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Research Article

Study Of The Efficacy, After Giving Equal Bolus Dose Of 8ml Of Ropivacaine 0.1% Vs Ropivacaine 0.2% With Fentanyl For Post-Operative Patient-Controlled Epidural Analgesia In Patients Undergoing Infra-Umbilical Abdominal Surgery And Lower Limb Orthopedic Surgery

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ABSTRACT
Background: Epidural analgesia is widely accepted as the prime modality of providing optimal post-operative analgesia after major surgery, and patient-controlled epidural analgesia (PCEA) has recently gained popularity. It is often used in the post-operative phase and can be given as boluses, infusions, or a combination of the two. Local anesthetic has been used as the mainstay for epidural analgesia, alone or in combination with opioids. Ropivacaine is a relatively new amino amide local anesthetic, with Fentanyl is the opioid often used. **Aims and Objectives:** To study the efficacy, after giving 8ml bolus dose of ropivacaine 0.1% versus 0.2% with fentanyl for postoperative patient-controlled epidural analgesia in patients undergoing infra-umbilical abdominal and lower limb orthopedic surgery at Pravara Rural Hospital, Loni. **Materials & methods:** 74 patients were included in the study where the patients were divided into two groups with Group 1 given Ropivacaine 0.1% with Fentanyl 2 µg/ml and Group 2 given Ropivacaine 0.2% with Fentanyl 2 µg/ml. The PCEA pump will be programmed to deliver a continuous epidural infusion at the rate of 8 ml/hour after the initial 8 ml bolus dose, with a PCEA bolus dose of 4 ml and lockout interval of 20 minutes. Postoperatively the intensity of pain by vas score, degree of motor blockade, level of sedation, the total volume of drug infused, variation in hemodynamic parameters, and adverse effects were observed. **Results:** Group 1 reported a mean VAS, significantly higher than Group 2's mean VAS. Overall, the data suggest that Group 1 consistently experiences higher VAS scores compared to Group 2 across the measured time intervals, indicating potentially differing levels of perceived discomfort or pain between the two groups. **Conclusion**: Ropivacaine 0.2% with fentanyl is more efficacious than Ropivacaine 0.1% with fentanyl when used as PCEA in the postoperative period for analgesia.

Keywords: Patient-Controlled Epidural Analgesia (PCEA), Ropivacaine, Postoperative Analgesia.

INTRODUCTION

Major abdominal and lower limb surgeries are amongst the most painful procedures. A technique known as patient-controlled anesthesia (PCA) allows patients to self-administer analgesic drugs to control their pain within predetermined bounds. Common PCA system types include, intravenous patient-controlled analgesia (IV PCA) where patients can press a button that is attached to an IV pump to administer a pre-set dose of intravenous medication and patient controlled epidural anesthesia, a catheter attached to a pump delivers the medication into the epidural space.

Post-operative acute pain can have major health effects on a patient if it is not well managed, primarily in the form of surgical complications, a longer recovery period, and an extended hospital stay. Furthermore, it may eventually lead to the development of chronic pain and detrimental social and psychological consequences that lower a patient's quality of life.(1) A challenge for anesthesiologists, postoperative pain control requires our constant attention.(2) New methods that alter

surgical stress responses and shorten hospital stays have been developed in response to the growing awareness of the undertreatment of postoperative pain and its possible negative effects on patients' well-being.[3] When compared to conventional treatments, (PCA) has been said to be more effective in providing patients with pain relief and satisfaction.[4] PCA is a useful technique for managing acute pain, which includes pain after surgical procedures, labor pain, trauma, or other medical conditions, as well as chronic and malignant pain.[5] Although various patient-controlled analgesia alternatives have been proposed, there hasn't been any scientific evidence to support one variation above the others. PCA is often used in the post-operative phase and can be given as boluses, infusions, or a combination of the two.Thus, the lockout interval, demand dose, bolus dose, drugs to be administered, and method of administration are all defined for PCA.[6] PCA enables the use of an infusion pump to self-titrate analgesic boluses according to the patient's level of pain relief. Common PCA system types include, intravenous patient controlled analgesia (IV PCA) where patients can press a button that is attached to an IV pump to administer a pre-set dose of intravenous medication and patient contolled epidural analgesia (PCEA), a catheter attached to a pump delivers the medication into the epidural space. One of the efficient method for postoperative analgesia is patient-controlled analgesia (PCA) preceded by initial intravenous titration, which can quickly provide a sufficient analgesic dose upon arrival at the postoperative care unit (PACU).[5] In the past, intravenous PCA was used for the administration of opioids; however, this approach carries a risk of drowsiness and respiratory depression. One of the many widely used modalities for optimal postoperative pain management for infra-umbilical abdominal and lower limb surgeries is epidural analgesia is PCEA. It has been gaining popularity as it has been demonstrated that patient involvement in pain management improves surgical outcomes.[6,7] By using opioids for epidural analgesia, concerns related to intravenous doses were avoided, and there were also reduced cardiovascular problems and adverse pulmonary events during the postoperative period.[8] The epidural approach, when used as PCEA following major surgery, ideally offers beneficial relief from pain with minimal side effects, it is considered a safer option.[5] While intravenous analgesia was associated with a higher incidence of opioid-related adverse effects, PCEA is highly compatible with interindividual demands by altering to patients' needs while minimizing overall discomfort.[9] Compared to using local anesthetic alone, the epidurally administered combination of opioids and local anesthetic enhances pain relief. It has been demonstrated that continuous infusion delivery of the medication results in improved analgesic effects.[10,11] Delay in the reversal of the sensory blockage is one of the several advantages of this combination over local anesthetic injection alone. Opioids reduce the total amount of local anesthetic required to provide sufficient analgesia when they are added to the combination of local anesthetics.[12,13] Research has shown that the principal mechanism by which opioids, when administered epidurally, maintain analgesia is sensory blocking.[15] Due to its strong lipophilicity, fentanyl diffuses quickly in the epidural region, action and absorption start rapidly.[6] Epidural analgesia with ropivacaine, a local anesthetic, and fentanyl has been found to work effectively.[16] Ropivacaine is a local anesthetic that is enantiomerically pure (S-enantiomer) and has an amide action. It acts slowly and reversibly, blocking sodium ion influx more effectively in nerve fibers that transmit pain (A-delta and C fibers) than in motor function (A beta fibers).[17] Increases the intensity of this action by potassium channel blockade which is dose-dependent.[18,19] The S(-) enantiomer of ropivacaine is also synthesized as a pure enantiomer due to its significantly reduced cardiotoxicity and neurotoxicity.

The present study is designed to study the efficacy of ropivacaine 0.1% versus 0.2% with fentanyl for post-operative patient-controlled epidural analgesia in patients undergoing infra-umbilical abdominal and lower limb surgery at Pravara Rural Hospital, Loni.

METHODOLOGY

This is an observational, prospective longitudinal study which includes sixty patients between 18 to 70 years of age, of either gender, belonging to ASA Class I or II, willing to give informed written and verbal consent and who are scheduled for elective infra-umbilical abdominal surgery and lower limb orthopedic surgery in department of Anaesthesiology and Critical Care, Pravara Rural Hospital, Loni.

Consent: The patients will be explained in detail regarding the anesthetic procedure and the study. Written and verbal consent will be taken for the procedure, as well as for his/her inclusion in the proposed study.

Preparation: As per the routine protocol of the institution, the patients will be thoroughly evaluated by a pre-anesthetic check-up with general, physical and systemic examination on the evening prior to the proposed surgery. The usage of the PCEA device and the visual analogue scale (VAS) will be explained to all patients, with 0 corresponding to no pain and 10 to the worst imaginable pain. All the patients will be fasted for a period of 6 hours pre-operatively.

Procedure:

The patients were moved to the operating room on the day of the procedure, and multi-para monitors were utilized to begin standard monitoring, which included an electrocardiogram (ECG), mean arterial blood pressure, respiration rate, and oxygen saturation. Airway equipment, breathing circuits, the emergency resuscitation trolley, and the anesthesia machine were all kept ready.

The identical drugs and procedures were used to provide spinal anesthesia to each patient. The patients were preloaded with 10 ml/kg of Ringer's Lactate solution and an 18G IV line was secured. A skin wheal was raised in the midline at the interspace between the spinous processes of the L2 and L3 vertebrae using 2 ml of 2% lignocaine while taking all aseptic precautions and after antiseptic skin preparation. An 18G Tuohy's needle was placed perpendicular to the skin and progressed until there was an abrupt decrease of resistance to pressure on the syringe's air-filled plunger for confirmation. The Tuohy's needle was used to thread the multiport epidural catheter in upward. After removing the Tuohy's needle, the catheter was pulled out until six centimeters of it remained in the epidural space. Following a negative blood and CSF aspiration, 2ml of 2% lignocaine with adrenaline was used as a test dose to ensure that the catheter was properly positioned in the epidural space before it was attached to the skin. After epidural catheterization, the required drug for spinal anesthesia in the desired dosage has been given. The post-surgery patient is shifted to the post-operative area where patient-controlled epidural analgesia will be started once the VAS score of the patient reaches more than or equal to 6. The drug will be administered epidurally via the PCEA pump. Initially, 8ml bolus dose will be given and later the PCEA pump will be programmed to deliver a continuous epidural infusion for 24 hours at the rate of 8ml/hour with a PCEA bolus dose of 4 ml and lockout interval of 20 minutes.

Sample Size

- From Pathale et al. the duration of analgesia with dose varied by 10% we expect 300 cases per year. Therefore for 90% confidence level the minimum estimated sample size is 74.

Statistical Analysis:

Statistical testing was conducted using the Statistical Package for the Social Sciences (SPSS) version 28.0. Continuous variables are presented as mean ± SD, median (IQR) and minimum-maximum values. Categorical variables are expressed as frequencies and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student's t-test and mann Whitney U test for non-normally distributed data. Nominal categorical data between the groups were compared using the Chi-squared test or Fisher's exact test, as appropriate. For all statistical tests, a p-value of less than 0.05 was considered to indicate a significant difference

OBSERVATIONS AND RESULTS

1. Demographic Data:

The table (1) compares the mean age, height, and weight between Group 1 and Group 2. Group 1 has a mean age of 46.05 ± 12.20 years, while Group 2 has a slightly higher mean age of 49.03 ± 12.16 years. The p-value of 0.297 indicates that there is no statistically significant difference in the mean age between the two groups. For height, Group 1 has a mean of 166.24 ± 5.71 cm, whereas Group 2 has a mean height of 165.51 ± 5.76 cm. The p-value of 0.586 shows that the difference in mean height is not statistically significant. Regarding weight, Group 1 has a mean of 70.84 ± 6.89 kg, compared to Group 2's mean weight of 69.16 ± 7.20 kg. The p-value of 0.310 indicates no statistically significant difference in mean weight between the two groups.

Table 1: Comparison of Mean Age, Height, and Weight between Group 1 and Group 2

0	Group 1	Group 2	p value
	Mean ± SD	Mean ± SD	
Age (years)	46.05 ± 12.20	49.03 ± 12.16	0.297
Height (cms)	166.24 ± 5.71	165.51 ± 5.76	0.586
Weight (kgs)	70.84 ± 6.89	69.16 ± 7.20	0.310

Test used: Student's t test

2. ASA

The table (2) compares the distribution of ASA (American Society of Anesthesiologists) physical status classifications between Group 1 and Group 2. In Group 1, 29 individuals (78.4%) are classified as ASA 1, while in Group 2, 32 individuals (86.5%) fall into this category. The p-value of 0.359 indicates that there is no statistically significant difference in the proportion of ASA 1 classification between the two groups. For ASA 2 classification, 8 individuals (21.6%) are in Group 1, compared to 5 individuals (13.5%) in Group 2. Both groups have a total of 37 individuals, representing 100% of each group. The overall comparison shows that the distribution of ASA classifications between Group 1 and Group 2 does not differ significantly.

Table 2: ASA Physical Status Classification Comparison between Group 1 and Group 2

ASA	Group 1		Group 2		p value
	Frequency	%	Frequency	%	
1	29	78.4%	32	86.5%	0.359
2	8	21.6%	5	13.5%	
Total	37	100%	37	100%	

Test used: Chi square test

3. Total Volume of Drug Infused, PCEA Bolus Doses, and Number of PCEA Boluses:

The table (3) compares the total volume of drug infused, the number of PCEA bolus doses, and the number of PCEA boluses between Group 1 and Group 2.

For the total volume of drug infused, Group 1 has a mean of 212.65 ± 7.15 ml, with a range of 200 to 224 ml and a median volume of 212 ml (IQR: 208 - 220 ml). In contrast, Group 2 has a mean volume of 202.92 ± 3.08 ml, with a range of 200 to 208 ml and a median volume of 204 ml (IQR: 200 - 204 ml). The p-value of <0.001 indicates a statistically significant difference in the total volume of drug infused between the two groups.

Regarding PCEA bolus doses, Group 1 has a mean of 12.70 ± 7.25 doses, with a range of 0 to 26 doses and a median of 12 doses (IQR: 8 - 20 doses). Group 2 has a mean of 2.19 ± 2.81 doses, with a range of 0 to 8 doses and a median of 1 dose (IQR: 0 - 4 doses). The p-value of <0.001 shows a statistically significant difference in the number of PCEA bolus doses between the two groups.

For the number of PCEA boluses, Group 1 has a mean of 3.16 ± 1.79 boluses, with a range of 0 to 6 boluses and a median of 3 boluses (IQR: 2 - 5 boluses). Group 2 has a mean of 1.46 ± 2.09 boluses, with a range of 0 to 4 boluses and a median of 1 bolus (IQR: 0 - 2 boluses). The p-value of <0.001 indicates a statistically significant difference in the number of PCEA boluses between the two groups

Table 3: Total Volume of Drug Infused, PCEA Bolus Doses, and Number of PCEA Boluses Comparison between Group 1 and Group 2

	Group 1			Group 2			P value
	Mean± SD	Min-Max	Median (IQR)	Mean ± SD	Min - Max	Median (IQR)	
Total Volume of Drug Infused (ml)	212.65 ± 7.15	200 - 224	212 (208 - 220)	202.92 ± 3.08	200 - 208	204 (200 - 204)	<0.001**

PCEA Bolus Doses (ml)	12.70 ± 7.25	0 - 26	12 (8 - 20)	2.19 ± 2.81	0 - 4	1 (0 - 4)	<0.001**
Number of PCEA Boluses (number)	3.16 ± 1.79	0 - 6	3 (2 - 5)	1.46 ± 2.09	0 - 2	1 (0 - 2)	<0.001**

Test used: Mann Whitney U test
**signifies highly significant p value<0.001

4. Requency of Rescue Analgesia:

The table (4) presents data on rescue analgesia for Group 1 and Group 2. In both groups, 100% of the participants, which is 37 individuals in each group, did not require rescue analgesia. The absence of a p-value indicates that there was likely no statistical comparison performed between the groups regarding rescue analgesia. Therefore, no inference can be made regarding the statistical significance of any difference between the two groups in terms of rescue analgesia.

Table 4: Frequency of Rescue Analgesia between Group and Group 2

Rescue Analgesia	Group 1		Group 2		p value
	Frequency	%	Frequency	%	
None	37	100.0%	37	100.0%	–
Total	37	100%	37	100%	

Test used: Chi square test

5. Adverse Effects:

The table (5) displays information on adverse effects observed in Group 1 and Group 2. In both groups, 100% of participants, totaling 37 individuals in each group, did not experience any adverse effects. The absence of a p-value suggests that no statistical comparison was conducted between the two groups regarding adverse effects. Therefore, no conclusions can be drawn regarding any potential differences in adverse effects between the two groups based on this data alone.

Table 5: Frequency of Adverse Effects between Group 1 and Group 2

Adverse Effect	Group 1		Group 2		p value
	Frequency	%	Frequency	%	
None	37	100.0%	37	100.0%	–
Total	37	100%	37	100%	

Test used: Chi square test

6. Heart Rate:

The table (6) presents a detailed comparison of mean heart rates (HR) between Group A and Group B at various time intervals over a 24-hour period. Initially, at 0 hours, no significant difference in HR is observed between the groups ($p = 0.204$), a pattern that persists through most time points, including 2, 4, 6, 8, 10, 12, 14, 16, 20, and 24 hours ($p > 0.05$). However, at 18 hours, Group A exhibits a significantly higher mean HR compared to Group B ($p = 0.017$*), indicating a notable divergence between the groups at this specific time point. Overall, except for the observed difference at 18 hours, the data suggest consistent non-significant disparities in HR between Group A and Group B throughout the majority of the measured time intervals.

Table 6: Comparison of Mean Heart Rates between Group 1 and Group 2 over a 24-Hour Period

Heart rate	Group 1	Group 2	p value
	Mean ± SD	Mean ± SD	
0 min	98.05 ± 6.81	100.81 ± 8.01	0.115
15 min	90.46 ± 8.45	94.46 ± 5.66	0.019*
30 min	86.27 ± 7.51	89.51 ± 4.05	0.026*
45 min	83.16 ± 6.25	85.27 ± 4.47	0.099
1 hrs	80.43 ± 5.44	83.16 ± 4.74	0.024*
2 hrs	78.54 ± 5.16	79.84 ± 5.04	0.278
3 hrs	76.76 ± 4.73	80.35 ± 5.64	0.004*

4 hrs	75.70 ± 4.72	78.57 ± 5.57	0.020*
5 hrs	75.70 ± 4.45	77.05 ± 4.88	0.217
6 hrs	74.49 ± 3.90	75.05 ± 3.79	0.527
10 hrs	73.89 ± 3.94	73.92 ± 3.19	0.974
14 hrs	72.78 ± 3.79	72.32 ± 2.65	0.548
18 hrs	71.68 ± 2.70	71.57 ± 2.26	0.852
24 hrs	71.14 ± 1.93	70.46 ± 1.82	0.126

Test used: Student's t test
*signifies significant p value<0.05

7. Mean Arterial Pressure:

This table (7) provides a comparison of the mean arterial pressure (MAP) between Group 1 and Group 2 at different time intervals. At 0 minutes, there is no significant difference in MAP between the two groups (p = 0.518). This trend continues consistently through 15, 30, 45 minutes, and 1 hour intervals, where p-values range from 0.184 to 0.539, indicating no statistically significant disparities. However, at the 4-hour mark, there is a notable difference with Group 1 showing a significantly higher MAP compared to Group 2 (p = 0.005*), suggesting a divergence in MAP at this time point. Similar trends are observed at 18 hours, where Group 1 again displays a significantly higher MAP compared to Group 2 (p = 0.025*). Overall, except for the observed differences at 4 and 18 hours, the data suggest consistent non-significant disparities in MAP between Group 1 and Group 2 across the majority of the measured time intervals.

Table 7: Comparison of Mean Arterial Pressure between Group 1 and Group 2 over a 24-Hour Period

Mean Arterial Pressure	Group 1	Group 2	p value
	Mean ± SD	Mean ± SD	
0 Min	69.65 ± 2.10	69.35 ± 1.83	0.518
15 min	70.41 ± 1.24	70.22 ± 1.40	0.539
30 min	70.70 ± 1.68	70.19 ± 1.61	0.184
45 min	71.35 ± 1.65	71.08 ± 1.71	0.491
1 hrs	71.97 ± 1.72	71.51 ± 1.79	0.264
2 hrs	72 ± 1.96	71.73 ± 1.50	0.507
3 hrs	71.51 ± 1.52	71.54 ± 1.19	0.932
4 hrs	71.65 ± 2.36	70.38 ± 1.28	0.005*
5 hrs	71.59 ± 2.02	71.22 ± 1.96	0.416
6 hrs	71.59 ± 2.01	70.92 ± 1.38	0.096
10 hrs	71.65 ± 1.75	70.92 ± 2.24	0.123
14 hrs	71 ± 1.93	70.43 ± 1.56	0.168
18 hrs	71.35 ± 2.11	70.43 ± 1.24	0.025*
24 hrs	71.30 ± 2	70.43 ± 1.31	0.152

Test used: Student's t test
*signifies significant p value<0.05

8. Respiratory Rate:

This table (8) presents a comparison of the respiratory rate between Group 1 and Group 2 at various time intervals. At 0 minutes, there is no significant difference in respiratory rate between the two groups (p = 0.371). Similarly, at subsequent time points (15, 30, 45 minutes, and 1, 2, 3, 4, 5, 6, 10, 14, 18, and 24 hours), the p-values range from 0.073 to 0.852, indicating no statistically significant disparities in respiratory rate between the groups. Although there is a trend of slightly higher respiratory rates in Group 2 at some time points, such as 15 minutes (p = 0.335) and 1 hour (p = 0.073), these differences do not reach statistical significance. Overall, the data suggest consistent non-significant differences in respiratory rate between Group 1 and Group 2 across the measured time intervals.

Table 8: Comparison of Respiratory Rate between Group 1 and Group 2 over A 24-Hour Period

Respiratory Rate	Group 1	Group 2	p value

	Mean ± SD	**Mean ± SD**	
0 Min	12.76 ± 0.5	12.65 ± 0.54	0.371
15 min	12.95 ± 0.58	15.78 ± 0.78	0.335
30 min	12.95 ± 0.52	12.59 ± 1.82	0.262
45 min	12.73 ± 1.69	12.78 ± 0.48	0.852
1 hrs	12.92 ± 0.49	12.19 ± 2.39	0.073
2 hrs	12.89 ± 0.46	12.76 ± 0.44	0.198
3 hrs	12.92 ± 0.6	12.84 ± 0.37	0.485
4 hrs	12.92 ± 0.55	12.78 ± 0.42	0.236
5 hrs	12.92 ± 0.49	12.89 ± 0.32	0.780
6 hrs	12.78 ± 0.58	12.86 ± 0.35	0.470
10 hrs	13 ± 0.53	12.84 ± 0.37	0.131
14 hrs	12.95 ± 0.58	12.84 ± 0.37	0.341
18 hrs	12.86 ± 0.54	12.86 ± 0.35	1.000
24 hrs	12.95 ± 0.52	12.86 ± 0.35	0.435

Test used: Student's t test

9. Oxygen Saturation:

The table (9) displays a comparison of oxygen saturation levels between Group 1 and Group 2 at different time points, along with associated p-values. At 0 minutes, there is no significant difference in oxygen saturation between the groups ($p = 0.321$). However, as the observation progresses, some time points show statistically significant differences. Notably, at 30 minutes and 45 minutes, Group 2 exhibits lower oxygen saturation compared to Group 1, with p-values of 0.020. This trend continues at 1 hour ($p = 0.156$) and 2 hours ($p = 0.040$). Subsequent time points do not demonstrate significant differences until 6 hours, where Group 2 again shows lower oxygen saturation compared to Group 1 ($p = 0.091$). However, from 5 hours to 24 hours, there are no significant differences observed between the groups ($p > 0.05$). Overall, while oxygen saturation levels are generally comparable between the groups, Group 2 displays lower saturation at some early time points, suggesting potential differences in oxygen uptake or circulation that warrant further investigation. The Student's t-test was used for statistical analysis.

Table 9: Comparison of Oxygen Saturation between Group 1 and Group 2 over a 24-Hour Period

Oxygen saturation	**Group 1**	**Group 2**	**p value**
	Mean ± SD	**Mean ± SD**	
0 Min	98.97 ± 0.16	99 ± 0.0	0.321
15 min	98.97 ± 0.16	98.89 ± 0.32	0.169
30 min	99 ± 0.00	98.86 ± 0.35	0.020
45 min	99 ± 0.00	98.86 ± 0.35	0.020
1 hrs	99 ± 0.00	98.86 ± 0.35	0.156
2 hrs	99 ± 0.00	98.95 ± 0.3	0.040
3 hrs	99 ± 0.00	98.89 ± 0.32	0.079
4 hrs	98.97 ± 0.16	98.89 ± 0.39	0.251
5 hrs	98.95 ± 0.23	98.95 ± 0.23	1.000
6 hrs	98.97 ± 0.16	98.86 ± 0.35	0.091
10 hrs	99 ± 0.00	98.97 ± 0.16	0.321
14 hrs	99 ± 0.00	98.97 ± 0.16	0.321
18 hrs	98.97 ± 0.16	98.97 ± 0.16	1.000
24 hrs	99 ± 0.00	99 ± 0.00	1.000

Test used: Student's t test

10.Visual Analgue Score:

The table (10) presents a comparison of Visual Analogue Score (VAS) between Group 1 and Group 2 at different time points, along with descriptive statistics and associated p-values. At 0 minutes, both groups exhibit similar VAS scores, with a mean of 6 and no statistically significant difference ($p = 1.000$). However, as time progresses, notable differences emerge.

At 30 minutes, Group 1 shows a higher mean VAS (3.65 ± 0.68) compared to Group 2 (3.24 ± 0.44), with a significant p-value of 0.003. This trend continues at subsequent time points, with Group 1 consistently reporting higher VAS scores compared to Group 2. The differences become more pronounced over time, with decreasing mean VAS scores in both groups. At 24 hours, the disparity is most significant, with Group 1 reporting a mean VAS of 1.05 ± 0.58, significantly higher than Group 2's mean VAS of 0.46 ± 0.51 ($p < 0.001$). Overall, the data suggest that Group 1 consistently experiences higher VAS scores compared to Group 2 across the measured time intervals, indicating potentially differing levels of perceived discomfort or pain between the two groups.

Table 10: Comparison of Visual Analogue Scores between Group 1 and Group 2 over a 24-Hour Period

Visual Analouge Score	Group 1			Group 2			p value
	Mean ± SD	Min - Max	Median (IQR)	Mean ± SD	Min - Max	Median (IQR)	
0 Min	6 ± 0	6 - 6	6 (6 - 6)	6.00 ± 0.00	6 - 6	6 (6 - 6)	1.000
15 min	4.49 ± 0.99	3 - 6	4 (4 - 5)	4.19 ± 0.4	4 - 5	4 (4 - 4)	0.203
30 min	3.65 ± 0.68	2 - 5	4 (3 - 4)	3.24 ± 0.44	3 - 4	3 (3 - 3.50)	0.003
45 min	3.16 ± 0.83	2 - 5	3 (2.5 - 4)	2.7 ± 0.52	2 - 4	3 (2 - 3)	0.010
1 hrs	2.65 ± 0.54	2 - 4	3 (2 - 3)	2.32 ± 0.53	2 - 4	2 (2 - 3)	0.007
2 hrs	2.59 ± 0.8	1 - 4	3 (2 - 3)	2.11 ± 0.39	1 - 3	2 (2 - 2)	<0.001 **
3 hrs	2.46 ± 0.73	1 - 4	2 (2 - 3)	2.16 ± 0.5	1 - 3	2 (2 - 2)	0.056
4 hrs	2.27 ± 0.65	1 – 4	2 (2 - 3)	2.05 ± 0.66	1 - 3	2 (2 - 2.5)	0.197
5 hrs	2.05 ± 0.62	1 – 3	2 (2 - 2)	1.76 ± 0.6	1 - 2	2 (1 - 2)	0.041*
6 hrs	1.89 ± 0.57	1 – 3	2 (2 - 2)	1.54 ± 0.51	1 - 2	2 (1 - 2)	0.009*
10 hrs	1.78 ± 0.71	1 – 3	2 (1 - 2)	1.35 ± 0.48	1 - 2	1 (1 - 2)	0.007*
14 hrs	1.54 ± 0.61	1 – 3	1 (1 - 2)	1.22 ± 0.42	1 - 2	1 (1 - 1)	0.012*
18 hrs	1.24 ± 0.6	0 – 2	1 (1 - 2)	0.86 ± 0.48	0 - 2	1 (1 - 1)	0.004*
24 hrs	1.05 ± 0.58	0 – 2	1 (1 - 1)	0.46 ± 0.51	0 - 1	0 (0 - 1)	<0.001 **

Test used: Mann Whitney U test
**signifies highly significant p value<0.001
*signifies significant p value<0.05

11.Modified Bromage Scale:

The table (11) compares the Modified Bromage Score between Group 1 and Group 2 at different time points, presenting descriptive statistics and associated p-values. Initially, at 0 minutes, Group 1 has a mean score of 2.89 ± 0.70, slightly lower than Group 2's mean score of 3.16 ± 0.50, although this difference is not statistically significant ($p = 0.064$). However, as time progresses, significant differences emerge. At 30 minutes, Group 1 shows a mean score of 3.73 ± 0.69 compared to Group 2's mean score of 4.05 ± 0.41 ($p = 0.016$*), indicating a lower level of motor blockade in Group 1. This trend continues through subsequent time points, with Group 1 consistently exhibiting lower scores compared

to Group 2. Notably, at 2, 3, and 4 hours, significant differences are observed ($p < 0.05$), indicating a sustained difference in motor blockade between the groups. However, from 5 hours onwards, the differences become non-significant ($p > 0.05$), suggesting convergence in motor blockade levels between the groups. Overall, the data indicate varying levels of motor blockade between Group 1 and Group 2, with Group 1 generally experiencing lower scores, particularly in the early hours post-treatment.

Table 11: Comparison of Modified Bromage Scores between Group 1 and Group 2 over a 24-Hour Period

Modified Bromage Score	Group 1			Group 2			P value
	Mean ± SD	Min - Max	Median (IQR)	Mean ± SD	Min - Max	Median (IQR)	
0 Min	2.89 ± 0.70	2 - 4	3 (2 - 3)	3.16 ± 0.50	2 - 4	3 (3 - 3)	0.064
15 Min	3.27 ± 0.80	2 - 4	3 (3 - 4)	3.49 ± 0.56	3 - 5	3 (3 - 4)	0.402
30 Min	3.73 ± 0.69	2 - 5	4 (3 - 4)	4.05 ± 0.41	3 - 5	4 (4 - 4)	0.016 *
45 Min	4.11 ± 0.70	3 - 5	4 (4 - 5)	4.32 ± 0.48	4 - 5	4 (4 - 5)	0.188
1 hrs	4.57 ± 0.69	3 - 6	5 (4 - 5)	4.76 ± 0.44	4 - 5	5 (4.5 - 5)	0.225
2 hrs	4.84 ± 0.50	4 - 6	5 (5 - 5)	5.16 ± 0.44	4 - 6	5 (5 - 5)	0.005 *
3 hrs	5.27 ± 0.65	4 - 6	5 (5 - 6)	5.57 ± 0.50	5 - 6	6 (5 - 6)	0.049 *
4 hrs	5.68 ± 0.53	4 - 6	6 (5 - 6)	5.95 ± 0.23	5 - 6	6 (6 - 6)	0.006 *
5 hrs	5.95 ± 0.23	5 - 6	6 (6 - 6)	6 ± 0	6 - 6	6 (6 - 6)	0.154
6 hrs	5.97 ± 0.16	5 - 6	6 (6 - 6)	6 ± 0	6 - 6	6 (6 - 6)	0.317
10 hrs	6 ± 0	6 - 6	6 (6 - 6)	6 ± 0	6 - 6	6 (6 - 6)	1.000
14 hrs	6 ± 0	6 - 6	6 (6 - 6)	6 ± 0	6 - 6	6 (6 - 6)	1.000
18 hrs	6 ± 0	6 - 6	6 (6 - 6)	6 ± 0	6 - 6	6 (6 - 6)	1.000
24 hrs	5.97 ± 0.16	5 - 6	6 (6 - 6)	6 ± 0	6 - 6	6 (6 - 6)	0.317

Test used: Mann Whitney U test
**signifies highly significant p value<0.001
*signifies significant p value<0.05

12.Sedation Score

The table (12) displays the Modified Observer's Assessment of Alertness/Sedation Scale (MOAA/S) Score between Group 1 and Group 2 at various time points, along with the mean and standard deviation values and the associated p-values. At 0 minutes, there is no significant difference in the Sedation Score between the two groups ($p = 0.324$). Additionally, at all subsequent time points (15 minutes, 30 minutes, 45 minutes, 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 10 hours, 14 hours, 18 hours, and 24 hours), the Sedation Score remains consistent with a mean of 5 and a standard deviation of 0 for both groups. However, no p-values are provided for these time points, likely indicating that statistical analysis was not conducted or that there were no observed differences between the groups. Overall, the data suggest that both Group 1 and Group 2 have similar Sedation Scores across all measured time intervals, indicating comparable

levels of sedation between the two groups throughout the observation period.

Table 12: Comparison of Sedation Scores (MOAA/S) Between Group 1 And Group 2 Over A 24 Hour Period

Sedation Score	Group 1	Group 2	p value
	Mean ± SD	Mean ± SD	
0 Min	5.03 ± 0.16	5 ± 0.00	0.324
15 min	5 ± 0.00	5 ± 0.00	–
30 min	5 ± 0.00	5 ± 0.00	–
45 min	5 ± 0.00	5 ± 0.00	–
1 hrs	5 ± 0.00	5 ± 0.00	–
2 hrs	5 ± 0.00	5 ± 0.00	–
3 hrs	5 ± 0.00	5 ± 0.00	–
4 hrs	5 ± 0.00	5 ± 0.00	–
5 hrs	5 ± 0.00	5 ± 0.00	–
6 hrs	5 ± 0.00	5 ± 0.00	–
10 hrs	5 ± 0.00	5 ± 0.00	–
14 hrs	5 ± 0.00	5 ± 0.00	–
18 hrs	5 ± 0.00	5 ± 0.00	–
24 hrs	5 ± 0.00	5 ± 0.00	–

Test used: Student's t test 8.

13. Total Number of Cases:

The total number of infra-umbilical obstetric and lower limb orthopedic cases in both the groups are comparable

Table (13): Comparison of number of infra-umbilical obstetric and lower limb orthopedic cases in both group 1 and 2.

Cases	Group 1	Group 2
Infra-umbilical obstetric	18	18
Lower limb orthopedic	19	19

DISCUSSION

Epidural analgesia is often considered optimal postoperative analgesia after major lower abdominal or lower limbs surgery[1-3], especially the patient-controlled epidural analgesia has gained popularity in recent years (4-6). Epidural infusions mostly consist of a local anaesthetic, an opioid or even a combination of both, in order to improve the analgesic efficacy and lessens the unwanted side effects (7,9). Ropivacaine has emerged as common local anaesthetic for epidural analgesia (10). Compared to its homologue Bupivacaine, Ropivacaine is associated with decreased motor block potency, fewer cardiac complications, faster recovery and less toxicity (11,12). Usually, lipophilic opioid drugs (such as fentanyl and sufentanil) are used as adjuvant drugs in combination with local anaesthetics to reduce its dose and side effects (13). It has been observed that combining fentanyl with ropivacaine shows a synergistic effect on spinal anesthesia (14,16). However, there is still lacunae in literature regarding the dosage of ropivacaine and fentanyl.

Based on the defined inclusion exclusion criteria, the study included 74 patients scheduled to underwent s elective infraumbilical abdominal surgery under epidural anaesthesia. The patients were equally divided into two groups, Group I (received 0.1% ropivacaine with fentanyl) and Group 2 (received 0.2% ropivacaine with fentanyl). A similar study was conducted by **Lee WK et al, 2003,** (95) wherein 210 patients undergoing lower abdominal or lower extremity surgery were included. Patients were equally divided into two groups: Group R - received epidural analgesia infusions at 7 mL/hour with 0.1% ropivacaine and Group RF- received analgesia with 0.1% ropivacaine plus 1 µg/mL fentanyl. Similarly, **Kim GH et al, 2020,** also studied compared analgesic effect of ropivacaine with fentanyl or ropivacaine alone for continuous femoral nerve block in 40 patients undergoing unilateral total knee arthroplasty.

The mean age, height and weight was comparable between the two groups with no statistically significant difference (p value >0.05). Further, in both the groups the proportion of patients with ASA Grade 1 were much higher than ASA status 2, but no significant co-relation could be derived (p value- 0.359). No significant difference in the demographic parameters were observed by **Lee WK et al, 2003 and Kim GH et al, 2020.** However, contrary to our results, **Kim GH et al, 2020** observed a greater number of patients with ASA grade 2 than ASA 1 physical status, but no significant difference was observed (p value >0.05).

Some studies have found several benefits of PCEA over conventional epidural continuous infusion or bolus techniques, including better analgesia and superior patient satisfaction [17]. We observed that the total volume of drug infused was significantly lower in Group 2 as compared to Group 1 (202.92 ± 3.08 vs 212.65 ± 7.15, p- value <0.001). Also, the dose of PCEA bolus and number of PCEA boluses required were less in Group 2 as compared to Group 1 patients (2.19 ± 2.81 vs 12.70 ± 7.25, and 1.46 ± 2.09 vs 3.16 ± 1.79, respectively). The difference was statistically significant between the two groups. This shows that 0.1% ropivacaine concentration was not sufficient enough, and thus required more number and amount of PCEA bolus doses. **Lee WK et al, 2003** observed that 0.1% ropivacaine used in Group R was inadequate**.**

We further observed that none of the patients in any group required rescue analgesia. Also, no side effects were observed in any of the study groups. Similar to our study, no side effects were observed by **Lee WK et al, 2003.** The mean respiratory rate (RR), oxygen saturation (SpO2) was almost comparable between the two groups with no significant difference being observed, while, mean arterial pressure (MAP) was also comparable between the two groups, showing significant difference at few time points (p value <0.05).

The mean VAS Score decreased in both the groups post-surgery, however, a significant difference was observed at 2hr and post 5hrs to 24hrs (p value < 0.05), with mean VAS score being significantly less in Group 2 patients as compared to Group 1 patients. This indicates that 0.2% ropivacaine with fentanyl has better efficacy with decreased post-operative pain. Similarly, **Lee WK et al, 2003.** observed that with regard to the VAS, pain relief was early in patients with ropivacaine and fentanyl, as compared to ropivacaine alone.

A significant difference was observed between the two groups for the motor blockade at few time points (p value <0.05), with higher mean Bromage score observed in Group 2 patients. This indicates that 0.2% Ropivacaine provides better pain relief with low degree of motor block.

Further, the sedation score was comparable between the two groups with no significant difference being observed. Our results are in line with study by **David AS et al, 1999**, wherein sedation of moderate to severe degrees (levels 4 and 5) was uncommon (7%) and occurred in similar numbers in all groups during infusion.

Limitations

There were few limitations in the present study, such as lack of data on parameters such as duration of anaesthesia, hospital stay, lack of group comparing fentanyl alone or ropivacaine alone and pain and side effects were evaluated in the short term only. Finally, this study was conducted in only 1 treatment center with a relatively small number of samples. Future studies are therefore recommended to recruit a larger number of participants and should be conducted in more than 1 center to obtain more accurate results in this regard.

CONCLUSION

Major abdominal surgeries and lower limb orthopedic surgeries are amongst the most painful procedures. Effective acute post-operative analgesia is known to have beneficial effects on patient outcome after abdominal surgery such as improving recovery of normal bowel function, cardiovascular stability, patient satisfaction, early mobilization, early enteral feeds, and reduced hospital stay. Compared to using local anaesthetic alone, the epidurally administered combination of opioids and local anaesthetic enhances pain relief. The present study was conducted with an aim to study the efficacy of 0.1% ropivacaine versus 0.2% ropivacaine with fentanyl for post-operative patient-controlled epidural analgesia in patients undergoing infra-umbilical abdominal surgery

and orthopaedic surgery at a tertiary care centre in Maharashtra.

The study included 74 patients with ASA status I & II, scheduled to underwent elective infraumbilical abdominal surgery under epidural anaesthesia. The patients were equally divided into two groups, Group I (received 0.1% ropivacaine with fentanyl) and Group 2 (received 0.2% ropivacaine with fentanyl). It was observed that the demographic parameters such as age, height and weight were comparable between the two groups.

In conclusion, the clinical findings of the present study show that both 0.1% and 0.2% Ropivacaine were well tolerated among all the patients. However, 0.2% Ropivacaine produced significant pain relief in terms of VAS score, maintained stable hemodynamic parameters and required lower concentration and doses of PCEA bolus.

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