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The Efficacy of Intrathecal Clonidine as an Adjuvant to 0.5% Bupivacaine for Prolonging Analgesia in Lower Abdominal Surgeries: A Comparative Study

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Abstract

Background
Regional anesthesia is preferred for lower abdominal surgeries due to its ability to keep patients awake and reduce airway management issues. While 0.5% hyperbaric bupivacaine is commonly used, it does not ensure prolonged postoperative analgesia. Clonidine, an α2 adrenergic agonist, has shown promise in prolonging sensory and motor blockade when used as an adjuvant. This study evaluates the efficacy of intrathecal clonidine as an adjuvant to 0.5% bupivacaine in prolonging analgesia for lower abdominal surgeries.

Methods
This prospective, randomized controlled study was conducted at MGM Medical College, Navi Mumbai, from November 2021 to September 2023. Sixty patients undergoing elective lower abdominal surgeries were randomly allocated into two groups of 30 each. Group 1 received 3 ml of 0.5% heavy bupivacaine with 30 µg clonidine, while Group 2 received 3 ml of 0.5% heavy bupivacaine with 0.2 ml saline. Onset and duration of sensory and motor blockade, duration of analgesia, hemodynamic parameters, and complications were recorded and analyzed statistically.

Results
Group 1 showed a significantly quicker onset of analgesia (2.25±0.18 minutes) and motor blockade (8.51±0.175 minutes) compared to Group 2. The duration of motor blockade (220±9.55 minutes) and analgesia (650±9.22 minutes) was significantly longer in Group 1. Hemodynamic parameters remained stable in both groups, but Group 1 experienced a higher incidence of mild postoperative complications such as nausea, sedation, and dry mouth.

Conclusion
Intrathecal clonidine as an adjuvant to 0.5% bupivacaine significantly prolongs the duration of sensory and motor blockade, as well as postoperative analgesia, making it a valuable addition to regional anesthesia protocols for lower abdominal surgeries. Future studies with larger, multicenter designs and extended follow-up periods are recommended to further validate these findings.

Keywords
Intrathecal clonidine, Bupivacaine, Postoperative analgesia, Lower abdominal surgery

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Introduction

Regional anaesthesia is preferred for lower abdominal and limb surgeries as it allows the patient to remain awake and reduces airway management issues. Spinal anaesthesia, widely used in such surgeries, has a simpler procedure and faster onset compared to epidural anaesthesia. Initially developed in the 19th century, spinal anaesthesia uses small doses of local anaesthetics, minimizing drug toxicity and reducing post-dural puncture headaches due to modern needle designs[1.]

Lignocaine, known for its rapid onset and motor block, was the initial choice for spinal anaesthesia but its short duration and association with transient neurologic symptoms and cauda equina syndrome limited its use[2,3.] Bupivacaine, being more potent and longer-lasting, is now commonly used despite its slower onset and reduced motor block[4.] While hyperbaric bupivacaine 0.5% provides a longer duration of action, it does not ensure prolonged postoperative analgesia, necessitating the use of adjuvants.

The discovery of opioid receptors by Yaksh and Rudy revolutionized pain management, leading to the use of spinal opiates like morphine for enhanced neuraxial blocks[5,6.] However, opioids can cause serious side effects, including respiratory depression, nausea, vomiting, pruritus, urinary retention, and herpes labialis activation[7-9.]

Clonidine, an α2 adrenergic agonist, potentiates local anaesthetics, prolonging sensory and motor blockade, and reducing the required anaesthetic concentration[10.] It has been effective in prolonging spinal anaesthesia with lidocaine, tetracaine, and bupivacaine[11-13.] Intrathecal clonidine in large doses provides sedation and postoperative analgesia but is inadequate alone for surgical anaesthesia, making it a suitable adjuvant[14,15.] Clonidine, recently introduced in India in parenteral form, needs further evaluation as an adjuvant to intrathecal bupivacaine for postoperative analgesia.

This study aims to evaluate the effects of intrathecal clonidine as an adjuvant to 0.5% bupivacaine (heavy) in lower abdominal surgeries, focusing on the onset and duration of sensory and motor blockade, duration of analgesia, hemodynamic parameters, and any complications.

Material and Methods

This clinical study was conducted at MGM Medical College, Navi Mumbai, from November 2021 to September 2023. After obtaining ethical committee approval, the study compared the efficacy of clonidine as an adjuvant to 0.5% bupivacaine (heavy) for subarachnoid block in lower abdominal surgeries. This prospective, randomized control study included 60 patients undergoing elective lower abdominal surgeries.

Inclusion criteria were patients aged 20-50 years, ASA grade I and II. Exclusion criteria included neurological disorders, allergy to the study drug, coagulation disorders, local infections at the injection site, and spine deformities.

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After clinical examination and laboratory investigations, informed written consent was obtained from all patients. Patients were kept nil by mouth from midnight before surgery and received tablet alprazolam (0.01 mg/kg) at bedtime.

On the day of surgery, patients were re-examined, assessed, and weighed. Intravenous access was established with an 18G needle, and preloading was done with 15 ml/kg Lactated Ringer's solution 30 minutes before the procedure. Monitoring equipment like pulse oximeter, non-invasive blood pressure (NIBP), and electrocardiogram (ECG) were checked and applied upon arrival in the operating room to record baseline parameters.

Patients were randomly allocated into two groups of 30 each:

- Group 1 (Clonidine): 0.5% heavy bupivacaine 3 ml with clonidine (30 µg) 0.2 ml.
- Group 2 (Control): 0.5% heavy bupivacaine 3 ml with 0.9% saline 0.2 ml.

Under aseptic conditions, a lumbar puncture was performed at the L3-L4 intervertebral space. After confirming free flow of CSF, the respective solutions were administered intrathecally, and patients were positioned supine. Hemodynamic parameters such as pulse rate, systolic and diastolic blood pressure, mean arterial pressure, and SpO2 were recorded.

Onset of analgesia was assessed by loss of sensation to pin prick every 30 seconds until the T10 dermatome level was achieved. The highest level of analgesia was noted after 10 minutes. Motor blockade intensity was assessed using the modified Bromage scale every 2 minutes for the first 10 minutes. Sensory blockade duration was assessed by two-segment regression. Analgesia duration was measured from the onset of the subarachnoid block to the time of rescue analgesia administration. Hemodynamic parameters were recorded at specific intervals, and ECG, SpO2, and sedation were continuously monitored. Side effects like nausea, sedation, dry mouth, and bradycardia were recorded.

The modified Bromage scale and visual analog score (VAS) were used to measure motor blockade and pain, respectively. Sedation was assessed using a defined sedation score. Data were collected, tabulated, and analyzed statistically, with $P < 0.05$ considered significant. Randomization ensured each population member had an equal chance of being chosen, producing similar groups pre-experiment. Statistical measures included mean, standard deviation (SD), and student's unpaired t-test for comparing two independent populations.

Results

The results of the study are as follows

The study compares the demographic profiles of two groups, each consisting of 30 patients, focusing on age, height, weight, and gender distribution. Group 1 has a mean age of 40.1±7.81 years, while Group 2 has a mean age of 39.60±7.95 years, with no significant difference between the groups ($p>0.05$). Both groups have similar height distributions, with Group 1 having a mean height of 159.2±3.16 cm and Group 2 at 159.5±3.01 cm ($p>0.05$). Weight distribution is also comparable, with Group 1 averaging 56.6±8.98 kg and Group 2 at 57.27±8.94 kg ($p>0.05$). Gender distribution shows a higher proportion of males in both groups, with Group 1 having 83.33% males and 16.67% females, while Group 2 has 86.67% males and 13.33% females. Overall, the demographic characteristics between the two groups are statistically similar, indicating a well-matched sample for further comparative analysis.

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Table 1: Comparison of Analgesia and Motor Blockade Onset and Duration Between Study Groups

	Group 1 (n=30)	Group 2 (n=30)	p-value
COMPARISON OF TIME OF ONSET OF ANALGESIA	2.25±0.18	2.5±0.19	P<0.05
COMPARISON OF TIME OF ONSET OF MOTOR BLOCKADE	8.51±0.175	9.32±0.14	P<0.05
COMPARISON OF DURATION OF MOTOR BLOCKADE	220±9.55	155.2±6.22	P<0.05
COMPARISON OF DURATION OF ANALGESIA	650±9.22	230.2±26.05	P<0.05

This table illustrates the comparison between two groups regarding the time of onset and duration of analgesia and motor blockade. Group 1 (n=30) showed a significantly quicker onset of analgesia (2.25±0.18 minutes) compared to Group 2 (2.5±0.19 minutes), with a p-value of less than 0.05. Similarly, the onset of motor blockade was faster in Group 1 (8.51±0.175 minutes) compared to Group 2 (9.32±0.14 minutes), also with a p-value of less than 0.05. The duration of motor blockade was significantly longer in Group 1 (220±9.55 minutes) compared to Group 2 (155.2±6.22 minutes), and the duration of analgesia was substantially prolonged in Group 1 (650±9.22 minutes) as opposed to Group 2 (230.2±26.05 minutes), both differences being statistically significant (p<0.05).

Table 2:Comparison of Maximum Height of Sensory Blockade Between Study Groups

Maximum height of sensory blockade (segments)	Group 1 (n=30)	Group 2 (n=30)
T4	2	1
T6	12	13
T8	13	14
T10	3	2

This table compares the maximum height of sensory blockade achieved in two groups of patients. In Group 1 (n=30), the distribution of sensory blockade heights is as follows: 2 patients reached T4, 12 patients reached T6, 13 patients reached T8, and 3 patients reached T10. In Group 2 (n=30), the distribution is slightly different: 1 patient reached T4, 13 patients reached T6, 14 patients reached T8, and 2 patients reached T10. Overall, both groups show a similar pattern in the maximum height of sensory blockade achieved during the study.

Table 3: Comparison of Time of Two Segment Regression Between Study Groups

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	Group 1 (n=30)	Group 2 (n=30)	p-value
COMPARISON OF TIME OF TWO SEGMENT REGRESSION	210.50±6.86	125±5.08	P<0.05

This table presents a comparison of the time for two segment regression between two study groups. Group 1 (n=30) had a mean regression time of 210.50±6.86 minutes, while Group 2 (n=30) had a mean regression time of 125±5.08 minutes. The difference in regression times between the two groups is statistically significant, with a p-value of less than 0.05, indicating that Group 1 experienced a significantly longer duration for two segment regression compared to Group 2.

Table 4: Comparison of Post Operative Complications Between Study Groups

POST OPERATIVE COMPLICATIONS	Group 1 (n=30)	Group 2 (n=30)
Nausea	4(13.33%)	2(6.66%)
Sedation	2(6.66%)	0(0%)
Dry mouth	3(9.99%)	1(3.33%)

This table compares the incidence of post-operative complications between two groups of patients. In Group 1 (n=30), the complications observed were as follows: 4 patients (13.33%) experienced nausea, 2 patients (6.66%) experienced sedation, and 3 patients (9.99%) reported dry mouth. In Group 2 (n=30), the incidence of complications was lower: 2 patients (6.66%) experienced nausea, no patients reported sedation, and 1 patient (3.33%) experienced dry mouth. Overall, Group 1 had a higher occurrence of post-operative complications compared to Group 2.

Discussion

Our study demonstrated that intrathecal clonidine, when used as an adjuvant to 0.5% bupivacaine, significantly enhances the duration of sensory and motor blockade, as well as postoperative analgesia, in patients undergoing lower abdominal surgeries. Specifically, the duration of analgesia in the clonidine group was 650±9.22 minutes, significantly longer than the 230.2±26.05 minutes observed in the control group.

Comparing these results with similar studies, Bafna et al[16]. (2020) reported that the duration of analgesia in their clonidine group was 354.50±38.48 minutes, which is considerably shorter than our findings . This discrepancy may be due to differences in patient demographics or surgical procedures. Similarly, Khandelwal et al[17]. (2017) found that the duration of analgesia in their clonidine group was 330.7±47.7 minutes, again shorter than in our study, but still significantly longer than their control group . These variations highlight the robust efficacy of clonidine in our specific patient cohort and surgical context.

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Further supporting our findings, Srinivasagam et al[18]. (2016) observed that the duration of sensory and motor blockades in their clonidine group was prolonged significantly compared to other adjuvants like buprenorphine and fentanyl . Specifically, they reported a duration of analgesia of approximately 540 minutes for clonidine, which, while shorter than our 650 minutes, still underscores clonidine's superior analgesic properties.

Routray et al[19]. (2017) found that clonidine extended the duration of postoperative analgesia to 510.84±24.10 minutes, compared to 434.95±19.16 minutes for fentanyl, further validating our results. Our study's longer duration of analgesia could be attributed to the specific concentration and administration techniques employed.

In terms of hemodynamic stability, Bajwa et al[20]. (2017) reported that clonidine provided prolonged postoperative analgesia with manageable hemodynamic changes and higher sedation scores compared to fentanyl . Our study noted similar hemodynamic stability, with clonidine patients experiencing minimal blood pressure and heart rate variations, aligning well with these findings and confirming clonidine's safety profile.

Conclusion

In conclusion, our study has demonstrated that intrathecal clonidine, when used as an adjuvant to 0.5% bupivacaine, significantly prolongs the duration of sensory and motor blockade, as well as postoperative analgesia, in patients undergoing lower abdominal surgeries. The duration of analgesia in the clonidine group was substantially longer than in the control group, indicating clonidine's superior efficacy in enhancing postoperative pain management. These findings are consistent with previous research, affirming clonidine's role as an effective adjuvant in spinal anesthesia.

Based on our findings, we recommend considering clonidine as a routine adjuvant to intrathecal bupivacaine for lower abdominal surgeries to achieve prolonged analgesia and improved patient comfort postoperatively. This recommendation is supported by the significant prolongation of analgesia and minimal hemodynamic changes observed in our study, which align with similar studies in the literature.

However, this study has some limitations. Firstly, the sample size was relatively small, and a larger cohort could provide more robust data. Secondly, the study was conducted at a single center, which may limit the generalizability of the results to other settings and populations. Lastly, the follow-up period was limited to the immediate postoperative phase, and longer-term outcomes were not assessed. Future studies with larger, multicenter designs and extended follow-up periods are recommended to confirm and expand upon these findings.

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