Original Article

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Anaesthesia Section

Effects of Differences in Epidural Needle Entry Point and Angle of Rotation of Needle Hub on the Onset and Duration of Sensory Blockade in Lower Limb Orthopaedic Surgeries: A Randomised Controlled Trial

GURUVAYURAPPAN ANNUSHHA GAYATHRI[1], RAMAMURTHY BALAJI[2], ANAND PUSHPARANI[3], BALASUBRAMANIUM GAYATHRI[4], GUNASEELAN MIRUNALINI[5]

ABSTRACT

Introduction: Epidural anaesthesia is a boon for providing prolonged analgesia for postoperative pain relief. The influence of epidural needle insertion on the onset of the block, which has not been studied previously, is significant.

Aim: To analyse the effect of epidural needle entry and rotation of the needle on the onset and duration of the block.

Materials and Methods: This double-blinded randomised controlled trial was conducted at the Department of Anaesthesiology, SRM Institute of Science and Technology, Chennai, Tamil Nadu, India from March 2020 to August 2021 on 70 patients undergoing leg and ankle surgeries. They were randomised into Group-ML (midline approach) and Group-PM (paramedian approach). In Group-ML, midline epidural needle entry was followed by catheter insertion. In Group-PM, the needle entry was paramedian, and the bevel was turned 45° towards the surgical site for catheter insertion. A 10 mL of 0.5% bupivacaine was administered. Postoperatively, epidural infusion was initiated using 0.125% bupivacaine with 2 µg/mL fentanyl. The time taken for catheter placement, onset of motor and sensory blockade, maximum sensory level attained, duration of sensory blockade, consumption of local anaesthetics, haemodynamic profile, and the need for rescue analgesia were monitored. Continuous data were analysed using the Student's t-test, and categorical data were analysed using the Chi-squared test with International Business Machines (IBM) statistical product and service solutions software version 27.0

Results: Both groups were comparable with respect to demographics. The mean age in Group-ML was 40.9±25.93 years, while in Group-PM it was 41.028±20.576 years, with a p-value of 0.981. The mean BMI in Group-ML was 24.91±2.998 kg/m^2, while in Group-PM it was 24.96±2.527 kg/m^2, which was statistically insignificant with a p-value of 0.944. A total of 21 males in Group-ML and 28 males in Group-PM participated in the study; the distribution was found to be statistically insignificant with a p-value of 0.067. The time taken for the placement of the epidural catheter was around 288 seconds in Group-ML and 322 seconds in Group-PM, with a p-value of 0.0035. The onset of sensory block was around 17 minutes in Group-ML and 13 minutes in Group-PM, respectively, with a p-value of 0.0001. The duration of sensory block or the time taken for two-segment regression of level was around 102 minutes and 128 minutes in Group-ML and Group-PM, respectively (p-value 0.0001). The rescue analgesic was required in seven patients of Group-ML and none in Group-PM, with a p-value of 0.005. The haemodynamic profile intra and postoperatively and postoperative VAS score were statistically insignificant between the groups.

Conclusion: The paramedian approach and epidural catheter insertion with the needle rotated at an angle of 45° towards the surgical side provide a rapid onset of the sensory and motor block with extended duration of the sensory blockade and reduced consumption of local anaesthetics.

Keywords: Analgesia, Bupivacaine, Catheter, Fentanyl, Paramedian approach

INTRODUCTION

The present-day surgical era demands speedy recovery following surgery with minimal pain and discomfort. Epidural analgesia is paramount among the modalities advocated for postoperative pain relief because it shortens Intensive Care Unit (ICU) stay and speeds up recovery in lower limb orthopaedic surgeries. Randomised studies analysing the advantages of preferential epidural anaesthesia to the side of surgery are very few [1,2]. Epidural analgesia speeds up recovery in lower limb orthopaedic surgeries and becomes ideal for ambulatory settings [3]. Neither gravity nor patient position can influence the spread of local anaesthetic in the epidural space [4]. Introducing the epidural needle in the paramedian position on the side of the surgery and rotation of the needle tip 45 degrees towards the operating side causes the preferential spread of the local anaesthetic toward the nerve roots innervating the operating side, resulting in effective drug spread to the target area [5]. Surgical anaesthesia is achieved with a 0.5% bupivacaine. Supplementing opioids to local anaesthetics improves analgesia, limits regression of sensory blockade, and decreases the dose of local anaesthetic [6]. Randomised studies analysing the advantages of preferential epidural anaesthesia to the side of surgery are very few [1,2]. The present study aimed to evaluate the results of epidural needle entry and rotation on the duration of sensory blockade in lower limb orthopaedic surgeries. Secondary objectives were to compare the time taken for placement of the epidural catheter, onset of sensory and motor blockade, intraoperative haemodynamic changes, and total volume of local anaesthetic consumed in the intraoperative and 24-hour postoperative period.

MATERIALS AND METHODS

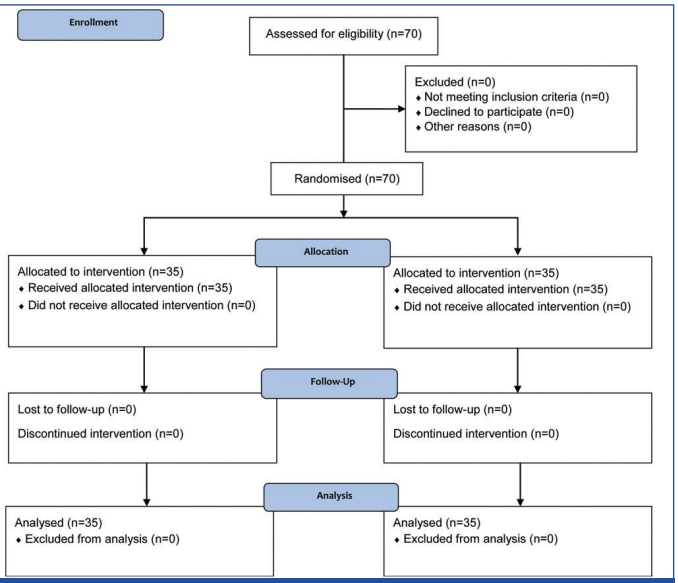
A double-blinded randomised control study was conducted at The Department of Anaesthesiology, SRM Institute of Science and Technology, Chennai, Tamil Nadu, India from March 2020 to August 2021. Institutional Ethical Committee approval (IEC NO 1896) and CTRI registration 2020/06/026246 (30/06/2020) were obtained. Informed consent, written in their own language, was obtained from all 70 patients.

Sample size calculation: The sample size was calculated based on a study by Hosseini B et al., [5]. Substituting m1 and m2 from the reference study with a 95% confidence interval and 80% power in the formula: $n=2^*\{(Z\alpha+Z(1-\beta))^{2*}((s1)^2+(s^2)^2)\}/(m1-m2)^2$, the authors obtained 28.57 as the sample size. For better statistical analysis, we included 35 subjects in each group (considering 20% dropouts).

Inclusion and exclusion criteria: Patients of age group between 18-60 years of both sexes of American Society of Anaesthesiologists (ASA) I and II were included. Patients who have a contraindication to central neuraxial blockade or a known history of allergy to local anaesthetics were excluded from the study.

Study Procedure

The types of surgeries the authors undertook were fracture of both bone leg Open Reduction and Internal Fixation (ORIF), Bimalleolar fracture ORIF, Fracture of both bone implant removal, and fracture of both bone Intramedullary or Interlocking (IMIL) nailing. The duration of the sensory blockade is noted as the time taken to regress to two segments below the highest level of sensory blockade attained [7]. The Consolidated Standards of Reporting Trials (CONSORT) flow diagram has been depicted in [Table/Fig-1]. The patients were allocated into two equal groups (Group-ML and Group-PM) by computer-generated random numbers. An anaesthesiologist not involved in the study performed the procedure.



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

The observer and patient were blinded to the study group. Group-ML (Midline approach): The needle entered the midline of the L4-L5 space, and the tip was placed in the usual cephalad direction of 90º, following which the catheter was inserted. Group-PM (Paramedian approach): After entering the epidural space, the needle tip was turned 45º towards the side of surgery, following which the catheter was introduced. The time taken from the needle piercing the skin to catheter placement was noted as t. A test dose of 3 mL of 2% Inj. Lignocaine with 1:2,00,000 adrenaline was injected. Patients were placed in the supine position following which 10 mL of 0.5% bupivacaine was injected into the epidural catheter as the initial dose. The evolution of sensory blockade was observed every two minutes until loss of sensation to pinprick at T10 sensory level was attained. This is noted as the time of sensory onset. If required, further boluses of 2 mL of 0.5% bupivacaine were administered to attain the mentioned target.

The highest level of sensory blockade attained at the end of 30 minutes from the initial dose is noted. Motor block level was evaluated using the Bromage Scale. The onset of motor blockade was taken as the time required to achieve a Bromage scale of 3. The time taken for the patient to be prepared for surgery was considered as the time when there is a complete loss of pinprick sensation up to the T10 level with a Bromage scale of 3 on the surgical site.

The duration of the sensory blockade is noted as the time taken to regress to two segments below the highest level of sensory blockade attained [7]. After regression of the sensory level to T12, additional top-ups of 2 mL of 0.5% bupivacaine were given to maintain a level of T10. The total volume of local anaesthetic consumed for top-ups was noted and summed up with the initial dose to calculate the total volume of local anaesthetic consumed intraoperatively. The total duration of surgery was noted. Inadequate surgical anaesthesia was documented as a failure, and the patient was subjected to general anaesthesia. Inj. Ephedrine 6 mg and Inj. Atropine 10 µg/kg was were used to treat a fall in blood pressure (>20%) or bradycardia. After surgery, patients were shifted to the Post Anaesthesia Care Unit (PACU) for epidural infusion, and the total volume of local anaesthetic consumption epidurally up to twenty-four hours in the postoperative period was recorded. Epidural infusion of 0.125% bupivacaine with 2 µg/mL Fentanyl was started at 4-7 mL/hour.

Postoperatively, the Visual Analogue Scale (VAS) score and haemodynamic parameters were recorded every 4th hour till 24 hours. When VAS ≥3, along with the existing epidural infusion, a bolus was given followed by increasing the rate by 1 mL/hr. When VAS ≥7, Inj. Morphine 3 mg was given intravenously as a rescue analgesic in both groups. A lock-out period of thirty minutes was planned before the subsequent dose of Inj. Morphine over the twenty-four hours postoperative period.

STATISTICAL ANALYSIS

Data were entered into an Microsoft excel spreadsheet (2010) and were analysed using the IBM statistical product and service solutions software version 27.0. Descriptive statistics including proportions, measures of central tendency, and measures of dispersion were used to describe the data. Continuous data were analysed using a Student's t-test (unpaired) while categorical data were analysed using a Chi-squared test. Student's t-tests were used to compare the means between the groups, and the Chi-square test was used to compare the proportions. A $p<0.05$ was considered to be statistically significant, $p<0.001$ as highly significant.

RESULTS

The groups were comparable with respect to age, gender, BMI distribution, ASA classification, and type of surgery [Table/Fig-2]. The time taken for the placement of the epidural catheter was around 288 seconds in Group-ML and 322 seconds in Group-PM with a p-value of 0.0035. However, the duration of motor blockade was not included in the present study [Table/Fig-3].

Parameters	Group-ML	Group-PM	p-value	Type of test
Age in years	40.9±25.93	41.028±20.576	0.981	Unpaired t-test
Gender distribution (M/F)	21/14	28/7	0.067	Chi-square test
BMI	24.914	24.96	0.944	Unpaired t-test
ASA (I/II)	14/21	15/20	0.808	Chi-square test
Diagnosis and procedures (#Both bone leg ORIF/#Bimalleolar ORIF/ Both bone Implant Exit/ Both bone IMIL nailing)	14/4/12/5	13/7/9/6	0.711	Chi-square test

[Table/Fig-2]: Patients gender, distribution, ASA, and diagnosis were analysed using Chi-squared test and Student's t-test was used for age and BMI p-value of <0.05 was significant.

Parameters	Group-ML	Group-PM	Confidence interval	p-value
Time taken to confirm catheter placement (minutes)	4.857±0.697	5.371±0.731	-0.854 to-0.173	0.003
Maximum sensory level attained (T10/T9/T8)	26/5/4	24/4/7	-	0.603
Volume of local anaesthetic consumption (mL)	22.114±5.06	18.314±4.185	1.585 to 6.014	0.001
Onset time of Sensory blockade (minutes)	17.657±3.438	13.51±4.189	2.319 to 5.974	0.0001
Duration of sensory blockade (minutes)	102.714±29.440	128.857±19.865	-38.122 to-14.163	0.0001
Onset time of motor blockade (minutes)	24.942±3.999	23±4.058	0.020 to 3.683	0.047
Number of persons requiring rescue analgesic (yes/no)	7/28	0/35	-	0.005
Comparison of total volume of local Anaesthetic consumed in postoperative period	132.82±14.324	121.14±14.044		0.001

[Table/Fig-3]: Block characteristics (categorical data was analysed using Chi-squared test and continues data using Student's t-test: p-value of <0.05 was significant).
Haemodynamic profile (intra and postop), VAS Score: Statistically insignificant between the groups mL: millilitre, VAS: Visual Analogue Scale, p<0.05 statistically significant p<0.001 statistically highly significant

The total volume of local anaesthetic consumption intra and postoperatively was reduced in Group-PM with statistical significance. The rescue analgesic was required in seven patients of Group-ML and none in Group-PM with a p-value of 0.005. The haemodynamic profile intra and postoperatively and postoperative VAS score were statistically insignificant between the groups.

On statistical analysis of intraoperative Systolic BP (SBP) from baseline till 150 minutes of surgery using unpaired t-test, p-values calculated for each subsequent interval were statistically insignificant between the two groups observed [Table/Fig-4].

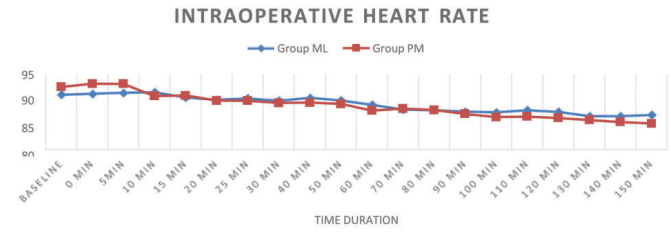
On statistical analysis of intraoperative DBP from baseline till 150 minutes of surgery using unpaired t-test, p-values calculated for each subsequent interval were statistically insignificant between Group-PM and Group-ML [Table/Fig-5]. On statistical analysis of intraoperative heart rate from baseline till 150 minutes of surgery using unpaired t-test, p-values calculated for each subsequent interval were statistically insignificant between Group-PM and Group-ML [Table/Fig-6].

Time interval	Group-ML	Group-PM	p-value
Baseline	124.3±16.169	128.40±14.150	0.2645
0 min	123.914±16.521	125.540±15.720	0.6745
5 min	124.657±14.202	119.820±19.283	0.2363
10 min	121.028±17.954	117.628±19.143	0.4462
15 min	117.200±17.789	116.250±20.353	0.8359
20 min	112.971±18.351	116.057±18.716	0.4881
25 min	110.800±18.276	112.114±19.329	0.7717
30 min	111.571±18.663	112.314±18.718	0.8684
40 min	111.257±17.449	111.657±17.812	0.9247
50 min	111.514±16.114	113.114±17.830	0.6949
60 min	112.600±16.922	114.457±16.654	0.6460
70 min	113.771±16.822	114.942±17.020	0.7731
80 min	113.600±16.186	116.342±14.734	0.4612
90 min	113.142±15.070	115.771±15.134	0.4690
100 min	114.514±13.463	117.714±12.910	0.3137
110 min	113.714±12.770	118.257±13.414	0.1513
120 min	114.142±13.831	117.828±12.339	0.2435
130 min	115.285±13.356	117.028±11.756	0.5641
140 min	116.914±12.081	118.228±10.737	0.6321
150 min	114.914±12.308	118.000±12.155	0.2950

[Table/Fig-4]: Comparison of intraoperative Systolic BP (SBP) in mmHg.

Time interval	Group-ML	Group-PM	p-value
Baseline	78.428±10.586	81.829±6.510	0.110
0 min	78.171±11.057	82.314±8.362	0.081
5 min	77.485±10.339	75.971±9.262	0.520
10 min	73.485±11.619	73.685±10.417	0.939
15 min	71.342±9.788	69.971±9.918	0.562
20 min	74.228±9.258	74.943±9.232	0.747
25 min	68.028±9.903	67.028±10.464	0.682
30 min	67.685±9.002	66.914±9.980	0.735
40 min	67.228±7.941	65.971±9.739	0.556
50 min	68.371±8.062	64.828±8.247	0.073
60 min	69.542±7.762	65.628±7.911	0.040
70 min	68.657±9.573	67.771±8.818	0.688
80 min	68.942±8.824	68.857±7.814	0.966
90 min	68.228±9.926	68.428±9.079	0.930
100 min	68.428±10.293	68.400±9.098	0.990
110 min	67.942±10.055	68.971±6.896	0.619
120 min	67.800±9.557	67.542±6.788	0.896
130 min	68.028±9.073	68.742±4.680	0.680
140 min	68.257±9.876	68.685±6.733	0.832
150 min	68.742±9.798	68.542±6.084	0.919

[Table/Fig-5]: Comparison of intraoperative.
Diastolic BP (DBP) in mmHg



[Table/Fig-6]: Comparison of intraoperative heart rate.

No significant fall in saturation was observed during the observation period. Saturation, heart rate, SBP, and DBP measured at 4-hourly intervals from baseline till 24 hours were found to be statistically insignificant between the two groups [Table/Fig-4-7].

Time interval	Group-ML	Group-PM	p-value
Baseline	99.514±0.886	99.428±0.814	0.673
0 min	99.628±0.689	99.457±0.816	0.346
5 min	99.48±0.950	99.685±0.471	0.268
10 min	99.342±0.968	99.628±0.546	0.132
15 min	99.628±0.598	99.628±0.546	1.100
20 min	99.571±0.850	99.771±0.426	0.217
25 min	99.514±0.853	99.771±0.426	0.115
30 min	99.885±0.403	99.828±0.382	0.545
40 min	99.600±0.694	99.828±0.382	0.093
50 min	99.885±0.403	99.828±0.382	0.545
60 min	99.771±0.645	99.857±0.355	0.491
70 min	99.742±0.700	99.771±0.426	0.834
80 min	99.771±0.645	99.885±0.322	0.352
90 min	99.771±0.546	99.885±0.322	0.291
100 min	99.771±0.689	99.828±0.452	0.683

110 min	99.885±0.403	99.828±0.382	0.545
120 min	99.628±0.598	99.828±0.382	0.100
130 min	99.914±0.284	99.771±0.490	0.139
140 min	99.828±0.452	99.914±0.284	0.614
150 min	99.857±0.355	99.885±0.322	0.730

[Table/Fig-7]: Comparison of intraoperative. Saturation rate in %.

Postoperative haemodynamics were comparable between the groups [Table/Fig-8]. Postoperative VAS Score was comparable between the groups [Table/Fig-9].

	Time in hrs	Group-PM	Group-ML	
		Mean±SD	Mean±SD	p-value
Systolic BP	0	127.5429±12.58697	124.4571±15.45457	0.37
	4	122.8286±12.02567	123.4857±15.21101	0.362
	8	117.2571±13.96707	123.3429±12.54391	0.84
	12	116.2857±14.27579	119.8286±16.335	0.656
	16	117.4571±15.21482	117.6±14.66127	0.644
	20	116.8±13.98697	116.5714±14.35124	0.966
	24	114.1429±13.31992	115.3429±14.88968	0.946
Diastolic BP	0	81.82857±6.510108	79.17143±9.733163	0.183
	4	82.31429±8.36228	79.22857±9.646961	0.681
	8	75.97143±9.262466	77.71429±9.739463	0.445
	12	74.2±10.16279	75.71429±8.244683	0.496
	16	71.4±9.653405	73.94286±8.467734	0.484
	20	75.4±8.423357	75.77143±7.448	0.845
	24	70.14286±8.029881	73.74286±7.337826	0.582
Heart rate	0	90.8±13.71731	88.28571±12.99677	1
	4	91.62857±13.75005	88.51429±12.91686	0.873
	8	91.65714±15.14429	88.88571±12.91686	0.084
	12	88.2±12.75516	89.08571±11.86039	0.502
	16	88.17143±13.58088	87.88571±12.10195	0.306
	20	86.17143±12.26301	85.74286±11.67537	0.145
	24	86.25714±12.6592	86.65714±10.56059	0.3
SpO_2	0	99.42857±0.814779	99.428±0.777844	0.576
	4	99.45714±0.81684	99.428±0.68	0.63
	8	99.68571±0.471008	99.457±0.610827	0.715
	12	99.62857±0.546955	99.314±0.758149	0.764
	16	99.62857±0.546955	99.485±0.612201	0.926
	20	99.77143±0.426043	99.542±0.81684	0.881
	24	99.77143±0.426043	99.628±0.68966	0.886

[Table/Fig-8]: Postoperative haemodynamics between the groups (continuous data using Student's t-test, p-value >0.05 was non significant).
SD: Standard Deviation

Hours	Group-ML	Group-PM	p-value
0	2.05±0.338	2±0.169	0.436
4	2.54±0.918	2.25±0.560	0.119
8	2.48±0.742	2.4±0.650	0.632
12	2.885±1.367	2.48±0.701	0.126
16	2.657±1.235	2.31±0.631	0.148
20	2.428±0.978	2.48±0.658	0.764
24	2.2±0.584	2.11±0.403	0.455

[Table/Fig-9]: Postoperative VAS Score between the groups.

DISCUSSION

Among the surgeries performed, orthopaedic surgeries carry a higher incidence of postoperative pain. Epidural anaesthesia is safer in high-risk patients and it also reduces cardiovascular, cerebral, and thromboembolic events postoperatively [6-8]. The paramedian epidural approach has been observed to have a decreased chance of piercing the dura mater and reduced incidence of paraesthesia [9]. A unilateral epidural block is due to the presence of plica mediana dorsalis and midline adhesion [10,11] that favours drug spread with the placement of a lateral, anterolateral, or paravertebral catheter. It has been reported that there is a 20% reduction in the volume of local anaesthetic consumed postoperatively with the paramedian technique. Only very few randomised clinical trials have been undertaken for unilateral epidural anaesthesia [12-15]. The present study was hence aimed to analyse whether adequate surgical anaesthesia can be attained with minimal use of local anaesthetic in the lateral approach of epidural catheter placement.

In the present study, patients in both groups were comparable with respect to age and gender distribution, Body Mass Index (BMI), American Society of Anaesthesiologists (ASA) classification, type, and duration of surgery. The time taken to confirm catheter placement was faster with Group-ML (288 seconds) compared to Group-PM (322 seconds) with a p-value of 0.0035. The midline approach is the standard technique for epidural anaesthesia in this institution. Hence, the current study had encountered a minimal time delay in identifying the epidural space in the paramedian approach compared to the midline approach. However, in both groups, patients did not experience any resistance during catheter insertion or elicitation of paraesthesia. Similarly, Huffnagle SL et al., stated that catheterisation over a cephalad-oriented bevel was easier for insertion [16]. Blomberg RG has stated that resistance with the introduction of the catheter and injection following it was felt more with midline than the paramedian technique [4]. Sen O et al., placed the tip of the epidural needle towards the operative side at an angle of 5-10 degrees from the midline [17]. They had no difficulty with the technique of identifying the epidural space and placement of the catheter, which was consistent with the present study. Buchheit T and Crews JC fixed the catheter after a 5-10° rotation towards the lateral position, rotating the epidural needle tip towards the side of surgery [18]. He observed reduced morphine consumption using unilateral epidural blockade. The maximum sensory level attained in the operative limb in both the ML group and PM group was T8. T8 was attained by only two patients of Group-ML and six patients of Group-PM. This difference is statistically insignificant between the groups. The PM group favours the unilateral epidural blockade and more nerve roots get concentrated with the local anaesthetic compared to Group-ML.

Podder S et al., studied the lumbar epidural catheter insertion in a flexed and unflexed spine comparing midline and paramedian approaches [19]. They quoted that spine flexion can be avoided, and the catheter can be placed easily in the paramedian approach, which turns as an advantage for patients finding difficulty with the sitting position [20]. The total volume of 0.5% bupivacaine consumed intraoperatively was around 22 mL in Group-ML and 18 mL in Group-PM with a p-value of 0.001. As more nerve roots get concentrated with the local anaesthetic in the paramedian approach, the local anaesthetic consumption gets reduced. Borghi B et al., injected 10 mL of 0.75% Ropivacaine with an additive of 10 µg sufentanil in two subsequent doses [21].

In the present present study, the total volume of local anaesthetic consumed postoperatively for 24 hours (mL) was around 132 mL in Group-ML and 121 mL in Group-PM, with statistical significance (p-value=0.001). Seven patients experienced pain that was not settled with the epidural infusion of 7 mL/hr in Group-ML and hence were administered Inj. Morphine 3 mg bolus twice during the observation period. No patients in Group-PM required rescue analgesic. The haemodynamic profile was stable throughout the intra and postoperative period in the groups.

In this study, seven patients in Group-ML had morphine requirements, whereas no patient in Group-PM was administered during the postoperative period. However, the difference was statistically significant with a p-value of 0.005. Only three patients in Group-PM required an infusion rate of 7 mL/hr. Similarly, Borghi B et al., provided analgesia with Patient-controlled Epidural Analgesia (PCEA) pump using 0.2% Ropivacaine and additive sufentanil 0.25 µg/mL. The rescue analgesic was used in three patients of Group-ML and none in Group-PM [21].

Limitation(s)

The present study has limitations such as the preferential spread of the drug in the paramedian position was not confirmed by a radiological technique, the parameters were observed only in the operative limb, only ASA class I and II patients were included in the study, and the time taken for postoperative ambulation was not taken into account as a few surgeries required immobilisation, and the time taken for spontaneous urination was not used for comparison as few patients were already catheterised.

CONCLUSION(S)

By rotating the epidural needle 45° in the paramedian approach towards the surgical site, the sensory blockade can be extended. Adequate intraoperative anaesthesia and postoperative analgesia can be achieved with a lesser volume of the local anaesthetic solution in the paramedian approach. Rotating the needle tip towards the surgical site increases the concentration of the local anaesthetic reaching the nerve roots on the surgical site, decreasing the volume required while providing adequate surgical anaesthesia.

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PARTICULARS OF CONTRIBUTORS:

1. Postgraduate, Department of Anaesthesiology, SRM Institute of Science and Technology, Chennai, Tamil Nadu, India.
2. Professor, Department of Anaesthesiology, SRM Institute of Science and Technology, Chennai, Tamil Nadu, India.
3. Professor, Department of Anaesthesiology, SRM Institute of Science and Technology, Chennai, Tamil Nadu, India.
4. Professor, Department of Anaesthesiology, SRM Institute of Science and Technology, Chennai, Tamil Nadu, India.
5 Associate Professor, Department of Anaesthesiology, SRM Institute of Science and Technology, Chennai, Tamil Nadu, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Anand Pushparani,
F2, Meenakshi Flats, Officers Colony, First Street,
Adambakkam, Chennai-600088, Tamil Nadu, India.
E-mail: pushpa82_dr@yahoo.com

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