Real World Outcomes of the Keynote 522 Regimen for Triple-Negative Breast Cancer

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BACKGROUND

- Keynote 522 established perioperative chemoimmunotherapy as the standard of care for early-stage, triple negative breast cancer (TNBC)
- There are well-documented disparities in breast cancer outcomes for women of black race and those of lower socioeconomic (SES)[1,2]
- However, the original study did not comment on the racial, ethnic, or socioeconomic characteristics of its participants
- We evaluate real-world outcomes of the Keynote 522 regimen in an NCI-designated comprehensive cancer center (CCC) with a racially diverse, high poverty catchment area

METHODS

- Retrospective chart review was performed on all TNBC patients with clinical stage II-III disease who received care at a combined academic/community hospital network in Northeast Ohio from 2020-2025 and were treated according to the Keynote 522 protocol
- The following variables were obtained via IRB –approved chart review: patient age, race, ethnicity, insurance provider, poverty index, ECOG score, comorbidity index, CPS, HER2 score, menopausal status, primary tumor classification, and immunotherapy-related adverse events (irAE)
- Primary outcomes included pCR, EFS, and rates of grade III or higher irAEs
- Analysis of pCR and EFS was performed using both univariate and multivariable Cox regression analysis, with multivariable analysis involving race, insurance provider, and irAE occurrence and grade

DEMOGRAPHICS

Demographics	N = 207
Age, years	55 (44, 64)
Race	
White	132 (65%)
Black/African American	66 (33%)
Other	4 (2%)
Poverty Index	16.0 (11.2, 16.0)
Menopausal Status	
Postmenopause	131 (66%)
Premenopause	67 (34%)
Charlson Comorbidity Index	4.00 (3.00, 5.00)
Insurance	
Marketplace (Obamacare)	20 (10%)
Medicaid	26 (13%)
Medicare	50 (25%)
Private (HMO, PPO, POS)	103 (52%)

RESULTS

Variable		Odds Ratio	P value
Age, years		0.97 (0.95 - 0.99)	**0.013**
Race	Reference: White		
	Black/African American	1.55 (0.79 - 3.12)	0.211
Poverty Index		1.03 (0.96 - 1.12)	0.394
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Menopausal Status	Reference: Postmenopause		
	Premenopause	1.30 (0.70 - 2.46)	0.411
Charlson Comorbidity Index		0.91 (0.77 - 1.07)	0.232
Insurance	Reference: Marketplace (Obamacare)		
	Medicaid	0.67 (0.15 - 2.68)	0.577
	Medicare	0.29 (0.07 - 1.01)	0.062
	Private (HMO, PPO, POS)	0.78 (0.20 - 2.52)	0.686
Immunotherapy-Related AE Grade	Reference: No irAE		
	Grade I/II	1.26 (0.67 - 2.41)	0.473
	Grade III/V	1.45 (0.57 - 3.94)	0.443

Table 1: Univariate analysis of pCR

Variable		Hazard Ratio	P value
Age, years		0.98 (0.95 - 1.01)	0.157
Race	Reference: White		
	Black/African American	1.19 (0.53 - 2.65)	0.676
Poverty Index		0.98 (0.88 - 1.10)	0.753
Menopausal Status	Reference: Postmenopause		0.019
	Premenopause	2.67 (1.18 - 6.06)	
Charlson Comorbidity Index		0.59 (0.12 - 2.96)	0.52
Insurance	Reference: Marketplace (Obamacare)		0.565
	Medicaid	0.67 (0.17 - 2.66)	0.647
	Medicare	0.74 (0.21 - 2.65)	0.152
	Private (HMO, PPO, POS)	0.84 (0.66 - 1.07)	
Immunotherapy-Related AE Grade	Reference: No irAE		0.043
	Grade I/II	0.39 (0.16 - 0.97)	0.043
	Grade III/V	0.44 (0.10 - 1.91)	0.271

Table 2: Univariate analysis of EFS

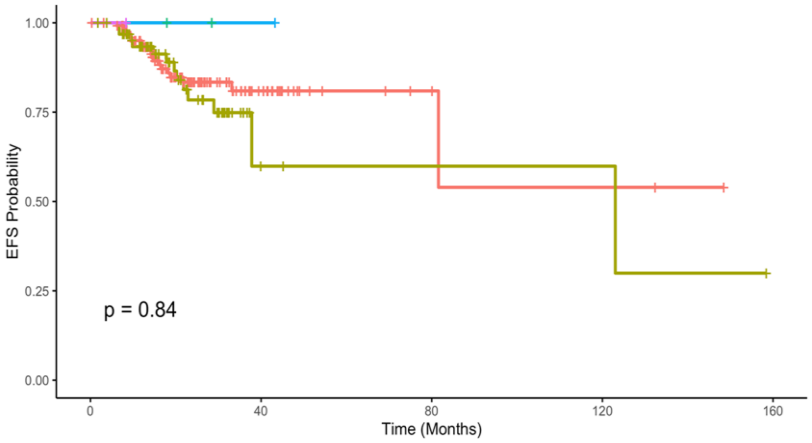


Figure 1: EFS Stratified by Race (Red=white, Green= black/AA, Blue=other)

DISCUSSION

- Two-year overall EFS was 82% (95% CI 76-89%)
- Of the evaluated factors, age at diagnosis was the only clinical/demographic factor that significantly correlated with pCR
- No statistically significant difference in EFS was observed across age, race, ethnicity, poverty index, or insurance provider
- Patients who experienced any irAEs were found to have lower associated risk of recurrence (HR 0.37, 95% CI 0.16-0.85, p-value 0.019)

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