COMPARISON OF APGAR SCORES AND UMBILICAL VEIN OXYGEN SATURATION AMONG NEONATES WHO'S MOTHERS HAD SPINAL ANAESTHESIA FOR ELECTIVE CAESAREAN DELIVERY WITH EITHER SUPPLEMENTAL OXYGEN OR ROOM AIR

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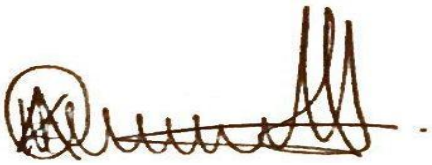
A DISSERTATION SUBMITTED IN PART
FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF
MASTER OF MEDICINE IN ANAESTHESIA OF
THE UNIVERSITY OF NAIROBI

STUDENT'S DECLARATION

I hereby declare that this dissertation is my original work and that it has not been submitted to any university or institution for examination or any other purposes.



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DEDICATION

This dissertation is dedicated to my dear wife, Dr. Majala Zawadi Mwang'ombe, my parents Dominic Mulu Katiku and Josephine Nduku Muli and my entire family whose love, support and encouragement has brought me this far.

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LIST OF ACRONYMS AND ABBREVIATIONS

APGAR	Appearance, Pulse, Grimace, Activity and Respiration
ASA-PS	American Society of Anaesthesiologist's Physical Status
BGA	Blood Gas Analysis
BP	Blood Pressure
CO_2	Carbon Dioxide
C/S	Caesarean Section
DNA	Deoxyribonucleic Acid
ECG	Electrocardiogram
ERC	Ethics and Research Committee
KNH	Kenyatta National Hospital
O_2	Oxygen
PaO_2	Arterial Oxygen Tension
pH	Measure of Hydrogen Ions in Blood
$PuvCO_2$	Partial Pressures of Carbon Dioxide in the Umbilical Vein
$PuvO_2$	Partial Pressures of Oxygen in the Umbilical Vein
SA	Spinal Anaesthesia
Spo_2	Oxygen Saturation in the Peripheral Capillaries
$Suvo_2$	Oxygen Saturations in the Umbilical Vein
UoN	University of Nairobi

OPERATIONAL DEFINITIONS

General Anaesthesia: A state of loss of consciousness, analgesia and areflexia induced by administration of one or more general anaesthetic agents.

Hypotension: Systolic blood pressures <100 mmHg or a decrease in blood pressure of greater than 20% of the pre-spinal values.

Neonate: Refers to a child less than 28 days of age.

Spinal anaesthesia: A form of regional anaesthesia that is obtained by blocking spinal nerves in the subarachnoid space using local anaesthetics and/or opioids.

Term pregnancy: Is considered as the period from 3 weeks before until 2 weeks after the estimated date of delivery.

ABSTRACT

Background

During spinal anaesthesia for caesarean delivery, some anaesthesia practitioners do not administer supplemental oxygen routinely to low-risk mothers. Benefits of maternal oxygen supplementation on both the foetus and neonate remain questionable. Recent data has raised concerns, that supplemental oxygen may cause harm to both the mother and the baby due to increased free radical activity[(1)]. In this cross-sectional comparative study, we assessed if there was any association between foetal outcomes as measured by the Apgar score and maternal oxygen levels during elective caesarean delivery under spinal anaesthesia.

Broad Objective

The main objective of this study was to compare the Apgar scores and umbilical vein oxygen saturation among neonates of term low-risk pregnant mothers who had spinal anaesthesia for elective caesarean delivery with either supplemental oxygen or room air.

Study Methodology

The study adopted a comparative cross-sectional study design and was carried out at the maternity theatre in Kenyatta National Hospital. The target population consisted of pregnant women at term scheduled for elective caesarean delivery under spinal anaesthesia. Over a period of 1.5 months, 80 term pregnant women were enrolled into the study by consecutive sampling method. Spinal anaesthesia was administered to equivalent dermatomal levels in all patients as per current KNH protocol. It was purely an observational study, where patients either fell into group A or group B. Patients in group A are the ones who had been provided with supplemental oxygen via nasal prongs at 2 litres per minute after spinal block, while group B are those who had been on room air after spinal block. Time of spinal administration, drug used, and the dose were recorded on the data collection tool.

Data Analysis

Data was entered, and analysis done using Statistical Package for Social Sciences (SPSS) version 21. Continuous data was analysed and presented as means and standard deviation, while categorical data was analysed and presented as frequencies and proportions. A comparison of the clinical outcomes and the saturation levels of umbilical venous oxygen between the two groups was done using Chi square test of association for categorical data while the differences in means of umbilical venous oxygen saturation were done using two sample students t test. A P value of < 0.05 was considered significant.

Results

In group A, the value of Apgar score at one minute varied from 7 to 9, at five minute it was from 8 to 10 and, at ten minute it was from 9 to 10. While in group B, the results of Apgar score were same with no statistically significant difference (P>0.05). The difference in values of $SuvO_2$ in group A vs group B [mean 38.5 (19.8) vs 33.5 (15.3)] as well, was found not to be statistically significant.

Conclusion

Provision of supplementary oxygen to term low-risk pregnant mothers undergoing elective caesarean delivery has no significant difference on the outcomes of neonates as far as their Apgar scores, umbilical vein blood gas and acid-base status is concerned. Therefore, there is no maternal indication for routine oxygen supplementation in low-risk mothers undergoing elective caesarean delivery under spinal anaesthesia.

Key words: Anaesthesia, Spinal, Oxygen, Free Air

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background

Spinal anaesthesia is a type of regional block achieved by injecting a local anaesthetic and/or opioid into the subarachnoid space. It is the most preferred mode of anaesthesia in an uncomplicated caesarean delivery. For purposes of surgery, the first spinal anaesthetic was conducted by August Bier on the 16th August 1898[2]. There is an association between reduction in blood pressure and spinal anaesthesia, but episodes and severity of maternal hypotension are variable and mainly depend on the level of the block. The higher the level of the block the higher the incidence of hypotension.

Oxygen supplementation is a form of treatment in which an increased concentration of oxygen is made available for breathing through nasal prongs or face masks. In a gravid patient, the diaphragm tends to be displaced upward thereby decreasing available space for lung expansion. This causes a decrease in expiratory reserve volume and residual volume leading to a 20% decrease in the functional residual capacity[3]. Furthermore, respiratory depression may occur during spinal anaesthesia depending on the level of block. In view of the above, some anaesthesia care givers will offer supplemental oxygen to women delivering via caesarean section under spinal anaesthesia to prevent maternal desaturation and at the same time optimize foetal oxygenation even though some patients may not need supplemental oxygen. It has been found that the ventilatory changes that occur during spinal anaesthesia are well tolerated in normal healthy patients without hypoxia occurring[4].

Beneficial effects of maternal oxygen supplementation on the foetus and neonate remain questionable, despite being a common practice. Studies have suggested that there could be harm by oxygen due to increased neonatal free oxygen radical activity[5]. Free oxygen radicals are chemically reactive species produced by reduction of molecular oxygen. Some of the effects include; damage to the DNA, oxidation of amino acids in protein, and lipid peroxidation. Hyperoxia and free oxygen radicals observed during neonatal resuscitation at birth with high inspired oxygen fractions has been associated with adverse neonatal outcomes[1].

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

There has been contention around the practice of routinely supplementing oxygen to uncomplicated pregnancies, where continuous monitoring with pulse oximetry is done, while undergoing caesarean delivery under spinal anaesthesia[6]. During foetal hypoxia, oxygenation together with the acid base status has been observed to improve by supplementing oxygen to the mother[7]. However, Khaw KS and colleagues in two different studies exhibited no advantageous effects on the foetal oxygenation and/or acid-base status in administering supplemental oxygen[1,8].

Supplemental oxygen to mothers during caesarean delivery under spinal anaesthesia is a common practice by some anaesthesia practitioners. J Crawford championed for supplemental oxygen in his book on obstetric anaesthesia (1984- 5thedition, Principles and practice of obstetric anaesthesia)[9]. Oxygen supplementation for caesarean deliveries was further supported by his opinion.

Supplemental oxygen is aimed at improving maternal oxygen saturations and overall neonatal outcome. Foetal oxygenation has been noted to be improved by maternal oxygen supplementation during neuraxial anaesthesia. Therefore, some anaesthesiologists tend to administer supplemental oxygen to mothers for caesarean delivery under spinal anaesthesia[5,10].

The clinical effect of oxygen supplementation on neonatal outcome is unclear. Some anaesthesia practitioners believe that it is of benefit to the foetus and has no detrimental effects. In a previous study, it was thought that oxygen supplementation might have harmful effects to the neonate due to elevated reactive oxygen species. Still on the same concept, some studies have shown that resuscitation of the neonate with supplemental oxygen leads to adverse outcomes due to elevated reactive oxygen species[11,12]. Current neonatal resuscitation guidelines advocate for use of air and reserve use of supplemental oxygen for failed initial attempts[13].

A study done by K.S. Khaw looked at the effects of supplemental oxygen to mothers under neuraxial anaesthesia at the time of caesarean delivery on lipid peroxidation and oxygenation of the mother and the foetus. They measured the Apgar scores, maternal and cord blood gases and lipid hydroperoxides. Lipid peroxides concentrations were found to be higher in the umbilical vein when compared to the umbilical artery blood, which suggested that the source of reactive oxygen species is the placenta, the interface where hyperoxia occurs. Of note is

that in this study there was no accompanying increment of purine metabolites (co-markers of ischaemia-reperfusion injury) thereby ruling out pathological generation of reactive oxygen species associated with conditions such as labour dystocia, non-reassuring foetal status and cord accidents. 8-isoprostane concentrations were higher in the umbilical vein compared to the mother's blood hence indicating that there was production of lipid peroxides in the placenta. They found an association between maternal oxygen pressures and concentrations of reactive oxygen species in the placenta. There was no significant change in the umbilical vein oxygen partial pressures of the foetus whose mother received supplemental oxygen compared to the foetus whose mother was on room air[(1)].

A review done by K.S Khaw et al ascertained that during elective caesarean delivery, use of supplemental oxygen (30%) in general anaesthesia or use of room air in neuraxial anaesthesia had no direct correlation with foetal hypoxia. It is of note that protracted incision-to-delivery interval did not contribute to foetal hypoxia and that the use of supplemental oxygen was not advantageous[(14)]. It is, therefore, not surprising that the use of supplemental oxygen in patients undergoing caesarean delivery is being challenged[(12,15)] and thought to be of no clinical use[(14)].

A study was done in Portugal to ascertain the association between supplemental oxygen and oxygen partial pressures of both the foetus and the mother during caesarean delivery at term under spinal anaesthesia. Results revealed that a rise in maternal oxygen fraction was not associated with a rise in foetal oxygen partial pressures[(16)].

The effect of supplemental oxygen on protracted incision-to-delivery interval was assessed by allocating mothers undergoing elective caesarean delivery under neuraxial anaesthesia to inhale different concentrations of oxygen. Umbilical blood gases and Apgar scores were analysed. $PuvO_2$ and oxygen content were similar in the groups that received high concentrations of oxygen and the group that was on room air[(8)].

T. Mutukwa et al from University of Zimbabwe carried out a study on the incidence of hypoxemia under spinal anaesthesia and determine if oxygen supplementation was necessary for mothers undergoing caesarean delivery under neuraxial anaesthesia. They found that the incidence of hypoxemia was 1.69% and that there was a relationship between height of block and change in oxygen saturation. They concluded that the routine supplementation of oxygen to mothers under spinal anaesthesia was not necessary[(17)].

High spinal block is one of the causes of desaturation during caesarean delivery under spinal anaesthesia necessitating supplementation of oxygen though not so common in our set up. A study done by Kimberly et al on the quality of spinal blocks administered at Kenyatta National Hospital for caesarean delivery concluded that at 8 minutes it provided a mean block height (to touch) at T6 with a range of T12 to T3, mean block height (to cold) at T5 with a range of T10 to T2 and mean block height (to pin prick) at T5 with a range of T12 to T2 dermatomes. They concluded that spinal blocks performed in KNH for Caesarean delivery were adequate for comfortable surgery[18].

Based on the above information, this study aimed at comparing the effect of supplemental oxygen and that of room air on Apgar score and umbilical cord venous oxygen saturations of neonates born to mothers undergoing elective caesarean delivery under spinal anaesthesia.

2.2 Justification

Although routine supplementation of oxygen to women for caesarean delivery under neuraxial anaesthesia is routinely practiced by many anaesthesia providers, actual data on the effect of supplemental oxygen on neonatal outcomes in Kenyatta National Hospital is not available. There has been no similar study undertaken regionally or locally. As a result of the lack of data on this, there are no standard operating procedures regarding routine oxygen supplementation as some mothers receive while others don't. It all depends on the anaesthesia provider rather than on the pulse oximetry readings. The results will ultimately serve to increase knowledge, quality of care provided to patients, and inform policy making on routine oxygen supplementation to mothers without any respiratory or uteroplacental complications undergoing caesarean delivery under spinal anaesthesia.

Should the study show no added benefits in supplementing oxygen to mothers undergoing elective caesarean delivery under spinal anaesthesia, it will be projected to inform national policy on the use of supplemental oxygen in limited resource county hospitals where oxygen is a scarce resource that could be reserved for more deserving patients and emergencies. The study will act to increase awareness to practitioners on the outcomes of routinely supplementing oxygen.

2.3 Research Question

Does maternal oxygen supplementation during elective caesarean delivery under spinal anaesthesia improve neonatal Apgar scores and neonatal umbilical vein oxygen saturations ($SuvO_2$)?

2.4 Null Hypothesis

Supplemental oxygen given to women at term during elective Caesarean delivery under spinal anaesthesia has no effect on neonatal Apgar score and $SuvO_2$.

2.5 Study Objectives

2.5.1 Broad Objective

To compare the Apgar scores and umbilical vein oxygen saturations among neonates of term low-risk pregnant mothers who had spinal anaesthesia for elective caesarean delivery with either supplemental oxygen or room air at the Kenyatta National Hospital.

2.5.2 Specific Objective

i) To measure Apgar scores in neonates whose mothers had received supplemental oxygen and those whose mothers had been on room air while undergoing elective caesarean delivery.

ii) To measure $SuvO_2$ in neonates whose mothers had received supplemental oxygen and those whose mothers had been on room air while undergoing elective caesarean delivery.

iii) To determine the difference in neonatal Apgar scores and $SuvO_2$ in mothers who had received supplemental oxygen and those who had been on room air during elective caesarean delivery under spinal anaesthesia.

3.0 CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study Design

This was a comparative cross-sectional study.

3.2 Study Site

This study was carried out at the maternity theatre in Kenyatta National Teaching and Referral Hospital. This is Kenya's busiest Level 6 hospital. On average, the number of caesarean deliveries conducted per annum is 5,963. 11.7% (698) of these are elective cases of which 92.7% (647) are done under spinal anaesthesia. The maternity theatre has two operating rooms; one is assigned for emergency cases while the other one is for elective cases as well as emergency cases as need arises. Most of the cases are done under spinal anaesthesia unless the clinical condition necessitates the use of a general anaesthetic or the patient declines to have spinal anaesthesia.

3.3 Study Population

The target population consisted of expectant mothers at term scheduled for elective caesarean delivery at the KNH maternity theatres.

3.4 Sample Size Determination

Sample size was calculated using the formula of difference of means as follows:

$$n = \left(\frac{r+1}{r}\right)\frac{\sigma^2(Z_\beta + Z_{\alpha/2})^2}{(\text{difference})^2}$$

Assumptions derived from a study by K S Shaw et al(19).

$\lceil n \rceil$ = Desired sample size per arm

r = Ratio of study subjects to comparable group (in this case 1:1)

σ = Standard deviation of the outcome variable (in this case 19)

Z_β = Desired power of the study (0.84)

$Z_{\alpha/2}$ = Level of statistical significance (1.96)

Difference = Effect size difference in means ($SuvO_2$ in Oxygen group = 65; Room air group = 53: difference = 65-53 = 12)

Substituting these in the formula gives us a sample size of 40 per arm as follows:

$$n = \frac{(1+1) \times (19^2)(0.84+1.96)^2}{1 \qquad 12^2}$$

n= 40

Therefore, 40 participants per arm

3.5 Sampling Procedure

Sampling was done using consecutive sampling method of all expectant mothers who had been admitted for elective caesarean delivery under spinal anaesthesia, of those who met the set inclusion criteria at Kenyatta National Hospital.

3.6 Inclusion Criteria

- Mothers with term pregnancies (ASA-PS I).
- Patients who gave informed consent.

3.7: Exclusion Criteria

- Patients with multiple gestation, congenital abnormalities, hypertensive diseases in pregnancy, cardio-respiratory disorders, ante partum haemorrhage, intrauterine growth restriction and uteroplacental disorders.
- Expectant mothers converted to general anaesthesia prior neonate delivery.
- Expectant mothers who got a high block, partial block or hemiblock.
- Patients who declined to give consent to participate in the study
- Patients who were not able to give informed consent.

3.8 Data Variables

Objective	Exposure Variable	Outcome Variable	Sources of Data
Assess Apgar scores in neonates whose mothers received supplemental oxygen while undergoing elective caesarean delivery	• Oxygen supplementation • Birth weight • Intra-operative Readings- Blood pressure, Respiratory rate, Heart rate, SpO_2.	• Apgar score at 1, 5 and 10 minutes	• Data collection tool • Patients file
Assess Apgar scores in neonates whose mothers were on room air while undergoing elective caesarean delivery	• Exposure to Room Air • Birth weight • Intra-operative Readings- Blood pressure, Respiratory rate, Heart rate, SpO_2.	• Apgar score at 1, 5 and 10 minutes	• Data collection tool • Patients file
Measure $SuvO_2$ in neonates whose mothers received supplemental oxygen while undergoing elective caesarean delivery.	• Oxygen supplementation • Maternal Intra-operative Readings- Blood pressure, Respiratory rate, Heart rate, SpO_2.	• $SuvO_2$	• Questionnaire • Patients file
Measure $SuvO_2$ in neonates whose mothers were on room air while undergoing elective caesarean delivery	• Exposure to Room Air • Maternal Intra-operative Readings- Blood pressure, Respiratory rate, Heart rate, SpO_2.	• $SuvO_2$	• Questionnaire • Patients file

3.9 Study Procedures and Data Collection

The principal investigator or his assistant, who was recruited and trained on how to collect data and samples from the patients, oversaw the process of data collection. Source of data was from the patients, patient's files, intra-operative readings from the monitor and results of BGA samples which were filled in the data collection tool. All patients awaiting elective caesarean delivery under spinal anaesthesia were reviewed in their respective antenatal wards. A signed informed consent for surgery and anaesthesia was confirmed either by the principal investigator or by the research assistant as they obtained an informed consent for participation in the study. Patients who declined to participate in the study as well as those who fell in the exclusion criteria were excluded from the study.

As per the Kenyatta National Hospital spinal anaesthesia protocol, all patients were cannulated using a large bore venous cannula (G18) and pre-loaded with 500-1000mls of ringer's lactate or normal saline over 30-60 minutes at the waiting area. Once the patient was in the operating room, a blood pressure cuff (BP), pulse oximeter (SpO_2) and ECG leads were placed, and baseline vital signs taken and recorded.

On completion of the above, the patient was requested to assume a sitting position on the operating table and the lumbo-sacral region cleaned and draped. Spinal anaesthesia was then administered as per the current KNH protocol for spinal anaesthesia for caesarean delivery (Appendix 3). Time of spinal administration, drugs used, and dose were noted down on the questionnaire. With patient lying supine on the operating table, a lateral tilt to the left was applied to assist in minimizing aortocaval compression. It was left to the discretion of the anaesthesia practitioner to decide whether to provide the patient with supplemental oxygen via nasal prongs (as is the general practice at KNH) or not. The principal investigator or his assistant assessed the block height (by testing the different modalities i.e. block to cold, block to pain and block to touch for the afferent fibres and bromage scale for the efferent fibres) and recorded in the questionnaire. Surgery was allowed to proceed if the block was found to be adequate. If the block was inadequate, the anaesthesia practitioner was at liberty to determine whether to repeat the spinal block or to convert to general anaesthesia.

Patients were monitored continuously, and intra-operative haemodynamic readings were recorded every 2 minutes for the first 10 minutes, thereafter recordings were every 5 minutes. In the event of symptomatic hypotension, symptomatic bradycardia and/or desaturation, the anaesthesia provider was notified and allowed to manage the patient as per the KNH protocol for spinal anaesthesia (Appendix 3). Once the baby was delivered, the umbilical cord was double-clamped and umbilical vein blood sample (1ml) drawn into a heparinized syringe and, bubbles pushed out. Sterility was maintained by performing a hand wash and drying using paper towels. Umbilical cord was cleaned using surgical spirit beginning at the centre and proceeding outwards. Once the injection site was dry a blood sample was drawn into the syringe. Labelling of the sample with the patients initials was done and taken for analysis promptly (within 30 minutes) to avoid inaccurate results[(20)]. The BGA parameters (pH, partial pressures of O_2 and CO_2 and oxygen saturations) were measured using a blood gas analyser (Rapid lab 348 EX which automatically calibrates itself every 2 hours and is manually maintained, primed and calibrated weekly). The BGA parameters were reviewed and recorded on the data collection tool.

Once the umbilical cord was cut and the neonate received by the paediatrician, he/she was dried while being stimulated. Apgar scoring and weighing of the infant were done concurrently.

3.10 Data Quality Assurance/ Bias Minimization

The following measures were considered to ensure quality of data;

a) A dermatome chart was included in the data collection tool to standardize identification of dermatomes.

b) A reference test point that is not anaesthetized on the patient's body was used when assessing for the block height.

c) The investigator ensured all the data collection tools were completely and correctly filled.

d) A routine check on the data collection tools was done and any arising inconsistency was resolved before release of the patient to the post-natal ward.

e) The research assistant was a qualified clinical officer who was trained by use of power point presentation as well as carrying out trial runs of data collection process with the principal investigator.

3.11 Ethical Consideration

- Permission was sought from KNH/UoN ERC.
- Written informed consent was sought from the participants.
- Participation was voluntary and there was no cost implication to the participants.
- There were no monetary benefits offered to the patients.
- For confidentiality purposes, only patients' initials were used on the questionnaires, instead of full names.
- The study did not interfere with the provision of care and health care services to the patients as it is not a requirement by the current spinal anaesthesia protocol to supplement oxygen for saturations of 90% and above.
- Respondents are entitled to information pertaining to the research.
- Study findings were availed to KNH/UoN ERC as well as the Department of Anaesthesia and Board of Postgraduate Studies.
- All data collected was kept confidential and secured in files with password protection.

3.12 Data Management and Analysis

Data was entered, and analysis done using Statistical Package for Social Sciences (SPSS) version 21. Continuous data was analysed and presented as means and standard deviation, while categorical data was analysed and presented as frequencies and proportions. A comparison of the clinical outcomes and the saturation levels of umbilical venous oxygen between the two groups was done using Chi square test of association for categorical data while the differences in means of umbilical venous oxygen saturation were done using two sample students t-test. A p-value of < 0.05 was considered significant

3.13: Study Findings Dissemination

Copies of the dissertation have been submitted to the Department of Anaesthesia, University of Nairobi. The findings of the study will be summarized and submitted to UON/KNH ERC and presentation done in conferences organized by Kenya society of Anaesthesiologists (KSA). The study findings will also be submitted to a peer reviewed journal for publication.

4.0 CHAPTER FOUR: STUDY RESULTS

4.1 Study Period

All eligible participants were recruited from July 2019 to September 2019 at the Kenyatta National Hospital.

4.2 Patient Demographics

The comparison of the patients' demographics and the indications for surgery in the two groups is as shown in the table below.

Table 1: Demographics

	Supplemental O2	**Room air**	**Total**	**p-value**
	N (%)	N (%)	N (%)	
Age				
20-24	7 (17.5)	9 (22.5)	16 (20.0)	0.576
25-29	14 (35.0)	13 (32.5)	27 (33.8)	0.813
30-34	16 (40.0)	10 (25.0)	26 (32.5)	0.152
35-39	3 (7.5)	8 (20.0)	11 (13.8)	0.105
BMI				
18.5-24.9	10 (25.0)	17 (42.5)	27 (33.8)	0.098
25.0-29.9	22 (55.0)	17 (42.5)	39 (48.8)	0.263
>=30.0	8 (20.0)	6 (15.0)	14 (17.5)	0.556
Indications for C/Section				
Breech presentation	11(27.5)	9(22.5)	20(25)	0.548
Previous C/Section	29(72.5)	31(77.5)	60(75)	

The mean age of the patients was 28.9 (SD=4.7) years, while the median age was 28.5 (IQR=6) years. There was no significant statistical difference between the two groups regarding age, BMI and indication for caesarean delivery.

4.3 Maternal Haemodynamic Parameters

Table 2: Systolic BP

Time (minutes)	Mean (SD)		p-value
	Supplemental O2	Room air	
2	106 (18)	110 (15)	0.078
4	105 (17)	108 (20)	0.352
6	103 (15)	106 (17)	0.485
8	105 (17)	107 (16)	0.612
10	104 (14)	108 (16)	0.305
15	106 (16)	111 (13)	0.073
20	108 (17)	108 (13)	0.918
25	111 (17)	108 (13)	0.419
30	111 (18)	112 (13)	0.960

Table 3: Diastolic BP

Time (minutes)	Mean (SD)		p-value
	Supplemental O2	Room air	
2	64 (16)	62 (11)	0.452
4	60 (15)	63 (18)	0.356
6	58 (15)	61 (15)	0.383
8	61 (15)	62 (16)	0.697
10	60 (13)	62 (14)	0.516
15	58 (14)	64 (11)	0.069
20	62 (12)	61 (14)	0.836
25	61 (15)	59 (13)	0.531
30	62 (13)	60 (11)	0.428

Table 4: Heart rate

Time (minutes)	Mean (SD)		p-value
	Supplemental O2	Room air	
2	98 (19)	97 (17)	0.677
4	97 (20)	89 (16)	0.054
6	95 (19)	86 (15)	0.052
8	94 (22)	85 (15)	0.051
10	94 (20)	88 (17)	0.160
15	95 (19)	90 (17)	0.192
20	92 (18)	91 (18)	0.843
25	92 (16)	89 (17)	0.400
30	93 (18)	90 (17)	0.413

Table 5: Respiratory rate

Time (minutes)	Mean (SD)		p-value
	Supplemental O2	Room air	
2	18 (4)	17 (3)	0.603
4	18 (3)	18 (3)	0.330
6	19 (3)	18 (4)	0.445
8	18 (4)	18 (4)	0.858
10	18 (3)	18 (4)	0.805
15	18 (3)	17 (4)	0.571
20	17 (4)	17 (3)	0.621
25	18 (3)	16 (3)	0.052
30	17 (4)	15 (3)	0.056

The intra-operative haemodynamic parameters of Blood pressure, Heart rate as well as Respiratory rate in the two groups were also comparable, with no statistical difference (Tables 2,3,4 & 5)

Table 6: SPO_2

Time (minutes)	Mean (SD)		p-value
	Supplemental O2	Room air	
2	98 (2)	98 (2)	0.145
4	99 (1)	97 (2)	0.004
6	99 (2)	97 (2)	0.001
8	99 (2)	97 (3)	0.003
10	99 (2)	97 (2)	0.001
15	99 (1)	96 (3)	0.001
20	99 (1)	97 (3)	0.001
25	99 (1)	97 (3)	0.001
30	99 (3)	96 (3)	0.001
35	98 (2)	97 (3)	0.002
40	99 (2)	97 (3)	0.001

The intra-operative maternal oxygen saturations readings were found to have no statistically significant difference at 2 minutes, but there was a significant difference at the other time intervals.

4.4 Spinal Block Assessment

Table 7: Table showing highest level of spinal block to touch

Time from spinal administration	Lowest block height	Highest block height	Mean block height
2 minutes	T12	T6	T8
5 minutes	T10	T5	T7
8 minutes	T8	T4	T6
10 minutes	T8	T4	T5

The highest level of spinal block to touch at 2 minutes, was found to have a range of T12 to T6 with a mean of T8; at 5 minutes the range was T10 to T5 with a mean of T7; at 8 minutes the range was T8 to T4 with a mean of T6 and at 10 minutes the range was T8 to T4 with a mean of T5.

Table 8: Table showing highest level of spinal block to cold

Time from spinal administration	Lowest block height	Highest block height	Mean block height
2 minutes	T12	T6	T7
5 minutes	T10	T5	T6
8 minutes	T8	T4	T5
10 minutes	T8	T4	T5

The highest level of spinal block to cold at 2 minutes, was found to have a range of T12 to T6 with a mean of T7; at 5 minutes the range was T10 to T5 with a mean of T6; at 8 minutes the range was T8 to T4 with a mean of T5 and at 10 minutes the range was T8 to T4 with a mean of T5.

Table 9: Table showing highest level of spinal block to pin prick

Time from spinal administration	Lowest block height	Highest block height	Mean block height
2 minutes	T10	T6	T7
5 minutes	T8	T5	T6
8 minutes	T8	T4	T5
10 minutes	T7	T3	T5

The highest level of spinal block to pin prick at 2 minutes, was found to have a range of T10 to T6 with a mean of T7; at 5 minutes the range was T8 to T5 with a mean of T6; at 8 minutes the range was T8 to T4 with a mean of T5 and at 10 minutes the range was T7 to T3 with a mean of T5.

Table 10: Table showing highest grade of Bromage score

Time from spinal administration	Minimum grade of block	Maximum grade of block	Mean grade of block
2 minutes	2	3	3
5 minutes	3	4	4
8 minutes	3	4	4
10 minutes	4	4	4

Motor block at 2 minutes, was found to have a grade range of 2 to 3 with a mean grade of 3; at 5 minutes the grade range was 3 to 4 with a mean grade of 4; at 8 minutes the grade range was 3 to 4 with a mean grade of 4 and at 10 minutes the grade was 4.

It was observed that;

a) The block height was adequate for surgery but was not too high to cause respiratory depression and hence desaturation.

b) The block was given to comparable dermatomal levels between the 2 groups.

4.5 Neonatal Outcome

This section presents the results of the Apgar scores, umbilical vein blood gas analysis and birth weights of neonates whose mothers received supplemental oxygen and those whose mothers had been on room air while undergoing elective caesarean delivery. The Man-Whitney U test was used to analyse the Apgar scores in the two groups, while Students t-test was used to analyse the different parameters of umbilical vein blood gas analysis and birth weights amongst the two groups. A p-value <0.05 was considered statistically significant.

Table 11: Apgar Scores

	Supplemental O2	**Room air**	**Total**	**p-value**
At 1 minute	**N (%)**	**N (%)**	**N (%)**	
7	4 (10.0)	4 (10.0)	8 (10.0)	
8	14 (35.0)	19 (47.5)	33 (41.3)	
9	22 (55.0)	17 (42.5)	39 (48.8)	
Mean rank	**42.8**	**38.3**		0.337
At 5 minutes				
8	4 (10)	4 (10)	8 (10)	
9	25 (62.5)	21 (52.5)	46 (57.5)	
10	11 (27.5)	15 (37.5)	26 (32.5)	
Mean rank	**38.7**	**42.3**		0.431
At 10 minutes				
9	5 (12.5)	2 (5)	7 (8.8)	
10	35 (87.5)	38 (95)	73 (91.3)	
Mean rank	**39.0**	**42.0**		0.238

There was no statistically significant difference between the two groups on the neonatal Apgar scores at 1, 5 and 10 minutes.

Table 12: Umbilical vein blood gas analysis

	Mean (SD)		p-value
	Supplemental O2	**Room air**	
pH	7.30 (0.09)	7.26 (0.11)	0.067
$PuvO_2$ (KPa)	3.22 (1.16)	2.76 (0.87)	0.054
$PuvCO_2$ (KPa)	5.61 (1.18)	6.12 (1.10)	0.056
$SuvO_2$ (%)	38.5 (19.8)	33.5 (15.3)	0.052
U-D (uterine incision – delivery) interval (sec)	117 (135)	101 (70)	0.487
Birth weight (g)	3143 (364)	3169 (394)	0.765

Although the Supplemental O_2 group was found to have better pH, $PuvO_2$, $PuvCO_2$ and $SuvO_2$ than the Room air group, the difference was not statistically significant. In regard to the birth weight and uterine incision to delivery interval, no difference was found as well between the 2 groups.

Table 13: Effect of maternal SPO_2 on $PuvO_2$ and $SuvO_2$

	Maternal SPO_2	
	Pearson Correlation	P value
$PuvO_2$	0.179	0.111
$SuvO_2$	0.175	0.120

Analysis by Pearson correlation test to assess the relationship between maternal SPO_2 and umbilical vein oxygen tension and saturation showed that there was a positive correlation (0.179 and 0.175 respectively) although very weak and statistically not significant (Fig. 1 & 2). Given the small number of patients in this study, it is apparent that the better the maternal oxygen saturation, the better the neonatal oxygen indices. Although the correlation appears statistically insignificant, it is a strong indication for maternal oxygen supplementation especially in cases of non-reassuring foetal status.

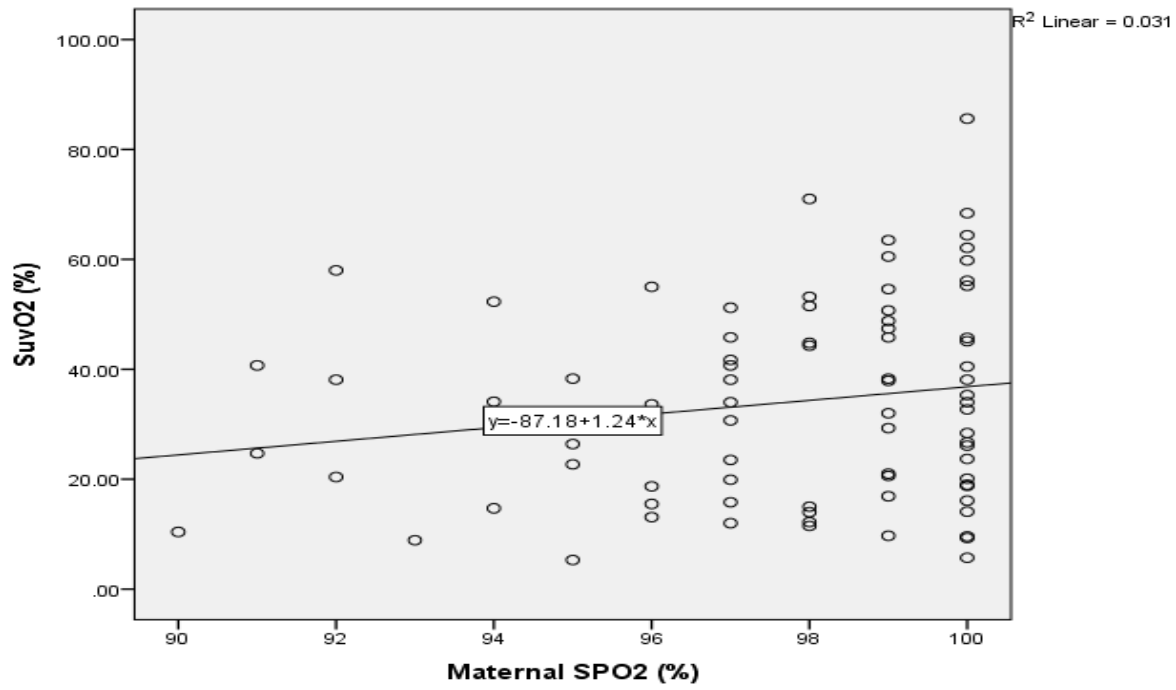

Figure 1: Scatter plot showing the relationship between maternal SPO_2 and $SuvO_2$.

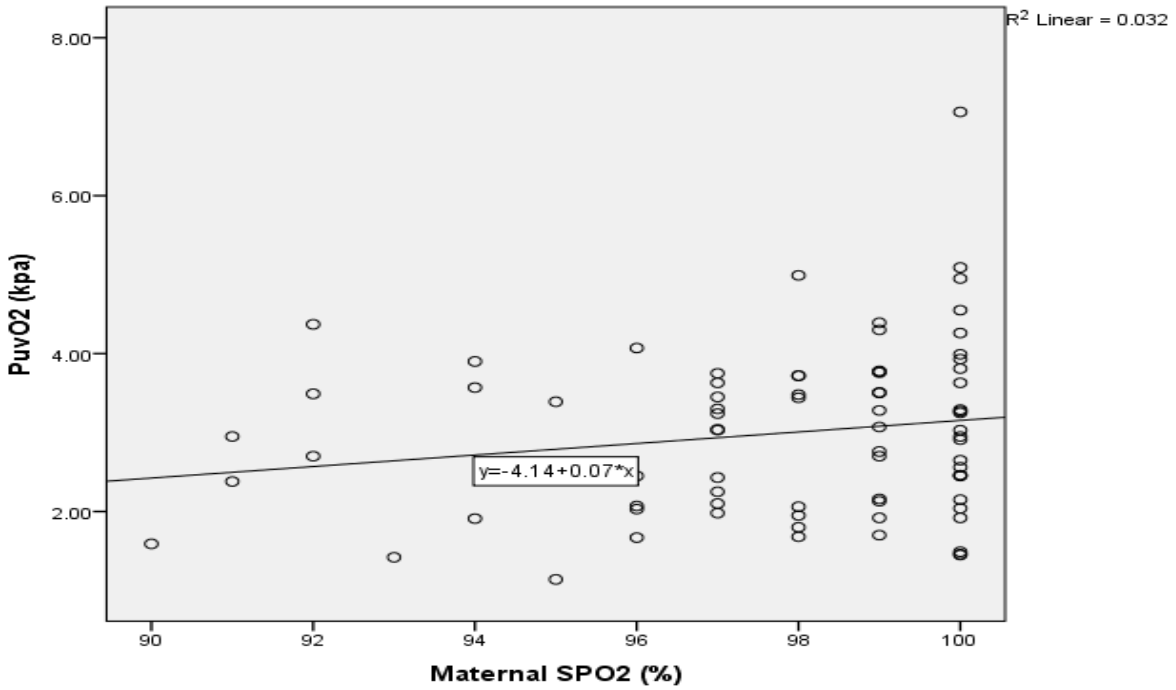

Figure 2: Scatter plot showing the relationship between maternal SPO_2 and $PuvO_2$.

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATION

5.1 Discussion

The main objective of this study was to compare Apgar scores and umbilical vein oxygen saturation among neonates of term low-risk pregnant mothers who had spinal anaesthesia for elective caesarean delivery with either supplemental oxygen or room air at the Kenyatta National Hospital. It was conducted in the maternity theatres. The reason behind routine supplementation of oxygen to mothers during elective caesarean delivery is to prevent maternal haemoglobin desaturation and improve foetal acid base status, oxygenation at birth and overall neonatal outcome. It is, therefore, necessary to ensure that the quality of anaesthesia being provided is of an acceptable standard and one that allows safe and comfortable surgery to be performed.

The optimal level of foetal oxygen before delivery during normal caesarean delivery is not known. A term foetus is well adapted to low blood oxygen tensions. The haemoglobin level of the term neonate at birth is 65-85% haemoglobin F (HbF) which has a high affinity for oxygen, thus binding it more avidly than adult haemoglobin (HbA). The oxy-haemoglobin dissociation curve for HbF is shifted to the left compared with that of HbA, resulting in HbF being more saturated than HbA at lower oxygen tensions. The foetus is also relatively polycythaemic (haematocrit > 45) and hence the higher foetal blood oxygen content than it would be in the adult under similar oxygen tensions.

The main focus in assessment of the infant as soon as it is born, includes looking at the adequacy of the placental unit in maintaining neonatal acid-base balance and oxygenation. Apgar score is a simple and reputable method that has been in use since 1952 when it was introduced by Dr. Virginia Apgar who was an anaesthesiologist. It is used clinically to assess the status of the newborn immediately after birth. A score of less than 7 at 5 minutes is an indication that the newborn might require some intervention. A score of more than 7 at 5 minutes and 10 minutes is considered normal meaning the newborn might not require any intervention other than the routine post-delivery care[21]. The interpretation of foetal blood gas analysis alone cannot conclusively predict a good or poor neonatal outcome, as a low pH is not always indicative of a poor neonatal outcome.

In this study, we decided to combine Apgar scoring and measurement of neonatal pH, $SuvO_2$, $PuvO_2$ and $PuvCO_2$ in assessing the effect of maternal oxygen supplementation on neonatal outcomes of low-risk pregnant mothers while undergoing caesarean delivery. By doing so,

we are able to pick any indication for intervention immediately after delivery as well as provide an assessment of oxygen supply to the foetus immediately before delivery and its ability to maintain aerobic metabolism.

By administering supplemental oxygen via nasal prongs to mothers, we found that it did not significantly improve Apgar scores, foetal oxygenation or acid-base status when compared to the room air group. The Apgar scores were found to be similar between the groups, with all scores ≥ 7 at 1minute, ≥ 8 at 5 minutes and ≥ 9 at 10 minutes (Table 11). Khas et al found that administration of 35% FiO_2 did not cause any change in the foetal umbilical vein PO_2 ($PuvO_2$). Even with increasing maternal hyperoxia, the Apgar scores and umbilical vein pH did not improve[19]. Kelly et al also demonstrated that supplementation with 35% oxygen did not improve foetal oxygenation during caesarean delivery under spinal anaesthesia[22]. K.S Khaw et al did a randomized, double-blind comparison of different inspired oxygen fractions during caesarean delivery and concluded that maternal use of oxygen fractions <0.5 did not cause any change in the partial pressure of oxygen in the umbilical vein(10). Siriussawakul A. et al looked at the effects of supplemental oxygen on maternal and neonatal oxygenation in elective caesarean delivery under spinal anaesthesia and did not find any clinically significant neonatal outcomes as demonstrated by normal umbilical arterial blood gases and Apgar scores in both groups hence concluding that if continuous pulse oximeter monitoring is available, supplemental oxygen may be optional[23]. Furthermore, Cogliano et al, found that maternal administration of oxygen while undergoing elective caesarean delivery under spinal anaesthesia did not improve the umbilical arterial or venous pH, or partial pressures of O_2 and CO_2 in the event of a prolonged uterine incision to delivery interval. They thus concluded that their data was not in support of routinely supplementing oxygen during elective caesarean delivery under spinal anaesthesia[24].

With hyperoxia, increases in the formation of free radicals has been exhibited, which may exacerbate tissue damage in ischaemia reperfusion injury. Hyperoxia mediates tissue injury in conditions such as bronchopulmonary dysplasia, retinopathy of prematurity, persistent ductus arteriosus, necrotizing enterocolitis and intracranial haemorrhage[14]. There is therefore, a possibility of damage from free oxygen radicals during routine supplementation of oxygen in uncomplicated caesarean deliveries. It is, therefore, not recommended[25].

Although routine oxygen supplementation to mothers undergoing elective caesarean delivery is practiced by some anaesthesiologists, there are patients who do not require supplementary oxygen as the ventilatory changes that occur after a spinal anaesthetic are usually well

tolerated in normal healthy patients without consequent hypoxia occurring[22]. In this study we attained a mean block height of T5 at 10 minutes which was similar to what Kimberly Kamau et. al. found when assessing spinal anaesthesia block height, satisfactory for caesarean delivery with no incidences of hypoxia[18].

Anaesthesiologists should consider close monitoring of patients under spinal anaesthesia by pulse oximetry to avoid unnecessary supplementation of oxygen, while being able to promptly identify and treat those patients that desaturate and are at risk of becoming hypoxaemic. This will also enable anaesthesiologists to provide affordable anaesthesia by reducing the additional cost (Ksh. 2,000 per hour) stemming from the use of oxygen and oxygen delivery devices that are not even readily available in most Kenyan public hospitals.

5.2 Conclusion

On evaluation of our results, we conclude that provision of supplementary oxygen to term low-risk pregnant mothers undergoing elective caesarean delivery has no significant difference on the outcomes of neonates as far as their Apgar scores, umbilical vein blood gas and acid-base status is concerned. Therefore, there is no maternal indication for routine oxygen supplementation in low-risk mothers undergoing elective caesarean delivery under spinal anaesthesia. It is more important to ensure that haemodynamic instabilities associated with spinal anaesthesia are managed adequately and promptly to avoid maternal discomfort and anxiety associated with oxygen supplementation via nasal prongs. This will also serve to avoid wastage of oxygen that could be used by other more deserving patients. It is important to note that haemodynamic instabilities, especially spinal-induced hypotension, result in poor placental perfusion without necessarily reducing maternal oxygen saturation. Maternal oxygen supplementation alone would be of no use in mitigating this problem unless there is evidence of maternal hypoxia.

5.3 Recommendations

a) Further research is needed to evaluate the pros and cons of supplementing oxygen in emergency caesarean delivery when there is a case of non-reassuring foetal status.

b) Continuous medical education is required to sensitize practitioners and regulatory bodies on the integral use of pulse oximetry in deciding which patient should receive supplemental oxygen.

c) Protocols for the use of oxygen in our setting need to be put in place.

5.4 Study Limitations

a) The study did not evaluate its objective in the less clinically stable women, i.e. the emergency caesarean deliveries and mothers with uteroplacental compromise.

b) Maternal and foetal cord blood samples were not analysed to establish reactive oxygen species as this test is not available in most of our institutions.

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APPENDICES

Appendix I (a): Consent Form

COMPARISON OF APGAR SCORES AND UMBILICAL VEIN OXYGEN SATURATIONS AMONG NEONATES WHOSE MOTHERS HAD SPINAL ANAESTHESIA FOR ELECTIVE CAESAREAN DELIVERY WITH EITHER SUPPLEMENTAL OXYGEN OR ROOM AIR.

Principal investigator: Dr. Antony Mulu, MMed Year IV, Anaesthesia Department, College of Health Sciences, University of Nairobi.

Introduction

I am Dr. Antony Mulu, the principal investigator of this study. I am a postgraduate student at The University of Nairobi pursuing a master's degree in Anaesthesia. I am conducting a comparative cross-sectional study on the use of supplementary oxygen and free air during elective caesarean delivery under spinal anaesthesia at Kenyatta National Hospital.

I am hereby requesting you to participate in this study by allowing us to collect data on age, weight, parity, past medical, surgical and anaesthetic history, current medical history and do a blood gas analysis on umbilical vein blood sample. Written below are the details about the study. If you agree to participate in the study, kindly sign at the end of this form.

Purpose of the research

Oxygen supplementation in term pregnant mothers undergoing elective caesarean delivery under spinal anaesthesia has been routinely practiced despite contradicting data in recent studies on the foetal benefits. There are, however, no studies done in Kenya and the whole of Africa investigating this association. This study will inform policy making on oxygen supplementation to mothers undergoing caesarean section and ultimately serve to increase knowledge, quality of care provided to patients and more importantly the outcome in our setup.

Procedure

The team will approach you in the ward, give you adequate information about the study and request you to participate in it. After consenting in writing to participate in the study, you will be recruited. You will be asked a number of questions concerning socio-demographic history, current and past medical history. We will allow the anaesthesia care provider to proceed with his anaesthetic plan without interference meanwhile we will note down drugs used, intra-operative readings and take a blood sample from the umbilical vein for blood gas analysis. The information you provide will be used to improve management.

Risks

The study poses no risk and your participation will not interfere with the regular management of your condition before, intra and post operation. All information given will be treated with utmost confidentiality.

Benefits

The study will improve quality of care and management of patients undergoing elective caesarean delivery under spinal anaesthesia.

Cost

There is no monetary cost required for you to participate in the study.

Right as a participant

You reserve the right to either accept or refuse to participate in the study and as such no remuneration or compensation will be offered to the participants of the study. You can withdraw from participating in the study any time you feel you want to. Refusing to participate in this study will not affect the care that you will receive. Accepting to participate does not deprive you of any of your legal rights. You will sign the consent form only if you accept to participate and a signed copy of the form will be given to you.

Questions

You are free to ask any questions that you wish even after the study has started or in the future. For any questions concerning the study or your rights as a study participant, you may contact the following:

Dr. Mulu Antony
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Dr. Gacii Vernon Mark
Mobile Number: 0733-709953
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Dr. Olang' Patrick Ragot
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Kenyatta National Hospital/University of Nairobi Ethics and Research Committee
College of Health Sciences
P.O. Box 19676- 00202 Nairobi
Telephone: (254-020) 2726300-9 Ext 44355
Email: uonknherc@uonbi.ac.ke

Voluntary Consent

I……. consent that the researcher has explained to me all the above information concerning this study. I have understood what will be done and that my participation in this study is voluntary. I also understand that my identity will be kept confidential. By signing this form, I voluntarily and willingly agree to participate in this study.

Name of participant	Signature	Date
……..…	……..	……

Name of person obtaining consent	Signature	Date
……	…….	……

If participant cannot read the form herself, a witness must sign here:

I was present while the informed consent, detailing the benefits, risks and procedures, were read to……... (Name of participant). All questions by the participant were answered and the participant has agreed to take part in the study.

Name of witness	Signature	Date
……	…….	……

I certify that the nature and purpose, the potential benefits and possible risks associated with participating in this study have been explained to the above individual.

Name of person obtaining consent	Signature	Date
……	…….	……

Appendix I (b): Fomu ya Idhini

COMPARISON OF APGAR SCORES AND UMBILICAL VEIN OXYGEN SATURATIONS AMONG NEONATES WHOSE MOTHERS HAD SPINAL ANAESTHESIA FOR ELECTIVE CAESAREAN DELIVERY WITH EITHER SUPPLEMENTAL OXYGEN OR ROOM AIR.

Mchunguzi Mkuu: Dr. Antony Mulu, MMed Year IV, Anaesthesia Department, College of Health Sciences, University of Nairobi.

Kianzilio

Mimi Dr. Antony Mulu, ndiye mchunguzi mkuu wa utafiti huu. Mimi ni mwanafunzi wa uzamili katika chuo kikuu cha Nairobi mwenye kutafuta bwana shahada ya Anaesthesia. Lengo la utafiti huu ni kulinganisha matumizi ya oksijeni nyongeza na hewa inayopeanwa kwenye mama waja wazito wakati wa upasuaji chini ya anaesthesia ya mgongo katika hospitali ya taifa ya Kenyatta.

Naomba ushiriki katika utafiti huu kwa kuturuhusu kukusanya takwimu juu ya umri, uzito, usawa, matibabu ya siku za nyuma na ya sasa hivi na kufanya vipimo vya viwango vya gesi kwenye sampuli ya damu itakayotolewa kwa mshipa. Maelezo zaidi kuhusu utafiti huu utayapata katika vipengele husika. Ukikubali kushiriki katika utafiti, kwa hisani tupe sahihi yako katika mwisho wa fomu hii.

Madhumuni

Uongezaji wa hewa ya oksijeni kwa mama waja wazito wenye kufanyiwa upasuaji imekuwa mazoea ijapokuwa kuna ujuzi tata kulingana na tafiti zipya zinazotueleza kinyume kuhusiana na faida za kijusi. Hata hivyo, hakuna utafiti umewahi fanyika katika Kenya au hata bara nzima la Afrika, kuchunguza uhusiano huu. Utafiti huu utasaidia katika kuunda sera maamuzi na hatimaye kutumika kuongeza maarifa, ubora wa huduma zinazotolewa kwa wagonjwa na muhimu zaidi ni matokeo katika mazingira yetu sisi wenyewe.

Utaratibu

Utapata kupewa taarifa ya kutosha kuhusu utafiti na kuombwa kushiriki. Baada ya kupeana idhini utapata kushiriki na kuulizwa maswali kadhaa kama vile historia ya matibabu ya sasa na siku za nyuma. Wakati operesheni itakapokuwa inaendelea, ishara za muhimu zitapata kusomwa na kujazwa. Sampuli ya damu kutoka mshipa kitovu itapata kuchukuliwa kwa ajili ya uchambuzi wa gesi za damu. Maelezo utakayotoa yatatumika kuboresha huduma.

Hatari

Hakuna hatari yoyote inayotarajiwa kwenye utafiti huu. Habari yoyote ya kibinafsi utakayotupea itawekwa kwa usiri.

Faida

Utafiti huu utasaidia kuboresha huduma kwenye mama waja wazito watakao jifungua kwa njia ya operesheni.

Gharama

Hakuna gharama ya kifedha itakayojiri kwa kushiriki katika utafiti.

Haki za Mshiriki

Una haki ya kukubali au kukataa kushiriki katika utafiti kwani hakuna malipo au fidia itakayopewa kwa washiriki wa utafiti. Unaweza amua kutokushiriki katika utafiti wakati wowote utakapotaka. Kutokushiriki katika utafiti huu hakutaathiri huduma utazopokea. Kushiriki nakwo hakutaondoa kivyovyote haki zako za kisheria. Kutia sahihi kwenye fomu hii, itakuwa kama ishara ya kwamba umepeana idhini ya kushiriki katika utafiti huu. Utapewa fomu moja yenye umetia sahihi kama nakala yako.

Maswali

Uko huru kuuliza maswali yoyote unayotaka hata baada ya utafiti kuanza au katika siku zijazo. Kwa maswali yoyote kuhusu utafiti huu au haki zako kama mshiriki wa utafiti, unaweza kuwasiliana na wafuatao:

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Idhini

Mimi……...nakubali ya kwamba mtafiti amenieleza taarifa yote kuhusu utafiti huu. Nimeelewa kitachofanywa na kushiriki kwangu katika utafiti huu ni kwa hiari. Nimeelezwa pia utambulisho wangu utawekwa kuwa siri. Kwa kutia sahihi kwenye fomu hii inaashiria kuwa nimekubali kushiriki katika utafiti huu kwa hiari.

Jina la mshiriki Sahihi Tarehe

…….. … …….. ……

Jina la mtu anayechukua idhini Sahihi Tarehe

…… ……. ……

Kama mshiriki hawezi jisomea fomu hii, shahidi lazima atie sahihi hapa:

Nilikuwepo wakati fomu hii ya idhini, iliyo na maarifa kuhusu faida, hatari na taratibu, ilipokuwa inasomwa kwa……. (Jina la mshiriki). Maswali yote yamshiriki yamejibiwa na amekubali kushiriki katika utafiti.

Jina la shahidi Sahihi Tarehe

…… ……. ……

Ninathibitisha ya kwamba hali na lengo, faida na hatari zinazohusiana na kushiriki katika utafiti huu, zimeelezwa kwa anayeshiriki.

Jina la mtu anayechukua idhini Sahihi Tarehe

…… ……. ……

Appendix II: Data Collection Tool

Serial Number ----------

TOPIC: COMPARISON OF APGAR SCORES AND UMBILICAL VEIN OXYGEN SATURATIONS AMONG NEONATES WHOSE MOTHERS HAD SPINAL ANAESTHESIA FOR ELECTIVE CAESAREAN DELIVERY WITH EITHER SUPPLEMENTAL OXYGEN OR ROOM AIR.

A. Data Abstraction Tool

Part 1: Demographic data

1. Date of Birth [DD/MM/YYYY]:……
2. Weight (kg)…… Height (m)……. BMI (kg/m^2)……..
3. Parity……. Gestation (weeks)……
4. Diagnosis……..

Part 2: Spinal Anaesthesia

1.Time of spinal administration …… (am/pm)

2. Drug, dosage and time used; i) Plain bupivacaine……
ii) Hyperbaric bupivacaine…….
iii) Fentanyl…….....
iv) Paracetamol……...
v) Diclofenac supp……..
vi) Metoclopropramide/ Ondansetron…….
vii) Others…….....

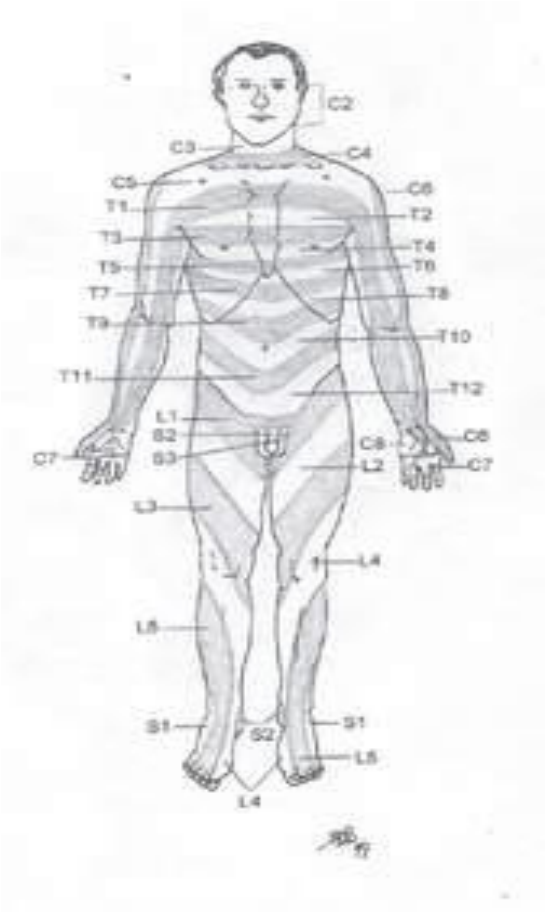
3.Spinal Block Test

	HIGHEST LEVEL OF BLOCK (DERMATOME)						MOTOR BLOCK
	TOUCH		COLD		PIN PRICK		
TIME FROM ADMIN OF SPINAL	**L**	**R**	**L**	**R**	**L**	**R**	**GRADE**
2 MINUTES							
5 MINUTES							
8 MINUTES							
10 MINUTES							

BROMAGE SCORE(MOTOR BLOCK TEST)

Grade	Criteria	Degree of block
I	Free movement of legs and feet	Nil (0%)
II	Just able to flex knees with free movement of feet	Partial (33%)
III	Unable to flex knees, but with free movement of feet	Almost complete (66%)
IV	Unable to move legs or feet	Complete (100%)

DERMATOME CHART



Part 3: Intra-operatively

1. **Vital signs Chart**

TIME	B.P	H.R	SPO2	R.R
Baseline [before S.A]				
2mins				
4 mins				
6mins				
8mins				
10mins				
15mins				
20mins				
25mins				
30mins				
35mins				
40mins				

2. Was the patient provided with supplemental oxygen.....? (yes/no)
3. Skin incision…….(am/pm)
4. Time of uterine incision……. (am/pm)
5. Time of delivery…….(am/pm)
6. Skin incision to delivery interval……(mins)
7. Uterine incision to delivery interval…….(seconds)

Part 4: Neonatal Outcomes

1. **Apgar Scores**
   - **1 minute……..**
   - **5 minutes……..**
   - **10 minutes……**

2. **Birth Weight (g)…….**

3. **BGA Results (Umbilical Vein)**
   - **P.H…….**
   - **O_2 sat. (%)……**
   - **PO_2 (kpa)…….**
   - **PCO_2 (kpa)……**

Appendix III: Spinal Anaesthesia Protocol

Kenyatta National 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 her co-operation
3. Inform the rest of the team in theatre so you can be assisted appropriately
4. Insert a good gauge I/V cannula (G 20 or larger)
5. Pre-load with ½ -1L N/saline / Hartmann's over 30- 60mins
6. Install your monitors (pulse, respiration, SPO_2, 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 gully pots for holding cleaning solutions
   c) Appropriate spinal needle (with introducer where required)
   d) 2 syringes & Needles
      i.) 5cc for infiltration of L.A to the site
      ii.) 2cc 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 1-2% lignocaine using a gauge 21 needle to maximum depth. Withdraw the needle as you continue to administer L.A and raise a skin wheal.
11. Give 1-2 mins 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 (hyperbaric) L.A is position dependent. The patient must be appropriately positioned after injection to allow desired distribution.
    b) **Bupivacaine** is usually 0.5% concentration. Most patients will require between 7.5mg (1.5mls) to 15mg (3mls).

c) Obstetric patients are more sensitive and will require between 7.5mg (1.5mls) to 10mg (2mls). Aim for a block up to T6. Test and record level of block.

d) Additive: **25mg Fentanyl** (0.5mls) is a useful additive to prevent the discomfort of gut handling during C/S etc. This must still make up the total volume of 2-2.5 mls of drug injected into the spinal canal. Other drugs have been used as additives but it's 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 C/S the volume & position are critical to achieve a good or disastrous spinal block.

13. Confirm the L.A has taken effect and note level/site of 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 C.S.F. 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 2-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's 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 1st 10-20mins after administration of the L.A into the C.S.F.

17. Post-operative pain management -I/M Pethidine 1mg/kg 4-6hourly for 24 hrs or S/C Morphine 10mg 4-6hourly for 24hrs, Diclofenac suppository (or equivalent) stat then 12 hourly for 48 hrs, then convert to oral analgesics and I/V Paracetamol 1g intra-op then QID for 24 hrs may be beneficial. Follow up visit, within 24hrs.

18. Critical observation

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

    b) $SPO_2 \leq 90\%$ - Increase the O_2 flow by mask or nasal prongs.

    c) BP –symptomatic Hypotension- Ephedrine -5mg-10mg PRN (you may occasionally need an infusion)-Phenylephrine-Adrenaline

d) Respiration –falling respiratory rate (usually temporary) may be due to hypotension-Treat hypotension, if no improvement give oxygen, assist with respiration briefly (if required) and 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-dural puncture headaches-May occur post operatively (but rarely) worse on standing & relieved by lying down.

Management

i. Bed rest

ii. Plenty of fluids (iv &/or oral) including caffeine

iii. NSAIDs & Betapyn (codeine, caffeine, paracetamol &Doxylamine)

iv. Epidural blood patch as a last resort (when conservative mgt fails)

19. Post-Op –monitor BP ¼ hourly for2hrs.

Positioning –make patient comfortable with pillow under the head.

Prepared by:

Dr. P.O.R. Olang' and Dr. David Otieno.

Consultant Anaesthesiologists,

Kenyatta National Hospital,

P.O. Box 20723 -00202,

NAIROBI.

January 1999.

Appendix IV: Activity Plan

Activity	March 2018 - March 2019	April 2019 - May 2019	June 2019	July 2019 – Sept. 2019	Oct. 2019 - Dec 2019	Jan 2020
Proposal Development						
Proposal Approval						
Training of research assistant						
Data Collection						
Data analysis and Report writing						
Report Submission						
Dissemination of results						

Appendix V: Budget

ITEM	UNIT COST	QUANTITY	TOTAL
BGA TEST	2,000	80	160,000
RESEARCH ASSISTANT	40,000	1	40,000
STATISTICIAN	30,000	1	30,000
PRINTING & BINDING	10,000	1	10,000
ETHICS & RESEARCH COMMITTEE FEE	2,000	1	2,000
TOTAL			**242,000**

Source of funds- Research grant from Kenyatta National Hospital.

Appendix VI: KNH/UON-ERC Letter of Approval

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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

APPROVED
30 MAY 2019
KNH/UoN-ERC

Ref: KNH-ERC/A/197

30th May, 2019

Dr. Mulu Antony Katiku
Reg. No. H58/80919/2015
Dept. of Anaesthesia
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Mulu,

RESEARCH PROPOSAL: COMPARISON OF APGAR SCORES AND UMBILICAL VEIN OXYGEN SATURATION AMONG NEONATES WHOSE MOTHERS HAD SPINAL ANAESTHESIA ELECTIVE CAESARIAN DELIVERY WITH EITHER SUPPLEMENTAL OXYGEN OR ROOM AIR (P227/03/2019)

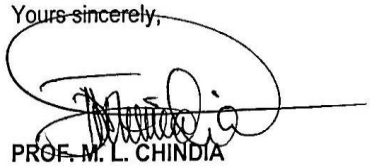
This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 30th May 2019 – 29th May 2020.

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 serious 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. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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*).
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 **http://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 Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Anaesthesia, UoN
Supervisors: Dr. Gachii Vernon Mark (UoN), Dr. Olang' Patrick Ragot (UoN)