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COMPARATIVE EVALUATION OF INTRATHECAL NALBUPHINE AND CLONIDINE AS ADJUVANTS TO HYPERBARIC BUPIVACAINE IN LOWER ABDOMINAL SURGERIES

Dr. Susantika Kundu* Postgraduate, Department of Anaesthesiology and Critical Care, Sri Siddhartha Medical College and Research Institute, Tumakuru, Karnataka, India*Corresponding Author

Dr. S. B. Gangadhar Professor and Head, Department of Anaesthesiology and Critical Care, Sri Siddhartha Medical College and Research Institute, Tumakuru, Karnataka, India.

ABSTRACT **Background:**Spinal anaesthesia using hyperbaric bupivacaine is widely preferred for lower abdominal surgical procedures because of its rapid onset, dependable neural blockade, and excellent safety profile. The incorporation of intrathecal adjuvants has become a common strategy to improve block quality, prolong postoperative analgesia, and reduce analgesic requirements. Nalbuphine, a mixed κ-opioid receptor agonist and μ-opioid receptor antagonist, and clonidine, a selective α_2-adrenergic receptor agonist, have both demonstrated beneficial effects when administered intrathecally. However, direct comparisons between these two agents remain relatively limited.**Methods:**This prospective, randomized, double-blind clinical study included 60 patients belonging to ASA physical status I–III, aged 18–60 years, who were scheduled for elective lower abdominal surgeries under spinal anaesthesia. Participants were randomly allocated into two equal groups. Group N received intrathecal nalbuphine (1.6 mg) combined with 3 mL of 0.5% hyperbaric bupivacaine, whereas Group C received intrathecal clonidine (30 μg) with an identical dose of hyperbaric bupivacaine. The onset and duration of sensory and motor blockade, time to first rescue analgesia, haemodynamic variables, postoperative pain scores using the Visual Analogue Scale (VAS), and adverse events were evaluated and compared.**Results:**Baseline demographic variables and clinical characteristics were comparable between both groups. The onset of sensory blockade did not differ significantly. However, patients receiving clonidine experienced a significantly prolonged duration of sensory block together with lower postoperative pain scores at 2 and 6 hours. The duration until first rescue analgesia was similar between the groups. Haemodynamic parameters remained stable throughout the study period, and the incidence of adverse effects was comparable.**Conclusion:**Both nalbuphine and clonidine proved to be safe and effective intrathecal adjuvants to hyperbaric bupivacaine. Clonidine produced a longer duration of sensory blockade and superior postoperative analgesia, making it more suitable for procedures requiring prolonged pain relief. Nalbuphine demonstrated favourable haemodynamic stability and may be considered an appropriate alternative for patients in whom cardiovascular stability is of particular importance.

KEYWORDS : Spinal anaesthesia; Hyperbaric bupivacaine; Intrathecal adjuvants; Nalbuphine; Clonidine; Lower abdominal surgery; Sensory block; Motor block; Postoperative analgesia; Haemodynamic stability.

INTRODUCTION

Spinal anaesthesia is one of the most frequently performed regional anaesthetic techniques for lower abdominal, pelvic, perineal, and lower limb surgeries because of its rapid onset, reliable sensory and motor blockade, ease of administration, and favourable safety profile. Compared with general anaesthesia, spinal anaesthesia offers excellent intraoperative analgesia, attenuates the surgical stress response, facilitates early postoperative recovery, and is associated with a lower incidence of postoperative nausea and vomiting.[1] However, the relatively short duration of action of hyperbaric bupivacaine often limits postoperative analgesia, necessitating the early administration of rescue analgesics.[2]

To overcome these limitations, several intrathecal adjuvants have been investigated to improve the quality of spinal anaesthesia and prolong postoperative pain relief. An ideal intrathecal adjuvant should enhance sensory blockade, prolong analgesia, reduce postoperative opioid consumption, maintain haemodynamic stability, and produce minimal adverse effects. Numerous agents, including opioids, α_2-adrenergic agonists, corticosteroids, and other adjuncts, have been evaluated with varying degrees of success.[2]

Nalbuphine is a synthetic opioid that functions as a κ-opioid receptor agonist and a μ-opioid receptor antagonist. Owing to its unique pharmacological profile, it provides effective spinal analgesia while reducing the incidence of adverse effects commonly associated with pure μ-opioid agonists, such as respiratory depression, pruritus, urinary retention, and excessive sedation.[3] Previous clinical studies have demonstrated that intrathecal nalbuphine prolongs sensory blockade, improves postoperative analgesia, and maintains satisfactory haemodynamic stability without significantly increasing complications.[4]

Clonidine is a selective α_2-adrenergic receptor agonist that exerts its analgesic effect by inhibiting nociceptive transmission at the dorsal horn of the spinal cord. It enhances the action of local anaesthetics through both presynaptic and postsynaptic mechanisms, thereby prolonging sensory and motor blockade while improving postoperative analgesia.[5] Meta-analyses have shown that low-dose intrathecal clonidine significantly prolongs the duration of spinal anaesthesia and reduces postoperative pain scores, although higher doses may increase the risk of hypotension and bradycardia.[6]

Although both nalbuphine and clonidine have independently demonstrated favourable outcomes as intrathecal adjuvants, direct comparisons between these two agents remain limited. Published studies have reported inconsistent findings regarding block characteristics, duration of analgesia, haemodynamic responses, and adverse-event profiles, possibly because of differences in study design, drug dosage, and patient populations.[7] [8] Furthermore, relatively few studies have specifically evaluated these agents in patients undergoing elective lower abdominal surgery, where effective postoperative analgesia plays a crucial role in enhancing recovery and patient comfort.

The present prospective, randomised, double-blind study was therefore undertaken to compare the efficacy of intrathecal nalbuphine (1.6 mg) and clonidine (30 μg) as adjuvants to 0.5% hyperbaric bupivacaine in patients undergoing elective lower abdominal surgery. The primary objectives were to compare the onset and duration of sensory and motor blockade, along with the time to first rescue analgesia. Secondary objectives included assessment of postoperative pain intensity using the Visual Analogue Scale (VAS), evaluation of haemodynamic parameters, and comparison of adverse-event profiles between the two treatment groups.

The findings of this study are expected to provide valuable evidence regarding the comparative efficacy and safety of these two commonly used intrathecal adjuvants, thereby assisting anaesthesiologists in selecting the most appropriate agent according to the duration of surgery, postoperative analgesic requirements, and individual patient characteristics.

MATERIALS AND METHODS

Study Design

A prospective, randomized, double-blind, controlled clinical study was conducted in the Department of Anaesthesiology and Critical Care, Sri Siddhartha Medical College and Research Institute,

Tumakuru, Karnataka, India, over a period of 18 months.The study protocol received approval from the Institutional Ethics Committee and the investigation was carried out in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was obtained from all participants before enrolment.[1]

Study Population
Sixty adult patients of either sex, aged between 18 and 60 years, belonging to the American Society of Anaesthesiologists (ASA) physical status I–III, and scheduled for elective lower abdominal surgery under spinal anaesthesia were included in the study.

Inclusion Criteria
Patients fulfilling the following criteria were considered eligible for enrolment:
- Age between 18 and 60 years
- Either male or female
- ASA physical status I, II, or III
- Scheduled for elective lower abdominal surgery under spinal anaesthesia
- Willingness to participate in the study with written informed consent

Exclusion Criteria
Patients presenting with any of the following conditions were excluded from the study:
- Refusal to participate
- Body mass index (BMI) >30 kg/m²
- Anatomical deformity of the vertebral column
- Infection at the proposed spinal puncture site
- Coagulation disorders or anticoagulant therapy
- Known hypersensitivity to bupivacaine, nalbuphine, or clonidine
- Pregnancy or lactation
- Significant hepatic, renal, or cardiovascular disease

Sample Size
The sample size was calculated to achieve 95% statistical power for detecting a minimum difference of 15 minutes in the duration of sensory blockade between the study groups, considering a standard deviation of 25 minutes, a significance level (α) of 0.05, and a confidence interval of 95%. Accordingly, 60 patients were enrolled, with 30 participants allocated to each study group.

Randomization and Blinding
Participants were randomly assigned to one of the two study groups using a computer-generated randomization sequence. Allocation concealment was ensured using sequentially numbered opaque sealed envelopes. The study drugs were prepared by an anaesthesiologist who was not involved in patient management or data collection. Both the patients and the investigators responsible for intraoperative observations and postoperative assessments remained blinded to group allocation throughout the study period, thereby ensuring a double-blind study design.

Study Groups
Patients were allocated into two groups:
Group N (n = 30):
- Hyperbaric bupivacaine 0.5% (3 mL) + Nalbuphine 1.6 mg (0.2 mL)

Group C (n = 30):
- Hyperbaric bupivacaine 0.5% (3 mL) + Clonidine 30 µg (0.2 mL)

Anaesthetic Technique
After confirming fasting status and obtaining informed consent, patients were shifted to the operating theatre. Standard ASA monitors, including electrocardiography (ECG), non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), and heart rate monitoring, were applied. Baseline haemodynamic parameters were recorded before administration of spinal anaesthesia.

All patients received intravenous preloading with Ringer's lactate solution (10 mL/kg) before the procedure. Under strict aseptic precautions, lumbar subarachnoid block was performed in the sitting position at the L3–L4 intervertebral space using a 25-G Quincke spinal needle. Following confirmation of free cerebrospinal fluid flow, the allocated study drug was injected intrathecally over approximately 10 seconds, after which the patient was immediately positioned supine.

Supplemental oxygen was administered throughout the procedure whenever required.

Outcome Measures
Primary Outcome Measures
The following parameters were evaluated:
- Time to onset of sensory block (loss of pinprick sensation at the T10 dermatome)
- Time to onset of complete motor block (Modified Bromage Score 3)
- Duration of sensory blockade (regression to S1 dermatome)
- Duration of motor blockade (return to Bromage Score 0)
- Time to first rescue analgesia (VAS score ≥4)

Secondary Outcome Measures
- The secondary outcomes included:
- Heart rate (HR)
- Systolic blood pressure (SBP)
- Diastolic blood pressure (DBP)
- Mean arterial pressure (MAP)
- Visual Analogue Scale (VAS) scores recorded at predefined postoperative intervals
- Incidence of adverse events including:
    - Bradycardia (HR <50 beats/min)
    - Hypotension (SBP <90 mmHg or >20% fall from baseline)
    - Nausea and vomiting

Rescue analgesia was administered in the form of intravenous paracetamol 1 g whenever the VAS score reached 4 or more.

Statistical Analysis
Data were compiled using Microsoft Excel and analysed using Statistical Package for the Social Sciences (SPSS) version 20.0. Continuous variables were expressed as mean ± standard deviation (SD), whereas categorical variables were presented as frequencies and percentages.

Comparison of continuous variables between the two groups was performed using the Independent Student's t-test or the Mann–Whitney U test, depending on data distribution. Categorical variables were analysed using the Chi-square test or Fisher's exact test wherever appropriate. A p-value less than 0.05 was considered statistically significant.

RESULTS
A total of 60 patients were enrolled in the study and completed the protocol without any dropouts. The participants were equally allocated into Group N (Nalbuphine, n = 30) and Group C (Clonidine, n = 30). Baseline demographic characteristics, anthropometric measurements, ASA physical status, and associated comorbidities were comparable between the two groups, indicating successful randomization and homogeneity of the study population.

Demographic Characteristics
The age distribution of patients was similar in both groups, with no statistically significant difference. Likewise, gender distribution, body mass index (BMI), occupational status, and associated comorbidities such as diabetes mellitus and hypertension were comparable, confirming that both groups were well matched before intervention.

Block Characteristics
The mean onset time of sensory blockade was 3.23 ± 0.82 minutes in Group N and 3.82 ± 0.88 minutes in Group C. Although the onset was marginally faster in the nalbuphine group, the difference was not statistically significant (p = 0.56).

Similarly, the onset of complete motor blockade was comparable between the two groups, with no statistically significant difference observed.

The duration of sensory blockade was significantly prolonged in patients receiving intrathecal clonidine. Group C demonstrated a mean sensory block duration of 263.1 ± 43.0 minutes, whereas Group N showed a duration of 248.1 ± 71.4 minutes, and this difference was statistically significant (p = 0.001).

Although the duration of motor blockade was numerically longer in the clonidine group (227 ± 56 minutes) compared with the nalbuphine group (201 ± 61 minutes), the observed difference did not achieve

statistical significance.

Postoperative Analgesia

The mean time to first rescue analgesia was 363.5 ± 69.9 minutes in Group N and 358.3 ± 69.8 minutes in Group C. Statistical analysis revealed no significant difference between the two groups (p = 0.90).

Postoperative pain intensity was evaluated using the Visual Analogue Scale (VAS) at predetermined intervals. During the initial postoperative period (0–30 minutes), pain scores remained comparable between both groups.

However, at 2 hours following spinal anaesthesia, patients in the clonidine group experienced significantly lower pain scores (VAS 1.77 ± 1.57) than those receiving nalbuphine (VAS 5.03 ± 0.81) (p < 0.001).

A similar trend persisted at 6 hours, with Group C recording a mean VAS score of 1.93 ± 1.51, compared with 5.47 ± 1.14 in Group N (p = 0.028). These findings indicate superior postoperative analgesia with intrathecal clonidine during the intermediate postoperative period.

Haemodynamic Parameters

Baseline heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were comparable between the study groups.

Following administration of spinal anaesthesia, haemodynamic parameters remained clinically stable in both groups throughout the intraoperative observation period. No statistically significant differences were observed in systolic blood pressure, diastolic blood pressure, or mean arterial pressure at any measured interval.

Heart rate showed a modest reduction in the nalbuphine group during the early intraoperative period. Significant differences were observed at 2, 10, and 30 minutes, with Group N demonstrating lower heart rates than Group C (p < 0.05). Nevertheless, these changes were clinically insignificant and did not necessitate pharmacological intervention.

Adverse Events

Both study drugs demonstrated favourable safety profiles.

Bradycardia occurred in 9 patients (30%) in Group N and 7 patients (23%) in Group C. Hypotension was observed in 6 patients (20%) receiving nalbuphine and 8 patients (27%) receiving clonidine.

Nausea and vomiting were reported in 5 patients (17%) in Group N and 8 patients (27%) in Group C.

No cases of respiratory depression, pruritus, neurological complications, post-dural puncture headache, or persistent neurological deficits were observed in either group.

The overall incidence of adverse events did not differ significantly between the two groups ($\chi^2 = 1.75$; p = 0.63).

Summary of Major Findings

The present study demonstrated that both intrathecal nalbuphine and clonidine are effective adjuvants to hyperbaric bupivacaine for lower abdominal surgery. While the onset of sensory and motor blockade was comparable, clonidine produced a significantly longer duration of sensory blockade and superior postoperative analgesia. Haemodynamic stability was maintained with both agents, although nalbuphine was associated with a slightly greater reduction in heart rate during the early intraoperative period. Importantly, both adjuvants exhibited similar safety profiles without any serious complications.

Table 1. Baseline Age Distribution of the Study Participants

Age Group	Group N (n = 30)	Group C (n = 30)	Total (N = 60)
20–30	10	9	19
31–40	6	3	9
41–50	7	7	14
51–60	7	11	18
Total	30	30	60

Table 2. Gender Distribution

Gender	Group N (n = 30)	Group C (n = 30)	Total
Male	17	10	27
Female	13	20	33
Total	30	30	60

Table 3. Occupational Distribution

Occupation	Group N	Group C	Total
Engineer	8	13	21
Farmer	5	4	9
Teacher	8	5	13
Unemployed	9	8	17
Total	30	30	60

Table 4. Comparison of Body Mass Index

Variable	Group N	Group C	p-value
BMI (kg/m²), Mean ± SD	23.98 ± 3.43	24.01 ± 3.75	0.299

Table 5. Distribution of Comorbidities

Comorbidity	Group N	Group C	Total
Diabetes Mellitus	10	13	23
Hypertension	10	10	20
No Comorbidity	10	7	17
Total	30	30	60

Table 6. Comparison of Block Characteristics

Parameter	Group N	Group C	p-value
Sensory block onset (min)	3.23 ± 0.82	3.82 ± 0.88	0.56
Motor block onset (min)	4.8 ± 0.7	4.7 ± 0.9	>0.05
Duration of sensory block (min)	248.1 ± 71.4	263.1 ± 43.0	0.001
Duration of motor block (min)	201 ± 61	227 ± 56	>0.05

Table 7. Comparison of Postoperative Analgesia

Parameter	Group N	Group C	p-value
Time to first rescue analgesia (min)	363.5 ± 69.9	358.3 ± 69.8	0.90
VAS Score at 2 hours	5.03 ± 0.81	1.77 ± 1.57	<0.001
VAS Score at 6 hours	5.47 ± 1.14	1.93 ± 1.51	0.028

Table 8. Comparison of Adverse Events

Adverse Event	Group N n (%)	Group C n (%)	p-value
Bradycardia	9 (30%)	7 (23%)	
Hypotension	6 (20%)	8 (27%)	
Nausea/Vomiting	5 (17%)	8 (27%)	
Overall Comparison			0.63

DISCUSSION

The present prospective, randomized, double-blind study compared the efficacy of intrathecal nalbuphine (1.6 mg) and clonidine (30 µg) as adjuvants to 0.5% hyperbaric bupivacaine in patients undergoing elective lower abdominal surgery. Both agents provided effective spinal anaesthesia with satisfactory intraoperative conditions and acceptable safety profiles. However, clonidine demonstrated superior prolongation of sensory blockade and improved postoperative analgesia, whereas nalbuphine exhibited favourable haemodynamic stability with comparable onset characteristics.

The baseline demographic characteristics, including age, sex, body mass index, occupation, ASA physical status, and associated comorbidities, were statistically comparable between the two groups. This ensured homogeneity of the study population and minimised the influence of confounding variables on the observed outcomes.

The onset of sensory and motor blockade was similar in both groups, indicating that the addition of either nalbuphine or clonidine did not significantly influence the time required for establishment of spinal anaesthesia. These findings are consistent with previous investigations, which reported that low-dose intrathecal nalbuphine and clonidine do not significantly alter the onset of sensory or motor blockade when combined with hyperbaric bupivacaine.[9]

One of the principal findings of the present study was the significantly prolonged duration of sensory blockade observed with intrathecal clonidine compared with nalbuphine. The prolonged sensory block produced by clonidine may be attributed to its selective α_2-adrenergic agonistic action, which suppresses nociceptive transmission within the dorsal horn of the spinal cord, enhances potassium channel activation, and potentiates the action of local anaesthetics.[5,10] Although motor blockade was also prolonged in the clonidine group, the difference did not reach statistical significance, suggesting that clonidine preferentially enhances sensory analgesia while preserving acceptable motor recovery.

Postoperative pain assessment using the Visual Analogue Scale (VAS) demonstrated significantly lower pain scores in the clonidine group at both 2 and 6 hours following surgery. These findings indicate superior

postoperative analgesia with clonidine during the intermediate postoperative period. Although the time to first rescue analgesia was comparable between the groups, the lower VAS scores observed with clonidine suggest that patients experienced better quality analgesia before reaching the threshold requiring additional analgesic administration. Similar observations have been reported by Agrawal et al., who demonstrated improved postoperative analgesia and reduced analgesic consumption with intrathecal clonidine compared with nalbuphine.[14]

Haemodynamic stability remains an important consideration when selecting intrathecal adjuvants. In the present study, systolic blood pressure, diastolic blood pressure, and mean arterial pressure remained comparable between the study groups throughout the intraoperative period. Although patients receiving nalbuphine exhibited slightly lower heart rates at selected time intervals, these changes were clinically insignificant and did not require pharmacological intervention. The absence of clinically significant hypotension or severe bradycardia in either group may be attributed to the relatively low dose of clonidine used in the present study. These observations are in agreement with previous reports demonstrating satisfactory haemodynamic stability with low-dose intrathecal clonidine.[6,15]

Both study drugs exhibited favourable safety profiles. The incidence of bradycardia, hypotension, nausea, and vomiting was low and comparable between the groups. Importantly, no patient developed respiratory depression, pruritus, neurological complications, post-dural puncture headache, or persistent neurological deficits. The absence of pruritus is particularly noteworthy and may be explained by the μ-opioid receptor antagonistic property of nalbuphine, which reduces opioid-related adverse effects commonly observed with pure μ-opioid agonists.[3,16]

The strengths of the present study include its prospective randomized double-blind design, uniform anaesthetic technique, standardized drug dosages, and comprehensive evaluation of both efficacy and safety outcomes. The comparable baseline characteristics between the two groups further strengthen the validity of the findings.

However, certain limitations should be acknowledged. The study was conducted at a single tertiary care centre with a relatively modest sample size, which may limit the generalizability of the findings. Only one dose of nalbuphine and clonidine was evaluated; therefore, dose-response relationships could not be established. In addition, long-term postoperative analgesic requirements, patient satisfaction, and functional recovery were not assessed. Future multicentric studies with larger sample sizes, different dose combinations, and extended follow-up may provide more comprehensive evidence regarding the optimal intrathecal adjuvant for spinal anaesthesia.

Overall, the findings of the present study suggest that both nalbuphine and clonidine are effective intrathecal adjuvants to hyperbaric bupivacaine. However, clonidine provides superior prolongation of sensory blockade and improved postoperative analgesia without increasing adverse effects, making it a suitable choice for procedures requiring prolonged analgesia. Nalbuphine, with its favourable haemodynamic profile and satisfactory analgesic efficacy, remains an effective alternative, particularly in patients where cardiovascular stability is of greater concern.

CONCLUSION

The present study demonstrated that both intrathecal nalbuphine (1.6 mg) and clonidine (30 μg) are safe and effective adjuvants to 0.5% hyperbaric bupivacaine for spinal anaesthesia in patients undergoing elective lower abdominal surgery. Both agents provided satisfactory intraoperative anaesthesia with comparable onset of sensory and motor blockade, stable haemodynamic parameters, and a low incidence of adverse effects.

However, intrathecal clonidine produced a significantly longer duration of sensory blockade and superior postoperative analgesia, as evidenced by lower postoperative Visual Analogue Scale (VAS) scores, without increasing the incidence of complications. In contrast, nalbuphine offered comparable block characteristics with favourable haemodynamic stability, making it a suitable alternative in patients where cardiovascular stability is an important consideration.

Based on the findings of this study, clonidine may be considered the preferred intrathecal adjuvant when prolonged postoperative analgesia is desired, whereas nalbuphine remains an effective and safe option for achieving reliable spinal anaesthesia with satisfactory analgesic efficacy.

Further multicentric studies involving larger sample sizes and evaluation of different dose regimens are recommended to establish the optimal intrathecal adjuvant for various surgical procedures and patient populations.

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