ORIGINAL ARTICLE

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Research funding: None

Declaration of conflict of interest: The author declares that he/she has no conflict of interest.

Declaration of use of artificial intelligence: The author declares that no artificial intelligence was used in the research or in the preparation of the article.

Received: 24 October 2024

Accepted: 14 December 2024

Online publication: 12 March 2025

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Cite as: Bonilla Sepúlveda OA. Comparison between clinical- ultrasound and pathologic tumor size in breast cancer. Descriptive study. Rev peru ginecol obstet. 2025;71(1). Doi: https://doi.org/10.31403/rpgo.v71i2731

Comparison between clinical-ultrasound and pathologic tumor size in breast cancer. Descriptive study

Comparación entre el tamaño tumoral clínico-ecográfico y patológico en cáncer de mama. Estudio descriptivo

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DOI: https://doi.org/10.31403/rpgo.v71i2731

RESUMEN

Introduction: Clinical evaluation of tumor size in the TNM classification is an integral part of the diagnosis of breast carcinoma. The surgical decision depends largely on the clinical stage. Objective: To determine the concordance between the clinical-ultrasound and pathological size of invasive breast carcinoma. Materials and methods: Observational, retrospective study. Surgical pathology and ultrasound reports of patients with invasive breast carcinoma were reviewed. Data from 271 cases were included. Concordance was defined as a size difference equal to or less than 5 mm. Demographic and clinical data were collected and analyzed using descriptive statistics. Results: Concordance between clinical and pathological tumor size was 30.8% (n: 73), and ultrasound was 52.9% (n: 18). The mean clinical size was 33 mm (SD: 17.4), ultrasound was 11.3 mm (SD: 6.8) and pathological was 22.2 mm (SD: 14.4). The Student t test showed a significant difference in clinical measurement (t= 7.5 mm, 95% CI 7.33 - 12.5; p: 0.000), Pearson correlation (r: 0.224; *p*: 0.001) and ultrasound measurement (t: 3.83 mm, 95% CI 2.27 - 7.40; *p*: 0.001), Pearson correlation (r: 0.342; *p*: 0.048). There were significant clinical-pathological differences by clinical stages. Conclusions: In the sample studied, it was found that the clinical and ultrasound measurement of tumor size had a low correlation with the pathological tumor size, clinically there was a tendency to overestimate and ultrasound to underestimate, affecting the clinical classification (TNM) for tumor size.
Key words: Breast cancer, Neoplasm staging, Size perception, Observational study

ABSTRACT

Introducción. La evaluación clínica del tamaño del tumor en la clasificación TNM, hace parte integral al diagnóstico del carcinoma de mama. La decisión quirúrgica depende en gran parte del estadio clínico. Objetivo: Determinar la concordancia entre el tamaño clínico- ecográfico y patológico del carcinoma invasivo de mama. Materiales y métodos. Estudio observacional, retrospectivo. Se revisaron los informes de patología quirúrgica y ecografía de pacientes con carcinoma invasivo de mama. Se incluyeron datos de 271 casos. La concordancia se definió como una diferencia de tamaño igual o menor a 5 mm. Se recopilaron los datos demográficos, clínicos, y se analizaron utilizando estadística descriptiva. Resultados. La concordancia entre el tamaño clínico y patológico del tumor fue del 30,8 % (n: 73), y ecográfico del 52,9 % (n: 18). El tamaño clínico medio fue de 33 mm (DE: 17,4), el ecográfico de 11,3 mm (DE: 6,8) y el patológico 22,2 mm (DE: 14,4). La prueba t Student mostró una diferencia significativa en la medición clínica (t= 7,5 mm, IC95% 7,33 a 12,5; *p*: 0,000), correlación Pearson (r: 0,224; *p*: 0,001) y la medición ecográfica (t: 3,83 mm, IC95 % 2,27 a 7,40; *p*: 0,001), correlación Pearson (r: 0,342; *p*: 0,048). Hubo diferencias clínicas patológicas significativas por estadios clínicos. Conclusiones. En la muestra estudiada se encontró que la medición clínica y ecográfica del tamaño tumoral tuvo una baja correlación con el tamaño del tumor patológico; por clínica se tendió a sobredimensionar y por ecografía a infraestimar, afectando la clasificación clínica (TNM) para el tamaño tumoral.
Palabras clave. Cáncer de mama, Estadificación de neoplasias, Percepción del tamaño, Estudio observacional

Introducción

According to information from the International Agency for Research on Cancer (IARC), malignant breast neoplasia in 2020 was the most frequent cancer in women worldwide, with 1 948 321 new cases, occupying the first place for cancer in women with 25.7%, with a total of 513,525 deaths due to this cause(1). Comparatively, for the same year in Colombia it is estimated that there were 15 509 new cases and 4 401 deaths(2).

The American Joint Committee on Cancer Staging System (AJCC) Issue 8[3] developed the TNM system, Tumor (T) Node (N), Metastasis (M) with the aim of determining the spread of the disease at the time of diagnosis. It thus allows patients to be grouped with respect to their prognosis. Tumor staging depends mainly on tumor size and lymph node status. Tumor size has been subdivided according to its largest diameter as follows:

T 1: Tumor equal to or less than 2 cm in its largest diameter

T 2: Tumor > 2 cm, up to 5 cm in greatest diameter

T 3: Tumor > 5 cm in its largest diameter

T 4: Tumor of any size: with direct extension to the chest wall (including ribs, intercostal muscles and serratus major) or skin involvement (edema, ulceration or satellite nodules)

The initial determination of tumor size in the TNM classification is done clinically or radiologically. The former is determined through clinical examination of the breast, which is performed with the patient lying down, palpating with the tips of the index, middle and ring fingers (fingers 2, 3 and 4), making small circles at different depths. When the mass is detected, the largest diameters are measured with a tape measure[4]. In case of small or subcentimeter lesions that are not palpable, breast imaging studies such as ultrasound, mammography and magnetic resonance imaging represent the method of choice due to their greater precision[5], with the final staging being based on pathological measurement.

The National Comprehensive Cancer Network® (NCCN®)[6] has determined precise guidelines for the management of each stage of breast carcinoma. This is why a discrepancy between the clinical/echographic and pathologic size of the tumor can lead to therapeutic decisions according to its category. In the case of surgical options, a low concordance at diagnosis may imply unnecessary or insufficient radical surgeries for patients.

The objective of this study was to determine the concordance between the clinical-echographic and pathological size of invasive breast carcinoma, to infer how accurate the staging is, as well as to describe the sociodemographic and clinical characteristics and explore associated factors in Medellin (Colombia).

Materials and methods

The design was an observational, retrospective study that included women over 18 years of age with a histologic diagnosis of invasive breast carcinoma, who underwent clinical or ultrasound measurement of the tumor and were taken to surgery, and who were listed in a surgeon's personal registry, between January 1, 2023, and December 31, 2023.

The patients who were candidates to be part of the study were identified through a search in the individual registry of health care providers (IRHP) of the investigator, with the code malignant tumor of the breast, unspecified part (C509), according to the international classification of diseases, tenth edition (ICD-10). Thus, patients with a histologic diagnosis of infiltrating breast carcinoma were identified and the medical records of eligible patients were reviewed. Patients with a diagnosis of carcinoma in situ or who received neoadjuvant treatment, or with incomplete medical history or data loss greater than 10% were excluded. Consecutive sequential sampling was performed, and 271 records were obtained that met inclusion criteria.

On admission to the oncology unit and the mastology service the TNM stage was determined, as an essential part of tumor staging based on the AJCC[3] 8th Edition guide. Tumor size was estimated by measuring the largest diameter with a tape measure performed by the surgeon and, in the case of non-palpable tumors, the ultrasound measurement was taken. All measurements were compared with the final postoperative tumor diameter, determined by histopathological examination, examined by experienced pathologists in the field. When the difference between the clinical-echographic and pathological measurements was less than 5 mm, it was considered concordant.

The variables measured were age, occupation, residence, insurance, family history of breast cancer, degree of consanguinity, reason for consultation, laterality, location by quadrant, focality, histological type, histological grade, TNM classification (tumor, node, metastasis), estrogen receptors, progesterone, HER2, Ki67, type of breast and axillary surgery, margins.

After standardization of the research protocol, the information was collected, tabulated and verified by the researcher in a database in Excel® format. Descriptive analysis of the sociodemographic and clinical variables was performed. Absolute frequencies and percentages, mean and standard deviation were calculated, according to the nature and distribution of the variables. The normal distribution was validated using the Shapiro Wilk goodness-of-fit test. The correlation with the clinical-ultrasound and pathologic tumor size was studied with the Pearson's test. For dichotomous qualitative variables, the chi2 test was used. For hypothesis testing, a confidence interval of 95 % and a significance level of 5 % were used. SPSS statistics software version 23 was used.

With regard to ethical aspects, the present study is considered a risk-free study, according to the classification established in Article 11 of Resolution No. 008430 of 1993 (issued by the Colombian Ministry of Health) and is in accordance with international standards, the Helsinki Declaration, and the ethical guidelines for biomedical research prepared by the Council for International Organizations of Medical Sciences -CIOMS.

Results

A total of 271 medical records that met the inclusion criteria were reviewed. The mean age was 61.9 years (SD: 12.4, min-max = 26-90), 74.5 % (n= 202) belonged to the contributory regime, 23.6 % (n= 64) to the subsidized regime and 1.8 % (n= 3) were private; 46.9% resided in Medellín (n= 46.9), 19.6 % (n= 52) in the metropolitan area, 31.7 % (n= 86) in other municipalities, and 2.2 % (n= 6) in another department. With respect to occupation, 63.8 % (n= 173) were housewives, followed by pensioners 15.1 % (n= 41), employees 10.3 % (n= 28), self-employed 4.4 % (n= 12) and students 6.3 % (n= 17).

The most frequent reason for consultation was mammographic alteration in 60.1 % (n= 163), followed by palpable mass in 36.2 % (n= 98). The most frequent histological type was ductal with 82.3 % (n= 223), histological grade 2 predominated (50.6 %), and 19.2 % (n= 52) had multifocal tumors. According to TNM classification, axillary nodes were involved in 9.6 % (N1); one case with metastatic stage was included. 88.2 % were estrogen receptor positive, and in 8.5 % (n= 23) HER2 was overexpressed (Table 1).

The mean clinical tumor size was 33 mm (SD: 17.4), ultrasound 11.3 mm (SD: 6.8) and pathological 22.2 mm (SD: 14.4). Comparison of means with the Student t-test for related samples showed a significant difference between clinicopathological measurements (t= 7.5 mm, 95% CI 7.33-12.5; *p*: 0.000) and their Pearson correlation (r: 0.224; *p*: 0.001). As well as the Student t-test for the means between ultrasound and pathology (t: 3.83 mm, 95% CI 2.27-7.40; *p*: 0.001) and the Pearson correlation (r: 0.342; *p*: 0.048) (Table 2).

Concordance (=/< 5 mm) was found between clinical-pathological tumor size in 30.8 % (n=73) and discordant (> 5 mm) in 69.2 % (n=164), of which 19.5 % (n= 32) were underestimated and 80.5 % (n= 132) were overestimated. On the other hand, ultrasound was concordant in 52.9 % (n= 18) and discordant in 47.1 %, of which 93.7 % (n= 15) were underestimated and 6.3 % (n= 1) were overestimated. Despite the difference in size, the stage classification was the same by clinical T1 (68.9 %), T2 (52.7 %), T3 (8.7 %), with an average of 43.4 %, and by ultrasound was similar in 62.5 % distributed in T1 (75 %) and T2 (50 %).

Table 3 shows the comparative analysis of tumor stage (TNM) by clinical and ultrasound with respect to the pathological stage, finding significant differences for the clinical stages.

Table 4 shows a bivariate analysis between clinical/ultrasound discordant size and pathological size and variables of clinical interest, in which no statistically significant variables were found. There was a non-significant tendency to perform more mastectomies in cases of clinical-pathological discordance (OR: 1.39, 95% CI 0.94-2.06, p: 0.08).

Discussion

The results of the present study indicate that the tumor size assessed by clinical and ultrasound is not concordant with that measured in the histopathologic specimen, significantly affecting the TNM classification for tumor size.

Clinical evaluation is easy to perform and is standard as part of the physical examination. Accuracy in estimating tumor size may depend on factors such as the underlying fat layer, skin thickness or the presence of edema, suggesting an overestimation of tumor diameter by

Table 1. Clinicopathological characteristics.

Variable	(n= 271) Frequency (%)	Variable	(n= 271) Frequency (%)
Family history of breast cancer		Progesterone receptors	
Yes	65 (23.3)	Positive	204 (75.3)
No	203 (74.9)	Negative	55 (20.3)
No data	3 (1.8)	No data	12 (4.4)
Degree of consanguinity	(n= 65)	HER 2	
First	9 (13.8)	Negative	226 (83.4)
Second	34 (52.3)	Indeterminate	7 (2.6)
Third	22 (33.8)	Positive	23 (8.5)
		No data	15 (5.5)
Reason for consultation		KI67	
Mammography abnormality	163 (60.1)	Under 20	123 (45.4)
Mass	98 (36.2)	Over 20	129 (47.6)
Pain	5 (1.8)	No data	19 (7)
Telorrhagia	3 (1.1)		
No data	2 (0.7)		
Breast laterality		Node (TNM)	
Right	147 (54.2)	N0	235 (86.7)
Left	121 (44.6)	N1	26 (9.6)
Bilateral	3 (1.1)	N2	5 (1.8)
No data	2 (0.6)	N3	5 (1.8)
Location			
Central	29 (10.7)		
Upper external quadrant	117 (43.2)	Metastasis (TNM)	
Upper medial quadrant	52 (19.2)	M0	270 (99.6)
Lower external quadrant	54 (19.9)	M1	1 (0.4)
Lower medial quadrant	17 (6.3)		
No data	2 (0.7)		
Focality		Surgery	
Unifocal	219 (80.8)	Quadrantectomy	173 (63.8)
Multifocal	52 (19.2)	Mastectomy	98 (36.2)
Histological type		Axilla	
Ductal	223 (82.3)	Sentinel lymph node	223 (82.3)
Lobular	22 (8.1)	Axillary dissection	48 (17.7)
Other types	26 (9.6)		
Histological grade		Margins	
Grade 1	53 (19.6)	Negative	243 (89.7)
Grade 2	137 (50.6)	Positive	28 (10.3)
Grade 3	78 (28.8)		
No data	3 (1.1)		
Estrogen receptors			
Positive	239 (88.2)		
Negative	20 (7.4)		
No data	12 (4.4)		

Table 2. Clinical-ultrasound and pathologic tumor size (TNM).

Variable	(n= 237)	Variable	(n= 34)	Variable	(n= 271)
Clinical size (mm)		Ultrasound size (mm)		Pathological size (mm)	
Mean	33	Mean	11.3	Mean	22.2
SD	17.4	SD	6.8	SD	14.4
Min-Max	10 - 120	Min-Max	5 - 40	Min-Max	1- 110
Clinical tumor (TNM)	Frequency (%)	Ultrasonographic tumor (TNM)	Frequency (%)	Pathological tumor (TNM)	Frequency (%)
T1	62 (26.2)	T1	32 (94.1)	T1	142 (52.4)
T2	145 (61.2)	T2	2 (5.9)	T2	111 (41)
T3	23 (9.7)	T3	0	T3	11 (4.1)
T4	7 (3)	T4	0	T4	7 (2.6)

SD: Standard deviation, Min-Max: Minimum-maximum

Table 3. Bivariate clinical-ultrasound and pathological analysis according to stage.

Clinical								
Stage	Outcome				OR	IC 95%		p value *
	Clinical stage		Pathological stage					
	n	%	n	%		L. inf.	L. sup.	
T1	62	26.2	142	52.4	0.32	0.22	0.46	0.00
T2	145	61.2	111	41	2.27	1.59	3.24	0.00
T3	23	9.7	11	4.1	2.54	1.21	5.32	0.01
T4	7	3	7	2.6	1.14	0.39	3.32	0.79
Ultrasonographic								
Stage T2	Outcome				OR 1,14	IC 95% 0,15		p value* 0,89
	Ultrasound stage		Pathological stage					
	n	%	n	%		L. inf.	L. sup.	
T1	32	94.1	142	52.4	14.53	3.41	61.80	0.00
T2	2	5.9	11	4.1	1.14	0.15	8.18	0.89

** Chi-square*

Table 4. Bivariate analysis between clinical/ultrasound-pathological discordant size and variables of clinical interest.

Variable	OR	95% CI	p value *
Mastectomy	1.39	0.94-2.06	0.08
Emptying	1.41	0.77-2.61	0.33
Positive margins	0.94	0.42-2.09	1.00
Multifocal	1.33	0.73-2.41	0.38
KI67 >20%	0.86	0.66-1.13	1.13
Estrogen receptor (-)	1.37	0.46-4.07	0.78
Progesterone receptor (-)	1.65	0.87-3.11	0.11
Lobular histologic type	0.81	0.33-1.96	0.61

*OR: Odds ratio, 95% CI: 95% confidence interval, * Chi-square*

palpation while others show the opposite[7]. Most commonly, ultrasound is used to assess tumor size, being non-invasive, does not require X-rays and is widely accepted by patients. However, the estimation of tumor size is variable because it is operator dependent[8].

Several studies have correlated pathologic tumor size and imaging, but few have compared clinical size. The available studies show significant correlation between ultrasonography, mammography and clinical examination[5,8-10].

Streng et al.[11] found that the sensitivity within 5 mm tolerance for ultrasound was 65.5 %, 61.3 % for mammography, 56.6 % for clinical examination. The highest correlation coefficient was observed for mammography (0.788), followed by ultrasonography (0.741) and clinical examination (0.671).

Ramirez et al.[12] compared the size of breast carcinoma by mammography, ultrasound and MRI. Their correlation coefficients were 0.76, 0.67 and 0.75, respectively. The authors conclude that mammography measurements correlated most closely with pathologic measurements.

Stein et al.[13], in a study of 6 543 patients reported a slightly higher correlation between mammography and pathologic examination than ultrasound (r = 0.61 vs. 0.60, respectively).

Heusinger et al.[14] found that there were differences in size for all methods evaluated, mammography (*p*: 003), ultrasonography (*p*: 0.001), clinical examination (*p*: 0.001), and the correlation was r: 0.75 (0.001), r: 0.68 (*p*: < 0.0010), r: 0.74, *p*: 0.001) respectively. Mammography overestimated tumor size compared to ultrasound and clinical examination.

Cortadellas et al.[15] found a strong correlation between the results of physical examination (0.62), ultrasound (0.68), mammography (0.57) and MRI (0.51) with respect to pathological anatomy. Ultrasonography was the best predictor of tumor size in breast cancer compared to clinical examination.

Lai et al.[16] described that ultrasound had a better concordance compared to MRI (54.3 % vs. 44.1 %). MRI overestimated tumor size, while ultrasound underestimated tumor size.

Bosch et al.[17], in a prospective study found that ultrasound was the best predictor of histologic tumor size compared to mammography and physical examination. Since ultrasound underestimated tumor size, they suggested a formula to calculate the probable histologic tumor size: ultrasound tumor size (mm) +3 mm.

Snelling et al.[18] assumed that ultrasound is better in tumors smaller than 3 cm, and that clinical examination is equivalent for tumor diameters larger than 3 cm.

Azhdeh et al.[19] found correlations between tumor size at clinical examination of 0.65, 0.69 for mammography, 0.78 for ultrasound and 0.97 for MRI, and the concordance rates with pathologic size were 64.3 %, 76.2 % and 82.1 %, respectively, with the highest concordance rate for MRI. Among the discordant cases, underestimation of ultrasound and mammography were more frequent (70 %).

Kathimanda et al.[20] found that 70 % had a good correlation between ultrasound and morphologic size, of the discordant 30 %, 20 % overestimated and 10 % underestimated (*p*: .002). In 50 % of the cases, the size on physical examination corroborated the ultrasound findings and only in 40 % of the cases the size on physical examination coincided with the morphologic findings; of the discordant 60 % 20 % overestimated, and 40 % underestimated (*p*: 0.001). In 65 % of cases, the clinical staging of breast carcinoma matched the pathological staging.

Hamza et al.[21] reported a correlation coefficient for radiological and pathological size of 0.61, p<0.0001. The overall agreement was 40.4 %, and stage classification was the same in 59.9 %. Radiological measurement overestimated stage in 59 (14.5 %) cases and underestimated stage in 104 (25.6 %) cases.

Among the limitations of the present work is the fact that it was designed as a retrospective study, although with the advantage that it was developed by a single surgeon, with the same practice setting and without significant variations in the protocol for measuring tumor size.

Conclusions

In the sample studied it was found that the clinical and ultrasound measurement of tumor size has a low correlation with the size of the pathologic tumor. Clinically it tends to overestimate and ultrasonographically to underestimate, affecting the clinical classification of tumor size (TNM) and therefore affecting the surgical decision of whether or not to perform conservation surgery.

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