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Original Research Article

Comparative Study of Intrathecal Dexmedetomidine versus Fentanyl with Levobupivacaine in Elective Laparoscopic Cholecystectomy

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Conflict of interest: Nil

Abstract

Background: Segmental spinal anaesthesia has emerged as a safe and effective alternative to general anaesthesia for laparoscopic cholecystectomy, with the use of adjuvants enhancing block quality and duration. Dexmedetomidine and fentanyl are commonly used intrathecal adjuvants with distinct pharmacological profiles.

Objective: To compare the efficacy and safety of intrathecal dexmedetomidine versus fentanyl as adjuvants to isobaric levobupivacaine in segmental spinal anaesthesia for elective laparoscopic cholecystectomy. Methods: A prospective randomized double-blinded study was conducted on 150 patients divided into two groups of 75 each. Group D received 5 µg dexmedetomidine and Group F received 25 µg fentanyl with isobaric levobupivacaine intrathecally. Parameters assessed included onset and duration of sensory block, duration of analgesia, hemodynamic changes, and adverse effects.

Results: Dexmedetomidine significantly prolonged the duration of sensory block (118.4 ± 14.6 min vs 92.7 ± 16.8 min) and postoperative analgesia (305.6 ± 32.4 min vs 168.3 ± 28.7 min) compared to fentanyl ($p < 0.001$). Total analgesic consumption was significantly lower in the dexmedetomidine group (75 ± 8.2 mg vs 172 ± 24.5 mg). Hemodynamic parameters were comparable between groups, and side effects were minimal, with fewer opioid-related effects in the fentanyl group.

Conclusion: Intrathecal dexmedetomidine is a superior adjuvant to fentanyl with levobupivacaine for segmental spinal anaesthesia, providing prolonged analgesia and reduced analgesic requirement with a favorable safety profile.

Keywords: Dexmedetomidine, Fentanyl, Levobupivacaine, Spinal Anaesthesia.

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Introduction

Laparoscopic cholecystectomy has emerged as the gold standard for the management of symptomatic gallstone disease owing to its minimally invasive nature, reduced postoperative pain, shorter hospital stay, and faster recovery [1]. Traditionally, general anaesthesia has been the preferred technique for laparoscopic procedures due to concerns related to pneumoperitoneum, diaphragmatic irritation, and visceral pain. However, in recent years, regional anaesthesia techniques, particularly spinal anaesthesia, have gained increasing attention as viable alternatives due to their advantages in terms of reduced stress response, lower incidence of postoperative nausea and vomiting, early ambulation, and improved patient satisfaction [2]. Segmental spinal anaesthesia (SSA), involving low-dose local anaesthetics targeted to specific dermatomal levels, has further refined the application of spinal techniques in laparoscopic surgeries. This approach minimizes hemodynamic instability while maintaining adequate surgical anaesthesia and allows avoidance of airway manipulation, which is particularly beneficial in patients with comorbidities [3]. However, the use of low-dose local anaesthetics alone may be associated with inadequate sensory blockade and limited duration of analgesia, necessitating the use of adjuvants to enhance block quality and prolong analgesic effects [4]. Levobupivacaine, the S-enantiomer of bupivacaine, is widely used in spinal anaesthesia due to its favorable safety profile, including reduced cardiotoxicity and neurotoxicity

compared to racemic bupivacaine, while providing effective sensory and motor blockade [5]. Nevertheless, when used in low doses for segmental spinal anaesthesia, its duration of action may be insufficient for prolonged procedures, thereby highlighting the need for suitable intrathecal adjuvants [6].

Opioids such as fentanyl have been extensively utilized as intrathecal adjuvants due to their rapid onset and potent analgesic properties mediated through μ-opioid receptors in the dorsal horn of the spinal cord. Fentanyl enhances the quality of intraoperative analgesia and reduces visceral pain associated with pneumoperitoneum; however, its use is often associated with side effects such as pruritus, nausea, vomiting, and potential respiratory depression [7]. Dexmedetomidine, a highly selective α2-adrenergic agonist, has emerged as a promising alternative intrathecal adjuvant. It exerts its analgesic effect by inhibiting the release of norepinephrine and suppressing neuronal firing in the dorsal horn, thereby enhancing both sensory and motor blockade. Several recent studies have demonstrated that intrathecal dexmedetomidine prolongs the duration of spinal anaesthesia, improves postoperative analgesia, and reduces the requirement for rescue analgesics without significant respiratory depression [8].

Comparative studies evaluating dexmedetomidine and fentanyl as intrathecal adjuvants have shown that dexmedetomidine provides longer duration of analgesia and better attenuation of visceral pain, particularly in abdominal surgeries, while fentanyl offers faster onset but shorter duration of action [9]. Additionally, dexmedetomidine has been associated with improved hemodynamic stability and reduced incidence of opioid-related adverse effects, although it may increase the risk of bradycardia and hypotension in some patients [10].

Despite growing evidence supporting the use of dexmedetomidine, limited data are available specifically comparing dexmedetomidine and fentanyl as adjuvants to isobaric levobupivacaine in segmental spinal anaesthesia for laparoscopic cholecystectomy. Given the increasing adoption of regional anaesthesia techniques in minimally invasive surgeries, a direct comparison of these agents is essential to determine the optimal adjuvant that provides effective anaesthesia with minimal side effects. Therefore, the present study aims to compare the efficacy and safety of intrathecal dexmedetomidine versus fentanyl as adjuvants to isobaric levobupivacaine in segmental spinal anaesthesia for elective laparoscopic cholecystectomy.

Material and Methods

This study was designed as a prospective, randomized, double-blinded comparative clinical study conducted in the Department of Anaesthesiology at a tertiary care teaching hospital. The study was carried out over a defined period after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants prior to inclusion in the study. The study adhered to the ethical principles outlined in the Declaration of Helsinki.

A total of 150 patients scheduled for elective laparoscopic cholecystectomy under segmental spinal anaesthesia were included in the study. Patients were randomly allocated into two equal groups of 75 each using a computer-generated randomization sequence. Group D consisted of patients receiving intrathecal dexmedetomidine, while Group F included patients receiving intrathecal fentanyl as adjuvants to isobaric levobupivacaine.

Patients aged between 18 and 60 years, belonging to American Society of Anesthesiologists (ASA) physical status I and II, and scheduled for elective laparoscopic cholecystectomy were included in the study. Patients with contraindications to spinal anaesthesia, coagulopathy, infection at the injection site, known allergy to study drugs, significant cardiac or neurological disorders, pregnancy, or refusal to participate were excluded from the study.

All patients underwent a thorough preoperative assessment including detailed medical history, physical examination, airway assessment, and relevant investigations such as complete blood count, renal function tests, blood sugar levels, and electrocardiogram. Patients were kept nil per oral as per standard guidelines prior to surgery. On arrival in the operating room, standard monitoring including non-invasive blood pressure, pulse rate, electrocardiogram, and oxygen saturation (SpO_2) was instituted. An intravenous line was secured and patients were preloaded with 10–15 ml/kg of crystalloid solution. Under strict aseptic precautions, spinal anaesthesia was administered in the sitting position at the L2–L3 or L3–L4 intervertebral space using a 25G Quincke spinal needle.

Group D received 1.5–1.8 ml of isobaric levobupivacaine combined with 5 μg dexmedetomidine, while Group F received 1.5–1.8 ml of isobaric levobupivacaine combined with 25 μg fentanyl intrathecally. The total volume of the injectate was kept constant in both groups. The study drug was prepared by an anaesthesiologist not involved in patient management or data collection to ensure blinding of both the patient and the investigator.

After administration of the drug, patients were positioned supine, and oxygen was administered via face mask at 4–6 L/min. Sensory block was assessed using pinprick method and the level of block was recorded. Motor block was assessed using the Modified Bromage Scale. Hemodynamic parameters including heart rate, systolic and diastolic blood pressure, mean arterial pressure, and oxygen saturation were recorded at regular intervals intraoperatively.

The onset time of sensory and motor block, maximum sensory level achieved, duration of sensory block, duration of motor block, duration of effective analgesia, and time to first rescue analgesic were recorded. Intraoperative adverse events such as hypotension, bradycardia, nausea, vomiting, pruritus, respiratory depression, and shoulder pain were noted and managed accordingly. Postoperative pain was assessed using the Visual Analog Scale (VAS), and rescue analgesia was administered when VAS score exceeded 4.

The primary outcome measures included duration of sensory block and duration of postoperative analgesia, while secondary outcomes included onset of block, hemodynamic stability, and incidence of side effects.

The collected data were entered into Microsoft Excel and analyzed using appropriate statistical software. Quantitative variables were expressed as mean ± standard deviation, while qualitative variables were expressed as frequencies and percentages. Comparison between the two groups was performed using Student's unpaired t-test for continuous variables and Chi-square test or Fisher's exact test for categorical variables. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 150 patients were included in the study, with 75 patients in each group. As described in Table 1, the demographic characteristics were comparable between both groups. The mean age in Group D was 44.82 ± 8.94 years, while in Group F it was 45.36 ± 9.72 years, showing no statistically significant difference ($p > 0.05$). The mean height was slightly higher in Group D (156.12 ± 5.21 cm) compared to Group F (154.48 ± 6.34 cm), but this difference was also not significant. The age range in Group D was 26–60 years and in Group F was 27–60 years. Gender distribution showed a predominance of females in both groups, with Group D having 50 females (66.7%) and 25 males (33.3%), while Group F had 52 females (69.3%) and 23 males (30.7%), with no significant difference between groups.

As shown in Table 2, preoperative vital parameters were comparable between both groups. The mean systolic blood pressure in Group D was 112.34 ± 6.12 mmHg compared to 110.18 ± 5.84 mmHg in Group F. Diastolic blood pressure was 74.12 ± 5.66 mmHg in Group D and 72.85 ± 5.92 mmHg in Group F. Mean pulse rate was 81.42 ± 7.15 bpm in Group D and 79.86 ± 6.88 bpm in Group F. Oxygen saturation remained stable in both groups, with values of 99.82 ± 0.28% in Group D and 99.88 ± 0.24% in Group F. Respiratory rate was also comparable, being 14.22 ± 0.64/min in Group D and 14.30 ± 0.71/min in Group F. All parameters showed no statistically significant difference ($p > 0.05$).

Table 3 demonstrates the characteristics of sensory block between the two groups. The highest sensory level achieved was T5 (range T4–T7) in Group D and T6 (range T4–T8) in Group F, with no significant difference ($p > 0.05$). The time to reach peak sensory level was faster in Group D (14.8 ± 2.5 minutes) compared to Group F (16.9 ± 2.2 minutes), but this difference was not statistically significant. However, the time for regression of sensory block by two segments was significantly prolonged in Group D (118.4 ± 14.6 minutes) compared to Group F (92.7 ± 16.8 minutes) with $p < 0.001$. The total analgesic requirement in 24 hours was markedly lower in Group D (75 ± 8.2 mg) compared to Group F (172 ± 24.5 mg), which was highly significant ($p < 0.001$). Additionally, the duration of effective analgesia was significantly longer in Group D (305.6 ± 32.4 minutes) compared to Group F (168.3 ± 28.7 minutes).

As depicted in Table 4, intraoperative pulse rate trends were similar in both groups at all time intervals. At 5 minutes, the pulse rate was 72.10 ± 3.45 bpm in Group D and 72.28 ± 3.52 bpm in Group F. At 15 minutes, it decreased to 62.44 ± 3.18 bpm in Group D and 62.73 ± 3.05 bpm in Group F. At 60 minutes, values were 71.02 ± 2.04 bpm in Group D and 70.88 ± 2.12 bpm in Group F. Even at 120 minutes, pulse rates remained comparable (70.55 ± 2.22 bpm vs 70.74 ± 2.35 bpm). No statistically significant differences were observed at any time interval ($p > 0.05$), indicating stable intraoperative hemodynamics in both groups.Table 5 shows postoperative side effects in both groups. Nausea was observed in 5 patients (6.7%) in Group D and 7 patients (9.3%) in Group F. Vomiting occurred in 1 patient (1.3%) in Group D and 3 patients (4.0%) in Group F. Pruritus was absent in Group D but noted in 4 patients (5.3%) in Group F. Respiratory depression was not observed in either group. Hypotension occurred in 3 patients (4.0%) in Group D and 5 patients (6.7%) in Group F, while bradycardia was seen in 1 patient (1.3%) in Group D and 3 patients (4.0%) in Group F. Urinary retention was noted in 2 patients (2.7%) in

Group D and 6 patients (8.0%) in Group F. All differences in side effects were statistically insignificant ($p > 0.05$), although opioid-related side effects were relatively higher in the fentanyl group.

Table 1: Demographic Characteristics of Study Population

Parameter	Group D (n=75)	Group F (n=75)	P value
Mean Age (years)	44.82 ± 8.94	45.36 ± 9.72	>0.05
Height (cm)	156.12 ± 5.21	154.48 ± 6.34	>0.05
Minimum Age (years)	26	27	—
Maximum Age (years)	60	60	—
Gender (F/M)	50 (66.7%) / 25 (33.3%)	52 (69.3%) / 23 (30.7%)	>0.05

Table 2: Comparison of Preoperative Vital Parameters

Parameter	Group D (n=75)	Group F (n=75)	P value
Systolic BP (mmHg)	112.34 ± 6.12	110.18 ± 5.84	>0.05
Diastolic BP (mmHg)	74.12 ± 5.66	72.85 ± 5.92	>0.05
Pulse Rate (bpm)	81.42 ± 7.15	79.86 ± 6.88	>0.05
SpO_2 (%)	99.82 ± 0.28	99.88 ± 0.24	>0.05
Respiratory Rate (/min)	14.22 ± 0.64	14.30 ± 0.71	>0.05

Table 3: Characteristics of Sensory Block

Parameter	Group D (n=75)	Group F (n=75)	P value
Highest Sensory Level	T5 (T4–T7)	T6 (T4–T8)	>0.05
Time to Peak Level (min)	14.8 ± 2.5	16.9 ± 2.2	>0.05
Regression by 2 Segments (min)	118.4 ± 14.6	92.7 ± 16.8	<0.001
Total Analgesic Dose (mg)	75 ± 8.2	172 ± 24.5	<0.001
Time to First Analgesia (min)	305.6 ± 32.4	168.3 ± 28.7	<0.001

Table 4: Intraoperative Pulse Rate Comparison

Time (min)	Group D (mean ± SD)	Group F (mean ± SD)	P value
5	72.10 ± 3.45	72.28 ± 3.52	>0.05
10	68.42 ± 4.10	68.20 ± 4.18	>0.05
15	62.44 ± 3.18	62.73 ± 3.05	>0.05
30	69.12 ± 2.94	69.05 ± 3.02	>0.05
45	70.68 ± 2.21	70.52 ± 2.28	>0.05
60	71.02 ± 2.04	70.88 ± 2.12	>0.05
90	71.36 ± 3.12	71.20 ± 3.05	>0.05
120	70.55 ± 2.22	70.74 ± 2.35	>0.05

Table 5: Postoperative Side Effects

Side Effect	Group D (n=75)	Group F (n=75)	P value
Nausea	5 (6.7%)	7 (9.3%)	>0.05
Vomiting	1 (1.3%)	3 (4.0%)	>0.05
Pruritus	0 (0%)	4 (5.3%)	>0.05
Respiratory Depression	0 (0%)	0 (0%)	—
Hypotension	3 (4.0%)	5 (6.7%)	>0.05
Bradycardia	1 (1.3%)	3 (4.0%)	>0.05
Urinary Retention	2 (2.7%)	6 (8.0%)	>0.05

Discussion

The present study was conducted to compare the efficacy and safety of intrathecal dexmedetomidine and fentanyl as adjuvants to isobaric levobupivacaine in segmental spinal anaesthesia for elective laparoscopic cholecystectomy. The findings demonstrated that while both adjuvants provided adequate intraoperative anaesthesia with comparable demographic characteristics and baseline vitals, dexmedetomidine showed clear superiority in terms of prolongation of sensory blockade and duration of postoperative analgesia, with a reduced requirement for rescue analgesics. The demographic parameters in the present study were comparable between the two groups, with mean ages of 44.82 ± 8.94 years in Group D and 45.36 ± 9.72 years in Group F, and no statistically significant difference in gender distribution. These findings are consistent with the study by Sharma et

al. [11], who reported no significant demographic differences between dexmedetomidine and fentanyl groups, ensuring homogeneity and eliminating confounding bias in outcome assessment.

Preoperative hemodynamic parameters including systolic blood pressure, diastolic blood pressure, pulse rate, oxygen saturation, and respiratory rate were comparable in both groups ($p > 0.05$), indicating similar baseline physiological status. Similar observations were reported by Verma et al. [12], who found that both dexmedetomidine and fentanyl groups had comparable baseline vitals, suggesting that any subsequent differences in intraoperative and postoperative outcomes could be attributed to the pharmacological properties of the adjuvants rather than baseline variations.

A key finding of the present study was the significantly prolonged duration of sensory blockade in the dexmedetomidine group, with regression to two segments occurring at 118.4 ± 14.6 minutes compared to 92.7 ± 16.8 minutes in the fentanyl group ($p < 0.001$). This is in agreement with findings by Gupta et al. [13], who demonstrated that dexmedetomidine significantly prolongs sensory block duration due to its action on presynaptic C-fibers and postsynaptic dorsal horn neurons, leading to inhibition of nociceptive transmission.

The duration of effective postoperative analgesia was markedly longer in the dexmedetomidine group (305.6 ± 32.4 minutes) compared to the fentanyl group (168.3 ± 28.7 minutes), and the total analgesic requirement in 24 hours was significantly lower (75 ± 8.2 mg vs 172 ± 24.5 mg, $p < 0.001$). These findings correlate well with the study by Singh et al. [14], which reported prolonged analgesia and reduced postoperative analgesic consumption with intrathecal dexmedetomidine when compared to fentanyl, emphasizing its role as a superior adjuvant in spinal anaesthesia.

Although the onset of sensory block was slightly faster in the dexmedetomidine group (14.8 ± 2.5 minutes) compared to the fentanyl group (16.9 ± 2.2 minutes), the difference was not statistically significant ($p > 0.05$). Similar findings were observed by Patel et al. [15], who noted that while fentanyl may offer a marginally faster onset due to its lipophilicity, dexmedetomidine provides a more sustained and stable block profile.

Intraoperative hemodynamic parameters remained stable and comparable between both groups at all time intervals, with no statistically significant differences observed. This suggests that both adjuvants are safe for use in segmental spinal anaesthesia, although dexmedetomidine may offer better attenuation of sympathetic responses. Comparable hemodynamic stability was reported by Sharma et al. [11], supporting the safety profile of dexmedetomidine.

Postoperative side effects were minimal in both groups, with slightly higher incidence of opioid-related adverse effects such as pruritus, nausea, and vomiting in the fentanyl group. In contrast, dexmedetomidine was associated with fewer such side effects, although occasional bradycardia and hypotension were observed. These findings are consistent with Verma et al. [12] and Singh et al. [14], who reported a lower incidence of opioid-related side effects with dexmedetomidine, making it a preferable adjuvant in clinical practice.

Overall, the findings of the present study highlight that intrathecal dexmedetomidine provides prolonged analgesia, reduced postoperative analgesic requirement, and a favorable side effect profile compared to fentanyl, making it a superior adjuvant to isobaric levobupivacaine in segmental spinal anaesthesia for laparoscopic cholecystectomy.

Conclusion

Intrathecal dexmedetomidine as an adjuvant to isobaric levobupivacaine in segmental spinal anaesthesia provides significantly prolonged sensory blockade, longer duration of postoperative analgesia, and reduced analgesic consumption compared to fentanyl, while maintaining stable hemodynamics and minimal side effects. Therefore, dexmedetomidine can be considered a more effective and safer alternative to fentanyl for elective laparoscopic cholecystectomy.

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