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Original Research Article

A comparative study on the block characteristics in spinal anaesthesia with premixed or succedent administration of hyperbaric bupivacaine and fentanyl in lower segment caesarean section

Bidya Ngangom[1], Nongthombam Ratan Singh[1], Lairikyengbam Sheityajit Roy[1], Sonia Naorem[1], Dhayanithy M.[2]*, Prithibiraj Ahanthem[1], Raees K.[1]

[1]Department of Anaesthesiology, Regional Institute of Medical Sciences, Imphal, Manipur, India
[2]Department of Anaesthesiology, North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong, Meghalaya, India

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***Correspondence:**
Dr. Dhayanithy M.,
E-mail: drdhaya8004@gmail.com

ABSTRACT

Background: Caesarean section (CS) is a lifesaving procedure when there is both or either maternal and fetal problem and the rate of CS had increased dramatically. Objectives were to compare between premixed and succedent administration of intrathecal hyperbaric Bupivacaine and Fentanyl on the block characteristics of spinal anesthesia among parturient women undergoing lower segment CS.
Methods: The study groups divided into two. The total sample size was 60, 30 patients in each group. In group A, all the patients were given 2 ml of hyperbaric Bupivacaine (0.5%) using a 5 ml syringe followed by 0.5 ml (25 mcg) Fentanyl citrate in a 2 ml syringe intrathecally at L3-4 space and in the group B, all the patients were given 2 ml of hyperbaric Bupivacaine (0.5%) plus 0.5 ml (25 mcg) Fentanyl citrate premixed in a 5 ml syringe intrathecally at L3-4 space.
Results: The mean time of onset of sensory block was significantly shorter in group A when compared to group B. The time to achieve maximum sensory block level and time to complete motor blockade was significantly shorter in group A when compared to group B. There was no significant difference between the groups in terms of hemodynamic changes and attainment of maximum sensory block levels and requirement of vasopressor.
Conclusions: There were no significant differences in the time to reach sensory block level T6, degree of motor blockade, Apgar score and complications. The time to achieve maximum sensory block level was significantly shorter in group A when compared to group B.

Keywords: Spinal anaesthesia, Caesarean section, Bupivacaine, Fentanyl

INTRODUCTION

Caesarean section (CS) is a lifesaving procedure when there is both or either maternal and fetal problem and the rate of CS had increased dramatically.[1] Regional anesthesia techniques are highly preferred for CS compared to general anesthesia.[2]

Bupivacaine, classified as an amide-based local anesthetic, is known for its potent effect, delayed onset (taking around 5-8 minutes), and prolonged duration of action (typically lasting 1.5-2 hours). Bupivacaine is the most common local anaesthetic (LA) used for many years intrathecally for CS with a dose ranging from 12 to 15 mg.[5] With higher doses of hyperbaric Bupivacaine, incidence of intraoperative visceral pain associated with higher blocks

is reduced and hence hyperbaric Bupivacaine is most commonly used as it produces more predictable block with less side effects.[6]

Several adjuncts have been used to enhance the effect of spinal anaesthesia. The varied neuraxial adjuvants used are opioids, sodium bicarbonate, vasoconstrictors, alpha-2 adrenoceptor agonists, N-methyl-d-aspartate (NMDA) antagonists (Ketamine) and γ-aminobutyric acid (GABA) receptor agonists.[7] Intrathecal opioids are most commonly used as they are synergistic with LA. Intrathecal Fentanyl most commonly used causes a decrease in visceral and somatic pain and improves the quality of block, decreases pain scores, and reduces analgesic requirement in postoperative period. Intrathecal fentanyl enhances analgesia with bupivacaine and achieves successful subarachnoid block by acting on mu-receptor found in spinal cord and resulted in improved quality and prolonged analgesia. In addition, fentanyl acts on afferent nociceptive path so it causes less adverse hemodynamic effects.[8]

Spread of drug in the intrathecal space is affected by mixing opioids and hyperbaric Bupivacaine due to alteration in density of hyperbaric solution.[9] The mean densities of Fentanyl were found to be 0.9957 in an in-vitro study, whereas the density of hyperbaric Bupivacaine was 1.0262.[10] The average density of cerebrospinal fluid (CSF) in full-term pregnant women is 1.000306.[11] Changes in the baricity of a solution by 0.0006 g/ml-1 can impact the dispersion of a local anesthetic solution within the CSF. Therefore, the inclusion of opioids in the local anesthetic mixture might modify its density, potentially influencing the spread of the anesthetic.[12]

Therefore, the amalgamation of local anesthetics with adjuvants like opioids, such as Fentanyl, has revolutionized spinal anesthesia, enhanced its efficacy and prolonged postoperative analgesia. However, the manner of administering these agents, whether as a premixed solution or as successive injections, remains a subject of debate. While numerous studies have explored the efficacy of intrathecal Bupivacaine-Fentanyl combinations, few have directly compared the outcomes of premixed versus successive administration methods. This gap in research leaves clinicians without clear guidance on the optimal technique for achieving optimal block characteristics in spinal anesthesia for LSCS.

The lacunae in existing literature emphasize the need for a comprehensive investigation into the comparative effects of premixed and successive administration of hyperbaric bupivacaine and fentanyl in LSCS. Specifically, there is a lack of consensus regarding the onset and duration of sensory and motor blocks, hemodynamic stability, postoperative analgesia duration, and maternal and neonatal safety profiles between these two administration techniques. Hence, it became imperative to conduct a randomized controlled trial to compare between premixed and succedent administration of intrathecal hyperbaric bupivacaine and fentanyl on the block characteristics of spinal anaesthesia among parturient women undergoing lower segment CS in a tertiary care centre, Manipur.

METHODS

A double blinded, randomized control trial was conducted in the Department of Anaesthesiology, Regional institute of medical sciences (RIMS), Imphal, Manipur from May 2022 to June 2024 consisting of 60 patients totally. The permission of the Research Ethics Board, RIMS, Imphal, Manipur was obtained before initiating the study. Informed written consent were taken from all patients.

Inclusion criteria

Inclusion criteria include age between 18 to 45 years, ASA (American Society of Anaesthesiology) category 1 and 2, parturient undergoing lower segment CS under spinal anaesthesia.

Exclusion criteria

Exclusion criteria include History of allergy to study drugs, bleeding disorder-platelet count<50,000/micro litre, prothrombin time >14 sec and international normalized ratio (INR) .1.5, local site infection, cardiac diseases, respiratory diseases, kidney diseases, neurological deficit, and spinal deformity.

The study groups were divided into two, named group A and group B. The total sample size was 60 (30 patients in each group). In group A, all the patients were given 2 ml of hyperbaric bupivacaine (0.5%) using a 5 ml syringe followed by 0.5 ml (25 mcg) Fentanyl citrate in a 2 ml syringe intrathecally at L3-4 space and in the group B, all the patients were given 2 ml of hyperbaric bupivacaine (0.5%) plus 0.5ml (25 mcg) Fentanyl citrate premixed in a 5 ml syringe intrathecally at L3-4 space. Patients were allocated based on a restricted randomization procedure using permuted blocks of 4 on an online software (www.sealedenvelope.com). The generated permuted blocks are BABA, BAAB, AABB, ABAB, BAAB, BABA, BBAA, ABBA, BBAA, BAAB, ABBA, BAAB, ABAB, ABAB, ABBA and AABB. There was no concealment of allocation.

In both the groups, pre-operative assessment was done a day prior to the scheduled day of surgery. Tablet Alprazolam 0.5 mg was administered at bedtime, a day prior to scheduled surgery. Two hours before the operative procedure injection Pantoprazole 40 mg and injection metoclopramide 10 mg was administered after intravenous access in the preoperative room with maintenance fluids.

On the OT table in both the groups, the standard monitors-heart rate (HR), non- invasive blood pressure (NIBP), oxygen saturation (SPO_2) and electro- cardiogram (ECG) was attached and initiated. All the patients received Ringers Lactate solution 10 ml per kg. as preloading solution within 30 minutes of subarachnoid block. In the

sitting position, the skin over the desired site for spinal block was infiltrated with LA (2% Lignocaine, 1 ml) under strict aseptic and anti-septic precaution. With the patient in the left lateral position, spinal anaesthesia was performed in the L_{3-4} interspace under strict sterile conditions through a 25 G Quincke needle. After confirming the spinal anaesthesia with free flow of cerebrospinal fluid, spinal anaesthesia was induced with 2 ml of 0.5% hyperbaric Bupivacaine with 0.5 ml of Fentanyl citrate (premixed or succedent), depending on the groups. Hypotension, defined as fall in the systolic blood pressure (SBP) more than 20% of the baseline blood pressure or less than 100 mm Hg. was treated with fluids (100 ml of Ringers Lactate) or with intravenous Mephentermine in increments of 3 mg as an when required. Time of analgesia at T10 dermatome i. e., time interval from the LA drug administration and the onset of cutaneous analgesia at T10 was assessed using a mid- clavicular line pinprick bilaterally every minute, till complete loss of cutaneous sensation at T6-T8, at which point the surgical procedure commenced. The maximum analgesic dermatome achieved was assessed and noted. The degree of motor block was assessed when the cutaneous sensation is lost at T10.[13]

Sedation score was recorded just before the initiation of surgery and thereafter every 30 minutes, the level of sedation was assessed and recorded.[4,8] Also, the duration of analgesia was recorded as the time interval from the time of intrathecal drug injection till the time when the patient first complains of pain i.e. the first demand for rescue analgesia. The adequacy of analgesia/effectiveness of the pain relief was assessed by virtual analogue scale.[14] If the patient first complained of pain or VAS>4, rescue analgesia was provided by intramuscular injection of Diclofenac 75 mg. The details of any other adverse effects (if any) were recorded and compared.

RESULTS

A total of 60 parturient who underwent elective lower segment CS under spinal anaesthesia were included in the study and the flow of the study is shown in Figure 1. All the participants belonged to ASA physical status II.

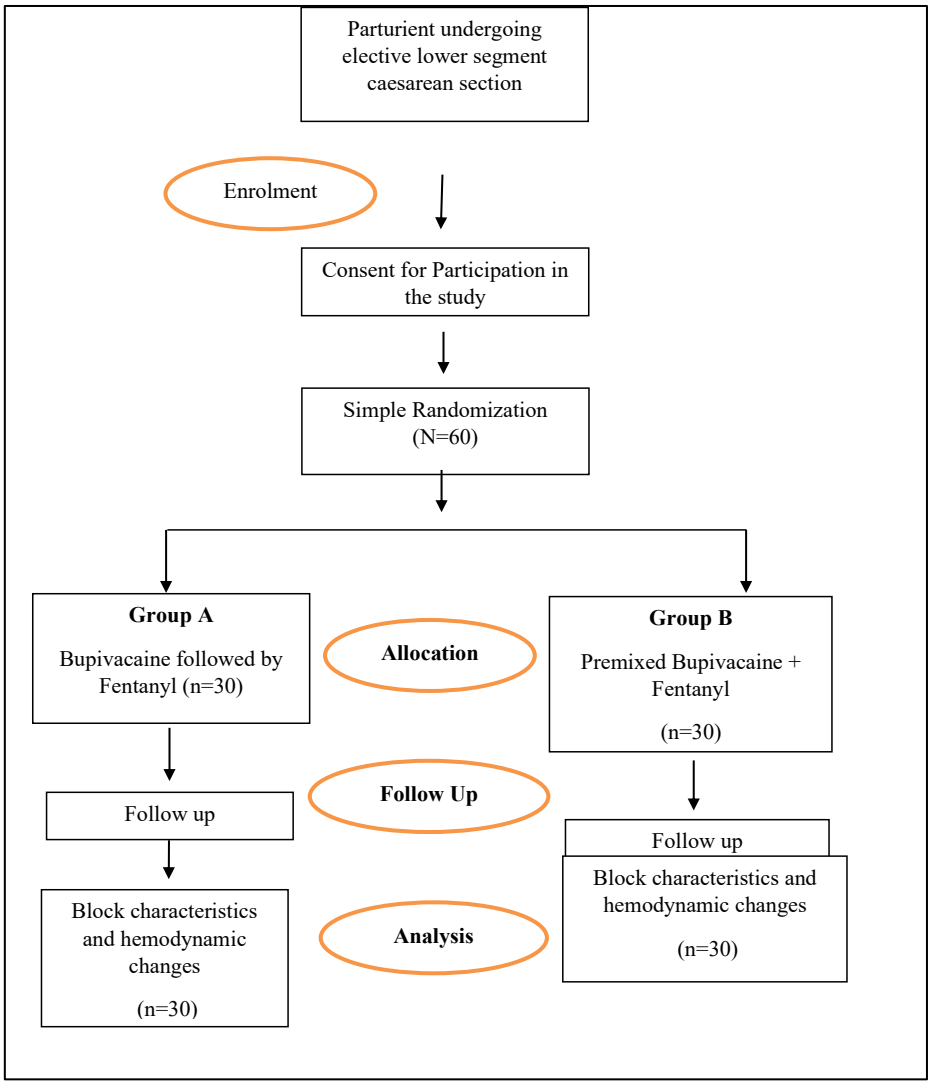

Figure 1: CONSORT diagram showing the flow of study participants.

Table 1: Distribution of the participants by age between the groups, (n=60).

Type of intervention	Age (in years)		P value*
	Mean	SD	
Group A	28.9	5.6	0.570
Group B	29.9	7.8	

*student's t-test

Table 1 shows that the study participants were comparable with respect to age (p=0.570). The participants were comparable between the groups with respect to their body weight (p=0.588). The participants were comparable between the groups with respect to their height (p=0.142).

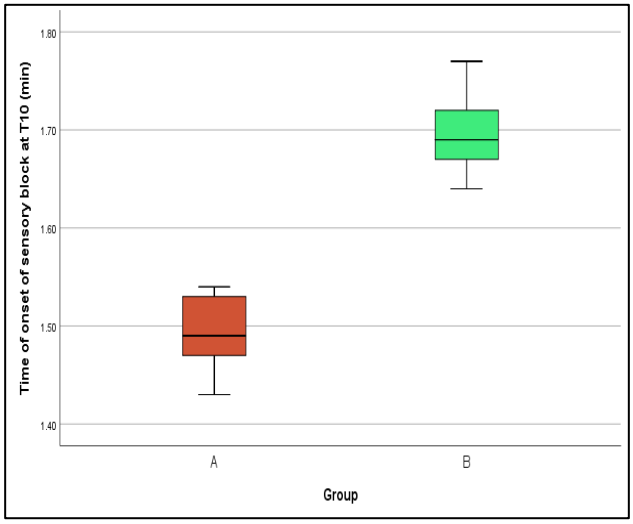

Figure 2: Comparison of onset of sensory block at T10 between the groups, (n=60).

Figure 2 shows that the mean time of onset of sensory block at T10 was shorter for the participants who received Bupivacaine followed by Fentanyl when compared to those who received premixed Bupivacaine + Fentanyl (1.5 min vs 1.7 min) and it was found to be statistically significant (p<0.001).

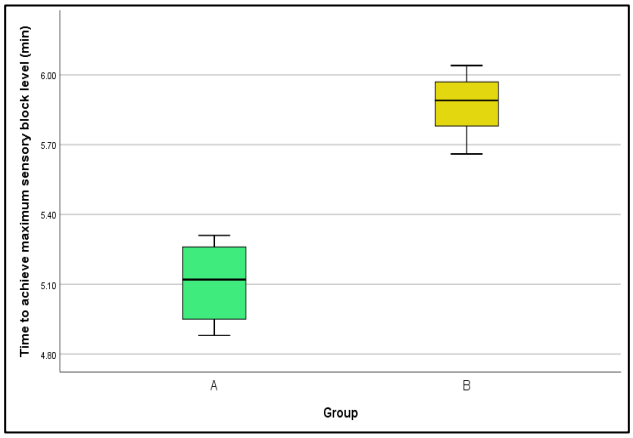

Figure 3: Comparison of time to achieve maximum sensory block level between the groups, (n=60).

Figure 3 shows that the time to achieve maximum sensory block level was shorter for the participants who received Bupivacaine followed by Fentanyl when compared to those who received premixed Bupivacaine + Fentanyl (5.1 min vs 5.9 min) and it was found to be statistically significant (p<0.001).

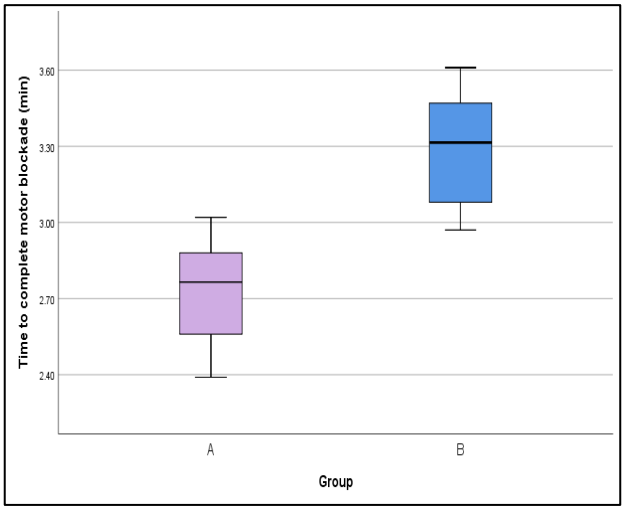

Figure 4: Comparison of time to complete motor blockade between the groups, (n=60).

Figure 4 shows that the time to time to complete motor blockade was shorter for the participants who received Bupivacaine followed by Fentanyl when compared to those who received premixed Bupivacaine + Fentanyl (2.7 min vs 3.3 min) and it was found to be statistically significant (p<0.001).

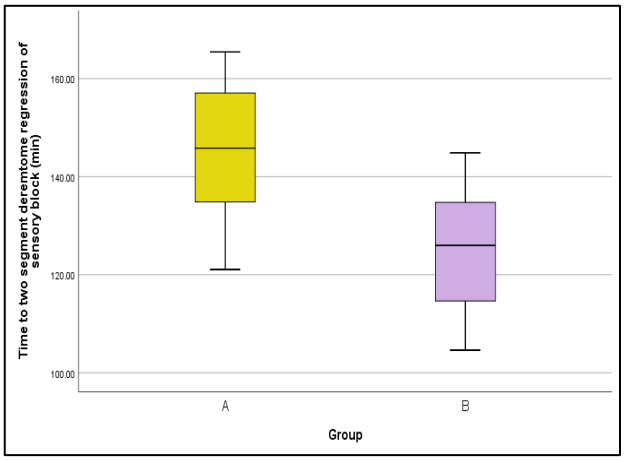

Figure 5: Comparison of time to two segment dermatome regression of sensory block (TTSR) between the groups, (n=60).

Figure 5 shows that the time to time to two segment dermatome regression of sensory block was longer for the participants who received Bupivacaine followed by Fentanyl when compared to those who received premixed Bupivacaine + Fentanyl (144.9 min vs 124.8 min) and it was found to be statistically significant (p<0.001).

The time to first rescue analgesic/ demand for rescue analgesic was longer for the participants who received Bupivacaine followed by Fentanyl when compared to those who received premixed Bupivacaine + Fentanyl (268.5 min vs 156.7 min) and it was found to be statistically significant (p<0.001).

Figure 6 shows that the effect size of change in mean heart rate over time between the two groups was 0.001 and it was not found to be statistically significant (p=0.796). Similarly, there was no significant difference in the mean heart rate over time (Effect size= 0.025; p=0.212)., which thus shows that the heart rate was stable in both groups over time.

Figure 7 shows that the effect size of change in mean systolic blood pressure over time between the two groups was 0.019 and it was not found to be statistically significant (p=0.298). However, the test for a difference in systolic blood pressure over time was statistically significant (Effect size= 0.147; p<0.001), which thus shows that there was a significant fall in systolic blood pressure followed by rise in it over time but there was no significant difference between the groups.

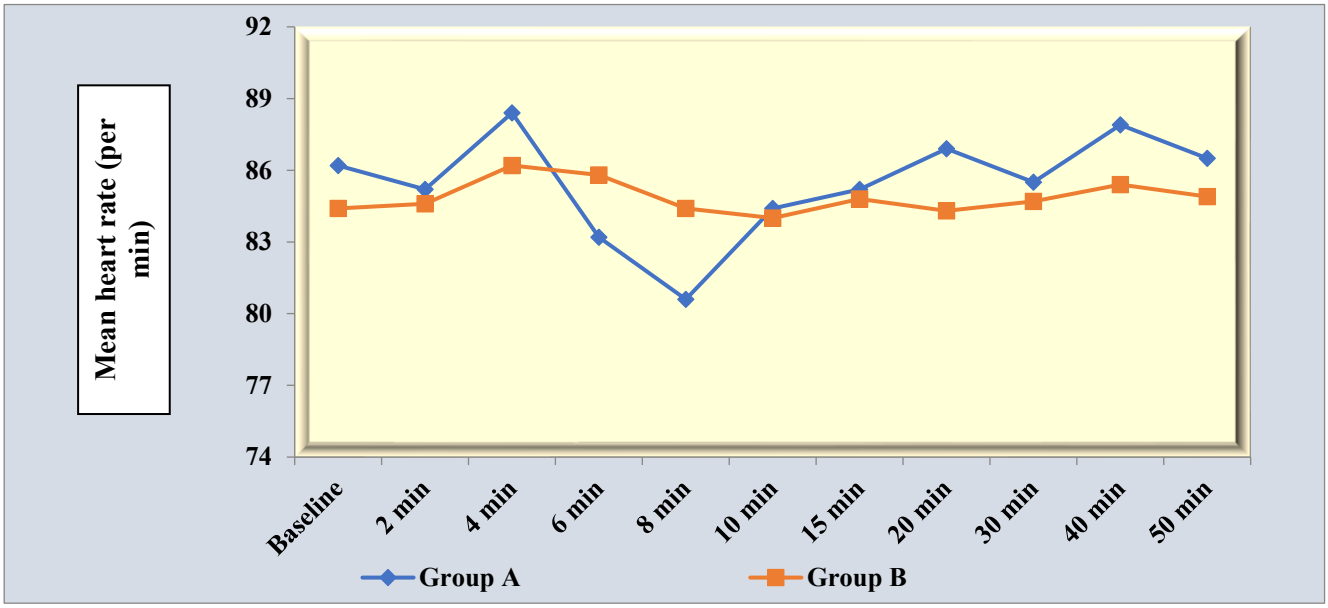

Figure 6: Mean heart rate at various time between the two groups, (n=60).

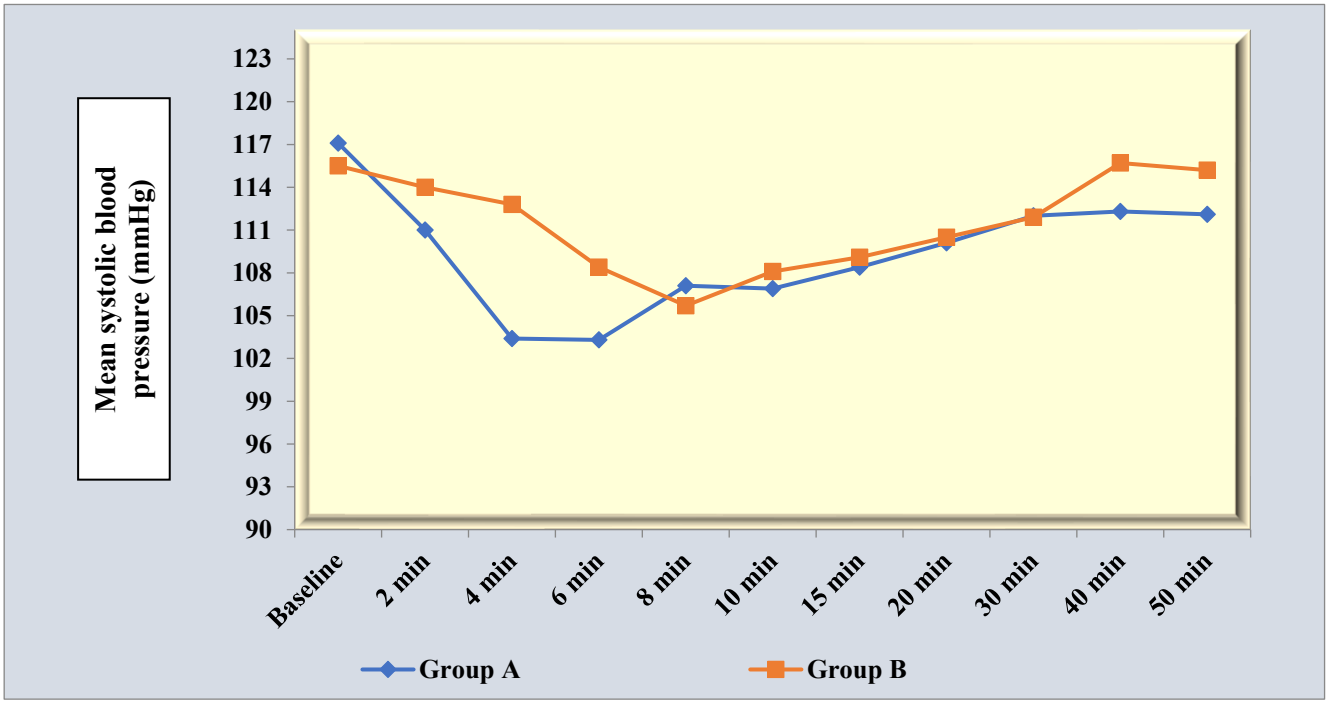

Figure 7: Mean systolic blood pressure at various time between the two groups, (n=60).

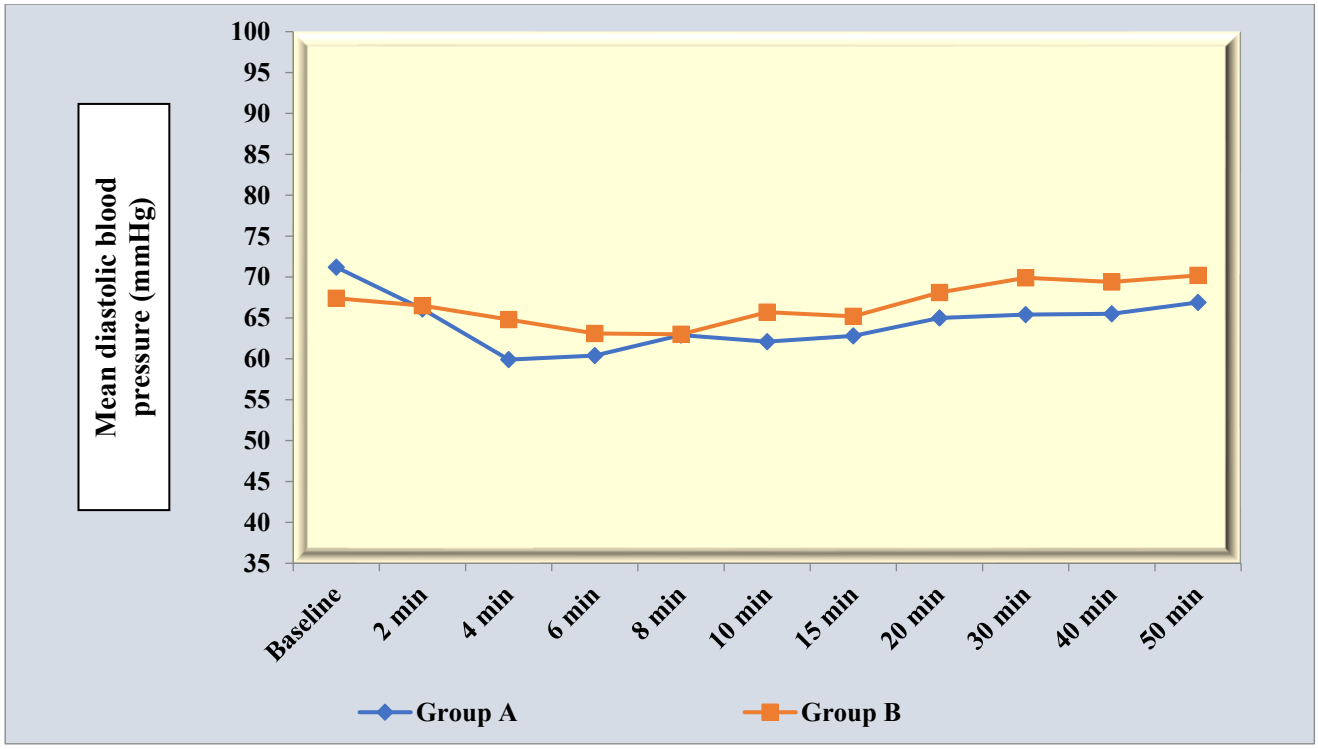

Figure 8: Mean diastolic blood pressure at various time between the two groups, (n=60).

Figure 8 shows that the effect size of change in mean diastolic blood pressure over time between the two groups was 0.040 and it was not found to be statistically significant (p=0.126). However, the test for a difference in diastolic blood pressure over time was statistically significant (Effect size=0.122; p<0.001), which thus shows that there was a significant fall in systolic blood pressure followed by rise in it over time but there was no significant difference between the groups.

Table 2: Comparison of side effects between the groups, (n=60).

Side effects	Type of intervention		P value*
	Group A (n=30), (%)	Group B (n=30), (%)	
Yes	4 (13.3)	3 (10.0)	0.999
No	26 (86.7)	5 (16.7)	

*Fisher's exact test

Table 2 shows that there was no significant difference in the side effects between the groups (p=0.999). Side effects were observed among 7 (11.7%) participants. Of those with side effects, sedation was observed among two women, nausea and vomiting were observed among five women. Pruritis and anxiety was not observed in any women.

There were no significant differences in the APGAR Score of the neonates at the first minute in both the groups. The APGAR Score at 5 minutes was 9/10 for all neonates in both the groups.

DISCUSSION

Spinal anesthesia is a preferred method for lower segment CS due to its direct and efficient delivery of anesthesia to the surgical site, promoting rapid onset and effective pain control with minimal systemic effects. A critical component of this anesthesia technique involves the use of hyperbaric Bupivacaine combined with Fentanyl, which enhances the analgesic quality and duration of the block. However, the method of administering these agents, whether mixed together before injection (premixed) or injected sequentially remains a subject of clinical debate and relatively scant research focus. Existing studies provide contrasting views on the superiority of either method in terms of onset time, quality of anesthesia, duration of action, and safety, leading to variability in clinical practice and potentially inconsistent patient outcomes. Premixed solutions may offer more uniform drug dispersion, while succedent administration might allow for more controlled and adjustable dosing based on immediate surgical and patient responses. Notably, each method may influence the distribution of the anesthetic within the cerebrospinal fluid differently, affecting both the intensity and the extent of the anesthesia. Hence, we conducted a randomized controlled trial to evaluate these two administration techniques by assessing the block characteristics, including the sensory and motor block onset and duration, hemodynamic stability, and the incidence of side effects in a tertiary care centre, to fill the existing knowledge gap, thereby enhancing safety and efficacy and potentially improving neonatal outcomes.

Total of 60 parturients who underwent elective lower segment CS under spinal anaesthesia, the mean age of the study participants was 29.4 years. The study participants were comparable with respect to age, body weight and height between the groups. The mean time of onset of sensory block at T10 was significantly shorter for the participants who received Bupivacaine followed by Fentanyl (Group A 1.5±0.03 mins) when compared to those who received premixed Bupivacaine + Fentanyl (Group B 1.7±0.03 mins). Similarly, the time to achieve maximum sensory block level (Group A 5.1 ±0.1 vs group B 5.9±0.1 mins) and the time to complete motor blockade (Group A 2.7±0.2 vs group B 3.3±0.2 mins) was significantly shorter for the participants who received sequential bupivacaine followed by fentanyl when compared to those who received premixed bupivacaine + fentanyl. The observed differences with sequential administration of Bupivacaine and Fentanyl compared to premixed Bupivacaine + Fentanyl during spinal anesthesia can be attributed to several factors. Firstly, the sequential administration allows for a more controlled and gradual release of the drugs into the intrathecal space. Bupivacaine, a local anesthetic, typically has a slower onset of action due to its lipophilic nature and slow diffusion across nerve membranes. By administering it first, it creates an optimal environment for the subsequent action of Fentanyl, an opioid agonist that acts rapidly upon binding to opioid receptors in the central nervous system. This sequential approach may result in a more precise targeting of the nerve roots, leading to faster onset and spread of sensory blockade. Conversely, the premixed formulation of Bupivacaine + Fentanyl may not allow for the same level of control over drug delivery. The drugs may not be uniformly distributed within the intrathecal space, potentially leading to variations in drug concentration and distribution. This could result in uneven sensory blockade and delayed onset of action compared to the sequential administration method. Also, a mixed solution being less viscous mixes freely in CSF and does not have gravity dependent spread, therefore an unpredictable level of block is attained. Similar results were seen in a study done by Malhotra et al where they reported faster onset of sensory/motor block in the sequential group (2.9±1.1 mins) and delayed in the premixed group (6.3±1.5 mins).[15] Similarly, a study conducted by Keera et al also had shown that the time to onset of sensory block was slightly shorter (Group S 5.07±2.4 vs group M 5.79±3.08 mins) and the mean level of maximal sensory block was slightly higher in sequential block group (3.4±1.273) when compared to the premixed group (3.65±1.392) also with the study results by Shivappagoudar et al where the mean time for onset of sensory block/motor block was shorter in the sequential block group (2.40±0.51/4.35±0.43mins) when compared to the premixed block group (6.70±0.50/7.32±0.64 mins). Similar observations were noted in various other studies conducted elsewhere.[16-18]

Another important observation in our study is that the time to two segment dermatome regression of sensory block was significantly longer for the participants who received sequential Bupivacaine followed by Fentanyl (144.9±13.1 mins) when compared to those who received Premixed Bupivacaine + Fentanyl (124.8±12.7 mins). Also, the time to first rescue analgesic/ demand for rescue analgesic was significantly longer for the participants who received Bupivacaine followed by Fentanyl (268.5±24.0 mins) when compared to those who received premixed Bupivacaine + Fentanyl (156.7±10.4 mins). This difference might be due to the fact that Fentanyl and Bupivacaine as a mixture dilutes the potency of fentanyl and receptor occupancy might decrease leading to less pronounced effect. On the other hand, if Fentanyl is administered separately a greater spread and thereby formation of stronger bonds with the opioid receptor in the spinal cord leads to denser and prolonged block.[19] Our study findings are supported by various other studies. For instance, a study conducted by Malhotra et al showed that the patients who received sequential block experienced prolonged durations of blocks (4.0±0.8 h) when compared to the patients who received premixed block (3.3±0.6 h).[15] Another study by Chekole et al concluded that the average time to first request for rescue analgesia was longer in the Sequential group(289.909±15.255mins) than in the premixed group (261.39±25.378 mins).[20] Even in a study by Kanwariya et al the duration of motor block and the time until the first dose of analgesic was required were significantly longer in sequential group (Group S 182±12.42 min/ 304.62±25.89 min) vs (Group M 156.7±12.39 min/ 283.37±28.37 min).[21] Bansal et al also showed that the regression time for sensory block (Group M=177.50±8.70 minutes, group S=185.83±7.17 minutes) and the duration until the need for rescue analgesia was significantly longer in the sequential group (Group M=200.50±11.08 minutes, group S=210.94±10.03 minutes).[22] Various other studies by Shivappagoudar et al and Kumar et al also yielded similar results. It was also noted that there was no significant difference in the attainment of maximum sensory block levels and requirement of vasopressor between the groups in our study.[17,18]

It is generally believed that hyperbaric Bupivacaine injected separately being denser, sinks down as compared to lesser dense mixture of bupivacaine and fentanyl, and takes a longer time to reach the final level. This delays the onset of sympathetic block and gives time for compensatory mechanisms of the body to prevent hypotension. This hypothesis is supported by studies by Malhotra et al, Keera et al, Shivappagoudar et al, Kumar et al, and Chekole et al in which premixed group reported a higher incidence of hypotension.[15-18,20] However, there was no significant difference between the groups in terms of hemodynamic changes (heart rate, systolic and diastolic blood pressure). Our study are in line with the study findings of Desai et al and Jahanara et al where there were no significant differences between the groups in terms of hypotension and vasopressor use.[23,24] This could be due to the relatively smaller sample size in our study which lacks enough power for arriving at statistical significance. Hence

our study results could be reported based on the clinical significance. Last but not the least, side effects were observed among 11.7% participants. Of those with side effects, sedation was observed among two women, nausea and vomiting was observed among five women. Pruritis and anxiety was not observed in any women. There was no significant difference in the side effects between the groups. The incidence of nausea, vomiting, and pruritus was less in all three groups and not statistically significant in a study by Shivappagoudar et al.[17] Even in a study by Desai et al there was no significant difference in the side effects between the groups, with both the groups showing lesser incidence of side effects.[23] Common side effects included itching and hypotension in a study by Bansal and Ladi.[22]

Strengths and limitations

One of the strengths of the study is the randomized controlled design, which allows for representative comparison between different administration methods of Bupivacaine and Fentanyl. Additionally, the inclusion of multiple outcome measures such as onset of sensory and motor blockade, regression of sensory block, duration of analgesia, and adverse effects provides a comprehensive evaluation of the interventions.

Our study also has certain limitations. Firstly, the study's single-center design may limit the generalizability of the results to other settings/patient populations. Furthermore, the study did not assess patient satisfaction or quality of anesthesia, which are important considerations in clinical practice. Lastly, the specific gravity of drugs and CSF was not measured to predict the spread of drug in relation to CSF. However, it could be concluded that sequential intrathecal injection of hyperbaric bupivacaine followed by fentanyl results in the early onset of sensory and motor blockade, delayed regression of the block, prolongation of analgesia, and stable hemodynamics as compared to premixed drug administration. However, further large multicentric randomized controlled trials could add more strength to our study findings.

CONCLUSION

There were no significant differences in the time to reach sensory block level T6, degree of motor blockade (Bromage scale), neonatal outcome as measured by Apgar score and complications like nausea, vomiting and shivering. However, onset of spinal anaesthesia is faster in the lateral position. Similarly, hypotension is more in the left lateral position. The insignificant difference in block height could be because of adjustments in table position.

Recommendations

Of 60 parturients who underwent elective lower segment CS under spinal anaesthesia, the mean age of the study participants was 29.4 years. The study participants were comparable with respect to age, body weight and height between the groups. The mean time of onset of sensory block at T10 was significantly shorter for the participants who received Bupivacaine followed by Fentanyl when compared to those who received premixed Bupivacaine + Fentanyl ($p<0.001$). The time to achieve maximum sensory block level was significantly shorter for the participants who received Bupivacaine followed by Fentanyl when compared to those who received premixed Bupivacaine + Fentanyl ($p<0.001$). The time to complete motor blockade was significantly shorter for the participants who received Bupivacaine followed by Fentanyl when compared to those who received Premixed Bupivacaine + Fentanyl ($p<0.001$). The time to time to two segment dermatome regression of sensory block was significantly longer for the participants who received Bupivacaine followed by Fentanyl when compared to those who received Premixed Bupivacaine + Fentanyl ($p<0.001$). The time to first rescue analgesic/ demand for rescue analgesic was significantly longer for the participants who received Bupivacaine followed by Fentanyl when compared to those who received Premixed Bupivacaine + Fentanyl ($p<0.001$). There was no significant difference between the groups in terms of hemodynamic changes (heart rate, systolic and diastolic blood pressure). However, there was a significant change in the systolic and diastolic blood pressure over time. There was no significant difference in the attainment of maximum sensory block levels and requirement of vasopressor between the groups. Side effects were observed among 7 (11.7%) participants and there was no significant difference in the side effects between the groups. It could be concluded that the sequential intrathecal injection of hyperbaric bupivacaine followed by fentanyl results in the early onset of sensory and motor blockade, better hemodynamic stability, improved the quality of anesthesia and increased first rescue analgesic request time. However, further large multicentric randomized controlled trials could add more strength to our study findings.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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