MATERNAL AND NEONATAL OUTCOME FOLLOWING CAESAREAN SECTION UNDER SPINAL VERSUS GENERAL ANESTHESIA IN KENYATTA NATIONAL HOSPITAL MATERNITY THEATRE.

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DECLARATION:

This dissertation is my original work and it has never been presented in any university for the award of a master's degree.

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DEDICATION

This book is dedicated to :

My parents,

Kindd, Revende Jidremotration

My LOVELY husband Fikiri.

Queen and Princess; my sweet lovely daughters.

To the medical professionals who provide health care for pregnant women.

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Above all; Glory be to God the Almighty.

LIST OF ACRONYMS:

ASA: American Society of Anesthesiologists

BP: Blood Pressure

APH: Ante Partum Hemorrhage

CSF: Cerebral Spinal Fluid

C\S: Caesarean Section

GA: General Anesthesia

KNH: Kenyatta National Hospital

MMR: Maternal Mortality Rate

NBU: New Born Unit

PDPH: Post Dural Puncture Headache.

SA: Spinal Anesthesia

WHO: World Health Organization

ABSTRACT

Introduction

The risk of maternal death with caesarean section is four times that associated with all types of vaginal Birth. Poor maternal and neonatal outcome are more commonly associated with general anesthesia for c/s as compared to spinal anesthesia. This study compared the safety and the effectiveness of the two techniques for maternal and neonatal outcome for all the indications for caesarean section

Methodology:

A Prospective Observational Descriptive study carried out in KNH maternity theater. A total of 196 patients were recruited in this study and they all completed the study.

Results

In this study, of 196 patients, 43.9% c/s were performed under GA. The rest were under SA regardless of the indication for the c/s. The preference of anesthesia for c/s was directed at SA regardless of the indication and was significant (p=0.032).

From the data, SA was performed in 40.8%, whilst GA 59.2% in a group of patients with immediate indications for c/s. For patients who had urgent indications for c/s, SA was performed in 60.8% out of 102 cases. SA was a predominant choice with elective indications. Out of 35 cases, 24 cases were performed under SA and 11 cases under GA.

Intra-operatively, the commonest maternal side effect observed from the two groups was Hypotension and was significant in the SA group (p<0.001). The total number of cases that got hypotension in SA group was 52 (47.3%) and in the GA group, 12(14%).

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The maternal morbidity and mortality that were defined in our study were; Headache, Backache, Generalized pain, ICU admission and intra-operative maternal death or maternal death in 24 hours; of which PDPH was observed significant.

Neonatal outcome as per the stratified indications for c/s: There was higher neonatal Apgar score in the SA group. Significantly neonatal admissions to NBU in the time defined were associated with GA; there were 22 admissions of which 77.3% were due to respiratory distress. In SA 8 admissions were observed and respiratory distress accounted for 6 neonates out of 8 admissions. From this data analysis, it was observed that GA was highly associated with poor neonatal Apgar score and morbidity as compared to SA.

Conclusions:

Spinal anesthesia and General anesthesia are both effective for c/s, but with significant differences in maternal and neonatal outcome. In a situation of no contraindication to SA and no maternal refusal, SA should be considered. It's significantly safer for both maternal and neonates.

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1 INTRODUCTION

Caesarean section refers to the procedure where a baby is delivered through an incision on the abdominal wall and uterus of the mother. It is often life saving and aims to preserve the health of the mother and her baby. Although the operation has become very safe over the years, it is still associated with greater maternal mortality and morbidity.^{1,2} The risk of maternal death with caesarean section is four times that associated with all types of vaginal birth, which is 1/1000 vaginal births.² It is known that there is a greater risk of neonatal respiratory distress with caesarean section than vaginal delivery, regardless of gestational age.^{1,2} This has been described as mild and transient¹, and caesarean section is considered to be safe for the fetus.

The type of anesthesia used and the care with which it is administered is an important determinant of the outcome of caesarean section.^{2,3} Spinal anesthesia and General anesthesia are commonly used for caesarean section and both have their advantages and disadvantages.⁴

Death due to anesthesia is the sixth leading cause of pregnancy-related mortality in the United States. Despite advances in the safety and administration of anesthesia for obstetric procedures, complications leading to death still occur. Deaths from this cause are particularly lamentable because many of these anesthetics are elective, and are provided to young mothers in the prime of life, and some might be prevented if more experienced anesthesia personnel were available.⁵

Most maternal deaths due to complications of anesthesia occur during general anesthesia for a caesarean section. Spinal anesthesia is not without risks which are, primarily due to the toxicity of local anesthetics and excessively high regional blocks.

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The incidence of these deaths is decreasing, however, but deaths due to general anesthesia remain static in number and hence account for an increased proportion of total deaths. Heightened awareness of the toxicity of local anesthetics and related improvements in technique may have contributed to a reduction in complications of Spinal anesthesia.⁵

The American Society of Anesthesiologists Closed Claims Study has shown that maternal death claims are predominantly related to the use of general anesthesia.⁶

Complications of anesthesia leading to death were categorized as airway management problems, (which included aspiration of gastric contents), problems with induction or intubation (esophageal intubation, inadequate ventilation), as well as respiratory failure, awareness (due to inadequate anesthesia), and respiratory problems for both the mother and the baby.^{2,7}

When maintained with halogenated volatile agents, GA has been associated with a greater risk of maternal blood loss compared with RA.⁸ However, it's a more rapidly administered procedure and is preferred in cases where speed is important.² The use of general anesthesia decreased from 35% in 1981 to 12% in 1992 in the largest obstetric services, and from 46% to 22% in the smallest services The anesthesia-related maternal mortality rate decreased from 4.3 per million live births in the first triennium (1979-1981) to 1.7 per million in the last (1988-1990).

In USA, the number of deaths involving general anesthesia have remained static, but the number of regional anesthesia-related deaths have decreased since 1984.⁵ Regional anesthesia was used for 78-85% (depending on strata) of patients undergoing cesarean section, resulting in a marked decrease in the use of general anesthesia.⁵

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The advantages of RA include the reduction of the incidences of GA complications and that of early bonding between the mother and the newborn, since the mother is awake during the procedure.² Specifically, Subarachnoid and Epidural anesthesia are similar in their safety profiles with a few differences.⁹

Regional anesthesia is the preferred method for caesarean section in the United Kingdom and the United States of America. ^{10,11}

Over 50% of the cases can be attributed to the fact that maternal mortality with RA has been reducing steadily over the years, while that of GA remains the same,⁵ and to greater familiarity of anesthesia residents with the procedure .The 1992 survey of obstetric anesthesia practice revealed better availability of regional anesthesia and analgesia for obstetric patients and less use of general anesthesia for caesarean section.⁵

2 LITERATURE REVIEW

Anesthesia

Definition

Anesthesia (from Greek αv - an- "without" + aisthesis "sensation"), has traditionally meant the condition of having the feeling of pain and other sensations blocked. This allows patients to undergo surgery and other procedures without the distress and pain they would otherwise experience. The word was coined by Oliver Wendell Holmes, Sr. in 1846. Another definition is a "reversible lack of awareness", whether this is a total lack of awareness (e.g. a general anesthetic), or a lack of awareness of a part of the body such as a spinal anesthetic or another nerve block.¹²

There are several forms of anesthesia

The following forms refer to states achieved by anesthetics working on the brain:

Deep sedation/analgesia: "Drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation." Patients may sometimes be unable to maintain their airway or breathe on their own.

Moderate sedation/analgesia or conscious sedation: "Drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation." In this state, patients can breathe on their own and need no help maintaining an airway.^{12,13}

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Minimal sedation or anxiolysis: "Drug-induced state during which patients respond normally to verbal commands." Though concentration, memory, and coordination may be impaired, patients need no help in breathing or maintaining an airway.

The level of anesthesia achieved ranges on a continuum of depth of consciousness from minimal sedation to general anesthesia. The depth of consciousness of a patient may change from one minute to the next.¹²

General anesthesia in its most general form can include

Analgesia:	blocking the conscious sensation of pain	
Hypnosis:	produces unconsciousness without analgesia	
Amnesia:	preventing memory formation	
Relaxation	preventing unwanted movement or muscle tone	
Obtundatio	on of reflexes; preventing exaggerated autonomic response	

2.1 OBSTETRIC ANESTHESIA FOR CAESAREAN SECTION

This involves caring for the women during child birth: Spinal and general anesthesia for caesarean section. Obstetric anesthetist is involved in the care of the parturient as part of the multi-displinary team including, obstetricians, midwives, health visitors and physicians.¹³ A minimum standard health service should aim to provide caesarean section for all maternal indications if not neonatal.¹⁴

The main maternal indications for caesarean section are Obstructed labor, Placental abruption, Previous C/S, pre-Eclampsia, Eclampsia, Placenta previa, Malpresentation and Cord prolapse.

In areas where HIV is prevalent, C/S may increasingly be indicated to reduce risk of transmission from mother to child.¹⁵

The WHO recommends C/S Classification as

Immediate: There is immediate threat to the life of the mother or fetus

Urgent: Maternal or fetal compromise that is not immediately life threatening.

Early: No maternal or fetal compromise but needs early delivery.

Elective: Delivery timed to suit mother and staff.

In most centers, General anesthesia is used when an immediate C/S is required, but urgent and other indications are performed under Regional anesthesia (SA or epidural).¹⁶

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Physiology and pharmacology of pregnancy

From early in the first trimester of pregnancy, a woman's physiology changes rapidly, predominantly under the influence of increasing progesterone production by the placenta. Cardiac output increases by approximately 50%, diastolic blood pressure falls in early to mid-trimester and turn to pre-pregnant level by term. Systolic blood pressure is less affected. Central venous and pulmonary arterial wedge pressures are not affected.

Utero-placental blood flow is not auto regulated and so is dependent on uterine blood pressure. Aortocaval occlusion occurs when the gravid uterus rests on the aorta or the inferior vena cava. Even in the absence of maternal hypotension, placental blood supply may be compromised in the supine position. After 20th week of gestation, a left lateral tilt should always be employed.¹⁶

Plasma volume increases 50% by term, while the red cell mass only increases by 30%, resulting in the physiological anemia of pregnancy Pregnant women become hypercoagulable early in pregnancy; (the first trimester). Plasma concentrations of factors I, VII, VIII, IX, X, and XII are all increased but anti-thrombin levels are depressed.

Gastric emptying and acidity are little changed by the pregnancy. However, gastric emptying is slowed in established labor and almost halted if systemic opioids are administered for analgesia.

Renal blood flow increases by 75% at term and glomerular filtration rate by 50%. Both urea and creatinine plasma concentrations fall.

The neurological tissues have a greater susceptibility to the action of local anesthetics. The volume of distribution increases by 5 liters, affecting predominantly polar agents. Although plasma cholinesterase concentration falls by about 25% in pregnancy, this is counteracted by an increase in volume of distribution, so the actual duration of action of agents such as suxamethonium is little changed.¹⁶

2.1.2 GENERAL ANESTHESIA FOR CAESAREAN SECTION

Conduct of general anesthesia for caesarean section

It is widely accepted that rapid sequence induction is required for GA for caesarean section; however, there is debate as to the best choice of agents to allow effective and safe control of the airway.

Induction agents

The traditional practice of cricoid pressure, thiopentone, suxamethonium, avoidance of opiates remains the most common approach by obstetric anesthetists in the UK. There is vast experience with thiopentone, and it is currently the induction agent of choice for caesarean section. A dose of 4mg/kg (up to maximum 500mg) has been suggested to avoid awareness, minimize maternal hypertension and prevent delayed waking in the event of failed intubation. Propofol is an alternative agent for c\s. However, it has been associated with more maternal awareness and worse apgar scores in the neonate when compared with thiopentone. No studies have shown superiority of propofol.^{16,17,19}

Muscle relaxants

Suxamethonium is currently the muscle relaxant of choice for rapid sequence intubation. It produces excellent intubation conditions quickly and reliably and in the event of failed intubation there is rapid offset. Where available rocuronium is becoming increasingly popular with obstetric anesthetists in place of suxamethonium. The disadvantage is the prolonged ventilation needed in the event of failed intubation. However, rocuronium avoids many of the potential side effects and complications of suxamethonium and produces equivalent intubating conditions although the onset may be slower.¹⁷

Effects of general anesthesia on the fetus

Most anesthetic agents, except for the muscle relaxants rapidly cross the placenta. Thiopentone can be detected in the fetus within 30 seconds of administration with peak umbilical vein concentration occurring around 1minute.Umbilical artery to umbilical vein concentration approach unity at 8minutes.Opioids administered before delivery may cause fetal depression. Hypotension, hypoxia, hypocapnea, and excessive maternal catecholamine secretion may all be harmful to the fetus.

Complications of general anesthesia on the parturient and management

General anesthesia for obstetric patients is associated with a higher incidence of awareness compared with the general population whose surgery is being performed under GA.^{13, 16,17}

Death caused by anesthesia generally results from; Hypoxemia, Acid aspiration associated with a failure to intubate the trachea, and difficulty in maintaining the airway during GA.¹³ In case of GA a pediatrician always should be a available to resuscitate the neonate. As a result of increased mortality and morbidity associated with GA, it is now only indicated if the

woman refuses a regional technique, or if there is a specific medical condition which precludes neuraxial blockade e.g. coagulopathy. General anesthesia may be required in order to facilitate an emergency delivery. There are no uniform definitions for emergency, urgent or elective C/S used consistently in all practices.¹⁷ In many poor resource settings, availability of appropriate equipment, such as spinal needle, local anesthetic agents and vasopressor drugs, will strongly influence the proportion conducted under neuraxial blockade.

2.1.3 REGIONAL ANESTHESIA FOR C/S

Loss of pain sensation, with varying degrees of muscle relaxation, in certain regions of the body while traditionally administered as a single injection, newer techniques involve placement of indwelling catheters for continuous or intermittent administration of local anesthetics.

Regional anesthesia for C/S was initially driven by maternal preference. However, RA is more than sixteen times safer than GA. Although it is safer, maternal refusal remains a contra-indication. Although it is reasonable to give nervous mothers a clear explanation of advantages and disadvantages mothers should not be forced into accepting RA.¹⁶

Types of regional anesthesia used for caesarean section

Spinal anesthesia

Also known as subarachnoid block Refers to Regional block resulting from a small volume of local anesthetics being injected into the subarachnoid space .The spinal canal is covered by the dura mater, through which the spinal needle enters. The spinal canal contains cerebrospinal fluid and the spinal cord. The local anesthetic is usually injected between the 4th and 5th lumbar vertebrae, because the spinal cord usually terminates at the 1st lumbar vertebra, while the canal continues to the sacral vertebrae.

It results in a loss of pain sensation and muscle relaxation usually up to the level of the chest (nipple line or 4th thoracic dermatome).¹

Epidural

The drug is injected through a catheter that has been introduced into the extradural space.⁹

Extended volume Epidural, combined spinal-epidural technique

This involves the injection of the local anesthetic agent commonly bupivacaine into the subarachnoid space through the lower back. A volume of local anesthetic or saline is injected into the epidural space shortly after the spinal injection to manipulate the desired spread of intrathecal local anesthetic. The epidural injection is believed to compress the spinal space resulting in a tailored increase in spread. A combined spinal-epidural involves a spinal injection followed by the insertion of an epidural catheter. Quick onset can be achieved with the spinal part. Further maintenance of the anesthesia is achieved through the epidural catheter.^{16,17}

Local Anesthetic Agents

Local anesthetic agents are used clinically to produce a temporary loss of sensation to a defined area of the body where the drug is administered. This is achieved either by topical application or injection.²¹

There are two basic types that are clinically useful, esters and amides. A few structurally non-related agents also possess local anesthetic properties.¹³

Mechanism of Action

Local anesthetics are agents which prevent transmission of nerve impulses without causing loss of consciousness.²¹

They reversibly interrupt nerve impulses by blocking fast sodium channels, which results in a reduction of the sodium ion influx and consequently impairment of the action potential across the membrane thus stopping conduction.

Preparations

Most local anesthetics are weak bases and poorly soluble in water so they are usually constituted in hydrochloride salts solutions. Dilute preparations are generally acidic and may additionally contain stabilizers, preservatives and fungicides.²¹ Only preservative-free local anesthetic agents may be injected intrathecally.

Adverse effects of local anesthesia

Adverse effects of local anesthesia are generally referred to as Local Anesthetic Toxicity.²¹ Effects may be localized or systemic.

Central nervous system effects of spinal anesthesia

The first evidence of local anesthetic toxicity involves the nervous system, including: ²¹ Agitation, Blurred Vision, Confusion, Tinnitus, Dizziness, a Metallic taste and Nausea. These can quickly progress to seizures, unconsciousness and cardiovascular collapse.

Cardiovascular system

Arrhythmias may be resistant to defibrillation and other standard treatments, and may lead to loss of heart function and death.²¹ Allergic reaction and anaphylaxis to amides is rare.

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Toxicity can also occur with any local anesthetic as an individual reaction by that patient. Direct infiltration of local anesthetic into skeletal muscle will cause temporary paralysis of the muscle.¹⁷

2.1.4 SPINAL ANESTHESIA FOR CAESAREAN SECTION

Spinal anesthesia is the most commonly used technique for elective C/Sin the UK and USA. It is rapid in onset, produces dense block and with intrathecal opioids can produce long acting postoperative analgesia. However, hypotension is much more common than with GA.^{13, 16, 17}

Spinal anesthesia has the definitive advantage that profound nerve block can be produced in a large part of the body by the relatively simple injection of a small amount of local anesthetic. However, the greatest challenge of the technique is to control the spread of that local anesthetic through the cerebrospinal fluid to provide block that is adequate (in both extent and degree) for the proposed surgery but without producing unnecessarily extensive spread and so increasing the risk of complications. The great interpatient variability in spread was observed and described as 'lauenhaft' (way wardness) by August Bier.²³

Advantages; Quick onset, good quality analgesia, easy to perform.¹⁶

Disadvantages of spinal anesthesia; Single shot (cannot be topped up), limited duration, inadequate analgesia that is difficult to correct and rapid changes in blood pressure and cardiac output.¹⁶

2.1.4.1 Spinal anatomy.²⁴

Fig 1. The curves of the spine in supine patient.



Mechanism of drug spread

The CSF of the vertebral canal occupies the narrow (2–3 mm deep) space surrounding the spinal cord and cauda equina, and enclosed by the arachnoid mater. As the local anesthetic solution is injected, it will spread initially by displacement of CSF and as a result of any currents created within the CSF. The next stage, which may well be the most crucial, is spread due to the interplay between the densities of both CSF and local anesthetic solution under the influence of gravity. Gravity will be 'applied' through patient position (supine, sitting, etc.) and, in any horizontal position, by the influence of the curves of the vertebral canal.¹⁷

Variations in spinal curvature are only of importance when they influence spread of local anesthetic solutions. Consequently a scoliosis is unlikely to influence spread unless the patient is kept in lateral position. A kyphosis, or a change in the normal lumbar lordosis e.g. in pregnancy is more likely to have an effect because the antero-posterior curves are crucial to the pattern of spread of a hyperbaric solution in the supine patient. Abnormal spinal curvature can be a cause of block failure, particularly if it moves the highest of the lumbar spine in the supine position from its usual level of L4-L5.²⁵

Pregnancy

Many of the physiological changes that occur during pregnancy increase the clinical effect of a local anesthetic injection. Physical spread of the solution can be increased by changes in the lumbar lordosis and in the volume and density of the CSF.²⁷ Cephalad spread is not related to the degree of weight gain during pregnancy,²⁸ but is greater in twins compared with singleton pregnancies. It is perhaps due to an effect on intra-abdominal pressure,or through a progesterone-mediated increase in neuronal sensitivity.^{16, 17, 27}

The mechanisms that may be involved include direct effects on membrane excitability, indirect actions on neurotransmitters, increased permeability of the neural sheath, potentiation of endogenous opioids and potentiation of gamma amino butyric acid-mediated increases in chloride conductance.²⁹

These physical and pharmacological factors add up to a considerable increase in the consequences of an intrathecal injection in the full-term pregnant patient.²⁹

2.1.4.2 Complications of spinal anesthesia

Although spinal anesthesia is considered very safe and effective, all procedures have potential complications.¹³ Spinal anesthesia may be associated with; PDPH, hypotension, backache, systemic toxic reaction, neurological deficit and arachnoiditis of which hypotension and PDPH are most significant.¹³

Hypotension during spinal anesthesia

A decrease of 25% in systolic or mean arterial blood pressure or an absolute decrease of 40mmHg.¹³ Small decreases in pressure are insignificant and may be associated with improved utero-placental blood flow. Rapidly developing hypotension after spinal anesthesia may cause unpleasant dizziness and nausea in about 50% of patients and significantly so compromise the fetus in utero and potentially cause maternal compromise in vital organs.^{13,33}

Management of hypotension during spinal anesthesia

Obstetric patients who have a functional spinal anesthesia should not be maintained in the supine position. The cardiovascular effects of aortocaval compression are least when the patient is in the full lateral position.^{33,37} When this is not practical, left uterine displacement should be achieved using a wedge or by tilting the operating table to the left. Although the optimal amount of tilt is undetermined and may vary among patients, the commonest recommendation taking into account surgical needs and patient comfort is to use 12-15 degrees.³⁷

A bolus of intravenous fluids ("prehydration" or "preload") is commonly administered immediately prior to the administration of spinal anesthesia.

The risk of hypotension may also be reduced by decreasing the dose of local anesthetic and limiting the extent of cephalic spread and sympathetic block.³³

There has been a shift from the long held belief that vasoconstrictors should be avoided following subarachnoid block, because of possible detrimental effect on uterine blood flow³³

There is now a growing body of evidence that alpha-adrenergic agonists (e.g. Phenylephrine and metaraminol) prevent spinal induced hypotension more effectively and results in improved umbilical artery pH.³⁵

Ephedrine appears to contribute to fetal acidosis by crossing the placenta and increasing fetal metabolic activity. Alpha-adrenergic agonists are now preferred, if available, and should be given pre-emptively and titrated to maintain maternal blood pressure near to baseline level.¹³

Post-dural puncture headache

The incidence is 0.5-1% and is often higher in teaching hospitals. Management of PDPH is usually conservative. Treatment of PDPH requires careful consideration of the benefits and risks. Most PDPH will resolve within one week. However, PDPH can be debilitating requiring the mother to remain supine.

Simple symptomatic treatment includes rehydration, non-steroidal antiinflammatory drugs, opioids, anti-emetics and remaining in a comfortable posture may be sufficient treatment for less severe headache. Both the prone position and abdominal binders have been advocated. Both will increase intra-abdominal pressure, which is transmitted to the epidural space and relieves the headache but both are uncomfortable and seldom recommended.

Therapeutic treatment aims to restore CSF volume, seal the dural puncture and prevent cerebral vasodilatation. Several drugs have been tested including, Sumatriptan and caffeine. The recommended dose of caffeine is 500 mg orally or intravenously, once or twice a day (One cup of coffee contains 50–100 mg of caffeine and soft drinks contain 35-50 mg). Sumatriptan is a 5-HT receptor agonist that promotes cerebral vasoconstriction and is used for the treatment of migranous headaches. In persistent cases, saline or blood patches may be applied epidurally. Epidural blood patch is contraindicated if the patient is febrile, has infection at the site of the epidural, coagulopathy or refuses.^{13, 17}

3 RESEARCH QUESTIONS

Is Spinal anesthesia as safe and efficacious as general anesthesia for all the indications for caesarean section?

What is the preference of the professionals at KNH in obstetric Anesthesia?

Is the maternal and the neonatal outcome significantly better with SA compared to GA?

3.1 STUDY JUSTIFICATION

Delivery by caesarean section has become more common in western countries, from 10- 25%, even up to 60%.³⁰ According to KHN records 2006-2008 c/s delivery is estimated to be 33-40%.

Spinal anesthesia is considered the method of choice if the parturient medical condition does not require emergency treatment; though this is not clear with other indications for C/S and in parturients with coexisting diseases like in case of pre-eclampsia / eclampsia! It is therefore, important to find out whether SA is safer than GA in relation to these other conditions in our parturients in KNH.

The effect on neonates is less clear with some studies showing no difference in neonatal outcome between the SA and GA patients and others maintaining that, neonatal outcome is better with SA than GA.³¹

Thus, this study aimed at determining specifically the type of anesthesia that is safer for the neonates in the practice of obstetric anesthesia at KNH irrespective of the indication for caesarean section. Other studies have been done on elective indications for caesarean section, yet it's important to establish the safety of the two techniques with other indications where the neonate is at high risk like in non reassuring fetal heart and coexisting diseases.

KNH is a referral and a training institution; the studies that are available have been done in hospitals where anesthesia is administered by the qualified anesthesiologist. Thus this study is aimed at bringing out the preference of the anesthetist in giving anesthesia to the parturient in relation to the indication of C/S in a training institution.

No similar study has been done at KNH comparing the two techniques of anesthesia in obstetric practice.

3.2 OBJECTIVES

3.2.1General objective

To compare maternal and neonatal outcome for caesarean section done under spinal and general anesthesia in maternity theatre at KNH.

3.2.2 Specific objectives

- To determine the preferred technique of anesthesia in relation to the indications for caesarean section.
- To compare the effects of spinal anesthesia with those of general anesthesia on the maternal outcome of caesarean section.
- To compare the neonatal outcome with the effects of spinal anesthesia and general anesthesia.
- To determine, what type of anesthesia is more efficacious in order to minimize maternal and neonatal morbidity and mortality rates due to anesthesia.

3.3 METHODOLOGY

3.3.1 Study site

This study was conducted in maternity theatre at KNH. KNH is a training institution and a national referral hospital. KNH maternity theatre receives patients from KNH labor ward. These patients include transfers, KNH-clinic attendants and non clinic attendants, and electives of any conditions. Annually, KNH-labor ward on average conducts 8000 deliveries and of these, 2700 parturients are delivered by caesarean section. On average, KNH maternity theatre operates 10 parturients per day.

KNH being a training institution, anesthetic procedures are commonly conducted by registrars under the supervision of a consultant on duty.

Study population

The study population was sampled from the entire population of parturients being delivered by C/S that met the inclusion criteria of this study. It is this sample size that was analyzed statistically to represent the entire population.

Study design

This was a prospective descriptive observational study. All mothers that meet inclusion criteria were included in the study.

3.3.2 Sample size

The sample size was determined by the following formula, by Fisher et al.

$$\frac{t^2 \times p(1-p)}{m^2} = n$$

Description

n =required sample size

t= confidence level at 95% (s² value 1.96)

p= estimated prevalence 15%

m= margin of error at 5% (standard value 0.05)

Calculated sample size

$$\frac{t^2 \times p(1-p)}{m^2} = n$$

$$\frac{1.96^2 \times 0.15(1 - 0.15)}{0.05^2} = 196$$

Thus, **n** = **196**: which is the sample size from the study population.

3.3.3 Inclusion criteria

Only Mothers scheduled for:

- 1. Caesarean section.
- 2. Mothers delivered under spinal or general anesthesia using any anesthetic drug combination and muscle relaxants.
- 3. Willingness to participate and written informed consent, were recruited in this study.

3.3.4 Exclusion criteria

All mothers delivered:

- 1. Under analgesia including, epidural analgesia for pain free child birth.
- 2. Those done C/S with coexisting morbidity of APH, cord prolapse, cardiac disease, renal disease, diabetes, and prematurity, unwillingness to participate and the anxious and very sick patients; were excluded in this study.

3.3.5 Study procedure

Prior to data collection there was a pre-operative visit to all patients scheduled for elective caesarean section and those triaged from labor ward. Pre-operative history was taken prior to surgery to identify any comorbidity prior to the anesthetic exposure. The considered morbidities in pre-operative history were [diagnosed: Headache, backache, neurological disease]. The patients were explained to the purpose of the study, aims, risks and benefits of the study and written informed consent was obtained for all those who participated in this study. Following the recruitment of the patients the patients were followed up to theatre and observed for intra-operative effects and serialized questionnaires were filled for each patient and later followed up in the ward within 24 hours post-operatively. Neonatal assessment after delivery was done guided by a standard and conventional Apgar scale.

Data collection and Data storage

Serialized questionnaires were stored in lockable file cabinets and only the Principal investigator and the statistician had access to them during the study. The data is now being stored as a password- protected document in soft copy.

3.3.6 Data analysis

Analysis of variables was done as per demographic presentation of the study population, Anesthesia type for C/S and the administration, maternal indication for C/S, effects of the anesthesia technique to maternal and neonatal outcome; morbidity and mortality in relation to the anesthesia technique and in the stratified indications for C/S in 24 hours. The data was entered in the computer and analyzed using Statistical Package for Social Science a statistical soft ware version 11.
Analysis involved descriptive statistics like mean and median age, frequency distribution. Statistical significance was sought using Chi-square test [Pearson Chi-square]. Results are presented in Tabular form, pie charts and bar graphs. Multiple regression models were not performed since all the participants in this study were in a stable condition and there was no history of other co- morbidities that were associated with C/S indication in the earlier stratified confounders during the pre-operative visit.

Ethical considerations

Authority was sought from the Ethical and Research committee of KNH/University of Nairobi to conduct the study in the institution and was duly approved. Patients' consent was sought and all records were handled confidentially [Appendices].

4 RESULTS

A total of 196 patients completed the study. These were the initial enrolled participants for the study. In this study group; all patients were done caesarean section under either General or Spinal anesthesia. The observed data from the study was analyzed for both maternal and the neonatal outcome comparing the anesthesia type.

4.1 ANALYSED STUDY RESULTS IN TABULAR AND CHART FORMS:



DEMOGRAPHIC PRESENTATION OF THE STUDY POPULATION

Figure1: Age with anesthesia type:

The mean age for GA was 27.2 years, while SA was 28.8 years. There was no significant difference in mean ages between the groups. (p=0.050). The overall mean age for the study participants was 28.1 years. Median ages of patients undergoing GA and SA was 27 and 28 years respectively.



Figure 2: Anesthesia type versus indications for C/S:

62(60.8%) patients whose indication for C/S was urgent, were done under SA and 40(39.2%) were done under GA. Out of 49 cases whose indication for C/S was immediate, SA was given to 20 patients and GA to 29 patients. Among elective cases, 24(68.6%) were done under SA, while 11(31.4%) were done under GA in the study group. It was statistically significant that SA was preferred by the professionals for C/S compared to GA in this study population (p=0.032).

Anesthetic drugs used for GA



Figure 3: Administration of GA for C/S :

Intravenous anesthetics; Propofol was the induction agent of choice for most of the patients under GA with 80.2%, followed by thiopentone at 16.3%. Ketamine was minimally used at 3.5%.

Table 1: Use of muscle relaxants with IV anesthetic drugs in GA

Muscle relaxant	General anest	Total		
	Thiopentone	Propofol	Ketamine	
Non-depolarizing	0	1	0	1
depolarizing	0	1	0	1
Combined non and depolarizing	14(16.5%)	66(77.6%)	1(1.2%)	81(95.3%)
None	0	0	3	3

Almost all patients done C/S under GA had a combination of intravenous anesthetic drug and muscle relaxants; both depolarizing and non-depolarizing 95.3%.



Figure 4: Administration of SA:

Of 110 patients who were operated on under SA, 96.4% had a combination of LA and opioid given intrathecally; in 3.6% of the patients, there was no addition of an opioid to the LA drug.

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Bolus	Lowest Systolic BP[mmHg] recorded				Total	P-val	
vasoconstrictor	90mmHg	89-51mmHg	≤50mmHg	None			
Yes	15(55.6%)	3(11.1%)	0(0%)	9(33.3%)	27(100.0%)	0.08	
No	26(31.3%)	6(7.2%)	1(1.2%)	50(60.2%)	83(100.0%)		

Table 2: Use of vasoconstrictor intra-operative in SA for Hypotension:

There was no significant association between vasoconstrictor and hypotension during spinal anesthesia in this study (p= 0.084).



Figure 5: Hypotension in relation to anesthesia type:

Hypotension was highly significant in SA with 79.2% in a group of patients whose systolic BP was \leq 90mmHg (p< 0.001).

 Table 3: Use of anti-emetics intra-operative for caesarean section.

Anti-emetics		General Anesthesia n=86	Spinal Anesthesia n=110	Total N=196
	Yes	77(89.5%)	83(75.4%)	160 (81.6%)
	No	9(10.5%)	27(24.5%)	36(18.4%)

There was significant use of anti-emetics in the GA group as compared to SA group (p= 0.010).



Analgesics used intra-operative

Figure 6: Use of analgesics intra-operative versus anesthesia type:

Combined analgesia administration, [opioid and NSAIDs] was statistically significant in the GA group (p<0.001).Use of NSAIDs as a sole analgesic was commonly observed in the SA group.

Maternal out-come in relation to anesthesia type post-operative in 24hrs:



Figure 7: Maternal Morbidity in relation to anesthesia type:

Spinal anesthesia was highly associated with more maternal headache than GA post-C/S (45.5%) (p<0.001).

Neonatal outcome in relation to the anesthesia type



Apgar score at birth

Figure 8[a]: Neonatal outcome: Apgar scores at 1st minute:

Neonatal outcome was significantly better with SA at birth; 100 neonates in a group of 110 had Apgar scores >=7 at 1st minute, compared to GA with 62 out of 86 neonates who scored >=7 (p = 0.020).

	Neonatal Apgar scores						
		At 1 st minute		At 5 th minute			
	Indications for C/S						
Anesthesia type	-	< 7	≥ 7	<7	≥ 7		
GA	Immediate	11	18	6	23		
	Urgent	10	30	2	38		
	Early	2	3	1	4		
	Elective	0	11	1	10		
	Immediate	5	15	2	18		
SA	Urgent	2	60	0	62		
	Early	0	4	0	4		
	Elective	3	21	0	24		

Table 4: Neonatal Apgar scores in all indication for C/S, SA versusGA.

Immediate and urgent indications were the most common indications for C/S in the two study groups. Neonatal outcome for the two groups in these indications was statistically significant in urgent indication for SA p=0.001 and not significant for both GA and SA in immediate. Early and elective were the least common and the neonatal outcome had no statistical significance at 1^{st} minute and 5^{th} minute (p=0.240 and p=0.342) respectively.



Figure 9[b]: Neonatal outcome after C/S immediate indication:

There was no statistically significant difference in neonatal outcome in the two study groups for the immediate indications for C/S (P= 0.343).



Figure 10[c]: Neonatal outcome after C/S in urgent indications:

Neonatal outcome was significantly better at 1^{st} minute with mothers being operated on under SA who had urgent indications for C/S (P< 0.001). At the 5th minute in the GA group 2 failed to improve. In the SA group all the neonates improved their Apgar scores to >= 7 at 5th minute.

Neonatal morbidity post- C/S delivery:

Table 5 [a]: Neonatal complications post-delivery in relation to anesthesia type.

		Anesthesia type			
Complicat	tions:	General Anesthesia(GA)	Spinal Anesthesia (SA)	Total	
	Respiratory Distress	17	6		23
	Others	5	2		8
	None	63	102		164
Total		85	110		195

*Others: [Low birth weight (LBW), congenital malformation]

General anesthesia was highly associated with neonatal respiratory distress post C/S delivery as compared to Spinal anesthesia (p=0.001).



Figure 11[a]: Neonatal admission to NBU after C/S with anesthesia type:

Neonatal admissions to the NBU immediately after delivery was statistically significant with GA group (P<0.001).

Table 6 [b]: Neonatal admission to NBU in all the indications for C/S, SA versus GA.

		Neonatal	admissions to NBU
Anesthesia type	Indications for C/S	Yes	No
GA	Immediate	10	19
	Urgent	10	30
	Early	2	3
	Elective	0	11
SA	Immediate	3	17
	Urgent	3	59
	Early	1	3
	Elective	1	23

More Neonatal admissions to NBU in the two groups predominantly occurred in the immediate and urgent indications.

5 DISCUSSION

In this prospective descriptive, observational study; there was a fairly equal age distribution of patients in the two groups of anesthetic technique used. The mean age for both techniques was 28.09 years with a standard deviation of 5.4. Age did not correlate with the type of anesthesia for C/S.

Regional anesthesia is recommended for most caesarean sections due to the risk of failed intubation and aspiration associated with general anesthesia. The type of anesthesia used and the care and competence with which it is administered is an important determinant of the outcome of caesarean section.^{2,3}

Caesarean section is most commonly performed under regional anesthesia in the United Kingdom, USA and Australia. In the UK in 1997, for example, a survey of obstetric units found that of 600, 455(78%) caesarean sections, were performed under regional anesthesia. 72% of the emergency caesarean sections were also performed under regional anesthesia.⁵

At the RWH in Melbourne in the year 2000, 12% of caesarean sections were performed under general anesthesia whilst 88% were done under regional anesthesia. In the U.S.A in particular, SA was used for caesarean section in over 80% of the cases as at 1992, regardless of the indication.⁵

In this study, out of 196 patients who had C/S, 43.9% were performed under GA. while 56.1% were under SA regardless of the indication for the C/S.

The indications for caesarean section in this study, were classified (WHO) as; immediate, urgent, early and elective indications. From the data, SA was performed in 40.8%, whilst GA 59.2% in the group of immediate indications for C/S. This shows a tendency of the anesthetists to prefer GA in cases of emergency C/S. For urgent indications, SA was done in 60.8% out of 102 cases. SA was also a predominant choice with elective indications: Out of 35 cases, 24 were performed under SA. In this study, the overall preference of anesthesia for C/S was directed at SA [p=0.032].Even some mothers who needed C/S for immediate and urgent indications were operated on under SA. This is in line with other studies that, spinal anesthesia for C/S is the current choice of anesthesia if no absolute contraindication in the mother exists.

In cases of immediate indication Grade I; immediate threat to life of mother or baby (1-10 minutes) as in acute fetal distress; GA is the anesthetic of choice

Grade II; Maternal or fetal compromise which is not life threatening

(10-30minutes) SA is the anesthetic of choice.³²

When the condition of the mother or fetus is in immediate jeopardy, caesarean section should not be delayed by waiting for a spinal anesthetic to take effect. Instead GA should be given.³³

There is vast experience with thiopentone, and it is currently the induction agent of choice for C/S. Propofol is an alternative agent. However, in some studies, propofol was reported to be associated with more maternal hypotension, possibly increased risk of poor neonatal Apgar scores.^{17,33} Ketamine also has a place in C/S. The current muscle relaxant for rapid sequence intubation in C/S is suxamethonium.

For the 86 patients that had C/S under GA, the following drugs were used for induction; Thiopentone, Propofol and ketamine. Propofol was the most commonly used agent of the three 80.2% followed by thiopentone 16.3% and ketamine was used in only 3.5%. The intravenous agents for C/S were combination with muscle relaxants both depolarizing used in (suxamethonium) non-depolarizing (Atracurium besvlate and or Cisatracurium) in 95.3%. Three (3) Of the cases operated on under GA did not get a muscle relaxant during C/S. These cases were those converted to GA after 'failed' spinals. SA was assumed to have worked but intraoperatively the patients complained of pain. There were two (2) cases that got either [depolarizing/non-depolarizing] muscle relaxants because lumbar puncture failed and no LA was injected intrathecally

Significantly higher use of analgesics and a combination of opioids and NSAIDS in each case (71 of 82 cases) was associated with cases performed under GA (p=0.010). Use of a single analgesic was limited to only a few cases in this study group; opioids 9.3% and NSAIDs 7.0%. 89.5% of cases in the GA group got anti-emetics as compared to 74.5% in the SA group (p=0.010)

This study reveals that, significantly higher number of anesthetists used a combination of local anesthetic and an opioid (96.4%) for spinal anesthesia.

The administration of SA observed in this study is in line with other studies. The addition of an opioid allows for the safe reduction of the local anesthetic dose with equal success and less severe side effects. Ultra low doses such as 5mg of bupivacaine with 25 micrograms of fentanyl have been reported to be adequate.³⁴

The use of analgesics in SA group was less compared to GA cases. Combined analgesics were used in 20 % of the cases in this group. Use of NSAIDS as a sole analgesic was higher 46.4% as compared to GA group. 1.2% of the cases in GA group did not get analgesic, whilst 22.7% in SA were done without added analgesia.

NSAIDs are now very popular for post-C/S analgesia, mainly as adjuncts to intra-spinal opioids.³³ This gives the impression that, spinal anesthesia gives better post-op analgesia and less costs to the patients compared to GA. One case in the GA group that was not given analgesics was a case of failed spinal. Presumably this patient had adequate analgesia with the failed spinal.

Intra-operatively maternal effects were observed in the two anesthetic groups. The effects that were considered in our study were; Hypotension of systolic BP Less than or equal to 90mmHg, resuscitation, vomiting, and skin rash following drug administration in both techniques. However, our data revealed that the commonest side effect from the two groups was hypotension and this was significant in the SA group (p<0.001). In the SA group 47.3% had BP recorded Less than or equal to 90mmHg as compared to 14% in the GA group.

The use of a vasoconstrictor in this study did not significantly correlate with the effect of hypotension (p=0.084). Of the 52 cases that got hypotension, only 27 cases got a vasoconstrictor. This is explained by the fact that, the

Medication was being given as treatment and not as prophylaxis which would have been the best method and the one recommended to prevent the effect.¹⁷

Our finding is in agreement with other studies that; hypotension is the most common adverse event when spinal anesthesia is used for caesarean section. The quoted incidence varies depending on the definition and technique and has been estimated to be as high as 80% (without preventive measures).³⁵ Most studies define hypotension as a mean systolic pressure of 70-80% of baseline or an absolute systolic pressure of less than 90-100 mmHg.

In our study, it's the absolute systolic pressure that was defined. We considered the lowest recordings in systolic BP of \leq 90mmHg intraoperatively. The incidence of hypotension in the SA group was 47.3% which is lower than that reported in most of the studies. This is due to the fact that there was active use of intravenous fluids before the administration of LA intrathecally which is also recommended in controlling hypotension during SA. However, the use of a vasoconstrictor in this study did not show any association with hypotension.

A bolus of intravenous fluids ("prehydration" or "preload") is commonly administered immediately prior to the administration of neuraxial anesthesia. However, studies investigating the efficacy of prehydration for preventing hypotension have had conflicting results, partly because of differences in anesthetic technique and the types and quantities of fluids. Intravenous infusion of one liter of lactated Ringer's solution was shown to decrease the incidence of both hypotension and fetal heart-rate abnormalities. "This benefit is not seen with more recent low-dose techniques, probably because the risk of hypotension is smaller".³⁶ The incidence of hypotension was not changed by prehydration with crystalloid prehydration at volumes of 7 ml/kg.^{37, 38}

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In our study, it was observed that crystalloids and colloids (lactated Ringer's solution, 0.9% normal saline, and gelatin polysuccinate) are the most commonly used intravenous fluids.

A prophylactic infusion of phenylephrine 100mcg per min can be used. Ephedrine has been shown to increase fetal acidosis but is a reasonable option where alpha agonists are not available.³⁹

Any fall in maternal blood pressure will be accompanied by reduction in uteroplacental blood flow, therefore, compromising fetal well-being. Further falls in maternal blood pressure will severely jeopardize maternal safety.³⁵

The maternal complications as defined in our study included: Headache, Backache, Generalized pain, ICU admission and intra-operative maternal death or maternal death within 24 hours of surgery.

Of the 196 study participants 53 of the cases developed headache post-op. The majority of these were in the SA group (50 cases); The 3 cases in the GA group that got headache, had failed spinal blockade and were converted to GA.

Potential disadvantages of SA include hypotension and PDPH. PDPH still occurs in SA as in line with our studies. The risk of a headache after spinal anesthesia is reduced to roughly 1:200 with the use of small-gauge (G26 0r 27) pencil-point needles.³³

Our data reveals that, there was higher neonatal Apgar score in the SA group. Out of 196 neonates in total; 100(51%) at birth scored \geq 7, in contrast to GA 62(31.6%) scoring \geq 7 (Figure 8[a]) (p<0.001).

There was one still birth in the GA group, though this was noted to be dead prior to the anesthetic exposure; but after the patient had been recruited in the study.

Neonatal outcome amongst the indications for C/S for both groups; immediate and Urgent indications were taken to be the indicators since the C/S in these conditions are considered emergencies requiring delivery from as low as 1- 10minutes and between 10-30 and 30-60minutes, (ASA and WHO) descriptions.^{17,41}

In urgent indication for C/S: Neonates delivered in this condition showed significantly better scores in the SA group, both at birth and at 5th minute.

To the contrary; neonatal Apgar score among the immediate indication mothers (figure 9[c]), showed little difference between the two groups, both at birth and the 5th minute. Early and Elective indications accounted for a very small percentage in the study population and the neonatal outcome was statistically not significant (table 6).

Significantly higher neonatal admission to NBU in the time defined was associated with GA. There were 22 admissions of which, 77.3% were due to respiratory distress and needed bag-mask ventilation during neonatal resuscitation at delivery and did not improve at the 5th minute. One neonate was admitted to NBU due to congenital malformations and four due to Low Birth Weight(<2500gm birth weight) (Table 6). In SA group, 8 admissions were observed and respiratory distress accounted for 6 neonates and 2 due to low birth weight. Similarly admissions to NBU were significant with the urgent indications for C/S being associated with GA. However, immediate indications still, there was little difference for the two groups.

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Comparative studies have been done comparing the neonatal outcome for the two anesthetic techniques and our findings are in agreement with other international findings.⁴²

Spinal anesthesia is not without neonatal complications as observed in this study and other related studies elsewhere, fetal distress in these patients is being associated with maternal hypotension that commonly occur during SA. Hypotension may exacerbate fetal acidemia. In a large epidemiological study the frequency of neonates with a pH<7.10 (biochemical evidence of significant asphyxia) was significantly higher with SA and associated with blood pressures severe hypotension prolonged over two minutes and increased use of vasopressors.³³ Prolonged hypotension of 5minutes or more or profound falls of systolic BP70mmHg or less may lead to fetal heart changes and poor Apgar scores or neurobehavioral impairment.³³

6 CONCLUSIONS

This study has demonstrated that Spinal anesthesia was significantly used as the anesthetic of choice (56.1%) by the anesthetists in the obstetric practice at KNH maternity theatre as compared to general anesthesia (43.9%). This is in agreement with the international guidelines in obstetric anesthesia for maternal and neonatal safety. Neonatal outcome assessed by Apgar score at birth was significantly higher with SA and early establishment of sustained respiration was better in SA at the 5th minute. General anesthesia was significantly associated with the neonatal NBU admission due to respiratory distress as compared to Spinal anesthesia.

Spinal anesthesia is significantly safer for neonates especially those whose fetal heart is compromised. However, side effects of anesthesia such as hypotension and headache are highly associated with Spinal anesthesia and the use of systemic analgesics was greater with General anesthesia.

For both groups no maternal death was recorded or severe morbidities like maternal ICU admission and resuscitation intra-operatively. Thus spinal anesthesia and general anesthesia are both effective for C/S, but with significant differences in maternal and neonatal outcome.

RECOMMENDATIONS

- Spinal anesthesia should be the preferred method for obstetric anesthesia.
- Measures should be put in place to reduce the incidence of hypotension during C/S under spinal anesthesia. Routine Left uterine displacement should be applied to all patients after spinal anesthesia. A combination of therapies, e.g. intravenous fluid pre-hydration (Crystalloids and colloids) and prophylactic vasopressors are more effective in preventing hypotension than single therapy.
- Availing small spinal needles like, Quincke needles 26/27G and atraumatic needles(Whitacre), for subarachnoid blocks to reduce incidence of PDPH.
- Guidelines should be formulated to guide the anesthetist in giving mothers the chance to benefit from spinal anesthesia hence improving on maternal and neonatal outcome.
- Spinal anesthesia is the most suitable and safest for both maternal and neonatal outcome if there is no maternal contraindication or refusal.

7 APPENDICES:

Appendix 1: Grading of urgency of caesarean section.41

I Immediate threat to life of mother or baby 1-10 minutes GA

II Maternal or fetal compromise which is not life threatening: 10-30 minutes Regional

III Needing early delivery but no maternal or fetal compromise. 30-60 minutes Regional

IV At a time to suit the patient and staff 1-24 hours Regional.

In contraindication of regional anesthesia, the failure of regional anesthesia and when there is a need for urgent delivery within 10 minutes

Appendix 2: Apgar Scale

Definition

it's a simple and effective method used to measure the newborn's health and to determine if the baby needs any immediate treatment. The Apgar scale is a measure for evaluating the condition of a newborn baby. *The five test criteria*: Appearance, Pulse, Grimace, Activity, and Respiration, form an acronym named after anesthesiologist <u>Virginia Apgar</u> who first introduced this type of testing on newborns in 1953.⁴⁴.

The five categories in the <u>Apaar Scale</u> (or <u>Apaar Test</u>) are evaluated using the following criteria:

SIGN	POINTS	;	
	0	1	2
<u>Appearance</u> * (color)	Pale or Blue	Body <u>pink</u> : <u>extremities</u> blue	Pink
<u>Pulse</u> (heartbeat)	Not detectable	Below 100	Over 100
<u>Grimace</u> (reflex irritabili	No response to ity) stimulation	Grimace	Lusty cry
<u>Activity</u> (muscle tone)	<u>Flaccid</u> (no or weak activ	Some movement ity) of extremities	A lot of activity
Respiration (breathing)	None	Slow, irregular	Good
*In non-white children, color of <u>mucus membranes</u> of mouth, of the whites of the eyes, of lips, palms, hands and soles of feet will be examined			

Most newborns score between seven and 10 and don't need any immediate treatment, such as help with breathing. Babies who score between eight and 10 are in good to excellent condition. Those who score between five and seven are in fair condition and may require some help with breathing. Infants who score under five may be in poor condition and require some help. The Apgar score is used beyond five minutes for babies with low scores, until the baby is in a good and stable condition.⁴⁴ There is some evidence that low scores at the five minute mark may be associated with a greater risk of problems, such as cerebral palsy The Apgar scale's beauty is its simplicity, it's easily performed and quickly and accurately measures the baby's health during the first moments of life outside the uterus.⁴⁴

Appendix 3: CONSENT EXPLANATION

My name is Dr Mukunzi Rosemary. Anesthetist registrar of the university of Nairobi at KNH in the department of anesthesia .I am doing a study, which is part of the award of Mmed in anesthesia UON and am yet to explain to you the proceeding;

Study: Maternal and neonatal outcome following C/S under SA versus GA in KNH maternity theatre.

Anesthesia. This is where a drug is given to the patient in order to take away the feeling of pain and other sensations stopped. This allows patients to undergo surgery and other procedures without the distress and pain they would otherwise experience. It's a reversible sate.

Purpose of study: This study is aimed at determining the anesthesia that is suitable for C/S in order to improve the condition of the mother and the baby after birth by Caesarean section since this way of delivery is meant to save both the mother and the baby.

Types used:

Spinal anesthesia: Is the most commonly used type for C\S, the drug is administered in the back using a needle designed for the type of anesthesia. The needle is introduced into the back and the medicine is pushed through it and then it reaches the area of action.

Risks of SA anesthesia

The commonly risks associated with spinal anesthesia are; headache after surgery, low blood pressure and the drug getting far from the expected area.; Others are; backache, neurological deficit,; these are rare conditions. The rick of headache and low blood pressure are manageable and when they occur they are not fatal.

General anesthesia.

The drug to induce the sleep is given through the vein that reaches the brain and patient goes in intended coma which is reversed after surgery. The patient is not controlling any part of her body. It's the anesthetist controlling the life of the patient. Patient is assisted to breath during GA by putting a breathing tube in the lungs that connects the patient to the machine to breathe for the patient.

Risks of GA in the mother; are associated with; difficult to put the tube in the lungs, and thus it goes through the stomach which can result into; aspiration of stomach contents, lack oxygen and then damage to the brain. Awareness during anesthesia may occur. When these complications occur they are very severe and fatal. It offers poor pain relief and the ambulation time is delayed. All these drugs cross the placenta and affect the baby prior to delivery.

Benefits

The advantages of spinal is that; one remains awake, gives adequate pain relief; thus enabling early ambulation and interaction of the mother with the baby. It has been found that, spinal gives the best outcome of the newborn with no associated respiratory problem of which every mother would love.

Compensation

There will be no compensation for study participation: The participation in this study is voluntary and you can decide to withdraw at any stage. The study is non-invasive and there will be no extra cost encountered due to the participation.

There is no interference or influence on management to the patient in the favor of this study at any point.

This study is conducted with the approval of the Kenyatta National Hospital Scientific and Ethical Committee

Confidentiality

Your identity will be protected with utmost confidentiality during the study and only initials will be used in reference to the participants included in this study. Consent form.

I -----I have understood the explanation of this study:

Maternal and neonatal outcome following C/S under SA versus GA in KNH maternity theatre.

I freely choose to participate in this study and I understand that whether or not the participation will not affect the management that I and my child to receive. I understand that at any point I can choose to withdraw from the study.

Signed	Date:
Jighed	

Investigator statement:

I Dr Mukunzi Rosemary, I certify that, I have fully explained to the patient; the study all about, the benefits and risks that are likely to occur. I have given room for questions and I, answering the questions satisfactorily to the patient. The patient has willingly consented to participate in this study and to with draw at any time.

MY NAME: DR MUKUNZI RM

Signature.....

Appendix 4: QUESTIONAIRE

MATERNAL AND NEONATAL OUTCOME FOLLOWING C/S UNDER SPINAL VERSUS GENERAL ANESTHESIA IN KNH MATERNITY THEATRE

Identification of the parturient
Name
File №
Date of birth (Age)
Occupational: Farmer Cival worker
Pre-Operative History:
History of: Headache Back pain
Diagnosed neurological disease;
pre-eclampsia /eclampsia others None
Indication of Caesarean (<i>classifications</i>)
Immediate Urgent Early
Elective
Type of anesthesia used; Spinal anesthesia (SA)
General Anesthesia (GA) Failed SA
General Anesthesia
Induction agent: Thiopentone propofol Ketamine

65
Muscle relaxant: Yes No
Long acting Intermediate Short
Regional Anesthetic
Agents used; L A drug only
Plus Vasoconstrictor
Bolus Vasoconstrictor
Plus opioid,
Anesthesia Intra-operative:
USE OF:
Analgesia 1.Opioids 2. NSAIDs anti-emetics
Effects of anesthesia to the mother:
Skin rash 🗌 Vomiting 🛄 Systolic; BP 90mmHg 🗌
89 -51mmHg C <=50 mmHg vomiting
Resuscitation None
Neonatal out-come post-C/S
At 1 st minute: Apgar 0 \bigcirc <7 \bigcirc ≥7 \bigcirc
5 Th Minute : $<7 \square \ge 7 \square$

Morbidity a	and Mortality	post-op	in 24hrs
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Morbidity

Maternal out-come
Backache Headache Generalized pain ICU Admiss
None
Neonatal out-come post -op
NBU Admission due: 1. Respiratory Distress
2. Others 3 None
Mortalities
Maternal;
Intra-operatively Post-operatively None
Neonatal ; Still Birth At 1 st minute At 5 th minute None

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Ref: KNH/UON-ERC/ A/203

Dr. Mukunzi Rosemary Dept. of Surgery School of Medicine <u>University of Nairobi</u>

Dear Dr. Mukunzi

Research proposal: "Maternal and Neonatal Outcome Following C/S under Spinal versus General Anaesthesia in KNH Maternity Theatre" (P281/10/2008)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and <u>approved</u> your above revised research proposal for the period 21st April 2009 –20th April 2010.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimen must also be obtained from KNH-ERC for each batch.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

PROF. A N GUANTAI SECRETARY, KNH/UON-ERC

c.c. The Chairperson, KNH/UON-ERC The Deputy Director CS, KNH The Dean, School of Medicine, UON The Chairman, Dept. of Surgery, UON Supervisor: Dr. Gacii Mark, Dept.of Surgery, UON