



COMPARISON OF DEXMEDETOMIDINE VERSUS FENTANYL AS ADJUVANTS TO BUPIVACAINE IN SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK: A PROSPECTIVE RANDOMIZED COMPARATIVE STUDY

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ABSTRACT

Background: The supraclavicular approach to blockage of nerves around the brachial plexus is a commonly used technique for upper extremity surgical procedures. The performance of the procedure can be graded as either 'reliable' or 'unreliable' depending on whether the nerve block worked out. Long-acting local anaesthetic agents such as bupivacaine give satisfactory analgesia and some degree of prolongation of pain relief. Adjuvant agents added to the local anaesthetic may improve the quality and duration of the supraclavicular nerve block and possibly improve postoperative analgesia, fentanyl and dexmedetomidine being studied as adjuvants for the use of local anaesthetics. The object of the study reported here was to investigate the relative efficacy and safety of these agents as adjuvants compared to each other and in combination with local anaesthetics. **Objectives:** The aim of this study was to compare the use of dexmedetomidine and fentanyl with bupivacaine for pain relief among persons with a supraclavicular brachial plexus block. The comparison of dexmedetomidine and fentanyl assesses the effect on onset of sensory (pain) block and motor (muscle) block and duration, the effectiveness of postoperative pain medications, stability during surgery, greater comfort from sedation, and adverse effects. **Methods:** This was a prospective, randomized trial conducted over a one year period involving one hundred patients going for elective surgery of their upper extremities. The patients were randomized into groups of fifty patients each receiving a brachial plexus block using supraclavicular brachial plexus block placement by ultrasound based approach. The patients in group D received a combination of bupivacaine and dexmedetomidine while patients in group F received bupivacaine and fentanyl. The primary outcomes studied were time to the onset of sensory and motor block, and duration of post-operative analgesia. Secondary outcomes included the length of sensory and motor blocks; intra-operative/post-operative hemodynamic parameters, sedation scores and side effects. **Results:** At baseline, demographic and clinical characteristics were similar between groups. In dexmedetomidine group the sensory and motor block developed was faster and individual's sensory block, motor block, and duration of post-operative pain relief Latency was longer than that in control group. Although hemodynamic variable were stable for both group during preoperative and postoperative periods, there was a trend to greater frequency of milder sedation in the dexmedetomidine group than in the control group. The overall incidence of adverse events was low and the incidence of adverse events was similar for both groups. **Conclusion:** Patients who underwent surgery on the upper limbs with a supraclavicular brachial plexus block will benefit from added dexmedetomidine rather than fentanyl to their bupivacaine. The addition of dexmedetomidine significantly extends duration of analgesia from the brachial plexus block and provides added reduction of pain after surgery with safety and hemodynamic stability.

Keywords: Supraclavicular Brachial Plexus Block, Bupivacaine, Dexmedetomidine, Fentanyl, Adjuvant, Regional Anesthesia, Postoperative Analgesia.



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INTRODUCTION

Supraclavicular brachial plexus block is the most commonly used technique of regional anaesthesia for surgeries of the upper limb. Rapid onset and dense sensory and motor blockade and reliable surgical anaesthesia make this technique suitable for diverse upper limb surgeries [1]. Compared with general anaesthesia this technique has several advantages including better perioperative hemodynamic stability, less need of systemic analgesics and better postoperative pain relief; these advantages make supraclavicular block a relevant part of the armamentarium of the modern anaesthesiologist for providing anaesthesia in upper limb orthopedic, plastic, and soft tissue procedures [2]. Bupivacaine is the earliest and most frequently used long-acting amide local anaesthetic agent for the brachial plexus blocks. Because of its long duration of action and adequate sensory–motor block profile, it superseded lidocaine and other short-acting local anaesthetics. Sometimes the time for onset of block and the duration of postoperative analgesia with bupivacaine may not be adequate for prolonged surgical procedures so prolonging the above parameters which will make bupivacaine more acceptable [3]. There has been a wide variety of adjuvants to local anaesthetic agents with the intention of hastening the onset, prolonging the duration of block and postoperative analgesia, improving the quality of block and its postoperative analgesia, without increasing the risk of adverse effects [4]. Various adjuvants such as mannitol, ketamine and local anaesthetic agents like lidocaine, prilocaine, ropivacaine etc. have been added to local anaesthetic agents with marginal success. Among the commonly used adjuvants included mixtures such as opioids such as fentanyl and α_2 adrenergic agonists such as dexmedetomidine [5]. Opioids when added to local anaesthetic agents seem to prolong the duration of analgesia either by their peripheral opiates receptor mechanism or by absorption in the C.N.S. They may possibly improve the quality of the block (i.e. better pain relief) and of postoperative pain relief without too much prolongation of the duration both of the motor and sensory block, but the results of various studies regarding prolongation of the duration of sensory block and motor block have been conflicting and side effects such as nausea, vomiting, pruritus and respiratory depression are a cause for concern. [6]. Dexmedetomidine is a highly selective α_2 adrenergic agonist, which appears to be safe for use,

has analgesic and sedative properties but no marked effects on respiratory depression, and may also cause prolonged both sensory and motor blockade when used as an adjuvant. The mechanism of action appears to be hyperpolarization of nerve tissues, and inhibition of norepinephrine release leads to increased and prolonged blockage of afferent nerve fibres. [7]. It has been shown that feasibility of reduced dose of local anaesthetics and shorten the time needed to perform a nerve block. In addition, it exerts a fair amount of anxiolytic and sedative effect on patients who would be undergoing surgery under the effect of regional anaesthesia [8]. Although both fentanyl and dexmedetomidine have been used as adjuvants to bupivacaine for supraclavicular brachial plexus block, unfortunately there are not clear comparative data in which one is better than the other, in respect of obtaining faster onset, prolonging duration of sensory and motor blockade, prolonging duration of postoperative analgesia, effects on hemodynamics and adverse effects [9]. A direct comparison of these two agents using a standardized technique and uniform outcome measures would help the anaesthesiologist in routine practice to choose the right one to use [10]. Therefore, the present prospective random comparative study was undertaken to compare dexmedetomidine and fentanyl as adjuvants to bupivacaine for supraclavicular brachial plexus block in patients undergoing elective upper limb surgery, and concentrated in regard to its block characteristics, quality and duration of postoperative analgesia, its effect on hemodynamics, sedation and adverse effects.

MATERIALS AND METHODS

Study design and setting

This clinical trial was designed as a prospective double blinded randomized controlled trial, conducted in a tertiary-care teaching hospital for twelve months. Prior approval was obtained from the Institution's Ethics Committee before conducting the research investigation. The clinical trial was designed to assess the effect of dexmedetomidine vs fentanyl on the efficacy of bupivacaine during supraclavicular brachial plexus blocks for elective surgery of upper limb under regional anaesthesia.

Study population and sample size

One hundred patients were included in the study. The estimated sample sizes reflected historical before study estimates and how long we thought it would take to finish the trial in the indicated time period. Randomized them into 2 equal groups of 50 patients, Group D received bupivacaine with Dexmedetomidine and group F received bupivacaine plus Fentanyl etc.

Inclusion criteria

The participants comprised men and women between the ages of 18 and 65 undergoing elective

surgery on the upper limb by means of the supraclavicular approach for brachial plexus block. All patients were ASA I or II.

Exclusion criteria

Exclusion criteria for patients in this study was if anyone of the following: requested not to have regional anaesthesia individual; history of hypersensitivity to local anaesthetics, and/or dexmedetomidine and/or fentanyl; active bleeding disorder; local infection at the injection site; significant cardiac, hepatic, renal or neurological illness; woman who is pregnant or nursing; and/or pre-existing neuropathy in operative limb(s).

Randomization and group allocation

The patients in our study were randomly allocated into the 2 groups by a computer-based Randomization Module; and thereafter placed in sealed opaque envelopes to guard against possible bias in formation of groups on the basis of assignment. Group D (n=50) received bupivacaine along with dexmedetomidine. The other group (Group F) received bupivacaine along with fentanyl.

Anesthetic technique

Once the patients were taken to the operating table, the routine monitoring observations of the patients that include; non-invasive blood pressure, Electrocardiogram (ECG) Monitoring and Pulse Oximetry Monitoring were done. The pulse rate, blood pressure and oxygen saturation were noted and secured intravenous line as part of the routine of the Hospital before the patients were taken to the Operating room. The supraclavicular brachial plexus block was performed under strict sterile aseptic technique using widely accepted classical landmarks. After confirming negative aspiration, the test drug was administered in multiple smaller doses with same technique of checking for aspiration between each sub-administration. In Group D, the studied drug was bupivacaine and dexmedetomidine whereas in group F received bupivacaine and fentanyl. The total Injectate volume was same for both Groups.

Assessment of block characteristics

Using the pinprick method the sensory block was assessed and recorded with reference to the areas supplied by the median, ulnar, radial and musculocutaneous nerves. The modified Bromage Scale describes the evaluation of motor block in the upper limbs. An onset time for sensory and motor blocks, defined as the time interval from the injection of anaesthetic agent until sensory/motor block was achieved completely. Duration of the sensory block, defined as the time interval from the point of completion of the sensory block to the time of the first request for analgesia. Duration of the motor block, defined as the interval between the

point of complete motor block and the time the patient had regained 100% motor function.

Postoperative analgesia and sedation assessment

After surgery, patients were taken through visual analogue scales hourly for pain and how much pain they are having, to judge total time taken since last use of sedation until they request first additional dosage. Also sedation level used throughout recorded and averaged hourly from pre-defined standard scale.

Hemodynamic monitoring and adverse effects

The rate at which your heart beats and the level of your blood pressure and blood oxygen saturation were measured before the operation, at regular intervals during it and afterwards. You were checked for very low blood pressure, slow heartbeat, feeling sick, itchy skin, shortness of breath and for signs of the local anaesthetic being poisonous to your body.

Statistical analysis

Statistical methods were used to examine the data collected through the measurement methods. Continuous variables were measured proportionate to their mean (average) and standard deviation; frequencies and percentages were used for categorical variables. Statistical tests were used to compare continuous interval data across groups; a p value <0.05 would indicate statistical significance.

RESULTS

A total of 100 patients were recruited and divided into group D receiving a population of bupivacaine with dexmedetomidine (n=50) and a population of bupivacaine plus fentanyl (n=50). Patient’s age, sex, weight, and ASA status were similar between the two groups at baseline. In group D, the time to onset of sensory and motor blocks were statistically significant earlier than group F. The sensory, and motor block duration and postoperative analgesia in group D was statistically significantly longer than group F. Both groups maintained stable hemodynamics throughout the study period. Patients in group D had mildly sedated patients more frequently than in group F. Patients in group D required rescue analgesics less frequently than group F but the times to receive those rescue analgesics was delayed. Adverse effects were very few in both groups and all reported comparable levels, but none experienced any seriously adverse effects. The authors concluded that the inclusion of dexmedetomidine to a supraclavicular brachial plexus block with bupivacaine creates a superior block with increases in duration of analgesic effect. Table 1 shows that both groups were comparable with respect to age, sex, and body weight, with no statistically significant differences between the groups.

Table 1: Demographic profile of patients

Parameter	Group D (n = 50)	Group F (n = 50)
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Age (years, mean ± SD)	42.6 ± 11.2	41.9 ± 10.8
Male/Female	32 / 18	30 / 20
Weight (kg, mean ± SD)	64.8 ± 8.5	65.3 ± 7.9

Table 2 shows a similar distribution of ASA I and ASA II patients in both groups.

Table 2: ASA physical status distribution

ASA status	Group D (n = 50)	Group F (n = 50)
ASA I	34 (68%)	36 (72%)
ASA II	16 (32%)	14 (28%)

Table 3 shows that the types of upper limb surgeries were comparable between the two groups.

Table 3: Type of surgery performed

Type of surgery	Group D (n = 50)	Group F (n = 50)
Forearm fracture fixation	22 (44%)	21 (42%)
Hand surgery	15 (30%)	16 (32%)
Elbow procedures	13 (26%)	13 (26%)

Table 4 shows that the onset of both sensory and motor block was faster in Group D compared to Group F.

Table 4: Onset time of sensory and motor block (minutes)

Parameter	Group D (mean ± SD)	Group F (mean ± SD)
Sensory block onset (min)	8.4 ± 1.6	10.2 ± 1.8
Motor block onset (min)	11.6 ± 2.1	13.8 ± 2.3

Table 5 shows that the duration of both sensory and motor block was longer in Group D compared to Group F.

Table 5: Duration of Sensory and Motor Block (Minutes)

Parameter	Group D (mean ± SD)	Group F (mean ± SD)
Sensory block duration (min)	620 ± 78	420 ± 65
Motor block duration (min)	540 ± 72	360 ± 58

Table 6 shows that the duration of postoperative analgesia was markedly longer in Group D than in Group F.

Table 6: Duration of Postoperative Analgesia (Minutes)

Parameter	Group D (mean ± SD)	Group F (mean ± SD)
Duration of analgesia (min)	680 ± 85	460 ± 70

Table 7 shows that mild sedation was more frequently observed in Group D compared to Group F.

Table 7: Sedation Scores Intraoperatively

Sedation score	Group D (n = 50)	Group F (n = 50)
Score 1	12 (24%)	28 (56%)
Score 2	28 (56%)	20 (40%)
Score 3	10 (20%)	2 (4%)

Table 8 shows that heart rate and mean arterial pressure remained stable and comparable in both groups.

Table 8: Hemodynamic parameters (mean values)

Parameter	Group D (mean ± SD)	Group F (mean ± SD)
Heart rate (beats/min)	72 ± 8	74 ± 9
Mean arterial pressure (mmHg)	88 ± 6	90 ± 7

Table 9 shows that patients in Group D required rescue analgesia later compared to Group F.

Table 9: Time to First Rescue Analgesic Requirement

Time to rescue analgesia	Group D (n = 50)	Group F (n = 50)
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< 6 hours	6 (12%)	24 (48%)
6–10 hours	18 (36%)	20 (40%)
> 10 hours	26 (52%)	6 (12%)

Table 10 shows that adverse effects were minimal and comparable between the two groups.

Table 10: Adverse Effects Observed

Adverse effect	Group D (n = 50)	Group F (n = 50)
Bradycardia	3 (6%)	1 (2%)
Hypotension	2 (4%)	2 (4%)
Nausea/Vomiting	1 (2%)	3 (6%)
Pruritus	0 (0%)	2 (4%)

Table 1 shows that the mean age (42.6 ± 11.2 vs 41.9 ± 10.8 years), sex distribution (32/18 vs 30/20), and body weight (64.8 ± 8.5 vs 65.3 ± 7.9 kg) were comparable between Group D and Group F, indicating baseline demographic similarity. Table 2 demonstrates that ASA I patients constituted 68% in Group D and 72% in Group F, while ASA II patients were 32% and 28%, respectively, confirming comparable preoperative physical status. Table 3 indicates a similar distribution of surgical procedures, with forearm fracture fixation being the most common (44% vs 42%), followed by hand surgeries (30% vs 32%) and elbow procedures (26% vs 26%). Table 4 shows that the onset of sensory block (8.4 ± 1.6 vs 10.2 ± 1.8 minutes) and motor block (11.6 ± 2.1 vs 13.8 ± 2.3 minutes) was faster in Group D compared to Group F. Table 5 demonstrates that the duration of sensory block (620 ± 78 vs 420 ± 65 minutes) and motor block (540 ± 72 vs 360 ± 58 minutes) was longer in Group D than in Group F. Table 6 shows that the duration of postoperative analgesia was prolonged in Group D (680 ± 85 minutes) compared to Group F (460 ± 70 minutes). Table 7 indicates that mild to moderate sedation (scores 2 and 3) was more frequent in Group D (76%) than in Group F (44%). Table 8 shows that mean heart rate (72 ± 8 vs 74 ± 9 beats/min) and mean arterial pressure (88 ± 6 vs 90 ± 7 mmHg) remained stable and comparable between the two groups. Table 9 demonstrates that more patients in Group D (52%) required rescue analgesia after more than 10 hours compared to Group F (12%), indicating prolonged analgesia with dexmedetomidine. Table 10 shows that adverse effects were infrequent and comparable between the groups, with slightly higher pruritus and nausea/vomiting in Group F and slightly higher bradycardia in Group D.

DISCUSSION

The present present prospective randomized comparative study was conducted over a period of 12 months in 100 patients undergoing elective upper limb surgeries under supraclavicular brachial plexus block to compare dexmedetomidine and fentanyl as adjuvants to bupivacaine [11]. The observations

made in the present study indicate that dexmedetomidine, when used as an adjuvant to bupivacaine, helps to achieve a faster onset of sensory and motor block and significantly prolongs the duration of sensory and motor blockade and also prolongs the duration of the postoperative analgesia when compared to fentanyl, while maintaining hemodynamic stability and lowering side effects [12,13]. In the present study, baseline demographic characteristics and ASA physical status were comparable in the two groups. Thus differences in block characteristics and analgesic profile can be attributed primarily to the pharmacological effects of the adjuvants used and not to confounding patient factors [14]. Faster onset of sensory and motor block attributed to dexmedetomidine in the present study could be explained by its action on α_2 adrenergic receptors, which enhances the local anesthetic effect due to hyperpolarization of nerve fibers and inhibition of the propagation of the action potential. This synergistic interaction with bupivacaine would thus account for an earlier establishment of surgical anesthesia in Group D [15].

The most striking aspect of our study was the significantly longer duration of sensory block, motor block and postoperative analgesia produced by dexmedetomidine compared with fentanyl. Dexmedetomidine prolongs the duration of block as well as enhances intraoperative and postoperative analgesia thus reducing the need for rescue analgesic to avoid pain [16]. The neural effects are probably due both to peripheral and/or central activity, including vasoconstriction at the site of injection (which will reduce local anesthetic systemic absorption) and direct action on the nerve fibers that enhances and prolongs neural blockade [17]. Fentanyl also improved the quality of analgesia through the addition to bupivacaine, but relatively its duration of block and age (dose) of postoperative analgesia was found to be less when compared to dexmedetomidine [18]. Although it is undoubtedly true that the distinct and plausible factor that all opioids (fentanyl and buprenorphine), show agonistic effects on the μ -receptors throughout the body, supporting its value in improving analgesia from peripheral opioid receptors and perhaps central

site absorption only improves the effect but does not tend to prolong the blockade of the various nerves in relation to the significantly longer act of 2 μ -adrenergic agonists such as dexmedetomidine [19]. Studies have reported on the concentration of local anesthetic in plasma and blood levels for sural, femoral, sciatic, ulnar, median, and radial nerves blocking contribute in some ways to fetotoxicity of local anesthetics especially when given intravenously. However, suggest a relevant risk of giving bolus doses of scar neuroaxonal local anesthetics that are capable of producing a blockade so its clinical implications should be taken seriously [20].

Despite some invalid results, most major side effects created take-mreplace the previous reference about 3-6% incidence of sexual dyspareunia. Fortunately, no serious adverse events (nausea, pruritus, vomiting, and hypotension) were reported. The study recommends the use of dexmedetomidine as a better additive to bupivacaine for prolongation of brachial plexus blocks. By using dexmedetomidine in block the rafficiation rate would be fullest and possibly warrant increased patient satisfaction. It will enable for prolongation of post-operative period thereby there will not be need for any early rescue doses of postoperative analgesics which will help better comfort and look after staff. Hemodynamic profile was well maintained in both groups all through the perioperative period without any significant variations between the groups. A mild sedation was seen to be more common in the dexmedetomidine group. Complicated side effects like deep sedation, hypotension, respiratory depression and increased nausea and vomiting were least in both groups.

CONCLUSION

This is a randomized controlled trial which followed up to 100 patients who were indicated for elective surgery upon their upper limbs for a period of 12 months. The findings demonstrate that dexmedetomidine acts as an effective adjunct to bupivacaine in supraclavicular brachial plexus blocks in contrast to fentanyl's use with bupivacaine, providing a definite advantage. For example, dexmedetomidine significantly shortened the onset and shortened the duration of both sensory and motor block to extended the duration of both; similarly, the length of postoperative period without pain after surgery was prolonged by 12hr (for the entire length of pain relief, not only the first 2hr) compared to the control group. Hemodynamics were stable throughout the (and measured against the two treatment groups); so this did not produce significant hemodynamic instability or increased incidence of complications. Finally, both groups experienced very few adverse effects, but mild sedation appeared

considerably often within the dexmedetomidine group compared to the fentanyl group.

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