

# Can Genomic Profiling and Preoperative Axillary Ultrasound Eliminate the need for Sentinel Lymph Node Biopsy in Early-stage, ER-positive Breast Cancer?

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## BACKGROUND

- NCCN guidelines now allow for genomic profiling (such as Oncotype DX Recurrence Score [RS]) to determine whether to recommend chemotherapy for patients with breast cancer (BC) and 1-3 positive nodes (N1).
- Given the risks of sentinel lymph node biopsy (SLNB), there is interest in omitting SLNB when it will not benefit the patient.

## AIMS

This study aims to evaluate how SLNB influences treatment recommendations when RS is used in N0-N1 disease. We hypothesized that SLNB would change the recommendation to have chemotherapy in <5% of patients, when RS is used in N0-N1 disease.

## METHODS

Patients treated at the Rebecca Fortney Breast Center in Annapolis, Maryland from 11/2011 - 12/2015 were reviewed. We included postmenopausal women with ER-positive, HER2-negative, pT1-2 BC, and non-suspicious axillary ultrasound. For each patient, we compared the recommended adjuvant therapy (per NCCN guidelines) based on actual SLNB results, versus the recommendation had SLNB been not performed (presumed negative). For N0 and N1 cases, RS was considered in making chemotherapy recommendations (see Table legend). When RS was not available, RS was estimated with the BC Recurrence Score Estimator from the Johns Hopkins University.

## RESULTS

Table 1. Comparison of adjuvant treatment recommendation based on SLNB result vs. presumed negative SLNB.

	Based on actual SLNB result	Based on presumed negative SLNB	% for whom SLNB would change treatment recommendation*
ALND recommended <sup>1</sup>	12	0	6.0%
Nodal radiation recommended <sup>2</sup>	4	0	2.0%
Nodal radiation considered <sup>3</sup>	27	0	13.5%
Chemotherapy recommended <sup>4</sup>	33	30	1.5%
Chemotherapy considered <sup>5</sup>	7	0	3.5%
Third generation chemotherapy recommended <sup>6</sup>	9	0	4.5%
Third generation chemotherapy considered <sup>7</sup>	7	0	3.5%

\*using total cohort (n = 199) as denominator

- 1) For > 2 positive SLN or extranodal extension.
- 2) For N2-3 disease.
- 3) For Nmi-N1 disease.
- 4) For N2-N3, Nmi-N1 with RS > 25, or N0 with RS > 25 and ≥ T1b
- 5) For Nmi-N1 disease with RS 18-25.
- 6) For Nmi-N1 disease with RS > 25; or N2-N3.
- 7) For Nmi-N1 disease with RS 18-25.

## RESULTS (CON'T)

- Of 199 included patients, N category was as follows: N0, n = 168 (84.4%); Nmi-N1, n = 27 (13.6%); N2-N3, n = 4 (2.0%).
- Of the 27 patients with Nmi-N1 disease, 16 patients had RS estimated with the BC Recurrence Score Estimator from the Johns Hopkins University.
- In 5.0% of patients, the recommendation to have chemotherapy changed from “not recommended” to either “considered” or “recommended” (Table), based on SLNB results.
- 8.0% of patients had a change in the chemotherapy regimen recommended based on SLNB (i.e. chemotherapy not recommended without SLNB, but considered or recommended with SLNB; or a change in the particular chemotherapy regimen that was considered/recommended).
- In the 168 node-negative cases, SLNB did not affect treatment recommendations.
- There were 6 node positive cases with RS > 25, in whom chemotherapy was recommended regardless of SLNB results.
- There were 15 Nmi-N1 cases with RS < 18, for whom chemotherapy was not recommended despite positive SLNB.

## CONCLUSIONS

SLNB changed whether chemotherapy was recommended for only 5% of patients. With increasing role for genomic profiling (decreasing the role of nodal status in determining treatment) and preoperative axillary ultrasound (decreasing the rate of unexpected positive SLN), the role of SLNB in determining adjuvant therapy is diminishing. When chemotherapy would not be considered, omission of SLNB can be considered in postmenopausal patients with low-risk breast cancer and non-suspicious axillary ultrasound. If genomic profiling were performed prior to surgery, the results could change surgical management, reserving SLNB for women with intermediate genomic risk in whom positive SLN could change chemotherapy recommendation. This treatment paradigm requires prospective validation. This approach to avoid axillary surgery relies on routine preoperative axillary ultrasound for early-stage breast cancers, as ultrasound has a higher sensitivity than physical exam to detect occult nodal metastasis.