Real-World Safety and Effectiveness of the KEYNOTE-522 Regimen for Triple-Negative Breast Cancer in a Private Oncology Practice in Rio de Janeiro, Brazil

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Abstract

The KEYNOTE-522 trial established neoadjuvant chemoimmunotherapy as the standard of care for stage II–III triple-negative breast cancer (TNBC), but real-world evidence on its safety and effectiveness remains limited.

This retrospective cohort study included 85 women with stage II–III TNBC treated with the KEYNOTE-522 regimen at a private oncology center in Rio de Janeiro, Brazil. Serious adverse events (SAEs) occurred in 18.8% of patients. Older age (OR = 1.07 per year; p = 0.003) and stage III disease (OR = 3.60; p = 0.048) were independently associated with increased toxicity risk. Pathological complete response (pCR) was achieved in 53.6% of patients, and overall survival (OS) was 87% after a median follow-up of 32.9 months.

In this real-world Brazilian cohort, patients experienced significant toxicity during neoadjuvant treatment. Despite this, pCR and OS were comparable to clinical trial results, supporting the regimen's effectiveness but underscoring the need for careful toxicity management.

Introduction

The KEYNOTE-522 trial established neoadjuvant chemoimmunotherapy as the standard of care for stage II–III TNBC. However, the regimen is associated with high rates of grade ≥3 adverse events, raising concerns in real-world settings where toxicity management may differ from clinical trial environments. Despite growing global adoption, real-world data on the safety and effectiveness of this approach—particularly in low- and middle-income countries—remain limited. We evaluate the real-world incidence of SAEs during neoadjuvant treatment,pCR, and OS outcomes among patients with stage II–III TNBC receiving the KEYNOTE-522 regimen.

Methods and Materials

A retrospective cohort study was conducted at a private oncology center in Rio de Janeiro, including women with stage II–III TNBC treated per the KEYNOTE-522 protocol. Treatment comprised pembrolizumab with paclitaxel–carboplatin, followed by pembrolizumab plus anthracycline–cyclophosphamide. Data were extracted from electronic medical records. SAEs were defined as treatment-related hospitalizations or deaths. Logistic regression identified predictors of toxicity, and survival was analyzed by Kaplan–Meier. pCR was defined as ypT0/Tis ypN0.

Results

A total of 85 women were included, with a median age of 46 years (range: 26–78); most were white (84.7%). Clinical stage II was the most common at diagnosis (53.6%) and 64.9% of tumors classified as grade 3. Pathogenic germline mutations were identified in 27.1% of patients.Treatment discontinuation was observed in 24.7% of cases, and corticosteroids due to SAEs were used in 14.1% of cases. There was one treatment-related death and 16 hospitalizations due to toxicity, resulting in a SAEs rate of 18.8% and a mean treatment delay of 13.5 days (±9.24). In multivariable analysis, older age was significantly associated with higher risk of SAEs, with a 7% increase in risk per year of age (OR=1.07; 95% CI: 1.03–1.12; p=0.003). Patients diagnosed at stage III had a 3.6-fold increased risk of SAEs compared to those at stage II (OR=3.60; 95% CI: 1.01–12.81; p=0.048). A pCR was achieved in 53.6% of patients.The OS rate was 87%, with a median follow-up of 32.9 months (95% CI: 31–35).

Variable	Total N (%)	Serious adverse event N (%)		OR (IC 95%)*	P-value
		No	Yes		
Age					
≤ 46 years	43 (50,6)	39 (56,5)	04 (25,0)	Reference	0,030
> 46 years	42 (49,4)	30 (43,5)	12 (75,0)	3,90 (1,14 – 13,31)	
Race					
Mixed or black	13 (15,3)	11 (15,9)	02 (12,5)	Reference	0,731
White	72 (84,7)	58 (84,1)	14 (87,5)	1,33 (0,26 – 6,68)	
Clinical stage					
II	45 (52,9)	39 (57,4)	06 (37,5)	Reference	0,158
III	39 (45,9)	29 (42,6)	10 (62,5)	2,24 (0,73 – 6,87)	
Missing	01 (1,2)				
Tumoral grade					
1 or 2	30 (35,3)	26 (41,9)	04 (25,0)	Reference	
3	48 (56,5)	36 (58,1)	12 (75,0)	2,17 (0,63 – 7,48)	0,221
Missing	07 (8,2)				
KI-67					
≥ 90%	27 (31,8)	23 (35,4)	04 (26,7)	Reference	0,522
< 90%	53 (62,4)	42 (64,6)	11 (73,3)	1,51 (0,43 – 5,27)	
Missing	05 (5,9)				
Germline mutation				Reference	0,067
Yes	23 (27,1)	22 (31,9)	01 (6,3)	7,02 (0,87 – 56,57)	
No	62 (72,9)	47 (68,1)	15 (93,8)		

Table 1 – Simple logistic regression between sociodemographic and tumor variables and severe adverse events (n=85)

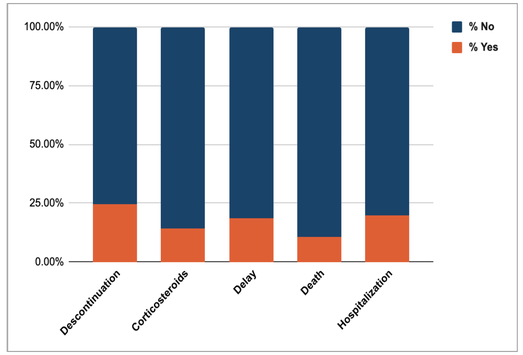


Chart 1. Events

Discussion

This real-world study confirms the feasibility of the KEYNOTE-522 regimen in stage II–III TNBC, showing a **pCR rate of 53.6%** and **87% overall survival** at 33 months—comparable to trial results. However, **18.8% of patients experienced serious adverse events (SAEs)**, mainly among older patients and those with stage III disease, leading to treatment delays or discontinuation.

Strengths include clinician-verified data, adherence to the full regimen, and being among the **first Latin American real-world reports** on chemoimmunotherapy for TNBC. Limitations involve the retrospective single-center design and limited sample size, which may affect generalizability.

These findings support the effectiveness of chemoimmunotherapy in routine care but highlight the need for **careful toxicity management and patient selection** to balance efficacy and safety in real-world settings.

Conclusions

In this Brazilian real-world cohort, the KEYNOTE-522 regimen achieved pCR and survival outcomes comparable to clinical trials but with notable toxicity. older age and stage III disease increased the risk of serious adverse events, underscoring the need for vigilant management and tailored treatment strategies in routine clinical practice.

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