UNIVERSITY OF NAIROBI

ASSOCIATION OF PRE-OPERATIVE FACTORS TO THEDEVELOPMENT OF SPINAL ANAESTHESIA INDUCED HYPOTENSION DURING CAESAREAN SECTION AT THE KENYATTA NATIONAL HOSPITAL

SUNDAY AWOT LUKE H58/33350/2019

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STUDENT'S DECLARATION

I declare that this thesis is my own original work and has not been submitted for a degree award in this or any other university. All resources contained herein have been duly acknowledged.

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DEDICATION

To my family, my brothers Stephen, Isaac and Thomas and especially my Mother Dina Disan Olweny, who continues to support me through all my endeavors. To my spouse Benard Barasa, sons Barasa Mukwhana and Ipoto Mukhwana, for the extra push I needed to complete this journey.

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LIST OF ABBREVIATIONS

ASA	American Society of Anesthesiologist
BMI	Body Mass Index
cm	Centimeters
CS	Caesarean Section
CSF	Cerebral spinal fluid
ERC	Ethics and Research Committee
GA	General Anaesthesia
HES	Hydroxyethyl starch
HRV	Heart rate variability
IV	Intra-Venous
Kg	Kilograms
KNH	Kenyatta National Hospital
L4/L5	Lumbar space 4/5
MAP	Mean Arterial Pressure
NIBP	Non-Invasive blood pressure
OR	Operating room
PRAM	Pulse rate, age and mean arterial pressure
PACU	Post Anaesthesia Care Unit
SAB	Subarachnoid block
SAIH	Spinal anaesthesia induced hypertension
SBP	Systolic blood pressure.
WHO	World Health Organization

DEFINITION OF KEY TERMS

Anesthesiologist: A physician doctor who has specialized in anaesthesia and critical care

Baseline blood pressure: Blood pressure taken within 1 hour before giving spinal anaesthesia.

Co-loading: Rapid administration of fluid bolus immediately after administration of spine anaesthetic.

Failed spinal: Occurs when a spinal anaesthetic has been administered but analgesia is not sufficient for surgery.

Neurological disorders in pregnancy: any disease that affects the brain or the nerves of the parturient.

Hypertensive disorders of pregnancy: chronic hypertension, pregnancy induced hypertension and unexplained maternal hypertension with systolic blood pressure equal to or more than 90mmHg. blood pressure equal to or more than 140mmHg and diastolic

Pre-loading: Administration of fluids within thirty minutes before giving spinal anaesthesia.

Sedation: Administration of a sedative drug to produce a state of calmness.

Spinal Anaesthesia: Administration of local anaesthetic into the subarachnoid space.

Spinal Hypotension: Reduction in blood pressure by more than 20% of baseline SPB

CONTENTS

STUDENT'S DECLARATION ii
SUPERVISOR'S APPROVAL iii
DEPARTMENTALS APPROVAL iii
DEDICATION iv
ACKNOWLEGEMENTS v
LIST OF ABBREVIATIONS vi
DEFINITION OF KEY TERMS vii
CONTENTS viii
ABSTRACT xi
1.0 CHAPTER ONE: INTRODUCTION 1
2.0 CHAPTER TWO: LITERATURE REVIEW 2
2.1 Spinal Hypotension 2
2.2 Spinal Hypotension Definition 3
2.3 Management of Spinal Induced Hypotension 4
2.4 Fluid Therapy 4
2.5 Use of Vasopressor 4
2.6 Positioning 5
2.7 Other Management Modalities 5
2.8 Factors Associated with Development of Spinal Hypotension During 6
2.8.1 Demographic Indices 6
2.8.2 Hemodynamic Parameters 7
2.8.4 Caval Compression 8
2.8.5 Drug Dosages 8
2.8.6 Puncture Site and Technique 8
2.8.7 Level of Blockade 8
2.9 Autonomic Function and Assessment of Autonomic Function 9
2.10 Validated Scales 9
2.11 Statement of The Problem 10
2.12 Justification of The Study 10
2.13 Research Questions 11
2.14 Study Objectives 11
2.14.1 Broad Objective 11

2.14.2 Specific Objectives 11
3.0 CHAPTER THREE: METHODS 12
3.1 Study Design 12
3.2 Study Site 12
3. 3 Study Population 12
3.4 Inclusion and Exclusion Criteria 12
3.5.1 Inclusion Criteria 12
3.5.2 Exclusion Criteria 12
3.6 Sample Size Determination 12
3.7 Sampling Technique 13
3.8 Study Procedure 13
3.8.1 Weight and Height 13
3.8.2 Vital Signs 14
3.8.3 Hemoglobin Level 14
3.8.4 Neonatal Birth Weight 14
3.8.5 Bromage Score and Sensory Level Assessment 14
3.8.6 Intraoperative Monitoring and Development of Hypotension. 14
3.9 Study Tools and Data Collection Procedure 15
3.10 Data Protection 16
3.11 Ethical Reviews, Approvals and Considerations 17
3.12 Data Analysis and Results 17
3.13 Data Dissemination Plan 17
4.0 CHAPTER FOUR: RESULTS 18
5.0 CHAPTER 5: DISCUSSION 24
5.1 Incidence of SAIH 24
5.2 Association of pre-operative factors with spinal anaesthesia induced hypotension 24
5.3 Association of vital signs with spinal induced hypotension 26
5.4 Adverse effects of SAIH in paturients undergoing Cesarean delivery at KNH 27
6.0 CHAPTER 6: STUDY LIMITATIONS 28
7.0 CHAPTER 7: RECOMMENDATIONS 29
8.0 CHAPTER 8: CONCLUSION 30
STUDY BUDGET 31
REFERENCES 32
APPENDICES 37
Appendix I: Consent and Study Explanation 37

Appendix II. Study Questionnaire 41
Appendix. III: KNH Protocol for Spinal Anaesthesia Maternity Theatre. 44
Appendix IV: Determination of Level of Blockade..... 48

ABSTRACT

Background: Hypotension is one of the most common complications of caesarean section under spinal anaesthesia. It leads to increased maternal morbidity and mortality, as well as poor neonatal outcomes if untreated. Knowledge of pre-operative risk factors that can predict development of hypotension intraoperatively, would significantly help in identification of patients most at risk of intraoperative hypotension, enhance early preparation and timely intervention.

Study Objective: To determine the association of pre- operative factors to the development of Spinal Anaesthesia Induced Hypotension (SAIH) and determine the incidence of spinal anaesthesia induced hypotension during cesarean section at the Kenyatta National Hospital.

Methods

Cross sectional observational study of paturients undergoing cesarean section under spinal anesthesia. Pre-operative maternal factors and baseline maternal vital signs were assessed. Logistic regression was used in multivariate analysis to determine and estimate the association between development of hypotension during cesarean section and socio-demographic, clinical and maternal factors.

Results: From 354 eligible patients, incidence of SAIH was 29.6%. The odds of developing SAIH was increased by increasing maternal age by 2.4% and hemoglobin levels by 0.7% while the odds of developing SAIH was reduced by increasing BMI by 2.41%, fasting time by 3.3%, number of previous cesareans section by 2.98%, increasing systolic blood pressure by 4.90, MAP by 1.27% and HR by 0.62%.

Conclusion: This study found the incidence of SAIH to be 29.6%. Of all the factors studied, increasing maternal age, increasing number of previous cesarean scar and increasing hemoglobin levels were associated with increased risk of hypotension.,

Key Words: Caesarean section, Hypotension, Spinal anaesthesia

1.0 CHAPTER ONE: INTRODUCTION

There has been rising numbers of caesarean sections globally[1] and it accounts for up to two thirds of surgeries performed in middle income economies like Kenya[2]. In South Africa, over half of the 2% anaesthesia related maternal mortality burden were attributed to spinal hypotension[3].

Spinal anaesthesia is the preferred anaesthetic technique for caesarean section because it is associated with less adverse outcomes and lower costs compared to general anaesthesia. It avoids the complications associated with General Anaesthesia (GA), has simplicity of technique, fast onset of action, facilitates early mother and newborn bonding and has been shown to have superior post-operative pain control[4].

Spinal hypotension is the most common and significant complication of spinal anaesthesia among others which include; reactive tachycardia, post dural puncture headache, nausea and vomiting, fetal acidosis and potential for high spinal blockade[4]. Incidence of spinal hypotension is about 20%- 78% of cases[5] and is avoidable and treatable. However, late or inadequate intervention can lead to poor neonatal and or maternal outcomes. Furthermore, identification of those at risk and early intervention has been shown to reduce the burden of morbidity and mortality.

Research has shown that certain preoperative factors may be associated with spinal induced obstetric hypotension. Increasing age, parity, higher fetal weight, increased BMI, height below 155cm, Systolic Blood Pressure (SBP) below 120mmHg, pre-operative Mean Arterial Pressure (MAP) of less than 90mmhg, history of hypotension and a high baseline heart rate have been associated with increased risk of developing spinal induced hypotension during cesarean delivery[6–10]. Preoperative factors are obtained as part of patient's routine care during a cesarean delivery and as such provide a readily available and inexpensive data set that can be used in profiling mothers most at risk. Moreover, preoperative identifiers of high-risk patients would enable prompt individualized management of patients and timely referral to centers better equipped to handle complications when necessary.

While different studies have achieved varied findings, very few studies have validated the use of the identified preoperative factors in predicting spinal induced hypotension during caesarean delivery. Hence identification of mothers most at risk still remains a challenge. This study aims to investigate the association between preoperative factors amongst parturients delivering via caesarian section to the development of spinal induced maternal hypotension**.**

2.0 CHAPTER TWO: LITERATURE REVIEW

Caesarian section is a clinical procedure where the fetus is delivered through surgical incisions on the abdominal and uterine wall[11] and spinal anaesthesia is the recommended anaesthetic technique unless contraindicated[4]. Uncomplicated caesarean section lasts between 45 to 90 minutes while complicated caesarean sections may take a longer duration[11].

Pregnancy is independently associated with increased anaesthetic risks and this is attributed to the various changes that occur in gravid women. Parturients have increased plasma volume, interstitial fluid and amniotic fluid with increasing gestational age associated with a raised heart rate and stroke volume. Despite increase in red blood cells, the approximate 50% increase in blood volume leads to dilutional anemia which is beneficial in decreasing the work of the heart by virtue of decreased blood viscosity. Cardiac displacement occurs upward and to the left with an increased cardiac output of up to 40% by end of first trimester. Additionally, flow murmurs are common in parturients with ECG changes including ST segment depression, left axis deviation and T wave flattening. While there is an increased fluid volume, progesterone leads to a decreased systemic vascular resistance, which in turn keeps blood pressure within normal or in most cases slightly lower. Aorto-caval compression further compounds the risk of hypotension among parturients when supine[12] and thus vigilance amongst this population cannot be underscored.

2.1 Spinal Hypotension

Spinal anaesthesia is administered by depositing a local anaesthetic drug within the subarachnoid space into the cerebral spinal fluid and it acts by peripheral blockade of the nerves with the sympathetic fibers being most sensitive. The most significant and important complication of spinal anaesthesia is spinal hypotension with varied incidences between 28-74% [5]. In parturients the combined effect of aorto-caval compression and a higher sensitivity to local anesthetics contributes to the increased incidence of hypotension [12].

Spinal blockade causes vasodilation leading to a decreased systemic vascular resistance and consequently a drop in blood pressure, which may lead to inadequate tissue perfusion and its sequelae of complications. They include nausea and vomiting, loss of consciousness, cardiac arrest and even death[4]. The effect of sympathetic blockade on capacitance vessels is pooling of blood especially in the regions distal to the block. Blockade higher than or equal to T6 (this abbreviation is not in the list of abbreviation), has significant effect in reduction of blood volume by up to 20%. Intrinsically, cardio inhibitory receptors of the Behold–

Jarisch Reflex (BJR), the aortic and carotid baroreceptors work synergistically in the regulation of arterial blood pressure. Risk of failure of this mechanism increases with higher blockade and it may lead to cardiac arrest and death[13].

Sympatholysis also results in unopposed parasympathetic activity which leads to reduced venous return and reduced cardiac pre-load. These changes may result in bradycardia, nausea and vomiting. Nausea and vomiting occur more frequently in cesarean delivery under spinal anaesthesia as compared with non-obstetric surgery. The vomiting centers are activated as a result of the transient brains stem ischemia that follows acute spinal hypotension. Release of emetogenic substances as a consequence of splanchnic hypoperfusion also contributes to the development of nausea and vomiting [14].

A fall in systolic blood pressure results in a reduction of splanchnic blood flow consequently compromising uterine blood flow due to loss of autoregulation at the placental bed leading to foetal hypoxia and acidosis[4,12]. Mothers with spinal anaesthesia-induced hypotension were shown to have more acidotic neonates. In a study by Olang et al, at KNH, transient hypotension increased risk of acidosis in the fetus but had no significant adverse effects on neonates[15]. The combined effect of afferent blockade and vasodilation leads to lowering of body core temperature which may lead to shivering with an increased oxygen consumption. Hypothermia has also been shown to promote hypercoagulation and infections[16].

2.2 Spinal Hypotension Definition

The definition of hypotension determines its incidence yet it still remains controversial as there is no consensus on a singular universal definition amongst research carried out in the area. In 2021, Yu et al, in a metanalysis of observational studies for prediction of spinal hypotension in elective cesarean deliveries found varied definitions of spinal hypotension[5]. They included use of less than 70% of baseline Systolic Blood Pressure SBP [17], a SBP of less than 90 mmHg until 15 minutes after delivery[10] and a 30% decrease in MAP [18]. Some studies had more than one definition of spinal hypotension for example a SBP of less than 80mmHg or the presence of hypotensive symptoms[19]. Due to these varied definitions, predictably different incidences of spinal hypotension were found.

The picture is similar in studies carried out within Kenya. Wanyama et al, defined spinal induced maternal hypotension as SBP below 100mmHg [9]similar to Olang et al [15], while Kahoro et al, defined spinal induced hypotension as SBP equal to or less than 90mmHg[20]. The recommendations from the American Society of Anesthesiologists/Society for Obstetric

Anesthesia and Perinatology Task Force, and the UK National Institute for Health and Care Excellence are that blood pressure following spinal anaesthesia for caesarean section should be maintained at above 90% of the initial SBP and avoid values less than 80% of the initial SBP [21,22]. For this study, spinal hypotension was defined as a decrease of 20% or more of the baseline SBP. (active voice: For this study, we defined spinal hypotension as a decrease of 20% or more of SBP from the baseline SBP)

2.3 Management of Spinal Induced Hypotension

Hypotension is an unwanted outcome during cesarean delivery and is associated with significant complications like acute kidney injury, stroke, cardiac arrest and even death. Consequently, the need to prevent and treat intraoperative hypotension cannot be overstated. Studies that looked at continuous cardiac output monitoring during spinal anaesthesia showed that reduction in arterial sympathetic tone is the principal mechanism of spinal hypotension, thus management modalities are focused towards this area[23].

A multimodal protocol approach is recommended for spinal induced maternal hypotension and includes pharmacological and non-pharmacological methods which are fluid therapy, use of vasopressors and caval decompression[20].

2.4 Fluid Therapy

Fluid administration is a key strategy in the management of spinal induced hypotension and is either used alone (44%) or with vasopressors (53%) [26]. Crystalloids are commonly used as they are easily available, with minimal impact on coagulation, less likely to induce allergic reactions and are cheaper than colloids. They are aqueous in nature and contain ions and minerals which have little osmotic effect in vivo. This property enables fluid replacements without detrimental ion imbalance or fluid shifts between the various body fluid compartments. However, there is risk of iatrogenic fluid overload with large amounts of infusions. Studies have shown that crystalloid co-loading reduced the incidence of hypotension in SA for cesarean delivery [24]. At KNH, crystalloids are given as first line fluids for prevention and treatment of spinal induced maternal hypotension together with vasopressors[20].

2.5 Use of Vasopressor

An ideal vasopressor should provide adequate hypotensive control with minimal side effects to both mother and foetus. Ephedrine, a sympathomimetic amine has both α and β agonist action and indirectly increases circulating catecholamines while phenylepinephrine is a

selective α1 receptor agonist and β agonist action is only achieved with higher doses. Phenylepinephrine is preferred to ephedrine as it is associated with less fetal adverse effects (acidosis) due to its minimal placental transfer, however they both have been shown to have similar efficacy in management of hypotension [25].

Norepinephrine has a weak β-adrenergic receptor agonist activity. In a randomized controlled trial by Ngan Kee et al, norepinephrine was found to be effective in management of hypotension but had less incidences of bradycardia and decrease in cardiac output than phenylephrine [26]. There was no difference in neonatal outcomes between norepinephrine and Phenylephrine in other studies[26,27]. Phenylepinephrine still remains the pressor of choice as further research is warranted before norepinephrine can be endorsed as superior to epinephrine.

2.6 Positioning

Prolonged seated time after administration of spinal anaesthesia is associated with hypotension in the parturient. Thus, in patients given spinal anaesthesia the seated time should be within 2 minutes to prevent hypotension[28] and allow for caval decompression with a left lateral tilt and or wedge placement. Caval displacements reduces pressure on the inferior vena cava caused by the gravid uterus, leading to an increased venous return which helps mitigate ensuing hypotension post spinal administration[4]. In this study parturients were preferably placed in the left lateral position see Appendix III.

2.7 Other Management Modalities

Acute spinal hypotension may lead to transient cerebral hypoxia which has been associated with increased incidence of nausea. Studies have shown that oxygen therapy can be used to manage the cerebral hypoxia and reduce incidence of nausea and vomiting[29].

Atropine has been successfully used to prevent bradycardia. In a study by Lim et al, atropine (given intravenously 1 min after SA) was shown to have a dose-dependent increase in heart rate and reduced vasopressors requirements [30]. Use of atropine routinely is not indicated. However, it can be used for parturients who are hypotensive with a low baseline heart rate. Effects of ondansetron on prevention of spinal induced hypotension and bradycardia have been widely studied. Its mechanism of action is postulated to be the chemoreceptor based cardio inhibitory Bezold-Jarisch reflex which blocks the serotonin receptors (5-HT3). There is a paradoxical response to acute drop of blood pressure leading to further failure of compensatory mechanisms of the circulatory system [13]. Despite its attributes in mitigating

spinal induced hypotension, routine use is not indicated as other studies have not demonstrated its effectiveness in the prevention of hypotension.

2.8 Factors Associated with Development of Spinal Hypotension During

2.8.1 Demographic Indices

Increasing maternal age has been associated with hypotension following spinal anaesthesia and maternal age 35 and above was identified as a risk factor for hypotension[8,31]. However, a regional study found that age had no significant association with development of spinal induced maternal hypotension [7]. Compensatory mechanisms are generally more effective in younger people.

Gravid women with 4 pregnancies and above have a 5-7-fold risk of developing maternal hypotension. Similarly, women who had previous cesarean sections were at an increased risk of spinal induced maternal hypotension as compared to those with vaginal deliveries[8]. Multiparous women were found to have an increased risk of developing spinal induced maternal hypotension compared to nulliparous women [32,33] but in a 2020 study, gravidity and cesarean section were not associated with spinal induced maternal hypotension [7].

An increased BMI has been shown to significantly increase the risk of developing spinal induced maternal hypotension. Wanyama et al, found that obese patients were more likely to develop hypotension at 83.1 % as opposed to non-obese at 69.1%. Additionally, they were more predisposed to moderate to severe hypotension than non-obese parturients under spinal anaesthesia at KNH [9]. Similar findings were made by the other studies[10,34], in contrast a study in the horn of Africa did not find any significant association between BMI and spinal induced maternal hypotension[7].

Maternal height < 155 cm was a risk factor associated with development of spinal hypotension according to studies by Kahoro et al [20] and Ngan et al [26] while Norris et al found no association between maternal height and hypotension in parturients [6].

In his study, Mayaan et al demonstrated that fetal weight above 3, 900 grams is associated with increased risk for development of spinal induced maternal hypotension [35]. These findings were similar to those by Fakherpour at al [8]while Shitemay et al found that to be true for weigh above 4000 grams [7].

Few studies have looked at the association of preoperative hemoglobin in parturients undergoing spinal anaesthesia and hypotension. An association was not found between associate preoperative hemoglobin level with spinal induced maternal hypotension[7] .

2.8.2 Hemodynamic Parameters

Preoperative MAP of 90≤ is associated with an increased incidence of hypotension according to a south African study [10] while a SBP ≤ 120 mmHg is also associated with an increased risk of developing hypotension[8,36].

A high baseline heart rate is a predictor of inadequate fluid status aimed at compensating for the ensuing circulatory insufficiency. It is positively associated with an increased risk of spinal hypotension development [10,18]. In his study, Kinsella et al did not yield any significant association between preoperative heart rate and spinal induced maternal spinal hypotension[17]similar to findings by Toyoma et al[32].

Oxygen saturations act as surrogates for perfusion index and therefore blood pressure status. Low saturations are a predictor for development of spinal induced maternal hypotension. Tachypnoea has also been shown to have a positive association with the development of spinal induced maternal hypotension[32].

Hypothermia has been studied more as a consequence of maternal spinal anaesthesia than as a predictive factor for hypotension. It was therefore of interest to find out how preoperative baseline temperatures are associated with development of hypotension in parturients undergoing spinal anaesthesia at KNH.

2.8.3 Hydration Status

Fluid status affects the body's response to regulate blood pressure e.g., in fluid depleted states, the body activates mechanisms of blood pressure control to compensate for the deficit and can therefore be prone to failure with an additional insult. The American Society of Anaesthesiologist (ASA) recommends preoperative fasting times of 6 to 8 hours for solid foods and up to 2 hours for clear fluids [21]. However, parturients enroute to labor often abstain from feeding due to anxiety associated with delivery hence are at a risk of dehydration. This then predisposes them to inadequate blood pressure maintenance and development of hypotension with its accompanying sequelae [10,12].

Fluid administration remains a standard practice and crystalloids remain the fluid of choice as they are considered physiological, cheaper and easily available. Preloading with either crystalloid or colloids has been shown to be superior to no fluid regime and protective against spinal induced hypotension. However, crystalloid co-loading was found to be superior to preloading[37]. There is consensus amongst most studies that fluid administration

preoperatively is protective against hypotension and thus associated with a decreased risk of development of spinal hypotension.

2.8.4 Caval Compression

Caval compression significantly reduces venous return, cardiac output and consequently blood pressure. Techniques for caval decompression have been associated with a decreased incidence of development of spinal induced maternal hypotension as they increase cardiac output and in return blood pressure[17]. They include lateral tilt at 15˚ and or positioning a wedge on the buttock of the mother within 15 minutes of spinal administration [38].

2.8.5 Drug Dosages

The local anesthetic of choice for cesarean section is bupivacaine. Changes within the maternal spinal cord allow for use of dosages as low as 5mg to 7mg of bupivacaine to provide adequate analgesia[26]. Addition of opioids have been shown to improve onset of action but increase risk for and severity of hypotension[8] hence low dose spinal anaesthesia has been identified as an important strategy in prevention of spinal induced maternal hypotension[6]. For this study plain bupivacaine 7.5mg and fentanyl 25mcg was used for all mothers according to the KNH protocol for obstetric spinal anaesthesia.

2.8.6 Puncture Site and Technique

Sub arachnoid blockade is preferably administered at the intervertebral space between the fourth and fifth lumbar spine, identified easily by use of tuffier's line which connects the posterior superior iliac crests at the level of L4/L5 intervertebral space[4]. A slow rate of drug infusion has been associated with a lower hypotensive incidence, a delayed onset of hypotension, shorter episodes of hypotension and less ephedrine requirements[39]. While in another study, the speed of drug infusion was not shown to affect either the onset or level of blockade[40]. However, barbotage achieved faster onset and accompanying higher levels of blockade [41]. All parturients received spinal anaesthesia with a slow infusion rate and avoidance of barbotage in accordance to the KNH protocol. See appendix III.

2.8.7 Level of Blockade

Caesarean section incision is performed at the level of T12 innervation yet the underlying viscera have innervation spanning all the way to T4. Therefore, the ideal level of blockade should extend all the way to the nipple line (T4-T5) to reduce risk of pain experience [4]. Blockade above T5 was significantly associated with development of hypotension in a

Kenyan study[20] and is a modifiable factor in development of hypotension. Increased incidence of cardiac depression and hypotension was noted with blockade above T5 level therefore low dose spinal anaesthesia is recommended.

Loss of sensation to cold occurs before loss of sensation to pinprick, an assessment of both was used to evaluate the afferent function and thus level of blockade, see appendix IV.

2.9 Autonomic Function and Assessment of Autonomic Function

Spinal anaesthesia induced hypotension is almost inevitable, hence assessment of inability to compensate for it would be worthwhile. This would provide essential information on adaptability of the patient to respond to hemodynamic instability post spinal anaesthesia administration. Research done on specific patient populations with unique alterations in the autonomic nervous system were attributed to their disease process and these alterations were found to have implications on cardiac and renal systems. Inadequate stress response as well as altered temperature regulation are admissible in the perioperative period and applicable to parturients undergoing caesarean delivery[4242,43]

Hans's et al used a variable called the point correlation dimension, to assess the risk of developing hypotension during caesarean delivery. Parturients with a high sympathetic tone as compared to parasympathetic tone were found to be more susceptible to develop spinal induced maternal hypotension[44] This was similar to findings that showed parturients with lower sympathetic tone had lower incidences of spinal induced maternal hypotension as they were presumed to have a lower sympathetic outflow [45]. Despite the promising results, the complexities of assessment of the autonomic nervous system despite advancement in technology have not made this an attractive option.

2.10 Validated Scales

Despite the relatively good number of studies on preoperative factors, there is no validated tool that uses the identified preoperative factors and their association with spinal induced maternal hypotension to stratify mothers most at risk. Thus, a great gap still exists in this area of research. Bishop et all used the PRAM (Pulse rate, age and MAP) score to predict spinal hypotension, however his study is not validated[10]. A study by Lim et all, used a computer-based scoring system where senior anaesthesiologist were presented with data which they used to profile mothers and their odds of developing hypotension [46]. The pitfalls of this design are that it requires a significant input and is thus not feasible in resource limited settings like Kenya.

Further research is warranted in this area to establish a reproducible scoring system that is easy to use and non-expensive.

My study therefore aimed to contribute to this area of research by investigating the association of preoperative factors with spinal induced hypotension during cesarean delivery. Spinal induced maternal hypotension was defined as per recommendations by the NICE and American Obstetric Association/ Society for Obstetric Anesthesia and Perinatology Task Force where they pronounced a consensus report on a single definition of spinal induced hypotension[21,22]. Results from this study can further be subjected to validation and contribute towards the development of a scoring system to advance recognition, diagnosis and management of spinal induced maternal hypotension in parturients undergoing cesarean delivery.

2.11 Statement of The Problem

Spinal induced maternal hypotension remains an important contributor to morbidity and mortality of both mother and child. It is avoidable, when predicted early using identifiers such as preoperative factors. Delayed recognition leads to poor clinical outcomes. There is therefore a need to establish data that can be used to identify women most at risk of developing spinal induced maternal hypotension during cesarean section and consequently improve clinical outcomes.

2.12 Justification of The Study

Hypotension following spinal anaesthesia for caesarean section is a frequent complication, occurring in up to 75% of patients. Suboptimal treatment of maternal spinal hypotension is associated with higher morbidity and mortality for both mother and newborn. Withal, early recognition and timely intervention have been shown to significantly reduce morbidity and mortality associated with maternal hypotension with improved clinical outcomes.

Currently, few studies have looked at the association between preoperative factors and the development of spinal induced maternal hypotension. There is lack of consensus in studies done on preoperative risk factors associated with development of maternal spinal hypotension, making it difficult to identify those at risk. Therefore, identification of mothers most at risk of developing spinal hypotension still remains a challenge.

The preoperative maternal factors obtained during routine patient care provide simple, accessible and inexpensive data that can be used in predicting spinal hypotension. This study was aimed at provision of data that will easily identify parturients most at risk of

development of spinal hypotension and can be adapted to enhance clinical decision making. Accurate and timely identification of mothers at risk will facilitate early preparation in the preoperative phase, expedite early intervention with targeted and individualized treatment, thereby improving maternal and neonatal outcomes.

2.13 Research Questions

1. Is there an association between certain pre-operative factors and the development of spinal anaesthesia induced hypotension (SAIH) during caesarean delivery at the KNH?

2. What is the incidence of spinal anesthesia induced hypotension (SAIH) at the Kenyatta National Hospital?

2.14 Study Objectives

2.14.1 Broad Objective

To determine the association of pre- operative factors to the development of Spinal Anaesthesia Induced Hypotension (SAIH) and to determine the incidence of spinal anaesthesia induced hypotension during cesarean section at the Kenyatta National Hospital.

2.14.2 Specific Objectives

a) To determine the association between maternal factors and development of SAIH during cesarean section at the Kenyatta National Hospital.
b) To determine the association between baseline maternal vital signs and development of SAIH during cesarean section at the Kenyatta National Hospital.
c) To determine the incidence of SAIH during cesarean section at Kenyatta National Hospital. (should this be your first objective?)

3.0 CHAPTER THREE: METHODS

3.1 Study Design

This was a cross sectional observational study.

3.2 Study Site

The study was conducted at the KNH maternity theatres. KNH has two 24-hour maternity theatres. They handle routine, complex, elective and emergency obstetric surgical procedures.

On average four hundred caesarean sections are performed per month.

3. 3 Study Population

Parturients who underwent caesarean section at the KNH maternity theatres.

3.4 Inclusion and Exclusion Criteria

3.5.1 Inclusion Criteria

Parturients who were scheduled to undergo cesarean section under spinal anaesthesia at the Kenyatta National Hospital Maternity Unit. Requirement of consent for inclusion?

3.5.2 Exclusion Criteria

- Parturients with fixed output cardiac disease such as Aortic Stenosis & Mitral Stenosis,
- Parturients on medication for hypertension disorders in pregnancy
- Parturients with any neurologic disorder
- Parturients with intravenous fluid instituted during the pre-operative period
- Parturients with bleeding disorders
- Parturients with infection at the spinal anaesthesia insertion site
- Parturients who intra-operatively are converted to General Anaesthesia.
- Parturient who are sedated during the caesarean delivery.
- Parturients with language and or communication barrier

3.6 Sample Size Determination

The Fischer's formula was used in this study to determine the optimum sample size. An assumption was made on the proportion (p) of the mothers who experience hypotension during caesarean delivery. We made an assumption based on a study conducted by Shitemay et al [7] where the incidence of hypotension after spinal anaesthesia was 64%. The following Fishers formula illustrates the sample size calculation expression and substitution:

$$n = \frac{Z^2 x\, P(1-P)}{d_2}$$

Where; z = 1.96 Standard deviation estimated at the 95% Confidence interval (CI). d = (0.05, 5%) precision of the study. p= the proportion (p) of the mothers with cases of hypotension after spinal anaesthesia.

Substituting the formula above:

1. $n_0 == 354$ $\quad \frac{96^2 x\, 0.164(1-0.64)}{0.05^2}$

3.7 Sampling Technique

Consecutive sampling technique was used until the required sample size was achieved.

3.8 Study Procedure

The study was conducted between 8am to 5 pm daily to ensure standardization of care and meticulous data collection by the principal investigator and research assistant.

The research assistant was a health professional who was trained on i) how to fill in the data sheet ii) how to identify the common adverse effects (if any) and alert the primary care physician. To ensure validity, the trained assistant undertook re-training sessions every two weeks during the conduct of the study.

Parturients scheduled to undergo caesarean delivery were identified using the theatre list. At the theatre unit, upon review by the anaesthetic team, patients scheduled for spinal anaesthesia and met our inclusion criteria proceeded with the study after obtaining informed consent at the labor ward.

A two-part structured questioner was used. One part was filled using answers from the patient and or file documentation while the second part was filled with measurements obtained from the patient. Measurements were taken as follows:

3.8.1 Weight and Height

Before the patient was wheeled in to the theatre, the weight and height was taken using a Seca weight and stadiometer machine model number 7551021998. The Machine was calibrated annually and has a sensitivity error rate of 1mm for height measurement. Weight sensitivity is±0.5kgs for weight 0 kgs to 20 kgs, ±1 kgs for weight 21kgs to 100kgs and ± 1.5kgs for 101kgs to 160kgs. Parturients were required to step on the weight with minimal clothing (theater gown) and bare heads and feet and they stood straight with arms hanging

loosely on the side. Feet were joined together, heels, buttocks and shoulder blades were to be in contact with the vertical surface of the stadiometer to reduce errors.

3.8.2 Vital Signs

Baseline vital signs: Blood pressure, Heart rate, Respiratory rate, SPO2 and temperature were taken using the Mindray anaesthetic machine model iMEC10 when the parturient arrived in theater.

Sensitivity of the various parameters using the above monitor are as follows: SBP below 80mmHg ± 5mmHg, SBP above 90mmHg ± 6mmhg, Heart rate± 2 beats per minute, SPO2± 3%, Temperature ± 1˚C. As part of the hospital protocol all monitors are calibrated annually. One baseline reading was obtained while the patient was on left lateral position as soon as they arrived in theater and were moved to the operating table. The patient was then requested to sit for administration of spinal anaesthesia as per the KNH protocol, see appendix III.

3.8.3 Hemoglobin Level

The hemoglobin level was obtained from the patient's most recent full blood count test done using either of the three machines: Sysmex XN 1000, Sysmex XN550, Sysmex XN 350. These machines are calibrated annually. Daily machine check was carried out by the laboratory technician on duty at the full blood count hematology laboratory for the day. The error rate for all the full blood count machines mentioned above for the hemoglobin level is ±0.5.

3.8.4 Neonatal Birth Weight

Neonatal birth weight was recorded by the receiving nurse who measured birth weight using the Seca pediatric weighing scale.

3.8.5 Bromage Score and Sensory Level Assessment

The Bromage scale was used to assess the degree of motor block and the sensory block height will be assessed using loss of cold sensation to alcohol swabs (appendix IV). Assessment of the motor and sensory block was done at two points: after urinary bladder catheterization and just before skin incision.

3.8.6 Intraoperative Monitoring and Development of Hypotension.

Vital signs were recorded every 3 minutes after spinal induction until after delivery of the placenta, then every 5 minutes thereafter until the end of surgery and parturient transferred to PACU.

Spinal anaesthesia induced hypotension (SAIH) was considered to be the first incidence of more than 20% drop in systolic blood pressure within 30 minutes after spinal anaesthesia induction. This is because spinal anaesthesia is fixed on average twenty (20) minutes after injection of local anaesthesia into the sub-arachnoid space. Hypotension occurring after this timeline was unlikely due to the spinal anaesthesia. SAIH was managed according to the KNH guidelines.

3.9 Study Tools and Data Collection Procedure

Data was collected using a serialized questionnaire.

To maintain confidentiality, subject identifiers were omitted. See Appendix II.

Demographic data were obtained from both the patient and the file while vital signs were measured by the researcher and trained research assistant, then filled into the questionnaire tabulated in Redcap software device for data collection.

All collected data was automatically saved into an excel sheet and an SPSS version 25 document. Data collected and signed consent forms were stored into a google cloud for reference.

The preoperative risk factors in this study include maternal demographic factors and maternal baseline vital signs. The maternal demographic factors include weight, height, BMI, parity, gravidity, presence of previous cesarean delivery scar, indication for CS, comorbidities, maternal hemoglobin level and preoperative fasting time while the vital signs are blood pressure, heart rate, oxygen saturations, respiratory rate and temperature.

Table 1: List of variables taken during the study

Category Of Variable	Variable	Measurement Tool/Source of Data	Units Of Measurements
Maternal factors	Age	Patient records/Patient	years
	Parity	Patient records/ Patient	
	Singleton/Multiple pregnancy	Patient records/ Patient	
	Indication for Caesarean section	Theater list	
	Previous Caesarean sections	Patient records/Patient	
	Foetal birth weight	Seca pediatric weighing scale	grams
	Weight	Seca weighing scale	Kilograms
	Height	Seca Stadiometer	Centimeters
	BMI	Derived formular	Kg/M^2
	Pre-operative fasting time	Patient records/ Patient	Hours
	Cormobids	Patient records/ Patient	
Anaesthetic variable	Preoperative drugs administered	Treatment sheet	
Vital signs	Baseline Heart rate	Mindray WATO EX 55	Beats per minute
	Baseline Oxygen saturations	Mindray WATO EX 55	Percentage (%) saturation
	Baseline Blood pressure	Mindray WATO EX 55	Mmhg
	Baseline MAP	Mindray WATO EX 55	Mmhg
	Baseline temperature	Mindray WATO EX 55	º Celcius
	Haemoglobin	Laboratory report	g/dl
	Intraoperative vital signs	Mindray WATO EX 55	
Anaesthetic factors	1.Intraoperative fluid given up to the time of hypotension 2. Intraoperative fluid given during the entire perioperative period.	Anaesthetic chart/ Observation	mL
	Intraoperative blood loss	Anaesthetic chart	mL
	Level of spinal blockade	Assessment by anaesthesia provider	Dermatome level
	Motor blockade score	Bromage score	Score 1-6
	Nausea	Patient/Observation	
	Vomiting	Patient/Observation	
	Dizziness	Patient/Observation	
Maternal factors	complications: Foetal complications (Poor Apgar score, Foetal death) Maternal complications (PPH, High spinal)	Patient/Observation	

3.10 Data Protection

A serialized questionnaire ensured that all data required for the study was well captured and only missed if not available. Data were checked for completeness, then saved in the redcap data tool with passwords for protection and autonomy of patients' details. Patient identifiers were only a number and the first initials of their names. Data were only accessible to the

primary investigator, research assistant and supervisors. All consent forms and any other documents were scanned and stored as electronic documents in a secured google file.

3.11 Ethical Reviews, Approvals and Considerations

The study commenced after obtaining approval from the Ethics Research Committee (KNHUON ERC).

Participation in the study was voluntary and participants were free to withdraw from the study at any time. None of the participants sought to withdraw from the study.
Spinal anaesthesia was administered by qualified anaesthesia providers or by students of anaesthesia in training under supervision of the qualified anaesthesia providers in accordance with the KNH protocol for obstetric spinal anaesthesia.

Patients were monitored continuously until the end of surgery for any adverse outcomes associated with spinal anaesthesia such as nausea, vomiting and dizziness. Appropriate and timely intervention was administered as per KNH guidelines. There were no additional costs or risk to the patients from this study.

3.12 Data Analysis and Results

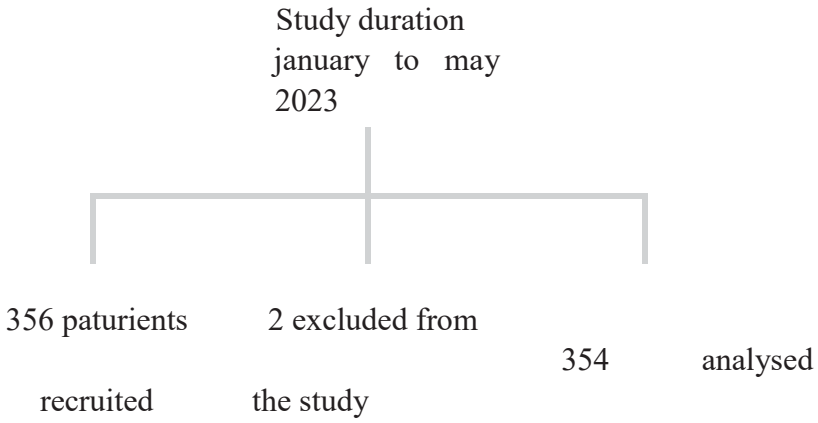
Univariate analysis, frequency distribution and proportion were used for categorical variables such as parity, body mass index, presence of previous caesarean scar, and measures of central tendency for numerical for continuous variables such as age, height, weight. To test for any association in bivariate analysis, categorical variables were compared using χ^2 whereas continuous variables were compared using parametric (t-test and Analysis of Variance) or nonparametric (Mann-Whitney U test and Kruskal Wallis) tests as appropriate. Logistic regression was used in multivariate analysis to determine and estimate the association between development of hypotension during cesarean section and socio-demographic, clinical and maternal factors.

3.13 Data Dissemination Plan

Data will be disseminated to the anaesthesia community of the Kenyatta National Hospital and shared with anesthesiologists within the country and beyond via presentations in seminars and publishing the findings in a reputable peer-reviewed journal. It will also be stored in the University of Nairobi online library registry.

4.0 CHAPTER FOUR: RESULTS

Patients recruitment characteristic



Two patients received sedation intraoperatively and were excluded from the study.

Maternal Characteristics

Table 1: Socio-demographic characteristics of paturients undergoing Cesarean Section under Spinal Anaesthesia at the Kenyatta National Hospital

Education level	
None	6(1.7)
Primary	37(10.5)
Secondary	148(41.8)
Tertiary	163(46.0)
BMI	
18.5-24.9	47(13.2)
25.0-29.9	191(54.0)
30.0+	116(32.8)
Parity	
0	76(21.5)
1	150(42.4)
2	72(20.3)
3	40(11.3)
4+	16(4.5)

Yes	41(11.6)
No	&&(##)

Previous scar

0	163(46.0)
1	116(32.8)
2	56(15.8)
3+	19(5.4)

Comorbidities*

Age in years	**Frequency(%)**
≤20	17(4.8)
21 _ 30	196(55.4)
31 _ 40	136(38.4)
>40	5(1.4)

*Comorbidities were hypertension, hypothyroidism, infections disease and diabetes mellitus.

Age ranges were 13 years to 49 years.

Table 2. Urgency for Cesarean Section in paturients at the Kenyatta National Hospital.

Urgency for Caesarean section	**Frequency(Percentage)**
Elective	150(43.27)
Non Elective	204(57.63)

Table 3. Distribution of Maternal characteristics of paturients who had Cesarean Section under Spinal Anaesthesia at the Kenyatta National Hospital.

Maternal factors	**Range (Min-Max)**	**Mean(SD)**
Age(years)	13-49	29.17(5.64)
Number of Caesarean Section	1-5	1.82(0.94)
Weight(Kgs)	46-120	77.65(14.36)
Height(cm)	139-178	158.78(6.35)
Body mass index.	21.00-49.60	30.84(5.43)
Fasting Period(Hours)	1-72	12.98(7.22)

Haemoglobin(g/dl)	7.9 -15.90	12.29(1.41)
Intraoperative volume given (ml) *	500-2000	654.07(284.87)
Intraoperative blood loss(ml)	300-1500	530.52(96.68)

*Intraoperative fluid given before spinal induction

Table 4. Distribution of Baseline Vital Signs of paturients undergoing Cesarean Section under Spinal Anaesthesia at the Kenyatta National Hospital.

Baseline vital signs	Range (Min-Max)	Mean(SD)
Systolic Blood pressure	82-179	125.10(15.19)
Diastolic Blood pressure	42-124	76.47(13.70)
Mean arterial blood pressure	47-130	89.97(13.85)
Heart rate	59-143	89.97(13.85)
Oxygen saturation	70-100	97.31(2.13)
Respiratory rate	15-35	19.67(4.651)

Table 5. Assessment of the block in paturients undergoing Cesarean Section under Spinal Anaesthesia at the Kenyatta National Hospital.

Sensory Level of blockade	Frequency(Percentage)
T6 and Above *	116(32.8)
Below T6*	238(67.2)
Bromage Score	
1	312(88.1)
2	26(7.3)
3	16(4.5)

*T≡ Thoracic nerve dermatome level.

Incidence of Hypotension.

Table 6. Incidence of Spinal Anaesthesia Induced Hypotension among paturients undergoing Caesarean Section at the Kenyatta National Hospital.

Hypotension	Frequency(Percentage)
Yes	105(29.66)
No	249(70.34)

Table 7: The probability of developing of Spinal Anaesthesia Induced Hypotension based on Preoperative Maternal Factors among Paturients at the Kenyatta National Hospital

Maternal Factors	Estimate (β_s)	Exp (β_s) = Odds	Standard Error	P-Value (Sig.)
Intercept	16.033	9186877.244	17.462	0.359
Age	0.024	1.024	0.023	0.311
Body Mass Index	-0.276	0.759	0.285	0.333
Fasting Period	-0.034	0.967	0.018	0.063
Hemoglobin	0.007	1.007	0.083	0.930
Number of Previous Caesarean Section	-0.014	1.0298	0.139	0.301

Hypotension = 16.033 + 0.024 (Age) + 0.094 (Weight) - 0.099 (Height) - 0.276 (BMI) – 0.034 (Fasting Period) + 0.007 (Number of Hemoglobin) - 0.014 (Number of previous CS)

Increasing maternal age (2.4%) and hemoglobin levels (0.7%) reduced the odds of developing

SAIH while increasing BMI (2.41%), Fasting time (3.3%) and number of previous Cesareans (2.98%)section increases the odds of developing SAIH.

Table 8: The probability of developing Spinal Anaesthesia Induced Hypotension based on baseline vital signs among Paturients at the Kenyatta National Hospital

Baseline vital signs	Estimate	Exp (β_s) =	Standard. Error	P-Value

	(β_s)	Odds		
Intercept	-0.9048	0.4046	7.6583	0.9060
Systolic BP	-0.0497	0.9515	0.015823	0.0017
Diastolic BP	0.0126	1.0127	0.0251	0.6150
Mean arterial BP	-0.0128	0.9873	0.030366	0.6726
Heart rate	-0.0062	0.9938	0.0080	0.4373
Oxygen saturation level	0.0648	1.0669	0.07671	0.3986
respiratory rate	0.0294	1.0298	0.0269	0.2733

Increasing systolic blood pressure (4.90%), MAP (1.27%)and HR (0.62%) reduced the odds of developing hypotension while increasing DBP (1.30%), SPO2(6.48%) and RR (2.94%)increases the odds of becoming hypotensive.

Table 9. The Association of Anaesthetic and Pregnancy Related Factors with the development of Spinal Anaesthesia Induced Hypotension among Paturients at the Kenyatta National Hospital

Outcome	Factors	Category	Frequency(Percent)	Chi value(df*)	P Value
Hypotension	**Bromage score**	1	312(88.1)	3.381(2)	**0.184**
		2	26(7.3)		
		3	16(4.5)		
	Sensory level of blockade	T6 and above	116(32.8)	1.073(2)	**0.585**
		Below T6	238(67.2)		
	Birth weight	High Birth weight	25(7.1)	1.211(2)	**0.546**
		Normal birth weight	287(81.1)		
		Low birth weight	42(11.9)		
	Pregnancy	Singleton	340(96.1)	5.883(3)	**0.117**
		Twin	14(3.9)		

******df*=degrees of freedom

Table 7. The Frequency of Adverse Events Among Paturients undergoing Caesarian Section under Spinal Anaesthesia at the Kenyatta National Hospital

Adverse Events	Frequency(Percentage)
Difficulty in breathing	24(6.8)
Nausea	39(11.0)
Vomiting	18(5.1)
Dizziness	18(5.1)

Our study found that 7(2%) of paturients experienced shivering, similarly 7(2%) had pruritus.

This chapter seems hurriedly done, there monotous use of table, not varied with figures. Present the finding is organized setions with appropriate subheadings

Have you analysed all the collected data variables relevant to your objectives?

5.0 CHAPTER 5: DISCUSSION

This study sought to determine the association between pre- operative factors and the development of spinal anaesthesia induced hypotension (SAIH) and to determine the incidence of SAIH during caesarean section at the Kenyatta National Hospital between January 2023 and May 2023.

5.1 Incidence of SAIH

We found an incidence of SAIH 29.66%. This is significantly lower than findings in a study done at Kenyatta National Hospital: Incidence of, and risk factors for hypotension during spinal anaesthesia for cesarean section, that found a 64% incidence [20] . While Kahoro's baseline was a BP taken immediately after administration of Spinal Anaesthesia, our baseline was recorded as soon as the patient arrived in thearter and before induction of spinal anaesthesia. Our incidence was in agreement with the south African study at a 30% incidence and at a 33% incidence in another study,[10,36]. All the above studies defined hypotension as a systolic pressure of below 90mmHg while our definition was a drop in 20% and more of the baseline systolic blood pressure in line with a consensus for definition of hypotension by the American Society of Anesthesiologists/Society for Obstetric Anesthesia and Perinatology Task Force, and the UK National Institute for Health and Care Excellence[21,22]. Different studies had varied operational definitions of hypotension, and this may account for the equally varied incidences of SAIH in studies done across the region and beyond [6–8,10,20,26,34].

5.2 Association of pre-operative factors with spinal anaesthesia induced hypotension

For every one-year increase in age, the odds of experiencing hypotension increased by a probability of 0.024 thus increasing maternal age was identified as a risk factor for development of SAIH in our study. This was consistent with several studies where increasing maternal age was identified as a risk factor for developing SAIH[8,10,36,47] and maternal age greater than or equal to 35 years were identified as risks factors for SAIH [31]. However, a study on incidence and associated factors for hypotension after spinal anesthesia during cesarean section at Gandhi Memorial Hospital, Addis Ababa did not find age to be significantly associated with development of spinal induced maternal hypotension [7.] The decreasing cardiac reserve with changes in the autonomic nervous system and baroreceptor reflex have been implicated to play a role in the tendency to develop SAIH in older paturients

[31,36]. Thus older paturients are at an increased risk of developing hypotension following spinal anaesthesia.

This study established that an increasing BMI reduces the odds of having a maternal induced spinal hypotension. This was consistent with results from a study of hypotension after spinal anesthesia for cesarean section: identification of risk factors using an anesthesia information management system [31] and a study from sub Saharan region[7.] Most studies however found increasing BMI to be risk factor for developing SAIH [8,9,34.] A possible mechanism for the reduced risk for hypotension, is the increased cardiac output and blood volume occurring inherently in obesity. Obese paturients tend to have a higher resting vascular resistance than that of those with normal pregnancy. In addition, they have an increase in blood volume of 3050ml for every 100 g increase in weight thus an increased cardiac output. [9,48]. This difference in starting vascular tone may account for the differences in response. Obese paturients do not experience a profound fall in vascular tone maintaining a relatively higher vascular tone and some degree of relative cushioning from blood pressure fall.

Increasing fasting period was found to be protective by reducing odds of developing hypotension in this study. There is a glaring paucity of data on maternal fasting times and its association to SAIH. In a study by Wei chei et al, an analysis of risk factors to hypotension occurring after caesarean spinal anesthesia for parturients with scarred uterus, no association was found between fasting time and maternal induced hypotension occurrence[49]. It will be ideal to have studies that seek to establish the relationship and effects of fasting on paturients undergoing cesarean delivery under spinal anaesthesia.

According to this study, higher haemoglobin levels were reported to be a risk factor for developing SAIH. In a cohort study done in the Dutch population high haemoglobin was correlated with a high SPB, however this was in a non-parturient population[50] Two other studies did not find an association between of pre-operative haemoglobin level with spinal induced maternal hypotension[7,10.] In this study, the prolonged fasting time may have led to a fluid deficient status inducing haemo-concentration.

The results from this study indicate that paturients with higher numbers of previous cesarean scar had increased likelihood of developing SAIH. This concurs with results that suggest an

increased incidence of maternal induced spinal hypotension in paturients with previous cesarean delivery scars[49.]

While findings from this study did not suggest neonatal birth weight to be predictive of developing SAIH, an Israeli study demonstrated that foetal weight above 3900 grams is associated with increased risk for development of spinal induced maternal hypotension [35]. Their findings were similar to a study done in Iran [8]. For paturients in Ethiopia this was found to be true for birthweights above 4000 grams [7]. Increased foetal weight is associated with increased abdominal pressures, compression of the subarachnoid space and reduction in CSF which may lead to more profound sympathetic blockade.

Bromage score was used to evaluate the intensity of motor blockade and by extension the adequacy of spinal anaesthesia desired blockade before skin incision. The association of Bromage score to the development of SAIH was not statistically significant. Similarly, level of blockade was not found to be a predisposing factor for development of SAIH.A study at Kenyatta National Hospital found that blockade above T5 was significantly associated with SAIH while studies have shown that blockade above T4 have significant association with development of SAIH [20]. Cardio- acceleratory fibers are more prominent above T4 close to the sympathetic chain. Anaesthesia beyond T4 is associated with blockade of cardio acceleratory fibers leading to decreased heart rate and cardiac output thus hypotension. [4]This is agreeable with the postulation that the higher the blockade the more profound the sympatholysis with loss of vascular tone and subsequent drop in blood pressure.

5.3 Association of vital signs with spinal induced hypotension

Four parameters were found to be predictive of developing SAIH: HR, SBP.DBP and MAP. Increasing SBP, MAP and HR were found to reduce one's likelihood of developing maternal induced spinal hypotension. Bishop et al in their study found an association between preoperative MAP and preoperative Heart Rate (HR) with development of SAIH. However, they did not find preoperative systolic and diastolic blood pressures to be predictive of developing SAIH[10,18]. Kahoro et al, Kinsellah et al and Toyoma et al on the other hand, did not find any predictive value between vital signs and SAIH [17,20,32.] A low baseline systolic blood pressure is indicative of a low systemic vascular resistance and therefore increased risk of developing hypotension. Further a high SPB, MAP and HR provides a higher safety margin of from circulatory instability as a consequence of spinal anaesthesia.

5.4 Adverse effects of SAIH in paturients undergoing Cesarean delivery at KNH

A total of 11% of paturients experienced nausea while only 5.1% had vomiting. In Kahoro's study 20% of paturients experienced nausea and vomiting while in Carpenter's study, 18% had nausea and 7 % had vomiting[20,36] . The lower numbers may be due to increased awareness of possible side effects from spinal anaesthesia during cesarean section as well as timely management. Treatment included use of antiemetic medication, vasopressors and oxygen supplementation where indicated.

6.0 CHAPTER 6: STUDY LIMITATIONS

This was a single-center observational study and Caesarean Section was carried out as per KNH protocol. Therefore, differences may arise from variation in protocols amongst the different levels of hospital care as from the study site.

The scope of the study is limited to parturients and the results of the study may not be generalized to the non- parturient population or males.

7.0 CHAPTER 7: RECOMMENDATIONS

Preoperative maternal factors and maternal vital signs can be used to predict those at risk of developing SAIH and expedite early intervention to avert associated morbidity and mortality. Further research can be done to improve the use of preoperative maternal factors risk profile base.

8.0 CHAPTER 8: CONCLUSION

This study found the incidence of SAIH is 29.7%. Of all the factors studied increasing maternal age, increasing number of previous cesarean scar and increasing hemoglobin levels were associated with increased risk of hypotension.,

STUDY BUDGET

RESEARCH ASSISTANT	120,000
STATISTICIAN	45,000
STATIONARY/SOFTWARE	10,000
PRINTING & BINDING	15,000
ETHICS & RESEARCH COMMITTEE FEE	2,000
MICELLENEOUS	15,000
TOTAL	207,000

The funds were drawn from my personal savings.

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APPENDICES

Appendix I: Consent and Study Explanation

STUDY TITTLE: ASSOCIATION OF PREOPERATIVE RISK FACTORS TO THE

DEVELOPMENT OF SPINAL HYPOTENSION DURING CAESEAREAN SECTION AT THE KENYATTA NATIONAL HOSPITAL

PARTICIPANT INFORMATION SHEET

PARTICIPANT INFORMATION SHEET FOR PATIENTS AND THEIR NEXT OF KINS

My name is Dr. Sunday Awot Luke a postgraduate student pursuing a Master of Medicine degree in Anesthesia and Critical Care at the University of Nairobi. I am conducting an observational study on the association of preoperative factors and their association to the development of spinal induced hypotension during cesarean section.

BACKGROUND

Hypotension is one of the most common complications of caesarean section under spinal anaesthesia. It leads to increased maternal complications such as nausea and vomiting, as well as poor neonatal outcomes if untreated. It is treatable using medications and positioning of the patient. Knowledge of pre-operative risk factors that can predict development of hypotension intraoperatively, would significantly help in identification of patients most at risk of intraoperative hypotension, enhance early preparation and timely intervention.

STUDY PURPOSE

This study aims to contribute and establish a safe and reproducible method that uses preoperative data to identify women most at risk for developing spinal induced maternal hypotension during cesarean section and consequently improve clinical outcomes.

PARTICIPATION

Participation is entirely voluntary, and withdrawal of consent at any time is allowed without the risk of victimization. You will not incur any cost, as no interventions will be carried out on you (the patient), I will only be observing you before and during the cesarean section. There is no monetary benefit, but your participation will be highly appreciated as it will help in improving the quality of care that the patients receive in the KNH maternity unit during cesarean section.

CONFIDENTIALITY

Your name and any other private information that could be used to identify you will not be included while collecting data for the study. You will be recorded using an allocated serialized number. Other information collected shall not be shared with any other parties.

STUDY PROCEDURE

Once you have consented to be involved in the project, I will assess your (patient's) documents, including doctors' files and nursing notes, while also observing your vital signs and interventions that will be given by the anaesthetic provider. This includes your real time Blood pressure, pulse rate, respiratory rate, oxygen saturation, weight, height, your baby's

weight upon delivery, fluid given, medications given and blood loss. We shall also monitor any complications that may arise like nausea, vomiting among others.

RISKS OF PARTICIPATION

There are no risks to the participants of this study.

BENEFIT OF PARTICIPATION

The benefit of participating will be contributing to data that will ultimately result in improvement of care of patients in our maternity unit who shall be undergoing ceserean sections.

STUDY APPROVAL

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

If further clarifications or queries arise, feel free to contact me on 0727045266 or any of my supervisors:

Dr. Jacqueline Andhonga – 0721810970

Dr. Caroline Mwangi – 0721546600

Kindly sign the consent below if you agree to participate in this study

CONSENT TO PARTICIPATE IN THE STUDY

I ……. HAVE

UNDERSTOOD THE STUDY AS EXPLAINED TO ME BY DR. SUNDAY AWOT, AND I

CONSENT TO PARTICIPATING. IT HAS ALSO BEEN EXPLAINED TO ME THAT WITHDRAWING FROM THE STUDY WILL NOT COMPROMISE THE CARE GIVEN

TO ME.

SIGNATURE OF PARTICIPANT/THUMB

STAMP……..

DATE……

NAME OF PRINCIPAL INVESTIGATOR: DR SUNDAY AWOT LUKE

TELEPHONE NUMBER: 0727045266

EMAIL: sundayawot@students.uonbi.ac.ke

NAME OF PRIMARY SUPERVISOR: DR CAROLINE MWANGI

TELEPHONE NUMBER: 07215466000

EMAIL: carlomwa@yahoo.com

KARATASI YA TAARIFA ZA MSHIRIKI KWA WANGONJWA NA JAMAA WAO

Jina langu ni Dkt Sunday Awot Luke, mwanafunzi wa shahada la uzamili anayefuata kikosi cha Anaesthesiology katika Chuo Kikuu cha Nairobi. Ninafanya utafiti unaolenga kuchunguza ishara za hatari ambazo zinazweza kuongeza asilimia ya mama kupata shinikizo la damu ya chini baada ya kupewa anaesthesia wa mgongo.

USULI

Utafiti huu utalenga vipimo kama umri, uzito wa mgonjwa, urefu, nambari ya mimba, shinikizo la damu, kiwango cha mapigo ya damu, kiwango cha kupumua, kipimo cha kueneza oksijeni, himoglobini na hematokriti. Kisha tutaangalia uhusiano wa hivi vipimo na uwezekano wa kupata shinikizo la damu la chini baada ya kupewa anaesthesia ya mgongo kwa minajili ya kuzalisha mtoto kwa njia ya upasuaji.

KUSUDI LA MAFUNZO

Utafiti huu utatathmini ikiwa kuna uhusiano yoyote na vipimo za mama kabla ya kupata dawa ya uti wa mgongo wa anaesthesia na kutokelezea kwa shinikozo yad amu ya chini wakati wa upasuaji kwa minajili ya kuzalisha mtoto.

USHIRIKI

Ushiriki ni kwa hiari ya mgonjwa. Mgonjwa anaweza kujiuzuli wakati wowote na hata pata madhara yoyote. Hakuna malipo ya kushiriki kwa huu utafiti wala mgonjwa hata lipishwa chochote kwa kushiriki.

USIRI

Jina lako na taarifa nyingine zozote za faragha ambazo zinaweza kutumika kukutambua hazitajumuishwa wakati wa kukusanya data ya utafiti. Utarekodiwa kwa kutumia nambari iliyotengwa. taarifa nyingine zilizokusanywa hazitashirikiwa na wahusika wengine wowote.

UTARATIBU WA UTAFITI

Ukishakubali kuhusika katika mradi huu, nitatathmini hati zako, zikiwemo faili za madaktari na maelezo ya uuguzi, huku nikitazama pia umri, uzito wa mgonjwa, urefu, nambari ya mimba, shinikizo la damu, kiwango cha mapigo ya damu, kiwango cha kupumua, kipimo cha kueneza oksijeni, himoglobini na hematokriti

HATARI ZA KUSHIRIKI

Hakuna hatari kwa washiriki wa utafiti huu.

FAIDA YA KUSHIRIKI

Manufaa ya kushiriki yatakuwa yakichangia data ambayo hatimaye italeta uboreshaji wa huduma ya wagonjwa katika kitengo cha wodi ya uzazi amboa watafanyiwa upasuaji kwa minajili ya kuzalisha mtoto.

IDHINI YA UTAFITI

Utafiti huo utafanywa kwa idhini kutoka kwa Hospitali ya Kitaifa ya Kenyatta na Kamati ya

Maadili ya Chuo Kikuu cha Nairobi

Ikiwa ufafanuzi zaidi au maswali yatatokea, jisikie huru kuwasiliana nami kwa 0727045266

Tafadhali saini kibali hapa chini ikiwa unakubali kushiriki katika utafiti huu

RIDHAA YA KUSHIRIKI KATIKA MASOMO

MIMI

…….

NIMEELEWA UTAFITI HUO JINSI NILIVYOELEZEWA NA DK. SUNDAY AWOT, NAMI NIMEKUBALI KUSHIRIKI. PIA IMEELEZWA KWANGU KUWA KUJIONDOA KWENYE MASOMO HATAKUATHIRI UTUNZI NILIOPEWA MIMI.

SAINI YA MSHIRIKI…….

TAREHE……

JINA LA UPELELEZI MKUU: DR SUNDAY AWOT LUKE

NAMBA YA SIMU: 0727045266

BARUA PEPE: sundayawot@students.uonbi.ac.ke

JINA LA MSIMAMIZI MSINGI: DR CAROLINE MWANGI

NAMBA YA SIMU: 07215466000

BARUA PEPE: carlomwa@yahoo.com

Appendix II. Study Questionnaire

Serial Number: **Patient Initials:**

A. MATERNAL FACTORS

1. Age Level of education. *(Tick one appropriate response)*

☐

YRS a. None b. Primary c. Secondary d. Tertiary 2.

Parity *(tick one appropriate response)*

1	2	3	4+

3.Pregnancy

SINGLETON	TWIN	TRIPLET	> 3

>t

4.Previous Cesarean sections

1	2	3	4	>4

5.Weight 6. Height 7. BMI

☐Kgs ☐cms ☐

8. fasting period

☐ Hours

9.Comorbids

☐ a. b. c.

10. Hemoglobin

☐ g/dl

11. Fetal birth weight

☐

B. VITAL SIGNS

Baseline	INTRAOPERATIVE													
Parameters	**3**	**9**	**12**	**15**	**18**	**21**	**27**	**33**	**36**	**39**	**45**	**48**	**51**	**54**
BP	**SBP**													
Grams														
				DBP										
MAP														
						HR								
SPO2														
						RR								
TEMP														
	SA													
	administration time (Tick Appropriately)													

C.ANESTHETIC FACTORS

Bromage Score	**After urinary catheterization**
	Before skin incision
Sensory Level of blockade using loss of cold sensation to alcohol swab	**Before skin incision**
	After urinary catheterization
Intraoperative volume given	

	Before hypotension	After hypote
RL mls		
NS mls		
COLLOID mls		
BLOOD mls	Total Intraoperative	

blood loss (mls

IV medication given to treat hypotension	Time	Drug	Dosage
Skin Incision time (Tick appropriately)			
Placental extraction time (Tick appropriately)			

D. ADVERSE EFFECTS

	Time
Nausea	
Vomiting	
Dizziness	
Difficulty in breathing	
Maternal complications (PPH, High spinal)	
Apgar score	
Others	

Appendix. III: KNH Protocol for Spinal Anaesthesia Maternity Theatre.

PROTOCOL FOR SPINAL ANAESTHESIA AT THE KENYATTA NATIONAL HOSPITAL

1. Know the indications & contra-indications
2. Inform the patient what you wish to do and have their cooperation
3. Inform the rest of the team in theatre so you can be assisted appropriately
4. Insert a good gauge I/V cannulae (20 or larger)
5. Pre-load with ½-1L N/saline / Hartmans over 30- 60mins
6. Install your monitors (pulse, respiration, SPO2, BP, ECG) and take baseline readings
7. Position the patient either sitting or lateral knee-chest. Make the patient comfortable
8. Open your Spinal Tray & clean the site and drape.
9. Reconfirm the position of the patient (knee chest)

Spinal Tray should contain: -

a) Sterile towels for draping the patient

b) 2 gulley pots for holding cleaning solutions

c) Appropriate spinal needle (with introducer where required)

d) 2 syringes & needles

i. 5ml syringe for infiltration of L.A to the site ii.

2ml syringe for administering the spinal medication iii.

Sterile gauze pads for cleaning & dressing

10. Identify the site: mid-line L3-4/ 4-5 & administer 3ml of 1% lignocaine using a gauze 21 needle to maximum depth. Withdraw the needle as you continue to administer L.A and raise a skin wheal.

11. Give 1-2 minutes for the L.A to take effect as you re-assure & position patient (if administered well, this usually covers one vertebra above & below, should you need to alter position of lumbar puncture)

12. While waiting for L.A to take effect, prepare your appropriate drug. You must have decided whether using plain or heavy L.A

    a) Remember Heavy L.A is position dependent. The patient must be appropriately positioned after injection to allow desired distribution.

    b) Bupivacaine is usually 0.5% concentration. The highest volume in tall patients will be 4 ml (20mg). Most patients will require between 7.5mg (1.5mls) to 15 mg (3ml).

    c) Obstetric patients are more sensitive and will require between 10mg (2ml) to
    12.5mg (2.5ml). Aim for a block up to T6. Test and record level of block.

    d) Additive: 25mg Fentanyl (0.5ml) is a useful additive to prevent the discomfort of gut handling during CS etc. This must still make up the total volume of 2-2.5 ml of drug injected into the spinal canal. Other drugs have been used as additives but its best to avoid them unless you have been trained to use them. The haphazard use of additives into the CSF may have disastrous results.

    e) Remember for CS the volume & position is critical to achieve a good or disastrous spinal block. Aim for a block up to T6.

13. Confirm the L.A has taken effect and note level/site for the block.

Insert the spinal needle. Usually there is a sudden give when the needle goes through the dura. Withdraw the stylet and check for CSF flow. Do not allow unnecessary drainage of CSF. Use the stylet to stop the flow temporarily, if you cannot administer the spinal drug immediately.

14. Administer the drug, dress the puncture site and position the patient appropriately to allow planned distribution of drugs. Rapid positioning after administration is critical if the drug used is hyperbaric (heavy).

15. Start your post-spinal monitoring & make adjustments accordingly. It is recommended to repeat BP readings at 1-minute intervals. You will need to respond rapidly to the initial changes in pulse & BP. Ask the patient to inform you immediately if nausea occurs. Nausea in spinal anaesthesia is most likely due to hypotension. It is an early warning sign that you must not ignore.

16. Test the level of the block. The tilt of the bed may have to be adjusted if using hyperbaric Local Anaesthetic to change drug distribution. This manipulation may only work within the first 10-20 minutes after administration of the L.A into the CSF.

17. Post-operative pain management - I/M Pethidine 1mg/kg 4-6 hourly for 24 hours - Diclofenac suppository (or equivalent) stat & 12 hourly for 48 hours then orals.

- Follow up visit, within 24 hours.

18. Critical observation

a) Pulse –symptomatic bradycardia –Atropine 0.1 -0.6mg

b) SPO2 saturation ≤90% - Increase the O2 flow.

c) BP –symptomatic Hypotension

- Ephedrine -5mg-10mg PRN (you may occasionally need an infusion)
- Phenylephrine
- Adrenaline

d) Respiration –falling respiratory rate (usually temporary)

- Give oxygen
- Assist with respiration briefly if required
- Reassure

e) Total Spinal Anaesthesia

i. Convulsions /loss of consciousness ii. Respiratory failure iii. Cardiovascular collapse

Intubate, ventilate, cardiac massage, vasopressors, anticonvulsants till vital signs stabilize. f) Post spinal headaches

May occur post operatively. Are worse on standing & relieved by lying down.

Management

i. Bed rest ii. Plenty of fluids iii. Non-Steroidal Anti-inflammatory Drugs (NSAIDS) iv. Epidural blood patch as a last resort

19. Post-Operatively –monitor BP ¼hourly for 2hrs.

Positioning –make patient comfortable with pillow under the head.

Prepared by:

Dr. P.O.R. Olang'and Dr. David Otieno, Consultant Anesthesiologist's,

Kenyatta National Hospital, P.O. Box 20723 -00202, NAIROBI.

January, 1999.

Appendix IV: Determination of Level of Blockade

1.Bromage Score

Ideal labor analgesic technique should provide complete pain relief with no motor block. The bromage score recommended to measure motor blockade in both limbs and throughout the perioperative phase as level of blockade may change. Motor blockade shall be tested after urinary catheterization and before skin incision is made.

Modified Bromage score as used by Breen et al[51]

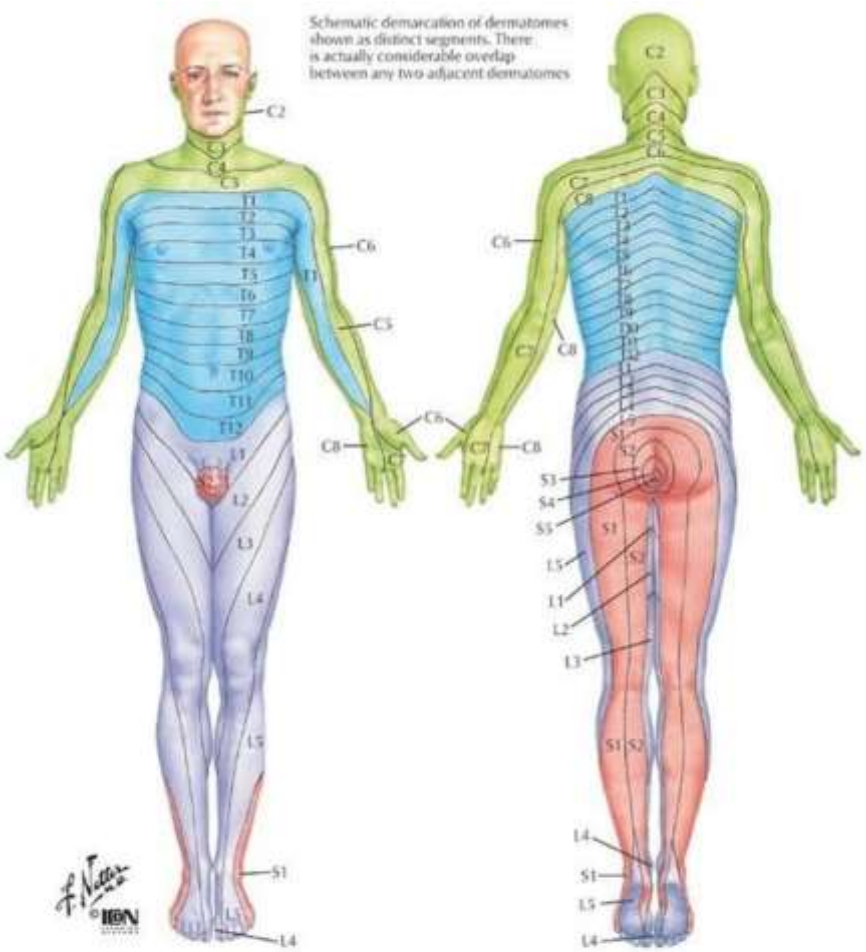
Score	Criteria
1	Complete block (unable to move feet or knees)
2	Almost complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

2. DERMATOME LEVELS

Pictorial representation of dermatome levels[52]

Dermatome levels shall be assessed by loss of cold sensation after urinary catheterization and prior to skin incision.

The schematic representation below shall be availed to the researcher, research assistant and anaesthetic provider.



Levels of principal dermatomes

C5	Clavicles
C5, 6, 7	Lateral parts of upper limbs
C8, T1	Medial sides of upper limbs
C6	Thumb
C6, 7, 8	Hand
C8	Ring and little fingers
T4	Level of nipples
T10	Level of umbilicus
T12	Inguinal or groin regions
L1, 2, 3, 4	Anterior and inner surfaces of lower limbs
L4, 5, S1	Foot
L4	Medial side of great toe
S1, 2, L5	Posterior and outer surfaces of lower limbs
S1	Lateral margin of foot and little toe
S2, 3, 4	Perineum