Target Therapy Oncology
Kyoto University
Graduate School of Medicine

9th TBC

SABCS 2012報告
知っておきたい注目演題

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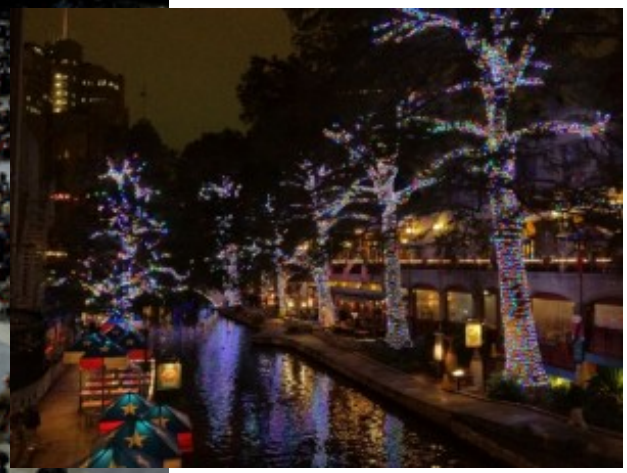
20121215 Tokyo

CTRC–AACR
SAN ANTONIO
BREAST CANCER
SYMPOSIUM

December 4-8, 2012
Henry B. Gonzalez Convention Center, San Antonio, Texas, USA



1990-2011

Year	Year No.	Registrations	Papers Accepted	Exhibitors	No. of Countries
1990	13th	526	201	15	24
1991	14th	685	237	23	25
1992	15th	749	218	22	22
1993	16th	763	240	23	26
1994	17th	1,056	264	28	29
1995	18th	1,283	301	20	38
1996	19th	1,533	303	22	42
1997	20th	1,980	365	40	43
1998	21st	2,530	433	40	47
1999	22nd	3,126	450	40	55
2000	23rd	3,796	438	40	61
2001	24th	3,320	432	38	52
2002	25th	4,876	543	56	67
2003	26th	5,820	590	68	82
2004	27th	6,810	721	84	86
2005	28th	7,666	805	106	89
2006	29th	8,017	893	97	83
2007	30th	8,503	813	105	86
2008	31st	8,936	1,064	98	92
2009	32nd	8,493	1,169	102	93
2010	33rd	7,913	1,035	91	93
2011	34th	7,724	1,264	79	103

まず
重要演題をざっとリストアップして
簡単に結果を説明します

日常診療に影響のある演題については
その後に詳しくお話していきます

ホルモン療法

- ATLAS trial: 10y vs. 5y のadj. TAM療法比較
- BIG1-98 trial: Lobular ca.でのadj. LET vs. TAM比較
- CONFIRM trial: フルベストラント 500mg > 250mg MBC

センチネルリンパ節生検

- ACOSOG Z1071: cN+乳癌術前化学療法後のSLNBについて　2個とるとFalse negative rate =12.6%
- SENTINA trial: 術前化学療法前、後のSLNBについて
  N1→N0症例でのfalse negative rate = 14.2%

化学療法 1

- CTNeoBC: 術前化学療法のMeta analysis　by FDA
  予後と相関するのはTとNともにpCR (DCIS遺残は問わない）の場合
- 35歳以下の患者における術前化学療法の成績
  35歳以下でpCR率高い　HR+HER2-でもpCRで予後改善
- UK TACT2 trial: accelerated Epi adj. therapyの意義
  ２週毎サイクルのEpiでも予後改善なし
- Intense dose-dense ETC adjuvant chemo
  ２週毎サイクルのidd E-PAC-CPAでPFS, OS改善

化学療法 2

- Eribulin 301: エリブリン vs. カペシタビン
  AT pre treat MBC
- CALOR trial: 局所再発 切除後の補助化学療法の意義
- 化学療法後のMDS/AMLの発生率
  10年間で0.5%の発生
- 化学療法による神経認知機能(chemo brain)の前向きfMRI試験（リサーチナースによる発表）
  疲労感や認知機能低下は化学療法開始前におきている

放射線療法・Ki-67

- UK START 10年:術後放射線治療の標準療法の確立
  40Gy/15frがUKの標準
- TARGIT-A trial: 術中照射デバイスの成績
  PgR+はTARGITでもよい？
- Gepar Trio trial: 術前治療前Ki-67による効果・予後予測
  カットオフをどこにしても差がでる
  <=15%, 15.1%-35%, 35%<で今後解析
- International Ki-67 reproducibility study
  （乳癌学会班研究も今後参加予定）

分子標的治療

Trastuzumab

- HERA trial: 2y vs. 1y トラスツズマブ術後補助療法
- PHARE trial: 0.5y vs. 1yトラスツズマブ術後補助療法
- N9831/B-31 統合解析:トラスツズマブ補助療法最終解析

Bevacizumab

- LEA study: Bevacizumab + LET vs. LET 1st MBC
  BEVの併用療法はPFSを有意に延長せず
- BEATRICE trial: 第III相ベバシズマブ補助療法試験 TNBC

開発中薬剤

- TRIO tiral PD0332991: r-PII CDK 4/6 阻害剤＋LET vs. LET
  1stMBC　有望な結果

分子標的治療バイオマーカー

Trastuzumab

- N9831 biomarker: EGFR陽性だとトラスツズマブ効果低い
- HER2遺伝子増幅なしでHER2遺伝子変異のある乳癌
  HER2mtあり　Neratinibが効く？

Pertuzumab+Trastuzumab

- CLEOPATRA biomarker: PIK3CA mtは予後不良因子
- NeoSphere TR study: 免疫応答が効果と関連

Zolendronic acid

- AZURE TR study: Vit.Dレベルが再発を予測する　E2低濃度がZAの利益のために必要
- JONIE trial: ZA+chemotherapy
  TNBC, 閉経後　でZAによりpCRが増加する傾向


JONIE

ATLAS - Adjuvant Tamoxifen: Longer Against Shorter

10 vs 5 years of adjuvant tamoxifen in ER+ disease: effects in the first & second decade after diagnosis

Presented on behalf of the

ATLAS collaborative group

All authors declare no relevant conflict of interest.

ATLAS trial, *Lancet* December 5, 2012*

San Antonio Breast Cancer Symposium – Cancer Therapy and Research Center at UT Health Science Center – December 4-8, 2012

10 years of tamoxifen vs 5

6846 women with ER+ disease completed 5 years of tamoxifen, then were randomised:

CONTINUE to year 10,
or STOP at year 5.

25% Asia/mid-East, 28% Latin America,
47% Europe/US/ANZ/South Africa

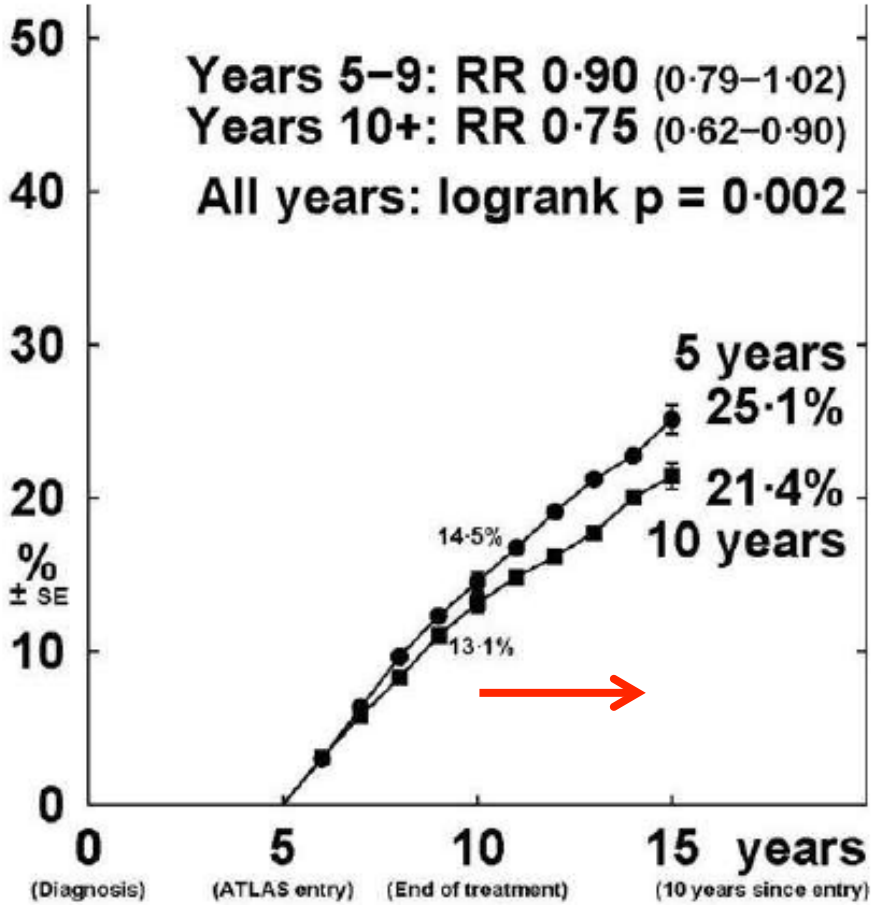
54% node-negative

8 yrs follow-up: compliance, recurrence, death

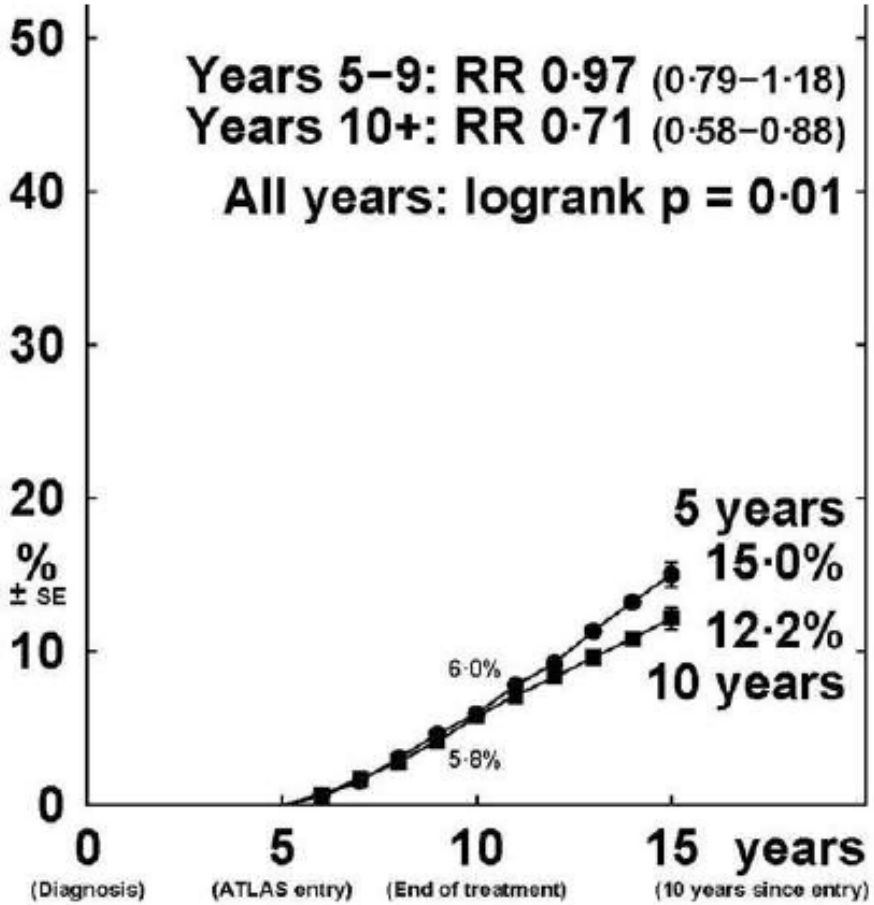
San Antonio Breast Cancer Symposium – Cancer Therapy and Research Center at UT Health Science Center – December 4-8, 2012

ATLAS: 6846 women, ER+, 10 vs 5 years tamoxifen

RECURRENCE



BREAST CANCER MORTALITY



Recurrence rates (% / year) and logrank analyses

Tamoxifen allocation	Years 5 – 9	Years 10 – 14	Year 15+
Continue to 10 years	2·83 (428 / 15115)	1·96 (165 / 8439)	2·54 (24 / 945)
Stop at 5 years	3·16 (471 / 14889)	2·66 (214 / 8038)	3·03 (26 / 859)
Rate ratio, from	0·90 SE 0·06	0·74 SE 0·09	0·85 SE 0·26
(O–E) / V	−24·8 / 224·7	−29·1 / 94·7	−2·1 / 12·5

Death rates (% / year: total rate – rate in women without recurrence) & logrank analyses

Tamoxifen allocation	Years 5 – 9	Years 10 – 14	Year 15+
Continue to 10 years	1·17 SE 0·09	1·38 SE 0·12	1·64 SE 0·39
Stop at 5 years	1·21 SE 0·09	2·01 SE 0·15	2·29 SE 0·47
Rate ratio, from	0·97 SE 0·10	0·70 SE 0·10	0·79 SE 0·27
(O–E) / V	−3·2 / 94·0	−27·2 / 77·5	−2·5 / 10·6

閉経前症例は10%弱

ER+ disease: Effects of tamoxifen duration on event rate ratio (RR), by time since diagnosis

	5 years tam. vs none: EBCTCG meta-analysis (n=10 645)	10 years tam. vs 5: ATLAS trial (n=6846)	10 years tam. vs none: estimated effects (product of two RRs)
Recurrence in:			
- years 0-4	**RR=0.53‡** (0.48-0.57)	**(1.0)**	**RR=0.53‡** (0.48-0.57)
- years 5-9	**0.68‡** (0.60-0.78)	**0.90** (0.79-1.02)	**0.61‡** (0.51-0.73)
- years 10+	**0.94** (0.79-1.12)	**0.75*** (0.62-0.90)	**0.70*** (0.54-0.91)
Breast cancer mortality in:			
- years 0-4	**0.71‡** (0.62-0.80)	**(1.0)**	**0.71‡** (0.62-0.81)
- years 5-9	**0.66‡** (0.58-0.75)	**0.97** (0.79-1.18)	**0.64†** (0.50-0.82)
- years 10+	**0.73†** (0.62-0.86)	**0.71§** (0.58-0.88)	**0.52‡** (0.40-0.68)
‡2p<0.00001	† 2p=0.0001	§ 2p=0.0016	* 2p<0.01

Side effects and main effects of 10 yrs tam. on 15-yr mortality in meta-analysis & ATLAS trial

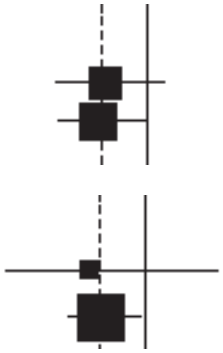
	5 yrs tam. vs 0: meta-analysis	10 yrs tam. vs 5: ATLAS trial	10 yrs tam. vs 0 (by addition)
Endometrial cancer & PE mortality	0.2% loss	0.2% loss	0.4% loss
Breast cancer mortality	9% gain	3% gain	12% gain

Estimated effects of 10 yrs tam. vs 0 on 15-yr mortality: absolute gain ~30x absolute loss

ATLAS

- TAM5年内服後に再発していない患者さんで10年内服する利益
- 子宮体癌は内服期間に応じて増加
- 閉経後ではAIスイッチが基本か
- 実際には５年終了時でまだ閉経前症例での適応か

Nodal status at diagnosis (p=0·82)				
Node-negative	252/1832 (14%)	295/1845 (16%)	−22·0	136·7
Node-positive/unknown	365/1596 (23%)	416/1573 (26%)	−36·2	195·0
Menopausal status at ATLAS entry (p=0·79)				
Premenopausal	64/326 (20%)	73/304 (24%)	−7·2	34·2
Postmenopausal or unknown	553/3102 (18%)	638/3114 (20%)	−48·8	297·6



ATLAS trial, *Lancet* December 5, 2012*

Relative effectiveness of letrozole compared with tamoxifen for patients with lobular carcinoma in the BIG 1-98 trial

Otto Metzger Filho, Anita Giobbie-Hurder, Elizabeth Mallon, Giuseppe Viale, Eric P. Winer, Beat Thürlimann, Richard D. Gelber, Marco Colleoni, Bent Ejlertsen, Hervé Bonnefoi, Alan S. Coates, Aron Goldhirsch for the BIG 1-98 Collaborative Group

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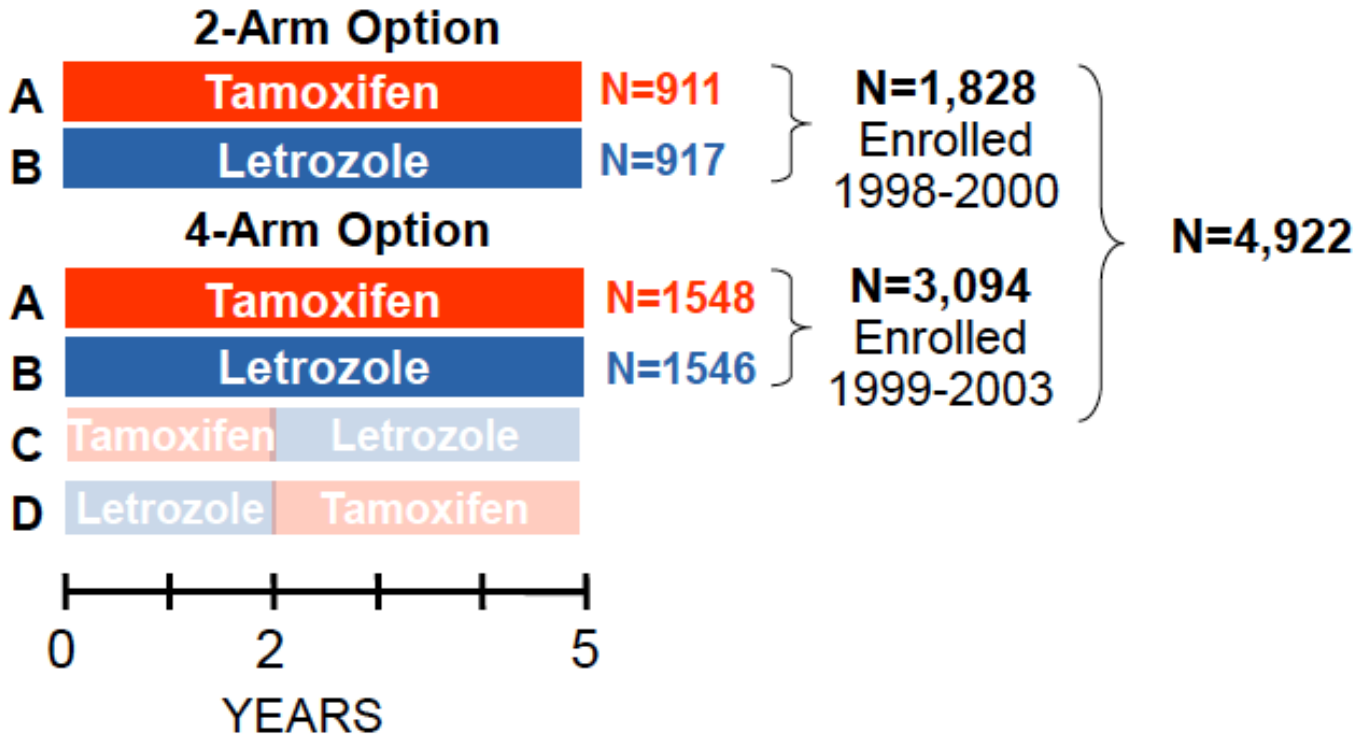
BIG 1-98 Analytic Cohort
Postmenopausal HR+ BC
12-year update (Lancet Oncol 2011)



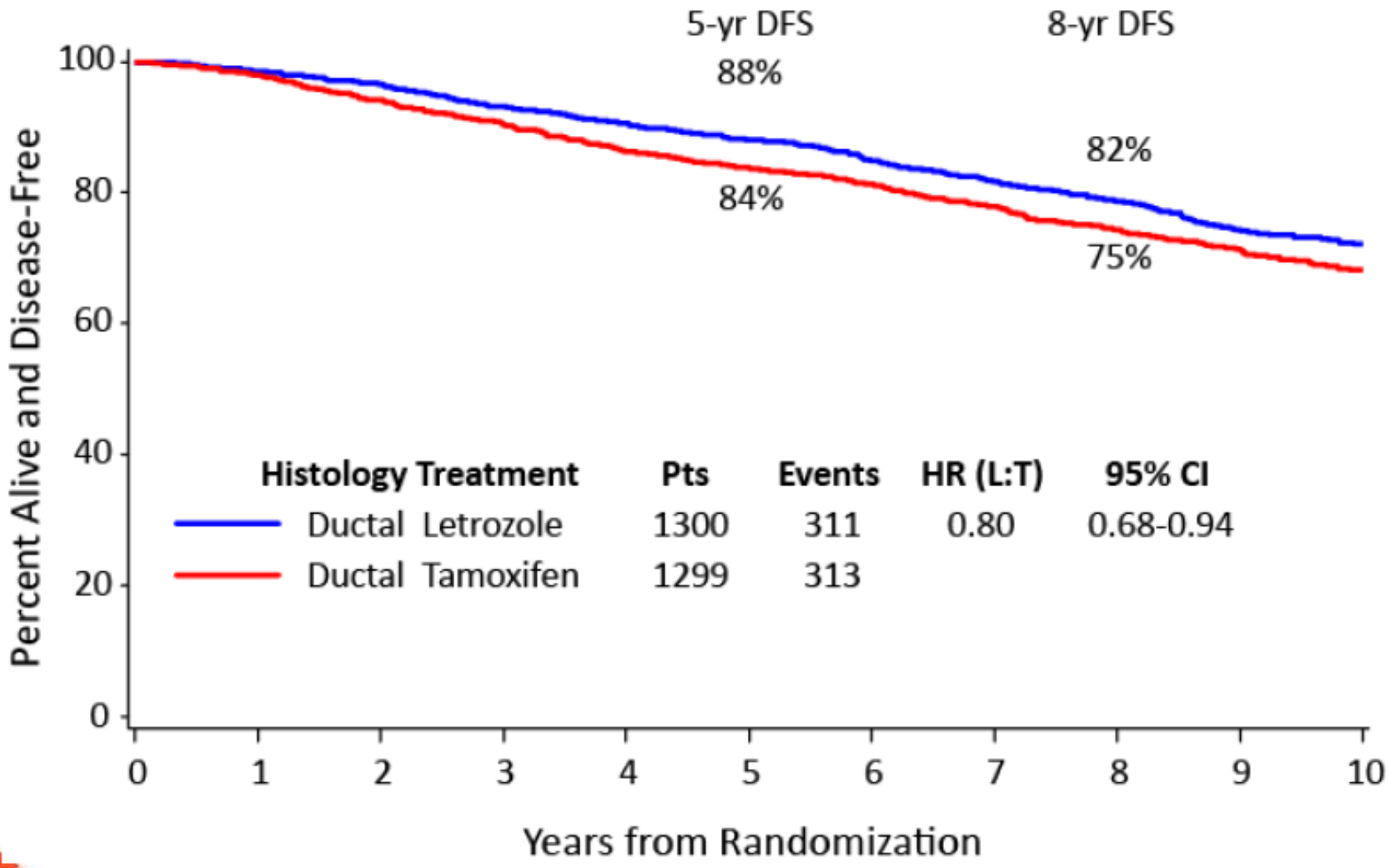
浸潤性小葉癌

- 非浸潤性小葉癌が併存（70~80%）
- 高い断端陽性率*（43% vs. 16% in IDC）
- 多くは mSBR grade-Ⅱ（~76%）
- ER陽性（~93%）
- AR陽性（~88% vs. ~56% in IDC）
- 稀にHER2陽性（~11%）
- E-cadherin 発現の消失
- 骨、卵巣などへの転移

＊ 温存手術

三上芳喜 10thKBCCC

Disease-free survival 乳管癌



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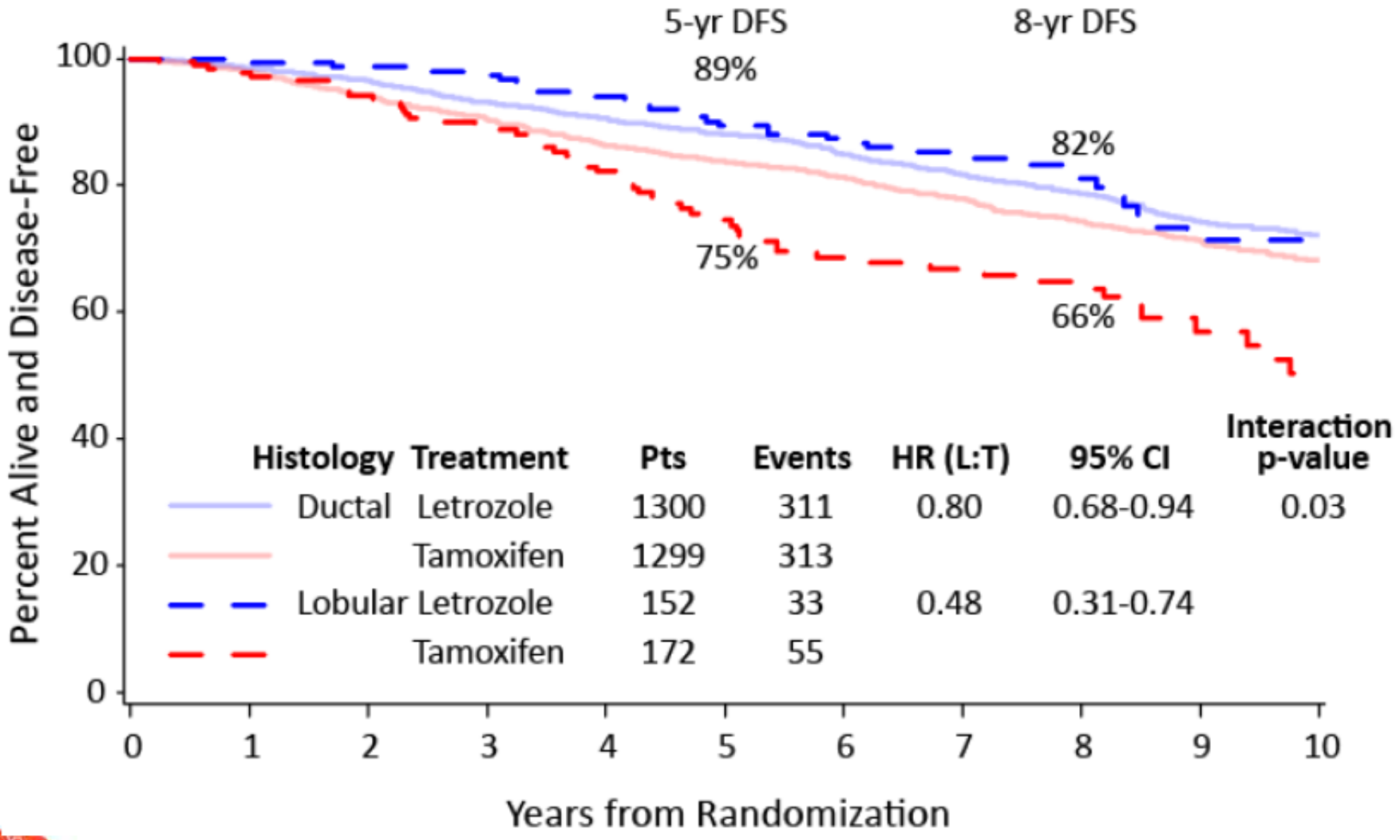
Disease-free survival 乳管癌　小葉癌



Histology	Treatment	Pts	Events	HR (L:T)	95% CI	Interaction p-value
Ductal	Letrozole	1300	311	0.80	0.68-0.94	0.03
	Tamoxifen	1299	313			
Lobular	Letrozole	152	33	0.48	0.31-0.74	
	Tamoxifen	172	55			

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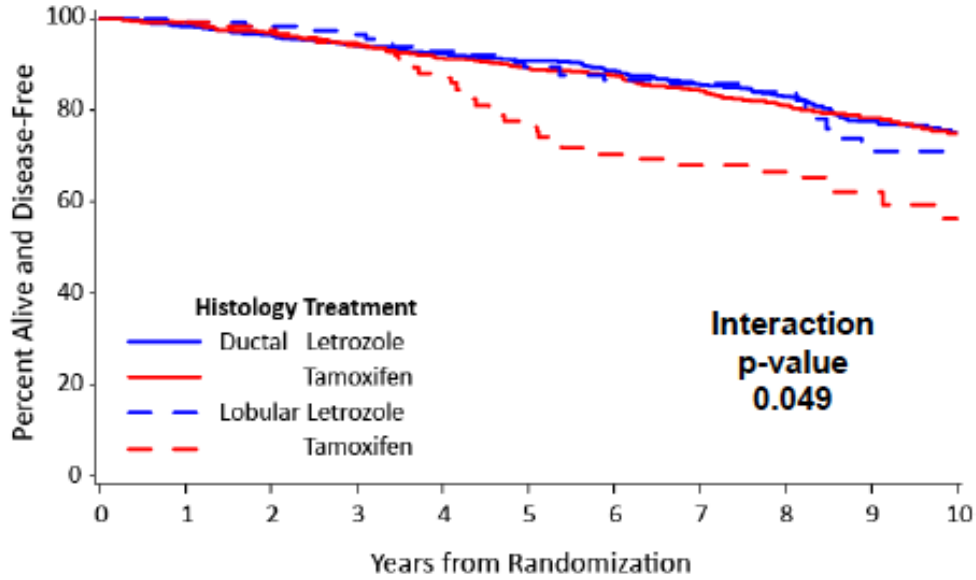
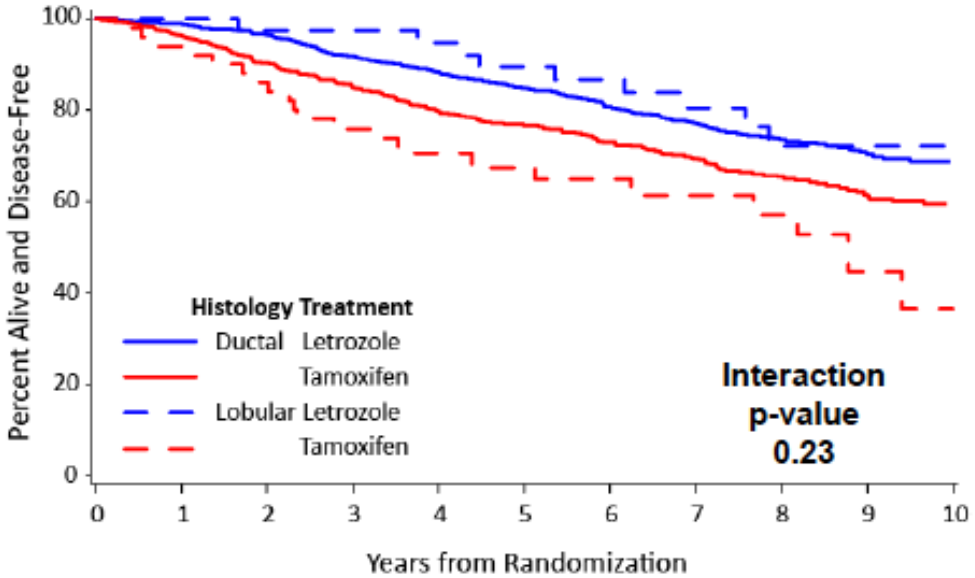
Disease-free survival

Luminal A



Luminal B



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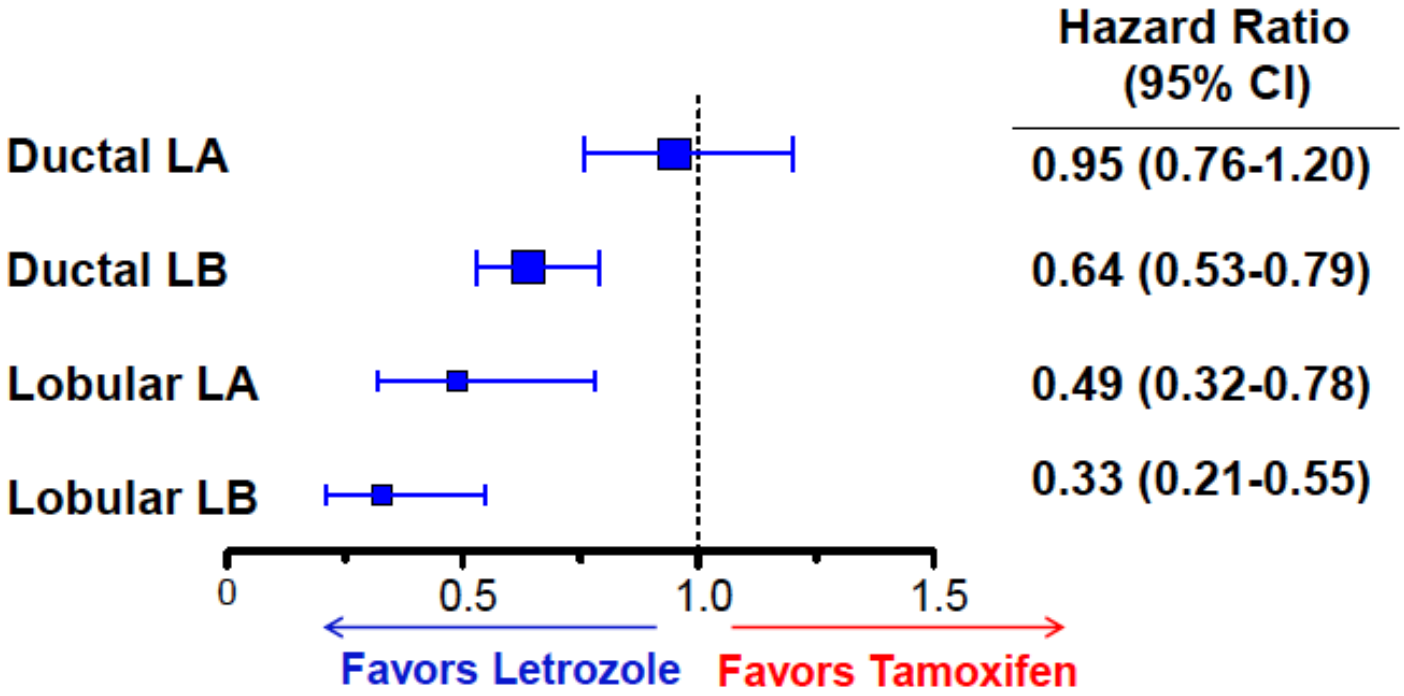
Multivariate Analysis
Cox Model for DFS (IPCW)[1]



Interactions **Treatment by histology (ductal/lobular), p=0.006**
Treatment by subtype (LA/LB), p=0.01

1. Included variables: age, tumor size, nodal status, histological grade, histology, local therapy, subtype (LA/LB) and treatment

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BIG 1-98

- 乳管癌に比較し、小葉癌ではLETを選択する利益が大きい
- Lumina Aの乳管癌はTAMでもよい？？

A Phase III, Open-Label, Randomized, Multicenter Study Of Eribulin Mesylate Versus Capecitabine In Patients With Locally Advanced Or Metastatic Breast Cancer Previously Treated With Anthracyclines And Taxanes

Peter A. Kaufman,[1] Ahmad Awada,[2] Christopher Twelves,[3] Louise Yelle,[4] Edith A. Perez,[5] Jantien Wanders,[6] Martin S. Olivo,[7] Yi He,[7] Corina E. Dutcus,[7] Javier Cortes[8]

[1]Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center, Lebanon, NH, USA; [2]Medical Oncology Clinic, Jules Bordet Institute, Brussels, Belgium; [3]Leeds Institute of Molecular Medicine and St James's Institute of Oncology, Leeds, UK; [4]Department of Medicine, University of Montreal, Montreal, Canada; [5]Mayo Medical Clinic, Jacksonville, FL, USA; [6]Eisai Ltd, Hatfield, UK; [7]Eisai Inc., Woodcliff Lake, NJ, USA; [8]Vall D'Hebron University Hospital, Barcelona, Spain

Study Design

- Global, randomized, open-label Phase III trial (Study 301)

Patients (N=1102)

Locally advanced or MBC

- ≤3 prior chemotherapy regimens (≤2 for advanced disease)
- Prior anthracycline and taxane in (neo)adjuvant setting or for locally advanced or MBC

Randomization 1:1

Eribulin mesylate
1.4 mg/m^{2†} 2- to 5-min IV
Day 1 & 8 q21 days

Capecitabine
1250 mg/m^2 BID orally
Days 1-14, q21 days

Co-primary endpoint

- OS and PFS

Secondary endpoints

- Quality of life
- ORR
- Duration of response
- 1-, 2- and 3-year survival
- Tumor-related symptom assessments
- Safety parameters
- Population PK (eribulin arm only)

- Stratification:
  - Geographical region, HER2 status

†Equivalent to 1.23 mg/m^2 eribulin

Statistical Plan: Analysis Of Co-Primary Endpoints

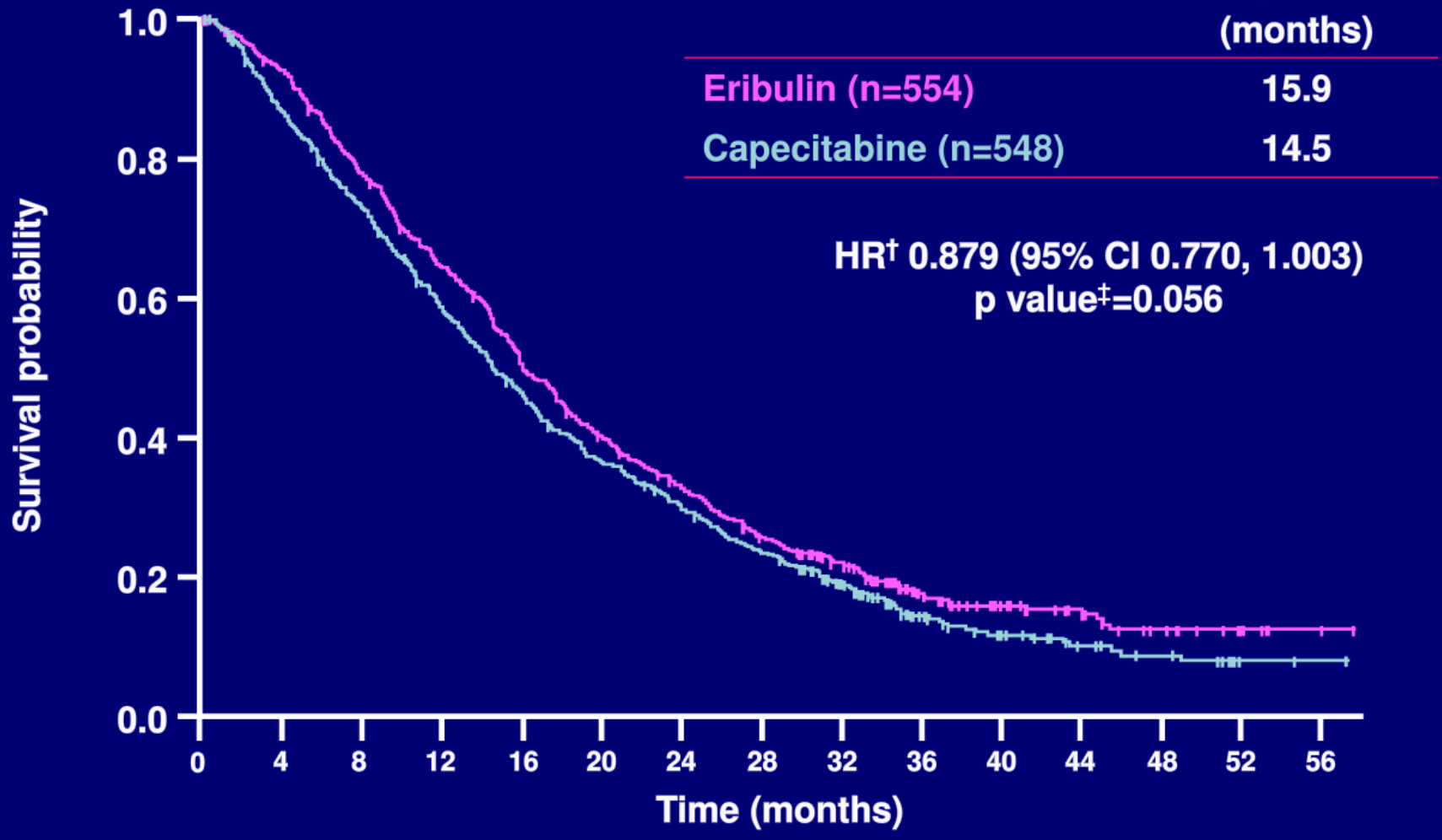
- Primary pre-defined analyses in the ITT population
  - Two-sided, stratified log-rank test stratified for HER2 and geographic region; HR based on Cox regression model
- 1,100 patients planned enrollment. OS determination, 905 events (final analysis, 82% events) sufficient for 90% probability if the HR <= 0.8 (Type I error = 0.04)
- Two planned interim analyses of OS: 453 and 603 deaths
  - O'Brien Fleming spending function utilized
- Final analysis would be declared positive if either
  - OS with eribulin is significantly better vs capecitabine (p≤0.0372)
  - PFS (independent review) with eribulin is significantly better vs capecitabine (p≤0.01) and HR for OS (eribulin/capecitabine) is <1

Patient and Disease Characteristics

		Eribulin (n=554)	Capecitabine (n=548)
Median age (range)		54.0 (24-80)	53.0 (26-80)
ECOG performance, %	0	45	42
	1	53	55
	2+	2	3
Number of prior chemotherapy regimens for advanced disease, %	0	21	19
	1	50	53
	2	28	27
	>2	1	1
Sites of disease†, %	Visceral	84	88
	Non-visceral only	15	11
HER2 status‡, %	Positive	16	15
	Negative	68	69
ER status‡, %	Positive	47	51
	Negative	42	39
PR status‡, %	Positive	41	43
	Negative	47	45
Triple (ER/PR/HER2) negative, %		27	25

ITT population
†Determined by independent assessment; missing patients for sites of disease were 1% for eribulin and 1% for capecitabine
‡Assays carried out and defined locally
Unknown patients for eribulin and capecitabine were: HER2 status 17% and 16% ; ER status 11% and 10%; PR status 12% and 12%, respectively

Overall Survival



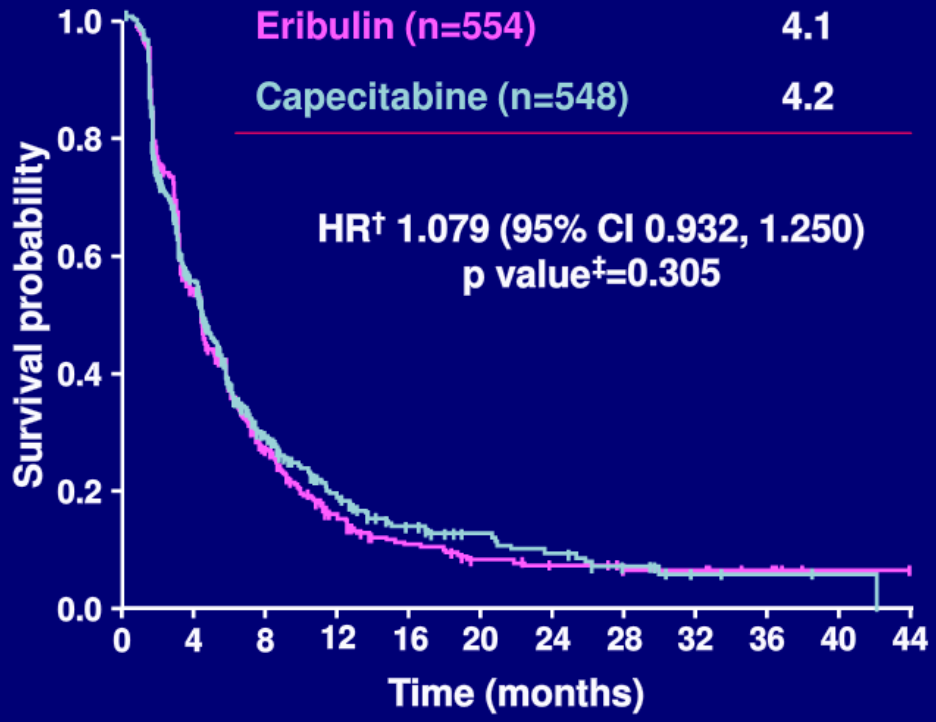
ITT population; †HR Cox model including geographic region and HER2 status as strata
‡p value from stratified log-rank test based on clinical database

Progression-Free Survival

Independent Review

	Median (months)
Eribulin (n=554)	4.1
Capecitabine (n=548)	4.2

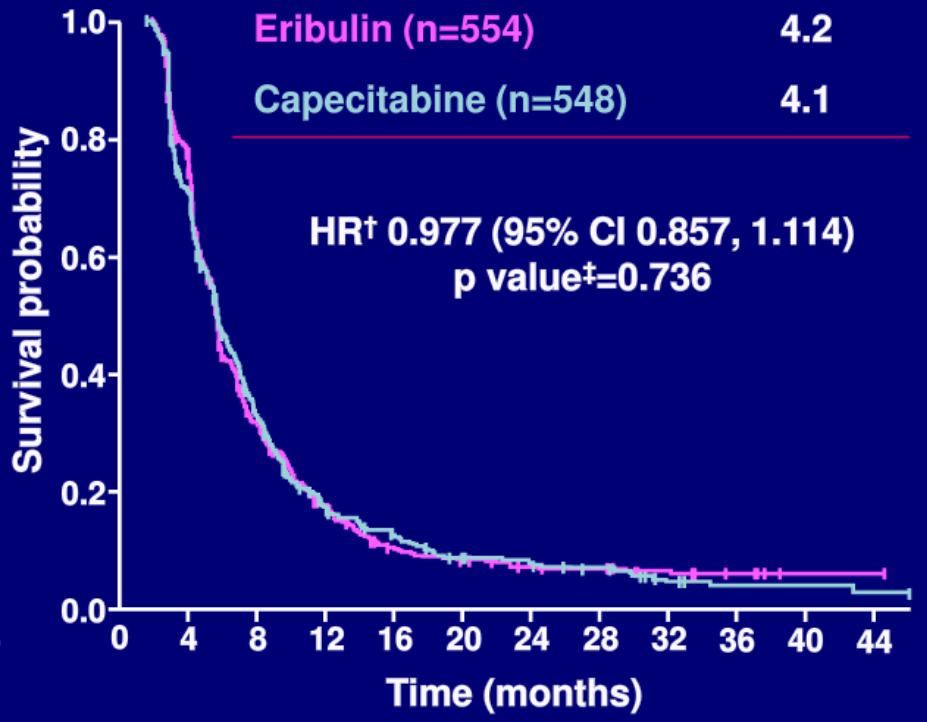
HR† 1.079 (95% CI 0.932, 1.250)
p value‡=0.305



Investigator Review

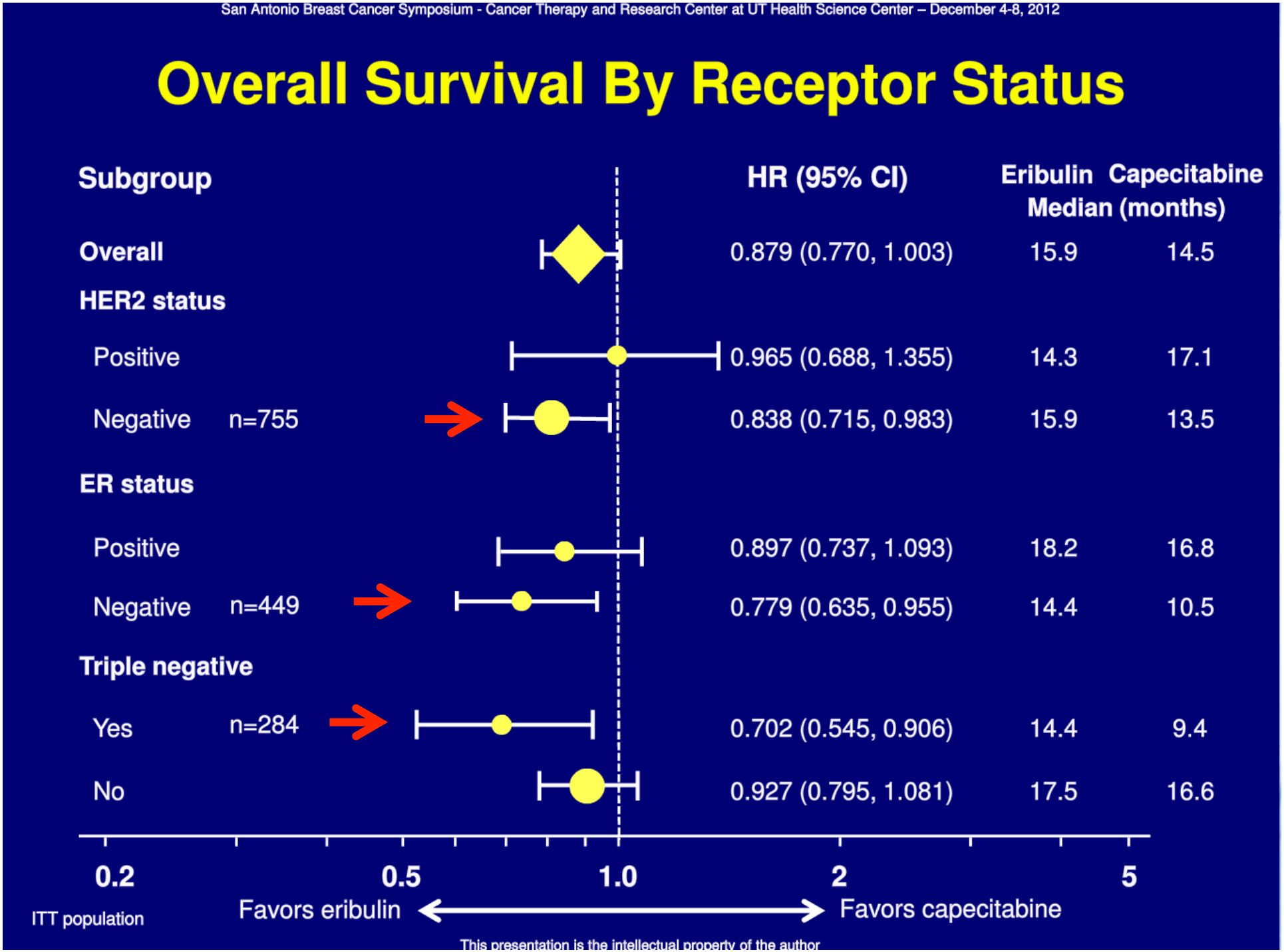
	Median (months)
Eribulin (n=554)	4.2
Capecitabine (n=548)	4.1

HR† 0.977 (95% CI 0.857, 1.114)
p value‡=0.736



ITT population; †HR Cox model including geographic region and HER2 status as strata
‡p value from stratified log-rank test based on clinical database

Overall Survival By Receptor Status



エリブリン vs. カペシタビン

- 臨床試験としてはnegative
- しかし、アンスラ・タキサン既治療で2nd-3rd ライン相当のMBCで、エリブリンはカペシタビンと少なくとも同等の抗腫瘍効果が期待できる

San Antonio Breast Cancer Symposium – December 4-8, 2012

NSABP
National Surgical Adjuvant Breast and Bowel Project

IBCSG
International Breast Cancer Study Group

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Chemotherapy Prolongs Survival for Isolated Local or Regional Recurrence of Breast Cancer: The CALOR Trial

S. Aebi, S. Gelber, I. Láng, S.J. Anderson, A. Robidoux, M. Martín, J.W.R. Nortier, E.P. Mamounas, C.E. Geyer, Jr., R. Maibach, R.D. Gelber, N. Wolmark, I. Wapnir, for the **CALOR** Trial Investigators

Chemotherapy as **A**djuvant for **LO**cally **R**ecurrent Breast Cancer.
IBCSG 27–02, NSABP B–37, BIG 1–02 (BOOG, GEICAM, IBCSG)

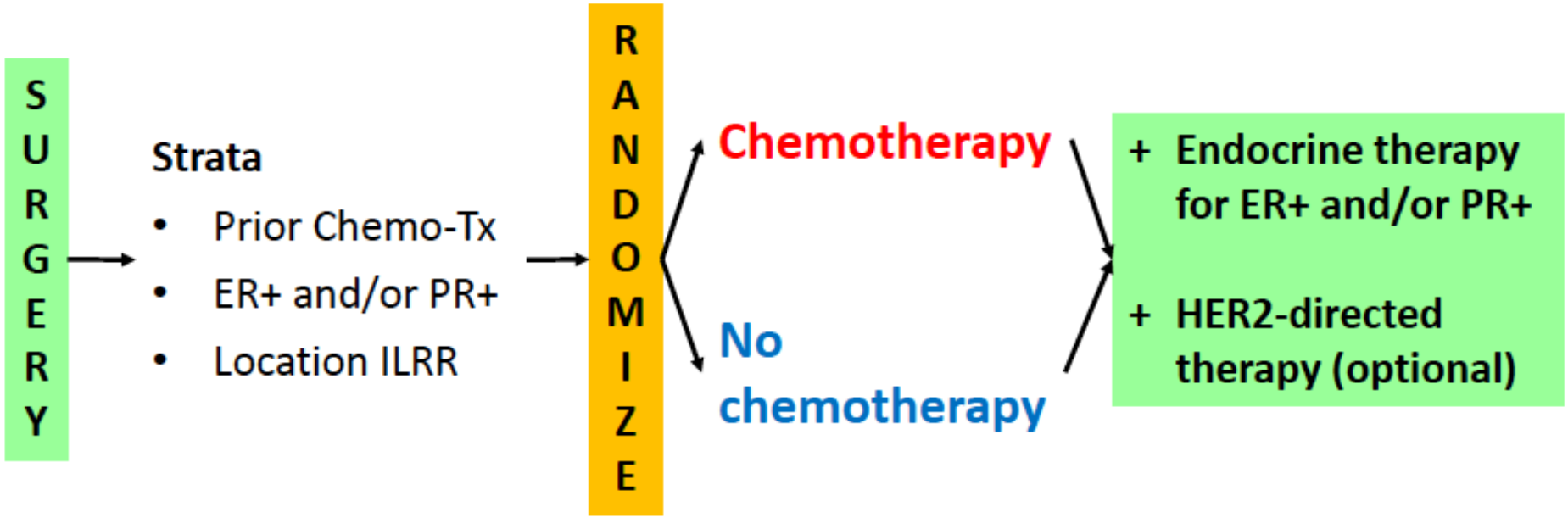
CALOR Trial – Eligibility Criteria

- **First ipsilateral local and/or regional recurrence**
  - breast (IBTR)
  - chest wall
  - mastectomy scar and/or skin
  - axillary or internal mammary lymph nodes

最初の同側乳房・胸壁再発など
切除をしていること

- **Complete gross excision of recurrence**
  - Negative or microscopically involved margins
- **No evidence of supraclavicular lymph nodes**
- **No evidence of distant metastasis**

CALOR Trial



- **Chemotherapy chosen by investigators**
  Recommendation: ≥ 2 drugs, 3 to 6 months of therapy

ILRR Radiation Therapy

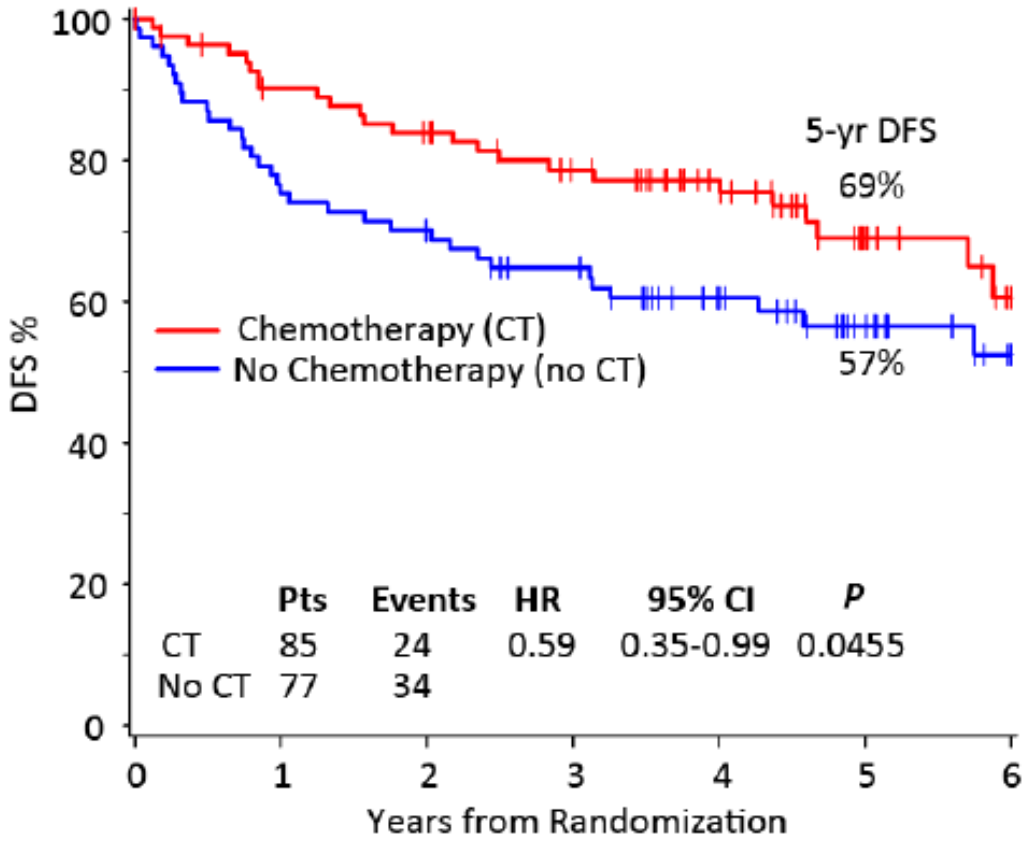
- Radiation therapy
  - Recommended for all patients
  - **Mandatory for patients with microscopically involved margins**
  - ≥ 40 Gy

当初は900例規模の試験であったがリクルートが進まなかった

Baseline Characteristics

	Chemotherapy N=85	No Chemotherapy N=77
Location of ILRR		
Breast	55%	53%
Mx scar/chest wall	32%	34%
Regional lymph nodes	13%	13%
ER Status of the ILRR		
Positive	66%	62%
PgR Status of the ILRR		
Positive	52%	45%

CALOR Trial – Disease-free Survival



Number at Risk

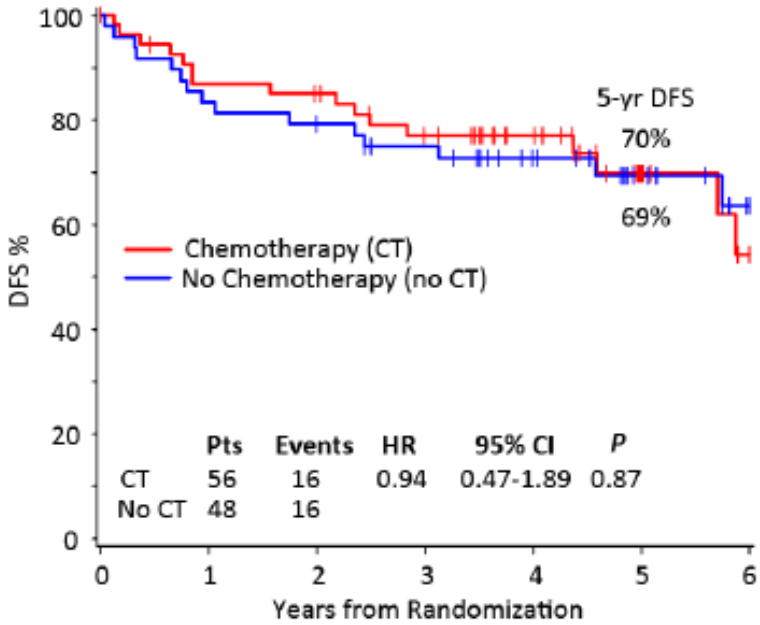
Chemotherapy	85	72	66	57	45	23	12
No Chemotherapy	77	58	53	46	34	21	10

Sites of First Failure after ILRR

	Chemotherapy N=85	No Chemotherapy N=77
Failures	24	34
Local / Regional	6	9
Distant	15	22
Soft tissue	0	2
Bone	8	5
Viscera	7	15
Contralateral breast	1	1
2nd non-breast malignancy	1	0
Deaths without failure	1	2

DFS ER Status

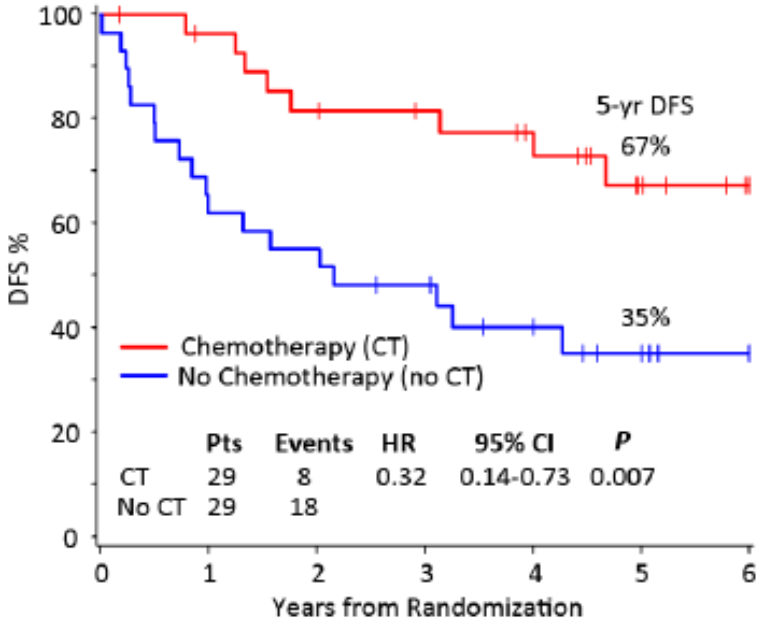
ER+



Number at Risk

Chemotherapy	56	47	44	37	28	13	6
No Chemotherapy	48	40	37	33	25	16	8

ER-

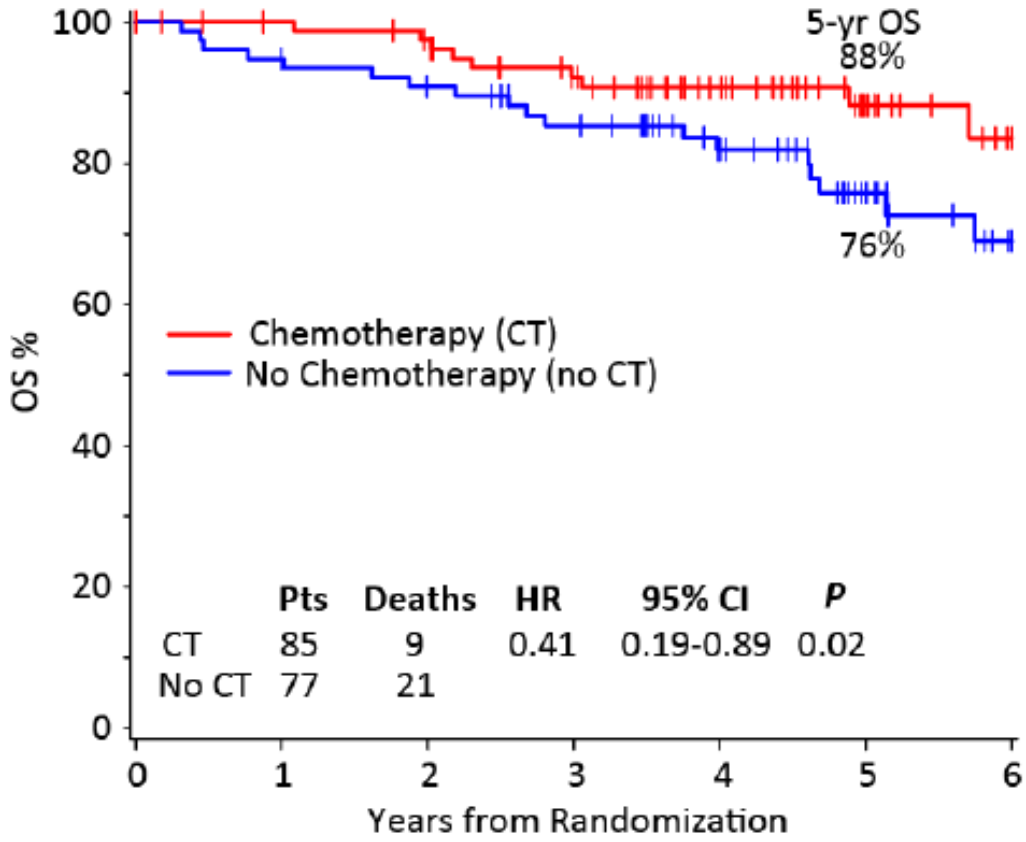


Number at Risk

Chemotherapy	29	26	22	20	17	10	6
No Chemotherapy	29	18	16	13	9	5	2

Univariate Interaction term: Treatment x ER: P = 0.044

CALOR Trial – Overall Survival

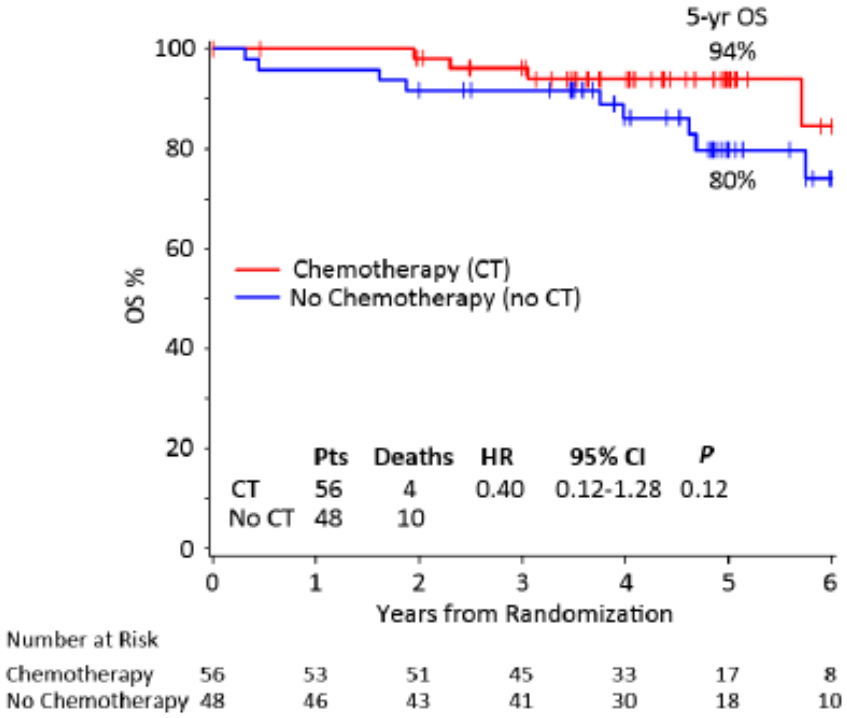


Number at Risk

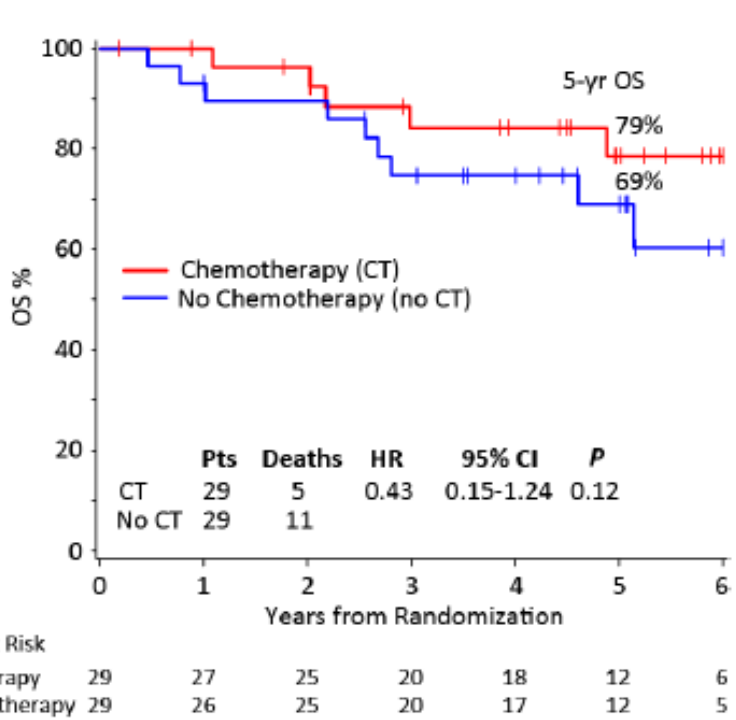
Chemotherapy	85	80	76	65	51	29	14
No Chemotherapy	77	72	68	61	47	30	15

OS by ER Status

ER+



ER-



局所再発切除後の補助化学療法

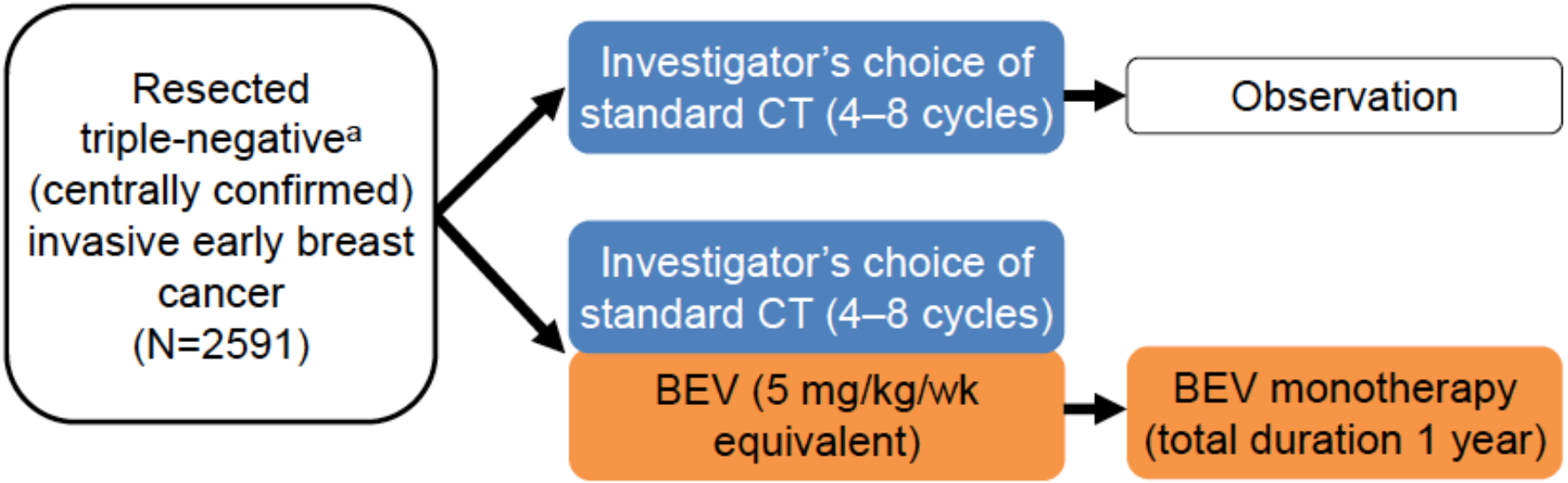
- 局所再発切除後の補助（？）化学療法は予後を改善する
- この利益はおそらくER-でのみ
- ER+はホルモン療法が実施されればよさそう

Primary results of BEATRICE, a randomized phase III trial evaluating adjuvant bevacizumab-containing therapy in triple-negative breast cancer

D Cameron[1], J Brown[2], R Dent[3], C Jackisch[4], J Mackey[5], X Pivot[6], G Steger[7], T Suter[8], M Toi[9], M Parmar[10], L Bubuteishvili-Pacaud[11], V Henschel[11], R Laeufle[11], R Bell[12]

[1]University of Edinburgh and NHS Lothian, Edinburgh, UK; [2]University of Leeds, Leeds, UK; [3]Sunnybrook Health Sciences Center and University of Toronto, Toronto, ON, Canada and National Cancer Center, Singapore, Singapore; [4]Klinikum Offenbach, Offenbach, Germany; [5]Cross Center Institute, Edmonton, Canada; [6]University Hospital Jean Minjoz, Besançon, France; [7]Medical University of Vienna, Vienna, Austria; [8]Bern University Hospital, Inselspital, Switzerland; [9]Kyoto University, Kyoto, Japan; [10]MRC Clinical Trials Unit, London, UK; [11]F Hoffmann-La Roche Ltd, Basel, Switzerland; [12]Andrew Love Cancer Centre, Geelong, Australia

BEATRICE:
Randomized open-label multicenter phase III trial



Stratification factors:

- Axillary nodal status (0 vs 1–3 vs ≥4)
- Adjuvant chemotherapy (anthracycline vs taxane vs anthracycline + taxane)
- Hormone receptor status (negative vs low)
- Surgery (breast-conserving vs mastectomy)

Chemotherapy options:

- Taxane based (≥4 cycles)
- Anthracycline based (≥4 cycles)
- Anthracycline + taxane (3–4 cycles each)

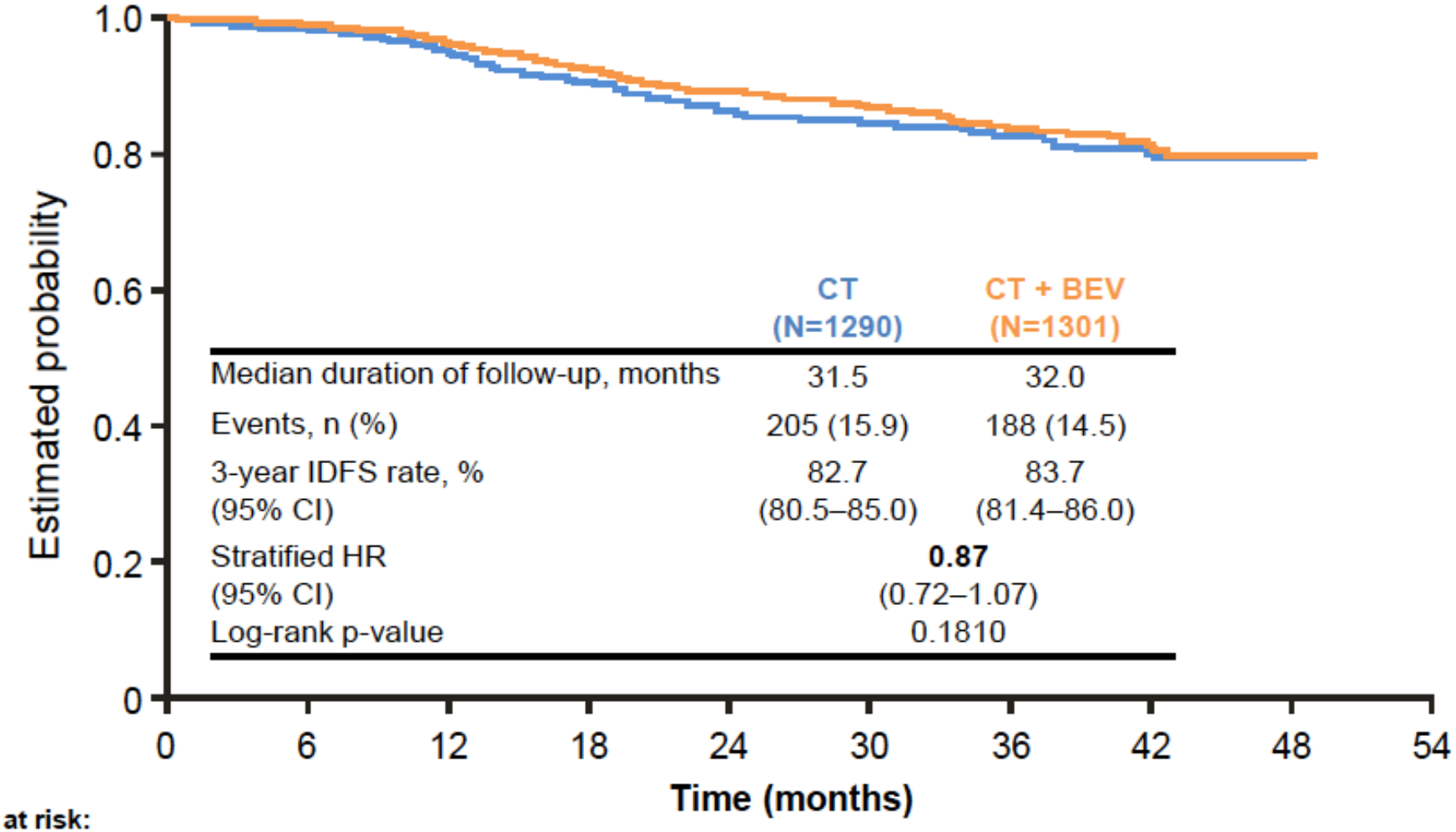
[a]HER2-negative and hormone receptor negative or low (total Allred score of 2 or 3; intensity score 1, proportion score 1 or 2)

Baseline demographics

Characteristic	CT (N=1290)	CT + BEV (N=1301)
Median age, years (range)	50 (22–80)	50 (20–84)
Tumor size (cm), % T1: >0–<2 T2: 2–<5 T3: ≥5	 35.5 59.0 5.5	 37.1 58.2 4.7
AJCC stage I, %	30.1	29.4
Hormone receptor status, % Negative Low	 94.9 5.1	 94.5 5.5
Positive axillary nodes, % 0 1–3 ≥4	 63.1 25.3 11.6	 63.3 24.8 11.9
Ductal/invasive histology, %	91.7	92.9
Grade 3 tumor, %	69.4	70.1
Breast-conserving surgery, %	63.3	63.6

Recruitment period: Dec 2007 to Mar 2010

Primary endpoint: IDFS[a]



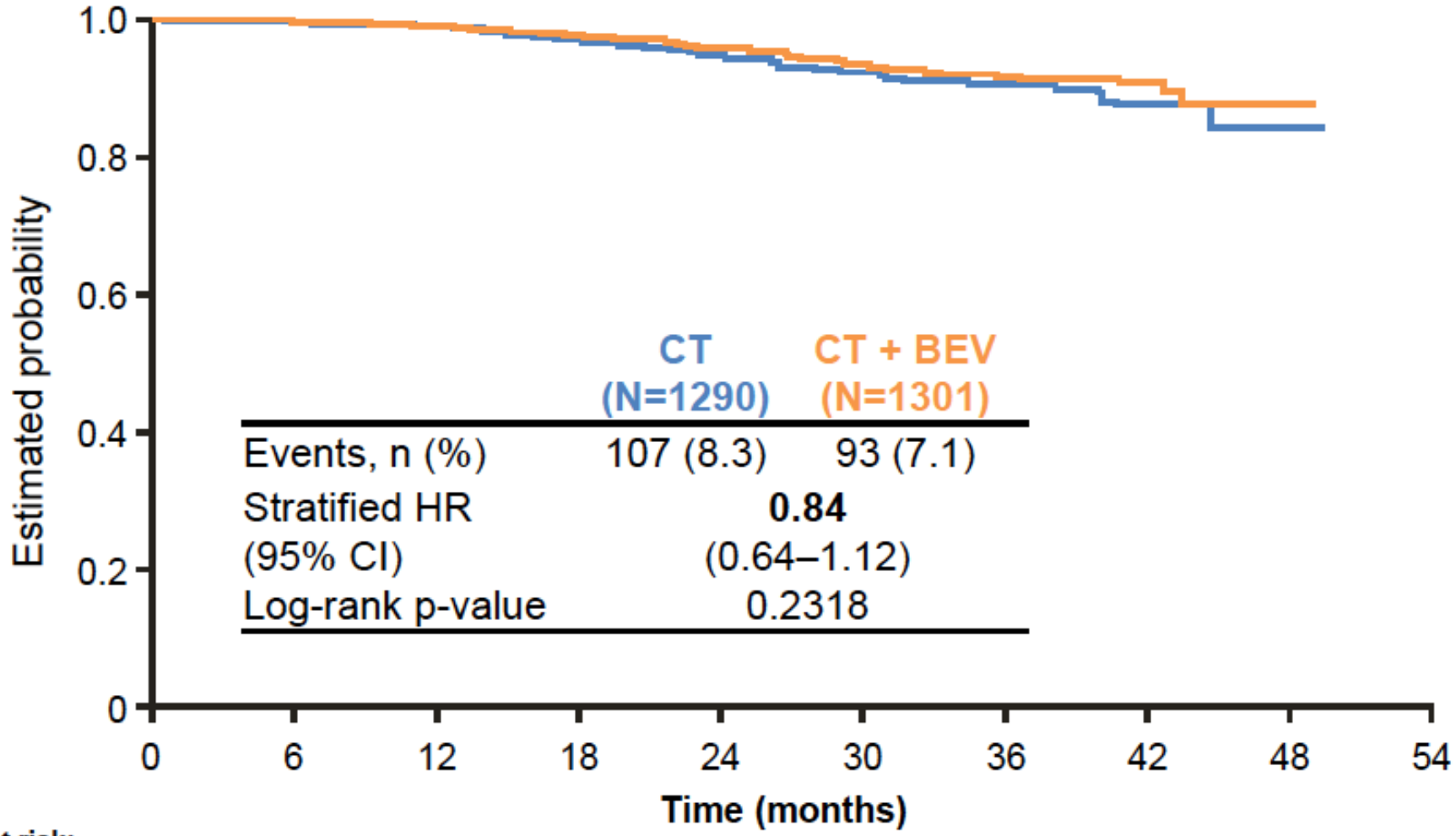
	CT (N=1290)	CT + BEV (N=1301)
Median duration of follow-up, months	31.5	32.0
Events, n (%)	205 (15.9)	188 (14.5)
3-year IDFS rate, % (95% CI)	82.7 (80.5–85.0)	83.7 (81.4–86.0)
Stratified HR (95% CI)	**0.87** (0.72–1.07)	
Log-rank p-value	0.1810	

No. at risk:

CT + BEV	1301	1244	1193	1129	1058	814	409	122	4	0
CT	1290	1221	1151	1086	994	772	383	105	2	0

[a]Intent to treat, not censored for non-protocol therapy

Interim OS (59% of required events)



	CT (N=1290)	CT + BEV (N=1301)
Events, n (%)	107 (8.3)	93 (7.1)
Stratified HR	**0.84**	
(95% CI)	(0.64–1.12)	
Log-rank p-value	0.2318	

No. at risk:

CT + BEV	1301	1264	1234	1196	1130	863	443	128	4	0
CT	1290	1248	1215	1169	1087	831	424	113	4	0

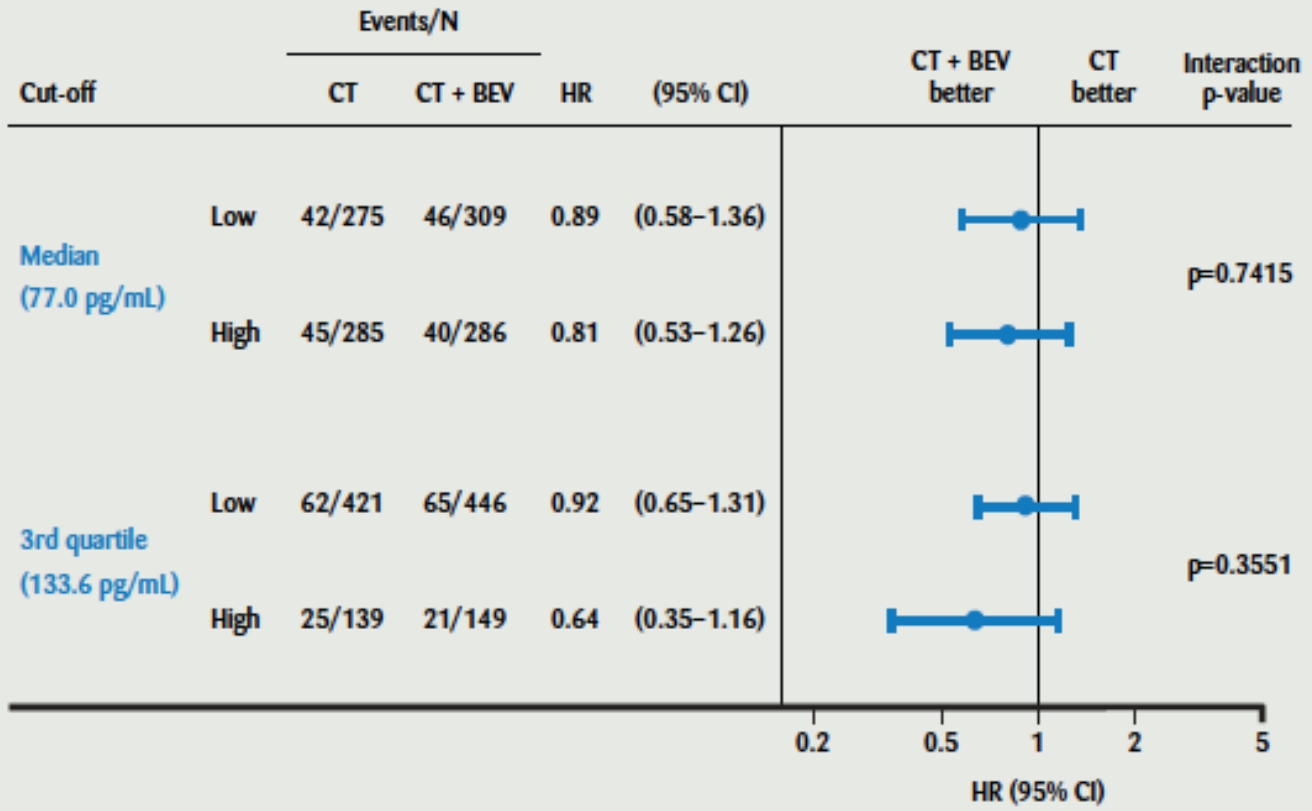
ベバシズマブの血液中バイオマーカー候補

- Plasma VEGF-A H
  - AVADO (PFS in BC)
- Plasma VEGFR2 H
  - AVADO (PFS in BC)
- Plasma ICAM-1 L
  - ECOG4599, AVAIL (PFS, OS in NSCLC)
- Plasma bFGF H
  - AVAIL (PFS in NSCLC)
- Plasma E-Selectin
  - ECOG4599 (PFS in NSCLC)

有意差がみられたもの

BEATRICE試験のバイオマーカー研究
Plasma VEGF-A

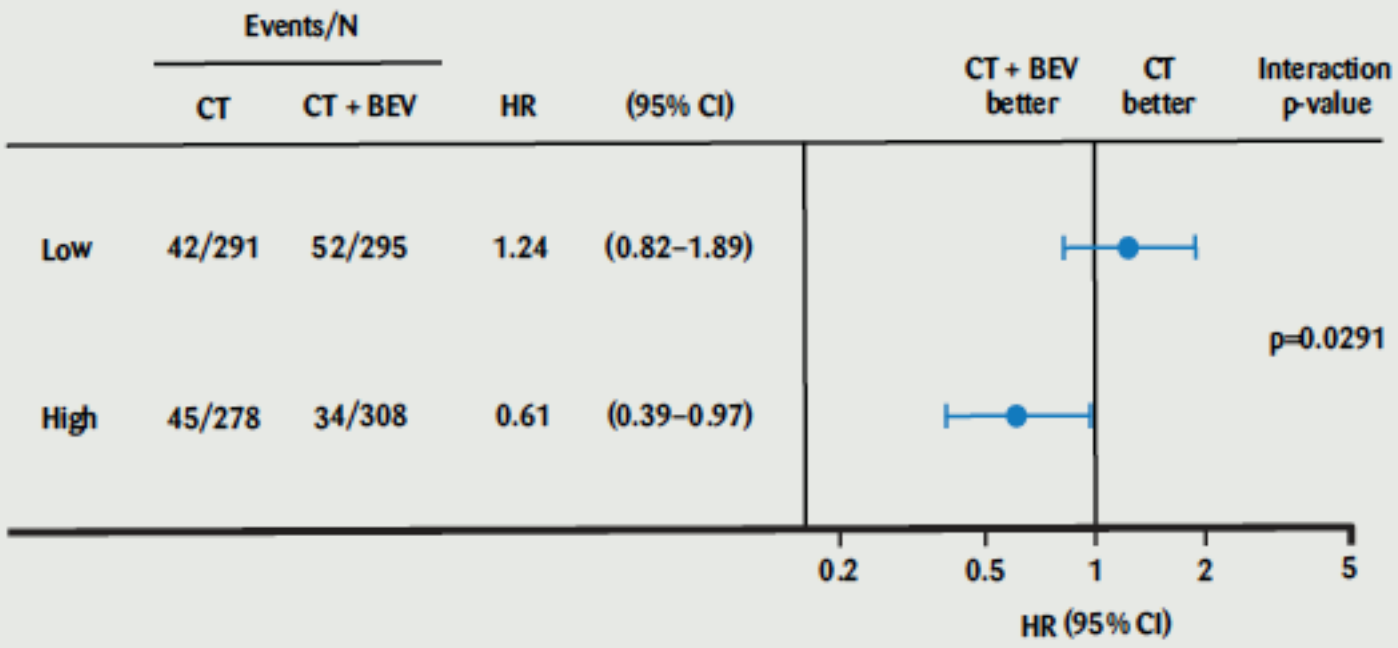
Figure 2. IDFS according to baseline plasma VEGF-A (median vs third quartile cut-off)



Carmeliet P et al. P3-06-34 SABCS2012

BEATRICE試験のバイオマーカー研究
Plasma VEGFR2

Figure 4. IDFS according to baseline plasma VEGFR-2 (median cut-off)



Median plasma VEGFR-2 concentration = 10.2 ng/mL.

ベバシズマブによる術後補助療法試験

- TNBCを対象としたベバシズマブによる術後補助療法では予後改善はなし
- 比較的予後のよい群がエントリーされていた
- バイオマーカー層別ができる日が来るか？

Trastuzumab plus Adjuvant Chemotherapy for HER2-positive Breast Cancer: Final Planned Joint Analysis of Overall Survival from NSABP B-31 and NCCTG N9831

EH Romond[1,2], VJ Suman[3], J-H Jeong[1,4], GW Sledge, Jr.[5], CE Geyer, Jr.[1,6], S Martino[7], P Rastogi[1,8], J Gralow[9], SM Swain[1,10], E Winer[11], G Colon-Otero[12], C Hudis[13], S Paik[1], N Davidson[8], EP Mamounas[14], JA Zujewski[15], N Wolmark[16], EA Perez[12]

[1]National Surgical Adjuvant Breast and Bowel Project Operations and Biostatistical Centers; [2]University of Kentucky; [3]Mayo Clinic; [4]Department of Biostatistics, University of Pittsburgh Graduate School of Public Health; [5]IU Simon Cancer Center; [6]University of Texas Southwestern Medical Center; [7]The Angeles Clinic and Research Institute; [8]University of Pittsburgh Cancer Institute; [9]University of Washington; [10]Medstar Washington Hospital Center; [11]Dana-Farber Cancer Institute; [12]Mayo Clinic, Jacksonville; [13]Memorial Sloan-Kettering Cancer Center; [14]Aultman Hospital; [15]Division of Cancer Therapy and Diagnosis, Cancer Therapy Evaluation Program, National Cancer Institute, National Institutes of Health, DHHS; [16]Allegheny Cancer Center Allegheny General Hospital

San Antonio Breast Cancer Symposium – December 4-8, 2012

Abstract #S5-5

NSABP B-31

Arm 1

Arm 2

NCCTG N9831

Arm A

Arm C

= doxorubicin/cyclophosphamide (AC) 60/600 mg/m^2 q 3 wk x 4

= paclitaxel (P) 175 mg/m^2 q 3 wk x 4

= paclitaxel (P) 80 mg/m^2/wk x 12

= trastuzumab (H) 4mg/kg LD + 2 mg/kg/wk x 51

分子標的治療の夜明けを感じた
最も感動した発表 2005年ASCO

NCCTG N9831 / NSABP B-31 joint analysis
Dr. Romond EH　　(5/16 2005, ASCO meeting)

"Thank you Dr. Sledge.

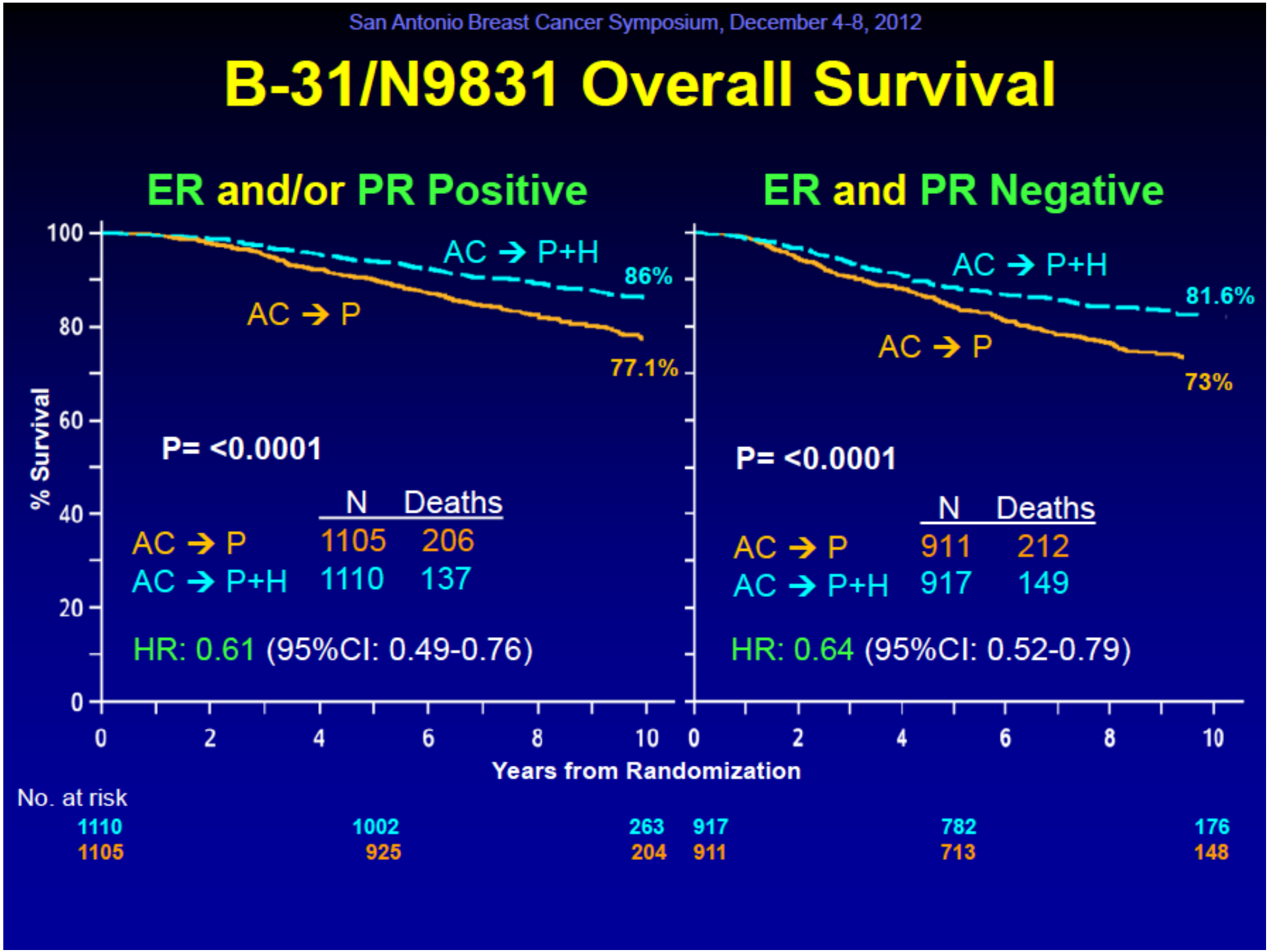
On behalf of 3,351 women who contributed to this trial,

secondary on behalf of my colleague...　"

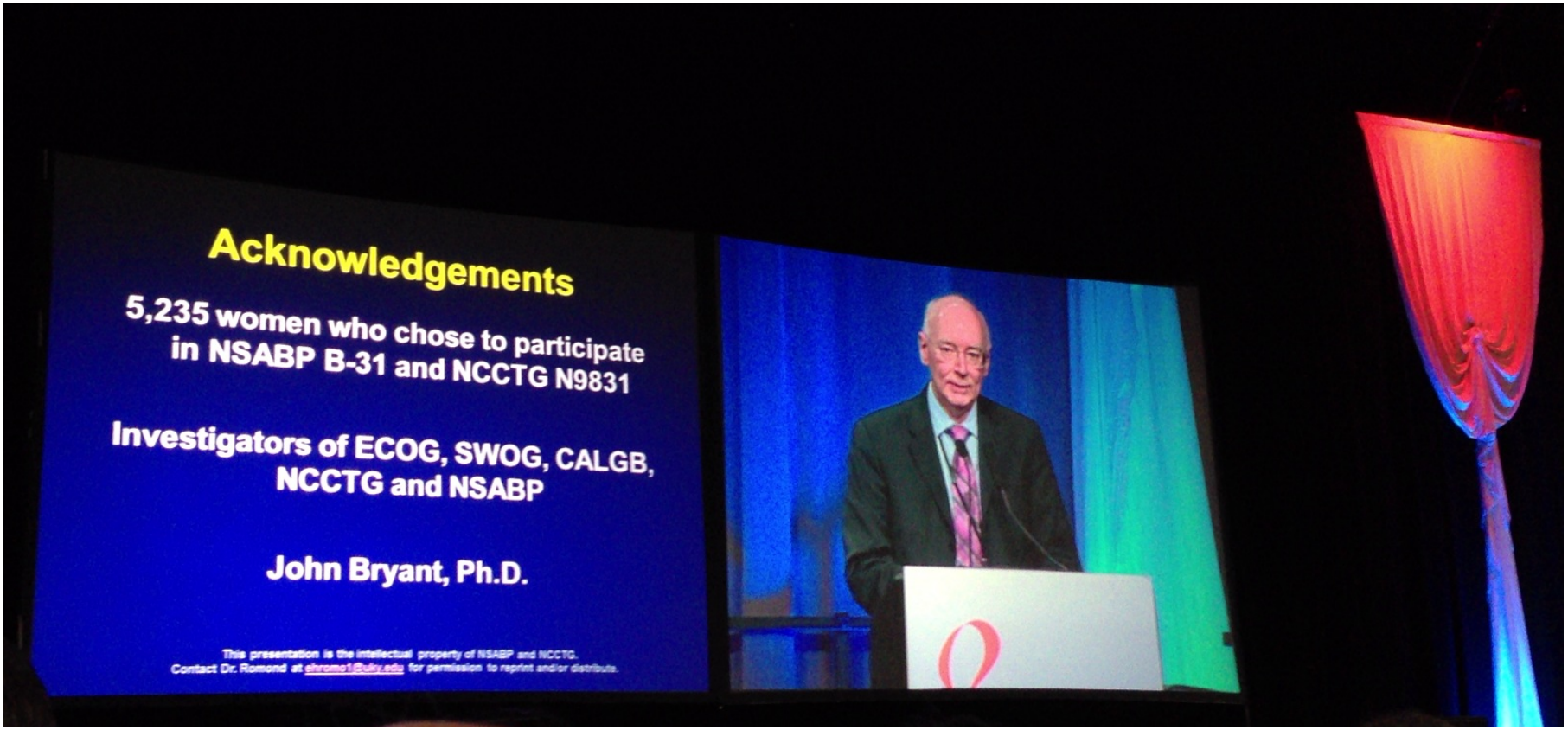
佐治重衡　2009年CSPOR年会

San Antonio Breast Cancer Symposium, December 4-8, 2012

B-31/N9831 Overall Survival



8.4年のフォローアップ期間を経て
2005年の再演が・・・



ご静聴ありがとうございました