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COMPARISON OF EFFECT OF 0.5% ROPIVACAINE VERSUS 0.5%ROPIVACAINE WITH MAGNESIUM SULPHATE FOR BRACHIAL PLEXUS BLOCK BY SUPRACLAVICULAR APPROACH IN PATIENTS UNDERGOING UPPER LIMB ORTHOPAEDIC SURGERIES – RANDOMISED BLINDED CONTROL TRIAL

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ABSTRACT

OBJECTIVES: This study was aimed to compare the effect of 0.5% ropivacaine versus 0.5% ropivacaine with magnesium sulphate on duration of sensory block for brachial plexus block by supraclavicular approach in patients undergoing upper limb orthopaedic surgeries.

METHODS: This randomized, double blinded, group allocation concealed study of patients was carried out after ethical committee clearance. 50 patients in the age group 18-60 years undergoing elective upper limb orthopaedic surgeries satisfying the inclusion and exclusion criteria were enrolled and randomly allocated into one of the study groups of 25 each. Group A received 30ml 0.5% ropivacaine and 1ml 0.9% saline and Group B received 30ml 0.5% ropivacaine and 150mg magnesium sulphate (prepared in 0.9% saline upto 1ml in volume) via nerve stimulator guided supraclavicular block. Onset and duration of sensory and motor block, duration of analgesia and postoperative analgesia using Visual Analogue Scale at predefined time points postoperatively were assessed.

RESULTS: Demographic parameters and duration of surgery were comparable. The mean duration of sensory block was significantly prolonged in Group B (517.17 ± 34.37 mins) than in Group A (398.54 ± 29.69 mins). The mean duration of motor block and duration of analgesia was significantly prolonged in Group B. However, the onset of sensory and motor block was delayed in Group B as compared to Group A.

CONCLUSION: Addition of magnesium sulphate to ropivacaine significantly prolonged the duration of sensory block of supraclavicular brachial plexus block.

KEYWORDS : Ropivacaine, Magnesium Sulphate, Supraclavicular Brachial Plexus Block

INTRODUCTION:

Peripheral nerve blockade has revolutionized the modern anaesthesia practice and has a significant contributory role in upper limb orthopaedic surgeries. Safety and unparalleled success rate have made this technique of anaesthesia very popular.

Brachial plexus blockade being the cornerstone of the peripheral nerve block technique has evolved as a safe alternative to general anaesthesia and for relief of perioperative pain for upper limb surgery. It is anatomically advantageous for being at a level where the brachial plexus nerve trunks are tightly packed together, which facilitates a very rapid block onset following single point injection producing "spinal of the arm"[1].

Regional nerve blocks are based on the concept that pain is conveyed by nerve fibers, which are amenable to interruption anywhere along their pathway. A variety of local anaesthetics can be used to perform ideal and complete block. Single shot block provide effective surgical anaesthesia but analgesia achieved is short lived. The possibility of both local and systemic toxicity precludes a simple increase in concentration and/or volume of administration of local anaesthetics as a means of increasing analgesic duration[2],thus various adjuvants are being used to not only improvise block characteristic but also to prolong analgesia where single shot block techniques are preferred.

Several pre-clinical and clinical studies have consistently shown that addition of magnesium (Mg2+) to local anaesthetic significantly prolongs peripheral nerve blocks.Better knowledge of pain mechanisms has highlighted the role of central sensitisation and N-methyl-D-aspartate (NMDA) receptors in post-surgical pain.[3] In the peripheral nervous system, N-methyl-D-aspartate receptors expressed on the central and peripheral terminals of primary afferent neurons are involved in nociception.[4] Magnesium, a naturally occurring cation in the body and N-methyl-D-aspartate (NMDA) receptor antagonist, has antinociceptive effect which is mediated by control of calcium influx into the cell,thus preventing the central sensitization caused by peripheral nociceptive stimulation.[5]

Magnesium sulphate has been used systemically for its analgesic, antihypertensive, anaesthetic sparing effects.[6,7] When used as an adjuvant combined with local anaesthetics during neuraxial anaesthesia in both spinal and epidural routes at different doses,[8,9] it improved the quality of postoperative analgesia with decreased postoperative opioid consumption.Though magnesium has analgesic property,it has not been studied well as an adjuvant to local anaesthetic agents in supraclavicular brachial plexus block.

Thus,with this randomised study we intend to investigate the effect of magnesium sulphate as an adjuvant to 0.5% ropivacaine in supraclavicular brachial plexus block that may enhance the duration of sensory and motor block and duration of analgesia as compared to 0.5% ropivacaine alone.

AIMS AND OBJECTIVES:

The aim of the study is to compare the effect of 0.5% ropivacaine versus 0.5% ropivacaine with magnesium sulphate for brachial plexus block by supraclavicular approach in patients undergoing upper limb orthopaedic surgeries.

PRIMARY OBJECTIVE:

- To compare the duration of sensory block in both the groups.

SECONDARY OBJECTIVES:

- To compare the onset time of sensory and motor block in both the groups.
- To compare the duration of motor block and duration of analgesia in both the groups.
- To observe for any side effects in the postoperative period upto 24 hours.

METHODS AND MATERIALS

This randomized, double blinded, single hospital study was conducted under the Department of Anaesthesiology and Critical Care, Gauhati Medical College and Hospital, Guwahati from 1st July 2018 to 30th June 2019. Clearance from Hospital ethical Committee was obtained to conduct the study(No.MC/190/2007/Pt-1/IEC/97).

SAMPLE SIZE CALCULATION:

In the study by Mukherjee K et al.[10], the reported duration of sensory blockade was 289.67 ± 62.5minutes in the control group. To detect a difference of duration of 60min with an α value of 0.05 and power of 80%, 17 patients in each group were required with a sampling ratio of 1. Sample size calculation was carried out using the online software www.select-statistics.co.uk. To account for possible dropout, we intended to take 25 patients in each group.

INCLUSION CRITERIA:

1. Aged 18 to 60 years.

2. American Society of Anaesthesiology (ASA) Physical Status I and II.
3. Scheduled for elective orthopaedic upper limb surgery under supraclavicular brachial plexus block.
4. Acquirement of informed and written consent.

EXCLUSION CRITERIA:

1. Patients with known hypersensitivity to local anaesthetics.
2. Infection at the site of block.
3. Patients with known coagulopathy or patients on anticoagulation therapy.
4. Patients with diabetes mellitus.
5. Pregnant and lactating patients.
6. Patients with body weight less than 50 kg.
7. Patients with morbid obesity.
8. Patients with chronic pain.
9. Patients with systemic use of corticosteroids for 2 weeks or longer within 6months of surgery and chronic opioid use.
10. If there were need of supplemental analgesia, sedation or conversion to general anaesthesia.

Fifty (50) patients meeting the inclusion criteria and consenting to participate in the study were divided into two groups A and B, by a computer-generated random selection using block randomization with variable size blocks 4,6,8 patients in a total of 8 such blocks. Concealment of allocation was done by opaque sealed envelope technique.

On the day of operation once the patient was shifted to the operation theatre(OT), a designated OT technician opened the sealed envelope. After allocation, the technician also prepared the drugs used in our study. To prepare the required dose of magnesium sulphate used in our study,1.5ml of 50% w/v of magnesium sulphate(MAGNEON,NEON Laboratories Ltd,India) was diluted with 0.9% saline to 5 ml thereby each ml consisting of 150mg of magnesium sulphate. The patients were blinded to their group assignment.

GROUP A(n=25):
Patients received nerve stimulator guided supraclavicular brachial plexus block with 30 ml 0.5% ropivacaine and 1 ml 0.9% saline.

GROUP B(n=25):
Patients received nerve stimulator guided supraclavicular brachial plexus block with 30 ml 0.5% ropivacaine and 150 mg magnesium sulphate(prepared in 0.9% saline upto 1ml in volume).

All the drugs used perineurally were preservative free. A designated resident doctor of our department, who was not involved in the study performed the supraclavicular block and injected the drugs to patients, as handed over by the designated technician. Standard monitoring in the form of measurement of baseline heart rate, ECG, non-invasive arterial blood pressure and peripheral oxygen saturation (SpO_2) was done upon arrival at the preoperative holding area. An intravenous infusion line was secured in the contra-lateral arm prior to the application of the proposed brachial plexus block and Lactated Ringer's solution was started. All anaesthetic equipments were checked.

The area around the proposed puncture site of the neck was prepared with povidone iodine and 70% isopropyl alcohol under all aseptic and antiseptic condition. Twenty two gauge 50-mm insulated stimulating short bevel needle (Stimuplex® @ B-Braun Medical, Germany) connected to a nerve stimulator (Stimuplex® @ DIG RC, B-Braun Medical, Germany) was used for the blocks. The proper functioning of the nerve stimulator, the connecting cables and the insulated stimulating needle were checked. The electrical circuit was checked to assure delivery of the set current. One pole (negative lead) of the stimulating needle was connected to nerve stimulator and the other pole (positive or ground lead) of stimulation needle was connected to an ECG electrode placed in the ventral area of the shoulder of the opposite side. The block was performed with the patient in supine position on the operation table with the head being turned slightly towards the opposite side. The needle was inserted 1 to 1.5 cm above the midclavicular point lateral to the pulsation of the subclavian artery and directed caudally parallel to the floor after skin infiltration with 1% lignocaine. In both the groups, the initial nerve stimulation current was set at 1mA with impulse duration of 0.1millisecond at 1Hz. The needle was advanced until a motor response was elicited. The needle was not inserted deeper than 2.5cm if a twitch from the brachial plexus was not present. The needle position was considered to be adequate when the motor response in the hand or wrist which was obtained remained visible even with a maximum current of <0.5mA. However, if the desired response was elicited at ≤ 0.2mA,the needle was slightly withdrawn. At this point the drugs were injected slowly (over 30s) with intermittent aspiration in both the groups A and B. After the injection of the drug the Stimuplex® needle was withdrawn and the area was firmly pressed with a gauge piece for even spread of the drug.

After the administration of supraclavicular block, the following were noted –

1. Sensory block onset time.
2. Motor block onset time.
3. Duration of sensory block.
4. Duration of motor block.
5. Duration of analgesia.
6. Postoperative analgesia.
7. Side-effects and complications.

Duration of sensory block was designated as the primary outcome. Other parameters evaluated were included in the secondary outcomes. Preoperatively, patients were not given any analgesic or sedative. After completion of injection of the perineural solution, a blinded research assistant evaluated every 3 minutes till the onset of sensory and motor block upto a maximum time of 30 minutes using a dedicated analogue watch.

Sensory block was assessed by pinprick test in the median, radial, ulnar and musculocutaneous nerve distributions using a 3 point scale.[11]

0 – normal sensation
1 – loss of sensation to pinprick
2 – loss of sensation to light touch

Sensory onset time was defined as the time interval between the end of total local anaesthetic administration and sensory blockade evidenced by loss of sensation to pinprick or by a score of 1 on pinprick response in the dermatomes of all the four nerves.[11]

Motor blockade was evaluated by Modified Bromage Scale (MBS). It was assessed by the ability to flex and extend the elbow and hand as:

0 – full flexion/extension movement in hand and arm against resistance
1 – movement against gravity but not against resistance
2 – flicker of movement in hand but not in arm
3 – no movement (complete motor block)[11]

Motor onset time was defined as the time interval between the end of total local anaesthetic administration and complete motor paralysis of wrist and hand or MBS 3.[11]

Successful block was defined as per Duncan M et al.[12] as complete absence of sensation in all the dermatomes in the operated extremity with no power to move any of the shoulder, elbow and wrist joints, evaluated at 30 minutes after block administration. Only the patients fulfilling the criteria for successful block were included in the study. A complete block was defined as one associated with Grade 2 sensory anaesthesia in the all the four nerve territory and Grade 3 motor block.[11] Analgesia was assessed at immediate postoperative period, 1st,3rd,6th,12th, 18th and 24thpostoperative hours using a pre-validated non-invasive pain scoring system (i.e. Visual Analogue Scale; VAS 0 – no pain, VAS 10 – worst pain imaginable).Duration of sensory and motor block was also assessed at the same time interval till the complete wearing off of the block which is Grade 0 for sensory block and Grade 0 for motor block.

Duration of sensory block was defined as the time interval(in minutes) between sensory blockade and reappearance of the pinprick response.[11] Duration of motor block was defined as the time interval (in minutes) between maximum motor blockade and complete movement of wrist and fingers.[11]

Duration of analgesia was taken as the time interval(in minutes) between the onset of sensory blockade and the first dose of rescue analgesic given to the patient.[11]

Intravenous tramadol 50 mg stat was used as rescue analgesic, when VAS score was more than or equal to 4 or at patient's request, up to

maximum of 3 doses in the first 24 hours postoperatively. Beyond that intramuscular injection of diclofenac 75 mg was used.

Intraoperatively, sedation with 1 mg intravenous midazolam was provided to all patients. Haemodynamic parameters including blood pressure, heart rate and SpO2 were monitored. Adverse events such as hypotension, bradycardia, hypoxemia (SpO_2<90%), nausea and vomiting,if any occurred were recorded and managed accordingly.

STATISTICAL ANALYSIS OF DATA

The data were entered into MS Excel spread sheets and analysis was carried out. The procedures involved were transcription, preliminary data inspection, content analysis and interpretation. For analysis, descriptive and inferential statistics were used. Chi square test was used to evaluate difference between categorical variables. Data was checked for normality using Kolmogorov-Smirnov and Shapiro-Wilk test. Unpaired t test and alternative non parametric Mann-Whitney U test was used depending on fulfilment of normality assumption. The statistical analyses were done by using the SPSS software version 21.0.

RESULTS:

Out of seventy two(72) patients assessed for eligibility, fifty(50) patients were included and forty seven(47) patients who had completed the study were finally analysed.

The demographic characteristics of the patients in both the study groups in terms of age, sex, ASA category, height, weight, the side in which surgery was performed and the duration of surgery were comparable and statistical tools did not show any significant difference.

TABLE 1: DEMOGRAPHIC VARIABLES.

Variables	Group A	Group B	P Value
Age(years)	37.46 ± 12.55	39.30 ± 10.54	**0.589**
Sex (M:F)	18:6	16:7	**0.677**
ASA I:II	13:11	16:7	**0.278**
Weight(kg)	64.58 ± 5.19	63.43 ± 5.68	**0.473**
Height(cm)	161.00 ± 5.93	161.82 ± 4.59	**0.597**
Side Of Surgery(R:L)	11:13	12:11	**0.664**
Duration Of Surgery(mins)	87.29 ± 25.06	86.30 ± 23.41	**0.890**

The duration of sensory block in group A was 398.54 ± 29.69 minutes while in group B was 517.17 ± 34.37 minutes which was statistically significant. The duration of motor block in group A was 344.33 ± 42.01 minutes and in group B was 454.43 ± 32.66 minutes while the duration of analgesia in group A was 452.46 ± 35.98 minutes and in group B was 543.87 ± 35.17 minutes and were statistically significant. However, the onset of sensory block in group A was 12.13 ± 2.72 minutes and in group B was 13.30 ± 1.99 minutes and onset of motor block in group A was 18.13 ± 2.99 minutes and in group B it was 19.43 ± 2.54 minutes and were statistically insignificant.

TABLE 2: ONSET AND DURATION OF SENSORY AND MOTOR BLOCK AND DURATION OF ANALGESIA.

Parameters	Group A	Group B	P Value
Onset Time Of Sensory Block(mins)	12.13 ± 2.72	13.30 ± 1.99	**0.068**
Onset Time Of Motor Block(mins)	18.13 ± 2.99	19.43 ± 2.54	**0.067**
Duration Of Sensory Block(mins)	398.54 ± 29.69	517.17 ± 34.37	**<0.0001**
Duration Of Motor Block(mins)	344.33 ± 42.01	454.43 ± 32.66	**<0.0001**
Duration Of Analgesia(mins)	452.46 ± 35.98	543.87 ± 35.17	**<0.0001**

Up to 3rd postoperative hour, there is no statistical difference of VAS between group A and B. However, there is highly statistically significant difference of VAS at 6th and 12th postoperative hour,with group B demonstrating significantly lower pain score values. This difference is lost beyond the 12th postoperative and the VAS at 18th and 24th postoperative hour was comparable between the two groups. The results indicated that the VAS scores were significantly less in the magnesium sulphate group in the postoperative period up to 24 hours as compared to the control group.

TABLE 3: POSTOPERATIVE VAS SCORES.

Duration	Mean		S.D.		Median		P Value
	A	B	A	B	A	B	
0 HR	0	0	0	0	0	0	**1.00**
1 HR	0.38	0.26	0.49	0.45	0	0	**0.41**
3 HRS	0.96	0.69	0.46	0.47	1	1	**0.07**
6 HRS	2.42	1.39	0.93	0.49	2	1	**<0.0001**
12 HRS	2.58	1.52	0.78	0.51	2	2	**<0.0001**
18 HRS	2.71	2.30	1.08	0.97	3	2	**0.18**
24 HRS	3.08	2.74	0.83	0.75	3	3	**0.15**

DISCUSSION:

In our study, we found that the mean duration of sensory blockade in group B(group receiving ropivacaine with magnesium sulphate) was prolonged as compared to group A(group receiving ropivacaine with normal saline). The difference between the two groups was highly statistically significant (p<0.0001). Our study results are similar to that of **Mukherjee K et al**[10]wherein the authors evaluated the efficacy of magnesium sulphate patients undergoing supraclavicular brachial plexus block for elective upper limb orthopaedic surgeries using same concentration and dose of drugs as in our study and found that the duration of sensory block in ropivacaine-magnesium sulphate group was significantly prolonged.

Our study concurs with the studies done by **Taneja P et al,**[13]**Gunduz A et al,**[14]**Dogru K et al,**[15]**Lee AR et al,**[16]**ElShamaa HA et al**[17]for a spectrum of surgical procedures under various peripheral nerve blocks,where the authors found that the duration of sensory block was significantly prolonged in the magnesium sulphate group as compared to those in the placebo group. It is worthy to note that the authors **Taneja P et al,**[13]**Gunduz A et al,**[14]**Dogru K et al**[15] used 150mg magnesium sulphate as an adjuvant for supraclavicular brachial plexus block as also used by **Mukherjee K et al**[10]and in our study.However, duration of sensory block observed in our study was higher than the study by authors **Haghighi M et al**[18]and **Akhondzade R et al**[19], inspite of **Haghighi M**[18]and colleagues using 600mg of magnesium sulphate in their study and **Akhondzade R**[19]and colleagues using 1000mg of magnesium sulphate in their study.This heterogeneity in the finding could be explained by the fact that both the authors used lidocaine in their respective studies which is a moderate acting local anaesthetic while we used ropivacaine which is a long acting local anaesthetic in our study.

Although the delaying in onset of sensory and motor block in the magnesium sulphate group as compared to the saline group was statistically insignificant but it was proportionately of clinical significance. The findings of our study are in accordance with the findings of the study done by **Mukherjee K et al**[10]**, Taneja P et al**[13]and **Lee AR et al.**[16] Magnesium sulphate might have resulted in alteration in the pH and baricity of the injectate local anaesthetic solution that could have led to this significant delay in onset of the block.[20,21]

The duration of motor block, in our study was significantly prolonged in group B (magnesium sulphate) as compared to group A (saline). The duration of analgesia was also significantly prolonged in the magnesium sulphate group. Our study concurs with the studies done by **Mukherjee K et al**[10]**,Taneja P et al,**[13]**Gupta D et al,**[22]**Verma V et al**[23]and **Akhondzade R et al**[19]for upper limb surgeries under brachial plexus block,where the authors found that the mean duration of motor block and mean duration of analgesia were significantly prolonged in the magnesium sulphate group as compared to the control group.

Magnesium sulphate when added intrathecally to local anaesthetic for combined spinal-epidural block by **Buvanendran A et al**[24]and for spinal block by **Ozalevli M et al**[21]in their respective studies,there was significant prolongation in the median duration of analgesia. Synergism between NMDA antagonist(magnesium sulphate) and local anaesthetics might have influenced the observation made by these authors in their respective studies. Magnesium competitively blocks calcium entry in the presynaptic nerve endings leading to decreased release of acetylcholine as well as antagonises NMDA receptors that prevents central sensitization from peripheral nociceptive stimulation.

However,the finding of our study was in contrary to that done by **Choi IG et al.**[25]The authors found no statistical difference in sensory

responsiveness,motor responsiveness, level of postoperative pain and opioid consumption between the groups receiving magnesium sulphate versus placebo.This discrepancy could be contributed by various factors such as use of lesser concentration and volume of ropivacaine.

The mean postoperative pain scores (VAS scores) of the patients in the magnesium sulphate group was found to be lower at all the different time points as compared to control group during the 24 hours period. Also,the numbers of patients with VAS≥4 at 6th and 12th post operative hour were significantly less in the magnesium sulphate group as compared to the saline group. Our study concurs with the study done by **Gupta D et al**[22] who found significant decrease in VAS score in 6th and 12th postoperative hour in the magnesium sulphate group when compared with the control group.

No significant difference was seen in the haemodynamic parameters measured preoperatively and intra operatively. On comparing the incidence of adverse effects we found no significant difference between the two groups.
The strength of our study lies in the fact that it is a randomized, observer and patient blinded study.

CONCLUSION:

From our study, it can be concluded that magnesium sulphate as an adjuvant effectively prolongs the duration of sensory block of supraclavicular brachial plexus block in patients undergoing upper limb orthopaedic surgeries along with prolongation of duration of motor block and duration of analgesia.

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