CIBC 2019

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The Westin Chicago River North
November 1-3, 2019

LOYOLA MEDICINE
Radiation Oncology

Is Less Becoming More in Radiation Therapy?

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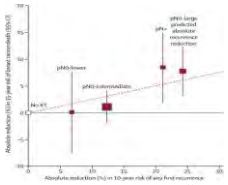
Disclosures

- **Zeiss Speaker's Bureau**
- **Merck Advisory Board**
- **Varian Advisory Board**

SOME BREAST CANCER PATIENTS MAY NOT NEED RADIOTHERAPY

Background

- Multiple randomized trials have demonstrated that RT after breast conserving surgery (BCS) substantially improves the local control of invasive breast cancer
- The EBCTCG has shown that the reduction in recurrence afforded by RT also provides a modest survival benefit
- Not all subgroups attain the same absolute benefit from RT, and survival benefit appears restricted to those with a larger absolute reduction in recurrence risk from RT of >10-20%



Background

- Given the burden, morbidity, and cost of RT, several studies have been undertaken to identify a sufficiently low-risk population of patients in whom omission of RT after BCS may be safely considered
- Prospective historical studies seeking to identify subgroup of low risk patients based upon clinicopathologic characteristics alone have been unsuccessful:
  - **Harvard prospective study:** T1N0 invasive cancers with wide excision only showed **7-yr LRR of 23%**
  - **Finnish trial:** T1N0 patients with segemental resection only showed **12-year LRR of 27%**

NSABP B-21:
T1 (≤ 1 cm) N0, BCS +ALND; RT vs. Tam vs. RT+Tam
8 Year In-Breast Tumor Recurrence

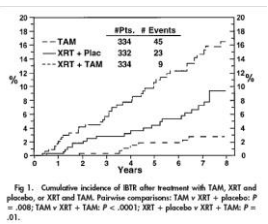
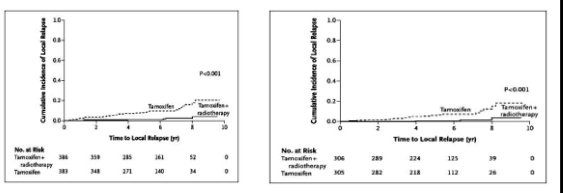


Fig 1. Cumulative incidence of IBTR after treatment with TAM, XRT and placebo, or XRT and TAM. Pairwise comparisons: TAM v XRT + placebo: $P = .008$; TAM v XRT + TAM: $P < .0001$; XRT + placebo v XRT + TAM: $P = .01$.

Fisher, JCO 2002

British Columbia Randomized Trial:
T1-2N0, BCS + Tamoxifen +/- RT
Age ≥ 50 years

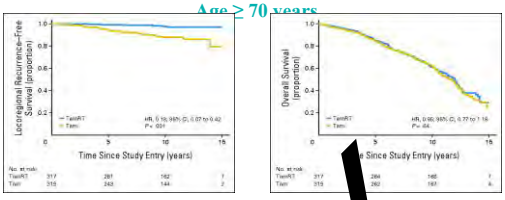


8 Yr Overall LF: 12.2% vs. 4.1%

Favorable T1 ER positive
8 Yr LF 9.9% vs. 4.4% at 8 years

Fyles, IJROBP 2006

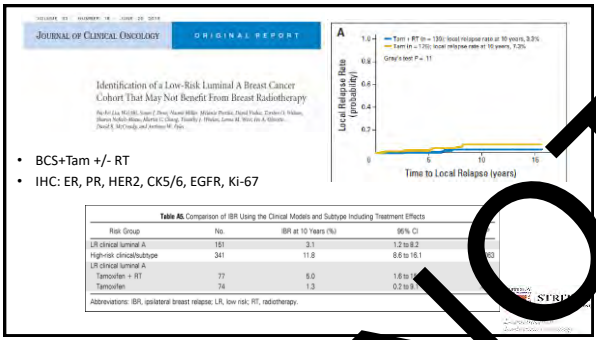
CALGB 9343:
T1N0, BCS + Tamoxifen +/- RT
Age ≥ 70 years



Time to Local Regional Recurrence

Overall Survival

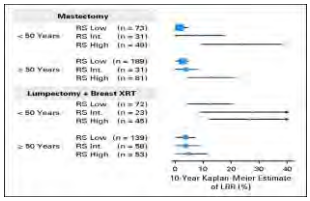
Hughes K S et al. JCO 2013;31:2382-2387



- BCS+Tam +/- RT
- IHC: ER, PR, HER2, CK5/6, EGFR, Ki-67

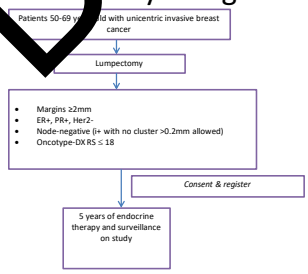
21-gene assay and Local-regional Failure

- LRR significantly associated with RS risk groups in tamoxifen-treated patients
- Genomic profiling may discriminate better in unirradiated patients (mastectomy patients) than L+XRT
- In pts tested with Oncotype-DX RS performed for systemic rx decision-making, useful to understand whether it can also be used to individualize RT decisions



Mamounas E P et al. JCO 2010;28:1677-1683

IDEA Study Design



IDEA Study Design

- Collaborative study
  - Lead site University of Michigan (PI: Reshma Jagsi)
  - 12 collaborating sites:
    - MSKCC, Hopkins, Harvard/MGH/BIDMC, Penn, Stanford, Yale, Loyola, MCW, ECU, UTSW, CINJ/Rutgers, Northwell
  - 200 patients enrolled over 3.3 years

Interim Analysis Plan

- After 400 person-years of follow-up, planned analysis to confirm, using a Bayesian statistical design, that accumulating data do not suggest with high confidence that the 5-year LRR is 6% or greater
- Conducted in February 2019

Patient Characteristics

- Mean age 62 years
- Mean tumor size 9.9 mm (Range 0.8 – 20 mm)
- Mean Oncotype-DX RS = 11
- MRI obtained in 33%

- Estrogen receptor+ 100%
  Progesterone receptor+ 100%
- Her2 negative 100%
- pN0 100%
- Histology Ductal 87.5%
  Lobular 12.5%
- Grade 1 42.5%
  Grade 2 54.5%
  Grade 3 3%
- No LVI 85.5%

Results

- 200 eligible patients enrolled between 06/15 and 10/18
- At 400 person-years of follow-up planned interim analysis:
  - Median f/u = 1.9 years (Mean =2 years; Range 0.5 to 3.8 years)
  - No disease recurrences (at any site) or patient deaths had been observed
- 11 patients (5.5%) discontinued endocrine therapy prior to the 5 years of therapy planned

Implications

- In this first report of a U.S. multicenter study using a genomic assay to select biologically low-risk patients for omission of RT after BCS, no concerning findings have emerged at first planned interim analysis
- Accrual occurred as targeted, strongly suggesting patient and provider interest in this approach
- Locoregional failures not yet observed
- Vast majority of patients continued prescribed endocrine therapy
- Long-term follow-up of this cohort and continued accrual to similar trials is important

Ongoing trials investigating omission of RT after lumpectomy for invasive breast cancer

- Prospective Cohort Studies:
  - LUMINA (OCOG): Age > 55, T1N0, ER>1% PR>20% Her2-, > 1mm margin
  - PRECISION (DFCI): Age 50-75, T1N0, ER>10% PR+ Her2-, no tumor on ink, PAM50 low
  - UK PRIMETIME: 2400 pts, Stage IA aged 60+, very low risk IHC4+C score
- RCTs:
  - ANZ 1601 (EXPERT): 1170 pts w luminal A disease (PAM50 ≤60) to be randomized
  - NRG DEBRA Trial (in development)

Future Directions

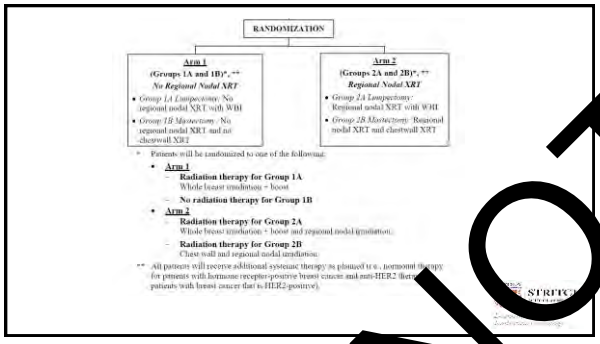
- Many patients treated with RT for early stage breast cancer do not benefit yet still experience treatment related costs and toxicity
- Understanding tumor biology may finally allow us to define which women can safely be spared the morbidity and burden of any RT
- Biologically favorable breast cancer is a common presentation, and the Radiation Oncology community is taking important steps towards transforming how we approach these patients with these trials
- Our ultimate goal is to determine which women benefit from radiation treatment and what that treatment should be

Can Response to Neoadjuvant Therapy Predict a Low Risk of Recurrence and the Ability to Avoid RT?

NSABP PROTOCOL B-51/RTOG PROTOCOL 1304
ClinicalTrials.gov NCT#01872975
A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy

Primary Objective:
To evaluate whether the addition of chestwall + regional nodal XRT after mastectomy or breast + regional nodal XRT after breast conserving surgery will significantly reduce the rate of events for invasive breast cancer recurrence-free interval (IBC-RFI) in patients who present with histologically positive axillary nodes but convert to histologically negative axillary nodes following neoadjuvant chemotherapy.

Estimated Enrollment: 1636 participants
Study Start Date: August 2013
Estimated Primary Completion: July 2023
Estimated Completion Date: August 2028

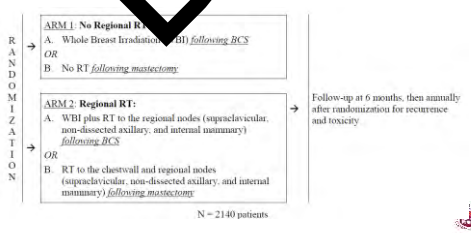


Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer (TAILOR RT)
ClinicalTrials.gov: NCT03488693

Primary Objective
To compare the breast cancer recurrence-free interval (BCRFI) between patients that received regional RT or not, defined as time from randomization to time of invasive recurrent disease in the ipsilateral chestwall, breast, regional nodes, distant sites or death due to BC.

Estimated Enrollment: 2140 participants
Study Start Date: May 2018
Estimated Primary Completion: September 2027
Estimated Completion Date: December 2027

The study population consists of women with newly diagnosed biomarker low risk node positive breast cancer with no evidence of metastases that have been treated by mastectomy or BCS.



HYPOFRACTIONATION

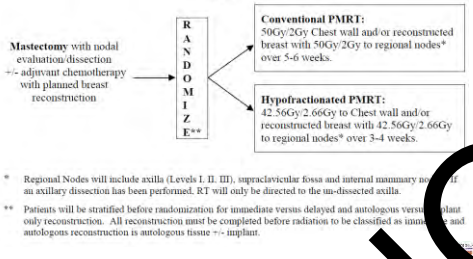
With the publication of multiple trials and Recent ASTRO Guidelines – "Standard" Whole breast radiation is now 3 – 4 weeks compared to historically 5 – 7 weeks

RT CHARM: PHASE III RANDOMIZED TRIAL OF HYPOFRACTIONATED POST MASTECTOMY RADIATION WITH BREAST RECONSTRUCTION
ClinicalTrials.gov: NCT03414970

Primary Objective
To evaluate whether the reconstruction complication rate at 24 months post radiation is non-inferior with hypofractionation.

Estimated Enrollment: 880 participants
Study Start Date: February 2018
Estimated Primary Completion: October 2021
Estimated Completion Date: August 2035

Schema



* Regional Nodes will include axilla (Levels I, II, III), supraclavicular fossa and internal mammary nodes if an axillary dissection has been performed. RT will only be directed to the un-dissected axilla.

** Patients will be stratified before randomization for immediate versus delayed and autologous versus implant only reconstruction. All reconstruction must be completed before radiation to be classified as immediate and autologous reconstruction is autologous tissue +/- implant.

Partial Breast Radiation

Partial-breast radiotherapy after breast conservation surgery for patients with early breast cancer (UK IMPORT LOW trial): 5-year results from a multicentre, randomised, controlled, phase 3, non-inferiority trial

Charlotte E Coles, Clare L Griffin, Anna M Kirby, Jenny Titley, Rajiv K Agrawal, Abdulla Alhasso, Indrani S Bhattacharya, Adrian M Brunt, Laura Ciurlionis, Charlie Chan, Ellen M Donovan, Marie A Ermon, Adrian N Harnett, Joanne S Haviland, Penelope Hopwood, Monica L Jefford, Ronald Kaggwa, Elinor J Sawyer, Isabel Syndikus, Yat M Tsang, Duncan A Wheatley, Maggie Wilcox, John R Yarnold, Judith M Bliss*, on behalf of the IMPORT Trialists†*

Lancet 2017; 390: 1048–60

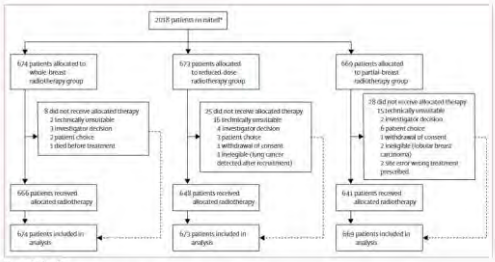


Figure 2: Trial profile
*Two patients withdrew consent for any of their data to be used in the analysis.

Lancet 2017; 390: 1048–60

	Cumulative number of events, n/N (%)	5-year cumulative incidence, % (95% CI)	Hazard ratio* (95% CI)	p value†
Local relapse				
Whole breast	9/674 (1%)	1·1% (0·5–2·3)	1	..
Reduced dose	3/673 (<1%)	0·2% (0·02–1·2)	0·33 (0·09–1·20)	0·077
Partial breast	6/669 (1%)	0·5% (0·2–1·4)	0·65 (0·23–1·84)	0·420
Local-regional relapse				
Whole breast	9/674 (1%)	1·1% (0·5–2·3)	1	..
Reduced dose	3/673 (<1%)	0·2% (0·02–1·2)	0·33 (0·09–1·21)	0·077
Partial breast	8/669 (1%)	0·8% (0·3–1·8)	0·88 (0·34–2·27)	0·793
Distant relapse				
Whole breast	13/674 (2%)	1·4% (0·7–2·6)	1	..
Reduced dose	10/673 (1%)	1·5% (0·8–2·8)	0·77 (0·34–1·75)	0·525
Partial breast	12/669 (2%)	1·6% (0·8–2·9)	0·92 (0·42–2·03)	0·838
Any breast cancer-related event				
Whole breast	33/674 (5%)	3·7% (2·5–5·4)	1	..
Reduced dose	24/673 (4%)	3·4% (2·2–5·3)	0·72 (0·43–1·22)	0·223
Partial breast	33/669 (5%)	4·0% (2·8–5·9)	1·00 (0·62–1·62)	0·982
All-cause mortality				
Whole breast	40/674 (6%)	5·0% (3·6–7·0)	1	..
Reduced dose	39/673 (6%)	4·1% (2·8–5·9)	0·97 (0·62–1·50)	0·881
Partial breast	37/669 (6%)	3·7% (2·5–5·4)	0·91 (0·58–1·42)	0·693

*A hazard ratio of less than 1 favors the experimental group. †Log-rank test, for each experimental group compared with whole-breast radiotherapy.

Table 2: Relapse and mortality by treatment group

Lancet 2017; 390: 1048–60

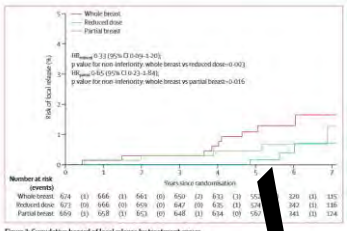


Figure 3: Cumulative hazard of local relapse by treatment group
HR=hazard ratio.

Lancet 2017; 390:

Abstract GS4-04: Primary results of NSABP B-39/RTOG 0413 (NRG Oncology): A randomized phase III study of conventional whole breast irradiation (WBI) versus partial breast irradiation (PBI) for women with stage 0, I, or II breast cancer

FA Vicini, RS Cecchini, JR White, TB Julian, DW Arthur, RA Rabinovitch, RR Kuske, DS Parda, PA Ganz, MF Schneid, KA Winter, S Pisa, HM Kuerer, LA Vallow, LJ Pierce, EP Mamounas, JF Costantino, HD Bear, I Germaine, G Gustafson, L Grossbard, IA Petersen, RS Huges, WJ Curran Jr., and N Wolmark

Primary Aim: to determine if PBI provides equivalent local tumor control post lumpectomy compared to WBI in pts with early-stage breast cancer.

The equivalency test was based on a 50% margin of increase in the hazard ratio (HR=1.5). Secondary endpoints included: overall survival (OS), recurrence-free interval (RFI), distant disease-free interval (DDFI), and toxicity.

Cancer Research, February 2019; Volume 79, Issue 4 Supplement Abstracts: 2018 San Antonio Breast Cancer Symposium; December 4-8, 2018; San Antonio, Texas

Methods:

- Eligible pts had lumpectomy with histologically-free margins and 0-3 positive axillary nodes.
- Pts were stratified by stage, menopausal status, hormone receptor status, and intent to receive chemotherapy and then randomized to PBI or WBI.
- PBI was 10 fractions of 3.4-3.85 Gy, given twice daily with either brachytherapy or 3D external beam radiation.
- WBI was 50 Gy in 2 Gy fractions given daily with a sequential boost to the surgical cavity. Follow-up was every 6 mos for 5 yrs and then annually. All analyses were by intent-to-treat.

Cancer Research, February 2019; Volume 79, Issue 4 Supplement Abstracts: 2018 San Antonio Breast Cancer Symposium; December 4-8, 2018; San Antonio, Texas

Results:

From 3-21-05 to 4-[illegible] 4216 pts were randomized:

- 2107 PBI; 2109 WBI
- 61% were postmenopausal; 81% were hormone receptor-positive; 29% intended to receive chemotherapy.

Stage distribution:

- DCIS, 24%;
- invasive pN_0, 65%;
- invasive pN_1, 10%.

As of 7-31-18, median follow-up was 10.2 yrs:

- 161 IBTRs as first events: 90 PBI *v* 71 WBI (HR 1.22; 90%CI 0.94-1.58).
- Per protocol-defined margin, to declare PBI and WBI equivalent regarding IBTR risk, the 90% CI for the observed HR had to lie entirely between 0.667 and 1.5.
- The percent of pts IBTR-free at 10 yrs was 95.2% PBI *v* 95.9% WBI.
- A statistically significant difference in the 10-yr RFI rate favored WBI (91.9% PBI *v* 93.4% WBI; HR 1.32; 95%CI 1.04-1.68; p=0.02).
- No statistically significant differences existed between PBI and WBI in DDFI (HR 1.31; 95%CI 0.91-1.91; p=0.15), OS (HR 1.10; 95%CI 0.90-1.35; p=0.35), or DFS (HR 1.12; 95%CI 0.98-1.29; p=0.11).
- Grade 3 toxicity was 9.6% PBI *v* 7.1% WBI, and grade 4-5 toxicity was 0.5% *v* 0.3%, respectively.

Cancer Research, February 2019; Volume 79, Issue 4 Supplement Abstracts: 2018 San Antonio Breast Cancer Symposium; December 4-8, 2018; San Antonio, Texas

Discussion:

- PBI did not meet the criteria for equivalence to WBI in controlling IBTR based on the upper limit of the hazard ratio confidence interval.
- However, the absolute difference in 10-yr rate of IBTR was <1% (4.8% PBI *v* 4.1% WBI).
- The risk of an RFI event was statistically significantly higher for PBI compared to WBI, but the absolute difference in 10-yr RFI rate was also small (8.1% PBI *v* 6.6% WBI).
- DDFI, OS, and DFS were not statistically different for PBI *v* WBI.
- Grade 3-5 toxicities, although low, were more common for PBI than WBI.
- The trial population was heterogeneous, ranging from Stage 0-2 breast cancer, and outcome by risk categories are being analyzed.

Cancer Research, February 2019; Volume 79, Issue 4 Supplement Abstracts: 2018 San Antonio Breast Cancer Symposium; December 4-8, 2018; San Antonio, Texas

What about a single dose of Radiation at the Time of Surgery?

LOYOLA MEDICINE
Radiation Oncology

TARGIT-A

William Small Jr., MD, FACRO, FA[illegible]R, FASTRO
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Stritch School of Medicin[illegible]yola Univer[illegible]y Chicago

Lancet 2010; 376: 91–102
Published Online
June 5, 2010
DOI:10.1016/S0140-6736(10)60837-9

Targeted intraoperative radiotherapy versus whole breast radiotherapy for breast cancer (TARGIT-A trial): an international, prospective, randomised, non-inferiority phase 3 trial

Jayant S Vaidya, David J Joseph, Jeffrey S Tobias, Max Bulsara, Frederik Wenz, Christobel Saunders, Michael Alvarado, Henrik L Flyger, [illegible]le Massarut, Wolfgang Eiermann, Mohammed Keshtgar, John Dewar, Uta Kraus-Tiefenbacher, Marc Sütterlin, Laura Esserman, Helle M R Holtveg[illegible]Roncadin, Steffi Pigorsch, Marinos Metaxas, Mary Falzon, April Matthews, Tammy Corica, Norman R Williams, Michael Baum

2012

[illegible]gen	0	497	13	510
Per[illegible]	34	342	9	385
Aviano	282	4	18	304
Dum[illegible]	213	46	7	266
Mu[illegible]ISK	251	0	6	257
[illegible]ICL	150	29	10	189
[illegible]heim	177	0	9	186
[illegible]chester	98	15	0	113
OCSF	92	13	5	110
London RFH/Whittington	96	9	1	106
London RFH	*80*	*5*	*0*	*85*
Whittington	*16*	*4*	*1*	*21*
Trondheim	101	1	4	106
Munich LMU	98	0	2	100
Padova	94	0	0	94
USC	58	10	7	75
Nantes	87	0	0	87
Hornburg	62	1	1	64
Zurich IBZS	59	0	0	59
Empoli	56	1	0	57
Berlin SGK	54	0	0	54
Frankfurt	42	0	2	44
Lublin	42	0	0	42
Zurich USZ	37	0	0	37
NY Poughkeepsie	35	0	0	35
Hannover	26	0	0	26
Toronto	23	0	1	24
London GST	3	16	0	19
Nebraska	2	16	0	18
Indiana	4	6	2	12
Virginia	11	0	0	11
Melbourne	0	9	0	9
NY Dobbs Ferry	4	0	0	4
London HJE	3	0	0	3
Bordeaux	1	0	0	1
Total	2372	1235	97	3704

Eligibility

- 45 years and older
- Unifocal invasive ductal carcinoma
- Further external beam given if:
  - Invasive lobular
  - EIC
  - Adverse Criteria
    - Decided at each center
    - Grade 3
    - LN involvement
    - LVSI

Margins

- If positive re-excise and EBRT

COMPLICATIONS

Number of complications

	TARGIT	EBRT
None	917	946
Any	196 (17.6%)	174 (15.4%)
	Chi sq = 1.74 p = 0.19	

Clinically important wound complications

	TARGIT	EBRT
Hematoma requiring surgical evacuation	11 (0.99%)	7 (0.63%)
Seroma requiring more than 3 aspirations	23 (2.07%)	9 (0.8%)
Infection requiring intravenous antibiotics or surgery	20 (1.9	14 (1.3%)

Clinically significant toxicity

	TARGIT	EBRT
Wound breakdown	31 (2.8%)	21 (1.9%)
RTOG grade 3 toxicity	6 (0.54%)	23 (2.1%)
Clinically significant toxicity	37 (3.3%)	44 (3.9%)
	P=0.44	


Articles

Final Accural

- 3,451 patients were entered from 33 centers in 10 countries from 2000 – 2012.
- 1,730 EBRT
- 1,721 TARGIT
- Median follow-up 2.4 years

General Characteristics

Duration	2000-2013
Patients	3451
Screen Detected	~ 75%
Age	~ 40% below 60 years
Tumor Size	87% up to 2cm
Tumor Grade	~15 % Grade 3
LN Metastasis	~ 20% Node Positive

	Events; 5-year cumulative risk (95%CI)		Absolute difference*
	TARGIT	EBRT	
All patients			
Local recurrence (n=3325)	21; 3·3% (2·1-5·1)	11; 1·3% (0·7-2·5)	12 (2·0%)
Any other recurrence (n=3325)	46; 4·9% (3·5-6·9)	17; 1·4% (1·0-6·4)	9 (0·5%)
Death (n=3451)	37; 3·9% (2·7-5·8)	51; 5·3% (3·9-7·3)	-14 (-1·4%)

TARGIT=targeted intraoperative radiotherapy. EBRT=external beam radiotherapy. *In Kaplan-Meier point estimate at 5 years (TARGIT minus EBRT). †TARGIT given at same time as lumpectomy. ‡TARGIT given after lumpectomy, as separate procedure.

Results of primary (local recurrence in the conserved breast, secondary (death), and exploratory (any other recurrence) outcomes for all patients and the two strata as per timing of randomization and delivery of TARGIT

	Events; 5-year cumulative risk (95%CI)		Absolute difference*
	TARGIT	EBRT	
All patients			
Prepathology†			
Local recurrence (n=2234)	10; 2·1% (1·1-4·2)	6; 1·1% (0·5-2·5)	4 (1·0%)
Any other recurrence (n=2234)	29; 4·8% (3·1-7·3)	25; 4·7% (3·0-7·4)	4 (0·1%)
Death (n=2298)	29; 4·6% (1·8-6·0)	42; 6·9% (4·3-9·6)	-13 (-2·3%)

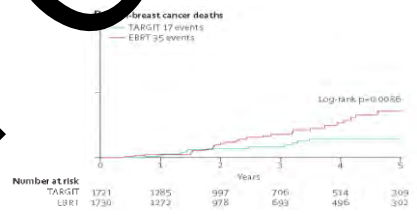
TARGIT=targeted intraoperative radiotherapy. EBRT=external beam radiotherapy. *In Kaplan-Meier point estimate at 5 years (TARGIT minus EBRT). †TARGIT given at same time as lumpectomy. ‡TARGIT given after lumpectomy, as separate procedure.

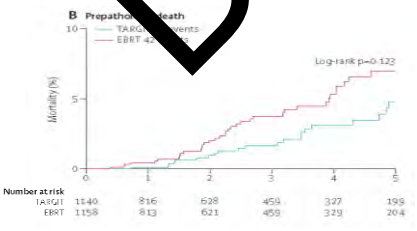
Treatment at the time of lumpectomy.

	Events; 5-year cumulative risk (95%CI)		Absolute difference*
	TARGIT	EBRT	
All patients			
Postpathology‡			
Local recurrence (n=1141)	13; 5·4% (3·0-9·7)	5; 1·7% (0·6-4·9)	8 (3·7%)
Any other recurrence (n=1141)	17; 5·2% (3·0-8·8)	12; 3·7% (1·9-7·0)	5 (1·5%)
Death (n=1153)	8; 2·8% (1·3-5·9)	9; 2·3% (1·0-5·2)	-1 (0·5%)

TARGIT=targeted intraoperative radiotherapy. EBRT=external beam radiotherapy. *In Kaplan-Meier point estimate at 5 years (TARGIT minus EBRT). †TARGIT given at same time as lumpectomy. ‡TARGIT given after lumpectomy, as separate procedure.

Pst-pathology treatment.

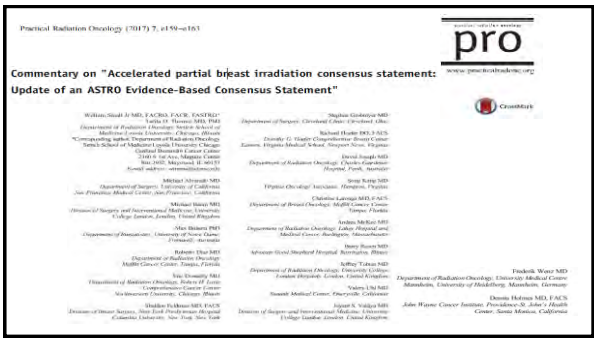




Kaplan-Meier analysis of local recurrence in the conserved breast and death for the two strata as per timing of randomization and deliver of TARGIT (prepathology vs postpathology)
Local recurrence was the primary outcome, death was a secondary outcome. Prepathology (n=2298), randomized before lumpectomy and TARGIT given concurrently with lumpectomy. Postpathology (n=1153), randomized after lumpectomy and TARGIT given by reopening the wound.
(B) Deaths in prepathology stratum.

TARGIT= targeted intraoperative radiotherapy

EBRT=external beam radiotherapy



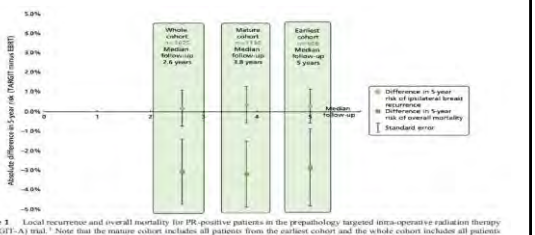


Figure 1 Local recurrence and overall mortality for PR-positive patients in the prepathology targeted intra-operative radiation therapy (TARGIT-A) trial.[1] Note that the mature cohort includes all patients from the earliest cohort and the whole cohort includes all patients from the mature cohort. Reproduced with permission from the National Institute for Health Research Journals Library

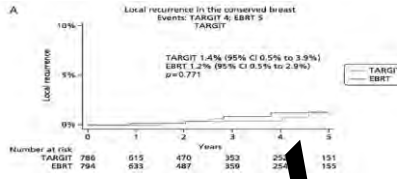


Figure 2 Local recurrence, death from cancer, and death from other causes in the prepathology PR-positive patients in the randomized TARGIT-A trial.[1] Reproduced with permission from the National Institute for Health Research Journals Library. EBRT, external beam radiation therapy. Other abbreviations as in Fig 1.

Intraoperative radiotherapy versus external radiotherapy for early breast cancer (ELIOT): a randomised controlled equivalence trial

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ELIOT TRIAL

- 1305 patients randomized
- Median follow-up 5.8 years.
- 5-year ipsilateral breast recurrence rate 4.4% vs. 0.4%.
- No difference in survival.

A subgroup analysis of good risk patients noted a 1.5 % local recurrence rate.

Questions?