

**Nelle pazienti con carcinoma mammario HR-positivo/HER2-negativo operato, a rischio intermedio, è opportuno considerare l'utilizzo di ONCOTYPE DX?**



12ª EDIZIONE  
Progetto **CANOA**

**CARCINOMA  
MAMMARIO:**  
QUALI NOVITA' PER IL 2022?

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

18-19 Marzo 2022  
Ospedaletto di Pescantina (VR)  
Park Hotel Villa Quaranta

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**Quale impatto nella pratica clinica?**

**Alessandra Fabi**  
**Medicina di Precisione in Senologia**

Gemelli



 Comprehensive  
Cancer Center

# Study results for the OncotypeDX test

	RS results 0–10	RS results 11–15	RS results 16–20	RS results 21–25	RS results 26–100	
<b>&gt;50 years N0</b> <b>Postmenopausal N1</b>	No CT benefit	No CT benefit	No CT benefit	No CT benefit	Substantial CT benefit	9/5-year outcomes
<b>≤50 years N0</b>	No CT benefit	No CT benefit	RS results 16-20 ~1.6% CT benefit	RS results 21-25 ~6.5% CT benefit	Substantial CT benefit	9-year outcomes
<b>Premenopausal N1</b>	RS results 0-25 2.9% CT benefit at 5 years				Substantial CT benefit*	5-year outcomes

CT benefit expressed in percentage points based on probability of distant recurrence with / without CT  
No CT benefit is considered for an absolute benefit <1%

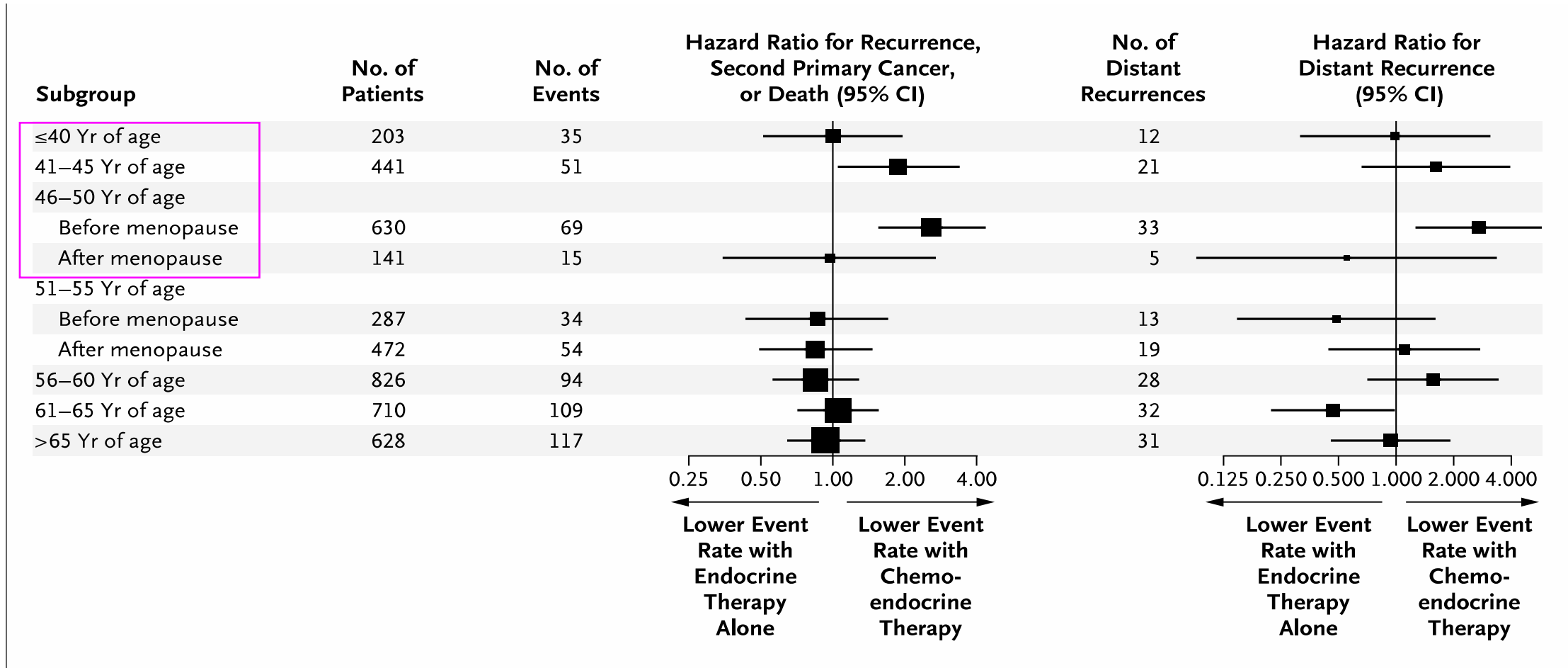
**Node-negative (N0)** patients: TAILORx analyses were performed by age and demonstrated that patients ≤ 50 years derived some clinically meaningful benefit from CT at 9 years starting with an RS result of 16;

**Node-positive (N1)** patients: RxPONDER data were analysed according to menopausal status and demonstrated that premenopausal patients with RS results 0-25 overall derived benefit from chemotherapy at 5 years.

\* Benefit of chemotherapy for premenopausal N1 patients with RS results 26-100 has not been formally assessed in a randomised study. The benefit derived from chemotherapy was significant for RS results 0-13 and 14-25 in the RxPONDER study and it is inferred to be substantial for patients with RS result 26-100.

# Effect of Age and Menopausal Status on Chemotherapy Benefit

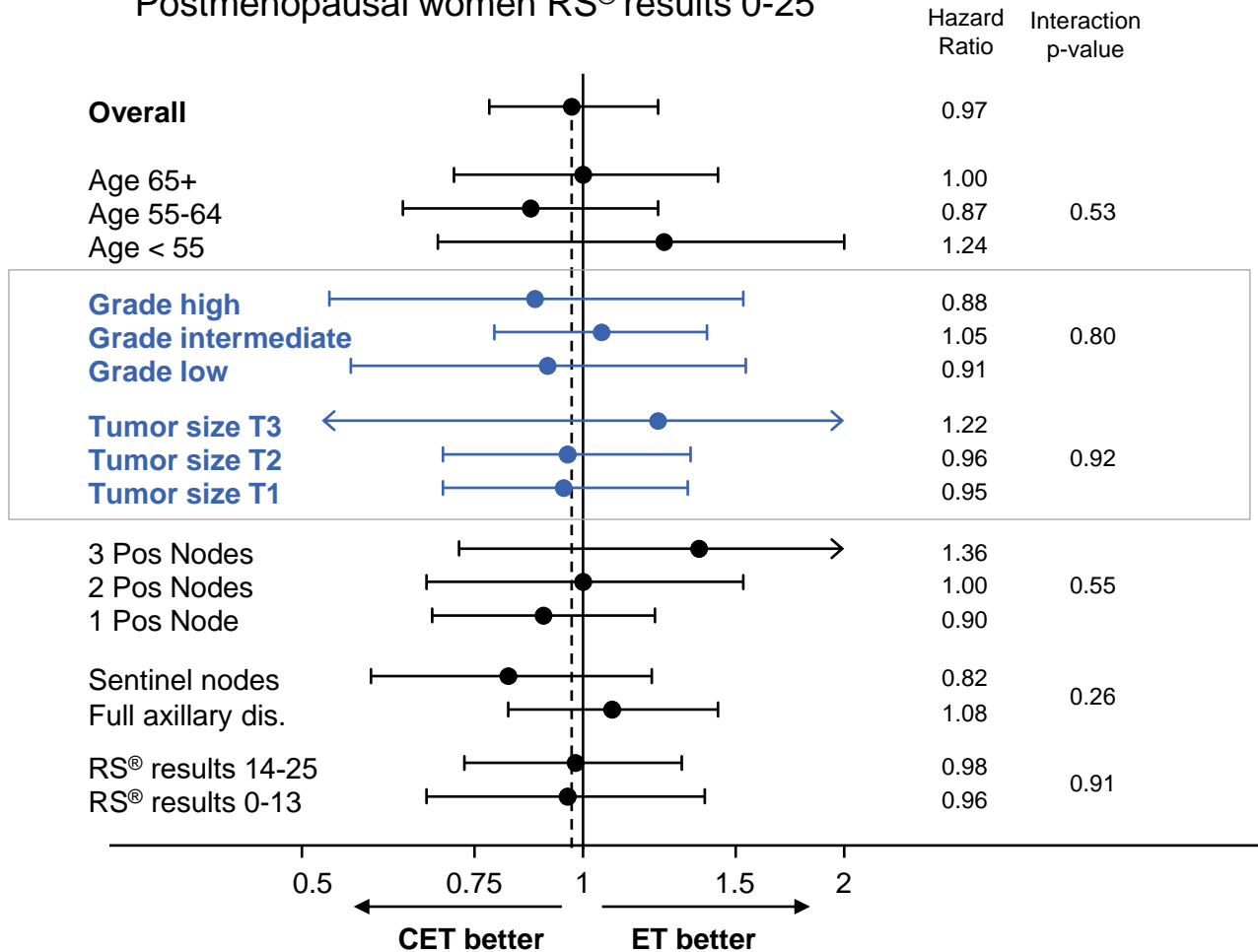
RS 16-25



Sparano et al, NEJM 2019

# N1 postmenopausal patients with Recurrence Score results 0-25 did not benefit from chemotherapy, regardless of clinical pathological parameters

**Forest Plot of invasive disease-free survival CET vs. ET**  
Postmenopausal women RS<sup>®</sup> results 0-25

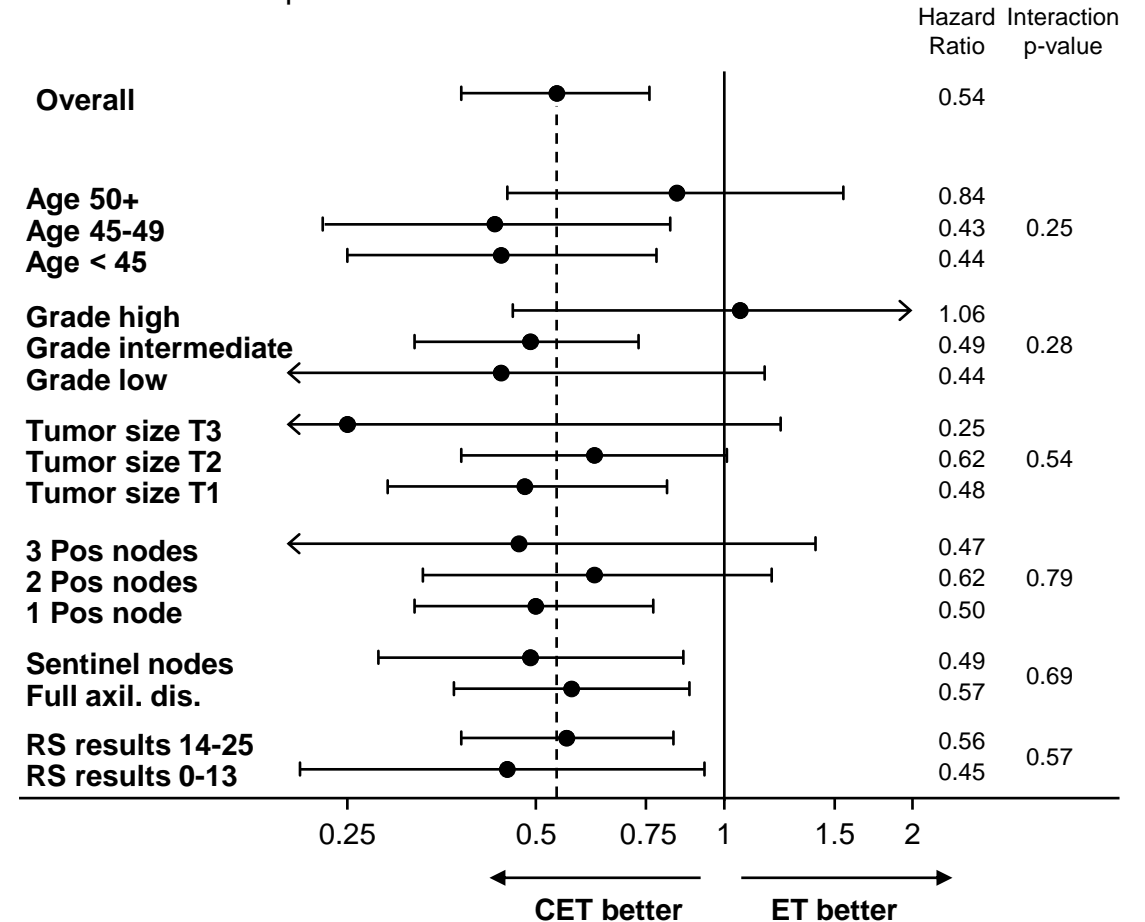


# Subgroup analyses for N1 premenopausal women with RS 0-25

**Chemotherapy benefit was observed across nearly all premenopausal subgroups**

Landmarked exploratory analysis for IDFS in premenopausal women on endocrine therapy arm:  
 Ovarian function suppression (n=126) vs. no ovarian function suppression (n=647) at 6 months: HR 0.73 (95% CI: 0.39-1.37), p=0.33

**Forest Plot of IDFS CET vs. ET Hazard Ratio and 95% CI**  
 Premenopausal women RS® results 0-25



IDFS: invasive disease-free survival; RS®: Recurrence Score results  
 CET: chemotherapy + endocrine therapy; ET: endocrine therapy alone

.....ci confrontiamo con Criteri Definiti

BASSO RISCHIO	ALTO RISCHIO
Le seguenti 5 caratteristiche	Almeno 4 delle seguenti caratteristiche
G1 T1 (a-b)* Ki 67 <20% ER>80% N Negativo	G3 T3 T4 Ki 67>30% ER<30% N Positivo (>3 linfonodi non indicazione al <i>test</i> )
*In caso di T1a non è indicato l'accesso al <i>test</i> in presenza di almeno altri 2 parametri favorevoli	

Si Auspica .....

**Conformità decisionale !**