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Effect of Adding Fentanyl to Ropivacaine on Axillary Brachial Plexus Block Characteristics: A Randomised Control Trial

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Abstract

Background: Axillary brachial plexus block is commonly used for forearm and hand surgeries. Ropivacaine provides long-acting sensory block with improved safety, but its duration is limited. Fentanyl has been evaluated as an adjuvant to prolong block duration, with conflicting results.

Methods: Fifty ASA I–II adults undergoing elective upper limb surgery were randomised into two groups: Group A received 40 mL of 0.5% ropivacaine; Group B received 40 mL of 0.5% ropivacaine with 100 mcg fentanyl. Blocks were performed using a nerve stimulator-guided multiple-injection technique. Sensory and motor onset, block duration, and duration of analgesia were recorded. Data were analysed using SPSS version 20; $p < 0.05$ was considered significant.

Results: Forty-seven patients completed the study. Sensory onset time was comparable between Group A (12.30 ± 8.67 min) and Group B (12.13 ± 6.82 min; $p = 0.416$). Sensory block duration was significantly longer in Group B (419.50 ± 82.71 min) compared to Group A (361.61 ± 61.57 min; $p = 0.031$). No significant differences were seen in motor block duration or analgesia duration. No major adverse events occurred.

Conclusion: Fentanyl (100 mcg) added to 0.5% ropivacaine significantly prolongs sensory block in axillary brachial plexus block without affecting onset, motor block, or analgesia duration.

Keywords: Axillary brachial plexus block, Ropivacaine, Fentanyl, Upper limb surgeries.

Introduction

Regional anaesthesia has become an increasingly preferred technique in modern anaesthetic practice owing to advances in nerve localisation technologies and a growing emphasis on multimodal analgesia. It offers several advantages over general anaesthesia, including superior intraoperative analgesia, attenuation of the stress response to surgery, reduced postoperative pain, lower incidence of nausea and vomiting, early ambulation, shorter hospital stay, and reduced healthcare costs.[1]

Brachial plexus block (BPB) is one of the most widely used regional techniques for upper limb surgeries and can be performed via interscalene, supraclavicular, infraclavicular, or axillary approaches. Among these, the axillary approach is particularly favoured for procedures at or below the elbow because it is technically straightforward, effective, and associated with a low risk of serious complications.[2]

Local anaesthetics remain the cornerstone of peripheral nerve blocks. However, because brachial plexus blocks often require large volumes to achieve complete anaesthesia, agents with a favourable safety profile and long duration are preferred. Ropivacaine, a long-acting amide local anaesthetic, has emerged as a safer alternative to bupivacaine due to its reduced cardiotoxicity and neurotoxicity, while providing comparable anaesthetic duration.[3] Moreover, ropivacaine demonstrates a greater degree of sensory–motor differentiation, with less motor blockade relative to sensory block, which facilitates earlier postoperative mobility.[4]

Despite these advantages, the effect of single-shot ropivacaine may wear off within hours after surgery, potentially leading to breakthrough pain during the early postoperative period.[5] To overcome this limitation, several strategies have been explored to prolong block duration, including continuous perineural catheter techniques, liposomal formulations, and the addition of adjuvants. Among these, the use of adjuvants such as opioids, α_2-agonists (clonidine, dexmedetomidine), steroids (dexamethasone), and vasoconstrictors (adrenaline) is the most practical and cost-effective approach in resource-limited settings.[6]

Since the discovery of opioid receptors on peripheral nerves, perineural administration of opioids has gained interest as a means to enhance local anaesthetic action.[7,8] Experimental studies have shown that opioids can exert direct peripheral antinociceptive effects by inhibiting action potential propagation and neurotransmitter release.[9,10] However, clinical results have been inconsistent: some studies report improved block quality and prolonged duration when opioids are added to local anaesthetics,[11-15] while others have found no benefit.[16,17]

Fentanyl, a synthetic μ-opioid receptor agonist, is one of the most commonly investigated opioid adjuvants due to its rapid onset, high lipid solubility, and minimal neurotoxicity.[18] It has been postulated to possess mild local anaesthetic-like activity, further supporting its potential peripheral action.[9]

Many randomised controlled trials (RCTs) have examined the effect of adding opioids to local anaesthetics for BPB in upper-limb surgeries [19-23]; however, to the best of our knowledge, no study has specifically assessed the effect of adding fentanyl to ropivacaine for axillary brachial plexus block in Nigeria, including north-western Nigeria. This study may therefore add to the global database for this population. We hypothesised that adding fentanyl would enhance the quality and prolong the duration of sensory and motor blockade, as well as postoperative analgesia, compared with ropivacaine alone.

Materials and Methods

Study Design

This prospective randomised, double-blinded study was conducted at Usmanu Danfodiyo University Teaching Hospital, Sokoto.

Ethical Consideration

Ethical approval for the study was obtained from the Usmanu Danfodiyo University Teaching Hospital health research ethical committee (UDUTH/HREC/2013/No.129), and informed consent was obtained from the participants.

Subjects and setting

Participants in the study were fifty patients of either sex, aged 18 to 60 years, with American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elbow, forearm and hand surgeries in the orthopaedics and plastic units of Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria, from November 2013 to May 2015. Excluded from the study were patients who did not give consent, those with a history of respiratory, cardiac, hepatic or renal failure, peripheral neuropathy, local infection, hypersensitivity to local anaesthetics, coagulopathy, or who were receiving anticoagulants.

Sample Size Calculation

The sample size was determined using figures from a similar study by Nishikawa et al[24] based on the following formula:

$$\text{Sample size, number per group (n/group)} = \frac{(\sigma_1^2 + \sigma_2^2)\,[Z_\alpha + Z_\beta]^2}{(M_1 - M_2)^2}$$

Where;

σ_1 – Standard deviation of lignocaine/saline group (from previous study [24]) = 79

σ_2 – Standard deviation of lignocaine/fentanyl group (from previous study [24]) =96

Z_α – = z score corresponding to 95% level of significance = 1. 96

Z_β – =z score corresponding to 80% statistical power of study = 0.84.

M_1 = mean duration of analgesia in lignocaine/saline group (previous study[24]). = 250 min

M_2 = mean duration of analgesia in lignocaine/fentanyl group (previous study[24]). = 323 min

$$\text{n/group} = \frac{(79^2 + 96^{2)}\,(1.96 + 0.84)^2}{(250 - 323)^2}$$

$$= \frac{(6241 + 9216) \times (2.8)^2}{(-73)^2}$$

$$= \frac{15457 \times 7.84}{5329}$$

$$= \frac{121182.88}{5329}$$

$$= 22.7$$

A 10% attrition was made for patients who might drop out of the study

$$10/100 \times 22.7 = 2.27$$

$$22.7 + 2.27 = 24.97$$

Therefore, a minimum sample size of 25 was studied per group, making a total of 50 patients.

Intervention Design

Upon arrival in the operating room, intravenous access was secured in the contralateral upper limb using an 18G cannula, and an infusion of normal saline was commenced. Patients were not pre-medicated. Standard monitoring, including non-invasive blood pressure (NIBP), peripheral oxygen saturation (SpO_2), and heart rate, was established using a multiparameter monitor (GE Dash 4000). Baseline readings were recorded, and monitoring was continued throughout the procedure.

Randomisation was performed using the sealed opaque envelope technique. Fifty cards labelled either A or B were prepared in equal numbers (25 each), sealed in identical envelopes, and placed in a box. A research assistant, dedicated solely to this task, randomly selected one sealed envelope for each patient. Envelopes containing cards labelled A allocated patients to Group A, while those labelled B allocated patients to Group B.

Group A (n=25) received 40ml of ropivacaine 0.5% plus 2 mL of normal saline, and Group B (n=25) received 40ml of ropivacaine 0.5% plus 2ml (100mcg) fentanyl.

The patient was placed supine with the arm to be operated on abducted 90°, elbow flexed at 90° and arm externally rotated. After appropriate skin preparation and draping, the axillary pulse was palpated, and the skin over it was infiltrated with 1 mL of 1% lignocaine. The brachial plexus was identified with the aid of a nerve stimulator (HNS 12, B Braun, Melsungen, Germany) and a 22G insulated short bevel needle with extension tubing (Stimuplex, B Braun), using the multiple stimulation technique. The nerve stimulator was set at a frequency of 2Hz and an initial stimulating current of 2 mA, which was gradually reduced to ≤ 0.5mA while maintaining a relevant muscular twitch. Median nerve was located by pronation of the hand or flexion of the wrist and 2nd and 3rd fingers; ulnar nerve by adduction of the thumb, flexion of the 4th and 5th fingers; radial nerve by extension of the forearm/wrist and fingers; and musculocutaneous nerve by flexion of the forearm. A total volume of 42 ml (10 ml each to median and musculocutaneous nerves, and 11 ml each to ulnar and radial nerves) of the appropriate drug solution was injected with intermittent aspirations after every 5 ml. Group A received 40ml of 0.5% ropivacaine plus 2ml normal saline, and Group B received 40ml of 0.5% ropivacaine plus 100mcg (2ml) fentanyl. All blocks were performed by one of the researchers, who was unaware of the injected solution. Another anaesthetist, unaware of the groupings, performed the assessment of the block.

The sensory block was assessed by response to pinprick on a 3-point scale (0-normal sensation, 1-impaired sensation, or 2-absent sensation) every 5 minutes until 30 minutes after the injection.

Variables

The onset time of sensory block, defined as the time between the last injection and total abolishing of pin prick response, was evaluated in 4 nerve areas (median, ulnar, radial and musculocutaneous). The motor block was evaluated by using a modified Bromage scale as follows (0- Normal motor function, 1-Ability to move only fingers, 2-Complete motor block with inability to move elbow, wrist & fingers). The onset time of motor block was defined as the time between the end of the last injection and complete motor block. Duration of sensory block was defined as the time between loss of pinprick response and return of paraesthesia. Duration of motor block was defined as the time interval between complete paralysis and complete recovery of motor function in the forearm and hand. The duration of sensory and motor block was assessed every 1 hour for the first 3 hours, and subsequently 3 hourly for the next 24 hours. Patients and their caregivers were also asked to note the time of return of paraesthesia, and the time they could move their fingers and raise the arm. Duration of analgesia was defined as the time between the onset of analgesia and the return of pain. It was determined using a visual analogue scale (VAS), by asking the patient about the absence or presence of pain every hour until the return of pain. Visual analogue scale score of ≥5 was considered the end point of analgesia. Any signs or symptoms of CNS or cardiovascular toxicity or any other adverse effects (drowsiness, nausea, vomiting, pruritus) were noted, managed, and recorded.

Statistical Analysis

Data obtained from the study were analysed electronically using SPSS version 20 (IBM Corp., Armonk, NY, USA), and were presented using relevant tables and figures. Statistical tests of association were performed with a confidence level set at 95%. Parametric data were summarised as mean ± (SD) and proportional data as frequency and percentage. Comparison of onset and duration of analgesia between the two groups was determined using the unpaired Student's t-test, while for quantitative variables, the Chi-square test was used. The null hypothesis was tested by calculating the p-value. A p-value of less than 0.05 was taken as significant.

Results

A total of 50 patients were enrolled in the study; 3(2 from group A and 1 from group B) were excluded from the study due to failed block, leaving a total of 47 patients for the final analysis (group A-23 and group B- 24).

Demographic and Clinical Characteristics of the Study Patients

Table 1 shows the demographic and clinical characteristics of the study patients. The age range of the patients studied was between 18 and 60 years, with a male: female ratio of 19:6. There was no statistically significant difference in the demographic profile of the patients, including age, sex, weight, ASA and duration of surgery, in the two groups.

Table I: Demographic and clinical characteristics of the study groups

Variable	Ropivacaine plus Normal Saline Mean (SD) n= 25	Ropivacaine plus fentanyl Mean (SD) n=25	Significance level (P-Value)
Age (Years)	34.28 (±11.58)	31.80 (±10.72)	0.436
Sex			
Male	20 (80%)	18 (72%)	0.508
Female	5 (20%)	7 (28%)	
Weight (kg)	62.12(±11.96)	61.68(±10.95)	0.893
ASA			
ASA I	12 (48%)	15 (60%)	0.659
ASA II	13 (52%)	10 (40%)	
Duration of Surgery (mins)	95.48±45.42	79.88±43.04	0.219

Values are presented as mean ± standard deviation. Comparisons between the Ropivacaine alone and Ropivacaine plus fentanyl groups were performed using an independent-samples t-test. A p-value < 0.05 was considered statistically significant. SD = Standard Deviation.

Block characteristics

Table 2 shows the block characteristics. Mean time of onset of sensory block in both groups was 12.30±8.67 minutes in Group A and 12.13±6.82 in Group B.

Table II: Characteristics of axillary brachial plexus block in the study groups

	Ropivacaine Plus Normal Saline Mean±SD (n = 23)	Ropivacaine Mean±SD (n = 24)	Significance level (p-value)
Mean onset of sensory Block (min)	12.30±8.67	12.13±6.82	0.416
Mean onset of motor Block (min)	15.65±8.09	16.25±8.89	0.125
Mean duration of sensory Block (min)	361.61±61.57	419.50±82.71	0.031
Mean duration of motor Block (min)	421.91±104.68	447.92±89.42	0.310
Duration of Analgesia (min)	485.43±102.36	502.79±112.03	0.532

Values are presented as mean ± standard deviation. Comparisons between the Ropivacaine and Ropivacaine plus fentanyl groups were performed using an independent-samples t-test. A p-value < 0.05 was considered statistically significant. SD = Standard Deviation.

There was no significant difference between the 2 groups in the onset of sensory block or motor block (p = 0.416 and 0.125, respectively; Figure 1).

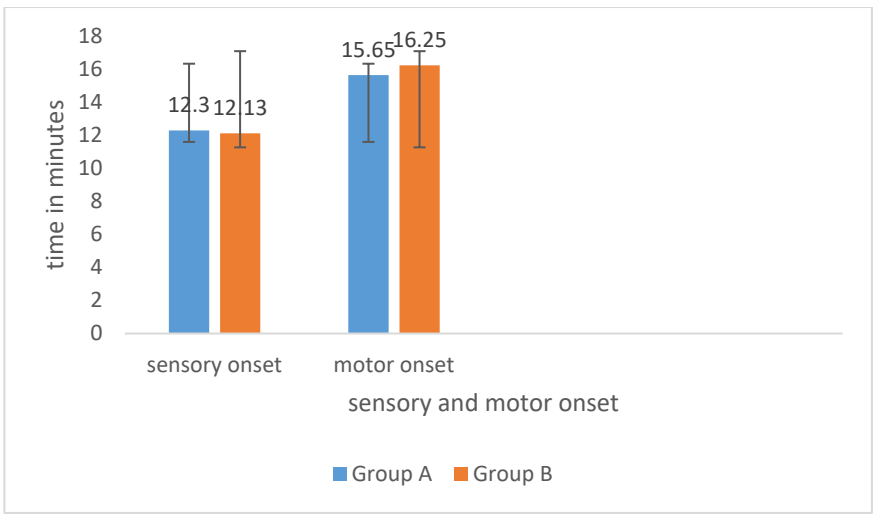

Fig 1. Comparison of onset times for sensory and motor block between Group A (Ropivacaine alone) and Group B (Ropivacaine with fentanyl). Analysis performed using an independent-samples t-test. There was no significant difference between the two groups (p > 0.05).

Duration of sensory and motor block

The duration of sensory block was significantly longer (p = 0.031) in the Ropivacaine plus fentanyl-treated group (419.50±82.71) compared to ropivacaine monotherapy (361.61±61.57; Figure 2).

However, there was no significant difference between the 2 groups in the duration of motor blockade (p=0.310; Figure 2).

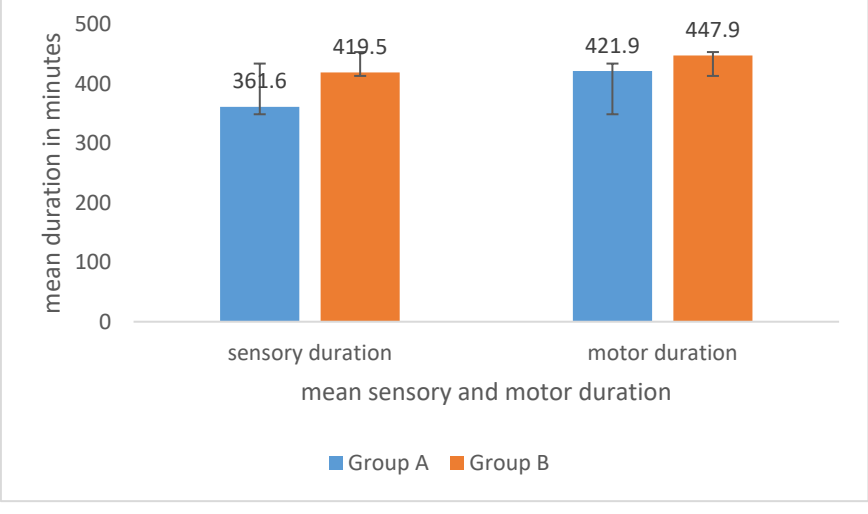

Fig 2. Duration of sensory and motor block in group A (Ropivacaine alone) and group B (Ropivacaine with fentanyl). Analysis performed using an independent-samples t-test. Sensory block was significantly longer in Group B ($p = 0.031$).

Duration of Analgesia

The duration of analgesia was not significantly different between Group A (485.43±102.36) and Group B (502.79±112.03; p=0.532).

Adverse effects

No major adverse events or signs of local anaesthetic systemic toxicity were recorded in either group. One patient (4%) in Group B experienced mild drowsiness (Ramsay score 3), which resolved spontaneously. No episodes of nausea, vomiting, pruritus, or respiratory depression were observed.

Discussion

This prospective, randomised study demonstrated that the addition of 100 mcg fentanyl to 0.5% ropivacaine (40 mL) for axillary brachial plexus block significantly prolonged the duration of sensory block compared with ropivacaine alone, without significant differences in onset time, duration of motor block, or duration of analgesia.

Since the identification of opioid receptors on primary afferent neurons, there has been growing interest in the peripheral administration of opioids to enhance local anaesthetic effects[7,8,25]. The peripheral antinociceptive action of opioids may involve inhibition of action potential propagation and suppression of excitatory neurotransmitter release in sensory fibres[26,27]. These effects are potentiated in the presence of tissue inflammation, which upregulates peripheral opioid receptors[28].

In the present study, the onset of sensory block was comparable between the two groups (12.30 ± 8.67 min for ropivacaine and 12.13 ± 6.82 min for the fentanyl group, p = 0.416). This aligns with the findings of Rajkhowa et al.[11], who reported no significant difference in onset time when 50 mcg fentanyl was added to 30 ml of 0.5% ropivacaine for supraclavicular brachial plexus block. Similarly, Narang et al.[21] found no significant difference in the onset of sensory block after using 2.5 mcg/ml fentanyl in 40 mL of 0.25% bupivacaine for axillary block. In a systematic review and meta-analysis, Song et al.[29] evaluated the effect of adding fentanyl as an adjuvant to brachial plexus block. They found no difference in the onset of sensory block. In contrast, some studies demonstrated faster onset with fentanyl added to local anaesthetics [12-15,22,23], while others showed delayed onset [30-32].

This study also demonstrated no significant difference in the onset time of motor block between the groups (15.65 ± 8.09 minutes for Group A and 16.25 ± 8.89 minutes for Group B, p = 0.125). This agrees with the findings of Rajkhowa et al. [11], who used 0.5% ropivacaine and fentanyl in a supraclavicular block with the aid of a peripheral nerve stimulator. Similarly, Hasan et al. [20] reported no difference in the onset time of motor block using a 38 ml mixture of bupivacaine/lignocaine with adrenaline plus 2 ml (100 mcg) of fentanyl in a supraclavicular brachial plexus block. In contrast, Seelam et al. [12] demonstrated a faster onset of motor block with the addition of 100 mcg of fentanyl to 30 ml of 0.5% ropivacaine for a supraclavicular block. Additionally, several other studies reported a faster onset of motor block after adding fentanyl to local anaesthetics [13-15,23,29]. However, some authors reported a delayed onset, which they attributed to a change in pH caused by the addition of fentanyl [30,31].

Local anaesthetic onset depends on the drug pKa, lipid solubility, concentration, dose, proximity of needle to nerve, tissue pH, and vascularity. The pKa determines the balance between the non-ionised (lipid-soluble) and ionised (water-soluble) forms. Ropivacaine has a pKa of 8.1, so fewer non-ionised molecules cross the nerve membrane than lignocaine. Fentanyl does not change the pKa, lipid solubility, or sodium-channel blockade properties. These factors probably explain why onset was similar between the 2 groups.

The duration of sensory block in this study was 361.61 ± 61.57 minutes in Group A (ropivacaine) and 419.50 ± 82.71 minutes in Group B (ropivacaine-fentanyl). The difference in the duration of sensory blockade between the two groups was statistically significant (p = 0.031). This finding agrees with Rajkhowa et al. [11], who concluded that adding fentanyl as an adjuvant to ropivacaine may prolong the duration of sensory and motor block. Similar studies have reported consistent results, including Seelam et al.[12,] who found that adding 100 mcg of fentanyl to 0.5% ropivacaine shortens the onset time and extends the duration of sensory and motor block. Farooq et al. [19] also reported a prolonged duration of sensory and motor block when 1 mcg/kg of fentanyl was added to 3mg/kg of 0.75% ropivacaine. Sahi et al. [15] demonstrated similar findings with a combination of 30 mL of 0.5% ropivacaine and 1 mcg/kg of fentanyl. Furthermore, studies using fentanyl with other local anaesthetics have demonstrated longer durations of sensory and motor blocks compared to controls. [13,20-23,32]

The prolongation of sensory block observed in Group B (ropivacaine-fentanyl) compared to Group A (ropivacaine-saline) might be attributed to several mechanisms. Fentanyl could exert local anaesthetic effects, influencing nerve terminal excitability and impulse propagation, although in vitro studies indicate this typically requires higher concentrations (50mcg/ml)[9]. It is conceivable that in vivo conditions differ, allowing lower doses (like 100mcg used here) to produce similar effects. Alternatively, fentanyl may diffuse from the brachial plexus sheath into neuraxial spaces, binding to dorsal horn opioid receptors and enhancing analgesia. Additionally, systemic uptake of fentanyl could potentiate local anaesthetic action through central mechanisms. The study's lack of systemic controls means these potential explanations remain speculative.

In contrast to the findings of the present study, Munipalle et al.[16], in their study involving 60 ASA I and II patients divided into two equal groups, concluded that the addition of fentanyl 2 mcg/kg to 30 mL of 0.75% ropivacaine for supraclavicular brachial plexus block using the paraesthesia technique did not affect the duration of action. Possible reasons for the discrepancy between these findings include differences in the type, concentration, and volume of local anaesthetic used, the dose of fentanyl, the brachial plexus approach employed, the nerve localisation technique, study methodology, and the patient population.

The duration of motor block in this study was 421.91 ± 104.68 minutes in Group A (ropivacaine) and 447.92 ± 89.42 minutes in Group B (ropivacaine–fentanyl), with a *p*-value of 0.310. Although Group B demonstrated a slight prolongation of motor block compared with Group A, the difference was not statistically significant. This finding is consistent with the study by Munipalle et al.[16], who also reported no significant difference in the duration of motor block between the groups. In contrast, Rajkhowa et al.[11], Sahi et al.[15], Farooq et al.[19], and Seelam et al.[12] observed a significant prolongation of motor block duration in the ropivacaine–fentanyl group. Other investigators have similarly reported a significantly longer duration of motor block when fentanyl was added to various local anaesthetics in brachial plexus blocks.[13,20,22,30]

The absence of a statistically significant difference in motor block duration between the groups in the present study may be attributed to the fact that peripheral mu-opioid receptors are predominantly located on sensory C fibres rather than motor Aα fibres. In addition, ropivacaine alone produces near-maximal sodium (Na^+) channel blockade, which may limit any further enhancement of motor block with the addition of fentanyl.

In the present study, the duration of analgesia was 485.43 ± 102.36 minutes in Group A and 502.79 ± 112.03 minutes in Group B (*p* = 0.532), indicating no statistically significant difference between the groups. This finding is consistent with the study by Munipalle et al.[16], which reported no improvement in the duration of postoperative analgesia with the addition of fentanyl to ropivacaine. In contrast, Rajkhowa et al.[11], Farooq et al.[19], and Seelam et al.[12] demonstrated that the addition of fentanyl to ropivacaine significantly prolonged the duration of analgesia. Similarly, Hembrom et al.[30] reported that the addition of 100 mcg fentanyl to 0.5% levobupivacaine significantly extended the duration of analgesia in a supraclavicular brachial plexus block performed under ultrasound guidance.

The observed prolongation of sensory block without significant improvement in analgesia may indicate that perineural fentanyl primarily augments local anaesthetic effect rather than producing prolonged systemic analgesia. This supports the notion that fentanyl's peripheral action may be limited in the absence of significant inflammation or in non-neuraxial routes.

No major adverse effects were recorded in this study, confirming fentanyl's safety at a dose of 100 mcg for axillary block, consistent with previous reports.[20,21,30]

Conclusion

Addition of 100mcg fentanyl to 40 mL of 0.5% ropivacaine for axillary brachial plexus block increased the duration of sensory block, without significantly altering the time of onset, duration of motor block and duration of analgesia. There appears to be no significant advantage in terms of prolonging the duration of analgesia when ropivacaine, a long-acting amide local anaesthetic, is combined with fentanyl for brachial plexus block.

Limitations of the study

1. Systemic administration of fentanyl was not included in any of the study groups to serve as a control. Inclusion of such a group would have helped to delineate the contribution of systemic fentanyl absorption to the observed prolongation of sensory blockade.
2. Plasma concentrations of fentanyl were not measured, which limited the ability to correlate systemic absorption with the clinical effects observed.
3. A peripheral nerve stimulator was used for nerve localisation instead of ultrasound guidance, which is currently regarded as the gold standard for peripheral nerve blocks owing to its superior precision, safety profile, and higher success rates.
4. This was a single-centre study, and the findings may therefore have limited generalisability to other patient populations or clinical settings.

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