To evaluate analgesic efficacy of dexamethasone as an adjuvant to ropivacaine in pectoral nerve block: A prospective randomized control study.

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Abstract

Background: Pectoral nerve (Pecs) block is an effective component of multimodal analgesic regimens for breast surgeries. In present study we compared analgesic effect of dexamethasone 8 mg as an adjuvant to 0.25% ropivacaine versus 0.25% ropivacaine alone in pectoral nerve block.

Methods: The study was conducted in a randomized manner on 60 female patients of American Society of Anesthesiologists (ASA) Grade I and II, aged between 18 to 65 years, scheduled to undergo modified radical mastectomy under general anesthesia (GA). The patients were randomly allocated into 2 groups of 30 patients each. Group A received ultrasound (US)-guided Pecs block with 30 ml of 0.25% ropivacaine and 10 ml normal saline (total volume 40 ml) and Group B received with 30 ml of 0.25% ropivacaine and 8 mg dexamethasone in and 10 ml normal saline (total volume 40 ml). Post-operatively visual analogue score (VAS), duration of analgesia and total analgesic consumption was noted. Student t-test, Mann Whitney U test and Chi-square test were used for statistical analysis.

Results: VAS were persistently low for first 4 hours in group B and for first 9 hours in group A (p value < 0.001 at some intervals). The mean duration of analgesia was prolonged in group B as compared to group A (612.33 ± 41.77 min in Group B and 307.70 ± 22.37min in group A) (p <0.001). Total analgesic consumption in first 24 hours post-operatively was also statistically lower in Group B (97.50± 34.96 mg) as compared to group A (177.50± 36.76) (p<0.001). No patient under study reported any adverse effects.

Conclusion: Addition of 8 mg dexamethasone as adjuvant to 0.25% ropivacaine for pectoral nerve block increases the duration of analgesia and significantly reduces the amount of analgesic requirement in first 24 hours postoperatively without any significant adverse effects.

Keywords: Pectoral nerve block; Dexamethasone; Duration of analgesia; Analgesic requirement.

Introduction

Carcinoma breast is one of the most common cancer affecting females. Age adjusted prevalence is as high as 25.8 per 100,000 women[1]. Indian women with breast cancer are found a decade younger as compared to western women.

The majority of females diagnosed with breast cancer undergo some type of surgery. Acute postoperative pain is an important risk factor for development of chronic post mastectomy pain. 40% of women have severe acute postoperative pain whereas 50% develop chronic post mastectomy pain[2]. Pain management of such surgeries should include a multimodal regimen.

With the advent of ultrasonography regional anaesthesia techniques have developed considerably. They help to improve postoperative analgesia with decreased hospital stay and improved patient satisfaction. Regional anaesthesia may also reduce cancer progression by attenuation of the surgical stress response, and by the direct protective action of local anesthetics on cancer cells migration[3].

Pectoral nerve (Pec) block is a superficial nerve block

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for providing surgical anesthesia and postoperative analgesia during breast surgery. It targets tissue planes between the pectoralis major and minor (Pec I) muscles. Blanco later described a modified Pec block or Pec II, where local an aesthetic was deposited between the pectoralis minor and serratus anterior muscles[4]. This breaks through the 'axillary door' and reaches the long thoracic nerve and reliably at least two intercostal nerves. This approach is aimed to block the axilla that is vital for axillary clearances.

Amongst local anesthetics available ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibers, resulting in a relatively reduced motor blockade. Thus, ropivacaine has a greater degree of motor sensory differentiation, which is useful when motor blockade is undesirable.

A common limitation of single injection peripheral nerve blocks is their brief duration of action. Investigators have tried mixing local anesthetic with adjuvant drugs like clonidine, opioids, ketamine, midazolam, dexmedetomidine in an attempt to prolong analgesia from nerve blocks. The glucocorticoid dexamethasone appears to be effective in a number of preclinical and clinical studies.

Although, its efficacy as an adjuvant is proven in other nerve blocks, the data supporting its use in Pec block is still in paucity. Hence, this study is planned to evaluate analgesic efficacy of dexamethasone as an adjuvant to ropivacaine in pectoral nerve block.

Material and methods:

The present study was conducted as a prospective randomized double-blind controlled manner, on 60 female patients aged between 18-65 years undergoing unilateral modified radical mastectomy under general anesthesia. After approval from the Institutional Ethics Committee was taken, CTRI registration was done (CTRI/2018/07/014739). Study was conducted between July 2018 and august 2019 and study was conducted according to declaration of Helsinki.

Before the study power analysis was performed based on the previous work done[5] and the minimum sample size was calculated with 95% level of confidence and 80% power. Sample size was estimated using pain scores as the primary variable. Assuming a standard deviation of 10 mm, the minimum needed sample size to detect a difference of 10 mm on the visual analogue score (VAS) of 10 cm, with type 1 error of 0.05 and power of 80%, was 54. Hence, each group required at least 27 patients.

Patients with any contraindication to regional anesthesia or allergy to the study drugs were excluded from the study.

A written informed consent was obtained from all the patients. Patients were randomly allocated into 2 study groups of 30 patients each using a computer-generated randomization. Group A received 30 ml 0.25% ropivacaine + 10 ml normal saline (total volume 40 ml). Group B received 30 ml 0.25% ropivacaine+ 10 ml normal saline containing 8 mg of dexamethasone (total volume 40 ml). Blinding was done using coded syringes. A routine thorough pre-anesthetic check-up was conducted preoperatively, one day prior to surgery. During the anesthesia interview, patients were familiarized with VAS preoperatively and about its use as a tool for measuring post-operative pain. Routine investigations including chest X-ray and electrocardiogram (ECG) were done prior to surgery.

All the patients were kept fasting overnight prior to surgery. All the patients received Tab. Alprazolam 0.25 mg orally at bed time and then 6 am in morning on day of surgery, with sip of water.

On day of surgery, after shifting the patient to operation theatre standard ASA monitors like ECG, pulse oximeter, and non-invasive blood pressure, end tidal carbon dioxide (EtCO2) were attached and baseline parameters were recorded. After securing 18-gauge intravenous (IV) cannula in the non- operated side, infusion of crystalloids was started. Preoxygenation with 100% O2 was given with a facemask. Patient received premedication with morphine 0.1 mg/kg IV. General anesthesia was induced using standard techniques. Pecs block was given with either of the study drugs, using ultrasound-based identification using Esaote MyLab One ultrasound machine with linear probe, with an imaging depth of 4 to 6 cm.

Pec block was performed in supine position, with the ipsilateral arm abducted to 90^0. After cleaning the infraclavicular and axillary regions with 10% povidone iodine solution, the probe was placed below the lateral third of the clavicle. After recognition of the appropriate anatomical structures, the block was performed. Sterile 22G, 50- 100 mm regional nerve block needle was advanced to the tissue plane between the pectoralis major muscle and pectoralis minor muscle at the vicinity of the pectoral branch of the acromio thoracic artery, and 10 mL out of 30 ml drug of 0.25% ropivacaine+ 5 ml normal saline (15 ml) (Group A) or 10 ml out of 30 ml drug volume of 0.25% ropivacaine + 5 ml of normal saline with dexamethasone (15 ml) (Group B) was deposited. Then the probe is moved laterally and held vertically to identify third or fourth rib in the anterior axillary line. In a similar manner, 20 mL+ 5 ml (25 ml) from the other syringe was deposited at the level of the third rib above the serratus anterior muscle with the intent

of spreading injectate to the axilla Anesthesia was maintained with oxygen and nitrous oxide mixture (50:50) and Isoflurane (0.2-1 MAC). Positive pressure ventilation was delivered with tidal volume and respiratory rate adjusted to maintain end tidal CO2 between 30 - 40mmHg. Injection paracetamol 1gm was administered intravenously for intraoperative analgesia. During surgery crystalloids were infused in accordance with maintenance of volume requirements.

The heart rate, respiratory rate, oxygen saturation, blood pressure (Systolic, diastolic and mean arterial), temperature, EtCO2 were noted every 5 min till the end of the surgery. Hypotension was defined as fall in mean arterial pressure of > 20% of baseline values and was treated with bolus of 100 ml fluid and if uncorrected, injection mephentermine 3 mg bolus, intravenously was given. Bradycardia was defined as pulse rate of ≤ 50/ min and was treated with an intravenous bolus of injection Atropine 0.6 mg. At the end of surgical procedure, residual neuromuscular block was adequately reversed using IV glycopyrrolate 0.02 mg/kg body weight and neostigmine 0.05 mg/kg body weight and patient was subsequently extubated. All patients were observed postoperatively by resident doctors who are unaware of the study drug.

On arrival in the post anaesthesia care unit (PACU), pain scoring was assessed using VAS. First assessment done in PACU was labelled as 0 hour and then it was assessed hourly following surgery till 12 hours, then at 18 hours and 24 hours. Any patient showing VAS more than 3 was given analgesia in the form of injection diclofenac 75 mg IV. Second rescue drug injection tramadol 50 mg IV was given if the patient still has VAS > 3. Total dose of analgesic given and number of rescue doses given during first 24 hour of post-operative period, were recorded. Total duration of analgesia was taken from the time of completion of injection to the request of first rescue analgesia.

Patient satisfaction score[19] was measured with a five-point numerical scale after 24hours as 1=very satisfied, 2=satisfied, 3=undecided, 4=dissatisfied and 5=very dissatisfied. Postoperative vitals were assessed till 24 hours. Any side effects like nausea, vomiting, sedation were noted.

Statistical analysis:

After completion of the study, the results were compiled and statistically analyzed. Data was entered in MS Excel and analysis was done using SPSS 16.0 version statistical program for Microsoft Windows. Continuous variables were presented as mean & standard deviation (SD) while categorical variables were presented as percent. The quantitative variables were compared using the unpaired student- test. The qualitative/ categorical data were compared using the Chi-square test. P value of <0.05 was considered statistically significant and <0.001 as highly significant.

Results:

The present study was conducted on 60 female patients, aged 18- 65 years, who underwent unilateral modified radical mastectomy surgery. Age, weight, height, body mass index (BMI) ASA and duration of surgery in both the groups is mentioned in table 1.

Table 1: Demographic data

Parameter	Group A (n=30)	Group B (n=30)	P value
Age in years (mean ± SD)	49.73 ± 9.54 0	48.50 ± 12.48	0.669
Weight in kg (mean ± SD)	68.97 ± 4.76	68.47 ± 4.87	0.689
Height in cm (mean ± SD)	164.53± 5.53	165.37± 5.25	0.552
BMI in kg/m2 (mean ± SD)	25.51± 1.93	25.06± 1.87	0.370
ASA grade (I:II)	13:17	14:16	0.795
Duration of surgery in mins (mean ± SD)	78.33± 10.20	75.17± 12.28	0.282

The mean age of patients in the Group A was 49.73± 9.54 years and in Group B was 48.50± 12.48 years.

Table 2: Analgesic efficacy in study groups

Parameter	Group A (n=30)	Group B (n=30)	P value
duration of analgesia in mins (mean ± SD)	310.67 ± 22.35	612.33 ± 41.77	<0.001
diclofenac consumption in mg (mean ± SD)	177.50 ± 36.76	97.50 ± 34.9 6	<0.001
number of rescue analgesics (mean ± SD)	2.37± 0.49	1.30± 0.47	<0.001

In present study, we observed that duration of analgesia was more in Group B (ropivacaine+ dexamethasone group) than Group A (ropivacaine alone) which was statistically highly significant between the groups being 612.33 ± 41.77 minutes in Group B and 307.70 ± 22.37 minutes in Group A (p< 0.001). We observed that post- operative injection Diclofenac iv consumption was more in Group A than Group B (p <0.001). None of the patient in either group required second rescue analgesic in the form of tramadol.

Table 3: Postoperative mean visual analogue scale trends in study groups.

VAS	Group A (n=30)	Group B (n=30)	P value
Baseline	0.20 ± 0.41	0.30 ± 0.47	0.380
1 hour	0.73 ± 0.64	0.77 ±0.90	0.869
2 hour	2.37± 0.49	1.30± 0.47	0.277
3 hour	1.33 ± 0.66	1.10 ± 0.96	<0.001
4 hour	3.10 ± 0.80	1.40 ± 1.13	<0.001
5 hour	0.80 ± 0.92	1.30 ± 0.99	0.048
6 hour	0.70 ± 0.79	1.40 ±1.13	0.007
7 hour	0.87 ± 0.86	1.03 ± 0.72	0.419
8 hour	1.17 ± 0.75	2.03± 1.16	0.001
9 hour	1.60 ± 0.81	3.03± 0.93	<0.001
10 hour	2.50 ± 0.90	1.93 ± 0.74	0.010
11 hour	3.07± 0.87	1.67 ± 0.55	<0.001
12 hour	2.50 ± 0.90	1.30 ± 0.53	<0.001
18 hour	1.73 ± 0.83	1.80 ± 0.89	0.764
24 hour	1.83± 0.91	1.60 ± 0.67	0.265

*p value< 0.05 significant; **p value <0.001 highly significant

Postoperative mean visual analogue scale trends in study groups is shown in table 3.

The post- operative VAS scores remained persistently low in both the groups post- operatively, except at 3 hours in Group A and 9 hours in Group B. There was statistically significant difference of VAS between two groups at certain time intervals like at 3-hour, 4 hour and from 8 to 11 hours. Group B showed lower VAS scores at all these time intervals.

Table 4: Patient satisfaction score (PSS)in study groups

Satisfaction Score	Group A (n=30)	Group B (n=30)	Chisquare test
1 (very satisfied)	15	17	0.268
2 (satisfied)	15	13	P value - 0.605
3 (undecided)	0	0	
4 (dissatisfied)	0	0	
5 (very dissatisfied)	0	0	

Patient satisfaction score (PSS) is shown in table 4. We observed good post- operative pain control in terms of low VAS and patients in both the groups were satisfied.

Discussion

Postoperative pain management is still a difficult task with studies showing that more than 80% of patients experience some kind of post-operative pain[6]. Regional anesthesia is an effective way of pain management. Number of regional nerve block techniques are available for breast surgery. Paravertebral blocks (PVB) are well reported in major chest wall procedures and have been shown to decrease intraoperative and post anesthetic care unit (PACU) opiate usage, post-operative nausea and vomiting, as well as overall hospital stay. However, their failure rates may be as high as 6.1%, other complications like vascular puncture being 6.8%, and hypotension being 4%[7].

Pectoral nerve blocks for breast surgery have been reported both in the anesthesia and plastic surgery literature. The last decade has brought a resurgence of interest in these blocks, to treat pain after traumatic rib fractures, persistent postoperative pain, and for oncologic, and cosmetic breast surgery. Similar to PVB, studies have shown a decrease in postoperative opiate use and hospital stay with Pec block[8]. Pec block is easy to learn and master, and is devoid of side effects as that of paravertebral block e.g. pneumothorax, epidural spread, hematoma formation.

For modified radical mastectomy with extensive surgical incision and axillary clearance, pectoral nerves are great modality for post- operative pain management. But block duration limits the effectiveness of a single injection technique. Dexamethasone is an attractive adjuvant to nerve block in many of preclinical and clinical studies. One purposed theory is that the steroids acts by reducing local anesthetic absorption via inducing a degree of vasoconstriction. Another theory states that dexamethasone increases the activity of inhibitory potassium channels on nociceptive C-fibers (via glucocorticoid receptors), thus decreasing their activity[9].

In present study we evaluated the analgesic efficacy of dexamethasone as an adjuvant to ropivacaine in pectoral nerve block. Both the groups were comparable in terms of age, weight, height, BMI, ASA and duration of surgery (table 1). The intra- operative and post- operative vitals in both the groups remain stable throughout. There were no side- effects observed in either of the group.

In this study, we observed that duration of analgesia (Table 2) was more in Group B (ropivacaine + dexamethasone group) than Group A (ropivacaine alone) which was statistically highly significant between the groups being 612.33 ± 41.77 minutes in Group B and 307.70 ± 22.37 minutes in Group A (p< 0.001). The post- operative VAS scores (Table 3) remained persistently low in both the groups post-operatively, except at 3 hours in Group A and 9 hours in Group B, which correlate well with the duration of analgesia. There was statistically significant difference of VAS between two groups at certain time

intervals, 3-hour, 4 hour and from 8 to 11 hours. Group B showed lower VAS scores at all these time intervals (table 3).

Our observations were similar with the findings of study by Sachdeva J, et al. they compared the effect of dexamethasone 8 mg as an additive to ropivacaine 0.2% on duration of ultrasound guided transversus abdominis plane block in cesarean section under spinal anesthesia. Their duration of analgesia was prolonged in dexamethasone group (5.92 ± 1.02 hours) than ropivacaine alone group (3.11± 0.82 hours) which was statistically significant (p= 0.00)[10].

Our findings were also similar with Shaikh MR, et al, with prolonged duration of analgesia (1091.11± 107.42 minutes) with dexamethasone 8 mg added to 0.25% bupivacaine, (duration of analgesia 544.07± 55.40 minutes) in supraclavicular brachial plexus block[11].

Our findings correlate well with the finding by Sharma UD, et al, where duration of analgesia was significantly prolonged in dexamethasone group when used as an adjuvant to ropivacaine in ultrasonography guided transverses abdominis plane block for post-operative analgesia after inguinal hernia repair under spinal anesthesia (p< 0.001). The mean duration of analgesia was greater in group RD (0.5% ropivacaine + 2 ml/8 mg dexamethasone) was 547.50 minutes as compared to group R (0.5%ropivacaine + 2 ml normal saline) 387.50 minutes[12].

Similarly, Vishnu VA, et al compared the effect of addition of dexamethasone 8 mg with bupivacaine 0.5% on duration of supraclavicular block. The mean duration of analgesia in dexamethasone group was 1278.8 ± 82.83 minutes compared with bupivacaine alone group where duration of analgesia was 425.6± 53.31 minutes. The effect of block was significantly prolonged with dexamethasone (p <0.0001)[13].

In our study, we observed that post- operative pain control was better in group B in terms of a smaller number of rescue analgesic required and less total inj. Diclofenac iv consumption in Group B (p <0.001) (Table 2).

Our findings correlate well with the finding by Ammar AS, et al, who studied the effect of adding dexamethasone 8 mg to bupivacaine 0.25% on transversus abdominis plane block for abdominal hysterectomy under general anesthesia. The postoperative analgesic consumption was more in bupivacaine only group during the post- operative 48 hours. Mean morphine requirements in Group A were 21.2 mg and in Group B were 4.9 mg, which was statistically significant (p= 0.003)[5].

Our observations were also similar with the findings of study by Akkaya A, et al. They evaluated effects of addition of dexamethasone 8 mg to 0.25% levobupivacaine in ultrasound guided bilateral transversus abdominis plane block for postoperative analgesia after cesarean section under spinal anesthesia. The mean saving analgesic doses of tramadol were significantly lower (p= 0.001) in dexamethasone group (50.0 ± 35 mg) compared with levobupivacaine alone group (92.9± 36 mg)[14].

We observed good post- operative pain control in terms of low VAS in both the groups and hence patients in both the groups were satisfied (Table 3, 4).

But this study has some inherit limitation. We could not evaluate effect of Pecs block on chronic post- surgical pain, on metastasis or recurrence of carcinoma breast. The beneficial effects of dexamethasone could be explained by its systemic absorption. Hence, a third group (Pecs block+ iv dexamethasone) could have been included to answer this query.

Conclusion

We conclude that, with the addition of dexamethasone 8 mg as an adjuvant to 0.25% ropivacaine there is good post- operative pain control in terms of low VAS scores as compared to 0.25% ropivacaine alone in pectoral nerve block in patients undergoing unilateral modified radical mastectomy. Dexamethasone 8 mg also significantly prolongs the duration of post-operative analgesia and there is reduced amount of analgesic consumption.

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