UNIVERSITÄTSKLINIKUM
Schleswig-Holstein

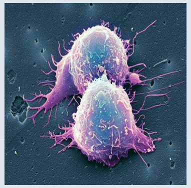
Universität zu Lübeck

Das tripelnegative Mammakarzinom

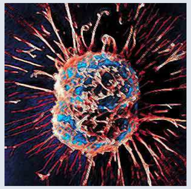
- eine therapeutische Herausforderung -

Priv.-Doz. Dr. med. Cornelia Liedtke
Klinik für Gynäkologie und Geburtshilfe
- Direktor: Prof. Dr. med. Achim Rody -
Universitätsklinikum Schleswig-Holstein / Campus Lübeck

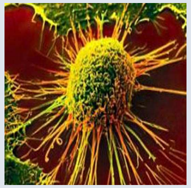
Überblick



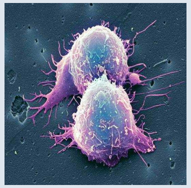
- Was ist das tripelnegative Mammakarzinom?



- Wie ist der klinische Verlauf?



- Welche Therapien können eingesetzt werden?



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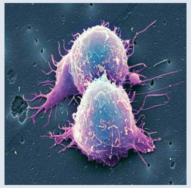
Überblick



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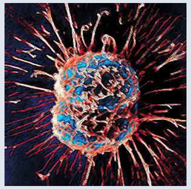

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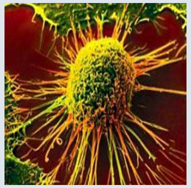

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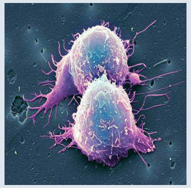
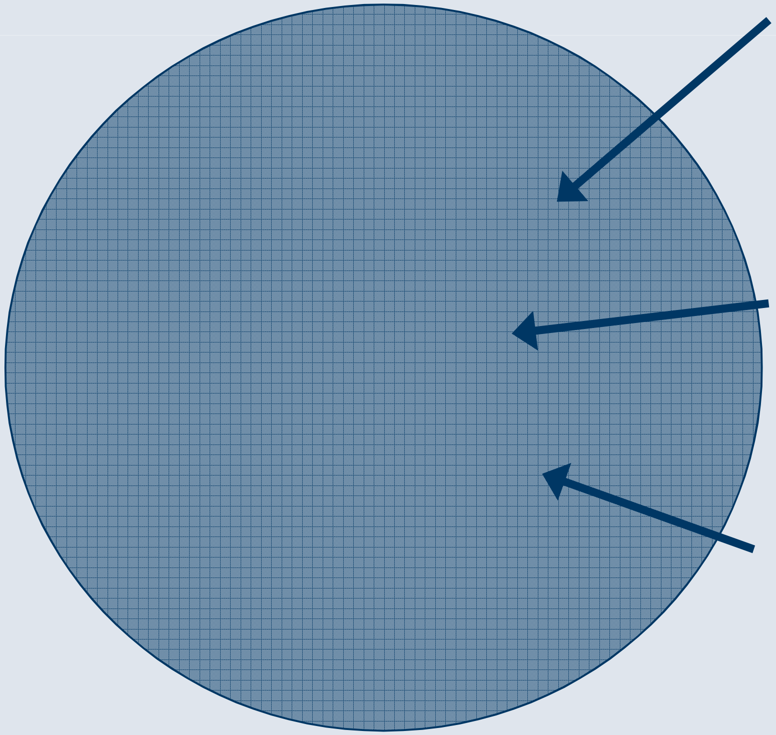


Was sind die neuen Therapieansätze?

Definition des TNBC



TNBC

Fehlende Östrogen-rezeptorExpression
(ER negativ)

Fehlende Progesteron-rezeptorexpression
(PR negativ)

Fehlende Überexpression / Amplifikation von HER2/neu
(HER2 negativ)

Gluz, Liedtke et al., Ann Onc 2009

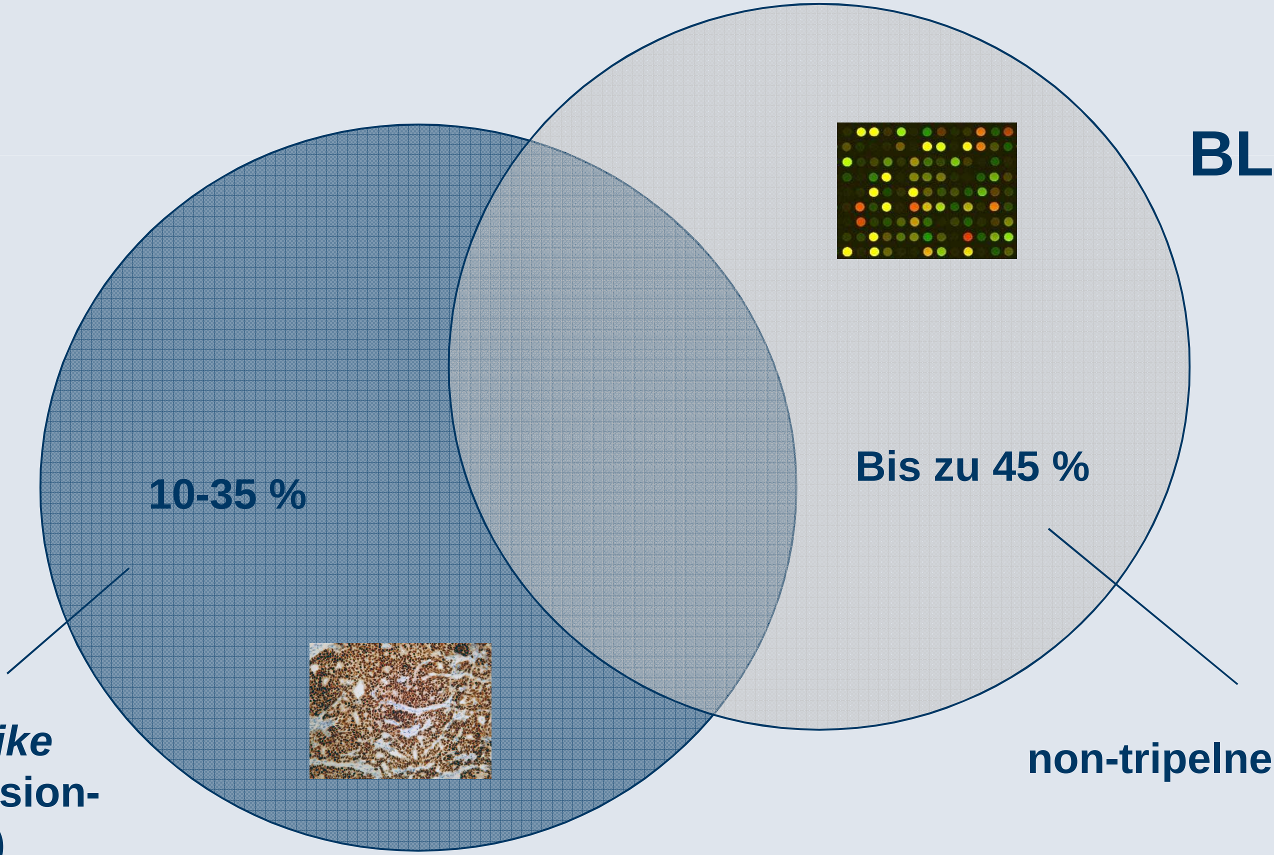
„Triple-negative breast cancer: disease entity or title ~~of convenience?”~~

of clinical relevance!

Carey L, Winer E, Viale G, Cameron D, Gianni L

Nat Rev Clin Oncol 2010

Zusammenhang zwischen TNBC und BLBC



BLBC

TNBC

10-35 %

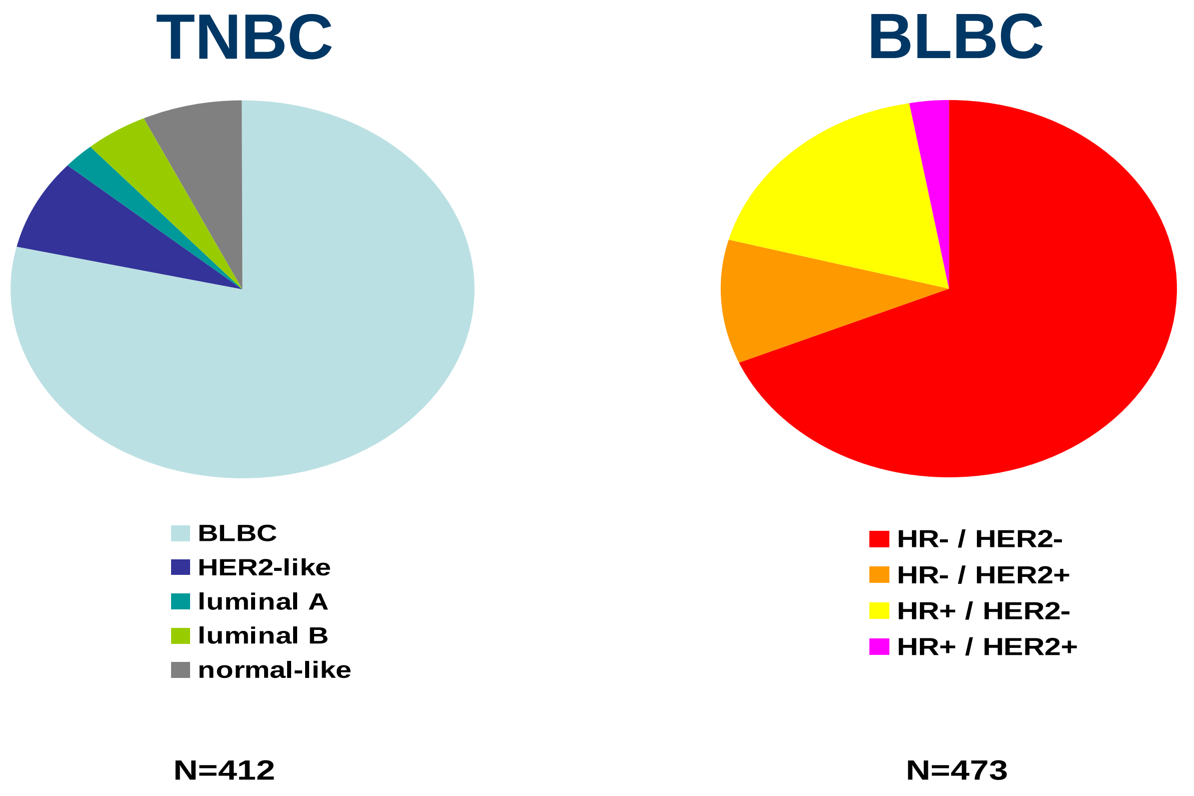
Bis zu 45 %

Non-basal-like
(in Genexpression-analysen)

non-tripelnegativ

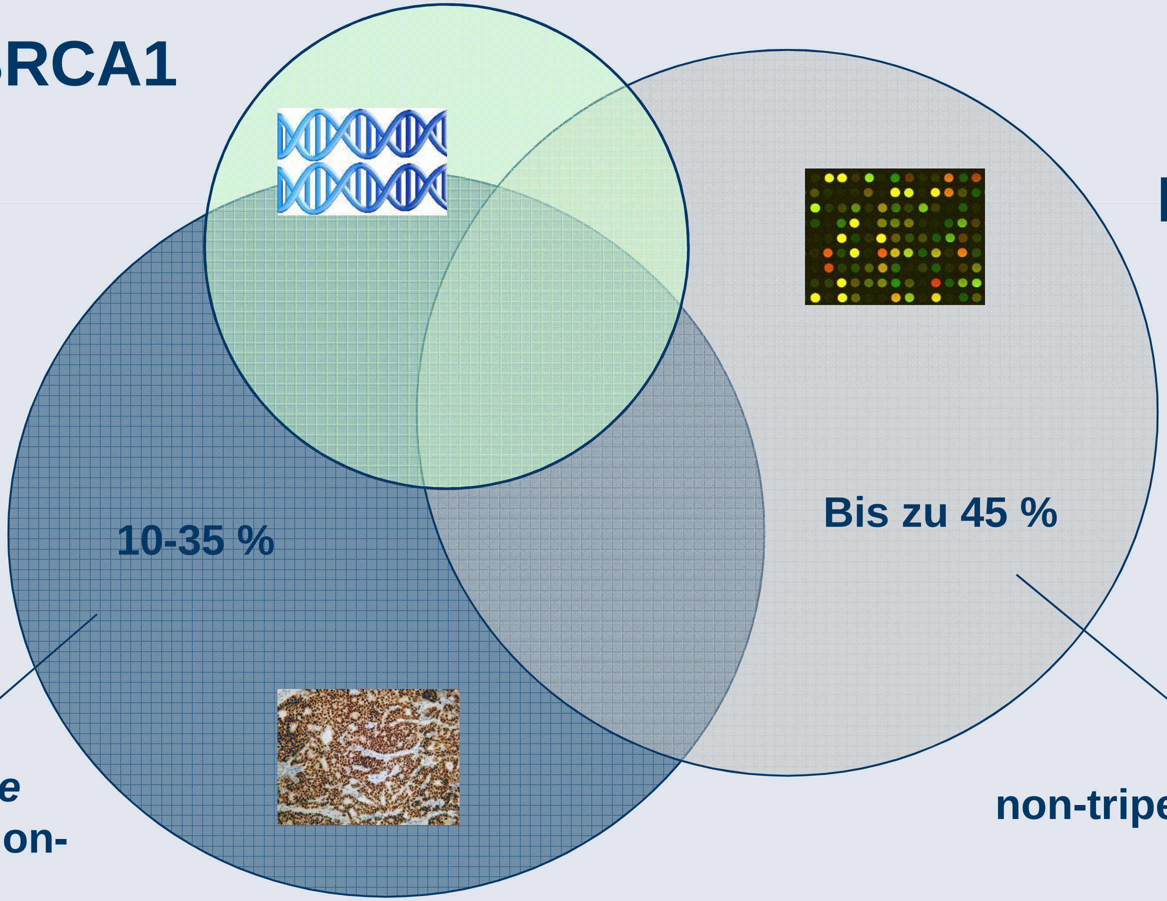
Gluz, Liedtke et al., Ann Onc 2009

Zusammenhang zwischen TNBC und TNBC



Prat et al., Oncologist 2013

Zusammenhang zwischen TNBC, BLBC und BRCA1



BRCA1

BLBC

TNBC

10-35 %

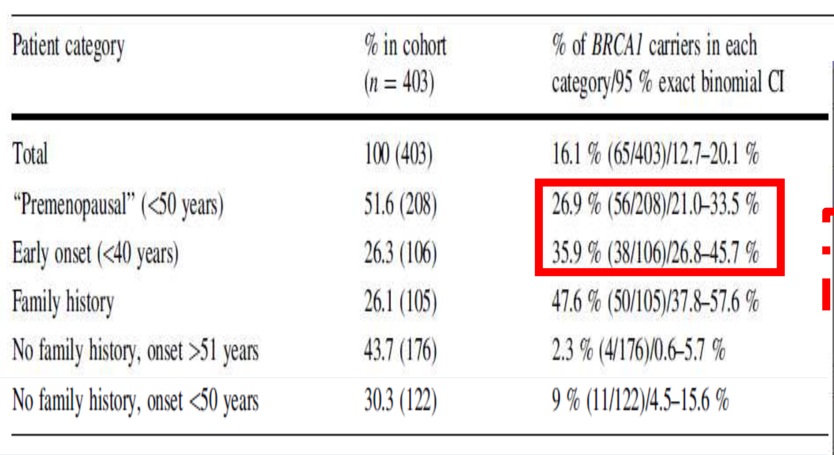
Bis zu 45 %

Non-basal-like
(in Genexpression-analysen)

non-tripelnegativ

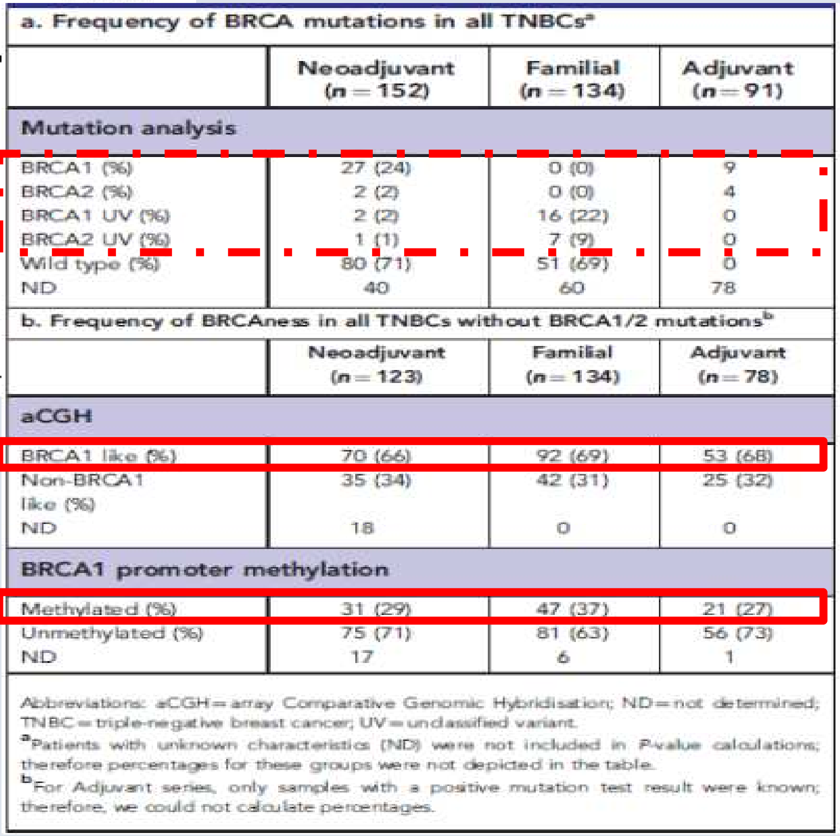
Gluz, Liedtke et al., Ann Onc 2009

Mutationswahrscheinlichkeit beim TNBC



Patient category	% in cohort (*n* = 403)	% of *BRCA1* carriers in each category/95 % exact binomial CI	% in *BRCA1*
Total	100 (403)	16.1 % (65/403)/12.7–20.1 %	
"Premenopausal" (<50 years)	51.6 (208)	26.9 % (56/208)/21.0–33.5 %	
Early onset (<40 years)	26.3 (106)	35.9 % (38/106)/26.8–45.7 %	
Family history	26.1 (105)	47.6 % (50/105)/37.8–57.6 %	
No family history, onset >51 years	43.7 (176)	2.3 % (4/176)/0.6–5.7 %	
No family history, onset <50 years	30.3 (122)	9 % (11/122)/4.5–15.6 %	

Fostira et al., Breast Cancer Res Treat 2012



a. Frequency of BRCA mutations in all TNBCs[a]

	Neoadjuvant (*n* = 152)	Familial (*n* = 134)	Adjuvant (*n* = 91)
Mutation analysis			
BRCA1 (%)	27 (24)	0 (0)	9
BRCA2 (%)	2 (2)	0 (0)	4
BRCA1 UV (%)	2 (2)	16 (22)	0
BRCA2 UV (%)	1 (1)	7 (9)	0
Wild type (%)	80 (71)	51 (69)	0
ND	40	60	78

b. Frequency of BRCAness in all TNBCs without BRCA1/2 mutations[b]

	Neoadjuvant (*n* = 123)	Familial (*n* = 134)	Adjuvant (*n* = 78)
aCGH			
BRCA1 like (%)	70 (66)	92 (69)	53 (68)
Non-BRCA1 like (%)	35 (34)	42 (31)	25 (32)
ND	18	0	0
BRCA1 promoter methylation			
Methylated (%)	31 (29)	47 (37)	21 (27)
Unmethylated (%)	75 (71)	81 (63)	56 (73)
ND	17	6	1

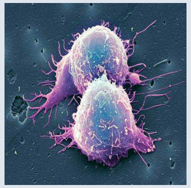
Abbreviations: aCGH = array Comparative Genomic Hybridisation; ND = not determined; TNBC = triple-negative breast cancer; UV = unclassified variant.

[a] Patients with unknown characteristics (ND) were not included in P-value calculations; therefore percentages for these groups were not depicted in the table.

[b] For Adjuvant series, only samples with a positive mutation test result were known; therefore, we could not calculate percentages.

Lips et al., BJC 2013

Überblick



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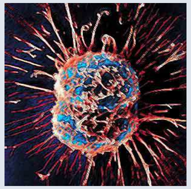

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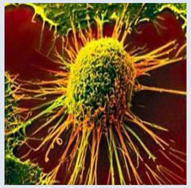

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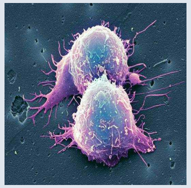
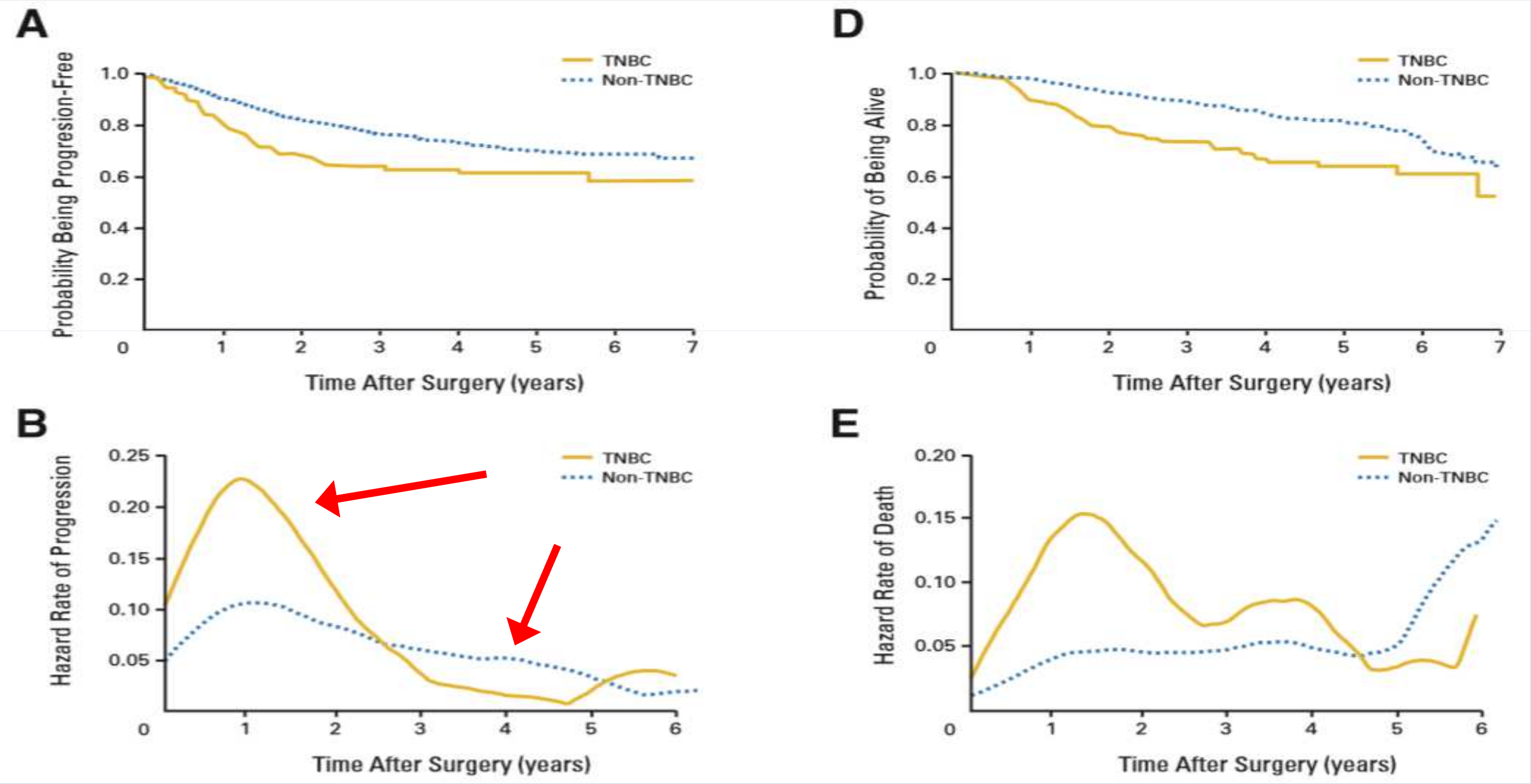


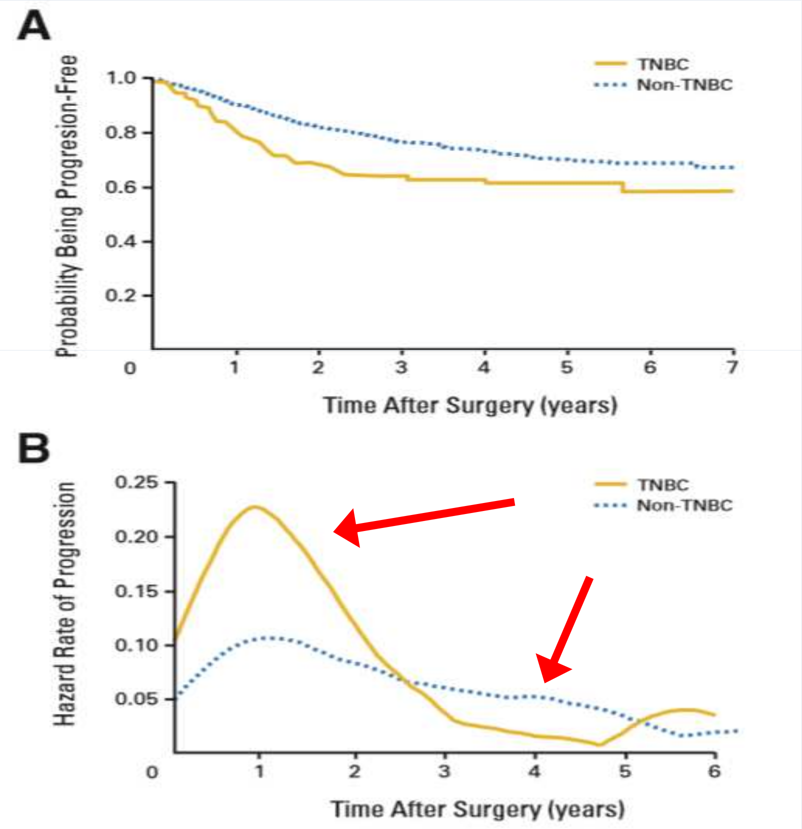
Was sind die neuen Therapieansätze?

Prognose des TNBC



Liedtke et al., J Clin Oncol 2008

Prognose des TNBC

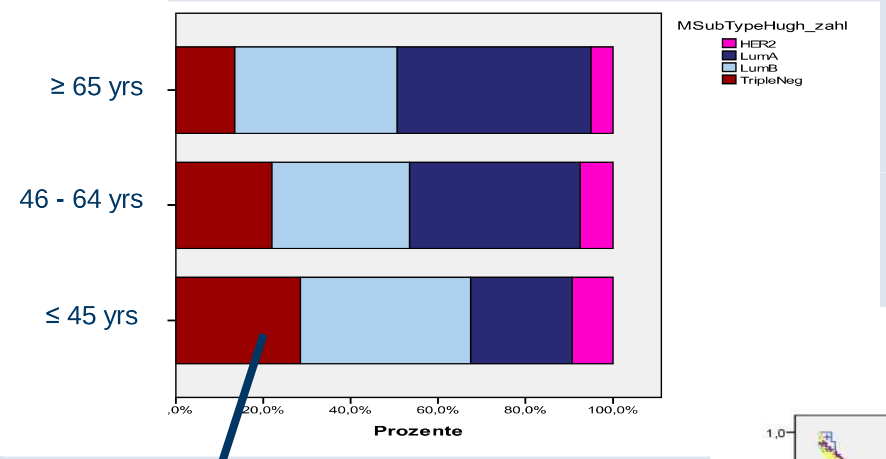


Aggressivere Biologie

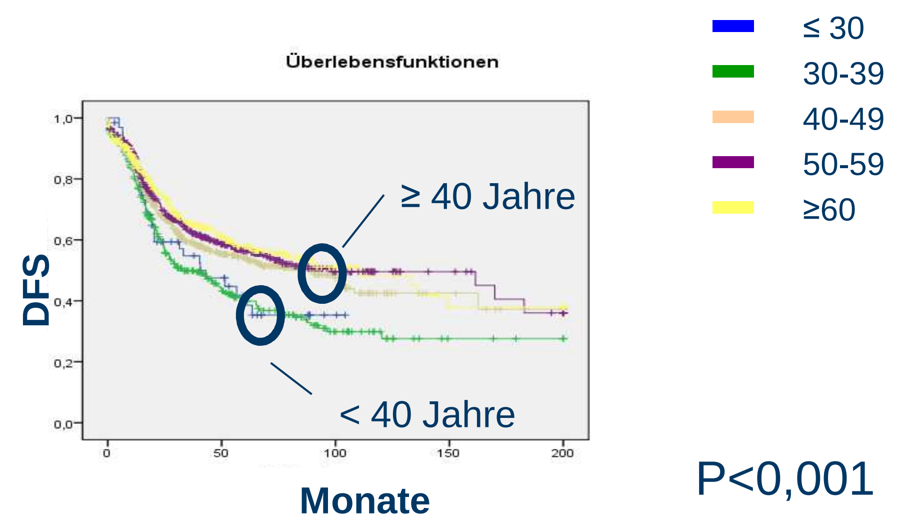
Fehlen therapeutischer Substanzen

Liedtke et al., J Clin Oncol 2008

Zusammenhang zwischen molekularen Subtypen und Alter

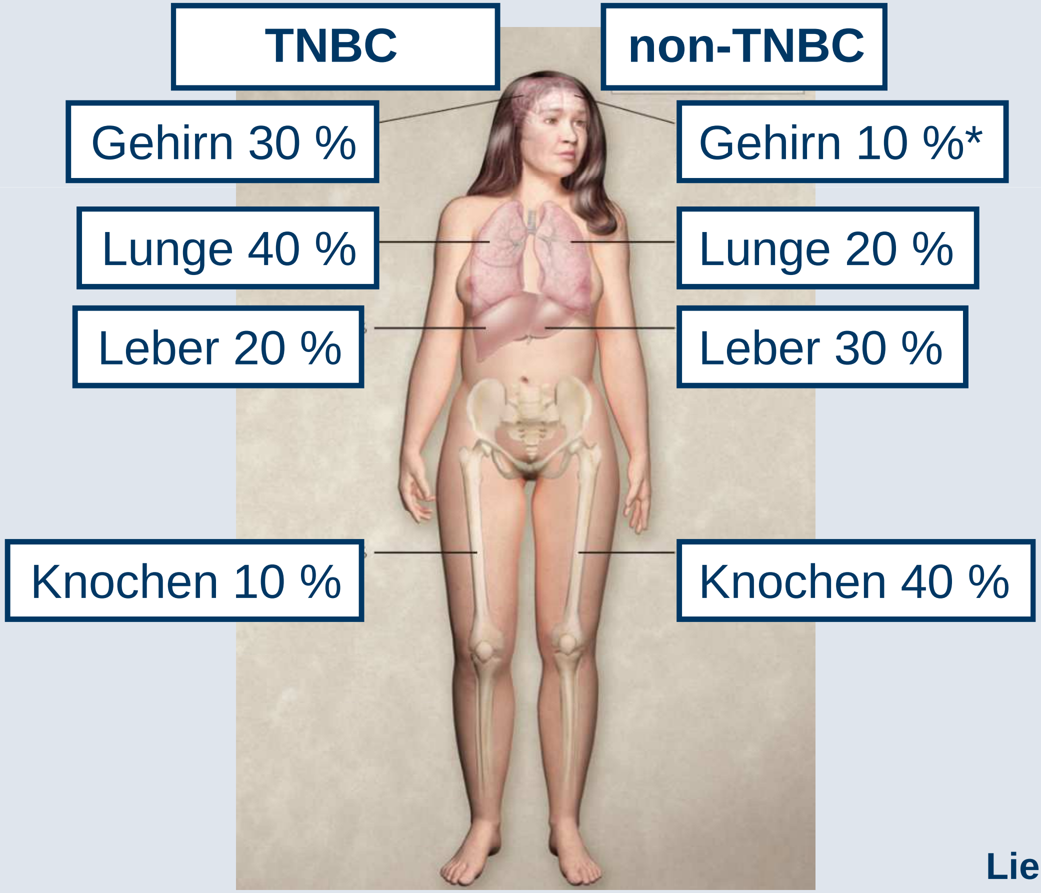


TNBC



Liedtke et al., in prep.

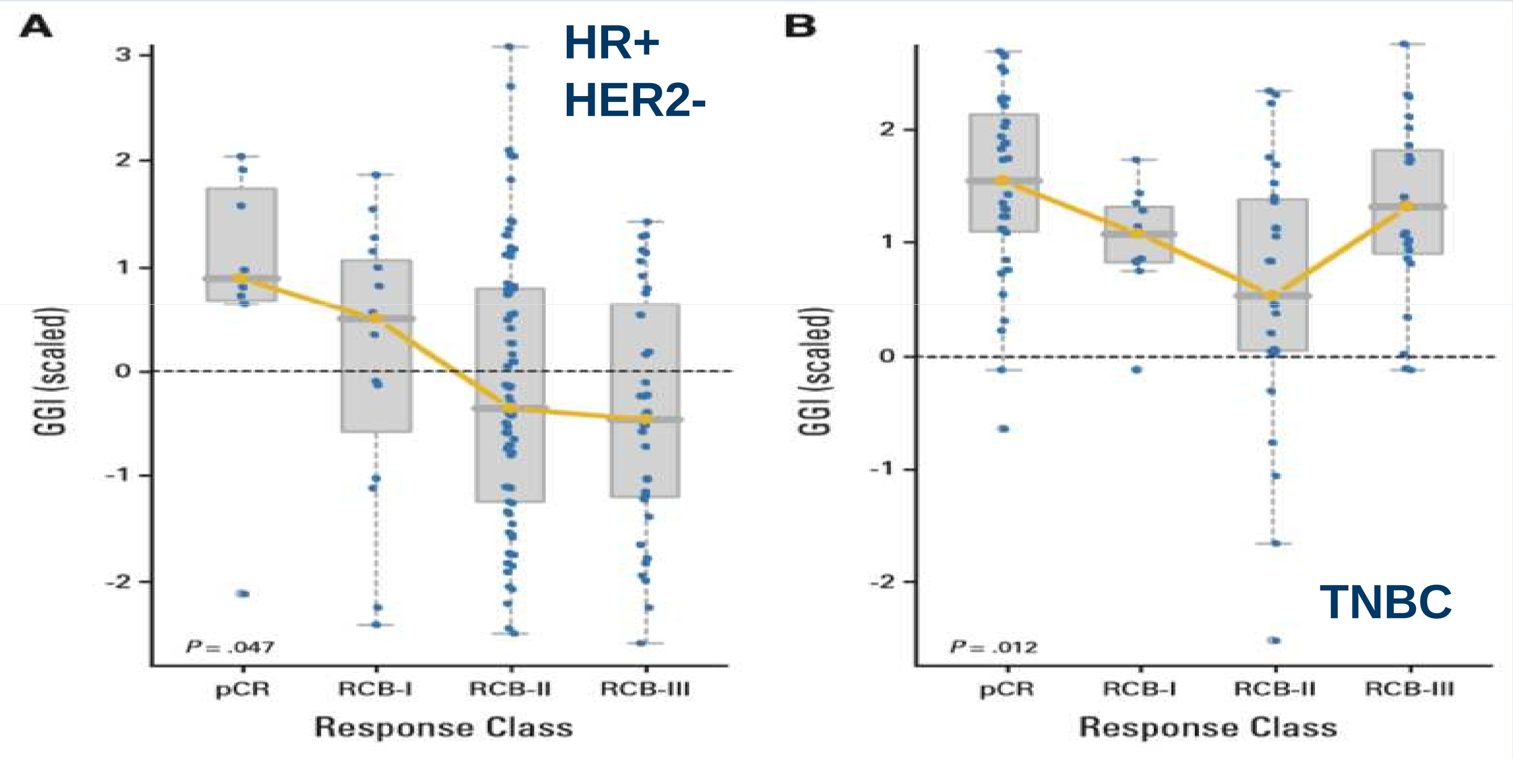
Lokalisation der Metastasen beim TNBC



TNBC	non-TNBC
Gehirn 30 %	Gehirn 10 %*
Lunge 40 %	Lunge 20 %
Leber 20 %	Leber 30 %
Knochen 10 %	Knochen 40 %

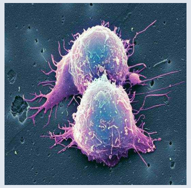
Liedtke et al., J Clin Oncol 2008
Foulkes et al., NEJM 2010

(Genomisches) Grading und Ansprechen auf neoadj. Chemotherapie



Liedtke et al., J Clin Oncol 2009

Überblick



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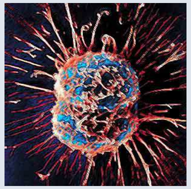

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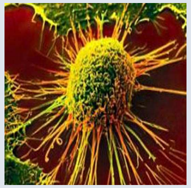

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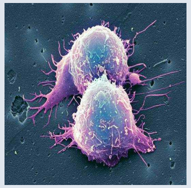
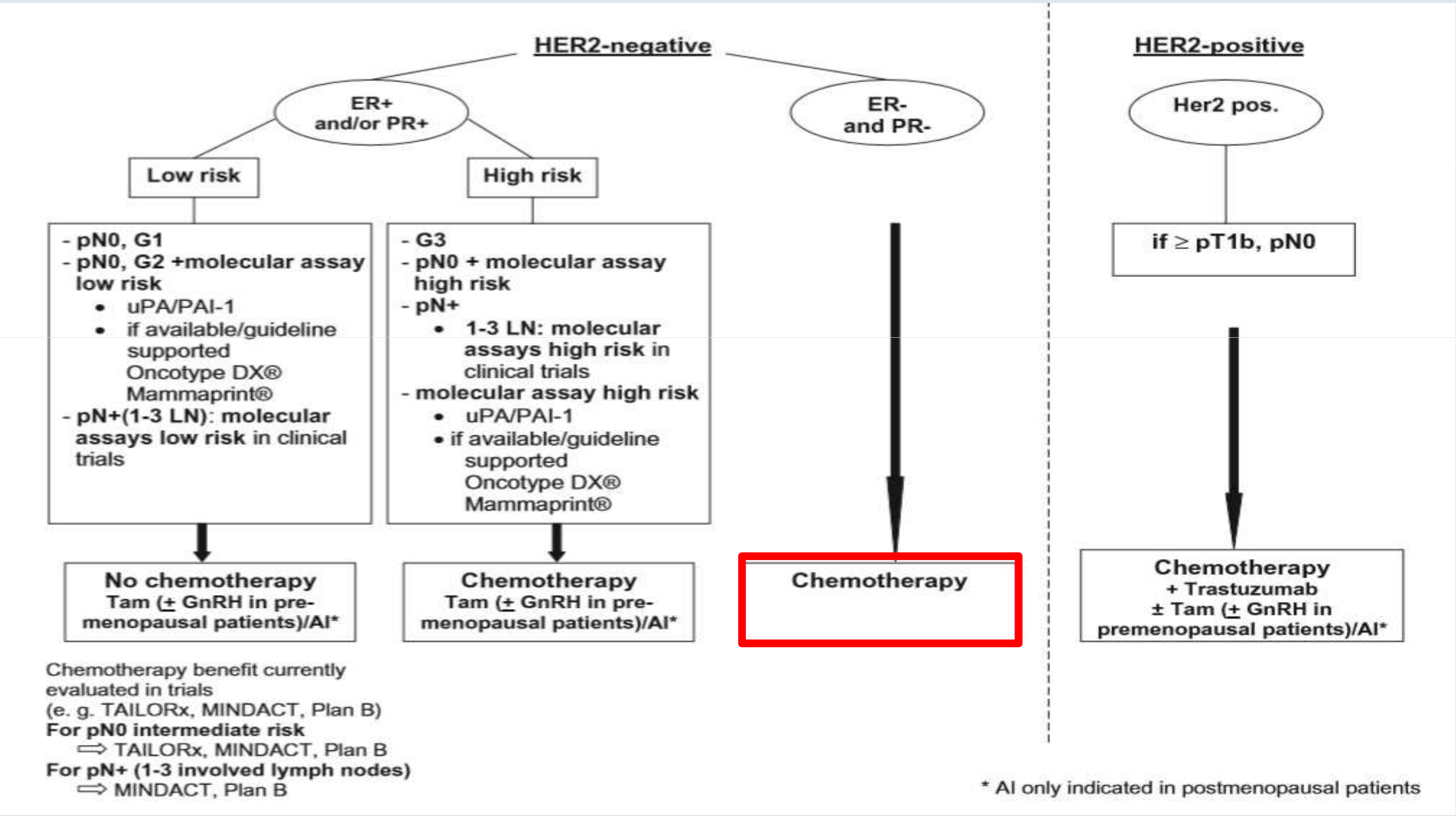


Was sind die neuen Therapieansätze?

Systemische Therapie bei verschiedenen molekularen Subtypen



HER2-negative

ER+ and/or PR+

Low risk

- pN0, G1
- pN0, G2 +molecular assay low risk
  - uPA/PAI-1
  - if available/guideline supported Oncotype DX® Mammaprint®
- pN+(1-3 LN): molecular assays low risk in clinical trials

No chemotherapy
Tam (± GnRH in pre-menopausal patients)/AI*

Chemotherapy benefit currently evaluated in trials
(e. g. TAILORx, MINDACT, Plan B)
For pN0 intermediate risk
⇨ TAILORx, MINDACT, Plan B
For pN+ (1-3 involved lymph nodes)
⇨ MINDACT, Plan B

High risk

- G3
- pN0 + molecular assay high risk
- pN+
  - 1-3 LN: molecular assays high risk in clinical trials
- molecular assay high risk
  - uPA/PAI-1
  - if available/guideline supported Oncotype DX® Mammaprint®

Chemotherapy
Tam (± GnRH in pre-menopausal patients)/AI*

ER- and PR-

Chemotherapy

HER2-positive

Her2 pos.

if ≥ pT1b, pN0

Chemotherapy
+ Trastuzumab
± Tam (± GnRH in premenopausal patients)/AI*

* AI only indicated in postmenopausal patients

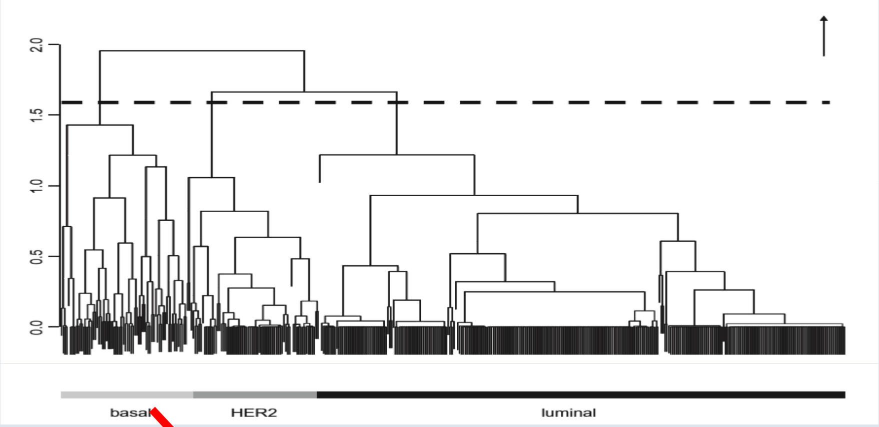
Harbeck […] Liedtke. Cancer Treatment Reviews 2010

Ansprechen gegenüber neoadjuvanter Chemotherapie

		pCR*-Rate	
	n	TNBC	andere
Liedtke et al.	**1118**	**22%**	**11%**
Bidard et al.	**293**	**17%**	**4%**
Fernadez-Morales et al.	**100**	**27%**	**11%**
Carey et al.	**107**	**27%**	**11%**
Kearn et al.	**145**	**17%**	**3%**
Rouzier et al.	**82**	**45%****	**18%****

* Pathologische Komplettremission
** basal/nicht-basal im Genexpressionsprofiling

In-vitro-Chemotherapiesensitivität bei Mammakarzinomsubtypen



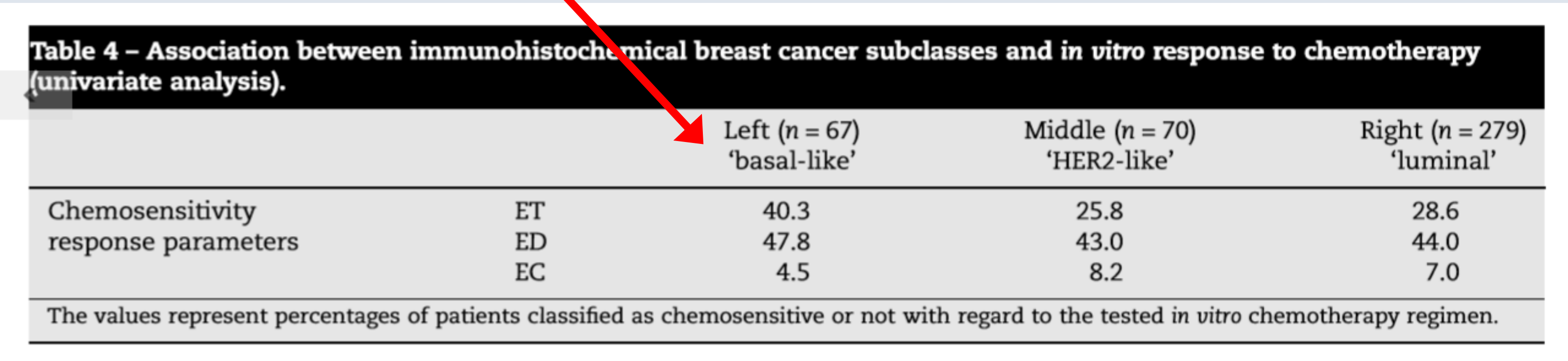


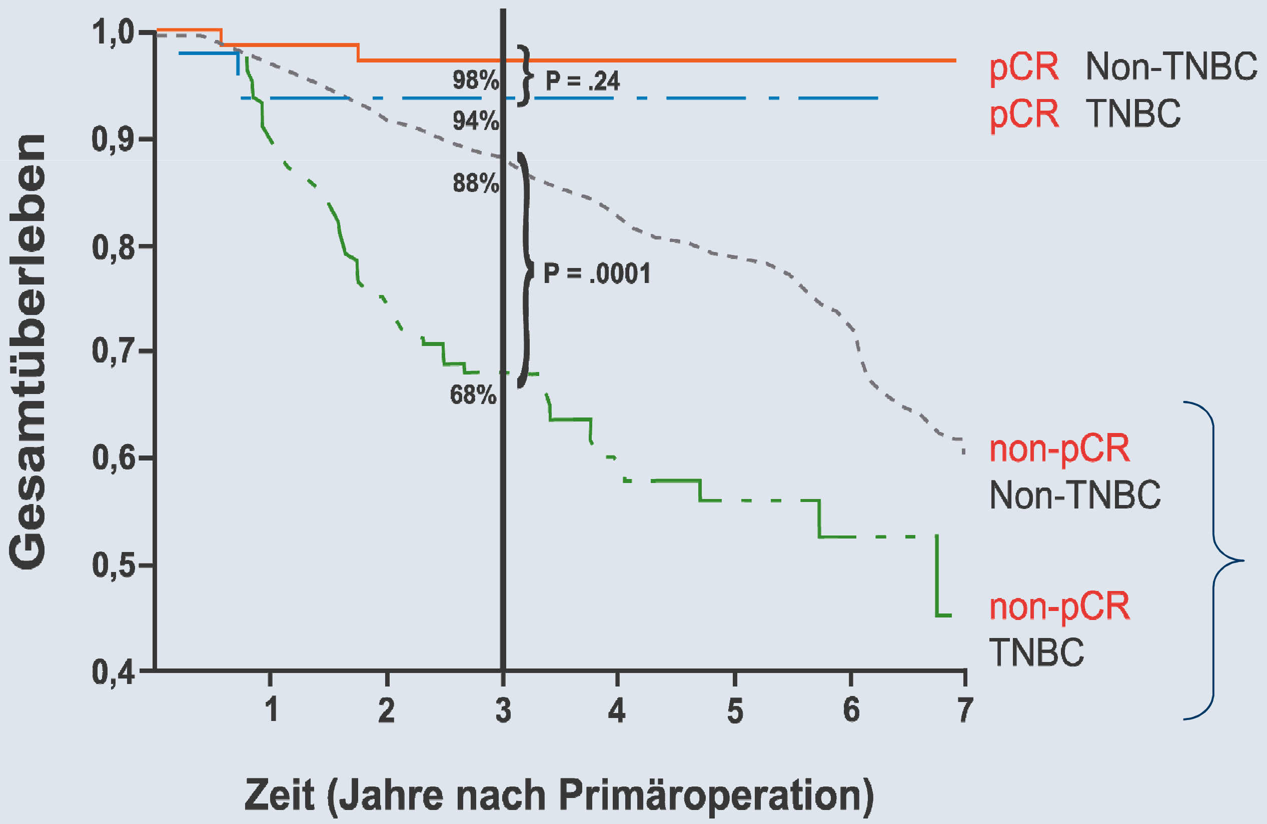
Table 4 – Association between immunohistochemical breast cancer subclasses and *in vitro* response to chemotherapy (univariate analysis).

		Left ($n = 67$) 'basal-like'	Middle ($n = 70$) 'HER2-like'	Right ($n = 279$) 'luminal'
Chemosensitivity response parameters	ET	40.3	25.8	28.6
	ED	47.8	43.0	44.0
	EC	4.5	8.2	7.0

The values represent percentages of patients classified as chemosensitive or not with regard to the tested *in vitro* chemotherapy regimen.

Liedtke et al., Eur J Cancer 2012

Prognose in Abhängigkeit vom Chemotherapieansprechen

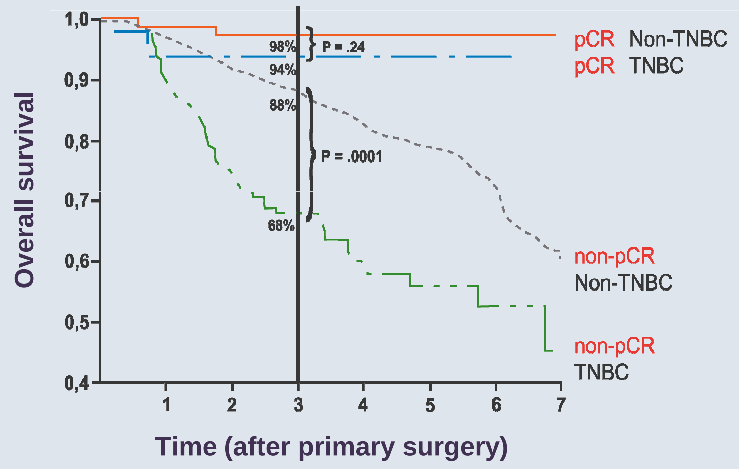


= CHEMO-SENSIBEL

= CHEMO-RESISTENT

Liedtke et al., J Clin Oncol 2008

Anforderungen an die Forschung zum TNBC



- Identifikation der molekularen Mechanismen für Chemotherapieresistenz
- Identifikation von Patientinnen mit/ohne Therapieansprechen
- Optimierung der Chemotherapie (-regime)
- Entwicklung neuer zielgerichteter Therapien

Liedtke et al., J Clin Oncol 2008

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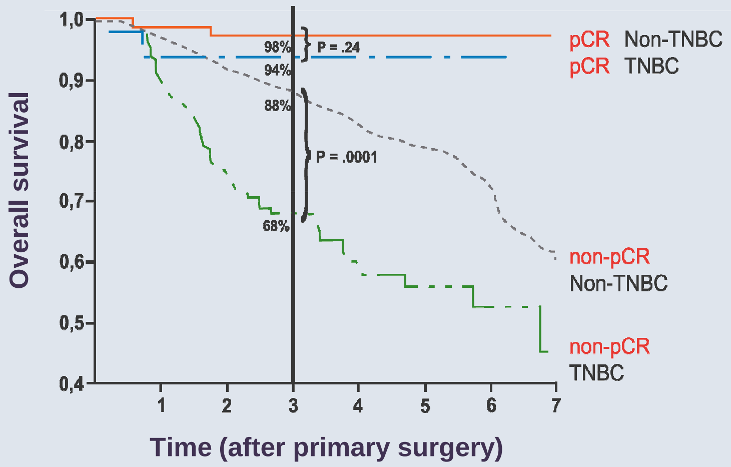

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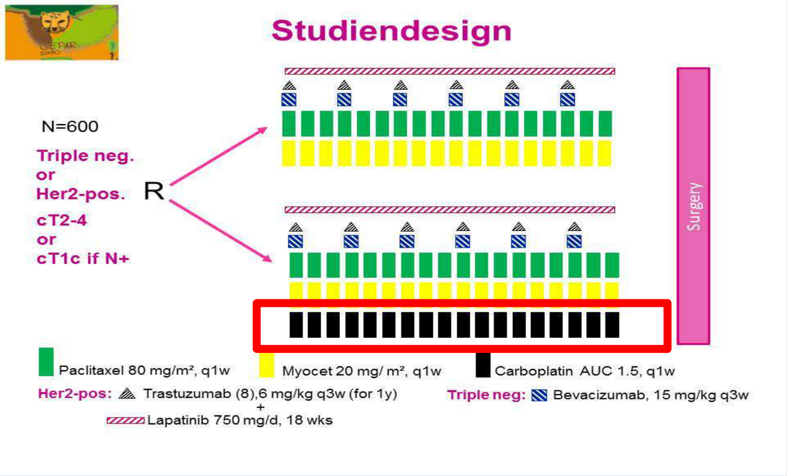
Liedtke et al., J Clin Oncol 2008

Die GeparSixto-Studie: Einsatz von Carboplatin



Studiendesign

N=600

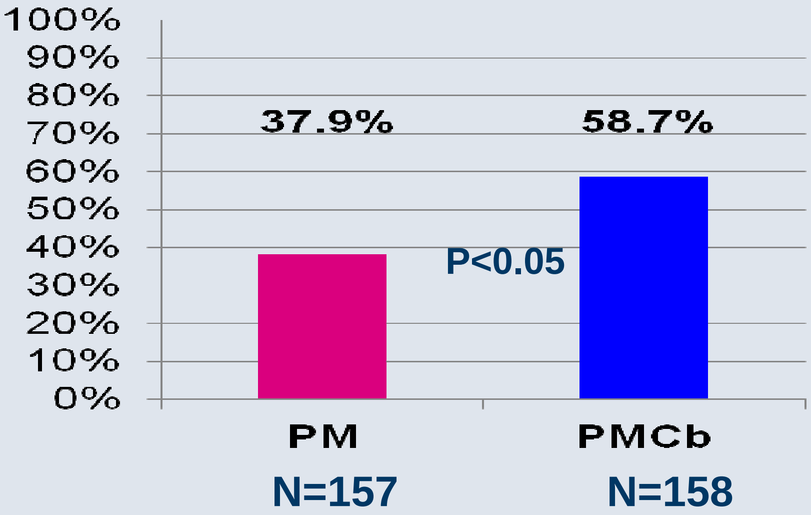
**Triple neg.
or
Her2-pos.**

**cT2-4
or
cT1c if N+**

🟩 Paclitaxel 80 mg/m², q1w
🟨 Myocet 20 mg/ m², q1w
■ Carboplatin AUC 1.5, q1w

Her2-pos: ▲ Trastuzumab (8),6 mg/kg q3w (for 1y)
+
▨ Lapatinib 750 mg/d, 18 wks

Triple neg: ▧ Bevacizumab, 15 mg/kg q3w



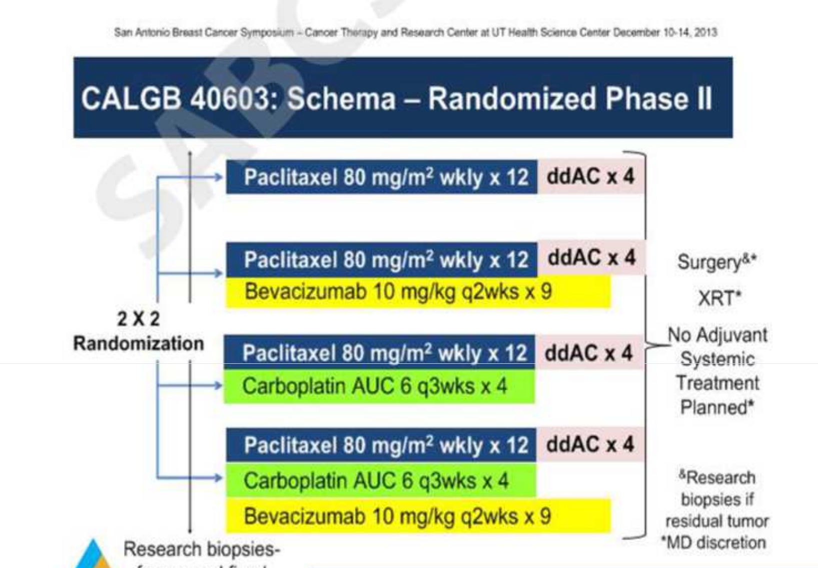
Von Minckwitz et al., ASCO 2013

Schwere unerwünschte Nebenwirkungen (SAEs) in der GeparSixto

	PM(+B) PMCb(+HL) (N=157)	PMCb(+B) (N=158)	PM(+HL) (N=136)
N with at least 1 SAE (%)	62 (39.5)	69 (43.7)	55 (40.4)
Infections	15	18	21
pneumonia	6	1	11
Blood	7	26	3
anemia	1	11	1
febrile neutropenia	6	6	1
Gastrointestinal	10	11	10
diarrhea	3	0	3

Von Minckwitz et al., ASCO 2013

Carboplatin neoadjuvant (CALBG 40603 / ALLIANCE)



San Antonio Breast Cancer Symposium – Cancer Therapy and Research Center at UT Health Science Center December 10-14, 2013

CALGB 40603: Schema – Randomized Phase II

2 X 2
Randomization

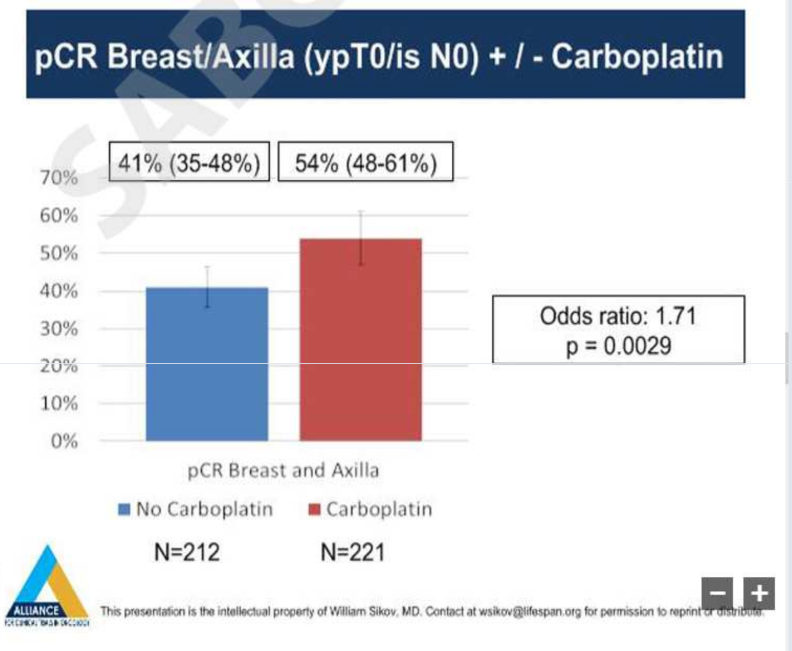
- Paclitaxel 80 mg/m² wkly x 12 | ddAC x 4
- Paclitaxel 80 mg/m² wkly x 12 | ddAC x 4
  Bevacizumab 10 mg/kg q2wks x 9
- Paclitaxel 80 mg/m² wkly x 12 | ddAC x 4
  Carboplatin AUC 6 q3wks x 4
- Paclitaxel 80 mg/m² wkly x 12 | ddAC x 4
  Carboplatin AUC 6 q3wks x 4
  Bevacizumab 10 mg/kg q2wks x 9

Surgery&*
XRT*
No Adjuvant Systemic Treatment Planned*

&Research biopsies if residual tumor
*MD discretion

Research biopsies-
frozen and fixed

This presentation is the intellectual



pCR Breast/Axilla (ypT0/is N0) + / - Carboplatin

Odds ratio: 1.71
p = 0.0029

N=212 N=221

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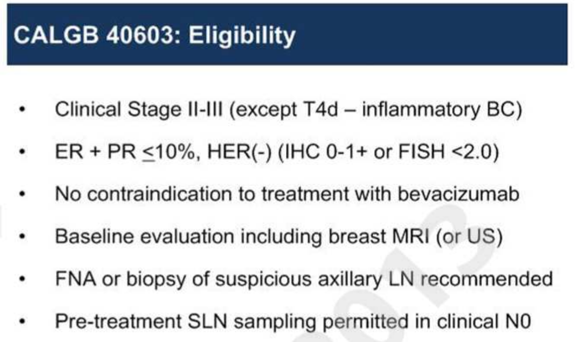
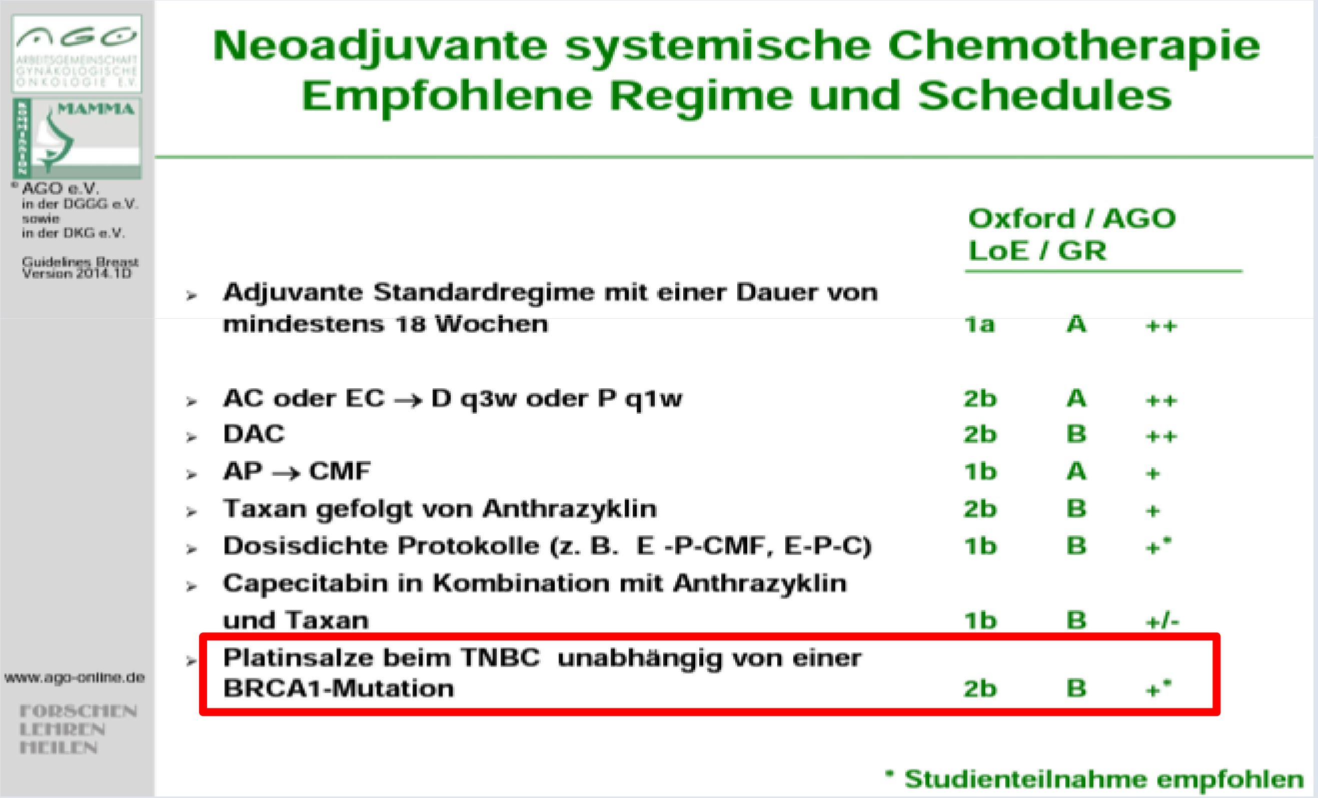


CALGB 40603: Eligibility

- Clinical Stage II-III (except T4d – inflammatory BC)
- ER + PR ≤10%, HER(-) (IHC 0-1+ or FISH <2.0)
- No contraindication to treatment with bevacizumab
- Baseline evaluation including breast MRI (or US)
- FNA or biopsy of suspicious axillary LN recommended
- Pre-treatment SLN sampling permitted in clinical N0

Sikov et al., SABCS 2013

AGO-Empfehlungen zur PST (bei TNBC)



ARBEITSGEMEINSCHAFT GYNÄKOLOGISCHE ONKOLOGIE E.V.
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Guidelines Breast
Version 2014.1D

www.ago-online.de

FORSCHEN
LEHREN
HEILEN

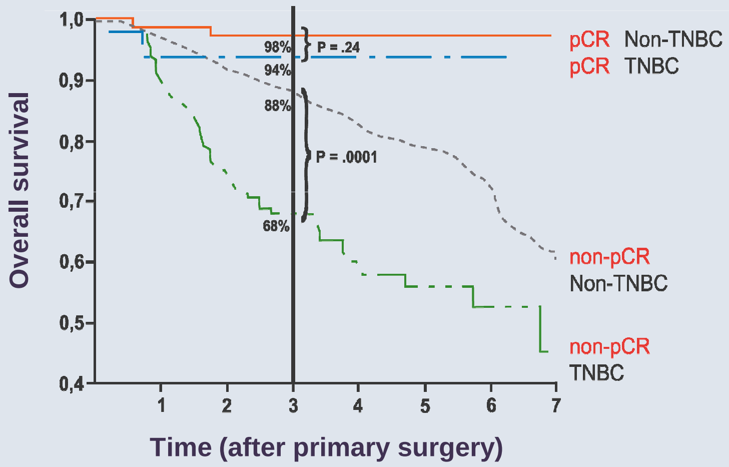
Neoadjuvante systemische Chemotherapie Empfohlene Regime und Schedules

	Oxford / AGO LoE / GR		
Adjuvante Standardregime mit einer Dauer von mindestens 18 Wochen	1a	A	++
AC oder EC → D q3w oder P q1w	2b	A	++
DAC	2b	B	++
AP → CMF	1b	A	+
Taxan gefolgt von Anthrazyklin	2b	B	+
Dosisdichte Protokolle (z. B. E -P-CMF, E-P-C)	1b	B	+*
Capecitabin in Kombination mit Anthrazyklin und Taxan	1b	B	+/-
Platinsalze beim TNBC unabhängig von einer BRCA1-Mutation	2b	B	+*

* Studienteilnahme empfohlen

AGO 2014

Anforderungen an die Forschung zum TNBC



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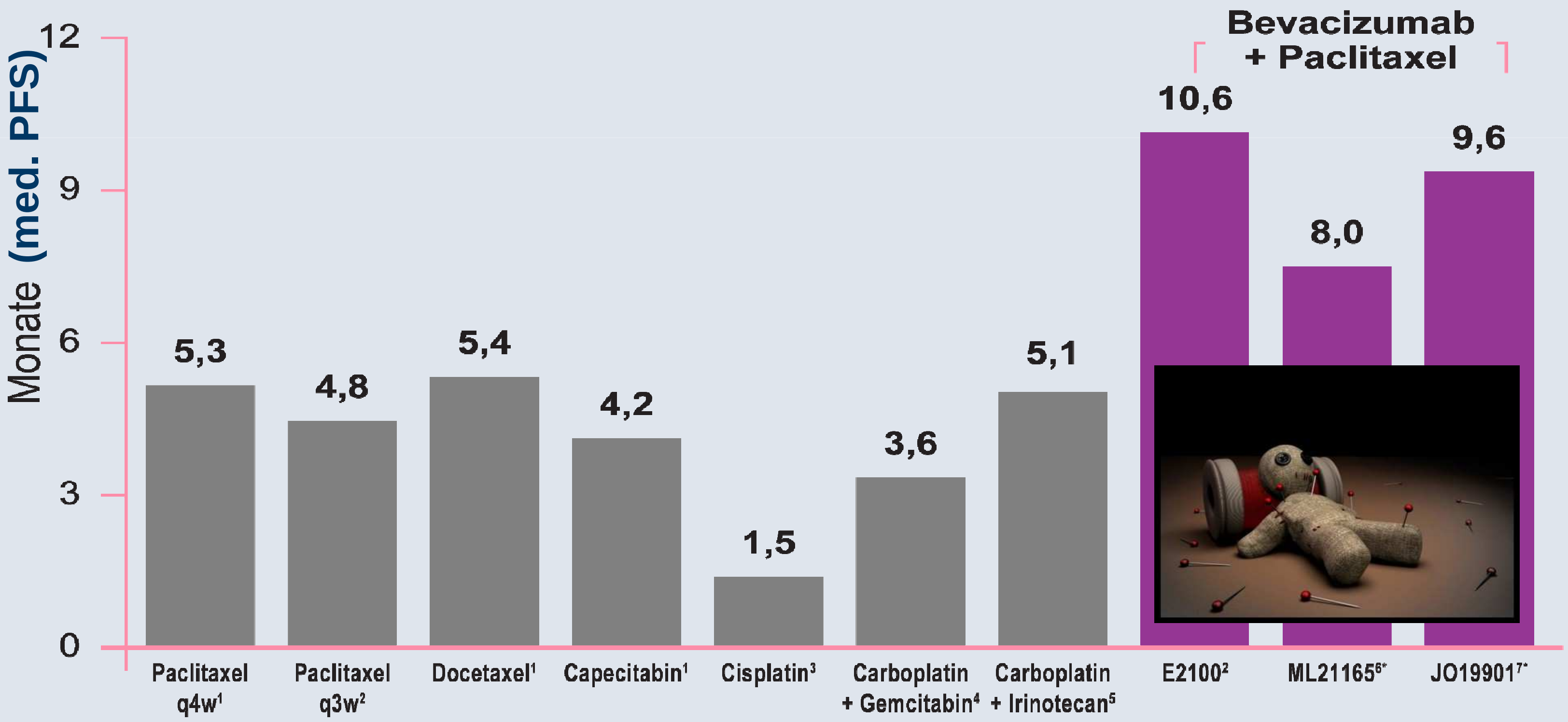
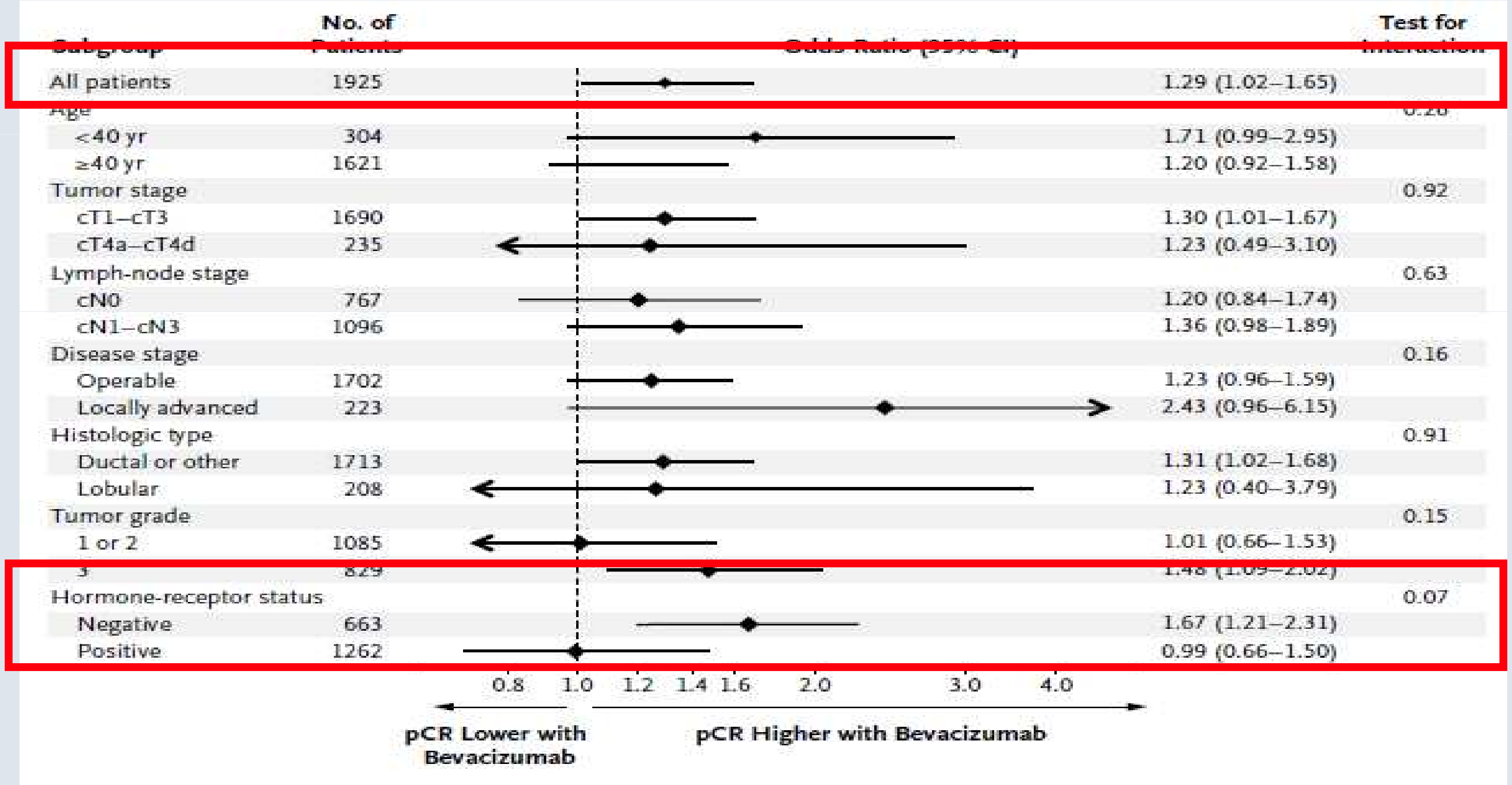
Liedtke et al., J Clin Oncol 2008

Effizienz von first-line-Regimen beim mTNBC



O'Shaughnessy et al., SABCS 2010; Finn et al., J Clin Oncol 2009; Baselga et al., Ann Oncol 2010; O'Shaughnessy et al. NEJM 2011; O'Shaughnessy et al., BCRT 2007; Schneeweiß et al., EMCC 2011; Aogi et al., BCRT 2011

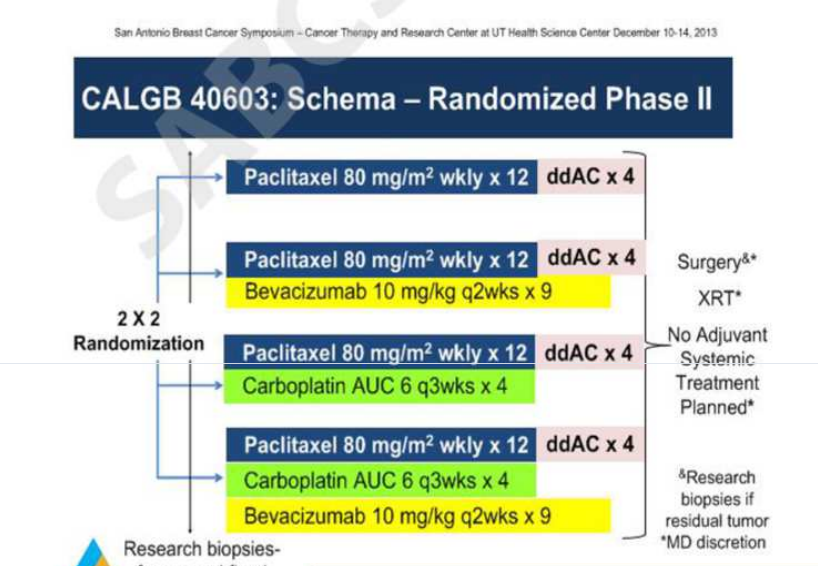
pCR-Raten durch Bevacizumab (Gepar Quinto)



Subgroup	No. of Patients	Odds Ratio (95% CI)	Test for Interaction
All patients	1925	1.29 (1.02–1.65)	
Age			0.28
<40 yr	304	1.71 (0.99–2.95)	
≥40 yr	1621	1.20 (0.92–1.58)	
Tumor stage			0.92
cT1–cT3	1690	1.30 (1.01–1.67)	
cT4a–cT4d	235	1.23 (0.49–3.10)	
Lymph-node stage			0.63
cN0	767	1.20 (0.84–1.74)	
cN1–cN3	1096	1.36 (0.98–1.89)	
Disease stage			0.16
Operable	1702	1.23 (0.96–1.59)	
Locally advanced	223	2.43 (0.96–6.15)	
Histologic type			0.91
Ductal or other	1713	1.31 (1.02–1.68)	
Lobular	208	1.23 (0.40–3.79)	
Tumor grade			0.15
1 or 2	1085	1.01 (0.66–1.53)	
3	829	1.48 (1.09–2.02)	
Hormone-receptor status			0.07
Negative	663	1.67 (1.21–2.31)	
Positive	1262	0.99 (0.66–1.50)	

Von Minckwitz et al., NEJM 2012

Bevacizumab neoadjuvant (CALBG 40603 / ALLIANCE)



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CALGB 40603: Schema – Randomized Phase II

2 X 2 Randomization

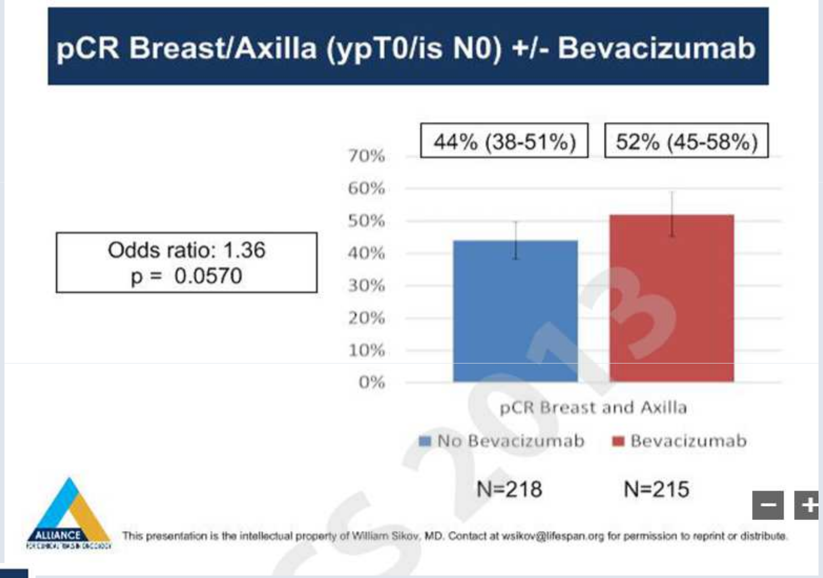
- Paclitaxel 80 mg/m² wkly x 12 | ddAC x 4
- Paclitaxel 80 mg/m² wkly x 12 | ddAC x 4
Bevacizumab 10 mg/kg q2wks x 9
- Paclitaxel 80 mg/m² wkly x 12 | ddAC x 4
Carboplatin AUC 6 q3wks x 4
- Paclitaxel 80 mg/m² wkly x 12 | ddAC x 4
Carboplatin AUC 6 q3wks x 4
Bevacizumab 10 mg/kg q2wks x 9

Surgery&*
XRT*
No Adjuvant Systemic Treatment Planned*

&Research biopsies if residual tumor
*MD discretion

Research biopsies- frozen and fixed

This presentation is the intellectual



pCR Breast/Axilla (ypT0/is N0) +/- Bevacizumab

Odds ratio: 1.36
p = 0.0570

N=218 N=215

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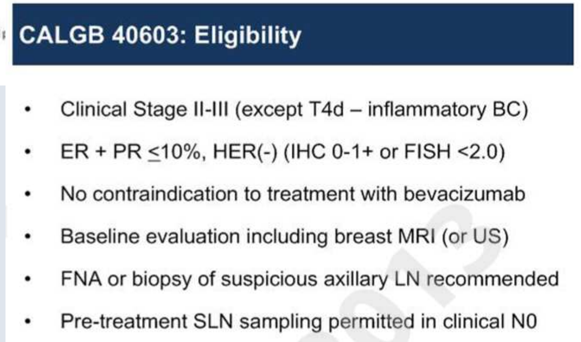
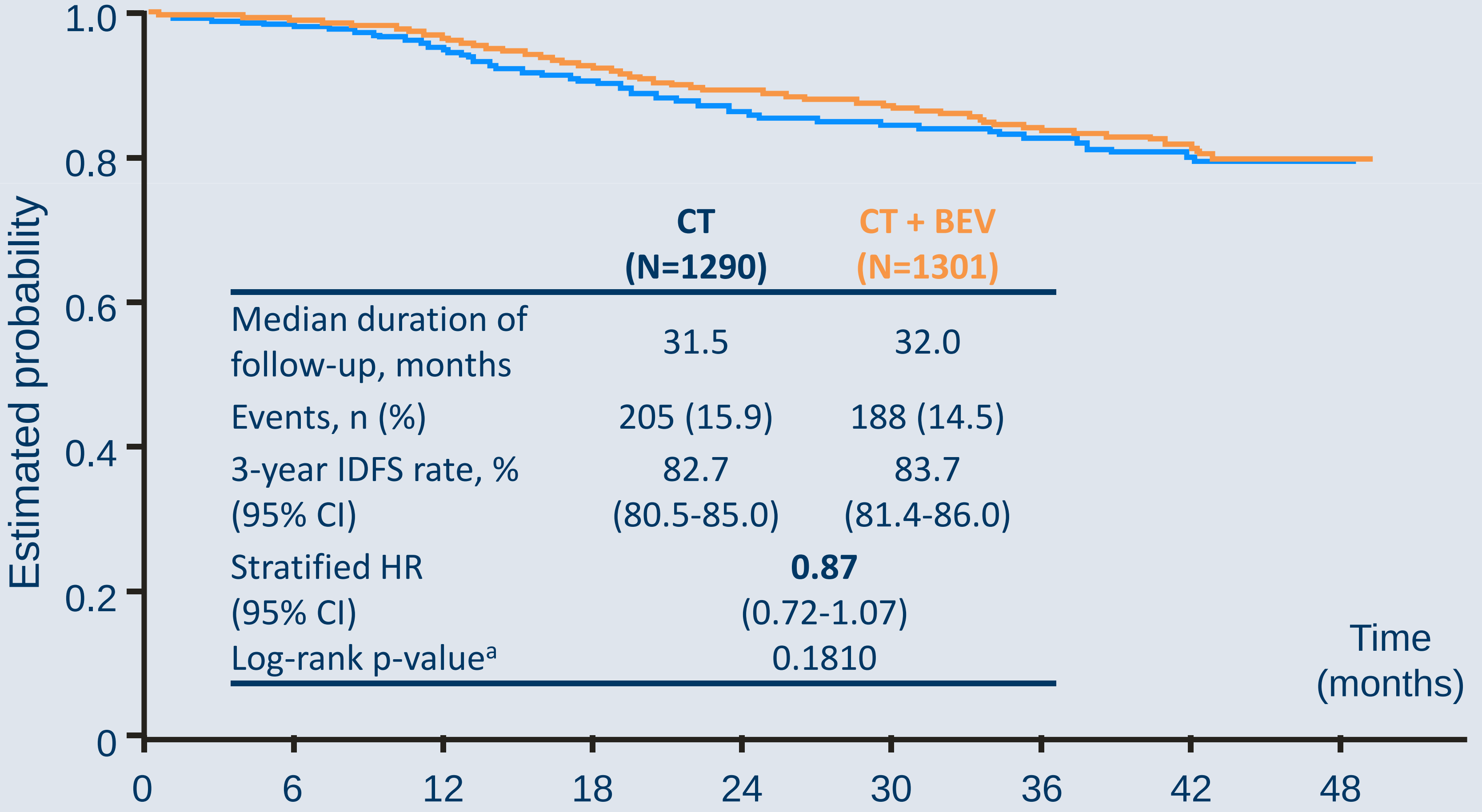


CALGB 40603: Eligibility

- Clinical Stage II-III (except T4d – inflammatory BC)
- ER + PR ≤10%, HER(-) (IHC 0-1+ or FISH <2.0)
- No contraindication to treatment with bevacizumab
- Baseline evaluation including breast MRI (or US)
- FNA or biopsy of suspicious axillary LN recommended
- Pre-treatment SLN sampling permitted in clinical N0

Sikov et al., SABCS 2013

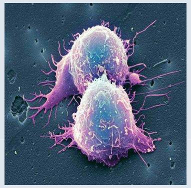
Rezidiv-freies Überleben durch Bevacizumab beim TNBC



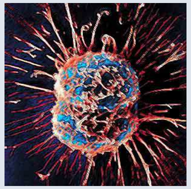
	CT (N=1290)	**CT + BEV (N=1301)**
Median duration of follow-up, months	31.5	32.0
Events, n (%)	205 (15.9)	188 (14.5)
3-year IDFS rate, % (95% CI)	82.7 (80.5-85.0)	83.7 (81.4-86.0)
Stratified HR (95% CI)	**0.87** (0.72-1.07)	
Log-rank p-value[a]	0.1810	

Cameron et al., SABCS 2012

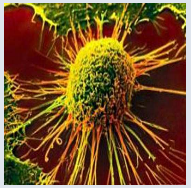
Überblick



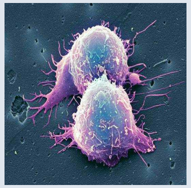
Was ist das tripelnegative Mammakarzinom?



Wie ist der klinische Verlauf?

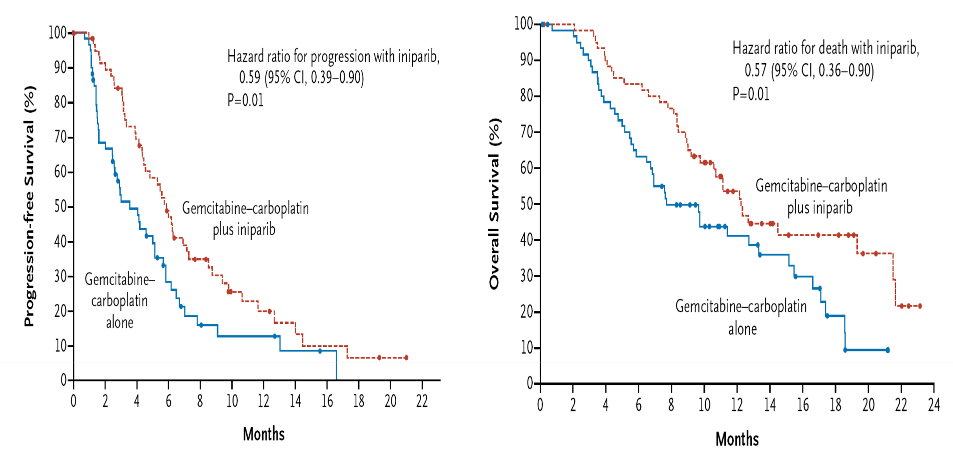


Welche Therapien können eingesetzt werden?

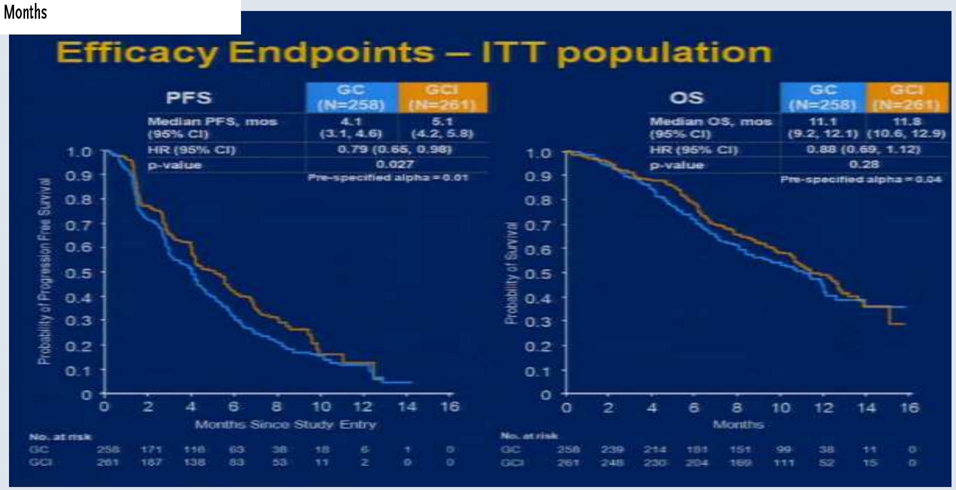


Was sind die neuen Therapieansätze?

Wirksamkeit von Iniparib (Phase II und III)



O‘Shaughnessy et al., NEJM 2011


Efficacy Endpoints – ITT population

PFS	GC (N=258)	GCI (N=261)
Median PFS, mos (95% CI)	4.1 (3.1, 4.6)	5.1 (4.2, 5.8)
HR (95% CI)	0.79 (0.65, 0.98)	
p-value	0.027	
	Pre-specified alpha = 0.01	

OS	GC (N=258)	GCI (N=261)
Median OS, mos (95% CI)	11.1 (9.2, 12.1)	11.8 (10.6, 12.9)
HR (95% CI)	0.88 (0.69, 1.12)	
p-value	0.28	
	Pre-specified alpha = 0.04	

No. at risk									
GC	258	171	116	63	38	18	6	1	0
GCI	261	187	138	83	53	11	2	0	0

No. at risk									
GC	258	239	214	181	151	99	38	11	0
GCI	261	248	230	204	169	111	52	15	0

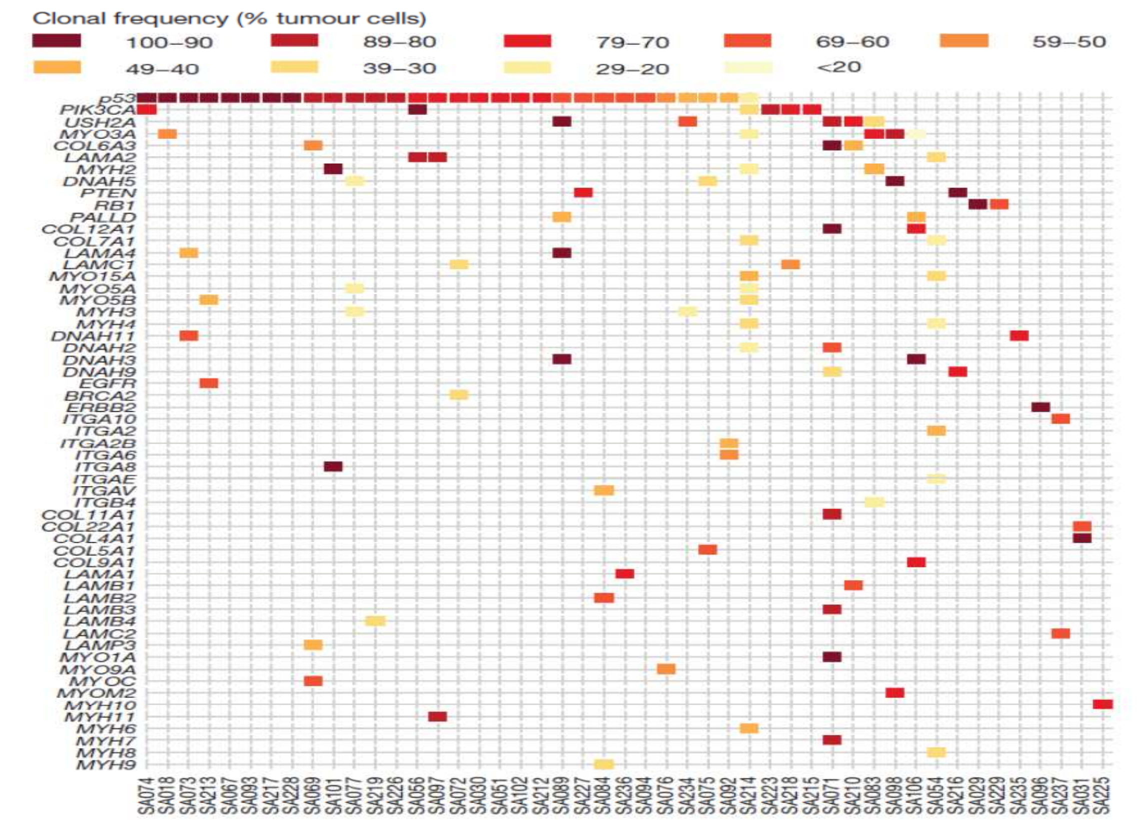
Probability of Progression Free Survival
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
2
4
6
8
10
12
14
16
Months Since Study Entry
Probability of Survival
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
2
4
6
8
10
12
14
16
Months

O‘Shaughnessy et al., Proc ASCO 2011

Molekulare Heterogenität des TNBC

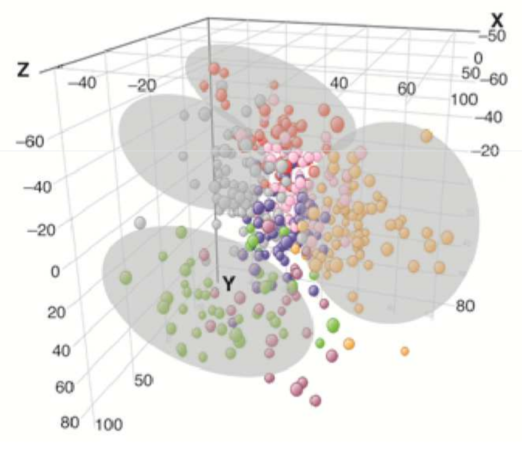
PIK3CA →

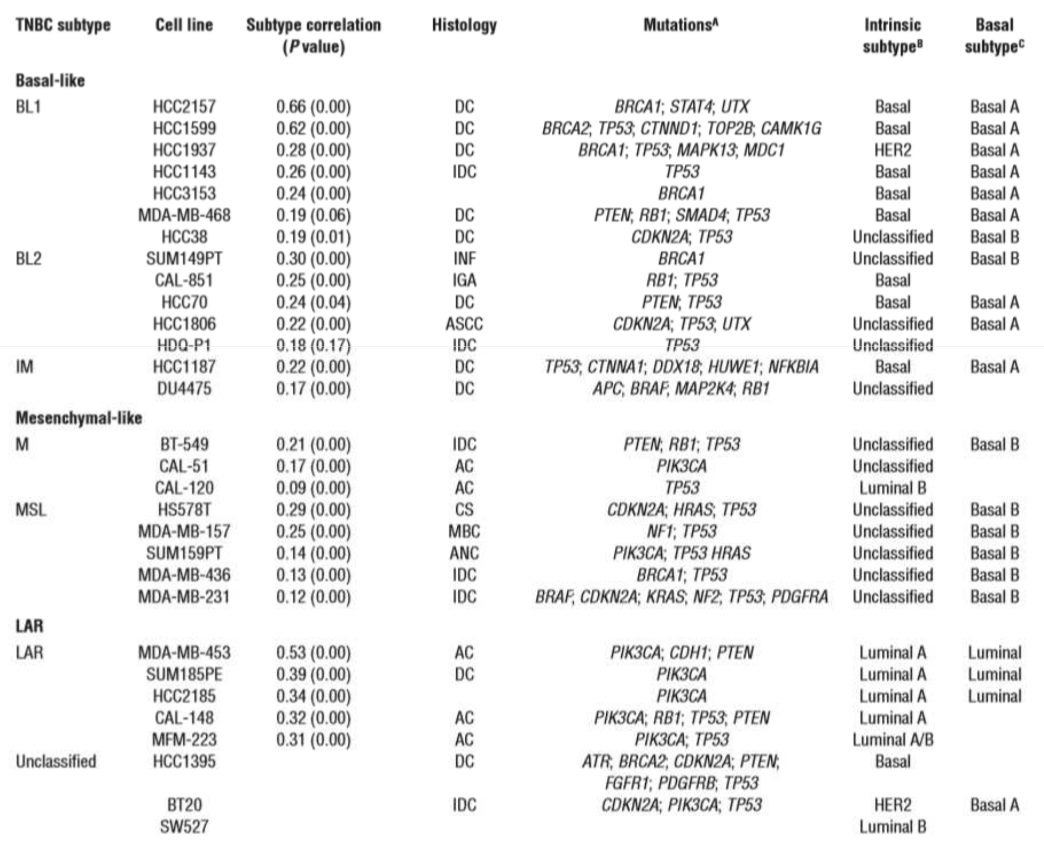
EGFR →



Shah et al., Nature 2012

Definition verschiedener Subtypen des TNBC

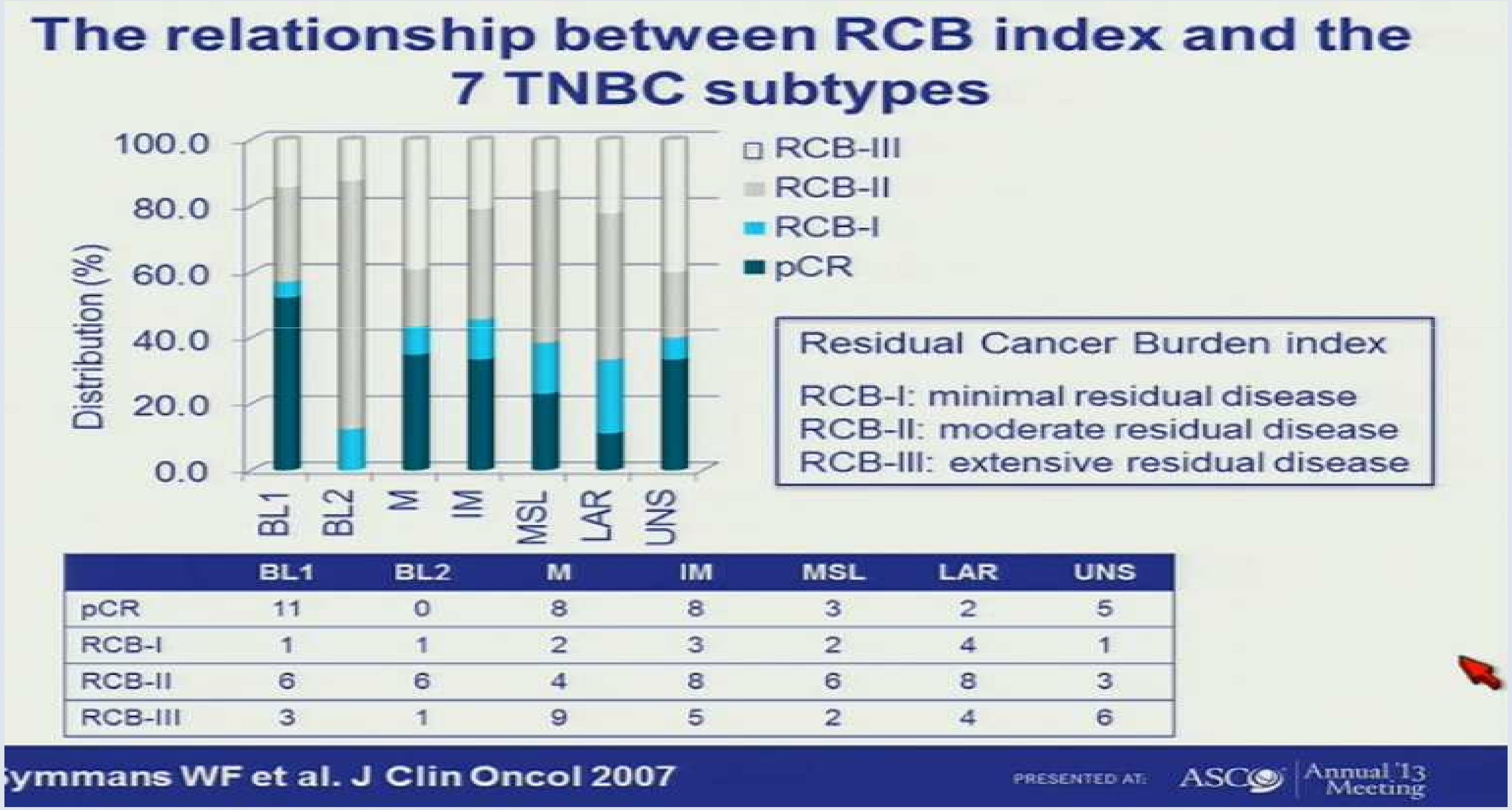




TNBC subtype	Cell line	Subtype correlation (*P* value)	Histology	Mutations^{A}	Intrinsic subtype^{B}	Basal subtype^{C}
Basal-like						
BL1	HCC2157	0.66 (0.00)	DC	*BRCA1; STAT4; UTX*	Basal	Basal A
	HCC1599	0.62 (0.00)	DC	*BRCA2; TP53; CTNND1; TOP2B; CAMK1G*	Basal	Basal A
	HCC1937	0.28 (0.00)	DC	*BRCA1; TP53; MAPK13; MDC1*	HER2	Basal A
	HCC1143	0.26 (0.00)	IDC	*TP53*	Basal	Basal A
	HCC3153	0.24 (0.00)		*BRCA1*	Basal	Basal A
	MDA-MB-468	0.19 (0.06)	DC	*PTEN; RB1; SMAD4; TP53*	Basal	Basal A
	HCC38	0.19 (0.01)	DC	*CDKN2A; TP53*	Unclassified	Basal B
BL2	SUM149PT	0.30 (0.00)	INF	*BRCA1*	Unclassified	Basal B
	CAL-851	0.25 (0.00)	IGA	*RB1; TP53*	Basal	
	HCC70	0.24 (0.04)	DC	*PTEN; TP53*	Basal	Basal A
	HCC1806	0.22 (0.00)	ASCC	*CDKN2A; TP53; UTX*	Unclassified	Basal A
	HDQ-P1	0.18 (0.17)	IDC	*TP53*	Unclassified	
IM	HCC1187	0.22 (0.00)	DC	*TP53; CTNNA1; DDX18; HUWE1; NFKBIA*	Basal	Basal A
	DU4475	0.17 (0.00)	DC	*APC; BRAF; MAP2K4; RB1*	Unclassified	
Mesenchymal-like						
M	BT-549	0.21 (0.00)	IDC	*PTEN; RB1; TP53*	Unclassified	Basal B
	CAL-51	0.17 (0.00)	AC	*PIK3CA*	Unclassified	
	CAL-120	0.09 (0.00)	AC	*TP53*	Luminal B	
MSL	HS578T	0.29 (0.00)	CS	*CDKN2A; HRAS; TP53*	Unclassified	Basal B
	MDA-MB-157	0.25 (0.00)	MBC	*NF1; TP53*	Unclassified	Basal B
	SUM159PT	0.14 (0.00)	ANC	*PIK3CA; TP53 HRAS*	Unclassified	Basal B
	MDA-MB-436	0.13 (0.00)	IDC	*BRCA1; TP53*	Unclassified	Basal B
	MDA-MB-231	0.12 (0.00)	IDC	*BRAF; CDKN2A; KRAS; NF2; TP53; PDGFRA*	Unclassified	Basal B
LAR						
LAR	MDA-MB-453	0.53 (0.00)	AC	*PIK3CA; CDH1; PTEN*	Luminal A	Luminal
	SUM185PE	0.39 (0.00)	DC	*PIK3CA*	Luminal A	Luminal
	HCC2185	0.34 (0.00)		*PIK3CA*	Luminal A	Luminal
	CAL-148	0.32 (0.00)	AC	*PIK3CA; RB1; TP53; PTEN*	Luminal A	
	MFM-223	0.31 (0.00)	AC	*PIK3CA; TP53*	Luminal A/B	
Unclassified	HCC1395		DC	*ATR; BRCA2; CDKN2A; PTEN; FGFR1; PDGFRB; TP53*	Basal	
	BT20		IDC	*CDKN2A; PIK3CA; TP53*	HER2	Basal A
	SW527				Luminal B	

Lehmann et al., JCI 2011

Differentielles Ansprechen auf Chemotherapie



The relationship between RCB index and the 7 TNBC subtypes

Residual Cancer Burden index

RCB-I: minimal residual disease
RCB-II: moderate residual disease
RCB-III: extensive residual disease

	BL1	BL2	M	IM	MSL	LAR	UNS
pCR	11	0	8	8	3	2	5
RCB-I	1	1	2	3	2	4	1
RCB-II	6	6	4	8	6	8	3
RCB-III	3	1	9	5	2	4	6

ymmans WF et al. J Clin Oncol 2007

PRESENTED AT: ASCO Annual '13 Meeting

Masuda et al., ASCO 2013

Das Immunsystem – eine Achillesferse?!

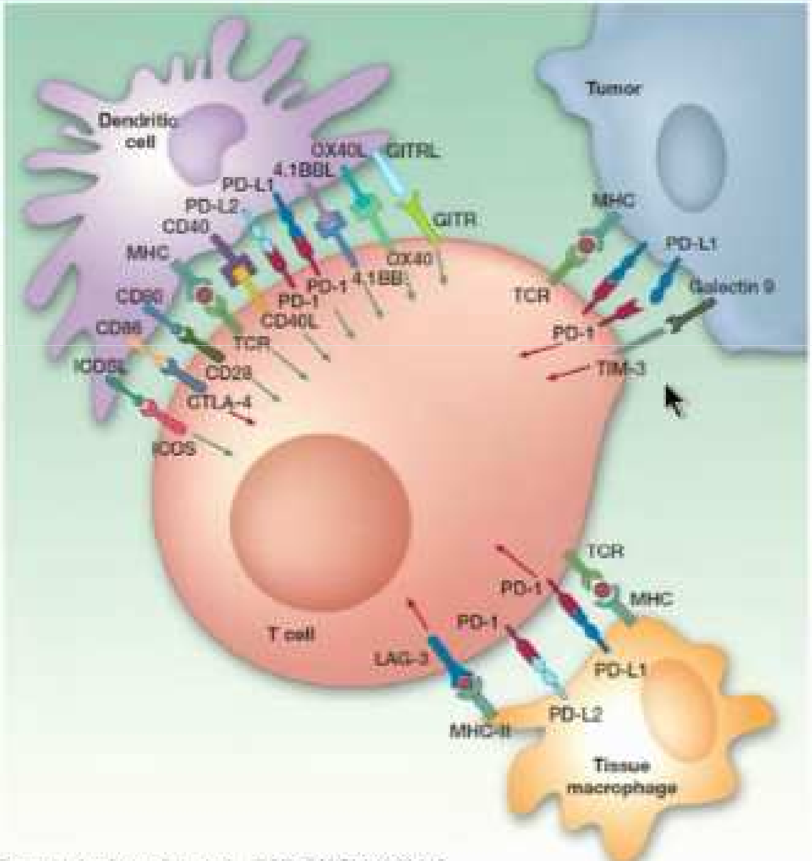
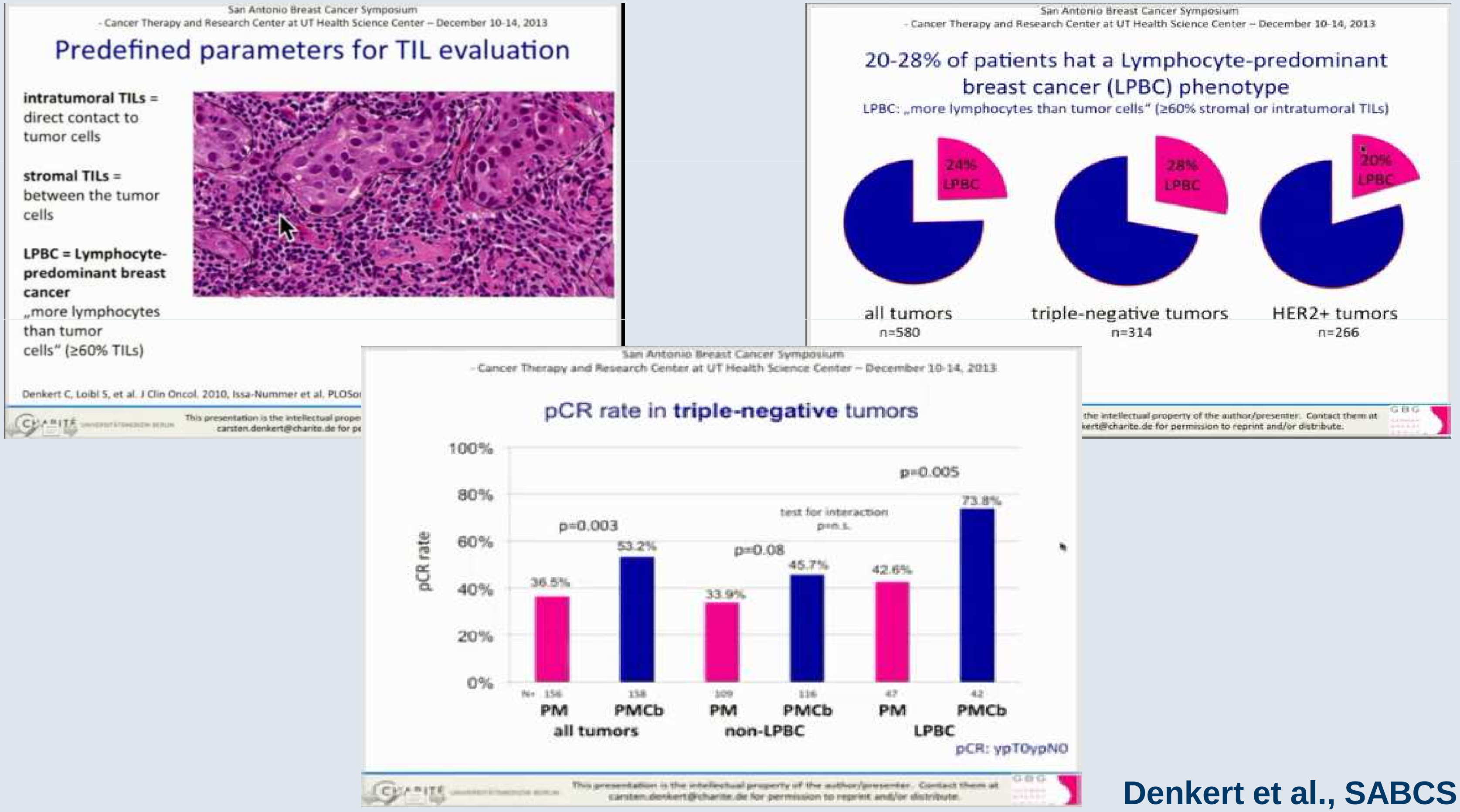

Dendritic cell
Tumor
OX40L
GITRL
4.1BBL
PD-L1
PD-L2
CD40
MHC
GITR
OX40
4.1BB
PD-1
PD-1
CD40L
CD80
CD86
ICOSL
TCR
CD28
CTLA-4
ICOS
MHC
PD-L1
Galectin 9
TCR
PD-1
TIM-3
TCR
PD-1
MHC
PD-1
LAG-3
PD-L1
PD-L2
MHC-II
T cell
Tissue macrophage

figure take from Ott et al., CCR. PMID:24089443

Definition von TILs



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- Cancer Therapy and Research Center at UT Health Science Center – December 10-14, 2013

Predefined parameters for TIL evaluation

intratumoral TILs = direct contact to tumor cells

stromal TILs = between the tumor cells

LPBC = Lymphocyte-predominant breast cancer „more lymphocytes than tumor cells" (≥60% TILs)

Denkert C, Loibl S, et al. J Clin Oncol. 2010, Issa-Nummer et al. PLOSo

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20-28% of patients hat a Lymphocyte-predominant breast cancer (LPBC) phenotype

LPBC: „more lymphocytes than tumor cells" (≥60% stromal or intratumoral TILs)

24% LPBC
28% LPBC
20% LPBC
all tumors
n=580
triple-negative tumors
n=314
HER2+ tumors
n=266

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pCR rate in **triple-negative** tumors

100%
80%
60%
40%
20%
0%
pCR rate
p=0.003
p=0.08
test for interaction
p=n.s.
p=0.005
36.5%
53.2%
33.9%
45.7%
42.6%
73.8%
N= 156
158
109
116
47
42
PM
PMCb
PM
PMCb
PM
PMCb
all tumors
non-LPBC
LPBC
pCR: ypT0ypN0

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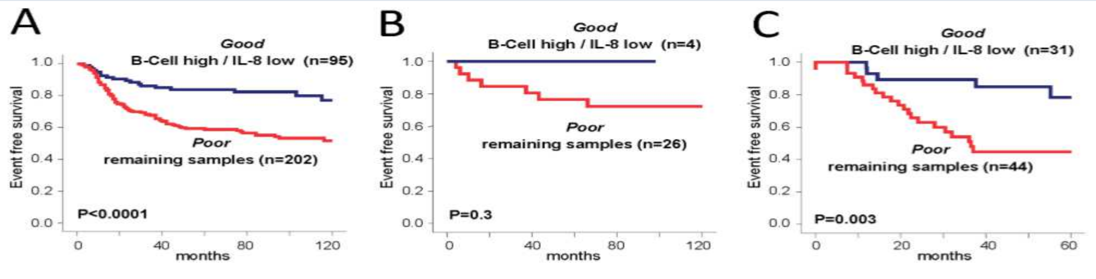
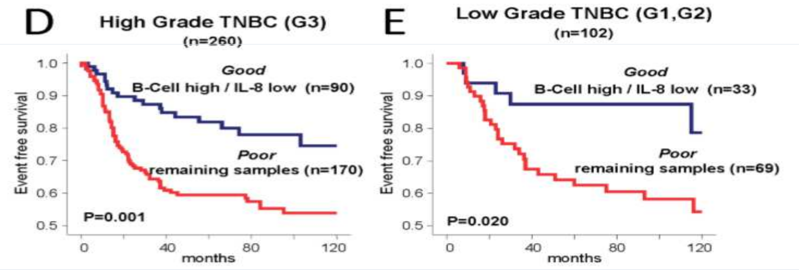
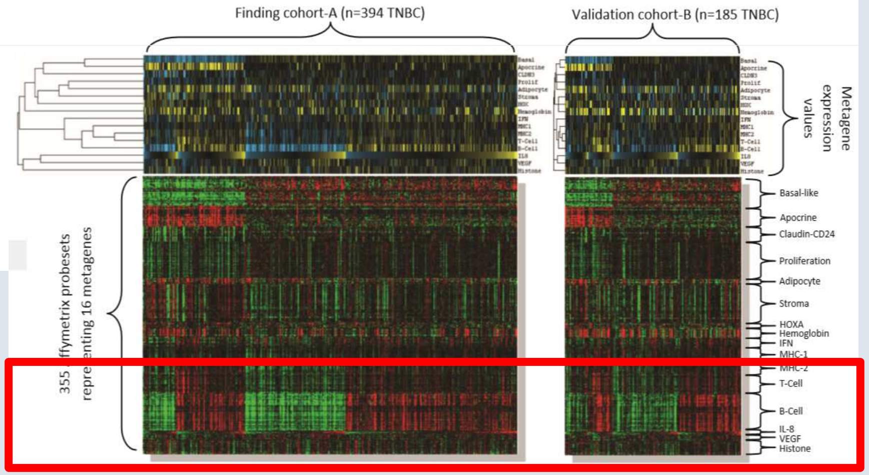
Denkert et al., SABCS

Prognostische Wertigkeit der B-Zell / IL-8 -Signatur beim TNBC

cohort 1 cohort 2 cohort 3



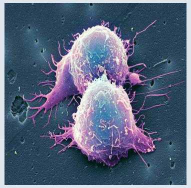




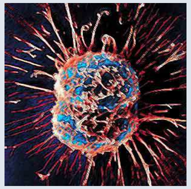
Hanker […] Liedtke et al., BCRT 2012

Rody […] Liedtke et al., BCRT 2011

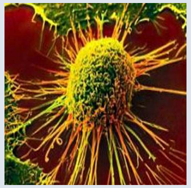
Überblick



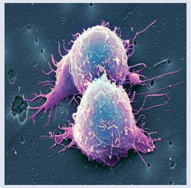
Was ist das tripelnegative Mammakarzinom?



Wie ist der klinische Verlauf?



Welche Therapien können eingesetzt werden?



Gibt es unterschiedliche Subgruppen?

Herzlichen Dank für Ihre Aufmerksamkeit …

UKSH UNIVERSITÄTSKLINIKUM Schleswig-Holstein

Universität zu Lübeck

Safe the Date …

Zwischen
„Luv + LEE"

Gynäkologisch-Onkologisches Symposium

Lübeck 28.06.2014

Wissen schafft Gesundheit

Klinik für Gynäkologie und Geburtshilfe