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Research Article

Intrathecal Fentanyl, Nalbuphine, and Dexmedetomidine as Adjuvants to Levobupivacaine: A Comparative Study

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ABSTRACT

Background: Regional anesthesia is widely employed for infraumbilical and orthopedic surgeries due to its safety, cost-effectiveness, and ability to provide prolonged postoperative analgesia while attenuating autonomic and endocrine responses. The addition of intrathecal adjuvants to levobupivacaine has been shown to improve block characteristics and extend analgesia. Aim: To compare the effects of intrathecal fentanyl, dexmedetomidine, and nalbuphine as adjuvants to levobupivacaine with respect to block efficacy, duration of action, postoperative analgesia, and perioperative complications.

Methods: This prospective, randomized, controlled clinical study was conducted at Sohag University Hospital on 120 ASA I–II patients aged 20–50 years undergoing lower abdominal and lower limb surgeries. Patients were allocated into four groups (n=30 each): Group L received levobupivacaine 15 mg alone; Group F received levobupivacaine + fentanyl 25 µg; Group D received levobupivacaine + dexmedetomidine 5 µg; Group N received levobupivacaine + nalbuphine 0.8 mg. Block characteristics, analgesia duration, hemodynamic parameters, adverse effects, and postoperative pain scores (VAS) were recorded. Statistical analysis used Student's t-test and Chi-square/Fisher's exact test, with $p < 0.05$ considered significant.

Results: Dexmedetomidine produced the fastest sensory onset (3.1 ± 0.6 min), the highest sensory level (T4), the longest motor block duration (225.4 ± 21.8 min), and prolonged analgesia (338.7 ± 22.1 min). Fentanyl improved analgesia (258.3 ± 20.8 min) but was associated with pruritus (36.7%). Nalbuphine showed intermediate efficacy (249.7 ± 23.1 min) with fewer side effects (pruritus 6.7%). Levobupivacaine alone resulted in the shortest block and analgesia duration (165.8 ± 22.4 min). Hemodynamics remained stable across groups, though bradycardia was more frequent with dexmedetomidine (26.7%). VAS scores were significantly lower in the dexmedetomidine group during the early postoperative period (2–8 hours).

Conclusion: Dexmedetomidine is the most effective intrathecal adjuvant to levobupivacaine for enhancing block quality and prolonging analgesia, though its use requires vigilance for bradycardia. Nalbuphine offers a balanced profile with moderate efficacy and fewer adverse effects, while fentanyl remains effective but is limited by pruritus. The choice of adjuvant should be individualized according to patient comorbidities and surgical requirements.

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Introduction

Regional anesthesia is a safe and cost-effective technique that provides reliable intraoperative conditions and prolonged postoperative pain relief while blunting autonomic and endocrine responses [1]. Spinal anesthesia, in particular, is widely used for infraumbilical and orthopedic surgeries because of its rapid onset, predictable outcomes, and avoidance of risks associated with general anesthesia [2-3]. It reduces the incidence of venous thrombosis, pulmonary embolism, cardiac complications in high-risk patients, bleeding, transfusion requirements, pneumonia, and respiratory depression.

To improve the quality of spinal anesthesia, several intrathecal adjuvants have been investigated. Opioids such as morphine, fentanyl, nalbuphine, and sufentanil, as well as non-opioid agents including epinephrine, clonidine, neostigmine, adenosine, midazolam, and magnesium sulfate, have been shown to enhance block characteristics and prolong analgesia [4].

Aim of the Work: This study aimed to compare the effects of intrathecal fentanyl, dexmedetomidine, and nalbuphine as adjuvants to levobupivacaine with respect to block efficacy, duration of action, postoperative analgesia, and perioperative complications.

Methods

This prospective, randomized, controlled clinical study was conducted at Sohag University Hospital following approval by the Ethics and Research Committee of Sohag Faculty of Medicine. Ethical committee approval number (soh-med-25—15PD), Written informed consent was obtained from all participants.

Inclusion criteria: ASA I–II patients aged 20–50 years, no known allergy to local anesthetics, and willingness to provide informed consent.

Exclusion criteria: Patient refusal, ASA ≥ III, anemia, heart disease, hypovolemia, shock, septicemia, hypertension, coagulation disorders, local infection, spinal deformities, or allergy to trial drugs.

Study groups (n=30 each):

- Group L: Levobupivacaine 15 mg (3 ml of 0.5% hyperbaric solution) [1]
- Group F: Levobupivacaine 15 mg + fentanyl 25 µg [2-3]
- Group D: Levobupivacaine 15 mg + dexmedetomidine 5 µg [5-8]
- Group N: Levobupivacaine 15 mg + nalbuphine 0.8 mg [4,9]

Monitoring included ECG, NIBP, and SpO_2. Patients were preloaded with 1000 ml Ringer lactate. Subarachnoid block was performed at L2–L3 using a 23G spinal needle under aseptic conditions.

Measurements: Sensory onset, motor onset, duration of motor block, duration of analgesia, VAS scores at 2–24 hours, and complications (hypotension, bradycardia, respiratory depression, desaturation, nausea/vomiting, pruritus, shivering). Rescue analgesia was IV ketorolac 1 mg/kg when VAS ≥ 4.

Statistical analysis: Student's t test for continuous variables and chi square/Fisher's exact test for categorical variables Repeated measures data were analyzed using two-way ANOVA with Bonferroni correction. Significance was set at $p < 0.05$.

Results

A total of 120 patients completed the study, with no significant differences in demographic profiles (age, gender, weight, ASA status) or duration of surgery among the groups (Table 1).

Dexmedetomidine produced the fastest sensory onset, highest sensory level, longest motor block duration, and prolonged analgesia compared to the other groups (Table 2). Fentanyl improved analgesia but was associated with a high incidence of pruritus (Table 3). Nalbuphine showed intermediate efficacy with fewer side effects. Levobupivacaine alone resulted in the shortest block and analgesia duration.

Hemodynamic parameters remained stable across groups. Heart rate (Table 4) and mean blood pressure (Table 5) did not differ significantly among groups. However, dexmedetomidine was associated with a higher incidence of bradycardia. Shivering was most common in the control group and absent in the dexmedetomidine group.

VAS scores (Table 6) were significantly lower in the dexmedetomidine group during the early postoperative period (2–8 hours), indicating superior analgesic efficacy. By 12–24 hours, pain scores converged across groups.

Table 1- Demographic data

Variable	Group D (n=30)	Group N (n=30)	Group F (n=30)	Group L (n=30)	P value
Age (years, mean ± SD)	37.40 ± 12.61	35.41 ± 13.51	37.41 ± 15.32	36.40 ± 13.61	0.97
Gender (M/F)	13 / 17	15 / 15	14 / 16	12 / 18	0.38
ASA physical status (I/II)	10 / 20	16 / 14	11 / 19	14 / 16	0.15

Duration of surgery (min, mean ± SD)	108.60 ± 14.06	107.50 ± 11.87	111.55 ± 23.05	101.50 ± 15.65	0.851

Table 2- Characteristics of sensory and motor block among study groups

Parameter	Group D (Dexmedetomidine)	Group N (Nalbuphine)	Group F (Fentanyl)	Group L (Control)	P value
Sensory onset to T10 (min, mean ± SD)	3.1 ± 0.6 **	4.1 ± 0.9 *	3.9 ± 0.8 *	4.8 ± 1.1	<0.001
Maximum sensory level (median (range))	T4 ± 0.9 **	T5 ± 1.1	T5 ± 1.0	T6 ± 1.2	<0.01
Two-segment regression (min, mean ± SD)	246.3 ± 18.5 **	192.8 ± 17.5 *	198.4 ± 16.2 *	132.5 ± 15.7	<0.001
Motor onset (Bromage 3, min, mean ± SD)	5.5 ± 1.1 **	6.9 ± 1.3	6.8 ± 1.4	7.2 ± 1.5	<0.001
Motor duration (min, mean ± SD)	225.4 ± 21.8 **	171.2 ± 19.5 *	178.6 ± 18.9 *	155.3 ± 20.1	<0.001
Analgesia duration (min, mean ± SD)	338.7 ± 22.1 **	249.7 ± 23.1 *	258.3 ± 20.8 *	165.8 ± 22.4	<0.001

*Values are presented as mean ± SD. * statistically Significant compared to the L group. **statistically Significant compared to group F

Table 3- Incidence of adverse effects among study groups

Adverse effect	Group D (Dexmedetomidine)	Group N (Nalbuphine)	Group F (Fentanyl)	Group L (Control)	P value
Hypotension	7 (23.3%)	4 (13.3%)	5 (16.7%)	4 (13.3%)	0.65
Bradycardia	8 (26.7%) **	1 (3.3%)	2 (6.7%)	1 (3.3%)	<0.01
Nausea and vomiting	3 (10%)	4 (13.3%)	6 (20%)	3 (10%)	0.58
Pruritus	0 (0%)	2 (6.7%) #	11 (36.7%) *	0 (0%)	<0.001
Shivering	0 (0%) *	2 (6.7%)	1 (3.3%)	5 (16.7%)	<0.05

*Values are presented as the number of patients (%). * statistically Significant compared to the L group. **statistically Significant compared to group F. # statistically significant compared to group D

Table 4- Comparison between groups with regard to heart rate (beats/min)

Time (min)	Group D (Dexmedetomidine)	Group N (Nalbuphine)	Group F (Fentanyl)	Group L (Control)	P value
Baseline	80.32 ± 3.34	82.60 ± 5.82	81.90 ± 8.42	85.90 ± 8.16	—
5	83.80 ± 7.66	80.32 ± 7.32	88.32 ± 6.54	88.60 ± 7.71	0.616
10	82.43 ± 15.21	78.32 ± 7.54	83.32 ± 7.71	83.80 ± 7.66	0.165
15	82.60 ± 5.82	76.45 ± 6.66	82.21 ± 5.32	82.60 ± 5.82	0.216
20	82.43 ± 15.21	76.33 ± 3.33	80.32 ± 7.43	80.21 ± 6.41	0.590
30	82.43 ± 15.21	82.60 ± 5.82	80.32 ± 3.34	79.80 ± 5.23	0.724
40	78.32 ± 7.54	83.80 ± 7.66	82.43 ± 15.21	80.21 ± 4.32	0.099
50	78.70 ± 3.22	82.43 ± 15.21	82.60 ± 5.82	80.40 ± 5.43	0.651
60	82.60 ± 5.82	78.70 ± 3.22	83.80 ± 7.66	78.32 ± 7.54	0.321
75	78.70 ± 3.22	80.32 ± 3.34	78.70 ± 3.22	78.21 ± 3.54	0.224
90	78.32 ± 7.54	82.43 ± 15.21	83.80 ± 7.66	80.40 ± 3.63	0.167
105	80.32 ± 3.34	78.70 ± 3.22	82.60 ± 5.82	77.60 ± 3.37	0.819
120	78.70 ± 3.22	78.70 ± 3.22	80.32 ± 3.34	78.70 ± 3.22	0.270
150	82.60 ± 5.82	78.32 ± 7.54	78.70 ± 3.22	80.32 ± 3.34	0.220
180	78.70 ± 3.22	82.43 ± 15.21	82.60 ± 5.82	80.23 ± 3.66	0.238

*Values are presented as mean ± standard deviation (beats/min). There was no statistically significant difference between the four study groups at any time point.

Table 5- Comparison between groups regarding mean blood pressure (mmHg)

Time (min)	Group D (Dexmedetomidine)	Group N (Nalbuphine)	Group F (Fentanyl)	Group L (Control)	P value
5	102.32 ± 11.07	102.45 ± 11.53	101.65 ± 7.96	101.25 ± 10.32	0.861
10	89.72 ± 10.8	90.20 ± 8.45	90.20 ± 8.45	93.10 ± 8.93	0.724
15	90.20 ± 8.45	96.60 ± 4.18	96.60 ± 4.18	92.10 ± 2.93	0.120

20	93.10 ± 8.93	89.72 ± 10.8	93.10 ± 8.93	89.72 ± 10.8	0.325
30	96.60 ± 4.18	90.20 ± 8.45	89.72 ± 10.8	88.79 ± 5.08	0.531
40	93.10 ± 8.93	93.10 ± 8.93	90.20 ± 8.45	91.50 ± 6.06	0.722
50	96.60 ± 4.18	96.60 ± 4.18	93.90 ± 3.32	90.20 ± 8.45	0.139
60	93.90 ± 3.32	89.72 ± 10.8	90.20 ± 8.45	96.60 ± 4.18	0.870
75	90.20 ± 8.45	90.20 ± 8.45	89.72 ± 10.8	93.90 ± 3.32	0.297
90	90.20 ± 8.45	93.10 ± 8.93	90.20 ± 8.45	90.01 ± 1.08	0.361
105	93.10 ± 8.93	90.20 ± 8.45	89.72 ± 10.8	94.50 ± 16.4	0.902
120	90.20 ± 8.45	93.90 ± 3.32	90.20 ± 8.45	92.79 ± 6.60	0.114
150	93.90 ± 3.32	90.20 ± 8.45	93.10 ± 8.93	92.43 ± 11.54	0.112
180	89.72 ± 10.8	96.60 ± 4.18	89.72 ± 10.8	93.33 ± 4.32	0.341

*Values are presented as mean ± standard deviation (mmHg). There was no statistically significant difference between the four study groups at any time point.

Table 6- Comparison between groups with regard to Visual Analog Scale (VAS) scores

Time (hour)	Group D (Dexmedetomidine)	Group N (Nalbuphine)	Group F (Fentanyl)	Group L (Control)	P value
Baseline	0	0	0	0	0.999
2	0	2 (2–2)	0	2 (0–2)	<0.001
4	0	2 (2–2)	0	4 (4–4)	<0.001
6	2 (0–2)	2 (2–2)	2 (0–2)	3 (2–6)	<0.001
8	2 (2–2)	2 (0–4)	2 (2–2)	3 (2–4)	<0.001
12	2 (2–2)	2 (–2)	2 (2–2)	2 (2–2)	0.999
18	2 (2–2)	2 (–2)	2 (2–2)	2 (2–2)	0.999
24	2 (2–2)	2 (–2)	2 (2–2)	2 (2–2)	0.999

*Values are presented as median (range). VAS = Visual Analog Scale (0 = no pain, 10 = worst pain). Statistical significance was observed at early time points (2–8 min), with Group L showing higher scores compared to Groups D and F.

Discussion

Neuraxial anesthesia especially spinal anesthesia has markedly changed over the past decades, there is different adjuvants had integrated to local anesthetics which affect and improve the quality of the block characteristics, prolonging post operative analgesia, prolong the block time and enhancing patient outcomes. [10-11]. The ideal adjuvants for each surgery is still questionable.

This study revealed that dexmedetomidine when added to levobupivacaine in spinal anesthesia, significantly accelerated the sensory onset to the T10 dermatome compared to nalbuphine, fentanyl, and levobupivacaine alone (P<0.001). This rapid onset aligns with the action of α-2 adrenoreceptor agonists [12]. Comparable results were noted by Kumar et al. [10], who found dexmedetomidine shorten the onset of the sensory block compared with fentanyl in ropivacaine-based spinal anesthesia used lower limb surgeries, this may be caused by synergistic effect of both drugs on spinal nociceptive modulation. Khare et al. [13] also reported that dexmedetomidine produced quicker sensory and motor block than nalbuphine with hyperbaric bupivacaine (P < 0.05).

Gupta et al. [14] found faster sensory block with fentanyl (6.25 ± 1.89 min) than with dexmedetomidine (8.70 ± 1.93 min) in hyperbaric levobupivacaine for lower abdominal surgeries. They thought this might be because fentanyl is highly lipophilic, though other factors like drug concentration or patient positioning could also play a role. Joseph et al. [15] also reported quicker onset with fentanyl (1.80 ± 0.74 min) compared to clonidine (1.94 ± 0.49 min) or buprenorphine (2.28 ± 0.46 min) (P = 0.006), again highlighting how fast lipophilic opioids penetrate neuraxial tissues.

Regarding the duration of sensory blockade, dexmedetomidine showed superior effect as it showing prolonged two-segment regression and longer total post analgesic time compared to nalbuphine, fentanyl, and the control group (P<0.001). Gupta et al. [14] corroborated a longer sensory blockade with dexmedetomidine (308.28±6.36 min) than fentanyl (232.28±7.01 min) in hyperbaric levobupivacaine. A meta-analysis by Gupta et al. [16] confirmed dexmedetomidine's superiority in sensory regression (SMD −3.34, CI [−4.07, −2.62], P<0.00001) and analgesia (SMD −7.34, CI [−11.08, −3.60], P=0.0001) versus fentanyl, despite high heterogeneity (I^2=59-97%).

Consistent patterns emerged across studies with varied anesthetics. Prasad et al. [17] reported longer two-segment regression with dexmedetomidine (144.88 ± 28.39 min) than with fentanyl (131.86 ± 31.61 min) (P = 0.033) in hyperbaric ropivacaine, and analgesia lasted much longer too (431.82 ± 85.38 min vs. 308.38 ± 66.92 min, P < 0.001). Saha et al. [18] found similar results in cesarean sections: dexmedetomidine gave a sensory block of 138.14 ± 14.35 min versus 131.86 ± 7.85 min for fentanyl (P < 0.05) with hyperbaric levobupivacaine. Sahoo and Pattanayak [19] also noted that

dexmedetomidine prolonged both sensory and motor block compared to fentanyl ($P < 0.0001$) in infra-umbilical surgeries, which delayed the need for rescue pain medication.

Motor block was also noticeably longer in the dexmedetomidine group. Agrawal et al. [12] found a longer motor block with dexmedetomidine (242 ± 22 min) than with fentanyl in hyperbaric bupivacaine ($P < 0.001$). Kumar et al. [10] and Khare et al. [13] reported the same, with dexmedetomidine outperforming both fentanyl and nalbuphine ($P < 0.05$). Joseph et al. [15] pointed out that fentanyl's shorter duration (168.9 ± 13.54 min) compared to clonidine (191.7 ± 24.82 min) or buprenorphine (177.27 ± 22.53 min) ($P < 0.001$) might actually be helpful when you want patients to move around sooner. Gupta et al. [14] reported 198.20 ± 6.52 min with dexmedetomidine versus 157.45 ± 6.30 min with fentanyl. Bhure and Jagtap [20] observed faster regression in the levobupivacaine-only group, which reinforces the idea that adjuvants should be chosen based on what you need for each case.

Postoperative pain scores varied between groups. Not surprisingly, levobupivacaine alone gave higher scores in the first few hours, while dexmedetomidine and fentanyl kept pain to a minimum. By 12 hours, though, the scores evened out across all groups ($P < 0.001$). Katti et al. [21] found nalbuphine was superior in post operative analgesia time (278.31±9.58 min) to fentanyl (230.83±7.98 min) in bupivacaine for lower limb orthopedic surgery. Koppal et al. [22] reported that nalbuphine lasted 430.3 ± 11.13 minutes versus fentanyl's 285.97 ± 8.8 minutes ($P = 0.001$) in isobaric levobupivacaine. Naaz et al. [23] showed dose-dependent effects with nalbuphine (441 ± 119.69 min and 450 ± 103.38 min) compared to fentanyl (300.0 ± 88.53 min) ($P = 0.05$). Satapathy et al. [24] confirmed 388 ± 24.88 minutes for nalbuphine versus 304.70 ± 15.76 minutes for fentanyl ($P < 0.001$).

Dexmedetomidine show its high ability to prolong post operative analgesia. Bajwa et al. [25] reported that clonidine is higher effect over fentanyl for longer analgesia, despite sedation. Kamel et al. [26] noted that both dexmedetomidine and fentanyl work better than magnesium, dexmedetomidine being the safer option. Soori et al. [11] placed dexmedetomidine as the optimum adjuvant choice for lower body surgeries.

Adverse effects were quite different across groups. Fentanyl caused much more itching (pruritus) than nalbuphine, dexmedetomidine, or the control group. Dexmedetomidine, on the other hand, tended to slow the heart rate more than the others. Shivering didn't happen at all in the dexmedetomidine group but was seen in the control group. Nausea and vomiting rates were similar across all groups, and hypotension occurred at about the same frequency too. Mehdi et al. [27] found epidural fentanyl and nalbuphine are comparable hemodynamically.

In our study the Hemodynamics showed significant bradycardia in dexmedetomidine group. contrasting Soori et al. [11] dexmedetomidine associated with bradycardia ($P=0.033$ for HR; $P=0.012$ for MAP). Khare et al. [13] and Prasad et al. [17] reported stability, suggesting protocol-driven management allows focus on block efficacy over hemodynamics.

The limitation of This study was single-center with a small sample size. The study used fixed doses of drugs.

Conclusion

This prospective, randomized study demonstrates that adding intrathecal adjuvants to local anesthetics (levobupivacaine) significantly influence the efficacy and safety of spinal anesthesia. Dexmedetomidine gave us the best block characteristics and the longest post operative analgesia, though its use requires careful monitoring for bradycardia. Nalbuphine offered moderate efficacy with a more favorable safety profile, making it a suitable alternative in patients where tolerability is paramount. Fentanyl remained effective as it also prolong post operative analgesia but was limited by pruritus, levobupivacaine alone associated with the shortest duration of sensory blockade and shortest pst operative analgesia duration.

In clinical practice, the choice of intrathecal adjuvant should be directed and controlled by patient comorbidities and surgical requirements. Dexmedetomidine may be preferred when prolonged anesthesia and analgesia are desired, nalbuphine can be considered in patients at risk of opioid related side effects, and fentanyl should be reserved for selected cases. Levobupivacaine alone is less optimal and benefits from the addition of an adjuvant.

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