

SENTINEL LYMPH NODE BIOPSY AFTER NEOADJUVANT CHEMOTHERAPY IN CLINICALLY NODE POSITIVE AXILLA OF BREAST CANCER

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ABSTRACT:

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Background: In the modern treatment of breast cancer, the Sentinel Lymph node biopsy indication is present in many clinical circumstances, instead of classical axillary lymphadenectomy. It presents the advantage of conservative surgery, which significantly decreases the rate of postoperative complications, offering the patients a better quality of Life and reducing the costs of patients care after surgery. Sentinel Lymph node biopsy (SLNB) vs. axillary Lymph node dissection (ALND) in the current surgical treatment of early stage breast cancer.

Aim of the Work: The aim of the present study is to evaluate staging the axilla with sentinel lymph node biopsy after neoadjuvant chemotherapy in previous clinically node positive axilla in breast cancer to avoid the morbidity of an ALND.

Patients and Methods: This was a prospective cohort study was held in El Demerdash hospital Ain Shams University hospitals, Cairo, Egypt started with one hundred and twenty female patients with clinically node positive axilla in breast cancer. Approval of the Ethical Committee and written informed consent from all participants were obtained. Patient selection was achieved through a number of inclusion and exclusion criteria.

Results: Our study showed that SLNB is acceptable in cN1/2 patients who become cN0 after neoadjuvant therapy: particularly in those with no residual disease in the breast, because SN status maintains its expected prognostic role, but also in cases with residual disease, because Axillary dissection (AD) has no influence on outcomes.

Conclusion: Sentinel lymph node biopsy will replace axillary lymph node dissection (ALND) in those patients with clinically node positive axilla without compromising their oncologic outcomes. Especially, rates of pathologic complete response (pCR) after neoadjuvant chemotherapy (NAC) have increased. In the neoadjuvant setting, SLN after NAC is feasible and accurate in clinically node positive patients as a continuous effort to avoid the morbidity of ALND.

Keywords: Sentinel lymph node biopsy, axillary lymph node dissection

INTRODUCTION:

Breast cancer is the most common invasive cancer in females worldwide. It accounts for 16% of all female cancers and

22.9% of invasive cancers in women. 18.2% of all cancer deaths worldwide, including both males and females, are from breast cancer. ⁽¹⁾

Breast cancer is the most common cancer among Egyptian women, accounting for 35% of all cases treated at the National Cancer Institute. However, most cases are detected very late and, in many circumstances, are not treated.⁽²⁾

Axillary dissection is a surgical procedure that incises the axilla to identify, examine, or remove lymph nodes. Axillary dissection has been the standard technique used in the staging and treatment of the axilla in breast cancer. Axillary dissection should be reserved for patients with proven axillary disease preoperatively or with a positive sentinel node biopsy.⁽³⁾

Axillary dissection is only therapeutic in patients who are node positive. Therefore, performing axillary dissection in all patients would lead to an overtreatment of at least 60% of patients who are all node negative. The introduction of sentinel-node biopsy has changed the approach to the axilla, as the status of the axilla can be established with less morbidity for patients when compared with complete axillary dissection. There is an increasing use of neoadjuvant chemotherapy in breast cancer, and the optimal timing of sentinel node biopsy can be controversial. Axillary dissection is advocated for all patients who complete neoadjuvant treatment to down-stage the breast tumor, except when sentinel node biopsy is negative and undertaken prior to the neoadjuvant treatment.⁽³⁾

Neoadjuvant treatment is a widely accepted treatment for breast cancer and has been proved to be equally effective option when compared to adjuvant therapy. Advantages are determination of an individual tumor's chemosensitivity, reduce micro metastatic disease and decrease disease burden to allow less extensive surgery.⁽⁴⁾

In recent years, increasing rates of tumor down staging have been reported, rates that have approached 94%, and more important, pCR is achieved by around 20_40% of patients after NAT. Pathologic complete

response has been associated with a better prognosis and overall survival.⁽⁵⁾

Sentinel node biopsy prior to chemotherapy could be considered the most accurate staging assessment of the axilla, while some would argue that performing the sentinel node biopsy after chemotherapy could allow patients who have had a complete pathological response to be spared the increased morbidity of an axillary clearance.⁽³⁾

Sentinel lymph node biopsy has replaced axillary lymph node dissection (ALND) in those patients with clinically node negative axilla and nowadays, patients with low burden disease in the SLNs may spare an ALND without compromising their oncologic outcomes. In the last decade, indications of neoadjuvant treatment (NAT) have been extended to patients with operable disease and with the use of targeted therapies; rates of pathologic complete response (pCR) after NAT have increased. In the neoadjuvant setting, SLN after NAT is feasible and accurate in clinically node negative patients and it has been explored in different randomized prospective studies in patients with clinically positive axilla in the continuous effort to avoid the morbidity of ALND.⁽⁶⁾

AIM OF THE WORK:

The aim of the present study is to evaluate staging the axilla with sentinel lymph node biopsy after neoadjuvant chemotherapy in previous clinically node positive axilla in breast cancer to avoid the morbidity of an ALND.

PATIENTS AND METHODS:

This was a prospective cohort study was held in El Demerdash hospital Ain Shams University hospitals, Cairo, Egypt started with one hundred and twenty female patients with clinically node positive axilla in breast cancer. Approval of the Ethical Committee

and written informed consent from all participants were obtained. Patient selection was achieved through a number of inclusion and exclusion criteria.

Place and timing of the study: our study was held at El Demerdash hospital between April 2017 till December 2019.

Inclusion Criteria: Patients ranging age from 20 to 70 years old. Patients with positive axillary L.Ns confirmed with fine needle aspiration biopsy (FNAB) before neoadjuvant chemotherapy who converted to clinically & radiologically negative axillary lymph nodes post neoadjuvant chemotherapy (NAC). Able to tolerate General Anesthesia

Exclusion criteria: Patients with any other malignancies. Patients with radiologically positive axillary lymph nodes post neoadjuvant chemotherapy (NAC). Patients with Lymphadenopathy due to any cause other than breast cancer. Patients with any organ metastasis secondary to breast cancer.

All patients included in the study were candidates for: Clinical assessment: Detailed medical and family history. Full Clinical examination including both breasts and axillae. Investigation: Routine laboratory investigations (CBC, coagulation profile, liver functions, kidney functions, RBS). ECG.

Postoperatively: Broad spectrum antibiotics. Surgical site suction drain was placed intraoperatively and was kept for 7-14 days. Hospital stay: from 24 to 48 hours. Follow up: after 1 week for result of histopathological examination of SLN, then 2 weeks to remove drain, then 6 months. This was carried out by clinical assessment.

Statistical Analysis:

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean,

Sonomammography on both breasts and axillae. Pelviabdominal CT and CT chest. Fine needle aspiration biopsy and cytology (FNABC) of radiologically positive axillary L.Ns. Chemotherapy: Each patient received 6 cycles of neoadjuvant chemotherapy. After completion of chemotherapy, we repeated breast ultrasound to ensure radiologically negative axilla (complete radiological response) post NAC that achieved in 50 patients and hence included in our study but the other 70 patients did not achieve complete radiological response though they were excluded from our study. Preoperatively: Patients were fully informed about the Risks and Benefits of the Procedures. Informed Consent was obtained from every Patient. Intraoperatively: Patients underwent sentinel lymph node biopsy using 1 cm of patent blue dye injected retroareolar at 3,6,9,12 o'clock then applying massage for whole breast for 15-20 minutes to allow the dye to reach from retroareolar plexus of Sappi to sentinel lymph node at axilla. After removal of sentinel lymph node (number 3-4 lymph nodes), was sent for pathologist for both intraoperative frozen and postoperative paraffin histopathological examination. Then completion of formal axillary clearance to assess safety and accuracy of sentinel lymph node biopsy (SLNB).

standard deviations and ranges when parametric. Also qualitative variables were presented as number and percentages.

The comparison between groups regarding qualitative data were done by using *Chi-square test and/or Fisher exact test* only when the expected count in any cell found less than 5.

The comparison between two independent groups with quantitative data and parametric distribution were done by using *Independent t-test* test.



Figure (1): Retroareolar injection of patent blue dye.



Figure (2): Shows patent blue dye stains sentinel lymph node



Figure (3): Shows patent blue dye stains sentinel lymph node



Figure (4): After excision of sentinel lymph node

Receiver operating characteristic curve (ROC) was used in the qualitative form to assess the diagnostic accuracy of paraffin section (axilla) and frozen section in differentiation between positive and negative cases taking paraffin section (SLN) as a gold standard.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:

P > 0.05: Non significant

P < 0.05: Significant P < 0.01: Highly significant.

RESULTS:

50 patients were included in our study, those are female patients with early breast cancer; without any other malignancies and without any Lymphadenopathy due to any cause other than breast cancer with mean Age 47.6 years.

Table (1): Shows demographic data about patient age, family history and side of tumor.

		No.= 50
Age (years)	Mean±SD	47.60 ± 13.41
	Range	22 – 68
Family history	Negative	17 (34.0%)
	Positive	33 (66.0%)
Side of tumor	Right	31 (62.0%)
	Left	19 (38.0%)

Table (2): Shows Site of tumor among the studied patients.

Site	Left		Right	
	No.	%	No.	%
1	3	15.8%	0	0.0%
2	3	15.8%	0	0.0%
3	4	21.1%	2	6.5%
4	1	5.3%	1	3.2%
5	1	5.3%	1	3.2%
7	2	10.5%	2	6.5%
8	1	5.3%	1	3.2%
9	0	0.0%	4	12.9%
10	2	10.5%	8	25.8%
11	1	5.3%	8	25.8%
12	1	5.3%	4	12.9%

Table (3): Shows tumor parameters and patients weight

		No.= 50
Breast mass size (cm)	Mean±SD	3.23 ± 0.64
	Range	1.5 – 4.2
BIRADS	4	32 (64%)
	5	18 (36%)
PT Weight	Mean±SD	77.84 ± 8.22
	Range	57 – 90

Table (4): Shows number of SLN

		Frequency	Percent
Number of SLN	3	28	56%
	4	22	44%

Table (5): Shows results of frozen section, paraffin section SLN and axilla among the studied patients

		No.= 50
Frozen section	Negative	35 (70.0%)
	Positive	15 (30.0%)
Paraffin section (SLN)	Negative	38 (76.0%)
	Positive	12 (24.0%)
Paraffin section (axilla)	Negative	42 (84.0%)
	Positive	8 (16.0%)

Table (6): Comparison between frozen section, paraffin section SLN and axilla of the studied patients.

	Frozen section	Paraffin section (SLN)	Paraffin section (axilla)	Test value*	P-value	Sig.
Negative	35 (70.0%)	38 (76.0%)	42 (84.0%)	2.758	0.252	NS
Positive	15 (30.0%)	12 (24.0%)	8 (16.0%)			

P > 0.05: Non significant (NS); P < 0.05: Significant (S); P < 0.01: Highly significant (HS)

*: Chi-square test

Table (7): Shows all factors that affect positivity and negativity of paraffin section of SLN

		Paraffin section (SLN)		Test value	P-value	Sig.
		Negative	Positive			
		No. = 38	No. = 12			
Age (years)	Mean±SD	47.42 ± 13.64	48.17 ± 13.23	-0.166•	0.869	NS
	Range	22 – 68	32 – 65			
Family history	Negative	15 (39.5%)	2 (16.7%)	2.114*	0.146	NS
	Positive	23 (60.5%)	10 (83.3%)			
Side of tumor	Right	25 (65.8%)	6 (50.0%)	0.965*	0.326	NS
	Left	13 (34.2%)	6 (50.0%)			
Breast mass size (cm)	Mean±SD	3.18 ± 0.68	3.37 ± 0.49	-0.875•	0.386	NS
	Range	1.5 – 4.2	2.3 – 4.2			
BIRADS	4	24 (63.2%)	8 (66.7%)	0.049*	0.825	NS
	5	14 (36.8%)	4 (33.3%)			
PT Weight	Mean±SD	77.42 ± 8.42	79.17 ± 7.78	-0.637•	0.527	NS
	Range	57 – 89	69 – 90			
Number of SLN	3	21 (55.3%)	7 (58.3%)	0.035*	0.852	NS
	4	17 (44.7%)	5 (41.7%)			

P > 0.05: Non significant (NS); P < 0.05: Significant (S); P < 0.01: Highly significant (HS)

*: Chi-square test; •: Independent t-test

Table (8): Shows relation of paraffin section (SLN) with frozen section and paraffin section (axilla) among the studied patients

		Paraffin section (SLN)		Test value	P-value	Sig.
		Negative	Positive			
		No. = 38	No. = 12			
Frozen section	Negative	35 (92.1%)	0 (0.0%)	36.842	0.000	HS
	Positive	3 (7.9%)	12 (100.0%)			
Paraffin section (axilla)	Negative	38 (100.0%)	4 (33.3%)	30.159	0.000	HS
	Positive	0 (0.0%)	8 (66.7%)			

P > 0.05: Non significant (NS); P < 0.05: Significant (S); P < 0.01: Highly significant (HS)

*: Chi-square test; •: Independent t-test

Completion of formal axillary clearance was done to assess safety and accuracy of sentinel lymph node biopsy (SLNB) revealed that there is no difference between results of positivity and negativity of both sentinel lymph nodes and other lymph nodes in axillary clearance.

Table (9): Shows diagnostic accuracy of frozen section and paraffin section (axilla) taking paraffin section (SLN) as a gold standard.

	Sensitivity	Specificity	PPV	NPV	Accuracy
Axilla	100%	66.7%	100.0%	90.5%	92.0%
Frozen section	100.0%	92.1%	80.0%	100.0%	94.0%

Table (10): Shows biological classification of patients

	Number of patients(50)	Percentage
Luminal A	8	16%
Luminal B	7	14%
HER 2neu	18	36%
Triple -ve	17	34%

DISCUSSION:

Breast cancer is the most common invasive cancer in females worldwide. It accounts for 16% of all female cancers and 22.9% of invasive cancers in women. 18.2% of all cancer deaths worldwide, including both males and females, are from breast cancer ⁽¹⁾

SLNB after NAC can be used to avoid non-therapeutic ALND and its associated morbidity in the 30 to 40 % of patients that present with positive LNs and are down-staged by NAC. As NAC (including the use of targeted agents) improves, the potential number of patients who could avoid ALND will certainly increase ⁽⁷⁾

Our study started with 120 patients diagnosed breast cancer who are clinically and pathologically positive axilla. they all underwent 6 cycles of chemotherapy and then underwent breast ultrasound showed that 70 patients did not achieve complete radiological response (CRR) so they were excluded from our study. on the other hand, 50 patients achieved CRR and hence included in our study.

Those 50 patients were included in our study with mean age 47.6 years and their age ranges from 22-68 years old. While American Cancer Society revealed that mean age of patients of breast cancer was 50 years old ⁽⁸⁾

In our study family history was positive in 33 patients with their percentage of 66%. While American Cancer Society revealed that family history was positive in more than 70% of patients of breast cancer. ⁽⁸⁾

This study showed that the site of tumor in 31 patients present with breast cancer on their right side with percent of 62% and the other 19 patients present with breast cancer on left side with their percentage of 38%.

In our study the most common site of tumor is at 10 & 11 o'clock in right breast

and at 2&3 o'clock in left breast and this is consistent with another study that revealed the most common site of tumor is upper outer quadrant at 10 & 11 o'clock in right breast and at 2&3 o'clock in left breast. ⁽⁹⁾

This study showed that the size of mass ranges from 1.5 cm to 4.2 cm with mean size of 3.23 cm in diameter. It also showed that 32 patients were BIRADS 4 with percentage of 64% and the other 18 patients were BIRADS 5 with percentage of 36 %. Regarding patient weight, it ranges from 57-90 kg with mean weight of 77.84 kg.

Then Patients underwent sentinel lymph node biopsy using 1 cm of patent blue dye injected retroareolar at 3,6,9,12 o'clock then applying massage for whole breast for 15-20 minutes to allow the dye to reach from retroareolar plexus of Sappi to sentinel lymph node at axilla.

After removal of sentinel lymph node (number 3-4 lymph nodes), sent for pathologist for both intraoperative frozen and postoperative paraffin histopathological examination.

In this study number of SLN, they were 3 lymph nodes in 28 patients with their percentage of 56% and were 4 lymph nodes in other 22 patients with percentage of 44%.

The SLN is the sole tumor-bearing node in up to 60 percent of cases overall, and in almost 90 percent of patients who harbor only micrometastatic disease. These observations have led to speculation that completion ALND may not be necessary in selected patients with a positive SLNB in less than three nodes because the need for systemic therapy is established and the risk of an axillary recurrence appears to be low. ⁽¹⁰⁾

In our study frozen section showed negative lymph nodes in 35 patients with percentage of 70% and positive lymph nodes in other 15 patients with percentage of 30% but paraffin section of SLN showed negative lymph nodes in 38 patients with percentage

of 76% and positive lymph nodes in 12 patients with percentage of 24%.

Other study showed that Data on frozen section assessment however is emerging showing sufficient, and perhaps superior intraoperative evaluation of nodal tumor burden, despite initial concerns that it consumes more of the specimen than cytological assessment. Analysis of published data to date shows that the accuracy of frozen section analysis with a combination of H&E staining and immunohistochemistry on sentinel lymph nodes lie between 73 to 96%.⁽¹¹⁾

Completion of formal axillary clearance was done to assess safety and accuracy of sentinel lymph node biopsy (SLNB) and sent for paraffin section and showed that negative lymph nodes in 38 patients with percentage of 76% and positive lymph nodes in 12 patients with percentage of 24% revealed that there is slight difference between results of positivity and negativity of both sentinel lymph nodes and other lymph nodes in axillary clearance.

Hormone receptor (HR) status is long known as independent predictor for chemotherapy response. In our study we found response to neoadjuvant chemotherapy is better in patients with positive HER 2 neu and in triple negative patients. We found 18 patients are positive for HER 2 neu with percentage of 36% and another 17 patients are triple negative with percentage of 34% and this consistent with other studies showed that the rate of pathological complete responses (pCR) differs between biological phenotypes, patients with a HR+/HER2- tumor had a very low chance of achieving a pCR but had still an excellent prognosis. Whereas patients with HR-/HER2+ tumors have only an excellent prognosis when achieving a pCR.⁽¹²⁾

There are several factors affecting the success and accuracy of sentinel lymph node

as using dual tracer with a radiolabelled colloid and a patent blue dye should be used; this will increase the SLN detection rate and the number of SLNs identified also decrease the FNR.⁽⁷⁾

Other limitations to our study are; the small group of patients, short follow up periods, use of patent blue dye only not using radiolabeled colloid.

The 2014 American Society of Clinical Oncology (ASCO) guidelines and 2015 National Comprehensive Cancer Network (NCCN) guidelines reflect the most conservative treatment, recommending completion ALND only for patients with more than 2 positive lymph nodes while most women who meet precise criteria (T1-2 tumor, 1-2 positive lymph-nodes, absence of previous neoadjuvant therapy and for which is planned breast conserving surgery with whole breast irradiation) should not undergo ALND.⁽¹³⁾

Micrometastases at sentinel node biopsy should not be considered an indication to ALND anymore, although in some countries this practice is not yet adopted. In 2011 St Gallen Consensus Conference has already moved forward a more conservative direction recommending that micrometastases in a single SLN should not be an indication for ALND irrespectively of the type of breast surgery given. The American Society of Clinical Oncology (ASCO) practice guidelines now allow to omit ALND to patients with micrometastatic and even 1-2 macrometastatic positive SLNs.⁽¹⁴⁾

The Venezuelan Mastology Society published its Consensus of Sentinel Lymph Node in Mammary Carcinoma in 2010. This recommends performing ALND in all cases of macrometastasis and leaves the decision in the hands of each working group in cases of micrometastasis.

The American Society of Clinical Oncology (ASCO) recommends performing

ALND in all patients with SLN, whether they have macro or micrometastasis.

Eventually our study showed that SLNB is acceptable in cN1/2 patients who become cN0 after neoadjuvant therapy particularly in those with no residual disease in the breast, because SN status maintains its expected prognostic role, but also in cases with residual disease, because Axillary dissection (AD) has no influence on outcomes.

Today there is growing updates to increase the efficacy and efficiency of SLN though a new approach called Targeted Axillary Dissection (TAD) was introduced. It requires the marking of metastatic nodes before the neoadjuvant treatment. In cases with initially pathologic nodes they recommend marking of the most explicit metastatic node to enable TAD. The marked node is likely to reflect the status of the lymph nodes after neoadjuvant treatment more accurately than common sentinel nodes.⁽¹⁵⁾

Another study presents the first documented case of the use of magnetic seeds to mark axillary lymph node metastasis in breast cancer prior to neoadjuvant chemotherapy with magnetometer-guided intraoperative identification of the marked lymph node. The magnetic seed is a new technology that uses a 1 × 5 mm surgical stainless steel marker. It can be detected using a magnetometer (Sentimag, Endomag, Cambridge, UK), which provides information on the direction to the marker and how far away it is. This means the marked node can be located in a similar fashion as the way in which a radioactive iodine seed would be detected, but without the regulatory problems associated with the use of radioactive materials. They believe marking positive lymph nodes before commencing neoadjuvant treatment with a magnetic seed could provide a simple and effective means of intraoperative localization of the marked node.⁽¹⁶⁾

Conclusion:

Sentinel lymph node biopsy will replace axillary lymph node dissection (ALND) in those patients with clinically node positive axilla without compromising their oncologic outcomes. Especially, rates of pathologic complete response (pCR) after neoadjuvant chemotherapy (NAC) have increased. In the neoadjuvant setting, SLN after NAC is feasible and accurate in clinically node positive patients as a continuous effort to avoid the morbidity of ALND.

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استئصال الغدة الليمفاوية المنتقاه بعد العلاج الكيميائي لسرطان الثدي

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المقدمة: تشريح الإبط هو اجراء علاجي في المرضى الذين لديهم عقدة إيجابية فقط. لذلك، أداء التشريح الإبطي في جميع المرضى من شأنه أن يؤدي إلى علاج لا يقل عن ٦٠٪ من المرضى الذين لديهم عقدة سلبية. قد تغير النهج المتبع في الإبطين بادخال تقنية الغدة الليمفاوية المنتقاه ، كما يمكن أن تثبت حالة الإبط مع أقل مضاعفات بالمقارنة مع التشريح الإبطي الكامل. هناك تزايد استخدام العلاج الكيميائي قبل العملية في سرطان الثدي، والتوقيت الأمثل لاستخدام تقنية الغدة الليمفاوية المنتقاه يمكن أن تكون مثيرة للجدل. يستخدم التشريح الإبطي لجميع المرضى الذين تمت معالجتهم بالعلاج الكيميائي قبل العملية لتقليص مرحلة ورم الثدي، إلا عندما تتأكد سلبية العقدة الليمفاوية المنتقاه قبل اجراءالعلاج الكيميائي قبل العملية.

الهدف: هو استخدام تقنية العقدة الليمفاوية المنتقاه بعد العلاج الكيميائي المستخدم قبل العملية في الحالات التي تعاني من تضخم بالغدد الليمفاوية بالإبط في سرطان الثدي لتجنب حدوث مضاعفات الاستئصال الكلي للعقد الليمفاوية بالإبط

المرضى والأساليب: هذه دراسة مستقبلية للمراقبة العشوائية أجريت في مستشفى الدمرداش، مستشفيات جامعة عين شمس، القاهرة، مصر، بما في ذلك خمسين مريضة مصابة بتضخم العقد الليمفاوية في سرطان الثدي، وتم الحصول على الموافقة المستنيرة من كل مريضة. مكان وتوقيت الدراسة: عقدت دراستنا في مستشفى الدمرداش بين أبريل ٢٠١٧ حتى ديسمبر ٢٠١٩.

النتائج: أظهرت دراستنا أن SLNB مقبول لدى مرضى 2 / cN1 الذين يصبحون cN0 بعد العلاج المساعد الجديد: لا سيما في أولئك الذين ليس لديهم مرض متبقي في الثدي، لأن حالة SN تحافظ على دورها التنبؤي المتوقع، لأن تشريح الإبطين الكامل ليس له تأثير على النتائج.

الخلاصة: تحل تقنية العقدة الليمفاوية المنتقاه محل التشريح الكلي للإبط في أولئك المرضى الذين يعانون عقدة ليمفاوية ايجابية للورم في الوقت الحاضر وذلك يؤدي الي انخفاض عبء المرض دون التأثير علي نتائج الأورام. نتيجة لاستخدام العلاج الكيميائي ومع استخدام العلاجات المستهدفة زادت معدلات الاستجابة الكاملة المرضية.