Timing of Recurrence after Neoadjuvant Chemo-Immunotherapy in Patients with Early-Stage Triple-Negative Breast Cancer

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ABSTRACT

Purpose: Neoadjuvant chemo-immunotherapy for high-risk triple-negative breast cancer (TNBC) has been shown to reduce the risk of recurrence and improve survival. However, the prognosis for patients with metastatic TNBC remains poor, especially for those with an early recurrence, who represent an urgent unmet need. Defining the most common timing of recurrences after chemo-immunotherapy is crucial for shaping the design of future clinical trials.

Experimental Design: We analyzed five clinical trials of neoadjuvant chemo-immunotherapy in early-stage TNBC to quantify the contribution of early recurrences (within 24 months from randomization) to the overall risk of relapse. Event-free survival data were extracted from Kaplan–Meier curves using PlotDigitizer. Events were evaluated up to 48 months, a time frame with consistent follow-up across trials and minimal later events. The primary endpoint was the proportion of early versus total recurrences by 48 months; secondary analyses stratified this by pathologic complete response status.

Results: Overall recurrence rates by 48 months in the immunotherapy arms were as follows: 14.3% (GeparNuevo), 14.8% (NSABP B-59/GeparDouze), 17.5% (KEYNOTE-522), 20.2% (IMpassion031), and 29.2% (NeoTRIP). The proportion of early relapse ranged from 64.6% in NSABP B-59/GeparDouze to 82.9% in GeparNuevo. This proportion was higher in patients with residual disease after neoadjuvant therapy (range, 69.4%–88.6%). Patients who achieved a pathologic complete response showed a similar proportion of early and late events.

Conclusions: Recurrences within 24 months account for most recurrences in patients with TNBC who relapse after neoadjuvant chemo-immunotherapy. Clinical trials are needed to define the optimal therapy for this patient population.

Introduction

Triple-negative breast cancer (TNBC) is characterized by aggressive clinical behavior and poor prognosis (1). Chemotherapy was the only treatment option for decades; however, the therapeutic landscape has been revolutionized by the introduction of novel therapies such as PARP inhibitors, antibody–drug conjugates (ADC), and immune checkpoint inhibitors (ICI; ref. 2).

In particular, ICIs combined with chemotherapy are now the standard of care for stage II/III TNBC in the neoadjuvant setting and for PD-L1–positive metastatic TNBC. In the neoadjuvant setting, the results of the KEYNOTE-522 trial led to the approval and clinical implementation of ICIs for high-risk patients (3). Neoadjuvant immunotherapy has also been evaluated in other clinical trials (4–6), which, with the exception of NeoTRIP (7), have demonstrated an increase in pathologic complete response (pCR) rates and a numerical reduction in the risk of recurrence, supporting the KEYNOTE-522 findings.

For patients with PD-L1–positive metastatic TNBC, the benefit of rechallenging with immunotherapy after prior use in the early setting is unknown. Additionally, even among immunotherapy-naïve patients, those with PD-L1–positive tumors and early recurrences (within 12 months after curative-intent treatment) have a worse prognosis than those with late recurrences, and the benefit of ICIs remains uncertain (8, 9). Patients with early recurrences represent a clear unmet need; yet, the proportion of these events after ICIs is unknown and likely underestimated.

In this study, we assess the time-dependent distribution of recurrences after neoadjuvant chemo-immunotherapy (with or without adjuvant immunotherapy) across five major clinical trials for stage II/III TNBC.

Materials and Methods

As reported in the original publications, all trials were conducted in accordance with ethical standards, received Institutional Review Board approval, and obtained written informed consent from participants.

We considered randomized trials on neoadjuvant chemo-immunotherapy in early-stage TNBC with sufficient median follow-up for a reliable estimation of 48-month event-free survival (EFS; refs. 3–7). This timeframe was selected for consistency and

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Translational Relevance

The relative contribution of early versus late recurrences to the overall risk of relapse in patients with early-stage triple-negative breast cancer treated with neoadjuvant chemo-immunotherapy remains unclear. In this analysis of five randomized clinical trials, the majority of relapses occurred within 24 months of treatment initiation, accounting for approximately 65% to more than 80% of all events. This proportion was even more pronounced among patients who did not achieve a pathologic complete response. These findings highlight that early relapse is the dominant pattern of recurrence in triple-negative breast cancer after neoadjuvant chemo-immunotherapy. There is a critical need to develop effective therapeutic strategies aimed at preventing early recurrences and improving long-term outcomes in this high-risk patient population.

comparability across studies. Also, recurrences beyond 48 months were infrequent. The NeoTRIP and NSABP B-49/GeparDouze trials were emended for early readout because of the very low number of new events with extended follow-up. A similarly low incidence of recurrences beyond 48 months was also observed in KEYNOTE-522.

For the purpose of this study, only immunotherapy-containing arms were analyzed to evaluate relapse patterns after ICI treatment.

Our goal was to determine the percentage of early relapses—defined as events occurring within 24 months after randomization—relative to all relapses observed by 48 months.

The 24-month time point from randomization was selected as it corresponds to approximately 12 months after the completion of treatment in the early setting—considering both the neoadjuvant and adjuvant phases—aligning with the standard definition of early relapse.

Additionally, to enhance granularity in the analysis, we assessed the time-dependent distribution of recurrences in 6-month intervals.

Due to the lack of access to individual patient-level data, EFS estimates were extracted from published Kaplan–Meier curves using *PlotDigitizer*, a software tool designed for the digitization of graphical data. High-resolution images of the Kaplan–Meier curves were obtained from the original publications and uploaded to the software's web page (https://plotdigitizer.com).

Data availability

The original data are not publicly available as they derive from clinical trials with restricted access due to data-sharing policies.

The data generated in this study are available upon request from the corresponding author.

Results

The main characteristics of the trials included in our analysis are summarized in **Table 1**.

The overall recurrence rates up to 48 months were 14.3% in GeparNuevo, 14.8% in NSABP B-59/GeparDouze, 17.5% in KEYNOTE-522, 20.2% in IMpassion031, and 29.2% in NeoTRIP. The proportions of early events (i.e., within 24 months) were 82.9% in GeparNuevo, 64.6% in NSABP B-59/GeparDouze, 70.4% in KEYNOTE-522, 72.2% in IMpassion031, and 70.6% in NeoTRIP

Table 1. Pivotal trials of immunotherapy involving patients with early-stage TNBC.

	KEYNOTE-522	GeparNuevo	IMpassion031	NSABP B-59/GeparDouze	NeoTRIP
Number of pts	1,174	174	333	1,550	280
Primary endpoint	pCR and EFS	pCR[a]	pCR[a]	EFS	EFS
Neoadjuvant regimen	Carboplatin–paclitaxel and AC/EC + pembrolizumab or placebo	Nab-paclitaxel and dose-dense EC + durvalumab or placebo	Nab-paclitaxel and dose-dense AC + atezolizumab or placebo	Carboplatin–paclitaxel and (dose-dense) AC/EC + atezolizumab or placebo	Carboplatin–nab-paclitaxel with or without atezolizumab
Per-protocol adjuvant therapy	Pembrolizumab or placebo × 9 cycles	None	Atezolizumab × 11 cycles	Atezolizumab or placebo up to 1 year after the first dose	AC/EC/FEC × 4 cycles
Optional adjuvant therapy	Not allowed	Treatment of physician's choice (not available)	Treatment of physician's choice[b]	Treatment of physician's choice (not available)	Not allowed
Median follow-up (months)	63.1	43.7	40.3	46.9	54
pCR rate in exp. arm (%)	63.1	53.4	57.6	63.3	48.6
4-Year EFS in exp. arm (%)	ITT: 82.5 pCR: 93.4 RD: 63.7	ITT: 85.7[c] pCR: 95.5[c] RD: 76.3[c]	ITT: 79.8 pCR: 94 RD: 61.1	ITT: 85.2 pCR: 93.2 RD: 70.6	ITT: 70.8 pCR: / RD: /
Proportion of events 0–18 months (%)[d]	57.6	43.4	51.5	45.9	51.0
Proportion of events 18–24 months (%)[d]	12.8	39.5	20.7	18.7	19.6

Abbreviations: A, doxorubicin; C, cyclophosphamide; E, epirubicin; exp, experimental; F, fluorouracil; ITT, intention to treat; Pts, patients; RD, residual disease.
[a]pCR was defined as ypT0 ypN0 in GeparNuevo and ypT0/Tis ypN0 in all other trials. However, in GeparNuevo, the results according to different pCR definitions were consistent.
[b]Adjuvant systemic therapy was administered in 20% (including capecitabine in 6% and other chemotherapy in 13%) and 33% (including capecitabine in 26% and other chemotherapy in 5%) of patients with residual disease in the atezolizumab and placebo arms, respectively.
[c]These percentages were extracted from the Kaplan–Meier curves of invasive disease-free survival, which corresponded to EFS as no inoperable progressions had occurred in GeparNuevo.
[d]The proportion is calculated based on all events occurring within 48 months in the experimental arm. Time is intended from randomization.

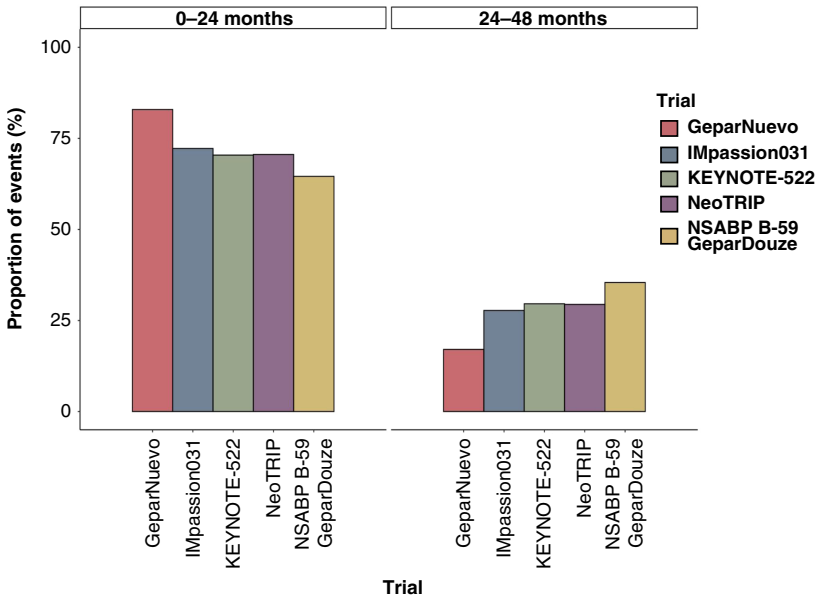

Figure 1.
Temporal distribution of events after neoadjuvant chemo-immunotherapy across five trials. Proportion of events occurring early (0–24 months) and late (24–48 months). Time is calculated from randomization (i.e., initiation of neoadjuvant therapy).

(**Fig. 1**). Among these events, the majority occur within 18 months from randomization, which corresponds to approximately 6 months after the completion of treatment in the early setting (**Fig. 2**; **Table 1**).

Among patients who achieved a pCR, the event rates up to 48 months were 4.5% in GeparNuevo, 6.8% in NSABP B-59/GeparDouze, 6.6% in KEYNOTE-522, and 6.0% in IMpassion031. Within this group, the corresponding proportions of early events were 53.3% (GeparNuevo), 57.4% (NSABP B-59/GeparDouze), 47% (KEYNOTE-522), and 40% (IMpassion031; **Fig. 3A**).

In patients with residual disease, the event rates up to 48 months were 23.7% in GeparNuevo, 29.4% in NSABP B-59/GeparDouze, 36.3% in KEYNOTE-522, and 38.9% in IMpassion031. Within this group, early events accounted for 88.6% (GeparNuevo), 69.4% (NSABP B-59/GeparDouze), 74.9% (KEYNOTE-522), and 80.7% (IMpassion031) of the overall events (**Fig. 3B**). The NeoTRIP trial was excluded from the pathologic response–stratified analysis because of the unavailability of this information.

Discussion

Early-relapsing TNBC represents a distinct clinical and biological entity characterized by aggressive behavior and intrinsic resistance to chemotherapy and ICIs, resulting in a poor prognosis (9, 10).

Most recently completed or ongoing clinical trials in the first-line metastatic setting have excluded patients with early relapse, particularly those with a disease-free interval (DFI) of less than 6 months, limiting the available data to guide treatment decisions for these patients.

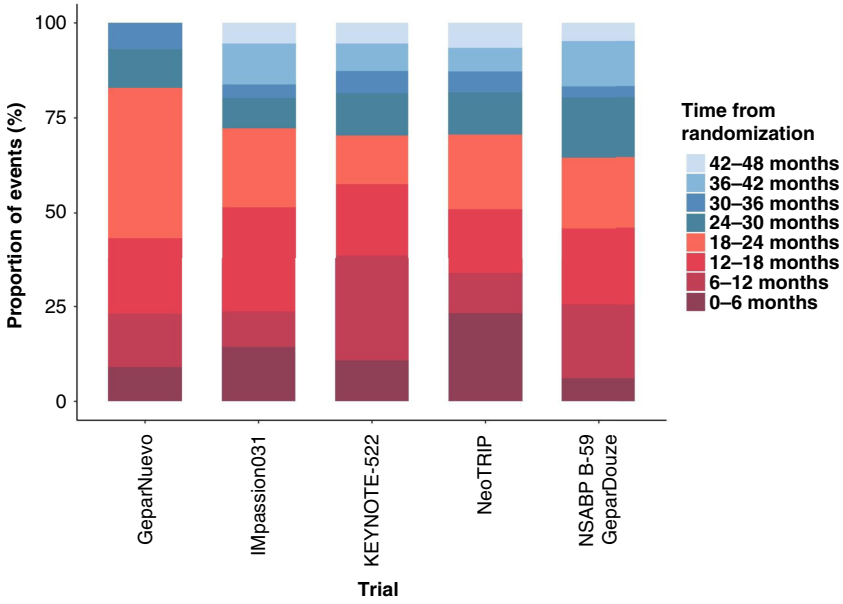

Figure 2.
Distribution of events after neoadjuvant chemo-immunotherapy across five trials stratified by 6-month intervals. Time is calculated from randomization (i.e., initiation of neoadjuvant therapy).

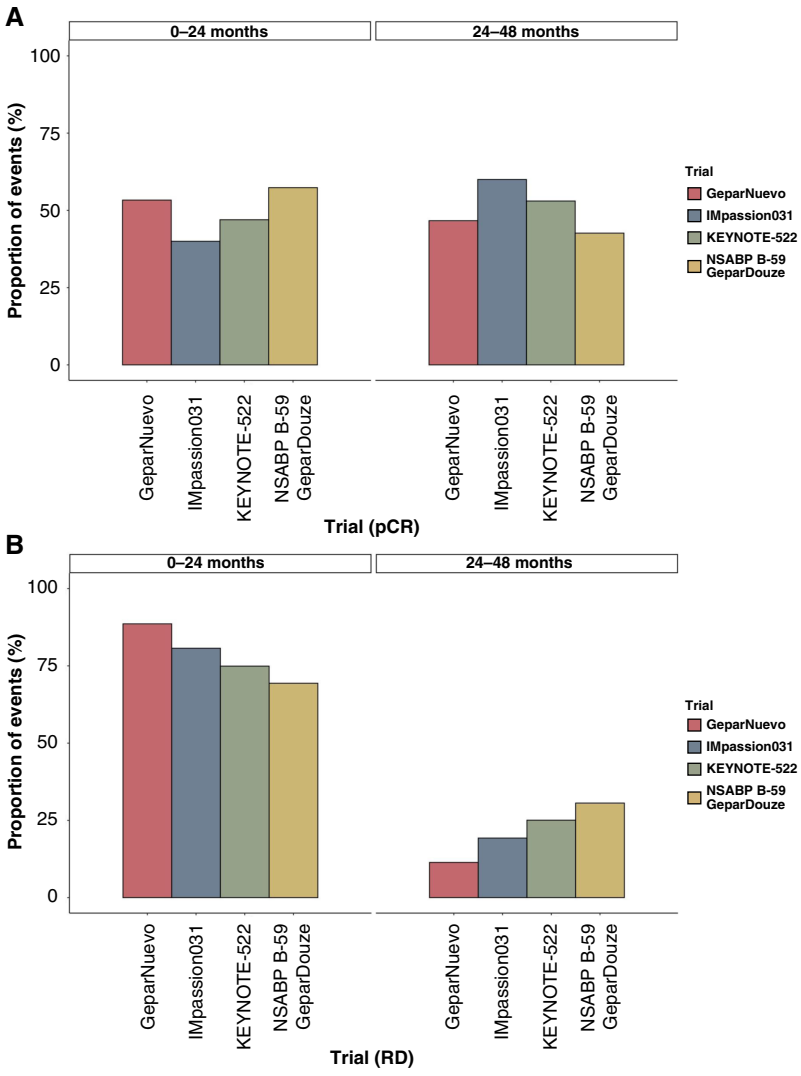

Figure 3.

Temporal distribution of events after neoadjuvant chemo-immunotherapy across five trials stratified by pCR status. **A,** Proportion of events occurring early (0–24 months) and late (24–48 months) in patients with pCR. **B,** Proportion of events occurring early (0–24 months) and late (24–48 months) in patients with residual disease (RD).

To date, the only randomized phase III trial focusing solely on patients with early-relapsing TNBC is the IMpassion132 trial, which failed to demonstrate a benefit from the addition of atezolizumab to first-line chemotherapy in PD-L1–positive tumors (9). Similarly, in the KEYNOTE-355 trial, the benefit of pembrolizumab in the small subgroup ($n = 65$) of patients with a DFI of 6 to 12 months is uncertain [HR for OS, 1.44 (95% confidence interval, 0.73–2.82); ref. 8]. Both studies excluded patients previously treated with ICIs.

More recent trials evaluating the combination of ICIs and ADCs in the first-line setting, such as TROPION-Breast05 (NCT06103864) and ASCENT-04 (NCT05382286), have allowed the inclusion of patients previously exposed to ICIs but excluded those with a DFI of less than 6 months. Considering patients with PD-L1–negative tumors, the ASCENT-03 and TroFuse-011 trials, which are investigating sacituzumab govitecan and sacituzumab tirumotecan, respectively, also exclude patients with a DFI <6 months. Currently, the TROPION-Breast02 (NCT05374512) trial, which evaluates first-line datopotamab deruxtecan therapy versus investigator's choice chemotherapy, is the only trial that does not require a minimum DFI.

Early recurrences have been well documented in patients with TNBC who received chemotherapy in the early setting (10, 11), but the proportion of patients experiencing such events following treatment with ICIs is unknown.

In the current study, we demonstrated that early events account for the majority of TNBC recurrences also after neoadjuvant/adjuvant immunotherapy. The proportion of early events ranged from approximately two thirds to more than 80% of all recurrences across the five trials and was even higher among patients with residual disease after neoadjuvant chemo-immunotherapy.

In contrast, patients who achieved a pCR exhibited a similar proportion of early and late events, and this recurrence pattern was also observed in the chemotherapy-only arms (Supplementary Fig. S1). Moreover, most early events occurred within 18 months of randomization—corresponding to a DFI of approximately 6 months after the completion of neoadjuvant/adjuvant treatment—and these patients represent a population with particularly poor outcomes (9). These findings highlight the urgent need to conduct dedicated studies in this patient population. Defining the optimal therapy for these patients should be a high priority for both industry and academic institutions. Hopefully, novel treatment strategies—such as combinations of ICIs with antiangiogenic agents or ADCs, novel bispecific, as well as other innovative strategies (12)—together with

a deeper understanding of the biological heterogeneity of TNBC (13), may help improve the dismal outcome of these patients.

From a clinical perspective, the timing of recurrences underscores the potential for implementing a "risk-tailored" follow-up strategy, suggesting a more intensive surveillance through clinical assessments, imaging, or ctDNA monitoring within the first 24 months.

There are some limitations to this study. This is an exploratory analysis not based on individual patient data. The use of PlotDigitizer carries inherent limitations, including potential minor inaccuracies and the inability to perform more detailed patient-level analyses. There is a significant heterogeneity across studies in terms of the types of therapies administered before and after surgery. As a consequence, the duration of treatments varied across trials and arms, which could have influenced differences in DFIs at the 24-month time point. Additionally, most studies have reported long-term outcome only for EFS. This endpoint encompasses not only distant metastatic recurrences but also progression during neoadjuvant treatment, contralateral invasive breast cancer, and second non-breast primary cancers. However, these events are expected to represent a minority of events compared with distant metastatic recurrences, given the high-risk TNBC population. In conclusion, this study suggests that early events are the major contributors to the overall risk of recurrence in patients with TNBC treated with neoadjuvant chemo-immunotherapy. These findings underscore the urgent need to understand the underlying biology of these treatment resistant tumors, design trials with novel therapies, and explore opportunities for tailored follow-up strategies.

Authors' Disclosures

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Authors' Contributions

L. Licata: Conceptualization, resources, data curation, investigation, visualization, methodology, writing–original draft. **M. Mariani:** Conceptualization, resources, data curation, formal analysis, investigation, methodology, writing–review and editing. **G. Viale:** Validation, visualization, writing–review and editing. **R. Dent:** Validation, visualization, writing–review and editing. **S.M. Tolaney:** Validation, visualization, writing–review and editing. **P. Schmid:** Validation, visualization, writing–review and editing. **E. Hamilton:** Validation, investigation, writing–review and editing. **C. Sotiriou:** Validation, visualization, writing–review and editing. **L. Pusztai:** Data curation, supervision, validation, visualization, methodology, writing–review and editing. **G. Bianchini:** Conceptualization, supervision, funding acquisition, validation, investigation, visualization, writing–review and editing.

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Note

Supplementary data for this article are available at Clinical Cancer Research Online (http://clincancerres.aacrjournals.org/).

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