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Original Research Article

A Prospective Study on the Use of Intrathecal Fentanyl as an Adjuvant to 0.75% Isobaric Ropivacaine for Subarachnoid Block in Infraumbilical Surgeries

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Conflict of interest: Nil

Abstract

Background: The utilization of subarachnoid blockade applies to all surgical procedures conducted in the infraumbilical region. This research aimed to assess the clinical effectiveness and safety of adding intrathecal fentanyl to 0.75% isobaric ropivacaine concerning the onset, duration, intensity, and recovery time of sensory and motor blockade in the subarachnoid block for infraumbilical surgery.

Methods: N=80 consenting adult patients of both genders, categorized as American Society of Anesthesiologists (ASA) I and II and scheduled for infraumbilical surgery, were randomly assigned into two groups of 40 patients each. They received either intrathecal administration of 4 mL of 0.75% ropivacaine with 0.4 mL of 0.9% sodium chloride (Group I: Ropivacaine Control Group - RC) or 20 µg of fentanyl (Group II: Ropivacaine with Fentanyl - RF). The study endpoints included variations in hemodynamics, onset of analgesia at T10, maximum sensory analgesic level, time to complete motor blockade, duration of sensory and motor blockade, and adequacy of surgical anesthesia.

Results: Intrathecal fentanyl expedited the onset of sensory blockade to the T10 dermatome and motor blockade. The addition of a small dose of intrathecal fentanyl to ropivacaine prolonged the duration of analgesia during the early postoperative period compared to intrathecal ropivacaine alone. Intraoperative hemodynamic variability did not show statistically significant differences between the groups.

Conclusion: Adding intrathecal fentanyl to 0.75% isobaric ropivacaine demonstrated a superior clinical profile compared to ropivacaine alone.

Keywords: Fentanyl, Ropivacaine, Subarachnoid Block.

Introduction

Subarachnoid blockade finds application in surgical interventions involving the lower portion of the body, encompassing procedures on the lower limbs, pelvis, perineum, and urological surgeries. It also proves beneficial in obstetric practice, offering anesthesia for both elective and emergency procedures. This technique involves dural puncture and the introduction of a small quantity of local anesthetic into the cerebrospinal fluid, which induces anesthesia by inhibiting sodium ion channels. Except for ropivacaine, all local anesthetic agents are racemic mixtures with varying potency and toxicity [1]. Ropivacaine, an extended-acting amide local anesthetic, shares numerous physicochemical properties with bupivacaine but exhibits reduced systemic toxicity and a wider safety margin due to its pure S-enantiomer form. Recent clinical evidence supports the effectiveness and safety of ropivacaine in regional anesthesia [2-4]. Ropivacaine's low lipid solubility results in a more distinct sensory-motor blockade by preferentially blocking sensory nerve fibers over motor fibers. The prompt recovery of motor function associated with ropivacaine is correlated with decreased occurrences of venous thromboembolism and shorter hospital stays [2-4]. Several factors influence the distribution of local anesthetic within the subarachnoid space, including the baricity of the local anesthetic solution, patient positioning during and immediately after injection, and the dose of the local anesthetic administered. Isobaric ropivacaine solution, with a baricity equal to that of cerebrospinal fluid (CSF) at 1.0, remains unaffected by patient positioning [5, 6].

Studies have explored the combination of local anesthetics and opioids in surgical contexts. While local anesthetics act on nerve axons, opioids exert their effects at receptor sites within the spinal cord. Fentanyl, functioning primarily as an agonist at μ-opioid receptors, enhances spinal analgesia [7, 8]. Given these considerations, this study aimed to assess the anesthetic effects of intrathecal fentanyl as an adjunct to 0.75% isobaric ropivacaine concerning the onset, duration, intensity, and recovery time of sensory and motor blockade in the subarachnoid block for infraumbilical surgery.

Material and Methods

This prospective study was conducted in the Department of Anesthesiology, Kakatiya Medical College, and MGM Hospital Warangal, Telangana. Institutional Ethical approval was obtained for the study. Written consent was obtained from all the participants of the study after explaining the nature of the study in vernacular language. Those voluntarily willing to participate in the study were included.

Inclusion Criteria

1. Elective patients undergoing infraumbilical surgeries
2. ASA I and II grades.
3. Aged from 18 – 60 years
4. Males and females
5. Voluntarily willing to participate in the study.

Exclusion Criteria

1. History of preexisting cardiac or pulmonary diseases
2. Neurological disorders
3. Renal and liver diseases
4. Spinal cord deformity
5. Bleeding or coagulation disorders
6. Allergic to one of the medications

A total of n=80 cases were included in the study based on the inclusion and exclusion criteria. Before enrollment, all patients underwent pre-anesthetic assessment. Exclusion criteria included a history of pre-existing cardiac or pulmonary diseases, neurologic or renal dysfunction, bleeding or coagulation disorders, spinal column deformity, known hypersensitivity to study drugs, use of medications altering pain perception, cutaneous infection, or patient refusal of the technique. Before initiating the subarachnoid block, patients were educated on sensory and motor assessment techniques. Patients were randomly assigned, using computer-generated numbers, into two treatment groups, each comprising 40 patients. Group I (RC) received an intrathecal solution consisting of 4 mL of 0.75% isobaric ropivacaine with 0.4 mL of 0.9% sodium chloride, while Group II (RF) received 4mL of 0.75% isobaric ropivacaine with 0.4 mL of fentanyl (20 μg). The study drugs were prepared by a blinded anesthesiologist not involved in patient assessment.

Upon arrival in the operating theater, standard monitoring devices were attached, and baseline vital parameters including heart rate, electrocardiogram, pulse oximetry, and non-invasive arterial blood pressure were recorded. An intravenous line was established, and patients were preloaded with 10 mL/kg of Ringer lactate solution 15 minutes before commencing the subarachnoid block. Under strict aseptic conditions, lumbar puncture was performed using a 25-gauge Quincke spinal needle via a midline approach at the L2-3 or L3-4 intervertebral space while the patient was seated. After confirming the free flow of cerebrospinal fluid, one of the study drug solutions was injected over 30 seconds, following which the patient was placed supine on a horizontal table. Sensory and motor blockade characteristics were assessed at 2-minute intervals following intrathecal injection until surgical anesthesia was achieved. Sensory block level to pinprick was evaluated bilaterally along the midclavicular line using a 27-gauge hypodermic needle, while motor blockade of the lower extremities was assessed bilaterally using the modified Bromage scale (0-3). Effective surgical anesthesia was deemed achieved when at least the T10 dermatome level was anesthetized. Post-operatively, sensory and motor block levels were assessed at 30-minute intervals until normal sensation returned.

Onset time of sensory blockade at the T10 dermatome, maximum cephalad dermatome anesthetized, time to achieve maximum sensory block, time to total regression of sensory block, time to achieve complete motor blockade, and time to complete recovery from motor blockade were observed. Hemodynamic parameters including systemic arterial blood pressure and heart rate were recorded at baseline, every 3 minutes for the first 10 minutes, and subsequently at 5-minute intervals intraoperatively. Oxygen was administered via a Hudson face mask at a rate of 3L/min. Any significant changes in heart rate and blood pressure were defined as variations exceeding 20% from baseline. Hypotension was managed with an additional Ringer lactate solution and a bolus of 6 mg mephentermine, while bradycardia (heart rate <55 beats/min) was treated with intravenous atropine (0.25-0.5 mg). Nausea and vomiting were addressed with ondansetron. Post-operatively, patients were evaluated for adverse effects such as nausea, vomiting, sedation, pruritus, shivering, urinary retention, or transient neurologic deficits, and managed symptomatically.

Statistical analysis was performed using Microsoft Excel and SPSS software for Windows. Analysis of

Variance (ANOVA), Student t-test, Chi-square test, and Mann-Whitney U test were employed as applicable. A 'p' value less than 0.05 was considered statistically significant.

Results

Table 1 presents the comparison of various variables between Group I (RC) and Group II (RF). Group I consisted of 40 cases who received an intrathecal solution comprising 4 mL of 0.75% isobaric ropivacaine with 0.4 mL of 0.9% sodium chloride, while Group II consisted of 40 cases who received the same volume of ropivacaine but with the addition of 0.4 mL of fentanyl (20 μg). The mean age of patients in Group I was 35.5 years with a standard deviation of 10.29, while in Group II, it was 36.7 years with a standard deviation of 12.34.

Table 1: Variables recorded in two groups of patients

Variables	Group I	Group II	P values
Age in years	35.5 ± 10.29	36.7 ± 12.34	0.845
Sex (male/Female)	27/13	30/10	0.321
Weight Kgs	61.27 ±	63.22 ±	0.147
Height in cms	164.81 ±	163.79 ±	0.224
ASA grade I/II	42/8	41/9	0.981

The difference in mean ages between the two groups was not statistically significant (P = 0.845), indicating that there was no significant age difference between the two groups. In Group I, there were 27 males and 13 females, while in Group II, there were 30 males and 10 females. The proportion of males to females did not significantly differ between the two groups (P = 0.321). The mean weight of patients in Group I was 61.27 kg, while in Group II, it was 63.22 kg. The difference in mean weights between the two groups was not statistically significant (P = 0.147), indicating that there was no significant difference in weight between the two groups. The mean height of patients in Group I was 164.81 cm, while in Group II, it was 163.79 cm. The difference in mean heights between the two groups was not statistically significant (P = 0.224), indicating that there was no significant difference in height between the two groups. In Group I, there were 42 cases classified as ASA grade I and 8 cases as ASA grade II. In Group II, there were 41 cases classified as ASA grade I and 9 cases as ASA grade II. The distribution of ASA grades did not significantly differ between the two groups (P = 0.981).

Table 2: Sensory and motor blockade characteristics between two groups

Parameter	Group I	Group II	P value
Onset time for sensory blockade at T10 (min)	3.15 ± 1.28	3.52 ± 1.33	0.0714
Maximum cephalad dermatome	T6(T6-T10)	T4(T4-T10)	0.150
Time taken to achieve max sensory blockade (Min)	9.92 ± 2.94	8.04 ± 1.41	0.0515
Total regression of sensory blockade (S1 level)	312.37 ± 34.87	361.74 ± 50.11	0.0012
Time taken to achieve complete motor blockade (Modified Bromage scale-o) (min)	12.5 ± 2.1	11.6 ± 2.03	0.0419
Duration of motor block in min(Modified Bromage scale-o) (min)	285.34	312.64	0.0016

Table 2: compares the efficacy and duration of spinal anesthesia using two different combinations of medications: Group I: Intrathecal ropivacaine (0.75%) + 0.9% NaCl (saline) Group II: Intrathecal ropivacaine (0.75%) + Fentanyl (20 μg). *Sensory Blockade*: Onset time: Group I had a slightly faster onset of sensory block at T10 (3.15 minutes) compared to Group II (3.52 minutes), however, the difference was not statistically significant (p=0.0714). *Maximum cephalad dermatome*: Group II achieved a slightly higher maximum sensory block level (T4) compared to Group I (T6), but again, the difference was not statistically significant (p=0.150). Time to peak sensory block: Group II reached peak sensory block faster (8.04 minutes) than Group I (9.92 minutes), with a statistically significant difference (p=0.0515). *Regression of sensory block*: Group I experienced faster regression of sensory block at the S1 level (312 minutes) compared to Group II (362 minutes), with a significant difference (p=0.0012).

Motor Blockade: Time to complete motor block: Group II achieved complete motor block slightly faster (11.6 minutes) than Group I (12.5 minutes), with a significant difference (p=0.0419). Duration of motor block: Group II had a longer duration of motor block (312 minutes) compared to Group I (285 minutes), with a significant difference (p=0.0016). Both groups showed effective sensory and motor blockades. Adding fentanyl (Group II) resulted in a faster peak sensory block, faster and

longer-lasting motor block, and slower regression of sensory block. However, the faster onset of sensory block and slightly higher maximum block level in Group I were not statistically significant.

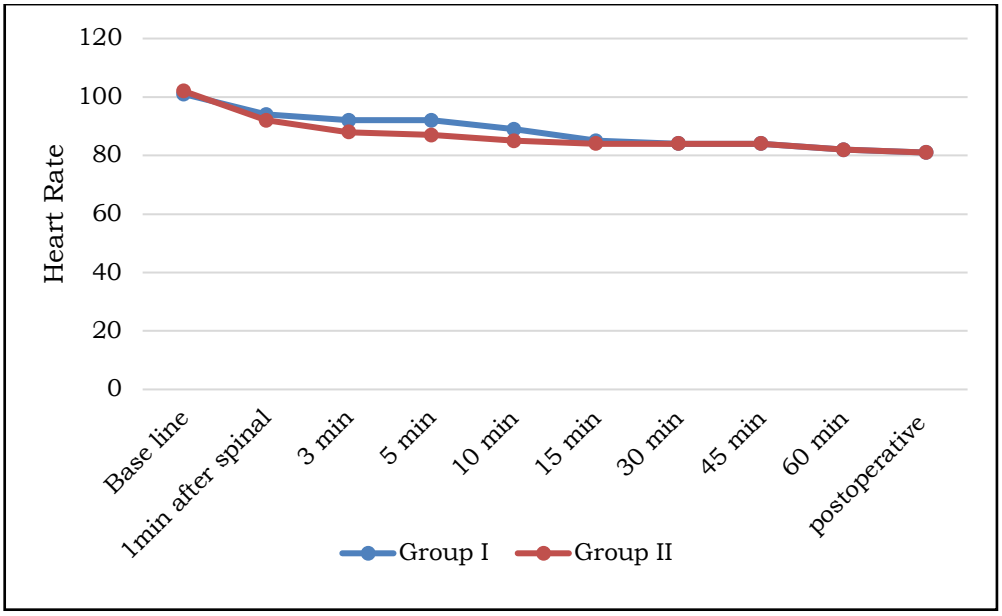

Figure 1: Comparison of heart rate in two groups at different intervals

Figure 1 shows the heart rate of two groups (possibly undergoing the same procedure) at various time intervals: baseline, after spinal administration, and postoperatively. Unfortunately, the table lacks information about the group definitions and the type of spinal anesthesia administered. Both groups experienced a decrease in heart rate after spinal administration, with the lowest point reached at 5 minutes (92 and 87 bpm for Groups I and II, respectively). From 5 minutes onwards, both groups showed a gradual increase in heart rate towards their baseline values. By 60 minutes and postoperatively, both groups reached similar heart rates (82 and 81 bpm, respectively). The initial decrease in heart rate after spinal administration suggests a vagal response caused by the anesthetic blocking sympathetic nerve activity. The gradual increase could indicate a return of sympathetic tone and recovery from the vagal response. Similar heart rates at later time points suggest comparable effects on heart rate by spinal anesthesia in both groups.

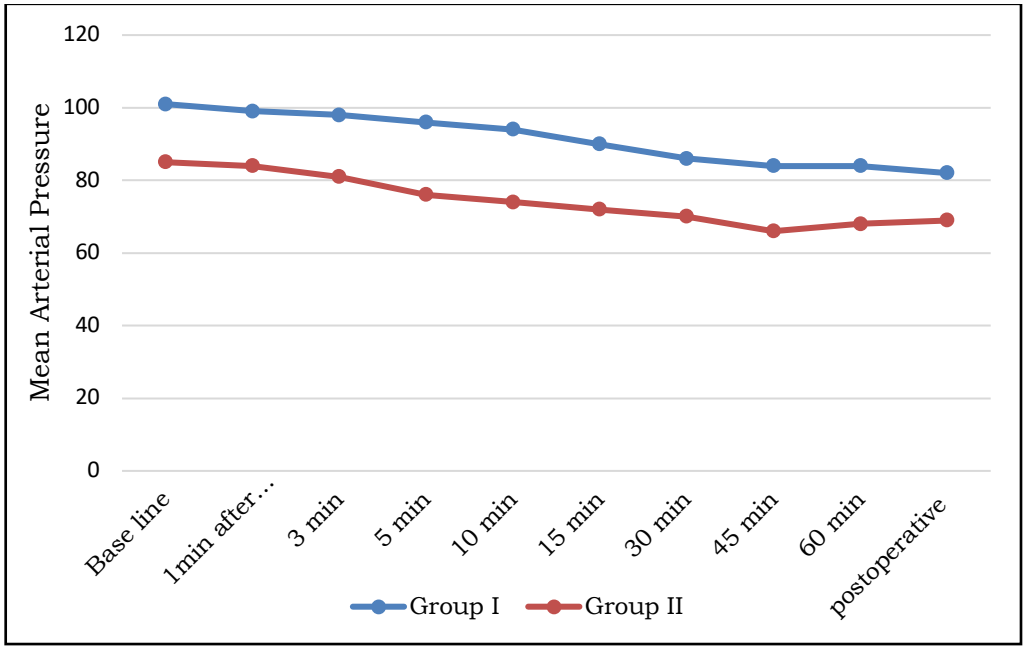

Figure 2: Comparison of mean arterial pressure between two groups at different intervals

Figure 2 compares the mean arterial pressure (MAP) of two groups (possibly undergoing the same procedure) at different time intervals: baseline, after spinal administration, and postoperatively. Both groups experienced a decrease in MAP after spinal administration, with the lowest points reached at 10-15 minutes (90 and 72 mmHg for Group I and II, respectively). From 15 minutes onwards, both groups showed a gradual increase in MAP towards their baseline values. By 60 minutes and postoperatively, both groups reached similar MAP values (82 mmHg and 69 mmHg, respectively). The decrease in MAP after spinal administration suggests a decrease in systemic vascular resistance due to the anesthetic blocking sympathetic nerve activity. The gradual increase could indicate a return of sympathetic tone and recovery from the vasodilation. Similar MAP at later time points suggests comparable effects on blood pressure by the spinal anesthesia in both groups. Respiratory depression was not observed in either group. Mild pruritus was noted in 3 cases and did not require any medical intervention. Shivering was observed in 4 cases and nausea in 6 cases they were managed with intravenous ondansetron.

Discussion

The current study assessed the clinical effectiveness and safety of adding intrathecal fentanyl to 0.75% isobaric ropivacaine for infraumbilical surgeries conducted under subarachnoid block. The combination of intrathecal fentanyl and 0.75% ropivacaine demonstrated good tolerability and provided effective surgical anesthesia. Notably, the addition of intrathecal fentanyl to ropivacaine resulted in a prolonged duration of sensory analgesia. Furthermore, all patients exhibited a shorter duration of motor blockade compared to sensory blockade, facilitating rapid recovery, early ambulation, and voiding. Ropivacaine, known for its improved safety profile in regional anesthesia techniques, has been utilized effectively for various surgical procedures, including total hip replacement, transurethral resection of the prostate, and lower abdominal or limb surgery. Previous studies have highlighted the cardiovascular stability provided by intrathecal ropivacaine, with minimal incidence of bradycardia. [9-12] These findings align with our observations, supported by similar outcomes reported by Nuray et al. [13] in their investigation involving intrathecal ropivacaine with fentanyl. Additionally, Wong et al. [14] compared the clinical efficacy and safety of two doses of 0.75% ropivacaine for spinal anesthesia in patients undergoing lower limb and lower abdominal surgery, concluding that both doses were equally effective and safe. Our study's duration of blockade profile correlates with these findings. Furthermore, the combination of opioids as adjuvants with local anesthetics, such as fentanyl with ropivacaine, has been recognized for enhancing analgesia without exacerbating motor and sympathetic block of spinal anesthesia, leading to a lower incidence of hypotension, and facilitating early recovery and mobilization. Studies have shown that adding small doses of intrathecal fentanyl to local anesthetics prolongs sensory analgesia without intensifying motor block or delaying recovery. [15, 16] In our study, the combination of 0.75% ropivacaine and fentanyl (20μg) accelerated the onset of sensory and motor blocks during subarachnoid blockade compared to ropivacaine alone. However, it's essential to note that the potency of intrathecal ropivacaine can be influenced by coadministration with opioids. Previous research by Yegin et al. [17] demonstrated delayed regression of block and a longer time to first request analgesia when intrathecal fentanyl was added to ropivacaine for transurethral resection of the prostate. The influence of hypobaric on the extent of the subarachnoid block has also been established, with Parlow et al. [18] explaining the higher cephalic levels of the sensory block when fentanyl was added to an isobaric local anesthetic solution. In our study, group RF exhibited a sensory level of T4, whereas group RC only reached up to the T6 dermatome. Despite ropivacaine's safety and tolerability during the subarachnoid block, a few adverse effects were noted in our study, including hypotension, bradycardia, pruritus, shivering, and nausea.

Conclusion

In conclusion, intrathecal fentanyl as an adjuvant to 0.75% ropivacaine demonstrated safety and tolerability for infraumbilical surgeries under subarachnoid blockade, with reduced systemic toxicity. Early mobilization and voiding facilitated post-operative recovery and earlier discharge. Given its favorable clinical profile and rapid recovery of motor function, this combination presents a reasonable choice for anesthesia management.

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