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A COMPARATIVE STUDY ON THE EFFICACY OF TWO REGIMENS OF SINGLE-SHOT SPINAL BLOCK FOR PAIN RELIEF IN WOMEN PRESENTING IN ESTABLISHED LABOUR

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ABSTRACT

***Background*: Most women experience moderate to severe pain during labour 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. Skillfully conducted obstetric analgesia, in addition to relieving pain and anxiety, may benefit the mother by increasing self esteem and improving bonding with the baby.**
***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 phase of labour.**
***Design*: A prospective randomised single-blind observational study**
***Setting*: Labour ward of Kenyatta National Hospital, Nairobi.**
***Subjects*: All consenting primiparous women presenting in active phase of labor with uncomplicated singleton pregnancy at term (> 37 weeks) and in cephalic presentation, who reported a > 70 mm VAS (Visual Analog Scale) pain score at cervical dilatation ≥ 5 cm at the time of request for labour analgesia.**
***Results*: Effective labour analgesia lasting up to 120 minutes was observed in the fentanyl-bupivacaine group but with a high incidence of breakthrough pain. The fentanyl-bupivacaine-morphine group had labour analgesia lasting up to 180 minutes or even more with a lower incidence of breakthrough pain. The one-minute and five-minute Apgar scores in the morphine group were significantly lower (p = 0.026 and 0.044 respectively) than in the fentanyl group but the difference in neonatal outcome had no clinical significance, and there were no significant differences in adverse effects, sensory levels, and motor power between the two groups.:**
***Conclusion* Effective analgesia for about 120 minutes was observed in the fentanyl-bupivacaine group with high incidence of breakthrough pain while the fentanyl-bupivacaine-morphine group had labour analgesia prolonged up to more than three hours. The difference in fetal outcome had no clinical significance for the morphine group, and there were no significant differences in adverse effect, sensory levels, and motor power between the two groups. These findings show that intrathecal analgesia is safe and the use of the combination of fentanyl-bupivacaine-morphine gives adequate and safe analgesia during labour and delivery.**

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 labour and delivery. The perception of pain during labour is subjective and influenced by cultural and social circumstances. However, skillfully conducted obstetric analgesia, in addition to relieving pain and anxiety, may benefit the mother and foetus in many other ways.

LITERATURE REVIEW

Non-pharmacologic analgesic techniques and systemic analgesia can be used for the relief of

pain during labor. However, neuraxial analgesia, particularly epidural technique, is the most effective method (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 labouring 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 labour 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 labour analgesia (14). Leslie *et al.* stated that intrathecal analgesia should be characterized as a single treatment that attempts to achieve a 4-hour window of ambulatory pain control for laboring women. They noted that repeat intracthecal narcotic injections are ineffective due to narcotic tachyphylaxis (18).

MATERIALS AND METHODS

All consenting primiparous women presenting in active phase of labour with uncomplicated singleton pregnancy at term (> 37 weeks) in cephalic presentation who reported a > 70 mm VAS (Visual Analog Scale) pain score at cervical dilatation ≥ 5 cm at the time of request for labour analgesia were recruited into the study. 48 patients were included in each of the two groups after randomization by tossing a fair coin.

Ninety six primiparous women in active phase of labour received single shot spinal analgesia for labour and delivery. Forty eight received a combination of bupivacaine-fentanyl and the other 48 received bupivacaine-fentanyl-morphine. The duration, progress and outcome of labour were investigated. Both groups received Fentanyl 25 mcg, bupivacaine 2.5 mg. In the second group, morphine 150 mcg was added. The total volume was made to 2 ml by adding sterile water for injection.

We recorded the maternal age, height, weight, important medical conditions, cervical dilatation at the time of request for spinal block, use and quantity of oxytocin augmentation, fetal weight, and Apgar scores.

A preload of 500 ml of intravenous (I.V.) balanced salt solution (Ringer's lactate/Hartmann's solution or Normal saline) was administered 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 two intrathecal medication regimens was injected after randomisation. 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, site of lumbar puncture and the anesthetist performing the block.

Maternal vital signs, 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.

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 mode of intervention recorded. Motor block was graded using the modified Bromage Scale described by Breen et al. 9 with 0 = no movement; and 6 = no detectable weakness of hip flexion. Evaluation of side effects was by direct questioning on a 4 point scale at each interval and 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 uterine contractions. 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 returned 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 one-time repeat block was offered 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 labour, 4. spinal given too late in labour). 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 duration of spinal analgesia. Normally distributed variables were compared utilizing Student's T-test. The Mann-Whitney U-test was used for non-normal distributions. A Kaplan-Meier analysis was used to compare the cumulative proportion of adequate intrathecal analgesia between the 2 groups.

RESULTS

The 105 study subjects were subdivided into 57 for FB (Fentanyl-Bupivacaine) and 48 for FBM (Fentanyl-Bupivacaine- Morphine) groups respectively. Since randomization of the study subjects could not achieve a 50/50 match, we went beyond our calculated sample size of 96 to reach our target. Six subjects from FB group were excluded from the analysis after randomization in order to have 48 per group. 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, augmentation of labour with oxytocin was employed equally in the two groups (Table 1). After induction of spinal analgesia, there was no significant difference in VAS Scores between the two groups until after 90 minutes. From then 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 2). 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 experienced weakness at the hips as assessed by the Bromage scale were able to regain motor strength within a few minutes (Table 3).

Complications experienced by the study participants and their frequencies in the two study groups were all reported as mild and did not affect the neonatal outcomes. The FBM group had a higher incidence of side effects than the FB group (table 4). On assessing the overall satisfaction with the method employed for labour analgesia, it was observed that 81.3% of the respondents in the FBM group reported that they were "very satisfied" with the analgesia provided in comparison to 54.2% in the FB group (figure 1). After induction of spinal analgesia, maternal heart rates were noted to show minimal variation in the two groups. Similarly, there were minimal variations in the respiratory rates (figures 2 and 3).

Table 1: Variables from the two groups.

Table 1
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
Use of oxytocin	31 (64.6%)	32 (66.7%)	0.732

The two study groups had similar demographic characteristics but there was a significant difference in the rate of cervical dilatation in favour of the FB group.

Table 2
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
	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 anaesthesia, there was no difference in VAS in the two groups until after 90 minutes at which point the patients in the FB group reported significantly higher VAS than those in the FBM group. The one-minute Apgar scores were lower in the FBM than in the FB group.

Table 3
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

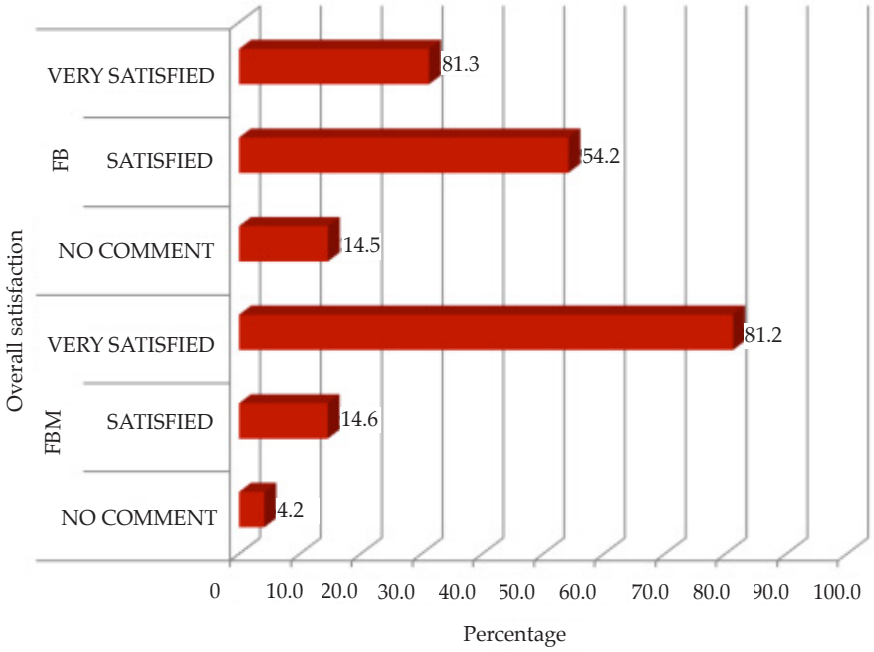
There was no difference between the two groups in terms of lower limb weakness after induction of spinal analgesia.

Table 4
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%)

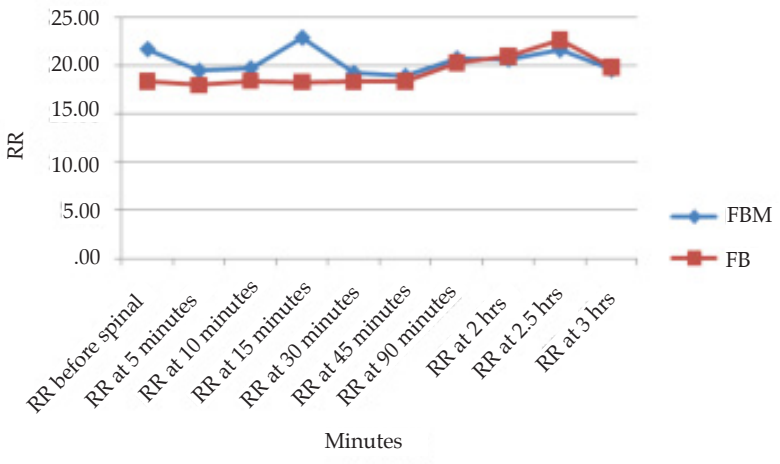
Patients in the FBM group had a higher incidence of side effects than those in the FB group. These were, however, noted to be mild and self-limiting.

Figure 1
Overall satisfaction



The patients in the FBM group had a higher level of satisfaction than those in the FB group. Less than 5% of patients in the FBM had reservations regarding their level of satisfaction compared to 14.5% in the FB group.

Figure 2
Variations in Maternal Respiratory Rates after spinal analgesia.



There were no significant variations in the respiratory rates in the two groups of patients after induction of spinal anaesthesia.

DISCUSSION

The combination of an opioid and a local anesthetic for intrathecal analgesia during labour has been well documented in previous studies across the world. Different combinations have been proposed in this technique. We, therefore, compared two regimens FBM (Fentanyl-Bupivacaine-Morphine) and FB (Fentanyl-Bupivacaine).

Parturients who received FB experienced pain relief for about 2 hours and the incidence of breakthrough pain was higher than in those who received FBM. At the time of second request, most patients could not receive the repeat block because it was almost time to deliver. Three patients 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. Whereas it is known that patients develop substantial tachyphylaxis to intrathecal narcotics, we did not notice any such effect in this study. In the study by Leslie NG *et al*, it was noted that repeat doses of narcotics resulted in little ongoing benefit (17). Leighton *et al (*18) 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 this study, the patients in the FBM group had their pain relieved for more than three hours. We could not tell exactly the time at which the analgesia ended in this group because all our candidates delivered within three hours from administration of the block. None of the candidates in the FBM group needed a repeat block or rescue analgesia.

Hess *et al (*11), made a similar observation in their study in which the mean duration of spinal analgesia was longer in the FBM group than in the FB group. Yeh at1o al also found a significant increase in the duration of analgesia when 150 mcg of morphine was added to their spinal drug combination.

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. 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 a similar study found that the incidence of nausea, vomiting and pruritis was not significantly different in the two groups.

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 unit. These findings are similar to those observed by Huei-Ming et al and Philip E et al in their studies.

Although none of our patients was asked 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 a few minutes before subsiding.

Satisfaction of our candidates was established using the 5 points scale shown in figure 1. 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.

In conclusion, single shot spinal analgesia for pain relief during labour and delivery is effective. The addition of morphine to the regimen, though associated with some side effects, was proven to result in a longer duration of action and an excellent level of block. In resource-poor settings, single shot spinal analgesia is a practical approach to pain relief in the labour and delivery. Considering its cost effectiveness in our set up, single shot spinal analgesia can be adopted and implemented without having the patient incur extra cost. It is important to select parturients who are in the active phase of labour and likely to progress quickly. In this respect, it is absolutely necessary to work in close consultation with the obstetricians and midwives.

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