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Comparative study of the haemodynamics and analgesic effects, the degree and duration of post operative analgesia of intrathecal Clonidine along with 0.5% Bupivacaine in parturients undergoing elective caesarean section

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Abstract
Background*: Post-operative analgesia plays an important role in the prevention of post-operative discomforts. Routine Sub Arachnoid blocks have limited duration of sensory and motor blocks. It can be overcome by adding adjuvants to local anaesthetics which prolongs the sensory and motor blocks.*
Aims And Objectives
The aim of the study was to compare the safety and efficacy of adding 50 μg Clonidine to 0.5% Bupivacaine in onset of block, duration of sensory block and motor block, requirement of opioid analgesics, backup analgesia in postoperative period.
MATERIALS AND METHODS
50 patients belonging to ASA 1 and ASA 2 status of age group between 2-35 years scheduled for elective caesarean sections were selected for this prospective randomized double blinded comparative study. They were randomly divided by sealed envelope technique into 2 groups. Group A (Control group), where patients received 1.8 ml of 0.5% Bupivacaine and Group B (Clonidine group), where patients received 1.8 mL of 0.5% Bupivacaine with 50 μg of Clonidine for sub Arachnoid block in patients scheduled for caesarean sections.
Results
There was no significant difference in onset of block between two groups. Duration of motor block and sensory block is significantly prolonged in group Clonidine than group A. Postoperative backup and opioid analgesic requirement is significantly lower in group Clonidine compared to group A.
Conclusions
Addition of Clonidine as an adjuvant to Bupivacaine for sub Arachnoid block significantly prolongs the duration of sensory and motor block in patients undergoing caesarean sections. Addition of Clonidine to local anaesthetics is remarkable, safe and cost effective method of providing postoperative analgesia. Requirements of opioid analgesic and backup analgesic, postoperative vomiting were significantly lower in Clonidine group compared to group A.
Keywords
Bupivacaine, Clonidine, Adjuvant, Sub Arachnoid Block, Post-Operative Analgesia.

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I. Introduction

Caesarean section is one of the most commonly performed surgical procedures. Any surgical procedure is painful and one of main aim of the Anaesthesiologist is to provide good operating conditions and effective postoperative analgesia. Most of the Anaesthestics used intrathecally have limited duration of action and analgesic effects. There has been a lot of renewed interest in the usage of intrathecal additive drugs that prolong duration of analgesia postoperatively to produce effective pain relief to patients without producing much hemodynamic changes.

The present study was designed to evaluate the efficacy of fixed dose of Clonidine added to 0.5% Bupivacaine heavy and plain Bupivacaine intrathecally in patients undergoing Elective caesarean section.

II. Aims And Objectives

To comparatively study the haemodynamics and analgesic effects, the degree and duration of post operative analgesia, duration of sensory and motor blockade of intrathecal Clonidine along with 0.5% Bupivacaine in parturients undergoing elective caesarean section

III. Materials And Methods

The present study was conducted in the Department of Anaesthesiology, Government Medical College, Ananthapuramu attached to Government General Hospital, Ananthapuramu. The protocol was approved by the hospital ethical committee.

Study Design: Prospective open label observational study

Study Location: This was a tertiary care teaching hospital based study done in Department of Anaesthesiology, Government Medical College, Ananthapuramu

Sample size: 100 patients

SELECTION OF CASES

Inclusion criteria

Patients undergoing elective Cesarean section
Patients in the age group of 20-35 years
ASA Grade I & II
Pregnancy of at least 34 weeks gestation
Single uncompromised fetus and uncomplicated pregnancy.

Exclusion Criteria

Contraindications to Sub Arachnoid Block
Bleeding diathesis & patients on anticoagulant therapy
Hypersensitivity to the study drug
Spinal deformities.
Fetal distress
Toxemia of pregnancy
CVS/CNS disorders
Neuromuscular diseases
Hypovolemia,
Obese patients
Patients with infection on the back

Before including the patient in to the study, detailed written informed consent was taken.

Patients were divided into 2 groups, each group consisting of 50 patients.

Group A: Patients who received SA with intrathecal 0.5% Bupivacaine heavy

Group B: Patients who received SA with 75 μg of intrathecal Clonidine along with 0.5% Bupivacaine heavy

Spinal anaesthesia Technique

After shifting to operation theatre, Patients baseline Heart rate, Non invasive Blood pressure, SPO_2, Respiratory rate were recorded. An IV line was secured with 18 G cannula. Preloading was done with RL. Under strict aseptic precautions, a midline lumbar puncture was performed in L3-L4 space using a 25G Quincke needle in left lateral decubitus position. After withdrawal of the needle, the patient was turned to the supine position with left uterine displacement.

Vital Signs and Side effects

Heart rate, systolic and diastolic blood pressure & mean arterial pressure, Respiratory rate & SPO_2 were recorded every 5^{th} minute throughout the intra operative period.

LEVEL OF ANALGESIA: –

Visual analogue pain score {VA (0 = no pain, 10= worst imaginable pain}

Side effects: Patients were monitored for the occurrence of side effects like nausea, vomiting, pruritus and respiratory depression for 6 hours.

Time for the first analgesic request was noted in all the three groups and this was managed with Inj Diclofenac 75 mg IM.

At the end of the study, data were compared and statistically analyzed using paired' test and chi-square tests.

OBSERVATIONS AND RESULTS

The present study was conducted in 100 patients and was divided into 2 Groups of 50 patients each.

HEART RATE:

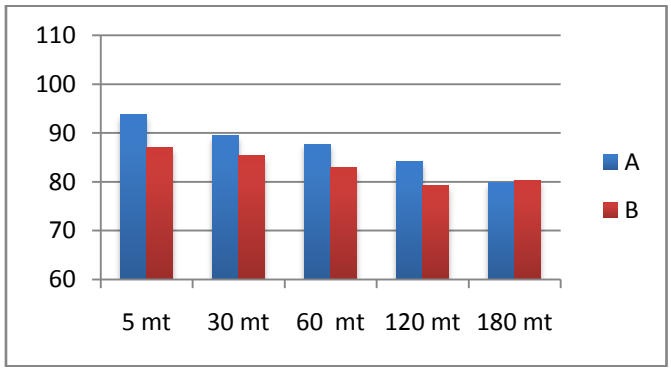
Heart rate is lower in patients who received intrathecal Clonidine. After 3 hours heart rate in all groups comparable ranging from 79 to 83 beats per minute in group A and 80 to 87 beats per minute in group B

TAB. 1: COMPARISON OF HEART RATE AMONG A & B GROUPS

TIME	A	B	A B
Pre Op	92	89.4	0.30429032 - NS
5 mts	94 ± 18	87 ± 20.2	0.040931223 - S
30 mts	89.5 ± 9.1	85.4 ± 11.4	0.044516844 - S
60 mts	87.7 ± 8	82.9 ± 7	0.003286967 - S
120 mts	84.1 ± 5.7	79.3 ± 4.6	0.001562324 - S
180 mts	80 ± 4.2	80.4± 7	0.60760147 - NS

P > 0.05 - NS: P < 0.05 - S

GRAPH: 1. COMPARISON OF HEART RATE AMONG A & B GROUPS



BLOOD PRESSURE:

The pre operative values of systolic BP of group A and B are 115 ± 6.52 and 114.2 ± 7.52.

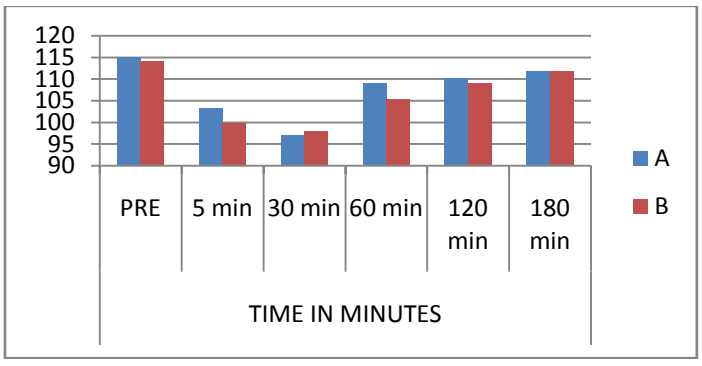
There is a reduction of blood pressure after 30 minutes, 60 and 120 minutes. These results significant only at 120 mts. The values were within physiological range and is not of clinical significance.

The mean arterial pressure showed very little changes between pre inductive values and values at different time intervals in different groups. The values at 60 minutes were found to be statistically significant but not clinically significant.

TAB: 6. COMPARISON OF SYSTOLIC BP AMONG A & B GROUPS:

GROUPS	TIME IN MINUTES					
	PRE	5	30	60	120	180
A	115 ± 6.5	103.3 ± 12.9	97.1 ± 16.4	109.1 ± 6.47	110.1 ± 15.0	111.9 ± 15
B	114.2 ± 7.5	99.7 ± 21.2	97.9 ± 10.4	105.4 ± 8.3	109.0 ± 5.4	111.7 ± 4.7
A B	0.23219174 P > 0.05, NS	0.4920342 P > 0.05, NS	0.1874922 P > 0.05, NS	P > 0.05, NS 0.0921321	P < 0.05, S 0.00312312	P > 0.05, NS 0.49102131

GRAPH: 6. COMPARISON OF SYSTOLIC BP AMONG A & B GROUPS

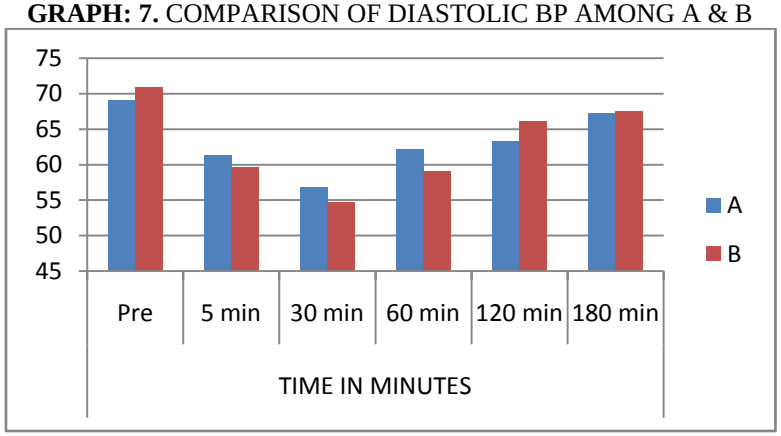


TAB: 7. COMPARISON OF DIASTOLIC BP AMONG A & B GROUPS

GROUPS	TIME IN MINUTES					
	Pre	5	30	60	120	180
A	69.04 ± 7.30	61.28 ± 10.58	56.76 ± 9.93	62.08 ± 7.39	63.22 ± 9.65	67.14 ± 4.45

B	70.9 ± 6.85	59.58 ± 12.85	54.62 ± 9.66	59.06 ± 10.05	66.06 ± 6.87	67.52 ± 5.82
AB	0.23668858 P > 0.05,NS	0.49998323 P > 0.05, NS	0.30048725 P > 0.05, NS	0.097410069 P > 0.05, NS	0.084255531 P > 0.05, NS	0.73652357 P > 0.05, NS

GRAPH: 7. COMPARISON OF DIASTOLIC BP AMONG A & B



TAB. 8: MEAN ARTERIAL PRESSURE

GROUP	TIME IN MINUTES					
	Pre	5	30	60	120	180
A	84.28 ± 6.1777	75.58 ± 10.4022	70.72 ± 9.6975	77.62 ± 6.639	80.24 ± 4.6315	82.7 ± 3.5927
B	85.38 ± 6.3563	72.48 ± 13.2268	69 ± 8.1290	74.62 ± 8.065	80.34 ± 5.4720	82.26 ± 4.5750
P value	0.6109353 No significant	0.29742422 No Significant	0.58097787 No Significant	0.0150789 Significant	0.45724484 No Significant	0.071011778 No significant

GRAPH: 8. MEAN ARTERIAL PRESSURE

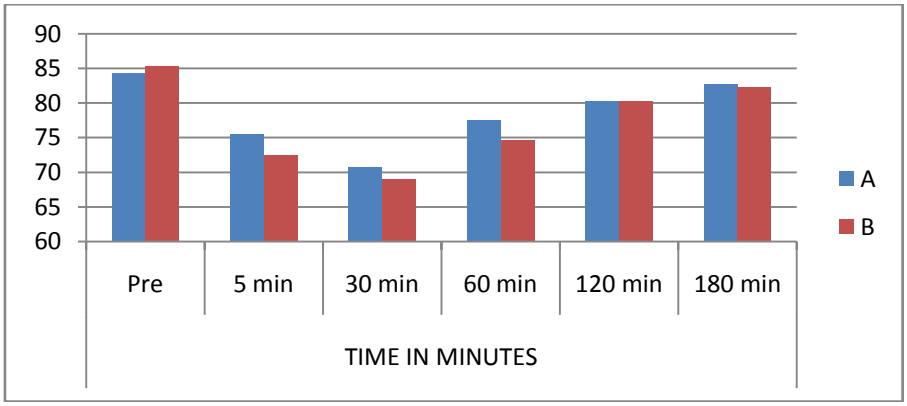


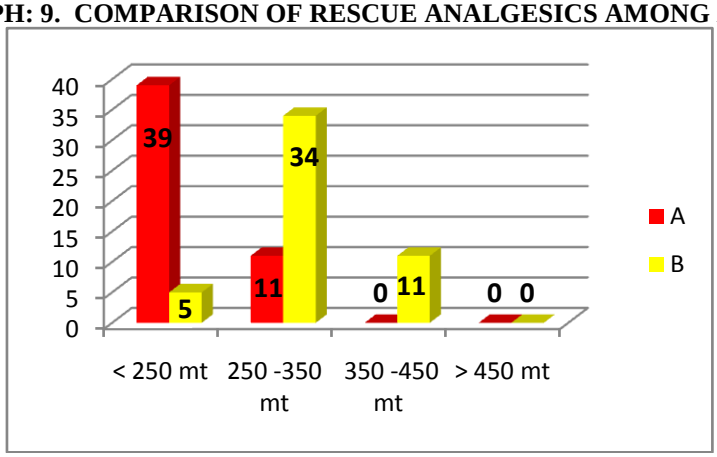
TABLE 9: RESCUE ANALGESICS AMONG A & B

Group	Time of rescue analgesia given in minutes			
	< 250	250 -350	350 -450	> 450
A	39	11	0	0
B	5	34	11	0
A	B	0.00000000	significant	

The mean time for the Rescue analgesics was less than 250 min for 39 patients in Group A whereas 250 – 350 minutes for 34 patients in Group B. The duration of analgesia was longer for patients in Group B compared to Group A which was statistically significant.

The number of patients requiring rescue analgesia, who received Inj. Diclofenac intra muscularly, was 78% n group A, 10% group B required analgesia within first 250 minutes. However 68% of patients in group B required analgesia between 250 – 350 minutes. When compared between groups A & B the values were statistically significant.

GRAPH: 9. COMPARISON OF RESCUE ANALGESICS AMONG A & B

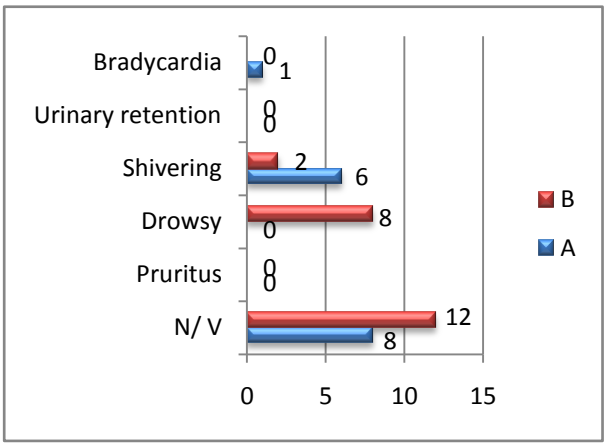


SIDE EFFECTS:

The incidence of nausea and vomiting is 16% n group A and 24% of group B. The incidence of drowsiness in group B is 16%.

Shivering was seen in 6% of patients in group A and 2% in group B. Bradycardia was seen in 2% of group A. no patient had an episode of urinary retention. When all the side effects were compared in groups A and B found to be statistically not significant.

SIDE EFFECTS	A	B
N/ V	8	12
Pruritus	0	0
Drowsy	0	8
Shivering	6	2
Urinary retention	0	0
Bradycardia	1	0
A B	0.1469727009 -	No significant



TAB: 10. COMPARISON OF THE SIDE EFFECTS GRAPH: 10. COMPARISON OF SIDE EFFECTS

IV. Discussion:

Clonidine an alpha $_2$ agonist had been used in the clinical practice. Several investigations suggest that the spinal action of Clonidine produces analgesia in humans. It is understood that Clonidine is more potent after neuraxial administration rather than systemic administration indicating spinal site of action and favoring neuraxial administration. Clonidine produces analgesia by its action on the alpha $_2$ adrenoreceptors by its cholinergic activation.

HEMODYNAMIC PARAMETERS

The present study showed a minimal changes in heart rate and blood pressure in the two groups from pre induction levels to 30 min , 60min and 120min and was statistically significant. The hemodynamic changes noted were within the physiological limits. The patients in both groups needed no vasopressors.

Hemodynamic effects of Clonidine after neuraxial or systemic administration begin within 30 min, reach maximum within 1-2 h, and last approximately 6-8 h after a single injection. Delayed onset of hypotension has not been observed with use of Clonidine for analgesia alone or in combination

No difference was noted in the incidence of intraoperative hypotension between patients who received Clonidine and those who did not. This suggests that the vasodilatation produced by spinal anaesthetic out weighted the effect of Clonidine which did not seem to have additional hypotensive effect when combined with spinal anaesthesia initially.

SIDE EFFECTS

The incidence of side effects are predominantly nausea and vomiting slightly increased in group B. The incidence is 16% in group A and 24% in group B.
Shivering was seen in 6% in group A and 1% in group B patients. No patient had urinary retention.
It has been suggested that nausea after intraspinal Clonidine may represent an accumulating effect of acetylcholine at the chemoreceptor trigger zone.
Most of our patients had very low incidence of nausea and vomiting because of low dose of intrathecal Clonidine was used. All patients had received preoperatively intravenous dose of Ondansetron to prevent nausea and vomiting but the incidence of nausea and vomiting could not be prevented in spite of it being given preoperatively.
Most of our patients did not need any antiemetic drugs or anti pruritic drugs as most of the symptoms are mild to necessitate treatment.

PAIN SCORE AND RESCUE ANALGESIA
In the present study 84% in group A had VAS between 2 to 3 within 2hours of spinal block. After 3 hours 44% in group B complained of mild pain VAS 4 to 6.
After 4hours 52% in group B had a VAS score between 4 to6.
All patients received Injection Diclofenac sodium 75 mg intramuscularly.
The number of patients requiring rescue analgesia, who received Inj. Diclofenac intra muscularly, was 78% in group A and 10% in group B required analgesia within first 250 minutes.
All patients who received Clonidine intrathecally had low Pain scores, long pain free intervals and majority of patients received Rescue analgesia after 350minutes after spinal anaesthesia
Intraoperatively quality of analgesia was excellent in Study group, visceral or traction pain, pain during exteriorization of uterus was obtunded.
SUMMARY
There is constant search for a method to produce or prolonged post operative analgesia and various pharmacological agents like opioids, α_2 agonists have been combined with the basic local anaesthetic drug to achieve this.
In our study
The duration of onset of sensory blockade is faster and much higher at T4 by 5 minutes in 12% patients in group B, whereas most patients had a blockade at T6.
The sensory block regressed less rapidly in group B. The maximum regression is seen at interval time of 100 to 150 minutes, 92% in group A and 70% in group B showed regression.
The recovery from motor block was observed at 180 minutes in 96% in group A and 52% in group B had complete motor block. Only 2% of patients had residual motor block in group B.
The mean Heart rate is lower in patients who received intrathecal Clonidine compared group A.
The Mean Arterial Pressure showed very little changes between pre inductive values and values at different time intervals in different groups. The values at 60 minutes were found to be statistically significant but not clinically significant
Patients in group B have prolonged analgesia than plain Bupivacaine. The time required for rescue analgesia is also more.
The side effects were minimal in both and there is no difference between them statistically.
In our study addition of Clonidine to Bupivacaine for spinal anaesthesia hastens the onset of both sensory and motor blockade and slight prolongation of duration of motor and sensory blockade. It also improved postoperative analgesia.

V. Conclusion

Intrathecal Clonidine prolongs the regression of the sensory block.
Clonidine prolongs the time to the first request of an analgesic. Clonidine decreases the risk of intraoperative pain and Intrathecal Clonidine increases the risk of arterial hypotension.
Intrathecal Clonidine had prolonged period of analgesia compared to plain Bupivacaine.
Clonidine has no relevant impact on the time to achieve complete sensory or motor block, on the extent of the cephalad spread of the sensory block.
There was only nausea, minimal sedation and respiratory depression was not seen in the intrathecal doses used in our study.
Intrathecal Clonidine used in our study is safe to use and have no side effects on the mother or on the fetus.

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