Real-World Survival Outcomes in Patients With HR+/HER2− Early Breast Cancer Meeting MonarchE and NATALEE Criteria: Analysis From a Brazilian cohort.

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Abstract

While adjuvant CDK4/6 inhibitors improve outcomes in selected patients with high-risk HR+/HER2− early breast cancer (BC), real-world evidence from Latin America remains limited. We aimed to evaluate clinical characteristics and survival outcomes of patients treated in a private oncology facility in Brazil, stratified by eligibility for MonarchE and NATALEE criteria.

Methods and Materials

We analyzed a real-world cohort of patients with HR+/HER2− BC at stages I–III, treated at Americas Oncologia, a private oncology facility, in Rio de Janeiro and São Paulo between 2012 and 2024. Patients who received adjuvant abemaciclib were excluded from the analysis. CDK4/6 eligibility was defined using clinical-pathological criteria from the MonarchE and NATALEE trials (excluding Ki-67 due to missing data). Survival analyses were conducted using Kaplan-Meier and Cox models for overall survival (OS) and disease-free survival (DFS), stratified by MonarchE-eligible, NATALEE-eligible, NATALEE-only (eligible for NATALEE but not MonarchE), and non-eligible subgroups.

Figure 1: Eligibility overview for MonarchE and NATALEE

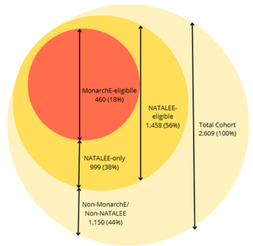


Figure 1: Among the 2,609 patients analyzed, 18% met the MonarchE eligibility criteria, 56% met the NATALEE eligibility criteria, and 44% were non-eligible. The NATALEE-only subgroup accounted for 38% of the cohort.

Results

Table 1: Subgroups baseline caracteristics

Characteristic	MonarchE N = 460[1]	NATALEE N = 1,458[1]	NATALEE-only N = 999[1]	Non-eligible N = 1,150[1]
Mean age (SD)	56.1 (14.6)	57.4 (14.5)	58.0 (14.4)	61.2 (12.9)
Neo/Adjuvant Chemotherapy	409 / 460 (89%)	1,120 / 1,458 (77%)	712 / 999 (71%)	236 / 1,150 (21%)
Endocrine therapy				
Aromatase inhibitor	239 / 460 (52%)	814 / 1,458 (56%)	575 / 999 (58%)	674 / 1,150 (59%)
Tamoxifen	176 / 460 (38%)	581 / 1,458 (40%)	405 / 999 (41%)	486 / 1,150 (42%)
None	75 / 460 (16%)	179 / 1,458 (12%)	105 / 999 (11%)	75 / 1,150 (6.5%)
Nodal status (N)				
0	0 / 460 (0%)	487 / 1,382 (35%)	487 / 923 (53%)	1,140 / 1,140 (100%)
1	272 / 460 (59%)	707 / 1,382 (51%)	436 / 923 (47%)	0 / 1,140 (0%)
2	151 / 460 (33%)	151 / 1,382 (11%)	0 / 923 (0%)	0 / 1,140 (0%)
3	37 / 460 (8.0%)	37 / 1,382 (2.7%)	0 / 923 (0%)	0 / 1,140 (0%)
Missing	0	76	76	10
Tumor stage (T)				
0	1 / 443 (0.2%)	6 / 1,356 (0.4%)	5 / 914 (0.5%)	3 / 1,147 (0.3%)
1	63 / 443 (14%)	220 / 1,356 (16%)	158 / 914 (17%)	1,039 / 1,147 (91%)
2	155 / 443 (35%)	796 / 1,356 (59%)	641 / 914 (70%)	104 / 1,147 (9.1%)
3	162 / 443 (37%)	251 / 1,356 (19%)	89 / 914 (9.7%)	1 / 1,147 (<0.1%)
4	62 / 443 (14%)	83 / 1,356 (6.1%)	21 / 914 (2.3%)	0 / 1,147 (0%)
Missing	17	102	85	3
Ovarian suppression	38 / 460 (8.3%)	109 / 1,458 (7.5%)	71 / 999 (7.1%)	17 / 1,150 (1.5%)
Postmenopausal	223 / 382 (58%)	746 / 1,220 (61%)	524 / 839 (62%)	726 / 968 (75%)

[1]Mean (SD); n / N (%)

Table 1: Most patients had stage I or II disease (84%), and 64% underwent breast-conserving surgery. 89% and 77% in the MonarchE and NATALEE group respectivelly received chemotherapy. Only a small proportion of patients underwent ovarian function suppression.

Table 2: 36 and 60 months DFS and OS by subgroup

	36-months DFS	60-months DFS	36-months OS	60-months OS
Overall population	0.91 (0.90; 0.93)	0.84 (0.81; 0.86)	0.97 (0.96; 0.98)	0.92 (0.90; 0.93)
MonarchE	0.81 (0.77; 0.86)	0.70 (0.64; 0.77)	0.95 (0.93; 0.98)	0.85 (0.81; 0.91)
NATALEE	0.87 (0.85; 0.90)	0.76 (0.73; 0.80)	0.96 (0.94; 0.97)	0.89 (0.86; 0.91)
NATALEE-only	0.90 (0.88; 0.93)	0.79 (0.76; 0.83)	0.96 (0.94; 0.98)	0.90 (0.87; 0.93)
Non-eligible	0.98 (0.96; 0.99)	0.94 (0.92; 0.97)	0.99 (0.98; 1.00)	0.97 (0.95; 0.98)

Figure 2: Disease-Free Survival by Subgroups

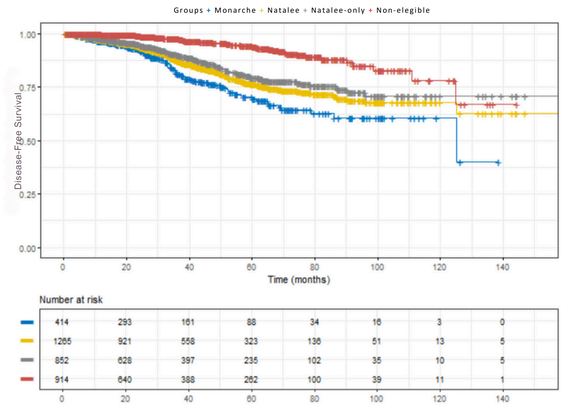


Figure 3: Overall Survival by Subgroups

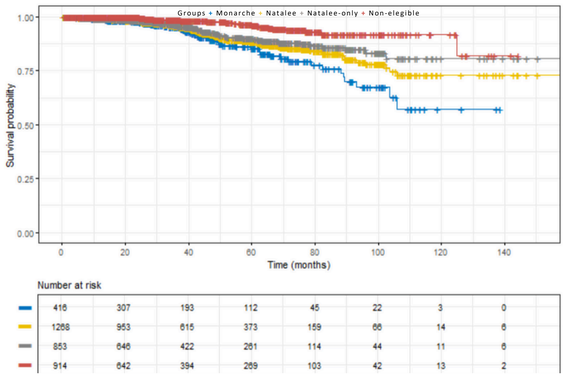


Figure 2 and 3: After a median follow-up period of 37 months, DFS analyses indicated that both MonarchE and NATALEE eligibility were associated with a higher risk of recurrence compared to non-eligible patients (HR 2.31 [1.67–3.18] and HR 2.23 [1.49–3.34], respectively; both p < 0.001). In the NATALEE-only subgroup, the recurrence risk was also significantly elevated (HR 1.34 [1.04–1.73]; p = 0.023). Both MonarchE and NATALEE-eligible patients showed worse OS compared to non-eligible patients (HR 2.45 [1.71–3.52], p < 0.001; and HR 2.91 [1.87–4.54], p < 0.001, respectively). In the NATALEE-only subgroup, OS was numerically lower, but the difference did not reach statistical significance (HR 1.18 [0.84–1.67]; p = 0.341). 36 and 60 months DFS and OS by subgroup are described in Table 2.

Table 3: Multivariable analysis of NATALEE-only subgroup

Variable	HR	95% CI	p-value
T			
1 or 2	—	—	
3 or 4	1.82	1.01, 3.27	0.045
N			
0	—	—	
1	1.03	0.59, 1.79	0.929

Table 3: Subgroup analysis of the 999 patients in the NATALEE-only group highlights the importance of T stage as a prognostic factor for DFS.

Conclusions

A significant number of patients with HR+/HER2− early BC treated in Brazilian private practice qualify for adjuvant CDK4/6 inhibitors, particularly under the broader NATALEE criteria. Both groups from the MonarchE and NATALEE trials showed worse OS compared to patients who were not eligible for these treatments. OS remained similar in the NATALEE-only group, whereas DFS differed significantly, driven by worse outcomes in T3/4 tumors.

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References

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