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Original study

The Effect of Retrolaminar Thoracic Paravertebral Block on Postoperative Analgesia after Breast Surgeries: Prospective Randomized Study

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Abstract

Background: **The retrolaminar approach of paravertebral block (PVB) is a recent approach which could replace the ordinary approach of PVB as it may have the same analgesic effect with decreased risk of side effects.**
Study Objectives: **This prospective randomized clinical trial aimed to compare the effect of retrolaminar and ordinary approach of PVB on postoperative analgesic profile after breast surgeries.**
Design: **Randomized clinical double-blinded trial.**
Setting: **Operative room, postoperative care unit, and follow-up clinic.**
Methods: **Sixty female patients scheduled for unilateral breast surgery under general anesthesia and PVB were randomly and equally distributed into two groups; group O, in which the patients received PVB by the ordinary approach, and group R, in which the patients received the PVB through retrolaminar approach.**
Main outcome measures: **The primary outcome was the total dose of morphine consumed in the first 24 hours after surgery and the secondary outcome was the incidence of complications.**
Results: **In comparison to the ordinary approach, the use of retrolaminar approach of PVB did not significantly change the postoperative morphine consumption (9 (9-6) mg versus (9 (9-6) mg P= 0.823) and did not significantly change the incidence of perioperative complications (P > 0.05). Also, it did not significantly affect the postoperative Numeric Metric Score (NRS) score (P > 0.05).**
Conclusion: **The retrolaminar approach of PVB has the same effect on the postoperative morphine consumption, the postoperative pain score, and the duration of postoperative analgesia as the ordinary approach in patients undergoing unilateral breast surgery without significant effect on the incidence of complications.**
Trial registration: **The study was registered at clinicaltrial.gov (ID; NCT04162951)**

Keywords: **Analgesia, Breast, Chronic Pain, Mastectomy, Postoperative pain.**

Introduction

Paravertebral block (PVB) was first performed in 1905 by Hugo Selheim. It involves local anesthetic injections alongside the vertebral column near the emergence of spinal nerves, this can result in ipsilateral somatic and sympathetic nerve root block[1,2].

It can be performed by introducing Touhy needle lateral to the spinous process and advanced till loss of resistance to air or normal saline felt due to penetration of the superior costotransverse ligament which is usually 1- 1.5 cm from the superior edge of transverse process[3,4]. The mechanism of action of PVB is through reaching of local anesthetics to the spinal nerves, the dorsal rami, and the sympathetic chain. The spinal nerves in the thoracic region are segmented into small bundles devoid of fascial sheath which render them more susceptible to the local anesthetics. The epidural spread of local anesthetics may play a role in its mechanism of action[5,6].

Thoracic PVB has been used successfully in breast surgeries and was found to be effective and safe. However, it had certain complications such as relatively high failure rate, pneumothorax, or vascular puncture[7].

The retrolaminar plane is the plane between the dorsal aspect of the lamina and the overlying muscles of the back including trapezius and erector spinae muscles. The retrolaminar approach is a modified PVB in which the local anesthetics are injected into the retrolaminar plane to achieve truncal sensory block like that of traditional PVB with minimal risk of puncturing the pleura or blood

vessels[8]. It is postulated that the local anesthetics injected in retrolaminar PVB penetrate through the superior costotransverse ligament to reach thoracic paravertebral space[9].

This prospective randomized clinical trial assumed that the use of retrolaminar approach of PVB may have the same effect of traditional PVB on the postoperative opioid consumption after breast surgeries while decreasing the risk of complications. The study was carried out to compare the effect of retrolaminar or traditional approach of PVB in patients presented for modified radical mastectomy on postoperative analgesic consumption and the incidence of complications.

Methods

The Institutional Ethical Committee of our Faculty of Medicine had approved this prospective randomized clinical trial (Tanta University - Address: Faculty of Medicine, Tanta, Gharbia Governate, Egypt - Protocol number: 33207/07/19– Chairperson: Prof Mona El-Gohary – Date of approval: July 2019). The study was then registered on clinical trial.gov before first patient enrollment with its (ID; NCT04162951). An informed written consent was signed by all the participants of the study that lasted from November 2019 to October 2023. All the participants received adequate explanation of the purpose, the benefits, and the potential hazards of the study before their enrollment. This study followed the applicable CONSORT guidelines. The study was conducted in accordance with the Helsinki Declaration-2013.

Adult female patients scheduled for breast surgery, aged 40- 60 years, and American Society of Anesthesiologists Class (ASA) I and II were included in the study. The patients were excluded if they refused to participate in the study, suffered from preoperative chronic pain, receiving opioid or gabapentoids preoperatively, or had allergy to local anesthetics, spine deformities, Body mass index (BMI) more than 36 kg/m2, and major cardiac, renal, respiratory, or hepatic diseases.

The enrolled patients were randomly distributed into two equal groups by Computer-generated software of randomization introduced into closed opaque envelopes:

- *Ordinary approach group (Group O):* The patients in this group received ultrasound-guided thoracic PVB by local anesthetic mixture at a volume of 0.2 ml/kg composed of plain bupivacaine 0.25% and fentanyl 2 µg/ml before induction of anesthesia.
- *Retro-laminar approach group (Group R):* The patients received ultrasound-guided trans-foraminal thoracic PVB by local anesthetic mixture composed of bupivacaine 0.25% and Fentanyl 2 µg /ml at a volume of 0.2 ml/kg before induction of anesthesia.

Anesthesia technique

Adequate preoperative assessment was done to all the patients in anesthesia clinic. Upon arrival at the operating theatre, an intravenous access was established in the contralateral hand or forearm. Fluid preload in the form of 7 ml/kg of lactated ringer was started over 20 min. The patient was connected to a monitor device consisting of pulse oximeter, non-invasive blood pressure, and 5-leads Electrocardiogram. All equipment to perform paravertebral block were prepared including the ultrasound machine (Philips CX 50 Extreme edition, Philips), local anesthetic drugs, and resuscitation equipment and drugs. The patient was turned to a sitting position to perform PVB either ordinary approach or retro-laminar approach according to the patient group. Both were performed by a single, experienced sonographer who was an expert in ultrasound-guided regional anesthesia but was not directly involved in the postoperative assessment.

Technique of ordinary approach of US-guided PVB

The skin of the ipsilateral dorsal region was sterilized with povidone-iodine 10% with covering of the probe of the Ultrasound machine with a sterile sheath. The 4th dorsal spine (T4) was identified by derangement from the 7th cervical spine (C7). Using the paramedian sagittal oblique approach, the high-frequency (linear probe 6-12 MHz, Philips CX 50 Extreme edition, Philips) transducer was placed sagittally 2–3 cm away from the thoracic midline with the probe mark toward the cephalad direction to identify the hyperechoic transverse process and between the two the transverse process, the superior costotransverse ligament (SCTL), thoracic paravertebral space (TPVS), and parietal pleura were clearly identified. For optimal visibility of the TPVS a slight oblique (outward) tilt was done. Local infiltration anesthesia in the form of 3 ml lidocaine 2 % was injected into the skin and subcutaneous tissue at T4, then a 22-gague, 100mm, short bevel needle (Pajunk) needle was introduced under real-time US guidance from caudal to cranial with an in-plane technique to target the TPVS. Then, a preprepared local anesthetic mixture 0.2 ml/kg (plain bupivacaine 0.25% and fentanyl 2 µg /ml) was injected slowly after exclusion of blood aspiration. Following the injection the block success is confirmed anterior displacement of the pleura, widening of the

paravertebral space, and an increased echogenicity of the pleura (Fig. 1 A, B, C).

Technique of retro-laminar approach of US-guided PVB

Sterilization of the ipsilateral dorsal region with povidone iodine was carried out followed by identification of T4 by derangement from C7. The skin and subcutaneous tissue 1.5 cm lateral to T4 were infiltrated by 3 ml of lidocaine 2%. The linear probe was placed 1.5 cm lateral to T4 spinous process in the paramedian sagittal plane until the lamina was visualized as a hyperechoic line with dense acoustic shadow underneath. A 22-gague, 100mm, short bevel needle (Pajunk) needle was inserted in plane from caudal to cephalic direction till contacting the lamina. Local anesthetic mixture (0.2 ml/kg) composed of plain bupivacaine 0.25% and 2 µg /ml was injected slowly. (Fig 1D, E, F)

After performing the regional block, the patient was turned to a supine position with adequate preoxygenation through a well-fitted face mask using 0.8 oxygen for 3 minutes. Anesthesia was induced by fentanyl 1.5 µg /kg, propofol 1.5 mg/kg, and cis-atracurium 0.15 mg/kg to facilitate tracheal intubation with suitable sized endotracheal tube. The patient was connected to a mechanical ventilator with its parameters adjusted to maintain end-tidal carbon dioxide 32-36 mmHg. The maintenance of anesthesia was performed by isoflurane 1 MAC in a mixture of oxygen and air 1:1 using a total flow of 1 L/min. Temperature probe was introduced into nasopharynx after intubation and bispectral index (BIS) monitor was used to assess the depth of anesthesia. An increase in the BIS reading above 60 or increase in the mean values of heart rate or mean arterial pressure by more than 20% were managed by an additional dose of fentanyl 0.5 µg /kg i.v and increase the concentration of isoflurane.

The isoflurane was switched off at the end of the surgery with reversal of muscle relaxation by a combination of atropine 0.01 mg/kg and neostigmine 0.05 mg/kg and fully awake extubation. The patient was transported to Post-anesthesia care unit (PACU) for continuing monitoring and follow-up and was discharged to the inpatient when her modified Aldrete's score reached 10 or more. All the patients received prophylaxis against postoperative nausea and vomiting in the form of dexamethasone 8 mg i.v after induction of anesthesia and ondansetron 8 mg i.v at the end of the surgery. Also, all the patients received routine analgesia composed of 1 gm paracetamol i.v infusion every 6 hours and ketorolac 30 mg i.v every 12 hours. Rescue analgesia was composed of 3 mg morphine slow i.v and was administrated when the pain score reached 4 or more and cab be repeated whenever required.

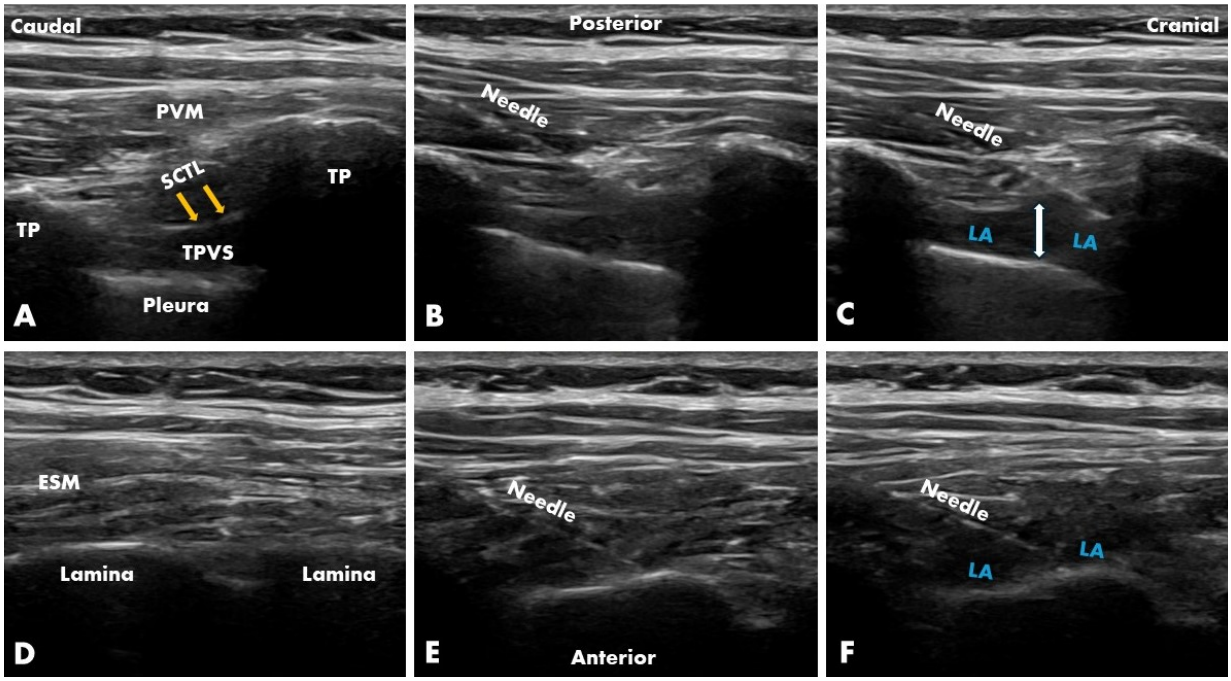

Fig. 1 — Ultrasound guided Paravertebral block (A-B-C) and retrolaminar block (C-D-E).
The upper row showed the ordinary approach, A: Showing the oblique parasagittal approach to visualize Paraspinal muscles (PVM), 2 transverse processes (TP), the superior costotransverse ligament (SCTL), Thoracic paravertebral space (TPVS), and parietal pleura, B: the advancement of the needle using in plane technique, C: Injection of the local anesthetic (LA) in the TPVS notice anterior displacement of the pleura, widening of the paravertebral space.
The lower row showed the retrolaminar approach, D: Identification of the lamina under the Erector spinae muscle (ESM), E: the advancement of the needle using in plane technique, F: Injection of LA after contacting lamina.

Data collection and Study outcomes

The measurements were collected by an assistant nurse who was blinded to the study and had no other role in it. The primary outcome was total morphine consumption in mg in the first 24 hours after surgery. The secondary outcome was the incidence of complications such as pneumothorax, hypotension, or intravascular injection. Pneumothorax was diagnosed by clinical examination of the chest, oxygen desaturation, increased peak air way pressure and confirmed by lung US or chest X-ray. It was managed by the insertion of chest tube. Intravascular injection was diagnosed by severe hypotension and bradycardia and managed by adequate monitoring of the patient and circulatory support. Hypotension was defined as a decrease in mean arterial pressure below 65 mmHg or a decrease by more than 20% of the preoperative value and was managed by intravenous fluids and incremental doses of ephedrine.

The postoperative pain was assessed by the Numeric rating Scale (0 to 10 metric score for assessment of the pain severity where 0 = no pain and 10 = worst pain) (NRS) immediately postoperative, 2, 4, 6, 8, 12, 16, 20, 24 h postoperatively. Patients experienced to express their pain by NRS preoperatively. Furthermore, the intraoperative fentanyl and isoflurane consumption were calculated. Moreover, the time for the first request of rescue analgesia was measured which represents the time interval between the recovery of the patient and the first administration of morphine. The patients were asked to rate their level of satisfaction the day after surgery using 4 points scale (4 = very satisfied, 3 = satisfied, 2 = dissatisfied, and 1 = very dissatisfied). Along 3 months from the surgery, the patients were followed up in the pain clinic every 2 weeks for 3 months for development of chronic pain with recording of the site and character of pain.

Sample size calculation revealed that 26 patients for each group will have 95 % power to detect a change in the mean difference in morphine consumption by 1 mg considering the standard deviation of postoperative morphine consumption of 0.98 mg which was reported by Kulhari, et al10. using one group t-test with alpha value 0.05. Thirty patients were included in each group for the possibility of dropout cases. Statistical analysis of the data was carried out by SPSS computer program (SPSS Inc., Chicago, IL, USA). The data were entered manually with the aid of an independent physician putting each subject's data in a single row to maintain the quality of data. The Chi-square test was used to analyze categorical data that were presented as number and frequency, while Unpaired t-test was used to analyze parametric data that was presented as mean and standard deviation. Mann-Whitney test was used to analyze abnormally distributed data that were expressed as median and interquartile range. Bonferroni correction (P value was adjusted by multiplication by the number of tests) was used to correct P value of pain score at multiple time points. The values were considered statistically significant when P was less than 0.05.

Results

The eligibility of this clinical trial was tried on 93 female adult patients undergoing breast surgery, 19 patients did not meet the criteria of the study, and 14 patients declined to participate in the trial, the other 60 patients were randomly distributed into two equal groups. All the enrolled patients underwent successful techniques, follow-up, and collection of data (Fig. 2). The baseline clinical characteristics and the demographics of patients including age, BMI, ASA class, and duration and side of surgery were comparable between the two groups (P = 0.561, 0.498, 0.760, 0.975, 0.567 respectively) (Table I).

The primary outcome of the study, which is the total morphine consumption in the first day after surgery was statistically insignificant between the two groups (9 (9-6) mg in group O and group R; P = 0.823). Moreover, the time for the first postoperative call for morphine rescue analgesia was indifferent among the two groups (480 (645-360) min in group O; 510 (675-415) min in group R; P = 0.318). Furthermore, the changes in intraoperative fentanyl consumption were statistically insignificant between the two studied groups (0.5 (0.625-0.0) µg /kg in group O; 0.5 (1.0-0.0) µg /kg in group R; P = 0.551). Also, the intraoperative isoflurane consumption was comparable between the two groups (22.27±3.95 ml in group O; 20.47±3.78 ml in group R; P= 0.076; CI9 5%: -3.796; 0.196). In addition, the postoperative NRS score of pain was not different between the two groups during any time interval in the first 24 hours after surgery (P = 0.692, 0.818, 0.683, 0.533, 0.354, 0.935, 0.334, 0.812, and 0.870 respectively) (Table II).

The use of retrolaminar approach did not significantly change the incidence of perioperative complications including bradycardia, tachycardia, hypotension, hypertension, or nausea and vomiting (P = 0.729, 0.747, 0.775, 0.640, and 0.739 respectively). The incidence of pneumothorax, oxygen desaturation, or intravascular injection was not reported in any patient of the two studied

Table I. — Demographic data in the studied groups.

		Group O	Group R	P-value
Age (Years) mean±SD		50.60± 5.93	49.70±6.00	0.561
Body Mass Index (Kg/m^2) mean±SD		28.90± 4.05	28.20±3.91	0.498
ASA class n(%)	I	8 (26.67%)	6 (20.00%)	0.760
	II	22 (73.33%)	24 (80.00%)	
Duration of the surgery (min) mean±SD		110.83±20.35	111.00±20.49	0.975
Side of surgery n(%)	Rt	7 (23.33%)	10 (33.33%)	0.567
	Lt	23 (76.67%)	20 (66.67%)	

Data were presented as mean ± standard deviation or as number and percent; Group O (Ordinary approach group (30 patients)) Group R (Retrolaminar approach group (30 patients)); ASA; American Society of Anesthesiologists. CI; Confidence interval.

Table II. — Postoperative opioid consumption, postoperative pain scores, and intraoperative anesthetic consumption in the two groups.

		Group O	Group R	P-value
Postoperative morphine consumption (mg) Median IQR		9 (9-6)	9 (9-6)	0.823
Time for the first request to morphine (min) Median IQR		480 (645-360)	510 (675.-415)	0.318
Intraoperative fentanyl consumption (ug/kg) Median IQR		0.5 (0.625-0.0)	0.5 (1.0-0.0)	0.551
Intraoperative isoflurane consumption (ml) mean ± SD		22.27±3.95	20.47±3.78	0.076
Numeric rating Score Median IQR	Immediately postoperative	1 (1.0-0.0)	1 (1-0)	0.692
	2 h	1 (2.0-0.0)	1 (2.0-0.0)	0.818
	4 h	1 (2.25-1.0)	2 (3.0-1.0)	0.683
	6 h	2 (3.0-1.0)	2 (3.0-1.0)	0.533
	8h	5 (6.0-3.0)	4 (5.0-2.0)	0.354
	12 h	3 (5.0-2.0)	3 (5-2.75)	0.935
	16 h	3 (3.0-2.0)	3 (4.0-2.0)	0.334
	20 h	3 (3.0-1.0)	3 (3.0-1.0)	0.812
	24 h	2 (3.0-1.0)	2 (3-0.75)	0.870

Data were presented as median and interquartile range (Q3-Q1) or mean ± standard deviation; Group O (Ordinary approach group (30 patients)) Group R (Retrolaminar approach group (30 patients)); *Denotes significant changes; CI; Confidence interval.

groups. The incidence of chronic pain 3 months after surgery was not significantly different between the two groups (P = 0.704). Also, the character and site of pain were comparable between the two groups (P = 0.737 and 0.735) (Table III). The patients of any group were not statistically more satisfied than those of the other group (P = 0.858) (Fig. 3).

Discussion

Limitations of the study

This clinical trial was limited by the small sample size, the use of a single type and single concentration of local anesthetic mixture. Moreover, the sample size calculation based upon the use of a small dose of postoperative morphine consumption limited the study. Also, lack of comparison to other fascial plane blocks as erector spinae plane block and serratus anterior plane block and specific data on procedural time or the ease of administration added to the limitations of the study. Besides, this clinical study is a non-inferiority study with small number of studied patients that limit the ability to address the potential side effects of the technique.

Paravertebral block is an effective regional anesthesia technique; however, its use may be accomplished by many side effects like pneumothorax, hypotension, or unintended epidural spread. Retrolaminar PVB technique was introduced as an alternative to the ordinary approach as its use might reduce the potential hazards of PVB, but its use is not established yet[11-13].

This prospective randomized double-blinded study evaluated the effect of retrolaminar thoracic PVB on postoperative morphine consumption and the incidence of complications after breast surgeries in comparison to the ordinary approach of PVB. The study observed that postoperative morphine consumption, the duration of post-operative analgesia, the postoperative pain score, the intraoperative anesthetic consumption, the incidence of perioperative complications, the incidence of chronic pain 3 months after surgery, or

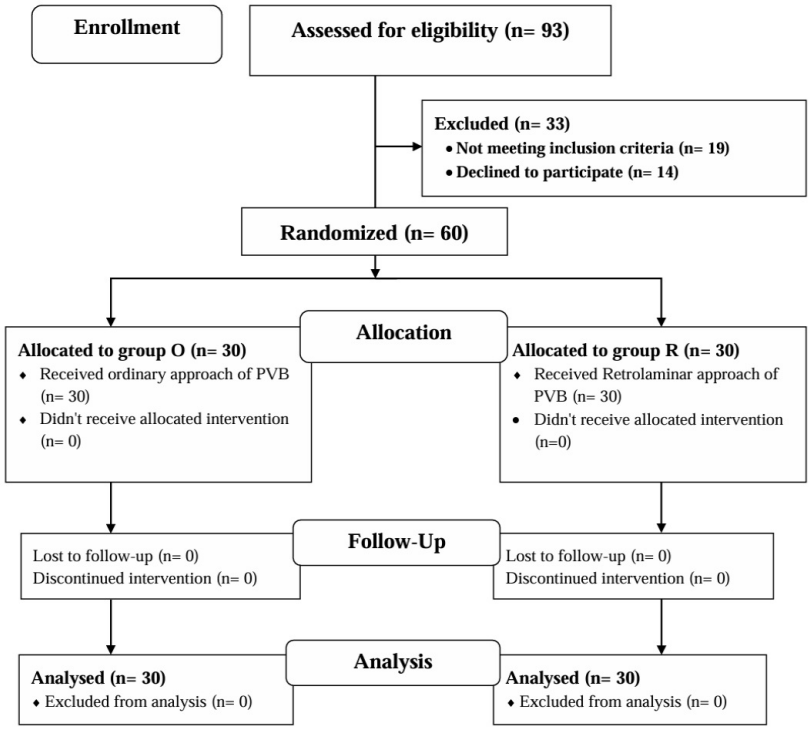

Fig. 2 — CONSORT flow chart of the study.

Table III. — The incidence of postoperative complications and chronic pain in the two groups.

			Group O	Group R	P Value
Bradycardia n(%)			4 (13.33%)	6 (20.00%)	0.729
Tachycardia n(%)			7 (23.33%)	5 (16.67%)	0.747
Hypotension n(%)			9 (30.00%)	8 (26.67%)	0.775
Hypertension n(%)			3 (10.00%)	2 (6.67%)	0.640
Nausea and vomiting n(%)			5 (16.67%)	6 (20.00%)	0.739
Pneumothorax n(%)			-	-	-
Oxygen desaturation n(%)			-	-	-
Intravascular injection n(%)			-	-	-
Chronic Pian n (%)	Incidence of Chronic pain		5 (16. 7%)	3 (10.00%)	0.704
	Character of pain	Burning pain	3 (10.00%)	2 (6.7%)	0.737
		Stabbing pain	2 (6.7%)	1 (3.3%)	
	Site of pain	Chest	3 (10.00%)	2 (6.7%)	0.735
		Axilla	1 (3.3%)	1 (3.3%)	
		Upper arm	1 (3.3%)	0 (0.00%)	

Data were presented as number and percent; Group O (Ordinary approach group (30 patients)) Group R (Retrolaminar approach group (30 patients)).

the patient's satisfaction were comparable between the two techniques.

The analgesic effects of PVB after breast surgeries were confirmed by the clinical studies of Kairaluoma et al14 and Boughey et al15 who evaluated the use of preoperative single injection of PVB in comparison to sham block in patients scheduled for breast surgery and reported less opioid medication consumption in the postoperative period, longer latency to the first opioid dose, and less pain at rest after 24 h.

The retrolaminar approach of PVB was evaluated by the cadaveric study of Sabouri A et al that evaluated ultrasound-guided retrolaminar block with 20 ml of methylene blue and bupivacaine 0.5% in fresh cadavers and ultrasound-guided PVB in other cadavers to assess the spread of injectate. They found that the injectate spread from the retrolaminar injection point to the paravertebral space and subsequently to the epidural space, intercostal space, and intervertebral foramina. The ordinary PVB seems to be better due to the rapid spread of the injectate to the epidural and intercostal spaces[16].

The effectiveness of retrolaminar technique was shown by the case report of Voscopoulos,

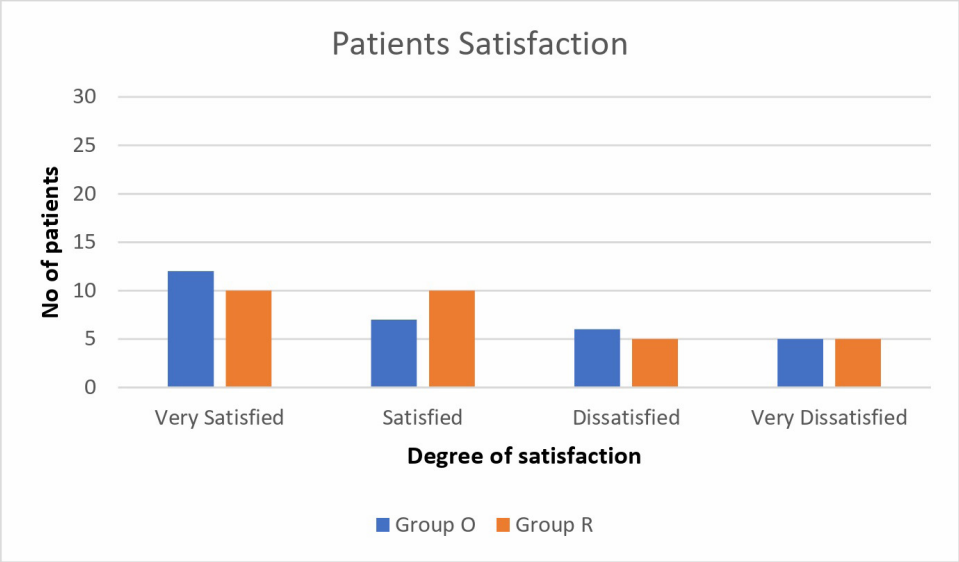

Fig. 3 — Patients satisfaction in the two studied groups.

et al who described a 37-year-old female patient undergoing bilateral mastectomy and tissue expander reconstruction under general anesthesia and bilateral ultrasound-guided retrolaminar block. The patient did not require any opioids in the first postoperative day and her pain score ranged from 1 to 4/10[17]. Furthermore, a narrative review by Kumari et al declared evidence that a retrolaminar block can effectively relieve pain during truncal surgery and had a lower rate of complications, was simpler to perform, and required shorter hospital stays[18].

The clinical study of Murouchi et al compared the use of retrolaminar block to the use of PVB in 30 patients undergoing breast surgery and suggested that the retrolaminar block was not inferior to the PVB except for the first day and was satisfactory and safe after mastectomy[9]. Moreover, the clinical trial of Sotome, et al compared the use of retrolaminar block or erector spinae plane block in patients scheduled for breast surgeries and concluded that erector spinae plane block and retrolaminar block are equally effective in analgesia after breast surgery[19].

On the other hand, the clinical study of Onishi et al evaluated double-level retrolaminar approach of PVB in 122 women who underwent breast cancer surgery under general anesthesia and concluded that the retrolaminar approach of PVB did not reduce the number of patients requiring postoperative analgesia, and the postoperative analgesic duration was only 2-3 h, which was unexpectedly shorter than that of PVB reported previously11. Moreover, the trial of Hwang et al assessed the analgesic efficacy of T3 single injection of ultrasound-guided retrolaminar PVB for 46 patients scheduled for breast surgeries and found that cumulative morphine consumption, the incidence of adverse events, and patient satisfaction did not differ between the two groups. The resting and coughing VAS scores at 1 hour postoperatively were higher in retrolaminar group. The retrolaminar group had a lower requirement of remifentanil than the control group intraoperatively[20].

Conclusion

It can be concluded that retrolaminar approach of PVB has the same analgesic effect as the ordinary approach of PVB in female patients after breast surgeries as the postoperative opioid consumption, the latency to the first opioid dose, and the postoperative pain score were comparable between them. Besides, the incidence of perioperative complications or chronic pain was similar between both techniques.

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Authors agree to sharing the data reported in this study including the protocol of the study, the ethical committee approval, and the row data of primary outcome. The data can be obtained through contacting corresponding author.

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