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A PROSPECTIVE STUDY TO COMPARE THE EFFICACY OF INTRATHECAL FENTANYL WITH BUPIVACAINE IN PATIENTS UNDERGOING LOWER LIMB ORTHOPAEDIC SURGERIES

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Abstract:

Background: Spinal anaesthesia is the most common neuraxial anaesthesia for infraumblical surgeries. Various adjuvants are used to enhance the quality and duration of spinal anaesthesia.

Aims and Objectives: The aim of this study was to evaluate the onset, duration of sensory and motor block, hemodynamic effects, duration of analgesia and adverse effects of fentanyl given intrathecally with 0.5% bupivacaine heavy in patients undergoing lower limb orthopaedic surgeries.

Materials and Methods: This prospective randomized double blinded study was conducted on total sixty patients undergoing lower limb orthopedic surgeries. They were divided into two groups of thirty five patients each. Group F received 25 μg fentanyl with 3 ml 0.5% bupivacaine heavy and group B received 3.0 ml 0.5% bupivacaine heavy. The onset and duration of sensory and motor blockade, duration of analgesia, haemodyamics, and side effects were assessed.

Results: The mean time of onset of sensory and motor blockade was significantly less in fentanyl ($p<0.001$) .Duration of sensory , motor block and duration of analgesia was more in fentanyl group(p value <0.001) whereas incidence of side effects such as bradycardia, hypotension, shivering were also less but the difference was not significant .

Conclusions: We concluded from our study that addition of fentanyl intrathecally as an adjuvant effectively augmented the quality of spinal anaesthesia and also provided stable haemodynamics and lesser side effects as compared to plain bupivacaine.

Keywords- Fentanyl, Bupivacaine, Spinal anaesthesia

1. INTRODUCTION

Spinal anaesthesia is a safe and most commonly used anaesthesia for infraumblical surgeries. It provides adequate surgical anaesthesia and also prolongs post-operative pain relief by using various local anaesthetic agents. It has a faster onset and effectively provides adequate sensory and motor blockade.[1]

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Varuous intrathecal adjuvants such as opioids, clonidine, neostigmine, ketamine, magnesium and benzodiazepines are known to prolong analgesia, improve quality of subarachnoid block and to reduce the incidence of side effects.[2]

The addition of intrathecal opioids to spinal anaesthesia are known to prolong the anaesthesia and also improve its quality.[3-4]

Fentanyl, a synthetic opioid and μ receptor agonist is a highly lipid soluble drug. On intrathecal administration it has a property of rapidly binding to dorsal horn opioid receptors in spinal cord. This causes rapid and quick onset of anaesthesia. It is known to be associated with many side effects such as respiratory depression, nausea and vomiting, pruritus, urinary retention, and hemodynamic instability[5], but it does't delay motor recovery.[6.] It has less risk of delayed respiratory depression.[7]

In this prospective randomized controlled study, we compared intrathecal bupivacaine 0.5 % heavy with fentanyl citrate as an adjuvant to 0.5 % bupivacaine heavy in spinal anaesthesia for lower limb orthopaedic surgeries.

AIMS AND OBJECTIVES

AIM- To compare the block characteristics between intrathecal 0.5% bupivacaine heavy and intrathecal fentanyl with 0.5% bupivacaine heavy.

Primary objective

To compare the effectiveness of fentanyl citrate as an adjuvant to intrathecal 0.5% bupivacaine heavy in terms of onset of motor block.

Secondary objective:

1. The time of onset of sensory blockade (upto T8).
2. The duration of sensory blockade (regression to L1) and motor blockade (regression to modified Bromage score 0).
3. Duration of analgesia and Visual Analogue Scale scores.
4. Incidence of side effects.

2. MATERIALS AND METHODS

Our study was carried out during 2022-2023. Seventy patients, belonging to age group of 18-60 years and ASA I & II were included in our study, who were posted for lower limb surgeries under spinal anaesthesia.

From the study done by Arora et al[8]. ,considering average time for onset of motor block as 5 minutes with standard deviation 1 min in Bupivacaine + Fentanyl group and average time for onset of motor block as 6 min with standard deviation 1 min in Bupivacaine + Magnesium sulphate at 95% confidence interval and 95% power of test, using the formula

$n = (S_1^2+S_2^2)(Z_{\alpha/2}+Z_{1-\beta})^2/ (\mu_1-\mu_2)^2$

where S_1 = 1min, S_2 = 1min

μ_1 = 5 min , μ_2 = 6 min

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$Z_{\alpha/2} = 1.96$, $Z_{1-\beta} = 1.64$

Putting these all values in the formula, we obtained n=35
So 35-35 patients were assigned under each group
So total sample size required for the study was 70.

Patients were randomized into 2 groups by sealed envelope method based on adjuvant drug received intrathecally. It was a double blinded study (the drug was prepared by other person, and the drug characteristics were noted by other.)

(i). Group F (n=35) - 3 ml 0.5% Bupivacaine heavy + Fentanyl 25 µg(0.5ml)..

(ii). Group B (n=35) – 3.ml 0.5% Bupivacaine heavy + 0.5 ml normal saline

INCLUSION CRITERIA- Patients giving consent, between age 18-60 years and belonging to ASA grade I and II.

EXCLUSION CRTERIA –

1. Patients with respiratory, cardiovascular, hepatic and renal diseases, obesity and pregnancy.
2. Any bleeding disorder and patient on anticoagulants or local infection.

Pre-anaesthetic assessment was done to screen major systemic illnesses, well informed consent was obtained from all patients included in study, they were explained about the procedure and about using 'visual analogue scale'. All the patients were examined a day before surgery to do complete general, physical and systemic examination. All the required routine and special investigations were carried out.

All patients were kept nil orally for 8 hours before the procedure.

Upon arrival of the patient in the operation theatre, intravenous access with 18 G cannula was inserted into the patient's forearm. All routine monitors including Pulse oximeter, B.P. cuff and E.C.G were connected and observations were recorded by multipara monitor. Preloading was done with approximately 10ml/kg of Ringer's lactate solution.

Under all aseptic precautions, Lumbar puncture was done in left lateral decubitus position at the L3-L4 interspace via midline approach using 25G Quincke spinal needle. Subarachnoid block (SAB) was performed, the study drug was injected and then patient was placed in supine position for the remaining of the study period. Intraoperatively, following spinal anaesthesia characteristics and outcomes were recorded and entered into proforma for statistical analysis.

1. The time of onset of sensory blockade (upto T8) was assessed by pin prick method.
2. Time of onset of motor blockade was assessed by Bromage scale. (upto modified Bromage score 3).

0 = no motor block
1 = able to bend the knee (hip blocked)
2 = able to dorsiflex the foot (hip and knee blocked)
3 = complete motor block (hip, knee and ankle blocked).

3. The duration of sensory blockade was upto regression to L1 and motor blockade was regression to modified Bromage score 0).

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4. Duration of analgesia (from induction till administration of rescue analgesic) and intra and postoperative Visual Analogue Scale scores. VAS score was assessed at 1,2,3,4,5 and 6 hours from induction. If >3 , rescue analgesia with inj. Tramadol 2mg/kg i.v.in 100ml normal saline was given to relieve post

5. Assessment of Haemodynamic parameters (PR, SBP, DBP and MAP) at 0, 15 30, 45, 60, 90 120, 150 minutes from induction. Any fall in MAP below 20% of baseline value was treated with bolus dose of inj. Mephenteramine 6 mg i.v. PR <60 beats /min was treated with inj. Atropine sulphate 0.3-0.6 mg i.v.

6. Observation and recording of side effects and complication of the study drugs and technique.

STATISTICAL METHODS

Data was composed in suitable spreadsheet i.e., EXCEL and SPSS. After compilation of data, it was analysed statistically by SPSS software version 20.0.

The two groups for the different characteristics of spinal anaesthesia, after checking the assumption for the normality were compared using unpaired and chi square test. Significance level was 95% confidence level ($p<0.05$).

3. OBSERVATIONS AND RESULTS

Table 1: Demographic profile (Mean±SD) associated with the groups

Demographic parameter	Group F (n=35)	Group B(n=35)	p value
Age (years)	47.23±9.99	43.9±10.56	>0.05
Height (in cm)	168.26±3.33	169.03±3.24	>0.05
Weight (in kgs)	65.87±6.5	65.93±9.54	>0.05

Table 1 shows that age, height and weight were comparable between the groups, p value > 0.05 which was statistically insignificant.

Table 2: Gender distribution

	GROUP-F (Fentanyl)		GROUP-B (Plain Bupivacaine)		TOTAL	
	Number	%	Number	%	Number	%
MALE	19	54.29	20	57.14	39	55.71
FEMALE	16	45.71	15	42.86	31	44.29
TOTAL	35	100	35	100	70	100
p-value	0.81 (Not Significant)					

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Table 3: Parameters of Spinal Anaesthesia

PARAMETERS	GROUP F (N = 35)	GROUP B (N=35)	P VALUE
Onset of sensory block (min)	1.86±0.20 mins	3.28±0.21 mins	<0.001
Onset of motor block (min)	3.13±0.29 mins	5.38±0.4 mins	<0.001
Duration of sensory block (min)	221.06±23.35 mins	174.33±10.26 mins	<0.001
Duration of motor block (min)	202.93±21.81 mins	127.2±22.95 mins	<0.001
Duration of analgesia (min)	307±11.59 mins	204.26±11.38 mins	<0.001
Time for first rescue analgesia (hour)	5.83±0.37	3.45±0.51	<0.001

Table shows that onset of sensory and motor blockade was less in group F whereas duration of the blockade and duration of analgesia was more in group F, p value < 0.001 which was statistically highly significant. The time for first rescue analgesia was more in group F (p<0.001).

Table 4- Intraoperative Mean Pulse Rate

The figure shows that the mean pulse rate was comparable between the groups as the p value > 0.05 which was statistically insignificant.

TIME (MIN)	**GROUP F**		**GROUP-B**		**t-value**	**df**	**p-value**
	MEAN	**SD**	**MEAN**	**SD**			
0 min	83.29	11.16	81.17	13.04	0.73	68	0.47
5 min	81.74	11.26	79.46	11.97	0.82	68	0.41
10 min	80.83	11.21	78.97	11.63	0.68	68	0.50
15 min	78.11	11.63	77.54	11.51	0.21	68	0.84
30 min	76.91	11.26	76.54	10.96	0.14	68	0.89
60 min	74.46	10.70	76.57	10.44	0.84	68	0.41
90 min	72.34	10.99	75.89	10.13	1.40	68	1.17
120 min	70.94	11.29	74.83	9.54	1.56	68	0.12
150 min	69.74	11.38	74.69	9.49	1.97	68	0.05

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Figure 1- Intraoperative Mean Arterial Pressure

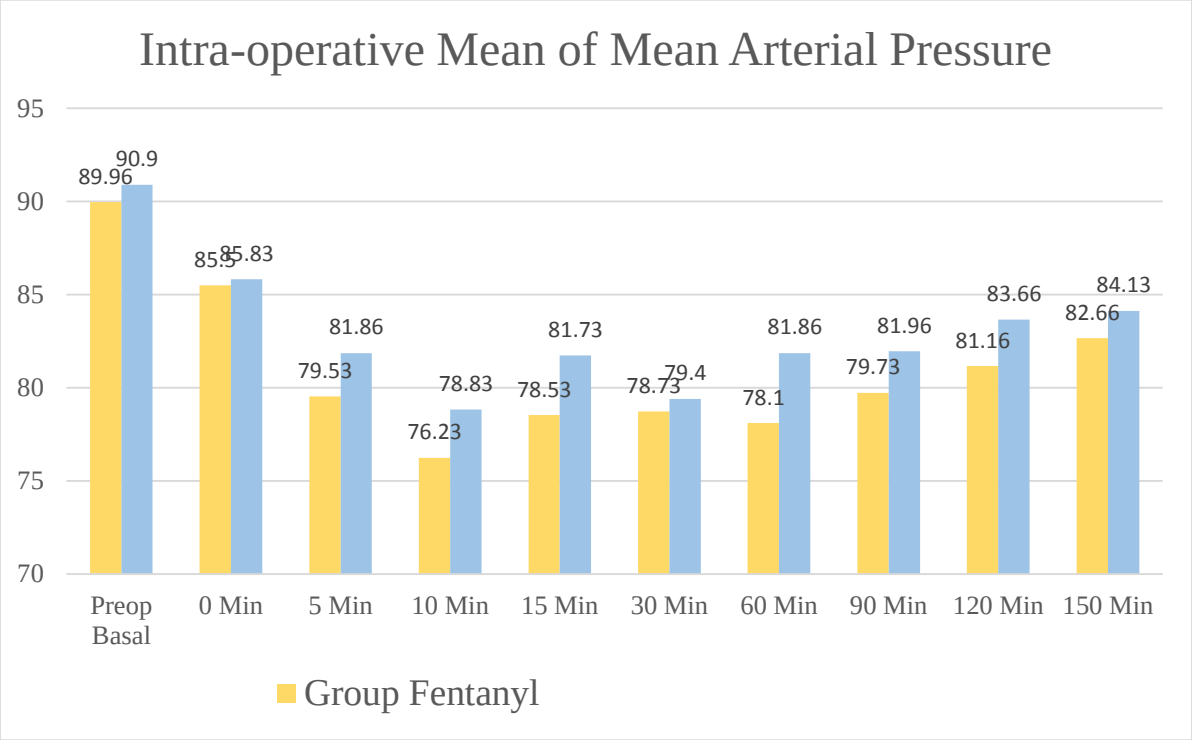

Figure 1 shows the mean arterial pressure, p value was > 0.05 throughout and the difference was statistically insignificant.

Table 5- VAS score Intra-operative and Post-operative intergroup Statistical Analysis of VAS Score

Time (Hours after induction				
	Group F Mean±SD	Group B Mean±SD	t value	P value
1	0±0	0.06±0.25	-1.439	0.155
2	0±0	1.26±0.44	-15.425	<0.001
3	0.93±0.25	2.9±0.92	-11.254	<0.001
4	1.7±0.46	3.03±1.32	-5.197	<0.001
5	2.66±0.75	1.33±0.47	8.142	<0.001
6	3.56±1	2±0	8.527	<0.001

Table 5 shows that group f had lower VAS scores throughout (p<0.001, statistically highly significant) , but the rescue analgesia was administered early in group B, at 5th and 6th hour Vas score was more in group F.

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Table 6- Side effects

Side-effects	Group F (n = 35)		Group B (n = 35)	
	No.	%	No.	%
Nausea	2	5.7	3	8.5
Respiratory Depression	0	0	0	0
Dyspnoea	0	0	0	0
Hypotension	4	11.4	6	17.14
Chest Pain	0	0	0	0
Bradycardia	2	5.7	0	0
Dysrhythmia	0	0	0	0
Shivering	2	5.7	3	8.5
Sedation	0	0	0	0

Table 6 shows that the incidence of side effects such as nausea, hypotension, bradycardia and shivering were more in group B but p>0.05 and was not significant.

4. DISCUSSION

Spinal anaesthesia is most commonly used neuraxial anaesthesia as it is safe, has a rapid onset of action and provies effective post-operative analgesia .

In our study, the demographic variables were comparable between both the groups and were statistically insignificant (p value >0.05) similar to the studies of Atallah et al.,[10] (Table 1 and 2)

The onset of sensory block with group F was faster than group B which was statistically significant with 'p' value of <0.001(Table 3). The onset of motor block in group F was rapid compared to group B and was statistically significant (p< 0.001) (Table 3). Khalili et al.,[11] and Khezri et al.,[12] in their study also concluded that addition of fentanyl had rapid onset of sensory and motor blockade.

The duration of both sensory block and motor block was more in group F as compared to group B and the difference was highly significant (p value <0.001) (Table 3).

Rajola Raghu et al.,[13] in their study also concluded that the duration of sensory and motor blockade was more in group fentanyl.

Hemodyanmic variables (PR, SBP, DBP, MAP) (Table 4 and Figure 1) were comparable in our study ,the difference was statistically insignificant (p >0.05). Similar findings were seen in studies Harbhej Singh et al.,[14], AtesDuman et al.,[15]

Duration of analgesia was more in Group F as compared to group B (Table 3), p value was <0.001 and the difference was highly significant. Bharti et al.,[16] and Dobrucali et al.[17] also had similar findings. The VAS scores (Table 5) were lessr in group F and the time for first rescue analgesia (Figure 4) was more than group B. Due to administration of rescue analgesia , VAS score were lower in group B at 5^{th} and 6^{th}hr as compared to group F. Khezri et al.,[12] in their study also had lower VAS scores.

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The incidence of side effects (Table 6) were compared, patients in group F experienced nausea (n= 2,5.7%), bradycardia (n=2, 5.7%), hypotension (n=4, 11.4%), shivering (n=2, 5.7%) whereas in group B it was, nausea (n=3, 8.5%), bradycardia (n = 0) , hypotension (n= 6, 17.14 %) and shivering (n= 3, 8.5%) . Opiods due to their action are known to have a inhibitory effect on nausea and vomiting and they also reduce shivering. But the difference between the groups was statistically insignificant (p>0.05). The findings of our study were similar with the studies of Sarika et al., [18] , and Banihashem N et al., [19] .

LIMITATIONS OF OUR STUDY-

The major limitation of our study was that the investigator was unable to objectively quantify and evaluate postoperative pain which being a subjective experience can be a major limiting factor in comparing and estimating the effectiveness of various modalities of treatment.

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We are grateful to the patients and their family undergoing surgeries for their cooperation in the study.

5. CONCLUSION

Fentanyl when added as an adjuvant to bupivacaine reduced the onset and improved the duration and efficacy of spinal anaesthesia, when compared to plain bupivacaine although it has some side effects like nausea, bradycardia, hypotension they were also less than seen in bupivacaine only group.

CONFLICT OF INTEREST – Nil

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