Original Article

A Ramdomized Placebo-Controlled Double Blind Study of Intercostal Nerve Block and Locally Administered Bupivacaine for Postoperative Pain Control after Subpectoral Breast Augmentation

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Background: Breast augmentation is among the most popular surgery procedures performed in the Asian countries. Subpectoral augmentation involves additional pain from muscle spasm following muscle dissection. Adequate pain control can have a substantial impact on morbidity and patient satisfaction. To date, no standard of care exists and management is based on surgeon preferences. The purpose of our study is to examine the role of intercostal nerve block and local bupivacaine injection in pain management following subpectoral breast augmentation.

Objective: To study the effect of field block and intercostal nerve block on postoperative pain in augmentation mammoplasty patients.

Materials and Methods: This study was a prospective, randomized, placebo controlled, double blinded clinical trial with ethical approval. Thirty-two consecutive women undergoing subpectoral breast augmentation were enrolled. Patient received general anesthesia and were allocated randomly to two study groups. Patient in group 1 received intercostal nerve block using 10 ml of 0.25% bupivacaine with epinephrine in one side of breast and normal saline in another side prior to implant placement. Patient in group 2 received locally administered 20 ml of 0.25% bupivacaine with epinephrine in one side of breast and placebo infiltration of normal saline in the contralateral breast. Primary outcome was pain measured with the visual analogue scale recorded at 2, 6, 12, 24 and 48 hours at rest and after movement. A *p*-value of <0.05 was considered statistically significant.

Results: Postoperative pain gradually decreased with time in all patients. By comparing analgesic outcomes in the same patients, we could control for the subjectivity of pain assessments. No difference in pain scores was found over time at rest or on movement when comparing intercostal nerve block to placebo or local infiltration to placebo. There were no significant complications.

Conclusion: No statistically significant difference in postoperative pain when comparing those receiving intercostal nerve block versus placebo and those receiving local administered bupivacaine versus placebo.

Keywords: Breast augmentation, Postoperative pain, Subpectoral breast augmentation, Intercostal nerve block, Field local anesthetic infiltration

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Nowadays, cosmetic surgery is more popular and acceptable of which breast augmentation is one of the three most popular procedures. This is not a complicated procedure and has low operative risk therefore short time of rest is needed[1].

The development of surgical techniques can diminish postoperative pain from the past but it will still exist[3,4]. Usually, given oral or intravenous analgesic drugs may not be enough and have adverse effects from the drugs i.e. headache, nausea, vomiting, constipation and even neurological or respiratory depression. Other techniques for decrease postoperative pain: intercostal nerve block, injection of analgesic drugs at pectoralis muscles, muscle relaxant drugs or use of electrical stimuli[2].

Local anesthesia is one of the methods that have less systemic adverse effects[5,8] so patients can return to normal life earlier[6,7,9].

Until recently, management of postoperative pain included only treatment modalities applied to patients after surgery in reduce already established pain. However, experimental data in the past suggests that surgery and other forms of peripheral tissue injury result in a disruption of stimuli processing at the peripheral and central nervous system (CNS) level, which lead to peripheral and central sensitization. Central sensitization refers to sensory changes in the undamaged tissue surrounding the injury, due to a

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hyperexcitability of spinal neurons, which produces secondary hyperalgesia[8]. Therefore, whenever, in clinical practice central sensitization occurs, pain treatment, to be effective, should not only be managing the nociception related to the tissue trauma, but also the CNS response to the trauma. Therefore, there is a hypothesis of 'pre-emptive analgesia' which is the effective prevention of central sensitization within the spinal cord or at other supraspinal pain pathway sites that effectively prevent central sensitization.

Materials and Methods

We conducted an observer-blinded, randomized, controlled trial, starting July 2015 to March 2016. Patients, who were scheduled for augmentation mammoplasty in Ramathibodi Hospital, were asked to participate in the study and allocated randomly to one of two study groups. Patients in group 1 received intercostal nerve block in one side of breast and another side was normal saline. Group 2 patients received field block in one side of breast and NSS in another (Figure 1).

The exclusion criterion was previous surgery on the breast or chest wall, history of anesthetic drug allergy and sensation problem on chest wall. The study received approval from the Committee on Human Rights Related to Research Involving Human Subjects, based on the Declaration of Helsinki. Written informed consent was obtained from all participants.

Sample size calculation was based on pain as the primary outcome measure, with a difference of one point on the pain numerical rating score considered to be clinically relevant. With an estimated standard deviation of 1.01, a power (β) of 0.80, and two-sided significance level (α) of 0.05, a minimum of 32 participants were to enroll in the study.

Computer-based randomization to random side of injection and technique of local anesthesia was performed and surgeon, nurse and patients were blinded.

Two, six, twelve, twenty-four and forty-eight hours after surgery, patients were asked to score the pain of both sides of the breast by means of a numerical rating score ranging from 0 (no pain at all) to 10 (unbearable pain). The Student T test was used to analyze scores for pain that were significantly different between experimental and controlled side at different time after augmentation mammoplasty.

Surgical technique

For all patients, general anesthesia with endotracheal tube was performed and 1% Lidocaine with adrenaline 5 ml was infiltrated at each incision site. The surgeon developed a dual plane through elevation of the pectoralis muscle under vision and bloodless surgical technique. After submuscular elevation, the implant is placed and wound was closed. For patients receiving nerve blocks, 5 ml of 1% Xylocaine with 1: 100,000 adrenaline and 5 ml of 0.5% Marcaine was injected into intercostal space from T3 to T6, 2.5 ml in each level. For patients receiving field blocks, 5 ml of 1% Lidocaine with 1: 100,000 adrenaline and 5 ml of 0.5% Marcaine dilute in NSS 10 ml was injected around the breast mound.

Intercostal block technique

After elevation of the pectoralis muscle, but before insertion of the implant, the intercostal nerve block is administered. The surgeon determines the levels of T3 to T6 at midaxillary line, and palpates each corresponding rib. The surgeon inserts the 25-gauge needle immediately inferior to the rib, taking care not to insert the needle past the internal intercostal muscle. The surgeon aspirates to ensure the injection is not intravascular and administers 2.5 ml of anesthetic in each intercostal space. And do the same with normal saline solution in controlled side (Figure 1).

Field block technique

The same as intercostal block, field block is administered after elevation of the pectoralis muscle before implant insertion. The surgeon injected 20 ml of anesthetic drug around the breast mound in subcutaneous layer by 25-gauge needle. In controlled side NSS is injected in the same technique (Figure 2).

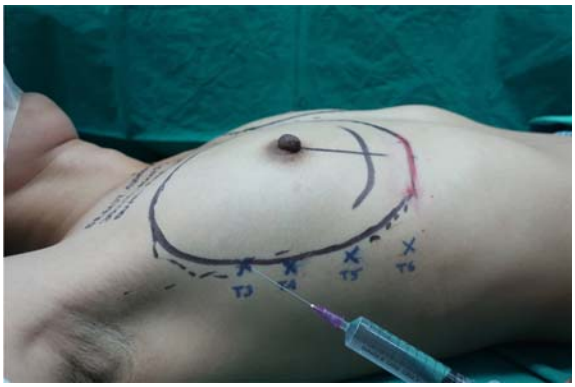

Figure 1. This picture shows T3 to T6 level of intercostal nerve block technique.

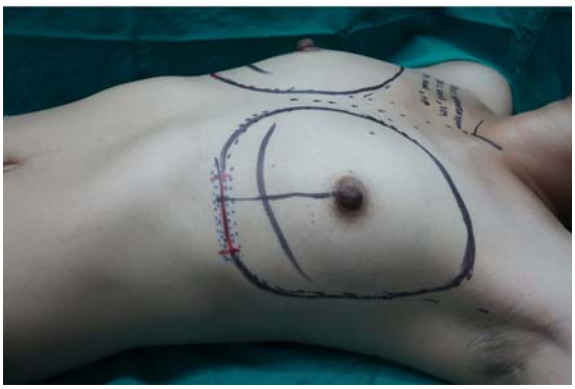

Figure 2. This picture shows surgical site injection of surgical field technique.

Results

Thirty-two patients completed the study. No significant difference in age, sex, BMI, underlying disease and history of drug use and smoking (Table 1). The results in Table 2 are pain comparison at rest between placebo with field block and between placebo with intercostal block. Pain at rest of field block was less than placebo side at 2 hours but there were no statistically significant differences. Pain at rest of intercostal block was less than placebo side at 6, 12 hours but there were no statistically significant differences. Table 3 is pain comparison on movement between placebo with field block and placebo with intercostal block, Pain of field block was higher than placebo side at 6 hour but there were no statistically significant differences. Pain of intercostal block was less than placebo side at 6, 12 hours and higher at 2 hours, but there were no statistically significant differences. Table 4 is comparison between field block with intercostal block at rest and movement. At rest pain of intercostal block was higher than field block at 2, 6 and 12 hours but there were no statistically significant differences. Pain on movement of the intercostal block was higher than field block at 2, 24 and 48 hours and lesser at 6 and 12 hours, but there were no statistically significant differences.

Discussion

There were no statistically significant differences in either group (field and intercostal group). The local anesthetic drugs that we gave to patients have duration of only six to eight hours, but patients still had no significant difference in pain at 12, 24 and 48 hours. Postoperative pain

Table 1. Demographic data

Characteristic	Field block, n = 16	Intercostal block, n = 16	*p*-value
Age (years)	30.3 (7.8)	28.4 (5.6)	0.440
BMI (kg/m^2)	19.9 (2.1)	18.8 (1.6)	0.128

Table 2. Pain at rest

Post-op time points	Field block (n = 16)	Placebo (n = 16)	*p*-value	Intercostal block (n = 16)	Placebo (n = 16)	*p*-value
2 hours	2.5 (0 to 7)	3 (0 to 7)	0.162	4 (0 to 8)	4 (0 to 7)	0.063
6 hours	2 (0 to 8)	2 (0 to 8)	0.564	3 (0 to 8)	3.5 (0 to 6)	0.770
12 hours	1.5 (0 to 6)	1.5 (0 to 6)	0.157	1.5 (0 to 8)	3 (0 to 6)	0.840
24 hours	0 (0 to 7)	0 (0 to 5)	0.156	1.5 (0 to 6)	1 (0 to 5)	0.162
48 hours	0 (0 to 5)	0 (0 to 5)	0.317	0 (0 to 5)	0 (0 to 6)	0.157

Table 3. Pain on movement

Post-op time points	Field block (n = 16)	Placebo (n = 16)	*p*-value	Intercostal block (n = 16)	Placebo (n = 16)	*p*-value
2 hours	4.5 (0 to 8)	4.5 (0 to 10)	0.325	6 (0 to 10)	5 (0 to 8)	0.407
6 hours	4 (0 to 9)	3.5 (0 to 9)	0.162	3 (0 to 9)	4 (0 to 8)	0.557
12 hours	3.5 (0 to 9)	3.5 (0 to 8)	0.171	3 (0 to 8)	4 (0 to 7)	0.597
24 hours	2.5 (0 to 8)	2.5 (0 to 8)	0.999	3 (0 to 7)	3 (0 to 5)	0.999
48 hours	1.5 (0 to 7)	1.5 (0 to 7)	0.999	2 (0 to 6)	2 (0 to 6)	0.157

Table 4. Pain comparison between anesthesia groups

Post-op time points	Pain at rest		*p*-value	Pain on movement		*p*-value
	Field block	Intercostal block		Field block	Intercostal block	
2 hours	2.5 (0 to 7)	4 (0 to 8)	0.026	4.5 (0 to 8)	6 (0 to 10)	0.269
6 hours	2 (0 to 8)	3 (0 to 8)	0.295	4 (0 to 9)	3 (0 to 9)	0.940
12 hours	1.5 (0 to 6)	1.5 (0 to 8)	0.999	3.5 (0 to 9)	3 (0 to 8)	0.940
24 hours	0 (0 to 7)	1.5 (0 to 6)	0.536	2.5 (0 to 8)	3 (0 to 7)	0.970
48 hours	0 (0 to 5)	0 (0 to 5)	0.764	1.5 (0 to 7)	2 (0 to 6)	0.985

gradually decreased with time in all patients. By comparing analgesic outcomes in the same patients, we could control for the subjectivity of pain assessments. No difference in pain scores was found over time at rest or on movement when comparing intercostal nerve block to placebo or local infiltration to placebo. There were no significant complications.

Conclusion

Our study demonstrates that local anesthesia by field or intercostal nerve block cannot reduce pain following breast augmentation.

What is already known on this topic?

Post operative pain after subpectoral breast augmentation is reduced by bloodless and meticulous technique but many surgeons prefer to inject local anesthesia for pain reduction. No study compare between placebo and local anesthesia in the same patient to prove effect of local anesthesia.

What this study adds?

Our study demonstrates that local anesthesia by field and intercostal nerve block can not reduce pain following breast augmentation.

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Potential conflicts of interest

The authors declare no conflicts of interest.

References

1. Butz DR, Shenaq DS, Rundell VL, Kepler B, Liederbach E, Thiel J, et al. Postoperative pain and length of stay lowered by use of exparel in immediate, implant-based breast reconstruction. Plast Reconstr Surg Glob Open 2015;3:e391.
2. Stanley SS, Hoppe IC, Ciminello FS. Pain control following breast augmentation: a qualitative systematic review. Aesthet Surg J 2012;32:964-72.
3. Tebbetts JB. Achieving a predictable 24-hour return to normal activities after breast augmentation: part I. Refining practices by using motion and time study principles. Plast Reconstr Surg 2002;109:273-90.
4. Tebbetts JB. Achieving a predictable 24-hour return to normal activities after breast augmentation: Part II. Patient preparation, refined surgical techniques, and instrumentation. Plast Reconstr Surg 2002;109:293-305.
5. Gottschalk A, Smith DS. New concepts in acute pain therapy: preemptive analgesia. Am Fam Physician 2001;63:1979-84.
6. Kang KH, Kim BS, Kang H. The benefits of preincision ropivacaine infiltration for reducing postoperative pain after robotic bilateral axillo-breast approach thyroidectomy: a prospective, randomized, double-blind, placebo-controlled study. Ann Surg Treat Res 2015;88:193-9.
7. Golembiewski J, Dasta J. Evolving role of local anesthetics in managing postsurgical analgesia. Clin Ther 2015;37:1354-71.
8. Filos KS, Vagianos CE. Pre-emptive analgesia: how important is it in clinical reality? Eur Surg Res 1999;31:122-32.
9. Bagul A, Taha R, Metcalfe MS, Brook NR, Nicholson ML. Pre-incision infiltration of local anesthetic reduces postoperative pain with no effects on bruising and wound cosmesis after thyroid surgery. Thyroid 2005;15:1245-8.
10. Pavlidis TE, Atmatzidis KS, Papaziogas BT, Makris JG, Lazaridis CN, Papaziogas TB. The effect of preincisional periportal infiltration with ropivacaine in pain relief after laparoscopic procedures: a prospective, randomized controlled trial. JSLS 2003;7:305-10.