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Clinical Efficacy Of Hyperbaric Bupivacaine With Clonidine In Two Different Doses With Respect To Sensory Characteristics, Motor Characteristics And Recovery Characteristics In Patients Undergoing Lower Limb Orthopaedic Surgeries

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ABSTRACT **BACKGROUND:** Intrathecal opiods as adjuvant to local anaesthetics, when administered intrathecally, act synergistically to overcome the property of reduced duration of postoperative analgesia.. Clonidine a selective partial α2 adrenergic agonist administered intrathecally with bupivacaine improved the quality and duration of postoperative analgesia. **METHODS:** In this Randomised comparative study, 60 patients aged between 20 years and 60 years belonging to ASA I and II undergoing lower limb Orthopaedic surgeries were selected. Sample size was calculated by keeping the confidence interval at 95% and power of study at 80%. **RESULTS:** The mean time of onset of sensory, motor blockade and the time to achieve maximum sensory level and sedation scores was compared in both the groups. The mean duration of effective analgesia in Group BC30 and in Group BC60 was 357.33±6.915 and 425.33±27.131 minutes respectively. **CONCLUSION:** In conclusion , the addition of clonidine 60 µg to hypaerbaric bupivacaine intrathecally prolonged both sensory and motor blocked with higher duration of sensory block when compared to motor block of spinal anaesthesia and hence the duration of analgesia when comared to clonidine 30µg .

KEYWORDS : Intrathecal; Clonidine; Bupivacaine; Post-operative Analgesia

INTRODUCTION:

Lower abdominal and lower limb surgeries may be performed under local, regional (spinal or epidural) or general anaesthesia[1]. Spinal block is still the first choice because of its rapid onset, superior blockade, low risk of infection as from catheter in situ, less failure rates and cost-effectiveness, but has the drawbacks of shorter duration of block and less postoperative analgesia[1].

Local anesthetic, Bupivacaine is the commonest agent used for spinal anesthesia, but its relatively short duration of action may lead to early analgesic intervention in the postoperative period.[2] Many adjuvants to local anesthetics have been used intrathecally to prolong the intraoperative as well as postoperative analgesia.[3] Opioids are commonly used as intrathecal adjuvants to improve the quality of intraoperative analgesia and prolong it in the postoperative period without significant motor or autonomic blockade. However, side effects such as pruritus, nausea, vomiting, urinary retention, and delayed respiratory depression have prompted further research toward non-opioid analgesics with less serious side effects.[4]

Clonidine, a selective partial α_2-adrenergic agonist, is being extensively evaluated as an adjuvant to intrathecal local anesthetics and has proven to be a potent analgesic, free of opioid-related side effects.[5] It is known to increase both sensory and motor blockade of local anesthetics. Intrathecal clonidine has been used as an adjuvant to local anesthetics in various surgical procedures without any clinically significant side effects. Previous studies have described the use of intrathecal clonidine in a wide range (15—150 μg).[6]

Various studies have used clonidine with wide dose range (15-400µg) for central neuraxial block either alone or in combination with different local anaesthetics or opioids.

This study has been undertaken to evaluate the efficacy and safety of intrathecal clonidine in conjunction with 0.5% hyperbaric bupivacaine in spinal anaesthesia for the patients who are scheduled for lower limb orthopaedic surgeries in our hospital. Two doses of clonidine (30 mcg and 60 mcg) will be assessed to find out dose ranging effects.

METHODOLOGY:

In this study, 60 patients aged between 20 and 60 years, undergoing elective lower limb orthopaedic surgery under spinal anaesthesia was selected. A detailed history complete physical examination and routine investigations was done for all patients. Informed written consent was taken.

The study population were randomly divided into 2 groups with 30 patients in each group. Group BC30- will receive hyperbaric bupivacaine 0.5% of 3 ml(15mg) and clonidine 30mcg and 0.2 ml NS.

Group BC60- will receive hyperbaric bupivacaine 0.5% of 3 ml(15mg) and clonidine 60mcg.

INCLUSION CRITERIA

- ASA-I and Π grade patients.
- Elective procedures
- Age between 20 and 60 years.
- Patient's willingness for study and written consents

EXCLUSION CRITERIA

- ASA grade IIIand above with other co_morbid conditions of cvs, cns,hepato-renal, metabolic.
- Age <20 and >60years.
- History of known drug hypersensitivity to local anaesthetics.
- Blood coagulation disorders.
- Unwilling patients.
- Spinal deformities, raised intracranial tension.
- Local sepsis

The statistical analysis between the two group was compared using student 't' test and Chi Square test.

The study was conducted after informed written consent is taken from patient in both group, patients were advised over night fasting, they were premedicated with 0.5 mg alprazolam orally before giving spinal Anaesthesia (to allay anxiety and apprehension).

In the preoperative room intravenous line was secured with 18 G IV cannula and the patients were preloaded with 15 mg per kg Ringer lactate 30 minutes prior to spinal anaesthesia.

Under Aseptic precaution with patient in lateral position 25 gaugequinke spinal needle was introduced into L3-L4 space after confirming clear flow of CSF 3 ml of test drug was injected Intrathecaly.

RESULTS:

Table 1:Comparisons of mean time to onset of sensory block

GROUP	Mean (minutes)	Std. Deviation	p value
BC30	2.43	0.504	t test= 9.6
BC60	1.63	0.556	<0.001

Table 1 shows the distribution of mean time to onset of sensory block.The mean time to onset of sensory block was 2.43 +/-0.54 and 1.63+/_0.556 in groups BC 30 and BC 60 respectively , which is statistically significant between the groups(p-0.001).

Table 2:Comparisons of mean time of motor blockage III

GROUP	Mean (minutes)	Std. Deviation	p value
Bc30	8.5	0.731	t test= 21.6
BC60	9.7	0.750	<0.001

Table 2 shows the mean time to motor block (bromage3).The mean time to motor block was 8.5+/- 0.73 and 9.1+/-0.75 in the groups BC 30 and the BC 60 respectively , which is statistically significant (p<0.001).

Table 3:Comparisons of mean time to reach highest sensory level

GROUP	Mean (minutes)	Std. Deviation	p value
BC30	9.33	0.547	t test=340.8
BC60	4.57	0.971	<0.001

Table 3 shows the mean time of reaching highest sensory level.The mean time of reaching highest sensory level was 9.33+/-0.547 and 4.57+/-0.971 minutes in the two groups respectively, which is statistically significant (p<0.001)

Table 4 : Distribution of subject according to highest sensory level achieved among the groups

Highest sensory level	GROUP (no. & %)		
	BC30	BC60	Total
T10	0	2	2
	0.00%	6.70%	3.30%
T8	19	16	35
	63.30%	53.30%	58.30%
T6	11	10	21
	26.60%	33.30%	35%
T4	0	2	2
	0.00%	6.70%	3.30%
Total	30	30	60
	100.00%	100.00%	100.00%
chi square test= 13.83, p value= 0.008			

Table 4 shows highest sensory level achieved at T8 level (63.30%, 53.3%) then T6 level (26.6%, 33.3%) in clonidine 30 and clonidine 60 groups, which was statistically significant (p=0.008).

Table 5 :Comparisons of mean time of two segment regression

GROUP	Mean (minutes)	Std. Deviation	p value
BC30	100.33	7.649	t test= 1926.6
BC60	111.67	11.769	<0.001

Table 5 shows the mean duration of two segment regression in the groups.The minimum duration in group BC 30 and in group BC 60 was 90 mins and maximum duration in group BC 30 and in group BC 60 was 110 and 140 mins respectively.The mean time of two segment regression was 100.33±7.649 and 111.67±11.761 in the groups BC 30 and BC 60 respectively, which was statistically significant (p<0.001).

Table 6: Comparisons of mean time of total duration of motor block

GROUP	Mean (minutes)	Std. Deviation	p value
BC30	244	8.944	t test=49306.2
BC60	301.33	38.928	<0.001

Table 6 shows the mean time of total duration of motor block.The minimum duration of motor block was 230 mins in group BC 30 and 240 mins in group BC 60 .The maximum duration of motor block in group BC 30 was 260 min and group BC 60 was 360 mins. The mean time of total duration of motor block is 244±8.94 and 301.3±38.92 among two group BC 30 and BC 60 respectively, which is statistically significant(p <0.001)

DISCUSSION:

It is the time taken from deposition of study drug till the patient does not feel the pin prick at L1 level. From our study we observed that time to achieve sensory level in group BC60 when compared to group BC30 ie.,1.63±0.556 and 2.43±0.54 minutes respectively.

Our study concurs with the findings of rucheearora et al.[7] who observed that the mean time of onset of sensory block was less in clonidine groups(15 and 30 µg) this was significantly shorter in clonidine group 30µg .This shows addition of increased doses of clonidine has reduced the onset of sensory block. But in Dr.K.P.Pollaiah MD etal[8] observed that there is no difference in the time of onset of sensory level i.e, 4.43 and 4.2 minutes in bupivacaine group and bupivacaine -clonidine combination group respectively.

Is defined as the time taken from deposition of the study drug to the maximum sensory blockade attained .From our study we observed that the highest sensory level achieved in both the groups was T8.

Dr Prabha, Dr Shrayavathi et al, in their study observed that mean cephalic level of sensory block on dependent side was T7 in bupivacaine with clonidine 30 mcg, T8 in bupivacaine clonidine 15mcg group and T10 in bupivacaine 6 mg group which concurs with our study that addition of clonidine increases the highest level of sensory level.[9]

From our study wobserved that the mean time of reaching highest sensory level was 9.33+/-0.547 and 4.57+/-0.971 minutes in the GroupBC 30 and GroupBC 60 respectively, which is statistically significant.

In the study conducted by Anil Thakur et al[10], the time to achieve the highest level of sensory block in bupivacaine 11mg group , bupivacaine 11 mg -clonidine15 mcg groupand bupivacaine11mg-clonidine30 mcg group was 16.40, 18.40 and 18.20 minutes respectively, in which addition of clonidine causes increased time to achieve the highest sensory levels when compared to bupivacaine alone, which differs from our study.

It is the time in minutes taken to regress the level of loss of pin prick sensation achieved to two lower sensory dermatomal level. We observed that the time for two segment regression in Group BC 30 and Group BC 60 was 100.33±7.649 and 111.67±11.769 minutes respectively which is statistically significant.

Anil Thakur et al, in their study observed that time to achieve two segment regression in bupivacaine 11mg group, bupivacaine 11 mg -clonidine15 mcg groupand bupivacaine11mg-clonidine30 mcg group was 72.6±15.42 , 105.6±30.15, 110.6±26.22 minutes respectively, Which concurs with our study where addition of increased doses of clonidine has increased the duration of two segment regression. similarly in the study conducted by Dr Prabha, Dr Shrayavathi et al the that time to achieve two segment regression in bupivacaine 6mg Group , bupivacaine-clonidine15 mcg Group and bupivacaine-clonidine30 mcg Group was 50±13, 107±26 and 142±21 minutes respectively which concurs with our study.

We observed in our study that the time of onset of motor blockade was 8.5±0.731minutes and 9.7±0.750 minutes in GroupBC 30 and GroupBC60 respectivelywhich is statistically significant.

Dr K P Polaiah M D et al, in their study observed that the onset of motor blockade was 5.450±0.411 and 5.573±0.0464 mins in bupivacaine 15mg and bupivacaine 15mg-clonidine 30mcg group respectively which is not significant. This differs from our study in which the addition of clonidine in increasing doses delays the onset of motor block.

CONCLUSION:

In conclusion , the addition of clonidine 60 µg to hypaerbaric bupivacaine intrathecally prolonged both sensory and motor blockade with longer duration of sensory block when compared to motor block of spinal anaesthesia and hence the total duration of analgesia when compared to clonidine 30µg .

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