**Best Practice in Radiation Oncology and Novel Therapeutic Approaches:**
An Annual Update

THE UNIVERSITY OF KANSAS
CANCER CENTER

# Management of Regional Lymph Nodes in Breast Cancer

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# Disclosures

- No industry-related disclosures relevant to this presentation
- Research disclosures:
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# Key Take-aways: Radiation Management of Regional Lymph Nodes in Breast Cancer

- ➔ When surgery is first line of therapy – most ( but not all) node positive breast patients benefit from regional nodal irradiation (RNI).
- ➔ When neoadjuvant systemic therapy is the first line of treatment – RNI can be omitted when clinical cN1 Breast Cancer at diagnosis that is down staged to pathologically node negative (ypN0)
- ➔ Moderate hypofractionation is safe and effective for delivery of RNI

# In the Adjuvant Systemic Therapy Setting:

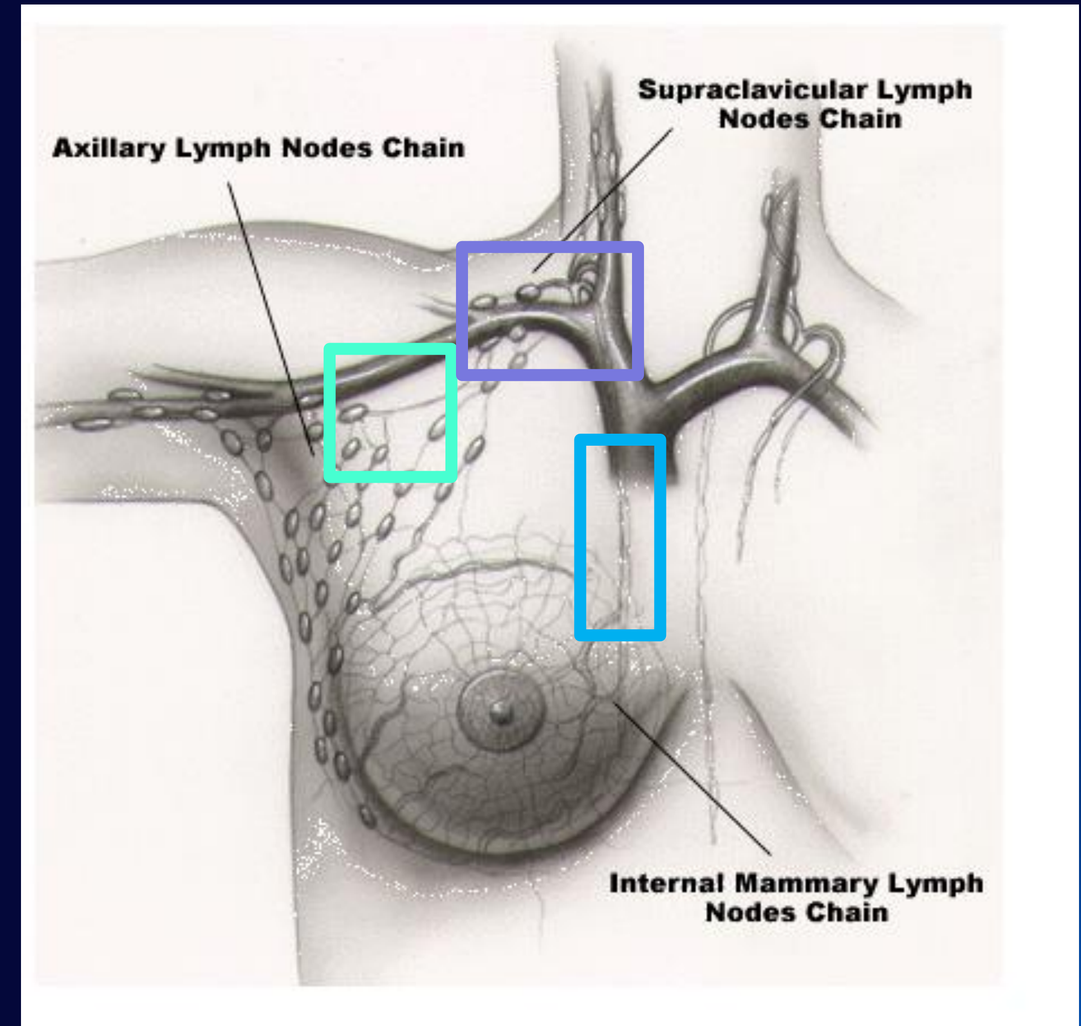
Modern evidence supports that regional nodal irradiation is indicated for T1-2 breast cancer with metastases to 1-3 (N1) axillary nodes

- ► 2014: EBCTCG meta-analysis PMRT
- ► 2015: NCIC MA.20 phase 3 clinical trial 10 yr
- ► 2015: EORTC 22922/10925 phase 3 clinical trial 10 yr
- ► 2016: DBCG IMN prospective trial
- ► 2021: EORTC 22922/10925 phase 3 clinical trial 15 yr
- ► 2023: EBCTCG meta-analysis RNI

# Regional Nodal Irradiation Targets in Modern Radiation Therapy Trials

Regional nodes:

- Axilla: what did not get removed with SN biopsy or dissection, “undissected” or “retained” axilla
- Supraclavicular
- Internal mammary: first 3 to 4 intercostal spaces



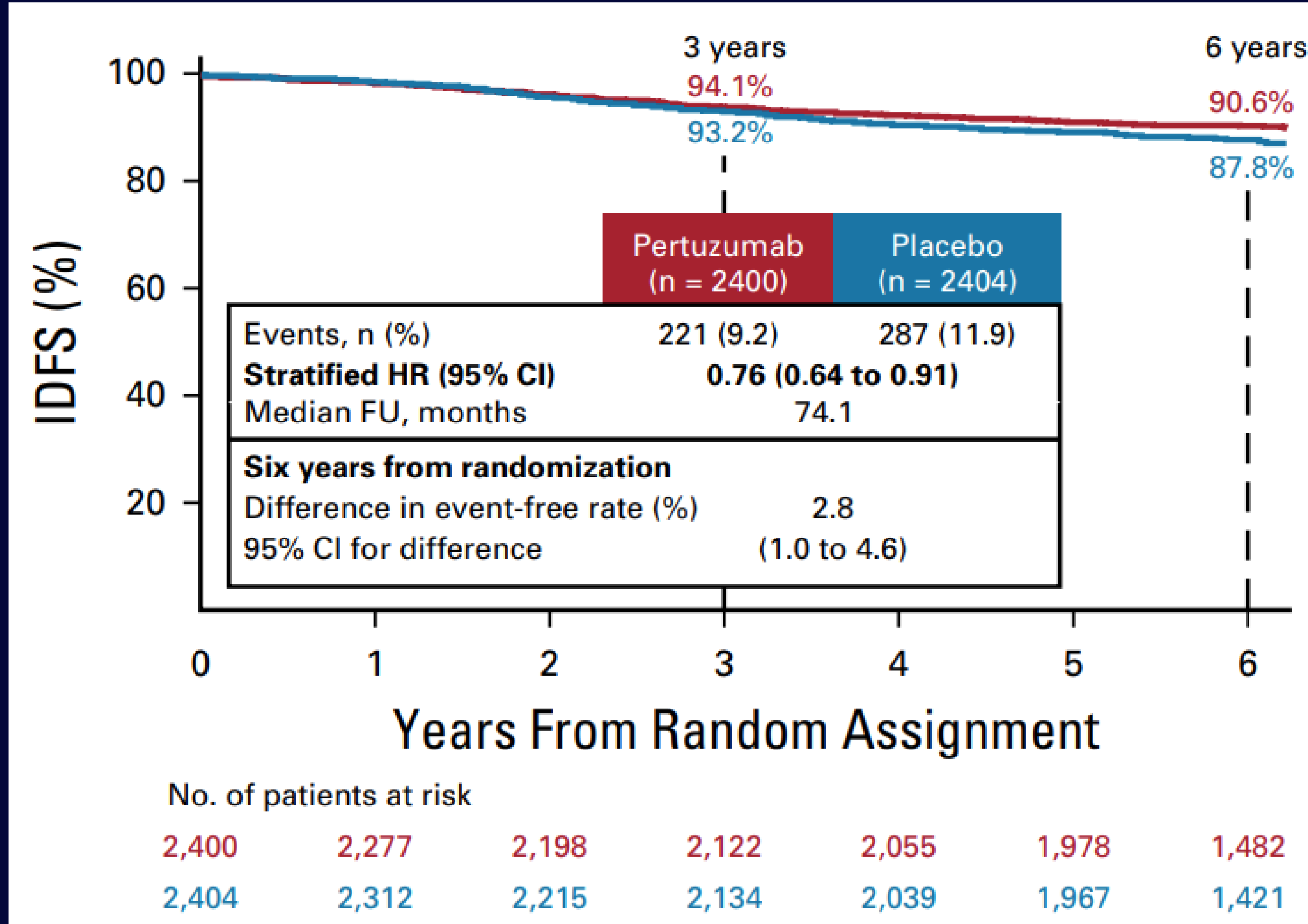
# Modern Regional Nodal Irradiation (RNI) Trials Improved 10 yr. Local Regional Control, Distant DFS, DFS

| | | | Local Reg. Recurrence | | | Distant Disease Free | | | Disease Free Surv. | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Trial** | **n** | **% N1** | **No RNI** | **RNI** | **p** | **No RNI** | **RNI** | **p** | **No RNI** | **RNI** | **p** |
| **NCIC MA.20** | 1832 | 85 | 6.8% | 4.3% | .009 | 82.4% | 86.3% | .03 | 77% | 82% | .01 |
| **EORTC 22922[10y]** | 4004 | 43 | 9.5% | 8.3% | | 75% | 78% | .02 | 69.1% | 72.1% | .04 |
| | | | ⬇ 1.9% | | | ⬆ 3.4 % | | | ⬆ 4 % | | |


*Whelan et al. NEJM 2015;373(19):1878-1879*

*Poortmans et al, NEJM 373: (4):317-327 2015*

# APHINITY: Difference in Invasive Disease-Free Survival at 6 Years is 2.8% Overall and 4.5% for N+



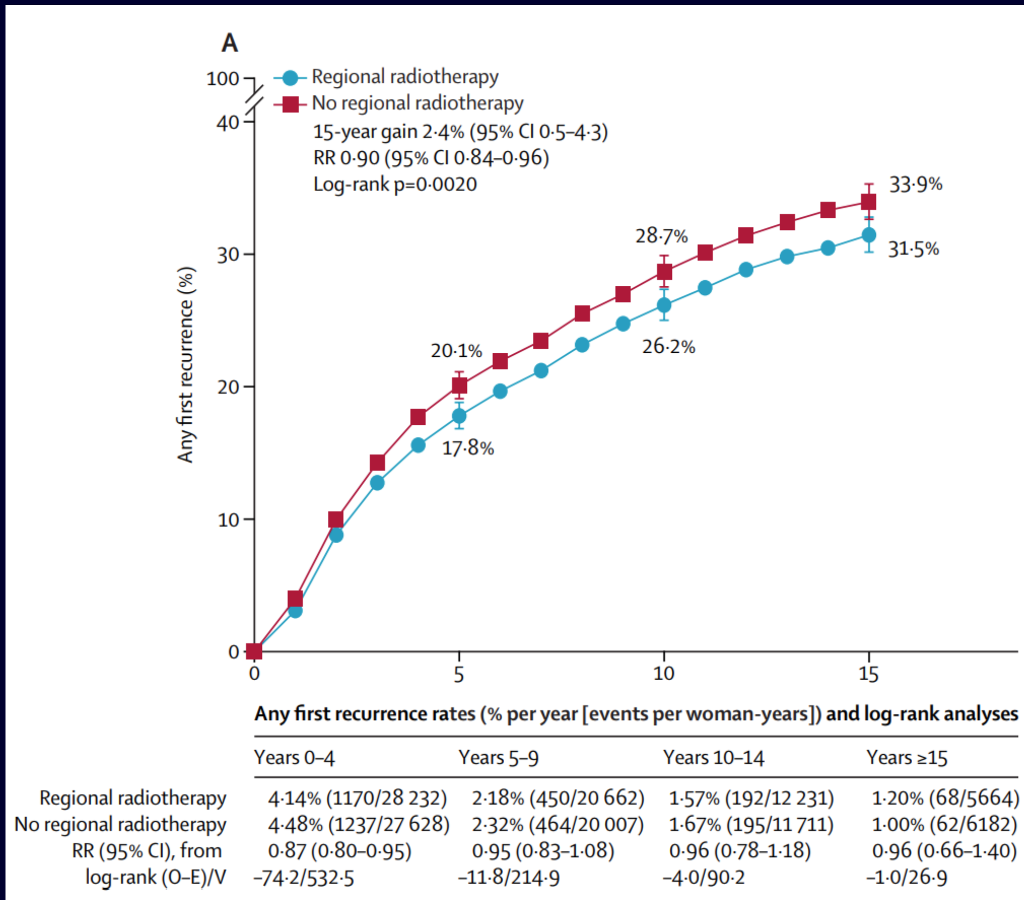

Piccart M et al. *J Clin Oncol.* 2021;39(13):1448-1457.

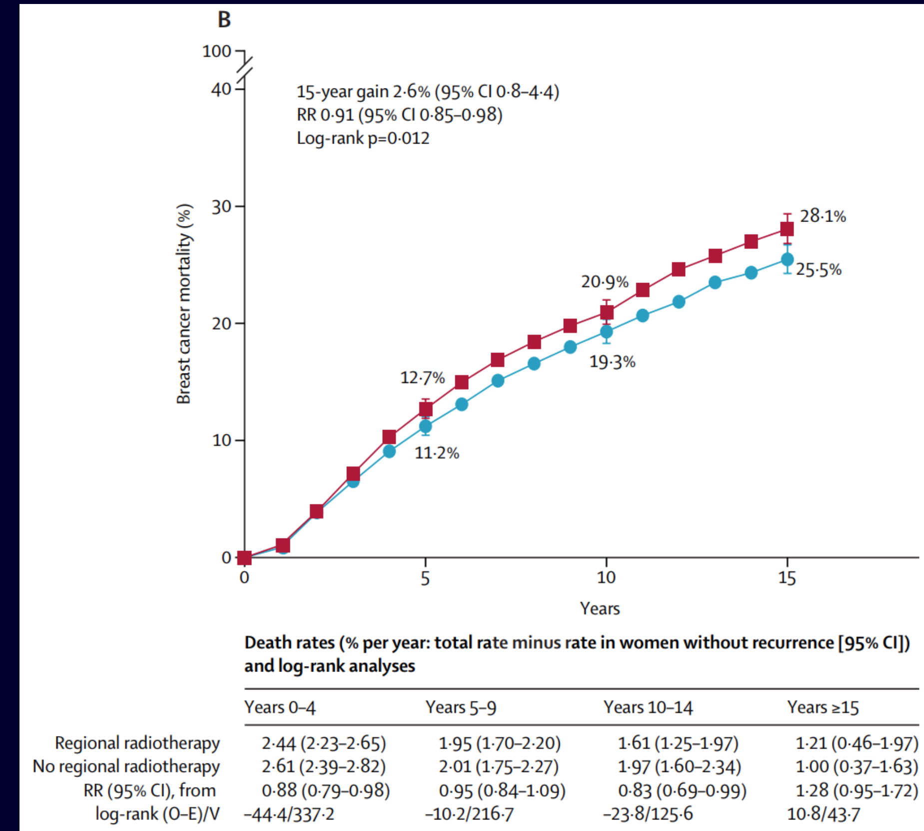
# EBCTCG Meta analysis 2023: Regional Nodal Irraidaiton

- 1961- 2008:
  - 17 eligible trials, 16 with data
- 1998-2008: 8 newer trials,
- n= 12167 → Effects of radiotherapy vs no radiotherapy to lymph node regions including:
  - Some or all of the internal mammary chain,
  - Supraclavicular fossa
  - Axilla (node levels 1–4)
- Trials Categorized by Era
  - 1961-1978 Older trials
  - 1998 – 2008 Newer trials

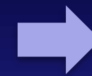
- Main endpoint: time to first breast cancer recurrence at any site (ie, locoregional recurrence, newly incident ipsilateral disease, or distant metastasis)
- Stratification: trial, year of follow up, age at entry, Nodal status (pN0, p1-3+, pn 4+), clinical nodal status used pwehn path status unavailable
- **Median follow up:**
  - **All 14 years**
  - **Older trials: 25.4 years**
  - **New trials: 13.7 years**

# EBCTCG Meta analysis 2023
# RNI Effect in All Trials 1961-2008



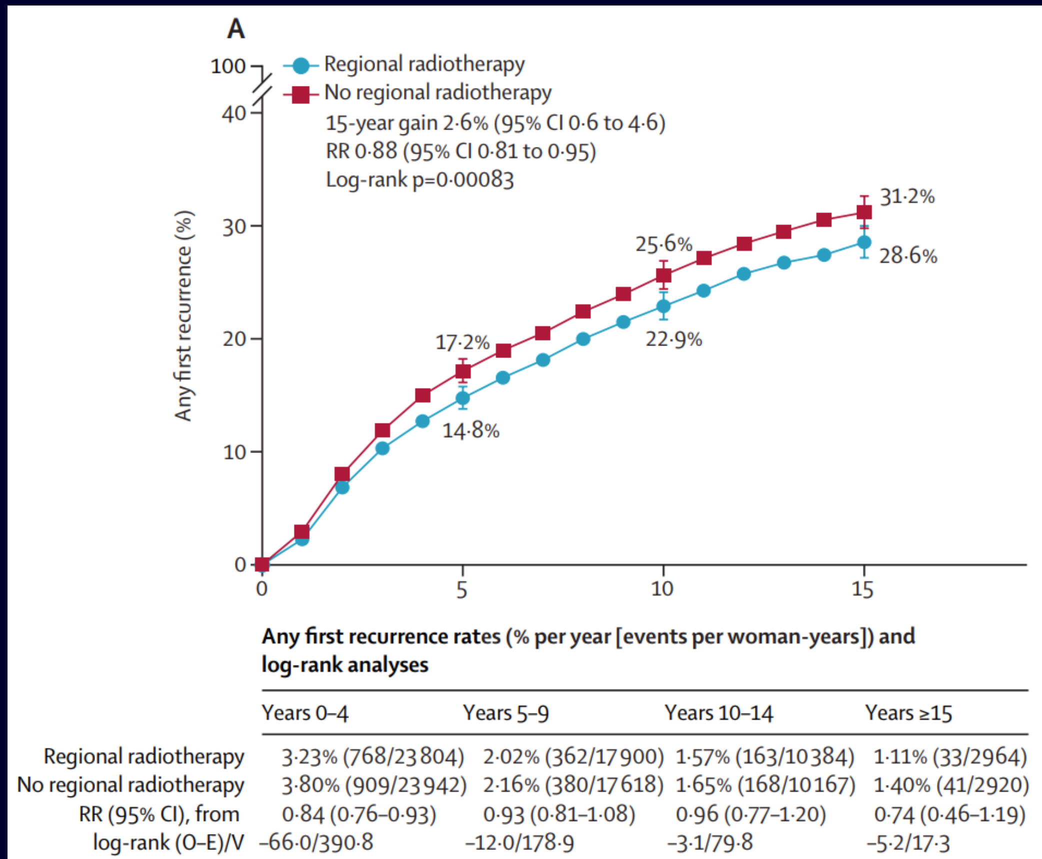

33.9% No RNI
31.5% RNI (p<0.002)
2.4% Gain 15 year
**Overall Control**



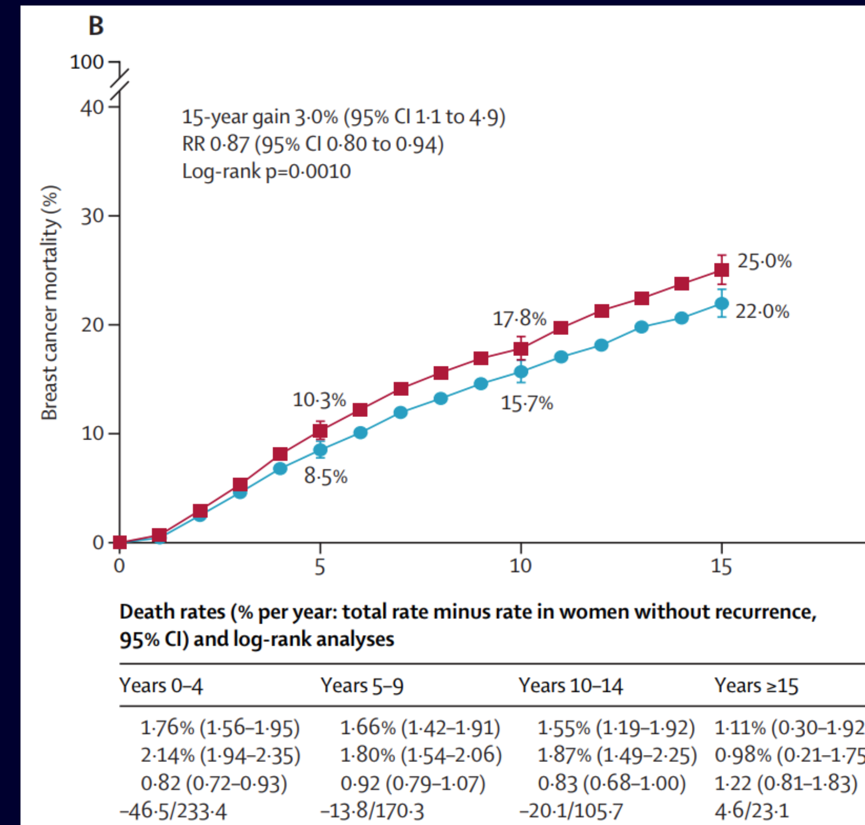
28.1% No RNI
25.5% RNI (p<0.001)
2.6% Improvement
15 year **Survival**

EBCTCG Lancet 2023

# EBCTCG 2023: RNI Effect in New Trials 1998-2008




| | Years 0–4 | Years 5–9 | Years 10–14 | Years ≥15 |
|---|---|---|---|---|
| Regional radiotherapy | 3·23% (768/23 804) | 2·02% (362/17 900) | 1·57% (163/10 384) | 1·11% (33/2964) |
| No regional radiotherapy | 3·80% (909/23 942) | 2·16% (380/17 618) | 1·65% (168/10 167) | 1·40% (41/2920) |
| RR (95% CI), from | 0·84 (0·76–0·93) | 0·93 (0·81–1·08) | 0·96 (0·77–1·20) | 0·74 (0·46–1·19) |
| log-rank (O–E)/V | –66·0/390·8 | –12·0/178·9 | –3·1/79·8 | –5·2/17·3 |




| Years 0–4 | Years 5–9 | Years 10–14 | Years ≥15 |
|---|---|---|---|
| 1·76% (1·56–1·95) | 1·66% (1·42–1·91) | 1·55% (1·19–1·92) | 1·11% (0·30–1·92) |
| 2·14% (1·94–2·35) | 1·80% (1·54–2·06) | 1·87% (1·49–2·25) | 0·98% (0·21–1·75) |
| 0·82 (0·72–0·93) | 0·92 (0·79–1·07) | 0·83 (0·68–1·00) | 1·22 (0·81–1·83) |
| –46·5/233·4 | –13·8/170·3 | –20·1/105·7 | 4·6/23·1 |

31.2% No RNI
28.6% RNI (p<0.00083)
2.6% Gain 15 year
**Overall Control**

25% No RNI
22% RNI (p<0.001)
3% Improvement 15 year **Survival**

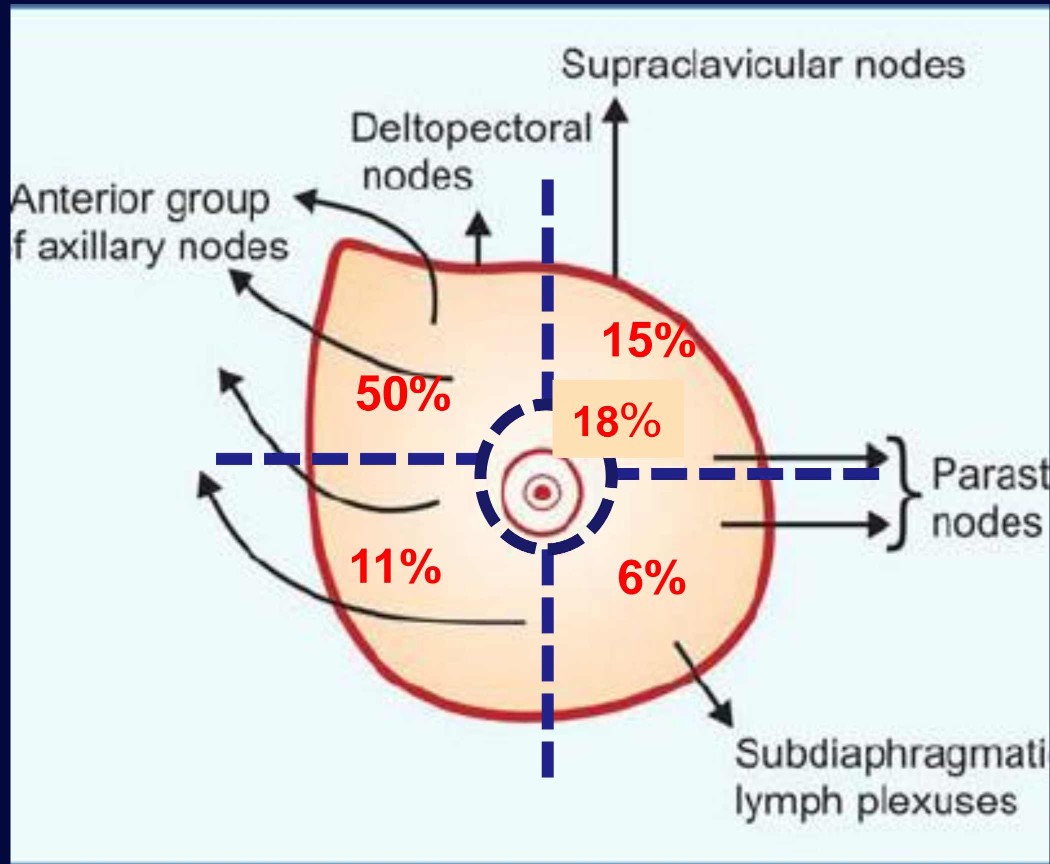
EBCTCG Lancet 2023

# EBCTCG 2023: Absolute Benefits of RNI

| | Regional radiotherapy | No regional radiotherapy | Gain from regional radiotherapy |
|---|---|---|---|
| **Any recurrence** | | | |
| pN0 | 19·0% | 21·3% | 2·3% |
| pN1–3 | 25·6% | 28·5% | 2·9% |
| pN4+ | 46·8% | 51·1% | 4·3% |
| **Breast cancer mortality** | | | |
| pN0 | 10·9% | 12·5% | 1·6% |
| pN1–3 | 20·3% | 23·0% | 2·7% |
| pN4+ | 40·5% | 45·0% | 4·5% |

EBCTCG Lancet 2023

# EBCTCG 2023 Meta-analysis T1-T3, N0: RNI Benefit?




Nodal Drainage and Breast Cancer Incidence by Quadrant

Location!
Location!
Location!

# N1 microscopic
# What is the Radiation Management?

- N= 468 with N1 Breast Cancer
- Mastectomy
- OSU 2001 -2013
- Micro metastasis n=90 (19%)
  - SNB 30%
  - AND 70%
- No PMRT
- Median follow up: 6.3 years

| 6 Year Outcome for N1 Breast Cancer | | | | |
|---|---|---|---|---|
| | **LRR** | **DM** | **DFS** | **OS** |
| MacroMet | 5% | 9% | 81.8% | 86.4% |
| **MicroMet** | **0** | **5.8%** | **90%** | **96.5%** |
| p | 0.143 | 0.368 | 0.065 | 0.09 |

- Very low rates of LRR and DM post mastectomy for patients with N1 microscopic breast cancer
- No radiation indicated

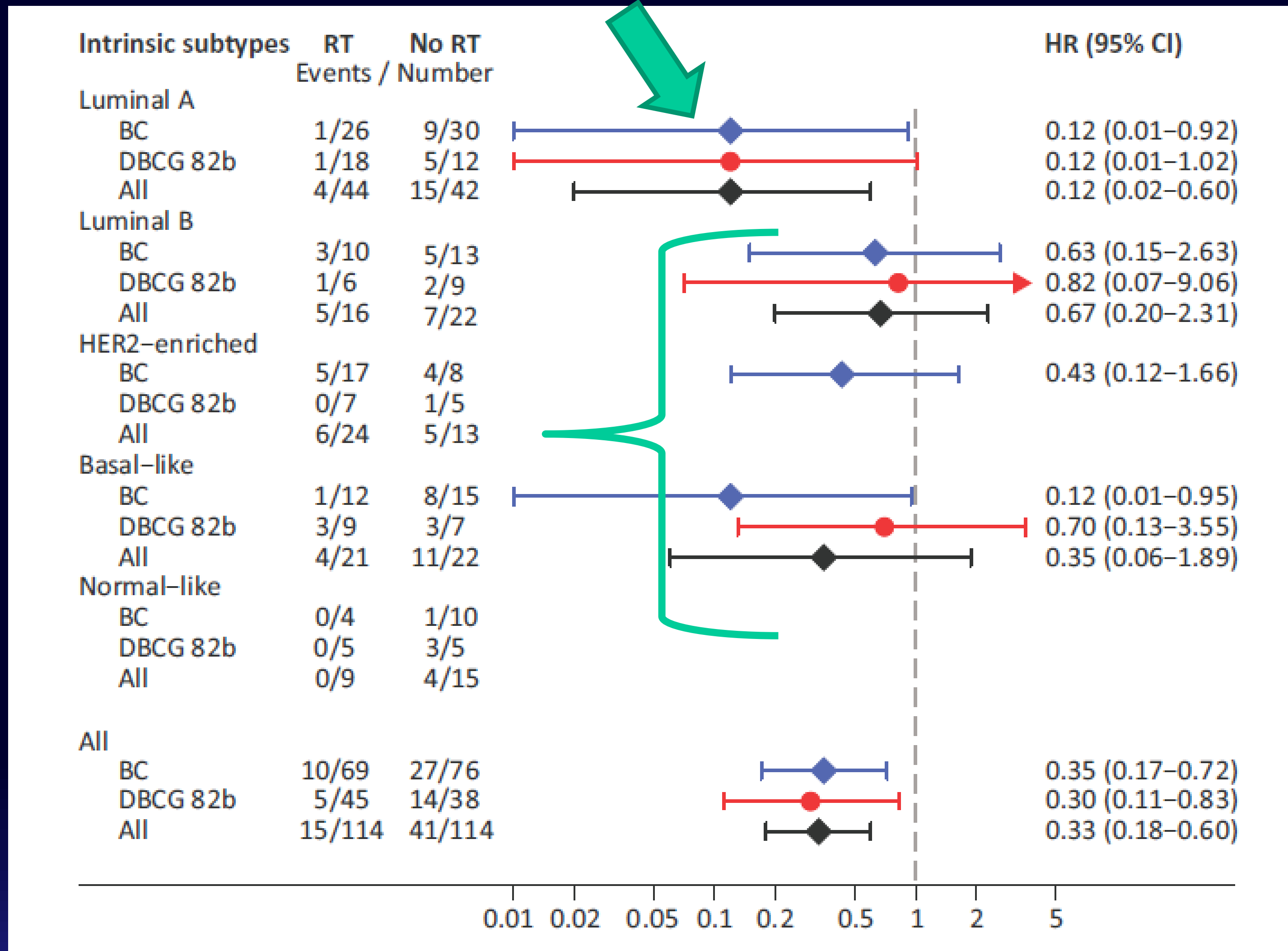
Bazan et al. ASO 2018

# Breast Cancer Biology Matters!

- Clinical trial data addressing axillary management focuses on number of nodal metastasis without attention to biological behavior of specific disease
- Current Breast Cancer management predicated on breast cancer subtype
- Well established that breast cancer subtype is prognostic for likelihood of local regional recurrence as well as distant metastasis
- MA.20 RNI benefit varied by hormone receptor (HR) status on multivariate analysis – largest benefit in HR negative N1 patients.

→ Cancer Care Ontario Guidelines recommend PMRT for N1 only in HR negative cases (*Brackstone et al, JCO 39: 2021)

# PMRT in Premenopausal Breast Cancer and Subtype: British Columbia (BC) & DBCG 82B Trials

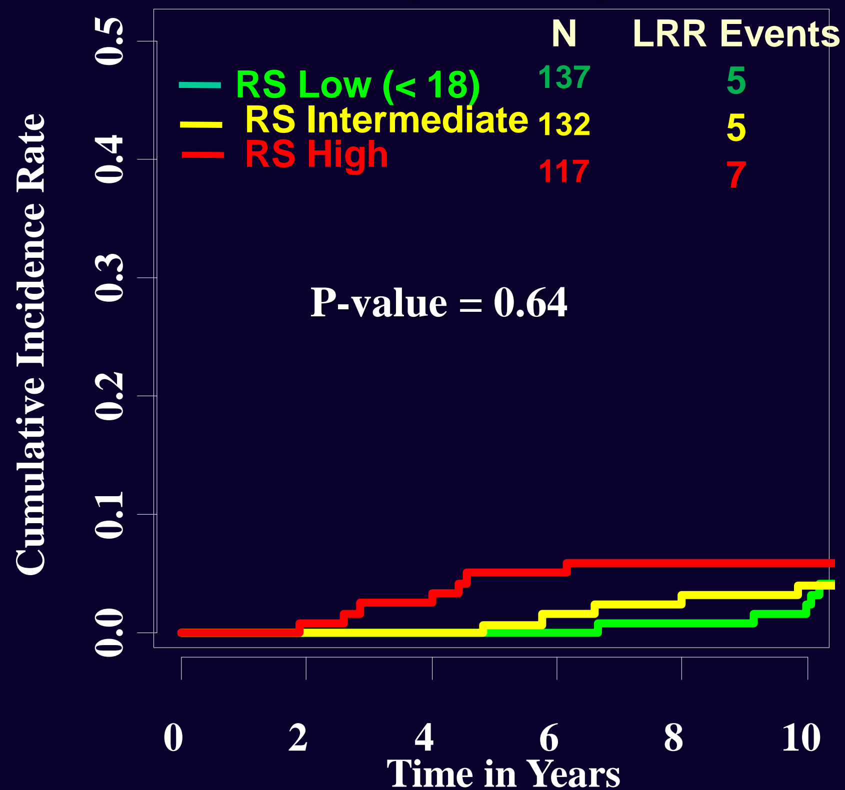


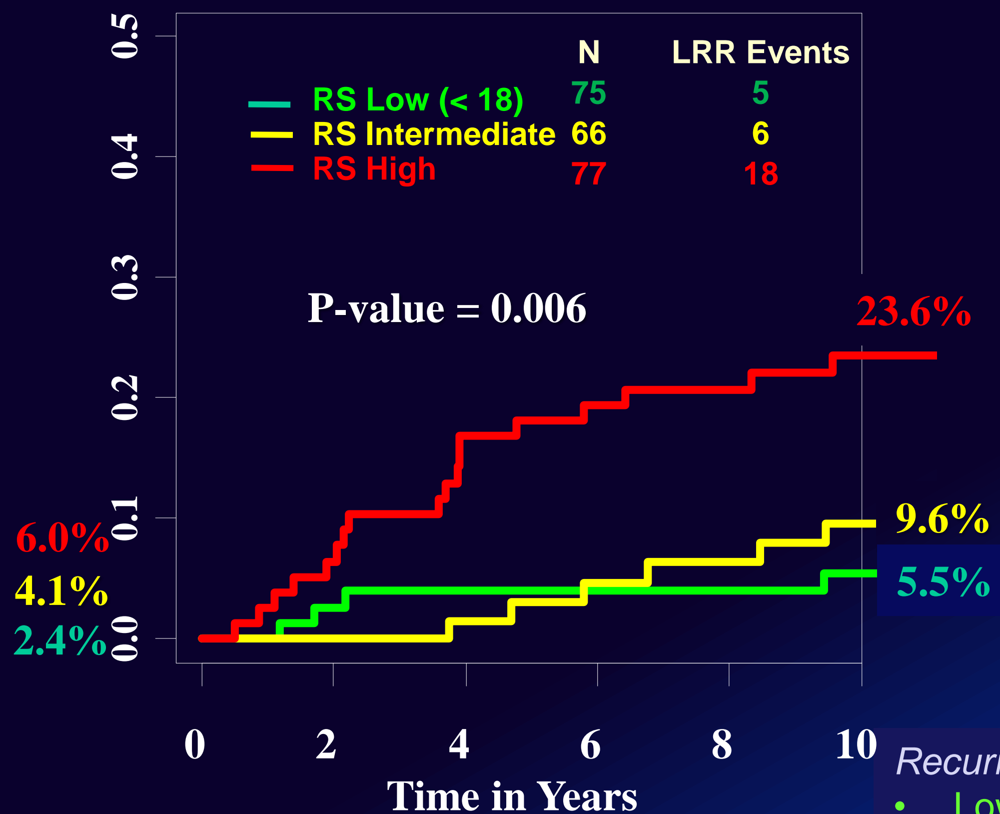

- N=228
- Node positive disease
- PAM50 genes essential for intrinsic subtype classification
- LRR **lowest** Luminal A
  - 4% BC
  - 6 % DBCG 82B
- ★ **RT benefit was greatest for Luminal A**

Laurberg et al, ACTA ONCOLOGICA, 2018

# Oncotype RS Multigene Assay Prognostic for LRR Post Mastectomy for ER/PR+ Breast Cancer

## NSABP B28: ER+, Node positive




- n = 1065
- Median follow-up was 11.2 years
- Breast radiation only Post lumpectomy ( No RNI)

Mamounas EP, et al. *JNCI 2017*

*Recurrence Score*:
- Low < 18
- Intermediate 18-30
- High > 30

# Longstanding Debate of Whether RNI Post-Neoadjuvant Systemic Therapy Should be Based on Clinical Nodal Status (cN1+) Versus Pathologic (ypN0) Status?

- Multiple retrospective analyses of prospectively collected clinical trial data identified that LRR is lower after neoadjuvant systemic therapy when there is pCR or ypN0:

  - ► 2012: NSABP B18 and NSABP B27
  - ► 2017: EORTC 10994 / BIG 1-00
  - ► 2019: GBG GeparTrio, GeparQuattro, GeparQuinto
  - ► 2023: TRYPHEANA and NeoSphere (HER2)

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# NRG NSABP B-51/RTOG 1304 Trial Phase III

- Clinical T1-3**N1**M0 breast cancer
- Pathology positive axillary node (**FNA/Core**)
- Neoadjuvant CT ± anti HER2

**ypN0** at definitive Breast Surgery + AND or SNB

Accrued: n= 1641 2013-2020

★ Primary Endpoint: IDFS

Randomization

**Arm 1**

**No Regional Nodal XRT**

A. Lumpectomy: Breast XRT
B. Mastectomy: Observation

**Arm 2**

**Regional Nodal XRT**

A. Lump.: Breast/Nodal XRT
B. Mast: Chestwall/ Nodal XRT

Stratification: Type of Surgery (Mast v. Lump) , ER-Status (+ v. –), HER2 Status (+ v. –), pCR in Breast (yes v. no)

*Mamounas et al, SABCS 2023*

# NRG NSABP B51 RTOG 1304 Clinical Trial

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- Accrued n=1641
  - Analysis for disease related endpoints: N = 1566
  - Analysis for overall survival: N= 1602
- Eligibility: (select)
  - cT1-3, cN1 (bx proven)
  - Known ER, PR, HER2 (per ASCO CAP guidelines)
  - Complete ≥8 weeks of neoadjuvant chemotherapy (with anti-HER2 therapy if HER2+)
  - ypN0 (By SNB with ≥ 2 SN or/ and Ax. Diss.)
  - Lumpectomy or mastectomy (negative margins)
- Median Follow-up Time: 59.5 months
- Primary endpoint: IBCRF
  - invasive local, regional, or distant recurrence, or death from breast cancer

*Mamounas et al., SABCS 2023*

# Statistical Considerations:

- Primary endpoint – invasive BC recurrence-free interval (IBCRFI)
- Study was designed to have 80% power to detect 35% reduction in annual IBCRFI rate (4.6% abs. risk reduction in 5-yr cumulative rate)
- Per protocol, final analysis was to occur after 172 events or 10 years after study initiation
- Time-driven analysis is reported
- Definitive analysis was based on the intent-to-treat principle
- Patients were analyzed as randomized, regardless of eligibility or protocol compliance
- Patients with no follow-up or not at risk for recurrence were excluded

NRG NSABP B51 RTOG 1304

# Population Characteristics:

→ All variables (patient, tumor, treatment, etc.) have equally balanced representation in Arms 1 and 2

| Variable | % |
|---|---|
| **Age:** (median) | 52 years |
| <50 years | 40.5 % |
| **Race/ Ethnicity:** Asian | 6 % |
| AA | 17.5 % |
| White | 69 % |
| Hispanic | 14 % |
| **Clinical Tumor Size:** cT1 | 21 % |
| cT2 | 60 % |
| cT3 | 19 % |
| **Tumor Subtype:** Triple-negative | 22 |
| ER+ and /or PR+ / HER2- | 21 |
| ER- / PR- / HER2+ | 24.5 |
| ER+ and /or PR+ / HER2+ | 32 |
| **Surgery:** Lumpectomy | 58 % |
| Mastectomy | 42 % |
| **Axillary Surgery:** SN | 55.5 % |
| ALND | 44.5 % |
| **pCR Breast** | 79 % |

**56.5%** (ER- / PR- / HER2+ and ER+ and /or PR+ / HER2+)

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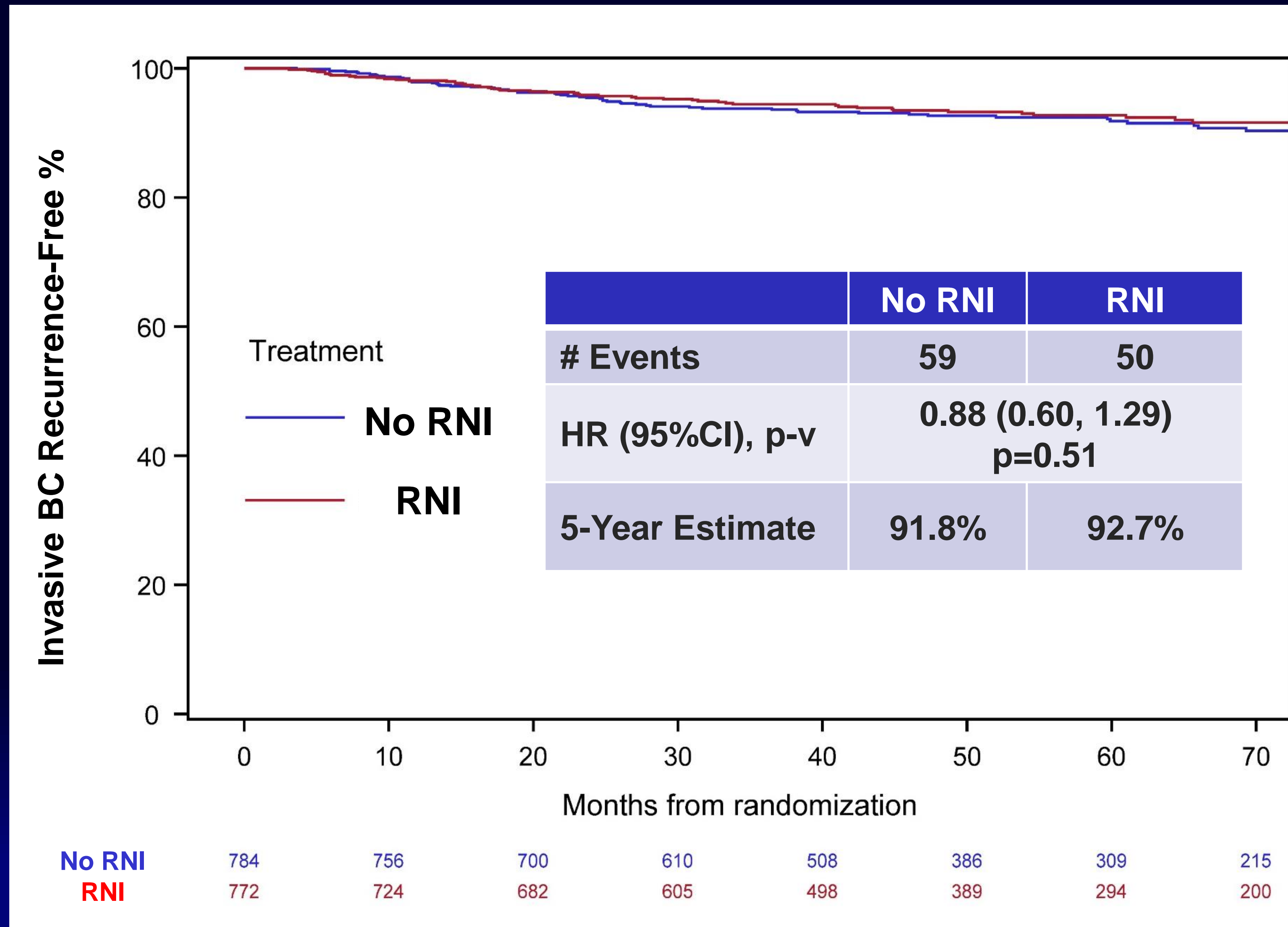
# Primary Endpoint:
## Invasive Breast Cancer Recurrence-free Interval (IBCRFI)




| | No RNI | RNI |
|---|---|---|
| # Events | 59 | 50 |
| HR (95%CI), p-v | 0.88 (0.60, 1.29) p=0.51 | |
| 5-Year Estimate | 91.8% | 92.7% |

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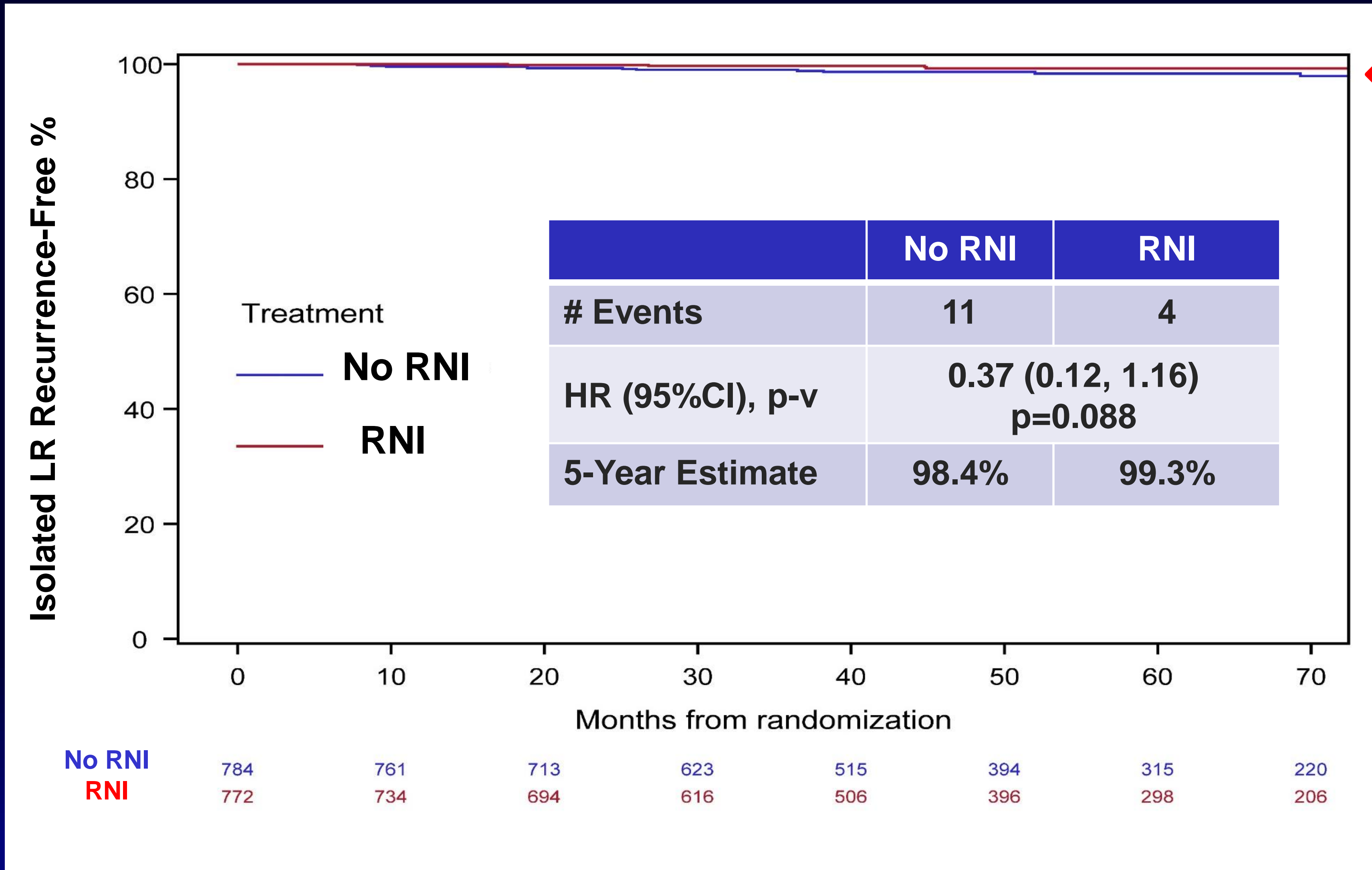
# Secondary Endpoint:

## Isolated Loco-Regional Recurrence-free Interval (ILRRFI)*




| | No RNI | RNI |
|---|---|---|
| # Events | 11 | 4 |
| HR (95%CI), p-v | 0.37 (0.12, 1.16)<br>p=0.088 | |
| 5-Year Estimate | 98.4% | 99.3% |

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NRG ONCOLOGY

# NRG NSABP B51 RTOG 1304 Results

| Characteristic | No RNI | RNI | HR (95% CI) |
|---|---|---|---|
| IBCRFI | 91.8% | 92.7 % | 0.88 (0.60,1.29) p=0.51 |
| LRRFI (isolated) | 98.4% | 99.3% | 0.37 (0.12, 1.16) p=0.088 |
| Distant Recurrence FI | 93.4 % | 93.4 % | 1.00 (0.67, 1.51) p=0.99 |
| Disease Free Survival | 88.5% | 88.3% | 1.06 (0.79, 1.44) p=0.69 |
| Overall Survival | 94 % | 93.6 % | 1.12 (0.75, 1.68) p=0.59 |

Median Follow-up Time: 59.5 mo.'s

*Mamounas et al., SABCS 2023*

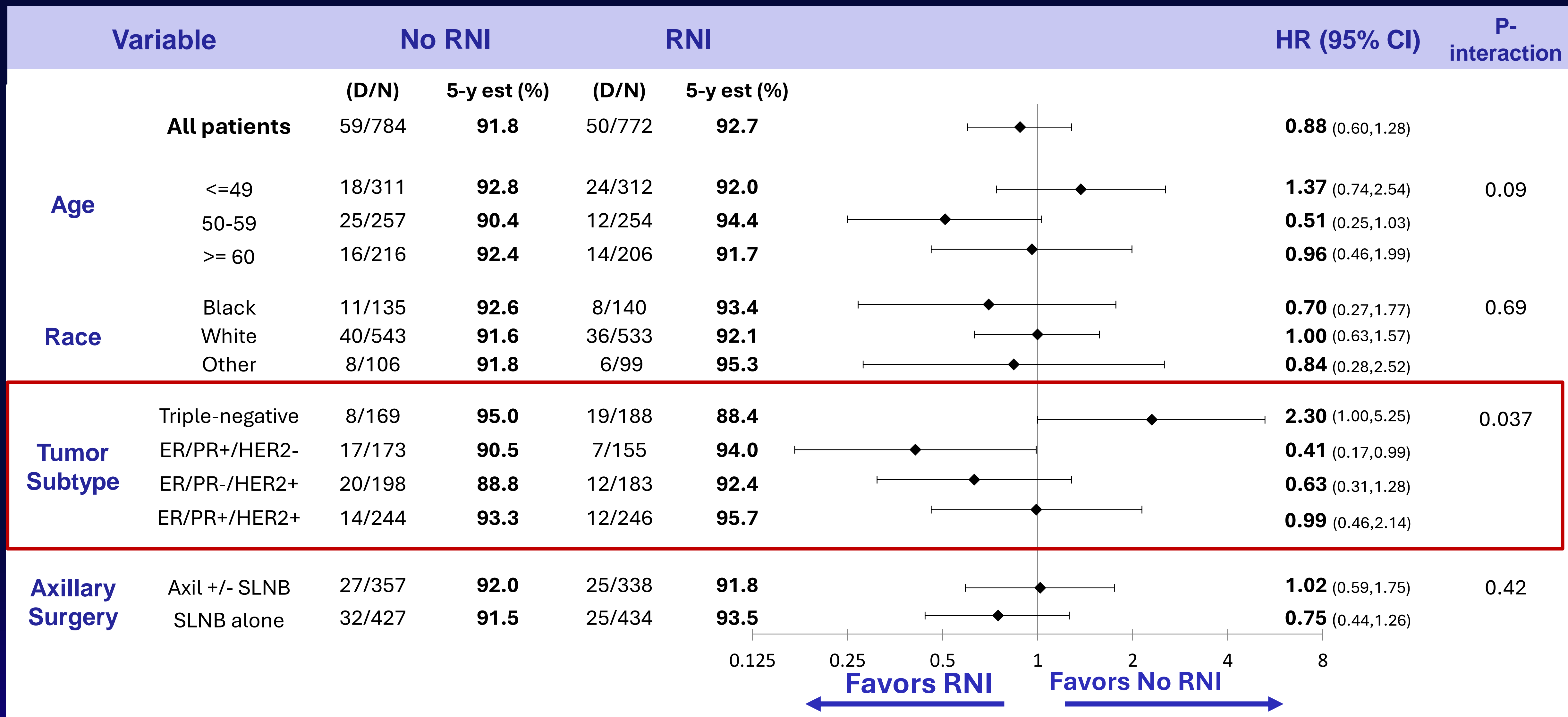
# IBCRFI – Subgroup Analysis by Stratification Factors

| Variable | | No RNI (D/N) | No RNI 5-y est (%) | RNI (D/N) | RNI 5-y est (%) | HR (95% CI) | *P*-interaction |
|---|---|---|---|---|---|---|---|
| | **All patients** | 59/784 | **91.8** | 50/772 | **92.7** | **0.88** (0.60,1.28) | |
| Surgery | Lumpectomy | 26/454 | **93.5** | 28/454 | **92.8** | **1.08** (0.63,1.84) | 0.28 |
| | Mastectomy | 33/330 | **89.5** | 22/318 | **92.6** | **0.72** (0.42,1.23) | |
| ER/PR | Negative | 28/367 | **91.7** | 31/371 | **90.4** | **1.12** (0.67,1.86) | 0.17 |
| | Positive | 31/417 | **92.1** | 19/401 | **94.9** | **0.66** (0.37,1.16) | |
| HER2 | Negative | 25/342 | **92.6** | 26/343 | **90.9** | **1.01** (0.59,1.76) | 0.47 |
| | Positive | 34/442 | **91.3** | 24/429 | **94.3** | **0.77** (0.46,1.31) | |
| pCR breast | No | 20/173 | **87.8** | 15/172 | **90.3** | **0.74** (0.38,1.45) | 0.59 |
| | Yes | 39/611 | **93.0** | 35/600 | **93.5** | **0.93** (0.59,1.47) | |
| Adjuvant Chemotherapy | No | 57/780 | **92.1** | 50/766 | **92.7** | **0.92** (0.63,1.34) | |
| | Yes | 2/4 | | 0/6 | | | |

0.125 0.25 0.5 1 2 4 8

Favors RNI ← → Favors No RNI

# IBCRFI – Exploratory Subgroup Analysis



| Variable | | No RNI (D/N) | No RNI 5-y est (%) | RNI (D/N) | RNI 5-y est (%) | HR (95% CI) | P-interaction |
|---|---|---|---|---|---|---|---|
| | **All patients** | 59/784 | **91.8** | 50/772 | **92.7** | **0.88** (0.60,1.28) | |
| Age | <=49 | 18/311 | **92.8** | 24/312 | **92.0** | **1.37** (0.74,2.54) | 0.09 |
| | 50-59 | 25/257 | **90.4** | 12/254 | **94.4** | **0.51** (0.25,1.03) | |
| | >= 60 | 16/216 | **92.4** | 14/206 | **91.7** | **0.96** (0.46,1.99) | |
| Race | Black | 11/135 | **92.6** | 8/140 | **93.4** | **0.70** (0.27,1.77) | 0.69 |
| | White | 40/543 | **91.6** | 36/533 | **92.1** | **1.00** (0.63,1.57) | |
| | Other | 8/106 | **91.8** | 6/99 | **95.3** | **0.84** (0.28,2.52) | |
| Tumor Subtype | Triple-negative | 8/169 | **95.0** | 19/188 | **88.4** | **2.30** (1.00,5.25) | 0.037 |
| | ER/PR+/HER2- | 17/173 | **90.5** | 7/155 | **94.0** | **0.41** (0.17,0.99) | |
| | ER/PR-/HER2+ | 20/198 | **88.8** | 12/183 | **92.4** | **0.63** (0.31,1.28) | |
| | ER/PR+/HER2+ | 14/244 | **93.3** | 12/246 | **95.7** | **0.99** (0.46,2.14) | |
| Axillary Surgery | Axil +/- SLNB | 27/357 | **92.0** | 25/338 | **91.8** | **1.02** (0.59,1.75) | 0.42 |
| | SLNB alone | 32/427 | **91.5** | 25/434 | **93.5** | **0.75** (0.44,1.26) | |

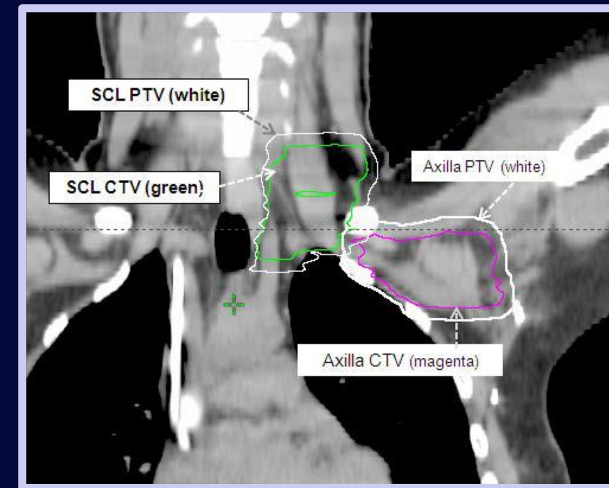
# NRG NSABP B51 RTOG 1304
# Location of Isolated LRR

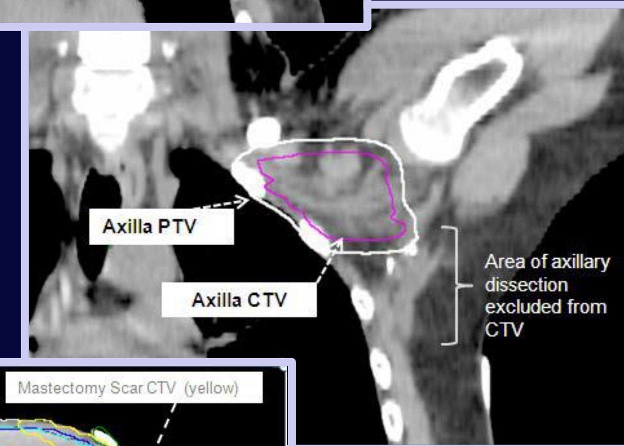
| Location | No RNI<br>\# | RNI<br>\# |
|---|---|---|
| Local | 2 | 4 |
| Regional | 8 | 0 |
| Loco-regional | 1 | 0 |
| Total | 11 | 4 |

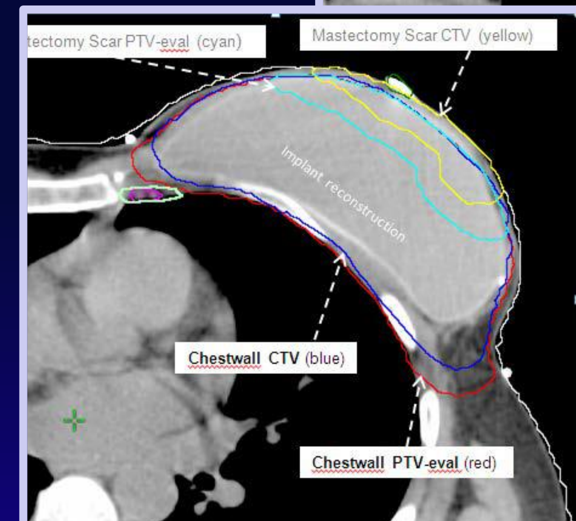
NRG ONCOLOGY

# First NCTN trial to utilize CT Target-based 3DCRT/ IMRT for RNI

- All patients underwent CT simulation followed by delineation of targets for breast/chest wall, regional nodes, and OAR (heart, lungs, thyroid, etc.)
- Physician approval of a composite radiation treatment plan with dose volume analyses (DVA) meeting protocol target and OAR dose constraints was required.
- Two-step radiation quality assurance (QA):
  - centralized benchmarking by each enrolling facility,
  - Individual review of each case
- ★ Per protocol or acceptable variation standards were met in
  - 94.4% for TV/OAR score; (no RNI:98.4%, RNI:92.0%)
  - 95.8% for overall DVA score; ( no RNI:98.0%, RNI:94.5%)



NRG
ONCOLOGY

# NRG NSABP B51 RTOG 1304
# TOXICITY

- **Toxicity**

➔ 1,559 patients (No RNI:800; RNI:759).

➔ No study-related deaths and no unexpected toxicities.

➔ Grade 4 toxicity was rare (No RNI: 0.1%, vs. RNI: 0.5%);

➔ Grade 3 toxicity was uncommon (No RNI: 6.5%, RNI:10%)

➔ Most common Grade 3 toxicity was radiation dermatitis (No RNI: 3.3%, RNI: 5.7%)

# Change in Practice KUMC Radiation Oncology: RNI Post Neoadjuvant Chemotherapy

- Clinical cT1-3, cN1 / ypN0:
  - Observation post mastectomy / Breast irradiation post lumpectomy
    - Subtypes: TN, HER2+
    - Response in breast: RCB-0 / RCB-1
    - Selective ER+/PR+/HER2-,
- Clinical cT4 or cN2-3/ ypN0: regional nodal irradiation
- Clinical cN0 or cN+ / ypN+: regional nodal irradiation

# Fractionation for RNI

- Chestwall and/or breast and regional nodal irradiation has historically used conventional fractionation 48-50 Gy / 2 Gy per treatment +/- boost for up to 6 weeks of treatment
- 3 Clinical Trials support that it is safe to utilize moderate hypofractionation for RNI:

| Trial | n | RNI |
| --- | --- | --- |
| Chinese Academy of Medicine | 820 | PMRT |
| Dana Farber FABREC | 440 | PMRT Reconstruction |
| Alliance RT CHARM (A221505) | 880 | PMRT Reconstruction |

# Phase III Trial Hypo fractionated PMRT
# No Difference in LRR

ELIGIBLITY
- 18-75 yo.
- Mastectomy+ AxND
- $\geq$ 4 Axillary nodes +

R

**Standard PMRT:**
50 Gy / 25 F
2.0 Gy

**Hypo fractionated PMRT:**
43.5 Gy /16F
2.9 Gy

Primary Endpoint: Local regional recurrence

- 2008-2006 Chinese Acad. Med
- n= 820
- 2D RT Chestwall + SCL nodes (No IMC)
  - Chestwall 6-9 MeV, SCL 6 MV
- Median age: 49 years
- Median Tsz: 2.5 cm
- Median + nodes: 6 (4 – 11)
- ER positive: 75%
- Median follow up: 4.8 years

| 5 year | 50 Gy/ 25 F | 43.5 Gy/ 15 F |
|---|---|---|
| Local Regional Recurrence | 8.3% | 8.1% |

Wang et al., Lancet Oncol 20: 2019

# Late Toxicity

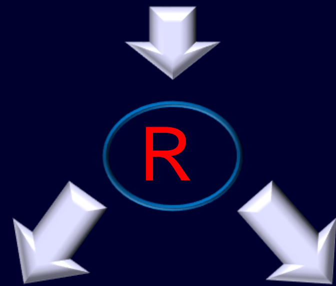
| Late toxicity | 50 Gy/ 25 F | 43.5 Gy/ 16 F | |
|---|---|---|---|
| Skin toxicity | .. | .. | 0·669 |
| Grade 1–2 | 90 (22%) | 86 (21%) | .. |
| Grade 3 | 0 | 1 (<1%) | .. |
| Lymphoedema | .. | .. | 0·961 |
| Grade 1–2 | 81 (20%) | 78 (19%) | .. |
| Grade 3 | 3 (1%) | 3 (1%) | .. |
| Shoulder dysfunction | .. | .. | 0·734 |
| Grade 1–2 | 13 (3%) | 7 (2%) | .. |
| Grade 3 | 1 (<1%) | 1 (<1%) | .. |
| Lung fibrosis | .. | .. | 0·081 |
| Grade 1–2 | 42 (10%) | 62 (15%) | .. |
| Grade 3 | 0 | 0 | .. |
| Ischaemic heart disease | .. | .. | 0·569 |
| Grade 1–2 | 1 (<1%) | 3 (1%) | .. |
| Grade 3 | 3 (1%) | 4 (1%) | .. |

- Similar incidence

Wang et al., Lancet Oncol 20: 2019

# Dana Farber FABREC Clinical Trial

ELIGIBLITY
- Stage I-III
- Mastectomy+ SN or AxND
- Immediate Breast reconstruction




**Standard PMRT:**
CW: 50 Gy / 25 F
Nodes: 46-50/ 23-25 F

**Hypo fractionated PMRT:**
CW:42.56 Gy /16F
Nodes: 39.9 Gy/ 15 F

- Opened: 2018
- Targeted Accrual: 400
- PMRT includes:
  - CW/ reconstructed breast
  - SCL
  - Axilla (optional)
  - IMC (optional)

PI: Rinaa Punglia MD

Primary Endpoint: FACT-B Physical Well Being at 6 months

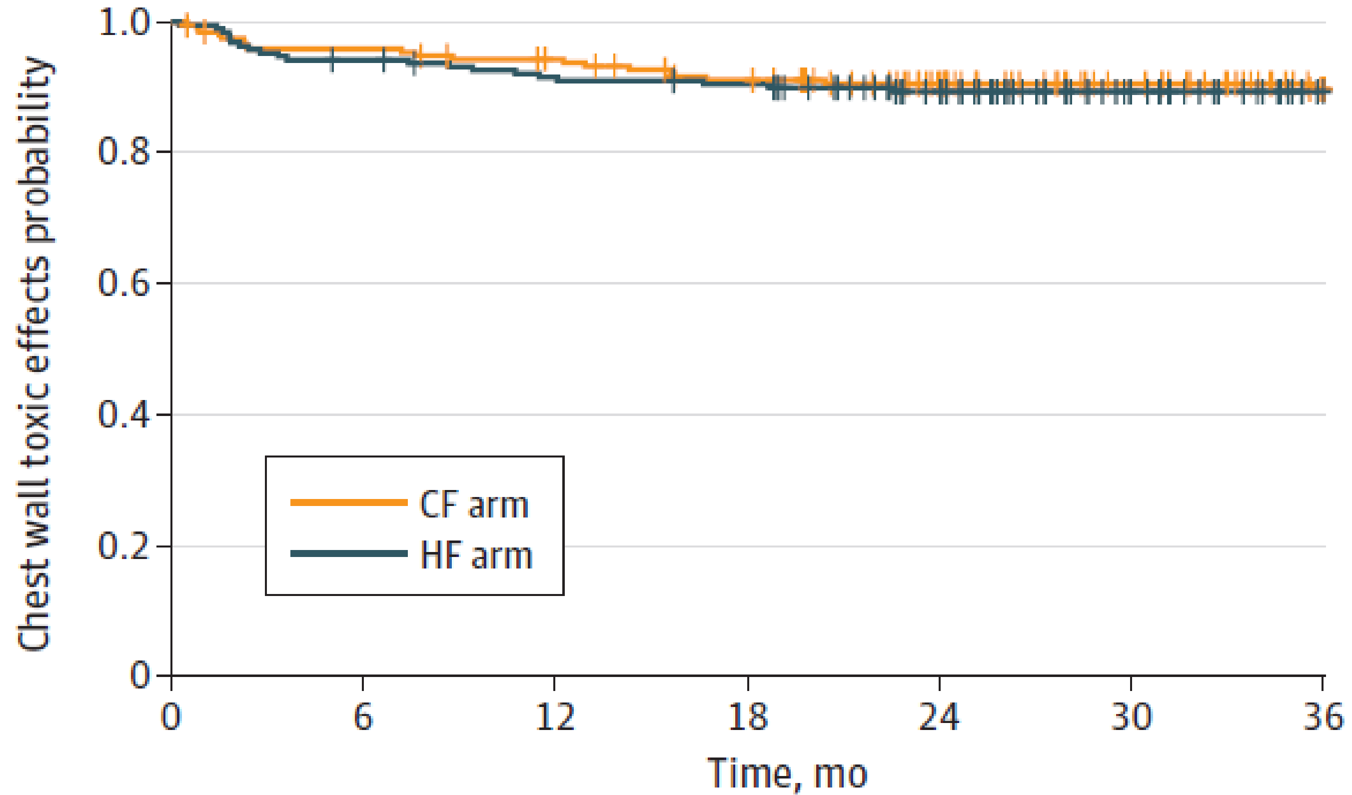
# FABREC Clinical Trial

- 3/2018 – 11/2021   n=400  18 centers
- Eligibility:
  - Stage 0-III treated with PMRT
  - s/p TM w/ Immediate placement of implant or TE
- QOL Instruments: baseline, 6, 12, 18 mo.
  - FACT-B
  - Breast-Q
  - Lymph-ICF
- Primary Endpoint:  Physical well being domain of FACT-B at 6 months with pre-specified stratification by Age < or ≥ 45 years.

Wong et al, JAMA Oncol 2024

- Population:
  - Median age 47 yrs (23-79)
  - Neoadjuvant CT:  67.8%
  - Neoadjuvant ET: 21.5%
  - Median Follow up:  4 years
- Results:
  - No difference in FACT B or CW toxicity HF vs CF
  - ↑ CW toxicity on MVA:
    - Post op infection (pre RT)
    - RT to TE (vs Implant)
    - Preop ET
    - Number of LN's removed
  - Age < 45:  less bother with HF ($p=0.045$)

# FABREC Clinical Trial




Wong et al, JAMA Oncol 2024

# Alliance A221505: RT CHARM

ELIGIBLITY
- Stage IIa-IIIa
- Mastectomy+ SN or AxND
- Breast reconstruction present or planned

R

**Standard PMRT:**
50 Gy / 25 F
2.0 Gy

**Hypo fractionated PMRT:**
42.56 Gy /16F
2.66 Gy

- Opened: 2017
- Targeted Accrual: 898
- Radiation targets:
  - CW/ reconstructed breast
  - Axilla
  - SCL
  - IMC

Primary Endpoint: Reconstruction Complication Rate

Poppe et al, ASTRO 2023

# Questions?

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