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How to Improve Diagnostic and Treatment Approach among Breast Cancer Patients in Mexico

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Abstract

Breast cancer is the first cause of malignancy and the leading cause of cancer related death in women in our country. Unfortunately, most cases are diagnosed in advanced stages; the main cause is the delay in diagnosis due to the lack of proper clinical facilities that include a multidisciplinary team trained in breast pathology, the scarce in specially trained radiologist and pathologist, as well as the lack of an established national diagnostic quality program. The aim of this review is to describe the magnitude of the problem, to recognize the implications in treatment costs and repercussions in patient's care and also to propose improvement actions.

Keywords: Breast cancer; Multidisciplinary teams; Diagnosis

Introduction

In Mexico, Breast Cancer (BC) ranks first place in both women cancer incidence and mortality. The states with the highest mortality reported due to BC are Coahuila (24.2), Sonora (22.6), and Nuevo León (22.4) [1,2]. However, the lack of a national epidemiological database limits accessibility to more precise data on incidence and distribution, having instead to currently characterize BC in the country through the use institutional registries or databases.

The current standard of care relies on the determination of the molecular BC subtype to tailor treatment, as each type of tumor poses unique disease characteristics and behavior. The diagnosis is frequently done by Immunohistochemistry (IHC) for Hormone Receptors (HR) and HER2 status determination with the aim to identify hormone sensitive, HER2-positive or triple negative patients.

Pathologists have traditionally played a crucial role in the diagnosis of BC patients. They became a necessary addition to the medical team, not only to present the anatomic pathology findings and discuss their implications, but also to play an important role on the use and interpretation of

advanced molecular testing [3].

Biomarkers in BC: Implications of an Accurate Diagnosis

Despite the importance of HR and HER2 determination for BC care, this procedure is not affordable or accessible equally across the country. In addition, its assessment is not widely standardized or quality control-certified. The implications identified so far concern time delays affecting diagnosis report and treatment initiation. In a survey conducted among Mexican medical oncologists, 25% of participants reported an inadequate treatment selection due to delay and/or incomplete information in the pathology report [4].

With the aim of improving diagnosis and tumor characterization, several countries have installed efficiency programs such as *In Vitro* Diagnosis (IVD) for HER2 testing, assuring that quality standards are maintained. However, not all IVDs are approved by regulatory agencies [5]. In addition, other countries have developed quality programs such as Norway with the protocol NordicQC; despite the existence of this protocol, only 67% of the laboratories in their nation meet the validation criteria [6]. In the United Kingdom, the UK National External Quality Assessment Services (UK-NEQAS) regulates quality control and reported that the use of approved supplies by national labs is approximately 71% [7]. However, these initiatives are not extensively adopted; in Belgium, only 4 out of 34 (12%) laboratories use validated assays [5]. In Mexico, the percentage of validated laboratories is unknown and a quality control protocol has not been established. Counting with a national certification and standardization is imperative to decrease the rate of false positive and negative results and avoid incorrect diagnoses; Vyberg et al. [8] showed that the false negative rate is 11% for laboratories with approved IVD compared to 25% for laboratories without an approved IVD, and the false positive rates were 0 and 5%, respectively.

In Mexico, a significant amount of BC patients receive care in medical centers accredited by the former Seguro Popular [9], this includes second- and third-level hospitals that are certified with an assessment protocol that outlines the minimum requirements to treat the disease. However, in the histopathological assessment only the sufficiency of materials and infrastructure are evaluated without validation of the process itself. In regards to IHC, it only requires the determination of estrogen and progesterone receptors, HER2 and Ki 67%; however, the quality of the assay is not considered [10]. Another important proportion of Mexican BC patients are treated in different social security public institutions and they also do not have an external quality control regulation to reassure a correct and timely diagnosis.

Finally, it is important to highlight the impact of these limitations to accurate and timely diagnosis, as they may result in incorrect treatment decisions, contributing to potential harm and increasing costs, consequently compromising patient outcome. In Canada, diagnostic accuracy is associated with an optimal use of high cost, which redeems by approximately $0.6 million Canadian dollars annually [11]. Dendukuri et al. [11] also estimated that out of 4218 new cases of HER2-positive BC, 240 would receive a false positive result; if these patients would not have been incorrectly treated with trastuzumab, the budget would have been reduced by $12 million Canadian dollars. In Norway, its estimated that for every $1 dollar saved in laboratories that use low quality supplies, can potentially increase the cost of care by about $6 dollars due to overtreatment [6].

Due to these discrepancies, as well as the possible implications derived from mistaken or delayed diagnoses in prognosis and treatment, including costs and unnecessary treatment in our limited resource setting, there is an increased urgency to attend a quality evaluation for the pathology laboratories, a correct interpretation of IHC tests and report standardization.

BC Management Based on Multidisciplinary Teams

Besides obtaining an accurate diagnosis that includes tumor subtype classification, treatment decision making should be done through a team collaboration that involves a surgical oncologist, medical oncologist, radiation oncologist and pathologist, as well as multiple supportive disciplines including palliative medicine, psychology, genetics, and nutrition. In order to achieve a comprehensive and coordinated approach to adequately treat each patient, the creation of models based on Multidisciplinary Teams (MDTs) centered in the patient has been proposed [12].

MDTs have been associated with an improvement in quality of care. These models enhance treatment coordination, increase adherence to clinical guidelines and evidence-based treatment, reduce delays in care, reduce treatment costs, increase references to clinical trials when appropriate, and may impact on patient outcomes [13]. Recently, it has even been shown that the active participation of a pathologist in the MDT with the inclusion of case reviews from other centers changed the diagnosis and treatment in a significant percentage of patients (from 4% to 29% of cases) [3,8]. In patients with prior treatment recommendations, submission to MDT evaluation has lead to changes in treatment decision in approximately 43% [12].

In a study from Pennsylvania, changes in surgical decisions occurred in up to 25% of the cases presented and discussed by the MDT [13]. In another review from Michigan, up to 32% of the cases changed the surgical treatment modality; one of the most common changes encountered was the indication of additional tests or biopsies due to the identification of concomitant lesions [14].

Multiple modalities to roll out the multidisciplinary sessions has been reported as effective, including face-to-face and virtual sessions, with duration ranging from 30 min to 2 h. The number of cases discussed and the selection vary according to each team guidelines, as well as the periodicity of meetings. The number of participants and the different specialties involved usually depends on the tumor to be discussed [15].

In the United States, there are multiple initiatives to promote the establishment of MDTs. In 2015, the American Society of Clinical Oncology (ASCO) applied a survey to 5357 members with practice outside the US, from 501 responders, 84% of them were participating in MDT, specifically for breast cancer. A change in treatment decision was reported in 44% to 49% and 14% to 21% changes in surgical management. 96% of responders reported that forming a MDT allowed for a reduction to treatment delays, as well as the improvement of educational strategies in their institution, and 94.8% considered it necessary and convenient to form MDTs dedicated to cancer care [16].

The National Cancer Institute (NCI) program for the community cancer centers has had as a priority the establishment of MDTs. During 2010, a review of the program results found that 71% of the participating centers had good adherence to the standards for MDTs.

Table 1: System to evaluate MDTs.

	Inputs	MDT meeting (processes)	Outputs	
TECHNICAL →	Information Equipment →	Information evaluation Expert review →	Implementation of the decision Documentation of the decision →	Clinical outcomes
NON- TECHNICAL - Cognitive Behavior	Assistance from all team members	Leadership Teamwork Open discussion	Consensus Communication with the patient Communication with the physician	

During this review, it was shown that navigation programs allowed MDTs to work more efficiently and with improved coordination, and that the continuous review of their performance allowed the identification of improvement opportunities [12].

In other countries like Germany, in year 2000, clinical guidelines and a certification program for centers that manage cancer were established. The main objective of this intervention was to standardize treatment regimens, set up recommendations based on evidence and positioning the multidisciplinary teams in cancer centers. After the implementation of this initiative, it has been possible to the treatment of patients managed in the participating cancer centers [17].

The relevance of MDTs has reached a normative level in other regions of the world. In Europe, the "Requirements for a Specialized Breast Unit" defined by EUSOMA (European Society of Mastology) describes the bases to define the standards and provides practical guidance, emphasizing that: "all European women should have a high quality, multidisciplinary and specialized breast care" [18].

Finally, different tools have been developed with measuring instruments that may be adapted according to the institution to evaluate MDTs performance [19-21]. The success of functional units and multidisciplinary work will require a staged plan due to the differences in access and infrastructure among our local institutions.

Currently in Mexico, there are not enough specialized breast cancer centers either sufficient MDTs oriented to breast cancer patients. In a report assessing the quality of the MDTs in our country based on a validated tool, it was shown that teams with high quality scores were the ones that most frequently managed to make a suitable clinical decision (83%), compared to the teams that did not comply with these quality standards [22]. Campos et al. [23] listed as main limitations the lack of appropriate complementary tests, and adequate radiological and pathology reports. However, despite the effort, the information published in Mexico about its clinical relevance and impact on the change of clinical decision is scarce.

In our country, MDTs are not a part of common practice for treatment decision making and these collaborations are not mandatory or regulated; therefore, decisions are being taken independently by the treating physicians and patient care is fragmented. The suggestion is to create a system to evaluate, incorporate and demand MDTs as standard of care in our country. The success of cross-functional units and multidisciplinary care relies on the adaptation to our local practices, our needs and limitations, and most depend on a step plan due to the access differences and infrastructure needs. The European model could be a better option to be adapted to our context, as described in Table 1.

Conclusion

Accurate BC diagnoses and tailored treatment decisions based on the consensus of a multidisciplinary team are essential to achieve proper care for BC patients. In many countries, MDT model has been adopted as a standard of care and has become common practice. However, in Mexico, we still face many barriers to achieve this goal. Efforts must be done to achieve a certification and quality control system that ensures the proper diagnosis of cases and the collaboration between institutions to establish MDTs that improve treatment decisions, further optimizing BC care. This practice would allow for improvement of resource utilization and, most importantly, avoid delays to accurate treatment initiation, with its subsequent impact in patient prognosis.

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