Tolerability of the KEYNOTE-522 regimen in a diverse real-world cohort of patients with early TNBC

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BACKGROUND

- The KEYNOTE-522 study demonstrated improvement in efficacy with neoadjuvant chemotherapy (NACT) in combination with pembrolizumab compared to chemotherapy alone for patients with early TNBC[1].
- At the time the practice-changing trial was published in 2021, race and ethnicity data of the trial population were not available.
- Real-world data on the toxicity of this regimen is limited, especially in racially diverse patient populations and the older patient population.
- Real-world studies aid in the generalizability and applicability of trial data[2].

OBJECTIVES

- Describe the toxicity of the KEYNOTE-522 regimen in a diverse, urban population at a large tertiary referral center.
- Evaluate the impact of race/ethnicity and age on tolerability of the KEYNOTE-522 regimen.

METHODS

Epic query for TNBC and pembrolizumab between 8/2021 – 2/2025
(n=235)

Received ≥1 dose NACT and ≥1 dose pembrolizumab for early-stage TNBC
(n=111)

- Patients with anatomic stage II-stage III TNBC.
- Toxicity was measured by rates of dose reductions, drug discontinuations, treatment delays, hospitalizations, and ED visits due to treatment-related adverse events.
- Descriptive statistics were used to describe patient data: non-parametric tests including Fisher's exact test, Kruskal-Wallis rank sum test, and Pearson's Chi-squared test were utilized in the stratified analyses by race/ethnicity and age.

There were no significant differences in tolerability of the KEYNOTE-522 regimen based on race and ethnicity in this real-world cohort including 111 patients of whom 26% were Black and 16% Hispanic. The observed discontinuation rate (of any agent) of 33% in the overall population was notably higher than the 23% rate reported in KEYNOTE-522.

- We observed higher rates of emergency department visits and hospitalizations in younger patients due to immune-related adverse events (irAEs), which warrant further study.
- We observed higher rates of pembrolizumab delays due to irAEs in patients who identified as Asian, which warrants further study.

RACE/ETHNICITY OF REAL-WORLD COHORT (N=111)

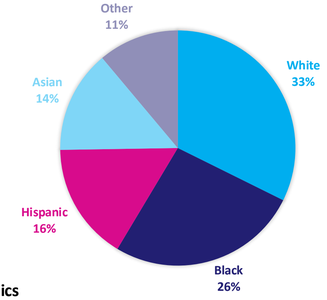


Figure 1. Cohort Demographics
82% (n= 91) of patients were stage II and 52% (n= 57) were lymph node negative. 33% (n=36) of patients identified as White, 26% (n=29) Black, 14% (n=16) Asian, 16% (n=18) Hispanic and 11% (n=12) identified as Other.

Table 1. Tolerability by Race/Ethnicity

	Overall Population 100% (N=111)	White 33% (N=36)	Black 26% (N=29)	Asian 14% (N=16)	Hispanic 16% (N=18)	Other 11% (N=12)	p-value
Dose reduction due to AEs	19% (21)	17% (6)	17% (5)	13% (2)	28% (5)	27% (3)	0.72
Drug discontinuation due to AEs	33% (36)	37% (13)	38% (11)	25% (4)	28% (5)	25% (3)	0.839
Drug delays due to AEs	55% (61)	44% (16)	62% (18)	63% (10)	67% (12)	42% (5)	0.403

Dose reductions, drug discontinuations and delays of any agent.

RESULTS

Table 2. Grade 3/4 Treatment-Related Adverse Events

	Overall Population 100% (N=111)	White 32% (N=36)	Black 26% (N=29)	Asian 14% (N=16)	Hispanic 16% (N=18)	Other 11% (N=12)	p-value
Median # of neoadjuvant pembrolizumab cycles	7.5	7	8	7	7.5	8	0.134
Pembrolizumab delays due to irAEs	11% (12)	17% (6)	7% (2)	25% (4)	0% (0)	0% (0)	0.051
Hospitalizations due to AEs	33% (36)	39% (14)	28% (8)	44% (7)	22% (4)	25% (3)	0.579
ED visits due to AEs	28% (31)	25% (9)	28% (8)	25% (4)	44% (8)	17% (2)	0.574

Immune related adverse events of pembrolizumab are shown above, as well as hospitalizations and emergency department visits due to treatment-related adverse events of any agent.

Table 3. Tolerability by Age

	Age <40 (N=18)	Age 40-65 (N=67)	Age >65 (N=26)	p-value
ED visits due to irAEs	44% (8)	10% (7)	23% (6)	0.006*
Hospitalizations due to AEs	50% (9)	25% (16)	44% (11)	0.05*
Hospitalizations due to irAEs	44% (8)	15% (10)	23% (6)	0.036*

Emergency department visits and hospitalizations when stratified by age <40, 40-65, and >65 years.

REFERENCES

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