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ORIGINAL RESEARCH

Comparison of efficacy of premixed versus succedent administration of fentanyl and bupivacaine in subarachnoid block in lower limb surgeries: A prospective double blinded randomized interventional study

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ABSTRACT

Aim and Objective: To evaluate the differences in level of sensory and motor block and incidence of hypotension whilst administering hyperbaric bupivacaine and fentanyl either in a single syringe or different syringes.

Primary Objective: To determine the difference in mean time of onset of sensory and motor block in three different groups.

Secondary Objective: To determine the difference in mean time of two segment regression of sensory level.

To determine the difference in change in hemodynamic responses from baseline to different time interval in three groups.

Methods: This Prospective, randomized, and double blinded, interventional study enrolled 90 patients of ASA grade I and II, of either sex aged 20-70, Body weight 40-70 kg undergoing lower limb surgeries like orthopedic procedures (lower limb fractures, implant removal) under Spinal Anaesthesia.

The study was conducted in following three groups of patients. A total of 30 patients were included in each group (n=30/group).

Control Group:

Group A: Received premixed 0.5% heavy bupivacaine 2.5ml and 0.5 ml of fentanyl in a single 5.0 ml syringe.

Group B: Received 0.5 ml of fentanyl in a 5.0 ml syringe followed by 0.5% heavy bupivacaine 2.5 ml in a 5.0 ml syringe.

Group C: Received 0.5% heavy bupivacaine 2.5 ml in a 5.0 ml syringe followed by 0.5 ml fentanyl in a 5.0 ml syringe.

Inclusion Criteria

1. The age group of 16-70 years.
2. ASA grade I or II.
3. Patients who were undergoing elective surgeries under general anaesthesia.

Exclusion Criteria

1. Patients not willing to participate in the study.
2. Cases with sepsis, bacteremia, or skin infection of local site.
3. History of severe hypovolemia, anaemia and compromised renal, cardiac, or respiratory status.
4. Cases with raised intracranial tension
5. History of blood coagulopathies.
6. Patient allergic to drugs used for study.
7. Failure of spinal anaesthesia, cases in which general Anaesthesia will be required.

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Results

A total of 90 patients were enrolled for the study.

The Patients were divided into 3 groups of 30 each (Group A, Group B & Group C).

The demographic data were comparable in terms of Age, Sex, Body Weight, type of surgery to ensure that there was no any confounding bias-

- **Age & Gender:** No significant difference in mean age among Group A (45.17±10.23 years), Group B (45±12.27 years), and Group C (45.4±10.71 years) ($p > 0.05$).
- **ASA Grade:** Most patients were ASA Grade II, with no significant difference in proportions.
- **Duration of Surgery:** No significant difference among Group A (65.63±9.86 min), Group B (66.47±11.10 min), and Group C (63.27±10.69 min).
- **Vital Parameters:** No significant differences in Heart Rate, SBP, DBP, MAP, and SpO2 at various time intervals.
- **Onset of Sensory Block:** Group A (6.39±0.85 min) had a significantly longer onset time than Group B (4.61±0.95 min) and Group C (3.11±0.57 min) ($p < 0.001$).
- **Onset of Motor Block:** Group A (7.15±1.15 min) had a significantly longer onset than Group B (5.50±1.08 min) and Group C (3.62±0.73 min) ($p < 0.001$).
- **Time to Two-Segment Regression:** Group A (85.20±7.87 min) was significantly lower than Group B (92.73±7.95 min) and Group C (94.60±6.76 min) ($p < 0.001$). No significant difference between Group B and Group C.
- **Time for First Rescue Analgesia:** No significant difference among Group A (55.17±5.10 min), Group B (57.17±5.28 min), and Group C (56.33±6.17 min).

Complications

Nausea was and vomiting reported to be the most common side effect in all three groups. The difference of proportion of nausea and vomiting in between groups was not statistically significant.

Conclusion

Using hyperbaric bupivacaine followed by fentanyl results in a rapid onset and prolonged duration of sensory and motor block.

Nausea and vomiting were reported to be the most common side effect in all three groups and among all the groups, we did not observe any episodes of hypotension or bradycardia.

Key words: Fentanyl, bupivacaine, subarachnoid block, lower limb surgeries, randomized study

INTRODUCTION

Spinal anesthesia blocks spinal nerve clusters, preventing pain signals from reaching the brain. Subarachnoid block (SAB) is a well-established and versatile technique for lower abdominal and lower limb surgeries, making it the preferred regional anesthesia method, especially in orthopedic procedures[1].

The subarachnoid block is preferred for anesthesia due to its low cost and low incidence of perioperative complications[2] including deep vein thrombosis (DVT), pulmonary embolism, blood loss or hypovolemic shock, and respiratory complications[3].

Drugs for nerve blocks are classified into non-opioids and opioids. Non-opioids include epinephrine, clonidine, dexmedetomidine, neostigmine, adenosine, ketorolac, midazolam, magnesium, sodium bicarbonate, and hyaluronidase. Opioids are either lipophilic (fentanyl, sufentanyl) or hydrophilic (morphine).

Subarachnoid anesthesia is very safe, requiring only a small drug dose to achieve strong and consistent pain relief and motor block with minimal systemic effects. In contrast, epidural anesthesia needs a larger drug dose, which can enter the bloodstream and cause side effects not seen with spinal anesthesia[4, 5].

Adjuvants or additives are often used with local anesthetics for its synergistic effect by prolonging the duration of sensory-motor block and limiting the cumulative dose requirement of local anesthetics[6].

Adjuvants are drugs added to local anesthetics to enhance pain relief, speed up onset, and prolong duration while reducing side effects. Among them, opioids are the most popular due to their superior effectiveness in spinal anesthesia[7].

Neuraxial opioids provide effective pain relief by acting directly on spinal nociceptors. Morphine is commonly used, along with other opioids like fentanyl, sufentanyl, hydromorphone, diamorphine, and meperidine.

Opioids and local anaesthetic administered together are known to have synergistic analgesic effects[8].

Choice of local anesthetic (LA) utilized in SAB is based on the pharmacologic properties of the drug[9].

The opioids potentiate anti-nociception of local anesthetics by G protein coupled receptor mechanisms by causing hyperpolarization of the afferent sensory neurons[10].

The dose, site of injection, lipophilicity, and the acid-base milieu of the site of drug deposition determine the extent of efficacy of the block[11].

The relative density of a local anesthetic in relation to that of the cerebrospinal fluid (CSF) at 37° Celsius is one of the most important physical properties that affect the level of analgesia obtained after the subarachnoid administration of the drug[12].

Hyperbaric bupivacaine is commonly used as it produces more predictable block with less side effects. An amide type of local anesthetic, has high potency, slow onset and long duration of action is commonly employed for spinal Anesthesia[4].

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High doses of intrathecal bupivacaine can cause excessive sensory and motor block, leading to arterial hypotension and delayed hospital discharge. Baricity refers to the drug's density compared to cerebrospinal fluid (CSF); hyperbaric solutions are heavier than CSF and spread according to gravity[13].

Spinal anaesthesia is ideal for lower abdominal and limb surgeries but can cause hypotension, its most common complication. This occurs due to sympathetic blockade, leading to vasodilation, blood pooling, reduced venous return, and decreased cardiac output[4].

Spinal anesthesia is available in isobaric (equal to spinal fluid density) and hyperbaric (denser than spinal fluid) forms. Both are commonly used intrathecally for lower limb surgeries[14].

Bupivacaine is available as 0.25%, 0.5%, and 0.75% clear isobaric solutions and as a hyperbaric 0.5% and 0.75% solution containing 80 mg/ml glucose. At room temperature, plain bupivacaine is slightly hypobaric compared with CSF[15].

Fentanyl has been used as an adjuvant to bupivacaine for spinal anaesthesia as it has been shown both to improve the quality of block and reduce the need for intraoperative supplementation of opioids[16].

Fentanyl is a lipophilic mu-receptor agonist opioid. Intrathecally, it exerts its effect by combining with opioid receptor in dorsal horn of spinal cord and may have supra-spinal spread and action[17].

The use of both fentanyl and morphine intrathecally has been shown to cause significant pruritus, nausea, and sedation in patients with lower limb surgeries[4].

Opioids and non-opioid adjuvants have been added to bupivacaine to increase the duration of effect, provide stable hemodynamics, and provide prolonged postoperative analgesia[4].

Intrathecal fentanyl reduces visceral and somatic pain, enhances block quality, lowers pain scores, and decreases postoperative analgesic needs. Mixing opioids with hyperbaric bupivacaine alters solution density, affecting drug spread in the intrathecal space[18].

At 37°C, the density of cerebrospinal fluid (CSF) is 1.00059 g/ml. Fentanyl has a baricity of 0.99410, while hyperbaric bupivacaine is 1.02360. When mixed in the same syringe, the solution's baricity becomes 1.01850, affecting its spread in CSF[19].

Commonly, adjuvants are mixed with LA in a single syringe before injecting the drugs intrathecally. Mixing of these drugs changes the density of both drugs, thus affecting their spread in the cerebrospinal fluid (CSF)[20].

Alterations in the Baricity of a solution to the extent of 0.0006 can alter the spread of LA in CSF[21].

Hyperbaric solutions are more predictable, with greater spread in the direction of gravity and less inter-patient variability.

This study aims to compare the onset and duration of block and assess hemodynamic effects when administering hyperbaric bupivacaine and fentanyl either in a single syringe or separate syringes.

METHODS

Preoperative Anaesthetic Evaluation Was done before the surgery, that includes;Complete history of patient including any known drug allergy.

GENERAL AND SYSTEMIC EXAMINATION

Pulse rate, NIBP, Respiratory rate and weight of the patient was noted.

INVESTIGATIONS

Hematology-Hb%, TLC, DLC, BT, CT.
Fasting/Random Blood sugar.
Blood urea, Serum Creatinine.
Liver function test (Bilirubin, SGOT, SGPT).
Serum electrolytes.
Chest X-ray.
Electro Cardiogram.

STUDY POPULATION

All the patients scheduled for elective surgery under spinal anaesthesia were screened during pre anaesthetic checkup for inclusion and exclusion criteria and who give informed and written consent were taken in the study population.

MATERIALS

- Anaesthesia work station.
- Monitors-ECG, NIBP, Pulse oximeter, temperature.
- Iv cannula 18G, RL, Colloids 25-gauge spinal needle, ampules of hyperbaric bupivacaine 0.5%, 5cc syringe, sterile gauze pieces, povidone iodine solution, sponge holding forceps.
- Emergency drugs-Adrenaline, Atropine, Mephentermine, Deriphylline, Steroid [hydrocortisone, dexamethasone], Ephedrine, Noradrenalin, Dopamine, Dobutamine, Xylo card 2%, Calcium gluconate, Furosemide, Sodium bicarbonate.
- Miscellaneous- Defibrillator, Suction apparatus, watch, adhesive tape, stethoscope, surgical gloves.

PROCEDURE

- **PREOPERATIVE ASSESSMENT:** Patients undergoing elective surgery under spinal anesthesia were evaluated through history, physical examination, and necessary investigations. They fasted for at least 8 hours before surgery.
- **CONSENT & EXPLANATION:** Patients received detailed information about the procedure, anaesthesia, and drugs, ensuring confidentiality.

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PREPARATION

Operating room temperature was maintained at 23-25°C.

Anaesthesia workstation, monitors, emergency drugs, and intubation equipment were checked.

IV access was secured with an 18G cannula, and patients received 10 ml/kg Ringer lactate over 15 minutes before anaesthesia.

SPINAL ANAESTHESIA PROCEDURE

Performed at L3-L4 interspace under aseptic precautions.

GROUP A: Premixed bupivacaine + fentanyl (single syringe).

GROUP B: Fentanyl first, then bupivacaine (separate syringes).

GROUP C: Bupivacaine first, then fentanyl (separate syringes).

Patients were positioned supine with a 15° head-down tilt to achieve T5-T6 block level.

Oxygen (4L/min) was given via a Venti-mask.

BLOCK ASSESSMENT & SURGERY

Sensory block was assessed via pinprick test (T8 level required for surgery to begin).

Vitals recorded every 5 min (first 30 min), then every 10 min intraoperatively, and every 30 min for 6 hours post-op.

BLOCK CHARACTERISTICS

SENSORY ONSET: Time to T10-T12 level (pinprick test).

MOTOR BLOCK: Measured using Bromage scale (Grade 3 = complete block).

REGRESSION: Time for sensory block to regress by two dermatomes.

POSTOPERATIVE MONITORING & MANAGEMENT

RESCUE ANALGESIA:IV Diclofenac 75 mg (Time to first dose recorded).

Patients monitored for 24 hours for adverse effects (nausea, vomiting, shivering, respiratory depression, sedation, hypotension).

TREATMENT PROTOCOLS

- Hypotension (MAP < 60 mmHg) → IV fluids, ephedrine.
- Bradycardia (HR < 50 bpm) → Atropine 0.6 mg.
- SpO2 < 90% → Increased oxygen or ventilation if needed.
- Nausea/Vomiting → IV metoclopramide 10 mg.
- Allergic reactions → IV hydrocortisone, antihistamines.
- **STUDY END POINT:**Complete sensory and motor block recovery.

RESULTS

Table 1: Age wise distribution of groups

Age Group (Years)	Group A	Group B	Group C
	N (%)	N (%)	N (%)
20-34	3(10)	5(16.7)	3(10)
35-49	21(70)	18(60)	20(66.7)
50-64	3(10)	3(10)	4(13.3)
>64	3(10)	4(13.3)	3(10)
Total	30(100)	30(100)	30(100)
p value = 0.968			

All study groups are comparable as per age distribution. This is evident from the chi square test performed and the P value (0.968) shows non-significant difference (P value>0.05) in age distribution among the groups.

Table 2: Mean Age and Weight of cases

Variable	Group A	Group B	Group C	Test ofSignificance
Age(Years)	45.17±10.23	45±12.27	45.4±10.71	p-value=0.990
Weight(Kg)	61.26±9.1	59.9±9.2	60.9±9.7	p-value=0.843

Mean Age of Group A is 45.17±10.23 years, 45±12.27 years for Group B and 45.4±10.71 for Group C. No significant difference of mean age is found between the study groups. This is also evident from the ANOVA test performed and the p-value (0.990) showed non-significant (>0.05) difference in age.

Mean weight of Group A 61.26±9.1kg, 59.9±9.2kg for Group B and 60.9±9.7 for Group C. No significant difference of mean weight is found between the study groups. This is also evident from the ANOVA test performed and the p-value (0.843) showed non-significant (>0.05) difference in weight.

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Table 3: Gender wise distribution of cases

Sex	Group A(%)	Group B(%)	Group C(%)
Female	8(26.7)	11(36.7)	9(30)
Male	22(73.3)	19(63.3)	21(70)
Total	30(100)	30(100)	30(100)
p value = 0.696			

Majority of patients are male but the difference of proportions of gender was not statistically significant. This is also evident from the chi square test performed, the p-value (0.696) showed non-significant (>0.05) difference in proportion of genders in between all study groups.

Table 4: ASA Grade wise distribution of cases

ASA Grade	Group A	Group B	Group C
	N (%)	N (%)	N (%)
Grade I	9(30)	8(26.6)	10(33.3)
Grade II	21(70)	22(73.4)	20(66.6)
Total	30(100)	30(100)	30(100)
p value = 0.583			

Majority of patients belongs from ASA Grade II (70% in group A, 73.4% in group B and 66.6% in group C) but the difference of proportion of ASA grade are not statistically significant. This is also evident from the chi square test performed, the p-value (0.858) showed non-significant (>0.05) difference in proportions of ASA class in between all study groups.

Table 5: Duration of surgery of cases

Study Group	Duration of surgery		Test of significance
	Mean	SD	
Group A	65.63	9.86	p value=0.480
Group B	66.47	11.10	
Group C	63.27	10.69	

Mean duration of surgery For Group A is 65.63±9.86, 66.47±11.10 for Group B and 63.27±10.69 for Group C. No significant difference of mean duration of surgery is found between the study groups. This is also evident from the ANOVA test performed and the p-value (0.480) showed non-significant (>0.05) difference.

Table 6: Mean Heart rate at different time interval

Heart Rate	Group A	Group B	Group C	Test ofsignificance
Baseline	84.27±5.61	83.7±5.79	81.8±7.05	p value=0.275
Immediatebefore drug	83.3±6.17	83.9±5.62	81.33±7.23	p value=0.269
5 min afterblock	85.8±10.36	79.43±8.84	83.03±12.06	p value=0.068
10 minafter block	80.33±10.5	77.8±7.43	79.97±9.17	p value= 0.511
15 minafter block	76.93±7.33	76.87±7.32	77.57±7.83	p value= 0.923
20 minafter block	78.57±9.85	80.23±6.83	78.67±7.04	p value= 0.667
25 minafter block	78.77±9.95	78.87±7.05	77.07±8.28	p value= 0.656
30 minafter block	74±7.57	76.4±7.22	72.53±7.03	p value= 0.121
60 minafter block	68.43±7.09	71.63±7.77	70.4±8.84	p value= 0.294
90 minafter block	83.17±6.63	82.2±8.1	81.2±7.33	p value= 0.589

There is no significantly difference in Heart rate in between all study Group at baseline, immediate before drug, 5 minutes after block, 10 min after block, 15 min after block, 30 min after block, 60 min after block, 90 min after block. This is also evident from the T test performed, the p-value showed non-significant (>0.05) difference in heart rate.

Table 7: Mean Systolic Blood Pressure at different time interval

SBP	Group A	Group B	Group C	Test ofSignificance
Baseline	133.47±9.4	134.33±9.54	132.2±10.66	p value= 0.703
Immediatebefore drug	131.87±8.76	132.67±8.51	133.77±12.11	p value= 0.759
5 min afterblock	118.43±7.78	120.57±7.86	118.47±6.64	p value= 0.449

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10 min afterblock	120.7±8.77	118.87±7.66	117.5±7.14	p value= 0.293
15 min afterblock	119.03±8.62	117.37±6.89	116.67±7.28	p value= 0.47
20 min afterblock	116.8±11.08	119.13±8.67	119.13±8.22	p value= 0.543
25 min afterblock	117.4±8.29	121.07±9.92	118.13±7.02	p value= 0.215
30 min afterblock	119.97±9.71	119.4±7.45	119.97±6.59	p value= 0.951
60 min afterblock	120.1±6.1	120.07±5.97	122.5±6.34	p value= 0.218
90 min afterblock	127.47±12.45	127.23±12.71	130.6±12.94	p value= 0.521

There is no significantly difference in SBP in between all study Group at baseline, immediate before drug, 5 minutes after block, 10 min after block, 15 min after block, 30 min after block, 60 min after block, 90 min/after block. This is also evident from the T test performed, the p-value showed non-significant (>0.05) difference in SBP.

Table 8: Mean Diastolic Blood Pressure at different time interval

DBP	Group A	Group B	Group C	Test of Significance
Baseline	85.5±6.54	87.23±5.51	86.93±5.04	p value= 0.46
Immediatebefore drug	86.27±4.31	87.57±5.97	87.23±4.9	p value= 0.593
5 min afterblock	77.93±6.14	78.6±5.75	78.63±6.75	p value= 0.829
10 min afterblock	77.6±5.93	78.67±4.78	79.87±6.16	p value= 0.305
15 min afterblock	75.57±7.19	78.43±6.82	78.53±6.47	p value= 0.168
20 min afterblock	75.03±6.82	77.67±8.84	78.77±5	p value= 0.115
25 min afterblock	75.2±8.91	79.5±5.32	77.43±9.16	p value= 0.12
30 min afterblock	79.67±8.08	77.2±7.22	79.13±8.55	p value= 0.455
60 min afterblock	78.93±7.25	80.3±5.81	81.4±4.21	p value= 0.271
90 min afterblock	81.13±8.33	83.47±6.68	81.77±6.71	p value= 0.442

This Table Depicts comparison of Mean Diastolic Blood Pressure in between Group A, Group B Group C. There is no significantly difference in Mean Diastolic Blood Pressure in between all study Group at baseline, immediate before drug, 5 minutes after block, 10 min after block, 15 min after block, 30 min after block, 60 min after block, 90 min after block. This is also evident from the T test performed, the p-value showed non-significant (>0.05) difference in Diastolic Blood Pressure.

Table 9: Mean of MAP at different time interval

MDP	Group A	Group B	Group C	Test of Significance
Baseline	105.62±7.27	105.22±5.31	105.27±7.16	p value= 0.968
Immediatebefore drug	106.26±4.99	104.81±5.53	103.92±7.48	p value= 0.331
5 min afterblock	101.23±8.9	104.36±13.68	104.64±9.76	p value= 0.422
10 min afterblock	83.69±5.2	85.3±5.6	83.28±5.23	p value= 0.307
15 min afterblock	81.92±5.02	83.62±4.82	81.86±4.97	p value= 0.296
20 min afterblock	77.68±5.07	80.3±5.65	80.28±5.01	p value= 0.09
25 min afterblock	96.22±4.97	96.58±5.79	95.64±7.48	p value= 0.84
30 min afterblock	94.33±5.85	96.46±4.66	93.79±6.6	p value= 0.172
60 min afterblock	89.94±5.55	92.11±5.92	92.74±5.04	p value= 0.126
90 min afterblock	89.92±7.09	92.7±4.07	89.61±7.34	p value= 0.122

This Table Depicts comparison of MAP in between Group A, Group B and Group C. There are is significantly difference in MAP in between all study Group at baseline, immediate before drug, 5 minutes after block, 10 min after block, 15 min after block, 30 min after block, 60 min after block, 90 min after block. This is also evident from the T test performed, the p-value showed non-significant (>0.05) difference in MAP.

Table 10: Mean SPO2 at different time interval

SPO2	Group A	Group B	Group C	Test ofSignificance
Baseline	99.9±0.31	99.9±0.31	99.93±0.25	p value= 0.876
Immediatebefore drug	99.9±0.31	99.9±0.31	99.93±0.25	p value= 0.876
5 min afterblock	99.2±0.92	99.3±0.75	99.43±0.68	p value= 0.521
10 min afterblock	99.67±0.61	99.37±0.72	99.37±0.72	p value= 0.152
15 min afterblock	99.4±0.67	99.2±0.92	99.3±0.79	p value= 0.631

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20 min afterblock	99.63±0.61	99.33±0.71	99.43±0.73	p value= 0.232
25 min afterblock	99.23±1.19	99.17±0.95	99.43±0.57	p value= 0.523
30 min afterblock	99.23±0.82	99.4±0.77	99.33±0.84	p value= 0.726
60 min afterblock	99.27±0.87	99.17±0.95	99.37±0.85	p value= 0.686
90 min afterblock	99.2±0.85	99.33±0.76	99.4±0.72	p value= 0.6

This Table depicts comparison of Mean SPO2 level in between Group A, Group B and Group C. There is no significantly difference in Mean SPO2 in between all study Group at baseline, immediate before drug, 5 minutes after block, 10 min after block, 15 min after block, 30 min after block, 60 min after block, 90 min after block. This is also evident from the T test performed, the p-value showed non-significant (>0.05) difference in Mean SPO2.

Table 11A: Mean time of onset of sensory block

Study Group	Mean time of onset of sensory block		Test of significance
	Mean	SD	
Group A	6.39	0.95	p value<0.001
Group B	4.61	0.95	
Group C	3.11	0.57	

Table 11B: Post hoc Tukey test

Pair wise (Post hoc test)	P value
Group A vs Group B	<0.001
Group A vs Group C	<0.001
Group B vs Group C	<0.001

Mean time of onset of sensory block For Group A is 6.39±0.85, 4.61±0.95 for Group B and 3.11±0.57 for Group C. Mean time of onset for sensory block for Group A is significantly (p-value <0.001) higher than group B and group C.

Table 12A: Mean time of onset of motor block

Study Group	Mean time of onset of motor block		Test ofsignificance
	Mean	SD	
Group A	7.15	1.15	p value<0.001
Group B	5.50	1.08	
Group C	3.62	0.73	

Table 12B: Post hoc Tukey test

Pair wise (Post hoc test)	P value
Group A vs Group B	<0.001
Group A vs Group C	<0.001
Group B vs Group C	<0.001

This Table depicts the Mean time of onset of motor block Mean time of onset of motor block For Group A is 7.15±1.15, 5.50±1.08 for Group B and 3.62±0.73 for Group C. Mean time of onset for motor block for Group A is significantly (p-value <0.001) higher than group B and group C.

Table 13A: Mean time to two segment regression (in mins.)

Study Group	Mean time to two segment regression		Test ofsignificance
	Mean	Standard Deviation	
Group A	85.20	7.87	p value<0.001
Group B	92.73	7.95	
Group C	94.40	6.76	

Table 13B: Post hoc Tukey test

Pair wise (Post hoc test)	P value
Group A vs Group B	0.001
Group A vs Group C	<0.001
Group B vs Group C	0.670

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Table:13 depicts the Mean time to two segment regression Mean time to two segment regression For Group A is 85.20±7.87, 92.73±7.95 for Group B and 94.60±6.76 for Group C. Mean time to two segment regression for Group A is significantly (p-value <0.001) lower than group B and group C (post hoc test). Difference of Mean time to two segment regression in between Group B and Group C is not statistically significant (>0.05).

Table 14: Mean time of first rescue analgesia (in mins.)

Study Group	Time of first rescue analgesia		Test of significance
	Mean	SD	
Group A	55.77	5.10	p value=0.617
Group B	57.17	5.28	
Group C	56.33	6.17	

Table no. 14 depicts the Mean time of first rescue analgesia Mean time of first rescue analgesia for Group A is 55.17±5.10, 57.17±5.28 for Group B and 56.33±6.17 for Group C. No significant difference of Mean time of first rescue analgesia is found between the study groups. This is also evident from the ANOVA test performed and the p-value (0.617) showed non-significant (>0.05) difference in Mean time of first rescue analgesia.

Table 15: Complication in Group A, Group B and Group C

Complication	Group A	Group B	Group C	Test of significance
	N (%)	N (%)	N (%)	
Nausea	18(60)	22(73.33)	19(63.33)	P value =0.528
Vomiting	5(16.6)	6(20)	4(13.3)	P value =0.787
Bradycardia	0	0	0	-
Hypotension	0	0	0	-

Nausea and vomiting were reported to be the most common side effect in all three groups. The difference of proportion of nausea and vomiting in between groups is not statistically significant. This is evident from chi square test performed and the p-value (0.617) showed non-significant (P value > 0.05)) difference in proportion of Nausea and vomiting complication in between Groups.

DISCUSSION

Spinal anaesthesia is a widely used technique for lower limb surgeries due to its reliability, cost-effectiveness, and minimal perioperative complications. Subarachnoid block (SAB) is an established method that provides profound sensory and motor blockade. Various drugs, including opioids and non-opioids, are used as adjuvants to local anaesthetic (LA) to enhance the efficacy and prolong the duration of anaesthesia.

Fentanyl is a commonly used opioid adjuvant with bupivacaine, contributing to improved block quality and reduced need for intraoperative supplementation. The method of drug administration-whether premixed in a single syringe or administered sequentially-can impact the spread, efficacy, and onset of anaesthesia.

OBJECTIVE

The study aims to compare the onset and duration of sensory and motor blockade, as well as hemodynamic effects, when administering fentanyl and hyperbaric bupivacaine either premixed or in separate syringes.

METHODS

This hospital-based, double-blind, randomized interventional study was conducted at S.M.S. Hospitals, Jaipur, with 90 patients undergoing lower limb surgeries under spinal anaesthesia. The participants were divided into three groups:

- **GROUP A:** Received premixed 0.5% heavy bupivacaine (2.5ml) with fentanyl (0.5ml) in a single syringe.
- **GROUP B:** Received fentanyl (0.5ml) first, followed by bupivacaine (2.5ml) in separate syringes.
- **GROUP C:** Received bupivacaine (2.5ml) first, followed by fentanyl (0.5ml) in separate syringes.

PREOPERATIVE PREPARATION

- Patients were assessed preoperatively through history, general physical examination, and necessary investigations.
- Patients were kept nil per oral for at least 8 hours before surgery.
- The procedure was explained, and informed consent was obtained.
- The operating room temperature was maintained at 23-25°C.
- IV access was secured, and patients were preloaded with Ringer's lactate (10ml/kg) before spinal anaesthesia.

ANAESTHETIC PROCEDURE

- Spinal anaesthesia was administered at the L3-L4 interspace with the patient in a sitting position.

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- After injection, the patient was placed in a supine position with a 15° head-down tilt to achieve a T5-T6 block.
- Oxygen (4L/min) was provided via a Venti-mask.
- Sensory and motor block levels were assessed at regular intervals using pinprick tests and the Bromage scale.
- Hemodynamic parameters (HR, SBP, DBP, MAP, and SpO2) were monitored at baseline and post-administration intervals.

RESULTS

DEMOGRAPHIC DATA

- **MEAN AGE:**No significant difference was found between the groups.
- **GENDER:**Majority of patients were male, with no statistically significant difference in distribution.
- **ASA GRADE:**Most patients were ASA Grade II, with no significant variation among groups.

SURGICAL PARAMETERS

- **MEAN DURATION OF SURGERY:**No significant difference among groups.
- **HEART RATE, SBP, DBP, MAP, ANDSpO2:** No significant differences at various time points.

BLOCK CHARACTERISTICS

ONSET OF SENSORY BLOCK

- **GROUP A:**6.39±0.85 min
- **GROUP B:**4.61±0.95 min
- **GROUP C:** 3.11±0.57 min
- Faster onset in Group C ($p<0.001$).

ONSET OF MOTOR BLOCK

- **GROUP A:**7.15±1.15 min
- **GROUP B:**5.50±1.08 min
- **GROUP C:**3.62±0.73 min
- Group C had the fastest onset ($p<0.001$).

TWO-SEGMENT REGRESSION TIME

- **GROUP A:**85.20±7.87 min
- **GROUP B:**92.73±7.95 min
- **GROUP C:**94.60±6.76 min
- Group A had significantly shorter duration ($p<0.001$).
- No significant difference between Groups B and C.

TIME TO FIRST RESCUE ANALGESIA

- **GROUP A:**55.17±5.10 min
- **GROUP B:** 57.17±5.28 min
- **GROUP C:**56.33±6.17 min
- No significant difference among groups.

ADVERSE EFFECTS

- No significant occurrences of hypotension, bradycardia, respiratory depression, or allergic reactions.
- Nausea and vomiting were managed with IV metoclopramide.
- Patients with stable vitals and complete recovery were discharged to the ward postoperatively.

CONCLUSION

Using hyperbaric bupivacaine followed by fentanyl results in a rapid onset and prolonged duration of sensory and motor block.

Nausea and vomiting were reported to be the most common side effect in all three groups and among all the groups, we did not observe any episodes of hypotension or bradycardia.

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CONFLICT OF INTEREST: None.

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