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Short Term Outcome of Management of Early Breast Cancer Patients in COVID-19 Era. Ain Shams University Experience

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ABSTRACT

Introduction: COVID-19 implied that a great number of infected individuals were hospitalized and possibly admitted to intensive care units. Cancer centers have rapidly changed models of care by delaying non-urgent surgeries. Breast surgeries were delayed for early breast cancer patients forcing clinicians to potentially alter treatment recommendations by neo-adjuvant chemotherapy until appropriate conditions were established. Aim of the work: to assess conservative breast cancer surgery after neo-adjuvant therapy in early breast cancer patients in COVID-19 era as regard surgical outcome, complications and early recurrence comparing results with previous results when patients underwent primary conservative breast surgery.

Patients and Methods: This is a cohort study that was conducted 52 patients with early breast cancer stage I and II a. Patients were divided into two groups (A) and (B). Group A included 26 patients who underwent primary conservative breast surgery. Group B included 26 patients who underwent conservative breast surgery after neo-adjuvant therapy during COVID-19 era.

Results: Intra-operative re-excision was done in 5 patients (19.2%) in group A and 3 patients (11.5%) in group B. Two patients (7.7%) in group A and 1 patient (3.8%) in group B were converted to modified radical mastectomy. Sentinel lymph node (SLN) was done in all 26 patients in group A while only 25 patients in group B with 1 patient undergoing axillary dissection from the start. SLN was positive in 8 patients (30.8%) in group A & 6 (24 %) patients in group B. Consequently, 8 patients (30.8%) in group A and 7 patients (26.9%) in group B underwent axillary dissection.

Conclusion: Conservative breast cancer surgery after neo-adjuvant therapy in early breast cancer patients in COVID-19 era has comparable results to primary conservative breast surgery. Thus, the obligatory decision to delay primary surgery during COVID-19 era by giving neoadjuvant chemotherapy was effective.

Key words: early breast cancer, COVID-19, neoadjuvant chemotherapy.

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INTRODUCTION

The transmission and progression of COVID-19 implied that a great number of infected individuals were hospitalized and possibly admitted to intensive care units (1). Cancer centers have rapidly changed models of care by delaying non-urgent surgeries, increasing home-based therapies, and expanding

telemedicine. Numerous organizations and institutions have issued general and disease-specific guidelines for cancer care (2). Breast surgeries were delayed for early breast cancer patients forcing clinicians to potentially alter treatment recommendations (3). Those patients were managed by neo-adjuvant chemotherapy and endocrine treatment until appropriate conditions were established (4). In the pandemic period, some priorities have also changed in the treatment of invasive breast cancer. ER+ early breast cancer patients should have neoadjuvant endocrine therapy during the COVID-19 pandemic. Triple negative and Her2 +ve breast cancer patients with T2 or larger tumor or LN involvement are candidates for neoadjuvant therapy, and there was no significant difference in the approach in these patients during the pandemic process. Patients with early breast cancer also encouraged to have neoadjuvant therapy before surgery during the COVID-19 pandemic (5).

Aim of the work

To assess conservative breast cancer surgery after neo-adjuvant therapy in early breast cancer patients in COVID-19 era as regard surgical outcome, complications and early recurrence comparing results with previous results when patients underwent primary conservative breast surgery before COVID-19 era.

PATIENTS AND METHODS

This is a cohort study that was conducted on patients with early breast cancer who underwent primary conservative breast surgery before COVID-19 era and those who underwent conservative breast surgery after neo-adjuvant therapy during COVID-19 era from March 2020 to October 2020.

The study included 52 patients with early breast cancer stage I and IIa. Patients were divided into two groups (A) and (B). Group A included 26 patients who underwent primary conservative breast surgery. Group B included 26 patients who underwent conservative breast surgery after neo-adjuvant therapy during COVID-19 era.

The study included any female patients with early breast cancer stages I and IIa. Exclusion criteria were any patient with a contraindication or refusal of breast conservative surgeries or radiotherapy, pregnancy and patients who refused to participate in the study. All patients were submitted to triple assessment including history and examination, bilateral sonomammography and core-needle biopsy, metastatic work up protocol including chest X-ray and pelvi-abdominal US.

US guided marking of the breast mass by titanium clips in patients who would receive neo-adjuvant chemotherapy (group B).

Multi-disciplinary team at the breast unit at General Surgery Department of Ain Shams University reviewed every single case independently.

The patients of group B repeated the bilateral sonomammography and metastatic work up after the neo-adjuvant therapy to assess the response of the tumor to the neo-adjuvant therapy and for detection of any new discovered metastasis.

Clinical response to neoadjuvant therapy was assessed at the end of the treatment. According to response evaluation criteria in solid tumors (RECIST) criteria, tumor size and lymph node size were assessed after chemotherapy.

- RECIST criteria utilized the following classifications for therapeutic response:
  1. Complete response (CR), primary tumor disappearance.
  2. Partial response (PR), 30% or greater decrease in longest diameter of primary tumor.
  3. Progressive disease (PD), 20% or greater increase in longest diameter of primary tumor
  4. Stable disease (SD), tumors that did not show either sufficient shrinkage to be classified as PR or sufficient increase to be classified as PD.

At the same day of operation, US guided wire localization (*fig. 1*) of impalpable breast mass, the wire was applied on the impalpable breast mass in patients of group A. In group B if the mass was not clinically felt, the wire was applied over the clip that was applied before neoadjuvant therapy.

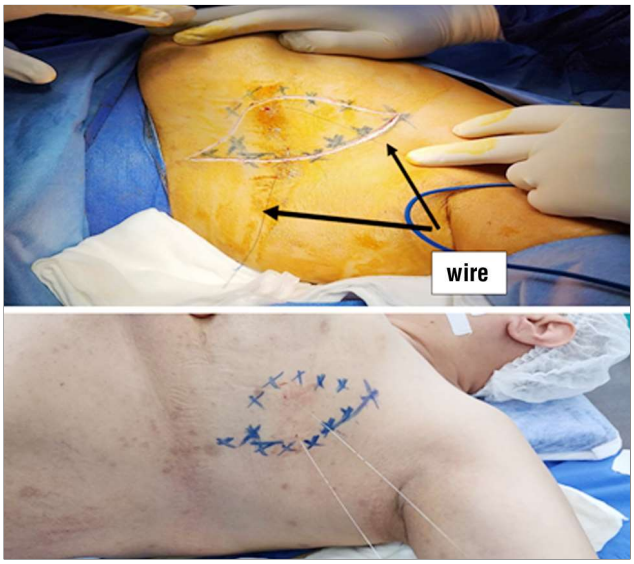

Figure 1 - Pre-operative wire localization of the breast mass

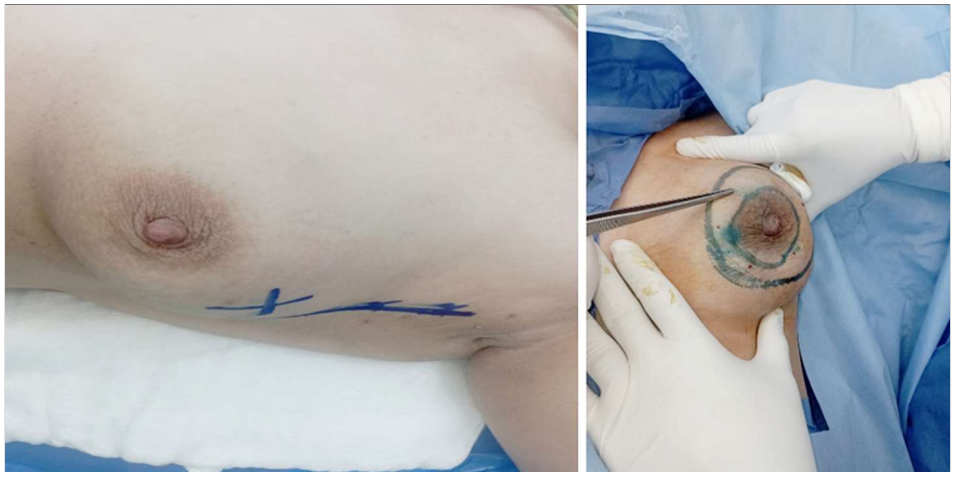

Figure 2 - Preoperative drawing

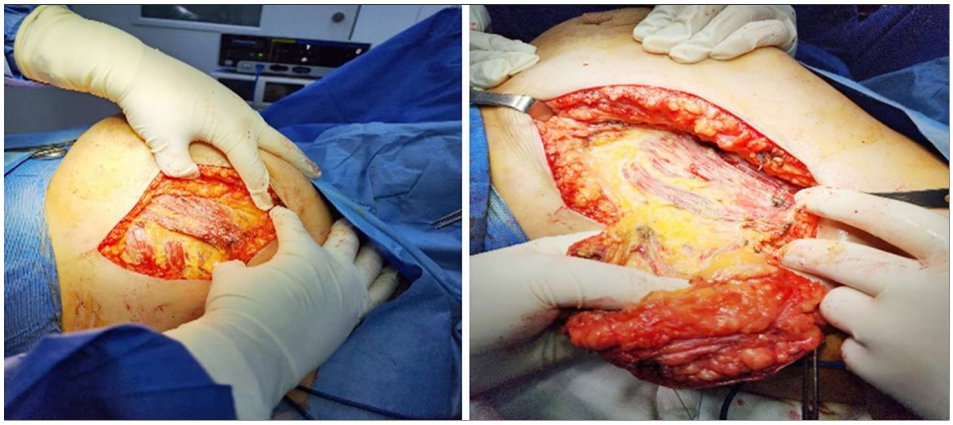

Figure 3 - Standard wide local excision

Operative technique

The patients were placed in the supine position with the arms abducted at 90° for axillary access, marking of the lump with an indelible marker on the skin (*fig. 2*). Injection of 2 cm of patent blue dye periareolar was then done. Massage of the areolar region for 10 minutes was done.

Standard wide local excision (*fig. 3*) was performed via an incision in a cosmetically pleasing location such as a peri-areolar, inframammary or circumareolar incisions. Some patients underwent a round block technique.

Excision of the lump with marking of the margins was done by a standard technique (*fig. 4*). The lump is then sent to intra-operative frozen section analyses to ensure obtaining microscopically tumor free margins.

Incision of the axilla was done and sentinel lymph node biopsy (at least 3 LN) was done guided by patent blue dye (*fig. 5*) and sent for frozen section. If one LN out of 3 SLN was positive for malignancy by frozen section, we would complete axillary clearance of level 1 and 2 in group B patients who received neo-adjuvant chemotherapy. If the 3 LN were negative, we would not proceed and closure of axilla was done.

The site of the resected tumor was marked by 4 titan clips at all margins for radiotherapy orientation to reduce radiation scattering.

Mobilization of the surrounding breast tissue around the defect was done and a few absorbable sutures were placed to approximate the cavity before closing the skin by 3-0 prolene subcuticular sutures (*fig. 6*).

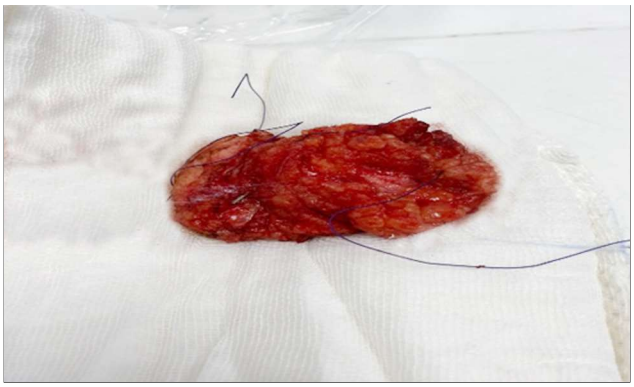

Figure 4 - Marking of the excised biopsy

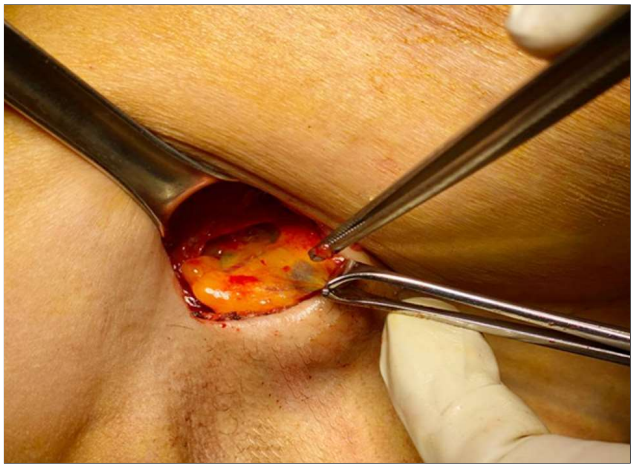

Figure 5 - Sentinel lymph node

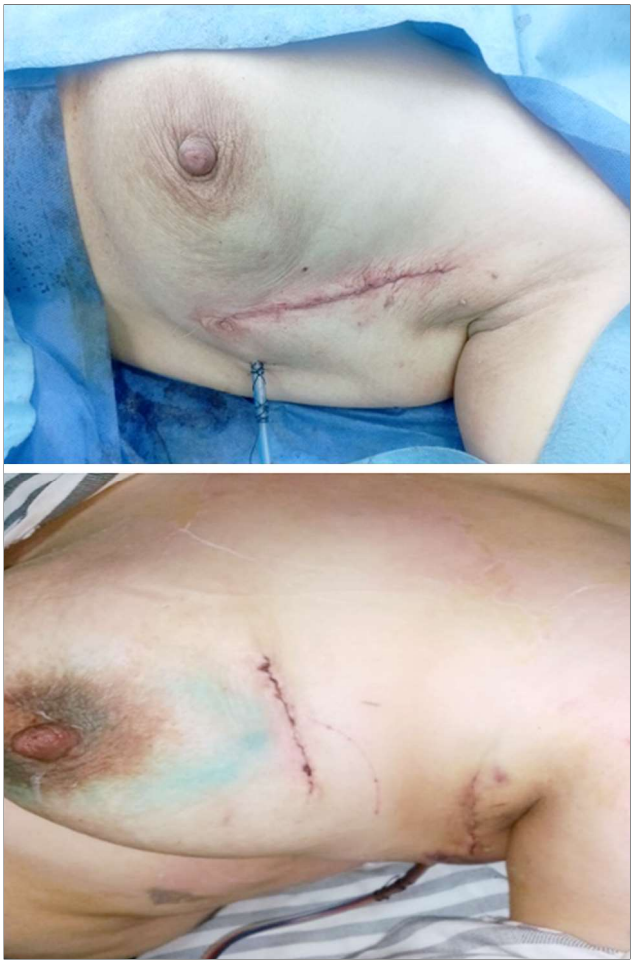

Figure 6 - Skin closure and suction drain

Post-operative management

All patients were discharged with a set of instruction and follow up schedule within twenty-four hours, unless staying for medical co-morbidities.

Patients were instructed to undergo arm and shoulder mobilization and a set of exercises to avoid stiffness of the should joint and decrease arm edema after axillary surgery and were advised to wear well-fitting sport bra.

Patients were given a follow up schedule upon discharge from the hospital as the following:

1. After 5-7 days for removal of breast and axillary drains.
2. After 10-14 days for stitches removal.
3. After the final pathology report is available, patients were referred to the oncology department to start their adjuvant radiotherapy and chemo-therapy.
4. Regular follow up schedule was given to the patients during 2 years' post-operative to discover any local recurrence or distant metastasis during this period.

RESULTS

Pre-operative parameters included patient characteristics and tumor characteristics.

Patient characteristics

The patients' demographics are summarized in *table 1*. They included age, medical comorbidities, BMI and breast size. The results showed no statistically significant differences between both groups.

Tumor characteristics

The Tumor characteristics are summarized in *table 2*. They included tumor size, stage, histological type. There was no statistically significant difference between results of both groups.

Response of the tumor to neo-adjuvant chemo-therapy (fig. 7)

- Clinical response was assessed at the end of the treatment using RECIST criteria and comparing data pre and post neoadjuvant therapy:
  a. RECIST criteria: tumor, size and lymph node size were assessed after chemotherapy. Six patients (about 23 % of group B patients) showed complete radiological response, while seven showed partial response and only one

Table 1 - Patients' parameters (age, BMI, medical comorbidities and breast size)

		Group A No. = 26		Group B No. = 26		Test value•	P-value	Sig.
Age	Mean ± SD	49.81 ± 10.75		49.73 ± 10.67		0.026	0.979	NS
	Range	28 – 65		25 – 66				
BMI	Mean ± SD	26.21 ± 3.05		26.27 ± 2.76		-0.074	0.941	NS
	Range	20.98 – 31.98		22.1 – 32.1				
		Group A		Group B		Test value*	P-value	Sig.
		No.	%	No.	%			
Co-morbidities	No	19	73.1%	17	65.4%	0.361	0.548	NS
	Yes	7	26.9%	9	34.6%			
HTN		3	11.5%	4	15.4%	0.165	0.685	NS
DM		3	11.5%	4	15.4%	0.165	0.685	NS
IHD		1	3.8%	2	7.7%	0.354	0.552	NS
		Group A		Group B		Test value*	P-value	Sig.
		No.	%	No.	%			
Breast size								
C		1	3.8%	3	11.5%	2.710	0.607	NS
D		1	3.8%	2	7.7%			
E		8	30.8%	4	15.4%			
F		11	42.3%	12	46.2%			
G		5	19.2%	5	19.2%			

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*:Chi-square test

Table 2 - Pathologic characteristics of the tumors in both groups

		Group A No. = 26		Group B No. = 26		Test value•	P-value	Sig.
Tumor size (cm)	Mean±SD	2.59 ± 1.00		2.30 ± 0.96		1.076•	0.287	NS
	Range	1.2 – 4.5		1 – 4.3				
Tumor stage	T0	0 (0.0%)		0 (0.0%)		0.315*	0.575	NS
	T1	10 (38.5%)		12 (46.2%)				
	T2	16 (61.5%)		14 (53.8%)				
		Group A		Group B		Test value*	P-value	Sig.
		No.	%	No.	%			
Histological type	IDC	23	88.5%	22	84.6%	0.165	0.685	NS
	ILC	3	11.5%	4	15.4%			
ER	No	8	30.8%	6	23.1%	0.391	0.532	NS
	Yes	18	69.2%	20	76.9%			
PR	No	11	42.3%	12	46.2%	0.078	0.780	NS
	Yes	15	57.7%	14	53.8%			
HER2-neu	No	20	76.9%	22	84.6%	0.495	0.482	NS
	Yes	6	23.1%	4	15.4%			
		Group A No. = 26		Group B No. = 26		Test value•	P-value	Sig.
Tumor grading	Grade 1	4 (15.4%)		5 (19.2%)		0.937*	0.626	NS
	Grade 2	14 (53.8%)		16 (61.5%)				
	Grade 3	8 (30.8%)		5 (19.2%)				
Molecular subtype	Luminal A	13 (50%)		14 (53.8%)		0.7946	0.851	NS
	Luminal B	5 (19.2 %)		6 (23.1%)				
	HER2-neu positive	4 (15.4%)		4 (15.4%)				
	Triple negative	4 (15.4%)		2 (7.7%)				
Lymph node status	N0	26 (100.0%)		26 (100.0%)		NA	NA	NA
Distant metastasis	M0	26 (100.0%)		26 (100.0%)		NA	NA	NA

P-value >0.05: Non-significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test; ‡: Independent t-test

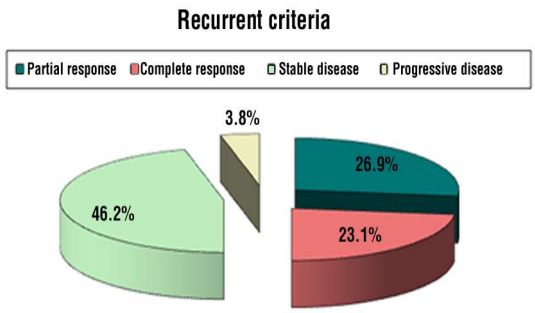

Figure 7 - Group B clinical response according to RECIST criteria post neo-adjuvant chemotherapy

showed progressive course. The rest had a stationary course.

b. Comparing the tumor size, lymph node status and metastasis before and after neo-adjuvant chemotherapy in group (B) patients (*table 3*).

The mean tumor size decreased from 2.30 cm to 1.59 cm. Before neo-adjuvant chemotherapy 12 patients was at T1 stage and rest was T2 stage. There was a noticeable shift after neo-adjuvant chemotherapy with 14 patients were T1, only six were T2 and six patients showed complete radiological response (T0). So, there were highly significant differences in tumor size after neo-adjuvant chemotherapy.

The patient who showed progressive course had developed positive axillary lymph nodes with no significant difference on the results. Neither of the patients were metastatic after neo-adjuvant therapy period.

Comparing the tumor size, lymph node status and metastasis between group (A) & group (B) after neo-adjuvant chemotherapy (table 4)

Before neo-adjuvant chemotherapy, there was no significant difference between group A& B as regard tumor size, lymph node status and metastasis. However, after neo-adjuvant therapy, the tumor size and stage decreased with a highly significant difference between both groups.

Table 3 - Tumor stage, lymph node status and metastasis before and after neo-adjuvant chemotherapy in group (B) patients

Group B		Pre neo-adjuvant chemotherapy	Post neo-adjuvant chemotherapy	Test value	P-value	Sig.
		No. = 26	No. = 26			
T size (cm)	Mean±SD Range	2.30 ± 0.96 1 – 4.3	1.59 ± 1.14 0 – 4	-4.020•	0.000	HS
T stage	T0 T1 T2	0 (0.0%) 12 (46.2%) 14 (53.8%)	6 (23.1%) 14 (53.8%) 6 (23.1%)	9.354*	0.009	HS
Lymph node status	N0 N1	26 (100.0%) 0 (0.0%)	25 (96.2%) 1 (3.8%)	1.020*	0.313	NS
Distant metastasis	M0	26 (100.0%)	26 (100.0%)	NA	NA	NA

P-value >0.05: Non-significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test; •: Paired t-test

Table 4 - Tumor stage, lymph node status and metastasis in group (A) & group (B) after neo-adjuvant chemotherapy

		Group A	Group B post neo-adjuvant chemotherapy	Test value	P-value	Sig.
		No. = 26	No. = 26			
T Size	Mean±SD Range	2.59 ± 1.00 1.2 – 4.5	1.59 ± 1.14 0 – 4	3.354•	0.002	HS
T Stage	T0 T1 T2	0 (0.0%) 10 (38.5%) 16 (61.5%)	6 (23.1%) 14 (53.8%) 6 (23.1%)	11.212*	0.004	HS
N Stage	N0 N1	26 (100.0%) 0 (0.0%)	25 (96.2%) 1 (3.8%)	1.020*	0.313	NS
Distant metastasis	M0	26 (100.0%)	26 (100.0%)	NA	NA	NA

P-value >0.05: Non-significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
* Chi-square test; •: Independent t-test

Operative evaluation

The operative time, intra-operative blood loss and intra-operative re-excision and conversion to modified radical mastectomy and axillary dissection were assessed (*table 5*). The results were statistically non-significant between both groups.

Intra-operative re-excision was done in 5 patients (19.2%) in group A and 3 patients (11.5%) in group B. Re-excision of the affected margins was done and free margins was confirmed by frozen section in 3 patients in group A and 2 patients in group B. Two patients (7.7%) in group A and 1 patient (3.8%) in group B were converted to modified radical mastectomy because of failure to achieve free margins. These data are summarized in *table 6*. The results showed no statistically significant differences between both groups.

Sentinel lymph node (SLN) frozen section result and conversion to axillary dissection

SLN was done to all the population of the study except one of group B triple negative cancer breast patient who showed progressive course after neo-adjuvant chemotherapy in the form of mass progression from 17 mm (T1) to 35 mm (T2) and appearance of two enlarged axillary lymph nodes that was suspicious by ultrasound, so level 1&2 axillary lymph nodes dissection was decided for this patient from the start.

SLN was positive in 8 patients (30.8%) in group A & 6 (24 %) patients in group B (*table 7*). Axillary dissection was done in those patients. Consequently, 8 patients (30.8%) in group A and 7 patients (26.9%) in group B underwent axillary dissection. The results were statistically non-significant between both groups.

Post-operative management

Post-operative hospital stay, complications and early local recurrence were assessed. Most of the patients were discharged within 24 hours post-operative (*table 8*) except 3 patients (1 from group A and 2 from group B) who had a past history of IHD. They were discharged after 48 hours' post-operative, as they

Table 5 - Operative time of the study

		Group A No. = 26	Group B No. = 26	Test value•	P-value	Sig.
Operative time (min)	Mean ± SD	101.00 ± 10.04	100.54 ± 10.61	0.161•	0.873	NS
	Range	85 – 119	82 – 120			

P-value > 0.05: Non-significant (NS); P-value < 0.05: Significant (S); P-value < 0.01: highly significant (HS)
•: Independent t-test; ‡: Mann Whitney test

Table 6 - Intra-operative re-excision and conversion to modified radical mastectomy after frozen section result in both groups

		Group A		Group B		Test value*	P-value	Sig.
		No.	%	No.	%			
Intra-operative re-excision	No	21	80.8%	23	88.5%	0.591	0.442	NS
	Yes	5	19.2%	3	11.5%			
Conversion to MRM	No	24	92.3%	25	96.2%	0.354	0.552	NS
	Yes	2	7.7%	1	3.8%			

P-value > 0.05: Non-significant (NS); P-value < 0.05: Significant (S); P-value < 0.01: highly significant (HS)
*: Chi-square test

Table 7 - SLN frozen section results and axillary clearance in both groups

		Group A		Group B		Test value*	P-value	Sig.
		No.	%	No.	%			
SIN frozen section resuls	Negative	18	69.2%	19	76 %	0.293	0.59	NS
	Positive	8	30.8%	6	24 %			
Axillary dissection	Yes	8	30.8%	7	26.9%	0.094	0.76	NS
	No	18	69.2%	19	73.1%			

P-value >0.05: Non-significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test

Table 8 - The median post-operative hospital stay

		Group A No. = 26	Group B No. = 26	Test value•	P-value	Sig.
Post-operative stay (in hours)	Median (IQR)	6 (6 - 12)	6 (6 - 12)	-0.606‡	0.544	NS
	Range	6 – 48	6 – 48			

P-value >0.05: Non-significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
•: Independent t-test; ‡: Mann Whitney test

needed postoperative ICU admission for monitoring for 24 hours as recommended by anesthesia team.

During the follow up period, one patient in group A developed hematoma formation and was managed conservatively. No recorded post-operative complications occurred in group B patients (*table 9*). Other known complications like are edema, hypertrophic scar, keloid, surgical site infection and flap necrosis did not occur. None of our patients had any local recurrence neither breast nor axillary during the postoperative 2 years follow up.

DISCUSSION

During COVID 19 pandemic, because of heavy load of affected patients who needed hospitalization or admission to intensive care units, early breast cancer management protocol was converted from primary surgical intervention to neo-adjuvant chemotherapy not in particular but as a part of national plan to free up hospital beds and vital hospital supplies for individuals infected by COVID-19 and to decrease the risk for the admitted patients of getting infection (6).

In the present study, the mean age of patients was 49.81 ± 10.75 years and 49.73 ± 10.67 years for groups A and B respectively. This is consistent a study published by Amin (7) in 2016, which revealed that the peak of incidence rates for breast cancer in Egypt lied between 50-60 years old, and their mean age was 50.6 years old.

The use neoadjuvant chemotherapy (NACT) in early breast cancer in group B showed the overall clinical response rate was 50%. Six patients (23.1%) showed complete clinical and radiological response and eight patients (26.9%) showed partial response). Out of the 6 patients who had complete clinical response (cCR), 3 patients (50% of patients with cCR and 11.5% of group B) had pathological complete response (pCR), and the other 3 patients (50% of patients with cCR and 11.5% of group B) had residual disease histologically. These results are comparable to other studies since clinical evidence of complete regression does not imply the presence of pathological complete response. A residual tumor is detected in approximately 30%–50% of patients with clinico-radiologic complete response (8).

In a meta-analysis done by Criscitiello et al (9) in 2018 that included 16 studies, done on 12311 patients with early breast cancer who received neo-adjuvant systemic therapy, the average pathological complete response across all these studies was 24% and ranged from 3–60% across studies. In our study, intra-operative re-excision after frozen section was done in 5 patients (19.2%) in group A and 3 patients (11.5%) in group B. These results are comparable with other studies. Heeg et al (10) study on 13185 patients who underwent primary BCS showed that the re-excision rate was 15.6 % (2057 patients). Kaczmarski et al (11) study on 291,065 female patient who underwent a primary BCT procedure, showed that the overall re-excision rate was 19.0%.

The rate of conversion of conservative breast surgery to modified radical mastectomy in this study was 7.7% (2 patients) and 3.8% (1 patient) in group A and group B respectively. The re-excision rate in Heeg et al (10) study was 3.7% among patients who underwent primary BCS.

Table 9 - Postoperative complications in the study

		Group A		Group B		Test value*	P-value	Sig.
		No.	%	No.	%			
Post-operative complications (hematoma)	No	25	96.2%	26	100.0%	1.020	0.313	NS
	Yes	1	3.8%	0	0.0%			

P-value >0.05: Non-significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*:Chi-square test

According to ACOSOG Z0011 trial, women with T1 or T2 invasive primary breast cancer, no palpable axillary adenopathy, and 1 or 2 sentinel lymph nodes containing metastases, no need for further axillary lymph node dissection. However, these conclusions apply only to patients meeting ACOSOG Z0011 eligibility criteria and should not be applied to the patients receiving neoadjuvant therapy (12). So, in patients who received neo-adjuvant chemotherapy, axillary lymph node dissection was done if one LN out of 3 SLN was positive for malignancy by frozen section.

SLN was positive in 8 patients (30.8 %) in group A & 6 patients (24 %) in group B. These results are comparable to Olivier et al (13) study that included 456 patients with early breast cancer where infiltrated sentinel lymph nodes were detected in 149 patients (32.7%).

Post-operative complications in the form of hematoma formation occurred only in one patient from group A (3.8 %). This patient was managed conservatively. There were no recorded complications in group B patients. None of the patients of the present study had any malignant recurrence neither locoregional in the breast and axillary lymph nodes nor systemic metastasis during the 2 years follow up proving that both protocols were applied safely from oncological point of view. Wimmer et al (14) suggested that resection in new margins after neo-adjuvant chemotherapy is safe according to "no tumor on ink". This study is a small study that was done on only 52 patients with no long term follow up for loco-regional recurrence for further studies to confirm our results.

CONCLUSION

Conservative breast cancer surgery after neo-adjuvant therapy in early breast cancer patients in COVID-19 era has comparable results to primary conservative breast surgery as regard surgical outcome, post-operative complications and early local recurrence. Thus, the decision to delay primary surgery during COVID-19 era by giving neoadjuvant chemotherapy was effective.

Conflicts of interest and source of funding:
None declared.

All authors confirm that they have met the criteria for authorship as established by the International Committee of Medical Journal Editors.

Ethical statement

This study was conducted at general surgery department, Ain Shams university hospitals. Approval of the Ethical Committee and written informed consent from all participants were obtained.

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