Journal of Chemical Health Risks

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JCHR (2024) 14(6), 797-806 | ISSN:2251-6727

Observational Study of 0.25% Levobupivacaine with Dexmedetomidine 1mcg/Kg Versus 0.375% Ropivacaine with Dexmedetomidine 1mcg/Kg in Usg Guided Infra Clavicular Brachial Plexus Block Administered to Patients Undergoing Upper Limb Surgeries.

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(Received: 16 September 2024 Revised: 11 October 2024 Accepted: 04 November 2024)

KEYWORDS

Levobupivacaine, Ropivacaine, Dexmedetomidine, Brachial plexus block, Ultrasound,

ABSTRACT:

Background**:**Pain is defined as "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.". There are various minimally invasive anesthetic techniques available today to deal with pain. Peripheral nerve block is one of them which entails injecting local anesthetic around the nerve or plexus to make particular dermatomes resistant to pain and noxious stimuli. The brachial plexus blocks are an excellent technique for anaesthesia while performing surgeries of the upper limb. The infraclavicular block was designed by neurologists to overcome the deficiencies of the axillary block. Compared to landmark techniques, the use of ultrasound guidance improves safety. The present study compared the onset and duration of sensory and motor blocks, duration of postoperative analgesia, and hemodynamics of 0.25% levobupivacaine with 1 mcg/kg dexmedetomidine versus 0.375% ropivacaine with 1 mcg/kg dexmedetomidine in infraclavicular brachial plexus blocks.

Materials and methods: A Prospective randomized double blinded observational study was conducted on sixty-two ASA physical status I and II patients, aged between18–60 years undergoing upper limb surgeries under Infraclavicular brachial plexus block. These patients were randomly allocated into either one of the two groups (Group LD and Group RD) by the computer-generated randomized numbers. Group LD was given 30 ml of 0.25% Levobupivacaine with 1mcg/kg Dexmedetomidine and Group RD was given 30 ml of 0.375% Ropivacaine with 1mcg/kg Dexmedetomidine. Both the groups were compared with respect to theonset and duration of sensory and motor block, duration of analgesia, hemodynamic parametersand complications if any.

Results: The outcomes were analysed using statistical software SPSS version 22.0, Repeated Measures Anova is applied to find the relationship between two groups. It was observed that the onset of sensory **(p value 0.04)** and motor blockade (**p value 0.01**) was faster, duration of action and was longer (**p value 0.0001**), and the time required for rescue analgesia was longer **(p value 0.0001)** with minimal hemodynamic complications**(p value 0.08**) in Levobupivacaine group compared to Ropivacaine group.

Conclusion: Based on this study results, it has been concluded thatboth the local anaesthetics Ropivacaine and Levobupivacaine when combined with Dexmedetomidine as an adjuvant, prolonged the block duration and decrease the need for rescue analgesia. After comparing various parameters, 0.25% levobupivacaine with 1 mcg/kg Dexmedetomidine is preferred to 0.375% Ropivacaine with 1 mcg/kg Dexmedetomidine for postoperative pain management due to its pharmacological properties.

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www.jchr.org
JCHR (2024) 14(6), 797-806 | ISSN:2251-6727

Introduction: Pain is defined as "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage."[1].

There are various minimally invasive anesthetic techniques available today to deal with pain which is commonly experienced during and after surgery. Peripheral nerve block is one of them which entails injecting local anesthetic around the nerve or plexus to make particular dermatomes resistant to pain and noxious stimuli. Use of regional an aestheticagent minimizes several risks associated with general anesthesia, such as airway trauma, longer recovery time, post operative nausea, vomiting, sore throat. Regional analgesia has also been found to be a desirable option because of its cost-effectiveness, benefit of postoperative analgesia, relatively stable hemodynamic parameters, early mobilization. The brachial plexus blocks are an excelle nt technique for anaesthesia while performing surgeries of the upper l imb. Georg Hirschel [2] first described the axillary approach to the brachial plexus in 1911 . Although these techniques sho wed many advances, they were s t i l l not without their shortcomin gs: the axillary block could not cover the lateral proximal arm because of the more proximal origin of the musculocutaneous nerve, and was relatively more challenging to undertake in patients who could not abduct their arm. In 1928 , Diedrich Kulenkampff developed the percutaneous supraclavicular approach and published i t with Persky in the same year. The infraclavicular block was designed by neurologists to overcome the deficiencies of the axillary block. This infraclavicular trans - pectoral perivascular technique was described by Bazy in 1914 and further elaborated on by Speigel in 1967 . Compared to landmark techniques, the use of ultrasound guidance improves safety by providing real - t ime visualization of the plexus, pleura, and vessels, important for continual visualization of the advancing needle[3] . Similar the study under ultrasound guidance was performed by Li Jw[4,5,6,7].The present study focuses on the use of levobupivacaine and ropivacaine which share similar pharmacologic properties. A number of adjuvants, including opioids, dexmedetomidine, midazolam, clonidine, and neostigmine, have been studied to accelerate the on set of the block and prolong its duration[8,9]. Dexmedetomidine is used in peripheral nerve blocks due to i t s anxiolytic and analgesic properties; i t is a highly selective alpha- 2 receptor agonist[8 ,10] . The present study has, therefore, been undertaken to compare the onset and duration of sensory and motor blocks, duration of postoperative analgesia, and hemodynamics of 0 . 25 % levobupivacaine with 1 mcg/ kg dexmedetomidine versus 0 . 375 % ropivacaine with 1 mcg/ kg dexmedetomidine in infraclavicular brachial ple xus blocks.

Aim and objectives

Aim of the study: To compare 0.25% Levobupivacaine and 1mcg/kg Dexmedetomidine (group LD) and 0.375% Ropivacaine and 1mcg/kg Dexmedetomidine (group RD) in Infraclavicular brachial plexus block for the patients undergoing upper limb surgeries.

The primary objectives of the s tudy were to compare the onset and duration of sensory block and motor block and duration of analgesia among 2 groups.The secondary objective was to observe the hemodynamic parameters and complications if any.

Study design, location, approval & duration: Thia is **a** prospective randomized double blinded observational s tudy. It was undertaken at ******* Medical College and Hospital for a period of one year, after obtaining the approval from the Institutional Ethics Committee, as per the reference no : 002/SBMC/IHEC/2022/1746 dated 22.09.2022.

Study materials and methodology:

AProspective rando mized double blinded observational study was conducted on sixty-two ASA physical status I and II patients, aged between 18–60 years undergoing upper l imb surgeries under Infraclavicular brachial plexus block. By applying inclusion and exclusion criteria seventy patients were selected after scrutinising seventy-five

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 797-806 | ISSN:2251-6727

patients. Out of seventy selected patients, sixty-two patients were taken up for the study. Informed consent was obtained from all selected patients for their participation in this research. Basic blood investigations such as complete hemogram, Random blood sugar and renal function tests were performed prior to surgery. X-ray of the chest-PA view and 12 lead ECG were taken for all the patients. All patients were advised to follow a minimum period of six hours fasting for solid food and two hours for transparent particulate free liquids prior to surgery. These patients were randomly allocated into either one of the two groups (Group LD and Group RD) by the computer-generated randomized numbers. Group LD was given 30 ml of 0.25% Levobupivacaine with 1mcg/kg Dexmedetomidine and Group RD was given 30 ml of 0.375% Ropivacaine with 1mcg/kg Dexmedetomidine. Both the groups were compared with respect to theonset and duration of sensory and motor block, duration of analgesia, hemodynamic parameters and complications if any. IV access was established by using 18G cannula on the non-operating hand and 100ml/hr Ringer lactate was started intravenously.The baseline vitals like respiratory rate, pulse rate, oxygen saturation and blood pressure were noted. All patients were made to lie down supine with the head turned slightly away from the arm being given the block. The Infraclavicular brachial plexus block was given under ultrasound guidance. Since this was a double blinded study, both the investigator and the patient were unaware about which localanaetheticdrug was given for the block. The injection was prepared by another anaesthesiologist based on the sealed envelope containing the computer-generated random number. The syringe was labelled with patients name and handed to the investigator who performed the block. Under asept ic precautions, the infraclavicular region i s identified with the aid of ultrasound and the block i s administered. The principle investigator observed and recorded the onset and duration of sensory and motor blockade, hemodynamic parameters during intra operative period. Later, post operatively the investigator assessed pain using VAS score hourly up to 10 hours. The sensory blockade was assessed using the pin prick method every minute till the complete anaesthetic effect was received. The sensory block was graded as [Fig/Table1]. Duration of the sensory block was the reversal of sensation from Grade 2 to Grade 1.The motor Block was assessed with the Modified Bromage Scale [Fig/Table2]. The onset of motor block time was noted from the time of injection to Grade 2 The Duration of the motor block was the time from Grade 2 to the reversal to Grade 1. The surgery was started after the complete sensory and motor block was attained. The hemodynamic parameters (the vital signs) were notedEvery 15 minutes during first 1 hour and there after every hour till the end of the surgery. Postoperatively the patients were examined at 30 minutes and at 60 minutes and every hourly thereafter till rescue analgesia was needed. The pain was analysed with the VAS score. The researcher noted the t ime required for the first rescue analgesia.

Grade of sensory Block	Symptom
Grade 0	Normal sensation/Sharp pain felt
Grade 1	Dull pain or Blunted sensation
Grade 2	No pain feeling even after pin prick

[Fig/Table1] Grades of sensory block

Grade of motor Block	Symptom
Grade 0	Full Flexion and Extension of elbow, wrists and fingers
Grade 1	Weakness in Grip
Grade 2	Unable to move fingers

[Fig/Table2] Modified Bromage scale

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 797-806 | ISSN:2251-6727

Sample Size: This sample size was calculated based on the primary objective of the study " Observational study of 0.25% Levobupivacaine with Dexmedetomidine 1mcg/kg versus 0.375% Ropivacaine with Dexmedetomidine 1mcg/kg in USG guided Infra clavicular brachial plexus block administered to patients undergoing upper limb surgeries." From the previous literature "Comparison of the onset time between 0.375% ropivacaine and 0.25% levobupivacaine for ultrasound-guided infraclavicular brachial plexus block: a randomized-controlled trial" by Ha-Jung Kim etal. [11]

SAMPLE SIZE CALCULATION FORMULA:

$$S_1 = 8.62; \quad S_2 = 8.39; \quad n_1 = 30; \quad n_2 =$$

$$n_p = \sqrt{\frac{(n_1 - 1)S_1^2 + (n_2 - 1)S_2^2}{n_1 + n_2 - 2}}$$

$$n_p = \sqrt{\frac{(29) * 8.62^2 + (29) * 8.39^2}{28}}$$

$$n_p = \sqrt{\frac{(29 * 74.3) + (29 * 70.3)}{28}}$$

n = 31(in each group)

Statistical analysis:

Data entered using MS excel and analysed using a statistical software SPSS version 22.0. Descriptive statistics is given by frequency, percentage, mean, SD and graphs. Repeated Measures ANOVA is applied to find the relationship between two groups when compared to different time points i.e., inter and intra comparison is found. Chi-square test is applied to find the association between demographic variables across two groups (outcome). P- Value <0.05 is considered significant throughout the study.

Observations and results:

Totally 70 patients were scrutinised for this study. 62 patients met the criteria and were included for this research. They were divided into two groups of 31 patients in each. These patients were randomly allocated into either one of the two groups (Group LD and Group RD) by the computer-generated randomized numbers. Group LD was given 30 ml of 0.25% Levobupivacaine with 1mcg/kg Dexmedetomidine and Group RD was given 30 ml of 0.375% Ropivacaine with 1mcg/kg Dexmedetomidine.

Mean Age,weight,ASA,Gender distribution showed a p value of >0.05 which was not of clinical significance in this study.The hemodynamics in both the groups in terms of heart rate, blood pressure and SpO2 remained stable throughout the procedure. Although there was a reduction in heart rate, systolic and diastolic blood pressurecompared to the baseline in both the groups which was statistically significant with a p value <0.05 [Fig/Table3,4,5,6]. During the intraoperative phase, no adverse consequences were noticed.In this study upon analyzing the onset of sensory and motor block in minutes, it was noticed that, the onset of both sensory and motor block was faster (mean 8.58, 13.2 min respectively) in Levobupivacaine with Dexmedetomidine group (LD) compared to Ropivacaine with Dexmedetomidine group (RD) and was statistically significant. [P=0.048 for sensory and p=0.01 for motor onset, therefore (p <0.05)]. [Fig/Table7].In this study upon analyzing the duration of sensory and motor block in hours, It was noticed that, the duration of both sensory and motor block was more in Levobupivacaine with Dexmedetomidine group with a mean of 11.2 hours for sensory and 10.4 hours for motor blockade compared to Ropivacaine with Dexmedetomidine group with a mean of 10.2 hours for sensory and 8.9 hours for motor blockade and this was statistically significant. [P =0.0001 for both sensory and motor block duration.[Fig/Table8]. In this study upon analyzing the mean **time for rescue analgesia** in hours, it was observed that Ropivacaine with Dexmedetomidine group (RD) required rescue analgesia within 11.6 hours of block whereas Levobupivacaine with Dexmedetomidine group (LD) required analgesia after 12.8 hours, therefore the P value (P=0.04) is statistically significant (p <0.05). . [Fig/Table 9].When two groups were analysed for **complications** it was observed that both Levobupivacaine with Dexmedetomidine GROUP (LD) and Ropivacaine with Dexmedetomidine group (RD) had few complications and thus the p value is insignificant. [Fig/Table 10].

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 797-806 | ISSN:2251-6727

[Fig/Table 3] Mean Spo2 distribution

Mean SPO2 (%)	Group LD		Group RD		P value
	Mean	SD	Mean	SD	
0 min	99.13	0.78	98.90	0.80	0.257
5 min	98.77	0.86	99.13	0.82	0.096
15 min	99.20	0.76	99.10	0.96	0.656
30 min	98.90	0.80	99.10	0.84	0.351
60 min	99.23	0.77	99.00	0.87	0.277
2 hrs	99.17	0.79	98.80	0.81	0.081
6 hrs	99.20	0.85	99.17	0.87	0.881
12 hrs	99.00	0.79	99.07	0.78	0.744
24 hrs	98.90	0.80	98.90	0.88	>0.999

[Fig/Table 4] MeanHeart ratedistribution

Mean Pulse Rate (beats per min)	Group LD		Group RD		P value
	Mean	SD	Mean	SD	
0 min	78.20	8.48	77.60	5.69	0.431
5 min	75.77	8.12	75.00	6.20	0.752
15 min	71.57	7.32	73.53	5.45	0.182
30 min	69.17	7.49	74.73	5.84	**0.002**
60 min	67.03	5.06	75.03	6.50	**<0.001**
2 hrs	65.70	3.81	75.37	6.57	**<0.001**
6 hrs	66.57	5.10	76.47	6.62	**<0.001**
12 hrs	67.37	6.24	76.27	6.48	**<0.001**
24 hrs	71.67	7.28	77.20	6.73	**0.003**

[Fig/Table 5] Mean systolic blood pressure distribution

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 797-806 | ISSN:2251-6727

Mean Systolic Blood Pressure (mm Hg)	Group LD		Group RD		P value
	Mean	SD	Mean	SD	
0 min	118.40	8.10	122.33	9.57	0.078
5 min	114.47	7.50	120.73	9.68	**0.030**
15 min	111.60	8.48	115.13	9.55	**0.014**
30 min	110.47	8.80	114.20	9.48	0.110
60 min	113.26	7.70	114.37	9.17	0.637
2 hrs	113.73	7.88	116.47	9.60	0.241
6 hrs	114.90	7.48	121.43	9.54	**0.014**
12 hrs	115.73	8.11	123.73	9.52	**0.001**
24 hrs	116.50	7.52	126.07	7.58	**<0.001**

[Fig/Table 6] Mean diastolic blood pressure distribution

Mean Diastolic Blood Pressure (mm Hg)	Group LD		Group RD		P value
	Mean	SD	Mean	SD	
0 min	75.13	5.51	81.40	4.80	**<0.001**
5 min	74.13	5.67	80.42	5.26	**<0.001**
15 min	73.23	5.67	79.22	5.67	**0.001**
30 min	73.22	5.66	78.22	5.47	0.053
60 min	73.17	5.53	77.54	5.21	0.384
2 hrs	73.07	5.84	77.23	5.54	0.412
6 hrs	73.01	5.52	77.73	5.64	**0.001**
12 hrs	74.45	5.46	79.32	5.65	**<0.001**
24 hrs	75.01	5.47	82.22	5.71	**0.001**

[Fig/Table 7] Onset of sensory and motor block

	Group				P-VALUE
	LD		RD		
	Mean	Standard Deviation	Mean	Standard Deviation	

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 797-806 | ISSN:2251-6727

Onset of Sensory block in min	8.58	1.522	9.6	1.655	**0.048**
Onset of Motor block in min	13.2	2.01	14.7	2.252	**0.01**

[Fig/Table 8] Duration of block

	Group				P-VALUE
	LD		RD		
	Mean	Standard Deviation	Mean	Standard Deviation	
Duration of Sensory block in hours	11.2	0.71	10.2	0.75	**0.0001**
Duration of motor block in hours	10.4	1.02	8.9	0.41	**0.0001**

[Fig/Table 9] Time of rescue analgesia

	Group				P-VALUE
	LD		RD		
	Mean	Standard Deviation	Mean	Standard Deviation	
Time of first rescue analgesic in hours	12.8	1.16	11.6	0.91	**0.0001**

[Fig/Table 10] Complications

		Group				P-VALUE
		LD		RD		
		Count	Column N %	Count	Column N %	
Complications	Bradycardia	0	0.0%	2	6.5%	0.08
	bradycardia, hypotension	6	19.4%	3	9.7%	
	Nil	25	80.6%	26	83.9%	

Discussion

Peripheral nerve blocks are cost - effective techniques that provide anaesthesia and pain relief without instrumentation of the airway and associated hemodynamic changes of general anaesthesia. Blocks play a key role in multimodal analgesic strategies that reduce opioid use. For example, the infraclavicular block addresses divisions and cords of the brachial plexus, providing anesthesia to the hand, forearm, elbow, and lateral upper arm. Performance of these blocks using ultrasound improves their accuracy and precision. Studies have demonstrated that the addition of dexmedetomidine to peripheral nerve blocks

Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 797-806 | ISSN:2251-6727

accelerates onset, prolongs sensory and motor blockades, and assures satisfactory sedation. On the other hand, the serious side effects of dexmedetomidine include bradycardia, hypotension, and oversedation[9 , 12] . Levobupivacaine and ropivacaine are amino - amide local anaesthetics, they share similar pharmacologic properties. In the present study, the onset and duration of sensory and motor blocks, duration of postoperative analgesia, and hemodynamic effects were compared using these drugs with dexmedetomidine as an adjuvant in two different groups.

Onset of action

In both groups, when compared the time of onset of sensory and motor block it was found that group LD had (an average) faster onset of both sensory and motor block than that in group RD. These finding were supported by a study conducted by Kulkarni etal.,[13] who compared the effectiveness of 0.5% levobupivacaine and 0.5% ropivacaine in supraclavicularbrachialplexusblock and found significant earlier onset of sensory blockade (p=0.027) and motor blockade (p=0.01) in 0.5% levobupivacaine group. In contrast, in a study by Ha-Jung Kim et al.,[11] in an ultrasound-guided infraclavicular brachial plexus block, on the times of onset of sensory block using 0.375% ropivacaine and 0.25% levobupivacaine, they proved that the time to sensory block onset was shorter in the ropivacaine group compared to levobupivacaine with a P-value of 0.001. According to Margarita M. Puig et al., [14] the onset of motor block in axillary brachial plexus block with 0.5% ropivacaine was much faster than that with 0.33% levobupivacaine.

Duration of blockade:

In both groups, when compared the duration of sensory and motor block it was found that group LD had (an average) longer duration of both sensory and motor block with a mean of 11.2 hours for sensory and 10.4 for motor, than that in group RD with a mean of 10.2 hours for sensory and 8.9 hours for motor block. As reported by Anjan Das, Singh AP, addition of dexmedetomidine to different local anaesthetics significantly prolonged the duration of both sensory and motor block. All these studies showed that the block duration was significantly increased with the use of dexmedetomidine as an adjuvant compared to normal saline, marked by a p-value less than 0.001. The results strongly favor the effectiveness of dexmedetomidine in extending regional anesthesia blocks without raising adverse effects[15,16].

Time of rescue analgesia:

In this study, the first rescue analgesic was required later in group LD compared to group RD, with mean durations of 12.8 and 11.6 hours respectively. In a study, Haramritpal Kaur etal.,[17] added 1 µg/kg dexmedetomidine to 0.25% levobupivacaine, which prolonged the time to rescue analgesia from a mean of 8.5 ± 0.77 hours with levobupivacaine to 9.2 ± 1.05 hours with the addition of dexmedetomidine; the difference was significant with $P < 0.05$. A recent study by Shamjith K et al[18]., added dexmedetomidine to 0.5% levobupivacaine in a brachial plexus block and prolonged the time to analgesia to 980 minutes with adequate intraoperative sedation and reduced postoperative analgesic requirements. In a 2017 study, Li, Ang et al. compared ropivacaine to levobupivacaine for peripheral nerve block and found that there was no significant difference in postoperative analgesia duration[19].

Complications : In this study, both groups LD and RD had very few complications, making p-value insignificant.A study by Shamjith Ket al., added dexmedetomidine to a mixture of levobupivacaine for brachial plexus block which caused bradycardia in 20% of patients[18]. Another study by Singh AP et al. revealed no adverse effect on the drug combination of dexmedetomidine with levobupivacaine used for supraclavicular brachial plexus block[16].

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