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Original article:

Comparison of paravertebral block and local wound infiltration for postoperative analgesia in patients undergoing modified radical mastectomy

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ABSTRACT

Introduction: The best modality for post-operative analgesia after Modified Radical Mastectomy (MRM) is still not fully established .Studies have claimed that local wound infiltration (LWI) is equally effective compared to Thoracic Paravertebral block (TPVB), and is hence is an easier and cheaper alternative .We therefore compared ultrasound guided TPVB with local infiltration for postoperative analgesia following MRM ,focusing on analgesic efficacy and impact on postoperative lung function.

Methods: Forty patients undergoing MRM were randomly allocated into two groups. Preoperative spirometry was performed in both to establish baseline values. Following general anesthesia (GA) ,they received either ultrasound guided Thoracic Paravertebral Block (TPVB) or Local Wound Infiltration (LWI). Post operatively pain at rest and motion, time to first rescue analgesia, total analgesic consumption, and lung function after 24 hours were measured.

Observations and Results: Analgesic efficiency was better in the TPVB group as shown by lower pain scores at rest and motion ; delayed demand for first rescue analgesic and decreased total analgesia consumption .There was significant decrease in post-operative lung function,after LWI even at 24 hours ; unlike the TPVB group where all lung function parameters returned to almost baseline values .

Conclusion: TPVB is associated with better post-operative analgesia ,lower pain scores, less analgesic consumption, as well as quick return of post-operative lung function after MRM .Since TPVB has considerable advantages over LIA, it should be the preferred option despite increased complexity and costs.

Keywords: Modified Radical Mastectomy, Thoracic Paravertebral block, Local Wound Infiltration

INTRODUCTION:

Breast cancer is the leading type of cancer in women in India, accounting for 25% of all cases[1]. The standard surgical procedure for breast cancer is Modified Radical Mastectomy which is associated with a significant degree of acute post-operative pain. .

Postoperative pain management is still inadequate after breast cancer surgery with a sizeable proportion of patients complaining of clinically significant acute pain in the post-operative period. Fecho et al (2012) studied post-operative pain in breast surgery subjects and found that as many as 57 % of subject's experienced severe pain[2] .Various modalities, in particular Regional blocks like Thoracic Epidural, Intercostal, Intrapleural block and more recently Thoracic paravertebral blocks TPVB and PECs blocks have been utilized for the management of post-operative analgesia after modified radical mastectomy[3]. At present most studies indicate that the TPVBs are possibly the best possible mode of post-operative analgesia after mastectomy [3 4 5].

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However, even today local wound infiltration with local anaesthetics LWI is commonly used complementary to systemic analgesics for postoperative pain relief [6 7]. This modality is routinely practiced in our country especially in economically constrained settings and is thus of relevance in India especially in smaller centres. Some studies have claimed that LWI is an effective modality in breast surgery[8].

Sidiropoulou et al. compared the efficacy of continuous wound infiltration with local anaesthetic versus thoracic paravertebral block (PVB) after breast surgery. They found that absolute pain scores were low and morphine consumption was similar in both groups.. Four hours after surgery, TPVB group showed a significant reduction in postoperative pain and reduced painful restricted movement, whereas the infiltration group had lower pain scores and painful restricted movement at 16 and 24 hours after surgery. They concluded that continuous wound infiltration of local anaesthetics is an effective alternative to TPVB after mastectomy[9].

Similarly, Boumann et al studied acute postoperative pain after major oncological breast surgery in women and did not find a significant difference in pain scores between GA combined with wound infiltration (GA-LWI, and TPVB combined with GA, (GA- TPVB) until postoperative day 2. They therefore concluded that both techniques are probably equally effective. As GA-LWI is easy to perform, with fewer complications and is more cost-effective they felt it should be preferred over GA- TPVB [10].

Paravertebral Block is technically demanding and not always feasible. The use of ultrasound FOR TPVB while improving accuracy and safety also leads to increased costs and requires advanced training. So to justify use of Paravertebral Block there should be evidence of significant benefits to its use.

As it is not entirely clear whether the advantages of TPVB are substantial enough so as to justify its use especially in resource poor settings , we conducted this randomised study to evaluate US guided TPVB and compared it to the more commonly used LWI ,which has few side effects but the efficacy of which is questioned.

AIMS & OBJECTIVES:

The aim of this study was to help establish the best post-operative analgesic regimen for major oncological breast surgery.

The primary objective was to determine if postoperative improved pain relief(both static and dynamic)is afforded following Modified Radical mastectomy by an ultrasound guided thoracic paravertebral block(TPVB) compared to local wound infiltration(LWI) .

Secondary objectives were to determine whether there is lower incidence of PONV and improvement in post-operative lung function and patient satisfaction with the use of a paravertebral block.

MATERIALS AND METHODS:

This study was carried out after approval by the medical ethics committee of Northern Railway Central Hospital. After written informed consent, patients of age between 18-85 years, scheduled for unilateral modified radical mastectomy MRM mastectomy were included in this prospective, open, randomised trial. All patients were ASA class I -III and exclusion criteria included patient's refusal to participate, contra-indication for regional anaesthesia like patient refusal, Infection at the insertion area, Coagulation disorders /on anti-coagulant drug, allergy to local anaesthetic drugs. Other exclusion criteria were previous lung/thoracic surgeries, Infection in thoracic cavity, Tumour in paravertebral area, Hepatic or Renal impairment, and patients with psychiatric illnesses that would interfere with perception and assessment of pain.

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Patients were randomised into 2 groups (20 in each group) by a lottery system using a sealed envelope technique. Patients were assigned to GA plus local wound infiltration (GA-LWI) or GA plus TPVB (GA-TPVB). .

All patients recruited for the study were familiarized pre-operatively with Visual Analog Scale (VAS) score and bedside spirometry conducted and their baseline values of Forced vital capacity (FVC), Forced expiratory volume (FEV1), Peak expiratory flow rate (PEFR) were recorded.

General Anaesthesia was induced in all patients with injection Propofol (2 mg/kg), Fentanyl citrate (1 μg/kg) and Atracurium 0.5 mg/kg and maintained with sevoflurane/isoflurane (0.9-1.3 MAC) in 66% N2O and 33% oxygen; Analgesia was supplemented with intravenous fentanyl (0.5 mcg/kg) if there was any hemodynamic response (more than 20% increases in Heart rate and Blood pressure (BP) from the baseline) to surgical incision.

Patients in Group A received a Thoracic Paravertebral block preoperatively according to a standard technique as described by Renes et al[11] A member of the study group (SK) performed all procedures taking all Aseptic precautions. The Spinous process of T7 were identified at the inferior angle of the scapula and an X mark were drawn on the skin 1–1.5 cm lateral to this spinous process. Under USG guidance, using a linear probe-8-11Hz (Titan Sonosite) and following a standard technique as described by Renes et al REF, an 18 Gauge Tuohy Epidural needle were inserted at thoracic level 3-4 and epidural catheter (19 G) was advanced through the needle 3–5 cm beyond the needle tip. A test dose of 3 ml of 2% lidocaine with 1:200,000 (1:2 lac) adrenaline was injected through the catheter to rule out accidental intrathecal or intravascular placement of catheter. Activation of the block was done using 0.5% Ropivacaine bolus to a total dose of 0.25 ml/kg volume.

In Group B, a total dose of 0.25 ml/kg of the allocated solution Ropivacaine 0.5% was used, at the end of the surgical procedure, shared in two equal parts, to infiltrate the subcutaneous and deeper layers of the mammary and axillary surgical incisions. Infiltration was performed under direct vision by surgeons.

If any episode of Hypotension occurred in either group it was dealt with first by giving a 200ml fluid bolus. If the blood pressure did not respond to the fluid alone, a dose of a vasopressor (mephentermine 6 mg) was given intravenously. Surgery was performed by a standard approach by 3 consultant surgeons. At the end of the surgery, patients of both groups was given standard reversal agents and extubated.Post-operatively patients of both group received Paracetamol 1gm IV every 6 hourly for 24 hours. Patients in Group A received continuous infusion of Ropivacaine 0.2% at 5 ml/hr via Paravertebral catheter placed in situ preoperatively.

Patients of both the groups received Injection Tramadol hydrochloride 50 mg IV as rescue analgesia, (when VAS was 4 or greater). Tramadol was chosen as the rescue analgesic as it is known to cause minimal respiratory depression and sedation.

Patient baseline characteristics such as Age, Weight, and ASA classification, were recorded. On arrival at the PACU, vital signs were noted. Postoperative pain was then measured by at 0 hrs (arrival at PACU), 8hrs, 24hrs and 48 hrs postoperatively at rest as well as motion (ipsilateral shrugging of shoulder/propped up position). Pain scores of 4 or more on the VAS were considered as insufficient analgesia and rescue analgesic was administered.Secondary outcome measures included Time to first rescue dose and Total dose of rescue analgesic consumed. Lung function post-operatively at 24 hours was measured by spirometry using the below mentioned parameters to measure decline if any from pre-operative values: FVC%, FEVI %and PEFR (L/Min).

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Patients were asked to report overall satisfaction with pain treatment (on a 4 point-verbal rating scale ranging from very dissatisfied at 1 to very-satisfied - rated 4). In addition, any side effects was recorded. [PONV-(Postoperative Nausea, vomiting) /Hypotension/Bradycardia/Pneumothorax etc].

The study by Boumann et al(2012) had revealed that in order to detect a standard deviation of 1.5 (SD 1.5) in VAS pain score difference at 24 hours after surgery, with a power of 80% and a significance level of 5%, 16 patients needed to be included per group. Assuming a drop-out of 10%, they included 18 patients per group. Covering for a higher dropout rate (25%), we decided to include 20 patients in each group.All data were analysed using Student's t-test and Fishers Exact Tests for parametric data, Mann Whitney U-tests for non-parametric data, and Chi-square tests for categorical data. A p-value < 0.05 was considered statistically significant. Trial recruitment was done in the period from August 2015 to July 2016.

OBSERVATIONS & RESULTS:

There were no relevant significant differences between groups with regard to Baseline characteristics (age, height and weight). [TABLE 1]

Significant differences were noted in the primary outcome parameters i.e. VAS Scores at rest and at motion [FIG. 1 & 2 and TABLE 2]. Patients in the TPVB group had statistically significant lower pain scores at all points except at admission into the PACU (0 hours).

Patients in group B(LIA group) demanded rescue analgesics earlier as compared to group A .The mean time of first analgesic demand was 8.5 ±0.7 hrs in group A and 5.6 ±1.5hrs in group B .The total dose of analgesic demanded over 24 hours was also observed to be higher in group B; Total tramadol consumption was 50mg±0.00 in group A (with only2 patients demanding rescue analgesic) and 116.67 mg ±25.82 in group B [TABLE 1].

In addition out of 20 patients in each groups, 6 patients in group B complained of nausea and had episodes of vomiting whereas no patients in group A complained of nausea and vomiting. [TABLE 1].

Lung function tests too showed notable differences between the two groups. [TABLE 3]

The mean pre op FEV1% was 94.2 ±10.4 and post op FEV1% was 93.6±11.2 in the TPVB group .The difference was not statistically significant (p=0.404).In group B the mean pre op FEV1% was 98.7 ±12.5 and post op FEV1% was 86.80±9.7 .The difference in pre op and post op FEV1% in the LWI group being highly significant (p<0.001).Similarly The mean pre op FVC% was 84.4 ±7.1 and post op FVC at 24 hours was 84.1 ±7.8 in the TPVB group- indicating the FVC was almost normal 24 hours after surgery. In the LWI group however the mean pre op FVC% was 87.1 ±7.8 and the 24 hour post op FVC% was 78.2 ±7.8 which was significantly lower .

The PEFR findings in the TPVB group also showed almost no change between pre-operative and postoperative values at 24 hours whereas the PEFR significantly dropped in the LWI group from a preoperative mean of mean of 353.2 ±38.6 to 326.1 ±40.1 ($p < 0.001$)

On comparing the satisfaction scale between two groups: 19 patients in group A were very satisfied, 1 patient was satisfied. In group B 11 patients were very satisfied, 5 patients satisfied, 1 patient was neutral and 3 patients were dissatisfied. Patients in group A were more satisfied as compare to patients in group B and the difference in satisfaction scale was statistically significant. [TABLE 1]

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Table 1: Population characteristics and peri-operative data

		GROUP-A TPVB	GROUP-B LWI	p-values
Age (in years) Mean (SD)		153 (3.73)	152 (4.84)	0.469
Height (in cm) Mean (SD)		58.75 (5.61)	56.15 (5.64)	0.152
Weight (in kg) Mean (SD)		48.55 (8.24)	52.9 (8.97)	0.119
ASA GRADES I/II/III		13/4/3	12/4/3	
Time to 1st demand of analgesia		8.5 (0.71)	5.67 (1.51)	0.048
Total Analgesic dose (mg)		50 (0.00)	116.67 (25.82)	0.013
PONV		0	6	0.008
Any other notable advese effects		Nil	Nil	
Satisfaction with treament	*Grades*			
	Bad	0	3	
	Moderate	0	1	
	Good	1	5	
	Excellent	19	11	

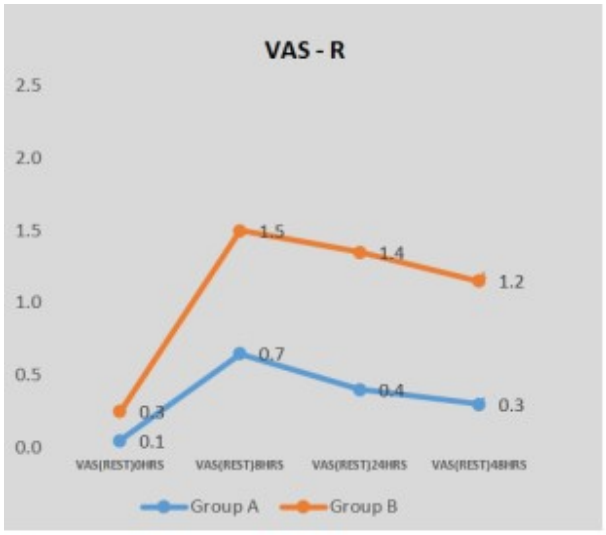

Fig. 1

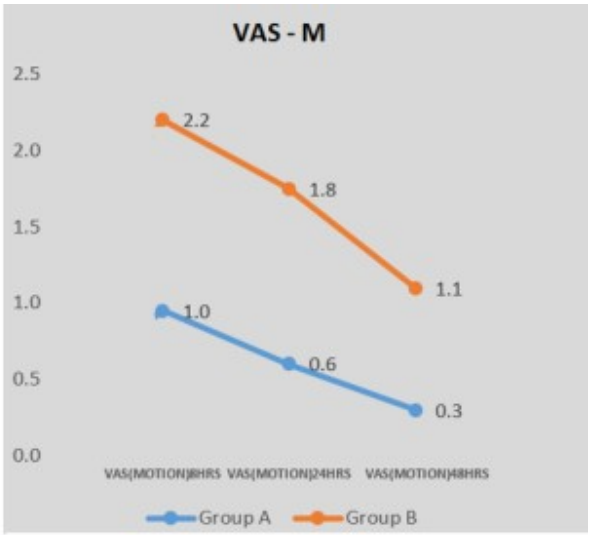

Fig. 2

TABLE 2 : VAS SCORES

	GRP	Mean	Std. Deviation	p-value
VAS(REST) 0 HRS	Group A	0.05	0.22	0.08
	Group B	0.25	0.44	
VAS(REST) 8 HRS	Group A	0.65	0.93	0.032
	Group B	1.5	1.43	
VAS(REST) 24 HRS	Group A	0.4	0.68	0.011
	Group B	1.35	1.42	
VAS(REST) 48 HRS	Group A	0.3	0.66	0.023
	Group B	1.15	1.46	
VAS(MOTION) 8 HRS	Group A	0.95	0.89	0.011
	Group B	2.2	1.88	
VAS(MOTION) 24 HRS	Group A	0.6	0.82	0.017
	Group B	1.75	1.89	
VAS(MOTION) 48 HRS	Group A	0.3	0.66	0.044
	Group B	1.1	1.59	

TABLE 3 : Lung Function Tests

	PREOP FEV1% Mean/(SD)	POSTOP FEV1% Mean/(SD)	p-values
GROUP-A TPVB	94.25 (10.40)	93.6 (11.29)	0.404
GROUP-B LWI	98.7 (12.52)	86.8 (9.75)	<0.001
	PREOP FVC % Mean/(SD)	POST-OP FVC % Mean/(SD)	
GROUP-A TPVB	84.45 (7.19)	84.1 (7.83)	0.542
GROUP-B LWI	87.15 (7.80)	78.2 (7.86)	<0.001
	PREOP PEFR(lit/min) Mean/(SD)	POST-OP PEFR(lit/min) Mean/(SD)	
GROUP-A TPVB	353.4 (31.63)	351.8 (31.78)	0.452
GROUP-B LWI	353.25 (38.62)	326.1 (40.11)	<0.001

DISCUSSION

The results of this study suggest that the TPVB provided better acute postoperative pain relief compared to LWI after modified radical mastectomy The median intensity of pain in the PACU was low overall in both groups with the TPVB group showing especially low pain scores both at rest and at motion .This is similar to Moller et al.'s study who compared found pain in the PACU was low[12] (Range: 0–4.6) in thei TPVB group versus 2.3 (range: 0–7) (in the placebo group). Also the number of patients who reported a pain score ≥3 was significantly lower in the paravertebral group during their stay in the PACU. These pain scores were similar to our results as we found median VAS scores around 1.4 in our .PVB group. As may be expected, the group with local infiltration, in our study, had lower pain scores compared to the placebo group in Moller's study (who did not receive any local anaesthetics.)

In contrast, Boumann et al.'s study had VAS scores greater than 4 and 5 only in the first few hours; thereafter they found VAS score less than 2 in all their patients whether receiving PVB or LWI[10]. It must be noted that all patients in both their groups received a basic analgesic regimen including paracetamol a non-steroidal anti-inflammatory drug (NSAID)

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(naproxen or diclofenac) in combination with piritramide a powerful opioid (about 0.75 times as potent as morphine)In contrast , in our study ,postoperatively patients received only Paracetamol 100mg IV every 6 hourly for 24 hours apart as routine analgesic besides the ropivacaine administration . Tramadol hydrochloride 50 mg IV was administered only as rescue analgesia when VAS>3.Thus it is evident that the use of multiple analgesic drugs in Boumanns study is the likely cause of the very low VAS scores they found in the immediate postoperative period.

It is our contention that the use of regional analgesia techniques reduces the doses of opioids and NSAIDS and decreases their deleterious side effects; thus excessive reliance on these drugs is not warranted when a good regional analgesia regimen is utilized. We believe over reliance on PCM, NSAIDS and opioids acted as confounding factors in Boumanns study, made it difficult for them to compare the individual contributions of TPVB and LWI towards pain relief. Finally it is also worth observing even in Boumann's study that the pain scores in TPVB group were consistently lower than the LWI group at all points of time except for the first hour, though this never achieved statistical significance .The reasons for not achieving statistical significance could include the confounding factors alluded to above.

Bansal et al also conducted an RCT comparing TPVB with local infiltration for postoperative analgesia following modified radical mastectomy[7] .They also found that mean requirement of Tramadol in the postoperative period was statistically significant in group with LWI with no requirement in PVB group .In our study the differences were not so stark but we also found postoperative tramadol consumption to be significantly higher in the local infiltration group.The percentage of patients having PONV in Bansal et al's study was low at 10% as compared to LWI group (75%). Here our results were at variance as only 30 % of the LWI group and none in our TPVB group suffered from PONV. We used propofol for induction whereas Bansal et al used Thiopentone . It is possible that the use of propofol as well as low doses of opioids and no NSAIDs in our study led to lower incidences of PONV in both groups and that the increased use of tramadol as rescue analgesic in the LWI group led to the small incidence of PONV in that set of patients .

Finally in our study, pulmonary function was assessed by spirometry before surgery and post-operatively .A significant decline in PFT Values seen in the LWI group. On the other hand there was complete normalisation of PFT values in the TPVB group at 24 hours post-surgery. The latter finding is broadly in agreement with Matyal et al.'s study in patients undergoing video-assisted thoracoscopic surgery where the use of ultrasound-guided thoracic paravertebral block caused postoperative respiratory function to return to baseline values within hours of surgery[13].

However we were unable to find any other study in the literature that had assessed pulmonary function tests after usage of TPVB, specifically in breast cancer surgery. Thus our study appears to be the only one that has studied this important aspect of post-operative recovery after the TPVB and LWI use in breast oncological surgery.We believe that this is an important finding, as pain related decreases in PFT values have not been documented in breast surgery so far …, despite these having important implications for post-operative atelectasis and delayed recovery especially in the elderly.

Other strengths of our study include utilizing an in plane real time US guidance via lateral approach which allowed us constant visualization of the needle tip while also constantly keeping the "sliding" pleura in view. Thus the dreaded complications of pneumothorax as well as inadvertent intra vascular and intra epidural injection were avoided.

Our study did have some limitations. Complete blinding of assessors and patients to the analgesic modality used was not possible. This could be achieved only with the use of sham blocks as well, which we judged as ethically unjustifiable, because of the possibility of significant adverse effects.

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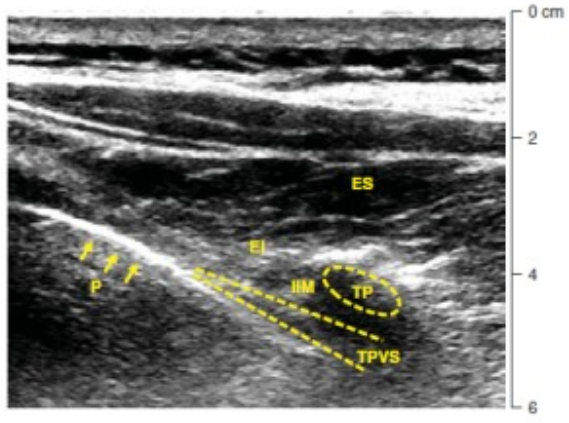
Another limitation was that we only had a first generation Sonosite (Titan) Ultrasound machine with which it was not possible to visualize the endothoracic fascia clearly. Karmakar and Chung have demonstrated that paravertebral injections ventral to the endothoracic fascia facilitates longitudinal spread while those dorsal to the fascia result in more unpredictable spread[14]. The inability to visualize the fascia meant we were unsure whether the needle penetrated it each time during placement.

CONCLUSION

Despite the above mentioned constraints, we have shown that TPVB with general anaesthesia is associated with better postoperative analgesia, as evidenced by lower pain scores (at both rest and motion),less analgesic consumption ,lower incidence of PONV and hitherto undemonstrated quick return of post-operative lung function compared to LWI after mastectomy . As Ultrasound guided TPVB has considerable advantages, it should be preferred over LIA , despite the increased complexity and costs.

Finally, our study was limited in time and there was no provision made to follow up these cases. on following these cases for prolonged periods which would be necessary to detect any differences in chronic pain development or even cancer recurrences between the groups receiving paravertebrals and those receiving local infiltration. A similarly designed study with prolonged follow up may yield evidence based answers to such questions in the future.



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