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Omission of Sentinel Lymph Node Biopsy

Pro

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Disclosures

Has no relevant financial relationships

Disclaimers

ASCO Special Articles

Sentinel Lymph Node Biopsy in Early-Stage Breast Cancer: ASCO Guideline Update

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Medical Debate Gaslighting: A form of psychological manipulation where one person subtly (or not so subtly) tries to make another doubt their sanity, perception of reality, or memory – maybe by trying to convince you that a practice changing guideline (see above) does not really exist.

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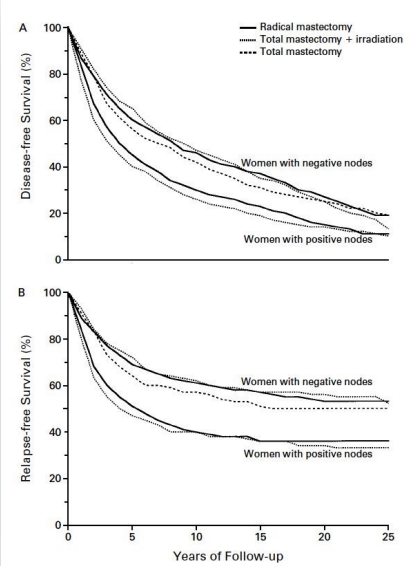
Arguments regarding surgical axillary staging

Why not:

- **NSABP B-04: Outcomes based on clinical nodal status**



Why:

- **Bonadonna et al: Differing outcomes based on extent of nodal disease**

Table 1. Characteristics of 179 Control Patients and 207 Patients Treated with Cyclophosphamide, Methotrexate and Fluorouracil (CMF), with Observed Failure Proportions.

Characteristic	Evaluable Patients				P Value
	Control		CMF		
	no.	*%*	*no.*	*%*	
Total with recurrence:	43/179	24.0	11/207	5.3	$<10^{-6}$
Nodes:					
1-3	21/125	16.8*	5/139	3.6	$<10^{-3}$
≥4	22/54	40.7*	6/68	8.8	$<10^{-4}$
Age:					
≤49 yr	17/74	22.9	6/95	6.3	$<10^{-2}$
≥50 yr	26/105	24.7	5/112	4.4	$<10^{-4}$
Menopause:					
Pre	20/82	24.3	5/95	5.2	$<10^{-3}$
Post	23/97	23.7	6/112	5.3	10^{-4}
Mastectomy:					
Radical	26/132	19.6†	9/148	6.1	$<10^{-3}$
Extended	17/47	36.1†	2/59	3.3	$<10^{-4}$
Stage:					
T_1	4/22	18.1	1/18	5.5	0.23
T_2	31/136	22.7	7/153	4.5	10^{-5}
T_3	8/21	38.1	3/36	8.3	$<10^{-2}$
Histology:					
Ductal	39/158	24.6	9/180	5.0	$<10^{-6}$
Lobular	4/15	26.6	2/21	9.5	0.18
Other	0/6	—	0/6	—	
Mean follow-up period (mo)	14.0		13.7		

*1-3 nodes vs 4 or more: $P < 10^{-3}$. †Radical vs extended: $P = 0.03$.

Why not:

- **RxPONDER: For post-menopausal woman with HR(+) cN0 or cN1, genomic assays often will determine adjuvant therapy**
- **There is a known morbidity associated with surgical staging of the axilla**

Why:

- **Still may guide therapy in certain cases**
  - **Premenopausal**
  - **T3/T4**
  - **cN1**
  - **TNBC**
  - **HER2(+)**

Fisher, et al., Cancer 1977; 39:2827-2839; Fisher, et al., N Engl J Med 2002;347:567-75; Bonadonna, et al., N Engl J Med 1976; 294: 405-410; Sparano, et al., N Engl J Med 2018;379:111-121; Kalinsky, et al., N Engl J Med 2021;385:2336-2347; Cardoso, et al., N Engl J Med 2016;375:717-729

What I am NOT arguing for:

- Omission of SLN for HER2(+) and triple negative breast cancer
  - Nodal burden helps to determine the extent systemic therapy
- Omission of SLN for premenopausal woman
  - RxPONDER noted that even with a low RS, nodal burden matters in premenopausal women

What I am arguing for:

- Omission of SLN for HR(+) postmenopausal woman with cT1N0 breast cancer

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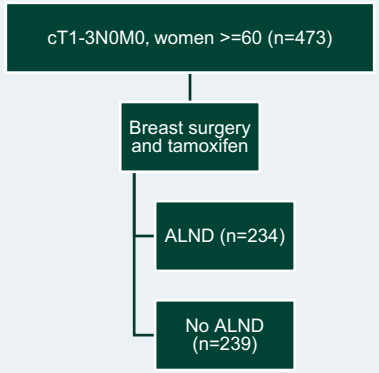
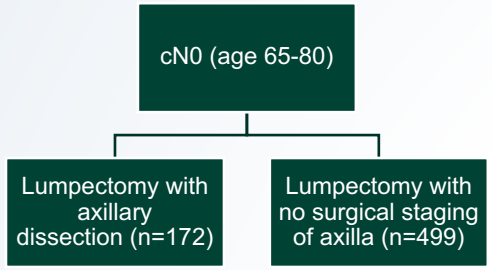
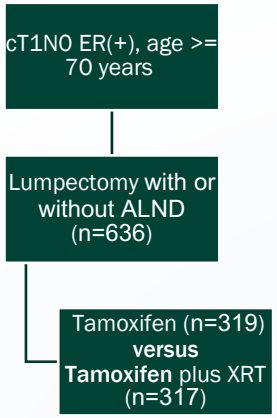
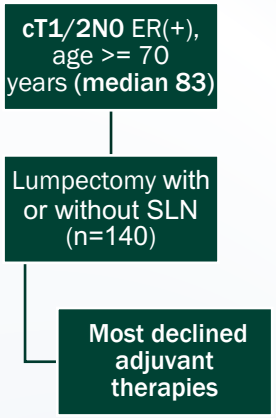
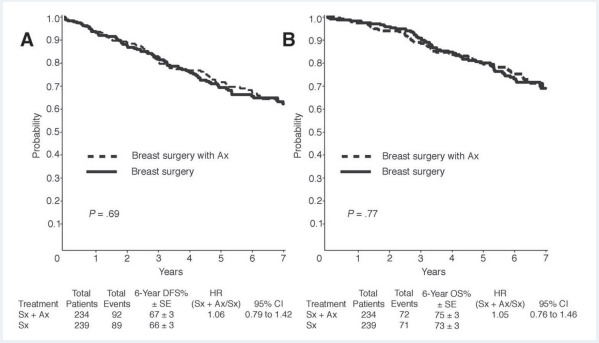
Choosing Wisely (ABIM/SSO/ASCO):
Don't routinely use sentinel node biopsy in clinically node negative women ≥70 years of age with early-stage hormone receptor positive, HER2 negative invasive breast cancer.

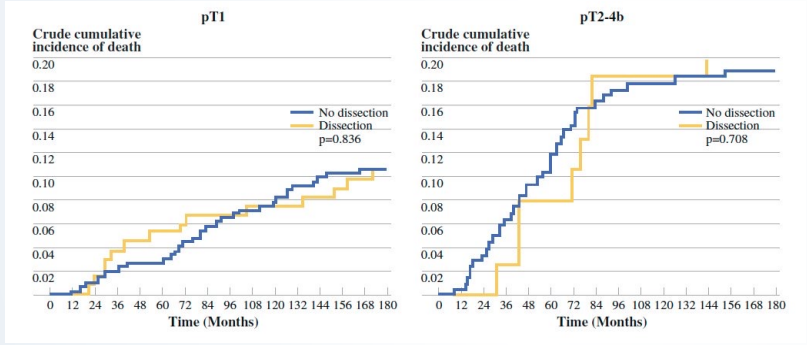


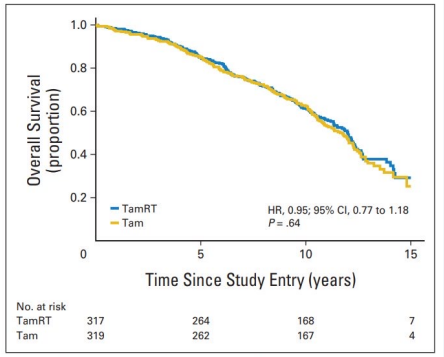


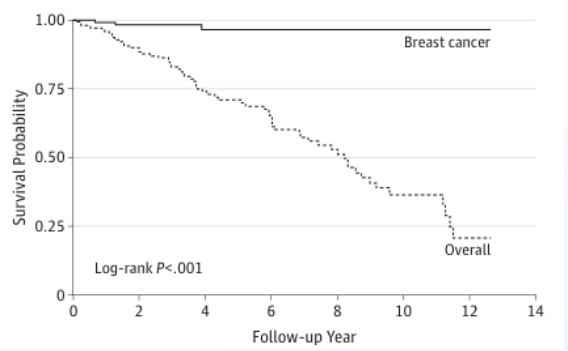












~40% T2

Rudenstam, et al., J Clin Oncol 2006;24(3):337-344

~7% T2

Martelli, et al., Ann Surg Oncol. 2011;18(1):125–33

Est. 3% failure rate

Hughes, et al., J Clin Oncol 2013;31(19):2382-7

26% T2

Chung, et al., JAMA Surg 2015;150(7):683-4

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A Prospective Study of Sentinel Node Biopsy Omission in Women Age ≥ 65 Years with ER+ Breast Cancer

cT1/2N0M0 ER(+)

Lumpectomy

No SLN (n=125)

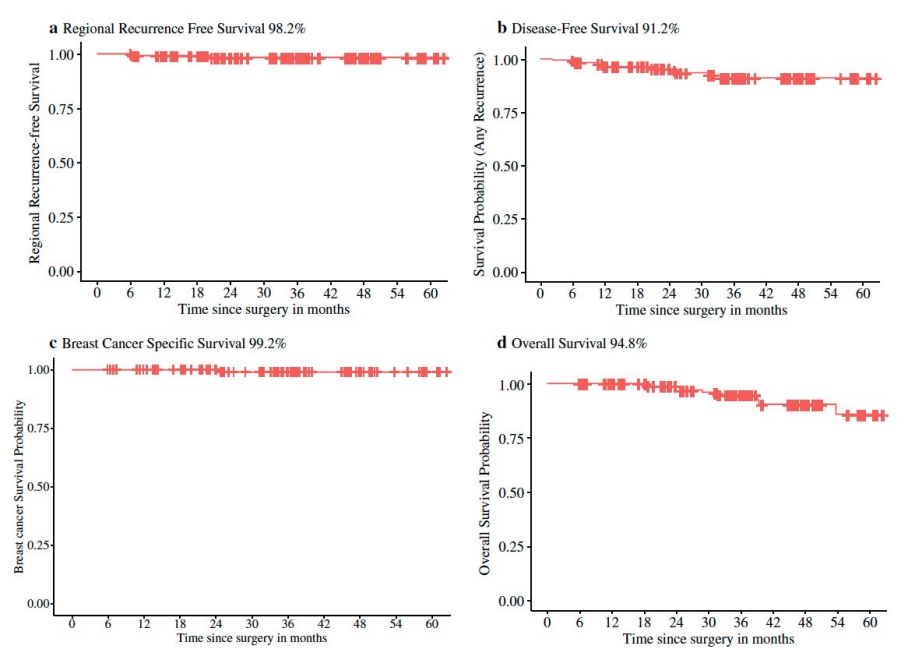


FIG. 2 Kaplan–Meier curves of estimated 3-year outcomes for regional recurrence-free survival (**a**), disease-free survival (**b**), breast cancer-specific survival (**c**), and overall survival (**d**)

- No isolated axillary failures
- 23% T2

Women older than aged 65 years with clinically staged T1-2N0 ER(+) breast cancer undergoing breast conservation surgery are unlikely to gain benefit from SLN.

Caveats to these studies:

1) No axillary imaging was mandated in these studies
2) Although mostly T1 tumors, but there were T2 tumors included

Chung et al., Ann Surg Oncol 2024;31:3160-3167

SLN versus no axillary surgery in patients with small breast cancers and negative results on axillary ultrasound: The SOUND Randomized Clinical Trial

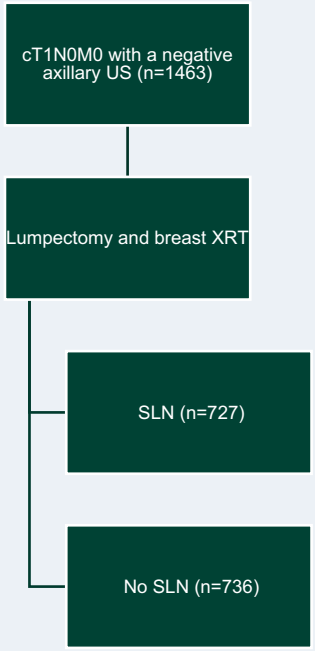


Table 1. Baseline Patient and Tumor Characteristics

Characteristic	Patients, No. (%) SLNB (n = 708)	No axillary surgery (n = 697)
Age at surgery, y		
<40	10 (1.4)	10 (1.4)
40-49	114 (16.1)	128 (18.4)
50-64	324 (45.8)	298 (42.8)
≥65	260 (36.7)	261 (37.4)
Median (IQR)	60 (52-68)	60 (51-68)
Menopausal status[a]		
Premenopausal	145 (20.6)	154 (22.3)
Perimenopausal or postmenopausal	558 (79.4)	538 (77.7)
Histotype		
Ductal	551 (77.8)	543 (77.9)
Lobular	61 (8.6)	59 (8.5)
Tubular	27 (3.8)	33 (4.7)
Other	69 (9.7)	62 (8.9)
Pathological tumor size		
pT1mic or pT1a	71 (10.0)	61 (8.8)
pT1b	251 (35.5)	240 (34.4)
pT1c	355 (50.1)	361 (51.8)
pT2	31 (4.4)	35 (5.0)
Median (IQR), cm	1.1 (0.8-1.5)	1.1 (0.8-1.5)
No. of positive SLNs		
0	599 (84.6)	12 (1.7)
1	83 (11.7)	10 (1.4)
≥2	14 (2.0)	0
SLNB not performed	12 (1.7)	675 (96.8)

Table 1. Baseline Patient and Tumor Characteristics (continued)

Characteristic	Patients, No. (%) SLNB (n = 708)	No axillary surgery (n = 697)
Ki-67 index[c]		
<20	455 (64.4)	439 (63.2)
≥20	252 (35.6)	256 (36.8)
Median (IQR)	15 (10-23)	15 (10-24)
ERBB2 overexpression		
Not overexpressed	660 (93.2)	650 (93.3)
Overexpressed	48 (6.8)	47 (6.7)
Surrogate subtype		
Luminal *ERBB2*-negative	617 (87.1)	617 (88.5)
ERBB2-enriched	48 (6.8)	47 (6.7)
Triple-negative	43 (6.1)	33 (4.7)
Grade[b]		
1	194 (27.7)	204 (29.9)
2	377 (53.8)	356 (52.2)
3	130 (18.5)	122 (17.9)
ER status		
0	56 (7.9)	44 (6.3)
>0	652 (92.1)	653 (93.7)
PgR status		
0	108 (15.3)	95 (13.6)
>0	600 (84.7)	602 (86.4)

- For the SLN group
  - 82.5% were node negative
  - Only 0.6% were pN2
- Adjuvant treatments
  - Majority received endocrine therapy (98% for HR(+))
  - Chemotherapy for ~19% of patients
  - Radiation therapy for 98%

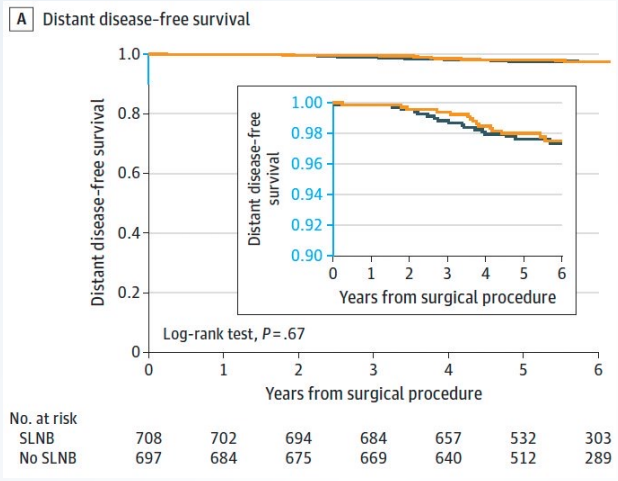
Gentilini et al., JAMA Oncol 2023;9(11):1557-1564

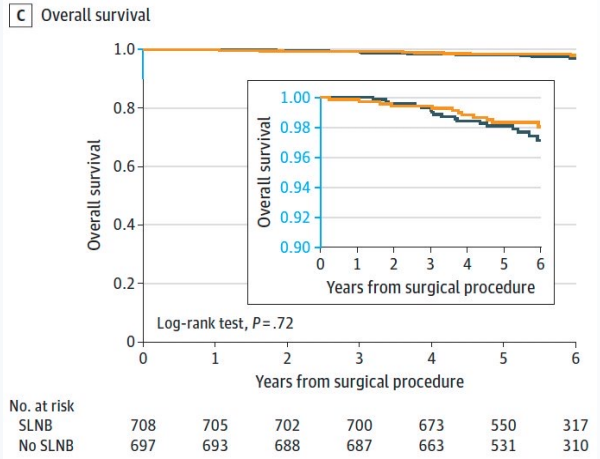
SLN versus no axillary surgery in patients with small breast cancers and negative results on axillary ultrasound: The SOUND Randomized Clinical Trial

Table 3. Summary of First Events, Deaths, and Follow-Up Time

Outcome	Events, No. (%) SLNB (n = 708)	Events, No. (%) No axillary surgery (n = 697)
First events		
Ipsilateral breast recurrence	7 (1.0)	6 (0.9)
Axillary recurrence	3 (0.4)	5 (0.7)
Ipsilateral breast and axillary recurrence	2 (0.3)	0
Distant metastasis	13 (1.8)	14 (2.0)
Contralateral breast cancer	5 (0.7)	7 (1.0)
Nonbreast primary tumors	17 (2.4)	22 (3.2)
Death from breast cancer	0	0
Death from cause other than breast cancer	5 (0.7)	6 (0.9)
Death from unknown cause	1 (0.1)	1 (0.1)
Follow-up, median (IQR), y	5.7 (5.0-6.8)	5.7 (5.0-6.6)
All deaths, cause		
Breast cancer	7 (1.0)	4 (0.6)
Cause other than breast cancer	10 (1.4)	12 (1.7)
Unknown cause	4 (0.6)	2 (0.3)
Follow-up, median (IQR), y	5.8 (5.0-6.9)	5.8 (5.0-6.8)

Abbreviation: SLNB, sentinel lymph node biopsy.





SLNB (control group) — No SLNB (experimental group)

- Omission of axillary surgery was not inferior in DDFS for patients with <2 cm, hormone positive tumors and a negative axillary US
- Caution that this data may not apply to premenopausal women
- Points to importance of multidisciplinary care
- Await 10-year data to confirm results

Gentilini et al., JAMA Oncol 2023;9(11):1557-1564

Axillary Surgery in Breast Cancer – Primary Results of the INSEMA Trial

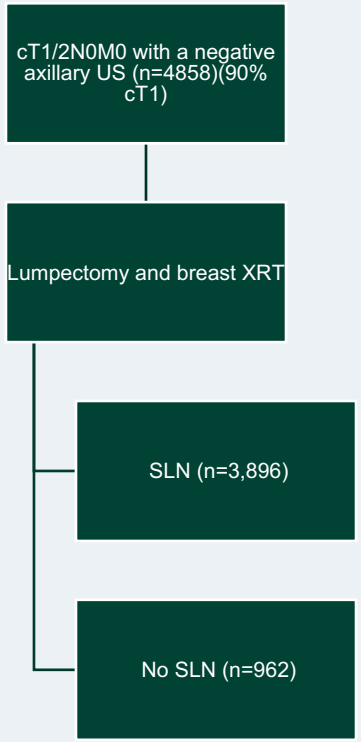


Table 1. Demographic and Clinical Characteristics of Patients in the Per-Protocol Population.*

Characteristic	No Sentinel-Lymph-Node Biopsy (N=962)	Sentinel-Lymph-Node Biopsy (N=3896)	All Patients (N=4858)
Age — no. (%)			
<35 yr	4 (0.4)	6 (0.2)	10 (0.2)
35 to <50 yr	110 (11.4)	407 (10.4)	517 (10.6)
50 to <60 yr	295 (30.7)	1278 (32.8)	1573 (32.4)
60 to <70 yr	355 (36.9)	1454 (37.3)	1809 (37.2)
≥70 yr	198 (20.6)	751 (19.3)	949 (19.5)
BMI — no./total no. (%)†			
<30	716/961 (74.5)	2913/3896 (74.8)	3629/4857 (74.7)
≥30	245/961 (25.5)	983/3896 (25.2)	1228/4857 (25.3)
Unknown	1	0	1
Preoperative tumor size — no (%)‡			
≤2 cm	871 (90.5)	3521 (90.4)	4392 (90.4)
>2 cm	91 (9.5)	375 (9.6)	466 (9.6)
Pathological tumor stage — no. (%)§			
pT0, pTis, or pTX	6 (0.6)	34 (0.9)	40 (0.8)
pT1	773 (80.4)	3082 (79.1)	3855 (79.4)
pT2	177 (18.4)	756 (19.4)	933 (19.2)
pT3 or pT4	6 (0.6)	24 (0.6)	30 (0.6)
Nodal status — no./total no. (%)¶			
Sentinel lymph nodes			
pN0		3275/3854 (85.0)	
pN1mi		133/3854 (3.5)	
pN1		438/3854 (11.4)	
pN2		8/3854 (0.2)	
Unknown		4	
All lymph nodes			
pN0		50/253 (19.8)	
pN1mi		1/253 (0.4)	
pN1		169/253 (66.8)	
pN2		33/253 (13.0)	
ER and PR status — no./total no. (%)‖			
Negative	15/961 (1.6)	58/3893 (1.5)	73/4854 (1.5)
Positive	946/961 (98.4)	3835/3893 (98.5)	4781/4854 (98.5)
Unknown	1	3	4
HER2 status — no./total no. (%)			
Negative	914/958 (95.4)	3755/3885 (96.7)	4669/4843 (96.4)
Positive	44/958 (4.6)	130/3885 (3.3)	174/4843 (3.6)
Unknown	4	11	15

Table 1. (Continued.)

Characteristic	No Sentinel-Lymph-Node Biopsy (N=962)	Sentinel-Lymph-Node Biopsy (N=3896)	All Patients (N=4858)
Intrinsic subtype — no./total no. (%)			
HR positive, HER2 negative	905/958 (94.5)	3705/3884 (95.4)	4610/4842 (95.2)
HER2 positive	44/958 (4.6)	130/3884 (3.3)	174/4842 (3.6)
Triple-negative breast cancer**	9/958 (0.9)	49/3884 (1.3)	58/4842 (1.2)
Tumor grade — no. (%)††			
G1	372 (38.7)	1463 (37.6)	1835 (37.8)
G2	552 (57.4)	2294 (58.9)	2846 (58.6)
G3	38 (4.0)	139 (3.6)	177 (3.6)
Ki-67 index — no./total no. (%)‡‡			
≤20%	800/909 (88.0)	3220/3705 (86.9)	4020/4614 (87.1)
>20%	109/909 (12.0)	485/3705 (13.1)	594/4614 (12.9)
Unknown	53	191	244
Histologic subtype — no./total no. (%)			
Invasive carcinoma (no special type)	726/962 (75.5)	2828/3895 (72.6)	3554/4857 (73.2)
Invasive or mixed lobular carcinoma	125/962 (13.0)	491/3895 (12.6)	616/4857 (12.7)
Other	111/962 (11.5)	576/3895 (14.8)	687/4857 (14.1)
Unknown	0	1	1

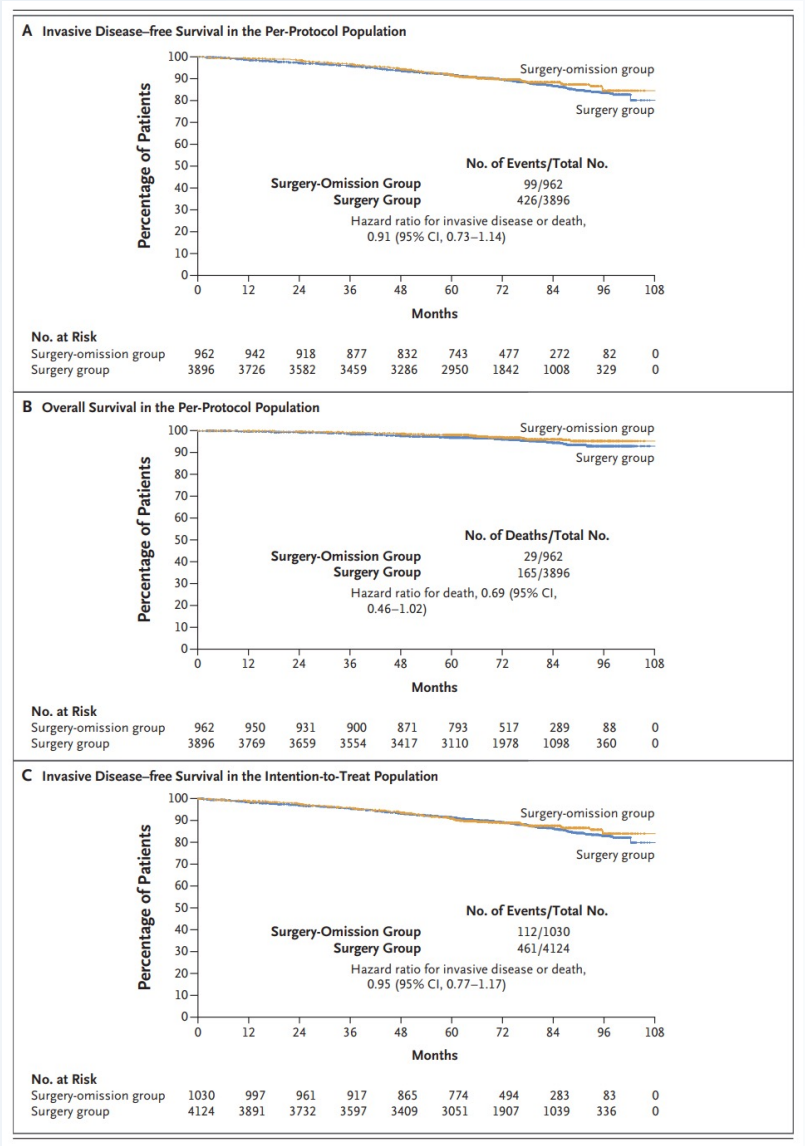
- Median age: 62
- Median tumor size: 15 mm
  - 79% pT1
- Median f/u: 73.6 months

Reimer, et al., N Engl J Med. 2025 13;392(11):1051-1064.

Axillary Surgery in Breast Cancer – Primary Results of the INSEMA Trial

Table 2. Summary of Primary-Outcome Events in the Per-Protocol Population.

Event	No Sentinel-Lymph-Node Biopsy (N=962)	Sentinel-Lymph-Node Biopsy (N=3896)	All Patients (N=4858)
Any primary-outcome event — no. (%)			
No	863 (89.7)	3470 (89.1)	4333 (89.2)
Yes	99 (10.3)	426 (10.9)	525 (10.8)
First primary-outcome event — no. (%)			
Invasive locoregional relapse	18 (1.9)	54 (1.4)	72 (1.5)
Invasive contralateral breast cancer	10 (1.0)	25 (0.6)	35 (0.7)
Distant relapse	26 (2.7)	104 (2.7)	130 (2.7)
Secondary cancer	32 (3.3)	150 (3.9)	182 (3.7)
Death	13 (1.4)	93 (2.4)	106 (2.2)
Locoregional relapse — no. (%)			
Axillary recurrence	10 (1.0)	12 (0.3)	22 (0.5)
Invasive ipsilateral breast recurrence	8 (0.8)	42 (1.1)	50 (1.0)
Death from any cause — no./total no. (%)			
Breast cancer	0	1/93 (1.1)	1/106 (0.9)
Second, nonbreast cancer	0	3/93 (3.2)	3/106 (2.8)
Other known cause	7/13 (53.8)	43/93 (46.2)	50/106 (47.2)
Unknown cause	6/13 (46.2)	46/93 (49.5)	52/106 (49.1)



- Significant decreases in shoulder/arm ROM issues, lymphedema, chronic pain
- Omission of sentinel lymph node biopsy was not inferior in DDFS
- Suitable for patients >50, with grade 1-2, HR(+)HER2(-), cT1 breast cancer

Reimer, et al., N Engl J Med. 2025 13;392(11):1051-1064.

"We believe these latter two trials are practice changing and are important for our community to know about so that it can be implemented and essentially represent a change in treatment paradigms."

What about adjuvant treatments in this patient population?

We have stated within the guideline that radiation and systemic treatment decisions should not be altered in the select patients with low-risk disease where sentinel lymph node biopsy can be omitted.

If you look at the numbers from both the INSEMA and the SOUND trial, the number of patients with pathologic N2 disease who did have their axilla surgically staged, it was less than 1% in both trials.

THE FUTURE.....

Expanding those eligible for omission.....cT2, post-NAT.....

VENUS

Sentinel lymph node biopsy vs no axillary surgery in early breast cancer clinically and ultrasonographically node negative

BOOG 2013-08 Trial

Omitting Sentinel Node Procedure in Breast Cancer Patients Undergoing Breast Conserving Therapy (2022)

EURBREAST-01

Omission of SLNB in triple negative and HER2-positive breast cancer patients with radiologic and pathologic complete response in the breast after NAST: a single-arm, prospective surgical trial (2024)

Avoiding Sentinel Lymph Node Biopsy in Breast Cancer Patients After Neoadjuvant Chemotherapy (ASICS)

This study evaluates whether SLNB can safely be omitted in breast cancer patients with HER2+ or TN tumors who achieve a radiological complete response on MRI after neoadjuvant systemic therapy

NAUTILUS

No axillary surgical treatment for lymph node negative patients after ultra-sonography [NAULITUS]: protocol for a prospective randomized clinical trial

SOAPET

Prospective study designed to evaluate the negative predictive value of LymphPET and to verify whether sentinel lymph node biopsy can be spared in patients with negative preoperative axillary assessment

ASLAN Trial

Selective avoidance of sentinel lymph node biopsy after neoadjuvant chemotherapy in human epidermal growth factor 2 positive / triple negative breast cancer patients with excellent response

NEO-NAUTILUS

No axillary surgical treatment for lymph node negative patients after ultra-sonography in a post-neoadjuvant setting

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Omission of Sentinel Lymph Node in Breast Cancer "The Take Home Points"

1) Omission of SLN
   - Post-menopausal woman >=50 with HR(+), cT1N0, grade 1-2, unifocal breast cancer with a negative axillary US undergoing lumpectomy
   - Patients meeting SSO Choosing Wisely recommendations; patients ≥70 years of age with HR+/HER2-negative and pT1, cN0 tumors

2) Performance on surgical staging of the axilla
   - HER2(+), triple negative, or grade 3 HR(+) breast cancer
   - cT2 HR(+) tumors, even if grade 1 or 2 (for now.....)
   - Patients undergoing mastectomy (for now.....)
   - Post-neoadjuvant patients regardless of response (for now.....)

3) *Monday morning:*
   - *Utilize these guidelines as a backbone to multi-disciplinary discussions regarding breast cancer patient management*

"Ideally, the adoption of omission of sentinel lymph node biopsy will lead to more multidisciplinary discussion and collaboration in the preoperative setting."

"More and more studies are going to show even more subsets of patients for whom SLNB can be omitted," Dr. Torres said. "As imaging improves, we will be able to tell with greater certainty whether a node is involved with cancer or not, and I suspect there will be
less need for performing SLNB."

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Omission of Sentinel Lymph Node Biopsy

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Sentinel Lymph Node Biopsy in Early-Stage Breast Cancer: ASCO Guideline Update

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1. Can SLNB be omitted in select patients?	1.1. SLNB can be omitted for select patients with a small (≤2 cm) breast cancer and a negative finding on preoperative ALN ultrasound and who fulfill all of the following criteria and for whom the detection of metastatic sentinel lymph node(s) would not change treatment recommendations. (Evidence quality: Moderate; Strength of recommendation: Strong) Postmenopausal and ≥50 years Unifocal invasive ductal carcinoma smaller than or equal to 2 cm Nottingham grades 1-2 Hormone receptor–positive, HER2-negative in patients intending to receive adjuvant endocrine therapy No suspicious lymph nodes on axillary US or only one suspicious node and biopsy is benign and concordant with axillary US findings. Undergoing upfront breast-conservation surgery followed by whole-breast RT in patients <65 years of age (see Good Practice Statement 1.2 and Qualifying statements for patients ≥65 years of age).
	Qualifying statements for Recommendation 1.1 In the INSEMA trial, ultrasound was primarily used to assess breast tumor size, and, when unavailable, mammogram followed by MRI were used in that order. Similarly, in the SOUND trial, preoperative tumor size was assessed by ultrasound but also physical examination and mammogram. MRI was performed in a minority of patients. For patients over age 70, the Choosing Wisely Statement does not require axillary US for determining omission of SLNB The SOUND clinical trial excluded patients with multiple suspicious lymph nodes, multifocality or multicentricity, bilateral breast cancer, synchronous distant metastases, previous cancer, ongoing pregnancy, or lactation. In the INSEMA trial, multifocal tumors were allowed; multicentricity was not allowed.
	1.2 For patients ≥65 years of age and who qualify by the following criteria for omission of SLNB, RT post breast-conserving surgery is not mandatory (extrapolating from the PRIME II trial and CALGB 9343), as the risk of lymph node involvement is very low: postmenopausal, invasive carcinoma smaller than or equal to 2 cm, Nottingham grades 1-2, hormone receptor–positive, HER2-negative in patients intending to receive adjuvant endocrine therapy, no suspicious lymph nodes on axillary US or only one suspicious node on axillary US and biopsy is benign and concordant. (Good Practice Statement; Refer to the Clinical Interpretation section corresponding to this recommendation for further discussion.)

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ASCO Guidelines