TILs as a predictor of response in triple-negative breast cancer: analysis of clinical and pathological outcomes in patients undergoing neoadjuvant chemotherapy vased on Keynote-522 protocol in a brazilian cancer center

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Introduction

Triple-negative breast cancer (TNBC) tumors are aggressive, highly immunogenic, and often associated with early recurrence. Studies suggest that high levels of tumor-infiltrating lymphocytes (TILs) are associated with improved clinical outcomes[1], including overall survival (OS) and disease-free survival (DFS). We evaluated the presence or absence of complete pathological response (pCR) according to the TILs found in the tumor analysis of patients included in this cohort.

Methods and Materials

This is a single center, retrospective, observational cohort study. Patients diagnosed with TNBC clinical stage (CS) II-III who received treatment based on the KeyNote-522 protocol from April 2022 to January 2025 in Ac Camargo Cancer Center were evaluated. Patients were divided into two groups with a TILs cutoff of >30 and ≤30.
The primary endpoint was the prevalence of pCR acording to TILs. The second endpoints were DFS and a exploratory analysis of diferente TILs cutoffs.
Survival curves were compared with the log-rank test. All analysis were performed using Rstudio.

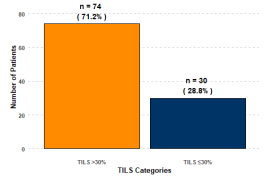


Chart 1. Distribution of patients by TILs category.

Results

A total of 121 patients, with a median age of 44 years, were analyzed, with the majority (69%) classified as CS II and 63% being premenopausal. TILs analysis was performed in 104 patients, with 74 (71%) having TILs ≤30 and 30 (28.8%) having TILs >30. In this group, pCR was achieved in 83.3% (chart 2).
In our cohort, thirteen patients experienced tumor recorrence, with 10 in the TILs ≤30 subgroup.

Regarding DFS and OS analysis, no statistically significant difference was observed (p = 0.58 and p = 0.88, respectively).
However, when analyzing the relationship between pCR and TILs, it was found that patients with TILs greater than 30 had a higher likelihood of pCR (OR 0.24; p < 0.01).
When TILs was evaluate as a non parametric variable, it showed a increase of TILs corresponde a higher pCR (p 0.0012).

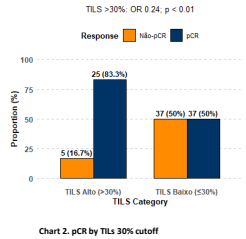


Chart 2. pCR by TILs 30% cutoff

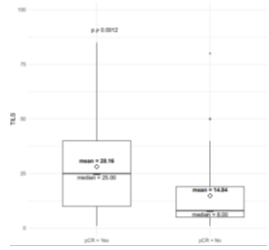


Chart 3. TILs by pCR group (non parametric comparision).

	Category	% (N)
Menopausal status	Pre menopausa	64.2% (77)
	Post menopausa	31.7% (38)
	Unkown	4.2% (5)
Histologycal Grade	Histologycal Grade 1	4.1% (5)
	Histologycal Grade 2	18.2% (22)
	Histologycal Grade 3	77.7% (94)
BRCA status	BRCAwt	66.9% (81)
	BRCAm	14.0% (17)
	Unkown	19.0% (23)

Table 1 Clinical and demographic characteristics of the patients included

Discussion

Our data aligns with the established literature, confirming that high TILs are associated with a higher prevalence of pCR in TNBC. While determining optimal TILs cutoffs can be challenging, a large pooled analysis has established that TILs ≥30% are significantly correlated with improved OS[1]. This positive association was also found by studies exploring different therapies, such as anthracycline-free regimens and immunotherapies (e.g., the NEOPACT Trial) [2], where the presence of immune biomarkers (TILs, PD-L1, DDIR, DetermaIO) predicts better treatment response. These insights underscore the potential of evaluating a broader panel of immune markers to refine prognostic stratification and guide future de-escalation strategies.

Conclusions

The presence of TILs greater than 30% was associated with a significant increase in pCR. The data obtained in this study suggest that tumor lymphocytic infiltrate may serve as a prognostic biomarker for pCR in patients with TNBC. Furthermore, these findings support the potential role of TILs as a practical biomarker for personalizing therapeutic strategies. However, it should be considered that the sample size was small, and further validation in larger, prospective studies is needed to firmly establish TILs as a guide for tailored therapy.

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