



A Comparative Study of two Doses of Intrathecal Clonidine with Hyperbaric Bupivacaine in Elective Lower Abdominal and Lower Limb Surgeries

Authors

Dr Santhosh. T^{1*}, Prof Dr C.S.Prakash²

¹Post Graduate Student, Dept of Anaesthesia, Rajah Muthiah Medical College and Hospital, Chidambaram, Tamil Nadu, India

²Professor, Dept of Anaesthesia, Rajah Muthiah Medical College and Hospital, Chidambaram, Tamil Nadu, India

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 in Rajah Muthiah Medical College and Hospital, Chidambaram. 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 30µg. Group III received bupivacaine 2.5mg + clonidine 45µg. Sensory and motor parameters and analgesia were monitored along with the vitals of the patient.

Results and Conclusion: This study shows that adding 45µg of clonidine significantly results in more duration of post operative analgesia than adding 30µg 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 in Rajah Muthiah Medical College and Hospital, Chidambaram. 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 parameters 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.
6. Bradycardia (<60/min) – if present was treated with Inj. Atropine.
7. Sedation score was noted according to Brain and Ready scoring.
8. Post operative observation:
 - a. Duration of procedure
 - b. Two segment regression time (i.e. the time taken to decrease from maximum sensory level by two segments from initial level is noted)
 - c. Duration of postoperative analgesia.
 - d. Time at which rescue analgesia was used.

Observation and Results

There was no significant difference in the, type of surgeries, age, sex, height weight and ASA status of the patients taking part in the study.

Table 1: Pulse Rate

Pulse rate (PR)	Group I		Group II		Group III	
	Mean	SD	Mean	SD	Mean	SD
Initial PR	88.3	9.5	85.6	9.8	84.9	11.3
Minimum PR	75.4	5.6	73.1	5.4	67.6	6.1
Average PR	82.5	5.9	80.8	6.3	73.6	5.3
Fall in PR	12.8	6.6	12.5	5.9	17.4	9.3
% fall in PR	14.1	6.1	14.2	5.4	19.6	8.6

'p' value for 3 groups = 0.0159, which is statistically significant.

The average fall in PR in Group I and II are comparable. But the fall is profound in Group III. This suggests that increasing the dosage of clonidine will decrease the pulse rate significantly.

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.

Table 2: Mean Arterial Pressure variation in study groups

MAP	Group I		Group II		Group III	
	Mean	SD	Mean	SD	Mean	SD
Initial MAP	89.7	6.7	90.5	7.5	90.1	8.4
Minimum MAP	83.1	7.6	83.2	6.7	78.6	6.5
Average MAP	89.4	5.6	89.8	4.9	83.5	4.3
Fall in MAP	6.6	8.0	7.3	66.4	11.5	10.1
% fall in MAP	7.1	7.9	7.8	6.8	12.1	10

'p' value = 0.151, which is insignificant.

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

Table 3: Sedation score

Sedation score	Group I		Group II		Group III	
	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.

Intra operative sedation was observed in group I but not of grade II or III or IV of brain and ready

sedation score causing either respiratory depression or desaturation.

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

	Group I		Group II		Group III	
	Onset of max.SL	Motor onset	Onset of SL	Motor onset	Onset of SL	Motor onset
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 5: Two segment regression

Two segment regression	Group I	Group II	Group III
Mean (mins)	86.5	102.1	122.6
SD	7.2	12.5	5.9
'p' value for 3 groups	0.0001, significant		

The two segment regression time was significantly prolonged in both the groups II and III, but more with group III.

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

The maximum sensory level of T8 was achieved in group III (21.3%) compared to 10% in each Group I and Group II. Almost all the 3 groups have achieved a minimum sensory level of T11.

Figure 1: Maximum sensory level (SL)

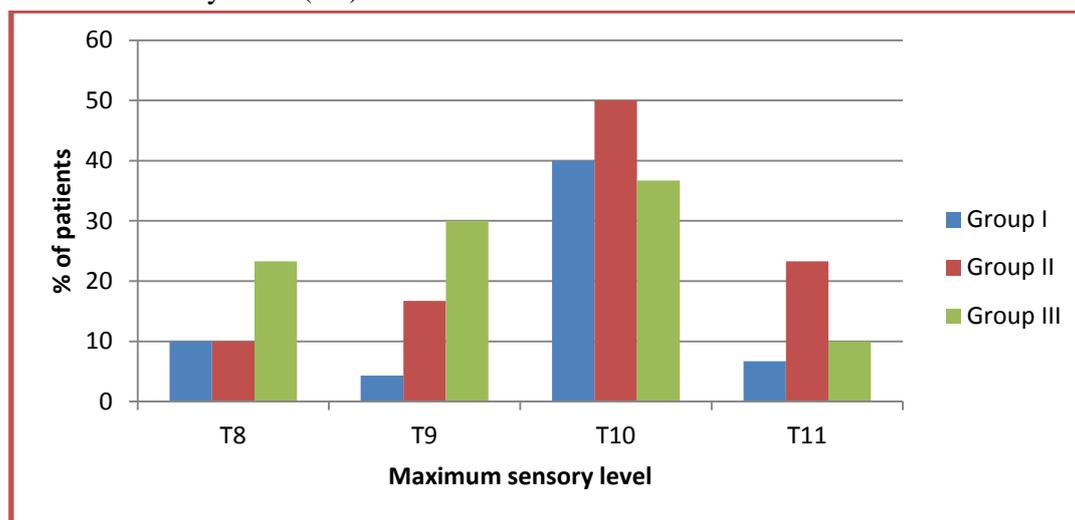


Table 7: Duration of motor blockade, surgery, post operative analgesia among the study groups

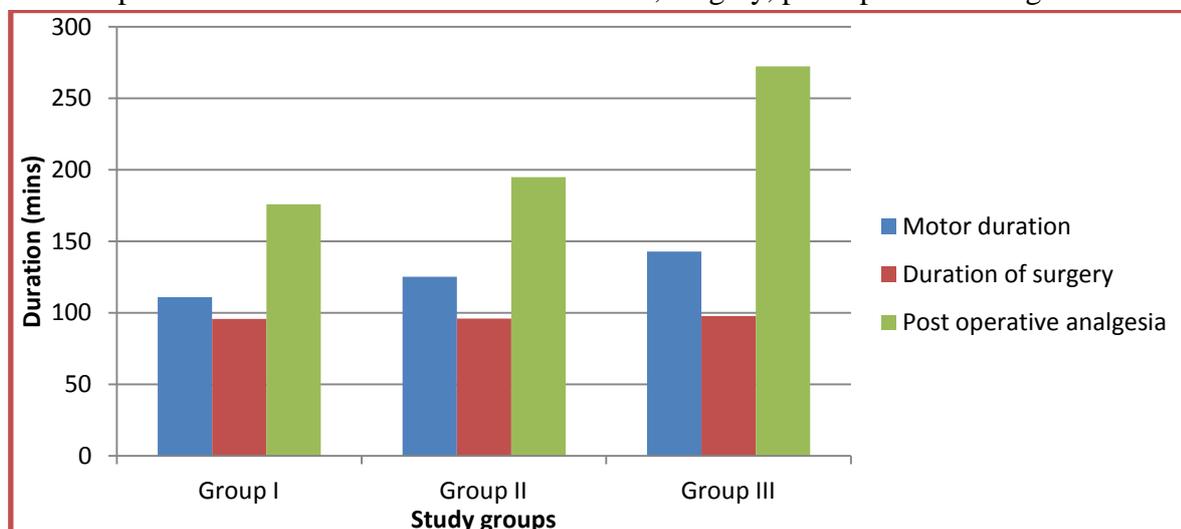
	Group I			Group II			Group III		
	Motor duration (mins)	Duration of surgery (mins)	Post op analgesia (mins)	Motor duration (mins)	Duration of surgery (mins)	Post op analgesia (mins)	Motor duration (mins)	Duration of surgery (mins)	Post op analgesia (mins)
Mean (mins)	110.9	95.7	175.9	125.2	95.8	194.9	142.7	97.6	272.2
SD	9.9	14.8	11.6	9.5	9.7	22.0	8.5	10.7	33.2

‘p’ value for duration of motor blockade in 3 groups = 0.0001, significant. The duration of motor blockade was significantly prolonged in both the groups II and III, but more with group III. ‘p’ value for duration of surgery in 3 groups = 0.7104, insignificant. The mean duration of surgery was 95.7, 95.8, 97.6 minutes with

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.

Figure 2 Comparison of the duration of motor blockade, surgery, post operative analgesia



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 (45µg 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 ± 11.6 minutes in group I. This is supported by a study conducted by Sethi et al² where they have used 1µg 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 45µg and 30µg 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 1µg 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 (1µg/kg). This was also in accordance with a study conducted by Dobrydnjov I et al⁶, using 6mg of 0.5% heavy bupivacaine with 15µg vs 30µg 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 1µg per kg clonidine group. Bonnet et al⁷ studied spinal clonidine 150µg 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 30µg and 45µg to bupivacaine significantly prolongs the duration of post operative analgesia when compared to bupivacaine alone in inguinal hernia surgeries. Adding 45µg of clonidine significantly results in more duration of post operative analgesia than adding 30µg of clonidine to bupivacaine without any side effects.

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