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Clinicopathological Characteristics, Neoadjuvant Treatment Patterns and survival in Non-Metastatic Triple-Negative Breast Cancer: A Real-World Experience from a Peruvian Oncology Center

Características clinicopatológicas, patrones de tratamiento neoadyuvante y sobrevida en cáncer de mama triple negativo no metastásico: experiencia del mundo real en un centro oncológico peruano

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ABSTRACT

In Peru, there is limited real world evidence regarding the clinical-pathological characteristics and neoadjuvant treatment patterns of non-metastatic triple negative breast cancer (NMTNBC), especially prior to the incorporation of immunotherapy. **Objectives:** Describe the clinical-pathological characteristics, neoadjuvant treatment patterns and the reasons for the use of carboplatin in a Peruvian cohort with NMTNBC. **Materials and methods:** Retrospective, descriptive and non-consecutive series, based on clinical records available of adult patients with non-metastatic TNBC treated between 2019 and 2023 in a Peruvian oncological institution. Characteristics according to the use of carboplatin were compared using the chi square test. The overall survival (OS) was explored through/with Kaplan-Meier and log-rank, being interpreted in a descriptive nature due to the unadjusted nature of the analysis. **Results:** 199 patients were included. The median age was 48 years old (IQR 42-56) and 57% debuted at clinical stage III. The median time between the end of neoadjuvant therapy and surgery was 54 days. A mastectomy was performed in 73% of the cases and a pathologic complete response (pCR) was reached in 14.6% of patients. Carboplatin was used in 28% of cases, mainly due to a lack of response or progression during neoadjuvant therapy (69.5%). Its use was concentrated among patients with a higher tumor burden and residual disease (tumor \geq 30 mm, ypT3-4, ypN (+), pathological stage III and RCB-III; $p < 0.05$). Amongst the 178 female patients evaluable for OS, 21 deaths were documented, with a follow-up mean of 28.5 months. The OS rate at 60 months was 65%. In the multivariate analysis, only lymphovascular invasion was associated with an increased risk of death (HR: 5.4, p -value= 0.04). **Conclusions:** In this Peruvian cohort, NMTNBC was presented with a high anatomical burden upon diagnosis, high frequency of mastectomy and low pCR. The use of carboplatin reflected an intensification strategy in patients with worse initial response; hence, its association with survival outcomes must be interpreted carefully and not as a causal effect.

Keywords

non metastatic triple negative breast cancer; neoadjuvant therapy; carboplatin; pathological complete response; overall survival; Peru (source: MeSH-NLM).

RESUMEN

En el Perú, existe evidencia limitada del mundo real sobre las características clínico-patológicas y los patrones de tratamiento neoadyuvante del cáncer de mama triple negativo no metastásico (CMTNNM), especialmente antes de la incorporación de la inmunoterapia. **Objetivos:** Describir las características clínico-patológicas, los patrones de tratamiento neoadyuvante y las razones para el uso de carboplatino en una cohorte peruana con CMTNNM. **Materiales y métodos:** Serie retrospectiva, descriptiva y no consecutiva, basada en historias clínicas disponibles de pacientes adultas con CMTNNM tratadas entre 2019 y 2023 en una institución oncológica peruana. Las características según el uso de carboplatino se compararon mediante la prueba de chi cuadrado. La supervivencia global (SG) se exploró mediante los métodos de Kaplan-Meier y log-rank, siendo interpretada de manera descriptiva debido al carácter no ajustado del análisis. **Resultados:** Se incluyeron 199 pacientes. La mediana de edad fue de 48 años (RIC: 42-56) y el 57% debutó en estadio clínico III. La mediana de tiempo entre el final de la terapia neoadyuvante y la cirugía fue de 54 días. Se realizó mastectomía en el 73% de los casos y se alcanzó respuesta patológica completa (RPC) en el 15% de las pacientes. El carboplatino se utilizó en el 28% de los casos, principalmente debido a falta de respuesta o progresión durante la terapia neoadyuvante (69,5% de las razones reportadas). Su uso se concentró en pacientes con mayor carga tumoral y enfermedad residual (tumor \geq 30 mm, ypT3-4, ypN (+), estadio patológico III y RCB-III; $p < 0,05$). Entre las 178 pacientes evaluables para SG, se documentaron 21 muertes, con un seguimiento medio de 28,5 meses. La tasa de SG a 60 meses fue del 65%. En el análisis multivariado, solo la invasión linfocelular se asoció con un mayor riesgo de muerte (HR=5,4; $p=0,04$). **Conclusiones:** En esta cohorte peruana, el CMTNNM se presentó con alta carga anatómica al diagnóstico, alta frecuencia de mastectomía y baja tasa de RPC. El uso de carboplatino reflejó una estrategia de intensificación o rescate en pacientes con peor respuesta inicial; por lo tanto, su asociación con los desenlaces de supervivencia debe interpretarse con cautela y no como un efecto causal.

Palabras clave

cáncer de mama triple negativo no metastásico; terapia neoadyuvante; carboplatino; respuesta patológica completa; supervivencia global; Perú (fuente: DeCS-BIREME).

INTRODUCTION

Breast cancer is a health priority worldwide and in Peru^(1,2). According to GLOBOCAN 2022 and the latest Metropolitan Lima Cancer Registry 2013-2015, it placed first in incidence and mortality amongst women⁽³⁾. Within this group, triple negative breast cancer (TNBC) represents approximately 15-20% of cases, and it's associated with a more aggressive presentation, higher tumor burden upon diagnosis and lower survival than other subtypes⁽⁴⁻⁶⁾.

In early stages of TNBC, neoadjuvant chemotherapy based on anthracyclines and taxanes has been the historical standard. The attainment of pathological complete response (pCR) is associated with better outcomes in the long term⁽⁷⁻⁹⁾. The incorporation of carboplatin increases the pCR in trials and meta-analysis, although its impact on overall survival has not been consistent⁽¹⁰⁻¹²⁾.

In clinical practice in Latin American countries, the use of carboplatin not always responds to a uniform scheme. It is often reserved for young patients, with a higher disease burden or suboptimal response to initial treatment. Nevertheless, there is little real-world information that describes the patterns of neoadjuvant

treatment and the clinical context in which carboplatin is used in a detailed manner.

The main objective was to describe the clinical-pathological characteristics, the neoadjuvant treatment patterns and the early results of patients with non-metastatic triple negative breast cancer (NMTNBC) treated in a Peruvian oncological institution. As a secondary objective, reasons for the use of carboplatin are described and the differences in characteristics and overall survival were explored, in an unadjusted manner, according to its administration.

MATERIALS AND METHODS

A retrospective, descriptive and non-consecutive series was utilized in a Peruvian oncological institution. The cohort was comprised of Peruvian patients, 18 and older, with histologically confirmed NMTNBC, treated between 2019 and 2023. The cases were identified retrospectively through clinical records and institutional registries available for revision (convenience cohort).

The qualitative variables were summarized with frequencies and percentages; the quantitative variables, with median and interquartile range (IQR)

when appropriate. The association amongst qualitative variables and the use of carboplatin was evaluated using the chi-square test. When appropriate, categories were grouped together and, in the case of 2x2 contingency tables, Fisher's exact test was applied.

The overall survival (OS) was established from the surgery date to the date of death or follow-up visit. Follow-up data were collected from medical records and cross-referenced with the National Registry of Identification and Civil Status (RENIEC) when the vital status was not clearly documented. The OS was estimated using Kaplan-Meier and the comparisons were made with log-rank. A p-value $p < 0.05$ was considered statistically significant. The analysis was performed on the R 4.3.2. software.

Ethical aspects

Due to its observational nature, this study involved no direct patient interaction or clinical intervention and was based on the analysis of anonymized medical records.

Confidentiality was strictly maintained throughout the study. The research protocol was reviewed and approved by the Protocol Review Committee and the Ethics Committees of the Instituto Nacional de Enfermedades Neoplásicas (INEN).

RESULTS

Patient Population and Baseline Clinicopathological Characteristics

A total of 203 patients were initially included in the study; four were subsequently excluded, leaving 199 patients evaluable for analysis. The clinicopathological characteristics of the study population are summarized in Table 1.

The median age at diagnosis was 48 years. Most patients had an Eastern Cooperative Oncology Group (ECOG) performance status of 1 (85.4%), and 57%

Table 1. Clinical and pathological characteristics of the Peruvian cohort with non-metastatic triple-negative breast cancer

| | n=199 |
|---------------------------------------|-------------|
| Age at diagnosis, years, Median [IQR] | 48 [42-56] |
| ECOG | |
| 0 | 23 (11.6%) |
| 1 | 170 (85.4%) |
| 2 | 4 (2.0%) |
| Not recorded | 2 (1.0%) |
| cT classification | |
| cT1 | 2 (1.0%) |
| cT2 | 62 (31.2%) |
| cT3 | 70 (35.2%) |
| cT4 | 54 (27.1%) |
| Not recorded | 11 (5.5%) |
| cN classification | |
| cN0 | 66 (33.2%) |
| cN1 | 91 (45.7%) |
| cN2 | 21 (10.6%) |
| cN3 | 10 (5.0%) |
| Not recorded | 11 (5.5%) |
| Baseline disease stage | |
| Stage II | 82 (41.2%) |
| II | 1 (0.5%) |
| IIA | 38 (19.1%) |
| IIB | 43 (21.6%) |
| Stage III | 114 (57.2%) |
| III | 5 (2.5%) |
| IIIA | 42 (21.1%) |
| IIIB | 54 (27.1%) |
| IIIC | 13 (6.5%) |
| Not recorded | 3 (1.5%) |
| Histology at biopsy | |
| No ductal | 49 (24.6%) |
| Ductal | 144 (72.4%) |
| Not recorded | 6 (3.0%) |
| Histological grade at biopsy | |
| G2 | 35 (17.6%) |
| G3 | 137 (68.8%) |
| Not recorded | 27 (13.6%) |

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| | n=199 |
|--|---------------|
| Ki-67 proliferation index | |
| Median [IQR] | 60% [40%-80%] |
| Not recorded | 7 |
| Neoadjuvant chemo-to-surgery interval (days) | |
| Median [IQR] | 54 [31-95] |
| Not recorded | 22 |
| Type of surgery | |
| Mastectomy | 146 (73.4%) |
| Lumpectomy | 45 (22.6%) |
| Not recorded | 8 (4.0%) |
| Histology of the surgical specimen | |
| Ductal | 125 (62.8%) |
| No ductal | 35 (17.6%) |
| pCR | 29 (14.6%) |
| Not recorded | 10 (5.0%) |
| Histological grade at surgical specimen | |
| G1 | 4 (2.0%) |
| G2 | 26 (13.1%) |
| G3 | 123 (61.8%) |
| Not recorded | 36 (18.1%) |
| Negative margins | |
| No | 7 (3.5%) |
| Yes | 172 (86.4%) |
| Not recorded | 20 (9.9%) |
| Lymphovascular invasion | |
| Absent | 106 (53.3%) |
| Present | 50 (25.1%) |
| Not recorded | 43 (21.6%) |
| ypT classification | |
| Tis | 2 (1.0%) |
| ypT0 | 27 (13.6%) |
| ypT1 | 42 (20.1%) |
| ypT2 | 58 (29.1%) |
| ypT3 | 27 (13.6%) |
| ypT4 | 18 (9.0%) |
| Not recorded | 27 (13.6%) |
| ypN classification | |
| mi | 3 (1.5%) |
| ypN0 | 88 (44.2%) |
| ypN1 | 47 (23.6%) |
| ypN2 | 15 (7.5%) |
| ypN3 | 9 (4.5%) |
| Not recorded | 37 (18.6%) |
| Pathological stage | |
| 0 | 9 (4.5%) |
| I | 24 (12.1%) |
| II | 63 (31.7%) |
| III | 60 (30.2%) |
| Not recorded | 43 (21.6%) |
| Radiotherapy | |
| Yes | 170 (85.4%) |
| No | 15 (7.5%) |
| Not recorded | 14 (7.0%) |
| Adjuvant capecitabine | |
| Yes | 134 (67.3%) |
| No | 47 (23.6%) |
| Not recorded | 18 (9.0%) |
| Post-surgical progression | |
| Yes | 67 (33.7%) |
| No | 104 (52.3%) |
| Not recorded | 28 (14.1%) |

IQR: interquartil range; cT: clinical classification of the primary tumor; cN: refers to the clinical classification of the regional nodal metastasis; pCR: pathologic complete response; ypT: pathological assessment of primary tumor after neoadjuvant therapy and surgery; ypN: pathological assessment of regional lymph node involvement after neoadjuvant therapy and surgery.

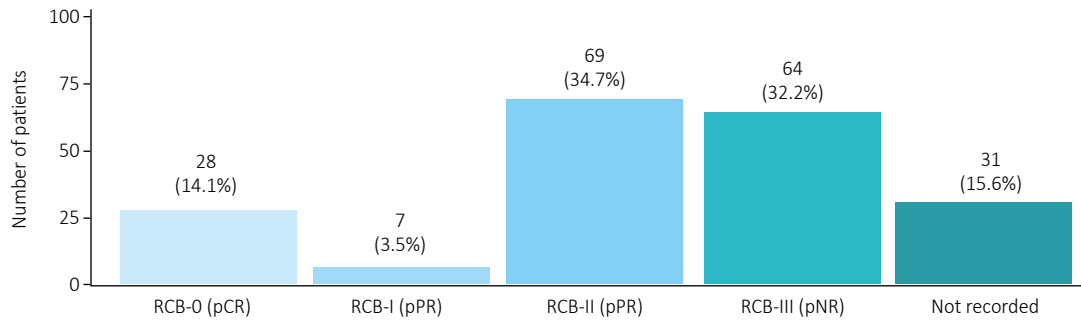


Figure 1. Distribution of pathological response according to Residual Cancer Burden (RCB)

presented with clinical stage III disease at diagnosis. The most frequent tumor categories were cT3 (35%) and cN1 (46%). Histopathological evaluation of biopsy specimens revealed predominantly ductal histology (72%) and histological grade 3 tumors (69%), with a median Ki-67 index of 60%. Additionally, BRCA mutations were identified in 7% of the study population, with a predominance of BRCA1 mutations.

Neoadjuvant Treatment, Surgical Outcomes, and Pathological Findings

The median interval between completion of neoadjuvant chemotherapy and surgery was 54 days. Mastectomy was performed in 73% of patients, and a pCR was achieved in 14.6% (Table 1).

On pathological evaluation of the surgical specimens, ypN0 status was observed in 44% of patients, and pathological stages II-III were the most frequently reported. The distribution of residual cancer burden (RCB) is shown in Figure 1: RCB 0 in 14% of cases, RCB I in 3.5%, RCB II in 34.7%, and RCB III in 32.2%. RCB data were unavailable for 15.6% of patients.

Carboplatin Use Indications and Associated Clinicopathological Features

Carboplatin was administered to 56 patients (28%). The clinicopathological characteristics according to carboplatin use are summarized in Table 2. Compared with patients who did not receive carboplatin, those treated with this agent were more frequently younger

Table 2. Clinical and pathological characteristics and use of carboplatin

| | Carboplatin | | p-value |
|-----------------------------|-------------|-------------|--------------------|
| | Yes n=55 | No n=132 | |
| Age at diagnosis, years | | | |
| <40 | 17 (50.0%) | 17 (50.0%) | 0.004 ^a |
| ≥40 | 38 (24.8%) | 115 (75.2%) | |
| ECOG | | | |
| 0 | 9 (39.1%) | 14 (60.9%) | 0.275 ^a |
| 1-2 | 46 (28.0%) | 118 (72.0%) | |
| cT classification | | | |
| cT1-cT2 | 13 (20.6%) | 50 (79.4%) | 0.068 ^a |
| cT3-cT4 | 39 (33.6%) | 77 (66.4%) | |
| cN classification | | | |
| cN0 | 17 (27.0%) | 46 (73.0%) | 0.339 ^a |
| cN1 | 25 (28.7%) | 62 (71.3%) | |
| cN2 | 5 (25.0%) | 15 (75.0%) | |
| cN3 | 5 (55.6%) | 4 (44.4%) | |
| cN classification (grouped) | | | |
| cN(-) | 17 (27.0%) | 46 (73.0%) | 0.654 ^a |
| cN(+) | 35 (30.2%) | 81 (69.8%) | |
| Baseline disease stage | | | |
| II | 20 (25.3%) | 59 (74.7%) | 0.275 ^a |
| III | 35 (32.7%) | 72 (67.3%) | |
| Histology at biopsy | | | |
| No ductal | 14 (31.8%) | 30 (68.2%) | 0.729 ^a |
| Ductal | 41 (29.1%) | 100 (70.9%) | |
| Grade histology at biopsy | | | |
| G2 | 9 (26.5%) | 25 (73.5%) | 0.706 ^a |
| G3 | 39 (29.8%) | 92 (70.2%) | |

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| | Carboplatin | | p-value |
|--|-------------------|-------------------|--------------------------|
| | Yes n=55 | No n=132 | |
| Ki-67 proliferation index | | | |
| <20% | 2 (25.0%) | 6 (75.0%) | |
| ≥20% | 52 (29.4%) | 125 (70.6%) | 1.000 ^b |
| Neoadjuvant chemo-to-surgery interval (days) | | | |
| ≤30 | 14 (35.0%) | 26 (65.0%) | |
| >30 | 35 (25.9%) | 100 (74.1%) | 0.262 ^a |
| Type of surgery | | | |
| Lumpectomy | 7 (15.9%) | 37 (84.1%) | |
| Mastectomy | 48 (33.6%) | 95 (66.4%) | 0.025 ^a |
| Histology of the surgical specimen | | | |
| Ductal | 10 (29.4%) | 24 (70.6%) | |
| No ductal | 40 (32.8%) | 82 (67.2%) | |
| pCR | 4 (13.8%) | 25 (86.2%) | 0.129 ^a |
| Histology grade at the surgical specimen | | | |
| G1 | 1 (25.0%) | 3 (75.0%) | |
| G2 | 4 (15.4%) | 22 (84.6%) | |
| G3 | 41 (34.5%) | 78 (65.5%) | |
| pCR | 0 (0.0%) | 10 (100.0%) | NE |
| Tumor size, mm | | | |
| <30 | 9 (13.0%) | 60 (87.0%) | |
| ≥30 | 39 (43.8%) | 50 (56.2%) | <0.001 ^a |
| Negative margins | | | |
| Yes | 51 (30.4%) | 117 (69.6%) | |
| No | 2 (28.6%) | 5 (71.4%) | 1.000 ^b |
| Lymphovascular invasion | | | |
| Present | 19 (38.8%) | 30 (61.2%) | |
| Absent | 30 (29.1%) | 73 (70.9%) | 0.234 ^a |
| Number of lymph nodes resected | | | |
| <15 | 27 (28.1%) | 69 (71.9%) | |
| ≥15 | 25 (31.6%) | 54 (68.4%) | 0.612 ^a |
| Number of involved lymph nodes | | | |
| 0 | 23 (23.7%) | 74 (76.3%) | |
| ≥1 | 29 (37.2%) | 49 (62.8%) | 0.053 ^a |
| ypT classification | | | |
| Tis | 0 (0.0%) | 2 (100.0%) | |
| ypT0 | 4 (14.8%) | 23 (85.2%) | |
| ypT1 | 6 (15.8%) | 32 (84.2%) | |
| ypT2 | 13 (23.2%) | 43 (76.8%) | |
| ypT3 | 13 (48.1%) | 14 (51.9%) | |
| ypT4 | 13 (72.2%) | 5 (27.8%) | <0.001 ^a |
| ypN classification | | | |
| ypN (-) | 17 (19.8%) | 69 (80.2%) | |
| ypN (+) | 27 (38.6%) | 43 (61.4%) | 0.009 ^a |
| mi | 1 | 2 | |
| Pathological stage | | | |
| 0 | 1 (11.1%) | 8 (88.9%) | |
| I | 1 (4.5%) | 21 (95.5%) | |
| II | 13 (21.0%) | 49 (79.0%) | |
| III | 30 (50.0%) | 30 (50.0%) | <0.001 ^a |
| Radiotherapy | | | |
| Yes | 46 (27.4%) | 122 (72.6%) | |
| No | 7 (46.7%) | 8 (53.3%) | 0.139 ^b |
| Adjuvant capecitabine | | | |
| Yes | 43 (32.6%) | 89 (67.4%) | |
| No | 9 (19.1%) | 38 (80.9%) | 0.082 ^a |
| Post-surgical progression | | | |
| Yes | 30 (46.2%) | 35 (53.8%) | |
| No | 23 (22.1%) | 81 (77.9%) | 0.001 ^a |
| RCB category | | | |
| RCB-0 (pCR)/RCB-I (pPR) | 6 (17.1%) | 29 (82.9%) | |
| RCB-II (pPR)/RCB-III (pNR) | 42 (32.1%) | 89 (67.9%) | 0.084^a |

^a Chi-square test was used. ^b Fisher's exact test was used.

IQR: interquartil range; cT: clinical classification of the primary tumor; cN: refers to the clinical classification of the regional nodal metastasis; pCR: pathologic complete response; ypT: pathological assessment of primary tumor after neoadjuvant therapy and surgery; ypN: pathological assessment of regional lymph node involvement after neoadjuvant therapy and surgery; RCB: Residual Cancer Burden; pPR: pathologic partial response; pNR: pathologic non-response; NE: not evaluated.

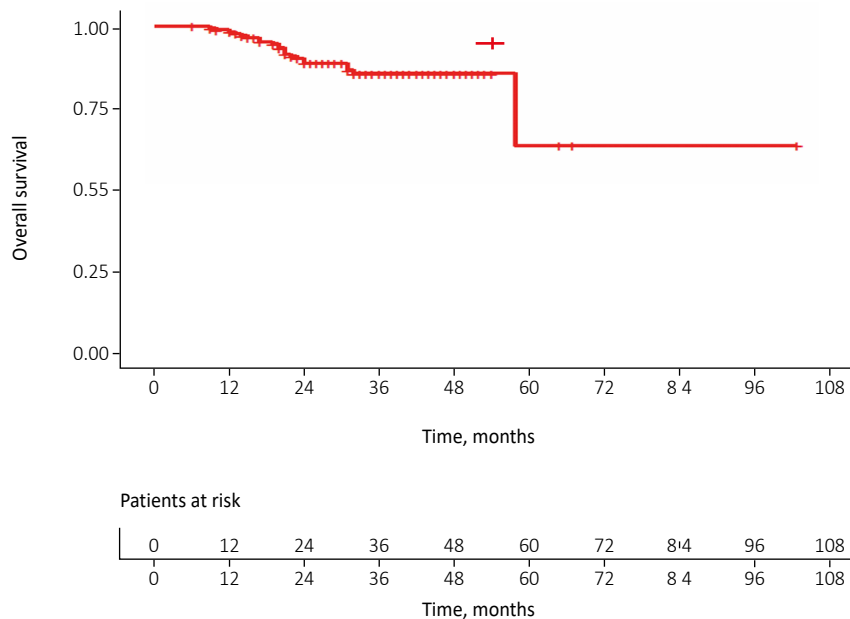


Figure 2. Overall survival in patients with non-metastatic triple-negative breast cancer

than 40 years ($p=0.006$), underwent mastectomy ($p=0.026$), and presented with a higher tumor burden and greater residual disease, including tumor size ≥ 30 mm, increased lymph node involvement, ypT3–4, ypN-positive status, pathological stage III disease, and RCB-III (all $p<0.05$).

The documented indications for carboplatin use included lack of response during neoadjuvant therapy (38.2%), disease progression (30.9%), age ≤ 40 years (34.5%), and high disease burden (20%). When lack of response and disease progression were analyzed jointly, these factors accounted for 70% of the recorded indications.

Overall Survival and Follow-up

For the analysis of OS, information for 178 patients was made available, amongst which 21 deaths were documented (11.8%). The follow-up median was 28.5 months (range: 6–103). The OS rate at 12, 36 and 60 months was estimated at 99%, 86% and 65%, respectively (Figure 2).

Exploratory Factors for OS estimates according to clinical and pathological characteristics

In Table 3, the exploratory unadjusted analysis, differences in OS were observed according to the age at

diagnosis ($p=0.029$), type of surgery ($p=0.033$), presence of lymphovascular invasion ($p=0.003$), lymph node involvement ($p=0.020$), ypN classification ($p<0.001$), grouped ypN classification ($p=0.001$), post-surgery progression ($p<0.001$) and carboplatin use ($p=0.001$). Due to the nature of the design and confounding by indication, these findings must not be interpreted as causal associations.

Univariate and Multivariate Analyses of Prognostic Factors for Overall Survival

In the univariate and multivariate analysis (Table 4), only the presence of lymphovascular invasion (HR=5.42; 95% CI, 1.08–27.17; $p=0.040$) and the use of carboplatin (HR=3.65; 95% CI, 1.14–11.64; $p=0.029$) were associated with an increased risk of death. Age ≥ 40 years showed a trend toward a lower risk without reaching statistical significance (HR=0.33; 95% CI, 0.10–1.06; $p=0.064$), while the grouped ypN classification lost significance in the adjusted model (HR = 1.65; 95% CI, 0.33–8.38; $p=0.543$). Given the limited number of events and the potential for confounding by indication, these findings should be interpreted with caution.

Adjuvant treatment

Regarding adjuvant treatment, most patients received radiotherapy (86%) and capecitabine (66.5%)

Table 3. Overall survival (OS) estimates according to clinical and pathological characteristics

| | n (events) | OS | | | p-value |
|--|------------|-------|-------|-------|---------|
| | | 12m | 36m | 60m | |
| All patients | 178 (21) | 98.9% | 86.2% | 64.7% | — |
| Age at diagnosis, years | | | | | 0.029 |
| <40 | 34 (7) | 97.1% | 72.9% | — | |
| ≥40 | 144 (14) | 99.3% | 89.0% | 66.8% | |
| ECOG | | | | | 0.335 |
| 0 | 20 (1) | 100% | 94.7% | — | |
| 1-2 | 158 (20) | 98.7% | 85.0% | 63.8% | |
| cT classification | | | | | 0.672 |
| cT1 | 2 (0) | 100% | 100% | — | |
| cT2 | 60 (8) | 96.5% | 84.1% | — | |
| cT3 | 60 (8) | 100% | 85.5% | 57.0% | |
| cT4 | 48 (3) | 100% | 93.0% | 93.0% | |
| cN classification | | | | | 0.716 |
| cN0 | 62 (6) | 96.6% | 89.2% | 89.2% | |
| cN1 | 84 (9) | 100% | 86.1% | 43.0% | |
| cN2 | 15 (2) | 100% | 86.7% | — | |
| cN3 | 9 (2) | 100% | 70.0% | — | |
| cN classification | | | | | 0.661 |
| cN (-) | 62 (6) | 96.6% | 89.2% | 89.2% | |
| cN (+) | 108 (13) | 100% | 85.3% | 42.6% | |
| Baseline disease stage | | | | | 0.941 |
| II | 78 (9) | 97.4% | 86.8% | 86.8% | |
| III | 100 (12) | 100% | 85.6% | 57.1% | |
| Histology at biopsy | | | | | 0.946 |
| Ductal | 45 (5) | 97.8% | 87.7% | — | |
| No ductal | 131 (16) | 99.2% | 85.8% | 64.3% | |
| Grade histology at biopsy | | | | | 0.880 |
| G2 | 33 (3) | 100% | 89.3% | — | |
| G3 | 123 (14) | 98.3% | 87.3% | 0.0%* | |
| Ki-67 proliferation index | | | | | 0.200 |
| <20% | 8 (2) | 87.5% | 43.8% | — | |
| ≥20% | 168 (19) | 99.4% | 87.1% | 65.3% | |
| Neoadjuvant chemo-to-surgery interval (days) | | | | | 0.736 |
| ≤30 | 38 (3) | 97.3% | 90.8% | — | |
| >30 | 130 (15) | 99.2% | 86.3% | 64.8% | |
| Type of surgery | | | | | 0.033 |
| Lumpectomy | 41 (1) | 100% | 96.9% | 96.9% | |
| Mastectomy | 137 (20) | 98.5% | 82.9% | 55.3% | |
| Histology of the surgical specimen | | | | | 0.364 |
| Ductal | 35 (5) | 97.1% | 87.7% | 43.9% | |
| No ductal | 116 (15) | 99.1% | 84.0% | 84.0% | |
| pCR | 26 (1) | 100% | 95.5% | — | |
| Histology grade at the surgical specimen | | | | | 0.694 |
| G1 | 4 (1) | 100% | 75.0% | — | |
| G2 | 25 (4) | 100% | 80.4% | 80.4% | |
| G3 | 115 (15) | 98.2% | 85.0% | 56.6% | |
| pCR | 8 (0) | 100% | 100% | — | |
| Tumor size, mm | | | | | 0.306 |
| <30 | 68 (7) | 100% | 86.5% | 86.5% | |
| ≥30 | 85 (13) | 98.8% | 83.0% | 55.3% | |

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| | n (events) | OS | | | p-value |
|--------------------------------|------------|-------|-------|-------|---------|
| | | 12m | 36m | 60m | |
| Negative margins | | | | | 0.958 |
| Yes | 164 (20) | 98.7% | 85.6% | 64.2% | |
| No | 7 (1) | 100% | 85.7% | — | |
| Lymphovascular invasion | | | | | 0.003 |
| Absent | 98 (8) | 99.0% | 91.2% | 68.4% | |
| Present | 50 (11) | 98.0% | 70.9% | — | |
| Number of lymph nodes resected | | | | | 0.800 |
| <15 | 93 (11) | 98.9% | 87.3% | 43.7% | |
| ≥15 | 78 (10) | 98.7% | 83.4% | 83.4% | |
| Number of involved lymph nodes | | | | | 0.020 |
| 0 | 93 (7) | 98.9% | 92.6% | 61.8% | |
| ≥1 | 78 (14) | 98.7% | 76.4% | 76.4% | |
| ypT classification | | | | | 0.353 |
| ypT0 | 25 (1) | 100% | 95.2% | — | |
| ypT1 | 38 (3) | 100% | 88.7% | 88.7% | |
| ypT2 | 56 (8) | 100% | 84.5% | 42.3% | |
| ypT3 | 25 (4) | 100% | 82.6% | — | |
| ypT4 | 18 (3) | 93.8% | 80.2% | 80.2% | |
| ypN classification | | | | | <0.001 |
| ypN0 | 82 (3) | 100% | 97.5% | 65.0% | |
| ypN1 | 46 (8) | 97.8% | 80.0% | 80.0% | |
| ypN2 | 15 (2) | 100% | 81.8% | — | |
| ypN3 | 9 (4) | 100% | — | — | |
| ypN classification, grouped | | | | | 0.001 |
| ypN (-) | 82 (3) | 100% | 97.5% | 65.0% | |
| ypN (+) | 70 (14) | 98.6% | 74.1% | 74.1% | |
| Pathological stage | | | | | 0.531 |
| 0 | 7 (0) | 100% | — | — | |
| I | 23 (2) | 100% | 87.9% | 87.9% | |
| II | 60 (8) | 100% | 87.0% | 43.5% | |
| III | 60 (9) | 100% | 79.7% | 79.7% | |
| Radiotherapy | | | | | 0.064 |
| Yes | 163 (18) | 99.4% | 87.2% | 65.4% | |
| No | 15 (3) | 92.9% | 75.7% | — | |
| Adjuvant capecitabine | | | | | 0.822 |
| Yes | 131 (15) | 99.2% | 87.4% | 58.2% | |
| No | 44 (5) | 97.6% | 84.2% | 84.2% | |
| Post-surgical progression | | | | | <0.001 |
| Yes | 65 (19) | 98.4% | 60.9% | 60.9% | |
| No | 100 (0) | 100% | 100% | 100% | |
| RCB | | | | | 0.591 |
| 0 (pCR) | 26 (2) | 96.2% | 92.1% | — | |
| I | 7 (1) | 100% | 83.3% | 83.3% | |
| II | 65 (7) | 100% | 89.4% | 44.7% | |
| III | 63 (10) | 98.4% | 76.7% | 76.7% | |
| Carboplatin | | | | | 0.001 |
| Yes | 52 (11) | 98.0% | 76.4% | — | |
| No | 124 (9) | 99.2% | 91.3% | 68.4% | |

* Estimated at 58 months.

m: months; IQR: interquartile range; cT: clinical classification of the primary tumor; cN: refers to the clinical classification of the regional nodal metastasis; pCR: pathologic complete response; ypT: pathological assessment of primary tumor after neoadjuvant therapy and surgery; ypN: pathological assessment of regional lymph node involvement after neoadjuvant therapy and surgery; RCB: Residual Cancer Burden.

Table 4. Univariate and Multivariate Analyses of Clinical Characteristics and Outcomes in the Overall Population

| | Univariate | | | Multivariate | | |
|-----------------------------|------------|---------------|---------|--------------|---------------|---------|
| | HR | IC del 95% | p-value | HR | IC del 95% | p-value |
| Age at diagnosis, years | | | | | | |
| <40 | Ref. | | | Ref. | | |
| ≥40 | 0.37 | [0.15, 0.93] | 0.035 | 0.33 | [0.10, 1.06] | 0.064 |
| Type of surgery | | | | | | |
| Lumpectomy | Ref. | | | | | |
| Mastectomy | 6.6 | [0.89, 49.19] | 0.066 | | | |
| Lymphovascular infiltration | | | | | | |
| Absent | Ref. | | | Ref. | | |
| Present | 3.84 | [1.47, 10.01] | 0.006 | 5.42 | [1.08, 27.17] | 0.04 |
| ypN classificayion,grouped | | | | | | |
| ypN (-) | Ref. | | | Ref. | | |
| ypN (+) | 6.67 | [1.90, 23.37] | 0.003 | 1.65 | [0.33, 8.38] | 0.543 |
| Carboplatin | | | | | | |
| No | Ref. | | | Ref. | | |
| Yes | 4.10 | [1.64, 10.24] | 0.002 | 3.65 | [1.14, 11.64] | 0.029 |

HR: hazard ratio; CI: confidence interval; Ref.: reference; m: months; IQR: interquartil range; cT: clinical classification of the primary tumor; cN: refers to the clinical classification of the regional nodal metastasis; pCR: pathologic complete response; ypT: pathological assessment of primary tumor after neoadjuvant therapy and surgery; ypN: pathological assessment of regional lymph node involvement after neoadjuvant therapy and surgery; RCB: Residual Cancer Burden.

DISCUSSION

This study describes a Peruvian cohort of triple negative non-metastatic breast cancer treated in a real clinical practice scenario, prior to the access to neoadjuvant pembrolizumab. The main findings were high anatomic burden upon diagnosis, high frequency of mastectomy, low pCR and the selective use of carboplatin as an intensification or rescue strategy rather than as a uniform part of the initial scheme.

The low pCR rate observed (14.6%) likely reflects the high proportion of patients presenting with locally advanced disease at diagnosis, the inherent heterogeneity of real-world cohorts, and the use of carboplatin in the setting of poor initial response to neoadjuvant therapy, rather than a lack of efficacy of the drug itself. This is consistent with the trend of carboplatin use in some populations of Latin America (around 30%), without an increase in survival. This interpretation is coherent with the Peruvian and regional experience, where the diagnosis in advanced stages, access barriers and logistic differences condition outcomes inferior to those obtained in clinical trials⁽¹²⁻¹⁷⁾.

The comparison between patients with and without carboplatin must be interpreted with special care, considering it has no impact on survival^(18,19). In our series, this medication was concentrated on younger patients, who also had a higher tumor burden and worse pathological response, and almost 70% of recorded indications corresponded to progression or lack of response during neoadjuvant therapy. In this context, a worse survival observed in the group exposed (to this drug) is compatible with confounding by indication and does not allow to infer a prejudicial effect of carboplatin.

In line with the previous interpretation, the multivariate analysis showed that lymphovascular invasion was independently associated with an increased risk of death, whereas the association observed with carboplatin use likely reflects the selection of patients with more aggressive disease and suboptimal response to initial treatment, in whom the choice of the antineoplastic agent was primarily driven by clinical judgment. Likewise, the loss of significance of the grouped ypN classification in the adjusted model, together with the wide confidence intervals, warrants caution when interpreting the magnitude of the observed effects, particularly given

the limited number of events and the potential for confounding by indication and treatment-selection bias related to carboplatin use in patients with more aggressive disease.

Another clinically relevant finding was the median of 54 days between the end of neoadjuvant therapy and surgery, an interval that falls within the range reported as reasonable in the literature (between 4 and 8 weeks) ^(20,21). Furthermore, two thirds of the cohort received adjuvant capecitabine, which suggests a high frequency of residual disease and a clinical practice aligned with postsurgical intensification in patients at higher risk of relapse ⁽²²⁾.

At 5 years, our cohort achieved an OS rate of 65%, which was lower than rates reported in high-income countries, including the United States, where the 5-year OS for non-metastatic TNBC reaches approximately 77% ⁽²³⁾, and Germany, where a real-world study reported a 5-year OS of 75.8% ⁽²⁴⁾. Within the Latin American context, however, our results are broadly consistent with regional evidence; a Colombian real-world study reported a 5-year OS of approximately 60% in non-metastatic TNBC patients ⁽²⁵⁾, and the largest previously published Peruvian series, comprising 2,007 patients treated over 15 years and including all stages, reported OS rates of 64%, 56%, and 47% at 3, 5, and 10 years, respectively ⁽²⁶⁾. These differences may reflect disparities in stage at diagnosis, access to early detection programs, availability of novel systemic therapies, and timely treatment delivery. Moreover, underlying biological heterogeneity across populations, including variations in tumor aggressiveness and molecular characteristics, may also play a role in observed survival differences.

Currently, the combination of pembrolizumab with neoadjuvant chemotherapy constitutes the standard for early high-risk triple negative breast cancer ⁽²⁷⁾; the international Clinical Practice Guidelines (CPG) ⁽²⁸⁾, and local regulatory documents (technical documents from INEN) have incorporated this treatment already ^(29,30). Historically, chemotherapy was the only treatment available in the country for this subtype ⁽³¹⁾ until its approval by public health systems at the end of 2025. Therefore, our results are especially valuable as a local historical baseline for future comparisons in the era of immunotherapy. In regards to the access to immunotherapy in Latin America and The Caribbean, real-world data (RWD) showed that the use of neoadjuvant pembrolizumab is nonexistent in public health systems in the region ⁽³²⁾.

An additional point to consider is the study of genetic mutations such as BRCA1/2. Among Latin American countries, the frequency of pathogenic BRCA has

been reported to be between 1.2 and 15.6% ⁽³³⁾. The percentage of BRCA testing reported in our cohort is similar to that reported in the region (<10%) ⁽³⁴⁾, where testing is limited in public systems due to its high costs and lack of coverage. Genetic testing is fundamental due to the possibility of using PARP inhibitors in adjuvant therapy in those patients who do not achieve pCR.

The study has important limitations: retrospective design, non-consecutive sample, unique center, missing data for several variables and absence of multivariable analysis to control confusion. Additionally, the carboplatin selection depended on the clinical criteria, which limits any causal interpretation. Amongst its strengths, the sample of institutional sample stands out, the detailed clinical-pathological characterization and the explicit description of the real context in which carboplatin was used in a Peruvian cohort.

In conclusion, this Peruvian cohort of NMTNBC was characterized by a high anatomical disease burden at diagnosis, with a predominance of stage III disease, a high frequency of mastectomy, and low rates of pCR. Survival outcomes were lower compared with those reported in high-income countries and were consistent with findings from other Latin American populations.

These findings are consistent with a high-risk population treated in real-world clinical practice in Latin America. Carboplatin was used in approximately one third of patients, reflecting patterns reported in the region. Its use was mainly as treatment intensification or rescue in cases of disease progression or inadequate response during neoadjuvant therapy; therefore, the observed differences between patients who did and did not receive carboplatin should be interpreted as descriptive rather than causal.

The median interval between completion of neoadjuvant therapy and surgery was 54 days, aligning with recommended timeframes. Overall, these results provide insight into real-world decision-making in a potentially curative setting and highlight the need for more effective treatment strategies, such as the incorporation of immunotherapy in combination with chemotherapy.

In conclusion, this study offers a baseline local reference preceding the widespread adoption of neoadjuvant immunotherapy within the Peruvian public health system and underscores the importance of future consecutive cohorts and well-adjusted analyses to more accurately estimate the independent effects of each therapeutic strategy. Currently, immunotherapy is available in Peru for the management of stage II-III

TNBC, presenting an opportunity to improve pCR rates and survival outcomes in this aggressive subtype. At the same time, this represents a challenge to quantify the real-world benefit of pembrolizumab in NMTNBC within a Latin American population.

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