Efficacy and safety of intercostal nerve anastomosis in immediate biplane breast reconstruction after nipple–areola-sparing mastectomy: a randomized, controlled, open-label clinical study

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Background

As the most common malignant tumor in women [1], breast cancer remains challenging clinically, with an increasing incidence rate [2], and a trend toward younger ages [3]. Although breast reconstruction techniques could reshape the natural shape of the breasts [4], the postoperative breast sensory abnormalities could still significantly affect the quality of life of patients [5]. Our previous research showed that intercostal nerve anastomosis using the anterior cutaneous branches of the third–fifth intercostal nerves in immediate subpectoral prosthetic breast reconstruction after nipple-areola-sparing mastectomy improved the local sensation and patients' quality of life [6], however, the recovery of patients' breast sensory still could not meet the needs.

Knowing the biplane technique applied in breast reconstruction with its improvement on pectoral muscle contraction induced implant displacement and morphological changes [7], as well as promising on autologous tissue to cover the prosthesis, we hypothesized that biplane breast reconstruction may provide a better environment which promotes vascularization around the nerve after the anastomosis surgery.

To investigate the efficacy and safety of this novel technique for intercostal nerve anastomosis in immediate biplane breast reconstruction after nipple–areola-sparing mastectomy, we carried out this randomized, controlled, open-label clinical study.

Conclusions

This study demonstrates intercostal nerve anastomosis improved the local sensation and quality of life of patients who underwent immediate biplane breast reconstruction after nipple–areola sparing mastectomy.

Methods and Materials

A） Experimental design

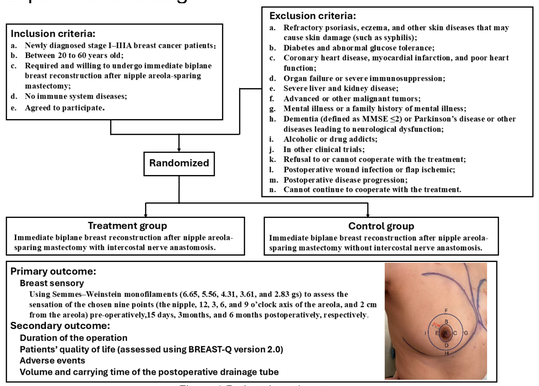


Figure 1 Patients' enrolment

B） Surgical techniques

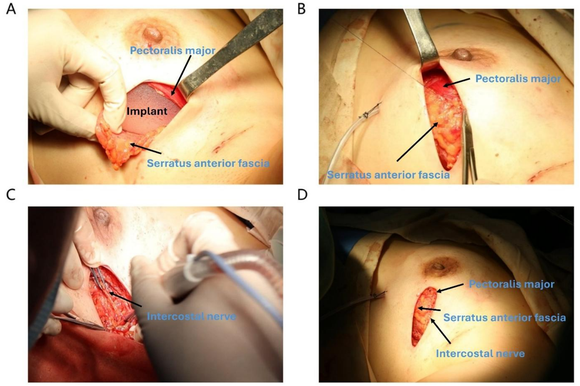


Figure 2 Surgical process. (A) Implant the prosthesis into the pocket. (B) Suture the pectoralis major and serratus anterior fascia to close the pocket. (C) Dissociate the 4th intercostal nerve. (D) Anastomosis the nerve with the tissue behind the areola.

Results

Patient characteristics

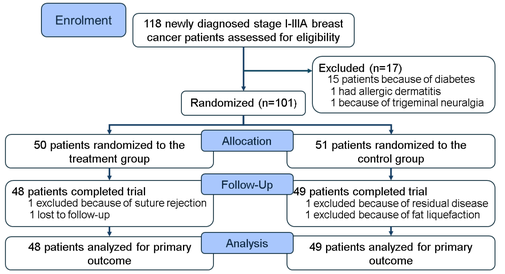


Figure 1 Flow diagram

Table 1. Patient Characteristics

Characteristic	Treatment group (n =48)	Control group (n =49)
Mean age (SD), yr	42.65 (6.88)	41.98 (8.12)
Mean BMI(SD), kg/m²	23.38 (3.08)	23.68 (3.03)
Disease stage (AJCC 8th edition, TNM), no./total (%)		
I	6/48 (13)	5/49 (10)
IIA	15/48 (31)	13/49 (26)
IIB	13/48 (27)	15/49 (31)
IIIA	14/48 (29)	16/49 (33)
Mean size of implant (SD), cc	280.73 (94.87)	282.35 (82.28)
Chemotherapy regimens, no./total (%)		
Without taxanes	06/48 (13)	07/49 (14)
Without anthracycines	06/48 (13)	05/49 (10)
Anthracycines combined with taxanes	36/48 (74)	37/49 (76)
Molecular subtype, no./total (%)		
Luminal A	14/48 (29)	17/49 (35)
Luminal B	17/48 (35)	15/49 (31)
HER-2-positive	10/48 (21)	12/49 (24)
Tri-negative	07/48 (15)	05/49 (10)

BMI, body mass index.
No differences between the two groups on any variable based on t-test or Pearson chi-square. *P* is greater than 0.05.

Safety of intercostal nerve anastomosis

Table 2. Secondary outcomes.

variable	Treatment group (n =48)	Control group (n =49)	*P*
Duration of operation (min)	135.58(19.03)	110.63(12.37)	0.008
Intraoperative blood loss (mL)	87.38(27.58)	80. 35(25.07)	0.53
Drainage volume (mL)	851.23(192.53)	862.92(216.44)	0.33
Drainage tube carrying time (days)	14.21(4.99)	14.33(4.50)	0.71

Results

Efficacy of intercostal nerve anastomosis

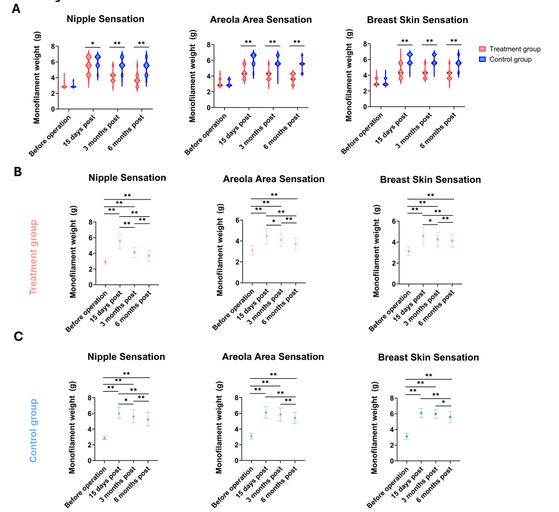


Figure 3 Local sensation of patients at different time points. (A) Comparison between the two groups of the breast sensory of different areas at different time points. (B) Comparison of the patients in the treatment group of the breast sensory of different areas at different time points. (C) Comparison of the patients in the control group of the breast sensory of different areas at different time points. General Linear Model followed by Bonferroni-adjusted pairwise comparison was used for the comparison, * $P < 0.01$, ** $P < 0.001$.

Intercostal nerve anastomosis improved patients' quality of life

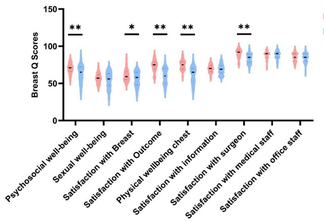


Figure 5. Results of the principal scales of BREAST-Q module. We used t-test for the comparison, * $P < 0.01$, ** $P < 0.001$.

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