Harmonic scalpel versus electrocautery in axillary lymph-node dissection in patients with breast cancer: a prospective randomized study

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Background
Multiple techniques have been used for tissue dissection and achieving hemostasis during breast surgery, including harmonic scalpel and electrocautery. However, there are some conflicting results between different studies regarding some parameters like operative time and seroma formation. This study aims to compare between the previous two techniques for axillary lymph-node dissection in breast cancer patients.

Patients and methods
We recruited 98 cases diagnosed with breast cancer for this prospective randomized study. The cases were divided into two groups according to the dissection technique, harmonic, and electrocautery groups. Intraoperative and postoperative parameters were compared between the two groups.

Results
Both patient and tumor criteria were comparable between the two groups. However, both operative time and blood loss showed a significant decrease with harmonic use. In addition, the same device led to a significant decrease in drain discharge and early drain removal. However, no significant difference was noted regarding the number of dissected lymph nodes and the duration of hospitalization. As regards postoperative complications, it showed no significant differences between the study groups.

Conclusion
Harmonic scalpel is more beneficial compared with the conventional electrocautery technique. It is associated with shorter operative time, less blood loss, less postoperative pain, less drainage discharge, and early drain removal.

Keywords:
axillary lymph-node dissection, breast cancer, electrocautery, harmonic scalpel

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Introduction

Breast cancer in the commonest malignancy in Egyptian ladies as it accounts for 32% of female malignancies [1]. It represents a crucial health problem to both Egypt and other countries due to its associated socioeconomic and emotional challenges [2]. It is the second most common cause of cancer-related female death after lung cancer [3].

Not only does axillary lymph-node status have a crucial role in the prognosis of patients with breast cancer, but also it helps to individualize the treatment plan for each patient. Both axillary lymph-node sampling along with sentinel lymph-node biopsy have some disadvantages. The former usually underestimates disease extent, while the latter does not have a 100% sensitivity [4–6]. Therefore, axillary lymph-node dissection is the most accurate method for nodal assessment in such cases. Also, it is associated with lower recurrence rates compared with the other methods [7].

Since the early 1970s, electrocautery has been and still a useful popular tool that is used by most surgeons to achieve a bloodless field in many surgical operations, including mastectomy [8]. However, its use has been linked with an increased risk for postoperative seroma formation. It was hypothesized that heat generated from the electrocautery blade causes thermal tissue damage, which leads to an inflammatory reaction causing disruption of both vascular and lymphatic plexus in the skin flap [9]. This will eventually lead to seroma formation [10].

Harmonic scalpel is an emerging surgical tool used for dissection and hemostasis, and it has been widely used in minimally invasive surgeries [11,12]. This ultrasound-based device works by generating

high-frequency vibrations of the metallic rod that causes breakdown of the hydrogen bond and protein denaturation. The produced motions could provide tissue coagulation and cutting at the same time [13,14].

In fact, harmonic scalpel has several advantages over electrocautery, it generates less heat, leading to less thermal damage, and minimal smoke is produced, leading to a more clearly operative field. Additionally, it is safe to be applied in patients with pacemakers, and it does not cause injury or excitement of axillary motor nerves [8,15].

Although many studies are present comparing the previous two hemostatic methods, there are some conflicting results between different studies regarding some parameters like operative time and seroma formation. That is why we conducted the current study aiming to compare between harmonic scalpel and electrocautery in axillary lymph-node dissection in breast cancer surgery.

Patients and methods

This prospective randomized study was conducted at Tanta University Hospitals, after gaining approval from the local ethical committee. The study was conducted over the period of 3 years, starting from January 2018 to January 2021.

A sample size of 98 patients (49 patients in each group) had 90% power to detect a 4.4-min difference in mean operative time as reported by Damani *et al*. [15] with SD values of 4.9 and 8.1 min in the harmonic scalpel and diathermy groups, respectively, using a one-group *t* test with a 0.05 two-sided significant level.

We included adult female cases presented with stages I–III breast cancer, who were classified as class I or II according to the American Society of Anesthesiologists [16]. Contrarily, we excluded patients with stage IV or recurrent breast cancer in addition to cases who underwent immediate reconstruction. Besides, cases who had previous chest radiotherapy or classified as American Society of Anesthesiologists more than II were also excluded.

Based on the previous sample size, a total of 98 cases were included, and they were randomly allocated into two equal groups using the closed-envelope method. The first group included 49 cases who underwent the surgical procedure using harmonic scalpel, and the second one included the remaining 49 cases who underwent the procedure using electrocautery.

Patient evaluation included detailed history taking, thorough general and local breast examination, in addition to routine preoperative laboratory investigations. Radiological assessment included breast ultrasonography, mammography, tissue biopsy (fine cut or true cut), and a metastatic workup. An informed written consent was obtained from all of the included participants, following complete explanation of the details and complications of each procedure.

All cases were performed under general anesthesia. Skin incision was performed by scalpel in both groups. After that, dissection of the upper and lower skin flaps was performed by either harmonic (Ethicon Generator and harmonic focus handle; Ethicon Endo-Surgery Inc., Somerville, New Jersey, USA) or electrocautery according to patient randomization. Of note, in the harmonic group, no sutures, clips, or electrocautery were used.

The breast tissue was then dissected and reflected off away from the pectoralis major muscle. In patients with breast-conserving surgery, we tried to achieve a minimal safety margin of 1 cm and the specimen was sent for frozen section to ensure complete microscopic clearance.

For exposure of the axilla, the clavipectoral fascia was opened, and both pectoralis muscles were retracted upward. The axillary vein was identified, and axillary dissection was started from the lateral end of the vein. Our dissection plane was created along the inferior border of the vein. All fatty tissue, vessels, and lymph nodes were dissected toward the breast. Also, tributaries from breast and pectoralis muscles were sealed with harmonic in the first group, cauterized, clipped, or sutured in the second group. Levels I–III axillary dissection was performed in all cases. Both long thoracic and thoracodorsal nerves were identified and safeguarded.

After ensuring good wash and hemostasis, a vacuum drain was inserted into the axilla and another one was inserted below the skin flaps. Skin closure was then performed by nonabsorbable sutures.

Blood loss was estimated by adding the blood collected in the suction apparatus to the blood sucked by gauze and dressings. Its preoperative weight was subtracted from its postoperative one to estimate the amount of blood.

After operation, all cases were transferred to the recovery room and then to the internal ward, where

early ambulation was encouraged. Pain was assessed via the visual analog scale (VAS), with 0 for no pain and 10 for the worst pain ever [17].

Most patients were discharged with drains within the first day after operation. They were informed how to evacuate and calculate the amount collected in the drain every 24 h. The amount was recorded and the total drain discharge was calculated after drain removal. We removed the drains when it discharged less than 10 ml per 24 h for two successive days. Postoperative seroma was defined by the presence of subcutaneous fluid collection causing patient discomfort after drain removal within 30 days from surgery [8,18].

Our primary outcome was operative time, whereas the secondary outcomes included intraoperative blood loss, postoperative drain volume, day of drain removal, incidence of seroma formation, and other postoperative wound complications.

Statistical analysis

We used the Statistical Package for the Social Sciences (SPSS 26, IBM/SPSS Inc., Chicago, Illinois, USA) software doe data analysis. Categorical data were expressed as frequencies and percentages, while in the quantitative data, we used mean and SDs (for normally distributed data) and median and range (for abnormally distributed data). To compare two groups with categorical variables, χ^2 test (or Fisher's exact test) were used. To compare two groups with normally distributed quantitative variables, independent samples *t* test was used and Mann–Whitney *U* test was used if the data were abnormally distributed. *P* values less than 0.05 are considered significant.

Results

Starting with demographics, the mean age of the included cases was 53.08 and 52.56 years in the harmonic and electrocautery groups, respectively. Additionally, BMI had mean values of 32.25 and 32.78 kg/m^2 in the same groups, respectively. Regarding systemic comorbidities, diabetes mellitus was present in 22.49 and 18.37% of cases, while hypertension was present in 22.49 and 24.94% of cases in the two groups, respectively. Ischemic heart disease was present only in one case in the harmonic group (2.04%). Neither of the previous variables was significantly different between the study groups ($P>0.05$), as shown in Table 1.

Both tumor size and stage did not show any significant differences between the two groups ($P=0.132$ and 0.164, respectively). Modified radical mastectomy was the commonest operation performed (61.22 and 57.14% of cases in the harmonic and electrocautery groups, respectively), while the remaining cases underwent conserving surgery with axillary dissection. The type of operation did not show a significant difference between the two groups ($P=0.184$).

The harmonic group showed a significant decrease in both operative time and blood loss ($P<0.001$). The former had mean values of 93.25 and 125.08 min, while the latter had mean values of 74.81 and 158.64 ml in the harmonic and electrocautery groups, respectively. Conversely, the number of dissected lymph nodes did not show a statistical difference between the two groups ($P=0.425$). The previous data are summarized in Table 2.

The harmonic group expressed significantly lower pain scores compared with the electrocautery group ($P=0.005$). Nevertheless, the duration of hospitalization had a median value of 1 day in the two groups. Total drain discharge showed a significant increase in the electrocautery group (1015.27 vs. 705.33 ml in the harmonic group; $P<0.001$). Additionally, the harmonic group showed significantly earlier drain removal compared with the other group (7.81 vs. 10.44 days in the other group; $P<0.001$). The previous data are shown in Table 3.

In general, the incidence of complications was comparable between the two groups ($P>0.05$). Hematoma was encountered in 0 and 2.04% of cases, whereas seroma was detected in 4.08 and 10.2% of cases in the harmonic and electrocautery

Table 1 Demographic criteria of the two groups

	Harmonic group (*N*=49)	Electrocautery group (*N*=49)	*P* value
Age	53.08±3.14	52.56±3.62	0.384
BMI (kg/m^2)	32.25±2.95	32.78±2.91	0.322
Comorbidities [*n* (%)]			
Diabetes mellitus	11 (22.49)	9 (18.37)	0.204
Hypertension	11 (22.49)	12 (24.49)	
Ischemic heart disease	1 (2.04)	0	

Table 2 Tumor criteria and operative data in the two groups

	Harmonic group (*N*=49)	Electrocautery group (*N*=49)	*P* value
Tumor size (mm)	25 (12.5–60)	28.06 (12–58.5)	0.132
TNM stage [*n* (%)]			0.164
I	13 (26.53)	15 (30.61)	
II	26 (53.06)	24 (48.98)	
III	10 (20.41)	10 (20.41)	
Operation type [*n* (%)]			0.184
Modified radical mastectomy	30 (61.22)	28 (57.14)	
Conserving surgery with axillary dissection	19 (38.78)	21 (42.86)	
Operative time (min)	93.25±7.44	125.08±8.21	<0.001*
Blood loss (ml)	74.81±21.3	158.64±48.73	<0.001*
Dissected lymph nodes	17 (13–22)	18 (12–22)	0.425

*Statistically significant ($P<0.05$).

Table 3 Postoperative data

	Harmonic group (*N*=49)	Electrocautery group (*N*=49)	*P* value
VAS	2 (1–3)	4 (2–5)	0.005*
Hospital stay (day)	1 (1–2)	1 (1–2)	0.634
Total drain discharge (ml)	705.33±126.18	1015.27±146.94	<0.001*
Duration of drainage (day)	7.81±1.73	10.44±2.59	<0.001*

VAS, visual analog scale. *Statistically significant ($P<0.05$).

Table 4 Complications in the two study groups

	Harmonic group (*N*=49) [*n* (%)]	Electrocautery group (*N*=49) [*n* (%)]	*P* value
Hematoma	0	1 (2.04)	0.368
Seroma	2 (4.08)	5 (10.2)	0.086
Surgical-site infection	2 (4.08)	2 (4.08)	1
Flap necrosis	0	0	1
Skin burn	0	0	1

groups, respectively. In addition, surgical-site infection was diagnosed in 4.08% of cases in the two groups. Neither flap necrosis nor skin burn were encountered in the current study. Table 4 illustrate these data.

Discussion

Multiple coagulating and cutting devices have been assessed aiming to decrease complication rate and blood loss during surgical breast procedures [19,20]. With recent technological advances, surgeons should keep themselves updated with recent devices that should make surgery easier and safer. Harmonic scalpel has proved itself as a safe and efficient dissection and hemostatic tool, especially in laparoscopic surgery [21].

The current study was conducted aiming to compare between harmonic scalpel and electrocautery in axillary lymph-node dissection in patients with breast cancer. We assessed intraoperative and early postoperative outcomes. A total of 98 cases were recruited and then divided into two equal groups, the first one underwent axillary dissection with the former tool, while the second group underwent the procedure with the latter one.

Our findings showed that age had mean values of 53.08 and 52.56 years in the two groups, respectively, with no significant difference in statistical analysis. Faisal *et al.* [8] also reported no significant difference between the two groups regarding age (P=0.707), which had mean values of 51.8 and 52.5 years in the same groups, respectively.

In our study, BMI of the included cases had mean values of 32.25 and 32.78 kg/m^2 in the same groups, respectively, with no significant difference between the two groups. Khan *et al.* [18] also negated any significant difference between the two groups regarding BMI, which had mean values of 28.4 and 28.1 kg/m^2 in the same groups, respectively (P=0.656). Our increased BMI values compared with the previous study could be explained by the increased prevalence of obesity in the Egyptian community.

The prevalence of different comorbidities was comparable between our study groups (P=0.0204).

Likewise, a previous study also negated any significant differences between the two groups regarding the prevalence of systemic comorbidities [8].

The mean values of tumor size were 25 and 28 mm in the harmonic and electrocautery groups, respectively, without any significance between the two groups. This is in accordance with the study conducted by Galatius *et al.* [22] who reported that the included cases had no significant difference regarding tumor size ($P>0.05$). Tumor size ranged between 5 and 60 mm in the harmonic group (median=25 mm), whereas it ranged between 11 and 42 mm in the other group (median=19 mm). Muhammad *et al.* [23] also reported tumor-size range near to ours.

Tumor stage did not constitute a significant variable between our study groups, and this was also reported by Archana *et al.* [21] who denied any significant difference between the two groups regarding that parameter.

In general, there were no significant differences between our two study groups regarding patient and tumor criteria. This implies proper randomization and should also nullify any bias that might have skewed the results in favor of one group rather than the other one.

Our findings showed that operative time showed a significant prolongation with electrocautery (125.08 vs. 93.25 min in the harmonic group; $P<0.001$). Of course, harmonic usage will save some time needed for tissue clipping, suturing, knotting, or cutting. These steps are often needed in the conventional technique.

This was also confirmed by Archana *et al.* [21] who reported that operative time had mean values of 112.33 and 151.38 min in the harmonic and electrocautery groups, respectively ($P<0.001$). He *et al.* [7] also confirmed the previous findings, as the same variable had mean values of 92 and 117 min in the two groups, respectively ($P<0.05$).

Conversely, another Egyptian study conducted at Suez Canal University reported significant prolongation of the same variable in the harmonic group ($P=0.0001$). It had mean values of 2.63 and 1.75 h in the harmonic and electrocautery groups, respectively [8]. Furthermore, Deo *et al.* [24] reported no significant difference between the two dissection methods regarding operative time ($P=0.37$). It had mean values of 104 and 100 min in the harmonic and electrocautery groups, respectively. The previous findings could be explained by the fact that the harmonic device was a novel dissection technique that required a period of adaptation. The effect of surgical experience was well explained in the study conducted by Muhammad *et al.* [23], who noticed a significant decrease in operative time in the late 10 cases performed by harmonic compared with the early 10 cases.

When it comes to blood loss in the current study, harmonic usage was associated with significant decrease in intraoperative blood loss, which had mean values of 74.81 and 158.64 ml in the harmonic and electrocautery groups, respectively ($P<0.001$). Multiple studies confirmed the previous findings [7,8,25]. He *et al.* [7] reported that the mean amount of blood loss was 75.6 and 190.4 ml in the same groups, respectively, with a significant decrease with harmonic usage ($P<0.05$). Faisal *et al.* [8] reported that intraoperative blood loss had mean values of 69.4 and 255.5 ml in the same groups, respectively ($P<0.002$).

In our study, both dissection techniques were comparable regarding the number of dissected lymph nodes. Other studies reported no significant difference between the two methods regarding the number of harvested lymph nodes [7,22]. Our dissected lymph-node ranges lied near the numbers reported in these studies.

It is worthy to mention that harmonic usage was associated with a significant decrease in pain scores after surgery. In line with our findings, a previous study also reported a significant decrease in pain scores in the harmonic group. VAS had a mean value of 4.9 compared with 6.7 in the electrocautery group ($P<0.05$) [7]. Khan *et al.* [18] confirmed the previous findings, as the included patients reported median VAS of 2 and 3 in the harmonic and electrocautery groups, respectively, with a significant difference between the two groups ($P<0.01$). This could be explained by lower heat generated from harmonic usage compared with electrocautery. Lower heat production is associated with less tissue damage and nerve-ending irritation.

In the current study, no significant difference was noted between the two groups regarding the duration of hospitalization, which had median value of 1 day in the two groups. Likewise, Adwani and Ebbs [26] reported that the two groups had the same mean duration of hospitalization. However, the authors reported longer hospital stay compared with ours (mean=7.33 days). This could be explained by different management plans and healthcare facilities

between different centers. On the contrary, another study reported a significant increase in hospital stay in the electrocautery group (median=6 vs. 3 days in the harmonic group; $P<0.002$) [23].

In our study, total drain discharge showed a significant decrease in the harmonic group compared with the electrocautery (705.33 vs. 1015.27 ml in the two groups, respectively; $P<0.001$). In the same context, another study confirmed our findings. Thr total drain volume had mean values of 1277.8 and 3300 ml in the harmonic and electrocautery groups, respectively, with a significant difference between the two groups ($P=0.002$) [8]. Moreover, another study reported that drain volume had mean values of 590 and 1085 ml in the same groups, respectively, with a significant difference between the two groups ($P=0.0194$) [24]. On the other hand, Galatius *et al.* [22] reported no significant difference between the two methods regarding total drainage volume that had median values of 645 and 585 ml in the harmonic and electrocautery groups, respectively ($P>0.05$).

Our results showed that drain removal was significantly earlier in the harmonic group (7.81 vs. 10.44 days in the electrocautery group; $P<0.001$). Khan *et al.* [18] reported that harmonic use was associated with a significant decrease in the duration of drains ($P<0.001$). Drains were removed after 12 days in the harmonic group versus 17 days in the electrocautery group. Other authors confirmed these findings [8].

The incidence of postoperative hematoma did not significantly differ between the two groups, as it was encountered in 0 and 2.04% of cases in the harmonic and electrocautery groups, respectively. Another study also negated any significant difference between the two hemostatic devices regarding hematoma formation ($P=0.122$). Postoperative hematoma was encountered in 0 and 4% of cases in the harmonic and electrocautery groups, respectively [18]. In addition, Damani *et al.* [15] confirmed the previous findings as the same complication was detected in 0 and 12% of the same groups, respectively ($P=0.235$).

Our findings showed no significant difference between harmonic and electrocautery devices regarding the incidence of postoperative seroma. It was encountered in 4.08 and 10.2% of cases in the two groups, respectively. Also, He *et al.* [7] reported that the postoperative seroma was encountered in 3.125 and 4.69% of cases in the harmonic and electrocautery groups, respectively ($P>0.05$). Deo *et al.* [24] also confirmed the previous findings. It was previously reported that the exact pathophysiology of seroma formation after such operations is still unclear [27], and the optimal method to prevent and treat that complication remains inconclusive [28,29]. On the contrary, another study reported a significant decrease in seroma formation with harmonic use ($P<0.003$). This complication was encountered in 8.3 and 33.3% of cases in the harmonic and electrocautery groups, respectively [8].

Surgical-site infection was encountered in 4.08% of cases in our two groups. These four cases were managed by systemic antibiotics and frequent wound dressing. Kozomara *et al.* [30] also reported similar incidence of wound infection in the two (6.45%) groups. Faisal *et al.* [8] reported a higher incidence of wound infection in their study, as it was encountered in 5.6 and 22.2% of cases in the harmonic and electrocautery groups, respectively. Yet, no significant difference was noted between the study groups ($P=0.569$).

In our study, we did not encounter any cases with skin-flap necrosis. Another study also negated any significant difference between the two groups regarding the incidence of flap necrosis ($P=0.083$). However, this complication was detected in 2.7 and 9.3% of cases in the harmonic and electrocautery groups, respectively [18].

We did not encounter any cases with skin burn in the current study, and this is in agreement with other authors who also denied the occurrence of skin burn in the two groups [7].

To summarize, although electrocautery is considered the conventional tool used by many surgeons, the application of harmonic scalpel technology would provide further benefits, including less blood loss, shorter operative time, and better postoperative course. It is recommended to use this technique for axillary dissection when available at any surgical center. However, the economic cost should be taken into consideration.

Our study has some limitations, first of all, it is a single-center study that included a relatively small sample size. Also, intermediate-term and long-term follow-up should have been assessed. These points need to be well-covered in the upcoming studies.

Conclusion

Based on the previous findings, it appears that harmonic scalpel is more beneficial compared with

the conventional electrocautery technique. The former is associated with shorter operative time, less blood loss, less postoperative pain, less drainage discharge, and early drain removal.

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Conflicts of interest
There are no conflicts of interest.

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