



8^a edizione

Progetto **CANOA**

CARCINOMA MAMMARIO:

QUALI NOVITA' PER IL 2018?

"Saper leggere" uno studio clinico per migliorare la pratica clinica

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Ospedaletto di Pescantina (VR) 23/24 Marzo 2018
Villa Quaranta Park Hotel

Quale impatto nella pratica clinica?

Chiara Saggia

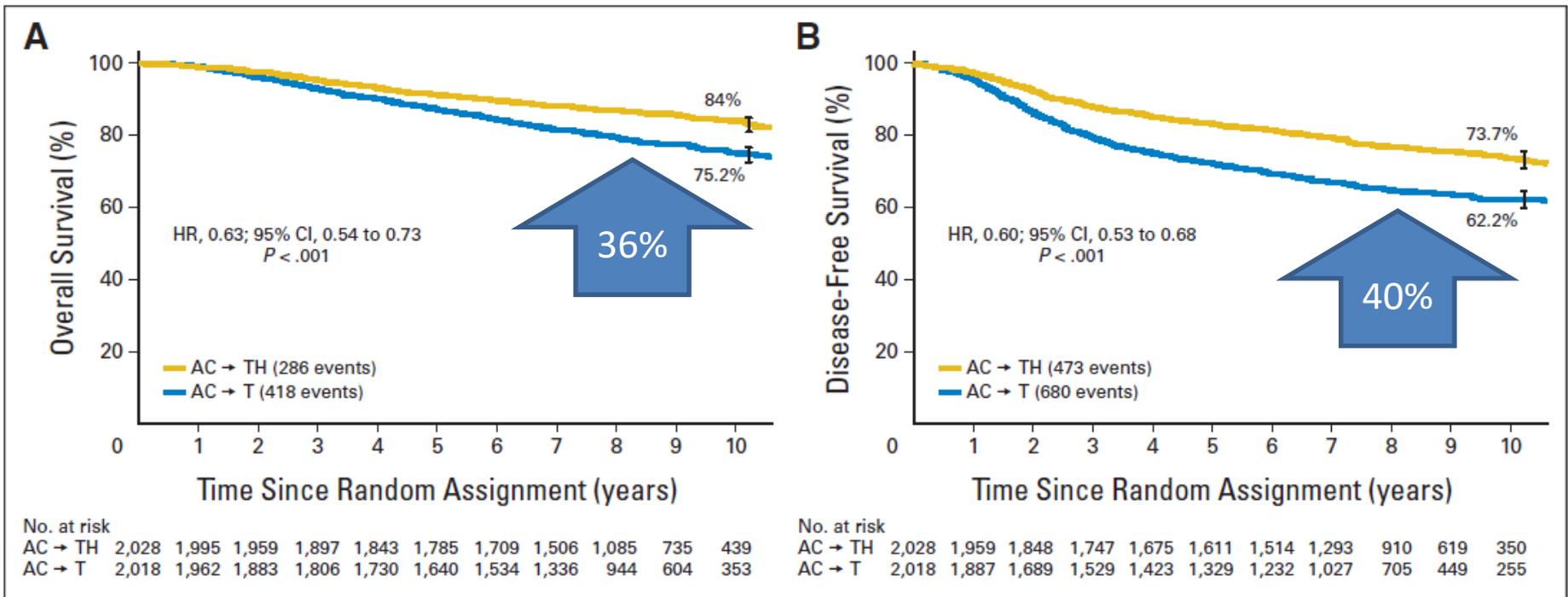
Oncologia

AOU "Maggiore della carità",
Novara

The standard

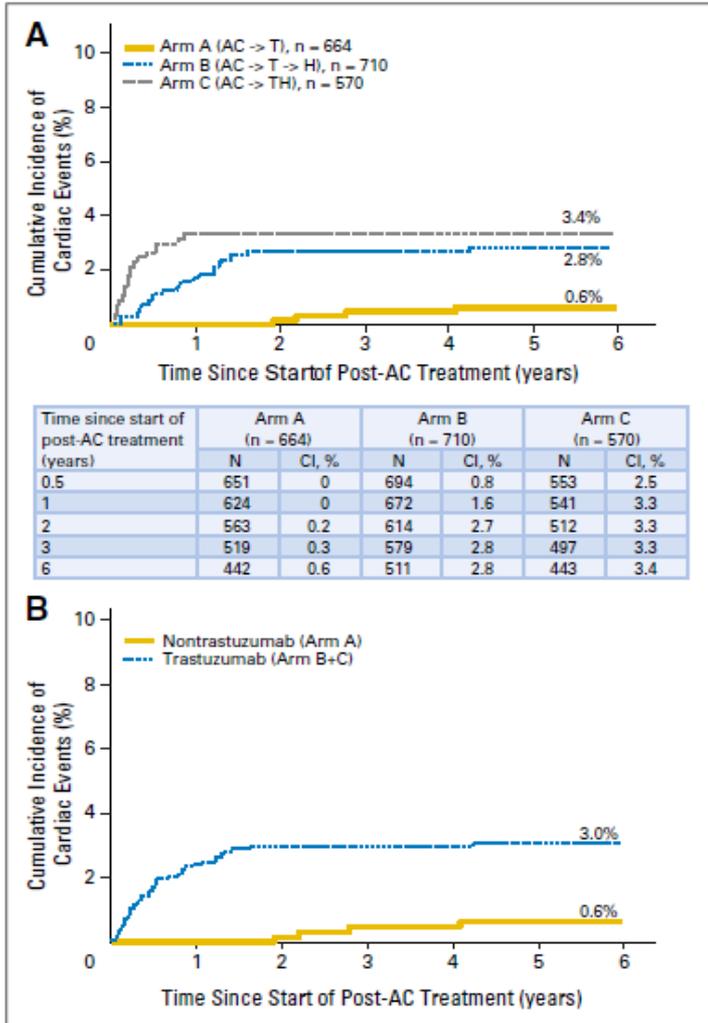
Trastuzumab Plus Adjuvant Chemotherapy for Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: Planned Joint Analysis of Overall Survival From NSABP B-31 and NCCTG N9831

Median follow-up 8.4 years

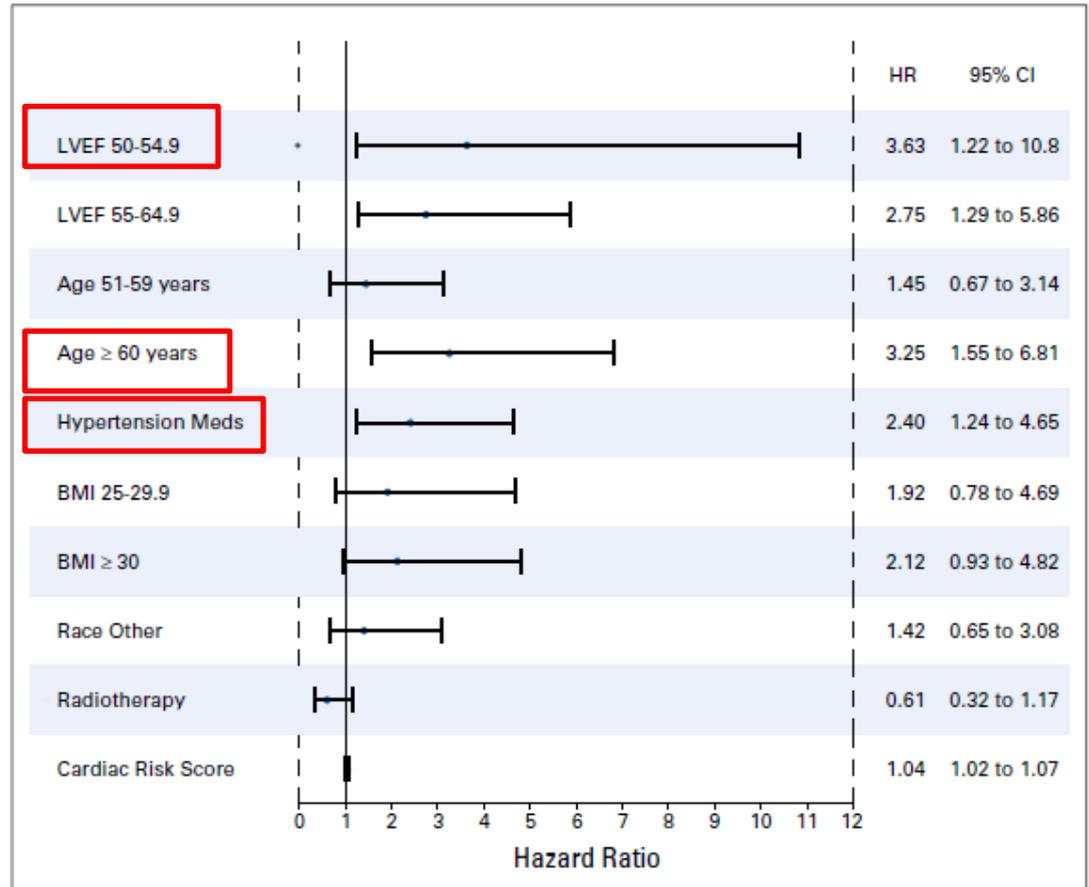


The standard

Long-Term Cardiac Safety Analysis of NCCTG N9831 (Alliance) Adjuvant Trastuzumab Trial



Median follow-up 6 years



The standard: Without anthracyclines...

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

OCTOBER 6, 2011

VOL. 365 NO. 14

Adjuvant Trastuzumab in HER2-Positive Breast Cancer

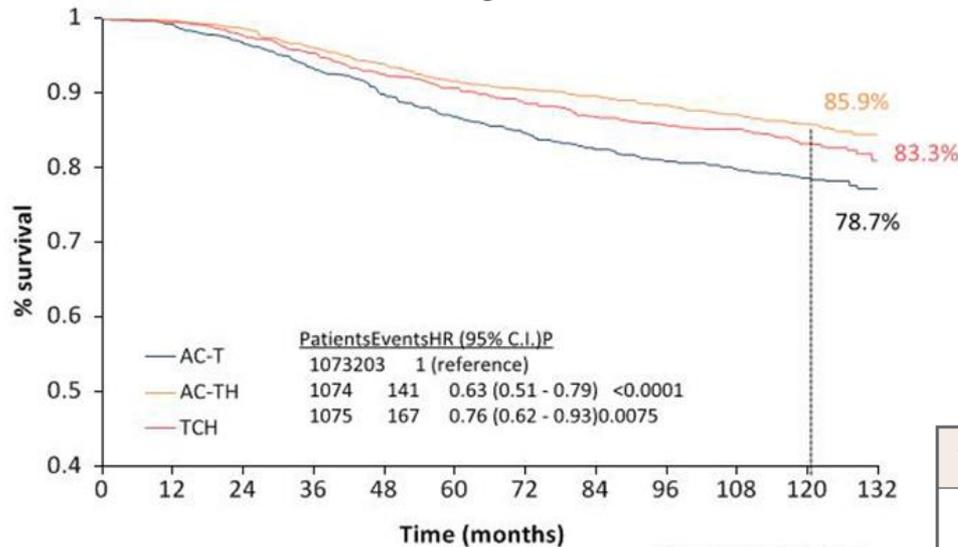


Table 2. Therapeutic Index for Critical Clinical Events.*

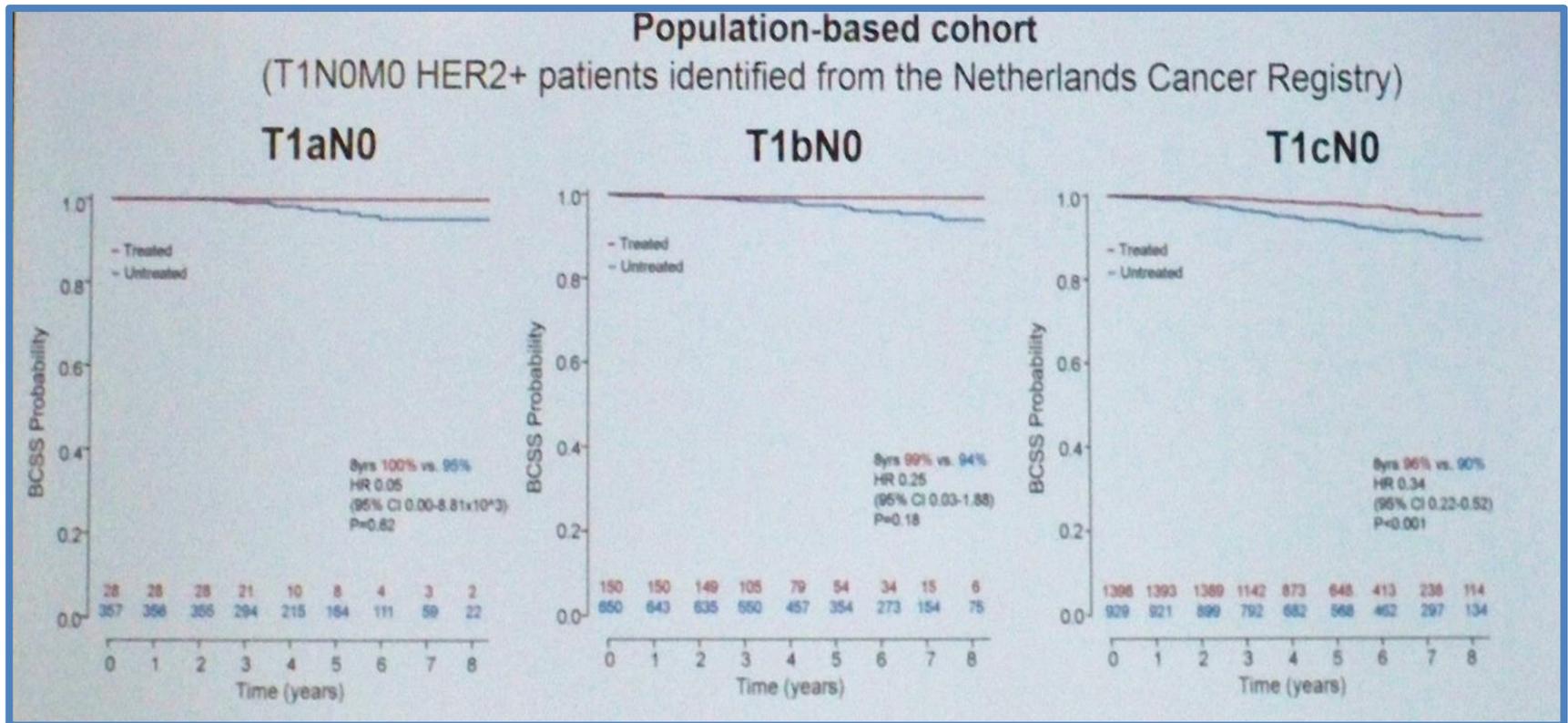
Clinical Event	AC-T	AC-T plus Trastuzumab	
		TCH	TCH
<i>number of events</i>			
Total events	201	146	149
Distant breast-cancer recurrence	188	124	144
Grade 3 or 4 congestive heart failure	7	21	4
Acute leukemia	6	1	1†

Less is sufficient?

Breast Cancer Research and Treatment

July 2016, Volume 158, Issue 2, pp 361–371 | [Cite as](#)

The effect of trastuzumab-based chemotherapy in small node-negative HER2-positive breast cancer



3512 patients

Less is sufficient?

[Breast Cancer Research and Treatment](#)

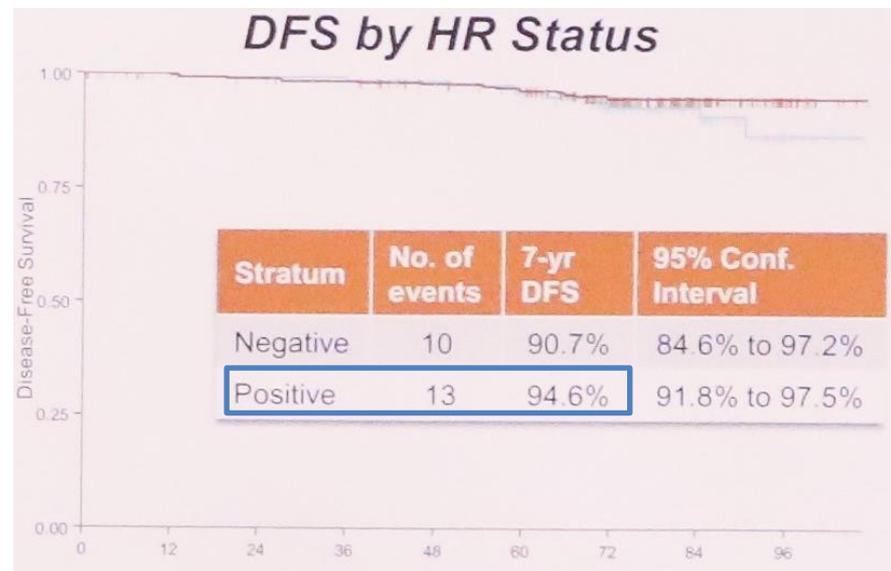
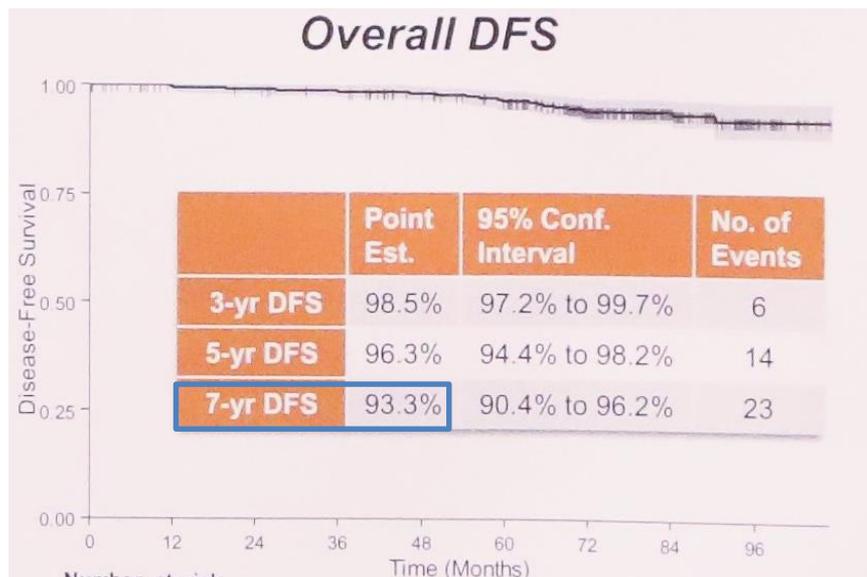
July 2016, Volume 158, [Issue 2](#), pp 361–371 | [Cite as](#)

The effect of trastuzumab-based chemotherapy in small node-negative HER2-positive breast cancer

1. **T1N0 HER2 + EBC** have a good prognosis but still a sizeable risk of *relapse e death*
2. Adjuvant CT and/or Trastuzumab seem to provide a clinical meaningfully decrease of this risk ($\geq 5\%$ ↓ death)
3. *Residual risk to trastuzumab-based therapy seems too small to justify to “add-on” therapy (regardless their potential benefit)*
4. *“De-escalation” should be instead considered*

Less is sufficient: De-escalation

Seven-year Follow-up of Adjuvant Paclitaxel and Trastuzumab (APT Trial) for Node-Negative, HER2+ Breast Cancer

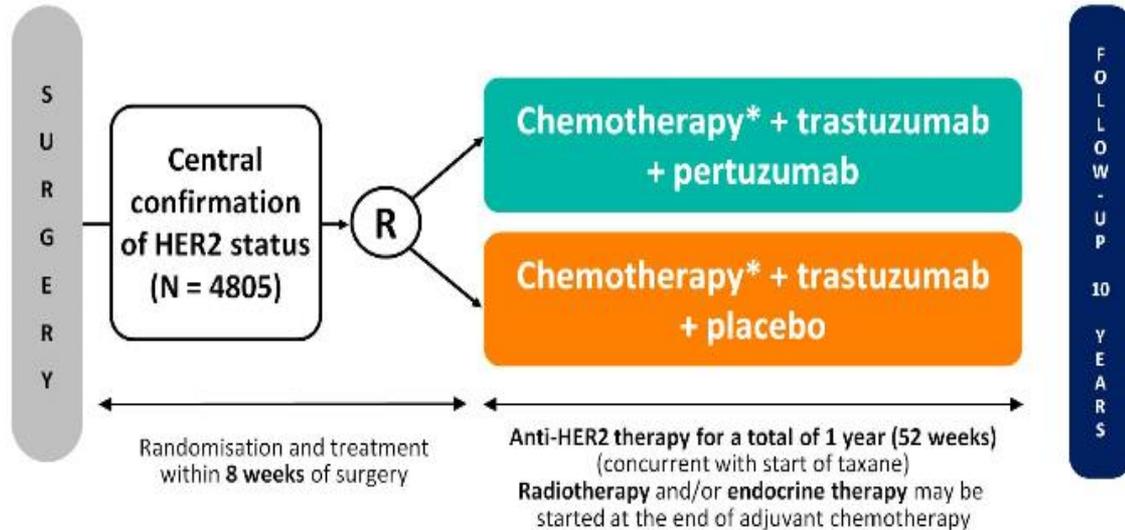


APHINITY: More is better?

ORIGINAL ARTICLE

Adjuvant Pertuzumab and Trastuzumab
in Early HER2-Positive Breast Cancer

APHINITY: Trial Design

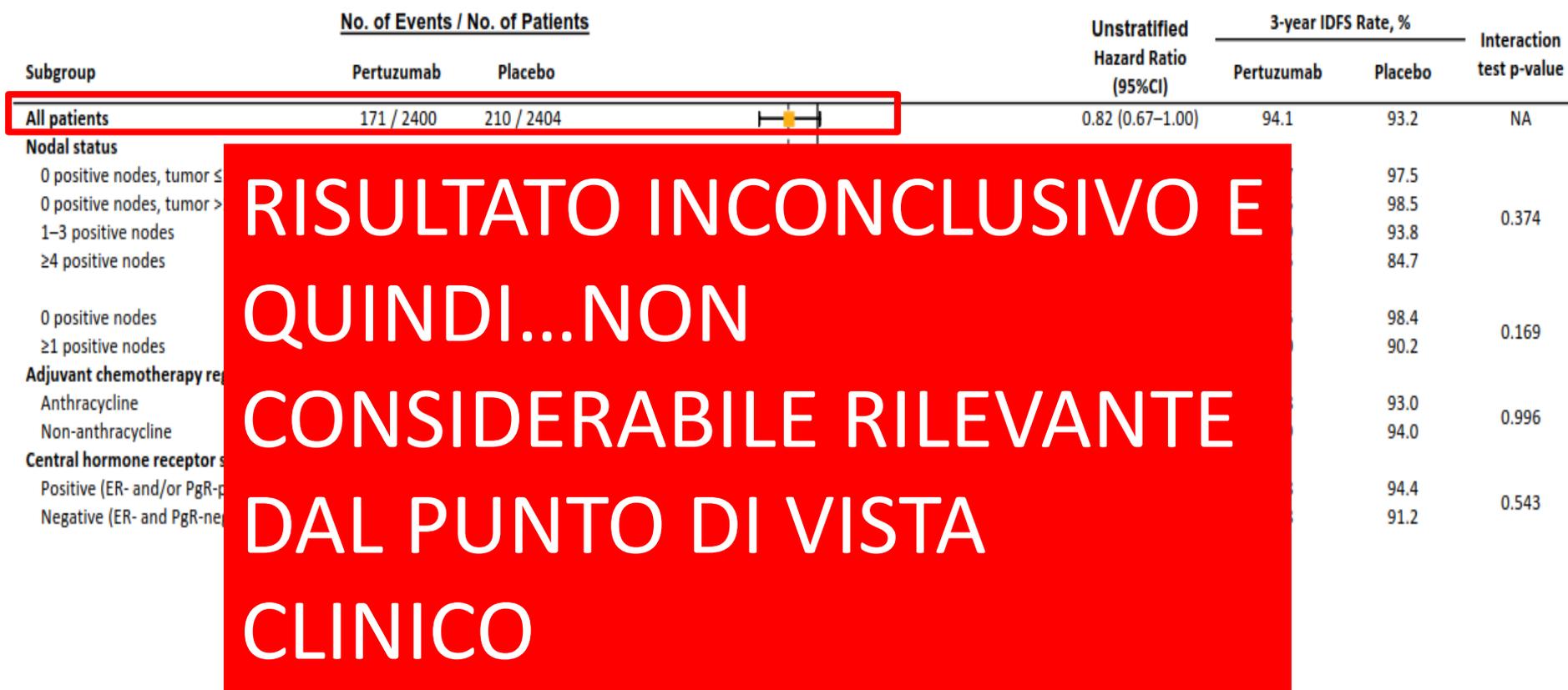


*A number of standard anthracycline-taxane-sequences or a non-anthracycline (TCH) regimen were allowed

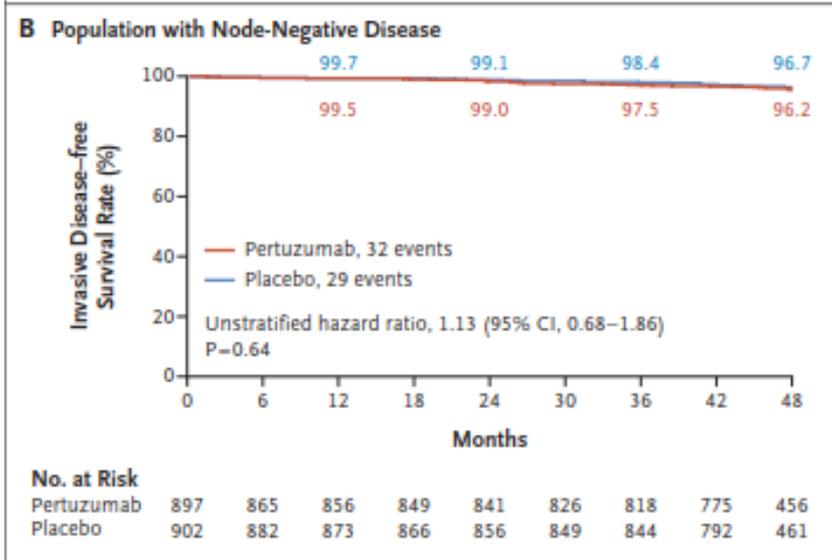
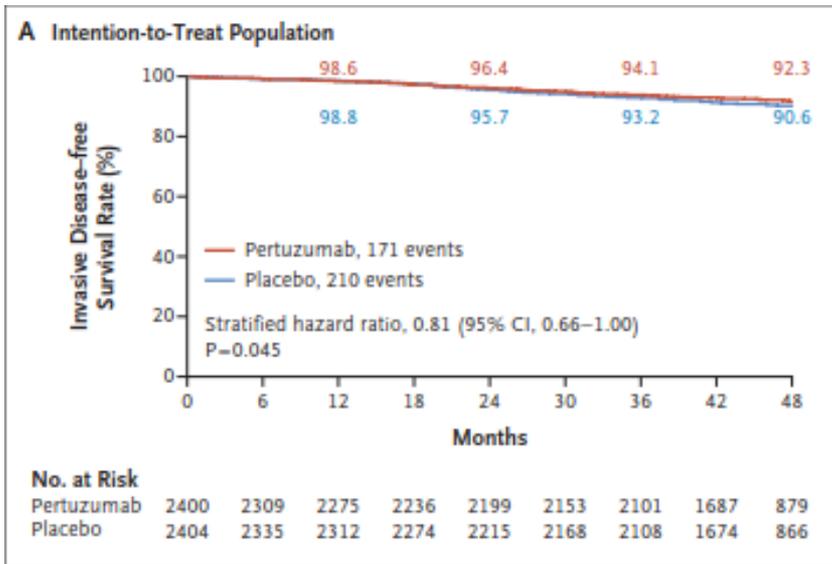
	EXPECTED 3-year IDFS rate Placebo vs. Pertuzumab
HR=0.75	89.2% vs. 91.8% ($\Delta=2.6\%$)

APHINITY: More is better?

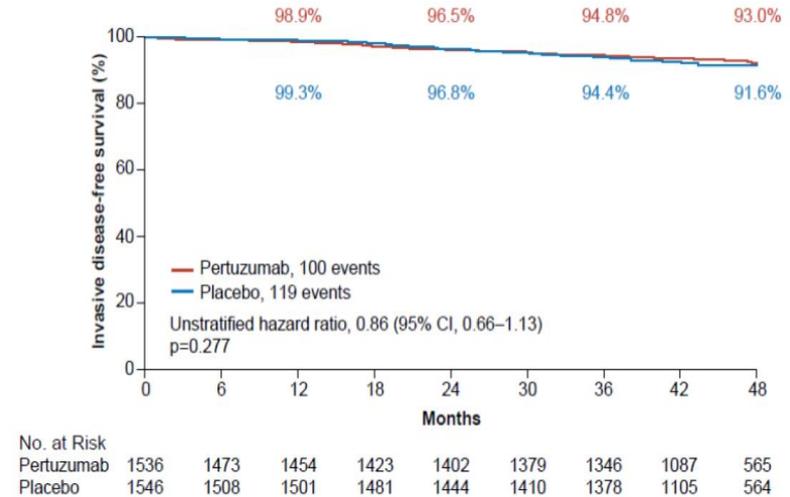
APHINITY: IDFS Forest Plot by Subgroups



APHINITY: ITT

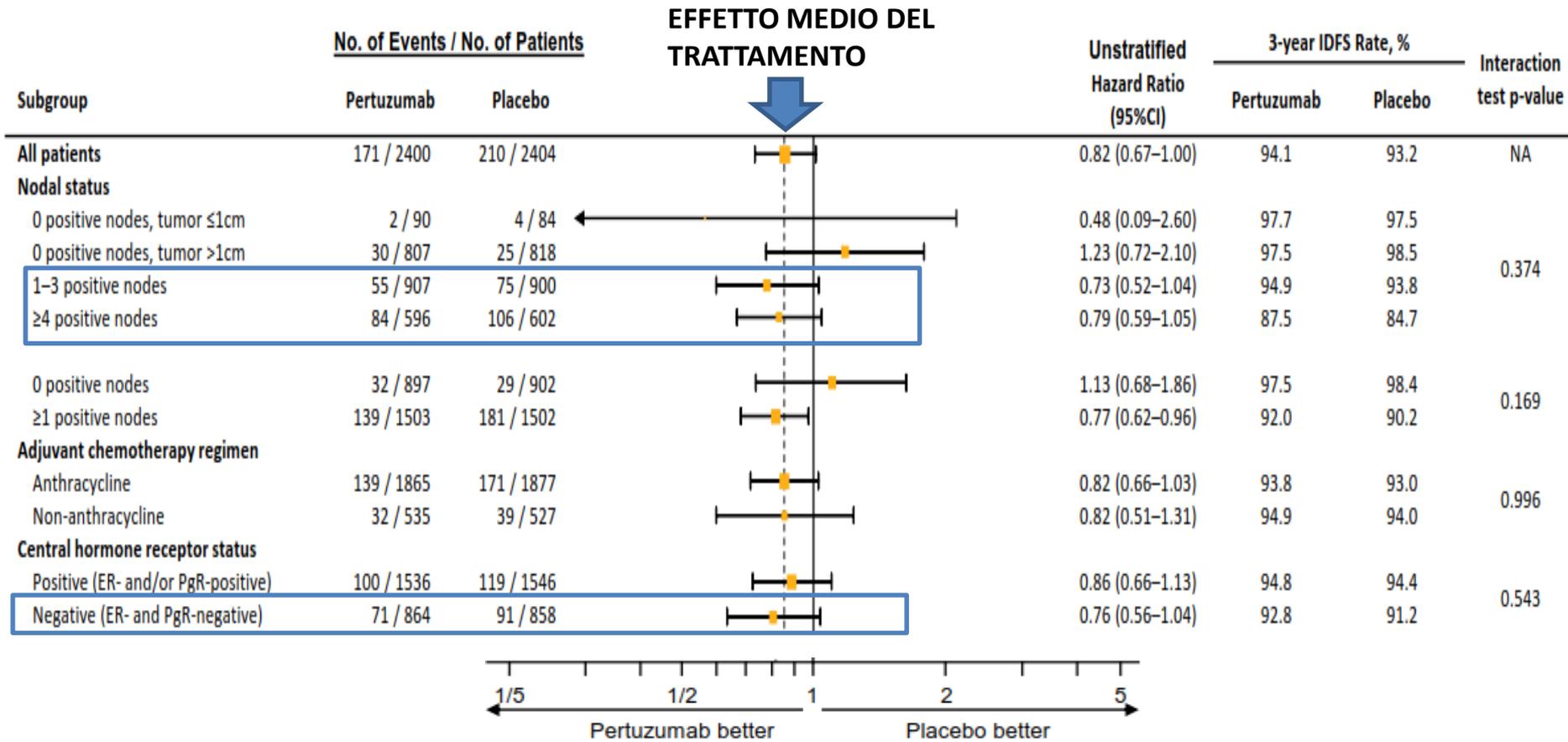


APHINITY: Hormone Receptor-positive Subgroup



ITT: devo trattare 112 paz per evitare un evento

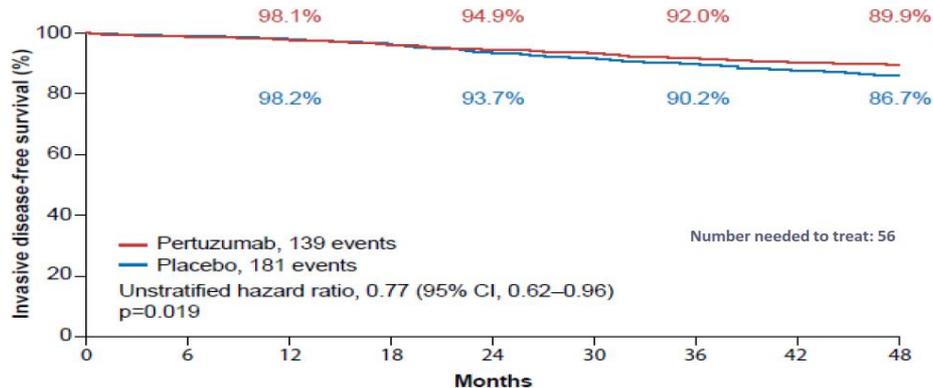
APHINITY: IDFS Forest Plot by Subgroups



APHINITY: SOTTOGRUPPI

APHINITY: Node-positive Subgroup

$\Delta=3.2\%$

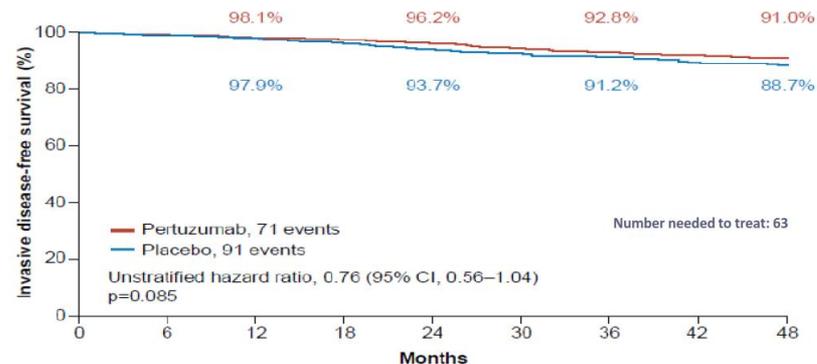


N + : devo trattare 56 paz per evitare un evento

No. at Risk	0	6	12	18	24	30	36	42	48
Pertuzumab	1503	1444	1419	1387	1358	1327	1283	912	423
Placebo	1502	1453	1439	1408	1359	1319	1264	882	405

APHINITY: Hormone Receptor-negative Subgroup

$\Delta=2.3\%$



ER- : devo trattare 63 pazienti per evitare un evento

No. at Risk	0	6	12	18	24	30	36	42	48
Pertuzumab	864	836	821	813	797	774	755	600	314
Placebo	858	827	811	793	771	758	730	569	302

DISCUSSIONE

- Le pazienti dello studio sono quelle del quesito quindi **la trasferibilità del dato alla clinica è possibile**
- Tuttavia dal punto di vista clinico rispetto IDFS **avremmo preferito come obiettivo primario OS per cui non è assolutamente sufficiente il follow-up di 3 anni presentato** e la DFS di cui mancano completamente i dati

DISCUSSIONE

CLINICO-PATHOLOGICAL FEATURES (T AND N) SHOULD BE FINE-TUNED TO DEFINE A CONTINUOUS RISK OF RELAPSE

