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To Compare the Analgesic Effect of MgSO4 and Clonidine Added to Ropivacaine in Ultrasound-Guided Tap Block for Postoperative Analgesia in Patients Scheduled for Cesarean Section under Subarachnoid Block

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Abstract: ***Background and Aims:Transversus abdominis plane (TAP) block has proven to be an effective component of multimodal analgesic regimens for a variety of abdominal procedures. Magnesium sulphate ($MgSO_4$) N-methyl-D-aspartate receptor antagonist and clonidine an alpha agonist have the potential to be an ideal adjuvant to local anaesthetic in TAP block. This study was designed to compare the efficacy of $MgSO_4$ and clonidine as an adjuvant to Ropivacaine in TAP block in patients scheduled for caesarean section under subarachnoid block (SAB). Methods: Thirty pregnant women belonging to American Society of Anaesthesiologists physical status 2, aged between 20 and 40 years, scheduled for elective caesarean section under SAB were recruited. Patients in Group C (n = 15) received 20 mL 0.25% Ropivacaine with Clonidine 150mcg, whereas those in Group M (n = 15) received 20 mL 0.25% Ropivacaine with 150 mg) MgSO4 in the ultrasound (USG)-guided TAP block performed on each side after the completion of the surgery under SAB. They were evaluated for pain using VAS score at 0, 2, 4, 6,8, 12,14,18 and 24 h, time to first rescue analgesic and duration of postoperative analgesia were noted. Results: The post-operative visual analogue scale (VAS) scores were lower in both Groups till 14 hours following which clonidine group showed significantly better analgesia than magnesium group. Rescue analgesia was 20.17 + 3.42 hrs in group C which was more when compared with group M which was 13.07 + 2.12 hrs. Over all pain reduction was good and patient had better satisfaction. Conclusion: Addition of Clonidine as an adjuvant to Ropivacaine provides better prolongation of post-operative analgesia as compared to Magnesium sulphate, without any significant untoward effects.***

Keywords: clonidine, magnesium sulphate, tap block, postoperative

1. Introduction

Pain can be defined as " whatever the experiencing person says it is, existing whenever he/she says it does."[1] Post delivery time is the most crucial period for a woman where she has to take care of herself and her new-born[2]. Inadequate pain control can affect the mother physically and mentally and cause ill bonding between the mother and child.

Transverse abdominis block is simple and, a preferred option for lower abdominal surgeries which was first described by Rafi in 2001[3].

Transversus abdominis plane block is an idyllic approach in easing post-operative pain in patients, especially when used as part of a multimodal analgesia regimen. Local anesthetic agents are injected into the neuro-fascial plane between the internal oblique and transversus abdominis muscle. [4,5]

The duration of the TAP block depends on the effect of administered local anesthetics, which can be prolonged by adding adjuvants[6,7]. In this study, we intended to compare the analgesic effect of MgSO4 and Clonidine added to Ropivacaine in ultrasound-guided TAP block for postoperative analgesia in patients scheduled for cesarean section under subarachnoid block.

2. Methods

After institutional ethical committee approval, this randomized, double-blind randomized controlled trial was conducted in 50 healthy parturients (ASA II) scheduled to undergo elective LSCS under spinal anesthesia (SA).

Exclusion criteria:
Patients who refused SA, had any contraindication to regional anesthesia, history of drug allergy or chronic pain, a coagulation disorder, or infection at the needle insertion site. Patients in whom SA was inadequate for the conduct of surgery were also excluded from the study.

Patients were divided into two equal groups of twenty-five each to receive either:
Group M (n = 25): TAP block with 20 ml of 0.20% ropivacaine bilaterally + 150mg MgSO4
Group C (n = 25): TAP block with 20 ml of 0.20% ropivacaine bilaterally + 150mcg clonidine

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Patients were allocated to the respective groups using random number chits. Group allocation was concealed in serially numbered sealed, opaque envelopes that were opened in the operating theatre just before the administration of SA. The study drug was prepared and coded by an anesthesiologist not involved in the study. The patient and the anesthesiology resident administering the TAP block and involved in data collection were also blinded to group assignment.

After written informed consent, patients were made familiar with 10 cm Visual Analog Scale (VAS) with 0 representing no pain and 10 representing the worst imaginable pain before administering the block.

After securing 18-gauge intravenous (IV) cannula, Ringer lactate infusion was initiated. After establishing standard anesthesia monitoring, baseline measurements such as heart rate (HR), non-invasive blood pressure, and peripheral oxygen saturation were recorded. Patients received standard spinal anesthesia comprising hyperbaric 0.5% bupivacaine 2ml in the left lateral position and surgery started once adequate level T6 had reached.

Once the surgery was over and the SAB sensory level regressed to T8 dermatome, USG-guided TAP block (using SonoSite™ Micromax machine, linear high-frequency probe, 6–13 MHz) was performed under all aseptic precautions with respective drug solutions. After draping the abdominal part between the twelfth rib bone and iliac crest with umbilicus at the center-external oblique muscle, internal oblique muscle, transversus abdominis muscle, and their fascia were identified beneath the skin and the subcutaneous tissue. A 22-gauge spinal needle was advanced by a USG-guided in-plane technique at the anterior axillary line and the exact location of the needle tip checked by USG. After checking the exact location of the needle tip, 1 mL of NS was injected to open the plane and after confirmation of the hypoechoic area on the USG image, the study solution of 20 mL was injected. An equal amount of the same solution was also injected on the opposite side using an identical technique

After completion of the surgical procedure and block, patients were transferred to the post-anesthesia care unit and observed for pain using the VAS score for twenty-four hours and later on shifted to the general obstetric ward.

The duration of postoperative analgesia, defined as the time (in hours) from the giving of the TAP block to the time to the first analgesic request in the postoperative period was recorded. Degree of pain was observed using the VAS every 30 min for 2 h, then every 2h for the next 14 h and thereafter every 4h till 24 hours. The TAP block was deemed a failure if the patient requested analgesia within the first 2 h of administering the block, and the case was not included in analyses. Patients were given injection diclofenac 1 mg/kg intravenous (to a maximum of 3 mg/kg/day) on-demand or if the VAS score was ≥3. A four-point patient satisfaction score (1 = Extremely satisfied, 2 = Satisfied, 3 = Dissatisfied, 4 = Extremely dissatisfied) was also noted. Other associated side effects such as dryness of mouth, hypotension (systolic blood pressure <20% of baseline), and bradycardia (heart rate <60 bpm) were also observed. All the observations were made by an anesthetist who was unaware of group allocation and blind to the study drug.

Statistical analysis:
Data was entered into Microsoft excel data sheet and was analysed using SPSS 22 version software. Continuous data was represented as mean and standard deviation. Independent t test was used as test of significance to identify the mean difference between two quantitative variables.

Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs

P value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyse data.

3. Results

Table 1: Demographic profile of patients

AGE in years	Group C		Group M		
	Mean	SD	Mean	SD	P value
	25.47	4.00	27.07	2.58	0.3
WEIGHT in kilogram	64.55	9.56	64..13	7.77	0.912

Mean age in Group C was 25.47 ± 4 yrs. Mean age in Group M was 27.07 ± 2.58yrs. Mean weight in kilogram in Group C was 79.13±07 kg and mean weight in Group M was 77.55±11kg. There was a no statistically significant difference found between two group with respect to age and weight.

Table 2: Comparison of duration of surgery, Motor regressed, Rescue analgesia between the two groups at different time intervals

	Group C		Group M		P value
	Mean	SD	Mean	SD	
Duration of surgery (in Minutes)	72.00	4.47	76.13	6.02	0.042
Motor regressed (minutes)	86.93	3.84	87.87	1.77	0.400
Rescue analgesia (hours)	20.13	3.42	13.07	2.12	**<0.001**

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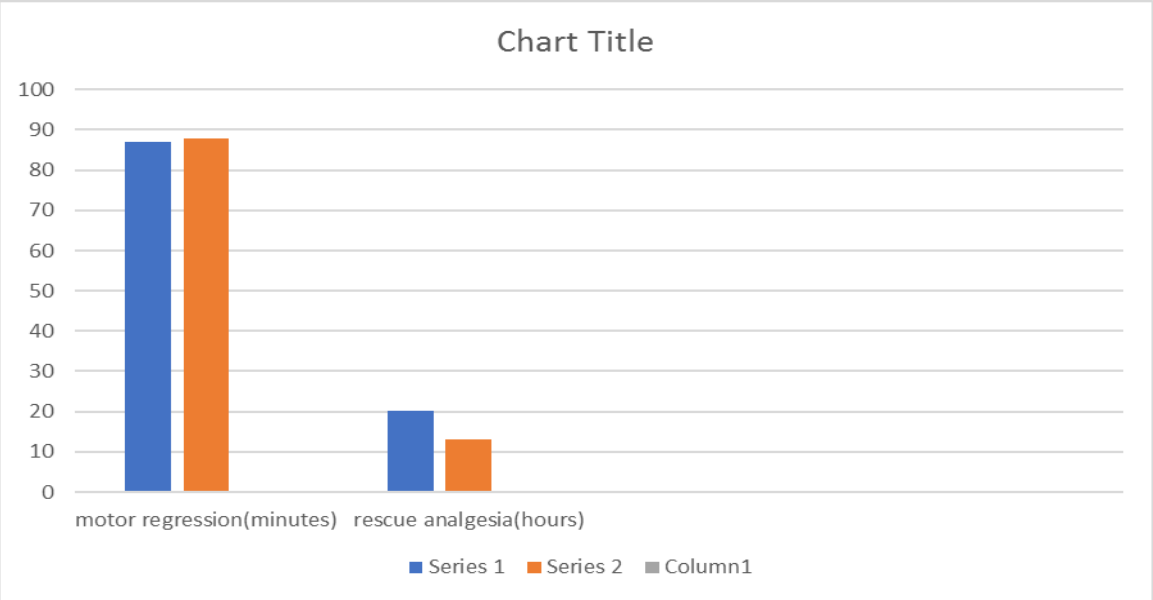

Table 3: Comparison of VAS score between the two groups at different time intervals

VAS score	Group C		Group M		
	Mean	SD	Mean	SD	P value
2hrs	0.13	0.35	0.20	0.41	0.638
4hrs	0.27	0.59	0.53	0.74	0.287
6hrs	0.67	0.62	0.87	0.74	0.429
8hrs	0.67	0.62	1.27	0.70	0.019
10hrs	0.87	0.64	1.87	0.92	0.002
12hrs	1.07	0.59	2.73	1.03	<0.001
14hrs	2.13	0.52	3.73	0.59	<0.001
18hrs	3.47	0.64	4.20	0.41	<0.001
24hrs	4.00	0.00	4.00	0.00	-

There was no statically significant difference found between two group with respect VAS sore at 2hrs, 4hrs, 6hrs.
There was statically significant difference found between two group with respect VAS sore at 8hrs, 10hrs, 12hrs, 14hrs, 18hrs, 24hrs.

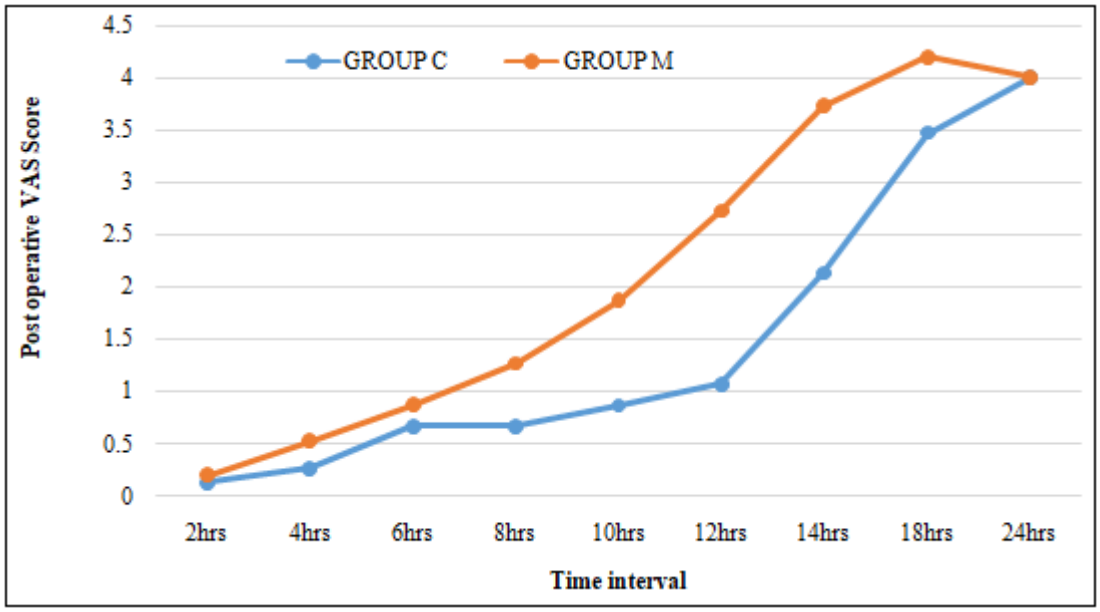

Figure 1: Graph showing Comparison of VAS score between the two groups at different time intervals

Rescue analgesia was 20.17 + 3.42 hrs in group C which was more when compared with group M which was 13.07 + 2.12 hrs. There was a statically significant difference found between two groups with respect Rescue analgesia.

Motor regressed was 86.93 + 3.84 minutes in group C and in Group M it was 87.87 + 1.77 minutes. Duration of surgery was 72. + 4.47 minutes in group C and in Group M it was 76.13 + 6.02 minutes.

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There was no statically significant difference found between two group with respect Motor regressed and Duration of surgery.

4. Discussion

Adequate pain relief is important after cesarean delivery to promote early recovery and improvise the mother's ability to care for her newborn. Post cesarean pain has two components somatic and visceral. TAP block alleviates somatic pain. Currently, opioids form the majority of post-cesarean analgesia, but have various side effects like nausea, vomiting, respiratory depression, and delayed mobility. In this study, we divided two groups of 25 samples each by random selection and drug from one of the groups C (0.20% Ropivacaine 20ml + Clonidine 150mcg) or M (0.20% Ropivacaine + Magnesium sulfate 150mg) was administered by blind technique. Neither the patient, the doctor administering the drug, and following up know about the group used.

Transverse abdominis plane block is a new technique for abdominal surgeries, which was first explained by Rafi in 2001[2] The thoracolumbar nerves are responsible for the segmental cutaneous supply of the abdominal wall. The anterolateral abdominal wall is mainly innervated by the anterior rami of the thoracolumbar spinal nerves (T6-L1), which become the intercostal (T6-T11), subcostal (T12), and ilioinguinal/iliohypogastric nerves(L1). There are four paired muscles in the anterolateral abdominal wall: rectus abdominis, transversus abdominis, internal oblique, and external oblique. The TAP plexuses lie on the transversus abdominis plane which is a potential anatomical space between the transversus abdominis and internal oblique (or rectus abdominis), and the field block by TAP infiltration is referred to as a TAP block. There are several different approaches for ultrasound-guided TAP block, such as lateral, posterior, and subcostal approaches[8].

The success of this block depends on identifying the plane between the internal oblique and transversus abdominis muscles. In blind technique, the plane is identified by the 'pop' sensation of a blunt needle passing through fascial planes, which is a subtle and imprecise endpoint. Correct localization is more difficult in obese patients where the depth is greater or in the elderly where the muscle layers may be thinner and in the pregnant patient where the muscles will be less taut. But these muscle layers can be easily identified using ultrasound technique and needle placement can be confirmed using 'real-time' imaging. The use of ultrasound may improve the success rate of this block and reduce complications like peritoneal perforation and intramuscular or intravascular administration of the drug. [9,10]

Sinha et al [11]compared the relative efficacy of bupivacaine versus ropivacaine for postoperative analgesia using ultrasound-guided TAP block in laparoscopic cholecystectomies and concluded that the analgesic effect was similar in both with better analgesia in the first hour and less systemic toxicity in ropivacaine as compared to bupivacaine.

Various studies are available in which adjuvants are added to local anesthetic to improve the duration and quality of analgesia

In this study, we compared non-opiods Magnesium sulphate and Clonidine added as an adjuvant to ropivacaine in UGS guided TAP block

Magnesium is an NMDA receptor antagonist and physiological antagonist of calcium.[12] As per the study by S Rana et al,[13] the addition of MgSO4 to bupivacaine in a dose of 150 mg has led to lower VAS pain scores, prolongation of analgesia, and less requirement of rescue analgesia. They compared 18 mL 0.25% bupivacaine (45 mg) with 2 mL normal saline (NS), with 18 mL 0.25% bupivacaine (45 mg) with 1.5 mL (150 mg) MgSO4 and 0.5 mL NS under ultrasound (USG)-guidance posted for total abdominal hysterectomy. Their study showed significantly lower VAS scores with the use of magnesium at 4, 6, and 12 h after the block. The duration of analgesia was prolonged with the use of MgSO4 150 mg (968.00 ± 161.06 vs. 397.67 ± 92.84 min, P = 0.0000).

In another study by K Al Raefey et al,[14] divided into three groups: Control group (C group, n = 30), bupivacaine group, bupivacaine magnesium group 20 ml volume (0.25 bupivacaine in B group or 0.25 bupivacaine plus 0.5 g of MgSo4 in M group). He concluded that Magnesium added to Bupivacaine had a longer duration of analgesia 19 ± 2.2 h when compared to bupivacaine alone 16 ± 2.5 h; resulted in improved postoperative analgesia in the form of increased duration and decreased analgesic requirements and was associated with less incidence of PONV.

In the present study adding 150mg of Magnesium sulphate to 0.20% of Ropivacaine duration of analgesia was similar to these studies with a duration of analgesia of 13.07 + 2.12 hrs.

Dogrul and colleagues[15] demonstrated that topical administration of clonidine elicits anti-nociception by blocking the emerging pain signals at the peripheral terminal through alpha 2 adrenoceptor without producing undesirable central side effects.1

Acharya R et al [16] compared the duration of postoperative analgesia between clonidine 1mcg/kg per side and levobupivacaine (0.25%) versus levobupivacaine (0.25%) alone in the bilateral TAP block after lower segment cesarean section (LSCS). Duration of analgesia was significantly longer in Group with clonidine (17.94 ± 0.76 h) compared to Group levobupivacaine (7.16 ± 0.41 h) (P < 0.001.

Another study by Singh R et al [17]compared the duration of postoperative analgesia with the addition of clonidine to bupivacaine in bilateral tap block for LSCS, duration of analgesia was significantly longer in Bupivacaine 0.25% 20ml with clonidine 1mcg/kg 17.8± 3.7 hours compared to bupivacaine alone 7.3 ± 1.2hrs.

Dupia R[18] et al compared two doses of clonidine 150mcg and 300mcg with 0.25% bupivacaine and found that even

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though increasing the dose of clonidine improves the duration of analgesia it was associated with various side effects like symptomatic bradycardia which had to be treated with atropine and increased sedation.

So considering all these we selected 150mcg of clonidine to reduce the side effects which will not be desirable especially in a post-cesarean patient. And in our study duration of analgesia was 20.17 + 3.42 hrs in group clonidine which was similar to previous studies.

The VAS scores were similar between the two groups at 2hrs, 4hrs, 6hrs.

There was a statically significant difference found between the two groups with respect VAS score at 8hrs, 10hrs, 12hrs, 14hrs, 18hrs, 24hrs.

There were no symptomatic side effects like bradycardia, sedation, and dry mouth.

5. Conclusion

We conclude from our study that the addition of Clonidine as an adjuvant to Ropivacaine provides better prolongation of postoperative analgesia as compared to Magnesium sulphate, without any significant untoward effects.

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