Original Research Article

Role of regional anaesthesia for modified radical mastectomy in a hospital in Central India: a retrospective observational study

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ABSTRACT

Background: The number of breast cancer surgeries in India are increasing in the recent years. Lifestyle changes and increased awareness are the two important factors contributing to the same. Newer methods of anaesthetic management are also being practised for overall benefit of the patient. Recent advances in the regional anaesthesia techniques especially under the guidance of ultrasonography, dramatically changed not only the operative outcomes but also the post-operative stay in the hospital. The present study was aimed to bring out differences between two popular options of opioid sparing regional anaesthesia techniques for post-operative analgesia for patients who had undergone modified radical mastectomy (MRM) for carcinoma breast at our centre.

Methods: A total of 88 patients of ASA II and III grading were enrolled in the study who had received either of erector spinae plane block (ESB) or thoracic paravertebral block (TPVB). Post-op numerical rating scale for pain and analgesic requirements were compared between the two groups. Hemodynamic parameters were recorded for comparing the influence of the blocks on hemodynamics.

Results: The demographic profile was similar between the 2 groups. The study showed that TPVB have a higher efficacy of analgesia when compared with that of ESB. However, there is no significant differences in the intra-op and post-op hemodynamics.

Conclusions: In view of a higher safety profile of ESB, administration of the same may still be preferred over the TPVB especially in those with less experienced hands in patients undergoing modified radical mastectomy.

Keywords: Modified radical mastectomy, Erector spinae block, Thoracic paravertebral block

INTRODUCTION

With changes in diet and environmental pollution the incidence of breast cancer has increased worldwide. Also because of newer cancer diagnostic techniques and awareness in the Indian population, the number of cases presenting for treatment at an early stage have increased. This study was undertaken as a large number of patients undergo modified radical mastectomy (MRM) surgeries at our hospital. The objective of the study was to compare the efficacy of ESB with TPVB in patients undergoing modified radical mastectomy at our hospital. Different techniques of providing anaesthesia and analgesia have been in vogue for safe and pain free conduct of surgery. The main techniques being local infiltration, thoracic epidural, pectoralis muscle blocks, paravertebral blocks at the thoracic region and ESB. ESB being the newest in the family of blocks. The earlier used blocks such as thoracic epidurals had the problem of difficulty in reaching the space and sometimes inadvertent puncture of duramater. Also, there was the problem of inadvertent...
lung puncture with the TPVB. ESB has mitigated the problems of either of the blocks.4

The numerical rating score (NRS) post-operative after surgery for 24 hours was the primary end point.

The secondary end points were requirements of analgesics intraoperatively and in 24 hour period after the surgery.

Intraoperative and immediate post-op hemodynamics were documented and analysed for the safety of the blocks.

Any inadvertent adverse events in the intra op and post-op period were also documented.

**METHODS**

This study is a retrospective observational study of patients who underwent MRM. For all patients undergoing these surgeries at Command Hospital Lucknow, the data from 1 October 2018 to 30 September 2020 was recorded.

A written informed consent was obtained from all patients, for receiving one of these blocks either ESB or TPVB as a part of the anaesthesia technique a day prior to surgery. The blocks performed by a single anaesthetist were recorded in two groups for ESB and TPVB. The data was recorded by an independent observer who visited the patients in the post-operative wards and recorded the findings.

The patient group consisted of patients in ASA II or III in age group 45 to 75 years and scheduled for MRM surgeries. Patients in ASA groups IV were excluded from the study as also patients who refused these blocks prior to surgery. Patients who had local skin infection or were receiving anticoagulants were also excluded from the study. Patients receiving analgesics for any other condition, morbid obesity, renal insufficiency, severe functional limitations, allergies or neoplastic spread of the carcinoma were also excluded from the study.

Patients suffering from any co-morbid conditions were optimised pre-operatively to minimise intra or post-operative complications prior to surgery. Night before surgery they were administered tablet alprazolam 0.50 mg which was repeated on morning of surgery as well.

Tramadol was used intravenously in the post-operative wards for analgesia for its higher safety profile in the aged patients. A post-operative consumption difference of 3.125 mg of tramadol was required to detect a significant difference of analgesic consumption. At alpha error of 0.05, SD of 6.25 mg and 80% power of study a total of 41 patients in each group were required for the study. We enrolled 88 patients for the study to include possible dropouts.

We hypothesized that the ESB groups will have higher analgesia with blocks and thus a lower requirement of analgesics in the post-operative period.

Statistical analysis was done by SPSS 25 (SPSS Inc., Chicago, Illinois, USA). Normal distribution of data was checked using a histogram and the Shapiro Wilk test. The parametric data was analysed by the student’s t test and the non-parametric data was tested using the Mann Whitney U test. P<0.05 was considered significant.

**Paravertebral group**

The patient were placed in the sitting position. Local anaesthetic was administered at the injection site and after adequate skin preparation an 18 G epidural Tuohy needle was used for identification of the T4 thoracic paravertebral space by LOR method. A total volume of 15 ml of 0.25% bupivacaine and 1% lignocaine with adrenaline was then injected along with 4 mg of dexamethasone.

**ESB group**

The patient was placed in the sitting position local anaesthetic was administered at the injection site and after adequate skin preparation a 25G spinal Whitacre needle was placed at the T4 level ESB over the transverse process of the T4 thoracic vertebra. A total volume of 15 ml of 0.25% bupivacaine and 1% lignocaine with adrenaline was then injected along with 4 mg of dexamethasone.

![Figure 1: Surface landmarks for the ESB.](image-url)
Both groups

All patients were given standardized GA with premedication with glycopyrrolate 0.2 mg IV, ondansetron 8 mg IV, fentanyl 2 mcg/kg IV. Patients were induced with propofol 2 mg/kg IV. Patients were intubated with atracurium 0.5 mg/kg. Anaesthesia was maintained with sevoflurane in oxygen and nitrous oxide mixture. Fentanyl was supplemented if HR and MAP increased by 20% of their basal values. Patients were allowed to breathe spontaneously at the end of the surgery and muscle relaxation was then reversed.

Patient’s intra-op hemodynamics and demand of first analgesic and total analgesics required for 24 hours period was recorded for the 2 groups. Tramadol diluted to 3.125 mg per ml was used in aliquots for post-op analgesia when required. Tramadol was injected slowly intravenously whenever required.

The NRS corroborating with VAS scores was documented at similar intervals for a total period of 24 hours after surgery. The observer was blinded to the type of blocks. The blocks were administered on alternate odd/even basis.

RESULTS

88 patients were selected in total for the recruitment for the study. 6 patients were excluded from the study as they were not meeting the inclusion criteria. No patients refused to participate in the study. A total of 82 patients were finally included in the study. They were allocated into the two groups of 41 each according to the intervention performed.

Table 1: Demographic profile of the two groups (expressed as mean±SD).

<table>
<thead>
<tr>
<th>Group demographic parameters and surgery data</th>
<th>Thoracic paravertebral group (TPVB) (N=41)</th>
<th>Erector spinae plane group (ESB) (N=41)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td>63.1 (5.6)</td>
<td>62.5 (7.4)</td>
<td>0.21</td>
</tr>
<tr>
<td>Height (in cms)</td>
<td>148.8 (7.4)</td>
<td>152.2 (6.8)</td>
<td>0.19</td>
</tr>
<tr>
<td>Weight (in kgs)</td>
<td>48.8 (3.6)</td>
<td>50.2 (4.3)</td>
<td>0.53</td>
</tr>
<tr>
<td>ASA status (II/III)</td>
<td>34/7</td>
<td>33/8</td>
<td>0.52</td>
</tr>
<tr>
<td>Duration of surgery (in mins)</td>
<td>84.32 (10.6)</td>
<td>82.22 (11.2)</td>
<td>0.48</td>
</tr>
</tbody>
</table>

Table 2: Assessment of the total analgesics required in the two groups (mean±SD) and complications.

<table>
<thead>
<tr>
<th>Variables</th>
<th>ESB</th>
<th>TPVB</th>
<th>P values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-op fentanyl (in mcg/kg)</td>
<td>110±10</td>
<td>90±15</td>
<td>0.04</td>
</tr>
<tr>
<td>Time to first analgesic request (in hours)</td>
<td>9.3±0.4</td>
<td>10.6±8</td>
<td>0.02</td>
</tr>
<tr>
<td>Total post op analgesics (tramadol in mg IV)</td>
<td>75 ±12.5</td>
<td>50±12.5</td>
<td>0.02</td>
</tr>
<tr>
<td>Complications: PONV, prolonged paraesthesia, intra op arrhythmias pneumothorax</td>
<td>0</td>
<td>Pneumothorax (2), profound fall in MAP (1)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>
Assessed for eligibility (N=88)

Excluded; not meeting inclusion criteria (N=6); declined to participate (N=0)

Enrolment

Allocated to group ESB; received planned intervention (N=41); did not receive allocated intervention (N=0)

Allocated to group TPVB; received planned intervention (N=41); did not receive allocated intervention (N=0)

Allocation

Follow up

Lost to follow up (N=0); discontinued treatment (N=0)

Lost to follow up (N=0); discontinued intervention (N=0)

Analysis

Analysed N=41

Analysed N=41

Figure 3: Consort flow diagram.

HR comparison between 2 groups

Figure 4: Comparison of intra operative heart rate variation in the two groups (in beats per min).
All patients were similar regarding age, height and weight in the 2 groups. The groups were based on the Regional anaesthesia intervention performed by the anaesthesiologist. The groups were also similar as regards the ASA status of patients and duration of surgery.

The mean duration of analgesia in the ESB group was 9.3±0.4 hours. The mean duration of analgesia with the TPVB was 10.6±0.8 hours. This was found to be statistically significant (p<0.05).

The total analgesics used for the ESB group was 75±12.5 mg and 50±12.5 mg for the TPVB group. Tramadol was used in 3.125 mg diluted aliquots for rescue analgesia. The complications were more in the TPVB group with 2 cases of pneumothorax and 1 case of profound fall in blood pressure. Both cases of pneumothorax resolved spontaneously without any sequela. Hypotension responded to intravenous normal saline infusion along with 3 mg of mephenteramine IV boluses.

The data regarding the intraoperative and early post-operative hemodynamics was compared in the two groups. The NRS scores were compared between the two groups from the PACU to the post-op ward for 24 hours post-surgery.

**DISCUSSION**

Indian subcontinent has a large number of breast cancer patients. A large number of surgeries takes place in the form of MRM with the breast conservation approach.

Surgeries were being conducted with the use of opioids for a long period of time. However, with the availability of modern local anaesthetic agents and popularity of both RA blocks and introduction of USG machine a large...
number of cases are being done with regional anaesthesia supplementation. This also prevents the side effects of opioids in the post-operative period.\textsuperscript{5}

Regional techniques are now being extensively used for MRM. Commonest used are the thoracic paravertebral block and the ESB. However presently there are limited number of studies conducted in India for the regional techniques for the same. The number of studies comparing the efficacy of the blocks for modified radical mastectomy are also few in number.

This retrospective comparison study showed that TPVB has a better efficacy than ESB with a single shot technique as far as analgesia in the post-op period is compared.

Both TPVB and ESB act on the spinal nerves in the thoracic region. Injection of local anaesthetic agent in the paravertebral space is by penetration of local anaesthetic into intercostal nerve, including its dorsal ramus, the rami communicantes and sympathetic chain. An average of somatic block of 5 to 8 somatic dermatomes has been demonstrated by somatography.\textsuperscript{5,6}

ESB act on the nerves in the pre-vertebral and paravertebral regions. It thus blocks the dorsal and ventral rami as the drug diffuses anteriorly and the intercostal spaces. The ESB can thus be also considered a peri-paravertebral technique.\textsuperscript{7,9}

This study utilized a mixture of local anaesthetic agents bupivacaine with lignocaine with adrenaline with dexamethasone. This ensured a faster action of analgesia with a longer offset time that was more pronounced in the TPVB. This was similar to a study by Fallatah et al who used TPVB and IV morphine for analgesia after breast surgery and found higher efficacy of TPVB in these surgeries.\textsuperscript{10}

Even though TPVB may lead to a rapid absorption of local anaesthetics through the paravertebral space the use of adrenaline in the local anaesthetic solution may prevent the same unless there is an inadvertent injection into a blood vessel.\textsuperscript{11}

A study by Rafat et al however showed an equal efficacy of TPVB and ESB in patients undergoing modified radical mastectomy in 70 patients at a hospital in Egypt.\textsuperscript{12}

Our study showed reduction of NRS scores to 1 to 4 in the post-operative period which was lower in the TPVB compared to ESB. A case study by Singh et al found similar or even higher reductions in pain scoring using a higher volume of bupivacaine alone.\textsuperscript{13}

A study by Bhuvaneshwari et al showed an effective analgesia for up to 18 hours after surgery using 25 ml of 0.25% bupivacaine and 2 mcg/kg fentanyl combination in TPVB for mastectomy.\textsuperscript{14}

A study by Swisher et al showed that TPVBs provide superior analgesia and reduced opioid requirements in non-mastectomy breast surgery when compared with ESB.\textsuperscript{7}

Even though the paravertebral techniques may be superior to ESB, complications in the form of pleural punctures or involvement of the sympathetic tract may be higher thus making it a riskier technique to use in patients.\textsuperscript{6}

Studies have also compared ESB with TPVB in other surgeries, majority of them being thoracic surgeries and upper abdominal surgeries. ESB and TPVB had similar analgesic effects. However, a higher patient satisfaction could be achieved with ESB it being associated with lesser number of punctures and lower complication rates.\textsuperscript{15}

Limitations

There were some limitations to the study. The study only included the patients undergoing MRM. Other breast surgeries like simple mastectomy have not been included in the study. The study does not compare the analgesia after the first post-op day. The study also does not compare the long term effects of the blocks such as, in mobilisation of the arm and development of limb edema in the patients subgroups. The study also does not compare the patient satisfaction with the two techniques in the post op period or in long term follow up. Catheter based continuous infusions did not form a part of the study.

CONCLUSION

Our study showed that the paravertebral techniques are still superior to the recently introduced ESB. This can be because a part of the drug infused may dissipate in the muscular mass and spaces around and this can lead to a lower concentration of the drug at the effector sites and thus poorer quality of analgesia.

However, of the various techniques described for analgesia to decrease the ESB may still be superior to epidurals, paravertebral, pectoral blocks or local infiltration because of ease of administration and lesser chances of complications.

As the patients differ in the age groups and ethnicity. Future studies with different LA agents and additives may be conducted to formulate an anaesthesia plan for best RA techniques in these patients in the Indian scenario.

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