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Original Research Article

Comparing the Efficacy of Epidural Dexmedetomidine and Buprenorphine with 0.5% Bupivacaine in Lower Limb Orthopaedic Surgeries

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Conflict of interest: Nil

Abstract:

Background: Effective postoperative analgesia is critical in lower limb orthopedic surgeries to facilitate early mobilization and improve outcomes. Epidural bupivacaine is widely used, but its limited duration necessitates adjuvants. Among these, buprenorphine (a partial μ-opioid agonist) and dexmedetomidine (a selective α2-adrenergic agonist) are promising, though direct comparisons remain limited.

Aim: To compare the efficacy and safety of epidural dexmedetomidine and buprenorphine when combined with 0.5% bupivacaine in patients undergoing elective lower limb orthopedic surgeries.

Materials and Methods: A prospective, randomized, double-blind clinical trial was conducted on 60 ASA I–II patients, aged 20–60 years, undergoing elective lower limb orthopedic surgeries. Patients were allocated into two groups: Group B received 9 ml of 0.5% bupivacaine with 180 μg buprenorphine, and Group D received 9 ml of 0.5% bupivacaine with 60 μg dexmedetomidine. Primary outcomes included time to first rescue analgesia, Visual Analogue Scale (VAS) scores, and hemodynamic stability.

Results: Both groups were comparable demographically. Mean operative duration was similar ($p=0.17$). Rescue analgesia requirement was significantly delayed in Group D (276.7 ± 49.3 min) compared to Group B (212.7 ± 39.0 min; $p<0.001$). VAS scores were significantly lower in the dexmedetomidine group from 120 minutes onward ($p<0.001$). Hemodynamic parameters remained stable in both groups, and adverse effects were minimal, with no significant intergroup differences.

Conclusion: Epidural dexmedetomidine with 0.5% bupivacaine provides superior and prolonged postoperative analgesia compared to buprenorphine, with stable hemodynamics and minimal side effects. It may be considered a more effective adjuvant for lower limb orthopedic surgeries.

Keywords: Epidural Anesthesia, Bupivacaine, Dexmedetomidine, Buprenorphine, Postoperative Analgesia, Orthopedic Surgery.

Introduction

Lower limb orthopedic surgeries are commonly associated with significant postoperative pain, which, if inadequately managed, can result in delayed mobilization, prolonged hospital stay, and increased morbidity. Epidural anesthesia with local anesthetics such as bupivacaine is frequently used due to its effectiveness in providing intraoperative anesthesia and postoperative analgesia. However, the relatively short duration of action of bupivacaine necessitates the use of adjuvants to enhance analgesic efficacy and reduce the total requirement of local anesthetic drugs [1].

Among various adjuvants, opioids such as buprenorphine have been widely studied. Buprenorphine, a partial μ-opioid receptor agonist and κ-antagonist, offers prolonged analgesia with minimal motor blockade and reduced risk of respiratory depression compared to conventional opioids [2]. It is lipid-soluble, allowing rapid diffusion across neural tissues, and has been shown to provide extended postoperative analgesia when used as an epidural adjuvant [3].

Dexmedetomidine, a highly selective α2-adrenergic receptor agonist, has emerged as another effective adjuvant in regional anesthesia. Its analgesic, sedative, and sympatholytic properties make it particularly valuable in enhancing neuraxial blockade. When administered epidurally,

dexmedetomidine has been demonstrated to prolong sensory and motor block duration, reduce local anesthetic requirement, and improve hemodynamic stability [4,5] Moreover, it provides better patient satisfaction without significant adverse effects when used at appropriate doses [6].

Although both buprenorphine and dexmedetomidine have shown efficacy as adjuvants to epidural bupivacaine, there is limited evidence directly comparing their relative effectiveness in lower limb orthopedic surgeries. A comparative evaluation is clinically relevant to optimize analgesic protocols, minimize side effects, and improve functional recovery. Therefore, the present study aims to compare the efficacy of epidural dexmedetomidine and buprenorphine, as adjuvants to 0.5% bupivacaine, in patients undergoing lower limb orthopedic surgeries.

Materials and Method

A prospective, randomized, double-blind, parallel-group clinical trial was conducted in the Department of Anaesthesiology, Chalmeda Anand Rao Institute of Medical Sciences, Karimnagar, a tertiary-care teaching hospital. The study compared epidural dexmedetomidine versus epidural buprenorphine as adjuvants to 0.5% bupivacaine in adult patients undergoing elective lower-limb orthopedic surgeries.

Inclusion Criteria:

- Patients of age 20-60 years.
- Patients with American Society of Anesthesiologists physical status I and II.
- Patients undergoing elective surgeries.
- Patients who are willing to give an informed written consent.
- Patients of both the gender.

Exclusion Criteria:

- Patients of age <20 years and >60 years.
- Patients with American Society of Anesthesiologists physical status III and IV.
- Patients undergoing emergency surgeries and communited fractures.
- Patients with local site infections.
- Patients with coagulopathies.
- Patients with a known allergy to the study drugs.
- Patients who are not willing to participate in the study.

Sample Size: The primary outcome was time to first rescue analgesia (minutes). Assuming a clinically meaningful difference of 60 minutes between groups, SD 80 minutes, two-tailed α=0.05 and power=80%, 27 participants per arm were required. To account for ~10% attrition, 60 patients (30 per group) were recruited. (If your pilot/previous data indicate different parameters, re-compute accordingly.)

Patients were randomized (1:1) using a computer-generated sequence with variable block sizes. Allocation was concealed in sequentially numbered, opaque, sealed envelopes opened by a pharmacy/third-party anesthesiologist not involved in care or assessment. Study solutions were prepared in identical 20-mL syringes. Patients, anesthesiologists performing blocks, surgeons, nursing staff, and outcome assessors were blinded to group allocation.

Method

All the patients meeting the inclusion criteria were taken into the study. A pre-designed, pre-tested, semi structured and pre-coded proforma was used for recording all the findings. The questions were partially closed ended. After obtaining Ethical clearance from the Institutional Ethical Committee, study was conducted.

Sample technique: Simple random sampling technique was used, so that every sampling unit got an equal chance of being included in it. After the inclusion criteria were met, the study population was randomly distributed into two groups.

GROUP B(n=30): 9 ml of 0.5% Bupivacaine with 180µg Buprenorphine in 1 ml normal saline.

GROUP D(n=30): 9 ml of 0.5% Bupivacaine with 60µg Dexmedetomidine in 1 ml normal saline.

Material Required:

- 18 G Tuohy's Epidural needle and 20 G catheter.
- Monitors – ECG, NIBP, SPO2.
- 2 cc syringe and 5 cc syringe.
- Betadine, spirit, gauze to disinfect the back.
- 16G,18G intravenous cannula.
- 0.9% Normal saline and Ringer lactate.
- Study drugs.

All patients were premedicated with T. Alprazolam 0.25mg, at 6 am on the day of surgery. inj. Ondansetron 4mg i.v was given 30 minutes before surgery.

Patients fasted per institutional policy and received standard premedication as per ASA guidelines. In the operating room, standard monitors (ECG, NIBP, SpO_2) were applied and baseline values recorded. An 18G IV cannula was secured; patients were preloaded with 8–10 mL/kg of balanced crystalloid.

Standard monitors like ECG, Non-invasive BP, and spO2 were connected to the patient. Intravenous access was done using 18 Gauge intravenous catheter and 15ml/kg Ringer`s lactate was preloaded.

With the patient in sitting position under strict aseptic precautions, with 18G Tuohy's epidural needle, L3-L4 interspinous space was entered & epidural space identified with loss of resistance technique. Catheter was threaded in the cephalad direction and secured 3-5 cm inside the epidural space and a test dose of 3 ml of 2% lignocaine with adrenaline was given after negative aspiration of blood and CSF.

Patients were shifted to Post Anaesthesia Care Unit (PACU) for monitoring and quality of analgesia assessed by using patient acceptance scale.

Rescue analgesia was given when VAS score more than 4 with inj. Diclofenac 75 mg, i.v., inj. Paracetamol 1g i.v. and 0.125% Bupivacaine 6 ml.

Any adverse effects like vomiting, nausea, pruritis, respiratory depression, headache, dry mouth and shivering were recorded both intraoperatively and postoperatively.

Following variables were observed in the patients:

1. Haemodynamic parameters.
2. Duration of Analgesia.
3. Side effects.

Visual Analogue Scale: The visual analog scale (VAS) is a validated, subjective measure for acute and chronic pain. Scores are recorded by making a handwritten mark on a 10-cm line that represents a continuum between "no pain" and "worst pain."

Statistical Analysis: Data were analyzed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Normality was assessed with Shapiro–Wilk. Continuous variables are presented as mean ± SD (or median [IQR] if non-normal) and compared using independent-samples t-test (or Mann–Whitney U). Repeated measures (hemodynamics, NRS) were analyzed with mixed-effects models or repeated-measures ANOVA with Greenhouse–Geisser correction, as appropriate. Categorical variables (adverse events) were compared using Chi-square or Fisher's exact tests. Two-tailed $p < 0.05$ was considered statistically significant. Effect sizes (mean difference with 95% CI; risk ratio) are reported.

Observation and Results

Table 1: Distribution of Demographic Variable among study population

Parameters	Group	
	Group B	Group D
Age (Years)		
20-29 Years	9	10
30-39 Years	10	8
40-49 Years	8	4
50-59 Years	3	5
≥60 Years	0	3
Gender		
Male	16	16
Female	14	14
ASA Status		
Grade I	25	20
Grade II	5	10

Both groups were comparable in sex distribution (male 16, female 14 in each arm), indicating balanced randomization. Age skewed toward younger adults in both groups; most participants were 20–39 years (Group B: 19/30; Group D: 18/30). A small fraction in Group D were ≥60 years (3 vs 0 in Group B). ASA physical status showed slightly more Grade II in Group D (10 vs 5), but the majority in both arms were Grade I (Group B: 25; Group D: 20), suggesting broadly similar pre-operative risk profiles.

Table 2: Mean distribution of average duration of surgery and rescue analgesia

Parameters	Group		p-value
	Group B	Group D	
Average duration of surgery (Minutes)			
Mean ± SD	181.67±6.23	183.56±7.56	0.17
Rescue Analgesia (Minutes)			
Mean ± SD	212.67±38.98	276.73±49.321	<0.001

The mean operative time was similar between groups (≈182–184 minutes; p=0.17), indicating comparable surgical exposures. Crucially, time to first rescue analgesia was significantly longer with dexmedetomidine (Group D 276.73 ± 49.32 min) than with buprenorphine (Group B 212.67 ± 38.98

min; p<0.001), demonstrating a clinically meaningful prolongation of postoperative analgesia when dexmedetomidine was used as the epidural adjuvant.

Table 3: Mean distribution of VAS Score

VAS	Group (Mean ± SD)		p-value
	Group B	Group D	
5 Min	5±2.7	5.7±1.5	0.15
30 Min	3.4±3.6	4.1±1.4	<0.001
60 Min	3.1±1.59	3.5±1.9	0.12
120 Min	3.0±4.0	2.0±1.6	<0.001
180 Min	3.4±3.5	1.6±0.9	0.002
320 Min	3.7±2.6	0.9±0.74	<0.001

Early pain scores were similar at 5 minutes (p=0.15) and 60 minutes (p=0.12). At 30 minutes, Group D showed a higher VAS than Group B (4.1 ± 1.4 vs 3.4 ± 3.6; p<0.001), but from 2 hours onward the pattern reversed in favor of dexmedetomidine: at 120 minutes (2.0 ± 1.6 vs 3.0 ± 4.0; p<0.001), 180 minutes (1.6 ± 0.9 vs 3.4 ± 3.5; p=0.002), and 320 minutes (0.9 ± 0.74 vs 3.7 ± 2.6; p<0.001), Group D consistently exhibited significantly lower pain scores. Overall, dexmedetomidine provided superior late postoperative analgesia despite similar very-early pain trajectories.

Table 4: Distribution of adverse drug reaction among study population

Adverse Drug Reactions	Group	
	Group B	Group D
Shivering	14	11
Hypotension	1	0
Bradycardia	1	0
Total	14	11

Adverse effects were infrequent and comparable. Shivering occurred slightly less often with dexmedetomidine (11 vs 14). Isolated hypotension and bradycardia events were reported only in Group B (one each), with none in Group D. The overall adverse-event counts (11 vs 14) suggest no safety signal against dexmedetomidine in this cohort.

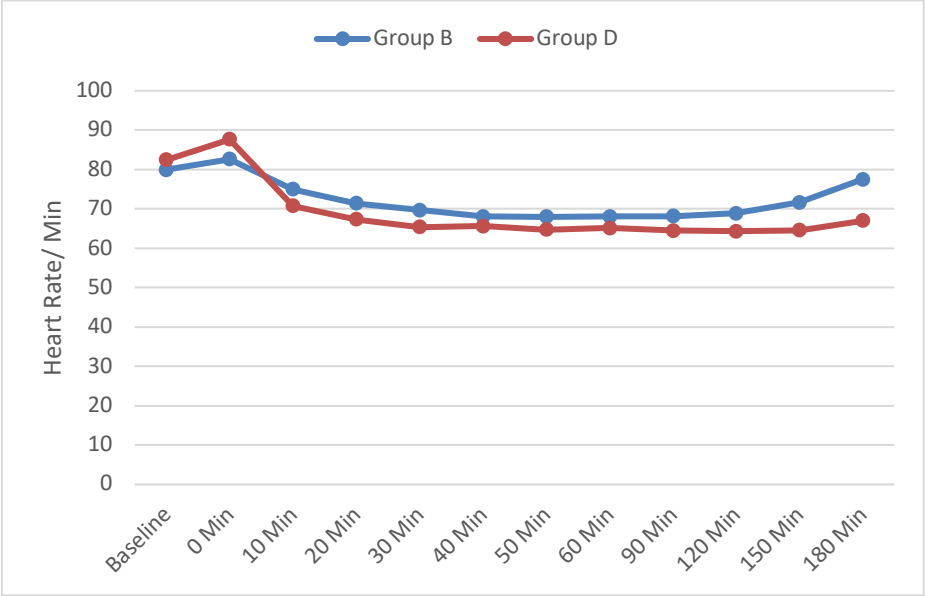

Figure 1: Distribution of Heart Rate among study population

Heart rates in both groups followed broadly stable intraoperative trajectories without clinically relevant divergence between arms, aligning with the low incidence of bradycardia recorded

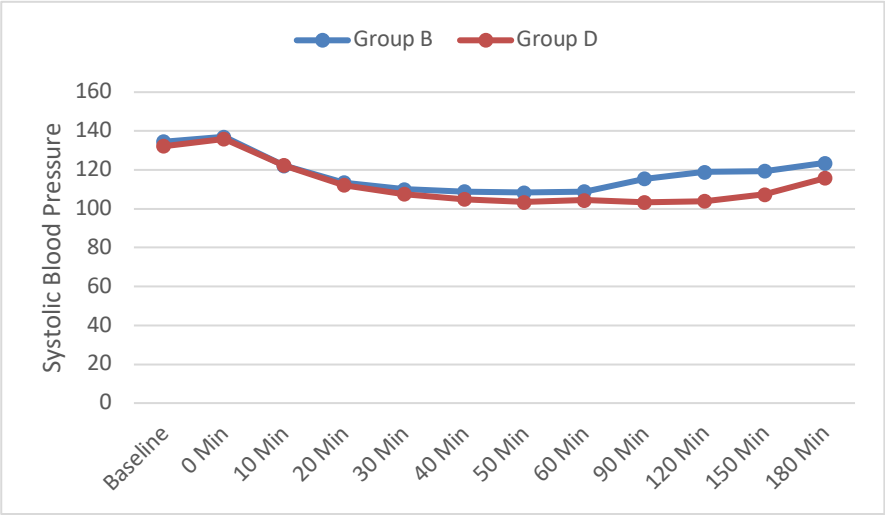

Figure 2: Distribution of Systolic Blood Pressure among study population

Systolic and diastolic pressures remained stable across time in both groups, with no persistent intergroup separation, mirroring the very low rates of hypotension reported (one case in Group B, none in Group D). Overall hemodynamic profiles appear comparable and clinically acceptable for both adjuvants.

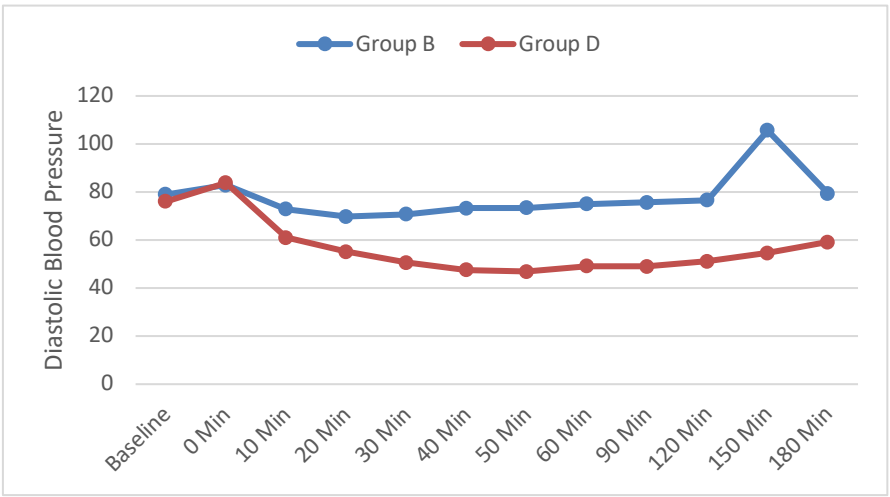

Figure 3: Distribution of Diastolic Blood Pressure among study population

Discussion

In this randomized comparison of epidural adjuvants with 0.5% bupivacaine for lower-limb orthopedic surgery, groups were demographically comparable, operative duration was similar, and the key clinical differences lay in analgesic quality and duration. Time to first rescue analgesia was significantly prolonged with dexmedetomidine (≈277 min) versus buprenorphine (≈213 min), and from 2 h onward VAS scores were consistently lower with dexmedetomidine; hemodynamics and adverse events were comparable and clinically acceptable, with very low incidences of hypotension or bradycardia.

These findings align with contemporary evidence that α2-agonist adjuvants enhance neuraxial analgesia beyond opioid adjuvants. In a 70-patient RCT of lower-limb orthopedic surgery, epidural dexmedetomidine + bupivacaine achieved faster sensory/motor onset, longer postoperative analgesia, and fewer rescue doses than fentanyl + bupivacaine, with stable cardiorespiratory profiles—mirroring our prolonged rescue-free interval and lower late-phase pain scores with dexmedetomidine [7]. Similarly, a 2016 randomized study comparing epidural dexmedetomidine vs clonidine with bupivacaine in lower-limb surgery reported earlier onset, longer duration, superior sedation, and comparable hemodynamics with dexmedetomidine, supporting the safety signal we observed [9].

Direct head-to-head epidural data versus buprenorphine are scarce; however, triangulation from nearby comparators and opioid literature is informative. A modern randomized trial in lower-limb orthopedics found that buprenorphine + bupivacaine produced longer analgesia than butorphanol + bupivacaine, confirming buprenorphine's potency as a neuraxial opioid adjuvant—yet our data suggest dexmedetomidine can still surpass this opioid benchmark in prolonging rescue-free time and reducing late pain intensity [9]. Classic double-blind work in orthopedic populations also established epidural buprenorphine's efficacy (dose-dependent prolongation of analgesia up to ≈12 h) with acceptable side-effects, which contextualizes our buprenorphine arm as an active and credible comparator [10].

Mechanistically, dexmedetomidine's spinal α2-receptor–mediated inhibition of C-fiber transmission and dorsal horn hyperpolarization likely underpins prolonged analgesia and opioid-sparing effects, while avoiding typical opioid adverse events (pruritus, nausea, respiratory depression). Contemporary reviews and clinical data support improved analgesia and sedation with an epidural dexmedetomidine adjuvant and a generally favorable safety profile when appropriately dosed—consistent with our low incidence of hypotension/bradycardia and absence of new safety signals [11].

Overall, our results strengthen the case that epidural dexmedetomidine, as an adjuvant to 0.5% bupivacaine, yields superior late-phase postoperative analgesia compared with an established neuraxial opioid (buprenorphine), without compromising hemodynamic stability. This is concordant with randomized evidence against other opioid comparators (fentanyl) and alternative adjuvants (clonidine), and with meta-analytic/physiologic rationale for α2-agonist efficacy. Future trials directly comparing epidural dexmedetomidine and buprenorphine with standardized doses and sedation/respiratory outcomes would clarify relative benefit-risk, but current data favor dexmedetomidine when prolonged, opioid-sparing analgesia is prioritized.

Conclusion

This study demonstrates that epidural dexmedetomidine, when combined with 0.5% bupivacaine, provides superior and longer-lasting postoperative analgesia compared with epidural buprenorphine. Patients in the dexmedetomidine group experienced significantly prolonged rescue-free analgesia and lower pain scores in the late postoperative period, with stable hemodynamics and minimal adverse effects. These results are consistent with published randomized trials showing the analgesic and opioid-sparing advantages of dexmedetomidine over traditional opioid adjuvants. Overall, epidural dexmedetomidine appears to be a more effective adjuvant than buprenorphine for lower-limb orthopedic surgeries, offering enhanced patient comfort without compromising safety.

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