

The Use of Ligasure Vessel Sealing System in Axillary Dissection; Effect on Seroma Formation

M. Tukenmez, O. Agcaoglu, N. Aksakal, S. Destek, N. Cabioglu, U. Barbaros, Y. Erbil, A. Bozbora, A. Dincceg, V. Ozmen, M. Muslumanoglu, A. Igci

Department of General Surgery, Istanbul University, Istanbul Faculty of Medicine, Istanbul, Turkey

Rezumat

Utilizarea sistemului de sigilare vasculară Ligasure în disecția axilară; efectul asupra formării de seroame

Scop: Seroamele reprezintă cea mai frecventă complicație chirurgicală după disecția axilară asociată chirurgiei mamare, cu o incidență de 10-50%. Scopul acestui studiu randomizat a fost de a evalua sistemul de închidere vasculară LigaSure și efectul utilizării acestuia asupra formării de seroame și a altor complicații rezultate în urma disecției axilare.

Metode: În perioada ianuarie 2006 - noiembrie 2007 au fost analizate prospectiv pacientele cu diagnostic histopatologic de cancer mamar. Pacientele cu biopsie pozitivă de ganglion santinelă sau care prezentau afectare ganglionară axilară au fost incluse în studiu, iar cele supuse terapiei neoadjuvante sau care urmau tratament anticoagulant au fost excluse din studiu. Pacientele au fost distribuite în două grupuri. Disecția axilară a fost efectuată în primul grup cu ajutorul LigaSure, iar în cel de-al doilea prin ligare și electrocauterizare.

Rezultate: Au fost analizate un total de 33 de paciente, cu vârsta medie de $51,4 \pm 13,7$ ani. În primul grup, vârsta medie a fost $54,1 \pm 13,2$ ani, iar în cel de-al doilea de $48,68 \pm 14,1$. Nu au existat diferențe semnificative statistice între cele două grupuri privind vârsta, indicele de masă corporală, cantitatea de țesut excizat, dimensiunea tumorii și numărul de ganglioni excizați. Utilizarea LigaSure reduce cantitatea de fluid drenat, precum și durata menținerii

tuburilor de dren, dar determină creșterea duratei operației. **Concluzii:** Nu au existat diferențe semnificative între cele două grupuri studiate privind complicațiile. Sistemul de închidere vasculară bipolar electrotermic LigaSure poate fi utilizat în siguranță în disecția axilară ca o alternativă la tehnicile tradiționale.

Cuvinte cheie: cancer mamar, disecția axilară, seroame, sistem de închidere vasculară

Abstract

Background: Seroma formation is the most frequent post-operative complication after axillary dissection for breast surgery with an incidence of 10 - 50 %. This prospective clinical randomized study was carried out to evaluate the Ligasure vessel sealing system and its effect on seroma formation and other complications for axillary dissection.

Methods: Between January 2006 and November 2007, the patients with histopathological diagnosis of breast cancer were analysed prospectively. The patients with positive sentinel lymph node biopsy or clinical axillary involvement were included in the study, and the patients who underwent neoadjuvant therapy or using anticoagulants have been excluded from the study. Patients were divided into two study groups. Axillary dissection was performed in the first group by LigaSure and in the second group by linking and electrocautery.

Results: There were a total of thirty three patients with a mean age of 51.4 ± 13.7 . In group one, mean age of patients was 54.1 ± 13.2 and 48.68 ± 14.1 in group two. There was no significant statistical difference between the groups regarding age, body mass index, excised tissue weight,

Corresponding author:

Mustafa Tukenmez, MD
Istanbul University
Istanbul Faculty of Medicine
E-mail: mustafatukenmez@hotmail.com

tumour size and number of excised lymph nodes. The use of Ligasure reduced drainage amount and duration of drain till removal, but increased operative time.

Conclusion: There were no significant differences between study groups regarding the complications. LigaSure electrothermal bipolar vessel sealing system can be safely used in axillary dissection as an alternative to traditional methods.

Key words: breast cancer, axillary dissection, seroma formation, vessel sealing system

Introduction

Breast cancer is the most frequently encountered malignancy in women and takes the second row lead after lung cancer in cancer related deaths. The incidence of breast cancer in various countries of the world ranges between 1% and 2% (1). Axillary lymph node involvement carries an important role in determining the prognosis of breast cancer, in the control of local disease; however, axillary dissection can cause complications such as seroma, lymphedema of the arm, hematoma, restricted arm movements, neuropathy and infection. (2) Sentinel lymph node biopsy decreases postoperative complications and axillary dissection rate in patients with clinically negative axillary involvement of lymph nodes; moreover, axillary dissection should be carried out in sentinel lymph node positive patients.

Electrocautery usage, local inflammatory reactions and leaving a dead space after removal of axillary content facilitates lymphorrhage and seroma formation. It is difficult to prevent lymphatic liquid collection in the axilla after axillary dissection. The most frequently seen early complication is seroma formation with 40-50% frequency. The reported frequency of seroma formation after removal of drainage following axillary dissection ranges from 35% rising to 97%. Seromas that are not drained and persistent lymphorrhage cause occurrence of wounds and infection (3-5). For hemostasis of vessels ranging from 1 to 7 millimetres in diameter, LigaSure (electrothermal bipolar vessel sealing system) has been developed by Valleylab (Tyco International Healthcare, Boulder, CO) as an alternative for linking systems, hemoclips, staplers, electrosurgical instruments, and other energy dependent technologies (for example: ultrasonic coagulators) (6-8) (Fig. 1).

The performance of LigaSure vessel sealing system has been evaluated in General Surgery, Urology and Gynecology and Obstetrics operations. As a conclusion, this system has been seen to reduce operating time, blood loss, harm to surrounding tissues, cohesions, and ease operations as well, in both open and closed operations (9-16).

The aim of this clinical randomized study is to define the effect of Ligasure on seroma formation when used in axillary dissection and to shorten the span of persisting lymphorrhage.

Materials and Method

All patients consulted and diagnosed as having breast cancer both clinically and histopathologically at Istanbul Faculty of Medicine, Department of General Surgery between January 2006 and November 2007 were included in this prospective randomized study. An ethical board approval was received and the patients were informed. Informed consent forms were signed by patients who decided to be included in the study. Patients submitted to neoadjuvant therapy or using anticoagulants were excluded from the study.

The groups for patients that would have mastectomies or axillary surgeries were assigned through draw. The patients with negative sentinel lymph node biopsy (SLNB) results had neither axillary dissection nor were they assigned to any group. Dissection was performed in the first group by LigaSure and in the second group by linking and electrocautery. Axillary dissection technique included the dissection of lymph nodes of level I and II. The margins of axillary dissection were as follows: upper margin posterolateral part of musculus pectoralis major and axillary vein; medial margin clavipectoral fascia or clavipectoral ligament and thorax wall; lateral margin anterior part of musculus latissimus dorsi and inferior margin the junction of the angular vein and thoracodorsal vein. Nervus thoracicus longus and nervus thoracodorsalis were seen and protected during the procedure.

Both groups were compared by means of body mass index (BMI), state of menopause, operation time, tissue mass, drainage amount after the operation and drain duration, tumour size, number of dissected axillary lymph nodes, and complications (seroma, wound infection, lymphedema, nerve damage, etc). The comparisons were made with Mann-Whitney U and chi square tests between the two groups. The results were stated as mean \pm standard deviation.



Figure 1. Intraoperative photo showing the use of Ligasure for sealing vessels in axillary dissection

Surgical technique

The patient was placed on the operating table and the arm was stretched aside 90°. A mammary massage was performed after the injection of isosulphane blue into the subareolar and peritumoral tissue in patients with clinically negative axillary lymph node exploration. The sentinel lymph node was excised and sent for frozen section. In patients with positive frozen exploration of carcinoma, axillary dissection was planned. Stewart incision was preferred in patients with mastectomy indication. The whole mammary tissue was excised with the pectoral fascia through Stewart incision and the axilla was penetrated by cutting the clavipectoral fascia along the outer edge of the pectoral muscle. For patients in group one, dissection was done with LigaSure precise forceps (Valleylab Boulder Colorado) beginning from the clavipectoral fascia. For the second group, dissection was performed by using electrocautery and ligation. The axillary vein was visualised and all branches rooting from the axillary vein below that level were ligated and cut. Nervus thoracicus longus and nervus thoracodorsalis were visualised and the whole fatty tissue was dissected including level I-II lymph nodes. The intercostobrachial nerve was followed from its origin on the chest wall and was protected unless involved by metastatic lymph nodes. Axillary lymph nodes were extracted with the mammary gland en bloc. Following bleeding control, aspirating silicon drains were placed under the flap and in the axilla. The skin was closed with rapid vicryl 3/0.

The drain under the flap was removed on postoperative day 2 and the axillary drain was removed after the daily drainage amount was detected to be under 30 cc/day.

Results

There were a total of 33 patients, including those with positive sentinel lymph node biopsies and those who underwent axillary dissection, included in the study. The mean age of patients was 51.4±13.7 and body mass index 28.1±4.5. The mean extracted tissue weight was 412.4±135.8 grams (gr) and operative time was 94±21 minutes (min). The mean drain

volume was 712±432 millilitres (ml) and the duration of drain stay was 8.7±4.5 days.

There were 3 patients in Group I and 2 patients in Group II with positive axillary lymph nodes. While there were no significant differences regarding age, menopausal status, body mass index, weight of extracted tissue, tumour size, number of lymph nodes between two groups, however, there were significant differences between study groups in terms of operative time, number of metastatic lymph nodes, drain volume, duration of drain stay (Table 1).

Discussion

Breast cancer is the most frequently encountered kind of tumour spotted in women worldwide. It is responsible for 32% of feminine cancers and 19% of deaths related to cancer. One woman out of eight in the USA and one woman out of ten in European countries has breast cancer.

The most important parameter in the prognosis of breast cancer is whether there is axillary lymph node involvement or not. Axillary lymph node dissection is performed for accurate staging of the disease, directing adjuvant therapies, and providing local tumour control in patients with lymph node involvement. Following axillary curettage, seroma is seen between 10% and 80%, and it necessitates aspirating (17).

Energy dependent thermal coagulation instruments have first been used by Bovie and Cushing in 1928 (18). In recent systems high frequency oscillating currents are being used for coagulation. There are two fundamental electrocautery systems such as monopolar or bipolar with regard to style of distributing sufficient energy to provide haemostasis.

LigaSure bipolar vessel sealing system provides haemostasis of vessels between 1 and 7 millimetres. LigaSure vessel sealing system transfers the appropriate amount of energy in tissue lumps or vessels according to their densities. Thus, as no exceeding energy is transferred, thermal convectional damage is limited to neighbouring tissues. With Ligasure, thermal radiation to nearby tissues is between 0.5 and 2 millimetres. With LigaSure Precise, which we use in axillary curettage, radiation is below 0.5 millimetres (19-21).

In a prospective study by Talbot and Magarey (22) and

Table 1. Comparison between study groups

	Group I (n:17)	Group II (n:16)	P value
Age	54.1 ± 13.2 (36-77)	48.6 ± 14.1 (23-70)	0.18
Pre/Postmenopausal	8/9	8/8	0.86
Body mass index	27.9 ± 5.3	28.3 ± 4.1	0.57
Tissue weight (gr)	413.6 ± 153.6	411.2 ± 118.9	0.81
Operative time (min)	103.5 ± 22.8	85.6 ± 14.4	0.014*
Tumour size (cm)	2.6 ± 1.7	2.7 ± 1.0	0.15
Number of lymph nodes	13.5 ± 4.2	13.8 ± 2.9	0.52
Metastatic lymph nodes	2.1 ± 1.3	3.3 ± 3.1	0.024*
Drain volume (ml)	620 ± 469	809 ± 380	0.047*
Duration of drain stay (days)	7.6 ± 4.6	10 ± 4.3	0.044*

published in 2002, three groups of 30 patients each having had axillary dissection because of breast cancer were followed over the postoperative period. Soaking closed drainage was kept until the drained liquid amount was below 50 millilitres in 24 hours in one group. This resulted in the drain being kept in place for an average of 9.6 days. In the second group, the drain was removed on the second postoperative day without considering the drained amount. No drains were inserted for the third group of patients. This study has shown that drainage insertion had no significant effect on seroma formation after operation. The time for seroma formation was 26.6 days in Group I, 25.7 days in Group II and 27.9 days in Group III. Additional analyses have shown that nodal involvement, number of nodes extracted and type of operation applied (lumpectomy or radical modified mastectomy) had no significant effect on seroma formation. While closed axillary drainage system is still the standard for preventing a seroma formation and controlling lymphorrhage after axillary dissection, there have been people who have tried to minimize the lymphorrhage. In a study by Corcoforo et al. depending upon facts such as using octreotide for abdominal and thoracic lymphatic leaks or that lymphatic tissues have somatostatin receptors and somatostatin analogues given systematically could reduce local inflammatory responses, octreotide, a synthetic somatostatin analogue, has also been used for treating lymphorrhage (23). In this prospective, randomized study of 261 patients who have undergone axillary dissection, 125 patients were treated with octreotide in the postoperative period (3 times a day 0.1 mg subcutaneously for 5 days) and the results were compared with a control group of 136 patients by means of lymphorrhage leakage and seroma formation. In the octreotide group, lymphorrhage amount (65.4 ml. versus 94.6 ml) and duration of lymphorrhage (7.1 days versus 16.7 days) was significantly less compared to the control group, but there was no significant difference in hospitalization and duration of inserted drains between the two groups. Though wound infection complications have been seen three times more in the octreotide group than the control group, average wound infection ratio was only 1.5%. Albeit the complications relevant with octreotide have been irritation at injection site and gastrointestinal disturbances, none of the mentioned complications have caused disuse of medication (23). Octreotide and its new long acting analogues could be used more widespread in controlling lymphorrhage and seroma formation (23).

Fibrin adhesive, a fibrin tissue adhesive composed from fibrinogen and thrombin, has also been reported to reduce lymphorrhage volume following lymphatic dissection. Moore et al. (24) have reported a phase II, multicentre, prospective, parallel, randomized study comparing drained amounts and duration of drains in patients treated with axillary drainage and fibrin adhesive versus standard axillary drainage. This study, in addition, has determined a dose-response curve for fibrin adhesive, too. In therapy groups, different doses of fibrin adhesive have been applied while closing the axilla following lumpectomy and axillary dissection or while closing the axilla and skin flaps following modified radical mastectomy. In

patients with lumpectomy and axillary dissection, 4 ml of fibrin adhesive injected in the axilla resulted in statistically significant reduction in drainage volume and duration of drains. (24)

In some studies shoulder movements of patients who had axillary dissection has been restricted so as not to go beyond 90 degrees in abduction and active upper extremity physiotherapy has been postponed till drains have been removed. This approach reduces seroma formation compared with early physiotherapy programs and does not alter long period range of motion negatively (25,26). Flew J. (27) recommends shoulder immobilization with suspenders or special bandages, but this approach carries the risk of long period movement restriction and may increase lymphedema risk.

In two prospective studies by Porter et al and Keogh et al, they separated breast cancer patients in two groups in which electrocautery was used in one and scissors were used in the other. In the group for which scissors were used seroma formation incidence has been reported to be lower. (28,29).

In another prospective randomized study by Lumachi et al (30), 76 patients have undergone axillary dissection by using ultrasonic dissector in one group and electrocautery in the other. When the two groups were compared, it has been shown that ultrasonic dissector usage had reduced the total drained amount. Also, Hanne Galatius et al. reported no significant difference between two groups in terms of perioperative bleeding time, drain amount, seroma formation and wound infection in 59 patients who had undergone axillary dissection by using ultrasonic dissector in one group and scissors in the other (6). Moreover, a recent meta-analysis comparing outcomes after breast surgery using ultrasonic dissector or electrocautery found a reduction in the mean intraoperative blood loss (236 vs. 365 mL) and drainage volume (699 vs. 896 mL), but the difference was not statistically significant and the mean operative time and rate of seroma development were similar (7).

Magri et al. (8) have used LigaSure precise in one group and surgical clips in another group out of 187 patients. They have reported that the duration of drainage was shorter in the LigaSure treated group.

Manouras et al (31) have performed axillary dissection with LigaSure in 60 patients in a prospective clinical study and compared the results to the literature. As for the data on conventional method and harmonic scalpel dissections in the literature, with LigaSure usage perioperative bleeding, postoperative drained amount and duration of drains, occurrence of lymphedema and seroma and operation time have been reported to be reduced comparatively.

In our study, operative time was found to be longer, but drain volume and duration of drain stay was shown to be shorter in group I compared to group II. In group I, the fact that LigaSure precise forceps does not have a cutter, the waiting for sealing of vessels and the cutting process using scissors could be the explanation for the longer operative time compared to group II.

As a conclusion, it is considered that coagulation and

cutting of lymphatic vessels with Ligasure during axillary dissection could reduce lymphorrhage, and this results in a shorter drain stay in the axilla. According to our experience and study results, LigaSure electrothermal bipolar vessel sealing system can be safely used in axillary dissection as an alternative to traditional methods.

Authors' contribution

Mustafa Tukenmez: Drafting of manuscript.
 Orhan Agcaoglu: Analysis and interpretation of the data.
 Nihat Aksakal: Analysis and interpretation of the data.
 Sabahattin Destek: Analysis and interpretation of the data.
 Neslihan Cabioglu: Analysis and interpretation of the data.
 Umut Barbaros: Study conception and design.
 Yesim Erbil: Study conception and design.
 Alp Bozbora: Study conception and design.
 Ahmet Dinccag: Study conception and design.
 Vahit Ozmen: Study conception and design.
 Mahmut Muslumanoglu: Study conception and design.
 Abdullah Igci: Critical revision of the manuscript.

Ethical approval

Istanbul University Ethical Committee (2005/1252). Project was supported by Istanbul University Scientific Research Project Department - Project no: T758/13092005

Conflict of interest

The authors have no conflict of interest.

References

- Jamal A. 2006 American Cancer Society Inc. Surveillance Research. *CA Cancer J Clin.* 2006;56:108-30.
- Akçal T: Aksiller disseksiyon. *Meme Hastalıkları. Unal G, Unal H, Nobel Tıp Kitabevleri, İstanbul 2001, s 422-7.*
- Lumachi F, Brandes AA, Burelli P, Basso SM, Iacobone M, Ermani M. Seroma prevention following axillary dissection in patients with breast cancer by using ultrasound scissors: a prospective clinical study. *Eur J Surg Oncol.* 2004;30(5):526-30.
- Galatius H, Okholm M, Hoffmann J. Seroma formation following breast cancer surgery. *Breast J.* 2003;9(5):385-8.
- Pineda V, Astudillo P, Manterola C, Vial M. Wound drainage after axillary dissection for carcinoma of the breast. *Cochrane Database of Systematic Reviews 2007. Issue 4. Art. No.: CD006823. DOI: 10.1002/14651858.CD006823*
- Galatius H, Okholm M, Hoffmann J. Mastectomy using ultrasonic dissection: effect on seroma formation. *Breast.* 2003;12(5):338-41.
- Currie A, Chong K, Davies GL, Cummins RS. Ultrasonic dissection versus electrocautery in mastectomy for breast cancer - a meta-analysis. *Eur J Surg Oncol.* 2012;38(10):897-901. Epub 2012 Jun 14.
- Magri K, Bertrand V, Sautière JL, Pivot X, Riethmuller D, Maillot R, et al. Cost effectiveness of Ligasure Precise versus surgical clips during axillary nodal dissection for breast cancer. *J Gynecol Obstet Biol Reprod (Paris).* 2006;35(4):341-7.
- Kennedy JS, Buysse SP, Lawes KR. Recent innovations in bipolar electrocautery. *Min Invas Ther & Allied Technol.* 1999;8:95-9.
- Goldstein SL, Harold KL, Lentzner A, Matthews BD, Kercher KW, Sing RF, et al. Comparison of thermal spread after ureteral ligation with the ultrasonic shears and LigaSure system. *J Laparoendosc Adv Surg Tech A.* 2002;12(1):61-3.
- Landman J, Kerbl K, Rehman J, Andreoni C, Humphrey PA, Collyer W, et al. Evaluation of a vessel sealing system, bipolar electrocautery, harmonic scalpel, titanium clips, endoscopic gastrointestinal anastomosis vascular staples and sutures for arterial and venous ligation in a porcine model. *J Urol.* 2003;169(2):697-700.
- Richter S, Kollmar O, Schilling MK, Pistorius GA, Menger MD. Efficacy and quality of vessel sealing: comparison of a reusable with a disposable device and effects of clamp surface geometry and structure. *Surg Endosc.* 2006;20(6):890-4. Epub 2006 May 12.
- Soon PS, Yeh MW, Sywak MS, Sidhu SB. Use of the Ligasure vessel sealing system in laparoscopic adrenalectomy. *ANZ J Surg.* 2006;76(9):850-2.
- Shen WT, Baumbusch MA, Kebebew E, Duh QY. Use of the electrothermal vessel sealing system versus standard vessel ligation in thyroidectomy. *Asian J Surg.* 2005;28(2):86-9.
- Lachanas VA, Prokopakis EP, Mpenakis AA, Karatzanis AD, Velegrakis GA. The use of Ligasure Vessel Sealing System in thyroid surgery. *Otolaryngol Head Neck Surg.* 2005;132(3):487-9.
- Marrazzo A, Casà L, David M, Lo Gerfo D, Noto A, Riili I, et al. Thyroidectomy with LigaSure versus traditional thyroidectomy: our experience. *Chir Ital.* 2007;59(3):361-5. Italian
- Pogson CJ, Adwani A, Ebbs SR. Seroma following breast cancer surgery. *Eur J Surg Oncol.* 2003;29(9):711-7.
- Kennedy JS, Stranahan PL, Buysse SP, Ryan TP, Pearce JA, Thomsen S. Large vessel ligation using bipolar energy: a chronic animal study and histologic evaluation. Paper present at: 7th International Meeting of the Society for Minimally Invasive Therapy; 1995.
- Peterson SL, Stranahan PL, Schmaltz D, Mihaichuk C, Cosgriff N. Comparison of healing process following ligation with sutures and bipolar vessel sealing. *Surg Technol Int.* 2002;10:55-60.
- Heniford BT, Matthews BD, Sing RF, Backus C, Pratt B, Greene FL. Initial results with an electrothermal bipolar vessel sealer. *Surg Endosc.* 2001;15(8):799-801. Epub 2001 May 14.
- Dubuc-Lissoir J. Use of a new energy-based vessel ligation device during laparoscopic gynecologic oncologic surgery. *Surg Endosc.* 2003;17(3):466-8. Epub 2002 Oct 31.
- Talbot ML1, Magarey CJ. Reduced use of drains following axillary lymphadenectomy for breast cancer. *ANZ J Surg.* 2002;72(7):488-90.
- Carcoforo P, Soliani G, Maestroni U, Maravedgias K, Sortini D, Avital I. Relationship between octreotide and breast surgery. *Breast J.* 2005;11(3):223.
- Moore M, Burak WE Jr, Nelson E, Kearney T, Simmons R, Mayers L, et al. Fibrin sealant reduces the duration and amount of fluid drainage after axillary dissection: a randomized prospective clinical trial. *J Am Coll Surg.* 2001;192(5):591-9.
- Lotze MT, Duncan MA, Gerber LH, Wöltering EA, Rosenberg SA. Early versus delayed shoulder motion following axillary dissection: a randomized prospective study. *Ann Surg.* 1981;193(3):288-95.
- Schultz I, Barholm M, Gröndal S. Delayed shoulder exercises

- in reducing seroma frequency after modified radical mastectomy: a prospective randomized study. *Ann Surg Oncol.* 1997;4(4):293-7.
27. Flew TJ. Wound drainage following radical mastectomy: the effect of restriction of shoulder movement. *Br J Surg.* 1979; 66(5):302-5.
28. Porter KA, O'Connor S, Rimm E, Lopez M. Electrocautery as a factor in seroma formation following mastectomy. *Am J Surg.* 1998;176(1):8-11.
29. Keogh G, Doughty J, McArdle C. Seroma formation related to electrocautery in breast surgery-a prospective randomized trial. *The Breast* 1998;7:39-41.
30. Lumachi F, Burelli P, Basso SM, Iacobone M, Ermani M. Usefulness of ultrasound scissors in reducing serous drainage after axillary dissection for breast cancer: a prospective randomized clinical study. *Am Surg.* 2004;70(1):80-4.
31. Manouras A, Markogiannakis H, Genetzakis M, Filippakis GM, Lagoudianakis EE, Kafiri G, et al. Modified radical mastectomy with axillary dissection using the electrothermal bipolar vessel sealing system. *Arch Surg.* 2008;143(6):575-80; discussion 581.