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Original Article

Anaesthesia Section

Comparison between Intrathecal Dexmedetomidine versus Nalbuphine as Adjuvants to Hyperbaric Bupivacaine in Lower Limb Orthopaedic Surgeries: A Randomised Clinical Trial

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ABSTRACT

Introduction: Spinal anaesthesia with local anaesthetics alone provides a limited duration of action for lower limb orthopaedic surgeries. Adjuvants can enhance anaesthetic efficacy while minimising side-effects. Both dexmedetomidine and nalbuphine have been used as intrathecal adjuvants.

Aim: To compare the efficacy and safety profiles of intrathecal dexmedetomidine versus nalbuphine as adjuvants to hyperbaric bupivacaine 0.5% in spinal anaesthesia for lower limb orthopaedic surgeries.

Materials and Methods: This randomised clinical trial was conducted at the Department of Anaesthesiology, Dhiraj Hospital, Vadodara, Gujarat, India, from January 2023 to June 2024. Sixty patients (American Society of Anaesthesiologists Physical Status (ASA PS) I-II, aged 20-60 years) undergoing elective lower limb orthopaedic surgeries were randomly allocated using a computer-generated sequence into two groups (n=30 each). Group D received hyperbaric bupivacaine 0.5% (3.3 mL=16.5 mg) with dexmedetomidine 10 µg, and Group N received hyperbaric bupivacaine 0.5% (3.3 mL=16.5 mg) with nalbuphine 1 mg intrathecally. Primary outcomes included the onset and duration of sensory and motor blockade. Secondary outcomes included haemodynamic parameters, sedation levels, duration of analgesia, and side-effects. Statistical analysis was performed using unpaired Student's t-tests and Chi-square tests, with p-value <0.05 considered statistically significant.

Results: The demographic profiles of patients in both groups were comparable, with no statistically significant differences observed. Dexmedetomidine provided a significantly faster onset of sensory blockade at L1 (2.06±0.32 vs 2.98±0.63 mins, p-value <0.0001) and motor blockade (2.58±0.32 vs 3.86±0.84 mins, p-value <0.0001). The duration of sensory blockade (490.9±32.81 vs 337.73±29.85 mins, p-value <0.0001) and motor blockade (456.6±35.19 vs 354.4±33.22 mins, p-value <0.0001) was significantly longer in Group D. Two-segment regression time was prolonged in Group D (159.47±14.38 vs 138.97±9.97 mins, p-value <0.0001). Systolic blood pressure was significantly lower intraoperatively in Group D. Time to first rescue analgesia was 420.8±39.14 mins in Group D versus 370.67±34.65 mins in Group N (p-value=0.001). Hypotension occurred in 23.33% of Group D patients versus 10.00% of Group N patients, while shivering was more common in Group N (16.67% vs 3.33%).

Conclusion: Both dexmedetomidine and nalbuphine are effective adjuvants to hyperbaric bupivacaine. Dexmedetomidine provides a longer duration of blockade with potential anti-shivering effects, whereas nalbuphine offers earlier motor recovery with more stable haemodynamics. Adjuvant selection should be individualised based on surgical requirements and patient characteristics.

Keywords: Alpha-2 agonist, Local anaesthetics, Opioid, Postoperative analgesia, Spinal anaesthesia

INTRODUCTION

Subarachnoid (spinal) block is a safe and effective alternative to general anaesthesia, particularly for surgical interventions involving the lower extremities and perineum [1]. This technique delivers local anaesthetic into the subarachnoid space, producing sensory and motor blockade. A key advantage over general anaesthesia is the avoidance of endotracheal intubation and its associated airway risks [2]. In addition to improving airway safety, subarachnoid block attenuates the perioperative stress response, reduces inflammation and metabolic disturbances, and promotes faster recovery compared with general anaesthesia [3]. In orthopaedic and hip fracture surgeries, spinal anaesthesia has also been shown to reduce intraoperative blood loss, likely by inducing vasodilation and inhibiting sympathetic tone. This reduction in blood loss helps lower the risk of venous thromboembolism [4].

Bupivacaine, a commonly used amide-type local anaesthetic for subarachnoid block in orthopaedic surgeries, inhibits pain transmission by blocking sodium channels [1,5]. Adjuvants, when co-administered, prolong anaesthesia and analgesia, improve block quality, and reduce potential toxicity, thereby overcoming the limited duration of local anaesthetics [2,5-8]. Dexmedetomidine, a selective α2-adrenergic agonist, hyperpolarises spinal neurons to inhibit nociceptive transmission and dose-dependently prolongs sensory and motor blockade with minimal respiratory depression [5,9,10]. Nalbuphine is a κ-opioid receptor agonist and partial µ-opioid receptor antagonist, exhibiting a ceiling effect on respiratory depression. Its safety profile has been demonstrated systemically [11,12]. Dexmedetomidine acts rapidly due to high lipid solubility, lasting 4-6 hours, while hydrophilic nalbuphine has a slower onset but may provide prolonged analgesia [13,14].

Swain A et al., emphasise tailoring intrathecal adjuvant selection to surgical and patient factors. They report that dexmedetomidine produces a strong prolongation of sensory and motor block, whereas nalbuphine offers effective analgesia with fewer adverse effects, providing a safer, balanced alternative in many settings [15]. However, direct comparative studies between these two agents

remain limited. Previous comparisons include studies by Singhal G et al., Michael RM and Mehta M, and Nagraj B et al., though these studies varied considerably in design, dosing protocols, and outcome measures [16-18].

The existing literature shows inconsistent results regarding optimal dosing, with limited data specifically in orthopaedic surgical populations. These gaps—particularly the lack of standardised dosing protocols and the variability in outcome measures—necessitated this comparative evaluation [1,16]. This study compares intrathecal dexmedetomidine and nalbuphine with bupivacaine to provide evidence-based guidance for effective and safe anaesthesia and analgesia.

The study was designed to compare the efficacy and safety of intrathecal dexmedetomidine versus nalbuphine as adjuvants to hyperbaric bupivacaine in spinal anaesthesia for lower limb orthopaedic surgeries, aiming to determine the optimal adjuvant choice for improved anaesthetic outcomes. The primary outcomes were the onset and duration of sensory and motor blockade. Secondary outcomes included haemodynamic stability, sedation levels, duration of postoperative analgesia, and incidence of adverse effects.

MATERIALS AND METHODS

This triple-blinded randomised clinical study was conducted in the Department of Anaesthesiology at Dhiraj Hospital, SBKS Medical Institute and Research Centre, Sumandeep Vidyapeeth, Vadodara, Gujarat, India, from January 2023 to June 2024. The study protocol was approved by the Institutional Ethics Committee (IEC/2023/AN/012) [IEC approval letter available on request] and registered with the Clinical Trial Registry (CTRI/2025/01/079279). Written informed consent was obtained from all participants prior to inclusion.

Sample size calculation: Sample size was calculated using the formula:

$$n=2\sigma^2(Z\alpha/2+Z\beta)^2/d^2$$

Where:

- σ=population standard deviation (32.81 based on pilot study)
- $Z\alpha/2$=1.96 (for α=0.05, two-tailed)
- $Z\beta$=0.84 (for 80% power)
- d=minimal clinically relevant difference (30 minutes)

$n=2(32.81)^2(1.96+0.84)^2/(30)^2=18.8$

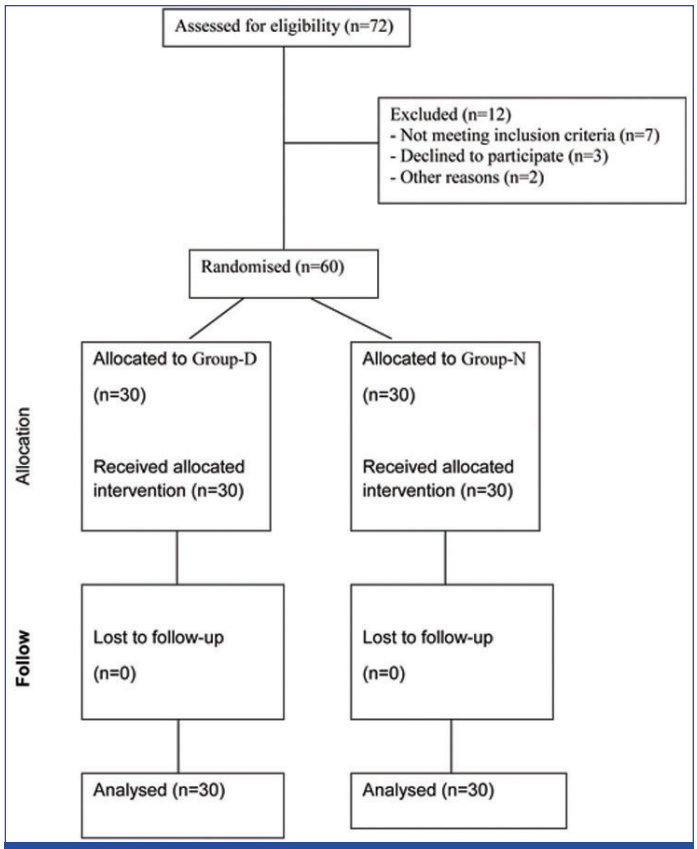
Considering potential dropouts, a sample size of 30 patients per group was determined.

Study population: Sixty patients aged 20-60 years, classified as ASA Grade I or II, scheduled for elective lower limb orthopaedic surgeries under spinal anaesthesia, were enrolled.

Inclusion criteria: Patients aged 20-60 years, classified as ASA physical status Grade I or II, scheduled for elective lower limb surgeries under spinal anaesthesia, willing to provide written informed consent, and had no known allergies to the study drugs were included in the study.

Exclusion criteria: Patients were excluded if they refused participation, were not nil per oral preoperatively according to standard protocol, or had a history of seizure disorders, known drug allergies, or neurological disorders including neuropathies. Patients classified as ASA physical status Grades III–V were ineligible. Pre-existing co-morbidities such as cardiac, respiratory, renal, or hepatic dysfunction, as well as pregnancy, led to exclusion. Additionally, contraindications to spinal anaesthesia—such as increased intracranial pressure, coagulopathy, local site infection, severe spinal deformity, severe thrombocytopenia, current anticoagulation therapy, haemodynamic instability, or patient refusal—resulted in exclusion.

Randomisation and blinding: Randomisation was performed using computer-generated random numbers, and group allocation was concealed in sequentially numbered, opaque, sealed envelopes to ensure allocation concealment [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram.

Group D (n=30): 10 µg dexmedetomidine (0.1 mL) with 3.3 mL 0.5% hyperbaric bupivacaine (total volume 3.4 mL) [19].

Group N (n=30): 1 mg nalbuphine (0.1 mL) with 3.3 mL 0.5% hyperbaric bupivacaine (total volume 3.4 mL) [20].

Syringes were prefilled with the study drug solution by the main investigator. The anaesthesiologist performing the block, the observer recording the data, and the patients were blinded to group allocation. The allocation sequence, enrolment, and assignment to interventions were performed by the main investigator. To minimise bias, strict blinding protocols were maintained throughout the study, and standardised data collection forms were used.

Study Procedure

After preoperative assessment and investigations, patients were kept nil by mouth for solids for eight hours and for clear liquids for two hours. Premedication included tab. alprazolam 0.25 mg at bedtime the night before surgery. In the operating room, an 18G intravenous cannula was placed, and patients were preloaded with Ringer's lactate solution (10 mL/kg). All patients received premedication with intravenous glycopyrrolate (0.004 mg/kg) and ondansetron (0.08 mg/kg). Baseline parameters (blood pressure, pulse rate, respiratory rate, SpO_2) were recorded. Spinal anaesthesia was performed with the patient in the sitting position using a 25G Quincke spinal needle at the L3-L4 or L4-L5 intervertebral space under strict aseptic precautions. After confirming free flow of cerebrospinal fluid, the study drug was injected intrathecally. Patients were immediately placed supine for uniform drug distribution.

Postoperative anaesthetic protocol: Patients were monitored in the postanaesthesia care unit for at least two hours. Standard monitoring included continuous ECG, pulse oximetry, and blood pressure measurements. Patients were transferred to the ward after satisfactory recovery from anaesthesia.

Assessment Parameters

Primary outcome measures:

- Onset of sensory blockade (time from intrathecal injection to loss of pinprick sensation)
- Duration of sensory blockade (time from onset to complete recovery)
- Onset of motor blockade (time to achieve Bromage grade 3)
- Duration of motor blockade (time from onset to complete recovery)

Secondary outcome measures:

- Haemodynamic parameters (heart rate, blood pressure, SpO_2, respiratory rate)
- Sedation levels (Ramsay Sedation Scale)
- Duration of postoperative analgesia

Incidence of adverse effects: Sensory blockade was assessed using the pinprick method with a 23G hypodermic needle at 2 and 5 minutes after injection, then at 5-minute intervals until two consecutive assessments showed the same level (fixation of level), after which assessments were done every 30 minutes. Onset was defined as the time from intrathecal injection to loss of pinprick sensation. The highest sensory level was determined, and the time to two-segment regression was recorded.

Motor blockade was assessed using the Bromage scale:

0: Able to move hip, knee, and ankle

1: Unable to move hip, able to move knee and ankle

2: Unable to move hip and knee, able to move ankle

3: Unable to move hip, knee, and ankle.

Assessments were performed at baseline, 5, 10, 15, 30, 45, 60, 90, and 120 minutes after intrathecal injection, and then every 30 minutes until complete motor block regression. Onset was defined as time to achieve Bromage grade 3, and duration as time from onset to complete recovery (grade 0). Haemodynamic parameters (heart rate, systolic and diastolic blood pressure, oxygen saturation, and respiratory rate) were monitored at baseline, 5, 10, 15, 30, 45, and 60 minutes intraoperatively, then every 30 minutes postoperatively until rescue analgesia was administered. The Ramsay Sedation Scale was used for its simplicity and reliability in assessing consciousness levels during regional anaesthesia. A score of 2-3 was considered optimal, providing anxiolysis without respiratory compromise. The Visual Analog Scale (VAS) was explained to all patients preoperatively. The VAS consists of a 10 cm horizontal line with 'no pain' at 0 cm and 'worst imaginable pain' at 10 cm. Postoperative pain was assessed using the VAS at 0, 10, 15, 30, and 60 minutes, then at 30-minute intervals until the patient received rescue analgesia. Duration of analgesia was defined as the time from intrathecal injection to VAS score ≥4. Rescue analgesia was provided with intravenous diclofenac sodium 75 mg when the VAS score reached ≥4.

Adverse effects: Adverse effects, including nausea, vomiting, pruritus, hypotension, bradycardia, respiratory depression, and shivering, were recorded.

Management of complications: Bradycardia (heart rate <60/min) was treated with intravenous atropine 0.6 mg. Hypotension (systolic blood pressure <90 mmHg or >30% decrease from baseline) was managed with intravenous mephentermine 6 mg.

Respiratory depression (defined as RR ≤10 breaths/min or SpO_2 <95%) was treated with oxygen 6 L/min via facemask.

STATISTICAL ANALYSIS

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) software version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean±standard deviation, and categorical variables as frequency (percentage). Normality was assessed using the Shapiro-Wilk test. Unpaired Student's t-tests were used to compare continuous variables between groups. Chi-square or Fisher's exact tests were applied for categorical variables. A p-value <0.05 was considered statistically significant. For multiple comparisons at different time points, Bonferroni correction was applied.

RESULTS

The demographic profiles of patients in both groups were comparable, with no statistically significant differences observed [Table/Fig-2].

Parameter	Group D (n=30)	Group N (n=30)	t-value	p-value
Age (years)	34.60±8.15	36.27±12.42	**0.628**	0.523
Sex (Male:Female)	21:9	23:7	-	0.559
Weight (kg)	59.47±6.59	61.67±8.92	**1.098**	0.276
ASA Grade (I:II)	16:14	14:16	-	0.606

[Table/Fig-2]: Demographic and baseline characteristics.
Values are presented as mean±SD or numbers. Unpaired student's t-test was used for statistical and Chi-square test for categorical variables p-value: p<0.05* statistically significant

The onset of sensory blockade at the L1 and T10 levels was significantly faster in Group D compared to Group N. Both sensory and motor blockade durations were significantly prolonged in Group D. Two-segment regression time was also significantly longer in Group D. Group D demonstrated a significantly prolonged duration of analgesia with reduced rescue analgesic requirements compared to Group N [Table/Fig-3].

Parameter	Group D Mean±SD	Group N Mean±SD	t-value	p-value
Onset of sensory block at L1 (mins)	2.06±0.32	2.98±0.63	**7.21**	<0.0001
Onset of sensory block at T10 (mins)	4.67±0.9	5.38±0.91	**3.05**	0.0008
Two-segment regression time (mins)	159.47±14.38	138.97±9.97	**6.46**	<0.0001
Onset of motor block (mins)	2.58±0.32	3.86±0.84	**7.88**	<0.0001
Duration of motor block (mins)	456.6±35.19	354.4±33.22	**11.56**	<0.0001
Duration of sensory block (mins)	490.9±32.81	337.73±29.85	**18.91**	<0.0001
Time to first rescue analgesia (mins)	420.8±39.14	370.67±34.65	**5.26**	0.001

[Table/Fig-3]: Characteristics of spinal block.
Values are presented as mean±SD or numbers. Unpaired student's t-test was used for statistical analysis p-value: p<0.001** statistically highly significant

The distribution of the highest sensory level achieved was not significantly different between groups, with T6 being the most common level in both groups. However, the time to achieve each level was significantly faster in Group D at all levels [Table/Fig-4].

Level	Group D n (%)	Group N n (%)	p-value	Time to achieve (min) Group D	Time to achieve (min) Group N	p-value for time
T4	5 (16.67)	2 (6.67)	0.404	7.42±0.68	8.15±0.92	0.018
T6	18 (60.00)	18 (60.00)	1.000	6.08±0.51	6.89±0.88	<0.001
T8	7 (23.33)	10 (33.33)	0.398	5.79±0.44	6.45±0.76	0.003

[Table/Fig-4]: Highest sensory level achieved and time to achieve each level.
Values are presented as mean±SD or numbers. Unpaired student's t-test t was used for statistical and Chi-square test for categorical variables p-value: p<0.05* statistically significant

Preoperative vital parameters were comparable between groups, except for systolic blood pressure, which was significantly higher in Group N compared to Group D. Intraoperative monitoring revealed progressive haemodynamic changes over time. Heart rate showed no significant differences initially but became significantly lower in Group D at 45 and 60 minutes. Systolic blood pressure was consistently lower in Group D throughout the monitoring period, with significant differences at all time points except baseline.

Diastolic blood pressure showed significant differences from 5-30 minutes. Respiratory Rate (RR) and Oxygen Saturation (SpO_2) remained stable and comparable between both groups throughout all recorded intervals (p-value >0.05) [Table/Fig-5].

Time (mins)	Parameter	Group D (n=30)	Group N (n=30)	t value	p-value
0	Heart Rate (beats/min)	80.63±11.36	80.53±8.08	0.041	0.968
	Systolic BP (mmHg)	118.73±7.44	126.53±11.24	3.093	0.003
	Diastolic BP (mmHg)	76.70±7.95	79.73±9.77	1.334	0.188
	Respiratory Rate (RR) (breaths/min)	14.87±1.52	15.10±1.43	0.606	0.547
	SpO_2 (%)	99.00±0.93	98.90±0.92	0.402	0.689
5	Heart Rate (beats/min)	76.63±11.02	77.93±7.31	0.548	0.587
	Systolic BP (mmHg)	113.53±7.39	118.17±9.56	2.154	0.036
	Diastolic BP (mmHg)	71.87±7.12	75.87±8.04	2.116	0.039
	Respiratory Rate (RR) (breaths/min)	14.83±1.45	15.00±1.32	0.475	0.637
	SpO_2 (%)	98.97±0.89	98.87±0.91	0.416	0.679
10	Heart Rate (beats/min)	75.40±9.92	76.80±6.86	0.642	0.526
	Systolic BP (mmHg)	108.80±6.63	114.13±8.42	2.761	0.008
	Diastolic BP (mmHg)	68.53±6.34	74.27±7.52	3.281	0.002
	Respiratory Rate (RR) (breaths/min)	14.80±1.37	15.03±1.29	0.646	0.521
	SpO_2 (%)	98.97±0.88	98.93±0.91	0.171	0.865
15	Heart Rate (beats/min)	72.87±10.85	74.93±7.04	0.888	0.378
	Systolic BP (mmHg)	107.13±6.25	112.87±7.79	3.089	0.003
	Diastolic BP (mmHg)	67.97±5.99	73.13±7.58	3.042	0.004
	Respiratory Rate (RR) (breaths/min)	14.77±1.35	15.10±1.26	0.997	0.323
	SpO_2 (%)	99.00±0.85	98.93±0.87	0.303	0.763
30	Heart Rate (beats/min)	72.57±10.83	76.43±5.81	1.772	0.083
	Systolic BP (mmHg)	103.93±6.73	109.93±8.11	3.066	0.003
	Diastolic BP (mmHg)	66.77±5.42	71.90±7.37	3.113	0.003
	Respiratory Rate (RR) (breaths/min)	14.87±1.41	15.07±1.25	0.610	0.544
	SpO_2 (%)	99.03±0.89	98.90±0.93	0.523	0.603
45	Heart Rate (beats/min)	71.10±10.13	76.43±4.90	2.611	0.011
	Systolic BP (mmHg)	102.13±6.41	109.07±9.31	3.588	0.001
	Diastolic BP (mmHg)	67.83±5.28	71.03±8.12	1.836	0.070
	Respiratory Rate (RR) (breaths/min)	14.80±1.47	15.13±1.23	0.974	0.334
	SpO_2 (%)	99.07±0.84	98.87±0.89	0.947	0.347
60	Heart Rate (beats/min)	70.60±10.19	74.87±4.25	2.152	0.037
	Systolic BP (mmHg)	103.97±8.44	109.00±8.82	2.312	0.025
	Diastolic BP (mmHg)	68.60±6.44	71.53±7.18	1.696	0.095
	Respiratory Rate (RR) (breaths/min)	14.83±1.39	15.07±1.33	0.700	0.486
	SpO_2 (%)	99.10±0.87	98.97±0.91	0.563	0.576

[Table/Fig-5]: Haemodynamic parameters.
Values are presented as mean±SD or numbers. Unpaired student's t-test was used for statistical analysis p-value: p<0.05* statistically significant

Sedation levels were comparable between groups throughout the study period. Both groups achieved and maintained a Ramsay Sedation Score of 2 (patient cooperative, oriented, and tranquil) by 45 minutes, which persisted throughout the intraoperative period. No patient in either group achieved deep sedation (RSS ≥3), indicating that both adjuvants provided adequate anxiolysis without excessive sedation [Table/Fig-6].

VAS pain scores remained zero for the first two hours postoperatively in both groups, indicating excellent initial analgesia. Pain scores gradually increased, peaking at six hours in Group D and then decreasing thereafter. The number of patients requiring rescue analgesia (VAS≥4) was slightly higher in Group N, though the difference was not statistically significant [Table/Fig-7].

Time point	Group D Mean±SD	Group N Mean±SD	p-value
Baseline	1.10±0.31	1.03±0.18	0.321
15 mins	1.93±0.37	1.97±0.18	0.642
30 mins	1.97±0.41	2.00±0.00	0.658
45 mins	2.00±0.00	2.00±0.00	-
60 mins	2.00±0.00	2.00±0.00	-
90 mins	2.00±0.00	2.00±0.00	-
120 mins	2.00±0.00	2.00±0.00	-

[Table/Fig-6]: Sedation assessment (Ramsay Sedation Scale).
Values are presented as mean±SD or numbers. Unpaired student's t-test was used for statistical and Chi-square test for categorical variables p-value: p<0.05* statistically significant

Time point	Group D Mean±SD	Group N Mean±SD	p-value	VAS ≥4 Group D n (%)	VAS ≥4 Group N n (%)
1 h	0.00±0.00	0.00±0.00	-	0	0
2 hrs	0.00±0.00	0.00±0.00	-	0	0
3 hrs	0.33±0.48	0.27±0.45	0.584	0	0
4 hrs	1.20±0.61	1.43±0.77	0.194	0	0
5 hrs	2.10±1.12	2.47±1.25	0.229	1 (3.33)	3 (10.00)
6 hrs	2.73±1.05	2.87±0.97	0.602	2 (6.67)	4 (13.33)
7 hrs	2.10±1.09	2.37±1.33	0.388	1 (3.33)	2 (6.67)
8 hrs	1.70±0.95	1.80±1.03	0.695	0	0
12 hrs	1.53±0.57	1.37±0.56	0.253	0	0

[Table/Fig-7]: Visual Analog Scale (VAS) pain scores - detailed analysis.
Values are presented as mean±SD or numbers. Unpaired student's t-test was used for statistical and Chi-square test for categorical variables p-value: p<0.05* statistically significant

Side-effect profiles showed trends toward more haemodynamic effects (hypotension, bradycardia) in Group D and more opioid-related effects (nausea, vomiting, pruritus) and shivering in Group N, although these differences were not statistically significant [Table/Fig-8].

Side-effect	Group D n (%)	Group N n (%)	p-value
Hypotension	7 (23.33)	3 (10.00)	0.166
Bradycardia	4 (13.33)	1 (3.33)	0.161
Nausea	2 (6.67)	4 (13.33)	0.389
Vomiting	0	2 (6.67)	0.150
Pruritus	0	3 (10.00)	0.076
Shivering	1 (3.33)	5 (16.67)	0.086
Respiratory depression	0	0	-

[Table/Fig-8]: Incidence of side-effects.
Values are presented as numbers (%). Chi-square was used for statistical analysis p-value: p<0.05*statistically significant

DISCUSSION

Spinal anaesthesia remains the technique of choice for lower limb orthopaedic surgeries due to its reliability, cost-effectiveness, and favourable safety profile compared to general anaesthesia [16]. This comparative study evaluated two promising adjuvants—dexmedetomidine and nalbuphine—when combined with hyperbaric bupivacaine, revealing distinct pharmacological profiles and clinical effects with important implications for clinical practice.

A randomised controlled study by Hala Eid EA et al., concluded that intrathecal dexmedetomidine at doses of 10 and 15 µg significantly prolongs the anaesthetic effects of spinal hyperbaric bupivacaine in a dose-dependent manner [19]. Satapathy S et al., compared 1 mg nalbuphine with 25 µg fentanyl as intrathecal adjuvants [20]. Based on these findings, in the present study, authors added 10 µg of dexmedetomidine and 1 mg of nalbuphine individually to 3.3 mL of 0.5% hyperbaric bupivacaine for spinal anaesthesia. The demographic characteristics of patients in both

groups were comparable, with no statistically significant differences observed. This finding was consistent with those of Singhal G et al., and Michael RM and Mehta M, who also reported no significant variation between groups regarding age, gender, weight, and ASA classification [16,17].

Onset and duration of blockade: In the present study, dexmedetomidine demonstrated a significantly faster onset of sensory blockade at the L1 level (2.06±0.32 vs 2.98±0.63 mins, p-value <0.0001) and motor blockade (2.58±0.32 vs 3.86±0.84 mins, p-value <0.0001) compared to nalbuphine. These findings are consistent with Michael RM and Mehta M, who reported a significantly earlier onset of sensory and motor blockade in the dexmedetomidine group (p-value <0.001) [17]. The faster onset with dexmedetomidine can be attributed to its high lipid solubility, allowing rapid penetration into neural tissues. The distribution of the highest sensory level achieved was comparable between groups, with T6 being the most common level (60% in both groups). However, the time to achieve each level was significantly faster in Group D at all levels (p-value <0.001). Similarly, Singhal G et al., reported that patients in the dexmedetomidine group achieved T6 sensory block earlier (6.65 mins) compared to the nalbuphine group (7.45 mins) [16].

The duration of sensory blockade was markedly prolonged with dexmedetomidine (490.9±32.81 vs 337.73±29.85 min, p-value <0.0001), as was the duration of motor blockade (456.6±35.19 vs 354.4±33.22 min, p-value <0.0001). These findings align with Singhal G et al., who reported sensory block durations of 417 and 323 minutes and motor block durations of 419.5 and 328.5 minutes for dexmedetomidine and nalbuphine, respectively [16]. Michael RM and Mehta M, observed similar prolongation using 10 µg dexmedetomidine with 15 mg of 0.5% bupivacaine [17]. The prolonged duration with dexmedetomidine is attributed to its α2-adrenergic agonist properties, which cause hyperpolarisation of spinal neurons and inhibition of nociceptive transmission.

Analgesia and recovery characteristics: Two-segment regression time was significantly longer in Group D (159.47±14.38 vs 138.97±9.97 min, p-value <0.0001). The duration of analgesia was also significantly prolonged in Group D (420.8±39.14 vs 370.67±34.65 min, p-value <0.001), with a corresponding reduction in rescue analgesic requirements. This finding was consistent with observations by Singhal G et al., who reported a significantly longer two-segment regression time and prolonged duration of analgesia with dexmedetomidine compared to nalbuphine, with the first rescue analgesia required at 417 minutes and 323 minutes, respectively [16]. Similarly, Michael RM and Mehta M, found that both the two-segment regression time and duration of analgesia were significantly greater in the dexmedetomidine group compared to the nalbuphine group (p-value <0.001) [17].

The VAS pain scores remained zero for the first two hours postoperatively in both groups, indicating excellent initial analgesia. Thereafter, pain scores gradually increased, peaking at six hours in Group D and slightly earlier in Group N, followed by a gradual decline. Although a higher number of patients in Group N required rescue analgesia (VAS ≥4), the difference was not statistically significant. These findings align with those of Nagraj B et al., who reported that the time for first rescue analgesia in nalbuphine and dexmedetomidine groups was 323 and 417 minutes, respectively [18]. Overall, dexmedetomidine demonstrated a longer duration of postoperative analgesia compared to nalbuphine and plain bupivacaine.

Haemodynamic parameters: At baseline, heart rates were comparable between the two groups (80.63±11.36 vs. 80.53±8.08 beats/min; p-value=0.968). Systolic blood pressure was significantly higher in Group N than in Group D (126.53±11.24 vs. 118.73±7.44 mmHg; p-value=0.003), whereas diastolic pressure showed no significant difference. At 5, 10, 15, and 30 minutes after spinal anaesthesia, systolic blood pressure remained consistently higher in Group N (p-value <0.05 at each interval), while diastolic pressure and heart rate showed no significant differences. From 45 minutes onward, Group N demonstrated significantly higher heart rates (p-value=0.011 at 45 mins; p-value=0.037 at 60 mins) and systolic blood pressure (p-value=0.001 at 45 mins; p-value=0.025 at 60 mins), whereas diastolic pressures remained comparable between the groups beyond 30 minutes. These haemodynamic changes reflect the α2-agonist effects of dexmedetomidine, causing sympatholysis and vagal stimulation. RR and SpO_2 remained stable and comparable between both groups throughout all recorded intervals (p-value >0.05). In contrast, Michael RM and Mehta M, reported no statistically significant changes in pulse rate, systolic, or diastolic blood pressure between the dexmedetomidine and nalbuphine groups at any time interval (p-value >0.05) [17].

Sedation and side-effects: In the present study, sedation levels were comparable between the two groups, consistent with the findings of Khare A et al., who reported that RSS remained at 2 throughout surgery [21]. Similarly, no significant difference was observed in the mean sedation scores between groups over time (p-value >0.05). Regarding side-effects, Group D showed a tendency toward more haemodynamic effects (hypotension: 23.33% vs. 10.00%; bradycardia: 13.33% vs. 3.33%), while Group N demonstrated more opioid-related effects (nausea: 13.33% vs. 6.67%; pruritus: 10.00% vs. 0%) and significantly more shivering (16.67% vs. 3.33%). Although these differences did not reach statistical significance, they are clinically relevant. Michael RM and Mehta M, reported no complications in either group, while Nagraj B et al., observed minimal side-effects similar to our findings [17,18]. The anti-shivering effect of dexmedetomidine observed in our study is supported by Li YZ et al., who demonstrated its efficacy in preventing post-anaesthetic shivering [22].

Adjuvant selection should be individualised based on surgical duration, patient profile, and recovery needs. Dexmedetomidine is preferable for longer procedures, prolonged postoperative analgesia, and prevention of shivering, particularly in younger patients with good cardiovascular reserve [22]. Nalbuphine is more suitable for shorter or day-case surgeries, elderly patients, and those with cardiovascular compromise or sensitivity to α2-agonists. Although not assessed in this study, cost considerations may also influence the choice of adjuvant [23].

Limitation(s)

The fixed doses used in the current study may not represent optimal dosing for all patients. Additionally, the single-centre design and lack of a control group receiving plain bupivacaine limit generalisability. Future dose-finding studies and longer follow-up periods could provide additional insights.

CONCLUSION(S)

Both dexmedetomidine (10 µg) and nalbuphine (1 mg) are effective adjuvants to hyperbaric bupivacaine 0.5% for spinal anaesthesia in lower limb orthopaedic surgeries. Dexmedetomidine provides significantly longer sensory and motor blockade with antishivering effects but is associated with more haemodynamic depression. Nalbuphine offers earlier motor recovery with better haemodynamic stability but is associated with more opioid-related side-effects. The choice between these adjuvants should be individualised based on surgical requirements, patient characteristics, and the desired balance between prolonged analgesia and early mobilisation.

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