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Original Research Paper

Anaesthesiology

OBSERVATIONAL STUDY BETWEEN HYPERBARIC BUPIVACAINE 0.5% VS HYPERBARIC BUPIVACAINE 0.5% WITH CLONIDINE 30MCG IN SPINAL ANESTHESIA FOR INFRA UMBILICAL SURGERIES AND LOWER LIMB SURGERIES.

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ABSTRACT

Background : The addition of adjuvants like clonidine to hyperbaric bupivacaine 0.5%, a commonly used local anesthetic, can enhance analgesic effects & prolongs duration of the anesthesia.The study aims to compare the efficacy of hyperbaric bupivacaine 0.5% alone vs bupivacaine with clonidine (30 mcg) in spinal anesthesia for infra umbilical and lower limb Surgeries. **Methodology:** Following institutional ethical approval, a prospective observational study was conducted on 46 patients aged 18 to 60, with ASA grades 1 and 2. Patients were assigned into two groups of 23 each: Group A: 12.5 mg of 0.5% hyperbaric bupivacaine with 30 mcg of Clonidine & Group B: 12.5 mg of 0.5% hyperbaric bupivacaine. Pain was assessed using visual analog scale (VAS) & motor blockade was evaluated using Bromage scale.Vital parameters were monitored & patients were observed for any complications. **Results:** Demographic parameters and baseline vitals were comparable between the groups. VAS scores were significantly lower in Group A .The mean VAS score was 3.17 in group A and 4.65 in group B patients. Bromage scale was higher in Group A. Bromage full was 211.30 in group A and 153.91 in group B patients. (fig.1) **Conclusion:** Adding Clonidine as an adjuvant to hyperbaric bupivacaine 0.5% in spinal anesthesia, increases the quality of anesthetic and postoperative analgesia for surgeries involving infra-umbilical region and lower limbs.

KEYWORDS : Hyperbaric Bupivacaine, Clonidine, Spinal anesthesia

INTRODUCTION:

- Spinal anesthesia is a widely utilized technique for infra-umbilical and lower limb surgeries due to its effectiveness in achieving both sensory and motor blockade.
- Hyperbaric bupivacaine 0.5% is commonly employed as the local anesthetic agent of choice.
- The use of adjuvants such as clonidine, an alpha-2 adrenergic agonist, has been shown to enhance analgesic efficacy and prolong the duration of anesthesia.
- This study aims to evaluate and compare the effects of hyperbaric bupivacaine 0.5% alone versus in combination with clonidine (30 mcg) in the context of spinal anesthesia.

The combination of hyperbaric bupivacaine with a adjuvant like clonidine intrathecally provides:

- Prolonged duration of sensory block.
- Extended motor blockade – It increases the duration of motor block, which is beneficial for longer surgical procedures.
- Improved postoperative analgesia – Reducing the need for additional analgesics.
- Reduced anesthetic requirement – decrease the required dose of bupivacaine, potentially lowering the risk of dose-related side effects.
- Stable intraoperative hemodynamics.

Objectives:

- To observe the effect of addition of clonidine to local anaesthetic in relation to local anaesthetic given as a sole agent for infraumbilical and lower limb surgeries.

Primary Objective:

- To observe the efficacy of clonidine in onset and duration of sensory blockade & onset and duration of motor blockade.

Secondary Objective:

- To observe intra-operative and post-operative analgesic efficacy of clonidine as an adjuvant.

Methodology:

- **Study Design:** A prospective observational study
- **Study Period:** March 2023 to March 2025
- **Study Setting:** Patients undergoing infra-umbilical and lower limb surgeries at Kanachur Institute of Medical Sciences, Mangalore
- **Ethical Consideration:** The study was conducted in accordance with the Institutional guidelines and Ethical committee clearance was obtained before the study

INCLUSION CRITERIA	EXCLUSION CRITERIA
• Patients of either gender undergoing infra-umbilical surgeries including antenatal cases and lower limb surgeries. • Adult patients aged between 18 to 60 years • American Society of Anaesthesiologist Physical status I-II.	• Lack of patient consent • Age < 18 years • Local infection at the site of puncture • Patient having any neurological deficit in lower limbs • Patients having history of haematological disorders • Patients with severe anaemia • Patients having a known allergy to study drug or additions • Neuromuscular disorders • American Society of Anaesthesiologist Physical status III, IV

- **Sample Size:** 46
- $n = \frac{2(Z\alpha + Z\beta)^{2\sigma 2}}{d^2}$

Zα: 1.96 at the 95% confidence level
Zb: 0.84 at 80% statistical power
σ: pooled standard deviation = 1.92
d: acceptable margin of error = 1.6
Z = 23 in each group
Estimate Sample Size = 23 in each group
Total Sample Size = 46

Study Methodology:

Following institutional ethical approval, a prospective observational study was conducted on 46 patients aged 18 to 60, with ASA grades 1 and 2. Patients were assigned into two groups of 23 each: Group A: 12.5 mg of 0.5% hyperbaric bupivacaine with 30 mcg of Clonidine & Group B: 12.5 mg of 0.5% hyperbaric bupivacaine. Pain was assessed using visual analog scale (VAS) & motor blockade was evaluated using Bromage scale.Vital parameters were monitored & patients were observed for any complications.

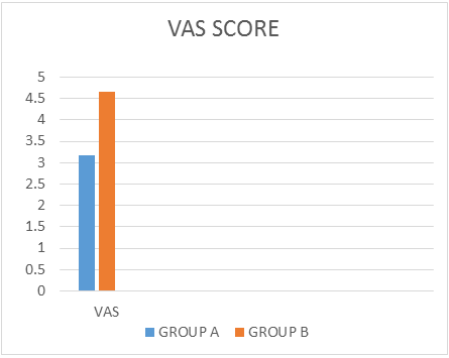
Assessment Tools:

- Visual analog scale (VAS) was used to assess pain that ranges from 0 to 10, where 0 indicates no discomfort and 10 indicates severe pain.
- Motor blockade was assessed with bromage scale:

0- Able to completely flex the hip
1- Able to flex knee, but no hip flexion
2- Plantar flexion at ankle but no knee flexion
3- Complete lack of lower-limb mobility

RESULTS

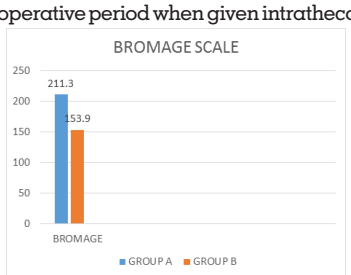
- The VAS score was comparatively lower in Group A than Group B.
- The mean VAS score was 3.17 ± 1.40 in group A and 4.65 ± 1.43 in group B patients.
- (P = 0.004 and the value is statistically significant)
- This signifies that the patients who received clonidine along with bupivicaine experienced lesser pain post operatively when compared to patients who received bupivacaine alone.



- The motor blockade was assessed using Bromage scale. In the current study the results showed significantly higher level of motor blockade in Group A compared to Group B

Categories	Group A				Group B				Mann-Whitney U	P Value
	Mean	Median	SD	IQR	Mean	Median	SD	IQR		
VAS SCORE	3.17	3.00	1.403	2,3	4.65	5.00	1.434	4,5.5	135.5	0.004
BROMAGE FULL	211.30	210.00	14.240	210,220	153.91	150.00	4.990	150,160	16.00	<.001

- The mean of Bromage scale was 211.30 ± 14.24 in group A and 153.91 ± 4.99 in group B patients.
- (P= <0.001 and the value is statistically significant)
- These results indicate that Clonidine may enhance the motor blocking effects of Bupivacaine during intra operative and postoperative period when given intrathecally.



CONCLUSION:

- The addition of 30 mcg intrathecal clonidine to hyperbaric bupivacaine 0.5% significantly prolonged both sensory and motor block durations compared to bupivacaine alone.
- Postoperative analgesia was notably enhanced in the clonidine group, resulting in reduced need for supplemental analgesics.
- Hemodynamic parameters remained within acceptable clinical limits in both groups, with no significant increase in adverse effects observed with clonidine.
- The quality of spinal anesthesia was improved with the use of clonidine as an adjuvant, without compromising patient safety.
- Intrathecal clonidine at a dose of 30 mcg is a safe and effective adjuvant to hyperbaric bupivacaine 0.5%, offering superior analgesic and anesthetic outcomes in infra-umbilical and lower limb surgical procedures.

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