Pathologic Complete Response by Breast Cancer Molecular Subtype in a Colombian Cohort: Real-World Evidence from Latin America

Mónica A. Solís-Velasco, MD[1]; Valeria S. Muñoz-Anacona, MD[2]; Daniel F. Penagos-Cabrera[1], MD; Luis A. Olave-Asprilla[1], MD; Adrián D. Fernández-Osorio, MD[3]; Uriel O. Cardona-Núñez[1], MD; Mauricio Zuluaga-Zuluaga, MD[1]; Vivian L. Román-Vásquez[4], MD; Álvaro J. Guerrero-Villota[2], MD

[1]Department of Surgical Oncology, Universidad del Valle, Cali - Colombia, [2]Department of Hematology and Oncology, Clínica Imbanaco, [3]Research Centre, Clínica Imbanaco, [4]Department of Breast Surgery, Clínica Imbanaco, Cali - Colombia

Background

- Pathologic complete response (pCR) after neoadjuvant therapy (NAT) is a validated surrogate for long-term outcomes in breast cancer.
- Real-world data from Latin America evaluating the pCR rate across molecular subtypes and its association with survival outcomes is limited.

Methods

- Retrospective study of 488 patients with stage I-III breast cancer who received NAT and surgery (2019-2024) at a tertiary center in Cali, Colombia.
- Molecular subtypes were assigned by IHC and FISH.
- Staging followed AJCC 8th edition.
- NAT according to institutional protocols:
  - Luminal: AC-T.
  - HER2: chemotherapy with either single-agent trastuzumab or dual blockade.
  - Triple-negative: AC-TC more often.
  - Non-standard regimens were used based on clinical judgment or comorbidities.
- Primary outcome: pCR (ypT0/Tis ypN0).
- Secondary outcomes: recurrence, disease-free survival (DFS), and overall survival (OS).
- Statistical analysis:
  - Associations were assessed using Chi-square, Wilcoxon rank-sum, and multivariate logistic regression.
  - Kaplan-Meier and log-rank tests were used for survival analyses.

Results

- Median age was 52 years (IQR: 44-61).
- Most tumors were invasive ductal carcinoma (93%).
- Molecular subtypes were:
  - Luminal A (13%), Luminal B (30%), HER2-Luminal B (17%), HER2-enriched (14%), and triple-negative (26%).
- Clinical stage II-III (97%), T1-T2 (56%), and node-positive (59%).
- Overall pCR rate was 34.6% (169/488), varying across molecular subtypes (Figure 1).
- Higher pCR was observed in:
  - **ER (1-10%)** vs. ER (>10%) (60% vs. 22.7%; **p=0.001**)
  - **PR (1-10%)** vs. PR (>10%) (37.1% vs. 18.8%; **p=0.016**)
  - **Ki-67 ≥20%** vs. Ki-67 <20% (39% vs. 13.3%; **p < 0.001**)
  - **Grade III** vs. Grade I-II (**p < 0.001**)
  - **T1-T2** vs. T3-T4 (39.5% vs. 28.5%; **p=0.012**).
- No pCR differences by clinical stage (p=0.484) or initial nodal status (p=0.690).
- **DFS:** improved in patients who achieved pCR (log-rank **p=0.047**; Figure 2).
- **OS:** no significant difference (log-rank p=0.35)
- **Recurrence:** lower in the pCR group (4.7% vs. 12.9%, **p=0.005**)
  - Distant metastases: pCR vs. non-pCR (2.96% vs. 9.1%, **p=0.011**)
- **Mortality:** pCR vs. non-pCR (1.2% vs. 3.1%, p=0.185)

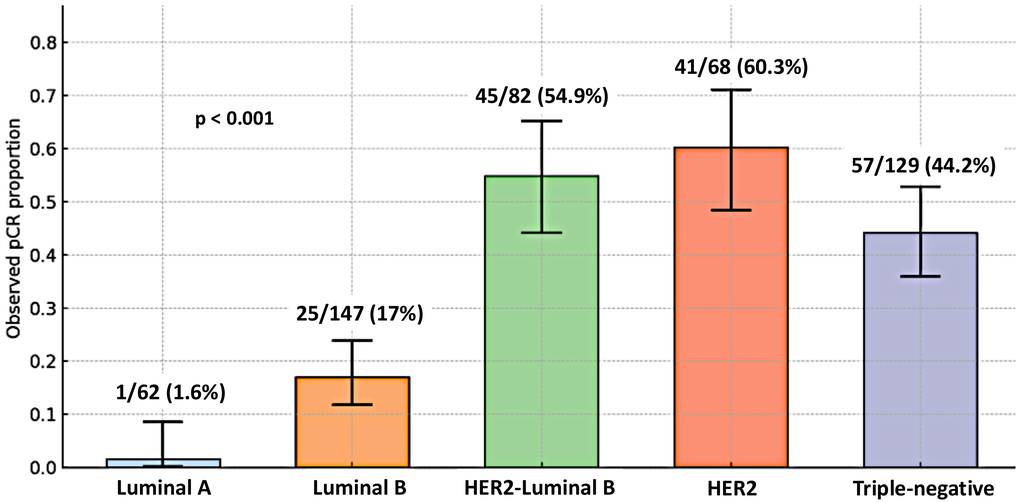


Figure 1. Observed pCR rate by molecular subtype (with 95% CI)

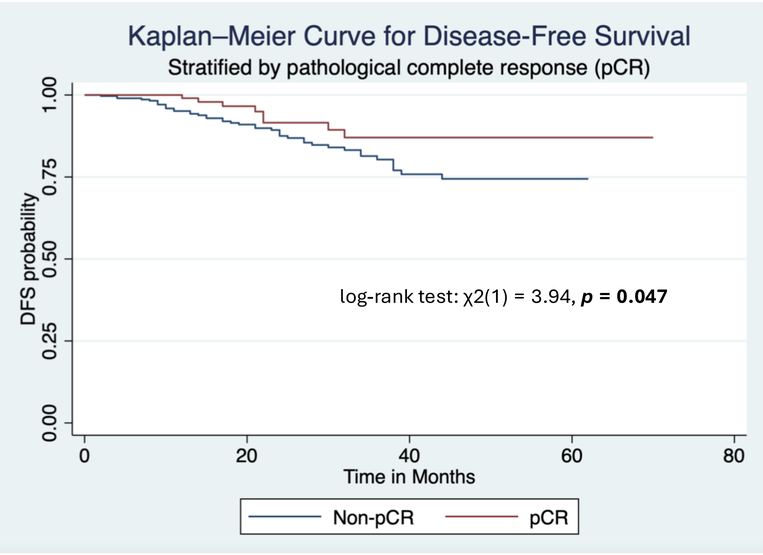


Figure 2. DFS stratified by pCR

Conclusions

- In this real-world Latin American cohort, pCR rates and their prognostic significance were consistent with international evidence.
- HER2-positive and triple-negative tumors showed the highest response, while luminal subtypes had limited benefit from standard NAT.
- pCR was independently associated with more favorable DFS.
- These findings support pCR value as a surrogate endpoint and highlight the need for subtype-adapted strategies in the neoadjuvant setting.

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