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COMPARISON OF EFFECTS OF SPINAL ADDITIVES FENTANYL OR CLONIDINE WITH HYPERBARIC BUPIVACCAINE WITH CONTROL GROUP RECEIVING ONLY HYPERBARIC BUPIVACAINE

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ABSTRACT

Background and goals of study: *Bupivacaine is the commonly used local anesthetic in spinal anesthesia and several spinal additives, commonly the opioids are added to enhance the block and duration of spinal anesthesia. Each of the drug added as spinal additive has its own advantages and disadvantages. This study was designed to compare the effects of intrathecal Fentanyl with 0.5 % Hyperbaric Bupivacaine and Clonidine with 0.5% Hyperbaric Bupivacaine with control group of patients who received only 0.5% Hyperbaric Bupivacaine.*

Methods: *45 patients were assigned to 3 groups of 15 each. Group A – 15 mg of 0.5% bupivacaine (H) + 0.5ml of Normal Saline; Group B – 15 mg of 0.5% bupivacaine (H) + 25 µg of Fentanyl; Group C – 15 mg of 0.5% bupivacaine (H) + 50 µg of clonidine (corrected to a volume of 0.5ml by adding Normal Saline). Intraoperative hemodynamic parameters, maximum sensory level blocked (until grade 3), time to achieve maximum sensory level, sensory Regression time to L1 (until grade 0), onset of grade 4 motor block, regression time to grade 1 motor block and sedation score were assessed.*

Results: *Maximum height of dermatomal block and the time to achieve it were similar in all these groups. Sensory regression to L1 is prolonged in the additive groups. Onset of grade 4 motor block was shorter in group B and C. Regression to grade 1 motor block is significantly prolonged in Groups B and C; and Group C is longer than Group B. Hemodynamic variables were relatively lower in clonidine group.*

Conclusion: *Clonidine qualitatively prolongs the duration of both sensory and motor block of spinal anesthesia with insignificant hemodynamic variation which can be easily managed. Fentanyl also prolongs the spinal anesthesia, but not to the extent of Clonidine, without any significant hemodynamic changes.*

KEYWORDS : Bupivacaine, Clonidine, Fentanyl, Spinal Anaesthesia

INTRODUCTION:

The history of spinal anesthesia dates back since August,15,1898 when Gustav August Bier performed the first spinal anesthesia with cocaine. Then came Arthur E.Barker who determined several factors involved in the spread of local anesthetic in subarachnoid space. It was Rudolph Matas who first used a spinal additive morphine with cocaine to enhance neuraxial anesthesia.

Several factors have been determined since the introduction of spinal anesthesia, till date and in evolution that modify the effects, extent or duration of spinal anesthesia.

Bupivacaine is the commonly used local anesthetic in spinal anesthesia and several spinal additives, commonly the opioids are added to enhance the block and duration of spinal anesthesia. Each of the drug added as spinal additive has its own advantages and disadvantages. The ease of administering spinal anesthesia and its superior analgesic property has gained popularity over general anesthesia.

This study was designed to compare the effects of intrathecal fentanyl with 0.5 % Hyperbaric Bupivacaine and clonidine with 0.5% Hyperbaric Bupivacaine with control group of patients who received only 0.5% Hyperbaric Bupivacaine.

METHODOLOGY:

The current study is a prospective randomised control study. 45 patients were assigned to 3 groups of 15 each. Randomization was done using computer generated random numbers. The study was performed after obtaining informed consents from all the patients. ASA PS – 1 & 2 patients between 20 and 40 years of age, who were posted for elective surgery, were included in the study. ASA PS 3, 4 & 5 patients, and those with contraindications for spinal anesthesia, were excluded from the study.

The three groups are as follows:

Group A – 15 mg of 0.5% bupivacaine (H) + 0.5ml of Normal Saline
Group B – 15 mg of 0.5% bupivacaine (H) + 25 µg of Fentanyl
Group C – 15 mg of 0.5% bupivacaine (H) + 50 µg of clonidine (Corrected to a volume of 0.5ml by adding Normal Saline)

Preoperative vitals were recorded and all patients were started with 18G IV cannula and preloaded with 500ml of Ringer Lactate fluid 15 minutes before the time of spinal anesthesia. No patients were sedated intra operatively. Table was ensured to be horizontal before spinal anesthesia. Under aseptic precautions spinal anesthesia was given to all patients in right lateral position, with 25G Quincke-Babcocks spinal needle, and in L3-4 space. Hypotension was defined as less than 20% from the basal mean arterial pressure and treated with ephedrine & intravenous fluids and bradycardia less than 60 and treated with atropine.

Intraoperatively, noninvasive blood pressure, recorded every five minutes in the first hour and every ten minutes thereafter, continuous five lead Electrocardiogram, and pulse-oximeter were used.

The following Clinical parameters were observed:

- Maximum sensory level blocked (Until grade 3)
- Time to achieve maximum sensory level
- Sensory Regression time to L1 (Until grade 0)
- Onset of grade 4 motor block
- Regression time to grade 1 motor block
- Sedation score

Assessment of sensory blockade was done using Hollman's Scale:

- Grade 1: Normal sensation of pin prick

- Grade 2: Pin prick felt as sharp pointed but weaker compared with the same area in other side.
- Grade 3: Pin prick felt as touch with blunt object
- Grade 4: No perception of pin prick

Assessment of sensory loss to pain was done by using 24 gauge intramuscular needle until the patient had grade 3 Sensory block.

Assessment of Motor Blockade was done using Bromage score:

Grade	Criteria	Degree of Block
I	Free movement of legs and feet	(0%)
II	Just able to flex knees with free movement of feet	(33%)
III	Unable to flex knees, but with free movement of feet	(66%)
IV	Unable to move legs or feet	(100%)

Assessment of Sedation Level was done using Ramsey Sedation Score :

- 1 - Anxious or agitated or restless
- 2 – Cooperative ,oriented
- 3 – Responds only to commands but awake
- 4 – Asleep and brisk response to commands
- 5 – Asleep and sluggish response to commands
- 6 – No response to auditory stimulus

RESULTS:

Age, height and weight among the three groups had no statistically significant difference, implying even distribution of the demographic parameters among the groups.

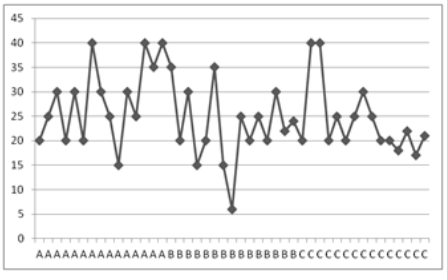
Maximum height of dermatomal block was similar in all these groups and the time to achieve it was also similar.

MAXIMUM SENSORY LEVEL BLOCKED

					95% Confidence Interval for Mean	
	N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound
1	15	5	1.424	.368	4.41	5.99
2	15	4	.884	.228	4.44	5.42
3	15	5.00	1.254	.324	4.31	5.69

Time to achieve maximum sensory level blocked:

					95% Confidence Interval for Mean	
	N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound
1	15	28.33	7.943	2.051	23.93	32.73
2	15	22.80	7.785	2.010	18.49	27.11
3	15	24.20	7.213	1.862	20.21	28.19



p – value by ANOVA was .133 which shows that statistically it is insignificant but seeing the mean values the time to achieve this is short with group B.

Sensory regression to L1 is prolonged in the additive groups (Groups B & C), but not significantly prolonged while comparing these two groups.

Sensory Regression to L1 :

					95% Confidence Interval for Mean	
	N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound
1	15	171.20	19.969	5.156	160.14	182.26
2	15	231.00	47.442	12.249	204.73	257.27
3	15	250.67	35.950	9.282	230.76	270.57

Onset of grade 4 motor block was shorter in group B and C with an average of around 5 to 7 minutes.

ONSET OF GRADE 4 MOTOR BLOCK IN MINUTES

					95% Confidence Interval for Mean	
	N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound
1	15	10.00	2.619	.676	8.55	11.45
2	15	6.87	4.138	1.068	4.58	9.16
3	15	5.73	1.870	.483	4.70	6.77

Regression to grade 1 motor block is significantly prolonged in Groups B and C compared to Group A; and Group C is longer than Group B.

Regression to grade 1 motor block in minutes:

					95% Confidence Interval for Mean	
	N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound
1	15	188.67	20.999	5.422	177.04	200.30
2	15	234.20	31.412	8.111	216.80	251.60
3	15	273.00	26.979	6.966	258.06	287.94

Hemodynamic variables were relatively lower in clonidine group.

All the patients in clonidine group were well sedated.

RAMSEY SEDATION SCORE

Score		GROUP		
		A	B	C
1		15	3	0
2			11	0
3			1	7
4			0	8
Total	Count	15	15	15

DISCUSSION:

The study results show significant prolongation of sensory and

motor blockade with clonidine. The average duration of motor blockade was 273 minutes which is ahead by 40 minutes compared to the average value with fentanyl and 85 minutes ahead with control group. The average duration of sensory blockade was 250.67 minutes in clonidine group while in fentanyl group it is 231 minutes and in control group 171 minutes. Even though there is a minimal blood pressure variability with clonidine which have been managed with ephedrine and intravenous fluids there was no significant bradycardia.

With clonidine it has an additional advantage of sedating the patient compared with fentanyl and it also lacks other side effects and respiratory depression that an intrathecal opioid will have. The sedative property of clonidine can be observed in any route the drug is given intrathecal, epidural, and nerve blocks[1].

Clonidine a selective partial agonist for α-2 adrenoreceptors centrally and peripherally[2,3]. The analgesic effect following its intrathecal administration is mediated spinally through activation of post-synaptic α-2 adrenoreceptors in the substantia gelatinosa of spinal cord and it works by blocking the conduction of C and Aδ fibres. The sedative property of the drug is due to its agonist action in α-2A receptors in the locus ceruleus of the brain stem[4]. Even though both the drugs fentanyl and clonidine produced an intense sub-arachnoid block clonidine is statistically significant in prolonging the blockade. Van der werff and C.J.Kalkmann in their study in using clonidine with hyperbaric bupivaccaine for caesarean section had a conclusion of prolonging sub-arachnoid blockade with no relevant maternal and neonatal side effects. In another study by Stephen Strebel et al compared various doses of clonidine as spinal additive to hyperbaric bupivaccaine 37.5, 75, and 150 microgram and the results were prolongation of spinal anesthesia in a dose dependant manner but the sedation score was not different . The hemodynamic variables had more variability in higher doses.

Fentanyl a lipophilic opioid acts directly on the μ receptor In the laminae 2 of the substantia gelatinosa of spinal cord whereby it provides pre-synaptic inhibition of the neurotransmitter release although minimal post-synaptic inhibition also occurs by hyperpolarizing the second order neurons[5,6]. The side effects of intrathecal opioids which is lacked by the α-2 agonists are pruritis in the face, neck and upper thorax, nausea and vomiting, urinary retention, depression of ventilation which is not usually observed in such low doses of fentanyl and also due to its lipophilicity

CONCLUSION :

Clonidine, when used as a spinal additive to hyperbaric bupivacaine in healthy adults, qualitatively prolongs the duration of both sensory and motor block of spinal anesthesia with insignificant hemodynamic variation which can be easily managed. Fentanyl also prolongs the spinal anesthesia, but not to the extent of Clonidine, without any significant hemodynamic changes. Clonidine has an additional advantage of arousable sedation.

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