

A Comparison Study Quality of Anaesthesia for Lower Limb Orthopaedic Surgery: Bupivacaine with Adjuvant Clonidine versus Bupivacaine with Adjuvant Midazolam

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Abstract

Background: Spinal anesthesia is the most commonly used anesthesia for orthopedic surgery. Despite of using long acting local anesthetic like Bupivacaine, the duration of anesthesia is short. Therefore, various drug combinations like Clonidine, Ketamine, Opioids etc. have been tried to prolong duration of analgesia. **Methodology:** This study was conducted among 60 participants GMERS Hospital, Valsad. Patients were randomly allocated to 2 groups. Thirty subjects were in each group who received either 0.5% heavy Bupivacaine 3 ml (15 mg) + Clonidine 0.3 ml (45 µg) (Group A) or 0.5% heavy Bupivacaine 3 ml (15 mg) + Midazolam 0.2 ml (1 mg) + 0.9% normal saline 0.1 ml (Group B). Time required for sensory block, motor blockade, level of sedation and post operatively pain measurement was assessed. **Result:** The present study showed that significant decrease in mean arterial pressure and heart rate at 30, 45 and 60 min in patients with adjuvant clonidine as compared to midazolam. Mean time for sensory onset, sensory regression to S2 from highest sensory level, two segment sensory regression, total duration of motor blockade and onset of grade-3 motor blockade in patient with adjuvant Clonidine was significantly higher as compared to adjuvant Midazolam. Post operatively there was no significant difference in mean postoperative systolic blood pressure, diastolic blood pressure, pulse rate, saturation and respiratory rate. Sedation score was also higher in patients with adjuvant Clonidine group. Most common reported adverse events with Clonidine was hypotension and bradycardia. **Conclusion:** Adjuvant Clonidine 45 µg intrathecal hyperbaric Bupivacaine (0.5%) significantly prolongs duration of motor and sensory block. It provides adequate hemodynamic stability, prolongs postoperative analgesia without any significant side effects.

Keywords: Bupivacaine; Clonidine; Motor blockade; Analgesia

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Introduction

Spinal anesthesia is the most commonly used anesthesia for orthopedic surgery. Despite of using long acting local anesthetic like Bupivacaine, the duration of anesthesia is short [1]. Therefore, various drug combinations like Clonidine, Midazolam,

opioids etc. have been used to prolong duration of analgesia. Clonidine as the Alpha 2-adrenergic agonist increases the effects of local anesthetics [2]. Intrathecal Clonidine is being assessed as an alternative to opioids to increase the analgesic effect of local anesthesia [3] Midazolam a short acting benzodiazepine acts on benzodiazepine-GABA

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receptor potentiates the analgesic effect of local anesthetic agent induced neuroaxial blockade [4]. Intrathecal or epidural Midazolam produces modulation of spinal nociceptive processing without neurotoxicity, sedation or respiratory depression [5].

This study was conducted to evaluate analgesic effect, hemodynamic stability and side effects of intrathecally administered Clonidine or Midazolam as an adjuvant to Bupivacaine heavy (0.5%) for orthopedic surgery.

Methodology

This randomized comparative study was carried out on 60 participants during Jan 2017 to December 2017 in GMERS hospital, Valsad after getting permission from the Institutional Ethical Committee. Subjects of 20 to 65 years age group and who fit in American Society of Anaesthesiologist Grade I and II operated for Lower limb orthopedic surgery were enrolled in the study. Subjects with regional anaesthesia's contraindication and known drug allergy were excluded. After obtaining written informed consent, patients were randomly allocated to 2 groups. Thirty subjects were in each group who received either 0.5% heavy Bupivacaine 3 ml (15 mg) + Clonidine 0.3 ml (45 µg) (Group A) or 0.5% heavy Bupivacaine 3 ml (15 mg) + Midazolam 0.2 ml (1 mg) + 0.9% normal saline 0.1 ml (Group B). All the drugs were introduced intrathecally. Randomization was done by computer method.

Under all aseptic precautions, subarachnoid block was done at L2-L3 or L3-L4 space with 23G Quincke's spinal needle in a sitting position. Time required for sensory block to reach level T10 as T0, time to reach highest sensory level as T1 and time for sensory regression to S2 as T3 were noted. Motor blockade was evaluated with modified Bromage score. Time for complete motor blockade was observed every minute till first 20 minutes. Level of sedation was assessed using Chernik sedation score at 60 minutes intra-operatively. Post operatively pain measurement was done by Ten Point visual analogue scale (VAS). Time to achieve highest sensory level was recorded. Patient's blood pressure, pulse rate, oxygen saturation and respiratory rate were recorded at 1, 5, 10, 20, 30, 45, 60 minutes after giving spinal anesthesia. Hypotension was defined as a decrease of systolic blood pressure more than 20% of baseline value. Bradycardia was defined as a decrease in pulse rate to less than 60 per min. All patients were observed for next 24 hours. Results were statistically analyzed using SPSS software. All the results are expressed as the number, mean ± standard deviation

(SD), percentages. The comparison of between the groups was performed by T test. A value of p less than 0.05 is considered significant.

Results

The present study was carried out among 60 participants belonging to ASA physical Status I and II, operated for lower limb orthopedic surgery. There was no significant difference in two groups of patients respect to gender, age, BMI and duration of surgery (Table 1, p>0.05).

Table 1: Demographic profile of study participants.

Demographic parameter	Group A (30)	Group B (30)	p value*
Age	44.0 + 1.6	45.0 + 1.4	>0.05
Weight	58.3 + 8.4	58.7 + 9.9	>0.05
Height	163.1 + 7.4	163.7 + 7.1	>0.05
BMI	23.3 + 3.6	21.6 + 3.3	>0.05
Male: Female	15:15	18:12	>0.05
ASA Grade I/II	25:5	21:9	>0.05
Duration of surgery	120 + 11.2	121.2 + 13.4	>0.05

*p value was calculated by T test

Table 2 describes the characteristics of spinal anesthesia in two groups. In Group A, mean time for sensory onset (8.0 ± 0.7), two segment sensory regression (148.0 ± 4.9), sensory regression to S2 from highest sensory level (276.8 ± 4.7), mean time for onset of grade-3 motor blockade (9.0 ± 0.7) and total duration of motor blockade (298.0 ± 9.6) was significantly higher as compared to Group B.

Table 2: Comparison of mean duration of surgery, 2 segments regression, onset of sensory block and motor blockade in Groups.

Variable	Group A	Group B	P value
Sensory onset	8.0 ± 0.7	4.7 ± 1.1	<0.05
Highest sensory level	12.1 ± 0.9	9.6 ± 1.1	<0.05
Two segment sensory regression from highest sensory level	148.0 ± 4.9	134.7 ± 3.9	<0.05
Sensory regression to S2 from highest sensory level	276.8 ± 4.7	188.6 ± 7.1	<0.05
Onset of grade-3 motor blockade	9.0 ± 0.7	7.3 ± 0.7	<0.05
Total duration of motor blockade	298.0 ± 9.6	216.2 ± 10.1	<0.05

*p value was calculated by t test.

The intraoperative pulse rate was significantly lower in Group A at 30, 45 and 60 min time point as compared to Group B (p <0.05). Fall in mean arterial pressure in Group A at 30, 45 and 60 min was also higher as compared to Group B and it was statistically significant (p <0.05).

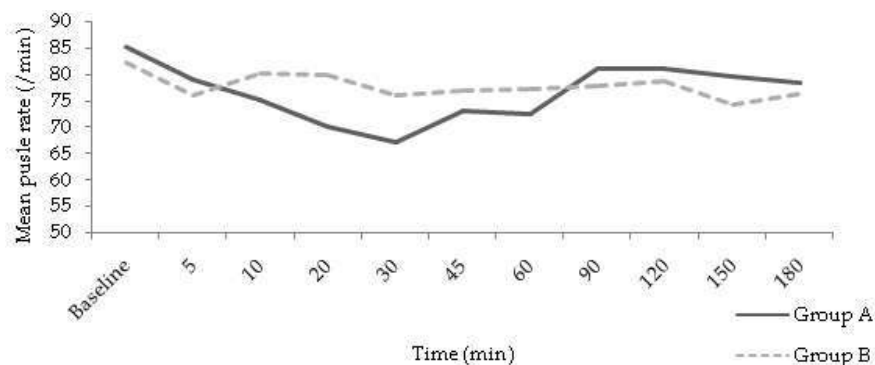


Fig. 1: Intraoperative mean pulse rate (/min) at different time intervals in 2 groups

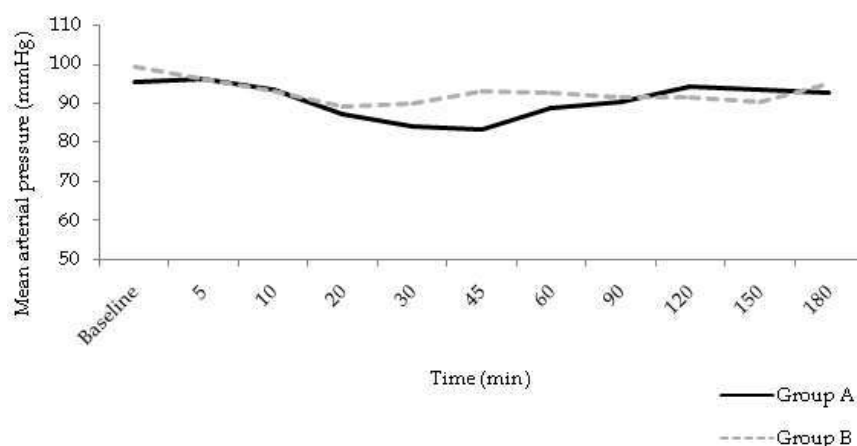


Fig. 2: Intra-operative mean arterial pressure (mmHg) at different time intervals in 2 groups

Post operatively there was no significant difference in mean postoperative systolic blood pressure, diastolic blood pressure, pulse rate, saturation and respiratory rate. Duration of post operative analgesia in group A (326.4 ± 4.3) was significantly higher as compared to Group B (252.8 ± 7.6). Only 4 patients developed sedation score 1 in group B. In Group A, sedation score 1 and 2 was observed in 22 and 8 patients respectively and it was significantly higher than Group A.

Adverse effects like hypotension and bradycardia were more common in Group A as compared to Group B (Hypotension: Group A- 30% v/s Group B-13.3%, Bradycardia: Group A- 26.6% v/s Group B-3.3%). Six subjects in Group A (20%) had dryness of mouth as compared to none in Group B. There was no significant difference in incidence of nausea, vomiting and shivering among these groups. Respiratory depression and urinary retention were not seen in any groups.

Discussion

Effective control of postoperative pain is an important challenge in perioperative care. Despite of use of a long acting local anaesthetic like bupivacaine, the duration of spinal anesthesia is short and higher doses of analgesics are required in the postoperative period. The present study showed that significant decrease in mean arterial pressure and pulse rate at 30, 45 and 60 min in patients in clonidine as compared to midazolam. Dobrydnjov noticed that significant bradycardia with 30 ug clonidine as compared to 15 ug clonidine [6]. One study with 75 ug clonidine reported significant decrease in MAP [7].

Mean time for sensory onset, sensory regression to S2 from highest sensory level, two segment sensory regression, total duration of motor blockade and onset of grade-3 motor blockade in patient with adjuvant Clonidine was significantly higher as compared to adjuvant Midazolam.

Mean time of total duration of motor blockade in group A was significantly higher than Group B. D. Kock observed that adjuvant Clonidine (45 ug) to spinal anesthesia significantly increases duration of sensory and motor Block. It provides adequate hemodynamic stability and prolong postoperative analgesia without significant side effects [8].

Neelakshi reported that postoperative analgesia duration was highest with Clonidine (426.7 + 151.8 mins) compared to Fentanyl group (284.6 + 30.1 mins), Midazolam group (270.5 + 36.2 mins) and control group (146.8 + 26.6 mins). Addition of Clonidine, Fentanyl and Midazolam to Bupivacaine heavy (0.5%) significantly improved the onset and duration of sensory and motor block, increased the duration of analgesia. Their result is comparable with our study [9]. Post operatively there was no significant difference in mean postoperative systolic blood pressure, diastolic blood pressure, pulse rate, saturation and respiratory rate. Similar to our study, Hema saxena reported that duration of post operative analgesia in patients with adjuvant Clonidine and Midazolam was higher than control group [10]. Sedation score was also higher in patients with adjuvant Clonidine. Most common reported adverse events with Clonidine was hypotension and bradycardia.

Conclusion

Adjuvant Clonidine 45 µg intrathecal hyperbaric Bupivacaine (0.5%) significantly prolongs duration of motor and sensory block. It provides adequate hemodynamic stability, increases postoperative analgesia without any significant side effects.

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