Poster 242P

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Clinical outcomes in patients with HR+/HER2− early breast cancer by prior systemic treatment: a subgroup analysis of the NATALEE trial

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KEY FINDINGS & CONCLUSIONS

- This subgroup analysis of NATALEE demonstrated an iDFS benefit with RIB + NSAI vs NSAI alone in patients who received any prior CT, prior neoadjuvant CT, prior adjuvant CT, and no prior CT
  - Disease characteristics (eg, stage, nodal status) varied between the prior CT subgroups
- iDFS benefit was observed with RIB + NSAI vs NSAI alone regardless of the duration of prior ET
  - Efficacy benefit with RIB + NSAI was observed in patients with up to 1 year of ET before initiation of RIB
- The majority of patients with N0 disease at diagnosis received prior CT, highlighting that they were considered to have risk of recurrence high enough to warrant CT

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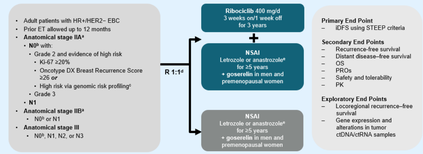
INTRODUCTION

- Current standard of care (SOC) for patients with hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2−) early breast cancer (EBC) includes surgical resection and adjuvant endocrine therapy (ET) ± chemotherapy (CT); neoadjuvant therapy (ET and/or CT) may also be used[1,2]
- The choice of (neo)adjuvant therapy is dependent on several factors, including risk of recurrence[2,3]
  - Additionally, guidelines recommend the consideration of age, comorbidities, tumor size, lymph node status, lymphovascular invasion, histological subtype, genomic information, and patient preferences[2]
- The phase 3 NATALEE trial demonstrated a statistically significant invasive disease–free survival (iDFS) benefit with adjuvant ribociclib (RIB) added to SOC nonsteroidal aromatase inhibitor (NSAI) vs NSAI alone in patients with HR+/HER2− EBC (hazard ratio, 0.749; 95% CI, 0.628-0.892; *P*=.0006; data cutoff: July 21, 2023)[4]
- NATALEE included patients who received any prior (neo)adjuvant CT and ≤52 weeks of ET prior to randomization[4]
  - monarchE, which assessed adjuvant abemaciclib + ET vs ET alone in HR+/HER2− EBC, included patients who received any prior (neo)adjuvant CT and ≤12 weeks of ET prior to randomization[5]
- Here, we present efficacy by prior systemic treatment (CT, ET) and treatment patterns from patients in NATALEE

METHODS

- In NATALEE, patients were randomized 1:1 to RIB 400 mg/d (3 weeks on/1 week off for 3 years) + NSAI (≥5 years) or NSAI alone; men and premenopausal women also received goserelin (**Figure 1**)
- Patients were eligible if they had anatomic stage IIA (high-risk N0 or N1), IIB, or III HR+/HER2− EBC
  - Patients with stage IIA N0 (T2N0) disease were required to be grade 3, or grade 2 disease and Ki-67 ≥20% or high genomic risk
- Patients who received any prior (neo)adjuvant CT were allowed and were analyzed by the following subgroups: any CT, adjuvant CT, neoadjuvant CT, and no CT
- Patients who received ET ≤52 weeks before randomization were allowed and were analyzed by the following subgroups: any duration ET, ET <12 weeks, ET ≥12 to <26 weeks, ET ≥26 weeks, and no prior ET
- In this analysis, prior ET was based on the last ET administered before randomization
  - Goserelin was not considered an ET in this analysis
  - Patients with no prior ET were excluded when analyzing by ET duration subgroups (eg, <12 weeks)
- Efficacy data were analyzed using Kaplan-Meier methods across the specified subgroups
- Hazard ratios were obtained using a stratified Cox model and data stratified by anatomic stage, menopausal status, prior (neo)adjuvant CT, and region
- Median iDFS follow-up was 33.3 months (data cutoff: July 21, 2023)

Figure 1. NATALEE Study Design



[a] Enrollment of patients with stage II disease was capped at 40%. [b] N0 was evaluated at diagnosis and after surgery, and the worse of the two findings was used in staging. [c] Genomic high risk is defined as at least one of the following: Oncotype Dx Breast Recurrence Score ≥26, Prosigna PAM50 score of "High Risk," MammaPrint score of "High Risk," EndoPredict EPclin Risk score of "High Risk". [d] Open-label design. [e] Per investigator choice. cfDNA/RNA, circulating tumor DNA/RNA; EBC, early breast cancer; ET, endocrine therapy; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; iDFS, invasive disease–free survival; N0, no nodal involvement/node-negative; N1, 1-3 axillary lymph nodes; N2, 4-9 axillary lymph nodes; N3, ≥10 axillary lymph nodes or collarbone lymph nodes; NSAI, nonsteroidal aromatase inhibitor; OS, overall survival; PK, pharmacokinetics; PRO, patient-reported outcome; R, randomized; STEEP, Standardized Definitions for Efficacy End Points in adjuvant breast cancer trials.

RESULTS

Baseline Characteristics by Prior CT

- Of the 5101 patients included, 4494 (88.1%) received prior CT; 607 (11.9%) received no prior CT (**Table 1**)
  - A total of 2180 patients (42.7%) received any prior neoadjuvant CT, and 2443 (47.9%) received any prior adjuvant CT; each group has 129 patients (2.5%) who received both neoadjuvant and adjuvant CT
- The median age was similar across the subgroups except for patients with no prior CT (median, 60 years)
- A lower percentage of Asian patients received no CT vs any CT, any neoadjuvant CT, or any adjuvant CT
- The majority of premenopausal patients (2071/2238 [93%]) received any CT
- Disease characteristics varied between the subgroups; patients who received any CT had a greater percentage of patients with stage III disease (65.1%) vs those with no CT (18.9%)
- The majority of patients with N0 disease (1113/1432 [78%]) received prior CT (**Supplementary Table 1**)

Table 1. Demographics and Baseline Clinical and Disease Characteristics by Prior CT

Parameter	Any CT		Any neoadjuvant CT[a]		Any adjuvant CT[a]		No CT	
	RIB + NSAI n=2249	NSAI alone n=2245	RIB + NSAI n=1085	NSAI alone n=1095	RIB + NSAI n=1223	NSAI alone n=1220	RIB + NSAI n=300	NSAI alone n=307
Median age, years	51.0	51.0	49.0	49.0	53.0	52.0	60.0	60.0
Race, n (%)								
White	1612 (71.7)	1601 (71.3)	805 (74.2)	808 (73.8)	844 (69.0)	834 (68.4)	264 (88.0)	267 (87.0)
Asian	328 (14.6)	321 (14.3)	164 (15.1)	140 (12.8)	181 (14.8)	207 (17.0)	13 (4.3)	13 (4.2)
Black or African American	38 (1.7)	44 (2.0)	19 (1.8)	25 (2.3)	20 (1.6)	21 (1.7)	4 (1.3)	3 (1.0)
Other[b]	139 (6.2)	157 (7.0)	57 (5.3)	77 (7.0)	86 (7.0)	81 (6.6)	13 (4.3)	19 (6.2)
Missing	132 (5.9)	122 (5.4)	40 (3.7)	45 (4.1)	92 (7.5)	77 (6.3)	6 (2.0)	5 (1.6)
Menopausal status, n (%)								
Premenopausal	1032 (45.9)	1039 (46.3)	548 (50.5)	568 (51.9)	514 (42.0)	511 (41.9)	83 (27.7)	84 (27.4)
Postmenopausal	1209 (53.8)	1199 (53.4)	535 (49.3)	524 (47.9)	702 (57.4)	705 (57.8)	215 (71.7)	221 (72.0)
Male patients	8 (<1)	7 (<1)	2 (<1)	3 (<1)	7 (<1)	4 (<1)	2 (<1)	2 (<1)
Prior surgery, n (%)								
Mastectomy	1493 (66.4)	1502 (66.9)	771 (71.1)	792 (72.3)	775 (63.4)	770 (63.1)	167 (55.7)	186 (60.6)
Breast-conserving surgery	839 (37.3)	833 (37.1)	336 (31.0)	329 (30.0)	510 (41.7)	514 (42.1)	142 (47.3)	133 (43.3)
Axillary lymph node dissection	1962 (87.2)	1942 (86.5)	988 (91.1)	1005 (91.8)	1027 (84.0)	1004 (82.3)	203 (67.7)	207 (67.4)
Sentinel lymph node biopsy	778 (34.6)	774 (34.5)	284 (26.2)	273 (24.9)	511 (41.8)	513 (42.0)	149 (49.7)	146 (47.6)
Other	129 (5.7)	132 (5.9)	48 (4.4)	61 (5.6)	83 (6.8)	75 (6.1)	15 (5.0)	29 (9.4)
Grade at diagnosis, n (%)								
GX	29 (1.3)	28 (1.2)	15 (1.4)	11 (1.0)	18 (1.5)	17 (1.4)	2 (<1)	4 (1.3)
G1	174 (7.7)	195 (8.7)	49 (4.5)	59 (5.4)	127 (10.4)	142 (11.6)	44 (14.7)	45 (14.7)
G2	1267 (56.3)	1261 (56.2)	593 (54.7)	630 (57.5)	704 (57.6)	664 (54.4)	192 (64.0)	190 (61.9)
G3	484 (21.5)	514 (22.9)	303 (27.9)	313 (28.6)	195 (15.9)	222 (18.2)	35 (11.7)	35 (11.4)
Not done/missing	295 (13.1)	247 (11.0)	125 (11.5)	82 (7.5)	179 (14.6)	175 (14.3)	27 (9.0)	33 (10.7)
N status at diagnosis, n (%)								
NX[c]	241 (10.7)	234 (10.4)	42 (3.9)	51 (4.7)	201 (16.4)	184 (15.1)	33 (11.0)	30 (9.8)
N0	533 (23.7)	580 (25.8)	130 (12.0)	153 (14.0)	415 (33.9)	441 (36.1)	162 (54.0)	157 (51.1)
N1	960 (42.7)	945 (42.1)	601 (55.4)	591 (54.0)	392 (32.1)	391 (32.0)	89 (29.7)	104 (33.9)
N2	324 (14.4)	285 (12.7)	203 (18.7)	180 (16.4)	129 (10.5)	112 (9.2)	7 (2.3)	7 (2.3)
N3	148 (6.6)	173 (7.7)	101 (9.3)	118 (10.8)	51 (4.2)	66 (5.4)	3 (1.0)	2 (<1)
Missing	43 (1.9)	28 (1.2)	8 (<1)	2 (<1)	35 (2.9)	26 (2.1)	6 (2.0)	7 (2.3)
Anatomic stage, n (%)								
I	6 (<1)	3 (<1)	0	1 (<1)	6 (<1)	2 (<1)	3 (1.0)	2 (<1)
II	769 (34.2)	789 (35.1)	291 (26.8)	292 (26.7)	498 (40.7)	507 (41.6)	242 (80.7)	245 (79.8)
III	1473 (65.5)	1452 (64.7)	794 (73.2)	802 (73.2)	718 (58.7)	710 (58.2)	55 (18.3)	60 (19.5)
Missing	1 (<1)	1 (<1)	0	0	1 (<1)	1 (<1)	0	0

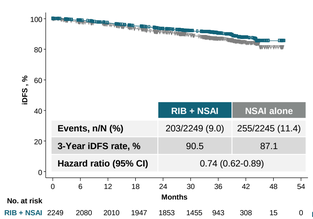
[a] Includes 129 patients (2.5%) who received both neoadjuvant and adjuvant CT. [b] Includes native Hawaiian, other Pacific Islander, American Indian, and Alaska Native. [c] These patients had disease that either could not be staged or was staged as NX and T4(X) as stage IIIB. CT, chemotherapy; G, grade; N, nodal; NSAI, nonsteroidal aromatase inhibitor; RIB, ribociclib.

Efficacy by Prior CT

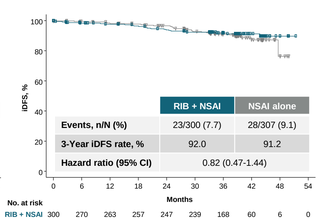
- A consistent iDFS benefit with RIB + NSAI vs NSAI alone was seen regardless of prior CT (**Figures 2** & **3**)
  - Results in the no CT subgroup should be interpreted with caution due to the small sample size

Figure 2.

A. iDFS in Patients Who Received Any CT



B. iDFS in Patients Who Received No CT

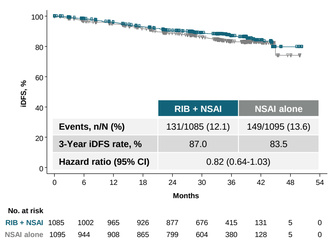


[a] Includes native Hawaiian or Pacific Islander, and American Indian or Alaska Native. [b] These patients had disease that either could not be staged or was staged as NX and T4(X) as stage IIIB.
ET, endocrine therapy; G, grade; N, nodal; NSAI, nonsteroidal aromatase inhibitor; RIB, ribociclib.

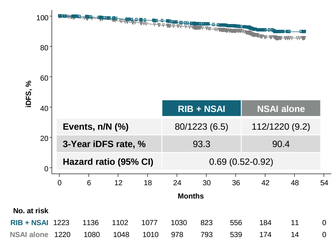
- iDFS benefit with RIB + NSAI was observed in premenopausal (hazard ratio [95% CI], 0.65 [0.48-0.87]) and postmenopausal (hazard ratio [95% CI], 0.82 [0.64-1.04]) patients who had any prior CT
- Baseline characteristics (eg, stage, nodal status) differed for patients across the prior CT subgroups and may have contributed to differences observed in iDFS benefit among these subgroups

Figure 3.

A. iDFS in Patients Who Received Any Neoadjuvant CT[a]



B. iDFS in Patients Who Received Any Adjuvant CT[a]



[a] Includes 129 patients who received both neoadjuvant and adjuvant CT.

Baseline Characteristics by Prior ET

- Overall, 68.5% of patients (3496/5101) received prior ET; 28.6% (1461/5101) of patients had ET <12 weeks, 25.7% (1313/5101) had ET ≥12 to <26 weeks, and 13.9% (711/5101) had ET ≥26 weeks (**Table 2**)
- Demographics and disease characteristics were balanced across the prior ET subgroups
- The median duration of last prior ET (excluding patients with no prior ET) was 3.1 months with RIB + NSAI and 3.2 months with NSAI alone

Table 2. Demographics and Baseline Clinical and Disease Characteristics by Prior ET

Parameter	Any duration ET		ET <12 weeks		ET ≥12 to <26 weeks		ET ≥26 weeks		No ET	
	RIB + NSAI n=1756	NSAI alone n=1740	RIB + NSAI n=744	NSAI alone n=717	RIB + NSAI n=650	NSAI alone n=663	RIB + NSAI n=358	NSAI alone n=353	RIB + NSAI n=793	NSAI alone n=812
Median age, years	52.0	52.0	50.0	50.0	54.0	52.0	53.0	55.0	53.0	52.0
Race, n (%)										
White	1266 (72.1)	1263 (72.6)	494 (66.4)	484 (67.5)	490 (75.4)	488 (73.6)	279 (77.9)	286 (81.0)	610 (76.9)	605 (74.5)
Asian	253 (14.4)	237 (13.6)	134 (18.0)	132 (18.4)	79 (12.2)	78 (11.8)	40 (11.2)	26 (7.4)	88 (11.1)	97 (11.9)
Black	28 (1.6)	23 (1.3)	16 (2.2)	7 (1.0)	7 (1.1)	12 (1.8)	5 (1.4)	4 (1.1)	14 (1.8)	24 (3.0)
Other[a]	112 (6.4)	134 (7.7)	44 (5.9)	51 (7.1)	47 (7.2)	57 (8.6)	21 (5.9)	25 (7.1)	40 (5.0)	42 (5.2)
Missing	97 (5.5)	83 (4.8)	56 (7.5)	43 (6.0)	27 (4.2)	28 (4.2)	13 (3.6)	12 (3.4)	41 (5.2)	44 (5.4)
Menopausal status, n (%)										
Premenopausal	791 (45.0)	758 (43.6)	396 (53.2)	369 (51.5)	256 (39.4)	270 (40.7)	137 (38.3)	116 (32.9)	324 (40.9)	365 (45.0)
Postmenopausal	961 (54.7)	976 (56.1)	346 (46.5)	346 (48.3)	392 (60.3)	392 (59.1)	221 (61.7)	234 (66.3)	463 (58.4)	444 (54.7)
Male patients	4 (<1)	6 (<1)	2 (<1)	2 (<1)	2 (<1)	1 (<1)	0	3 (<1)	6 (<1)	3 (<1)
Prior surgery, n (%)										
Mastectomy	1129 (64.3)	1123 (64.5)	482 (64.8)	459 (64.0)	417 (64.2)	424 (64.0)	227 (63.4)	235 (66.6)	531 (67.0)	565 (69.6)
Breast-conserving surgery	700 (39.9)	688 (39.5)	289 (38.8)	288 (40.2)	261 (40.2)	262 (39.5)	149 (41.6)	136 (38.5)	281 (35.4)	278 (34.2)
Axillary lymph node dissection	1497 (85.3)	1474 (84.7)	634 (85.2)	592 (82.6)	557 (85.7)	568 (85.7)	302 (84.4)	307 (87.0)	668 (84.2)	675 (83.1)
Sentinel lymph node biopsy	673 (38.3)	661 (38.0)	302 (40.6)	302 (42.1)	236 (36.3)	244 (36.8)	134 (37.4)	114 (32.3)	254 (32.0)	259 (31.9)
Other	115 (6.5)	120 (6.9)	41 (5.5)	52 (7.3)	47 (7.2)	48 (7.2)	27 (7.5)	19 (5.4)	29 (3.7)	41 (5.0)
Grade at diagnosis, n (%)										
GX	24 (1.4)	18 (1.0)	7 (<1)	6 (<1)	7 (1.1)	6 (<1)	10 (2.8)	6 (1.7)	7 (<1)	14 (1.7)
G1	157 (8.9)	174 (10.0)	72 (9.7)	70 (9.8)	60 (9.2)	65 (9.8)	25 (7.0)	39 (11.0)	61 (7.7)	66 (8.1)
G2	1011 (57.6)	997 (57.3)	430 (57.8)	425 (59.3)	385 (59.2)	375 (56.6)	195 (54.5)	194 (55.0)	448 (56.5)	454 (55.9)
G3	335 (19.1)	349 (20.1)	136 (18.3)	131 (18.3)	120 (18.5)	140 (21.1)	77 (21.5)	75 (21.2)	184 (23.2)	200 (24.6)
Not done/missing	229 (13.0)	202 (11.6)	99 (13.3)	85 (11.9)	78 (12.0)	77 (11.6)	51 (14.2)	39 (11.0)	93 (11.7)	78 (9.6)
N status at diagnosis, n (%)										
NX[b]	214 (12.2)	192 (11.0)	80 (10.8)	83 (11.6)	75 (11.5)	65 (9.8)	59 (16.5)	44 (12.5)	60 (7.6)	72 (8.9)
N0	457 (26.0)	499 (28.7)	213 (28.6)	228 (31.8)	152 (23.4)	170 (25.6)	92 (25.7)	100 (28.3)	238 (30.0)	238 (29.3)
N1	718 (40.9)	712 (40.9)	306 (41.1)	281 (39.2)	277 (42.6)	280 (42.2)	133 (37.2)	146 (41.4)	331 (41.7)	337 (41.5)
N2	234 (13.3)	190 (10.9)	88 (11.8)	73 (10.2)	105 (16.2)	76 (11.5)	41 (11.5)	41 (11.6)	97 (12.2)	102 (12.6)
N3	99 (5.6)	118 (6.8)	45 (6.0)	42 (5.9)	32 (4.9)	59 (8.9)	21 (5.9)	16 (4.5)	52 (6.6)	57 (7.0)
Missing	34 (1.9)	29 (1.7)	12 (1.6)	10 (1.4)	9 (1.4)	13 (2.0)	12 (3.4)	6 (1.7)	15 (1.9)	6 (<1)
Anatomic stage, n (%)										
I	9 (<1)	4 (<1)	3 (<1)	2 (<1)	5 (<1)	2 (<1)	1 (<1)	0	0	1 (<1)
II	665 (37.9)	668 (38.4)	292 (39.2)	294 (41.0)	236 (36.3)	253 (38.2)	136 (38.0)	120 (34.0)	346 (43.6)	366 (45.1)
III	1081 (61.6)	1067 (61.3)	449 (60.3)	421 (58.7)	409 (62.9)	408 (61.5)	220 (61.5)	232 (65.7)	447 (56.4)	445 (54.8)
Missing	1 (<1)	1 (<1)	0	0	0	0	1 (<1)	1 (<1)	0	0

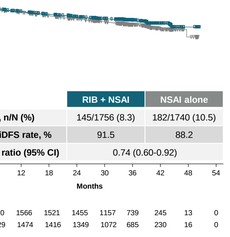
[a] Includes native Hawaiian or Pacific Islander, and American Indian or Alaska Native. [b] These patients had disease that either could not be staged or was staged as NX and T4(X) as stage IIIB.
ET, endocrine therapy; G, grade; N, nodal; NSAI, nonsteroidal aromatase inhibitor; RIB, ribociclib.

Efficacy by Prior ET

- Consistent iDFS benefit was observed with RIB + NSAI vs NSAI alone in patients who received prior ET or not and regardless of the duration of prior ET received (**Figure 4** and **Table 3**)

Figure 4.

A. iDFS in Patients Who Received Any Duration ET



B. iDFS in Patients Who Received No ET

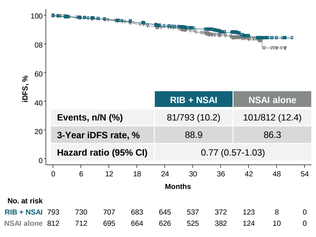


Table 3. iDFS by Prior ET Duration

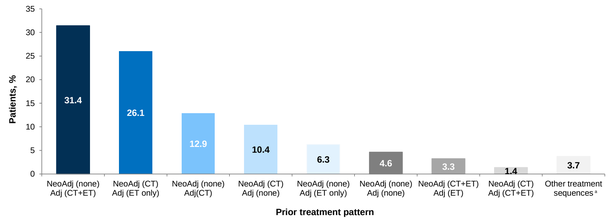
Prior treatment		RIB + NSAI	NSAI alone
ET <12 weeks	Events, n/N (%)	61/744 (8.2)	77/717 (10.7)
	Hazard ratio (95% CI)	0.75 (0.54-1.06)	
	3-year iDFS rate, %	91.9	88.6
ET ≥12 to <26 weeks	Events, n/N (%)	54/650 (8.3)	69/663 (10.4)
	Hazard ratio (95% CI)	0.73 (0.51-1.04)	
	3-year iDFS rate, %	91.1	87.8
ET ≥26 weeks	Events, n/N (%)	30/358 (8.4)	36/353 (10.2)
	Hazard ratio (95% CI)	0.74 (0.45-1.22)	
	3-year iDFS rate, %	91.3	88.4

ET, endocrine therapy; iDFS, invasive disease–free survival; NSAI, nonsteroidal aromatase inhibitor; RIB, ribociclib.

Treatment Patterns of Prior CT and ET in the Overall Population

- Overall, the most common prior systemic treatment pattern was no treatment in the neoadjuvant setting, and subsequent CT and ET in the adjuvant setting (**Figure 5**)
  - The second most common prior systemic treatment pattern was CT in the neoadjuvant setting and subsequent ET in the adjuvant setting
- In the overall population, most patients (55.3%) did not receive any neoadjuvant treatment (CT, ET, or other); 38.8% of patients received only CT in the neoadjuvant setting
  - Among the patients who did receive neoadjuvant CT, most (67.2%) received only ET in the adjuvant setting
- For patients who had prior treatment in the adjuvant setting, the majority received CT and ET (33.7%) or only ET (36.5%); 14.0% received only CT and 15.4% had no prior treatment (CT, ET, or other) before randomization

Figure 5. Patterns of Prior Treatment for the Overall Population



[a] All other treatment patterns occurred in <1% of patients in the overall population.
Adj, adjuvant; CT, chemotherapy; ET, endocrine therapy; NeoAdj, neoadjuvant.

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