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Research Article

Comparison of Thoracic Epidural Analgesia and Modified PECs Block in carcinoma breast patients undergoing modified radical mastectomy

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Abstract: **Background:** Acute postoperative pain due to ineffective pain control is a common risk factor for chronic pain to develop following modified radical mastectomy (MRM). Regional anaesthesia techniques including modified PECs block or thoracic epidural analgesia (TEA), may improve postoperative analgesia for these patients. **Aim:** To prospectively compare the quality of analgesia provided by modified PECs block and TEA in patients with carcinoma breast undergoing MRM. **Material and Method:** Sixty females with carcinoma breast (ASA I/II, aged 30–60years), scheduled for elective MRM were randomized into three groups of 20 each. Group-C: general anaesthesia only (GA), Group-E: TEA with GA and Group-P: modified PECs block with GA. Groups were compared statistically for their postoperative VAS scores, need for rescue analgesia and associated complications i.e. hypotension, nausea & vomiting (PONV). **Results:** The VAS scores of modified PECs and TEA group were found to be significantly lower (mean VAS= 0.92± 1 and 0.91± 1.12 respectively) than GA group (mean VAS =3.02 ± 0.56) (P value <0.0001). The results also demonstrated significantly lower need of rescue analgesia in modified PECs and TEA group but higher incidence of complications like hypotension in TEA group and PONV in GA group in comparison to PECs group. **Conclusion:** Modified PECs block in conjunction with GA provides superior analgesia in the postoperative period in comparison to TEA plus GA or GA alone. It is associated with reduced incidence of PONV and hypotension. It can thus be considered a safe alternative for post breast surgery pain management.

Keywords: Modified Radical Mastectomy, GA, Modified PECs block, TEA.

INTRODUCTION

Breast cancer is the second most common malignancy after cervical cancer in India (Kamath, R. et al 2013). In majority of cases partial or total mastectomy combined with axillary exploration is required for the management of breast cancer. The most underrated complication and the commonest complaint post MRM is the Pain. Direct injury during surgery to the nerves or the formation of traumatic neuroma or scar tissue, can lead to chronic pain. Thus, adequate management of acute postoperative pain can help prevent the postoperative patient discomfort and aid in faster recovery. Although multi modal analgesia for pain management is the first line of treatment post MRM, but nonsteroidal anti-inflammatory drugs (NSAIDs) or opioid analgesics used are associated with potential adverse events. Thus, regional analgesic techniques have been advocated for effective pain management in MRM patients. Thoracic epidural analgesia (TEA) reduces cardiac and sympathetic activity and thereby improves perioperative function of vital organs along with additional benefit of prolonged post-operative analgesia (Hiremath, V.R. 2014). But still, it is not devoid of its procedure related complications. As an alternative for this technique a novel series of blocks -PECs Block (PEC I and PEC II) have been designed (Blanco, R. et al 2012). The PECs I block (Blanco, R. et al 2011; Blanco, R. 2011) is a recently described, easy and reliable superficial block that targets the lateral and median pectoral nerves at an interfascial plane between the pectoralis major (PMm) and minor (Pmm) muscles. PECs II block aims to block

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the axilla that is vital for axillary clearances and the intercostal nerves, necessary for wide excisions, tumorectomy, sentinel node exeresis and several types of mastectomies (Blanco, R. et al 2012). ''Modified PECs block'' is a novel approach combining both PEC I block and PEC II block. This breaks through the 'axillary door' and reaches the long thoracic nerve and reliably at least two intercostal nerves (Blanco, R. et al 2012).

This study aims at comparing prospectively the quality of analgesia provided by modified PECs block and TEA in patients with carcinoma breast undergoing MRM surgery.

MATERIAL AND METHOD

After the approval of Institutional Ethical Committee (Govt. Medical College and Dr. Susheela Tiwari Government Hospital, Haldwani), written informed consent was taken from 60 ASA physical status I–II patients (aged 30–60 years) scheduled for elective MRM between November' 2016 to May' 2018. This was a prospective randomized study in which the study population was allocated groups via computer generated sealed chits into three groups of 20 each.

GROUP 'C' (control group)– surgery was conducted under general anaesthesia (GA).

GROUP 'E' (study group)– surgery was conducted under GA and epidural catheter was inserted at the T4-5 intervertebral space, or one space closer to this space considered being an easier access, before the induction of GA.

GROUP 'P' (study group)– surgery was conducted under GA and while all facial planes were exposed by surgeon, epidural catheter was placed in the PEC-I and PEC- II (modified PEC) planes just before the closure.

The technique and drugs used in GA were standardized in all the three groups. Surgeons were explained regarding the procedure in advance. The patients were explained the procedure of measuring pain in the postoperative period by using Visual Analogue Scale (VAS 0-10) in advance. On the arrival of the patients in Operation Theatre necessary measurements were taken to meet the institutional protocols in the pre-operative room. Epidural catheter placement was done by loss of resistance technique in patients of Group 'E' by the attending anaesthesiologist before instituting GA. Following this the patient was made to lie down supine and GA was provided.

In all three groups after preoxygenating with 100% oxygen for 3 minutes anaesthesia was induced using inj. propofol 2 mg/kg IV and muscle relaxation was achieved using inj. vecuronium 0.1 mg/kg IV. Tracheal intubation done and controlled ventilation using 1-2% isoflurane with 66 % nitrous oxide in oxygen was initiated. MRM was performed through transverse or oblique incision along with axillary clearance done by surgeon. Ondansetron 0.15mg/kg IV was given 30 minutes before extubation. The residual neuromuscular blockade was antagonized with neostigmine 50 µg/kg & glycopyrrolate 8 µg/kg, intravenously.

Two catheters placement was done in patients of Group 'P' by the attending anaesthesiologist before surgical closure while all facial planes were exposed by the surgeon. One catheter inserted through the cephalad skin flap with the catheter tip placed between the pectoralis major (PMm) and minor muscle (Pmm)- PEC I [Figure-1]. Instead of using a second catheter we used the axillary surgical drain inserted through the caudal skin flap with the tip placed between the Pmm and the serratus anterior muscle(Sam)- PEC II[Figure-2]. In PEC II the drug was given through the drain at defined intervals, following which the drain was kept clamped for 20 minutes to avoid spillage from the site of nerves to be blocked. Following this the surgical closure was done and patient was reversed and sterile dressing was done at both the catheter sites.

A loading dose of 10ml 0.25% Bupivacaine was given in Group 'E' patients and 10 ml and 20ml of 0.25% Bupivacaine in PEC I and PEC II planes respectively (modified PECs block) were given in Group 'P' patients, as the 'zero' dose in immediate post-operative phase once they arrived in post-anaesthesia care unit (PACU), which was considered as 0 hour. Thereafter, the patients were given the same doses of 0.25 % Bupivacaine as a routine procedure via the catheters placed in situ for the next 24 hours every 6 hourly at 6^{th}, 12^{th}, 18^{th} and 24^{th} hour. Patients of all the three groups were given analgesic Inj. Paracetamol 20 mg/kg IV 8 hourly as per the routine protocol followed post-surgery. No other analgesics were added although continuous follow up was maintained. Patients VAS, hemodynamic and respiratory parameters and complications were recorded at postoperative 0, 1, 6, 12, 18 and 24 hour and charted in the record table and patient's proforma. At any point, if any patient's VAS Score recorded >4, rescue analgesia-1 was provided in form of Inj. Tramadol 2 mg/kg IV, even then if patient complained of pain with VAS >4 Inj. Diclofenac Sodium (Dynapar Aqueous) 1.5mg/kg in 100 ml NS infusion, was given as rescue analgesia-2. The frequency and type of rescue analgesia was recorded for all the three groups. Inj. Ondansetron 0.1 mg/kg IV was given for antiemesis to patients with PONV. The decrease in systolic blood pressure (SBP) was treated with IV fluid and Inj. Mephentermine 6 mg in incremental dose.

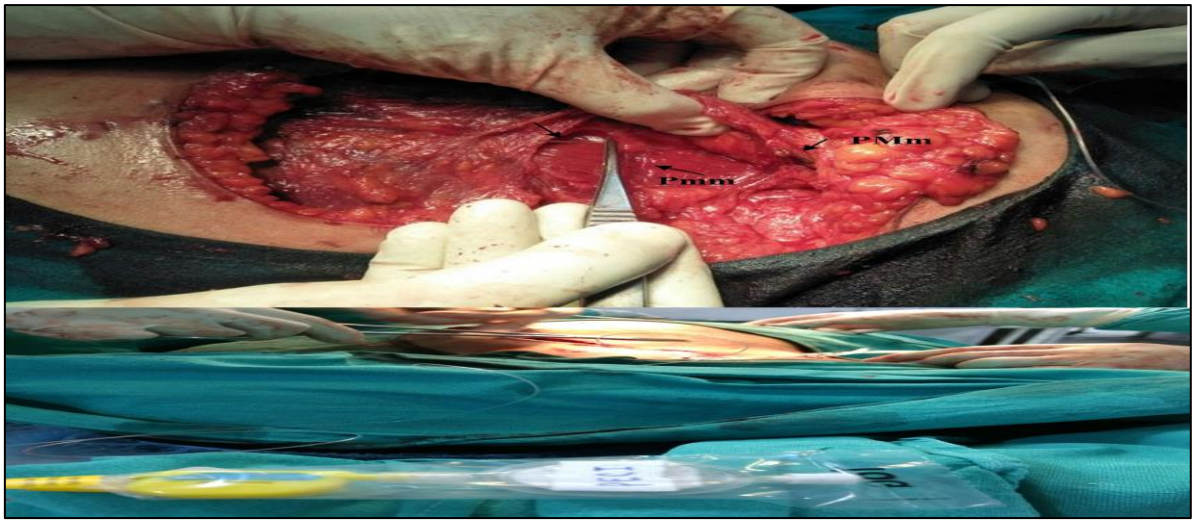


Fig. 1: PEC I

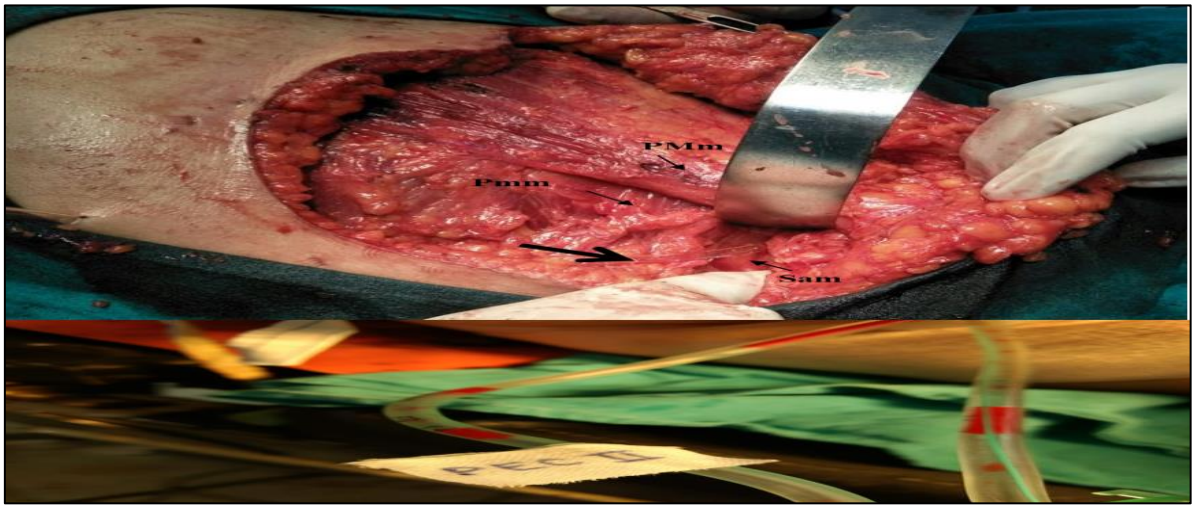


Fig. 2: PEC II

Statistical Analysis

The categorical variables were presented in form of number and percentage (%) while the continuous variables were presented in form of mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test and if the normality was rejected then non parametric test was used.

Statistical Tests Were Applied As the Following-

- Quantitative variables were compared using ANOVA/Kruskal Wallis test (when the data sets were not normally distributed) between the three groups and independent T test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups.
- Qualitative variables were correlated using Chi-Square test/Fisher's exact test.

A p value of <0.05 was considered as statistically significant. Finally the data was entered in MS EXCEL spreadsheet and analyzed using Statistical Package for Social Sciences (SPSS) version 21.0.

RESULTS

All the three groups were comparable demographically. Distribution of Mallampati score, surgical side, ASA physical status grades, and associated comorbidities were also comparable.

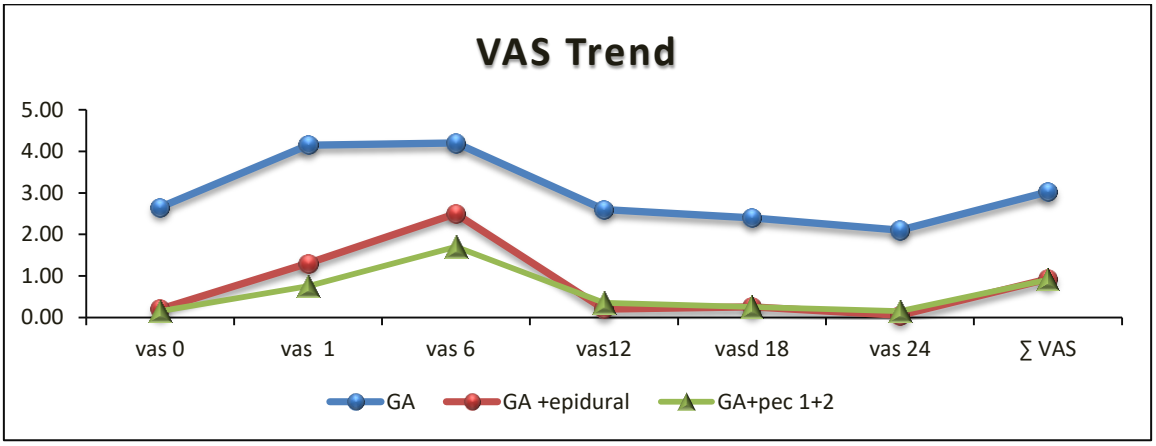
COMPARISON OF VAS SCORE

VAS scores of Group 'E' and P were found to be significantly lower (mean VAS= 0.92± 1 and 0.91± 1.12 respectively) than Group 'C' (mean VAS =3.02 ± 0.56) (P value <0.0001) (Table-1). Although the VAS scores compared between Group 'E' and Group 'P' was statistically similar (P value=0.670). The VAS Scores were found to be highest at the 6th hour mean VAS being 4.2, 2.5 and 1.7 for Group 'C', E and P, respectively. While lowest VAS cores were recorded at 24th hour for Group 'C' (2.1) and Group 'E' (0.05) and Group 'P' (0.15), (Chart-1). The VAS score was lowest at Zero hour also in Group 'P' (0.15).

Table-1: VAS Scores

	Group 'C'	Group 'E'	Group 'P'	P value	Group 'C' v/s Group 'E'	Group 'C' v/s Group 'P'	Group 'E' v/s Group 'P'
VAS 0							
Mean ± Stdev	2.65 ± 2.13	0.2 ± 0.52	0.15 ± 0.37	<.0001	0.0001	0.0001	0.948
VAS 1							
Mean ± Stdev	4.15 ± 1.31	1.3 ± 1.53	0.75 ± 1.07	<.0001	<.0001	<.0001	0.262
VAS 6							
Mean ± Stdev	4.2 ± 1.74	2.5 ± 1.64	1.7 ± 1.92	0.0005	0.004	0.0004	0.171
VAS12							
Mean ± Stdev	2.6 ± 1.14	0.2 ± 0.62	0.35 ± 0.75	<.0001	<.0001	<.0001	0.407
VAS 18							
Mean ± Stdev	2.4 ± 1.43	0.25 ± 0.64	0.25 ± 0.72	<.0001	<.0001	<.0001	0.983
VAS 24							
Mean ± Stdev	2.1 ± 1.17	0.05 ± 0.22	0.15 ± 0.37	<.0001	<.0001	<.0001	0.298
∑ VAS							
Sample size	20	20	20				
Mean ± Stdev	3.02 ± 0.56	0.92 ± 1	0.91 ± 1.12	<.0001	<.0001	<.0001	0.67
Median	3	0.67	0.67				
Min-Max	1.67-3.83	0-4	0-4				
Inter quartile Range	2.750 - 3.417	0.333 - 1.167	0 - 1.250				

Chart- 1: VAS Trend



RESCUE ANALGESIA

Maximum requirement of rescue analgesia-1 was reported in the Group 'C'(85%), with 55% of Group 'C' patients requiring it only once, 25% requiring it twice and 5% requiring it thrice over the 24 hours of post-operative period(Table-2). 20% Group 'E' cases and 10% Group 'P' cases required rescue analgesia-1, only once.

Table- 2: Rescue Analgesia- 1 Distribution

RESCUE ANALGESIA- 1 requirement	ANAESTHESIA			Total	P value	Group 'C' vs Group 'E'	Group 'C' vs Group 'P'	Group 'E' vs Group 'P'
	Group 'C'	Group 'E'	Group 'P'					
Zero	3 (15.00%)	16 (80.00%)	18 (90.00%)	37 (61.67%)	<.0001	0.0004	<.0001	0.6610
Once	11 (55.00%)	4 (20.00%)	2 (10.00%)	17 (28.33%)				
Twice	5 (25.00%)	0 (0.00%)	0 (0.00%)	5 (8.33%)				
Thrice	1 (5.00%)	0 (0.00%)	0 (0.00%)	1 (1.67%)				
Total	20 (100.00%)	20 (100.00%)	20 (100.00%)	60 (100.00%)				

X2=30.639. df=6

Requirement of rescue analgesia-2 was significantly more in Group 'C' cases when compared to Group 'P' (p value .001), although statistically insignificant, but the requirement of rescue analgesia-2 in Group 'E' patients was also markedly less than the Group 'C' (p value .004) and comparable to Group 'P' (p value 1.000) (Table- 3).

Table- 3: Rescue Analgesia- 2 Distribution

RESCUE ANALGESIA 2 requirement	ANAESTHESIA			Total	P value	Group 'C' vs Group 'E'	Group 'C' vs Group 'P'	Group 'E' vs Group 'P'
	Group 'C'	Group 'E'	Group 'P'					
Zero	8 (40.00%)	18 (90.00%)	19 (95.00%)	45 (75.00%)	0.001	0.004	0.001	1.000
Once	11 (55.00%)	2 (10.00%)	1 (5.00%)	14 (23.33%)				
Twice	1 (5.00%)	0 (0.00%)	0 (0.00%)	1 (1.67%)				
Total	20 (100.00%)	20 (100.00%)	20 (100.00%)	60 (100.00%)				

X2=19.933. df=4

NAUSEA AND VOMITING

In total 18 patients suffered with nausea and/or vomiting, out of which 55.00% (n=11) patients were from Group 'C' and, 25.00% (n=5) and 10.00% (n=2) from Group 'E' and Group 'P'. The comparison was statistically insignificant (p value =0.053) between Group 'C' and Group 'E', and statistically significant for Group 'P' when compared to Group 'C' (p value =0.006). (Table- 4)

Table- 4: Nausea and Vomiting Distribution

NAUSEA &/or VOMITING	ANAESTHESIA			Total	P value	Group 'C' vs Group 'E'	Group 'C' vs Group 'P'	Group 'E' vs Group 'P'
	Group 'C'	Group 'E'	Group 'P'					
NO	9 (45.00%)	15 (75.00%)	18 (90.00%)	42 (70.00%)	0.007	0.053	0.006	0.407
YES	11 (55.00%)	5 (25.00%)	2 (10.00%)	18 (30.00%)				
Total	20 (100.00%)	20 (100.00%)	20 (100.00%)	60 (100.00%)				

HYPOTENSION

Hypotension was considered at systolic blood pressure less than 20% of baseline. Incidence of hypotension was 20% in Group E (n=4) and 0% in Group 'C' and P which was statistically insignificant with p value =0.014. (Table -5)

Table- 5: Hypotension Distribution

HYPOTENTION	ANAESTHESIA			Total	P value	Group 'C' vs Group 'E'	Group 'C' vs Group 'P'	Group 'E' vs Group 'P'
	Group 'C'	Group 'E'	Group 'P'					
NO	20 (100.00%)	16 (80.00%)	20 (100.00%)	56 (93.33%)	0.014	0.106	-	0.106
YES	0 (0.00%)	4 (20.00%)	0 (0.00%)	4 (6.67%)				
Total	20 (100.00%)	20 (100.00%)	20 (100.00%)	60 (100.00%)				

HEMODYNAMIC AND RESPIRATORY PARAMETER MEASUREMENTS:

No statistically significant difference was found between the three studied groups at baseline values of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Pulse Rate (PR), Respiratory Rate (RR) and oxygen saturation (SPO2)). As regards to intergroup hemodynamic changes, we found statistically significant decrease in TEA in SBP and MAP, while there was no significant hemodynamic difference reported in GA and modified PECs group (P-value> 0.05).

DISCUSSION

As we discussed earlier that pain is the commonest complaint after breast cancer surgery, if inadequately managed, this acute pain might result in a chronic pain syndrome termed as, Post Mastectomy Pain Syndrome (PMPS).

This study was undertaken to assess the efficacy of 0.25% Bupivacaine in TEA and modified PECs block in conjunction with GA for superior postoperative pain management in comparison to general anaesthesia alone. Postoperative requirement of rescue analgesia in the first 24 hours and postoperative complications including nausea, vomiting and hypotension were also assessed.

All the three groups were comparable in all respects except the technique used for post-operative analgesia. Therefore, it is reasonable to presume that any difference in the groups with regards to the incidence of pain, need of rescue analgesia, nausea, vomiting and postoperative complications was basically a result of the difference in the technique adopted in each group.

The 24 hour follow up revealed that patients receiving modified PECs block in conjunction with GA had lowest VAS scores followed by the patients receiving TEA for pain in comparison to patients receiving GA alone. VAS scores of Group 'P' (mean $\sum$ VAS= 0.91 ± 1.12) and Group 'E' (mean $\sum$ VAS = 0.92 ± 1) was found to be considerably lower than Group 'C' (mean $\sum$ VAS = 3.02 ± 0.56) (Table-1). This finding is in consonance with the findings that of Satish Kumar

et al (2018), who involved fifty patients, the 25 patients receiving PEC along with GA, VAS score was significantly lower at rest and on abduction post-operatively at all-time intervals (P < 0.001) than in the other group of 25 patients receiving general anaestthesia alone. Barbara Versyck et al (2017) divided 140 patients undergoing mastectomy into two equal groups of receiving either PEC block with levobupivacaine or placebo. Numeric Rating Scale (NRS) score was compared at 4-hour intervals for the next 24 hour post surgery, showed that patients in the PEC Group experienced significantly less pain than patients in the control group ($P = 0.048$). Lahiry et al (2016) in their study compared the VAS score postoperatively between TEA and GA groups in MRM patients. The VAS score varied significantly in the immediate post-operative period. Although at 8, 16 and 24 hours post operation the values were not significantly different in both the groups. Schnabel et al (2010) published an analysis from fifteen randomized controlled trials (between 1999 and 2009) on thoracic paravertebral blocks (TPVBs) including 877 patients that were successfully performed for pain management after breast surgery. They observed a significant difference in worst postoperative pain scores between TPVB and GA at 2 h, 2–24 h and 24–48 h implying that only general anaesthesia without regional analgesic techniques was associated with very poor postoperative pain control. We also found the similar observation in our study where GA without regional analgesia (TEA and/or PECs block) was associated with poor postoperative pain control. Mohamed Ahmed Elbadawy Mohamed et al (2018) in their study compared PECII block versus thoracic epidural (TE) and reported statistically significant difference between groups according to VAS from 2hrs postoperative to 8hrs postoperative.

When we compared the three groups for analgesic consumption in form of rescue analgesia, we found a significantly higher requirement of both the rescue analgesia in the GA group (p value <0.0001 and 0.001 for rescue analgesia 1 and 2 respectively) while the requirement was insignificant in the rest two groups(Table-2 and 3). In the same line with our results, the studies of Bashandy and Abbas (2015) and Yuki et al (2017) compared PEC block vs GA in breast cancer surgery using 0.25% bupivacaine and 0.25% levobupivacaine respectively, and found that the total amount of postoperative morphine and mean fentanyl consumption was significantly lower in the PEC group than in the GA group, respectively. El-Sheikh et al (2016) studied TPVB versus PEC block for analgesia after breast surgery, also reported that the mean intraoperative fentanyl consumption was significantly lower in PEC group rather than paravertebral, and the mean time for first request of morphine was prolonged in PEC group than in TPVB group. All these studies are in line with our results in showing the superiority of PECs block as a regional analgesic technique by consuming lesser amount of rescue analgesics in first 24 hours. This might be because modified PECs block along with blocking the pectoral nerves also breaks through the 'axillary door' and reaches the long thoracic nerve and reliably block at least two intercostals nerve. But on the other hand, this result was in disagreement with Hetta and Rezk (2016) who compared PEC II block versus TPVB for unilateral radical mastectomy with axillary evacuation using single shots of bupivacaine 0.25%. They reported TPVB to be superior to PECs block in both lower postoperative morphine consumption (12 mg versus 20 mg; p value<0.001) and delayed time to first request for morphine (9-13 hours) (P value < 0.001). They explained their result by that deposition of LAs in pectoralis-serratus interfascial plane failed to block the anterior cutaneous branches that supply the parasternal part of breast region. In addition, the relatively large vascular space allowed rapid clearance of LAs resulting in shorter duration of analgesia and more postoperative opioid consumption. This difference with our findings might be due to the difference in the study design. The authors believed that blocking the pectoral nerves is beneficial only for procedures that involve stretching of pectoralis muscles, such as subpectoral prostheses. Therefore, they injected the whole amount of LAs in the fascial plane between Pmm and Sam. Thus, they did not block the pectoral nerves.

Our study showed that 11 patients in GA group, 5 patients in TEA group (25%) and only 2 patients in PEC group (10%) suffered with PONV within the 24 hour (Table-4). The lower incidence of PONV in PEC group in comparison with GA and TEA group might be due to the lower analgesic consumption as a result of adequate pain relief, which might play a role. In agreement with our findings are the results of the study done by Mohamed Ahmed Elbadawy Mohamed et al (2018) they compared PEC II block versus thoracic epidural (TE) and also reported lower incidence of PONV in the PEC group than the TEA group. Bashandy and Abbas (2015) and Yuki et al (2017) studied MRM patients under GA with and without PEC blocks, both the studies found lower PONV scores in the PEC group than the patients who received GA only. In contrast to our study Wahba et al (2014) in their study observed that PONV was comparable between TPVB (56.7%) and PEC (53.3%). They stated that higher incidence might be because of the high dose used of morphine.

Regarding hypotension (SBP<20% of baseline value), it was seen only in the TEA group in 4 cases (Table-5). This hemodynamic response is due to bilateral sympathetic blockade observed in TEA group. As the PECs blocks are peripheral nerve blocks, they do not result in sympathectomy so no hemodynamic instability. No incidence of bradycardia was recorded. Our finding is consistent with that of, Soni et al (2015) who performed double-blinded and randomized study

of 60 women scheduled for unilateral breast surgery to evaluate the incidence of hypotension and the need of vasopressors. They reported, 33% developed hypotension in epidural group due to the hemodynamic perturbations requiring more fluid & vasopressor consumption. Júnior et al (2013) in meta-analysis study reported that epidural anaesthesia was associated with a higher incidence of hypotension compared to paravertebral block. Results of studies conducted by Biswas et al (2016) Rajan et al (2016) and Lahiry et al (2016) also showed significantly higher incidence of hypotension and bradycardia in patients receiving TEA, compared to the other regional analgesic technique.

Intergroup hemodynamic changes did not show any statistically significant decrease in PR, SBP, DBP and MAP in the three groups, although hypotension as already discussed was recorded in 4 patients in the TEA Group. In agreement with the results of the current study, Blancoa et al (2011) performed the PECII block in 50 patients undergoing modified radical mastectomies, and reported no change in hemodynamics with the PECs block as there is no sympathetic block that was associated with it as that is associated to paravertebral and epidural blockades. Also similar results were found in study of, ELdeen, H.M. (2016), who compared PEC block with thoracic spinal at the T5 in breast cancer surgery. He reported no change with PEC block in hemodynamics as it was away from sympathetic supply of breast and chest area whereas the thoracic spinal blocks bilateral sympathetic supply to breast and chest area, and the extent of the spread of the drugs is greater.

Although we have found modified PECs block as a superior modality as postoperative pain management in patients undergoing MRM but still we have certain limitations in our study in terms of small sample size studied, limited review of literature and using a subjective tool of pain assessment, VAS score.

CONCLUSION

Our study concludes that modified PECs block when used in conjunction with GA provides superior analgesia in the postoperative period in comparison to TEA in conjunction with GA or GA alone. It is associated with reduced incidence of PONV in comparison to GA alone and had no incidence of hypotension in comparison to TEA. Therefore, the uniqueness of modified PECs block proves it to be a relatively safe and superior modality for pain management post-MRM patients.

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