**International Journal of Medical and Pharmaceutical Research**
**Website**: https://ijmpr.in/ | Print ISSN: 2958-3675 | Online ISSN: 2958-3683
**NLM ID:** 9918523075206676
Volume: 4 Issue:3 (May-June 2023); Page No: 133-144

**Original Article**



# Comparison of 0.75% Epidural Ropivacaine with and without Fentanyl for Prolongation of Postoperative Analgesia in Adults for Elective Lower Limb Orthopaedics Surgery- An Observational Study

**Dr. Mansi Sawarkar[1], Dr. Sunita Shende[2], Dr. Ullhas Misal[3]**

[1]Junior Resident, Department of Anaesthesiology, GMC Miraj.
[2]Associate Professor, Department of Anaesthesiology, GMC Miraj.
[3]Professor and Head of Department, Department of Anaesthesiology, GMC Miraj.

## ABSTRACT

**Introduction:** Epidural analgesia is an effective postoperative analgesia for surgical procedures. The use of Ropivacaine with adjuvant like Fentanyl is a newer development in the neuraxial blockade and the studies are scarce, so this study to compare the onset and duration of motor and sensoryblockade, efficacy of post-operative analgesia and side-effects seen with 0.75% Ropivacaine with Fentanyl and 0.75% Ropivacaine without any adjuvant in adult lower limb orthopaedics surgery.
**Method**: 84 patients were divided into two groups of 42 each. Group RF received 15ml of 0.75% Ropivacaine plus 50micrograms of Fentanyl (total=16ml) and Group R received 15ml 0.75% Ropivacaine plus 1 cc NS (total = 16ml) epidurally. Duration of sensory and motor block was observed intraoperatively and postoperatively along with pain scores (Visual Analogue Scale VAS) and side effects (nausea, vomiting, bradycardia, hypotension).
**Results**: The groups were demographically comparable. Duration of sensory block was longer in RF group and so was haemodynamic stability and delayed requirement of rescue analgesia. None of the groups showed any side effects.
**Conclusion**: We conclude that 0.75% Ropivacaine with Fentanyl provides an excellent post-operative analgesia, with no side effects and stable haemodynamics with good patient satisfaction than 0.75% ropivacaine without adjuvant and can be used effectively in all lower limb surgeries.

**Key Words**: *Analgesia, Epidural, Ropivacaine, Fentanyl, Neuraxial Block, Regional Anaesthesia.*

***Corresponding Author**
Dr. Mansi Sawarkar
*Junior Resident, Department of Anaesthesiology, GMC Miraj*

## INTRODUCTION

Epidural block helps control postoperative pain, improves patient satisfaction, helps in early ambulation, helps early recovery and shorten hospital stay. Epidural anaesthesia is increasingly being used as a sole anaesthetic for procedures involving lower limbs, pelvis, lower abdominal surgeries. Epidural anaesthesia is the most commonly used technique for providing not only perioperative surgical anaesthesia but postoperative analgesia in lower abdominal and lower limb surgeries[1]. Analgesia with pure local anaesthesia without any adjuvant needs higher doses, many a time for achieving desired postoperative analgesic effect, resulting in a higher risk of local anaesthesia toxicity. Therefore, keeping in mind the numerous benefits of epidural technique and the new amide local anaesthetic Ropivacaine, having lesser systemic toxicity as well as lesser propensity of motor block during postoperative period, the following study has been undertaken to study the addition of adjuvants[2].

Structurally, Ropivacaine is very similar to both bupivacaine and mepivacaine, and it is the S-enantiomer of pRopivacaine (1-propyl-2′, 6′- pipecoloxylidide hydrochloride monohydrate).Ropivacaine is less lipophilic than other local anaesthetics, such as bupivacaine, and is less likely to penetrate large myelinated motor fibres. Ropivacaine is also manufactured as a pure S(-) enantiomer; the S(-) enantiomer has significantly less cardiotoxicity and neurotoxicity[3,4].

Opioids are the most frequently used local anaesthetic adjuvants and their use in neuraxial blocks have evolved over the last 50 years[5].

Fentanyl was one of a series of opioids synthesizedin an effort to produce opioid analgesics with enhanced analgesic activity and potency and fewer adverse effects compared with morphine or meperidine[6,7]. Fentanyl, N-(1-phenethyl-4-piperidyl) propionanilide, is structurally related to meperidine.Fentanyl's popularity as an intraoperative agent relates

directly to the cardiovascular stability it provides, even in critically ill patients[8,9]. Biochemically, it is a Mu-selective opioid agonist which results in its analgesic properties. However, it has the capability to activate other opioid system receptors such as the delta and potentially the kappa-receptors[10].

The use of Ropivacaine with adjuvant is a newer development in the neuraxial blockade and the studies are scarce, therefore the present study was conducted to assess the efficacy of addition of Fentanyl as an adjuvant to 0.75% Ropivacaine in epidural analgesia.

**AIM**

To compare the efficacy of 0.75% epidural Ropivacaine with Fentanyl as an adjuvant and plain epidural 0.75% Ropivacaine without Fentanyl, for prolonging postoperative analgesia.

**OBJECTIVES**

**1.** PRIMARY – To study the duration of postoperative analgesia with and without Fentanyl as an adjuvant and requirement of rescue drug.

**2.** SECONDARY-

a.To assess intraoperative onset of sensory and motor block.
b.To assess intraoperative duration of sensory and motor block.
c.To study the side effects /complications if any like bradycardia,hypotension,nausea and vomiting.

**MATERIALS AND METHODOLOGY**

This single centre, prospective, analytical, observational study was conducted in the Department of Anaesthesiology in tertiary care centre. Prior approval of Institutional Ethics Committee was taken before start of the study. A written informed consent was taken from all the patients prior to their enrolment in the study.

**Study Design**: Prospective, analytical, observational study
**Study Setting**: Department of Anaesthesiology in tertiary care centre.
**Study Population**: 84 cases (randomly divided in two groups of 42 patients each) undergoing elective orthopaedic lower limb surgeries, during the study period and meeting the inclusion and exclusion criteria.
**Duration of Study**: March 2021 – October 2022
**Sample Size:**84 cases

**Inclusion Criteria**

1. Patients aged between 18-60 years.
2. Patients of either gender.
3. Patients undergoing elective lower limb orthopaedic surgeries.
4. Patients giving consent to participate in the study.

**Exclusion Criteria**

1. Patients aged less than 18 years and more than 60 years of age.
2. Patients allergic to any of the study drugs.
3. Pregnant women.
4. Patients requiring on table supplementation with general anaesthesia.
5. Patients with pre-existing renal, liver and cardiac diseases.
6. Patients with coagulopathy disorder.
7. Patients with infection at the local site.
8. Patients who do not consent to participate in the study.

**Ethical Consideration**

Prior approval of the Institutional Ethics Committee was taken before conducting the study.

**Informed consent**

Written informed consent was taken from all the patients who were included the study. The consent form is attached in Annexure. The consent form was prepared in the vernacular language (English, Hindi and Marathi). For the patients who could not read and write, the consent form was explained to them in their vernacular language in the presence of an unbiased, non-related witness, provided the witness was literate. Confidentiality was maintained throughout the study and would be further maintained during any future sharing or publication of the result. A copy of the Information Sheet of the Informed Consent Form was provided to the patients. The signature of the witness and the thumb impression of the patient (illiterate) or the signature of the patient (literate) was taken on the consent form. Thus, the participation in the study was fully informed, voluntary and without any coercion.

**Methodology**

A total of 84 patients were included in the study. Demographic details like age, gender, height, weight, ASA grading were recorded. Detailed history of present illness along with personal and past history were taken from all the patients and recorded. General examination was done and heart rate, blood pressure, oxygen saturation was recorded. Routine investigations like complete blood count, renal function tests- urea and creatinine and liver function test – bilirubin, serum transaminases, prothrombin time and INR ratio were done. Pre-anaesthetic fitness was done as per standard guidelines. Patients were kept fasting overnight. After arrival into operation theatre, standard monitoring with non invasive blood pressure, pulse oximeter and ECG leads were attached. Baseline systolic BP, diastolic BP, heart rate and SpO2 were taken from an average of two readings taken 5 min apart. A peripheral intravenous line secured with 18 Guage intravenous cannula and ringer lactate solution was started as maintenance fluid.
Premedication: Inj. Ondensetron 0.1mg/kg i.v.

After thorough aseptic precautions, with patient in the lateral position, epidural space was located using 18G Touhy's needle at L1-L2 level or L2-L3 level with loss of resistance technique. The 18 G epidural catheter was inserted and aspirated to rule out subarachnoid or intravascular placement of catheter. The placement was confirmed with 3 ml of 2% Lignocaine with Adrenaline 1:20,000 and fixed such that 3 -5 cm of epidural catheter was inside space. Duration of surgeries chosen for the study was of 90-120 minutes.

The patients were randomly divided into two groups of 42 each (total sample size – 84):
Group R and Group RF.
Test drug was administered according to the group assigned as follows:

- GROUP R: Received 15ml 0.75% Ropivacaine plus 1 cc NS (total = 16ml).
- GROUP RF: Received 15ml of 0.75% Ropivacaine plus 50 micrograms of Fentanyl (total=16ml).

The surgery was started after the attainment of sensory block assessed by the loss of sensations checked by pinprick by 24G hypodermic needle.
The categorizations were done as follows:

- Grade 0: Sharp pin felt.
- Grade 1: Analgesia, dull sensation felt.
- Grade 2: Anaesthesia, no sensation felt.

The motor block was assessed by the Modified Bromage scale and surgery was done after achieving Grade 2 of motor block.
Modified Bromage Scale[11].

| | |
|---|---|
| Bromage 0 | Subject is able to move the hip, knee and ankle and is able to lift his leg against gravity |
| Bromage 1 | Subject is unable to lift his leg against gravity but is able to flex his knee and ankle |
| Bromage 2 | Subject is unable to flex his hip and knee, but is able to flex his ankle |
| Bromage 3 | Subject is unable to flex his hip, knee and ankle, but is able to move his toes |
| Bromage 4 | Complete paralysis |

The time of onset of sensory and motor blockade were noted. The duration of sensory block was recorded till complete sensory recovery. Duration of motor block was recorded till complete motor functioning of the lower limb.
Heart rate, Systolic BP, Diastolic BP and SpO2 were recorded at following predefined intervals:

- After premedication
- After epidural
- At 5 minutes
- At 5 minute interval till 30 minutes
- At 30 minute intervals till 120 minutes

The pain was assessed by the Visual Analogue Scale (VAS) score as follows: The VAS score was assessed hourly till 12 hours and noted. All the data was recorded in excel format and analysed. The duration of requirement of first rescue analgesia was recorded and inj. Tramadol 50mg diluted with normal saline upto 8 ml was given via epidural

catheter when VAS score was greater than 5. Anaesthetic failure in the surgical area was defined as when the patient experienced pain during surgery, managed by giving general anaesthesia and such patients were not included in the study.

**Statistical Analysis**

The data was analysed using statistical software (IBM SPSS, IBM Corporation, Armonk, NY, USA).

Descriptive statistics: The Numerical/Continuous data were expressed as Mean ± Standard Deviation and the Categorical data were expressed as Percentages. Analytical statistics: The Numerical/Continuous data were analysed by the 'Paired t test' and 'Unpaired t test', as required. The Categorical data were analysed by the Chi square test (Fischer's exact test was used when more than 20% of the cells had value less than 5). P value of less than 0.05 was considered as "statistically significant" and indicated by "*" in the Tables. Bar charts, Pie diagrams, Line diagrams and Scatter charts were used for the presentation of the data as applicable.

**RESULTS**

Table 1: Inter-Group comparison of sensory block in the two Groups

| PARAMETER | GROUP R | | GROUP RF | | P VALUE |
|---|---|---|---|---|---|
| | MEAN | SD | MEAN | SD | |
| **Onset (min)** | 13.38 | 0.67 | 9.77 | 0.88 | <0.001* |
| **Duration (min)** | 294.97 | 5.76 | 336.73 | 3.99 | <0.001* |

Table 1 and Figures 1 and 2 show the onset and duration of sensory block in the two Groups. The onset was earlier with longer duration in the Group RF as compared to Group R; P value: less than 0.001.

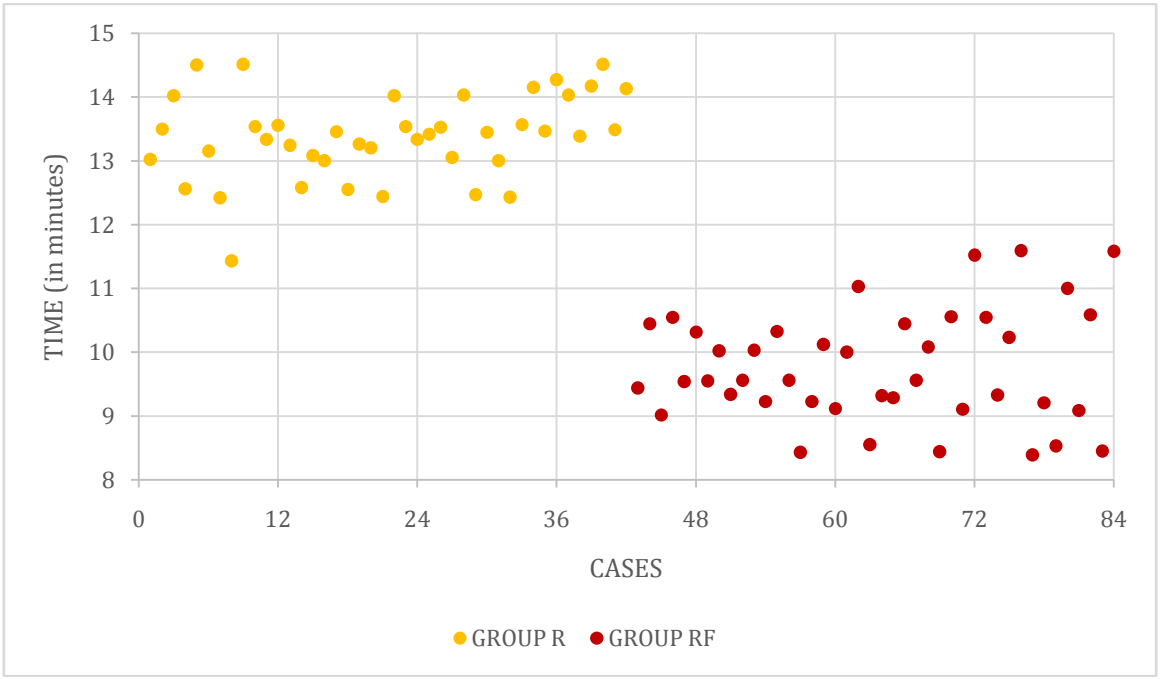


Figure 1: Distribution of the onset of sensory block in the two Groups

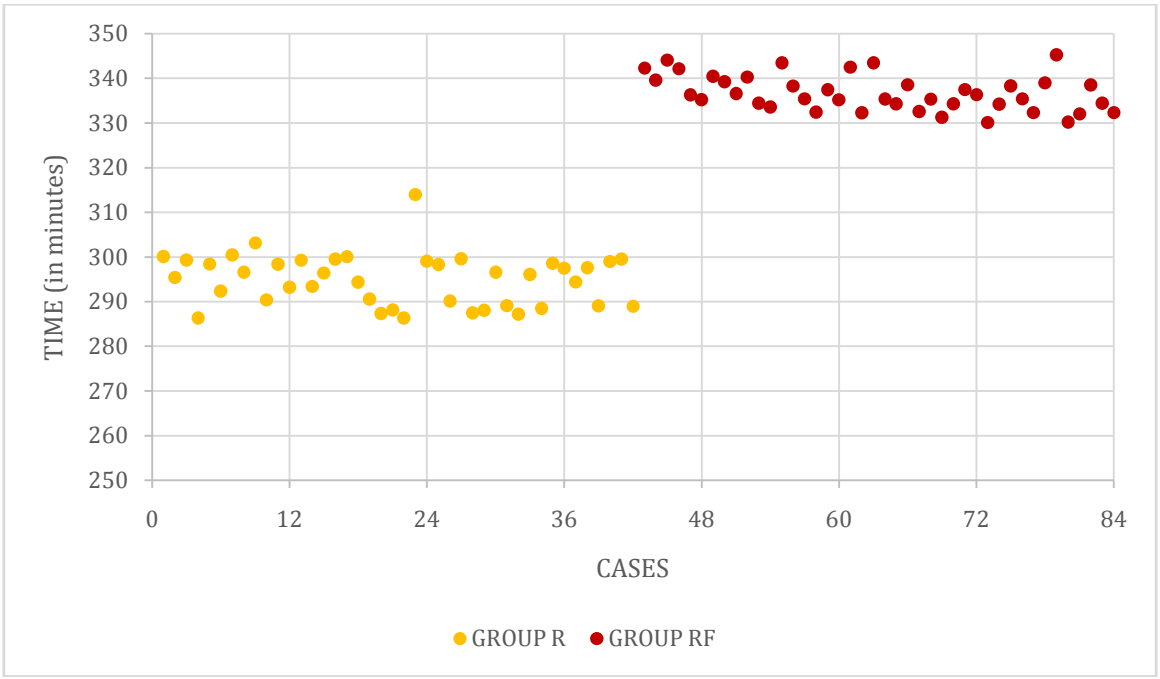


Figure 2: Distribution of the duration of sensory block in the two Groups

Table 2: Inter-Group comparison of motor block in the two Groups

| PARAMETER | GROUP R | | GROUP RF | | P VALUE |
|---|---|---|---|---|---|
| | MEAN | SD | MEAN | SD | |
| **Onset (min)** | 25.48 | 0.63 | 21.68 | 1.71 | <0.001* |
| **Duration (min)** | 103.14 | 3.62 | 104.43 | 3.22 | 0.089 |

Table 2 and Figures 3 and 4 show the onset and duration of motor block in the two Groups. The onset was earlier in Group RF with similar duration of block in the two Groups.

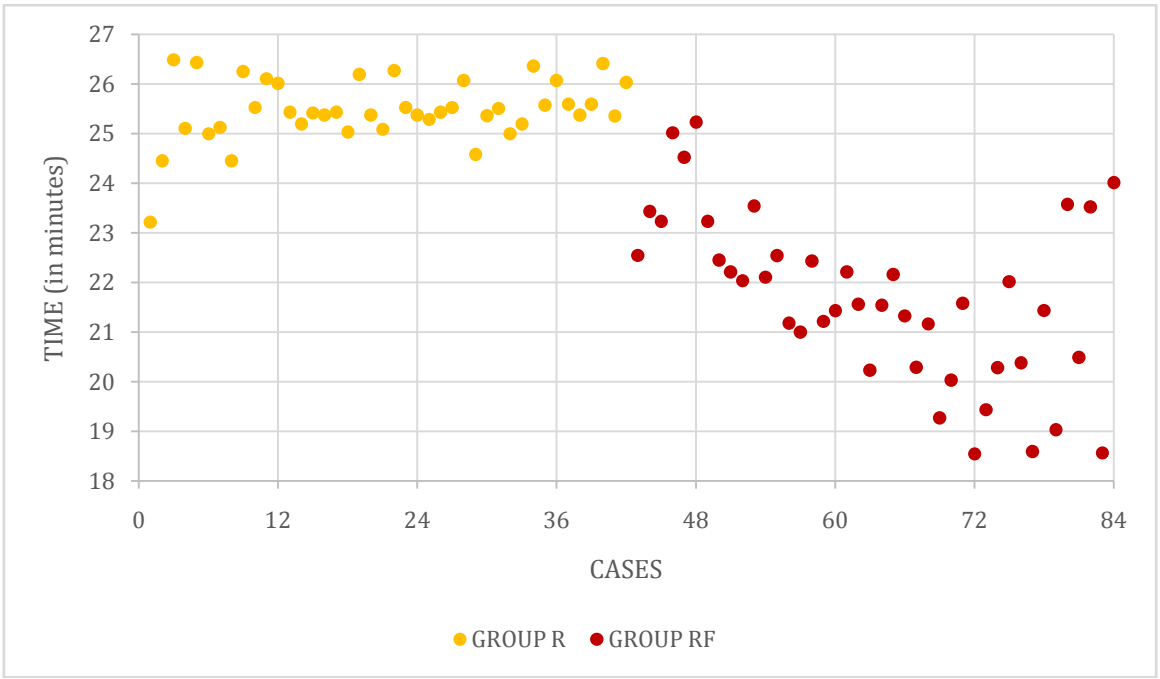


Figure 3: Distribution of the onset of motor block in the two Groups

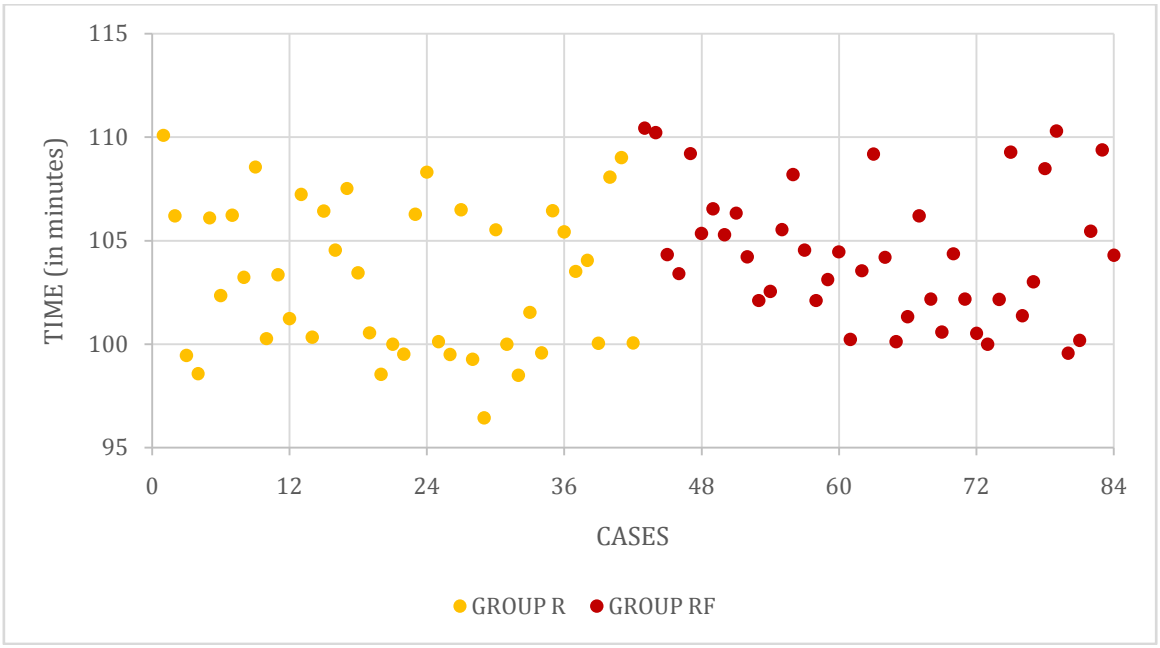

Figure 4: Distribution of the duration of motor block in the two Groups

Table 3: Inter-Group comparison of the heart rate in the two Groups

| PARAMETER | GROUP R | | GROUP RF | | P VALUE |
|---|---|---|---|---|---|
| | MEAN | SD | MEAN | SD | |
| **Baseline** | 80.10 | 7.18 | 79.17 | 5.94 | 0.520 |
| **After premedication** | 76.17 | 5.51 | 76.62 | 6.55 | 0.733 |
| **After epidural** | 76.62 | 5.60 | 74.05 | 6.31 | 0.051 |
| **At 5 minutes** | 77.10 | 5.05 | 71.98 | 5.76 | <0.001* |
| **At 10 minutes** | 75.45 | 4.95 | 70.14 | 5.32 | <0.001* |
| **At 15 minutes** | 74.60 | 4.72 | 68.95 | 3.91 | <0.001* |
| **At 20 minutes** | 71.93 | 4.59 | 68.10 | 3.10 | <0.001* |
| **At 25 minutes** | 69.38 | 4.10 | 68.98 | 3.05 | 0.609 |
| **At 30 minutes** | 71.60 | 2.66 | 68.95 | 4.20 | 0.001* |
| **At 60 minutes** | 71.67 | 4.51 | 72.90 | 2.62 | 0.128 |
| **At 90 minutes** | 74.48 | 4.81 | 74.48 | 2.72 | 0.999 |
| **At 120 minutes** | 75.19 | 4.39 | 76.79 | 3.04 | 0.056 |

Table 3 and Figure 5 show the comparison of heart rate in the two Groups. The heart rate was significantly higher in Group R from 5 minutes to 20 minutes and at 30 minutes, it was significantly lower in Group RF; P value: less than 0.05. Thereafter, it was similar.

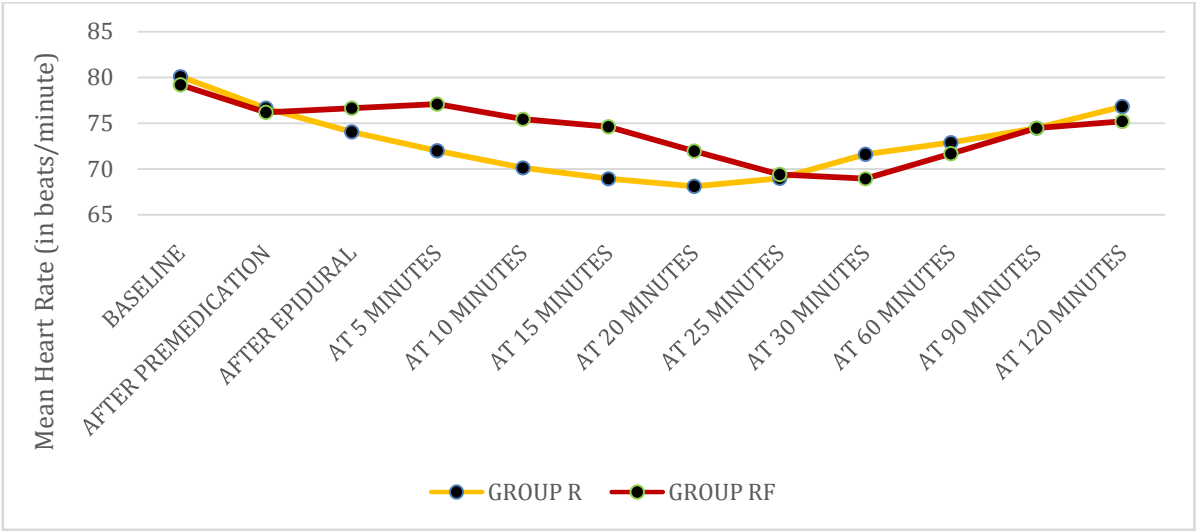


Figure 5: Inter-Group comparison of the heart rate in the two Groups

Table 4: Inter-Group comparison of the SBP in the two Groups

| PARAMETER | GROUP R | | GROUP RF | | P VALUE |
|---|---|---|---|---|---|
| | MEAN | SD | MEAN | SD | |
| **Baseline** | 123.76 | 5.86 | 125.14 | 4.15 | 0.216 |
| **After premedication** | 121.33 | 5.2 | 125.29 | 5.03 | 0.001* |
| **After epidural** | 120.95 | 4.7 | 123.24 | 4.57 | 0.026* |
| **At 5 minutes** | 120.9 | 4.49 | 121.29 | 4.65 | 0.703 |
| **At 10 minutes** | 121.05 | 4.22 | 119.19 | 4.48 | 0.054 |
| **At 15 minutes** | 118.57 | 3.81 | 117.38 | 4.6 | 0.200 |
| **At 20 minutes** | 118.33 | 3.97 | 115.29 | 5.11 | 0.003* |
| **At 25 minutes** | 116.88 | 3.81 | 113.05 | 5.88 | 0.001* |
| **At 30 minutes** | 119.57 | 3.01 | 109.95 | 7.67 | <0.001* |
| **At 60 minutes** | 119.95 | 3.08 | 115.57 | 5.77 | <0.001* |
| **At 90 minutes** | 121.33 | 2.75 | 120.19 | 5.46 | 0.230 |
| **At 120 minutes** | 121.48 | 2.54 | 124.14 | 5.14 | 0.003* |

Table 4 and Figure 6 show the comparison of SBP in the two Groups. The SBP in the Group R was lower till administration of epidural and then it was more than Group RF; P value: less than 0.05. Thereafter, it was similar.

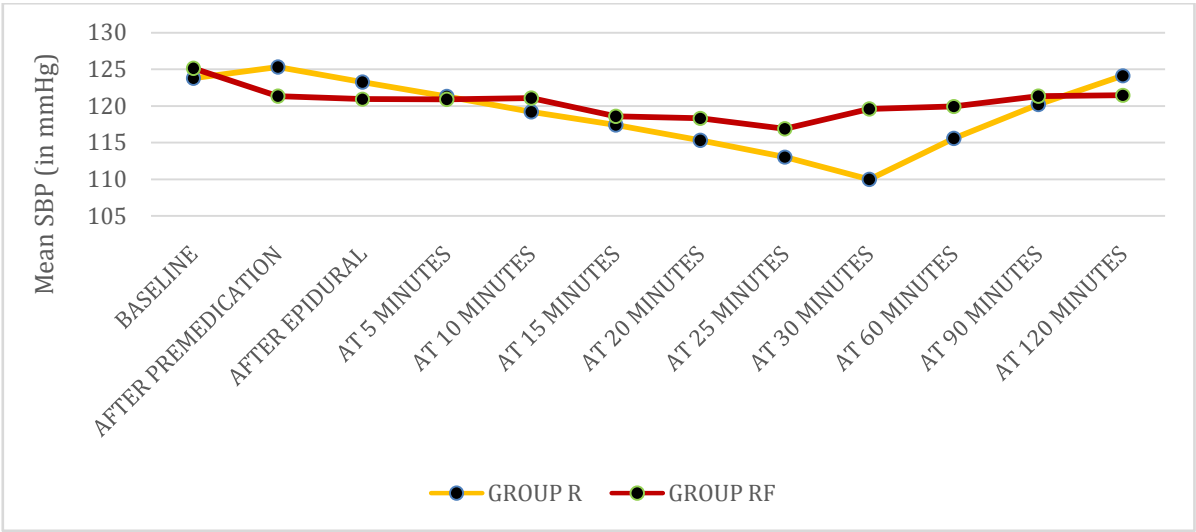


Figure 6: Inter-Group comparison of the SBP in the two Groups

Table 5: Inter-Group comparison of the DBP in the two Groups

| PARAMETER | GROUP R | | GROUP RF | | P VALUE |
|---|---|---|---|---|---|
| | MEAN | SD | MEAN | SD | |
| **Baseline** | 80.95 | 4.24 | 79 | 3.64 | <0.001* |
| **After premedication** | 78.62 | 3.81 | 75.67 | 4.5 | 0.002* |
| **After epidural** | 78.57 | 3.37 | 73.71 | 4.67 | <0.001* |
| **At 5 minutes** | 78.67 | 3.27 | 72.24 | 4.15 | <0.001* |
| **At 10 minutes** | 78.86 | 3.34 | 70.43 | 3.96 | <0.001* |
| **At 15 minutes** | 78.86 | 3.34 | 68.62 | 4.08 | <0.001* |
| **At 20 minutes** | 79.1 | 3.48 | 67.1 | 4.33 | <0.001* |
| **At 25 minutes** | 79 | 3.07 | 65.52 | 4.28 | <0.001* |
| **At 30 minutes** | 79.43 | 3.31 | 65.05 | 4.68 | <0.001* |
| **At 60 minutes** | 80.05 | 3.01 | 68 | 3.98 | <0.001* |
| **At 90 minutes** | 80.05 | 2.78 | 70.81 | 4.4 | <0.001* |
| **At 120 minutes** | 79.57 | 2.52 | 74.52 | 5.66 | <0.001* |

Table 5 and Figure 7 show the comparison of DBP in the two Groups. The DBP in the Group R was higher than Group RF; P value: less than 0.05.

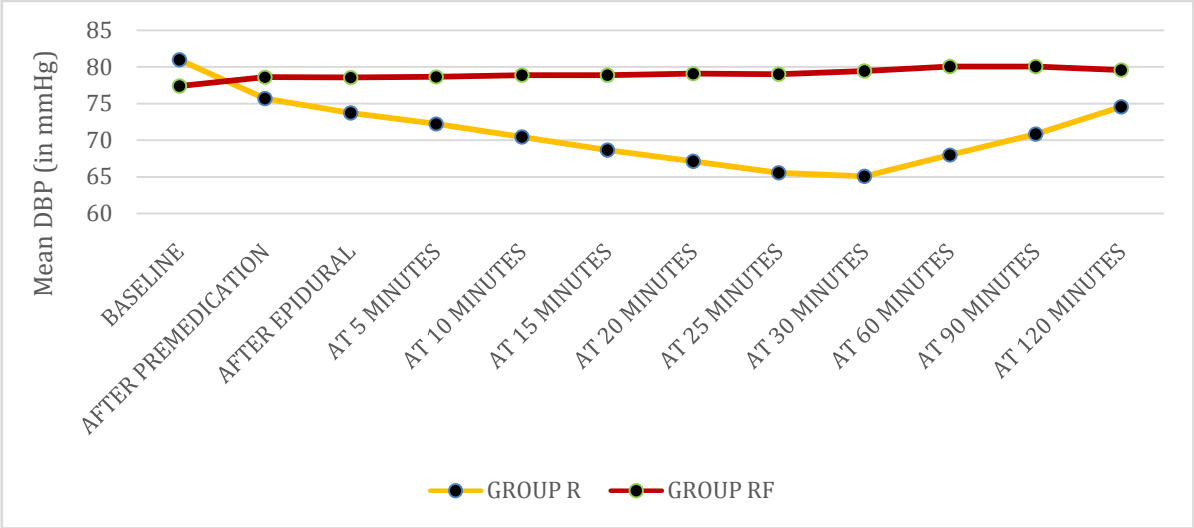


Figure 7: Inter-Group comparison of the DBP in the two Groups

Table 6: Inter-Group comparison of the VAS score in the two Groups

| PARAMETER | GROUP R | | GROUP RF | | P VALUE |
|---|---|---|---|---|---|
| | MEAN | SD | MEAN | SD | |
| **At 1 hour** | 0.21 | 0.42 | 0.00 | 0.00 | 0.002* |
| **At 2 hours** | 1.33 | 0.72 | 0.07 | 0.26 | <0.001* |
| **At 3 hours** | 2.45 | 0.83 | 1.07 | 0.75 | <0.001* |
| **At 4 hours** | 3.86 | 1.05 | 2.21 | 1.00 | <0.001* |
| **At 5 hours** | 5.52 | 0.83 | 3.74 | 1.01 | <0.001* |
| **At 6 hours** | 3.71 | 1.83 | 4.95 | 1.19 | <0.001* |
| **At 7 hours** | 3.19 | 1.17 | 4.17 | 1.96 | 0.007* |
| **At 8 hours** | 3.40 | 0.73 | 2.52 | 0.74 | <0.001* |
| **At 12 hours** | 3.33 | 0.61 | 4.07 | 0.71 | <0.001* |

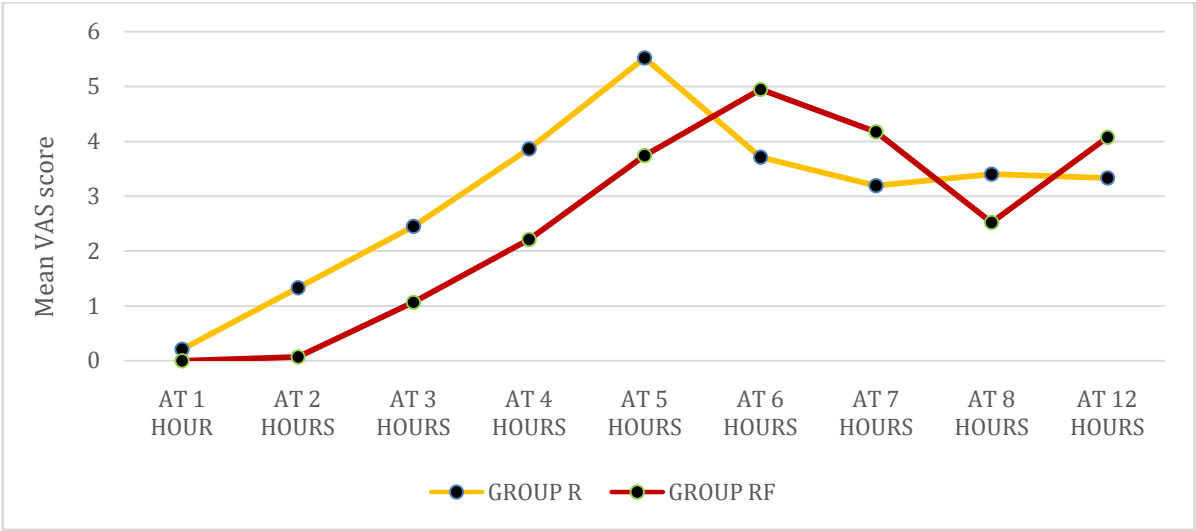


Figure 8: Inter-Group comparison of the VAS score in the two Groups

Table 6 and Figure 8 show the distribution of the VAS score in the two Groups. The VAS score was significantly lower in Group RF till 5 hours and then it was higher; P value: less than 0.05. At the end of 12 hour follow up, the VAS score was significantly lower in Group RF; P value: less than 0.001.

Table 7: Inter-Group comparison of requirement of first rescue analgesia in the two Groups

| **PARAMETER** | **GROUP R** | | **GROUP RF** | | **P VALUE** |
|---|---|---|---|---|---|
| | **MEAN** | **SD** | **MEAN** | **SD** | |
| **Duration (hrs)** | 5.29 | 0.55 | 6.50 | 0.71 | <0.001* |

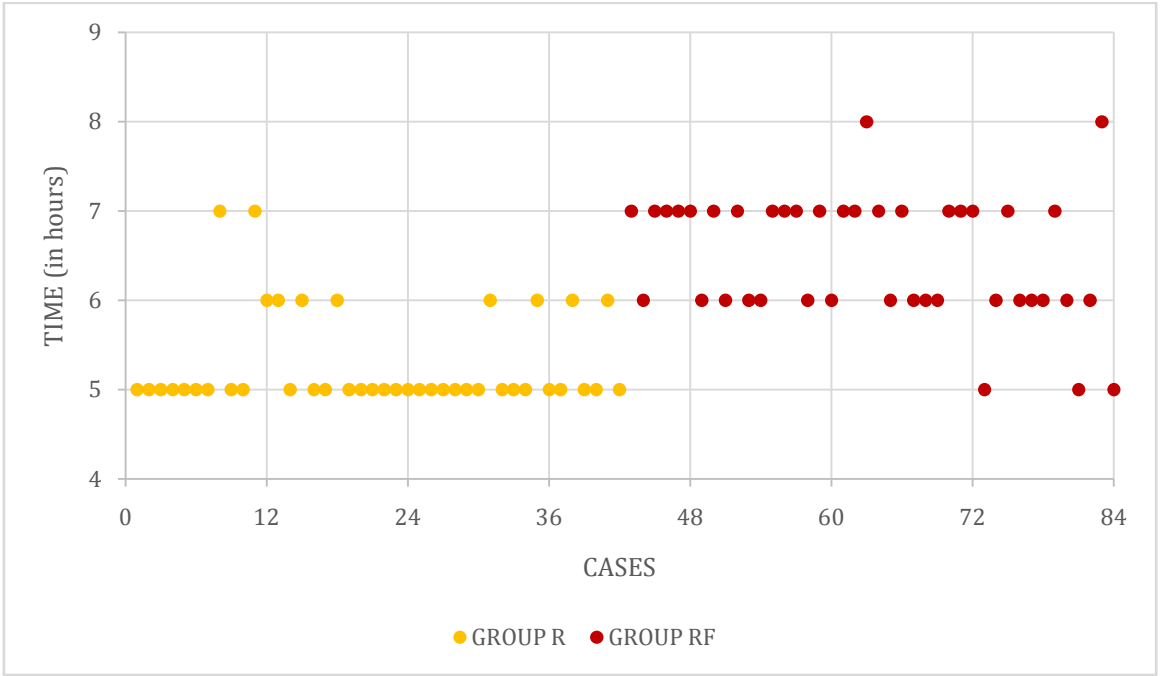


Figure 9: Distribution of the duration of first rescue analgesia in the two Groups

Table 7 and Figure 9 show the requirement of first rescue analgesia in the two Groups. The requirement was significantly later in Group RF than in Group R; P value: less than 0.001.

**DISCUSSION**

Addition of adjuvants have been traditionally used to prolong the effects of the local anaesthetics while reducing their dosage requirement. There is a search for newer adjuvants which increase the potency of the anaesthetic while

having minimal side effects of their own. Therefore, the present study was conducted to evaluate the efficacy of addition of Fentanyl to Ropivacaine.

It was concluded that, that both groups were demographically similar in relation to age, gender, height and weight and ASA grading.

**Onset of Sensory block**: In the present study, it was observed that the onset of sensory block was significantly earlier in Group RF (9.77 ± 0.88 minutes) as compared to Group R (13.38 ± 0.67 minutes); P value: less than 0.001. In the study by **Sindhu B. et al**[12], they observed that the onset of analgesia and time to attain maximum sensory level of T6-T7 was faster in Group RF as compared to Group R (7.17 ± 1.82 minutes vs 11.47 ± 2.18 minutes for onset; 12.40 ± 1.98 minutes vs 15.80 ± 1.88 minutes for peak T6-T7 level ); P value: less than 0.001. Thereafter, the effects were similar in the two Groups. In the study by **Cherng C. et al**[13], they observed that the onset of analgesia was faster in Group EF as compared to Group IF (13.0 ± 3 minutes vs 16.2 ± 3.5 minutes for onset to T10 dermatome); P value: less than 0.05. Similar were the findings in the meta-analysis by **Hillyard S. G. et al**[14], where the onset of sensory block was much faster with the addition of Fentanyl (overall MD −1.66 min, 95% CI −2.40 to −0.91 min, P value: less than 0.001.
These findings were similar to the present study.

**Onset of Motor block**: In the present study, it was observed that the onset of motor block was significantly earlier in Group RF (21.68 ± 1.71 minutes) as compared to Group R (25.48 ± 0.63 minutes); P value: less than 0.001. In the study by **Sindhu B. et al**[12], they observed that the establishment of motor blockade was significantly faster in Group RF (15.67 ± 2.12 minutes) as compared to Group R (21.57 ± 2.14 minutes); P value: less than 0.001. In the study by **Cherng C. et al**[13], they observed that the onset of motor block was more rapid in Group EF than Group IF for Bromage scale 1 (11.9 ± 4.6 minutes vs 16.9 ± 4.7 minutes, respectively) and Bromage scale 2 (24.4 ± 5.9 minutes vs 30.8 ± 5.6 minutes, respectively); P value: less than 0.05.In the study by **Boztuğ N. et al**[15], they observed that when used intrathecally, the onset time for motor blockade was earlier in Group RF (8.50 ± 6.89 minutes) as compared to Group R (9.30 ± 8.46 minutes); P value: 0.01.
These findings were similar to the present study.

**Duration of Sensory Block**: In the present study, the duration of the sensory block was significantly longer in Group RF (336.73 ± 3.99 minutes) as compared to Group R (294.97 ± 5.76 minutes); P value: less than 0.05. In the study by **Sindhu B. et al**[12], they observed that the duration of analgesia was prolonged in Group RF (338.07 ± 7.71 minutes) as compared to Group R (299.10 ± 22.35 minutes); P value: less than 0.001. In the study by **Cherng C. et al**[13], they observed that the onset of analgesia was faster in Group EF as compared to Group IF (13.0 ± 3 minutes vs 16.2 ± 3.5 minutes for onset to T10 dermatome); P value: less than 0.05. In the study by **Henandez-Miranda H. et al**[16], they observed a significant shorter latency period in Group A (with Fentanyl) as compared to Group B (without Fentanyl); P value: less than 0.001. In the study by **Boztuğ N. et al**[15], they observed that in intrathecal dose the offset time for pinprick at level L2 was significantly shorter in Group RF (99.56 ± 15.81 minutes) as compared to Group R (110.70 ± 31.22 minutes); P value: 0.01.

**Duration of Motor Block**: In the present study, the duration of motor block was similar in the two Groups (103.14 ± 3.62 minutes in Group R vs 104.43 ± 3.22 minutes in Group RF); P value: 0.089. In the study by **Sindhu B. et al**[12], they observed that the duration of motor blockade was significantly longer in Group RF (261.20 ± 10.33 minutes) as compared to Group R (229.30 ± 13.79 minutes); P value: less than 0.001. The drug dose used was also more as compared to our present study. In the study by **Cherng C. et al**[13], they observed that the onset and duration of motor block was more rapid in Group EF than Group IF for Bromage scale 1 (11.9 ± 4.6 minutes vs 16.9 ± 4.7 minutes, respectively) and Bromage scale 2 (24.4 ± 5.9 minutes vs 30.8 ± 5.6 minutes, respectively); P value: less than 0.05. In the study by **Boztuğ N. et al**[15], they observed that when used intrathecally the offset time for motor blockade was significantly shorter in Group RF (104.20 ± 24.29 minutes) as compared to Group R (186.40 ± 44.34 minutes); P value: 0.04. These findings were similar to the present study.

**Heart rate**: When compared between the two groups, it was observed that the heart rate was significantly higher in Group R as compared to Group RF from 5 minutes to 20 minutes; P value: less than 0.05. At 30 minutes, the heart rate in Group RF was significantly lower than in Group R; P value: 0.001.At the other point of times, the heart rates were similar in the two Groups; P value: more than 0.05.

**SBP**: When compared between the two groups, it was observed that the SBP in the Group R was lower than the Group RF till administration of epidural; P value: less than 0.05. Then, the SBP in Group RF was less than in Group R from 20 to 60 minutes; P value: less than 0.05. At 120 minutes, the SBP was higher in Group RF; P value: 0.003. At the other point of times, the SBP were similar in the two Groups; P value: more than 0.05.

**DBP**: When compared between the two groups, it was observed that the DBP was higher in Group R compared to Group RF at all points of time; P value: less than 0.05.

**SpO2** and **ECG** were within normal limits throughout the intraoperative period. Thus, the heart rate, SBP and DBP are significantly lower in Group RF.

In the study by **Henandez-Miranda H. et al**[16], they also observed a significant drop in the hemodynamic parameters in both the Groups.

This was similar to the present study.

This may be due the fact that Fentanyl has a synergistic action with Ropivacaine at the dorsal horn of the spinal cord. Thus, it may manifest hypotension more readily when administered as a combination, particularly in the hypovolemic patients[17-19].

However, no significant hypotensive side effects were noted in the present study.

**VAS**: When compared between the two Groups, it was observed that the mean VAS scores were significantly lower in Group RF till 5 hours as compared to Group R; P value: 0.05 as the sensory block started regressing in Group R before Group RF and rescue analgesia was given in Group R. Thereafter, the scores were higher in Group RF as compared to Group R as rescue analgesia was already given in Group R after 5-6 hours ; P value: less than 0.05. At the end of the follow up period at 12 hours, the mean VAS score in Group RF was significantly lower than Group R; P value: less than 0.001.

In the study by **Henandez-Miranda H. et al**[16], they observed that the post-operative pain was significantly later in Group A (with Fentanyl) as compared to Group B (without Fentanyl); P value: less than 0.001. In the study by **Khanna A. et al**[20], they included a total of 90 patients undergoing TKR and observed that the pain relief as per VAS score was initially comparable in the Groups with 0.1% Ropivacaine only and with 0.1% Ropivacaine with Fentanyl. Thereafter, they observed that the median pain scores were significantly less at rest and at motion in the latter Group from 12 hour onwards. In the study by **Kampe S. et al**[21], they observed that the pain scores at rest and on coughing were 0 in the Group R+S at all points of time while in Group R, two patients had pain scores of 20–40 mm at rest and on coughing 4 h after starting the epidural infusion, and one patient had pain scores of 50 mm at rest and on coughing 16 h after the start of the infusion. In the study by **Ferrer Gómez C. et al**[22], they observed that the VAS values were significantly lower with the addition of Fentanyl at 15 minutes (P value: 0.005), 30 minutes (P value: 0.029), 60 minutes (P value: 0.017) and 90 minutes (P value: 0.002).

These findings were similar to the present study. Thus, it can be effectively concluded that the overall pain relief is better in Group RF as compared to Group R.

**Requirement of First rescue analgesia**: In the present study, it was observed that the first rescue analgesia was required at 5.29 ± 0.55 hours in Group R as compared to 6.50 ± 0.71 hours in Group RF. Thus, there was significant delay in the requirement in Group RF as compared to the Group R; P value: less than 0.001. In the study by **Lee W. K. et al**[23], they observed that they observed that the pain relief in Group R seemed to peak at about 3 hours while in the Group RF was at 4.5 hours. This was similar to the present study.

In the study by **Khanna A. et al**[20], they observed a significant reduction in the consumption of local anaesthesia with the Ropivacaine-Fentanyl Group than with Ropivacaine. In the study by **Kampe S. et al**[21], they observed that the patients in Group R+S required 6 times less Piritramide than Group R over 48 hours; P value: less than 0.001. They also observed that while the requirement of Piritramide was minimal but constant over the study period in Group R+S, the requirement peaked at 16 to 24 hours in Group R.

These findings were similar to the present study. Thus, it can be effectively concluded from the present study that the time to requirement of rescue analgesia is significantly later in Group RF as compared to Group R.

**Side effects**: None of the patients in either group had episodes of nausea, vomiting, hypotension and bradycardia.

## CONCLUSION

From the study findings between the comparison of the efficacy of 0.75% epidural Ropivacaine with Fentanyl as an adjuvant and plain epidural 0.75% Ropivacaine without Fentanyl we conclude with addition of Fentanyl as an adjuvant to Ropivacaine produces:

1. Faster onset of sensory and motor blockade.
2. Increase in duration of sensory block.
3. Increase in total duration of analgesia.
4. Prolongation of postoperative analgesia and hence delay in the requirement of first rescue analgesia.
5. Better quality of sensory and motor block with optimal range of hemodynamic parameters.
6. No evidence of side effects in both the groups.

**LIMITATIONS**

1. Sample size was small. A larger sample size should be considered to prove the real efficacy of the drugs.
2. Single centre study was conducted. Multicentric studies should be conducted to prove efficacy and effectiveness of the drugs.

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