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ABSTRACT

PURPOSE As the fifth international consensus on advanced breast cancer (ABC) established guidelines for the management of this disease, the aim of this article was to present the applicability of the consensus recommendations and to generate knowledge to improve access.

METHODS Sixty-one recommendation statements were selected and discussed by 15 breast cancer experts from Latin America (LA). After the discussion, the level of consensus was determined through a vote. In addition to this, the level of access to each of the recommendations presented, according to the country and health system, was exposed.

RESULTS Latin American experts had a high level of agreement with the ABC5 consensus recommendations (range, 83%-100%). Twelve of 61 statements are not available for all patients in LA. Among the limitations to access, the following ones are described: limited access to certain technologies (stereotactic body radiotherapy, positron emission tomography–computed tomography), the high costs of drugs that limits access to treatment with CDK4/6 inhibitors, pertuzumab, or poly(ADP-ribose) polymerase inhibitors, and the lack of molecular tests for access to therapeutic targets, as well as the difficult geography and cultural diversity of our continent.

CONCLUSION Despite the great relevance of the recommendations of the ABC5 consensus guidelines, we highlight that we still need to improve access for all patients, regardless of the country or health system they are in, for which we call to action to policy makers and patient groups to improve clinical outcomes of patients with advanced breast cancer in our region.

INTRODUCTION

In Latin America (LA) and the Caribbean, breast cancer (BC) is the most common women cancer, with more than 200,000 new cases in 2020; furthermore, BC mortality had an annual mean increase of 1.48 per 100,000 cases from 1990 to 2015, compared with 0.7 per 100,000 rate worldwide. This difference could be attributed to patients’ age, limited access to novel anticancer therapies, and late detection (30%-50% de novo metastatic disease).

Advanced breast cancer (ABC) includes metastatic breast cancer (MBC) and inoperable locally advanced breast cancer (LABC). Owing to its prevalence in the region, a number of conferences have been held with the objective of standardizing ABC treatments, evaluating ABC guidelines’ applicability in our continent, proposing ways to improve patient access to health systems, and generating information to facilitate the decision-making process on health policies and in future clinical guidelines.

When the fifth European School of Oncology–European Society for Medical Oncology international consensus guidelines for advanced BC (ABC5) took place in Lisbon, Portugal, in November 2019, the second ABC LA meeting was co-organized by the Peruvian Society of Mastology and the European School of Oncology and conducted online (because of the COVID–19 pandemic) in October 2020. Herein, we present the assessment, adaptation, and implementation of ABC5 consensus guidelines to the context of LA.
**METHODS**

Before the second LA ABC meeting, 61 recommendation statements from ABC5 consensus guidelines were selected by the co-chairs and sent via email to an expert panel (oncologists) that represented different health subsystems from their countries. They evaluated and voted (agree/disagree/abstain) according to their health subsystem. The following instructions were given to the panel members: (1) all questions must be answered, (2) abstain if any question triggered conflict of interest or there were not enough data, and (3) no changes in the wording of statements or new statements developed with new evidence presented after the ABC5 conference were added to the recommendations. During the online meeting, the statements and the consensus rates among the LA experts were presented and discussed.

Fifteen experts from five LA countries (Colombia, Ecuador, Peru, Bolivia, and Chile) evaluated the recommendation statements. Additionally, 300 participants from Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Mexico, Nicaragua, Paraguay, Peru, and Venezuela gathered in the meeting to discuss selected issues.

The 61 recommendation statements (Supplement Data) were organized in 10 sections to facilitate the discussion. The degree of consensus was assessed through a voting process. The feasibility of each recommendation was investigated by each expert in his/her own country. Yes option was used when the statement was fully achieved across all the health subsystems. The comment section was used to explain why the statement was not fully applied in each country (Data supplement). The level of evidence and grade of recommendation were established according to ABC5 consensus guidelines.

**RESULTS**

**Section I: ABC Definitions**

The LA panel fully agreed (100%) with the definition of adequate ovarian function suppression (OFS; either bilateral oophorectomy or luteinizing hormone-releasing hormone [LHRH] agonists). A higher agreement in contrast with the 85% of the ABC5 consensus participants was shown, and it is also widely available. However, it is important to remark that in LA, bilateral oophorectomy could be a more suitable treatment, especially when monthly LHRH agonists are not available and less frequent visits to the hospital are needed. In addition, cultural context must be considered for a shared decision.

**Section II: General Statements**

*Quality-of-Life Assessments*

The specific tools for quality-of-life (QoL) evaluation in patients with ABC should be developed. Statement was endorsed by the LA panel (93% of agreement). Nevertheless, this is difficult to implement because of some regional limitations. In this regard, some efforts have been made in our region to collect information on treatment side effects using electronic devices, such as tablets, for subsequent evaluation. However, this strategy was not adopted mainly because of the lack of time to analyze the collected data. As a solution, side effects could be registered in patient journals for later evaluation. Similarly, cellphone apps or telemedicine could be used to monitor side effects. Additionally, the panel calls on the LA scientific community to conduct clinical trials for the development of these tools.
Biosimilars

This statement had 100% agreement among LA panelists which was similar to the ABC5 voting (90%). Currently, biosimilars are available in almost all countries; however, the validation process is heterogeneous and depends on local regulatory agencies; with respect to this, the panel encourages oncologists to remain aware and monitor the quality of biosimilars in each country. Similarly, we suggest considering biosimilars already approved by American or European regulatory agencies. Finally, although the use of biosimilars means money saving for health care systems, we claim that its prices should be even less to benefit more and more patients.

Section III: Assessment and Treatment General Guidelines

Image and Disease Assessment Guidelines

The LA panel fully agrees (100%) with these statements, similar to those from the 81% and 89% of the ABC5. Imaging frequency could be decreased or increased on clinical condition and tumor markers. Longer periods between imaging evaluations were applied during the COVID-19 pandemic to decrease the number of visits to the hospital.

Locoregional Treatment General Guidelines

Easy–to–treat lesions, such as the bone ones, could be treated with stereotactic radiotherapy as it is subscribed by both the ABC5 consensus (91%) and the LA panel of experts (100%). Nevertheless, stereotactic radiotherapy availability is limited to cancer centers located in large cities.

Systemic Treatment General Guidelines

The LA panel agreed (100%) with the biomarker–guided therapy statement. Estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) immunohistochemistry are widely available. On the contrary, target therapies for PD-L1+, PIK3CA+, and gBRCAmut ABC are only approved in some countries and not in all health subsystems, as will be discussed below. In that sense, the test should be performed only if there is access to therapy.

Chemotherapy General Guidelines

The panel fully agrees (100%) with this statement. However, because of the lack of oral vinorelbine, oral cyclophosphamide with methotrexate is a more suitable alternative. Regarding visceral crisis, an alternative treatment was proposed: cisplatin with fluorouracil infusion, this regimen is suitable even for patients with hyperbilirubinemia. Conversely, carboplatin plus gemcitabine could be used for lung visceral crisis. In addition, carboplatin monotherapy can be effective for visceral crisis, highlighting that the most important factor is the previous treatment effectiveness.

HER2-Negative MBC

The different chemotherapy approaches are fully accepted by the LA panel. Yet, it is important to consider toxicity (eg, alopecia, cardiac, etc) and patient’s preference. Regarding this, nab–paclitaxel could be used in case of severe allergic reactions to paclitaxel. In addition, capcitabine is also a good option for patients with liver metastasis as it is directly metabolized by the liver. Similarly, lobular carcinomas which often affect serosae in the form of peritoneal carcinomatosis, ascites, or pleural effusion could be treated with liposomal anthracycline.

In LA, the most common chemotherapy drugs are available. In some countries, certain drugs such as peg–doxorubicin or nab–paclitaxel are only available in the private health subsystem. Although approved in Europe, oral vinorelbine is not approved in LA. In that regard, ixabepilone, approved in LA (but not in Europe), is available only in the private health system.

Section IV: ER-Positive/HER2-Negative MBC

In this section, the ABC5 consensus was accepted by almost all the LA panelists (93%-100%). Endocrine therapy (ET) with CDK4/6 inhibitors must be used to treat visceral metastases. However, CDK4/6 inhibitors should be closely monitored because they can trigger liver toxicity; in that sense, we must be aware not to use ribociclib plus tamoxifen because of their negative interaction.

Prolonged overall survival (OS) has been reported for patients with hormone receptor–positive (HR+) HER2– ABC when CDK4/6 inhibitors are used in both endocrine-sensitive (hazard ratio [HR], 0.75 [95% CI, 0.63 to 0.89]) and endocrine–resistant (HR, 0.77 [95% CI, 0.77 to 0.89]) diseases. In that regard, achieving access to CDK4/6 inhibitors in LA is essential. The availability of CDK4/6 inhibitors varies among countries. In Colombia and Ecuador, they are widely available in all health care subsystems; in Bolivia, only the national health fund subsystem covers its use; and in Peru and Chile, CDK4/6 inhibitors are only available in the private subsystem. When CDK4/6 inhibitors are not available, ET alone is the best option to treat HR+/HER2– patients. Furthermore, it is essential to start treatment with ovarian suppression in premenopausal women, followed by the use of aromatase inhibitors. If suppression treatment is not successful, oophorectomy is recommended. Another option is the use of the gonadotropin–releasing hormone (GnRH) antagonist (eg, degarelix), although there is less information on its use. An important drawback for the ovarian suppression treatment is the local cultural perception which can be addressed with education campaigns.

After CDK4/6 inhibitors, everolimus is also an option, as well as alpelisib which could be used to treat PIK3CA tumors. Regarding the mentioned treatments, everolimus is available in the Chilean and Colombian Ministry of Health
therapy could be stopped after 5 years with close monitoring. Finally, in the context of long-term remission, anti-HER2 is acceptable if TDM-1 is not available.

Section V: HER2-Positive ABC

Although the panel fully agrees (100%) with these statements, not all the strategies are widely available. An important step made by the region was to make trastuzumab available for ABC in all LA countries, except in Bolivia’s public health subsystem (Table 1). This implies that trastuzumab can be used as a first approach and across the treatment. The most important recommendation for HER2+ ABC is to continuously block the HER2 pathway until stopping anticancer therapy as it prolongs survival. OS for patients with HER2+ ABC in LA is expected to improve. Nevertheless, this strategy was just available for 73% of panelists.

Contrastingly, ado-trastuzumab emtansine (TDM-1) is only available in private subsystems of all the countries covered in this study, except in Colombia and Chile where it is also offered by their public systems. Lapatinib is widely available in Colombia and Chile, but only patients of the Peruvian National Cancer Institute have access to it.

The panel supports (100%) the use of a dual blockade approach as first line; however, it is only available for 86% of panelists. Furthermore, its use is reasonable in second line or later if pertuzumab is not previously used. Similarly, for patients with disease recurrence within the first year after finishing adjuvant therapy with trastuzumab, dual blockade is acceptable if TDM-1 is not available.

Finally, in the context of long-term remission, anti-HER2 therapy could be stopped after 5 years with close monitoring.

Section VI: Triple-Negative ABC

As chemotherapy is widely available for TNBC treatment, the panel fully supported the statement for non-HER2-associated disease. Regarding platinum, carboplatin AUC 2 as monotherapy, weekly (2 weeks on—1 week off) or every 3 weeks at AUC 5, is a reasonable treatment option.

For the androgen receptor–positive (AR+) TNBC, there is not strong evidence to use androgen antagonists. For gBRCAmut patients with PD-L1 negative disease or without access to checkpoint inhibitors, poly(ADP-ribose) polymerase inhibitors (PARPis) is the best treatment option. Since PD-L1 is positive, there is no evidence regarding the sequence.

Regarding the access to PARPi’s for patients with gBRCAmut, we have summarized key information on Table 1.

Section VII: Hereditary ABC

Most panelists (93%-100%) subscribe these statements; however, only 54% of panelists had access to germline testing, and 29% had access to somatic testing; besides, this therapy was only available for private health systems. It is imperative to discriminate whether the aim of BRCA1 test is to direct treatment or to assess the patient genetic risk by a geneticist. It is important to consider performing the test only when the targeted therapy is available.

Section VIII: Precision Medicine

The majority of panelists agree with the precision medicine statement although access to therapy is limited. Atezolizumab which is used as therapy for PD-L1+ ABC is only approved in Peru and Chile but is only available in the private sector. Furthermore, alpelisib for PIK3CA+ ABC was only approved in Chile (among the countries that participated in the panel) and is only available in the private sector.

Section IX: Specific Sites of Metastases

Bone Metastases

The LA expert panel fully agrees (100%) with the specific sites of metastases statements because of the fact that radiological tests and radiotherapy are available in the health systems of the participating countries. It is important to note that there is a limited access to radiotherapy in Bolivia. Bisphosphonates are broadly available in LA and can be prescribed once a month or once every 3 months. Oppositely, denosumab is restricted to private health systems and into some public systems.

Brain Metastases

The LA panel strongly agrees with these statements. If metastasis is detected only in the brain, local therapy (surgery or radiotherapy), while continuing the same systemic therapy, must be used.

Trastuzumab plus chemotherapy is a better option compared with lapatinib plus chemotherapy to treat HER2+ ABC. On the other hand, when chemotherapy is omitted (eg, frail patients or low burden of metastases), trastuzumab plus lapatinib could be used.

Chest Wall and Regional (nodal) Recurrences

We completely agree with these statements as both strategies are widely used in LA. Still if locoregional recurrence is observed, localized and systemic treatments should be used. There is no solid information about treatment duration.
<table>
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<tr>
<th>Health Subsystem of Each Country</th>
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<td>Access²</td>
<td>Access¹</td>
<td>Access²</td>
<td>Access¹</td>
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<td>Breast Cancer Subtype</td>
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**NOTE.** Updated in December 2022.

**Abbreviations:** ABC, advanced breast cancer; AI, aromatase inhibitor; FONASA, Fondo Nacional de Salud; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; IHC, immunohistochemistry; ISH, fluorescence in situ hybridization; MINSA, Ministerio de Salud de Perú; ND, no data available; OFS, ovarian function suppression; TDM-1, ado-trastuzumab emtansine; TNBC, triple-negative breast cancer.

*Only approved in the National Institute of Neoplastic disease of Peru.

*In Bolivia, it is approved for other neoplasms but can be used for breast cancer in private.
Usually, therapy should be stopped when two or three treatments are ineffective and the disease keeps progressing. Having said this, patients, family, and psychologists need to be connected to determine when to stop therapy.

**Section X: ABC Statements for LABC**

LABC is defined as a large locally advanced inoperable disease. The majority of members of the LA panel agreed with statements regarding LABC. There is a high prevalence of stage III BC in LA (30% versus <10% in Europe). A higher BC mortality-to-incidence ratio (MIR) was detected in LA in contrast to Europe, Oceania, or North America, with heterogeneity among countries (e.g., Brazil with a 0.23 MIR and 0.38 in Uruguay, compared with the average of LA and Caribbean with a ratio of 0.28). This could be explained by a diagnosis at late stage, low uptake of screening programs, and difficult access to the health system (geographical or financial issues). Furthermore, COVID–19 (lockdowns and restrictions) has worsened BC diagnosis and clinical outcomes.

Positron emission tomography–computed tomography (PET–CT) is suggested for stage 3 disease, even in TNBC or HER2 BC subtypes. PET–CT machines per million inhabitants in LA is <1, in contrast to high-income countries (≥2). When chemotherapy is indicated, the tumor remains inoperable after neoadjuvant therapy, so radiotherapy is an option. Until now, there is no solid evidence that concurrent chemoradiation is suitable; furthermore, toxicity is important too. If platinum is used, hematological toxicity should be a signal to stop treatment. For inoperable locally advanced HR+/HER2– tumors, ET should be used the same as in metastatic disease.

Regarding access to radiotherapy, the number of radiotherapy machines per 1,000 patients with cancer by country are Bolivia (0.5), Peru (0.7), Ecuador (0.8), Colombia (0.9), and Chile (0.9).

**DISCUSSION**

In conclusion, through this study, the expert panel endorsed the ABC Global Charter and its 10 goals for the current 10 years in ABC treatment (Table 2) to improve OS, QoL, and access to therapy. Similarly, the ABC consensus guidelines constitute one of the key instruments in the management of advanced BC.

This is the second meeting of BC experts from LA. The 61 statements discussed were highly endorsed by the LA panel, even in a higher degree of agreement than the ABC5 consensus meeting (range: 83%–100%). However, there are some important drawbacks: limited access to some strategies, high-cost drugs, and lack of molecular tests, rendering 12 of the 61 statements not feasible in LA.

Some biomarkers (ER, PR, and HER2) are widely available while others such as PD–L1, BRCA, or PIK3CA, are only available in countries (and health subsystems) where the target therapy is approved. Furthermore, there is limited access to genetic assessment.

Moreover, the gap of radiotherapy machines per patient with cancer is still large. Similarly, there is limited access to PET–CT in LA.

Access to therapy is heterogeneous in intercountries and intracountries. Trastuzumab is widely available for patients with HER2+ ABC in all countries’ subsystems that are part of this consensus evaluation. Pertuzumab is available in each health subsystem except in the public subsystems of Peru and Bolivia. In general, CDK4/6 inhibitors, check point inhibitors, and PARP inhibitors are only available for patients under the private system of each country, with some exceptions such as the public health subsystem of Colombia.

The implementation of the ABC5 recommendations faces some important barriers, and the main one is the limited resources. Other barriers are the low coverage of screening programs to detect BC at earlier stages, the overwhelmed cancer centers, the lack of education which leads to a poor access to the prevention and detection of curable precancerous conditions, the heterogeneous coverage of the health subsystems of each country, and the national regulatory agency performance which deepens the problem. On the other hand, there are patient’s cultural issues that can

| TABLE 2. ABC Global Charter: 10 Goals for the Current 10 Years in ABC |
|-------------------------|------------------|
| **ABC Goal** | **Details** |
| Help patients with ABC live longer by doubling ABC median overall survival by 2025 | |
| Enhance our understanding about ABC by increasing the collection of high-quality data | |
| Improve the QoL of patients with ABC | |
| Ensure that all patients with ABC receive the best possible treatment and care by increasing availability of and access to care from a multidisciplinary team | |
| Improve communication between HCPs and patients with ABC through the provision of communication skill training for HCPs | |
| Meet the informational needs of patients with ABC by using easy-to-understand, accurate, and up-to-date information materials and resources | |
| Ensure that patients with ABC are made aware of and are referred to nonclinical support services | |
| Counteract the stigma and isolation associated with living with ABC by increasing public understanding of the condition | |
| Ensure that patients with ABC have access to treatment regardless of their ability to pay | |
| Help patients with ABC continue to work by implementing legislation that protects their right to work and ensures flexible and accommodating workplace environments | |

Abbreviations: ABC, advanced breast cancer; HCPs, health care professionals; QoL, quality of life.
interfere with the implementation of these guidelines such as the lack of knowledge of native languages (eg, Quechua, Wayuu, and Mapuche, among many others in each country).

Finally, this report claims an improvement in the approach of ABC in LA, as well as a call to action to the decision-making personnel in the region. We also remark on the importance of cancer survivors and advocates as valuable and powerful resources as they can overcome the lack of trust, knowledge gaps, and stigma to improve cancer care and outcomes in their communities. Similarly, we also suggest some options to eliminate barriers; for instance, the use of navigation systems, improvement of processes, and better information to patients; as on many occasions, the system provides the necessary care, but patients are not aware of it.

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Collection and assembly of data: Fernando Valencia, Henry L. Gómez, Silvia P. Neciosup, Ronald Limón, María del Carmen Torrico, Lena Morillas, Roberto Torres, Ingiborg Araya, Rodolfo Gómez, Tannia Soria, René Muñoz, Mauricio Riofrío, Marco Gálvez, Pilar Benites, Fatima Cardoso

Data analysis and interpretation: Fernando Valencia, Henry L. Gómez, Silvia P. Neciosup, Ronald Limón, Cesar Sánchez, Rodolfo Gómez, Ricardo Bruges, Tannia Soria, Mauricio Riofrío, Rossana Ruiz, Fatima Cardoso

**MANUSCRIPT WRITING**: All authors

**FINAL APPROVAL OF MANUSCRIPT**: All authors

**ACCOUNTABLE FOR ALL ASPECTS OF THE WORK**: All authors

**AUTHORS’ DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**

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Open Payments is a public database containing information reported by companies about payments made to U.S.-licensed physicians (Open Payments).

Fernando Valencia

Consulting or Advisory Role: Sanofi, Boehringer Ingelheim, Tecnofarma

Speakers’ Bureau: Janssen, Merck Sharp & Dohme Peru SRL, Johnson & Johnson Services, Inc

Consulting or Advisory Role: Pfizer, Novartis

Research Funding: Roche, Novartis

Travel, Accommodations, Expenses: Novartis, Pfizer

Ingiborg Araya

Research Funding: Roche

Travel, Accommodations, Expenses: MSD Oncology, Roche

Ricardo Bruges

Consulting or Advisory Role: Bristol Myers Squibb, Merck, Novartis, Pfizer

Research Funding: Bristol Myers Squibb/Medarex, MSD Oncology, Pfizer

Travel, Accommodations, Expenses: Pfizer, Tecnofarma, MSD Oncology, Tecnofarma, Pfizer

Carlos Vargas

Honoraria: BMS, AstraZeneca, Merck Serono, Ipsen, Janssen, Bayer, GlaxoSmithKline, Pfizer, Lilly

Consulting or Advisory Role: Pfizer, Bms

Travel, Accommodations, Expenses: Pfizer

Tannia Soria

Honoraria: Roche, AstraZeneca

Speakers’ Bureau: Roche, AstraZeneca, MSD Oncology

Travel, Accommodations, Expenses: MSD Oncology, Roche
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