SCIENTIFIC CULTURE
www.sci-cult.com

SCIENTIFIC CULTURE, Vol. 12, No. 1.1, (2026), pp. 3601-3608
Open Access. Online & Print

DOI: 10.5281/zenodo.121.126263

EFFECTIVENESS OF MAMMOGRAPHY AND BREAST ULTRASOUND IN DETECTING LESIONS SUSPICIOUS OF BREAST CANCER (BI-RADS 4 AND 5)

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Received: 11/12/2025
Accepted: 20/01/2026

ABSTRACT

To evaluate the effectiveness of mammography and breast ultrasound in the detection of lesions suspicious of breast cancer (BI-RADS 4 and 5). This cross-sectional study examined 315 cases involving mammographic and ultrasound reports categorised as BI-RADS 4 or 5. These cases underwent image-guided biopsies between 2018 and 2023. Cases involving radiotherapy or chemotherapy were excluded. Data were collected from medical histories and pathology reports from biopsies. The following variables were recorded: age; BI-RADS classification; type of study; and histological type. Descriptive statistics were used and chi-square tests were performed. Statistical significance was considered at $p < 0.05$. Of the BI-RADS 4 cases, 28.78% were classified by ultrasound and 90% by digital mammography. Seventy-one point twenty-two percent of BI-RADS 5 were detected by ultrasound and 10% by digital mammography. Ultrasound detected 80.98% (n = 166) of malignant cases. Digital mammography identified 23.64% (n = 26) of malignant cases. In subcategory 4A, 13 out of 70 cases (18.5%) were confirmed as cancerous, with a 95% confidence interval (CI) of 10.2% to 29.6%. For BI-RADS 4B: In subcategory 4B, 14 out of 70 cases (20.0%) were found to be cancerous, with a 95% confidence interval (CI) ranging from 11.3% to 31.2%. In subcategory 4C, 15 out of 18 cases (83.3%) were confirmed as cancerous, with a 95% confidence interval (CI) ranging from 58.5% to 96.4%. Finally, for the BIRADS 5 category: Of the 157 cases classified as BIRADS 5, 95.5% (150 cases) were found to be cancerous, with a 95% CI ranging from 91% to 98%. Overall, 73.42% (n = 116) of BI-RADS 4 cases were benign, while 95.54% (n = 150) of BI-RADS 5 cases were malignant. The cancer detection rate by ultrasound for BIRADS 4 was 41%, compared to 16.1% for mammography. Ultrasound detected 95.8% of the total number of patients with BIRADS-5, and mammography detected 90.9%. Conclusion: BI-RADS category 5 offers high diagnostic predictability, whereas BI-RADS category 4 still yields a high number of false positives, primarily within subcategories 4a and 4b. Combining ultrasound and digital mammography improves the overall diagnostic capacity.

KEYWORDS: Breast cancer, digital mammography, breast ultrasonography, effectiveness, diagnosis, biopsy, effectiveness, BI-RADS 4, BI-RADS 5.

1. INTRODUCTION

In 1994, the Radiological Society of North America concluded that palpation or inspection could not be used to detect breast cancer early or differentiate between benign and malignant pathologies. Since 1974, mammography has been the only imaging technique to demonstrate a statistically significant reduction in breast cancer mortality among screened patients (1). The advent of high-resolution ultrasound, magnetic resonance imaging (MRI) and assisted biopsies has made breast imaging a fundamental pillar in the diagnosis, monitoring and intervention of breast pathology (2).

The American College of Radiology developed the Breast Imaging Reporting and Data System (BI-RADS) to standardise breast imaging reporting, assess the risk of breast pathology and facilitate biopsy decision-making (3). BI-RADS classifies lesions into seven categories (from zero to six), each of which carries different management recommendations. However, significant intra- and interobserver variability in BI-RADS terminology has resulted in considerable variation in biopsy rates in the US, with studies finding that between 55% and 85% of breast biopsies reveal benign lesions (2).

BI-RADS category 4 is called 'suspicious findings' and warrants biopsy (4). This category is subdivided into 4a, 4b and 4c, representing a broad probability of malignancy: BI-RADS 4a: 2–10%; BI-RADS 4b: 11–40%; BI-RADS 4c: 41–95%. Over the decades, the positive predictive value (PPV) of BI-RADS tissue biopsy category 4 has not improved (4). In the United States, the estimated PPV is 21%, resulting in high rates of false positives in mammography.

Like mammography, the ultrasound report is established by the BI-RADS classification. Its main utility lies in determining the difference between solid and cystic lesions and between palpable and non-palpable lesions (5, 6). It is also considered the initial study for patients under 30 years of age with an average risk of developing breast cancer who present with a palpable mass, as well as for pregnant or breastfeeding patients (5, 6). However, to date, there is no evidence to support its use as a screening test (7).

Generally, the performance of mammography is considered to depend on whether it is performed on a symptomatic or asymptomatic population (8). Diagnostic mammography may have higher sensitivity and lower specificity than screening mammography (sensitivity: 82–94% and 83–86%; specificity: 55–84% and 89–90%, respectively). Chika F. E. et al. found an overall breast cancer detection rate of 14.41% for BI-RADS 4 mammograms (9). Luo et al. showed that the false positive rate for categories 4a, 4b, and 4c was 84.3%, 40%, and 0%, respectively (10).

Breast imaging is based on the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS), which provides a standardised vocabulary for describing, evaluating and managing imaging findings (11). BIRADS Assessment Category 5 is used when the probability of malignancy is estimated to be 95% or greater based on imaging findings. However, Yao et al. found that the actual positive predictive value of a BIRADS 5 assessment ranges from 78% to 97.5%. Therefore, not all BIRADS 5 lesions are malignant (12).

This study aims to evaluate the diagnostic effectiveness of digital mammography and/or breast ultrasound in detecting breast cancer in the different BI-RADS 4 subcategories and BI-RADS 5, in patients treated at CEDIUL in Barranquilla during the period 2018–2023.

2. MATERIALS AND METHODS

Cross-sectional study. Patients with BI-RADS 4 or 5 mammography and/or ultrasound reports who underwent image-guided biopsy at the CEDIUL diagnostic imaging center in Barranquilla, Colombia, between 2018 and 2023 were included. The center serves the population affiliated with the state-subsidized and contributory regimes of Colombia's General Social Security System. Patients who had previously received radiotherapy or chemotherapy or who had a history of breast cancer were excluded.

Convenience sampling was carried out using a sample size of 39,330, representing the 2018 prevalence of breast cancer in Colombia (an incidence of 44.1%, margin of error of 3%, design effect of 1, and confidence level of 95%). A total of 315 cases were obtained.

Procedure: The researchers working in the institution collected the secondary data from the medical records and pathology reports of patients diagnosed with breast cancer (ICD 500 or C 502) between January 2018 and December 2023. Patients were included in chronological order until the sample size was complete. A Senographe Essential direct digital mammography system from General Electric was used with caudal craniographic (CC) and oblique mediolateral (MLO) projections in each modality. The ultrasound machine used was a Voluson E8 and a Logic S7. Biopsies were performed by two interventional radiologists with over ten years of experience in breast pathology. Ultrasound and/or stereotactic guidance was used as applicable. Magnum bar needles and Trucut calibers 14G and

12G were used. The material obtained was analyzed in the pathological anatomy service of the institution. The information was recorded on a form designed for this purpose and then entered into an Excel database and sent to the institution's epidemiological team.

Measured variables. The following variables were considered in the study: age (less than 40 or greater than or equal to 40), BI-RADS classification (4a, 4b, 4c, 5), study type (mammography or ultrasound), categorization (in situ, proliferating, non-proliferative), and histological type (according to pathology). The type of lesion was also considered (nodule, asymmetry, microcalcification), as was laterality (right and left), quadrant (CSI, CSE, CII, ICD), findings of interval AC, and the relationship between benignity and malignancy (according to the Dupont classification, classification and Page, and according to infiltrative compromise reported in pathology).

The data were processed using the statistical software STATA version 18. For continuous variables, measures of central tendency and dispersion according to the distribution of the data (normal or non-normal) were utilized. The qualitative variables were summarized using absolute and relative frequency measures. The prevalence of breast cancer during the study period was ascertained. Subsequently, the proportion of breast cancer diagnoses in the BI-RADS 4 and BI-RADS 5 subclassifications was evaluated using Fisher's exact test and the Chi-square test, both in ultrasound and mammography, analyzing their corresponding statistical significance. The following study will present the prevalence of breast cancer in the period studied. To this end, we employed Fisher's exact test and the Chi-square test to ascertain the proportion of breast cancer diagnoses in each of the subclassifications of the BI RADS 4 and BI RADS 5, both ultrasound and mammography, and their respective statistical significance. We further estimated the positive predictive value (PPV) and the detection rate of breast cancer. The objective of this study was to ascertain whether there was a significant difference between digital mammography and ultrasound in BI-RADS 4 and BI-RADS 5 cases. A p-value of 0.05 was determined to be statistically significant.

Ethical aspects. This research is regarded as low-risk due to its reliance on secondary sources. The confidentiality of the information was guaranteed; informed consent was not required, as the study was based on clinical records. The ethical considerations were reviewed and endorsed by the ethics committees of two institutions: the first was the ethics committee of Simón Bolívar University, and the second was the ethics committee of CEDIUL.

3. RESULTS

3.1. Characteristics of the Participants

The total number of women included in the study was 315, with a mean age of 57.78 years (±12.14). The majority of the participants (92.38%) were over 40 years of age, 7.12% (24 cases) were under 40 years old, and 57 were between 70 years old and older (18.10%).

Ultrasound was the most frequently utilized imaging modality, employed in 65.08% of cases, followed by mammography in 34.92%. With regard to the administration of biopsies, 64.76% of patients underwent the procedure under ultrasound guidance, while 35.24% were performed using stereotaxic techniques.

The lesions were most frequently located in the upper external quadrant of the breast (56.19%), with the internal quadrants and retroareolar quadrants being the least affected. The right side demonstrated the highest degree of commitment, with 52.06% of the subjects exhibiting this characteristic. In contrast, 3.17% of the subjects displayed bilateral commitment, indicating a balanced engagement with both sides.

Radiological findings indicate that 67.3% of the lesions were characterized as nodules, while 21.9% were classified as microcalcifications and/or asymmetries. The BI-RADS classification for mammography revealed that 49.84% of patients were designated as BI-RADS 5, constituting the highest risk category. On a global scale, 50.16% of patients were categorized as BI-RADS 4, while the remaining 49.84% were categorized as BI-RADS 5.

With respect to breast density, the majority of patients (63.78%) were found to have breasts classified as B density, with a mere 4.72% being categorized as extremely high-density (D) breasts.

Table 1: Characteristics of the Participants.

Variable	n	%
Age (average +/- SD)	57,78	12,14
Age group		
<40 years	24	7,62
>=40 years	291	92,38
Diagnostic test		

Echography	205	65,08
Mammography	110	34,92
Type of biopsy		
Echography	204	64,76
Stereotaxy	111	35,24
Location of the lesion		
CSE	177	56,19
Bilateral	3	0,95
CIE	60	19,05
CII	16	5,08
CSI	52	16,51
Retroareolar	7	2,22
Breast side		
Bilateral	10	3,17
Right	164	52,06
Left	141	44,76
Type of injury		
Asymmetry	34	10,79
Microcalcifications	69	21,9
Nodule	212	67,3
Nodule		
Micro_asim	103	32,7
Nodule	212	67,3
BIRADS		
BIRADS 4A	70	22,22
BIRADS 4B	70	22,22
BIRADS 4C	18	5,71
BIRADS 5	157	49,84
BIRADS Global		
BIRADS 4	158	50,16
BIRADS 5	157	49,84
Breast density		
To	22	17,32
B	81	63,78
C	18	14,17
D	6	4,72
Global density		
Hyperdense	24	18,9
Non-hyperdense	103	81,1

Global cancer detection and according to ultrasound and digital mammography

As illustrated in Table 2, the overall detection of malignant pathology was 60.95% (n = 192), with a 95% confidence interval (CI) of 55.46% to 66.18%. In contrast, the detection of benign pathology was 99.05% (n = 123), with a 95% CI of 33.82% to 44.54%.

With regard to malignancy, ultrasound detected 80.98% (n=166) of malignant cases and 19.02% (n=39) of benign cases. Conversely, digital mammography identified 23.64% (n=26) of malignant cases and 76.36% (n=84) of benign cases.

The BI-RADS classification system was utilized to assess the cases, and 28.78% (n=59) of the cases were assigned to BI-RADS 4 category by ultrasound, while 90% (n=99) of the cases were classified as BI-RADS 4 by digital mammography. In the BI-RADS 5 category, 71.22% (n=146) of the cases were classified by ultrasound, while 10% (n=11) were classified by digital mammography.

With respect to age, patients under 40 years of age constituted 9.76% (n=20) of cases in ultrasound and 3.64% (n=4) in mammography. A significant proportion of the cases were observed to belong to the age group of 40 years and above, with 90.24% (n=185) of the cases in ultrasound and 96.36% (n=106) in mammography falling into this category (p value = 0.051).

It is imperative to acknowledge that the diagnostic approach employed is contingent upon the nature of the observed lesion. In instances of asymmetries and microcalcifications, the most frequently employed technique is mammography, while ultrasound is the preferred modality for the detection of nodules. In this particular context, ultrasound facilitated the detection of 202 nodules, which constitutes 98.54% of the lesions identified by this method, in contrast to the three cases of asymmetries, which amount to 1.46%. Conversely, the use of digital mammography facilitated the identification of 69 cases of microcalcifications, constituting 62.73% of the lesions evaluated through

this modality. Additionally, 31 cases of asymmetries were detected, accounting for 28.18% of the lesions, and 10 nodules were identified, amounting to 9.09% of the total lesions.

Ultimately, an analysis of breast density revealed that it was hyperdense in 12.68% (n = 9) of cases observed through ultrasound and in 26.79% (n = 15) of cases identified through mammography.

Table 2: Diagnostic Results of Ultrasound And Digital Mammography According to the Variables Studied.

Variable. N (%)	Global	Echography	Mammography
Malignancy			
Benign	123 (39,05)	39 (19,02)	84 (76.36)
Malignant	192 (60,95)	166 (80,98)	26 (23.64)
BIRADS Global			
BIRADS 4	158 (50,15)	59 (28,78)	99 (90)
BIRADS 5	157 (49,84)	146 (71,22)	11 (10)
Age group			
<40	24 (7,61)	20 (9,76)	4 (3,64)
>=40	291 (92,38)	185 (90,24)	106 (96,36)
Type of injury			
Asymmetry	34 (10,80)	3 (1,46)	31 (28,18)
Microcalcifications	69 (21,90)	0 (0)	69 (62,73)
Nodule	212 (67,30)	202 (98,54)	10 (9,09)
Breast density			
Hyperdense		9 (12,68)	15 (26,79)
Non-hyperdense		62 (87,32)	41 (73,21)

3.2. Global Cancer Detection According to the Radiology Society's Classification as BI-RADS 4 And 5

A global evaluation of cases classified as BI-RADS 4 and 5 revealed a significant discrepancy in the distribution of benign and malignant lesions. The analysis revealed that 73.42% (n=116) of the cases classified as BI-RADS 4 were benign, while 26.58% (n=42) were malignant. In the cases classified as BI-RADS 5, 95.54% (n=150) were malignant, compared to 4.46% (n=7) that were benign (p-value < 0.0001). Please refer to Table 3.

The detection rate of cancer by ultrasound classified as BIRADS-4 was 44.07%, and the detection rate of cancer by mammography classified as BIRADS-4 was 16.16%, with an OR: The mean value was 4.1 (1.9–8.5), and the p-value was less than 0.001.

The cancer detection rate by ultrasound in patients with BIRADS-5 was 95.8%, and by mammography was 90.9%. Please refer to Table 3.

With respect to the age distribution, 25% (n=6) of benign cases and 75% (n=18) of malignant cases were observed in patients younger than 40 years of age. In the group of patients over 40 years of age, 40.21% (n=117) of the cases were benign and 59.79% (n=174) malignant, with no significant difference (p value = 0.142).

The investigation revealed that the mean age of cancer in the study population was 57.78%, with the presence of cancer at advanced ages of life. The study established that the minimum age of identification was 27 years, and the maximum age was 94 years.

Table 3: Comparison Of Diagnostic Results Between Benign and Malignant Lesions According to the Variables Studied.

Variable. n (%)	Benign	Malignant	P value
Global			
BIRADS 4	116 (73.42)	42 (26.58)	< 0.0001
BIRADS 5	7 (4.46)	150 (95.54)	
Echography			
BIRADS 4	33 (55.93)	26 (44.07)	< 0.0001
BIRADS 5	6 (4.11)	140 (95.89)	
Mammography			
BIRADS 4	83 (83.84)	16 (16.16)	< 0.0001
BIRADS 5	1 (9.09)	10 (90.91)	
Age group			
<40	6 (25)	18 (75)	0.142
>=40	117 (40.21)	174 (59.79)	
Laterality of the lesion			
Bilateral	5 (50,00)	5 (50,00)	
Right	67 (40,85)	97 (59,14)	0,0014
Left	51 (36,17)	90 (63,82)	
Location of the lesion			
CSE	69 (38,98)	108 (61,02)	< 0.01
Bilateral	0	3 (100)	
CIE	30 (50,00)	30 (50,00)	
CII	8 (50,00)	8 (50,00)	
CSI	15 (28,85)	37 (71.15)	
Retroareolar	1 (14,29)	6 (85,71)	
Laterality of the lesion			

Cancer detection rate according to BIRADS 4 classification and its subcategories and BI-RADS 5 confirmed by pathology

The following table presents the distribution of confirmed cancer cases according to the BIRADS classification, which reflects the probability of malignancy for each category and its 95% confidence interval (CI). The following categories are delineated below:

The patient's case was designated as BIRADS 4 (overall). Of the 158 cases classified as BIRADS 4, 26.5% (42 cases) were confirmed as cancer, with a 95% confidence interval ranging from 19.8% to 34.1%. This finding suggests that the probability of cancer in this category exhibits significant variability but remains within a moderate range.

BIRADS 4A: In subcategory 4A, 13 of 70 cases (18.5%) were confirmed as cancer, with a 95% confidence interval of 10.2% to 29.6%. This finding is consistent with the anticipated low probability of malignancy within this category.

BIRADS 4B: In subcategory 4B, 14 of 70 cases (20.0%) were found to be cancer, with a 95% confidence interval ranging from 11.3% to 31.2%. The

probability of cancer is marginally elevated in comparison to 4A, yet it remains within the intermediate range.

BIRADS 4C: Within the 4C subcategory, 15 of the 18 cases (83.3%) were confirmed as cancer, with a 95% confidence interval of 58.5% to 96.4%. This finding indicates a high probability of malignancy, approaching BIRADS category 5.

BIRADS 5: Of the 157 cases classified as BIRADS 5, 95.5% (150 cases) were found to be cancer, with a 95% confidence interval ranging from 91% to 98%. This finding aligns with the established definition of this category, which suggests a high probability of malignancy.

In summary, the probability of cancer increases as the BIRADS classification progresses from 4A to 5. Category 4C and 5 show the highest rates of malignancy.

Table 3. Cancer Rate According to BIRADS Classification Confirmed by Pathology.

BIRADS classification confirmed by pathology	Cancer Percentage	95% CI
4	42/158 (26,5%)	19,8% - 34,1%
4A	13/70 (18,5%)	10,2 % - 29,6%
4B	14/70 (20,0%)	11,3% - 31,2%
4C	15/18 (83,3%)	58,5% - 96,4%
5	150/157 (95,5%)	91% - 98%

4. DISCUSSION

The present study aims to evaluate the effectiveness of BI-RADS categories 4 and 5 in detecting breast cancer using digital mammography and ultrasound. The findings indicated that ultrasound exhibited a sensitivity of 84.34% in detecting breast cancer in patients with non-palpable nodules, in comparison to mammography, which demonstrated a sensitivity of 98.81% for asymmetries and/or microcalcifications. The cancer detection rate was 95.54% in the BI-RADS 5 category, confirming its high diagnostic predictability. The BI-RADS 4 category presented an overall detection rate of malignancy of 26.4%, distributed in its different subcategories: BI-RADS 4A (18.5%), BI-RADS 4B (20%), and BI-RADS 4C (83.3%). This indicates a significant identification of cases of BI-RADS 4C.

The findings of this study are consistent with the mounting scientific evidence underscoring the sensitivity of ultrasound in identifying nodular lesions, as compared to mammography, which is much more useful in detecting asymmetries and microcalcifications for the purpose of breast cancer detection. A study that evaluated the combined detection of mammography and ultrasound in a screening program demonstrated the necessity of these studies in identifying breast cancer, as they are capable of detecting different types of lesions. The study also demonstrated that complementary ultrasound enhances the detection of breast cancer and, in some cases, requires supplementation to ensure the certainty of malignant pathologies. The findings showed that when supplemented, the sensitivity increases to 81.3%, contrasting with the 61.5% sensitivity observed with mammography and ultrasound alone (Buchberger, 2018).

Another pivotal study by Ohuchi et al., which evaluated the combination of mammography and ultrasound, demonstrated that ultrasound can markedly improve the detection rate in this group, underscoring the significance of its combined use in breast cancer screening (Nature). This finding is consistent with other research indicating that ultrasound significantly enhances the detection of invasive cancers that would otherwise remain undetected by mammography alone. Consequently, the use of ultrasound as a complementary modality to enhance the study and detection of breast lesions has been proposed.

Within the global identification of BI-RADS 4, 26.5% of cases with cancer were confirmed, also evidencing that within the subcategory of BI-RADS 4C, the detection was 83.3%, thus showing its relationship with the high probability of malignancy.

With respect to the observations concerning the positive predictive value (PPV) in the BI-RADS 5 category, the results obtained (95.54%) are consistent with the ranges reported in previous studies, wherein the PPV varied between 78% and 97.5%. These data underscore the efficacy of this category in predicting malignancy in suspicious lesions, thereby confirming that the BI-RADS 5 category remains a highly robust diagnostic instrument in clinical practice (MDPI) (Nature). However, while the majority of BI-RADS 5 lesions are malignant, a small percentage may be benign, as reported in the literature. This finding underscores the importance of clinical and pathological correlation prior to making definitive therapeutic decisions, thereby preventing unnecessary interventions in patients with benign lesions (Nature).

A salient limitation of this study is its retrospective design, which introduces potential biases in the selection and collection of data. Moreover, while the sample size was sufficient to identify substantial variations, it might restrict the applicability of the findings to other populations, particularly beyond the immediate context of Barranquilla. A notable constraint pertains to the

utilization of a solitary center, a choice that may be influenced by factors inherent to local clinical practices.

Notwithstanding, this study boasts significant strengths. The present study incorporates pathological confirmation of the biopsy, which is conducted concurrently with the diagnostic imaging procedures. First, the care center where the imaging studies were carried out is a reference within the Department of Atlántico. It is equipped with state-of-the-art technology and has a highly trained staff, ensuring the quality of the data in the sample studied. Additionally, the center has a diverse population, which allows for the creation of groups with different characteristics and risk classifications. This is necessary to demonstrate the suitability of the radiologists with whom the center has more than 10 years of experience in breast pathology. This ensures reliability in the interpretation of the results obtained under the standardized BIRADS system. This finding indicates that the integration of mammography and ultrasound, in conjunction with the collaborative analysis of both modalities, facilitates a comprehensive assessment of the diagnostic efficacy in this demographic. This approach enables the early detection of breast pathology and provides a reference point for the necessity of further evaluative studies of this specific pathology.

5. CONCLUSIONS OF THE STUDY

The findings of this study underscore the significance of employing ultrasound and mammography in a complementary manner in the management of patients classified as BI-RADS 4 and 5. The high sensitivity of ultrasound suggests that it should be preferred in young women or women with dense breasts, while mammography may remain a key tool in diagnostic confirmation due to its high specificity.

In clinical practice, there is a need to consider the integration of both modalities into diagnostic protocols. This integration would improve accuracy and reduce the need for unnecessary biopsies. Future research endeavors may concentrate on validating these findings in other populations and exploring the role of new technologies, such as tomosynthesis or the use of artificial intelligence, to enhance diagnostic accuracy in these categories.

In light of the high rate of false positives in BI-RADS category 4, it is imperative to devise strategies that enhance diagnostic accuracy and mitigate the necessity for superfluous invasive interventions.

A salient limitation of this study is its retrospective design, which introduces potential biases in the selection and collection of data. Moreover, while the sample size was sufficient to identify substantial variations, it might restrict the applicability of the findings to other populations, particularly beyond the immediate context of Barranquilla.

Acknowledgements: We would like to express our gratitude to the medical and administrative team of CEDIUL, Barranquilla, Dr. Guido Parra, our methodological advisor, Floralinda Garcia, statistical advisor Laura Arzuza for their invaluable support in data collection and their willingness to facilitate the development of this study. We extend our gratitude to the technical team of the Simón Bolívar University for the advice, direction and dedication in each phase of the project.

Conflict of interest: The authors declare that there are no conflicts of interest related to this study. No specific funding was received from public, private, or nonprofit agencies to conduct this research.

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