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Efficacy and safety of intrathecal clonidine vs fentanyl added to bupivacaine for lower abdominal procedures

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Abstract. Intrathecal adjuvants such as fentanyl and clonidine may enhance the quality and duration of spinal anaesthesia and postoperative analgesia with bupivacaine, but their comparative efficacy and side-effect profiles remain important. The present study aimed to compare the effects of intrathecal fentanyl and clonidine as adjuvants to 0.5% bupivacaine on block characteristics, postoperative analgesia, haemodynamic, sedation, and adverse effects in patients undergoing lower abdominal surgery. This randomised double-blind comparative study was conducted in the Department of Anaesthesiology, Balrampur Hospital, Lucknow, among 96 patients aged 18-60 years, ASA physical status I-II, scheduled for lower abdominal surgeries. Patients were randomly allocated into three groups (n = 32 each): Group B received 2.5 mL of 0.5% bupivacaine with 0.5 mL normal saline, Group F received 2.5 mL of 0.5% bupivacaine with fentanyl 25 ug, and Group C received 2.5 mL of 0.5% bupivacaine with clonidine 30 ug. Outcomes included block onset and duration, rescue analgesia time, VAS score, haemodynamic, sedation, and adverse events. Baseline characteristics were comparable among groups. Group C showed the fastest onset of sensory block (1.45 ± 0.30 min) and the longest duration of sensory block (150.23 ± 28.47 min), followed by Group F and Group B ($p < 0.0001$). A similar pattern was observed for motor block onset and duration ($p < 0.0001$). Time to first rescue analgesia was significantly prolonged in Group C (6.00 ± 1.50 h) compared with Group F (4.50 ± 1.22 h) and Group B (2.80 ± 0.76 h) ($p < 0.0001$). Postoperative VAS scores were significantly lower in Group C. Haemodynamic variables remained largely comparable. Sedation was higher with clonidine, with marked sedation observed only in Group C. Intrathecal clonidine 30 ug with bupivacaine provided better block characteristics and longer postoperative analgesia than fentanyl 25 ug or bupivacaine alone, but with higher sedation

Keywords: spinal anaesthesia; postoperative analgesia; lower abdominal surgery; haemodynamic; sedation

Introduction

Spinal anaesthesia is widely used for lower abdominal surgery because it is simple, effective, economical, and provides reliable sensory and motor blockade with early postoperative recovery. However, intrathecal bupivacaine alone has a limited duration of action, which may not provide adequate postoperative analgesia in all patients. To overcome this limitation, several intrathecal adjuvants have been studied to prolong block duration, improve analgesia, and reduce postoperative analgesic requirements. Among these, fentanyl and clonidine are commonly used because they act through different mechanisms and have distinct efficacy and adverse-effect profiles [1].

N.M. Fonseca *et al.* [1] evaluated the addition of fentanyl and sufentanil to spinal local anaesthetics in a systematic review and meta-analysis and found that these opioids reduced postoperative pain and opioid consumption and prolonged analgesia, although pruritus increased significantly. Their work confirmed the analgesic efficacy of intrathecal fentanyl but also highlighted opioid-related adverse effects as a relevant limitation. R. Jouybar *et al.* [2] studied the effect of intrathecal fentanyl in patients undergoing caesarean section and reported improved quality of spinal anaesthesia and better postoperative pain relief when fentanyl was added to bupivacaine. Although their findings

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support fentanyl as an effective intrathecal adjuvant, the study was limited to obstetric patients and therefore cannot be directly generalised to lower abdominal surgeries in the general adult population.

J. Bhatia & C. Suryawanshi [3] compared intrathecal bupivacaine-fentanyl with bupivacaine-midazolam in lower abdominal and lower limb surgeries and showed that fentanyl improved intraoperative conditions and prolonged analgesia. However, their study compared fentanyl with another adjuvant rather than with clonidine, which remains an important alternative non-opioid intrathecal additive. M.M. Manoharan *et al.* [4] compared intrathecal dexmedetomidine and clonidine as adjuvants to spinal anaesthesia and observed that α2-adrenergic agonists significantly prolonged sensory and motor block as well as postoperative analgesia. Their findings emphasised the usefulness of clonidine-like drugs in neuraxial anaesthesia, but the study did not address whether clonidine is superior or inferior to fentanyl in routine lower abdominal surgery.

S. Dattatri *et al.* [5] assessed different doses of intrathecal clonidine with bupivacaine and found that low-dose clonidine effectively prolonged sensory and motor block while maintaining acceptable haemodynamic stability. This study supported the role of clonidine as an effective spinal adjuvant, but it did not compare clonidine directly with fentanyl, which is commonly used in clinical practice. E.E. Shchegolkov & O.A. Loskutov [6] analysed the principles of pain management and the role of neuraxial and regional anaesthesia in surgical patients and emphasised that regional techniques are valuable for improving perioperative outcomes and reducing complications. Although this review was not limited to intrathecal fentanyl or clonidine, it supports the continuing relevance of optimising neuraxial analgesic strategies. In another Ukrainian study, T. Ovsiienko *et al.* [7] evaluated low-opioid multimodal anaesthesia and demonstrated that opioid-sparing approaches can provide adequate antinociceptive protection with improved perioperative pain control. Their work is important because it underlines the need for alternatives that reduce opioid exposure while preserving effective analgesia.

Thus, existing evidence suggests that intrathecal fentanyl improves spinal block quality and postoperative analgesia, whereas clonidine and other α2-agonists may prolong block duration and analgesia, though often with more sedation. L.H. Sun *et al.* [8] demonstrated the efficacy of intrathecal fentanyl with bupivacaine in caesarean delivery, but their results were limited to obstetric patients. A. Nayak *et al.* [9] also supported the analgesic value of fentanyl in abdominal hysterectomy, although clonidine was not included in the comparison. A. Sabertanha *et al.* [10] and Y. Gu *et al.* [11] reported beneficial effects of intrathecal fentanyl in orthopaedic populations, but these findings cannot be directly extrapolated to lower abdominal surgery. R.B. Joseph *et al.* [12] compared clonidine, fentanyl, and buprenorphine in lower abdominal and lower limb procedures, yet the mixed surgical sample limited procedure-specific conclusions. Therefore, a direct comparison of fentanyl and clonidine with 0.5% bupivacaine in adult patients undergoing lower abdominal surgery remains necessary. Therefore, the present study was undertaken to compare intrathecal fentanyl and clonidine as adjuvants to 0.5% bupivacaine in lower abdominal surgery and to determine which drug provides a better balance between effective block characteristics, prolonged postoperative analgesia, haemodynamic stability, and tolerable side effects.

Materials and Methods

This prospective randomised double-blind comparative study was conducted in the Department of Anaesthesiology, Balrampur Hospital, Golaganj, Lucknow, Uttar Pradesh, India. The study was carried out over a period of 18 months (January 2023 – June 2024). The study protocol was approved by the Institutional Ethics Committee of Balrampur Hospital (Approval No.: 10/IEC-DHR/2023) prior to patient enrolment. Written informed consent was obtained from all participants. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki [13] and complied with international guidelines on ethics and data protection issued by the European Commission [14].

A total of 96 adult patients scheduled for elective lower abdominal surgeries under spinal anaesthesia were included in the study. Patients were aged between 18 and 60 years and belonged to American Society of Anesthesiologists (ASA) [15] physical status I or II. The sample size consisted of 32 patients in each group, which was considered adequate to allow meaningful comparison of block characteristics and analgesic duration between the three treatment groups based on previous similar studies evaluating intrathecal adjuvants. Patients were randomly allocated into three groups using computer-generated randomisation. Allocation concealment was achieved using sealed opaque envelopes. Both the patient and the anaesthesiologist assessing outcomes were blinded to the study drug, while drug preparation was performed by an independent anaesthesiologist not involved in data collection. Patients of either sex, aged 18-60 years, weighing 50-80 kg, and classified as ASA grade I-II undergoing elective lower abdominal surgeries were included in the study. Patients were excluded if they refused consent, had ASA grade III-IV, pregnancy or lactation, hypersensitivity to local anaesthetic drugs or study medications, chronic opioid use, neurological disorders, infection at the puncture site, coagulation abnormalities, or were receiving long-term analgesic therapy.

Standard monitoring including electrocardiography (ECG), non-invasive blood pressure (NIBP), pulse rate, and oxygen saturation (SpO_2) was applied before the procedure. Patients were preloaded with 10-15 mL/kg of Ringer's lactate solution. Spinal anaesthesia was administered in the sitting position at the L3-L4 or L4-L5 intervertebral space using a 25-gauge Quincke spinal needle under strict aseptic precautions. After confirmation of free flow of cerebrospinal fluid, the study drug was injected intrathecally. Patients were divided into three groups:

- Group B (Control group): 2.5 mL of 0.5% hyperbaric bupivacaine + 0.5 mL normal saline;
- Group F: 2.5 mL of 0.5% hyperbaric bupivacaine + fentanyl 25 µg;
- Group C: 2.5 mL of 0.5% hyperbaric bupivacaine + clonidine 30 µg.

The doses of fentanyl (25 µg) and clonidine (30 µg) were selected based on previous clinical studies [16,17] demonstrating effective prolongation of spinal anaesthesia with minimal haemodynamic instability and acceptable side-effect profiles. Sensory block onset was defined as the time from intrathecal drug injection to loss of pinprick sensation at the T10 dermatome level, assessed using a sterile needle. Duration of sensory block was defined as the time from drug administration to regression of sensory level to S1 dermatome. Motor block was evaluated using the Modified Bromage Scale: 0 = full movement of hip, knee and ankle; 1 = inability to raise extended leg; 2 = inability to flex knee; 3 = inability to flex ankle. Motor block onset was defined as the time to achieve Bromage grade 3, while duration was defined as the time until regression to Bromage grade 0.

Pain intensity was assessed using the Visual Analogue Scale (VAS). The time to first rescue analgesia was recorded when VAS ≥ 4. Sedation was evaluated using the Ramsay Sedation Scale. Haemodynamic parameters and adverse effects such as hypotension, bradycardia, nausea, vomiting, and respiratory depression were monitored. Data were analysed using SPSS version 26.0. Continuous variables were expressed as mean ± standard deviation (SD) and compared using one-way ANOVA, while categorical variables were analysed using the Chi-square test. A p-value < 0.05 was considered statistically significant.

Results

A total of 96 patients were enrolled and completed the study, with 32 patients in each of the three groups. No patient was excluded after randomisation, and all participants were included in the final analysis. The results are presented in tabular and graphical form to improve clarity and to facilitate comparison among the groups. The three groups were comparable with respect to age, sex distribution, body mass index (BMI), ASA physical status, and type of surgical procedure. The mean age was 46.12 ± 10.98 years in Group B, 45.23 ± 11.56 years in Group F, and 44.78 ± 12.34 years in Group C, with no statistically significant difference (F = 0.1098, p = 0.8961). Similarly, age-group distribution was comparable across the groups ($\chi^2 = 2.229$, p = 0.9732). The baseline demographic and clinical characteristics of the patients are summarised in Table 1.

Table 1. Clinico-demographics parameters

Parameter	Group-B (n = 32)	Group-F (n = 32)	Group-C (n = 32)	p-value
Age (years) (Mean ± SD)	46.12 ± 10.98	45.23 ± 11.56	44.78 ± 12.34	F = 0.1098, p = 0.8961
Age group (years)				
18-30	5	7	6	
31-40	11	6	8	X = 2.229,
41-50	9	10	8	p = 0.9732
51-60	5	8	6	
61-70	2	1	3	
Gender				
Male	18	16	15	X = 0.2510,
Female	14	16	17	p = 0.8821
BMI (kg/m²) (Mean ± SD)	26.89 ± 3.91	27.34 ± 4.27	28.15 ± 4.05	F = 0.7840, p = 0.4596
ASA Grade				X = 0.6563, p = 0.7203
I	21	23	20	
II	11	9	12	

Note: values are presented as mean ± standard deviation (SD) or number of patients (n), as appropriate. Group comparisons for continuous variables were performed using one-way ANOVA, and categorical variables were analysed using the Chi-square test. A p-value < 0.05 was considered statistically significant

Source: developed by author

Sex distribution was also balanced: Group B had 18 males and 14 females, Group F had 16 males and 16 females, and Group C had 17 males and 15 females ($\chi^2 = 0.2510$, p = 0.8821). Mean BMI values showed no significant difference among the groups (Group B: 26.89 ± 3.91 kg/m²; Group F: 27.34 ± 4.27 kg/m²; Group C: 28.15 ± 4.05 kg/m²; F = 0.7840, p = 0.4596). ASA grade distribution was likewise similar, with no statistically significant variation ($\chi^2 = 0.6563$, p = 0.7203). The distribution of surgical procedures was also comparable. Appendectomy, inguinal hernia repair, and hydrocele surgery were similarly represented in all three groups ($\chi^2 = 1.214$, p = 0.8757). This baseline comparability is important because it indicates that the observed differences in analgesia, block characteristics, and sedation are likely related to the intrathecal adjuvants rather than to differences in patient profile or

surgical type. The haemodynamic variables recorded during the intraoperative period included pulse rate, systolic blood pressure, diastolic blood pressure, and oxygen saturation. These findings are shown in Figures 1-4.

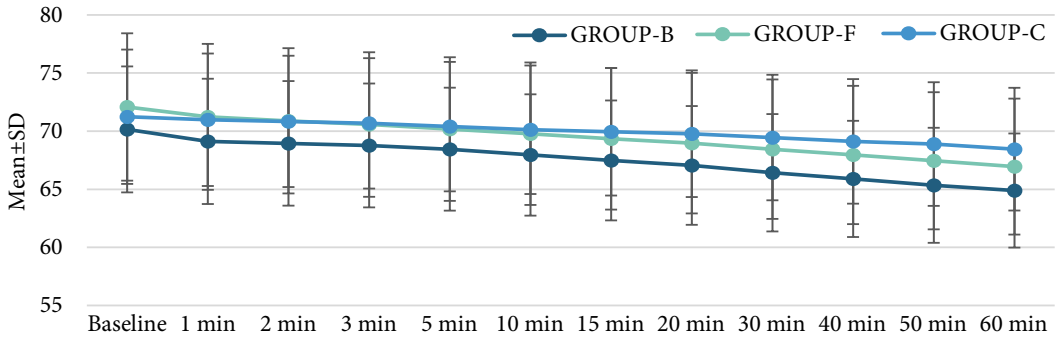

Figure 1. Graphical representations of Mean Pulse (min)

Source: developed by author

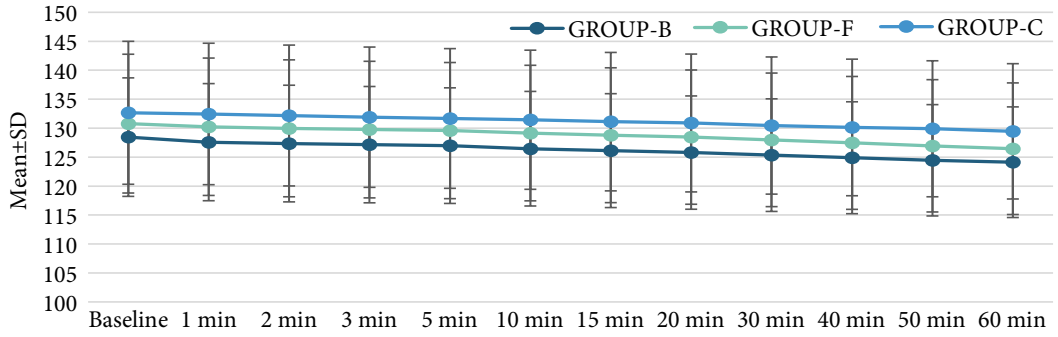

Figure 2. Graphical representations of Mean Systolic Blood Pressure (SBP)

Source: developed by author

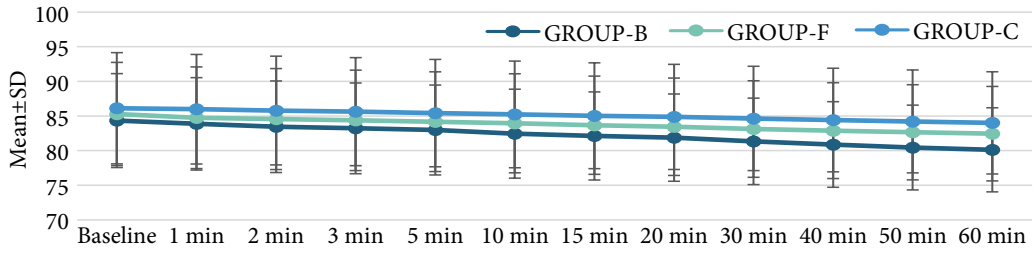

Figure 3. Graphical representation of Mean Diastolic Blood Pressure (DBP)

Source: developed by author

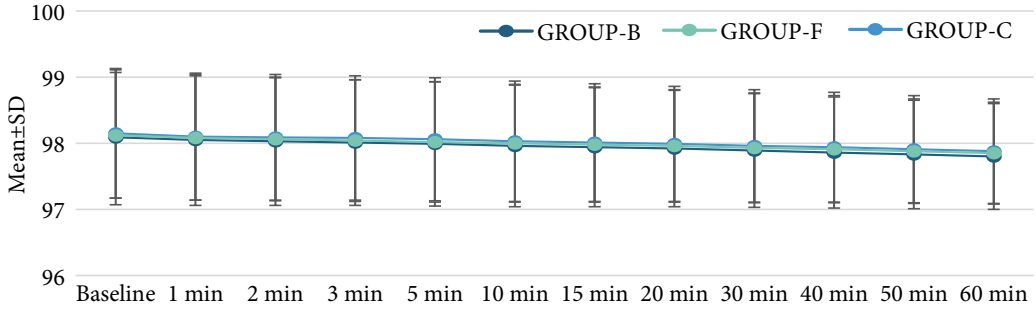

Figure 4. Graphical representation of Mean SpO_2

Source: developed by author

Baseline pulse rates were similar in all groups: 70.15 ± 5.42 beats/min in Group B, 72.08 ± 6.34 beats/min in Group F, and 71.24 ± 5.78 beats/min in Group C (F = 0.8730, p = 0.4211). No significant intergroup differences were observed from 1 minute to 40 minutes after spinal anaesthesia. However, at 50 minutes and 60 minutes, Group B showed a slightly lower pulse rate compared with Groups F and C. At 50 minutes, pulse rates were 65.34 ± 4.95, 67.45 ± 5.90, and 68.89 ± 5.32 beats/min, respectively (F = 3.493, p = 0.0345). At 60 minutes, the corresponding values were 64.89 ± 4.91, 66.95 ± 5.85, and 68.45 ± 5.28 beats/min (F = 3.557, p = 0.0325). Although these differences were statistically significant, their actual magnitude was small and did not indicate clinically important haemodynamic instability. Thus, while pulse rate varied slightly at later time points, none of the study regimens caused a major adverse cardiovascular effect.

Systolic blood pressure remained stable throughout the observation period. Baseline values were 128.45 ± 10.23 mmHg in Group B, 130.78 ± 11.98 mmHg in Group F, and 132.65 ± 12.34 mmHg in Group C, with no significant difference among groups. Similar findings were noted at all subsequent time intervals. Diastolic blood pressure also showed no significant variation. Baseline values were 84.34 ± 6.78 mmHg in Group B, 85.29 ± 7.45 mmHg in Group F, and 86.12 ± 8.03 mmHg in Group C (F = 0.4589, p = 0.6334), and no statistically significant differences were seen during follow-up. Oxygen saturation remained highly stable and comparable across all groups at all measured intervals. Baseline SpO_2 values were 98.15 ± 0.98% in Group B, 98.09 ± 1.02% in Group F, and 98.12 ± 0.95% in Group C (F = 0.02976, p = 0.9707). No episodes of clinically significant desaturation were observed. These results suggest that the addition of fentanyl or clonidine to intrathecal bupivacaine did not adversely affect haemodynamic or respiratory stability.

Clear and consistent differences were observed among the groups at all postoperative time points. At 0.5 hours, mean VAS scores were 2.05 ± 0.22 in Group B, 2.00 ± 0.20 in Group F, and 1.03 ± 0.18 in Group C (F = 262.8, p < 0.0001). At 1 hour, the pattern remained similar, with values of 2.04 ± 0.21, 2.00 ± 0.20, and 1.02 ± 0.17, respectively (F = 283.5, p < 0.0001). By 3 hours, the difference became more pronounced: Group B had a mean VAS score of 3.02 ± 0.25, Group F 2.01 ± 0.21, and Group C 1.04 ± 0.16 (F = 711.8, p < 0.0001).

At 6 hours, Group B continued to show the highest pain score (3.14 ± 0.24), followed by Group F (2.04 ± 0.20), while Group C maintained the lowest value (1.01 ± 0.16) (F = 884.1, p < 0.0001). At 12 hours, Group C still had a lower mean pain score (2.02 ± 0.18) than Groups B and F, both of which were around 3.0 (F = 232.2, p < 0.0001). At 24 hours, the same trend persisted, with values of 2.07 ± 0.20 in Group B, 2.01 ± 0.21 in Group F, and 1.00 ± 0.16 in Group C (F = 316.3, p < 0.0001).

These findings demonstrate that clonidine provided the most effective postoperative analgesia among the three regimens. Fentanyl also improved pain control compared with bupivacaine alone, but its effect was less pronounced than that of clonidine. Clinically, the lower VAS scores in Group C indicate better patient comfort and a more sustained analgesic benefit during the postoperative period. Postoperative pain intensity was assessed by the VAS and is presented in Table 2.

Table 2. Mean VAS Score

VAS score (time interval)	Group-B (n = 32)	Group-F (n = 32)	Group-C (n = 32)	p-value
Baseline	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	—
0.5 hrs	2.05 ± 0.22	2.00 ± 0.20	1.03 ± 0.18	F = 316.3, p < 0.0001*
1 hr	2.04 ± 0.21	2.00 ± 0.20	1.02 ± 0.17	F = 262.8, p < 0.0001*
3 hrs	3.02 ± 0.25	2.01 ± 0.21	1.04 ± 0.16	F = 283.5, p < 0.0001*
6 hrs	3.14 ± 0.24	2.04 ± 0.20	1.01 ± 0.16	F = 711.8, p < 0.0001*
12 hrs	3.01 ± 0.23	3.00 ± 0.22	2.02 ± 0.18	F = 884.1, p < 0.0001*
24 hrs	2.07 ± 0.20	2.01 ± 0.21	1.00 ± 0.16	F = 232.2, p < 0.0001*

Note: values are expressed as mean ± SD. Group comparisons were performed using one-way ANOVA. $p < 0.05$ was considered statistically significant

Source: developed by author

Baseline sedation scores were identical in all groups (1.00 ± 0.00), indicating that all patients were fully awake and comparable before anaesthesia. In the early postoperative period, Group C consistently exhibited higher sedation scores than Groups B and F. At 0.5 hours, the mean sedation score was approximately 2.02 in Group B, 2.06 in Group F, and 3.08 in Group C. At 1 hour, the values were 2.00, 2.06, and 3.04, respectively. A similar pattern was seen at 3 hours and 6 hours, with Group C remaining around a score of 3 while the other two groups remained close to 2.

By 12 and 24 hours, Groups B and F had returned to baseline sedation levels, while Group C remained slightly above baseline. This indicates that clonidine was associated with greater postoperative sedation than fentanyl or bupivacaine alone. However, the sedation observed in Group C was not accompanied by respiratory depression or oxygen desaturation, suggesting that although clonidine caused more sedation, it remained clinically manageable under routine monitoring. Sedation was evaluated using the Ramsay Sedation Scale, and the findings are depicted in Figure 5.

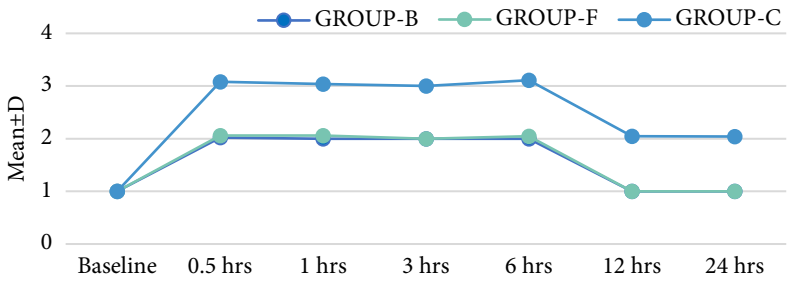

Figure 5. Graphical representation of mean Ramsay sedation scores
Source: developed by author

Sensory and motor block characteristics

Significant differences were observed among the groups in terms of onset and duration of both sensory and motor block. The onset of sensory block was fastest in Group C (1.45 ± 0.30 min), followed by Group F (1.52 ± 0.28 min), and slowest in Group B (2.01 ± 0.35 min), with a highly significant difference (F = 30.72, p < 0.0001). This suggests that both adjuvants accelerated the onset of sensory block compared with bupivacaine alone, with clonidine showing the greatest effect. The duration of sensory block was longest in Group C (150.23 ± 28.47 min), intermediate in Group F (119.78 ± 19.65 min), and shortest in Group B (90.15 ± 14.72 min) (F = 61.30, p < 0.0001). Thus, clonidine prolonged sensory blockade by about one hour compared with bupivacaine alone and by about 30 minutes compared with fentanyl. This is clinically meaningful because longer sensory block generally translates into improved early postoperative pain relief.

A similar trend was observed for motor block. The onset of motor block was fastest in Group C (2.84 ± 0.81 min), followed by Group F (3.08 ± 0.78 min), and slowest in Group B (4.12 ± 0.95 min) (F = 20.51, p < 0.0001). The duration of motor block was also significantly prolonged in Group C (110.47 ± 18.76 min), followed by Group F (100.32 ± 15.45 min), while Group B had the shortest duration (74.95 ± 10.23 min) (F = 46.22, p < 0.0001). From a practical point of view, faster onset of block may improve operating room efficiency, while prolonged sensory blockade can reduce the need for immediate postoperative analgesics. Although longer motor block may potentially delay ambulation, the extension seen with clonidine was moderate and accompanied by a clear analgesic benefit. The main efficacy outcomes related to spinal block are presented in Table 3.

There was a highly significant difference among the groups (F = 57.02, p < 0.0001). Group B required rescue analgesia after 2.80 ± 0.76 hours, Group F after 4.50 ± 1.22 hours, and Group C after 6.00 ± 1.50 hours. The time to first rescue analgesia is one of the most clinically relevant outcomes. This finding clearly demonstrates that both fentanyl and clonidine prolonged the duration of postoperative analgesia compared with bupivacaine alone, but clonidine produced the longest analgesic effect. Compared with the control group, fentanyl extended analgesia by approximately 1.7 hours, whereas clonidine extended it by approximately 3.2 hours. Compared with fentanyl, clonidine provided an additional 1.5 hours of postoperative pain relief. Clinically, this reduction in early rescue analgesic requirement may improve patient comfort and reduce the need for additional systemic analgesics.

Table 3. Mean block parameters, min

Block parameters	Group-B (n = 32)	Group-F (n = 32)	Group-C (n = 32)	p-value
Onset of sensory block	2.01 ± 0.35	1.52 ± 0.28	1.45 ± 0.30	F = 46.22, p < 0.0001*
Duration of sensory block	90.15 ± 14.72	119.78 ± 19.65	150.23 ± 28.47	F = 30.72, p < 0.0001*
Onset of motor block	4.12 ± 0.95	3.08 ± 0.78	2.84 ± 0.81	F = 61.30, p < 0.0001*
Duration of motor block	74.95 ± 10.23	100.32 ± 15.45	110.47 ± 18.76	F = 20.51, p < 0.0001*

Note: values are expressed as mean ± SD. Group comparisons were performed using one-way ANOVA. *p < 0.05 was considered statistically significant
Source: developed by author

Overall, the frequency of complications was low and comparable among groups. Excessive sedation was observed only in Group C, where it occurred in 25% of patients. Hypotension was recorded in 6.25% of Group B, 15.6% of Group F, and 3.12% of Group C, but this difference was not statistically significant. Other complications, including bradycardia, nausea, vomiting, pruritus, urinary retention, post-dural puncture headache, and respiratory depression, did not differ significantly among groups. Notably, no patient developed clinically significant respiratory depression, which supports the safety of both adjuvants at the doses used.

Taken together, the results show a clear pattern. Bupivacaine alone provided the least favourable profile, with slower block onset, shorter block duration, earlier need for rescue analgesia, and higher postoperative pain scores. The addition of fentanyl improved these outcomes, but the combination of clonidine with bupivacaine produced the best overall results.

Intrathecal clonidine was associated with the fastest onset of sensory and motor block, the longest sensory and motor block duration, the longest time to first rescue analgesia, and the lowest postoperative VAS scores at all measured intervals. These results indicate superior analgesic efficacy and better prolongation of spinal anaesthesia. The main drawback of clonidine was increased sedation, but this did not result in respiratory compromise or major haemodynamic instability. The adverse effects observed in the three groups are presented in Figure 6.

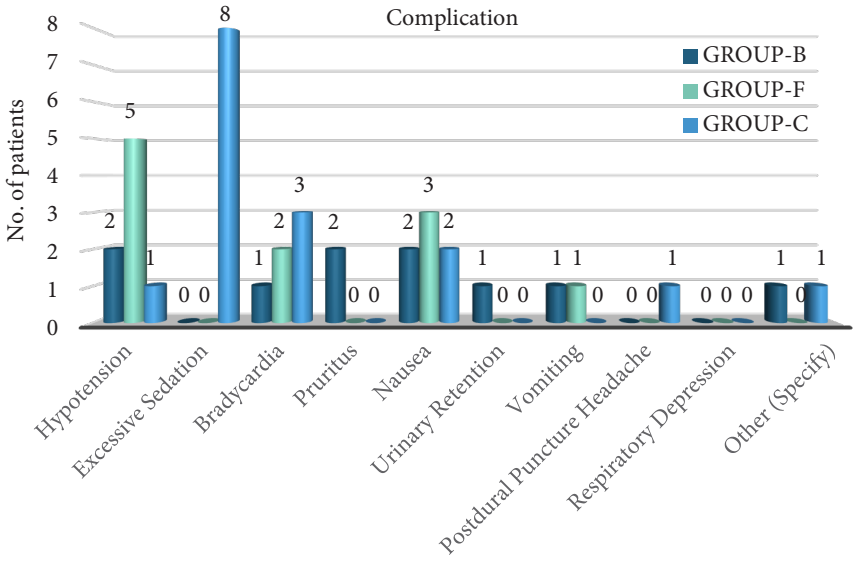

Figure 6. Graphical representation of complications

Source: developed by author

From a clinical perspective, these findings suggest that clonidine at a dose of 30 µg is a useful intrathecal adjuvant to 0.5% bupivacaine in lower abdominal surgery when prolonged analgesia is desired. Fentanyl also provides benefit over bupivacaine alone, but its effect appears less pronounced than that of clonidine. Overall, the present results support the use of low-dose clonidine as an effective and relatively safe option for improving spinal anaesthesia and postoperative pain control.

Discussion

Clonidine, as an α2-agonist, suppresses the transmission of Aδ and C fibres, hence prolonging the effects of local anaesthetics. When administered intrathecally, it induces analgesia by activating postsynaptic α2-receptors in the substantia gelatinosa of the spinal cord [18]. To mitigate the adverse effects of fentanyl, the combination of intrathecal clonidine and bupivacaine has been investigated for its potential to provide prolonged analgesia. Unlike intrathecal fentanyl, intrathecal clonidine used as an adjunct to bupivacaine in present study yielded prolonged analgesia. M.B. Khezri *et al.* [19] demonstrated as early as 2014 that intrathecal clonidine added to bupivacaine provided longer postoperative analgesia than fentanyl. Likewise, B.S. Bajwa *et al.* [16] reported superior analgesic prolongation with clonidine, though at the cost of higher sedation. The present findings corroborate these previously published results, confirming that clonidine offers greater prolongation of postoperative analgesia than fentanyl when used as an intrathecal adjuvant to bupivacaine.

Present study data indicate that the mean ages were similar among groups: Group-B (46.12 ± 10.98 years), Group-F (45.23 ± 11.56 years), and Group-C (44.78 ± 12.34 years) ($F = 0.1098$, $p = 0.8961$). The age distribution exhibited no significant difference ($X = 2.229$, $p = 0.9732$). The gender distribution exhibited parallels, with male-to-female ratios of 18:14 in Group-B, 16:16 in Group-F, and 17:15 in Group-C ($X = 0.2510$, $p = 0.8821$). The BMI values exhibited no significant differences across the groups (Group-B: 26.89 ± 3.91, Group-F: 27.34 ± 4.27, Group-C: 28.15 ± 4.05; $F = 0.7840$, $p = 0.4596$). The consistent demographic and health indicators underscore the robustness and reliability

of present study's participant profiles. The ASA grade distribution was consistent among all groups, primarily comprising ASA grade I (X = 0.6563, p = 0.7203). Appendectomies were conducted on 15 patients in Group B, 13 in Group F, and 14 in Group C. Inguinal hernia repair surgery was performed on 12 patients in Group B, 16 in Group F, and 14 in Group C. Hydrocele surgery was conducted on 5 patients in Group B, 3 in Group F, and 4 in Group C. The variations in the distribution of surgical types among the groups were not statistically significant (X = 1.214, p = 0.8757). The data demonstrate uniformity in ASA grades and surgical procedures among the study groups, hence ensuring comparability in clinical characteristics. At baseline, pulse rates were similar among Group-B (70.15 ± 5.42), Group-F (72.08 ± 6.34), and Group-C (71.24 ± 5.78), indicating no significant difference (F = 0.8730, p = 0.4211). The SBP exhibited a progressive decline over time across all groups; however, these variations did not attain statistical significance among the groups. The DBP exhibited a small decline across all groups with time; however, the variations among the groups remained statistically insignificant at each interval. At baseline, mean SpO2 values were comparable among Group-B (98.15 ± 0.98), Group-F (98.09 ± 1.02), and Group-C (98.12 ± 0.95), indicating no significant difference (F = 0.02976, p = 0.9707). The consistent SpO2 readings throughout groups suggest no significant differences in oxygen saturation levels among the three groups over the follow-up period. At baseline, all groups exhibited a VAS score of 0.00 ± 0.00, signifying the absence of first pain. Notable disparities in pain assessments were seen at later time intervals following treatment. The data demonstrate that during the post-operative period, patients in Group-C consistently reported much lower pain levels than those in Group-B and Group-F. The combination of Bupivacaine and Clonidine in Group-C seems to offer enhanced analgesic efficacy, as indicated by the VAS values recorded at all assessed time intervals. S. Kaushik [20] also observed no significant changes in demographic factors, including age, height, weight, sex ratio, and duration of operation, between the two groups examined. No statistically significant differences were observed in intra-operative haemodynamic measures, including mean arterial pressure (MAP) and heart rate (HR), during the procedure. Present study investigation and that of B.S. Bajwa *et al.* [16] revealed similar demographic profiles and haemodynamic parameters across study groups, demonstrating consistency and baseline comparability. B.S. Bajwa *et al.* [16] found that intrathecal clonidine, when combined with hyperbaric bupivacaine, produced longer postoperative analgesia and delayed the first request for rescue analgesia compared with fentanyl. The present study confirms these findings, as the clonidine group showed significantly lower postoperative VAS scores and a longer time to first rescue analgesia than the fentanyl group. This agreement may be attributed to the α2-adrenergic action of clonidine, which prolongs spinal analgesia by suppressing nociceptive transmission at the spinal cord level. The higher sedation seen in the clonidine group in both studies is also consistent with the known pharmacological profile of the drug.

Present study examined the anaesthetic effectiveness of three distinct combinations: Bupivacaine alone (Group-B), Bupivacaine combined with Fentanyl (Group-F), and Bupivacaine combined with Clonidine (Group-C). The results indicated substantial disparities in the onset and duration of sensory and motor blockages across the groups. Group-C demonstrated the longest duration until the initial analgesic demand (6.00 ± 1.50 hours), which was considerably greater than that of Group-F (4.50 ± 1.22 hours) and Group-B (2.80 ± 0.76 hours), F = 57.02, p < 0.0001. The results demonstrate that Bupivacaine combined with Clonidine (Group-C) generated a more rapid onset and extended duration of both sensory and motor blocks, leading to a postponed requirement for rescue analgesia in comparison to Group-B and Group-F. Consistent with present research, A.R. Chhabra *et al.* [21] shown that 60 μg of clonidine outperformed fentanyl, prolonging both the duration of the subarachnoid block and postoperative analgesia. V. Mahendru *et al.* [17] found that 30 μg intrathecal clonidine and 25 μg fentanyl produced comparable sensory and motor block characteristics, whereas the present study demonstrated superior block prolongation with clonidine. This difference may be related to variations in surgical population, methodology, and criteria used for block assessment, since V. Mahendru *et al.* [17] studied lower limb surgery and included a different comparative framework. Such variability suggests that the effect of intrathecal adjuvants may be context-dependent rather than unpredictable. Therefore, the present study remains relevant because it provides procedure-specific evidence for lower abdominal surgery and shows that clonidine may offer greater analgesic benefit than fentanyl, albeit with more sedation. The clonidine cohort exhibited analgesia for a significantly extended period (497.20 ± 139.78 min) in contrast to the fentanyl cohort (416.87 ± 105.67 min) (P < 0.05).

The start, peak, and duration of sensory and motor block are same in both groups; however, the analgesic duration in the clonidine group significantly exceeds that of the fentanyl group (P < 0.05). In present study, the clonidine cohort exhibited elevated sedation scores compared to the fentanyl cohort (P < 0.05). N. Kothari *et al.* [22] found that the addition of 50 μg of clonidine to bupivacaine induced drowsiness in 35-45% of subjects. The preceding finding clearly indicates that clonidine sedation is dose-dependent. In the research conducted by B.S. Bajwa *et al.* [16], the dosage of clonidine was limited to 50 μg to mitigate adverse effects.

In present study investigation, all groups commenced with a Ramsay Sedation Score of 1.00 ± 0.00 at baseline, signifying the absence of sedation. At 12 and 24 hours, sedation scores reverted to baseline for Group-B and Group-F (1.00 ± 0.00), however Group-C exhibited somewhat higher values (2.05 ± 0.00 and 2.04 ± 0.00, respectively). The results demonstrate that patients administered Bupivacaine with Clonidine (Group-C) exhibited markedly

elevated sedation levels relative to those in Group-B and Group-F, especially during the immediate postoperative phase, with lingering effects noted for up to 24 hours following administration. Likewise, B.S. Bajwa *et al*. [16] study indicates that the haemodynamic stability seen in both groups of present study experiment corroborates the principle that minimal dosages of intrathecal clonidine or fentanyl are not associated with systemic side effects such as bradycardia, hypotension, or sedation. Only one patient required intravenous atropine administration due to significant bradycardia. A. Bhattacharjee *et al*. [23] concluded that the addition of 75 μg of clonidine and 25 μg of fentanyl to bupivacaine prolonged perioperative analgesia during caesarean operations. The principal finding of present study investigation was the elevated incidence of excessive sedation in Group-C (25%), in contrast to the absence of reported cases in Group-B and Group-F. Group-C also showed a lower but non-significant incidence of hypotension (3.12%) compared to Group-B (6.25%) and Group-F (15.6%). No statistically significant differences were observed among the groups for complications such as bradycardia, pruritus, nausea, urinary retention, vomiting, post-dural puncture headache, respiratory depression, and specified minor issues. On the other hand, fentanyl prolonged postoperative analgesia more than clonidine did, and clonidine caused more side symptoms, such as nausea, vomiting, and hypotension studied by A. Bhattacharjee *et al*. [23]. Similar to present findings, G. Singh *et al*. [24] study in patients scheduled for transurethral resection of the prostate found that intrathecal clonidine combined with bupivacaine produces more satisfying anaesthesia and analgesia and has less side effects than fentanyl.

Present study contributes to the growing body of research on intrathecal anaesthesia by highlighting the varied sedative effects and impact on hypotension associated with different combinations of intrathecal analgesics. While the present study observed a higher incidence of sedation in Group-C and a potential benefit in mitigating hypotension compared to other groups, present study findings are consistent with previous studies regarding the efficacy of clonidine in extending postoperative analgesia. The present study used fixed low doses of fentanyl (25 μg) and clonidine (30 μg) as intrathecal adjuvants to 0.5% bupivacaine and therefore does not support conclusions regarding individualised dosing. No widely accepted national or international protocol was identified that specifically recommends this exact combination and dose for lower abdominal surgery. Current formal guidance more commonly addresses intrathecal opioids in obstetric neuraxial anaesthesia rather than clonidine-based non-obstetric spinal regimens. Therefore, the significance of the present study lies in providing procedure-specific comparative evidence rather than in refining an established protocol. Its novelty is the direct comparison of bupivacaine alone, bupivacaine with fentanyl, and bupivacaine with clonidine in lower abdominal surgery, with simultaneous assessment of block characteristics, postoperative analgesia, haemodynamic effects, sedation, and adverse events. The findings indicate that clonidine produced longer analgesia and lower postoperative pain scores than fentanyl, although with greater sedation.

Conclusions

This study showed that both fentanyl and clonidine improved the quality of spinal anaesthesia and postoperative analgesia when added intrathecally to 0.5% bupivacaine for lower abdominal surgery. However, clonidine 30 μg produced the most favourable analgesic profile. It was associated with a faster onset of sensory and motor block, longer duration of both blocks, lower postoperative VAS scores, and a significantly prolonged time to first rescue analgesia compared with fentanyl 25 μg and bupivacaine alone. These findings indicate that clonidine provides more sustained postoperative pain relief and better overall block characteristics in this surgical setting. From a practical perspective, the results suggest that low-dose intrathecal clonidine may be a useful adjuvant when prolonged analgesia is desired after lower abdominal procedures. At the same time, the greater sedation observed in the clonidine group should be taken into account, particularly in patients in whom early alertness is important. Thus, the choice of intrathecal adjuvant should balance analgesic benefit against the potential for increased sedation.

The study has some limitations. It was conducted at a single centre with a relatively small sample size, and only fixed doses of fentanyl and clonidine were evaluated. In addition, longer postoperative follow-up and broader assessment of patient-centred outcomes were not included. These factors may limit the generalisability of the findings. Overall, clonidine appears to be a more effective intrathecal adjuvant than fentanyl for prolonging postoperative analgesia in lower abdominal surgery, although with higher sedation. Further multicentric studies with larger samples are needed to confirm these findings, evaluate different dose regimens, and better define the balance between analgesic efficacy and adverse effects.

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Conflict of Interest

Author declares no conflict of interest.

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Ефективність та безпека інтратекального введення клонідину порівняно з фентанілом у поєднанні з бупівакаїном при операціях у нижній частині живота

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Анотація. Інтратекальні ад'юванти, такі як фентаніл і клонідин, можуть покращувати якість та тривалість спінальної анестезії та післяопераційної аналгезії з використанням бупівакаїну, проте їх порівняльна ефективність та профіль побічних ефектів залишаються важливими питаннями. Метою даного дослідження було порівняння впливу інтратекального фентанілу та клонідину як ад'ювантів до 0,5 % бупівакаїну на характеристики блокади, післяопераційну аналгезію, гемодинаміку, седацію та побічні ефекти у пацієнтів, яким проводили операції на нижній частині живота. Це рандомізоване подвійне сліпе порівняльне дослідження було проведено у відділенні анестезіології лікарні Балрампур, Лакхнау, серед 96 пацієнтів віком 18-60 років, фізичний статус ASA I-II, яким було призначено операції на нижній частині живота. Пацієнтів було випадково розподілено на три групи (n = 32 у кожній): Група B отримала 2,5 мл 0,5 % розчину бупівакаїну з 0,5 мл фізіологічного розчину, група F отримала 2,5 мл 0,5 % розчину бупівакаїну з 25 мкг фентанілу, а група C – 2,5 мл 0,5 % розчину бупівакаїну з 30 мкг клонідину. Результати включали час настання та тривалість блокади, час застосування додаткової аналгезії, оцінку за шкалою VAS, гемодинаміку, седацію та побічні ефекти. Базові характеристики були порівнянними між групами. Група C показала найшвидший початок сенсорної блокади (1,45 ± 0,30 хв) та її найдовшу тривалість (150,23 ± 28,47 хв), за нею йшли група F та група B ($p < 0,0001$). Подібна закономірність спостерігалася щодо початку та тривалості моторної блокади ($p < 0,0001$). Час до першого застосування додаткової аналгезії був значно довшим у групі C (6,00 ± 1,50 год) порівняно з групою F (4,50 ± 1,22 год) та групою B (2,80 ± 0,76 год) ($p < 0,0001$). Післяопераційні показники за шкалою VAS були значно нижчими у групі C. Гемодинамічні показники залишалися в основному порівнянними. Седативний ефект був сильнішим при застосуванні клонідину, причому виражена седація спостерігалася лише у групі C. Інтратекальне введення 30 мкг клонідину разом з бупівакаїном забезпечило кращі характеристики блокади та тривалішу післяопераційну аналгезію, ніж 25 мкг фентанілу або бупівакаїн окремо, але з вищим рівнем седації

Ключові слова: спінальна анестезія; післяопераційна аналгезія; хірургія нижньої частини живота; гемодинаміка; седація