controls at time 48 hours in oral fluid intake (p=0.03). At time 48 hours, all interventional patients received oral intake compared to 38(86.4%) of the controls. Among those who were given oral fluids, at 24 hours, majority received oral sips, while majority received soft diet at time 48 and 72 hours.

Table 8; oral intake at 24 and 48 hours

		Type				Type		
	All	**Control**	**Cases**	**P-value**	**All**	**Control**	**Cases**	**P-value**
	At 24 hours				**At 48 hours**			
Oral Intake, n (%)	71(78.9)	31(70.55)	40(87.0)	**0.0971**	84(93.3)	38(86.4)	46(100.0)	**0.03**
Types								
No oral Intake	19(21.1)	13(29.5)	6(13.0)		6(6.7)	6(13.6)	0(0.0)	
Liquid diet	17(18.9)	7(15.9)	10(21.7)	**0.2544**	29(32.2)	18(40.9)	11(23.9)	**0.0101**
Oral sips	48(53.3)	22(50.0)	26(56.5)		14(15.6)	7(15.9)	7(15.2)	
soft diet	6(6.7)	2(4.5)	4(8.7)		41(45.6)	13(29.5)	28(60.9)	

Table 9; Oral intake at 72hrs

		Type		
	All	**Conventional**	**Intervention**	**P-value**
	At 72 hours			
Oral intake	87(96.7)	43(97.7)	44(95.7)	**0.9999**
Types				
No oral Intake	3(3.3)	2(2.3)	1(4.3)	
Liquid diet	17(18.9)	14(31.8)	3(6.5)	**0.0095**
Oral sips	4(5.6)	3 (9.1)	1(2.2)	
Soft diet	67(86.7)	26(79.5)	41(93.5)	

5.0 CHAPTER 5

DISCUSSION

Fluid therapy perioperatively is the most controversial and most discussed areas in anesthetic practice. Main goal of IVF is to provide adequate intravascular volume and prevent tissue perfusion.

In this study we included ASA 1 and ASAII patients undergoing abdominopelvic surgery to minimize confounding factors. However, majority of the patients recruited were from gynecology because few patients from General surgery and urology were eligible for the study. Demographic data was similar between the two groups. With respect to gender and weight there was no statistically significant difference between groups.

Main fluids used for volume replacement were crystalloids and colloids (voluven). The intervention group received more colloids than the conventional group in this study. In other studies conducted by Forget et al, Sevim Cesar et al and Prabhu et al demonstrated that patients in the PVI group received less crystalloid and total fluids infused intraoperatively (28 29 36).However a study done by M. Fischer demonstrated cumulative volume of fluid infused throughout surgery was larger in the PVI group than the control group with a P value of <0.001(35).Goal directed fluid therapy has been shown to have a role in perioperative outcome. However, results on GDFT after major abdominal surgeries show variabilities. For instance, definition of standard fluid therapy and GDFT vary in different studies. Other factors that differ in studies include triggers for bolus fluid administration, what type and quantities of should be used, defined goals for GDFT and different procedures with different fluid pathophysiology (37).

PONV is a common complication following general anesthesia. PONV often leads to dehydration delayed return of gastrointestinal function, need for nasogastric tube, increased fluid administration and prolonged length of stay. It is hypothesized decreased bowel mucosal perfusion may be a factor in PONV and therefore intravenous fluid therapy is crucial in reducing PONV. In this study none of the patients had clinically significant PONV; however few patients had mild symptoms despite that the patients recruited were females and were undergoing gynecology surgeries which are risk factors for PONV. Prophylactic and multimodal treatment of PONV might explain the low incidence of PONV. In this study patients who were at high risk

of PONV were not excluded from the study, furthermore nitrous oxide was also used to maintain anesthesia. These factors were major confounders in assessing for PONV.

Early feeding and early ambulation have been associated enhanced recovery after surgery. Early feeding decreases the incidence of ileus and negates the need of post-operative fluids administration. Benefits of adequate nutrition post-operatively include; wound healing, reduces infection and maintains muscle strength. Hypervolemia has been associated with decreased bowel motility and ileus. While hypovolemia has been associated with impaired wound healing because of low oxygen tension at surgical incision site. Early mobilization has been shown to reduce skeletal muscle loss and improve respiratory function and oxygen delivery to tissues. This study showed 96% of the patients were able to tolerate oral intake by the third day both in the intervention and control groups. However, more patients in the intervention compared to the control group resumed soft diet by 48hrs. Rizk et al and C. Nethan et al concluded that the PGDT group had shorter time to resume soft diet ($P< 0.001$ $P<0.001$). However, in this study it was difficult to make a conclusion as there was no standardized protocol on how to initiate oral feeding post-operatively.

Post-operative complications are often correlated with increased morbidity and duration of hospital stay. During the follow up study period none of the patients demonstrated acute post-operative complications. This may be due to low impact of PVI based fluid therapy in the studied population which was low risk patients undergoing low-moderate risk abdominal-pelvic surgeries. Duration of follow up of patients was short to document significant post-operative complications and length of hospital stay. It has been demonstrated not all surgical populations benefit from PGDT. The study population needs to be at substantial risk of having complications after surgery. A decrease in post-operative morbidity in high risk patients has been shown with GDFT (38,39).

5.1 STRENGTHS OF THE STUDY

Patients were well distributed between the two groups of study with regards to Age, weight and type of surgery

The device was non-invasive and didn’t endanger the patients.

5.2 LIMITATIONS OF THE STUDY

Unable to reach desired sample size as elective theaters were interrupted at the onset covid 19 pandemic in Kenya

Lack of equal representation among the different surgical populations we intended to study. This was due limited theater days allocations for elective surgery

Post-operative care was not standardized for all patients.

5.3 RECOMMENDATIONS

Follow up randomized controlled trial to study further the effects on goal directed therapy on recovery of patients.

5.4 CONCLUSION

There was no difference in the total crystalloids and cumulative fluids given between the intervenstion group and the conventional group

In both groups none of the patients demonstrated significant symptoms of PONV; however, the intervention group had fewer patients with mild symptoms of PONV compared with the conventional group

Patients in both groups were able to tolerate oral intake by 48hrs. However, it was difficult to compare both groups as there was no standardized protocol on how to initiate oral feeds.

In both groups , post-operative complications were not demonstrated during the study period

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APPENDICES

APPENDIX 1; PARTICIPANT INFORMATION AND CONSENT FORM

TITLE OF STUDY: EFFECT OF PLETHYSMOGRAPHY VARIABILITY INDEX BASED FLUID THERAPY IN ENHANCING RECOVERY AFTER ABDOMINAL-PELVIC SURGERY

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Email: idris6664@gmail.com

INTRODUCTION

I would like to tell you about a study being conducted by the above principal researcher. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: I) Your decision to participate is entirely

voluntary II) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal III) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records**.**

May I continue? Yes ( ) No ( )

This study has approval by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol no. _____

WHAT IS THIS STUDY ABOUT?

The Principal Investigator above will do a research on a non-invasive monitoring technique that guides on how fluids are administered during surgery. Participants in the study will be given fluids either according to the routine standard monitoring or according to the non-invasive monitor measurements in addition to the routine standard monitoring. Allocation of participants will be non-random, using alternate participants to allocate to either group. We are asking for your consent to consider participating in the study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained research assistant on your demographic data which will last approximately 5 minutes before you undergo the surgery. Your weight and height will be taken. In theatre baseline vitals will be taken and an intravenous access will be done. After general anesthesia PVI monitor will be attached to the index finger and measurements will be taken every 5 minutes. Fluids will be administered guided by the PVI measurements in addition to the standard monitoring. After surgery you will be interviewed in the Post Anesthesia Care Unit and in the wards on your recovery.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving free additional monitoring during the surgery and post-operatively. Also, the information you provide will help us to improve our intraoperatively monitoring and objective method of administering fluids intraoperatively.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

Participating in the study will not cost you anything

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits**.**

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity by signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes ( ) No ( )

Participant printed name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____ Date: _____

Signature

_____

Role in the study: _____ [i.e. study staff who explained informed consent form.]

For more information contact _____ at _____ from

_____ to _____

Witness Printed Name (If witness is necessary, A witness is a person mutually acceptable to both the researcher and participant)

Name _____ Contact information _____

Signature /Thumb stamp: _____ Date; _____

IDHINI YA KUSHIRIKI

ATHIRI YA KUTUMIA PVI KWA KUWEZESHA UPONYAJI BAADA YA UPASUAJI

MTAFITI MKUU: DORCAS MOKEIRA BUNDI

CHUO KIKUU CHA NAIROBI

MAELEZO

Ningependa kueleza juu ya utafiti ambao utafanywa. Sababu kuu ya maelezo yataweza kusaidia wewe kufanya uamuzi wa kushiriki katika utafiti au la. Nataka uelewe uko na uhuru wa kukubali au kukataa kushiriki katika utafiti. Mara tu utakapokubali kushiriki katika huu utafiti taomba uweke sahihi katika hii fomu. Nataka uelewe kwamba i) uamuzi wa kushiriki katika huu utafiti ni wa uhuru. ii) Unaweza kata kuhusishwa katika huu utafiti iii) Usipokubali kuhusishwa kwa huu utafiti haitadhuru matibabu utapata.

Naweza kuendelea?

Ndio [ ] La [ ]

UTAFITI NI WA NINI?

Kuwekewa maji kwa mishipa ni sehemu muhimu katika kusaidia uponyaji baada ya upasuaji. Maji mingi au kidogo wakati wa upasuaji yaweza leta shida katika uponyaji na kuongeza muda wa kukaa hospitali.

Utafiti huu utasaidia kuboresha jinsi maji yanavyo pewa wakati wa upasuaji na kusaidia kupunguza shida bada ya upasuaji.

Utafiti utahusu kuulizwa maswali kadhaa kabla ya upasuaji kisha unapokuwa katika chumba cha ahueni, na kwa wadi.

NINI ITAFANYIKA NIKIKUBALI KUSHIRIKA KATIKA UTAFITI HUU?

Utaulizwa maswali juu ya hali yako na sababu ya upasuaji. Utapimwa kilo na urefu wako. Kisha katika chumba cha upasuaji utalalishwa. Tutaangalia vile maji yanapewa wakati wa upasuaji kutumia chombo cha kuongoza wakati maji yanafaa kupewa. Baada ya upasuaji tutafuatilia na kuuliza maswali juu ya hali yako na uponyaji .

NIA

Nia yangu ni kuweza kutathmini kama kutumia chombo cha kusaidia wauuguzi kujua jinsi ya kupeana maji wakati wa upasuaji

HATARI

Utafiti huu hauhusishi kuongezewa madawa yeyote au upasuaji mwingine isipokuwa ule ulikuwa unahitaji. Hii inafanya kusikuwe na hatari yoyote kwa mgonjwa anaposhiriki utafiti huu.

FAIDA YA UTAFITI

Matokeo ya utafiti huu utasaidia kuboresha huduma za afya wagonjwa wapewa wakiwa katika vyumba vya ahueni.

KUSHIRIKI

Kushiriki utafiti huu ni kwa hali ya kujitolea. Hakuna malipo kushiriki wala fidia yoyote utakayo pata kwa Kushiriki utafiti. Kutokubali kushiriki hakuta kuwa na madhara yoyote kwa matibabu yako. Matibabu yata endelea kama vile yalikuwa yamepangiwa. Uko na ruhusa ya kutoka katika utafiti huu wakati wowote bila kukatiza matibabu yako.

USIRI

Baadaye nitafanya uchambuzi wa takwimu na taarifa hii itachapishwa katika kitabu ambacho kitakuwa chini ya mamlaka ya Chuo Kikuu cha Nairobi. Taarifa zote zitawekwa kwa usiri.

Naomba kukupa fursa ya kuuliza maswali yoyote yanayo husiana na utafiti huu.

Ikiwa umekubali kushiriki,tafadthali tia Sahihi kwenye nafasi iliyotolewa.

Asante

KITAMBULISHO IV: SHAHADA YA IDTHINI

Mimi……naitikia ya kwamba nimesoma nanimeelezewa kuhusu utafiti huu na nimeelewa. Nimepata nafasi ya kuuliza maaswali niliyokuwa nayo.Naelewa kushiriki ni kwa hiari yangu na niko na ruhusa ya kusimamisha kushiriki kwangu wakati wowote ule bila madthara kwangu.Nimeelewa pia hakuna malipo au fidia kushiriki utafiti huu.

Sahihi ya mgonjwa……Tarehe……..

Sahihi ya mtafiti……Tarehe…….

Kwa maelezo zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitiaanwani na nambari za simu zilizo andikwa hapa chini wakati wowote,

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APPENDIX II : QUESTIONNAIRE

SECTION I

DEMOGRAPHIC DATA

Age (Years) _____

Gender M [ ] F [ ]

Weight (kg) _____ Height (cm)_____ IBW_____

ASA CLASS I [ ] II [ ]

SECTION II

INTRA-OPERATIVE DATA

A. Type of operation_____
B. Induction time_____
C. Induction drugs and dosages
    I. _____
    II. _____
    III. _____
    IV. _____
D. Maintenance drugs and dosages
    I. _____
    II. _____
    III. _____
    IV. _____
E. Analgesia, dose and time
    I. _____
    II. _____
    III. _____
    IV. _____

F. Mechanical ventilation settings

Mode VCV [ ] PCV [ ] Other [ ] Specify_____

Tidal volume_____

Frequency_____

PEEP_____

I: E Ratio_____

G. Start of surgery_____

End of surgery_____

Duration of surgery_____

H. Hemodynamic data intraoperative (Every 10minutes)

BP												
MAP												
HR												
SPO2												
PVI												

BP												
MAP												
HR												
SPO2												
PVI												

I. INTRA-OPERATIVE FLUID MANAGEMENT

Type of fluid	Amount	Time given

Total amount of crystalloids administered_____

Total amount of colloid administered_____

Blood transfusion Yes [ ] No [ ]

If yes amount of blood transfused_____

Total amount of fluid given intraoperatively_____

Urine Output_____

Vasopressor drug use Yes [ ] No [ ]

If yes type of vasopressor given, dose and time

_____

_____

_____

_____

_____

SECTION III

PACU

A. Hemodynamic data

BP												
HR												
SPO2												
MAP												

B. PONV

PONV impact scale_____

C. IVF

Total amount of fluid infused_____

POD1 (24HOURS)

A. PONV Impact scale_____

B. Oral intake Yes [ ] No [ ]

If yes Oral sips [ ] Liquid diet [ ] Soft diet [ ]

C. Ambulation Yes [ ] No [ ]

D. Post-operative complications

Paralytic ileus Yes [ ] No [ ]

Wound dehiscenceYes [ ] No [ ]

Reduced urine output Yes [ ] No [ ]

Need for repeat surgery Yes [ ] No [ ]

POD2 (48 HOURS)

A. PONV Impact scale_____

B. Oral intake Yes [ ] No [ ]

If yes Oral sips [ ] Liquid diet [ ] Soft diet [ ]

C. Ambulation Yes [ ] No [ ]

D. Post-operative complications Yes[ ] No [ ]

Paralytic ileus Yes [ ] No [ ]

Wound dehiscence Yes [ ] No [ ]

Reduced urine output Yes [ ] No [ ]

Need for repeat surgery Yes [ ] No [ ]

POD 3 (72 HOURS)

A. PONV Impact scale_____

B. Oral intake Yes [ ] No [ ]

If yes Oral sips [ ] Liquid diet [ ] Soft diet [ ]

C. Ambulation Yes [ ] No [ ]

D. Post-operative complications Yes[ ] No [ ]

Paralytic ileus Yes [ ] No [ ]

Wound dehiscence Yes [ ] No [ ]

Reduced urine output Yes [ ] No [ ]

Need for repeat surgery Yes [ ] No [

APPENDIX III: ASA CLASSIFICATION

The ASA physical status classification system is a system for assessing the fitness of patients before surgery.

ASA 1: A normal healthy patient. Example: Fit, nonobese (BMI under 30), a non-smoking patient with good exercise tolerance.

ASA 2: A patient with a mild systemic disease. Example: Patient with no functional limitations and a well-controlled disease (e.g., treated hypertension, obesity with BMI under 35, frequent social drinker or is a cigarette smoker).

ASA 3: A patient with a severe systemic disease that is not life-threatening. Example: Patient with some functional limitation as a result of disease (e.g., poorly treated hypertension or diabetes, morbid obesity, chronic renal failure, a bronchospastic disease with intermittent exacerbation, stable angina, implanted pacemaker).

ASA 4: A patient with a severe systemic disease that is a **constant threat to life.** Example: Patient with functional limitation from severe, life-threatening disease (e.g., unstable angina, poorly controlled COPD, symptomatic CHF, recent (less than three months ago) myocardial infarction or stroke.

ASA 5: A moribund patient who is not expected to survive without the operation. The patient is not expected to survive beyond the next 24 hours without surgery. Examples: ruptured abdominal aortic aneurysm, massive trauma, and extensive intracranial haemorrhage with mass effect.

ASA 6: A brain-dead patient whose organs are being removed with the intention of transplanting them into another patient.

APPENDIX IV: POST-OPERATIVE NAUSEA AND IMPACT SCALE

Questions	Answers	Score*
Did you have vomiting or dry retching?	No	0
	Once	1
	Twice	2
	Three or more times	3
Have you experienced a feeling of nausea? If yes, has it interfered with your daily activities?	Not at all	0
	Sometimes	1
	Often/most of the times	2
	All the time	3

*Addition of numerical responses to questions 1 and 2 gives the PONV impact scale score. PONV Impact Scale Score of ≥5 defines clinically important PONV. PONV=Postoperative nausea vomiting

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