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Original Article

Anaesthesia Section

Efficacy of Magnesium Sulfate and Dexmedetomidine as Adjuvants to Ropivacaine in Supraclavicular Brachial Plexus Block: A Randomised Clinical Study

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ABSTRACT

Introduction: Peripheral nerve blocks have recently proven to be extremely promising in terms of patient satisfaction. In upper limb procedures, rapid and deep anaesthesia can be achieved with supraclavicular ultrasound-guided access to the brachial plexus. To improve the quality of local anaesthesia, adjuvants such as magnesium sulfate and dexmedetomidine have been added to the local anaesthetic.

Aim: To evaluate the efficacy of magnesium sulfate and dexmedetomidine as adjuvants to ropivacaine in supraclavicular Brachial Plexus Blockade (BPB).

Materials and Methods: A prospective randomised double-blind study was conducted in the Department of Anaesthesiology from June 2016 to November 2017 (1 year and 6 months) at King George's Medical University, Lucknow, Uttar Pradesh, India. A total of 60 patients were divided into two groups using a computer-generated random number for upper limb surgeries (below the mid-humerus) under supraclavicular brachial plexus block. Group A (n=30) received ropivacaine 0.5% (30 mL) plus dexmedetomidine 50 µg for the supraclavicular block, and Group B received ropivacaine 0.5% (30 mL) plus magnesium sulfate 150 mg in 1 mL Normal Saline (NS) 0.9% for the same block. A comparison of these two groups was conducted for the time of onset, duration of sensory and motor block, haemodynamic stability, postoperative analgesia, and complications. Statistical analyses such as Student's t-test, Chi-square test, and Mann-Whitney U-test were used.

Results: The mean age of Group A was 28.03±5.86 years and Group B was 31.07±7.06 years. The sensory block and motor block onset were significantly faster among patients of Group A (6.47±1.43 min and 8.50±1.46 min) compared to Group B (9.57±1.22 min and 11.77±1.19 min). The mean duration of analgesia was significantly longer ($p<0.001$) in Group A (1034.10±61.07 min) compared to Group B (460.00±35.82 min). The duration of sensory block and motor block was also significantly higher ($p<0.001$) in Group A compared to Group B. Both groups were haemodynamically stable, but sedation was significantly higher in Group A.

Conclusion: Dexmedetomidine 50 µg is a superior adjuvant compared to magnesium sulfate 150 mg with ropivacaine 0.5% in supraclavicular brachial plexus block as it significantly hastens onset time and prolongs the duration of sensory and motor blocks and the duration of analgesia.

Keywords: Haemodynamic stability, Limb surgeries, Local anaesthesia, Postoperative analgesia

INTRODUCTION

Brachial Plexus Block (BPB) has become an important tool for anaesthesiologists over the last decade as it is a safe alternative to general anaesthesia for upper limb surgery [1]. In addition to providing excellent pain control, it also reduces the side-effects of general anaesthesia and leads to a shortened stay in the post-anaesthesia care unit [2]. The supraclavicular brachial plexus block was introduced into clinical practice in Germany by Kulenkampff in 1911. It is the most effective block for the upper extremities and is administered at the level of the brachial plexus trunks [3].

Ropivacaine, a type of local anaesthetic, causes reversible inhibition of sodium ion influx, thereby blocking impulse conduction in nerve fibers [4]. It is less toxic to the heart and the Central Nervous System (CNS) than other long-acting local anaesthetics [5]. Although local anaesthetics are sufficient for supraclavicular BPB, their shorter duration of postoperative analgesia is a limitation. Therefore, various adjuvants such as opioids, clonidine, neostigmine, dexamethasone, midazolam, etc., have been added to achieve a rapid, impenetrable, and prolonged block, but the results are either inconclusive or associated with side-effects. Magnesium is required for the presynaptic release of acetylcholine from nerve terminals and may have similar effects to drugs that block calcium entry [6]. It is used for its analgesic, antihypertensive, and anaesthetic effects [7,8]. Dexmedetomidine has a high specificity ratio for the $\alpha 2$ receptor ($\alpha 2/\alpha 1$ 1600:1) compared to clonidine ($\alpha 2/\alpha 1$ 200:1), making it a complete $\alpha 2$ agonist. It is used for intravenous (i.v.) sedation and analgesia in intensive care units and in non intubated patients undergoing surgery and other procedures [9]. The present study was conducted to evaluate the intraoperative and postoperative analgesic efficacy and safety of ropivacaine with dexmedetomidine and magnesium sulfate in supraclavicular BPB.

MATERIALS AND METHODS

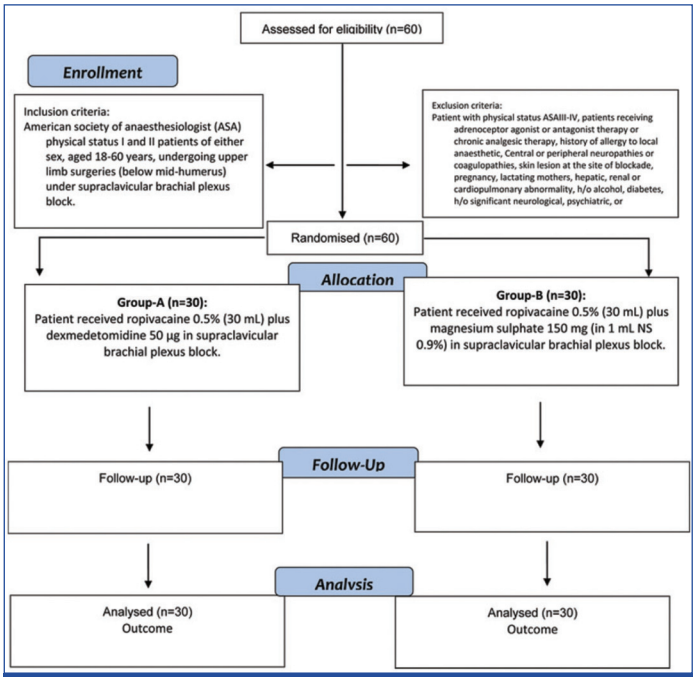
A prospective randomised double-blind study was conducted in the Department of Anaesthesiology from June 2016 to November 2017 (1 year and 6 months) at King George's Medical University, Lucknow, Uttar Pradesh, India. After obtaining approval from the Institutional Ethical Committee (Ref. Code 82nd ECM II B- thesis / P7) present study was conducted. Written informed consent was obtained from all study participants.

Inclusion and Exclusion criteria: Patients with an American Society of Anaesthesiologists (ASA) status of I and II, of either sex, aged 18 to 60 years, undergoing upper limb surgery (below mid-humerus) with supraclavicular brachial plexus block were included. Patients with a physical status of ASA III-IV, a history of hypersensitivity or allergies, coagulopathies, local skin lesions, pregnancy, a history

of significant neurological, psychiatric, or neuromuscular disorders, upper limb surgery requiring bone grafting, and patients refusing participation were excluded from the study.

Sample size calculation: Based on previous studies, the mean difference in onset of sensory block between the ropivacaine group (22.2) and the dexmedetomidine group (14.55) in supraclavicular brachial plexus block was 7.65 [10]. The sample size calculation was performed using the formula $n=2(Z\alpha/2+Z[1-\beta])^2\times\sigma^2/(\mu1-\mu2)^2$, assuming a significance level of 0.05 ($Z\alpha/2=1.96$) and 90% power ($Z[1-\beta]=1.28$). The calculated sample size was 26.66 in each group. To increase the power of the study and enable parametric analyses, 30 participants were enrolled in each group.

Patients were randomly allocated into two groups, each with 30 participants, using a computer-generated random number. Patients in Group A received ropivacaine 0.5% (30 mL) plus dexmedetomidine 50 µg for a supraclavicular block [10]. Patients in Group B received ropivacaine 0.5% (30 mL) plus magnesium sulfate 150 mg (in 1 mL of NS 0.9%) for the same block [11]. The Consodilated Standards of Reporting Trails (CONSORT) flowchart had been presented in [Table/Fig-1].



[Table/Fig-1]: Consort flow diagram.

Study Procedure

H2 arrival in the operating room, the patient's Heart Rate (HR), Blood Pressure (BP), saturation (SPO_2), and Electrocardiogram (ECG) were recorded. An 18G intravenous line was placed, and an infusion of Ringer's lactate solution was started. The patient was positioned supine with the head turned away from the side to be blocked. The skin was prepared, and the transducer was placed in the transverse plane centered over the clavicle. Local anaesthesia was infiltrated with a 25 to 27G needle at the site of interest. After negative aspiration, 30 mL of the study drug was injected over a period of one minute, with aspiration repeated every 3 mL once correct needle placement was confirmed. Haemodynamic variables (HR, SBP, DBP, ECG) were recorded every five minutes for the first 30 minutes, every 15 minutes until the first hour, then hourly until the end of surgery, every 15 minutes during the first postoperative hour, and then every 30 minutes until six hours, and hourly until the effect of the blockade wore off.

The blockade was assessed every five minutes until complete sensory and motor block wore off, after which hourly assessments of the duration of sensory and motor blockade were conducted. A pinprick test was performed to evaluate sensory blockade using a 23 G blunt hypodermic needle in the distribution of all four nerves (median, ulnar, radial, and musculocutaneous), applying a 3-point scale: 0= normal sensation, 1=loss of stinging sensation (analgesia), 2=loss of tactile sensation (anaesthesia) [12]. The Modified Bromage scale [13] was used to assess motor block. The time of onset of sensory and motor blockade was defined as the time interval between the end of administration of the total local anaesthetic and complete sensory or motor blockade [14]. Quality of block criteria were based on patient complaints: Excellent (4)=no patient discomfort, Good (3)= mild discomfort without the need for additional analgesics, Moderate (2)=discomfort requiring additional analgesics, and unsuccessful (1)=patient required general anaesthesia [10].

In the recovery room, patients were asked to rate their pain on a 10-point Visual Analogue Scale (VAS). Pain was then assessed regularly every 30 minutes for the first 120 minutes and then every 60 minutes for up to 24 hours. The duration of the motor blockade was measured from the onset of the motor block to the complete recovery of full muscle power and was determined by asking the patients to record the time when they could first move their fingers of the blocked limb [14].

The duration of analgesia was defined as the time between the end of the administration of the local anaesthetic and the first administration of an adjuvant analgesic [14]. Patients' pain was assessed using the VAS, a scale of 0 to 10, where 0 indicates no pain and 10 indicates very severe pain. If the VAS score was ≥4, 1 mg/kg of diclofenac sodium was injected intramuscularly. The total amount of diclofenac sodium consumed postoperatively in the first 24 hours was noted.

Patients were asked about nausea, vomiting, and rash and were observed for tachycardia (>20% above baseline), bradycardia (<50 beats per minute), hypotension (>20% below baseline), hypertension (>20% above baseline), hypoxemia (SpO_2 <90%), sedation, or other adverse events during the 24-hour postoperative period. The Ramsay sedation score was used to assess sedation after performing the block (1=anxious, agitated, restless, 2=cooperative, oriented, calm, 3=responding only to commands, 4=asleep but with a lively response to light tapping of glabellas or loud acoustic stimuli, 5=sluggish response to light tapping of glabellas or loud acoustic stimuli, and 6=no response to light tapping of glabellas or loud acoustic stimuli) [15].

STATISTICAL ANALYSIS

Statistical Package for Social Sciences (SPSS) version 15.0 was used to perform statistical analysis. Values were expressed as number (%) and mean±Standard Deviation (SD). The comparison between these two groups was conducted using the t-tests, Chi-square tests, and Mann-Whitney U tests and a p-value <0.05 was considered statistically significant.

RESULTS

In present study, 30 patients (50%) who received 0.5% ropivacaine with 50 µg dexmedetomidine for supraclavicular BPB were categorised as Group A, and 30 patients (50%) who received 0.5% ropivacaine with 150 mg magnesium (in 1 mL NS 0.9%) for supraclavicular BPB were categorised as Group B. The age, gender distribution, ASA status, body weight, and duration of surgery were similar in both groups [Table/Fig-2].

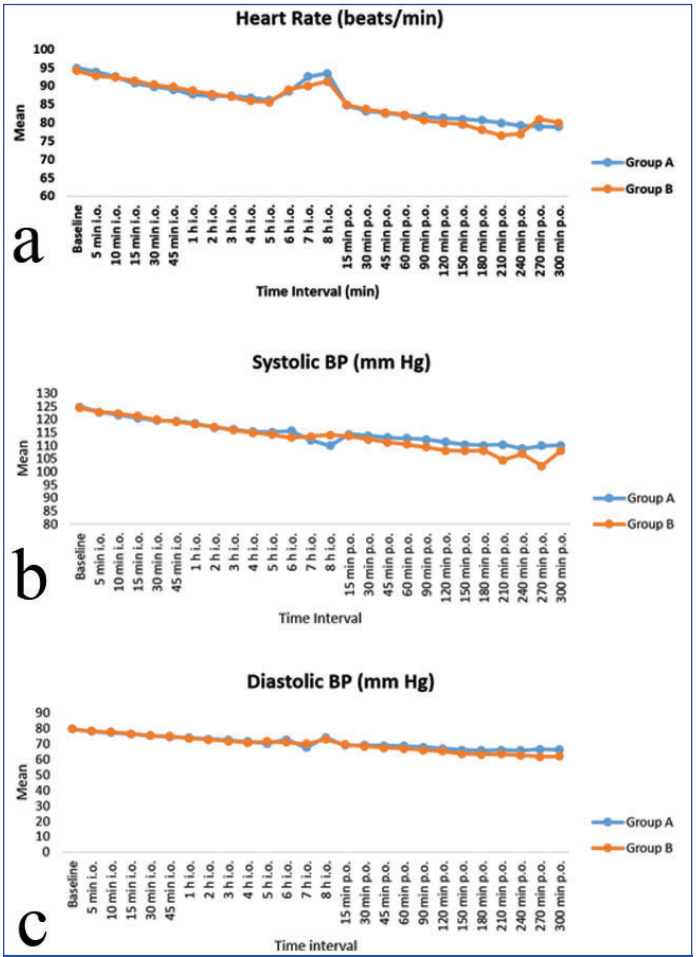
The mean onset of sensory block was significantly earlier in Group A patients (6.47±1.43 min) than in Group B (9.57±1.22 min). In Group A patients, the mean onset of motor block (8.50±1.46 min) was significantly earlier than in Group B patients (11.77±1.19 min). Patients in Group A (1034.10±61.07 min) had a significantly longer duration of analgesia than those in Group B (460.00±35.82 min). In Group A patients, the mean duration of sensory block (949.53±65.93 minutes) was higher than in Group B (440.93±35.90 minutes), which

Parameters		Group A (n=30)		Group B (n=30)		p-value
		Mean	±SD	Mean	±SD	
Age (years)		28.03	5.86	31.07	7.06	0.067
Gender	Male	12	40	11	36.67	0.791
	Female	18	60	19	63.33	
ASA	Grade I	13	43.33	13	43.33	1.00
	Grade II	17	56.67	17	56.67	
Height (cm)		162.43	7.13	164.3	5.93	0.275
Weight (kg)		70.37	9.26	73.6	9.66	0.191
BMI (kg/m^2)		26.57	1.99	27.18	2.6	0.312

[Table/Fig-2]: Comparison of baseline characteristics in between Group A and Group B. N=60

Variables	Group A (n=30)		Group B (n=30)		Statistical significance	
	Mean	SD	Mean	SD	't'	p-value
Onset of sensory block (min)	6.47	1.43	9.57	1.22	-9.017	<0.001
Onset of motor block (min)	8.50	1.46	11.77	1.19	-9.500	<0.001
Duration of analgesia (min)	1034.10	61.07	460.00	35.82	44.414	<0.001
Duration of sensory block (min)	949.53	65.93	440.93	35.90	37.108	<0.001
Duration of motor block (min)	856.83	56.05	336.60	36.16	42.721	<0.001
Total analgesic in 24 hrs (mg)	104.37	15.01	143.77	22.99	7.860	<0.001

[Table/Fig-3]: Comparison of duration of block between Group A and Group B.



[Table/Fig-4]: Comparison of haemodynamic parameter between groups: a) Heart rate (beats/min); b) Systolic BP (mmHg); c) Diastolic BP (mmHg).

was statistically significant (p<0.001). In Group A patients, the mean duration of the motor block (856.83±56.05 minutes) was significantly prolonged compared to Group B (336.60±36.16 minutes). The total amount of diclofenac was significantly higher in patients in Group B (143.77±22.99 mg) than in those in Group A (104.37±15.01 mg) [Table/Fig-3]. Both groups were haemodynamically stable. Heart rate, SBP, and DBP decreased in both groups during the intra- and postoperative period compared to baseline values in each monitoring period [Table/Fig-4].

Excellent block quality was observed in a higher proportion of patients in Group A compared to Group B (53.33% versus 43.33%). The difference in block quality between Group A and Group B patients was not statistically significant (p=0.442) [Table/Fig-5].

Quality of block	Group A (n=30)		Group B (n=30)		Total (N=60)		p-value
	n	%	n	%	n.	%	
Excellent	16	53.33	13	43.33	29	48.33	0.442
Good	14	46.67	17	56.67	31	51.67	
Poor	0	0	0	0	0	0	

[Table/Fig-5]: Comparison of quality of block between Group A and Group B.

Vomiting, tachycardia, and hypertension were not noted in any of the patients. In Group A patients (6.67%), the incidence of nausea was higher than in Group B (3.33%). Bradycardia was observed in 10% of patients in both groups. In Group A patients (13.33%), the incidence of hypotension was higher than in Group B (10%). Sedation was observed only in 10 (33.3%) patients in Group A, whereas no sedation was observed in Group B. The difference in the incidence of sedation between Group A and Group B (33.3%) was found to be statistically significant (p=0.001) [Table/Fig-6]. The difference in the incidence of skin rash and respiratory depression was not found to

Complications	Total (N=60)	Group A (n=30)		Group B (n=30)		Statistical significance	
		No.	%	No.	%	χ^2	p-value
Nausea	3	2	6.67	1	3.33	0.351	0.554
Vomiting	0	0	0	0	0	-	-
Skin rashes	2	2	6.67	0	0	2.069	0.150
Tachycardia	0	0	0	0	0	-	-
Bradycardia	6	3	10	3	10	0.000	1
Hypotension	7	4	13.33	3	10	0.162	0.688
Hypertension	0	0	0	0	0	-	-
Sedation	10	10	33.33	0	0	12.000	0.001
Respiratory depression	3	3	10	0	0	3.158	0.076

[Table/Fig-6]: Comparison of adverse effect (complication) between Group A and Group B.

Time	Group A			Group B			Mann-Whitney U test	
	Md	Mean	SD	Md	Mean	SD	Z	p-value
Baseline	2	2	0	1.00	1.00	0	7.681	<0.001
5 min	2	2	0	1.00	1.00	0	7.681	<0.001
10 min	2	2	0	1.00	1.00	0	7.681	<0.001
15 min	2	2	0	1.00	1.00	0	7.681	<0.001
20 min	2	2	0	1.00	1.00	0	7.681	<0.001
25 min	2	2	0	1.00	1.00	0	7.681	<0.001
30 min	2	2.40	0.62	1.00	1.00	0	7.277	<0.001
45 min	2	2	0	1.00	1.00	0	7.681	<0.001
60 min	2	2	0	1.00	1.00	0	7.681	<0.001
75 min	2	2	0	1.00	1.00	0	7.681	<0.001
90 min	2	2	0	1.00	1.00	0	7.681	<0.001
150 min	2	2	0	1.00	1.00	0	7.681	<0.001
210 min	2	2	0	1.00	1.00	0	7.681	<0.001
270 mn	2	2	0	1.00	1.00	0	7.681	<0.001

[Table/Fig-7]: Comparison of Ramsay Sedation Score at different time intervals.

be statistically significant between Group A and Group B. In Group A and Group B, the difference between the Ramsay sedation values of patients was statistically significant (p<0.001) [Table/Fig-7].

DISCUSSION

Sensory and motor block onset was earlier in the dexmedetomidine group (Group A) compared to the magnesium group (Group B). Additionally, in patients of the dexmedetomidine group, sensory and motor block durations were higher compared to the magnesium group. Block quality was excellent in Group A patients (53.33%) compared to 43.33% in Group B, while it was found to be good in 56.67% in Group B compared to 46.67% in Group A. However, more complications were found in Group A compared to Group B. Similarly, Shukla U et al., (2020) found that dexmedetomidine produced an earlier onset and longer duration compared to those receiving $MgS0_4$ [10,16]. According to Nema N et al., in the dexmedetomidine group, the onset of sensory block (7.20±2.483 min) was earlier compared to the control group (14.20±5.229 min), and the onset of motor block was earlier in the dexmedetomidine group (11.83±3.824 min) compared to the control group (21.00±8.566 min) [17]. Numerous studies, including those by Kathuria S et al., Bharti N et al., and Das A et al., support these findings [10,18,19]. Each of these studies found that the addition of dexmedetomidine to ropivacaine resulted in an early onset of motor and sensory blockade during supraclavicular blockade. In the dexmedetomidine group, sensory and motor blockade started earlier compared to the control group, which is comparable to present study [10-19]. Esmaoglu A et al., mixed dexmedetomidine with levobupivacaine for axillary blockade and revealed that it prolonged the duration of blockade and analgesia, which is comparable to this study [20]. In a study conducted by Das A et al., the duration of sensory and motor blockade in supraclavicular BPB was prolonged by the addition of 100 µg of dexmedetomidine to a 0.5% ropivacaine solution [19].

In present study, the mean duration of analgesia was significantly longer in the dexmedetomidine group compared to the magnesium group. Additionally, the total amount of diclofenac required was significantly higher in patients in the magnesium group than in the dexmedetomidine group. Similarly, a previous study reported that the addition of dexmedetomidine or $MgS0_4$ to ropivacaine resulted in a longer duration of postoperative analgesia [10]. Consistent with present study, Das A et al., (2014) demonstrated that the addition of dexmedetomidine reduced the need for rescue analgesia throughout the postoperative period [19]. In agreement with these results, Chinnappa J et al., found that in supraclavicular block, the duration of sensory and motor block was prolonged by the addition of dexmedetomidine to ropivacaine in the dexmedetomidine group (630.6±208.2 and 545.9±224.0 min) compared with the ropivacaine group (400.8±86.6 and 346.9±76.9 min) [11]. Additionally, the analgesia duration was shorter in the ropivacaine group (411.0±91.2 min) than in the dexmedetomidine group (805.7±205.9 min). In a study by Mukherjee K et al., fewer rescue analgesics were required in the magnesium group [21]. Conversely, in a study by Bharti N et al., during the 24-hour postoperative period, the dexmedetomidine group required fewer rescue analgesics (p<0.0001) [18].

Heart rate decreased in both groups during the intra- and postoperative period compared to baseline values in each monitoring period. Shukla et al., also found that haemodynamic parameters were similar between the groups [16]. Similar results were also observed by Das A et al., [19]. In a study by Kathuria S et al., one patient had bradycardia in the group receiving intraoperative ropivacaine and dexmedetomidine [10]. All patients were treated with i.v. atropine. Similar to this study, in a study by Kathuria S et al., hypotension was noted in two patients in the group receiving ropivacaine and dexmedetomidine [10].

The Ramsay Sedation Score was used in this study to assess the degree of sedation of the patients. In Group A, sedation was observed in 10 out of 30 patients. Popping DM et al., who described sedation by dexmedetomidine based on some systemic drug absorption, support this study [12]. The study by Bharti N et al., reported that patients taking dexmedetomidine were more sedated than those in the control group for two hours (p<0.0001) [18].

Limitation(s)

The present study was a single-centre study. The use of ultrasound guidance could have significantly decreased the total volume of local anaesthetics. However, it was not used in present study.

CONCLUSION(S)

In supraclavicular block, dexmedetomidine 50 µg is a better adjuvant than magnesium sulfate 150 mg with ropivacaine 0.5%, as it significantly prolongs the duration of sensory and motor blockade, the duration of analgesia, and accelerates the time of onset of blockade. It also delays the time until the first need for rescue analgesics in the postoperative phase. Conscious sedation makes the patient cooperative during the procedure. No serious complications occurred with either drug, but dexmedetomidine was associated with side-effects, particularly bradycardia and hypotension. Large-scale multicentre studies must be done to validate the results of present study.

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