Management of Breast Cancer in Older Women Genomics

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Conflicts of interest

- Receipt of grants/research supports
  - None
- Receipt of travel supports
  - Pfizer, Sandoz
- Receipt of honoraria
  - Eli Lilly, Pfizer, Seagen
- Receipt of consultation fees
  - Daiichi, Pfizer, Sandoz

Adjuvant chemo & mortality in 65+ stage I-III BC

Nodal status	ER	*Giordano** No. total 41,390 No. w/ chemo 4,500 HR (95% IC)	*Elkin* No. total 5,081 No. w/ chemo 1,711 HR (95% IC)
pN0	any	1.05 (0.85-1.31)	NA
pN+	+	1.05 (0.85-1.31)	NA
pN0 & pN+	-	NA	**0.85 (0.77-0.95)**
pN+	-	**0.72 (0.54-0.96)**	**0.76 (0.65-0.88)**
pN+ > 70 yo	-	**0.74 (0.56-0.97)**	NA

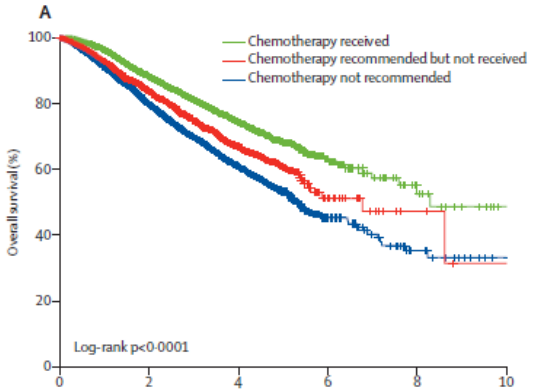
**: BC specific mortality*

Adjuvant chemo is useful FIRST in ER-, pN0 or pN+, even > 70 yo

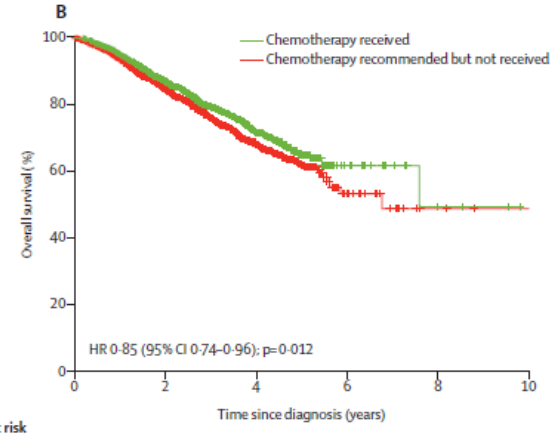
Giordano & Elkin J Clin Oncol 2006

Addition of chemotherapy to local therapy in women aged 70 years or older with triple-negative breast cancer: a propensity-matched analysis

Jennifer A Crozier, Todd A Pezzi*, Caitlin Hodge, Slavica Janeva, Beth-Ann Lesnikoski, Laila Samiian, Amanda Devereaux, William Hammond, Riccardo A Audisio, Christopher M Pezzi*



Number at risk (number censored)						
Chemotherapy received	5833 (1056)	4138 (3361)	1384 (4576)	76 (4629)	15 (4645)	2 (4647)
Chemotherapy recommended, not received	2111 (394)	1398 (1151)	444 (1533)	23 (1552)	3 (1554)	1 (1555)
No chemotherapy	4722 (832)	3006 (2365)	963 (3155)	64 (3192)	18 (3205)	4 (3209)



Number at risk (number censored)						
Chemotherapy received	1884 (357)	1301 (2503)	411 (2868)	20 (2884)	3 (2887)	0 (2887)
Chemotherapy recommended, not received	1884 (352)	1266 (1037)	408 (1389)	22 (1407)	3 (1409)	2 (1410)

Crozier Lancet Oncol 2020

General recommendations for adjuvant chemo & trastuzumab in older BC patients

- **Focus** on ER- and HER2+ (if > 5 mm)
- **Regimen**
  - **Validated** — **4 AC, 6 CMF**
  - Options — 4 TC; paclitaxel qw x 12?; liposomal doxorubicin?
  - No! — capecitabine, docetaxel qw
  - **No data!** — Sequential regimen
- **Primary prophylaxis** of febrile neutropenia w/ G-CSF
- **No restriction on trastuzumab if chemo indicated**
  - **4 TC + trastuzumab**
  - **Paclitaxel qw x 12 + trastuzumab (Tolaney)**
  - *TCH x 6?? (but very unlikely in older patients since carboplatin AUC 6!)*
  - **Trastuzumab alone: can be considered, especially for unfit patients** (+ ET if ER+)
  - **Shorter duration for trastuzumab** (6 months?)

Cheung, Livi, Brain in Geriatric Oncology/Elsevier, Editors Extermann, Fulop, Dale, Klepin & Brain 2019
Brain J Ger Oncol 2019, Biganzoli Lancet Oncol 2021

rapid communicatio

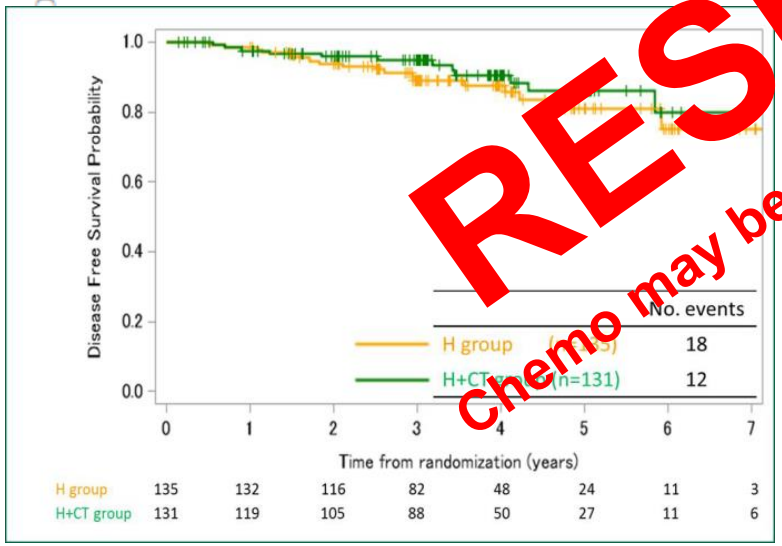
Randomized Controlled Trial of Trastuzumab Wi or Without Chemotherapy for HER2-Positive Early Breast Cancer in Older Patients

Masataka Sawaki, MD, PhD[1]; Naruto Taira, MD, PhD[2]; Yukari Uemura, PhD[3]; Tsuyoshi S to, PhD[4]; nichi Baba, MD[5]; Kokoro Kobayashi, MD[6]; Hiroaki Kawashima, MD, PhD[7]; Michiko Tsuneizumi, MD, ; Noriko eawa D, PhD[9]; Hiroko Bando, MD, PhD[10]; Masato Takahashi, MD, PhD[11]; Miki Yamaguchi, MD, [12]; omu Ta hima, MD, Ph Takahiro Nakayama, MD, PhD[14]; Masahiro Kashiwaba, MD, PhD[5]; Toshiro PhD[15]; taka Yamamoto MD, PhD[16]; Hiroji Iwata, MD, PhD[1]; Takuya Kawahara, PhD[17]; Yasuo Ohashi, PhD[18]; Hiro ni PhD[19], for the RESPECT study group

RESPECT!

Chemo may be not necessary at anytime?

275 patients
2009-2014
Non-inferiority
HR 1.22-1.69 β 20%
Follow-up 4.1 years (0.3-8)



HER2-positive elderly patient
Age: 70-80 years old
Stage : I (pT≥1 cm), IIA, IIB, IIIA / M0
HER2 : IHC 3+ or FISH+

Randomization

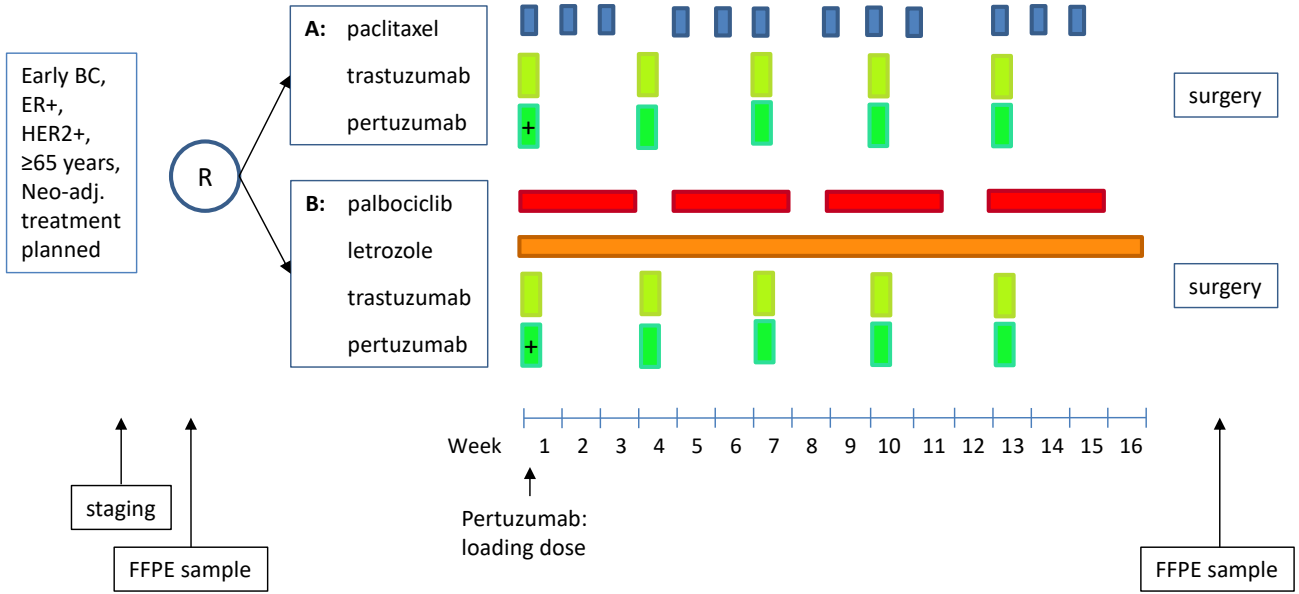
Trastuzumab monotherapy
H-mono 150 patients
Trastuzumab (1 year)

Trastuzumab + Chemotherapy
H+CT 150 patients
Trastuzumab (1 year) + CT
(Investigator's choice from PTX/DTX/AC/EC/CMF)

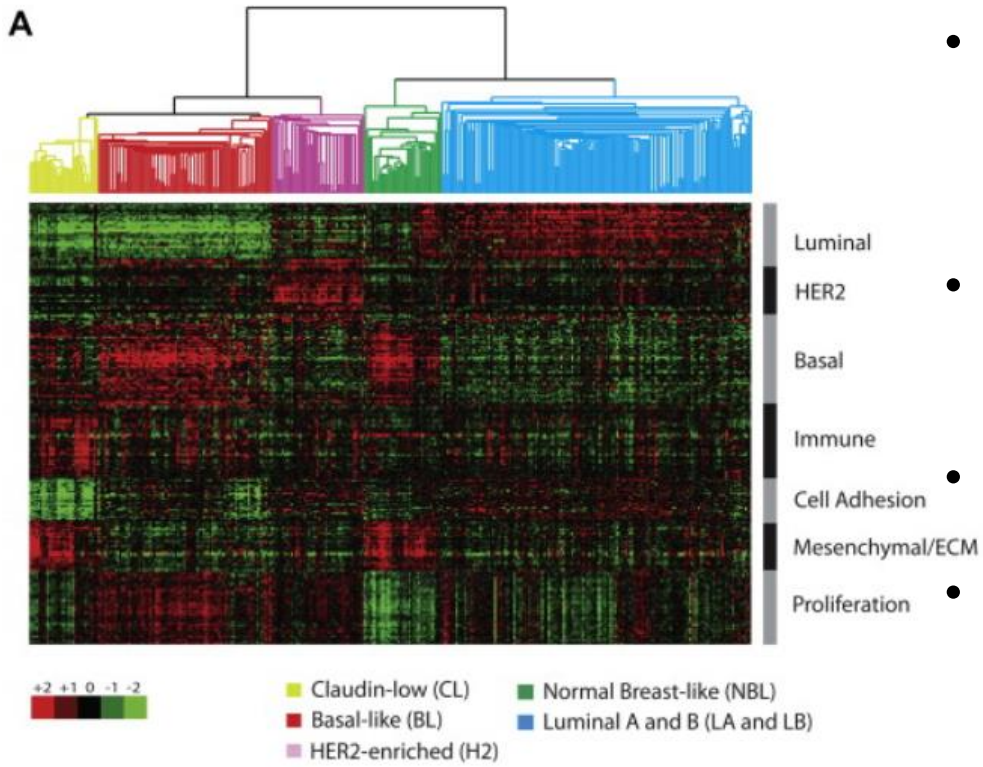
Sawaki JCO 2020

IBCSG 55-17 TOUCH

Phase II open-label, multicenter, randomized trial of neoadjuvant palbociclib in combination with hormonal therapy and HER2 blockade versus paclitaxel in combination with HER2 blockade for elderly patients with hormone receptor positive/HER2 positive early breast cancer



Early 2000s: 1st GEP (intrinsic classification)

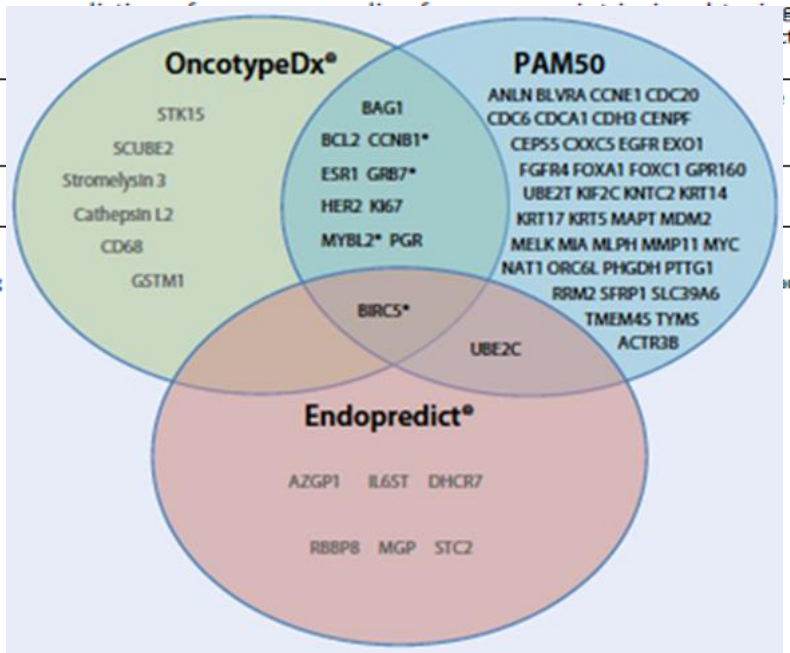


- Quantification of mRNA or cDNA of genes involved in tumour proliferation
- To identify patients requiring chemo despite good standard prognostic factors
- To avoid chemo in others
- Better individual risk stratification

Prat Mol Oncol 2011

	MammaPrint	Oncotype DX	Breast Cancer Index	Mapquant DX	PAM 50 ROR	EndoPredict
Provider	Agendia	Genomic Health	Biotheranostics	Ipsogen	NanoString	Sividon
Type of Assay	70-gene assay	21-gene recurrence score	2-gene ratio (H/I) and molecular grade index	Genomic grade	50-gene assay	12-gene assay
Type of Sample	Fresh or frozen or FFPE	FFPE	FFPE	Fresh or frozen or FFPE	FFPE	FFPE
Technique	DNA microarray or qRT-PCR	qRT-PCR	qRT-PCR	DNA microarray or qRT-PCR	qRT-PCR	qRT-PCR
Clinical Application	Prognosis of N0, < 5 cm, stage I/II, age < 61	Prediction of recurrence risk in ER+ and N0 treated with TAM	Prognostic in ER+,	Molecular	Originally for	Recurrence prediction for ER+ HER2–
Results Presentation	Dichotomous, good or poor prognosis	Continuous variable				Dichotomous, low or high risk
Level of Evidence	II	I				I
FDA Approval	YES	NO				NO

Abbreviations: ER+, estrogen receptor–positive; FDA, U.S. Food and Drug … de Index; qRT-PCR, quantitative reverse transcription polymerase chain reaction; TAM, tamoxifen.



Bartlett JNCI 2016

MINDACT
Microarray In Node-negative and 1 to 3 positive lymph node Disease may Avoid ChemoTherapy
EORTC 10041 / BIG 3-04

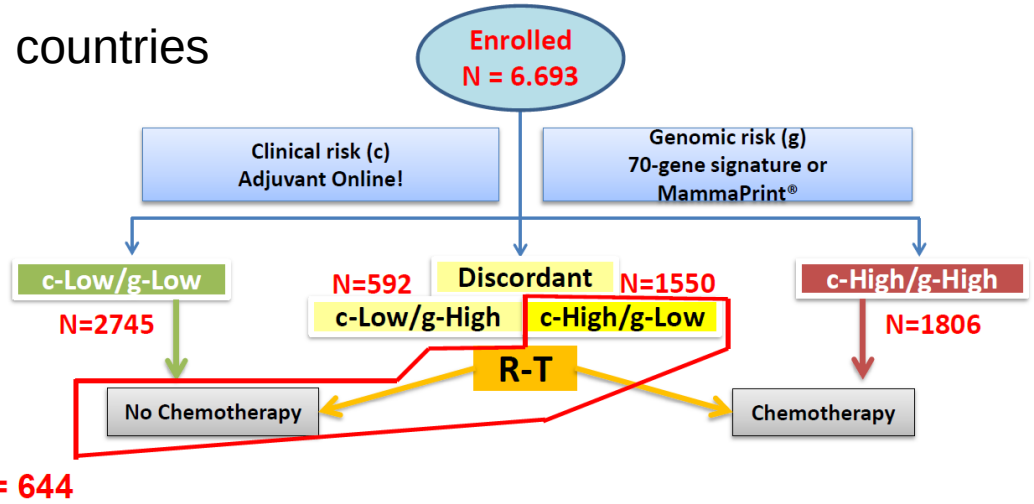
TRANSBIG

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 AUGUST 25, 2016 VOL. 375 NO. 8

70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer

F. Cardoso, L.J. van't Veer, J. Bogaerts, L. Slaets, G. Viale, S. Delaloge, J.-Y. Pierga, E. Brain, S. Causeret, M. DeLorenzi, A.M. Glas, V. Golfinopoulos, T. Goulioti, S. Knox, E. Matos, B. Meulemans, P.A. Neijenhuis, U. Nitz, R. Passalacqua, P. Ravdin, I.T. Rubio, M. Saghatchian, T.J. Smilde, C. Sotiriou, L. Stork, C. Straehle, G. Thomas, A.M. Thompson, J.M. van der Hoeven, P. Vuylsteke, R. Bernards, K. Tryfonidis, E. Rutgers, and M. Piccart, for the MINDACT Investigators*

- 6,600 pts **< 70 yo**
  - 02/2007-08/2011
  - 112 institutions in 9 European countries
  - 11,291 registered patients
  - 6,673 enrolled (59.1%)

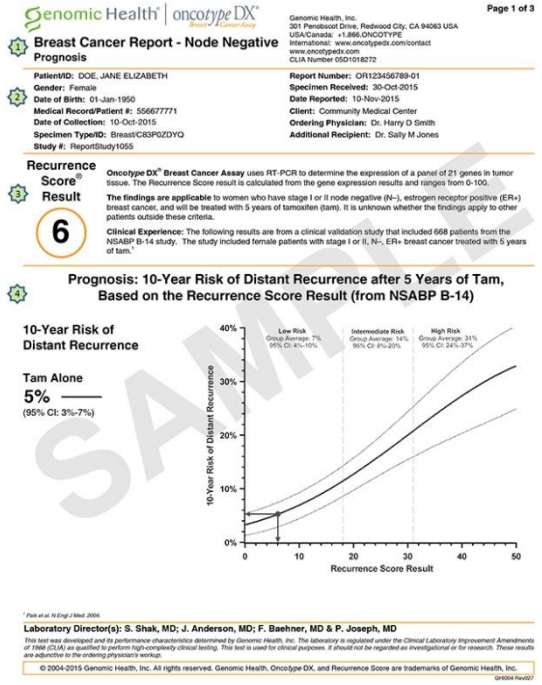


Mammaprint
Risk of distant recurrence
@ 5 years
w/ no treatment

Primary goal
In patients w/ high-risk clinical & low-risk GEP and no chemotherapy, lower boundary of the 95% CI for the rate of 5-yr survival w/o distant M+ ≥ 92% (i.e. the noninferiority boundary) at a 1-sided significance level of 0.025

OncotypeDX

pN0



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www.oncotypedx.com
CLIA Number 05D1018272

Breast Cancer Report - Node Negative
Prognosis

Patient/ID: DOE, JANE ELIZABETH
Gender: Female
Date of Birth: 01-Jan-1950
Medical Record/Patient #: 556677771
Date of Collection: 10-Oct-2015
Specimen Type/ID: Breast/C83P0ZDYQ
Study #: ReportStudy1055

Report Number: OR123456789-01
Specimen Received: 30-Oct-2015
Date Reported: 10-Nov-2015
Client: Community Medical Center
Ordering Physician: Dr. Harry D Smith
Additional Recipient: Dr. Sally M Jones

Recurrence Score® Result

6

***Oncotype DX*® Breast Cancer Assay** uses RT-PCR to determine the expression of a panel of 21 genes in tumor tissue. The Recurrence Score result is calculated from the gene expression results and ranges from 0-100.

The findings are applicable to women who have stage I or II node negative (N–), estrogen receptor positive (ER+) breast cancer, and will be treated with 5 years of tamoxifen (tam). It is unknown whether the findings apply to other patients outside these criteria.

Clinical Experience: The following results are from a clinical validation study that included 668 patients from the NSABP B-14 study. The study included female patients with stage I or II, N–, ER+ breast cancer treated with 5 years of tam.[1]

Prognosis: 10-Year Risk of Distant Recurrence after 5 Years of Tam, Based on the Recurrence Score Result (from NSABP B-14)

10-Year Risk of Distant Recurrence

Tam Alone
5%
(95% CI: 3%-7%)

[1] Park et al. N Engl J Med. 2004.

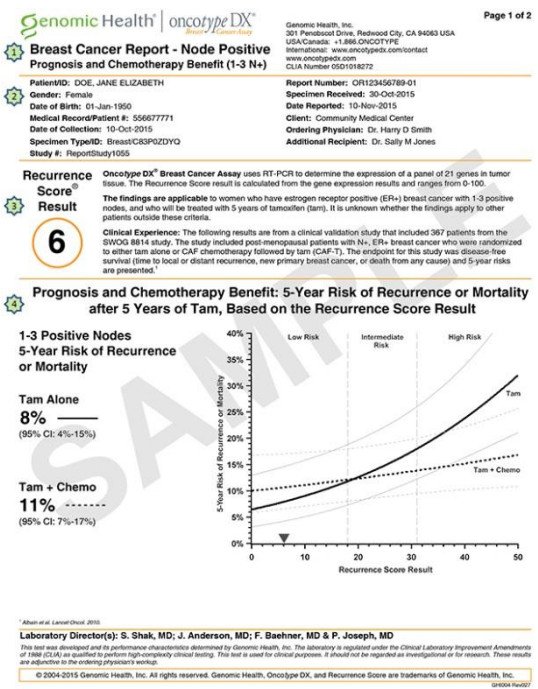
Laboratory Director(s): S. Shak, MD; J. Anderson, MD; F. Baehner, MD & P. Joseph, MD

This test was developed and its performance characteristics determined by Genomic Health, Inc. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. These results are adjunctive to the ordering physician's workup.

GH004 Rev027

Risk of distant recurrence
@ 10 years
w/ TAM 5 years

pN+



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www.oncotypedx.com
CLIA Number 05D1018272

Breast Cancer Report - Node Positive
Prognosis and Chemotherapy Benefit (1-3 N+)

Patient/ID: DOE, JANE ELIZABETH
Gender: Female
Date of Birth: 01-Jan-1950
Medical Record/Patient #: 556677771
Date of Collection: 10-Oct-2015
Specimen Type/ID: Breast/C83P0ZDYQ
Study #: ReportStudy1055

Report Number: OR123456789-01
Specimen Received: 30-Oct-2015
Date Reported: 10-Nov-2015
Client: Community Medical Center
Ordering Physician: Dr. Harry D Smith
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Recurrence Score® Result

6

***Oncotype DX*® Breast Cancer Assay** uses RT-PCR to determine the expression of a panel of 21 genes in tumor tissue. The Recurrence Score result is calculated from the gene expression results and ranges from 0-100.

The findings are applicable to women who have estrogen receptor positive (ER+) breast cancer with 1-3 positive nodes, and who will be treated with 5 years of tamoxifen (tam). It is unknown whether the findings apply to other patients outside these criteria.

Clinical Experience: The following results are from a clinical validation study that included 367 patients from the SWOG 8814 study. The study included post-menopausal patients with N+, ER+ breast cancer who were randomized to either tam alone or CAF chemotherapy followed by tam (CAF-T). The endpoint for this study was disease-free survival (time to local or distant recurrence, new primary breast cancer, or death from any cause) and 5-year risks are presented.[1]

Prognosis and Chemotherapy Benefit: 5-Year Risk of Recurrence or Mortality after 5 Years of Tam, Based on the Recurrence Score Result

1-3 Positive Nodes
5-Year Risk of Recurrence or Mortality

Tam Alone
8%
(95% CI: 4%-15%)

Tam + Chemo
11%
(95% CI: 7%-17%)

[1] Albain et al. Lancet Oncol. 2010.

Laboratory Director(s): S. Shak, MD; J. Anderson, MD; F. Baehner, MD & P. Joseph, MD

This test was developed and its performance characteristics determined by Genomic Health, Inc. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. These results are adjunctive to the ordering physician's workup.

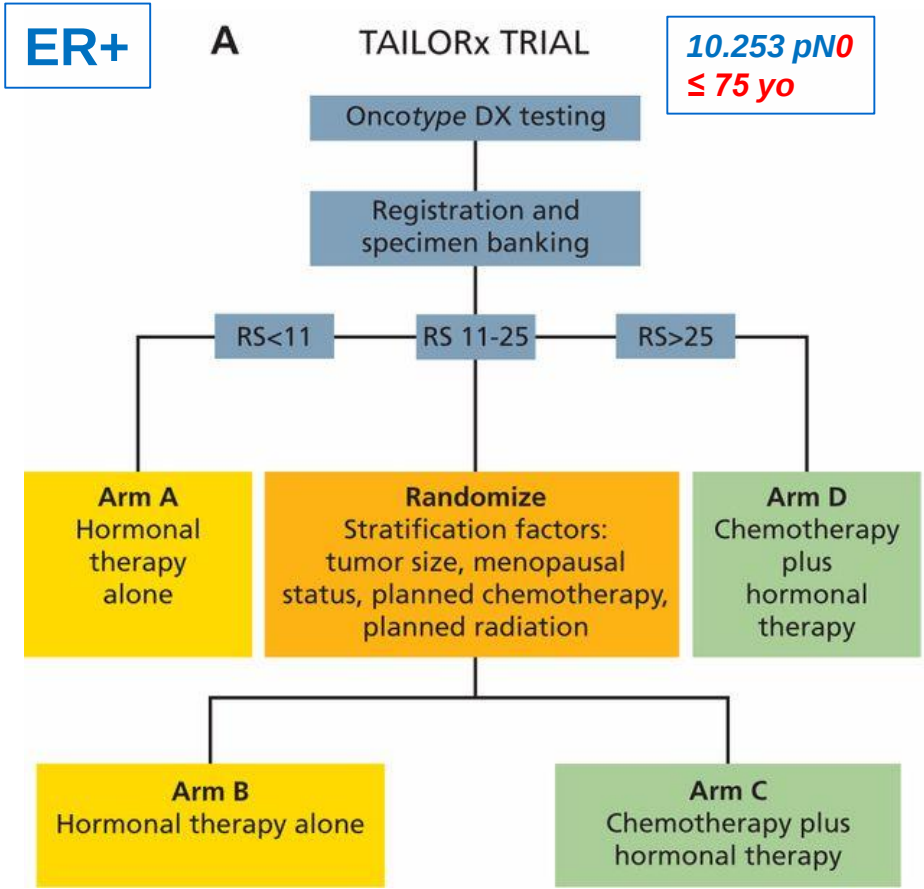
GH004 Rev027

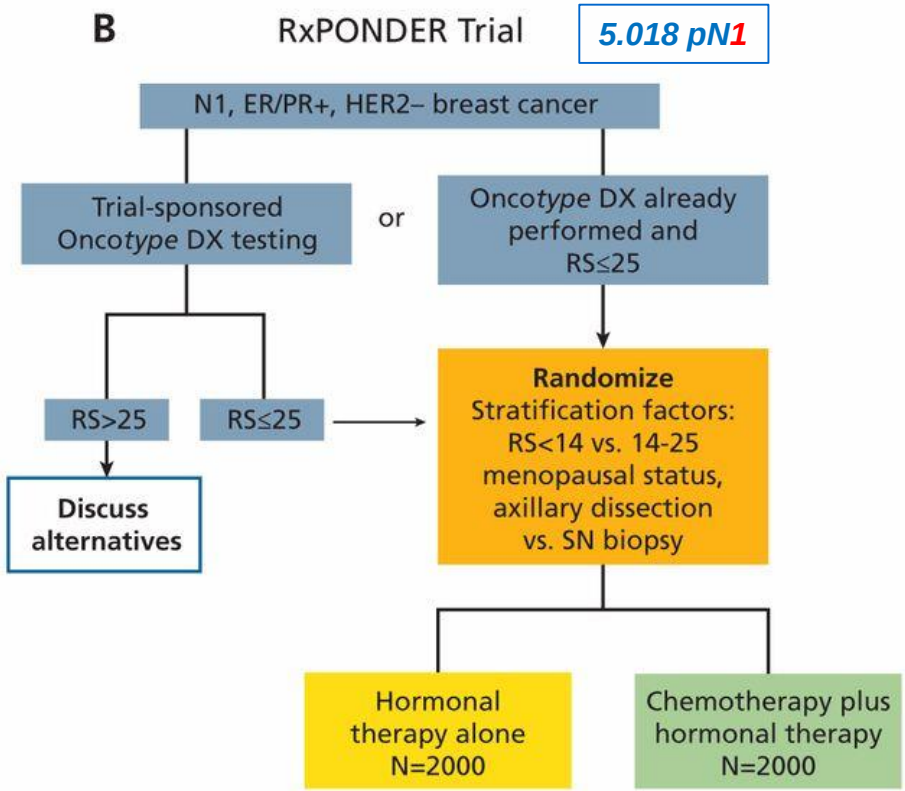
Risk of distant recurrence
@ 5 years
w/ TAM 5 years

Individual results

0-17 v 18-30 v ≥ 31
0-10 v 11-25 v ≥ 26

ER+



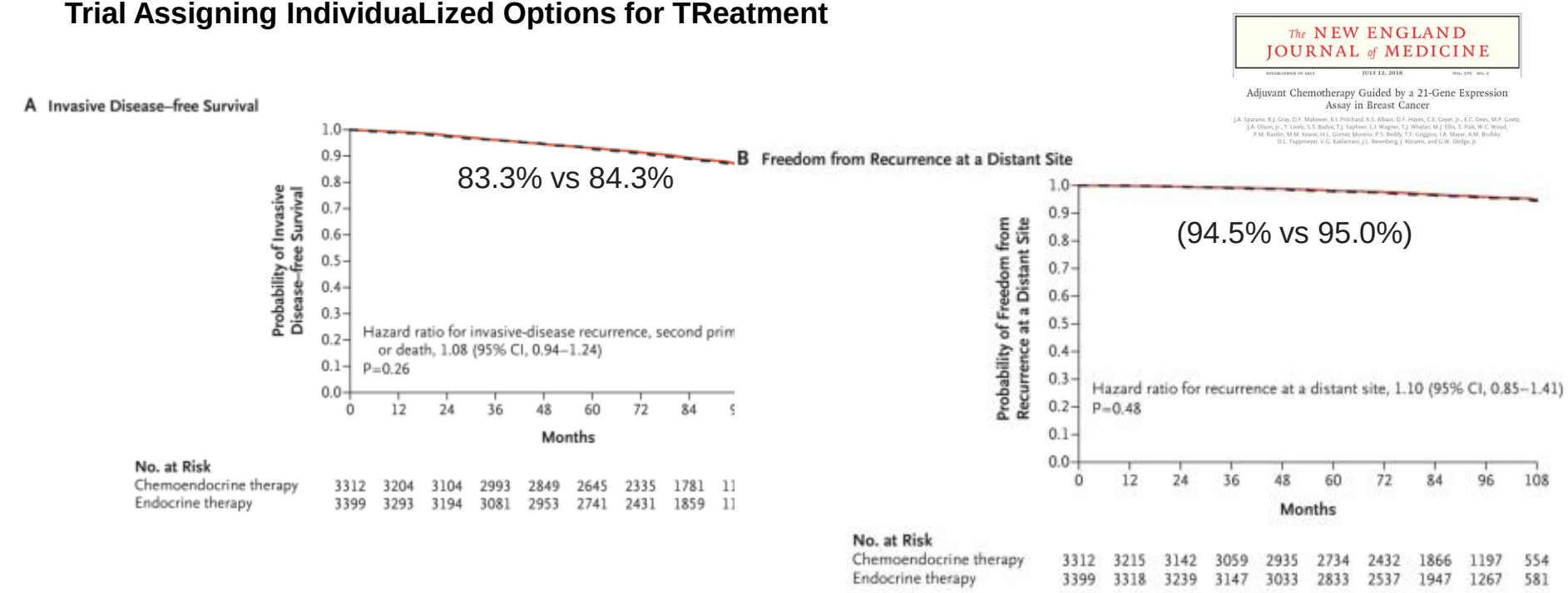


70-75 yo RS 0-10 111/1.626 (7%)
RS 11-25 300/6.897 (4%)

70-75 yo RS ≤ 25 581/5018 (12%)

TAILORx @ 9 years (ET vs chemo-ET) if RS 11-25

Trial Assigning IndividuaLized Options for TReatment



Similar distant/locoregional site (92.2% & 92.9%) and OS (93.9% & 93.8%)
Chemotherapy benefit for iDFS varied w/ RS & age (P=0.004)
Some chemo benefit in women ≤ 50 yo and RS 16-25

Sparano NEJM 2018

RxPONDER

A Clinical Trial Rx for Positive Node, Endocrine Responsive Breast Cancer

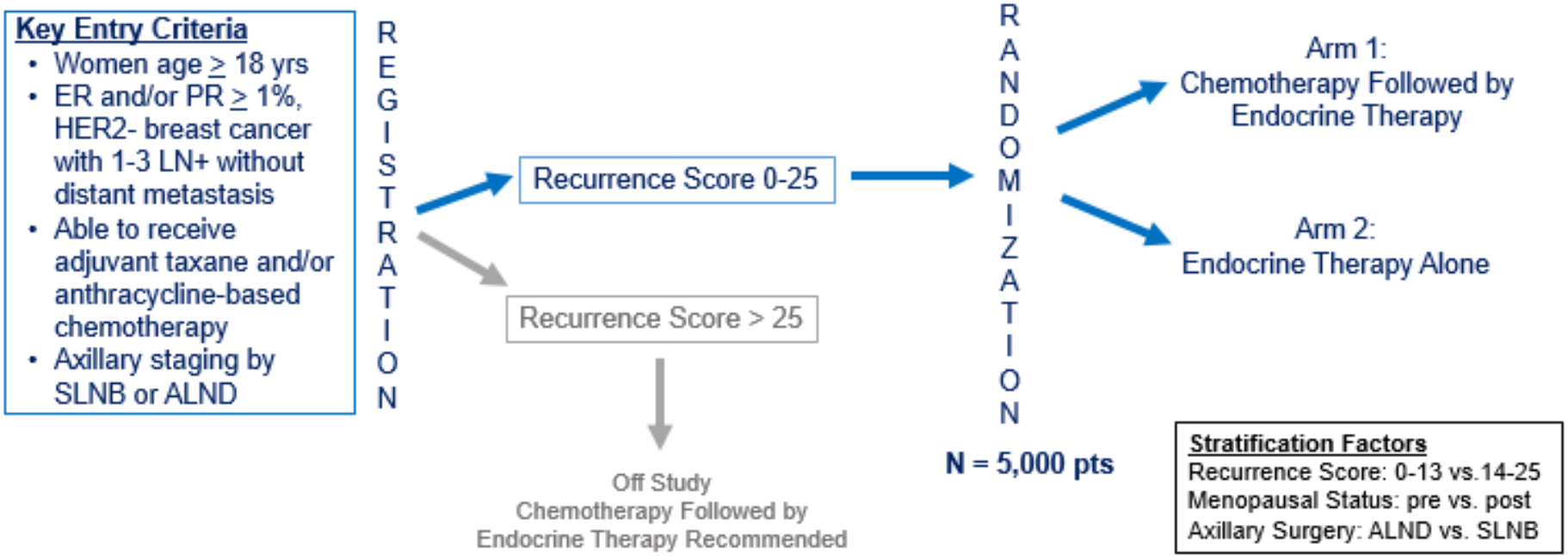
ORIGINAL ARTICLE

21-Gene Assay to Inform Chemotherapy Benefit in Node-Positive Breast Cancer

Kevin Kalinsky, M.D., William E. Barlow, Ph.D., Julie R. Gralow, M.D., Funda Meric-Bernstam, M.D., Kathy S. Albain, M.D., Daniel F. Hayes, M.D., Nancy U. Lin, M.D., Edith A. Perez, M.D., Lori J. Goldstein, M.D., Stephen K.L. Chia, M.D., Sukhbinder Dhesy-Thind, M.D., Priya Rastogi, M.D., Emilio Alba, M.D., Ph.D., Suzette Delaloge, M.D., Miguel Martin, M.D., Catherine M. Kelly, M.B., Manuel Ruiz-Borrego, M.D., Miguel Gil-Gil, M.D., Claudia H. Arce-Salinas, M.D., Etienne G.C. Brain, M.D., Ph.D., Eun-Sook Lee, M.D., Jean-Yves Pierga, M.D., Ph.D., Begoña Bermejo, M.D., Manuel Ramos-Vazquez, M.D., Ph.D., Kyung-Hae Jung, M.D., Ph.D., Jean-Marc Ferrero, M.D., Anne F. Schott, M.D., Steven Shak, M.D., Priyanka Sharma, M.D., Danika L. Lew, M.A., Jieling Miao, M.S., Debasish Tripathy, M.D., Lajos Pusztai, M.D., Ph.D., and Gabriel N. Hortobagyi, M.D.

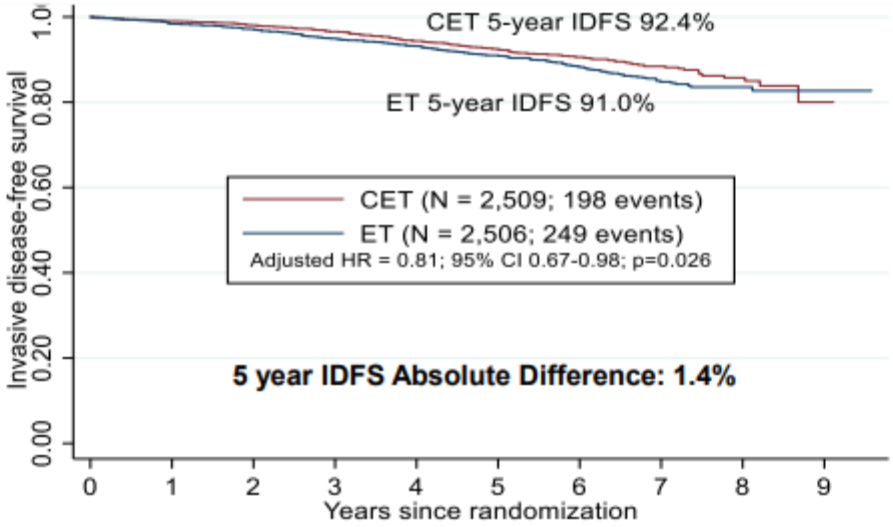
NEJM 2021 + SABCS 2021

RxPONDER Schema



ALND = Axillary Lymph Node Dissection, SLNB = Sentinel Lymph Node Biopsy

IDFS in Overall Population by Treatment Arm



Number at risk

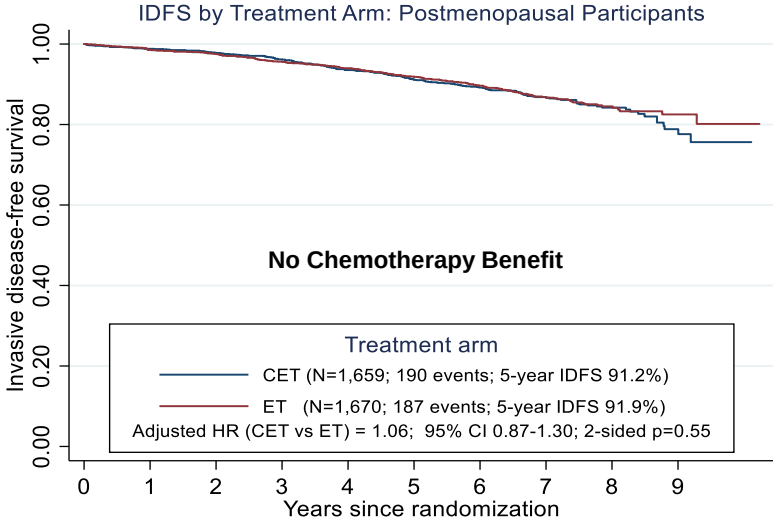
CET	2509	2277	2104	1893	1648	1397	857	403	122	4
ET	2506	2327	2161	1910	1696	1404	846	397	135	11

CET = Chemotherapy + Endocrine Therapy; ET = Endocrine Therapy Alone

447 observed IDFS events (54% of expected at final analysis) at a median follow-up of 5.1 years

Updated Analysis: Postmenopausal Women Have No Chemotherapy Benefit

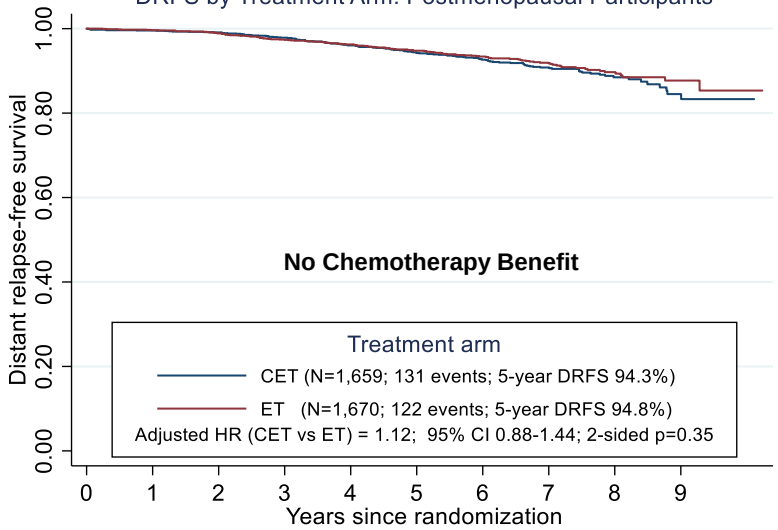
Invasive Disease-Free Survival



Number at risk

CET	1659	1557	1498	1427	1258	1118	848	540	243	64
ET	1670	1599	1550	1465	1314	1164	879	547	247	67

Distant Relapse-Free Survival

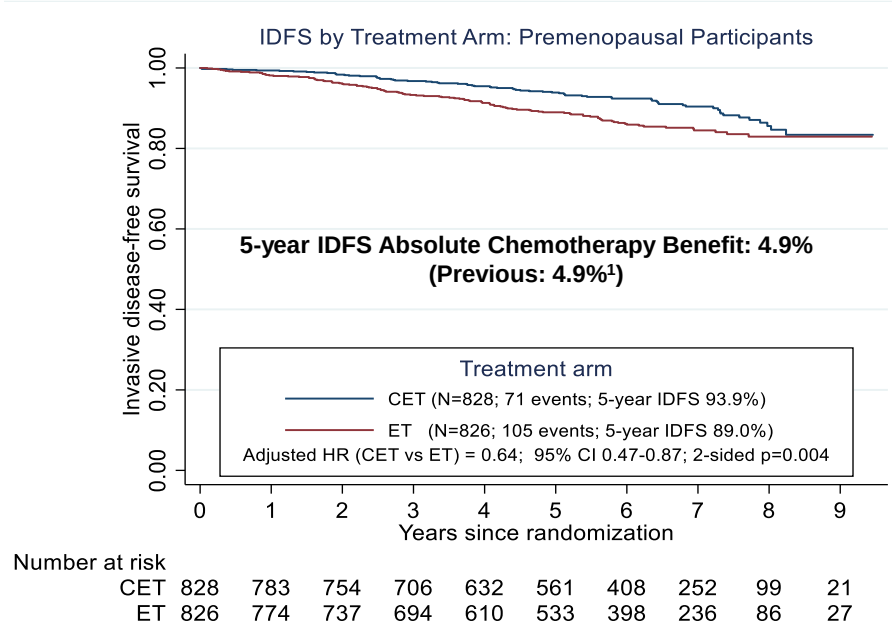


Number at risk

CET	1659	1567	1514	1448	1291	1152	884	571	261	71
ET	1670	1614	1569	1491	1345	1201	916	582	264	71

Updated Analysis: Premenopausal Women Have Chemotherapy Benefit

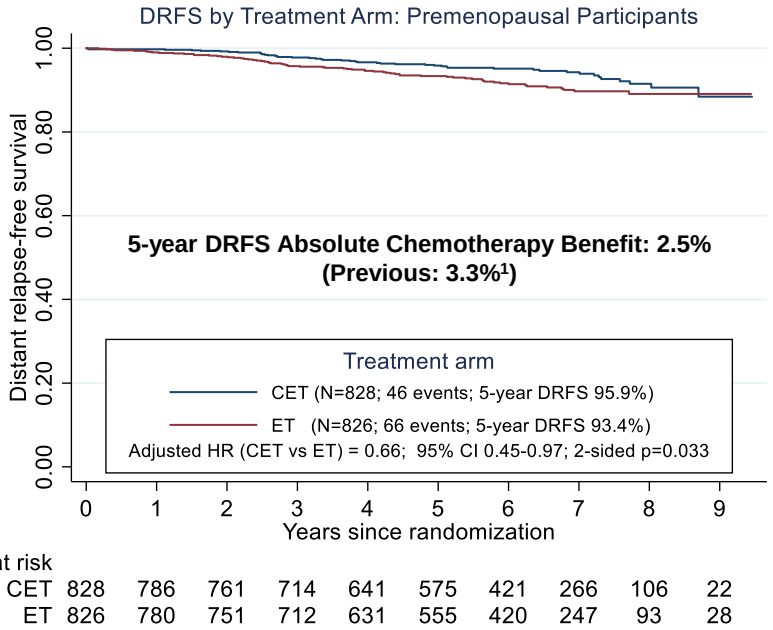
Invasive Disease-Free Survival



Number at risk

CET	828	783	754	706	632	561	408	252	99	21
ET	826	774	737	694	610	533	398	236	86	27

Distant Relapse-Free Survival



Number at risk

CET	828	786	761	714	641	575	421	266	106	22
ET	826	780	751	712	631	555	420	247	93	28

[1] Kalinsky et al, New England Journal of Medicine: December 1, 2021

Shortfall

- Chemotherapy benefit if RS > 25?
  - TAILORx 73/1.389 (5%) patients 70-75 yo
    - 10 declined chemo
  - RxPONDER ?

High recurrence score > 70 yo

- Higher likelihood of death

  (HR 1.47, 95% CI 1.15-1.90)

- Chemo → lower risk of death in younger
  but not in older group

JOURNAL OF GERIATRIC ONCOLOGY
The official journal of the International Society of Geriatric Oncology
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21-gene recurrence score testing in the older population with estrogen receptor-positive breast cancer

Scott Kizy, Ariella M. Altman, Schelomo Marmor, Jason W. Denbo, Eric H. Jensen, Todd M. Tuttle, Jane Yuet Ching Hui*
Department of Surgery, University of Minnesota, United States

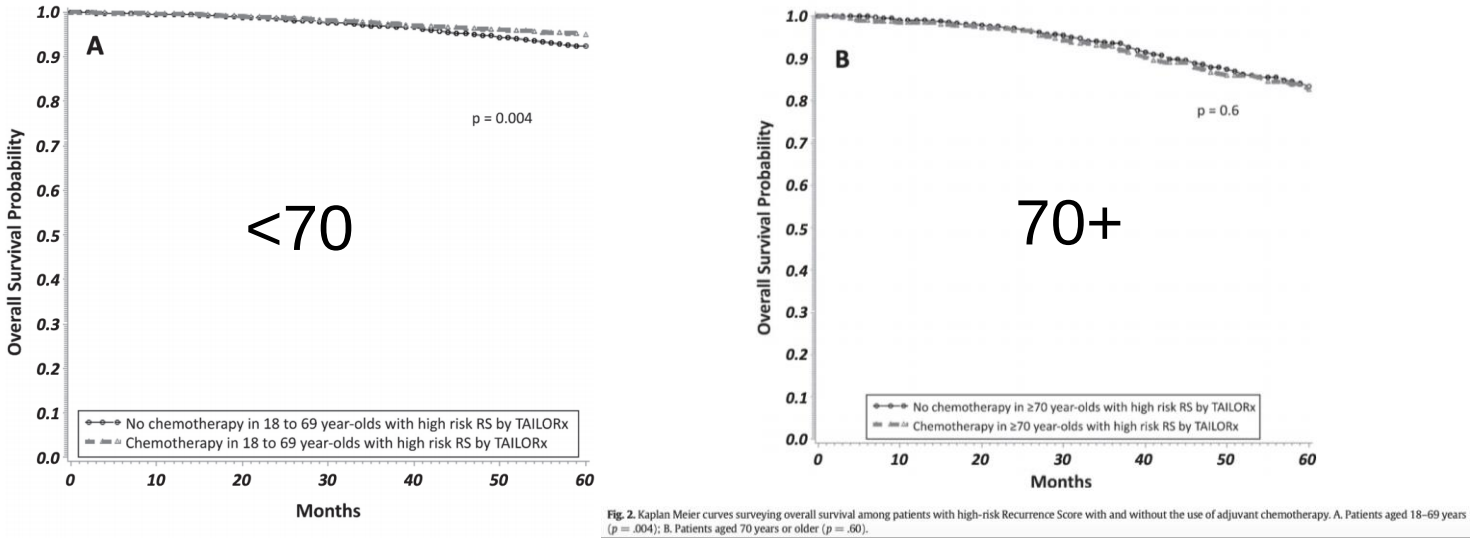

Fig. 2. Kaplan Meier curves surveying overall survival among patients with high-risk Recurrence Score with and without the use of adjuvant chemotherapy. A. Patients aged 18–69 years ($p = .004$); B. Patients aged 70 years or older ($p = .60$).

Kizy JGO 2019

Hazard ratios for risk of breast cancer specific death among patients ≥65 with estrogen-receptor positive breast cancer who had high-risk recurrence score (RS > 25) diagnosed in 2004–2015, SEER registries.

	HR	CI	
Progesterone Receptor			
Positive	REF		
Negative	**1.42**	**1.35**	**1.50**
Grade			
I & II	REF		
III	**1.85**	**1.76**	**1.94**
Chemotherapy			
No/Unknown	REF		
Yes	**0.63**	**0.60**	**0.67**
Lymph Node Status			
N0	REF		
N1 (1–3 positive nodes)	**1.56**	**1.46**	**1.68**
N2 (4–9 positive nodes)	**2.32**	**1.95**	**2.76**
N3 (≥10 positive nodes)	**3.82**	**3.22**	**4.53**
Tumor Size			
T1 (≤2 cm)	REF		
T2 (2- ≤ 5 cm)	**2.08**	**1.92**	**2.25**
T3 (>5 cm)	**3.04**	**2.72**	**3.40**
Race			
White	REF		
Black	**1.30**	**1.20**	**1.40**
Asian/Pacific Islander	**0.72**	**0.64**	**0.81**
Hispanic	0.96	0.88	1.05
AI/AN	**1.59**	**1.15**	**2.21**

HR: Hazards ratio; CI: confidence interval.
bold text designates statistical significance.

Journal of Geriatric Oncology 12 (2021) 206–211

Contents lists available at ScienceDirect

Journal of Geriatric Oncology

ELSEVIER

21-gene recurrence score testing utilization among older women from different races: A population-based study

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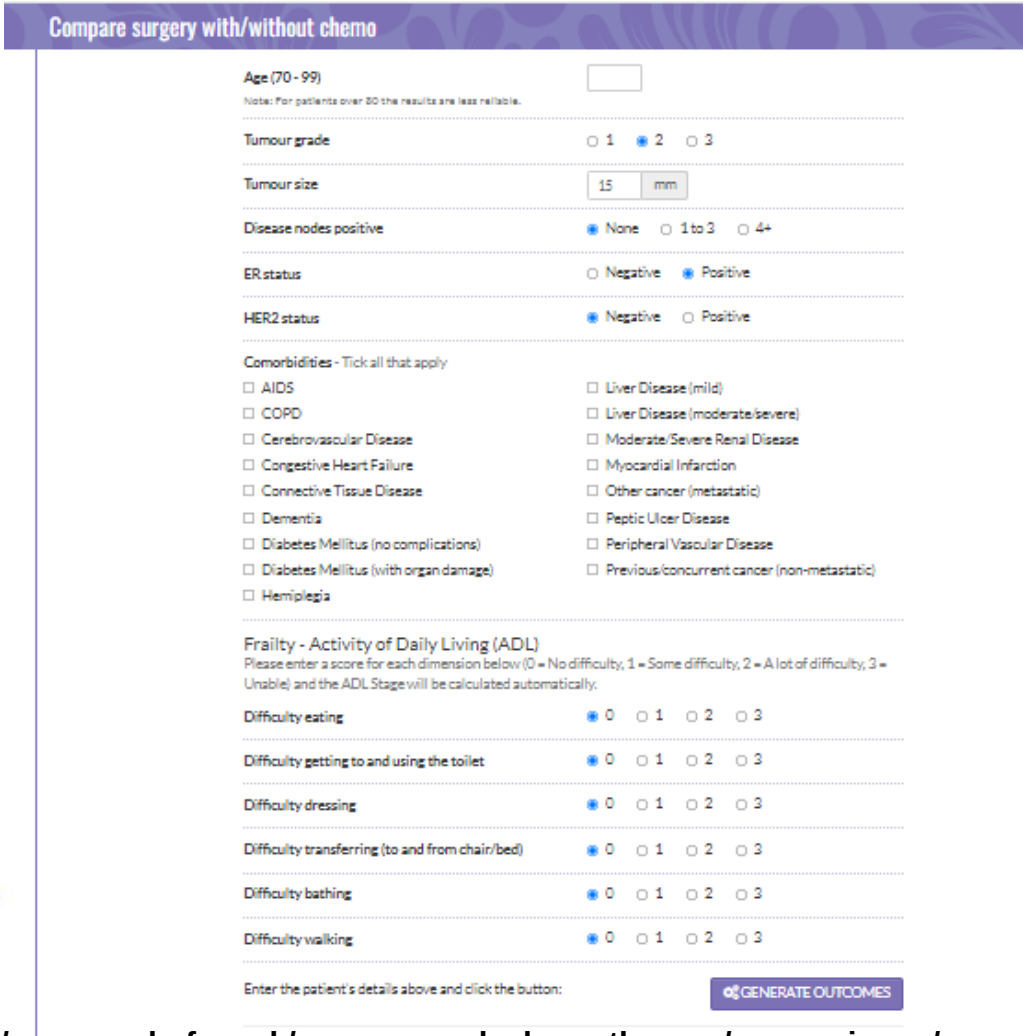
SEER 2004-2015
235.171 women 65+
33.584 w/ RS (14.3%)
BCSM

Gulbahce JGO 2021

Age gap tool
&
chemo

Tumour & age
+ Comorbidities
+ ADL



https://agegap.shef.ac.uk/surgery_and_chemotherapy/comparisons/new

The University Of Sheffield. | Cardiff University / Prifysgol Caerdydd | Sheffield Hallam University | FUNDED BY NIHR | National Institute for Health Research

CARG-BC

- 473 pts evaluable/501
  - ✓ 283 development
  - ✓ 190 validation
- Median age 70 (65-85)
- Stage I/II/III: 39%/41%/20%
- Phenotype
  - ✓ 24% TNBC
  - ✓ 48% ER+
  - ✓ 10% HER2+ER+
  - ✓ 17% HER2+ER-
- 46% grade 3-5 AEs
  - ✓ Haem 25%/non-haem 36%

Risk predictor	Response	Score
BC stage	II-III	3
	I	0
Anthracyclines	YES	1
	NO	0
Treatment duration	> 3 months	4
	≤ 3 months	0
Hemoglobin	≤ 12/13 g/dL (F/M)	3
	> 12/13 g/dL (F/M)	0
Liver function	Abnormal	3
	Normal	0
Falls in last 6 months	≥ 1	4
	0	0
Limitations in walking > 1 mile	Somewhat	3
	Not	0
Someone available to give good advice about a crisis?	None of the time	3
	Most of the time	0

Magnuson J Clin Oncol 2021

PORTRET: 5-year recurrence, overall mortality, and other-cause mortality

- **PREDICT**
  1. Age
  2. pT
  3. Tumour grade
  4. Nodal status
  5. Hormone-receptor status
  6. HER2 status
  7. Ki67 (≥10%)
  8. Mode of detection (symptomatic or screen-detected)

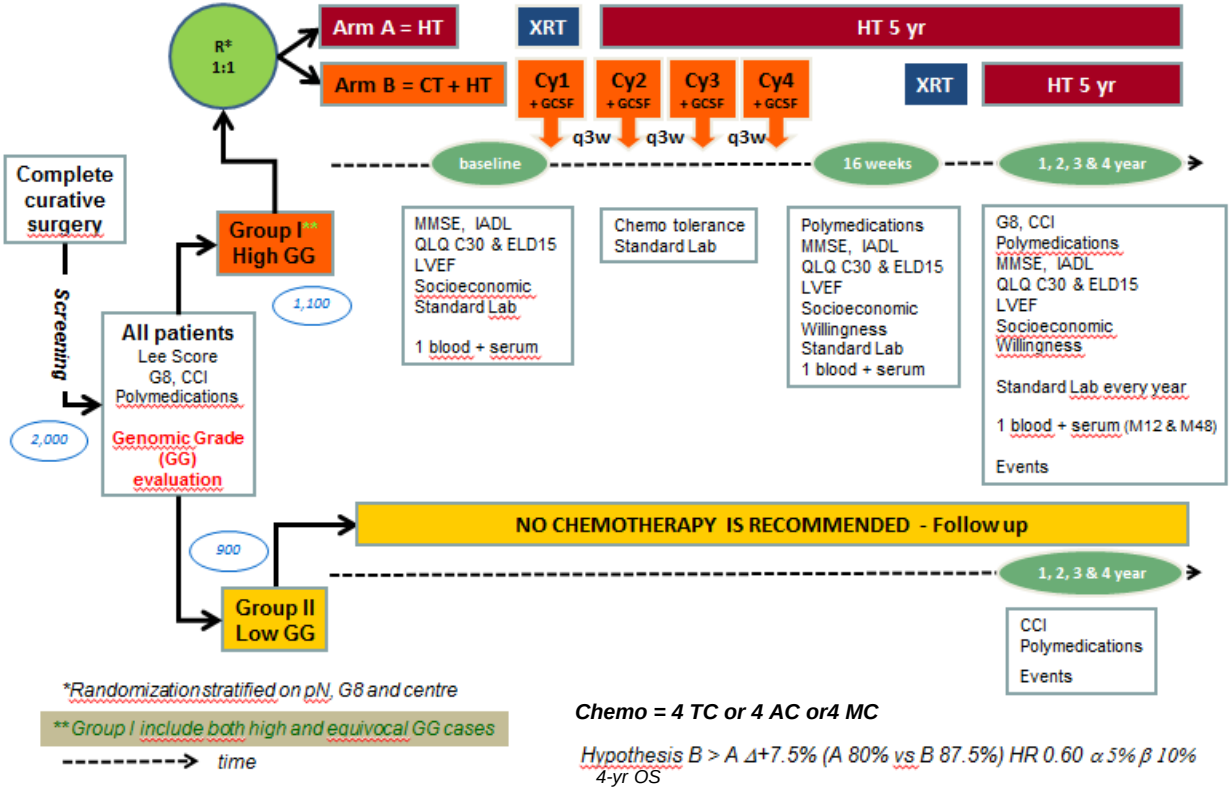
+

  9. Absolute number of comorbidities (ICD-10)
  10. Walking difficulties
  11. Dementia or cognitive impairment
  12. Polypharmacy (≥ 5 types of drugs/day)
  13. Sensory deficits (hearing aid, poor vision)

van der Plas-Krijgsman Lancet Healthy Longev 2021

ASTER 70s (EUDRACT N° 2011-004744-22, PHRC national 2011, NCT01564056)

Adjuvant chemotherapy for ER+ HER2- BC in 70+ patients

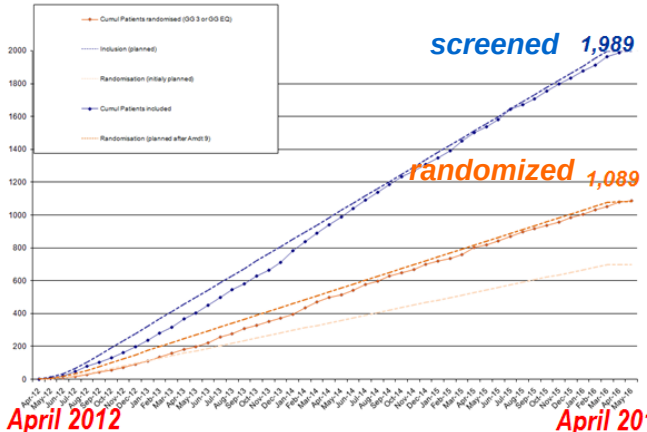


CGA

Microarray qRT-PCR

UNICANCER

GERICO



Chemo = 4 TC or 4 AC or4 MC

Hypothesis B > A Δ+7.5% (A 80% vs B 87.5%) HR 0.60 α 5% β 10%
4-yr OS

April 2012

April 2016

Key points	ASTER 70s
Specific for the older population	70+ women with early-stage breast cancer
Frequent/common and meaningful question	Adjuvant chemotherapy for luminal cases
Non-restrictive inclusion criteria	40% G8 ≤14, 18% prior cancer, 11% isolated local relapse
De-escalation/optimization primary question	Chemotherapy de-escalation
Other research questions	HRQoL, acceptability
Methodology	Observational arm for ineligible patients as internal control control, 1 PISIC, OS
Education of both patients & physicians	Changes in institutions (MDT, guidelines)
Collaboration w/ geriatrician	GO consultations
Time	GO and research nurses
Translational research (biobank)	Genomic grade as signature + TR program

~ 2000 patients enrolled in 4 years

Differences do exist across countries

- **Incidence**
- **Life expectancy** (definition of old)
- **Over- versus under-treatment** (cultural factors)
- **Screening tool** (BMI and G8)

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But actually constantly!

- **Poorly evidence-based** (refrain)
- **More targeted therapy** (key and lock)
- **Adjustment is needed** (leitmotiv)
- **De escalation** (research question)


Reuters

SIOG 2022

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ANNUAL CONFERENCE

GENEVA SWITZERLAND

28-30 OCT

Martine Extermann

CO-CHAIR, SIOG 2022 SCIENTIFIC PROGRAMME COMMITTEE

Vérène Dougoud

CO-CHAIR, SIOG 2022 SCIENTIFIC PROGRAMME COMMITTEE

Optimising treatment in older cancer patients is precision medicine too!

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