ORIGINAL ARTICLE ASIAN JOURNAL OF MEDICAL SCIENCES

To evaluate the efficacy of magnesium sulfate and fentanyl as an adjuvant to ropivacaine in supraclavicular brachial plexus block for post-operative pain relief in the upper limb surgeries: A comparative randomized study

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Submission: 19-11-2022 Revision: 30-12-2022 Publication: 01-02-2023

ABSTRACT

Background: Adjuvants to local anesthetics have been used to prolong the duration of analgesia after brachial plexus block surgery. This study evaluates the effects of adding magnesium sulfate and fentanyl with ropivacaine in the supraclavicular brachial plexus block to prolong the duration of analgesia. **Aims and Objectives:** The aim of the present study was to compare the onset and duration of sensory and motor blockade with the quality of perioperative analgesia and post-operative side effects if any, provided by magnesium sulfate and fentanyl as adjuvants to ropivacaine in supraclavicular block. **Materials and Methods:** A total of 80 patients with American Society of Anesthesiologists Grade I/II scheduled for elective upper limb surgeries were randomly allocated into two groups. Group M received 30 ml of 0.5% ropivacaine with 250 mg magnesium sulfate and Group F received 30 ml of 0.5% ropivacaine with 50 µg fentanyl for supraclavicular brachial plexus block using PNS guidance. The onset and duration of sensory and motor block, time for the requirement of rescue analgesia, and adverse events during the perioperative period were noted. **Results:** Onset of sensory block. In group M, the mean onset of sensory blockade was 8.91 ± 1.11 min and in Group F, the mean onset of sensory blockade was 12.12 ± 1.14 min. The mean onset of motor block was 11.57 ± 1.62 min in Group M, and 15.17 ± 1.43 min in Group F. Duration of sensory block is 432.9 ± 38.24 min in Group M and 553.45 ± 39.91 min in Group F, respectively, Duration of motor block in Group M is 392.55 ± 35.22 min and in Group F is 517 ± 44.51 min which was statistically significant. **Conclusion:** Fentanyl prolonged the duration of sensory and motor block and duration of postoperative analgesia as compared to magnesium sulfate when used as an adjuvant to ropivacaine in supraclavicular brachial plexus block and was not associated with any major adverse events.

Key words: Ropivacaine; Magnesium sulfate; Fentanyl; Supraclavicular brachial plexus block

Access this article online

Website: http://nepjol.info/index.php/AJMS

DOI: 10.3126/ajms.v14i2.49660

E-ISSN: 2091-0576

P-ISSN: 2467-9100

INTRODUCTION

Anesthesia and analgesia for surgeries of the upper extremity are commonly provided using the brachial plexus block.[1,2]

Bupivacaine is frequently used as a local anesthetic for brachial plexus block because it offers the advantage of providing a long duration of action.[2,3]

One of the first local anesthetic agents that emerged as a possible replacement for Bupivacaine was Ropivacaine.[4]

Ropivacaine is a long-acting amide local anesthetic with an improved safety profile when compared to Bupivacaine.[4,6]

Magnesium sulfate and fentanyl are adjuvant drugs used in combination with Ropivacaine to enhance the

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analgesic efficacy of the block and facilitate early onset and prolongation of the duration of blockade. A number of studies have evaluated the efficacy of both drugs.[5,7]

Aim and objectives

The aim of the study was to evaluate the efficacy of magnesium sulfate and fentanyl as an adjuvant to ropivacaine in supraclavicular brachial plexus block.

Primary objective

1. The primary objective of the study is to evaluate the efficacy of magnesium sulfate and fentanyl in prolonging postoperative analgesia in supraclavicular brachial plexus block.

Secondary objective

The secondary objectives are as follows:

1. To evaluate and compare the onset and duration of sensory and motor blockade of 0.5%. Ropivacaine with magnesium sulfate and fentanyl in supraclavicular brachial plexus block
2. To observe undesirable effects and complications, if any
3. To observe hemodynamic changes if any.

MATERIALS AND METHODS

The present study was conducted in a cohort of 80 patients admitted to JA Group of Hospitals, belonging to the physical status of ASA Grade I and II, aged 18–60 years, undergoing upper limb surgeries, after obtaining approval from the ethical committee of the institute and informed and written consent from the patient.

Type of study

This study was prospective, randomized, and double-blinded study.

Sample size

The sample size was 80.

$$n = \frac{(s1^2 + s^2)(z_{\alpha/2} + z_{1-\beta})^2}{(\mu_1 - \mu_2)}$$

$$n = \frac{[(1.64)^2 + (5.6)^2](1.96 + 0.84)^2)}{(13.2 - 15.8)^2} = 40$$

Inclusion criteria

The following criteria were included in the study:

- Patient giving consent to participate in the study
- ASA Physical Grade I and II
- Age group 18–60 years and weight between 45 and 70 kg.

Exclusion criteria

The following criteria were excluded from the study:

- Patients not giving consent to participate in the study
- ASA Grade III and IV
- Patients with respiratory, cardiovascular, renal diseases, obesity, and pregnancy
- Age below 18 years or above 60 years.

All 80 patients satisfying the inclusion criteria were investigated for routine baseline pre-operative CBC, RBS, chest X-ray, and a 12 lead ECG. Eighty patients, who fulfilled the eligibility criteria, were chosen, explained about the procedure and their consent was taken in written format. Patients were subsequently randomized into two groups of 40 each. Randomization was done using slips-in the box technique and patients were allocated into two groups, Group A and Group B.,

Group F:

- Patients received 30 ml of 0.5% Ropivacaine with Fentanyl 1 ml (50 mg) bringing the total quantity to 31 ml of the drug to be injected.

Group M:

- Patients received 30 ml of 0.5% Ropivacaine with $MgSO_4$ 0.5 ml (250 mg) +0.5 ml NS bringing the total quantity to 31 ml of a drug to be injected.

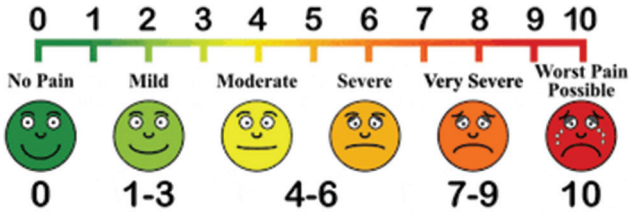
Technique

Supraclavicular block classical approach (nerve stimulator technique): The patient was placed in a dorsal recumbent position without a pillow, with arms by the side, and head turned (30–45) toward the opposite side. A small pillow/sandbag/towel folded was placed below the shoulder blades for adequate positioning. The patient was asked to lower the shoulder and supinate the arm. The neck and the shoulder were painted and draped. Peripheral nerve stimulator-guided single shot brachial plexus nerve block was given. Wrist flexion and extension of fingers were taken as acceptable responses. The total volume of the anesthetic solution was injected at an incremental dose of 5 ml each, preceded by negative aspiration. A 3-min massage was performed to facilitate even drug distribution.

The onset of sensory block was evaluated using a 3-point scale (0 – Normal sensation, 1 – reduced sensation, and 2 – no sensation). The onset of motor block was assessed by a 4-point scale (0 – no paralysis, 1 – shoulder abduction, 2 – elbow flexion, 3 – wrist flexion, and 4 –complete block.[8] The surgery was allowed to commence after complete anesthesia was achieved. The total duration of analgesia was taken from the time of complete sensory block to the request of rescue analgesia with VAS ≥3.

VAS score[10]

Post-operative pain was assessed by visual analog score scale consisting of a 10 cm horizontal scale with gradations marked with "0" indicating no pain at all and 10 indicating the worst pain imaginable.



VAS score rating: 0=No pain 1–3=Mild pain 4–6=moderate pain 7–10=Severe pain VAS score was noted at time for first rescue analgesic (TRA1).

VAS score >3 was managed with rescue analgesia by inj. Tramadol 2 mg/kg i.v.in 100 ml normal saline to relieve the pain.

TRA1

It refers to the period of time between the onset of the brachial plexus block and the first dose of rescue analgesic that the patient requires, that is, VAS score >3.

Side effects and complication

Any side effect or complication due to the drug or technique was noted including hypotension, hypertension, bradycardia, tachycardia, post-operative nausea vomiting, sedation, shivering, and respiratory depression.

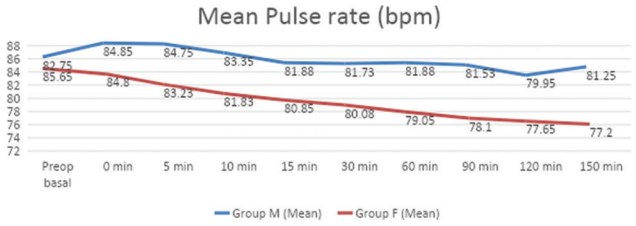
Sample size and statistical analysis

Evaluation of study data in the electronic form required performing additional statistical analyses. Data were composed in a suitable spreadsheet, that is, EXCEL and SPSS. After the compilation of data, it was analyzed statistically by SPSS software version 22.0. To compare the two groups for the different characteristics of a supraclavicular block, after checking the assumption for the normality either the Chi-square test or an independent t-test was applied. The significance level was 95% confidence level (P<0.05). Data were described as a frequency (percentage) distribution as well as in Mean±SD. Data were presented through suitable statistical graphs.

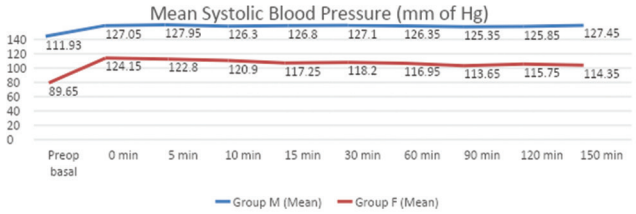
All the observations and particulars of each patient were recorded in a proforma.

RESULTS

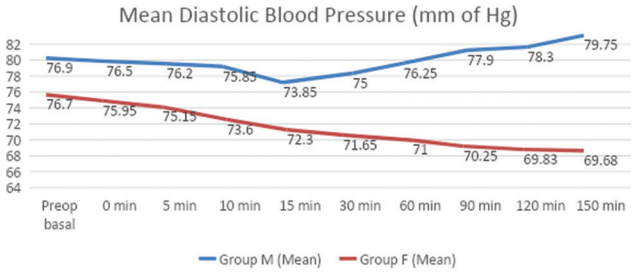
Hemodynamic variables



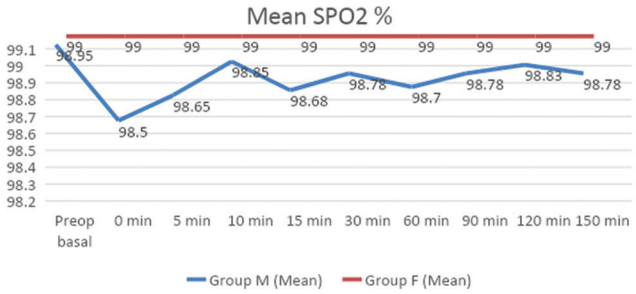
The association between the intervention groups and heart rate was not statistically significant since P>0.05 as an unpaired t-test.



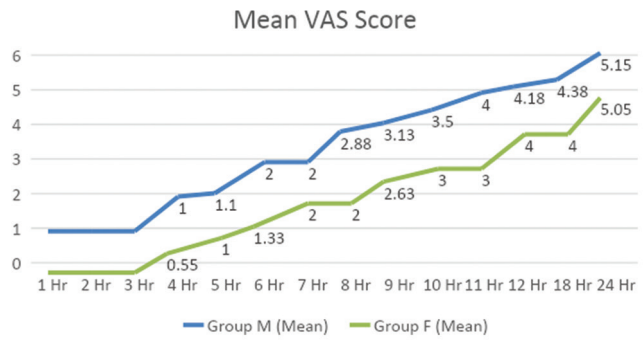
The association between the intervention groups was statistically significant since P<0.05.



The association between the intervention groups and heart rate was not statistically significant since P>0.05 as per unpaired t-test.

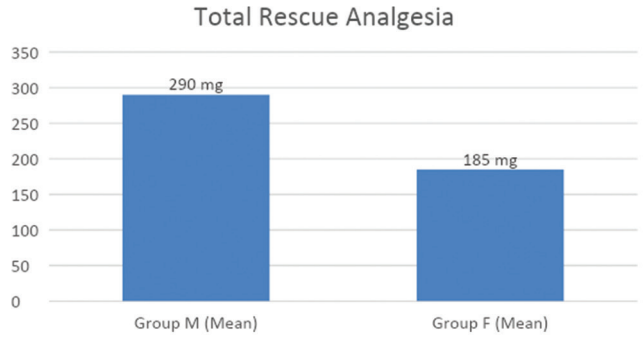


P>0.05, which is statistically insignificant.



P<0.001 highly significant.

The association between the intervention groups and the first rescue analgesia time distribution is considered to be statistically significant P<0.001.



The total rescue analgesia usage for 24 h in Group M was 290±30.38 mg of inj. Tramadol iv and the total rescue analgesia usage for 24 h in Group F was 185±36.16 mg of inj. Tramadol iv and P<0.001 which is statistically significant.

DISCUSSION

In the present study, we have studied intraoperative and post-operative analgesia and see the effect of two adjuvants added to ropivacaine in a supraclavicular brachial plexus block**.** In our study, ropivacaine was used along with adjuvant magnesium sulfate and fentanyl in the supraclavicular brachial plexus block. After the Institutional Ethical Committee clearance, patients were randomized into two groups, that is, Group F received 0.5% ropivacaine (30 ml) with fentanyl (50 mcg) and Group M received 0.5% ropivacaine (30 ml) with magnesium sulfate (250 mg) plus 0.5 ml NS. We assessed the effect of supraclavicular brachial plexus block in our study in term of onset and the duration of sensory and motor blockade. The duration of analgesia and hemodynamic changes intraoperatively and side effects if any, perioperatively was noted. Demographic variables (Table 1) were comparable in our study P>0.05, making it the difference statistically insignificant. The demographic characteristics were also comparable in a study conducted by Dharmarao and Holyachi[20] and Cham et al.,[28] In Group M, the mean onset of sensory blockade was (Table 2) 8.91±1.11 min and in Group F, the mean onset of sensory blockade was 12.12±1.14 min, Rajkhowa et al.,[26] studied 66 ASA I and II patients aged 18–65. The mean onset of sensory block in Group RT was 10.6 min while it was 11.1 min in Group RF. The mean onset of motor block in Group RT was 11.3 min while it was 15.4 min in Group RF, Nahida et al.,[11] In Group M, the mean onset of motor blockade (Table 3) was 22.7±18.98 min and in the group, N mean onset of motor blockade was 31.12±2.47 min.

In our study, duration of sensory block is 432.9+38.24 min in Group M and 553.45+39.91 min in Group F and the duration of motor block in Group M is 392.55±35.22 min and in Group F is 517±44.51 min, similar study Nahida et al.,[11] conducted a study on 60 patients were randomly divided into two groups, magnesium sulfate group or received 0.75% ropivacaine to the addition of magnesium sulfate and group normal saline group 0.75% ropivacaine to the addition of normal saline. group M, mean duration of the sensory block is 229±19.12 min and in group, N mean duration of the sensory block is 150±15.12 min, P<0.0243which was statistically significant. Rajkhowa et al.,[26] in their study also showed that the addition of fentanyl (50 mcg) to ropivacaine 0.5% (30 ml) for supraclavicular brachial plexus blocks significantly prolonged sensory block. Similar study like Shridevi and Asokan[12]., M.D. Allene et al[13]., Anjuna and shivkumar [14]., Kumar.S et al[16]. Table 4 time of first rescue analgesia or total duration of analgesia: The time of first rescue analgesia in Group M was 511.63±45.58 min and in Group F was 672.1±49.32 min. Duration of analgesia was longer in Group F as compared to Group M. Our finding correlated with Patil and Deshpande[9] duration of analgesia longer in the magnesium group as compared to the ropivacaine group. In another study conducted by Taneja et al.[21] It was concluded that 150 mg magnesium sulfate given with Ropivacaine 0.5% 30 ml in supraclavicular brachial plexus block increased the duration of analgesia and delayed the analgesic requirement in the post-operative period. Our study, the VAS score at 4, 6,8, 9, and 10 h after induction was higher in group magnesium as compared to group fentanyl, showing improved pain control by fentanyl. VAS score at 1st h from induction was 0 in Group F and 0 in Group M. At 2nd h – 0 in Group F and 0 in Group M. At 3rd h – 0 in Group F and 0 in Group M. At 4th h – 0.55±0.5 in Group F and 1±0 in Group M. At 5th h – 1±0 in Group F and 1.1±0.3 in Group M. At 6th h – 1.33±0.47 in Group F and 2±0 in Group M. At 7th h – 2±0. in Group F and 2±0 in Group M. At 8th h

Table 1: Demographic profile of study participants

Demographic parameter	Group M (n=40)	Group F (n=40)	P-value
Age (years)	39.1±13.94	37.28±16	0.588
Weight	59.58±6.5	59.54±6.88	0.981
Gender	27	31	0.453
Male			
Female	13	9	

The difference between the two groups was statistically insignificant (P>0.05)

Table 2: Intergroup statistical analysis of onset and duration of sensory block

Time (minutes)	Group M versus F			
	Group M (Mean±SD)	Group F (Mean±SD)	t-value	P-value
Onset of sensory block	8.91±1.11	12.12±1.14	−12.764	<0.001
Duration of sensory block	432.9±38.24	553.45±39.91	−13.795	<0.001

The mean difference was statistically significant (P<0.001)

Table 3: Intergroup statistical analysis of onset and duration of motor block

Time (minutes)	Group M versus F			
	Group M (Mean±SD)	Group F (Mean±SD)	t-value	P-value
Onset of motor block	11.57±1.62	15.17±1.43	−10.548	<0.001
Duration of motor block	392.55±35.22	517.25±44.51	−13.896	<0.001

The mean difference was statistically significant. (P<0.001)

Table 4: Intergroup statistical analysis of rescue analgesia

Parameter	Group M (Mean±SD)	Group F (Mean±SD)	t-value	P-value
Rescue analgesia	511.63±45.58 minutes	672.1±49.32 minutes	−15.114	<0.001

– 2±0 in Group F and 2.88±0.33 in Group M. At 9th h – 2.63±0.49 in Group F and 3.13±0.33 in Group M. At 10th h 3±0 3.5±0.51 in Group F and 3.5±0.51 in Group M. VAS score >3 was managed with the administration of rescue analgesia with inj. Tramadol 2 mg/kg i.v. in 100 ml normal saline to relieve post-operative pain. The VAS score at 4 h, 6 h, 8 h, 9 h, and 10 h in Group M and Group F was statistically significant. Similar findings were seen in a study done by Kaur et al.,[19]and Akhondzade et al.[24] Similar study like Mohan kumar et al[15]., Attri et al[17]., Hashim and Hasan[18].,Sahi.P et al[22].,Elazyed MA et al[23]., Yangste N et al[25].,Wasudeo B et al[27]., Mukharjee et al [29]., Iwata et al[30].

There were no complications found in both the groups either during the surgery or for the first 24 h after surgery.

Limitations of the study

The major limitation of our study was that the investigator was unable to objectively quantify and evaluate post-operative pain which being a subjective experience can be a major limiting factor in comparing and estimating the effectiveness of various modalities of treatment.

CONCLUSION

Magnesium when added to 0.5% Ropivacaine for supraclavicular brachial plexus block shortened the onset of sensory and motor blockade as compared to addition of fentanyl to 0.5% Ropivacaine. Addition of fentanyl with 0.5% Ropivacaine prolonged the post-operative analgesia in the supraclavicular brachial plexus block.

ACKNOWLEDGMENT

We acknowledge all the support extended to us by our head of the department, teachers, my parents, residents, and technical staff in overall smooth conduct for our research work.

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Source of Support: Nil, **Conflicts of Interest:** None declared.