A COMPARISON OF TWO REGIMENS OF SINGLE-SHOT SPINAL BLOCK FOR THE RELIEF OF PAIN DURING LABOR AND DELIVERY.

A DISSERTATION PRESENTED IN PART-FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN ANAESTHESIOLOGY.

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A COMPARISON OF TWO REGIMENS OF SINGLE-SHOT SPINAL BLOCK FOR THE RELIEF OF PAIN DURING LABOR AND DELIVERY.

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DECLARATION

This dissertation is my original work, and to the best of my knowledge, has not been submitted for any degree in any other university.

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This dissertation has been submitted for the award of the degree of Masters of Medicine in Anesthesiology with our approval as university supervisors.

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Oh God thank you for the life, health and energy you gave to me during these hard times.

To have achieved my professional goals, has not only been because of my inbuilt abilities but also because I have had the opportunity to have met great people who contributed to my life with knowledge and words of encouragement:

My thanks and appreciation to Dr Patrick R. Olang for persevering with me as supervisor throughout the time it took me to complete this research and write the dissertation. This has been accomplished through his great ability and inspiration towards advanced research.

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To my family, "your support, assistance and prayers have helped me reach this far – thank you all".

To my friends and colleagues, "your support throughout this course has been greatly appreciated.

My special thanks to Michelle Hassan her assistance in statistical analysis.

"May god bless you all".

DEDICATION

I lovingly dedicate this study to my wife Geovanie Mbuyu Ntambwe and my daughter Brittanie Bodika Ntambwe. "May the two of you find gratitude your sacrifice through the achievement".

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LIST OF ABBREVIATIONS:

BMI: Body Mass Index

BP: Blood Pressure

Cm: Centimeter

ERC: Ethics and Research Committee

FB: Fentanyl-Bupivacaine

FBM: Fentanyl-bupivacaine-Morphine

Ht: Height

Kg: Kilogram

KNH: Kenyatta National Hospital

L1: 1st lumbar vertebra

Mg: milligram

Min: minutes

Ml: milliliter

Mm: millimeter

RR: Respiratory Rate

S2: 2nd sacral vertebra

T10: 10th thoracic vertebra

VAS: Visual Analog Scale

Wt: Weight

µg: Microgram

Yrs: Years

ABSTRACT.

Background/Introduction:

Most women experience moderate to severe pain during labor and delivery, often requiring some form of pharmacologic analgesia. The lack of proper psychological preparation combined with fear and anxiety can greatly enhance the patient's sensitivity to pain and further add to the discomfort during labor and delivery. However, skillfully conducted obstetric analgesia, in addition to relieving pain and anxiety, may benefit the mother in many other ways.

The old perception of "the true African woman" was of one able to withstand labor pain and deliver spontaneously. Those who for one reason or another ended up delivering through caesarian section were looked down upon. Over time, the perception of labor pain has been influenced by many factors and most women in Africa will now opt for pain relief during labor if it is available.

Non-pharmacologic analgesic techniques and systemic analgesia can be used for the relief of pain during labor. However, neuraxial analgesia, particularly epidural techniques, are the most effective methods available today[1].

Objective:

To assess and compare the satisfaction and efficacy of two regimens of single-shot spinal blocks for the relief of labor pain in women who present in active labor.

Design:

This was a prospective randomized single-blind interventional study in which two regimens of spinal analgesia for labor were used at The Kenyatta National Hospital in Kenya.

Research Methodology:

All consenting primiparous women presenting in active labor with uncomplicated singleton pregnancy at term (> 36 weeks) in the vertex position who report a > 70 mm VAS (Visual Analog Scale) pain score at cervical dilatation ≥ 5 cm at the time of request for labor analgesia were recruited into the study. 48 patients were included in each of the two groups.

We hypothesized that spinal analgesia with the addition of preservative-free morphine to a solution with bupivacaine and fentanyl would prolong analgesic effect over that of bupivacaine/fentanyl alone and that this technique would provide an effective means of pain relief during labor.

Data was collected on a pretested data sheet and analyzed using Statistical Package for Social Scientists (SPSS) software version 16.0. The results were presented in the form of tables, graphs and charts.

Results

The single shot spinal analgesia was performed in 105 parturients, 57 in FB and 48 in FBM groups. Three parturients from the FB group were excluded because they underwent caesarian section due to obstetric indications after successful single shot spinal analgesia while 6 others were left out after randomization.

Demographic maternal baseline data didn't show a significant statistical difference between the two groups. Though we had a significant statistical p-Value for the cervical dilation at the initiation of the injection, this didn't have any clinical significance during the progress of labour and outcome of the fetus.

Parturients from the FB group had pain relief for about 2 hours with higher incidence of breakthrough pain, while in the FBM group pain relief was for more than 3 hours (until delivering time).

Hence we had 81.2% in FBM group very satisfied against 31.3% in FB group, this can be explained by the short duration of analgesia among the FB parturients.

The rate of complication was higher in FBM but was all mild and no medication was required, only hypotensive parturients received boluses of ephedrine. At the time of delivery, the Apgar score at 1 minute was lower in FBM group but at 5 minutes there was no significant difference between the two groups.

CHAPTER ONE

INTRODUCTION

The pain of childbirth is the worst pain most women will ever experience in their entire lives. Pain relief in labor is still considered an 'option or a luxury' especially in developing countries. Mothers-to-be can 'enjoy their labor' by educating themselves about the types of pain relief they can choose from and by taking advantage of what modern medicine has to offer. Numerous myths and misconceptions persist about the modern labor analgesic techniques. The belief that these techniques are an 'easy way out' that compromises the safety of both mother and child has made most mothers-to-be feel guilty for asking for pain relief in labor.
Epidurals and spinals are the most effective and reliable means of labor pain relief. They are not only safe for most mothers and their babies but those who do not use them may be exposing themselves to unnecessary risks which are not usually considered.

LITERATURE REVIEW

Non-pharmacologic analgesic techniques and systemic analgesia can be used for the relief of pain during labor. However, neuraxial analgesia, particularly epidural techniques, is the most effective methods[1].

Access to epidural analgesia for laboring women in developing countries can be challenging and is often impossible. Intramuscular opiates can be used but these too are not always available, with analgesic care often limited to maternal back massage and deep breathing techniques. Limited pharmacologic resources and inadequate numbers of trained healthcare workers available to provide analgesic services leave many women in these countries with inadequate to no pain relief.

Although the perception of labor pain can be affected by many factors including age, educational status, ethnic background, parity, and individual pain threshold, [2–3] Onah and Kuti demonstrated that the majority of Nigerian women perceived labor as severely painful and would be receptive to pain relief.[4–5]

Whereas continuous epidural and combined spinal-epidural analgesia are the most commonly used methods in developed countries for the relief of labor pain, some studies have shown that single-shot spinal analgesia can provide satisfying pain relief and might be adopted for use in areas with limited resources. Rust et al. [6] administered intrathecal fentanyl, morphine, and Lidocaine to 90 consecutive laboring patients and found that 84 (93%) reported excellent pain relief. Kuczkowski and Chandra[7] investigated the maternal satisfaction of Indonesian parturients who received single-dose spinal analgesia with bupivacaine, morphine, and clonidine during labor. They found that 81% were 'very satisfied' and 11% were 'satisfied' with their analgesia. Viitanen et al.[8] studied 671 multiparous women who received spinal analgesia with low dose bupivacaine and fentanyl during labor and concluded; "single-shot spinal block is a viable method of pain relief in most multiparous women in active labour."

Although pain relief from single shot spinal techniques can be effective, it may often be of insufficient duration to last the length of labor. Two further studies have addressed the duration of spinal analgesia for labor as part of a combined spinal-epidural technique. Yeh et al. found that the addition of 150 μg of morphine sulfate to a combination of intrathecal bupivacaine 2.5 mg and fentanyl 25 μg prolonged the request for epidural activation for analgesia from 148 min to 252 min.[10] Hess et al. in a similar study design, showed that the addition of morphine 125 μg to a mixture of intrathecal bupivacaine 2.0 mg and fentanyl 12.5 μg failed to prolong spinal analgesia significantly beyond 80 min when administered as part of a combined spinal-epidural technique.[11]

In a study using intrathecal morphine as the sole analgesic for labor, Scott P.V. et al concluded that intrathecal morphine could abolish the pain of labor, whether spontaneous or induced, while preserving the mother's full awareness of labor and her co-operation in the second and third stages of labor[12].

Minty RG et al, in a review to establish the safety and efficacy of single-dose spinal analgesia during labor concluded that modern obstetrics in rural and small urban centres might find single-dose intrathecal narcotics a useful alternative to parenteral or epidural analgesia for appropriately selected patients[13].

In a study to determine the duration of intrathecal labor analgesia instituted early (3-5cm) versus late (7-10cm cervical dilatation), Viscomi et al concluded that cervical dilatation and stage of labor significantly impacted the effective duration of intrathecal sulfentanyl/ bupivacaine labor analgesia[14].

STUDY JUSTIFICATION/RATIONALE

Pain is a completely subjective sensation, so no one else can judge how much or how little the pain is.

Access to epidural analgesia for laboring women in developing countries can be challenging and is often impossible. Intramuscular opiates can be used but are not always available or efficacious. Analgesic care is often limited to maternal back massage and deep breathing techniques. Limited pharmacologic resources and inadequate numbers of trained healthcare workers available to provide analgesic services leave many women in these countries with inadequate to no pain relief.

Although continuous epidural and combined spinal-epidural analgesia are the most commonly used methods in developed countries for the relief of labor pain, some studies have shown that single-shot spinal analgesia can provide satisfying pain relief and might be adopted for use in areas with limited resources.

Clinical importance

The pain of childbirth which has been characterized as the most severe type of pain is made of visceral and somatic pain.

The visceral type of pain originate from uterine contraction and cervical dilation Involving the thoracic and lumbar vertebrae T10 – L1; the somatic due to pressure by the descending fetal head on the pelvic floor of the vagina and perineum involves the pudendal nerve (sacral vertebrae S2-4) [15]

Some insight has been given into the genetic component of the analgesic response to intrathecal opioids given in labor. Ruth L at al showed that while the way to routine genetic testing to guide analgesic therapy is still a long one, a true pharmacogenetic effect of the μ opioids receptor gene has been demonstrated that explains differences in analgesic requirement observed routinely in obstetric anaesthesia practice.

A significant increase in sensitivity to the analgesic effect of intrathecal fentanyl in laboring women carrying a common variant of the μ opioids receptor gene was shown.[17]

This is clinically relevant with a need to reduce doses and minimize opioids related side effects as optimal labor analgesia remains a challenge.

OBJECTIVES

Broad Objective:

To compare two regimens of single-shot spinal block for pain relief during labor.

Specific Objectives:

Among women undergoing single-shot spinal block for labor analgesia for vaginal delivery at The Kenyatta National Hospital and Kijabe Mission Hospital labor wards, to:

- Evaluate the effectiveness of the two regimens of spinal block in pain relief during labor.
- Determine the incidence of side effects associated with the two regimens used for labor pain relief
- Assess patient satisfaction with the pain relief provided by the two regimens.
- Compare duration of labor analgesia provided by the two regimens.

Secondary Objective:

To determine the factors which may influence the level of satisfaction with the mode of analgesia used.

Postulated factors include:

- delayed access to pain relief
- Duration of labor outlasting duration of pain relief
- Inadequate analgesia throughout labor

STUDY DESIGN

Prospective, randomized, single-blind, interventional study.

STUDY AREAS AND POPULATION

The study was conducted at the labor wards of Kenyatta National

Hospital in Kenya. Kenyatta National Hospital is Kenya's premier Teaching and Referral Hospital situated in Nairobi with a 21 bed labour ward and two delivery rooms each with two delivery couches. It handles 6800-7500 deliveries annually. The study population included all healthy primiparous patients in labor expected to undergo spontaneous vertex delivery (SVD).

ELIGIBILITY CRITERIA

Inclusion criteria.

All consenting primiparous women in active labor:

(a) With uncomplicated singleton pregnancy at term (> 36 weeks) in the vertex position who report a > 70 mm VAS score at cervical dilation ≥ 5 cm at the time of request for labor analgesia.

(b) Whose labor pain began to return after successful spinal analgesia, prompting a request for rescue medication

Exclusion Criteria

All women in active labor:

a) Who declined to give consent for the study
b) Who were multiparous
c) Who ended up with cesarean delivery

d) Who had maternal hypertension, diabetes, obesity (BMI > 30), multiple pregnancy or allergy to the analgesic medications.

e) Who failed to achieve labor analgesia after spinal block

f) In whom dura puncture failed

MATERIALS, METHODS AND DATA COLLECTION

All primiparous women in active labor who met inclusion criteria were asked to participate in this study. At the time of labor analgesia request, patients were randomized to receive one of 2 intrathecal regimens: (A). 25 ug fentanyl, 2.5 mg plain Bupivacaine and normal saline to bring volume of mixture to 2 mL; (B). 25 ug fentanyl, 2.5mg plain bupivacaine, 150 ug preservative-free morphine sulfate and normal saline to bring the volume of the mixture to 2 mL. We recorded the maternal age, height, weight, important medical conditions, cervical dilatation at the time of request of spinal block, use of oxytocin augmentation and amount, fetal weight, and Apgar scores.

All women who consented to participate in the study received 500 mL of intravenous (I.V.) balanced salt solution (Ringer's lactate/Hartmann's solution or Normal saline) prior to block initiation. Spinal block was performed at either L_{3-4} or L_{4-5} interspaces, with the parturient in the lateral or sitting position. A 25G Quincke point spinal needle was used, and one of the 2 intrathecal medication regimens was injected after randomization. After performance of the spinal block, the parturient was placed in the lateral position with the bed at a slight head-up angle. After 5 min, the parturient was asked to take the opposite lateral position. The following spinal block details were recorded: patient position at the time of spinal block, puncture interspace and the anesthetist performing the block.

Maternal vital signs (blood pressure, heart rate, and respiratory rate), pain score, and cervical dilatation were recorded before the spinal block. After spinal injection, vital signs, pain score, sensory level to pinprick, motor blockade, and side effects(pruritus, nausea, vomiting, and

sedation) were evaluated at 5, 10, 15, 30, 45, 60 minutes and then every 30 minutes until the end of the spinal analgesia.

As each technique has advantages and disadvantages, regional anesthesia as in the case of spinal anesthesia, according to studies published in the American College of Obstetricians Gynecologists in 2002 is associated with hypotension in 67%, postdural puncture headache 37%, transient painful sensation in the buttocks or lower extremities 7%, transient fetal heart rate decrease 8%.[16]

Hypotension (defined as a > 30% drop in systolic BP) was treated with intravenous ephedrine (5-10mg boluses) and/or intravenous fluid bolus of 250-500mL of balanced salt solution and the treatment means recorded. Motor block was graded using the modified Bromage Scale described by Breen et al. [9] as follows: 0 = no movement; to 6 = no detectable weakness of hip flexion. Evaluation of side effects was a direct questioning on a 4 point scale at each interval rated as "none, mild, moderate, severe."

Visual analog scale (VAS) was used to assess pain intensity ranging from 0 mm for no pain to 100 mm for worst pain imaginable. Pain scores were recorded during a uterine contraction. A successful spinal analgesic block was defined as reduction of pain score to < 20 mm. The end of analgesia was defined as the time when VAS returns to > 50 mm or at the time of request for rescue medication after onset of successful analgesia. Patients who did not achieve a successful block were dropped from the study. At the time of request for rescue medication, a repeat block was offered one time utilizing the same study drug as used for the first injection, with a second set of data collected. Where the block was not repeated, the type and amount of rescue analgesics was recorded. Rate of cervical dilatation was calculated from the time of block placement until the time of full dilatation. Parturients were asked to rate the adequacy of their pain relief using a 4 points scale after delivery: 'not adequate', 'moderately adequate', excellent', or 'unable to say'. If the pain relief was inadequate, the reason was recorded (1. too little relief during time of blockade, 2. no relief achieved, 3. analgesia ended before the second stage of labor, 4. spinal given too late in labor). Overall satisfaction was assessed following delivery utilizing a 5 point scale (very satisfied, satisfied, no comment, unsatisfied, very

unsatisfied). Patients were also asked if they would have a spinal block again, if this form of pain relief became available. Postpartum pain relief was as per the current hospital protocol. Patients who underwent delivery before the end of successful analgesia or who delivered by cesarean section were excluded from analysis.

The primary outcome was the length of time from drug injection until the end of spinal analgesia. Normally distributed variables were compared utilizing Student's T-test. The Mann-Whitney *U*-test will be used for non-normal distributions. A Kaplan-Meier analysis was used to compare the cumulative proportion of adequate intrathecal analgesia between the 2 groups.

SAMPLING AND SAMPLE SIZE CALCULATION

The technique of systematic random sampling was adopted.

A power analysis shows that to have a power of 0.9 to detect a 30% difference in duration of successful spinal analgesia (45 minutes based upon the data from Yeh et. al.[10] mean of 148 ± 44 min) assuming a significance of 0.01, 32 patients were randomized per group. Assuming that there was to be a 30% drop out rate due to early delivery and cesarean delivery, we increased the sample size by 50% to 48 per group. A *P* value of <0.05 was considered to be significant.

BIAS MINIMIZATION

Sampling Bias.

The study subjects were allocated to one of the two groups. All eligible parturients were given a coin to toss, head up entered the FB group and tail up entered the FBM group.

Measurement Bias.

Each participant was educated on arrival on the use of the Visual Analog Scale to estimate the severity of pain.

Data collection sheet was simple and clear. Physiological measurement was done using automated machines and recorded on the anesthetic chart as well as the data collection sheet.

Information Bias

The members of staff on duty were made conversant with the inclusion and exclusion criteria as well as the data collection sheet before they interacted with the study subjects.

ETHICAL CONSIDERATIONS.

The study was done after the approval of the KNH/UON Ethics and Research committee. No other technique except what is described here was performed.

Each participant was given a consent form after full explanation and understanding. She was asked to append her signature on the consent form.

Participation in this study did not interfere with the care given and the participants were free to withdraw from the study at any stage without any penalties or consequences.

The study subjects neither incurred extra costs nor received any token of appreciation for taking part in this study.

Data collected from each participant was identified by a specific code and only the research team had access to the records. Confidentiality was maintained at every stage of the study.

RESULTS

During the study period, we enrolled a total number of 105 patients who consented to participate in the study. In this study, spinal analgesia was used for labor and delivery. Three patients in the FB (Fentanyl + Bupivacaine) group were dropped from the study since they ended up with caesarian delivery due to obstetric indications.

The 105 study subjects were subdivided into 57 for FB and 48 for FBM (Fentanyl + Bupivacaine + Morphine) groups respectively. Since we had to toss a coin for randomization of the study subjects, it was not possible to get a 50/50 match. We, therefore, went beyond our calculated sample size of 96 to reach our target. 6 subjects from FB group were excluded from the analysis after randomization in order to have 48 per group.

The Kijabe Hospital arm of the study was abandoned after the hospital's Ethics and Research Committee questioned the safety of the study at the initial stages. By the time they gave us permission to proceed with the study, a decision had been made to conduct both arms of the study at The Kenyatta National Hospital to avoid any further delays.

Table 1: Body Weights (Kg).

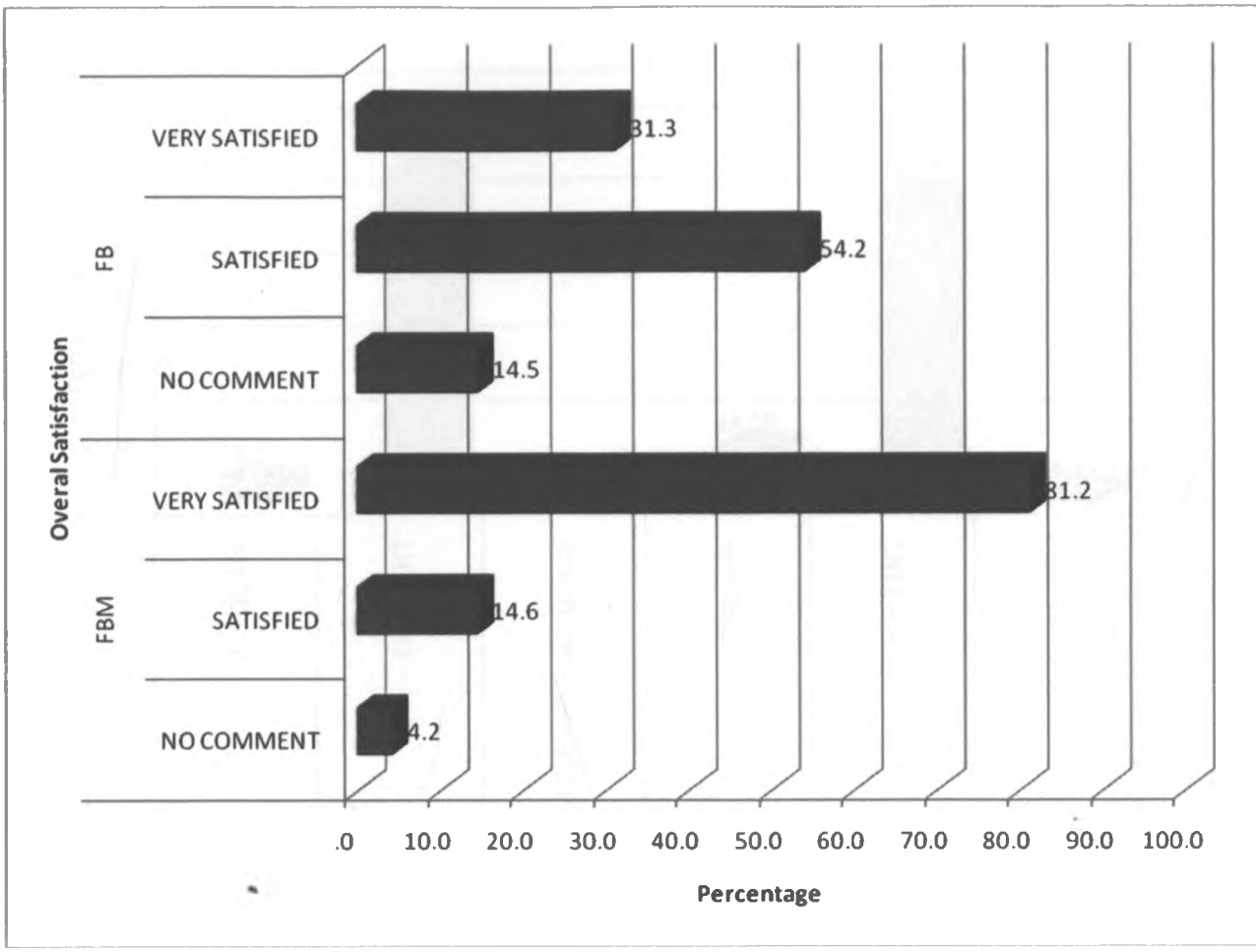
STUDY GROUP		WEIGHT (KG)			
	N	Minimum	Maximum	Mean	Std. Deviation
FBM	48	54	89	70.08	9.400
FB	48	52	92	69.63	10.497

Table 2: Gestational Ages (Weeks)

STUDY GROUP		GESTATIONAL AGE IN WEEKS			
	N	Minimum	Maximum	Mean	Std. Deviation
FBM	48	38	41	39.06	0.932
FB	48	37	42	39.44	1.128

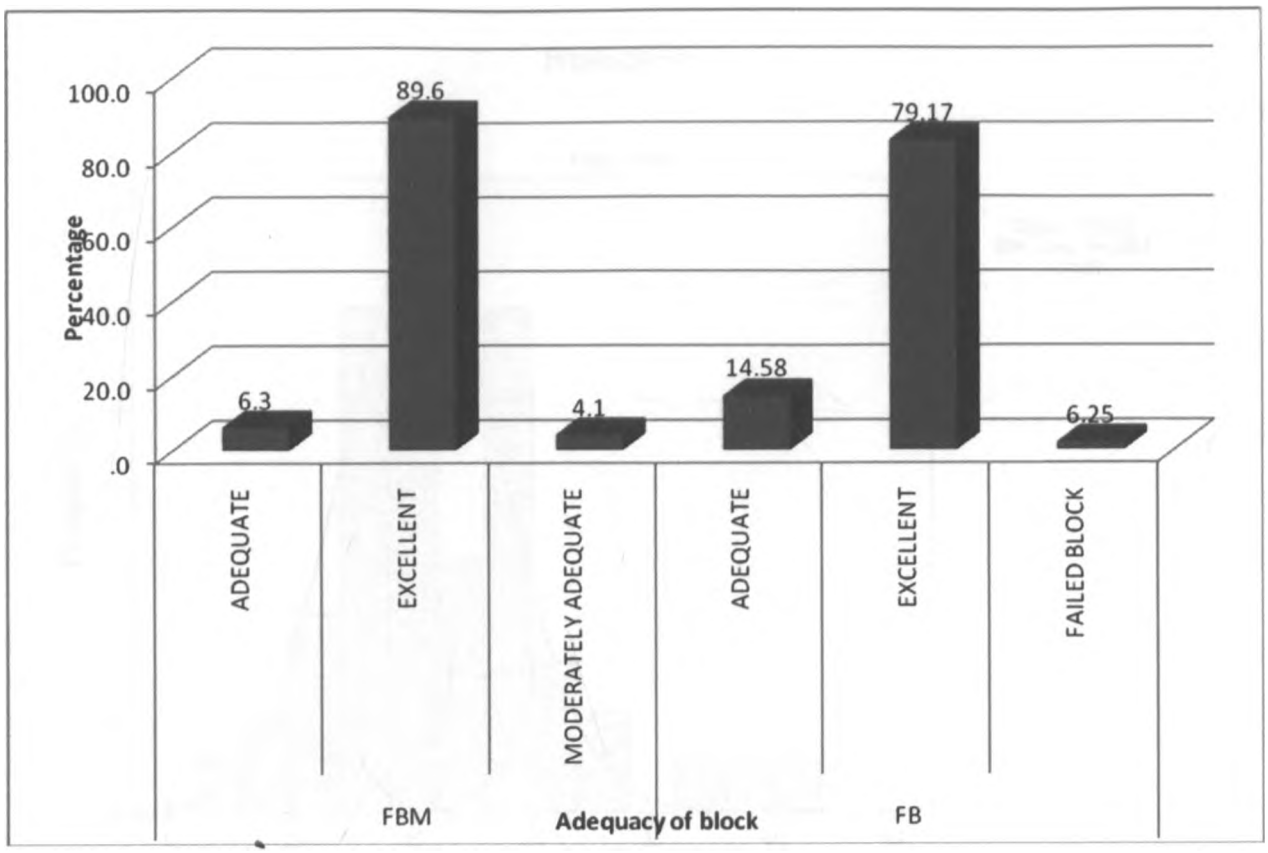
The two groups had patients with almost similar body weights and gestational ages (tables 1 and 2).

Figure 1: Overall satisfaction



On assessing the overall satisfaction with the method employed for labor analgesia, it was observed that 81.3% of the respondents in the FBM group reported that they were "very satisfied" with the analgesia provided comparison to 54.2% in the FB group (figure 1).

Figure 2: Adequacy of spinal block



With regard to the adequacy of spinal block achieved, 89.6% in the FBM group had excellent block compared to 79.1% in the FB group. In 6.25% of the study subjects, the block was repeated because the analgesia ended before the second stage of labor (figure 2).

Figure 3: Age distribution in the FBM group.

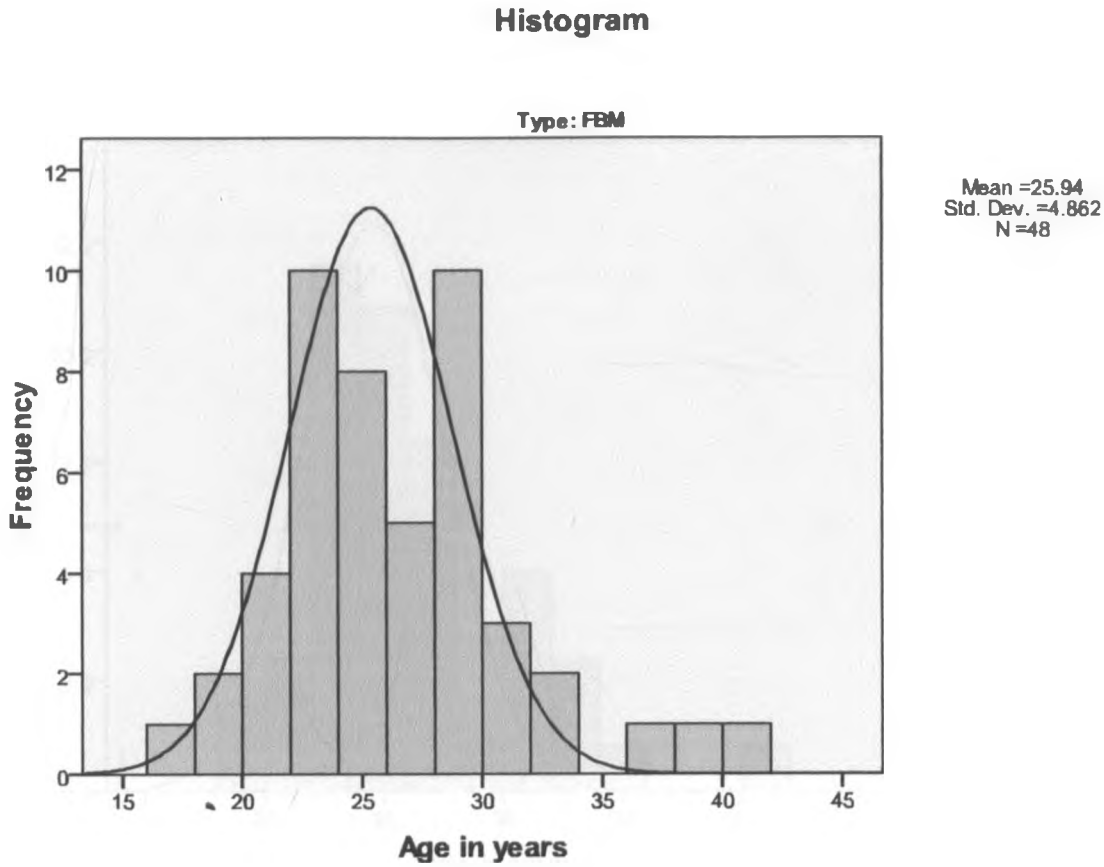
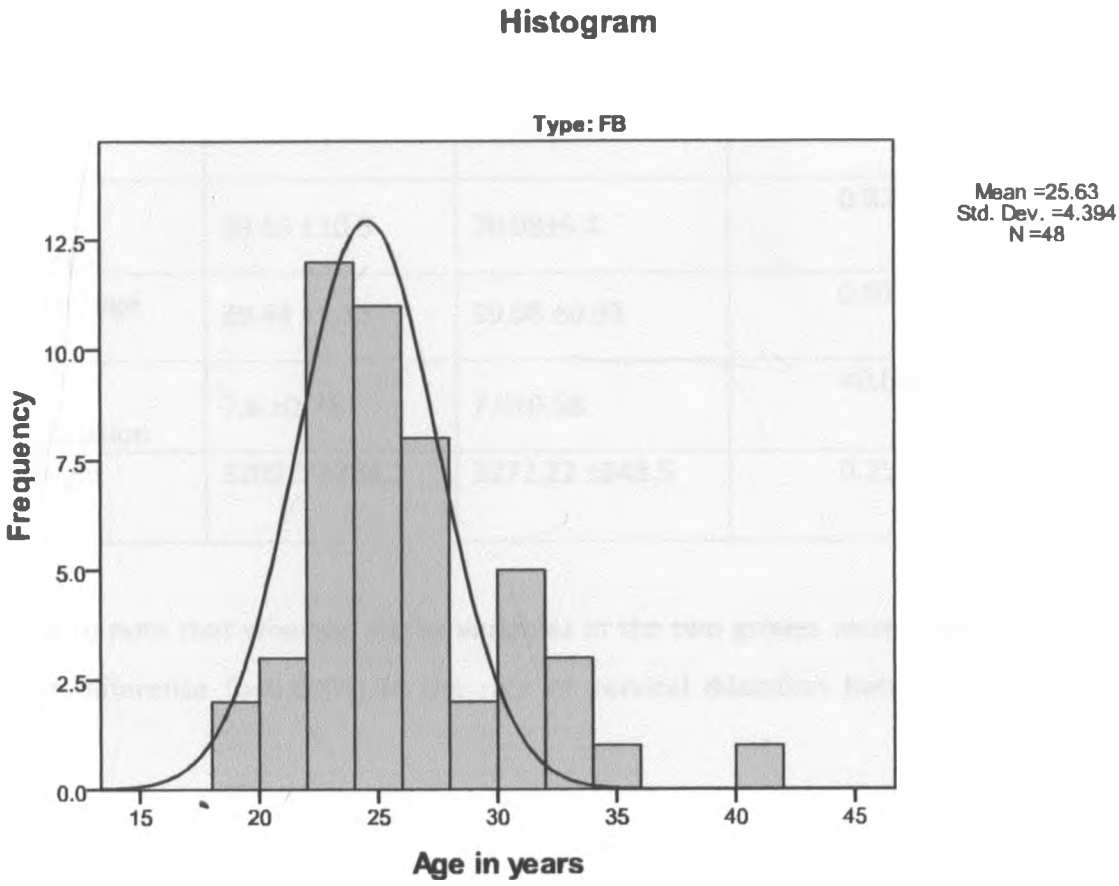


Figure 4: Age distribution for FB group.



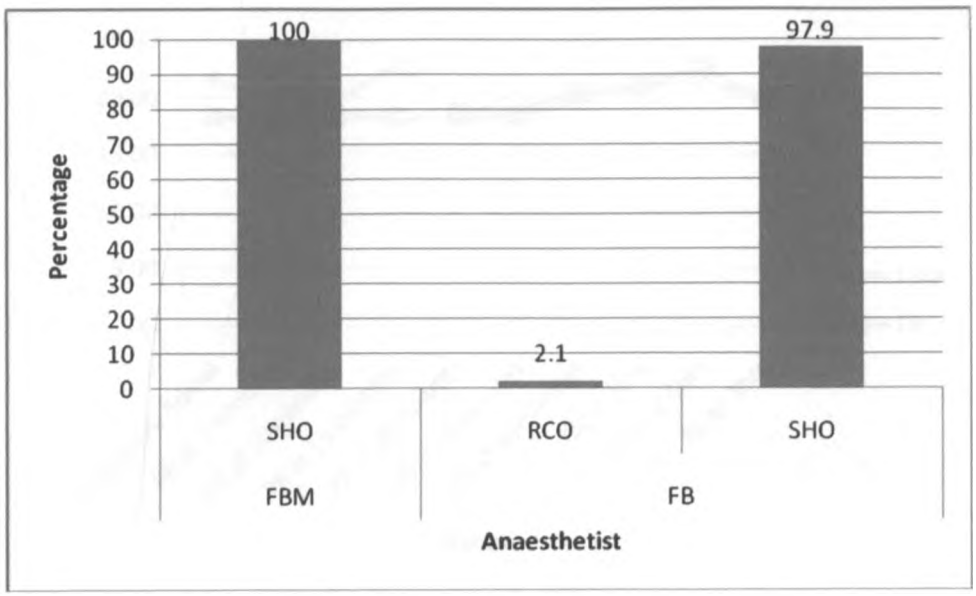
The age distributions in the two groups were similar as shown in figures 3 and 4

Table 3: Variables from the two groups.

	FB group (N=48)	FBM group (N=48)	P-value
Age (years)	25.63 ±4.4	25.94 ±4.9	0.742
Weight (Kgs)	69.63 ±10.5	70.08±9.4	0.822
Gestational age (weeks)	39.44 ±1.13	39.06 ±0.93	0.079
Cervical Dilation	7.6 ±0.71	7.0±0.58	<0.0001
Fetal Weight (grams)	3209.5 ±264.2	3272.22 ±248.5	0.257

It was interesting to note that whereas all the variables in the two groups were similar, there was a significant difference ($p<0.0001$) in the rate of cervical dilatation between the two groups.

Figure 5: Distribution of Analgesia Providers.



The principal investigator was able to administer spinal analgesia in all the patients in the FBM group. In the FB group, however, 2.1% of patients received spinal analgesia administered by a Registered Clinical Officer.

Figure 6: Variations in Maternal Heart Rates after spinal analgesia.

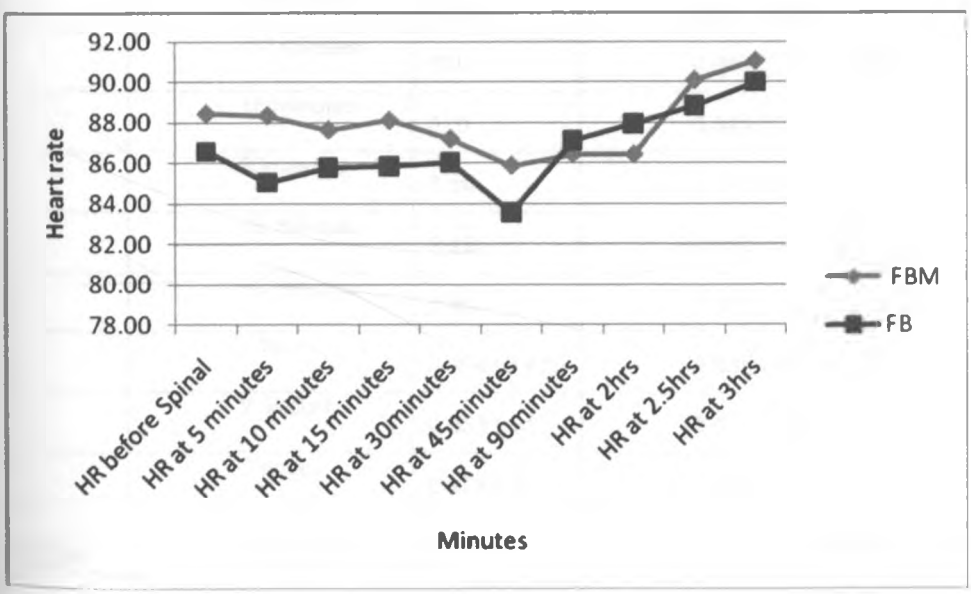
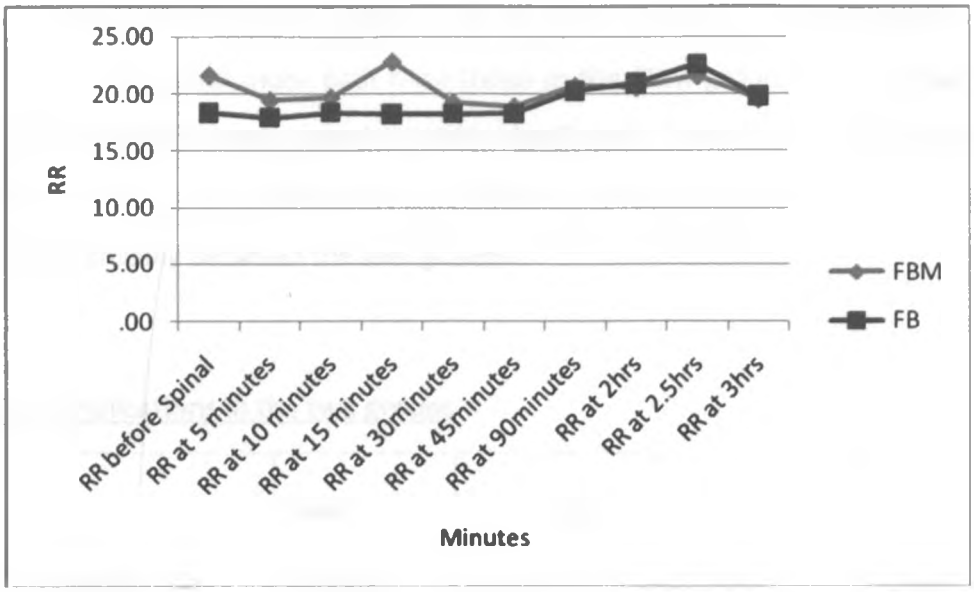


Figure 7: Variations in Maternal Respiratory Rates after spinal analgesia.



After induction of spinal analgesia, maternal heart rates were noted to show minimal variation in the two groups. Similarly, there were minimal variation in the respiratory rates (figures 6&7).

Table 4: Variations in VAS and APGAR Score after spinal analgesia.

		FBM	FB	P-value
VAS	Before Spinal	7.67 ±1.872	8.02 ±1.35	0.29
	5 minutes	0 ±0	0.04±0.289	0.32
	10 minutes	0±0	0.04±0.29	0.32
	15 minutes	0±0	0.04±0.29	0.32
	30minutes	0 ±0	0.06±0.43	0.32
	45 minutes	0 ±0	0.10±0.722	0.32
	90 minutes	0 ±0	1.39±1.76	<0.0001
	2 hours	0.104±0.425	2.63±1.82	<0.0001
	2.5hours	0.63±1.31	3.62±1.96	<0.0001
	3 hours	0.87±1.66	3.43±3.65	0.007
Apgar	1 minute	6.88 0.937	7.27 ±0.765	0.026
	5 minutes	8.0 ± 0.869	8.33 ± 0.69	0.044

After induction of spinal analgesia, there was no significant difference in VAS Scores between the two groups till after 90 minutes. From this time onwards, it was noted that the patients in the FB group reported more pain than those in the FBM group. On the other hand, the one-minute Apgar Scores were noted to differ significantly between the two groups (p=0.0206) in favor of the FB group. The five-minute Apgar scores did not, however, show any significant difference clinically between the two groups.

Table 5 Complications in the two groups

	FBM	FB
Nausea	4 (8.4%)	2 (4.2%)
Pruritis	7 (14.6%)	3 (6.3%)
Shivering	3 (6.3%)	1 (2.1%)
Hypotension	5(10.4%)	2(4.2%)

Table 5 indicates the complications experienced by the study participants and their frequencies in the two study groups. They were all reported as mild and did not affect the neonatal outcomes. The FBM group had higher incidence of side effects than the FB group.

Table 6: Oxytocin Administration

FBM	32 (66.7%)
FB	31 (64.6%)

Augmentation of labour with oxytocin was employed equally in the two groups

Table 7: Bromage Scale

	FBM	FB
No movement	1	0
Move knees only	1	0
Weakness of hip flexion	3	2
No weakness of hip flexion	43	46
Total	**48**	**48**

There was minimal effect on the patients' ability to move their limbs after induction of the block. Only one patient in the FBM group was unable to move her limbs after the block. Those who experience weakness at the hips as assessed by the Bromage scale were able to regain motor strength within a few minutes (Table 7).

DISCUSSION

Pain relief during labour and delivery is a procedure that is gaining popularity in the developing countries. Most commonly used techniques are epidural or combined spinal epidural. The major constraint faced with the above technique is the cost. Only a few parturients can afford it in our set up and hence the need to implement an alternative technique which is cost friendly: THE SINGLE SHOT SPINAL ANALGESIA.

Different combinations have been proposed in this technique. We, therefore, compared two regimens FBM (Fentanyl-Bupivacaine-Morphine) and FB (Fentanyl-Bupivacaine).

The combination of an opioid and a local anesthetic for intrathecal analgesia during labour has been well documented in previous studies across the world.

Parturients who required pain relief were given either FB or FBM regimen. Request for analgesia was indicated by a VAS ≥ 7 at time of first block and ≥ 5 if the need arose to repeat it.

Women who received FB did experience pain relief for about 2 hours and the incidence of breakthrough pain was higher than in those who received FBM. This short duration is consistent with a pharmacokinetic explanation. At the time of second request most of our clients didn't receive the repeat block because it was almost time to deliver and instead an intravenous analgesic such as tramadol was given. Three candidates requested for a second spinal block not long after the first. The second block provided them with sufficient analgesia up to the time of delivery, and did not affect the progress of labour or delivery.

The candidates in the FBM group had their pain relieved for more than 3 hours. We could not tell exactly the time at which the analgesia ended in this group because all our candidates delivered within 3 hours from administration of the block. None of the candidates in the FBM group needed a repeat block or rescue analgesia.

The administered dose of FB did not last through the duration of labour although most of our parturients delivered within three hours. Hess et al, made a similar observation in their study

whereby the mean duration of spinal analgesia was longer in the FBM group than in the FB group. Yeh at al also found a significant increase in the duration of analgesia when 150 mcg of morphine was added to their spinal combination.

Satisfaction of our candidates was established using 5 points scale following delivery. Figure 1 shows that among the two groups, the FBM had 81.2% of the parturients indicating that they were very satisfied. This is explained by the fact that from time of injection until delivery no breakthrough pain was noted in this group. Those who rated their level of satisfaction as "satisfied" or "no comment" were those who felt that the pain relief was provided late into the labour. They wished it had been provided earlier especially in those who regained sensation before delivery. In Indonesia, Chandra and Kuczkowski investigated the maternal satisfaction of Indonesian parturients who received single shot spinal analgesia and they found that 81% were 'very satisfied' and 11% were 'satisfied' with their analgesia.[7]

The lower rate of "satisfied" women in the FB group can be explained by shorter duration of analgesia experienced as exemplified by the high incidence of breakthrough pain.

The effectiveness of the block is extrapolated from the adequacy of block graph in figure 2 and in Table 4. Well administered spinal analgesia was effective enough to cover the duration of labour depending on the type of regimen received by the candidate. It was excellent in 89.6% and 79.17% for FBM and FB respectively.

It is not easy to separate effectiveness from duration of analgesia; hence in the group with a long duration of analgesia the effectiveness of the block was rated as "high".

The incidence of side effects in this study was higher in the FBM than FB group. None of the side effects was, however, severe enough to cause concern. The hypotension which occurred in 10.4% and 4.2% for FBM and FB respectively was treated with intravenous boluses of ephedrine 5mg as per the protocol for spinal analgesia. Nausea was experienced by 8.4% and 4.2% in the FBM and FB groups respectively. These same candidates also had hypotension, and by treating the hypotension, the nausea resolved.

Pruritus occurred in 14.6% in FBM and 6.3% in FB groups respectively. No medication was prescribed as it was mild, and it resolved spontaneously. Huei-Ming et al in similar study found that the incidence of nausea, vomiting and pruritis was not significantly different in the two groups.

The small dose of morphine used to supplement analgesia prolonged the duration of pain relief at the expense of some side effects, though mild but did not affect the outcome of the delivery. Leighton et al reported that intrathecal injection of morphine and fentanyl provided analgesia for labour pain with a rapid onset and an average analgesia duration of 140-222 minutes.

In a study done in Taiwan, Huei-Ming et al, reduced the dose of morphine to minimize its side effects and noted that this did not affect the quality of analgesia.

In this study there were no significant differences between the two groups regarding oxytocin augmentation. A total of 63 parturients had oxytocin administered. This constituted 66.7% in the FBM group and 64.6% in the FB group. The initiation of oxytocin infusion was independent of the type of spinal analgesia regimen given. It was given as a routine protocol in the department of Obstetrics. These findings are similar to those observed by Huei-Ming et al and Philip E et al in their studies.

Although none of our parturients was ask to ambulate, when checking mobility using Bromage scale after single short spinal analgesia, only one candidate could not move her lower limbs. Where weakness of hip was noted, it only took few minutes before subsiding. Dense motor block may interfere with "pushing" during delivery thus prolonging labour or necessitate instrumental delivery.

CONCLUSION

Single shot spinal analgesia for pain relief during labour and delivery is effective in provision of analgesia in the labour ward. This study has revealed that the mothers were very satisfied with the analgesia provided for pain relief during labour and delivery. The addition of morphine to the regimen, though associated with some side effects, was proven to have a longer duration of action and an excellent level of block. It is important to remind ourselves that the perception of labour is subjective and influenced by cultural and social circumstances.

Epidural analgesia in labour and delivery is preferred and widely used because its effects extend to the post-delivery period. In resource poor settings, single shot spinal analgesia can be practiced and would offer pain relief in the labour and delivery period. Considering its cost effectiveness in our set up, single shot spinal analgesia can be adopted and implemented without having the patient incur extra cost. Single shot spinal analgesia does not need a lot of funding and expertise to be practiced and hence making it better for resource poor settings.

With the implementation of single shot analgesia for labour and delivery, it is important to select parturients who are in the active phase of labour and likely to progress quickly.

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RECOMMENDATIONS

- Implementation of single shot spinal analgesia for labour and delivery in our labour ward would be beneficial for the parturients.
- Education to nurses, doctors and anesthetists attending to the parturients on single shot spinal analgesia is necessary.
- Protocols need to be formulated on single shot spinal analgesia to be used in the labour ward.
- Hospitals should ensure sustainable supplies of the drugs and spinal needles for single shot spinal analgesia.

LIMITATIONS

The availability of the drugs and spinal needles was a challenge before the initiation of the study thus causing a delay in its commencement.

Seeking ethical approval from the Ethics and Research Committees of KNH/UON as well as A.I.C. Kijabe Hospital resulted in delay in the commencement of this study.

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APPENDIX 1

BUDGET AND ITS JUSTIFICATION

ITEM	UNIT COST (KShs.)	QUANTITY	TOTAL COST(KShs.)
Stationery	550	3	1650
Printer cartridges	2750	4	11000
Binding	450	5	2250
Modem 3G+	1999	1	1999
Laptop	45000	1	45000
Internet downloads	2200	2	4400
Flush disk 2GB	1800	1	1800
Spinal needles G25	85	100	8500
Fentanyl sulphate 100µg	90	100	9000
Morphine sulphate 10mg	100	50	5000
Bupivacaine 0.5% 10mls	235	100	23500
Lignocaine 2% 20mls	80	5	400

Ephedrine 3% 1ml	200	100	20000
Normal Saline 500mls	200	100	20000
Hartmanns solution	200	100	20000
Methylated spirit 5litres	1200	1	1200
Betadine (aqueous) 250ml	180	3	540
Branula G16	100	100	10000
Branula G18	100	100	10000
Hypodermic needles G21	10	150	1500
Hypodermic needles G25	10	150	1500
Infusion sets	100	100	10000
ECG electrodes	300	300	90000
Syringes (Assorted)	10	350	3500
Statistician's fee		15000	15000
TOTAL			317739 Ksh

APPENDIX 2

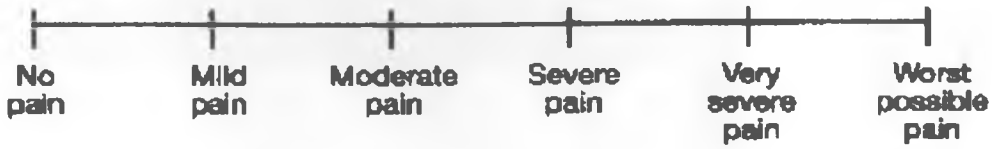
VISUAL ANALOG SCALE

The visual analogue scale (VAS) commonly consists of a vertical or horizontal line, 10 cm in length, with end points labeled "no pain" and the "worst pain".

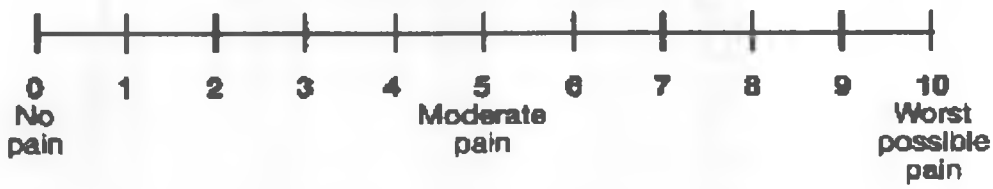
In this type of scale the patient is asked to place a mark on the line that corresponds to the intensity of the pain experienced.

Visual analogue scale (VAS) will be used to assess pain intensity ranging from 0 mm (for no pain) to 100 mm (for worst pain imaginable). Pain scores will be recorded during uterine contractions. A successful spinal analgesia block will be defined as reduction of pain score to < 20 mm. The end of analgesia will be defined as the time when VAS returns to > 50 mm or at the time of request for rescue medication after onset of successful analgesia. At the time for request for rescue medication, a repeat block will be offered one time utilizing the same study drug as used for the first injection, with a second set of data collected.

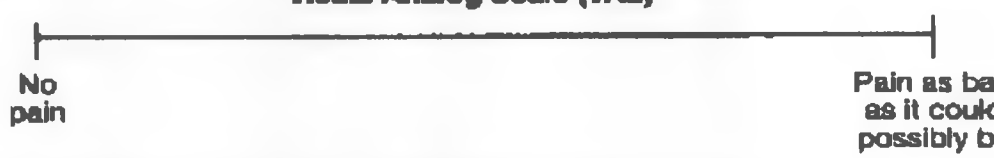
Simple Descriptive Pain Intensity Scale[1]



0–10 Numeric Pain Intensity Scale[1]



Visual Analog Scale (VAS)[2]



[1] If used as a graphic rating scale, a 10 cm baseline is recommended.
[2] A 10-cm baseline is recommended for VAS scales.

Single-Shot Spinal Block for Labor Pain

Code_____ Date: _____ Ht. ____ Wt. ____ Medical Hx: _____

Anesthetist/title: _____ G P Gestational age: _____ Cervical Dilation @ request: _____

Position: **Lateral** **Sitting** Interspace: _____ Intrathecal regimen: **Bupiv/Fenta** **Bupiv/Fenta/Morph**

	Before spinal	Time 5	Time 10	Time 15	Time 30	Time 45	Time 60
Blood pressure							
Heart Rate							
RR							
Sensory level							
VAS							
Motor Block							
Side effects: P Sh N/V Se							
Treatment							

	Time 90	Time 2hr	Time 2.5hr	Time 3hr
Blood pressure				
Heart Rate				
RR				
Sensory level				
VAS				
Motor Block				
Side effects: P Sh N/V Se				
Treatment				

Bromage scale	
1	No movement
2	Move feet only
3	Move knees only
4	Weakness of hip flexion
5	No weakness of hip flexion

Side effect scale	
1	None
2	Mild
3	Moderate
4	severe

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Apgar 1/5	
Fetal Weight	
Oxygen Y/N	
Oxytocin	
Rate of Cervical Dilation	
Would you have a spinal again? Y/N	

Complications: **multiple attempts** **blood** _____

Time request additional relief: _____ Repeat Block: **Yes** **No**

If not, type and amount of rescue analgesics: _____

Adequacy of block: **excellent** **moderately adequate** **not adequate** **could not say**

If inadequate, why? _____

Overall satisfaction: **very satisfied** **satisfied** **no comment** **unsatisfied** **very unsatisfied**

APPENDIX 4

CONSENT EXPLANATION

My names are: Dr Papytcho Ntambwe Tshibuyi, I am a postgraduate student of Anesthesia and Intensive Care at the University of Nairobi.

The Study

You are invited to participate in this study. The goal of the study is to establish which of the two regimens of spinal analgesia for pain free labour is more appropriate.

Prior to the administration of spinal anesthesia under aseptic conditions, we shall administer to you some intravenous fluids to reduce the risk of developing low blood pressure.

Your participation in this study is completely voluntary; you are free to withdraw at any time with no penalty. The results will only be used for research purposes. Your identity will be kept confidential as provided by the law. Your data will be assigned a code that is unique, and only the research team will have access to them. You will not be required to pay any extra fees and there will be no money paid to you for participating in this study.

Study Approval

This study will be conducted with the approval of The Kenyatta National Hospital /University of Nairobi's Ethics and Research Committee.

Study Procedure

I, the principal investigator, will give you the explanation of the study. The Anesthetist who will administer the anesthetic will collect and record the data on my behalf. He/she will be in a position to further explain the procedures to.

Thank you.

APPENDIX 5

INFORMED CONSENT FORM

Study title: "A COMPARISON OF TWO REGIMENS OF SINGLE SHOT SPINAL BLOCK FOR THE RELIEF OF PAIN DURING LABOR AND DELIVERY"

I,.....of P.O. Box..... , after being fully explained to by ***Dr Papytcho Ntambwe Tshibuyi*** and/or the research team the purpose, technique, advantages, possible complications and guarantees of confidentiality, do voluntarily agree to participate in this study. I have also been told that declining to participate in, or withdrawing from the study will not in any way compromise the care I receive.

Signature ..... (Patient)

.....

(Name and signature of the staff performing the technique).

Designation.....

FOMU YA IDHINI YA KUSHIRIKI

Kitchwa cha utafiti: "KULINGANISHA UTUMIAJI WA MBINU MBILI TOFAUTI ZA SHOTI MOJA YA 'SPINAL BLOCK' KWA KUPUNGUZA UCHUNGU WAKATI WA KUZAA."

Mimi.....wa S.L.P....., baada ya kuelezewa kwa kina sababu, mbinu ya kupunguza uchungu wa kuzaa utakaotumiwa, manufaa, madhara na kupewa hakikisho ya kuweka siri jina langu, nakubali kwa hiari kushiriki katika utafiti huu. Sitalipishwa chochote kwa kushiriki katika utafiti huu, na sita lipwa kwa njia yoyote. Nimehakikishiwa kwamba, nikikataa kushiriki katika utafiti huu, sita dhulumiwa kwa njia yoyote ile.

Sahihi ya mshiriki.....

Jina, sahihi ya dakitari.....

Kitengo cha dakitari.....

APPENDIX 6

TIME FRAME

Table 1: Tentative schedule for the proposed research

Activity	Time Frame	Indicator
Research Proposal Development	February – May 2011	Proposal Approval by Supervisor
Ethical Committee Presentation	June -August 2011	Approval by Ethical Committee
Data Collection	6 weeks	Letter of Approval From Ethical Committee
Data Analysis	February to March 2012	Research First Draft
Final Research Document Presentation	July 2012	Final Research Document

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Ref: KNH-ERC/ A/195

3rd August 2011

Dr. Papytcho Ntambwe Tshibuyi
Dept.of Surgery/Anaesthesia
School of Medicine
University of Nairobi

Dear Dr. Tshibuyi

RESEARCH PROPOSAL: "A COMPARISON OF TWO REGIMENS OF SINGLE-SHOT SPINAL BLOCK FOR THE RELIEF OF PAIN DURING LABOUR AND DELIVERY" (P248/06/2011)

This is to inform you that the KNH/UON-Ethics & Research Committee has reviewed and **approved** your above cited research proposal . The approval periods are 3rd August 2011 2nd August 2012.

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 specimens must also be obtained from KNH/UON-Ethics & Research Committee for each batch.

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

This information will form part of the data base 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 Deputy Director CS, KNH
the Dean, School of Medicine
The chairman, Dept. of Surgery/Anaesthesia, UON
The HOD, Records, KNH
Supervisors: Dr. Patrick Ragot Olang', Dept.of Surgery, UON
Dr. Mark W. Newton, AIC Kijabe Hospital

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