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Comparison of Intrathecal 0.75% Ropivacaine-Fentanyl and 0.5% Bupivacaine-Fentanyl in Equipotent Doses for Lower Abdominal and Lower Limb Surgeries Under Spinal Anesthesia

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Abstract

An observational & comparative study was designed to compare the efficacy, safety of Ropivacaine-Fentanyl versus Bupivacaine-Fentanyl intra-thecally for lower abdominal and lower limb surgeries not exceeding 2 hours.

70 patients of either gender with ASA I & II aged between 18 to 55 years were randomized into two groups, n = 35 each. Group R received 3 ml of (0.75%) Ropivacaine+ Fentanyl 25 µg (0.5 ml) and Group B received 3 ml of (0.5%) Bupivacaine+ Fentanyl 25 µg (0.5 ml). Spinal anesthesia procedure was standardized. Hemodynamic parameters, onset and duration of sensory & motor blockade, level achieved, duration of analgesia, regression and side effects were checked.

Onset and Regression of sensory blockade in ropivacaine group was faster with a P <0.001 which was statistically significant. Onset of motor blockade was rapid in both the groups, but duration of motor blockade was significantly shorter in ropivacaine group. Ropivacaine group were recorded with excellent analgesia and stable hemodynamics with no side effects.

From the present study we concluded that with addition of fentanyl to local anesthetics there is prolongation of analgesic effect. The hemodynamic parameters and SpO_2 are comparable in both the groups. Postoperative analgesic consumption is less in both groups. When bupivacaine-fentanyl combination was introduced intra-thecally, they produced a significantly longer duration of analgesia. Their sensory block and motor block were also longer than ropivacaine-fentanyl combination. Shorter duration of motor block with ropivacaine allows for early ambulation, voiding and physiotherapy, therefore it is preferred in day care surgeries.

Keywords: Duration of Analgesia; Fentanyl; Intrathecal Ropivacaine; Intrathecal Bupivacaine; Motor Block; Sensory Block.

Introduction

Karl August Bier introduced spinal anesthesia in clinical practice, in 1898.[1,2] It provides sensory and motor block, both of which are must for surgical work. Hyperbaric lignocaine (50 mg/ml) and Bupivacaine were commonly used in past for but were associated with many adverse events, hence their use has declined with development of newer agents.[3] This made researcher look for newer and safer local anesthetic agents.[4]

Ropivacaine, an amino-amide local anesthetic (LA) agent is a relatively newer agent whose chemical structure is nearly similar to bupivacaine. Incidence of transient neurological symptoms

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(TNS) is low compared to lignocaine. The duration of motor block is shorter than bupivacaine, allow rapid mobilization.[5] Currently Ropivacaine's isobaric preparations are only available commercially; hyperbaric solutions are prepared freshly by adding 50% glucose.[6]

Postoperative analgesia can be prolonged with the use of various intrathecal adjuvants. We have used fentanyl with local anesthetic which offers advantages of synergistic analgesic effect. This enhances analgesia that is required for surgery and this is attained even with the subtherapeutic doses of local anesthetic. With this adequate analgesia is attained with a dose of LA that is otherwise an inadequate dose for producing analgesic effect.[7]

Aims of Study

The main aim of the study was to compare equipotent doses of 0.75% Ropivacaine (3 ml) with 0.5% Bupivacaine (3 ml), when both the local anesthetist agents are combined with Fentanyl 25 µg (0.5 ml) for spinal anesthesia in patients posted for lower abdominal and lower limb surgery.

Objectives of Study

Objectives of the study were to compare the time of onset of sensory as well as motor block, the duration of sensory as well as motor block, the highest level of sensory block, the analgesic duration in both the groups, the vital parameters (heart rate; systolic, diastolic and mean blood pressure) and the occurrence of side effects (Nausea, Hypotension, Pruritus, Vomiting, Bradycardia, Rigor, Respiratory Depression) if any in either of the two groups and evaluate the safety of the two drugs.

Materials and Methods

We planned to conduct a observational study which was comparative in nature. The study was conducted in the Dhiraj General Hospital, Piparia. We enrolled seventy patients that met inclusion criteria and none of the exclusion criterias. The study was conducted as per local as well as global ethical norms as well as local regulatory guidelines. Data was collected to study and compare the effect of equipotent doses of 0.5% Bupivacaine (3 ml) and 0.75% Ropivacaine (3 ml) that were administered along with Fentanyl 25 µg for spinal anesthesia in patients that underwent lower abdominal and lower limb surgeries.

Patients of either sex aged between 18 and 55 years, scheduled for abdomen or lower limb surgeries not exceeding more than 2 hours with American Society of Anesthesiologists Grade l & ll (ASA I & II) were included in study. Patient of ASA III or IV, with coagulopathy, spine deformity, any skin infections at site of injection of LA, allergy to LA and patients that did not want to participate in the study were excluded from the study.

Sample Size of seventy (70) patients was included for data analysis.

Once enrolled, the participant underwent a detailed pre-anesthetic check-up with regards to patients demographics, vitals, systemic examination, and investigations.

The study population of 70 patients was randomly allocated to either of the two groups mentioned below, on the day of the surgery using Chit method:

Study Groups

Group B - 0.5% Bupivacaine (3ml) + Fentanyl 25 µg (0.5 ml)

Group R- 0.75% Ropivacaine (3 ml) + Fentanyl 25 µg (0.5 ml)

Procedure for study drug administration:

On arrival of patient in the operation theatre Standard monitoring, ECG, Non-Invasive blood pressure and SpO_2 were applied and all the baseline vitals were noted. An 18G intravenous cannula was secured in preloading with Ringer lactate at the rate of 10 ml/kg was started. Premedication inj. Glycopyrrolate 0.2 mg and inj. Ondansetron 4 mg given intravenously. Penetration with 23 gauge Quinke's spinal needle at L4-L5 interspace and either of the study drug was administered. Following this, patient was made to lie down in supine position.

Sensory block was assessed with Pin prick using hypodermic needle. Onset of sensory block (difference in the time from intrathecal injection of drug to the time taken to achieve T10 segment level block), highest level of sensory blockade, two level regression time, total duration of sensory block (time period from onset of block to the sensory block regressed by two segment from T10) were recorded.

Assessment was done at 2 min, 5 min and at 5 min interval thereafter until 2 consecutive levels of sensory block were identical (i.e. fixation of the level) after which assessment was done every 30 mins.

Motor block was assessed using modified Bromage scale. Time of onset of the motor block (time when modified Bromage scale 3 was attained

post intrathecal administration of the drug), Duration of motor blockade (time period between modified Bromage scale 3 to modified Bromage scale 0).

It was assessed 5 min, 10 min, 15 min, than every 15 minutes upto 120 minutes and than 30 minute intervals until the motor block had regressed completely.

Pulse rate and Systolic, Diastolic and mean blood pressure were recorded before giving spinal anesthesia, after spinal anesthesia, at 5 min, 10 min, 15 min, 30 min, and after that every 15 min till the end of the surgery.

A ≥20% decrease in systolic arterial pressure (SAP) or decrease in mean arterial pressure (MAP) below 60 mmHg indicated significant hypotension. These were managed using injection mephentermine 6 mg in increments intravenously along intravenous fluid replacement. Significant bradycardia (HR <60 beats/min) was treated with inj. atropine sulphate 0.6 mg intravenously.

Duration of surgery was noted, and duration of spinal anesthesia was recorded. Analgesic requirement was recorded for each patient. Side-effects and complications, if present, were recorded and treated.

Statistical Analysis

Data were analyzed using SPSS software version 18.0. *'f' test and 't' test* were applied for comparison of continuous data. *'Chi' test* was applied for comparison of nominal data. '*p*' value of 0.05 was considered as statistically significant. (Confidence interval of 95% was taken into account).

Results

The distribution of patients with respect to age, height, weight was statistically not significant in both the groups. (Table 1): Graph 1: Mean age, height and weight of patients in both the groups.

Mean time to onset of motor block was greater in Group B (7.91±0.70 minutes) compared to group Group R (5.86±0.69 minutes): Graph 2

Average duration of motor block was greater in Group B (193.71±18.48 minutes) compared to Group R (121.71±15.81 minutes): Graph 2

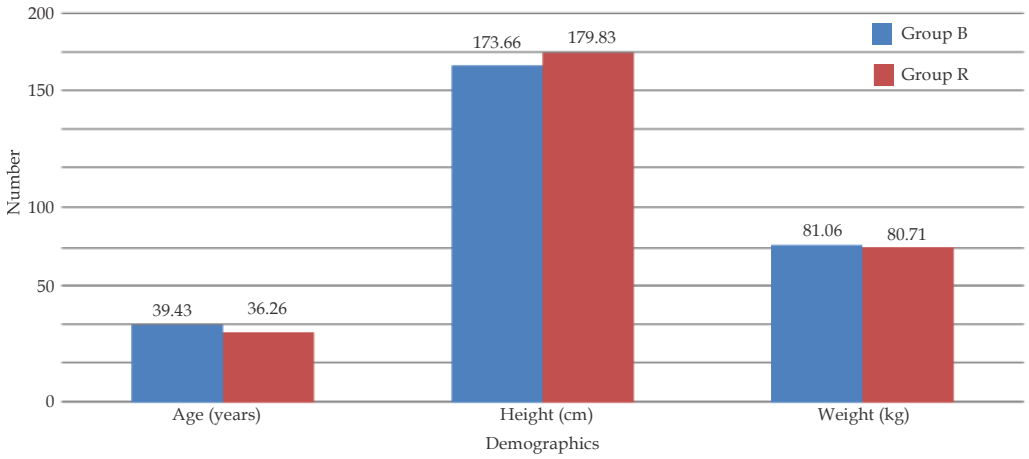
Mean time to onset of sensory block was higher in Group B (7.16±0.74 minutes) compared to Group R (5.40±0.76 minutes): Graph 3

Mean duration of sensory block higher in Group B (217.71±20.59 minutes) compared to Group R (137.43±19.26 minutes): Graph 3

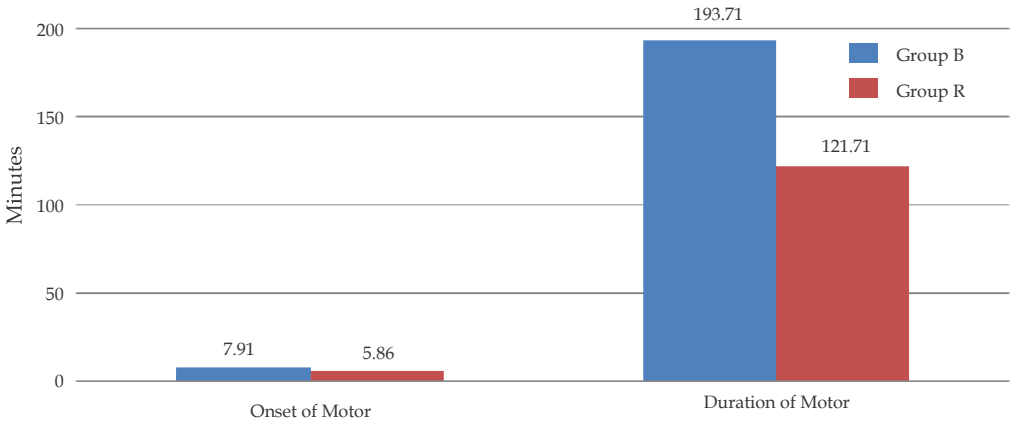
Duration of analgesia in the Group B was higher (427.43±44.28 minutes) compared to Group R (305.43±28.63 minutes): Graph 3

There was statistically no significant difference in pulse rate; systolic, diastolic and mean blood pressure between to groups: Graph 4

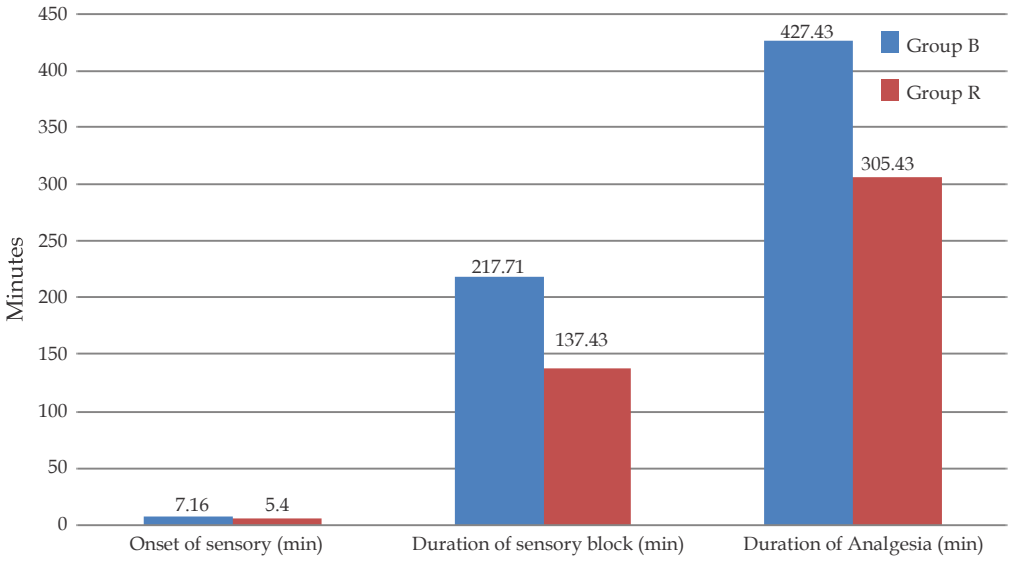
Intraoperatively, 8 patients in Group B and 5 patients in Group R developed hypotension while 2 patients in Group B and 3 patients in Group R developed bradycardia. Overall the safety profile was comparable. None of the patients in any of the groups had any post-operative complications.



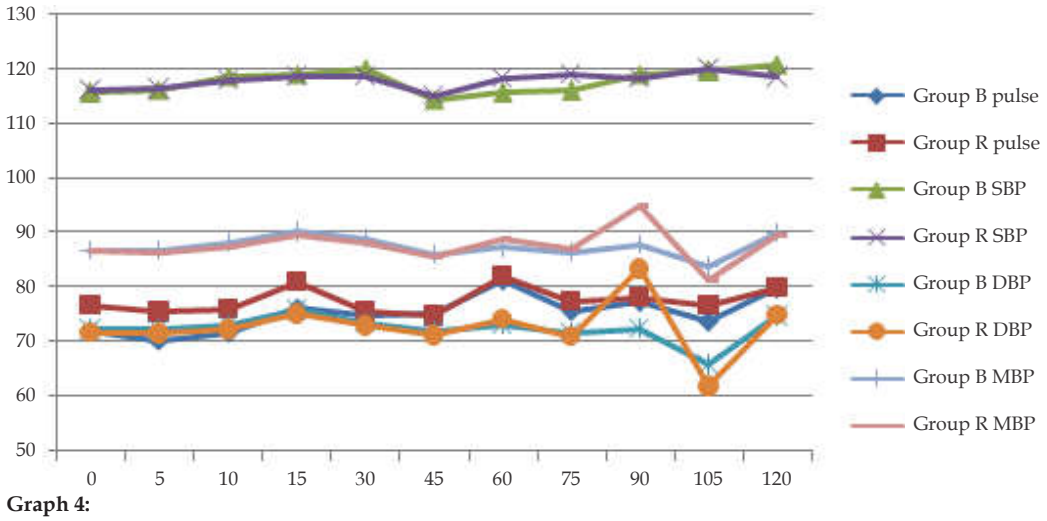
Graph 1:



Graph 2



Graph 3



Graph 4:

Discussion

In surgeries below umbilicus, the local anesthetic drug given in subarachnoid space in small incremental doses is ideal as it provides sensory and motor block that is complete, rapid and deep with advantage of rapid recovery and minimal side-effects. Various agents, especially opioids, are added to prolong the intraoperative and postoperative analgesia. This allows for use of lower doses of both the drugs and thereby helps avoid unwanted side effects of large doses.

In our study there was no difference observed in demographic data (Age, Weight, Gender distribution, American Society of Anesthesiologists status) of both the group. Thus both the groups were comparable in terms of demographics and there was no statistically significant difference between the two groups. (p>0.05). Lee YY, et al. (2005), Koltka K et al. (2009), Layek A, et al. (2015) in their studies also did not find any significant difference between the two groups in demographic data considering age, weight, gender of the patient and ASA status.[9,10,12]

In our study, we added Fentanyl 25 μg (0.5 ml) with 0.5% Bupivacaine (3 ml) in Group R and Fentanyl 25 μg (0.5 ml) with 0.75% Ropivacaine (3 ml) in Group B. The literature suggest that fentanyl in the doses from 10-25 mcg is safe and provides prolonged analgesia without having any impact on motor block. Hence in our study we had combined a dose of 25 μg of fentanyl with bupivacaine and ropivacaine.[14-16]

In our study, we observed the mean onset of sensory block was delayed in Group B (7.16± 0.74) as compared to Group R (5.40± 0.76 min) (p value <0.01) which was statistically highly significant, however, the duration of sensory block was longer in Group B (217.71±20.59 minutes) as compared to Group R (137.43±19.26 minutes) which was also statistically highly significant. (p<0.01). Koltka K et al. (2009) observed that mean time onset of sensory blockade was 10±4.5 minutes in Group B and 9±4.0 minutes in Group R. The duration of sensory block was 185±40 minutes and 160±40 minutes in Group B and Group R respectively.

In our study, the mean time to onset of motor block was shorter in Group R (5.86±0.69 minutes) as compared to Group B (7.91±0.70 mins) which was statistically highly significant (p<0.01). The mean duration of motor block was longer in Group B (193.71±18.48 minutes) as compared to Group R (121.71±15.81 minutes) which was statistically highly significant (p<0.01). The result of the following studies are comparable to our study: Koltka K et al. (2009) observed that mean time onset of motor blockade was comparable in both the groups. However, the duration of motor block was 182±46 minutes was significantly longer in Group B as compared to Group R 139±39.[10] Jagtap S et al. (2014) observed that mean onset time of motor blockade was 6.02±2.1 minutes in Group B and 6±3.6 minutes in Group R. The duration of motor block was 242.8±47.06 minutes and 268±49.9 minutes in Group B and Group R respectively.[11] This was in constrast to our study that onset of motor block in Group R is delayed or equivalent as compared to Group B.

In our study, the mean duration of analgesia was prolonged in Group B (427.43 ± 44.28 min) as compared to group R (305.43 ± 28.63 minutes) which was statistically highly significant (p<0.0001). This is comparable to the studies done by Jatap S et al. and Saran et al.

Study by Varun S et al. was in contrast to our study in onset of analgesia that in Group R is delayed or equivalent as compared to Group B. We observed that there was no statistically significant change in mean pulse rate, systolic blood pressure as well as diastolic blood pressure in both groups intraoperatively and postoperatively in the present study. (p>0.05).[8] Jagtap S et al. (2014), Layek A et al. (2015), Padmanabhan K. R. et al. (2016) also did not observe change in mean vital parameter.[11-13]

In our study, intraoperatively, 8 patients in Group B and 5 patients in Group R developed hypotension while 2 patients in Group B and 3 patients in Group R developed bradycardia. None of the patient developed postoperative nausea, vomiting, rigors or hypotension. Overall the safety profile was comparable. Koltka K et al. (2009) observed bradycardia in 8% patients in bupivacaine group and 12% patients in ropivacaine group.[10] It was concluded by Jagtap S et al. (2014) that bradycardia occurs in 3.3% population in both the groups. Similarly, there was hypotension in 3.3% patients in ropivacaine group and 10% patients in bupivacaine group.[11] On the contrary, Layek A et al. (2015) did not observe any incidence of bradycardia or hypotension.[12]

Conclusion

Bupivacaine-fentanyl combination produces a longer duration of analgesia, sensory block and motor block than ropivacaine-fentanyl combination. Shorter duration of motor block with ropivacaine allows for early ambulation, voiding and physiotherapy therefore it is preferred in day care surgeries with shorter hospital stay.

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