

ORIGINAL PAPER

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Research funding: None

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

The author declares that the material contained in the manuscript has not been previously published or sent to another biomedical journal.

Received: 13 October 2020

Accepted: 20 February 2021

Online publication:

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Cite as: Bonilla Sepúlveda OA. Ultrasound BIRADS in women with or without mastalgia. Rev Peru Ginecol Obstet. 2021;67(2). DOI: <https://doi.org/10.31403/rpgov67i2318>

Ultrasound BIRADS in women with or without mastalgia

BIRADS ecográfico en mujeres con o sin mastalgia

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DOI: <https://doi.org/10.31403/rpgov67i2318>

ABSTRACT

Introduction: Mastalgia occurs in 70 % of women, being the common cause for imaging studies, in many cases without indication. The incidence of breast cancer among women with mastalgia is 2.5 % with no association between the two. **Objective:** To determine the prevalence of BIRADS (Breast imaging reporting and data system) 4-5 among women with or without mastalgia, to describe demographic and clinical characteristics, and to determine the association between mastalgia and BIRADS ultrasound report 4-5. **Methods:** Cross-sectional analytical study in 323 users attended at the del Prado Clinic in Medellín (Colombia), between June and October 2018. The proportion of mastalgia and BIRADS 4-5 reports was calculated. Demographic and clinical characteristics were evaluated. **Results:** The prevalence of mastalgia was 21.4 %, and of BIRAD 4-5 was 6.2 %. Among those who had mastalgia, the frequency of BIRADS 4-5 was 2.9 %, with no statistical association OR 2.5 (95 % IC 0.58 to 11.3; p : 0.2). **Conclusions:** Suspicious ultrasound findings were not associated with mastalgia, which is a common indication for breast ultrasound; findings are often normal or benign.

Key words: Breast neoplasms, Mammography, Ultrasonography, mammary.

RESUMEN

Introducción. La mastalgia se presenta en el 70 % de las mujeres, siendo la causa de realizar estudios de imagen, en muchos casos sin indicación. La incidencia de cáncer de seno entre las mujeres con mastalgia es del 2,5 % sin demostrar asociación entre ambas. **Objetivo.** Conocer la prevalencia de BIRADS (*Breast imaging reporting and data system*) 4-5 entre mujeres con o sin mastalgia, describir las características demográficas, clínicas, y determinar la asociación entre mastalgia y el reporte ecográfico BIRADS 4-5. **Métodos.** Estudio analítico transversal en 323 usuarias atendidas en la Clínica del Prado en Medellín (Colombia), entre junio y octubre de 2018. Se calculó la proporción de mastalgia y de reportes BIRADS 4-5. Se evaluaron las características demográficas y clínicas. **Resultados.** La prevalencia de mastalgia fue de 21,4 %, y de BIRAD 4-5 de 6,2 %. Entre las que tuvieron mastalgia, la frecuencia de BIRADS 4-5 fue 2,9 %, sin encontrar asociación estadística OR 2,5 (IC95 % 0,58 a 11,3; p : 0.2). **Conclusión.** Los hallazgos ecográficos sospechosos no se asociaron a mastalgia, siendo esta una indicación común de ultrasonido mamario; frecuentemente los hallazgos son normales o benignos.

Palabras clave. Neoplasias de la mama, Mamografía, Ultrasonografía mamaria.

INTRODUCTION

Breast pain is called "mastalgia" or "mastodynia" and is a common symptom among women who undergo breast ultrasound⁽¹⁾. 70% of women suffer from breast pain at least once in their life⁽²⁾ and it is the cause of medical consultation in 47%⁽³⁾.

Cyclic mastalgia is the most common and manifests as throbbing pain, tension or bilateral and cyclical breast discomfort with the menstrual period, of slight intensity and lasting less than five days, having little influence on daily life, it resolves spontaneously and does not require more treatment than general measures. Only when it falls outside these parameters is it considered pathological⁽⁴⁾.

Breast ultrasound is not indicated in mastalgia, however in many cases it is requested as the first line of study, even if no alterations have been found in the physical examination, being of choice for young women



under 40 years of age or older with dense breast tissue⁽⁵⁾. If the clinical examination is suspicious, mammography should be requested and ultrasound-guided biopsy is indicated in the event of the suspicious finding⁽⁶⁾.

Mastalgia is associated with cysts and fibrocystic changes, which are seen on ultrasound as anechoic images with posterior enhancement, and imaging follow-up is not required for this cause⁽⁷⁾.

Since breast cancer is the most common cancer in women in the world, causing 521,907 deaths per year⁽⁸⁾, breast pain becomes a cancer concern for many; however, only in 2.5% of cases is there an association between the two⁽⁹⁾. In this regard, the National Comprehensive Cancer Network (NCCN) carries out clinical practice guidelines for the detection and diagnosis of breast cancer, and does not consider mastalgia an alarm sign⁽¹⁰⁾. For its part, the American College of Radiology (ACR) considers that ultrasound is indicated in the evaluation and characterization of palpable masses and other signs and / or symptoms related to the breast⁽¹¹⁾.

In the detection of cancer, ultrasound has a greater sensitivity compared to mammography (95.7% versus 60.9%)⁽¹²⁾. In patients with mastalgia, biopsy by fine needle aspiration, cutting, or surgery is not justified⁽¹²⁾.

The objective of the study is to know the prevalence of BIRADS among women with or without breast pain, to describe the demographic and clinical characteristics, and to determine the association between breast pain and BIRADS ultrasound report 4-5. It is the first cross-sectional study in Latin America to determine the association between suspected ultrasound malignancy by BIRADS classification and mastalgia.

METHODOLOGY

A cross-sectional study was performed out among women who underwent breast ultrasound between June 1 and December 31, 2018, at the Ultrasound Unit of the del Prado Clinic. The sample was calculated by applying the Joseph Fleiss formula, with a confidence of 95%, a power of 80%, taking into account a prevalence of mastalgia of 22%, for a sample of 323 patients, consecutive sequential sampling was

carried out. The patients were informed about the type of study and those interested agreed to participate on a voluntary basis.

Participants answered a survey in order to identify demographic and clinical characteristics. For diagnosis, the Breast Imaging Reporting and Data System scale, BIRADS, edition 5⁽¹³⁾, was used in order to group the findings of mammography, ultrasound and magnetic resonance into six categories: BIRADS = 0 needs additional evaluation; 1 = Normal; 2 = benign lesion; 3 = probably benign lesion; 4 = suspected malignancy; 5 = highly suspicious of malignancy; 6 = malignancy proven by biopsy. This scale has a predictive value of malignancy according to each class, being for BIRADS = 0 = 1%, 2 = 0%, 3 = <2%, 4 = 10-90%, 5 = > 90%, 6 = 100%. It has been widely used and validated in the world and scores 4 and 5 determine suspicion of malignancy and warrant a breast biopsy⁽¹³⁾.

The following variables of the studied population were evaluated: age, educational level, parity, menstruation, planning, indication and finding on ultrasound and its corresponding BIRADS score.

For the analysis, the statistical program Epidat 3.2 free distribution program was used. The information of the continuous variables is summarized using the median and the interquartile range (IQR) and the categorical variables as proportions. BIRADS 4-5 results are reported as prevalence. Normal distribution was determined using the Kolmogorov-Smirnov test and bivariate analysis of the categorical variables was performed using the Chi-square test and an association was determined with a 95% confidence interval and a *p* value <0.05.

This is a non-intervention study under the survey modality, classified as risk-free and complies with international regulations for medical research (Declaration of Helsinki and the Belmont Report), and Resolution 8430 of 1993 of the Ministry of Health of the Republic of Colombia.

RESULTS

Of the total of 323 patients surveyed in the established period, 68 patients underwent ultrasound for mastalgia, with a prevalence of 21.4%. In those surveyed, 67% were under 50 years of



age, and of the total, 41% of patients were in amenorrhea, and among those who menstruated, 14% were abnormal. Among the patients of childbearing age, 68% used some planning method, the most used being oral contraceptives (25%) (Table 1).

Breast mass was the most frequent indication for ultrasound, in 94 patients (29%), followed by mammographic alterations that warrant ultrasound supplementation with diagnostic intent, and in third place was mastodynia in 68 patients (21%). The other indications are described in detail in Table 2.

In the patients who had abnormal findings on ultrasound, the most frequent were cysts ($n = 57$; 17.7%), followed by non-suspicious BIRADS 2-3 nodules with 52 patients (16.1%), while 151 patients (47%) had normal ultrasound scans. (Table 3).

TABLE 1. DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

Variable	(n= 323) Frequency (%)
Age (years). Median Interquartile range	45 20
Education	
Elementary education	47 (14.6)
High school	188 (58.2)
Technical education	34 (10.5)
Professional	50 (15.5)
None	4 (1.2)
Parity	
Childless	88 (27.2)
With children	235 (72.8)
Menstruation	
Normal	145 (44.9)
Abnormal	46 (14.2)
Amenorrhea	132 (40.9)
Contraception	
No	103 (31.9)
Oral contraceptives	81 (25.1)
Injectable	26 (8.0)
Surgical	52 (16.1)
Intrauterine device	35 (10.8)
Other	15 (4.6)
Condom	11 (3.4)

Regarding the patients with a BIRADS 4-5 ultrasound report, the total prevalence was 6.2%, and among those with breast pain it was 2.9%. The association between the patients who had mastalgia and the BIRADS 4-5 ultrasound report was

TABLE 2. INDICATION FOR ULTRASOUND

Indication	(n= 323) Frequency (%)
Normal control	46 (14.2)
Pain	68 (21.4)
Mass	94 (29)
Theloreia	5 (1.5)
Asymmetry	3 (0.9)
Polymastia	1 (0.3)
Breast implant	23 (7.3)
Mammographic alteration	83 (25.4)

TABLE 3. ULTRASOUND FINDINGS AND BIRADS DISTRIBUTION

Finding	(n= 323) Frequency (%)
Simple cyst	50 (15.5)
Complicated cyst	1 (0.3)
Complex cyst	6 (1.9)
Nodule of benign appearance	21 (6.5)
Probably benign nodule	31 (9.6)
Low probability suspicious nodule	18 (5.6)
High probability suspicious nodule	2 (0.6)
Fatty lobule	15 (4.6)
Prosthesis contracture	4 (1.2)
Prosthesis rupture	4 (1.2)
Polymastia	2 (0.6)
Intramammary ganglion	6 (1.9)
Macromastia	1 (0.3)
Ductal ectasia	2 (0.6)
Scar	7 (2.2)
None	152 (47.1)
Biopolymers	1 (0.3)
BIRADS	(n= 323) Frequency (%)
0	1 (0.3)
1	145 (44.9)
2	114 (35.3)
3	43 (13.3)
4	18 (5.6)
5	2 (0.6)
6	0 (0)



determined, with the OR: 2.5 (95% CI 0.58-11.3. $p=0.2$), without finding a statistically significant association (Table 4). Other associations were made, finding significant differences in the age group under 50 years of age, and in fibrocystic mastopathy, which are described in detail in Table 5.

DISCUSSION

Breast pain is a very common symptom in women, which can affect their quality of life, and being the indication for imaging studies such as breast ultrasound, patients often associate breast pain with the belief that they have breast cancer, which generates them stress and anxiety. Results of this study show a prevalence of breast pain of 21.4%.

The study by Yildirim et al.⁽¹⁴⁾ and Khan et al.⁽¹⁵⁾, where 5,463 patients were retrospectively evaluated, investigated the association between mastalgia and breast cancer without finding an association.

In the study by Kızılkaya et al.⁽⁹⁾ identified malignant tumors in 2.5% of 530 patients with symptoms of mastalgia, and in the study by Fariselli et al.⁽¹⁶⁾ in Italy with 200 patients, found that 2.5% of patients with mastalgia had subclinical cancer. The results of this study show that the prevalence of BIRADS 4-5 in cases with mastalgia was similar at 2.9%.

In a prospective study by Joyce et al.⁽¹⁷⁾ of 5,841 patients, 57% had breast pain as their only symptom, 1.2% had cancer, and all cancer patients were older than 35 years. In the study by Yüksekaya et al.⁽⁵⁾ that included 937 patients with mastalgia did not find any cancer cases.

Bilgin et al.⁽¹⁸⁾ found that 41.1% of the cases were sonographically normal, while 50.6% had fibrocystic changes and 0.6% had cancer, of which 83.3% were older than 40 years. The results of this study show that among those with BIRADS 4-5, 50% were older than 50 years.

TABLE 5. ASSOCIATION OF MASTALGIA WITH OTHER CLINICAL VARIABLES

Variable	OR	IC 95%	p
Nulliparous	1.12	1-1.25	0.07
Under 50 years old	1.91	1.12-3.29	0.012
Higher education	0.8	0.47-1.36	0.43
Premenopausal	0.82	0.53-1.27	0.37
Hormonal contraception	0.92	0.60-1.43	0.74
Fibrocystic mastopathy	1.48	1.34-1.62	0.00

OR=odds ratio. IC 95%= confidence interval 95%. P= value.

Weaknesses of this study include the fact that the pain scale was not measured, nor was mastalgia classified as cyclical or non-cyclical, this being another limiting factor.

In conclusion, suspicious ultrasound findings were not associated with mastalgia, this being a common indication for breast ultrasound, the findings are often normal or benign.

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TABLE 4. MASTALGIA AND ASSOCIATION WITH BIRADS 4-5 IN PATIENTS TREATED AT THE DEL PRADO CLINIC. BIVARIATE ANALYSIS.

Variable	Outcome				OR	IC 95%		p
	BIRADS 0-1-2-3 n =303		BIRADS 4-5 n =20			Lower limit	Upper limit	
	n	%	N	%				
With mastalgia	67	20.7	2	0.6	2,5	0.58	11.3	0.2
Without mastalgia	236	73	18	5.5				

OR=odds ratio. IC 95%= confidence interval 95%. P= value.



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