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Original Article

A Prospective Study Comparing Two Clinical Doses of Fentanyl as an Adjuvant to Isobaric Ropivacaine 0.75% in Intrathecal Block

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Abstract

Aim: Subarachnoid block is the simple technique of regional anesthesia commonly employed for infraumbilical surgeries. Neuroaxial administration of fentanyl along with local anesthetics improves the quality of intraoperative analgesia, reduces the need for sedation, and also provides post-operative pain relief for longer duration. This study was designed to compare the two doses of fentanyl with isobaric ropivacaine in spinal anesthesia in terms of analgesic efficacy, hemodynamic stability, and effect on sensory and motor characteristic.

Method: This prospective randomized, double-blind study involving 20 patients in each group. Group A received injection isobaric 0.75% ropivacaine 4.0 ml + 1 ml cerebrospinal fluid (CSF), Group B received injection isobaric 0.75% ropivacaine 4.0 ml + fentanyl 12.5 µg (0.5 ml) + CSF 0.5 ml, and Group C received injection isobaric 0.75% ropivacaine 4.0 ml + fentanyl 25 µg (0.25 ml) + CSF 0.75 ml. On set time, onset of sensory and motor block, highest dermatomal level blocked, duration of sensory and motor block, and quality of motor block were noted. Vital parameters and adverse effects were also noted perioperatively. Data analysis was done with unpaired *t*-test, one-way ANOVA, and *post hoc* Tukey test.

Results: Onset of sensory block was comparable. Onset of motor block, duration of sensory, and motor block were statistically prolonged in Group B and Group C.

Conclusion: About 12.5 µg fentanyl with isobaric ropivacaine provides better hemodynamics, early onset of sensory and motor block, and prolonged period of analgesia without undesirable side effects.

Key words: Fentanyl, Ropivacaine, Subarachnoid block

INDRODUCTION

Subarachnoid block is well-established technique, for providing anesthesia for lower limb surgeries, pelvis, perineum, urological, gynecological, and obstetrical procedures.[1] Among various local anesthetic drugs, bupivacaine is most commonly used intrathecal local anesthetic, already have undergone many researches. Ropivacaine is purely S-isomer imparting less toxicity to the cardiovascular[2] and central nervous systems[3] though producing less intense motor blockade and postoperative analgesia.[4] Therefore, studies were conducted with addition of different adjuvants to isobaric ropivacaine[5,6] such as clonidine,[7,8] fentanyl,[9] or dexmedetomidine.[10] Fentanyl is an opioid that has shown to improve analgesic potency of ropivacaine and prolong postoperative analgesia for spinal anesthesia.[11] In this study, we decided to evaluate effect adding of two different doses of fentanyl as an adjuvant to 0.75% isobaric ropivacaine on onset, duration of sensory and motor blockade, and quality of motor block in subarachanoid block for lower abdominal and lower limb surgery.

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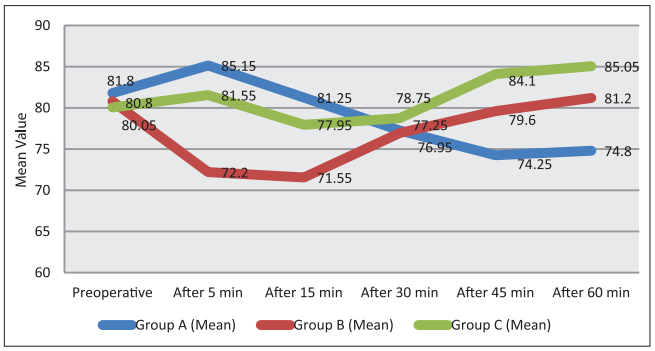
MATERIALS AND METHODS

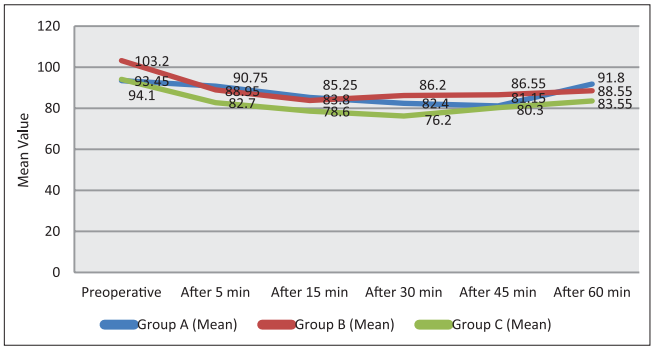
After obtaining approval from the Ethics Committee and written informed consent, this prospective double-blind randomized clinical study was conducted on 60 ASA Grade I and Grade II patients, of either sex aged between 20 and 60 years, undergoing elective surgery (of < 120 min) on lower abdomen and lower limb under spinal anesthesia. Patient's refusal, history of sensitivity to local anesthetic, patient on anticoagulant therapy or with abnormal bleeding or coagulation profile, infection at the site of injection, spinal abnormalities, previous spine surgery, and presence of comorbid diseases contraindicating spinal block were excluded from this study. Detailed pre-anesthetic examination was done and anesthetic procedure was briefly explained to the patient. Patients were randomly allocated into three groups of 20 patients in each, using computer-generated randomization chart: Group A (Control group) - Injection 0.75% isobaric ropivacaine – 4.0 ml + 1 ml cerebrospinal fluid (CSF), Group B - Injection 0.75% isobaric ropivacaine – 4.0 ml + fentanyl 12.5 μg (0.5 ml) + CSF 0.5 ml, and Group C - Injection isobaric 0.75% ropivacaine – 4.0 ml + fentanyl 25 μg (0.25 ml) + CSF 0.75 ml.

The patients were kept nil orally for 8 h before surgery. After shifting the patient on the OT table, routine monitors such as non-invasive blood pressure (NIBP), pulse oximeter (SpO_2), and continuous electrocardiogram were applied. Baseline heart rate (HR), BP, respiratory rate (RR), and SpO_2 were recorded. A wide bore intravenous access was secured and preloading with 10 ml/kg ringer lactate was done. Under strict aseptic precautions, lumbar puncture was performed by midline approach in lateral position using 25G quincke spinal needle at L3–L4 intervertebral space. After performing successful lumbar puncture, isobaric ropivacaine 0.75% with or without fentanyl was administered according to assigned study groups. Operator and investigator were blinded about the drug which was prepared by independent investigator. Table was kept in neutral position and all patients were made supine immediately following the injection. The completion of injection was taken as time zero of induction of anesthesia. After spinal anesthesia, the patient's HR, MAP, RR, and SpO_2 were recorded at 0 min, 5 min, 10 min, 15 min, 20 min, 25 min, and 30 min and then every 15 min till the end of the procedure. Postoperatively, HR, NIBP, and SpO_2 were recorded every 2 h until the sensory and motor functions were back to normal.

The sensory and motor blockade parameters were assessed after spinal anesthesia at 2 min intervals until



Graph 1: The mean pulse rate has been shown in line graph



Graph 2: The mean arterial pressure has been shown in line graph

the surgical anesthesia was achieved, and postoperatively, every 15 min until the sensory and motor functions were back to normal. Time of onset of sensory and motor block, highest dermatomal level of sensory block achieved, and duration of sensory and motor block were noted. Onset time of sensory blockade was defined as the interval between intrathecal administration of drug and loss of pinprick sensation at T10 level. Level of sensory block was assessed by loss of pinprick sensation using 24G hypodermic needle bilaterally along midclavicular line at L1, T12, T10, T8, T6, and T4 levels. Duration of sensory block was defined as the interval from intrathecal administration to the point of regression of sensory blockade from T10 to S1, was noted by pinprick with 24G hypodermic needle on posteromedial aspect of thigh.

Onset time of motor blockade was defined as the time interval intrathecal administration of drug and the Bromage score 3 recorded. Motor block was assessed using 3 points modified Bromage scale.[11] Grade 0 = no weakness, Grade 1 = can flex knees but can not raise legs, Grade 2 = only foot movements, Grade 3 = complete paralysis. Duration of motor blockade was defined as interval from intrathecal administration to the point in which the Bromage score was back to zero recorded. Duration of pain-free period, the time interval from intrathecal injection of drug till demands of first rescue dose of analgesic.

Level of sedation was assessed using the sedation score described by Chernik *et al*.[12] Score 0 = wide awake, Score 1 = sleeping comfortably, responding to verbal commands, Score 2 = deep sleep, but arousable, and Score 3 = deep sleep, not arousable. It was assessed pre-operative then after 15 min, 30 min, 45 min, 60 min, and 120 min.

The occurrence of adverse events that include bradycardia, hypotension, pruritus, respiratory depression (RR/min and SpO_2), sedation, shivering, and nausea and vomiting were recorded and managed accordingly.

On patient's demand for analgesia, Injection diclofenac 75 mg IM was given.

Statistics

Data were compiled and analyzed using software SPSS version 16. $P < 0.05$ was considered statistically significant. The means of groups were compared using unpaired *t*-test while the means between more than one group was compared using one-way ANOVA and *post hoc* Tukey test. The final data were represented using Tables and Graphs.

RESULTS

Spinal anesthesia was successful in all the patients. The mean age, sex, height, weight, and duration of surgery were similar in all groups [Table 1].

The mean onset time of sensory block in Group A was 4.09 ± 1.08 min, in Group B was 3.64 ± 1.00 min, and in Group C, it was 3.24 ± 1.05 min. ($P > 0.05$). All values were comparable. Highest sensory level was recorded in Group A was T6-T12/T6 while in Group B and Group C, it was T4-T12/T4. In almost, all three groups T8-T12 level dermatomal analgesia was achieved satisfactory and distribution appeared to be uniform.

Table 2 shows Group C had lowest time of onset of motor block whereas longest duration of sensory, motor block, and period of analgesia among the three groups where fentanyl 25 μg was added to ropivacaine which was statistically found significant ($P < 0.05$) using unpaired *t*-test.

DISCUSSION

Subarachnoid block has been used in both elective and emergency procedures.[13] Recently, ropivacaine is being getting used commonly as local anesthetic of choice.[14] Fentanyl as adjuvant to ropivacaine enhances analgesic effect of local anesthetic drug without intensifying motor and sympathetic block in spinal anesthesia, thus leading to lower incidences of hypotension, early recovery, and mobilization, with additional benefit of decreasing total dose of local anesthetic drug needed.[1]

Khaw *et al*.[14] concluded that during spinal anesthesia in lateral position hyperbaric solution tends to spread more in cephalic direction while isobaric solution tends to concentrate at lumbar segments which were similar to our study showing comparatively lower segmental analgesic distribution with isobaric ropivacaine. Isobaric ropivacaine produces less intense, unpredictable, and variable height of block when given intrathecally for spinal anesthesia,[6] but in our study, not a single patient felt any discomfort during surgery did not require any analgesic supplementation.

In our study, we found that following subarachnoid block changes in HR, MAP, and RR as shoen in Graphs 1 and 2, were not clinically significant similar to study done by Nuray and Berrin with intrathecal ropivacaine with fentanyl. They did not find any significant difference with respect to hemodynamic parameters.[15] The mean onset time of sensory block in Group A was 4.09 ± 1.08 min, in Group B was 3.54 ± 1.00 min, and in Group C, it was 3.65 ± 1.05 min and compared with each other. Our results were similar to study conducted by Boztug *et al*.[16] who studied the effects of intrathecal isobaric ropivacaine 10 mg and intrathecal ropivacaine 8 mg with fentanyl 25 μg for outpatient arthroscopic knee surgery. 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. Chaudhary *et al*.[17] observed the same results of onset of sensory block when compared isobaric ropivacaine 15 mg (0.75%) and isobaric ropivacaine 13 mg (0.75%) with fentanyl 10 μg given intrathecally.

Table 1: Showing demographic data: Mean±SD

Demographic data	Group A	Group B	Group C	*P* value
Age (years)	38±10.8	42.±11.21	41±9.8	NS
Sex (M/F)	16/4	18/2	17/3	NS
Weight (kg)	58.5±8.47	56.3±10.22	60.3±8.28	NS
Height (cm)	151±10.54	153±8.25	156±20	NS
Duration of surgeries (min)	92.50±28.72	78.50±29.11	87.25±20.23	NS

NS: Non significant *P*>0.05, SD: Standard deviation

Table 2: Sensory and motor characteristics in all groups (mean±SD)

Characteristics	Group A	Group B	Group C
Onset of sensory block (min)	4.09±1.08	3.64±1.00	3.24±1.05
Highest dermatomal level	T6(T6-T12)	T4(T4-T12)	T4(T4-T12)
Duration of sensory block (min)	227.3±62.5	324.45±43.78	383.6±49.7
Onset of motor block	12.01±1.57	9.05±1.05	7.88±1.00
Duration of motor block	202.3±64.1	281.35±36.16	318.50±31.70
Period of analgesia	237.8±63.8	347.7±59.6	407.7±52.6

SD: Standard deviation

Table 3: Comparison of sedation score between the groups

Groups	After 15 min	After 30 min	After 45 min	After 60 min
Group A	0.15±0.37	0.25±0.44	0.10±0.31	0.05±0.22
Group B	0.10±0.31	0.20±0.62	0.15±0.49	0.00±0.00
Group C	0.20±0.41	0.30±0.66	0.05±0.22	0.05±0.22
P value	0.687, NS	0.862, NS	0.679, NS	0.609, NS

Table 3B: *Post-hoc*

Tukey test

Group pairs	After 15 min ("*t*," *P* value)	After 30 min ("*t*," *P* value)	After 45 min ("*t*," *P* value)	After 60 min ("*t*," *P* value)
Group A–B	0.43, *P*=0.901	0.27, *P*=0.960	0.44, *P*=0.898	0.87, *P*=0.664
Group B–C	0.43, *P*=0.901	0.27, *P*=0.960	0.44, *P*=0.898	0.00, *P*=1.000
Group C–B	0.87, *P*=0.662	0.55, *P*=0.849	0.88, *P*=0.653	0.87, *P*=0.664

One-way ANOVA was applied to find out the statistical significance among the groups. Non-significant *P* values were obtained for all time intervals. *Post hoc* Tukey shows the significance between different pairs of groups for different time intervals

Table 4: Complications seen in all the three groups

Complications	Group A	Group B	Group C
Uneventful	14	15	8
Nausea and vomiting	1	0	1
Hypotension	2	3	4
Mild pruritus	0	0	3
Bradycardia	2	2	4
Pain	1	0	0

As shown in Table 4, incidence of complications was less in Group A and B as compared to Group C

Highest sensory level was recorded in Group A was T6-T12/T6 while in Group B T4-T12/T4, and Group C, it was T4-T12/T4. Parlow *et al.*[18] established the fact that hypocricity influenced the extent of subarachnoid block and explained high cephalic levels of sensory block when fentanyl was added to isobaric local anesthetic solution.

In the present study, sensory level of T4 was observed in Group C and Group B, but in Group A the extent of sensory block reached only up to T6 dermatome, which is similar to Gupta *et al.*[1] where they showed maximum dermatomal involvement was T6 (T6-T10) in Group RC and T4 (T4-T10) level in Group RF. Seetharam and Bhat[19] also reported T6 level (T4-T9) with 19.5 mg ropivacaine plus 20 μg of fentanyl was used.

In the present study, duration of sensory block was maximum in Group C. Statistically when Group A was compared with B; Group B was compared with C and Group A when compared with Group C, the difference was highly significant ($P < 0.05$). Higher dose (25 μg) of fentanyl appears to be more promising to increase the duration of sensory block. Seetharam and Bhat.[19] reported in their study that duration of sensory block is prolonged by addition of fentanyl 25 μg to isobaric ropivacaine 18.5 mg in subarachnoid block as compared to isobaric ropivacaine alone. They observed the duration of sensory analgesia of 341.6 ± 15.03 min in fentanyl group and 240.4 ± 13.08 min in the control group. Gupta *et al.*[20] and Yegin *et al.*[21] reported in a study that duration of sensory block was prolonged significant ($P < 0.05$) in Group RF (ropivacaine with fentanyl) as compared to Group R (control) in different surgeries.

Jagtap *et al.*[22] showed that adding fentanyl improved the quality and duration of analgesia when they compared fentanyl plus ropivacaine with fentanyl plus bupivacaine alone for spinal anesthesia in minor urological procedures. Similarly, Seetharam and Bhat,[19] Boztug *et al.*,[16] Sanli *et al.*,[23] and Layek *et al.*[24] found that time for analgesic requirement prolonged in fentanyl group compared to the control group.

This study had shown statistical significant difference among all three groups. Isobaric ropivacaine plus 25 μg fentanyl offered rapid onset than ropivacaine alone and with 12.5 μg fentanyl. Our results were similar to studies conducted by Gupta *et al.*[1] and Chaudhary *et al.*[17] Boztug *et al.*[16] and Seetharam and Bhat.[19] reported that onset of motor block was faster in Group RF than Group R, but results were statistically insignificant.

In the present study, duration of motor block was prolonged significantly ($P < 0.05$) by addition of fentanyl in both groups ($P < 0.05$). Results of the present study are comparable to results of Seetharam and Bhat.[19] and Gupta *et al.*[1]

Mean duration of post-operative analgesia was 237.8 ± 63.6 min in Group A, 347.7 ± 59.6 min in Group B, and

407.7 ± 52.6 in Group C. Statistically the changes in duration of postoperative analgesia were highly significant ($P < 0.05$). Yegin *et al*.[21] reported in the study that duration of pain relief from intrathecal fentanyl administration until the first request for supplemental analgesia was significant prolonged: 213.0 ± 29.3 min (Group F- hyperbaric ropivacaine 15 mg with fentanyl 10 mcg) as compared to other group (Group S - hyperbaric ropivacaine 15 mg) it was 161.2 ± 32.6 min. Similarly, study done by Seetharam *et al*.[22] observed same thing.

Seetharam and Bhat.[19] reported S2 regression time (Group R vs. Group RF, 240.4 ± 13.087 min vs. 341.6 ± 15.032 min) and Sanli *et al*.[23] 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. These finding were similar to our results showing prolongation of analgesia duration in Group C.

Degree of muscle relaxation: In the present study, all patients achieved Bromage score 3 except in two patients of Group A, it was score 2.

Group A - Bromage score of 3/3 in (90%) of cases.

Group B - Bromage score of 3/3 in (100%) of cases.

Group C - Bromage score of 3/3 in (100%) of cases.

In Group B and Group C, all the 20 (100%) patients were having Bromage scale of 3 and are well comparable in two groups.

The sedation score as per Chernick`s score in the present study was 0 to 2 [Table 3]. However, it is not statistically significant ($P > 0.05$). Sedative effect of fentanyl is due to systemic absorption of lipid-soluble opioid, although cephalad migration of opioid in the CSF and subsequent interaction with opioid receptors located in the ventral medulla may also be responsible.

As shown in Table 4, hypotension was recorded in four cases of Group C and three cases of Group B and two cases of Group A. Bradycardia was seen two cases in Group A, two cases in Group B, and four cases in Group C. The incidence of vomiting was in one case each in Group A (5%) and Group C (5%). Hence, it is very obvious that higher doses of fentanyl not only enhance the beneficial effects of isobaric ropivacaine but also increase the number of side effects as compared to isobaric ropivacaine with 12.5 μg fentanyl. Complications were not clinically significant and could be managed easily. A dose of 12.5 μg fentanyl appears to be safe as an adjuvant to achieve rapid onset and long duration of analgesia with least possible acceptable complication and side effect.

Limitation of this study: There were differences in injection technique, amount of dilution with CSF, speed of injection, brand of drug used, and differences in drug concentration.

CONCLUSION

Addition of 12.5 μg fentanyl to isobaric ropivacaine for spinal anesthesia prolongs the duration of sensory block and duration of analgesia without significantly affecting hemodynamics and onset of sensory block. Thus, it improves the overall quality of anesthesia of ropivacaine, at the same time preserves its benefits like good hemodynamic stability as compared to plain ropivacaine and 25 μg fentanyl with ropivacaine combination.

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