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Intra-operative evaluation of the sentinel lymph node for T1-N0 breast-cancer patients: Always or never? A risk/benefit and cost/benefit analysis

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Abstract

Aim: To investigate whether omitting intra-operative staging of the sentinel lymph node (SLN) in T1-N0 breast-cancer patients is feasible and convenient because it could allow a more efficient management of human and logistic resources without leading to an unacceptable increase in the rate of delayed axillary lymph node dissection (ALND).
Methods: According to the experimental procedure, T1a–T1b-patients were to not receive any intra-operative SLN evaluation on frozen sections (FS). In all T1c-patients, the SLN was macroscopically examined; if the node appeared clearly free of disease, no further intra-operative assessment was performed; if the node was clearly metastatic or presented a dubious aspect, the pathologist proceeded with analysis on FS. T2-patients, enrolled in the study as reference group, were treated according to the institutional standard procedure; they all received SLN staging on FS.
Results: The study included 395 T1-N0-patients. Among the 118 T1a–T1b-patients whose SLN was not analyzed at surgery, 12 (10.2%) were recalled for ALND. In the group of 258 T1c-patients, 112 received SLN analysis on FS and 146 did not. An SLN falsely negative either at macroscopic or FS examination was found in 33 (12.8%) cases. Overall, the rate of recall for ALND was 11.6% as compared to 8.4% in T2-patients. Using the experimental protocol, the institution reached a 9.6% cost saving, as compared to the standard procedure.
Conclusions: Omission of SLN intra-operative staging in T1-N0-patients is rather safe. It provides the institution with both management and economical advantages.

Keywords: Breast-cancer; Sentinel lymph node; Intra-operative evaluation; Axillary lymph node dissection

Introduction

Resection of the primary tumor together with axillary lymph node dissection (ALND) has long been the standard surgical management of early-stage breast-cancer. However, axillary metastases are found in only ~40% of the cases;[1,2] the remaining patients derive no benefit from axillary surgery but unnecessarily face common morbidities from ALND.[3] For patients with early-stage tumor (T1–T2) and clinically negative lymph nodes (N0), this problem is now obviated by the use of the sentinel lymph node biopsy (SLNB). This minimally invasive, safe and acceptably accurate procedure has a high negative predictive value for axillary status[4–6] and is nowadays the recommended method for axilla staging.[7–9]

Nevertheless, several aspects need further evaluation: 1) is ALND mandatory for all patients with metastatic SLN?; 2) what is the prognostic significance of SLN micrometastases, particularly those evidenced only by immunohistochemistry, and of isolated tumor cells? 3) can patients presenting both SLN micrometastasis and small-size tumor be spared ALND? 4) is it necessary to always perform SLNB and, when needed, ALND during the initial surgery or could these procedures be postponed in specific instances?

This last question emerges from several considerations[8,10,11]: screening mammography has increased the

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proportion of patients presenting a ≤1 cm tumor; these patients have a low probability of nodal disease as the incidence of positive SLN increases with tumor size; the presence of SLN micrometastases is predominantly associated with pT1a–1b tumors; intra-operative false-negative SLN staging on frozen sections (FS) is largely due to the failure to detect micrometastasis by hematoxylin–eosin; pT1c–pT2-patients mostly benefit from FS examination since the sensitivity of the procedure increases with tumor size.

Based on these considerations, the present study was designed to investigate whether intra-operative SLN staging on FS could be omitted in T1-N0-patients and deferred to definitive evaluation on paraffin sections (PFS). As for risk/benefit and cost/benefit, we hypothesized that this approach could provide patients with shorter surgery duration and hospital stay without substantially increasing the rate of second surgery for ALND, but allowing more efficient use of human resources and logistic facilities.

Patients and methods

Study hypothesis

The main hypothesis was that intra-operative SLN evaluation on FS could be omitted, with measurable efficiency gains, in all patients clinically staged T1a–T1b, and in the subgroup of T1c-patients presenting a SLN macroscopically free of disease. We investigated whether this approach was associated with an unacceptably high rate of recall for ALND, thereby counterbalancing/nullifying the advantages deriving from the reduced duration of the initial surgery. The rate of delayed ALND in T2-patients due to false-negative SLN on FS, was used as reference. Indeed, an overview of our whole case series across the period 1998–2004 has given an acceptable false-negative rate of 8–9%.

A second objective was to assess the accuracy and negative predictive value of the macroscopic evaluation performed by the pathologist in T1c-patients.

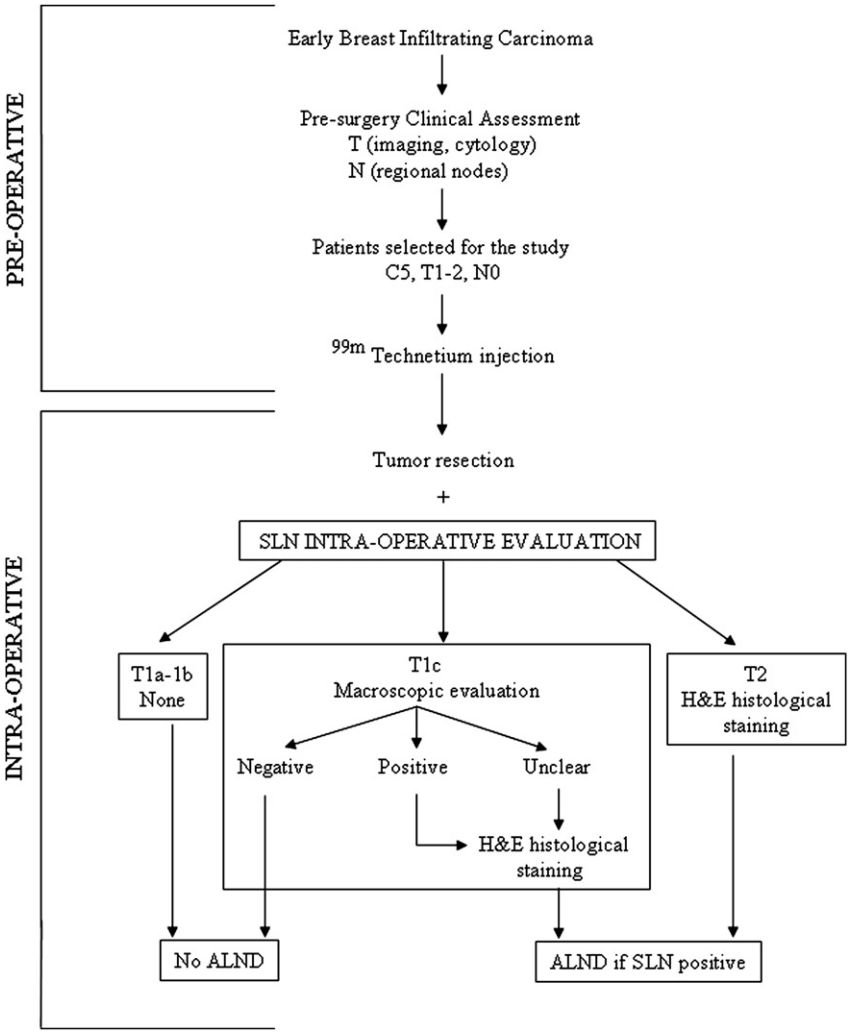

Fig. 1. Study design and protocol both for intra-operative evaluation of the sentinel lymph node and complete axillary dissection. SLN, sentinel lymph node; H&E, hematoxylin–eosin; ALND, axillary lymph node dissection.