A RANDOMIZED DOUBLE-BLIND CLINICAL STUDY COMPARING THE EFFICIENCY OF FENTANYL WITH ROPIVACAINE VERSUS DEXMEDETOMIDINE WITH ROPIVACAINE AS ANAESTHETIC DOSE THROUGH EPIDURAL CATHETERIN LOWER LIMB SURGERIES

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KEYWORDS

ROPIVACAINE, DEXMEDETOMIDINE, Epidural anesthesia

ABSTRACT

Introduction: Epidural anesthesia is used in modern lower limb surgeries for pain management, offering flexibility and prolonged analgesia. It requires higher doses and can be combined with sedatives like fentanyl and lordexmedetomidine to reduce local anesthetic doses. **Aims:** The study compares the efficacy of 0.75% ropivacaine with fentanyl and 0.75% ropivacaine with dexmedetomidine in onset of action and duration quality of epidural anesthesia during lower limb surgeries. **Methodology:** A prospective randomized double blind clinical study at Krishna Institute of Medical Sciences in India found that epidural 0.75% ropivacaine with dexmedetomidine offers better onset and longer duration of sensory and motor block compared to epidural 0.75% ropivacaine with fentanyl. **Results:** The study compared sensory block onset, motor block duration, and adverse effects between DR and FR groups, finding DR group had lower heartrates post-intervention and more bradycardia cases. **Discussion:** The study found similar gender distribution, procedural efficiency, and faster sensory block onset in the DR group, emphasizing the importance of tailoring anesthetic choices to individual patient profiles. **Conclusion:** Exmedetomidine is preferred over opivacaine in lower limb surgeries due to its early onset, longer sensory and motor block duration, stable hemodynamics, and less adverse effects.

INTRODUCTION

Epidural anesthesia is commonly used for pain management in modern lower limb surgeries, offering greater flexibility, better hemodynamic stability, and prolonged analgesia compared to spinal anesthesia. [1]
Epidural anesthesia requires larger volume of local anaesthetic, increasing LA toxicity risk. Opivacaine is preferred due to minimal cardiovascular and neurotoxic effects, but requires higher doses. [2]
The addition of sedatives like fentanyl and lordexmedetomidine to epidural anesthesia serves to reduce the required dose of local anesthetics and delay sensory blockade onset.[3]

Fentanyl acts as an agonist at the μ-opioid receptor, augmenting analgesia but may increase side effects like pruritus, urinary retention, nausea, vomiting, and respiratory depression. [4,5]
Dexmedetomidine, an α2agonist, targets pre- and post-synaptic sympathetic nerve terminals and central nervous system, reducing sympathetic outflow and causing sedative, analgesic, sympatholytic, and hemodynamic effects. [6]
The study compares the effectiveness of two drugs combined with ropivacaine and dexmedetomidine for providing adequate anesthesia during lower limb surgeries, evaluating factors such as onset, duration, pain relief, and adverse effects.
The study compares the efficacy of fentanyl with ropivacaine and dexmedetomidine with ropivacaine as an anesthetic dose through an epidural catheter in lower limb surgery, aiming to optimize perioperative care.

AIM&OBJECTIVES

The study aims to compare and evaluate the efficacy of 0.75% ropivacaine with fentanyland 0.75% ropivacaine with dexmedetomidine for onset of action and duration quality of epidural anesthesia.
The study compares the duration of anesthesia using fentanyl withropivacaine and dexmedetomidine withropivacaine during lower limb surgeries, assessing sensory and motor block onset, time required, and hemodynamic changes.

MATERIALS&METHODS

The hypothesis suggests that epidural 0.75% ropivacaine with dexmedetomidine offers better onset and longer duration of sensory and motor block compared to epidural 0.75% ropivacaine with fentanyl.
Prospective randomized double blind clinical study.

The study, conducted at Krishna Institute of Medical Sciences, Karad, India, aimed to analyze patients admitted and planned for lower limb surgery from October 2022 to April 2024.

The study used 96 samples, with 96 in each group, to analyze the difference in mean mean and power between the two groups.

INCLUSION CRITERIA: The inclusion criteria include patients aged 18-60 years, with ASA grade II or II, and those undergoing elective lower limb surgeries.

EXCLUSION CRITERIA: The exclusion criteria include coagulopathies, congenital abnormalities of the spine and meninges, active CNS disease, history of allergy to study the drug, and local infection.

The study involved enrolling 96 patients, dividing them into two groups, GroupRF and Group RD, using software, and randomizing patient assignment and treatment allocation using R-software.

The study was conducted at Krishna Hospital in Karad, India, over 18 months. Patients were included after providing written informed consent. Pre-operative assessments included hemograms, blood tests, electrocardiograms, chest X-rays, and catheterization profiles. Post-surgery, patients were positioned in supine positions and administered a single epidural anesthetic bolus dose. The modified Bromage Scale was used to assess motor block during and after regional anesthesia, particularly epidural spinal anesthesia. Understanding dermatome level is crucial for diagnosing and managing conditions related to nerve damage or spinal cord injuries.

OBSERVATION&RESULTS

Table1:Distribution of Sex in both the groups

Label/Group	DR		FR		p-value
	Frequency	Percentage	Frequency	Percentage	
Male	35	36.46	39	40.63	0.3314
Female	13	13.54	9	9.38	

The table shows gender distribution in two groups, DR and FR, with 35 males and 39 females, respectively, and a non-significant p-value of 0.3314.

Table2:Distribution of Age (years) in both the groups

Label/Group	DR		FR		p-value
	Mean	SD	Mean	SD	
Age(years)	41.94	12.63	41.44	12.24	0.8443

The table shows mean and standard deviation of age in two groups, DR and FR, with a non-significant p-value of 0.8443.

Table3: Distribution of Body weight in both the groups

Label/Group	DR		FR		p-value
	Mean	SD	Mean	SD	
Bodyweight	58.98	6.43	57.96	6.91	0.4556

The table shows mean and standard deviation of bodyweight for two groups, DR and FR, with a non-significant p-value of 0.4556.

Table4: Distribution of Duration of the surgery(min) in both the groups

Label/Group	DR		FR		p-value
	Mean	SD	Mean	SD	
Duration of the surgery(min)	107.38	9.08	106.73	10.90	0.7532

The table shows mean and standard deviation of surgery durations for two groups, DR and FR, with a non-significant p-value of 0.7532.

Table5: Distribution of Time of onset of Sensory Block Till T-10 level(min) in both the groups

	Group	N	Mean	Std. Deviation	Std.ErrorMe	Pvalue
Time of onset of Sensory Block tillT-10level(min)	DR	48	7.42	.498	.072	<0.0011
	FR	48	9.31	1.386	.200	

The study compared the onset time of sensory block to T-10 level in two groups: DR and FR, finding a statistically significant difference in the DR group.

Table 6:Maximum sensory level achieved in both the groups

		Group		Total
		DR	FR	
Maximum sensory block level	T4	13	0	13
	T5	17	23	40
	T6	16	17	33
	T7	2	8	10
Total		48	48	96
Chi-sqvalue-17.53,pvalue-0.001,significant				

The table shows the maximum sensory block levels achieved by patients in two groups: DR and FR, with T5 being the most common and T6 being the most common.

Table 7:Mean time of onset of motor block[Bromage3](min)in both the groups

	Group	N	Mean	Std. Deviation	Std.ErrorMe	Pvalue
Time of onset of motor Block(min)	DR	48	18.02	.956	.138	<0.001
	FR	48	21.17	1.191	.172	

The table compares the mean time of motor block onset between two groups, DR and FR, with DR having a faster onset time.

Table 8: Distribution of Duration of sensory block [Time for Sensory regression to S1 level] (min) in both the groups

	Group	N	Mean	Std.	Std.Error Mean	Pvalue
Duration of sensory	DR	48	430.69	10.800	1.559	
	FR	48	301.25	36.283	5.237	

The table shows that the DR group has a significantly longer sensory block duration than the FR group, with a standard deviation of 10.800 and a standard error of 1.559.

Table 9: Distribution of Duration of motor block [Time for motor regression from Born age 3 to 0] (min) in both the groups

	Group	N	Mean	Std.	Std.Error Mean	Pvalue
Duration of motor block(min)	DR	48	321.31	50.448	7.282	
	FR	48	236.73	19.199	2.771	<0.01

The table compares motor block durations between two groups, DR and FR, with DR having a significantly longer duration of 321.31 minutes compared to FR's 236.73 minutes.

Table10:Mean time to two segmental regressions in both the groups

	Group	**N**	**Mean**	**Std.**	**Std.Error Mean**	**Pvalue**
Mean time to two segmental regressions	**DR**	**48**	**141.63**	**7.448**	**1.075**	
	FR	**48**	**104.98**	**9.068**	**1.309**	**<0.001**

The table compares mean time to two segment regressions between two groups, DR and FR, with the DR group showing a significantly longer mean time.

Tab11 displays the mean time for regression to Bromage 1 in both groups.

	Group	**N**	**Mean**	**Std.**	**Std.Error Mean**	**P.value**
Mean time for regression to bromage 1	**DR**	**48**	**254.98**	**15.231**	**2.198**	
	FR	**48**	**181.56**	**16.464**	**2.376**	**<0.01**

The table compares regression time between two groups, DR and FR, with 48 participants. The DR group has a significantly longer regression time than the FR group.

Table 12:Distribution of Heart Rate in both the groups

	Group	N	Mean	Std.Deviation	Std.ErrorMean	
Baseline	DR	48	77.08	9.069	1.309	0.34
	FR	48	79.19	12.271	1.771	
justafter	DR	48	84.83	12.105	1.747	0.003
	FR	48	91.73	10.202	1.472	
5m	DR	48	78.46	9.839	1.420	0.062
	FR	48	82.94	13.179	1.902	
10m	DR	48	84.25	6.708	.968	0.94
	FR	48	84.15	7.707	1.112	
15m	DR	48	79.85	8.361	1.207	0.007
	FR	48	84.75	8.895	1.284	
20m	DR	48	88.02	9.438	1.362	0.032
	FR	48	92.33	9.947	1.436	
25m	DR	48	74.08	9.036	1.304	<0.001
	FR	48	83.88	12.729	1.837	
30m	DR	48	82.77	7.224	1.043	0.29
	FR	48	84.35	7.298	1.053	
40m	DR	48	79.75	6.902	.996	0.007
	FR	48	83.67	6.984	1.008	
50m	DR	48	80.69	11.933	1.722	0.99
	FR	48	80.67	12.545	1.811	
60m	DR	48	80.31	11.892	1.716	

	FR	48	78.44	12.956	1.870	0.46
	Group	N	Mean	Std.Deviation	Std.ErrorMean	
75m	DR	48	79.21	11.805	1.704	0.96
	FR	48	79.08	14.551	2.100	
90m	DR	48	79.63	13.324	1.923	0.94
	FR	48	79.42	14.092	2.034	
120m	DR	48	78.25	11.887	1.716	0.40
	FR	48	80.29	11.984	1.730	
150m	DR	48	79.96	12.289	1.774	0.28
	FR	48	82.60	11.665	1.684	
180m	DR	48	74.71	11.166	1.612	0.10
	FR	48	78.56	12.003	1.733	
210m	DR	48	83.23	13.018	1.879	0.46
	FR	48	81.27	13.066	1.886	
240m	DR	48	84.60	7.339	1.059	0.20
	FR	48	82.60	7.860	1.134	
300m	DR	48	83.58	6.968	1.006	0.21
	FR	48	81.77	7.224	1.043	

The table shows that the DR group showed significantly lower heartrates post-intervention, particularly at 15m, 20m, and 25m, compared to the FR group.

Table13:Distribution of Mean arterial pressure in both the groups

MAP at different time interval	Group	N	Mean	Std.Deviation	Std.ErrorMean	Pvalue
Baseline	DR	48	79.85	12.901	1.862	0.88
	FR	48	79.48	12.582	1.816	
justafter	DR	48	77.98	12.581	1.816	0.84
	FR	48	78.48	12.109	1.748	
5m	DR	48	79.60	14.573	2.103	0.96
	FR	48	79.48	13.852	1.999	
10m	DR	48	80.08	14.232	2.054	0.58
	FR	48	78.48	14.688	2.120	
15m	DR	48	79.96	11.778	1.700	0.75
	FR	48	80.73	12.467	1.800	
20m	DR	48	80.40	11.202	1.617	0.56
	FR	48	81.65	9.946	1.436	
25m	DR	48	89.92	4.649	.671	0.91
	FR	48	90.02	4.455	.643	
30m	DR	48	90.33	3.628	.524	0.61
	FR	48	89.94	3.916	.565	
40m	DR	48	78.71	13.830	1.996	0.53
	FR	48	76.92	14.471	2.089	
50m	DR	48	89.27	5.949	.859	0.44
	FR	48	90.10	4.421	.638	
60m	DR	48	89.90	6.969	1.006	0.95
	FR	48	89.98	5.341	.771	

MAPatdifferenttimeinterval	Group	N	Mean	Std.Deviation	Std.ErrorMean	Pvalue
75m	DR	48	82.04	11.061	1.596	0.61
	FR	48	80.75	13.455	1.942	
90m	DR	48	90.63	5.051	.729	0.59
	FR	48	90.08	4.757	.687	
120m	DR	48	90.81	6.985	1.008	0.65
	FR	48	90.27	4.306	.622	
150m	DR	48	79.31	13.318	1.922	0.24
	FR	48	76.00	14.253	2.057	
180m	DR	48	81.92	11.994	1.731	0.13
	FR	48	77.85	13.761	1.986	
210m	DR	48	78.50	12.260	1.770	0.18
	FR	48	75.25	11.363	1.640	
240m	DR	48	78.13	13.446	1.941	0.46
	FR	48	80.15	13.113	1.893	
300m	DR	48	79.40	10.204	1.473	0.85
	FR	48	79.79	10.941	1.579	

The table compares mean arterial pressure (MAP) between two groups, DR and FR, with 48 participants. No significant differences were found at baseline or subsequent intervals.

Table14 Distribution of Spo2 in both the groups

SPO2atdifferentimeint	Group	N	Mean	Std.Deviation	Std.ErrorMean	Pvalue
baseline	DR	48	98.90	.857	.124	0.01
	FR	48	98.29	1.336	.193	

justafter	DR	48	98.38	1.160	.167	0.85
	FR	48	98.42	1.108	.160	
5m	DR	48	98.44	1.009	.146	0.62
	FR	48	98.33	.996	.144	
10m	DR	48	98.56	1.147	.166	0.24
	FR	48	98.83	1.117	.161	
15m	DR	48	98.38	1.231	.178	0.86
	FR	48	98.42	1.048	.151	
20m	DR	48	98.31	1.075	.155	0.72
	FR	48	98.23	1.115	.161	
25m	DR	48	98.40	1.233	.178	0.79
	FR	48	98.46	1.091	.157	
30m	DR	48	98.48	.989	.143	0.55
	FR	48	98.35	1.041	.150	
40m	DR	48	98.58	1.145	.165	0.17
	FR	48	98.90	1.077	.155	
50m	DR	48	98.38	1.196	.173	0.86
	FR	48	98.33	1.117	.161	
60m	DR	48	98.58	1.028	.148	0.43

SPO2 atdifferentimeint	Group	N	Mean	Std.Deviation	Std.ErrorMean	Pvalue
	FR	48	98.75	1.021	.147	
	DR	48	98.67	1.226	.177	0.17
75m	FR	48	98.31	1.133	.164	
	DR	48	98.71	1.091	.157	0.017
90m	FR	48	98.17	1.098	.158	
	DR	48	98.00	.989	.143	0.14
120m	FR	48	98.31	1.075	.155	
	DR	48	98.96	1.091	.157	0.63
150m	FR	48	98.85	1.031	.149	
	DR	48	98.25	.911	.131	0.018
180m	FR	48	98.75	1.120	.162	
	DR	47	98.38	1.171	.171	0.88
210m	FR	48	98.42	1.108	.160	
	DR	48	98.44	1.009	.146	0.61
240m	FR	48	98.33	.996	.144	
	DR	48	98.56	1.147	.166	0.24
300m	FR	48	98.83	1.117	.161	

The table compares SPO2 levels between two groups, DR and FR, with DR having higher mean values at baseline and 90 minutes, and FR having higher values at other time points.

Table15: Adverse effect in the study subjects in both the groups

		Group		Total
		DR	FR	
Adverse effects	Bradycardia,	7	5	12
	Bradycardia,Hypotension	1	0	1
	Drowsiness	1	0	1
	Hypotension	0	11	11
	NA	42	17	59
	Shivering	0	5	5
	Vomiting	0	7	7
Total		48	48	96
Chi-sqvalue-35.92,pvalue-<0.001,significant				

The table shows a significant difference in adverse effects between two groups, DR and FR, with DR having more cases of bradycardia and FR having more hypotension, shivering, and vomiting.

DISCUSSION

The study reveals a similar gender distribution across the DR and FR groups, with no significant difference in the DR group's sex ratio, indicating no significant impact on the study outcomes. [7]

Bathametal's study found that males comprised 67.5% of the BD group and 60% of the BF group, indicating that gender distribution often doesn't significantly differ between experimental groups. [8]

SukhminderJit Singh Bajwa's [9] study found a male-to-female ratio of 38/12 in the RD group and 42/8 in the RF group, with an unsignificant statistical difference of 0.81.

The study's gender distribution, despite a common trend of male dominance, is statistically non-significant, suggesting that while legender is a significant demographic factor, its distribution among experimental groups is not significantly impacted.

The study found similar age, body weight, and surgery durations between the DR and FR groups, indicating homogeneity in these factors. Understanding these differences helps evaluate the generalizability of the findings.

The study found that the mean and duration of surgery were similar between the RF and RD groups, suggesting no significant difference in the study outcomes. [9]

Batham et al [8] reported longer mean an duration times for the procedure in the BD group and BF group, indicating similar procedural efficiency and patient handling in both groups.

Studies show that procedural times are relatively stable across study conditions, with variations not significantly affecting outcomes. Understanding the duration of surgery is crucial for evaluating surgical interventions.

The DR group showed a faster onset time of sensory block compared to the FR group, suggesting quicker treatment takes effect quickly, potentially improving patient comfort and reducing anxiety.
The study reveals a significant difference in sensory block levels between the DR and FR groups, suggesting that the DR treatment is more effective in achieving higher levels.
The study found a faster onset time of 18.02 minutes in the DR group, indicating quicker therapeutic effect and potential for prompt intervention in inclinical scenarios.
Parashar et al [10] found that the RD group experienced a significantly faster motor block onset than the RF group, indicating the effectiveness of the RD combination in achieving quicker motor block.
Kumarietal's study found faster onset times for motorblocks in RD combination groups compared to RF, highlighting potential benefits in clinical settings, including improved surgical efficiency and patient comfort. [11]
The study, along with Parashar et al [10] and Kumar et al [11], shows that RD combinations have faster onset times than RF combinations, enhancing the efficacy of anaesthetic treatments.
The study found that DR treatment provides a significantly longer sensory block duration than FR treatment, potentially reducing the need for additional alanalgesic interventions during and after surgical procedures. [7,12]
The study reveals that the DR group achieves a longer motor block duration, indicating the superior efficacy of dexmedetomidine-based treatments in maintaining a prolonged motor block. [8]
The study found that dexmedetomidine-based treatments result in longer-lasting sensory blocks, which is crucial for optimizing surgical and postoperative care, enhancing patient comfort and reducing the need for additional analgesics. [8,10]
The study found that DR treatment maintained motorblock for longer periods, enhancing postoperative pain management and patient comfort, and reducing the need for additional analgesics. [9]
The study found significant differences in heart rate between the DR and FR groups post-intervention, indicating superior cardiovascular stability provided by dexmedetomidine compared to fentanyl.
The study found no significant differences in mean arterial pressure (MAP) between the DR and FR groups, indicating that neither treatment significantly impacts MAP, ensuring hemodynamic stability.
The study found no significant differences in oxygen saturation levels between the DR and FR groups, indicating that the treatments did not significantly influence oxygen saturation levels.
The study found a significant difference in adverse effects between the DR and FR groups, emphasizing the importance of tailoring anesthetic choices to individual patient profiles. [7]

CONCLUSION

Exmedetomidine is a preferred choice over opivacaine in lower limb surgeries due to its early onset, longer duration of sensory and motor block, stable hemodynamics, and less adverse effects.

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