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RESEARCH ARTICLE

A PROSPECTIVE DOUBLE BLIND RANDOMISED CONTROL STUDY ON "COMPARISON OF DEXAMETHASONE AND NALBUPHINE AS ADDITIVES TO 0.5% ROPIVACAINE FOR SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK UNDER ULTRASOUND GUIDANCE".

Divya G.M and Kiran A. Honnannavar

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Abstract

Introduction:-

Regional anaesthesia techniques provides important advantages compared with general anaesthesia and systemic analgesia, including good pain control, reduced side-effects and shortened stay in the post-anaesthesia care unit. But these early advantages can be short-lived and limited by the relatively brief duration of action of currently available local anaesthetics (LAs) potentially resulting in block resolution before the period of worst postoperative pain. Increasing the volume (dose) of LA's prolongs the duration of analgesia, but may also increase the risk of LA systemic toxicity.

A variety of perineuraladjuvants including buprenorphine, clonidine, dexamethasone, magnesium sulphate and midazolam was used to prolong the duration of analgesia of nerve blocks with varying grades of success.[1-5] Adjuvants with local anaesthetics in brachial plexus block are used to achieve a quick, dense and prolonged block.[1,6,7,8.]

Supraclavicular brachial plexus block is the preferred regional anaesthesia for upper limb surgeries.[9] Here the brachial plexus is presented most compactly at the proximal division or at the trunk level that provides most reliable anaesthesia for upper limb surgeries by anaesthetising the middle and lower trunks over 80% of the times (median, radial and ulnar).[10]

Dexamethasone being a corticosteroid, when it is perineurally administered exert its effect by a direct inhibition of signal transmission in nociceptive C-fibres. It his having local anti-inflammatory effect, and locally induced vasoconstriction prolonging the local anaesthetic effect.[11]Nalbuphine being mixed agonist antagonist at opioid receptors is found to provide analgesia and less addictive potential and respiratory depression. Nalbuphine prolongs duration of sensory and motor blockade and also reduces the need for rescue analgesics.[12]

There are number of studies performed using combination of ropivacaine with adjuvants like dexamethasone or nalbuphine individually. Thus we are comparing both dexamethasone and nalbuphine with ropivacine on the various objectives .

Corresponding Author:- Divya G.M

Methods:-

The study was conducted after ethical committee clearance prospectively in 90 patients of 18 to 60 years of age undergoing upper limb surgeries.The patients were included in the study by applying the following inclusion and exclusion criteria.

Inclusion criteria:

1 Age group:18 -60 of either sex.
2 Belonging to ASA – class 1 and class2.
3 Surgeries involving upper limb .

Exclusion Criteria:

1. Patient's refusal for procedure.
2. Patients with significant coagulopathies and other contra-indications for supraclavicular brachial plexus block.
3. Patients with pre existing significant systemic diseases.
4. Patients allergic to amide local anaesthetics.
5. Any local infection at the site of block.

Prospective double blind randomized controlled study was conducted in operation theatres of tertiarycenter, SDM college of medical sciences and hospital, Dharwad, from Dec 2018 to June 2020.

1. Approval was obtained from institutional ethical committee and from RGUHS.
2. Patient and bystander of the patients was explained about the procedure in the language best understood by them and a written informed consent was obtained.
3. Randomisation was done using computer generated random number series.
4. An anaesthesiologist who is experienced in performing ultrasound guided supraclavicular brachial plexus block performed this block.
5. Principal investigator and the patients were blinded to the drugs used.
6. The patient selected as per the criteria for the study were randomly placed into either of the 3 groups and block was performed using the following drugs.

Group RD:
30ml of 0.5% ropivacaine and 1ml of dexamethasone .

Group RN:
30ml of 0.5% ropivacaine and 1ml of nalbuphine.

Group RS:
30ml of 0.5% ropivacaineand 1ml of normal saline.

Patients underwent routine pre-anaesthetic evaluation which included physical examination and relevant laboratory investigations.NPO according to standard guidelines was followed. Patients were premedicated with T.Alprazolam 0.5mg HS and T. Metoclopromide 10mg HS and on the morning of surgery. Patient was shifted to OT and positioned supine , intravenous cannula was secured in the non operative limb. Routine monitors like electrocardiography, pulseoximeter and noninvasive blood pressure were attached to the patient.

Patient was positioned supine with head turned away from the limb to be operated. The injection site was prepared and covered with sterile drapes. Using sonosite ultrasound machine, linear ultrasound probe ,with a frequency range of 6-13mhz placed over the supraclavicular region. Sterile water based gel was used as acoustic couplant between probe and skin. The plexus was then approached using an in-plane (ip) technique with a insulating needle. Once the needle tip reached the nerve sheath and following negative aspiration for blood/air, 31ml of the study drug was injected around the plexus under vision.

1. Onset of sensory blockade: the onset of sensory blockade was defined as the time interval between injection of local anaesthetic and loss of prick sensation in radial, median and ulnar dermatomes on the ipsilateral upper limb.
2. Onset of motor blockade: the onset of motor blockade was defined as the time interval from administration of the drug to loss of movements of ipsilateral upper limb.
3. Duration of sensory block was defined as time interval between loss of prick sensations to its reappearance.

4. Duration of motor block was defined as time interval between loss of movements of ipsilateral upper limb to reappearance of the movements.
5. Duration of analgesia defined as the time interval between onset of sensory blockade and the 1st dose of rescue analgesic given to the patient.

Sensory block will be graded into three.
Grade 0: Sharp prick felt.
grade 1: Analgesia, dull sensation felt.
Grade 2: Anaesthesia, no sensation felt.

Assessment
Sensory block was assessed by checking for prick sensation every 3min till the onset of loss of sensation or grade 2 , then hourly up to 24 hours from time of complete block onset.

Motor block will be graded using modified bromage scale for upper extremities.
Grade 0:able to raise extended arm to 90 degree.
Grade 1:unable to extend arm,able to flex elbow and fingers.
Grade 2:unable to flex elbow, able to move fingers.
Grade 3:unable to move arm,elbow or fingers.

Motor block was assessed every 3min till loss of elbow and finger movements or grade 3, then hourly till elbow and finger movements regained in the postoperative period.

In case of block failure general anaesthesia was administered to the patient and such a case was excluded from study. Intravenous injection of diclofenac75mg diluted in 10ml normal saline was given as rescue analgesia if patient complains of pain in the post operative period.

The number of doses of rescue analgesics noted and compared in different groups. Injection ondansetron 4mg is given at the end of surgery.

Hypotension (systolic blood pressure more than 20% fall from baseline value), bradycardia (heart rate <50/min) and postoperative complications like nausea and vomiting were noted and treated appropriately. Postoperative analgesia was assessed using visual analogue scale numbering 1(no pain) to 10(worst pain). Time for first request for postoperative analgesic (duration of analgesia) was noted.

Statistical analysis:
Onset , duration of sensory and motor blockade and duration of analgesia was compared between 3 groups by analysis variance test (ANOVA). Chi-square used to study requirement of rescue analgesics.

Results:-

Table 1:- Comparison of three groups (RS, RD, RN) with mean changes in time from induction of block to onset of sensory block and onset of motor block by one way ANOVA.

Time from induction of block to	RS group		RD group		RN group		F-value	P-value
	Mean	SD	Mean	SD	Mean	SD		
Onset of sensory block	11.43	15.20	8.33	10.00	8.87	8.80	0.6052	0.5483
Onset of motor block	19.07	10.01	12.50	11.53	14.83	9.03	3.1693	0.0469*

*p<0.05

Table 2:- Comparison of three groups (RS, RD, RN) with mean duration of motor block, duration of sensory block andduration of analgesia by one way ANOVA.

Variables	RS group		RD group		RN group		F-value	P-value
	Mean	SD	Mean	SD	Mean	SD		
Duration of motor block	511.93	125.25	721.17	165.30	678.43	148.84	16.8787	0.0001*
Duration of sensory block	615.70	132.20	842.67	179.42	795.37	151.86	17.7430	0.0001*
Duration of analgesia	694.97	130.48	1004.97	221.82	895.23	161.41	24.0967	0.0001*

*p<0.05 indicates significant

Table 3:- Comparison of three groups (RS, RD, RN) with rescue analgesic requirement ie., number of doses of diclofenac 75mg.

	RS group	%	RD group	%	RN group	%	Total	%
0	1	3.33	7	23.33	1	3.33	9	10.00
1	6	20.00	18	60.00	16	53.33	40	44.44
2	22	73.33	5	16.67	13	43.33	40	44.44
3	1	3.33	0	0.00	0	0.00	1	1.11
Total	30	100.00	30	100.00	30	100.00	90	100.00
Chi-square=142.338 P = 0.0634								

In our study we did not notice any side effects like nausea, vomiting, pruritis , hypotension, hypoxaemia, pneumothorax or hematoma.

Discussion:-

Onset of sensory and motor blockade

Dar FA et al conducted study in 80 patients ,onset of sensory blockade in group R was 17.5 ±4.2minutes, in group RD was 14.6±3.3minutes. Onset of motor block in group R was 20.6±3.0 minutes, in group RD was 18.0±4.5 minutes.Faster onset of sensory and motor blockade in dexamethasone additive group ,which was statistically significant .In our study there was no statistically significant difference in the onset of sensory blockade. Similar faster onset motor block in RD group was noticed in our study.[7]

Bindal et al conducted study in 120 patients ,concluded that onset of sensory blockade in control group with ropivacaine alone (group R) was 16.00 ±1.438minutes, and in ropivacaine with dexamethasone(RD) additive group was 9.27 ±0.980 minutes.Onset of motor blockade in control group with ropivacaine(group R) was 20.27±1.799 minutes and in ropivacaine with dexamethasone (RD) additive group was 14.07±1.929 minutes. Statistically significant faster sensory and motor onset was noticed in dexamethasone additive group. In our study there was no statistically significant difference in the onset of sensory blockade. Similar faster onset motor block in RD group was noticed in our study.[13]

Nazir et al conducted a randomized controlled study in 60 patients ,they concluded that onset of sensory blockade in control group with bupivacaine alone was 14.62±1.73 minutes, and in bupivacaine with nalbuphine additive group was 4.89±1.5 minutes. Onset of motor blockade in control group with bupivacaine alone was 18.86±1.75 minutes and in bupivacaine with nalbuphine additive group was 8.83±1.9 minutes.Statistically significant faster sensory and motor onset was noticed in nalbuphine additive group.This study was consistent with our study except for the mean sensory onset, sensory onset in our study didn't make significant difference.[14]

Gupta K et al conducted study in sixty adult patients mean onset of sensory blockade in group 1 was 10.36±1.7 minutes , group 2 was 9.57±1.5minutes .Mean onset of motor blockade in group 1 was 18.16±1.3 minutes, group 2 was 14.10±1.24minutes . There was no significant difference in the onset of sensory and motor blockade in between the two groups, which was not consistent with our study.[15]

Duration of sensory and motor blockade

In the study conducted by Dar FA et al duration of sensory blockade in group R was 483 minutes , duration of sensory block in group RD was 762 minutes. Duration of motor block in group R was 402 minutes and in RD group was 522 minutes. There was statistically significant prolongation of sensory and motor blockade in RD group compared to group R. The results were similar to our study.[7]

In the study conducted by Bindal et al sensory blockade duration in control group with ropivacaine alone was 222.5±8.78, and in ropivacaine with dexamethasone additive group was 1084.73±11.91 minutes. Duration of motor blockade in control group with ropivacaine alone 182.5±10.48 and in ropivacaine with dexamethasone additive group was 976.0±24.7 minutes. The results are consistent with our study.[13]

In the study conducted by Nazir et al found that mean duration of sensory blockade with nalbuphine additive 373.17 ± 15.56 minutes vs. 157.82 ± 11.05 minutes in control group with bupivacainealone . Motor block duration in nalbuphine additive group was 313.92 ± 16.22 minutes vs. 121.87 ± 16.62 minutes in control group with bupivacaine alone .The results were similar to our study.[14]

Gupta K et al in their study found that duration of motor block in group 1(20 mL of 0.5% bupivacaine with 1 mL of normal saline) was 257.69±30.19, group 2 (20 mL of 0.5% bupivacaine with 1 mL of nalbuphine 10 mg) was 278.53±34.61 minutes.Statistically significant prolonged duration of motor blockade in group 2, which was consistent with our study.[15]

Duration of analgesia

Bindal et al conducted study in 120 patients ,duration of analgesia in group R was 283.17±7.71 minutes and group RD was 1211.83±32.86. Statistically and clinically significant prolongation in duration of analgesia was noticed in dexamethasone additive group which was consistent with our study.[13]

Nazir et al conducted a randomized controll study in 60 patients , found that duration of analgesia in group C was 171.65±19.79 minutes and in group N was 389.3±14.52 minutes. Statistically significant prolongation in duration of analgesia was observed in group N, parallel results were noticed in our study.[14]

Gupta K et al conducted study in sixty adults, mean duration of analgesia in group 1 was 341.31±21.42 minutes and in group 2 was 481.53±42.45 minutes. Statistically significant prolongation in duration of analgesia was observed in group 2, parallel results were noticed in our study.[15]

Analgesic consumption in the post operative period

Bindal et al conducted study in 120 patients ,median first 24 hour analgesics consumption in group R was 3(3-4) doses of diclofenac 75mg, and in group RD was 0(0-1) dose of diclofenac75mg. Statistically significant reduction in post operative requirement of diclofenac dose was noted in RD group.[13]

Das A et al conducted study in seventy-eight patients in Group LN (n = 39), 30 ml 0.5% levobupivacaine + 10 mg (diluted in 2 ml 0.9% saline) nalbuphine hydrochloride, and in Group LC (n = 39), 30 ml 0.5% levobupivacaine + 2 ml normal saline (0.9%) were administered in supraclavicular block.Group LC had received 110.21± 8.32 mg diclofenac, group LN received 80.34±6.7 mg diclofenac in post operative 24 hours follow up period,which was statistically significant.[16]

Adverse effects

In our study we did not notice any side effects like nausea, vomiting, pruritis , hypotension, hypoxaemia, pneumothorax or hematoma.

Dar FA et al in their study in 80 patients , no side effects were noticed in their patients.[7]

Gupta K et al in their study did not notice any side effects like sedation, pruritis,pneumothorax, nausea,vomiting, no significant haemodynamic fluctuations were present.[15]

Das A et al in their study in seventy-eight patients they have found nausea, vomiting, sedation, and pruritus between both study groups, but the incidence was quite comparable between two groups ($p > 0.05$). For nausea, the patients needed no active management except increasing the fluid transfusion rate. Two patients in LN Group and one patient in LC Group suffered from vomiting. All the three patients managed with slow intravenous metoclopramide 10 mg. Sedation though was higher in nalbuphine group, it was quite arousable and did not cause any respiratory depression. Similarly, pruritus was higher in nalbuphine group, but it was self-limiting.[16]

Conclusion:-

We conclude that perineuraldexamethasone or nalbuphine added to ropivacaine in supraclavicular brachial plexus block is extremely effective in reducing the time of motor block onset and prolonging the duration of sensory and motor blockade. It is also effective in providing prolonged postoperative analgesia. No side effects were evidenced.

Bibliography:-

1. Marhofer P, Columb M, Hopkins PM, Greher M, Marhofer D, Bienzle M, Zeitlinger M. Dexamethasone as an adjuvant for peripheral nerve blockade: a randomised, triple-blinded crossover study in volunteers. British journal of anaesthesia. 2019 Apr 1;122(4):525-31.
2. Brummett CM, Norat MA, Palmisano JM, Lydic R. Perineural administration of dexmedetomidine in combination with bupivacaine enhances sensory and motor blockade in sciatic nerve block without inducing neurotoxicity in rat. The Journal of the American Society of Anesthesiologists. 2008 Sep 1;109(3):502-11.
3. Kothari D. Supraclavicular brachial plexus block: A new Approach. Indian J Anaesth.2003; 47(4):287-288.
4. Candido KD, Winnie AP, Ghaleb AH, Fattouh MW, Franco CD. Buprenorphine added to the local anesthetic for axillary brachial plexus block prolongs postoperative analgesia. RegAnesth Pain Med. 2002 Mar-Apr;27(2):162-7.
5. Chakraborty S, Chakrabarti J, Manda MC, Hazra A, Das S. Effect of clonidine as adjuvant in Bupivacaine-induced supraclavicular brachial plexus block: A randomized controlled trial. Indian J Pharmacol. 2010; 42(2):74-77.
6. Biradar PA, Kaimar P, Gopalakrishna K. Effect of Dexamethasone added to Lidocaine in supraclavicular brachial plexus block: A prospective, randomized, double blind study. Indian J Anaesthesia.2013; 57:180-4.
7. Dar FA, Najar MR, Jan N. Effect of addition of Dexamethasone to Ropivacaine in supraclavicular brachial plexus block. Indian J Pain. 2013;27:165-9.
8. Cummings III KC, Napierkowski DE, Parra-Sanchez I, Kurz A, Dalton JE, Brems JJ, Sessler DI. Effect of dexamethasone on the duration of interscalene nerve blocks with ropivacaine or bupivacaine.British journal of anaesthesia. 2011 Sep 1;107(3):446-53
9. Ilfeld BM, Morey TE, Enneking FK. Continuous Infraclavicular Brachial Plexus Block for Postoperative Pain Control at HomeA Randomized, Double-blinded, Placebo-controlled Study. Anesthesiology: The Journal of the American Society of Anesthesiologists. 2002 Jun 1;96(6):1297-304.
10. Miller RD. Basics of Anesthesia .7th edition. Page 307.
11. Jæger P, Grevstad U, Koscielniak-Nielsen ZJ, Sauter AR, Sørensen JK, Dahl JB. Does dexamethasone have a perineural mechanism of action? A paired, blinded, randomized, controlled study in healthy volunteers. BJA: British Journal of Anaesthesia. 2016 Nov 1;117(5):635-41.
12. Rosow C. Agonist-antagonist opioids: theory and clinical practice. Can J Anaesth. 1989 May;36(3 Pt 2):S5-8.
13. Bindal D, Narang N, Mahindra R, Gupta H, Kubre J, Saxena A. Effect of dexamethasone on characteristics of supraclavicular nerve block with bupivacaine and ropivacaine. Anesth Essays Res. 2018;12(1):234-239.
14. Nazir N, Jain S. Randomized controlled trial for evaluating the analgesic effect of Nalbuphine as an adjuvant to Bupivacaine in supraclavicular block under ultrasound guidance. Anesth Essays Res. 2017;11:326-9.
15. Gupta K, Jain M, Gupta PK, Rastogi B, Zuberi A, Pandey MN. Nalbuphine as an adjuvant to 0.5% Bupivacaine for ultrasound-guided supraclavicular brachial plexus blockade. Indian JPain. 2016;30:176-80.
16. Das A, RoyBasunia S, Mukherjee A, Biswas H, Biswas R, Mitra T, Chattopadhyay S, Mandal SK. Perineuralnalbuphine in ambulatory upper limb surgery: A comparison of effects of levobupivacaine with and without nalbuphine as adjuvant in supraclavicular brachial plexus block – A prospective,double-blinded,randomized controlled study. Anesthesia Essays and Researches. 2017;11(1):40-46.