

# Use of Neoadjuvant Chemotherapy and Dissection of the Positive Sentinel Lymph Nodes in the Treatment of Breast Cancer Only on Stage T1 to T2

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## Abstract

**Objective:** breast cancer is the most common cancer in women. Its curative treatment is based on mastectomy, which can be radical or by quadrants. Surgery is done with Axillary Lymph Node Dissection (ALND) in the radical or Sentinel Lymph Node Dissection (SLND) in the condom. In this sense, this article evaluates the displacement of surgery with positive sentinel in patients with Neoadjuvant Chemotherapy (NAC) and radiotherapy compared to standard or radical treatment. Methods: this is a retrospective study based on the analysis of the medical records of Hospital São Vicente de Paulo (HSVP) in Guarapuava-PR from 2011 to 2020. Patients with early stage breast cancer, with maximum stage IIIA, were selected. quadrantectomy, NAC and positive sentinel lymph node biopsy.

**Results:** The results showed recurrence in 2 patients in the control group (7%) and in one patient in the study group (17%) which resulted in subsequent death.

**Conclusion:** Although this research was small, some subjective results were identified, as is the case of patients with standard breast cancer treatment, in the intermediate stage, post-menopause and positive lymph nodes in the biopsy, who demonstrated a better response to treatment when compared to with other patients. . In addition, young patients had a worse response compared to others. However, more comprehensive studies with longer follow-up are needed to draw meaningful conclusions.

**Keywords:** Breast cancer • Sentinel node • Lymph node dissection • Neoplasms in women • Neoadjuvant chemotherapy

## Introduction

Breast Cancer & Cancer statistics [1] is, in 2020, the first on the list of the most frequent neoplasms in women with an incidence of 9.7% and is also the cancer with the highest death rate in 2018 in this sex, being 16.4% of deaths from oncology disease in Brazil. Treatment for this disease varies [2] associate or individually, between surgery, radiotherapy, chemotherapy, hormone therapy and biological therapy. Standard treatment [3] is non-conservative with Axillary Lymph Node Dissection (ALND) in patients with positive sentinel lymph nodes biopsy (BLS) to prevent the development of metastases or expectant in cases of negative BLS. The current studies, however, follow the treatment line conservative with tumor dissection and BLS being less invasive even in cases of positive BLS.

The most frequent ALND complication is a consequence of the axillary lymph node chain removal, leading to upper limbs: lymphedema, mobility loss, pain, sensorial loss and impairment shoulder function. However, the study made by Alliance for Clinical Trials in Oncology (ACOSOG) showed that only SLND has an equivalent result in patients survival with specific characteristics,

such as absence of axillary node enlargement on physical examination, maximum of two positive lymph nodes sentinel and disease evaluate T1 to T2 without mastectomy. This results brings benefits to patients, then decreases invasion intervention to remove the axillary lymph node chain which improves the rehabilitation and quality of life [4,5].

Other study made by European Organization for Research and Treatment of Cancer (EORTC) with title 10981-22023 AMAROS, randomized multicenter study carried out by means of a non-inferiority test (equivalence) in patients with primary invasive breast cancer T1 and T2, without palpable lymphadenopathy in physic exam. It aims to evaluate if axillary radiotherapy provides comparable regional control with fewer side effects than ALND [6]. Similarly, the study INSEMA (Intergroup-Sentinel-Mamma Trial) investigated the radiotherapy techniques and their dose-dependent distribution in both breasts and their benefit's [7].

The current study took into account the patient's characteristics in stage T1 and T2 lymph node N0 or N1 in stage TNM, sentinel lymph node biopsy and treatment with neoadjuvant chemotherapy. A study group was composed with the NAC and expectant conduct in patients with positive BLS and subsequent use of radiotherapy, in addition, a control group, which used and treatment based on BLS after the NAC, did ALND if the BLS result was positive and expectant otherwise. Both groups were formed to better assess the situation of the study patients and verify their significance. The study's aim was evaluating if surgery de-escalation in patients with a positive sentinel in NAC patients and radiotherapy was comparable, in terms of diseaseless survival and overall survival, with standard therapy with either NAC and ALND or NAC and expectant. It is also the objective of this study to identify the patterns of breast cancer involvement in patients from Hospital São Vicente de Paulo, Paraná.

Breast cancer is, in 2020, the first on the list of the most frequent neoplasms in women with an incidence of 9.7% and is also the cancer with the highest mortality rate in 2018 in this sex, with 16.4% of deaths from disease.

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oncology in Brazil. Axillary Lymph Node Dissection (ALND), the gold standard treatment for this cancer, has complications resulting from the consequences of removing the axillary lymph node chain leading to greater morbidity, lymphedema of limbs upper limbs, upper limb pain, sensory loss in the arm and shoulder function. Therefore, in this study, the possibility of withdrawing surgery was evaluated in patients with lower risk diseases with a positive sentinel test. For this, ALND was replaced by less interventional surgery and NAC and radiotherapy were used to improve disease-free survival and overall survival of patients.

## Methodology

This study is cross observational, made in retrospect, with a qualitative approach. The study is based on Hospital São Vicente de Paulo (HSVP) records of breast cancer patients treated in the years 2011 to 2020. Treatment information for these patients was sought, mostly on initial stage diseases. Two groups were formed, the first - control group - defined from patients up to stage IIIA who underwent CAN before any surgery, had a sentinel lymph node biopsy performed with methylene blue and subsequently constructed an ALND regardless of the result. The study group was initially evaluated in the same way up to stage IIIA, with prior CAN, evaluation of sentinel lymph node biopsy and subsequently performed SLND and added radiotherapy after surgery. After these interventions, the patients were followed up at the service to assess their disease progression. Patients who were assisted at two years after surgery were analyzed for disease recurrence.

The objective of the study was to add information to the practice of reducing invasive interventions in the treatment of breast cancer, seeking equivalent treatment results and prognosis even with less intervention. The study also seeks to assess non-inferiority in patients with positive BLS undergoing expectant treatment or undergoing axillary lymphadenectomy, seeking to establish more information regarding disease-free survival and overall survival in specific patients.

This study's research was accomplished from 2011 to 2020 to check the course of the disease at least two years after the surgical treatment. Patients were selected by TNM stage on T1 or T2, N0, N1 or N2 and M0; NAC and biopsy of sentinel lymph nodes. These datas are available in the patient's charts, however have not yet been assessed. This collection of information was based on the study proposed by the ACOSOG Z0011 study and seeks more information regarding this treatment.

The data collected were: age, gender, tumor hormone receptor status, tumor histological type, chemotherapy type, if it did radiotherapy, which clinical stage, which tumor pathological stage, post treatment time, treatment's start and finish year, number of lymph node metastasis, number of lymph nodes removed, if it did quadrantectomy, what is the diseaseless survival time, if there was a recurrence, if it had a distance metastasis or death. These data will be stored confidentially for 5 years.

The research project was submitted to the Research Ethics Committee (CEP) of the Centro Universitário Campo Real, in agreement with the Resolution 466/12 of the National Health Council - CNS with opinion number 4.473.522, which's approval date is December 18, 2020. Permission to use data within the medical records system at Hospital São Vicente de Paulo was requested and was authorized by it. No patient names were used, they were differentiated by numbers and birth data.

## Results

Data were selected from a list of patients with breast cancer linked to HSVP care, as shown in Figure 1. These patients were treated in the hospital São Vicente de Paulo between the years 2011 and 2018, to assess survival in up to two years finishing in 2020. Initially, there were 166 oncological patients with breast cancer from which the first line treatment is axillary lymphadenectomy were removed, leaving 79. It also was removed: thirty two patients who didn't undergo neoadjuvant chemotherapy, six patients with insufficient post

surgery time, three patients with insufficient information and four patients with metastasis (Figure 1).

The Table 1 shows the main results of patients' characteristics and their tumor. Most of the patients' results are post-menopause, stage IIA, histological subtype non-special and all female (Table 1).

The follow-up of these patients resulted in three recurrences whose investigated characteristics are shown in Table 2 The recurrence rate was 93% and 83% in control group and study groups respectively. Patients who relapsed

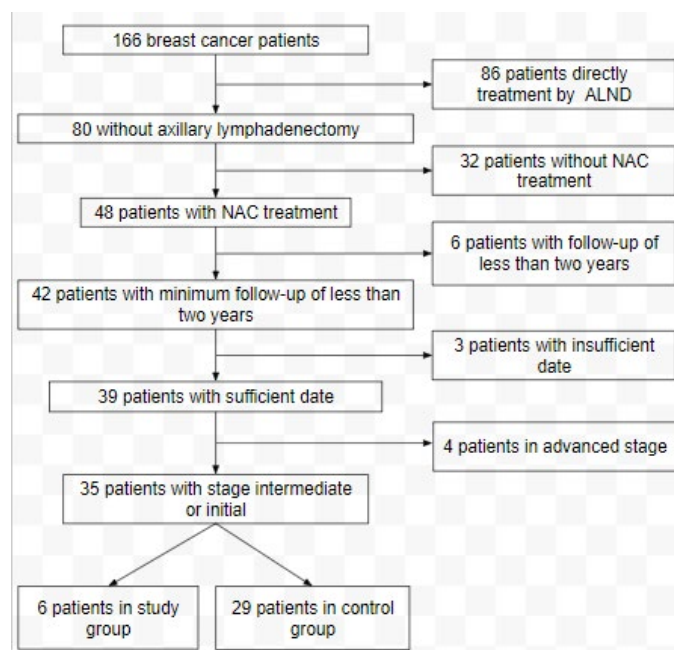


Figure 1. Patient selection flowchart.

Table 1. Patients' characteristics and their tumor.

|                  |                                | Control group (29) | Study group (6)   |
|------------------|--------------------------------|--------------------|-------------------|
| Age              | Minimum-Maximum                | 55.5               | 53.17             |
|                  | Less than or equal to 50 years | 10 (34.4%)         | 3 (50%)           |
|                  | More than 50 years             | 19 (65.5%)         | 3 (50%)           |
| Clinical stage * | T1                             | 8 (27.5%)          | 2 (33.3%)         |
|                  | T2                             | 21 (72.4%)         | 4 (66.6%)         |
|                  | N0                             | 25 (86.2%)         | 2 (33.3%)         |
|                  | N1                             | 3 (10.3%)          | 4 (66.6%)         |
|                  | N2                             | 1 (3.4%)           | 0                 |
|                  | IA                             | 5 (17.26%)         | 0                 |
| Receptors        | IB                             | 1 (3.4%)           | 0                 |
|                  | IIA                            | 20 (68.9%)         | 4 (66.6%)         |
|                  | IIB                            | 2 (6.8%)           | 2 (33.3%)         |
|                  | IIIA                           | 1 (3.4%)           | 0                 |
|                  | ER+                            | 25 (86.2%)         | 5 (83.3%)         |
|                  | PR+                            | 16 (55.1%)         | 5 (83.3%)         |
|                  | HER+                           | 7 (24.1%)          | 1 (16.6%)         |
|                  | Triple negative                | 2 (6.8%)           | 0                 |
|                  | Gx                             | 13 (44.8%)         | 3 (50%)           |
|                  | G1                             | 3 (10.3%)          | 0                 |
| Lymph Nodes      | G2                             | 12 (41.3%)         | 3 (50%)           |
|                  | G3                             | 1 (3.4%)           | 0                 |
|                  | Positive                       | 3 patients (10%)   | 6 patients (100%) |
| Histology        | Non-special subtype            | 15 (51.7%)         | 4 (66.6%)         |
|                  | Lobular                        | 4 (13.7%)          | 2 (33.3%)         |

\*According to AJCC, 8<sup>th</sup> edition

were between 10 and 20 months post initial treatment by quadrantectomy post neoadjuvant chemotherapy. The difference in time in relation to patients shown in Graphic 1 is mainly due to the difference in the number of patients between groups. Furthermore, it's believed that the relapsed and metastasized patient from the study group represents a discrepancy from the others, seeing the different characteristics that increase their risk and worsen their prognosis (Table 2).

In Table 2 there were ten female patients with differential characteristics in the groups. Some patterns also stand out within both groups resulting in a better prognosis.

The Figure one demonstrates the main findings regarding the lives of patients in both groups. It must be remembered that the significance of the Figure is low due to the disparity in the number of members in each group, so it is only demonstrative (Figure 2).

## Discussion

Three patients with characteristics positive ER and PR, negative HER and non-special histological subtype had relapses in both groups demonstrating that they obtained, in general, similar results. This study has limitations because of your scarce number of patients and your time of twenty four months follow-up from the medical record. However, the same brings an interesting base and complementary basis to other studies already published, in order to establish parameters for further research with bigger sample and longer time follow-up, such as the study that is already underway by the group of the researchers whose name is Alliance A11202. Furthermore, the study comes with the intention of adding more information for studies already published, like [4-10].

Giuliano AE, et al. [4] made with 856 patients for approaching nine years, showed that disease-free survival was 80.2% for group SLND and 78.2% for group ALND. Also reports an annual rate of 0.9% to 1.5% of distance recurrence after endocrine therapy, being very rare in the ALND and SLND, regardless of hormone positive receptor. In comparison, the groups SLND and ALND didn't show disease-free general survival bottom stage T1 and T2 with up to two positive lymph nodes in patients treated from conservative surgery and NAC. In comparison, the current study is equivalent in disease-free survival of the study group by 83% and differs from the control group by 93%.

Sanne ALB, et al. [6] carried out in patients with breast cancer also at stage T1 and T2 without neoadjuvant treatment, the standard ALND group was compared with another that used axillary radiotherapy. The study had a recurrence rate of 0.53% in the ALND group and 1.02% in the axillary radiotherapy group. At five years, the ALND group had a rate of 0.33% and the radiotherapy group 1.19%. The disease-free survival in five years in ALND groups was 82.7% and in the radiotherapy group it was 86.9%, besides death in 11% and 10%, respectively. The overall survival in five years were 93.3% in ALND group and 92.5% in axillary radiotherapy group. Both groups are recurrence rate of 4% after twenty five years. This study also defines that

doesn't have difference long-term in the choice of these two treatments, but in ALND-related morbidity and lymphedema occurs in 23% for ALND group compared to 11% for radiotherapy group after five years. This demonstrates that the focus of research is to minimize patient's morbidity due to invasive treatment of ALND, whether through NAC, radiotherapy or Temporary Anchorage Device (TAD) - implantation of radioactive seeds after NAC, among others possibilities. Their study doesn't show a difference between patients that used radiotherapy after NAC in terms of disease-free survival, but two of the three patients with recurrence received radiotherapy.

De Wild SR, et al. [11] speech about Neoadjuvant Systemic Therapy (NST) in order to reduce the tumor size after surgery and induce a Pathologic Complete Response (pCR) of armpit being able to obtain a response in 74% of HER2+ patients. This answer type is ideal for patients that intend to do no-invasive surgery like SLND. He also comments on the interference of molecular subtypes and the number of lymph nodes that can interfere with the patient's prognosis and treatment variation between ALND and SLND. According to this study, the evidence for breast cancer treatment with SLND is low, as well as TAD therapy, but in association, despite the few studies with both, is a promising alternative. The Canadense study Beney M, et al. [5] brings retrospective analysis of success in use of TAD post SLND and NAC. The same showed that 25% of patients got pCR in breast and 50% in armpit and thirty four out of thirty five patients showed success without complication in implantation. It was also verified that of 1248 SLND patients, only 14 need to undergo the surgery again, now with ALND due to insufficient previous results. This association shows that there is a possibility of further increasing the quality of treatment of these specific patients and encompassing others with greater tumor and lymph nodes involvement, in addition to what has already been proposed in previous studies.

It was found in Jean-Francois B, et al. [8] study that NAC with sentinel lymph nodal biopsy is well applied by more than 30% of the patients who today used ALND therapy. The research brings, comparatively, the result of previous studies done with patients with only one sentinel lymph node representing 26.5% in SN FNAC study, 20.4% in Giuliano AE, et al. [4] study and 31% in SENTINA study. In the last, clips are also implanted in the surgery in which was demonstrated a False Negative Rate (FNR) of 7.4%.

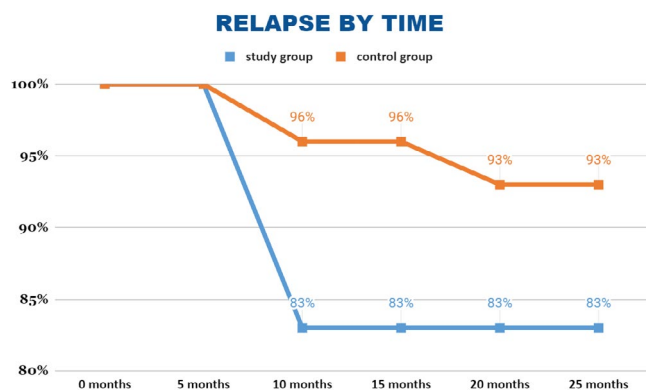
Weiss A, et al. [12] done with 539 patients classified with HER2+ and Triple-Negative Breast Cancer (TNBC) brought more specific data by TNM staging and treatment response based on NAC. He found an overall survival in five years of 59.9% for patients with residual disease and positive lymph nodal, 83% in patients with pCR and positive lymph nodal and 90% for pCR and negative lymph nodal. Also concluded that the patients in specific treatment with NAC and stage II or III have a 76% rate of progression to Lymph Node Negative (ypN0), being initial patients with negative nodal reaching 90% and patients with negative nodule reaching from N1 to N3 presenting involution of metastasis.

Goel N, et al. [13] evaluated the axillary response after NAC treatment in 99 patients with stage N2 and N3 disease, 18 in the SLND group having an

Table 2. Patients characteristics with positive lymph Node.

| Group | Ag | Men  | T | N | Stage | Lymp | Histological        | ER | PR | HER | Rad | Recor    | Met | He  |
|-------|----|------|---|---|-------|------|---------------------|----|----|-----|-----|----------|-----|-----|
| C     | 65 | Post | 1 | 1 | IIA   | 0/12 | Non-special subtype | +  | +  | -   | No  | 10 Month | No  | No  |
| C     | 50 | Post | 1 | 0 | IB    | 0/5  | Non-special subtype | +  | +  | -   | Yes | 20 Month | No  | No  |
| C     | 39 | Pre  | 1 | 2 | IIIA  | 5/10 | Non-special subtype | +  | +  | -   | Yes | Less     | No  | No  |
| C     | 60 | Post | 2 | 1 | IIB   | 3/7  | Non-special subtype | +  | +  | +   | Yes | Less     | No  | No  |
| C     | 59 | Post | 2 | 1 | IIB   | 2/4  | Non-special subtype | +  | +  | -   | No  | Less     | No  | No  |
| E     | 67 | Post | 2 | 1 | IIB   | 1/4  | Non-special subtype | -  | -  | +   | Yes | Less     | No  | No  |
| E     | 58 | Post | 1 | 1 | IIA   | 1/3  | Non-special subtype | +  | +  | -   | Yes | Less     | No  | No  |
| E     | 68 | Post | 1 | 1 | IIA   | 1/3  | Lobular             | +  | +  | -   | Yes | Less     | No  | No  |
| E     | 48 | Post | 2 | 1 | IIB   | 1/1  | Non-special subtype | +  | +  | -   | Yes | Less     | No  | No  |
| E     | 36 | Pre  | 2 | 0 | IIA   | 1/7  | Non-special subtype | +  | +  | -   | Yes | 20 Month | Yes | Yes |

Ag: Age; MEN: Menopause; T e N: Stage TNM T (tumor size and infected lymph Nodes); G: Histological stage; Stage: tumor stage; Lymph: Number of positive lymph divided by number of removed lymph Nodes; Histological: Tumor histological pattern; ER: Estrogen Receptor; PR: Progesterone Receptor; HER: HER2+ receptor ; Rad: Radiotherapy treatment; Recor: Recording in months; Met: Metastasis; He: Patient died within 24 months of cancer; C: Control group; E: Study group.



**Figure 2.** Recurrence of breast cancer by time in months and by group. **Note:** Due to the low number of patients and the difference in number between one group and another, we did not find it relevant to carry out a statistical analysis of these data. However, we brought the largest amount of information contained in the medical records so that new studies can be based on these data.

overall pCR rate of 63.4% with about 11% in the group with residual breast disease. In general, it was found that patients with N2 or N3 post NAC had 79% of residual lymph node disease in surgery and the 20% of patients with complete response.

The patients who underwent NAC with SLND, 14% needed ALND because they had not been treated properly. In this group 55% complete answers and 39% pCR. Of a total of 525 patients [14] 40% were treated with SLND and 11% needed to be referred to ALND after SLND. In patients N0, 91% ended up with negative nodules and in N1 and N2 patients, 45% responded with a negative node at the end and 35% had residual disease. In the SLND group 11% of the patients with N1 or N2 had recurrence in thirty six months being 54% of which were distant. In N0 groups the recurrence was 5.7% and N1 or N2 group was 4% both in five years. This demonstrates the importance not only of treatment type, but patient staging and its relationship to recurrence and pCR, the higher the staging, the lower the effectiveness of the treatment. This study evaluated a recurrence at thirty six months at 11% compared to ours at 24 months which was 17% and metastasis at 54% with ours at 16.6%.

Barrio AV, et al. [15] was done with 769 patients with nodule positive breast cancer then treated with NAC and axillary surgery. Of these, 91% of patients were converted to N0 by fistic exam and 92% had three or more sentinel nodes recovered, avoiding 234 times the ALND. The nodal recurrence rate was 0.4%.

## Conclusion

Offering a treatment that has treatment equivalence and lower risks for oncological patients is the absolute priority for the health professional aimed on this area, which turns into the individual's quality of life. To help this process, it is ideal to increase efficient alternatives with less possible interventions so that treatment has the same effectiveness and less risks to quality of life. It boils down to less surgical removal interventions, less chemotherapy that interfere in general metabolism and less quantity of invasive procedures. Therefore, alternatives are increasingly being sought for improvement of oncological treatment for the benefit of patients.

Based on previous studies and on this study, we can suggest that only a specific group of patients with positive SBV benefit from the NAC + radiotherapy + SLND treatment, still requiring investigation regarding more characteristics to verify the real benefit. Another factor that is suggested is the greater involvement of lymph nodes, which seems to respond negatively to treatment, but which is still controversial.

We can infer that despite the good evolution of the patients, some factors brought less favorable outcomes, as is the case with young patients, requiring a deeper investigation in this group, even with other methods or associations. Although our study group is small and does not bring significant statistics,

it suggests interesting points for larger studies. Perhaps postmenopausal patients, intermediate stages and with positive lymph node biopsy would benefit more from this type of treatment.

## Contribution to the field

Breast cancer is, in 2020, the first on the list of the most frequent neoplasms in women with an incidence of 9.7% and is also the cancer with the highest mortality rate in 2018 in this sex, with 16.4% of deaths from disease. oncology in Brazil. Axillary Lymph Node Dissection (ALND), the gold standard treatment for this cancer, has complications resulting from the consequences of removing the axillary lymph node chain leading to greater morbidity, lymphedema of limbs upper limbs, upper limb pain, sensory loss in the arm and shoulder function. Therefore, in this study, the possibility of withdrawing surgery was evaluated in patients with lower risk diseases with a positive sentinel test. For this, ALND was replaced by less interventional surgery and NAC and radiotherapy were used to improve disease-free survival and overall survival of patients.

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