Localized Therapy: Updates from a Surgery Perspective

Adrienne Nicole Cobb, MD MS
Assistant Professor
Surgical Oncology
Froedtert & Medical College of Wisconsin

Disclosures

Adrienne Nicole Cobb, MD MS has no relevant financial relationships to disclose.

Outline

Local Therapy

- Contralateral Mastectomy in Patients with Germline Mutations by Katharine Yao, MD
- ACOSOG Z11102 by Judy Boughey, MD
- Local-Regional Management and Prognosis by Jennifer Plichta, MD, MS, FACS

Clinical Controversies

- To Clip or Not to Clip by Abigail Caudle, MD MS and Viviana Galimberti, MD

Axillary Management

- Axillary Management by Tracy-Ann Moo, MD
- The OPBC-04/EUBREAST-06/OMA Study by Giacomo Montagna MD

Local Therapy

Contralateral Mastectomy in Patients with Germline Mutations
Katharine Yao, MD

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Germline Mutations and Penetrance

Germline mutation	ASCO	St Gallen	NCCN
BRCA1/2	High (3-5X)	High (>3-5X)	High (>3-5X)
PALB2	Moderate	High	High
T53	High	High	High
PTEN	High	---	High
CDH1	High	Moderate	High
STK11	High	Moderate	High
CHEK2	Moderate	Moderate	---
ATM	Moderate	Low	Moderate (2-3X)
BARD1	---	Moderate	Moderate
RAD51c	---	Low	Unknown
RAD51d	---	Low	Unknown
BRIP1	---	Low	---
NF1	---	Low	Doubt

Corso et al Ann Surg Oncol 2022;29:5821

	Overall CBC risk at 20yrs	First BC at <40yo	First BC at >=50yo
BRCA1	40%	60%	38%
BRCA2	26%	68%	20%

Kuchenbaecker JAMA 2017; 317:2402

Yao, K. SABCS Educational Session 12/6/22

Contralateral Mastectomy in Patients with Germline Mutations
Katharine Yao, MD

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Pros and Cons of CPM in Gene Carriers

PROs

- Decrease contralateral breast cancer risk*
- QOL
- Patient satisfaction/regret*
- Avoid future imaging
- Survival benefit??*

CONs

- Operative risks*
- Long term impact to cosmesis/sexuality*
- Delay adjuvant therapy
- Survival benefit??*

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Contralateral Mastectomy in Patients with Germline Mutations
Katharine Yao, MD

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Check for updates

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asco special articles

Management of Hereditary Breast Cancer: American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology Guideline

Nadine M. Tung, MD[1]; Judy C. Boughey, MD[2]; Lori J. Pierce, MD[3]; Mark E. Robson, MD[4]; Isabelle Bedrosian, MD[5]; Jill R. Dietz, MD[6]; Anthony Dragun, MD[7]; Judith Balmana Gelpi, MD, PhD[8]; Erin W. Hofstatter, MD[9]; Claudine J. Isaacs, MD[10]; Ismail Jatoi, MD, PhD[11]; Elaine Kennedy[12]; Jennifer K. Litton, MD[5]; Nina A. Mayr, MD[13]; Rubina D. Qamar, MD[14]; Mark G. Trombetta, MD[15]; Brittany E. Harvey, BS[16]; Mark R. Somerfield, PhD[16]; and Dana Zakalik, MD[17]

- Germline BRCA status should not preclude breast conserving surgery
- Breast conserving therapy should be offered to carriers of moderate penetrance genes (mutation status alone should not dictate decision for bilateral mastectomy)
- Radiation does not increase risk of cancer recurrence in BRCA carriers
- Data on radiation toxicity in ATM carriers is inconsistent, breast conserving surgery is encouraged

Tung et al JCO 2020:38:2080

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Contralateral Mastectomy in Patients with Germline Mutations
Katharine Yao, MD

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CPM Discussion with Affected Mutation Carriers

Germline mutation	<60yo	≈>60yo
BRCA1/2		
ATM		
CHEK2		
PALBB2		
NF1, BARD1, BRIP1		

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ACOSOG Z11102

Impact of Breast Conservation Therapy on Local Recurrence in Patients with Multiple Ipsilateral Breast Cancer – Results from ACOSOG Z11102 (Alliance)

Impact of Breast Conservation Therapy on Local Recurrence in Patients with Multiple Ipsilateral Breast Cancer – Results from ACOSOG Z11102 (Alliance)

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Judy C. Boughey, Kari M. Rosenkranz, Karla V. Ballman, Linda McCall, Bruce G. Haffty, Laurie W. Cuttino, Charlotte D. Kubicky, H. Carisa Le-Petross, Armando E. Giuliano, Kimberly J. Van Zee, Kelly K. Hunt, Olwen M. Hahn, Lisa A. Carey, Ann H. Partridge

Impact of Breast Conservation Therapy on Local Recurrence in Patients with Multiple Ipsilateral Breast Cancer – Results from ACOSOG Z11102 (Alliance)

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Background - MIBC

- Increased diagnosis of multiple ipsilateral breast cancer (MIBC)
  - Improved imaging, increased use of breast MRI
- Historical, retrospective studies showing high rates of local regional recurrence with BCT

Primary Author of Study	Surgical Years	Number of Patients (n)	Median Follow-up (Months)	Number of Recurrences	Outcome
Leopold	1968-1981	10	64	4	NA
Kurtz	1975-1983	61	71	15	NA
Wilson	Prior to 12/1988	13	71	3	6-year LRR: 25%

Many surgeons recommend mastectomy

Boughey, J. SABCS GS4-01 12/9/22

Impact of Breast Conservation Therapy on Local Recurrence in Patients with Multiple Ipsilateral Breast Cancer – Results from ACOSOG Z11102 (Alliance)

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Z11102 - Prospective single arm phase II trial to evaluate breast conservation in women with two or three lesions in the breast

Inclusion Criteria

- Women age ≥40
- 2 or 3 foci of breast cancer
- At least one foci of invasive disease
- ≥ 2 cm normal tissue between lesions
- No more than 2 quadrants with disease
- cN0 or cN1 disease

Exclusion Criteria

- Focus of disease >5cm on imaging
- Bilateral breast cancer
- Prior ipsilateral breast cancer
- Known BRCA 1/2 mutations
- Neoadjuvant therapy
- Men

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

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Impact of Breast Conservation Therapy on Local Recurrence in Patients with Multiple Ipsilateral Breast Cancer – Results from ACOSOG Z11102 (Alliance)

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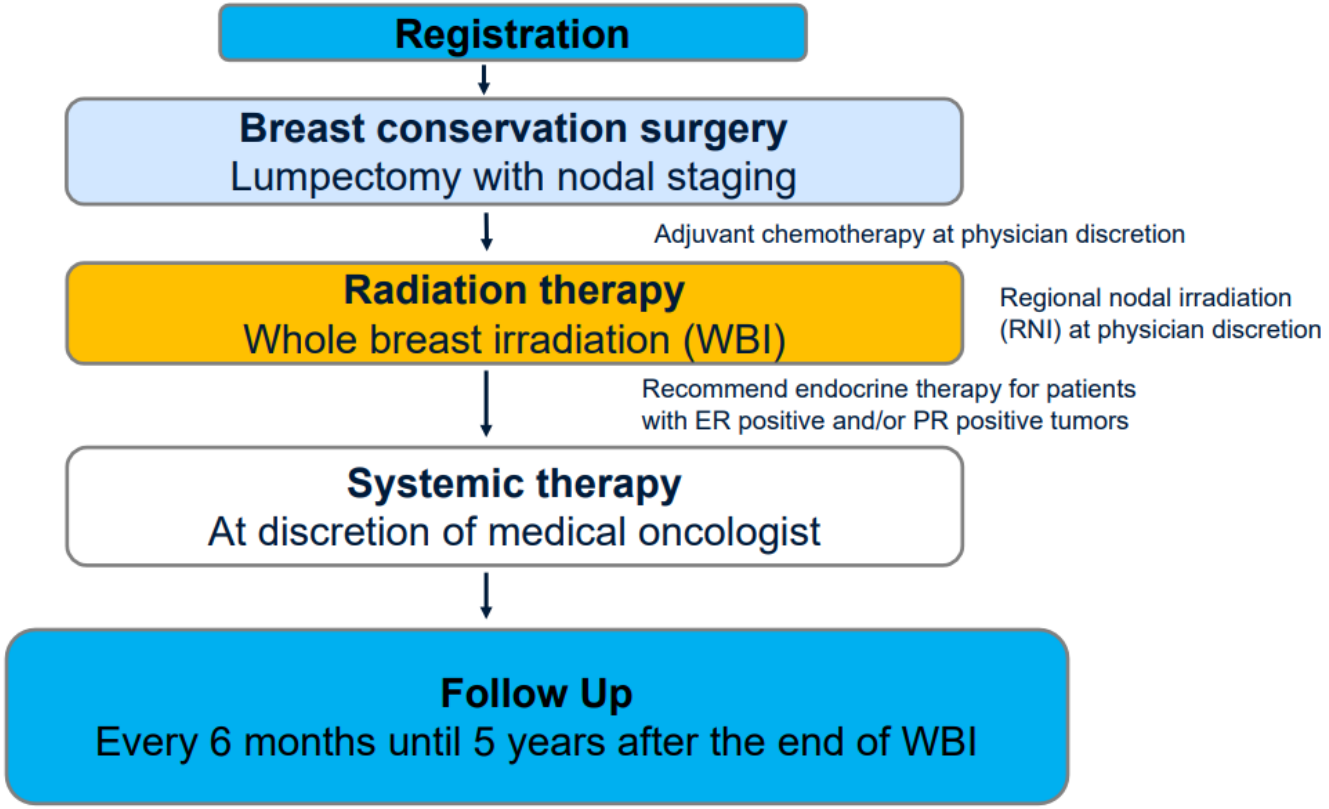

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

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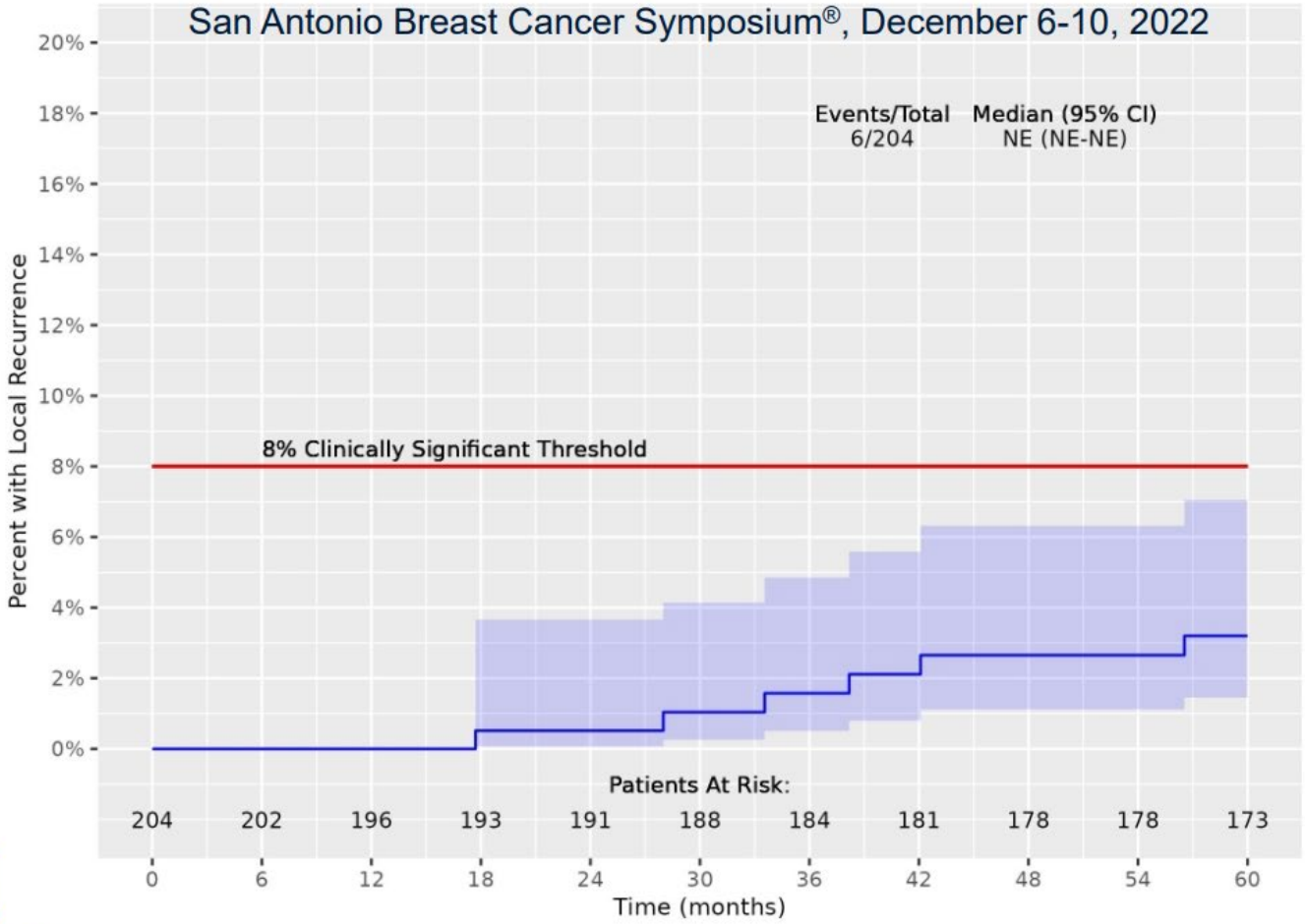

3.1%
(95% CI:
1.3 - 6.4)

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Impact of Breast Conservation Therapy on Local Recurrence in Patients with Multiple Ipsilateral Breast Cancer – Results from ACOSOG Z11102 (Alliance)

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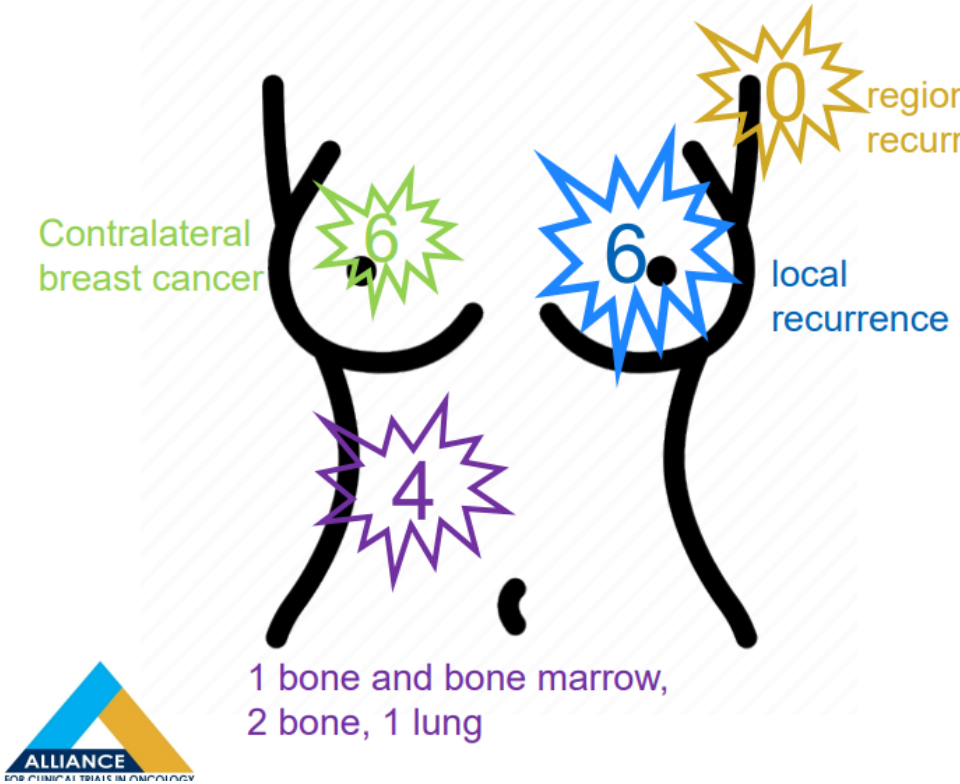
Outcomes



- Local and distant recurrence – 0
- New non-BC primaries – 3
  (1 gastric, 1 lung, 1 ovarian)
- Died – 8
  - Non-breast cancer death – 7
  - Breast cancer death – 1

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Impact of Breast Conservation Therapy on Local Recurrence in Patients with Multiple Ipsilateral Breast Cancer – Results from ACOSOG Z11102 (Alliance)

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Z11102 Conclusions

- In MIBC breast conserving surgery with adjuvant radiation with lumpectomy site boosts has a low LR rate - 3.1% at 5 years
  - Studied population – predominantly post-menopausal, ER+/HER2-, 2 foci, node negative
- Factors impacting local recurrence
  - Preop MRI (to evaluate for extent of disease)
  - Adjuvant endocrine therapy (for ER+ breast cancer)

BCT is a reasonable consideration in MIBC

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

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Locoregional Management

Poster Spotlight:
Local-Regional Management and Prognosis
Jennifer Plichta, MD, MS, FACS

San Antonio Breast Cancer Symposium®, December 6-10, 2022

7-gene predictive biosignature improves risk stratification for breast ductal carcinoma in situ patients compared to clinicopathologic criteria, identifying a low risk group not clinically benefiting from adjuvant radiotherapy

Abstract #1309906

Authors: Rachel Rabinovitch, MD, Frank A. Vicini, MD, Chirag Shah, MD, Julie A. Margenthaler, MD, Brian Czerniecki, MD PhD, Pat Whitworth, MD, David Dabbs, MD, G Bruce Mann, MBBS PhD, Fredrik Wärnberg, MD PhD, Sheila Weinmann, MPH PhD, Michael Leo, PhD, Jess Savala, MD, Steven Shivers, PhD, Karuna Mittal, PhD, Troy Bremer, PhD

Poster Spotlight:
Local-Regional Management and Prognosis
Jennifer Plichta, MD, MS, FACS

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Background

- **The study aim was to analyze a cohort of women with DCIS treated with BCS +/- RT to determine if the biosignature could identify a subset of women who do not benefit from RT and evaluate the biosignature in patients meeting "low risk" or "high risk" clinicopathological criteria.**

- "Low risk" defined by favorable clinicopathological criteria
  - Age >50 or Grade 1-2, and RTOG 9804-like disease (G1-2, screen detected)

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Poster Spotlight:
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Jennifer Plichta, MD, MS, FACS

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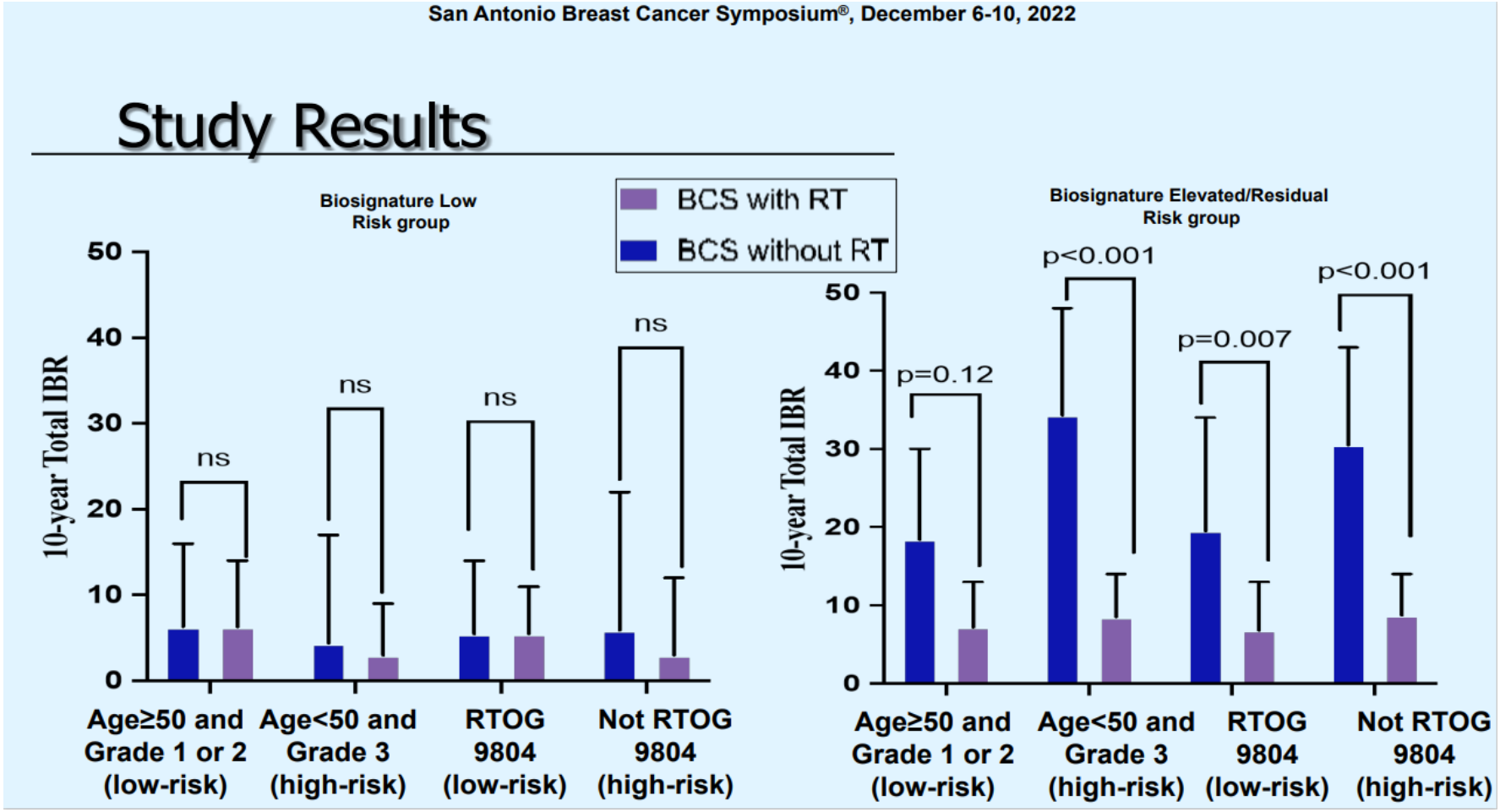

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Poster Spotlight:
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Take Home Points

- Biosignature Low Risk = excellent outcomes and no significant RT benefit, even with G3 disease or age <50y
- Biosignature Elevated/RRt = clinically meaningful IBR benefit with RT, even with favorable clinicopathologic features

- ***Practice Today: Clinicopathological factors may be inadequate for assessing RT benefit, and this 7-gene biosignature may provide superior prediction of 10-yr risk and RT benefit than standard risk models.***

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Clinical Controversies

“To Clip or not to Clip”
Viviana Galimberti, MD

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Can we de-escalate by omitting AD after NAT ?

Galimberti, V. SABCS Clinical Controversies 12/7/22

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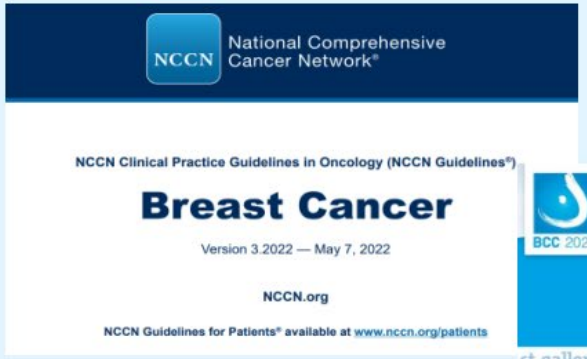

SNB is permitted instead of AD considered in a patient who presented with (cN1) and received NAT that downstage to clinically negative if…..

- **Marking of sampled axillary nodes with tattoo or clip**
- **Using dual tracer, and by removing more than 2 negative sentinel nodes.**

Galimberti, V. SABCS Clinical Controversies 12/7/22

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Axillary recurrence after SNB alone
cN+ ➡ ypN0 after NAT

Author	N. of pts	Axillary recurrence	Follow up
Kahler Ribeiro Fontana S	**123**	**1.6%**	**10 yrs**
Martelli G	81	0%	7 yrs
Wong SM	58	0%	5 yrs
Barrio A	234	1.6%	3 yrs
Piltin MA	139	0.7%	2 yrs

Kahler-Riberio Fontana , et al. EJSO 2020
Martelli G. et al Ann Surgery 2022
Piltin MA , et al. Ann Surg Oncol 2020

Wong SM, et al . Ann Surg Oncol 2021
Barrio A, et al. JAMA 2021

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ELSEVIER

European Journal of Surgical Oncology (EJSO)

Volume 42, Issue 3, March 2016, Pages 361–368

Sentinel node biopsy after neoadjuvant treatment in breast cancer: Five-year follow-up of patients with clinically node-negative or node-positive disease before treatment

V. Galimberti[a], S.K. Ribeiro Fontana[a], P. Maisonneuve[b], F. Steccanella[a], A.R. Vento[a], M. Intra[a], P. Naninato[a], P. Caldarella[a], M. Iorfida[c], M. Colleoni[c], G. Viale[d, e], C.M. Grana[f], N. Rotmensz[b], A. Luini[a]

396 pts after a follow up of 61 months, IQR 38-82

- Axillary failure occurred in only 1 (0.7%) initially cN1/2 → cN0
- 5 yr. DDFS was 81.1% in initially cN0 and 73.4% in initially cN1/2 (p= 0.33)
- 5 yr. OS was 93.3% in initially cN0 and 86,3% in initially cN1/2 (p= 0.12)

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Viviana Galimberti, MD

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Summing up

CLIP	NOT CLIP
FNR <10%	FNR <10% with >2 negative SNs
	FNR >10%with <2 SNs
More expensive	Less expensive
More time consuming	Easy to identify
More difficult to identify	Low axillary recurrence
Unknown how many nodes should be clipped	GOOD OUTCOMES
Unknown what to do in case of lost clip	
NO DATE ON OUTCOME	

Galimberti, V. SABCS Clinical Controversies 12/7/22

"The Case for Clipping Nodes"
Abigail Caudle, MD MS

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Targeted Axillary Dissection

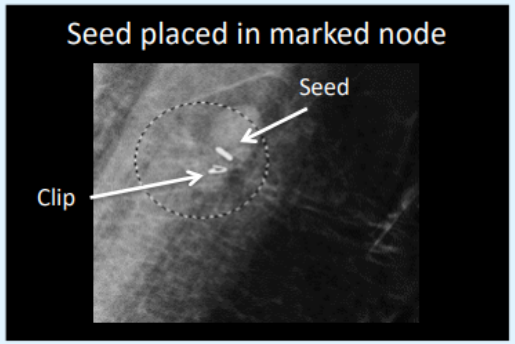
Metallic clip placed when FNA of lymph node shows metastases

At surgery, remove:

- LN with ***KNOWN*** disease (with clip)

and

- LNs most likely to harbor disease (SLN)



Caudle et al. *JAMA-Surg.* 2015;150(2):137-43

"The Case for Clipping Nodes"
Abigail Caudle, MD MS

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Why Localize the Clipped Node?

Clipped node not retrieved as a SLN:

- MD Anderson[1]: 23%
- Turkey[2]: 19%
- SenTa[3]: 37%
- RISAS[4]: 29%

[1]Caudle et al. *JCO*, 2016
[2]Diego et al. *Ann Surg Onc*, 2016
[3]Kuemmel et al. Ann Surg 2020
[4]Simons et al. *JAMA Surgery*, 2022

	SLND Alone	Marked Node Alone	SLN + Marked Node
MD Anderson	10.1%	4.2%	**2%**
SenTa	23.9%	7.2%	**4.3%**
RISAS	18.6%	6.8%	**2.5%**

Caudle et al. *JCO* 2016
Kuemmel et al. *Ann Surg*. 2022
Simons et al. *JAMA Surgery*. 2022

Caudle, A. SABCS Clinical Controversies 12/7/22

“The Case for Clipping Nodes”
Abigail Caudle, MD MS

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Low Volume Disease Important

- Study of 702 CN+ patients who underwent NAC followed by SLND

SLND results	Additional Disease Found
Isolated Tumor Cells	17% (1/6)
Micrometastases	64% (28/44)
Macrometastases	62% (75/121)

Moo et al. *Ann Surg Oncol*. March 2018

Axillary Management

Spotlight Poster Discussion: Axillary Management
Tracy-Ann Moo, MD

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Axillary dissection to determine nodal burden to inform systemic therapy recommendations in patients with clinically node-positive breast cancer: Pre-planned substudy of TAXIS (OPBC-03, SAKK 23/16, IBCSG 57-18, ABCSG-53, GBG 101)

- Background: Chemotherapy recommendations in luminal breast cancer based on number of positive LNs in upfront and post NAC setting, and in recent trials number of LNs also impacts use of genomic testing
- AIM: Examine role of ALND in systemic therapy decision making
  - cN+ , adjuvant and NAC therapy
- Multicenter phase III trail, 8/2018-6/2022

Weber et al. SABCS Spotlight Poster Discussion, 2022.

Memorial Sloan Kettering Cancer Center

Moo, T. SABCS Poster Spotlight Discussion 15 12/8/22

Spotlight Poster Discussion: Axillary Management
Tracy-Ann Moo, MD

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Axillary dissection to determine nodal burden to inform systemic therapy recommendations in patients with clinically node-positive breast cancer: Pre-planned substudy of TAXIS (OPBC-03, SAKK 23/16, IBCSG 57-18, ABCSG-53, GBG 101)

Axillary treatment of HR+ / Her2- breast cancer patients with upfront surgery			
n = 297			
	TAS+ART	ALND	
Number of patients (%)	145 (48.8)	152 (51.2)	
			p-value
Median number of removed lymph nodes [IQR]	5 [4-8]	19 [14-26]	
Median number of positive lymph nodes [IQR]	3 [1-4]	4 [2-9]	<0.001

Axillary treatment of breast cancer patients after neoadjuvant systemic treatment			
n = 143			
	TAS+ART	ALND	
Number of patients (%)	71 (49.7)	72 (50.3)	
			p-value
Median number of removed lymph nodes [IQR]	4 [3-6]	16 [12-19]	
Median number of positive lymph nodes [IQR]	1 [1-3]	2 [1-5]	<0.001

Weber et al. SABCS Spotlight Poster Discussion, 2022.

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Spotlight Poster Discussion: Axillary Management
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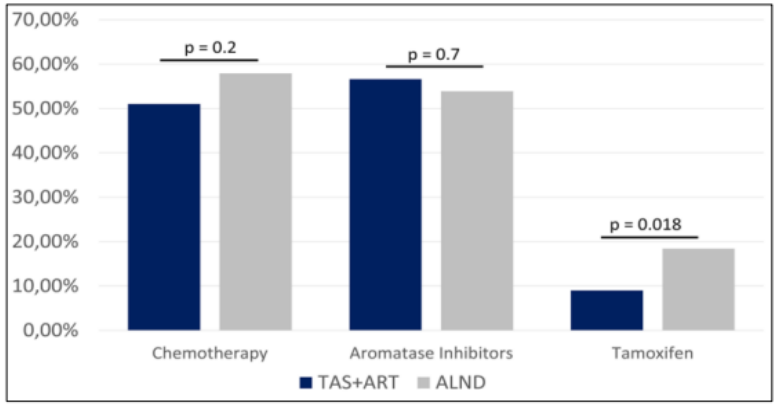
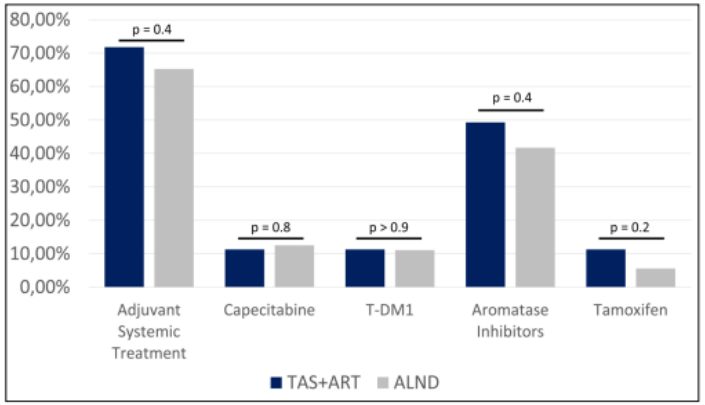
Axillary dissection to determine nodal burden to inform systemic therapy recommendations in patients with clinically node-positive breast cancer: Pre-planned substudy of TAXIS (OPBC-03, SAKK 23/16, IBCSG 57-18, ABCSG-53, GBG 101)

Adjuvant systemic therapy in HR+ / Her2 - patients with upfront surgery using TAS and ART compared to ALND



Adjuvant systemic therapy after neoadjuvant systemic treatment using TAS and ART compared to ALND



Type of Axillary surgery did not impact adjuvant systemic therapy

Weber et al. SABCS Spotlight Poster Discussion, 2022.

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Spotlight Poster Discussion: Axillary Management
Tracy-Ann Moo, MD

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Summary

- Increasing body of evidence demonstrating low rates of axillary recurrence with use of SLNB only in cN1→ypNo, supporting safety
- In HR+/Her 2- disease not otherwise meeting criteria for ALND
  - ALND is in most cases not necessary for adjuvant systemic therapy decision making
- Promising results for pre-operative repeat core needle biopsy/FNA after NAC may help to further tailor axillary surgery in this setting

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OPBC-04/EUBREAST-06/OMA Study

Oncological Outcomes with Omission of ALND

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EUBREAST NETWORK
EUROPEAN BREAST CANCER RESEARCH ASSOCIATION OF SURGICAL TRIALISTS

ONCOPLASTIC BREAST CONSORTIUM

The OPBC-04/EUBREAST-06/OMA Study

Oncological Outcomes Following Sentinel Lymph Node Biopsy (SLNB) or Targeted Axillary Dissection (TAD) in Breast Cancer Patients Downstaging From Node Positive To Node Negative with Neoadjuvant Chemotherapy

Giacomo Montagna, MD, MPH, Mary Mrdutt, MD, Susie X. Sun, MD, Callie Hlavin, MD, Emilia Diego, MD, Stephanie M. Wong, MD, MPH, Andrea V. Barrio, MD, Astrid Botty, MD, Neslihan Cabioglu, MD, PhD, Varadan Sevilimedu, MBBS, DrPH, Laura Rosenberger, MD, MS, Shelley Hwang, MD, Abigail Ingham, MBchB, Bärbel Papassotiropoulus, MD, Bich Doan Nguyen-Sträuli, MD, Christian Kurzeder, MD, Danilo Diaz Aybar, MD, Denise Vorburger, MD, Dieter Michael Matlac, MD, Edvin Ostapenko, MD, Fabian Riedel, MD, Florian Fitzal, MD, Francesco Meani, MD, Franziska Fick, MD, Jaqueline Sagasser, MD, Jörg Heil MD, PhD, Hasan Karanlık, MD, Konstantin J. Dedes, MD, Laszlo Romics, MD, PhD, Maggie Banys-Paluchowski, MD, PhD, Mahmut Muslumanoglu, MD, Maria Del Rosario Cueva Perez, MD, Marcelo Chevaz Diaz, MD, Martin Heidinger, MD, Mathias K. Fehr, MD, Mattea Reinisch, MD, Mustafa Tukenmez, MD, Nadia Maggi, MD, Nicola Rocco, MD, PhD, Nina Ditsch, MD, Oreste Davide Gentilini, MD, Regis R. Paulinelli, MD, PhD, Sebastian Sole Zarhi, MD, Sherko Kümmel, MD, PhD, Simona Bruzas, MD, Simona di Lascio, MD, Tamara Parissenti, MD, Tanya L. Hoskin, MS, Uwe Güth, MD, Valentina Ovalle, MD, Christoph Tausch, MD, Henry M. Kuerer, MD, PhD, Abigail S. Caudle, MD, Jean-Francois Boileau, MD, MSc, Judy C. Boughey, MD, Thorsten Kühn, MD, PhD, Monica Morrow, MD and Walter P. Weber, MD

Montagna, G. SABCS GS4-02 12/9/22

Oncological Outcomes with Omission of ALND

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Background: Axillary Staging in Node-Positive Patients After NAC

- In node-positive patients treated with NAC, 4 prospective studies have demonstrated that the false-negative rate of SLNB is > 10%
- As all patients in these trials had ALND, they did not provide data on axillary recurrence
- Single-center studies have demonstrated low rates of axillary recurrence after SLNB alone but are limited by small sample size and concerns about generalizability

Boughey J, JAMA 2013
Kühn T, Lancet Oncol 2013
Boileau J, J Clin Oncol 2015

Classe J, Breast Cancer Res Treat 2019
Piltin M, Ann Surg Oncol 2020
Martelli G, Ann Surg 2020

Barrio A, JAMA Oncol 2021
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Cabioglu N, Eur J Surg Oncol 2021
Damin A, Breast Cancer Res Treat 2021

Montagna, G. SABCS GS4-02 12/9/22

Oncological Outcomes with Omission of ALND

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Surgical Groups

SLNB n = 666

- Dual-tracer mapping: 666 **(100%)**
- Clip placement: 152/666 **(23%)**
- Clipped node removed (without localization): 129/154 **(86%)**
- **Median follow-up: 4.2 years**

TAD n = 478

- Dual-tracer mapping: not required
- Clipped node removed: 466/478 **(99%)**
- Localization technique
  - Radioactive seed: 343/478 **(72%)**
  - Wire: 115/478 **(24%)**
  - Ultrasound: 11/478 **(2.3%)**
  - Other (Magseed, tattoo and wire, seed and wire): 9/478 **(1.9%)**
- **Median follow-up: 2.7 years**

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Oncological Outcomes with Omission of ALND

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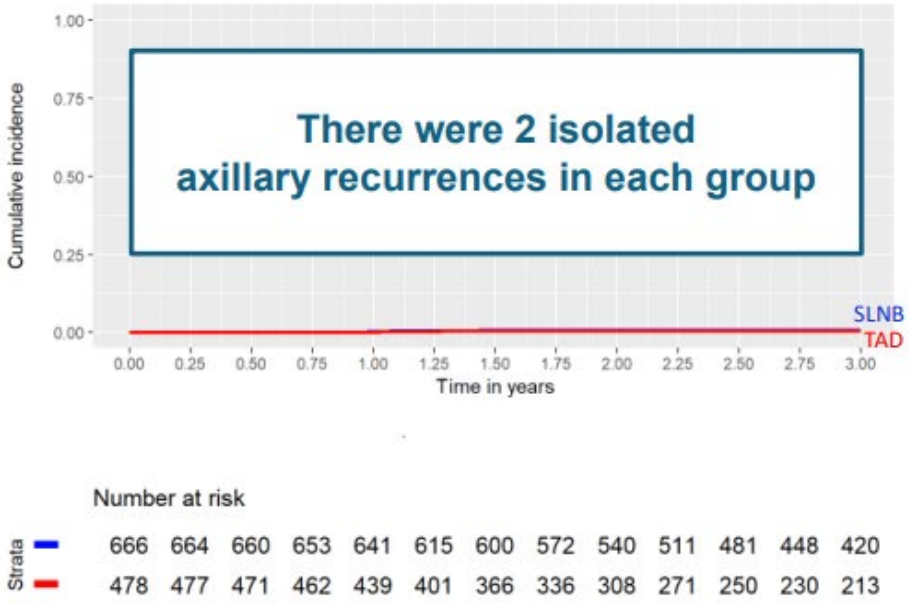
Any Axillary Recurrence (TAD vs SLNB)

3-year rate of any axillary recurrence TAD vs SLNB (0.5% vs 0.8%, p = 0.55)



Montagna, G. SABCS GS4-02 12/9/22

Oncological Outcomes with Omission of ALND

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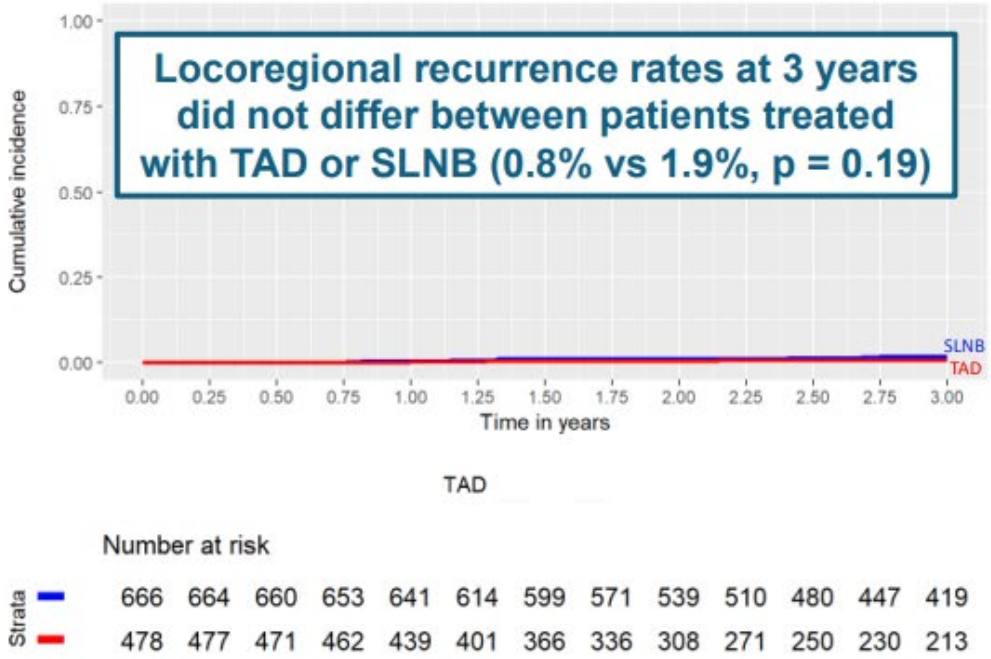
Locoregional Recurrence (TAD vs SLNB)



Montagna, G. SABCS GS4-02 12/9/22

Oncological Outcomes with Omission of ALND

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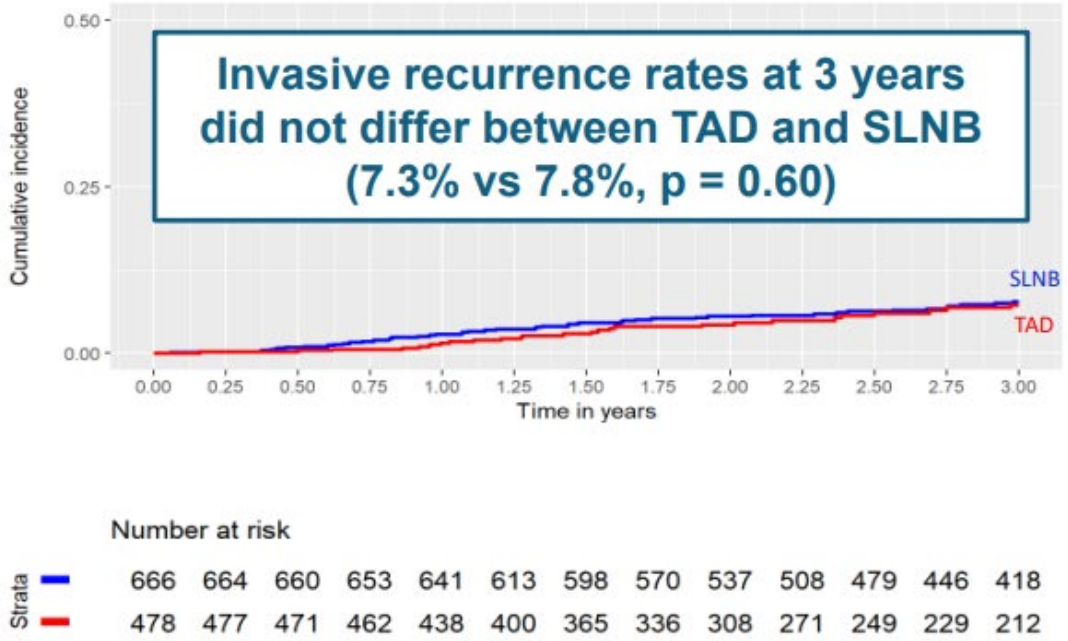
Any Invasive Recurrence (TAD vs SLNB)



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Oncological Outcomes with Omission of ALND

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Conclusions

- Early axillary recurrence after omission of ALND in node-positive patients who downstage to node negative with NAC is a very rare event
  - was not significantly lower in TAD than in SLNB (in spite of more TAD patients receiving nodal RT)
  - longer follow-up is needed

- Compared to SLNB only, TAD allows for removal of fewer lymph nodes (median: 1)
  - it is unknown whether this difference is clinically meaningful and whether TAD is cost-effective

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THANK YOU!

Extra Slides

Impact of Breast Conservation Therapy on Local Recurrence in Patients with Multiple Ipsilateral Breast Cancer – Results from ACOSOG Z11102 (Alliance)

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		Total (N=204)
Age	Mean (SD)	61.1 (10.2)
Number of lesions	Two	197 (96.6%)
	Three	7 (3.4%)
Clinical T Category	T1	121 (59.3%)
	T2	83 (40.7%)
Clinical N Category	N0	195 (95.6%)
	N1	9 (4.4%)
Histology	All Ductal	119 (58.3%)
	All Lobular	16 (7.8%)
	DCIS/Ductal	46 (22.5%)
	DCIS/Lobular	5 (2.5%)
	Ductal/Lobular	18 (8.8%)
Highest Histologic Grade on Biopsy	G1 (Low)	53 (26.0%)
	G2 (Intermediate)	96 (47.1%)
	G3 (High)	52 (25.5%)
	GX	3 (1.5%)
Margins	≥2mm	174 (85.3%)
	<2mm	30 (14.7%)

		Total (N=204)
Tumor Biology	ER+/Her2-	167 (83.5%)
	ER-/Her2-	10 (5.0%)
	Her2+ (any ER)	23 (11.5%)
	Missing	4
Axillary Surgery	SLN only	172 (84.3%)
	ALND (+/- SLN)	30 (14.7%)
	No ax surgery	2 (1.0%)
Pathologic T Category	T1	157 (77.0%)
	T2	45 (22.1%)
	T3	2 (1.0%)
Pathologic N Category	N0	158 (77.5%)
	N1	37 (18.1%)
	N2-3	7 (3.5%)
	NX	2 (1.0%)
Adjuvant Chemotherapy	Yes	59 (28.9%)
	No	145 (71.1%)
Adjuvant Endocrine Therapy in ER+ BC	Yes	175 (89.7%)
	No	20 (10.3%)

Median follow-up of 66.4 months (range: 1.3-90.6)

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Breast MRI

- Initially required, 2015 amended to allow patients without MRI
- 189 patients (92.6%) had MRI, 15 patients (7.4%) no MRI
- Local Recurrence
  - 3/189 with MRI and 3/15 without MRI

	Estimated 5-year LR (95%CI)	HR (95% CI)	P value
Breast MRI (n=189)	1.7 (0.6 – 5.2)	1.00 (ref)	0.002
No Breast MRI (n=15)	22.6 (7.9 – 55.1)	13.5 (2.7 – 66.9)	