Archives of Anesthesiology and Critical Care (Spring 2022); 8(2): 134-138.

Available online at http://aacc.tums.ac.ir

Research Article

Evaluation of Magnesium as an Adjuvant in Ropivacaine Induced Interscalene Brachial Plexus Block: A Prospective, Double-Blinded, Randomized Controlled Study

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ARTICLE INFO

Article history:
Received 09 November 2021
Revised 01 December 2021
Accepted 15 December 2021

Keywords:
Magnesium sulphate;
Ropivacaine;
Interscalene brachial plexus block

ABSTRACT

Background: Interscalene block is a commonly performed procedure for surgery of shoulder and upper arm, however very few studies have studied the effect of magnesium sulphate when added in interscalene block.
Aims: The primary aim was to compare block characteristics along with postoperative analgesia and the secondary aim was to study the side effect profile and postoperative analgesic requirements.
Methods: We randomly recruited 60 American Society of Anaesthesiologists (ASA) physical status I and II patients, undergoing surgeries of the shoulder to receive ultrasound-guided interscalene block with 1 mL normal saline or 150 mg Magnesium sulphate added to 20ml of 0.5% ropivacaine.
Statistical analysis used: Statistical Package for Social Sciences (SPSS version 21.0) was used for analysing the data. Chi-square test or Fisher's exact probability test were used for categorical variables; while the continuous variables were compared by unpaired t-test or Mann-Whitney U test.
Results: With the addition of magnesium sulphate, onset of sensory (10.03 ± 1.03 vs 12.73 ± 1.14 min) and motor block (15.17 ± 2.02 min vs 17.87 ± 1.41) was hastened. The duration (sensory 528.00 ± 14.98 min vs 376.83 ± 13.16 min, motor 429.83 ± 11.57 min vs 319.97 ± 6.800 min) and postoperative analgesia (527.77 ± 21.96 min vs 402.97 ± 12.83 min) ($p < 0.001$) were all prolonged by magnesium sulphate, with resultant decrease in requirement of postoperative analgesic dosage.
Conclusion: Magnesium when added to local anaesthetics in interscalene block, effectively improves all characteristics of block and provides better postoperative analgesia.

The interscalene block (ISB) is a commonly performed procedure of regional anaesthesia for surgery of shoulder and upper arm. This technique when performed meticulously has advantages from the perspective of surgery and anesthesia as it avoids polypharmacy and provides better hemodynamic stability and postop analgesia. With ultrasound guidance, it is possible to precisely locate the neural structure to be blocked and added advantage of low volume of drug required to block the plexus [1-3]. Ropivacaine is an amide local anaesthetic and is long-acting with better sensorimotor differentiation and cardiovascular stability than bupivacaine [4-5].

Local anaesthetics alone provide limited duration of analgesia postoperatively, and hence various adjuvants have been studied including alpha-2 agonists like clonidine and dexmedetomidine, opioids like fentanyl, and dexamethasone in an attempt to achieve a dense block as well as to prolong its duration [6]. $MgSO_4$ has analgesic, antihypertensive and anaesthetic sparing properties. $MgSO_4$ when administered by different routes has decreased postoperative opioid consumption [7]. However, it has not been sufficiently

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studied as an additive in ISB with Ropivacaine. Hence, we undertook this study with the aim of evaluating the efficacy of MgS04 in a dose of 150mg as an adjuvant to 0.5% Ropivacaine in USG guided Interscalene block for shoulder surgery.

Primary aims of our study were to observe onset and duration of sensory and motor block and total duration of analgesia. Secondary aims were to study the postoperative analgesic consumption and to study side effects if any.

Methods

The study was conducted in a prospective, randomized, double blind manner after obtaining clearance from Institutional Ethical Committee (IEC no- ECR/275/Inst/MH/2013/RR-16). Sixty patients in the age group 18 - 60 years and ASA physical status I and II, of either sex, undergoing shoulder surgeries were included. Patients with age < 18 or > 60 years, contraindication to interscalene block, history of allergy to local anaesthetics, ASA physical status III and IV, injection site infection, central or peripheral neuropathies, patient refusal, pregnant or lactating women were excluded from the study.

A thorough pre operative assessment with detailed history, general and systemic examination and review of investigations was done. Visual analogue scale (VAS) (0, no pain and 10, worst pain imaginable) was also explained to the patient. After explaining the procedure and its safety, a written, valid, informed consent was obtained and adequate starvation confirmed, on the day of surgery.

On arrival to the OT, patients' baseline pulse rate, electrocardiogram and non-invasive blood pressure was recorded, a wide bore intravenous line established and an infusion started with lactated Ringer's solution. Hemodynamic variables were measured every 5 min thereafter till the end of surgery. Each patient was randomly given either 20 ml 0.5% ropivacaine +1 ml normal saline (Group A) or 20 ml of 0.5% ropivacaine +150 mg (in 1 ml 0.9% saline) magnesium sulfate (Group B), by two different syringes, for USG guided interscalene block.

The lateral neck was examined using a high frequency US probe (SonoSite NanoMaxx Ultrasound System with L25 13-6 MHz probe), and the roots and trunks of the brachial plexus were identified. A 2-inch, 22-gauge Stimuplex insulated needle (PNS Organon TOF Watch) was placed into the interscalene groove via an in-plane approach to enable visualization of the entire needle. The local anesthetic solution was injected in 5- to 10-mL aliquots, after careful aspiration. Homogenous spread of LA was observed.

Both groups were compared with respect to primary objectives of onset and duration of block as well as the total duration of analgesia. Total consumption of postoperative analgesics and side effect profiles were compared as secondary objectives.

Sensory block was assessed by pin prick method. Complete sensory block was considered when there was complete loss of sensation to pin prick.

Assessment of motor block was carried out by the same observer at each minute till complete motor blockade after drug injection. Onset of motor blockade was defined as reduction of muscle power to grade 3 or less. Complete motor block was defined as complete inability to move the limb and fingers (grade 0).

After the operation, VAS score was measured hourly.

Inj. diclofenac sodium 75mg was given intramuscularly (IM) when VAS ≥ 3. Number of diclofenac injections given to each patient during the first 24 h of postoperative period was recorded (maximum three IM injections in 24 h duration, duration between two doses not less than 8 hours).

The time from the end of anaesthetic injection in the operated hand till the first request for postoperative rescue analgesic was recorded in each patient.

The duration of sensory block was defined as the time interval between injection and complete recovery of sensation.

The duration of motor block was defined as the time interval between completion of injection and complete recovery of motor power.

The total duration of analgesia was defined as the time from completion of injection to the time when VAS >3.

The sample size was determined separately for each of the primary outcomes by using the effect sizes from the previously published studies. For each group, a sample size of 30 for the onset of block, 27 for the duration of block and 29 for postoperative analgesia was calculated to be sufficient to detect a clinically significant difference, considering 5% level of significance (type I error probability) and 80% power. As the maximum sample size calculated was 30, we took the sample size for our study as 30 in each group.

The data on normally distributed continuous variables are presented as mean and standard deviation across two study group. Inter-group statistical comparison of the distribution of categorical variables is tested using Chi-square test or Fisher's exact probability test. Comparison of means of normally distributed continuous variables is done using independent sample t-test (or unpaired t-test). Comparison of medians of non-normally distributed continuous variables was done using the Mann-Whitney U test. The underlying normality assumption was tested before subjecting the study variables to t-test.

Statistical significance was considered at $p<0.05$. The data was analyzed using Statistical Package for Social Sciences (SPSS) for MS Windows.

Results

Both groups were comparable with respect to the demographic profile, baseline values of hemodynamic variables and surgical duration (Table 1). The distribution of the type of surgeries was comparable in both the groups.

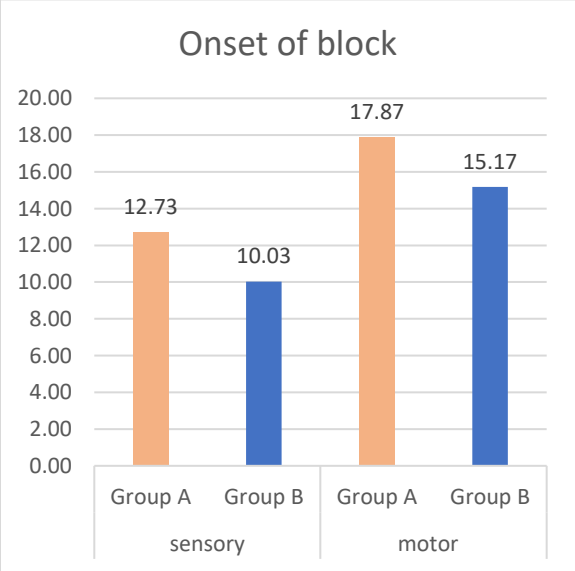
Table 1- Demographic variables, baseline hemodynamic parameters and surgical duration

Parameter	Group A (n=30)	Group A (n=30)	P
Age in years	43.33 ± 12.19	38.17 ± 12.15	0.106NS
Sex (M: F)	18: 12	19:11	0.999NS
ASA (I/II)	21 / 9	22 / 8	0.999NS
Duration of surgery (min)	133.00 ± 7.35	132.70 ± 7.87	0.879NS
HR (/min)	76.00 ± 8.74	76.77 ± 8.76	0.115NS
SBP (mmHg)	120.93 ± 9.32	120.67 ± 9.32	0.912NS
DBP (mmHg)	77.63 ± 6.85	76.47 ± 6.07	0.488NS

M: Male, F: Female, HR: Heart Rate, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, NS: Not significant

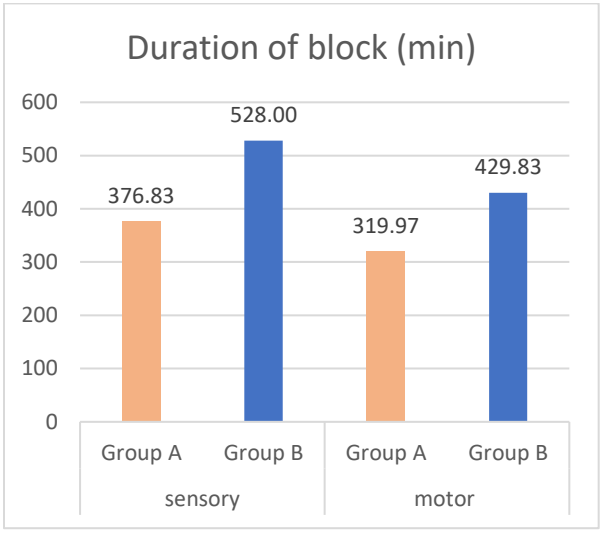
The mean onset of sensory block in Group A and Group B was 12.73± 1.14 min and 10.03 ± 1.03 min respectively and the mean onset of motor block was 17.87± 1.41 min and 15.17 ± 2.02 min respectively. Both were significantly delayed in Group A (p<0.001) (Figure 1).

Figure 1- Onset of sensory and motor block



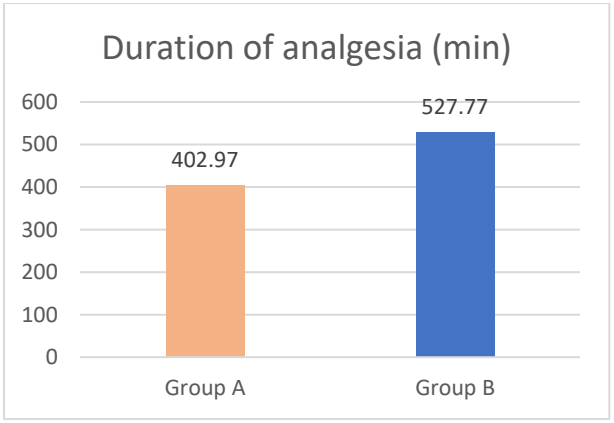
The mean of duration of sensory block in Group A and Group B was 376.83 ± 13.16 min and 528.00 ± 14.98 min respectively and the mean duration of motor block was 319.97± 6.800 min and 429.83± 11.57 min respectively. Both were significantly prolonged in Group B (p<0.001) (Figure 2).

Figure 2- Duration of sensory and motor block



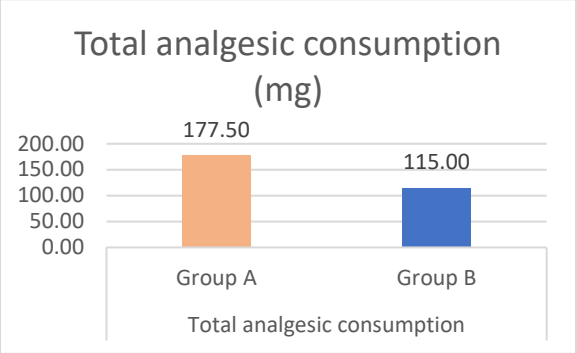
The mean duration of analgesia in Group A and Group B was 402.97± 12.83 min and 527.77± 21.96 min respectively. It was significantly prolonged in Group B (p<0.001) (Figure 3).

Figure 3- Total duration of analgesia



Eleven out of the 30 patients in group A required 3 doses (225mg), while the rest requires 2 doses (150mg) of Inj. Diclofenac sodium as postoperative analgesic. In Group B, 2 patients required 3 doses, 12 required 2 doses while 16 patients required only 1 dose of analgesic. The mean consumption was 177.5+36.75 mg in Group A and 115+47.16 in Group B. the difference was highly significant statistically(p<0.0001) (Figure 4).

Figure 4- Total analgesic consumption



Discussion

The present study shows that MgSO4 150 mg when added to 20ml of 0.5% ropivacaine, in ultrasound guided interscalene block (ISB), improves all block characteristics such as block onset, duration of sensory as well as motor block and total duration of analgesia.

Ropivacaine is a long-acting amide local anaesthetic and has improved safety profile as compared to bupivacaine [2,8]. Since ropivacaine has a high pKa (8.2) and low lipid solubility, it preferentially blocks nerve fibres that transmit the pain sensations. The block in effect is largely a sensory block while the motor blockade is dose dependent [2]. It is used in concentration of 0.2%, 0.5% and 0.75% for various peripheral blocks.

Sahu et al reported that use of 10 ml had no added advantage over use of 20 ml ropivacaine in relation to diaphragmatic paresis, though Iwata et al have recommended the lowest possible volume of 10 ml [9-10]. Our study was conducted with ISB as the sole anaesthetic technique and hence we used the 20ml volume for improved intraoperative anaesthesia and post operative analgesia as used in various previous studies [9].

Magnesium is the second most abundant intracellular cation. It plays a pivotal role in presynaptic release of acetylcholine from nerve endings and produces effects similar to calcium-channel blockers. Its anti-nociceptive effects are attributed to regulation of intracellular influx of calcium and antagonism of NMDA receptors [11-12]. It blocks the effects of excitatory amino acids on NMDA receptors. Lee et al concluded that addition of 10% MgSO4 to a long-acting local anaesthetic the duration of analgesia was prolonged and reduced post operative pain after ISB. These findings are similar to our results [13]. Dogru et al, in their study showed that when MgSO4 was added to levobupivacaine for axillary brachial plexus block, it not only hastens the onset of block but prolongs the duration of postoperative analgesia as well [14]. Deshpande et al studied effect of MgSO4 on addition to ropivacaine in axillary brachial plexus block as well and found a significantly faster onset of sensory and motor action in MgSO4 group [15]. Multiple studies have used MgSO4 by various routes. Mukherjee et al and Verma et al concluded that a dose of 150 mg of MgSO4 was optimal when added to 30 ml ropivacaine in supraclavicular block for prolongation of sensory and motor blockade along with longer duration of post operative analgesia and was not associated with any side effects. We also found a prolonged sensory and motor blockade with MgSO4 in our study [16-17]. Magnesium sulfate has also been compared with other adjuvants like dexamethasone and shown to be superior [18].

As per the surface charge theory by Akutagawa et al, when added to local anaesthetics, there is a dependent effect exerted by MgSO4 in peripheral nerve block [19]. The modulation of external Mg2+ ions attracted by the negative charge of outer membrane surface affects the Na+ channel gating causing hyperpolarization resulting in nerve conduction block.

The peri-operative analgesia as well as anaesthetic-sparing effects of MgSO4, are explained by various mechanisms including blockade of NMDA receptors, prevention of central sensitization, abolishing hypersensitivity and muscle relaxing effect [20-23]. MgSO4 supplementation has also been proven to provide better patient comfort as well as quality of sleep in the postoperative period without any major adverse effects [22]. Although we did not compare these parameters in our study, rescue analgesia was not required by any of the patients who received magnesium sulphate.

There were no block failures or adverse events noted in any of the studied patients as proper use of ultrasound and careful aspiration before injection of local anaesthetic was ensured.

Though our study was conducted on an adequate sample size calculated as per the primary objectives, we recommend that the findings be confirmed with larger studies carried out across multiple centres. The beneficial effects on the block characteristics observed in our study could be partly attributed to action of MgSO4 after its systemic absorption. However, we could not quantify this effect in our study. In future, studies can be conducted, which include measurement of serum magnesium levels as well.

Conclusion

MgSO4 is highly effective when added in a dose of 150 mg, to 0.5% ropivacaine in USG-guided interscalene brachial plexus block. It hastens the onset and prolongs the duration of both sensory as well as motor component of the block. Addition of magnesium sulphate is associated with significant prolongation of duration of analgesia, with resultant reduction in the consumption of systemic analgesics postoperatively.

Acknowledgements

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