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Original article

## Evaluation of axillary involvement by ultrasound-guided lymph node biopsy: A prospective study



*Évaluation de l'envahissement ganglionnaire axillaire par un prélèvement échoguidé : étude prospective*

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### ABSTRACT

**Objectives.** – The primary aim of this prospective study was to evaluate the accuracy of pre-operative ultrasound (US) alone and associated with a fine needle aspiration cytology (FNAC) or a core needle biopsy (CNB) in the diagnosis of axillary node involvement in patient with breast cancer. The secondary study objective was to determine if this US ± FNAC or CNB can lead to the adequate axillary surgery in cN0 and cN1 patient.

**Methods.** – A total of 121 consecutive women with stage cT1 to cT2, cN0/cN1, invasive breast cancer were prospectively identified at our institution between February 2, 2013 and August 30, 2013. The sensitivity, specificity, VPP, NPV were calculated, with confidence intervals, using the definitive histological result of the sentinel node biopsy (SLNB) or axillary lymph node dissection (ALND) as the baseline.

**Results.** – Twenty-seven CNB and 2 FNAC were performed. For the whole series, the sensitivity and the specificity of US alone were 48.7% [36–59%] and 89% [83–94%]. For US ± FNAC or CNB, the sensitivity and the specificity were 35.9% [26–38%] and 98.8% [94–100%]. Seven women with cN1 clinical examination had SLNB, which permit to decrease the number of ALND of 16.3%. It would have avoided unnecessary SLNB, prompting immediate ALND in 9 patients with cN0 axillae, which means a reduction of SLNB of 8.6%. US ± FNAC or CNB lead to the adequate surgery in 72.7% of cases.

**Conclusion.** – US ± CNB or FNAC is also a relatively efficient and safe test and should be considered routinely. It allowed triaging patients to the well axillary surgery (SLNB or ALND).

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### R É S U M É

**Objectifs.** – L'objectif principal de cette étude était d'évaluer les performances de l'échographie axillaire associée ou non à un prélèvement axillaire histologique ou cytologique échoguidé (PA) dans la stadification ganglionnaire pré-thérapeutique chez les patientes ayant un cancer du sein. L'objectif secondaire était de déterminer si cette échographie associée ou non à un PA permettait de décider du bon geste axillaire chez les patientes cN0 et cN1.

**Méthodes.** – Les résultats de 121 échographies axillaires, chez des patientes cN0/cN1 prises en charge par chirurgie première, ont été recensés de façon prospective entre le 2 février et le 30 août 2013. La sensibilité, la spécificité, la VPP et la VPN étaient calculés en utilisant comme critère de jugement l'envahissement du creux axillaire évalué par un ganglion sentinelle (GS) ou un curage axillaire (CA).

#### Mots clés :

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**Résultats.** – Vingt-sept PA ont été réalisés (25 microbiopsies et 2 cytoponctions). Sur l'ensemble de la population, la sensibilité et la spécificité étaient de 48,7 % [36–59 %], et 89 % [83–94 %] pour l'échographie seule. La sensibilité et la spécificité étaient de 35,9 % [26–38 %], et 98,8 % [94–100 %] pour l'échographie associée à un PA. Sept patientes cN1 ont pu bénéficier d'une procédure du GS, ce qui a diminué le nombre de CA de 16,3 %. Neuf patientes cN0 ont pu bénéficier d'un CA leur évitant un GS inutile. Le couple échographie associée ou non à un PA a permis de réaliser le bon geste axillaire (GS ou CA) dans 72,7 % des cas.

**Conclusion.** – L'échographie axillaire associée à un PA est un examen sensible et très spécifique pour déterminer le statut axillaire et permettre de réaliser le bon geste axillaire.

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## 1. Introduction

Locoregional lymph node involvement is a key element in the staging of patients with invasive breast cancer. Lymph node status represents a major prognostic factor and can influence adjuvant treatment, such as radiotherapy, intra-operative accelerated partial breast radiotherapy, immediate reconstruction and axillary surgery in case of neoadjuvant chemotherapy. Sentinel lymph node biopsy (SLNB) has supplanted axillary node dissection (ALND) as the gold standard for the operative nodal staging of T1-2 N0 breast cancer. The decision to limit axillary lymph node dissection to SLNB is based on the clinical and radiological examination of the axillae. Although SLNB is less invasive and associated with lower morbidity, up to 50% of sentinel nodes will contain tumor deposits and require complete ALND [1]. However, some criteria have changed since the publication of the ACOSOG-Z0011 trial especially in patients with micrometastasis [2].

No pre-operative non-invasive exam is sufficiently accurate to determine node status before surgery [3]. Multiple non-surgical methods have been used with varying success to predict lymph node involvement, including physical examination, digital mammography, ultrasonography, computed tomography (CT) scan, positron emission tomographic (PET) imaging and magnetic resonance imaging (MRI) [4–11]. Physical examination, the oldest method of investigation of axillary lymph nodes, has limited reliability, and thus, axillary ultrasound (US) with fine needle cytology (FNAC) or core needle biopsy (CNB) has become the standard for pre-operative evaluation of axillary lymph nodes [12]. When there are no palpable nodes (cN0), identifying axillary node involvement pre-operatively can save the patient and surgeon a SLNB procedure and can reduce operating time. Conversely, when there are palpable nodes (cN1), if the combination of US ± FNAC or CNB shows no node involvement, ALND can be avoided and SLNB can be performed. Accurately screening patients to determine whether axillary lymph nodes are suspicious is necessary to refer the patient for the appropriate type of axillary surgery.

In this paper, we present a prospective study whose primary objective was to evaluate the accuracy of pre-operative US alone and associated with FNAC or CNB (in terms of sensitivity, specificity, positive (PPV) and negative predictive value (NPV)) for the diagnosis of axillary lymph node involvement in patients with breast cancer. The secondary objective was to determine whether US associated or not with axillary biopsy leads to appropriate axillary surgery in cN0 and cN1 patients.

## 2. Methods

### 2.1. Patients

This study was approved by the ethics committee and scientific board of the Georges-François-Leclerc Cancer Center. The committee considered that US ± FNAC or CNB constituted routine treatment, since this is the treatment recommended by the National

Cancer Institute and, therefore, the need for informed consent was waived.

The data were prospectively collected between February and August 2013. Patients undergoing surgery for invasive breast cancer, cN0 or cN1, T1 or T2 were prospectively reviewed. Patients with a clinical finding of nodes fixed to each other, patients with T3 or T4 tumor, patients with ductal or lobular carcinoma in situ and those treated with pre-operative chemotherapy were excluded from the study.

The following data are prospectively recorded for all patients: age, cT stage, cN stage, multifocal tumor, US tumor size, tumor type, histologic size, Scarff-Bloom-Richardson (SBR) classification, Ki67, estrogen receptor status, progesterone status, HER2 overexpressed or amplified, immunochemistry classification (luminal A, luminal B, luminal B HER2, triple negative), HER2 overexpressed or amplified, surgical techniques and pathological result (breast conserving surgery, mastectomy, SLNB, number of sentinel nodes (SN), result of frozen section of SN, combination of serial sectioning and immunochemistry, ALND, number of metastatic nodes in ALND).

### 2.2. Physical examination

Physical examination was performed by the radiologist before mammography and US. Physical examination was considered as normal if no axillary lymph nodes were palpable, and considered as abnormal if one or more movable axillary lymph nodes were palpable.

### 2.3. Ultrasound and final reference standard

The US, FNAC and CNB were performed by one of 5 dedicated breast radiologists using a Toshiba Aplio<sup>®</sup> or Xario<sup>®</sup> machine (Toshiba Medical Systems<sup>®</sup>, Zoetermeer, Netherlands) and a high frequency (8 MHz) linear array probe at the time of examination of the primary tumor. All patients underwent US imaging of the ipsilateral and contralateral axillary lymph nodes. The radiologist categorized the axillary lymph nodes as normal or suspicious. The radiological criteria for classifying a lymph node as suspicious were a round shape, a hypoechoic cortex, a local or a general thickening of the cortex, and a loss of symmetry compared the other side. If a lymph node was suspected to be pathological, FNAC or CNB was performed, at the discretion of the operator. US-guided CNB was performed using a 14- or 16-G spring-loaded Magnum<sup>®</sup> core biopsy device (Bard Biopsy Systems, Tempe, AZ, USA). US-guided FNAC was performed with a 21-G needle (BD Mircolance 3<sup>®</sup>). In case of cytologically proven axillary metastasis, the patient underwent primary ALND. If the US was normal or if the result showed normal lymphatic tissue, SLNB using radiocolloid and blue dye injection was performed, followed by ALND for sentinel node positivity. As per the American Joint Committee on Cancer breast cancer stage classification published in 2010, any patients with isolated tumor cells (pN0(i+)) were considered to be node-negative and did not undergo any additional lymph node surgery [13].

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