# Management of the Axilla

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#### **Disclosures**

Nothing to Disclose



## **Axillary Management: Questions to Ponder**

- When to Consider No Axillary Surgery in Patients with Early-Stage Breast Cancer Undergoing Breast Conservation (INSEMA)?
- Who is at Risk for Residual Axillary Nodal Disease after Neoadjuvant Chemotherapy (Alliance 011202)?
- When to Dissect and When to Radiate?



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#### **DECEMBER 10–13, 2024**

HENRY B. GONZALEZ CONVENTION CENTER • SAN ANTONIO, TX

# No axillary surgery versus axillary sentinel lymph node biopsy in patients with early invasive breast cancer and breast-conserving surgery: Final primary results of the Intergroup-Sentinel-Mamma (INSEMA) trial

<u>Toralf Reimer</u><sup>1</sup>, Angrit Stachs<sup>1</sup>, Kristina Veselinovic<sup>2</sup>, Thorsten Kühn<sup>2,3</sup>, Jörg Heil<sup>4,5</sup>, Silke Polata<sup>6</sup>, Frederik Marmé<sup>7</sup>, Thomas Müller<sup>8</sup>, Guido Hildebrandt<sup>9</sup>, David Krug<sup>10</sup>, Beyhan Ataseven<sup>11</sup>, Roland Reitsamer<sup>12</sup>, Andrea Stefek<sup>13</sup>, Carsten Denkert<sup>14</sup>, Inga Bekes<sup>2,15</sup>, Dirk-Michael Zahm<sup>16</sup>, Marc Thill<sup>17</sup>, Michael Golatta<sup>4,5</sup>, Johannes Holtschmidt<sup>18</sup>, Michael Knauer<sup>19,20</sup>, Valentina Nekljudova<sup>18</sup>, Sibylle Loibl<sup>18</sup>, Bernd Gerber<sup>1</sup>

on behalf of the INSEMA investigators

1 Department of Obstetrics and Gynecology, University of Rostock, Germany; 2 Department of Obstetrics and Gynecology, University Hospital Ulm, Germany; 3 The Filderhospital, Filderstadt-Bonlanden, Germany; 4 Breast Center of St. Elisabeth Hospital, Heidelberg, Germany; 5 Department of Gynecology and Obstetrics, University of Heidelberg, Germany; 6 Evang. Waldkrankenhaus Spandau, Germany; 7 Faculty of Medicine Mannheim, University Heidelberg, Department of Obstetrics and Gynecology Mannheim, Germany; 8 Department of Obstetrics and Gynecology, Hanau City Hospital GmbH, Hanau, Germany; 9 Department of Radiotherapy, University Medicine Rostock, Germany; 10 Department of Radiotherapy and Radiation Oncology, University Hospital Hamburg-Eppendorf (UKE), Germany; 11 KEM, Evangelical Clinics Essen Centre, Essen, Germany; 12 University Hospital Salzburg, Department of Senology, Salzburg, Austria; 13 Johanniter-Hospital Genthin-Stendal, Germany; 14 Institute of Pathology, Philipps-University Marburg and University Hospital Marburg (UKGM), Marburg, Germany; 15 Breast Center St. Gallen, Kantonsspital St. Gallen, Switzerland; 16 SRH Wald-Klinikum Gera GmbH, Germany; 17 Agaplesion Markus Hospital, Frankfurt am Main, Germany; 18 German Breast Group, Neu-Isenburg, Germany; 19 Tumor and Breast Center Eastern Switzerland, St. Gallen, Switzerland; 20 Austrian Breast and Colorectal Cancer Study Group (ABCSG), Vienna, Austria.

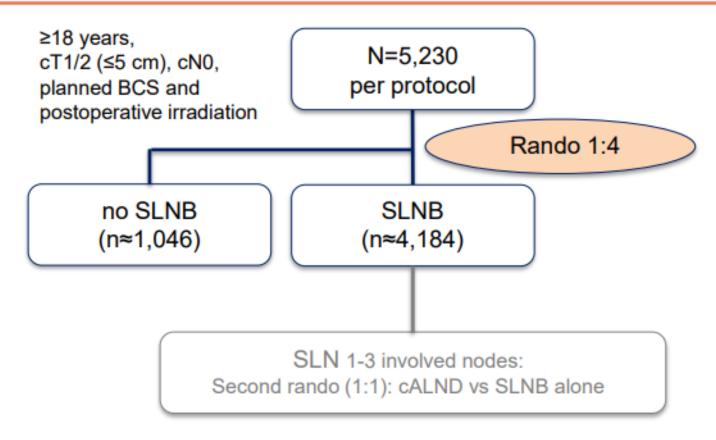






#### Study Design INSEMA Trial





iDFS, invasive disease-free survival; BCS, breast-conserving surgery; SLNB, sentinel lymph node biopsy; cALND, completion axillary lymph node dissection



#### Primary objective:

 To compare iDFS after BCS (noninferiority question) between no axillary surgery and SLNB patients (first randomization)

#### Key secondary objective:

- To compare iDFS after BCS between SLNB alone and completion ALND patients (second randomization)
- Recruitment in Germany and Austria (2015-2019)



## **Consort Flow Diagram**

Universität

Rostock

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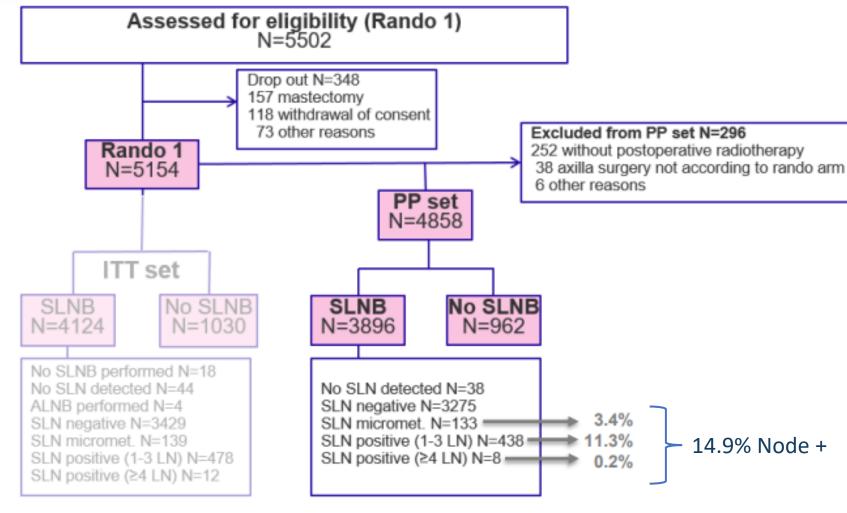


GBG

GERMAN

BREAST

GROUP



#### **Baseline Characteristics: Per-Protocol Set**



10.8% were aged <50 years

HR+/HER2-



95.2% had

subtype

Parameter	Category	No SLNB N=962 N (%)	SLNB N=3896 N (%)
Age	median (IQR)	62 (53-68)	62 (53-68)
	<65 years	583 (60.6)	2387 (61.3)
	≥65 years	379 (39.4)	1509 (38.7)
Preop. tumor size	≤2 cm	871 (90.5)	3521 (90.4)
	>2 cm	91 ( 9.5)	375 ( 9.6)
Grading	G1	372 (38.7)	1463 (37.6)
	G2	552 (57.4)	2294 (58.8)
	G3	38 ( 3.9)	139 ( 3.6)
Tumor type	NST (No Special Type=IDC)	726 (75.5)	2828 (72.6)
	Invasive/mixed lobular carcinoma	125 (13.0)	491 (12.6)
	other	111 (11.5)	576 (14.8)
ER/PgR	both negative	15 ( 1.6)	58 ( 1.5)
	ER and/or PgR positive	946 (98.4)	3835 (98.5)
HER2 status	negative	914 (95.4)	3755 (96.7)
	positive	44 ( 4.6)	130 ( 3.3)



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# **Post-Operative Systemic Therapy**

Parameter	Category	No SLNB N (%)	SLNB N (%)	Overall N (%)	Odds Ratio (95% CI)
Chemotherapy	No Yes Missing	856 (89.6) 99 (10.4) 7	3355 (87.1) 499 (12.9) 42	4211 (87.6) 598 (12.4) 49	0.78 (0.62-0.98)
Endocrine Therapy	No Yes Missing	40 (4.2) 916 (95.8) 6	201 (5.2) 3648 (94.8) 47	241 (5.0) 4564 (95.0) 53	1.26 (0.89-1.78)
Other Adjuvant Therapy	Anti-HER2 Bisphosphonate Denosumab	19 (2.0) 92 (9.6) 13 (1.4)	82 (2.1) 361 (9.4) 50 (1.3)	101 (2.1) 453 (9.4) 63 (1.3)	0.93 (0.56-1.54) 1.05 (0.57-1.94) 1.03 (0.81-1.31)



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## **Post-Operative Systemic Therapy**

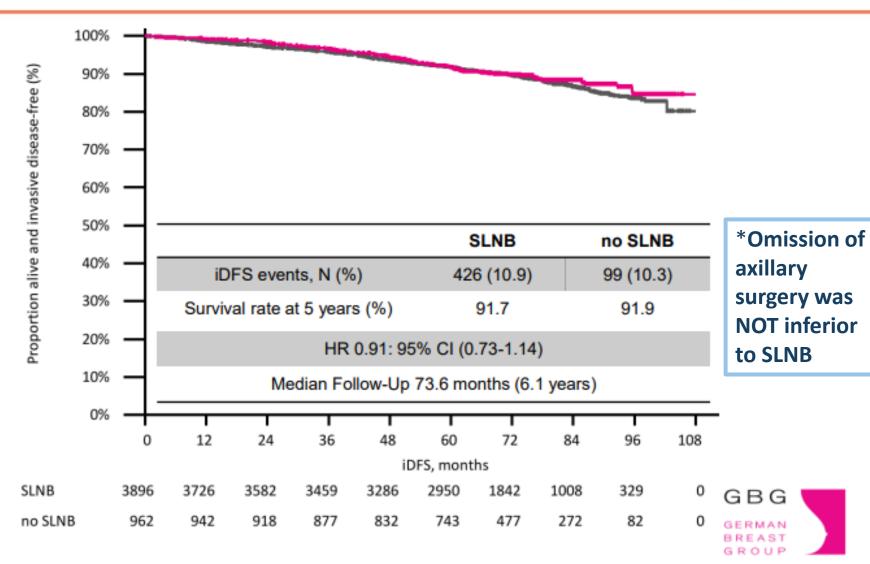
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#### Primary Endpoint: Per-Protocol Analysis



Confidence interval for the HR lies entirely below the non-inferiority margin of 1.271

The primary endpoint in ITT set was also met



## Primary Endpoint Events (N=525)



Parameter	Category	no SLNB N=962	SLNB N=3896	Overall N=4858
First iDFS event	Invasive locoregional recurrence	18 (1.9)	54 (1.4)	72 (1.5)
	- Axillary recurrence	10 (1.0)	12 (0.3)	22 (0.5)
	<ul> <li>Invasive ipsilateral breast recurrence</li> </ul>	8 (0.8)	42 (1.1)	50 (1.0)
	Invasive contralateral BC	10 (1.0)	25 (0.6)	35 (0.7)
	Distant relapse	26 (2.7)	104 (2.7)	130 (2.7)
	Secondary malignancy	32 (3.3)	150 (3.9)	182 (3.7)
	Death	13 (1.4)	93 (2.4)	106 (2.2)

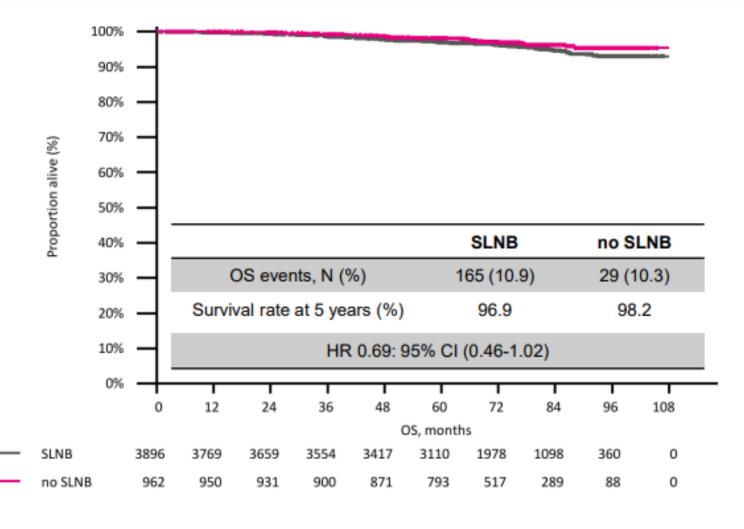
<sup>\*</sup>Clinical exam every 6 months and annual mammogram and US





## Overall Survival: Per-Protocol Analysis









## Invasive Disease-Free Survival In Subgroups



Subgroup	N patients		Hazard Ratio (95% CI)	p-Value	Test for Interaction
Overall	4858	<b>-∳</b> - <b> </b>	.913 (.734, 1.14)	0.417	
Age					0.954
under 65 years	2970	<del></del>	.903 (.658, 1.24)	0.527	
65 years or older	1888	<del>∳</del>	.911 (.673, 1.23)	0.546	
Clinical tumor size					0.389
up to 2cm	4392	<b>-</b> ₩-	.951 (.752, 1.20)	0.674	
over 2cm	466		.715 (.387, 1.32)	0.285	
Tumor grading					0.446
G1/G2	4682	<b>-</b> ■	.891 (.710, 1.12)	0.320	
→ G3	176		1.22 (.545, 2.72)	0.631	
Histological tumor type					0.806
Invasive carcinoma NST	3554	<b>-</b> ₩	.943 (.735, 1.21)	0.647	
Invasive or mixed lobular carcinoma	616		.882 (.483, 1.61)	0.683	
other	687		.741 (.368, 1.49)	0.400	
		0.4 0.6 0.8 1 1.271 2 2.5			



## **Long-Term Safety Analysis**

Parameter	No SLNB	SLNB	p-value
Lymphedema	1.8%	5.7%	< 0.001
Restriction of Arm or Shoulder Mobility	2.0%	3.5%	< 0.001
Pain with Arm or Shoulder Movement	2.0%	4.2%	< 0.001

#### Conclusion



- The INSEMA trial enrolling 5,500 patients significantly demonstrated that omitting SLNB in cN0 patients with early breast cancer and scheduled for breast-conserving therapy, did not result in inferior outcome (HR 0.91 [95% CI: 0.73-1.14]; non-inferiority margin 1.271).
- Patients had very good overall survival with 96.9% and 98.2% at 5 years with vs without SLNB.
- This de-escalation concept is suitable for patients:
  - aged ≥50 years with
  - grading G1-G2 and
  - HR+/HER2- subtype and
  - a preoperative tumor size up to 2 cm





## **INSEMA Application Considerations**

- Requires Multidisciplinary Discussion and Individualized Implementation
- SLNB Still Has a Role in Guiding Adjuvant Therapy for:
  - Patients < age 50</li>
  - HER2+ Disease
  - Triple Negative Disease
- SLNB Has a Role in De-escalating Radiation Therapy
- Omission of SLNB May Cause Under-Treatment with CDK 4/6 Inhibitors



## **Axillary Management: Questions to Ponder**

- When to Consider No Axillary Surgery in Patients with Early-Stage Breast Cancer Undergoing Breast Conservation (INSEMA)?
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- When to Dissect and When to Radiate?



#### DECEMBER 10-13, 2024

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Factors Influencing Additional Nodal Disease and Pathologic Nodal Upstaging with Axillary Dissection in Patients with Residual Node-Positive Breast Cancer After Neoadjuvant Chemotherapy Enrolled on Alliance A011202 Clinical Trial



Judy C. Boughey M.D., Vera Suman, Ph.D., Kelly J. Hunt, M.D., Bruce G. Haffty, M.D., M.S., Thomas Buchholz, M.D., W. Fraser Symmans, MBChB., Tracy L. Rieken, Travis J. Dockter, Jordan D. Campbell, Anna Weiss, M.D., Julie A. Bradley, M.D., MHCDS, Joshua M. V. Mammen, M.D., Ph.D., Ann H. Partridge, M.D., MPH, Lisa A. Carey, M.D.



#### A11202 Trial Schema

Clinically T1-3 N1 M0 Breast Cancer Axillary Ultrasound with FNA or Core Biopsy Documenting Positive lymph Nodes



Neoadjuvant Chemotherapy Completed (minimum of 4 cycles), Clinically Negative Axilla After Neoadjuvant Chemotherapy



Surgery with Sentinel Lymph Node Surgery/Targeted Axillary Dissection



Positive Lymph Node(s) Identified



ARM 1 ALND + Nodal XRT (without XRT to Dissected Axilla)

ARM 2 Axillary XRT and Nodal XRT



# 1º endpoint - DRFI Invasive Breast Cancer Recurrence-Free Interval

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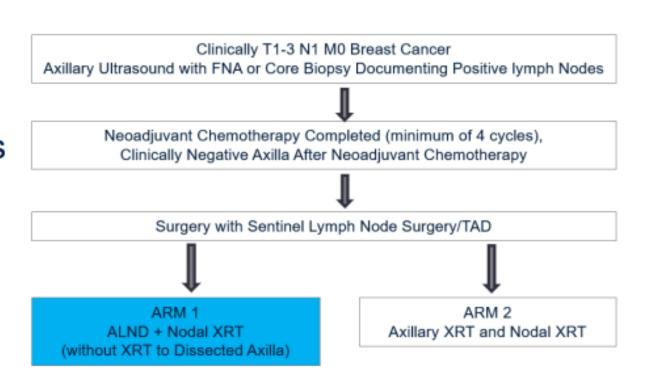






#### **Aim**

- Evaluate the nodal burden at SLN surgery in A11202 patients
- In the ALND group evaluate:
  - Additional positive nodes
  - Factors associated with additional positive nodes
  - Nodal upstaging









#### 369 sites from 2014-2022







positive node defined as metastasis ≥ 0.2 mm

1736 eligible & randomized



841 patients (48.4%) ALND



895 patients (51.6%) No ALND





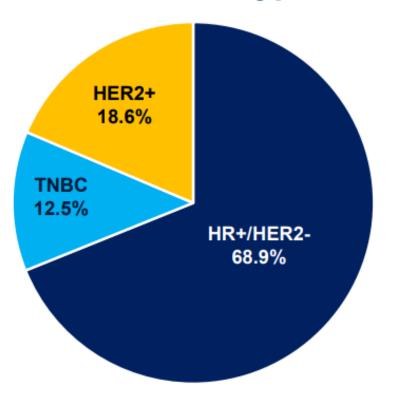


#### San Antonio Breast Cancer Symposium, December 10-13, 2024

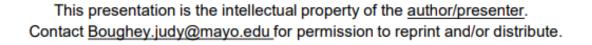
		ALND (n=841)	AxRT(n=895)
	<50	372 (44.2%)	416 (46.5%)
Acc Cross = (0/)	50-59	251 (29.8%)	267 (29.8%)
Age Group, n (%)	60-69	172 (20.5%)	165 (18.4%)
	70+	46 (5.5%)	47 (5.3%)
Condon n (0/)	Female	837 (99.5%)	893 (99.8%)
Gender, n (%)	Male	4 (0.5%)	2 (0.2%)
	Not reported	53 (6.3%)	55 (6.1%)
	American Indian or Alaskan Native	6 (0.7%)	0 (0.0%)
D (0/)	Asian	36 (4.3%)	40 (4.5%)
Race, n (%)	Black or African American	127 (15.1%)	150 (16.8%)
	Native Hawaiian or Pacific Islander	2 (0.2%)	2 (0.2%)
	White	617 (73.4%)	648 (72.4%)
	Infiltrating ductal	695 (82.7%)	748 (83.6%)
	Infiltrating lobular	60 (7.1%)	59 (6.6%)
Histologic Type, n (%)	Mixed ductal/lobular	37 (4.4%)	31 (3.5%)
	Other	48 (5.7%)	57 (6.4%)
	Not provided	1	0
	TI	154 (18.3%)	179 (20.0%)
Clinical TCategory, n (%)	T2	501 (59.6%)	512 (57.2%)
	T3	186 (22.1%)	204 (22.8%)
	High	350 (41.6%)	342 (38.3%)
Uistalasia Crada n (0/)	Intermediate	403 (47.9%)	456 (51.0%)
Histologic Grade, n (%)	Low	73 (8.7%)	77 (8.6%)
	Unknown	15 (1.8%)	20 (2.1%)



#### **Tumor Subtype**

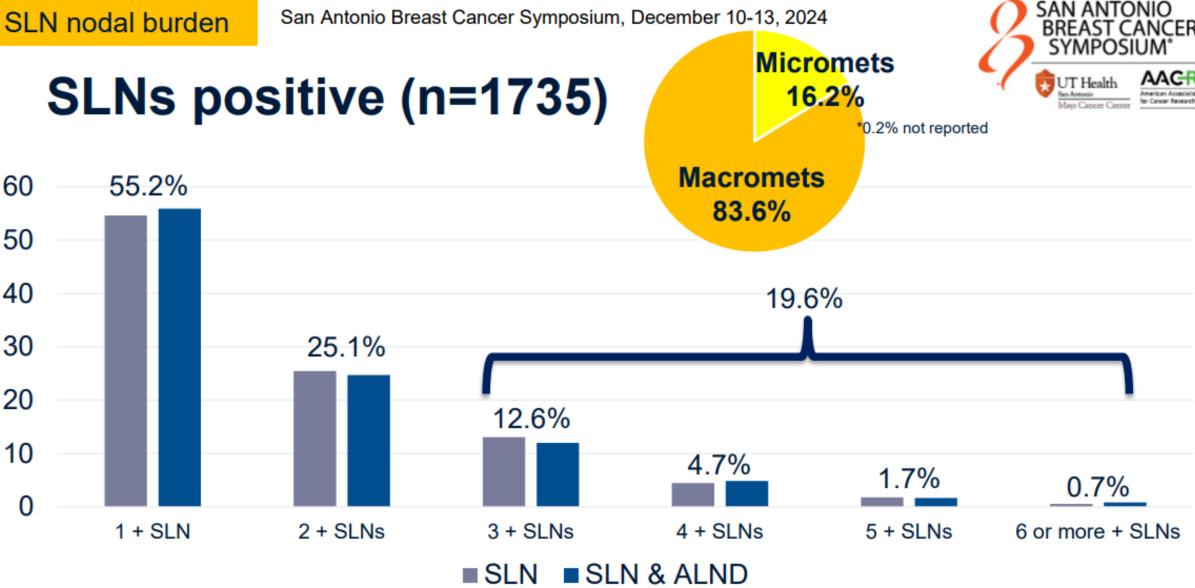












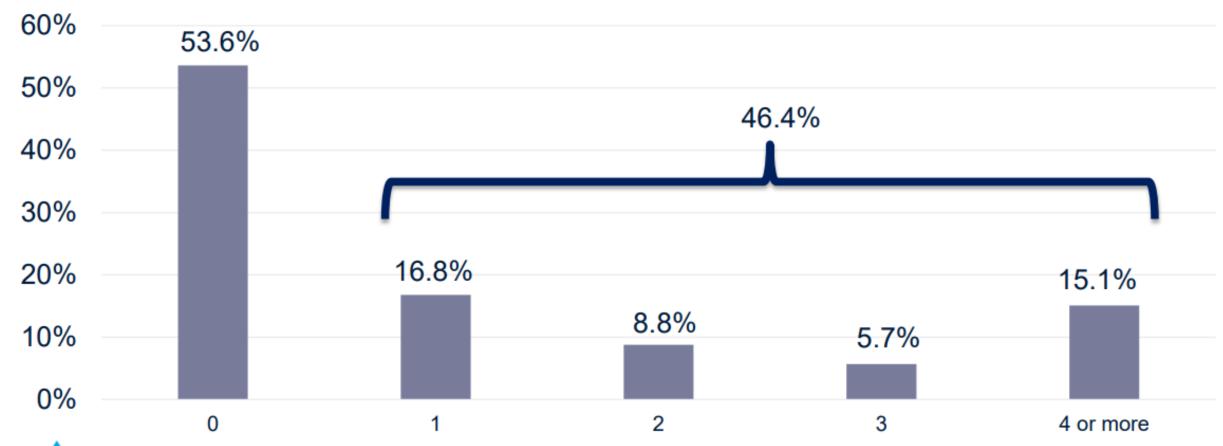








# # of positive nodes on ALND (n=841)









# Factors Impacting Likelihood of Additional Positive Nodes on ALND



- Impact of SLN met size;
  - SLN macromet 47.8% additional + LN(s)
  - SLN micromet 38.4% additional + LN(s)

p=0.064

Impact of Tumor Biology;

• TNBC 39.8% additional + LN(s)

HER2+ 40.3% additional + LN(s) p=0.053

HR+/HER2- 49.1% additional + LN(s)

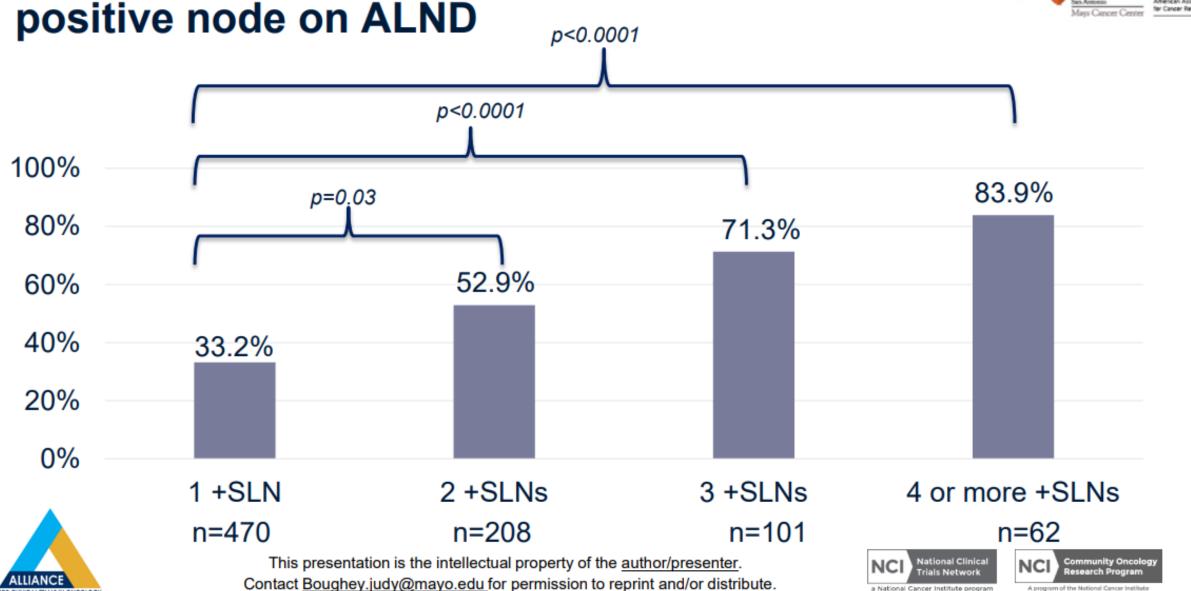






# Percentage of patients with at least 1 additional







#### Additional Positive Nodes on ALND

#### Factors NOT significantly associated

- Patient Age
- Palpable Nodes at Diagnosis
- Tumor Biologic Subtype
- SLN micro/macrometastasis
- Localized resection of clipped node

#### Factors significantly associated

- cT3 at diagnosis
- Residual breast disease ypT3
- Mastectomy
- # of positive SLNs
- # of additional nodes on ALND

On MVA - # of positive SLNs, ypT category and number of additional nodes removed on ALND were associated with additional positive nodes







# Impact of ALND on ypN category

ALND resulted in pathologic nodal upstaging in 25.4% of patients

Increase from ypN1 to ypN2

19.3% (162 patients)

Increase from ypN1 to ypN3

3.8% (32 patients)

Increase from ypN2 to ypN3

2.4% (20 patients)

No change in stage

74.6%



Did not vary by number of SLNs examined







# Summary

- Patients in A11202 had predominantly HR+/Her2- disease
- Rate of additional positive nodes on ALND was 46%
  - Higher than the 27% in Z11 and 33% in AMAROS
- Likelihood of additional positive nodes on ALND influenced by;
  - # of positive SLNs, ypT3 disease and number of LNs removed at ALND
- ALND led to upstage of nodal stage in 25%
  - All subtypes greatest in HR+/Her2-

Data from A11202 are awaited regarding oncologic outcomes with omission of ALND







## **Axillary Management: Questions to Ponder**

- When to Consider No Axillary Surgery in Patients with Early-Stage Breast Cancer Undergoing Breast Conservation (INSEMA)?
- Who is at Risk for Residual Axillary Nodal Disease after Neoadjuvant Chemotherapy (Alliance 011202)?
- When to Dissect and When to Radiate?





#### **OPTIMIZING LOCAL THERAPY**

# Axillary Management: When to dissect and when to radiate

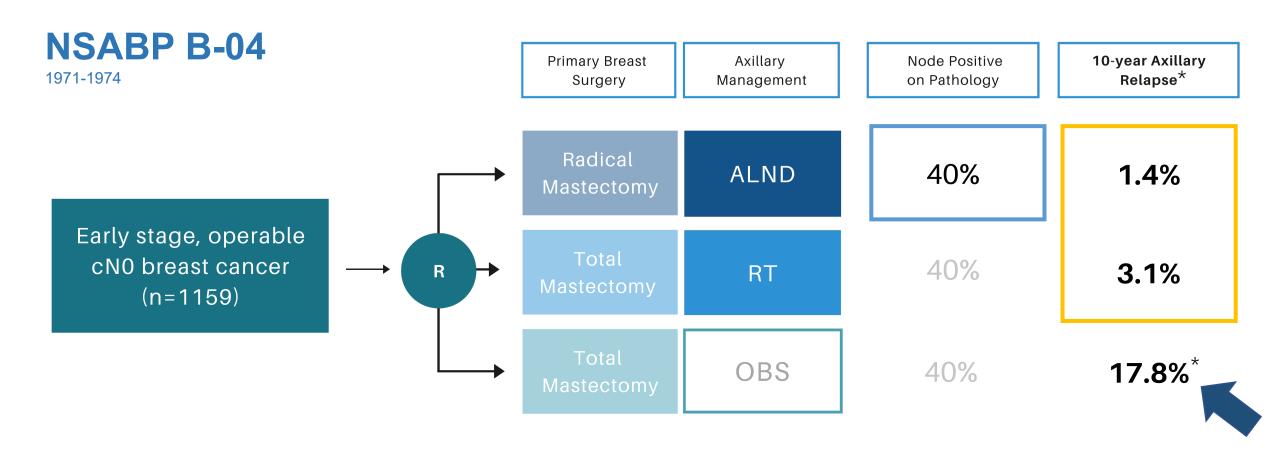
#### Stephanie M Wong, MD MPH

Breast Surgical Oncology, Jewish General Hospital
Director, JGH Stroll Cancer Prevention Centre High Risk Breast Clinic
Assistant Professor, McGill University Medical School

## **Key Points:**

 No randomized trials have ever shown a diseasefree survival or overall survival advantage between ALND vs. AxRT

•Isolated axillary recurrences are a rare event

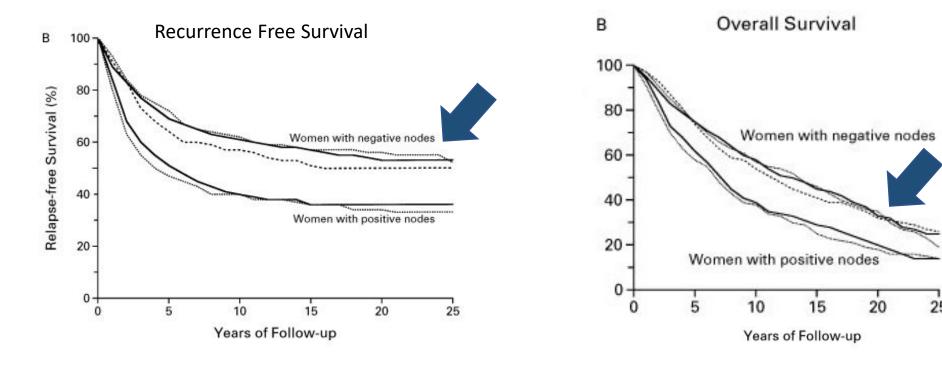


<sup>\*</sup>development of clinically evident (and pathologically proven) progression of untreated lymph nodes



1971-1974

Radical mastectomy
 Total mastectomy + irradiation
 Total mastectomy



Axillary management (ALND vs. RT) did not alter survival

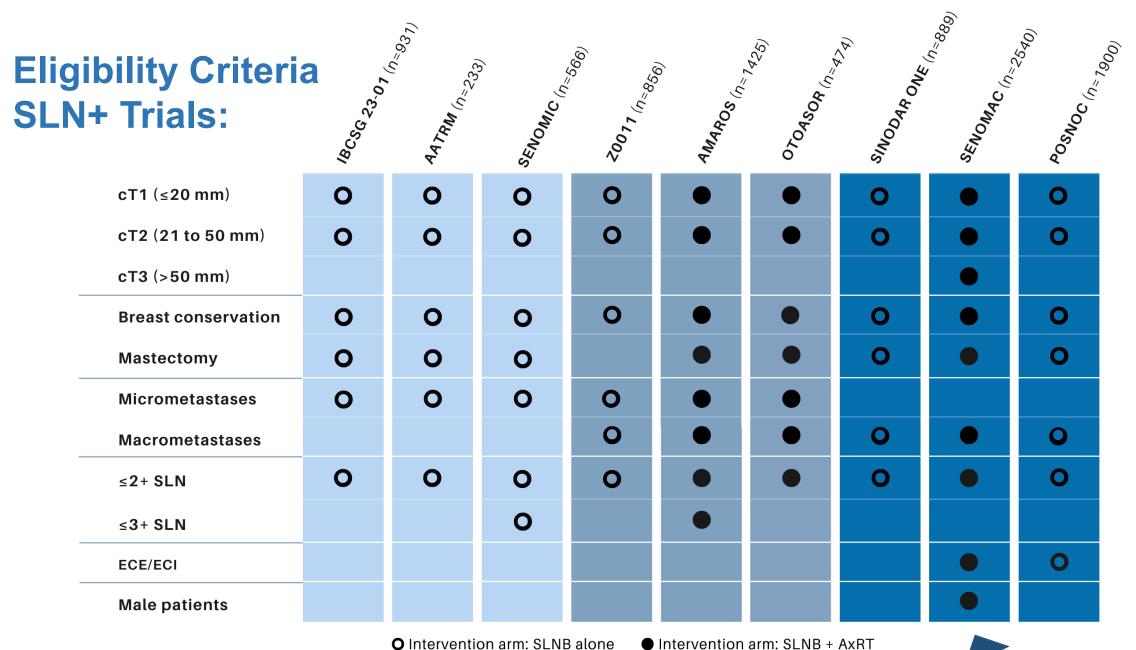
### OUTCOMES FROM cN0 SLN+ TRIALS IN UPFRONT SURGERY

Micrometastatic SLN	Tumor Size	No. SLN+	BCS (%)	Axillary management	Positive non-SLN on cALND (%)	Axillary recurrences (%)	Median FU (years)
IBCSG 23-01 (n=931)	≤5 cm	≤2	91%	ALND <i>v</i> observation	13%	<1.0% v 2.0%	10
<b>AATRM</b> (n=233)	<3.5 cm	≥1	88%	ALND <i>v</i> observation	13%	1.0% v 1.7%	5.1
SENOMIC (n=566)	≤5 cm	≤3	62%	Observation	-	0.9%	3.2
Micro- and Macrometastatic SI	_N						
<b>Z0011</b> (n=856)	≤5 cm	≤2	100%	ALND <i>v</i> observation	27%	0.5% v 1.5%	10
<b>AMAROS</b> (n=1425)	≤5 cm	≤4 <sup>†</sup>	83%	ALND <i>v</i> AxRT	33%	0.9% v 1.8%	10
OTOASOR (n=474)	≤3 cm	≤2	84%	ALND <i>v</i> AxRT	39%	2.0% v 1.7%	8
Macrometastatic SLN							
SINODAR ONE (n=889)	≤5 cm	≤2	76%	ALND <i>v</i> observation	44%	0.2% v 0.2%	2.8
SENOMAC (n=2540)	≤10 cm	≤2	64%	ALND v AxRT*	35%	<0.4% v <0.5%	3.9

### AXILLARY MANAGEMENT IN CNO PATIENTS

## **Evolving data, current controversies...**

- cT3N0 patients & extracapsular extension with 1-2 SLN+
- cN0 mastectomy population with 1-2 SLN+
- Patients with 3 positive SLNs
- ALND to determine eligibility for adjuvant systemic therapies

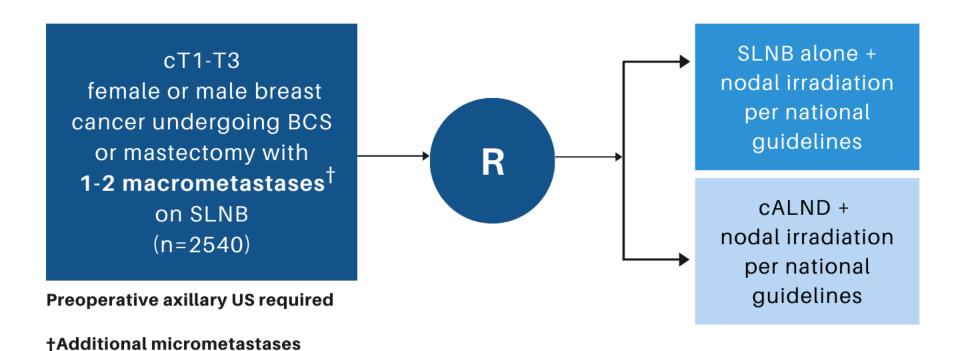


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# **SENOMAC** 2015-2021

eligible; SLN extracapsular

extension eligible



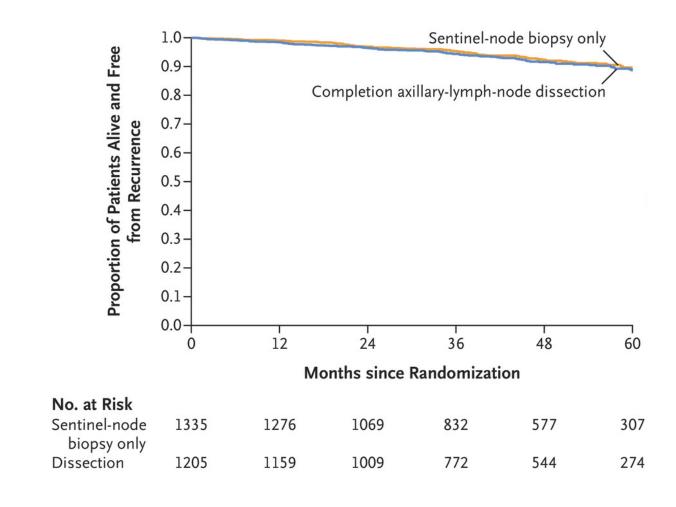
1° endpoint: Overall survival

2° endpoints: Recurrence free survival, BCSS, PROs

### SENOMAC 2015-2021

### **Cohort characteristics:**

Median age: 61 years 94% T1-T2 tumors 87% HR+HER2-89% received nodal RT



No difference in 5-year RFS: 89.7% SLNB vs. 88.7% cALND HR 0.89 (95% CI, 0.66-1.19)

### AXILLARY MANAGEMENT IN T3N0 & ECE



Tumor Size	SLNB only	cALND	HR for recurrence or death (95% CI)		
<b>T1 or T2</b> (n=2393)	84/1262	81/1131	0.94 (0.69-1.28)		
<b>T3</b> (n=147)	5/73	10/74	0.47 (0.16-1.39)		
Extracapsular extension			!		
<b>Yes</b> (n=870)	34/461	31/409	0.94 (0.58-1.54)		
<b>No</b> (n=1662)	55/871	60/791	0.86 (0.60-1.25)		
			SLNB better 1.0 cALND better		

### AXILLARY MANAGEMENT IN T3N0 & ECE



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<b>No</b> (n=1662)	55/871	60/791		0.86 (0.60-1.25)		
			SLNB better 1.0 cALND bette	er		

### AXILLARY MANAGEMENT IN CNO PATIENTS

## **Evolving data, current controversies...**

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#### MASTECTOMY PATIENTS WITH SLN+

## **Controversy with mastectomy patients:**

• Worse tumor characteristics: more extensive, multicentric disease

- Do not receive incidental radiation to the level I axilla that occurs in >70% of BCS patients undergoing WBRT
- Until recently, less well represented in clinical trials...

### MASTECTO MY PATIENTS + SLN MACROMETS (N1)

## **SENOMAC**

2015-2021

Breast Surgery	SLNB only	cALND	HR for recurrence or death (95% CI)
<b>BCS</b> (n=1620)	48/845	46/775	0.98 (0.65-1.47)
Mastectomy (n=920	) 41/490	45/430	0.79 (0.52-1.21)
			SLNB better 1.0 cALND better

Mastectomy patients with 1-2 SLN+ (macrometastases) Axillary RT recommended to provide effective local control\*

(\*ALND can be reserved for patients for whom PMRT is contraindicated or not required)

### AXILLARY MANAGEMENT IN CNO PATIENTS

## **Evolving data, current controversies...**

- cT3N0 patients & extracapsular extension
- cN0 mastectomy population
- cN0 patients with three positive SLNs
- ALND to determine eligibility for adjuvant systemic therapies

### AXILLARY MANAGEMENT IN CNO PATIENTS WITH 3 SLN+

cN0 with 3-4 SLN+	% AxUS	% ≥3 SLN+	No. pts	Axillary management
<b>AMAROS</b> (n=1425)	60%	4.9%	71	ALND v AxRT
SENOMAC (n=2540)	100%	<b>2</b> % <sup>†</sup>	52	ALND v AxRT
INSEMA R2 (n=485)	100%	-		ALND <i>v</i> observation

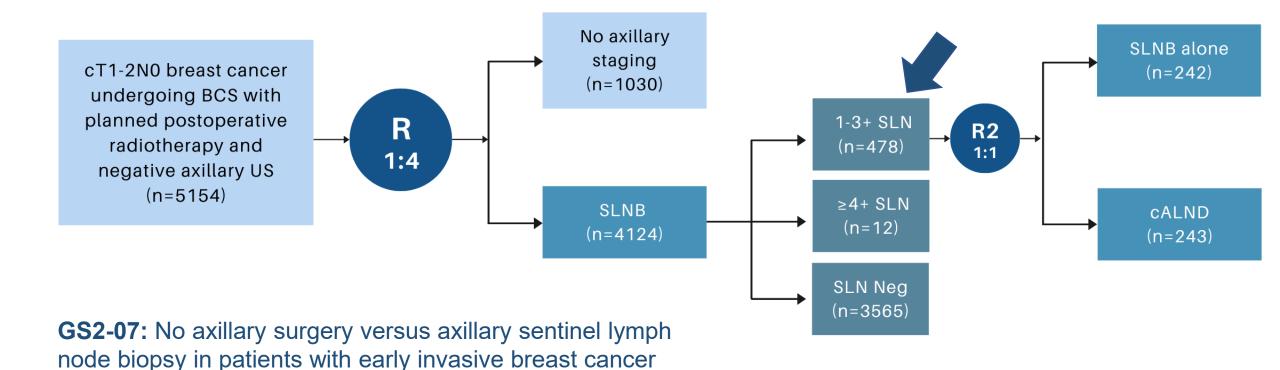
<sup>†</sup>Up to 2 macrometastatic SLN with additional micrometastases in 1 or more SLN

# **INSEMA Trial (GBG-75 / ABCSG-43)**

and breast-conserving surgery: Final primary results of the

Intergroup-Sentinel-Mamma (INSEMA) trial.

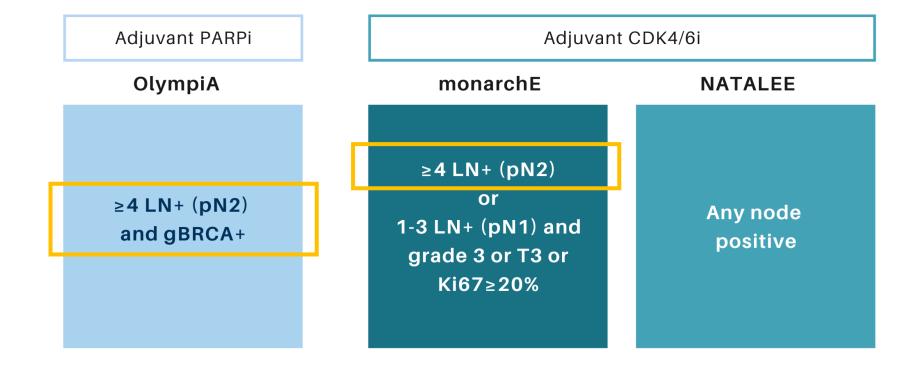
2012-2021

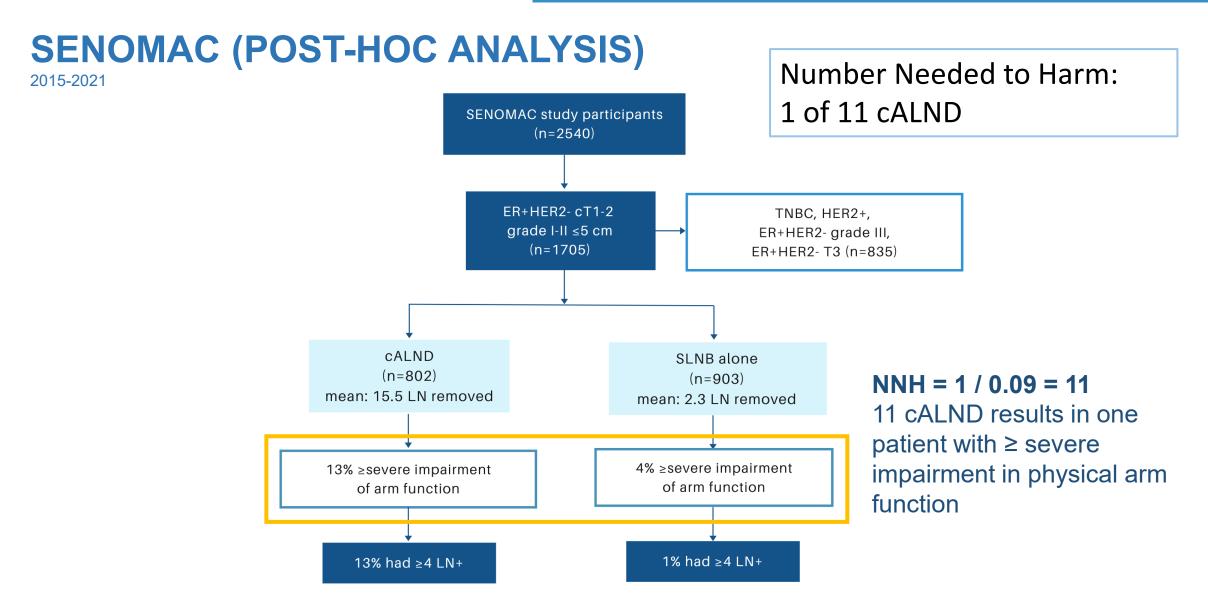


## **Evolving data, current controversies...**

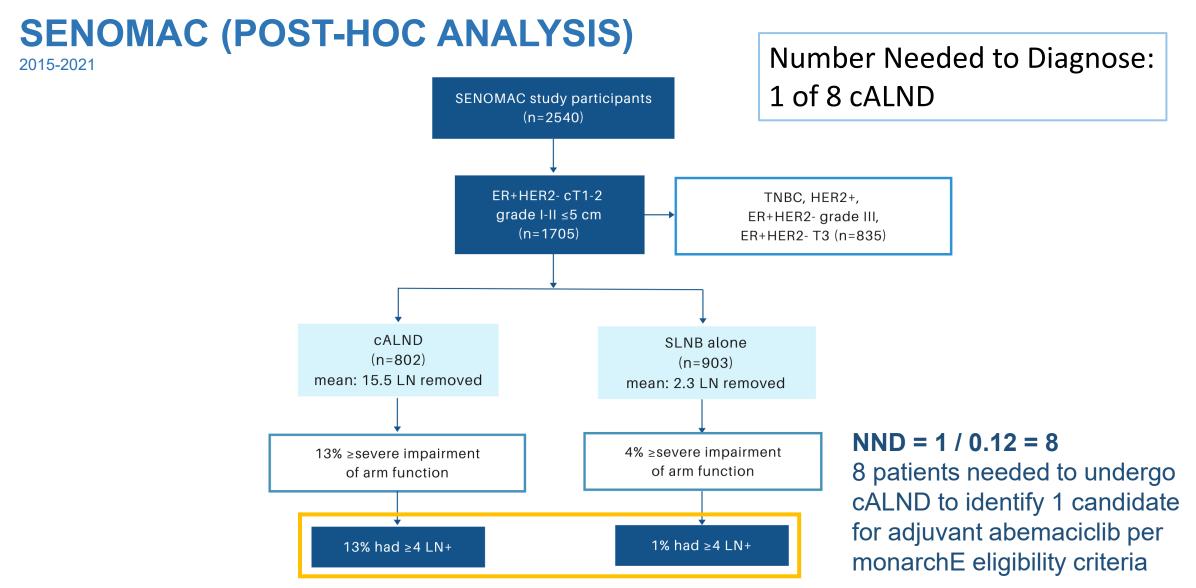
- cT3N0 patients & extracapsular extension with 1-2 SLN+
- cN0 mastectomy population with 1-2 SLN+
- Patients with 3 positive SLNs
- ALND to determine eligibility for adjuvant systemic therapies

# In ER+HER2- patients who undergo upfront SLNB and have 1-2+ SLN, should we return to OR for cALND?





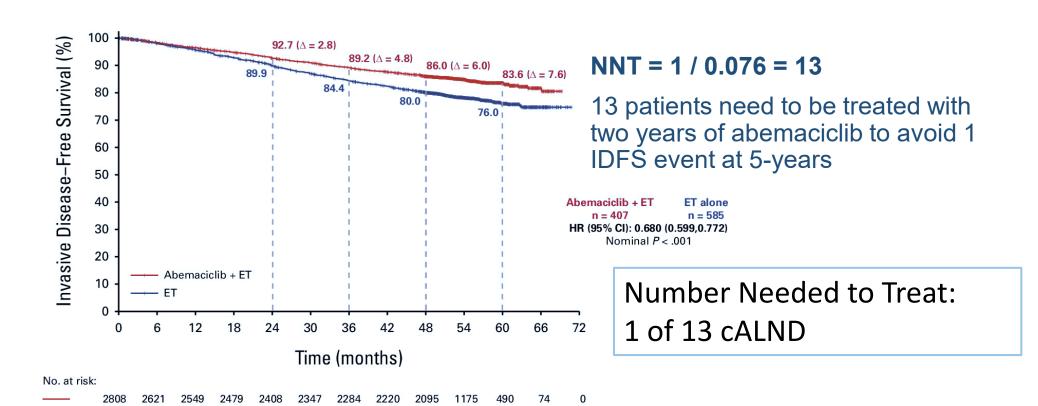
### AXILLARY MANAGEMENT IN MONARCHE ELIGIBLE PATIENTS



## SENOMAC (POST-HOC ANALYSIS WITH MONARCHE DATA)

2195 2125

2015-2021



## **SENOMAC (POST-HOC ANALYSIS)**

2015-2021

## NND x NNT = 104 patients

would need to undergo cALND to avoid one invasive disease-free survival event at 5-years due to the use of abemaciclib;

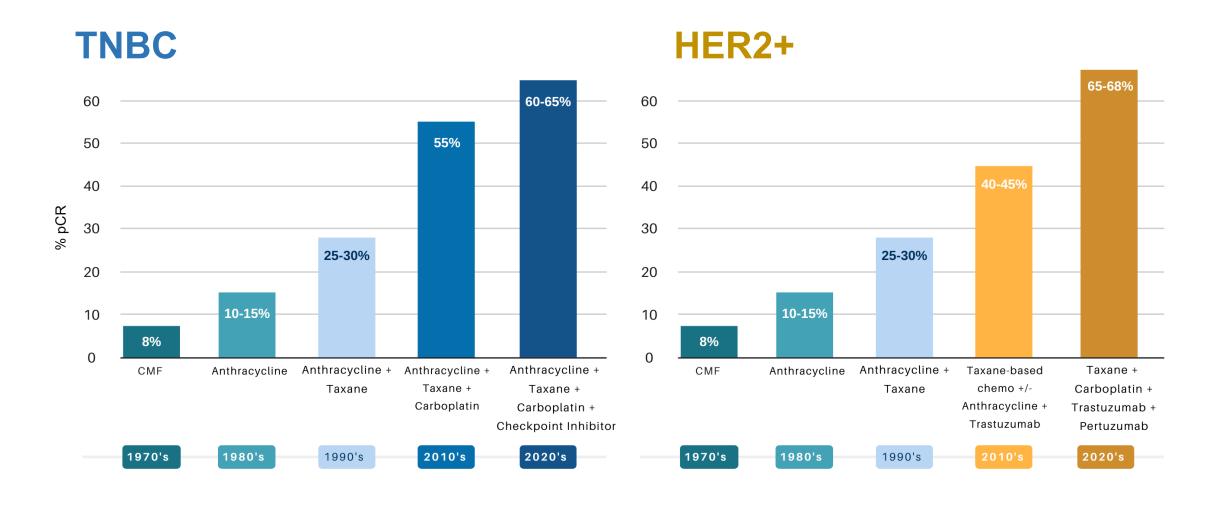
## **NNH = 11 patients**

needing to undergo cALND results to harm one patient with severe or very severe impairment in physical arm function

\*cALND is likely to do more harm than good!

# Clinically node positive (cN+) patients

### IMPROVING pCR WITH NAC IN TNBC AND HER2+ CANCERS



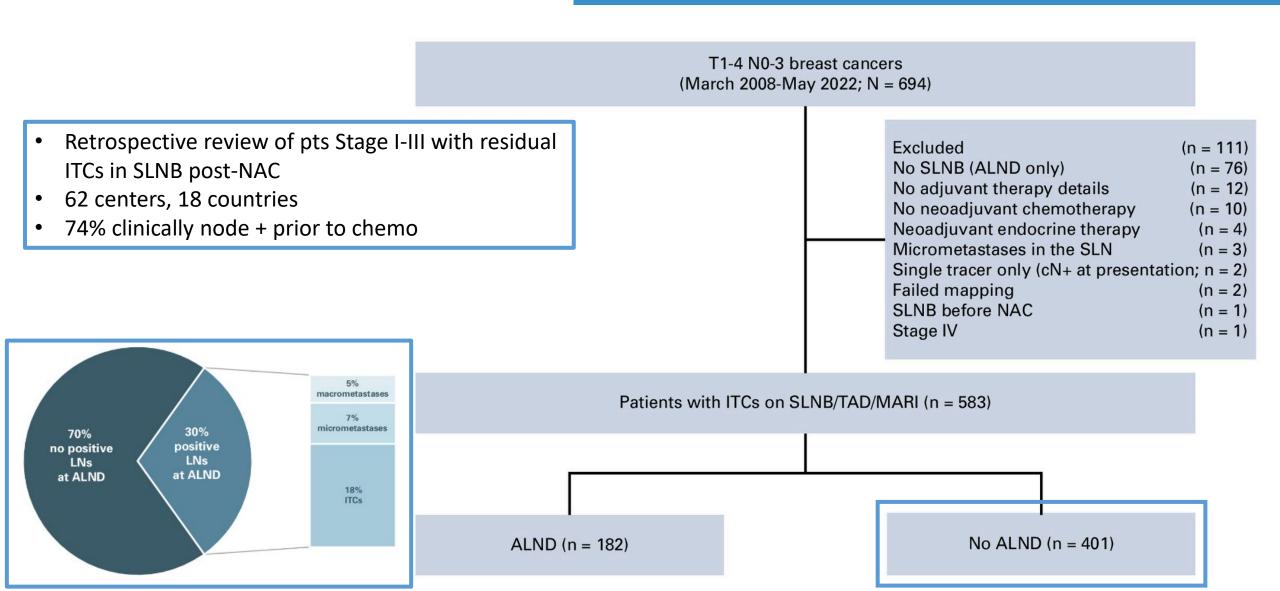
Adapted from T Mamounas

### OMISSION OF ALND IN cN1/ypN0

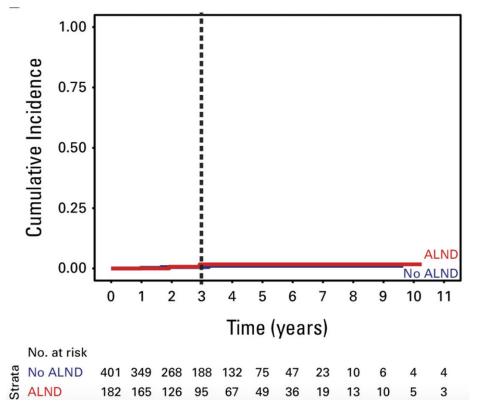
	Type of Surgery	No. ypN0 with SLN alone	% AxRT	Median FU (months)	Axillary Recurrence	Distant Recurrence
<b>IEO Milan</b> (n=147) 2000-2010	SLNB	70	35%	61	0	12.8% at 4 yrs
<b>Mayo</b> (n=315) 2009-2019	SLNB	159	78%	34	0.6% at 3 yrs	-
McGill (n=132) 2013-2018	SLNB	60	71%	36	0	13.7% at 5 yrs
<b>MSKCC</b> (n=555) 2014-2019	SLNB	234	78%	35	0.4% at 3 yrs	6.1% at 4 yrs
<b>EUBREAST 06</b> (n=1144) 2014-2020	SLNB	666	78%	50	0.8% at 3 yrs	7.8% at 3 yrs
	TAD	478	85%	32	0.5% at 3 yrs	7.3% at 3 yrs
<b>NEOSENTITURK</b> (n=2358) 2018-2020	SLNB / TAD	1179	100%	28	0.3% at 3 yrs	-

Galimberti et al, EJSO 2016; Piltin et al, Ann Surg Onc 2020; Wong et al, Ann Surg Onc 2021; Barrio et al, JAMA Oncol 2021; Montagna et al, JAMA Oncol 2024; Cabioglu et al, SABCS 2022 Adapted from Mittendorf SABCS 2023

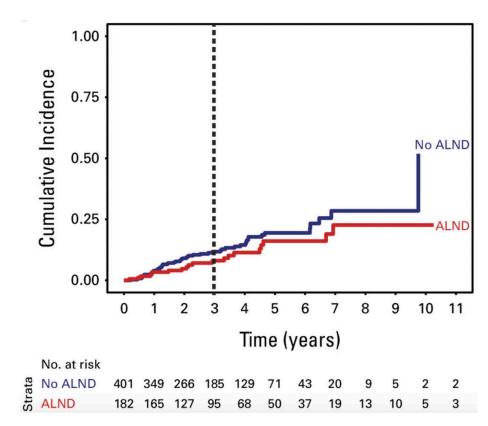
### RESIDUAL ITCS POST NAC: OPBC-05/ ICARO STUDY



## RESIDUAL ITCS POST NAC: OPBC-05/ ICARO STUDY OUTCOMES WITH OMISSION OF ALND



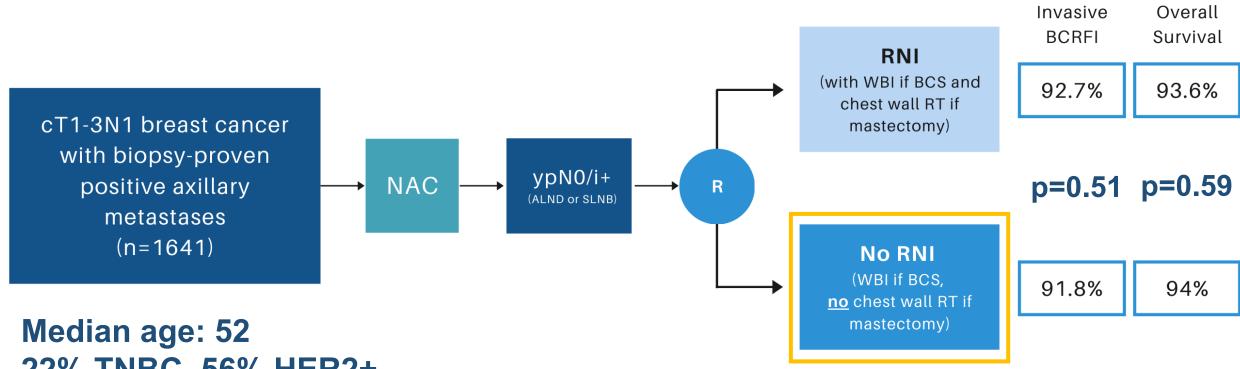
No diff. in isolated axillary recurrences at 5 yrs (ALND 1.7% v No ALND 1.1%; P = 0.7)



No diff. in any invasive recurrence at 5 yrs (ALND 16% v No ALND 19%; P = 0.13)

### **NRG / NSABP B-51 / RTOG 1304**

2013-2020



22% TNBC, 56% HER2+

**Breast pCR: 78.5%** 

42% Mastectomy, 58% BCS

55.5% SLNB alone

Type of surgery (mastectomy, BCS);
HR status; HER2 status;
Adjuvant chemotherapy (yes/no); Breast pCR (yes/no)

5-year

5-year

## **Summary (cN+ population):**

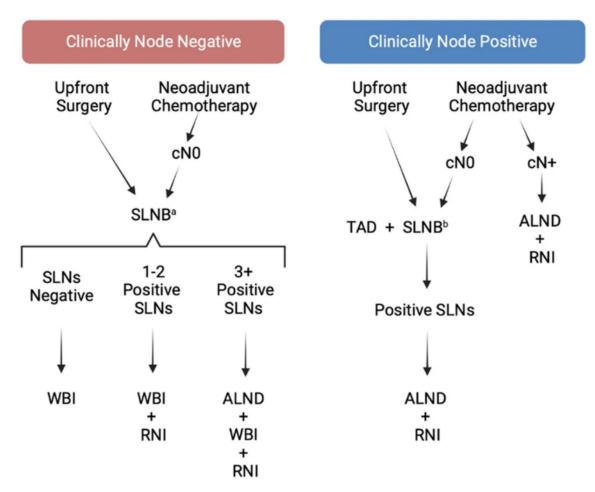
- Omission of ALND + RNI is appropriate for cN1 patients who convert to cN0/ypN0 after NAC
- Omission of ALND is appropriate for similar patients with residual ITCs; role of RNI remains less clear

 Ongoing trials are evaluating whether AxRT can be used in lieu of ALND for cN1 patients with residual nodal disease in the SLN post NAC

### **Current Axillary Management Algorithm**

From: Axillary Management: How Much Is Too Much?

### **Summary of Axillary Management Algorithm**



>70 years with cT1, N0 ER+ or significant comorbidities

No Axillary Staging

<sup>a</sup> SLNB with single tracer (radiocolloid) + blue dye upon difficulty with identification

<sup>b</sup>SLNB with dual tracer, removal of clipped node and at least 3 sentinel nodes

Summary of Axillary Management Algorithm



# Thank you

## **Any Questions?**