

# The Analgesic Effect of Dexamethasone and Magnesium Sulphate (MgSO<sub>4</sub>) as an adjuvant to 0.25% Bupivacaine in ultrasound guided Pectoral Nerve Block (PEC Block) for unilateral Modified Radical Mastectomy: A Comparative Study

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## Abstract

**Background:** Postoperative pain following unilateral modified radical mastectomy (MRM) has been managed with Pectoral nerve block (PEC block). Several initiatives are ongoing to get the effective and safe way of prolongation analgesic effect postoperatively. Therefore, many types of adjuvants are adding to the local anaesthetic agents to prolong their analgesic effect. In this study either dexamethasone or magnesium sulphate (MgSO<sub>4</sub>) has added as an adjuvant to 0.25% bupivacaine in pectoral plane block (PEC block) for unilateral modified radical mastectomy. Here we observed which of the adjuvant would prolong the analgesic effect of 0.25% bupivacaine.

**Methods:** This randomized controlled trial was conducted at the Department of Anaesthesia, Analgesia, Palliative and Intensive Care Medicine, Dhaka Medical College following approval of the ethical committee. These patients were selected from the department of General Surgery, Dhaka Medical College during pre-anaesthetic checkup periods. Total 50 patients were scheduled for modified radical mastectomy and divided into Group A and Group B (each group contain 25 patients). The patients of the both groups were given pectoral plane block under ultrasound guide with 0.25% bupivacaine. The patients of Group A received magnesium sulphate 150 mg and Group B received dexamethasone 10 mg as an adjuvant to 0.25% bupivacaine. Pectoral nerve block was performed before induction of general anaesthesia and onset of sensory block was assessed among the both groups. All patients were observed peri-operatively and data were recorded into the data collection form. Finally, data was analyzed by SPSS version 22.

**Observation and Results:** Socio-demographic profile were similar among the both groups ( $p > 0.05$ ). No significant difference was noted in terms of ASA score and BMI ( $p > 0.05$ ). Mean duration of the analgesia (min) and time requirement of rescue analgesic therapy were significantly higher in dexamethasone group ( $p < 0.05$ ) than MgSO<sub>4</sub> group. Post-operative requirement of pethidine (72.5±8.5 vs 55.2±5.4 mg;  $p < 0.045$ ) was also higher in MgSO<sub>4</sub> group. Side effects profile like nausea and vomiting also significantly small in dexamethasone (4%) group than people received MgSO<sub>4</sub> group (20%) ( $p < 0.05$ ).

**Conclusion:** Use of dexamethasone in comparison to MgSO<sub>4</sub> as an adjuvant to bupivacaine could prolong analgesia in postoperative period for pectoral plane block in unilateral modified radical mastectomy.

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**Keywords:** Dexamethasone, Magnesium Sulphate, Radical Mastectomy

## Introduction

Postoperative pain management is always concern for an anaesthesiologist. An anaesthesiologist has to overcome acute pain during post-operative period for the patient who undergoing massive surgery.<sup>1</sup> Breast surgery is such a surgery which cause severe acute postoperative pain arises from injured skin, muscles and nerve. That is a consistent risk factor for converting in chronic pain in association with its severity.<sup>2</sup> The management of acute postoperative pain is required not only for patient's satisfaction but for better outcomes and

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early mobilization of patients. The regional analgesic techniques are regarded as the best choice to reduce acute post-operative pain.<sup>3</sup> Postoperative pain management after breast surgery can be done with varieties of regional techniques such as thoracic paravertebral block (TPVB), thoracic segmental epidural block (TEB), intercostal nerves block.<sup>4</sup> These techniques may also be used for anaesthesia as well as in the managing postoperative pain. Wahba *et al.*, 2014 compared the analgesic effect and opioid consumption of PEC block with TPVB in women undergoing modified radical mastectomy.<sup>5</sup> Overall they observed that within 24 h after surgery patients treated with PEC block consumed a significantly smaller amount of opioid compared to those in the TPVB group; moreover the time for first request of opioid was longer in the PEC group. In 2011 the pectoral nerve block which is a less invasive new technique described by Blanco *et al.*<sup>6</sup> PEC block is the myofascial plane block. The PEC block is less invasive and has fewer complications as compared to the other procedures mention above. It is a novel superficial nerve block, alternative to neuraxial and paravertebral blocks which provides good analgesia during and after breast surgery such as modified radical mastectomy.

Various adjuvants have been used to improve the quality and to increase the duration of the local anaesthetic action in different peripheral nerves and regional block techniques including NMDA antagonists (ketamine, magnesium), GABA agonists (midazolam), adrenergic agonists (clonidine, adrenaline), COX inhibitors (ketorolac), steroid (Dexamethasone ) and Ach esterase inhibitors (neostigmine) etc. Dexamethasone is a glucocorticoid with known potent long-acting effects. It may reduce pain and

the inflammatory response to tissue damage after surgery.<sup>7,8</sup> In people who receive nerve block with additional additional dexamethasone to the local anaesthetic agents around the nerve (perineural or fascial plane), has shown prolonged pain relief from the peripheral nerve block. When combined with local anaesthetics agents dexamethasone could prolonged their duration by preventing the propagation of pain signals along the myelinated C fibres.<sup>9</sup>

Magnesium sulfate has been shown to prolong the effect of local anaesthetics when used as an adjuvant in nerve blocks techniques.<sup>10</sup> Magnesium, a cation existing inside the cell whose quantities are second only to potassium, acts as a physiological calcium antagonist. Effect of Magnesium as N-methyl-D-aspartate (NMDA) receptor antagonism and sympathetic blocking have been noted. Magnesium is now used to help reduce the consumption of anaesthetics and pain medications. Lee *et al*, 2012 also reviewed that magnesium blocks the effects of excitatory amino acids (e.g. glutamate, aspartate) on NMDA receptors and thus contributes to prevention of central pain sensitization.<sup>10</sup>

In this study we added dexamethasone or magnesium sulphate as an adjuvant for pectoral nerve block in unilateral modified radical mastectomy. We assessed which of the adjuvant either Dexamethasone or Magnesium Sulphate could capable of prolonging the analgesic effect of bupivacaine in postoperative period in PEC block. By this way we could able to compare among the two adjuvants in aspect of duration of analgesia, rescue analgesia, postoperative pethidine requirement, patient's satisfaction and their side-effects. This would help us to choose better adjuvant for bupivacaine in PEC Block for postoperative pain management and we would

be able to reduce opioid consumption during postoperative periods. That might be helping us early mobilization of patients, reduction opioid dependency and incidence of convergence of chronic pain.

## Methods

This randomized controlled trial was carried out in department of anaesthesia, analgesia, palliative and intensive care medicine with collaboration with general surgery department of DMCH after getting the approval from institutional review board of Dhaka medical college and hospital (DMCH). This study was conducted from March 2017 to September 2019.

During pre-anaesthetic visit the patients were allocated according to inclusion criteria and included for the study. Then they were explained about the study purpose, advantages and risks of procedure and instructed to demand analgesia as per requirement and informed written consent was obtained. Patients were educated about both Wong-Baker FACES pain rating scale and the 10 cm visual analogue scale (VAS) during the preoperative assessment (where 0=no pain, 10=worst pain).<sup>11</sup> Exclusion criteria of this study were Patients with known allergy or sensitivity to local anaesthetic agents, who were taking dexamethasone or magnesium sulphate as part of treatment for other indication, Those having a history of treatment for a chronic pain condition and were on daily analgesics for more than 4 weeks or any psychiatric disorders, Patients having chest wall and spine deformity, Pregnant patients or patients who had undergone prior breast surgery (except diagnostic biopsies) and patient who were not interested to take part of the study had been excluded from the study.

Patient with American Society of Anesthesiologists (ASA) Physical Status I, II, and

III undergoing modified radical mastectomy were included for the study. Patients were randomly allocated into two groups, group A and group B with 25 patients in each group by computer-generated random numbers. On arrival in pre-anaesthetic room patient's identification was done and informed consent was checked. Then short history was taken from the patient and through clinical examination was reviewed. With permission of the patients an intravenous line was introduced in the contra lateral arm of the surgical side. The patients were attached with standard ASA monitors that include a pulse oximeter, electrocardiography, noninvasive blood pressure device and a temperature monitor.

The researcher prepared the drug with the local anaesthetic mixed with the adjuvant according to the randomization. The PEC I and PEC II blocked was performed by ultrasound guidance in all patients. Group A received magnesium sulfate as adjuvant to 0.25% bupivacaine and Group B received dexamethasone as adjuvant to 0.25% bupivacaine. Infra-clavicular and axillary regions were disinfected using chlorhexidine-alcohol or povidone iodine if the patient was allergic to chlorhexidine-alcohol. The ultrasound machine with a high frequency linear (8 - 12 MHz) probe was used for the block in aseptic way.

We used cold and pinprick tests to confirm the anaesthesia area over T2 - T6 after of performing the block every 5 minutes until sensory block. After confirmation of adequate block Pulse oximeter reading, electrocardiography tracing, noninvasive blood pressure measured and temperature was recorded. Then the patient was transferred to operation room. Where the patients were pre-oxygenated appropriately and general anaesthesia was induced with propofol 2 mg/kg, fentanyl 2 mcg/kg and suxamethonium 1.5 mg/kg. General anaesthesia was maintained with

isoflurane along with 50% O<sub>2</sub> and N<sub>2</sub>O. Vecuronium 0.1 mg /kg was given as part anaesthesia for muscle relaxations. Patient's blood pressure and heart rate values were maintained within 20% of the baseline. 1 mg Vecuronium in incremental dose was given as part anaesthesia for muscle relaxations when the patients required. Neostigmine 0.05 mg /kg and atropine 0.02 mg/kg were used to recover of the patients. After regaining of full muscle power patients were extubated. When the patient opened eye in responding to verbal command than transferred to the post-anaesthetic care unit (PACU).

Patient's postoperative data was collected by an anaestheologist in PACU. Who was instructed how to fill up structured data collection form and was unaware of the study procedures. On arrival PACU pain was assessed by Wong-Baker FACES pain rating scale than this score was correlated with Visual analogue scale (VAS). Then postoperative pain was reassessed by Wong-Baker FACES after 2<sup>nd</sup>, 4<sup>th</sup>, 6<sup>th</sup>, 8<sup>th</sup>, 10<sup>th</sup>, 12<sup>th</sup>, 14<sup>th</sup>, 16<sup>th</sup>, 18<sup>th</sup> and 24<sup>th</sup> hours later and correlated with Visual analogue scale (VAS). The time when first dose of pethidine was given by the patient's request in post-operative period it was called first rescue analgesia which was recorded in minutes. Incremental intravenous pethidine hydrochloride 12.5 mg was given if VAS was >5 and were repeated every 10 minutes until the VAS was ≤4. The total amount of incremental intravenous pethidine hydrochloride was recorded in mg. Recovery from the block was considered when the first post-operative rescue pethidine dose was given. Postoperative recovery was assessed by modified Aldrete's scoring. If patient had reached at the score 10 out of 10 than they were shifted from PACU. Patients' demographic data were collected including age, BMI, ASA, and duration of surgery.

Baseline mean arterial blood pressure and heart rate were recorded before induction and every 15 minutes intra-operatively until the end of the surgery. The duration of the block was calculated from the pre-operative time when the block was tested and considered to be successful until the first dose of post-operative rescue opioid dose (post-operative VAS of more than 5). The total number of doses of postoperative opioid used was recorded for all patients. Patient's followed up and data were collected before PACU discharge.

All the side effects in PACU whenever observed were recorded. All data were collected by the investigators and recorded in data collection form. As After completion of the collection, data editing, validation and checking were done to remove the inconsistencies. Finally, data were inputted into the statistical software. And data analysis was done by SPSS version 22.

Every patient's data were collected and recorded on a separate data sheet. All data were collected from anaesthetic records, demographic information were collected from the patients or her guardian. Following the collection of all necessary data, most of the data were entered into SPSS 22.0 (IBM SPSS, Chicago, IL, USA) for statistical analysis and rest of the were analyzed by Microsoft Excel. Statistical analysis was performed by using t-test for mean ±SD of onset time of PEC block, the total duration of analgesia after the block and the mean duration of surgery. Chi-square was performed by to analyze qualitative data like VAS score. After analyses of all data P < 0.05 was considered statistically significant and P<0.001 was considered highly statistically significant.

**ERC clearance:** ERC clearance (Memo No. MEU-DMC/ECC/2019/107) was obtained prior commencement of data collection.

## Result and Observation

According to sample size 50 patients were selected according to inclusion criteria and rest of all were excluded in aspect of exclusion criteria and who did not give consent. So finally, data were analyzed for forty patients and they were comparable with each other with respect to age, demographic criteria, ASA class, BMI, duration of analgesia and post-operative pethidine of patients in two groups. They are describing as below:

**Table-I: Distribution of patients by mean age (yrs.) in two groups**

Age	Group A (%)	Group B (%)	Total (%)	p-value
30-39	5 (20%)	3 (12%)	8(16%)	
40-49	13 (52%)	14 (56%)	27(54%)	
50-60	7 (28%)	8 (32%)	15(30%)	
Total	25	25	50	
<b>Mean ± SD</b>	<b>47.88± 8.78</b>	<b>46.95± 7.92</b>	<b>47.41± 8.35</b>	<b>0.065**</b>

Values are expressed as Mean ±SD and within parenthesis percentage (%) over column in total. \*p value is determined by chi-square test.

There were no significant differences between the two groups of patients regarding age. Among total population, majority patients belonged to age group 40-49 years (54%) and followed by in decreasing order 50-60 years (30%), 30-39 years (16%) (Table-I). No statistical difference was found in ASA score between two groups. Majority patients score II in both groups (68% and 76% respectively). Among total study population 72% patients scored II and followed by in decreasing order I (12%) and III (10%) (Table II).

**Table-II: Distribution of patients by ASA classification in two groups**

ASA Class	Group A (%)	Group B (%)	Total (%)
I	5 (20%)	4 (16%)	9 (12%)
II	17 (68%)	19 (76%)	36 (72%)
III	3 (12%)	2 (8%)	5 (10%)
<b>Total</b>	<b>25</b>	<b>25</b>	<b>50</b>

Within parenthesis percentage (%) over column in total.

The time required for surgery in both groups was 113.5±11.8 minutes and 110.3±12.90 minutes respectively. Mean value of onset of analgesia (mint) was 15.5±2.23 (mint) and 19.6± 2.45(mint) in group MgSO<sub>4</sub> and in group dexamethasone respectively. No statistical difference found in surgery time and onset of analgesia between two groups (Table-III).

**Table III: Comparison between surgery time and on set of analgesia among patients in two groups:**

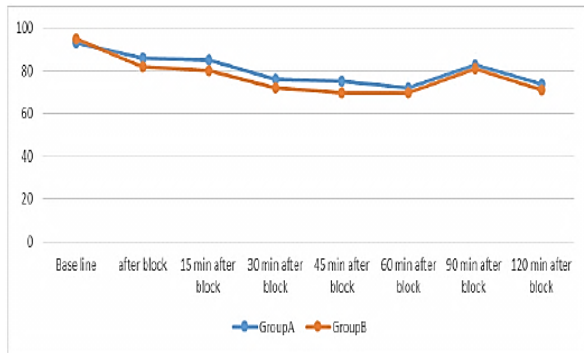
Variable	Group A (n=25)	Group B (n=25)	*p value
<b>Surgery time (mint)</b>	113.5±11.8	110.3±12.90	0.464*
<b>Onset of analgesia (mint)</b>	15.5±2.23	19.6±2.45	0.480*

Data expressed mean± SD. \*Unpaired student t test was done to analyze the data.

No significance variation was not found in case of mean heart rate (HR) throughout the perioperative period (Figure-1). Figure-2 showed that Systolic Blood pressure (SBP) had well maintain during the perioperative period in both group. In MgSO<sub>4</sub> group 12% patients had suffered hypotension during perioperative period.

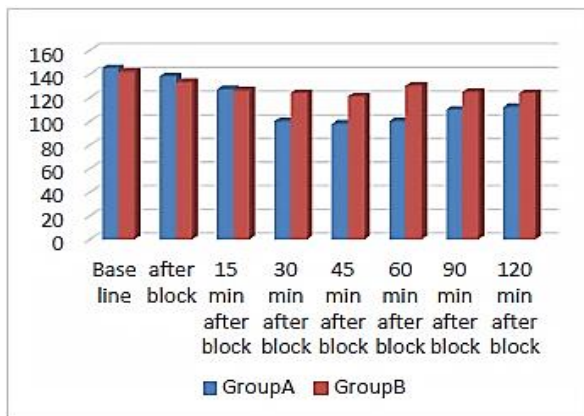


**Figure 1: Mean HR during perioperative period (Beat/ Min)**



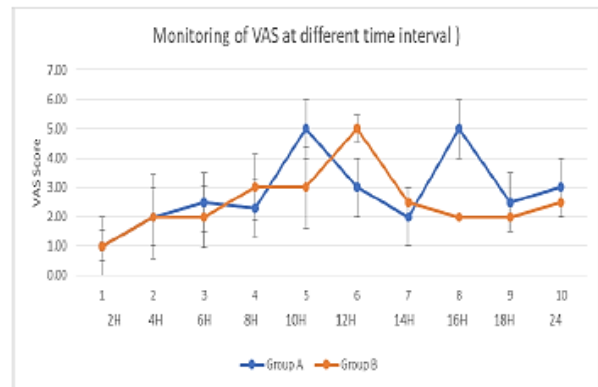
Mean value of Visual Analogue Score (VAS) on 2rd, 4th, 6th, 8th, 10th, 12th, 14th, 16th, 18th and 24th hours on post-operative day were  $1 \pm 0.54$ ,  $2 \pm 0.95$ ,  $2.5 \pm 1.45$ ,  $3 \pm 1.47$ ,  $5 \pm 1.20$ ,  $3 \pm 0.48$ ,  $2 \pm 1.23$ ,  $5 \pm 1.37$ ,  $2 \pm 1.27$ ,  $2.5 \pm 1.34$  and  $3 \pm 1.43$  in MgSO<sub>4</sub> group and  $1 \pm 0.54$ ,  $2 \pm 1.44$ ,  $2.2 \pm 1.41$ ,  $2.5 \pm 1.26$ ,  $3 \pm 1.12$ ,  $2.5 \pm 1.20$ ,  $2 \pm 1.35$ ,  $2 \pm 1.42$  and  $2 \pm 1.21$  in group dexamethasone (Figure-3). VAS score was higher among MgSO<sub>4</sub> group at 10th hours and 16th hours in groups. In case of dexamethasone group VAS score was more at 12th hour. After 24 hours there was no significant difference in VAS score among two groups. VAS score was significantly decreased after receiving rescue analgesia among the both group (Figure-3).

**Figure 2: Mean SBP during perioperative period (mmHg)**



Mean duration of analgesia for group MgSO<sub>4</sub> was  $590.4 \pm 18.6$  minutes and for group dexamethasone was  $714.6 \pm 19.4$  minutes. Mean value of post-operative pethidine requirements were  $72.5 \pm 8.5$  mg and  $55.2 \pm 5.4$  mg respectively in both groups. Statistical difference (p value <0.05) was found in duration of analgesia and post-operative pethidine consumption in between two group. The post-operative pethidine consumption was statistically higher among group MgSO<sub>4</sub> due to duration of analgesia was short (Table-IV).

**Figure 3: Comparison median of Visual Analogue Score between two groups (Data expressed mean ± SD. Chi-square test was done to analyze the data.)**



**Table-IV: Distribution of patients by mean duration of analgesia and total requirement of pethidine in first 24 hr.**

Variable	Group A (n=25)	Group B (n=25)	P value
Time to first analgesic demand (min)	$590.4 \pm 18.6$	$714.6 \pm 19.4$	0.015*
Total amount of Pethidine Requirement in first 24 hrs.	$72.5 \pm 8.5$	$55.2 \pm 5.4$	0.021*

Data expressed mean ± SD.\*Unpaired student t test was done to analyze the data.

**Table V: Distribution of patients by side effects**

Variable	Group A (%)	Group B (%)	*p value
Post-Operative Nausea Vomiting	5(20%)	1(4%)	0.005*
Hypotension	3(12%)	0	0.032*
Respiratory depression	0	0	

Within parenthesis percentage (%) over column in total. Chi-square test was done to analyze the data.

Statistical difference was found in side effects between two groups and side effects were higher among MgSO<sub>4</sub> group. In MgSO<sub>4</sub> group, 20% patients had post-operative nausea vomiting and 12% had hypotension. In dexamethasone group, 4% had post-operative nausea vomiting and others had complications (Table-V).

## Discussion

Post-operative pain following mastectomy operation is known to have a number of after-effect like poor recovery, prolonged hospital stay and even increased liability to chronic persistent pain.<sup>12</sup> Because of that a variety of techniques have been introduced including infiltration of local anaesthetic agents, intercostal nerve block, thoracic epidural anaesthesia, pectoral nerves block and paravertebral block (PVB) etc, to keep post-operative pain to the minimum.<sup>13</sup> Hala (2016) in their study on the anaesthesia for conservative breast surgery found that duration of analgesia was prolonged (994±55 min) in PEC block than the thoracic spinal anaesthesia (TSA) (383±45 min).<sup>14</sup> They also observed that total fentanyl requirement (75±15µg vs. 150 ± 20 µg) was less in first 24 h postoperatively in the PEC block group than that in the TSA group in breast cancer excision. Like above study we found prolongation of analgesia during post-operative period (590.4±18.6min vs. 714.6±19.4min) and total amount of pethidine (mg) requirement was

less in first 24 hr.'s among the both groups.

Lee *et al.* in 2012 showed that, on adding magnesium sulfate to a bupivacaine–epinephrine mixture for interscalene nerve block, there were prolonged duration (664±165min) of analgesia and reduction of postoperative pain.<sup>10</sup> Like this we found a significantly prolong duration (590.4±18.6min) of action of bupivacaine with lower pain scores (VAS) among patients of MgSO<sub>4</sub> group in PEC block.

In 2018 a randomized controlled trial was carried by Ibrahim E. and Sultan W, they added adenosine or magnesium sulphate as adjuvants for pectoral nerves block in modified radical mastectomy.<sup>15</sup> There had resulted that VAS was lower in MgSO<sub>4</sub> Group compared to other groups. In our study Both Groups showed significant longer duration of the block and VAS was higher in MgSO<sub>4</sub> Group at 10th and 16th hours than dexamethasone group. In this study duration of the block was 573.9±9.6min and total post-operative morphine used 6±1.5mg which has a similar result of our study. The total peri-operative opioid used was higher in Placebo group (p< 0.05). Like above study we observed that total opioid consumption was 72.5±8.5 mg in MgSO<sub>4</sub> group.

Ahmed had shown in 2018 the efficacy of pectoral nerve block using bupivacaine with or without magnesium sulfate (100mg) was concluded that the MgSO<sub>4</sub> Group was the least group suffered from postoperative pain at all times of measurement.<sup>16</sup> In that study they observed time of 1st rescue analgesia was 470.4±15.6min. They assessed that the total postoperative pethidine requirement was significantly low (52.3±12.3 mg) in MgSO<sub>4</sub> Group. Likewise in our work we observed that in MgSO<sub>4</sub> group pethidine requirement 72.5±8.5 mg and

duration of analgesia ( $590.4 \pm 18.6$  min) was quite similar to us. We also observed high percentage (12%) of hypotension in  $MgSO_4$  group that closely match to this study (10%). They also observed that HR and SBP well maintain intraoperative and postoperatively at 1, 2, 3, and 6 hrs. in our study we record HR and SBP form baseline and every 15 min interval, which showed HR and SBP maintain during this period.

Tomar GS *et al.* in 2016 assessed that dexamethasone along with bupivacaine as adjuvant for thoracic PVB, helps in improving the quality and enhancing the postoperative analgesia duration for nephrectomy.<sup>17</sup> No other significant side effects were noted and patients with dexamethasone had low VAS score up to 610.48 minutes. Comparably mean value of Visual Analogue Score on 2nd, 4th, 6th, 8th, 10th, 12th, 14th, 16th, 18th and 24th hours on post-operative day were  $1 \pm 0.54$ ,  $2 \pm 1.44$ ,  $2.2 \pm 1.41$ ,  $2.5 \pm 1.26$ ,  $3 \pm 1.12$ ,  $2.5 \pm 1.20$ ,  $2 \pm 1.35$ ,  $2 \pm 1.42$  and  $2 \pm 1.21$  in group dexamethasone, which was quite similar with this study.

Mamdouh *et al.*, in their clinical study 2014, added dexamethasone (8mg) to low volumes of local anaesthetics for ultrasound-guided supraclavicular brachial plexus block.<sup>18</sup> The study was concluded by significantly decreased the onset time and prolonged the duration of sensory ( $13.45 \pm 0.97$  8.20 hrs) and motor blockade ( $11.86 \pm 1.38$  hrs). It had very few incidences of complications. In our investigation dexamethasone (10mg) had showed prolonged duration of the analgesia ( $714.6 \pm 19.4$  min) and had less incidences of complications. Haemodynamic parameters among the groups studied study had showed that there was no significant increase in HR and MABP in response VAS in group until 10 hrs. Like this study we

observed HR and SBP were well maintain with in first 120 min of perioperative period.

Ketamine 50 mg or dexamethasone 4 mg added to bupivacaine 0.5% in TPVB for MRM prolonged the time to first analgesic request with no serious side effects (Mona and Aasma, 2017).<sup>19</sup> That study was concluded by observing lower postoperative pain scores, longer time to first rescue analgesic ( $(18.0 \pm 6.0, 10.3 \pm 4.5$  hrs), opioid consumption ( $2.63 \pm 5.24$  and  $3.60 \pm 6.92$  mg) were observed in ketamine group than dexamethasone group. A randomized controlled trial was by Siddeshwara *et al.* in 2019 observed that PEC block with dexamethasone 4 mg as an adjuvant provided longer duration of analgesia than the TPVB in patients undergoing MRM without any adverse effects.<sup>20</sup>

So, both dexamethasone and  $MgSO_4$  are useful adjuvant to 0.25% bupivacaine for pectoral nerve block in unilateral modified radical mastectomy. Dexamethasone is better than Magnesium Sulfate in aspect of duration of analgesia, lower VAS score, pethidine consumption and incidence of side effects in first 24 hours post-operative period.

### Limitation of the study:

There were some limitations of this study:

1. The present study was conducted among the patient with stage I and stage II breast cancer who did not received any neo-adjuvant therapy prior to surgery.
2. We did not assess the duration of sensory block in our patients using repeated neurological examinations, due to difficulties assessing sensory block after surgery. We therefore used the time until first analgesic request as a marker of the sensory block.
3. In this study two different drugs were used but their systemic effects would not observed.



## Conclusion

A significant difference is found where action of bupivacaine is prolonged with Dexamethasone adjuvant.

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