Ultrasound guided thoracic Paravertebral block versus wound infiltration of bupivacaine for management of postoperative pain after modified radical mastectomy

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Abstract: Background: Pain after breast surgery is usually severe, and continuous thoracic paravertebral block (cTPVB) has been considered to be an effective pain treatment. Recently, continuous local wound infiltration (cLWI) has become increasingly popular but the outcome of this method regarding the analgesic effect has not been fully evaluated. Objective: We sought to determine the effectiveness of ultrasound guided paravetebral block and wound infiltration of Bupivacaine for postoperative pain management after modified radical mastectomy. Patient and methods: This prospective randomized study was carried out on 40 ASA grade (I-II) adult female patients classified into two groups, group (A) after general anesthesia, a catheter was threaded in the paravertebral space guided by ultrasound, before disconnection of anesthesia by 30 minutes we gave a loading dose of bupivacaine 0.25%, after one hour we gave a maintenance dose through elastomric pump. Group (B) at the end of surgery we placed a catheter subcutaneously, after closure of the wound we gave a loading dose of bupivacaine 0.25 %, after one hour we gave a maintenance dose through elastomeric pump. Results: showed that no statistical difference between the two groups as regard pain visual analogscore (VAS), nausea and vomiting, morphine consumption, hemodynamically, alertness and satisfaction. Conclusion: The present study demonstrated that both cLWI and cTPVB techniques were effective in management of acute postoperative pain after modified radical mastectomy, decreased morphine and antiemetic consumption, reduced nausea and vomiting.

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Introduction

Breast surgery is an exceedingly common procedure and associated with an increased incidence of acute and chronic pain (Eric et al., 2015). Effective postoperative pain control is an essential component of the care of the surgical patient, inadequate pain control, a part from being inhuman, may result in increased morbidity or mortality (Koneti and Jones. 2013). Paravertebral block seems to produce an effective block of the painful pathways, characterized by unilateral regional blockade of several dermatomes. It also allows a sympathetic block that could have some benefit in oncology (Mercedes et al., 2016). TPVB may be an effective analgesic approach for breast cancer surgery. Many studies showed TPVB to be a feasible and effective method for reducing pain after breast surgery. Most included studies showed TPVBs to provide effective analgesia, reduce opioid consumption, and decrease the risk of developing chronic postsurgical pain (Abdullah et al., 2015). In recent years, real-time ultrasonographic guidance has been introduced for nerve blocks, which is rapidly evolving and becoming increasingly more useful in the field of regional anesthesia. Nowadays, the ultrasound (US) technique is being used to locate the nerve plexus and its spatial relationship with other surrounding tissues as it provides the real-time view. US guidance not only determines the size, depth, and exact location of the plexus, but also its neighboring structures and achieves a satisfactory and dense blockade, but due to variable user experience, the results may vary (Jagdish et al., 2016). Sonographic navigation makes paravertebral space (PVS) much easier to find and optimizes introduction of a local anesthetic thus providing adequate long-term pain relief without complications (Matinian et al., 2014). Postoperative continuous infusion with local anesthetics in the incision is a simple, effective and novel technique, in which an elastomeric pump and a catheter were applied. Some studies have shown that intraoperative infiltration with local anesthetics in the incision achieves good postoperative analgesia, decreases pain scores, reduces opioid requirements and improves respiratory function. (Ventham et al., 2013).

2. Patient and methods

This prospective randomized study was carried out on 40 ASA grade (I-II) adult female patients

admitted to Al-Azhar University Hospitals scheduled for elective unilateral modified radical mastectomy under general anesthesia. After approval from ethical committee, an informed consent was obtained from all patients in this research.

Exclusion criteria included: patient refusal, patients undergoing bilateral radical mastectomy, infection at block site, bleeding disorders or patients on anticoagulant therapy, mental dysfunction and allergy to amide group of local anesthesia. Patients randomly were classified into two equal groups each of 20 patients: Group (A): Ultrasound guided continuous paravertebral block by bupivacaine through a catheter in additional to general anesthesia and group (B): continuous local wound infiltration of bupivacaine through a subcutaneous catheter.

Anesthetic technique: On arrival to the operating room. I.V cannula (20gauge) was inserted. The patients monitored by electrocardiogram (ECG) lines were established for heart rate, mean arterial blood pressure (noninvasive) and pulse oximetry. Fentanyl lug / kg each 30 minutes were given intravenously to all patients. Two minutes later anesthesia was induced with propofol 2 mg / kg and rocuronium0.6 mg / kg to facilitate endotracheal intubation. After endotracheal intubation anesthesia was maintained with controlled ventilation of the lungs with 100% oxygen and isoflurane 0.6-1.2%.

• In group (A): (n=20) received general anesthesia in addition to continuous thoracic paravertebral block (cTPV). The cTPV block was performed by placing an epidural catheter in the paravertebral space after general anesthesia and before surgery, using ultrasound machine Sonosite M turbo ultrasound machine. Thirty minutes before disconnection of anesthesia we gave a loading dose 0.3 mg bupivacaine 0.25 % because of its delayed onset in paravertebral block. One hour after giving the loading dose an infusion of 0.25 % bupivacaine started

at $0.2\,$ ml /kg / hour and continued through epidural catheter for the next 20 hours by elastomeric pump (accufuser).

Group B: (n=20) received general anesthesia in addition to continuous local wound infiltration (cLWI). The cLWI was performed at the end of the surgery; the infiLtralong catheter was inserted at the site of wound, the wound infiltrated after closure with a loading dose of 0.3 ml / kg of 0.25 % bupivacaine. One hour after giving the loading dose an infusion of 0.25 % bupivacaine started at 0.2 ml /kg / hour and continued through the InfiltraLongTM catheter for the next 20 hours by elastomeric pump (accufuserTM). The comparison occurred between two groups in regards of degree of postoperative pain relief by visual analog score (VAS), effect on hemodynamic stability, total morphine consumption in 24 hours postoperatively, postoperative nausea and vomiting (PONV), alertness by using Observers assessment of alertness and sedation score (OAAS), patient satisfaction and complications.

Statistical analysis:

Data were collected, tabulated, coded then analyzed using SPSs® computer software version 22. Firstly, numerical variables were presented as mean ± standard deviation or median (inter-quartile range) whenever appropriate. On the other hand, categorical variables were presented as number of cases (percent). Unpaired Student's test was used for between–groups comparison of numerical variables if they showed normal distribution, otherwise Mann- Whitney test was used which was also applied for ordinal data. Chisquare test or Fisher's exact test were used, whenever appropriate, for comparison between groups as regard categorical variables. A difference with "P" value < 0.05 was considered statistically significant otherwise it was insignificant.

3. Results

Table (1): Patient characteristics, Demographic data.

		Group (A) $(n = 20)$	Group (B) $(n = 20)$	P value
Age(year) Mean ± SD		57.36 ± 11.3	59.52 ± 12.5	0.56
Weight (kg) Mean ± SD		68±12.2	71±13.7	0.46
Height (cm) Mean ± SD		164±8.3	167±7.1	0.22
ASA n (%)	I II	8(40%) 12 (60%)	6(30%) 14(70%)	0.74

This prospective study was carried out on 40 female patients scheduled for elective unilateral modified radical mastectomy. Patients randomly were classified into two equal groups each of 20 patients:

Group (A) Ultrasound guided continuous paravertebral block by bupivacaine through a catheter in addition to general anesthesia and group (B) continuous local wound infiltration of bupivacaine through a

subcutaneous catheter. There was no statistically significant difference between the two groups of the study as regards their demographic data (age, weight, height and ASA classification) as shown in Table(1).

As regards of postoperative pain by visual analog score (VAS), there was no statistically significant difference between pain scores of both groups at all measuring time intervals as shown in Table (2).

There was no statistically significant difference between the two groups as regards total dose of morphine consumption as shown in Table(3).

The differences in mean arterial blood pressure (MAP) between the two groups were not statistically significant as shown in Table(4).

Table (2): VAS at the measuring intervals.

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TIME	Group (A)	(n=20)	(n = 20) Group (B) $(n = 20)$				D volue	
	Mean	±	SD	Mean	±	SD	P-value	
30 minutes	2.50	±	1.15	2.31	±	1.11	0.59	
1 hour	1.30	±	1.12	1.4	±	1.15	0.78	
2 hour	1.58	±	1.50	1.63	±	1.32	0.91	
4 hour	1.30	±	1.13	1.46	±	1.41	0.69	
6 hour	1.5	±	0.96	1.7	±	1.12	0.54	
12 hour	1.9	±	1.1	2.1	±	1.3	0.60	
24 hour	1.8	±	1.2	1.9	±	1.4	0.80	

Table (3): Post-operative opioid consumption.

	Group (A) (n = 20)		Group (B) $(n = 20)$			P-value	
	Mean	±	SD	Mean	±	SD	1-value
morphine consumption (mg)	6.9	±	0.8	7.1	±	0.9	0.46

Table (4): Changes in the mean arterial blood pressure.

TIME	Group (A) (n =	Group (A) $(n = 20)$			Group (B) (n = 20)		
	Mean	±	SD	Mean	±	SD	P-value
Base line	104.78	±	11.52	105.26	±	11.69	0.89
30 minutes	81.3	±	9.57	83.5	±	8.72	0.45
1 hour	81.45	±	9.61	82.5	±	5.99	0.68
2 hour	84.55	±	8.34	87.25	±	6.87	0.27
4 hour	87.1	±	7.49	85.2	±	5.75	0.37
6 hour	83.8	±	8.36	85.59	±	7.25	0.47
12 hour	86.32	±	6.53	84.76	±	8.08	0.50
24 hour	86.85	±	6.94	84.9	±	6.56	0.36

There was no statistically significant difference between the two groups as regards the incidence of post-operative nausea and vomiting (PONV) as shown in Table (5).

Comparison of the two groups as regard degree of sedation showed no statistical difference by using

observers assessment of alertness and sedation score **(OAAS)**, scores varied between 1 and 2 points All patients responded immediately when called and all were cooperative and able to take deep breaths as shown in Table (6).

Table (5): Post-operative nausea and vomiting and total dose of metoclopramide.

	Group (A) $(n = 20)$	Group (B) $(n = 20)$	P value
No nausea or vomitingn (%)	(1785 %)	16 (80 %)	
Nausean (%)	2 (10%)	3 (15%)	0.89
Vomitingn (%)	1 (5%)	1 (5%)	
dose of metoclopramide (mg) Mean±SD	1.55± 0.15	1.6 ± 0.17	0.33

Table (6): Comparison between the two groups as regards degree of sedation.

TIME	SCORE	Group (A) (n	Group (A) $(n = 20)$		= 20)	P value
TIME	SCORE	N	%	N	%	r value
Base line	1	20	100	20	100	1.00
	2	0	0.0	0	0.0	1.00
30 minutes	1	15	75	14	70	0.72
30 minutes	2	5	25	6	30	0.72
1 hour	1	16	80	17	85	0.67
1 nour	2	4	20	3	15	0.07
2 hour	1	16	80	18	90	0.65
2 nour	2	4	20	2	10	
4 hour	1	17	85	17	85	1.00
4 Hour	2	3	15	3	15	
6 hour	1	18	90	17	85	0.63
o nour	2	2	10	3	15	0.03
12 hour	1	19	95	18	90	0.54
12 hour	2	1	5	2	10	0.34
24 hour	1	20	100	19	95	0.31
24 Hour	2	0	0.0	1	5	0.51

The degree of patients' satisfaction of analgesia shows non-significant results between the two groups as shown in Table (7).

Table (5): Patient satisfaction.

Satisfaction	Group (A) (n	= 50)	Group (B) (n =	P-value		
Saustaction	N	%	N	%	r-value	
Very satisfied	7	35	8	40	0.92	
Acceptably satisfied	11	55	9	45		
Somewhat satisfied	2	10	3	15	0.92	
Very unsatisfied	0	0.00	0	0.00		

4. Discussion

Breast cancer is one of the most prevalent cancers amongst women in the world. Unfortunately, even after adequate treatment, some patients experience severe pain either due to disease progression or due to treatment related side effects. The persistent pain causes a negative physical and psychosocial impact on patients' lives (Aanchal et al., 2014). Effective postoperative pain management is now an integral part of modern anesthetic practice. Postoperative pain management not only minimizes patient suffering but also can reduce cardiorespiratory morbidity and facilitate rapid recovery (Abigail et al., 2011). As regards to demographic data (age, weight, height, ASA classification) there was no statistically significant difference between two groups. As regards of postoperative pain: this study showed that there was no statistically significant difference between pain scores of both groups at all measuring time intervals, there was no statistically significant difference between two groups in visual analog score (VAS), there was no statistically significant difference between the two groups as regards the total dose of morphine consumption.

Esther Bouman et al. (2014) and Sidiropoulou et al. (2008) are in agreement with our results as regard of pain scores of PVB and LWI in post-operative pain management after MRM. Branka Strazisar and Nikola Besic. (2013) involved 60 patients were enrolled in the prospective randomized study undergoing axillary lymphadenectomy in breast carcinoma patients; The study reported that wound infusion of local anesthetic reduces acute pain and enables reduced opioid consumption. On the other hand Nirmala et al. (2015) reported that no difference in analgesia between the treatment group, which received levo-bupivacaine irrigation through the axillary wound drain every four hours for the first 24 hours postoperatively, and the control group, which received irrigation with normal saline. Instead of perforated catheters, they used axillary drains, which were clamped for 20 minutes every four hours following the application. Thus, a local anesthetic was not administered continuously. Our patients with a continuous infusion of local anesthetic had a lower consumption of opioids and a reduced need for antiemetic drugs these results are in accordance with the conclusions of the majority of investigators who

studied the role of local anesthetics in postoperative pain management. As regards of nausea and vomiting our study showed that no significant difference between two groups. This is in agreement with Esther Bouman et al. (2014). The study of Gherghinescu M. et al. (2015) on Postoperative pain management with a continuous-infusion elastomeric pump providing local anesthetic in thoracotomy was compared with a single-shot epidural in combination with continuous local anesthetic infusion and continuous thoracic epidural infusion, showed that none of the patients presented nausea. As regard of patient sedation, our study showed that no significant difference between the two groups. The study of Branka Strazisar and Nikola Besic. (2013) showed that almost all patients from the test group had an excellent alertness (OAAS) score already on the day of the surgical procedure. As regards to patient satisfaction, the degree of patients' satisfaction of analgesia shows non-significant results between the two groups. Patients in both groups had lower pain score, PONV, and sedation. These are criteria favorable for better patient comfort and early discharge from hospital. Ferreira Laso et al. (2014) study showed that all participants reported high level of satisfaction. On the other hand Parul Bansal et al. (2012) examined the efficacy of single shot wound infiltration compared with continuous paravertebral block, on forty patients undergoing MRM. reported that PVB with general anesthesia is associated with better postoperative analgesia, lower incidence of PONV, and better alertness score compared to general anesthesia with local infiltration. This is in contrast with the results of our study but this may return to that we used continuous wound infiltration technique by InfiltraLongTM catheter with multiholed catheter 19 gauge. 88 hole in the first 22 cm of 70 cm total length of the catheter and elastomeric pump (accufuserTM) by fixed rate of bupivacaine and thoracic paravertebral block guided by ultrasound compared to that study performed without catheter, pump or ultrasound. As regard to hemodynamic changes. The present study showed that there was no statistically significant difference between two groups.

Conclusion

This study demonstrated that both cLWI and cPVB techniques were effective in management of acutepostoperative pain after modified radical mastectomy. As cLWI is easily to perform with fewer complications. The use of ultra-sound (U-S) guided TPVB is feasible, effective, has a high success rate, and decrease the incidence with of complications The use of InfiltraLongTM catheter give a high quality of distribution of local anesthesia, easy to place and

remove, safe, radiopaque, no kinking and multiple holes.

Recommendations

According to the results obtained, it is recommended to:

• Reducing the cost of the catheter of LWI by designing a catheter as epidural catheter but with multiple holes. Following up the patient to evaluate chronic pain up to one year.

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