Does Race Impact Outcomes in Triple Negative Breast Cancer?

Kevin Holcomb, MD FACOG[1], Janna Andrews, MD[1], Lisa Ensign, PhD MS[2], Lihong Diao, MD MS[2], Cynthia Liu[2,3], Aaron Galaznik, MD MBA[4], Bryant Fields, MSc[2]

[1]Weill Cornell Medicine, New York, NY; [2]Acorn AI by Medidata, a Dassault Systèmes Company, New York, NY; [3]Columbia University Mailman School of Public Health, New York, NY; [4]Acorn AI by Medidata, a Dassault Systèmes Company, Boston, MA;

acornai
a Medidata company

INTRODUCTION

- Previous studies have shown lower breast cancer survival rates in African American (AA) women[1]
- One factor driving this difference is the known higher prevalence of triple negative breast cancer (TNBC)
- Enrollment in clinical trials can potentially mitigate baseline covariates that may confound results in uncontrolled settings
- The potential impact of factors on survival included age, body mass index (BMI), baseline leukocytes, dose adjustments and adverse events[2]

OBJECTIVE

- By using a pooled clinical trial population, we seek to reduce the impact of social determinants on outcome and to explore the relative survival by race within a TNBC population

METHODS

- Phase II and III open-label, metastatic breast cancer studies (mBC) were selected from the Medidata Enterprise Data Store (MEDS), comprised of 22,000+ historical trials
- Patients were stratified by race (AA versus Non-AA)
- Overall survival (OS), progression-free survival (PFS) and duration of response (DOR) were assessed using a Kaplan-Meier analysis.
- Baseline and on-treatment covariates were compared using Wilcoxon and Chi-square tests

STUDY POPULATION

- The database for this study contained 1215 patients with TNBC enrolled between 2010 and 2017

Table 1. Demographic Information

		AA	Non-AA
N (%)		147 (12)	1068 (88)
Sex, N (%)	Female	147 (100)	1068 (100)
Age at Diagnosis (yr)	Median Missing	51.0 18	50.0 216
Ethnicity, N (%)	Hispanic/Latino Non-Hispanic Missing	1 (0.7) 142 (96.6) 4 (2.7)	87 (8.1) 959 (89.8) 22 (2.1)

OVERALL RESULTS

- Clinical trial baseline measurements of AA vs Non-AA patients are presented in Table 2
- The median BMI was significantly higher in AA compared to Non-AA (30.3 vs 25.8)

Table 2. Trial Baseline Measurements

		AA	Non-AA	P-value
N (%)		147 (12)	1068 (88)	
Time since Diagnosis (yr)	Median Missing	0.8 4	1.3 61	<0.001*
Age at Randomization	Median Missing	54.0 0	51.0 0	0.11
Number of Prior Therapies	Median Missing	4 12	4 40	0.2
ECOG Status, N (%)	0 1 2	79 (53.7) 64 (43.5) 1 (0.7)	627 (58.7) 420 (39.3) 4 (0.4)	0.49
Weight (kg)	Median Missing	81.7 4	68.0 20	<0.001*
BMI (kg/m^2)	Median Missing	30.3 4	25.8 24	<0.001*
Obesity, N (%)	Yes (BMI > 30) No (BMI ≤ 30)	79 (53.7) 64 (43.5)	274 (25.7) 770 (72.1)	<0.001*
Baseline Leukocytes (10^9/L)	Median Missing	5.6 2	6.0 8	0.21

*Indicates significant results

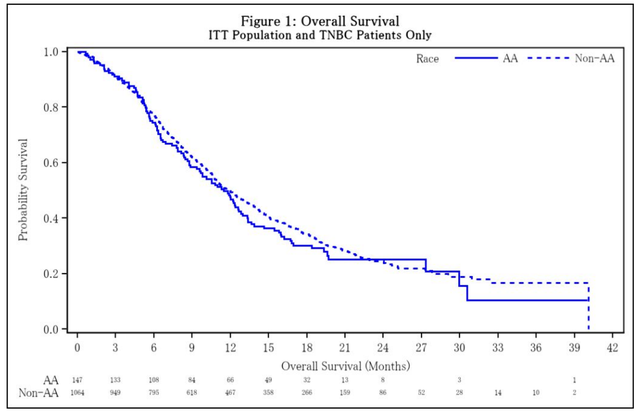
- Clinical trial outcomes of AA vs Non-AA patients are presented in Table 3
- A larger proportion of AA patients had neutropenia and WBC adverse events compared to Non-AA patients
- The median overall survival of AA was 13 days shorter than in Non-AA, but was not statistically significant

Table 3. Trial Outcomes

		AA	Non-AA	P-value
N (%)		147 (12)	1068 (88)	
Dose Modifications	N (%) Median per 100 days	113 (76.9) 3.6	777 (72.8) 4.2	0.20 0.05
Neutropenia Adverse Events	N (%) Median per 100 days	73 (49.7) 1.9	398 (37.3) 1.6	0.004* 0.27
Any WBC Adverse Events	N (%) Median per 100 days	**84 (57.1)** **2.0**	**406 (38.0)** **1.9**	**0.03*** **0.67**
		AA	**Non-AA**	**HR (95% CI)**
Overall Survival (days)	Median	349	362	0.9 (0.7, 1.1)
Progression Free Survival (days)	Median	128	140	0.9 (0.8, 1.1)
Duration of Response (days)	Median	140	172	0.8 (0.6, 1.1)

*Indicates significant results

SURVIVAL CURVES



CONCLUSIONS

- This cohort reflects previous findings that African-American women are often underrepresented in breast cancer clinical trials[3]
- In a controlled setting, AA metastatic TNBC study subjects demonstrated shorter, but not-significant OS, PFS and DOR compared to their non-AA counterparts
- In this cohort of studies, AA patients experienced more dose modifications on study
- Further investigation of potential biological and treatment factors associated with racial disparity in TNBC is warranted

REFERENCES

[1]Ismail-Khan R et al. A Review of Triple-negative Breast Cancer. Cancer Control. 2010;17(3):173-176.

[2]Siddharth S, Sharma D. Racial Disparity and Triple-Negative Breast Cancer in African-American Women: A Multifaceted Affair between Obesity, Biology, and Socioeconomic Determinants. *Cancers (Basel)*. 2018;10(12):514. Published 2018 Dec 14. doi:10.3390/cancers10120514.

[3]Analysis of racial distribution amongst patients in phase III cancer clinical trials. J Clin Oncol 37, 2019 (suppl; abstr 6588)

CONTACT INFORMATION

Sheila Diamond, MS, CGC
Medidata Institute
sdiamond@mdsol.com | 646-362-2545