

Original Research

Impact of completion axillary lymph node dissection in patients with breast cancer and isolated tumour cells or micrometastases in sentinel nodes



G. Houvenaeghel ^{a,q,*}, J.M. Boher ^{o,p}, F. Reyal ^b, M. Cohen ^a, J.R. Garbay ^c, J.M. Classe ^d, R. Rouzier ^e, S. Giard ^f, C. Faure ^g, H. Charitansky ^h, C. Tunon de Lara ⁱ, E. Daraï ^j, D. Hudry ^k, P. Azuar ¹, P. Gimbergues ^m, R. Villet ⁿ, P. Sfumato ^{o,p}, E. Lambaudie ^a

- ^a Institut Paoli Calmettes and CRCM, 232 Bd Ste Marguerite, Marseille, France
- ^b Institut Curie, 26 rue d'Ulm, 75248, Paris, France
- ^c Institut Gustave Roussy, 114 rue Edouard Vaillant, Villejuif, France
- ^d Institut René Gauducheau, Site hospitalier Nord, St Herblain, France
- ^e Centre René Huguenin, 35 rue Dailly, Saint Cloud, France
- f Centre Oscar Lambret, 3 rue Frédéric Combenal, Lille, France
- ^g Centre Léon Bérard, 28 rue Laennec, Lyon, France
- ^h Centre Claudius Regaud, 20-24 rue du Pont St Pierre, Toulouse, France
- ⁱ Institut Bergonié, 229 Cours de l'Argonne, Bordeaux, France
- ¹ Hôpital Tenon, 4 rue de la Chine, Paris, France
- ^k Centre Georges François Leclerc, 1 rue du Professeur Marion, Dijon, France
- ¹ Hôpital de Grasse, Chemin de Clavary, Grasse, France
- ^m Centre Jean Perrin, 58 rue Montalembert, Clermont Ferrand, France
- ⁿ Hôpital des Diaconnesses, 18 rue du Sergent Bauchat, Paris, France
- ° Department of Biostatistics and Methodology, Institut Paoli Calmettes, 13009, France
- ^p Aix-Marseille University, Unité Mixte de Recherche S912, Institut de Recherche pour le Développement, 13385, Marseille,

France

^q Aix Marseille Université, France

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KEYWORDS Axillary lymph node dissection; **Abstract** *Background:* Omission of completion axillary lymph node dissection (ALND) is a standard practice in patients with breast cancer (BC) and negative sentinel nodes (SNs) but has shown insufficient evidence to be recommended in those with SN invasion.

* Corresponding author: Institut Paoli Calmettes, 232 Bd de Sainte Marguerite, 13009, Marseille, France. Fax: +33 491223613. E-mail addresses: g.houvenaeghel@orange.fr, houvenaeghelg@ipc.unicancer.fr (G. Houvenaeghel).

http://dx.doi.org/10.1016/j.ejca.2016.08.003 0959-8049/© 2016 Elsevier Ltd. All rights reserved. Breast cancer; Sentinel node; Micrometastases; Isolated tumour cells *Methods:* A retrospective analysis of a cohort of patients with BC and micrometastases (Mic) or isolated tumour cells (ITCs) in SN. Factors associated with ALND were identified, and patients with ALND were matched to patients without ALND. Overall survival (OS) and recurrence-free survival (RFS) were estimated in the overall population, in Mic and in ITC cohorts.

Findings: Among 2009 patients analysed, 1390 and 619 had Mic and ITC in SN, respectively. Factors significantly associated with ALND were SN status, histological type, age, number of SN harvested and absence of adjuvant chemotherapy. After a median follow-up of 60.4 months, ALND omission was independently associated with reduced OS (hazard ratio [HR] 2.41, 90 confidence interval [CI] 1.36-4.27, p = 0.0102), but not with increased RFS (HR 1.21, 90 CI 0.74-2.0, p = 0.52) in the overall population. In matched patients, the increased risk of death in case of ALND omission was found only in the Mic cohort (HR 2.88, 90 CI 1.46-5.69), not in the ITC cohort. The risk of recurrence was also significantly increased in the subgroup of matched Mic patients (HR 1.56, 90 CI 0.90-2.73).

Interpretation: A separate analysis of Mic and ITC groups, matched for the determinants of ALND, suggested that patients with Mic had increased recurrence rates and shorter OS when ALND was not performed. Our results are consistent with those of previous studies for patients with ITC but not for those with Mic. Randomised controlled clinical trials are still warranted to show with a high level of evidence if ALND can be safely omitted in patients with micrometastatic disease in SN.

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Research in context

Evidence before this study

A search in Medline/PubMed was undertaken using the following terms: breast cancer, sentinel nodes, axillary lymph node dissection, overall survival, recurrence-free survival, adjuvant chemotherapy, and radiotherapy. Studies were selected upon criteria of higher level of evidence. This literature review showed that omission of ALND was recognised as standard practice in patients with BC and negative SN. In those with SN invaded by micrometastases (Mic) or ITC, two randomised trials showed no increased recurrence rates in patients who did not undergo ALND, but the level of evidence is too low to recommend this attitude in current practice.

Added value of this study

Our findings are consistent with those of the main randomised trials that showed that ALND can be safely omitted in patients with BC and ITC in SN. However, they differ from those previously published for patients with Mic: while other studies found no negative impact of ALND omission, we observed increased recurrence rates and reduced OS in this subgroup of patients.

Implications of all the available evidence

Our findings suggest that ALND omission might not be safe in patients with Mic in SN. Before ALND omission in this population becomes current practice, more evidence from well-designed randomised studies is warranted.

1. Introduction

It is now admitted that omission of completion axillary lymph node dissection (ALND) is safe and avoids the adverse effects of ALND in patients with breast cancer (BC) and negative sentinel nodes (SNs) [1]. Several studies evaluated the non-inferiority of ALND omission in patients with SN invasion [2-4]. The randomised trials ACOSOG Z0011 (1 or 2 Mic in SN) [2] and IBCSG 23-01 (isolated tumour cells [ITCs] or Mic in SN) [3] supported the non-inferiority of ALND omission, without statistical differences in recurrence-free survival (RFS) rates between ALND omission and systematic ALND. However, current data are considered insufficient to support new standard practices of ALND omission when SN is invaded. An ongoing randomised study is assessing the non-inferiority of ALND omission versus ALND, in order to provide more evidence to recommend this strategy [5]. In the meantime, the aim of our work was to assess the impact of ALND omission on overall survival (OS) and RFS in a large cohort of patients with BC and Mic or ITCs in SN and to identify factors that determine the decision to perform ALND.

2. Methods

Patients with histologically proven invasive $BC \le 5$ cm, clinically negative axillary lymph nodes (LNs), absence of neoadjuvant therapy, and LN status determined upon SN biopsy were included if the pathological examination

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