

Clinical Study to Evaluate the Effectiveness of Epidural Dexmedetomidine for Postoperative Analgesia in Lower Limb Vascular Surgeries

Sargam Goel¹, Mohammed Omar Kamal Ansari², Sudhakar Koppad³

¹Senior Resident, Department of Anaesthesiology, University College of Medical Sciences, Delhi 110095, India. ²Senior Resident, Department of Anaesthesiology, ESI Post Graduate Institute of Medical Science and Research, Rajajinagar, Bengaluru, Karnataka 560010, India. ³Consultant, Department Of Anaesthesiology and Critical Care, Bhagwan Mahaveer Jain Hospital, Vasanthnagar, Bengaluru, Karnataka 5600052, India.

Abstract

Background: The synergism between epidural local anaesthetics and opioids is well established but studies regarding combination of local anaesthetic with Dexmedetomidine as a continuous infusion for epidural analgesia are very few. This study compares the effectiveness of epidural infusion of Ropivacaine with Dexmedetomidine and Ropivacaine with Fentanyl for postoperative analgesia in lower limb vascular surgeries with respect to the Quality of analgesia, Motor block, Sedation, Patient satisfaction, Hemodynamic effects and Adverse effects if any. **Methods:** Sixty patients scheduled for lower limb vascular surgeries between 18-70yrs of ASA 1,2,3 were prospectively randomized by computer generated method into 2 groups of 30 each. Group 1: Ropivacaine + Fentanyl. Group 2: Ropivacaine + Dexmedetomidine. Ethics committee approval was granted and patients consent was taken. Data was analyzed with the help of Chi-square test and SPSS software version 21.0. Epidural catheter was inserted at the start of surgery and used for both anaesthesia and postoperative analgesia. 0.75% Ropivacaine 3-4mg/kg was administered as a bolus dose at the start of surgery for anaesthesia. After the surgery, patient was shifted to the recovery room. 3 hours after the elapse of the bolus Ropivacaine dose, a continuous infusion of 0.1% Ropivacaine + 0.04micrograms (mcg)/kilograms (kg)/hour (hr) of Dexmedetomidine or 0.1% Ropivacaine + 0.2mcg/kg/hour Fentanyl for 48 hours at the rate of 4millilitres (ml)/hour was started through the epidural catheter. The patient was assessed at regular intervals for 48 hours. **Results:** There was no statistically significant difference between the two groups in terms of VAS at rest and on movements, Motor blockade, sedation, hemodynamics, Patient satisfaction ($p > 0.05$). There was no adverse effect in any patient. **Conclusion:** Dexmedetomidine as an adjuvant to Ropivacaine provides good postoperative analgesia, stable hemodynamics, no unwarranted motor blockade and minimal sedation without any adverse effects. This is comparable to Fentanyl.

Keywords: Epidural Analgesia; Ropivacaine; Fentanyl; Dexmedetomidine; Vascular Surgeries.

Introduction

Postoperative pain is both distressing and detrimental for the patient. Despite its importance, analgesia is often under attended in the evolution and management of acute injuries and disease processes. Vascular patients often have a higher degree of comorbidities as compared to other patients such as diabetes mellitus, hypertension, cardiac disease, renal disease, chronic obstructive pulmonary disease and coagulation abnormalities.

Postoperative pain adds to these comorbidities.

Epidural analgesia is one of the most common techniques offering superior pain relief and early mobilization in these patients. For this various local anaesthetics, opioids and other adjuvants have been used in the past.

Ropivacaine is a long acting amide local anaesthetic with minimal cardiovascular and central nervous system side effects and lesser motor blockade. The addition of an opioid does provide a dose sparing effect of local anaesthetics and superior

Corresponding Author: Mohammed Omar Kamal Ansari, Senior Resident, Department of Anaesthesiology, ESI Post Graduate Institute of Medical Science and Research, Rajajinagar, Bengaluru, Karnataka 560010, India.
E-mail: dromar143@gmail.com

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analgesia but with increased incidence of adverse effects. Dexmedetomidine is another adjuvant which is a highly selective α -2 adrenoceptor agonist with minimal side effects.

The synergism between epidural local anaesthetics and opioids is well established but studies regarding combination of local anaesthetic with Dexmedetomidine as a continuous infusion for epidural analgesia are very few. So this study was undertaken to evaluate the effectiveness of epidural Dexmedetomidine in lower limb vascular surgeries by comparing an epidural infusion of 0.1% Ropivacaine and 0.04mcg/kg/hr Dexmedetomidine with 0.1% Ropivacaine and 0.2 micrograms(mcg)/kilogram(kg)/hour(hr) Fentanyl in the postoperative period.

Methods

The present study was a randomized study conducted in the Department of Anaesthesiology at our institute. 60 patients of physical status ASA grade 1, 2 and 3 who were electively posted for lower limb vascular surgery procedure under epidural anaesthesia, during November 2013 to October 2014 were included in the study. The study was approved by the hospital ethics committee. This was a hospital based, prospective, randomized control study. A medical biostatistician was consulted for sample size determination.

Method of Randomization

Patients were randomized into two groups by the use of computer generated method.

Group 1: 0.1% Ropivacaine + 0.2 micrograms(mcg)/kilogram(kg)/hour(hr) Fentanyl

Group 2: 0.1% Ropivacaine + 0.04mcg/kg/hr Dexmedetomidine.

Inclusion Criteria

Patient's informed consent, Age group of 18 - 70 years of both sexes and ASA grade I, II and III patients posted for elective lower limb vascular surgeries.

Exclusion Criteria

Patient refusal, Pregnant/Lactating patient, patients posted for emergency surgeries, Local site infection, Severe hypovolaemia, Bleeding/Coagulopathy or on anticoagulants, Spine deformities, Catheter dislodgement, Allergy to local

anaesthetics or Dexmedetomidine and hepatic diseases.

Material Required

18 G Tuohy needle, 20 G catheter, 2 cc, 5 cc, and 10 cc sterile syringes, Bowl, Sponge holding forceps, Swabs, Chlorhexidine solution, Povidone iodine, Tegaderm for fixing catheter, Local anaesthetics - 2% Lignocaine, and Ropivacaine 0.75%, Adjuvants - Fentanyl, Dexmedetomidine.

Procedure

- In left lateral position, the area for block and catheter fixation was cleansed with Povidone iodine.
- Under aseptic precautions a skin wheal is raised in L2 - L3/ L3 -L4 interspace with 2ml of 2% lignocaine. A 18G Touhy needle is passed through this space for about 1cm and after removing stylet a 10ml epidural syringe firmly attached to the hub of Touhy needle. Needle is slowly advanced until it enters the epidural space, confirmed by loss of resistance to air. After confirming needle in epidural space, the epidural syringe is disconnected and absence of blood or CSF is checked.
- After an epidural test dose, 0.75% Ropivacaine 3-4mg/kg is administered as a bolus dose and the time of administration is noted. The epidural catheter is placed cephalad until 4cms in the space. The markings at the skin level are noted and the catheter is secured using transparent adhesive tegaderm.
- After the surgery, patient is shifted to the recovery room. 3 hours after the elapse of the bolus Ropivacaine dose, a continuous infusion of 0.1% Ropivacaine + 0.04 micrograms (mcg)/kilograms (kg)/hour (hr) of Dexmedetomidine or 0.1% Ropivacaine + 0.2mcg/kg/hour Fentanyl is started for 48 hours at the rate of 4 millilitres (ml)/hour through the catheter placed in epidural space.

These drugs are used as continuous epidural infusion in a 50 ml syringe, using syringe pump at 4ml per hour. An epidural bolus of 5ml was given as rescue analgesia after confirming the position of the catheter when patient's VAS was > 4 and the patient was followed up. If pain continued to be the same, a second rescue analgesic, Inj. Paracetamol 1g by intravenous route was given. Catheter was removed if not in place and patient was excluded from the study.

The Following Parameters were Monitored

- Degree of sensory block or analgesia-(using VAS scores).
- Degree of motor blockade (using modified Bromage scale).
- Hemodynamic parameters- heart rate (HR), blood pressure (BP) and oxygen saturation (SpO₂).
- Sedation (by five point scale).
- Patient satisfaction (patient satisfaction score).
- Side effects, if any.

Quality of Analgesia [1]

Patients were assessed with a 10-cm visual analogue scale (VAS)

VAS 1: VAS at rest.

VAS 2: VAS at movements, while asking the patients to move the toes and flex the knee joint.

Visual Analog Scale

0	No Pain
1 - 3	Mild Pain
4 - 6	Moderate Pain
7 - 10	Severe Pain

0: Absolutely no pain
 1: Negligible pain
 2: Very very minimal pain
 3: Very minimal pain
 4: Minimal Pain
 5: Pain requiring relief
 6: Pain with little distress
 7: Severe pain
 8: Very severe pain
 9: Very very severe pain
 10: Unimaginable pain

2. Modified Bromage Scale [2]

- 0 →No block.
- 1 →Inability to raise extended leg.
- 2 →Inability to flex knee.
- 3 →Inability to flex ankle and foot.

3. Five Point Sedation Scale [3]

- 1 → Alert and wide awake.
- 2 → Arousable to verbal command.
- 3 → Arousable to gentle tactile stimulation.
- 4 → Arousable to vigorous shaking.
- 5 → Unarousable.

4. Satisfaction Score: Patient’s satisfaction was evaluated 48 hours after surgery with a two point score

- 1 = satisfied
- 2= unsatisfied

At the end of study, data was pooled and analysed. The comparison of normally distributed continuous variables between the groups was performed using Student’s t test. Nominal categorical data between the groups were compared using Chi-squared test or Fisher’s exact test as appropriate. p<0.05 was considered statistically significant. Patient demographics (age, gender, weight) and VAS (rest and movement), motor block, sedation, patient satisfaction, rescue analgesia and hemodynamics at 15, 30, 45minutes (min), 1 hour (hr), 4, 8, 12, 16, 20, 24, 32 and 48hrs were observed in Dexmedetomidine (group 2) and Fentanyl (group 1) groups. Conclusion was drawn regarding the effectiveness of postoperative analgesia and relative efficacy of the two drugs.

Results

In demographics with respect to age, sex, weight, gender and ASA grading no significant difference between two groups was noted.

Graph 1: Comparison of VAS at rest between the two groups

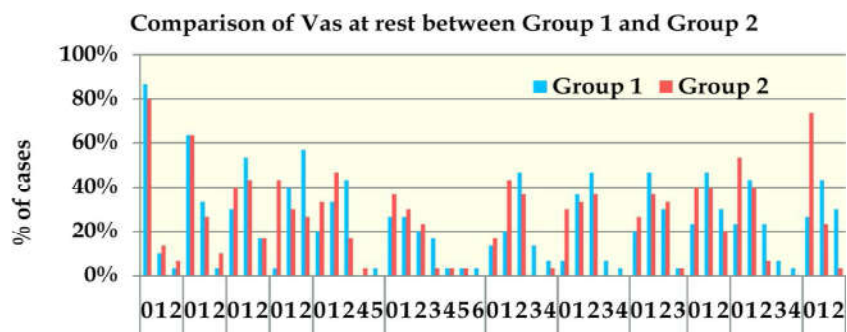
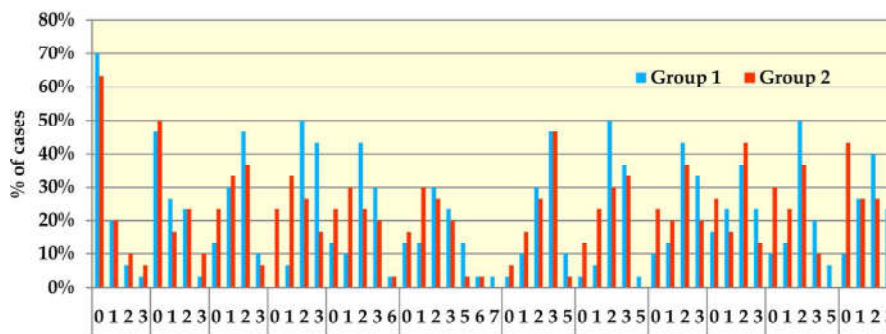


Table 1: Comparison of VAS at rest between two groups

VAS at rest		Group 1 (n=30)		Group 2 (n=30)		p Value
		Frequency	%	Frequency	%	
15 min	0	26	86.7%	24	80.0%	0.757
	1	3	10.0%	4	13.3%	
	2	1	3.3%	2	6.7%	
30 min	0	19	63.3%	19	63.3%	0.543
	1	10	33.3%	8	26.7%	
	2	1	3.3%	3	10.0%	
45 min	0	9	30.0%	12	40.0%	0.691
	1	16	53.3%	13	43.3%	
	2	5	16.7%	5	16.7%	
1 hr	0	1	3.3%	13	43.3%	0.001
	1	12	40.0%	9	30.0%	
	2	17	56.7%	8	26.7%	
4 hrs	0	6	20.0%	10	33.3%	0.125
	1	10	33.3%	14	46.7%	
	2	13	43.3%	5	16.7%	
	4	0	0.0%	1	3.3%	
	5	1	3.3%	0	0.0%	
8 hrs	0	8	26.7%	11	36.7%	0.639
	1	8	26.7%	9	30.0%	
	2	6	20.0%	7	23.3%	
	3	5	16.7%	1	3.3%	
	4	1	3.3%	1	3.3%	
	5	1	3.3%	1	3.3%	
12 hrs	0	4	13.3%	5	16.7%	0.117
	1	6	20.0%	13	43.3%	
	2	14	46.7%	11	36.7%	
	3	4	13.3%	0	0.0%	
	4	2	6.7%	1	3.3%	
16 hrs	0	2	6.7%	9	30.0%	0.097
	1	11	36.7%	10	33.3%	
	2	14	46.7%	11	36.7%	
	3	2	6.7%	0	0.0%	
	4	1	3.3%	0	0.0%	
20 hrs	0	6	20.0%	8	26.7%	0.874
	1	14	46.7%	11	36.7%	
	2	9	30.0%	10	33.3%	
	3	1	3.3%	1	3.3%	
24 hrs	0	7	23.3%	12	40.0%	0.355
	1	14	46.7%	12	40.0%	
	2	9	30.0%	6	20.0%	
32 hrs	0	7	23.3%	16	53.3%	0.053
	1	13	43.3%	12	40.0%	
	2	7	23.3%	2	6.7%	
	3	2	6.7%	0	0.0%	
48 hrs	0	1	3.3%	0	0.0%	0.001
	1	8	26.7%	22	73.3%	
	2	13	43.3%	7	23.3%	
	3	9	30.0%	1	3.3%	

Comparison of Vas at Movement between Group 1 and Group 2

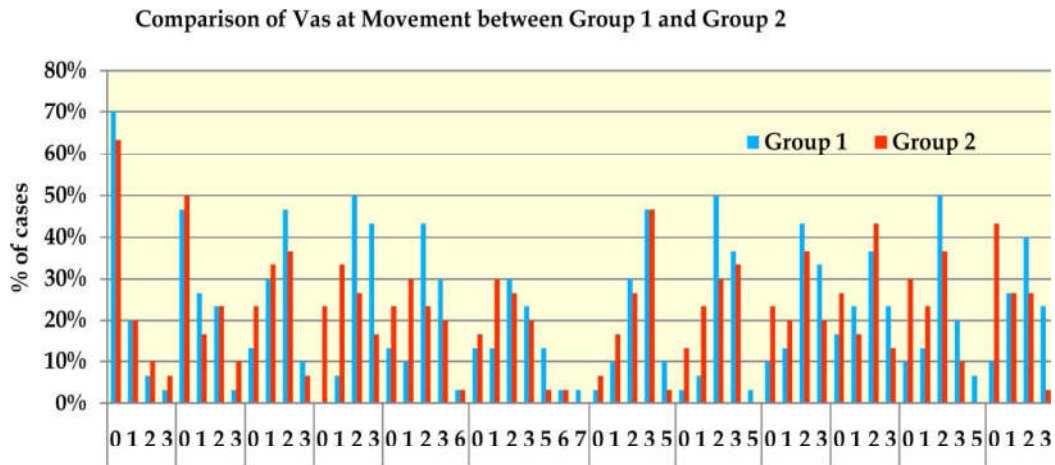


Graph 2: Comparison of VAS on movements between the two groups

1. Quality of analgesia – VAS score

VAS at rest at 1 hr and 48hours of the study was lower in Dexmedetomidine group, having statistically significantly p value of 0.001.

VAS on movements at 1 hr and 48hours was lower in Dexmedetomidine group, having statistically significant p value of < 0.001 and 0.009 respectively.



Graph 2: Comparison of VAS on movements between the two groups

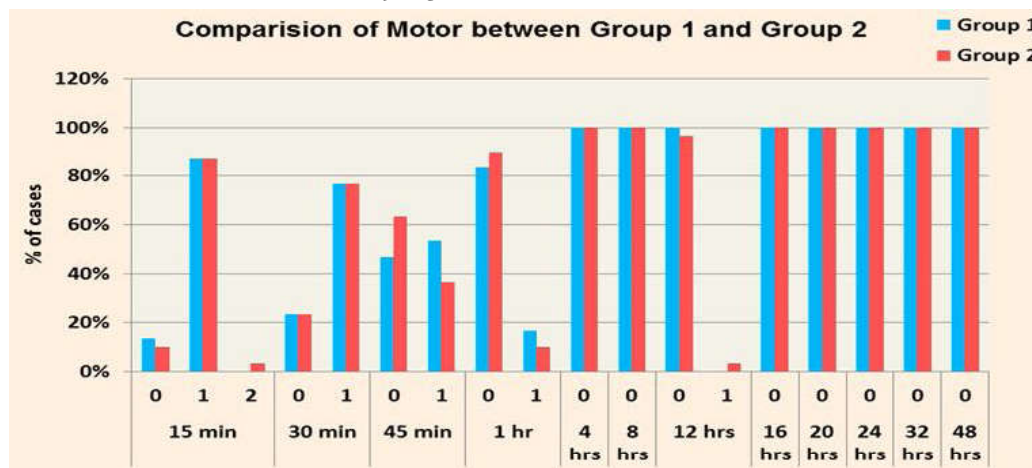
Table 2: Comparison of VAS at movement between two groups

VAS at movement		Group 1 (n=30)		Group 2 (n=30)		p value
		Frequency	%	Frequency	%	
15 min	0	21	70.0%	19	63.3%	0.889
	1	6	20.0%	6	20.0%	
	2	2	6.7%	3	10.0%	
	3	1	3.3%	2	6.7%	
30 min	0	14	46.7%	15	50.0%	0.631
	1	8	26.7%	5	16.7%	
	2	7	23.3%	7	23.3%	
	3	1	3.3%	3	10.0%	
45 min	0	4	13.3%	7	23.3%	0.698
	1	9	30.0%	10	33.3%	
	2	14	46.7%	11	36.7%	
	3	3	10.0%	2	6.7%	
1 hr	0	0	0.0%	7	23.3%	<0.001
	1	2	6.7%	10	33.3%	
	2	15	50.0%	8	26.7%	
	3	13	43.3%	5	16.7%	
4 hrs	0	4	13.3%	7	23.3%	0.183
	1	3	10.0%	9	30.0%	

	2	13	43.3%	7	23.3%	
	3	9	30.0%	6	20.0%	
	6	1	3.3%	1	3.3%	
8 hrs	0	4	13.3%	5	16.7%	0.548
	1	4	13.3%	9	30.0%	
	2	9	30.0%	8	26.7%	
	3	7	23.3%	6	20.0%	
	5	4	13.3%	1	3.3%	
	6	1	3.3%	1	3.3%	
	7	1	3.3%	0	0.0%	
12 hrs	0	1	3.3%	2	6.7%	0.756
	1	3	10.0%	5	16.7%	
	2	9	30.0%	8	26.7%	
	3	14	46.7%	14	46.7%	

VAS at movement	Group 1 (n=30)		Group 2 (n=30)		p Value	
	Frequency	%	Frequency	%		
20 hrs	0	3	10.0%	7	23.3%	0.367
	1	4	13.3%	6	20.0%	
	2	13	43.3%	11	36.7%	
	3	10	33.3%	6	20.0%	
24 hrs	0	5	16.7%	8	26.7%	0.570
	1	7	23.3%	5	16.7%	
	2	11	36.7%	13	43.3%	
	3	7	23.3%	4	13.3%	
32 hrs	0	3	10.0%	9	30.0%	0.115
	1	4	13.3%	7	23.3%	
	2	15	50.0%	11	36.7%	
	3	6	20.0%	3	10.0%	
	5	2	6.7%	0	0.0%	
48 hrs	0	3	10.0%	13	43.3%	0.009
	1	8	26.7%	8	26.7%	
	2	12	40.0%	8	26.7%	
	3	7	23.3%	1	3.3%	

2. Motor Block: No statistically significant difference in motor blockade between two groups.

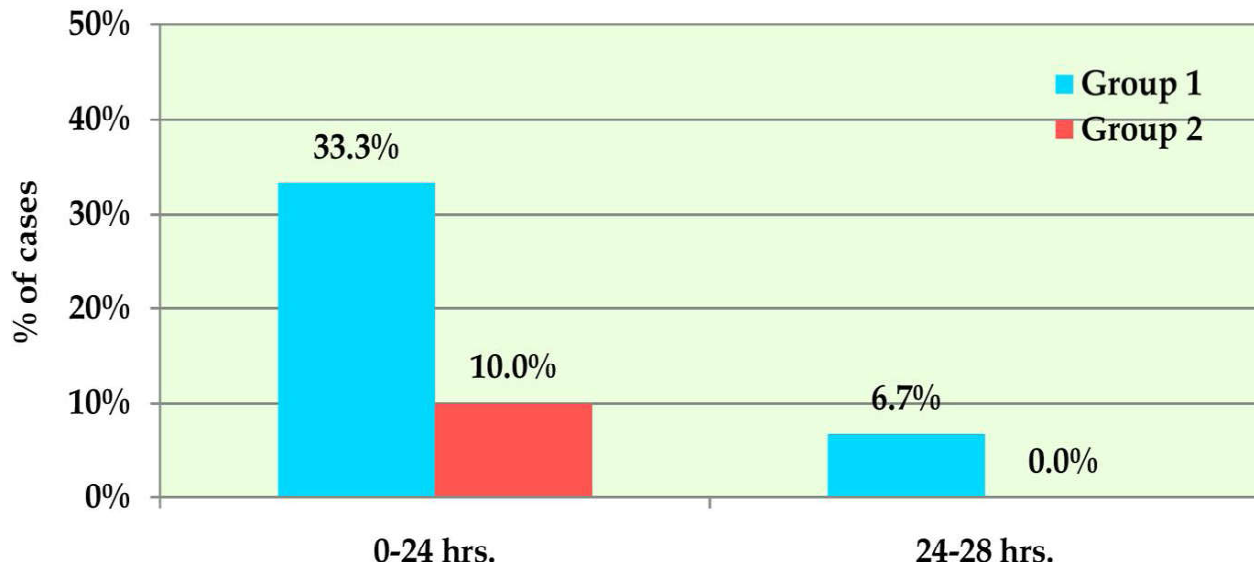


Graph 3: Motor block

Table 3: Comparison of motor blockade between two groups

Motor	Group 1 (n=30)			Group 2 (n=30)			p value
	Frequency		%	Frequency		%	
15 min	0	4	13.3%	3	10.0%	0.565	
	1	26	86.7%	26	86.7%		
30 min	2	0	0.0%	1	3.3%	1.000	
	0	7	23.3%	7	23.3%		
45 min	1	23	76.7%	23	76.7%	0.194	
	0	14	46.7%	19	63.3%		
1 hr	1	16	53.3%	11	36.7%	0.706	
	0	25	83.3%	27	90.0%		
4 hrs	1	5	16.7%	3	10.0%	-	
8 hrs	0	30	100.0%	30	100.0%	-	
12 hrs	0	30	100.0%	29	96.7%	1.000	
	1	0	0.0%	1	3.3%		
16 hrs	0	30	100.0%	30	100.0%	-	
20 hrs	0	30	100.0%	30	100.0%	-	
24 hrs	0	30	100.0%	30	100.0%	-	
32 hrs	0	30	100.0%	30	100.0%	-	
48 hrs	0	30	100.0%	30	100.0%	-	

Comparison of Rescue analgesia between Group 1 and Group 2



Graph 4: Rescue analgesia

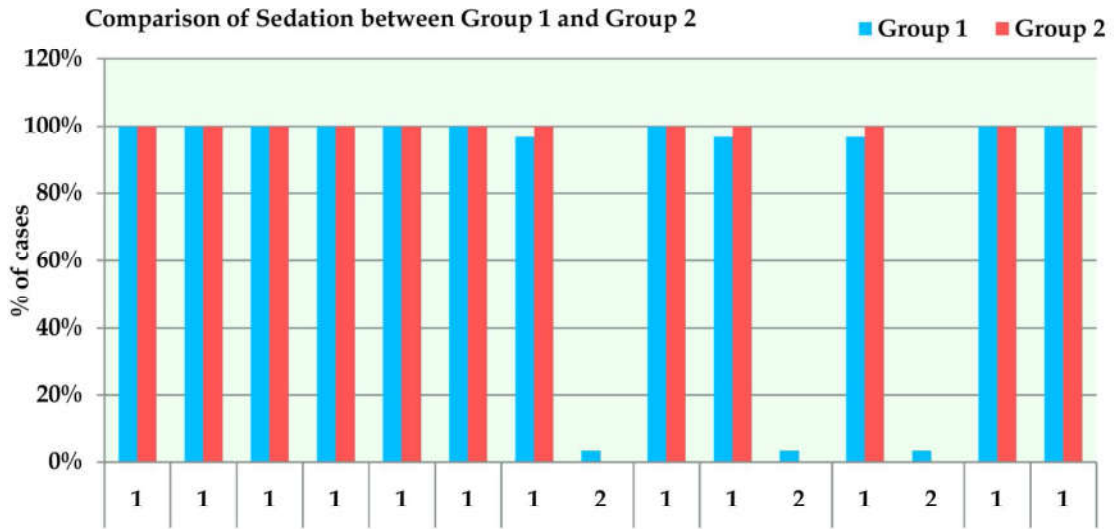
3. Rescue Analgesia

Only 3 patients who were administered Dexmedetomidine required rescue analgesia in the first 24 hours after the surgery, whereas none of them required rescue analgesics in the next 24 - 48 hours. In Fentanyl group, 10 patients in the first 24 hours and 2 patients in 24-48 hours required rescue

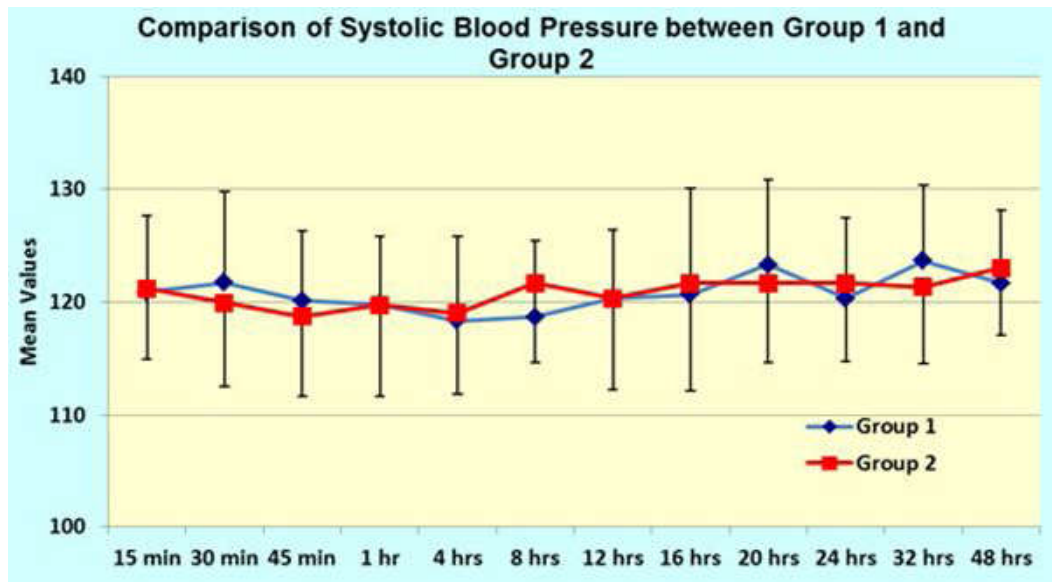
analgesics. But these figures were not statistically significant.

4. Sedation

No statistically significant difference between both groups with respect to sedation.



Graph 5: Comparison of sedation

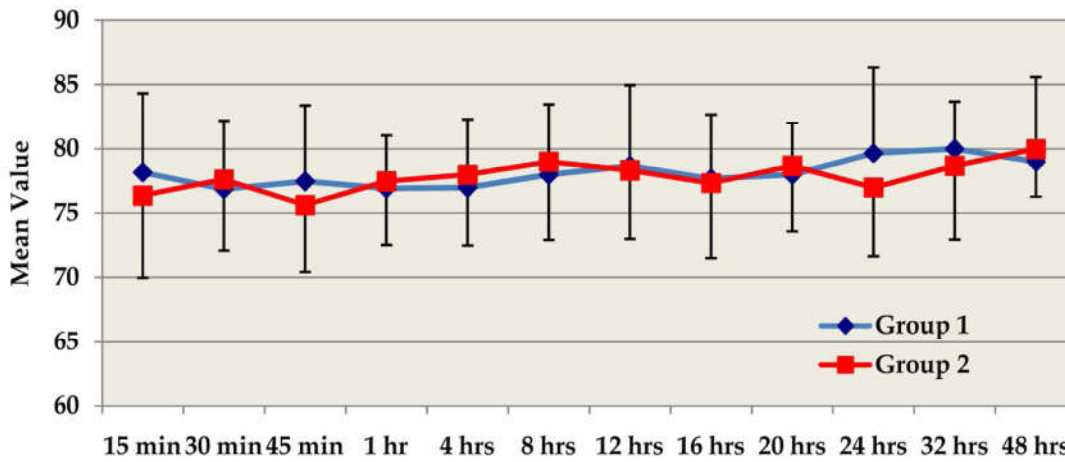


Graph 6: Systolic blood pressure comparison

Table 5: Comparison of sedation between two groups

Sedation	Group 1 (n=30)		Group 2 (n=30)		p Value
	Frequency	%	Frequency	%	
15 min	1	30	30	100.0%	-
30 min	1	30	30	100.0%	-
45 min	1	30	30	100.0%	-
1 hr	1	30	30	100.0%	-
4 hrs	1	30	30	100.0%	-
8 hrs	1	30	30	100.0%	-
12 hrs	1	29	30	100.0%	1.000
	2	1	0	0.0%	
16 hrs	1	30	30	100.0%	-
20 hrs	1	29	30	100.0%	1.000
	2	1	0	0.0%	
24 hrs	1	29	30	100.0%	1.000
	2	1	0	0.0%	
32 hrs	1	30	30	100.0%	-
48 hrs	1	30	30	100.0%	-

Comparison of Diastolic Blood Pressure between Group 1 and Group 2



Graph 7: Diastolic blood pressure comparison

Table 6: Comparison of systolic blood pressure between two groups

SBP	Group 1 (n=30) Mean ± SD	Group 2 (n=30) Mean ± SD	p Value
15 min	120.90 ± 6.74	121.20 ± 6.29	0.859
30 min	121.73 ± 8.08	119.93 ± 7.41	0.372
45 min	120.10 ± 6.18	118.73 ± 7.10	0.442
1 hr	119.77 ± 6.04	119.73 ± 8.09	0.986
4 hrs	118.33 ± 7.47	119.00 ± 7.12	0.725
8 hrs	118.67 ± 6.81	121.67 ± 6.99	0.098
12 hrs	120.30 ± 6.15	120.33 ± 8.09	1.000
16 hrs	120.67 ± 9.44	121.67 ± 9.50	0.684
20 hrs	123.33 ± 7.58	121.67 ± 6.99	0.380
24 hrs	120.33 ± 7.18	121.67 ± 6.92	0.855
32 hrs	123.67 ± 6.69	121.33 ± 6.81	0.186
48 hrs	121.67 ± 6.48	123.00 ± 5.96	0.410

Table 7: Comparison of diastolic blood pressure between two groups

DBP	Group 1 Mean ± SD	Group 2 Mean ± SD	p Value
15 min	78.17 ± 6.16	76.37 ± 6.39	0.271
30 min	76.87 ± 5.39	77.63 ± 5.53	0.589
45 min	77.47 ± 5.95	75.63 ± 5.19	0.209
1 hr	76.93 ± 4.14	77.47 ± 4.93	0.652
4 hrs	77.00 ± 5.35	78.00 ± 5.51	0.479
8 hrs	78.00 ± 5.51	79.00 ± 6.07	0.507
12 hrs	78.67 ± 6.29	78.33 ± 5.31	0.825
16 hrs	77.67 ± 5.04	77.33 ± 5.83	0.814
20 hrs	78.00 ± 4.07	78.67 ± 5.07	0.577
24 hrs	79.67 ± 6.69	77.00 ± 5.35	0.093
32 hrs	80.00 ± 3.71	78.67 ± 5.71	0.288
48 hrs	79.00 ± 6.62	80.00 ± 3.71	0.473

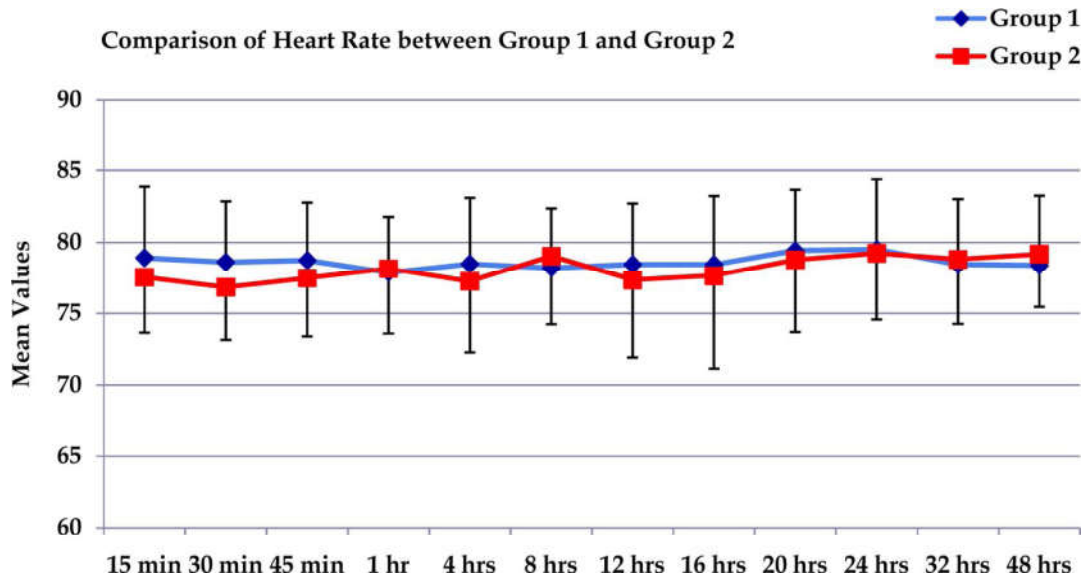
5. Comparison of systolic and diastolic blood pressure between two groups

Monitoring of systolic and diastolic pressures throughout the infusion period in both groups did not show any significant statistical difference and there was no episode of hypotension or

hypertension at any of the time intervals

6. Comparison of heart rate between the two groups

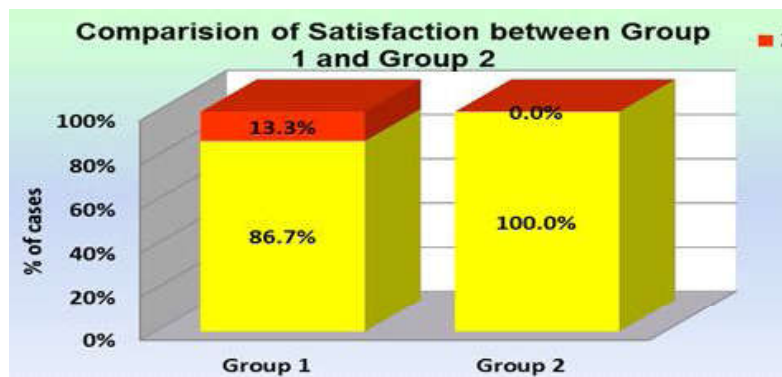
Heart rate remained stable around 76-79 in both the groups without any statistically significant



Graph 8: Heart rate comparison

Table 8: Comparison of heart rate between two groups

HR	Group 1 Mean ± SD	Group 2 Mean ± SD	p value
15 min	78.90 ± 4.99	77.53 ± 3.88	0.241
30 min	78.60 ± 4.27	76.83 ± 3.67	0.091
45 min	78.73 ± 4.04	77.47 ± 4.08	0.232
1 hr	77.87 ± 3.90	78.13 ± 4.53	0.808
4 hrs	78.47 ± 4.63	77.23 ± 4.94	0.322
8 hrs	78.20 ± 4.16	79.03 ± 4.78	0.474
12 hrs	78.43 ± 4.29	77.33 ± 5.40	0.386
16 hrs	78.43 ± 4.81	77.63 ± 6.48	0.726
20 hrs	79.43 ± 4.24	78.77 ± 5.08	0.583
24 hrs	79.50 ± 4.90	79.23 ± 4.67	0.830
32 hrs	78.43 ± 4.59	78.80 ± 4.54	0.757
48 hrs	78.37 ± 4.88	79.17 ± 3.70	0.477



Graph 9: Satisfaction score

Graph 9: Satisfaction score

Satisfaction	Group 1		Group 2		p value
	Frequency	%	Frequency	%	
1	26	86.7%	30	100.0%	0.112
2	4	13.3%	0	0.0%	
Total	30	100%	30	100%	

difference between them. There was no incidence of bradycardia in any patient.

7. Satisfaction Score

All the 30 patients in Dexmedetomidine group were satisfied with the analgesia given to them as compared with 26 in the Fentanyl group. But as p value was > 0.05 , this difference was considered to be statistically insignificant.

There were no adverse drug reactions in any patient in both the groups in the present study.

Discussion

Central neuraxial blockade in the form of epidural is very popular for lower limb surgeries as this technique avoids the disadvantages associated with general anaesthesia like airway manipulation, polypharmacy and other untoward effects like postoperative nausea, vomiting and the need for supplemental intravenous analgesics. Epidural anaesthesia can be used as sole anaesthetic for procedures involving the lower limbs, pelvis, perineum and lower abdomen. It has the ability to maintain continuous anaesthesia after placement of an epidural catheter, thus making it suitable for procedures of long duration.

Demographics

There was no statistically significant difference between age, sex, weight and ASA grading-- in the present study. This was comparable to other studies [2,3,4,5].

Comparison of the Hemodynamic Variables

In the present study, there were no statistically significant differences observed between Dexmedetomidine and Fentanyl in terms of blood pressure, pulse rate, and oxygen saturation throughout the study.

In the study by Bajwa et al in orthopaedic surgeries [2], though there was a decrease in heart rate and MAP (mean arterial pressure) in Dexmedetomidine group 30-35 min and 30-50 min after the bolus injection of epidural respectively, the hemodynamics remained stable in both Fentanyl and Dexmedetomidine groups postoperatively. This can be explained by the bolus injection of the drugs given at the time of start of the study. In the study by Ashraf et al [4] where they compared Dexmede-

tomidine and Bupivacaine with only Bupivacaine, heart rate was significantly lower in Dexmedetomidine group. These results of Bajwa et al and Ashraf et al can be explained by the bolus administration of the drugs. But in the studies by Bajwa et al [3] in vaginal hysterectomies and Saravana Babu et al [5], there were no statistically significant differences in mean arterial pressure and heart rate between their groups which is comparable to the present study.

Motor Block [2]

Motor block was assessed by modified Bromage scale. The present study did not find any significant difference in the motor blockade between the two groups. There was no motor blockade i.e. modified Bromage scale grade 0 at 4, 8, 16, 20, 24, 32 and 48 hours in both the groups.

Other studies [2,3], have assessed motor blockade during the intraoperative period for surgical anaesthesia where they have assessed the time for complete motor blockade to Bromage grade 3 and the mean time for regression to Bromage grade 1. This is not comparable to the results of the present study because we gave a continuous analgesic infusion and assessed motor block postoperatively only. Hence, our study did not measure the time for regression to Bromage scale 1 and 3.

Assessment of Pain by VAS

Pain was assessed by visual analogue scale (VAS) score from 0 to 10 in the present study. We measured pain as VAS at rest and VAS on movements). The present study did not find any statistically significant differences in VAS at rest and at movements between the two groups except at 1 hour (p value 0.001 at rest and < 0.001 on movements) and 48 hours (p value 0.001 at rest and 0.009 on movements) after the start of study which revealed better analgesia in Dexmedetomidine group. Since the studies done previously gave the drug bolus at the time of epidural insertion for both anaesthesia and postoperative analgesia rather than starting a continuous infusion, so they compared the VAS scores for surgical anaesthesia and duration of analgesia or the mean time to sensory regression in Fentanyl and Dexmedetomidine groups.

In the study by Bajwa et al [2] for lower limb orthopaedic surgeries, where they administered Ropivacaine, 15 ml of 0.75% epidurally in both the groups with addition of 1 $\mu\text{g}/\text{kg}$ of Dexmedetomidine in one group and 1 $\mu\text{g}/\text{kg}$ of

Fentanyl in the other, the mean time to sensory regression in Dexmedetomidine group was 366 min and in Fentanyl group was 242 min. So the duration of postoperative analgesia was significantly prolonged in Dexmedetomidine group.

Rescue Analgesia

In the present study, rescue analgesia was given when the VAS score was > 4 which was similar to other studies. Considering the total amount of rescue analgesia used over and above the continuous infusion for the entire study period of 48 hours in the present study, the number of patients receiving rescue analgesia in the first 24 hours (10 patients-Fentanyl group, 3 patients - Dexmedetomidine group) was less than in the subsequent 24 hours (2 patients - Fentanyl group, 0 patients - Dexmedetomidine) in the study population. This can be explained by the psychological factor for pain in the patients in the first 24 hours after the surgery. The difference between Dexmedetomidine and Fentanyl was not statistically significant with respect to requirement of rescue analgesia. This result was not comparable to the results of Bajwa et al [2] in lower limb orthopaedic surgeries where the time to first rescue top up was 366.62 min in Dexmedetomidine group and 242.16 min in Fentanyl group and the number of analgesic top up doses in Dexmedetomidine were significantly lower. The study by Bajwa et al [3] in vaginal hysterectomies also had similar results.

Sedation

In the studies by Bajwa et al [2] in lower limb orthopaedic surgeries and vaginal hysterectomies [3], the drugs were given epidurally for surgical anaesthesia also. So they assessed sedation as a useful property of the adjuvants used. They found that the sedative properties of Dexmedetomidine were far superior to Fentanyl. The sedation scores were significant on statistical comparison. Ashraf et al [4] reported a significant increase in sedation score in the Dexmedetomidine group. But none of the patients in the studies by Bajwa et al and Ashraf et al had respiratory depression. Saravana Babu MS et al [5] assessed sedation as a side effect of their study. They found that sedation was similar in both the groups and statistically non-significant. This was comparable to the results of the present study.

Side Effects

None of the patients of either group in the present study had any side effects.

In the study by Bajwa et al [2] in orthopaedic surgeries, the incidence of nausea and vomiting was significant in Fentanyl group at doses of 1 µg/kg. Dry mouth was significant in the Dexmedetomidine group at doses of 1µg/kg. None of the patients in either group had respiratory depression.

Bajwa et al [3] in vaginal hysterectomies compared 1.5µg/kg Dexmedetomidine with 2µg/kg Clonidine in vaginal hysterectomies. They observed dry mouth as a side effect in both the groups but was statistically non-significant. Other side effects like nausea, vomiting, headache, shivering and dizziness were comparable in both groups and statistically non-significant. Respiratory depression was not observed in any patient in either group. These side effects can be explained by the bolus administration of the drugs in larger doses as compared to the present study in which a continuous analgesic infusion was given.

Saravana Babu MS et al [5] found that the incidence of side effects was comparable in both the groups in their study and was statistically non-significant. None of the patients showed respiratory depression or motor block.

Patient Satisfaction

In our study, 86.7% of the patients who were administered Fentanyl were satisfied as compared to 100% of the patients who were given Dexmedetomidine. Other studies did not assess the patient satisfaction hence could not be compared with. The drugs were not withdrawn in any patient at any point of time.

Limitations of the Study

- The dose equivalence of Dexmedetomidine and Fentanyl when used in epidural anaesthesia could not be calculated because no previous studies were available for the reference of dose equivalence.
- Another limitation is that the analgesic infusion in the present study was started at the end of 3rd hour after the epidural Ropivacaine bolus. To prevent the acute postoperative pain window and its impact on morbidity, the present study has not considered waiting till sensory regression.

Recommendations

1. The present study recommends the use of Dexmedetomidine as an adjuvant to Ropivacaine

for postoperative analgesia in lower limb vascular surgeries

2. Both Dexmedetomidine and Fentanyl provide stable hemodynamics, no unwarranted motor blockade and minimal sedation without any adverse effects when used as an infusion with Ropivacaine.
3. The present study does not recommend using Dexmedetomidine over Fentanyl as no additional benefits were observed at the infusion doses used in the study .
4. Both the adjuvants are comparable in terms of patient satisfaction and the requirement of rescue analgesia.
5. This study recommends continuous infusion of Local anaesthetics with Dexmedetomidine and Fentanyl over bolus doses to minimise the side effects.

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