

A Comparative Study of two Doses of Intrathecal Clonidine with Hyperbaric Bupivacaine in Elective Lower Abdominal in a Tertiary Care Centre**Dr Sachin Devendrarao Shende¹, Sougat sourendra Sarkar²**¹Assistant professor department of pharmacology Mayo institute of medical sciences Gomti nagar²Associate professor department of pharmacology Mallareddy institute of medical sciences**Corresponding Author****Sougat sourendra Sarkar**

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ABSTRACT

Introduction: For lower limb and lower abdominal surgeries, the standard anaesthetic technique is subarachnoid block. Adrenaline being the first spinal adjuvant used to increase the duration and to reduce the toxicity of spinal anaesthesia in 1903. From then on many drugs have been tried in search for an ideal adjuvant. They are opioids, sodium bicarbonate, ketamine, neostigmine, midazolam and the latest inclusion is clonidine.

Aim: To study the effects of adding two doses of clonidine (30 and 45 mcg) to 12.5 mg hyperbaric bupivacaine in lower abdominal and lower limb surgeries. Sensory and motor parameters and analgesia were monitored.

Materials and Methods: After getting the ethical committee approval the study was conducted in 90 patients undergoing elective lower abdominal and lower limb surgeries. It was a double blinded study in which patients were randomly allocated into 3 groups I, II and III. Group I received only intrathecal bupivacaine 2.5mg. Group II received bupivacaine 2.5mg + clonidine 30 μ g. Group III received bupivacaine 2.5mg + clonidine 45 μ g. Sensory and motor parameters and analgesia were monitored along with the vitals of the patient.

Results and Conclusion: This study shows that adding 45 μ g of clonidine significantly results in more duration of post operative analgesia than adding 30 μ g of clonidine to bupivacaine and bupivacaine alone without any side effects.

Keywords: Intrathecal clonidine, spinal adjuvant, additives to bupivacaine.**INTRODUCTION**

For lower limb and lower abdominal surgeries, the standard anaesthetic technique is subarachnoid block. Adrenaline being the first spinal adjuvant used to increase the duration and to reduce the toxicity of spinal anaesthesia in 1903. From then on many drugs have been tried in search for an ideal adjuvant. They are opioids, sodium bicarbonate, ketamine, neostigmine, midazolam and the latest inclusion is clonidine. Initially opioids have been the standard choice as spinal adjuvants. But since many side effects and complications like early and late depression of ventilation, pruritus, nausea, vomiting, urinary retention, central nervous system excitation, viral reactivation, sexual dysfunction, delayed gastric emptying, ocular dysfunction etc are inevitable to this group of drugs there is an active search for an alternative ideal adjuvant which is devoid of these side effects and complications.

Preservative free clonidine when administered into epidural or subarachnoid space produce dose dependent analgesia and unlike opioids does not produce any of its side effects. Activation of post synaptic alpha 2 receptors in the substantia gelatinosa of the spinal cord is the presumed mechanism by which it produces analgesia.

Clonidine in appropriate doses with bupivacaine in subarachnoid block seems to prolong the duration of surgical anaesthesia and postoperative analgesia without any of its side effects like dry mouth, hypotension, bradycardia, which is not usual in these doses with added advantages like sedation, anti-shivering.

The present study has been taken in search for a minimal dose of clonidine as an adjuvant with bupivacaine which produces maximum post operative analgesia without or with minimal incidence of its side effects.

AIM

To study the effects of adding two doses of clonidine (30 and 45 mcg) to 12.5 mg hyperbaric bupivacaine in lower abdominal and lower limb surgeries. Sensory and motor parameters and analgesia were monitored.

MATERIALS AND METHODS

After getting the ethical committee approval the study was conducted in 90 patients undergoing elective lower abdominal

and lower limb surgeries. It was a double blinded study in which patients were randomly allocated into 3 groups I, II and III. Sensory and motor parameters and analgesia were monitored along with the vitals of the patient. GROUP I: 12.5 mg (2.5ml) Intrathecal hyperbaric bupivacaine + 0.3ml normal saline
 GROUP II: 12.5 mg (2.5ml) Intrathecal hyperbaric bupivacaine + 0.3ml containing 30 mcg clonidine
 GROUP III: 12.5 mg (2.5ml) Intrathecal hyperbaric bupivacaine + 0.3ml containing 45 mcg clonidine

Inclusion Criteria

- Patients aged between 20 and 60 years of both sexes.
- Patients belonging to physical status ASA I and II.
- Patients posted for elective lower abdominal and lower limb surgeries.

Exclusion Criteria

- ❖ Patient refusal.
- ❖ Patients with a history of known sensitivity to the drugs used.
- ❖ Patients with history of bleeding disorders, coagulopathies and on anti-coagulants.
- ❖ Caesarean section.
- ❖ Abdominal Hysterectomy.
- ❖ Patients with local infection.

Monitoring(haemodynamic aparameters monitored in three groups)

- ❖ Heart rate
- ❖ Blood pressure
- ❖ Pulse oximetry - SpO₂
- ❖ Respiratory rate
- ❖ Sedation score (Brain and Ready score)

Patients were put in lateral position and with strict aseptic precaution lumbar puncture was done with quincke standard 23 gauge spinal needle. After ensuing free flow of CSF, the drug was injected as per the group assigned. The assigned amount of clonidine and normal saline and bupivacaine were taken in a sterile syringe. After injection patient were put up in supine position. After attaining adequate peak level of sensory block, the surgeon was asked to proceed.

The Following Parameters Were Recorded

1. Time of highest level of sensory block achieved by pin prick (Visual Analog Scale).
2. Onset and duration of motor blockade assessed by using bromage scale.
3. Pulse rate, Blood pressure, respiratory rate, SpO₂ were monitored every 5 minutes for 30 minutes and every 15 minutes for next 90 min and then 30 min once for next 4 hours.
4. Any discomfort like nausea, vomiting, dry mouth and shivering are noted.
5. Hypotension is said to have occurred if the MAP falls less than 70 mm Hg and was treated with 100% O₂, Intravenous fluid bolus and Inj. Ephedrine in incremental doses.

Bradycardia (<60/min) – if present was The fall in pulse rate was significant in 3 groups , but not less than 60 per min in group II or group III (except in 1 case) requiring inj. Atropine to treat it.

The fall in Mean Arterial Pressure was not significant in all 3 groups. Thus, 30 and 45 µg of Clonidine does not produce any change in Mean Arterial Pressure values. The fall in MAP was not sign

Table 3: Sedation score

Sedation score	Group I		Group II		Group III	
	No.	No.	No.	%	No.	%
0	30	100	26	86.7	12	40
1	-	-	4	13.3	18	60
2	-	-	-	-	-	-
Mean	0		0.13		0.6	
SD	-		0.35		0.4983	

'p' value for all 3 groups = 0.0001, which is significant.

ifificant in 3 groups and the requirement of inj. Ephedrine is similar in all groups

Table 4: Onset of maximum sensory level (SL) and motor blockade in the study groups

	Group I	Onset of Motor onset max.SL	Group II	Motor onset	Group III	Motor onset
			Onset of SL		Onset of SL	
Mean	7.9	8.63	8.17	9.07	8.83	9.33
SD	0.88	1.03	0.99	0.83	1.05	0.84

p' value for the onset of sensory level in all the 3 groups = 0.0028, significant. The onset of maximum sensory blockade was significantly prolonged in group III when compared to other two groups 'p' value for motor onset in all the 3 groups = 0.029, significant. The onset of motor blockade was significantly prolonged in group III when compared to other 2 groups.

Table 6: Maximum Sensory level (SL) among the study groups

Max. SL	Group I		Group II		Group III	
	No.	%	No.	%	No.	%
T8	3	10	3	10	7	21.3
T9	13	43.3	5	16.7	9	30
T10	12	40	15	50	11	36.7
T11	2	6.7	7	23.3	3	10

standard deviation of 14.8, 9.7, 10.7 in group I, group II, group III respectively.

'p' value for duration of post op analgesia in 3 groups = 0.0001, significant. The post operative period till the patient demands systemic analgesic (i.e., VAS score > 5) from the initiation of subarachnoid blockade. The post op analgesia prolongs with the addition of clonidine.

DISCUSSION

All the three groups were comparable in relation to age, height and weight. Post-operative analgesia was significantly prolonged in both the group II & III, but significantly much more in group III (45 μ g clonidine). In group III, it was 272.2 ± 33.2 minutes, while in group II it was

194.9 ± 22 minutes, when compared to $175.9 \pm$

11.6 minutes in group I. This is supported by a study conducted by Sethi et al² where they have used 1 μ g per kg dose of clonidine with 12.5 mg of 0.5% bupivacaine and found that this dose prolongs the duration of post operative analgesia by 614 minutes in clonidine group.

Intra operative sedation was observed in group III but not of grade II or III or IV of brain and ready sedation score causing either respiratory depression or desaturation. This observation is in accordance with a study conducted by Sethi et al² where they have observed sedation in 50 percent of their patients without significant respiratory depression or desaturation.

The fall in pulse rate was significant in 3 groups, but not less than 60 per min in any group (except in one case) requiring inj. Atropine to treat it. The fall in mean arterial pressure was not significant in 3 groups and the requirement of inj. Ephedrine is similar in all groups. But the study conducted by Sethi et al² there was significant fall in mean arterial pressure though not requiring vasopressor treatment. Thus, doses of 45 μ g and 30 μ g clonidine does not produce any change in mean arterial pressure values and is hemodynamically stable. In the studies conducted by Anil Thakur et al¹ and Birbal Baj et al³, there was significant fall in mean arterial pressure with increasing doses of clonidine.

The two segment regression time was significantly prolonged in both the groups II and III, but more with group III. It was 122.6 ± 5.9 minutes in group III, 102.1 ± 12.5 minutes in group II and 86.5 ± 7.2 minutes in group I. A study conducted by Sethi et al² also showed that there was prolongation in two segment regression time of 218 minutes in clonidine, while using 1 μ g per kg group.

The duration of motor blockade was significantly prolonged in both the groups II and III, but more so with group III in our study. The mean duration was 142.7 ± 8.5 minutes in group III, 125.2 ± 9.5 minutes in group II, and 110.9 ± 9.9 minutes in group I. In a study conducted by Sethi et al² the duration of motor blockade was 205 minutes in clonidine group (1 μ g/kg). This was also in accordance with a study conducted by Dobrydnjov I et al⁶, using 6mg of 0.5% heavy bupivacaine with 15 μ g vs 30 μ g of clonidine for unilateral spinal anaesthesia in unilateral inguinal hernia surgeries.

The onset of maximum sensory blockade and the onset of motor blockade was significantly prolonged in group III when compared to other 2 groups. This observation is in accordance with a study conducted by Sethi et al².

The side effects of clonidine like dry mouth was not observed in any of the cases of group II & III. While in a study conducted by Sethi et al² they observed significant incidence of dry mouth with the dose of 1 μ g per kg clonidine group.

Bonnet et al⁷ studied spinal clonidine 150 μ g as adjuvant with 2.5 mg bupivacaine in orthopaedic surgeries. It effectively prolonged the post-op analgesia without any side effects.

CONCLUSION

Our study shows that adding clonidine 30 μ g and 45 μ g to bupivacaine significantly prolongs the duration of post operative analgesia when compared to bupivacaine alone in inguinal hernia surgeries. Adding 45 μ g of clonidine significantly results in more duration of post operative analgesia than adding 30 μ g of clonidine to bupivacaine without any side effects.

REFERENCES

Anil Thakur et al. Intrathecal Clonidine as an adjuvant to Hyperbaric Bupivacaine in patients undergoing Inguinal Hernior- aphy - A randomised double blinded study Journal of Anaesthesiology Clinical Pharmacology 2013 - 29(1): 66-70.

1. BS Sethi, Mary Samuel, Deepak Shreevatsava. Efficacy of Analgesic effects of low dose Clonidine as an adjuvant to Hyperbaric Bupivacaine. Indian Journal of Anaesthesia 2007 - Mar - 29 (1) : 66-70.
2. Dr Birbal Baj et al. Intrathecal Clonidine as an adjuvant to Hyperbaric Bupivacaine in patients undergoing surgeries under spinal anaesthesia - A randomised double blinded study. IOSR Journal of Dental and Medical Sciences 2015 - Sep.
3. Raj Bahadur Singh, Neetu Chopra et al. Role of Intrathecal Clonidine as an adjuvant to Hyperbaric Bupivacaine in patients undergoing lower abdominal surgeries - A randomised double blinded study. Anaesthesia Essays and Researches. 2014 - Oct: 307-12.
4. N Ratan Singh et al. Effect of Intrathecal Clonidine as an adjuvant to Hyperbaric Bupivacaine in patients undergoing caesarean section. International Journal of Health Sciences and Research. 2014: 5(1): 100-105.
5. Dobrydnyov i et al. Clonidine combined with small dose bupivacaine for inguinal hernia surgery. Anaes analg., 2003;96:1496-503.
6. Bonnet et al, spinal clonidine as an adjuvant with hyperbaric bupivacaine in orthopaedic surgeries., British journal of anaesthesia,1989; 63;1;93-96.
7. Fogarty et al, spinal clonidine vs morphine with bupivacaine in patients undergoing total hip replacement surgeries., British journal of anaesthesia, 1993;71;5;661-64.