



Comparative Study of Intrathecal Fentanyl versus Buprenorphine as Adjuvant To 0.5% Hyperbaric Bupivacaine in Orthopaedic Lower Limb Surgeries

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ABSTRACT

Background: Intrathecal anaesthesia is widely administered anaesthetic technique for lower limb orthopaedic surgeries. Various adjuvants have been used to prolong the analgesic effect of Bupivacaine intrathecal anaesthesia. Our study aims to assess the effects of buprenorphine and fentanyl as an adjuvant to bupivacaine for postoperative analgesia in lower limb Orthopaedic surgeries after spinal anaesthesia.

Methods and Materials: 60 patients posted for orthopaedic lower limb surgery were randomly categorised into two groups and receiving 25µg of fentanyl and 60µg of buprenorphine respectively in group A and B as adjuvants to 15mg of 0.5% hyperbaric bupivacaine (3ml). The primary objective was to compare the onset and duration of sensory and motor block and to assess the highest level of sensory block. The secondary outcome were duration of post operative analgesia, hemodynamic parameters and side effect or complications.

Results: The onset of sensory block, time to highest sensory level and time for 2 segment regression was prolonged in Group B as compared to Group A. No significant difference in the mean

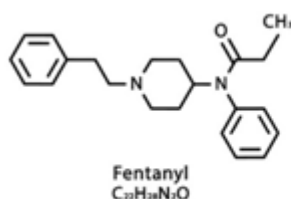
duration of analgesia between both the groups while motor blockade was significantly higher in group B as compared to Group A.

Conclusion: The duration of sensory block, motor block and duration of post-operative analgesia was better in buprenorphine group as compared to fentanyl group.

I. INTRODUCTION

Neuraxial blockade is the most common and widely used anaesthetic technique for lower limb orthopaedic surgeries. Local anaesthetic provides excellent intraoperative analgesia but weaning of analgesic effect especially in prolonged surgeries is a practical limitation often experienced. Opioids improve intraoperative analgesia and prolong duration of post operative analgesia.¹ Intrathecal opioids amplify sensory blockade with no effect on sympathetic activity.²

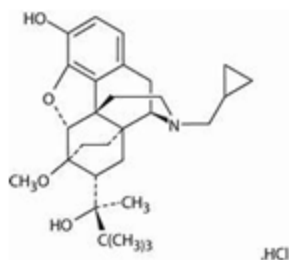
Fentanyl is a lipophilic phenylpiperidine derivative. It is a synthetic opioid agonist. Intrathecal administration will improve intraoperative sensory block without much effect on sympathetic or motor blockade. Post operative analgesia duration and quality is also significantly improved.³



Chemical structure of Fentanyl



Buprenorphine is a semi synthetic μ -receptor agonist-partial or full δ -receptor agonist and competitive antagonist at receptor. It is a centrally acting lipid soluble agent exhibiting its property at both spinal and supra spinal level.⁴ High



Chemical structure of Buprenorphine

affinity, lipid solubility and high affinity for opioids make buprenorphine good spinal adjuvant for tackling intraoperative and post operative pain.⁵

This study was conducted to compare the two drugs as better adjuvant with respect to onset and duration of sensory and motor block, duration of analgesia, haemodynamic stability and adverse effects associated with them when given intrathecally with hyperbaric 0.5% bupivacaine.

OBJECTIVE

PRIMARY OBJECTIVE

1. Onset and duration of sensory and motor block.
2. Highest Level of Sensory Block.

SECONDARY OBJECTIVE

1. Duration of post operative analgesia.
2. Hemodynamic parameters
3. Any complications or side effects present during the procedure.

II. MATERIALS AND METHODS

This study was conducted under the Department of Anaesthesiology at MGM Medical College, Kamothe, Navi Mumbai for a period of 1 year from 1st June 2022 to 31st May 2023. Patients belonging to American Society of Anesthesiologists (ASA) Physical Status I and II patients, aged between 18- and 60-years undergoing elective lower limb orthopaedic surgery under spinal anaesthesia were included in the study.

Patients with known allergy to any local anaesthetic or opioid like fentanyl, buprenorphine, Pregnancy and lactation, progressive neurodegenerative disorder, spine deformities, Hypovolemic shock and patients with contraindications for subarachnoid block were excluded from the study.

Detailed pre anaesthetic evaluation was carried out with history, general physical examination. and systemic examinations including

airway assessment and the surface anatomy of the lumbar spine. Vital parameters including pulse rate, respiratory blood pressure, oxygen saturation was noted.

Institutional ethical committee approval and written, valid informed consent explaining the risk to the patient involved in the procedure were obtained.

Patients were randomly divided into 2 groups (n=30). Sequentially numbered sealed opaque envelopes were used for allocation concealment.

Group A: received 15 mg Hyperbaric Bupivacaine 0.5% (3ml) with Fentanyl 25 μ g.

Group B: received 15 mg Hyperbaric Bupivacaine (0.5%) 3ml with Buprenorphine 60 μ g.

- Patient were made familiar to the method of assessment of sensory and motor block. After ensuring adequate NBM status patients were wheeled into the operation theatre, standard ASA monitors were applied, and baseline readings were noted. An intravenous line was secured, and ringer lactate solution was started at 15 ml/kg. Subarachnoid block was given in sitting position via midline approach under strict aseptic precautions using 25 G Quincke Babcock needle and the patients were made supine after drug injection. Highest level of sensory block was assessed by light touch, cold swab and pinprick method in caudal to cephalic direction every two minutes till onset of sensory block. Motor block was assessed by modified Bromage scale.⁶
- Grade I: Free movement of legs and feet.
- Grade II: Just able to flex knees with free movement of feet.
- Grade III: Unable to flex knees but with free movement of feet.



- Grade IV: Unable to move legs or feet.

A sensory level of T10 and modified Bromage score of three for motor blockade is considered satisfactory. Any side effects such as nausea, vomiting, shivering, hypotension, bradycardia were noted. Post operative pain was assessed by Numeric pain rating where 0 indicates no pain while 10 indicates worst pain. NRS was assessed every 30 minutes. An NRS score >3 received rescue analgesia with Inj Paracetamol 20mg/kg and time was noted.

III. STATISTICAL ANALYSIS :

Power analysis suggested that a sample size of 30 patients per group was required to achieve a power of 70% and significance of 0.05 to detect difference in mean onset of analgesia between the groups. Data are expressed as mean±SD as appropriate. Statistical analysis was performed by SPSS 20.0 software.

IV. RESULT:

Table 1 shows demographic data where there is no significant difference between both groups.

Table 1: Distribution of study subjects according to the age and sex

	Group A		Group B		Total	
	N	%	n	%	N	%
Age (in years)						
<=30	15	50.0%	8	26.7%	23	76.7%
31-40	4	13.3%	4	13.3%	8	26.7%
41-50	6	20.0%	7	23.3%	13	43.3%
51-60	5	16.7%	11	36.7%	16	53.3%
Gender						
Male	16	53.3%	16	53.3%	32	106.7%
Female	14	46.7%	14	46.7%	28	93.3%

Table 2 indicates descriptive statistics for quantitative variables like height(cm), weight(kg), ASA grade and duration of surgery in minutes. No significant difference was observed (p>0.05).

Table 2: Between groups comparison of Height, Weight, ASA grade and Duration of surgery

Group	N	Mean	SD	SEM	t-stat	p-value
Height (cm)	Group A	30	168.267	11.635	2.208	0.061, NS
	Group B	30	164.167	9.674		
Weight (kg)	Group A	30	62.200	7.667	-0.870	0.388, NS
	Group B	30	64.467	12.034		
ASA grade	Group A	30	1.533	0.629	0.680	0.499, NS
	Group B	30	1.433	0.504		
Duration of surgery in (min)	Group A	30	96.333	30.680	1.441	0.155, NS
	Group B	30	86.667	20.229		



Table 3 indicates comparison of intraoperative parameters.

The onset of sensory block (minutes) was longer in group B(4.833± 0.791) as compared to group A(2.233±0.898) (p< 0.001)

The time for two segment regression was higher in group B(106.00 ± 10.70) when compared to group A (79.867±13.63)(p< 0.001)

No significant difference was observed in the mean duration of analgesia among the groups Group

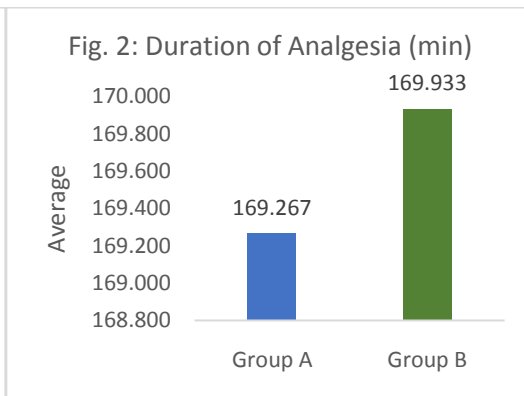
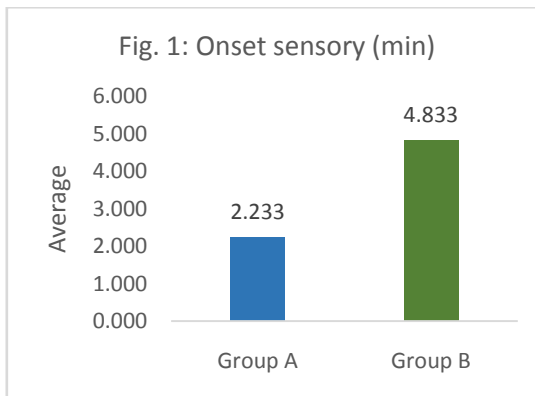
A(169.267±9.217) Group B (169.933±9.566) (p=0.784)

Time to achieve Bromage 0 was higher in Group B(517.000±64.656) as compared to Group A (275.667±43.206) (p< 0.001)

Time to achieve Bromage 3 was higher in Group B(4.833±0.791) as compared to Group A (2.233±0.898) (p< 0.001)

Table 3: Comparison of Intraoperative Observations

Group		N	Mean	SD	SEM	t-stat	p-value
i. Onset sensory block (min)	Group A	30	2.233	0.898	0.164	-	<.001**
	Group B	30	4.833	0.791	0.145	11.90	
ii. Time for 2 segment regression (min)	Group A	30	79.867	13.630	2.488	-8.26	<.001**
	Group B	30	106.000	10.700	1.953		
iii. Duration of Analgesia(min)	Group A	30	169.267	9.217	1.683	-0.27	0.784, NS
	Group B	30	169.933	9.566	1.747		
iv. Time to achieve Bromage 0 (min)	Group A	30	275.667	43.206	7.888	-17.00	<.001**
	Group B	30	517.000	64.656	11.804		
v. Time to achieve Bromage 3 (min)	Group A	30	2.233	0.898	0.164	-11.90	<.001**
	Group B	30	4.833	0.791	0.145		



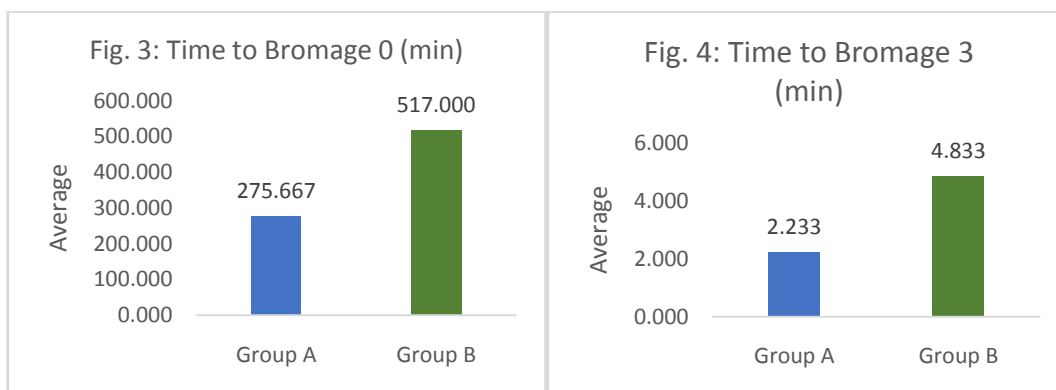


Table 4 indicates comparison of heart rate between both the groups at different durations. There is no significant difference between the mean heart rate among Group A and Group B ($p < 0.05$).

Table 4: Between group comparison of Heart rate at various durations

	Group A		Group B		t-stat	p-value
	Mean	SD	Mean	SD		
Baseline	74.533	12.114	70.667	9.618	1.369	0.176, NS
at 15 minutes	82.667	13.979	78.200	9.517	-1.816	0.075, NS
at 45 minutes	81.000	11.456	79.067	9.154	1.996	0.051, NS
at 90 minutes	80.467	12.359	78.667	10.039	0.953	0.345, NS
at 180 minutes	83.533	12.851	78.800	11.260	-0.812	0.42, NS

Table 5 indicates comparison of systolic blood pressure between both the groups at different durations. There is no significant difference between the systolic blood pressure among Group

A and Group B ($p < 0.05$) at each duration except at 90 minutes. At 90 minutes, the systolic blood pressure was significantly higher in group A as compared to group B ($p < 0.01$)

Table 5: Between group comparison of SBP at various durations

	Group A		Group B		t-stat	p-value
	Mean	SD	Mean	SD		
Baseline	123.333	11.842	128.000	7.611	1.447	0.153, NS
at 15 minutes	100.333	14.735	96.667	6.065	1.260	0.213, NS
at 45 minutes	96.667	10.283	95.667	8.976	0.000	1.00, NS
at 90 minutes	106.000	13.025	102.000	9.965	2.896	0.005**
at 180 minutes	128.333	12.888	132.000	7.611	1.819	0.074, NS

Table 6 indicates comparison of diastolic blood pressure between both the groups at different durations. There is no significant difference

between diastolic blood pressure among Group A and Group B ($p < 0.05$) at each duration.

Table 6: Between group comparison of DBP at various durations



	Group A		Group B		t-stat	p-value
	Mean	SD	Mean	SD		
Baseline	78.000	7.611	74.667	5.074	0.722	0.473, NS
at 15 minutes	67.000	10.222	67.000	5.960	0.401	0.690, NS
at 45 minutes	64.667	8.604	62.667	5.833	1.054	0.296, NS
at 90 minutes	75.000	7.311	72.667	6.397	1.218	0.228, NS
at 180 minutes	81.667	7.466	79.667	4.138	0.515	0.609, NS

Table 7 indicates first rescue analgesic time (min) between both the groups. There is no significant difference between first rescue analgesic time among Group A and Group B ($p < 0.05$) at each duration.

Table 7: Comparison of first rescue analgesic time

Group	N	Mean	SD	SEM	t-stat	p-value
First rescue analgesic time (min)						
Group A	30	172.167	8.060	1.472	0.73	0.46, NS
Group B	29	170.345	10.933	2.030		

NS: Not significant

V. DISCUSSION:

Intrathecal anaesthesia is main stay for lower limb surgeries. August Bier administered the first spinal anaesthesia in humans.⁷ Post operative pain relief holds equal importance as intraoperative pain management thus various drugs have been used as adjuvants to local anaesthetics to prolong the effects of spinal anaesthesia. For the purpose of our study, we have compared the effects of Fentanyl and Buprenorphine on analgesia and motor blockade. After a thorough literature survey, we can conclude that there isn't enough evidence to support better efficacy between the two drugs. Our study is a double blinded comparative study to assess the effectiveness of intrathecal Fentanyl versus Buprenorphine as adjuvants to hyperbaric Bupivacaine for prolongation of intraoperative and post operative analgesia. Variation in hemodynamic parameters and side effects were secondary outcomes of the study.

ONSET OF SENSORY BLOCK

Mean time of onset of sensory block in Group A (Bupivacaine Fentanyl) and Group B (Bupivacaine Buprenorphine) was 2.333 minutes and 4.833 minutes respectively. Thus, indicating that addition of fentanyl hastened the onset of sensory block.

ANALGESIA

Mean duration of analgesia was higher in Group B (Bupivacaine+Buprenorphine) as compared to Group A (Bupivacaine+Fentanyl) and these values were statistically significant as seen in Table 3. Opioids and local anaesthetics exert their antinociceptive effects in the spinal cord through mu receptors and sodium pump respectively.

Fentanyl is a short acting opioid receptor agonist which gets rapidly metabolised from the site of action whereas buprenorphine is a partial agonist (agonist and antagonist) which gets absorbed into spinal venous plexus slowly thereby remaining available at site of action for a longer duration. Buprenorphine also has higher affinity for narcotic receptors making it the favourable drug.

ONSET OF MOTOR BLOCK

There was an earlier onset of motor blockade in Group B (Bupivacaine Buprenorphine) as compared to Group A (Bupivacaine Fentanyl) which was statistically significant ($p < 0.001$).

MOTOR BLOCKADE REGRESSION (BROMAGE 0)

Mean time for motor regression to Bromage 0 is statistically significant ($p < 0.001$) as seen in Table 3(iv). Addition of Buprenorphine prolongs the duration of motor blockade.

SIDE EFFECTS



Few mild side effects were observed in both the groups which were not statistically significant.

VI. CONCLUSION

We can conclude that addition of 25 µg Fentanyl and 60 µg Buprenorphine to 0.5% hyperbaric Bupivacaine enhances the quality of sensory block and analgesia after subarachnoid block thereby providing better peri operative analgesia and reducing incidence of complications associated with higher doses of drugs.

Intrathecal Bupivacaine + Fentanyl provides faster onset of sensory analgesia and motor blockade whereas Bupivacaine + Buprenorphine prolongs duration of post operative analgesia with better motor blockade.

Ethical consideration

The Institutional Ethics Committee of MGM Medical College, Navi Mumbai, Maharashtra, India reviewed and approved the research study entitled "Comparative study of Intrathecal Fentanyl versus Buprenorphine as adjuvant to 0.5% Hyperbaric Bupivacaine in orthopaedic lower limb surgeries"

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Nil

Conflicts of interest

There are no conflicts of interest.

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