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Editorial / Editorial

Innovation and Equity in Breast Cancer. HER2-Low: A Real Opportunity or a Mirage for Low- and Middle-Income Countries?

Innovación y equidad en cáncer de mama: ¿HER2-low, oportunidad real o espejismo para países de ingresos medios y bajos?

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Equity in breast cancer treatment in the era of innovation is one of the greatest public-health challenges, particularly in low- and middle-income countries (LMICs). While the past two decades have brought notable advances in diagnosis, targeted therapies, and precision medicine, gaps between population groups, geographic regions, and socioeconomic strata remain profound [1]. Likewise, multiple recent studies indicate that these inequities appear as differences in stage at diagnosis, lower access to mammography, and greater difficulty receiving standard treatments ultimately translating into lower survival rates.

In the international context, particularly in Latin America, these disparities are consistently associated with structural determinants such as poverty, geographic location, limited availability of specialists, and restrictions on timely access to surgery and systemic treatments [2]. In response to these gaps, the World Health Organization (WHO), through the Global Breast Cancer Initiative, has highlighted the need to strengthen early detection, ensure pathology services, and expand financial coverage to reduce avoidable mortality from this disease [3].

Against this backdrop, the HER2-low subtype category emerges and reshapes the traditional HER2 classification, also raising new questions about equity and innovation. The DESTINY-Breast04 trial demonstrated a significant survival benefit for Trastuzumab Deruxtecan in patients with previously treated advanced HER2-low breast cancer [4]. This evidence created global expectations but also concern that the benefits of this new therapeutic category may not be accessible to most women in resource limited settings.

Accurate determination of HER2-low status depends on the quality of pre-analytic and analytic pathology processes. However, studies have shown that even in centers located in high-income areas, there is substantial inter-observer variability among pathologists when distinguishing HER2 0 from HER2 1+ [5]. Limited reproducibility implies that, without investment in diagnostic infrastructure and quality-control programs, HER2-low may become a theoretical concept with little real-world clinical impact in LMIC practice. In Brazil, for example, multidisciplinary groups have documented structural failures throughout the "specimen journey," from biopsy procurement to pathological interpretation, and have recommended specific actions to standardize and strengthen HER2 evaluation [6].

In addition to diagnostic barriers, financial and regulatory obstacles persist. Access to high-cost targeted therapies such as Trastuzumab Deruxtecan is often delayed for years after international approval. Even when medicines obtain local approval, their inclusion in public and social-security formularies tends to be slow and dependent on constrained budgets. Global surveys have shown that—even for medicines included on the WHO Essential Medicines List—inequities in access across countries remain substantial and persistent [7].

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Health systems in LMICs face additional challenges: insufficient pathology infrastructure, shortages of oncologists and radiologists, limited availability of immunohistochemistry, lack of decentralization of services, and low health literacy. These gaps are reflected in diagnostic timelines that, in many contexts, exceed three to six months from first symptoms to histologic confirmation, and in the proportion of patients who do not complete the diagnostic pathway or do not initiate treatment [8].

In Ecuador, breast cancer is the leading cancer among women. According to GLOBOCAN 2022 estimates, 3,903 new breast cancer cases (12.6% of all cancer diagnoses) and 1,154 deaths were recorded (7.1% of cancer mortality) [9]. Structural barriers persist in the country, including delays in access to diagnostic studies, which contribute to many cases being identified at advanced stages.

Access to innovative therapies remains restricted; Trastuzumab Deruxtecan is not part of the national basic formulary and is available only in private institutions or through individual purchases. This creates a scenario in which adoption of the HER2-low classification could reproduce the "technological mirage" described in the international literature. Moreover, there is a perception based on qualitative reports and sectoral assessments of insufficient specialist coverage and limited opportunities for continuing education in breast pathology, which is also poorly documented in up-to-date public sources.

The incorporation of precision-medicine tools such as genomic assays and circulating tumor DNA (ctDNA) remains marginal, because these tests are not covered by the public system and their use depends on ability to pay for it, thus replicating barriers seen in other LMICs. In this context, preventing HER2-low from widening inequities requires strengthening diagnostic infrastructure, decentralizing services, ensuring sustainable financing, and prioritizing equity in national guidelines. Only under these conditions can the HER2-low classification translate into better outcomes rather than an expansion of existing gaps, a risk widely documented in LMIC settings.

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