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Original Research

To assess the effectiveness of analgesia and anesthesia using intrathecal administration of Butorphanol and Fentanyl in combination with Bupivacaine 0.5% Heavy for lower limb orthopedic surgery

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ABSTRACT:
Aim: To assess the effectiveness of analgesia and anesthesia using intrathecal administration of Butorphanol and Fentanyl in combination with Bupivacaine 0.5% Heavy for lower limb orthopedic surgery. **Materials and methods:** This prospective randomized double-blind study was conducted on 120 patients undergoing various lower limb orthopaedic surgeries under subarachnoid block at tertiary care center.After meeting inclusion criteria 120 patients were randomly divided into 2 groups, 60 each based on computer generated randomization table. Group A: Received 2.5ml of 0.5% hyperbaric bupivacaine with 0.5ml (25µg fentanyl) a total volume of 3ml intrathecally. Group B: Butorphanol was diluted using distilled sterile water to obtain 25µg in 0.5ml. This was then added to 2.5ml of 0.5% hyperbaric bupivacaine to make a total volume of 3ml. **Results:** The two groups were similar in terms of Age, Sex, Height, Weight, BMI, degree of SAB, ASA score, and kinds of surgery (P values >0.05). The durations for the initiation of sensory and motor blockage were similar across the two groups. The group that received intrathecal butorphanol saw a significantly slower decline to S2 level compared to the group that received intrathecal fentanyl (P<0.0001). Group A had a significantly greater number of patients who required rescue analgesia during the postoperative period compared to group B (P=0.03). In group A, the average time to first request for rescue analgesia was 256.74 ± 10.11 minutes, whereas in group B it was 291.70 ± 7.11 minutes (P<0.0001). **Conclusion:** Both 25µg fentanyl and 25µg butorphanol, when administered intrathecally with 12.5 mg of hyperbaric bupivacaine, effectively induce anesthesia for lower limb procedures. The combination of bupivacaine and butorphanol administered intrathecally offers a longer period of sensory blocking and better pain relief compared to the combination of fentanyl and bupivacaine administered intrathecally.
Keywords: Intrathecal, Butorphanol, Fentanyl, Bupivacaine 0.5%, lower limb

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INTRODUCTION

Subarachnoid block (SAB) is a widely used anesthetic method that has been conducted for over a century. It was initially carried out by August Bier by injecting cocaine into the cerebrospinal fluid (CSF) of a patient. It is the preferred anesthetic and widely accepted as the best option for procedures involving the lower abdomen, lower limbs, and perineum [1]. Lidocaine has been the predominant local anesthetic used for spinal anesthesia (SAB) because to its rapid onset and shorter duration of effect. However, its usage has been linked to a greater occurrence of transitory neurologic symptoms and caudaequina syndrome [1,2]. Postoperative pain after spinal anesthesia is a common complication in patients undergoing lower limb orthopedic surgeries. Neuraxial opioids are widely used in conjunction with local anesthetics as they permit the use of lower dose of local anesthetics, while providing adequate anesthesia and analgesia [2]. Neuraxial opioids also allow prolonged analgesia in

the postoperative period and faster recovery from spinal anesthesia [3]. The use of opioids in conjunction with local anesthetic forspinal anesthesia has been associated with decreased pain scores and reduced analgesic requirement in the post-operative period [4,5].The Animal studies have also demonstrated antinociceptive synergism between intrathecal opioids and local anesthetics during visceral and somatic nociception [6,7]. Present study was undertaken to compare the efficacy of anesthesia and analgesia of intrathecal bupivacaine butorphanol mixture with intrathecal bupivacaine fentanyl mixture for lower limb orthopedic procedure, as there are only a limited number of studies have explored the use of intrathecal butorphanol in human subjects previously[3-7].Hence our aim was to compare the effectiveness of intrathecal hyperbaric bupivacaine with fentanyl and hyperbaric bupivacaine with butorphanol for lower limb orthopedic surgeries.

MATERIALS AND METHODS

This prospective randomized double-blind study was conducted on 120 patients undergoing various lower limb orthopaedic surgeries under subarachnoid block at tertiary care center over period of 12 months. Patients belonging to American society of anesthesiologists (ASA) physical status I and II, patients aged between 18 to 72 years, patients scheduled for elective lower limb orthopedic surgery and patients willing to give informed written consent.Exclusion criteria: Patients in whom spinal anesthesia or the study drugs are contraindicated, patients with neurological disease, spinal deformities, local skin infection or mental disorders; those who are morbidly obese, hemodynamic unstable or having coagulation disorders, or patients with liver disease, impaired renal functions and ASA Physical status >2 or a history of opioid dependence.Preanesthetic check-up was done one day prior to the surgery. Patients were evaluated for any systemic diseases and laboratory investigations were recorded. The procedure of SAB was explained to the patients and written informed consent was obtained.After meeting inclusion criteria 120 patients were randomly divided into 2 groups, 60 each based on computer generated randomization table.

Group A: Received 2.5ml of 0.5% hyperbaric bupivacaine with 0.5ml (25µg fentanyl) a total volume of 3ml intrathecally.

Group B: Butorphanol was diluted using distilled sterile water to obtain 25µg in 0.5ml. This was then added to 2.5ml of 0.5% hyperbaric bupivacaine to make a total volume of 3ml.

METHODOLOGY

Intrathecal drugs were preparedbeforehand to maintain the blinding process. Baseline heart rate, systolic blood pressure, diastolic blood pressure respiratory rate and peripheral arterial oxygen saturation were recorded for all subjects. All patients received 10ml/kg of lactated ringer solution as preload within 20-30 minutes. Subarachnoid block was performed under strict aseptic conditions in the lateral position at the level of L3-4 or L4-5 Inter vertebral space using 25G Quincke spinal needle. The midline approach was used to perform the spinal blocks after infiltrating the skin with 1ml of 2% Lidocaine. Following the SAB, the patient was put in supine position. Intraoperative, vitals were recorded at 5 minutes intervals for the first 15 minutes from the time of injection of spinal solution and there after every 30 minutes for the complete period of surgery and every thirty minutes in the postoperative period. This data was recorded by the primary investigator, who was unaware of the patient allocation. Hypotension less than 20% of base line was treated with fluid boluses and 6 mg IV boluses of Mephenteramine, while bradycardia (HR<50bpm) was treated with0.6 mg IV atropine. The highest level of sensory block was determined in the midclavicular line bilaterally, by pinprick test using a 20-G hypodermic needle every 2 minutes till the level was stabilized for four consecutive tests. The highest level of sensory block and the time taken to attain it from the time of the intrathecal injection was recorded. Further sensory testing was performed at 20 minutes intervals till the recovery of S2 dermatome. Motor block was assessed using the modified Bromage scale, till achievement of the highest motor level; at the end of the surgery and then at 30min. Side effects such as hypotension, bradycardia nausea vomiting, sedation, pruritus, shivering and respiratory depression was recorded. The quality of postoperative analgesia was assessed using LVAS at 15min, 30min and thereafter every 30minutes, till 2 hours postoperatively; and then every hour, till 4 hours postoperative duration. The time of first request of rescue analgesia was recorded.

Parameters Evaluated

- Duration of sensory block: Defined as the time from intrathecal injection to regression of pinprick sensation to S2 level.
- Degree of motor block: was assessed using Modified Bromage score
  - 0=full movement
  - 1=inability to raise extended leg, can bend knee
  - 2=inability to bend knee, can flex ankle, D. 3=no movements
- Duration of motor block: Defined as the time from intrathecal injection to the regression of motor block to Bromage score 0.
- Hemodynamic parameters: HR, systolic BP, Diastolic BP, Mean arterial pressure was assessed every 5 minutes till 30 minutes then every 30 minutes till end of study period.

The segmental level of sensory block to pin-prick was assessed on both sides. The surgery was allowed to start once sensory block had reached at least T10 dermatome. General anesthesia was induced when the case was labelled as failure. A fall of Systolic BP

<20% of baseline was considered as hypotension and was treated with intravenous mephentermine 6 mg bolus and lactated Ringer's solution as required. Heart rate of <50 beats/minute was considered as bradycardia and was treated with Inj atropine 0.6mg IV. The end of study period was defined as the time at which the sensory block had regressed below the S2 dermatome or at which the Bromage score was 0, whichever occurred later.

ASSESSMENT OF ANALGESIA

Pain was assessed by visual analogue score (VAS)Duration of complete analgesia was defined as the time from the intrathecal injection to VAS >0 - <4 and duration of effective analgesia as the time to VAS >4. Analgesics were avoided until demanded by the patient and the time taken for the first pain medication was also noted (when VAS >6). VAS was also recorded every 30 minutes postoperatively. 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 S2 dermatome. The incidence of hypotension was recorded,(arterial blood pressure < 20 % of baseline) and was treated with Inj. Mephentermine 6 mg intravenous increments and bradycardia as pulse rate < 50/ min was recorded and treated by atropine 0.6 mg intravenous stat. Side effects like hypotension, bradycardia, respiratory depression (RR<10), shivering, nausea, vomiting, pruritis were recorded in the perioperative period. Neurological examination was done to rule out any neurological deficits at discharge.

STATISTICAL ANALYSIS

Statistical analysis was done using SPSS software 21.0. Data obtained was tabulated in the Excel sheet and Chi-sqaure test for proportion, t – test for Quantitative data. Block characteristics were compared using Mann – Whitney U test.

RESULTS

The two groups were similar in terms of Age, Sex, Height, Weight, BMI, degree of SAB, ASA score, and kinds of surgery (P values >0.05) (Tables 1 and 2).The durations for the initiation of sensory and motor blockage were similar across the two groups. The group that received intrathecal butorphanol saw a significantly slower decline to S2 level compared to the group that received intrathecal fentanyl (P<0.0001). Group A had a significantly greater number of patients who required rescue analgesia during the postoperative period compared to group B (P=0.03). In group A, the average time to first request for rescue analgesia was 256.74 ± 10.11 minutes, whereas in group B it was 291.70 ± 7.11 minutes (P<0.0001).

Table1: Basic parameter of the participants

Parameter	Group A=60	GroupB=60	P
Age (Years)	42.56±4.45	39.42±3.36	0.353 **NS**
Weight(kgs)	68.98±3.16	70.16±3.43	0.656 **NS**
Height(cm)	169.22±3.72	170.15±8.47	0.479 **NS**
BMI	23.45±1.65	23.11±1.67	0.07**NS**
LPValue(2-3)/(3-4)	25/35	21/39	0.42**NS**
ASAstatus I/II	46/14	42/18	0.15**NS**
Type of surgery			0.09**NS**
Fracture	7	19	
femurFracture	18	12	
tibiaFractureofbbofleg	24	21	
Arthroscopy	11	8	

Table2: Gender distribution

Gender	GroupA=60		GroupB=60		Total	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Male	54	90%	48	80%	84	85%
Female	6	10%	12	20%	18	15%

Table3: Block characteristics

Parameter	GroupA=60	GroupB=60	Pvalue
Duration of Surgery	113.52±3.77	113.48±3.67	0.12
Duration of motor blockade	173.7±11.17	180.77±14.72	0.003
Duration of analgesia	256.74±10.11	291.70±7.11	0.0001
Time for sensory regression to s2 level(min)	171.16±9.11	181.14±14.77	0.0001

Table4: Level of block in the groups

Highest Level of Sensory Blockade	Group A		GroupB		Total	
	Frequency	%	Frequency	%	Frequency	%
T1	0	0	15	25	15	12.5
T6	14	23.33	2	3.33	16	13.33
T7	12	20	10	16.67	22	18.33
T8	17	28.33	15	25	32	26.67
T9	17	28.33	18	30	35	29.17
Total	60	100	60	100	120	100

DISCUSSION

The use of opioids in conjunction with local anesthetic for spinal anesthesia has been associated with decreased pain scores and reduced analgesic requirement in the postoperative period [5]. Opioids as epidural adjuvants to local anesthesia improve the quality of the block and provide a dose sparing effect [8]. The principal findings of this study are that intrathecal butorphanol- bupivacaine mixture provides longer duration of sensory blockade and superior analgesia (with lesser requirement for rescue analgesia) as compared to intrathecal fentanyl-bupivacaine mixture. The observed duration of analgesia with 20 ml 0.5% Bupivacaine alone to be 2-7 hours (mean 4.76) in our study is consistent with studies of Modig and Paalzov (mean 4.3 hours) and Paech et al (mean 5.2 hours)[9,10]. We found that the duration of analgesia was prolonged with the addition of 100 μgfentanyl (3-9 h; mean 6.12), consistent with that given by Kim et al and Paech et al [10,11]The duration of analgesia was longest with B butorphanol combination (5-10 h; mean 7.87). Studies by Abboud et al, Tan and Gupta et al, using epidural butorphanol for post-operative analgesia have reported the duration of analgesia to be 4-6 h, 5 h and 5.35 h with 0.5 mg, 1 mg, 2 mg and respectively [12-14].Malik et al have also reported in their study that butorphanol provided a longer duration of analgesia than fentanyl, similar to our study[15]. In our study, both fentanyl and butorphanol along with bupivacaine, provided adequate anesthesia and analgesia; but significantly lesser analgesic requirement was observed in the group receiving intrathecal butorphanol and bupivacaine mixture compared to intrathecal fentanyl and bupivacaine mixture. The time for first request of analgesia with the use of intrathecal butorphanol and fentanyl, in conjunction with bupivacaine, in our study was about 5 hours and 4 hours respectively from the time of spinal injection. Kim et al. have reported the duration of analgesia of approximately 7 hours after the use of 4 mg bupivacaine with 25 μg fentanyl for TURP [10].Singh V et al have reported that lesser number of patients receiving intrathecal butorphanol requested for rescue analgesia as compared to those receiving intrathecal fentanyl [16].We studied the 25 μg dose of intrathecal fentanyl and butorphanol and the results of our study are consistent with experimental evidence of synergistic interaction between spinal opioids and local anesthetics, which are characterized by enhanced somatic analgesia without effect on the degree or level of the local anesthetic induced sympathetic or motor blockade[7]. The synergism between intrathecal opioids in addition to local anesthetics may be due to the drugs' separate mechanism of action; blockade of Na+ channel by local anesthetics and voltage gated Ca++ channels with opioids [17]. The combination of opioids with LA allows for a reduction in doses of the LA, thus lessening the likelihood of side effects[18].A low incidence of side effects was observed in our study. We noticed 10 patients (16.67%) in the fentanyl treated group and 3 patients (5%) in the butorphanol-treated group having hypotension requiring treatment with small doses of intravenous mephenteramine (6 mg in 10 and 12 mg in 3 patients) in addition to crystalloid bolus. Earlier studies comparing25 μg intrathecal fentanyl and butorphanol with hyperbaric bupivacaine, have reported the instance of hypotension as 20% in the fentanyl group and 17% in the butorphanol group[16]. However, animal studies have reported that fentanyl does not potentiate the effect of Bupivacaine on efferent sympathetic pathways [7]. Furthermore, the addition of fentanyl (20-25 μg) to low-dose bupivacaine (4 mg) has been reported to increase the perioperative quality of spinal blocks with fewer cardiovascular changes in elderly patients[18]. 6 patients (10%) in the group receiving fentanyl- bupivacaine had pruritis compared with none in the group receiving butorphanol bupivacaine. The pruritis was mild in nature and did not require any treatment. Mallik et al reported an incidence of pruritus with epidural fentanyl to be 23% and with epidural butorphanol as 1.4%[15].The patients were continuously observed for respiratory depression with SpO2 (< 90%) and RR (< 10). No case of respiratory depression was observed in any group, consistent with other studies [15]. Although 8 patients had sedation in the group receiving butorphanol-bupivacaine, as compared with none in the group receiving fentanyl; none of them had respiratory depression. Sedation is a reported side effect of neuraxial administered butorphanol [19].

10 patients were catheterized during the postoperative period due to difficulty in voiding, although the average times to voiding were comparable among both the study groups. Previous studies have reported that intrathecal bupivacaine is associated with a clinically significant disturbance of bladder function and spontaneous voiding may not be expected until the sensory blockade has regressed to the S3 level

[20]. No patient had urinary retention in either of the groups, consistent with the study by Ackerman et al. The side-effect observed in the majority of patients with butorphanol was somnolence as observed by other authors as well [12,15]. None of the patients in the study experienced nausea or vomiting as we promptly treated all episodes of hypotension.

CONCLUSION

Both 25µg fentanyl and 25µg butorphanol, when administered intrathecally with 12.5 mg of hyperbaric bupivacaine, effectively induce anesthesia for lower limb procedures. The combination of bupivacaine and butorphanol administered intrathecally offers a longer period of sensory blocking and better pain relief compared to the combination of fentanyl and bupivacaine administered intrathecally.

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