Patients with small, clinically and imaging node-negative, HR-positive/HER2-negative early breast cancer undergoing mastectomy do not show increased node-positivity and missed adjuvant systemic treatment options

Martin Heidinger, MD[1,2,3], Giacomo Montagna, MD, MPH[4], Florian S. Halbeisen[5], Nadia Maggi, MD[1,2,3], Marie Louise Frevert, MD[1,2], Rama Kiblawi, MD[1,2], Julie M. Loesch, MD[1,2], Fabienne D. Schwab, MD[1,2,3], Christian Kurzeder, MD[1,2,3], Tibor A. Zwimpfer, MD[2,3], Walter P. Weber, MD[1,3]

[1] Breast Clinic, University Hospital Basel, Basel, Switzerland; [2] Gynaecology & Obstetrics, University Hospital Basel, Basel, Switzerland; [3] University of Basel, Basel, Switzerland; [4] Breast Service, Department of Surgery, Memorial Sloan Kettering Cancer Center, New York, New York; [5] Surgical Outcome Research Center, University Hospital Basel and University of Basel, Basel, Switzerland

Abstract #998

Introduction

The SOUND/INSEMA trials demonstrated oncological non-inferiority of sentinel lymph node biopsy (SLNB) omission in patients with small, clinically and imaging node-negative (cN0/iN0), hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer (BC) undergoing breast-conserving treatment (BCT)[1,2]. SLNB omission in the same cohort of patients undergoing mastectomy has not been studied. This study aimed to identify factors associated with nodal positivity and adjuvant treatment indications in this population after BCT or mastectomy.

Would SLNB omission in SOUND/INSEMA eligible patients undergoing mastectomy lead to an increased rate of missed node-positivity or missed adjuvant treatment indications compared to those after BCT?

Methods

- Retrospective single-center cohort, prospectively maintained database.
- Patients with cT1-T2, cN0/iN0, HR+/HER2- early BC.
- Breast conserving therapy or mastectomy including SLNB between 01/2014 and 12/2024.

Adjuvant treatment indications based on node-criteria as shown in the table.

Treatment	Indication
Abemaciclib[3] *monarchE*	• ≥4 positive lymph nodes • 1-3 positive lymph nodes and either grade 3 disease, or tumor size ≥5cm, or Ki67 ≥20%
Ribociclib[4] *NATALEE*	• pT1pN1 (excluding pN1mi) • pT2pN1*
Nodal irradiation *MA20*[5], *EORTC22922/10925*[6], *international guidelines, institutional guidelines*	Absolute indication: Breast conserving surgery** • ≥3 macrometastatic nodes • 1-3 macrometastatic nodes and medially/centrally located tumor • 1-3 macrometastatic nodes and ≥pT2 and grade 3 Mastectomy** • ≥2 macrometastatic nodes Relative indication: Breast conserving surgery** • ≥1 macrometastatic node Mastectomy** • ≥1 macrometastatic node

* provided that no additional criteria would render the pT2 status per se eligible for ribociclib treatment (i.e., grade 3; or grade 2 plus Ki67 ≥20% or grade 2 plus Oncotype Dx RS of ≥26), irrespective of nodal status

** provided that no non-nodal criteria would render the patient eligible for nodal radiotherapy (premenopausal and medially/centrally located tumor and grade 3 and ≥pT2; or premenopausal and medially/centrally located tumor and ≥pT3)

Statistical analysis

Multivariable logistic regression to evaluate associations of nodal positivity and adjuvant treatment indications with clinicopathological features (R [v4.2.2]).

Results

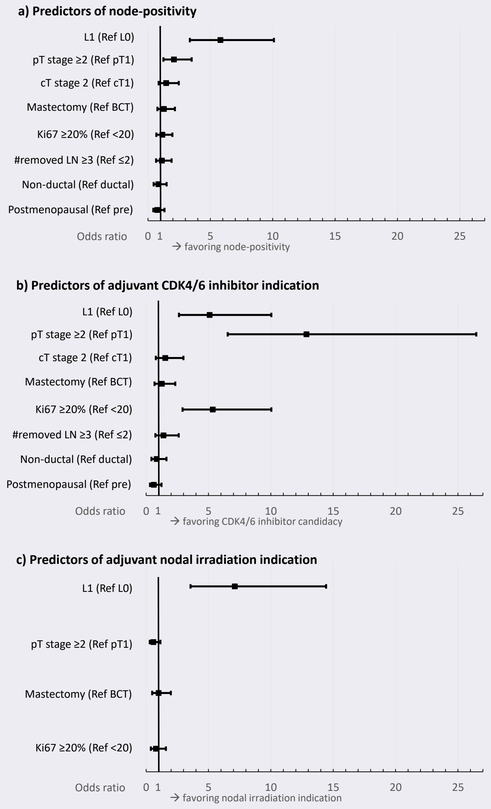
Table 1. Patient and tumor characteristics

Characteristic	Breast-conserving therapy n=309	Mastectomy n=145	p-value
Menopausal status			0.021
Pre, n(%)	66 (21.4%)	45 (31.0%)	
Post, n(%)	241 (78.0%)	97 (66.9%)	
Clinical tumor stage			0.050
cT1, n(%)	223 (72.2%9	91 (62.8%)	
cT2, n(%)	86 (27.8%)	54 (37.2%)	
Risk features			
Lobular, n(%)	34 (11.0)	32 (22.1)	0.006
Multifocal, n(%)	30 (9.7)	34 (23.5)	<0.001
Grade III, n(%)	37 (12.0)	29 (20.0)	0.026
Pathologic nodal stage			0.162
pN0, n(%)	264 (85.4)	119 (82.1)	
pN+, n(%)	45 (14.6)	26 (17.9)	
Number of positive lymph nodes			0.149
One, n(%)	37 (12.0%)	19 (13.1%)	
Two, n(%)	6 (1.94%)	7 (4.8%)	
≥Three, n(%)	3 (1.0%)	1 (0.7%)	

Table 2. Adjuvant treatment indications based on node-criteria

	Breast-conserving therapy	Mastectomy	p-value
CDK4/6 inhibitor			
Abemaciclib, n/N(%)	19/309 (6.1)	11/145 (7.6)	0.550
Abemaciclib, cT1, n/N(%)	10/223 (4.5)	4/91 (4.4)	1.000
Ribociclib, n/N(%)	24/309 (7.8)	14/145 (9.7)	0.586
Ribociclib, cT1, n/N(%)	18/223 (8.1)	9/91 (9.9)	0.658
Nodal irradiation			
Absolute indication			
All patients, n/N(%)	14/309 (4.5)	7/145 (4.8)	1.000
cT1, n/N(%)	8/223 (3.6)	6/91 (6.6)	0.242
Relative indication			
All patients, n/N(%)	29/309 (9.4)	15/145 (10.3)	0.736
cT1, n/N(%)	18/223 (8.1)	9/91 (9.9)	0.658

Figure 1. Multivariable analysis of factors associated with a) nodal positivity, b) CDK4/6 inhibitor indications, and c) nodal irradiation indication



Discussion

- Patients undergoing mastectomy do present with larger, multifocal tumors, which are more frequently high grade and of lobular histology.
- Results on missed adjuvant treatment indication are consistent between the total cohort and patients with cT1 BC.
- Lymphovascular invasion was found to be a common predictor for node-positivity and adjuvant treatment indication.
- Particularly in postmenopausal women with low-risk tumors undergoing mastectomy SLNB is not thought to impact adjuvant treatment indications.

Conclusions

- In patients with cT1-cT2, cN0/iN0, HR+/HER2- early BC, type of surgery was not associated with node-positivity or adjuvant treatment eligibility.
- In appropriately selected patients, omission of SLNB may be considered even in the setting of a mastectomy.
- Further investigation of the extension of SLNB omission eligibility to patients undergoing mastectomy is warranted.

References

1. Gentilini, OD et al. JAMA Oncol. 2023;9(11):1557-1564
2. Reimer, T et al. New England Journal of Medicine. 2025;392(11):1051-1064
3. Rastogi, P et al. Journal of Clinical Oncology. 2024 Mar 20;42(9):987-993.
4. Hortobagyi, GN et al. Annals of Oncology. 2024;36(2):149-157
5. Whelan, T et al. New England Journal of Medicine. 2015;373(4):307-316
6. Poortmans, P et al. New England Journal of Medicine. 2015;373(4):317-327

San Antonio Breast Cancer Symposium®, December 9-12, 2025

This presentation is the intellectual property of the author/presenter. Contact them at martin.heidinger@usb.ch for permission to reprint and/or distribute.
Copies of this poster obtained through Quick Response (QR) Code are for personal use only and may not be reproduced without permission from SABCS® and the author.