

Granulomatous mastitis in reference centers in Medellín (Colombia), 2019. Descriptive study

Mastitis granulomatosa en centros de referencia en Medellín (Colombia), 2019. Estudio descriptivo

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Abstract

Objective: To describe the sociodemographic data, clinical manifestations, paraclinical and treatment, among the series of patients diagnosed with granulomatous mastitis. **Method:** A descriptive, retrospective study of an institutional database between January 1, 2016 to December 31, 2019. Data from medical records of demographic, clinical and paraclinical data were collected and analyzed using descriptive statistics. **Results:** The prevalence in the sample was 2.12%, all cases were women, mixed race, the mean age at diagnosis was 30.4 years, the most frequent reason for consultation was inflammatory breast changes (12, 66.7%), followed by mass (5, 27.8%). Most of the patients received antibiotics as initial treatment (13, 72.2%), steroid therapy (8, 44.4%) and methotrexate (2, 11.1%), while 3 patients (16.7%) underwent surgery. Resolution occurred on average in 7 months and 5 patients (27.8%) had recurrence. **Conclusions:** Granulomatous mastitis affects women of child-bearing age, presents with inflammatory changes and pain, tends to present a chronic evolution with some episodes of recurrence and spontaneous resolution in almost all cases.

Keywords: Granulomatous mastitis. Breast. Mastitis. Treatment.

Resumen

Objetivo: Describir los datos sociodemográficos, las manifestaciones clínicas, los estudios paraclínicos y el tratamiento en una serie de pacientes diagnosticadas de mastitis granulomatosa. **Método:** Estudio descriptivo, retrospectivo de una base de datos institucionales, entre el 1 de enero de 2016 y el 31 de diciembre de 2019. Se recopiló la información de registros médicos correspondiente a datos demográficos, clínicos y paraclínicos, y se analizaron utilizando estadística descriptiva. **Resultados:** La prevalencia en la muestra fue del 2.12%, todos los casos fueron mujeres y de raza mestiza, la media de edad al momento del diagnóstico fue de 30.4 años y el motivo de consulta más frecuente fueron los cambios inflamatorios mamararios (12, 66.7%), seguidos por una masa (5, 27.8%). La mayoría de las pacientes recibieron antibióticos como tratamiento inicial (13, 72.2%), terapia con esteroides (8, 44.4%) y metotrexato (2, 11.1%), mientras que 3 pacientes (16.7%) se sometieron a cirugía. La resolución se dio en promedio en 7 meses, y 5 pacientes (27.8%) tuvieron recurrencia. **Conclusiones:** La mastitis granulomatosa afecta a las mujeres en edad fértil, se presenta con cambios inflamatorios y dolor, tiende a presentar una evolución crónica con algunos episodios de recurrencia y hay resolución espontánea en casi todos los casos.

Palabras clave: Mastitis granulomatosa. Mama. Mastitis. Tratamiento.

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Introduction

Granulomatous mastitis is a rare benign inflammatory disease of the breast, originally described in 1972 by Kessler and Wolloch¹. Its etiology is not known, but the most accepted hypothesis is that it may be an autoimmune reaction located in the breast²⁻⁴.

Its true prevalence is unknown. In a study by Baslaim et al.⁵ with histopathological confirmation, benign breast disease was found in 1.8% out of 1,106 women, and in the United States of America, an estimated incidence of 2.4 per 100,000 women, or 0.37%, has been reported⁶. Although there are reports in the entire world, it has higher racial predilection for Latin and Asian women⁵.

It mainly affects women of childbearing age, although the age range in the literature is broad (11-83 years)⁷⁻⁹. Most patients have a recent history of pregnancy and breastfeeding^{4,5,10}.

The most common clinical presentation is a breast lump, of hard consistency, with abscess formation, predominantly unilateral (bilateral involvement is rare)¹¹⁻¹³. It can be located on any quadrant, with the most common location being the subareolar region, or it can occur diffusely. The patient may also present with pain, erythema, single or multiple fistula formation, swelling or axillary lymphadenopathy¹⁴. The disease can be locally aggressive, with reported recurrence rates of 16-50%¹⁵⁻¹⁷.

Granulomatous mastitis diagnosis can only be confirmed by histopathology. Diagnostic tools include ultrasound-guided core needle biopsy (CNB)^{3,18,19}. Before 1980, surgical excision of the entire lesion was more common^{4,19}, but CNB^{3,20} is currently preferred.

Biopsy specimen, on histopathological examination, is characterized by the presence of non-caseating multinucleated giant cell granulomas, limited to mammary lobes with microabscesses²¹⁻²³. Fine needle aspiration cytology often reveals an abundance of epithelioid histiocytes, on a background where neutrophils predominate^{11,12}.

The purpose of this study was to carry out a retrospective review of the clinical aspects, diagnosis and treatment of patients who attended mastology outpatient services at three referral clinics in the city of Medellín, with histopathological diagnosis of granulomatous mastitis, between January 1, 2016 and December 31, 2019.

Method

Retrospective, descriptive study of users cared for at mastology outpatient services of *Profamilia* clinics, *Clinica Medellín* and *Clinica del Prado*, in the city of Medellín, between January 1, 2016, and December 31, 2019. A total of 848 users were cared for, and a search was made on medical records with code N61X "Inflammatory disorders of breast" of the International Classification of Diseases (ICD-10). Fifty-three records corresponding to non-puerperal mastitis diagnosis were identified. An independent database was created for this patient cohort, and a subgroup analysis of the 18 cases with granulomatous mastitis histopathological diagnosis and a microbiological test that ruled out bacterial infection, tuberculous or fungal. Demographic data and clinical and pathological characteristics were obtained from medical records. Data on ethnicity, age, history of smoking, date of last delivery, clinical characteristics as main complaint, physical findings, affected side, ultrasound and mammography findings, types of treatment, such as antibiotic therapy, steroids or methotrexate, surgical intervention, follow-up, and recurrence were included.

Three necessary criteria were established for the diagnosis of granulomatous mastitis:

- Negative culture for aerobic microorganisms.
- Histopathological confirmation, by CNB or lumpectomy, of non-caseating granuloma confined to the mammary lobes, not associated with trauma or post-surgical.
- Histochemical stain negative for Ziehl-Neelsen and methenamine silver.

A descriptive analysis of sociodemographic and clinical variables was carried out. Absolute frequencies and percentages, means and standard deviations were calculated, according to the nature and distribution of variables. Normal distribution was validated using the Shapiro Wilk goodness-of-fit test. A bivariate analysis was carried out with the chi-square test in order to establish the association between resolution or recurrence and treatment modalities. For hypotheses testing, a 95% confidence interval, and a significance level of 5% were established. Epidat software, version 3.1, was used.

Ethical aspects

This research was submitted to the medical ethics committee of *Clinica Profamilia*, and medical management authorized the study protocol. This was a

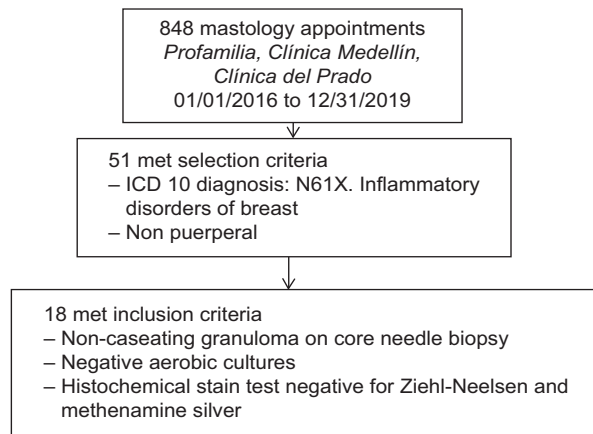


Figure 1. Patient flowchart.

risk-free research in accordance with the classification set forth in Article 11 of Resolution No. 008430 of 1993 (issued by the Ministry of Health of Colombia).

Results

From January 1, 2016, to December 31, 2019, 848 patients diagnosed with ICD-10 code N61X "Inflammatory disorders of the breast" were provided care. Fifty three women diagnosed with non-puerperal mastitis were identified, and 18 met the inclusion criteria for granulomatous mastitis; for this cohort, prevalence is 2.12% (Fig. 1).

Sociodemographic and clinical characteristics

Sociodemographic characteristics are shown in table 1. All cases (18, 100%) were women of mestizo ethnicity, the majority cared for at *Clínica Profamilia* (11, 61.1%) and residents of Medellín (10, 55.6%). Mean age was 30.4 years (standard deviation [SD]: 5.7; range: 27-48). Most patients (17, 94.4%) had no history of tobacco use or family history of breast cancer (14, 77.8%). Average last delivery date was 6.5 years earlier (SD: 5.3; range: 3-19).

Clinical characteristics are shown in table 2. The most common main complaint was inflammatory changes (12, 66.7%), followed by breast mass and associated mastalgia (12, 66.7%). Average symptom-onset time was 20.4 months (SD: 44.5; range: 1-180). Breast compromise did not show a dominant laterality, and the most common location was central or retroareolar (10, 55.6%). The most common clinical signs were skin thickening (18, 100%) and fistula or scar (16,

Table 1. Sociodemographic characteristics

Variable	Frequency (%) (n = 18)
Age (years)	
Mean	30.4
Standard deviation	5.7
Range	23-39
Medical Center	
Profamilia	11 (61.1)
Clínica Medellín	6 (33.3)
Clínica Prado	1 (5.6)
Gender	
Females	18 (100%)
Males	0 (0%)
Race	
Caucasian	0 (0%)
Mestizo	18 (100%)
Black	0 (0%)
Occupation	
Not employed	11 (61.1)
Employed	6 (33.3)
Independent	1 (5.6)
Residence	
Medellin	10 (55.6)
Metropolitan area	2 (11.1)
Rest of Antioquia	6 (33.3)
Insurance	
Contribution	12 (66.7)
Subsidized	6 (33.3)
Family history of breast cancer	
Yes	4 (22.2)
No	14 (77.8)
Tobacco use	
Yes	1 (5.6)
No	17 (94.4)
Date of last delivery (years)	
Mean	6.5
Standard deviation	5.3
Range	3-19

88.9%). Only 5 patients (27.8%) had lumps and one (5.6%) erythema on physical examination. There were no cases with adenopathies or fever.

Paraclinical examinations

Paraclinical investigations are detailed in table 3. Only one patient (5.6%) had prolactin determined and it was abnormal. All patients (18, 100%) underwent breast ultrasound, and Breast Imaging Reporting and Data System (BI-RADS) category 2 was the most common. Only in 2 cases (11.2%) was mammography performed.

Table 2. Clinical characteristics

Variable	Frequency (%) (n = 18)
Main complaint	
Mass	5 (27.8)
Inflammatory changes	12 (66.7)
Thelorrhea	1 (5.6)
Mastalgia	
Yes	12 (66.7)
No	6 (33.3)
Symptom-onset time (months)	
Mean	20.4
Standard deviation	44.5
Range	1-180
Breast laterality	
Right	8 (44.4)
Left	9 (50)
Bilateral	1 (5.8)
Mass on physical examination	
Yes	5 (27.8)
No	13 (72.2)
Mass size (cm)	
Mean	5.4
Standard deviation	2.9
Range	2-10
Localization	
Central	10 (55.6)
Upper medial quadrant	5 (27.8)
Upper outer quadrant	3 (16.7)
Skin thickening	
Yes	18 (100)
No	0 (0)
Fistula/scar	
Yes	16 (88.9)
Single	7 (38.9)
Multiple	9 (50)
No	2 (11.1)
Adenopathies	
Yes	0 (0)
No	18 (100)
Erythema	
Yes	1 (5.6)
No	17 (94.4)
Fever	
Yes	0 (0)
No	18 (100)

Follow-up

Follow-up data are shown in table 4. Average follow-up was 4.6 months (SD: 4.7; range: 1-17). In nearly all cases was the disease resolved (17, 94.4%), with mean resolution time being 7 months (SD: 8.2; range: 2-36). There were 5 cases (27.8%) with recurrence, with an average of 2.7 episodes (SD: 2.2; range: 1-6).

Table 3. Paraclinical investigations

Laboratory tests	
Variable	Frequency (%) (n = 18)
Prolactin measurement	
Yes, normal	0 (0)
Yes, abnormal	1 (5.6)
No	17 (94.4)
Imaging	
Ultrasound findings	
Nodule	1 (5.6)
Cyst	1 (5.6)
Collection	13 (72.2)
Distortion	1 (5.6)
Benign nonspecific	2 (11.1)
Ultrasound BI-RADS	
0	0 (0)
1	0 (0)
2	8 (44.4)
3	5 (27.8)
4	5 (27.8)
5	0
6	0
Mammography	
Yes	2 (11.2)
No	16 (88.9)

Treatment

Treatment modalities are shown in table 5. Antibiotic therapy was the most commonly used treatment (13, 72.2%), with mean duration being 10 days (SD: 3.3; range: 7-15), mostly with multiple antibiotics (8, 44.4%); the most commonly used antibiotics were dicloxacillin, clindamycin and ciprofloxacin. Ultrasound-guided drainage was performed in 6 cases (33.3%) and mastotomy in 3 (16.7%).

Corticosteroids were used in 8 cases (44.4%), with an average prednisone dose of 18 mg (SD: 10.3; range: 5-30) and mean duration being 5.4 weeks (SD: 3.7; range: 3-12). The regimen used in most cases was high-dose (0.5 mg/kg/day), with gradual dose reduction.

In two cases (11.1%), methotrexate was used, with mean treatment duration being 46.5 days (SD: 61.5; range: 3-90).

Surgery was carried out only in 3 cases (16.7%), among which there was one (5.6%) mastectomy.

In the different participating institutions, the diagnostic approach and treatment algorithms are at the discretion of the treating physician. There is a tendency for the granulomatous mastitis diagnosis to be made as an exclusion disease, with histopathological

Table 4. Follow-up

Variable	Frequency (%) (n = 18)
Recurrence	
Yes	5 (27.8)
No	13 (72.2)
No. of recurrences	
Mean	2.7
Standard deviation	2.2
Range	1-6
Follow-up (months)	
Mean	4.6
Standard deviation	4.7
Range	1-17
Resolution	
Yes	17 (94.4)
No	1 (5.6)
Time to resolution (months)	
Mean	7.0
Standard deviation	8.2
Range	2-36

confirmation by immunohistochemistry, and treatment in most cases includes anti-staphylococcal antibiotic therapy as monotherapy or combination therapy, and in few cases, patients undergo surgery. Table 6 shows the bivariate analysis for the association between granulomatous mastitis resolution or recurrence and different types of treatment.

Discussion

The prevalence of granulomatous mastitis in the present study was 2.12%, similar to that reported by Baslaim et al.⁵, who found a prevalence of 1.8%. In the United States of America, an incidence of 0.37% was reported⁶, and higher rates have been described in Latin and Asian women⁵.

Mean age in this series was 30 years, with a range between 23 and 39 years, similar to that reported by other authors, such as DeHertogh et al.⁹ and Han et al.⁷, in whose series mean age was between 20 and 49 years. Most patients have a recent history of pregnancy and breastfeeding^{4,5,10}; in the present study, average date of last delivery was 6.5 years earlier.

The most common clinical presentation in this series were inflammatory changes of the breast, such as inflammation, skin thickening, pain, and abscess and fistula formation. It can affect any quadrant, with higher tendency for the subareolar region, similar to that reported

Table 5. Treatment

Variable	Frequency (%) (n = 18)
Antibiotics	
Yes	13 (72.2)
No	5 (27.8)
Antibiotic therapy duration (days)	
Mean	10
Standard deviation	3.3
Range	7-15
Antibiotics	
Penicillin	2 (11.1)
Macrolide	1 (5.6)
Clindamycin	2 (11.1)
Multiple	8 (44.4)
Not reported	5 (27.8)
Ultrasound-assisted drainage	
Yes	6 (33.3)
No	12 (66.7)
Mastotomy	
Yes	3 (16.7)
No	15 (83.3)
No. of drains	
1	18 (100)
2	0 (0)
Steroid treatment	
Yes	8 (44.4)
No	10 (55.6)
Prednisone daily dose (mg)	
Mean	18
Standard deviation	10.3
Range	5-30
Time on steroid treatment (weeks)	
Mean	5.4
Standard deviation	3.7
Range	3-12
Methotrexate	
Yes	2 (11.1)
No	16 (88.9)
Time on methotrexate treatment (days)	
Mean	46.5
Standard deviation	61.5
Range	3-90
Surgery	
Yes	3 (16.7)
Quadrantectomy	2 (11.1)
Mastectomy	1 (5.6)
No	15 (83.3)

by Akcan et al.¹⁴, although, in their study, masses were the most common finding, which is why it is necessary for breast carcinoma to be ruled out^{24,25}. Other differential diagnoses include other causes of granulomatous

Table 6. Bivariate analysis for the association between granulomatous mastitis resolution and recurrence and different types of treatment

Resolution				Recurrence			
Variable	OR	95% CI	p	Variable	OR	95% CI	p
Antibiotic therapy	1.25	0.80-1.93	0.09	Antibiotic therapy	0.02	0.00-0.41	0.00
Echo-guided drainage	1.09	0.92-1.29	0.46	Echo-guided drainage	1.71	1.06-2.76	0.06
Mastotomy	1.07	0.93-1.22	0.64	Mastotomy	8	0.53-120	0.09
Steroids	1.11	0.90-1.36	0.30	Steroids	9	0.74-108	0.06
Methotrexate	1.06	0.94-1.21	0.71	Methotrexate	3	0.15-59.8	0.45
Surgery	1.07	0.93-1.22	0.64	Surgery	1.37	0.09-19.6	0.81

CI: confidence interval; OR: odds ratio.

inflammation due to infections such as tuberculosis, parasitic or fungal infections, and non-infectious causes such as sarcoidosis, Wegener's granulomatosis, giant cell arteritis, polyarteritis or foreign body reaction^{2,18,26,27}.

In the present study, ultrasound was carried out in all 18 cases, with the most common findings being heterogeneous collection, echogenicity areas with cutaneous fistula and overlying skin thickening. BI-RADS 2-3 categories were the most frequent, similar to findings reported by other authors²⁸.

Treatment remains controversial and is not universally accepted; it includes the use of antibiotics, corticosteroids, methotrexate, and surgery. In general, it is a self-limiting disease with a natural course of 6 to 12 months regardless of which treatment is received, and in more than half the patients who do not receive any treatment the disease resolves completely^{16,29}. In this study, 94% of cases did resolve completely in an average period of 7 months; a significant percentage (28%) had recurrence.

In this study, non-surgical management was preferred (81.3%). Some authors have suggested conservative management as the most appropriate treatment method³⁰⁻³³. Oral antibiotics were administered to 72% of patients, due to an initial diagnosis of infectious mastitis. Hovanessian Larsen et al.³ report that antibiotic therapy was not useful and only 6 (3%) of their patients had improvement. The bivariate analysis of the present study showed no benefit; it can be argued that antibiotics should not have a significant effect because pathogenesis does not include bacterial infection^{3,34}.

According to the autoimmune theory, steroids are the first-line treatment. In this series, 44% of patients received prednisone. It was reserved for clinical presentation with

advanced or more severe symptoms because high doses of steroids can lead to significant side effects. Administration period in this study was 5 weeks, while other studies report an average duration of 5 months^{9,14,35}. Azlina et al.¹⁷ found recurrence rates of up to 50%. The bivariate analysis of the present study showed no benefit in recurrence resolution or reduction.

Methotrexate was used in those patients who were resistant to steroid therapy after 3 months, as well as for recurrence after steroid therapy initiation with variable responses^{35,36}. Akbulut et al.³⁵ retrospectively analyzed 541 cases of granulomatous mastitis treated with steroids, methotrexate or both between 1972 and 2010, and found a high rate of recurrence, as well as the occurrence of adverse side effects. In the present study, the bivariate analysis showed no improvement in recurrence resolution or decrease.

On the other hand, regarding surgical intervention, when commonly used in clinical practice, recurrence rates of 16% to 50% have been reported, which is why some authors recommend for extirpation to be carried out with negative margins^{15-17,37}. In this study, surgery was performed in 16.7% of patients, and, in one case, it was mastectomy. In the literature review, recurrence rates ranged from 5.5% to 50%³¹. In this study, there was recurrence in 5 patients (27.8%); in the bivariate analysis, antibiotic therapy showed a significant recurrence reduction.

Limitations

The limitations of this study include its retrospective nature and that the use of oral contraceptives was not available as a variable.

Conclusions

Granulomatous mastitis is a benign inflammatory disease of the breast, of unknown cause, infrequent and difficult to diagnose, which affects women of childbearing age and generally occurs with inflammatory changes, mastalgia, and in many cases, with a breast mass. Ultrasound is useful for determining abscessed masses and collections characteristics, for taking biopsies, and for percutaneous drainage. Final diagnosis requires histological confirmation. Treatment can range from observation to the use of corticosteroids, with surgical resection being reserved for few cases. Reported recurrence is high, and long-term follow-up is essential.

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Conflicts of interest

The author declares that he has no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The author declares that the procedures that were followed adhered to the ethical standards of the responsible committee for experimentation on human beings and were in agreement with the World Medical Association and the Declaration of Helsinki.

Confidentiality of data. The author declares that he has followed the protocols of his work center on the publication of patient data.

Right to privacy and informed consent. The author has obtained informed consent from the patients and/or subjects referred to in the article. This document is in his possession.

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