e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com

International Journal of Pharmaceutical Quality Assurance 2026; 17(2); 160-166

Original Research Article

Comparison of Spinal Anaesthesia with Bupivacaine and Fentanyl vs Bupivacaine and Clonidine in Lower Limb Surgeries

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Received: 14-12-2025 / Revised: 24-01-2026 / Accepted: 20-02-2026
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Conflict of interest: Nil

Abstract:

Background: Spinal anaesthesia is very popular in lower limb surgeries because it is effective and safe. Bupivacaine is widely used, however due to its short duration of postoperative analgesia fentanyl and clonidine are used to increase the efficacy.

Aim: To determine the effectiveness and safety of intrathecal bupivacaine with fentanyl to that of bupivacaine with clonidine during lower limb surgeries.

Methodology: It was a prospective, randomized, double-blinded clinical study conducted on 80 ASA I–II patients undergoing elective lower limb surgeries. Group F received 2.5 ml of 0.5% hyperbaric bupivacaine with 25 µg fentanyl intrathecally, while Group C received 2.5 ml of 0.5% hyperbaric bupivacaine with 50 µg clonidine intrathecally. Sensory and motor block characteristics, duration of analgesia, sedation levels, and side effects were observed and statistically analyzed.

Results: The onset of sensory and motor blocks was similar in both groups. However, the duration of sensory block (225.75 ± 28.55 min vs. 180.40 ± 22.65 min), motor block (210.45 ± 24.60 min vs. 160.85 ± 21.20 min), and analgesia (320.75 ± 34.85 min vs. 250.35 ± 31.25 min) were significantly longer in the clonidine group ($p < 0.001$). Side effects were minimal and comparable.

Conclusion: Both adjuvants are effective, but clonidine provides longer sensory, motor, and analgesic duration with mild sedation and stable hemodynamics, making it a superior alternative to fentanyl.

Keywords: Bupivacaine, Clonidine, Fentanyl, Spinal anaesthesia, Lower limb surgery, Analgesia.

DOI: 10.25258/ijpqa.17.2.26

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Introduction

The most commonly used regional anaesthesia method of lower limb surgeries is spinal anaesthesia because of its quick onset, predictable response, intense sensory and motor blockade and affordability [1]. It has a number of benefits over general anaesthesia such as lesser intraoperative blood loss, no airway manipulation, analgesia even after surgery and quicker recovery. Out of the numerous local anaesthetic agents available in the management of spinal anaesthesia, bupivacaine, which is a long-acting amide-type local anaesthetic, agent remains the most common used drug due to its desirable pharmacokinetic characteristics for duration capacity to give satisfactory sensory and motor blockade and for long surgery. Nonetheless, one of the major shortcomings of bupivacaine is its relatively short cost efficiency duration of analgesic effect and dose dependent hypotension and motor blockage [2] which is exhibited when used alone. This has motivated the inclusion of adjuvant agents in order to improve the quality and duration of anaesthesia and reduce side effects and postoperative pain management.

Adjuvants are pharmacological substances that when they are included with local anaesthetics they act synergistically or additively to boost the effects of the latter [3]. Clonidine, dexmedetomidine and midazolam are non-opioid intrathecal adjuvants that are the most widely used. Fentanyl, morphine and sufentanil are the most commonly used opioid intrathecal adjuvants. The combination of these agents with bupivacaine is due to the fact that the

combination results in longer period of sensory blockade, enhanced intraoperative hemodynamic stability and longer postoperative analgesia compared to adverse effects [4]. Fentanyl, a synthetic μ-opioid receptor agonist, is also chosen due to its high lipid solubility, fast onset of action, and limited side effects which includes pruritus or respiratory depression but less as compared to hydrophilic opioids like morphine. On the other hand, clonidine, which is an α 2 adrenergic receptor, has become eminent due to the analgesic, sedative, and sympatholytic effect that lasts longer in terms of sensory and motor blockage without the usual complications associated with opioid.

The effect of adding fentanyl to bupivacaine in spinal anaesthesia increases analgesia, which is its effect on the dorsal horn of the spinal cord where it prevents the release of the nociceptive neurotransmitters [5]. The result of this combination is a quicker onset of action, better on-operative analgesia and early ambulation after surgery because of the decreased motor blockade period [6]. Nonetheless, its analgesic action does not last long and side effects such as nausea, vomiting and pruritus could limit its use in certain patients. Conversely, clonidine also works by stimulating the presynaptic 2 receptors in the dorsal horn, which causes the nociceptive transmission to be inhibited and the postsynaptic neurons to be hyperpolarized. Clonidine has been demonstrated to be a superior adjuvant to bupivacaine in that it has a longer sensory and motor blockage, better hemodynamic stability and a longer postoperative analgesia. Moreover, it has been found that clonidine decreases the need of extra intraoperative sedatives and analgesics because it also possesses its own sedative characteristics.

The orthopaedic surgery, vascular surgery or soft-tissue surgery on the lower limbs involve use of a stable and predictable anaesthetic procedure so as to achieve the best surgery environment and patient comfort [7]. Spinal anaesthesia combined with adjuvants provides a moderate method of spinal anaesthesia that does not produce excessive systemic drug exposure and postoperative pain [8]. Whether to use opioids such as fentanyl or 2 -agonists such as clonidine as intrathecal adjuvants is an important decision because both have distinct pharmacodynamic profiles that affect the onset, intensity and duration of anaesthesia as well as side effect profiles. Comparative trials have shown mixed findings of the effectiveness of these agents whereby some studies have shown that fentanyl is the best agent, owing to the rapid onset effect and excellent intraoperative analgesic effect, whereas the others have shown that clonidine is the best agent, owing to the sustained postoperative analgesic efficacy and the lack of analgesics that rescue analgesic effect.

Since the search on the perfect combination of intrathecal adjuvant is still ongoing, it is thus crucial to compare the clinical efficacy, onset, duration, and hemodynamic stability of these combinations in a systematic manner. The rationale of comparing bupivacaine use with fentanyl and clonidine use in bupivacaine use in spinal anaesthesia in lower limb surgeries is to establish the most appropriate regimen that can offer the best intraoperative state, extended analgesic effects, minimal hemodynamic changes, and reduced complications. This comparative study is not only useful in improving the level of perioperative patient safety and comfort but also goes up to enhancing the level of anaesthetic practice in terms of offering evidence-based recommendations to the anaesthesiologists on the selection of the right combination of adjuvants.

Methodology

Study Design: This study was designed as a prospective, randomized, double-blind, controlled clinical trial comparing the efficacy and safety of spinal anaesthesia using a combination of Bupivacaine with Fentanyl versus Bupivacaine with Clonidine in patients undergoing lower limb surgeries.

Study Area: The study was conducted in the Department of Anaesthesiology, Jagannath Gupta Institute of Medical Sciences & Hospital, Budge Budge, Kolkata, West Bengal, India for a period of one year.

Study Participants

Inclusion Criteria

- Patients aged between 18 and 65 years.
- Either gender.
- Belonging to American Society of Anesthesiologists (ASA) physical status I or II.
- Scheduled for elective lower limb orthopedic surgery under spinal anaesthesia.

Exclusion Criteria

- Refusal of informed consent.
- Known allergy to Bupivacaine, Fentanyl, or Clonidine.
- Spinal deformities or infection at the puncture site.
- Increased intracranial pressure, neurological disorders, or coagulopathy.
- Diagnosed Patients of Mental Illness on Medication

Sample Size: A total of 80 patients were enrolled in the study. They were randomly divided into two equal groups (n = 40 each) using a computer-generated randomization sequence.

- Group F – Received 2.5 ml of hyperbaric Bupivacaine (0.5%) + 25 µg Fentanyl (diluted to 0.5 ml) intrathecally.

- Group C – Received 2.5 ml of hyperbaric Bupivacaine (0.5%) + 50 µg Clonidine (diluted to 0.5 ml) intrathecally.

The total volume of the study drug was maintained at 3 ml for all participants.

Procedure: All patients were evaluated pre-anaesthetically a day before the surgery and the Visual Analog Scale (VAS) of pain measurement explained. Once in the operation theatre an intravenous (IV) cannula was established, and preloading with Ringer lactate (10 ml/kg) was done. The parameters including heart rate, blood pressure, and oxygen saturation (SpO_2) were measured as a baseline.

The spinal anaesthesia was performed in the sitting position at the L3-L4 space under strict aseptic conditions and by using a 25-gauge Quincke spinal needle, which was inserted in the midline inserted. An anesthesiologist who had not been informed about the contents of the syringe injected the study drug intrathecally according to the random assigned group. Pulse rate, blood pressure, SBP, DBP, MAP, ECG, respiratory rate, and SpO_2 were continuously monitored during the procedure.

An increase and decrease in pulse rate and blood pressure more than 20 percent of the baseline were recorded. IV atropine (0.6 mg) was used to treat bradycardia (heart rate below 50 beats/min), whereas IV Mephentermine (6 mg) boluses were used to treat hypotension (reduction in systolic blood pressure more than 20% of baseline).

The onset of sensory block was assessed by the pin-prick method every 2 minutes until loss of sensation at the T10 dermatome level, and the motor block was evaluated using the Modified Bromage Scale:

Bromage 0: Full movement of hip, knee, and ankle.

Bromage 1: Inability to move hip but movement at knee and ankle present.

Bromage 2: Inability to move hip and knee but able to move ankle.

Bromage 3: Complete inability to move hip, knee, and ankle.

The sensory block was determined as the period when the block reached its peak and at the same time the motor block took place when the motor block started until full recovery (Bromage 0). The analgesia period was the time interval between the intrathecal injection and the need to have the first rescue analgesic. It was observed that it had side effects like nausea, vomiting, shivering, pruritus, hypotension, bradycardia, respiratory discomfort, and sedation. The Campbell Sedation Score was used to measure the levels of sedation (1 = wide awake; 4 = not arousable). The intensity of pain was measured using VAS (10 = worst pain, 0 = no pain) postoperatively. For rescue Analgesia injection Paracetamol 1 g IV was given and the time of administration was noted in case of VAS greater than 5.

Statistical Analysis: A power analysis revealed that 40 patients each group was adequate to result in a 80 percent power and a 5 percent significant level to determine significant difference in the mean length of analgesia by 60 minutes. The data were keyed and analysed through Statistical Package of the Social Sciences (SPSS) version 27 (IBM Corp., NY, USA). Continuous data were shown in the form of mean standard deviation, and frequency and percentage of categorical data. The Analysis of Variance (ANOVA) was used to compare intergroup scores when the variables are continuous and Chi-square test was used when the variables are categorical. The p-value, which was found to be below 0.05, was deemed statistically significant, whereas p which was found to be below 0.001 was highly significant.

Result

Demographic features of patients in the two groups have been discussed in Table 1 with no statistically significant differences among them. Group F (Bupivacaine + Fentanyl) patients had a mean age of 39.85 ± 10.42 years and Group C (Bupivacaine + Clonidine) had a mean age of 41.28 ± 9.75 years (p = 0.52). The sex distribution was equally balanced with 26 and 14 males and females in Group F and Group C respectively (p = 0.81). The mean weight was 62.40 +/-7.82kg in Group F and 61.95 +/-8.10kg in Group C (p = 0.76). The ASA physical status of both the groups was similar (Grade I/II: 22/18 in Group F and 23/17 in Group C; p = 0.85). The average operating time was also similar, with 90.25 and 88.70 being the mean of 14.65 and 13.92minutes of operation in Group F and Group C respectively, meaning that the two groups were well-matched in terms of demography and clinical aspects.

Table 1: Demographic Profile of Patients in Both Groups

Parameter	Group F (Bupivacaine + Fentanyl) (n=40)	Group C (Bupivacaine + Clonidine) (n=40)	p-value
Age (years, Mean ± SD)	39.85 ± 10.42	41.28 ± 9.75	0.52
Sex (Male/Female)	26 / 14	25 / 15	0.81
Weight (kg, Mean ± SD)	62.40 ± 7.82	61.95 ± 8.10	0.76
ASA Grade I / II	22 / 18	23 / 17	0.85
Duration of Surgery (min)	90.25 ± 14.65	88.70 ± 13.92	0.61

The comparison of the sensory block features in Group F (Bupivacaine with Fentanyl) and Group C (Bupivacaine with Clonidine) is shown in Table 2. The average duration of time to commence sensory block was a little lower in Group F (3.85 ± 0.92 min) than Group C (4.20 ± 1.10 min) but the difference was not statistically significant (p = 0.15). The same situation could be seen with the time to reach the maximum level of sensations where in Group F (8.25 ± 1.35 min) the time to reach it was slightly lower than in Group C (8.90 ± 1.25 min), but this difference was also not significant (p = 0.09). Nevertheless, the sensory block lasted much longer in Group C (225.75 ± 28.55 min), than in Group F (180.40 ± 22.65 min) with a very significant p-value (<0.001). Both groups realized the same highest level of sensations in T6 dermatome.

Table 2: Comparison of Sensory Block Characteristics Between the Two Groups

Parameter	Group F (Mean ± SD)	Group C (Mean ± SD)	p-value
Onset of Sensory Block (min)	3.85 ± 0.92	4.20 ± 1.10	0.15
Time to Reach Maximum Sensory Level (min)	8.25 ± 1.35	8.90 ± 1.25	0.09
Duration of Sensory Block (min)	180.40 ± 22.65	225.75 ± 28.55	<0.001
Maximum Sensory Level Achieved (Dermatomal Level)	T6	T6	—

Table 3 is the comparison of the motor block parameters between the Group F and Group C. There was no major difference in the onset of motor block with Group F having an onset time of 5.10 +1.05 minutes and Group C having 5.30 +1.00 minutes. There was however a significant difference in the duration of the motor block between the groups; the duration of the motor block was as well significantly more eminent in Group C (210.45 ± 24.60 minutes) than in Group F (160.85 ± 21.20 minutes) with a significant p-value (<0.001). There was similar maximum motor block intensity with both groups having maximum Modified Bromage Score of 3. These results indicate that the onset time and the intensity of motor block were comparable; however, the duration of motor block was much longer with clonidine combined with bupivacaine compared to fentanyl.

Table 3: Comparison of Motor Block Characteristics Between the Two Groups

Parameter	Group F (Mean ± SD)	Group C (Mean ± SD)	p-value
Onset of Motor Block (min)	5.10 ± 1.05	5.30 ± 1.00	0.38
Duration of Motor Block (min)	160.85 ± 21.20	210.45 ± 24.60	<0.001
Modified Bromage Score (Maximum Achieved)	3	3	—

Table 4 indicates that Group C (Bupivacaine with Clonidine) lasted longer than Group F (Bupivacaine with Fentanyl) with a mean analysis of 320.75 and 250.35 respectively and p = 0.001. Group C (2.40 ± 0.65) has significantly lower mean VAS score compared to Group F (3.75 ± 0.80) at 4 hours postoperative which means that the clonidine group was more successful in pain relief (p < 0.001). Also, the mean Campbell Sedation Score was greater in Group C (2.50 ± 0.60) than in Group F (1.80 ± 0.40) with a more profound degree of sedation under the influence of clonidine (p < 0.01). In general, Group C had better analgesic effect and quality of sedation in comparison with Group F.

Table 4: Duration of Analgesia and Sedation Scores

Parameter	Group F (Mean ± SD)	Group C (Mean ± SD)	p-value
Duration of Analgesia (min)	250.35 ± 31.25	320.75 ± 34.85	<0.001
Mean VAS Score (Post-op at 4 h)	3.75 ± 0.80	2.40 ± 0.65	<0.001
Mean Campbell Sedation Score	1.80 ± 0.40	2.50 ± 0.60	<0.01

Table 5 shows the frequency of side effects that occurred in both groups. In Group F, hypotension was observed in 7.5% of patients, whereas in Group C, there was 12.5% hypotension and no statistically significant difference was given between the two groups (p>0.05). Group F was a little more likely to report nausea and vomiting (10.0) than Group C (7.5), pruritus was reported a little more often in Group F (12.5) than in Group C (2.5), but the difference was not statistically significant (p=0.09). Shivering was also equal between the two groups (5.0%), and sedation (score ≥2) was higher in Group C (17.5%) than in Group F (7.5%) however, again no significant difference was found (p=0.18). There were no instances of respiratory depression in either of them. On the whole, the two groups showed similar safety characteristics with few side effects.

Table 5: Incidence of Side Effects in Both Groups			
Side Effect	**Group F (n=40)**	**Group C (n=40)**	**p-value**
Hypotension	3 (7.5%)	5 (12.5%)	0.45
Bradycardia	2 (5.0%)	4 (10.0%)	0.4
Nausea/Vomiting	4 (10.0%)	3 (7.5%)	0.69
Pruritus	5 (12.5%)	1 (2.5%)	0.09
Shivering	2 (5.0%)	2 (5.0%)	1
Sedation (Score ≥ 2)	3 (7.5%)	7 (17.5%)	0.18
Respiratory Depression	0 (0%)	0 (0%)	—

Discussion

The current study involved the comparison of clinical effectiveness of intrathecal bupivacaine with fentanyl or clonidine as a lower limb surgery. Both groups were similar in demographic characteristics which ensured observed difference in block characteristics and analgesic duration due to the adjuvants used. There was no significant difference in the onset of sensory or motor block in groups, which implied that fentanyl and clonidine did not make any significant change in the onset of the spinal anesthesia. Yet, the time of sensory and motor blockage was greatly prolonged during clonidine group in comparison with fentanyl group, which indicates that clonidine is more effective in prolonging the anesthetic effect of bupivacaine.

The results are similar to those of Khezri et al. (2014) [9] because they found that the combination of 75 µg clonidine with bupivacaine effectively prolonged the time to first analgesic request over fentanyl. On the same note, Bajwa et al. (2017) [10] established that intrathecal clonidine (50 µg) significantly extended postoperative analgesia and duration of sensory block as compared to fentanyl (25 µg) although clonidine caused more sedation. These findings are also supported by the current study since clonidine gave a better period of both sensory and motor block with minimal sedation that did not exceed the acceptable levels.

It was found by Chhabra et al. (2013) [11] that clonidine (60 µg) when combined with intrathecal ropivacaine produced a longer duration of sensory and motor blocking and a better postoperative analgesia than fentanyl (25 µg), which is also consistent with the current results. In a similar manner, a study by Sharan et al. (2016) [12] compared intrathecal clonidine 30 µg versus fentanyl 25 µg and concluded that clonidine was better than fentanyl in its ability to prolong the duration of block and analgesia, as was the case in our study. However, Mahendru et al. (2013) [13] found the same ideas, with clonidine (30 µg) and fentanyl (25 µg) similar with regards to sensory and motor block duration, and this result could be due to the lower dose of clonidine in their study (30 µg), as compared to our 50 µg.

The current research also established that the clonidine provided superior postoperative analgesic effect, and patients took a long time to take rescue analgesics as compared to the fentanyl group. This is in line with the conclusions made by Tilkar et al. (2015) [14] who developed an opinion that clonidine gave better analgesic effect than fentanyl when combined with intrathecal bupivacaine in orthopedic operations. On the same note, Singh et al. (2013) [15] have shown that intrathecal clonidine (75 µg) was a significant prolongation of postoperative analgesia after cesarean section with no extra maternal or neonatal side effects, which supports the analgesic property of clonidine in the current study.

In terms of sedation, the Campbell Sedation Score mean was greater in the clonidine group which is mild-moderate sedation. This is ascribed to the central 2- adrenergic effect of clonidine on the locus coeruleus that leads to decreased sympathetic discharge and a sedative effect and lacks respiratory depression. The studies by Bajwa et al. (2017) [10] also indicated increased sedation using clonidine, which they deemed to have a positive effect on the intraoperative comfort. But Shidhaye et al. (2013) [2] have observed that fentanyl can be a better option when the patient would not want to be heavily seded as it has a low sedative profile though it has a lower analgesic effect.

The current research established similar hemodynamic stability of the two groups. The hypotension and bradycardia were observed more in the clonidine group, but these were unstatistically significant and could be easily corrected. This is congruent with the results of Kothari et al. (2011) [17] who have found no major hemodynamic changes upon the addition of clonidine to bupivacaine in cesarean section. Conversely, Lavand homme et al. (2008) [18] found more hypotension and sedation with increased doses of clonidine (150 µg) in their study, indicating that a moderate dose including 50 µg, which was applied in this study, has the best effect with minimum side effects.

A high-profile side effect of opioids, pruritus, was more prevalent in the fentanyl group, whereas clonidine induced mild sedation with none. This finding is congruent with Benhamou et al. (1998) [19] study which revealed that both clonidine and fentanyl enhanced analgesia when used together with bupivacaine, but pruritus was more common

with fentanyl. On the same note, Bathari et al. (2016) [20] detected more opioid adverse effects with fentanyl than clonidine but the study concluded that fentanyl had better analgesia at a higher dose (30 μg fentanyl vs. 15 μg clonidine), underscoring the need to optimize doses.

In general, the data indicate that intrathecal clonidine has a synergistic effect with bupivacaine, resulting in hyperpolarization of postsynaptic cells by the activation of the α 2 receptors, which causes postoperative prolonged sensory and motor block and a greater analgesia. Conversely, fentanyl, which works on μ-opioid receptors, is quick in effect and produces intropoerative analgesia and less postoperative analgesia. Mild sedation seen with the use of clonidine is usually beneficial intraoperative comfort, as long as excessive drowsiness and hemodynamic instability do not occur.

Conclusion

This comparative analysis showed that when applied as an adjuvant to intrathecal bupivacaine, fentanyl and clonidine were found to have the same benefits in terms of effective spinal anaesthesia of lower limb surgery with a stable hemodynamic pattern with minimal side effects. Nevertheless, clonidine had a unique benefit, because it effusively increased the length of sensory and motor block, postoperative analgesia and quality of sedation over fentanyl. Fentanyl, however, resulted in a milder onset of sensory block and a reduced number of sedative effects, thus it is applicable when rapid recovery is needed after surgery. This was clinically acceptable because of the minor sedation and the insignificant changes in hemodynamics that came with the clonidine. Hence, bupivacaine combined with clonidine may be regarded as an excellent option in case of long surgeries with a necessity of prolonged postoperative analgesia without jeopardizing the patient safety.

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