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Survival outcomes of Black/African American patients with HER2-negative, advanced breast cancer across three academic cancer centers in the United States

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Objective

- To compare overall survival and progression-free survival between Black/African American and non-Black/African American patients with HER2-negative, advanced breast cancer (aBC) in three academic cancer centers from different regions in the United States

Conclusions

- The overall survival of Black/African American patients with HER2-negative aBC was shorter than that of non-Black/African American patients after controlling for staging and hormone receptor status. Additional work is needed to understand differences in time and access to pathology testing and other aspects of care
- As the treatment landscape for metastatic breast cancer continues to evolve, future studies should assess differences in treatment utilization of novel agents and survival outcomes between patients of different races in the HER2-low breast cancer population

Plain language summary

Why did we perform this research?

There is limited data on how long Black/African American patients with breast cancer continue to live after receiving treatment compared to patients of other races. This study focuses on patients with advanced breast cancer that does not express HER2 at very high levels (described as HER2-negative disease). We aimed to compare the average length of time Black/African American patients were alive after start of treatment to that of non-Black/African American patients.

How did we perform this research?

We collected information about the outcomes of patients with HER2-negative advanced breast cancer at three different cancer centres. We compared patients who were recorded as Black/African American in medical records to those who were not.

What were the findings of this research?

The average length of time Black/African American patients were alive after receiving treatment was shorter than that of non-Black/African American patients after considering how far along their disease was when treatment started and whether the tumor was responsive to hormonal treatment.

What are the implications of this research?

With the availability of new treatment options, additional studies are needed to confirm if the average length of time Black/African American patients with HER2-negative advanced breast cancer were alive continue to differ from that of non-Black/African American patients.

References

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3. Modi, et al. *N Engl J Med*. 2022;387(1):9-20

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Introduction

- Black/African American patients are underrepresented in breast cancer clinical trials. Based on 18 clinical trials (n = 12,334) which led to the approval of breast cancer therapeutics between 2010 and 2020, only 3.7% of participants were reported to be Black/African American, compared to approximately 30% in the general population[1]
- There is also a paucity of data on Black/African American patients with breast cancer in real-world settings. Registry data suggests that Black/African American women have the highest mortality rates among all ethnicity groups despite lower incidence rates[2]
- Novel HER2-targeted agents in breast cancer may benefit some patients previously classified as HER2-negative.[3] In this stratified analysis of patients with HER2-negative aBC, we aim to evaluate the survival outcomes of Black/African-American patients in real-world settings across three academic cancer centers representing different regions in the United States

Methods

- Study design: Retrospective cohort study via chart review
- Study population: Adult patients diagnosed with HER2-negative aBC between 2010 and 2020 (see Table 1)
- Study period: From diagnosis of aBC until death, last follow up at the study site, or December 31, 2021, whichever occurred earlier
- Study sites: Huntsman Cancer Institute, UT, H. Lee Moffitt Cancer Center, FL, and Winthrop P. Rockefeller Cancer Institute, AR contributed patient-level de-identified data
- Ethics approval: This study was exempted from ethical review by the University of Utah Institutional Review Board
- Outcomes of interest included (1) patient characteristics at diagnosis of aBC, (2) first line treatment patterns, (3) overall survival and progression-free survival
- Patients were stratified by race as documented in electronic medical records

Table 1. Study eligibility criteria

Inclusion criteria
1. Diagnosis of aBC (stage IIIB, IIIC and IV)
2. Aged 18 years and older at diagnosis of aBC
3. Classified as HER2-negative, i.e.: • HER2 IHC 0: IHC 0 • HER2-low: IHC1+, IHC 2+/ISH-
4. Received at least one line of therapy for aBC with documented therapy start date
5. ≥2 encounters on separate dates for breast cancer in study period
Exclusion criteria
1. Diagnosis of primary cancers other than breast cancer

Abbreviations: aBC, advanced breast cancer; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization

- Overall survival (OS) was the time between initiation of first line treatment for aBC and death, while progression-free survival (PFS) was the time between initiation of first line treatment for aBC and disease progression or death
- Median survival was estimated using Kaplan-Meier analyses with censoring performed at date of last follow up or December 31, 2021, whichever occurred earlier
- We compared differences in survival between Black/African-American and non-Black/African-American patients using Cox regression. Hazards ratios were estimated and further adjusted for staging and hormone receptor status. The proportional hazards assumption was assessed by visual inspection and goodness-of-fit test of Schoenfeld residuals
- Stratified analysis was conducted by staging and hormone receptor status at diagnosis of aBC and presented as forest plots of median survival and 95% confidence intervals of each stratum

Results and interpretation

- A total of 869 patients met the eligibility criteria, among which 95 (10.9%) were Black/African American. The non-Black/African American patients (n = 774, 89.1%) were mostly non-Hispanic White (n = 649, 83.9%), followed by non-White Hispanic (n = 75, 9.7%), Asian American and Pacific Islanders (n = 32, 4.1%) and other racial/ethnic groups (n = 18, 2.3%)
- Around two-thirds of patients with HER2-negative disease were classified as HER2-low. Compared to non-Black/African American patients, fewer Black/African American patients in our cohort had positive hormone receptor status and stage IV disease. Histology type was also significantly different between Black/African American and non-Black/African American patients (**Table 2**)
- There were no significant differences in the treatment patterns between Black/African American and non-Black/African American patients in our study cohort but trends of slightly higher use of CDK4/6 inhibitor were observed among non-Black/African American patients with stage IV hormone receptor-positive disease compared to their Black/African American counterparts (**Table 2**)
- No differences were observed in survival outcomes in the unadjusted analysis. However, controlling for stage and hormone receptor status, Black/African American patients had shorter OS but no differences in PFS (**Figure 1**). Median OS and PFS were consistently shorter for Black/African American patients in subgroups defined by stage and hormone receptor status (**Figure 1** & **Table 3**)

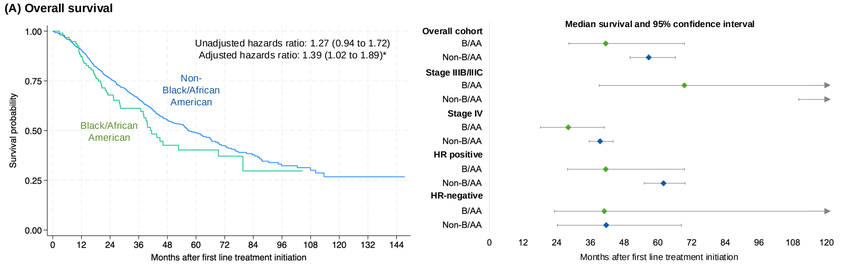
Table 2. Patient characteristics and first-line treatment regimens

Characteristic/Variable	Black/African American (n=95)		Non-Black/African American (n=774)		P-value
Age in years, median (IQR)	54.4 (45.1 to 62.6)		57.0 (47.7 to 65.3)		0.13
HER2 expression, n (%)					0.26
HER2 IHC 0	31 (32.6)		210 (27.1)		
HER2-low	64 (67.4)		564 (72.9)		
Hormone receptor, n (%)					**0.003**
Positive	57 (60.0)		609 (78.7)		
Negative	38 (40.0)		162 (20.9)		
Unknown	0 (0)		3 (0.4)		
Staging, n (%)					**<0.001**
Stage IIIB/IIIC	60 (63.2)		339 (43.8)		
Stage IV	35 (36.8)		435 (56.2)		
Histology type, n (%)					0.01
Lobular	2 (2.1)		110 (14.2)		
Ductal	83 (87.4)		581 (75.1)		
Other	6 (6.3)		55 (7.1)		
Unknown	4 (4.2)		28 (3.6)		
Histology grade, n (%)					**0.003**
Grade 1	1 (1.1)		44 (5.7)		
Grade 2	27 (28.4)		335 (43.3)		
Grade 3	58 (61.1)		345 (44.6)		
Unknown	9 (9.5)		50 (6.5)		
First-line treatment regimen, n (%)	**HR+**	**HR-**	**HR+**	**HR-**	
Stage IIIB/IIIC	**(n = 29)**	**(n = 31)**	**(n = 236)**	**(n = 100)**	0.97 (HR+)
Chemotherapy alone	16 (55.2)	29 (93.5)	118 (50.0)	93 (93.0)	0.57 (HR-)
Chemotherapy + IO/TT	0 (0)	1 (3.2)	2 (0.8)	6 (6.0)	
Endocrine therapy alone	3 (10.3)	0 (0)	28 (11.9)	0 (0)	
Endocrine therapy + CT	9 (31.0)	0 (0)	81 (34.3)	0 (0)	
Endocrine therapy + any CDK4/6i	1 (3.4)	0 (0)	7 (2.9)	0 (0)	
Clinical trials	0 (0)	1 (3.2)	0 (0)	1 (1.0)	
Stage IV	**(n = 28)**	**(n = 7)**	**(n = 373)**	**(n = 62)**	0.21 (HR+)
Chemotherapy alone	9 (32.1)	6 (85.7)	79 (21.2)	49 (79.0)	0.96 (HR-)
Chemotherapy + IO/TT	1 (3.6)	1 (14.3)	6 (1.6)	11 (17.7)	
Endocrine therapy alone	9 (32.1)	0 (0)	117 (31.4)	0 (0)	
Endocrine therapy + CT/IO/TT	1 (3.6)	0 (0)	28 (7.5)	0 (0)	
Endocrine therapy + any CDK4/6i	7 (25.0)	0 (0)	137 (36.7)	0 (0)	
CDK4/6i alone	0 (0)	0 (0)	2 (0.5)	0 (0)	
TT +/- IO	0 (0)	0 (0)	3 (0.8)	1 (1.6)	
Clinical trials	1 (3.6)	0 (0)	1 (0.2)	1 (1.6)	

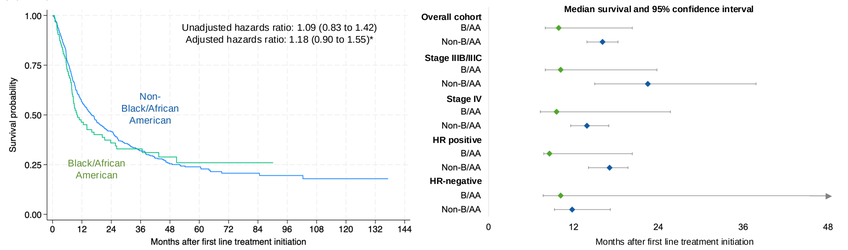
CDK4/6i, cyclin-dependent kinase 4 and 6 inhibitors; CT, chemotherapy; HER2, human epidermal growth factor receptor 2; HR+, hormone receptor-positive; HR-, hormone receptor-negative; IHC, immunohistochemistry; IO, immunotherapy; IQR, interquartile range; TT, targeted therapy.

Figure 1. Overall survival and progression-free survival at first line

(A) Overall survival



(B) Progression-free survival at first line



*Adjusted for staging and hormone receptor status at diagnosis of advanced disease
Note: Bars in Forest plots represent 95% confidence interval of median survival while bars ending with arrows indicate that median/upper limit of confidence interval was not reached.

Table 3. Comparison of median survival stratified by staging and hormone receptor status

Variable	Black/African American (n=95)		Non-Black/African American (n=774)	
Overall survival (Months)	**n**	**Median (95% CI)**	**n**	**Median (95% CI)**
Full patient cohort	95	41.4 (28.3 to 69.4)	774	56.7 (50.0 to 66.2)
Staging: Stage IIIB/IIIC	60	69.4 (39.1 to NR)	339	NR (110.1 to NR)
Stage IV	35	28.1 (18.2 to 40.9)	435	39.4 (35.5 to 44.0)
Hormone receptor status: Positive	57	41.4 (27.8 to 69.4)	609	62.0 (55.1 to 69.7)
Negative	38	40.9 (23.1 to NR)	162	41.6 (24.2 to 68.3)
Progression-free survival at 1L (Months)	**n**	**Median (95% CI)**	**n**	**Median (95% CI)**
Full patient cohort	95	9.9 (8.0 to 20.3)	773	16.1 (13.9 to 18.3)
Staging: Stage IIIB/IIIC	60	10.2 (8.0 to 23.8)	339	22.5 (15.0 to 37.8)
Stage IV	35	9.6 (7.3 to 25.7)	434	13.9 (11.6 to 17.0)
Hormone receptor status: Positive	57	8.6 (7.8 to 20.3)	609	17.1 (14.1 to 19.7)
Negative	38	10.2 (7.7 to NR)	161	11.8 (9.3 to 17.2)

1L, first line; B/AA, Black/African American; CI, confidence interval; HR, hormone receptor.