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Research Article

A Comparative Study of Fentanyl with Ropivacaine versus Dexmedetomidine with Ropivacaine for Epidural Anaesthesia in Lower Limb Orthopaedic Surgery: A Randomized Controlled Trial

Dr. Antu Datta[1], Dr. Biswajit Sutradhar[2], Dr. Ranjit Reang[3]
[1]Post Graduate Trainee, Department of Anaesthesiology, Agartala Government Medical College & G.B.P Hospital, Tripura, India.
[2]Associate Professor (Guide), Department of Anaesthesiology, Agartala Government Medical College & G.B.P Hospital, Tripura, India.
[3]Associate Professor (Co-Guide), Department of Anaesthesiology, Agartala Government Medical College & G.B.P Hospital, Tripura, India.
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INTRODUCTION

Epidural anaesthesia has become a cornerstone of modern anaesthesia practice, offering effective intraoperative and postoperative pain relief, particularly for abdominal and lower limb surgeries.[1] It facilitates early mobilization, reduces postoperative pain, and improves recovery, resulting in shorter hospital stays and better patient outcomes.[2]

Local anaesthetics such as bupivacaine and ropivacaine are widely used for epidural anaesthesia. However, achieving adequate anaesthesia and analgesia often requires higher doses, which may increase the risk of systemic toxicity and adverse hemodynamic effects.[3] To enhance efficacy and reduce these risks, adjuvant drugs are commonly added to local anaesthetics.[4]

Opioids such as fentanyl provide potent analgesia but may be associated with respiratory depression, nausea, vomiting, pruritus, and delayed recovery due to prolonged motor blockade.[5] Dexmedetomidine, a selective α2-adrenergic agonist, has emerged as a promising alternative because of its analgesic, sedative, and sympatholytic properties, with a lower incidence of opioid-related adverse effects.[6–8]

The choice of adjuvant significantly influences the quality of anaesthesia and patient outcomes. While fentanyl offers effective analgesia, dexmedetomidine may provide a more balanced profile with improved analgesia and fewer side effects.[9] This randomized controlled trial was designed to compare the efficacy and safety of fentanyl and dexmedetomidine as adjuvants to ropivacaine in epidural anaesthesia for major lower limb orthopaedic surgeries. The study evaluated onset and duration of anaesthesia, duration of analgesia, hemodynamic stability, and adverse effects.

Although several studies have reported superior potentiation of ropivacaine by dexmedetomidine compared with fentanyl,[10–12] similar data from this region are scarce. Therefore, this study was undertaken to provide evidence regarding the optimal epidural adjuvant for lower limb orthopaedic surgery.

MATERIALS AND METHODS

Study Design and Participants

This single-blind randomized controlled trial was conducted at Agartala Government Medical College and G.B.P. Hospital, India (September 2024–May 2025), following Institutional Ethics Committee approval and trial registration (CTRI/2024/09/074201). Written informed consent was obtained from all participants.

Inclusion Criteria:80 adult patients, aged 18–50 years, weighing 40–90 kg, height 142–170 cm, ASA physical status I or II, scheduled for elective lower limb orthopaedic surgery under epidural anaesthesia.

Exclusion Criteria:ASA grade III, local anaesthetic/study drug hypersensitivity, anaemia, chronic respiratory disease, hypovolemia, shock, septicaemia, coagulation disorders, spinal/vertebral anomalies, local site infection, or emergency surgery.

Sample Size, Randomization, and Blinding

Based on a previous study's mean sensory block onset time (95% confidence level, 80% power), the minimum sample size required was 30 patients per group. Factoring in a 10% non-response rate, 80 patients (n = 40 per group) were enrolled.

Participants were allocated in a 1:1 ratio using variable block randomization. Allocation concealment was maintained via sequentially numbered opaque sealed envelopes. To ensure single-blinding, the total drug volume for both groups was adjusted to 18 mL by diluting adjuvants with normal saline.

Study Groups and Anaesthetic Technique

Patients were randomized into two groups:
Group RF (n = 40):16 mL of 0.75% ropivacaine + fentanyl 1 mcg/kg.
Group RD (n = 40):16 mL of 0.75% ropivacaine + dexmedetomidine 1 mcg/kg.
Preoperatively, all patients fasted for 6 hours, received oral alprazolam (0.5 mg) the night before and morning of surgery, and were preloaded with Ringer's lactate (10 mL/kg). IV ondansetron (4 mg) and omeprazole (40 mg) were administered prophylactically.
Under aseptic conditions, the epidural space was identified at L3–L4 using an 18G Tuohy needle via the loss-of-resistance technique. A catheter was advanced 3–5 cm into the space. Following negative aspiration for blood/CSF, a 3 mL test dose (lignocaine with 1:200,000 epinephrine) was given, followed by the study drug at ~1 mL/s. Supplemental oxygen (4 L/min) was provided throughout.

Outcome Measures and Assessments

The primary outcome was the onset time of sensory blockade at the T10 dermatome (defined as the interval between drug administration and loss of cold sensation).
Secondary outcomes included:
* Maximum sensory level achieved and time taken.
* Time to complete motor blockade.
* Times to two-segment sensory regression and regression to S2.
* Duration of analgesia (time to first rescue analgesia).
* Total 24-hour postoperative local anaesthetic consumption.
* Haemodynamic changes and adverse events.

Clinical Grading Systems

Sensory Block: Evaluated using a 22G blunt needle via pinprick along the midclavicular line. Graded as 0 (sharp pain), 1 (analgesia/dull sensation), or 2 (anaesthesia/no sensation).
Motor Block: Assessed via the Modified Bromage Scale from Grade 0 (no weakness) to Grade 3 (unable to flex ankle). Complete block was defined as achieving Grade 3.
Sedation: Monitored using the Modified Ramsay Sedation Score (1–6).

Management of Complications

Haemodynamics were monitored at regular intervals. Bradycardia (HR < 60 bpm) was treated with IV atropine 0.6 mg. Hypotension (SBP drop > 20% from baseline or < 90 mmHg) was managed with fluid boluses and IV ephedrine 5 mg.
Postoperative pain was assessed via a 10-point Visual Analogue Scale (VAS). Rescue analgesia—consisting of IV tramadol (1 mg/kg) and 6 mL epidural ropivacaine—was administered when VAS 5. The catheter was removed at 24 hours.

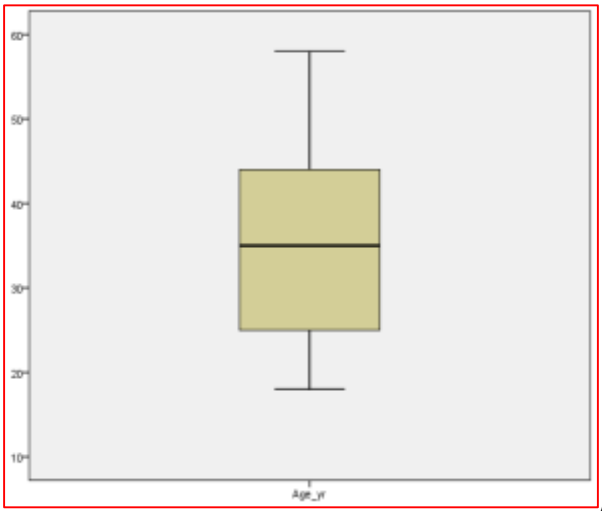
Statistical Analysis

Data were analysed using SPSS version 21.0. Continuous variables were expressed as mean standard deviation and compared using the independent samples t-test. Categorical variables were presented as frequencies (%) and analysed using the chi-square test. Statistical significance was set at $p < 0.05$.

RESULTS

Eighty(80) patients undergoing lower limb orthopaedic surgery were enrolled and randomly allocated into two equal groups (n=40 each): Group RF received 16 mL of 0.75% ropivacaine with fentanyl 1 µg/kg epidurally, while Group RD received 16 mL of0.75% ropivacaine with dexmedetomidine 1 µg/kg epidurally. Continuous variables were expressed as mean ± standard deviation and analyzed using ANOVA, whereas categorical variables were compared using the Chi-square test or Fisher's exact test, with a p value <0.05 considered statistically significant.
The mean age of the study population was 35.3 ± 10.8 years (range 18–58 years) and was normally distributed. Sensory onset at T10 was significantly faster in Group RD (8.50 ± 1.90 min) than in Group RF (10.29 ± 2.59 min), and the difference was statistically highly significant ($p = 0.0007$). Group RD demonstrated a significantly faster onset of motor block (10.8 ± 1.9 vs 12.5 ± 2.3 min; $p=0.03$) and a shorter time to complete motor block (13.25 ± 2.37 vs 16.60 ± 2.07 min; $p<0.0001$) compared with Group RF. Sensory blockade was prolonged in Group RD, as evidenced by a longer time for dermatomal regression to S1 (309.25 ± 3.37 vs 277.68 ± 5.31 min; $p<0.0001$) and delayed requirement of first rescue analgesia (326.08 ±

3.75 vs 292.05 ± 3.44 min; p<0.0001). Sedation scores were significantly higher in Group RD than in Group RF (3.5 ± 0.5 vs 1.4 ± 0.4; p<0.001). Hemodynamic assessment revealed significantly lower heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure in Group RD at most observation periods (p<0.001). Adverse effects such as nausea, shivering, and respiratory depression were significantly more frequent in Group RF, whereas hypotension and bradycardia occurred only in Group RD but without statistical significance. Overall, epidural dexmedetomidine as an adjuvant to ropivacaine provided faster onset of block, prolonged sensory and motor blockade, longer postoperative analgesia, higher sedation scores, and favorable hemodynamic characteristics compared with fentanyl while maintaining an acceptable safety profile.



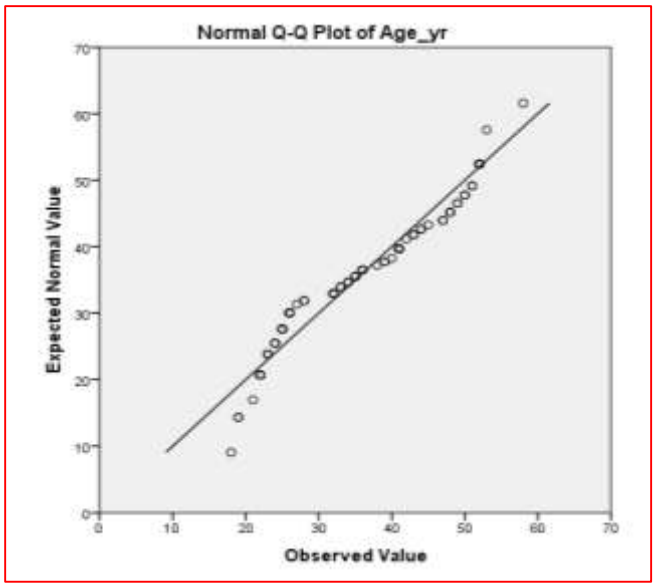


Figure 1 (A&B): Distribution of the cases by age distribution (N=80)

Table 19: Comparison of weight & height of the participants (N=80)

Height (Cm)	157.4 ± 12.3	157.2 ± 11.4	.512

COMPARISON OF SENSORY BLOCKADE

Sensory Onset at T10	Group RF	Group RD	p-value
Mean Time (min)	10.29 ± 2.59	8.50 ± 1.90	0.0007

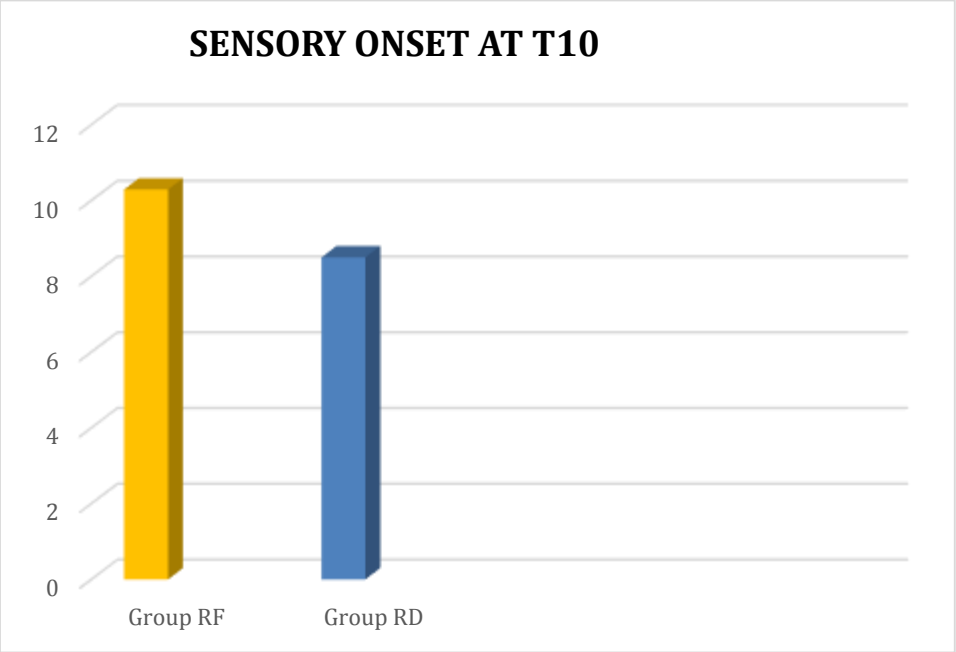


Table 2: Comparison of sensory block of the participants (N=80)

Comparison of Motor Blockade

	Group RF	Group RD	p-value
Onset of Motor Block	12.5 ± 2.3 min	10.8 ± 1.9 min	0.03
Time to complete motor block	16.60±2.07 Minutes	13.25 ± 2.37 Minutes	<0.0001

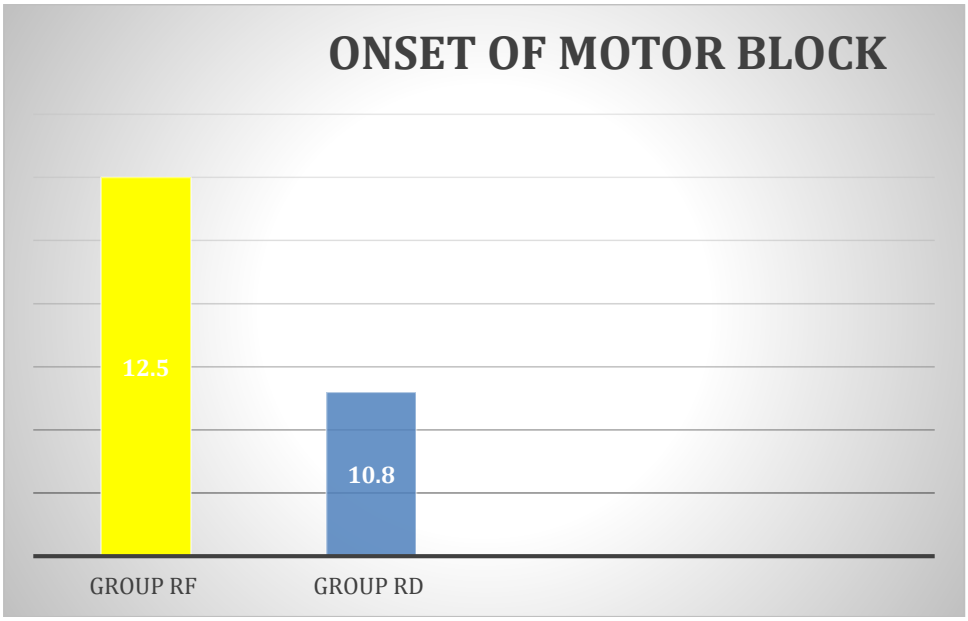


Table 3: Comparison of motor block of the participants (N=80)

Mean Time for Two Segmental Dermatomal Regression

	Group RF	Group RD	p-value
Mean Time (min)	222.25 ± 4.19	235.35 ±2.87	<0.0001

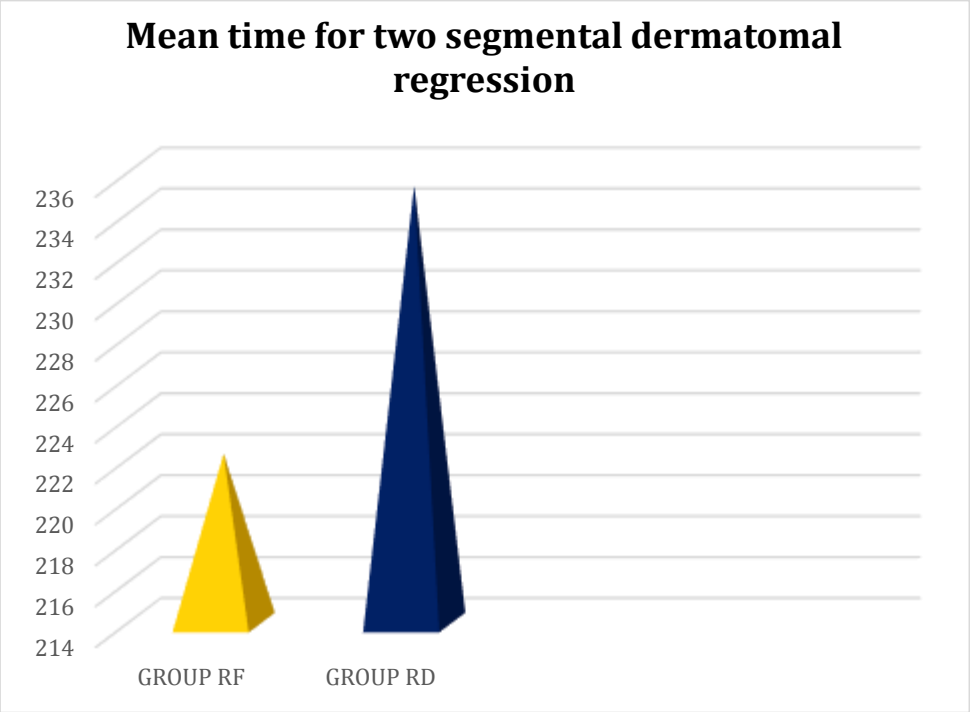
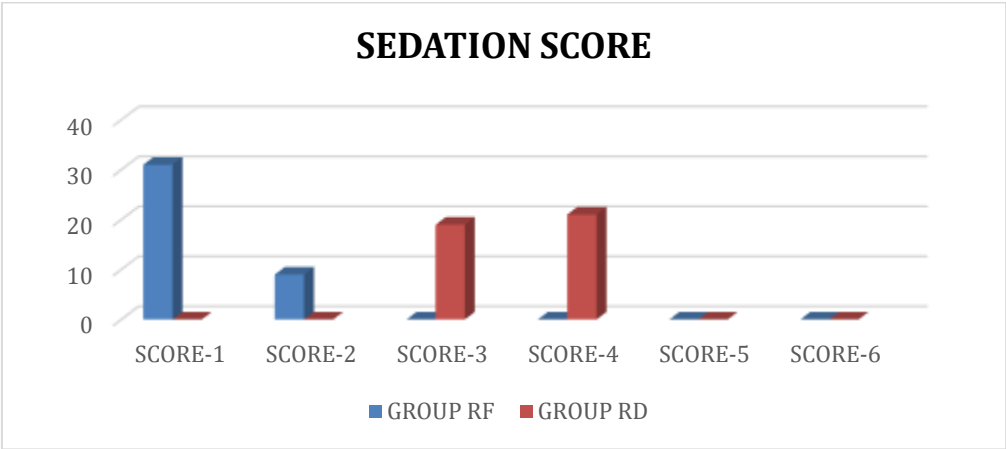


Table 4: Comparison of two segmental dermatomal regression of the participants (N=80)

Comparison of Two Groups on the Basis of Sedation Score

Sedation score	Group RF	Group RD	p-value
1	31 (77.5%)	0 (0%)	<0.0001
2	9 (22.5%)	0 (0%)	<0.0001
3	0 (0%)	19 (47.5%)	<0.0001
4	0 (0%)	21 (52.5%)	<0.0001
5	0 (0%)	0 (0%)	
6	0 (0%)	0 (0%)	



Comparison of Both Groups on the Basis of Side Effects

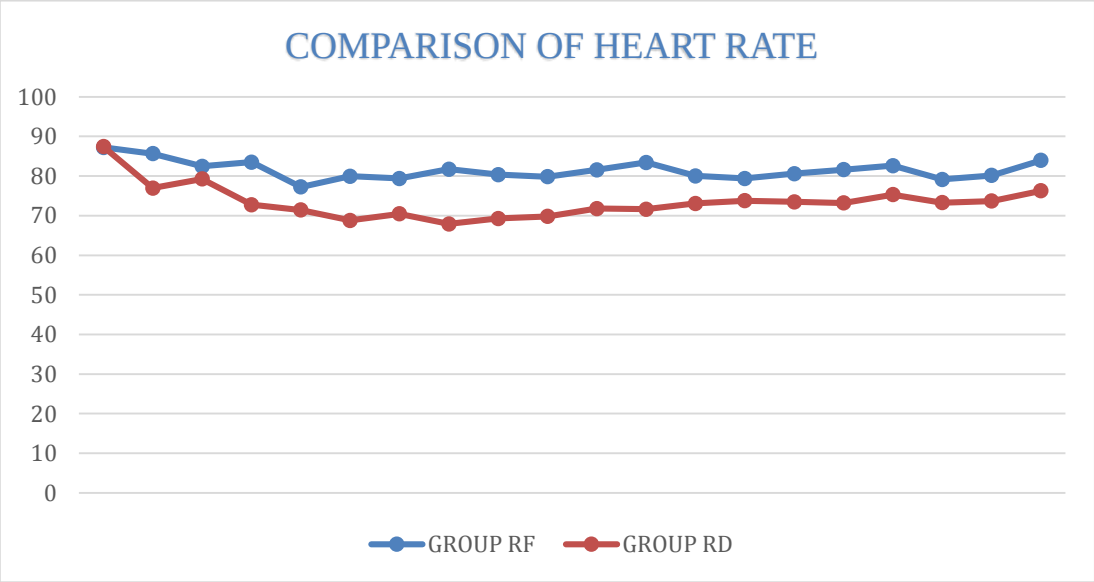
Table 5: Comparison of sedation score of the participants (N=80)

Adverse Effect	Group RF	Group RD	p-value
Nausea	10 (25 %)	0 (0%)	0.0011
Vomiting	0 (0%)	0 (0%)	

Shivering	11 (27.5 %)	0 (0%)	0.0004
Hypotension	0 (0%)	3 (7.5%)	0.2422
Bradycardia	0 (0%)	3 (7.5%)	0.2422
Respiratory Depression	7 (17.5 %)	0 (0%)	0.0118

Comparison of Both Groups on the Basis of Heart Rate

Time (Minutes)	Group RF, mean±SD	Group RD, mean±SD	p-value
0	87.24 ± 10.95	87.41 ± 10.15	0.936
3	85.66 ± 5.03	76.97 ± 6.51	<0.001
6	82.44 ± 5.78	79.26 ± 9.45	0.084
9	83.51 ± 6.62	72.74 ± 4.03	<0.001
12	77.24 ± 6.79	71.41 ± 4.94	<0.001
15	79.95 ± 5.81	68.79 ± 4.25	<0.001
20	79.37 ± 6.63	70.44 ± 4.65	<0.001
30	81.73 ± 5.22	67.92 ± 4.19	<0.001
45	80.34 ± 4.58	69.28 ± 4.83	<0.001
60	79.83 ± 5.70	69.79 ± 3.95	<0.001
90	81.56 ± 5.94	71.77 ± 5.40	<0.001
120	83.44 ± 5.97	71.62 ± 3.83	<0.001
150	80.02 ± 4.52	73.08 ± 4.71	<0.001
180	79.37 ± 5.08	73.77 ± 4.50	<0.001
240	80.61 ± 4.75	73.49 ± 4.67	<0.001
300	81.61 ± 3.96	73.21 ± 4.89	<0.001
360	82.63 ± 4.12	75.31 ± 4.56	<0.001
480	79.15 ± 8.54	73.28 ± 6.38	0.002
600	80.15 ± 4.79	73.67 ± 4.83	<0.001
720	83.95 ± 4.94	76.26 ± 4.55	<0.001

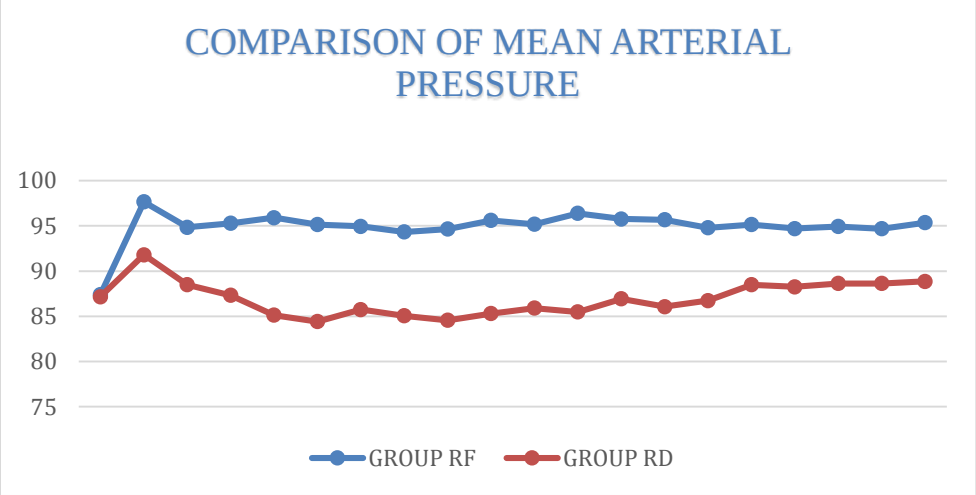


COMPARISON OF BOTH GROUPS ON THE BASIS OF MEAN ARTERIAL PRESSURE

Table 6: Comparison of Heart Rate of the Participants (N=80)

Time (Minutes)	Group RF, mean±SD	Group RD, mean±SD	p-value

0	87.40 ± 7.76	87.17 ± 8.86	0.897
3	97.66 ± 4.05	91.80 ± 4.32	<0.001
6	94.84 ± 4.40	88.50 ± 4.00	<0.001
9	95.28 ± 3.83	87.33 ± 3.47	<0.001
12	95.90 ± 3.52	85.13 ± 4.02	<0.001
15	95.14 ± 4.45	84.43 ± 3.99	<0.001
20	94.96 ± 3.78	85.75 ± 4.66	<0.001
30	94.33 ± 4.04	85.05 ± 4.39	<0.001
45	94.65 ± 3.89	84.56 ± 4.22	<0.001
60	95.61 ± 4.16	85.30 ± 4.96	<0.001
90	95.19 ± 4.06	85.90 ± 4.92	<0.001
120	96.38 ± 4.15	85.49 ± 4.26	<0.001
150	95.76 ± 4.49	86.93 ± 4.67	<0.001
180	95.68 ± 4.02	86.07 ± 4.71	<0.001
240	94.79 ± 4.50	86.74 ± 5.25	<0.001
300	95.14 ± 4.39	88.49 ± 5.37	<0.001
360	94.71 ± 4.45	88.27 ± 5.33	<0.001
480	94.93 ± 4.45	88.64 ± 5.58	<0.001
600	94.68 ± 4.36	88.64 ± 5.58	<0.001
720	95.36 ± 4.38	88.86 ± 5.54	<0.001



COMPARISON OF BOTH GROUPS ON THE BASIS OF OXYGEN SATURATION

Table 7: Comparison of mean arterial pressure of the participants (N=80)

Time (Minutes)	Group RF, mean±SD	Group RD, mean±SD	p-value
0	99.76 ± 0.59	99.69 ± 0.69	0.604
3	99.61 ± 0.80	99.31 ± 0.66	0.097
6	99.02 ± 0.95	99.36 ± 0.78	0.099
9	99.59 ± 0.74	99.67 ± 0.62	0.602
12	99.61 ± 0.80	99.49 ± 0.82	0.515

15	99.51 ± 0.81	99.49 ± 0.85	0.914
20	99.32 ± 0.85	99.62 ± 0.78	0.108
30	99.71 ± 0.60	99.59 ± 0.68	0.389
45	99.61 ± 0.67	99.56 ± 0.75	0.742
60	99.61 ± 0.67	99.62 ± 1.09	0.947
90	99.61 ± 0.67	99.51 ± 0.85	0.548
120	99.76 ± 0.44	99.51 ± 0.85	0.1
150	99.61 ± 0.59	99.62 ± 0.78	0.952
180	99.46 ± 0.71	99.49 ± 0.85	0.865
240	99.66 ± 0.69	99.64 ± 0.78	0.91
300	99.66 ± 0.69	99.62 ± 0.78	0.784
360	99.63 ± 0.70	99.62 ± 0.78	0.934
480	99.76 ± 0.44	99.64 ± 0.78	0.369
600	99.63 ± 0.70	99.62 ± 0.78	0.934
720	99.63 ± 0.70	99.62 ± 0.78	0.934

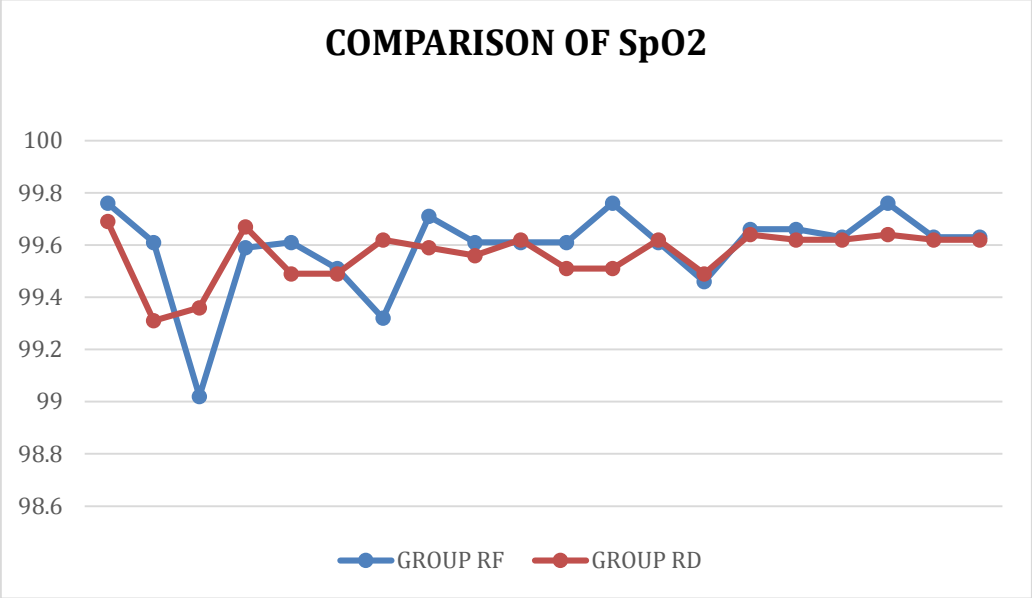


Table 8: Comparison of SpO2 of the participants (N=80)

DISCUSSION

In this randomized study of 80 patients undergoing lower limb orthopaedic surgery under epidural anaesthesia, both groups were comparable with respect to age, sex, height, weight, ASA status, and duration of surgery, indicating adequate baseline homogeneity and minimizing confounding factors.

The addition of dexmedetomidine to ropivacaine resulted in a significantly faster onset of sensory blockade at the T10 level compared with fentanyl (8.50 ± 1.90 vs. 10.29 ± 2.59 min, p = 0.0007). Similar findings have been reported in previous studies, which demonstrated earlier sensory block onset with dexmedetomidine than fentanyl [16,20]. Although some studies reported an even faster onset, the overall trend consistently favours Dexmedetomidine as a superior epidural adjuvant for rapid sensory block establishment [22].

Motor blockade characteristics also favoured Dexmedetomidine. Patients in Group RD achieved motor block earlier and demonstrated prolonged block duration, as evidenced by significantly delayed two-segment regression and regression to S1 compared with Group RF (p < 0.0001). These findings are consistent with previous reports that observed prolonged

motor blockade with dexmedetomidine [14,19]. The enhanced and sustained blockade may be attributed to the synergistic interaction of dexmedetomidine with local anaesthetics at spinal α2-adrenergic receptors, resulting in inhibition of nociceptive transmission and augmentation of neural blockade [23,24].

Duration of analgesia was significantly prolonged in the dexmedetomidine group, as reflected by the longer time to first rescue epidural top-up (326.08 ± 3.75 vs. 292.05 ± 3.44 min, $p < 0.0001$). Similar observations have been reported previously, supporting the superior analgesic efficacy of dexmedetomidine when used as an epidural adjuvant [13,17]. The prolonged analgesia likely results from reduced release of substance P and inhibition of pain signal transmission at the dorsal horn of the spinal cord [22,23].

Sedation scores were significantly higher in Group RD ($p < 0.0001$), with most patients achieving Ramsay sedation scores of S3–S4, whereas patients receiving fentanyl predominantly remained in S1–S2 categories. Comparable findings have been reported in earlier studies [16,20]. The sedative effect of dexmedetomidine, mediated through α2-receptors in the locus coeruleus, provides cooperative sedation resembling natural sleep without causing significant respiratory compromise.

Hemodynamic analysis revealed a significant reduction in heart rate and blood pressure in the dexmedetomidine group throughout the study period. Heart rate reduction became prominent from 30 minutes onward, while systolic, diastolic, and mean arterial pressures declined from the early post-intervention period. These findings are consistent with the known sympatholytic properties of dexmedetomidine [11]. Despite these changes, oxygen saturation remained stable in both groups, indicating preservation of respiratory function, a finding comparable to previous studies [20].

Regarding adverse effects, fentanyl was associated with significantly higher incidences of nausea, shivering, and respiratory depression, whereas dexmedetomidine showed only occasional bradycardia and hypotension, which were not statistically significant. Similar observations have been reported previously, demonstrating a lower incidence of opioid-related adverse effects with dexmedetomidine [13,16]. Overall, dexmedetomidine provided faster sensory and motor block onset, prolonged analgesia, better sedation, and fewer opioid-related adverse effects than fentanyl, making it a valuable epidural adjuvant to ropivacaine for lower limb orthopaedic surgeries [13,16,20,22].

CONCLUSION

Dexmedetomidine is a superior adjuvant to ropivacaine compared to fentanyl for epidural anaesthesia in lower limb orthopedic surgeries. It provides a faster onset of sensory and motor block, shorter time to reach maximum sensory level, superior quality of analgesia with prolonged duration and extended motor block with higher sedation scores. Its overall efficacy in enhancing the quality and duration of epidural anaesthesia makes it a preferable choice over fentanyl with minimal side effects and may be recommended as adjuvant with ropivacaine for epidural anaesthesia in lower limb orthopedic surgery.

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