Modified Radical Mastectomy With Axillary Dissection Using the Electrothermal Bipolar Vessel Sealing System

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Hypothesis: The use of the electrothermal bipolar vessel sealing system is feasible, safe, and effective in modified radical mastectomy with axillary dissection in terms of lymph vessel sealing, hemostasis, and perioperative complications.

Design: Prospective study.

Setting: University surgical department.

Patients: Between January 1, 2003, and December 31, 2003, 60 patients with locally advanced breast cancer (T2 or T3) admitted for modified radical mastectomy with axillary dissection were included in this study. The entire procedure was performed by the same surgical team using the electrothermal bipolar vessel sealing system.

Main Outcome Measures: Final outcome, operative time, hospitalization stay duration, intraoperative blood loss, postoperative mastectomy and axillary drainage volume and duration, and postoperative complications (seroma, bleeding, skin burn, hematoma, lymphedema, pneumothorax, and wound infection or necrosis).

Results: The mean (SD) intraoperative blood loss was 45 (12) mL, and the mean (SD) operative time was 105 (7) minutes. No postoperative bleeding, seroma, hematoma, lymphedema, or other complications occurred. The mean (SD) mastectomy and axillary drainage volumes were 20 (8) and 155 (35) mL, respectively, and the mean (SD) drainage durations were 1.3 (0.2) and 2.7 (0.5) days, respectively. The mean (SD) hospital stay was 3.7 (0.6) days.

Conclusions: In this first report (to our knowledge) of modified radical mastectomy with axillary dissection using the electrothermal bipolar vessel sealing system, the technique was feasible, safe, and effective. The device simplified the surgical procedure, while achieving efficient lymph vessel sealing and hemostasis. Compared with historical data regarding the conventional or harmonic scalpel, this technique seems to result in reduced operative time, perioperative blood loss, drainage volume and duration, and incidence of seroma or lymphedema. Prospective randomized controlled studies are necessary to evaluate the effect of this technique on perioperative complications.


Although surgical treatment for breast cancer has shifted dramatically from radical operations to breast-conserving surgical techniques, modified radical mastectomy with axillary dissection remains the most frequently performed surgical procedure for locally advanced breast cancer.1,2 The most common complications of conventional modified radical mastectomy with axillary dissection using scalpel, suture ligation, and electrocautery are seroma and lymphedema, with incidences of 11% to 85%7,9 and 2% to 50%,7,10,11 respectively. Other frequent complications are hematoma, prolonged axillary drainage, wound infection or necrosis, and intraoperative and postoperative bleeding.6,7,12

Lymph vessel sealing and hemostasis are usually performed using clips, suture ligation, or electrocautery. However, suture ligation is time-consuming and carries the risk of knot slipping, while clips may become dislodged. Moreover, electrocautery produces thermal spread to adjacent tissues13 and is considered a risk factor for seroma4,7 and other wound complications after mastectomy.7 Recently, modified radical mastectomy14,15 and axillary dissection14,16,17 using the harmonic scalpel have been described.

The electrothermal bipolar vessel sealing system, a novel hemostatic device, has been used in general surgery with safety and efficacy regarding hemostasis, complications, and reduction of operative

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time. To our knowledge, there is no report of its use in modified radical mastectomy, breast-conserving surgery, or axillary dissection. The objectives of this study were to evaluate the feasibility, safety, and efficacy of modified radical mastectomy with axillary dissection using the electrothermal bipolar vessel sealing system in terms of lymph vessel sealing, hemostasis, and perioperative complications and to describe and standardize this novel operative technique.

**METHODS**

This was a prospective study of modified radical mastectomy with axillary dissection. Surgery was performed using the electrothermal bipolar vessel sealing system (LigaSure Precise; Valleylab, Boulder, Colorado).

**PATIENTS**

Sixty consecutive adult female patients with unilateral, locally advanced primary breast cancer (T2 or T3) admitted for modified radical mastectomy with axillary dissection between January 1, 2003, and December 31, 2003, were included in the study. Patients with early breast cancer (T1), previous breast surgery, and neoadjuvant chemotherapy were excluded. Institutional review board approval was obtained before study initiation, and written informed consent was obtained from all patients before surgery. Modified radical mastectomy and axillary dissection were performed by the same surgical team in all cases.

**OPERATIVE TECHNIQUE**

Following skin incision with the conventional scalpel, flaps were raised using the electrothermal bipolar vessel sealing system. Dissection of the breast tissue, being reflected off the pectoralis major muscle, was performed with the device. 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 the device. Axillary lymph node dissection was initiated from 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 pectoralis major muscle were ligated by the device. The thoracodorsal vessels and nerve and the long thoracic, subscapular, medial, and lateral anterior thoracic nerves were identified and protected. Two closed suction drains were placed, one in the axilla and the other on the chest wall.

Level II axillary dissection was performed in all patients, and if the level III lymph nodes were positive on frozen section analysis, the dissection was extended to include level III (this occurred in 3 of 60 patients). Frozen section analysis of level III axillary lymph nodes was performed when macroscopically enlarged or palpable lymph nodes were identified. Sentinel lymph node biopsy was not performed in any patient because of the lack of necessary equipment and experience to perform this technique and because there is no nuclear medicine department in our hospital.

In all cases, the entire procedure of modified radical mastectomy with axillary dissection was performed using the electrothermal bipolar vessel sealing system device (Figure 1). Lymph vessel sealing and hemostasis were achieved using the electrothermal bipolar vessel sealing system; no clips, sutures, or electrocautery was used. Histopathologic evaluation of the specimens confirmed that permanent complete sealing of lymph and blood vessels was achieved (Figure 2 and Figure 3).

**POSTOPERATIVE TREATMENT**

Each drain was removed when the drainage volume was less than 30 mL in 24 hours. All patients were discharged from the hospital after drain removal and were followed up weekly for

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**Figure 1.** Use of the electrothermal bipolar vessel sealing system device in axillary lymph node dissection.

**Figure 2.** Axillary lymph node dissection specimen showing axillary fat and a lymph vessel. The use of the electrothermal bipolar vessel sealing system resulted in permanent complete sealing of the lymph vessel. The arrow indicates the coagulation zone (hematoxylin-eosin, original magnification ×100).

**Figure 3.** Immunostaining (illustrating the endothelium of vessels) of an axillary lymph node dissection specimen showing axillary fat and a lymph vessel (the absence of red blood cells is characteristic of lymph vessels). The arrow indicates the complete coagulation zone (CD34, original magnification ×100).
4 weeks and then every 2 months. Postoperative complications were evaluated during the hospital stay and at follow-up visits. To assess lymphedema, arm circumference was measured at 3 positions (10 cm below, 5 cm above, and 10 cm above the olecranon) in both arms before surgery and at every postoperative visit. Lymphedema was defined as at least a 2-cm difference in arm circumference between the treated (ipsilateral) side and the contralateral arm at any 1 of 3 sites for arm circumference measurement. Patients with tumor size exceeding 5 cm (stage pT3) and those with 4 or more positive axillary lymph nodes on histopathologic examination received postoperative radiation therapy.

**DATA COLLECTED**

Collected data were age, final outcome, pathologic findings, hospitalization stay duration, intraoperative blood loss, operative time (from skin incision to skin closure), postoperative mastectomy and axillary drainage volume and duration, and postoperative complications such as bleeding, seroma, skin burn, hematoma, lymphedema, pneumothorax, need for blood transfusion, and wound infection or necrosis. Data are given as the mean (SD) and range or as the number and percentage of patients.

**RESULTS**

During the 1-year study, 60 consecutive modified radical mastectomies with axillary dissection were performed by the same surgical team. Lymph vessel sealing and hemostasis were achieved using the electrothermal bipolar vessel sealing system in all patients; no clips, sutures, or electrocautery was used.

The follow-up period among our patients ranged from 3 to 4 years, with a mean follow-up of 3.7 (0.2) years. Clinical data and postoperative complications among the study patients along with historical data from other studies in the literature are given in the Table. Intraoperative bleeding was not significant in any patient, and no seroma, hematoma, lymphedema, pneumothorax, flap necrosis, wound infection, or postoperative bleeding was observed. Because great care was taken to avoid the skin surface during coagulation with the jaws of the device, no patient experienced skin burns. No perioperative blood transfusion was required, and there was no mortality.

Among 60 study patients, 13 patients (22%) had positive axillary lymph nodes: 9 patients (15%) had 1 to 3 positive lymph nodes, and 4 patients (7%) had 4 or more positive lymph nodes. Five patients (8%) with stage pT3 tumor and 4 patients (7%) with 4 or more positive lymph nodes received postoperative radiation therapy.

**COMMENT**

Conventional modified radical mastectomy with axillary dissection using scalpel, clamp-and-tie techniques, and electrocautery is frequently associated with complications such as seroma and lymphedema. Other less common complications include hematoma, prolonged axillary drainage, wound infection or necrosis, and intraoperative and postoperative bleeding.

The rate of seroma formation has been reported to be affected by the type of surgical procedure. It is more frequent if the flaps are raised by electrocautery than by scalpel and if axillary dissection is performed with the conventional technique than with the harmonic scalpel, as well as occurring more often in modified radical mastectomy than in breast-conserving surgery in axillary lymph node dissection, and in modified radical mastectomy without immediate reconstruction than with immediate recon-
struction. In addition, tumor size, age 60 years or older, total amount of drainage, neoadjuvant chemotherapy, and volume of drainage exceeding 30 mL in the 24 hours before drain removal have been associated with seroma formation. Moreover, Lumachi et al correlated axillary drainage with the patient's body mass index, lymph node status, number of lymph nodes removed, type of operation (greater in modified radical mastectomy than in breast-conserving surgery), and technique of axillary dissection (greater with the conventional scalpel than with the harmonic scalpel). Seroma formation can be associated with other more serious complications such as infection, lymphedema, skin flap necrosis, and delayed wound healing and may result in a prolonged hospital stay and more postoperative visits. Suggested techniques to reduce the incidence of seroma formation include immediate reconstruction, sentinel lymph node dissection, and a flap tacking procedure that closes the axillary fossa dead space and tacks the mastectomy flaps to the chest wall. Administration of tranexamic acid and application of fibrin sealant have also been reported to significantly decrease the duration and amount of fluid drainage and the incidence of seroma formation.

Lymphedema is also a common complication of axillary lymph node dissection. Potentially associated with lymphedema are arm infection or injury, extent of axillary dissection, weight gain following surgery, and postoperative radiation therapy to the axilla. Lymphedema may range from mild to disabling disfigurement and is difficult to treat and a permanent condition in many patients. Recurrent episodes of cellulitis and lymphangitis may also be expected, as well as disability, cosmetic deformity, and physical discomfort. Sentinel lymph node biopsy techniques allowing less axillary surgery and more precise radiation therapy planning that delivers less irradiation to the axilla should contribute to a decrease in the incidence of lymphedema.

Efficient lymph vessel sealing is essential for the prevention of seroma, lymphedema, and prolonged axillary drainage. Furthermore, adequate hemostasis is fundamental for a safe operative technique to avoid intraoperative hemorrhage (which increases operative time and the risk of complications) and to avoid postoperative hemorrhage and hematoma. Therefore, definitive lymph vessel sealing and hemostasis in breast surgery are of utmost importance for a safe and successful operation and for an eventful postoperative course.

Hemostasis and lymph vessel sealing in modified radical mastectomy with axillary dissection are usually performed using suture ligation and electrocautery. The estimated blood loss has been reported to be significantly more with the use of the scalpel vs electrocautery and with the use of the scalpel and electrocautery vs carbon dioxide laser. Porter et al reported that, compared with the scalpel, the use of electrocautery in raising the skin flaps reduces blood loss but significantly increases the rate of seroma formation. Hoefler et al found that the use of electrocautery for flap creation was the only perioperative factor associated with an increased rate of postoperative wound complications. Compared with the scalpel, electrocautery resulted in a 44% increase in the probability of a wound complication (such as seroma, necrosis, infection, hematoma, lymphedema, and pneumothorax), resulting in a prolonged hospital stay.

The electrothermal bipolar vessel sealing system and the harmonic scalpel are innovative devices designed as alternatives to conventional vessel sealing techniques. Recently, the harmonic scalpel has been used in modified radical mastectomy and in axillary dissection. Deo and Shukla reported encouraging results in terms of operative time, axillary drainage, seroma formation, and intraoperative blood loss. In a comparison of electrocautery with the harmonic scalpel, significantly reduced blood loss and drainage volume and duration were found in the group operated on using the harmonic scalpel, but there was no difference in the rate of seroma formation, which was high in both groups (16% vs 22%). In contrast, in a prospective controlled study comparing conventionally performed modified radical mastectomy with that performed using the harmonic scalpel (with both groups undergoing conventional axillary dissection), Galatius et al reported similar operative times, perioperative bleeding, and wound complications with the 2 techniques. However, a high incidence of seroma formation was found, developing in two-thirds of the patients in both groups, while the use of the harmonic scalpel resulted in greater drainage and seroma volume and more seroma aspirations, although this was not statistically significant. In axillary dissection, the use of the harmonic scalpel (compared with the conventional technique) has been reported to result in a significant reduction in drainage volume and duration and in a nonsignificant reduction in seroma formation; however, the reported incidence of seroma formation with this technique was high (20%).

To our knowledge, there are no previous reports about the use of the electrothermal bipolar vessel sealing system in modified radical mastectomy, breast-conserving surgery, or axillary dissection. The benefits of using this device in breast surgery are minimal thermal injury to the tissue and better sealing of small vessels and lymphatic channels.

The electrothermal bipolar vessel sealing system uses a combination of mechanical pressure and high-current low-voltage energy. Electrical energy denatures collagen and elastin fibers within the vessel walls and surrounding connective tissue, while mechanical pressure applied by the instrument apposes the walls to allow proteins to form as a seal. The device fuses the vessel walls, obliterating the vascular and lymph vessel lumen; this seems to be an efficient way to seal blood and lymph vessels permanently and completely (Figure 2 and Figure 3). A precise and optimal amount of energy is delivered that ensures complete coagulation with minimal surrounding thermal spread. The tissue fusion mechanism of the device results in strong burst strength measurements compared with conventional monopolar, bipolar, and ultrasonic coagulation systems. Vessels sealed with the electrothermal bipolar vessel sealing system were shown to withstand well above (≥3 times) physiologic systolic blood pressure without bursting. An important issue concerning the use of this modality is the extent of lateral thermal spread and associated tissue in-
jury. However, several experimental studies28-30 have proven that this extent is minimal, limited to 2 to 3 mm. This is an important property in breast surgery, particularly in axillary dissection, as it allows safe lymph vessel and vascular ligation, with minimal risk of damage to delicate adjacent structures such as the long thoracic nerve, the thoracodorsal pedicle, the great vessels of the axilla, and the brachial and subclavianplexus.

The electrothermal bipolar vessel sealing system has been proven to be safe and effective regarding hemostasis, complications, and reduced operative time in several surgical procedures, including urologic,31 gynecologic,32 and general surgical cases.18,19 Similar results have been reported in other studies.6,7,15 Surgical technique, parameters of these complications ranging from 0% to 18% have been observed in a previous study33 of total thyroidectomy. The present study was conducted to evaluate the feasibility, safety, and efficacy of the use of the electrothermal bipolar vessel sealing system in modified radical mastectomy with axillary dissection in terms of lymph vessel sealing, hemostasis, and perioperative complications and to standardize this operative technique. Our results using this technique are encouraging. The device is handy, easy to use, and reliable, and no technical difficulties were noted. In addition, it was safe and effective with respect to hemostasis, complications, operative time, and lymph vessel sealing. Although there was no control group in our study, a comparison of our results with data from other studies in the literature suggests that there may be substantial benefit from the use of this device in breast surgery (Table).

Efficient ligation of blood and lymph vessels was achieved in all patients. No significant intraoperative bleeding occurred, while the mean estimated blood loss was much less than that in other reported series6,8,12,14,15,21 (Table). No postoperative hemorrhage or hematoma was observed. Furthermore, unlike other studies10,15,17,20,27 with reported incidences ranging from 11% to 85%, no patient in our study experienced seroma formation. The mean axillary drainage volume and duration were substantially less than those in other reported studies.6,8,9,12,14,17,24,25,27 Such a reduction in seroma formation and in axillary drainage volume and duration could be attributed to the sealing properties of the electrothermal bipolar vessel sealing system on lymph and blood vessels and to the minimal surgical trauma caused by the device. Moreover, because age,25 and the total amount of drainage17 have been associated with seroma formation, our results regarding the rate of seroma formation may be attributable to younger patient age and to lower mean drainage volume compared with the data from other studies. In addition, no skin burn, wound infection, or necrosis was noted; in contrast, rates of these complications ranging from 0% to 18% have been reported in other studies.5,7,15 Surgical technique, particularly the use of electrocautery, is a known risk factor for wound complications5; therefore, our results could be explained by the minimal thermal spread and surgical trauma caused by the device. However, age and seroma formation have also been identified as risk factors for wound complications5,25, therefore, the younger mean age of our patients and the lower incidence of seroma formation compared with other studies may have contributed to this finding. In addition, this wound complication rate may have resulted from the fact that only 5 (8%) of our patients had other comorbidities such as diabetes mellitus or cardiovascular diseases.

Furthermore, no upper limb lymphedema has been observed in our patients. However, this result should be carefully evaluated because the follow-up period of our patients is short, ranging from 3 to 4 years, and the frequency of lymphedema is known to rise with an increasing interval since surgery.10,11 Because postoperative radiation therapy is associated with the rate of lymphedema,10,11 our incidence of lymphedema may also be attributable to the low percentage of patients (15% [9 of 60]) receiving postoperative radiation therapy. Finally, the mean operative time for modified radical mastectomy with axillary dissection in our study was much shorter than that in other reported series in the literature.6,8,12,14,15,21

The use of the electrothermal bipolar vessel sealing system seems to be more expensive than conventional techniques. This is probably the major disadvantage of the device. However, the potential added cost should be compared with the benefit in operative time savings and in the reduction of resources used in the operating room. The increased comfort of the surgeons associated with shortened operative time should also be emphasized. The benefits and the potential reduction of complications may render this device cost-effective.

In conclusion, the electrothermal bipolar vessel sealing system is a useful adjunct for breast surgery. Our results show that modified radical mastectomy with axillary dissection using this device is feasible, safe, and effective. The main advantage of this technique is that it simplifies the surgical procedure and eliminates the need for clips, electrocautery, and clamp-and-tie maneuvers, while achieving efficient lymph vessel sealing and hemostasis. In our study, which is the first reported series of the use of the electrothermal bipolar vessel sealing system in breast surgery to our knowledge, the device was found to be safe and effective in terms of hemostasis, lymph vessel sealing, operative time, and complications. Although our investigation was not a randomized controlled study and may be limited by the small number of patients, the technique seems to result in reduced operative time, perioperative blood loss, drainage volume and duration, and formation of seroma or lymphedema compared with historical data regarding conventional or harmonic scalpel techniques. Prospective randomized controlled studies comparing this technique with conventional or harmonic scalpel techniques are necessary to evaluate the effect of this technique on perioperative complications.

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