Comparing the Effect of Adding 8MG Dexamethasone to 0.25% Bupivacaine to Plain bupivacaine 0.25% in Erector Spinae Plain Block in Modified Radical Mastectomy Patients: A Randomized Controlled Study.

Original Article

Jyotsna Guleria[1], Ajay Sood[2], and Chaudhary Usha K[3]

[1] Medical officer, IGMC, Shimla, HP

[2]Department of Anaesthesia, IGMC,Shimla, Himachal Pradesh, India

[3]Department of Anaesthesia, IGMC, Shimla,HP,India

ABSTRACT

Background: Ultrasound guided (USG guided) Erector spinae plane block is a simple, safe regional block being used for carcinoma breast patients posted for Modified Radical Mastectomy(MRM). Nowadays, many adjuvants are added to local anaesthetics to increase the duration of analgesia and make them more effective. As there were no studies on effect of adding dexamethasone as an adjuvant to bupivacaine in erector spinae block in MRM patients, a double blind, randomised controlled study was done in carcinoma breast patients**.**

Purpose of study was to determine the pain free duration postoperatively. secondary outcome was to study total rescue analgesia requirement in 24 hours, Patient satisfaction score and any other side effects like postoperative nausea and vomiting, bradycardia etc. Seventy ASA 1&2 females , diagnosed with carcinoma Breast and posted for elective MRM surgery in age group of 18-65 years were enrolled.Group 1 patients received Ultrasound guided Erector spinae plane block with 20ml Bupivacaine 0.25% plain and Group 2 patients received 20 ml of Bupivacaine 0.25% with 8mg of injection Dexamethasone.

Results: Group 2 had longer pain free duration (17 ± 6.18 hours) compared to Group 1 (6.97 ± 4.01 hours) (*p value*=0.0001). In Group 2: Tramadol consumption as rescue analgesia was lesser, lower incidence of Postoperative nausea and vomiting, better patient satisfaction score compared to Group 1. Haemodynamic stability was comparable in both groups.

Conclusions: Adding dexamethasone to local anaesthetics decreases consumption of rescue analgesia or opioids and increases the duration of analgesic effect of ESP block.

Key Words: Erector spinae plane(ESP) block, dexamethasone, modified Radical mastectomy (MRM),

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Corresponding Author: Usha Kumari Chaudhary, MD, Department of Anaesthesia, IGMC, Shimla, HP,India,
Tel.: +919459301813, **E-mail:** chaudhary.ushaarvind@gmail.com

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Background

Breast cancer is the most common type of cancer diagnosed in women, accounting for more than 1 in 10 new cancer diagnosis each year[1]. The modern approach to breast cancer management is multidisciplinary which includes surgery, radiotherapy, hormonal therapy, and chemotherapy. Most commonly performed surgery is Modified Radical Mastectomy(MRM)[2].

There are various techniques of regional anaesthesia for relieving postmastectomy pain. Thoracic epidural anaesthesia, intercostal nerve block, paravertebral block, serratus anterior block, erector spinae plane block and pectoral nerve 1&2 blocks are the options available.

Ultrasound guided Erector Spinae Plane block (USG guided ESP block) is newly diagnosed simple and effective regional block. Here, local anaesthetic drug is deposited deep to the erector spinae muscle. It results in blockade of ventral and dorsal rami of multiple thoracic spinal nerves after the drug diffuses to paravertebral space. Erector spinae plane is larger, thus providing extensive craniocaudal spread. ESP block is easy to perform, non-time consuming because of its simple and clear sonoanatomy[3].

To improve the duration of local anaesthetic and quality of anaesthesia, various adjuncts like clonidine, dexmedetomidine, opioids, dexamethasone, soda bicarbonate have been added.

Dexamethasone has anti-inflammatory action and

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tendency to block the potassium channel mediated discharge of C-fibres. Due to this property, it has shown to prolong the duration of sensory and motor blockade[4]. It has also shown to reduce the postoperative nausea and vomiting events[5] So, we decided to add dexamethasone as an adjunct to bupivacaine to see its the effects on the characteristics of block . The aim was to study the effect of adding 8mg inj. Dexamethasone and to 0.25% bupivacaine and to compare it with 0.25% plain bupivacaine in erector spinae block for modified radical mastectomy surgery.

The Pain free duration, total rescue analgesia requirement in 24 hours, Patient satisfaction score and any other side effects postoperative nausea and vomiting, Bradycardia etc. were observed.

METHODS

This double blind, randomized controlled study was planned in a a Tertiary care centre Department of Anaesthesia, after taking approval of Institutional Ethics Committee and registration with Clinical Trials Registry of India (CTRI/2022/01/039733) on 27/01/2022. First patient was enrolled on 27/1/2022 and accomplished last enrollement on 6/10/2022 . Seventy females, of American Society of Anaesthesiology (ASA) physical status I & II, between age group of 18-65 years, who were diagnosed with carcinoma Breast and posted for elective MRM surgery, were enrolled in the study. Patients who refused to give consent or had uncontrolled hypertension, hypotension, bradycardia (HR<50bpm), were allergic to any of the drugs to be used in the study, bleeding diathesis and BMI > 30kg/m2 were excluded from the study.

After taking written informed consent, patients were randomized into one of the groups according to computer generated permuted block random numbers. The random numbers were put in a sealed opaque white envelopes and envelope was opened on the day of surgery.

Group 1 Patients received Ultrasound Guided ESP Block with 20ml Bupivacaine 0.25% plain (10ml0.5% bupivacaine +10 ml of NS) on the operating side.

Group 2 Patients received Ultrasound Guided Erector spinae plane block with 20 ml of Bupivacaine 0.25% + 8mg of injection Dexamethasone (10ml of 0.5% bupivacaine+2ml dexamethasone +8ml normal saline) on the side to be operated upon.

Anesthetic protocol

The patients enrolled to the study were admitted to the hospital one day before the surgery, pre-anesthetic check-up was done and the procedure was explained to the patient. The patients were also explained about VAS score .The patients were kept, nil per oral after mid-night and tablet ranitidine 150mg and tabl*et al*prazolam 0.25mg were given at 10PM, the night before surgery and 6 AM on the day of surgery, according to the institutional protocol. On the day of surgery, patient was taken into the operating room & all the monitors were attached including 5 lead echocardiography (ECG), SpO2, NIBP (non-invasive blood pressure) and temperature monitoring. An 18-gauge cannula was secured on the hand opposite to operating side and 0.9% Normal Saline was given. Patient was given intravenous inj. Fentanyl 1microgm/kg. The drugs were prepared by an anaesthetist who was not participating in the study and labelled as test drug.The block was given by an expert anaesthetist, who was blind to the drug given and the patient also did not know the drug given.

The USG guided Erector spinae block was given using a linear Ultrasound probe of high frequency (6-13 MHz, Sonosite M Turbo) with patient in sitting position and under all aseptic techniques, C7 spine was palpated up to T4 and point was marked. The transducer was placed 3cm lateral to T4 spinous process and Trapezius, Rhomboid major and erector spinae muscles were identified from outwards to inwards. A 22-gauge spinal needle was inserted with in-plane approach from cranial to caudal direction till the tip reaches fascial plane between erector spinae muscle and transverse process. The position was confirmed by injecting 2ml of normal saline to see for hydro dissection. Once confirmed, total 20ml of test drug was injected with intermittent aspiration.

After completion of block, patient was positioned in supine and was preoxygenated, induced with Fentanyl 1micro gm/kg and Propofol 2-2.5mg/kg. After confirmation of ventilation, injection atracurium 0.5mg/kg was given and trachea was intubated. Intraoperatively, anesthesia was maintained with 33% O2+66%N2O+Isoflurane to maintain adequate MAC. Patient was given IV inj. ondansetron 0.1mg/kg and inj. diclofenac 1.5mg/kg. Intraoperatively patient was monitored for HR, SBP, DBP, MAP, EtCO2 and temperature monitoring.

After completion of procedure, muscle relaxant was reversed followed by extubation, patient was shifted to Post anaesthesia care unit, and watched for pain through 11point VAS score (0 to 10). The patient was given rescue analgesia in the form of injection tramadol 100 mg if VAS(Visual Analogue Scale) score was >4. Inj. Tramadol 100mg was planned to be repeated subsequently if at any time in the postoperative monitoring period the patient again had a VAS >4, provided there was a gap of 8 hours between the two doses. The time to first rescue analgesia and total rescue analgesia needed in 24 hours was noted. Patients were assessed at 0 hour, 1hour, 2hour, 3hour, 4hour, 6hour, 12hour, 24hour post-surgery. Time 0 hour was the time taken, when patient was shifted to Post anaesthesia care unit . Any other side effects, like postoperative nausea and vomiting, hypotension, bradycardia were also checked. The incidence and severity of nausea and vomiting was assessed by four-point categorical scale (0 = no nausea; 1 = nausea present, no vomiting; 2 = nausea

present, vomiting present, and 3 = vomiting >2 episodes). Patient's satisfaction with the technique was assessed at 24 h after operation on an 11-point satisfaction score (0 = unsatisfied, 10 = most satisfied).

Sample size calculation was done based on a study by Basak Altiparmak[6] *et al*, 2019; 71.4% of the patients who were given Erector spinae plane block, with 0.25% Bupivacaine needed Rescue Analgesia. By assuming that by adding 8mg Dexamethasone along with 0.25% Bupivacaine, there occurs 50% decrease in requirement of Rescue Analgesia, with 95% two-sided confidence level, 80% power of study, with equal number of patients in each group. Sample size came out to be 70 (35 in each group).

The quantitative data with normal distribution were presented as the means ± SD and the data with non-normal distribution as median with 25th and 75th percentiles (interquartile range). The data normality was checked by using Kolmogorov-Smirnov test. The cases in which the data was not normal, we used non parametric tests. The following statistical tests were applied for the results:

The comparison of the variables which were quantitative and not normally distributed in nature were analysed using Mann-Whitney Test (for two groups) and variables which were quantitative and normally distributed in nature were analysed using Independent t test.

The comparison of the variables which were qualitative in nature were analysed using Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used.

The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 25.0. For statistical significance, *p value* of less than 0.05 was considered statistically significant

RESULTS

The demographic data was comparable as regards to age, sex, ASA physical status and BMI in both the groups. The duration of surgery was also comparable in both the groups.The demographic data was comparable as regards to age, sex, ASA physical status and BMI in both the groups. The duration of surgery was also comparable in both the groups. The baseline vitals SBP, DBP, MAP, Heart Rate and SpO2 were comparable in both the groups and were within the normal range (Table 1, Figure 1).

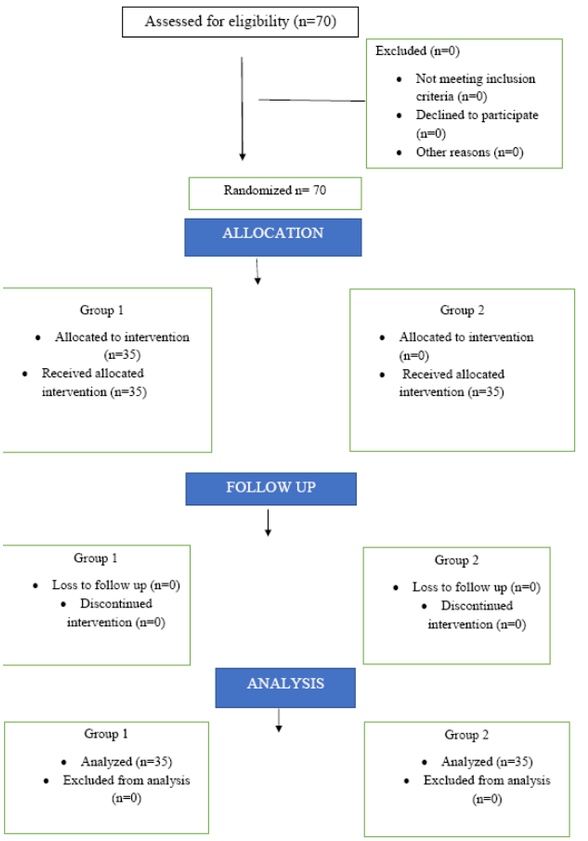

Fig. 1: Flow chart of patients Recruited and Analyzed in Two Groups

Table 1: demographic data

Variable	Group 1(n=35)	Group 2(n=35)	*p value*
Age (years)	51.49 ± 8.85	50.29 ± 8.92	0.574
ASA status 1/2*	30/5	31/4	1
Relevant history* No/HIV positive/ Hypertension/ Hypothyroidism/Type 2 Diabetes mellitus	29/1/2/2/1	31/0/3/1/0	0.81
Duration of surgery(min.)	85 ± 21.86	80.71 ± 14.56	0.338

Value expressed as Mean±SD*Fisher's exact test

The VAS scoring was done after the patient was shifted to PACU after extubation, where time 0 hour was the time when the patient was shifted to PACU. There was significant difference seen in post-operative VAS score at 0 hours, 1 hour, 2 hour, 3 hour (VAS < 4) on an average between both the groups except at 4 hours & 6 hours in group 1(Figure 2).

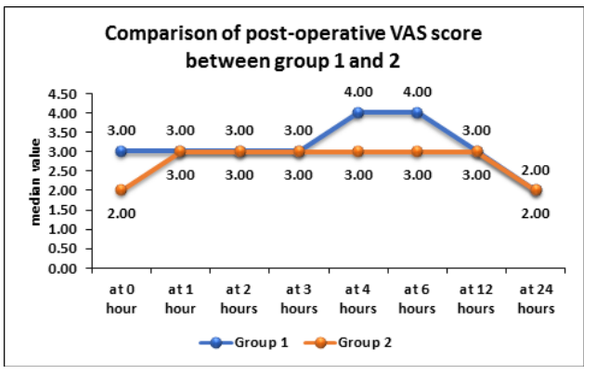

Fig. 2: Comparison of trend of post-operative VAS score at different time intervals between group 1 and 2.

Was no significant difference seen in post-operative VAS score at 12 hours (*p value*=0.317) and at 24 hours *(p value*=0.215) between group 1 and 2.

None of the patients required rescue analgesia at 0-hour, 1 hour, 2 hours and 3 hours in both groups (Figure 3). Proportion of patients who required rescue analgesia at 4 hours & 6 hours was significantly higher in group 1 as compared to group 2. [At 4 hours, 28.57% vs 0% respectively (*p value*=0.0009), At 6 hours, 48.57% vs 0% respectively (*p value*=0.198)]

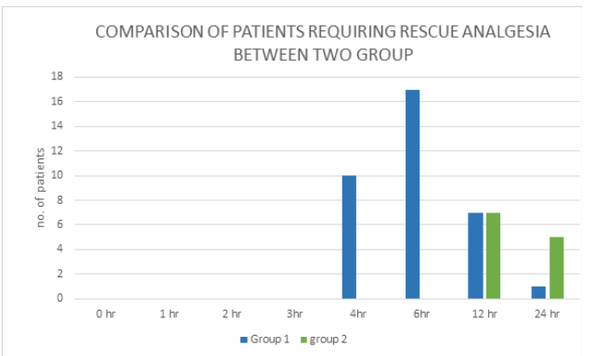

Fig .3: Rescue analgesia requirement in study subject among various groups.

Time to first rescue analgesia was the time elapsed between the shifting of patient to PACU and the first rescue analgesic given when patient complained of pain with VAS > 4. Time for first rescue analgesia (Table 2) in group 2 was 17 ± 6.18 hours which was significantly higher as compared to group 1 (6.97 ± 4.01 hours) (*p value*=0.0001).

All the 35 patients in group 1 required only one top up of inj. tramadol 100mg in 24 hours, bringing the total consumption to 35, whereas in group 2, only 12 patients required single top up of inj tramadol 100mg in 24 hours, making a total consumption of 1200mg. This total consumption was statistically significant and more in group 1 patients, compared to group 2 patients. (*p value* <0.0001).

Table 2: Comparison of time to first rescue analgesia(hours) between group1and 2.

Time for first rescue analgesia(hours)	Group 1(n=35)	Group 2(n=12)	*P value*
Mean ± SD	6.97 ± 4.01	17 ± 6.18	0.0001*

Independent t test*Values* expressed as Mean ± SD*Indicates *p value* <0.05

Postoperatively, 8 patients of group 1 had nausea, which was significantly higher than group 2 patients(*p*=0.005). None of the groups had severe nausea and vomiting, so no intervention was required.

Patient satisfaction related to postoperative analgesia was assessed by 11-point satisfaction score (0=unsatisfied and 10=most satisfied). Maximum patients in group 2, had rated the satisfactory pain relief after the block administration with a scale of 9 or more than 9, compared to group 1. Patient satisfaction score in 24 hours was 9.97±0.17 in group 2, which was significantly higher as compared to 8.69±1.39 in group 2 (Figure 4).

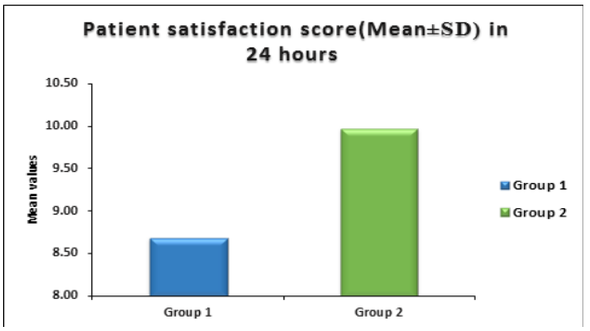

Fig. 4: Comparison of patient satisfaction score in 24 hours between group 1 and 2

There was no significant difference between the two groups regarding post-operative heart rate and mean blood pressure (Figures 5,6)

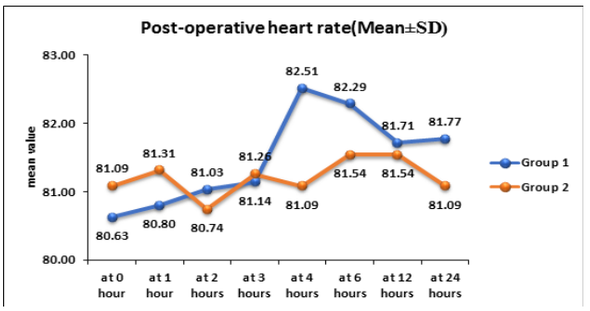

Fig. 5: Comparison of trend of post-operative heart rate (beats per minute) at different time intervals between group 1 and 2.

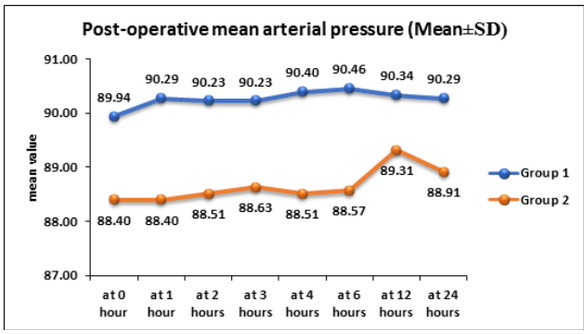

Fig. 6: Comparison of Postoperative Mean arterial pressure (mmhg)

DISCUSSION

Erector spinae plane blocks are gaining increased recognition for an efficacious thoracic analgesia.

The longer length of erector spinae plane because of erector spinae muscle running along the length of thoracolumbar spine, provides extensive craniocaudal spread of the local anaesthetic drug. Sensory block is provided to multi dermatomal levels across the posterior, lateral and anterior thoracic wall. The local anaesthetic diffuses to the paravertebral space, acts on both ventral and dorsal rami of the thoracic spinal nerves, in addition to the rami communicans of the sympathetic chain causing the analgesic effect.3 Thus, ESP block provides good analgesic effect as depicted significantly by the study.It also, does not alter the haemodynamic parameters. In a study by Singh S *et al*[3], there were no changes with respect to HR, SPO2 and MAP in perioperative period in patients receiving ESP block.

We therefore, planned a study to compare the effect of adding 8mg dexamethasone to 0.25% plain Bupivacaine in ESP block in patients undergoing modified radical mastectomy. We hypothesised that adding dexamethasone will prolong the pain free duration and will reduce the requirement of rescue analgesia.

In our study, mean postoperative VAS score was significantly lower in group 2 at 0, 1st hr, 2nd hr, 3rd hour, 4th hour and 6th hour as compared to group 1. But in both the groups VAS score was <4 except in group 1, where it was >4 at 4 hours and 6 hours. So, rescue analgesia was required to more patients at 4 and 6 hours, in group 1 patients.

Our results are in accordance with the study conducted by Farahata TE-M *et al*[7], in which unilateral ESP block was given for total hip arthroplasty. The VAS scores in Dexamethasone group were lower at 6 hours (1.31±0.74 vs 2.74±1.211; p<0.001), 8 hours (2.00±0.93 vs 3.07±1.156; p<0.001), 12 hours (2.38±0.98 vs 3.21±1.025; p<0.001),16 hours (3.79±1.20 vs 4.93±1.421; p<0.001), and 24 hours (3.50±1.27 vs 4.43±1.500; p=0.003) postoperatively when compared to plain Levobupivacaine in first group. The addition of Dexamethasone to bupivacaine in ESP block in group 2 improved the VAS score throughout the postoperative period.

In our study, the patients who received dexamethasone in ESP block required less rescue analgesia indicating that dexamethasone has efficacious synergistic effect with local anaesthetics, analgesic property and this can be due to its anti-inflammatory action. In our study, time for first rescue analgesia was prolonged in group 2 compared to group 1 (p *value* = 0.0001) concluding that dexamethasone increases the period for requirement of first rescue analgesia.

These results were in accordance with the results of another study conducted by Farahata TE-M *et al*[7], where patients received ESP block for total hip arthroplasty. In his study, there was a significant delay in demand for first rescue analgesia in the Dexamethasone group (13.07±4.105 hours) compared to group receiving plane 0.5% levobupivacaine (6.79±2.040 hours) with p-value <0.001. The time to rescue analgesia was 13.07±4.105 hour in this study compared to 17±6.18 hour in our study. This difference in time could be due to use of 4 mg dexamethasone by him compared to 8mg dexamethasone in our study.

Total consumption of rescue analgesia was 3500mg in group 1, with all the 35 patients requiring only one dose of inj. tramadol 100mg, that is single top up, in 24 hours. Whereas in group 2, only 12 patients required one top up of inj. tramadol 100mg in 24 hours, requiring total of 1200mg. In a similar study conducted by Ammar AS and Mahmoud KM,[8] lesser morphine requirements was observed in dexamethasone group [4.9(0-8.0) vs. 21.2 (12.0-27.3) mg, p=0.003] as compared to plain bupivacaine group during 48 hours of postoperative period.

Thus, adding dexamethasone to local anaesthetics decreases the consumption of rescue analgesia or opioids, by increasing the duration of analgesic effect of ESP block.

The results of above studies prove that adding dexamethasone to local anaesthetics is an effective and safe strategy. It binds to glucocorticoid receptors, inhibits potassium conductance and thus, reduces stimulus transmission in unmyelinated c-fibres which carry nociceptive information. Moreover, dexamethasone causes a degree of vasoconstriction to the tissues, and local anaesthetic will have slower uptake and absorption, thus prolonging its duration.[9] So, Dexamethasone as an adjuvant to local anaesthetic has been added in many peripheral nerve blocks for prolongation of analgesia.

In our study, no patient complained of nausea and vomiting in group 2(22.86% vs 0% respectively). PONV was significantly higher in group 1 compared to group 2. Our results are supported by the study conducted by Kumar V *et al*,[10] in which he used dexamethasone as an adjuvant to ropivacaine in serratus anterior plane block. The nausea and vomiting scores were significantly higher in group

receiving plain ropivacaine at 2 hours (10/30 patients) and 12 hours (9/30 patients) as compared to dexamethasone group (2/30 patients and 1/30 patients; p=0.02, p=0.01 respectively).

This property of dexamethasone preventing nausea and vomiting, is believed to be because of various mechanisms ranging from their anti-inflammatory effect to regulation of hypothalamic-pituitary-adrenal axis. It also acts directly at the solitary tract nucleus, interact with neurotransmitter serotonin, and receptor proteins, tachykinin NK1 and NK2, alpha-adrenaline, etc. it also reduces pain, and the concomitant use of opioids thus further reducing chances of postoperative nausea and vomiting[11].

The better satisfaction in group 2 was due to the better pain relief, as most of the patients were pain free even after 24 hours, there was no breakthrough pain. The VAS scores of <4, not only improved postoperative outcome, but also helped patients with early mobilisation and physiotherapy, easy healing, and early discharge from hospital. So, patients were more satisfied with the addition of dexamethasone to the ESP block.

CONCLUSIONS

We recommend that adding Dexamethasone to the bupivacaine in ESP Block for MRM results in prolonged pain free period, better pain relief, less PONV and the better patient satisfaction scores.

Limitations:The limitation of the study is lesser sample size. We could follow up the patients for more than 24 hours, to know maximum analgesia duration. Dexamethasone, due to its systemic absorption can cause delayed wound healing, hyperglycemia, adrenal suppression, which was not evaluated.

LIST OF ABBREVIATION

(ASA): American Society of Anaesthesia, **(BMI):** Body Mass Index, **(ICBN):** intercostobrachial nerve, **(ESP) block:** Erector spinae plane block, **(ECG):** echocardiography, **(MAC):** Minimum Alveolar Concentration, **(MRM):** Modified Radical Mastectomy, **(NIBP):** non-invasive blood pressure, **(PONV):** Post Operastive Nausea Vomiting, **(PPMP):** Persistent Post-Mastectomy Pain, **(SpO2):** Saturation of Oxygen in peripheral blood, **(USG):** ultrasonography, **(VAS):** visual Analogue Scale.

CONFLICT OF INTERESTS

There are no conflicts of interest

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