UPDATES FROM THE ST. GALLEN B.C.C. 2019

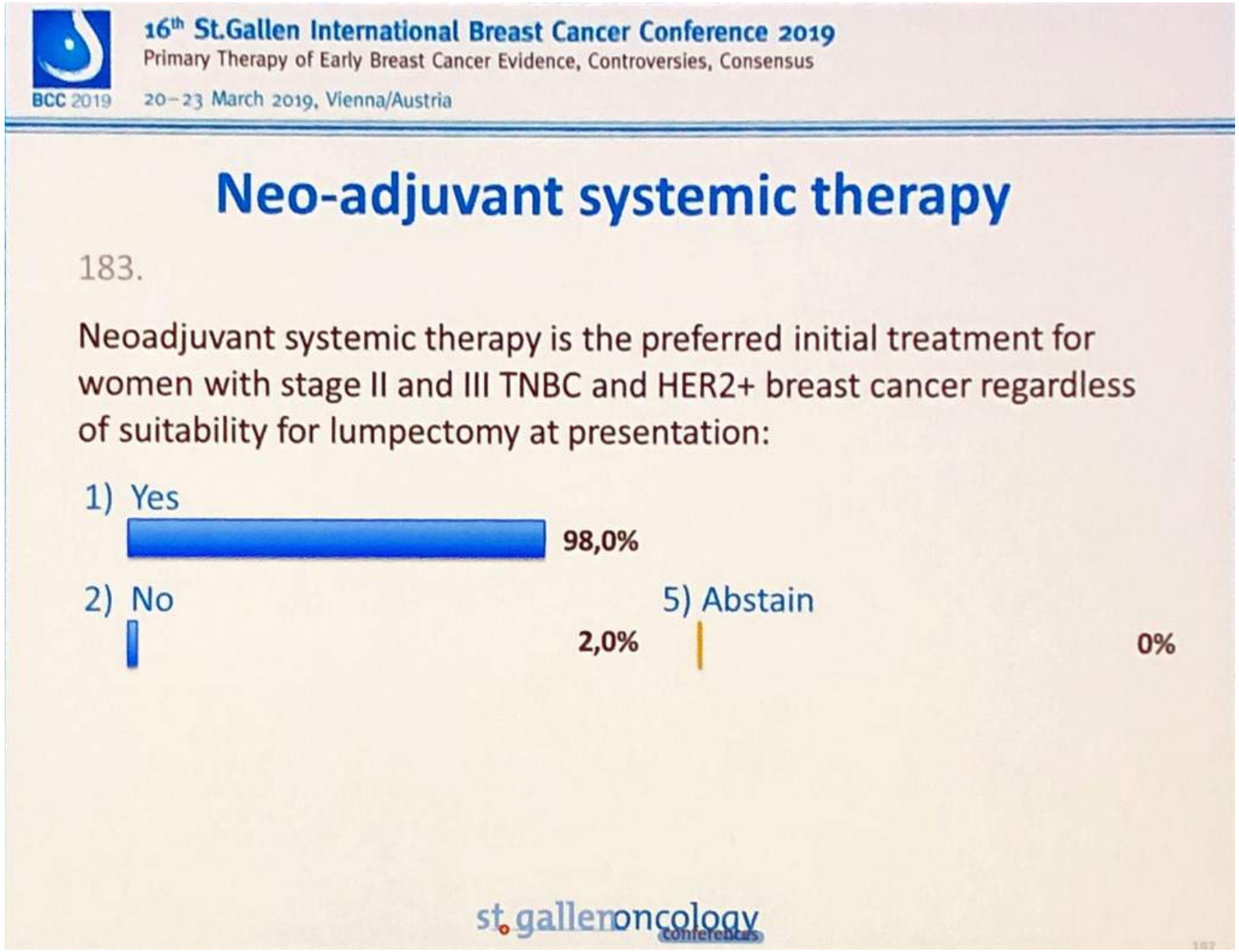
Andrea Villasco, Lorenzo Novara, Nicoletta Biglia

NEOADJUVANT CHEMOTHERAPY

NEOADJUVANT CHEMOTHERAPY: RATIONALE

- **pCR**: strong and independent **prognostic factor**
- **non-pCR**: higher risk population who can benefit from **additional treatment strategies**
- **Mammary and axillary downstaging**: rise in BCS and ALND avoidance

NEOADJUVANT CHEMOTHERAPY: BACK FROM THE… END



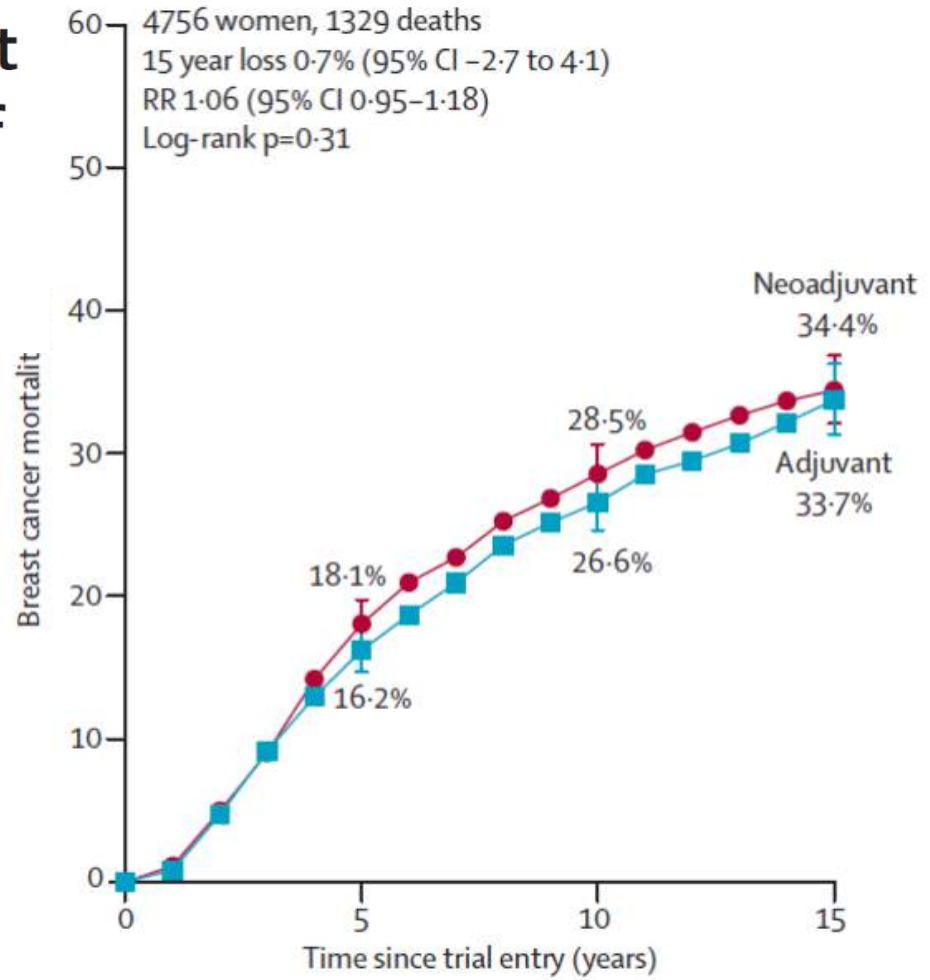
WHY SHOULD WE CHOOSE NEOADJUVANT CHEMOTHERAPY?

Long-term outcomes for neoadjuvant versus adjuvant chemotherapy in early breast cancer: meta-analysis of individual patient data from ten randomised trials

*Early Breast Cancer Trialists' Collaborative Group (EBCTCG)**

THE LANCET Oncology
Volume 19, Issue 1, January 2018, Pages 27-39

- **No significant difference between** NACT and adjuvant chemotherapy was noted for **distant recurrence** (RR 1·02 [95% CI 0·92–1·14]; p=0·66), **breast cancer mortality** (RR 1·06 [0·95–1·18]; p=0·31), or **death from any cause** (RR 1·04 [0·94–1·15]; p=0·45).



Breast cancer mortality crude rates (events per woman-years) and log-rank analyses

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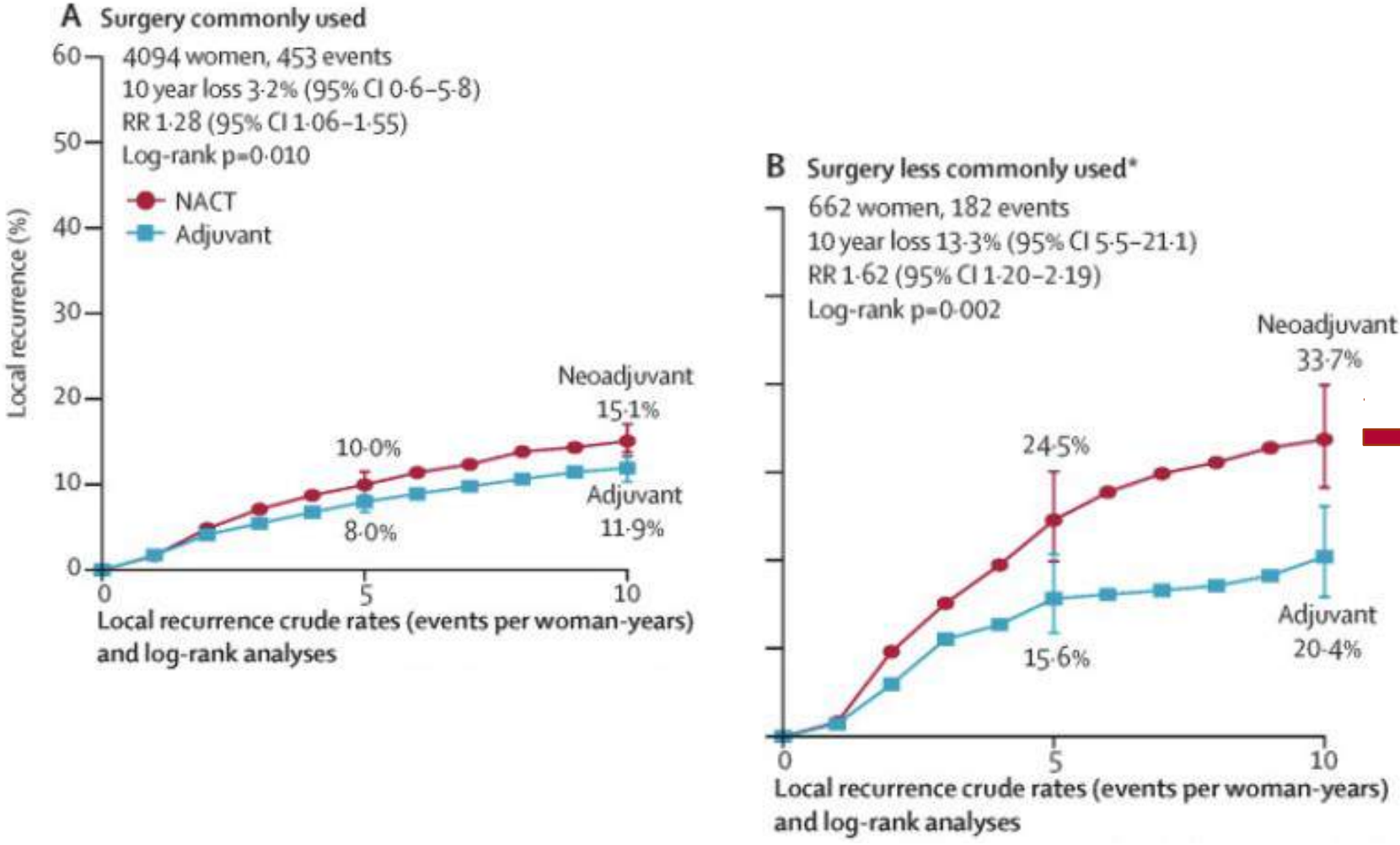
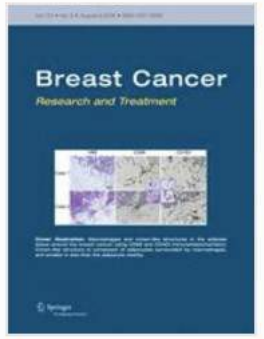
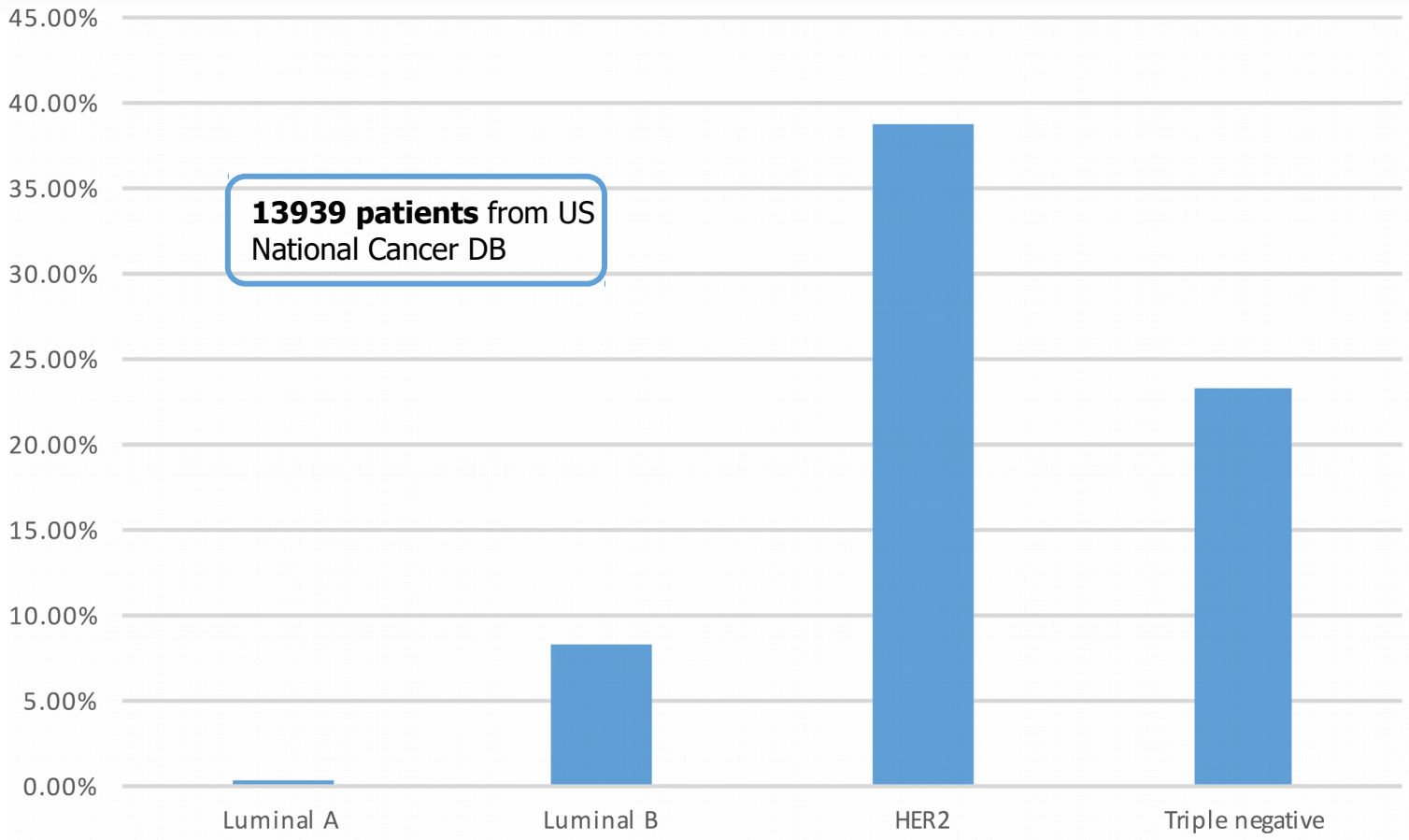


The absolute increase in 10-year local recurrence with NACT was largest in the two trials, in which, after NACT, many women did not have breast surgery

EFFECTIVENESS OF NACHT BASED ON MOLECULAR SUBTYPE

Response rates and pathologic complete response by breast cancer molecular subtype following neoadjuvant chemotherapy





Breast Cancer Research and Treatment
August 2018, Volume 170, Issue 3, pp 559–567 | Cite as

Overall, **19% of all patients achieved pCR**, the lowest in luminal A (0.3%) and the **highest in Her2 (38.7%)**

EFFECTIVENESS OF NACHT BASED ON MOLECULAR SUBTYPE

JAMA Oncology | Review

Melissa Pilewskie, MD; Monica Morrow, MD

Axillary Nodal Management Following Neoadjuvant Chemotherapy

A Review

JAMA Oncol. 2017;3(4):549-555. doi:10.1001/jamaoncol.2016.4163

Table 5. Rates of Axillary Nodal Pathologic Complete Response (ypNO) by Tumor Subtype

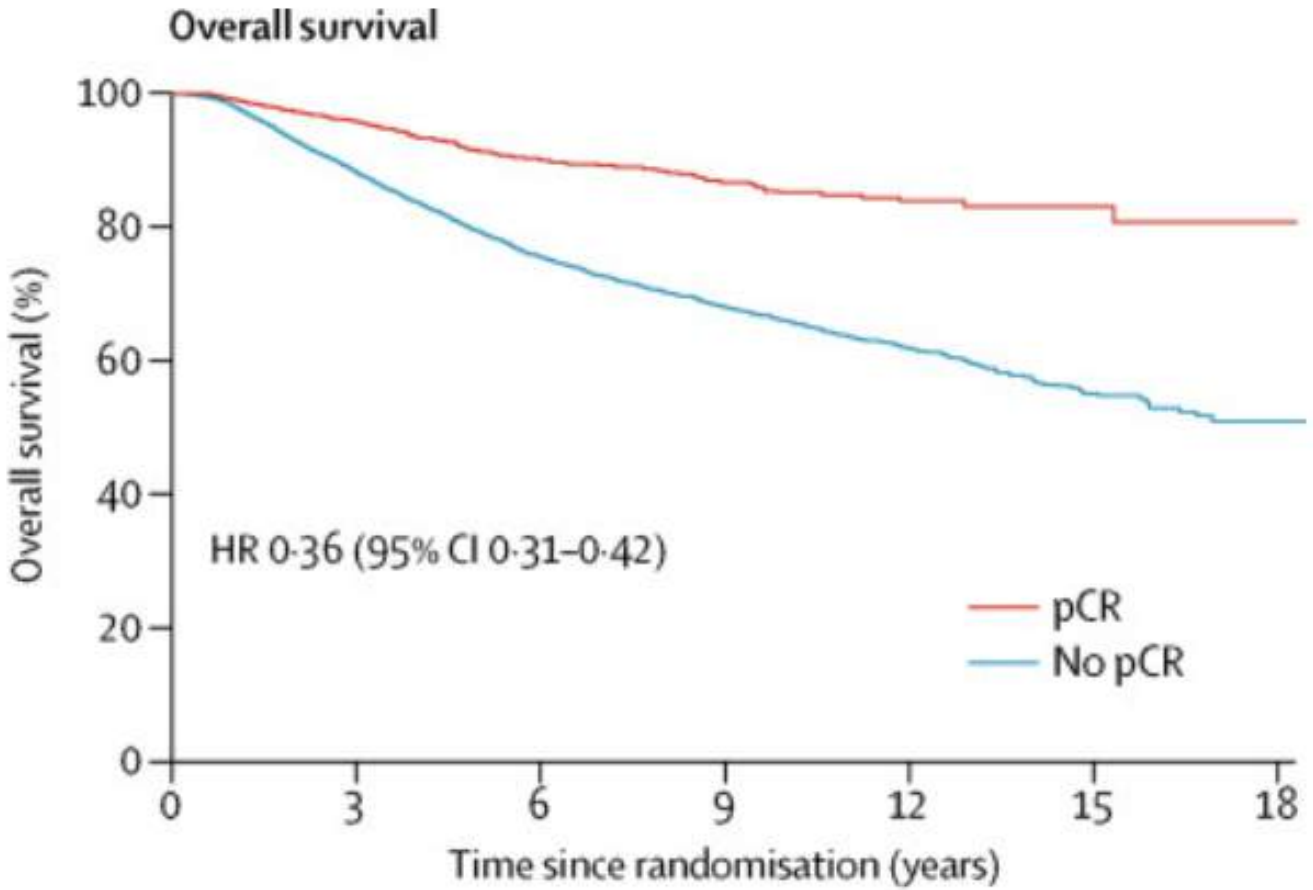
Source	No./Stage	Pathologic Complete Response, %			Chemotherapy Regimen
		HR+/ HER2−	HER2+	Triple Negative	
Zhang et al,[53] 2013	301/Stage II-III	46	72	69	51% Taxane based; 95% HER2+ received trastuzumab
Boughey et al,[25] 2014	756/pN+	21	65	49	75% Anthracycline and taxane; 89% HER2+ received trastuzumab
Kim et al,[27] 2015	415/pN+	29	49	54	86% Anthracycline and taxane; 10% HER2+ received trastuzumab
Mamtani et al,[28] 2016	195/pN+	21	82	47	97% Dose-dense doxorubicin, cyclophosphamide, and paclitaxel, 9% carboplatin; 100% HER2+ received trastuzumab plus pertuzumab
A L-Tweigeri et al,[48] 2016	80/Stage II-III	50	79	73	Fluorouracil, epirubicin, and cyclophosphamide, cisplatin/docetaxel; 100% HER2+ received trastuzumab
Diego et al,[29] 2016	30/pN+	0	69	67	Chemotherapy regimen unknown; 100% HER2+ received trastuzumab

Rates of **axillary pathological complete response** after NACHT according to **molecular subtypes.**

WHY SHOULD WE CHOOSE NEOADJUVANT CHEMOTHERAPY?

Pathological complete response and long-term clinical benefit in breast cancer: the CTNeoBC pooled analysis

THE LANCET
Volume 384, Issue 9938, 12–18 July 2014, Pages 164-172



12 international trials and **11955 patients**

Patients who attain **pathological complete response** defined as ypT0 ypN0 or ypT0/is ypN0 **have improved OS.**

WHY SHOULD WE CHOOSE NEOADJUVANT CHEMOTHERAPY?

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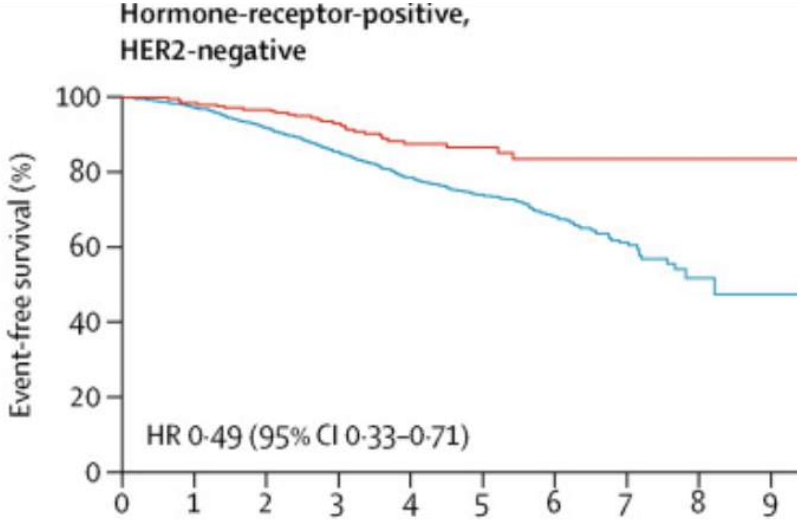

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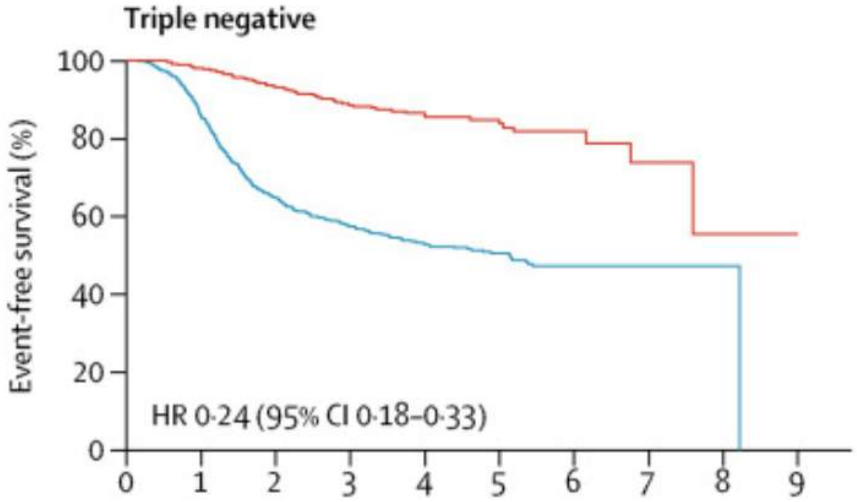
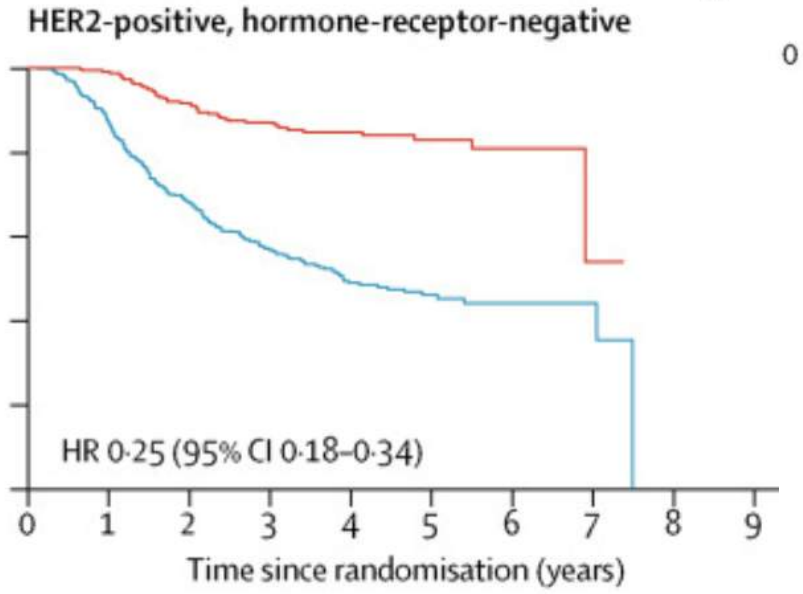




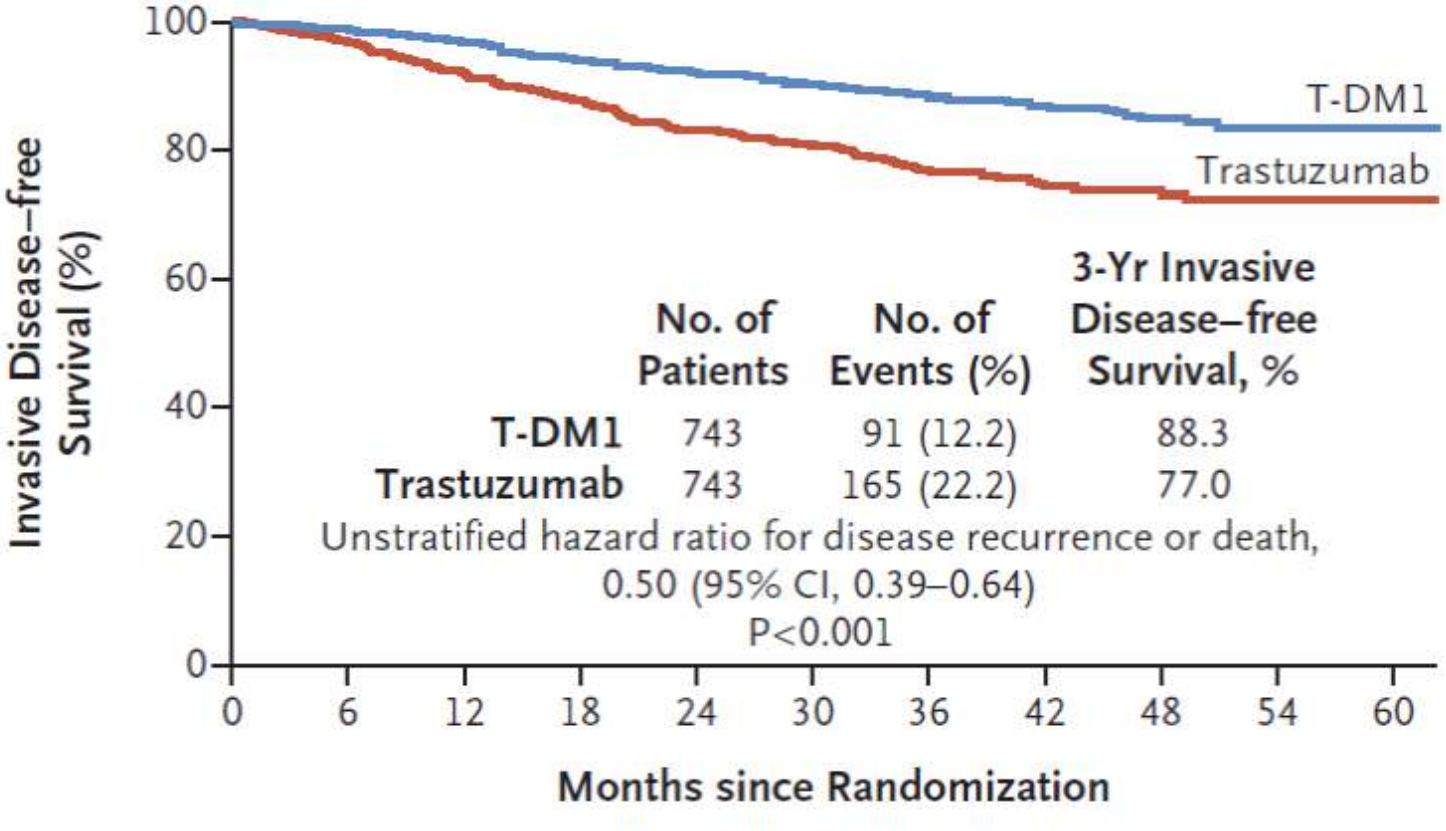
Patients who attain **pathological complete response** defined as ypT0 ypN0 or ypT0/is ypN0 **have improved DFS.**

NON-PCR: OPTIONS

The NEW ENGLAND JOURNAL of MEDICINE
February 14, 2019

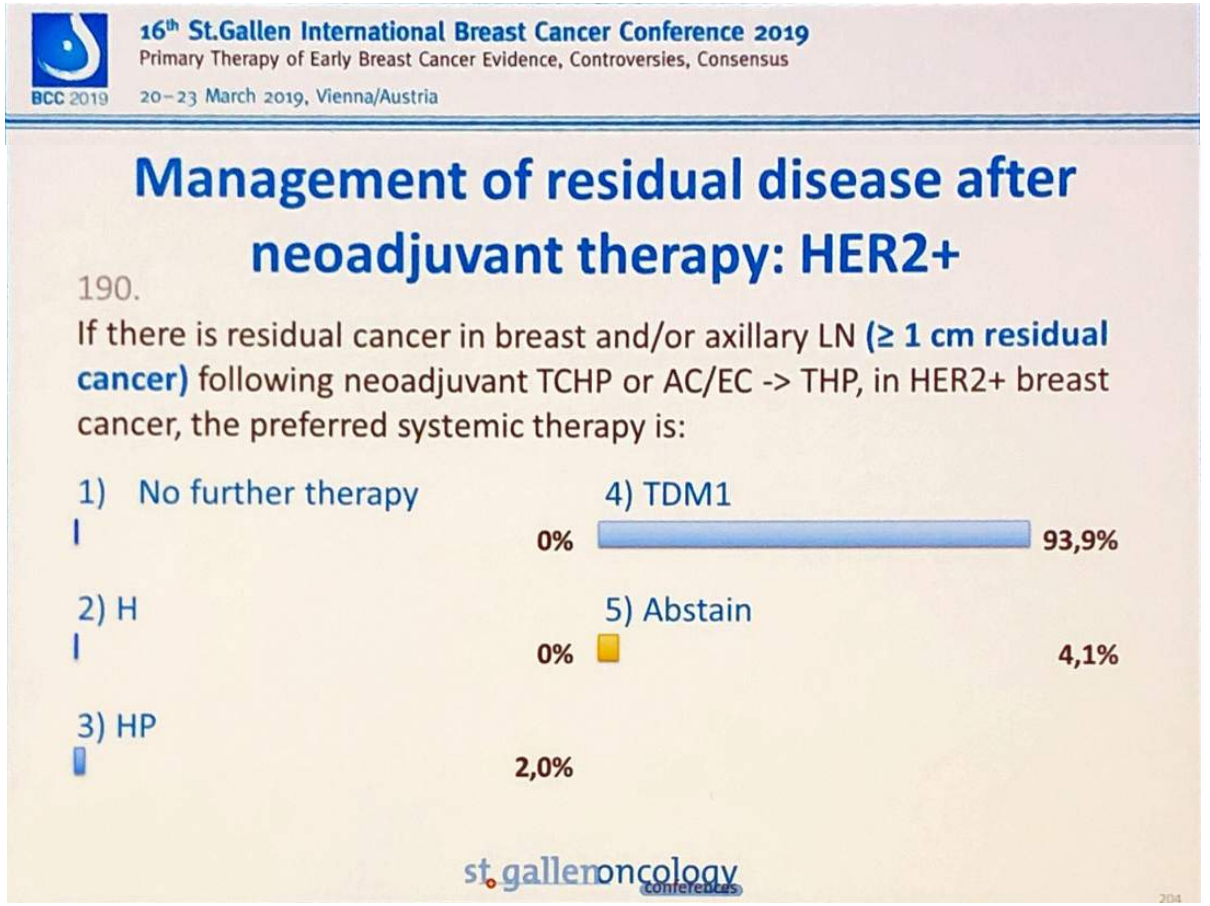
Trastuzumab Emtansine for Residual Invasive HER2-Positive Breast Cancer

1486 patients with HER2-positive early breast cancer who were found to have **residual invasive disease in the breast or axilla at surgery after receiving neoadjuvant therapy** containing a taxane (with or without anthracycline) and trastuzumab. Patients were randomly assigned to receive **adjuvant T-DM1** (743 pt) or **trastuzumab** (743) for 14 cycles.



The risk of recurrence of invasive breast cancer or death was **50% lower with adjuvant T-DM1 than with trastuzumab alone**

NON-PCR: OPTIONS FOR HER2 + BC



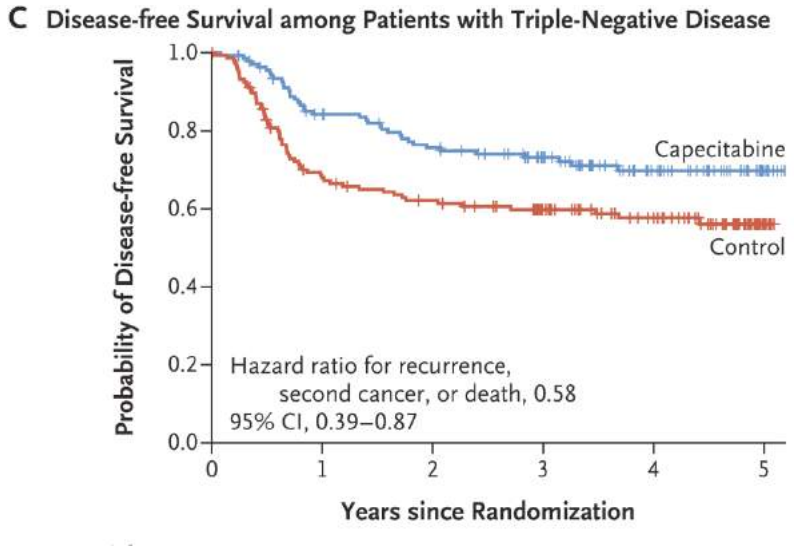
NON-PCR: OPTIONS

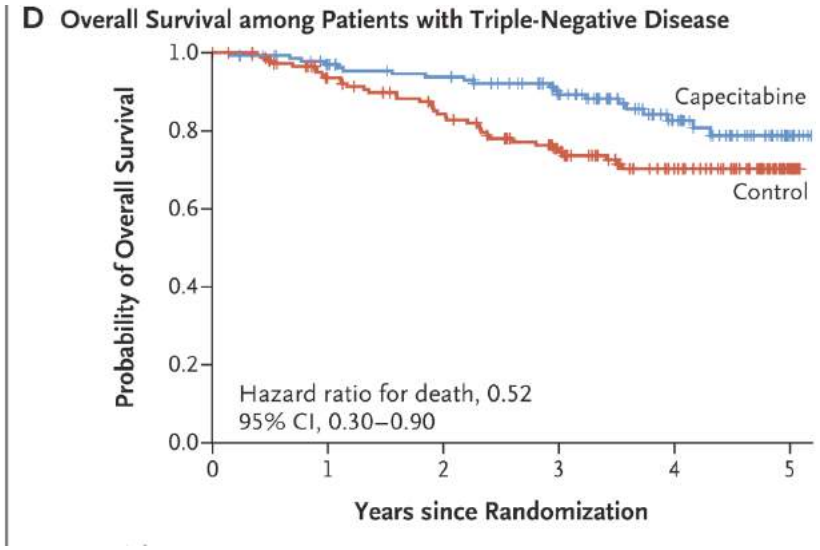
The NEW ENGLAND JOURNAL of MEDICINE
June 1, 2017

Adjuvant Capecitabine for Breast Cancer after Preoperative Chemotherapy

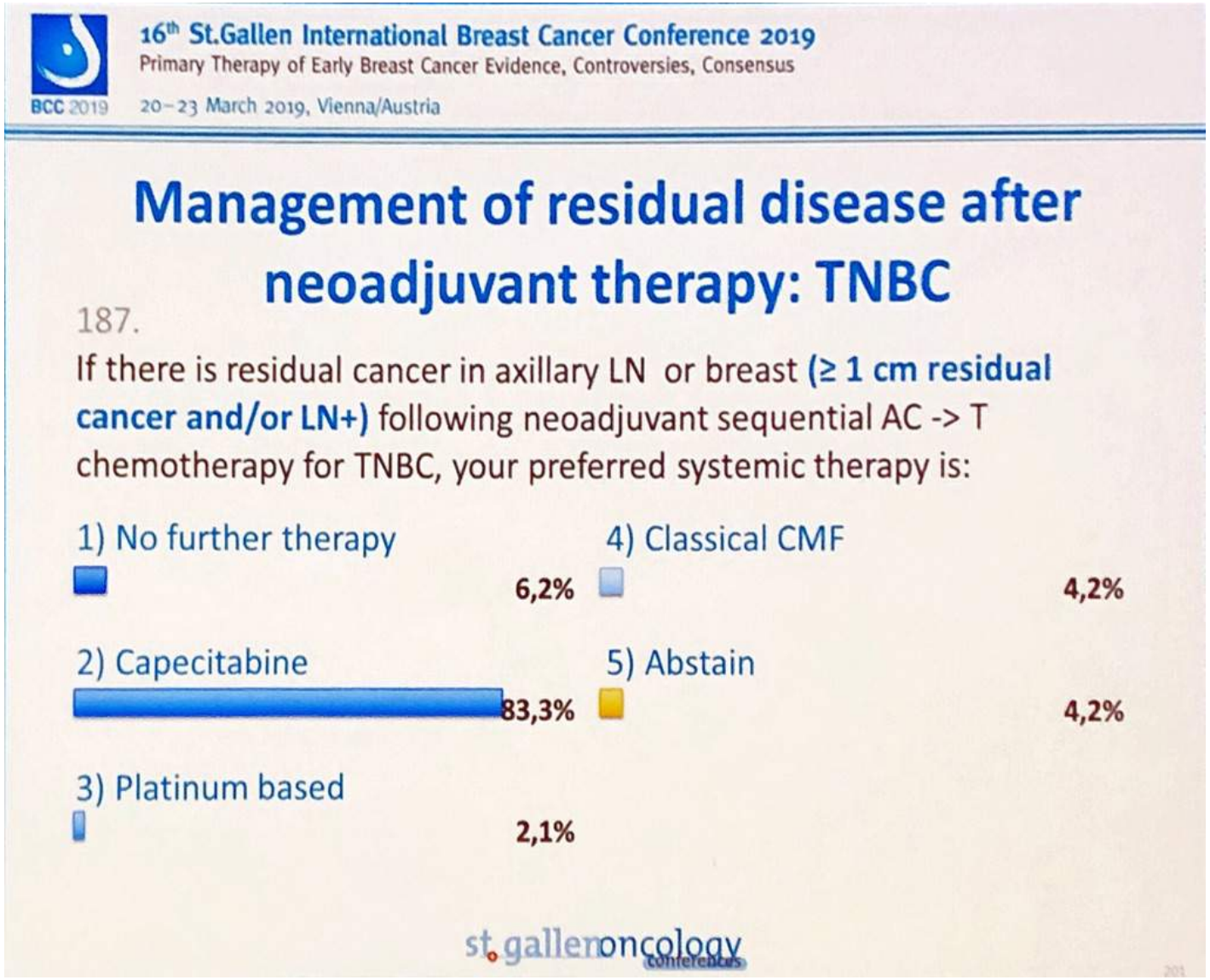
910 patients with HER2-negative residual invasive breast cancer after neoadjuvant chemotherapy (containing anthracycline, taxane, or both) to receive standard postsurgical treatment either with **capecitabine or without** (control).

After standard neoadjuvant chemotherapy, the **addition of adjuvant capecitabine therapy is safe and effective in prolonging disease-free survival and overall survival** among patients with HER2-negative breast cancer **who had residual invasive disease on pathological testing**.





NON-PCR: OPTIONS FOR TNBC



SURGERY AFTER NACHT

SURGERY OF THE BREAST

16 th St. Gallen International Breast Cancer Conference

Primary Therapy of Early Breast Cancer

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Walter Weber, Switzerland

News in surgery of patients with early breast cancer

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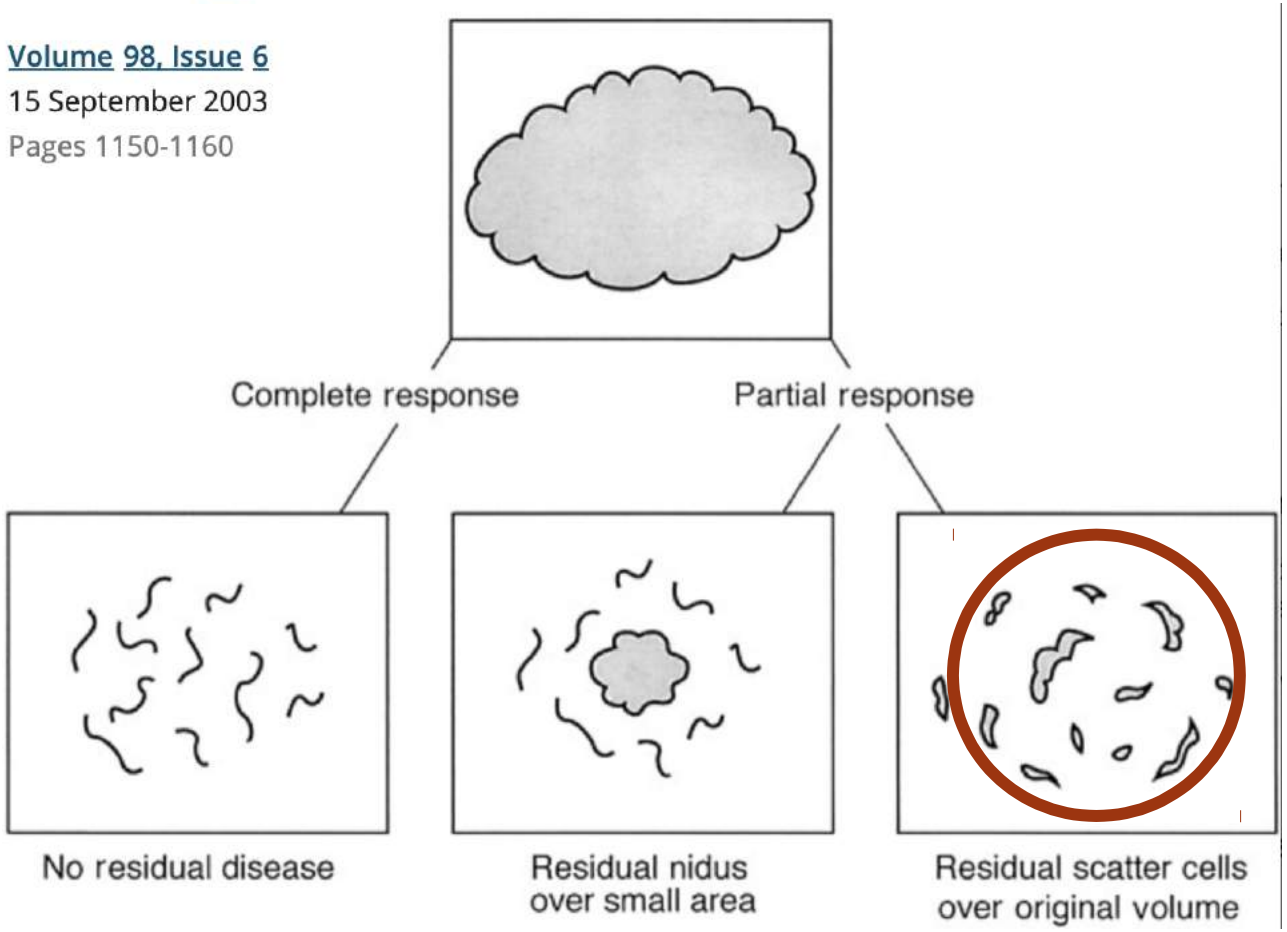
Neoadjuvant chemotherapy for breast carcinoma

Thomas A. Buchholz M.D. ✉,

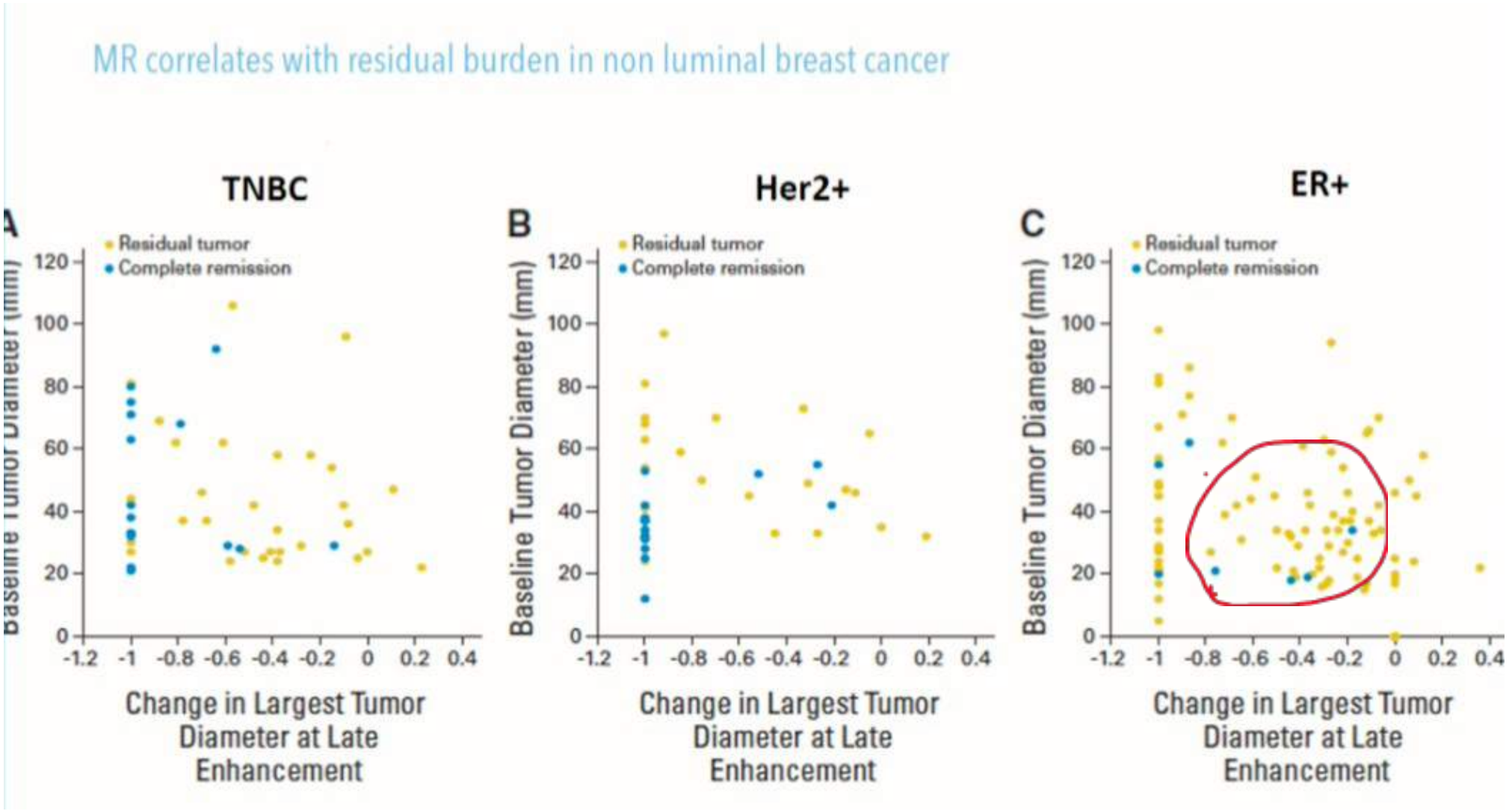
Volume 98, Issue 6
15 September 2003
Pages 1150-1160



TN, HER2

HR+

Extent of residual burden?



Loo, JCO, 2011

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Annals of Surgical Oncology

November 2018, Volume 25, Issue 12, pp 3541–3547 | Cite as

Margins in Breast-Conserving Surgery After Neoadjuvant Therapy

Jungeun Choi, Alison Laws, Jiani Hu, William Barry, Mehra Golshan, Tari King

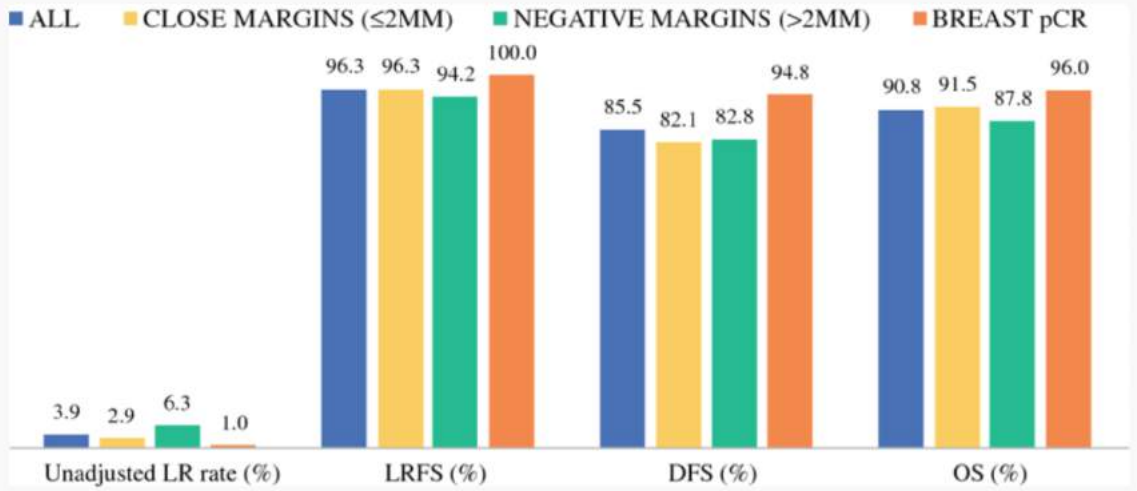


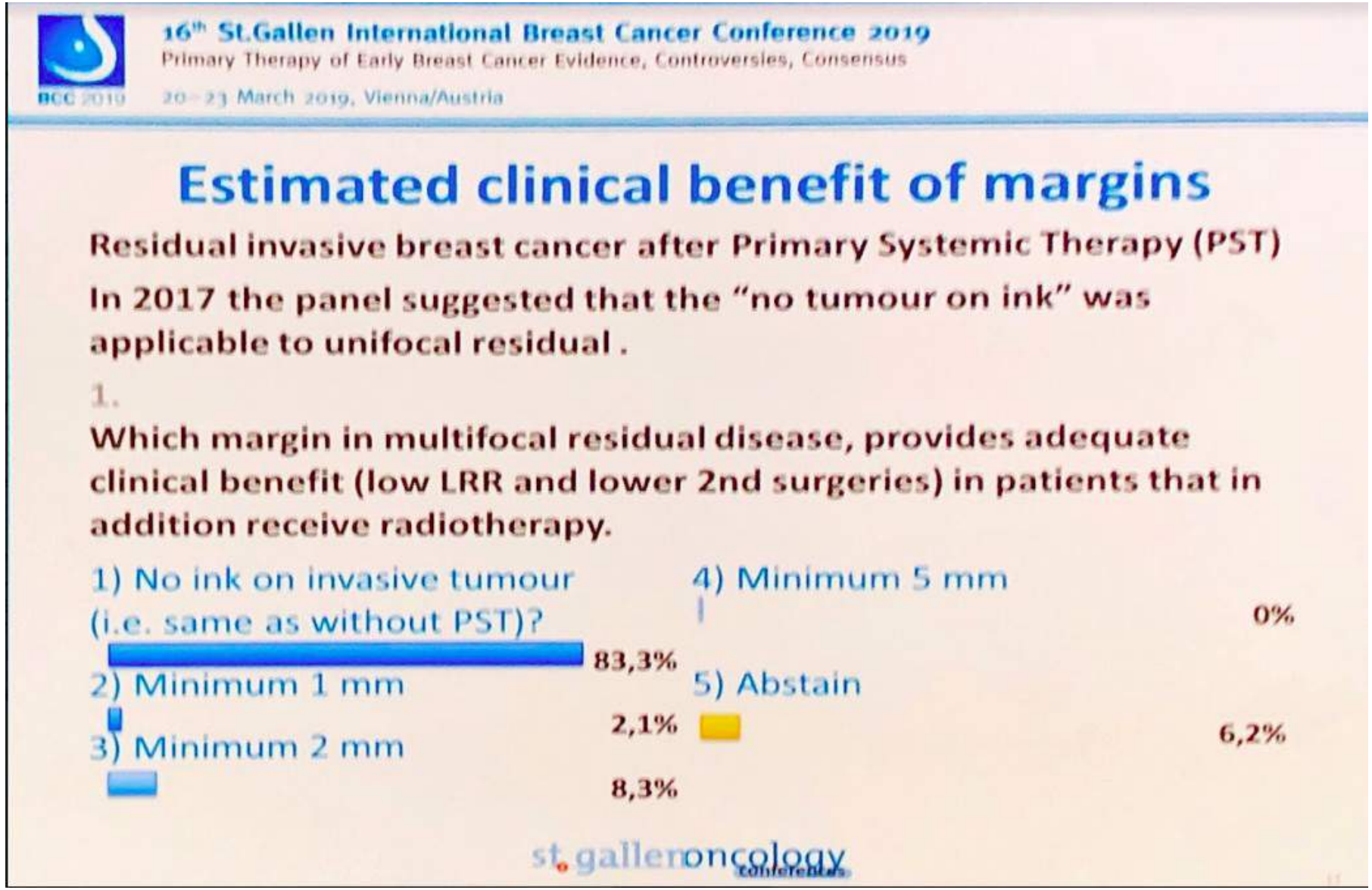
Fig. 1

Five-year local recurrence and survival outcomes by margin width using Kaplan–Meier methods. *LRR* local recurrence rate; *LRFS* local recurrence-free survival; *DFS* disease-free survival; *OS* overall survival

- Retrospective
- 382 patients
- **37,7% TN**
- **49,2% LUM**
- **13,1% HER2**

LR occurred in 3 of 103 (2.9%) patients with 1.1 to 2 mm margins, 11 of 174 (6.3%) patients with > 2 mm margins, and 1 of 105 (1.0%) patients with a breast pCR. **On multivariate analysis, margin width (pCR, >2mm vs < 2mm) was not associated with LRFS, DFS or OS.**

SURGERY OF THE BREAST



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Extent of surgery post neoadjuvant – setting: Estimating the extent of surgery

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Annals of Surgical Oncology

June 2017, Volume 24, Issue 6, pp 1492–1498 | Cite as

Do Calcifications Seen on Mammography After Neoadjuvant Chemotherapy for Breast Cancer Always Need to Be Excised?

Yara Feliciano, Anita Mamtani, Monica Morrow, Michelle M. Stempel, Sujata Patil, Maxine S. Jochelson

Mammogramm	MRI	n = 90	pCR (%)
Microcalc ↑→	Enhancement ↓	40 (44%)	3 (7%)
Microcalc ↑→	Enhancement 0	32 (35%)	19 (60%)
Microcalc ↓0	Enhancement ↓	10 (11%)	3 (30%)
Microcalc ↓0	Enhancement 0	8 (9%)	4 (50%)

Many of the **tumor bed calcifications seen on post-NAC mammography** are associated with **benign disease**, but **MRI does not predict the absence of residual tumor with sufficient accuracy** to allow calcifications to be left in place. **Complete excision of all indeterminate or malignant-appearing calcifications remains standard practice.**

MANAGEMENT OF THE AXILLA

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European Journal of Surgical Oncology (EJSO)

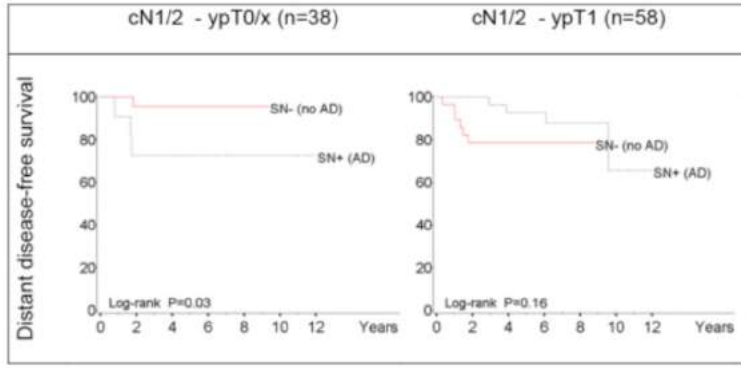
Volume 42, Issue 3, March 2016, Pages 361-368

V. Galimberti [a]

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

- Single institution retrospective analysis of prospective database[1]
  - 70 patients, cN1/2 → NACT → cN0 → neg. SLN→ no ALND
  - Single tracer (^{99}Tc)
  - Isolated tumor cells considered SLN negative
  - Median follow-up 61 months

→ **No axillary recurrence**



SNB is acceptable in **cN1/2 patients who become cN0 after neoadjuvant** therapy: particularly in those with no residual disease in the breast, because SN status maintains its expected prognostic role, but also in cases with residual disease, because **AD has no influence on outcomes**.

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Meta-analysis of sentinel lymph node biopsy after neoadjuvant chemotherapy in patients with initial biopsy-proven node-positive breast cancer

S. R. Tee, L. A. Devane, D. Evoy, J. Rothwell, J. Geraghty, R. S. Prichard and E. W. McDermott

Volume 105, Issue 12

November 2018

Pages 1541-1552

- Node-positive disease at presentation with pathological confirmation who underwent NAC
- SLNB after NAC;
- Followed by ALND as part of management.

Reference	SLN identification rate (%)	False-negative rate (%)
Zetterlund *et al.*[14]	77·9	14
Enokido *et al.*[15]	90·9	16
Carrera *et al.*[16]	91	10
Boileau *et al.*[17]	87·6	8
Ge *et al.*[18]	88	25
Yagata *et al.*[19]	85	16
Boughey *et al.*[10]	92·7	12·6*
Park *et al.*[20]	94·9	22·0
Rebollo-Aguirre *et al.*[21]	85	8
Alvarado *et al.*[22]	93·0	21
Thomas *et al.*[23]	87	20
Ozmen *et al.*[24]	92	14
Newman *et al.*[25]	98	8

FNR	Meta-analyse Tee
In all	14%
Dual tracer	11%
>2 SLN identified	4%

MANAGEMENT OF THE AXILLA

Diagnostic Accuracy of Different Surgical Procedures for Axillary Staging After Neoadjuvant Systemic Therapy in Node-positive Breast Cancer A Systematic Review and Meta-analysis

Annals of Surgery: March 2019 - Volume 269 - Issue 3 - p 432–442

Simons, Janine M., MD*

ANNALS OF SURGERY

- Meta-analysis of 20 studies (2217 patients)[1]

	n (studies)	n (patients)	Identification rate	False-negative rate
SLN only	17	2002	89%	Overall: 17% <3 SLNs: 22% ≥3 SLNs: 8%
MARI	1	95	97%	7%
TAD	2	120	100%	2-4%

WHEN TO PERFORM ALND AFTER NACHT

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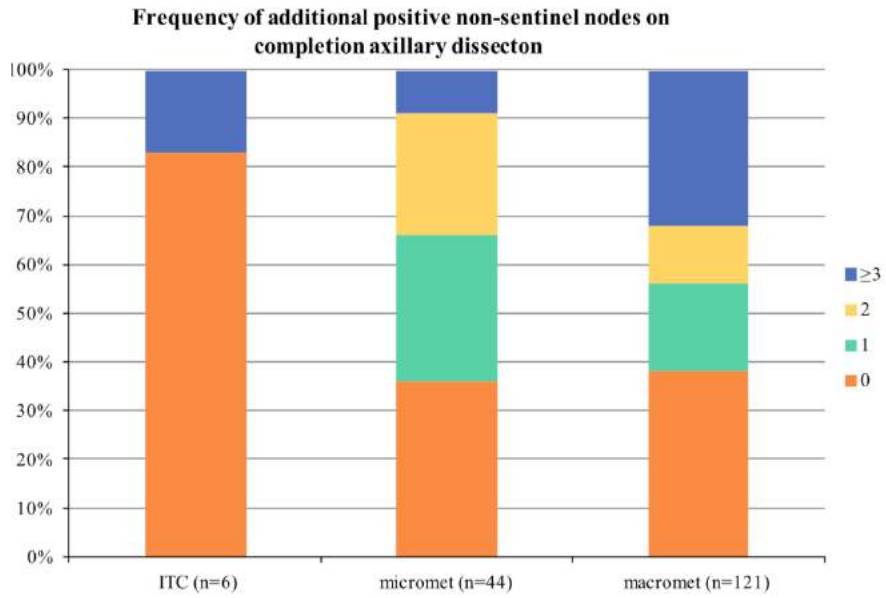
Annals of SURGICAL ONCOLOGY

OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

Is Low-Volume Disease in the Sentinel Node After Neoadjuvant Chemotherapy an Indication for Axillary Dissection?

Ann Surg Oncol (2018) 25:1488–1494

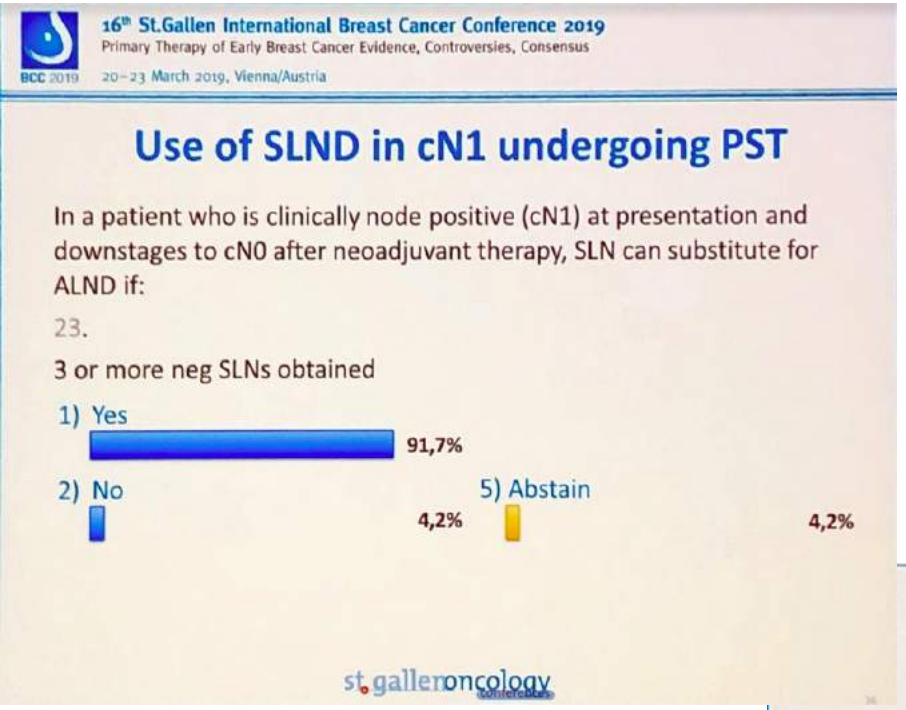
Tracy-Ann Moo, MD[1], Marcia Edelweiss, MD[2], Sabina Hajiyeva, MD[2], Michelle Stempel, MPH[1], Monica Raiss, BA[1], Emily C. Zabor, MS[3], Andrea Barrio, MD[1], and Monica Morrow, MD[1]

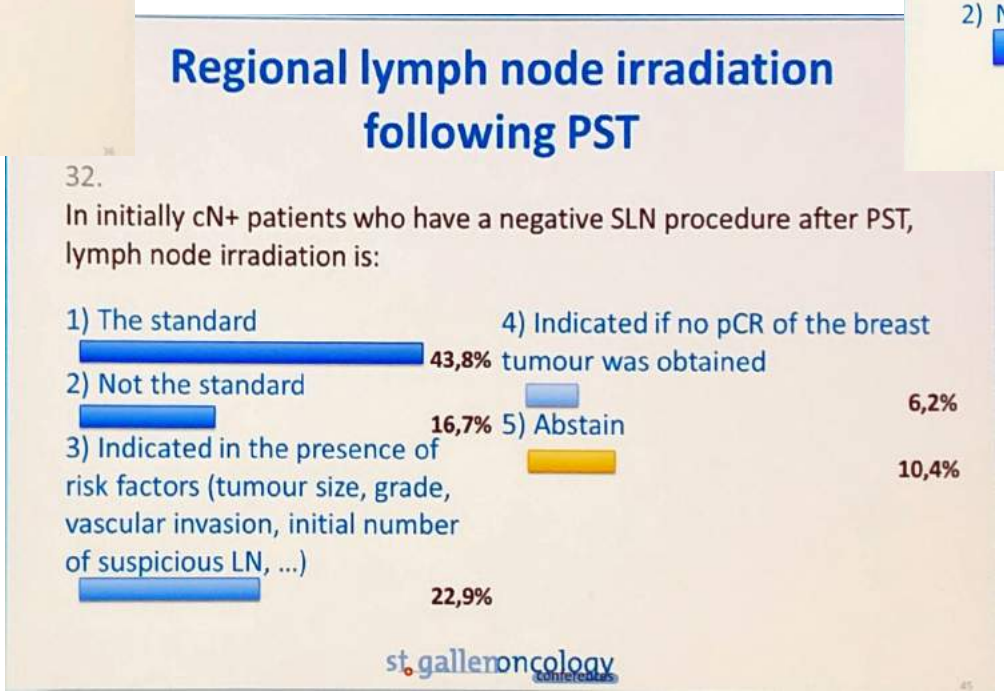


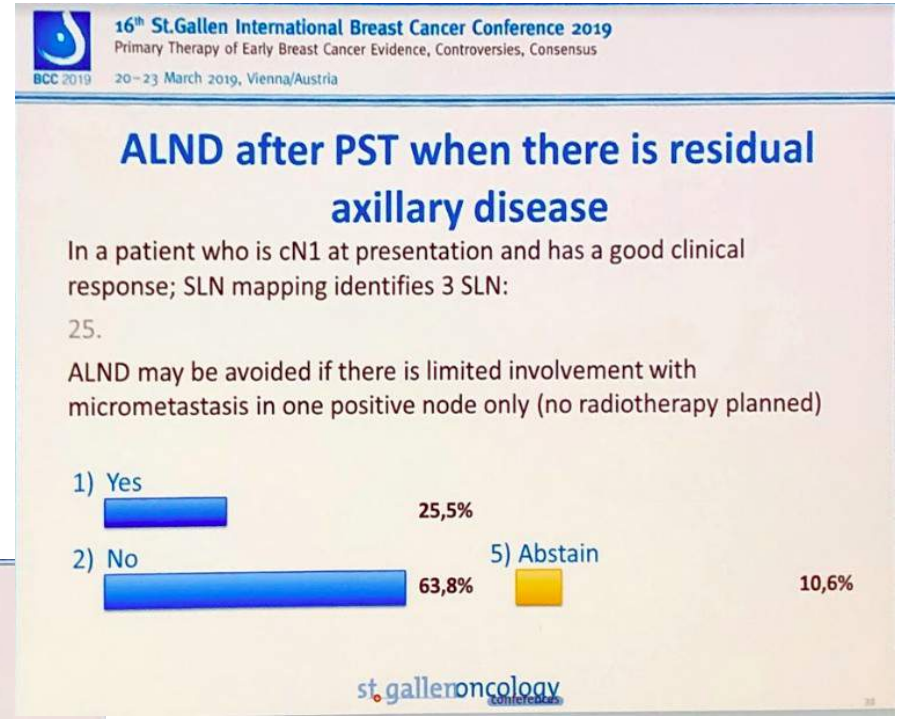
Perform ALND if:

- cN2 before NACT (or > 2 nodes radiological susp)
  - ypN1 (non SN pos in 50-60%)
  - ypN1mic (non SN pos in 30-40%)
  - ypN0(is+) (non SN pos in 30-60%)

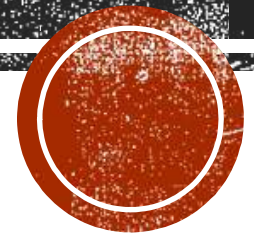
PANEL DECISIONS







ALND AFTER SLNB: STANDARD AND CONTROVERSIES



ALND AFTER SLNB: TRENDS

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Paolo Veronesi, Italy

Standards and controversies in sentinel node

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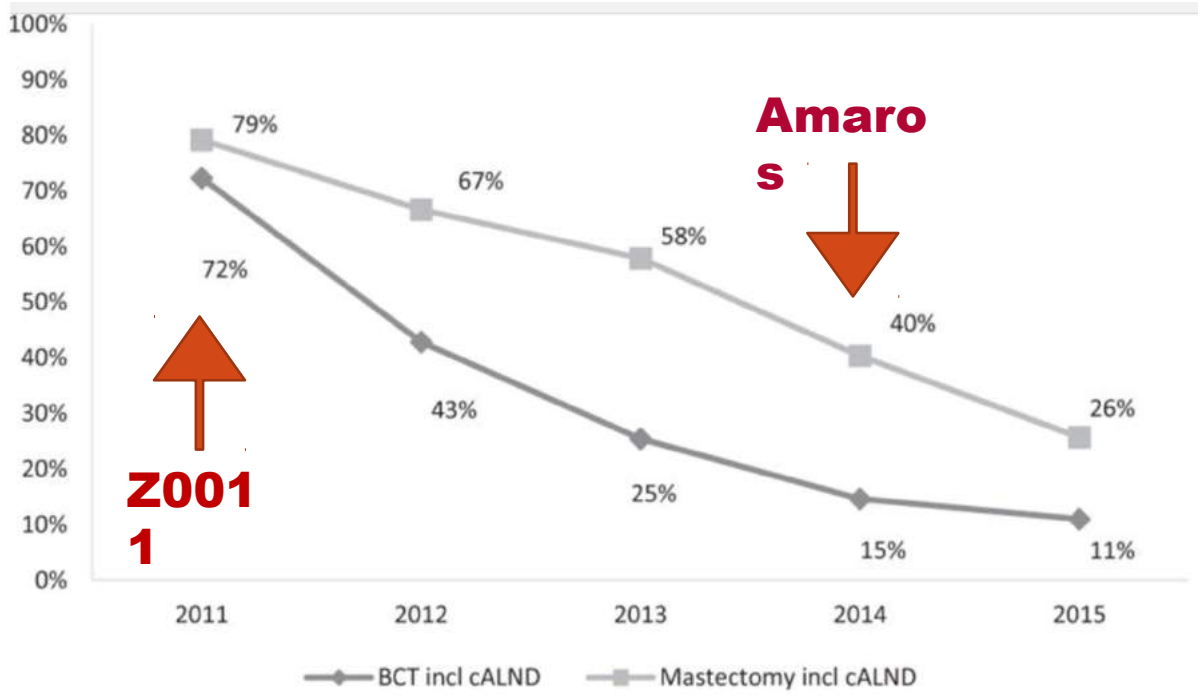
Trends on Axillary Surgery in Nondistant Metastatic Breast Cancer Patients Treated Between 2011 and 2015: A Dutch Population-based Study in the ACOSOG-Z0011 and AMAROS Era Annals of Surgery. 268(6):1084–1090, DEC 2018 Ingrid G. Poodt



Between 2011 and 2015 the use of **ALND** decreased from **75% to 17%** in **cT1-2N0 sentinel node-positive patients** (*P* < 0.001).

ALND AFTER SLNB: ATTITUDE-CHANGING TRIALS

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JAMA | Original Investigation September 12, 2017

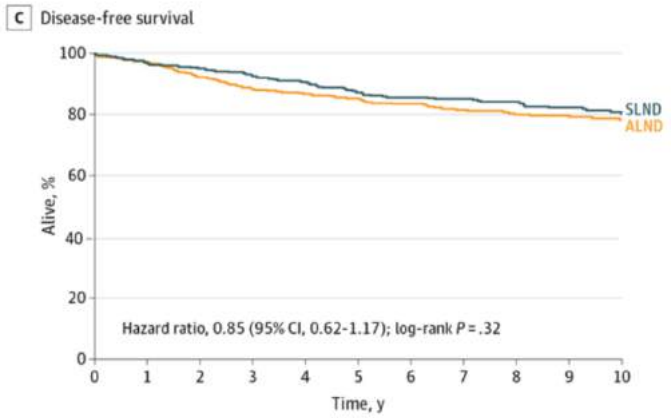
Effect of Axillary Dissection vs No Axillary Dissection on 10-Year Overall Survival Among Women With Invasive Breast Cancer and Sentinel Node Metastasis

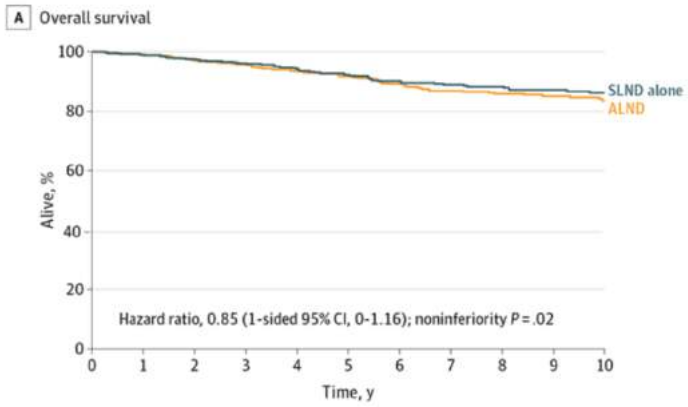
The ACOSOG Z0011 (Alliance) Randomized Clinical Trial

Armando E. Giuliano, MD; Karla V. Ballman, PhD; Linda McCall, MS; Peter D. Beitsch, MD; Meghan B. Brennan, RN, ONP, PhD; Pond R. Kelemen, MD; David W. Ollila, MD; Nora M. Hansen, MD; Pat W. Whitworth, MD; Peter W. Blumencranz, MD; A. Marilyn Leitch, MD; Sukamal Saha, MD; Kelly K. Hunt, MD; Monica Morrow, MD

LOCO REGIONAL RECURRENCES		NODAL RECURRENCES		BREAST RECURRENCES	
SLN	ALND	SLN	ALND	SLN	ALND
5.6%	6.2%	1.5%	0.5%	4.1%	4.7%
P= 0.36		P= 0.28			

DISEASE FREE SURVIVAL		OVERALL SURVIVAL	
SLN	ALND	SLN	ALND
80.2%	78.2%	86.3%	83.6%
P=0.44		P=0.72	





ALND AFTER SLNB: ATTITUDE-CHANGING TRIALS

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BCC 2019

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Standards and controversies in sentinel node

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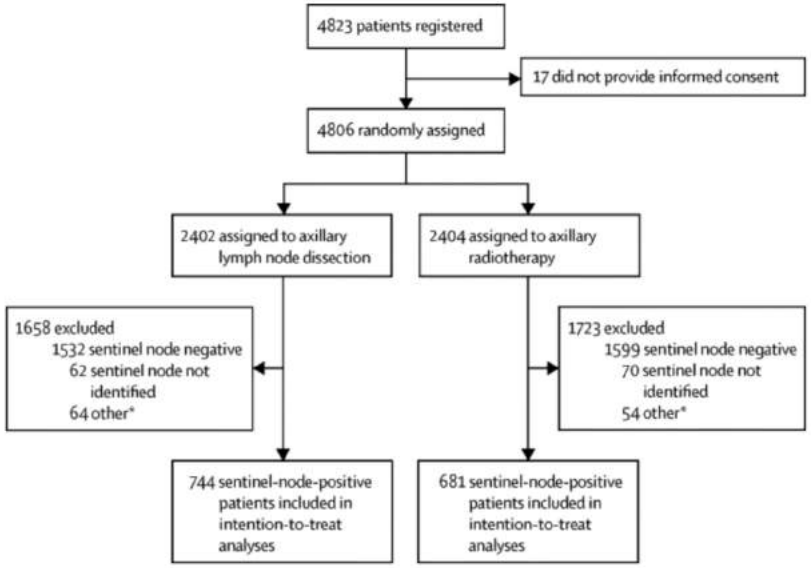
Radiotherapy or surgery of the axilla after a positive sentinel node in breast cancer (EORTC 10981-22023 AMAROS): a randomised, multicentre, open-label, phase 3 non-inferiority trial

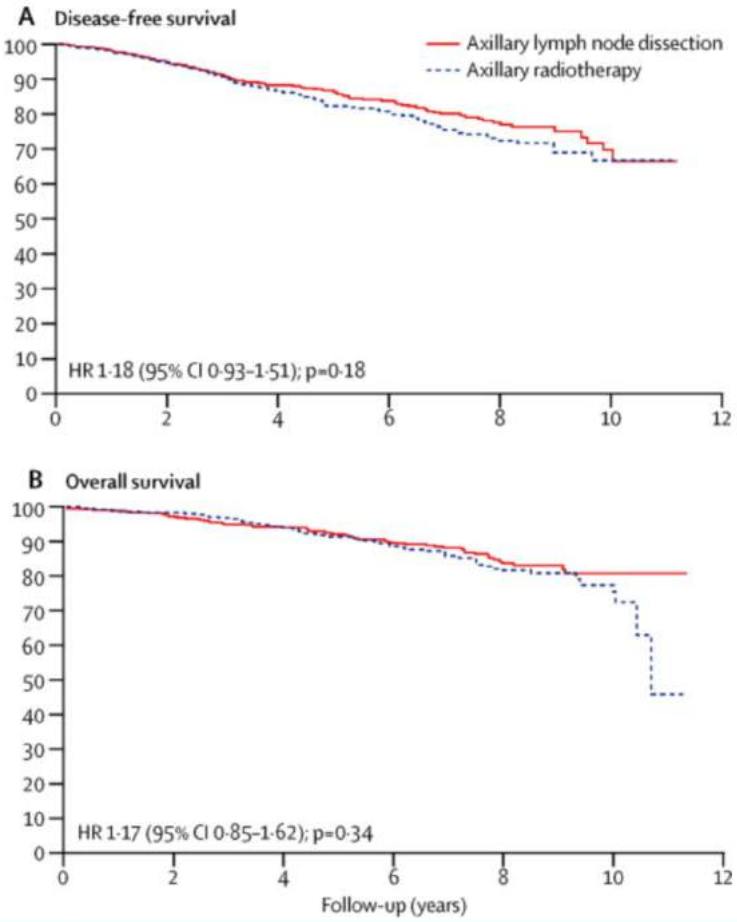
Mila Donker MD [a]

THE LANCET Oncology

Volume 15, Issue 12, November 2014, Pages 1303-1310



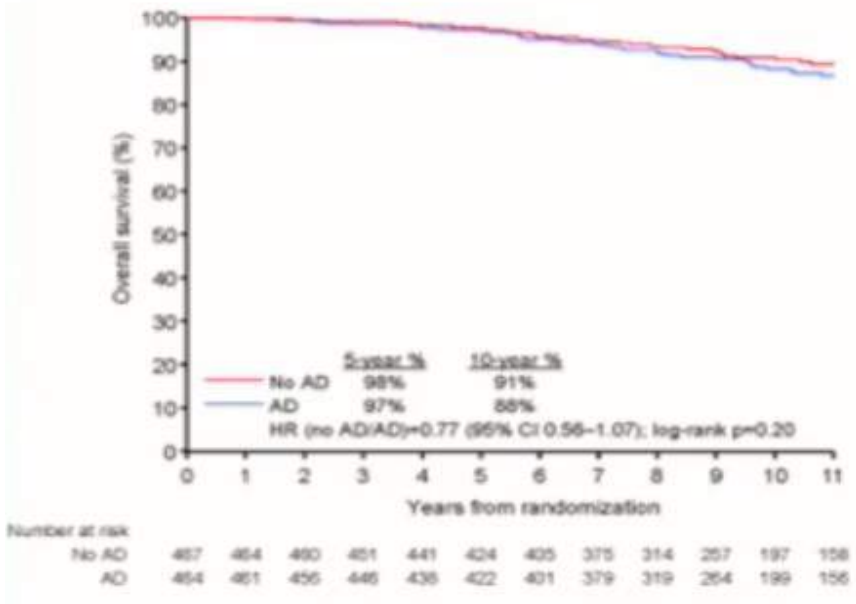
Type of breast surgery	ALND	AxRT
Breast-conserving surgery	609 (82%)	557 (82%)
Mastectomy	127 (17%)	121 (18%)



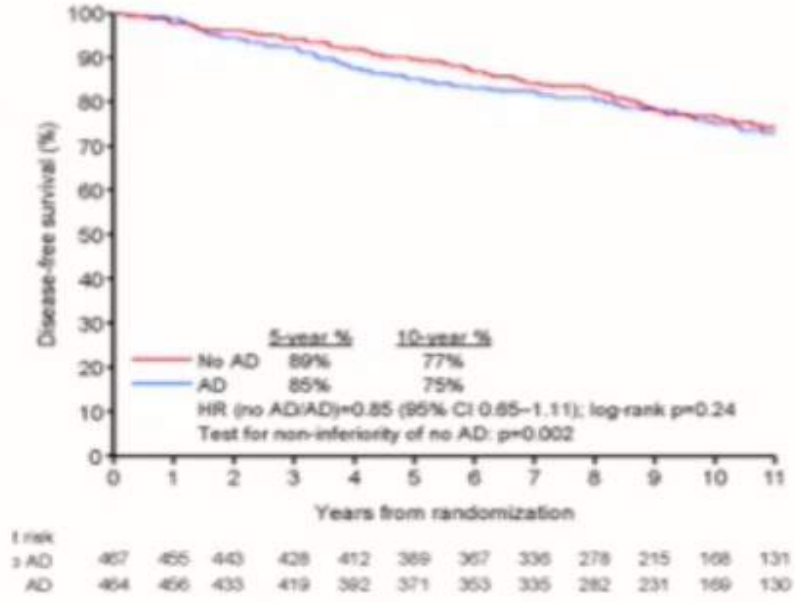
Axillary dissection versus no axillary dissection in patients with breast cancer and sentinel-node micrometastases (IBCSG 23-01): 10-year follow-up of a randomised, controlled, phase 3 trial

*Viviana Galimberti, Bernard F Cole, Giuseppe Viale, Paolo Veronesi, Elisa Vicini, Mattia Intra, Giovanni Mazzarol, Samuele Massarut, Janez Zgajnar, Mario Taffurelli, David Littlejohn, Michael Knauer, Carlo Tondini, Angelo Di Leo, Marco Colleoni, Meredith M Regan, Alan S Coates, Richard D Gelber, Aron Goldhirsch, for the International Breast Cancer Study Group Trial 23-01**

Overall Survival



Disease-Free Survival



934 pazienti; follow up 9.7 anni

ALND AFTER SLNB: NEW STANDARDS

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JAMA Network Insights

Management of the Node-Positive Axilla in Breast Cancer in 2017

Selecting the Right Option

Monica Morrow, MD

JN

Breast Conserving Surgery plus whole-breast irradiation

- Metastasis in ≥3 SLN → Axillary LN Dissection
- Metastasis in 1-2 SLN → No Axillary LN Dissection

MASTECTOMY

- Macrometastases (> 2mm) SLN → Axillary LN Dissection
- Micrometastases (≤ 2mm) SLN → No Axillary LN Dissection

Management of a patient with breast cancer and no palpable axillary lymph nodes planning primary surgery

1. Perform sentinel lymph node biopsy
   Prebiopsy axillary imaging is not necessary
2. Determine axillary management based on results of sentinel lymph node biopsy and planned breast surgical procedure

		Axillary management
Biopsy results	Metastases in ≥3 sentinel lymph nodes or matted lymph nodes found intraoperatively	Axillary lymph node dissection
Biopsy results	Metastases in 1-2 sentinel lymph nodes	
Surgery type	Breast-conserving surgery plus whole-breast irradiation	No axillary lymph node dissection Selective use of nodal radiotherapy for high-risk patients[a]
Surgery type	Mastectomy	
Size of node metastases	Micrometastases (≤2 mm)	No axillary lymph node dissection
Size of node metastases	Macrometastases (>2 mm)	
Postmastectomy radiotherapy	Postmastectomy radiotherapy is indicated	No axillary lymph node dissection
Postmastectomy radiotherapy	Postmastectomy radiotherapy is contraindicated or total number of lymph nodes with metastases needs to be determined to assess need for postmastectomy radiotherapy	Axillary lymph node dissection

Consider neoadjuvant therapy for patients with *ERBB2/HER2*-positive or triple- negative breast cancer and planned mastectomy if adjuvant chemotherapy is indicated based on patient and tumor features

[a] High-risk patients include those with large tumors (≥ 3 cm), lymphovascular tumor invasion, or microscopic extracapsular extension of metastases in sentinel nodes.

ALND OMISSION AFTER SLNB: NEIGHBOURS STANDARDS

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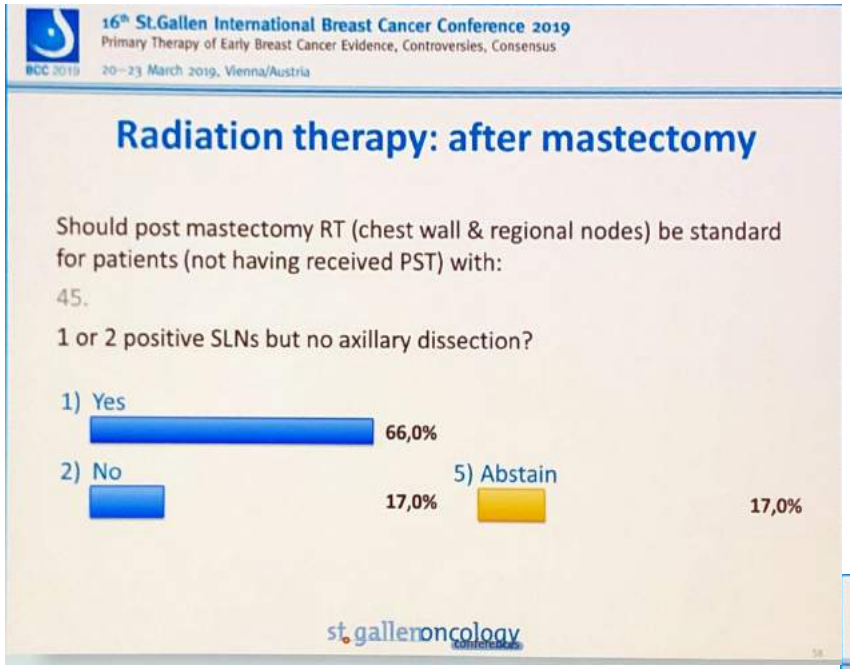
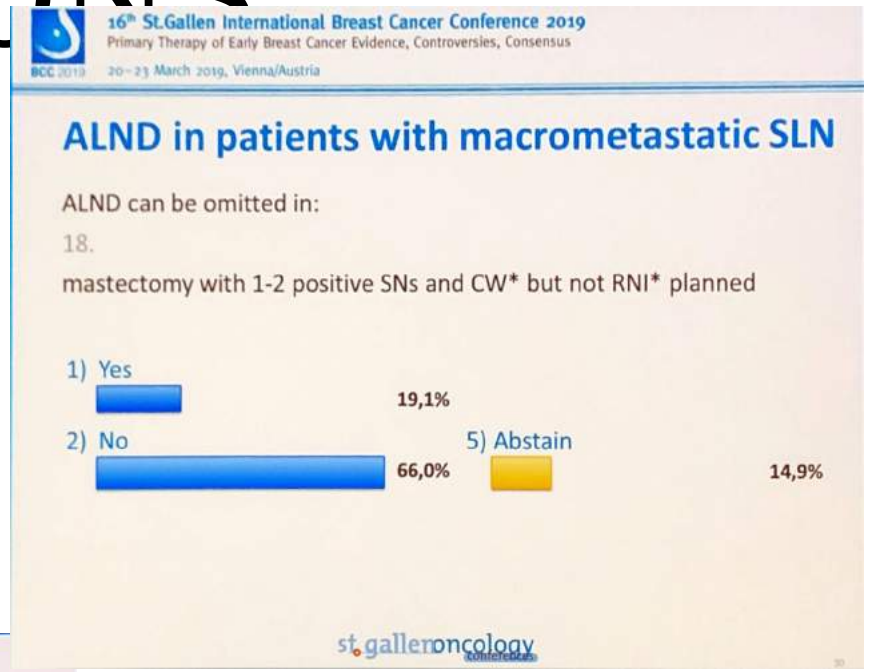
- Radiotherapy and Conservative Surgery

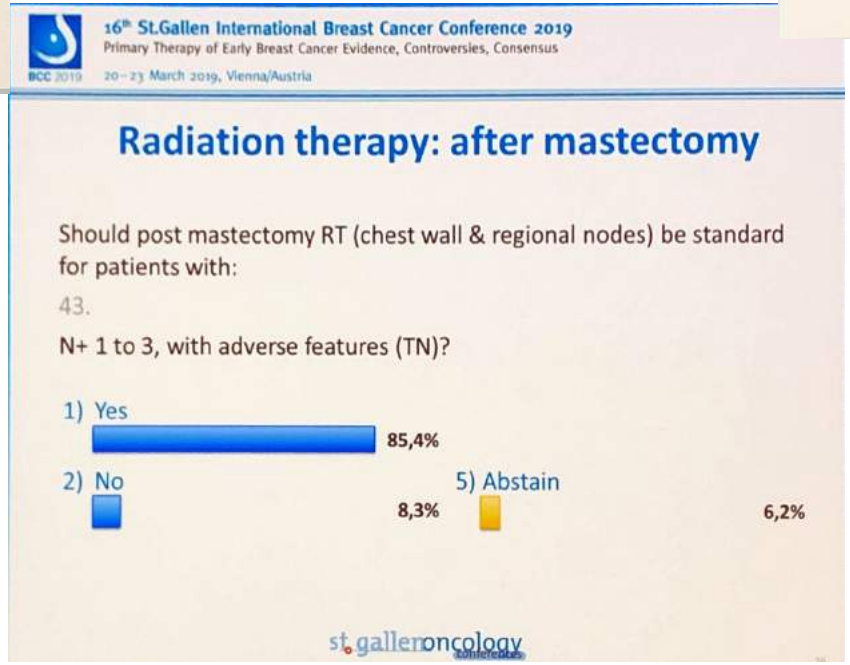
EIO guidelines for 1-2 macrometastatic lymph nodes without axillary dissection

	MOLECULAR SUBTYPE	RT
Luminal A	➢ ER+ and/or PR+, HER2-, and low Ki67 (<20%)	ONLY BREAST
Luminal B	➢ ER+ and/or PR+ and HER2+ (luminal-HER2 group) ➢ ER+ and/or PR+, HER2-, Ki67 (≥20%)	BREAST + I-II level
HER2+	➢ ER-, PR-, and HER2+	BREAST + I-III level
Basal-like o triple negative	➢ ER-, PR-, HER2-, and CK5/6 and/or EGFR+	BREAST + I-III level

PANEL DECISIONS







ADJUVANT ENDOCRINE THERAPY

ADJUVANT ENDOCRINE THERAPY: PREMISES

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Ivana Sestak, UK

Risk assessment of late recurrence

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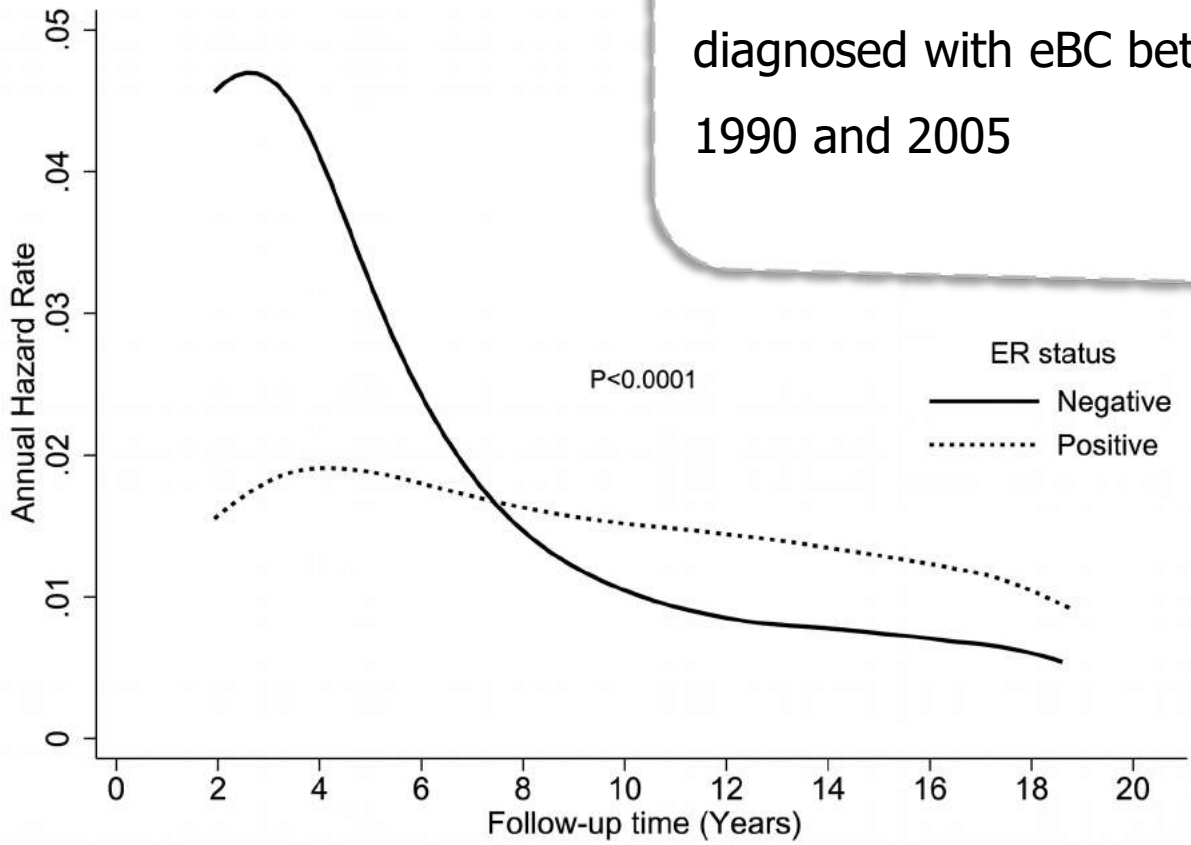
Crossover Effects of Estrogen Receptor Status on Breast Cancer-Specific Hazard Rates by Age and Race

Yu Ren, Dalliah M. Black, Elizabeth A. Mittendorf, Peijun Liu, Xu Li, Xianglin L. Du, Jianjun He, Jin Yang, Kelly K. Hunt, Min Yi

Published: October 21, 2014 • https://doi.org/10.1371/journal.pone.0110281

PLOS ONE

Retrospective study on 439.444 SEER patients diagnosed with eBC between 1990 and 2005



EXTENDED ADJUVANT ENDOCRINE THERAPY: STUDIES

ADJUVANT ENDOCRINE THERAPY: PREMISES

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Hongchao Pan, Ph.D.

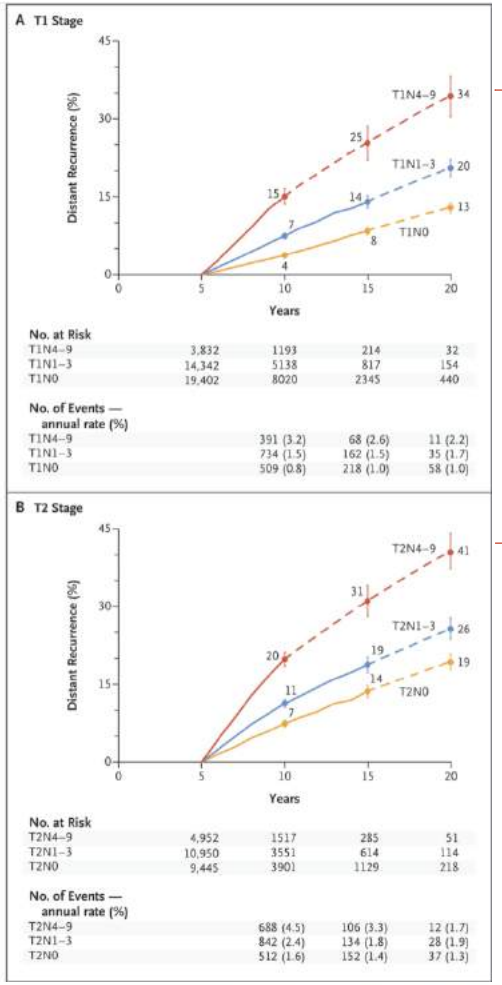
The NEW ENGLAND JOURNAL of MEDICINE

November 9, 2017

N Engl J Med 2017; 377:1836-1846

DOI: 10.1056/NEJMoa1701830

20-Year Risks of Breast-Cancer Recurrence after Stopping Endocrine Therapy at 5 Years

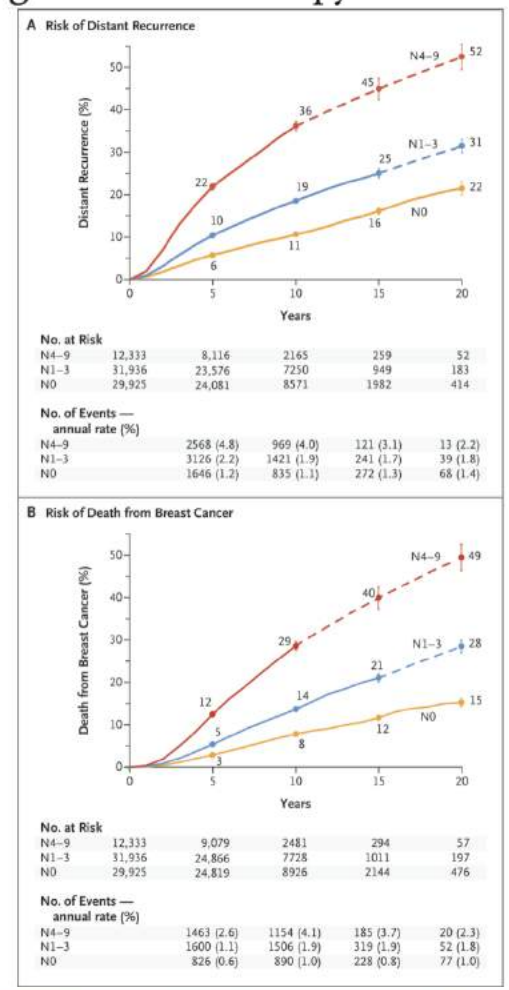


+7%

+6%

+6%

62923 women in 88 trials without BC events **after 5 years** of scheduled **endocrine therapy**



EXTENDED ADJUVANT ENDOCRINE THERAPY: CTS5

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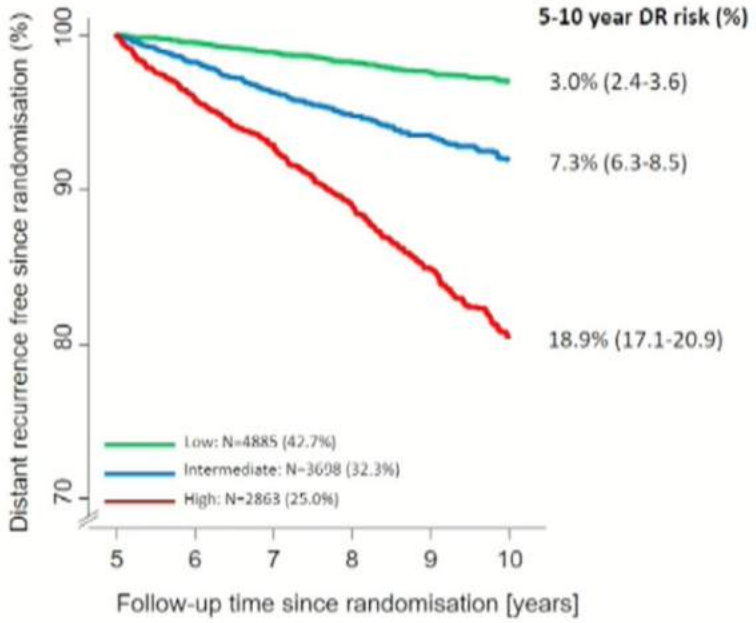
VOLUME 36 · NUMBER 19 · JULY 1, 2018

JOURNAL OF CLINICAL ONCOLOGY

Integration of Clinical Variables for the Prediction of Late Distant Recurrence in Patients With Estrogen Receptor–Positive Breast Cancer Treated With 5 Years of Endocrine Therapy: CTS5

Mitch Dowsett, Ivana Sestak, Meredith M. Regan, Andrew Dodson, Giuseppe Viale, Beat Thürlimann, Marco Colleoni, and Jack Cuzick

CTS5 (ATAC) was **significantly prognostic for late DR** in the ATAC cohort (hazard ratio, 2.47; 95% CI, 2.24 to 2.73; P , .001) and BIG 1-98 validation cohort (hazard ratio, 2.07; 95% CI, 1.88 to 2.28; P , .001).



Clinical variable	HR (95% CI)	P-value
Number of positive nodes	1.14 (1.12-1.15)	<0.0001
Tumor size (mm)	1.10 (1.08-1.12)	<0.0001
Grade (1 vs. 2, 1 vs. 3)	2.26 (1.58-3.22) 3.37 (2.33-4.86)	<0.0001 <0.0001
Age (years)	1.04 (1.02-1.05)	<0.0001
Endocrine therapy (T vs. A)	0.84 (0.67-1.04)	0.108

ATAC	BIG1-98
N=5216	N=8010
Median FUP: 9.8 years	Median FUP: 8.1 years

Evaluable clinical variables and distant recurrence-free at 5 years

N=11446

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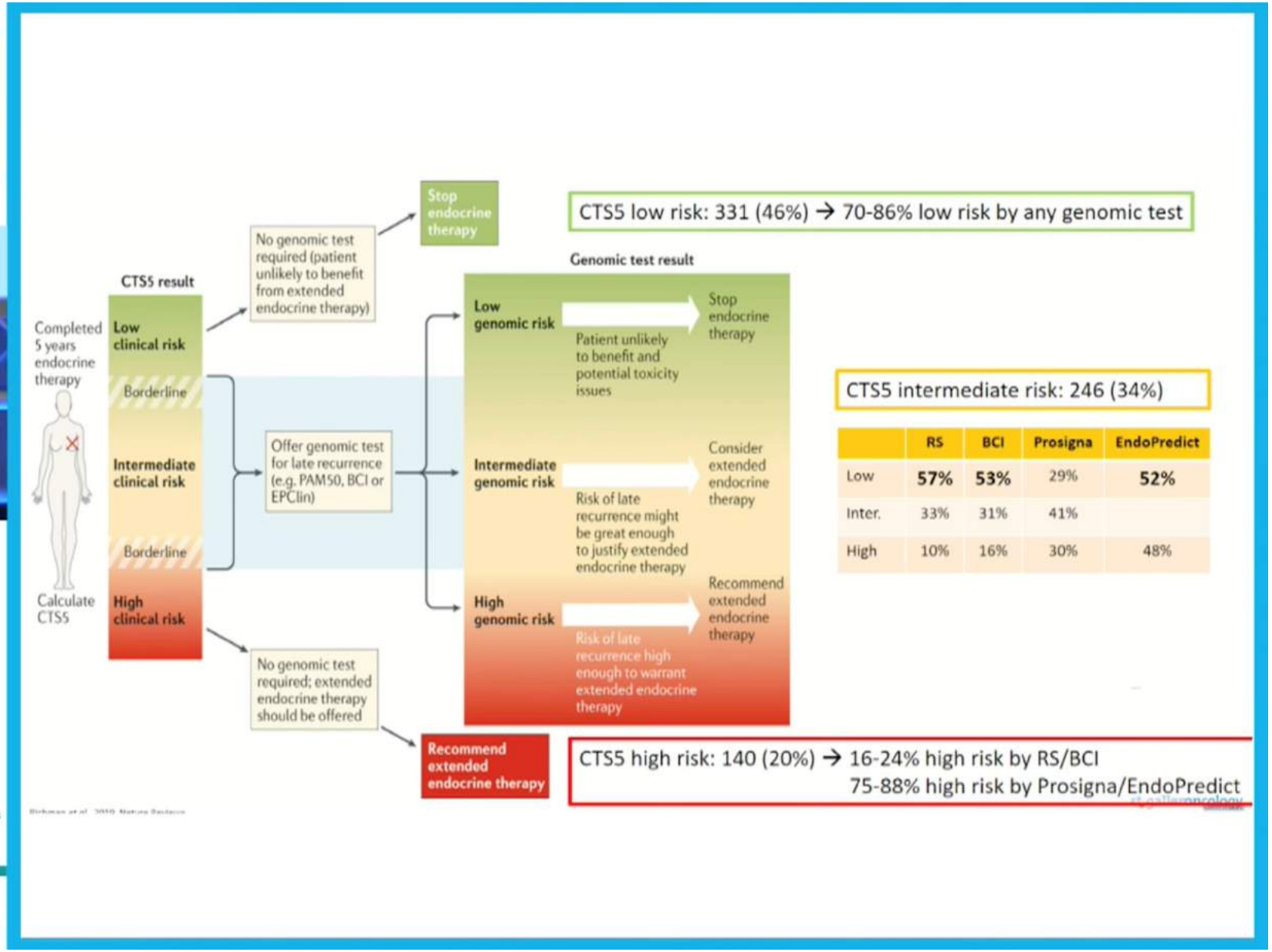


	RS	BCI	Prosigna	EndoPredict
Low	57%	53%	29%	52%
Inter.	33%	31%	41%	
High	10%	16%	30%	48%

EXTENDED ADJUVANT ENDOCRINE THERAPY: CTS5

REMIND!

- **CTS5** was validated on a population including **HER2 + patients** when trastuzumab therapy was not yet a standard of care

↓

NOT APPLICABLE TO ER+/HER2+ PATIENTS

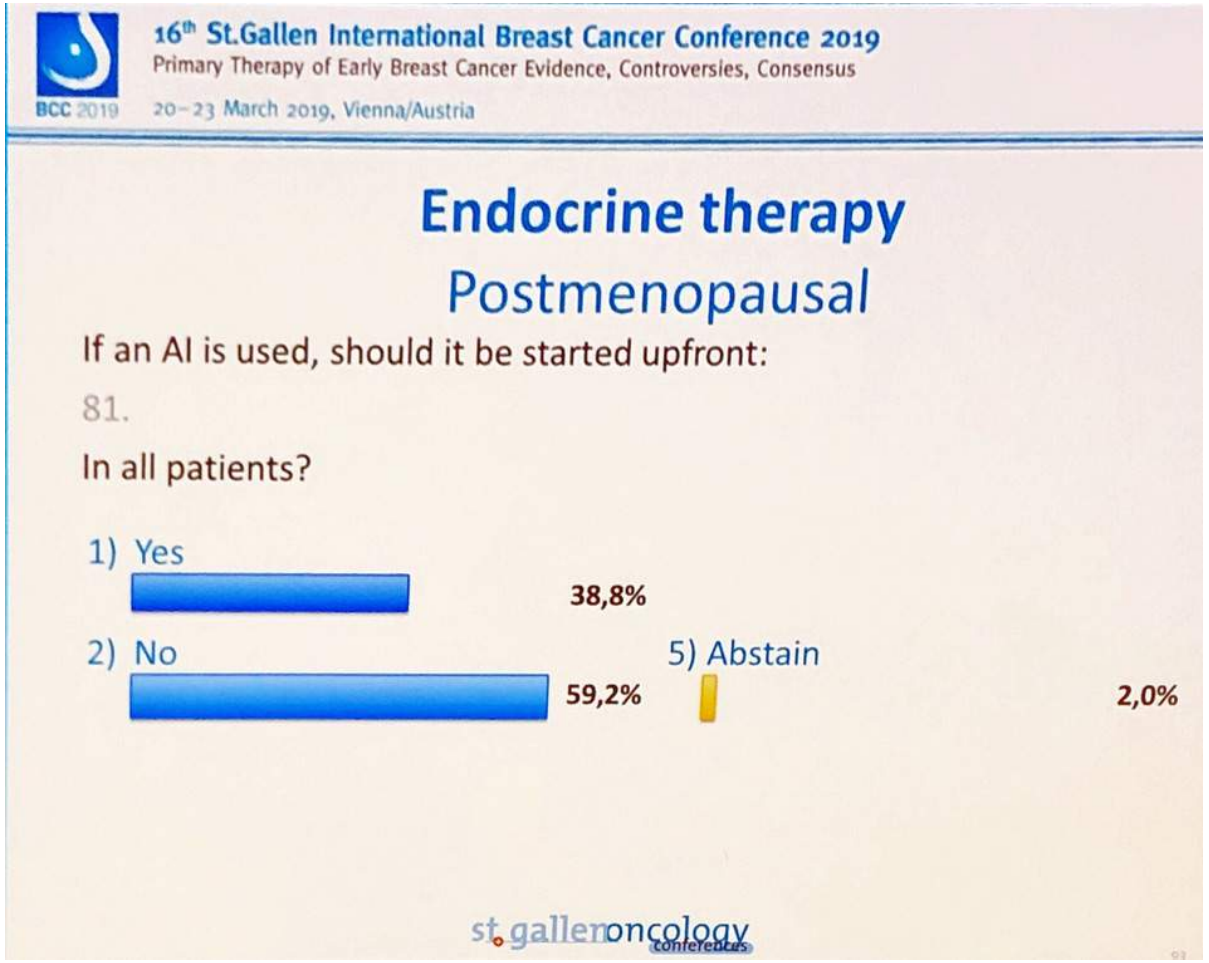
TREATED WITH TRASTUZUMAB!

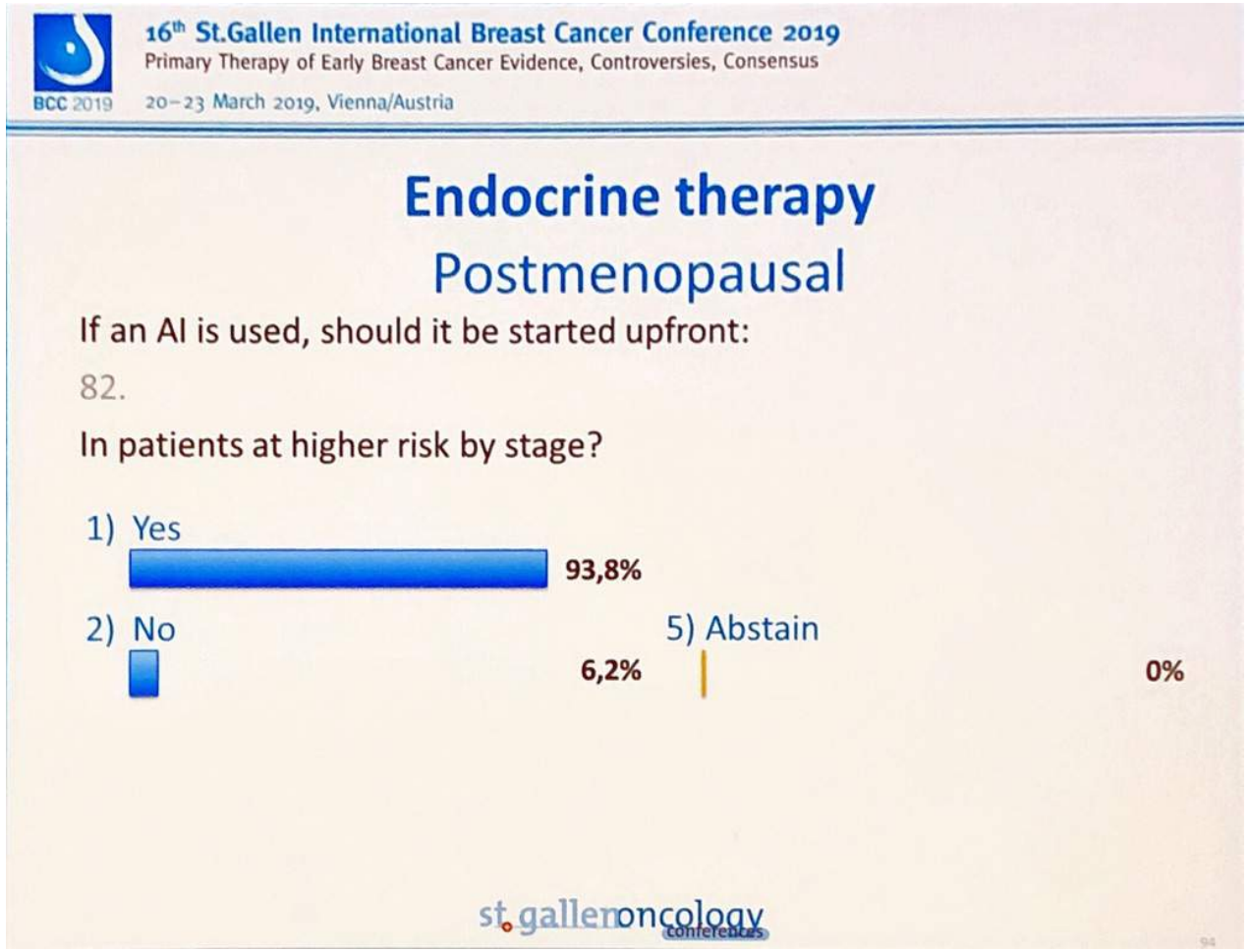
- CTS5 was validated on a population of **postmenopausal** patients

↓

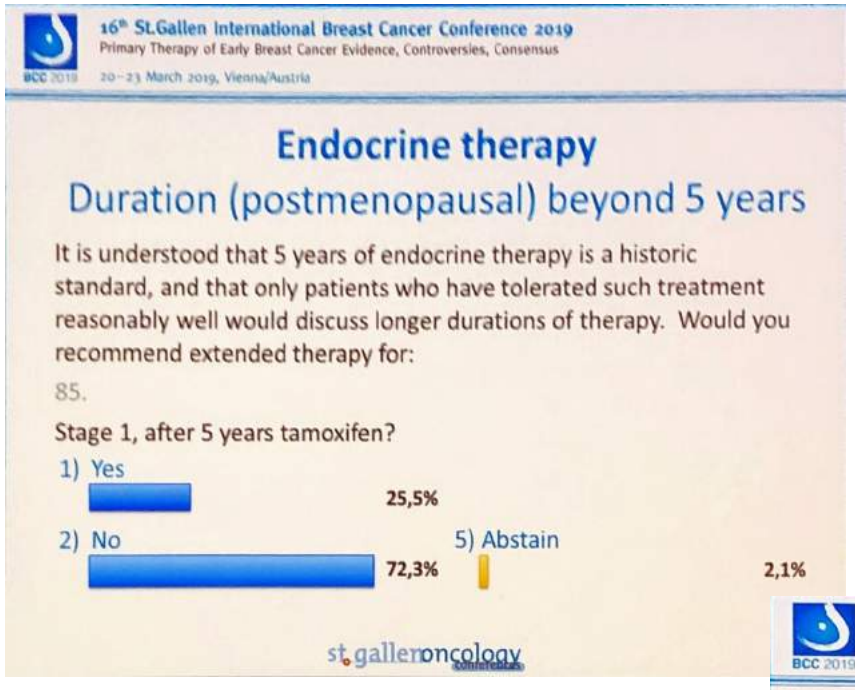
NOT APPLICABLE TO PREMENOPAUSAL PATIENTS

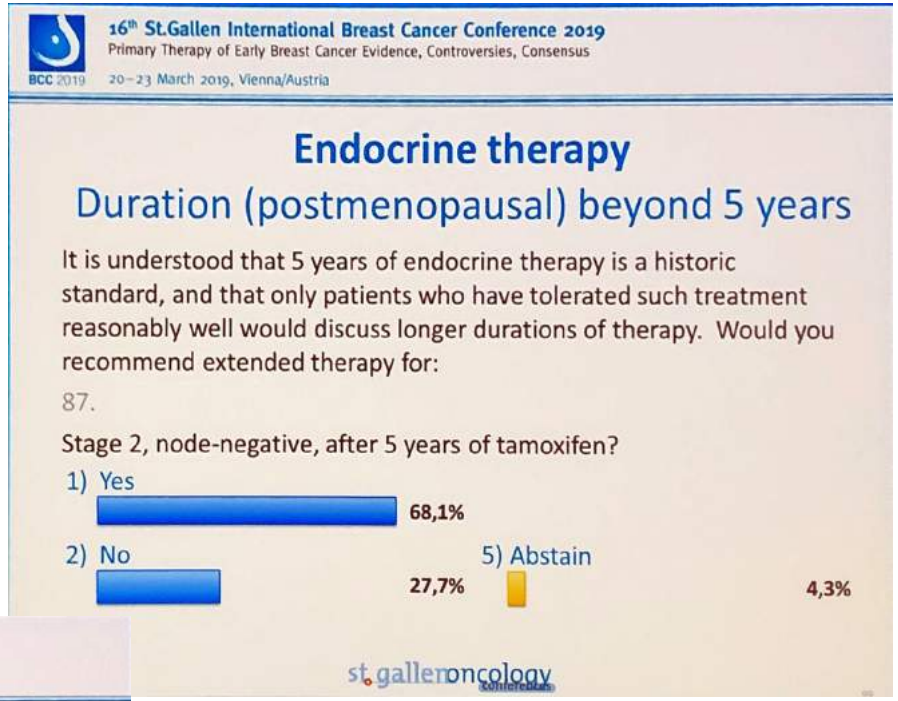
PANEL DECISION ON A-ET IN POSTMENOPAUSAL WOMEN

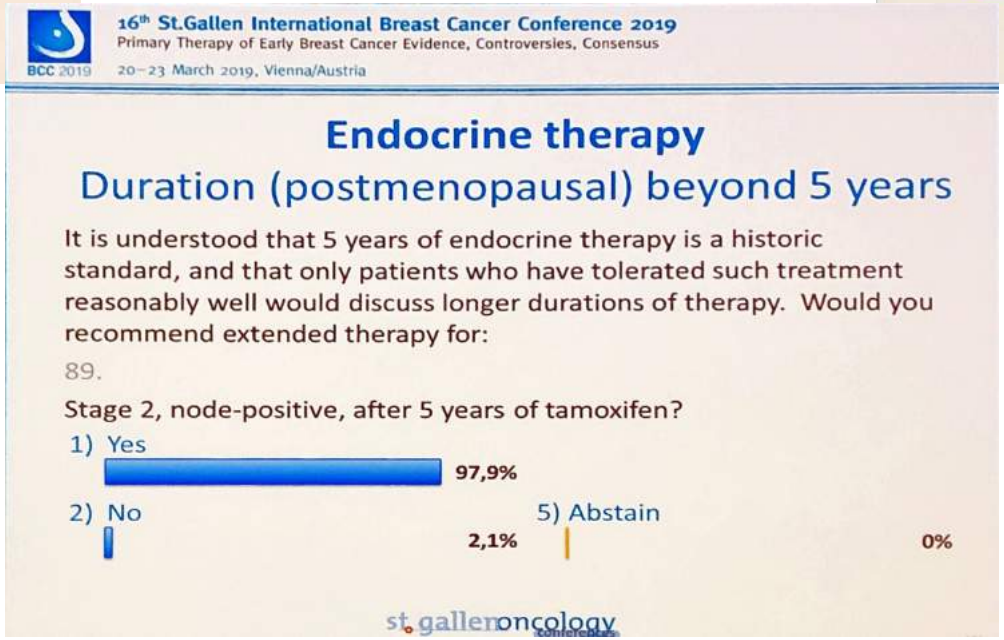




PANEL DECISION ON EA-ET IN POSTMENOPAUSAL WOMEN







PANEL DECISION ON EA-ET IN POSTMENOPAUSAL WOMEN