TO EVALUATE THE EFFECT OF CLONIDINE AS AN ADJUVANT TO 0.5% ROPIVACAINE IN ERECTOR SPINAE PLANE BLOCK FOR POSTOPERATIVE ANALGESIA IN BREAST SURGERIES: A RANDOMISED CONTROLLED TRIAL

THESIS

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ANAESTHESIOLOGY AND CRITICAL CARE

JULY 2020 **Dr. SHREYA NEOGY**

AIIMS, JODHPUR

DECLARATION

I hereby declare that the thesis titled "**TO EVALUATE THE EFFECT OF CLONIDINE AS AN ADJUVANT TO 0.5% ROPIVACAINE IN ERECTOR SPINAE PLANE BLOCK FOR POSTOPERATIVE ANALGESIA IN BREAST SURGERIES:A RANDOMISED CONTROLLED TRIAL**" embodies the original work carried out by me at All India Institute of Medical Sciences, Jodhpur

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CERTIFICATE

This is to certify that the thesis titled "**TO EVALUATE THE EFFECT OF CLONIDINE AS AN ADJUVANT TO 0.5% ROPIVACAINE IN ERECTOR SPINAE PLANE BLOCK FOR POSTOPERATIVE ANALGESIA IN BREAST SURGERIES:A RANDOMISED CONTROLLED TRIAL**" is the bonafide work of DR. SHREYA NEOGY carried out under our guidance and supervision, at Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences, Jodhpur.

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Professor and Head,
Department of Anaesthesiology & Critical Care
All India Institute of Medical Sciences, Jodhpur.

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"Individually, we are one drop. Together, we are an ocean."

Ryunosuke Satoro

Nothing worthwhile has ever been accomplished without the guidance and encouragement of our teachers and the support of our family and friends. As I stand on the verge of one of my life's most distinguished accomplishments, Ryunosuke Satoro's words ring truer than ever.

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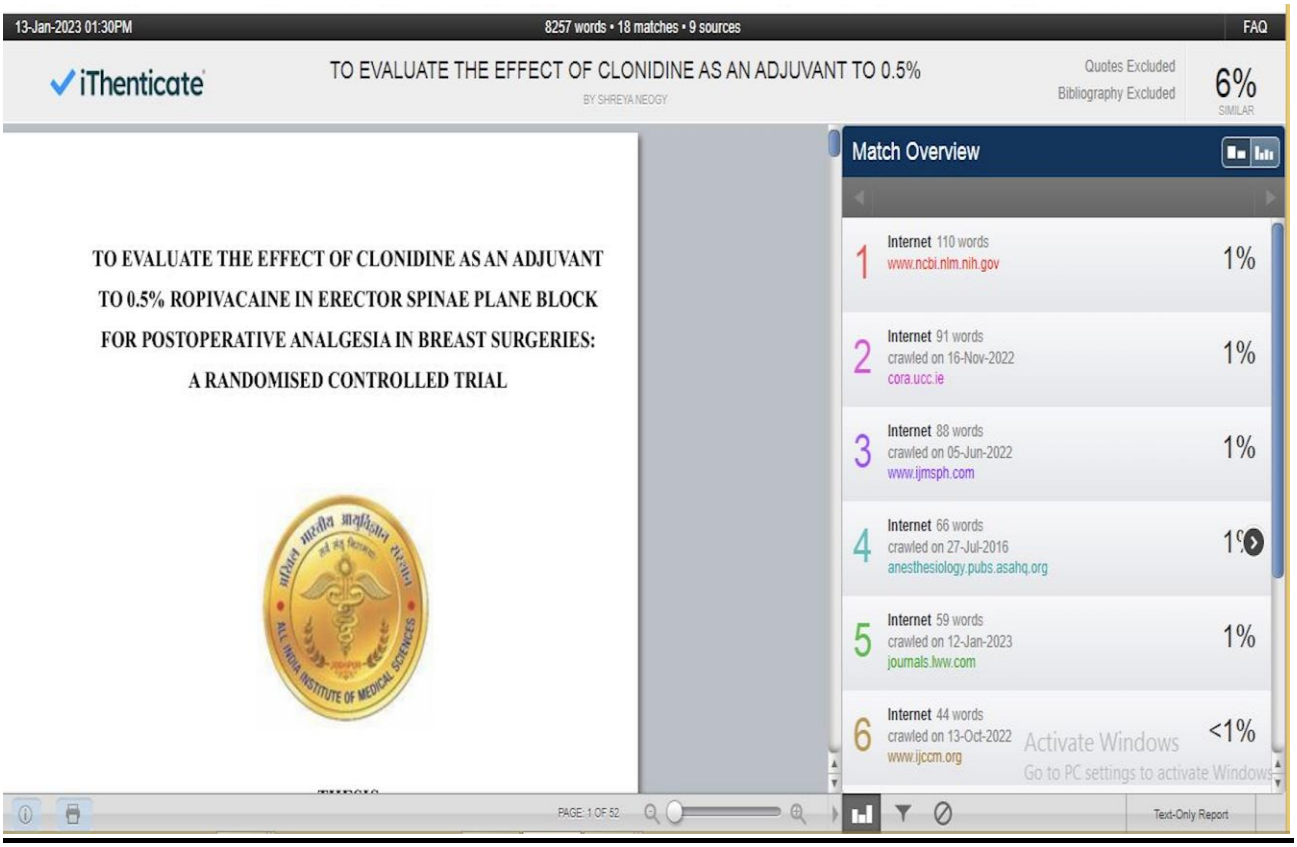
Dr. SHREYA NEOGY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LIST OF ABBREVIATIONS

- HR: Heart rate
- SBP: Systolic blood pressure
- DBP:Diastolic blood pressure
- MAP: Mean arterial blood pressure
- SpO2:Saturation of oxygen
- NIBP:Non-invasive blood pressure
- SD:Standard deviation
- ESP: Erector spinae plane
- TPVB:Thoracic paravertebral block
- MRM:Modified radical mastectomy
- VAS:Visual analogue scale
- ASA:American society of anaesthesiologists
- PECS:Pectoralis
- ECG:Electrocardiogram
- VATLS:Video assisted thoracoscopic lobectomy surgery
- PCA: Patient controlled analgesia
- RC: Ropivacaine and Clonidine
- R: Ropivacaine

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SUMMARY

Background: Patients undergoing breast surgeries experience significant postoperative pain. Multimodal pain management protocols including the available pharmacological options have demonstrated improved pain control with less reliance on opioids. Use of regional anaesthesia (RA) techniques as a component of multimodal pain protocol can replace opioid-based analgesia.Recently, the erector spinae plane (ESP) block has been introduced in clinical practice as part of a multimodal pain strategy. The present study has been carried out to compare the effect of clonidine as an adjuvant to 0.5% Ropivacaine in ESP block for postoperative analgesia in breast surgeries.

Objectives: Our primary objective is to evaluate the analgesic efficacy of clonidine as an adjuvant in Erector Spinae Plane block in terms of duration of analgesia defined as time to first rescue analgesic (patient demand/VAS≥4) after breast surgeries.Onset of sensory block, number of dermatomes blocked, duration of sensory block, quality of analgesia (Visual Analogue Scale), total analgesic requirement in 24 hr postoperatively, and adverse effects/complications if any are noted.

Materials and methods: Patients aged between 18 - 65 years of age, belonging to ASA Physical Status I and/or II and undergoing unilateral modified radical mastectomy under general anaesthesia have been included in the study.They were allotted into one of the two groups- Group R (received inj 0.5% Ropivacaine in ESP block) and Group RC(received inj Clonidine 1µgm/kg with 0.5% Ropivacaine in ESP block). Unilateral ESP block under USG guidance was given on the side of surgery at T4 level, before induction of GA. Sensory level of block and onset of sensory block have been assessed. Vitals(HR,SBP,DBP,MAP,SPO2) were noted since ESP block application and thereafter every 5 minutes for thirty minutes. Intra-operative vitals were also noted till 90minutes. Postoperatively, patients was followed up for 24hours and VAS score were recorded every 30mins till 2 hours in PACU and then at 2,4,6,9,12,18 and 24^{th} hour in the ward. Rescue analgesia IV diclofenac 1.5mg/kg was administered on patient demand or whenever VAS ≥ 4. At the end of the observation period,rescue analgesia required,side effect and patient satisfaction were recorded.

Results: Total eighty six patients were assessed for eligibility; fourteen patients were excluded in the beginning of the study as they were not meeting the inclusion criteria. Total

seventy two patients were enrolled for the study and randomised. The median time to first rescue analgesic was 18 hours in RC and 10 hours in R group. About 16% of patients of RC group and 33.3% of patients of R group demanded rescue analgesic in postoperative period. On comparison there was insignificant difference between groups in time to first rescue analgesic, p-value(0.40). Quality of analgesia defined by VAS score was also comparable between the study groups ($p>0.05$) at measured time points. Mean time to sensory block onset was 10.7 +/- 3.0 min in group RC and 10.3 +/- 0.9 min in group R (p 0.513). Mean number of dermatomes blocked was 4.4 +/- 1.0 in group RC and 4.5 +/- 0.5 in group R. Vital parameters (Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure) of patients since ESP block application,every 5mins till thirty minutes were comparable between the study groups($p>0.05$) except oxygen saturation. Independent sample 't' test showed the difference in oxygen saturation to be statistically significant($p<0.05$) at measured time points, the difference is clinically insignificant as the lowest spo2 being 98% which did not required intervention. Intraoperative vitals were studied between both the groups and were found comparable($p>0.05$). No adverse effects were noted in any patient.

Conclusion: There is no effect of addition of Clonidine as an adjuvant to 0.5% Ropivacaine in ESP block on the time to first rescue analgesic, time to sensory block onset, the quality of analgesia, duration od sensory block, number of dermatomes blocked and total analgesic requirement in 24hours. No adverse effects/complications are noted.

INTRODUCTION

One of the most frequent surgical procedures performed in hospitals is breast surgery, and even relatively simple breast surgeries are associated with severe postoperative pain. The axillary component of the procedure is the main source of the severe initial postoperative pain that affects nearly 60% of breast surgery patients. With all their inherent drawbacks and adverse effects, opioid analgesics are nonetheless frequently utilised in current treatment techniques. Pain is a disagreeable feeling and emotional state brought on by real or potential tissue injury. According to how long it lasts, pain is typically categorised into two categories: acute pain and chronic pain. Acute pain is defined as pain that lasts less than one month and is related to surgical trauma, tissue injury, or disease states, whereas chronic pain is defined as pain that lasts more than three months.[1] There is little agreement on which elements of this multimodal therapy produce the best analgesia, despite the fact that current best practises emphasise a "multimodal approach" (i.e., employing a variety of medications and strategies to control pain after surgery).[2] Modified radical mastectomy (MRM), the most common surgical treatment for breast cancer, involves extensive skin removal from the entire breast with axillary evacuation. By reducing the need for general anaesthesia and opioids and regulating the surgical stress response, effective acute pain management protects immunological function. Poor postoperative pain management has detrimental physiological and psychological effects.[3] Regional blocks have been demonstrated to decrease postoperative pain scores, opioid needs, postoperative nausea and vomiting, pulmonary problems, and length of stay in the post-anaesthesia care unit for breast procedures. In relation to breast cancer surgery, there is also some evidence that regional anaesthesia techniques may help to reduce the use of opioids, which have been linked to immunosuppression and the progression of cancer, and may indirectly contribute to tumour inhibition by attenuating the surgical stress response.[4]

To completely anaesthetize patients during breast surgery, the pectoral nerves, intercostobrachial, intercostal (III, IV, V, and VI), and long thoracic nerve must be blocked. [3] The ESP block is an interfascial plane block that involves injecting local anaesthetics under ultrasound guidance deep into the erector spinae muscle, which is located next to the transverse processes of the thoracic vertebrae. Forero first described the ESP block in 2016 as a treatment for thoracic neuropathic pain.[5] As the erector spinae fascia stretches from the nuchal fascia cranially to the sacrum caudally, the medication spreads in a craniocaudal

manner over a number of levels. Without causing any systemic adverse effects, ESP block delivers both intraoperative and postoperative analgesia. [6]

The spinalis, longissimus thoracis, and iliocostalis muscles, which run vertically in the back, combine to form the erector spinae muscle (ESM). The local anaesthetic (LA) is placed near the tip of the transverse process of the vertebra, deeper than the ESM, to perform the ESP block. As a result, one dermatome has a median amount of LA in the cranio-caudal fascial plane for every 3.4 ml of injected volume. It also diffuses at various levels laterally to the intercostal space and anteriorly to the paravertebral and epidural areas. The spinal nerve's ventral and dorsal rami are affected by the LA. The anterior and lateral branches make up the ventral ramus (intercostal nerve).The entire anterolateral wall is sensory innervated via its terminal branches. The posterior wall receives sensory innervation from the dorsal ramus, which is split into two terminal branches. Additionally, the diffusion of LA to the paravertebral area via the costotransverse foramina and the intertransverse complex (levators, rotators, and intercostal muscles: intertransverse and costotransverse ligaments) results in visceral and somatic analgesia. [7]

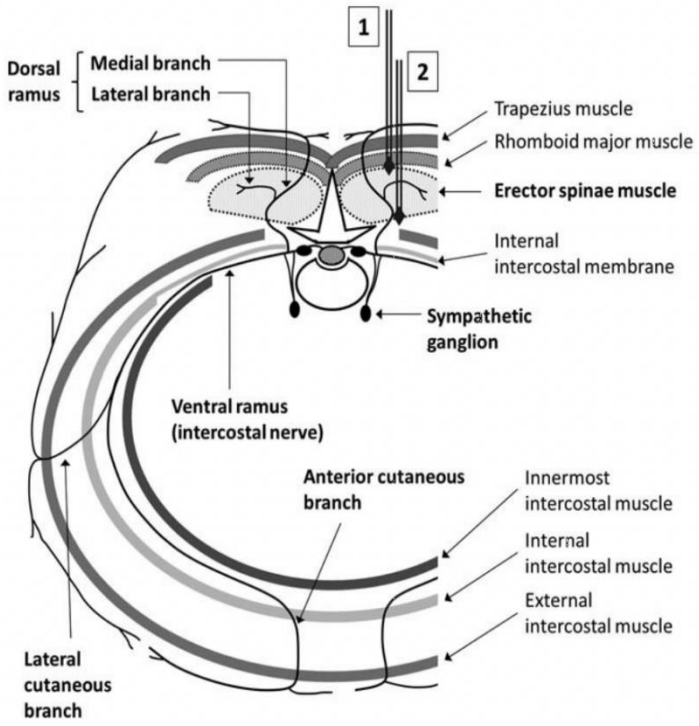

Figure 1: Anatomy of ESP block

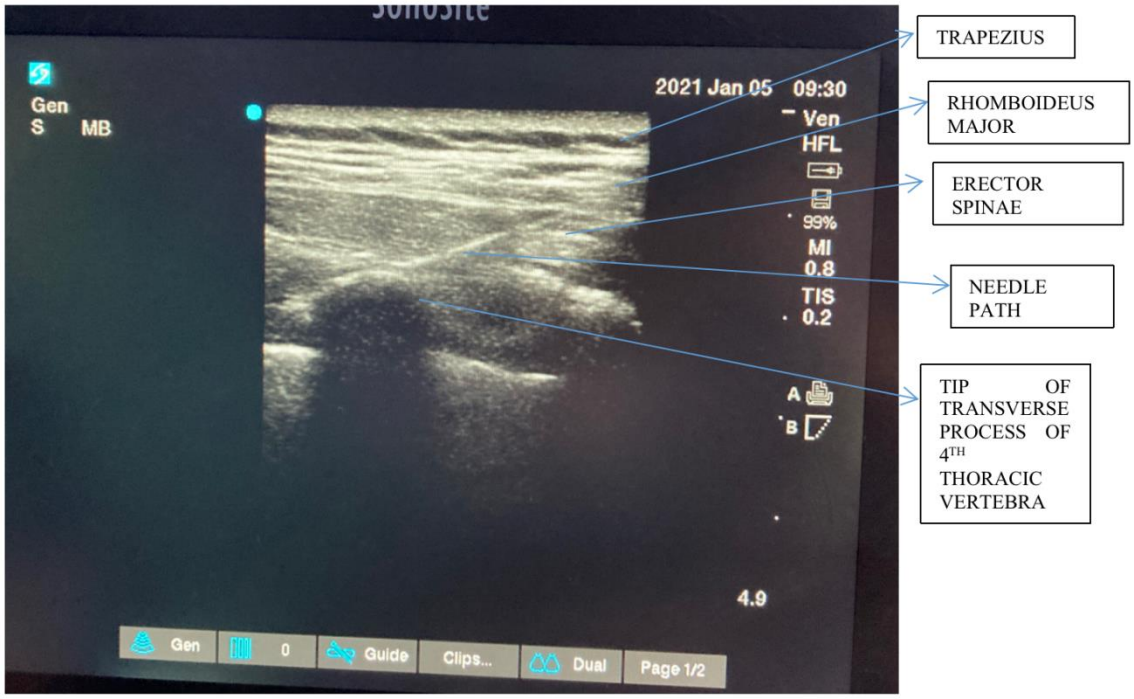

Figure 2:- Ultrasound image of ESP block at T4 level

Since sonoanatomy is easily visible and there are no nearby structures that could be injured by a needle, ESP block has a very minimal risk of problems.[8]A pneumothorax or hematoma is prevented by the transverse process, which serves as an anatomical barrier and prevents needle insertion into the pleura or blood vessels. Additionally, the distance between the needle and the vertebral canal means there is very little chance of spinal cord injury. A motor neuron and bladder function are preserved by an ESP block, allowing for early mobility. Since motor function is unaffected, spinal cord function can be immediately postoperatively evaluated neurologically.[4]

For analgesia during breast surgery, a number of nerve blocks, including paravertebral and pectoralis nerve blocks, have been researched. Both paravertebral blocks and pectoralis nerve blocks are well established in clinical practise, and both have been proven to be efficient for delivering analgesia following breast surgery. These methods do, however, have a number of shortcomings. For instance, the spread of local anaesthetic can obstruct the surgical field after completing the pectoralis nerve block. On contrary, paravertebral blocks can result in serious side effects like pneumothorax and intrathecal or epidural injections of local anaesthetic.[4]

An amide type local anaesthetic, ropivacaine is produced as the hydrochloride monohydrate of the S-enantiomer.[9] Ropivacaine 0.5% (5 pg/ml), with or without epinephrine, has been demonstrated in brachial plexus investigations to give an efficient, long-lasting sensory and motor block. According to reports, ropivacaine is more toxic than lidocaine but less hazardous than bupivacaine.[2] It blocks motor and sensory nerve fibres in distinct ways. The onset, duration, and intensity of motor block are frequently slower, shorter, and less intense than those of bupivacaine. Compared to Bupivacaine, it has less cardiotoxicity. [10]

There has always been a hunt for medications that can be used as adjuvants to the regional nerve block and prolong analgesia with fewer side effects. Because of their sedative, analgesic, perioperative sympatholytic, and cardiovascular stabilising effects with less need for anaesthesia, alpha-2 adrenergic receptor agonists have drawn attention. To prolong nerve blocks, alpha-2 agonists are used with local anaesthetics. [6] Through either local vasoconstriction and facilitation of C fibre blocking or straightforward diffusion along the nerve, their concomitant injection enhances the nerve block characteristic of local anaesthetics.[10]

A selective alpha-2 adrenergic agonist with partial alpha-1 agonist properties is clonidine hydrochloride. It is an imidazoline derivative that functions as an agonist on the central alpha-2 adrenergic system. 2-((2,6-dichlorophenyl) amino)-2-imidazoline hydrochloride is the chemical name for clonidine. Clonidine activates a pathway in the nucleus tractus solitarius (NTS) that suppresses excitatory cardiovascular neurons by acting as an alpha-adrenergic agonist. In the posterior hypothalamus and medulla, clonidine produces an alpha-antagonist action. The central nervous system's (CNS) final reaction is a decreased sympathetic outflow, which clinically results in a reduction in arterial blood pressure. [11]

In this study, we have planned to evaluate the effect of clonidine as an adjuvant to 0.5% ropivacaine in ESP block for breast surgeries. We have hypothesized that Clonidine as an adjuvant to 0.5%Ropivacaine in erector spinae plane block increases the duration of analgesia after unilateral modified radical mastectomy .

AIM

To determine the efficacy of using clonidine as an adjuvant to 0.5%Ropivacaine in erector spinae plane block for post operative analgesia in breast surgeries.

OBJECTIVES

Primary objective:

To evaluate the analgesic efficacy of clonidine as an adjuvant in Erector Spinae Plane block in terms of duration of analgesia defined as time to first rescue analgesic (patient demand/VAS≥4) after breast surgeries.

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Secondary objectives:

1. Onset of sensory block(Block completion to grade 1 sensory block)
2. Number of dermatomes blocked
3. Duration of sensory block (ESP block to Onset of pain)
4. Quality of analgesia (Visual Analogue Scale)
5. Total analgesic requirement in 24 hr postoperatively
6. Adverse effects/complications if any

HYPOTHESIS

Clonidine as an adjuvant to 0.5%Ropivacaine in erector spinae plane block increases the duration of analgesia after unilateral modified radical mastectomy.

REVIEW OF LITERATURE

Saritaswami *et al* conducted a RCT on 60 patients scheduled for upper limb surgeries under supraclavicular block by dividing them into two equal groups,Group C: (Bupivacaine 0.25% (35 cc) + clonidine 1 μg/kg) and Group D: (Bupivacaine 0.25% (35 cc) + dexmedetomidine 1 μg/kg). 80 patients posted for upper limb surgeries were assessed for suitability to enroll in the study. Seven patients declined to participate in the study. Five patients were excluded as they were posted for soft tissue surgeries of the upper limb. Eight patients were excluded as they were found to be on beta blockers, anticoagulation drugs and had uncontrolled diabetes mellitus. The remaining 60 patients fulfilling the inclusion criteria were randomly assigned to one of the two groups. Motor block was determined according to a modified Bromage scale for upper extremities on a 3-point scale:-

Grade 0: Normal motor function with full flexion and extension of elbow, wrist and fingers

Grade 1: Decreased motor strength with ability to move the fingers only

Grade 2: Complete motor block with inability to move the fingers

Sedation of patient was assessed by the Ramsay Sedation Score. At the end of the procedure, quality of operative conditions were assessed according to the following numeric scale:-

Grade 4: (Excellent) No complaint from patient

Grade 3: (Good) Minor complaint with no need for the supplemental analgesics

Grade 2: (Moderate) Complaint that required supplemental analgesia

Grade 1: (Unsuccessful) Patient given general anaesthesia

There was no protocol deviation pre-operatively and intraoperatively, except for one patient in group C who had to be given general anaesthesia for inadequate block. Both groups were comparable in terms of age, gender, weight and type of surgeries(P>0.001). The baseline hemodynamic parameters were comparable in both groups. Significantly lower pulse rate was observed at 60, 90 and 120 min, but not less than 60 beats/min, in Group D as compared with Group C (P<0.001). Systolic and diastolic blood pressure were found to be significantly lower than baseline from 30 to 120 min in Group D as compared with Group C (P<0.001). No treatment was required for this fall in blood pressure. The haemodynamic parameters were comparable at the end of 180 min. Onset of sensory block was faster in Group D than in Group C, while onset of motor block was faster in Group C than in Group D, but the difference was not statistically significant (P>0.001). Duration of sensory block was 227 min in Group C as compared with 413 min in Group D. Statistically significant longer duration of

sensory block was observed in Group D(*P*=0.001). The duration of motor block was 292min in Group C as compared with 472min in Group D. Again, duration of motor block was significantly longer in Group D(*P*=0.001). There was significant increase in duration of analgesia in Group D 456min as compared with Group C 289 min. The difference was statistically significant(*P*=0.001) In Group D, 80% of the patients achieved Grade IV quality of block as opposed to 40% in Group C (*P*<0.05). There were a total 17 patients in Group C with Grade 2 and 3 block and six patients in Group D who required sedation or sedation with analgesia. One patient in Group C required general anaesthesia as the block was inadequate. In this randomized, double-blinded trial, comparison was done between dexmedetomidine and clonidine (α agonist) as an adjuvant to Bupivacaine in supraclavicular brachial plexus block, and it was found that there was a significantly increased duration of sensory and motor blockade in the dexmedetomidine group than in the clonidine group without any adverse effects.

Rosemary *et al* conducted a study on 48 ASA Physical Status 1 or 2 adult patients scheduled to undergo upper-extremity surgery (primarily hand surgery) under brachial plexus anesthesia.Patients were randomized to receive either ropivacaine 0.5% or bupivacaine 0.5%, according to a blind parallel group design. Each patient received a subclavian perivascular block according to the technique described by Winnie. After a paresthesia was elicited and negative aspiration was confirmed, 3 ml of the study drug was injected rapidly to produce a pressure paresthesia. The remaining 29 ml was then injected over a period of approximately 1 min, with negative aspiration for blood confirmed after each 5-ml increment. The intercostobrachial and medial brachial cutaneous nerves (T2) were then blocked separately by a subcutaneous injection of 3 ml of study drug over the axillary artery pulse. Sensory and motor function was evaluated before the block and at 2, 5, 10, 15, 20, 25, and 30 min after the block, then every 15 min until 5 h postblock, every 30 min until 12 h postblock, and every 60 min until complete recovery. Dermatomes located in the surgical field could not be tested during the operative procedure but were evaluated before and after the surgery. Sensory block was assessed in the C2 through T2 dermatomes and graded as follows:

0 = no loss of sensation to pinprick;

1 = analgesia (patient feels touch but not sharp);

2 = anesthesia (patient does not feel touch).

Motor block at the shoulder was assessed by asking the patient to elevate the arm while keeping the elbow straight (superior trunk function) and at the hand by grip strength (middle and

inferior trunk function); it was graded as follows: 0 = no weakness, 1 = paresis, and 2 = paralysis. This study demonstrated that bupivacaine 0.5% and ropivacaine 0.5% were equally effective in providing brachial plexus anesthesia. Duration of anesthesia was also similar between agents, and both may be considered long-acting local anesthetics. So for subclavian perivascular brachial plexus block, ropivacaine 0.5% and bupivacaine 0.5% were similar in terms of onset of sensory and motor block, duration of sensory and motor block, incidence of analgesia, anesthesia, paresis and paralysis, and the need for supplementation.

Bakr *et al* conducted a study on 60 patients with ASA physical status I– II (18–60 years old and weighing 50–90 kg) scheduled for MRM were enrolled and randomly assigned into 2 groups (30 in each) to receive a preoperative US Pecs block with 30 mL of 0.25% bupivacaine only (group 1, bupivacaine group [GB]) or 30 mL of 0.25% bupivacaine plus 1 µg/ kg dexmedetomidine (group II, dexmedetomidine group [GD]). The patients were followed-up 48 hours postoperatively for vital signs (heart rate [HR], noninvasive blood pressure [NIBP], respiratory rate [RR], and oxygen saturation [Sao2]), visual analog scale (VAS) scores, time to first request of rescue analgesia, total morphine consumption, and side effects. Serum levels of cortisol and prolactin were assessed at baseline and at 1 and 24 hours postoperatively.

A significant reduction in the intraoperative HR, systolic blood pressure (SBP), and diastolic blood pressure (DBP) starting at 30 minutes until 120 minutes in the GD group compared to the GB group ($P < 0.05$) was observed. The VAS scores showed a statistically significant reduction in the GD group compared to the GB group, which started immediately up until 12 hours postoperatively ($P < 0.05$). There was a delayed time to first request of analgesia in the GD group 25hrs compared to the GB group 17 hrs ($P = 0.029$), and there was a significant decrease of the total amount of morphine consumption in the GD group (9 + 3.6 mg) compared to the GB group (12 + 3.6 mg) ($P = 0.001$). There was a significant reduction in the mean serum cortisol and prolactin levels at 1 and 24 hours postoperative in the GD patients compared to the GB patients ($P < 0.05$). The addition of 1 µg/kg dexmedetomidine to an US-modified Pecs block has superior analgesia and more attenuation to stress hormone levels without serious side effects, compared to a regular Pecs block in patients who underwent MRM.

Chandni *et al* conducted a RCT on 64 adult female patients with ASA PS 1 and 2 who were scheduled for unilateral modified radical mastectomy with first group under USG guided ESP block(with 20cc 0.2% Ropivacaine) and the second group under USG guided PECS II block (25 cc 0.2% ropivacaine). Various parameters observed included sensory blockade, duration of analgesia and any adverse effects. The blocks were performed under aseptic precautions 30 minutes before surgery with a 22 gauge echogenic needle and linear array probe. The patients were observed for 30 minutes after performing the block. The anaesthesiologist who was blinded to the technique of block assessed the sensory level of block with pin-prick sensation in each side from T1 to T8. The total number of dermatomes that had less pain to pin prick compared with opposite side were noted. If the pin-prick sensation did not decrease in any segment up to 30 minutes, it was considered as a block failure and patients were excluded from the analysis. The patient's ECG and SpO2 were monitored continuously, and heart rate (HR) and NIBP were recorded at baseline, after performing the block, and every 5 minutes for 30 minutes. Any block-related complications, such as hypotension, vascular puncture, pneumothorax were looked for. General anaesthesia was administered in a standardised manner. Postoperatively patient-controlled analgesia pump was connected to the patients. Postoperative pain was assessed using a numerical rating scale (NRS, 0–10; 0 = no pain and 10 = worst imaginable pain). No basal infusion was given and only bolus doses of 1- 2 mg morphine with a 10 minute lock out interval was allowed. The total analgesic consumption in 24 hours was taken as the primary outcome measure. The secondary outcome measures included duration of analgesia (time to first rescue analgesia after administration of block), the level of sensory blockade as assessed preoperatively and the postoperative pain scores. Adverse effects such as hypotension, respiratory depression were looked for and treatment planned (fluid bolus 10 ml/kg and oxygen supplementation with simple face mask at 5L/min). The quantitative variables were compared using the unpaired student *t*-test. The qualitative variables were compared using the Chi-square test. $P < 0.05$ was considered statistically significant. This prospective study shows that PECS block performed in patients scheduled for MRM results in better pain control and less postoperative morphine consumption in the first 24 hours. Hence it is a superior block than ESP in patients scheduled for MRM surgeries.

Kulhari.S *et al* conducted a study on forty adult female patients undergoing radical mastectomy who were randomly allocated into two groups. Group 1 patients received a TPVB with ropivacaine 0.5%, 25 ml, whereas Group 2 patents received a PecS II block using same volume of ropivacaine 0.5% before induction of anaesthesia. Patient-controlled

morphine analgesia was used for postoperative pain relief. The duration of analgesia was significantly prolonged in patients receiving the PecS II block compared with TPVB [mean (sd), 294.5 (52.76) vs 197.5 (31.35) min in the PecS II and TPVB group, respectively; P<0.0001]. The 24 h morphine consumption was also less in the PecS II block group [mean (sd), 3.90 (0.79) vs 5.30 (0.98) mg in PecS II and TPVB group, respectively; P<0.0001]. Postoperative pain scores were lower in the PecS II group compared with the TVPB group in the initial 2 h after surgery [median (IQR), 2 (2-2.5) vs 4 (3-4) in the Pecs II and TPVB group, respectively; P<0.0001]. Seventeen patients in the PecS II block group had T2 dermatomal spread compared with four patients in the TPVB group (P<0.001). No block-related complication was recorded. It was found that the PecS II block provided superior postoperative analgesia than the TPVB in patients undergoing modified radical mastectomy without causing any adverse effect.

Kalyani *et al* conducted a RCT on 60 adult patients posted for upper limb surgeries under supraclavicular block By dividing them into two groups:-

Group I: 30 ml 0.75% ropivacaine +1 ml normal saline

Group II: 30 ml 0.75% ropivacaine +1 mcg/kg clonidine diluted to 1 ml with normal saline.

Dexmedetomidine when added to local anaesthetic in supraclavicular brachial plexus block enhanced the duration of sensory and motor block and also the duration of analgesia. The time for rescue analgesia was prolonged in patients receiving dexmedetomidine. It also enhanced the quality of block as compared with clonidine.Following operation, all patients were observed in postanesthesia care unit and received rescue analgesic (aqueous diclofenac 75 mg slow IV) on demand. The time from the end of anesthetic injection in the operated hand until 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 statistical analysis was performed using two-independent sample *t*-test and $P \leq 0.05$ was statistically significant.There was no statistically significant difference in the demographic profile and the baseline values of hemodynamic variables between the two groups. One patient in the control group had block failure and was given general anesthesia. He was excluded from further statistical analysis involving block characteristics and hemodynamic changes after the block. Significantly lower pulse rate was observed from 60 min to 180 min in the clonidine group,

but was not clinically significant and did not need any intervention Mean arterial pressure dropped at 30-min and remained so until 150-min in the clonidine group.No treatment was required for this fall in blood pressure. The hemodynamic parameters were comparable by 180-min. The onset of sensory block and motor block was significantly faster in clonidine group than control group.The duration of sensory block was 703.83 ± 42.90 min in clonidine group when compared to 556.38 ± 37.96 min in control group. The duration of motor block was 621.67±46.76 min in clonidine group and 500.86 ± 44.58 min in control group [Figure 4]. Both were significantly prolonged in clonidine group ($P < 0.001$). The mean time for rescue analgesia in control group was 613.10 ± 51.797 min and in clonidine group was 878.33 ± 89.955 min. Significantly prolonged duration for rescue analgesia was observed in clonidine group ($P < 0.001$)Ropivacaine 0.75% used in brachial plexus block is well tolerated and provides effective surgical anesthesia as well as relief of postoperative pain. Clonidine as an adjuvant to ropivacaine significantly enhances the quality of supraclavicular brachial plexus block by faster onset, prolonged duration of sensory and motor block and improved postoperative analgesia, without associated adverse effects.

Zhixin *et al* conducted a RCT on 90 adult patients aged 20–65 years, had an American Society of Anesthesiologists physical status (ASA) of I or II, who were posted for VATLS(video assisted thoracoscopic lobectomy surgery) under USG guided ESP block.He divided them into three groups,first group was given Ropivacaine alone, second group was given Dexamethasone as an adjuvant to Ropivacaine and the third group was given Dexmedetomidine as an adjuvant to Ropivacaine. After obtaining a written informed consent, all patients were taught to evaluate their own pain by using a 10-cm visual analog pain scale (0= no pain, 10= maximum pain imaginable) and how to use the patient controlled analgesia (PCA) device at the preoperative visit. All patients were then randomized to one of three groups using computer generated random numbers and a 1:1:1 allocation ratio.Patients were placed in a standard lateral position to apply ESPB before inducing anesthesia. An assistant, who was neither involved in the study nor was participating in the perioperative period or the postoperative follow-up, prepared study drugs. Groups received 0.5% ropivacaine 30 mL (R) or 0.5% ropivacaine 30 mL with 10 mg dexamethasone (RS) or 0.5% ropivacaine 30 mL with 1 μg/kg dexmedetomidine (RM), deep to the erector spinae muscle adjacent to transverse processes.lowing standardized monitoring, which included noninvasive blood pressure (NIBP), electrocardiogram (EKG), and pulse oximetry (PO).They were performed at the T5 level of the spine using an in-plane approach.Sensory block of the 5th intercostal space in the

midaxillary line was assessed by bilaterally using cold perception for 30 min after applying the nerve block. The patient was excluded from the study if sensory blockade was unsuccessful.Sufentanil (0.1–0.2 μg/kg) and flurbiprofen (50 mg) were intravenously administered, followed by patientcontrolled analgesia (PCA) pump use before the end of the surgery. PCA capacity was 250 mL and contained 7.5 μg/kg sufentanil and 250 mg flurbiprofen. The infusion rate was maintained at 2 mL/h, and the patient-controlled bolus was 2 mL with a lockout interval of 15 min. They were trained to press for an additional bolus if a 10 cm visual analog scale (VAS) for postoperative pain exceeded 3, and first time request for pressing PCA was recorded. In the situation when the VAS score remained ≥4 after using the PCA, the patients received tramadol 100 mg intramuscularly injectionas rescue analgesic. He performed a cold perception test in comparison with the contralateral intercostal area. Duration of sensory block was the time period from establishing the block to 100% cold perception in all sensory areas (100%= no difference to the contra-lateral side; 0%= complete sensory loss).The primary end point was postoperative PCA use during the first 72 h. Secondary outcomes included: (I) consumption of sufentanil, remifentanil, and propofol during anesthesia; (II) a 10 cm VAS for pain (0–10; 0, no pain; 10, worst imaginable pain) and changes in the VAS score at various time points: wake up in PACU and 2, 4, 6, 8, 12, 24, 48, 72 h after surgery; (III) optimum duration of sensory block; (IV) initial request for using PCA; and (V) incidence of postoperative nausea and vomiting(PONV) and rescue analgesia in the ward and the hospital stay after surgery.There was no significant difference in intraoperative characteristics among groups, which includes duration of surgery and the consumption of sufentanil, remifentanil, and propofol. Group RM demonstrated longer durations of sensory block and delayed first time of using the PCA machine than that in group R and group RS. Group RM demonstrated reduced total PCA machine use, the requirement for rescue analgesia, and postoperative hospital stay than group R and RS. There was no significant difference in the PONV occurrence rate among the groups. Dexmedetomidine, which was used as an adjuvant of ESPB with ropivacaine, prolonged sensory block duration, provided effective acute pain control after surgery, and reduced the need for rescue analgesia. It also shortened postoperative hospital stay for patients undergoing VATLS. However, dexamethasone had no clinically relevant effect on the duration of sensory block and postoperative pain control by ropivacaine at ESPB.

MATERIALS AND METHODS

STUDY SETTING: This prospective, randomized study was carried out in department of Anaesthesia and Critical Care at All India Institute of Medical Sciences (AIIMS), Jodhpur.

STUDY DESIGN: Prospective, interventional,comparative trial.

INCLUSION CRITERIA: Patients aged between 18 - 65 years of age, belonging to ASA Physical Status I and/or II and undergoing unilateral modified radical mastectomy was included in the study.

EXCLUSION CRITERIA: Patients refusal, pregnant patients, patients with baseline cognitive deficits, coagulopathy, liver and renal dysfunction, and known allergy to amide local anaesthetics or opioid was excluded.

DURATION OF STUDY: . The study was carried out in 72 patients. Enrollment of patients started in September 2021 and ended in August 2022. Approval was taken from the Institutional Ethics Committee (IEC Reg No.- AIIMS/IEC/2021/3327, dated 12/03/2021) and the study was registered with Clinical Trial Registry – India (CTRI Reg. No. CTRI/2021/09/036792 dated 01/09/2021).

On the day before surgery, enrolled patients were acquainted with visual analogue scale. Based on the computer-generated random numbers they were alotted into one of the two groups- Group R (will be receiving inj 0.5% Ropivacaine in ESP block) and Group RC(will be receiving inj Clonidine 1µgm/kg with 0.5% Ropivacaine in ESP block). The group allocation numbers were concealed in sealed opaque envelopes that were opened only after shifting the patient to preoperative holding area by a person not involved in the study.He also prepared and handed over the drug to be administered for the block during the procedure.The monitors attached included non-invasive blood pressure (NIBP), electrocardiography (ECG), and peripheral oxygen saturation (SPO2). An 18 G I.V cannula was secured in the opposite hand and fluid was started.

Patients in both groups received ESP block on the side of surgery.The blocks were performed under aseptic precautions 30 minutes before surgery with a 22 gauge echogenic needle using ultrasound machine and linear array probe (38 mm, 7-12 MHz frequency). Erector spinae

plane block was given with the patient in the sitting position.To give the block,the high frequency linear probe was placed in a transverse orientation to visualize right lateral tip of T4 transverse process. After identifying the three muscles namely trapezius, rhomboid major, and erector spinae, superficial to the hyperechoic transverse process, the probe was turned 90 degree longitudinally. After infiltrating 2 ml of 2% lignocaine, the block needle was inserted in a cephalo caudad direction to contact the transverse process.The correct placement was indicated by linear fluid spread that lifted the erector spinae muscle off the underlying transverse processes and intercostal muscles.After hydrodissection with saline solution,20ml of LA solution containing 0.5% ropivacaine with or without clonidine(1microgram per kg),as per the group allocation and prepared by person uninvolved in the study was injected.

The patients were observed for 30 minutes after performing the block.The sensory level of block was assessed with pin-prick sensation from T1 to T8 and compared from the other side.

Sensory block grading :

0 -> no loss of sensation to pinprick

1 -> Analgesia(patient feels touch but not pin prick)

2->Anaesthesia(patient does not feel touch)

The total number of dermatomes that has less pain to pin prick compared with opposite side was noted. Onset of sensory block was defined as the time starting after drug administration to sensory grade 1.The patient's ECG and SpO2 was monitored continuously, and heart rate (HR) and NIBP was recorded at baseline, after performing the block, and every 5 minutes for 30 minutes. Any block-related complications,like hypotension, bradycardia, hematoma, pneumothorax, sedation ,nausea, vomitting, dry mouth were recorded.

General anaesthesia was then given in both groups.Intraoperative monitoring of HR ,BP(systolic diastolic mean) were recorded at baseline,induction,after securing airway,at skin incision,then every 15 mins till end of surgery.Intraoperaively,additional dose of 1 microgram per kg fentanyl was given when HR or BP increased to more than 20% of baseline parameters.Injection paracetamol 1gm iv was given on surgical closure and 6hourly in the postoperative period. After completion of surgery,patient was shifted to PACU,where baseline VAS score were recorded and intervention was started. In both the groups,VAS was recorded every 30mins till 2 hours in PACU and then at 2,4,6,9,12,18 and 24^{th} hour in the ward. Rescue analgesia IV diclofenac 1.5mg/kg was administered on patient demand or

whenever VAS ≥ 4 was recorded. At the end of the observation period,rescue analgesia required,side effect and patient satisfaction were recorded.

SAMPLE SIZE CALCULATION

The sample size was determined using data from a formerly published study done by Kulhari.S *et al* on forty adult female patients underging radical masectomy and found that the duration of analgesia was significantly prologned in patients receiving PecS II block compared with TPVB.They reported the duration of analgesia to be (294.5 +/- 52.76) min in patient receiving PecS II block. To detect a 15% increase in analgesia duration following the intervention, we had estimated a sample size of 66 (33 patients per group) at 95% CI, 90% power and 10% contingency. Considering block failure rate to be maximum of 10%, the final sample size was determined to be 72(36 patients per group).

STATISTICAL ANALYSIS

The data normality is checked by using Shapiro-Wilk test. The quantitative data are presented as the mean ± SD as well as Median,Q1 and Q3. The comparison of the variables that are quantitative in nature are analyzed using Independent t test and Mann-Whitney U test(for two groups). The comparison of the variables that are ordinal in nature are analyzed using Fischer's exact test(for two groups). For statistical significance, p value of less than 0.05 is considered statistically significant.

The data entry is done in the Microsoft EXCEL spreadsheet and the final analysis is done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 21.0.

RESULTS

In this study total eighty six patients were assessed for eligibility; fourteen patients were excluded in the beginning of the study as they were not meeting the inclusion criteria. Total seventy two patients were enrolled for the study and randomised. They were allocated to intervention groups RC and R, analysed and the results were computed.

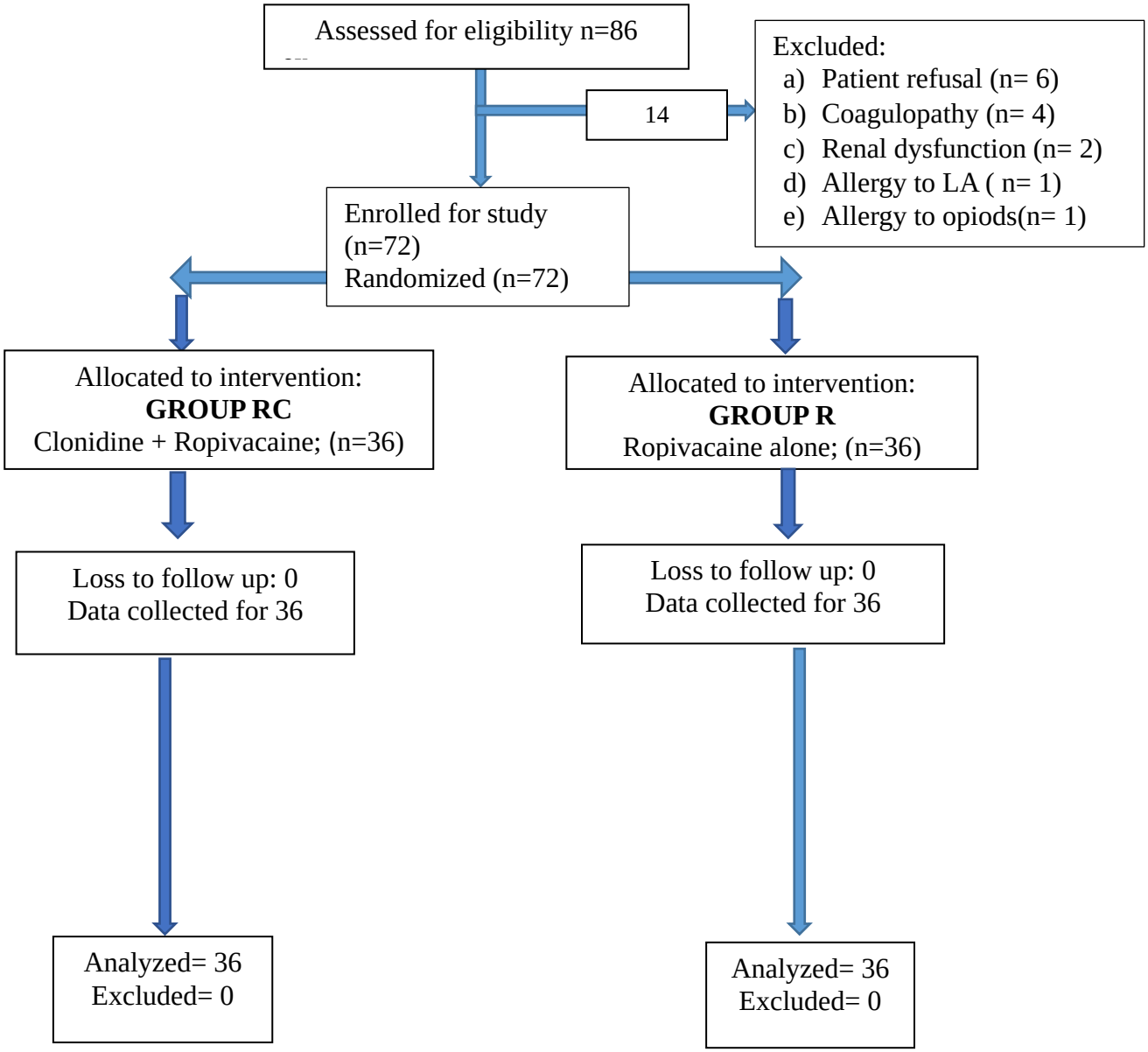

Figure 3: CONSORT figure representing the enrolment and randomization of cases

Table 1:- Comparison of study groups according to age

Parameter	Group RC	Group R	p-value
Age(years)	54.7 +/- 12.6	52 +/- 13.0	0.410

The above table shows the age of patients of the RC (ropivacaine+clonidine) and R(ropivacaine) groups, calculated as Mean +/- SD. The difference between both the groups is insignificant, statistically for the parameter age of patients($p>0.05$). Independent sample 't' test is used to compare the age of patients between the study groups.

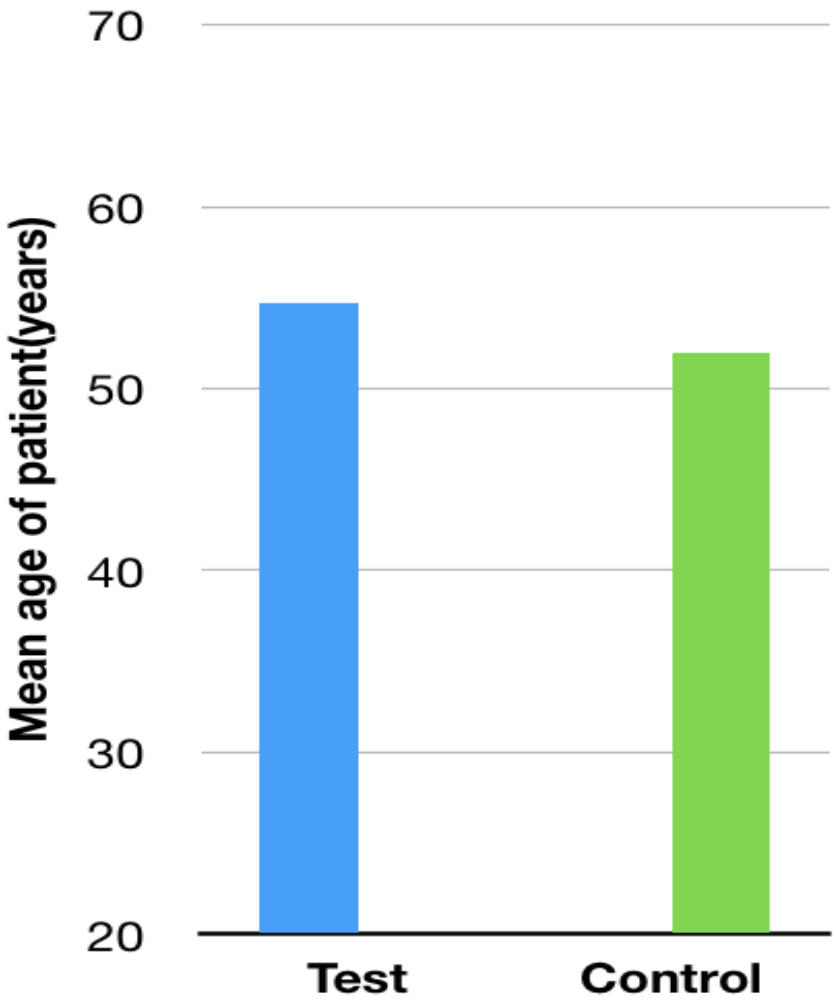

Figure 4: Comparison of mean age of patients (in years) in group RC(test) and R(control).

Table 2:- Comparison of study groups according to body weight

Body Weight (kg)	Group RC	Group R	p-value
Mean±SD	61.89 ± 12.22	59.94 ±10.76	0.4937

The above table shows the body weight of patients of the RC (ropivacaine+clonidine) and R(ropivacaine) groups, calculated as Mean +/- SD. The difference between both the groups is insignificant, statistically($p>0.05$). Unpaired student 't' test is used to compare the age of patients between the study groups.

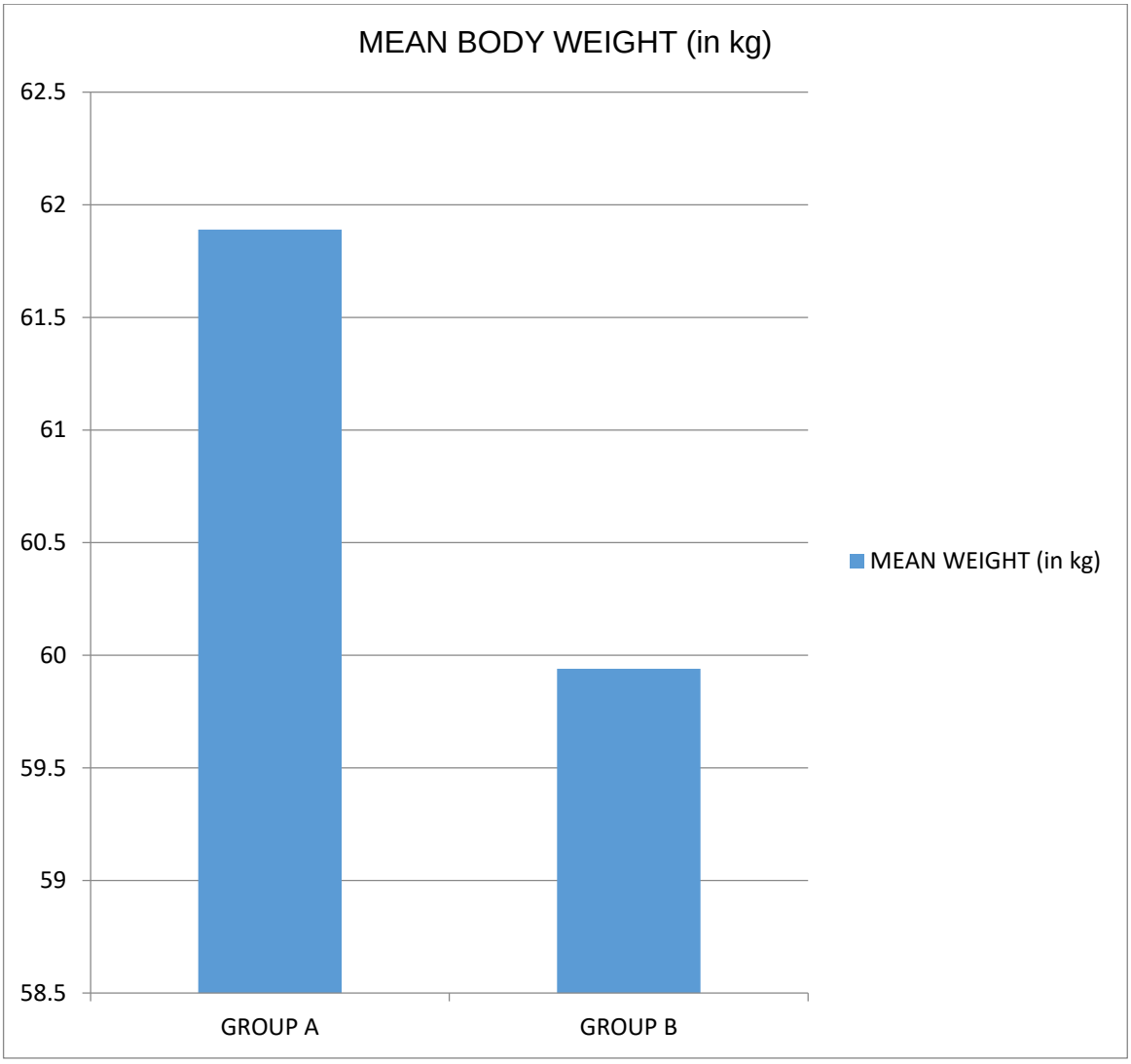

Figure 5: Comparison of mean body weight of patients (kg) in groups RC(group A) and R (group B).

Table 3:- Comparison of study groups according to height

Height (cm)	Group RC	Group R	p-Value
Mean±SD	152.14 ± 4.78	152.68 ± 5.64	0.67

The above table shows the body weight of patients of the RC (ropivacaine+clonidine) and R(ropivacaine) groups, calculated as Mean +/- SD. The difference between both the groups is insignificant, statistically(p>0.05).Unpaired student 't' test is used to compare the age of patients between the study groups.

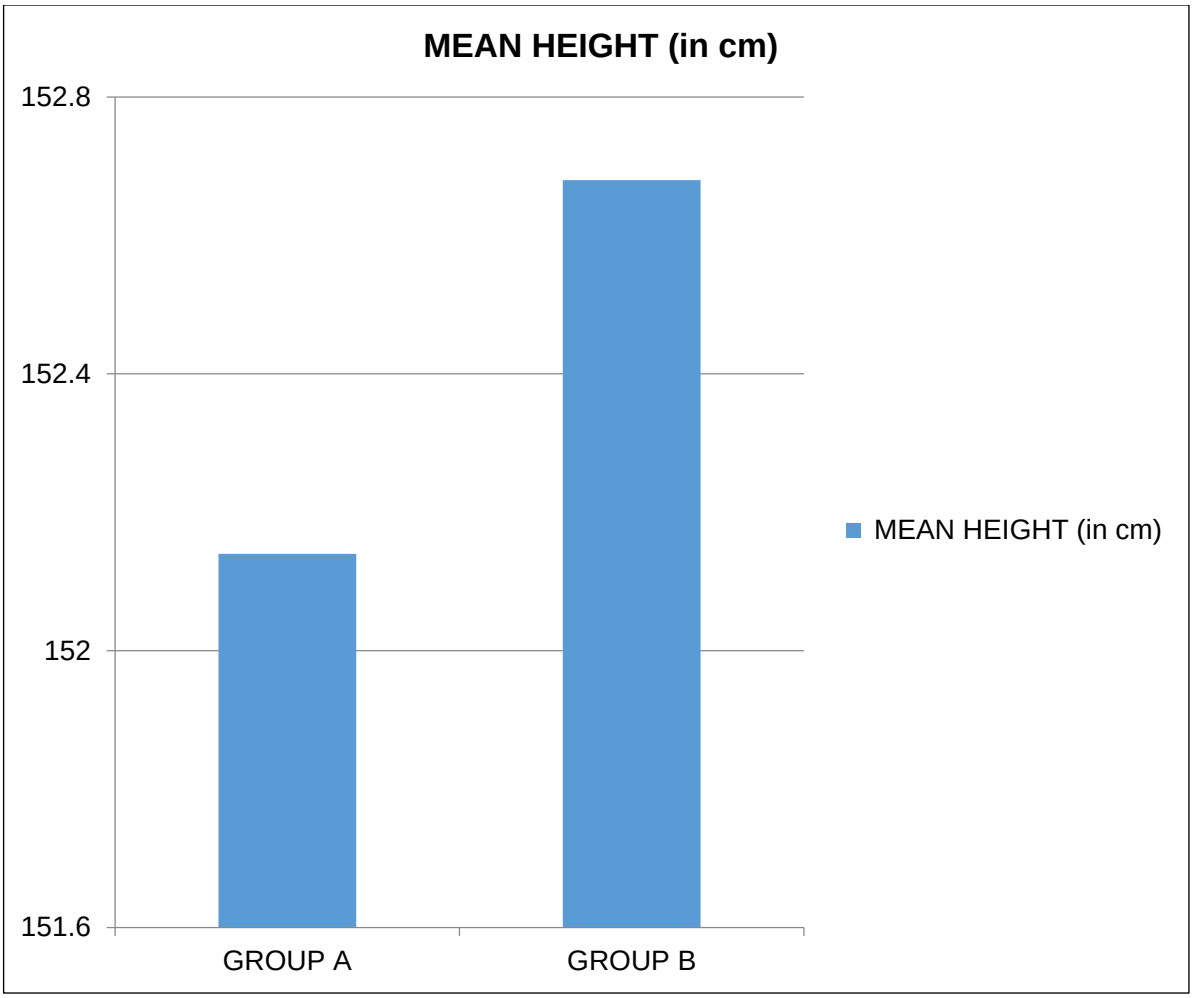

Figure 6: Comparison of mean height of patients(in cm) in groups RC(group A) and R(group B).

Table 4:- Comparison of study groups according to time to sensory block onset

Parameter	Group RC	Group R	p-value
Time to sensory block onset(minutes)	10.7 +/- 3.0	10.3 +/- 0.9	0.513

The above table shows the time to sensory block onset of the RC (ropivacaine+clonidine) and R(ropivacaine) groups, calculated as Mean +/- SD. The difference between both the groups is insignificant, statistically for the parameter time to sensory block onset($p>0.05$). Independent sample 't' test is used to compare the mean time to sensory block onset between the study groups.

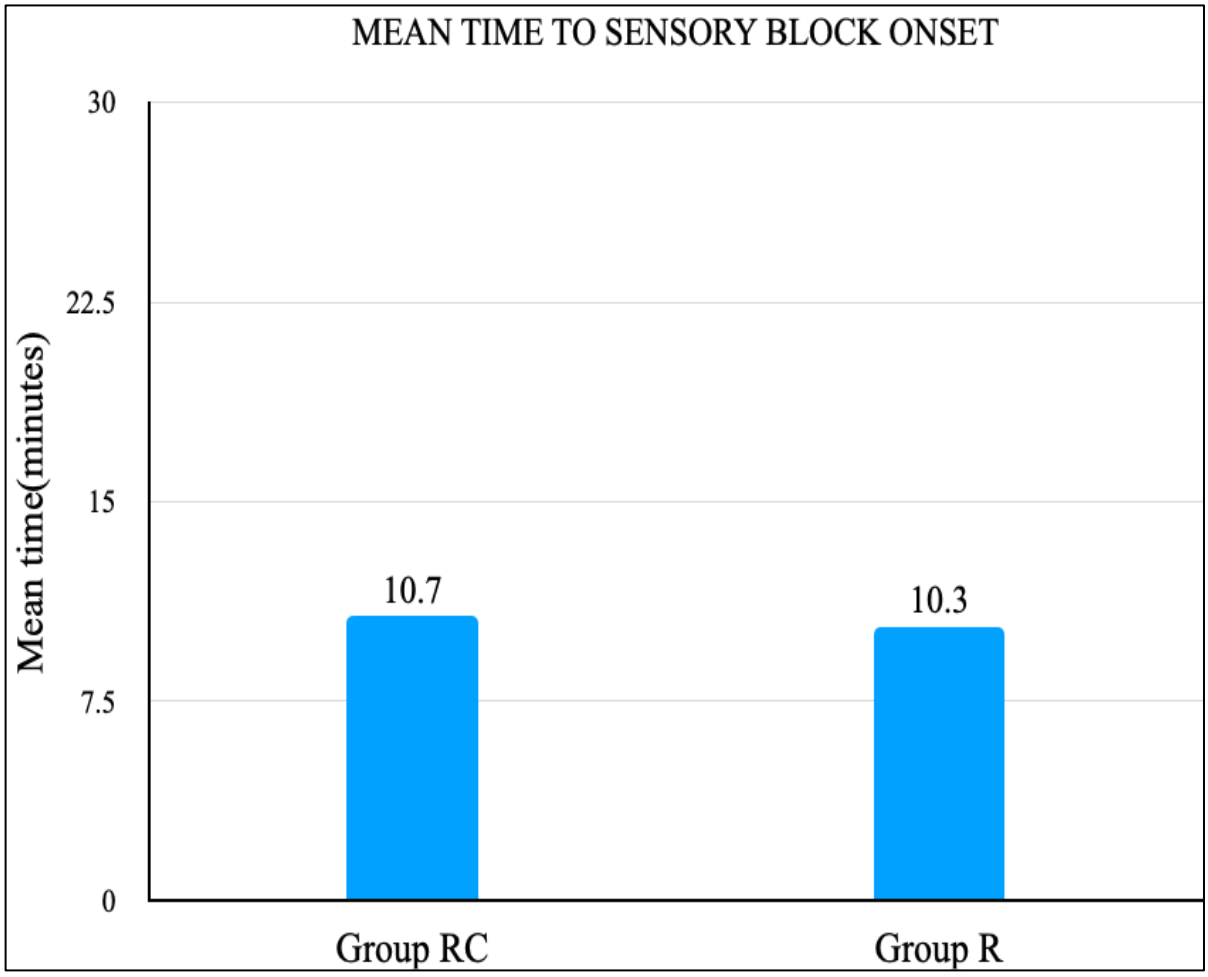

Figure 7: Comparison of time to sensory block onset(in minutes) in group RC and group R.

Table 5 :- Comparison of study groups according to number of dermatomes blocked

Parameter	Group RC	Group R	p-value
Number of dermatomes blocked	4.4 +/- 1.0	4.5 +/- 0.5	0.606

The above table shows the number of dermatomes blocked in the RC (ropivacaine+clonidine) and R(ropivacaine) groups, calculated as Mean +/- SD. The difference between both the groups is insignificant, statistically for the parameter number of dermatomes blocked($p>0.05$). Independent sample 't' test is used to compare the mean number of dermatomes blocked between the study groups.

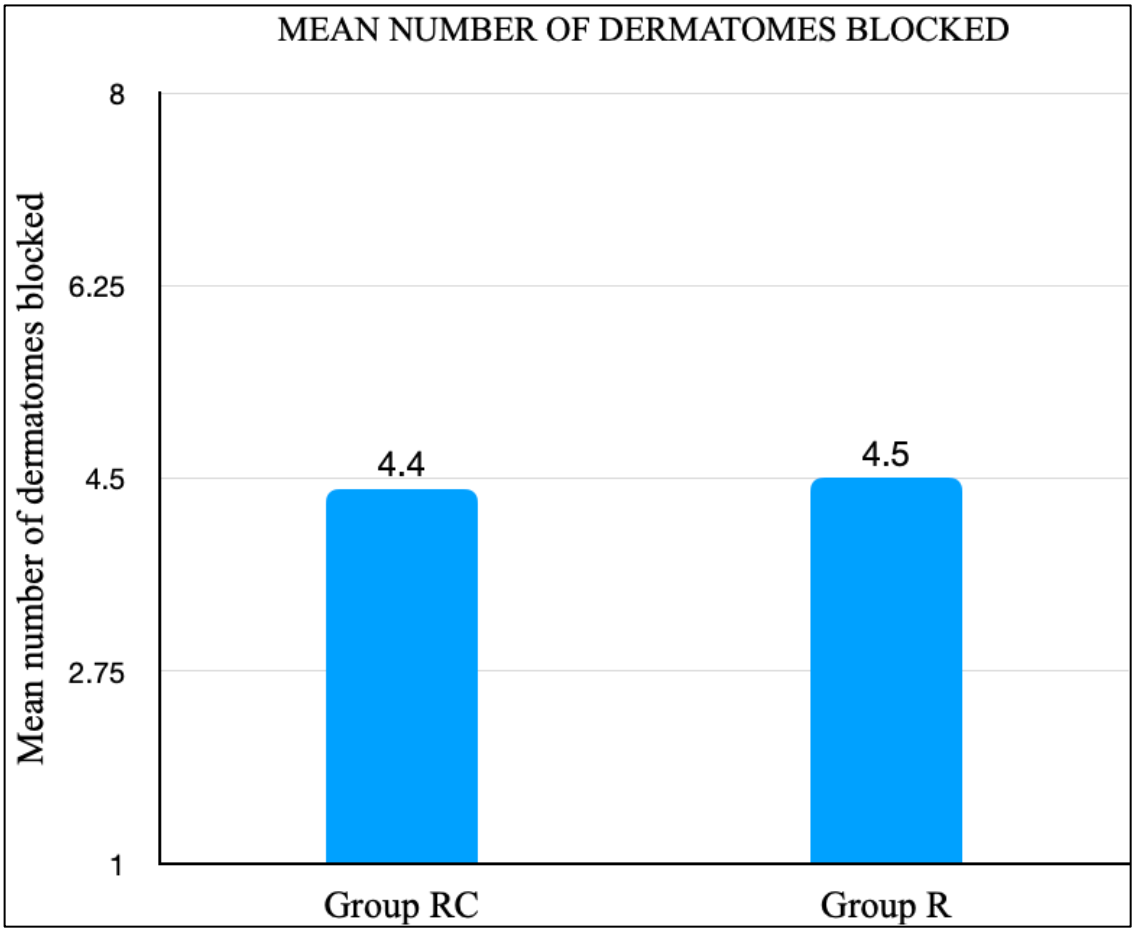

Figure 8: Comparison of number of dermatomes blocked in group RC and group R.

Table 6 :- Comparison of study groups according to time to first rescue analgesic

A) Calculation according to Mann-Whitney U test

Group	Median of time to first rescue analgesic(hrs)	IQR		p-value
		Q1	Q3	
RC	18.00	13.25	21.25	0.400
R	10.50	6.25	21.75	

The above table shows the median time to first rescue analgesic(hours), Q1, and Q3 in the RC (ropivacaine+clonidine) and R(ropivacaine) groups.The median time to first rescue analgesic is 18 hours in RC and 10 hours in R group. Mann-Whitney U test is used to calculate it.There is no significant difference on time to first rescue analgesic between both the groups(p>0.05).

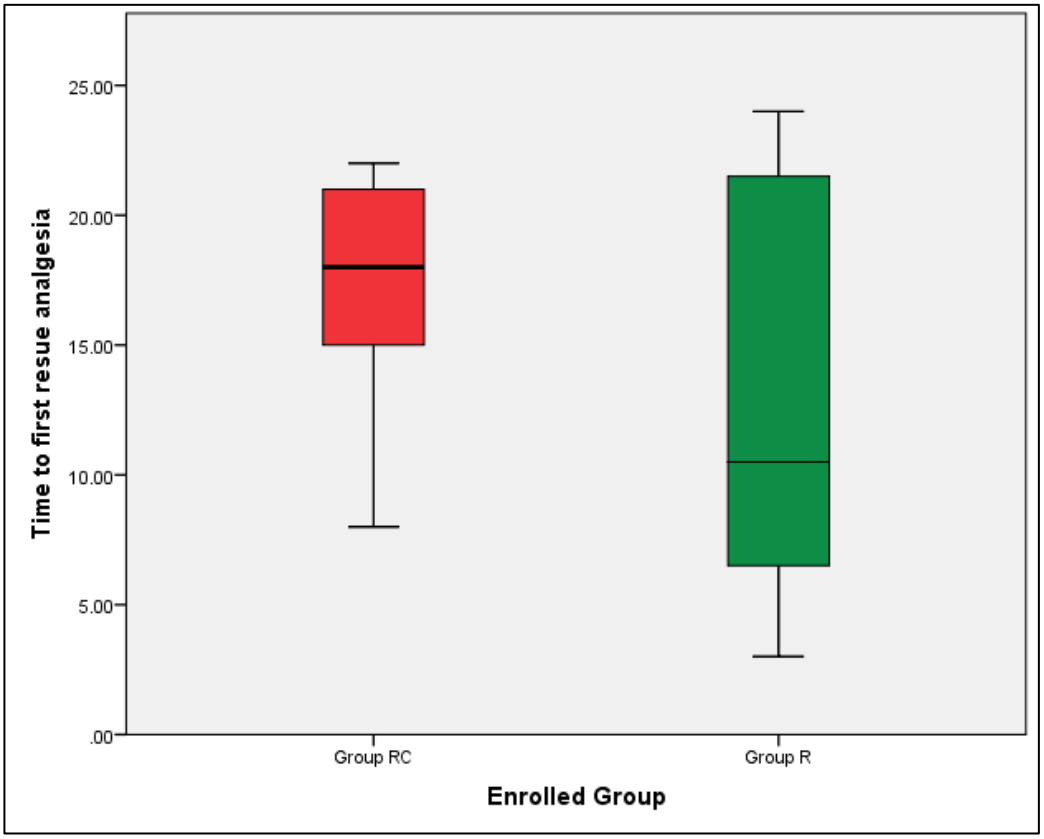

Figure 9:- Comparison of median time to first rescue analgesic(in hours) in RC and R group.

B) Calculation according to Chi-square test

Group	Median of time to first rescue analgesic(hrs)	IQR		p-value
		Q1	Q3	
RC	16.000	9.999	22.001	0.925
R	9.000	2.210	15.790	

The above table shows the median time to first rescue analgesic(hours), Q1, and Q3 in the RC (ropivacaine+clonidine) and R(ropivacaine) groups.The median time to first rescue analgesic is 16 hours in RC and 9 hours in R group. Chi-square test is used to calculate it. There is no significant difference on time to first rescue analgesic between both the groups(p>0.05).

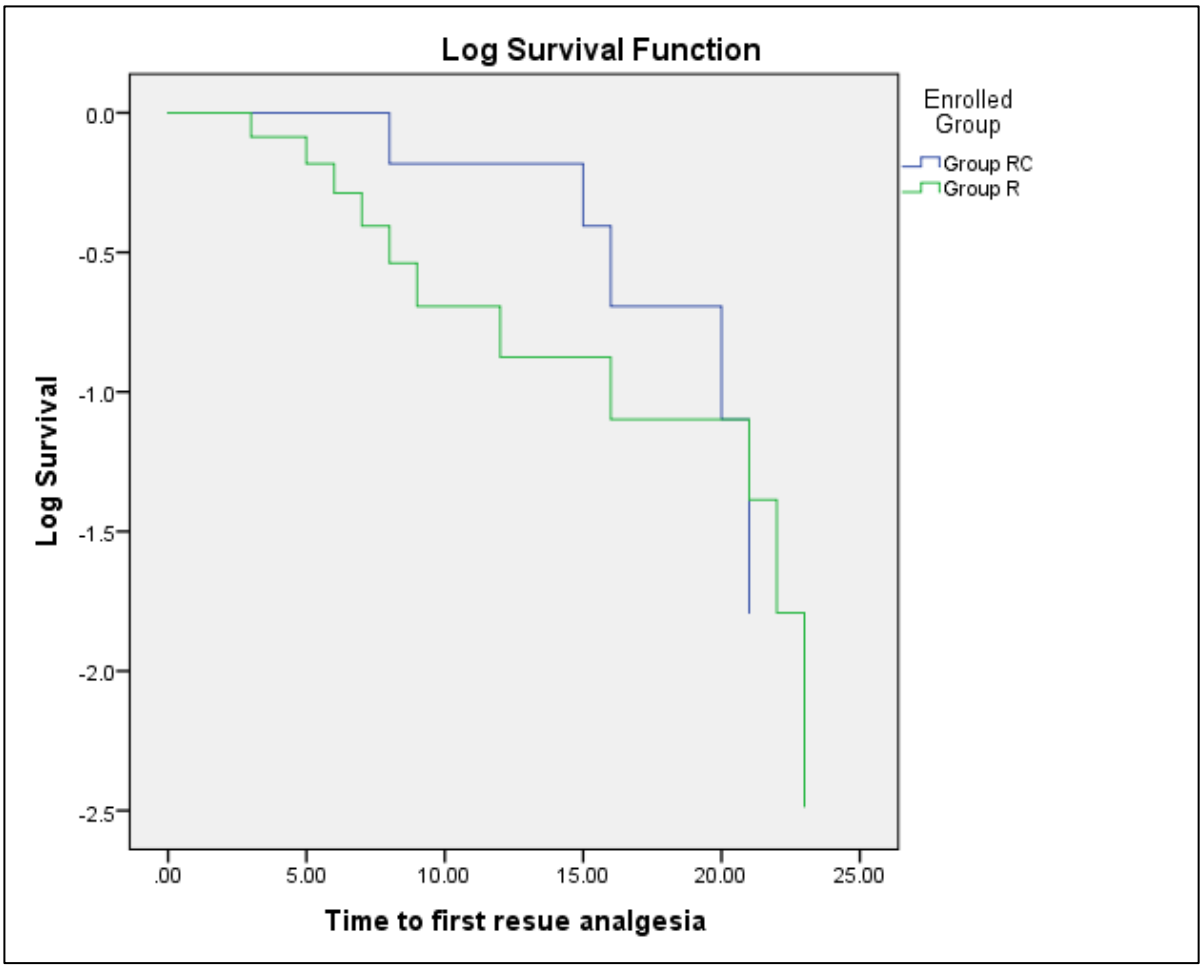

Figure 10:- Distribution of time to first rescue analgesic(in hours) in RC and R group shown by Kaplan-Meier survival curve.

Table 7:- Comparison of study groups according to number of patients requiring and not requiring rescue analgesic

Parameters	Group RC	Group R	p-value
No of patients requiring rescue analgesic	6(16%)	12(33.3%)	0.086
No of patients not requiring rescue analgesic	30(84%)	24(66.6%)	

The above table shows the number of patients requiring and not requiring rescue analgesic calculated as percentage. Six patients in RC group and twelve patients in R group requires rescue analgesic. The difference between both the groups is statistically insignificant (p>0.05). P-value is calculated using Chi-square test.

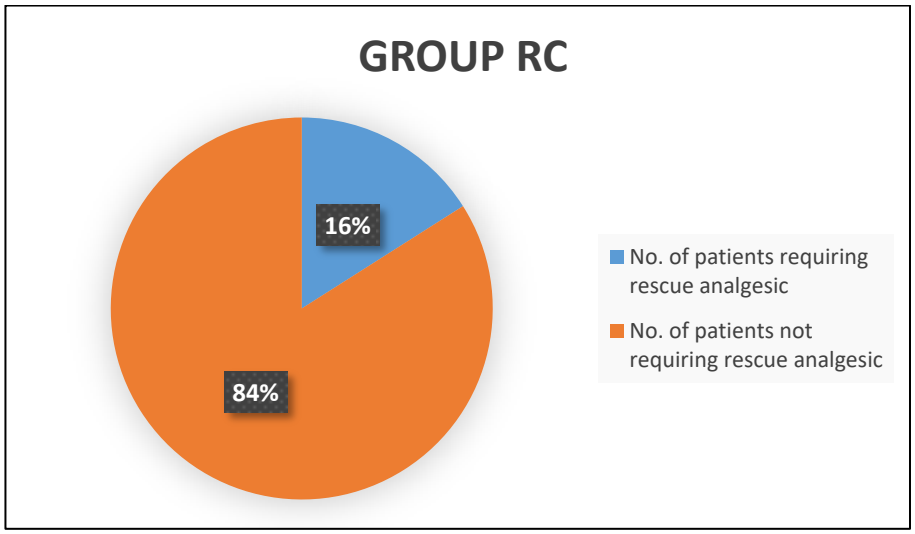

Figure 11:- Comparison of number of patients requiring and not requiring rescue analgesic in the RC group.

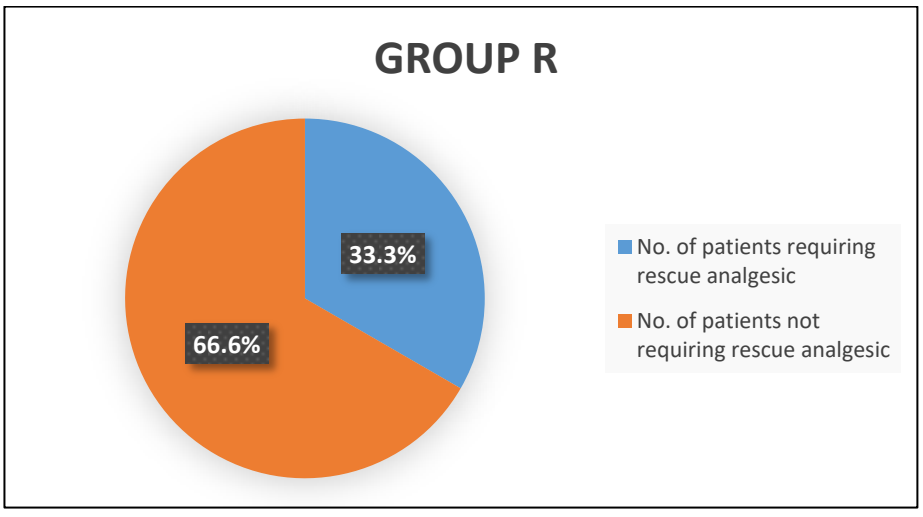

Figure 12:- Comparison of number of patients requiring and not requiring rescue analgesic in the R group.

Table 8:- Comparison of study groups according to the quality of analgesia defined by Visual Analogue Scale (VAS)

Parameters	Group	Mean	Std. Deviation	p-value
VAS_R_30Min	RC	2.2778	1.00317	0.244
	R	2.5429	0.81684	
VAS_R_60Min	RC	2.2500	0.96732	0.414
	R	2.5278	0.90982	
VAS_R_90Min	RC	2.1667	1.08233	0.002
	R	2.9167	0.90633	
VAS_R_2Hr	RC	1.9722	0.65405	0.894
	R	2.0833	0.60356	
VAS_R_4Hr	RC	2.1111	0.57459	0.355
	R	2.2222	0.72155	
VAS_R_6Hr	RC	2.1389	0.96074	0.463
	R	2.0833	0.80623	
VAS_R_9Hr	RC	2.0278	0.44633	0.168
	R	2.2778	0.97427	
VAS_R_12Hr	RC	1.9722	0.55990	0.675
	R	2.0278	0.60880	
VAS_R_18Hr	RC	2.0833	0.76997	0.817
	R	2.1389	0.79831	
VAS_R_24Hr	RC	2.2778	0.94449	0.790
	R	2.2500	1.15573	
VAS_M_30Min	RC	2.7778	0.59094	0.323
	R	3.1111	0.70823	
VAS_M_60Min	RC	2.9722	0.77408	0.053
	R	3.3611	0.89929	
VAS_M_90Min	RC	3.1111	1.06309	0.435
	R	3.7500	0.96732	
VAS_M_2Hr	RC	2.9722	0.65405	0.630
	R	3.0556	0.58282	
VAS_M_4Hr	RC	3.0833	0.55420	0.131
	R	3.2500	0.73193	
VAS_M_6Hr	RC	3.1111	0.94952	0.595
	R	3.1111	0.78478	
VAS_M_9Hr	RC	3.0278	0.44633	0.391
	R	3.1944	1.06421	
VAS_M_12Hr	RC	3.0556	0.47476	0.749
	R	3.0000	0.67612	
VAS_M_18Hr	RC	3.1667	0.91026	0.233
	R	3.1389	0.68255	
VAS_M_24Hr	RC	3.2222	0.92924	0.420
	R	3.2222	1.22150	

The above table shows the resting(R) and motor(M) VAS scores of the RC and R groups at 30minutes, 1hour, 90minutes, 2hours, 4hours, 6hours, 9hours, 12hours, 18hours and 24thhour

of the postoperative period, calculated as Mean +/- SD. The difference between both the groups is found to be statistically significant for resting VAS score at 90min($p<0.05$), but is insignificant for VAS score at other time points. Independent sample 't' test is used to compare the mean VAS score between the study groups. Although VAS(resting) at 90 minutes is significant statistically, but is insignificant clinically(Mean VAS at 90mins being 2.1 and 2.9 for RC and R groups respectively), as they are beyond the criteria to administer rescue analgesic(VAS greater or equal to 4).

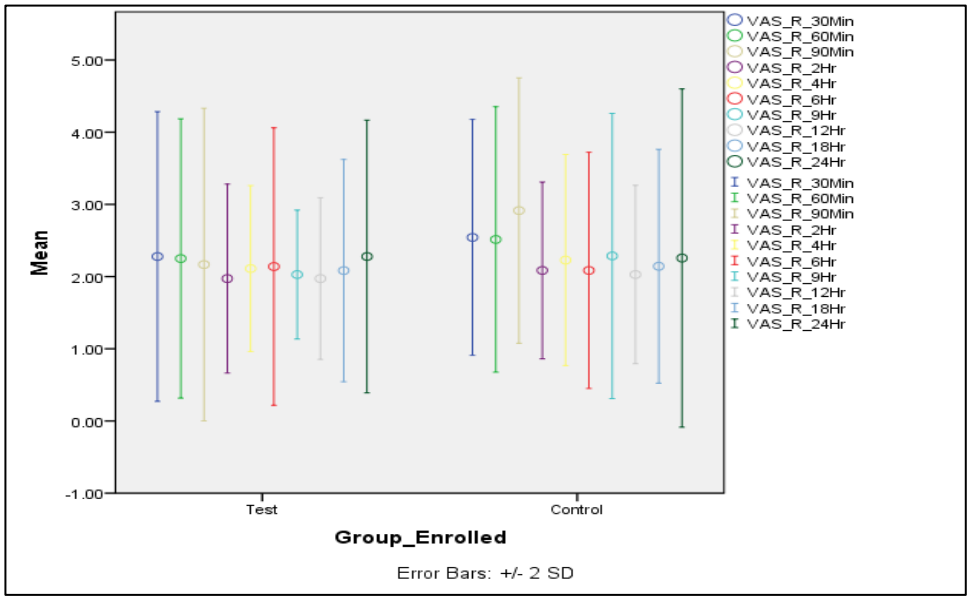

Figure 13:- Comparison of mean resting VAS score for RC(test) and R(control) groups, indicated by open dots. The lines indicate error bars taken as +/-2SD.

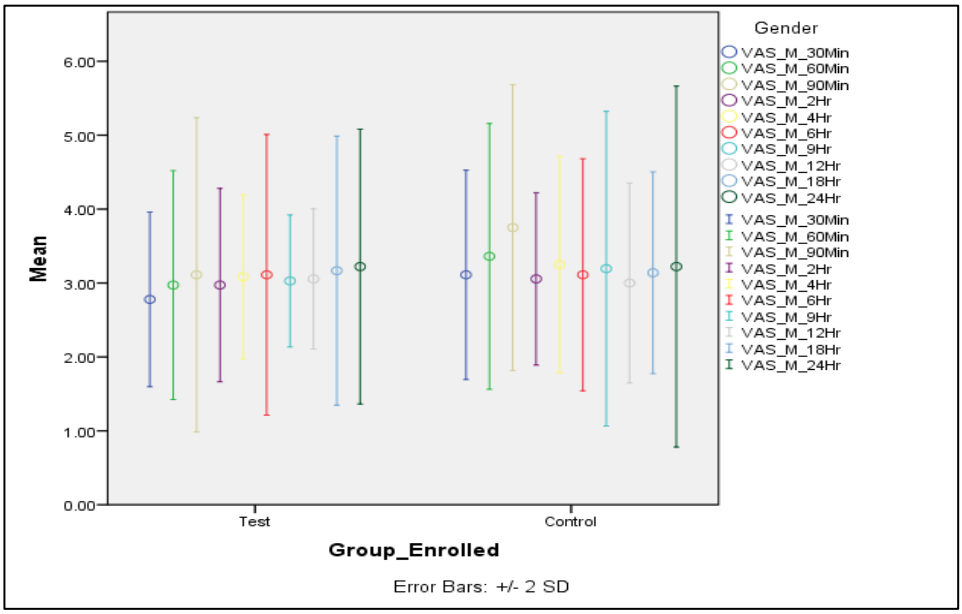

Figure 14:- Comparison of mean motor VAS score for RC(test) and R(control) groups, indicated by open dots. The lines indicate error bars taken as +/-2SD.

Table 9:- Comparison of study groups based on difference between heart rate of patients at the baseline (time since ESP block application),and heart rate at every five minutes till thirty minutes

Parameters	Group						
	RC			R			
	Median	Q1	Q3	Median	Q1	Q3	p-value
Time to block (baseline-5mins) HR(per min)	0.0	-1.0	0.0	0.0	0.0	0.0	0.224
Time to block (baseline-10mins) HR(per min)	0.0	0.0	0.0	0.0	0.0	0.0	0.688
Time to block (baseline-15mins) HR(per min)	0.0	-1.0	0.0	0.0	0.0	0.0	0.342
Time to block (baseline-20mins) HR(per min)	-2.0	-3.0	0.0	-2.0	-3.0	-1.0	0.632
Time to block (baseline-25mins) HR(per min)	0.0	0.0	0.0	0.0	0.0	0.0	0.723
Time to block (baseline-30mins) HR(per min)	0.0	0.0	0.0	0.0	0.0	0.0	0.586

The above table shows the difference between heart rate of patients of group RC and R, at the baseline(time since ESP block application),and heart rate at every five minutes till thirty minutes, calculated as median.Q1(25th percentile),Q3(75th percentile) and p-values are mentioned above. Mann-Whitney U test and Independent sample 't' test is used to compare them. The differences have been found to be statistically insignificant(p>0.05).

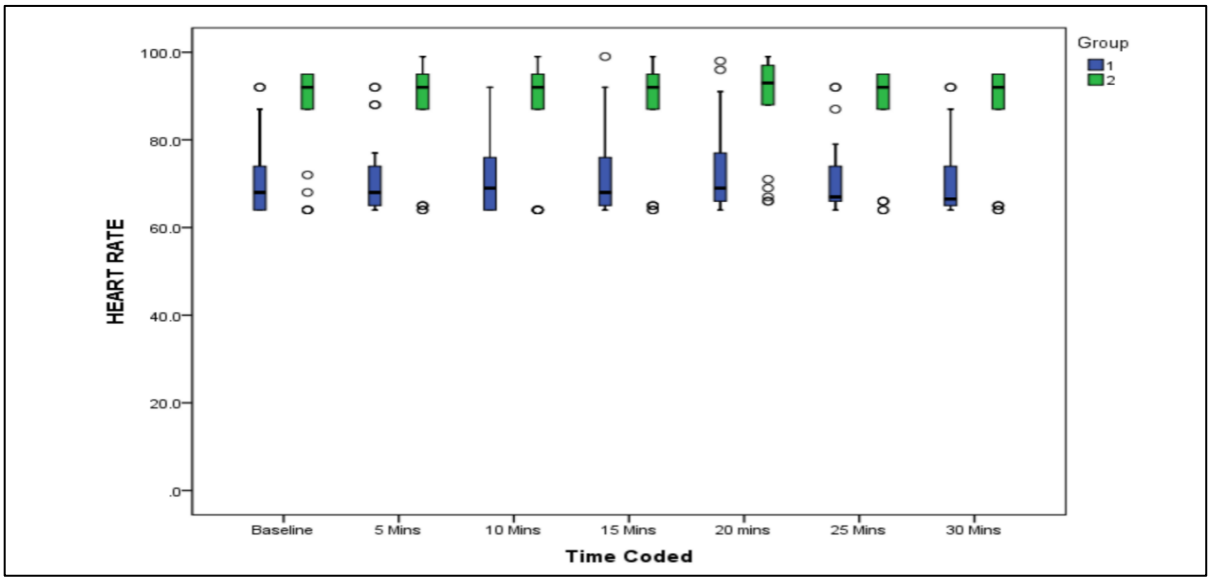

Figure 15:- Comparison of median heart rate(per min) of patients of group RC(group 1) and group R(group 2).

Table 10:- Comparison of study groups based on difference between systolic blood pressure of patients at the baseline (time since ESP block application),and systolic blood pressure at every five minutes till thirty minutes

Parameters	Group						
	RC			R			
	Median	Q1	Q3	Median	Q1	Q3	p-value
Time to block (baseline-5mins) SBP(mmHg)	0.0	0.0	0.0	0.0	0.0	0.0	0.458
Time to block (baseline-10mins) SBP(mmHg)	0.0	0.0	2.0	0.0	0.0	0.0	0.317
Time to block (baseline-15mins) SBP(mmHg)	0.0	0.0	0.0	0.0	0.0	0.0	0.251
Time to block (baseline-20mins) SBP(mmHg)	0.0	0.0	2.0	0.0	-1.0	0.0	0.123
Time to block (baseline-25mins) SBP(mmHg)	0.0	0.0	2.0	0.0	0.0	0.0	0.114
Time to block (baseline-30mins) SBP(mmHg)	0.0	0.0	0.0	0.0	0.0	0.0	0.249

The above table shows the difference between systolic blood pressure of patients of group RC and R, at the baseline(time since ESP block application),and systolic blood pressure at every five minutes till thirty minutes, calculated as median.Q1(25th percentile),Q3(75th percentile) and p-values are mentioned above.Mann-Whitney U test and Independent sample ‘t’ test is used to compare them.The differences have been found to be statistically insignificant (p>0.05).

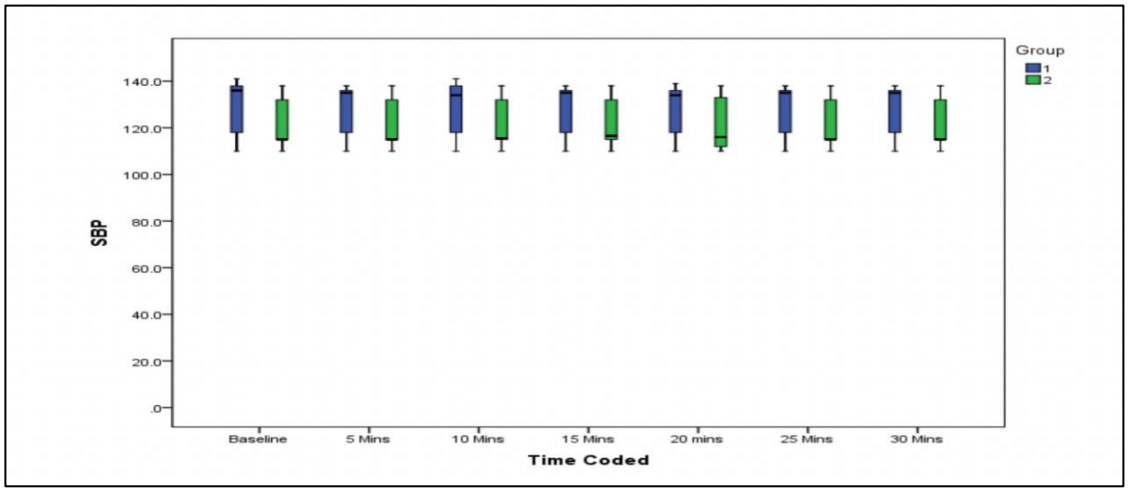

Figure 16:- Comparison of median systolic blood pressure(SBP in mmHg) of patients of group RC(group 1) and group R(group 2).

Table11:- Comparison of study groups based on difference between diastolic blood pressure of patients at the baseline(time since ESP block application),and diastolic blood pressure at every five minutes till thirty minutes

Parameters	Group						
	RC			R			
	Median	Q1	Q3	Median	Q1	Q3	p-value
Time to block (baseline-5mins) DBP(mmHg)	0.0	0.0	0.3	0.0	0.0	0.0	0.368
Time to block (baseline-10mins) DBP(mmHg)	0.0	0.0	1.0	0.0	0.0	0.0	0.237
Time to block (baseline-15mins) DBP(mmHg)	0.0	0.1	0.0	0.0	0.0	0.0	0.161
Time to block (baseline-20mins) DBP(mmHg)	0.0	0.0	3.0	0.0	-1.0	0.0	0.223
Time to block (baseline-25mins) DBP(mmHg)	0.0	0.1	2.0	0.0	0.0	0.0	0.214
Time to block (baseline-30mins) DBP(mmHg)	0.0	0.1	0.0	0.0	0.0	0.0	0.169

The above table shows the difference between diastolic blood pressure of patients of group RC and R, at the baseline(time since ESP block application),and diastolic blood pressure at every five minutes till thirty minutes, calculated as median.Q1(25th percentile),Q3(75th percentile) and p-values are mentioned above.Mann-Whitney U test and Independent sample 't' test is used to compare them.The differences have been found to be statistically insignificant(p>0.05).

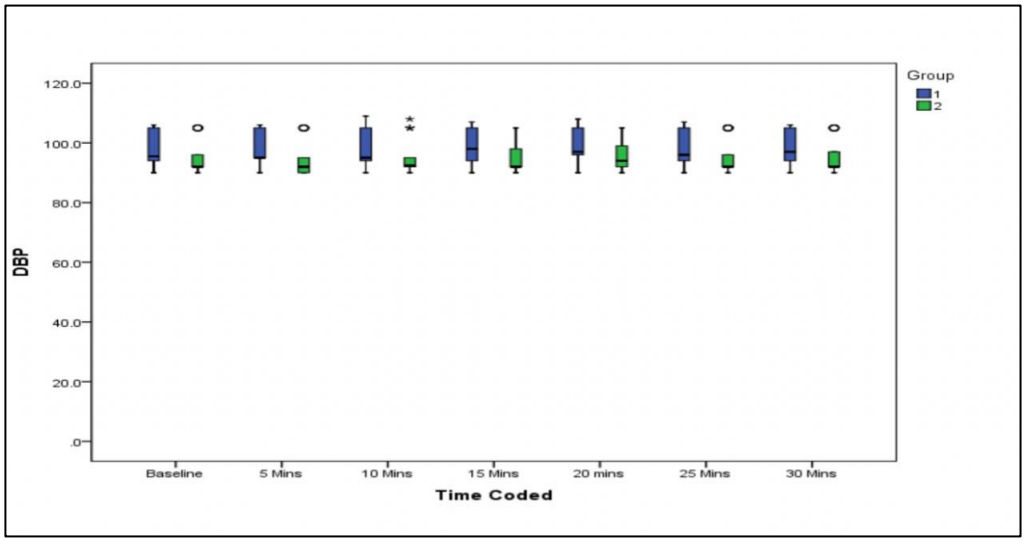

Figure 17:- Comparison of median diastolic blood pressure(DBP in mmHg) of patients of group RC(group 1) and group R(group 2).

Table 12:- Comparison of study groups based on difference between mean arterial blood pressure of patients at the baseline(time since ESP block application),and mean arterial blood pressure at every five minutes till thirty minutes

Parameters	Group						
	RC			R			
	Median	Q1	Q3	Median	Q1	Q3	p-value
Time to block (baseline-5mins) MAP(mmHg)	0.0	0.0	0.3	0.0	0.0	0.0	0.823
Time to block (baseline-10mins) MAP(mmHg)	0.0	0.0	22.3	0.0	0.0	0.0	0.467
Time to block (baseline-15mins) MAP(mmHg)	0.0	0.0	21.3	0.0	0.0	0.0	0.342
Time to block (baseline-20mins) MAP(mmHg)	0.0	-0.3	22.3	0.0	0.0	0.3	0.617
Time to block (baseline-25mins) MAP(mmHg)	0.0	-0.3	0.0	0.0	0.0	0.0	0.244
Time to block (baseline-30mins) MAP(mmHg)	0.0	-0.3	0.0	0.0	0.0	0.0	0.184

The above table shows the difference between mean arterial blood pressure of patients of group RC and R, at the baseline(time since ESP block application),and diastolic blood pressure at every five minutes till thirty minutes, calculated as median.Q1(25th percentile),Q3(75th percentile) and p-values are mentioned above.Mann-Whitney U test and Independent sample ‘t’ test is used to compare them.The differences have been found to be statistically insignificant(p>0.05).

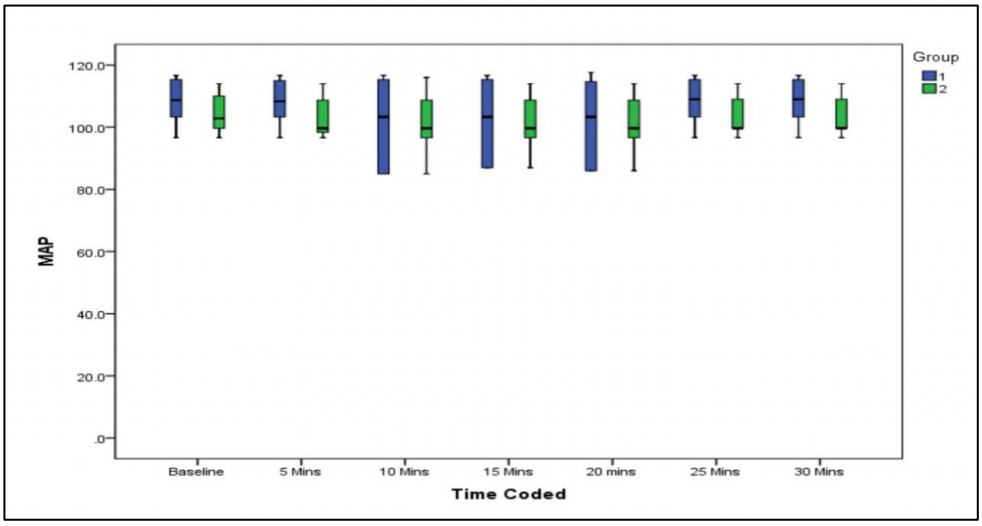

Figure 18:- Comparison of median MAP(mean arterial blood pressure in mmHg) of patients of group RC(group 1) and group R(group 2).

Table 13:- Comparison of study groups based on difference between oxygen saturation of patients at the baseline(time since ESP block application),and oxygen saturation at every five minutes till thirty minutes

Parameters	Group						
	RC			R			
	Median	Q1	Q3	Median	Q1	Q3	p-value
Time to block (baseline-5mins) SpO2(percent)	0.0	0.0	0.0	0.0	0.0	2.0	0.001
Time to block (baseline-10mins) SpO2(percent)	0.0	0.0	0.0	0.0	0.0	2.0	0.007
Time to block (baseline-15mins) SpO2(percent)	0.0	0.0	0.0	0.0	0.0	2.0	0.001
Time to block (baseline-20mins) SpO2(percent)	0.0	0.0	0.0	0.0	0.0	2.0	0.001
Time to block (baseline-25mins) SpO2(percent)	0.0	0.0	0.0	0.0	0.0	2.0	0.001
Time to block (baseline-30mins) SpO2(percent)	0.0	0.0	0.0	0.0	0.0	2.0	0.001

The above table shows the difference between oxygen saturation of patients of group RC and R, at the baseline(time since ESP block application),and diastolic blood pressure at every five minutes till thirty minutes, calculated as median.Q1(25th percentile),Q3(75th percentile) and p-values are mentioned above.Mann-Whitney U test and Independent sample 't' test is used to compare them.The differences have been found to be statistically significant(p>0.05).

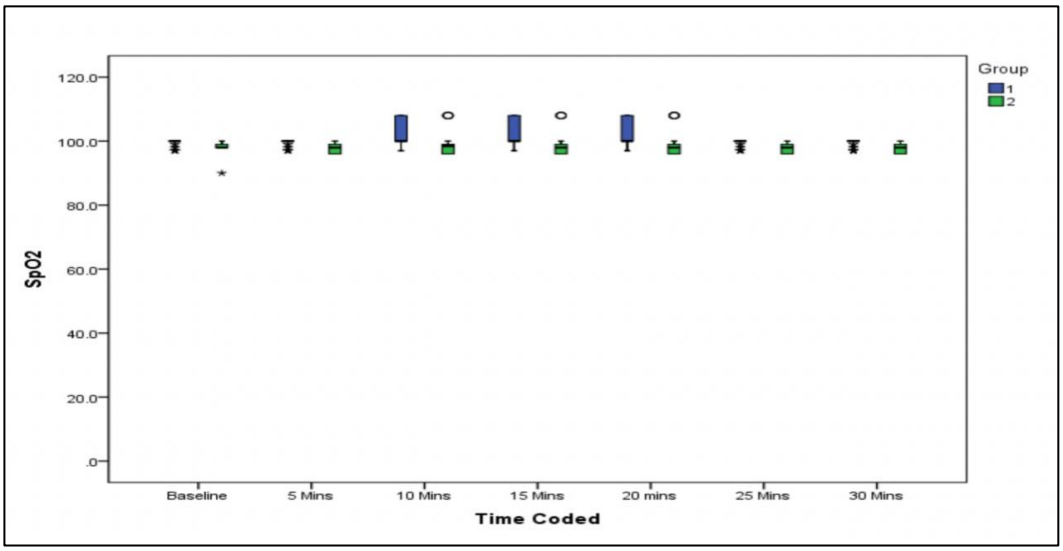

Figure 19:- Comparison of median SpO2(oxygen saturation in percent) of patients of group RC(group 1) and group R(group 2).

Table 14:- Comparison of study groups based on oxygen saturation every 5 minutes since ESP block application till 30mins

Parameters	Group RC	Group R	p-value
Time to block - baseline spo2	99.5 +/- 1.1	98.3 +/- 2.0	0.002
Time to block - 5 min spo2	99.5 +/- 1.1	98.0 +/- 1.6	<0.001
Time to block -10 min spo2	99.7 +/- 4.1	99.2 +/- 3.9	0.016
Time to block -15 min spo2	99.7 +/- 4.1	99.1 +/- 3.9	0.015
Time to block -20 min spo2	99.7 +/- 4.1	99.1 +/- 3.9	0.015
Time to block - 25 min spo2	99.5 +/- 1.1	98.0 +/- 1.6	<0.001
Time to block - 30 min spo2	99.5 +/- 1.1	98.0 +/- 1.6	<0.001

The above table shows the mean oxygen saturation of patients at baseline and for every 5mins thereafter ESP block application ,till 30mins,for RC and R groups, calculated as Mean +/- SD. Though the Independent sample ‘t’ test shows the difference in oxygen saturation to be statistically significant($p<0.05$) at measured time points, the difference is clinically insignificant as the lowest spo2 being 98% is well beyond defined safe limits . No treatment was required for this fall in spo2.

<u>Table 15:-</u> Comparison of study groups based on difference between heart rate of patients at the baseline(pre-induction),and heart rate after induction,after securing airway,at skin incision,at 15mins,at 30mins,at 45 mins, at 1hr,at 75mins and at 90mins

Parameters (per min)	Group						p-value
	RC			R			
	Median	Percentile 25	Percentile 75	Median	Percentile 25	Percentile 75	
Intraoperative hemodymanics (baseline-after induction) HR	0.0	0.0	0.0	0.0	0.0	0.0	1.000
Intraoperative hemodymanics (baseline-after securing airway) HR	0.0	-18.0	0.0	0.0	0.0	0.0	0.058
Intraoperative hemodymanics (baseline-after skin incision) HR	0.0	-5.0	0.0	0.0	0.0	0.0	0.191
Intraoperative hemodymanics (baseline-15mins) HR	0.0	-1.0	0.0	0.0	0.0	0.0	0.100
Intraoperative hemodymanics (baseline-30mins) HR	0.0	0.0	0.0	0.0	0.0	0.0	0.498
Intraoperative hemodymanics (baseline-45mins) HR	0.0	0.0	0.0	0.0	0.0	0.0	0.698
Intraoperative hemodymanics (baseline-1hr) HR	0.0	-1.0	0.0	0.0	0.0	0.0	0.139
Intraoperative hemodymanics (baseline-75mins) HR	0.0	-1.0	0.0	0.0	0.0	0.0	0.097
Intraoperative hemodymanics (baseline-90mins) HR	0.0	-1.0	0.0	0.0	0.0	0.0	0.249

The above table shows the difference between heart rate of patients of group RC and R, at the baseline(pre-induction),and heart rate after induction,after securing airway,at skin incision,at 15mins,at 30mins,at 45 mins, at 1hr,at 75mins and at 90mins, calculated as median.Q1(25th percentile),Q3(75th percentile) and p-values are mentioned above.Mann-Whitney U test and Independent sample 't' test is used to compare them.The differences have been found to be statistically insignificant(p>0.05).

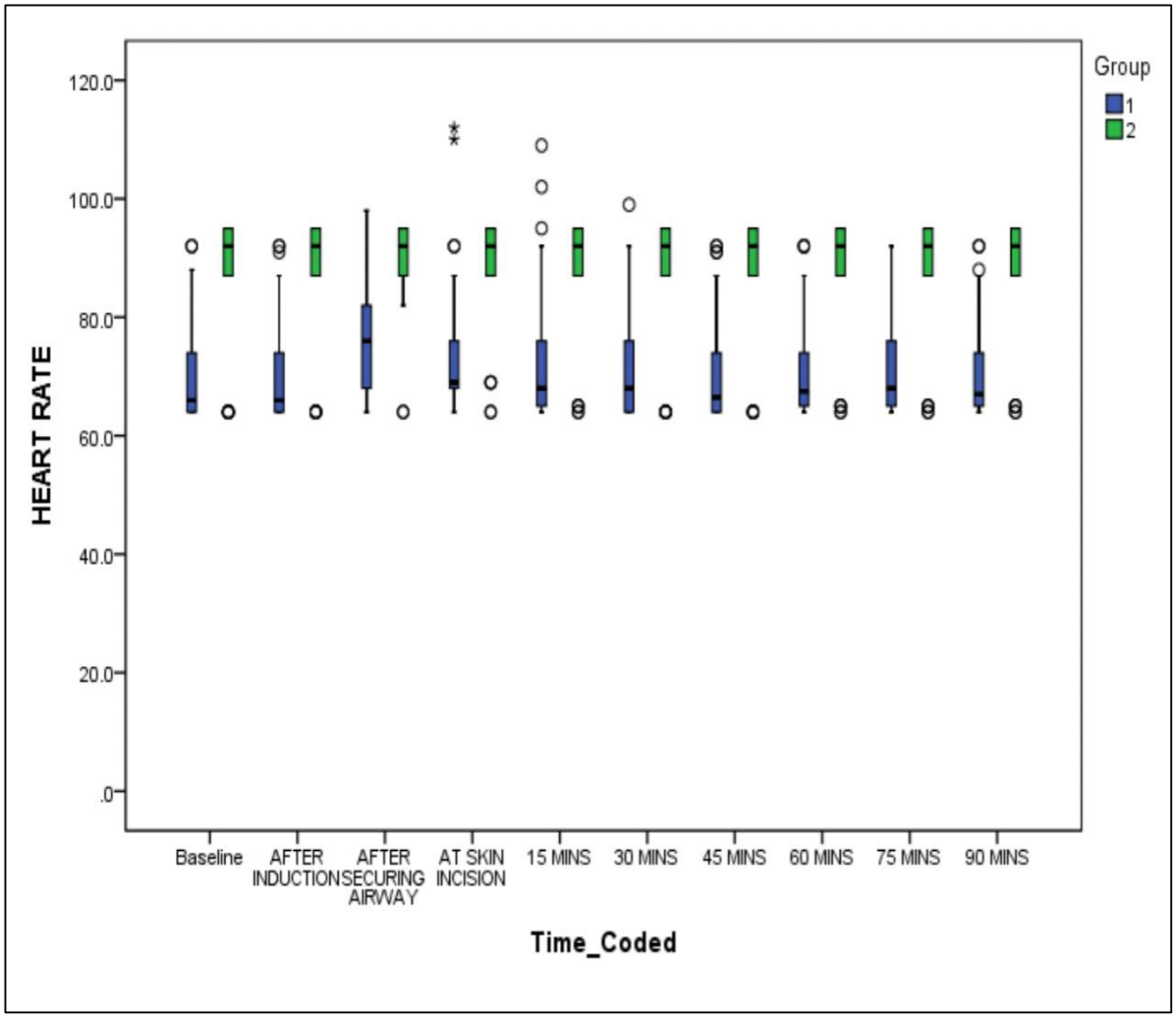

Figure 20:-Comparison of median heart rate(per min) of patients of group RC(group 1) and group R(group 2).

Table 16:- Comparison of study groups based on difference between systolic blood pressure of patients at the baseline(pre-induction),and systolic blood pressure after induction,after securing airway,at skin incision,at 15mins,at 30mins,at 45 mins, at 1hr,at 75mins and at 90mins

Parameters (mmHg)	Group						p-value
	RC			R			
	Median	Percentile 25	Percentile 75	Median	Percentile 25	Percentile 75	
Intraoperative hemodynamics (baseline-after induction) SBP	0.0	0.0	0.0	0.0	0.0	0.0	0.345
Intraoperative hemodynamics (baseline-after securing airway) SBP	0.0	-9.0	0.0	0.0	0.0	0.0	0.139
Intraoperative hemodynamics (baseline-after skin incision) SBP	0.0	0.0	4.0	0.0	0.0	0.0	0.207
Intraoperative hemodynamics (baseline-15mins) SBP	0.0	0.0	0.0	0.0	0.0	0.0	0.498
Intraoperative hemodynamics (baseline-30mins) SBP	0.0	-1.0	0.0	0.0	0.0	0.0	0.191
Intraoperative hemodynamics (baseline-45mins) SBP	0.0	-1.0	0.0	0.0	0.0	0.0	0.339
Intraoperative hemodynamics (baseline-1hr) SBP	0.0	-2.0	0.0	0.0	0.0	0.0	0.339
Intraoperative hemodynamics (baseline-75mins) SBP	0.0	-1.0	0.0	0.0	0.0	0.0	0.257
Intraoperative hemodynamics (baseline-90mins) SBP	0.0	-1.0	0.0	0.0	0.0	0.0	0.429

The above table shows the difference between systolic blood pressure of patients of group RC and R, at the baseline(pre-induction),and systolic blood pressure after induction,after securing airway,at skin incision,at 15mins,at 30mins,at 45 mins, at 1hr,at 75mins and at 90mins, calculated as median.Q1(25th percentile),Q3(75th percentile) and p-values are mentioned above.Mann-Whitney U test and Independent sample 't' test is used to compare them.The differences have been found to be statistically insignificant(p>0.05).

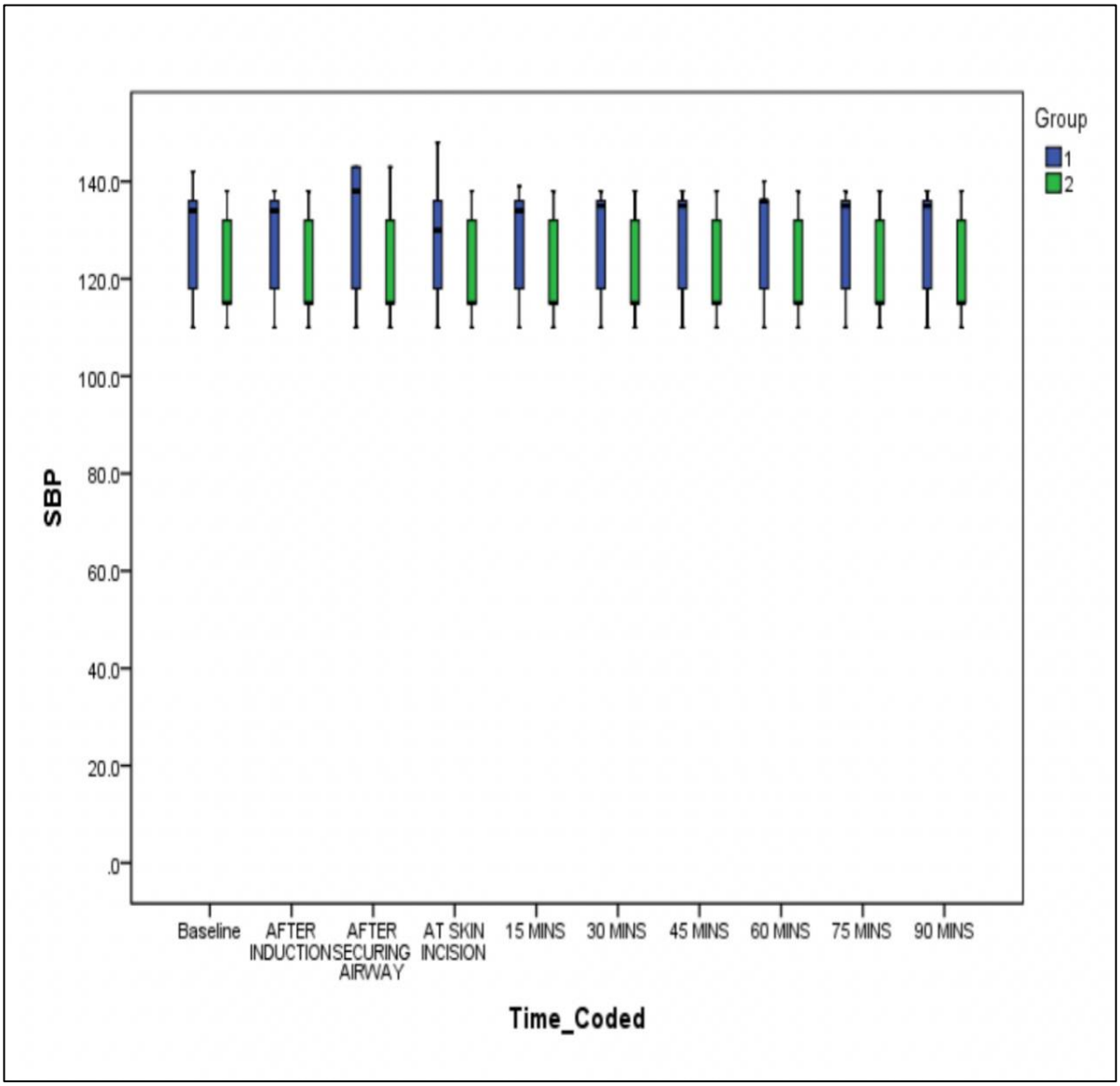

Figure 21:-Comparison of median systolic blood pressure(mmHg) of patients of group RC(group 1) and group R(group 2).

Table 17:- Comparison of study groups based on difference between diastolic blood pressure of patients at the baseline(pre-induction),and diastolic blood pressure after induction,after securing airway,at skin incision,at 15mins,at 30mins,at 45 mins, at 1hr,at 75mins and at 90mins

Parameters (mmHg)	Group						p-value
	RC			R			
	Median	Percentile 25	Percentile 75	Median	Percentile 25	Percentile 75	
Intraoperative hemodynamics (baseline-after induction) DBP	0.0	0.0	0.0	0.0	0.0	0.0	0.143
Intraoperative hemodynamics (baseline-after securing airway) DBP	0.0	-6.0	0.0	0.0	0.0	0.0	0.212
Intraoperative hemodynamics (baseline-after skin incision) DBP	0.0	0.0	2.0	0.0	0.0	0.0	0.106
Intraoperative hemodynamics (baseline-15mins) DBP	0.0	0.0	0.0	0.0	0.0	0.0	0.428
Intraoperative hemodynamics (baseline-30mins) DBP	0.0	-1.0	0.0	0.0	0.0	0.0	0.291
Intraoperative hemodynamics (baseline-45mins) DBP	0.0	-1.0	0.0	0.0	0.0	0.0	0.249
Intraoperative hemodynamics (baseline-1hr) DBP	0.0	-2.0	0.0	0.0	0.0	0.0	0.439
Intraoperative hemodynamics (baseline-75mins) DBP	0.0	-1.0	0.0	0.0	0.0	0.0	0.167
Intraoperative hemodynamics (baseline-90mins) DBP	0.0	-1.0	0.0	0.0	0.0	0.0	0.239

The above table shows the difference between diastolic blood pressure of patients of group RC and R, at the baseline(pre-induction),and diastolic blood pressure after induction,after securing airway,at skin incision,at 15mins,at 30mins,at 45 mins, at 1hr,at 75mins and at 90mins, calculated as median.Q1(25th percentile),Q3(75th percentile) and p-values are mentioned above.Mann-Whitney U test and Independent sample 't' test is used to compare them.The differences have been found to be statistically insignificant(p>0.05).

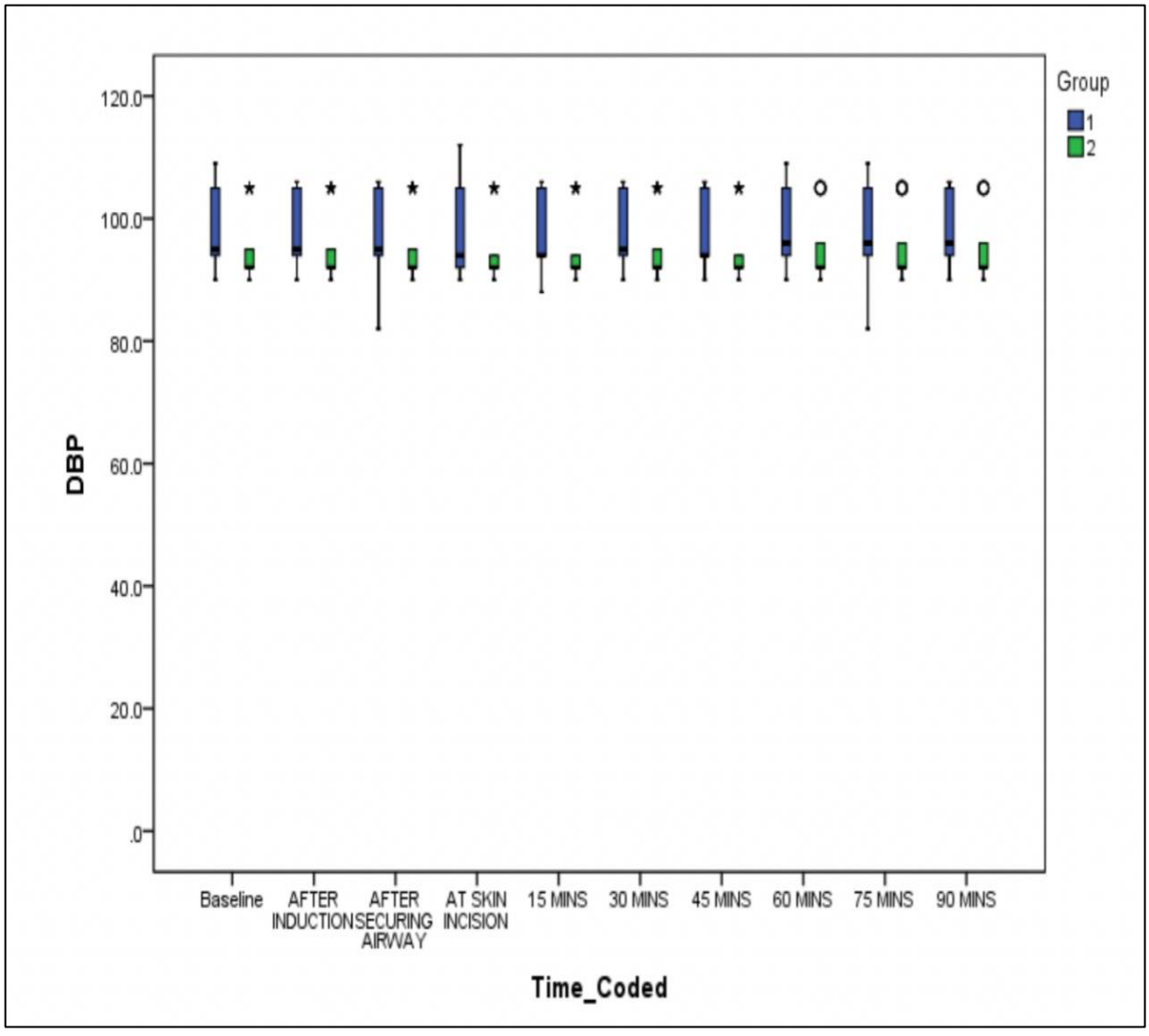

Figure 22:- Comparison of median diastolic blood pressure(mmHg) of patients of group RC(group 1) and group R(group 2).

Table 18:- Comparison of study groups based on difference between mean arterial blood pressure of patients at the baseline(pre-induction),and mean arterial blood pressure after induction,after securing airway,at skin incision,at 15mins,at 30mins,at 45 mins, at 1hr,at 75mins and at 90mins

Parameters (mmHg)	Group						p-value
	RC			R			
	Median	Percentile 25	Percentile 75	Median	Percentile 25	Percentile 75	
Intraoperative hemodynamics (baseline-after induction) MAP	0.0	0.0	0.0	0.0	0.0	0.0	0.397
Intraoperative hemodynamics (baseline-after securing airway) MAP	0.0	-3.0	0.0	0.0	0.0	0.0	0.138
Intraoperative hemodynamics (baseline-after skin incision) MAP	0.0	0.0	3.3	0.0	0.0	0.0	0.477
Intraoperative hemodynamics (baseline-15mins) MAP	0.0	0.0	0.7	0.0	0.0	0.0	0.477
Intraoperative hemodynamics (baseline-30mins) MAP	0.0	-0.3	0.0	0.0	0.0	0.0	0.063
Intraoperative hemodynamics (baseline-45mins) MAP	0.0	0.0	0.3	0.0	0.0	0.0	0.363
Intraoperative hemodynamics (baseline-1hr) MAP	0.0	-1.3	0.0	0.0	0.0	0.0	0.228
Intraoperative hemodynamics (baseline-75mins) MAP	0.0	-1.0	0.0	0.0	0.0	0.0	0.171
Intraoperative hemodynamics (baseline-90mins) MAP	0.0	-1.0	0.0	0.0	0.0	0.0	0.171

The above table shows the difference between mean arterial blood pressure of patients of group RC and R, at the baseline(pre-induction),and mean arterial blood pressure after induction,after securing airway,at skin incision,at 15mins,at 30mins,at 45 mins, at 1hr,at 75mins and at 90mins, calculated as median.Q1(25th percentile),Q3(75th percentile) and p-values are mentioned above.Mann-Whitney U test and Independent sample 't' test is used to compare them.The differences have been found to be statistically insignificant($p>0.05$).

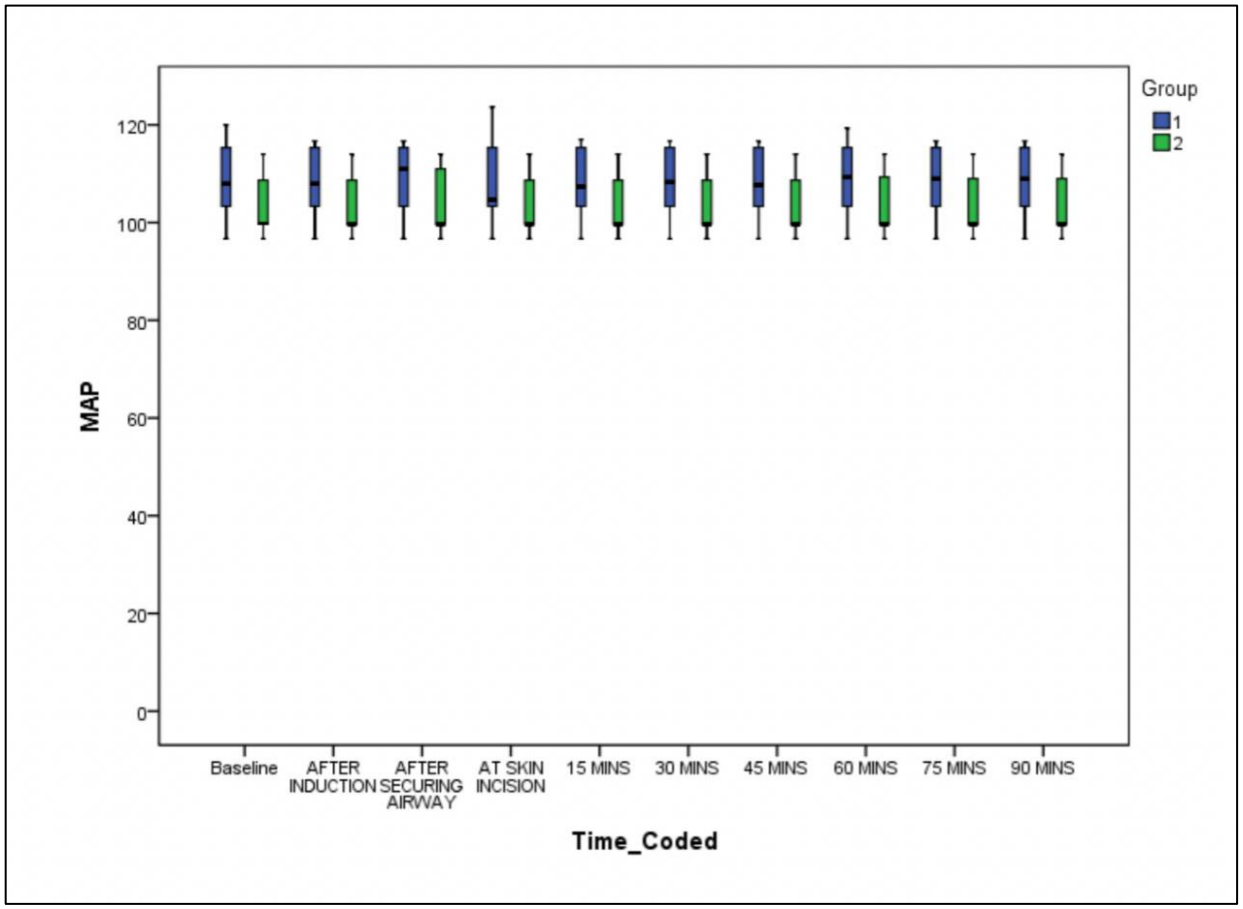

Figure 23:-Comparison of median MAP (mmHg) of patients of group RC (group 1) and group R (group 2).

Six patients of RC group(at 8hours, 15hours, 16hours, 20hours, 21hours,and 22hours) and twelve patients of R group(at 3hours, 5hours, 6hours, 7hours, 8hours, 9hours, 12hours, 16hours, 18hours, 21hours,23hours,and 24hours) complained of pain in first 24hours of postoperative period.Rescue analgesic injection Diclofenac 1.5mg/kg intravenously has been given at the above mentioned time points.There is no other adverse effects/complications of ESP block in both the study groups.

DISCUSSION

In general, the postoperative phase following breast surgeries is very painful, especially in the first few days. In addition to promoting early ambulation and hospital release, providing enough analgesia for acute postoperative pain can enhance functional outcomes and stop the onset of chronic pain. For the effective relief of initial postoperative pain following MRM surgery, a wide range of IV and oral pharmaceutical alternatives, including opioids, nonsteroidal anti-inflammatory medications (NSAIDs), acetaminophen, etc., are available. Each of these medications has unique benefits and drawbacks, limiting the extent to which they can be used universally. Multimodal pain management strategies that take advantage of the current pharmacological choices have shown to improve pain management while reducing the need for opioids.[3]

The 2016 introduction of the ESP block piqued the curiosity of numerous nerve block specialists. It has been proven to be useful in delivering postoperative analgesia following a variety of operations, including breast surgery. Clonidine's role as an adjuvant in the ESP block for postoperative analgesia following breast operations has been evaluated in a few systematic reviews and metaanalyses that have been published. These assessments, though, were constrained by the inclusion of a scant number of research that qualified. As a result, we designed a trial to determine whether clonidine, in combination with 0.5% ropivacaine, is an effective analgesic after breast surgery.

The present study has enrolled seventy-two female patients, aged between 18 to 65 years, belonging to ASA physical status class I and/or II and scheduled for modified radical mastectomy surgery. Our aim is to determine the efficacy of using clonidine as an adjuvant to 0.5%Ropivacaine in erector spinae plane block for post operative analgesia in breast surgeries.The primary objective is to evaluate the analgesic efficacy of clonidine as an adjuvant in Erector Spinae Plane block in terms of duration of analgesia defined as time to first rescue analgesic(patient demand/VAS greater or equal to 4) after breast surgeries. Secondary objectives include onset of sensory block(Block completion to grade 1 sensory block), number of dermatomes blocked,duration of sensory block(ESP block to Onset of pain), quality of analgesia(Visual Analogue Scale), total analgesic requirement in 24 hr postoperatively,and adverse effects/complications if any.

Thirty-six patients are enrolled in each group. All the patients have received the allocated intervention and have been followed up to 24hours. There is no lost to follow up and all the patient's data are analysed as per the randomized group.

PATIENT DEMOGRAPHICS

Age

In our study, mean age of patients of both groups are compared and no statistically significant difference has been found between them(P>0.05).

Body weight

In our study,mean body weight of patients of both groups are compared and no statistically significant difference has been found between them(P>0.05).

Height

In our study,mean height of patients of both groups are compared and no statistically significant difference has been found between them(P>0.05).

PRIMARY OBJECTIVE

Time to first rescue analgesic(patient demand/VAS greater or equal to 4)

In our study, median time to first rescue analgesic is 16 hours in RC and 9 hours in R group. p-value is 0.400 as found in Mann-Whitney U test and 0.925 as found in Chi-square test. This suggests no significant difference in the duration of analgesia defined as time to first rescue analgesic between patients who received clonidine as adjuvant to 0.5% ropivacaine and patients who received 0.5% ropivacaine alone. Studies done by Kalyani *et al*, Daniel M.*et al* and Kelika *et al* contradict our finding.

Kalyani *et al*[10] conducted a RCT on 60 adult patients posted for upper limb surgeries under single shot supraclavicular block by dividing them into two groups,one receiving clonidine along with 0.75% Ropivacaine and the other receiving 0.75% Ropivacaine alone and found that the duration of analgesia was prolonged in patients receiving clonidine (878.33 ± 89.955 min), than the group who didn't receive clonidine(613.10 ± 51.797 min).

Daniel M.*et al* [11] conducted a RCT on 1054 adult patients posted for surgeries without general anaesthesia(solely on peripheral nerve blocks), in which test group(573 patients) were

given single shot local anaesthetic with clonidine and local anaesthetic alone for the control group(481 patients).In controls, duration of postoperative analgesia(time to first rescue analgesic) was on average 461 min (range, 128 to 1,151 min). Clonidine significantly increased the duration(586min) (95% CI 74–169; P < 0.001).

Kelika *et al* [12] conducted a study on ninety adult patients posted for upper limb orthopedic surgery under supraclavicular brachial plexus block and were divided into two groups. Test group received clonidine as adjuvant with 0.5% bupivacaine and the other group received tramadol as adjuvant. The time for rescue analgesia was the longest in patients who received clonidine (491.8 ± 33.9 min) whereas for tramadol it was (313.3 ± 21.4 min),which was statistically significant (P < 0.001).

We also observed increased time to first rescue analgesic and reduced number of rescue analgesic in few of our patients but the difference was not statistically significant. One of the reasons could be that in benefit has been observed in peripheral nerve blocks as in the above mentioned studies whereas in facial plane blocks such as ESP volume of drug is more important than the role of adjuvants. Not only the role of adjuvant has been debatable but studies have also shown that varying concentration of local anaesthetic does not have an effect on postoperative analgesia. One such study the effectiveness of two different concentrations of ropivacaine (0.5% versus 0.2%) given via transverse abdominis plane (TAP) block was comparable in providing postoperative analgesia for patients undergoing appendectomy.[40]

SECONDARY OBJECTIVES

Onset of sensory block(Block completion to Grade 1 sensory block)

In our study, there is no statistically significant difference between time to sensory block onset of RC and the R group(P-value 0.513).This suggests that the onset of sensory block is similar in patients receiving Clonidine as adjuvant to 0.5% ropivacaine and in patients receiving ropivacaine alone. But the studies conducted by Daniel M et al, Kelika et al, and Anil *et al* contradicts our finding on onset of sensory block.

Daniel M.*et al* [11] conducted a RCT on 1054 adult patients posted for surgeries without general anaesthesia(solely on peripheral nerve blocks), in which test group(573 patients) were given single shot local anaesthetic with clonidine and local anaesthetic alone for the control

group(481 patients).In controls, average time to onset of sensory block was 15 min (range, 4–26). Clonidine significantly shortened that time;(12.5 min) (95% CI –4.1 to –0.4; P 0.02).

Kelika *et al* [12] conducted a study on ninety adult patients posted for upper limb orthopedic surgery under supraclavicular brachial plexus block and were divided into two groups. Test group received clonidine as adjuvant with 0.5% bupivacaine and the other group received tramadol as adjuvant.Patients who received clonidine had the shortest time for the onset of blockade, i.e. (396.0 ± 60.2 s) with a $P < 0.01$.The difference in the onset time was statistically significant between the two groups.

Anil *et al* [13] conducted a RCT on twenty-four patients posted for upper extremity surgery under ultrasound-guided axillary brachial plexus block (ABPB) with 20 mL of lidocaine 2% with 1:200,000 epinephrine plus 2 mL of either normal saline 0.9% (Group 1) or a mixture of clonidine 1 µg/kg and normal saline 0.9% (Group 2).The median (IQR) overall onset time of sensory block was significantly shorter in Group 2 vs. Group 1 (5 (5–7.5) min vs. 10 (8.8–12.5) min; $p < 0.001$) and (5 (2.5–7.5) min vs. 7.5 (6.3–7.5) min; $p = 0.001$), respectively. So, the addition of clonidine to lidocaine with epinephrine resulted in shorter onset time.

Number of dermatomes blocked

In our study, there is no statistically significant difference between number of dermatomes blocked, of RC and R group(P-value 0.606).This suggests that the mean number of dermatomes blocked is similar in patients receiving Clonidine as adjuvant to 0.5% ropivacaine and in patients receiving ropivacaine alone. One of the probable reasons could be that in fascial plane blocks such as ESP volume of drug is more important than the role of adjuvants.

Duration of sensory block(ESP block to onset of pain)

In our study,six patients RC group and twelve patients in R group complained of pain(VAS greater or equal to 4) requiring rescue analgesic.In RC group, earliest time point when patient complained of pain is 8hours and for R group is 3hours in postoperative period. This suggests that duration of sensory block (defined as time of ESP block application to onset of pain) in patients who received clonidine as adjuvant to 0.5% ropivacaine compared to patients who received 0.5% ropivacaine alone is statistically insignificant. Hence, the duration of sensory block is comparable between the two groups. Kalyani *et al,*Daniel M.*et al,* Kelika *et al,* Duma *et al* and Anil *et al* also came to the same conclusion in their studies.

Kalyani *et al*[10] conducted a RCT on 60 adult patients posted for upper limb surgeries under single shot supraclavicular block by dividing them into two groups,one receiving clonidine along with 0.75% Ropivacaine and the other receiving 0.75% Ropivacaine alone and found that the duration of sensory block was (703.83 ± 42.90) min in clonidine group when compared to (556.38 ± 37.96) min in control group.

Daniel M.*et al* [11] conducted a RCT on 1054 adult patients posted for surgeries without general anaesthesia(solely on peripheral nerve blocks), in which test group(573 patients) were given single shot local anaesthetic with clonidine and local anaesthetic alone for the control group(481 patients).In controls, the average duration of sensory block was 269\min. Clonidine significantly prolonged the duration(350min) (95% CI 37–111; P < 0.001).

Duma *et al* [14] conducted a RCT on forty adult patients who were given axillary brachial plexus block,in which twenty patients of test group was given 0.5% levobupivacaine with clonidine and the other group was given levobupivacaine alone. It was found that the levobupivacaine-clonidine group appeared to have a significantly longer duration of sensory block than the other group 1340(606–2074) min in the levobupivacaine-clonidine group and 1065(912–1218) min in the levobupivacaine group.

Kelika *et al* [12] conducted a study on ninety adult patients posted for upper limb orthopedic surgery under supraclavicular brachial plexus block and were divided into two groups.Test group received clonidine as adjuvant with 0.5% bupivacaine and the other group received tramadol as adjuvant.The duration of sensory block was 320min in test group whereas it was 250min in control group,which was statistically significant.

Anil *et al* [13] conducted a RCT on twenty-four patients posted for upper extremity surgery under ultrasound-guided axillary brachial plexus block (ABPB) with 20 mL of lidocaine 2% with 1:200,000 epinephrine plus 2 mL of either normal saline 0.9% (Group 1) or a mixture of clonidine 1 µg/kg and normal saline 0.9% (Group 2).The median (IQR) overall duration of sensory and motor block was signifificantly longer in Group 2 vs. Group 1 (225 (200–231) min vs. 168 (148–190) min; p < 0.001) and (225 (208–231) min vs. 168(148–186) min; p < 0.001), respectively.So,the addition of clonidine to lidocaine with epinephrine resulted in prolonged duration of sensory block.

Quality of analgesia(Visual Analogue Scale)

In our study, the difference between resting VAS scores of RC and R groups has been found to be statistically significant at 90minutes postoperatively($P<0.05$) but is insignificant at rest of the major time points. Although VAS(resting) at 90 minutes is significant statistically, but is insignificant clinically(Mean VAS at 90mins being 2.1 and 2.9 for RC and R groups respectively), as they are beyond the criteria to administer rescue analgesic(VAS greater or equal to 4).This suggests that clonidine as adjuvant has no significant effect on the quality of analgesia. Study done by Yogesh *et al* contradicts our finding.

Yogesh *et al* [15] conducted a study on ninety adult patients undergoing elective upper limb surgeries under supraclavicular block divided into three groups: Group N: Received injection bupivacaine 0.5% 15 ml + injection. Lignocaine with adrenaline 2% 15 ml + normal saline 0.5 ml. Group D: 1 µg/kg dexmedetomidine. Group C: 1.5 µg/kg clonidine as studied drug in place of normal saline. VAS score in the post-operative period at 6hours was higher in Group N (5.12 ± 0.68) when compared to Group C (4.5 ± 0.73) and Group D (2.07 ± 0.94), respectively. So,the addition of Clonidine proved to have better patient satisfaction than bupivacaine alone.

Total analgesic requirement in 24 hr postoperatively

In our study, the total analgesic requirement in the group receiving clonidine as adjuvant is the same as the group receiving ropivacaine alone. Six patients in RC group and twelve patients in R group required rescue analgesic. The number of patients requiring rescue analgesic in Group R is twice the number of patients requiring rescue analgesic in RC group but the difference between both the groups is statistically insignificant ($p>0.05$). Hence there is no significant difference between the total analgesic consumption between both the groups.

Vitals since ESP block application

The comparison of vitals of patients since ESP block application,every five minutes till thirty minutes showed that HR, SBP, DBP and MAP are similar in the test group and control group except for oxygen saturation which was higher in control group(the difference is clinically insignificant as the lowest SPO2 being 98% is well beyond defined safe limits).This suggests that addition of Clonidine to Ropivacaine did not have significant effect on the vitals of the patients since time to ESP block application in our study.

Intraoperative hemodynamics

The comparison of vitals of patients since the start of surgery,after induction,after securing airway,at skin incision,then every fifteen minutes till ninety minutes showed that HR, SBP, DBP and MAP are similar in the test group and control group.This suggests that addition of Clonidine to Ropivacaine did not have significant effect on the intraoperative hemodynamics of the patients in our study.

Adverse effects/complications if any

There has been no adverse effects/complications of ESP block, like hypotension, bradycardia, hematoma, pneumothorax, sedation, nausea, vomitting, dry mouth in both the study groups.

CONCLUSION

There is no effect of addition of Clonidine as an adjuvant to 0.5% Ropivacaine in ESP block on the time to first rescue analgesic, time to sensory block onset, the quality of analgesia, duration od sensory block, number of dermatomes blocked and total analgesic requirement in 24hours. No adverse effects/complications are noted.

STRENGTHS OF OUR STUDY

1. All the blocks were performed by a single anaesthesiologist throughout the study period.
2. All the blocks were performed using ultrasound guidance.
3. Randomization and allocation concealment was strictly followed throughout the study.

LIMITATIONS OF OUR STUDY

1. We could not assess the other benefits of adequate pain control (functional outcome, early ambulation, early discharge, and development of chronic pain).
2. Although sample size calculation was based on the data from the published literature and clinically important reasonable assumption, we believe that further studies with multicentric design and large sample size are required to reciprocate the findings of our study.

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ANNEXURES

ANNEXURE – 1

INSTITUTIONAL ETHICS COMMITTEE CERTIFICATE

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/ 3492 **Date: 12/03/2021**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3327**

Project title: **"To evaluate the effect of clonidine as an adjuvant to 0.5% ropivacaine in ESP block for post operative analgesia in breast surgeries: RCT"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.D. Dissertation**
Student Name:	**Dr. Shreya Neogy**
Guide:	**Dr. Bharat Paliwal**
Co-Guide:	**Dr. Manoj Kamal, Dr. Pradeep Bhatia, Dr. Sadik Mohammed & Dr. Rakesh Kumar**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC. On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Basni Phase-2, Jodhpur, Rajasthan-342005; **Website:** www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

ANNEXURE – 2

Informed Consent Form

Title of the project: TO EVALUATE THE EFFECT OF CLONIDINE AS AN ADJUVANT TO 0.5% ROPIVACAINE IN ESP BLOCK FOR POST OPERATIVE ANALGESIA IN BREAST SURGERIES: A RANDOMIZED CONTROLLED TRIAL

Name of the Principal Investigator: Dr.Shreya Neogy

Patient/Volunteer Identification No.:_____

I, _____ S/o or D/o_____

R/o_____

give my full, free, voluntary consent to be a part of the study : 'TO EVALUATE THE EFFECT OF CLONIDINE AS AN ADJUVANT TO 0.5% ROPIVACAINE IN ESP BLOCK FOR POST OPERATIVE ANALGESIA IN BREAST SURGERIES:A RANDOMIZED CONTROLLED TRIAL' the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and I am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by a responsible individual from AIIMS Jodhpur or from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _____ _____

Place: _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____ _____

Place: _____ Signature of Principal Investigator

Witness 1	Witness 2
Signature:_____	**Signature:** _____
Name:_____	**Name:**_____
Address:_____	**Address:**_____

ANNEXURE – 3

ऑल इंडिया इंस्टिट्यूट ऑफ मैडिकल साईंसिस

जोधपुर, राजस्थान

सूचित सहमति पत्र

परियोजना का शीर्षक: TO EVALUATE THE EFFECT OF CLONIDINE AS AN ADJUVANT TO 0.5% ROPIVACAINE IN ESP BLOCK FOR POST OPERATIVE ANALGESIA IN BREAST SURGERIES:A RANDOMIZED CONTROLLED TRIAL

प्रधान अन्वेषकका नाम: Dr.Shreya Neogy

मैं_____ एस/ओयाडी/ओ _____ आर/ओ _____

अध्ययन: EFFECT OF CLONIDINE AS AN ADJUVANT TO 0.5% ROPIVACAINE IN ESP BLOCK FOR POST OPERATIVE ANALGESIA IN BREAST SURGERIES:A RANDOMIZED CONTROLLED TRIAL का एक हिस्सा बनने के लिए मेरी पूर्ण, नि:शुल्क,स्वैच्छिक सहमति, प्रक्रिया और प्रकृति जिसके बारे में मुझे अपनी भाषा में बताया गया है,मैं पुष्टि करता हूं कि मुझे प्रश्न पूछने का अवसर मिला है।

मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और मुझे किसी भी कारण दिए बिना किसी भी समय अध्ययन से बाहर निकलने के मेरे अधिकार की जानकारी है।

मैं समझता हूं कि मेरे और मेरे मेडिकल रिकॉर्ड के बारे में एकत्रित की गई जानकारी को एम्स, जोधपुर या विनियामक प्राधिकरणों से ज़िम्मे व्यक्ति द्वारा देखा जा सकता है। मैं इन लोगों के लिए मेरे रिकॉर्डों तक पहुंच की अनुमति देता हूं

रोगी / पहचानसंख्या: _____

तारीख : _____ _____

जगह: _____

हस्ताक्षर / बाएं अँगूठे का छाप

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त की गई है

तारीख :_____ _____

जगह: _____ प्रधान अन्वेषक के हस्ताक्षर

1. गवाह 1

हस्ताक्षर: _____

नाम :_____

पता :_____

2. गवाह 2

हस्ताक्षर : _____

नाम: _____

पता: _____

ANNEXURE – 4

PATIENT INFORMATION SHEET

1. Risks to the patients: No interventions or life-threatening procedure will be done.
2. Confidentiality: Your participation will be kept confidential. Your medical records will be treated with confidentiality and will be revealed only to doctors/ scientists involved in this study. The results of this study may be published in a scientific journal, but you will not be identified by name.
3. Provision of free treatment for research related injury. Not applicable.
4. Compensation of subjects for disability or death resulting from such injury: Not Applicable
5. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
6. You have complete freedom to participate and to withdraw from research at any time without penalty or loss of benefits to which you would otherwise be entitled.
7. Your participation in the study is optional and voluntary.
8. The copy of the results of the investigations performed will be provided to you for your record.
9. You can withdraw from the project at any time, and this will not affect your subsequent medical treatment or relationship with the treating physician.
10. Any additional expense for the project, other than your regular expenses, will not be charged from you.

ANNEXURE – 5

रोगी सूचना पत्रक

1. रोगियों के लिए जोखिम: कोई हस्तक्षेप या जीवनधमकी प्रक्रिया नहीं की जाएगी।

2. गोपनीयता: आपकी भागीदारी को गोपनीय रखा जाएगा। आपके मेडिकल रिकॉर्ड को गोपनीयता के साथ इलाज किया जाएगा और केवल इस अध्ययन में शामिल डॉक्टरों / वैज्ञानिकों को पता चलेगा। इस अध्ययनके परिणाम एक वैज्ञानिक पत्रिका में प्रकाशित हो सकते हैं, लेकिन आपको नाम से पहचाना नहीं जाएगा।

3. अनुसंधान संबंधी चोट के लिए नि: शुल्क उपचार की व्यवस्था। लागू नहीं।

4. ऐसी चोट से उत्पन्न विकलांगता या मृत्यु के लिए विषयों का मुआवजा: लागू नहीं है

5. किसी भी समय दंड या लाभों के नुकसान के बिना किसी भी समय भाग लेने के लिए व्यक्ति को स्वतंत्रतालेने और अनुसंधान से वापस लेने के लिए स्वतंत्रता, जिसके तहत विषय अन्यथा हकदार होगा

6. आपको जुर्माना या लाभ के नुकसान के बिना किसी भी समय भाग लेने और अनुसंधान से वापस लेने कीपूरी आजादी है, जिस पर आप अन्यथा हकदार होंगे।

7. अध्ययन में आपकी भागीदारी वैकल्पिक और स्वैच्छिक है।

8. प्रदर्शन की जांच की परिणामों की प्रति आपके रिकॉर्ड के लिए आपको उपलब्ध कराई जाएगी।

9. आप किसी भी समय परियोजना से वापस ले सकते हैं, और यह आपके बाद के चिकित्सा उपचार याउपचार चिकित्सक के साथ संबंध को प्रभावित नहीं करेगा।

10. परियोजना के लिए कोई भी अतिरिक्त व्यय, आपके नियमित खर्चों के अलावा, आपसे शुल्क नहीं लियाजाएगा।

ANNEXURE – 6

APPENDIX-III

PROFORMA

All India Institute of Medical Sciences(AIIMS),Jodhpur
Department of Anaesthesiology and Critical Care

Thesis Title: TO EVALUATE THE EFFECT OF CLONIDINE AS AN ADJUVANT TO 0.5%ROPIVACAINE IN ESP BLOCK FOR POST OPERATIVE ANALGESIA IN BREAST SURGERIES:A RANDOMIZED CONTROLLED TRIAL

Date:

Patient's name:

Age:

Registration ID:

Diagnosis:

Time to Sensory block onset:

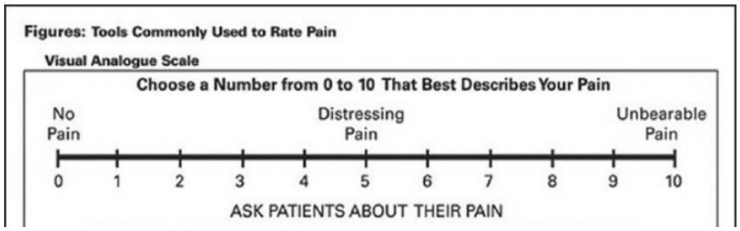
Number of dermatomes blocked:

Time to Block	Pulse	Systolic BP	Diastolic BP	Mean BP	SPO_2	Remark
Baseline						
5 min						
10 min						
15 min						
20 min						
25 min						
30 min						

PATIENT SATISFACTION BY VAS SCORING:

Time	30 min	1 hr	90 min	2 hr	4 hr	6 hr
VAS(R/M)						
Rescue Analgesic (Y/N)						
Remarks						

Time to First rescue analgesic:



Total analgesic in 24 hours:

Complications in 24 hrs:

Intraoperative Hemodynamics				
Time	Heart Rate	Systolic BP	Diastolic BP	Mean BP
Baseline				
After Induction				
After Securing Airway				
At Skin Incision				
15 min				
30 min				
45 min				
1 hr				
75 min				
90 min				

ANNEXURE – 7

MASTER CHART