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## A study to compare the haemodynamic stability and side effects when using 0.5 percent levobupivacaine vs combination of 0.5 percent levobupivacaine and hyaluronidase, in ultrasound guided axillary brachial plexus block for forearm and hand surgeries

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### Abstract

**Background:** One key component of enhanced recovery protocols is standardized analgesic and anesthetic regimens. Peripheral nerve blocks in particular help in enhanced recovery of the patient by the possibility of early mobilization of the patient. Local Anesthetics are drugs that prevent conduction of electrical impulses on the membranes of nerve and muscle. Adjuvants are pharmacological drugs that when co-administered with local anaesthetic agents may improve speed of onset as well as the quality and duration of analgesia. Hyaluronidase drug works as a spreading factor by increasing tissue membrane permeability and reducing the viscosity.

**Objective:** To find if there are any hemodynamic problems or any side effects when Levobupivacaine is used alone compared to Levobupivacaine when used with Hyaluronidase.

**Materials and Methods:** After institutional ethical committee clearance 60 ASA PS class 1 and 2 adult patients in age group of 18 to 60 years who underwent elective upper limb surgeries in Sridevi Institute of Medical Sciences, Tumkur from October 2017 to October 2019 were included. Any patient with history of bleeding disorders, documented neuromuscular disorders, known allergy to Local anesthetics drugs, Psychiatric patients and if on anticoagulants were excluded from the study. Patients were alternately assigned to two groups Group A and Group B each containing 30 patients. Patients undergoing Ultrasound guided Axillary Brachial plexus block with.

Group A: 20 ml of 0.5% Levobupivacaine and Hyaluronidase 300 Units (15U/ml of local anesthetic).

Group B: 20 ml of 0.5% Levobupivacaine.

The patients were given Ultrasound guided Axillary brachial plexus block. Hemodynamic parameters like pulse rate, non-invasive blood pressure, oxygen saturation was monitored. Mean arterial blood pressure (MAP) and pulse rate (PR), oxygen saturation was recorded before application of the block as well as immediately after block & 3 min intervals until the end of the operation. Any drop-in blood pressure more than 20% from the baseline signifies hypotension and was managed with Inj ephedrine 6 mg. Any decrease in pulse rate of less than 60 beats /min was managed with Inj. atropine 0.6mg. Any other complication other than this was noted.

**Results:** Mean pulse rate was similar in both groups with Group A 81.87 and Group B 81.43. Mean arterial pressure between 2 groups was also similar MAP of Group A 105.3 and Group B 105.07.

**Conclusion:** No significant hemodynamic changes were noted between both the groups. Hyaluronidase used as adjuvants along with local anaesthetics to improve the quality of block has no adverse effect on the hemodynamics, unlike other agents (adrenaline, dexmedetomidine, clonidine). It has a good safety profile.

**Keywords:** Haemodynamic, stability, complications, comparison, anesthetic, adjuvant

### Introduction

The popularity of peripheral nerve blocks grew because it decreases pain postoperatively, reduces incidence of nausea, decreases need for post-operative analgesics, shortens post anesthesia care time, and most importantly increases patient satisfaction [1-3]. Multimodal perioperative care pathways designed for enhanced recovery achieve early recovery after surgical procedures by maintaining preoperative organ function and reducing the stress response following surgery. One key component of such enhanced recovery protocols is standardized analgesic and anesthetic regimens.

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Peripheral nerve blocks in particular help in enhanced recovery of the patient by the possibility of early mobilization of the patient [2-4]. Local Anesthetics are drugs that prevent conduction of electrical impulses on the membranes of nerve and muscle [13]. They are classified into-Aminoesters and Aminoamides. Levobupivacaine is an aminoamide local anesthetic. Adjutants are pharmacological drugs that when co-administered with local anaesthetic agents may improve speed of onset as well as the quality and duration of analgesia. Various additives can be added to local anesthetic for enhancing the peripheral nerve block [5] like Epinephrine, Clonidine, Dexmedetomidine, Buprenorphine, Dexamethasone, Tramadol, Sodium bicarbonate and hyaluronidase. Hyaluronidase is widely used in ophthalmologic nerve blocks for better spread of the drug. It depolymerizes the mucopolysaccharide hyaluronic acid, a component of the mucoprotein substance or tissue cement. Hyaluronidase thereby renders the tissues more readily permeable to injected fluids (spreading effect) by increasing tissue membrane permeability and reducing the viscosity. This study puts in a sincere effort to find if there are any hemodynamic problems or any side effects when Levobupivacaine is used alone compared to Levobupivacaine when used with Hyaluronidase and also will check the complications if any.

### Materials and Methods

An observational prospective study was carried out among 60 adult patients in the age group of 18-60 years belonging to ASA PS 1 and 2 scheduled to undergo elective upper limb orthopedic procedures in the orthopedic theatre of Sridevi Institute of Medical Sciences, Tumkur after, from October 2017 to February 2019. All the patients were assessed and those with normal clinical, hematological, biochemical and radiological parameters were selected. Informed written consent was obtained from all the patients and they were alternately assigned to two groups Group A and Group B each containing 30 patients.

**Group A:** Patients undergoing Ultrasound guided Axillary Brachial plexus block with 20 ml of 0.5% Levobupivacaine and Hyaluronidase 300 Units (15U/ml of local anesthetic).

**Group B:** Patients undergoing Ultrasound guided Axillary Brachial plexus block with 20 ml of 0.5% Levobupivacaine. American Society of Anesthesiology Physical status Class 1 (A normal healthy patient) and Class 2 (A patient with mild systemic illness and weight 40 to 80kg alone were included in the study. Any patient with history of bleeding disorders, documented neuromuscular disorders, known allergy to Local anesthetics drugs, Psychiatric patients and if on anticoagulants were excluded from the study. Considering the mean sensory block onset time as around 13.8 minutes in the treatment group [6] and expecting a difference of 5 to 6 minutes from the control group, using a standard error of 6 the required sample size was calculated to be 30 in each group.

Patients were assessed preoperatively and the procedure was explained to the patients. Written informed consent was obtained. Assessment of pain using Pin Prick intra operatively and VAS-Visual analogue score post operatively was explained to the patients preoperatively. All Patients were given 1mg Midazolam intravenous as premedication. On arrival of the patient in the operating room, monitors were connected and baseline vital signs were recorded. Monitors included Pulse oximetry, Non-invasive blood

pressure and Electrocardiogram. An intravenous access was obtained in the opposite arm under local anesthesia. The patients were given Ultrasound guided Axillary brachial plexus block as described: The patient was made to lie supine with a small pillow below head and the upper limb to be blocked kept with the arm abducted to 90° and the elbow flexed. The anaesthetist who prepared the drug combination did not participate in the monitoring or assessment of the patient. The person assessing the axillary block as well as monitoring was blinded to the groups the patients belongs. The USG probe is cleaned and covered in a sterile cover and the patient's skin is prepared with povidone iodine and draped with sterile towel. The probe is placed perpendicular to the axis of the arm at the point where the pectoralis major muscle inserts onto the humerus and adjusted to visualize the brachial plexus around the axillary artery and 2% lignocaine solution was injected to the skin at the needle entry point. The 'IN PLANE' ultrasound technique was used [7-9]. A 50 mm needle was inserted 1-2 cm away from the centre of the probe. Needle angle was maintained at 0-45 degrees to the skin. Needle was initially inserted in the superficial plane until the needle was visualized on the scan. The radial nerve is identified posterior to the artery and 5ml of the drug was injected. Similarly, the median, ulnar and musculocutaneous nerves were identified and 5 ml was injected around each nerve. Immediately after injection has been stopped; the needle was withdrawn and the arm was kept adducted with the hand resting on the chest.

The following parameters were observed following the block.

Hemodynamic parameters like pulse rate, non-invasive blood pressure, oxygen saturation was monitored. Mean arterial blood pressure (MAP) and pulse rate (PR), oxygen saturation was recorded before application of the block as well as immediately after block & 3 min intervals until the end of the operation. Any drop-in blood pressure more than 20% from the baseline signifies hypotension and was managed with Inj ephedrine 6 mg. Any decrease in pulse rate of less than 60 beats/min was managed with Inj. atropine 0.6mg. Any other complication other than this was noted.

### Results

**Table 1:** Comparison of sex between Group A and Group B

Sex	Group A (Levobupivacaine and hyaluronidase)		Group B (Levobupivacaine)		$\chi^2$	P
	Count	Percent	Count	Percent		
Male	15	50.0	13	43.3	0.27	0.605
Female	15	50.0	17	56.7		

**Table 2:** Comparison of age between Group A and Group B

Age	Group A (Levobupivacaine and hyaluronidase)		Group B (Levobupivacaine)	
	Count	Percent	Count	Percent
18 - 20	0	0.0	2	6.7
20 - 29	6	20.0	7	23.3
30 - 39	5	16.7	4	13.3
40 - 49	5	16.7	1	3.3
50 - 59	9	30.0	9	30.0
>=60	5	16.7	7	23.3
Mean $\pm$ SD	44.9 $\pm$ 13.6		43.4 $\pm$ 16.2	

**Table 3:** Comparison of height between Group A and Group B

Group	Mean height (cm)	SD	N	t value	P
Group A (Levobupivacaine and hyaluronidase)	164.8	8.7	30	1.04	0.303
Group B (Levobupivacaine)	162.5	8.5	30		

**Table 4:** Comparison of weight between Group A and Group B

Group	Mean weight (Kg)	SD	N	t value	P
Group A (Levobupivacaine and hyaluronidase)	66.8	6.0	30	1.22	0.227
Group B (Levobupivacaine)	64.8	6.7	30		

**Table 5:** Comparison of ASA PS between Group A and Group B

ASA PS	Levobupivacaine and hyaluronidase		Levobupivacaine		χ <sup>2</sup>	P
	Count	Percent	Count	Percent		
Grade I	25	83.3	25	83.3	0	1.000
Grade II	5	16.7	5	16.7		

**Table 6:** Comparison of diagnosis between Group A and Group B

Diagnosis	Levobupivacaine and hyaluronidase		Levobupivacaine	
	Count	Percent	Count	Percent
Fracture DER Left	7	23.3	4	13.3
Fracture DER Right	8	26.7	10	33.3
Malunited Fracture DER Left	1	3.3	0	0.0
Fracture DER Left	1	3.3	0	0.0
Fracture BB forearm left	0	0.0	3	10.0
Fracture BB forearm Right	0	0.0	1	3.3
United BB fracture left	0	0.0	2	6.7
United BB fracture right	0	0.0	1	3.3
Fracture BB forearm	6	20.0	0	0.0
United fracture BB forearm	5	16.7	0	0.0
Implant in situ left forearm	0	0.0	1	3.3
Implant in situ right radius	0	0.0	2	6.7
Fracture shaft of radius	1	3.3	1	3.3
Right forearm DCP Implant	0	0.0	1	3.3
Radial head fracture Right	0	0.0	1	3.3
Infected plate Left forearm	0	0.0	1	3.3
Ganglion wrist Right	0	0.0	1	3.3
Fracture R Little finger DIP	1	3.3	0	0.0
Fracture 5th finger	0	0.0	1	3.3

**Table 7:** Comparison of surgery between Group A and Group B

Surgery	Levobupivacaine and hyaluronidase		Levobupivacaine	
	Count	Percent	Count	Percent
CMR Pinning	15	50.0	15	50.0
Implant Removal	5	16.7	8	26.7
Closed IM nailing	2	6.7	0	0.0
Radial head excision	6	20.0	6	20.0
Osteotomy and pinning	1	3.3	0	0.0
K-Wire fix	1	3.3	0	0.0
Excision	0	0.0	1	3.3

**Table 8:** Comparison of oxygen saturation between Group A and Group B

Intraoperative	No. of cases	Mean ± S.D. (%)	P value
Group A	30	99 ± 0.0046	
Group B	30	99 ± 0.0026	
Postoperative	No of cases	Mean ± S.D.	0.9602
Group A	30	100 ± 0.001	
Group B	30	99 ± 0.00111	

**Table 9:** Comparison of pulse between Group A and Group B

	Mean (min)	S.D.	P value
Group A	81.87	1.737	0.343
Group B	81.43	1.775	

**Table 10:** Comparison of mean arterial pressure between Group A and Group B

	Mean (mm/Hg)	S.D.	P value
Group A	105.3	2.748	0.962
Group B	105.07	2.703	

**Discussion**

Adjuvants are used along with local anaesthetics to improve the quality of block. An ideal adjuvant should provide a faster onset, longer duration of analgesia and better hemodynamic stability. Hyaluronidase has no effect on the hemodynamic, unlike other agents (adrenaline, dexmedetomidine, clonidine). It has a good safety profile. No significant hemodynamic changes were noted between both the groups in this study preoperatively, intra operatively and postoperatively. The patients in both groups of this study did not show any statistically significant difference with respect to age, sex, height, weight and ASA physical status.

**Hemodynamic stability**

The Pulse, mean arterial pressure and oxygen saturation remained stable both during intraoperative and postoperative period. The blood pressure never decreased below 20% of baseline values. No significant hypotension and bradycardia were observed.

**Side-effects**

Side effects like bradycardia, hypotension, hypoxemia, nausea, vomiting, features of local anesthetic toxicity and any other side effects were not seen in any patients.

**Conclusion**

No significant hemodynamic changes were noted between both the groups. Hyaluronidase used as adjuvants along with local anaesthetics to improve the quality of block has no adverse effect on the hemodynamic, unlike other agents (adrenaline, dexmedetomidine, clonidine). It has a good safety profile.

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