Evaluating real world pCR rates at an urban center following KEYNOTE-522 for early-stage TNBC

Justine Anderson, MD[1]; Javier Dejesus, MD[1]; Elena Baldwin, MD[1]; Grace Van Hyfte, MSc[1]; Prathyusha Pandu, MD[2]; Nithya Krishnamurthy, BA[1]; Mohammad Rattu, PharmD[1]; Rebecca Farley, Pharm D[1]; Amy Tiersten, MD[1]; Rima Patel, MD[1]
[1] Department of Medicine, Division of Hematology and Medical Oncology, Icahn School of Medicine at Mount Sinai, Tisch Cancer Center, New York, NY, USA
[2]Department of Medicine, Mount Sinai West/Morningside, New York, NY, USA

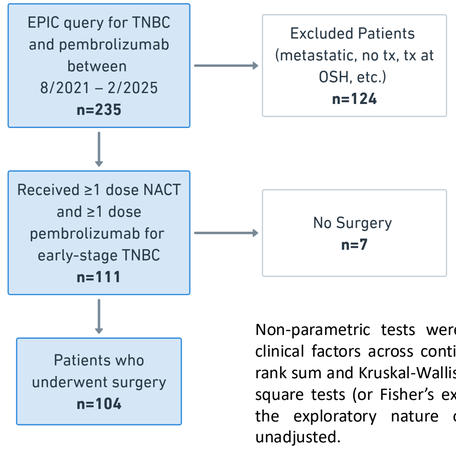
BACKGROUND

- KEYNOTE-522 was a practice changing study of patients with early-stage, locally advanced TNBC that established combination chemoimmunotherapy as the new standard of care in 2021, demonstrating that patients who received a combination of chemotherapy and pembrolizumab had a statistically significant pCR rate of 64.8% compared to 51.2% with chemotherapy alone[1].
- Race and ethnicity data were not available at time of trial publication, and it is unknown whether pCR rates with this regimen vary by race/ethnicity.
- Dose-dense doxorubicin/cyclophosphamide (ddAC) administered q2 weeks is standard of care, yet KEYNOTE-522 used ddAC q3 weeks and it is unknown how outcomes vary by AC q2 weeks with pembrolizumab, as well as with the administration of AC before paclitaxel/carboplatin (TC).
- Real-world studies aid in the generalizability and applicability of trial data[2].

OBJECTIVES

- Determine the efficacy of the KEYNOTE-522 regimen, as measured by pCR, in a real world, diverse, urban population.
- Assess factors impacting the likelihood of achieving pCR

METHODS



Non-parametric tests were used to evaluate differences between clinical factors across continuous and categorical variables: Wilcoxon rank sum and Kruskal-Wallis rank sum for continuous variables, and chi square tests (or Fisher's exact tests) for categorical variables. Due to the exploratory nature of our analysis, p-values are reported unadjusted.

In a diverse real-world population of 104 patients of whom 25% were Black and 15% Hispanic, pCR rates with neoadjuvant pembrolizumab and chemotherapy were comparable to those in the KEYNOTE-522 trial.

- Dose dense AC administered every 2 weeks was associated with a higher pCR rate than AC administered every 3 weeks.
- The higher pCR rates in Asian and Hispanic patients compared to White and Black warrant further study.
- pCR rates were lower in patients older than 65 years those this differences was not statistically significant.

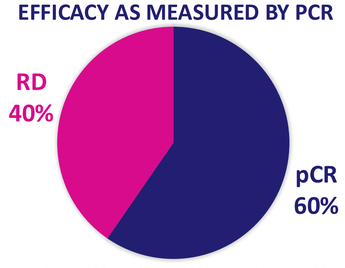


Figure 1. Of the 104 evaluable patients, 62 patients (60%) achieved pCR while 42 patients (40%) had residual disease. The pCR rate in the KEYNOTE-522 study for patients who received the combination of chemotherapy and immunotherapy was 64.8%.

Table 1. Demographics Table

Demographics	# of patients (%)
Age (median)	55 years
Stage	
Stage II	86 (83%)
Stage III	18 (17%)
Lymph Node Involvement	44 (43%)
Race	
White	35 (34%)
Black	26 (25%)
Hispanic	17 (16%)
Asian	16 (15%)
Other	10 (10%)

RESULTS

Table 2. pCR by race/ethnicity

	Overall Population 100% (N=104)	White 34% (N=35)	Black 25% (N=26)	Asian 15% (N=16)	Hispanic 15% (N=17)	Other 10% (N=10)	p value[1]
pCR	60% (62)	49% (17)	46% (12)	75% (12)	65% (11)	100% (10)	0.01*

When stratified by race/ethnicity, Asian and Hispanic patients had higher pCR rates than White and Black patients

Table 3. pCR by age

	<40 years 17% (N=18)	40-65 years 62% (N=64)	65+ years 21% (N=22)	p value[1]
pCR	72% (13)	62% (40)	41% (9)	0.1

There was no statistically significant difference in pCR based on age. 32% (N=33) of pts <50 years and 68% (N=71) of pts >50+ years achieved pCR (p=0.063). Limitations of this analysis include disproportionate sample sizes within age categories.

Table 4. pCR by chemotherapy regimen

	AC first (n=37)	TC first (n=67)	p value
pCR	23 (62%)	39 (63%)	0.694
	AC q2 weeks (n = 64)	**AC q3 weeks (n = 40)**	**p value**
pCR	44 (69%)	18 (45%)	0.016*

There was no significant difference in pCR rate (p=0.694) based on which regimen was given first; however, there was a statistically significant difference in pts who received dose-dense AC every 2 weeks (69%, N=44) vs. every 3 weeks (45%, N=18, (p=0.016)
AC = doxorubicin/cyclophosphamide; TC = paclitaxel/carboplatin

REFERENCES

1. Schmid P, Cortes J, Pusztai L, et al. Pembrolizumab for Early Triple-Negative Breast Cancer. New England Journal of Medicine. 2020;382(9):810-821. doi:doi:10.1056/NEJMoa1910549
2. Thao T. Vo, Sangmi Kim, Ashley Jaksa, Benjamin Bates, Wei Zhou, Mark D. Stewart, Mehmet Burcu; Diversity by Design: Real-World Data to Enhance Representation in Clinical Cancer Research. Clin Cancer Res 1 November 2025; 31 (21): 4396–4404. https://doi.org/10.1158/1078-0432.CCR-25-1255

Author contact: justine.anderson@mountsinai.org