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A COMPARATIVE STUDY OF ROPIVACAINE VERSUS ROPIVACAINE WITH DEXMEDETOMIDINE AS AN ADJUVANT IN SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK

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ABSTRACT

BACKGROUND :Supraclavicular approach to brachial plexus block is a versatile and reliable regional anesthesia technique and a suitable alternative to general anesthesia for upper limb surgical procedures.
Ropivacaine , a long acting local anesthetic, with less tendency for neurotoxicity and cardiotoxicity is a great local anesthetic for the procedure.
Use of adjuvant Dexmedetomidine , a potent alpha 2 adrenoreceptor agonist improves the quality of anesthesia as well as intra-operative and post-operative analgesia while maintaining haemodynamic stability, arousable sedation and mild respiratory depression.
MATERIALS AND METHODS: Eighty patients aged between 18 and 60 years with ASA grade I or II posted for elective upper limb surgeries were included in the study and were randomly divided into 2 groups with forty patients in each. Group A received 0.5% ropivacaine (31 mL) and Group B received 0.5% ropivacaine + dexmedetomidine 1microgram/kg (31mL). Both groups were compared for onset time and duration of sensory blockade, onset time and duration of motor blockade ,total duration of analgesia and associated side effects.
CONCLUSION : Dexmedetomidine as an adjuvant to ropivacaine in the supraclavicular brachial plexus block for upper limb surgeries , significantly shortens the onset time and prolongs the duration of sensory and motor blocks, with longer duration of post-operative analgesia , with associated significant sedation and a few manageable side effects like bradycardia and hypotension.

INTRODUCTION :

Pain and sufferings are the primary reasons for which patients seek medical care and treatment and this has been continuing from ages. With the knowledge of anatomy of various nerve structures and familiarity with the pharmacology of anesthetic drugs , various regional anesthesia techniques had developed as a remedy to get rid of the pain in the perioperative. (1)

Brachial plexus block is a versatile and reliable regional anesthesia technique and suitable alternative to general anesthesia for upper limb surgical procedures. Supraclavicular approach to brachial plexus block is the most commonly used approach and it provides the most complete and reliable anesthesia for upper limb surgeries. (2)

Local anesthetics alone in supraclavicular brachial plexus block provide good operative conditions but have shorter duration of postoperative analgesia and increasing the dose of anesthetics lead to an increase in dose related side effects. This led to a search for an anesthetic with lesser side effects but better anesthetic effect. (3)

With the use of Ropivacaine , a long acting local anesthetic , that belongs to amino amide group, some of the side effects of local anesthetics could be overcome. Being a pure S (-) enantiomer, it causes less neurotoxicity and cardiotoxicity than other racemic mixtures or R enantiomers of local anesthetics.Use of Dexmedetomidine along with Ropivacaine in brachial plexus block lead to an achievement of faster, denser and prolonged block.Dexmedetomidine is a very selective and potent a2-adrenoceptor agonist with selectivity for a-receptors a2:a1 at a ratio of 1620:1 , used for its anxiolytic, sedative, and analgesic properties. (4,5)

The present study was undertaken to compare analgesia and effectiveness regarding onset and duration of complete motor and sensory block of 0.5% ropivacaine alone versus 0.5% ropivacaine with dexmedetomidine in patients undergoing elective upper limb surgeries.

MATERIALS AND METHODS :

A randomized double blinded prospective study was undertaken in eighty (80) patients of age in between 18 to 60 years, with physical status ASA I and II, undergoing elective upper limb surgeries, lasting for more than 60 minutes under supraclavicular brachial plexus block. The study was carried out at SILCHAR MEDICAL COLLEGE AND HOSPITAL, Silchar, Assam, during the period of June 1st, 2019 to May 31st, 2020. The study was conducted after obtaining the Institutional Ethical Committee clearance and written informed consent from the patients (study subjects).The patients included in the study were those undergoing elective upper limb surgeries under brachial plexus block.

INCLUSION CRITERIA:

1. Patients aged between 18-60 years, of both sexes.
2. Patients with ASA grade I and II, scheduled for elective upper limb surgeries.
3. Patients who had given written informed consent.

EXCLUSION CRITERIA:

1. An allergy to local anesthetic drug.
2. Any bleeding disorder.
3. Uncontrolled diabetes mellitus, hypertension.
4. Pregnant women.
5. Pre-existing peripheral neuropathy.

PREOPERATIVE PREPARATION :

All the patients selected for the study were evaluated thoroughly on the day prior to surgery. During the pre-anesthetic evaluation, a thorough examination was done which involved proper history taking, examination of various systems including the surface anatomy where the block was to be given and meticulous airway assessment was also carried out prior to surgery. The anesthetic procedure that was planned for surgery and procedure of development of paraesthesia were also explained to the patients ellaborately and an attempt was made to alleviate the anxiety. After obtaining written informed consent, pre-anesthetic preparation was started which included overnight fasting and

all the patients were prescribed oral Alprazolam 0.5 mg the night before surgery. Routine laboratory investigations were performed which included complete haemogram , random blood sugar, routine urine examination, chest X-ray and if required, an ECG.

METHOD OF COLLECTION OF DATA :

Supraclavicular brachial plexus block was carried out on patients planned for an elective upper limb surgery. All drug solutions were prepared by an anesthesiologist not involved in administration of anesthesia, patient care and data collection so as to prevent bias. The patients were randomly allocated into two groups:

Group A (n = 40): Patients in this group received 30 millillitres(mL) of 0.5% Ropivacaine + 1mL saline.

Group B (n = 40): Patients in this group received 30 millillitres(mL) of 0.5% Ropivacaine + 1 microgram (μg)/kilogram (kg) of Inj.Dexmedetomidine reconstituted with Normal saline to 1ml.

All necessary equipments and drugs needed for administration of general anesthesia and for emergency resuscitation were kept ready in order to manage failure of block or any local anesthetic related toxicities. In no patients , the total dose of ropivacaine exceeded 3mg/kg.

DRUG SOLUTION USED AND DOSAGE :

- Ropivacaine 0.75% ampoule was used. 20 mL of this was diluted to 30 mL with 10 mL of 0.9% normal saline to make it 0.5%.
- Dexmedetomidine (100microgram/1mL) was used. Dose of 1 μg/kg taken in a 1mL syringe and reconstituted to 1ml with 0.9% NS was then added to the ropivacaine solution.

A SET CONTAINING THE FOLLOWING WERE USED :

- Insulated stimulator needle: Stimuplex® A 22G 50mm (B Braun, Germany).
- Peripheral nerve stimulator
- 2 mL syringe with 26 G hypodermic needle for skin infiltration of local anesthetic.
- ECG electrode.
- Two 20 mL and one 1mL syringes.
- Sterilize gauze pieces, one sterile swab holding forceps, sterile bowl for povidone iodine, rectified spirit and sterile drapes.

PROCEDURE :

Intravenous access was obtained in the upper limb opposite to that undergoing surgery or in the lower limb with 18 G cannula. Standard monitors with three lead ECG, pulse oximeter, non-invasive blood pressure were connected and the vitals were monitored in the patients. All the patients were premedicated with Inj. Ranitidine 150 mg and Inj. Ondansetron 8 mg IV stat 30 minutes prior to surgery.

Before the start of the procedure, the pre-operative or the baseline values of pulse rate, blood pressure, respiratory rate, oxygen saturation and the sedation score of the patients were recorded. After documenting the baseline parameters, the patients received Inj. Midazolam 1 mg prior to the block.

Under aseptic conditions, brachial plexus block was performed by supraclavicular approach after proper patient positioning. After antiseptic painting and draping, a skin wheal was raised above the midpoint of clavicle with a sub-dermal injection of local anesthetic (2mL Inj. Lidocaine). The stimuplex needle was connected with the nerve stimulator, with current output set at 1.0 mA-1.5 mA and repeat twitch mode selected by the assistant under the guidance of an anesthetist. The needle was inserted caudally, slightly in a medial and posterior direction. On needle insertion, a twitch of the upper trunk (shoulder) was considered as the evidence of the needle approaching the brachial plexus. Wrist flexion and flexion of the fingers were taken as acceptable responses and the current was gradually reduced to 0.4 mA, maintaining the visible twitches. The total volume of the anesthetic solution was injected at an incremental dose of 4 mL each, preceded by negative aspiration for air or blood.

- Group A received 31 ml of 0.5 % Inj.Ropivacaine and 1mL Normal saline.
- Group B received 30 ml of 0.5% Inj.Ropivacaine and Inj.Dexmedetomidine 1□g/kg reconstituted to 1mL with 0.9% Normal saline.

Immediately after block, patients were evaluated for the assessment of onset of sensory and motor blockade. Vitals were recorded before and after the procedure, at 5 minutes, there after every 15 minutes for the first 1 hour , every 30 minutes for the next 3 hours , then at 6 hours, 8 hours, 12 hours and last at 24 hours after the block.

If the block was considered to be adequate, surgeons were allowed to apply tourniquet and start the surgery. If the block was considered to be inadequate for surgery, the patient was administered general anesthesia.

The intraoperative and postoperative haemodynamic parameters, respiratory parameters and sedation scores following brachial plexus block were recorded and compared with the preinduction or the baseline value.

DEFINITIONS OF STUDY PARAMETERS :

Time of onset of sensory block – The time of onset of complete sensory block was defined as the time taken from the end of injection of study drug to the development of anesthesia in all three sensory nerves of the upper limb. Onset of sensory block was assessed by pin prick test, in areas innervated by radial, ulnar, and median nerve. Sensory block was graded as:

- Grade 0 - Normal sensation to pin prick
- Grade 1 - Dull response to pin prick (onset)
- Grade 2 - No response to pin prick (peak).

Time of onset of motor block – Onset of complete motor block is defined as the time from the end of injection of study drug to loss of motor power at the shoulders. Motor block at shoulder was assessed by asking the patient to raise hand above the head with a movement of arm and forearm.

BROMAGE SCALE FOR MOTOR BLOCK:

- Grade 0 - Normal motor function (no effect)
- Grade 1 - Decrease motor strength compared to contra lateral limb
- Grade 2 - Complete motor block.

Duration of sensory block - It is the time from onset of sensory block to onset of pain at the surgical site with a pin prick.

Duration of motor block- It is the time from the onset of motor block to complete recovery of motor block (able to raise hand above head with a movement of arm and forearm).

Duration of analgesia - It is the time from onset of sensory blockade (grade 1) to pain at the surgical site.

RESULTS :

Both groups were compared for onset time and duration of sensory blockade, onset time and duration of motor blockade and total duration of analgesia. All the data were filled in proforma and were statistically analyzed by Students' *t*-test and *P* value calculated by Microsoft Office Excel software and $P < 0.05$ was considered statistically significant.

The surgical characteristics were comparable in all the

groups. The duration of surgery was comparable in the two groups with no statistically significant differences.

TABLE 1 : COMPARISON OF DEMOGRAPHIC PARAMETERS

Demographic parameters Mean ± SD	Group A (n=40)	Group B (n =40)	P value
Age(yrs)	37.5 ± 13.18	37.43 ± 14.3	0.06
Weight(kg)	59.55 ± 8.13	60.45 ± 8.05	0.17
Sex	Male =22(55%) Female=18(45%)	Male = 22(55%) Female=18(45%)	1
ASA status(I/II)	33/7	32/8	1
Duration of surgery(in mins)	102.75 ± 19.84	104.38 ± 23.77	0.74

In this study, the onset of sensory block was faster in Group B (Dexmedetomidine group) having a mean value of (14.05±1.79) mins in comparison to Group A (Ropivacaine alone group) having a mean value of (17.12±1.09) mins and statistically high significant $p < 0.001$.

TABLE 2 : TIME OF ONSET OF SENSORY BLOCK(IN MINUTES).

	Groups	n	Mean	SD	Min.	Max.	P value
Time of onset of sensory block (in mins)	Group A	40	17.13	1.09	15	21	<0.001
	Group B	40	14.05	1.79	12	18	

The onset of motor block was also faster in Group B (Dexmedetomidine group) having a mean value of (19±1.83) mins in comparison to Group A (Ropivacaine alone group) having a mean value of (25.3±1.11) mins and statistically highly significant $p < 0.001$.

TABLE 3 : TIME OF ONSET OF MOTOR BLOCK(IN MINUTES).

	Groups	n	Mean	SD	Min.	Max.	P value
Time of onset of motorblock (in mins)	Group A	40	25.3	1.11	23	27	<0.001
	Group B	40	19	1.83	15	22	

It was observed that the duration of sensory block was longer in Group B (Dexmedetomidine group) having a mean value of (736.4±51.6) mins in comparison to Group A (Ropivacaine alone group) having a mean value of (420.93±52.91) mins and statistically high significant $p < 0.001$.

TABLE4:DURATION OF SENSORY BLOCK(IN MINUTES).

	Groups	n	Mean	SD	Min.	Max.	P value
Duration of sensoryblock (in mins)	Group A	40	420.93	52.91	361	577	< 0.001
	Group B	40	736.4	51.6	604	801	

It was observed that the duration of motor block was longer in Group B (Dexmedetomidine group) having a mean value of (705.4±36.78) mins in comparison with Group A (Ropivacaine alone group) having a mean value of (359.375±28.27) mins and statistically high significant $p < 0.001$.

TABLE 5 : DURATION OF MOTOR BLOCK (IN MINUTES)

	Groups	n	Mean	SD	Min.	Max.	P value
Duration of motor block (in mins)	Group A	40	359.38	28.27	300	423	< 0.001
	Group B	40	705.4	36.78	613	762	

In the study population, the duration of analgesia was prolonged in Group B (Dexmedetomidine group) having a mean value of (830.675±84.32) mins in comparison to Group A (Ropivacaine alone group) having a mean value of (330.1±29.82) mins and statistically high significant $p < 0.001$.

TABLE 6 : TOTAL DURATION OF ANALGESIA(IN MINUTES).

	Groups	n	Mean	SD	Min.	Max.	P value
Total duration of analgesia (in mins)	Group A	40	330.1	29.82	234	369	<0.001
	Group B	40	830.68	84.32	659	987	

In our study, it was observed that there was no difference in heart rate(Figure 1), systolic blood pressure(Figure 2) and diastolic blood pressure(Figure 3) till 10 minutes after block. Differences appeared from 15 minutes onwards and continued till 100 minutes after block with a significant p value <0.05. After 100 mins, the differences between the haemodynamic parameters in both the groups decreased with a non significant p value >0.05.

13 patients out of 40 patients in Group B experienced bradycardia, 14 out of 40 patients experienced hypotension and 13 of them experienced both bradycardia and hypotension.

FIGURE 1: COMPARISON OF HEART RATE AT DIFFERENT TIME INTERVALS (BEATS/MIN) BETWEEN THE GROUPS

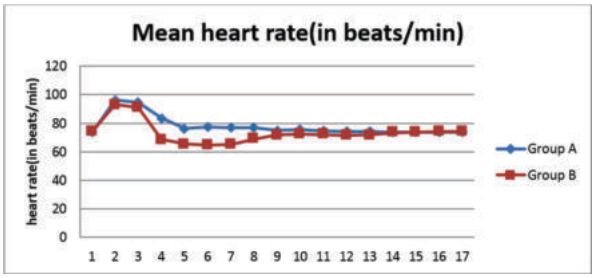


FIGURE 2 : COMPARISON OF SYSTOLIC BLOOD PRESSURE (in mmHg) BETWEEN THE GROUPS.

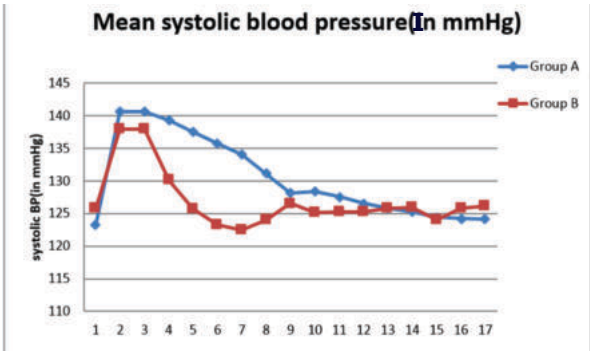
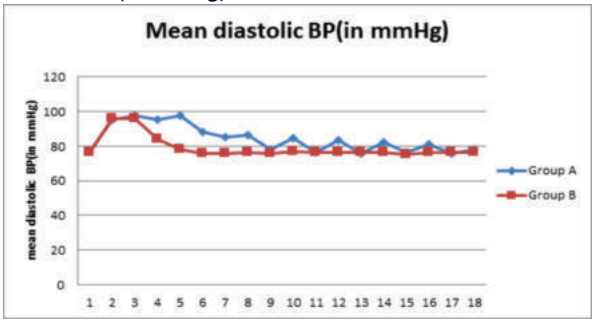


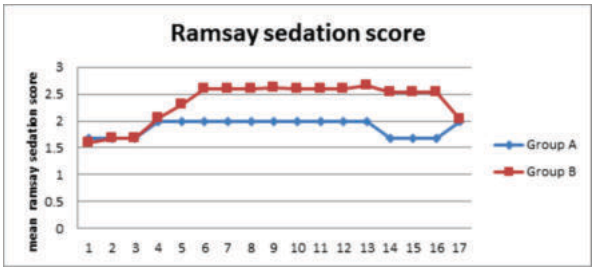
FIGURE 3: COMPARISON OF DIASTOLIC BLOOD PRESSURE (in mmHg) BETWEEN THE GROUPS:



The higher incidences of bradycardia and hypotension in The higher incidences of bradycardia and hypotension in the dexmedetomidine group could not be ignored and were managed by simply awakening the patient and with intravenous fluid administration respectively. Bradycardia and hypotension are potentially life threatening, and should be detected in time to avoid dangerous consequences. Thus, when dexmedetomidine was used as an adjuvant to ropivacaine, monitoring of the patient was required at least for 12 hours.

In our study, postoperative sedation was assessed using Ramsay sedation scale. In Group A, all patients were awake and alert and had sedation score of 1 or 2 , while in Group B, sedation score reached upto 4 at 100 mins, 125 mins, 200 mins, 4 hours, 6 hours till 8 hours after block followed by an decrease in the sedation score following 8 hours. The Ramsay sedation score was highly significant between the two groups from 30th min to 8th hour with highly significant p value of <0.001. (Figure 4)

FIGURE 4 :COMPARISON OF RAMSAY SEDATION SCORE IN BETWEEN THE GROUPS:



* 1-17 in Figure 1 , Figure 2 , Figure 3 and Figure 4 denote different time intervals at which the readings were taken (from baseline to 24 hours).

1-Baseline reading, 2-Reading just after the block,3-Reading at 5 mins, 4-Reading at 15 mins, 5-Reading at 30 mins, 6-Reading at 45 mins, 7-Reading at 60 mins, 8-Reading at 100 mins, 9-Reading at 125 mins, 10-Reading at 150 mins, 11-Reading at 175 mins, 12-Reading at 200 mins, 13-Reading at 4 hrs, 14-Reading at 6 hrs, 15-Reading at 8 hrs, 16-Reading at 12 hrs, 17-Reading at 24 hrs.

Other side effects such as nausea, vomiting, respiratory depression, signs of local anesthetic toxicity, inflammation at the puncture site or nerve lesion, pruritus or urinary retention were not observed in any patient of either group and most importantly patient discomfort could be avoided with the use of dexmedetomidine added to ropivacaine which made it an attractive adjuvant to be used in peripheral nerve block.

DISCUSSION :

ONSET OF SENSORY BLOCK :

Similar observations that the onset of sensory block was faster on addition of dexmedetomidine to ropivacaine were found by **Vinit Khemka et al.**,(6) with a mean value of (17.6±1.25) mins in the test group as compared to the mean value (20.1±1.62) mins in the control group, by **Vandana Mangal et al.**,(7) with a mean sensory onset time in test group (5.61±1.224) mins and in control group (6.74±1.449) mins, by **H M Hajashareef et al.**,(8) with a mean value of 6.8 mins in the test group as compared to the mean value 9.2 mins in the control group and by **Jithendra Chinnappa et al.**,(9) with a mean value of (9.5±5.8) mins in the test group as compared to the mean value (13.0±4.1) mins in the control group.

ONSET OF MOTOR BLOCK :

Similar observations that the onset of motor block was faster on addition of dexmedetomidine to ropivacaine were found by **Vinit Khemka et al.,**(6) with a mean value of (22.5±1.50) mins in the test group as compared to the mean value (24.5±1.48) mins in the control group, by **Vandana Mangal et al.**,(7) with mean onset time of motor block in test and control group to be (9.23±2.361) min and (11.21±2.569) min respectively, by **H M Hajashareef et al.,** (8) with a mean value of 9 mins in test group as compared to the mean value 13.12 mins in control group , by **Jithendra Chinnappa et al.,** (9) with a mean value of (15.6 ± 6.3) mins in the test group as compared to the mean value (23.5 ±5.6) mins in the control group.

DURATION OF SENSORY BLOCK :

Our observations correspond to other studies where addition of dexmedetomidine to ropivacaine by **Vinit Khemka et al.,** (6) found a mean value of (790.3±41.23) mins in test group and mean value of (561.0±33.87) mins in control group while comparing the duration of sensory block in between the groups. Similarly, the duration of sensory block with mean values (613±165.404) mins , 709 mins and (630.6 ± 208.2) mins in test group and mean values (572.7±145.709) mins, 506.2 mins and (400.8 ± 86.6) mins in control group were found by **Vandana Mangal et al.**,(7), **H M Hajashareef et al.,** (8) and **Jithendra Chinnappa et al.,** (9) respectively.

DURATION OF MOTOR BLOCK :

Similarly like our observations , that the duration of motor block was also prolonged on addition of dexmedetomidine to ropivacaine was also found by **Vinit Khemka et al.,** (6) **Vandana Mangal et al.**, (7) **H M Hajashareef et al.,** (8) and **Jithendra Chinnappa et al.,** (9) where the mean values came out to be (680.7± 69.38) mins, (572.7±145.709) mins, 669.2 mins and (545.9±224.0) mins in the test group as compared to (508.0±17.89) mins, (508.0±17.89) mins, 478.8 mins and (346.9±76.9) mins in the control group respectively.

DURATION OF ANALGESIA :

The duration of analgesia was prolonged by addition of dexmedetomidine to ropivacaine with mean values of (298.33±70.36) mins, (704.8±178.414) mins, 831.8 mins and (805.7±205.9) mins in the test group as compared to mean values (406.17±73.15) mins, (593.19±114.44) mins, 568.2 mins and (411.0±91.2) mins in the control group as observed by **Vinit Khemka et al.,** (6) **Vandana Mangal et al.**, (7) **H M Hajashareef et al.,** (8) and **Jithendra Chinnappa et al.,** (9) respectively.

HAEMODYNAMIC VARIATIONS :

Our study could be related to the comparative study of ropivacaine 0.5% and ropivacaine 0.5% with dexmedetomidine 50 μg in ultrasound guided supraclavicular brachial plexus block for upper limb orthopedic surgery by **H M Hajashareef et al.,** (8) where there was no difference in heart rate, systolic blood pressure and diastolic blood pressure in both groups till 10 mins. From 15 mins onwards, Group RD (ropivacaine + dexmedetomidine) showed drop in the heart rate which were statistically significant.

COMPLICATIONS AND SIDE EFFECTS :

There was no incidence of headache, nausea, vomiting, hypotension, bradycardia, chest pain, coughing, convulsions and respiratory depression and procedure related complications. There was no incidence of neurotoxicity and cardiotoxicity seen in either of the groups in our study.

CONCLUSION :

From this randomized double blinded prospective study , we concluded that, dexmedetomidine at a dose of 1μg/kg, when used as an adjuvant with ropivacaine 0.5% in supraclavicular brachial plexus block for any upper limb surgery, significantly hastened the onset of sensory and motor block, prolonged the duration of sensory and motor block and increased the duration of analgesia, thus providing a longer

pain free period post-operatively. It's use was associated with side effects like bradycardia and hypotension from 15th to 100th minutes of block which could be managed with patient awakening and fluid resuscitation respectively. Dexmedetomidine also caused significant sedation following the block which lasted for around 8 hours but was potentially harmless. Thus, the use of dexmedetomidine with local anesthetic solution in perineural block was found to be better considering patient comfort and morbidity.

CONFLICT OF INTEREST :None.
SOURCE OF SUPPORT :None.

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