

Original Article

Axillary pathologic response after neoadjuvant chemotherapy in locally advanced breast cancer with axillary involvement[☆]A. Jiménez-Ballvé^{a,*}, A. Serrano-Palacio^a, J.A. García-Sáenz^b, A. Ortega Candil^a, O. Salsidua-Arroyo^a, J.M. Román-Santamaría^c, A. Pelayo Alarcón^d, M.E. Fuentes Ferrer^e, J.L. Carreras-Delgado^a^a Servicio de Medicina Nuclear, Hospital Clínico San Carlos, Instituto de Investigación Sanitaria Hospital Clínico San Carlos, Madrid, Spain^b Servicio de Oncología Médica, Hospital Clínico San Carlos, Instituto de Investigación Sanitaria Hospital Clínico San Carlos, Madrid, Spain^c Servicio de Ginecología y Obstetricia, Hospital Clínico San Carlos, Instituto de Investigación Sanitaria Hospital Clínico San Carlos, Madrid, Spain^d Servicio de Anatomía Patológica, Hospital Clínico San Carlos, Instituto de Investigación Sanitaria Hospital Clínico San Carlos, Madrid, Spain^e Unidad de Gestión Clínica de Medicina Preventiva, Instituto de Investigación Sanitaria Hospital Clínico San Carlos, Madrid, Spain

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ABSTRACT

Aim: To compare axillary involvement (N+) at initial staging in locally advanced breast cancer (LABC) with axillary lymphadenectomy histologic results after neoadjuvant chemotherapy treatment (NeoChemo).**Material and methods:** Retrospective study between November 2011 and September 2013 of LABC cases treated with neoadjuvant chemotherapy based on docetaxel (associated with trastuzumab in HER2-positive cases and carboplatin/adriamycin in HER2-negative cases). Those clinically or radiologically suspected cases of axillary involvement were histologically confirmed. When there was no suspicion of axillary involvement, sentinel lymph node radioguided biopsy (SLNRB) was performed using intradermal injection of ^{99m}Tc-nanocolloid albumin prior to neoadjuvant treatment. Axillary lymphadenectomy after NeoChemo was undertaken in all cases with positive axilla. Final pathologic response was classified as complete (pCR) when there was no evidence of tumoral disease and as non-pathologic complete response (no pCR) in the opposite case.**Results:** A total of 346 patients treated with docetaxel were reviewed, identifying 105 LABC. Axillary involvement at initial staging was detected in 70 (67%) before starting NeoChemo. From these 70, 73% (n = 51) were N+ (fine needle biopsy and/or biopsy) and the remaining 19 (27%) were occult N+ detected by SLNRB. Axillary lymphadenectomy detected pCR in 56% (39/70), increasing up to 84% pCR when initial N+ status was reached using SNLB. On the other hand, when N+ was detected using fine needle biopsy/lymph biopsy, pCR was only 45%.**Conclusion:** More than 50% of women affected by locally advanced breast cancer with tumoral axillary involvement at initial diagnosis present free metastatic axilla after therapeutic neoadjuvant chemotherapy effect. This increases up to almost 90% in case of occult metastatic axilla detected with sentinel node biopsy prior to starting neoadjuvant chemotherapy.

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Respuesta patológica en la axila tras quimioterapia neoadyuvante en el cáncer de mama localmente avanzado con afectación axilar

RESUMEN

Objetivo: Comparar la afectación axilar (N+) al diagnóstico en el cáncer de mama localmente avanzado (CMLA), con el resultado histopatológico en la axila tras el tratamiento quimioterápico neoadyuvante (QTN).**Material y métodos:** Estudio retrospectivo entre noviembre de 2011 y septiembre de 2013 de los CMLA tratadas con QTN basada en docetaxel (asociando trastuzumab en los casos HER2 positivos y carboplatino/adriamicina si HER2 negativos). Los casos con sospecha clínica/radiológica de N+ se confirmaron histológicamente. Si no existía sospecha, se estadificó con la técnica de biopsia radioguiada del ganglio centinela (BRGC), mediante la inyección de ^{99m}Tc-nanocoloide de albúmina, previa a la QTN. En los casos N+ se realizó linfadenectomía axilar (LA) tras QTN. Clasificamos la respuesta patológica final como completa (RCp) cuando no hubo evidencia de enfermedad tumoral y como no respuesta patológica (NRp) en caso contrario.**Resultados:** Revisamos 346 pacientes tratados con docetaxel, donde identificamos 105 CMLA. En 70 (67%) se evidenció infiltración tumoral axilar antes de iniciar la QTN. De estas, el 73% (n = 51) presentaban N+ por punción-aspiración con aguja fina (PAAF) y/o biopsia ganglionar, y las restantes 19 (27%) presentaban

Palabras clave:

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N+ oculta demostrada por la BRGC. La LA evidenció RCp axilar en el 56% (39/70); aumentando hasta un 84% cuando el estatus inicial N+ se alcanzó por BRGC, frente a un 45% cuando se llegó al diagnóstico de N+ por PAAF/biopsia ganglionar.

Conclusión: Más de la mitad de las mujeres con cáncer de mama localmente avanzado con afectación tumoral axilar al diagnóstico presentan axilas libres de enfermedad metastásica tras el efecto terapéutico de la quimioterapia neoadyuvante. Esto aumenta hasta casi el 90% cuando se trata de axilas metastásicas ocultas detectadas mediante el ganglio centinela antes de iniciar la quimioterapia neoadyuvante.

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Introduction

The term locally advanced breast cancer (LABC) includes large tumors which are sometimes associated with skin and/or the chest wall involvement or present fixed axillary lymph nodes, involvement of the internal ipsilateral mammary lymph node chain or the supraclavicular lymph nodes and also includes the inflammatory histological type. According to the TNM classification of the 7th Edition of the American Joint Committee on Cancer (AJCC) LABC corresponds to stage IIB and III tumors which are initially considered as non-resectable.¹ From 5% to 10% of the breast cancers debut as locoregionally advanced disease. Primary systemic therapy or neoadjuvant chemotherapy (NCT) is the standard treatment of choice in LABC (T4, N2–N3). On the other hand, evidence of a high rate of complete response (CR) achieved in some subtypes of initially operable less advanced breast cancers has also made NCT an option in earlier stage IIA (cT2cN0M0) tumors.^{2,3}

The main objectives of NCT are to reduce the tumor size (requiring a larger number of conservative surgical interventions), predict the prognosis of the disease according to tumor response to chemotherapy, reduce or eliminate distant micrometastases and monitor response to antineoplastic treatment *in vivo*.⁴

For correct initial disease staging in breast cancer, physical examination is performed by breast and axillary palpation in addition to different complementary imaging methods (ultrasonography, mammography, MR and PET-CT). In cases in which the axilla is suspected of malignancy confirmation is recommended by fine needle aspiration puncture (FNAP) and/or lymph node biopsy. To the contrary, when the axilla is clinically and radiologically not pathological, radioguided sentinel lymph node biopsy (RGSLSNB) is the technique of choice for adequate initial regional staging.^{5–8}

The definitive test to assess response to systemic neoadjuvant treatment is pathological examination. Complete disappearance of tumoral disease in the breast and axilla is considered as CR. Approximately 40% of the patients with triple-negative tumors and around 60% of those with human epidermal growth factor receptor type 2 (HER2) positive tumors achieve CR after completion of neoadjuvant treatment. Some patients with luminal B tumors and a high proliferative index also achieve CR, although the percentage in this subgroup is much lower at less than 10%.^{9,10}

The aim of this study was to compare metastatic axillary involvement at diagnosis (N+) with the final histopathological result in the axilla on completion of NCT.

Material and methods

Patients

We performed a retrospective study from November 2011 to September 2013 including all the cases with criteria of LABC according to size and/or lymph node involvement and who were candidates to receive systemic neoadjuvant treatment.

1.1.1. Inclusion criteria

- Both males and females of any age.

- Histological confirmation of invasive mammary carcinoma.
- Histological study of axillary lymph node tissue prior to initiating neoadjuvant treatment.
- Stages II and III (cT2–4 cN0–3 M0) according to the TNM classification of the 7th edition of the AJCC.
- Absence of evidence of distant metastasis at the time of diagnosis.
- Molecular taxonomy study of the tumor.
- Standard line of neoadjuvant chemotherapy treatment with 4–6 three-month cycles of docetaxel combined with trastuzumab in HER2-positive cases and carboplatin/adriamycin in HER2-negative cases according to the criteria of the multidisciplinary team.
- Multidisciplinary treatment by the Breast Disease Unit of our center.
- Signed informed consent.

1.1.2. Exclusion criteria

- Progression of metastasis during treatment.
- Surgery undergone in another hospital.

The breast and axilla studies were performed by physical examination and diagnostic imaging, including mammography, ultrasonography and MR. PET-CT was also carried out in some particular cases according to the criteria of the multidisciplinary team. Clinical and/or radiological suspicion of axilla malignancy was confirmed by FNAP and/or ultrasound (US)-guided lymph node biopsy. In cases with no suspected lymph node involvement, staging was made by RGSLSNB prior to beginning NCT.

In all the cases the RGSLSNB technique consisted of an intradermal, periareolar injection of 4 doses of 1 mCi (37 MBq) of ^{99m}Tc-albumin nanocolloid (Nanocoll®, General Electric). A lymphoscintigraphy was performed with the acquisition of sequential planar images at 30 and 60 min post-injection and immediately after a SPECT-CT of the chest with a dual-head gamma camera (Infinia Hawkeye 4, General Electric Healthcare). Afterwards, surgical sentinel lymph node (SLN) resection was undertaken guided by a gamma probe (Crystal photonics) as well as a portable gamma camera (Sentinella S102, Oncovision) which allows double confirmation of the absence of radioactivity in the surgical bed.

On finding axillary metastasis (N+) by FNAP/US-guided biopsy or RGSLSNB at diagnosis, axillary lymph node dissection (ALND) was performed after having completed NCT, independently of the clinical and radiological response obtained in the axilla and the primary tumor.

Histologic study

Histologic diagnosis of the primary tumor was obtained by FNAP or thick needle biopsy, which was always followed by an immunohistochemical study by fluorescent *in situ* hybridization (FISH) when the Herceptest was erroneous. The determinations made in the primary tumor sample were histological type, estrogen receptors (ER), progesterone receptors, HER2 and the Ki67 proliferation index. Four molecular subtypes were classified according to the expression of the ER, PR, HER2 and Ki67 based on the genomic

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