29ª Sesiones interhospitalarias madrileñas de cáncer de mama

Fecha:
Martes, 10 de Junio de 2014.
Hora:
15.00-16.00. Recepción
16.00-17.30. Sesión Clínica

Con la colaboración de:

InstitutoRoche

Novedades bibliográficas en Cáncer de Mama segundo trimestre 2014

DR LUIS MANSO
UNIDAD TUMORES DE MAMA Y GINECOLÓGICOS
HOSPITAL 12 DE OCTUBRE
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1. miR-30a suppresses **breast cancer** cell proliferation and migration by targeting Eya2.
Fu J, Xu X, Kang L, Zhou L, Wang S, Lu J, Cheng L, Fan Z, Yuan B, Tian P, Zheng X, Yu C, Ye Q, Lv Z.
Biochem Biophys Res Commun. 2014 Mar 7;445(2):314-9. doi: 10.1016/j.bbrc.2014.01.174. Epub 2014 Feb 4.
PMID: 24508260 [PubMed - indexed for MEDLINE]
Related citations

2. The prognostic value of Ki67 in systemically untreated patients with node-negative **breast cancer**.
Pathmanathan N, Balleine RL, Jayasinghe UW, Bilinski KL, Provan PJ, Byth K, Bilous AM, Salisbury EL, Boyages J.
J Clin Pathol. 2014 Mar;67(3):222-8. doi: 10.1136/jclinpath-2013-201793. Epub 2014 Jan 8.
PMID: 24403187 [PubMed - indexed for MEDLINE]
Related citations

MET is a potential target for use in combination therapy with EGFR inhibition in triple-negative/basal-


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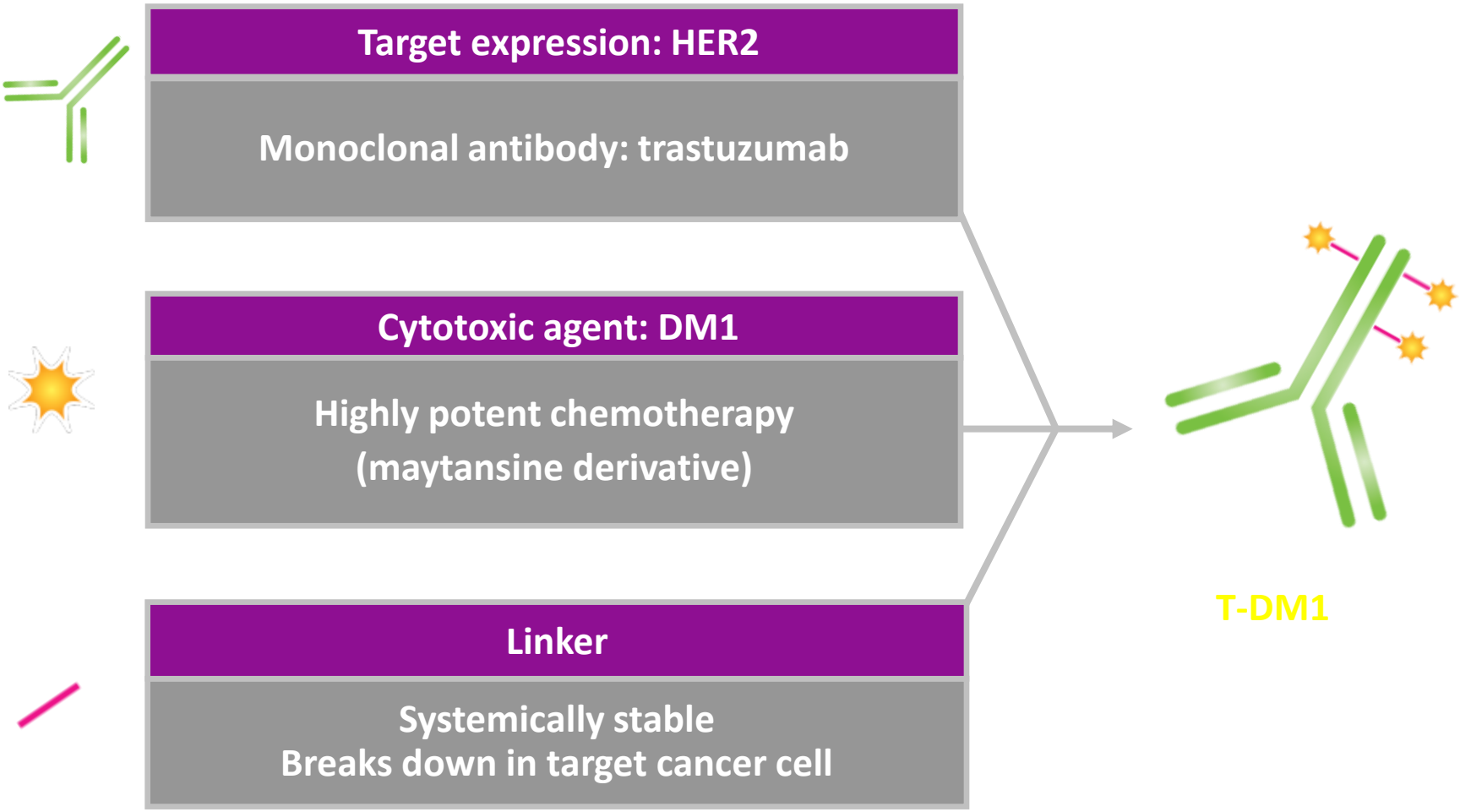
Trastuzumab emtansine versus treatment of physician's choice for pretreated HER2-positive advanced breast cancer (TH3RESA): a randomised, open-label, phase 3 trial

Ian E Krop, Sung-Bae Kim, Antonio González-Martín, Patricia M LoRusso, Jean-Marc Ferrero, Melanie Smitt, Ron Yu, Abraham C F Leung, Hans Wildiers, on behalf of the TH3RESA study collaborators*

Lancet Oncol 2014; 15: 689–99 Published **Online** May 2, 2014



Trastuzumab emtansine versus treatment of physician's choice for pretreated HER2-positive advanced breast cancer (TH3RESA): a randomised, open-label, phase 3 trial

*Ian E Krop, Sung-Bae Kim, Antonio González-Martín, Patricia M LoRusso, Jean-Marc Ferrero, Melanie Smitt, Ron Yu, Abraham C F Leung, Hans Wildiers, on behalf of the TH3RESA study collaborators**

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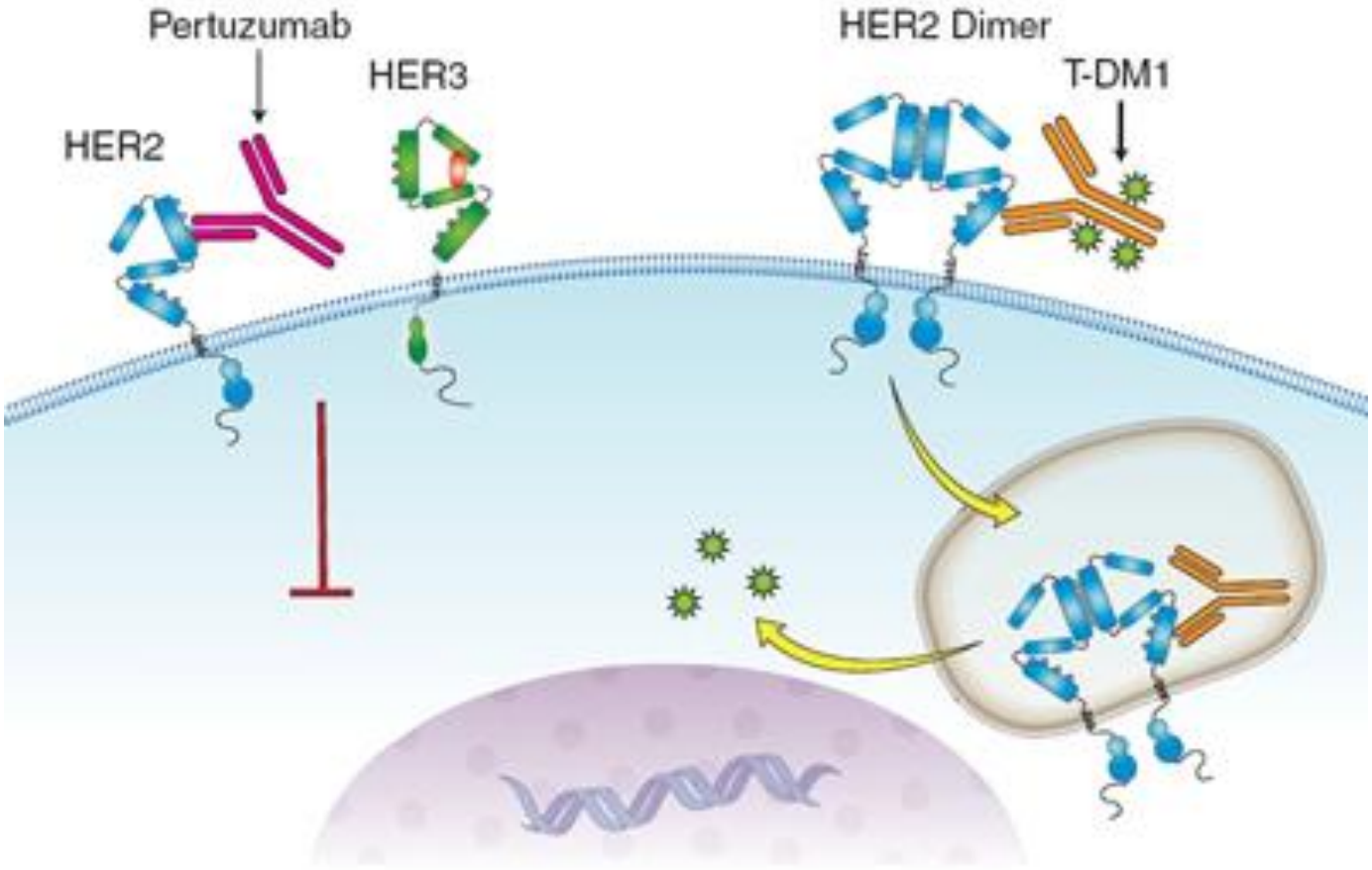
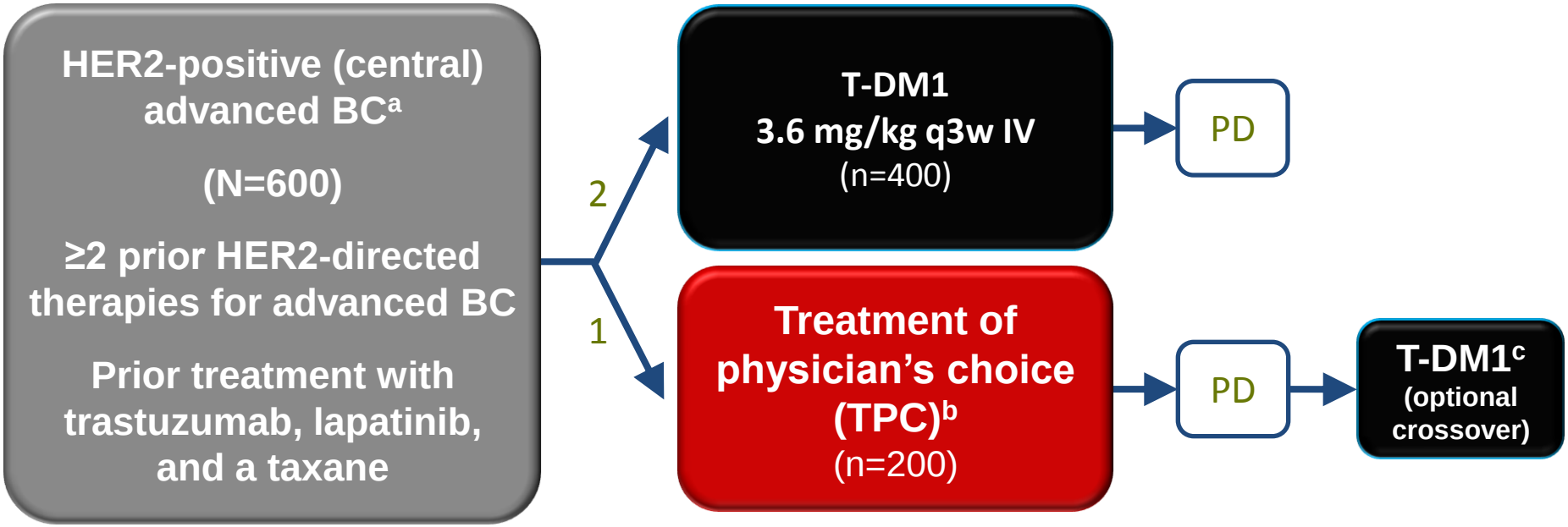


TH3RESA Study Schema



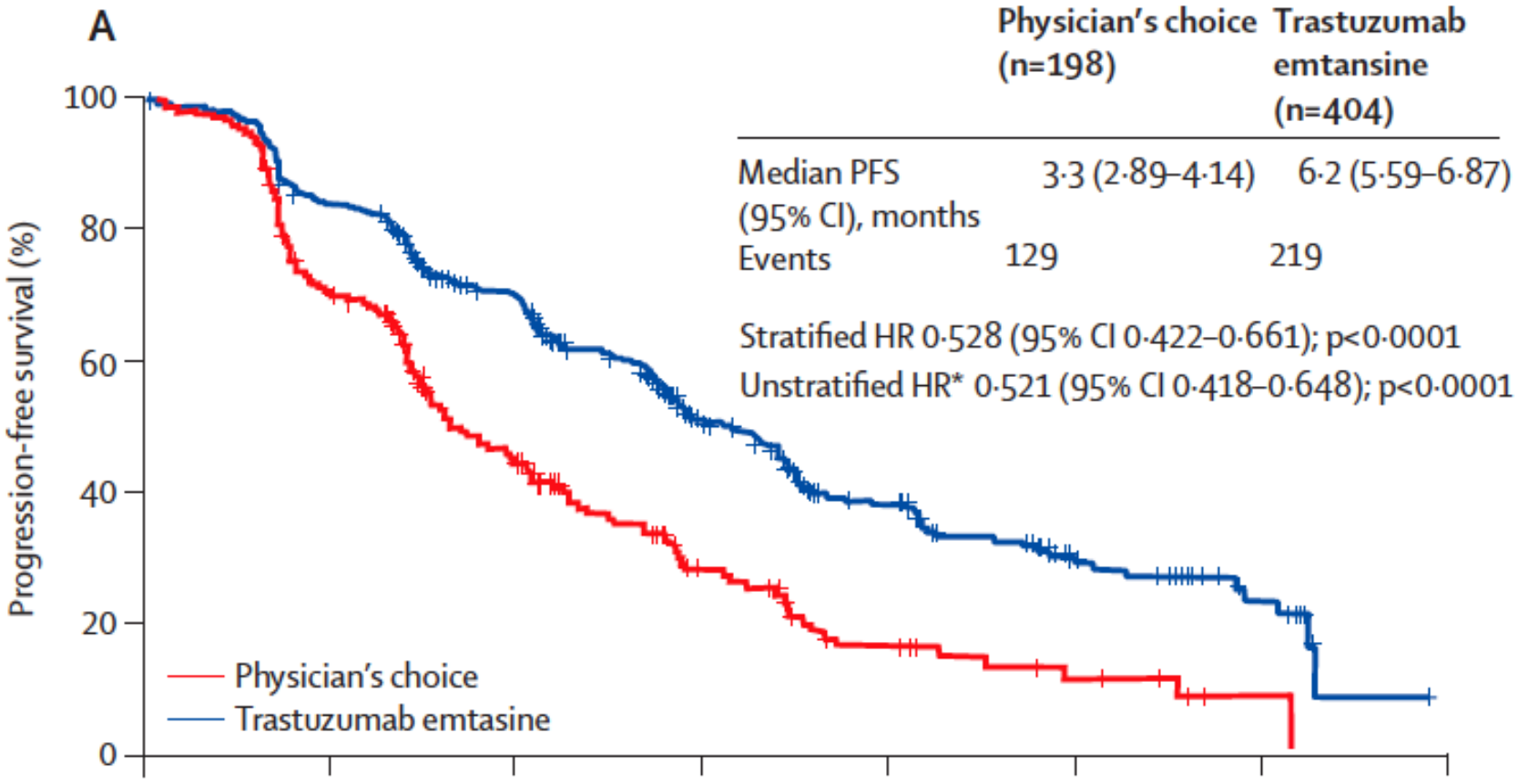
- **Stratification factors:** World region, number of prior regimens for advanced BC,[d] presence of visceral disease
- **Co-primary endpoints:** PFS by investigator and OS
- **Key secondary endpoints:** ORR by investigator and safety

[a] Advanced BC includes MBC and unresectable locally advanced/recurrent BC.
[b] TPC could have been single-agent chemotherapy, hormonal therapy, or HER2-directed therapy, or a combination of a HER2-directed therapy with a chemotherapy, hormonal therapy, or other HER2-directed therapy.
[c] First patient in: Sep 2011. Study amended Sep 2012 (following EMILIA 2nd interim OS results) to allow patients in the TPC arm to receive T-DM1 after documented PD.
[d] Excluding single-agent hormonal therapy.
BC, breast cancer; IV, intravenous; ORR, objective response rate; PD, progressive disease; q3w, every 3 weeks.

	Physician's choice (n=198)	Trastuzumab emtansine (n=404)
Age (years)	54 (28–85)	53 (27–89)
<65	164 (83%)	345 (85%)
65–74	28 (14%)	46 (11%)
≥75	6 (3%)	13 (3%)
World region		
USA	48 (24%)	99 (25%)
Western Europe	85 (43%)	171 (42%)
Other	65 (33%)	134 (33%)
Race		
White	161 (81%)	325 (80%)
Asian	24 (12%)	57 (14%)
Other*	13 (7%)	22 (5%)
ECOG PS†		
0	82 (41%)	180 (45%)
1	101 (51%)	200 (50%)
2	15 (8%)	22 (5%)
Hormone receptor status‡		
ER positive and/or PR positive	103 (52%)	208 (51%)
ER negative and PR negative	85 (43%)	185 (46%)
Unknown	10 (5%)	11 (3%)
Visceral disease involvement	150 (76%)	302 (75%)
Disease extent		
Metastatic	187 (94%)	391 (97%)
Unresectable locally advanced or recurrent	11 (6%)	13 (3%)
Measurable disease	163 (82%)	345 (85%)
Number of previous regimens for advanced breast cancer§¶	4 (1–19)	4 (1–14)
≤3	78 (39%)	131 (33%)
4–5	65 (33%)	149 (37%)
>5	55 (28%)	122 (30%)
Previous exposure to HER2-directed therapy		
Trastuzumab	198 (100%)	404 (100%)
Duration (months)	23·7 (0·7–508·8)	24·3 (1·4–140·5)
Lapatinib	198 (100%)	404 (100%)
Duration (months)	7·62 (0·1–48·0)	7·98 (0·1–71·2)
Previously treated asymptomatic brain metastasis	27 (14%)	40 (10%)

	Physician's choice (n=185)
Treatment category	
Single-agent trastuzumab emtansine	1 (<1%)*
Combination with HER2-directed agent	153 (83%)
Trastuzumab plus chemotherapy	126 (68%)
Trastuzumab plus lapatinib	19 (10%)
Trastuzumab plus hormonal therapy	3 (2%)
Lapatinib plus chemotherapy	5 (3%)
Single-agent chemotherapy	31 (17%)
Chemotherapy agents†	
Vinorelbine	59 (32%)
Gemcitabine	29 (16%)
Eribulin	16 (9%)
Paclitaxel	16 (9%)
Docetaxel	10 (5%)
Other	32 (17%)

All randomised patients

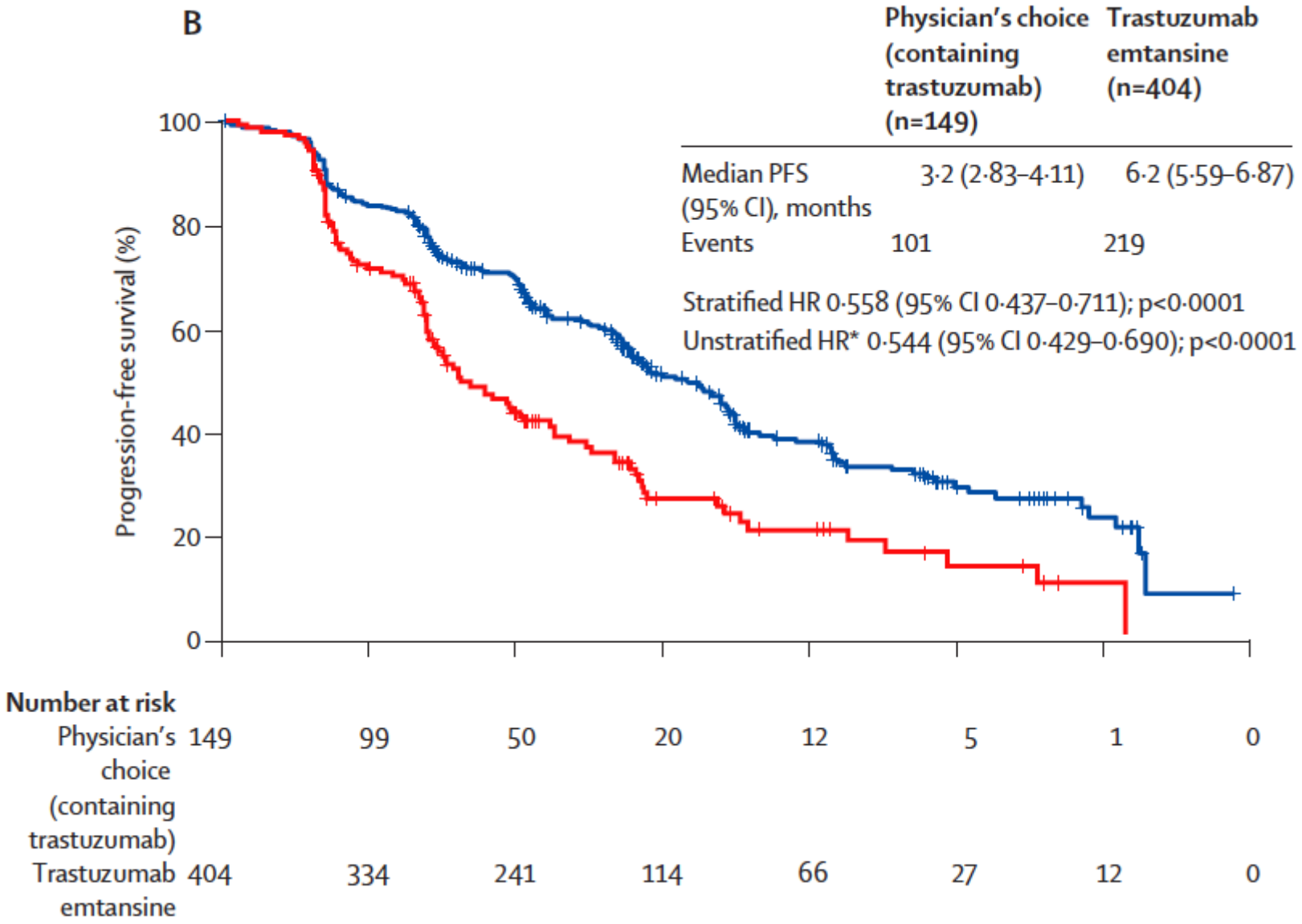


	Physician's choice (n=198)	Trastuzumab emtansine (n=404)
Median PFS (95% CI), months	3·3 (2·89–4·14)	6·2 (5·59–6·87)
Events	129	219

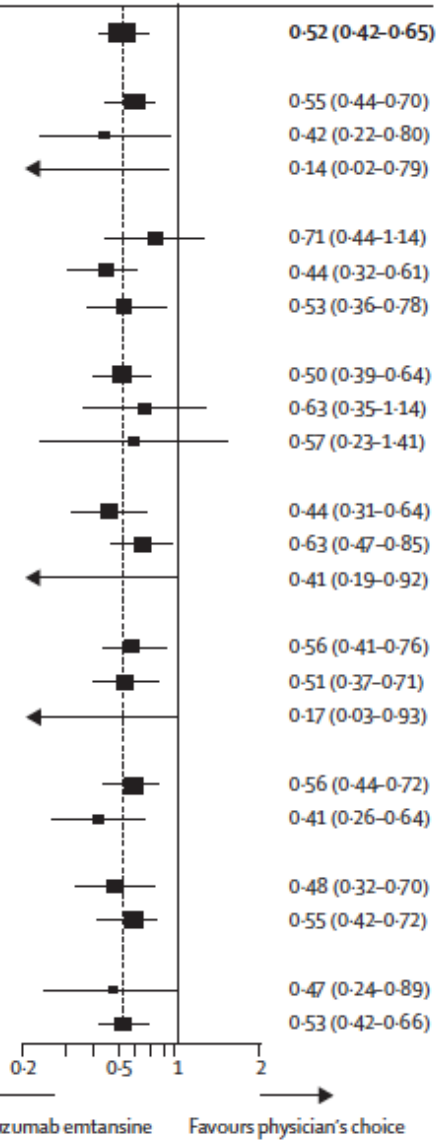
Stratified HR 0·528 (95% CI 0·422–0·661); p<0·0001
Unstratified HR* 0·521 (95% CI 0·418–0·648); p<0·0001

Number at risk								
Physician's choice	198	120	62	28	13	6	1	0
Trastuzumab emtansine	404	334	241	114	66	27	12	0

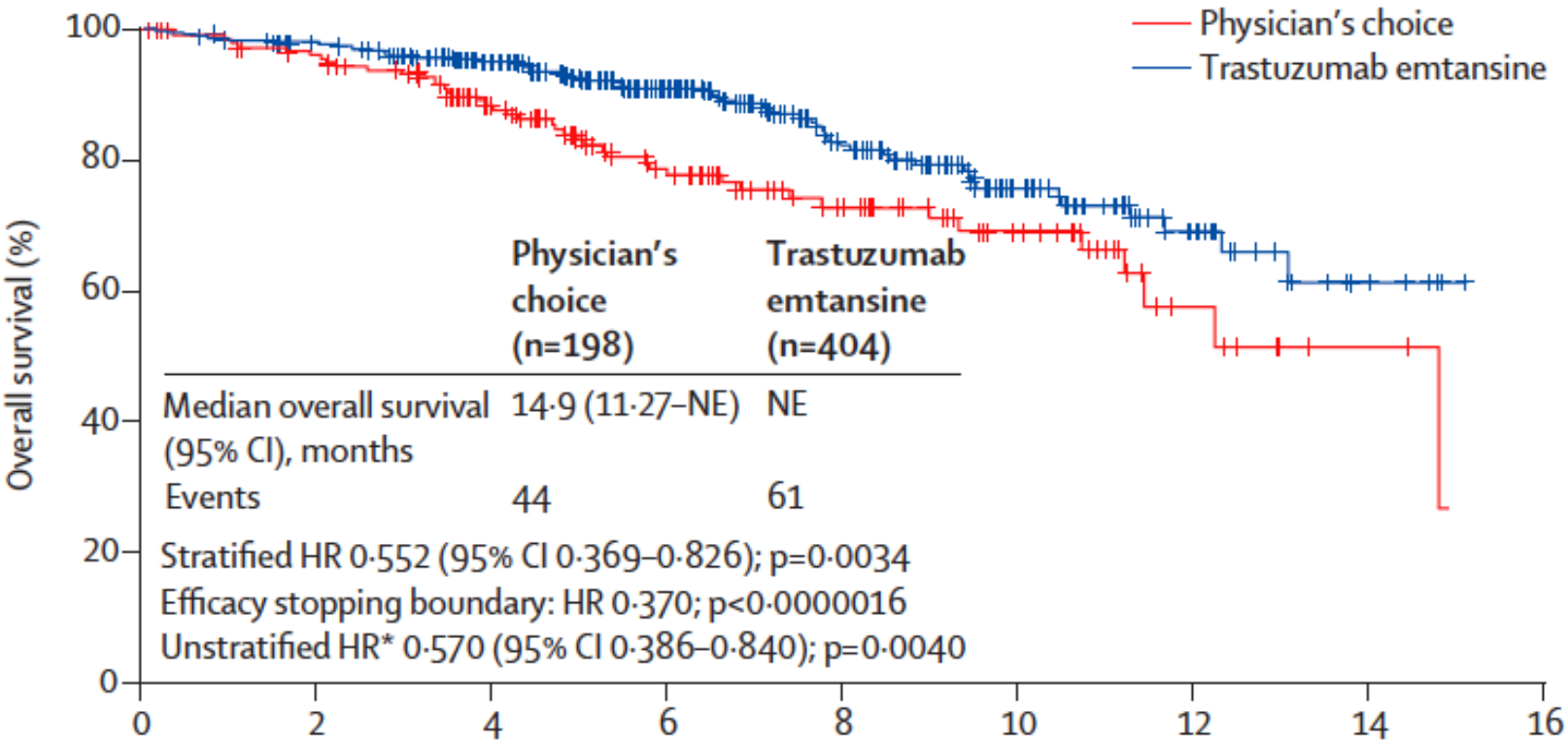
Trastuzumab containing regimen



	All patients, N	Physician's choice			Trastuzumab emtansine			HR* (95% CI)
		n	Event	Median PFS, months	n	Event	Median PFS, months	
All patients	**602**	**198**	**129**	**3·3**	**404**	**219**	**6·2**	**0·52 (0·42–0·65)**
Age group								
<65 years	509	164	108	3·4	345	191	5·8	0·55 (0·44–0·70)
65–74 years	74	28	17	3·2	46	25	6·9	0·42 (0·22–0·80)
≥75 years	19	6	4	3·0	13	3	NE	0·14 (0·02–0·79)
World region								
USA	147	48	24	4·1	99	58	5·8	0·71 (0·44–1·14)
Western Europe	256	85	61	3·2	171	91	6·9	0·44 (0·32–0·61)
Other	199	65	44	3·1	134	70	5·8	0·53 (0·36–0·78)
Race								
White	488	161	104	3·4	325	177	6·3	0·50 (0·39–0·64)
Asian	81	24	17	2·8	57	30	5·4	0·63 (0·35–1·14)
Other	35	13	8	3·3	22	12	6·6	0·57 (0·23–1·41)
ECOG PS								
0	262	82	48	3·6	180	84	7·0	0·44 (0·31–0·64)
1	301	101	68	3·1	200	120	5·4	0·63 (0·47–0·85)
2	37	15	13	1·6	22	13	6·9	0·41 (0·19–0·92)
ER and PR status†								
ER+ and/or PR+	311	103	66	3·9	208	109	5·9	0·56 (0·41–0·76)
ER– and PR–	270	85	58	2·9	185	105	6·0	0·51 (0·37–0·71)
Unknown	21	10	5	3·9	11	5	8·3	0·17 (0·03–0·93)
Disease involvement								
Visceral	452	150	95	3·4	302	168	6·2	0·56 (0·44–0·72)
Non-visceral	150	48	34	3·1	102	51	6·7	0·41 (0·26–0·64)
Number of previous regimens for advanced disease‡								
≤3	209	78	49	3·3	131	60	6·9	0·48 (0·32–0·70)
>3	391	120	80	3·4	271	158	5·8	0·55 (0·42–0·72)
Previously treated asymptomatic brain metastasis								
Yes	67	27	16	2·9	40	24	5·8	0·47 (0·24–0·89)
No	535	171	113	3·6	364	195	6·2	0·53 (0·42–0·66)



Overall survival at first interim analysis



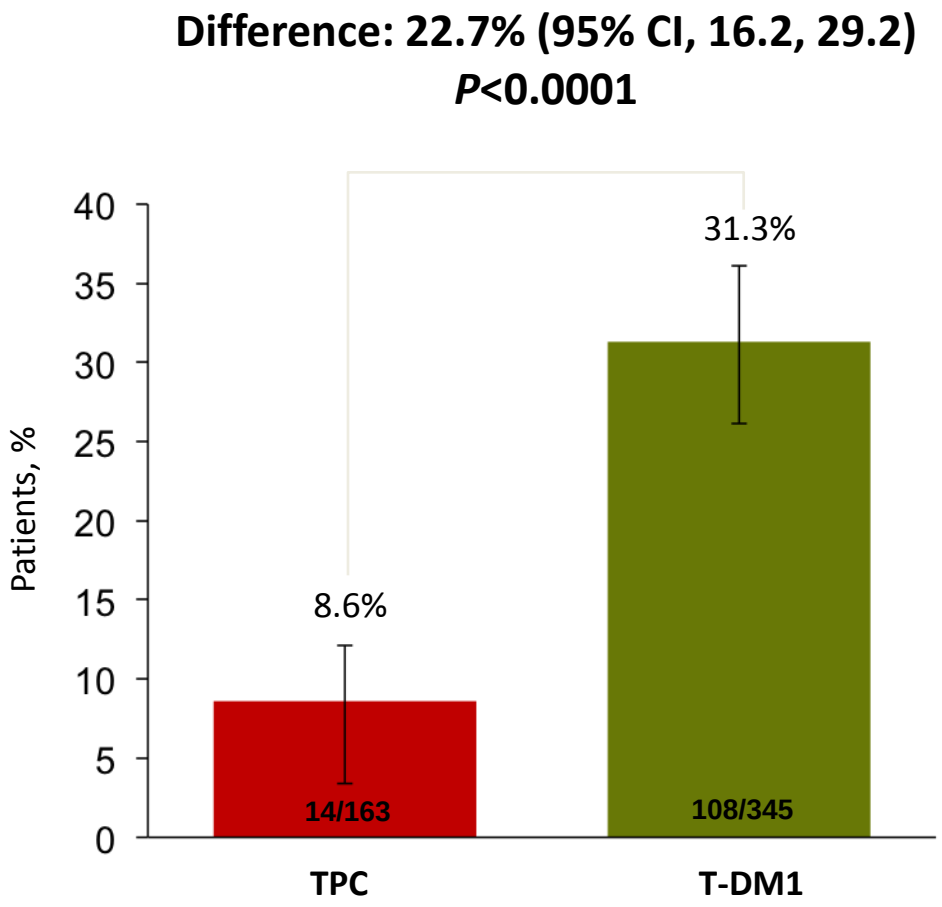
	Physician's choice (n=198)	Trastuzumab emtansine (n=404)
Median overall survival (95% CI), months	14·9 (11·27–NE)	NE
Events	44	61

Stratified HR 0·552 (95% CI 0·369–0·826); p=0·0034
Efficacy stopping boundary: HR 0·370; p<0·0000016
Unstratified HR* 0·570 (95% CI 0·386–0·840); p=0·0040

Number at risk

Physician's choice	198	169	125	80	51	30	9	3	0
Trastuzumab emtansine	404	381	316	207	127	65	30	7	0

ORR in Patients With Measurable Disease



Overview of AEs

	TPC (n=184[a])	T-DM1 (n=403[a])
All-grade AEs, %	88.6	93.5
Grade ≥3 AEs,[b] %	43.5	32.3
AEs leading to treatment discontinuation,[c] %	10.9	6.7
AEs leading to dose reduction, %	19.6	9.4
LVEF <50% and ≥15% decrease from baseline,[d] %	1.1	1.5

[a] One patient randomized to the TPC arm received 2 cycles of T-DM1 by mistake; this patient was included in the T-DM1 group for safety analyses.
[b] Grade 5 AEs: TPC, 1.6% (n=3); T-DM1, 1.2% (n=5). Three were considered related to T-DM1: hepatic encephalopathy, subarachnoid hemorrhage, and pneumonitis. One was considered related to TPC: noncardiogenic pulmonary edema.
[c] For any study drug.
[d] No patient experienced an LVEF <40%.
LVEF, left ventricular ejection fraction.

Grade ≥3 AEs With Incidence ≥2% in Either Arm[a]

	TPC (n=184)		T-DM1 (n=403)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Nonhematologic AEs, %				
Diarrhea	21.7	**4.3**	9.9	0.7
Abdominal pain	12.5	2.7	6.5	1.2
AST increased	5.4	2.2	8.4	2.2
Fatigue	25.0	2.2	27.0	2.0
Asthenia	15.8	2.2	15.6	1.0
Cellulitis	3.3	2.2	1.2	0.5
Pulmonary embolism	2.2	2.2	0.5	0.5
Dyspnea	9.2	1.6	9.9	2.0
Hematologic AEs, %				
Neutropenia	21.7	**15.8**	5.5	2.5
Febrile neutropenia	3.8	**3.8**	0.2	0.2
Anemia	10.3	2.7	8.9	2.7
Leukopenia	6.0	2.7	0.7	0.2
Thrombocytopenia	3.3	1.6	15.1	**4.7[b]**

[a] Medical Dictionary for Regulatory Activities (MedDRA) preferred term.

[b] Grade 5 subarachnoid hemorrhage was reported for 1 patient with grade 4 thrombocytopenia; grade 4 tumor hemorrhage was reported for 1 patient with grade 3 thrombocytopenia. The incidence of grade ≥3 hemorrhage of any type was 2.2% (T-DM1) and 0.5% (TPC).

AST, aspartate aminotransferase.

Highlighting indicates grade ≥3 AEs with >3% difference between the TPC and T-DM1 arms.

Conclusions

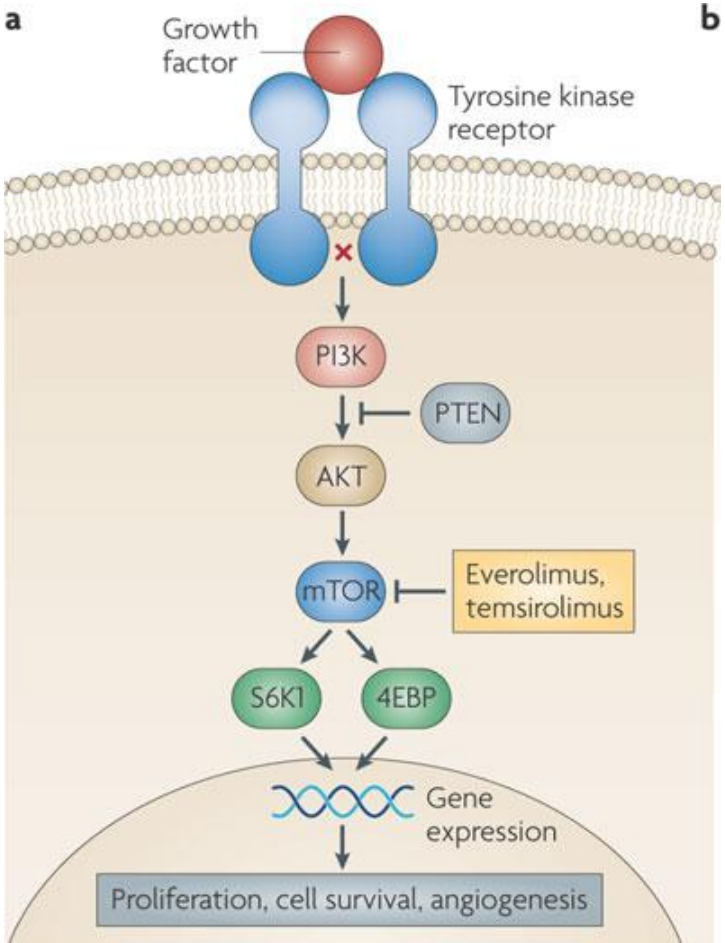
- **T-DM1 demonstrated improved efficacy and safety compared with TPC**
  - **Significant improvement in PFS**
    - HR=0.528; *P*<0.0001
    - A clear and consistent treatment effect across subgroups
  - **Interim OS favored T-DM1 but efficacy stopping boundary not crossed**
    - HR=0.552; *P*=0.0034
  - **Safety and ORR favored T-DM1**
    - Fewer grade ≥3 AEs with T-DM1 vs TPC: 32.3% vs 43.5%
    - Fewer discontinuations and dose reductions due to AEs with T-DM1
    - ORR 31.3% vs 8.6%, *P*<0.0001

- **These data reaffirm the results from the EMILIA study, demonstrating a consistent benefit with T-DM1 in patients with previously treated HER2-positive advanced BC**

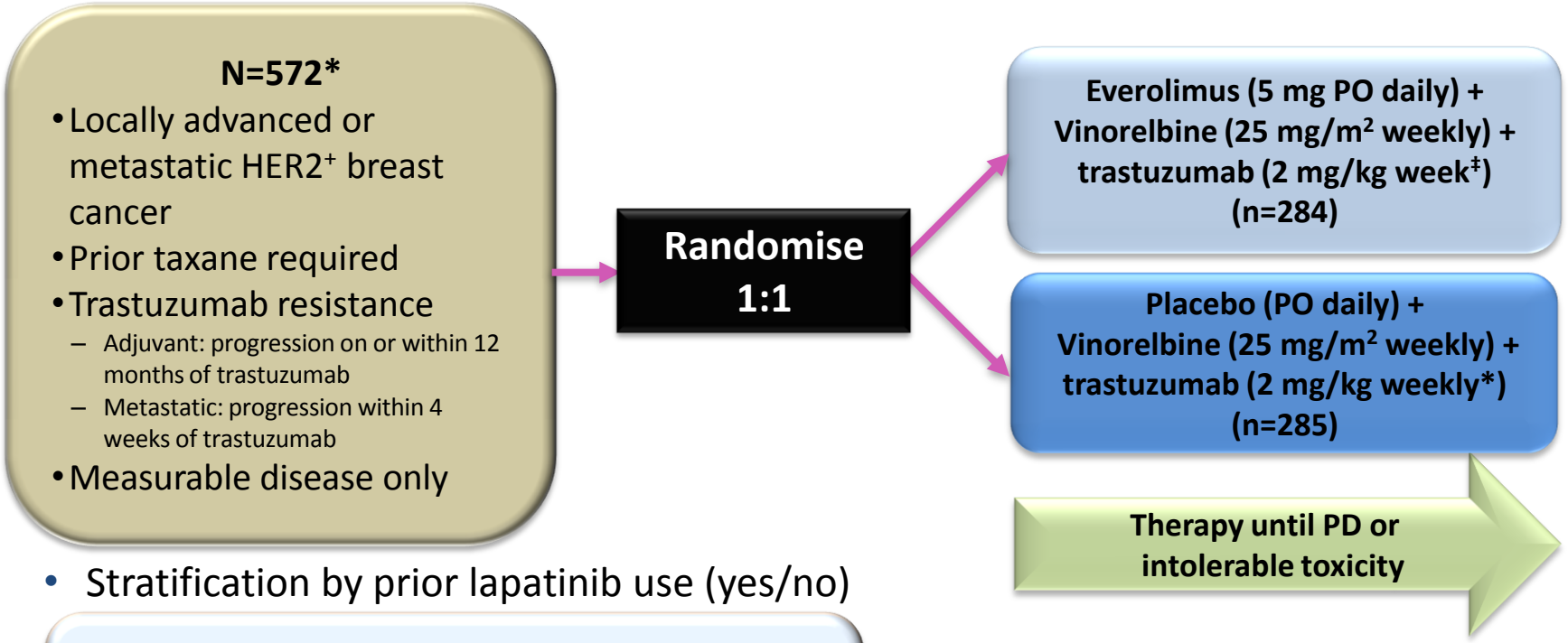
Everolimus for women with trastuzumab-resistant, HER2-positive, advanced breast cancer (BOLERO-3): a randomised, double-blind, placebo-controlled phase 3 trial

Fabrice André, Ruth O'Regan, Mustafa Ozguroglu, Masakazu Toi, Binghe Xu, Guy Jerusalem, Norikazu Masuda, Sharon Wilks, Francis Arena, Claudine Isaacs, Yoon-Sim Yap, Zsuzsanna Papai, Istvan Lang, Anne Armstrong, Guillermo Lerzo, Michelle White, Kunwei Shen, Jennifer Litton, David Chen, Yufen Zhang, Shyanne Ali, Tetiana Taran, Luca Gianni

Lancet Oncol 2014; 15: 580–91 Published **Online** April 15, 2014



BOLERO-3: Study design



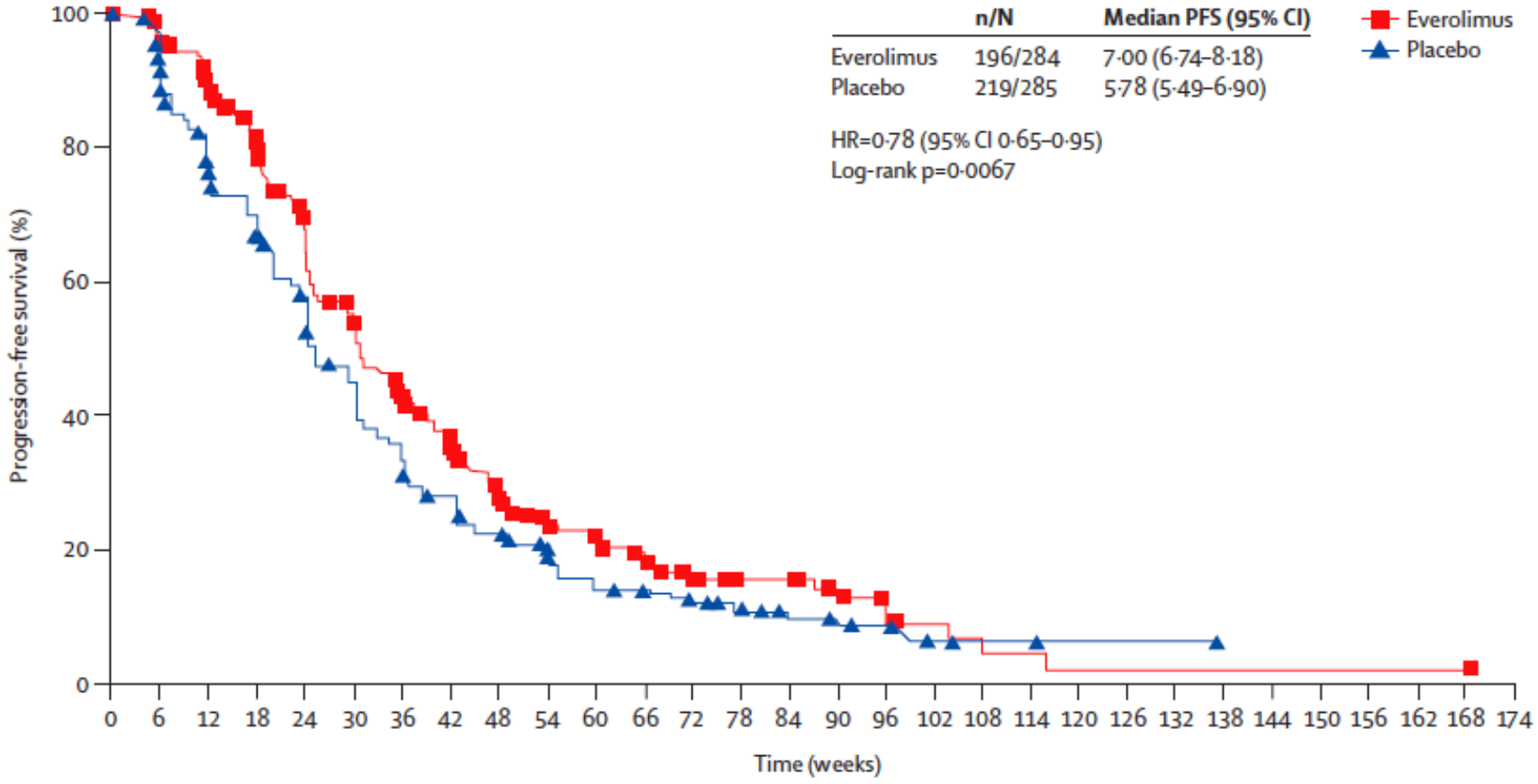
- Stratification by prior lapatinib use (yes/no)

Endpoints:
Primary: PFS
Secondary: OS, ORR, time to deterioration of ECOG PS, safety, DoR, CBR, and QoL

*Actual enrollment was 569; ‡Following a 4-mg/kg loading dose on day 1, cycle 1 (1 cycle = every 21 days).
CBR = clinical benefit rate; DoR = duration of response; ECOG = Eastern Cooperative Oncology Group; HER2 = human epidermal growth factor receptor 2; ORR = overall response rate; OS = overall survival; PD = progressive disease; PFS = progression-free survival; PO = oral; PS = performance status; QoL = quality of life.

O'Regan et al. Presentation at ASCO Annual Meeting 2013 (Abstract 505).

BOLERO-3: Primary endpoint progression-free survival by local assessment



Patients with High pS6 May Derive More Benefit from Addition of Everolimus

Subgroup	n	Events	Median PFS, weeks (95% CI)	HR (95% CI)
EVE pS6 high	23	15	29.4 (18.1, 55.1)	0.48 (0.24, 0.96)
PBO pS6 high	22	20	17.1 (11.7, 24.0)	
EVE pS6 low	66	47	24.9 (23.6, 31.0)	1.14 (0.77, 1.68)
PBO pS6 low	77	57	30.0 (24.0, 36.1)	

- Optimal high and low pS6 cut-point selected as ≥ and < 75th percentile (histo-score = 160)
- Marker-treatment interaction (*P* = 0.038)
- Shorter median PFS in high pS6 subgroup treated with placebo
- Median pS6 level shows little effect on treatment

Effect of PTEN Levels on Treatment Benefit from Addition of Everolimus

Subgroup	Therapy	n (# of Events)	Median PFS, wks (95% CI)	HR (95% CI)	*P* Value*
Subgroups defined by low or normal PTEN level					
H-score ≥ 50	EVE	100 (72)	30.1 (24.3, 35.6)	0.97 (0.71, 1.33)	0.11
	PBO	108 (85)	30.0 (24.0, 35.4)		
H-score < 50	EVE	15 (11)	41.4 (17.3, 66.9)	0.52 (0.21, 1.26)	
	PBO	14 (11)	23.7 (10.6, 25.1)		
Subgroups defined by optimal cut-point of PTEN level (20th %ile)					
H-score ≥ 20th %ile	EVE	89 (67)	30.1 (24.0, 35.3)	1.05 (0.75, 1.45)	0.01
	PBO	100 (78)	30.1 (24.0, 36.0)		
H-score < 20th %ile	EVE	26 (16)	41.9 (24.0, 53.1)	0.41 (0.20, 0.82)	
	PBO	22 (18)	23.1 (12.1, 24.7)		

- Median PFS gain is 18-19 weeks for the low PTEN subgroup

*Treatment-biomarker interaction.
PTEN optimal cut-point selected as ≥ and < 20th percentile. Histo-score = 100.

	Everolimus group (n=280)			Placebo group (n=282)		
	Grade 1–2	Grade 3	Grade 4	Grade 1–2	Grade 3	Grade 4
Neutropenia	24 (9%)	98 (35%)	106 (38%)	22 (8%)	90 (32%)	85 (30%)
Stomatitis	138 (49%)	37 (13%)	0	74 (26%)	4 (1%)	0
Anaemia	85 (30%)	47 (17%)	6 (2%)	66 (23%)	16 (6%)	1 (<1%)
Leucopenia	22 (8%)	85 (30%)	21 (8%)	23 (8%)	71 (25%)	11 (4%)
Fatigue	87 (31%)	33 (12%)	1 (<1%)	107 (38%)	11 (4%)	0
Pyrexia	101 (36%)	7 (3%)	0	62 (22%)	3 (1%)	0
Diarrhoea	96 (34%)	11 (4%)	0	84 (30%)	2 (<1%)	0
Nausea	91 (33%)	7 (3%)	0	100 (35%)	3 (1%)	0
Decreased appetite	88 (31%)	4 (1%)	0	46 (16%)	3 (1%)	0
Constipation	82 (29%)	1 (<1%)	0	87 (31%)	1 (<1%)	0
Weight decreased	81 (29%)	2 (<1%)	0	43 (15%)	1 (<1%)	0
Cough	80 (29%)	1 (<1%)	0	53 (19%)	1 (<1%)	0
Asthenia	60 (21%)	14 (5%)	0	44 (16%)	10 (4%)	2 (<1%)
Headache	70 (25%)	2 (<1%)	0	56 (20%)	2 (<1%)	1 (<1%)
Rash	69 (25%)	0	0	49 (17%)	2 (<1%)	0
Epistaxis	60 (21%)	3 (1%)	0	38 (13%)	0	0
Vomiting	58 (21%)	2 (<1%)	0	57 (20%)	2 (<1%)	0
Dyspnoea	47 (17%)	4 (1%)	1 (<1%)	32 (11%)	9 (3%)	0
Arthralgia	46 (16%)	1 (<1%)	0	33 (12%)	2 (<1%)	0
Febrile neutropenia	3 (1%)	30 (11%)	14 (5%)	1 (<1%)	7 (2%)	3 (1%)
Abdominal pain	45 (16%)	0	0	48 (17%)	1 (<1%)	0
Peripheral oedema	42 (15%)	0	0	24 (9%)	2 (<1%)	0
Pain in extremity	39 (14%)	2 (<1%)	0	40 (14%)	2 (<1%)	0
Thrombocytopenia	30 (11%)	7 (3%)	3 (1%)	5 (2%)	1 (<1%)	0
Myalgia	36 (13%)	2 (<1%)	0	31 (11%)	0	0
Nasopharyngitis	38 (14%)	0	0	28 (10%)	0	0
Back pain	37 (13%)	0	0	41 (15%)	2 (<1%)	0
Upper respiratory tract infection	37 (13%)	0	0	26 (9%)	0	0
Increased alanine aminotransferase	26 (9%)	8 (3%)	1 (<1%)	17 (6%)	8 (3%)	0
Upper abdominal pain	32 (11%)	2 (<1%)	0	36 (13%)	3 (1%)	0
Insomnia	34 (12%)	0	0	25 (9%)	0	0
Hypokalaemia	21 (8%)	11 (4%)	1 (<1%)	16 (6%)	2 (<1%)	0
Increased aspartate aminotransferase	24 (9%)	6 (2%)	1 (<1%)	14 (5%)	7 (2%)	0
Mouth ulceration	28 (10%)	3 (1%)	0	6 (2%)	0	0
Muscle spasms	29 (10%)	2 (<1%)	0	45 (16%)	1 (<1%)	0
Increased gamma-glutamyltransferase	11 (4%)	13 (5%)	5 (2%)	7 (2%)	14 (5%)	2 (<1%)
Bone pain	24 (9%)	2 (<1%)	1 (<1%)	20 (7%)	2 (<1%)	0
Peripheral neuropathy	26 (9%)	1 (<1%)	0	33 (12%)	6 (2%)	0
Hyperglycaemia	19 (7%)	6 (2%)	0	10 (4%)	4 (1%)	0
Peripheral sensory neuropathy	23 (8%)	2 (<1%)	0	15 (5%)	1 (<1%)	0
Decreased haemoglobin	8 (3%)	14 (5%)	0	14 (5%)	3 (1%)	0
Hypertension	20 (7%)	2 (<1%)	0	8 (3%)	1 (<1%)	0
Hypertriglyceridaemia	20 (7%)	2 (<1%)	0	7 (2%)	1 (<1%)	0
Pneumonitis	13 (5%)	1 (<1%)	2 (<1%)	4 (1%)	4 (1%)	1 (<1%)
Decreased white blood cell count	3 (1%)	8 (3%)	5 (2%)	7 (2%)	11 (4%)	5 (2%)
Pneumonia	9 (3%)	5 (2%)	1 (<1%)	3 (1%)	2 (<1%)	1 (<1%)
Musculoskeletal pain	12 (4%)	2 (<1%)	0	14 (5%)	1 (<1%)	0
Decreased neutrophil count	1 (<1%)	7 (3%)	5 (2%)	1 (<1%)	3 (1%)	4 (1%)
Hypocalcaemia	8 (3%)	1 (<1%)	1 (<1%)	2 (<1%)	0	1 (<1%)
Interstitial lung disease	7 (3%)	3 (1%)	0	2 (<1%)	0	0
lymphopenia	4 (1%)	5 (2%)	0	5 (2%)	0	1 (<1%)

(Table 4 continues on next page)

	Everolimus group (n=280)			Placebo group (n=282)		
	Grade 1–2	Grade 3	Grade 4	Grade 1–2	Grade 3	Grade 4
(Continued from previous page)						
Exertional dyspnoea	7 (3%)	1 (<1%)	0	9 (3%)	2 (<1%)	0
Increased blood alkaline phosphatase	6 (2%)	1 (<1%)	0	5 (2%)	2 (<1%)	0
Increased blood triglycerides	4 (1%)	2 (<1%)	1 (<1%)	3 (1%)	0	0
Cellulitis	3 (1%)	4 (1%)	0	1 (<1%)	0	0
Herpes zoster	4 (1%)	3 (1%)	0	3 (1%)	2 (<1%)	0
Device-related infection	2 (<1%)	4 (1%)	0	0	0	0
Diabetes mellitus	3 (1%)	3 (1%)	0	2 (<1%)	1 (<1%)	0
Pleural effusion	5 (2%)	1 (<1%)	0	2 (<1%)	4 (1%)	0
Cataract	3 (1%)	2 (<1%)	0	4 (1%)	3 (1%)	0
Hyponatraemia	2 (<1%)	1 (<1%)	2 (<1%)	2 (<1%)	3 (1%)	0
Gastroenteritis	2 (<1%)	2 (<1%)	0	1 (<1%)	1 (<1%)	0
Hypotension	3 (1%)	1 (<1%)	0	3 (1%)	2 (<1%)	0
Sepsis	1 (<1%)	3 (1%)	0	0	1 (<1%)	0
Convulsion	0	2 (<1%)	1 (<1%)	2 (<1%)	0	0
Granulocytopenia	0	3 (1%)	0	0	0	0
Lethargy	2 (<1%)	1 (<1%)	0	9 (3%)	2 (<1%)	0
Pulmonary embolism	0	1 (<1%)	2 (<1%)	1 (<1%)	2 (<1%)	4 (1%)
Acute renal failure	0	3 (1%)	0	0	0	0
Syncope	1 (<1%)	2 (<1%)	0	0	1 (<1%)	0
Agranulocytosis	1 (<1%)	0	1 (<1%)	0	3 (1%)	1 (<1%)
Deterioration of general physical health	0	0	2 (<1%)	0	2 (<1%)	0
Hypoxia	1 (<1%)	1 (<1%)	0	0	1 (<1%)	1 (<1%)

Data are number of patients (%). Any adverse events with 10% or greater incidence, or grade 3 and 4 adverse events with 0·5% or greater incidence, are shown.

Table 4: **Adverse events in the safety population**

Grade 3–4 adverse events occurring in greater than or equal to 5% more patients in the everolimus group than in the placebo group were neutropenia, stomatitis, anaemia, leucopenia, fatigue, and febrile neutropenia (table 4). Non-infectious pneumonitis was reported in 28 (10%) of 280 patients in the everolimus group and 12 (4%) of 282 patients in the placebo group; most of these events were grade 1–2, with six cases of grade 3–4 non-infectious pneumonitis reported in the everolimus group and fi ve cases reported in the placebo group.

Take-Home Message

- The addition of everolimus was associated with a statistically significant but low-magnitude improvement in median progression-free survival (7.0 months vs 5.8 months; P = .0067).
- Both hematologic and non-hematologic toxicity rates were higher in patients treated with everolimus.
- These data suggest that non–HER2 targeted therapies such as everolimus are a viable strategy for the treatment of trastuzumab-resistant HER2-positive breast cancer. However, due to significant toxicity, clinicians should consider the risks and benefits of adding everolimus to treatment regimens.

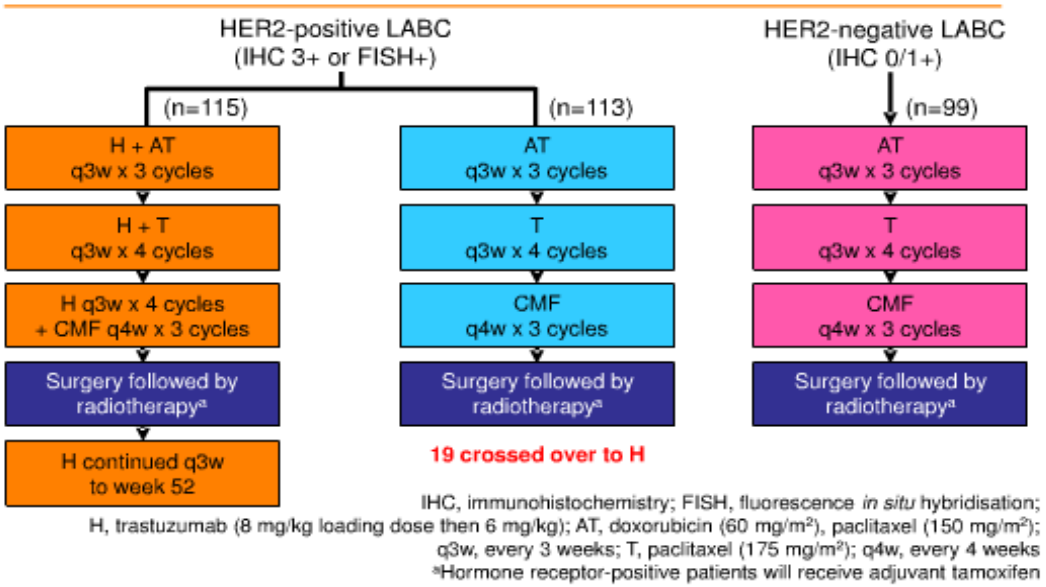
Neoadjuvant and adjuvant trastuzumab in patients with HER2-positive locally advanced breast cancer (NOAH): follow-up of a randomised controlled superiority trial with a parallel HER2-negative cohort

Lancet Oncol 2014; 15: 640–47 Published **Online** March 20, 2014

Luca Gianni, Wolfgang Eiermann, Vladimir Semiglazov, Ana Lluch, Sergei Tjulandin, Milvia Zambetti, Angela Moliterni, Federico Vazquez, Mikhail J Byakhov, Mikhail Lichinitser, Miguel Angel Climent, Eva Ciruelos, Belen Ojeda, Mauro Mansutti, Alla Bozhok, Domenico Magazzù, Dominik Heinzmann, Jutta Steinseifer, Pinuccia Valaqussa, Jose Baselqa

Updated results from our primary analysis to establish the long-term benefit of trastuzumab-containing neoadjuvant therapy.

NOAH study design

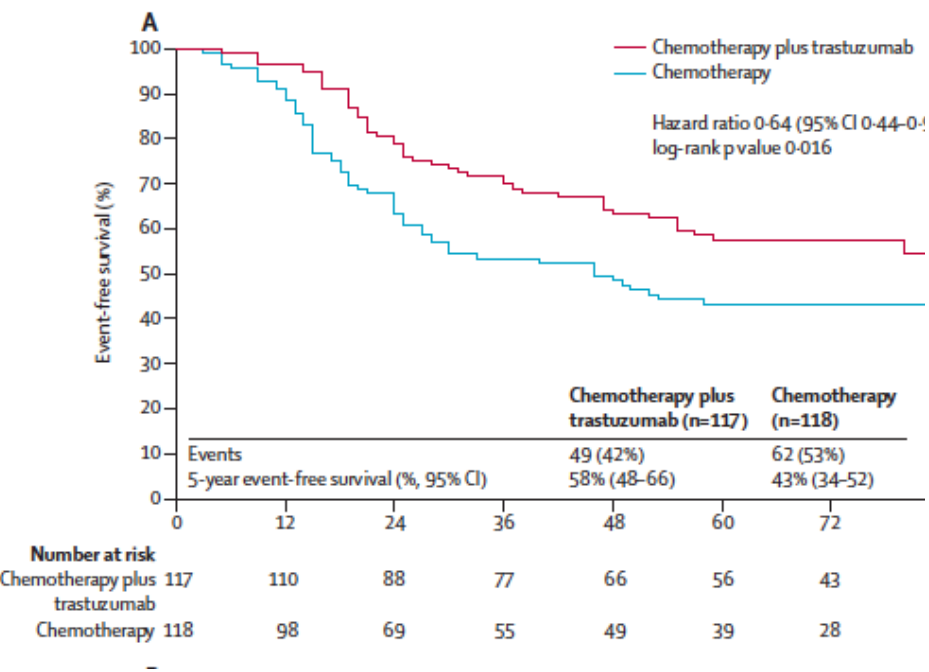


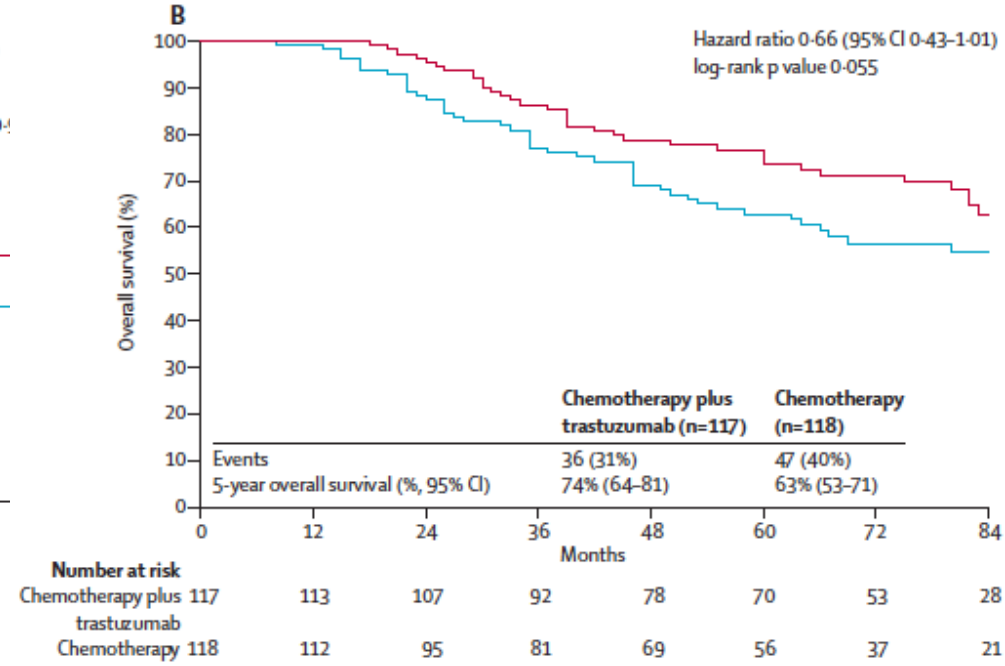
IHC, immunohistochemistry; FISH, fluorescence *in situ* hybridisation; H, trastuzumab (8 mg/kg loading dose then 6 mg/kg); AT, doxorubicin (60 mg/m²), paclitaxel (150 mg/m²); q3w, every 3 weeks; T, paclitaxel (175 mg/m²); q4w, every 4 weeks

[a]Hormone receptor-positive patients will receive adjuvant tamoxifen

Event-free survival (A) and overall survival (B)

Median follow-up was 5.4 years

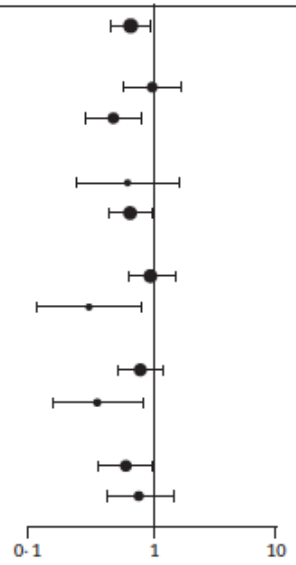




The primary endpoint was event-free survival, defined as the interval between randomisation and documented disease recurrence, progression, or death from any cause,

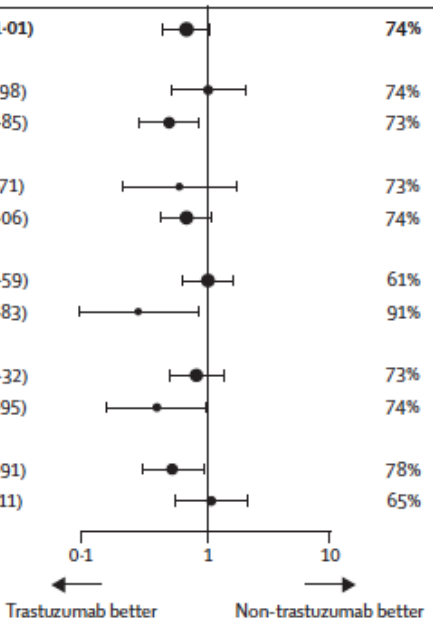
A

	Subgroup n (%)	Events n (%)	HR (95% CI)	5-year event-free survival (%)	
				Trastuzumab and neoadjuvant chemotherapy	Neoadjuvant chemotherapy alone
Overall	**235 (100%)**	**111 (47%)**	**0·64 (0·44–0·93)**	**58%**	**43%**
Age (years)					
≤50	108 (46%)	51 (47%)	0·95 (0·55–1·65)	52%	50%
>50	127 (54%)	60 (47%)	0·46 (0·27–0·78)	63%	38%
Nodal status					
N0	35 (15%)	17 (49%)	0·60 (0·23–1·60)	60%	42%
N1/N2	200 (85%)	94 (47%)	0·63 (0·42–0·95)	57%	44%
pCR*					
No	167 (71%)	94 (56%)	0·92 (0·61–1·49)	38%	41%
Yes	68 (29%)	17 (25%)	0·29 (0·11–0·78)	87%	55%
Inflammatory					
No	188 (80%)	85 (45%)	0·76 (0·49–1·16)	56%	49%
Yes	47 (20%)	26 (55%)	0·34 (0·15–0·80)	64%	24%
ER/PgR					
Both negative	151 (64%)	66 (44%)	0·58 (0·35–0·94)	62%	48%
Either positive	84 (36%)	45 (54%)	0·74 (0·41–1·44)	49%	36%



B

	Subgroup n (%)	Events n (%)	HR (95% CI)	5-year overall survival (%)	
				Trastuzumab and neoadjuvant chemotherapy	Neoadjuvant chemotherapy alone
Overall	**235 (100%)**	**83 (35%)**	**0·66 (0·43–1·01)**	**74%**	**63%**
Age (years)					
≤50	108 (46%)	33 (31%)	1·00 (0·50–1·98)	74%	78%
>50	127 (54%)	50 (39%)	0·48 (0·27–0·85)	73%	51%
Nodal status					
N0	35 (15%)	14 (40%)	0·58 (0·20–1·71)	73%	48%
N1/N2	200 (85%)	69 (35%)	0·66 (0·41–1·06)	74%	65%
pCR*					
No	167 (71%)	70 (42%)	0·99 (0·62–1·59)	61%	61%
Yes	68 (29%)	13 (19%)	0·27 (0·09–0·83)	91%	71%
Inflammatory					
No	188 (80%)	62 (33%)	0·80 (0·48–1·32)	73%	68%
Yes	47 (20%)	21 (45%)	0·38 (0·15–0·95)	74%	44%
ER/PgR					
Both negative	151 (64%)	50 (33%)	0·51 (0·29–0·91)	78%	60%
Either positive	84 (36%)	33 (39%)	1·05 (0·53–2·11)	65%	67%



	Hazard ratio (95% CI)	p value	$p_{interaction}$
Multivariate analyses			
Trastuzumab (n=117) *vs* no trastuzumab (n=118)	0·77 (0·53–1·13)	0·1870	0·037
pCR (n=68) *vs* no pCR (n=167)	0·32 (0·19–0·54)	<0·0001	..
Subgroup analyses			
pCR			
Trastuzumab (n=45) *vs* no trastuzumab (n=23)	0·29 (0·11–0·78)	0·0135	..
No pCR			
Trastuzumab (n=72) *vs* no trastuzumab (n=95)	0·92 (0·61–1·39)	0·6987	..
Trastuzumab			
pCR (n=45) *vs* no pCR (n=72)	0·17 (0·08–0·38)	<0·0001	..
No trastuzumab			
pCR (n=23) *vs* no pCR (n=95)	0·57 (0·29–1·13)	0·1089	..

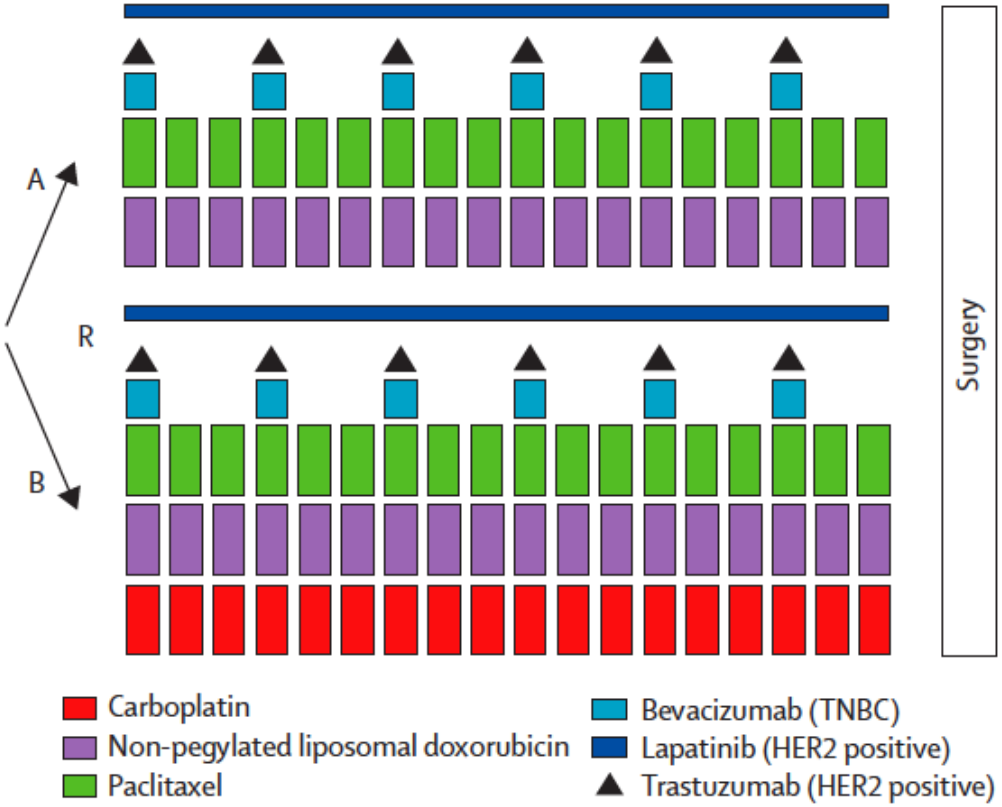
pCR=pathological complete response.

Table 4: **Multivariate and subgroup analyses of pCR and event-free survival**

Neoadjuvant carboplatin in patients with triple-negative and HER2-positive early breast cancer (GeparSixto; GBG 66): a randomised phase 2 trial

Lancet Oncol 2014; 15: 747–56 Published **Online** May 1, 2014

Gunter von Minckwitz, Andreas Schneeweiss, Sibylle Loibl, Christoph Salat, Carsten Denkert, Mahdi Rezai, Jens U Blohmer, Christian Jackisch, Stefan Paepke, Bernd Gerber, Dirk M Zahm, Sherko Kümmel, Holger Eidtmann, Peter Klare, Jens Huober, Serban Costa, Hans Tesch, Claus Hanusch, Jörn Hilfrich, Fariba Khandan, Peter A Fasching, Bruno V Sinn, Knut Engels, Keyur Mehta, Valentina Nekljudova, Michael Untch



All patients:
paclitaxel 80 mg/m2 plus nonpegylated liposomal doxorubicin 20 mg/m2, both given once a week for 18 weeks.

Triple-negative breast
bevacizumab 15 mg/kg/3 weeks

HER2-positive:
Trastuzumab + lapatinib 750 mg

CARBO AUC 2

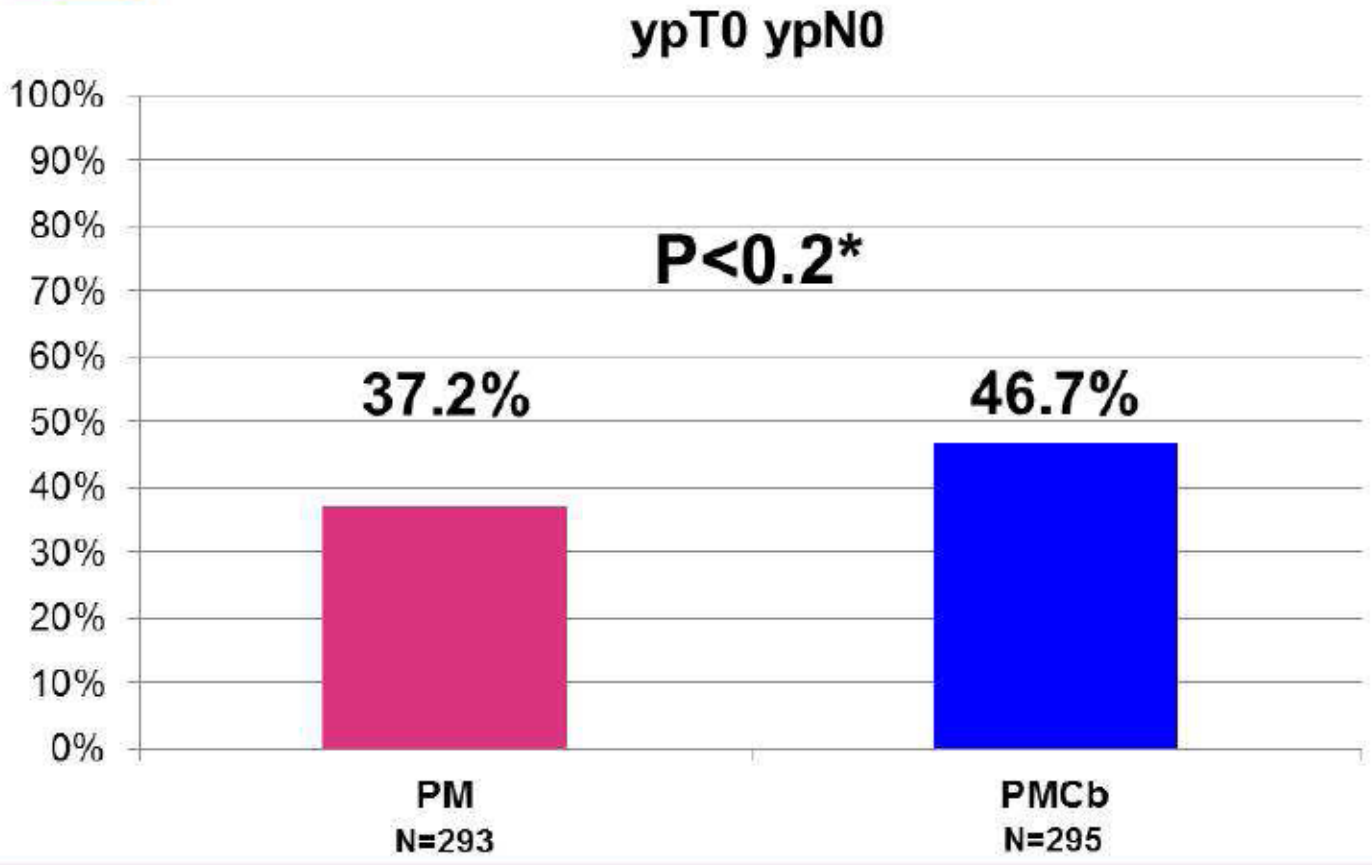
Patients & Tumor Characteristics

	PM (N=293)	PMCb (N=295)
age (median yrs)	47	48
palpable T-size (median cm)	3.0	3.0
	%	%
cT 3 / 4	18.8	16.9
cN +	42.4	37.6
grade 3	64.5	65.1
TNBC (N=315)	53.6	53.6
HER2-positive (N=273)	46.4	46.4
- HER2-positive / HR-negative	18.8	18.3
- HER2-positive / HR-positive	27.6	28.1

AGO-B BREAST STUDY GROUP

GBG GERMAN BREAST GROUP

Primary Endpoint: pCR



AGO-B BREAST STUDY GROUP * Level for significance $\alpha = 0.2$

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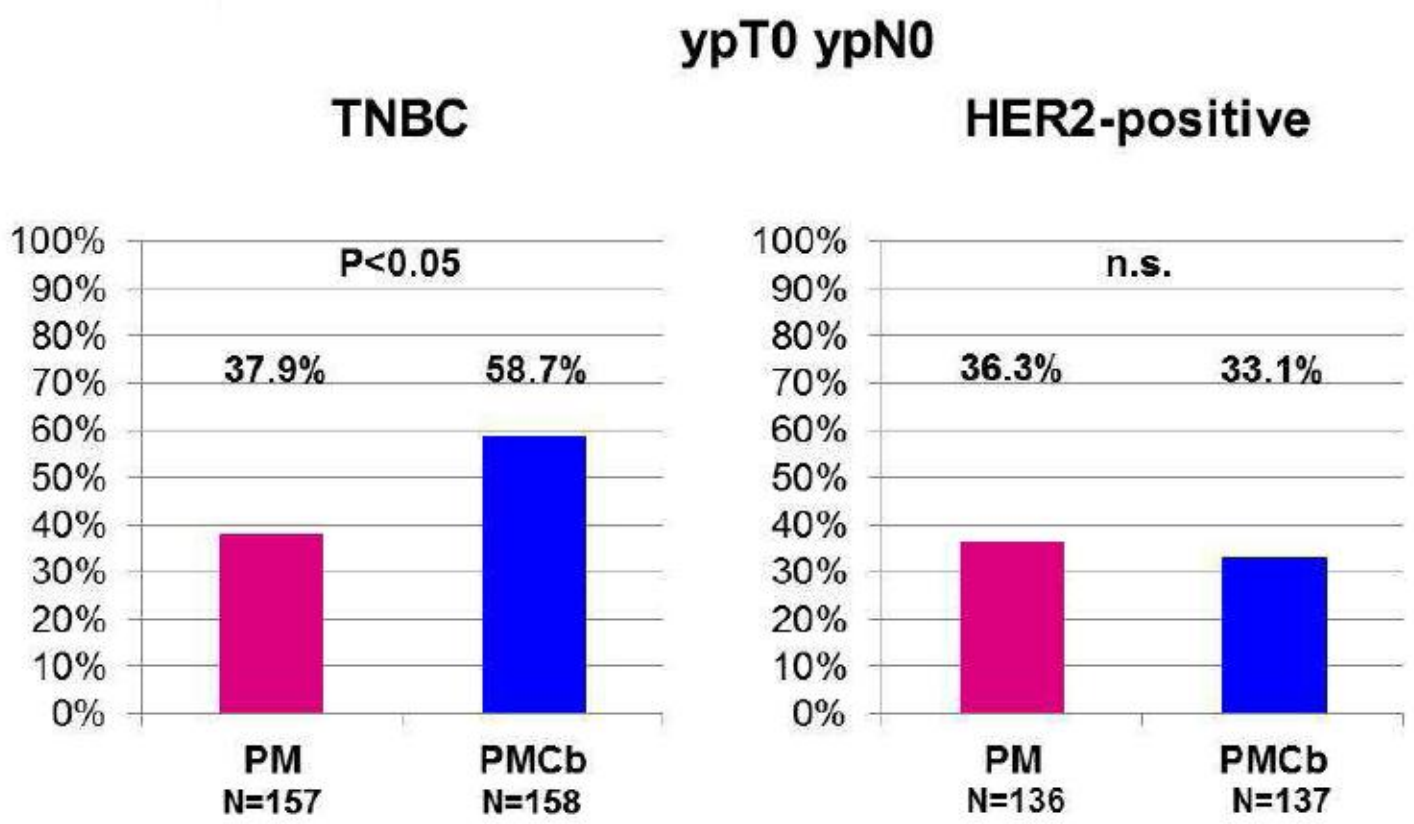
Presented By Gunter Von Minckwitz, MD at 2013 ASCO Annual Meeting

The significance level was set to a two-sided α of 0.20 for the primary endpoint only, for all other tests the α was set to 0.05.

pCR Rates by Subtypes



AGO-B
BREAST STUDY GROUP

GBG
GERMAN BREAST GROUP

Presented By Gunter Von Minckwitz, MD at 2013 ASCO Annual Meeting

	Treatment without carboplatin (n=293)				Treatment with carboplatin (n=295)				p value*
	Grades 1–2	Grade 3	Grade 4	Grade 5	Grades 1–2	Grade 3	Grade 4	Grade 5	
Anaemia	258 (88%)	1 (<1%)	0	0	242 (82%)	42 (14%)	3 (1%)	0	<0·0001
Neutropenia	135 (46%)	63 (22%)	16 (6%)	0	84 (29%)	126 (43%)	66 (22%)	0	<0·0001
Febrile neutropenia	0	12 (4%)	2 (<1%)	1 (<1%)	0	19 (6%)	6 (2%)	0	0·140
Thrombocytopenia	28 (10%)	1 (<1%)	0	0	155 (53%)	38 (13%)	4 (1%)	0	<0·0001
Nausea	155 (53%)	12 (4%)	0	0	184 (62%)	29 (10%)	0	0	0·009
Vomiting	75 (26%)	6 (2%)	1 (<1%)	0	102 (35%)	16 (5%)	0	0	0·087
Diarrhoea	153 (52%)	32 (11%)	0	0	156 (53%)	49 (17%)	2 (<1%)	0	0·033
Mucositis	212 (72%)	44 (15%)	1 (<1%)	0	193 (65%)	45 (15%)	5 (2%)	0	0·654
Anorexia	88 (30%)	8 (3%)	1 (<1%)	0	99 (34%)	22 (8%)	0	0	0·025
Fatigue	211 (72%)	40 (14%)	0	0	205 (70%)	48 (16%)	1 (<1%)	0	0·358
Hand-foot syndrome	146 (50%)	48 (16%)	0	0	135 (46%)	27 (9%)	0	0	0·009
Skin rash (acneiform)	31 (11%)	6 (2%)	0	0	25 (9%)	0	0	0	0·015
Nail changes	98 (33%)	11 (4%)	0	0	81 (28%)	2 (1%)	0	0	0·012
Peripheral sensory neuropathy	190 (65%)	21 (7%)	0	0	173 (59%)	19 (6%)	0	0	0·746
Fever	85 (29%)	17 (6%)	3 (1%)	0	67 (23%)	11 (4%)	0	0	0·100
Infection	119 (41%)	37 (13%)	7 (2%)	1 (<1%)	126 (43%)	37 (13%)	3 (1%)	1 (<1%)	0·642
Thromboembolic events	12 (4%)	7 (2%)	3 (1%)	0	14 (5%)	7 (2%)	3 (1%)	0	1·000
Pneumonitis	6 (2%)	6 (2%)	3 (1%)	0	0	1 (<1%)	0	0	0·011
Arterial hypertension	33 (11%)	9 (3%)	0	0	29 (10%)	5 (2%)	0	0	0·295
LVEF decrease, congestive heart failure (NYHA), and myocardial infarction	6 (2%)	0	0	1 (<1%)	5 (2%)	2 (<1%)	0	0	1·000
Other cardiac disorders	24 (8%)	3 (1%)	1 (<1%)	1 (<1%)	20 (7%)	0	0	0	0·030
Surgical complications	3 (1%)	2 (<1%)	0	0	5 (2%)	4 (1%)	0	0	0·450
Other non-haematological adverse events	219 (75%)	67 (23%)	6 (2%)	0	212 (72%)	76 (26%)	1 (<1%)	0	0·777

Gepar-Sixto

- Results of the GeparSixto phase II study showed with an alpha significance level of 0.2 a significant increase of the pCR rate from 37.2 to 46.7% by the addition of carboplatin.
- An absolute increase by >20% was observed in patients with TNBC (37.9% vs. 58.7%), but no increase in patients with HER2-positive breast cancer (36.3% vs. 33.1%).
- The observed high efficacy has to be weighed against a high rate of treatment discontinuations (39% for PM(+B/+HL) and 48% for PMCb(+B/+HL)).
- A large biomarker program will try to identify subgroups of TNBC with even higher benefit from carboplatin.
- Results have to be set into context with the upcoming CALGB 40603* phase II study adding bevacizumab and/or carboplatin to weekly paclitaxel followed by dose-dense AC.

AGO-B BREAST STUDY GROUP

*NCT00861705 and poster at Alliance meeting Nov 2011

GBG GERMAN BREAST GROUP

Presented By Gunter Von Minckwitz, MD at 2013 ASCO Annual Meeting

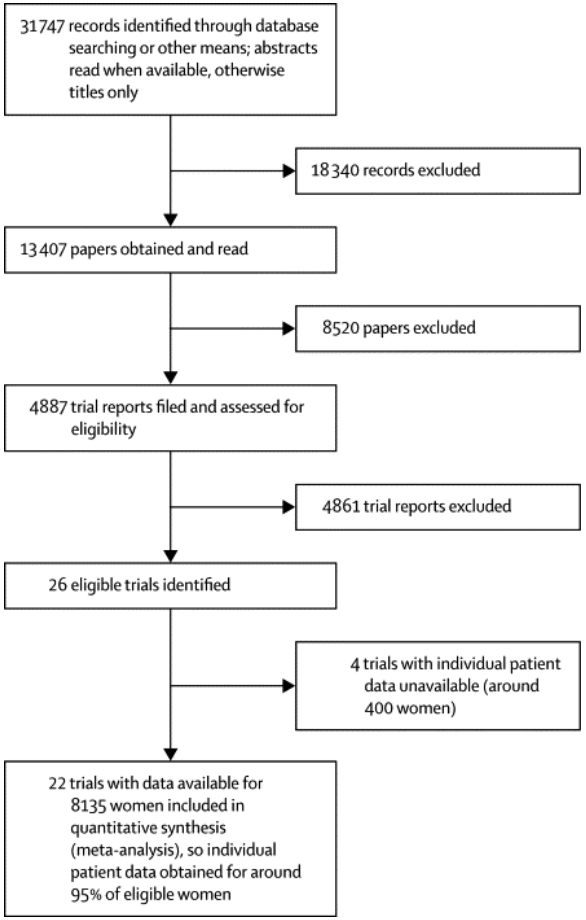
Take-Home Message

- The addition of carboplatin appears to increase pathologic response rates in triple-negative disease but not HER2-positive disease.
- The optimal regimen and the effect on survival remain to be elucidated.

Effect of radiotherapy after mastectomy and axillary surgery on 10-year recurrence and 20-year breast cancer mortality: meta-analysis of individual patient data for 8135 women in 22 randomised trials

Lancet 2014 Mar 19;

EBCTCG (Early Breast Cancer Trialists' Collaborative Group)*



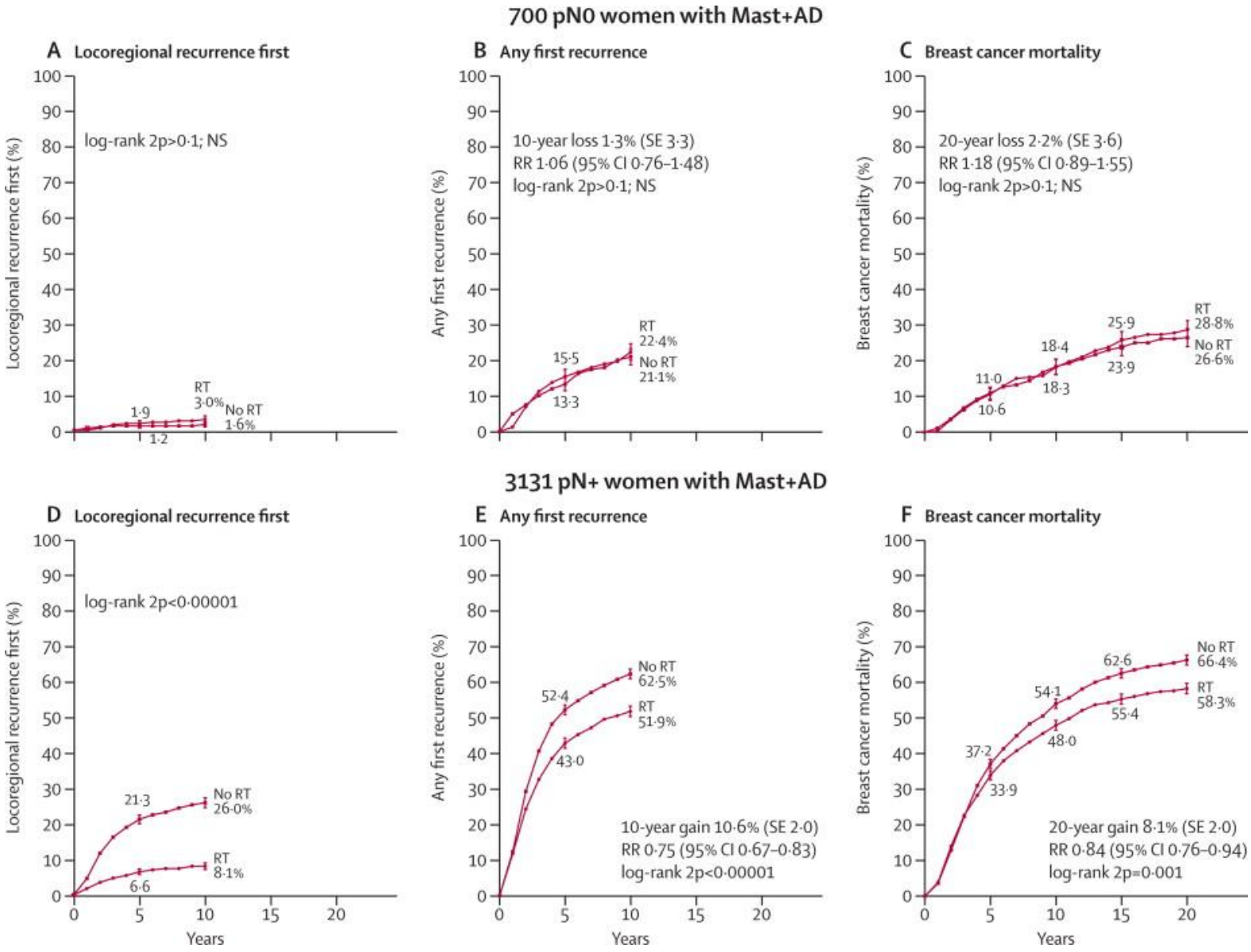


Figure 2 Effect of radiotherapy (RT) after mastectomy and axillary dissection (Mast+AD) on 10-year risks of locoregional and overall recurrence and on 20-year risk of breast cancer mortality in 700 women with pathologically node-negative (pN0) disease and ...

The Lancet, 2014

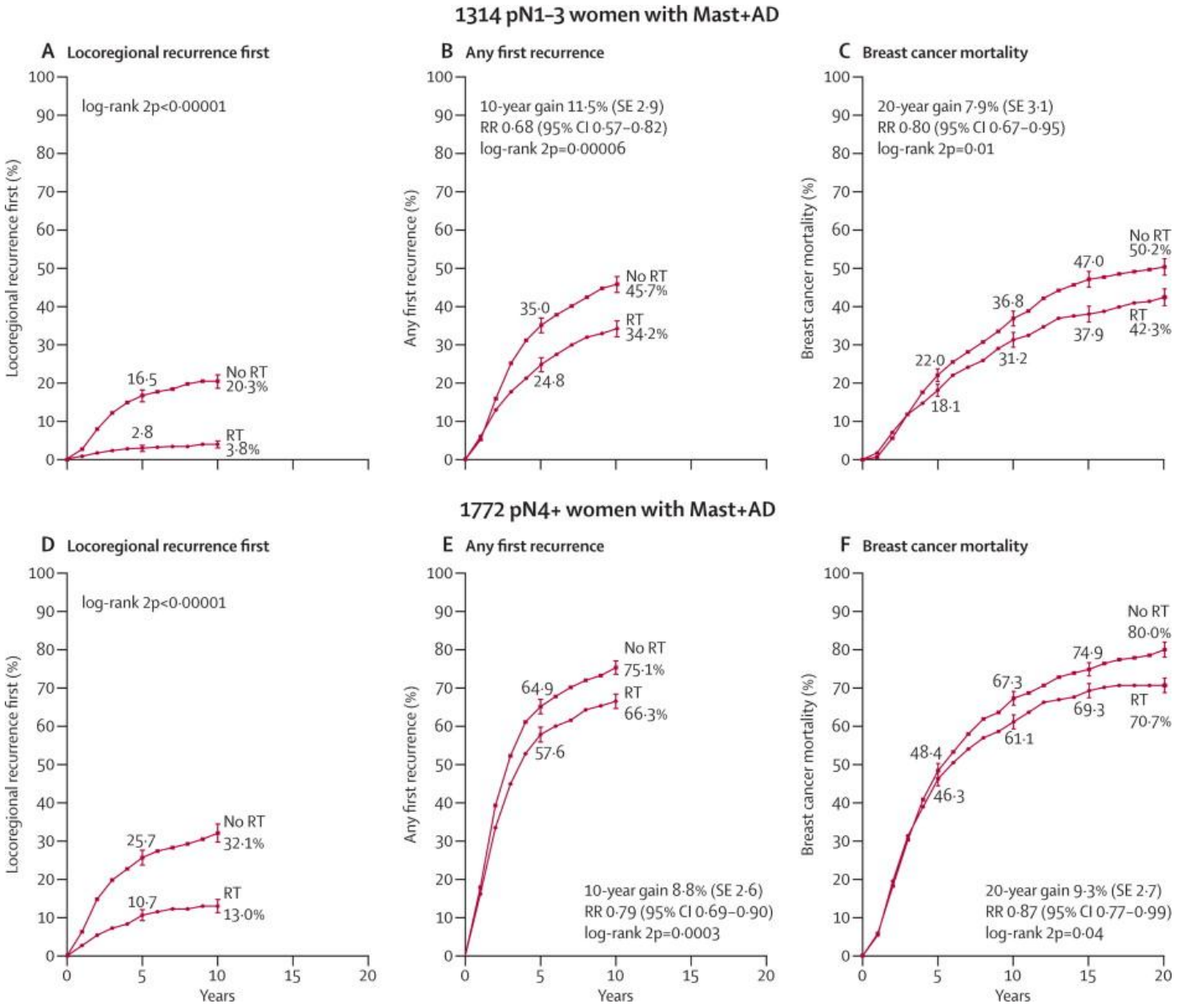


Figure 3 Effect of radiotherapy (RT) after mastectomy and axillary dissection (Mast+AD) on 10-year risks of locoregional and overall recurrence and on 20-year risk of breast cancer mortality in 1314 women with one to three pathologically positive nodes (pN...

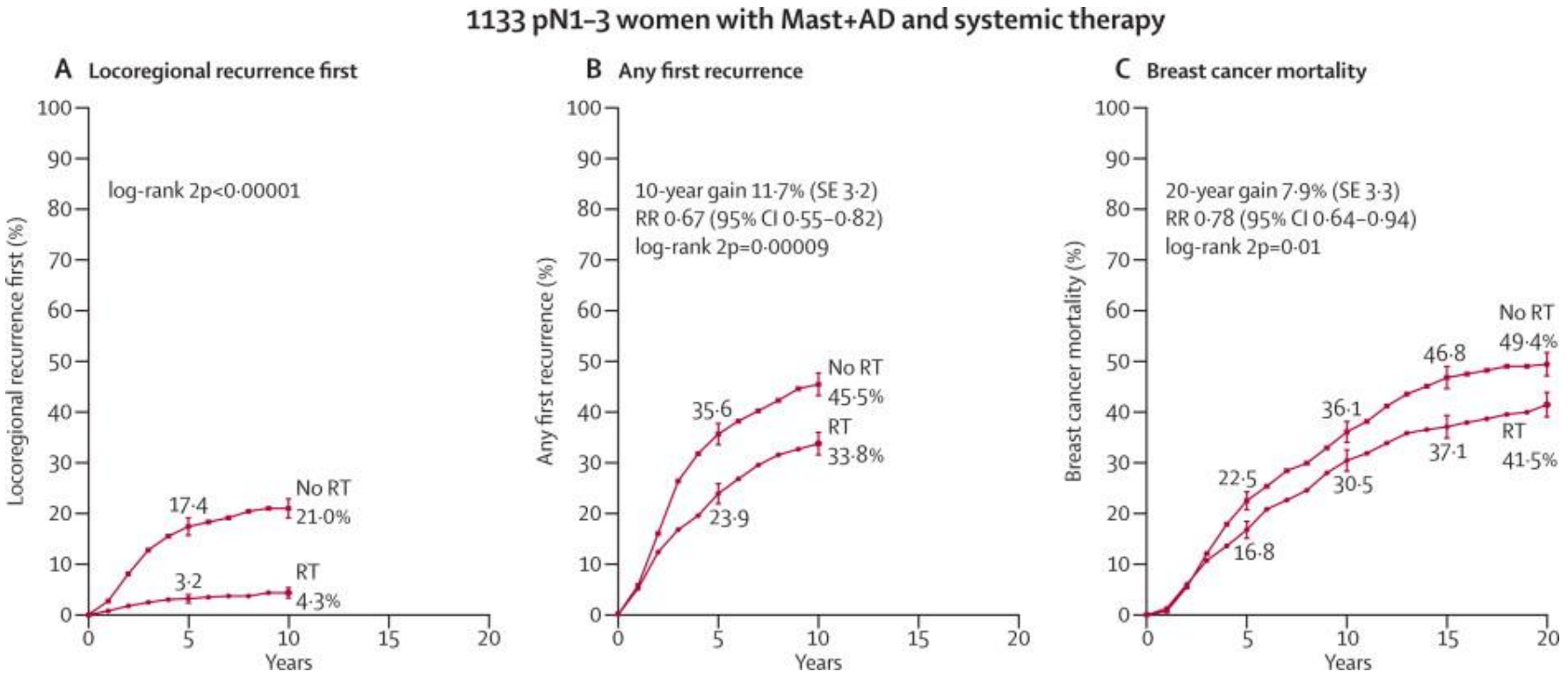


Figure 5 Effect of radiotherapy (RT) after mastectomy and axillary dissection (Mast+AD) on 10-year risks of locoregional and overall recurrence and on 20-year risk of breast cancer mortality in 1133 women with one to three pathologically positive nodes (pN...

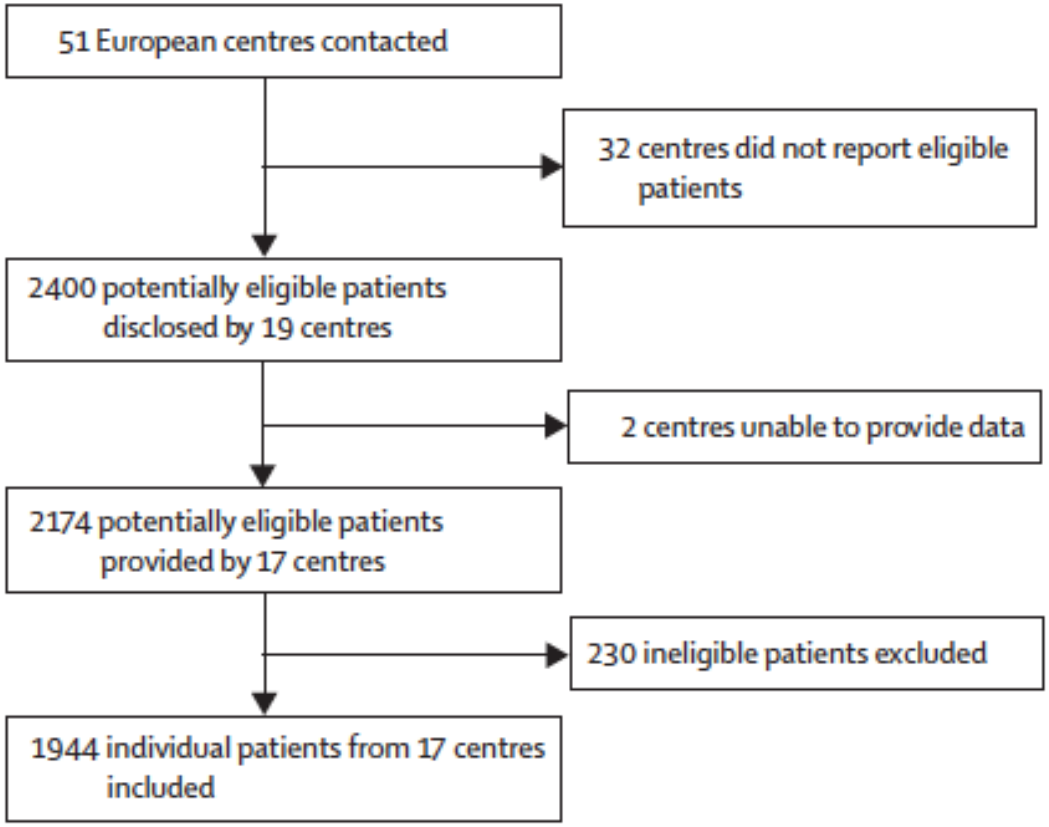
Take-Home Message

- Radiotherapy did not significantly affect locoregional recurrence, overall recurrence, or breast cancer mortality in women with axillary dissection and no positive nodes.
- In women with axillary dissection and more than one node, radiotherapy significantly reduced locoregional recurrence, overall recurrence, and breast cancer mortality.
- Systemic therapy in patients with axillary dissection and one to three nodes further reduced locoregional recurrence, overall recurrence, and breast cancer mortality.

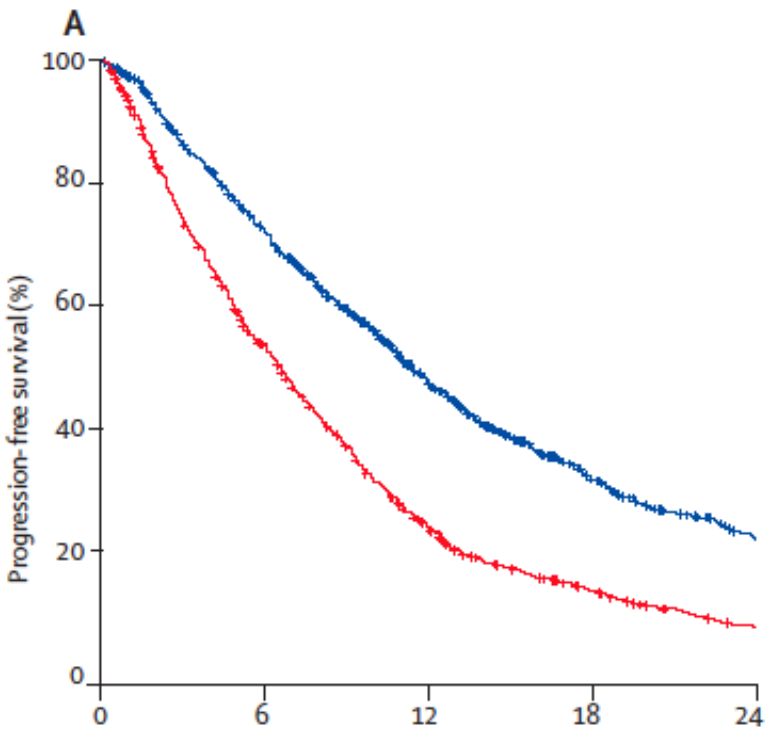
Clinical validity of circulating tumour cells in patients with metastatic breast cancer: a pooled analysis of individual patient data

Lancet Oncol 2014; 15: 406–14 Published **Online** March 11, 2014

François-Clément Bidard, Dieter J Peeters, Tanja Fehm, Franco Nolé, Rafael Gisbert-Criado, Dimitrios Mavroudis, Salvatore Grisanti, Daniele Generali, Jose A Garcia-Saenz, Justin Stebbing, Carlos Caldas, Paola Gazzaniga, Luis Manso, Rita Zamarchi, Angela Fernandez de Lascoiti, Leticia De Mattos-Arruda, Michail Ignatiadis, Ronald Lebofsky, Steven J van Laere, Franziska Meier-Stiegen, Maria-Teresa Sandri, Jose Vidal-Martinez, Eleni Politaki, Francesca Consoli, Alberto Bottini, Eduardo Diaz-Rubio, Jonathan Krell, Sarah-Jane Dawson, Cristina Raimondi, Annemie Rutten, Wolfgang Janni, Elisabetta Munzone, Vicente Carañana, Sofia Agelaki, Camillo Almici, Luc Dirix, Erich-Franz Solomayer, Laura Zorzino, Helene Johannes, Jorge S Reis-Filho, Klaus Pantel, Jean-Yves Pierga*, Stefan Michiels**



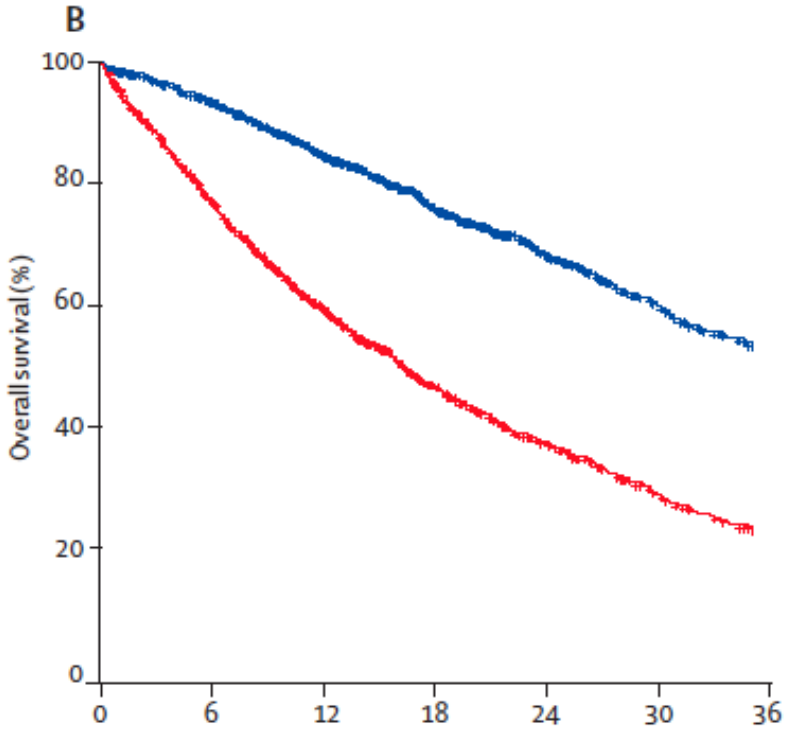
Kaplan-Meier analysis of progression-free survival and overall survival, by baseline CTC count



Number at risk

CTC <5	1014	685	394	211	115
CTC ≥5	885	439	174	79	35

	Patients	Events	Median progression-free survival in months (95% CI)
— CTC <5	1014	735	11·4 (10·6–12·1)
— CTC ≥5	885	772	6·5 (5·9–7·0)

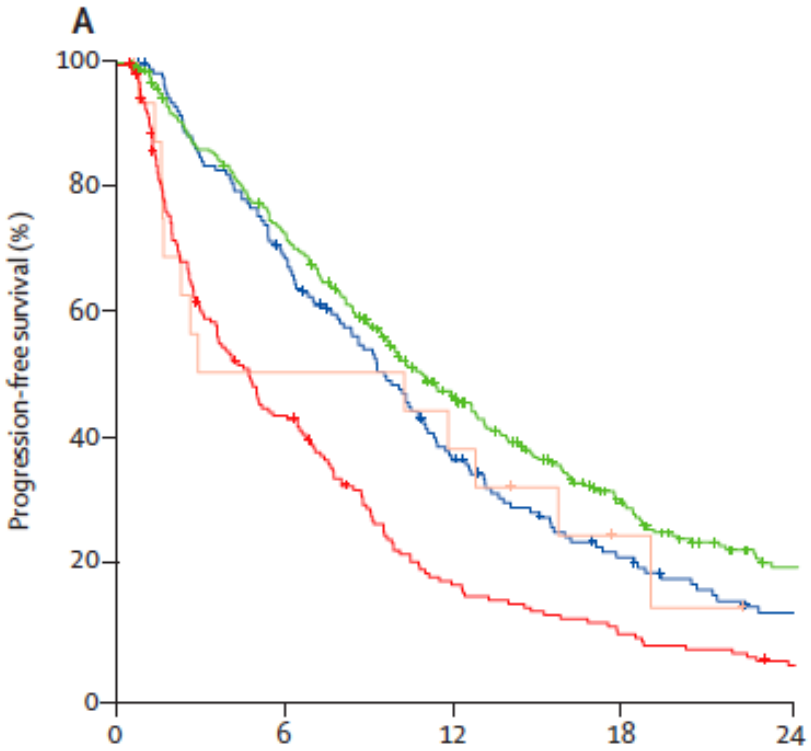


Number at risk

CTC <5	1033	896	701	496	333	230	162
CTC ≥5	911	639	396	237	147	85	53

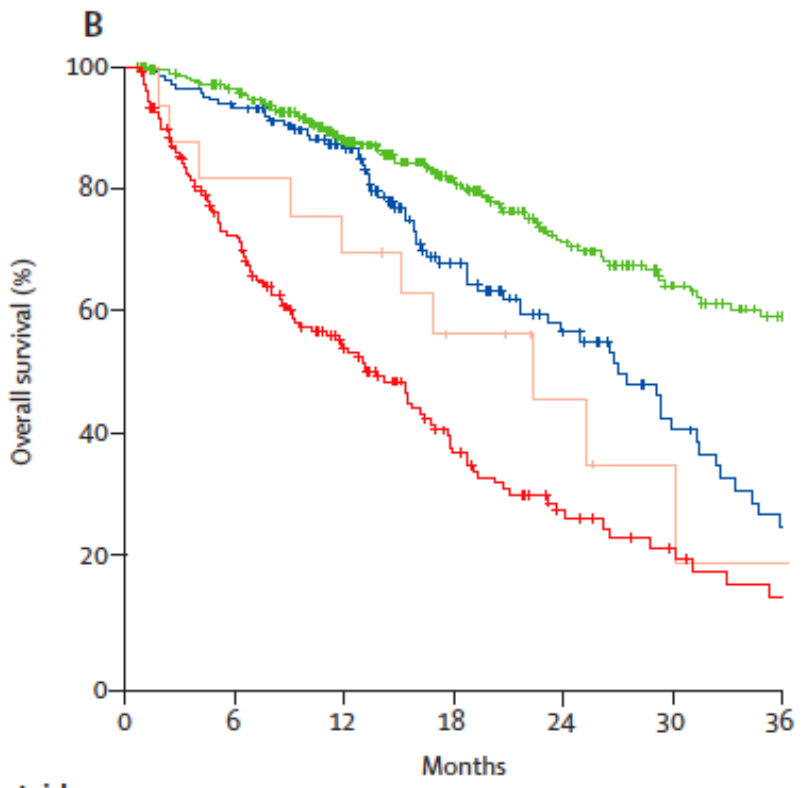
	Patients	Events	Median overall survival in months (95% CI)
— CTC <5	1033	371	37·1 (32·8–41·9)
— CTC ≥5	911	558	15·5 (13·5–16·8)

Kaplan-Meier analysis of progression-free survival and overall survival, by early change in CTC count (landmark analysis at 5 weeks)



Number at risk					
Decrease	149	101	49	24	11
Increase	17	8	6	2	..
Stable negative	327	226	126	59	25
Stable positive	179	73	25	12	3

	Patients	Events	Median progression-free survival in months (95% CI)
Decrease ≥5–<5	149	131	9·6 (8·2–11·1)
Increase <5–≥5	17	13	6·7 (1·8–NA)
Stable negative <5–<5	327	243	10·7 (9·7–12·7)
Stable positive ≥5–≥5	179	166	4·8 (3·7–6·5)



Number at risk							
Decrease	149	135	104	59	36	20	11
Increase	17	13	11	7	4	2	1
Stable negative	327	296	231	160	102	68	50
Stable positive	179	116	68	36	18	10	5

	Patients	Events	Median overall survival in months (95% CI)
Decrease ≥5–<5	149	70	27·0 (21·7–31·5)
Increase <5–≥5	17	10	22·4 (11·9–NA)
Stable negative <5–<5	327	104	41·5 (36·8–52·7)
Stable positive ≥5–≥5	179	116	13·1 (9·4–16·4)

Take-Home Message

- In this European study from 17 centers and 1944 patients with metastatic breast cancer, circulating tumor cell (CTC) counts were found to be associated with an independent prognostic effect for progression-free and overall survival.
- The data support the prognostic value of CTC detection at baseline and during treatment and can potentially be used as a tool for treatment decisions

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Multicentric neoadjuvant phase II study of panitumumab combined with an anthracycline/taxane based chemotherapy in operable triple negative breast cancer: Identification of biologically-defined signatures predicting treatment impact

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Take-Home Message

- In this phase II neoadjuvant trial of triple-negative breast cancer patients with resectable stage II or stage III disease, the addition of the EGFR-targeting monoclonal antibody panitumumab to standard therapy (5-fluorouracil/epirubicin/cyclophosphamide) followed by docetaxel resulted in a pathologic complete response (pCR) rate of 46.8%. Conservative surgery was performed in 87% of cases
- Several biomarkers suggested an improvement in pCR and the regimen was largely well-tolerated. The association of high EGFR and low cytokeratin 8/18 expression in tumor cells on one hand and high density of CD8+ tumor-infiltrating lymphocytes on the other hand were significantly predictive of pCR
- Future prospective trials could further test the addition of EGFR-targeting in triple-negative disease

JOURNAL OF CLINICAL ONCOLOGY ASCO SPECIAL ARTICLE

Consensus and Guidelines · May 05, 2014

Systemic Therapy for Patients With Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline

Sharon H. Giordano, Sarah Temin, Jeffrey J. Kirshner, Sarat Chandarlapaty, Jennie R. Crews, Nancy E. Davidson, Francisco J. Esteva, Ana M. Gonzalez-Angulo, Ian Krop, Jennifer Levinson, Nancy U. Lin, Shanu Modi, Debra A. Patt, Edith A. Perez, Jane Perlmutter, Naren Ramakrishna, and Eric P. Winer

- **What is the optimal medical therapy for advanced human epidermal growth factor receptor 2 (HER2) –positive breast cancer, specifically HER2-targeted therapy, either alone or in combination with chemotherapy and/or endocrine therapy?**

Take-Home Message

- **Clinicians should recommend the combination of trastuzumab, pertuzumab, and a taxane for first-line treatment, unless the patient has a contraindication to taxanes.**
- **If a patient's HER2-positive advanced breast cancer has progressed during or after first-line HER2-targeted therapy, clinicians should recommend trastuzumab emtansine (T-DM1) as second-line treatment.**
- **If a patient's HER2-positive advanced breast cancer has progressed during or after second-line or greater HER2-targeted therapy, but she has not received T-DM1, clinicians should offer T-DM1.**
- **If a patient's cancer is hormone receptor positive and HER2 positive, clinicians may recommend either:**
  - HER2-targeted therapy plus chemotherapy. Type: evidence based. Evidence quality: high. Strength of recommendation: strong.
  - Endocrine therapy plus trastuzumab or lapatinib (in selected cases). Type: evidence based. Evidence quality: high. Strength of recommendation: moderate.
  - Endocrine therapy alone (in selected cases). Type: evidence based. Evidence quality: intermediate. Strength of recommendation: weak.

Validity of Adjuvant! Online program in older patients with breast cancer: a population-based study

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THE LANCET Oncology 14 May 2014

- Adjuvant! Online is a prediction tool that can be used to aid clinical decision making in patients with breast cancer.
- All consecutive patients aged 65 years or older who were diagnosed with invasive or in-situ breast cancer between Jan 1, 1997, and Dec 31, 2004, in the southwestern part of the Netherlands.
- 2012 patients. Median age of patients in the cohort was 74·0 years (IQR 69·0–79·0).
- 904 (45%) of 2012 patients died during follow-up, whereas 326 (16%) patients had recurrence.

Take-Home Message

- Adjuvant! Online overestimated 10-year overall survival by 9·8% ([95% CI 5·9–13·7], p<0·0001) and 10-year cumulative recurrence survival by 8·7% ([6·7–10·7], p<0·0001).
- Based on the results of this study, the authors conclude that the Adjuvant! Online program was of limited value in older patients with breast cancer.
- The authors propose the development of a prediction algorithm specifically for this population

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CLINICAL TRIAL

Germline *BRCA* mutation evaluation in a prospective triple-negative breast cancer registry: implications for hereditary breast and/or ovarian cancer syndrome testing

Priyanka Sharma · Jennifer R. Klemp · Bruce F. Kimler · Jonathan D. Mahnken · Larry J. Geier · Qamar J. Khan · Manana Elia · Carol S. Connor · Marilee K. McGinness · Joshua M. W. Mammen · Jamie L. Wagner · Claire Ward · Lori Ranallo · Catherine J. Knight · Shane R. Stecklein · Roy A. Jensen · Carol J. Fabian · Andrew K. Godwin

May 07, 2014

- NCCN guidelines recommend genetic testing for all triple-negative breast cancer (TNBC) patients aged <60 years. However, due to the lack of prospective information in unselected patients, these guidelines are not uniformly adopted by clinicians and insurance carriers.
- The aim of this study was to determine the prevalence of BRCA mutations and evaluate the utility of NCCN guidelines in unselected TNBC population.

Take-Home Message

- This study tested 211 triple-negative breast cancer patients of all ages for germline BRCA1/BRCA2 mutations. Overall, 15% of patients in this population had BRCA mutations (11% BRCA1; 4% BRCA2).
- Significant family history (SFH) was defined >1 relative with breast cancer at age ≤50 or ≥1 relative with ovarian cancer
- Using SFH or age ≤50 as criteria, 25 and 34 % of mutations, respectively, were missed.
- Mutation prevalence in patients meeting NCCN guidelines was 18.3 % (32/175) and 0 % (0/32) in patients who did not meet guidelines (p = .0059).
- BRCA mutation testing based on current NCCN guidelines correctly identified all carriers in this study, supporting the routine use of these guidelines in clinical practice

EJC
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Article in Press

Early assessment with ^{18}F-fluorodeoxyglucose positron emission tomography/computed tomography can help predict the outcome of neoadjuvant chemotherapy in triple negative breast cancer

David Groheux, Elif Hindié, Sylvie Giacchetti, Anne-Sophie Hamy, Frederique Berger, Pascal Merlet, Anne de Roquancourt, Patricia de Cremoux, Michel Marty, Mathieu Hatt, Marc Espié

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Take-Home Message

- Given the benefit of pathological complete response (pCR) in patients with triple-negative breast cancer treated with neoadjuvant chemotherapy, investigators prospectively evaluated the role of (18)FDG-PET/CT after two cycles of neoadjuvant chemotherapy.
- In this study of 50 patients using a threshold of a 42% decrease in SUV, investigators showed that the pCR rates were 59% and 0% among responders and non-responders, respectively, and the 3-year event-free survival rates were 77.5% and 47.1%, respectively.
- Interim PET/CT appears to have a potential role in evaluating and predicting response in patients with triple-negative breast cancer


SIN NERVIOS NI HISTERISMOS: USTED ¿CUANTAS PIERNAS TENÍA CUANDO ENTRO EN EL QUIROFANO?
DOS
¡IMPOSIBLE


CURIOSÍSIMO... ¿Y COMO DICE UD. QUE SE LLAMA?
"HACHUPUNTURA"
¿Y ES EFECTIVO PARA DEJAR DE FUMAR?
A LOS 6 MESES, RADICAL
CREO