

Harmonic Focus Versus Electrocautery in Axillary Lymph Node Dissection for Breast Cancer: A Randomized Clinical Study

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Abstract

Background: Electrocautery has been proven to be associated with prolonged serous drainage that might result in several complications in patients requiring axillary lymph node dissection for breast cancer. We proposed that the Harmonic Focus might outperform electrocautery in axillary lymph node dissection, resulting in shorter operative times and reduced postoperative complications. **Patients and Methods:** One hundred twenty-eight women with confirmed T1-3 N1-2 breast cancer were randomly assigned to undergo mastectomy or breast-conserving surgery with axillary dissection by using Harmonic Focus or electrocautery. Sixty-four has surgery with Harmonic Focus (group A) and 64 with electrocautery (group B) by the same surgical team. Operative time, blood loss, total drainage volume and days, incidence of seroma, hematoma, pain score, and flap necrosis were recorded. **Results:** Using Harmonic Focus significantly diminished operative time, blood loss, total drainage volume, days of stay, and visual analogue scale as compared with traditional electrocautery. There was no statistical difference between the 2 groups regarding seroma, hematoma, and flap necrosis. **Conclusion:** Axillary lymph node dissection using Harmonic Focus is feasible, safe, and a more comfortable design for the surgeon.

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Keywords: Axillary lymph node dissection, Breast cancer, Electrocautery, Harmonic focus, Seroma

Introduction

Axillary lymph node dissection plays an important role in the surgical management of breast cancer, despite the trends toward breast-conserving treatment and the sentinel node biopsy.^{1,2} Since the 1970s, electrocautery has been a popular surgical tool to raise flaps and excise the breast specimen in order to perform a bloodless mastectomy. Inadequate sealing of lymph nodes can result in lymphatic leaks, chylous fistula, infection, lymphedema, and seromas.³⁻⁷ Seroma is defined as the serous fluid collection under the skin flaps or in the axillary dead space.^{8,9} Wound seroma may result in late drain removal and increased long-term morbidity. It is the source of significant morbidity and discomfort. The presence of an axillary drain

requires management, is uncomfortable for the patient, and causes pain and limited arm movement. Wound seroma can eventually result in flap necrosis, wound dehiscence, delay in recovery, adjuvant treatment, and usually requires repeated needle aspirations. The harmonic scalpel has been used extensively in laparoscopic surgery for surgical dissection, and initial experiments in 'open' surgery suggests that it could significantly reduce the blood loss and surgery time.⁹⁻¹³ In this study, we compared the operative details and morbidity of 64 Harmonic Focus (the new hand-held ultrasonic dissector, Ethicon Endo-Surgery, Inc, Cincinnati, OH; Figure 1) axillary lymph node dissections with 64 matched control patients undergoing axillary lymph node dissection with electrocautery. The purpose of this study was to evaluate the effectiveness of Harmonic Focus in reducing these complications.

Materials and Methods

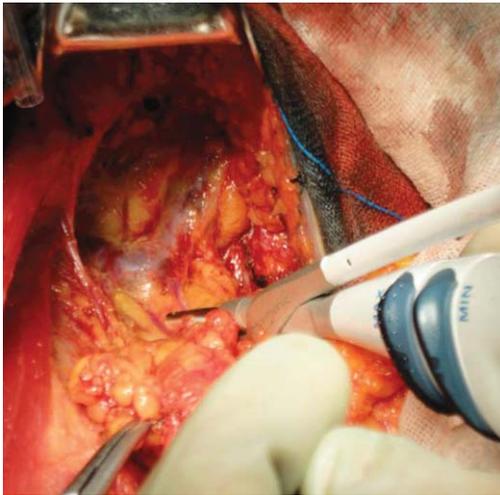
Patient Eligibility and Study Design

One hundred twenty-eight operable breast cancer women at the Department of Thyroid and Breast Surgery, Jinan Military General Hospital, undergoing axillary lymph node dissection for confirmed breast cancer from June 2010 to March 2011 were included. The

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Figure 1 Lateral Thoracic Artery was Cut Off

protocol was approved by the Ethics Committee for Analysis of Research Projects on Human Experimentation. All patients had pathologically confirmed axillary metastasis before axillary lymph node dissection by either sentinel node biopsy or percutaneous axillary biopsy.

One hundred twenty-eight consecutive patients with confirmed T1-3 N1-2 breast cancer were enrolled in the study after obtaining informed written consent. All patients agreed to participate in the trial investigating the efficacy of a new technique that could improve their postoperative course. One hundred twenty-eight women (median age, 48.5 years; range, 23-72 years) were randomized in 2 groups by closed envelope method either to do mastectomy (or breast-conserving) and axillary lymph node dissection using Harmonic Focus (group A) or using electrocautery (group B). A database of information was recorded, and charts of patients were reviewed for the variables reported in Table 1. Patients who underwent neoadjuvant chemotherapy or immediate breast reconstruction were not included in the study. The tumor staging was obtained at final pathologic examination according to the tumor-node-metastasis system classification.¹⁴ The presence of distant metastases was excluded by routine laboratory tests, chest x-ray, liver ultrasound, and bone scans.

Operative Technique

Six experienced surgeons were capable of using both techniques. In all patients, skin incisions were made with a scalpel; the dissection of skin flaps and removal of the breast with pectoral fascia from the pectoralis major muscle were performed with conventional electrocautery, whereas dissection of the axilla was performed with electrocautery in group B patients. In group A patients, Harmonic Focus (transects and seal vessels ≤ 5 mm; Figure 1) was used to control bleeding vessels; the entire procedure of axillary dissection was performed using the Harmonic

Table 1 Clinical and Operative Details

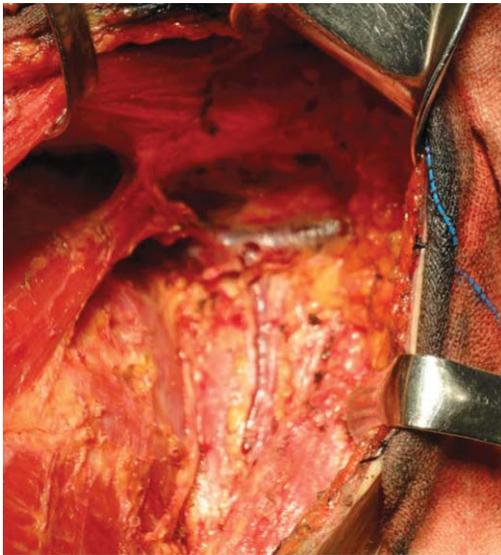
Variable	Harmonic Focus (A)	Electrocautery (B)	P
Number of Patients	64	64	> .05
Age at Diagnosis (Years)	46.3 \pm 9.2	45.6 \pm 8.5	> .05
BMI	25.2 \pm 3.1	24.5 \pm 2.2	> .05
Stage II	48	49	> .05
Stage III	16	15	> .05
Operating Time (Minutes)	92 \pm 15	117 \pm 20	< .05
Estimated Blood Loss (mL)	75.6 \pm 25.5	190.4 \pm 96.2	< .05
Total Drain Volume (mL)	656.8 \pm 150.5	985.7 \pm 590.6	< .05
Mean Drain Days	8.9 \pm 1.5	13.5 \pm 3.9	< .05
Type of Surgery			
MRM	49	50	> .05
TM and SLNB and ALND	8	8	> .05
BC and ALND	7	6	> .05
VAS Score	4.9 \pm 1.4	6.7 \pm 1.1	< .05
Total Number of Removed Lymph Nodes	21.4 \pm 1.5	20.9 \pm 1.8	> .05
Postoperative Complications			
Postoperative Bleeding	0	0	
Hematoma	0	0	
Seroma	2	3	> .05
Wound Infection	0	0	
Flap Necrosis	0	0	
Skin Burn	0	0	
Pneumothorax	0	0	
Postoperative Hospital Stay (Days)	11.5 \pm 2.3	14.7 \pm 4.3	< .05

Abbreviations: ALND = axillary lymph node dissection; BC = breast-conserving; BMI = body mass index; MRM = modified radical mastectomy; SLNB = sentinel lymph node biopsy; TM = total mastectomy; VAS = visual analogue scale.

Focus (Figure 2). Lymph vessel sealing and hemostasis were achieved using Harmonic Focus; no clips, sutures, or electrocautery was used. Dissection of the breast tissue, which was reflected off the pectoralis major muscle, was performed with Harmonic Focus. Thirteen patients underwent a lumpectomy with intent to obtain ≥ 1 cm margins. Margins were routinely inked to assess the microscopic completeness of the lumpectomy. Intraoperative frozen section analysis allowed resection of suspicious or positive margins at the time of lumpectomy. Clavipectoral fascia was opened, and the axilla was exposed. The pectoralis major and pectoralis minor were retracted upward. The axillary vein was exposed, and all of its small tributaries were ligated with Harmonic Focus. Axillary lymph node dissection was initiated from

Harmonic Focus and Electrocautery in Lymph Node Dissection

Figure 2 Appearance After Dissection of the Axilla Using the Harmonic Focus With Preservation of the Long Thoracic Nerve, Thoracodorsal Nerve, and Lateral Anterior Thoracic Nerves



the lateral end of the vein. A plane of dissection was created along the inferior border of the axillary vein, and all the fat, lymph nodes, and blood vessels were dissected off the axillary vein toward the breast. All axillary vein and artery branches directed toward the breast and pectorals major muscle were ligated by Harmonic Focus. The thoracodorsal vessels and nerve and the long thoracic, subscapular, medial, and lateral anterior thoracic nerves were identified and protected (Figure 2). Level I–III (including Rotter's nodes) axillary dissection was performed in all patients. Then, the surgical field was doused by 1000 mL sterile distilled water (42°C). Two 16-F vacuum drains were inserted in the axilla. A short-term (12 hours) antibiotic prophylaxis was used in all patients. Both subjective and objective recording were done using visual analogue scale by the end of the first 24 hours and calculating the total dose of sufentanil citrate (postoperative pain pumps: sufentanil citrate 150 μ g and sodium chloride injection 100 mL, 2 mL per hour) required by the end of the first 48 hours. The amount of drainage was measured daily by the nursing staff. After discharge, the amount of drainage was recorded by the patients themselves, who underwent 1 or more office visits. Drains were removed when the drainage volume was < 10 mL over 24 hours for 2 consecutive days.

The medical records of the patients were reviewed for age and body mass index. The clinical outcome was measured in terms of operating time (from skin incision to skin closure), intraoperative blood loss (estimated by sponge count and weight), total drain volume, duration of drains, seroma, and wound complications such as

bleeding, seroma, skin burn, hematoma, and wound infection or flap necrosis.

Postoperative radiotherapy and adjuvant treatments were applied according to the protocols based on National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (Breast Cancer v.2.2010). All patients underwent adjuvant chemotherapy (followed by docetaxel, FEC 6 or TC 4). Patients with tumor size exceeding 5 cm (stage pT3), breast-conserving therapy and those with 4 or more positive axillary lymph nodes on histopathologic examination received postoperative radiation therapy.

Statistical Analysis

For descriptive statistics of qualitative variables the frequency distribution procedure was performed to calculate the number of cases and percentages. For descriptive statistics of quantitative variables: the mean, range, and standard deviation were used to describe central tendency and dispersion. For analysis of the differences in proportions, χ^2 test was used, Fishers exact test was used if the assumptions of the Chi-square test were violated. Independent samples *t* test was used to compare the level of quantitative variables between the 2 study groups. Data were analyzed on a personal computer running SPSS 15 for windows. All tests results were considered significant if $P \leq .05$.

Results

In the Harmonic Focus group, electrocautery was used for mastectomy and in the second Harmonic Focus was used. Hemostasis was achieved in 64 patients of the Harmonic Focus group without ligature, clamp, or cautery. The 2 groups were comparable in terms of demographic data, tumor staging, extent of surgery, and postoperative complications (Table 1). There was a significant statistical difference between the 2 groups in operating time (92 ± 15 minutes vs. 117 ± 20 minutes; $P < .05$), mean volume of blood loss (75.6 ± 25.5 mL vs. 190.4 ± 96.2 mL), mean total volume of drainage fluid (656.8 ± 150.5 mL vs. 985.7 ± 590.6 mL), and mean number of days until removal of the drain (8.9 ± 1.5 days vs. 13.5 ± 3.9 days). The average number of postoperative length of stay was also significantly less in the Harmonic Focus group (11.5 and 14.7 days, $P < .001$) as shown in Table 1. There was no significant difference in total nodes between the Harmonic Focus and electrocautery group (21.4 ± 1.5 and 20.9 ± 1.8 , $P > .05$). None of the patients in either group developed wound infection, postoperative bleeding, hematoma, or pneumothorax. No patient experienced skin burns or flap necrosis. Two patients in the Harmonic Focus group developed seromas compared with 3 patients in the electrocautery group. This was not statistically significant ($P > .05$).

Discussion

The status of the axillary nodes represents the most important prognostic factor that helps to estimate an individualized prognosis and guide treatment decisions in patients with breast cancer.¹⁵ Axillary lymph node sampling usually underestimates the extent of nodal disease, whereas the sentinel node biopsy technique does not at present reach 100% sensitivity.^{16–18} Thus, axillary lymph node dissection still remains the most accurate way of determining the lymph node status, and this treatment is associated with lower local recurrence rate than other treatments.

Wound seroma is the most common wound-related postoperative complication after axillary lymph node dissection using scalpel, clamp-and-tie techniques, and electrocautery.⁶⁻⁹ Though the ability to cut and seal vessels to control surgical bleeding has contributed to the increased use of electrocautery devices, the application of extremely high heat can cause lateral thermal tissue damage. LigaSure provides an automated click and play solution for ligating vascular tissue. Most recently, the ENSEAL (Ethicon Endo-Surgery Inc., Cincinnati, OH) device provides temperature control with a unique electrode configuration and composition that heats tissue at a low temperature while under extremely high compressive force to produce a durable vascular seal. A high-frequency alternating current applied to living tissue by an active electrode flows through the tissue by pathways offering the least resistance and return to an opposing electrode. The electrical current is set in motion and sustained by electromotive force termed voltage to complete the circuit across the difference in electrical potential between the 2 electrodes. Greater voltage produces greater thermal necrosis. Harmonic energy is mechanical versus electrical energy, and is not regulated through impedance. It is more suitable for patients with an implanted cardiac pacemaker. Ultrasonic energy generated by the Harmonic Focus causes a breakage of hydrogen bonds and the formation of denatured protein coagulum. Denatured protein forms a sticky coagulum. This coagulum seals off the vessels and lymph nodes in decreased blood loss and lymphatic drainage. Internal tissue heat generated from friction then welds vessel walls. Simultaneous cutting and coagulation takes place at a lower temperature than in electrosurgery with minimal lateral thermal spread, minimal charring and desiccation, and minimal smoke for improved visibility.¹⁹⁻²¹

The harmonic scalpel has been extensively used as an alternative surgical tool for dissection and the perfect hemostasis especially in the field of minimally invasive surgery,^{22,23} but experience with the harmonic scalpel in 'open' surgery is limited by uncomfortable design for the surgeon. Open surgery using Harmonic Focus is more comfortable for the surgeon. The Harmonic Focus has recently been used in open thyroid surgery and found to be associated with lower operating time and blood loss.¹⁷ As noted, the Harmonic Focus offers distinct advantages in an easy-to-use ergonomic design for right-handed surgeons. It feels similar to conventional surgical instrumentation, and it provides good mobilization of tissue planes. It can precisely grasp, dissect, cut, and coagulate near vital structures with minimal thermal spread and tissue desiccation.

In the field of axillary lymph node dissection, our study revealed that the use of the Harmonic Focus efficiently reduced intraoperative blood loss and operative time. This is in agreement with most of the literature.^{11,12} Although drainage days were reduced with the use of Harmonic Focus, the incidence of seroma formation was not avoided. The pathophysiology and mechanism of seroma formation is still poorly understood and needs further study to reveal its exact mechanism.²⁴ The optimal way of prevention and treatment of seroma remain inconclusive.^{25,26} The lowered postoperative pain score was because of the minimal lateral thermal damage observed with the Harmonic Focus in comparison with electrocautery and this resulted in less irritation to

pain nerve endings. The minimal lateral thermal damage can potentially decrease the flap necrosis rate.

The goal is to find a way to minimize adverse effects and achieve safe surgery. When surgeons learn how to use the Harmonic Focus, they will find that the device is much more efficient than other types of surgical instruments.^{27,28} On the other hand, a major criticism of the Harmonic Focus is its cost. Unfortunately, the Harmonic Focus is still costly (in China the Harmonic Focus is approximately RMB ¥7200). However, when taking the reduced operating time and length of stay into consideration, the device actually might be cost-effective for patients and doctors.

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Disclosure

All authors have no conflicts of interest.

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Harmonic Focus and Electrocautery in Lymph Node Dissection

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