Journal of Cardiovascular Disease Research

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 04, 2023

ORIGINAL RESEARCH

A Comparative Study of Two Different Doses of Clonidine with Bupivacaine Intrathecally in Lower Limb Surgeries under Spinal Anaesthesia

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Received: 10 March 2023 **Revised:** 06 April 2023 **Accepted:** 16 April 2023

ABSTRACT

Background: Regional anaesthesia is the preferred technique for most of the lower abdomen and lower limb surgeries. This study is to evaluate the efficacy, duration of analgesia and safety profile of bupivacaine heavy, bupivacaine heavy with Clonidine in 2 different doses in lower limb surgeries done under spinal anaesthesia.

Material and Methods: 177 patients (ASA grade I & II), aged of 20-65 years of either sex scheduled for lower limb surgeries were randomly divided by envelop method into 3 groups of 59 patients each. Group I was given 15 mg 0.5% bupivacaine heavy with 0.5 ml normal saline.GroupII received 15 mg 0.5% bupivacaine heavy with 15 mcg Clonidine and group III was given 15 mg 0.5% bupivacaine heavy with 30 µg Clonidine for subarachnoid block. Time of onset of sensory block upto t10, time of onset of motor block, duration of motor block, duration of analgesia were noted.

Results: supplementation of hyperbaric bupivacaine with clonidine in doses of 15 mcg and 30 mcg given intrathecally in spinal anaesthesia produces statistically significant shorter onset of sensory and motor block with longer duration of sensory and motor block when compared to bupivacaine alone ($p<0.005$).

Conclusion: Clonidine15 mcg as adjuvant to hyperbaric bupivacaine provides maximum benefit with minimal side effect as compared to clonidine 30 mcg dose.

Keywords: Bupivacaine, Clonidine, Motor block, Spinal anaesthesia.

INTRODUCTION

Spinal anaesthesia is the preferred technique for most of the lower abdomen and lower limb surgeries. It allows the patient to remain awake, minimizes or completely avoids the problem associated with airway management.spinal anaesthesia technique is simple to perform; the

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 04, 2023

onset of anaesthesia is more rapid, avoids poly pharmacy and also provides post-operative analgesia.

Pain is a distressing experience associated with actual or potential tissue damage with emotional, sensory, social and cognitive impairments.(1)

Bupivacaine is the commonly used cost-effective drug which gives satisfactory analgesia for 90–120 min.

It is three to four times more potent than lignocaine.(3) And longer duration of action. Hyperbaric bupivacaine 0.5% is extensively used in India for spinal anaesthesia.

Additives such as opioids and α2 agonists extend the analgesia in the postoperative period.(2)

Clonidine is a selective partial agonist for alpha-2 adrenoreceptors. It is known to increase both sensory and motor block. The analgesic effect following its intrathecal administration is mediated spinally through activation of postsynaptic alpha-2 receptors in substantia gelatinosa of spinal cord and it works by blocking the conduction of C and A delta fibers, increases potassium conductance in isolated neurons.(4)

The purpose of the study is to evaluate the efficacy, duration of analgesia and safety profile of bupivacaine heavy, bupivacaine heavy with Clonidine in 2 different doses in lower limb surgeries done under spinal anaesthesia.

MATERIAL & METHODS

After obtaining approval from the institutional ethics committee this prospective, randomized double blind study was conducted on 177 patients (ASA grade I & II), aged of 20-65 years of either sex scheduled for lower limb surgeries in G.R Medical college and J.A group of hospitals Gwalior (M.P).

Patient who not give consent, uncooperative patients, infection at the site of injection, coagulopathy or bleeding diathesis, neurologic disease, severe hypovoluemia, pregnancy and lactating women, patient with history of allergy or intolerance to local anaesthetics, history of any significant pulmonary, cardiovascular, hepatoreanal psychiatric or metabolic disease were excluded from study.

All included 177 patients were randomly divided by envelop method into 3 groups of 59 patients each as follows:-

Group I (n=59) was given 15 mg 0.5% bupivacaine heavy with 0.5 ml normal saline for subarachnoid block.

Group II (n=59) was given 15 mg 0.5% bupivacaine heavy with 15 mcg Clonidine(0.1ml)and o.4 ml normal saline for subarachnoid block

Group III (n=59) was given 15 mg 0.5% bupivacaine heavy with 30 µg Clonidine(0.2ml) and 0.3 ml norml saline for subarachnoid block.

On the day of the surgery 20 gauge peripheral intravenous catheter was be inserted into the patient's forearm and preloading was done with approximately 10ml/kg of crystalloid., routine monitors such as ECG, Pulse oximeter(spo2) and non invasive blood pressure(NIBP) monitors were attached

Under all aseptic precautions cleaning, painting and draping were done in lateral position. The subarachnoid space was entered at the L3-L4 inter vertebral space via midline approach using 23 G Quincke spinal needle. C.S.F 0.2 ml was withdrawn before injection of the study drug to ensure free flow of C.S.F. The study drug was injected and the patient was put in supine position for the remaining of the study period following parameters were observed.

1) TIME OF ONSET OF SENSORY BLOCK UPTO T10: it was Time from the end of anaesthetic injection to complete loss of pinprick sensation at T10 level.

2) TIME OF ONSET OF MOTOR BLOCK(BROMAGE 2): Time for onset of inability to dorsiflex the foot .Ability to move the lower extremities were assessed by using modified bromage scale

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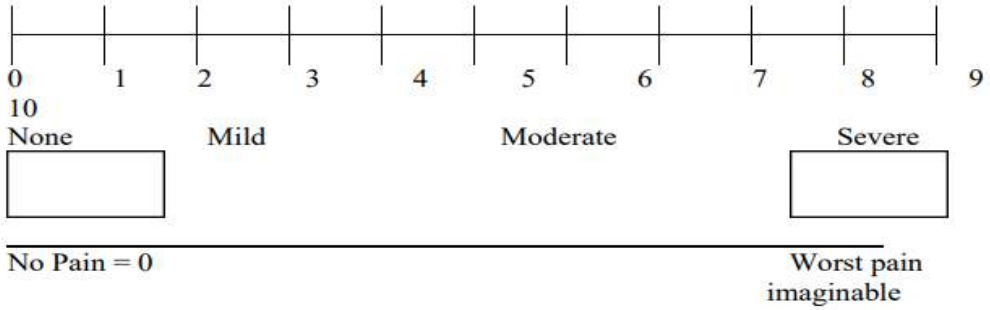
Modified BROMAGE SCALE :- Bromage 0=no block Bromage 1=able to bend the knee (hip blocked) Bromage 2=able to dorsiflex the foot (hip and knee blocked) Bromage 3=complete motor block (hip, knee and ankle blocked)

3) Duration of SENSORY BLOCK:- The duration of sensory block was defined as the time of regression of two segments in the maximum block height, evaluated by pinprick

4) DURATION OF MOTOR BLOCK (BROMAGE 0) Time from the end of anaesthetic injection to ability to move lower extremity. 5) DURATION OF ANALGESIA: - Time interval between onset of analgesia and onset of pain was taken as duration of analgesia.

6) ASSESSMENT OF HAEMODYNAMIC PARAMETERS Any change of ± 20% blood pressure was recorded as hypertension or hypotension and was treated with appropriate medication 7) VAS SCORE AT FIRST DEMAND OF ANALGESIC: - Post operative pain was assessed using a visual analogue scale consisting a 10 cm horizontal scale with gradation marked as 0 means no pain at all and 10 means worst imaginable. All the patients were given injection Tramadol 2mg/kg of body weight intravenously for pain relief.



Any side effect or complication due to drugs and technique like hypotension, hypertension, bradycardia, tachycardia, post operative nausea and vomiting etc. were recorded if occurs during study..

Statistical Analysis

Evaluation of study data in electronic form required performing additional statistical analysis. Data was composed in suitable spreadsheet EXCEL and SPSS. After compilation of data, it was analyzed statistically by SPSS software version 20.0. Significance level will be 95% confidence level ($p<0.05$). Data was described as a frequency (Percentage) distribution as well as in Mean±SD. Data was presented through suitable statistical graphs

RESULTS

In our study ASA score, age, weight and sex distribution and duration of surgery were comparable ($p>0.05$).

Table 1: Demographic profile

Age (years)	Group I	Group II	Group III	p value
Mean ± SD	43.5± 9.2	45.2± 8.1	43.5±11.7	0.672
Weight (in Kg)	63.86±9.77	62.36±10.54	63.58±9.25	0.679
Male	43 (72.9%)	53 (89.8%)	47 (79.7%)	
Female	16 (27.1%)	6 (10.2%)	12 (20.3%)	0.063
Total	59 (100%)	59 (100%)	59 (100%)	
Duration of surgery	2.35±0.56	2.43±0.63	2.45±0.63	0.419

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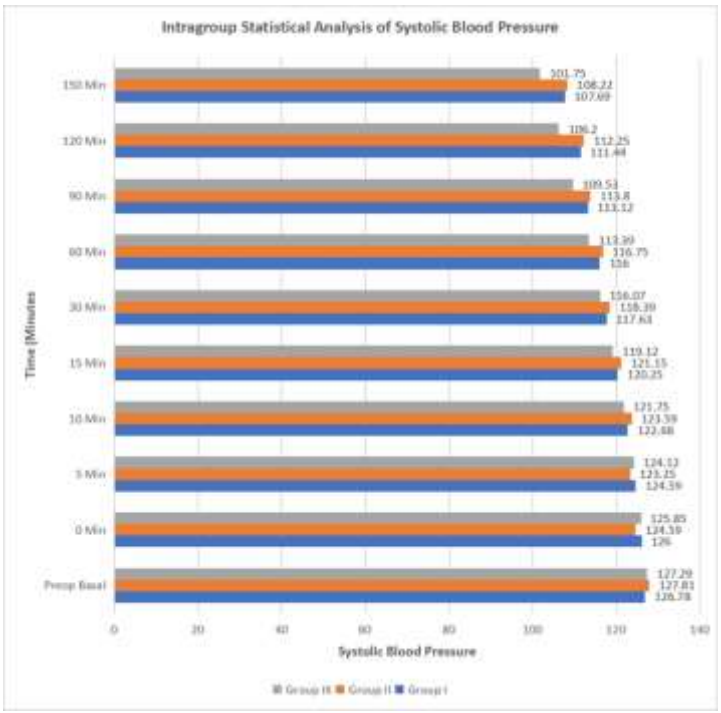
Group I had mean onset of sensory block was 8.93 min, group II it was 5.34 min and in group III it was 4.75 min.Onset of sensory block was found more significantly lower in group III in comparison to group II and I. (P value<0.001). Onset of motor block was found significantly lower in group III in comparison to group II and I. (p value <0.001). . Duration of sensory AND motor block was found significantly higher in group III in comparison to group II and I. Significant difference in rescue or duration of analgesia was observed between groups. Duration of analgesia was more in group III as compared to group II and group I. (p value<0.001).

Table 2: subarachnoid block characteristics

Mean±SD	**Group 1 (n=59)**	**Group 2 (n=59)**	**Group 3 (n=59)**	**P value**
Onset of sensory block	8.93±0.86	5.34±0.36	4.75±0.23	<0.001
Onset of motor block	12.17±0.87	6.84±0.36	6.26±0.24	<0.001
Duration of sensory block	179.92±8.38	210.08±7.57	245.95±6.97	<0.001
Duration of motor block	159.92±8.38	189.73±8.12	225.95±6.97	<0.001
Duration of analgesia (hrs.)	6.54.56±0.56	8.98±0.60	10.47±0.38	<0.001

Mean Systolic Blood Pressure of participants was statistically insignificant up to 15 Min after that group III had significantly lower Blood Pressure in comparison to group I and II.



Graph 4: Statistical Analysis of Systolic Blood Pressure

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participants between three groups was almost similar at all follow up time intervals, no significant difference was observed.
Mean diastolic blood pressure of participants between three groups was almost similar at all follow up time intervals, no significant difference was observed.
Mean SPO2 of participants between three groups was similar at all follow up time intervals.
Mean VAS Score of participants of all three groups increased over a period of time. No specific trend VAS score was observed between groups. At 6 hours mean VAS score of participants was significantly different. At 7 hr all three groups were having same mean VAS score and again h 8 hr group I had 79 | P a g e significantly different VAS score again, significantly different VAS score was observed at 10 and 11 hr.
Bradycardia was found in 2 patients in group 3 .inj. atropine was given to these patients. Shievering found in 2 pts in group 1 but these side effect was insignificant.

DISCUSSION

Spinal anaesthesia is the preferred technique for most of the lower abdomen and lower limb surgeries. It allows the patient to remain awake, minimizes or completely avoids the problem associated with airway management.
This study is to evaluate the efficacy, duration of analgesia and safety profile of bupivacaine heavy, bupivacaine heavy with Clonidine in 2 different doses in lower limb surgeries done under spinal anaesthesia.
Onset time of sensory blockade (mean±SD) which was 8.93±0.86 min in Group I, 5.34 ± 0.36 min in Group II and 4.75 ± 0.23 min in Group III. The onset of sensory blockage was found to be earlier in Group III as compared to Group I and Group II. The difference was statistically significant ($p<0.05$). Our observations are in accordance with the findings **Khandelwal et al**[5] who compared the effect of Clonidine 30 mcg added to 0.5% bupivacaine heavy in spinal anaesthesia and found it to be statistically significant ($p<0.01$).
The mean (±SD) duration of sensory block was 179.92 ±8.38 min in Group I, 210.08 ±7.57 min in Group II and 245.95 ±6.97 in Group III. Sensory blockade duration is significantly prolonged in both Groups II and III as compared to Group I. In correlation with the current study, a study conducted by **Singh R et al**[6] evaluated the effect of Clonidine when used as an adjuvant with bupivacaine heavy and when added along with bupivacaine-fentanyl combination. They found prolonged duration of sensory block and hence support our study.
mean (±SD) onset of motor blockage in group I,II and III were 12.17 ±087,6.86 ±0.36 and 6.26 ±0.24 respectively. The onset of motor block was found to be rapid in Group II and III as compared to Group I. The difference was statistically significant ($p<0.05$). The onset of motor block was found to be delayed in Group II as compared to Group III. Our observations are in accordance with the findings by **Kanazi et al**[7] observed significant early onset of motor block when 30mcg Clonidine is used as an adjuvant with bupivacaine in spinal anaesthesia.
Duration of motor blockade (mean±SD) was 159.92±8.38 min in group I, 189.73±8.12 min in Group II and 225.95±6.97 min in Group III. Motor blockade duration is significantly prolonged in both Group II and III as compared to Group I .**Kanazi et al**[7]observed significant prolong duration of motor block when 30mcg Clonidine is used as an adjuvant with bupivacaine in spinal anaesthesia.
Duration of analgesia was 6.54±0.56 hrs in Group I, 8.98±0.60 hrs in Group II and 10.47±0.38 hrs in Group III. The duration of analgesia as assessed by VAS score was prolonged in Group III as compared to other groups (III>II>I). Our findings are supported by **Ganesh M et al**[8]who evaluated that addition of 30 mcg of Clonidine to bupivacaine heavy intrathecally significantly increase duration of analgesia from 167.9±20.6 to 344.4±28.9 min respectively ($p<0.001$).

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In our study the baseline pulse rate in Group I 86.71±6.08 bpm , Group II 86.05±5.2 bpm and Group 85.63±5.26 bpm. Statistically significant reduction in pulse rate in Group III compared to Group I and II ($p<0.05$). The fall in pulse rate <20 % in all the three Groups throughout the procedure In correlation with the study conducted by **Mahendru et al**[9]assess the effect of hyperbaric bupivacaine 12.5 mg + NS ,12.5 mg bupivacaine +25 mcg fentanyl and 12.5 bupivacaine +30 mcg clonidine and 12.5 mg bupivacaine with 5 mcg of dexmeditomidine. The attenuation of pulse rate was significant in clonidine group in comparison to fentanyl and NS.

Baseline value of mean±SD of SBP were 126.78±4.87 in group I, 127.81 ± 4.71 in Group II and 127.29±5.13 in Group III statistically significant ($p<0.001$) in mean systolic blood pressure that was observed in all the time intervals except 5 min time interval .In Group II statistically significant p value <0.001 in mean systolic blood pressure was observed in all the time interval. Our observations are in accordance with **Singh RB et al**[10]who observed statistically difference in systolic blood pressure when clonidine was added as an adjuvant to bupivacaine in spinal anaesthesia.

CONCLUSION

Clonidine 30 µg is associated with prolonged recovery of motor block and causes hypotension and bradycardia. Clonidine 15 µg is associated with a stable hemodynamic profile and can be a useful adjuvant in spinal anesthesia for ambulatory procedures as it does not cause prolongation of motor blockade. From the present study it can be concluded that the supplementation of hyperbaric bupivacaine with clonidine in doses of 15 mcg and 30 mcg given intrathecally in spinal anaesthesia produces significant shorter onset of sensory and motor block with longer duration of sensory and motor block when compared to bupivacaine alone .Clonidine 30 µg is associated with increased duration of motor block and causes significant hypotension. Clonidine in dose of 15 µg is associated with a stable hemodynamic profile and can be a useful adjuvant in spinal anesthesia for lower limb surgeries procedures as provides maximum benefit with minimal side effects.

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