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A randomized controlled study of Ropivacaine with adjuvants in ultrasound-guided supraclavicular brachial plexus block

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Abstract

Background: *Adjuvants in brachial plexus block can improve the patient care by prolonging postoperative analgesia and early mobilization of patient with stable hemodynamics. Brachial plexus block has possible complications like local anaesthetic systemic toxicity, pneumothorax, nerve injury etc. These limitations can be overcome by use of ultrasound-guided block with adjuvants like Dexmedetomidine and Clonidine to prolong the duration of block and postoperative analgesia. Ropivacaine has greater degree of motor differentiation and less cardiotoxicity. Setting and Design: A prospective double-blind randomized controlled trial comprising of 90 subjects posted for elective upper extremity surgeries. Aim: To compare the onset, duration of sensory block, motor block and analgesia of 0.5 % Ropivacaine with Clonidine 1 mg/kg and 0.5 % Ropivacaine with Dexmedetomidine 1 mg/kg in upper extremity surgeries.*

Methods: *Ninety patients aged between 18–60 yrs of American Society of Anaesthesiology (ASA) Physical Status Class 1 and 2, scheduled for various elective upper extremity surgeries were selected and randomly allocated into two groups of 45 patients each. Group A received 20 mL of 0.5 % Ropivacaine with Dexmedetomidine 1 mg/kg and Group B received 20 ml of 0.5 % Ropivacaine with Clonidine 1 mg/kg in 2 mL of distilled water. Parameters were compared between the study groups.*

Results: *In Group A, 73.3 % of the patients showed onset of sensory block of 8 minutes. And 26.7 % of patients showed onset of sensory block of 10 minutes. In Group B, 44.4 % of patients showed onset of sensory block of 8 minutes, and 26.7 % of patients showed onset of sensory block of 10 min. There was a statistically significant decrease in onset of block and increase in mean duration of sensory and motor block in Group A as compared to Group B.*

Conclusion: *Dexmedetomidine added to 0.5 % ropivacaine in supraclavicular brachial plexus block decreased the time of onset of sensory and motor block and prolonged the postoperative analgesia.*

Keywords: *Ropivacaine, adjuvants, Dexmedetomidine, Clonidine, brachial plexus block*

Introduction

Use of ultrasound-guided[1, 2] anaesthesia blocks has been found to be safe and effective compared to paraesthesia and nerve stimulation techniques. Local anaesthetic Ropivacaine[3, 4] has greater degree of motor to sensory differentiation, which may further help in early ambulation. Furthermore with the use of adjuvants[5–13] can prolong duration of analgesia. In recent times, ultrasound-guided supraclavicular brachial plexus block has become popular, which reduces volume and dose of local anaesthetic requirement and avoids complications related to needle placements.

Material and Methods

The present study was carried out as a randomized, double-blinded controlled method. Written and informed consent was taken from the subjects. They were randomly allocated into two groups of 45 patients each. Preanaesthetic check up was performed on the previous day of the surgery. Group A received 20 mL of 0.5 % ropivacaine with dexmedetomidine 1 mg/kg. In Group B 20 mL of 0.5 % ropivacaine with clonidine 1 mg/kg in was administered. The patients aged 18–60 yrs with ASA Physical Status 1 and 2, scheduled for various elective surgeries at lower arm, and at the level of elbow, forearm, and hand were included in the study. Patients with ASA Physical Status 3 and 4, neurological deficits, bleeding disorder, infection at the site of injection were excluded from study. Patient in supine position, head turned to contralateral side, under asepsis, ultrasound-guided supraclavicular brachial plexus block was performed using ropivacaine as local anaesthetic with adjuvant either dexmedetomidine or clonidine. Sensory block was assessed using pinprick test. 3 point scale, 0 — Normal sensation, 1 — Loss of sensation of pinprick (analgesia), 2 — Loss of sensation of touch (anaesthesia) and motor block evaluated every 2 minutes until 30 minutes after injection using *Modified Bromage Score*[14].

Grade 0 — No block, total arm and forearm flexion.

Grade I — Partial block, total forearm and partial arm flexion.

Grade II — Almost complete block, inability to flex the arm and decreased ability to flex the forearm.

Grade III — Total block, inability to flex both the arm and forearm.

Time of onset of sensory block defined as the time interval between the end of total local anaesthetic administration and complete sensory block. The time interval between end of local anaesthetic administration and complete resolution of anaesthesia on all nerves was taken as the duration of sensory block. Onset of motor block defined as the time interval between the end of local anaesthetic administration and complete motor block. Duration of motor block is defined as time interval between end of local anaesthetic administration and complete resolution of motor block. Heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) and saturation of oxygen (SpO_2) will be recorded every 5 minutes till completion of surgery. Adverse effects were duly noted and treated.

Statistical analysis: Simple randomization method was employed. Duration of the study was approximately 6 months. The following formula was employed to arrive at the sample size.

$$\textbf{Sample size} = \frac{\mathbf{Z}^2 * (\mathbf{p}) * (1 - \mathbf{p})}{\mathbf{c}^2}$$

Where:

Z — value (e.g. 1.96 for 95 % confidence level);

p — percentage picking a choice, expressed as decimal (.5 used for sample size needed);

c — confidence interval, expressed as decimal (e.g., .04 = ±4).

Data was analysed using SPSS 22 version software for determining the statistical significance. Results were expressed as mean, median, mode, standard deviation and proportions. Since the data doesn't follow normality, the non-parametric tests are applied. The Wilcoxon – Mann – Whitney U test was used to determine whether there was a statistical difference between the groups. And Friedman test was applied to find the difference within the group. *P* value of < 0.05 was considered statistically significant. Post-operative pain was assessed using *Visual Analogue Scale.*

0 — Patients does not complain of pain

1–3: Patient complaining of mild pain

4–6: Patients complaining of moderate pain

7–8: Patient complaining of severe pain

9–10: Patient complaining of excruciating pain.

Rescue analgesia of diclofenac sodium 75mg intramuscularly was administered when patient visual analogue score is > 5.

Results

Both the study groups were comparable in terms of age, gender, weight, duration of surgery (***Table 1***). Sensory

Table 1: Demographic data in mean standard deviation or No (%)

Demographic data	Group A(n=45)	Group B(n=45)	P- value
Age in years	46.4±4.42	43±4.85	0.487
Gender M/F	24/21	23/22	0.675
ASA I/II	25/20	26/19	0.344
Weight (mean)	68.12	65.45	0.652
Duration of surgery in min	106±7	113±10	0.432

onset of block in Group A: None (0 %) of the patients belonged to the onset sensory of 6 minutes, the majority of the patients 33 (73.3 %) belongs to 8 minutes of onset sensory, 12 (26.7 %) patients between 10 minutes. Group B: 20 (44.4 %) of the patients belonged to the onset sensory of 8 minutes of onset sensory, 12 (26.7 %) patients between 10 minutes. The Mean and Standard deviation of sensory onset in Group A: 8.53 ± 0.89 with mean rank 56.33, and Group B: 7.33 ± 1.35, with mean rank of 34.67. Comparing of both groups using Mann – Whitney — U test statistic = 525.0, *p* value 0.000, since $p < 0.05$ there is a statistical significance difference in sensory onset between the groups (***Table 2***).

The Mean and Standard deviation of motor onset in Group A: 13.22 ± 1.31 with mean rank 61.50, and Group B: 10.93 ± 1.45, with mean rank 29.50. Comparing of both groups using Mann – Whitney — U test statistic = 292.5, *p* value 0.000, since $p < 0.05$ there is a statistical significance difference in motor onset between the groups (***Table 3***).

The Mean and Standard deviation of sensory duration in Group A: 394.7 ± 61.6 with mean rank 23.0, and Group B: 631.3 ± 47.3, with mean rank 68.0. Comparing of both groups using Mann – Whitney — U test statistic = 1.000, *p* value 0.000, since $p < 0.05$ there is a statistical significance difference in sensory duration between the groups (***Table 4***).

Table 2: Comparison of sensory onset between the groups.

Onset sensory	Mean	Median	Mode	SD	Min	Max	Mean Rank	Sum of Ranks	Mann-Whitney U	p-value
Group A	8.53	8.0	8.0	0.89	8	10	56.33	2535.0	525.0	0.000
Group B	7.33	8.0	6.0	1.35	6	10	34.67	1560.0		

Table 3: Comparison of motor onset between the groups

Onset motor	Mean	Median	Mode	SD	Min	Max	Mean Rank	Sum of Ranks	Mann-Whitney U	p-value
Group A	13.22	12.0	12.0	1.31	12	15	61.50	2767.5	292.5	0.000
Group B	10.93	10.0	10.0	1.45	8	14	29.50	1327.5		

Table 4: Comparison of Sensory duration between the groups

Sensory Duration	Mean	SD	p-value
Group A	394.7	61.6	0.0000
Group B	631.3	47.3	

Table 5: Comparison of Motor duration between the groups

Motor Duration	Mean	SD	p-value
Group A	548.7	37.6	0.0000
Group B	606.4	33.0	

The Mean and Standard deviation of motor duration in Group A: 548.7 ± 37.6 with mean rank 27.2, and Group B606.4 ± 33.0, with mean rank 63.8. Comparing of both groups using Mann – Whitney — U test = 191.0, *p* value 0.000, since $p < 0.05$ there is a statistical significance difference in motor duration between the groups (***Table 5***).

The Mean and Standard deviation of analgesia duration in Group A: 413.8 ± 61.8 with mean rank 23.0, and Group B 1054.9 ± 96.6, with mean rank 68.0. Comparing of both groups using Mann – Whitney — U test statistic = 0.000, *p* value 0.000, since $p < 0.05$ there is a statistical significance difference in analgesia duration between the groups (***Table 6***).

Table 6: Comparison of Analgesia duration between the groups

Analgesia Duration	Mean	SD	p-value
Group A	413.8	61.8	0.0000
Group B	1054.9	96.6	

Discussion

The quality of supraclavicular brachial plexus block and the duration of postoperative analgesia can be improved by various adjuvants namely epinephrine, clonidine, opioids, bicarbonate, neostigmine, verapamil, butorphenol. In this study there was significant increase in mean duration of sensory and motor block in both the groups. This prolonged duration of sensory and motor blockade when dexmedetomidine and clonidine was used as adjuvants to local anaesthetics in peripheral nerve block has been reported in earlier studies by Kenan Kaygusuz MD et al and Singelyn FJ et al.[15, 16] Chakraborthy S et al[17] conducted a study with a small dose (30 mg) of clonidine as adjuvant to 0.5 % bupivacaine significantly prolonged the duration of analgesia without producing any adverse effects other than sedation. The use of dexmedetomidine resulted in faster onset of sensory and motor block. The role of clonidine as adjuvant to ropivacaine in faster onset of sensory and motor block is controversial, with most of previous studies showed no effect on onset of block but with the use of dexmedetomidine with local anaesthetics have shortened the onset time of sensory and motor block.[18, 19] Singh S et al[20] and Kenan Kaygusuz MD et al[15] conducted study with clonidine and dexmedetomidine as adjuvants to local anesthetics an dose of 1 mg/kg body weight in which there was no significant difference in the ventilator frequency or oxygen saturation[23]. The hemodynamic parameters (heart rate, mean blood pressure) recorded did not show statistical difference in both the groups.

Conclusion

In present study it was found that addition of clonidine and dexmedetomidine to 0.5 % ropivacaine are effective in supraclavicular brachial plexus block. However, dexmedetomidine was found to be a better alternative to clonidine to obtain early onset and prolonged duration of sensory and motor block and postoperative analgesia.

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Рандомізоване контрольоване дослідження ропівакаїну з ад'ювантами при ультразвуковій блокаді надключичного плечового сплетення

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Резюме

Довідка: *ад'юванти при блокаді плечового сплетення можуть покращити догляд за пацієнтом шляхом подовження післяопераційного знеболення та ранньої мобілізації пацієнта зі стабільною гемодинамікою. Блокада плечового сплетення може мати ускладнення, такі як системна токсичність місцевого анестетика, пневмоторакс, пошкодження нерва тощо. Ці обмеження можна подолати за допомогою блокади під контролем ультразвуку з ад'ювантами, такими як дексмедетомідин і клонідин, для подовження тривалості блокади та післяопераційної аналгезії. Ропівакаїн має більший ступінь моторної диференціації та меншу кардіотоксичність. Оформлення: проспективне подвійне сліпе рандомізоване контрольне дослідження, що включає 90 суб'єктів, призначених для планових операцій на верхніх кінцівках. Мета: порівняти початок, тривалість сенсорної блокади, моторної блокади та аналгезії 0,5 % ропівакаїну з клонідином 1 мкг/кг і 0,5 % ропівакаїну з дексмедетомідином 1 мкг/кг при операціях на верхніх кінцівках.*

Методи: *Було відібрано дев'яносто пацієнтів віком від 18 до 60 років за фізичним статусом 1 і 2 Американського товариства анестезіологів (ASA), яким заплановано різні планові операції на верхніх кінцівках, і випадковим чином розподілено на дві групи по 45 пацієнтів у кожній. Група А отримала 20 мл 0,5 % ропівакаїну з дексмедетомідином 1 мкг/кг, а група В отримала 20 мл 0,5 % ропівакаїну з клонідином 1 мкг/кг у 2 мл дистильованої води. Параметри порівнювали між групами дослідження.*

Результати: *у групі А у 73,3 % пацієнтів сенсорна блокада настала через 8 хвилин. У 26,7 % пацієнтів сенсорна блокада настала через 10 хвилин. У групі В у 44,4 % пацієнтів сенсорна блокада виникла через 8 хвилин, а у 26,7 % пацієнтів — через 10 хвилин. Спостерігалося статистично значуще зниження настання блокади та збільшення середньої тривалості сенсорної та моторної блокади в групі А порівняно з групою В.*

Висновок: *додавання дексмедетомідину до 0,5 % ропівакаїну при блокаді надключичного плечового сплетення зменшувало час виникнення сенсорного та моторного блоку і подовжувало післяопераційну аналгезію.*

Ключові слова: *ропівакаїн, ад'юванти, дексмедетомідин, клонідин, блокада плечового сплетення*