Ultrasonic Shear Device versus Monopolar Electric Cautery in Conservative Breast Surgery Following Neoadjuvant Chemotherapy: A Comparative Study

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Abstract

Background: Surgical devices are commonly used during breast-conservative surgery (BCS) to provide better hemostasis. Ultrasonic shear has recently gained momentum as an effective tool for intraoperative bleeding reduction. This comparative study was designed to determine the efficacy of Harmonic focus in reducing postoperative complications of BCS following neoadjuvant chemotherapy (CTH), in comparison to the conventional method using monopolar diathermy.

Methods: We conducted a prospective, non-randomized, comparative, study on patients scheduled to undergo BCS with axillary dissection or sentinel lymph node biopsy after neoadjuvant CTH. Patients were recruited consecutively throughout the study period and were divided in an equal manner to undergo either monopolar electrocautery or Harmonic focus®.

Results: Patients in the Harmonic Focus group had significantly shorter operative time than the monopolar electrocautery group (101.32 ± 27.3 versus 139.3 ± 31.9 minutes, respectively; $p < 0.001$). Besides, the blood loss was significantly lower in the Harmonic Focus group (117.14 ± 35.6 versus 187 ± 49.8 mL, respectively; $p < 0.001$). Postoperatively, patients in the Harmonic Focus group had a significantly lower volume of chest wall drain ($p < 0.001$) and shorter time till drain removal ($p < 0.001$). Likewise, patients in the Harmonic Focus group had a significantly lower volume of axillary drain and shorter time till drain removal than monopolar electrocautery ($p < 0.001$). The incidence of postoperative complications was comparable between both groups ($p = 0.128$).

Conclusions: In conclusion, the current study confirms the superiority of Harmonic Focus, compared to monopolar electrocautery, amongst patients receiving neoadjuvant CTH before BCS.

Background:

Breast cancer (BC) is the most prevalent cancer type in women and takes pole position in cancer-related deaths as well(1). The latest release of the GLOBOCAN statistics in 2018 revealed that BC comprises 11.6% of total cancer cases and 6.6% of all cancer-related mortality(2). Prevalence rates in the Middle East are comparatively higher; where BC is involved in 27.7% to 38.2% of all reported tumors in the region(3). In Egypt, BC is again the apex of all cancers in women; causing 32.04% of cases(4) and 15% of deaths(5). Locally-advanced BC is a diverse group of tumors that encompasses inoperable or operable tumors without the presence of distant metastasis(6). Over the past few decades, breast conservative surgery (BCS) has emerged as a promising technique for patients wishing to preserve their breast, with comparable survival rates to conventional mastectomy(7); it is usually accompanied by axillary lymph node dissection owing to the high possibility of metastasis and the prognostic importance of histological examination of axillary lymph nodes(8).

Recent literature demonstrated that the use of BCS has increased in the setting of locally-advanced BC to reach up to 80% in some cohorts, especially after the use of neoadjuvant chemotherapy (CTH). Although it was originally proposed for inoperable, locally-advanced, BC, the use of neoadjuvant CTH in the setting

of earlier, operable, cases has been recently popularized by many centers(9). Neoadjuvant CTH has the potential of converting inoperable to operable cases, reducing tumor size before surgery, and evaluation of treatment response(10). While initial trials showed no survival benefits of neoadjuvant regimen over adjuvant CTH, the emergence of taxanes, and other novel agents, has dramatically improved the pathological response following neoadjuvant CTH and, hence, improved the clinical outcomes of the patients(11).

Despite being generally safe, BCS is not a complication-free procedure; the surgery can be complicated by postoperative wound infection, seroma, dehiscence, bleeding, as well as thromboembolic events(12). The utilization of neoadjuvant CTH can potentially increase the risk of postoperative complications, especially infection, owing to its associated neutropenia(13). Nonetheless, the impact of neoadjuvant chemotherapy on the postoperative complications of BCS is still controversial.

Surgical devices are commonly used during BCS to provide better hemostasis of small blood vessels, hence reducing the risk of bleeding and prolonged operation(14). Conventional electrocautery is a widely available, easy-to-use, and cheap method for blood vessel sealing during the surgery; however, the tool is limited by the induction of postoperative inflammatory reaction and wide burn area, which can increase the risk of postoperative seroma; besides, the excessive smoking from electrocautery may compromise the surgical field(15).

In a recent systematic review, electrocautery was associated with the highest incidence of postoperative seroma among surgical devices for BCS(16). Ultrasonic shear has recently gained momentum, mainly in the setting of laparoscopic surgery, as an effective tool for intraoperative bleeding reduction(17). In patients scheduled for BC surgery, the Ultrasonic shear has been investigated for reducing the incidence of postoperative seroma with equivocal results(18,19). This comparative study was designed to determine the efficacy of Harmonic focus in reducing postoperative complications of BCS following neoadjuvant CTH, in comparison to the conventional method using monopolar diathermy.

Methods:

Prior to the study's initiation and first patient enrollment, official approvals of the responsible ethics committee were gained (IRB No. 3128 and 124 respectively).

Study Design and Population:

We conducted a prospective, non-randomized, comparative through the period from January 2018 to December 2020: Adults (aged > 18 years old) who were scheduled to undergo BCS with axillary dissection or sentinel lymph node biopsy after neoadjuvant CTH were included. We excluded cases with a history of disease recurrence, radiation therapy, and those who refuse to sign the informed consent. Patients were recruited consecutively throughout the study period and were divided in an equal manner to undergo either monopolar electrocautery or Harmonic focus®.

Sample Size Calculation:

The sample size calculation is based on Bohm et al study. With the difference in proportions of overall seroma (20.4% vs. 5.8%), a predetermined 80% power of the study, and 95% level of confidence, the sample size was calculated to be 86 patients (43 patients for each technique) using the G*Power version 3.1.9.2.

Preoperative Data Collection and Surgical Techniques:

Data regarding demographic characteristics, body mass index (BMI), history of chronic disease, histopathological type of tumor, hormonal status, tumor size, tumor stage, neoadjuvant chemotherapy regimen, and radiological response were collected from all patients. All the patients enrolled in the study had metastatic workup in the form of a CT chest, abdomen, and pelvis with a bone scan when indicated; patients with metastatic disease were excluded from the study. With immunohistochemistry done for all patients, all patients received chemotherapy (AC for four cycles) followed by (Taxol four cycles) and Herceptin added to the patients with Her2neu overexpression. Clinical and radiological assessment of the response done every four cycles. The radiological response to neoadjuvant chemotherapy was assessed according to the Response Evaluation Criteria in Solid Tumors (RECIST v1.1).

All patients underwent the BCS according to the institution's standard protocols after NCTH. In the monopolar diathermy group, we utilized ErbeVio 300 D to dissect the skin flap, with wide local excision with a safety margin and, axillary dissection as indicated. In the Harmonic group, the Harmonic Focus was utilized for the wide local excision along with axillary dissection. The blood and lymphatic vessels were sealed using Harmonic Focus, without any attempts to use cautery or clips. In patients who underwent BCS, after identification of nerve supply, the Harmonic Focus was used to ligate veins and arterial supply of the resected segment of the breast, as well as dissection of axially lymph nodes and the surrounding blood vessels (**Fig.1**). Finally, two 16-F vacuum drains were allocated in the chest wall and axilla. The intraoperative blood loss was measured by calculating the weight of used sponges, with each gram corresponds to mL of blood loss.

Broad-spectrum antibiotics were prescribed for 12 hours after the operation. Postoperative pain was recorded until the end of the 7th postoperative day using a visual analog scale (VAS). The assessment of the surgical site for infection or necrosis was done until the patients' discharge. Patients were discharged with drains and were instructed to measure the daily amount of drain volume. The drains were removed within an average of five days after the operation. The patients were followed up on weekly basis for four weeks to assess the development of seroma.

Study's Endpoints:

The primary endpoint of the present study was the incidence of postoperative seroma and the means seroma cumulative volume 30 days after the surgery. The seroma was diagnosed by ultrasound (US) or subcutaneous aspiration-proven serious fluid beneath the skin flaps to the extent that causes the patient's

discomfort within one month after the operation. The secondary endpoints included intraoperative blood loss, operative time, amount of chest wall and axillary drain, days till chest wall and axillary drain removal, hospital stay, postoperative pain, and incidence of postoperative complications.

Statistical analysis:

The statistical data analysis was done using Microsoft® Excel® 2013 (15.0.4420.1017) 32-bit software. The mean ($\pm$ standard deviation [SD]) and frequencies were used to summarize continuous and categorical data, respectively. The hypothesis of the association between qualitative data was tested using Chi-square or Fisher's exact tests; while hypothesizing of the association between quantitative data was performed using Mann-Whitney tests. A p-value of less than 5% was used to reject the null hypothesis.

Results:

A total of 100 patients were divided into a 1:1 ratio to undergo Harmonic Focus or monopolar electrocautery. One patient in the Harmonic Focus was lost during the follow-up period, thus a total of 99 patients were included in the final dataset analysis. The mean age in the monopolar electrocautery and the Harmonic Focus groups was 49.51 ± 11.3 and 48.1 ± 11.1 years old, respectively ($p = 0.53$). There were no statistically significant differences between studied groups in terms of sex ($p = 0.51$), BMI ($p = 0.51$), smoking ($p = 0.78$), family history of BC ($p = 0.96$), history of other chronic diseases, histological types ($p = 0.32$), receptor status, tumor size, TNM stage ($p = 0.15$), chemotherapy regimens, and radiological response ($p = 0.72$; **Table 1**).

In terms of intraoperative characteristics, patients in the Harmonic Focus group had significantly shorter operative time than the monopolar electrocautery group (101.32 ± 27.3 versus 139.3 ± 31.9 minutes, respectively; $p < 0.001$). Besides, the blood loss was significantly lower in the Harmonic Focus group (117.14 ± 35.6 versus 187 ± 49.8 mL, respectively; $p < 0.001$). No significant differences were detected in other intraoperative characteristics (**Table 2**).

Postoperatively, patients in the Harmonic Focus group had a significantly lower volume of chest wall drain (86.83 ± 20.7 versus 147.5 ± 35.4 in monopolar electrocautery; $p < 0.001$) and shorter time till drain removal (2.551 ± 0.67 versus 4.12 ± 0.96 in monopolar electrocautery; $p < 0.001$). Likewise, patients in the Harmonic Focus group had a significantly lower volume of axillary drain and shorter time till drain removal than monopolar electrocautery ($p < 0.001$). The frequency of pain was lower in the Harmonic Focus group 72 hours after the procedure (4.1% versus 28%; $p = 0.007$). The incidence of postoperative complications was comparable between both groups ($p = 0.128$). The incidence of postoperative complications was comparable between both groups ($p = 0.128$). Two patients developed postoperative seroma in the Harmonic Focus group and three patients in the monopolar electrocautery group ($p = 0.63$; **Table 3**).

The association analysis showed that patients with seroma were more likely to have Her2-positive status (80% versus 36.1% in no seroma group; $p = 0.001$), advanced TNM stages ($p = 0.018$), and shorter days to chest drain removal (2.551 ± 0.67 versus 4.12 ± 0.96 days in no seroma group; $p = 0.046$). On the other hand, we found that there were no significant differences between patients with and without seroma regarding the type of neoadjuvant chemotherapy ($p = 0.42$), the number of cycles ($p = 0.49$), radiological response ($p = 0.43$), pre and post-chemotherapy tumor sizes, intraoperative blood loss ($p = 0.25$), operative time ($p = 0.21$), and postoperative characteristics ($p > 0.05$; **Table 4**).

The regression analysis showed that Her-2 positive status was an independent predictor of seroma development (OR = 11.72, 95% CI [1.1 – 128.6], $p = 0.046$; **Table 5**).

Discussion:

Neoadjuvant CTH has emerged as an effective modality in the setting of BCS, which has the advantages of downstaging tumor size before surgery and assessing treatment response. In return, neoadjuvant CTH can permit less-invasive surgery, better cosmetic outcomes, and fewer risks of postoperative lymphedema. An additional advantage of neoadjuvant CTH is its ability to aid intraoperative tumor recognition and reduce the possibility of extensive residual disease(10). On the other hand, the utilization of neoadjuvant CTH can potentially increase the risk of certain postoperative complications, especially infection, owing to its associated neutropenia(13); nonetheless, the impact of neoadjuvant CTH on postoperative complications of BCS is still controversial. Despite that the Ultrasonic shear is a well-established tool in various surgery, there is a controversy regarding its superiority over conventional methods in the setting of BCS. Moreover, no previous study has examined the superiority of Ultrasonic shear in patients receiving neoadjuvant CTH. In the present comparative study, we found that the use of the Harmonic Focus scalpel was associated with shorter operative time and less blood loss than conventional electrocautery. Moreover, patients in the Harmonic Focus group had a significantly lower volume of drain and shorter time till drain removal, compared to the monopolar electrocautery group; as well as less pain at the 3rd postoperative day. On the other hand, patients in the Harmonic Focus scalpel group had comparable rates of postoperative complications to patients in the monopolar electrocautery group.

Proper hemostatic control is critical intraoperatively to reduce blood loss, time of surgery, and, subsequently, postoperative morbidity and operative expenses. As mentioned before, conventional electrocautery is limited by excessive time for tissue dissection and wide thermal damage; which, in return, can result in excessive blood loss and prolonged operative time(20). The Ultrasonic shear works by dividing the tissues longitudinally through high-frequency ultrasonic waves, which takes potentially less time for tissue damage than conventional methods. Besides, the Ultrasonic shear produces a lower temperature than electrocautery, hence, less liability to excessive tissue damage and blood loss. Finally, the coagulating shears lead to the development of coagulum that effectively seals blood vessels(21). In the present comparative study, we demonstrated that the Ultrasonic shear had the advantage of less operative time and blood loss, compared to monopolar electrocautery, in the setting of BCS with

lymphadenectomy. Our findings are in line with recent systematic reviews indicating less amount of blood loss following Harmonic scalpel, compared to conventional methods(22,23); however, it should be noted that no previous studies are assessing Ultrasonic shear in the setting of neoadjuvant CTH.

Previous reports demonstrated that drainage volume and duration till drain removal are positively correlated with the risk of local infectious complications(24). In the present study, we demonstrated that the Ultrasonic shear led to lower drainage volume and shorter time till drain removal, compared to monopolar electrocautery. This was in agreement with a 2016 meta-analysis of 12 studies, which demonstrated lower drainage volume following Harmonic scalpel, compared to conventional electrocautery(22). In another two reports from China and Germany, Harmonic Focus significantly reduce the drainage volume and time until drain removal, compared to monopolar electrocautery, among women undergoing BCS(18). These findings are hypothesized to stem from the ability of the Ultrasonic shear to deal with lymphatic vessels with no re-opening again(25).

Postoperative seroma, a term used to describe an accumulation of serous fluid beneath the flap or in the axially dead space, is a common complication following BC surgery, with a reported incidence of 2-80% according to the nature of the procedures(26). Although seroma is not associated with a significant increase in mortality, it can trouble the postoperative course of the affected patients by increasing the risk of prolonged draining, infection, and reoperation, which, in return, can significantly delay adjuvant chemotherapy(26). Surgical techniques and devices are thought to significantly impact the risk of postoperative seroma. For example, electrocautery was found to be associated with the highest incidence of postoperative seroma among surgical devices for BC surgery(16). On the other hand, the Ultrasonic shear is thought to reduce the incidence of seroma through minimal tissue damage, proper hemostasis, and lower risk of flap necrosis, compared to other techniques. However, in the present study, we demonstrated that the rate of postoperative seroma was comparable between Ultrasonic shear and monopolar electrocautery. In concordance with our findings, Archana et al.(25), and Selvendran et al.(27), reported no significant difference between Ultrasonic shear and monopolar electrocautery regarding the incidence of post-BC surgery seroma. Similar findings were reported by other studies(28,29). Nonetheless, it should be noted that the current body of evidence shows conflicting results regarding the role of Ultrasonic shear in reducing the incidence of seroma as other reports demonstrated a significant reduction in seroma following Harmonic scalpel, as compared to monopolar electrocautery, in patients undergoing BC surgery(22,23). Such contradictory results can be explained by wide variations in patients' characteristics, type of surgery, surgeon's experience, the definition of seroma, and length of follow-up amongst the published studies. Further, a well-designed trial with multinational collaboration is warranted to investigate the impact of Ultrasonic shear on seroma prevention following BC surgery.

Older age, large tumor size, advanced tumor stage, and history of anticoagulants or tamoxifen are among the common patient-related risk factors for postoperative seroma(30). In our cohort, we found that Her-2 positive status was an independent predictor of seroma development; while patients with seroma were more likely to have advanced TNM stages and shorter days to chest drain removal. Our findings are in

line with previous reports indicating significant associations between hormonal status and the risk of postoperative seroma.

Conclusions:

the current study confirms the superiority of Harmonic Focus, compared to monopolar electrocautery, in many intra and postoperative parameters such as operative time, amount of blood loss, drainage volume, and length of drain placement amongst patients receiving neoadjuvant CTH before BCS. On the other hand, the present study found no significant difference between Harmonic Focus and monopolar electrocautery regarding the incidence of postoperative seroma and other complications. Nonetheless, Harmonic Focus is a feasible and safe technique, and it should be favored over conventional techniques in well-equipped centers. Further, a well-designed trial with multinational collaboration is warranted to investigate the impact of Ultrasonic shear on seroma prevention amongst patients receiving neoadjuvant CTH before BCS.

Abbreviations

BCS	breast-conservative surgery
CTH	chemotherapy
BC	Breast cancer
BMI	body mass index
RECIST	Response Evaluation Criteria in Solid Tumo
NCTH	Neoadjuvant chemotherapy
AC	Adriamycin, Cyclophosphamide
TT	Trastuzumab
T	Taxol
CT	Computed tomography
US	Ultrasound
OR	Odds ration
CR	Clinical response
DP	Disease persistent
SD	Stationary response
PR	Partial response

Declarations

- **Ethics approval and consent to participate:** Official approvals of the responsible ethics committee were gained from Suez Canal University Hospitals, National Cancer Institute of Egypt and Saudi German Hospital, Jeddah (IRB No. 3128 and 124 respectively).
- **Consent for publication:** Not applicable
- **Availability of data and materials:** Not applicable
- **Competing interests:** The authors declare that they have no competing interests
- **Funding:** authors declare that they have no funding
- **Authors' contributions:**
 - Study conception and design: IK, IS and HS
 - Acquisition of data: IK, HS, MF
 - Analysis and interpretation of data: IK, IS and MF
 - Drafting of manuscript: IK, IS and HS
 - Critical revision of manuscript: IK, IS, HS, MF.
- **All authors have read and approved the manuscript.**
- **Acknowledgment:** None

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Tables

Table 1: Preoperative data of the studied groups.

Variables	HF Group (n = 49)	CE Group (n = 50)	P value
Age (mean ± SD) Years	49.51 ± 11.3	48.1 ± 11.1	0.53
Females (No, %)	48 (98%)	48 (96%)	0.51
BMI (mean ± SD) Kg/m ²	30.65 ± 5.4	31 ± 6.5	0.78
Smoking (No, %)	7 (14.3%)	7 (14%)	0.96
Family history (No, %)	2 (4.1%)	2 (%)	0.98
DM (No, %)	13 (26.5%)	12 (14%)	0.77
HTN (No, %)	13 (26.5%)	12 (14%)	0.77
Others No, (%)	15 (30.6%)	21 (42%)	0.24
Histological Type (No, %)			
● Invasive duct carcinoma	41 (83.7%)	42 (84%)	0.32
● DCIS	4 (8.2%)	7 (14%)	
● Invasive lobular carcinoma	1 (2%)	0	
● Invasive micropapillary carcinoma	2 (4.1%)	0	
● Lobular Carcinoma.	1 (2%)	0	
● Medullary breast cancer	0	1 (2%)	
Receptors status (No, %)			
● ER positive	32 (65.3%)	37 (74%)	0.27
● PR positive	30 (61.2%)	31 (62%)	0.32
● Her2 positive	18 (36.7%)	20 (40%)	0.33
Pre-CTH tumor size (mean ± SD) Years	3.3 ± 0.6	3.2 ± 0.57	0.39
Post-CTH tumor size (mean ± SD) Years	1.6 ± 0.6	1.5 ± 0.58	0.13
Clinical Nodes (No, %)			
● 0	17 (34.7%)	31 (62%)	0.023
● 1	15 (30.6%)	10 (20%)	

●	2	17 (34.7%)	9 (18%)		
<i>TNM stage</i>					
●	I	3 (6.1%)	3 (6%)	0.15	
●	II	22 (44.9%)	28 (56%)		
●	III	29 (59.1%)	19 (38%)		
<i>Type of CTH</i>					0.17
●	AC+TT	6 (12.3%)	13 (26%)		
●	AC +T	43 (87.7%)	37 (74%)		
<i>No. of Cycles</i>					0.5
●	4 cycles	1 (2%)	1 (2%)		
		48 (98%)	2 (4%)		
●	6 cycles	0	47 (94%)		
●	8 cycles				
<i>Radiological Response</i>					
●	CR	5 (10.2%)	5 (10%)	0.72	
		2 (4.1%)	4 (8%)		
●	DP	4 (8.2%)	2 (4%)		
		38 (77.6%)	39 (78%)		
●	SD				
●	PR				

BMI: Body mass index; CTH: Chemotherapy; DM: Diabetes mellitus; HTN: Hypertension.

Table 2: Intraoperative data of the included patients

<i>Variables</i>	<i>HF Group (n = 49)</i>	<i>CE Group (n = 50)</i>	<i>P value</i>
<i>Duration of operation (mean ± SD) minutes</i>	101.32 ± 27.3	139.3 ± 31.9	0.001
<i>Blood loss (mean ± SD) mL</i>	117.14 ± 35.6	187 ± 49.8	0.001
<i>No, of total lymph node (mean ± SD)</i>	18.24 ± 4.7	17.46 ± 5.9	0.46
<i>No, of positive lymph node (mean ± SD)</i>	3.2 ± 4.4	2.8 ± 4.7	0.69
<i>pTNM (No, %)</i>			
● I	29 (59.2%)	39 (78%)	0.168
● II	6 (12.2%)	5 (10%)	
● III	14 (28.6%)	6 (12%)	

pTNM: pathological TNM

Table 3: Postoperative data of the included patients

<i>Variables</i>	<i>HF Group (n = 49)</i>	<i>CE Group (n = 50)</i>	<i>P value</i>
<i>Volume of chest wall drain (mean ± SD) mL</i>	86.83 ± 20.7	147.5 ± 35.4	0.001
<i>Days to chest wall drain removal, (mean ± SD)</i>	2.551 ± 0.67	4.12 ± 0.96	0.001
<i>Volume of axillary drain (mean ± SD) mL</i>	160.71 ± 32.2	283.5 ± 69.7	0.001
<i>Days to axillary drain removal, (mean ± SD)</i>	5.61 ± 1.8	9.74 ± 2.3	0.001
<i>Hospital stay, (mean ± SD), Days</i>	1.16 ± 0.37	2.28 ± 0.57	0.001
<i>Postoperative Complications (No, %) (excluding seroma)</i>			0.128
● Hematoma	1 (2%)	1 (2%)	
● Numbness	2 (4.1%)	1 (2%)	
● Shoulder stiffness	5 (10.2%)	2 (4%)	
● Wound infection	0	2 (4%)	
<i>Seroma (No, %)</i>	2 (4.1%)	3 (6%)	0.63
<i>Pain (No, %)</i>			
● 12 hours	20 (40.85%)	27 (54%)	0.48
● 24 hours	14 (28.6%)	19 (38%)	0.32
● 36 hours	2 (4.1%)	14 (28%)	0.007

Table 4: Comparison of patients with and without seroma

<i>Variables</i>	<i>Seroma (n = 5)</i>	<i>No Seroma (n = 94)</i>	<i>P value</i>
<i>Age (mean ± SD)</i> <i>Years</i>	51.6 ± 6.5	48.6 ± 11.4	0.56
<i>Females (No, %)</i>	5 (100%)	91 (96.8%)	0.89
<i>BMI (mean ± SD)</i> <i>Kg/m²</i>	30.8 ± 6.1	31.2 ± 5.2	0.89
<i>Smoking (No, %)</i>	0	14 (14.9%)	0.35
<i>Family history (No, %)</i>	1 (20%)	3 (3.2%)	0.07
<i>DM (No, %)</i>	1 (20%)	24 (25.5%)	0.78
<i>HTN (No, %)</i>	2 (40%)	23 (24.5%)	0.43
<i>Receptors status (No, %)</i> ● <i>Her2 positive</i>	4 (80%)	34 (36.1%)	0.001
<i>TNM stage</i> ● <i>I</i> ● <i>II</i> ● <i>III</i>	1 1 3	5 32 57	0.018
<i>Type of CTH</i> ● <i>AC+TT</i> ● <i>AC +T</i>	2 (20%) 3 (60%)	17 (18.1%) 77 (81.9%)	0.42
<i>No. of Cycles</i> ● <i>4 cycles</i> ● <i>6 cycles</i> ● <i>8 cycles</i>	0 0 5 (100%)	1 (1.1%) 3 (3.3%) 90 (95.7%)	0.49
<i>Radiological Response</i> ● <i>CR</i> ● <i>DP</i> ● <i>SD</i> ● <i>PR</i>	0 2 2 1	27 22 24 21	0.43

<i>Pre-CTH tumor size (mean ± SD)</i>	3.4 ±0.9	3.2 ±0.59	0.58
<i>Years</i>			
<i>Post-CTH tumor size (mean ± SD)</i>	2 ±0.7	1.6 ±0.6	0.17
<i>Years</i>			
<i>Duration of operation (mean ± SD) minutes</i>	101 ±28.9	121.5 ±35.3	0.21
<i>Blood loss (mean ± SD) mL</i>	180 ±39.1	150.9 ±56.1	0.25
<i>No, of total lymph node (mean ± SD)</i>	16.4 ±4.9	17.9 ±5.3	0.53
<i>Volume of chest wall drain (mean ± SD) mL</i>	90 ±28.2	118.9 ±42.2	0.13
<i>Days to chest wall drain removal, (mean ± SD)</i>	2.551 ± 0.67	4.12 ± 0.96	0.046
<i>Volume of axillary drain (mean ± SD) mL</i>	192 ±62.2	224.3 ±83	0.39
<i>Days to axillary drain removal, (mean ± SD)</i>	7.4 ± 1.5	7.7 ± 2.9	0.81
<i>Hospital stay, (mean ± SD), Days</i>	1.8 ±0.8	1.73 ±0.7	0.82

BMI: Body mass index; CTH: Chemotherapy; DM: Diabetes mellitus; HTN: Hypertension.

Table 5: Multiple logistic regression of predictors of postoperative complications

<i>Variables</i>	<i>Postoperative complications (excluding seroma)</i>			<i>Seroma</i>		
	<i>OR</i>	<i>95% CI</i>	<i>P value</i>	<i>OR</i>	<i>95% CI</i>	<i>P value</i>
<i>Her-2Positive</i>	1.338	(0.31 – 5.6)	0.69	11.721	(1.1 – 128.6)	0.044
<i>T4 stage</i>	0.177	(0.21 – 1.5)	0.115	2.532	(0.32-19.8)	0.37
<i>Days to chest wall drain removal > 3 days</i>	0.128	(0.015- 1.1)	0.06	0.272	(0.027 - 2.72)	0.26

Figures

Figure 1

A: Dissection of breast tissue using harmonic scalpel. B. After wide local excision of Lt breast mass C. Dissection of axilla using harmonic scalpel D. Post axillary dissection with harmonic scalpel