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A Comparative Study between Low Dose Bupivacaine-Fentanyl and Bupivacaine-Clonidine with Plain Bupivacaine in Spinal Anaesthesia in Orthopaedic Patients

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ABSTRACT

60 adults of either sex belonging to American Society of Anesthesiologists (ASA) Class I & II, scheduled for lower limb and hip surgery under subarachnoid block were enrolled in the randomized and double blind controlled study. Patients were randomly allocated to three groups consisting of 20 patients each (Groups B, C and F). Group B (Bupivacaine) received an intrathecal injection of 2.5ml of 0.5% hyperbaric bupivacaine with 0.5ml of normal saline. Group C (Clonidine) received an intrathecal injection of 2.5ml of 0.5% hyperbaric bupivacaine with 30mcg of clonidine in 0.5ml of normal saline and Group F (Fentanyl) received an intrathecal injection of 2.5ml of 0.5% hyperbaric bupivacaine with 25mcg of fentanyl in 0.5ml of normal saline. Significant difference among the three study groups was observed in the time of two segment regression and duration of motor block (regression to Bromage 0). There was a significant difference regarding time to rescue analgesia and the total dose of rescue analgesics required during the postoperative 24 hours in groups C and F as compared to group B. Our study demonstrated that the use of intrathecal fentanyl and clonidine as adjuvants to hyperbaric bupivacaine in orthopaedic surgical procedures provides good quality intraoperative analgesia and hemodynamic stability with minimal side effects and excellent quality of postoperative analgesia.

Keywords: Clonidine; Fentanyl; Spinal Anaesthesia; Orthopaedic patients.

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INTRODUCTION

Spinal anaesthesia is the most commonly used technique for lower limb and abdominal surgeries. However, postoperative pain control is a major problem because spinal anaesthesia using only local anaesthetics is associated with relatively short duration of action, and thus early analgesic intervention is needed in the postoperative period. A number of adjuvants, such as clonidine and midazolam, and others have been studied to prolong the effect of spinal anaesthesia[1,2]. Opioids and local anaesthetics administered together intrathecally have shown to have a synergistic effect[3,4]. Intrathecal opioids enhance analgesia from sub-anaesthetic doses of local anaesthetic and make it possible to achieve spinal anaesthesia using otherwise inadequate doses of local anaesthetic[5]. The addition of fentanyl to hyperbaric bupivacaine improves the quality of intra operative and early post operative subarachnoid block[6].Clonidine is an antihypertensive agent which mainly acts by central α2 adrenoreceptor stimulation, resulting in diminished Sympathetic outflow[7].The intrathecal application of clonidine increases the duration of both sensory and motor block,[8-11] as well as postoperative analgesia[12].

MATERIAL AND METHOD

After obtaining approval from the hospital ethics committee, a written and informed consent was obtained from the patients for participation in this study. 60 patients of either sex in the age group of 18-70 years, belonging to the physical status ASA I and ASA II scheduled for elective lower limb and hip surgeries were included in the study. Patients with bleeding disorders, neurological disorders or neuromuscular disease, raised intracranial pressure, severe valvular heart lesions, and those allergic to local anaesthetics were excluded from the study. The patients were randomly allocated into three groups of 20 patients each by systematic random sampling.

Group B (Bupivacaine – Control Group): received an intrathecal injection of 2.5ml of 0.5% hyperbaric bupivacaine with 0.5ml of normal saline.

Group C (Clonidine): received an intrathecal injection of 2.5ml of 0.5% hyperbaric bupivacaine with 30 mcg of clonidine in 0.5ml of normal saline.

Group F (Fentanyl):received an intrathecal injection of 2.5ml of 0.5% hyperbaric bupivacaine with 25mcg of fentanyl in 0.5ml of normal saline. On the day of surgery in the operating room, multichannel monitor was attached to the patient and baseline heart rate, non-invasive blood pressure, oxygen saturation and electrocardiogram was recorded. Intravenous line was established using 16G or 18G size intravenous cannula. The patients were preloaded with Ringer lactate solution, 15ml/kg body weight half an hour before the subarachnoid block. The block was performed in sitting position with a 25G Quincke's

needle, using midline approach at the L3-L4 intervertebral space. Significant hypotension if any (systolic BP <30% of base line or <90mmHg) was treated with intravenous ephedrine 5mg and intravenous fluids as required. Bradycardia (heart rate < 40 beats per minute) was treated with intravenous atropine 0.3 to 0.6 mg. Nausea and vomiting was treated with intravenous Granisetron 1mg. Oxygen (4litres/min) was administered via face mask.

The following parameters were studied in the intraoperative period.

1. Onset and total duration of sensory block: The onset at T10 and total duration of sensory block was assessed by pinprick test performed at 2, 5, 10, 15, 20 and 30 minute, intervals thereafter until complete regression of the block.

2. Motor blockade: This was assessed by Modified Bromage Scale as under:

Grade 0: No paralysis.

Grade 1: Unable to raise extended leg.

Grade 2: Unable to flex knee.

Grade 3: Unable to flex ankle (complete block)

3. Alteration in vital parameters like heart rate and blood pressure.

4. Other undesirable sequelae like nausea, vomiting or any other complication.

The patients were evaluated for 24 hours regarding the total duration of analgesia, postoperative analgesic requirements and other sequelae. Postoperative pain was recorded by using visual analogue scale (VAS); initially every 1 hourly for two hours, then every 2 hourly for the next 8 hours and then every 4 hourly till 24 hours. Injection Diclofenac (75mg) was given intramuscularly as rescue analgesic when VAS was > 4.

The data obtained was tabulated in Microsoft Excel and was statistically analyzed using Statistical Package for Social Sciences (SPSS) Version 16.0.

RESULTS AND DISCUSSION

No statistically significant difference was observed between the three groups regarding age, sex distribution, height, ASA class and the duration of surgery. There was no significant difference among the three groups regarding onset of sensory block, highest level of sensory block and onset of motor block to Bromage 3. The two segment regression time from highest level of sensory block ranged between 84 to 111 minutes with a mean of 92.8$\pm$6.296 minutes in group B, 103-123 minutes with a mean of 114.5$\pm$4.571 minutes in group C and 103-129 minutes with a mean of 115.4$\pm$7.243 minutes in group F. The statistical difference among the groups was significant ($p < 0.001$) (Table 1). The time of regression of motor blockade to Bromage 0 ranged from 120 to 149 minutes with a mean of 141.4$\pm$7.119 minutes in group B, 173-198 minutes with a mean of 184.7$\pm$7.066 minutes in group C and 178-199 minutes with

a mean of 188.1±6.223 minutes in group F. The statistical difference between the groups was significant (p = < 0.001) (Table 2 and Figure 1).

Table 1: Time of two segment regression from highest level of sensory block (min)

Group	N	Mean	SD	Range	P-value	Remarks
Group B	20	92.8	6.296	84-111	<0.001	Sig.
Group C	20	114.5	4.571	103-123		
Group F	20	115.4	7.243	103-129		

Table 2: Regression to Bromage O (min)

Group	N	Mean	SD	Range	P-value	Remarks
Group B	20	141.4	7.119	120-149	<0.001	Sig.
Group C	20	184.7	7.066	173-198		
Group F	20	188.1	6.223	178-199		

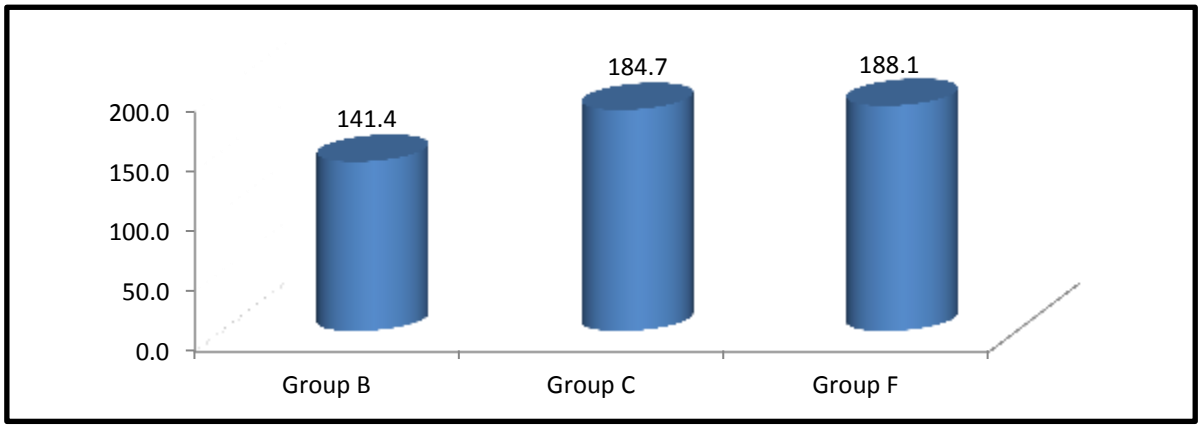

Figure 1: Regression to Bromage O (min)

The time to first analgesic request ranged from 136 to 214 minutes with a mean of 177.1±23.490 minutes in group B, 224-288 minutes with a mean of 259.6±19.985 minutes in group C and 224 to 296 minutes with a mean of 256.1±21.328 minutes in group F. The statistical difference was significant among the study groups (p < 0.001) (Table 3 and Figure 2).The requirement of total analgesic dose in the first 24 hours ranged from 150 to 225 mg with a mean of 198.8±36.702 mg in group B, 150 to 225 mg with a mean of 168.8±33.320mg in group C and 150 to 225 mg with a mean of 172.5±35.262mg in group F. The statistical difference was significant among the study groups (p < 0.001) (Table 4).

Table 3: Time to rescue analgesia (minutes)

Group	N	Mean	SD	Range	P-value	Remarks
Group B	20	177.1	23.490	136-214	<0.001	Sig.
Group C	20	259.6	19.985	224-288		
Group F	20	256.1	21.328	224-296		

Table 4: Total analgesic dose in first 24 hours (mg)

Group	N	Mean	SD	Range	P-value	Remarks
Group B	20	198.8	36.702	150-225	<0.001	Sig.
Group C	20	168.8	33.320	150-225		
Group F	20	172.5	35.262	150-225		

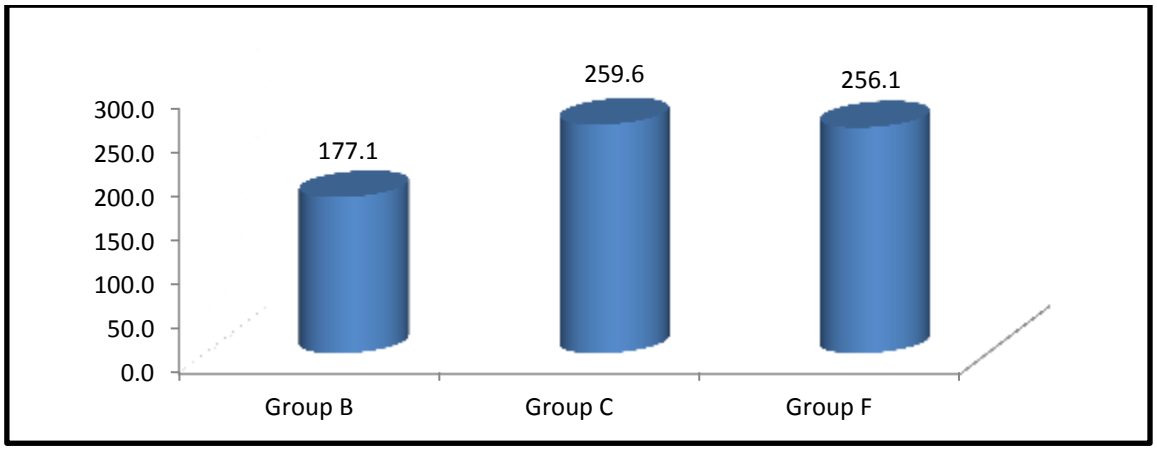

Figure 2: Time to Rescue Analgesia (min)

There was no significant difference found regarding vital parameters (heart rate, blood pressure, respiratory rate, oxygen saturation) and adverse affects (nausea, vomiting, respiratory depression, pruritus and urinary retention) during the postoperative period upto 24 hours. Our study compared clonidine and fentanyl as adjuvants to hyperbaric bupivacaine. In Group F, the onset of sensory block ranged from 6.3 to 9.1 minutes with a mean of 7.4±0.756 minutes. In group C onset of sensory block ranged from 5.2 to 9 minutes with a mean of 7.1±1.098 minutes and in Group B onset of sensory block ranged from 6.0 to 9.8 minutes with a mean of 7.4±0.904 minutes. Our results were comparable to those of Subi M Al-Ghanem et al[6] and GE Kanazi et al[13]. The mean time of two segment regression from highest level of sensory block observed in our study was 115.4±7.243 minutes in Group F, 114.5±4.571 minutes in Group C and 92.8±6.296 minutes in Group B. When statistically compared the result was significant ($p < 0.001$) among the three groups. Similar results were recorded by GE Kanazi et al[13]. However our result was in discordance with Rajni Gupta et al[14] who found the time of two segment regression from highest level of sensory block was 76±20.3 minutes in Group F. They have used 25mcg of fentanyl as adjuvants to 12.5mg hyperbaric bupivacaine. The time of regression of motor block to Bromage 0, observed in our study ranged from 178 to 199 minutes with a mean of 188.1±6.223 minutes in Group F, 173 to 198 minutes with a mean of 184.7±7.066 minutes in Group C and 120 to 149 minutes with a mean of 141.4±7.119 minutes in Group B. The statistical difference among the three study groups was significant ($p < 0.001$).The duration of regression of motor block to Bromage 0, in our study was markedly prolonged in Group F, when compared to the duration of regression of motor block to Bromage 0 in Group F 155±46 minutes (p value < 0.001) in the study done by SubiM Al-Ghanem et al[6]. The requirement of rescue analgesics observed among the three study groups in the postoperative period when Visual Analogue Scale (VAS) score was ≥ 4 was prolonged in Group F and Group C as compared to Group B. The total requirement of rescue analgesics during the postoperative 24 hours was less Group F and

Group C as compared to Group B, when Visual Analogue Scale (VAS) score was ≥4. The trends in requirement of rescue analgesics during postoperative 24 hours when Visual Analogue Scale score for ≥ 4 in Group F, observed in our study were comparable to the study done by Rajni Gupta et al[14] .We noted significantly delayed requirement of rescue analgesic and significantly reduced 24 hours rescue analgesic requirement with 30 mcg clonidine (P = 0.05) and 25 mcg fentanyl (P = 0.009) which supports the analgesic efficacy of intrathecal adjunct. Similarly, significantly improved analgesic efficacy was seen by Rajni Gupta et al[14], on comparison of fentanyl as intrathecal adjuvant (P < 0.001). The adverse effects observed in our study were comparable with the study done by GE Kanazi et al[13] and Rajni Gupta et al[14].The most significant side effects reported about the use of intrathecal α2 adrenoreceptor agonists are bradycardia and hypotension. In the present study, these side effects were not significant probably because we used small doses of clonidine. These doses of adjuvants used in our study did not affect the near maximal sympatholysis caused by local anesthetics. Small dosages of adjuvants may also be responsible for minimal or no sedation observed in any of the groups in the study.

CONCLUSION

The use of intrathecal fentanyl and clonidine as adjuvants to hyperbaric bupivacaine in orthopaedic surgical procedures provides good quality intraoperative analgesia and hemodynamic stability with minimal side effects and excellent quality of postoperative analgesia.

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