ORIGINAL ARTICLE

INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACEUTICAL SCIENCES

Published by JK Welfare & Pharmascope Foundation Journal Home Page: www.pharmascope.org/ijrps

Comparison of the use of levobupivacaine with dexamethasone versus plain levobupivacaine in patients undergoing forearm surgeries under an infraclavicular block - a double-blinded randomized controlled trial

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Article History:

Received on: 25.07.2019
Revised on: 12.10.2019
Accepted on: 18.10.2019

Keywords:

Brachial Plexus Block, ultrasound-guided infraclavicular block, levobupivacaine, dexamethasone, perineural adjuvants

ABSTRACT

Regional anesthesia can provide greater patient satisfaction. An infraclavicular approach to block the brachial plexus aided with ultrasound is proven to be safe. Lesser toxic, levobupivacaine, advocates its use, with the addition of dexamethasone, to prolong the action. After approval from the ethics committee, the consenting patients, for orthopedic forearm surgeries, were recruited, randomized into two groups of 20 patients. Group-A**,** received 30mls of 0.5% levobupivacaine with dexamethasone 4mgs(1ml) and Group-B,30mls of 0.5% levobupivacaine and 1ml normal saline.18-70 Year olds, ASA I-III, weight greater than or equal to 50 kg, were included and non-consenting, coagulopathic, local infection, pregnant women, general anesthesia requirement, less than 50kg, allergy to local anesthetic, were excluded. Both groups received the infraclavicular block. The onset and duration of sensory and motor blockade were noted. Comparisons made at 3 and 20 minutes. Required data was acquired. Visual Analogue Scale(VAS)used to assess pain. The onset of sensory and motor blockade was assessed and graded separately on radial, median and ulnar nerves, with significant findings of about 70-80% in Group-A at 4-5 minutes,80-87% complete at 20 minutes.87.5% Patients in both groups achieved adequate surgical anesthesia. There was a significant improvement in sensory grading of the median nerve and ulnar nerve between at 3 minutes and 20 minutes and also in motor grading improvement at 20 minutes duration in the Group-A than Group-B. Postoperatively, the VAS score showed scores hovering around 1-4, over 24 hours, with no difference, in scores, duration, and use of rescue analgesia in both arms. There were no statistical differences in the onset and duration of sensory and motor blockade in both groups, with some difference in the quality of analgesia between the nerves studied in group-A. Although a larger sample size might have brought out some difference in pain scores, with the addition of dexamethasone, its clinical implication is doubtful.

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ISSN: 0975-7538

DOI: https://doi.org/10.26452/ijrps.v11i1.1780

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INTRODUCTION

Regional neural blockade with local anesthetic can reduce pain following orthopedic surgery and result in greater patient satisfaction. Safety of the ultrasound-guided brachial plexus block, via the infraclavicular approach, has been proven.

Levobupivacaine is a long-acting local anesthetic and is an S(-) enantiomer of bupivacaine. It has a better margin of Safety, in terms of having less cardiovascular and central nervous system side effects. Pharmacological agents used as adjuvants that increase the duration of local anesthetic action prolong the postoperative analgesia of the patient during the postoperative period. Perineural dexamethasone prolonged the duration of analgesia and motor blockade when used with local anesthetics.

MATERIALS AND METHODS

This was a randomized controlled double-blinded study, approved by the Institutional Review Board (IRB Min No:9885[INTERVEN] dated 20.01.2016), Clinical Trial Registry of India(REF/2016/02/010691). The consenting patients, for orthopedic forearm surgeries, were recruited, randomized into two arms of 20 patients in each groupFigure 1.Group-A received 30mls of 0.5% levobupivacaine with dexamethasone 4mgs (1ml) and Group-B 30mls of 0.5% levobupivacaine with 1ml normal saline. Patients aged 18-70 years-Figure 2, ASA I-III, weight greater than or equal to 50 kg, were included, and those unwilling for the block, presence of coagulopathy, local infection, pregnant women, general anesthesia requirement, weight less than 50kg, allergy to local anesthetic, were excluded. Both groups received ultrasound-guided brachial plexus block via the infraclavicular approach with complex peripheral nerve stimulating needle. The onset and duration of sensory and motor blockade were noted. Comparisons made at 3 and 20 minutes. Required data were acquired as per the study protocol. Postoperatively, the pain was assessed using the Visual Analogue Scale(VAS).

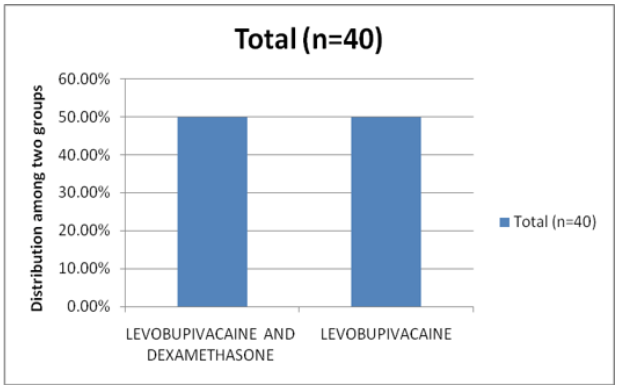

Figure 1: Total number of cases

RESULTS AND DISCUSSION

The data collected in the perioperative period have been analyzed with appropriate statistical methods. There were no significant differences in the baseline characteristics of both treatment arm. The onset of sensory and motor blockade was assessed and graded separately on radial, median and ulnar nerves, with significant findings of about 70-80% in Group-A at 4-5 minutes, 80-87% complete at 20 minutes. 87.5% of patients in both groups achieved adequate surgical anesthesia Figure 3. However, there was a significant improvement in sensory grading of the median nerve and ulnar nerve between at 3 minutes, 20 minutes, and also in motor grading improvement at 20 minutes duration in the Group-A than Group-B. Postoperatively, the VAS score showed scores hovering around 1-4, over 24 hours, however, with no difference, in scores, duration, and use of rescue analgesia in both arms.

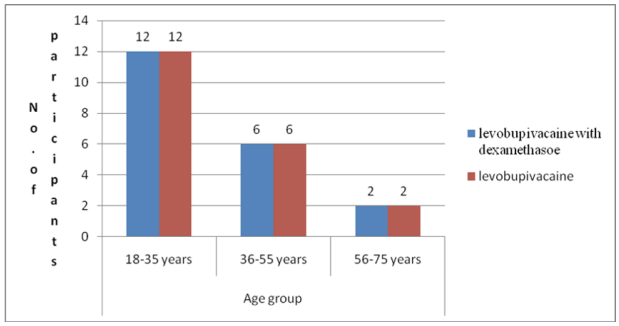

Figure 2: Age distribution

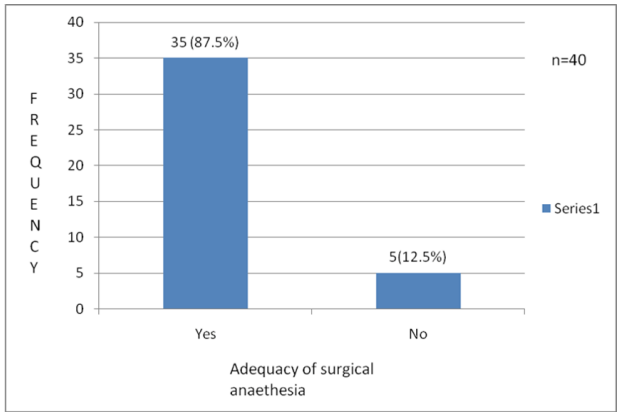

Figure 3: Adequacy of surgical anesthesia

In orthopedic surgeries involving the forearm, surgical anesthesia can be achieved by regional anesthesia techniques, which frequently involve a brachial plexus block.

For surgeries involving the upper extremities, irrespective of its indication, regional anesthesia is far superior to general anaesthesia (Oliveira *et al.*, 2014). This technique provides a longer duration of pain relief, minimizes intra and post-operative requirements of opioids .while at the same time avoiding the complications of general anesthesia which include airway trauma, PONV (Postopera-

Table 1: Modified Bromage Scale Grading of motor blockade

	Levobupivacaine with dexamethasone Motor grading				Levobupivacaine Motor grading			
Time	Grade 0	Grade 1	Grade 2	Grade 3	Grade 0	Grade 1	Grade 2	Grade 3
5min	5	6	5	0	4	9	2	2
10min	2	9	8	0	2	10	7	2
15min	1	6	12	3	2	8	11	1
20min	1	0	11	6	1	3	16	1

Table 2: VAS scores

VAS Score		0	1	2	3	7
Time in hours	3 hours	28(70.00%)	8(20.00%)	4(10.00%)		
	6 hours	24(60.00%)	11(27.50%)	4(10.00%)	1(2.50%)	
	12 hours	22(55.00%)	11(27.50%)	4(10.00%)	2(5.00%)	1(2.50%)
	24 hours	21(52.50%)	7(17.50%)	11(27.50%)		1(2.50%)
Levobupivacaine with dexamethasone						
VAS Score		**0**	**1**	**2**	**3**	**7**
Time in hours	3hrs	13(65.00%)	5(25.00%)	2(10.00%)		
	6hrs	11(55.00%)	8(40.00%)	1(5.00%)		
	12hrs	11(55.00%)	6(30.00%)	2(10.00%)	1(5.00%)	
	24hrs	10(50.00%)	5(25.00%)	5(25.00%)		
Levobupivacaine						
VASscore		**0**	**1**	**2**	**3**	**7**
Time in hours	3hrs	15(75.00%)	3(15.00%)	10		
	6hrs	13(65.00%)	3(15.00%)	3(15.00%)	1(5.00%)	
	12hrs	11(55.00%)	5(25.00%)	2(10.00%)	1(5.00%)	1(5.00%)
	24hrs	11(55.00%)	2(10.00%)	6(30.00%)		1(5.00%)

tive Nausea and Vomiting). Deposition of local Anesthetic, close to the brachial plexus, with the help of ultrasound-guidance, via the infraclavicular approach, for surgeries below the elbow, will be effectively achieved (Chin *et al.*, 2013). It provides better analgesia in the postoperative period and quicker recovery from the anesthesia. Inadequate management of postoperative pain has several detrimental effects, which interferes with wound healing, increased stress response, potentiating the risk of myocardial infarction. Dexamethasone has been added to local anesthetics, amongst numerous adjuvants, such as clonidine, buprenorphine, neostigmine, tramadol, epinephrine, which have helped, improve postoperative analgesia (Bailard *et al.*, 2014). Clinical studies in regional anesthesia, have time and again, assessed the efficacy of dexamethasone mixed with local anesthetics and instilled perineurally, including epidural (Lauretti *et al.*, 2013; Naghipour *et al.*, 2013) brachial plexus (Persec *et al.*, 2014) , femoral and sciatic (Fredrickson *et al.*, 2013) and facial and dental blocks (Jürgens *et al.*, 2012).

Acute postoperative pain assessment, such as duration of analgesia, pain scores, opioid consumption, are found to better by perineural instillation of local anesthetic with dexamethasone (Waldron *et al.*, 2013). The extent of blockade is assessed most accurately, by assessing each individual nerve separately, as the innervation of the arm is from different terminal nerves 24 and 48 hour pain scores, were significantly lower, postoperatively, with lesser opioid consumption and its related side effects, by the addition of dexamethasone to LA, cor-

responding to less opioid consumption over those 24– 48 hours, thereby reducing opioid-related side effects (Oliveira *et al.*, 2014).

Perineural local anesthetic with added dexamethasone, via the brachial plexus, demonstrated delayed latency and recovery of motor block, consistent with the findings of Choi et al (Choi *et al.*, 2014). According to a study done by Jasminka, single-shot dexamethasone in a mixture with Levobupivacaine for supraclavicular block results in prolonged analgesia duration and less analgesic use in comparison with Levobupivacaine (Abdallah *et al.*, 2015). Dexamethasone is a highly potent, long-acting glucocorticoid with little mineralocorticoid effects, has shown to prolong peripheral nerve blockade in animals. However, in humans, when added to bupivacaine microspheres, the duration of analgesia is prolonged (Albrecht *et al.*, 2015; Holte *et al.*, 2002) .In our study we found that there was considerable improvement of sensory grading from 5 to 85 % in Group-A and also the difference between two groups was 20% for grade-1 sensory grading of radial nerve, but no statistical significance, in radial nerve sensory grading between the time duration of 3 to 20 minutes Table 1. This group also had 60-75% of the patients had the onset of sensory blockade for radial nerve around 4-5 minutes and 85% at the end of 20 minutes, whereas 75% achieved sensory blockade of radial nerve after 20 minutes in Group-B. However, this was not statistically significant. There was a considerable improvement in sensory grading from 10 to 90 % in Group-A, and also, the difference between the two groups was 30% for grade-1 with statistically significant improvement in median nerve sensory grading between duration of 3 minutes and 20 minutes Table 1. There was a significant improvement of sensory grading from 10 to 90% in group-A, and also, the difference between the two groups was 45% for grade 1, which shows a statisticaly significant improvement in ulnar nerve between duration of 3 minutes and 20 minutes. In our study, almost 80% of the patients had the onset of a motor blockade at the end of 10 minutes. The difference between the two groups is, although not significant. In our study, we identified 65% improvement in motor grading to grade-2 in group-A and 85% improvement to grade 2 in group-B at the end of 20 minutes.

Overall there is a significant improvement of a motor blockade at the end of 20 minutes (p-value is 0.025). Infraclavicular block, in particular, has its advantages over the supraclavicular block. It has fewer complications, provides complete surgical anesthesia of the operative part, and immobilization of the upper limb during surgery. The infraclavicular block has several advantages to its credit. Primarily, it completely blocks the brachial plexus at its formation of the three cords positioning itself, laterally, medially and posteriorly, closely alongside the axillary artery.

Therefore, it is easily approachable and establishment of anesthesia for upper limb surgery complete with a single injection. Tourniquet pain is caused by the compression of the intercostobrachial nerve (T2 root value). With the infraclavicular block, this nerve is blocked top; thereby, the occurrence of tourniquet pain is a rare entity (Sardesai *et al.*, 2006; Benumof, 2000). Furthermore, in this approach, the risk of pneumothorax, injury to major structures in the neck is also low as compared with the interscalene and supraclavicular approaches to brachial plexus block. Finally, the infraclavicular block can safely and easily perform with neutral arm and neck position (Conroy and Awad, 2011). In our study, patients were assessed for sensory blockade by a distribution of ulnar, median, and radial nerves. A modified Bromage scale for the upper extremity was used to assess motor power. In our study, among the 40 patients who underwent orthopedic forearm surgeries, the infraclavicular block was able to provide adequate surgical anesthesia for 87.5% of patients. But the success of the block was not statistically significant (p-value was 0.33). In our study, postoperative pain was measured using a visual analog scale ranging from 0-10 and was recorded at various time intervals. There were no differences in postoperative pain scores in both arms Table 2. Only 5% of patients in group-A required aceclofenac at the end of 2 hours compared to 15% of patients in group-B. Depending on the approach to block the brachial plexus, such as interscalene and supraclavicular, which have potential neurological complications, presenting as respiratory distress, Horner's syndrome, and recurrent laryngeal nerve injury (Pehora *et al.*, 2017). However, none of the patients developed any complications directly attributable to the intervention, with the approach used in this study. There was no incidence of postoperative nausea and vomiting in any of the patients.

CONCLUSIONS

This study demonstrated no statistical differences in the onset and duration of sensory and motor blockade in both groups, with some difference in the quality of analgesia between the nerves, studied in the group with added dexamethasone. Although a larger sample size might have brought out some difference in the post-operative pain scores, in favor of

the addition of dexamethasone, its clinical implication is doubtful.

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