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Research Article

Effects of fentanyl on isobaric ropivacaine in subarachnoid anaesthesia for lower abdominal and lower extremity surgeries

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ABSTRACT

Background: The addition of fentanyl to ropivacaine has shown to improve the quality of analgesia without compromising its benefits such as early mobilization and early voiding. This study evaluated the effects of adding fentanyl 25 mcg to isobaric ropivacaine 0.75% for spinal anaesthesia with regards to the onset of sensory block, maximum sensory level reached and the time to achieve it, time to two dermatome segment regression, onset of motor block, time for maximum motor blockade, duration of motor block, hemodynamic parameters and incidence of side effects.
Methods: Hundred patients, male and female, ASA I or ASA II, aged 18 to 65 years scheduled for elective lower abdominal and lower extremity surgeries were randomized into two groups. Group R (control group) received 0.75% isobaric ropivacaine 22.5 mg (3 ml) and Group RF (study group) received 0.75% isobaric ropivacaine 22.5 mg (3 ml) and 25 mcg of fentanyl (0.5 ml). Intra operatively, sensory blockade was assessed by pin-prick method and motor parameters were assessed by modified Bromage scale at different time intervals. Haemodynamic parameters were monitored and side effects were also recorded
Results: Both groups were comparable with respect to age, height, weight and duration of surgery. There was no significant difference in hemodynamics, onset of sensory and motor block, peak level of block, recovery from motor block, return of micturition and incidence of side effects with the addition of fentanyl to ropivacaine. There was a significant prolongation of the duration of sensory block (250.8±20.7 VS 362.1±15.1* min) and postoperative analgesia (320.56+15.32 VS462.41±38.42 *min) in Group RF ($P < 0.001$).
Conclusions: It was concluded that the addition of 25 mcg fentanyl to 22.5mg of 0.75% isobaric ropivacaine for spinal anaesthesia significantly increases the duration of sensory block and decreases the rescue of analgesia with better hemodynamic stability, early recovery and mobilization.

Keywords: Spinal anaesthesia, Isobaric Ropivacaine, Fentanyl, Sensory block, Analgesia

INTRODUCTION

Subarachnoid blockade used in all surgical procedures carried out on the lower half of the body, which includes surgery on the lower limbs, pelvis, perineum, and urological procedures. It also used in obstetric practice to provide anesthesia for elective and emergency procedures. Dural puncture was performed and the small amount of local anesthetic drug was deposited into the cerebrospinal fluid to produce anesthesia, which works by inhibition of sodium ion channel. All local anesthetic drugs except ropivacaine were racemic mixtures with different potency and toxicity.[1]

Ropivacaine, a relatively new amide local anaesthetic with similar local anaesthetic properties as bupivacaine, is the first single-enantiomer local anaesthetic to be produced commercially.[2] Animal studies have

demonstrated that intrathecal ropivacaine has little effect on spinal cord blood flow and that it produces similar sensory block to that of an equivalent dose of bupivacaine, with a reduced degree of motor block.

The low lipid solubility of ropivacaine leads to greater sensory-motor differentiation by blocking sensory nerve fibres more readily than motor fibres. Early recovery of motor function is associated with decreased incidences of venous thrombo-embolism and shorter hospitalization.[3,4]

Recently, however, its use as a spinal anaesthetic agent has been evaluated in many procedures because of its equivalent spinal anaesthetic effect and its lower risk of neurotoxicity and cardiotoxicity, compared with bupivacaine and lidocaine. Postoperative analgesia is a concern with ropivacaine that limits its usage. The addition of adjuvants to ropivacaine has shown to improve the quality of intra-operative and postoperative analgesia without compromising its benefits such as early mobilization and early voiding. Some studies have shown that intrathecal opioids can greatly enhance analgesia from subtherapeutic doses of local anaesthetic.

Fentanyl has been widely used as an adjuvant to local anesthetics for enhancement of analgesia without intensifying motor and sympathetic block of spinal anesthesia, thus resulting in lower incidence of hypotension, early recovery and mobilization. Various reports have shown that the addition of small dose intrathecal fentanyl (10-25 µg) to local anesthetics during spinal anesthesia has enhanced the duration of sensory analgesia without intensifying the motor block or prolonging recovery.

METHODS

The clinical study was conducted on 100 patients at the Mahatma Ghandi memorial Hospital, Warangal, Telangana state, India during the period April 2015 to March 2016 by obtaining approval from institutional ethical committee. Adult patients scheduled for elective surgeries of the lower abdomen and lower extremities were taken in to the study. Only adults belonging to ASA grade I and II were included. Patients with neurological disorders, anaemia, and hypertension, cardiac and respiratory disorders were eliminated from this study. After a thorough clinical examination and relevant laboratory investigations of all patients, an informed, valid, written consent was obtained, both for conduct of study as well as administration of spinal anaesthesia.

A total of 100 ASA Grade I and II adults for elective surgeries of lower abdomen and lower extremities under spinal analgesia were divided into 2 groups each consisting of 50 patients. All patients were kept nil by mouth from midnight before surgery and tablet diazepam 5mg and tablet ranitidine 150 mg PO was administered at bed time the day before surgery. The patients were re-examined, assessed and weighed pre-operatively on the day of surgery. Intravenous access was established with a 23G intravenous cannula and preloading was done with 15 ml/kg Lactated Ringer's solution 30 minutes before procedure. Anaesthesia machine and accessories were checked and drugs, including emergency drugs like atropine were kept ready. Also monitoring equipments like pulseoximeter, noninvasive blood pressure (NIBP) and electrocardiogram (ECG) monitors were checked and applied to each patient on arrival to the operating room and baseline parameters were recorded. Under strict aseptic conditions, with the patient in the sitting position, a lumbar puncture was performed at L3-L4 intervertebral space. After ensuring free flow of CSF, subarachnoid block was performed with 3.5 ml of test drug.

This study was conducted in the form of a prospective, randomized, double-blind, controlled fashion. The patients were randomized by closed envelope method into two groups: Group R received 3 ml (22.5 mg) of 0.75% isobaric ropivacaine+0.5 ml normal saline Group RF received 3 ml (22.5 mg) of 0.75% isobaric ropivacaine + 25 µg fentanyl (0.5 ml). The anaesthesiologist was blinded to the solution administered intrathecally.

Following intrathecal injection, parameters like HR, systolic blood pressure (SBP), diastolic blood pressure (DBP) recorded every 2 min for the first 10 min, then every 5 min till 60 min, then every 20 min till completion of surgery and for every 1hour in postoperative period for 6 hours.

Level of sensory blockade was checked bilaterally along the mid clavicular line by assessing changes in pinprick sensation by use of a safety pin protruding 2 mm through a guard every 1 min till no sensation (Grade 2) was achieved (Graded according to Gromley and Hill (normal sensation - 0, blunted sensation - 1, no sensation - 2). Sensory block was assessed until sustained peak level of sensory block was reached (i.e., once the level had stabilized after four consecutive tests). Time taken for T10 level of blockade, peak level of blockade achieved and its time taken were noted.

The degree of motor block was assessed using modified Bromage scale (0 = no motor block, 1 = inability to raise extended legs, 2 = inability to extend knees, and 3 = inability to extend ankle joints).

Duration of analgesia was assessed from the onset of sensory block to first request for rescue analgesia. Analgesics were avoided until demanded by the patients. Injection tramadol 50 mg intravenous (IV) was given at patient's first request for analgesia. Occurrence of side effects like hypotension, bradycardia, nausea, vomiting, shivering, pruritus, respiratory depression (respiratory rate <8/min) and urinary retention were attended and managed. Hypotension was treated with intravenous mephentermine 3-6 mg or phenylephrine 50 µg and additional lactated Ringer's solution.

Statistical analysis

Statistical analysis was performed using SPSS version 16.0 (SPSS Inc., Chicago, IL). All repeated measures tests were compared using repeated measures ANOVA comparing the mean and the standard deviations. Chi-square test was used for ASA grading, type of surgery and side effects. Individual time period and remaining all parameters were compared using Student's t-test. Significance is assessed at 5 % level of significance. P value <0.05 was considered significant.

RESULTS

Spinal an aesthesia was successful in all the patients. The demographic profiles of the patients among the groups were comparable with regards to age, sex, and weight and body mass index. The distribution of vital data and mean duration of surgery was comparable among the groups. The age and sex distribution was given in (Table 1) and the surgical procedures performed in the different groups were given in (Table 2).

Table 1: Demographic data.

Parameter	RC (control group)	RF (Fentanyl group)
Age in years (Mean±SD)	32.7±12.61	33.8±11.71
Weight in kg(Mean±SD)	54.5±8.92	58.6±12.22
Height in cm (Mean±SD)	152±9.56	154±10.23
Sex M/F (N0)	35/15	33/17
ASA GradeI/II (No)	26/24	27/23
Duration of surgery min	90.12±10.24	86.35±11.56

Hemodynamic stability

- The hemodynamic stability was assessed by heart rate, systolic, diastolic and means arterial pressures. When we observed the trend of mean heart rates there is no significant difference among the groups Mean heart rates of both the groups were above 70/min indicating the hemodynamic stability in groups at given doses. The trend of MAP, showed no significant difference in MAP among the groups before administration of premedication but both group had slight lower MAP after premedication.

Assessment of sensory blockade

- Sensory blockade was assessed for every 2 mins for the first 10 mins and thereafter every 15 mins during surgery and post operatively. All the durations were calculated considering the time of spinal injection as time 0. Sensory blockade was checked with an alcohol swab in mid axillary line and the time taken for the highest level of sensory blockade, two dermatomal regression from the maximum level and regression to S1 level was noted.

Table 2: Type of surgical procedures in two groups.

Surgical procedure	Group A	Group B
Herniorrhaphy	5	6
Eversion of sac	10	6
Haemorrhoidectomy	5	6
Fistulectomy	5	5
Orthopaedic procedures	25	27

- ***Onset of sensory blockade:*** The onset of sensory blockade was determined by applying pinprick for every 30sec interval after the completion of injection of the drug in CSF. Mean time for onset of sensory block was 4.02 ± 1.03 min for R group while for RF group, it was 3.54 ± 1.06 min and both were comparable.

- ***Highest level of sensory block (dorsal):*** Highest sensory level recorded for R group was T7, for RF group it was T4 and time taken to reach maximum level was 9.20±1.25 and 7.54±2.1min respectively.

- ***Duration of sensory blockade:*** The duration of sensory blockade was defined by the time interval between the onsets of sensory analgesia to the two segment regression. The duration of sensory blockade was 250 .8±20.7 min in the R group, 362.1±15.1 min in the RF group and there exist a significant difference between two groups.

There was no significant difference in the meantime of onset of T10 level of sensory block and peak level of sensory block and time taken to reach peak level of block between the two groups but there exist a significant difference in time for sensory regression of two dermatomes and duration of sensory blockade in two groups and addition of fentanyl increased the duration.

Assessment of motor blockade

Motor blockade was assessed by modified Bromage Scale (Bromage, 1965). Time of onset, time taken for motor blockade to reach Modified Bromage Scale 3 and regression of motor blockade to modified Bromage Scale 0 was noted. All patients in the both groups achieved complete motor block.

- ***Time of onset of motor block:*** The mean onset time of complete motor block was similar in both groups. Time was 5.53±0.2 in R group and 5.12 ±0.6min.

- ***Duration for motor blockade to reach modified Bromage scale 3:*** peak onset of motor block reached

in12.54±1.9min in R group 11.57±1.02 min in RF group and values were comparable with each other.

- ***Duration for motor block regression to modified Bromage scale 0:*** the mean duration of motor block was245±10.5 and 250.44±17.53min in R & RF groups respectively.

The mean onset, time of complete motor block and time for recovery from motor blockade was similar in both groups, considered as insignificant. However there exist a significant difference in time to micturition (352.25±20.14 Vs375±17.85* min), fentanyl increased the duration.

Comparison of sensory and motor blockade in two groups was shown in table 3.

Table 3: Comparison of sensory and motor blockade in two groups.

Parameter (time in minutes)	RC control group	RF fentanyl group
Highest level of sensory block (dorsal)	T4-T9/T7	T4-T10/T4
Time of onset of sensory block	4.02+1.03	3.54+1.06
Time for attaining highest level of sensory block	9.20+1.45	7.54+2.1
Duration of sensory blockade	250.8±20.7	362.1±15.*
Time of onset of motor block	5.53±0.2	5.12±0.6
Duration for motor blockade to reach Modified Bromage scale 3	12.54+1.9	11.57+1.02
Duration for motor block regression to Modified Bromage scale 0	245.52+10.5	250.44+17.53
Time of first request of analgesic	320.56+15.32	462.41±38.42 *
Time for Micturation	352.25±20.14	375±17.85*

Postoperative analgesia (from onset of analgesia to the rescue analgesia)

No patients required supplemental analgesia intra-operatively. The mean time of first analgesic request was significantly prolonged in the fentanyl group (462.41±38.42 min) than the control group (320.56+15.32min).

Intra and postoperative complications

Intra-operative hypotension was observed in 3 patients of fentanyl group and 2 patients of control group. Two patients in both groups had shivering and were treated with IV tramadol 50 mg. Only one patient in the fentanyl group had pruritus and was treated with IV ondansetron 8 mg

DISCUSSION

Spinal anaesthesia was a very old and popular anaesthetic technique with a high success rate and a good safety profile. In order to improve further and understand safety issues as well as the clinical use of spinal anaesthesia, new local anaesthetics and analgesic additives were being investigated for different applications. As the practice of medicine focuses increasingly on out-patient care, spinal anaesthetics should provide short acting and adequate anaesthesia without compromising early ambulation and discharge from the day surgery unit. Ropivacaine was one local anaesthetic that could have been potential in this area.[5]

Ropivacaine was used extensively for intrathecal anaesthesia in obstetric and nonobstetric out-patient procedures, including ambulatory knee surgery, endoscopic urological surgery or anorectal surgery. Analgesic adjuvants such as clonidine, ketamine and opioids like fentanyl have also been used concurrently with low-dose intrathecal ropivacaine, to improve intra-operative analgesia due to their synergetic action.

Fentanyl has been widely used as an adjuvant to local anaesthetics for enhancement of duration of sensory analgesia without intensifying motor and sympathetic block of spinal anaesthesia, thus resulting in lower incidence of hypotension, early recovery and mobilization.

The present study was designed to study the effects fentanyl on isobaric ropivacaine in the subarachnoid blockade for lower abdominal and lower limb surgeries.

Clinical efficacy and safety of two doses of 0.75% ropivacaine, 3.5 ml (26.25 mg) and 4.5 ml (33.75 mg) for spinal anaesthesia were compared by Wong et al.6 in patients undergoing lower limb and lower abdominal surgery and concluded that both doses had the same efficacy and safety in these patients . Gupta et al.7 studied intrathecal 20 mcg fentanyl as an adjuvant to 4 ml of 0.75% isobaric ropivacaine for infraumbilical surgery under subarachnoid block found to effective. In this study 3ml of 0.75% isobaric ropivacaine and 25µg fentanyl was selected as study dose based on previous studies.

In our study we found that following subarachnoid block; changes in HR, SBP and DBP were similar in both the groups. Mean HR, SBP and DBP at baseline were 71.23±8.11 bpm, 125.72±11.78 mmHg and 75.62±6.82 mmHg in Group RF and 73.1±7.23 bpm, 127.36±10.93 mmHg and 74.23±7.54 mmHg in control group R respectively, which were comparable. Following spinal

anaesthesia the differences in the HR, SBP and DBP between the two groups was found to be statistically insignificant at all intervals measured. Nuray and Berrin in their study of intrathecal ropivacaine with fentanyl did not find any significant difference with respect to hemodynamic parameters.[8] The outcome in their study was comparable to our study.

In this study onset of T10 level of sensory block and peak level of sensory block and time taken to reach peak level of block between the two groups were similar and comparable with each other. Parlow et al established the fact that hypobaricity influenced the extent of subarachnoid block and explained high cephalic levels of sensory block when fentanyl was added to isobaric local anaesthetic solution.[9] In the present study, sensory level of T4 was observed in group RF but in group RC the extent of sensory block reached only up to T7 dermatome. Koltka et al reported that 19.5 mg ropivacaine with 20 µg of fentanyl for spinal anaesthesia in lower abdominal surgeries, peak level of sensory block achieved was T7 (T4-T9), Kaushik rao et al.[10,11] with 19.5 mg ropivacaine with 20 µg of fentanyl was T6 (T4-T9). These results were in accordance with our results. In our study, there was no significant difference in the mean onset time for T10 level of blockade between the two groups however Boztug et al studied the effects of intrathecal ropivacaine and intrathecal ropivacaine with fentanyl for out-patient arthroscopic knee surgery.[12] 10 mg (3 ml) of the isobaric ropivacaine was compared with 8 mg isobaric ropivacaine combined with 25 µg fentanyl. The onset for T10 level of blockade was faster in Group R compared to Group RF (3.60±1.84 min vs. 5.25±2.04 min), but the results were not statistically significant. Sanli et al. evaluated the effects of addition of fentanyl to ropivacaine for caesarean section. Group S received 15 mg hyperbaric ropivacaine+0.5 ml saline; Group F received 15 mg hyperbaric ropivacaine+10 µg fentanyl in 0.5 ml intrathecally. Time to reach the peak level of block did not differ significantly between both the groups (Group S vs. Group F, 9.3±1.7 min vs. 8.4±1.3 min). This was comparable to the result of our study.

Duration for 2 dermatomal regression of sensory blockade and total duration of sensory blockade were significantly increased in fentanyl group. Kaushik rao et al reported S2 regression time (Group R vs. Group RF, 240.4±13.087 min vs. 341.6±15.032 min) and Sanli et al.13 reported time to regression to L5 (Group S vs. Group F, 150.3±13.4 min vs. 168.3±17.3 min) were prolonged significantly in fentanyl group.[11] Fentanyl is highly lipid soluble and rapidly binds to opioid receptors present in the dorsal horn of spinal cord helps on faster onset of sensory block. Fluctuating pressure changes occur in cerebrospinal fluid due to respiration and cardiac cycle. This creates a backward and forward movement of cerebrospinal fluid such that after intrathecal injection, net transfer of fentanyl occurs in a cephaled direction. This explains the higher sensory levels achieved in fentanyl group compared to control group.[14]

There was no significant difference in onset times for complete motor blockade, complete recovery from motor blockade in our study. These results were in accordance with the Kaushik rao et al, Boztug et al and Sanli et al proved that fentanyl do not alter the motor effects of ropivacaine spinal anaesthesia.[11-13]

Postoperative analgesia requirements in this study prolonged significantly in fentanyl group. The total analgesic requirements also decreased. Duration of action of intrathecal fentanyl is 4-6 hours. This explains the considerably longer duration of analgesia in the study group when compared to using bupivacaine alone.14 previous study by Yegin et al showed that when intrathecal fentanyl was added to ropivacaine for transurethral resection of prostrate, the regression of block was delayed and time to first request of analgesia was longer. Jagtap et al showed that adding fentanyl improved the quality and duration of analgesia when they compared fentanyl plus ropivacaine with fentanyl plus bupivacaine alone for spinal anaesthesia in minor urological procedures.[15,16] Chung et al showed that adding 10 µg fentanyl to 18 mg hyperbaric ropivacaine improved intra-operative spinal anaesthesia for Caesarean sections and increased the analgesia in the early postoperative period. Similarly, Kaushik rao et al, Boztug et al Sanli et al and Layek et al found that time for analgesic requirement prolonged in fentanyl group compared to control group.[11-13,17,18]

Intraoperative hypotension seen in 5 patients (3 in R vs2in RF), postoperative shivering in 4 patients (2 in each group), pruritus in one patient of RF group. Koltka et al reported 20% of patients who received ropivacaine with fentanyl had hypotension and 3% had bradycardia. Kaushik rao et al had shown that incidence of hypotension was 8% in Group RF and 3% in Group R, with no episodes of bradycardia in either group, showing that combination of ropivacaine with fentanyl provides good cardiovascular stability. Two patients had shivering and one had pruritus.[10,11]

CONCLUSION

From our study, the addition of fentanyl to ropivacaine for spinal anaesthesia seems to prolong the duration of sensory block and duration of analgesia postoperatively without significantly affecting hemodynamics, onset of sensory and motor block, peak level of sensory block and return of micturition. Thus, it improves the overall quality of anaesthesia of ropivacaine, at the same time preserves its benefits like good hemodynamic stability, early recovery and mobilization.

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