**ORIGINAL RESEARCH**

# Randomized Controlled Study of Dexmedetomidine and Fentanyl as Adjuvants with Ropivacaine in Supraclavicular Brachial Plexus Block in Upper Limb Surgeries

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## ABSTRACT

**Background:** Background: Peripheral nerve blocks have advantages over general anesthesia as it decreases the need for postoperative analgesia and the incidence of nausea and vomiting, shortens post anaesthesia care unit time and increases patient satisfaction. Supraclavicular Brachial Plexus Block provides anesthesia and analgesia of the upper extremity in the most consistent and efficient manner. Ropivacaine has become a safer substitute for bupivacaine as local anaesthetic for peripheral nerve blocks but to overcome shorter duration and to further improve the duration and quality of analgesia, various adjuvants have been added to the local anesthetics and we studied the effect of dexmedetomidine and fentanyl as adjuvants with ropivacaine.
**Aim:** To compare the effect of dexmedetomidine and fentanyl as an adjuvant to ropivacaine in supraclavicular brachial plexus block in upper limb surgeries.
**Methods:** A total 96 patients were recruited into 3 groups by simple randomization technique:
Group RD : 0.5% Ropivacaine with 1mcg/kg Inj.Dexmedetomidine to make 30 ml
Group RF : 0.5% Ropivacaine with 1mcg/kg Inj. Fentanyl to make 30 ml
Group RC : 0.5% Ropivacaine 30 ml.
**Results:** Onset of motor and sensory blockade was earliest in dexmedetomidine group (11.55±3.19 and 13.42± 4.51 in minutes) followed by fentanyl group (15.16±4.54 and 14.32±5.24 in minutes) and last in control group. In fentanyl group mean duration of motor and sensory block was maximum (13.10±2.56 and 13.42± 4.51 in hours) followed by dexmedetomidine group (12.84±2.45 and 12.10±2.82 in hours) and least in control group. Dexmedetomidine group took more time for first rescue analgesia (16.06±2.28) and had better Visual analogue score (3.90±1.08) as compared to group RF and group RC.
**Conclusion:** We concluded that Dexmedetomidine and Fentanyl in a dose of 1mcg/kg as an additive to 0.5% ropivacaine in a total volume of 30 ml for supraclavicular block for upper limb surgeries quite effacaciously prolongs the duration of blockade and provides better quality of anaesthesia. Dexmedetomidine provides over all better blockade characterstics in terms of onset time, VAS score and time to request for first analgesic postoperatively without causing any major adverse effects.
**Keywords:** Supraclavicular block, Dexmedetomidine, Fentanyl, Ropivacaine, upper limb surgery.

## Introduction

Regional anaesthesia has taken the place of general anaesthesia as the primary anaesthetic technique for procedures on the upper limbs due to the development of new safer local anaesthetics and their advantages over general anesthesia as avoidance of polypharmacy, decreased need for postoperative analgesics, lower incidence of nausea and vomiting, shorter post anaesthesia care unit time and improved patient satisfaction [1,2].

Regional anaesthesia by providing complete muscular relaxation and with associated effect of sympathetic blockade lowers postoperative pain, vasospasm and edema while maintaining stable intraoperative conditions thus provides nearly optimal operating conditions [3].

Supraclavicular technique has been more widely used and its blockade can be provided by using either landmark guided, peripheral nerve stimulator guided or ultrasound guided technique [4].

Prior to recent years, Peripheral Nerve Stimulation (PNS) was the gold standard technique for nerve location and regional nerve block but now-a-days ultrasound (USG) guided blocks have gained popularity since they allow for direct nerve visualisation, but their use is limited due to cost and the level of expertise required [5].

Peripheral Nerve Stimulator enables accurate drug delivery, precise needle positioning, faster onset times, higher success rates for nerve blocks, and lowered local anesthetics doses [6,7].

A propyl group is substituted for the butyl group on the piperidine ring in ropivacaine which is a single (S)-stereo-isomer that differs from levobupivacaine [8].

It prevents peripheral afferents from acting on voltage-dependent Na+ channels. Being less lipophilic as compared to other long-acting local anaesthetics like bupivacaine, it has lesser side effects to the cardiac and central nervous system [9].

Many adjuvants have been tried to prolong the duration of local anesthetics (eg. Opioids, α-2 agonist, midazolam, ketamine and magnesium sulphate [10]. When combined with ropivacaine or bupivacaine, fentanyl and dexmedetomidine increase the anesthetic's analgesic potency, encourage early block accomplishment, and lengthen the duration of the anaesthesia [11].

Dexmedetomidine increases postoperative analgesia and duration of the sensory and motor block when added to ropivacaine in a dose-dependent manner [12,13].

A potent synthetic opioid analgesic with a quick onset and brief duration of action, fentanyl has a strong agonistic activity at the μ-opioid receptor and when used with local anaesthesia in peripheral nerve blocks, the peripheral absorption of fentanyl into the systemic circulation potentiates their action via central opioid receptor-mediated analgesia [14,15].

## Materials & Methods

The goal of this study, which was conducted at a medical school with tertiary care, was to evaluate the efficacy of dexmedetomidine and fentanyl as an adjuvant to ropivacaine in supraclavicular brachial plexus blocks during upper limb surgeries.96 patients of either sex, aged 18 to 65, with ASA grades I and II and weighing 50 to 80 kilograms (kgs), who were scheduled for elective upper limb surgeries under supraclavicular brachial plexus block, participated in a prospective, randomized, double-blinded study that lasted for two years after receiving approval from the hospital ethical committee. Patient with history of allergy to local anaesthetics, local site infection, pregnant women, Patients on any kind of chronic analgesic medication or NSAIDS and history of peripheral neuropathies and coagulation disorders were excluded from the study.

**Samplesize:** A total number of 96 patients scheduled for upper limb orthopaedic surgeries were randomized into three groups of 32 patients in each group by using Buderer's Formula.

It is estimated that minimum 29 patients were required in a group to detect 3 hours' difference in mean duration of analgesia to have a power of 80% and α error of 0.05%. A total of 96 patients were recruited for the current trial, accounting for a 10% dropout rate.

**Randomization technique and blinding:** After approval from Institutional Ethical Committee, these patients were randomly divided into three groups, each of 32 patients.

Group RF (n=32): 0.5% Inj. Ropivacaine with 1mcg/kg Inj.Fentanyl to make 30ml

Group RD(n=32): 0.5% Inj. Ropivacaine with 1mcg/kg Inj. Dexmedetomidine to make 30ml

Group RC(n=32): 0.5% Inj.Ropivacaine 30 ml

Double blinded technique was used by closed enveloped technique using computer generated random number table.

**Procedure:** A detailed pre-anaesthetic check up was done. Patients were asked to remain nil per orally 6 hours prior to surgery after obtaining informed consent. All patients received tab alprazolam 0.5 mg orally the night before surgery and a preoperative fasting status of 6 h was ensured and the block procedure and the Visual Analogue Scale (VAS) score were explained to the patient. Preoperative baseline vital parameters were recorded [16].

Intravenous line was secured with an 18 G cannula and Intravenous fluid started. Preoperative baseline vital parameters were recorded using multichannel monitor for NIBP, SpO2, and ECG monitoring [16].

The patient was positioned with their head rotated to the other side while they were lying on their back and the arm on the operating side is internally rotated, adducted, and held over the abdomen in a resting posture with the forearm flexed [16].

A landmark for a supraclavicular approach is 1.5–2 cm above the clavicle's midpoint, lateral to the clavicular head of the sternocleidomastoid. Following the correct skin preparation, a small skin wheal of local anaesthetic (2% lignocaine) was raised at this level. [25].

Using Inmed nerve stimulator-mapper-locator NSML-100, the positive electrode was attached to an ECG lead and placed over the ipsilateral shoulder, and the negative electrode is attached to a 20G insulated needle.

While the needle was being introduced into the skin in a downward and inward motion, the PNS was programmed to give 1.5-2.5 mA current at 1 Hz frequency and 0.1 ms of pulse length. By advancing the needle towards the lower trunk divisions, we attempted to induce a twitch in either the flexion or extension of the fingers. The local anaesthetic solution was administered after the negative aspiration and slow current reduction to 0.5 mA had produced the desired finger twitch [25].

The patient chart was used to extract baseline health information and demographic profile data. “The onset time of sensory blockade of each nerve was assessed by pinprick test along the distribution of cutaneous innervation of radial, ulnar and median nerve. Sensory blockage was graded as follows:

Grade 0: Sharp pain felt

Grade I: Analgesia, dull sensation felt

Grade II: Anesthesia, no sensation felt

When there was a dull sensation to pinprick along the distribution of any of the nerves, sensory onset was thought to have been attained. When there was a total loss of pinprick sensation, complete sensory blockade was taken into consideration [16].

Duration of sensory block was determined by noting the time when there was return of dull sensation to pinprick and using a modified Bromage scale, mobility at the elbow, wrist, and fingers was used to measure motor weakness [16].When Grade I Bromage motor blockage was attained, the beginning of the condition was taken into account, when Grade III Bromage blockage was attained, peak motor block was taken into account and up to complete blockage at 3,5,10,15, and 20 minutes, the onset of motor and sensory blockade was measured [16]. The time from the beginning of the full sensory block to the start of pain and the need for analgesia in the postoperative period was used to calculate the overall length of the sensory block and the time from the commencement of the motor block and the full recovery of motor activity was used to calculate the overall duration of the motor blockade [16].

**Modified bromage scale:**

Grade 0 Normal motor function with full extension of elbow, wrist, and fingers

Grade I Ability to flex and extend wrist and fingers

Grade II Ability to flex and extend only fingers

Grade III Complete motor block with the inability to move elbow, wrist, and finger.

The hemodynamic variables, ventilation rate and oxygen saturation were monitored initially at 5 min intervals. In the recovery room, patients were asked to rate their pain on 11 points visual analog scale (VAS) and thereafter pain was assessed regularly every 30 min for the first 2 hrs and then every 1 hourly till 24 h.Testing for sensory and motor block regression was done every 15 min until complete resolution. Injection Diclofenac sodium aqueous 75 mg intravenously was administered when VAS score was ≥4[16].

Statistical analysis: Data were input into a Microsoft Excel spreadsheet and analysed using SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. The data had been summarised using the mean and standard deviation for numerical variables and count and percentages for categorical variables. In two-sample t-tests, independent samples or unpaired samples were utilised.To compare the means of three or more samples of numerical data, the one-way analysis of variance (one-way ANOVA) method was used (using the F distribution).A chi-squared test (or "2 test") is any statistical hypothesis test in which, when the null hypothesis is true, the test statistic's sampling distribution is a chi-squared distribution. Using a table of numbers from Student's t-distribution, one may get a p-value. A p-value of 0.05 or less was considered as statistically significant, while 0.001 was not.

## Results

Data are presented in Mean ± SD or absolute numbers and *p-value <0.05 is statistically significant and ** p-value <0.001 is highly significant statistically. Out of the 96 patients recruited, 3 were withdrawn because of inadequate level of the block. In terms of age, gender and weight, all the groups were comparable and thus the data was statistically insignificant (p-value>0.05)

As shown in Table 1 and 1a, mean onset of motor block (min) was found earlier in Group D followed by Group F and last to occur in Group C and mean block duration (min) among the three groups was more in Group F followed by group D and then group C. When onset of motor block was compared among the groups using t-tests,it was found to be highly statistically significant (p-value <0.001) and duration of motor block was found to be significant.

**Table1: Onset and duration of Motor Block**

| | Group F | | Group D | | Group C | | |
|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | P value |
| Onset of motor block (min) | 15.16 | 4.54 | 11.55 | 3.19 | 15.88 | 4.88 | <0.001 (HS) |
| Durationof Motor block (hrs) | 13.94 | 2.58 | 12.84 | 2.45 | 6.91 | 2.36 | <0.001 (HS) |

**Table1a: T and P value of Onset and duration of Motor blocks**

| | Group F vs D | | Group F vs C | | Group D vs C | |
|---|---|---|---|---|---|---|
| | T value | P value | T value | P value | T value | P value |
| Onset of motor block (min) | 3.68 | <0.001 | 0.61 | 0.55 | 4.20 | <0.001 |
| Duration of Motor block (hrs) | 0.74 | 0.46 | 1.72 | 0.09 | 2.63 | 0.01 |

As shown in Table 2 and 2a, mean onset of sensory blockade was found earlier in group D followed by group F which was found to be statistically significant (p-value 0.04) and the mean duration of sensory block (hrs) was found to be more in Group F followed by Group D and then C. Statistically highly significant difference was seen in both onset and duration of the sensory block (p-value < 0.001) during comparison

**Table2: Onset and duration of sensory block**

| | Group F | | Group D | | Group C | | |
|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | P value |
| Onset of sensory block (min) | 14.32 | 5.24 | 13.42 | 4.51 | 16.50 | 4.86 | 0.04(S) |
| Duration of sensory block (hrs) | 13.10 | 2.56 | 12.10 | 2.82 | 6.50 | 2.29 | <0.001(HS) |

In our study, as shown in Table 3 and 3a, it was discovered that Group D took the longest amount of time to take its first analgesic dosage out of the three groups. This difference was statistically significantly different from the other two groups (p-value 0.001) after comparing all the groups.

**Table2a: T and P value of onset and duration sensory blocks**

| | Group F vs D | | Group F vs C | | Group D vs C | |
|---|---|---|---|---|---|---|
| | T value | P value | T value | P value | T value | P value |
| Onset of sensory block (min) | 1.74 | 0.09 | 11.37 | <0.001 | 9.86 | <0.001 |
| Duration of sensory block (hrs) | 1.48 | 0.14 | 10.87 | <0.001 | 8.72 | <0.001 |

**Table3: Time taken for 1st analgesic dose**

| | Group F | | Group D | | Group C | | |
|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | P-value |
| Time taken for 1st analgesic dose (hrs) | 15.29 | 2.62 | 16.06 | 2.28 | 10.56 | 2.65 | <0.001 |

**Table3a: T and P value of time taken for 1st analgesic dose**

| | Group F vs D | | Group F vs C | | Group D vs C | |
|---|---|---|---|---|---|---|
| | T value | P value | T value | P value | T value | P value |
| Time taken for 1st analgesic dose (hrs) | 1.26 | 0.21 | 7.17 | <0.001 | 8.90 | <0.001 |

Table 4 and 4a shows the mean of VAS score was better in group D and difference among three groups was found to be highly significant statistically (p-value <0.001).

**Table 4: VAS score**

| | Group F | | Group D | | Group C | | |
|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | P value |
| VAS scale | 4.35 | 0.98 | 3.90 | 1.08 | 6.31 | 0.82 | <0.001 (HS) |

**Table4a: T and P value of VAS score**

| | Group F vs D | | Group F vs C | | Group D vs C | |
|---|---|---|---|---|---|---|
| | T value | P value | T value | P value | T value | P value |
| VAS scale | 1.75 | 0.08 | 8.64 | <0.001 | 10.07 | <0.001 |

## Discussion

We conducted this study to evaluate the effect of addition of Dexmedetomidine and fentanyl as adjuvants to ropivacaine in PNS guided supraclavicular brachial plexus anaesthesia.We observed that the mean onset of motor blockade(in minutes) was earliest with dexmedetomidine (11.55±3.19) and was statistically highly significant as compared to fentanyl (15.16±4.54) and control group (15.88±4.88) and similarly the mean onset of sensory blockade was also earliest with dexmedetomidine (13.42±4.51) but the difference was not statistically different with fentanyl but when both the groups were compared with control group it was found that the statistical difference was high. We also observed that fentanyl has better duration of both motor and sensory blockade followed by Dexmedetomidine and less duration of both blockade with control group.

According to Farooq N.et al., fentanyl produced a motor block with a maximum mean duration that was statistically significant (p value 0.001) [16].

However, Hamed MA.et.al found in their trial that the inclusion of dexmedetomidine increased postoperative analgesia and extended the duration of the block compared to fentanyl and bupivacaine alone [17].

Similar to our work, M Umamaheshwar et al. found that adding dexmedetomidine rather than fentanyl to 0.5% ropivacaine enhanced the blockage more. There was no increased frequency of adverse effects [18].

When used as an adjuvant to 30 mL of 0.5% ropivacaine, Soma C. Cham. et. al.'s study found that both dexmedetomidine and fentanyl improved readiness for surgery in supraclavicular brachial plexus block, but dexmedetomidine prolonged the duration of sensory and motor block and postoperative analgesia as compared to fentanyl without having any significant side effects [19].

Dr. P. Manohar.et.al observed in his study that compared to the use of 30 ml Bupivacaine 0.5% alone, addition of 50 mcg Fentanyl or 50 mcg dexmedetomidine enhanced onset of block and also increased the duration of surgical anaesthesia with prolongation of post-operative analgesia. Furthermore, blockade characteristics improved better with addition of Dexmedetomidine than Fentanyl without increasing incidence of unwanted side-effects [20].

Mangal V.et.al observed that Dexmedetomidine significantly shortens the onset of sensory and motor blockade when added with Ropivacaine in supraclavicular block [21].

Similar to our study, Das B.et.al observed that the time taken for first rescue analgesia was more in group RD than group R and concluded that dexmedetomidine has longer duration of postoperative analgesia in which statistically significant difference was there. When compared to fentanyl and the control group, dexmedetomidine had better visual analogue score and statistically highly significant difference was found(p-value<0.001) [22].

Liu Z.et.al result showed that no significant difference was found in VAS scores between both the groups immediately and 4 hours after surgery (1.7 ± 0.4, 1.8 ± 0.9), however, 8,12 and 24 hours after the surgery, the VAS scores were all less in Dexmedetomidine (2.4 ± 0.6, 2.2 ± 0.9 and 2.1 ± 0.4 respectively) and was statistically significant (p-value <0.05) [23].

**Limitations:** In order to rule out issues like nerve damage, which is a possibility with the supraclavicular method, as well as asymptomatic pneumothorax, the research did not follow-up patients with a postoperative chest radiograph.

## Conclusion

In this randomized controlled double blinded prospective study, we concluded that both dexmedetomidine and fentanyl when added to ropivacaine have provided prolonged duration of anaesthesia and better postoperative analgesia as compared to ropivacaine alone but dexmedetomidine has been found to be a better adjuvant by showing quicker onset of motor and sensory blockade, have better VAS score and took more time to request for rescue analgesic. Hence ,in view of findings of our study,We conclude that both dexmedetomidine and fentanyl when added with Ropivacaine in supraclavicular brachial plexus block for upper limb orthopedic surgeries provided better quality of anaesthesia without causing any major adverse events as compared when we use Ropivacaine alone.

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