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Molecular testing for breast cancer: Systematic review of availability in Latin American and Caribbean countries.

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ABSTRACT

To systematize the availability in clinical practice of genomic and genetic tests for breast cancer (BrCa) in Latin American and Caribbean (LAC) countries.

Methods: The PRISMA 2020 framework was used for the literature review and web search, published in Spanish and English, using an explicit method to compile and synthesize the findings, between January 2010 and December 2023.

Results: Five genomic tests used in clinical practice were found: *Oncotype^{Dx}, MammaPrint, Breast Cancer Index (BCI), EndoPredict, and Prosigna*. These tests are offered in 14 of 48 (27%) LAC countries. The most provided test is Oncotype present in 11/14 countries (79%), followed by EndoPredict in 9/14 countries (64%), and the least offered is BCI present in 1/14 countries

(7%). Of the available genetic tests, ten were found to analyze BRCA 1/2 genes and fourteen for genomic panels, offered in 18 of 48 countries (38%) in LAC.

Discussion: Molecular tests for breast cancer have changed the management of this neoplasm in the countries that have incorporated them into clinical practice. Genomic tests have made it possible to identify patients who do not require chemotherapy. Genetic testing is available in those countries that have investigated for many years the frequency of susceptibility genes in women at risk. LAC countries should carry out cost-benefit studies on the use of molecular testing and promote evidence-based guidelines on the prevention of HSCLC and the therapeutic management of patients with HSCLC.

INTRODUCTION

Molecular tests are now available for the analysis of genetic and genomic variants that are part of the clinical management of patients with breast cancer (BrCa). *Genetic* testing identifies inherited mutations in specific genes, while genomic testing generally analyzes the sequence or expression of groups of genes, large fragments of the genome, and even the entire genome. (Linchar et al., 2015) In clinical practice, genetic variant analysis is targeted to patients with family and personal history of BrCa or other early onset tumors to determine the existence of hereditary cancer syndrome, on the other hand, genomic expression signatures are offered to patients with early-stage estrogen receptor-positive (ER+) BrCa, as prognostic for endocrine therapy and predictive of chemotherapy benefit. (Linyton et al., 2019) (Griguolo et al., 2022)

Azim et al., (2012) evaluated the medical utility of six genomic tests developed for early BrCa: Oncotype^{Dx}, MammaPrint®, Genomic Grade Index (GGI), PAM50, Breast Cancer Index (BCI), and EndoPredict. They performed a critical review of available studies on these tests to determine analytical validity, clinical validity, and utility. They found that Oncotype^{Dx} and MammaPrint® have analytical validity and clinical validity, but none of the tests evaluated demonstrated clinical utility.

Linchar et al., (2015), specify that the sample type for DNA analysis requires a blood sample or a tissue sample (such as saliva or cheek swab). They indicated that one of the guidelines for BRCA testing includes high-risk individuals with a personal or family history of BrCa or ovarian developed at a young age (less than 50 years), established by the American College of Medical Genetics and the United States Preventive Services Task Force (USPSTF). They concluded that genetic testing will become increasingly important in the prevention, diagnosis, and treatment of hereditary MHCA and that the incorporation of multigene panels into clinical practice will allow an increasing number of genes to be routinely tested for mutations associated with this cancer.

Vargas-Aguilar et al, (2018) identified six clinically available genomic expression signatures as prognostic markers: *IHC4 assay, Oncotype*^{DX}*, EndoPredict, Prosigna-PAM50, MapQuant Dx, The Breast Cancer Index*, indicating that the first generation of prognostic signatures (Oncotype DX, MammaPrint, Genomic Grade Index) predict recurrence at five years and subsequent tests (Prosigna, EndoPredict, Breast Cancer Index) possess better prognostic value for recurrence and are predictive of early relapse. They report that there are no useful prognostic genetic tests for hormone-negative tumors, nor predictors of response to treatment.

Litton et al., (2019), studied molecular testing in BrCa, evidencing its significant evolution, as initial tests sequenced only BRCA 1 and 2 genes. With the development of next-generation sequencing, multiple genes can now be analyzed simultaneously, saving time for patients waiting for results before making treatment decisions. About gene expression assays, they explain that before the advent of genomic signatures, there were no adequate tools to select patients for treatment with adjuvant chemotherapy, with a large evidence base (meta-analyses, retrospective and prospective studies, retrospective and prospective comparative observational studies, and prospective and observational studies), prospective comparative observational studies and retrospective observational studies) showing the clinical utility of the *Oncotype DX, MammaPrint, EndoPredict, Prosigna PAM50, and Breast Cancer Index* tests can be used in cases of node-negative ER+ breast cancer to guide decisions about adjuvant therapy.

Lulu et al, (2021) studied the *Oncotype DX, MammaPrint, Prosigna, and Breast Cancer Index* molecular assays to report their prognostic (recurrence/survival) or predictive (response to treatment) value. They found that all four assays provide prognostic value for the risk of recurrence and there is sufficient evidence for the therapeutic value of *Oncotype*^{DX} (Predictive of chemotherapy benefit) and *Breast Cancer Index* (Predictive of prolonged endocrine therapy).

Bernet et al. (2022) conducted a review of the 4 most widely used genomic expression signatures in clinical practice in Spain: *MammaPrint, Oncotype*^{DX} *EndoPredict and Prosigna PAM50*. They indicated that, due to the nature of breast cancer, the use of these tests has become an increasingly used tool for the correct stratification, prognosis, and treatment of cancer. They expressed that before the advent of genomic tests, there was no adequate tool to identify patients who could benefit from chemotherapy and those who could not, since, historically, adjuvant chemotherapy was recommended for patients with tumors larger than 1 cm and with lymph node involvement, considered in many cases as "overtreatment". The authors describe in this study the differences between them both in their development and in their technical and clinical validation.

The objective of this research is to systematize the availability in clinical practice of genomic tests that allow defining the risk of recurrence and treatment prediction in patients

with early-stage BrCa, as well as the availability of genetic tests that determine pathogenic variants (PV) of susceptibility to BrCaH, in Latin American and Caribbean (LAC) countries.

METHOD

The PRISMA 2020 framework (Page et al., 2021) was used as a reference to conduct a systematic review of the literature and web pages on the subject, using an explicit method to compile and synthesize the findings that address the following questions: Which LAC countries have genomic tests for BrCaH and genetic tests for BrCaH? and What are these genomic and genetic tests? The events studied are the existence of genomic tests and genetic tests in LAC for BrCa and the clinical applicability of these tests, and the outcome is the proportion of countries that offer molecular tests for BrCa and the availability of the service of these tests in each country.

As a source of information, a bibliographic search was carried out in databases in *PubMed, Scielo*, and websites of digital platforms of laboratories that offer genetic tests for BrCa in LAC, published in Spanish and English between January 2010 and December 2023. The following terms were used: "Pruebas genéticas", "Pruebas genomicas", "Oncotype", "Mammaprint", "Endopredict", "Prosigna", "Breast Cancer Index", with a specific search using the name of each of the 48 countries or territories included in the study. Titles and abstracts of articles were reviewed, the inclusion criteria being: randomized studies, meta-analysis, cohort studies, case-control studies, systematizations, and cross-sectional studies. Series and case reports and studies outside the period and in languages other than English or Spanish were excluded.

To evaluate the availability of the tests, in addition to the bibliographic review from secondary sources, a direct search was made through telephone calls, text messages, and e-mails to laboratories and institutions to confirm the existence or not of the tests. In the case of information from laboratories and institutions, all those accessible on the web were included.

Regarding the data extraction process: one reviewer (JG) collected the information related to the topic, which was validated with the second reviewer (MC). The information collected was organized in tables according to the specific objectives. The existing tests were grouped by country, classifying them into first and second-generation tests.

To synthesize the information, a flow chart, a table of genomic expression tests for BrCa, and a table of availability of genetic tests for BrCaH in LAC were elaborated.

In the search process, both investigators reviewed and selected independently at the beginning and then jointly. In case of discrepancy, inclusion/exclusion criteria were reviewed jointly.

In terms of limitations, it is recognized that there may be laboratories and institutions in the countries studied that offer genetic testing and gene expression testing for BrCa that do not have web-based digital platforms.

RESULTS

We reviewed 356 scientific articles, identifying 186 on genomic and genetic testing for BrCa, of which 25 were included because of their relevance to the topic, seven of them identified in previous reviews, and 19 were found in this review. A total of 2,821 websites were reviewed, selecting 56 web publications to be included in the systematization.

Genomic tests

Five genomic tests are used for expression analysis of multiple genes that determine the probability of distant metastasis and prognosis of adjuvant treatment in BrCa (recurrence and prediction): *Oncotype*^{Dx} (Syed Y. 2020), (Lulu et al., 2021), (American Cancer Society, 2023), (Genomic Health, Inc.), *MammaPrint*® (Sánchez-Forgach, et al., 2017), (Brandão et al., 2019); *EndoPredict* (Longwood Diagnóstica), (Dubsky et al., 2013), (Muller et al., 2013), (Sestak et al., 2019); *Breat Cancer Index* (BCI) (Zhang, Y. et al., 2013), (Sgroi et al., 2013), (Sanft et al., 2015), (NOEGenomic, 2023) and *Prosigna* (Kelly et al., 2012), (Dowsett et al., 2013), (Gonzalez et al., 2015). These are described below:

***Oncotype*^{DX}:** Analyzes quantitative expression levels of 21 genes through RT-PCR, of which 16 are cancer-related genes and 5 are reference genes. It is analyzed from RNA extracted from a paraffin-embedded tumor sample. (Lulu et al 2021) It is indicated for patients with early-stage BrCa, estrogen receptor-positive ER (+), human epidermal growth factor HER2 (-) with LN (-), or up to three LN (+). (American Cancer Society, 2023).

This assay calculates a recurrence score based on the weighted expression of each gene at high risk, intermediate risk, and low risk, extensively validated by clinical studies worldwide. (Bernet et al., 2022) The higher this score, the higher the risk of distant recurrence and the greater the likelihood that the patient will benefit from chemotherapy, while a low risk indicates the opposite. It is currently the only validated multigene assay for predicting chemotherapy benefits as well as prognosis (Syed Y. 2020, Genomic Health, Inc).

MammaPrint: Analyzes 70 BrCa-associated genes using DNA microarrays, designed to assess 10-year recurrence in patients with early BrCa, independent of conventional clinical and pathological factors. A low-risk score allows waiving the use of adjuvant chemotherapy (AGENDIA, 2023, Sanchez-Forgach, et al., 2017). Its use as a prognostic biomarker has been widely validated, both retrospectively and prospectively. However, its value as a predictive and clinically useful tool remains controversial (Brandão et al., 2019).

EndoPredict: This molecular test is based on the quantification of mRNA levels of 12 genes (eight cancer genes, three reference genes, and one control gene) by quantitative RT-PCR in formalin and paraffin-embedded (FFPE) tissue. The score allows for establishing a low-risk group or a high-risk group for recurrence (Longwood Diagnostics, Dubsky et al., 2013, Sestak et al., 2019). It prognoses and predicts the risk of metastasis of patients with ER (+), HER2 (-) BrCa treated only with endocrine therapy, and unlike previous tests this one includes clinicopathological factors such as tumor size and nodal status (Muller et al., 2013, Longwood Diagnosis, Myriad Genetics).

Breast Cancer Index (BCI): analyzes gene expression of eleven genes via RT-PCR, incorporates a biomarker associated with tumor response to endocrine therapy and a biomarker associated with the cell cycle, providing a quantitative and objective molecular assessment of tumor proliferative status. (Zhang, Y. et al., 2013, Sanft et al., 2015) It provides information on a patient's individualized risk of distant recurrence and prediction of the likelihood of benefit from prolonged (greater than 5 years) endocrine therapy. The test is designed for women diagnosed with early-stage invasive hormone receptor-positive (HR+), LN (-), or 1-3 LN (+) nodes who do not have distant recurrence (Sgroi et al., 2013, NEOGenomic, 2023).

Prosigna (PAM50): The assay analyzes gene expression of 50 classifier genes and five control genes to identify intrinsic subtypes (luminal A/B, HER2-enriched, basal-like) via RT-PCR of tumor tissue in FFPE. This assay estimates the risk of distant recurrence in postmenopausal women with early-stage HR (+) hormone receptors 5-10 years after diagnosis and after 5 years of treatment with hormone therapy. (Kelly et al., 2012, Dowsett et al., 2013) The results of the analysis are reported in three risk categories with a score from 0-100: Cancer cases with LN (-) are classified; as low (0-40), intermediate (41-60), and high (61-100) risk. Cancer cases with LN (+) are classified as low (0-40) and high (41-100) risk. (Gonzalez et al., 2015) (Table 1).

Availability of genomic tests in LAC.

Laboratories offering these tests were found in 14 of 48 countries (27%) in LAC. The most offered test is *Oncotype* first generation, present in 11 out of 14 countries (79%), followed by *EndoPredict* second generation, present in 9 out of 14 countries (64%). *MammaPrint and Prosigna* are present in 8 out of 14 countries (57%) respectively. The least offered is *BCI*, which is available in only 1 of 14 countries (7%).

The countries with the highest web visibility on the availability of these tests are *Mexico*: ABC Medical Center, Genetics Services, GeneLab, Patiacan, s.f, Senocuidado, Milenia Labs and Syn Lab s.f; *Argentina*: OMICS Exact Sciences, One Light Solution, s.f, Varifarma, Argenetics, s. f; *Brazil*: Fleury Genomica, Agendia, NEOGenomic; Syn Lab n.d.; *Chile*: South Genetics, One Light Solution, n.d., Varifarma; *Colombia*: Amarey (n.d.), GenCell, Genética Avanzada, Syn Lab

n.d.; *Peru*: Centro Oncológico Aliada, GeneCode S.A.C., Varifarma and Syn Lab; *Uruguay*: South Genetics, One Light Solution, n.d., Longwood and Varifarma.

Two tests were identified as available in Paraguay: South Genetics-Oncotype, Varifarma; *Dominican Republic*: South Genetics, Medipath Instituto de patología molecular; *Puerto Rico*: Puerto Rico Pathology; *Ecuador*: Varifarma, Syn Lab n.d. Laboratories offering one of the tests were found in *Bolivia*: Instituto BioClínico Cruceño Ltda Análisis Clínicos & Diagnostico; *Guatemala*: Integra Cáncer Instituto; *Honduras*: Fertilab. (Table 2).

No evidence of the availability of these tests was found in Central America (El Salvador, Nicaragua, Costa Rica and Panama); The Caribbean (Cuba, Bahamas, Barbados, Haiti, Cayman Islands, Trinidad and Tobago, Jamaica, Dominica, Guyana, Suriname, Antigua and Barbuda, Grenada, Belize, St. Kitts and Nevis, St. Vincent and Grenadines, St. Lucia, Aruba, Guadeloupe, Turks and Caicos Islands, Virgin Islands, Martinique, St. Barthelemy, Anguilla, Netherlands Antilles, Bonaire, Curaçao, Bermuda, Falkland Islands, and Monserrat).

Some interesting facts: In *Mexico* MammaPrint is included in the Clinical Guides for treatment against BrCa; in *Argentina*, Oncotype has insurance coverage; in *Colombia* Oncotype^{Dx} and MammaPrint are included in the clinical practice guide; in *Venezuela* Oncotype^{Dx}, MammaPrint, and Prosigna are included in the Venezuelan Guide for the diagnosis and treatment of BrCa, however, they indicate that they are of limited use due to their high cost and availability, but they do have sample collection for sending abroad for the required analysis. (Ambios, n.d.)

Genetic tests

The genetic tests currently available for BrCaH are directed to the analysis of BRCA 1/2 genes and non-BRCA genes (gene panels).

For the analysis of BRCA 1/2 genes, ten tests were found: myBRCA; *BRCA1 and BRCA2 Plus; BRCA1 and BRCA2 Combi; BRCA1 and 2 (8838); BRCA1 and BRCA2; BRCATIX; BRCA 1/ 2; BRCA analysis; BRCA 1 and 2 NGS Express; and BRCA Panel*. These tests are offered by South Genetics, CentoGen, Genómica Medica- Laboratorio de Diagnóstico Molecular, ROSSI, Milenia Labs, Patiacan, s.f, and Genetix, Quest Diagnostics (Table 1).

Fourteen gene panel tests were found that include BRCA gene analysis: *Oncorisk; myBRCA HiRisk; CentoBreast; CentoCancer; CentoCancer Comprehensive; BRCA Plus (C8836); Cancernext (8824); BRACATIX Plus; Oncotix; Onocopanel; SENTIS Breast and Ovarian; BRACA +16; BreastDetect; and BRCA Plus*. These tests are performed by Genetic Services, South Genetics, CentoGen, Genómica Medica-Laboratorio de Diagnóstico Molecular), Genetix, ADN Uruguay, SynLab, Biocells Genomics, and Quest Diagnostics.s, f. (Table 3).

Availability of genetic testing in LAC

In 18 of 48 countries (38%) in LAC, these tests are available for women at risk of BrCaH, ranging from genetic tests for the analysis of familial VP (BRCA 1/2) to the analysis of genetic panels that include up to 118 genes related to the risk of common hereditary cancers, such as BrCa, ovarian, colorectal, pancreatic and others. (Table 2).

Of these tests, the most commercialized in the region are myBRCA (analysis of BRCA 1/2 genes) and *myBRCA HiRisk* (analysis of 26 genes, including BRCA1/2), marketed in Mexico, Argentina, Colombia, Ecuador, Paraguay, Peru, Uruguay, Bolivia, Venezuela, Panama, and the Dominican Republic. The countries with the highest visibility in terms of supply through digital platforms of different genetic tests are Mexico, Argentina, and Colombia. In some countries, there is information to the public about the cost of these tests (between $1500 and $2000).

In Central America, the following countries offer counseling and tests for BRCA 1 / 2 gene analysis and genetic panels: *Costa Rica* (Hospitales Clínica Bíblica and Metropolitano), *Guatemala* (Integra Cancer Institute), *Honduras* (Laboratorios Centro Ginecológico), *El Salvador* (Fertilab s.f.) and *Panama* (South Genetic and Vida Tec). In Nicaragua, these analyses are not offered; only a sample is taken to be sent abroad, at an approximate cost of US$3,000 (Vivian Pellas Hospital).

No evidence of the availability of these tests was found on websites in Caribbean countries and territories in Belize, Cuba, Bahamas, Barbados, Haiti, Cayman Islands, Trinidad and Tobago, Jamaica, Dominica, Guyana, Suriname, Antigua and Barbuda, Grenada, Belize, St. Kitts and Nevis, St. Vincent and Grenadines, St. Lucia, Aruba, Guadeloupe, Turks and Caicos Islands, Virgin Islands, Martinique, St. Barthelemy, Anguilla, Netherlands Antilles, Bonaire, Curaçao, Bermuda, Falkland Islands, and Monserrat.

Limitations of genetic testing for BrCaH

Four studies discuss the limitations of the use of genetic testing for BrCaH. These include: a) indications and interpretations of VP of less common non-BRCA genes are not established; b) testing costs are not standardized and depend on the laboratory and health insurance coverage. (Valencia et al., 2017); c) lack of financial resources impacts the performance of BRCA 1/2 testing in the at-risk population. (White et al., 2018); d) geographic access to services, potential provider discrimination and bias, and lack of education and awareness of both patient and provider are barriers to the identification of VP carriers. (Reid et al., 2022) and e) shortage of genetic counselors, and lack of physician knowledge on how to evaluate, identify, and refer patients to genetic counseling are factors that limit optimization of genetic testing. (DeTroye, A. et al., 2022)

DISCUSSION

This is the first study to provide information on the availability at the LAC level of molecular tests (genetic and genomic), both for diagnosis and for prognosis of recurrence and prediction of treatment for BrCa. Advances in molecular biology have changed the management of this cancer in countries that have incorporated these tests into clinical practice. In countries that do not have these tests, treatment for women diagnosed with breast cancer is determined by clinicopathological factors and patients receive a combination of endocrine therapy and chemotherapy, which in many cases is not required, in addition to the uncertainty of the duration of endocrine treatment. According to Litton et al., (2019) and Bernet et al., (2022), this dilemma was resolved with the development of genomic expression testing, as, these tests identify patients who would not benefit from chemotherapy.

However, clinicopathologic factors remain highly relevant in the management of MCA, therefore, genomic tests that incorporate these risk factors become more valuable and should be further considered for integration into clinical practice. Of the five genomic tests studied *Oncotype^{Dx}, EndoPredict, and Prosigna* are the ones that incorporate these factors.

Concerning genetic tests for breast cancer, the availability of a variety of tests in the Latin American region is evident. Mexico, Argentina, Colombia, and Chile are the countries with the greatest offer, related to what was described by Martínez and Corriols (2023) who demonstrated that these countries concentrate the greatest proportion of biomedical research on genes with VP related to BrCaH in the last two decades. Conversely, countries that do not research the subject do not have this evidence.

This study is the first systematic review of the availability and use of genetic and genomic testing for BrCa in LAC, demonstrating the importance and need to continue studying it, mainly in those countries where the prevalence, the genes involved, and the inherited PV are unknown. The challenge of increasing access to these tests in less developed countries remains, related by some authors to limitations of financial resources, lack of insurance coverage, lack of personnel training, lack of support structures, education, and genetic counseling for patients and families, as well as development and implementation of health policies. I conclude that the approach to HmAmCa among LAC countries is unequal and that knowledge on this subject is still insufficient; the countries that have done the most research are those that currently have the molecular tools that allow better management of HmAmCa.

It is recommended that LAC countries carry out cost-benefit studies on the use of molecular tests in the prevention of breast cancer and the therapeutic management of patients with breast cancer and promote evidence-based guidelines with interventions for screening, diagnosis, and treatment of breast cancer, including molecular tests in health sector care plans.

Regarding the limitations of the study, the possible underreporting of information on the availability of molecular tests for breast cancer due to a lack of response from some laboratories consulted at the international level and the possible omission of providers who do not use websites when searching for information.

Financing

This study was financed by the UNAN-Managua.

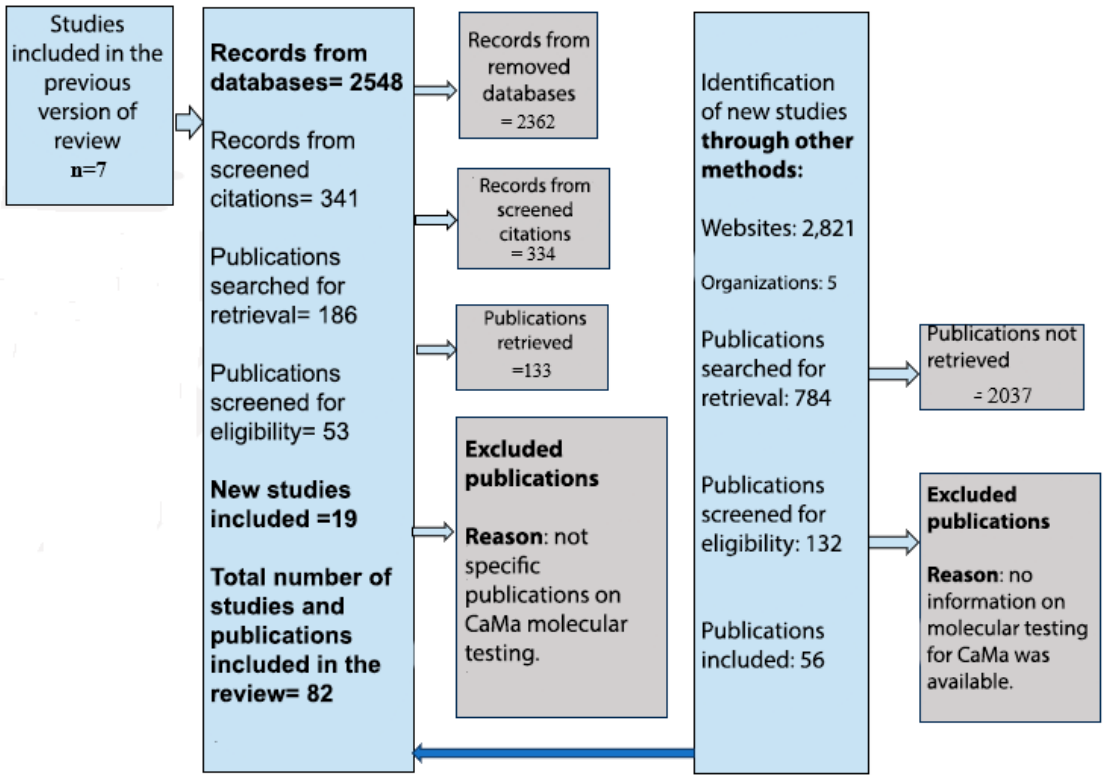
Conflict of interest

The authors declare that they have no conflict of interest.

ANNEXES

Figure 1

Flowchart for information selection



Source: PRISMA 2020 Template

Table 1

Specifications of the genomic tests for BrCa available in LAC

Variable	Oncotype DX	MammaPrint	EndoPredict	Breast Cancer Index	Prosigna
Análisis	21 genes	70 genes	12 genes	11 genes	50 genes
Technique	RT-PCR Quantitative	DNA-microarrays	RT-PCR Quantitative	RT-PCR Quantitative	RT-PCR
Indications	Early stage, RE (+), HER2 (-), LN (-), or up to three LN (+).	Early stage, independent of conventional clinical and pathologic factors	Early stage, RE (+), HER2 (-), treated with endocrine therapy alone, tumor size and nodal status	Early stage CaMa invasive, HR (+), LN (-) o 1-3 LN (+)	Early stage Postmenopausal, RH (+), LN (-), LN (+)
Clinical utility	Prediction and prognosis	Prediction	Prediction and prognosis	Prediction and prognosis	Prediction
Type of sample	Formalin-fixed tumor tissue				

Source: Own elaboration

Table 2

Availability of genomic expression tests for BrCa in LAC.

First generation			Second generation		
Country	**Oncotype**	**MammaPrint**	**EndoPredict**	**BIC**	**Prosigna PAM50**
México	Centro médico ABC	Genetics services	GeneLab (Patiacan, s.f.)	-	Senocuidado Milenia Labs Syn Lab s. f

First generation			Second generation		
Country	**Oncotype**	**MammaPrint**	**EndoPredict**	**BIC**	**Prosigna PAM50**
SOUTH AMÉRICA					
Argentina	OMICS Exact Scencies	One Light Solution, s.f.	Varifarma		Argenetics, s.f.
Brazil	Fleury Genomica	Agenda		NEOGenomic	Syn Lab s. f
Chile	South Genetics	One Light Solution, s.f.	Varifarma	-	South Genetics
Colombia	Amarey. (s.f.)	Gencell Genética avanzada	Gencell Genética avanzada	-	Syn Lab s. f
Uruguay	South Genetics	One Light Solution, s.f.	Longwood s. f Varifarma s. f		
Paraguay	South Genetics		Varifarma		
Peru	Centro Oncológico Aliada GenCode	Centro Oncológico liada	Varifarma		Syn Lab s. f
Bolivia	Instituto BioClínico Cruceño (South Genetics)				

First generation			Second generation		
Country	**Oncotype**	**MammaPrint**	**EndoPredict**	**BIC**	**Prosigna PAM50**
Ecuador			Varifarma		Syn Lab s. f
CENTRAL AMERICA					
Guatemala	Integra Cáncer Instituto				
Honduras					Fermilab
CARIBBEAN					
Dominican Republic	South Genetics		Medipath Instituto de patología molecular		
Puerto Rico	Puerto Rico Pathology	Puerto Rico Pathology			

Source: Own elaboration

Table 3

Availability of genetic tests for BrCaH in LAC.

Country	Laboratory	Test name	Genetic test specifications
North America			
Mexico	Genetic Services	Onco Risk	IAnalysis for 30 genes including BRCA 1 and 2 genes
	South Genetics	myBRCA	Analysis for BRCA 1 y 2 genes
		myBRCA HiRisk	It analyzes 26 genes (including BRCA1 and BRCA2)
	CentoGen	BRCA1, BRCA2 Plus	BRCA1, BRCA2
		BRCA1, BRCA2 Combi	BRCA1, BRCA2
		CentoBreast®	It analyzes 28 genes: including BRCA 1 y 2
		CentoCancer	It analyzes 67 genes: including BRCA 1 y 2
		CentoCancer® comprehensive	Analyzes 118 genes including BRCA 1 y 2
	Mayo Clinic	Not specified	Análisis de genes BRCA 1/2
	Medical Genomics - Molecular Diagnostics Laboratory	BRCA 1 y 2 (C8838)	It analyzes BRCA 1/2 genes
		BRCA Plus (C8836):	Analysis for 8 genes; including BRCA 1/2

Country	Laboratory	Test name	Genetic test specifications
Mexico	Medical Genomics - Molecular Diagnostics Laboratory	CancerNext (C8824)	Analysis 34 genes including los genes BRCA 1/2
	Genos Medica	BRCA 1/2 (C8838)	It analyses BRCA ½ genes
	Milenia Labs	BRCA 1 y 2 NGS Express	It analyses BRCA ½ genes
		Paneles PreSENTIA	19 panels that analyze specific genes and allow you to target only the type of cancer you want to prevent
	Patiacan, s. f	BRCA analysis	Analysis of genes 1 and 2 BRCA
Suramérica			
Argentina	South Genetics	myBRCA	Analysis of genes 1 and 2 BRCA
		myBRCA HiRisk	It analyses 26 genes (including BRCA1 y BRCA2) myBRCA y myBRCA HiRisk
	Centro Nacional de Genética Médica	Not specified	Analysis of BRCA 1 and 2 genes
	IAF Instituto Alexander Fleming, Centro Mamario	Not specified	Genetic counseling and genetic testing.
	LDM Laboratorio de diagnóstico molecular	Hereditary cancer test	Not specified

Country	Laboratory	Test name	Genetic test specifications
Argentina	ROSSI	BRCA1 y BRCA2	BRCA 1 and 2 Complete Sequencing BRCA1 and BRCA2 - Ashkenazi panel gene mutations BRCA1 & BRCA2 - Ashkenazi - Sephardic panel gene mutations BRCA 1 and BRCA 2 MPLA
Chile	Clínica Alemana	Not specified	Genetic counseling and testing
	South Genetics 41	Hereditary cancer test	It analyzes 47 genes including BRCA1 and BRCA2.
	Biogenetics	BRCA 1/ 2	BRCA 1 y 2 Secuenciación completa
Colombia	South Genetics	myBRCA	Analysis of BRCA 1 and 2 genes
		myBRCA HiRisk	It analyzes 26 genes (including BRCA1 and BRCA2).
	Genetix	BRACATIX	Analysis of BRCA 1 and 2 genes
		BRCATIX PLUS	Sequencing of 25 genes
		Oncotix	It analyzes 51 genes including BRCA1 and BRCA2
		Oncopanel	Analysis of genes of clinical interest according to the patient's personal and family history.
Ecuador	South Genetics	myBRCA	Analysis for BRCA 1 y 2
		myBRCA HiRisk	It analyses 26 genes (including BRCA1 and BRCA2)
	SynLab	BRCA +16	It analyses BRCA genes plus 16 no BRCA genes
	Biocells Genomics	BreastDetect®	37 including BRCA1 and BRCA2 genes

Country	Laboratory	Test name	Genetic test specifications
Paraguay	South Genetics	myBRCA	Analysis for los genes BRCA 1 y 2
		myBRCA HiRisk	It analises 26 genes (incluidos los BRCA1 y BRCA2)
	Biosur	BRCA 1/2	Analysis for los genes BRCA 1 y 2 Muestra requerida: sangre
Perú	South Genetics	myBRCA	Analysis for los genes BRCA 1 y 2
		myBRCA HiRisk	It analyses 26 genes (incluidos los BRCA1 y BRCA2)
	Syn Lab	BRCA +16	It analises los genes BRCA +16 genes
	Progenie	Not specified	Not specific
Uruguay	South Genetics	myBRCA	Analysis for genes BRCA 1 y 2
		myBRCA HiRisk	It analises 26 genes (incluidos los BRCA1 y BRCA2)
	ADN Uruguay	BRCA 1/ 2	It analyses los genes BRCA 1/ 2
		SENTIS Mama y Ovario	It analises 26 genes, incluidos BRCA 1/2
Bolivia	South Genetics	myBRCA	It analises los genes BRCA 1/2
		myBRCA HiRisk	It analises 26 genes (incluidos los BRCA1 y BRCA2)
Venezuela	South Genetics	myBRCA	Analysis for los genes BRCA 1 y 2
		myBRCA HiRisk	It analyses 26 genes; including BRCA1/2
Brazil	Fleury GENOMICA	Not specified	Hereditary breast cancer panel: analysis of 25 genes
Centroamérica			

Country	Laboratory	Test name	Genetic test specifications
Costa Rica	Hospital Clínica Bíblica	BRCA 1/ 2	Analysis for BRCA 1/2
		Genetic panel	Analysis for 83 genes; including BRCA1/2
	Hospital Metropolitano	Not specified	Blood sampling and shipment to Germany
Guatemala	Integra Cáncer Instituto	Not specified	It analyses 61 genes, including BRCA1/. genes It analyses 84 genes; including RCA1/2
		Not specified	It analises 61 y 84 genes; incluidos BRCA1/2
Honduras	Fertilabh	BRCA 1/ 2	It analises BRCA 1 / 2 genes
		Not specified	It analyses30 y 32 genes incluidos BRCA 1/2
Panamá	South Genetics	myBRCA	It analises de los genes BRCA 1/ 2
		myBRCA HiRisk	It analyses 26 genes; including BRCA1/2
	Vida tec	Oncogene	It analyses 11 genes including BRCA 1/2
		MyBRCA	Analysis for genes BRCA 1/2
		myBRCA HiRisk	Analysis for 26 genes; including BRCA1/2
El Salvador	Laboratorios Centro ginecológico	Test BRCA 1 2	Analysis for genes BRCA 1/2
CARIBE			

Country	Laboratory	Test name	Genetic test specifications
República Dominicana	South Genetics	myBRCA	Analysis for los genes BRCA 1/2
		myBRCA HiRisk	It analyses 26 genes (including BRCA1 and BRCA2)
	Medipath Instituto de patología molecular	BRCA 1/ 2	It analises BRCA ½ genes
Puerto Rico	Laboratorio Clínico Principal	Not specified	Not specified
	Quest Diagnostics. s.f.	Panel BRCA	It analises BRCA 1/2 genes
		BRCA Plus	It analyses 7 genes; including BRCA1/2 genes

Source: Own elaboration

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