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Original Research Article

Comparative evaluation of fentanyl and magnesium sulphate as an adjuvant to 0.375% bupivacaine in ultrasound guided supraclavicular brachial plexus block

Manu Gupta[1,*]

[1] *Dept. of Anaesthesiology, Atal Bihari Vajpayee Institute of Medical Sciences (ABVIMS) and Dr. Ram Manohar Lohia Hospital, New Delhi, India*

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ABSTRACT

Background: Supraclavicular block helps in achieving good anaesthesia along with complete muscle relaxation while providing hemodynamic stability and excellent post-operative analgesia. The addition of opioids to local anaesthetics injected during brachial plexus block has been shown to decrease the post-operative systemic analgesic requirements. This study was designed to compare the effectiveness of addition of $MgSO_4$ (150 mg) and Fentanyl (50 micrograms) to 0.375% bupivacaine with placebo in supraclavicular brachial plexus block.

Materials and Methods: A prospective double-blind randomised controlled study was conducted comprising of 75 patients undergoing upper limb surgeries under ultrasound guided supraclavicular brachial plexus block. Patients were randomized into one of the three groups (n=25) and designated as Group P (20ml of 0.375% Bupivacaine only), Group M (150 mg Magnesium sulphate with Bupivacaine) and Group F (50 micrograms Fentanyl with Bupivacaine). The primary purpose of the study was to compare the onset and quality of sensory as well as motor blockade in all three groups.

Results: The onset time (in minutes) of sensory as well as motor blockade was significantly shorter in group P ($p<0.001$). Mean duration of sensory blockade (7.65±1.05 hours) and motor blockade (8.17±1.17 hours) was longest in group F when compared to group M and group P ($p<0.001$). Percentage of patients requiring rescue analgesia were significantly less in group F (16%) than group M (32%) and group P (80%) respectively ($p<0.001$). The mean time prior to administration of rescue analgesia in groups F, M and P were 14.21±4.29, 9.86±1.49 and 8.50 ±2.37 hours respectively ($p<0.001$).

Conclusion: Although the additives delay the onset of action of local anaesthetic agents in brachial plexus block, Fentanyl as an adjuvant provided superior analgesia when compared to Magnesium sulphate as well as placebo with respect to duration of motor and sensory blockade. In addition, patients who received fentanyl as an adjuvant, required lesser rescue analgesia in the post-operative period.

1. Introduction

Brachial plexus block has proved to be a good alternative to General Anaesthesia (GA) for upper limb surgeries. Supraclavicular block helps in achieving good anaesthesia along with complete muscle relaxation while providing hemodynamic stability and excellent post-operative analgesia.[1] Various techniques by which Brachial plexus block can be given are interscalene block, supraclavicular Block, infraclavicular Block, axillary Block.[2]

Supraclavicular block seems to be the most convenient and safest method for peri-operative pain management in surgeries below shoulder joint.[3] Even though various newer drugs are now available; bupivacaine is one of the most frequently used local anaesthetic for supraclavicular block

* *Corresponding author.*
E-mail address: manugupta9391@gmail.com (M. Gupta).

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as it has long duration of action for more than 3 to 6 hours with good motor blockade. Although, duration of action of local anaesthetic in brachial plexus block may provide good intraoperative anaesthesia, wearing off of the dense block remains a challenge in postoperative period.[4] Additives to local anaesthetics for brachial plexus block enhance the quality and duration of analgesia.[5] Vasoconstrictors have been used to prolong sensory blockade but the results were either inconclusive or associated with side-effects.[6]

The anti-nociceptive action (due to regulation of calcium influx into the cell and antagonism of N-methyl D-aspartate receptors) of Magnesium sulphate (MgSO4) has been used to augment quality and duration of analgesia in supraclavicular brachial plexus block.[7] Various investigators have also observed that per-neural MgSO4 administration during general anaesthesia has reduced anaesthetic requirement and postoperative analgesic consumption.[8–10]

The addition of opioids to local anaesthetics injected during brachial plexus block has been shown to decrease the post-operative systemic analgesic requirements.[11–14] Anti-nociceptive effect of fentanyl is initiated by activation of peripheral opioid receptors.[15]

The purpose of this study was to compare the effectiveness of addition of $MgSO_4$ (150 mg) and fentanyl (50 micrograms) to 0.375% bupivacaine with placebo in supraclavicular brachial plexus block.

2. Materials and Methods

A prospective double-blind randomised controlled study was conducted after obtaining the institutional ethical committee approval and clinical trial registration (CTRI/2018/05/019823) in tertiary care hospital of New Delhi. Total 75 patients of either gender, between 16 to 60 years of age, belonging to American Society of Anaesthesiologist (ASA) grade I or II, posted for upper limb surgeries distal to mid-humerus done under ultrasound guided supraclavicular brachial plexus block were included in the study. Patients with ASA grade 3 or higher, patients with known hypersensitivity to study drugs, lactating or pregnant mothers, patients with hepatic as well as cardiac or renal abnormalities, long term analgesic therapy, comorbidities like hypertension, diabetes, bleeding diatheses and local site skin infection, contraindication to supraclavicular brachial plexus block and those refusing to participate in study were excluded.

Sample size calculation was done using G-Power software (Version 3.2.1, Germany) with reference to a previous study by Yaghoobi et al.[16] Total of 75 patients (25 in each group) were included in the study to attain minimum 90% power and to reduce the alfa error to 5% as well as to compensate for 10% attrition rate.

Patients were allocated into three groups by block randomization method using computer generated random number table as likewise:

Group P (n=25): 20ml of 0.375% Bupivacaine + 2 ml of Normal Saline

Group M (n=25): 20ml of 0.375% Bupivacaine + 150 mg magnesium sulphate

Group F (n=25): 20ml of 0.375% Bupivacaine + 50 micrograms fentanyl

Standard preanesthetic evaluation and laboratory investigations were done a day prior to the surgery. A written informed consent was obtained and 6 hours fasting was advised prior to the procedure. All standard ASA monitors were attached after shifting the patient to operation theatre. An 18G peripheral intravenous cannula was inserted and Ringer's lactate intravenous fluid was started. The procedure was explained to every patient and Supraclavicular brachial plexus block was performed under ultrasound guidance using Honda electronics HS-2100 portable ultrasound machine with linear (6–12 MHz) probe. The brachial plexus and its relation to the surrounding structures were observed while the patient was supine and the head turned to the contralateral side. In the supraclavicular fossa, the probe was placed transversely to visualize the subclavian artery and the brachial plexus (Figure 1). The subclavian artery was viewed as a pulsating hypoechoic structure on top of the hyperechoic first rib and the brachial plexus was located lateral to it as a cluster of hypoechoic nodules (Figure 2). After all aseptic precautions, skin preparation and local anaesthetic infiltration, a 50-mm 22-gauge insulated needle was then introduced lateral to the ultrasound probe following the in-plane technique. Once the needle penetrated the brachial plexus cluster, the group specific local anaesthetic mixture was injected incrementally after negative aspiration for blood or air just next to the artery. Then the needle was repositioned to inject at the lower pole of the artery. Local anaesthetic dispersion at the time of injection was noted under real time ultrasound imaging (Figure 3). The Primary Objective of the study was to compare the onset and quality of sensory blockade in the three groups. In addition, the secondary objectives were to compare motor blockade, postoperative analgesia, hemodynamic parameters and incidence of any adverse events between the groups.

Sensory block assessment was done by pinprick test on a three-point scale [0=Sharp pain, 1= Analgesia (loss of sensation to pinprick), 2= Loss of touch] every 2 minutes till onset of satisfactory sensory blockade for surgery or till 30 minutes. Motor blockade was assessed using modified Bromage scale [0= No block (total arm and forearm flexion), 1= Partial block (total forearm and partial arm flexion), 2= Almost complete block (inability to flex the arm and decreased ability to flex the forearm), 3= Total block (inability to flex both arm and forearm)]. It was documented every 2 minutes till onset of satisfactory motor blockade for surgery or till 30 minutes after the block. Post-operatively,

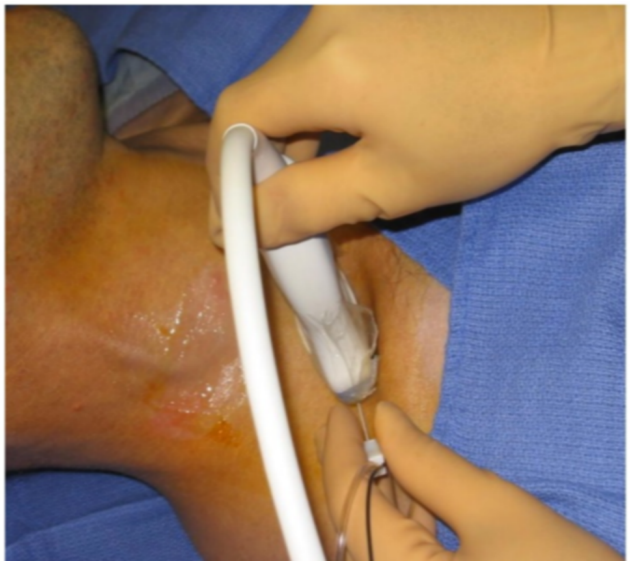

Fig. 1: Ultrasound probe position on neck for supraclavicular approach of brachial plexus block

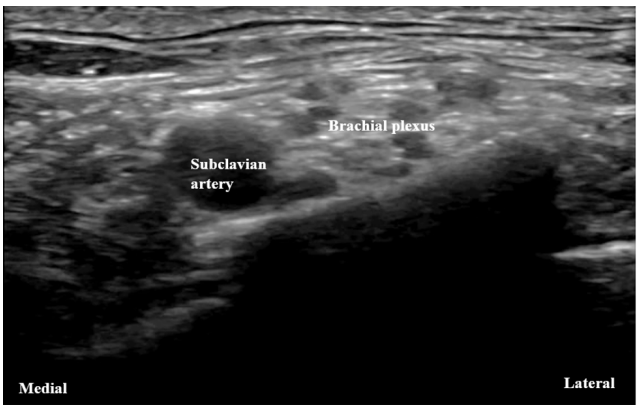

Fig. 2: Ultrasound image of brachial plexus as hypoechoic cluster from supraclavicular approach

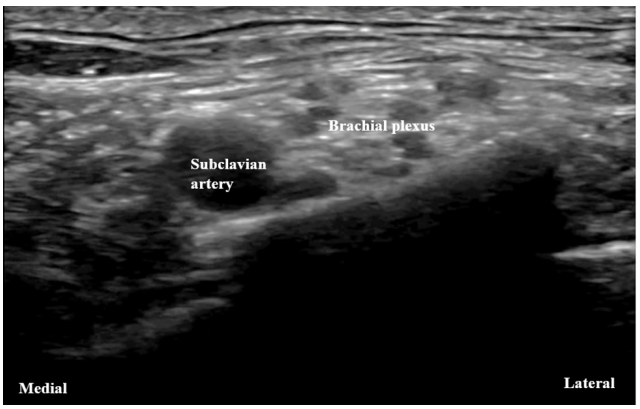

Fig. 3: Ultrasound image of needle approaching brachial plexus and spread of local anaesthetic agent from supraclavicular approach

it was measured every 30 minutes till 4 hours, every 2 hours till 12 hours and then every 6 hourly till 24 hours after the surgery.

The onset of sensory blockade was defined as the time from the end of group specific study drug injection till loss of sensation to pinprick (score 1). Similarly, the onset of motor blockade was documented as the time interval between the end of injection and complete motor paralysis of the wrist and hand (modified Bromage score 3). The duration of sensory blockade was the time interval between onset of sensory blockade score 1 before and offset of sensory blockade to score 1 after the surgery as assessed by pin-prick test. The duration of motor blockade was defined as the time interval between onset of modified Bromage score 3 before and achievement of modified Bromage score 0 after the surgery.

Pain assessment was done using visual analogue scale (VAS) where 0 was no pain and 10 was worst imaginable pain. Postoperatively VAS score was assessed every 30 minutes till 4 hours and thereafter whenever patient complained of pain till 24 hours.

Any adverse events like nausea, vomiting, pruritus, urinary retention, bradycardia and respiratory depression were noted during as well as after the block procedure. Complications of supraclavicular brachial plexus block like pneumothorax or phrenic nerve injury were also noted postoperatively.

Assessment of sensory block (pin prick test) and motor block (Modified Bromage Scale) were carried out every 2 minutes following this. If after 30 minutes of instituting the block, desired sensory and motor blockade was not achieved, it was considered as block failure and in such cases General Anaesthesia (GA) was administered to the patients. Patients having patchy sensory blockade which required supplementation analgesia during or before surgery and in whom GA was administered were excluded from further statistical analysis. Injection Atropine 1 mg was administered intravenously in cases of symptomatic bradycardia and Injection Mephentermine 6 mg was administered intravenously in cases of hypotension (Mean arterial pressure (MAP) <60 mm-Hg).

After the surgery, VAS score was noted as described previously and injection Diclofenac sodium 75 mg was administered intravenously when VAS score was more than 4 as rescue analgesia.

Pulse rate (PR), MAP, peripheral oxygen saturation (SpO_2) and respiratory rate (RR) before as well as after the block procedure were recorded at 0, 5, 10, 20, 30, 60, 120, 180, 240 minutes and thereafter every 6 hours till 24 hours after the surgery. Onset time of Percentage of patients needed rescue analgesia in study populationed in the study protocol.

The CONSORT flow diagram for the study has been depicted in Figure 4. The collected data was analysed using

the software, named Statistical Package for Social Science (SPSS 24.0 version, IBM Corp., Armonk, New York, USA) and it was found to be normally distributed as assessed by Shapiro-wilk test. Quantitative variables like age of the patients, weight, onset and duration of sensory as well as motor blockade, duration to rescue analgesia and VAS scores were expressed as mean±standard deviation (SD) and compared using ANOVA as well as Bonferroni post-hoc analysis. Qualitative variables like gender, ASA grade, patients requiring rescue analgesia and incidence of adverse events were expressed as frequencies and percentages. They were compared using Chi-square test or Fisher's exact test whenever appropriate. A p-value less than 0.05 was considered statistically significant.

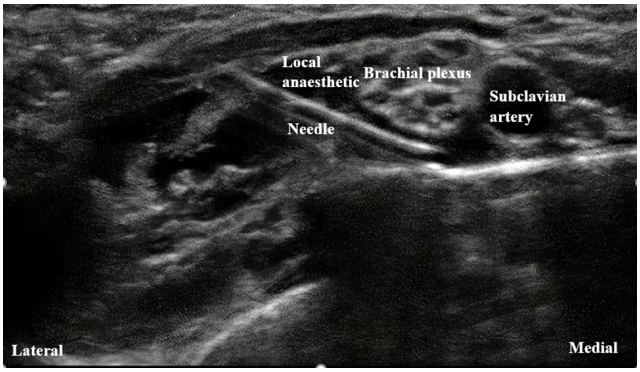

Fig. 4: CONSORT flow diagram of patients undergoing supraclavicular block

3. Results

The demographic variables like age, gender, weight and ASA grade were comparable among all the three groups (Table 1). Mean PR, MAP, SpO_2 and RR were comparable among the three groups both intra as well as post-operatively (p-values>0.05).

Onset and duration of sensory as well as motor blockade has been tabulated in Table 2. The onset time of sensory blockade was comparable between groups F and M (p=0.746) but the onset time was significantly shorter in group P when compared to group F and M individually (p<0.001). The mean onset time of motor blockade was comparable in groups F and M (p value=0.421) but onset of motor block was significantly faster in group P (p<0.001). Mean duration of sensory blockade (7.65±1.05 hours) and motor blockade (8.17±1.17 hours) was longest in group F when compared to group M and group P (p<0.001).

Enumeration of mean VAS score of patients have been depicted in Table 3. Statistically significant difference in VAS score between three groups were seen from 6 hours to 18 hours after the block procedure. The difference in VAS scores were not significant at 6 and 24 hours time points and mean post-operative VAS score was found to be less in Group F with respect to Group M and group P.

Percentage of patients requiring rescue analgesia were significantly less in group F (16%) than group M (32%) and group P (80%) respectively (p<0.001) as described in Figure 5. The mean time prior to administration of rescue analgesia in groups F, M and P were 14.21±4.29, 9.86±1.49 and 8.50 ±2.37 hours respectively (p<0.001). On post-hoc analysis, mean time to rescue analgesia was significantly different only between groups F and P (p=0.006) but not between groups F and M (p=0.076) or P and M (p=0.176).

4. Discussion

In modern anaesthesia practice, peripheral nerve blocks have a significant contributory role. Safety and unparalleled success rate have made this technique of anaesthesia as very popular in ambulatory and inpatient anaesthesia. The use of ultrasound for the same has improved the precision and success of these blocks. These nerve blocks minimize stress response and decrease the anaesthetic drug usage by providing intraoperative anaesthesia as well as extend analgesia to the postoperative period without any major systemic side effects.[17]

Supraclavicular blocks have been administered at the level of nerve trunk of the brachial plexus. The three-nerve trunk contained in a very small, compact but easily accessible and relatively superficial area is the sole sensory, motor, and sympathetic supply of upper limb. Thus, this block results in a prompt onset of foreseeable and profound anaesthesia with high level of certainty. Ultrasound provides clinicians with real-time images which are useful for better identification of the anatomical structures, safe needle placement, and adequate spread of local anaesthetics.[18]

Local anaesthetics alone for supraclavicular brachial plexus block provide good operative conditions but have shorter duration of postoperative analgesia. Various studies have used fentanyl and magnesium sulphate as individual adjuncts for brachial plexus block to either increase the duration and density of block or to expedite the onset.[19–22]

In this prospective, randomized double blind study we had compared the effect of adding magnesium sulphate 150 mg, fentanyl 50 mcg and placebo i.e., 2ml of normal saline to bupivacaine (0.375% & 20 ml volume) in supraclavicular block on the onset and quality of sensorimotor blockade along with postoperative analgesia in patients undergoing upper limb surgery (distal to mid-humerus).

The demographic profile of patients was statistically insignificant between three groups and was similar with other research investigationsthus providing uniformity for comparison.[10,23]

The onset of sensory block (p=0.746) and motor block (p=0.421) was comparable between group F and group M but there was statistically significant prolongation in onset of sensory and motor block by addition of fentanyl and magnesium sulphate compared to LA alone and the results

Table 1: Demographic data of study participants in three groups

Variables		Group F (Fentanyl)	Group M (Magnesium Sulphate)	Group P (Normal Saline)	p-value
Age (years) [Mean ± SD]		35.29 ±11.32	36.00±13.01	31.17±11.91	0.339
Weight (kg) [Mean ± SD]		64.50±9.20	62.32±8.39	62.67±7.81	0.641
Gender [n (%)]	Male	16 (64)	16 (64)	17 (68)	0.899
	Female	9 (36)	9 (36)	8 (32)	
ASA Grade [n (%)]	I	24 (96)	21 (84)	23 (92)	0.583
	II	1 (4)	1 (4)	2 (8)	

Table 2: Duration and onset of sensory as well as motor blockade in study participants

Variables	Mean ± SD			p-value			
	Group F (Fentanyl)	Group M (Magnesium Sulphate)	Group P (Normal Saline)	Overall	F vs M	F vs P	M vs P
Onset of sensory block (Minutes)	8.13±2.47	8.35±1.88	4.09±0.91	<0.001	0.746	<0.001	<0.001
Duration of sensory Blockade (Hours)	7.65±1.05	6.27±0.94	4.17±0.56	<0.001	<0.001	<0.001	<0.001
Onset of motor block (Minutes)	11.13±3.21	11.79±2.16	5.98±0.88	<0.001	0.421	<0.001	<0.001
Duration of motor block (Hours)	8.17±1.17	6.27±0.94	4.33±0.96	<0.001	<0.001	<0.001	<0.001

Table 3: VAS scores in study participants between three groups

Post operative VAS score	Mean ± SD			p-value			
	Group F (Fentanyl)	Group M (Magnesium Sulphate)	Group P (Normal Saline)	Overall	F vs M	F vs P	M vs P
4 hours	0.03 ± 0.21	0	0	0.599	0.344	0.323	0.899
6 hours	0.08 ± 0.41	0.23 ± 0.75	2.04 ± 1.23	<0.001	0.419	<0.001	<0.001
8 hours	0.29 ± 0.81	1.95 ± 1.21	3.71 ± 1.63	<0.001	<0.001	<0.001	<0.001
12 hours	2.58 ± 1.28	3.45 ± 1.34	3.71 ± 1.20	0.008	0.029	0.003	0.500
18 hours	3.17 ± 0.56	3.59 ± 0.67	3.88 ± 0.91	0.005	0.024	0.002	0.234
24 hours	3.92 ± 1.14	3.55 ± 0.91	3.88 ± 0.68	0.344	0.232	0.878	0.169

were in concordance with other studies.[10,22] In contrary to our study findings, Verma et al found a quicker onset of sensorimotor blockade with Magnesium sulphate.[19]

In our study, both the duration of sensory and motor blockade was significantly longer in group F when compared to group M and group P (p<0.001). Similarly, the duration of both sensory and motor blockade was significantly longer in group M vs group P (p<0.001). Similar observations were made by various other researchers in their respective studies.[10,20,22] Hence, we can conclude that Fentanyl came out to be superior with respect to duration of motor and sensory blockade.

Postoperative pain was assessed using VAS score at various intervals in our study. The VAS score was statistically significant when three groups were compared from 6^{th} hour after the institution of block. Similarly, when group F and group M were compared for VAS score, the difference was significant from 8^{th} hour and became non-significant at 24^{th} hour.

The need for rescue analgesia was significantly different between groups F and P (p=0.006) but not between groups F and M (p=0.076). In addition, we observed that the need for rescue analgesic was less in group M when compared to group P but the results were not statistically significant (p=0.176). Similar observations were made by Das A et al, Lee AR et al. and EL Shamaa HA et al in their respective studies.[10,20,24]

No complications related to the block and local anaesthetics were observed in any of the study patients.

The strength of our study was the comparison of 3 groups including the one with placebo. Whereas the previous studies have compared mostly two adjuncts.

There might be some bias in the study due to systemic absorption of both the adjuvants which might

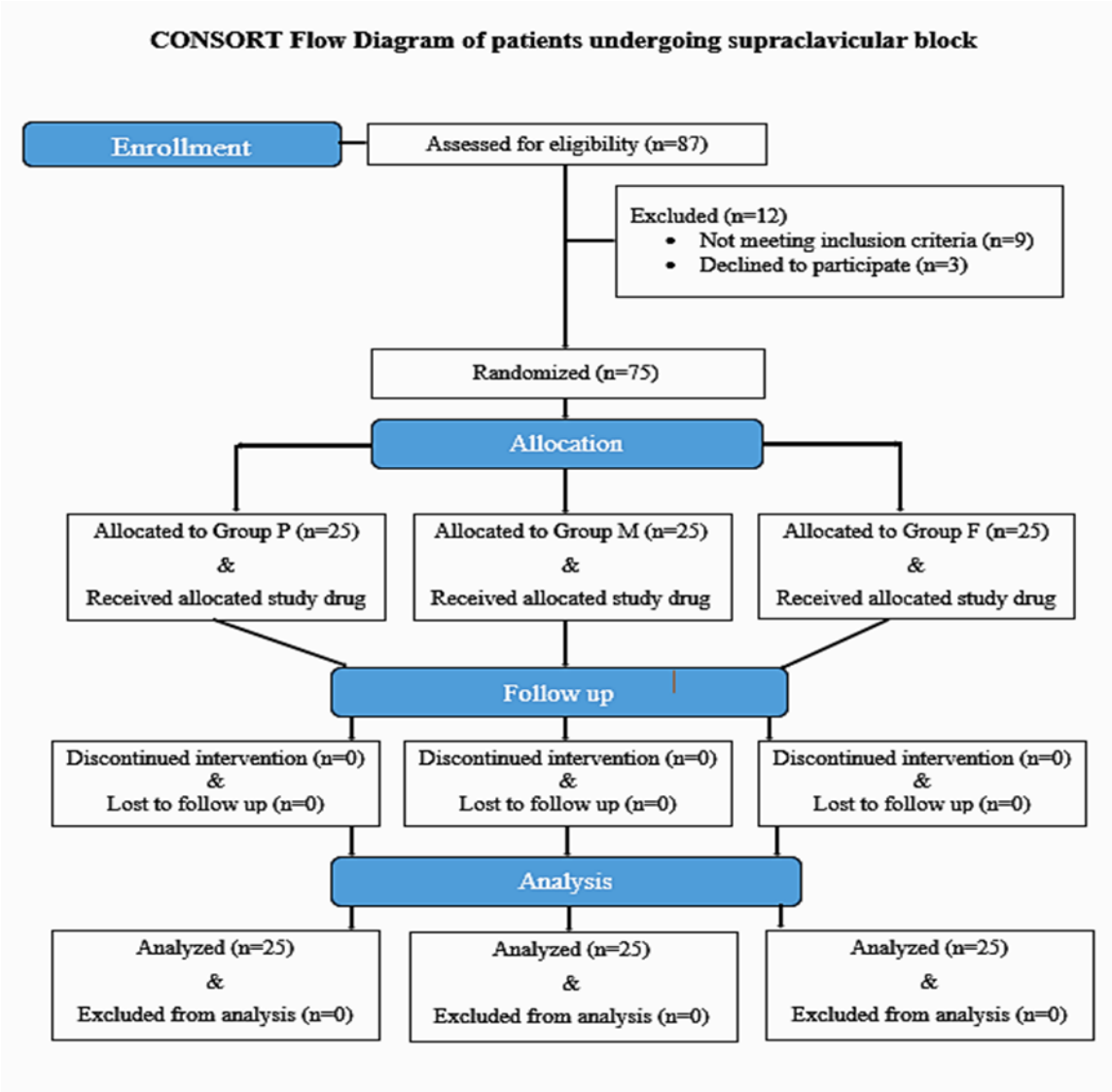

Fig. 5: Percentage of patients needed rescue analgesia in study population

have contributed to the initial effects. This however does not explain the prolonged sensory and motor blockade. Moreover, the sample size could have been increased to improve the power of the study and more centres could have been incorporated to perform a multicentric study.

5. Conclusion

Although both the additives delay the onset of action of local anaesthetic agents in Brachial plexus block, Fentanyl as an adjuvant provided superior analgesia when compared to Magnesium sulphate as well as placebo with respect to duration of motor and sensory blockade. In addition, patients who received fentanyl as an adjuvant, required lesser rescue analgesia and time to first rescue analgesia was significantly longer in them. To conclude, fentanyl is a better adjuvant when compared to magnesium sulphate when added to bupivacaine for perioperative anaesthesia in upper limb surgeries under supraclavicular blocks.

6. Source of Funding

None.

7. Conflict of Interest

None.

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Author biography

Manu Gupta, Senior Resident

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