

COMPARISON OF FENTANYL AND DEXMEDETOMIDINE AS AN ADJUVANT TO LEVOBUPIVACAINE IN BRACHIAL PLEXUS BLOCK IN UPPER LIMB ORTHOPAEDIC SURGERIES: A PROSPECTIVE, DOUBLE BLIND, RANDOMISED CONTROLLED STUDY

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ABSTRACT

Background: Supraclavicular brachial plexus block is a preferred anaesthetic technique for conducting upper limb orthopaedic surgeries. This study was conducted with the aim of comparing the efficacy of Fentanyl and Dexmedetomidine when used as an adjuvant with Levobupivacaine in terms of the blockade characteristics such as duration of analgesia, onset time of sensory and motor block, and associated side effects. **Materials and Methods:** After approval from institutions ethical committee and written informed consent, seventy patients were included in this double blind randomised controlled study. They were divided in two groups of 35 each, with group LF receiving 20 ml 0.5% levobupivacaine with 1 ml fentanyl(50mcg) and group LD receiving 20 ml 0.5% levobupivacaine with 1 ml dexmedetomidine (50mcg). Students's t test and Chi square test were used for statistical analysis of continuous and categorical data, respectively. **Result:** Group LD had significantly longer duration of analgesia as compared to group LF (384 \pm 79.57 vs 342.48 \pm 89.38, $p < 0.001$). Group LD required lesser number of rescue analgesics (2.36 \pm 0.64) in first 24 hrs of postoperative period. Bradycardia was observed in 4 patients while hypotension was observed in 3 patients in group LD but no statistical difference was observed in the overall side effect profile of the two groups. **Conclusion:** Dexmedetomidine provides prolonged duration of analgesia with a comparable side effect and adverse event profile as compared to fentanyl when used as an adjuvant in the brachial plexus block.

INTRODUCTION

Regional anaesthesia is a safe approach for orthopaedic surgeries because of its simplicity, ability to preserve consciousness, avoidance of airway instrumentation, rapid recovery and significant postoperative analgesia. Brachial plexus block is one such approach that has been widely used for upper limb orthopaedic surgeries. It can be administered by various approaches with supraclavicular approach being preferably used for forearm surgeries.^[1] The block is performed at the level of the brachial plexus trunks where the majority of sensory, motor and sympathetic innervation is confined to a very small surface area.^[2,3] Levobupivacaine is a levo isomer of commonly used drug bupivacaine which provides almost comparable anaesthetic effect but with lower incidence of cardiotoxicity.^[4] Use of adjuvants is a commonly

used method to prolong the effect of local anaesthetics, but the ideal adjuvant is yet to be ascertained. Though fentanyl and other opioids have been used to prolong the duration of analgesia, newer drugs such as dexmedetomidine are supposed to provide similar effects alongwith the ability to provide conscious sedation, similar to its intravenous properties.^[5,6] The addition of fentanyl to regional nerve/plexus blocks has shown to prolong the duration of sensory and motor block but at the cost of delayed onset when compared with plain local anaesthetic. The addition of dexmedetomidine to local anaesthetics has shown similar prolongation of the duration of sensory blockade and post-operative pain relief but with limited effect on onset and motor blockade.^[7]

This study was conducted with the aim of comparing the efficacy of Fentanyl and Dexmedetomidine when added to 0.5% Levobupivacaine as an adjuvant in the

supraclavicular brachial plexus lock with regards to the blockade characteristics such as the onset time of sensory and motor block, duration of analgesia, and associated side effects.

MATERIALS AND METHODS

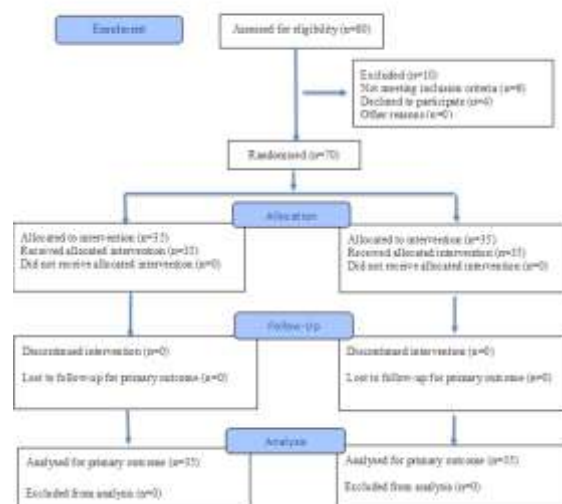
After approval from ethical committee and written informed consent from patients, a prospective, double blind, randomised controlled study was carried out in the Operation theatre complex in a tertiary care institute over a duration of one year. Seventy patients were randomized into two groups of 35 each according to inclusion criteria [Figure 1]. The inclusion criteria were patients of age group 18-65 years, scheduled for forearm surgeries with ASA physical status I to II and belonging to either gender. Exclusion Criteria were patients with known hypersensitivity to local anaesthetic drugs, bleeding disorders, pre-existing neuropathy, any hepatic, renal, neurological, psychiatric, or neuromuscular disease, pregnant females and infection at local site. On arrival in the operation theatre, monitors according to ASA protocols were attached and baseline heart rate, blood pressure and oxygen saturation were recorded. In preoperative room, an intravenous line (IV) was secured on the unaffected limb and IV fluid was administered at rate of 10 ml/kg. All the patients were administered 1mg of Inj Midazolam IV. Patients were randomly allocated to either of the two groups on the basis of computer generated random sequences. Patients in group LF received 20 ml of 0.5% Levobupivacaine with 50 mcg Fentanyl diluted upto total volume of 21 ml while group LD received 20 ml of 0.5% Levobupivacaine with 50 mcg Dexmedetomidine as an adjuvant diluted upto 21 ml of volume. The patient was laid in semi-fowler position with head turned to the opposite side and arm adducted to the side. After sterilisation of local area with chlorhexidine solution, local anaesthetic infiltration with 2% lignocaine was done 1-2 cm posteriorly to the midpoint of clavicle after palpating the subclavian artery. A stimplex needle was inserted laterally to the artery directed posteriorly and towards ipsilateral nipple and drug was given after distal motor response was elicited. Following negative aspiration, 21 ml of local anaesthetic solution admixed with an adjuvant was injected. Anaesthetist administering the block was not part of the study.

The primary objective of the study was comparison of duration of analgesia in both the groups. Blockade characteristics like onset of sensory and motor effects, requirement of rescue analgesic and adverse events were included in secondary objectives. Assessment of sensory block was done by pinprick method every minute after drug injection. Sensory onset was considered when there was complete loss of sensation to pinprick. Assessment of motor block was evaluated using assessment of motor power in upper limb and onset of the block was considered

when there was complete motor block with inability to move fingers. The block was labelled as failed, if anaesthesia was found to be inadequate in any major nerve distribution even after 30 minutes of drug injection and was excluded from the study. Duration of sensory block was defined as the time interval between complete sensory block to complete recovery from cold and pain sensation as tested by a spirit swab and pinprick in all nerves. The duration of motor block was defined as the time interval between the end of the local anaesthetic administration and the recovery of complete motor function of the hand and forearm. Numeric rating scale was used for assessment of pain and was observed for 24 hrs. Rescue analgesia was administered to the patient when score ≥ 4 . Duration of analgesia was calculated from the time of sensory onset to first dose of rescue analgesic. Inj Tramadol 100 mg iv was administered as rescue analgesic when VAS scores of ≥ 4 was recorded. All patients were observed for occurrence of adverse effects such as nausea, vomiting, dryness of mouth, pruritus, sedation, respiratory distress, phrenic nerve palsy, pneumothorax, Horner's syndrome, recurrent laryngeal nerve palsy and vascular injury. Hypotension was defined as fall in mean arterial pressure $>20\%$ of baseline value and bradycardia when HR ≤ 60 /minutes. These were corrected with 200 ml fluid bolus or ephedrine 6 mg if required and Inj Atropine 0.6 mg IV, respectively. Depth of sedation was measured using Ramsay Sedation Scale.

On the basis of Elfawal et al,^[8] the sample size was calculated using n-Master 2.0 software taking superiority margin of onset time of sensory block as 6.3 at 80% power and 5% alpha error. Thus, the required sample size was 32 cases in each group, considering 10% drop out rate, 35 patients were included in each group. The randomisation was achieved with computer generated random numbers.

Figure 1: CONSORT 2025 Flow Diagram



Data was entered and compiled in Microsoft excel sheets. For normally distributed data, mean □

standard deviation were calculated using independent Student's t-test. For comparison of proportions, Chi square test was used. The person performing the analysis was blinded about the intervention groups. P-value <0.05 and confidence interval (CI) of 95% were considered significant. SPSS trial version was utilised for data analysis.

RESULTS

Seventy patients were randomly divided in two groups of 35 each [Figure 1]. Demographic characteristics were comparable in all the groups. [Table 1]. The mean duration of analgesia in Group LF was significantly shorter than group LD ($p < 0.001$). This led to significant reduction of total analgesic requirement in the Group LD [Table 2].

Significant difference was observed in the onset of sensory and motor blockade between the two groups ($p < 0.001$) [Table 2]. A statistically significant difference was observed between the total duration of sensory blockade with group LD having prolonged duration ($p < 0.001$) [Table 2]. There was a statistically significant difference observed in the duration of motor blockade too ($p < 0.001$) with group LD registering longer duration [Table 2].

Side effects and adverse events were not statistically significant between the two groups ($p = 0.813$), but incidence of bradycardia and hypotension was observed to be more in group LD [Figure 2]. Numeric rating scale for pain was comparable in both the groups. No sedation was observed in any of the patients in any of the groups. Haemodynamic parameters were also comparable across all the groups during periods of monitoring.

Table 1: Demographic characteristics

S.no.	Variable	Group LF(n=35)	Group LD(n=35)	P value
1	Age	33.90±12.19	35.72±8.19	0.18
2	Weight	65.60±6.89	66.06±6.54	0.32
3	Height	165.03±6.32	166.75±6.13	0.47
4	BMI	23.88±2.35	22.96±2.53	0.65
5	Gender(Male/Female)	18/17	17/18	0.50
6	ASA(I/II)	15/20	17/18	0.66

Table 2: Blockade characteristics of group LF and group LD

S. no.	Variable	Group LF(n=35)	Group LD(n=35)	P value
1	Time of onset of Sensory block(min)	12.35±1.65	14.05±2.09	<0.001
2	Duration of Sensory block(min)	351.27±68.59	410±78.95	<0.001
3	Onset of Motor block(min)	15.85±4.51	16.14±3.15	<0.001
4	Duration of Motor block(min)	279.79±57.79	355±65.57	<0.001
5	Total duration of analgesia(min)	342.48±89.38	384±79.57	<0.001
6	Rescue Analgesic required(gram)	3.15±0.45	2.36±0.64	<0.001

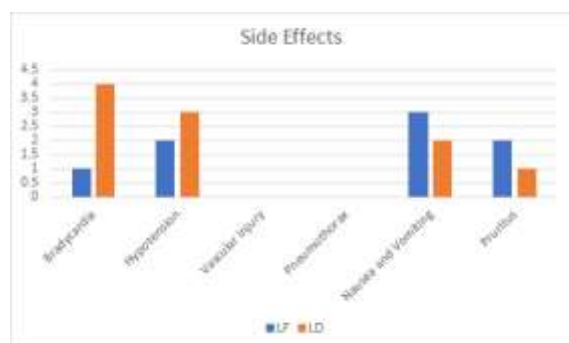


Figure 2: Side Effects in group LF and LD

DISCUSSION

Levobupivacaine is widely used for peripheral nerve blockade in combination with other local anaesthetics like lignocaine and a variety of adjuvants to produce desirable effect. Levobupivacaine provides an optimal duration of sensorimotor blockade with a comparatively safer drug profile as compared to bupivacaine.^[4] There has always been a search for an ideal adjuvant in regional nerve blocks that would provide rapid onset of action, prolong the duration of analgesia and have minimal or no side effects. The present study was conducted to compare the effect of

levobupivacaine with fentanyl or dexmedetomidine in terms of duration of analgesia, onset and total duration of sensory and motor blockade along with their possible side effects. Both the groups were comparable with respect to demographic characteristics i.e. gender, ASA physical status grading, age, weight, height and body mass index.

The total duration of analgesia was significantly greater in group LD as compared to group LF (384±79.57 min vs 342.48±89.38 min) ($p < 0.001$). Swaro et al. observed significant increase in duration of analgesia in dexmedetomidine group (471.44±65.88 min) as compared to fentanyl group (366.48±38.02 min) ($p < 0.01$).^[9] Sahi et al. also made the similar observations where mean duration of total analgesia was maximum in the dexmedetomidine group (619.92±21.67 min.) followed by fentanyl group (559.82±21.66 min) ($p < 0.01$).^[10] Dharmarao et al also made the similar observations that addition of dexmedetomidine significantly prolongs the duration of analgesia (801.75±46.07 min vs 590.25±40.41 min; $p < 0.001$).^[11] The analgesic effect of fentanyl could be attributed to its direct action on the peripheral nervous system. The existence of endogenous and exogenous opioid receptors in the peripheral nervous system and the initiation of anti-

nociceptive action by the activation of such receptors offer the possibility of extended analgesic action.^[12] The mechanism of the analgesic effect of dexmedetomidine is multifactorial. It produces analgesia peripherally by reducing norepinephrine release and increasing the potassium conduction in C and A delta neurons responsible for passage of pain stimulus, whereas it produces analgesia and sedation centrally by inhibition of substance P release in the nociceptive pathway at the level of the dorsal root ganglia and locus ceruleus.^[13-15]

In present study, mean time of onset of sensory block was significantly lower with fentanyl as compared to dexmedetomidine [Table 2]. This was in contrast to the previous studies conducted by various researchers. Hamed et al. observed a statistically significance difference between dexmedetomidine group (5.75 ± 2.2 min) as compared to fentanyl group (11.8 ± 3.4 min) in supraclavicular block.^[16] As compared to this study, their onset time of sensory blockade was lower which may be attributed to higher dosage of adjuvant ($1\mu\text{g}/\text{kg}$) used in their study. In the study by Swaro et al, they observed that the onset of sensory block was faster in Group BD (2.108 ± 0.68 minutes) than in Group BF (8.4 ± 1.27 minutes), with a p-value < 0.001 .^[9] This finding is also opposite to our observations and may be due to use of difference in the properties of local anaesthetics used and the difference in dosage used. In the study by Sahi et al the onset of sensory blockade was comparable in both the groups (2.32 ± 0.51 min vs 2.53 ± 0.48 min, respectively).^[10] Cham et al also observed faster onset with dexmedetomidine group as compared to fentanyl group due to higher volume of local anaesthetic used (2.13 ± 0.34 minutes and 2.06 ± 25 min, respectively; $p < 0.05$).^[17] Dharmarao et al. observed comparable onset times as compared to our study but onset was till faster in dexmedetomidine group (13.95 ± 1.34 min vs 14.18 ± 1.41 min).^[11]

In this study, duration of sensory blockade was observed to be significantly higher in group LD as compared to group LF [Table 2]. Various previous researchers have made the similar observations. Swaro et al. observed that the duration of sensory block was 452.96 ± 77.12 minutes in dexmedetomidine group as compared to 363.4 ± 38.36 minutes in patients receiving fentanyl as adjuvant.^[9] Sahi et al observed mean duration of the sensory blockade to be higher in dexmedetomidine group (582.47 ± 20.96 min) as compared to fentanyl group (474.82 min ± 10.87 min), (P-value < 0.01).^[10]

In the present study, the mean time of onset of the motor blockade was significantly lower with fentanyl group (10.41 and 23.03 min) as compared to dexmedetomidine (11.88 and 25.77 min) group (P-value < 0.01). But the total duration of motor block was significantly higher with dexmedetomidine as compared to fentanyl group (405.16 min versus 297.97 min; P-value < 0.01). The results of our study are comparable to various previous studies who have made the similar observations regarding the duration

of motor blockade with the use of dexmedetomidine as an adjuvant in perineural blockade. In a study conducted by Aggarwal et al. made similar observation about duration of analgesia and sensorimotor blockade but their duration was higher probably because they used higher dosage of dexmedetomidine $100\mu\text{g}$ as compared to our study $50\mu\text{g}$ dexmedetomidine.^[18] Dharmarao et al. observed that onset of motor blockade was not statistically significant among the two study groups, but difference in the duration of motor blockade was statistically significant (649.56 ± 42.73 min vs 456.75 ± 32.93 min).^[11]

In contrast to previous studies, sedation was not reported in any of the groups. Dharmrao P et al. observed mean sedation scores were significantly higher in dexmedetomidine group than fentanyl group in the 1st 24 hours post-operative period ($P < 0.01$).^[11] They observed that 6 patients had a sedation score of 3 in dexmedetomidine group, although there were no cases of respiratory depression in any of the patients in both groups.

Haemodynamic parameters were comparable in both the groups, in this study. Though dexmedetomidine group had higher incidence of bradycardia and hypotension, it was not statistically significant at any time during perioperative period. Similar observations have been made by previous studies conducted by various researchers.^[19-21] Abdallah et al. conducted a meta analysis and made observations that perineural application of dexmedetomidine as a local anaesthetic adjuvant stated that dexmedetomidine produced reversible bradycardia in 7-20% of brachial plexus lock patients with no incidence of hypotension.^[22] Swaro et al and Sahi et al also made the similar observations with higher incidence of bradycardia in Dexmedetomidine group as compared to other adjuvants.^[9,10]

This study had a few limitations such as comparatively small sample size, non-measurement of plasma drug levels for better co relation with systemic effects and non-inclusion of geriatric age group patients who frequently require carefully titrated medications to undergo such procedures.

CONCLUSION

This study observes that addition of dexmedetomidine as an adjuvant to levobupivacaine produces a more prolonged duration of sensorimotor blockade and post-operative analgesia as compared to fentanyl as an adjuvant in supraclavicular approach of brachial plexus block. Further research may be required to assess the amount of drug that can be safely used as an adjuvant for regional anaesthesia.

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