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POST OPERATIVE ANALGESIC EFFECT OF INTRATHECAL FENTANYL AS AN ADJUVANT TO 0.5% HYPERBARIC BUPIVACAINE COMPARED TO 0.5% HYPERBARIC BUPIVACAINE IN SUBARACHNOID BLOCK IN LOWER LIMB ORTHOPAEDIC SURGERIES: AN OBSERVATIONAL STUDY.

Anaesthesiology

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ABSTRACT

Background: Pain is an unkind sensory and sensitive practice associated with actual or potential tissue damage and also is associated with uncomfortable sensations in body. Postoperative pain management holds the key aspect of postoperative care. In this study, we have compared the intrathecal 0.5% hyperbaric bupivacaine with intrathecal fentanyl as adjuvant to 0.5% hyperbaric bupivacaine in terms of safety, efficacy, and postoperative analgesia in patients undergoing lower limb orthopaedic surgeries and also studied the side effects of the drugs used. **Material:** An analytical, prospective, observational study was conducted in Department of anaesthesia of a tertiary care teaching hospital. All adult patients eligible by the mentioned inclusion and exclusion criteria were considered as sample who were observed and analysed. Total 112 patients were included in the study, which were divided in two equal groups. Group I (BF)- Patients who received 3 ml of 0.5% hyperbaric bupivacaine and 25 µg of fentanyl intrathecally. Group II (B)- Patients who received 3 ml of 0.5% hyperbaric bupivacaine and 0.5 ml of CSF intrathecally. **Results:** In present study there was no statistical significant difference in mean age, sex, weight, and ASA grade between two groups. In the study there was statistically significant difference in mean VAS score between two groups at post op 3rd hrs,4th and 5th hrs. At these intervals mean VAS score was high in group II compared to group I. Mean time of First Rescue Analgesia in group I was 4.85 ± 0.47 hrs and in group II was 3.5 ± 0.53 hrs which highly statistically significant. There was no statistical significant difference in side effects amongst the two groups. There was statistically significant difference in mean HR between two groups at post op 4th and 5th hr. Mean HR was high in group II compared to group I at these two intervals. In the study there was no statistically significant difference in mean SBP, DBP and MAP between two groups from baseline to post op 6 hrs. **Conclusion:** Present study concluded that addition of 25 µg fentanyl to intrathecal bupivacaine offers longer duration of postoperative analgesia. So, it has suggested that fentanyl is a better choice with regards to postoperative analgesia in lower limb orthopaedic surgeries.

KEYWORDS

Analgesic Effect, Intrathecal Fentanyl, Hyperbaric Bupivacaine, Subarachnoid Block, Lower Limb orthopaedic surgeries.

INTRODUCTION

Pain is an unkind sensory and sensitive practice associated with actual or potential tissue damage and also is associated with uncomfortable sensations in body. Postoperative pain management holds the key aspect of postoperative care. Postoperative pain relief helps in early patient mobilization, reduction of respiratory complications, good post-operative outcome, decreased morbidity and improved satisfaction of patients. [1]

Regional anaesthetic techniques present the most flexible techniques. And subarachnoid block is among the regional technique with long history of effective use for a variety of surgical procedures and pain relief. Prof. August Karl Gustav Bier was the first to publish the report on his successful spinal Anaesthesia on his assistant Hildebrandt.[2]

Spinal anaesthesia is one of the most commonly used anaesthesia technique for lower limb orthopaedic surgeries due to its well-known advantages.[3] Moreover, the technique is simple to perform. One important disadvantage of the technique is finite duration of anaesthesia and a higher incidence of hypotension.

Bupivacaine is an amino-amide has been local anaesthetic of choice for spinal anaesthesia. Bupivacaine was introduced by Ekenstam in 1957.[4] The introduction into clinical practice of bupivacaine in 1963 was the start of prolonged period of clinical value of this long -acting local anaesthetic agent. [5,6] The use of Lignocaine for spinal anaesthesia has become controversial due to concerns related to transient radicular irritation.[7] Bupivacaine has rapid onset and medium to long duration of action i.e., 2 to 2.5 hours and lower incidence of transient radicular irritation. It is used widely for spinal anaesthesia now a days.[8,9]

Intrathecal administration of opioids and local anaesthetics has a potent synergetic analgesic effect.[10,11] Fentanyl became the adjuvant of choice because of its potency, rapid onset and short duration of action with lower incidence of respiratory depression.[12] Nevertheless, addition of opioids as adjuvant to local anaesthetic agent is associated with side effects such as nausea, vomiting, pruritus, urinary retention, herpes labialis activation, and respiratory depression.

In this study, we have compared the intrathecal 0.5% hyperbaric bupivacaine with intrathecal fentanyl as adjuvant to 0.5% hyperbaric bupivacaine in terms of safety, efficacy, and postoperative analgesia in patients undergoing lower limb orthopaedic surgeries and also studied the side effects of the drugs used.

MATERIAL AND METHODS

An analytical, prospective, observational study was conducted in Department of anaesthesia of a tertiary care teaching hospital. All adult patients eligible by the mentioned inclusion and exclusion criteria were considered as sample who were observed and analysed. Total 112 patients were included in the study, which were divided in two equal groups. **Group I** (BF)- Patients who received 3 ml of 0.5% hyperbaric bupivacaine and 25 µg of fentanyl intrathecally. **Group II** (B)- Patients who received 3 ml of 0.5% hyperbaric bupivacaine and 0.5 ml of CSF intrathecally.

Inclusion Criteria -

1. Patients with ASA grade I and II
2. Patients with age 18-60 years of either sex.
3. Patients undergoing lower limb orthopaedic surgeries like joint replacement, fixation of fractures.
4. Patients giving written informed consent.

Exclusion Criteria -

1. Patients refusing to give written informed consent.
2. Patients with ASA grade III or more.
3. Patients with spinal deformity.
4. Patients with infection at local site of spinal injection.
5. Patients with cardiopulmonary diseases.
6. Patients on anticoagulant treatment or with coagulation disorders.
7. Patients having allergy to local anaesthetic and study drug.

8. Patients requiring on table supplementation with general anaesthesia.

DETAILED PROCEDURE

Patients to be posted for lower limb orthopaedic surgeries undewent a detailed history and pre-anaesthetic evaluation on the previous day of the surgery. Routine investigations like haemoglobin, platelet count, blood grouping, serum electrolytes, blood sugar were done. Written informed consent was taken prior to scheduled operation from the patients and relatives. Patients were kept nil by mouth 6 hours before surgery.

A peripheral intravenous line was secured with 20 Gauge intravenous cannula and ringer lactate solution was started as maintenance fluid. All patients were premedicated with Inj. Ondansetron (0.1mg/kg). The selection of adjuvant as 25 µg inj. fentanyl with 3 ml of inj. 0.5% hyperbaric bupivacaine was decided by senior anaesthetist.

All patients were monitored with electrocardiography, pulse oximetry and blood pressure (NIBP). Baseline parameters were recorded.

Under aseptic precautions, subarachnoid block was given with 25-gauge Quincke needle in siting position in L3-L4 interspace and depending upon the selection of drug by senior anaesthetist, after confirming free and clear flow of CSF, either 25 µg inj. fentanyl administered with 3 ml of 0.5% hyperbaric inj. bupivacaine or 3 ml of 0.5% hyperbaric inj. bupivacaine with 0.5 ml CSF was injected intrathecally by senior anaesthetist.

Group I (BF)- Patients who received 3 ml of 0.5% hyperbaric bupivacaine and 25 µg of fentanyl intrathecally Group II (B)- Patients who received 3 ml of 0.5% hyperbaric bupivacaine and 0.5 ml of CSF intrathecally.

The onset and duration of sensory and motor block, haemodynamic parameters(vitals), total duration of analgesia, and potential adverse effects were measured.

Vitals like, heart rate, blood pressure, ECG, SpO2 were measured for every 5 minutes for 30 minutes. Symptomatic hypotension and bradycardia were treated with inj. Mephenteramine and inj. Atropine respectively.

-Pinprick method was used for the assessment of the sensory blockade.
-Modified Bromage scale was used to assess the degree of motor blockade.

The Modified Bromage scale :

• Bromage 0-Patients are able to have movement at hip, knee and ankle.
• Bromage 1-Patients are unable to have movement at hip but able to have movement the knee and ankle.
• Bromage2-Patient unable to have movement at hip and knee but are able to have movement at ankle.
• Bromage 3-Patient are unable to have movement at hip, knee, ankle.

Observations were recorded as:

Time of subarachnoid block administration.

Onset of sensory block: It is the time from intrathecal injection till the loss of pin-prick sensation at the level of T10 dermatome.

Onset of motor block time: It is the time from intrathecal injection to motor blockade level 2 in Modified Bromage scale.

Peak sensory block time: It is the time from intrathecal injection to maximum sensory level achieved.

Time of two segment regression of sensory blockade of the dermatome.

Time of wearing off of motor blockade: It is the time till patient is able to raise extended leg.

Time to first dose or request of postoperative rescue analgesia: It is the point of time at which the patient complaints of post operative pain.

Any significant adverse effects such as nausea, vomiting, pruritus, shivering, sedation, hypotension, bradycardia, and respiratory discomfort were documented.

Patients were monitored for degree of pain with the visual analogue score (VAS). Postoperative rescue analgesia (inj. diclofenac 75 mg i.v.) was given when the VAS score would be >4 and the time of injection of first analgesic drug was noted. This was taken as duration of analgesia.

Data entry was done into Microsoft excel data sheet and was analysed with the help of SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. **Chi-square test** was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation. **Independent t test or Mann Whitney U test** was used as test of significance to identify the mean difference between two quantitative variables and qualitative variables respectively. **p value** (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

RESULTS

- In present study, total 112 patients were included in the study, which were divided in two equal groups. **Group I** (BF)- Patients who received 3 ml of 0.5% hyperbaric bupivacaine and 25 µg of fentanyl intrathecally. **Group II** (B)- Patients who received 3 ml of 0.5% hyperbaric bupivacaine and 0.5 ml of CSF intrathecally.
- Mean age of subjects in group I was 43.80 ± 11.11 years and in group II was 45.12 ± 11.44 years. There was no statistically significant difference in mean age between two groups.
- In group I, 51.78% were males and 48.21% were females and in group II, 55.35% were males and 44.64 % were females. There was no statistically significant difference in sex distribution between two groups.
- Mean weight in group I was 67.44 ± 3.27 kgs and in group II was 68.25 ± 3.33 kgs. There was no evidence of any statistically significant difference in relation to mean weight between the two groups.
- Mean height in group I was 151.82 ± 6.46 cm and in group II was 151.01 ± 6.17 cm. There was no any evidence of statistically significant difference in mean height between the two groups.
- In group I, 83. 92% had ASA grade I and 16.07% had ASA grade II and in group II, 78.57% had ASA grade I and 21.42% had ASA grade II. There was no statistically significant difference in ASA grade between two groups.
- Mean time of first rescue analgesia in group I was 4.85 ± 0.47 hours and in group II was 3.5 ± 0.53 hours. There was statistically significant difference in mean time of first rescue analgesia between two groups.
- In group I which received fentanyl, most common side effect evident was nausea in 17.85% and in the group II, most common side effect was nausea in 16.07%. There was no statistically significant difference in side effects amongst the two groups.
- In group I, 44.62 % had side effects and in group II, 35.7% had side effects. There was no evidence of statistically significant difference in side effects amongst the two groups.

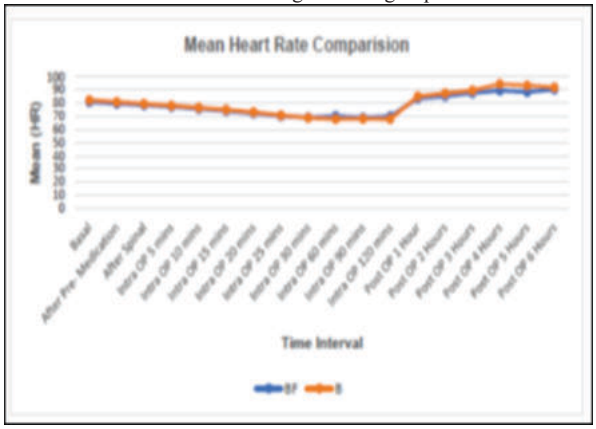

Figure No. 01: Line diagram showing mean heart rate comparison between two groups at different intervals of time

- In the study there was no statistically significant difference in mean HR between two groups from baseline to post op 3 hrs. There was statistically significant difference in mean HR between two groups at post op 4th and 5th hr. Mean HR was high in group II compared to group I at these two intervals.

- In the study there was no statistically significant difference in mean SBP, DBP and MAP between two groups from baseline to post op 6 hrs.

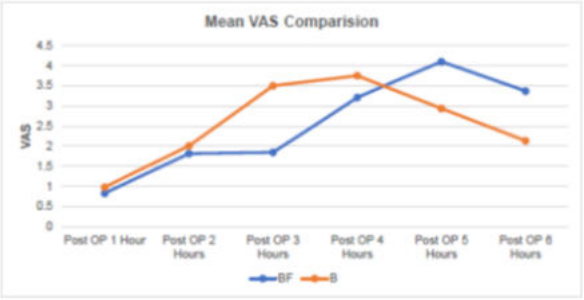

Figure No. 02: Line diagram showing mean VAS comparison on between two groups at different intervals of time

- In the study there was statistically significant difference in mean VAS score between two groups at post op 3rd hrs,4th and 5th hrs. At these intervals mean VAS score was high in group II compared to group I. Mean First Rescue Analgesia in group I was 4.85 ± 0.47 hrs and in group II was 3.5 ± 0.53 hrs.

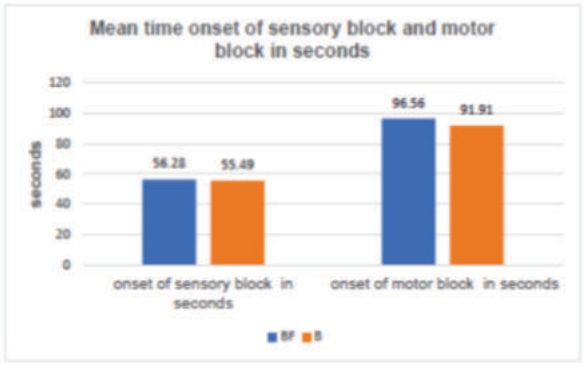

Figure No. 03: Bar diagram showing mean onset of sensory block time and motor block time in seconds comparison between two groups

Time	Group				P Value
	Bupivacaine +Fentanyl		Bupivacaine		
	Mean	SD	Mean	SD	
Onset of sensory block in seconds	56.28	10.16	55.49	7.11	0.686
Onset of motor block in seconds	96.56	20.36	91.91	21.56	0.324
Peak sensory block time (seconds)	440.81	41.90	455.21	71.15	0.273
Time of 2 segment regression of sensory level minutes	135.37	5.40	96.30	2.95	< 0.001
Time of wearing off motor block (minutes)	183.73	4.37	184.18	7.74	0.747

- Mean time onset of sensory block in group I was 56.28 ± 10.16 seconds and in group II was 55.49 ± 7.11seconds. There was no statistically significant difference in onset time of sensory block between two groups. Mean time of onset of motor block in group I was 96.56 ± 20.36 seconds and in group II was 91.91 ± 21.56 seconds. There was no statistically significant difference in onset time of motor block between two groups.
- Mean time of peak sensory block in group I was 440.81 ± 41.90 seconds and in group II was 455.21 ± 71.15 seconds. There was no statistically significant difference in time of peak sensory block between two groups.
- Mean time of 2 segment regression of sensory level in minutes in group I was 135.37 ± 5.40 min and in group II was 96.30 ± 2.95 min. There was statistically significant difference in time of 2 segment regression of sensory level between two groups.
- Mean time of wearing off motor block in group I was 183.73 ± 4.37 min and in group II was 184.18 ± 7.74 min. There was no significant difference in time of wearing off motor block between two groups.

DISCUSSION

Spinal anaesthesia is also called subarachnoid block, intrathecal anaesthesia is an example of neuraxial regional anaesthesia. Intrathecal anaesthesia is a commonly used anaesthetic procedure, either on its own or in combination with epidural anaesthesia, sedation or general anaesthesia. It is most commonly used for the infraumbilical surgeries.

Although it has been proved beneficial in acute and chronic pain treatment. Administration of local anaesthetics has limitations by its duration of action and the dose dependent side effects on the cardiac and central nervous system. Adjuvants are frequently used along with local anaesthetics due to its synergistic or additive effect by providing longer duration of sensory-motor block and limiting the cumulative dose requirements of local anaesthetics and its effects. A large variety of opioids ranging from morphine, fentanyl, sufentanyl, buprenorphine and tramadol has been utilised with varying degree of success. However, their utilisation has been limited by their side effect like respiratory depression, nausea, vomiting, shivering and pruritus, associated with its neuraxial use.

Amongst all, fentanyl, dexmedetomidine and clonidine are frequently used as additives to intrathecal bupivacaine.

Many studies have been conducted on fentanyl with hyperbaric bupivacaine and other local anaesthetics for prolongation of post operative analgesia and their results will be discussed briefly and compared with present study.

There was no significant statistical difference between both the groups in relation to age, sex distribution, weight, height, ASA status, ECG, and SpO2. They were comparable.

A study was conducted by Gajanan Chavan, Aparna Chavan, Alok Ghosh. to evaluate effect of intrathecal fentanyl as adjuvant in spinal anaesthesia. In which the time for first dose of rescue analgesic was delayed in Group I (192.12± 21.04 min) compared to Group II (207 ± 17.57min), which was statistically significant (P < 0.01). Similar results were observed in present study.[13]

According to a study carried out by Shilpa Bansal, Vaishali V. Deshpande, to assess clinical effects of intrathecal hyperbaric bupivacaine with fentanyl in patients undergoing lower limb surgeries, duration of analgesia was significantly prolonged BF group (239.0 ± 30.74 min) than in B group (158.0 ± 17.49), which was clinically significant (P < 0.001). Similar results were observed in present study.[14]

A study conducted by Devyani Desai, Pinal Bumiya, MR Upadhyay, Ambarish Vashishtha, to assess the effect of low dose Bupivacaine and fentanyl for femur surgeries in elderly patients. Duration of analgesia was significantly higher in group B (117.66±11.04 min) than in BF (225.5 ±13.82) group, (p<0.001). Hence this study showed similar results to our study.[15]

Hence, the present study showed that the first rescue analgesia was significantly prolonged in group I (bupivacaine +fentanyl) compared to group II (bupivacaine).

According to the study conducted by Gajanan Chavan, Aparna Chavan, Alok Ghosh, the results regarding the mean heart rate were similar to our study. The mean heart rate in both groups were similar. Incidence of bradycardia was comparable in two groups, and only 2 patients in group BF, developed bradycardia requiring treatment with inj. Atropine. This development of bradycardia was similar with our present study. They observed no significant variations when compared to SBP. This result was similar to our study.[13]

A similar study was conducted by Devyani Desai, Pinal Bumiya, MR Upadhyay, Ambarish Vashishtha, it also showed similar results with regards to MAP with our study. Both the groups were comparable when MAP was considered. They were statistically insignificant.[15]

In a study conducted by Gajanan Chavan, Aparna Chavan, Alok Ghosh, they confirmed that the VAS was significantly different in these two groups at post operative 3 and 4 hours. Which was similar to our study.[13]

According to a study conducted by Shilpa Bansal, Vaishali V.

Deshpande, on intergroup comparison, VAS was significantly of higher value in group BF than group B. This was similar to our results.[14]

A study conducted by Devyani Desai, Pinal Bumiya, MR Upadhyay, Ambarish Vashishtha, showed that mean time for post-operative analgesia was significantly longer in group BF than group B (225.5 ± 13.82 min and 117.66 ± 11.04 min respectively) (p-value < 0.001). This was similar to our study.[15]

According to a study conducted by Gajanan Chavan, Aparna Chavan, Alok Ghosh, there was no evidence of statistical difference in onset of sensory and motor block amongst the two groups (P > 0.05). This was similar to our study, but duration of 2 segment regression in group I was 134.12 ± 10.81 min compared to 89.85 ± 10.98 min in group B which is statistically significant (P < 0.0001). This was similar with our present study.[13]

A similar study conducted by Devyani Desai, Pinal Bumiya, MR Upadhyay, Ambarish Vashishtha, where 25 µg inj. fentanyl with low dose bupivacaine was used. Both the group were comparable in onset and offset of motor blocked. This is similar or in agreement with our study. Time of onset of sensory blocked was 126.7 +/- 26.14 sec in group B and 81.96 +/- 27.54 sec in group BF which was highly significant (p-value <0.001). Which was not in agreement with our study.[15]

In a study conducted by Shilpa Bansal, Vaishali V. Deshpande, the side effects are comparable in both groups. In group BF 30% experienced side effects compared to 33.3% in group B, which was statistically insignificant. This was similar to our study.[14]

CONCLUSION

According to results from this study there was statistically significant difference with regards to mean time of rescue analgesia and VAS score of two groups. It was prolonged in Group I (bupivacaine + fentanyl group) as compared to Group II (bupivacaine group).

Therefore, this study concluded that addition of 25 µg fentanyl to intrathecal bupivacaine offers longer duration of postoperative analgesia. So, it has suggested that fentanyl is a better choice with regards to postoperative analgesia in lower limb orthopaedic surgeries.

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