PS2-04-25 • Efficacy of maintenance endocrine therapy combined with trastuzumab + pertuzumab following taxane induction in HR+/HER2+ metastatic breast cancer: A real-world reproduction of the PATINA trial control arm.

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BACKGROUND

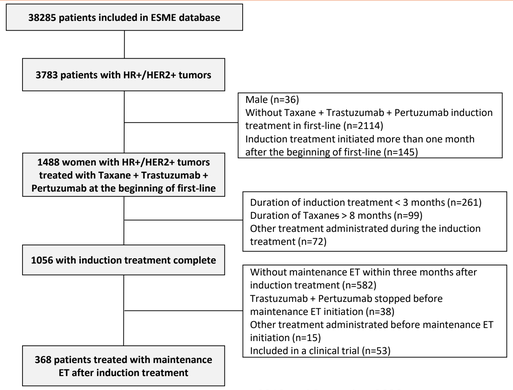
- The PATINA trial demonstrated that adding the CDK4/6 inhibitor palbociclib to maintenance endocrine therapy (ET) and trastuzumab ± pertuzumab significantly prolonged median progression-free survival (PFS).
- In the PATINA trial, median PFS was 44.3 months (95% CI, 32.4-60.9) in the palbociclib arm vs 29.1 months (95% CI, 23.3-38.6) in the control arm, with a hazard ratio of 0.74 (95% CI, 0.58-0.94).
- Given its potential to redefine treatment standards, our objective was to replicate and validate the control arm outcomes of the PATINA trial using real-world data.

METHODS

- We conducted a retrospective analysis using data from the multicenter, real-world Epidemio-Strategy and Medical Economics (ESME) database, encompassing 18 French Comprehensive Cancer Centers (NCT03275311).
- Eligible patients had hormone receptors-positive and HER2-positive (HR+)/HER2+ metastatic breast cancer (MBC), who initiated first-line treatment with a taxane plus trastuzumab + pertuzumab, who did not progress after completion of chemotherapy and subsequently received maintenance therapy with trastuzumab + pertuzumab combined with endocrine therapy.
- Real world progression free survival (rwPFS) and were estimated from maintenance ET initiation in the overall cohort and in subgroups of patients.
- A sensitivity analysis was conducted in the subgroup of patients treated before 2018, which aligns with the PATINA study population.
- Multivariable analyses were performed using Cox proportional-hazards model including age, tumor grade, recurrent status, number of metastatic sites, presence of visceral metastases, and hormone receptor status (ER+/PR+, ER+/PR- or ER-/PR+).

RESULTS

PATIENTS FLOW DIAGRAM



Inclusion between January 2013 and December 2023

PATIENT'S CHARACTERSTICS

	Total, n = 368
Age at metastatic diagnosis (years)	
Median (Range)	56 (20;88)
< 65 years	271 (73.6%)
Menopausal status	
Yes	217 (59.0%)
No	151 (41.0%)
Hormone receptor status	
ER+/PR- or ER-/PR+	156 (43.5%)
ER+/PR+	203 (56.5%)
Missing	9
Histological grade at primary tumor diagnosis	
Grade I/II	221 (62.8%)
Grade III	131 (37.2%)
Missing	16
Time from initial diagnosis to metastatic diagnosis (months)	
< 6 months (De Novo)	245 (66.6%)
6-60 months	45 (12.2%)
> 60 months	78 (21.2%)
Recurrent status	
Recurrent	123 (33.4%)
De Novo (<6 months)	245 (66.6%)
Number of metastatic organ sites	
< 3 sites	265 (72.0%)
≥ 3 sites	103 (28.0%)
Type of Metastases	
Visceral	211 (57.3%)
Non-Visceral	157 (42.7%)

Abbreviations: ER, estrogen receptor; PR, progesterone receptor.

	Total, n = 123
Treatment received before metastatic disease	
Chemotherapy/targeted therapy	96 (78.0%)
Anti-HER2	63 (51.2%)
Radiotherapy	103 (83.7%)
Endocrine therapy	102 (82.9%)

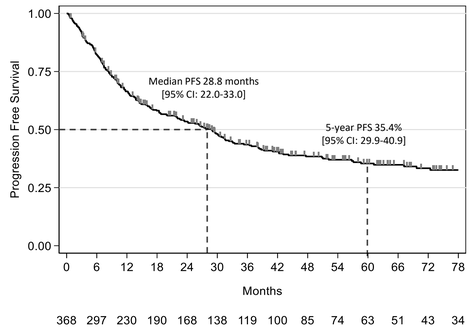
HORMONE THERAPY MAINTENANCE

	Total, n = 368
Aromatase inhibitor +/- LHRH analog	304 (82.6%)
Tamoxifene +/- LHRH analog	47 (12.8%)
Fulvestrant	5 (1.4%)
Other	12 (3.3%)

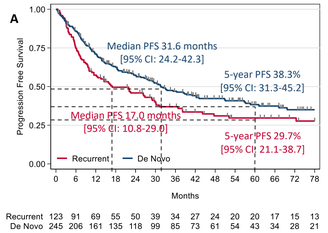
REAL-WORLD PROGRESSION-FREE SURVIVAL

Median follow-up time of 57.8 months [95% CI: 53.1-63.6]

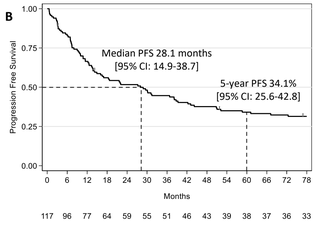
WHOLE POPULATION



RECURRENT VS DE NOVO



PATIENTS TREATED BEFORE 2018



UNIVARIABLE AND MULTIVARIABLE ANALYSIS

Univariable analysis of progression-free survival

	Event/n	Median [95%CI]	HR [95%CI]	*p*-value
Histological grade at primary tumor diagnosis				0.347
Grade I/II	136/221	28.1 [20.0; 36.4]	1.00	
Grade III	72/131	29.5 [16.2; 57.1]	0.87 [0.66; 1.16]	
Age at metastatic diagnosis				0.686
< 65 years	158/271	29.5 [19.9; 36.8]	1.00	
≥ 65 years	61/97	28.1 [14.5; 38.1]	1.06 [0.79; 1.43]	
Recurrent status				0.042
Recurrent	81/123	17.0 [10.8; 29.0]	1.00	
De Novo (<6 months)	138/245	31.6 [24.2; 42.3]	0.75 [0.57; 0.99]	
Number of metastatic sites				<0.001
<3 sites	139/265	38.2 [30.1; 58.6]	1.00	
≥ 3 sites	80/103	10.8 [8.5; 16.5]	2.17 [1.65; 2.87]	
Type of Metastases				0.013
Non-Visceral	81/157	33.1 [26.3; 69.7]	1.00	
Visceral	138/211	23.4 [14.9; 30.8]	1.41 [1.07; 1.86]	
Hormone receptor status				0.659
ER+/PR- or ER-/PR+	92/156	29.5 [15.8; 38.2]	1.00	
ER+/PR+	120/203	29.0 [20.0; 38.4]	0.94 [0.72; 1.23]	

Abbreviations: CI, confidence interval; ER, estrogen receptor; HR, hazard ratio; PR, progesterone receptor.

Multivariable analysis of progression-free survival

	HR [95%CI]	*p*-value
Histological grade at primary tumor diagnosis		
Grade I/II	1.00	
Grade III	0.92 [0.69; 1.23]	0.572
Age at metastatic diagnosis		
< 65 years	1.00	
≥ 65 years	0.99 [0.72; 1.35]	0.935
Recurrent status		
Recurrent	1.00	
De Novo (<6 months)	0.75 [0.56; 1.00]	0.050
Number of metastatic sites		
<3 sites	1.00	
≥ 3 sites	2.07 [1.50; 2.85]	<0.001
Type of Metastases		
Non-Visceral	1.00	
Visceral	1.13 [0.83; 1.55]	0.438
Hormone receptor status		
ER+/PR- or ER-/PR+	1.00	
ER+/PR+	0.96 [0.73; 1.28]	0.796

Abbreviations: CI, confidence interval; ER, estrogen receptor; HR, hazard ratio; PR, progesterone receptor.

CONCLUSION

In this real-world analysis from the ESME cohort, patients with HR+/HER2+ metastatic breast cancer receiving first-line taxane-based induction followed by maintenance trastuzumab, pertuzumab, and endocrine therapy achieved outcomes comparable to those of the PATINA control arm.

These findings validate the relevance and reproducibility of the control arm results in routine clinical practice, despite a higher proportion of recurrent cases.

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