ASSOCIATION BETWEEN PREOPERATIVE ANXIETY AND HYPOTENSION DURING SPINAL ANAESTHESIA IN WOMEN UNDERGOING ELECTIVE CAESAREAN DELIVERY

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DECLARATION

Principal investigator:

I declare that this proposal is my 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 beloved wife and daughter for the constant support and prayers

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My parents, wife and daughter for their love, support and wise counsel.

Above all, the Almighty God, for giving me strength and perseverance.

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LIST OF ABBREVIATIONS

ASA – American Society of Anaesthesiologists

B.P – Blood Pressure

C.O – Cardiac Output

C-Section – Caesarean section

E.C.G - Electrocardiograph

G.A - General Anaesthesia

HSCIC - Health and Social Care Information Centre

I.V – Intravenous

KNH – Kenyatta National Hospital

KSA – Kenya Society of Anaesthesiologists

L.A – Local Anaesthesia

NHS- National Health Service

R.A - Regional Anaesthesia

S.H.O – Senior House Officer

WHO - World Health Organization

U.K –United Kingdom

OPERATIONAL DEFINITIONS

Caesarean section refers to a surgical procedure used to deliver a baby through an incision in the mother's abdomen and a second incision in the mother's uterus under anaesthesia

Spinal anaesthesia refers to a spinal block or subarachnoid block (SAB); a form of regional anaesthesia involving injection of a local anaesthetic into the subarachnoid space, generally through a fine needle.

Post-regional anaesthesia hypotension is defined as a 10% to 30% fall from baseline levels or fall of systolic blood pressure below 100 mmHg.

Preoperative anxiety is described as an unpleasant state of uneasiness or tension, which may be associated with abnormal hemodynamics as a consequence of sympathetic, parasympathetic, and endocrine stimulation.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Background

Spinal anaesthesia is the most popular form of regional anaesthesia used for Caesarean delivery in the world today; approximately 78% of women having a Caesarean section will receive regional anaesthesia (spinal or epidural). Hypotension is the most common complication associated with spinal anaesthesia, occurring in up to 64% of cases[1]. Hypotension after spinal anaesthesia depends on many factors, including dose of local anaesthetic, patient positioning, height of patient, fluid preloading and co-loading. Neonates born by Caesarean delivery under spinal anaesthesia are more acidaemic compared with those delivered under either epidural or general anaesthesia[2-4].

The principal mechanism by which spinal anaesthesia causes maternal hypotension is the blockade of sympathetic efferent neurons. Anxiety is known to cause generalized sympathetic activation prior to elective surgery in most patients. Patients with higher baseline sympathetic activation have been shown to have more marked hypotension after spinal anaesthesia[5].

Together, these findings provided a rational basis for the hypothesis that patients with higher preoperative anxiety would experience more marked hypotension after the induction of spinal anaesthesia. No studies have been done to assess preoperative anxiety on the development of hypotension after neuraxial anaesthesia at The Kenyatta National Hospital.

Objective

This study aimed to determine the association between preoperative anxiety and arterial blood pressure changes during spinal anaesthesia for elective Caesarean delivery at the Kenyatta National Hospital.

Research Methodology

This was a prospective observational study to assess the effect of preoperative anxiety on arterial blood pressure changes during spinal anaesthesia for caesarean delivery at the Kenyatta National Hospital maternity theatres.

Study population

The study population was all patients scheduled for elective caesarean delivery at The Kenyatta National labour ward.

Sample size

The sample size was determined by the Cochran (1963:75) formula to yield a representative sample of 100.08

Results

This study showed that the incidence of hypotension in elective caesarean section was much lower than in previous studies. Hypotension occurred in only 26(23.2%) of the respondents. In this study patients were subjected to an S-Anxiety scale a day before surgery to evaluate how the respondents felt at that moment, majority 69(61.6%) of the patients were severely anxious. However according to VAS score on the day of surgery majority 66(58.9%) of the patients were moderately anxious and only 4(3.6%) were severely anxious. This comparison was attributed to high numbers of postponement or cancellation of elective caesarean sections due to overwhelming emergencies in maternity theatres, patients remained anxious in the ward, starved and awaiting indefinitely for surgery and were relieved of anxiety when taken to theatre. This study showed that majority of the patients were contented with capabilities of the facility and minorityof the patients were actually unaware of the mode of anaesthesia to be administered. The results of this study showed that 28(25.26%) of the respondents were aged between 32 and 34 years, and 43(38.4%) of the respondents had a parity of 1 + 0. The most common indication of caesarean section was one previous scar 55(49.1%). Majority (72.7%) of the patients who had hypotension were severely anxious. Majority (57.7%) of the patients who did not have hypotension were severely anxious. Likelihood Ratio Chi-square test (p-value = .302) indicated that there was insignificant association between anxiety levels and presence of hypotension

The study supports the null hypothesis that the level of preoperative anxiety is not associated with the occurrence of hypotension during spinal anaesthesia for caesarean delivery and more than one factor are infact attributed to occurrence of hypotension.

INTRODUCTION

Spinal anaesthesia is the most popular form of regional anaesthesia used for Caesarean delivery in the world today; approximately 78% of women having a Caesarean section will receive regional anaesthesia (spinal or epidural). Hypotension is the most common complication associated with spinal anaesthesia, occurring in up to 64% of cases[1].Hypotension after spinal anaesthesia depends on many factors, including dose of local anaesthetic, patient positioning, height of patient, fluid preloading and co-loading. Neonates born by Caesarean delivery under spinal anaesthesia are more acidaemic compared with those delivered under either epidural or general anaesthesia[2-4].

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Together, these findings provide a rational basis for the hypothesis that patients with higher preoperative anxiety would experience more marked hypotension after the induction of spinal anaesthesia. No studies have been done to assess preoperative anxiety on the development of hypotension after neuraxial anaesthesia at The Kenyatta National Hospital.

LITERATURE REVIEW

Caesarean section deliveries are at an all-time high in the world today. Approximately 18.5 million caesarean sections are performed yearly worldwide[6] and are expected to keep rising. A government-funded research may help explain the national trend in Kenya today. At The Kenyatta National Hospital, thecaesarean section rate has steadily increased from an average of 18% from 1977 to 1983 to an average of about 20% from 1984 to 1989 and currently stands at approximately 29%[7]. The trend roughly corresponds to those seen in other countries throughout the world.

In Europe, nearly one in three babies are now delivered surgically - up from one in five just over a decade ago[8]. The latest maternity figures show that 25 per cent of mothers in England had a caesarean - a slight increase from the previous year, according to data from the Health and Social Care Information Centre (HSCIC)[9]

Table 1*:* Hospital deliveries by age and number of caesareans in the U.K, 2006 -2012

Age of Delivery (Years)	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
Under 19	43,063	42,671	42,084	40,010	37,112	33,621
20-24	121,300	124,789	126,328	125,924	126,922	123,213
25-29	163,333	172,650	178,333	179,522	183,912	185,549
30-34	175,660	176,789	175,436	176,780	187,284	190.910
35-39	102,335	105,918	103,770	103,635	105,289	102,950
40-44	21,202	22,045	22,651	22,970	23,740	24,285
45-49	977	1,043	1,157	1,231	1,314	1,348
Total no. of caesareans	**145,051**	**153,406**	**154,814**	**157,356**	**163,512**	**163,859**
Total no. of deliveries	**629,207**	**649,837**	**652,638**	**652,377**	**668,195**	**668,936**
% of caesarean sections	**23.05%**	**23.61%**	**23.72%**	**24.12%**	**24.47%**	**24.50%**

Source: NHS Maternity Statistics 2006-2012

It was noted in the data analysis in the year 2011-2012 in NHS hospitals in the United Kingdom that older mothers were more inclined to have an elective C section - with 18 per cent over the age of 35 years opting not to give birth naturally. One in 10 mothers aged 25 to 34 years had the elective surgery with just five per cent of those under 25 years giving birth by caesarean section, according to the hospital data from 2011 and 2012[9]. Previously recognized contributors to the rise include delayed child bearing, the rising obesity rate among moms-to-be, and an increase in multiple birth deliveries. The new analysis also found that longer labor times and an increase in induced labors are also factors.

Researchers from the National Institute of Child Health and Human Development analyzed data from more than 228,000 deliveries at 19 hospitals across the U.S. from 2002 to 2008.Among their findings[10]:

1. One in three first-time moms delivered by C-section.
2. Previous surgical birth was the most common reason for C-sections, accounting for almost a third of all cesarean deliveries.
3. The C-section rate among older moms was double that of younger ones.
4. 44% of women who attempted vaginal delivery had labor induced, and the C-section delivery rate was almost twice as high in these women as in women whose labors were spontaneous (21% vs. 12%).

In the contemporary study of caesarean delivery practice in the United States, half of all C-section deliveries to women whose labors were induced were performed before cervical dilation had progressed to 6 centimetres in diameter. The study suggests that "clinical impatience" may have played a role[8]. Only about a third of women who had a previous caesarean delivery attempted vaginal delivery, known as vaginal birth after caesarean (VBAC). Their success rate was just under 60%, meaning that roughly one in five women who had had a previous surgical delivery achieved a vaginal birth[10].

Hypotension

Hypotension during caesarean section under spinal anaesthesia remains a frequent occurrence. In obstetrics, incidence rates of up to 80% have been observed[11-15]. Post-regional anaesthesia hypotension is defined as a 10% to 30% fall from baseline levels or fall of systolic blood pressure below 100 mmHg.

Spinal anaesthesia-induced hypotension is caused by an increase in venous capacitance because of pharmacologic sympathectomy causing venodilatation in the lower part of the body. The situation is further compounded in pregnancy by aortocaval compression. Hypotension caused by a reduction in systemic vascular resistance is physiologically compensated by an increase in cardiac output (C.O). However, a high level of spinal block can inhibit the cardio accelerator fibres leading to a fall in the heart rate, and hence the C.O thus, instead of a compensatory increase, C.O usually decreases. The combined effect of reduced C.O and decreased systemic vascular resistance accounts for the high incidence of hypotension after spinal anaesthesia in parturients.

Since, there is no auto-regulation of the placental bed blood flow, uterine blood flow is pressure dependent. As a consequence, prolonged maternal hypotension is detrimental to the foetus and is also frequently associated with maternal nausea and vomiting. Brief episodes of maternal hypotension can lower foetal Apgar scores; prolong foetal acidosis, and the time to sustained respiration.

Hypotension and nausea after conduction of spinal anaesthesia are the most common side effects. In the expectant mother, this may lead to myocardial ischaemia, dysrrythmias and maternal collapse. Ventilatory impairment may also occur in hypotension due to impaired medullary blood flow and hypoxia of the respiratory centre[16].

Various methods have been studied to prevent hypotension in women undergoing caesarean section. These include application of left lateral uterine displacement accomplished by placing a wedge of 12 cm height beneath the right buttock. Although widely used, this procedure is variably applied, and does not reliably prevent hypotension as optimal degree of tilt is unknown and is often overestimated[17]

Other forms of prevention of hypotension include fluid therapy, leg wrapping and intravenous vasopressors.[18 19.] Several previous studies have shown that leg wrapping is moderately effective in preventing hypotension, but this technique does not appear to have found wide acceptance in clinical practice.

It would be important to note that from previous studies despite these measures hypotension still remains a widespread problem in spinal anaesthesia for cesarean section delivery.

Management of spinal anaesthesia-induced hypotension for caesarean delivery

Non-pharmacological prophylaxis of hypotension is popular, but the clinical efficacy and practicality of procedures such as leg wrapping is questionable. Crystalloid pre-hydration is a common practice despite its lack of efficacy[20]. Recent research has addressed the controversy

about the choice and use of vasopressors[21]. Although use of ephedrine is supported by history, it has limited efficacy and there are concerns about its propensity to cause foetal acidosis[22 23].
Evidence from recent clinical trials suggests that concerns about uteroplacental vasoconstriction caused by phenylephrine are unfounded[24]. Aggressive use of phenylephrine to maintain maternal BP near to baseline values reduces maternal symptoms without causing foetal acidosis.
Prophylactic use of vasoconstrictors in preventing spinal hypotension has remained highly debatable, although some studies have proven that it can actually decrease the incidence of hypotension by up to 50% [25 26 27]

A European survey in 2010 among anaesthesiologists in Europe on "management of spinal anaesthesia-induced hypotension for caesarean delivery" noted that ephedrine was still routinely used by more than 70% of survey responders practicing primarily in Europe, for the treatment of hypotension associated with spinal anaesthesia in women undergoing caesarean delivery. However, more than 40% also use phenylephrine. One quarter of responders used either ephedrine or phenylephrine, depending on heart rate and / or blood pressure. Recent literature supports the use of phenylephrine as the first-line drug to treat most patients with hypotension. Nevertheless, many clinicians appear to continue to use ephedrine routinely[28].

Anxiety before elective surgery

Most patients awaiting elective surgery experience anxiety[37-40]. Anxiety is described as an unpleasant state of uneasiness or tension, which may be associated with abnormal hemodynamics as a consequence of sympathetic, parasympathetic, and endocrine stimulation[29]. Patients may perceive the day of surgery as the biggest and most threatening day in their lives. The degree to which each patient manifests anxiety related to future experiences depends on many factors. These include age, gender, level of education, previous experience of surgery and type and extent of the proposed surgery[29].

In a pilot study by *L Ebirim, M Tobin on "Factors Responsible for Pre-Operative Anxiety in Elective Surgical Patients", t*he most common reason for anxiety among studied subjects was the possibility of surgery being postponed (69.6%), followed by the fear that mistakes may be made during the surgical operation resulting in harm to the patient (64%). Fear of not receiving enough attention from care givers (63.2%), was the third most common reason for worry amongst the respondents. Fear of ''not waking up' after surgery (58.4%) was the fourth on the list of most common anxieties in the surgical population. The respondents were least worried about having

post-operative nausea and vomiting (8%). About 9.6% of the respondents indicated that they were not worried about any of the items listed on the questionnaire. Thus 90.4% of the respondents were anxious about one or more of the items listed[29]

In a study in 2007 by *Jawaid et al* to ascertain the preoperative anxiety level and different factors responsible in patients admitted for an elective surgical procedure in a tertiary care public hospital, 56% of patients said that their anxiety would be lessened if the procedure was explained to them in detail. Only 32.1% of the patients knew all the details of surgery preoperatively. In the United Kingdom in1983,a study by *Bunker et al* revealed that 82% of patients who underwent surgery had expressed their desire to know more about the procedure prior to surgery[30].

L. Ebirim recommended that to reduce anxiety, adequate explanation of peri-operative events should be given to the surgical patients during the pre-operative visit to enable them know what to expect and understand what the doctors are trying to do. Further studies on the subject with a larger sample size, employing Spielberger's state trait anxiety inventory in addition to VAS were needed to clarify the relationship between preoperative anxiety and gender, age and educational levels among the surgical population.

It was noted by Jawaid et al that Pre-anaesthetic assessment before surgery reduces pre-operative anxiety. They recommended that the establishment of preoperative counselling clinics and proper informed consent taken before surgery would help in reducing preoperative anxiety and improving the quality of care.

Anxiety and Hypotension

S. Orbach-Zinger et al did a study in 2012 on the influence of preoperative anxiety on hypotension after spinal anaesthesia in women undergoing caesarean delivery. 100 healthy term parturients undergoing elective caesarean delivery under spinal anaesthesia were enrolled. Direct psychological assessment tools of preoperative anxiety were verbal analogue scale (VAS) (0–10) anxiety score and State-Trait Anxiety Inventory questionnaire (STAI-s). Salivary amylase was measured as an indirect physical assessment of anxiety.

Direct and indirect anxiety data were transformed into ordinal groups of low, medium, and high anxiety (VAS: low 0–3, medium 4–6, high 7–10; STAI-s: low ,40, medium 40–55, high .55;log10 salivary amylase: low ,3, medium 3–4, high .4). Spinal anaesthesia was performed using

hyperbaric bupivacaine 10 mg and fentanyl 20 µg. All patients received i.v. crystalloid 500 ml pre-hydration and 500 ml co-hydration. Hypotension was treated by a standardized protocol.

Results of the study showed that Ninety-three patients were included in analysis. There was a significant effect of direct psychological measures on anxiety. There was a significant difference between low and high anxiety groups but not between other anxiety groups. Salivary amylase levels were insignificant in predicting hypotension. The results suggested that a simple subjective preoperative anxiety score may predict hypotension after spinal anaesthesia. It is speculated that this is associated with an anxiety-mediated increase in baseline sympathetic activation[31]

The risk factors for hypotension include preoperative hypertension, older age, type of spinal anaesthesia and higher infant birth weight[32]. In prospective studies of hypotension after spinal anaesthesia for caesarean section incidences of hypotension of up to 65.1% have been reported. Age > 35 years and BMI > 35 were two non-modifiable risk factors that increased the incidence[33] [34].

Study Justification

Previous studies have shown high prevalence of anxiety among patients before surgery yet few studies exist to show its effects (if any) on the outcome of anaesthesia/ surgery[37-38]

Anxiety isknown to cause generalized sympathetic activation. The principal mechanism by which spinal anaesthesia causes maternal hypotension is the blockade of sympathetic efferent neurons. Patients with high baseline sympathetic activation tend to have more marked hypotension after spinal anaesthesia. Therefore, patients with higher sympathetic activation due to preoperative anxiety should experience more marked hypotension after induction of spinal anaesthesia[35 -36]

In obstetrics, incidence of hypotension after induction of spinal anaesthesia been observed to be as high as 80%[11-15] .Several non-pharmacological and pharmacological interventions have been studied and recommended to prevent and treat hypotension during spinal anaesthesia. Very few have shown that anxiety alleviation methods can actually decrease the incidence of hypotension after spinal anaesthesia.

No study similar to this has been undertaken before at The Kenyatta National Hospital

The findings of this study will be used to formulate policies for improvement of maternal health care in obstetrics, thus reducing maternal morbidity and mortality.

Broad Objective

- To determine the association between the level of pre-operative anxiety and intra-operative hypotension in patients undergoing elective caesarean section under spinal anaesthesia at The Kenyatta National Hospital.

Specific Objectives

- To determine the incidence of hypotension during elective cesarean deliveries under spinal anaesthesia.
- To determine the level of preoperative anxiety in patients undergoing elective caesarean sections under spinal anaesthesia.

Hypothesis

The level of preoperative anxiety is not associated with the occurrence of hypotension during spinal anaesthesia for caesarean delivery.

RESEARCH METHODOLOGY

Study Design

This was a prospective observational cross-sectional study. Consenting parturients undergoing elective caesarean section under spinal anaesthesia were included, anxiety levels using direct psychological assessment tools and State-Trait Anxiety Inventory questionnaire were captured. Patients were closely observed for development of hypotension during spinalanaesthesia.

Study site

The study site wasthe Maternity Theatre of Kenyatta National Hospital (KNH) in Nairobi County, Kenya. Kenyatta National Hospital is the oldest hospital in Kenya founded in 1901. It is currently the largest teaching andreferral hospital in the country and has a bed capacity of 1800 and over 6000 staff members.

Study procedure

This study utilized the purposive sampling of parturients referred for spinal anaesthesia in the labour ward theatres of Kenyatta National Hospital. All consenting parturients who met the inclusion criteria were recruited to participate in the study upon enrolment for spinal anaesthesia. They were allowed time to read and understand the consent form and seek clarification aboutthe study beforegiving consent.

The patients were then givenself-administered questionnaires the day before the caesarean section to describe their feelings. On the morning of surgery; the observation checklist was completed appropriately by the anaesthetist upon examination both pre-operatively and intra-operatively.

Direct psychological assessments of preoperative anxiety using a verbal analogue scale (VAS) and State-Trait Anxiety Inventory questionnaire (STAI-s) were recorded. Direct and indirect anxiety data transformed into ordinal groups of low, medium, and high anxiety (1-5 =Not anxious, 6-10=Mild anxiety, 11-20 = Moderate anxiety, 21-30 =Severe anxiety, 31-40= Very severe; STAI-s: Low, 0-10, medium 11–20, moderate .21-30, severe 31-40)

Spinal anaesthesia was performed as per the KNH protocol (hyperbaric bupivacaine 7.5mg and fentanyl25 mcg). All patients receivedintravenous crystalloid (Normal saline or Hartmann’s solution) 500 ml pre-hydration over 10-20 minutes and 500 ml co-hydration.

Blood Pressure was measured non- invasively by the *Philips intellivue MP-40* monitor with the appropriate size BP cuff. Hypotension was defined as a 10% to 30% fall from baseline levels or fall of systolic blood pressure below 100 mmHg; this was treated as per the KNH standardized protocol (fluid bolus and ephedrine).

Systolic arterial pressure (SAP) was measured at baseline and every minute after induction of spinal anaesthesia for the first 15 minutes then every 5 minutes till the end of surgery.

Data was recorded as per the anaesthetist's assessment tool and State-Trait Anxiety Inventory questionnaire (STAI-s). Vital signs were captured as per the anaesthesia record chart.

Study population

The study population was all patients scheduled for elective caesarean delivery at The Kenyatta National labour ward.

Criteria for selection and enrolment of patients

Inclusion criteria;

All consenting parturients admitted at the KNH for elective caesarean section under spinal anaesthesia.

Exclusion criteria;

- Active labour
- Preexisting hypertension/hypotension
- Pregnancy induced hypertension
- Pre-eclampsia
- Cardiac disease
- Other active medical or psychiatric disorders requiring regular medication
- Any contraindication to spinal anaesthesia
- Refusal by patient to give consent for the study

Sampling procedure

Consecutive sampling of patients admitted at the KNH Maternity or Labour ward who fulfilled the inclusion criteria was undertaken until the desired sample size was obtained.

Sample Size Determination

The study sample was determined based on the concept of sample size for a prevalence survey with finite population correction because the target population was less than tenthousand. The sample size was determined based on two assumptions. The first assumption wasthe margin of error of 5% to improve the reliability and validity of the results. The second assumption was related to the proportion of the patients with desired characteristics which was unknown and in such a case 50% was proposed to ensure maximum sample size.

Sample size calculation

The sample size was determined by the Cochran (1963:75) formula to yield a representative sample for proportions considering the assumptions mentioned above.

$$n_0 = \frac{Z^2 pq}{e^2}$$

Where

n_0 Is the sample size

$Z^2$is the abscissa of the normal curve that cuts off area desired at 95% confidence level (The value for Z is found in statistical tables which contain the area under the normal curve)

p= estimated proportion of population with desired characteristic (which is unknown, therefore, 50%)

q is 1-p

eis the desired level of precision (5%)

Required sample

$$n_0 = \frac{(1.96^2)(.5)(.5)}{.05^2} = 384.16$$

=384

Since the number of elements that fit the inclusion criteria was less than 10000, we applied the finite population correction for proportions.

$$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$$

$$n = \frac{384}{1 + \frac{(384-1)}{135}}$$

n =100.08

$$n \simeq 100$$

Thus a sample of 110 patients was taken to increase the representativeness of the sample, minimize sampling errors and increase generalisability of the results and cater for attrition (10%).

Study protocol and data collection

All patients admitted to KNH Labour ward who fulfilled the inclusion criteria were studied using a data collection tool that determined the various variables. The information was obtained from the data recorded from the file and questions posed to the participants

Data collection instruments

Data was collected using self-administered structured questionnaires and Clinician assessment checklist. The questionnaire contained the S-Anxiety scale of ten statements that evaluated how respondents felt "right now, at that moment". Clinician assessment contained information on patient's socio-demographic profile and vital signs observation checklist.

Data Collection Procedure

All consenting patients for elective caesarean section who met the inclusion criteria were identified and allowed time to read and understand the consent form and seek clarification over the study then give the consent to participate.

Direct psychological assessments of preoperative anxiety using a verbal analogue scale (VAS) and State-Trait Anxiety Inventory questionnaire (STAI-s) were recorded. Direct and indirect anxiety data weretransformed into ordinal groups.

Spinal anaesthesia was performed as per The Kenyatta National Hospital protocol. Systolic arterial pressure (SAP) was measured at baseline and every minute after induction of spinal anaesthesia. The effect of low, medium, and high anxiety groups on the maximum percentage change in Systolic arterial pressure wasdetermined.

Pre-testing study tool

Pre-testing of study instrument was carried out to structure and modify the research instrument by clarifying grammar and language used so as to avoid bias and misinterpretation of the questions. The questionnaire waspre-tested for consistency, timing, accuracy and reliability. The pre-testing was conducted in a different hospital. The questions were then be modified and rectified to remove those that were not relevant to the study or with ambiguous meanings.

Data management

At the end of each interview and observation the duly filled research questionnaires were cross checked for completeness and any missing entries corrected. The quantitative data collected was coded, processed and cleaned. The qualitative data wasanalyzed through the selection of concepts, categories and themes. It involved reading through the data and developing codes that draw similar connections between categories and themes. Data wasanalyzed by the use of SPSS (Statistical Package for the Social Sciences) version 20 as per the specific research questions using frequencies and percentages. Strength of significant associations with risk ratiosand relationship between the independent and dependent variables was established using Chi-square test of association and Logistic regression models since the responses were categorical. Findings were presented in the form of text, charts, graphs and tables.

Logistical considerations

The research was approved by the KNH/UON Ethics & Research Committee. Respondents were required to give consent to participate. They were informed that it was voluntary and they had the right to accept, withdraw or refuse to participate at any time without any penalties. The researcher gave full information about what the research entailed and ensured all participants were competent to give consent. Full consent and explanation arein Appendix I. The research tools were administered by duly obtaining the consent of the participant. Participants' privacy was highly maintained by ensuring that they werenot exposed to the public when filling the questionnaire. The researcher ensured the anonymity of respondents by concealing their identity and keeping the research data confidential for research purposes only. All concerns causing any sort of discomfort to respondents were resolved immediately and mitigation strategies put in place.

Ethical considerations

No names of patients were used in this study. Privacy and confidentiality were guaranteed to all participants. The study had no harmful effects on subjects whatsoever. No extra costs were incurred by study subjects. Those who declined inclusion in the study and/or left the study at any point were neither victimized nor their clinical care compromised. Permission to conduct the study was approved by the Kenyatta National Hospital/University of Nairobi – Ethics & Research Committee prior to commencement. Study findings will be availed to the University of Nairobi, Kenyatta National Hospital administration and the Kenya Society of Anaesthesiologists' to facilitate appropriate policy formulation aimed at improving patient care.

RESULTS

The study was conducted between 1st January 2015 and 31st March 2015. One hundred and seventy eight patients were approached for recruitment into the study. Fifty nine patients ended up as emergencies were automatically excluded, four patients declined consent to be enrolled in the study. Three patients, who did not meet the inclusion criteria (two werehypertensive, onecardiac disease in pregnancy), were not enrolled into the study. One hundred and twelve patients who fulfilled the inclusion criteria were recruited into the study. There was a response rate of 100%.

Baseline Characteristics of the participants

The mean age of the respondents was 31.32(±0.97) years within the range of 22 to 44 years. Majority (25.26%) of the respondents were aged between 32 and 34 years as shown in figure 1. Majority 43(38.4%) of the respondents also had a parity of 1 + 0 shown in table 2

Figure 1: Distribution of Respondents' Ages in Years

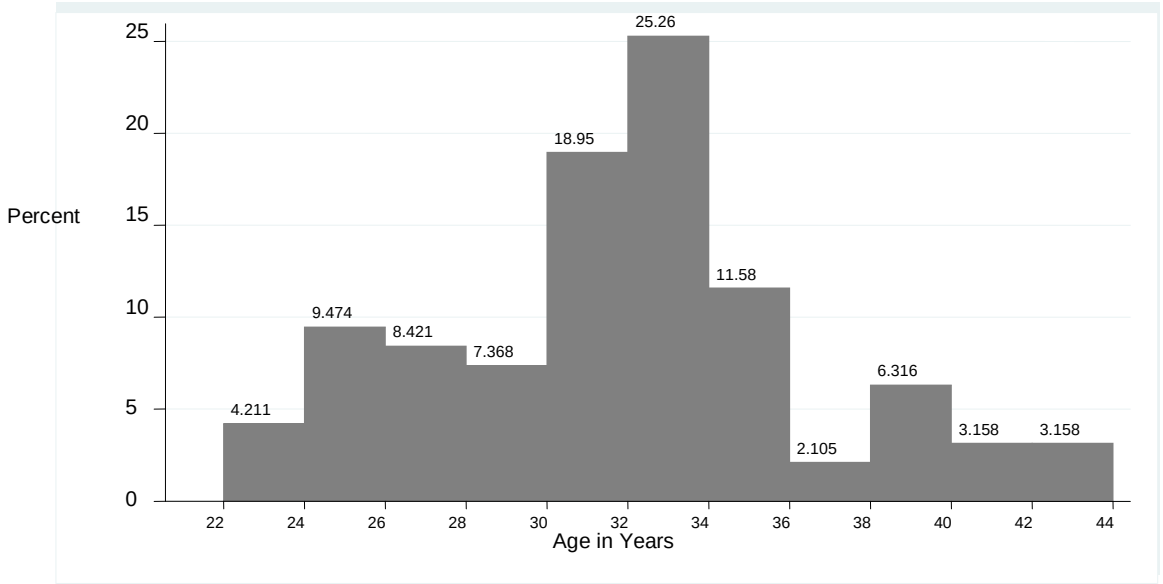


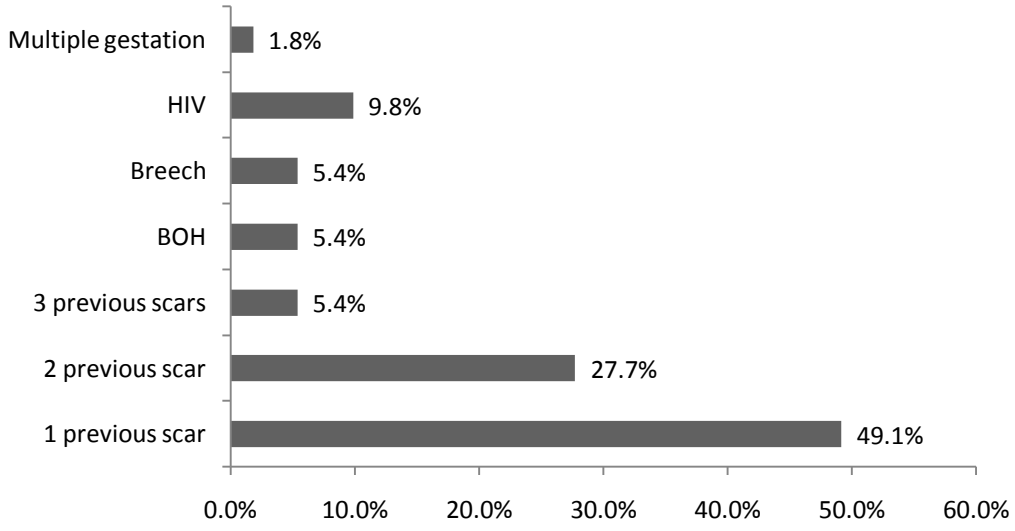
Table 2: Respondents' Parity

Parity	Frequency	Percent
0 + 0	5	4.5%
1 + 0	43	38.4%
0 + 1	2	1.8%
2 + 0	26	23.2%
3 + 0	11	9.8%
4 + 0	2	1.8%
0 + 4	1	0.9%
0 + 3	6	5.4%
0 + 2	1	0.9%
1 + 1	12	10.7%
1 + 2	1	0.9%
3 + 1	2	1.8%

Indication for elective caesarean section

The most common indication of caesarean section was one previous scar in mothers who were not keen on vaginal delivery after caesarean section (49.1%). Other indications included two previous scars (27.7%), three previous scars (5.4%), BOH (5.4%), breech (5.4%), HIV (9.8%) and multiple gestation (1.8%) shown in figure 2

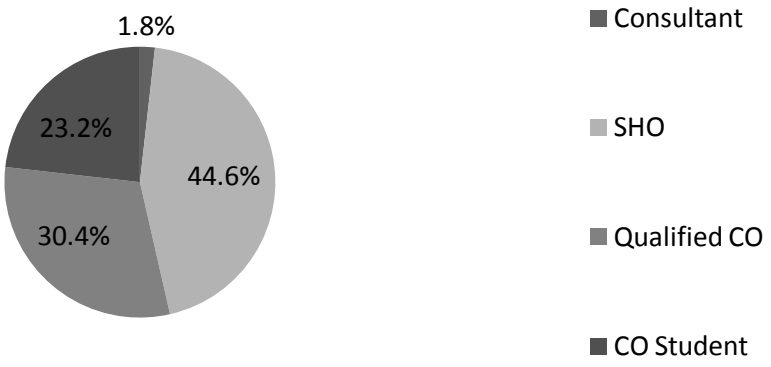
Figure 2: Indication for Caesarean Section



Cadre of Anaesthetist administering spinal anaesthesia

Spinal anaesthesia was mostly administered by Senior House Officers (SHO) 50(44.6%). Others who administered spinal anaesthesia were qualified Clinical officers (CO) 34(30.4%), higher diploma student clinical officers 26(23.2%) and consultant anaesthetists 2(1.8%) as shown in figure 3

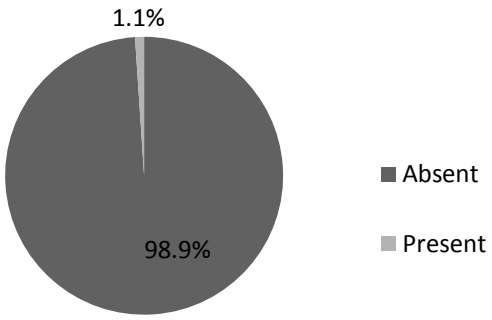
Figure 3: Anaesthetist Cadre administering spinal anaesthesia



Presence of co-morbidities in elective caesarean sections

Only 1(1.1%) of the respondents had other co-morbidities. This respondent was suffering from diabetes shown in figure 4.

Figure 4: Presence of Co morbidities in elective caesarean sections



Blood pressure changes after administration of spinal anaesthesia

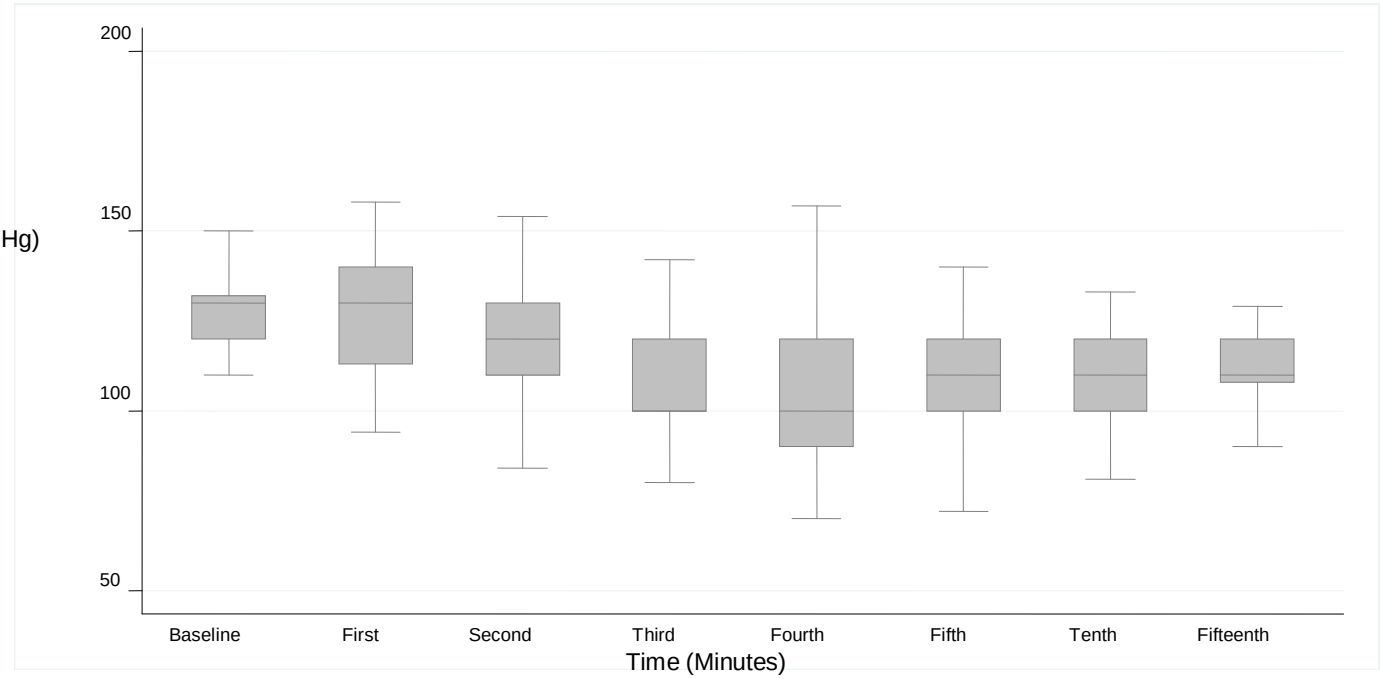
The mean systolic blood pressure decreasedfrom a high of 129.03mmHg at baseline to a low mean of 104.98mmHg in the 4thminute, thereafter it rose during the 5th, 10th and 15th minutes. There weresignificant differences in systolic blood pressures during the times indicated(Kruskalwallis test p-value < .001) as shown in table 3 and figure 5.

Table 3: Systolic Blood Pressure by Time

	Systolic blood pressure (mmHg)		
Time	N	Mean	Std. Deviation
Baseline	112	129.03	15.186
1st minute	112	126.61	14.772
2nd minute	111	122.50	25.287
3rd minute	111	111.04	17.681
4th minute	110	104.98	19.059
5th minute	90	109.30	19.320
10th minute	45	113.13	17.261
15th minute	32	116.22	16.750

Figure 5: Systolic Blood Pressure by Time

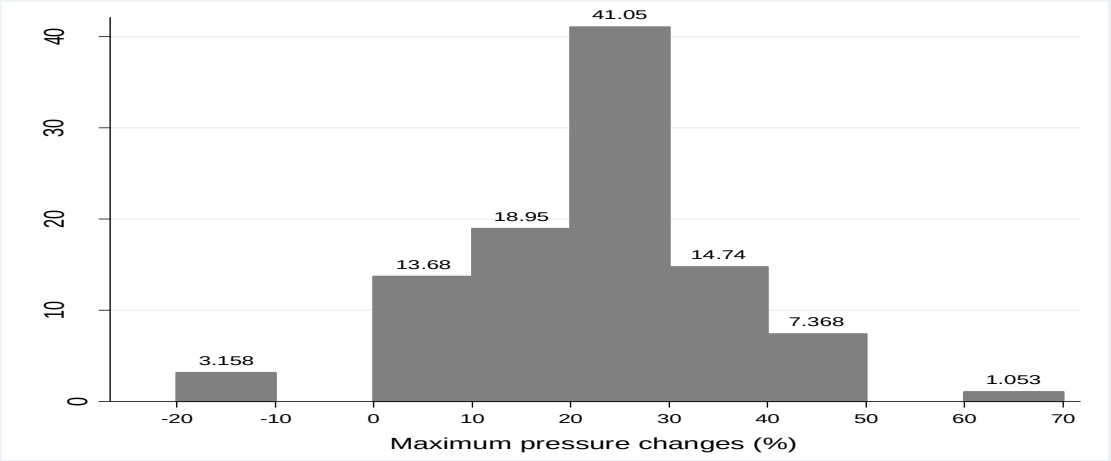
Change in mean systolic blood pressure over time after induction of spinal anaesthesia



Maximum Systolic Blood Pressure Changes

To assess systolic blood pressure changes baseline pressure was compared with consecutive pressure measurements and the change expressed as percentage of the baseline. Maximum pressure percentage changes were then obtained. Majority (41.05%) of the respondents had pressure change of between 20% and 30%. The maximum percentage pressure changes ranged from -20% to 70% as shown in figure 6

Figure 6: Maximum Systolic Blood Pressure Changes

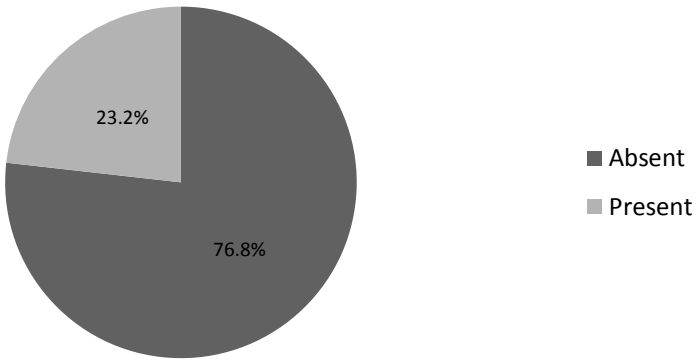


Prevalence of hypotension

To assess prevalence of hypotension maximum pressure changes was taken into account such that if a patient's maximum pressure change was 30% and more (i.e. if pressure dropped from the baseline by 30% or more) she was considered to have hypotension.

Hypotension occurred to a minority 26(23.2%) of the respondents. The proportion of respondents who suffered from hypotension were significantly lower than the proportion of respondents who did not suffer from hypotension (One Sample Chi-Square test p-value <.001) as shown in figure 7

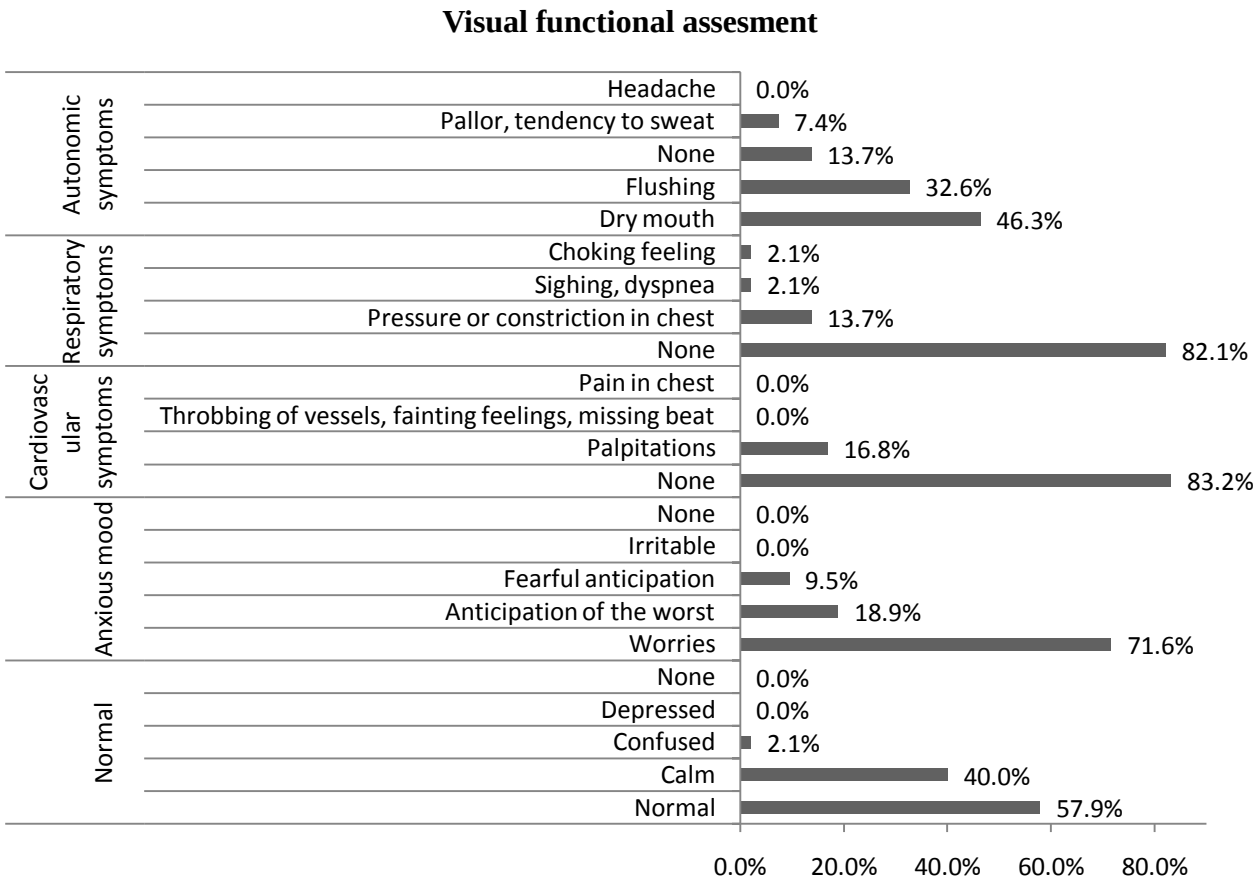
Figure 7: Hypotension Occurrence



Visual functional and mental status assessment

Majority of the patients had dry mouth (46.3%), no respiratory symptoms (82.1%), no cardiovascular symptoms (83.2%), were worried (71.6%) and normal (57.9%) as shown in figure 8

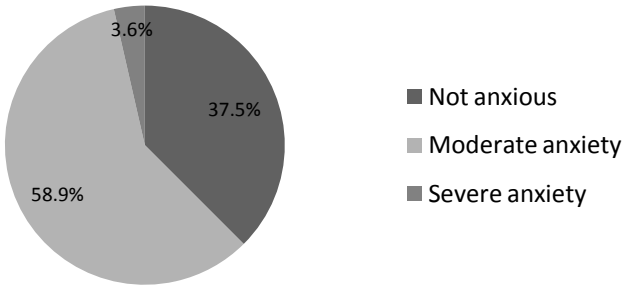
Figure 8: Visual Functional Assessment Parameters



Assessment of presence of anxiety using VAS scores

To assess presence of anxiety using VAS scores the total VAS scores of patients were grouped as 1-5 not anxious, 6-10 moderately anxious and 10-20 severely anxious. According to VAS score majority 66(58.9%) of the patients were moderately anxious; 42(37.5%) were not anxious while 4(3.6%) were severely anxious. One sample Chi-square test (p-value <.001) indicate that anxiety levels differed significantly between respondents as shown in figure 9

Figure 9: Anxiety levels according to VAS score



The S-Anxiety scale

Using the S-Anxiety scale being;"contented with the facility being equipped to give best possible care" and "being confident of coming out of the surgery safely" had the highest mean of 3.48 while "being aware of the type of anaesthesia to be administered" had the lowest mean score of 2.22. as shown in table 4.

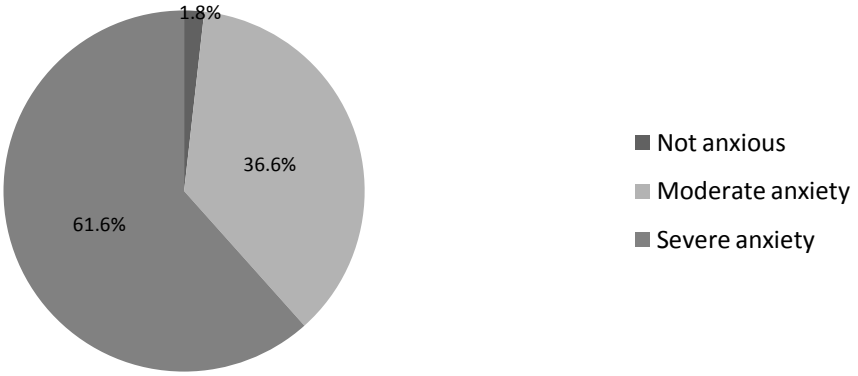
Table 4: S-Anxiety Scale Parameters

Statement	N	Minimum	Maximum	Mean	Std. Deviation
I am happy	112	1	4	3.32	.796
I am not feeling nervous anxious or on edge	112	1	4	3.08	.769
I feel secure	112	2	4	3.30	.704
I am aware of the type of surgery l am to undergo	112	2	4	3.44	.650
I trust in the surgeon's capabilities	112	1	4	3.46	.700
I am aware of the type of anaesthesia to be administered	112	1	4	2.22	1.121
I trust in the anaesthetist's capabilities	112	1	4	3.38	.765
I am contented the facility is equipped to give me the best possible care	112	2	4	3.48	.653
I am not worried there will be complications in surgery	112	2	4	3.35	.732
I am confident l will come out of surgery safely	112	1	4	3.48	.789

To determine anxiety levels of the respondents using the S-Anxiety scale, their scores were grouped as 1-20 not anxious, 21-30 moderately anxious and 31-40 severely anxious. According to S-Anxiety scale majority 69(61.6%) of the patients were severely anxious, 41 (36.6%) were

moderately anxious and 2(1.8%) were not anxious. One sample Chi-square test (p-value <.001) indicate that anxiety levels differed significantly between respondents as shown in figure 10.

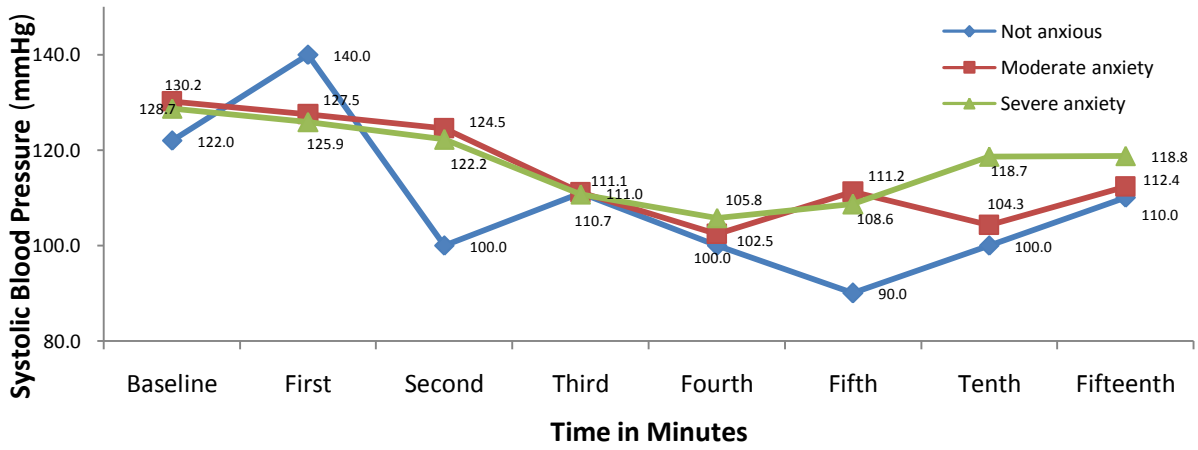
Figure 10: Anxiety Levels according to S-Anxiety Scale



Systolic Blood Pressure vs. Time by Anxiety level

There was great oscillation in the blood pressure for patients who were not anxious as compared to the rest over time of observation. Kruskal Wallis test indicated that there was insignificant difference for the different anxiety levels in blood pressure levels of patients at different time intervals (p-values: .765 (Baseline), .349 (1^{st} minute), .086 (2^{nd} minute), .919 (3^{rd} minute), .936 (4^{th} minute), .283 (5^{th} minute), .066(10^{th} minute) and .554 (15^{th} minute) as shown in figure11

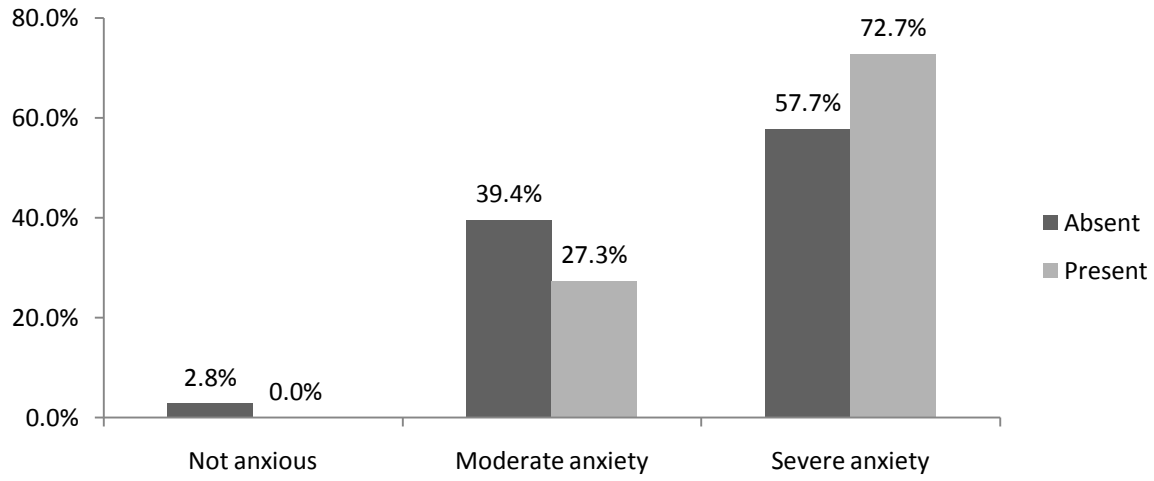
Figure 11: Systolic Blood Pressure vs. Time by Anxiety level (STAI-s)



Anxiety Level Vs Hypotension Presence

Majority (72.7%) of the patients who had hypotension were severely anxious. Majority (57.7%) of the patients who did not have hypotension were severely anxious. Likelihood Ratio Chi-square test (p-value = .302) indicated that there was insignificant association between anxiety levels and presence of hypotension. As shown in figure 12.

Figure 12: Anxiety Levels vs. Hypotension Presence



Discussion

This study showed that the incidence of hypotension in elective caesarean section was much lower than in a previous study done in 2009 by Kahoro et al. Hypotension occurred in 26(23.2%) of the respondents. However hypotension after spinal anaesthesia depends on many factors, including dose and type of local anaesthetic, patient positioning, height of patient, B.M.I. fluid preloading and co-loading, which were not captured in this study. Furthermore this study only captured planned elective caesarean sections which could further explain the lower incidence.Therefore a study is needed to evaluate the incidence of hypotension in emergency caesarean section.

Most patients awaiting elective surgery experience anxiety, several studies have been carried out all through various surgical disciplines to assess and alleviate anxiety among patients before surgery. The degree to which each patient manifests anxiety related to future experiences depends on many factors (age, gender, level of education, previous experience of surgery and type and extent of the proposed surgery). In this study patients were subjected to an S-Anxiety scale a day before surgery to evaluate how the respondents felt at that moment, majority 69(61.6%) of the patients were severely anxious, 41 (36.6%) were moderately anxious and 2(1.8%) were not anxious.

Using the S-Anxiety scale; "being contented with the facility being equipped to give best possible care" and "being confident of coming out of the surgery safely" had the highest mean of 3.48 while "being aware of the type of anaesthesia to be administered" had the lowest mean score of 2.22.This actually has been portrayed in the *Jawaid et al study* where 56% of patients said that their anxiety would be lessened if the procedure was explained to them in detail.

This study clearly shows that despite trusting the capabilities of the institution and the personnel, patients did not have information on the mode of anaesthesia despite consenting for elective spinal anaesthesia. The patient's anxiety would have been lessened if in the preoperative review, the procedure was explained to them in detail.

However due to high numbers of postponement or cancellation of elective caesarean sections due to overwhelming emergencies in maternity theatres, patients remained anxious in the ward, starved and awaiting indefinitely for surgery.This was shown on the comparison of anxiety levels the evening before surgery and the morning of surgery using the Visual analogue scale (VAS)and S-Anxiety scale as shown in table 5

Table 5: Comparison between VAS and S anxiety Scale

	STAI anxiety level			**Total**
	Not anxious	Moderate anxiety	Severe anxiety	
Anxiety levels using VAS				
Not anxious	0	7	35	42
Moderate anxiety	2	30	34	66
Severe anxiety	0	4	0	4
Total	2	41	69	112

The results of this study showed that 28(25.26%) of the respondents were aged between 32 and 34 years and the mean age of the respondents was31.32(±0.97) years, which actually corresponds with the data analysis in the year 2011-2012 in NHS hospitals in the United Kingdom that older mothers were more inclined to have an elective C section with 18 per cent over the age of 35 years opting not to give birth naturally. The previously recognized contributors to the rise include delayed child bearing, the rising obesity rate among moms-to-be, and an increase in multiple birth deliveries.

The study showed us that, 43(38.4%) of the respondents in this study had a parity of 1 + 0, and most common indication of caesarean section was one previous scar 55(49.1%). These results showed that previous surgical birth was the most common reason for C-sections and C-section rate among older moms was high.The national Institute of Child Health and Human Development which analyzed data from more than 228,000 deliveries at 19 hospitals across the U.S. from 2002 to 2008.Among their findings was that previous surgical birth was the most common reason for C-sections and the rate among older moms was double that of younger ones. This trend is noted in Kenya today as more and more mothers deliver in their thirties and furthermore opt for caesarean section as a mode of delivery.

The study therefore supports the null hypothesis that the level of preoperative anxiety is not associated with the occurrence of hypotension during spinal anaesthesia for caesarean delivery and more factors are infact attributed to occurrence of hypotension

Study Limitations

1. This study was not powered enough to make conclusive statements on the risk factors associated hypotension after spinal anaesthesia.
2. Anxiety levels among patients were greatly increased due to fears of frequently postponing surgeries, these could not be captured in the study as some ended up as emergencies and were automatically excluded from the study.

Conclusion

1. This study showed there was insignificant association between anxiety levels and presence of hypotension after spinal anaesthesia in elective caesarean sections.
2. Using the S-Anxiety scale patients were contented with the facility being equipped to give best possible care and being confident of coming out of the surgery safely had the highest mean while being aware of the type of anaesthesia to be administered had the lowest mean score.
3. The most common indication of caesarean section was one previous scar in women who were not keen on vaginal birth after caesarean section.

Recommendations

1. Preoperative evaluation of patients should factor in on the patients choice of anaesthesia after properly enlightening the patients on the available options.
2. Knowledge of important risk factors which are associated with the development of hypotension after spinal anaesthesia should be surveyed and measures to prevent them put in place.
3. A study should be carried out as to why one previous scar is the most common indication for elective caesarean section.
4. Further studies are needed to evaluate effects of preoperative anxiety levels on intraop hemodynamics effects and outcomes of surgery among patients across all surgical disciplines.

Dissemination of results

The results of the study have been shared with the staff at Kenyatta National Hospital through a departmental presentation. A copy of the original book was given to the department of Anaesthesia, the university library, and the Research and Ethics Committee. Findings will also be submitted for possible publishing in a peer reviewed journal.

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APPENDICES

Appendix 1: Consent for Participation in Anxiety Study

Consent explanation.

My name is Dr. Khalid A. Ahmed a postgraduate student in Anaesthesia at the University of Nairobi. As part of my course work I am required to perform clinical research. I am conducting a study at the Kenyatta National Hospital on anxiety levels among patients who undergo spinal anaesthesia in KNH maternity theatre, their morbidity and mortality outcomes.

The aim of this study is to help doctors improve the care given to patients in cesarean section deliveries. Any information obtained in the course of the study is beneficial in the management of the patients. You will not be subjected to any risks in your care before, during and after the operation.

I have included you my study because you will be undergoing a planned cesarean section under spinal anaesthesia. To do this, I will give you a confidentialself administered questioner to fill on how exactly you feel at that moment. ThenI will take your medical history and your blood pressure before you go to theatre. I will also look at the medical treatment you have received so far, any surgical interventions done and your ongoing treatment. During the cesarean section I will monitor your blood pressure and changes that occur during the operation.

Thereafter I will do statistical calculations on this information and publish it in a book that will be in the custody of the University of Nairobi.

This study has been approved by Kenyatta National Hospital/University of Nairobi – Ethics & Research Committee which oversees and approves any researches done are of no harm to the patients and will contribute to improve care of patients.

Your participation in this study is voluntary and you may withdraw at any point without affecting the treatment and care being given to you in any way.

All information gathered will be treated with utmost confidentiality. No names or other identifiers will be used in the study. As a consequence I shall need your consent to be included in the study.

For further information and clarification you may contact:

Dr. Khalid A. Ahmed. Telephone number – 0722 703 007

Dr. P.O.Olang – supervisor. Telephone number - 0722523116

KNH/UON – Ethics & Research Committee. Telephone number – 2726300

Idhini Ya Kushiriki Katika Utafiti

Maelezo.

JinalanguniDaktari Khalid A. Ahmed, mwanafunziwashahadayapilikatikachuokikuu cha Nairobi. Kama sehemu ya masomoyanguninastahilikufanyautafitiwakitabibu.

Lengolangu ni kufanyautafitikatikaHospitali ya Taifa ya Kenyattajuu yakuweponauhusianobaina ya wasiwasinakuteremkakwashinikizo la damukatikaupasuajiwasezerayanikutumianjiayakupeanadawayaganzikwenyeutiwamgongo. Lengo la utafitihuu ni kusaidiamadaktarikuboreshahudumainayotolewakwawagonjwa.Nimekuchaguakuwakwautafitihuu kwasababuupasuajiwakoumepangiliwanautapewadawayaganzikwenyeutiwamgongo .

Kwakufanyahivyo, nitakuulizamaswalikuhusuhaliyako ya kiafya,kishanikupimeshinikizo la damukwasasakishanitakupafomuinayokuulizanamnahisiazakozilivyokwahivisasa.Kishatutaangalia mabadiliko ya shinikizo la damuwakatiwaupasuaji.

Baada ya haponitafanyamahesabu ya takwimuna tarifa hiinakutangaza matokeo hayokatikakitabu ambachokitakuwachini ya ulinziwaChuoKikuucha Nairobi.

Utafitihuuumeidhinishwanakamati ya utafitimaalum ya Chuokikuucha Nairobi naHospitalikuu ya Kenyatta kuhakikishahakutakuanamadharayoyotekwamgonjwanamatokeo ya utafitiyatatumiwakuimarishamatibabu.

Taarifa zote zitakazokusanywazitashughulikiwanausiri. Hakunamajinaauvitambulishovinginevitakavyotumikakatikautafiti. Kwahiyonitahitajiidhiniyakoku wamshirikikatikautafitihuu.

Ushirikiwakokatikautafitihuu niwahiarinaunawezakuondokakatikahatuayoyotebilakuathirimatibabuutakayopewakwanjia yoyote. Taarifa zote zitakazopatikanakatikamwendowautafitihuu ni kwa manufaayamgonjwa.

Kwamaelezozaidina ufafanuzi,unawezakuwasilianana:

DaktariKhalid A. Ahmed. Nambariyasimu – 0720860448

Daktari P.O. Olang. Nambariyasimu - 0722523116

KNH/UON – Ethics & Research Committee. Nambariyasimu – 2726300

Consent Form

I _____ have been explained the purpose and conditions of my involvement in the study by Dr Khalid A. Ahmed. I agree to the above and do give consent for to be included in the study

Name: _____

Signature/Thumb print: _____

Date: _____

Witness Name: _____

Signature/Thumb print: _____

Date: _____

For further information and clarification you may contact:

Dr. Khalid A. Ahmed. Telephone number – 0722 703 007

Dr. P.O.Olang – Supervisor. Telephone number - 0722523116

KNH/UON – Ethics & Research Committee. Telephone number – 2726300

Fomu ya Idhini

Mimi _____ nimeelezewamadhumuninamasharti ya ushirikiwangukatikautafitinaDaktariKhalid A. Ahmed. Nakubaliananamaelezo hayo nanimemruhusudaktarikufanyautafitihuokwangu.

Jina: _____

Sahihi: _____

Kidolechagumba: _____

Tarehe: _____

Jina la shahidi: _____

Sahihi: _____

Kidolechagumba: _____

Tarehe: _____

Kwamaelezozaidinaufafanuzi, unawezakuwasilianana:

DaktariKhalid A. Ahmed. Nambariyasimu – 0720860448

Daktari P.O. Olang. Nambariyasimu - 0722523116

KNH/UON – Ethics & Research Committee. Nambariyasimu – 2726300

Appendix 2: Spinal Anaesthesia Protocol Kenyattanational Hospital 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 & drape.

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

9. Reconfirm the position of the patient (knee chest)
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 ¼ hourly for 2hrs.- Positioning –make patient comfortable with pillow under the head.

Prepared by:

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Kenyatta National Hospital,

P.O. Box 20723 -00202,

NAIROBI. January, 1999.

Appendix 3: Clinicians Patients Assessment Tool

DATE……..

TIME……..

PATIENT INFORMATION

PATIENT'S NAME (INITIALS)

……

AGE…….. PARITY……

GESTATIONAL AGE ……

SERIAL NUMBER……WARD…….

LEVEL OF EDUCATION ……

COUNTY OF ORIGIN …….

BASELINE HB ……. HEIGHT…… WEIGHT ……..

INDICATION FOR CESAREAN SECTION ……

CADRE OF ANAESTHETIST TO GIVE SPINAL ANAESTHESIA

CONSULTANT ☐ SHO ☐ QUALIFIED C.O ☐ D STUDENT ☐

TIME OF THE PREOPERATIVE EVALUATION .....

COMORBID CONDITIONS

YES ☐ NO ☐

If yes state the type

…….

Visual Functional and Mental Status Assessment

Patient's mental status

1) Normal
    1. Normal
    2. Calm
    3. Confused
    4. Depressed

2) Anxious mood

1. Normal
2. Worries
3. Fearful anticipation
4. Irritable

3) Cardiovascular symptoms

1. None
2. Tachycardia
3. Pain in chest
4. Throbbing of vessels, fainting feelings, missing beat

4) Respiratory symptoms

1. None
2. Pressure or constriction in chest,
3. choking feelings,
4. Sighing, dyspnea.

5) Autonomic symptoms

1. Dry mouth
2. Flushing
3. Pallor, tendency to sweat
4. Headache

Key: 1-5= Not anxious, 6-10= Moderate anxiety, 10-20 =Severe anxiety

Bed Side Vital Signs

1. BLOOD PRESSURE …….
2. HEART RATE …….

Vitals in theatre before Spinal anaesthesia induction **(baseline)**

BLOOD PRESSURE ……

HEART RATE ……

TYPE OF BUPIVACAINE: HEAVY ☐ PLAIN ☐

Vital signs after induction of Spinal anaesthesia

Time	Blood Pressure	Heart Rate	Ephedrine	I.V Fluids (ml)	Others Dose/Volume
1st minute					
2nd minute					
3rd minute					
4th minute					
5th minute					
10th minute					
15th minute					

Others (Other Drugs, Fluids or Blood and its Products used)

_____

Appendix 4: The S-Anxiety scale

It consists of **ten** statements that evaluate how respondents feel "right now, at this moment"

		Very much so	Moderately so	Somewhat	Not at all
1	I am happy				
2	I am not feeling nervous anxious or on edge				
3	I feel secure				
4	I am aware of the type of surgery I am to undergo				
5	I trust in the surgeons capabilities				
6	I am aware of the type of anaesthesia to be administered				
7	I trust in the anesthetists capabilities				
8	I am contented the facility is equipped to give me the best possible care				
9	I am not worried there will be complications in surgery				
10	I am confident I will come out of surgery safely				

		SANA	**KIASI**	**KIASI FULANI**	**LAA**
1	Niko nafuraha				
2	Sinawasiwasiwaladhiki				
3	Nahisinimokwenyeutulivu				
4	Najuaniainaganiyaupasuaj initakaofanyiwa				
5	Naaminiuwezonaujuziwa madaktariwaupasuaji				
6	Naelewaainaya ‘anestezi’ nitakayofanyiwa				
7	Naaminiuwezonaujuziwa madaktariwa ‘anestezi’				
8	Nimeridhikahospitaliikovi faanataalumayakunihudu mia				
9	Sinawasiwasikutakuwanas hidayoyotewakatiwaupasu aji				
10	Naaminiupasuajiutakamili kasalamasalmin				

Key

1 = VERY MUCH SO

2 = MODERATELY SO

3 = SOMEWHAT

4 = NOT AT ALL

SCALE

1–10: minimal anxiety

11–20: mild anxiety

21–30 moderate anxiety

31–40: severe anxiety

Appendix 5:Budget

CONCEPT	**AMOUNT (KSH.)**
Stationery	5,000
Printing & Photocopying	10,000
Binding	3,000
KNH/UON Ethics & Research Processing Fee X2	2,000
Statistician	20,000
Contingency	5,000
TOTAL	**45,000**

Appendix 6: Approval Letter

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
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(254-020) 2726300 Ext 44355

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KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/158

8th April, 2015

Dr. Khalid A.A. Aj-Moody
Dept. of Anaesthesia
School of Medicine
University of Nairobi

Dear Khalid

Research Proposal: Association between Pre-Operative Anxiety and Hypotension during Spinal Anesthesia in Women Undergoing Elective Caesarean Delivery (P64/02/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 8th April 2015 to 7th April 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chair, KNH/UoN-ERC
The Dean, School of Pharmacy
The Chair, Dept. of Anaesthesia,
Supervisors: Dr. Patrick O.R. Olang, Dr. Thomas M. Chokwe