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The Level of Axillary Clearance in Breast Conserving Surgery for Breast Cancer Treatment

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Abstract: Background: Breast cancer is the most common cancer in women and is the leading cancer death in women aged 20 to 59 years. Mastectomy and breast conserving surgery (BCS) are the major elements for treating such conditions, beside lymph node dissection (lymphadenectomy) at different axillary levels with other treatment like chemotherapy, radio therapy and hormonal therapy.

Objectives: The feasibility of minimizing axillary dissection in the treatment of breast cancer with an optimal oncological outcome and low mortality.

Methods: A prospective analytic study was adopted over a period of twelve months from March the 1st, 2021 till March the 1st, 2022.Then patients were observed after surgery till October the 1st ,2022. Data was collected from patients who were diagnosed to have breast cancer and treated at Imam Al-Hussein medical city, Safeer Al-Imam Al-Hussein hospital and Al-Kafeel hospital in Karbala, Iraq. The prognostic factor was the number of positive lymph nodes that are removed at each level and their correlation to other study variables.

Results: the mean age of the study group was 53.2 years, and the number of cases collected were 70. Thirty nine patients had mastectomy and 31 had breast conserving surgery. Most of the patients were at stage II of the disease identified during surgery and the axillary lymph nodes dissection were performed at different levels. The number of positive lymph nodes after axillary dissection was not related to the level of axillary dissection.

Conclusions: level I axillary dissection (limited axillary lymph nodes dissection) is recommended in the treatment of early breast cancer with synergistic effect of neoadjuvant chemoradiotherapy, since the number of positive lymph nodes are not increased with extensive axillary dissection, further dissection is recommended when there are multiple masses, higher stage or grade of the disease and or big mass larger than 5cm.

Keywords: Breast cancer, axillary dissection, level of axillary dissection, early breast cancer, partial axillary clearance.

Introduction: The breast is the protuberant part of the human, breast is generally described as overlying the second to the sixth ribs and extended from the lateral border of the sternum to the anterior axillary line, blood supply is from the perforating branches of mammary artery, lateral branches of posterior intercostal arteries, and branches from axillary artery. And the venous drainage follow the arteries in their course (1).

The lymphatics of the breast drain predominantly into the axillary lymph nodes about 85% and internal mammary lymph nodes approximately 15% which predominantly drain from the tumor located in the posterior one third of breast (2).

Breast cancer is the most common site-specific cancer in women and is the leading cause of death from cancer for women age 20 to 59 years after lung cancer. Based on surveillance, Epidemiology, and End Results

registries (SEER) data, 266,120 new cases were estimated in 2018 with 40,920 estimated deaths attributed to breast cancers(3) (4).

It accounts for 30%of all newly diagnosed cancers in women and is responsible for 14% of the cancer-related deaths. In England and Wales, 1 in 12 women and 1in 8 women in US will develop the disease during their lifetime. And the incidence increase in the percentage with increase age, older or equal to 59 years (5).

Sociodemographic index levels are significant determinants of breast cancer incidence and mortality (6) .However, breast cancer mortality remains high due to limitations in early diagnosis and treatment options (7).

In recent decades, the standard axillary management of early-stage breast cancer has changed dramatically. Axillary lymph node dissection (ALND) has been replaced by sentinel lymph node dissection (SLND) for the treatment of clinically negative lymph node breast cancer (8).

The American College of Surgeons Oncology Group (ACOSOG) Z0011 was a milestone in the surgical treatment of the axilla in patients with early breast cancer, and it significantly contributed to reducing the extent of breast surgery (9, 10).

Consequently, the omission of ALND resulted in reduced morbidity and improved quality of life (11).

Aim of study

Determining the extent of axillary dissection with optimal oncological outcome in the treatment of breast cancer.

Methods

a prospective analytic study that was conducted at Imam Al-Hussein medical city, Safeer Al-Imam Al-Hussein hospital and Al-Kafeel hospital in Karbala, Iraq, over a period of twelve months from March the 1st ,2021 to March the 1st ,2022. Then patients were observed after surgery till October the 1st ,2022.

During this period a total of 70 female patients with breast cancer enrolled in this study, their age is ranging between 30 year and 75 year old with primary invasive and noninvasive breast cancer with negative and or positive axillary lymph nodes. Verbal informed consent was obtained from all patients included in this clinical study to collect their personal data and follow up.

Some of patients undergo mastectomy with complete axillary dissection while other had breast conserving surgery with axillary dissection, the level of the axillary dissection was determined by the senior surgeon decision, during surgical intervention by different surgeons, the removed lymph nodes are then sent to the histopathology analysis gathered from multilaboratories according to the World Health Organization Classification of Breast Cancer. According to the M.D.T decision surgery was done for most cases, while in other cases the surgery is done depending on the surgeon,s opinion, these factors have a collective effect on the impact result of this study.

Related demographic date for each patient was recorded prior to surgery including the chief complaint that lead the patient to the initial seek of medical care and the associated other complaints and investigations that lead to the diagnosis of breast cancer.

Age, number of pregnancies, family history of breast cancer, history of previous surgeries and history of other treatment for breast cancer including chemotherapy , radiotherapy and hormonal therapy.

The weight of each patient was measured prior to surgery with their heights to calculate the body mass index (BMI= Weight in Kg/square the Height in meters).

The contained data involved include staging, histological subtype, grading, level of axillary dissection, number of lymph node excised from axilla and either positive or negative all the data were filled for each case according to a written questionnaire and the patients were followed till the hospital discharge and the appearance of the histopathological results and for nearly three to four months after surgery.

The patient were prepared to surgery after admission to hospital including triple assessment, metastatic work up and base line investigations were done including (complete blood count, virology screen, ECG, renal functions test and liver functions tests) and fitness for general anesthesia and surgery was established after controlling any existing medical conditions like diabetes and hypertension, all patients agreed to surgery and signed a written consent.

Under general anesthesia the patient is placed in supine position with the relative arm abducted to 90 degrees and a sandbag or a folded bed sheet is placed under the thorax and shoulder of the affected side in some patients, skin was sterilized, opened ,tumor and the required lymph nodes are removed, the wound is cleaned with normal saline after establishing hemostasis and a drain is inserted (redivac drain) in the site and exit from a separated small incision, wound is then closed in layers.

Inclusion criteria

Patients who were diagnosed clinically, radiologically and histologically to have primary invasive or non-invasive breast cancer and undergo mastectomy or breast conserving surgery with axillary dissection.

Exclusion criteria

1. Patients with recurrent breast cancer.
2. Patients with distant metastasis.
3. Patients with secondary breast cancer that have breast metastasis from other sites.
4. Patients with bilateral breast cancer.
5. Patients unfit for surgery.
6. Incomplete follow up.

Statistical analysis

Analysis of data was carried out using the available statistical package of SPSS-27 for windows, data were presented in simple measures of frequency, percentage, mean and standard deviation (12). The significance of difference of different means (quantitative data) were tested using Students-t-test for difference between two independent means or Paired-t-test for difference of paired observations (or two dependent means), Pearson correlation (two tailed) was calculated for the correlation between two quantitative variables, the correlation coefficient value (r) was either positive (direct correlation) or negative (inverse correlation), Statistical significance was considered whenever the P value was equal or less than 0.05 (13)

Results

The study sample include 70 patients with a mean age of (53.2) years and a standard deviation of (10.7) years. As show in table 1. Which show the peak of age is 50 to 59 year at presentation.

Mass was the most common chief complaint that brought attention of the patients to seek medical care 46 (65.7 %), of the patients complained the feeling of a lump in the breast, 23 (32.8 %) were in pain, 19 patients (27.1 %) had a bloody discharge from the nipple, while 30 patients (42.8 %) had nipple retraction, beside their chief complaints 15 patients (21.4 %) were discovered to have a breast mass through screening at the breast clinic in Imam Al-Hussein medical city and two patients (2.8 %) were discovered incidentally while seeking medical care for another complaint.

Most of the patients 60 (85.7%) have a BMI of less than 30 kg/m2, 10 patients (14.3 %) have a BMI of 30-40 kg/m2.

Five patients (7%) are not married or never been pregnant, 42 patients (60%) have a gravida of 1-3, 21 patients (30%) have had 4-7 pregnancies and only 2 patients (3%) have 8-10 previous pregnancies.

Forty two patients (60%) have a positive family history of breast cancer, 28 patients (40%) reported a negative family history.

The demographic variables of the study sample are illustrated in (table 1).

Variable		N (%)
Age (years)	<30	0
	30-39	11 (15.7)%
	40-49	11 (15.7)%
	50-59	24 (34.3)%
	60-69	21 (30)%
	> 70	3 (4.3)%
Chief complaint	Mass	46 (65.7%)
	Painful mass	23 (32.8 %)
	Nipple retraction	30 (42.8 %)
	Screening	15 (21.4 %)
	Incidental	2 (2.8 %)

	Bloody discharge	19(27.3%)
BMI (kg/m2)	<30	60 (85.7 %)
	31-40	10 (14.3 %)
	>40	0
Number of pregnancies	Null	5 (7%)
	1_3	42 (60%)
	4_7	21 (30%)
	8_10	2 (3%)
Family history of breast cancer	Positive	42 (60%)
	Negative	28 (40%)

Ultrasound was done for all the patients (100%), 63 patients (90%) had mammography, MRI was done for 25 patients (35%) ,CT scan for 67 patients (96%), FNA for only 10 patients (14%) and true cut biopsy was done for 65 patients (93%) and excisional biopsy done for 5 patients (7.1%).

Most of the patients had a single mass (61 patients) (87%), 41(67.2%) of them had a single mass of less than 2cm in diameter, 17(27.8%) between 3-5 cm and 3 (8.1%) larger than 5 cm in diameter.

Six patients (9%) had two masses, 3 of them had two masses that the largest was less than 2 cm in diameter, 2 had two masses were the largest was 3-5cm in diameter and 1 patient had two masses were the largest was above 5cm in diameter.

Three patients (4%) had three masses, the size of the largest mass was less than 2cm in one patient, between 3-5cm in one patient and larger than 5 in the last patient as in table 2.

Staging according to Manchester staging system placed half of the patients (35 patients) in stage II of the disease, 30 patients (43%) were in stage I and 5patients (7%) in stage III, none of the patients was in advanced stage IV of the disease (within exclusion criteria).

The results of histopathological examination types as follow the commonest type is IDC 38(54.2% patients) while only 6(8.5%) had DC insito, the other common type is ILC 19(27%) while the LC insito 7(10%).

Ten patients (14%) had grade 1 disease, the most common grade was the second with 44 patients (63 %), followed by the third 16 (23 %).

Regarding the types of treatment for breast cancer, 45 patients (64.2%) were on neoadjuvant chemotherapy before surgery, 25 patients (35.7%) on adjuvant chemotherapy,53 patients (75.7%) had radiotherapy and 5 (7.1%) was on hormonal therapy postsurgery.

Mastectomy done for 39 patients and BCS done for 31 patient with axillary dissection for all of them, 25 had negative-node axilla and 45 had positive-node axilla in different levels of dissection which showed 38 patient had positive axillary LN less than 5 in number and only 7 patient had positive LN more than 5 in each patient and those 7 patients all had either multiple masses or mass larger than 5 cm.

Also we noted the number of lymph nodes dissected from each patient in each level as follow, level I ranging from 8 to 12 LN ,level II from 13 to 18 LN and level III more than 19 LN.

In this study we noted that the number of malignant LN dissected from axilla of those patients didn't increase with aggressive axillary dissection (by increasing the level of axillary dissection), study variables regarding the type of surgery as demonstrated in figure 1.

Figure 1: Type of surgery that was done on the study sample.

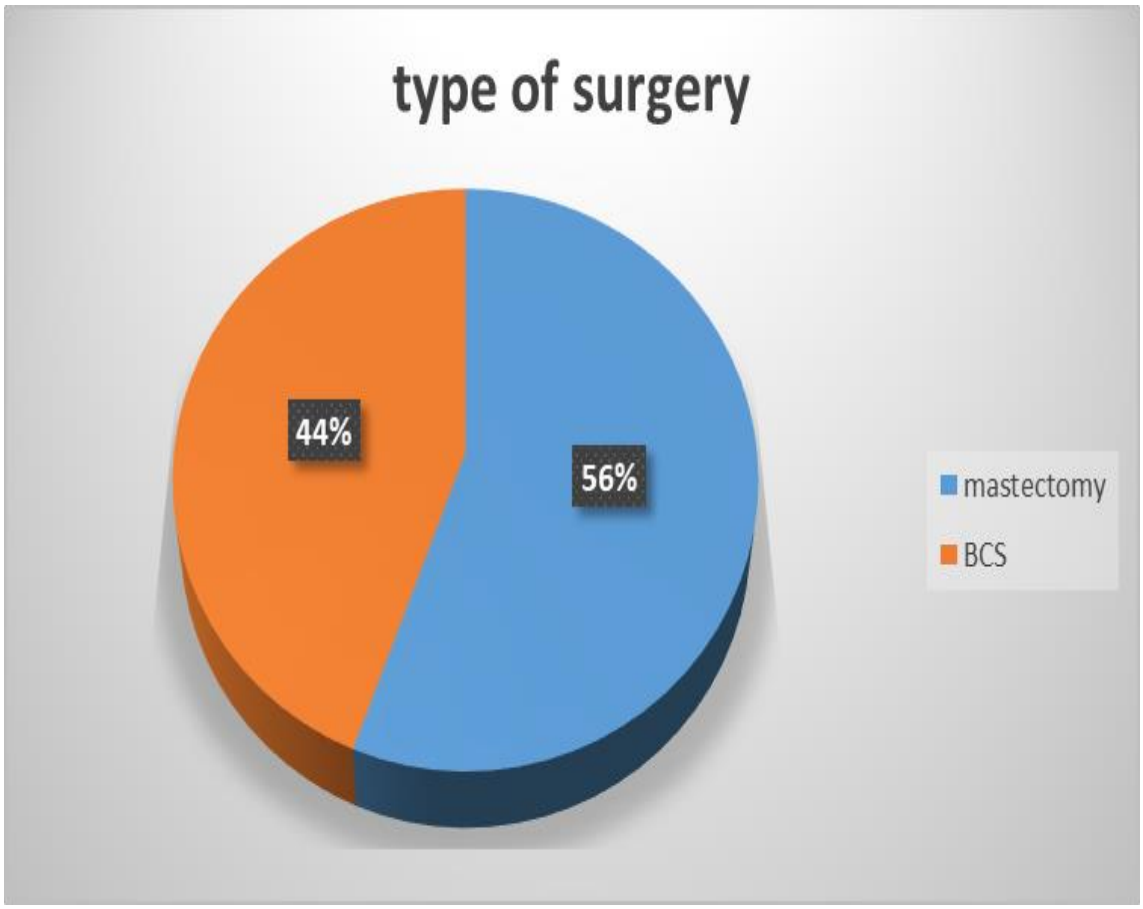

Table 2: Variables for investigations, No. of masses, staging, grading, HPE, types of treatment and types of surgery.

Variable		no		%	
Performed investigations	ultrasound	70		100%	
	mammography	63		90%	
	CT scan	67		96%	
	MRI	25		35%	
	FNA	10		14%	
	True cut biopsy	65		93%	
	Excisional biopsy	5		7.1%	
Variable		no (%)	<2 cm	3_5 cm	>5 cm
Number of masses	1	61 (87%)	41	17	3
	2	6 (9%)	3	2	1
	3	3 (4%)	1	1	1
Staging of the disease	Stage I	30		43%	
	Stage II	35		50%	
	Stage III	5		7%	
	Stage IV	0		0%	
Grade	1	10		14%	

	2	44	63 %
	3	16	23%
Histopathological types	DC insito	6	8.5%
	LC insito	7	10%
	IDC	38	54.2%
	ILC	19	27%
Type of treatment	Neoadjuvant chemotherapy	45	64.2%
	Adjuvant chemotherapy	25	35.7%
	Radiotherapy	53	75.7%
	Hormonal therapy	5	7.1%
	Surgery	70	100%
Types of surgery	Mastectomy	39	55.7%
	BCS	31	44.3%

The extracted lymph nodes that resulted in malignant cells growth were subdivided into two groups, those that resulted in less than 5 positive lymph nodes and those that resulted in 5 or more positive lymph nodes after histopathological examination of the removed nodes.

At level one axillary dissection 10 patients out of 15 had positive malignant lymph nodes and 5 patients had negative lymph nodes, 8 of the 10 positive patients had less than 5 positive malignant cells and 2 had 5 or more , P value was larger than 0.05 and not significant (P=0.075).

At level II of axillary dissection 46 patients were included 27 of them (58.7 %) had positive malignant cells at the histopathological examination, 22 of the positive malignant removed lymph nodes were less than 5 and 5 were more than 5, 19 patients had negative lymph nodes removed, P value was not significant at the alpha level of 0.05 (P=0.084).

At level three of axillary dissection only 9 patients were involved, 8 of them (88.9 %) resulted in malignant lymph nodes, all the positive patients had less than 5 positive lymph nodes , and only one patient had negative removed lymph nodes, p value was larger than 0.05 and not significant (P=0.189).

Table3: the statistical correlation between the number of the removed lymph nodes and the level of axillary surgery.

level of axillary dissection	Patients	positive axilla	negative axilla	LN +ve <5	LN +ve ≥5	P value
level I	15	10	5	8	2	0.075
level II	46	27	19	22	5	0.084
level III	9	8	1	8	0	0.189
Total	70	45	25	38	7	_

Table 4: the statistical correlation between the number of positive removed lymph nodes and some other study variables.

Correlation with Positive LNs		
Variable	**P value**	**R**
Age	0.0664	0.052
Nipple retraction	0.0066	0.322**
No. Of masses	0.0002	0.426**
Axillary surgery level	0.3709	0.108
Grade of the disease	0.0251	0.174**
Stage of the disease	0.0372	0.139**
Family history	0.0001	0.057**
BMI	0.4564	0.249
Number of pregnancies	0.0571	0.838
**. Correlation is significant		

Discussion

Axillary management for breast cancer has become increasingly complex and multidisciplinary. The surgical option are no surgery vs sentinel lymph node biopsy (SLNB) vs axillary lymph node dissection (ALND) (14).

The mean age of the study group (n=70) was 53.2 years, breast cancer could occur at any age but its more common as age advances, Mcpherson et al. concluded that breast cancer is the single most common cause of mortality in women at the age of 45-50 years and women who have menopause after age of 55 increase risk to develop breast cancer by two fold compared to women who experience the menopause before the age of 45 (15).

Kelsey et al. also concluded that Age related incidence rates increased rapidly with advanced age until about 45-50 years of age were continue to increase but at a slower rate, so as age increases the incidence also increases(16).

Obesity by itself is a risk factor for breast cancer, but the current study did not establish any significant correlation, which could be explained by the limited number of the study patients, larger scale studies like PIKE et al. study in japan had concluded that the incidence is lower in japan and after adjustment of any other risk factors the higher incidence of obesity is what makes the higher incidence in the western countries (17). Chan et al. study that analyzed the results of 82 follow up studies in meta-analysis have also concluded that higher BMI is associated with poorer general outcome and higher mortality for women with breast cancer (18).

Feeling of a mass (lump) ,nipple retraction and breast pain remains the most common symptom, the same results were explained during Renganathan et al. study in Oman (19).

There was a significant correlation between the presence of malignant lymph nodes and the sign of nipple retraction, Smallwood et al. had established a study on 460 patients with mastalgia 44 of them had cancer, 8 of them reported pain and all the 44 patients have nipple retraction, they concluded that nipple retraction is markedly linked to malignant masses and that should always be thoroughly investigated (20).

Most of the study sample (60%) patients have a positive family history of breast cancer, family history was also significantly associated with the number of positive malignant lymph nodes, (60 %) of the patients also had 1-3 pregnancies, Colditz et al. study on 2249 patients who were diagnosed with invasive breast cancer have found that there is a consistent increase in risk among women who have a mother or sister with history of breast cancer (21). The results of a study showed that most of the study population have 1-3 children and few had no children, there was no significant statistical

correlation between the number of positive LNs and the number of pregnacies, However, in some studies like Balekouzou et al., Laamiri et al. and Tamakoshi et al. studies found that multiparity was associated with a reduced risk of developing breast cancer (22, 23, 24). Mahouri et al. study in Iran that involved 168 women with pathologically confirmed primary breast cancer and compared with 504 age-matched controls with two years follow up also concluded that having more than five full-term pregnancies is associated with an increased risk of breast cancer (25). In a study of African-American women by Palmer et al. high parities were associated with an increased risk of developing breast cancer among people younger than 45 years (incidence rate ratio [IRR] for four or more births, 2.4; 95% CI, 1.1–5.1) and a decreased risk among people older than 45 years (IRR, 0.5; 95% CI, 0.3–0.9) (26).

Most of the patients in this study had a solitary mass (87%), few had two or three masses (multiple) but the presence of more than one mass was significantly associated to higher risk of finding positive malignant lymph nodes during the histopathological examination. Chung et al. study the imaging of breast cancer patients and also concluded that multiple masses are more associated with malignant forms, solitary masses carry more benign etiologies compared to multiple masses with irregular outline borders (27).

Thirty nine patients had mastectomy and 31 patients had BCS during the current study, several studies including Veronesi et al. and Blicher-Toft both of them conducted a 20 year cohort study have demonstrated that the long term survival of women who undergo BCS is the same compared to women who have radical mastectomy, BCS is the surgery of choice for women with breast cancer who had a relatively small masses (28) (29).

IDC was the most common histopathological type followed by ILC, Weigelt et al. study that meta-analyzed 5 other studies have also concluded that IDC is the most common type of breast cancer with a prevalence of 65-78 % (30).

The patients at this study were treated with level I , level II and level III axillary dissection, the number of total and negative removed lymph nodes was increasing at every higher level of dissection, yet the number of malignant positive lymph nodes was not significantly increasing, most of the study patients were at stage I and stage II of the disease, making level I or no more than 10 lymph node dissection optimal for the surgical treatment, some authors like Axelsson et al. who conducted a study on 13851 patients that were registered in the Danish Breast Cancer(DBCG) Cooperative Group recommend removing no more than 10 lymph nodes, or at least 10 lymph nodes to avoid any misclassification of any node positive patient as a node negative, they also concluded that there is a strong positive correlation between tumor size and the number of node negative patients , the number of positive lymph nodes is also related to the histopathological grade of the disease the same significant correlation is found during the current study (31)

The 70 patient of the current study had axillary surgery at different levels and different number of lymph nodes are dissected from the axilla and were sent for staging which is an important prognostic factor, the impact level of dissection and the number of dissected lymph nodes from axilla have changed with the availability of the new strategies of treating breast cancer such as systemic adjuvant chemotherapy and radiotherapy and hormonal therapy and the use of SLNB, but for the patients who cannot receive a SLNB axillary lymph node dissection axillary dissection remain the standard of care (32), the question remains as to whether other oncological treatment can replace axillary surgery for node- positive patients who do not fit the Z0011 criteria, the other question is how to achieve a good axillary control with less lymphadenectomy and morbidity, some studies showed that The OS(overall survival) and DFS (disease free survival) are not significantly different comparing axillary dissection and axillary radiation in short or long term outcomes. The Early Breast Cancer Trialists' Collaborative Group (EBCTCG) reported a meta-analysis by Noël et al. which showed that early breast cancer patients who received postoperative radiotherapy could gain 1.2% more in their overall survival rate (33). A trial by Yao K et. al. was conducted as part of the National Surgical Adjuvant Breast Project B-o4 and found that axillary node dissection does not affect the survival rates. [34]

Surgeons started to reduce the number of removed lymph nodes, even in patients not fulfilling the inclusion criteria used by the Z0011-study [35], Some of studies results may indicate that even with an advanced axillary finding the ALND might be less beneficial for the patient [36, 37] On the other hand, effective systemic therapy reduce breast cancer mortality by around one-third (38). Hence partial axillary dissection (level I) carry less morbidity with keeping in mind the nice compensatory action of these new local and systemic treatment with minimal axillary dissection to avoid or lessen axillary morbidity, Veronesi et al. studied 539 node positive cases in which they did complete axillary dissection; 98.5% had metastases in level I nodes (28)

Only level (I) dissection was noted to be accurate for qualitative analysis in one randomized study from the

Scottish Cancer Trials (39), the current study patients were treated with level I , level II and level III axillary dissection, the number of total and negative removed lymph nodes was increasing at every higher level of dissection, yet the number of malignant positive lymph nodes was not significantly increasing, with no significant survival difference in LN positive breast cancer patients with 10 or less removed lymph nodes compared to more than 10 removed lymph nodes. Ebner et al. study on 9625 patients from 17 breast centers also concluded that the removal of more than 10 LNs did not result in a significant survival benefit even in high risk breast cancer patients. (40)

Roses et al. concluded that level I and II axillary dissection should be abandoned because of the significant high morbidity rate (41). more recent study by AKHTER et al. also recommend replacing level I and level II surgeries by Sentinel lymphadenectomy because its associated with less complications (42). The latest update of the NCCN guidelines(National comprehensive cancer network) for breast cancer supports the omission of an ALND in patients with a T1/2 tumor, maximum 2 positive sentinel lymph nodes with breast conserving surgery and planned whole breast radiotherapy and no preoperative chemotherapy.

Conclusion

1. The number of positive lymph nodes after axillary dissection as a treatment for breast cancer is not related to the level of axillary dissection.
2. Level I axillary dissection is recommended in patient with early breast cancer, clinically node negative axilla, small single mass , low grade and stage tumors
3. The number of positive lymph nodes was related to the number of masses, the presence of nipple retraction, histopathological grade, stage of the disease and the presence of positive family history of breast cancer.
4. In a node-positive breast cancer, a higher yield of excised LNs resulted in no increase in positive nodal count.

Recommendation

1. Starting SLNB in our clinical practice is mandatory.
2. Level I axillary dissection is recommended over level II and III since the number of positive lymph node is not related to the level of dissection.
3. The extend of axillary dissection can be reduced with the use of new strategies in treating axilla such as neoadjuvant, adjuvant chemotherapy, radiotherapy and hormonal therapy.
4. Establishing further studies with larger sample size for more accurate statistical power and longer follow up period for better assessment of prognosis is recommended.

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