Effectiveness of Multiple Injection Thoracic Paravertebral Block for Breast Surgery as an Alternative to General Anaesthesia

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Abstract

Background and Aim: General anaesthesia is currently the conventional technique used for breast surgeries. Thoracic Paravertebral Block (TPVB) has been used for analgesia in unilateral procedures such as thoracotomy, breast surgery, chest wall trauma, hernia repair and renal surgery.

Methods: A total of 60 adult females, ASA physical status I and II, 18-50 years, patients scheduled for unilateral breast surgery (biopsy, fibroadenoma resection, simple mastectomy). Patients were randomly assigned into 2 groups of equal size (n=30).

Group A: Patients received unilateral Thoracic Paravertebral Block (TPVB).

Group B: Patients received General Anaesthesia (GA).

Objective: Comparing effectiveness of unilateral thoracic PVB as a good alternative to general anaesthesia in elective breast surgery.

Conclusion: This study demonstrated that multiple injection thoracic paravertebral block can be used as a sole anaesthetic technique, provide better perioperative pain control, reduce both intraoperative and postoperative opioid requirement, PONV in patients undergoing breast surgery.

Key Words: TPVB – Breast – Opioid.

Introduction

BREAST surgeries is perhaps the most common surgery in women. Nearly 40% of post-operative breast surgery patients experience significant acute postoperative pain, with a pain score above five reflecting inadequacy of conventional pain management [1]. Moreover, the incidence of chronic postoperative pain in breast surgery patients is as high as 50%, and inadequate analgesia is considered as an independent risk factor [2].

General Anaesthesia (GA) is the conventional technique used for surgical treatment of breast lump. However, the side-effects and complications of GA, such as post-operative pain, nausea and vomiting, increase morbidity for most patients undergoing breast surgery. Since the last two decades, there is a search for optimal regional techniques for operative procedures on the breast, which would reduce Post-Operative Nausea and Vomiting (PONV) and also provide prolonged post-operative sensory block, minimising narcotic requirements [3].

It has been proposed that injection of local anaesthetic drug into the thoracic paravertebral space could easily lead to the establishment of a block appropriate for the breast surgeries without any significant side-effects. Paravertebral Block (PVB) can uniquely eliminate the cortical responses to thoracic dermatomal stimulation. It is associated with a decreased need for opioids for controlling postoperative pain, [4] decreased PONV, improved patient outcome, lowered postoperative pulmonary complications and, finally, decreased duration of Post-Anaesthesia Care Unit (PACU) stay [8].

In the present study, an effort has been made to compare the efficacy of thoracic PVB as an anaesthetic procedure for elective breast surgeries with GA, duration of post-operative pain relief being the primary end point.

Patients and Methods

The study was conducted in Kasr Al-Ainy Hospital, Cairo University, after approval of the local ethical committee and a written informed consent from all patients. This study was conducted from September 2013 to June 2015. Patients were randomly allocated into two equal groups, 30 patients each using individual closed envelop randomization.
**Group A**: Patients received unilateral Thoracic Paravertebral Block (TPVB).

**Group B**: Patients received General Anaesthesia (GA).

**Inclusion criteria**: ASA physical status I and II, aged 18-50 years, scheduled for a unilateral breast surgery (biopsy, fibroadenoma resection, simple mastectomy), were enrolled in this randomised observer blinded prospective clinical study.

**Exclusion criteria**: Patients who refused to participate, less than 18 years of age, ASA physical status 3 or more, body mass index >35, known pregnancy, lactating mothers, bleeding disorders, allergy to any of the study drugs, patients having any contraindication to placement of PVB, kyphoscoliosis, presence of acute herpes zoster, chronic pain syndrome, chronic analgesic use and psychiatric disease were excluded from this study.

Considering a 30% increase in the duration of post-operative analgesia to be clinically relevant, with a power of 80% (\( \beta = 0.2 \)) at 0.05 level of significance (\( \alpha = 0.05 \)), we required 25 patients in each group. We took 30 patients in each group considering the possibility of dropouts.

**Pre-operative assessment**:

All routine investigations include: CBC, coagulation profile, liver function tests, renal function tests, blood grouping, chest X-ray.

Patients were thoroughly explained about the procedures to be undertaken and the risks and benefits associated. They were made well conversant with the Visual Analogue Scale (VAS) for post-operative pain. Patients were advised preoperative fasting for a period of 6h.

On arrival to the operation theatre prior to both the procedures, all necessary equipment for GA and resuscitation were kept ready in case of a block failure or any complication. Baseline vital parameters like pulse rate, Non-Invasive Blood Pressure (NIBP), respiratory rate and peripheral arterial oxygen saturation (SpO\(_2\)) were noted. The patients were shifted to the OT after surgical anaesthesia was achieved. Time to perform the blocks and time to surgical anaesthesia were noted. Monitoring was continued throughout the operative procedure, recorded at 15-min interval in the intraoperative and at 1-h intervals in the post-operative period.

Patients assigned to receive thoracic PVB were given incremental doses of iv midazolam (up to a maximum dose of 0.06mg/kg) in the block room before block placement to decrease anxiety and discomfort during the procedure while maintaining a meaningful patient contact. Fentanyl (2mcg/kg) was given as pre-emptive analgesic for block placement. The classic technique, which essentially includes loss of resistance, was used to identify the paravertebral space. With the patient in lateral decubitus with operative site non-dependant, relevant anatomical landmarks were identified and marked with a sterile permanent skin marker. Similarly, points corresponding to 2.5cm lateral to the upper border of spinous processes of the T3 to T6 vertebrae were marked as needle insertion sites, and each space was infiltrated with 2ml of 1% lignocaine.

An 18-gauge Tuohy needle with depth label on its shaft was introduced perpendicular to the skin in all planes to touch the transverse process of the lower vertebra up to a maximum depth of 4cm initially. In case of non-contact with bone, it was presumed that the needle was in between two transverse processes.

The needle was then withdrawn to the subcutaneous tissue and placed with a cephalic or caudal direction to the same depth of 4cm. If bone was still not encountered, the needle was advanced 1 cm further and the above stated method was repeated until the transverse process was spotted. After identification of the transverse process, the needle was walked off the superior surface of the transverse process and slowly advanced 1-1.5cm until a loss of resistance to saline was obtained with a 5-ml glass syringe. Loss of resistance is said to occur while needle pierced superior costotransverse ligament to enter into the thoracic paravertebral space [9].

Five milliliters of 0.5% bupivacaine solution was injected at each level after repeated negative aspiration for blood or cerebrospinal fluid, whether or not paraesthesia was elicited. We assessed the onset of unilateral pinprick discrimination at 5min and every 5min thereafter up to 30min. A block was considered as “unsuccessful” if onset of pinprick discrimination was not evident within 15min or failure to achieve adequate sensory block (T2-T6) within a maximum time of 30min. If the block was considered as failed, the patient was administered GA and the case excluded from the study. Numbers of dermatomes having complete loss of sensation to pinprick were noted. Intraoperatively, intermittent doses of fentanyl 25mcg and propofol 10mg were given for supplemental sedation if heart rate or Mean Arterial Pressure (MAP) increased more than 20% of the baseline value.
The control group underwent GA with endotracheal intubation. Premedication was done with Intravenous (iv) midazolam (0.04-0.06mg/kg) and analgesia with iv fentanyl (2 µg/kg). The induction of anaesthesia was done with I.V. propofol (2mg/kg) followed by iv atracurium (0.5mg/kg) to facilitate tracheal intubation.

Patients received top-ups of iv atracurium (0.1 mg/kg) at regular intervals and iv fentanyl (1 µg/kg) at 1-h intervals if the surgery extended beyond 1h. Heart rate and MAP were maintained within 20% of the baseline values by giving additional bolus doses of fentanyl 25mcg and propofol 10mg. At the end of surgery, all patients were reversed from muscle relaxation with iv neostigmine (40-70 µg/kg) and iv atropine (20-30 µg/kg) titrated to clinical effect, as per the usual protocol.

Post-operatively, all patients were monitored in the recovery room for the first 24h. Patients were assessed for pain and nausea and vomiting just after shifting to recovery from OT by a resident not involved in the study. Thereafter, in the recovery room, data were collected at 2, 4, 6, 12 and 24h, calculated from the time of block placement by the same resident.

Post-operative pain was assessed with a VAS score of 0-10 (0=no pain and 10=worst imaginable pain). VAS scores ≥4 were treated with rescue analgesic tramadol in boluses of 50mg iv, repeated if necessary after 15min. If analgesia was still inadequate after 30min, inj. Diclofenac sodium 75mg intramuscular was administered as a backup analgesic. The total doses of administered tramadol and diclofenac during the first 24-h period were recorded. Time to the first analgesic requirement was noted. Duration of postoperative analgesia was defined as the time between the last suture application and the request for first rescue analgesic at VAS score ≥4.

Number of patients experiencing PONV were accounted for and treated accordingly.

Apart from these, patients were monitored throughout the study period for any evidence of complications.

Statistical method: Discrete categorical data are presented as n (%) and median; continuous data are given as mean ± SD. Differences in demographic, surgical, anaesthetic and post-operative data were tested by independent Student’s t-test (continuous data) or by Pearson Chi-square test and Fisher’s exact test as appropriate (categorical data). For descriptive purposes, p-value differences <0.05 are noted in the tables. All analyses were conducted using SPSS for Windows (Version 12.0; SPSS Inc., Chicago, IL, USA).

Results

The study was conducted over a 21-month period (September 2013 to June 2015). One patient in the paravertebral group was converted to GA due to inadequate block and was also excluded from the study. Therefore, data from 59 patients were available for analysis; Group A (n=29) and Group B (n=30).

Demographic patterns and pre-operative vital parameters were similar when the two groups were compared (Table 1).

Intraoperative vital parameters were comparable in the two groups (p>0.05).

The requirement of fentanyl during the surgery was significantly lower in Group A (107.76±11.77 mcg) as compared with Group B (150.83±26.65 mcg), p<0.0001 (Table 2).

The total dose of propofol was higher in Group A (219.82±74.48mg) than in Group B (122.67±15.07mg), p<0.0001, as would be expected for any regional procedure to maintain immobility.

Time to request for analgesic for the first time was considered as the duration of postoperative analgesia (Table 3). It ranged from 135 to 456min in Group A and from 86 to 170min in Group B. The mean duration of post-operative analgesia was 303.97±76.08min in Group A and 131.33±21.36min in Group B, the difference being statistically significant (p<0.001).

Total dose of tramadol as rescue analgesic during the first 24h was 105.17±20.46mg in Group A as compared with 176.67±52.08mg in Group B (p<0.001). Back-up analgesic in the form of intramuscular diclofenac sodium had to be used in six patients (20%) in Group B as compared with none in Group A (p=0.01).

The VAS scores in the immediate post-operative period and after 2 and 4h in the post-operative period were significantly higher in Group A (p<0.05).

The VAS scores at 6, 12 and 24h were comparable in the two groups, but at the expense of higher analgesic consumption in Group B. VAS score at request for first rescue analgesic was comparable in both the groups (4.24±0.58 vs 4.67±0.88 in Group A and Group B, respectively, p=0.06). Max-
The incidence of PONV requiring treatment was 10.34% in Group A and 30% in Group B.

We have not observed any incidence of inadvertent intravascular injection, haemodynamic instability or persistent pain after the block procedure.

Table (1): Demographic patterns and pre-operative vital parameters.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group P (n=29)</th>
<th>Group G (n=30)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>40.1±7.12.63</td>
<td>39.9±3.12.09</td>
<td>0.94</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>51.07±5.76</td>
<td>51.87±5.32</td>
<td>0.58</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>154.97±4.33</td>
<td>153.43±4.29</td>
<td>0.34</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>21.27±6.02</td>
<td>22±6.00</td>
<td>0.23</td>
</tr>
<tr>
<td>ASA status (I/II)</td>
<td>19/10</td>
<td>21/9</td>
<td>0.71</td>
</tr>
<tr>
<td>Preoperative pulse (bpm)</td>
<td>75.38±7.08</td>
<td>77.33±7.35</td>
<td>0.30</td>
</tr>
<tr>
<td>Preoperative MAP (mmHg)</td>
<td>89.14±5.74</td>
<td>92±8.35</td>
<td>0.13</td>
</tr>
<tr>
<td>Preoperative SpO2 (%)</td>
<td>99.03±0.82</td>
<td>99.15±0.75</td>
<td>0.75</td>
</tr>
</tbody>
</table>

Data are given as mean ± SD, except ASA physical status.

N : Number of patient. Mgs : Milligrams.

Table (2): Intraoperative data.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group P (n=29)</th>
<th>Group G (n=30)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Preoperative pulse (bpm)</td>
<td>77.11±7.05</td>
<td>76.75±6.29</td>
<td>0.83</td>
</tr>
<tr>
<td>• Preoperative MAP (mmHg)</td>
<td>92.0±8.62</td>
<td>89.93±7.68</td>
<td>0.33</td>
</tr>
<tr>
<td>• Preoperative SpO2 (%)</td>
<td>99.05±0.83</td>
<td>99.08±0.62</td>
<td>0.87</td>
</tr>
<tr>
<td>• Total fentanyl (mcg)</td>
<td>107.76±11.77</td>
<td>150.83±26.65</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>• Total propofol (mg)</td>
<td>219.82±74.48</td>
<td>122.67±15.07</td>
<td>&lt;0.0001*</td>
</tr>
</tbody>
</table>

Data are given as mean ± SD. Bpm : Beats per minute. Mins : Minutes.

Table (3): Postoperative analgesia and PONV.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group P (n=29)</th>
<th>Group G (n=30)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Time to first analgesic at VAS ≥4 (mins)</td>
<td>303.97±76.08</td>
<td>131.33±21.36</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>• Total tramadol (mg)</td>
<td>15.17±20.46</td>
<td>176.67±52.08</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>• VAS score at 2hrs</td>
<td>0.31±0.72</td>
<td>3.37±1.19</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>• VAS score at 4hrs</td>
<td>2.13±0.64</td>
<td>3.03±0.81</td>
<td>0.02*</td>
</tr>
<tr>
<td>• VAS score at 6hrs</td>
<td>2.63±0.72</td>
<td>2.43±0.50</td>
<td>0.11</td>
</tr>
<tr>
<td>• VAS score at 12hrs</td>
<td>2.97±0.49</td>
<td>2.67±0.43</td>
<td>0.55</td>
</tr>
<tr>
<td>• VAS score at 24hrs</td>
<td>2.58±0.50</td>
<td>2.73±0.45</td>
<td>0.23</td>
</tr>
<tr>
<td>• VAS score at first rescue analgesic</td>
<td>4.24±0.58</td>
<td>4.67±0.88</td>
<td>0.06</td>
</tr>
<tr>
<td>• PONV requiring treatment; n (%)</td>
<td>3 (10.34)</td>
<td>9 (30)</td>
<td>0.21</td>
</tr>
</tbody>
</table>

Data are given as mean ± SD. PONV: Postoperative Nausea and Vomiting.

Discussion

Regional anaesthesia using thoracic PVB has been described as an ideal alternative to GA for selected breast surgery patients. Benefits include prolonged post-operative pain relief, a reduction of PONV and the potential for ambulatory discharge. The means to assess post-operative pain control was the time to first analgesic consumption, the total amount of analgesic consumed in the first 24h period after surgery and the VAS scores at different times in the first post-operative day [6].

The time to first analgesic in the post-operative period was significantly greater in Group A than in Group B. This is due to the longer duration of post-operative analgesia achieved with PVB. Mean requirement of tramadol (rescue analgesic) in the first 24h was also lesser in Group A as compared with Group B. No patient in Group A required injection diclofenac (back-up analgesic) in contrast to six patients in Group B.

In the present study, 27 (90%) of the patients in Group A completed the surgery with PVB and light sedation. Two patients (6%) in Group A had to be supplemented with local anaesthetic infiltration for adequate anaesthesia as a result of inconsistent block of the targeted dermatomes [13]. One patient (3%) had to be converted to GA due to failed block. Technical difficulty in locating the paravertebral space has been cited as the reason for failure by authors. Failure rates with PVB are consistent with that of other regional techniques. Multiple-injection PVB decreases the chance of inconsistent block associated with a single-injection technique [17]. In a review of eight randomized controlled trials of the use of PVB in breast surgeries and hernia repairs, the overall failure rates of PVB were not >13% [13].

Results of our study did not show post-operative analgesia with PVB to be as prolonged as shown in the study by Klein and colleagues [10], who found reduced pain scores even at 72h post-operatively.

Duration of post-operative pain relief may depend on various factors like the drug and its dose, presence of additive, single or multiple injections, continuous infusion or bolus injection, ultrasound or neurostimulation guidance, use of PCA in the post-operative regimen and age of the patient. High speed of injection and patient positioning can promote contralateral spread.

Greengrass et al. demonstrated superior analgesia and significantly decreased 24-hour morphine
consumption following breast surgeries in patient who received TPVB combined with general anaesthesia [11].

In this study there was statistical difference in the first rescue of analgesia between control group and TPVP block group where the mean first rescue of analgesia in the control group (in hours) was 0.417±.88624 while in the TPVP block group was 6.00±1.60357.

Also Greengrass et al., [12], showed an important advantage of PVB with bupivacaine in patients undergoing breast surgery is the long-lasting post-operative analgesia.

Previous studies [10,15,16], reported that multiple injection does improve the duration and quality of analgesia, with a higher probability of procedural complications. On the other hand, single injection provides more patient comfort and lowers the need for sedation during performance of the PVB, thereby improving patient satisfaction [5,11]. On the contrary, a single-injection technique has been reported to produce a safe but unpredictable block [14].

Postoperative Nausea and Vomiting (PONV) are being the common irritating complaints to any patient especially during the first 24 hours following surgery. Since opioids given intravenously proved to have several disadvantages, including PONV and a delay in the recovery of body functions such as bowel movement and mobilization, several studies have focused on the use of regional analgesia to overcome this complain postoperatively.

In our study, the incidence of PONV requiring treatment was 10.34% in Group A and 30% in Group B.

Similarly Conveney et al., compared thoracic PVB with general anesthesia in breast cancer operations, they showed that twenty percent of patients in the paravertebral group required medication for nausea and vomiting during their hospital stay compared with 39% in the general anesthesia group [17].

To conclude, in view of excellent analgesia in the early post-operative period, requirement of significantly lesser amount of postoperative analgesics, decrease in the occurrence of PONV and low rate of serious complications, along with potential for early ambulation and home discharge, thoracic PVB can be used as a suitable alternative to GA as the anaesthetic procedure in elective breast surgeries.

References
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