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Comparative study between fentanyl and dexmedetomidine as adjuvant to ropivacaine in supraclavicular brachial plexus block: A prospective and randomized study

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ABSTRACT

Background: Supraclavicular brachial plexus block (BPB) is being utilized extensively for upper limb surgeries. To improve block quality, several adjuvants have been used successfully. Fentanyl and dexmedetomidine has been evaluated as adjuvants for such block done using ropivacaine. However, block qualities have been modified to a variable extent with use of such adjuvants. **Aims and Objectives:** Hence, the study was designed to compare fentanyl and dexmedetomidine as adjuvants during ropivacaine-induced supraclavicular BPB. **Materials and Methods:** Sixty adults undergoing upper limb surgeries were randomly divided in to two groups to receive either fentanyl or dexmedetomidine as adjuvants to ropivacaine for supraclavicular BPB. The onset of sensory block was the primary outcome measure. Duration of sensory bloc, motor block characteristics, and adverse events were also evaluated. **Results:** Considerably faster onset of sensory and motor blockade was found with the use of fentanyl as adjuvant over dexmedetomidine (sensory, 8.2 ± 1.19 vs. 12.07 ± 0.96, $P < 0.001$; and motor, 7.0 ± 0.43 vs. 30.43 ± 1.41, $P < 0.001$). However, the duration of sensory and motor blockade were found considerably prolonged with the use of fentanyl over dexmedetomidine. **Conclusion:** Fentanyl can be a better alternative to dexmedetomidine as adjuvant to ropivacaine for supraclavicular BPB in view of faster onset of sensory and motor block. While prolonged duration of sensory block appears to be beneficial, the prolonged motor block can cause delay patient mobility.

Key words: Adjuvants; Brachial plexus block; Dexmedetomidine; Fentanyl; Ropivacaine; Supraclavicular

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INTRODUCTION

Regional anesthesia plays a dominant role for surgeries to the upper extremities. Brachial plexus block (BPB) avoids adverse events related with laryngoscopy and intubation of general anesthesia. Requirement of adequate intraoperative sensory and motor blockade and postoperative analgesia is quite essential in upper extremity orthopedic surgeries. Supraclavicular BPB has become a popular approach to block the brachial plexus due to its cost effectivity, high success rate, high margin of safety, and efficient post-operative pain control.[1] A continuous quest is on to determine the better adjuvant to achieve quick onset of block and extended duration of block with less adverse event.

Bupivacaine was used frequently in the past for brachial plexus anesthesia due to its advantage of long duration of action and a favorable ratio of sensory to motor block.[2,3]

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Ropivacaine is a long-acting amide local anesthetic similar to bupivacaine with a potentially improved cardiac as well as central nervous system safety profile.[3,4] Several adjuvants such as adrenaline, midazolam, neostigmine, opioids, and clonidine have been tried to speed up block achievement, increase its efficiency by increasing the block level and blockade time and quality of post-operative recovery. Fentanyl is a short acting μ-receptor agonist. Fentanyl, when added to local anesthesia in peripheral nerve blocks, potentiates the local anesthesia action through central opioid receptor-mediated analgesia by the peripheral uptake of fentanyl to the systemic circulation. Recently, dexmedetomidine, a selective α2-adrenoceptor agonist, has been tested in several studies. A few studies have compared the efficacy of both the drugs either independently or in combination with other adjuvants.[5-7] There are limited studies comparing dexmedetomidine with fentanyl as adjuvant to ropivacaine with variable benefit. The quest for the ideal adjuvant still continues and instigated us to compare dexmedetomidine with fentanyl as adjuvants to ropivacaine supraclavicular BPB among patients undergoing upper limb orthopedic surgeries.

Aims and objectives

Fentanyl and dexmedetomidine were compared as adjuvants to ropivacaine regarding onset of sensory block (primary outcome) during supraclavicular BPB. In addition, the duration of sensory block and duration of analgesia yielded were compared. Other block characteristics such as onset and duration of motor block were compared. Adverse events, if any, were noted.

MATERIALS AND METHODS

After obtaining the Institutional Ethics Committee's permission (BSMC/Aca:-275 Dated January 27, 2020) and written informed consent from each patient, this prospective randomized and double blind study was conducted over a period of 1½ year (March 2020–August 2021).

Inclusion criteria

Willing patients, aged between 18 and 60 years of either sex, weighing 50–80 kg, belonged to American Society of Anesthesiologists (ASA) physical status I and II, scheduled for upper limb (elbow, forearm, hand) orthopedic, plastic surgery, and under supraclavicular BPB were included in this study.

Exclusion criteria

Patients with known allergy to study drugs, documented neuromuscular disorders, severe respiratory distress, heart block, renal, hepatic diseases, and any contraindications to BPB were excluded from this study.

Sample size calculation

The sample size was calculated using the formula as mentioned in the literature.[8] N (sample size per group)=2 $(Z_{\alpha/2}+Z_{1-\beta})^2/(\mu_1-\mu_2/\sigma)^2$. From a previous literature,[2] the mean values of sensory onset time of the two groups are 11.9 and 9.0 (μ_1 and μ_2, respectively) while the effect size (σ) was assumed to be 2.6 s. Setting the power of the study at 80% and allowing an alpha error of 5%, the sample size is calculated to be 30 in each group.

After thorough pre-anesthetic assessment and after obtaining necessary investigations as per institutional protocol, 60 patients were selected. They were equally divided into two groups (n=30), Group RF (Ropivacaine-Fentanyl) and Group RD (Ropivacaine-Dexmedetomidine) by computer generated randomization table.

Preoperatively, all patients were kept on 8 h fasting. Study participants received tab. Alprazolam (0.5 mg) previous night of surgery. In the morning of surgery, the respective participants were received tab. pantoprazole (40 mg) and tab. domperidone (10 mg) per orally.

On arrival in the operation room, ASA standard monitors were attached. Baseline and continuous SpO_2, electrocardiogram, heart rate (HR), and mean arterial pressure (MAP) were recorded. An i.v. access was secured with an 18G cannula and Ringer's lactate was started. The details of the block procedure and the visual analog scale (VAS) score were explained to each participant in their own vernacular language. After proper positioning, under strict aseptic precautions, the subclavian artery was palpated and a skin wheal was made by injecting 2 mL of 2% lidocaine. Supraclavicular neural localization was achieved using a nerve stimulator connected to a 22-gauge, 4 cm long stimulating needle. The position of the needle was felt adequate when an output current of <0.5 mA elicited a slight desired distal motor response. On localization of the brachial plexus and after negative aspiration confirmation for blood/air, incremental injections of a total volume of 35 mL of solution were administered (time-0). Group RF received ropivacaine at a dose of 3 mg/kg of 0.75% with fentanyl 1 μg/kg as adjuvant. Group RD received 3 mg/kg of 0.75% ropivacaine with 1 μg/kg of dexmedetomidine. Both the study drug solutions were diluted with the required amount of normal saline to make the final volume of 35 mL. In two identical syringes, the study drug's solutions were prepared, by a nurse who was unaware of the study.

Sensory and motor blockade was assessed every 5 min for 30 min or until onset of block and thereafter every 30 min during the surgery and then every hourly until they have resolved.

Sensory block was assessed by pinprick test using a 3-point scale in all nerve territories: (0=sharp pin felt, 1=dull sensation felt [analgesia], 2=no sensation felt [anesthesia]).

Motor block was assessed using modified Bromage scale criteria[9] which state as follows: Grade 0=able to raise the extended arm to 90° for a full 2 s, grade I=able to flex the elbow and move the fingers but unable to raise the extended arm, grade II=unable to flex the elbow but able to move the fingers, and grade III=unable to move the arm, elbow, and fingers.

Onset of sensory block was defined as the period from the end of total local anesthetic administration to achieving complete sensory block (anesthetic block score 2) on all nerve territories. Duration of sensory block-time interval between the end of local anesthetic administration to complete resolution of anesthesia in all nerve distributions. Onset of motor block means the time interval between administrations of local anesthetic solution to loss of upper limb movements (grade III). Complete motor block indicates absence of voluntary movements in hand and forearm (Grade III). Duration of motor block is time interval between the end of local anesthetic administration to recovery of complete motor function of the hand and forearm. If the desired sensory and motor block were not achieved 30 min after completion of study drug delivery, that patient was excluded from the study.

Ramsay sedation scale[10] was used to assess the level of sedation. The levels of sedation used were as follows: Level 1=restless, or anxious-agitated, or all; level 2=tranquil, cooperative and oriented; 3=responding only to verbal commands; 4=active response to mild tap on glabella or loud auditory stimulus; 5=sluggish response to mild glabellar tap or loud auditory stimulus; and 6=absence of response to mild glabellar tap or no response against loud auditory stimulus). Hypoxia was defined as SpO_2 <90% and treated with oxygen by mask. Bradycardia was defined as HR <50/min, tachycardia was defined as HR >100 beats/min, and hypotension was decrease in systolic blood pressure (SBP) by 20% from baseline values. HR, SBP, diastolic blood pressure, MAP, and SpO_2 were recorded at 0, 5, 10, 15, 30, 45, and 60 min and then every 30 min interval till the end of surgery. Complications such as inadvertent intravascular administration, pneumothorax, arrhythmias, and paresis were noted. Rescue analgesia was given on patient's demand. The time from commencement of block to the patient's first request for rescue analgesic (VAS >4) is defined as total duration of analgesia. Inj. diclofenac sodium 75 mg iv infusion over 30 min was given. Participant's pain perception was assessed using VAS (0–10), with "0" no pain at all and "10" worst pain imaginable. VAS score was measured every hourly till first rescue analgesia.

RESULTS

Following data collection, all the inputs were put into computer software (Microsoft Word and Microsoft Excel 2019) to generate the result in tabular and graphical formats. Statistical software (SPSS version 22) was used for analysis of the outcome variables. The numerical variables were compared by Student's unpaired t-test and categorical variables were compared by Chi-square test as appropriate, between groups. P<0.05 was considered as statistically significant.

No patient was excluded from this study due to block failure. Hence, data from all sixty patients were available for analysis. Both the groups were found comparable regarding demographic parameters (Table 1).

Considerably faster onset of sensory and motor blockade was found with the use of fentanyl as adjuvant over dexmedetomidine. However, the duration of sensory and motor blockade was found significantly prolonged with the use of fentanyl over dexmedetomidine (Table 2).

Two patients suffered skin rashes in patients receiving fentanyl as adjuvant. In patients receiving dexmedetomidine adjuvant, four patients suffered bradycardia in the intraoperative period and one patient in the post-operative period compared to none in fentanyl adjuvant group. Bradycardia treated with inj. atropine 0.6 mg i.v. One patient in dexmedetomidine adjuvant group had hypotension that was managed with inj. mephentermine 3 mg bolus 3 times. In patients receiving dexmedetomidine, four patients had a sedation score of 3, but there were no cases of respiratory depression in any of

Table 1: Demographic characteristics

Parameters	Group RF (n=30)	Group RD (n=30)	P-value
Age in years	40.43±7.43	38.43±7.43	0.30
Body weight in kg	65.06±3.21	64.33±3.02	0.37
Gender Male: Female	19:11	21:9	0.58
ASA 1:ASA 2	22:8	23:7	0.77

ASA: American Society of Anesthesiologists

Table 2: Block characteristics

Parameters	Group RF (n=30)	Group RD (n=30)	P-value
Onset of sensory blockade (minutes)	8.2±1.19	12.07±0.96	<0.001
Duration of sensory blockade (minutes)	416.47±6.44	374.73±6.59	<0.001
Onset of motor blockade (minutes)	7.0±0.43	30.43±1.41	<0.001
Duration of motor blockade (minutes)	365.57±4.15	332.89±3.95	<0.001

the patients in both the groups. Nausea and vomiting were seen in one patient in the dexmedetomidine group and none in fentanyl group (Table 3).

HR was found lower in dexmedetomidine group at all time-points from 30 min after block and onwards. Although the differences were found statistically significant, the decreased HRs were not clinically significant (Figure 1).

Although the MAP at different time-points was found lower in dexmedetomidine group and differences were statistically significant at all time-points of observation, such low values were not clinically important to produce any deleterious effect (Figure 2).

DISCUSSION

In the present study, considerably faster onset of sensory and motor blockade was observed with the use of fentanyl as adjuvant over dexmedetomidine (mean, onset sensory 8.2 vs. 12.07, and mean onset motor 7.0 vs. 30.43). Furthermore, duration of sensory and motor blockade was significantly longer with the use of fentanyl over dexmedetomidine (mean duration sensory 416.47 vs. 374.73; mean duration motor 365.57 vs. 332.89, respectively).

The magnitude of hastening of sensory block onset using fentanyl in the present study was about 4 min compared with dexmedetomidine (mean, 8 vs. 12 min, respectively). The extent of hastening of sensory block was reported to be variable from approximately 3 min[2,11] to no discernible effect.[12,13] These studies reported about faster onset of sensory and motor block with fentanyl compared to dexmedetomidine.

However, comparable onset of sensory block between use of fentanyl and dexmedetomidine as adjuvants have been observed by other studies[12,13] There are other studies[14-16] who have found contrast findings, that is, use of dexmedetomidine as adjuvant has achieved shorter onset of sensory and motor block with dexmedetomidine compared to fentanyl.

The present study also finds duration of sensory and motor blockade to be significantly longer with the use of fentanyl over dexmedetomidine. Farooq et al.,[2] have found that fentanyl acted as a better adjuvant than dexmedetomidine for achievement and duration of sensory and motor blockade. Fentanyl as adjuvant yield earlier onset of motor block over dexmedetomidine, although the magnitude of effect varied from no discernible effect,[12,13] 3 min earlier,[17] 5 min earlier[11] to 9 min of hastening.[2] Debnath et al.,[16] observed duration

Table 3: Adverse events

Parameters	Group RF (n=30)	Group RD (n=30)
Skin rash	2	0
Bradycardia	0	5
Hypotension	0	1
Nausea, vomiting	0	1
Sedation	0	4

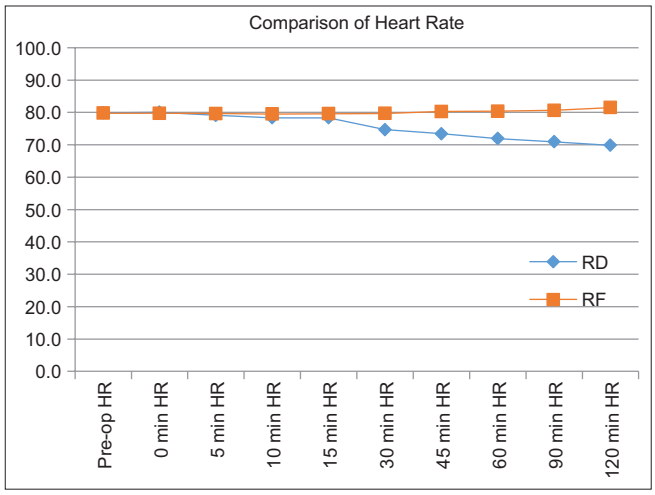

Figure 1: Heart rates at different time-points

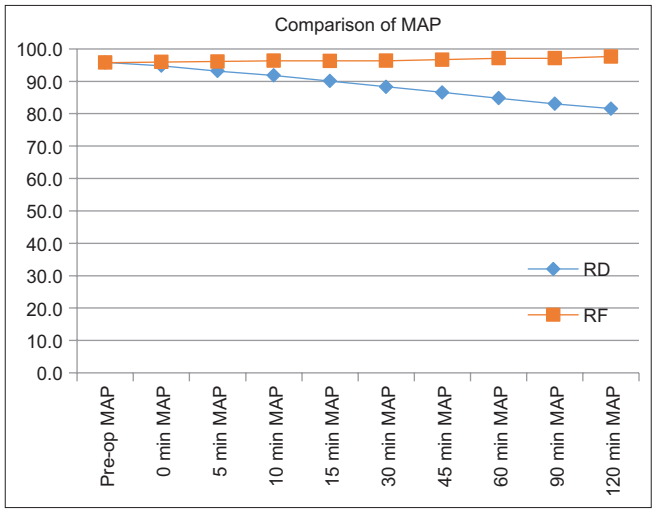

Figure 2: Mean arterial pressure at different time-points

of sensory block to be significantly prolonged in dexmedetomidine group (826 vs. 592 min) as compared to fentanyl. Dharmarao and Holyachi[14] observed that the duration of sensory block can be considerably prolonged with use of dexmedetomidine compared to fentanyl (mean, 801 vs. 590 min, respectively). It is hypothesized that local action due to the presence of α2-adrenergic receptors in brachial plexus can contribute to faster onset and longer duration of LA block.[18] The use of perineural dexmedetomidine can prolong the duration of sensory and motor block more than intravenous dexmedetomidine.[18]

In the present study, HR and MAP were considerably higher in fentanyl group than dexmedetomidine. Considerably higher incidence bradycardia and hypotension was noted with the use of dexmedetomidine over fentanyl. This may be attributed to activation of postsynaptic α-2 receptors by dexmedetomidine which leads to sympatholysis and results in decrease in blood pressure and HR.[19]

In the present study, comparatively higher number of patients had arousable sedation with the use dexmedetomidine over fentanyl. The sedative effect can be attributed to systemic absorption of the drug and its action on locus ceruleus.[19] Perineural injection of clonidine and dexmedetomidine can have adverse effects such as bradycardia, hypotension, and sedation.[20]

Hussain et al.,[21] found that incidence of intraoperative hypotension is more with intravenous dexmedetomidine that with perineural use. While prolonged analgesic effect can be considered an advantage of perineural administration of dexmedetomidine, the motor block-prolonging effect has the potential to delay ambulation and discharge following outpatient surgery.[21]

Liu, et al.,[22] in their study, observed lethargy and nausea as the major adverse effects in both ropivacaine-dexmedetomidine combination and ropivacaine alone groups. Despite the common sense that, one would expect that combination of two anesthetics would cause more adverse reactions than single anesthetic the authors observed the incidence of adverse reaction in the combined treatment group to be considerably lower than that of ropivacaine alone.[22] In a meta-analysis Dai et al., reported that bradycardia and hypotension appears to be the major postoperative adverse events, while they also mentioned about other adverse events such as postoperative drowsiness, dyspnea, and Horner's syndrome.[23]

In a meta-analysis, Hussain et al.,[24] showed that dexmedetomidine at a dose >50 mcg as adjuvant can significantly prolong motor and sensory block in BPB[24] In a meta-analysis of 12 randomized controlled trials (n=671), Dai et al.,[23] found that both high doses (>50 mcg) and low doses (<50 mcg) of dexmedetomidine have improved ropivacaine induced BPB.[23] This translates in to the fact that the effect of ropivacaine for BPB may not be related with the dose of dexmedetomidine. In a study, Jung et al.,[25] reported that dexmedetomidine at a dose of 2 mcg/kg can be the most optimal dosage for BPB when compared with 1 and 1.5 mcg/kg. The optimal dosage of dexmedetomidine as adjuvant to BPB needs to be consolidated through multi-centric robust study.

The observations of the present study cannot be effectively compared with other studies due to high heterogeneity among different studies in the related field. Variable inclusion criteria, different characteristic among patients and small sample size-all can contribute to heterogeneity across the studies. Moreover, different definition of outcome measures and different scales and criteria to measure outcome parameters further increase this heterogeneity.

Limitations of the study

Small sample size was a limitation for the study. Dexmedetomidine has dose-dependent effect on modifying the quality of block. However, we could not evaluate the effect of other doses of dexmedetomidine.

CONCLUSION

Fentanyl can be a better alternative to dexmedetomidine as adjuvant to ropivacaine for supraclavicular BPB in view of faster onset and longer duration of sensory block and favorable adverse event profile.

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Author's Contribution:
SB- Study design, study conduct, data collection, first draft; **SKH-** Concept, design, data analysis, first draft; **TB-** Study design, review of literature, data analysis, revision of draft; **DD-** Study design, review of literature, data analysis, revision of draft; **RB-** Design, review of literature, data analysis, revision of draft; **SC-** Concept, study design, analysis, revision of draft; **DS-** Concept, daily guidance, data analysis, revision of draft.

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