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The Efficacy of Adding Midazolam As An Adjuvant To Lidocaine Bupivacaine Mixture In Ultrasound Guided Supraclavicular Block

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A B S T R A C T

Background: Brachial plexus block is useful technique that serves as a valuable alternative to general anesthesia for procedures involving the upper limbs. It provides optimal muscle relaxation, stable intra-operative hemodynamics and effective post-operative pain control.
The purpose of this work was to assess the effectiveness of adding midazolam to local anesthetic mixture (lidocaine /bupivacaine) for analgesia and anesthesia in supraclavicular block with ultrasound-guidance during upper limb surgeries.
Patients and methods: 40 patients from those scheduled to unilateral upper limb surgery below the level of midarm.at our hospital. The patients were allocated into two equal groups. Group "M" (lidocaine bupivacaine) mixture + Midazolam, and group "C" (lidocaine bupivacaine). **Results** Our results showed that there was no difference between the two groups regarding sensory onset. In contrast, patients in group M showed an earlier onset of motor block. Furthermore, both sensory and motor block durations were longer in Midazolam than control group. There was no difference between the 2 groups regarding respiratory rate, ECG, blood pressure, pulse rate and oxygen saturation.
Conclusion: From of the findings of this study, we conclude that adding midazolam to mixture of bupivacaine 0.25 % and Lidocaine 1 % for supraclavicular brachial plexus block results in rapid onset of sensory block and prolongs both sensory and motor block duration.

1 Introduction

Brachial plexus block is useful technique that serves as a valuable alternative to general anesthesia for procedures involving the upper limbs. It provides optimal muscle relaxation, stable intra-operative hemodynamics and effective post-operative pain control. (***Shaikh and Veena*** , **2012)**

There are several techniques to the brachial plexus block have been described, however, the supraclavicular approache is the easiest and most suitable for anesthesia and management of perioperative and intraoperative pain during surgeries below the level of the shoulder joint. (***El-Baradey and Elshmaa , 2014)***.

The use of ultrasound has significantly enhanced the safety of performing a supraclavicular brachial plexus block. This advancement allows anesthesiologists to clearly visualize key anatomical structures, including the first rib, subclavian artery, and the dome of the

lung. Placement of the needle and spread of the local anesthetic agent be seen in real-time resulting in resurgence in the use of this block **(Yadav et al; 2008).**

Although local anesthetics administered alone in supraclavicular brachial plexus block provide excellent surgical conditions, their duration of postoperative pain relief is limited. Therefore, various adjuvants such as nalbuphine**,** dexamethasone, clonidine**,** neostigmine, magnesium**,** and dexmedetomidine have been added to local anesthetics in brachial plexus block to achieve dense, quick, and prolonged block; however, the results are either inconclusive or associated with side effects. **(Nazir and Jain , 2017) (Yadav et al; 2008) and (Kumari , et al, 2017)**.

Midazolam short acting benzodiazepine, exerts analgesic effect by modulating gamma–aminobutyric acid receptors (GABA) type A, when combined with local anesthetics through various routes, it significantly prolong duration of postoperative pain relief (**Shaikh and Veena**, **2012)**.

The ideal postoperative analgesic approach should be simple, effective, provides high-quality of pain relief, it should make use of available medications and equipments, and produces minimal side effects, thereby has good acceptance among both surgeon and patient.

2.SUBJECTS AND METHODS

2.1 Site of study:

This study was conducted in ibn sina hospital from December 2021 till December 2022.

2.2 Sample size:

This was prospective, single blind, randomized controlled trial. We recruited **(40)** patients divided into two groups, **(20)** patients in each group, patients admitted for unilateral upper limb surgery below the level of midarm.

2.3 Inclusion criteria

Patient acceptance, cooperative patient, ASA I and ASA II, Age 21-60 years old, both gender. BMI < 35 kg/m^2, unilateral upper limb surgeries below the level of the midarm.

2.4 Exclusion criteria

patient refuse, peripheral neuropathy Infection at the injection site, coagulopathy, disturbed conscious level. allergy to used drugs,.

3.Results

Table (1) showed that there was no statistical significance difference between the two groups in age, sex distribution, ASA grade and duration of operations.

Table (2) showed that the onset of sensory block in group M is non significant (P > 0.05) earlier than group C. Onset of motor block in group M which was significantly (P < 0.05) earlier than that of group C.

Regarding duration of sensory block, it was 520.28±47.2 minutes in group M which was significantly (P < 0.05) longer than group C 410.33±41.02 minutes.

Duration of motor block was 250.7±47.7 minutes in group M, and it was significantly (P < 0.05) longer than group C 180.14±36.3 minutes.

Table (3) showed that there was no significant difference in respiratory rates between the 2 studied groups

Table (4) showed that there was no significant difference in heart rates between the 2 studied groups.

Table (5) showed that there was no significant difference in mean arterial blood pressures between the 2 studied groups.

Table (6) showed that there was no significant difference in oxygen saturation between the 2 studied groups preoperative and intraoperative.

In this table (7) there was no significant difference in VAS score in first three hours.

From 4 to 16 hours VAS was significantly lower in group M. In 20 and 24 hours post block there was no significant difference in the 2 studied groups.

Table (8) showed that there was significant difference between the 2 groups in sedations score. As in group C sedation score was 1 in 100 % of cases. In group M sedation score was 2 in 19.04% and was 3 in 80.95% of cases.

Table (9) showed that there was no significant difference in complications of both groups.

Table 1: Demographic data distribution between studied groups

			Group C	Group M	T	P
Number of patients			21	21		
Age (years): mean ± SD			34.57±11.95	37.71±12.25	-0.841	0.405
Weight (KG): mean ± SD			74.85±11.76	74.04±12.8	0.213	0.832
Sex	Male	N	17	14	1.109	0.292
		%	81.0%	66.7%		
	Female	N	4	7		
		%	19.0%	33.3%		
ASA	I	N	17	15	0.525	0.469
		%	81.0%	71.4%		
	II	N	4	6		
		%	19.0%	28.6%		
Surgery duration (min): mean ± SD			79.47±18.9	87.38±21.07	-1.277	0.209

Table 2: Sensory and motor block onset and duration (in minutes) (Mean ± SD)

	Group C	Group M	T	P
Sensory block onset (min)	6.14±0.77	5.6±0.7	1.121	0.297
Motor block onset(min)	9.95±1.56	8.57±1.02	3.380	<0.05*
Duration of sensory block (min)	410.33±41.02	520.28±47.2	-4.315	<0.001*
Duration of motor block (min)	180.14±36.3	250.7±47.7	-4.288	<0.001*

Table 3: Respiratory rates (RR) distribution in different times in both groups (cycles/minute) preoperative and intraoperative.

	Group C mean ± SD	Group M mean ± SD	T	P
RR_preoperative	13.8±0.81	14.0±0.0	-1.073	0.290
RR_10Min	13.18±1.07	12.93±0.43	1.527	0.085
RR_20Min	13.18±1.39	11.93±0.53	1.564	0.081
RR_30Min	13.01±0.78	12.89±0.67	1.676	0.081
PR 40Min	13.11±0.64	12.92±0.67	0.94	0.35
PR 50Min	13.20±0.68	13.00±0.51	1.08	0.29
RR_60Min	13.23±0.76	13.09±0.62	0.661	0.512
RR_70Min	13.19±0.61	13.07±0.72	1.04	0.24
RR _80Min	13.21±0.72	13.10±0.68	1.21	0.19
RR _90Min	13.29±0.65	13.09±0.76	1.34	0.12
RR 100Min	13.34±0.62	13.08±0.65	1.42	0.11
RR_110Min	13.59±0.74	13.10±0.58	1.58	0.07
RR_120Min	12.91±0.84	13.11±0.46	-1.756	0.069

Table 4: Heart rates (HR) distribution between groups (beat/minute) preoperative and intraoperative.

	Group C	Group M	T	P
HR_preoperative	99.33±8.38	98.71±8.45	0.238	0.813
HR_10Min	90.61±7.57	90.95±8.89	-0.131	0.897
HR_20Min	85.33±4.47	85.23±4.14	0.072	0.943
HR_30Min	86.09±6.01	85.61±6.71	0.242	0.810
HR_40Min	85.75±6.41	85.51±6.22	0.341	0.746
HR 50Min	85.00±6.88	85.38±6.42	0.312	0.802
HR_60Min	84.57±6.05	85.0±6.89	-0.214	0.832
HR_70Min	84.98±6.18	86.11±6.42	0.247	0.847
HR_80Min	85.11±6.87	87.65±6.00	0.254	0.799
HR_90Min	85.65±7.06	88.24±6.75	0.341	0.704
HR_100Min	86.22±7.14	89.24±6.84	0.421	0.674
HR_110Min	86.89±7.25	89.87±7.45	0.578	0.532
HR_120Min	87.95±7.36	90.09±8.14	-0.894	0.377

Table (5): Mean arterial pressure (MAP) distribution among studied groups at different time:

	Group (c)	Group (M)	T	P
MAP at Zero min	91.85±8.94	90.8±10.23	-0.610	0.369
MAP at 15 min	91.42±8.69	89.2±7.57	-0.162	0.314
MAP at 30 min	84.09± 8.99	80.95±9.66	-0.330	0.406
MAP at 45 min	79.61±8.61	78.6±9.27	-0.236	0.931
MAP at 60 min	81.47±12.78	73.85±8.7	-0.385	0.111
MAP at 90 min	77.7±7.36	78.6±9.95	-0.236	0.098
MAP at 110 min	83.09± 8.99	88.2±7.57	-0.161	0.315

Table 6: O2 saturation distribution between groups preoperative and postoperative.

	Group C	Group M	t	P
O2_preoperative	97.95±5.35	98.21±4.98	-0.221	0.805
O2_10Min	98.83±10.2	99.04±10.98	-0.131	0.897
O2_20Min	99.07±9.87	98.82±3.87	0.541	0.623
O2_30Min	96.09±5.87	95.61±5.94	0.262	0.800
O2_40Min	96.57±5.81	95.12±5.65	0.241	0.847
O2_50Min	97.46±5.11	96.35±5.14	0.297	0.835
O2_60Min	97.57±5.87	96.12±5.64	0.214	0.832
O2_70Min	97.11±7.88	96.77±6.24	-0.674	0.574
O2_80Min	97.95±7.38	98.09±7.31	-0.886	0.321
O2_90Min	96.95±7.0	97.09±7.11	-0.899	0.221
O2_100Min	97.0±7.75	97.09±7.79	-0.014	0.845
O2_110Min	97.55±7.64	98.18±7.37	-0.745	0.724
O2_120Min	97.95±7.38	98.09±7.31	-0.886	0.321

Table 7: Visual analogue scale (VAS) distribution between studied groups postoperative.

VAS	Group C	Group M	MW	P
VAS_1H	0 (0 – 0)	0 (0 – 0)	------	-------
VAS_2H	0 (0 – 0)	0 (0 – 0)	------	-------
VAS_3H	0 (0 – 0)	0 (0 – 0)	------	-------
VAS_4H	2 (0 - 3)	1 (0 - 1)	7.65	<0.001*
VAS_5H	3 (1 - 5)	1 (1 - 3)	11.321	<0.001*
VAS_6H	3 (1 - 5)	1(1 - 3)	10.984	<0.001*
VAS_7H	3 (2 - 5)	1(1 - 3)	9.541	<0.001*
VAS_8H	3 (2 - 5)	1(1 - 3)	7.594	<0.001*
VAS_12H	4(2 - 6)	2 (2 - 4)	9.058	<0.001*
VAS_16H	5 (3 - 6)	2 (2 - 4)	10.021	<0.001*
VAS_20H	5 (3 - 6)	4 (3 - 5)	1.942	0.068
VAS_24H	7 (4 - 6)	6(4 - 6)	0.847	0.402

Table 8: Sedation score distribution between Group

			Group		Total	X^2	P
			Group C	Group M			
Sedation score	1	N	21	0	21	36.3	<0.001 **
		%	100.0%	0.0%	50.0%		
	2	N	0	4	4		
		%	0.0%	19.04%	9.52%		
	3	N	0	17	17		
		%	0.0%	80.95%	40.47%		
	4	N	0	0	0		
		%	0.0%	0.0%	0.0%		
	5	N	0	0	0		
		%	0.0%	0.0%	0.0%		

Table 9: Complication

	Group C		Group M		X^2	P
Horner. Syndrome	4	19.0%	3	14.2%	0.69	0.41
Vomiting	0	0.0%	0	0.0%	-----	------
Nausea	0	0.0%	0	0.0%	-----	------
Pneumothorax	0	0.0%	0	0.0%	-----	------
Vascular injury	0	0.0%	0	0.0%	-----	------
Pherenic nerve block	0	0.0%	0	0.0%	-----	------

4. Discussion

Provision of anesthesia for any surgical procedure should be such that the technique must meet the demands of the surgery, ensure patient comfort, and the expertise of anesthesiologist.

Peripheral nerve blocks are rising adoption for many upper limb surgeries ,facilited by technological advances like ultrasound and peripheral nerve stimulator.

It provides stable hemodynamic, effective, and prolonged postoperative pain relief. Due to their simplicity, safety, and effectiveness regional anesthesia are gaining popularity as it promotes cardiovascular stability and early postoperative rehabilitation **(Kopp et al , 2010).**

Various adjuncts like midazolam, tramadol, clonidin, pethidine, buprenorphine, morphine, fentanyl and sufentanyl, have been noted for their ability to prolong postoperative pain relief. **(Bazin , et al ,1997)** and **(Keeler,et al ,1992)**

In our study, there was no significant variation in the onset of sensory block between the two groups. In contrast, the onset of motor block occured earlier in M Group and this difference was statistically significant.

The onset of motor blockade occurred more rapidly than that of sensory blockade in both groups.

Winnie, et al, 1997, also reported this, and explained this to the somatotrophic arrangement of fibres in a nerve bundle at the trunks level, in which sensory fibres are located more centrally than motor fibres. Consequently, a perineurally local anaesthetic injected will begin to block motor fibres before diffusing inward to affect the centrally located sensory fibres. **(Akkenapaili, et al , 2016)**

This result is consistant with **Shaikh and Veena , 2012 ,** in which motor block was earlier and sensory block onset has not changed.

Also consistant with **Jagadish and Pradip et al, 2017**, A clinical comparison between bupivacaine and midazolam with plain bupivacaine in supraclavicular brachial plexus block, there was earlier onset in midazolam group in both motor and sensory block .

In contrast to the findings of **Jarbo, et al, 2005**, brachial plexus block with bupivacaine and midazolam enhances analgesic effects and statistically significant rapid onset of sensory and motor block.

In **Akkenapalli and Sasidhar, 2016,** study A comparative study of brachial plexus block using bupivacaine with midazolam versus bupivacaine alone in upper limb surgeries ,there was statistically significant faster onset in midazolam group in both sensory and motor block . but the onset of motor block was found to be faster than the sensory block which is consistant with our study .

In **Singh, et al, 2016.** Reported that adding midazolam as an adjunct to lignocaine at two different doses in ultrasound-guided supraclavicular brachial plexus block , there was statisticaly significant early onset of both motor and sensory block .

Another study **Moharam, et al, 2017.** Evaluation of midazolam as an adjuvant to bupivacaine in supraclavicular brachial plexus block , the result is significantly earlier onset of both motor and sensory block in midazolam group.

In contrast to our study, **Gautam, et al, 2013,** a comparison on brachial plexus block using local anesthetic agents with and without midazolam, in midazolam group there was earlier onset in both motor and sensory block, which was statisticaly significant .

In our study there were no statistically significant hemodynamic changes (blood pressur, pulse , oxygen saturation) in both groups. This finding was in agreement with **Shaikh and Veena, 2012.** In another study by **Gautam, et al, 2013**, there were no statistically significant difference in hemodynamic between two groups. This also correlates with **(Jagadish and Pradip et al, 2017)**.

In midazolam group, the respiratory rate decreased from baseline during the first 30 minutes. No ventilatory support was required, except for oxygen delivery via face mask during that period. The maximum sedation score observed was three, while most patients remained asleep but responsive to verbal commands. In contrast, all patients in control group were fully awake, with a sedation score of one.

The sedation and respiratory depression observed in group M may be due to systemic absorption and depression effect on respiratory center. These effect were transient, likely due to rapid clearance of midazolam (6-11 ml/kg/min) .

No sedation was observed in either groups during the postoperative period. This is consistent with the study by **Shaikh and Veena, 2012**. The addition of midazolam not only enhanced analgesia but also provided beneficial sedation effect. These effect were in agreement with **Nishiyama, et al, 2002**. Sedation score in group M was score (two) in 4 cases, score (three) in 17 cases .

Our results demonstrated longer duration of sensory block compared to motor block. Authors explained that large nerve fibres require a higher concentration of

local anaesthetic than small fibres, so the minimum effective concentration of local anaesthetic is greater for large (motor) fibres than for small (sensory) fibres. Thus, motor function return earlier than pain perception resulting in a shorter duration of motor block relative to the sensory block **(Raghu , et al ,2015)**.

The duration of motor block was staistically significant prolongation in midazolam group than in control group. This finding contrast with the result of **Jarbo, et al, 2005,** who found that no different in the duration of motor blockade between the two groups.

Midazolam group demonstrated statistical significantly prolonged sensory block, consistent with finding from previous studies. Patients in the Midazolam group reported significantly lower pain scores and required rescue analgesia later than those in the Control group. This is consistent with the study by **Shaikh and Veena , 2012** and **Jarbo, et al, 2005** .

In **Jagadish and Pradip et al , 2017** study there was statisticaly significant prolongation in sensory block , and non significant prolongation in motor block .

In **Akkenapalli and Sasidhar, 2016 ,** study there was statisticaly significant prolongation In sensory block , and statisticaly significant prolongation in motor block.

In **Singh, Verma and Sood, 2016 ,** study there was statisticaly significant prolongation In sensory block , and statisticaly significant prolongation in motor block.

In **Moharam, et al ,2017 ,** study there was statisticaly significant prolongation In sensory block ,and statisticaly significant prolongation in motor block.

Gautam, et al , 2013 , study show statisticaly significant prolongation In sensory block, and statisticaly significant prolongation in motor block .

In the present study there was only one adverse effect which is horner syndrome , and it was non significant in both groups.

VAS was significant lower in group M at 4 to 16 hours but no significance at 20 or 24 hours .

5. Conclusions

combining midazolam with bupivacaine 0.25 % and lidocaine 1 % for supraclavicular brachial plexus block was found fasten onset of sensory block and prolong both sensory and motor block duration. Furthermore ,midazolam did not affect blood pressure, heart rate and oxygen saturation . It increases post-operative pain relief , decrease rescue analgesia needed without increasing the risk of side effects .

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