Original Research

A Randomised Comparative Study Of Dexmedetomidine Vs Fentanyl As An Adjuvant To 0.5 % Levobupivacaine In Peripheral Nerve Stimulator Guided Supraclavicular Brachial Plexus Block In Adult Patients Undergoing Elective Upper Limb Surgeries

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Abstract
Aim: To compare the sensory and motor blocking properties 0.5% Levobupivacaine + Dexmedetomidine or Fentanyl combinations in supraclavicular brachial plexus block using nerve stimulator for elective upper limb surgeries.
Material and Methods: Sixty patients aged between 18 – 60 years belonging to ASA class I and II posted for elective upper limb surgeries were randomly divided into two groups. Each group consisting of 30 patients to receive supraclavicular brachial plexus block with 30 cc of 0.5% Levobupivacaine + 50µg, 0.5 cc Dexmedetomidine (group D) and 30 cc of 0.5 % Levobupivacaine + 100mg, 2 cc Fentanyl (group F).
Results: 0.5% Levobupivacaine + Dexmedetomidine combination have quick onset of sensory and motor blockade than 0.5% Levobupivacaine + Fentanyl. There is significant prolongation in duration of sensory and motot blockade with 0.5 % Levobupivacaine + Dexmedetomidine than 0.5% Levobupivacaine + Fentanyl.
Conclusion: It can be concluded that while adding Dexmedetomidine as an adjuvant to 0.5 % Levobupivacaine produces quick onset of sensory and motor blockade, more prolonged duration of sensory blockade and more prolongation in duration of analgesia than with Fentanyl.
Keywords: Upper Limb, Surgeries, Supraclavicular Brachial Plexus, Dexmedetomidine, Fentanyl

Introduction

Brachial plexus block is a common means of nerve block and has been widely used in hand surgery. Brachial plexus block has evolved as an important tool in the anaesthesiologist's arsenal as a safe alternative to general anaesthesia for upper limb surgery and relief of perioperative pain. Its increased popularity is because of advancements in regional anaesthesia techniques in terms of local anaesthetic drugs, newer adjuvant drugs, and the use of peripheral nerve stimulators and ultrasound for the safe and successful conduct of block. It helps in reduced hospital stay, less financial burden, and also leads to avoidance of undesirable side effects of general anaesthesia. Since the introduction of first brachial plexus block using cocaine by Halstead (1884), the technique of brachial plexus block has evolved from the classical blind technique to the use of nerve stimulators and ultrasound guidance for supraclavicular brachial plexus block. (1) Many additives to local anaesthetics such as opioids, clonidine, neostigmine, and tramadol etc. have been used to increase the duration of the block to improve postoperative pain management (2) and to avoid the need for placing a catheter for continuous local anaesthetic drug infusion. Drugs like Morphine, Neostigmine, Fentanyl, Hyaluronidase, Midazolam, Dexmedetomidine, Clonidine, Dexamethasone etc., have been added to local anaesthetics as an adjuvants to improve the quality of blockade and duration of

action and postoperative analgesia. Dexmedetomidine (3) is an alpha 2 agonist widely used as an adjuvant to regional techniques. It prolongs the duration of action to more than 10 hours without causing any respiratory depression. Dexmedetomidine is highly selective (4) time more selective than clonidine), specific and potent α2-adrenergic agonist having analgesic, sedative, antihypertensive, and anaesthetic sparing effects when used in systemic route (3) Adding dexmedetomidine to local anaesthetics during peripheral nerve blockade and regional anaesthesia procedures may also prove efficacious for the surgical patients. Fentanyl is a potent synthetic opioid analgesic. The addition of opioids in brachial plexus block is reported to improve success rate and postoperative analgesia (1,3). The current study is designed with aim to evaluate and compare the effect of adding dexmedetomidine and fentanyl to 0.5% levobupivacaine in Peripheral Nerve Stimulator guided supraclavicular brachial plexus block in adult patients in terms of onset and duration of sensory and motor block, quality of block, duration of postoperative analgesia, haemodynamic changes (viz. Heart Rate, Mean Arterial Pressure, Systolic Blood Pressure, Diastolic Blood Pressure and O2 Saturation (SpO2) if any), requirement of rescue analgesia and to find out any complications.

Materials And Methods

After approval of the institutional ethics committee all participants were asked for written and informed consent and were divided into two groups. Eighty patients of American Society of Anaesthesiologist (ASA) physical status Grade I and II of either sex and age between the 18 to 60 years admitted to SVBP Hospital associated to LLRM Medical College, Meerut undergoing various upper limb elective surgeries were included in the study.

Inclusion Criteria

1. ASA grade –I and grade –II Patients
2. Age- 18 to 60 years of either sex

Exclusion Criteria: Patient refusal, Infection at injection site, Coagulopathy, Pregnancy, Major Central Nervous System, Cardiovascular System, Respiratory System and Haematologic system abnormalities. Randomization was done using sealed envelopes technique. A sealed envelope was randomly selected and opened by a qualified anaesthesiologist with instructions to draw up the relevant drug. The syringe was labelled with the patient's name and handed over to the investigator who then performed the block. Patients were randomly divided into two groups i.e. GROUP D -Levobupivacaine (25 cc) + Dexmedetomidine (50 mcg, 0.5 cc) + 4.5 cc Normal Saline- Total volume 30 cc and GROUP F- Levobupivacaine 0.5% (25 cc) + Fentanyl (100 mg, 2 cc) + 3 cc normal saline- Total volume 30 cc.An independent observer (qualified anaesthesiologist not included in the study) then was present to observe the onset and offset of sensory and motor blockade, haemodynamic changes (viz. Heart Rate, Mean Arterial Pressure, Systolic Blood Pressure, Diastolic Blood Pressure and O2 Saturation), rescue analgesic requirement and complications which occurred.

Sensory Block: Was assessed by pin-prick method by a three-point scale:

- 0-normal sensation
- 1-loss of sensation of pin-prick (analgesia)
- 2-loss of sensation of touch (anaesthesia)

Motor Block: Motor block assessment was done according to Modified Bromage scale for upper extremities on a three-point scale:

- Grade 0: normal motor function with full flexion and extension of elbow, wrist and fingers.
- Grade 1: decreased motor strength with ability to move fingers only.
- Grade 2: complete motor block with inability to move fingers. Sensory and motor blocks were evaluated every minute until 5 minutes after injection and then every 5 minute until 30 minutes, and after that every 30 minutes until 120 minutes or till duration of surgery. Rescue analgesia was given on patient's demand. Total duration of analgesia was defined as the time from commencement of block to the patient's first request for rescue analgesic. Injection diclofenac sodium aqueous solution, 75 mg IV infusion was given as rescue analgesic. Patients undergoing the study were also observed for incidence of complications like: Drowsiness, Pruritus, Nausea/vomiting, Horner's syndrome, Phrenic nerve palsy, Pneumothorax, Respiratory depression and any signs and symptoms for local anaesthetic toxicity and were recorded in case any complications occur. As seen over many supraclavicular blocks distal responses produces more effective block rather a proximal one. Proximal responses are contraction of the biceps, triceps, flexor carpi radialis or flexor carpi ulnaris. Those are to be ignored. Initial proximal (deltoid) responses are observed followed by more distal (extension/flexion of wrist) responses. The distal responses are the flexion or extension of the wrist or fingers, which are to be accepted.

Statistical Analysis

Statistical analysis was performed using SPSS (Statistical Package for the Social Sciences) for Windows (version 16.0). Categorical variables were described as frequency (percentage), mean ± standard deviation was used for continuous parameters. Differences between two groups were compared by the Student T test. For non-parametric variables, the data are presented as median (min-max). In this case, the nonparametric Mann–Whitney test was used for statistical comparisons. Categorical variables were compared between two or more groups using the Chi-square test. For all analyses, a two-tailed p-value of <0.05 was considered statistically significant.

Results

The mean age of the study group D was 36.45 + 12.8 years (mean+s.d.) and group F was 38.96+9.38 years respectively 18-60 years. The gender wise distribution of study participants showed that majority of them were males (67.5%) and 32.5% were females. There were 22 males in Group D and 22 males in Group F. There were 8 females in Group D and 8 females in Group F. Table 1 shows the mean change in Pulse rates over the follow up period between both study groups. The mean difference between both groups was significant at 3, 5, 10, 15, 20, 30, 60 and 120 minutes after administration of the drug.

Table 1: Pulse Rate variation among study subjects

HEART RATE	Group D		Group F		p-value
	Mean	SD	Mean	SD	
At Baseline	79.9	16.6	81.7	17.1	0.42
1 min	87.1	9.9	81.8	8.7	0.35
2 min	85.06	8.13	83.53	8.63	0.32
3 min	85.5	7.29	81.5	7.93	0.050*
5 min	76.9	8.15	84.1	6.91	<0.001*
10 min	75.1	6.2	80.7	7.68	0.05*
15 min	73.6	5.74	80.1	7.65	0.39
20min	71.6	6.56	80.16	7.16	0.05*
30min	70.4	4.59	80.5	6.74	0.04*
60 min	68.6	5.52	80.06	7.31	0.01*
120 min	65.5	5.77	79.6	7.49	<0.001*

Table 2: Mean Arterial Blood Pressure (MAP) variation among study subjects

MAP Levels	Group D		Group F		p-value
	Mean	SD	Mean	SD	
At Baseline	94.96	4.72	99.56	4.14	0.001
1 min	100	4.41	99.63	4.21	0.03
2 min	100.7	4.13	98.8	4.31	0.06
3 min	100.4	3.40	97.63	3.95	0.07
5 min	96.3	2.99	97.26	4.05	0.02*
10 min	96.2	4.09	96.7	4.06	0.68
15 min	94.7	2.99	96.23	4.01	0.01*
20min	92.7	3.10	95.9	4.59	0.003*
30min	93.76	3.82	96.2	4.03	0.019*
60 min	92.6	3.80	95.96	4.10	0.001*
120 min	90.3	3.79	95.8	4.23	<0.001*

The mean difference w.r.t. SBP between both groups was significant at baseline, 30 min, 60 min, and 120 minutes after administration of the drug. The mean difference w.r.t. DBP between both groups was significant at 15, 20, 60, and 120 minutes after administration of the drug. Table 2 shows the mean change in Mean Arterial Blood Pressure over the follow up period between both study groups. The mean difference between both groups was significant at baseline, 5min, 15min, 20 min, 30 min, 60 minutes and 120 min after administration of the drug. Table 3 shows the mean time of onset of sensory block and motor block among the study groups. The mean time of onset of sensory block in Group D (Levobupivacaine + Dexmedetomidine) was found to be slight quicker than Group F (Levobupivacaine + fentanyl) and the difference between both groups was found to be significant (p= <0.001) and the mean time of onset of motor block in Group D was 11.8 ± 1.94 minutes and in Group F was 18.8 ± 0.97 minutes, so quick onset of motor block with Levobupivacaine + Dexmedetomidine combination and the difference was found to be significant (p <0.001).

Table 3: Mean time of onset of sensory and motor block among study subjects

Onset of Block (in Minutes)	GROUP	N	Mean	SD	p-Value
Sensory Block	Group D	30	7.42	1.38	<0.001*
	Group F	30	12.9	1.47	
Motor Block	Group D	30	11.86	1.94	<0.001*
	Group F	30	18.86	0.97	

Table 4: Mean duration of sensory and motor block among study subjects

Duration of Block (in Minutes)	GROUP	N	Mean	SD	p-Value
Sensory Block	Group D	30	938.5	45.5	<0.0001*
	Group F	30	860.6	17.79	
Motor Block	Group D	30	884.5	66.8	<0.001*
	Group F	30	755	38.84	

The duration of sensory block was prolonged in Group D (Levobupivacaine + Dexmedetomidine) in comparison to Group F (Levobupivacaine + Fentanyl) and the mean difference between both groups in duration of sensory block was found to be highly significant (p < 0.001) and duration of motor block between both groups was found to be significant (p= <0.001) (Table 4).It was found out that the duration of analgesia was significantly (p<0.001) prolonged in Group D (Levobupivacaine + Dexmedetomidine) than Group F (Levobupivacaine + Fentanyl). Table 5 shows the description of complications encountered among study participants. No incidence of complications were noted in any patient in either of the two groups.

Table 5: Complications among study groups

			Complication		Total
			No	Yes	
Group	Group D	N	30	0	30
		%	100 %	0%	50.0%
	Group F	N	30	0	30
		%	100 %	0%	50.0%
Total		N	60	0	60
p-value = <0.001					

Discussion

In our study, the average age of the study group was 37.70 + 11.09 years. Both groups had predominantly male patients. There was statistically non-significant difference in age, and sex distribution in the two groups. In our study we found out that there is significance difference in onset of sensory and motor blockade in both of our study groups. The combination of Levobupivacaine + Dexmedetomidine showed earlier onset of sensory blockade (7.42±1.38) than levobupivacaine + fentanyl combination (12.9±0.973 mins). This difference was found to be statistically significant on data analysis (p<0.001). Also the combination Levobupivacaine + Dexmedetomidine showed earlier onset of motor blockade (11.86±1.947) than levobupivacaine + fentanyl combination (18.86±0.973 mins) and this difference between the study groups was also found statistically significant (p <0.0001). We also found out in our study that there is prolonged sensory blockade by the Levobupivacaine+Dexmedetomidine combination (Group D) in comparison to Levobupivacaine + Fentanyl combination (Group F). The mean duration of sensory blockade Group D was 938.55±45.57 mins and for Group F was 860.66±17.79 mins, and this difference in duration of sensory blockade was found to be statistically significant (p=<0.001).

In our study the mean duration of motor blockade in Group D was 884.59±66.86 mins and in Group F was 755±38.84. The difference in duration of motor blockade in both study groups was found to be significant statistically (p<0.001). We found out significant prolongation in duration of analgesia in groups received Levobupivacaine+ Dexmedetomidine than the other group. The mean duration of analgesia in group received Levobupivacaine+ Dexmedetomidine was 938±45.57 mins and in Levobupivacaine+Fentanyl group was 860.66±17.79. The mean difference between the groups was found to be statistically highly significant (p=<0.001). In a study conducted by Eissa R.E et al (5), addition of dexmedetomidine to 0.5% Levobupivacaine was better than Fentanyl when both are used as adjuvants in ultrasound guided brachial plexus block as demonstrated by prolongation of duration of sensory block, improved quality of postoperative analgesia. Esmaoglu et al (6) in 2010 have shown that dexmedetomidine shortened the sensory block onset time (9.03±1.15 min in dexmedetomidine group vs. 10.46 ± 1.30 min in control group), the motor block onset time (9.50±1.04 min in dexmedetomidine group vs 11.10±1.24 min in control group) and prolonged the duration of the sensory block (887 ± 66.23 min in dexmedetomidine group and 673±73.77 min in control group), duration of the motor block (773±67.62 min in dexmedetomidine group and 575 ± 65 min in control group) and postoperative analgesia 1008.69 ± 164.04 min in dexmedetomidine group and 887.14±260.82 min in control group.

Cline et al (7) found that sensory analgesia was significantly longer with levobupivacaine than with ropivacaine, but ropivacaine patients showed a faster recovery of motor function, while Piangatelli et al (8) showed a faster onset of infraclavicular brachial plexus block with 0.5% levobupivacaine than with 0.5% ropivacaine. In a study conducted by Arvinder et al (9), they concluded that the time to onset of sensory and motor block was 10.54 ± 2.333 min and 12.21±2.529 min in group received only levobupivacaine (Group I) while it was 3.24±0.951 min and 2.83±1.197 min in group received levobupivacaine + dexmedetomidine (Group II), respectively. The duration of sensory and motor block was 7.79±2.007 h and 9.18±1.701 h in Group I, and it was 16.31±2.606 h and 17.52±2.098 h in Group II, respectively. The duration of analgesia was 678.68 ± 20.492 min in Group I and 1273.79 ± 83.139 min in Group II. On statistical comparison, these values were highly significant (P < 0.001). Side effects such as nausea, vomiting, hypoxemia, pruritis, or urinary retention were not observed in either of the groups.A study conducted by Mandir Kaur et al (10) in 120 ASA I and II patients concluded adding dexmedetomidine as an adjuvant to 0.5% levobupivacaine in supraclavicular brachial plexus block shortens the time of onset of sensory and motor block and significantly prolongs the duration of sensory and motor blockade and duration analgesia when compared to addition of fentanyl to levobupivacaine. Kaur et al (10) concluded that Addition of dexmedetomidine to 0.25% levobupivacaine for supraclavicular plexus block shortens sensory, motor block onset time and motor

block durations, extends sensory block, and analgesia durations. Reduction in total levobupivacaine dose also increases the safety margin of the block. Soumya et al (11) concluded that dexmedetomidine added to levobupivacaine in supraclavicular brachial plexus block prolongs the duration of block and the duration of postoperative analgesia. In their study the mean duration of sensory blockade, motor blockade and duration of analgesia with levobupivacaine with dexmedetomidine combination were 840±50.23 minutes, 898±32.33 minutes and 997±154.23 minutes respectively. Local anaesthetics bind directly to the intracellular voltage dependent sodium channels. They block primarily open and inactive sodium channels, at specific sites within channel. Lipid solubility appears to the primary determinant of intrinsic anaesthetic potency (ropivacaine is less lipid soluble than levobupivacaine). Chemical compounds which are highly lipophilic tend to penetrate the nerve membrane more easily, so that less molecules are required for conduction blockade resulting in enhanced potency. For this reason, a strict correlation between the lipid solubility of the local anaesthetic and its potency and toxicity exists. Sinnott et al (12) compared three concentrations of either ropivacaine or levobupivacaine (0.0625, 0.125 and 0.25%) for sciatic nerve block in the rat, and demonstrated that the duration of block induced by 0.25% levobupivacaine was nearly 30% longer than that of ropivacaine. Alley et al (13) evaluated three intrathecal doses of levobupivacaine and bupivacaine (4, 6 and 8 mg) in healthy volunteers and found no differences in clinical profile of sensory and motor blocks and recovery from spinal anaesthesia. The same group also compared the same doses of ropivacaine and bupivacaine in a similar study on volunteers (14) and reported that ropivacaine is half as potent as bupivacaine. The relative potency of the three long-acting local anaesthetics (bupivacaine, levobupivacaine and ropivacaine) has been also evaluated in patients by determining the minimum local anaesthetic concentration (MLAC) producing adequate pain control in 50% of patients receiving an epidural block for labour pain with an up-and-down sequential allocation technique; clinical findings confirmed results of animal studies, showing no differences in the MLAC of levobupivacaine (0.083%) and bupivacaine (0.081%) and nearly 50% higher MLAC values for ropivacaine (15, 16). The incidence of hematoma, pneumothorax, accidental intravascular injection, post block vomiting/convulsions/neuralgia were nil in either group. Intraoperative no complications were noted in any patient in either of the groups. Hemodynamic parameters like HR/BP/SpO2 were within normal limits in both groups. No patient required any intervention.

Conclusion

It can be concluded that while adding Dexmedetomidine as an adjuvant to 0.5 % Levobupivacaine produces quick onset of sensory and motor blockade, more prolonged duration of sensory blockade and more prolongation in duration of analgesia than with Fentanyl. Both of the drug combinations have better haemodynamic profile with negligible adverse effects.

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