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**ORIGINAL ARTICLE**

**INTRAOPERATIVE CHANGES WHEN MIDAZOLAM ADDED TO BUPIVACAINE 0.5% IN BRACHIAL PLEXUS BLOCK BY SUPRACLAVICULAR APPROACH**

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**ABSTRACT**

**OBJECTIVE:** To compare the effect of Bupivacaine 0.5% with Midazolam & Bupivacaine 0.5% used for supraclavicular approach to brachial plexus block in adult patients intraoperatively. **STUDY DESIGN:** Randomized controlled clinical trial. **PLACE AND DURATION OF STUDY:** Rajah Muthiah Medical College and Hospital, Chidambaram, from April 2015 to August 2016. **METHODOLOGY:** A randomized controlled clinical trial was conducted on 60 ASA- 1 or 2 adult patients undergoing upper limb surgeries under supraclavicular brachial plexus block. Patients were randomly allocated into 2 groups of 30 each. Patients in group M were administered 27.5 ml of 0.5 % Bupivacaine with 2.5 ml of Midazolam (0.05 mg/kg) and those in group B were administered 27.5 ml of 0.5% Bupivacaine with 2.5 ml of distilled water. Hemodynamic variables (heart rate, blood pressure), pain scores, sedation score were noted and compared using unpaired student's t- test with significance at  $p < 0.05$ . **RESULTS:** The onset of sensory and motor block was significantly faster in group M compared to group B ( $p < 0.05$ ). Hemodynamics did not differ between the groups in the studied period. **CONCLUSION:** Bupivacaine ( 0.5 %) in combination with Midazolam (0.05 mg/kg) quickened the onset of brachial plexus block for upper limb surgery.

**Keywords:** Supraclavicular block. Midazolam. Brachial plexus block. Bupivacaine

**1. INTRODUCTION**

Peripheral nerve blocks provide an ideal operation condition when used optimally. They are said to cause least interference with the vital physiological functions of the body with reduced stress response. Local anesthesia traces its origin to Dr Karl Koller (Crile, 2003), a young Viennese ophthalmologist, who in 1884 employed a solution of cocaine for topical corneal anesthesia in patients undergoing eyes surgeries.

Brachial plexus block has been widely used for upper limb surgeries. A supraclavicular Approach for blockade of the brachial plexus was first described by Kulenkampf, (1911). It is the most commonly used approach in providing surgical anesthesia. It includes blocking of the brachial plexus where it is most compactly arranged, with less requirement of the anaesthetic solution and rapid onset of action. Because of Bupivacaine's long duration of action, it is used most

frequently among local anaesthetics for brachial plexus block. Opioids, Clonidine, Neostigmine, Dexamethasone have been added to Brachial plexus block to prolong the analgesic effect (Brummett and Williams, 2011). Midazolam is a water soluble Benzodiazepine. It is known to produce antinociception and potentiate the effect of local anaesthetic when given in neuraxial block. Midazolam enhance the affinity of the receptors for GABA (Collins, 1993). As a result of this drug- induced increased affinity of GABA receptors for the inhibitory neurotransmitter, an enhanced opening of chloride gating channels results in increased chloride conductance, thus producing hyperpolarization of the postsynaptic cell membrane.

The objective of this study was to determine the onset time of Midazolam – Bupivacaine combination compared to plain Bupivacaine (0.5%) for Brachial plexus block intraoperatively.

**2. METHODOLOGY**

A Randomized controlled clinical trial was conducted at Rajah Muthiah Medical College and Hospital, Chidambaram from April 2015 to August 2016. After obtaining approval

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from hospital academic and ethics committee and written, informed valid consent, 60 patients were enrolled in the study. The study population included patients of either sex, ASA grade 1 and 2 in the age range of 18 - 60 years. All patients were posted for upper extremity surgeries below the shoulder joint and received brachial plexus block by supraclavicular approach. 60 adult patients of either sex who are scheduled to undergo upper limb orthopaedic procedures. The Inclusion criteria were ASA grade 1 and 2 and adult patients posted for Upper limb surgery below shoulder joint. Patients of ASA Grade 3 and 4, pregnancy, any bleeding disorder and patient on anticoagulants, Severe respiratory disease, Neuro deficit were excluded.

Standard venous cannulation and ASA monitors were applied. A senior and experienced Anaesthetist performed the brachial plexus block using a supraclavicular approach. The patient was asked to be in the dorsal recumbent position without a pillow, arms at his/her sides and head turned to side opposite to the one being blocked. Small pad was placed below bilateral shoulder. The patient was asked to lower the shoulder and flex the elbow, so that the forearm rests on his/her lap. Part of neck was aseptically cleaned and draped. Then, the lateral (posterior) border of the sternocleidomastoid (SCM) muscle was identified and followed distally to the point where it met the clavicle. The point of needle entrance was about 1 in (2.5 cm) lateral to the insertion of the SCM in the clavicle or one "thumb breadth" lateral to the SCM. Palpation of the subclavian artery at this site confirms the landmark. Local infiltration of 1 ml of 2% lignocaine was given at the proposed puncture site. We used a 22G short bevel 3.5 cm needle to perform this technique. The needle was inserted caudally in the horizontal plane, parallel to the neck to enter the fascial sheath 1 to 2 cm deep to the skin. Once the desired response was obtained, careful negative aspiration was done to exclude intravascular placement. The drug solution was injected.

Patients in group M received 0.5% Bupivacaine (27.5 ml) + Midazolam 50 µg/kg (2.5ml) making a total volume of 30 ml. Patients in group B received 0.5% Bupivacaine (27.5ml) + distilled water (2.5ml) making a total volume of 30 ml. Sensory block was assessed by pinprick using the blunt end of a 27-gauge needle at 0, 2, 5, 10, 15, 20 and 30 min. Sensory block was graded according to the following scale: 0 = no block (normal sensation), 1 = partial block (decreased sensation), and 2 = complete block (no sensation). Motor block was measured at 0, 10, 20 and 30 min by assessing the following motor functions: flexion at the elbow (musculocutaneous nerve), extension of the elbow and the wrist (radial nerve), opposition of the thumb and index finger (median nerve), and opposition of the thumb and small finger (ulnar nerve). Motor block was graded according to the following scale: 0 = no block (full muscle activity), 1 = partial block (decreased muscle activity), and 2 = complete block (no muscle activity).

Sedation score was assessed by using the sedation scale described by Culebras *et al.*<sup>24</sup> (1- awake and alert; 2-sedated, responding to verbal stimulus; 3-sedated, responding to mild physical stimulus; 4-sedated, responding to moderate or severe physical stimulus). Heart rate, noninvasive blood pressure, oxygen saturation and sedation score were measured

until the end of surgery. The data obtained in this study was analysed using unpaired 't' test which gives p value to be applied as follows :

- If  $p > 0.05$ , it means that there is no significant difference between the means of two groups studied.
- If  $p = 0.05$ , it indicates that there is a significant difference at 5% level of significance.
- If  $p < 0.01$ , it indicates that the data is significant at 1% level of significance. If  $p < 0.001$ , it is highly significant.

### 3.RESULTS:

Sixty ASA I and II of either sex aged between 18-60 years, posted for upper limb surgeries under supraclavicular brachial plexus block were carefully selected for the study with the inclusion and exclusion criterias. They were randomly divided into 2 groups of 30 each. No significant difference were found among the two groups with respect to mean age, gender distribution, weight, duration of surgery

**Table 1:- COMPARISION OF AGE IN TWO GROUPS**

Groups	N	Mean Age(years)	Standard Deviation
Group M	30	28.70	9.46
Group B	30	35.06	11.49

**Table 2:- COMPARISION OF WEIGHT IN TWO GROUPS**

Groups	N	Mean Weight (Kg)	Standard Deviation
Group M	30	64.06	8.57
Group B	30	64.63	8.23

Intraoperative Heart rate, Systolic Blood Pressure, Diastolic Blood Pressure variation between the groups, group M and group B at regular intervals from 0-120 min, is not statistically significant ( $p > 0.05$ ) .

**Table 3:- COMPARISION OF HEART RATE IN TWO GROUPS**

Heart Rate (Minutes)	Group M (beats/min)	Group B (beats/min)	P value M vs B
0 min	74.20 ± 6.48	74.36 ± 8.22	0.293
5 min	72.33 ± 7.02	75.26 ± 7.2	0.948
15 min	72.36 ± 15.09	74.43 ± 7.45	0.161
30 min	77.00 ± 7.24	72.83 ± 7.85	0.678
60 min	74.20 ± 7.81	75.40 ± 9.01	0.207
90 min	75.40 ± 7.83	73.10 ± 7.24	0.415
120 min	76.86 ± 8.48	73.56 ± 7.55	0.429

**Table 4: COMPARISON OF SYSTOLIC BLOOD PRESSURE (mm Hg) IN TWO GROUPS**

Time (Minutes)	Group M (mm Hg)	Group B (mm Hg)	P value M vs B
0 min	107.00 ± 7.94	106.33 ± 6.14	0.576
5 min	113.00 ± 8.36	110.33 ± 8.50	0.342
15 min	120.66 ± 11.42	119.66 ± 11.29	0.782
30 min	120.33 ± 9.27	119.00 ± 10.93	0.302
60 min	113.00 ± 11.49	114.66 ± 13.32	0.129
90 min	117.66 ± 11.65	116.33 ± 10.66	0.278
120 min	113.66 ± 10.33	111.00 ± 10.61	0.811

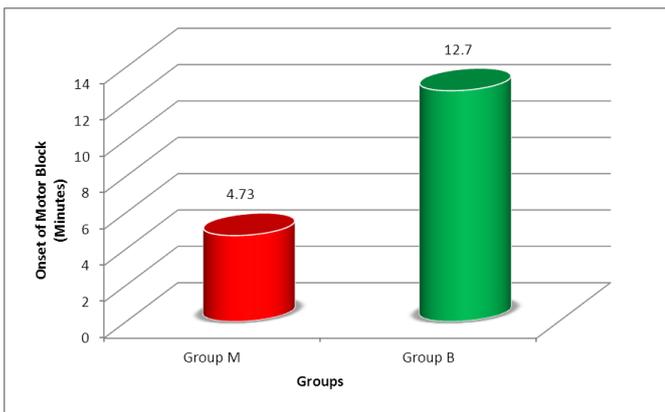
**Table 5: COMPARISON OF DIASTOLIC BLOOD PRESSURE (mm Hg) IN TWO GROUPS**

Time (Minutes)	Group M (mm Hg)	Group B (mm Hg)	P value M vs B
0 min	74.33 ± 5.68	73.33 ± 4.79	0.120
5 min	77.66 ± 5.68	75.66 ± 5.04	0.607
15 min	77.66 ± 7.27	78.33 ± 5.92	0.209
30 min	80.00 ± 6.43	79.00 ± 7.11	0.260
60 min	77.00 ± 6.51	75.66 ± 9.35	1.000
90 min	77.00 ± 6.51	75.00 ± 5.72	0.281
120 min	75.66 ± 7.27	76.00 ± 8.13	0.487

Onset of sensory and motor block appeared earlier in group M than in group B (p < 0.05). The mean onset time of motor blockade for Group M was 4.73 ± 1.68 minutes and for Group B was 12.70 ± 2.35 minutes. The p value was < 0.05 which is statistically significant. The mean onset time of sensory blockade for Group M was 4.33 ± 0.95 minutes and for Group B was 14.47 ± 1.65 minutes.

**Table 6:- COMPARISON OF ONSET OF MOTOR BLOCK IN TWO GROUPS**

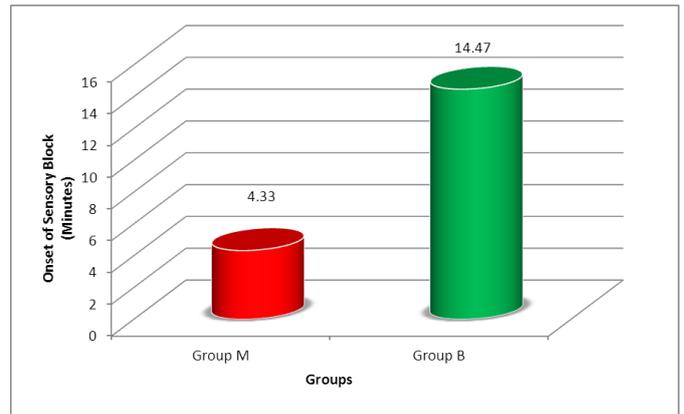
Groups	N	Mean Duration(min)	Standard Deviation	P value
Group M	30	4.73	1.68	0.048
Group B	30	12.70	2.35	



**Figure 1:- COMPARISON OF ONSET OF MOTOR BLOCK IN TWO GROUPS**

**Table 7:- COMPARISON OF ONSET OF SENSORY BLOCK IN TWO GROUPS**

Groups	N	Mean Duration(min)	Standard Deviation	P value
Group M	30	4.33	0.95	0.040
Group B	30	14.47	1.65	



**Figure 2:- COMPARISON OF ONSET OF SENSORY BLOCK IN TWO GROUPS**

Perioperatively sedation scores were higher in group M compared to group B (p < 0.05) as patients in group B were all awake (score 1) throughout the intraoperative period while in group M, 6 patients at 10 minutes, 10 patients at 20 minutes and 15 patients at 30 minutes were sedated and responded to verbal stimulation (score 2). The highest sedation score was 2 in group B and no patient had sedation score of 3 or more that required assistance for airway maintenance.

**Table 8: SEDATION SCORE**

Sedation score	Group M	Group B	P Value M Vs B
Mean ±SD	2.94 ± 0.23	1.18 ± 0.43	0.001

#### 4.DISCUSSION

In our study, Midazolam was used as adjuvant in local anesthetic. Our study was a randomised, prospective, double blinded and controlled study. 60 patients posted for upper limb surgeries below shoulder joint were given brachial plexus block by supraclavicular approach. The patients were randomly allocated into two groups using standard randomisation code.

One group of patients received 0.5% Bupivacaine (27.5 ml) with Midazolam 2.5 ml (2.5 mg) making a total volume of 30 ml. They formed Group 'M' or Midazolam group. The control group received 0.5% Bupivacaine (27.5 ml) with distilled water (2.5 ml) making a total volume of 30 ml. They formed Group 'B' or Bupivacaine group.

Eight patients failed to achieve satisfactory levels of anaesthesia and required induction of general anaesthesia. They were excluded from the study. The assessment of onset and duration of block was carried out by the principal investigator who was blinded to the drugs administered in the block. Parameters observed included onset time of sensory block, onset time of motor block, sedation score and side effects.

Clinically and statistically the age and weight of the patients were comparable in both groups.

There was no significant differences between the study groups with respect to pattern of changes in heart rate, systolic blood pressure, diastolic blood pressure perioperatively .

In the study conducted by Koj Jarbo et al(2005) it was concluded that Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, oxygen saturation were comparable between groups and did not change significantly in the intraoperative or postoperative period. No adverse events were encountered in either group of patients.

In our study, we observed that onset time of Motor block was earlier in Midazolam group (Group M) having a mean value of  $4.73 \pm 1.68$  minutes in comparison with Bupivacaine group (Group B) having a mean value of  $12.70 \pm 2.35$  minutes, which is statistically significant.

In our study, we observed that onset time of Sensory block was earlier in Midazolam group (Group M) having a mean value of  $4.33 \pm 0.95$  minutes in comparison with Bupivacaine group (Group B) having a mean value of  $14.47 \pm 1.65$  minutes, which is statistically significant.

In the study conducted by Safiya et al(2012) they found that there was considerable delay in establishing the complete motor blockade and sensory blockade with Bupivacaine (Group B) alone. In contrast, the onset of Motor and Sensory blockade was earlier in Midazolam group (Group BM).

In the study conducted by Koj Jarbo et al(2005), they found the onset of sensory and motor blocks was significantly faster in patients who received a combination of midazolam and bupivacaine.

The above observations were similar to our study results. Hence we conclude that Bupivacaine 0.5% with Midazolam has an advantage of early onset of sensory and motor blockade when compared to Bupivacaine 0.5% alone for supraclavicular brachial plexus block at equal volume.

Sedation scores were higher in patients in group M compared to group B in this study, at 20 minutes after injecting the agent until 30 minutes postoperatively. This could be due to

systemic absorption of the drug (midazolam) and its effect on central nervous system to produce sedation(Safiya et al., 2012)<sup>3</sup>. Mean sedation score in group M was higher as compared to group B. The highest sedation score was 2, i.e. the patient was asleep and responding to verbal stimulus. No patient experienced airway compromise or required airway assistance.

In this study, blood pressure, heart rate, respiratory rate and oxygen saturation remained stable throughout the procedure and postoperatively as they did not differ significantly during the study period.

## 5.CONCLUSION

On the basis of our study, we can draw the conclusion that at equal volumes bupivacaine 0.5% with Midazolam has an advantage over Bupivacaine 0.5% alone for supraclavicular brachial plexus block intraoperatively in terms of

- ❖ Early onset of sensory blockade.
- ❖ Early onset of motor blockade.

Higher sedation score.

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