GAVIN PUBLISHERS

OPEN ACCESS

Plastic Surgery and Modern Techniques

Review Article

Di Monta G, et al. Plast Surg Mod Tech 5: 158.

DOI: 10.29011/2577-1701.100058

Impact of Electrothermal Bipolar Vessel Sealing System in Breast Surgery with Axillary Lymph Node Dissection and in Stage III Melanoma Patients: A Review of Current Evidence for its use in Surgical Practice

Di Monta G[1], Caracò C[2], Di Marzo M[3], Mori S[1], Rinaldo M[4], Marone U[4*]

[1]UOSD Oncoplastic Surgery, Istituto Nazionale Tumori IRCCS Fondazione "G. Pascale", Naples, Italy

[2]UOSD Melanoma and Skin-Tumors Surgery, Istituto Nazionale Tumori IRCCS Fondazione "G. Pascale", Naples, Italy

[3]UOC Colon-Rectal Surgery, Istituto Nazionale Tumori IRCCS Fondazione "G. Pascale ", Naples, Italy

[4]UOC Breast Surgery, Istituto Nazionale Tumori IRCCS Fondazione "G. Pascale", Naples, Italy

[*]**Corresponding author:** Ugo Marone, UOC Breast Surgery, Istituto Nazionale Tumori IRCCS Fondazione "G. Pascale", Via M. Semmola - 80131 Naples, Italy

Citation: Di Monta G, Caracò C, Di Marzo M, Mori S, Rinaldo M, et al. (2021) Impact of Electrothermal Bipolar Vessel Sealing System in Breast Surgery with Axillary Lymph Node Dissection and in Stage III Melanoma Patients: A Review of Current Evidence for its use in Surgical Practice. Plast Surg Mod Tech 5: 158. DOI: 10.29011/2577-1701.100058

Received Date: 17 January, 2021; **Accepted Date:** 29 January, 2021; **Published Date:** 05 February, 2021

Abstract

To consolidate the feasibility, safety and effectiveness in performing axillary lymph node dissection in breast surgery and in patients with stage III melanoma, using the electrothermal bipolar vessel sealing system, we revisit and analyze the main studies on the subject, in order to identify its use as the best in this surgical practice. This skill is a bipolar electrosurgical technology for sealing blood vessels of up to 7 mm in diameter, introduced in recent years and used widely for a variety of laparoscopic and open surgical procedures, with several companies that have offered increasingly modern and manageable type of devices. All of these instruments allow to dissect smoothly, fuse the vessel walls, obliterating the vascular and lymph vessel lumen and cut effectively, greatly limiting the use of sutures and other alternative devices, making the best efficient way to seal blood and lymph vessels permanently and completely; all the studies revisited suggest their usefulness in breast surgery, especially in axillary dissection, because the reduction of the duration until drain removal and total drainage volume, and the complication rates comparable to those seen on using conventional devices.

Keywords: Axillary lymph node dissection; Breast cancer; Melanoma; Electrothermal bipolar vessel sealing system; Lymphorragy

Introduction

Although axillary surgery in breast cancer patients has gone from a more invasive to a minimalist approach, lymph node dissection of the axilla remains the elective option in case of locally advanced T3-T4 tumors, inflammatory carcinoma, clinically positive lymph nodes, sentinel lymph node positive (micro or macrometastatic) after primary systemic therapy or failure to regain the sentinel node. At least 10 lymph nodes removed are considered to be indicated and a level I and II lymphadenectomy is enough, except in the case of level II involvement where dissection is extended to the III Fisher/Berg level [1].

In patients with stage III melanoma, surgical practice has changed as two studies have shown that there is no survival benefit in radical lymph node dissection after sentinel lymph node biopsy. Active surveillance for patients who do not undergo a complete lymph node dissection (CLND) as a result of positive sentinel lymph node, should include ultrasound of lymph node stations as a key component of the follow-up strategy. CLND should be discussed with the patients clarifying the risks, benefits and alternatives of the procedure, including the overall risk of hosting non-sentinel metastatic lymph nodes and the impact of dissection on stage, regional disease control and survival [2].

In this regard, the Italian Melanoma Intergroup has developed a nomogram to predict the risk of positivity of non-sentinel lymph nodes, which can help surgeons discuss with

patients the opportunity of CLND [3]. Although, with the advent of new adjuvant treatments in melanoma therapy, it is probably less necessary to indicate a CLND, in case of obvious clinical involvement of the axilla, in the absence of systemic disease, elective lymph node dissection should be included considering the option of choice.

The most common complications of axillary dissection using traditional aids as scalpel, suture ligation and electrocautery are seroma and lymphedema, with incidences of 11% to 85% and 2% to 50% respectively. Other frequent complications are hematoma, prolonged axillary drainage, wound infection or necrosis, intraoperative and postoperative bleeding and functional limitation of the shoulder and the upper limb [4].

We know that lymph vessel sealing and hemostasis are usually performed using clips, suture ligation or electrocautery. This latter in particular, produces thermal spread to adjacent tissues and is considered a risk factor for seroma and other wound complications [5,6].

From head and neck surgery, started in recent years the use of the electrothermal bipolar vessel sealing system (EBVSS), an open sealer/divider surgical curved instrument, and its use has rapidly spread also in general surgery and in plastic surgery [7].

The aim of this paper is to consolidate the feasibility, safety and effectiveness in performing axillary lymph node dissection in breast surgery and in patients with stage III melanoma, using the EBVSS, revisiting and analyzing the main studies on the subject (Table 1), in order to identify its use as the best in this surgical practice.

Authors	Type of surgery	Study	Type of device
2008 Manouras	MRM and ALND	Prospective	LigaSure™ Precise
2011 Cordatellas	MRM and ALND	Prospective R.	LigaSure™ Precise
2014 Tukenmez	MRM and ALND	Prospective R.	LigaSure™ Precise
2017 Chang	SSM	Retrospective	LigaSure™ Small Jaw
2018 Inoue	MRM and ALND	Prospective	LigaSure™ Small Jaw
2018 Hirano	SSM	Retrospective	LigaSure™ Small Jaw
2018 Di Monta	ALND	Prospective	LigaSure™ Small Jaw

Table 1: Main studies on electrothermal bipolar vessel sealing system.

Search strategy and selection criteria

Data for this review were identified by a search of PubMed using the search terms “axillary lymph node dissection”, “breast cancer”, “melanoma”, “electrothermal bipolar vessel sealing system”, “lymphorragy”. Relevant references from identified articles were also included. Only English language articles published between 2008 and 2018 were included for analysis.

Operative surgical technique and application of electrothermal bipolar vessel sealing system

In the axillary CLND, the procedure is carried out through a transverse or S italic skin incision, preparing the skin flaps using the EBVSS exposing the axilla, identifying the lateral edge of the great pectoral muscle (Figure1) with subsequent opening of the clavipectoral fascia. The pectoralis major and pectoralis minor muscles were retracted upward, exponing the axillary vein. Dissection is practiced creating a surgical plane along the inferior bord of the axillary vein (Figure 2) by removing the I and level II lymph nodes and if involved, the third level, en-block with the adipose bearing above-axillary, identifying and preserving the vascular-nervous thoracic-dorsal beam, the long thoracic nerve and the axillary vein. The dissection of the fatty-beam tissue such as sealing and section of lymphatic and blood vessels is carried out with EBVSS. At the end of the surgical procedure, a drainage closed in suction is inserted through the lower skin flap. It was removed when 24-hour drainage fluid volume was less or equal to 30 mL or a maximum of 30 days after surgery. Similarly, in skin and nipple sparing mastectomy, after having made the skin incision and having found an adequate cleavage plane between the gland and the subcutaneous tissue, the total removal of the mammary parenchyma can be performed with the EBVVS, with the advantage of being able to use the instrument under cover without damaging the overlying skin envelope by dominating several small annoying bleeding, making the dissection more homogeneous and easier mostly in the internal quadrants and,

where preserved, close to the areola-nipple complex.

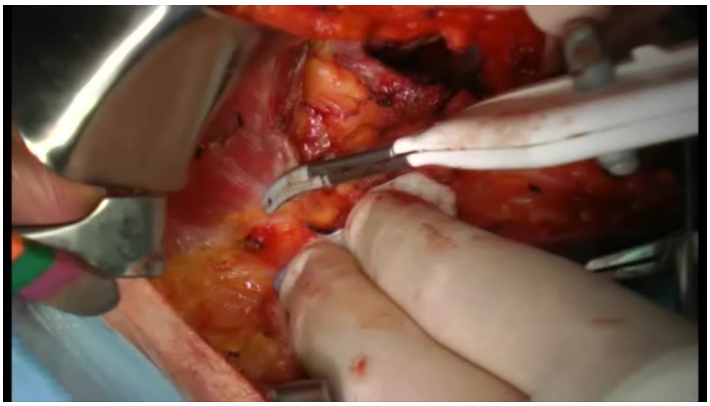

Figure 1: Intraoperative view of pectoral fascia incision by EBVSS.

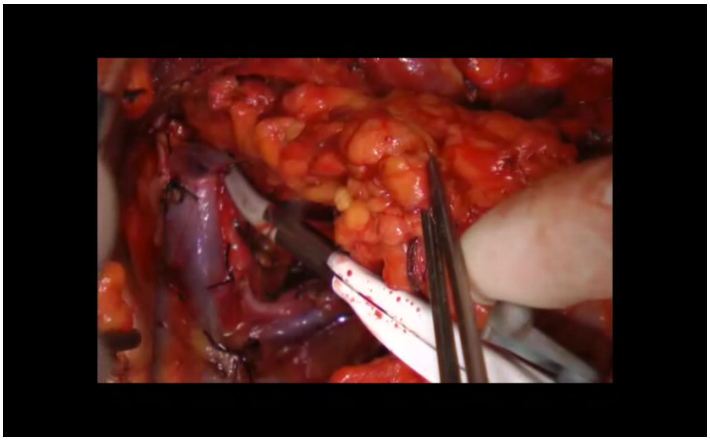

Figure 2: Intra-operative view of axillary lymph node dissection practiced by EBVSS along the inferior bord of the axillary vein.

Discussion and literature review

We have already seen how the main problems related to the axillary lymph node dissection are the sieroma with prolonged axillary drainage, and less frequently intra- and postoperative bleeding. Specifically the pathophysiology of seroma formation is not clearly understood and different hypotheses have been proposed, largely based on evidence from pa-tients undergoing axillary dissection after mastectomy. Woodworth et al. suggested that seroma formation is a consequence of surgical disruption of lymphatics and capillaries with ensuing leakage of fluid into the dead space created by surgical dissection. In others studies, seroma is considered to be a consequence of inflammatory exudates, showing high concentrations of proteins in fluid aspirates [8]. It has been suggested that efficient methods of sealing blood and lymph vessels during CLND may play a key role in reducing postoperative lymphorrhea.

Energy-based ligation and cutting tools such as electrothermal bipolar vessel sealing systems are commonly used in minimally invasive or open surgical procedures. The system uses electrothermal energy to denature collagen and elastin within the vessel wall and surrounding connective tissue and is reported to take 3.5 seconds to seal a 7-mm vessel in diameter with a blade temperature that never exceeds 80℃.

It is utilized for the synthesis and coagulation of blood vessels that uses a combination of pressure (supplied by the forceps) and radio frequency applied on the target tissues.

The manageability and success of the device among operators emerges from the first study carried out in 2008, in the first report about the use of the EBVSS in breast surgery with axillary dissection. Manouras et al. indeed reported sixty patients with unilateral, locally advanced breast cancer admitted for modified radical mastectomy with axillary dissection using the electothermal bipolar vessel sealing system, founding, after a follow-up period ranged from 3 to 4 years, no significant intraoperative bleeding in any patient, and no seroma, hematoma, lymphedema, pneumothorax, flap necrosis, wound infection, or postoperative bleeding [4]. They concluded that, just because definitive lymph vessel sealing and hemostasis in breast surgery are of utmost importance for a safe and successful operation and for an uneventful postoperative course, the device is handy, easy to use, and reliable, safe and effective with respect to hemostasis, complications, operative time, and lymph vessel sealing.

Hemostasis is achieved through the fusion of collagen and elastin from the intimal wall of the vessel creating a permanent synthesis. EBVSS confines its effect to the tissues or al vessels without carbonization and with a minimal thermal diffusion to the adjacent tissues. The generator automatically senses the resistance of the tissues consequently adjusting the output voltage in order to reduce thermal damage. The instant response technologist identifies the impedance characteristics of the tissue located inside the clamps of the instrument and distributes the appropriate quantity of radio frequency necessary to perform the complete synthesis of the vessels. It is equipped with a safety system that interrupts the process when the synthesis has been obtained and warns the operator with an acoustic signal; at this point the operator can proceed with cutting.

In 2011 Cortadellas T et al, reported a prospective randomized study, in wich a total of 100 women with breast cancer who required axillary dissection were randomized to the EBVSS or conventional axillary dissection group. There were no significant differences between the two groups in the mean age, body mass index (BMI), use of neoadjuvant treatment, the distribution of performed surgical procedures, histopathological findings, total number of lymph nodes, and number of positive lymph nodes, however, intraoperative blood loss ≥200 mL was recorded in

30.8% of patients assigned to the EBVSS group as compared with 69.2% of patients assigned to the conventional axillary dissection group (P<0.001). There were moreover differences in favor of EBVSS in the duration of axillary dissection (mean 48 vs 63.2 min.; P=0.004), days of suction drain (4.3 vs 5.7 days, P=0.012), and length of hospitalization (5.1 vs 6.5 days, P=0.021); axillary drain volume was also lower in the EBVSS group, although statistical significance was not reached, and also the mean number of postsurgical seroma punctures and the amount of seroma fluid drained. A low rate of surgical complications was recorded in both groups and hematoma, wound infection, wound dehiscence, lymphedema, and pain occurred more frequently in the conventional axillary dissection group, but without significant differences. The results of the study provided further evidence of the feasibility, safety and efficacy of the EBVSS in breast cancer surgery with axillary dissection, supporting the routine use of this technology during this surgical procedure [9].

Further studies conducted reach similar conclusions. Tukenmez et al reported 33 patients with breast cancer divided in two study groups: axillary dissection was performed in the first by EBVSS and in the second by linking and electrocautery. 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, affirming at the end that coagulation and cutting of lymphatic vessels with EBVSS during axillary dissection could reduce lymphorrhage and this result in a shorter drain stay in the axilla. It's obvious that the advantages of these tools include permanent sealing, reduced foreign body inflammatory reaction, minimal thermal effect on surrounding tissues, and reduced tissue tangling and carbonization. They also appear to be effective in closing lymphatic vessels that normally remain open with electrocautery. These energy-based devices allow effective reduction of surgery time and safe tissue removal with no increase in postsurgical complications. EVVSS is therefore ideal for all those operations that require the ligation and division of vessels, bands of tissue and lymphatic vessels.

In 2017, in the retrospective study of Chang YW et al, 81 patients with breast cancer undergoing skin sparing mastectomy (SSM) were selected and divided into two group, electrocautery and EBVSS, based on the devices used for SSM [10]. The study population included 50 patients in the electrocautery group and 31 in the EBVSS group. Mean total volume of drainage, surgery time and duration of drainage was significantly less in the EBVSS group. Regarding complications, in the latter group, 4 patients (12.9%) experienced skin necrosis and 3 (9.7%) seroma respect to 12 (24%), 9 and 7 (14%) in the electrocautery group. In the discussion, the authors put attention on the fact that in SSM the entire breast has to be removed through a small incision and the skin flap has to be protected from ischemia and because of subdermal vessels are not clearly seen, the use of electrocautery without vessel sealing could result in more frequent bleeding. The result of the study suggested that patients in the EBVSS group had a shorter operative time than those in the electrocautery group. This might be due to reduced bleeding with sealing of subdermal vessels before dissection. In SSM, more time is needed to control a bleeding focus due to the small operative view compared with that in conventional total mastectomy; thus, reduction of bleeding could have influenced operative time in the study. The report moreover showed that the use of EBVSS could significantly reduce total volume and duration drainage in SSM. The reduction of drainage resulted from adequate sealing of lymphatics by electrothermal energy and pressure. The rate of flap necrosis is known to be decreased by the use of energy devices such as EBVSS in conventional total mastectomy.

Flap necrosis is associated with lateral thermal spread from the device used during the operation. Sutton et al. showed that electrocautery had the highest mean temperature and the widest thermal spread [11]. In the Chang study, patients in the electrocautery group tended to experience more postoperative skin necrosis requiring debridment (24 vs 12.9%, respectively) [12]. Interesting ideas especially on the relationship between high body mass index and lymphorrhea emerged in the work of Inoue Y et al, in which ninety-two patients with breast cancer who underwent total mastectomy and CLND were included [13]. The patients were divided into two groups: the EBVSS group (n=43) in which CLND was performed using EBVSS; and the conventional-CLND group (n=49), in which CLND was performed using a conventional technique. The CLND procedure included the dissection of the level I and II lymph nodes. A closed suction drain was placed in the axillary fossa in all cases. The drain was removed when the total drainage volume in the drainage volume in the previous 24 hours was 30 mL or less. The authors evaluated the operative time, bleeding, wound infection, drainage volume, time to drain removal and the hospitalization period between the two groups and also the clinical usefulness of EBVSS according to the BMI. Thus, patients with a high BMI had a greater drainage volume and a longer time to drain removal. There were no significant differences in the operative time , or the bleeding and wound infection rates of the two groups, however, the drainage volume of the EBVSS group was significantly lower than that in the conventional CLND group: the time to drain removal and the hospitalization period in the EBVSS group were also significantly shorter in comparison to the conventional CLND group. In the subset analysis according to BMI, the use of EBVSS was more effective, in terms of drainage volume, time to drain removal and the hospitalization period in the group with high BMI. The findings of the study suggest the usefulness of EBVSS for CLND in patients with breast cancer, especially in those with a high BMI.

Hirano J et al, in 2018, retrospectively reviewed records of 148 consecutive patients with breast cancer who underwent skin

sparing mastectomy, assigned in two groups, those in whom EBVSS was used and those in whom EBVSS was not used, evaluating the duration of SSM, blood loss during surgical procedure, duration of postoperative hospital stays. The patients in the non-EBVSS group experienced significantly shorter operation duration than that of the EBVSS group, however, the EBVSS group demonstrated significantly better findings with regard to blood loss during SSM and postoperative hospital stay. Postoperative complications included one case with hemorrhage that required reoperation, 5 cases with insufficient circulation that resulted in skin necrosis (4 cases) and flap loss (one case), and 2 cases in which infection developed at the surgical site, one of which required removal of the tissue expander.

In our previous study, 36 patients who underwent axillary lymph node dissection for metastatic melanoma were compared with a historical control group of another our report [14] using descriptive statistics, in which 33 patients of the control group received standard surgical treatment with conventional electrocautery only.

In this study, the use of the EBVSS instrument for nodal dissection in cutaneous melanoma was associated with reduced postoperative lymph output and reduced duration of suction drainage. The drainage volume at postoperative day 10 was reduced by one-third compared with conventional electrocautery data. Even more than the reduction in time to drainage removal, this shows the ability of electrothermal bipolar vessel sealing to reduce postoperative lymph produc-tion. These findings suggest that the EBVSS can be safely used in nodal dissection as an alternative to traditional methods in patients with cutaneous melanoma [14,15].

Conclusions

The EBVSS device allows to dissect smoothly, works like a clamp, fuses the vessel walls, obliterating the vascular and lymph vessel lumen and cut effectively, greatly limiting the use of sutures and other alternative devices, making the best efficient way to seal blood and lymph vessels permanently and completely.

Thanks to radiofrequency technology, it allows surgeon to work safely near delicate structures, ensuring complete coagulation with minimal surrounding thermal spread where thermal diffusion could damage nerve structures as the long thoracic nerve, the thoracodorsal pedicle, the great vessels of the axilla, and the brachial and subdermal plexus

Its ergonomics is additionally designed to be used in confined surgical space, where access and visibility are limited, making easier dissection in less accessible anatomical spaces, such as when it's necessary to remove the apical axillary nodes or preparing the flaps in skin sparing mastectomy.

Its use can reduce the days until drain removal and postoperative drainage volume comparing to the conventional devises, although seroma formation could not be completely avoided so the optimal way to prevent and treat it remains inconclusive, at the other hand other complications such as postoperative bleeding and skin flap necrosis were not observed when EBVSS was used.

In conclusion, the study suggest the usefulness of the EBVSS in breast surgery especially with axillary dissection, because it reduces the duration until drain removal and total drainage volume, and the complication rates comparable to those seen on using conventional devices.

Acknowledgements

Conflict of interest: The authors have no conflicts of interest to declare.

Ethical Statements: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

References

1. NCCN Clinical Practice Guidelines on Oncology Breast Cancer - Version 3-2019, September 6,2019
2. Ascierto PA, Borgognoni L, Botti G, Guida M, Marchetti P, et al. (2019) New paradigm for stage III melanoma: from surgery to adjuvant treatment. J Transl Med 17: 266.
3. Rossi CR, Mocellin S, Campana LG, Borgognoni L, Sestini S, et al. (2017) Prediction of Non-sentinel Node Status in Patients with Melanoma and Positive Sentinel Node Biopsy: An Italian Melanoma Intergroup (IMI) Study. Ann Surg Oncol 25: 271-279.
4. Manouras A, Markogiannakis H, Genetzakis M, Filippakis GM, Lagoudianakis EE, et al. (2008) Modified radical mastectomy with axillary dissection using the electothermal bipolar vessel sealing system. Arch Surg 143: 575-580.
5. Porter KA, O'Connor S, Rimm E, lopez M (1998) Electrocautery as a factor in seroma formation following mastectomy. Am J Surg 176: 8-11.
6. Hoefer RA Jr, DuBois JJ; Ostrow LB, Silver LF (1990) Wound complications following radical mastectomy: an analysis of perioperative factors. J Am Osteopath Assoc 90: 47-53.
7. Prokopakis EP, Lachanas VA, Vardouniotis AS, Velegrakis GA (2010) The use of the Ligasure vessel sealing system in head and neck surgery: a report on six years of experience and a review of the literature. B-ENT 6: 19-25.
8. Woodworth PA, McBoyle MF, Helmer SD, Beamer RL (2000) Seroma formation after breast cancer surgery: incidence and predicting factors. Am Surg 66: 444-450.
9. Cortadellas T, Córdoba O, Espinosa-Bravo M, Mendoza-Santin C, Rodríguez-Fernández J, et al. (2011) Electrothermal bipolar vessel sealing system in axillary dissection: a prospective randomized clinical study.Int J Surg 9: 636-640.

10. Chang YW, Kim HS, Jung SP, Woo SU, Lee JB, et al. (2017) Comparison of skin-sparing mastectomy using LigaSure™ Small Jaw and electrocautery. World J Surg Oncol. 15: 129.

11. Men V, Muslumanoglu M, Igci A, Destek S, Cabioglu N, et al. (2014) The use of Ligasure vessel sealing system in axillary dissection; effect on seroma formation. Chirurgia (Bucur) 109: 620-625.

12. Sutton PA, Awad S, Perkins AC, Lobo DN (2010) Comparison of lateral thermal spread using monopolar and bipolar diathermy, the Harmonic Scalpel and the Ligasure. Br J Surg. 97: 428-433.

13. Inoue Y, Yamashita N, Ueo H, Tanaka K, Saeki H, et al. (2018) The Clinical Usefulness of the LigaSure™ Small Jaw in Axillary Lymph Node Dissection in Patients with Breast Cancer. Anticancer Res 38: 2359-2362.

14. Hirano J, Kinoshita S, Kazama T, Shimada N, Miyake R, et al. (2018) Value of Vessel Sealing System in Skin- Sparing Mastectomy in Patients with Early Breast Cancer. Clin Surg 3: 2055.

15. Di Monta G, Marone U, Amore A, Benedetto L, Caracò C (2018) Electrothermal Bipolar Vessel Sealing System Dissection Reduces Drai-nage Fluid Output or Time to Drain Re-moval Following Axillary and Ilio-Inguinal Node Dissection in Melanoma Patients: A Pilot Study. Journal of Cancer Therapy 9: 613-622.

Table legend: MRM, modified radical mastectomy; ALND, axillary lymph node dissection; SSM, skin sparing mastectomy; R., randomized.