VOLUME-9, ISSUE-2, FEBRUARY-2020 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Anaesthesiology

PROSPECTIVE RANDOMIZED DOUBLE BLINDED COMPARATIVE STUDY OF SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK USING LEVOBUPIVACAINE VERSUS ROPIVACAINE.

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ABSTRACT

Background: Over decades various local anaesthetic agents have been used for utility of supraclavicular brachial plexus block. Levobupivacaine, an excellent local anaesthetic as well as Ropivacaine, a long-acting local anaesthetic.

Methodology: Patients were randomly allocated into two study groups (30 patients each) of all patients received 30 ml of 0.5% injection Levobupivacaine and injection Dexmedetomidine 1μg/kg (LD) while in other group all patients received 30 ml of 0.5% injection Ropivacaine and injection Dexmedetomidine 1μg/kg (RD).

Results: Time to onset and duration of both sensory and motor block was comparable in two groups (P>0.05). Though mean duration of analgesia was significantly (p<0.005) more for Group-LD when compared to Group-RD. The difference in mean score of VAS in both groups was significantly better for LD-Group at 12, 14 and 16 hour post-operative period (P<0.05) though initially it was comparable.The consumption of Diclofenac as rescue analgesia was significantly higher in Group-RD as compared to Group-LD.

Conclusion: Addition of dexmedetomidine along with levobupivacaine for supraclavicular brachialplexus block enhances the duration of postoperative analgesia as well diminished requirement for rescue analgesia in postoperative period compaired to along with ropivacaine.

KEYWORDS : Levobupivacaine versus ropivacaine, Dexmedetomidine, Analgesia.

INTRODUCTION

The greatest millstones of medicine must be conquering pain which has impact on every human life since 1846, mankind's greatest fears, the pain of surgery, was eliminated with anaesthesia.[1]

Regional anaesthesia techniques provide important advantages over general anaesthesia, including excellent pain control, reduced side effects (trauma to lips, teeth, pharynx, vocal cords; nausea, vomiting; bronchospasm, aspiration; prolonged somnolence, prolonged paralysis; malignant hyperthermia;risk of anaphylactic or anaphylactoid reactions), and shortened stay in the post-anaesthesia care unit.[2-6]

Peripheral nerve blocks has become technique of choice for anaesthesia and postoperative analgesia in orthopaedic, plastic, and peripheral vascular surgery and for the treatment of chronic pain syndrome.[7]

Brachial plexus blockade is one of the approaches to sensorimotor regional neural blockade by which surgical anaesthesia of the upper limb may be achieved. It is preferred in upper limb surgeries because it has certain advantages.[8,9] Supraclavicular approach gives the most effective block for all portions of upper extremity.[10]

Over decades various local anaesthetic agents have been used for utility of supraclavicular brachial plexus block. Levobupivacaine, an excellent local anaesthetic drug with lesser side effects is also used for utility of the supraclavicular brachial plexus block. Ropivacaine, a long-acting local anaesthetic that is being used for supraclavicular brachial plexus block in upper limb surgery. The aim of prolonging the duration of peripheral nerve blocks to treat postoperative pain is a key issue in regional anaesthesia.

Adjuvants with local anaesthetics in brachial plexus block are used to achieve a quick, dense, and prolonged block.[11]Various adjuvants like tramadol[12],sufentanyl[13] clonidine[13]and fentanyl[14] have been employed in the search for near ideal agent. Currently, Dexmedetomidine, an α_2-receptor agonist, a congener of cloniodine, has also been reported to improve the quality of intrathecal and epidural anaesthesia.[15,16]

In this study we will assess and compare the effects of levobupivacaine and ropivacaine along with dexmede tomidine as an adjuvant to both local anaesthetic agents.

MATERIALS AND METHODS

The present prospective randomized double blinded comparative study was done in 60 in-patients admitted in the orthopaedics ward in NSCB Medical College and Hospital, Jabalpur (M.P) after obtaining institutional ethical approval and written informed consent from patients.

All patients underwent through a pre-anaesthetic check-up (detailed history, thorough physical examination, routine investigation and any especial investigation if required were done) and patients of either sex between 25 – 55 years of age, of ASA class-I and II and of weight >50Kg who were posted for elective surgeries on arm, forearm, hand or wrist were included in study.

Patients who have refused to be the part of study, who has allergy to local anaesthetics, infection at needle insertion site, on anticoagulant therapy or with bleeding disorders, has cardiopulmonary contraindications, pregnant woman, neuropathy or Diabetes mellitus, liver or renal dysfunctions were excluded from the study.

Patients were randomly allocated into two study groups (30 patients each) by using the computer generated table of random numbers:

- **Group LD:** All patients received 30 ml of 0.5% injection Levobupivacaine and injection Dexmedetomidine 1μg/kg.
- **Group RD:** All patients received 30 ml of 0.5% injection Ropivacaine and injection Dexmedetomidine 1μg/kg.

After taking thorough history and informed consent, the patients were placed on the operation table in supine position. Before starting the procedure all the standard monitors (NIBP cuff, pulse oximetery probe, ECG) were connected to all the

patients and intravenous access was secured by using an IV cannula of 18G. All patients were pre-medicated with i/v injection Midazolam1mg.

Under all aseptic precautions, after painting and draping the supraclavicular brachial plexus block was performed by using 5cm 22G. In Group LD all patients in this group received 30mL of 0.5% inj. Levobupivacaine and inj. Dexmedetomidine 1μg/Kg. In Group RD all patients in this group received 30ml of 0.5% inj. Ropivacaine and inj. Dexmedetomidine1μg/Kg.

If there was failure of the block in the area of nerve distribution, patients were provided general anaesthesia and these patients were excluded from our study.

The onset and duration of sensory block was studied using *Hollmen sensory score scale*. The loss of sensation to pin prick in the midline (with 22G blunt hypodermic needle) was checked every 30 seconds after injection of the drug till the onset of loss of sensation and then every half hourly till the sensations were regained.

The motor blockade was assessed by using *Modified Bromage scale score* every 1 minute till the loss of movements and then every half hourly till the movements are regained. The cutoff score for sensory block was taken as Hollmen sensory scale score of 2.

Post operative pain was assessed by visual analog scale (VAS) at 2h, 4h, 6h, 8h, 10h,12h, 14h,16, 20h, and 24h after surgery. VAS score of zero -denote no pain, 1-3 -mild pain, 4–7 - moderate pain, 8–10 -severe pain. When VAS score became >3, rescue analgesia was provided with the i.m. injection Diclofenac Sodium75mg.

Sedation score was assessed according to the *Ramsay sedation scale* (RSS) from 1- 6 where higher score suggest higher sedation.

After completion of the study, the results were statistically analyzed using Chi-square test for nonparametric data and Student unpaired *t*-test for parametric data for inter-group comparison. Statistical analysis was done using SPSS III Statistics for Windows, Version 20.0. The value of $p<0.05$ was considered significant.

RESULTS

Patients of two study groups had a comparable (p=0.8076) mean age of the patients was 36.83±10.51years in Group-LD and 37.53±11.62 years in Group-RD. There were 19 (63.33%) males while 11 (36.66%) were females patients in Group-LD, and males were 22 (73.33%) and females were 8 (26.66%) in Group-RD (p>0.05).

Pre-operative vitals like mean blood pressure, and mean pulse rate were also comparable in both groups (P>0.05).

Time to onset and duration of both sensory and motor block was comparable in two groups (P>0.05). Though mean duration of analgesia was significantly (p<0.005) more for Group-LD when compared to Group-RD.

The difference in mean score of VAS in both groups was significantly better for LD-Group at 12, 14 and 16 hour post-operative period (P<0.05) though initially it was comparable.

A mean 80±19.02 mg of Diclofenac was administered to the patient of Group-LD as rescue analgesia, while patients of Group-RD consumed 100±35.95 mg of Diclofenac. The consumption of Diclofenac as rescue analgesia was significantly higher in Group-RD as compared to Group-LD.

The mean sedation score on Ramsay sedation scales core was 2.3±0.83 for Group-LD while 2.4±0.77 for Group-RD with no difference in sedation scores ($p>0.05$).

Table 01: Comparison of sensory and motor parameters between two study groups.

Parameters	LD Mean±SD	RD Mean±SD	*P-value*
Sensory Block			
Onset (Min.)	9.34±1.45	9.99±1.49	*0.0912*
Duration (Min.)	769.16±76.23	739.16±44.89	*0.0683*
Motor Block			
Onset (Min.)	13.87±1.22	14.37±1.41	*0.1471*
Duration (Min.)	667.13±57.96	643.5±39.28	*0.0696*
Duration of analgesia (Min.)	942.7±80.63	885.76±43.92	*0.0012*
Inj. Diclofenac consumption (mg)	80±19.02	100±35.95	*0.0093*
Sedation Score (RSS)	2.3±0.83	2.4±0.77	*0.6319*

Table 2: Post-operative VAS score

VAS Score	LD Group Mean±SD	RD Group Mean±SD	*p-value*
2 hr	0±0	0±0	1.0
4 hr	0±0	0±0	1.0
6 hr	0±0	0±0	1.0
8 hr	0±0	0±0	1.0
10 hr	0±0	0.067±0.36	0.3215
12 hr	0.4±0.77	1.6±0.93	<0.01
14 hr	2.36±1.49	3.46±0.77	<0.01
16 hr	2.53±1.88	1.46±1.96	0.036
20 hr	0.3±1.02	0±0	0.1134
24 hr	1.3±1.48	1.93±1.7	0.1303

The incidence of any adverse events was almost comparable in both groups. No life threatening complications were noted in the patients of either group.

DISCUSSION

Inadequate management of surgical pain can delay surgical recovery, decrease patient satisfaction and increase the length of hospitalization, readmission rates and overall healthcare costs. Currently pain relief by regional anaesthesia is the most effective method to manage acute pain and is more effective in comparison with intravenous patient controlled analgesia.[17] Brachial plexus block is commonly used as a sole anaesthetic technique or may be supplemented with general anaesthesia for surgeries of the upper limb.

Meanwhile both groups were comparable demographically. In present study the mean onset and recovery time of both sensory block and motor block was comparable in both groups.

The duration of post operative analgesia was significant higher in LD-group then RD-group in our study. **Connolly *et al* (2001)** observed similar findings where ropivacaine 225mg was equipotent to levobupivacaine150mg which was used for sciatic femoral block. [18] In patient controlled continuous interscalene analgesia, **Borghi Betalin 2006**[19] reported that 0.25% levobupivacaine provided similar quality of anaesthesia as provided by 0.4% ropivacaine and better anaesthesia was achieved with 0.25% levobupivacaine when compared with 0.25% ropivacaine in similar clinical setting. These results were similar to our findings. Duration of block is also influenced by protein binding level of local anaesthetic agent so higher the binding drug could achieve longer duration of effect. The levobupivacaine (95%) has not significantly but slightly higher protein bounding in comparison to that in ropivacaine (94%).[20,21] Levobupivacaine

reported to have a longer duration of analgesia in comparison to ropivacaine when used in neuraxial block techniques as observed by many authors Which may be due to more lipophilic nature of Levobupivacaine.[22-25]

Patki *et al*[26] (2013) showed a mean duration of postoperative analgesia was 738.83 minutes and significantly less need for rescue analgesia in first 24 hours using 30ml of 0.5% ropivacine along with 50μg of dexmedetomidine injected for supraclavicular block. Another recent study by **Rashmi et al (2017)**[27] reported a mean duration of postoperative analgesia was 872 minutes (vs. 885.76 minutes in current study) by using 30ml ropivacaine with 50μg of dexmedetomidine in interscalene brachial plexus block. While **Kaygusuz et al (2012)**[28] used 39ml of 0.5% of levobupivacaine with 1μg/Kg of dexmedetomidine in axillary brachial plexus block showed that the mean time for first analgesic requirement was1279.54 minutes. This observed difference in durations of post-operative analgesia may be attributed due to difference in concentration of local agent.

In another study by **Nallam et al (2016)** [29], they found that Levobupivacaine combined with varying doses of dexmedetomidine showed prolongation in duration of postoperative analgesia where group using 100 μg of dexmedetomidine analgesia was for 1033.6 minutes while it was 776.4 minutes in the group using 50μg of dexmedetomidine. In context of our present study mean duration of analgesia in group using 0.5% levobupivacaine combined with 1μg/Kg dexmedetomidine is 942.7 minutes. It is somehow related to the variation in doses of dexmedetomidine in our study.

Sudani et al (2016)[30] noticed the mean duration of sensory block of 811.66 minutes and less requirement of rescue analgesia with 0.75% ropivacaine with 25μg of dexmedetomidine in supraclavicular brachial plexus block. In a prospective double blinded study, it was found that dexmedetomidine gives greater post operative analgesia.[31] The effect of dexmedetomidine on brachial plexus block with ropiovacaine showed that dexmedetomidine not only enhance the efficacy of block, but also reduces the ischaemia reperfusion injury caused by tourniquet in upper limb surgery.[32]

Similar to present study, 30ml of 0.5% ropivacaine along with 1μg/Kg dexmedetomidine was injected for supraclavicular brachial plexus block produced a mean 807.5 minutes (vs. 885.76 minutes in present study) post-operative analgesia. By adding dexmedetomidine for supraclavicular blockade, longer duration of post-operative analgesia could be achieved without significant clinical side effects.[33]

When comparing two different local anaesthetic agents their molality also must be accountable because of different molecular weights. Levobupivacaine possess around 7%-8% more active molecules than ropivacaine.[34] Pertaining to this study it was proven the duration of sensory and motor block significantly longer in patients of levobupivacaine group. This observed difference in different parameters of block is not merely due to different molecular weight, but somehow also related to variable protein binding of levobupivacaine which is 95% and 92% of ropivacaine. However type of block as well as site of administration influence the difference in parameters between two local anaesthetic agents.

Results of above study cannot be concluded to a generalized clinical practice because of contention in literature about controversial results, with different results according to site of deposition of local agents.[35,36] Potency of drug is also influenced by the type of block administered.[37,38]

In Another study by **Singh AP et al**[39] in which 30ml of 0.5% of levobupivacaine with 100μg of dexmedetomidine was administered for supraclavicular brachial plexus block. They found the mean duration of post operative analgesia was 1273.79 minutes. The prolonged duration of post operative analgesia (1273.79 minutes) in previous study may be attributed to increased dose of Dexmedetomidine (100μg). Above mentioned studies are also in agreement with present one but observed variability in parameters is due to variations in concentration of adjuvant dexmedetomidine.

To be concluded the addition of dexmedetomidine along with levobupivacaine for supraclavicular brachialplexus block enhances the duration of postoperative analgesia as well diminished requirement for rescue analgesia in postoperative period.

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