Section: Anesthesiology

Original Research Article

A COMPARATIVE STUDY OF ADDITION OF FENTANYL TO BUPIVACAINE VERSUS ADDITION OF BUTORPHANOL TO BUPIVACAINE IN INTRATHECAL BLOCK FOR INFRA UMBILICAL SURGERIES

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Received : 07/07/2025
Received in revised form : 16/08/2025
Accepted : 02/09/2025

Keywords:
Fentanyl, bupivacaine, intrathecal block, surgery.

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DOI: 10.47009/jamp.2025.7.5.169

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2025; 7 (5); 887-892

ABSTRACT

Background: Administration of local anaesthetics alone for neuraxial block gives less satisfactory block for abdominal surgeries as it will not block visceral fibres. Intrathecal opioids have become a widely accepted technique for providing effective postoperative pain relief and provides prolonged analgesia. Most often we use fentanyl as an adjuvant, as compared to fentanyl, butorphanol is cost effective, easily available and has longer duration of action. The objective is to compare fentanyl and butorphanol as an adjunct to bupivacaine in patients undergoing elective infra umbilical surgeries. **Materials and Methods:** Hospital-based prospective-comparative study was conducted in 120 adult patients aged 18-70 years undergoing elective infra-umbilical surgeries under spinal-anaesthesia. Study population was divided into 2 groups. Group "BB" received 0.5%hyperbaric bupivacaine 15mg+25µg butorphanol (diluted to 0.5ml 0.9%ns) Total volume:3.5 ml. Group "BF" received 0.5%hyperbaric bupivacaine 15mg+25µg fentanyl. Total volume: 3.5 ml. Pre-anaesthetic checkup, Airway-assessment, spinal-column-examination, Vital-parameters, Assessment-of-Sensory-Blockade, Assessment-of-Motor-Blockade, Modified-Bromage-Scale, Assessment-of-analgesia, Quality-of-intraoperative-analgesia, Sedation-scores, Post operatively, monitoring of vital signs, VAS scores and sedation scores was assessed. **Result:** Time-of-onset-of-motor-block, time-for-two-segment, duration-of-motor-block, duration of sensory block, duration of complete analgesia was significantly more in BB-group compared to BF-group. Dose of rescue analgesia, VAS at 4 and 6 hours was significantly more in the BF-group compared to BB-group. Heart rate was comparable in both groups at all times except at 40 and 60 min where it was significantly more in BF-group compared to BB-group. SBP, DBP was similar in both group at all times. Side effects were very minimal in either group. **Conclusion:** 25µg butorphanol seems to be an attractive alternative to 25µg fentanyl as an adjuvant to spinal bupivacaine in infra umbilical surgical procedures.

INTRODUCTION

Spinal anesthesia is the most popular, effective and commonly used regional anesthetic technique for infra-umbilical surgeries. Administration of local anaesthetics alone for neuraxial block gives less satisfactory block for abdominal surgeries as it will not block visceral fibres. More over when local anaesthetics alone are administered larger dose is required and duration of postoperative analgesia is shorter. Addition of small doses of opiates improve the quality of blockade, decreases the dose of local anesthetic requirement and gives prolonged post-operative analgesia.[1] Various narcotic agents such as fentanyl, morphine, buprenorphine are used as additives

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Intrathecal opioids have become a widely accepted technique for providing effective postoperative pain relief and provides prolonged analgesia. Intrathecal opioids reduce the release of gamma amino butyric acid and glycine by a calcium independent process from dorsal horn neurons. But unwanted side effects such as nausea, itching, respiratory depression are more common with intrathecal opioids.[2] Fentanyl is a highly lipid soluble and mu receptor agonist, with rapid onset of action although provides extended post operative analgesia but it is of short duration. Butorphanol is a mixed opioid agonist-antagonist,[3] which can prove to be particularly advantageous because of the potential to maintain or even enhance opioid induced analgesia, while simultaneously eliminating the common mu-opioid side effects such as nausea emesis, pruritic, and respiratory depression. Effective in reducing post operative shivering.[3] Butorphanol is available without restriction compared to fentanyl. Butorphanol has been in use since 1978 in western countries and a number of studies have been performed establishing its safety and efficacy but was not available in India till 2002. Since its launch in India, it has been commonly used by intravenous route, intramuscular route, and epidural route but its intrathecal use is less explored.[4] However as there are fewer studies have explored the use of intrathecal butorphanol in human subjects previously, also there is a controversy regarding the dose of intrathecal butorphanol in various studies and there is paucity of literature comparing intrathecal butorphanol and its quality of analgesia to other narcotics used by intrathecal route.[5,6] Most often we use fentanyl as an adjuvant, as compared to fentanyl, butorphanol is cost effective, easily available and has longer duration of action. In this prospective, comparative study we tried to compare fentanyl and butorphanol as an adjunct to bupivacaine in patients undergoing elective infra umbilical surgeries, to compare safety and efficacy of anesthesia and duration of postoperative analgesia and number of analgesics used in the first 24 hours postoperatively.

MATERIALS AND METHODS

Present study was undertaken in Malla Reddy Narayana Multispecialty Hospital, Hyderabad during the period January 2018-september 2018. The study was undertaken after obtaining ethical committee clearance as well as after obtaining informed consent from patients. Patients included for the study were all ASA physical status 1 or 2 of either sex presenting for infra umbilical surgeries. This study was conducted in 120 adult patients aged between 18-70 years undergoing elective infra umbilical surgeries under spinal anaesthesia in Malla Reddy Narayana Multi-Speciality Hospital. A detailed history, complete physical examination and routine investigations were done for all patients. Informed written consent was taken.

Sample Size Calculation: The sample size was calculated using G power software. At first effect size was calculated by taking the mean and standard deviation (Group I, 250.10 ±4.05, group II 246 ± 7.11) from a previous study29. The effect size was 0.69. Taking the effect size =0.69 with alpha =0.05 and 1- beta (power) = 0.95 the total sample size calculated was 112, however because of possibility of dropout of cases we have taken 120 cases (60 in each group).

The study population was divided into 2 groups with 60 patients in each group. Group “BB” received 0.5% hyperbaric bupivacaine 15 mg + 25 µg butorphanol (diluted to 0.5ml 0.9%ns) Total volume:3.5 ml. Group “BF” received 0.5% hyperbaric bupivacaine 15 mg + 25 µg fentanyl. Total volume: 3.5 ml.

Those with ASA grade 1 and 2, aged 18 –70 yrs, scheduled to undergo elective infra umbilical surgeries under subarachnoid block were included. Those belonging to ASA grade 3 and grade 4, physically dependent on narcotics, history of drug allergy, gross spinal abnormality, localized skin sepsis, hemorrhagic diathesis or neurological involvement / diseases, head injury cases, cardiac, pulmonary, hepatic or renal disorders, peripheral neuropathy, inadequate subarachnoid blockade and who were later supplemented by general anaesthesia were excluded.

Method of study: Pre anaesthetic checkup was carried out pre operatively with a detailed history, general physical examination and systemic examination. Airway assessment and spinal column examination were done, and were reviewed on the day of surgery. The laboratory examination was done in selected cases like Hemoglobin, Urine analysis, Blood sugar, Blood urea, Serum creatinine, Coagulation profile, Blood grouping and Rh typing, ECG-for patients over 40 years of age, Chest X- ray Preoperatively.

Patient’s informed consent was taken. Nil per oral status was confirmed. The procedure of subarachnoid block was explained and the patient was informed to communicate to the anaesthesiologists about perception of any pain or discomfort during the surgery. They were premedicated with tab ranitidine 150 mg orally 10:00 pm at night.

Procedure: Patient was shifted to the OT table; IV access was obtained on the forearm with 18 Gauge IV cannula and all patients received Lactated Ringer's solution; 10 mL/kg was infused intravenously before the block as preloading within 20-30 minutes. The monitors connected to the patient included non-invasive B.P (Blood Pressure), peripheral arterial oxygen saturation using pulse-oximeter (SpO2), electrocardiogram (ECG). Baseline PR (Pulse Rate), BP, RR (Respiratory Rate), SpO2 were recorded in all the patients. Intrathecal drugs were prepared by an anaesthetist beforehand in order to maintain the blinding process. The primary investigator entered the operation theatre after preparing the drug and was therefore blinded to the patient allocation. The same person recorded all the vital parameters

ISSN (O): 2687-5365; ISSN (P): 2753-6556

intraoperatively and postoperatively. Under strict aseptic precautions, lumbar puncture was performed in sitting position by midline approach by using disposable Quincke spinal needle (25 G) at L3-L4 intervertebral space after infiltrating the skin with 1ml of 2% lidocaine. Then the test drug was injected. Patients were monitored continuously using non-invasive blood pressure, pulse-oximeter and electrocardiogram. Following spinal anesthesia patient was put in supine position. After spinal anaesthesia, Oxygen (4L/min) by facemask was given. Fluid therapy was maintained with lactated Ringer's solution (10mL/kg/hr). The following parameters were observed and recorded:

Vital parameters: Heart rate (HR), blood pressure (B.P)-systolic blood pressure (SBP) and diastolic blood pressure (DBP), respiratory rate (RR) and peripheral arterial saturation (SpO2) monitored at subarachnoid block (SAB),2,4,6,8,10, 20, 30, 60, 90, 120 minutes.

Assessment of Sensory Blockade: The onset of sensory block was tested by pin-prick method using a hypodermic needle. The time of onset was taken from the time of injection of drug into subarachnoid space to loss of pin prick sensation. The highest level of sensory block and time required to achieve it was noted. The time for two dermatomal segments regression of sensory level was noted. The duration of sensory blockade was taken two segment regression.

Assessment of Motor Blockade: This was assessed by Bromage scale. The time interval between injection of drug into subarachnoid space and the patient's inability to lift the straight extended leg was taken as onset time (Br.3). The duration of motor block was taken from time of injection to complete regression of motor block. (ability to lift the extended leg) (Br 0).[7]

Modified Bromage Scale: Grade 0 - Full flexion of knees and feet. Grade 1 - Just able to flex knees, full flexion of feet. Grade 2 - Unable to flex knees, but some flexion of feet possible. Grade 3 - Unable to move legs or feet.[8]

Assessment of analgesia: Pain was assessed by visual analogue score (VAS). VAS consists of a 10 cm line anchored at one end by a label such as" No pain'' and at the other end by a label such as the "Worst Pain Imaginable" or "Pain as Bad as Can Be". The patient simply marks the line to indicate the pain intensity and the provider then measures the length of the line to mark a point scale. All the patients were instructed about the VAS and to point out the intensity of pain on the scale 0-no pain, 10-worst pain.[7]

Quality of intraoperative analgesia was assessed on a four-point modified Belzarena scale Unable to tolerate pain Able to tolerate discomfort with additional analgesia Some discomfort but no additional analgesics required Completely satisfied.[9]

Sedation scores were assessed every 15 minutes both intra and post operatively using a four-point score. Grade 0 – Patient wide awake. Grade 1 – Patient is sleeping comfortably, but responding to verbal Commands. Grades 2 – Deep sleep but arousable. Grade 3 – Deep sleep, unarousable.

Post operatively, monitoring of vital signs, VAS scores and sedation scores was continued every 30 minutes until the time of regression of sensory block to L1 dermatome. The incidence of hypotension (arterial blood pressure < 20 % of baseline), and was treated with Inj. Mephentermine 6 mg intravenous increments and bradycardia as pulse rate < 50/ min was treated by atropine 0.6 mg intravenous stat. Side effects like sedation, nausea, vomiting urinary retention were monitored in the recovery room and then shifted to the ward. Neurological examination was done to rule out any neurological deficits at discharge.

Statistical analysis: The demographic data were analysed using either Student's t-test or Chi-square test. Quantitative data was analysed by student's t test and qualitative data was analysed by Chi-square test. Haemodynamic data was analysed by ANOVA Repeated measures. All values were expressed as mean ± standard deviation. $P < 0.05$ was considered statistically significant.

RESULTS

Table 1: Demographic Profile in the study group

Characteristics	BB group	BF group	P value
Age (years)	39.06+12.2	39.6+12.1	0.799
Height (cm)	5.6+0.3	5.47+0.2	0.17
Weight (kg)	56.6+10.3	56.3+6.7	0.82
ASA grade 1	33 (55%)	38 (63.3%)	0.852
Males	37 (61.7%)	33 (55%)	0.579
Females	23 (38.3%)	27 (45%)	0.579

Both the groups were comparable for age, height, weight, ASA grade and gender (p>0.05). [Table 1]

Table 2: Comparison of Onset of Sensory and Motor Block, and recovery parameters in two groups

Parameters	BB group	BF group	P value
Time of onset of sensory block (min)	3.3+0.7	3.1+0.8	0.419
Time of onset of motor block (min)	6.5+1.3	5.8+1.2	0.005
Highest sensory level	7.2+1.6	7.1+1.4	0.878
Time for two segment	132.6+13.5	102.9+8.3	0.000

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Duration of motor block (min)	207.8+13.5	159.5+11.7	0.000
Duration of sensory block (min)	132.6+13.5	102.9+8.3	0.000
Duration of complete analgesic	378.9+203.7	189.9+21.8	0.000
Dose of rescue analgesia	2.11+0.69	2.8+0.68	0.000
VAS at 2 hrs	0.03+0.25	0.03+0.25	1
VAS at 4 hrs	0.61+1.19	1.06+1.2	0.043
VAS at 6 hrs	1.98+1.5	3.3+1.08	0.000

Time of onset of motor block, time for two segment, duration of motor block, duration of sensory block, duration of complete analgesia was significantly more in BB group compared to BF group. Dose of rescue analgesia, VAS at 4 and 6 hours was significantly more in the BF group compared to the BB group. [Table 2]

Table 3: Comparison of heart rate in two groups

Heart rate	BB group	BF group	P value
Baseline	84.4+13.6	78.5+10.9	0.01
2 min	82.6+12.1	80.3+12.1	0.312
4 min	80.9+12.3	77.6+11.04	0.125
6 min	78.7+12.5	77.3+12.2	0.531
8 min	76.7+11.6	74.2+9.7	0.219
10 min	74.6+11.8	73.9+10.6	0.745
20 min	71.3+11.2	73.6+10.8	0.221
30 min	70.9+9.5	74.1+8.5	0.059
40 min	69.9+9.94	74.8+9.3	0.006
60 min	70.9+10.1	75.1+9.4	0.021
90 min	72.3+9.6	75.5+9.3	0.053
120 min	73.9+8.8	75.7+8.5	0.257

Heart rate was comparable in both the groups at all times of follow up except at 40 and 60 min where it was significantly more in the BF group compared to the BB group. [Table 3]

Table 4: Comparison of systolic blood pressure in two groups

SBP (mmHg)	BB group	BF group	P value
Baseline	128.4+12.2	131.5+14.4	0.212
2 min	124.8+14.8	126.6+12.9	0.476
4 min	120.9+13.5	121.5+13.7	0.825
6 min	116.5+12.4	117.4+12.3	0.685
8 min	112.5+12.5	116.7+15.1	0.097
10 min	110.6+11.7	112.2+11.6	0.445
20 min	110.5+12.2	111.9+10.9	0.49
30 min	109.5+11.9	111.6+9.6	0.306
40 min	109.4+11.7	111.1+11.1	0.436
60 min	111.03+12.8	112.3+10.5	0.559
90 min	113.4+12.3	116.2+9.8	0.173
120 min	117.1+12.6	118.8+10.1	0.426

Systolic blood pressure was similar in both the group at all times of follow up. [Table 4]

Table 5: Comparison of diastolic blood pressure in two groups

DBP (mmHg)	BB group	BF group	P value
Baseline	79.3+11.5	80.1+7.7	0.669
2 min	75.6+10.1	77.2+9.5	0.391
4 min	71.3+9.9	73.4+8.1	0.207
6 min	67.9+9.6	70.3+7.4	0.145
8 min	66.3+9.7	67.6+7.9	0.413
10 min	64.7+8.1	65.6+8.9	0.61
20 min	65.8+9.4	66.1+8.8	0.913
30 min	66.6+8.8	67.5+8.9	0.608
40 min	66.8+9.4	65.7+6.7	0.528
60 min	67.3+8.8	65.9+8.2	0.380
90 min	69.5+10.1	68.4+7.4	0.476
120 min	72.3+8.9	70.8+7.4	0.328

Diastolic blood pressure was similar in both the group at all times of follow up. [Table 5]

Table 6: Comparison of side effects in two groups

Side effects	BB group		BF group		Total
	No.	%	No.	%	
Bradycardia	4	6.7	1	1.7	5
Hypotension	2	3.3	5	8.3	7
Nausea	2	3.3	2	3.3	4
Pruritus	0	0	2	3.3	2

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Shivering	1	1.7	1	1.7	2
Vomiting	1	1.7	2	3.3	3

Side effects were very minimal in either group cases and minor and could be managed simply. [Table 6]

DISCUSSION

In our study, majority of patients were middle aged in both the groups. In group BB there were 37 males and 23 females and in group BF there were 33 males and 27 females. The mean height and the mean weight in either group were also identical. The type of surgeries performed were also identical in both the groups. These parameters were kept identical in both the groups to avoid variations in intraoperative and postoperative outcome of patients.

The mean time for onset of sensory block in group BB was 3.2667±0.73338 minutes and in group BF it was 3.1500±0.84020minutes. The onset of sensory block in both groups was not statistically significant. The mean time for onset of motor block in group BB was 6.4667±1.30795 minutes and in group BF was 5.8167±1.15702 minutes. There was statistically no significant difference with regard to onset of motor block between two groups. Reddy GN et al,[6] concluded that there is no statistical difference in time of onset of sensory block and time of onset of motor block. Kumar B et al,[10] concluded that there is no statistical difference in time of onset of sensory block and time of onset of motor block. Our result correlates with the above-mentioned studies.

With regard to the highest sensory level attained, patients of group BB, 13.3% achieved T10 level, 36.7% attained T8 level, 1.7% achieved T7, 43.3% achieved T6 level and 5.0%achieved T4 level. In group BF 10.8% achieved T10 level, 38.3% achieved T8 level, 1.7% achieved T7, 38.3% achieved T6 level, 1.7% achieved T7 and 5.0% achieved T4 level. This implied that there is no significant difference between the two groups with regard to sensory level block (p >0.05). Reddy GN et al,[6] found that maximum sensory level achieved is T6. Mean is between T8-T10. The highest sensory level achieved across all 3 groups were comparable. Kumar B et al 10 found that the median highest sensory level achieved and the times to reach peak sensory level were comparable among the two groups.

Time of two segment regression and duration of sensory block (2 segment regression is taken) was considerably slower in group BB with 132.6333±13.50953 min compared to group BF which was 102.9667±8.29941 min. Singh V et al,[11] found that time for two segment regression in fentanyl group and butorphanol group is 85±25 and 106±21 respective, which is statistically significant.

Mean duration of motor recovery in group BB was 207.7667±13.53510 min and in group BF was 159.5000±11.79989 min. There was statistically significant difference in duration of motor and sensory recovery. Bhatia U et al,[12] found that duration of motor block of butorphanol group is 246±32.6 and of fentanyl group is180±16.8.

Mean duration of complete analgesia (without need of analgesics) in group BB was 378.33±203.70250 min and in group BF was 189.9833±21.80926 min which was statistically significant. Kumar B et al,[10] observed that in butorphanol group first rescue analgesic requested after 365.9±12.3 minutes and in fentanyl group it was after 308.6±14.9 min. which is statistically significant. Reddy IR et al,[13]found that time for first request of analgesia with from time of spinal injection in butorphanol and fentanyl group are 5 hours and 4 hours respectively which is statistically significant.

VAS at end of 2 hour in group BB was 0.333±0.25820 and 0.333±0.25820 in group BF. VAS at end of 4 hour in group BB was 0.6167±1.19450 and in group BF it was 1.0667±1.21943. VAS at end of 6 hour in group BB was 1.9833±1.45546 and in group BF it was 3.3167±1.08130. VAS was statistically significant at 4 & 6 hours, implying patient in group BB had better pain relief (lower VAS) in postoperative period than group BF. Kumar B et al 10 noted that patients receiving butorphanol had lower LVAS pain scores at all observed times than patients who received fentanyl, although this difference in LVAS scores reached a statistical significance only at 1-hour postoperative duration (P=0.0260).

Two groups did not differ significantly with respect to heart rate at any interval. patients had bradycardia which was treated by 0.6 mg atropine successfully. Reddy GN et al 6 found no significant differences. Bhatia U et al,[12] note that haemodynamic parameters of both groups were comparable at all time intervals and were clinically & statistically insignificant except from 45-90 minutes pulse rate and mean arterial BP were lower in Group-B than Group-F which were statistically significant. Our study correlates with the above-mentioned studies.

In our study two groups did not differ significantly with respect to change in mean systolic and mean diastolic pressure. Patient in butorphanol group (n=2) experienced hypotension and fentanyl group (n=5) also develop hypotension which was statistically not significant. And, hypotension in both group successfully treated with small dose of inj. Mephenteramine / Ephedrine. We did not see statistically significant hypotension in both groups which was comparable with study by Reddy GN et al.[6]

Hypotension defined as MAP below 60 mmHg Bradycardia defined as HR below 50/min Respiratory depression defined as RR below 14/min in group BB, 3.3% patients had hypotension, 6.7% patients had bradycardia, 3.3% patients had nausea, 1.7% patients had vomiting and 1.7%patients had shivering. In group BF, 3.3% of patients had nausea, 3.3% patients had vomiting 3.3%pruritus, 8.3%

ISSN (O): 2687-5365; ISSN (P): 2753-6556

patients had hypotension, 1.7% of patients had bradycardia. None of the patients had respiratory depression. Singh V et al,[11] demonstrated that 25µg of fentanyl or butorphanol intrathecal have no difference regarding intraoperative bradycardia, itching or pruritus, postoperative nausea/ vomiting or psychomimetic behaviour. None of the patient in both groups had respiratory depression with 25µg dose of intrathecal fentanyl / butorphanol. Kaur J et al,[14] noted that no case of respiratory depression was observed in any group, incidence of pruritus was higher in group BF (25%) as compared to group (BB). Three cases in group BF and one in group BB had nausea. Two patients in group BF had vomiting.

CONCLUSION

On the basis of the present clinical comparative study, we can conclude that 25 µg butorphanol seems to be an attractive alternative to 25 µg fentanyl as an adjuvant to spinal bupivacaine in infra umbilical surgical procedures.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556