ORIGINAL ARTICLE

Idiopathic Granulomatous Mastitis—A Prospective Study of 49 Women and Treatment Outcomes with Steroid Therapy

Tanu S. Pandey, MD, MPH, FACP,* Jennifer C. Mackinnon, MD, MM,† Leah Bressler,‡ Amy Millar,§ Elizabeth E. Marcus, MD,¶ and Pamela S. Ganschow, MD*

*Department of Medicine, John H. Stroger Jr. Hospital of Cook County/Rush University Medical Center, Chicago, Illinois; †Department of Medicine, Froedtert and The Medical College of Wisconsin, Milwaukee, Wisconsin; ‡Physician Assistant Program, College of Health Professions, Rosalind Franklin University of Medicine and Science, North Chicago, Illinois; §Rush Medical College, Rush University Medical Center, Chicago, Illinois; ¶Department of Surgery, John H. Stroger Jr. Hospital of Cook County/Rush University Medical Center, Chicago, Illinois

Abstract: Idiopathic granulomatous mastitis (IGM) is an infrequently reported benign breast disease of unknown etiology. Surgical treatment has been widely advocated but can be disfiguring. We describe demographic and clinicopathologic features of women with IGM in a safety net hospital, and evaluate steroid therapy as a breast-conserving modality of treatment. We also examine a possible ethnic predominance in Hispanic women. We conducted an observational prospective cohort study of all women with biopsy-proven granulomatous mastitis in the breast clinics of an urban safety net public hospital from 2006 to 2010. Demographic, ethnic and clinical data, treatment history, and response to treatment were collected. Patients were followed up prospectively to determine the type of treatment prescribed, complete resolution of disease, and median time to resolution. A nested case–control study was conducted to examine Hispanic prevalence using chi-square statistic. The mean age was 35 years. 80% were Hispanic. 80% presented with a painful breast mass. 59% initially received antibiotics with incomplete resolution. 90% women were prescribed oral steroids, 3% underwent surgical treatment, and 6% remained under observation with spontaneous resolution. Of those who received steroid, 80% had complete resolution of disease with a median time to complete resolution of 159 days (IQR 120–241 days). Ethnicity data in a nested case–control study revealed that women in the IGM group were more likely to be Hispanic than in the control group with an odds ratio of 3 (95% CI 1.42–6.24, p-value 0.0032). IGM is a benign but locally aggressive breast disease. Treatment with steroids is an effective breast-conserving option. Predominance in Hispanic women of childbearing age suggests a common genetic, environmental, immunologic, or infectious etiology and warrants further study with a multi-disciplinary approach.

Key Words: benign breast disease, breast granuloma, breast lump, granulomatous breast disease, mastitis

BACKGROUND

Granulomatous disease of the breast is uncommon and may be seen in tuberculosis, connective tissue disorders, and sarcoidosis (1). Idiopathic granulomatous mastitis (IGM) is an infrequently reported chronic disease of the breast of unclear etiology. First described by Kessler and Woolloch (2), IGM has a diverse spectrum of presentation including single or multiple painful or painless breast mass(es) (Fig. 1), breast ulcers, and sinus or abscess formation (Fig. 2). Definitive diagnosis requires histologic evaluation of the breast and the pathologic hallmark is noncaseating granulomas (Fig. 3) with cells of chronic inflammation such as histiocytes and multinucleated giant cells (Fig. 4). To label it as idiopathic, secondary causes of breast granulomas must be excluded.

Idiopathic granulomatous mastitis frequently presents with a clinical picture similar to infectious mastitis and breast cancer, resulting in treatment with antibiotics and surgical interventions. Limited data are available regarding etiologic factors and best possible
treatment, and include case reports, retrospective case series, and literature reviews (3–5). Primary treatment strategies include observation until spontaneous remission, oral corticosteroids, and surgery including lumpectomy, partial mastectomy, or total mastectomy (5). There is no clinical consensus on the ideal therapeutic management and both surgical and nonsurgical treatment with steroids have been advocated as the first line of treatment. Treatment types and outcomes of 116 cases of IGM reported from 1972 to 2006 were analyzed in a review in 2007 and surgery was described as the most common approach practiced by specialists (3). Highest success rates were seen with partial and total mastectomy and the lowest with oral steroid therapy. Some studies have advocated surgery as the primary treatment modality (6–8), whereas others have supported steroid therapy as first choice (9,10). However, recurrence rates were found to be high in all types of surgery except total mastectomy (3,8,11,12). Clinical trials comparing the effectiveness of different treatment options have not been done. A case series of nine women in Indiana was reported was by the Centers for Disease Control and Prevention in 2009 (13). No treatment with steroids was prescribed in this study and a Hispanic predominance was suggested. This is the largest case series ever reported where eight of the nine women were of Hispanic origin. Other reports of cases from Asia and
Middle East have suggested a possible higher prevalence in women there (7). However, published literature is limited and tangible existing ethnic predisposition cannot be concluded based on them. Reports of IGM masquerading as breast carcinoma have been published, sometimes resulting in total mastectomy (14). Granulomatous disease of the breast may be associated with autoimmune diseases and it has been suggested that breast feeding and use of oral contraceptives may have a role in IGM (3,15,16).

The gold standard for definitive diagnosis is core breast biopsy (17). Mammography is frequently read as suspicious for malignancy with ill-defined focal densities and spiculated pattern (Fig. 5). Ultrasound may show a single mass or multiple heterogeneous masses with diffuse parenchymal edema, fluid in fat planes, and abscess formation. MRI findings include parenchymal enhancement, with asymmetrical signal intensity changes, not specific for IGM. Ozturk et al. described mammographic, ultrasonographic, and MRI findings of IGM as being inconclusive for differentiating benign from malignant disease due to the heterogeneous spectrum of presentation (18).

We report a case series of 49 women with biopsy-proven IGM at a hospital-based breast clinic in an urban academic public healthcare system in Chicago. We conducted an observational study to evaluate outcomes with nonsurgical treatment with steroids, as well as to examine demographic and ethnic data. There were three questions that we posed for the research study: (a) Is nonsurgical treatment with steroids a feasible breast-conserving option for women with IGM? (b) What is the duration of treatment with steroids for complete resolution of disease? (c) Is there a higher prevalence in Hispanic women and possible etiology related to the place of birth?

METHODS

This is an observational prospective cohort study conducted at the John H. Stroger Jr. Hospital of Cook County in Chicago, IL, the largest public hospital in Illinois and third largest in the United States. The hospital accepts specialty referrals from more than 200 primary care clinics serving mostly under- and uninsured patients. At our institution, a nonsurgical initial approach has been adopted to treat IGM. We conducted a prospective cohort study of women with newly diagnosed IGM to evaluate response to oral steroid treatment and a nested case–control study to address Hispanic predominance.

Study Population

We recruited 49 women between 2006 and 2010 in the breast consult clinic at John H. Stroger Jr. Hospital of Cook County. Women were eligible for the study if they had newly diagnosed biopsy-proven granulomatous mastitis. There were no specific exclusion criteria. All cases presenting to the reporting authors between 2006 and 2010 were included in the study.

Study Design and Recruitment

We actively recruited women referred to the breast clinic with biopsy-proven granulomatous mastitis during their regular clinic visit. Each participant was given a unique study identifier. Baseline data were obtained from patients, electronic medical records, and paper charts, as well as on the telephone. Medical record abstraction was done to include the following information: date of birth, medical record number, age, ethnicity, city, state and country of birth by patient report, place of last 5 years of residence, date and site of first visit for breast problem, date of first visit to the breast consult clinic, presenting clinical manifestations, physical examination findings, pertinent family history, obstetrical history including last

Figure 5. Mammographic appearance of IGM: BI-RADS 4 (Suspicous for malignancy).
childbirth and breast feeding by medical record or patient report, medication list, review of systems, imaging results including mammography and breast ultrasound, dates and results of fine-needle aspiration and core biopsy, initial date and dose of prescribed therapy, duration of treatment and response to treatment. A systematic evaluation was done to exclude secondary causes of breast granulomas like tuberculosis, connective tissue disorders, and fungal infections for which laboratory tests were done including complete blood count, metabolic panel, liver function tests, sedimentation rate, antineutrophilic antibody, rheumatoid factor, antineutrophil cytoplasmic antibodies (p and c), C-reactive protein, HIV antibody test, rapid plasma reagin test, prolactin level, thyroid-stimulating hormone level, Tuberculin testing, and chest x-ray. Breast core biopsy was performed and samples were sent for histology and microbiological smears, gram stain, and cultures for bacteria, fungus, and acid fast bacilli. These diagnostic measures were performed as part of routine care for evaluation of the breast abnormality and were not a specific intervention for the study.

As part of the therapeutic plan, steroid treatment was initiated with oral prednisone at a starting dose of 40 mg with follow-up visits every 2–4 weeks. The dose was tapered by 5–10 mg every 2–4 weeks based on symptom relief described by the patient and on clinical breast examination performed by the physician. Mean follow-up duration after complete resolution was 6–12 months. Preventive treatment for osteoporosis was prescribed with Alendronate, calcium, and Vitamin D if the treatment was anticipated to last for more than 3 months. Those without clinically detectable disease and spontaneous resolution were followed up with observation for 6–12 months. Those who did not resolve with multiple courses of steroids or those who had major adverse effects from steroids were referred for excision. Follow-up data were collected prospectively at clinic visits by three authors (TP, JM, LB) and verified by the principle investigator (TP).

The protocol for the study was approved by the Institutional Review Board of our institution. All participants provided informed consent. No commercial entity had any role in the study design, data accrual, statistical analysis, or preparation of the manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Primary Measures of Assessment and Statistical Analysis

We identified the following primary outcome measures: (a) type of treatments—observation, steroid, or surgery, which was determined at the discretion of the physician and patient; (b) the response to treatment including initial response and complete resolution; (c) the time to complete resolution. Initial response to steroid treatment was defined as decrease in pain, swelling, erythema, tenderness, and the size of lump within 2 weeks of treatment initiation as described by the patient and confirmed by clinical breast examination by the provider. Complete resolution was defined as absence of pain, swelling, erythema, tenderness, and lump after treatment. Time to complete resolution was defined as the number of days from the date of initiation of treatment to the last day of treatment. Median time to resolution was measured in the number of days with an interquartile range. Flares and recurrences were also analyzed. Recurrence was defined as reoccurrence of symptoms after complete resolution and a symptom-free period. Flare was defined as increase in symptoms while on treatment. Side effects from the treatment were described and were defined as any symptom resulting from the treatment. Surgical treatment was defined as complete excision, lumpectomy, or mastectomy. Treatment of ulcers, sinuses, and abscess drainage while receiving steroid treatment was not described as definitive surgical treatment but as supplemental surgical interventions. Data were collected in Microsoft Access and statistical analysis was performed using the statistical software (STATA; STATACorp LP, College Station, TX).

Nested Case–Control Study

A nested case–control study was conducted to examine a Hispanic predisposition. We sought to investigate the prevalence of IGM in patients of Hispanic ethnicity in our study population and the question asked was “are woman with IGM more likely to be Hispanic?” We sampled a group of age-matched control patients from all patients with a visit to the breast clinics during the dates of the IGM registry (January 2006 to December 2010). We categorized our IGM patients into 10 age groups by 5-year increments. We then randomly selected patients from our control group in a 4:1 match to the IGM population for each age group and
extracted information on the self-identified ethnicities of these control populations, as reported on initial intake. Our control group was composed of 196 patients. Ethnicities were categorized as either “Hispanic” or “Other.” Statistical analysis utilized a chi-squared test and odds ratio with 95% confidence intervals was performed on STATA.

We also collected data on origin of the Hispanic women from Mexico by the state of birth. We then compared these data to the states of origin of Mexicans immigrating to Chicago by obtaining data on the general immigration patterns with help from the Mexican Embassy. The aim was to examine if the geographical distribution of Mexican women with IGM was different from or similar to the general trend of immigration from Mexico to Chicago.

RESULTS

Forty-nine women with newly diagnosed biopsy-proven IGM presented to the authors during the study period and all were enrolled in the study. The baseline characteristics of these women and clinical features at presentation are described in Table 1. The mean age was 35 years (range 24–67). Of the 49 women, 39 women presented with a painful breast mass with overlying erythema. Treatment plans prescribed, outcomes of those prescribed steroid treatment, and time to complete resolution were recorded in Table 2. Forty-four women were prescribed oral steroids and 100% responded with some relief of symptoms in the first 2 weeks of steroid treatment. Thirty-five had complete resolution of disease on steroid therapy. Time to complete resolution on steroid therapy was also recorded as in Table 2. The median time to resolution was 159 days (5.3 months) with an interquartile range of 120–241 days. The participants were followed up for 6–12 months after complete resolution. During this time, 23% had recurrence of disease and all resolved with a second course of steroids.

Table 1. Demographic and Clinical Characteristics

| Characteristics                                      | Total (n = 49), n (%) |
|------------------------------------------------------|----------------------|
| Age at presentation                                  |                      |
| <35                                                  | 28 (57)              |
| 35–45                                                | 16 (33)              |
| >45                                                  | 5 (10)               |
| Ethnicity                                            |                      |
| Hispanic                                             | 39 (80)              |
| African-American                                     | 7 (14)               |
| Other                                                | 3 (6)                |
| Country of birth                                     |                      |
| Mexico                                               | 34 (69)              |
| United States                                        | 11 (22)              |
| Other                                                | 4 (8)                |
| Time since last delivery                             |                      |
| ≤5 years                                             | 31 (63)              |
| >5 years                                             | 12 (25)              |
| Nulliparous                                          | 4 (8)                |
| Unknown                                              | 2 (4)                |
| Time since last breastfed                            |                      |
| ≤5 years ago                                         | 29 (59)              |
| >5 years ago                                         | 9 (18)               |
| Nulliparous                                          | 4 (8)                |
| Never                                                | 5 (10)               |
| Unknown                                              | 2 (4)                |
| Antibiotic treatment†                                 |                      |
| Antibiotics received                                 | 29 (59)              |
| Resolution with antibiotics                          | 0 (0)                |
| Predominant symptom at presentation                  |                      |
| Painful breast mass                                  | 39 (80)              |
| Painless breast mass                                 | 8 (16)               |
| Purulent drainage                                    | 1 (2)                |
| None; image detected                                | 1 (2)                |
| Pattern of disease                                   |                      |
| Unilateral                                           | 47 (96)              |
| Bilateral                                            | 2 (4)                |

*Patient ethnicity marked other includes Caucasian, Asian, and multiethnic patients.
†Antibiotic treatment indicates antibiotics prescribed prior to definitive pathologic diagnosis.

The clinical course of IGM in the study is outlined in Figure 6. To summarize, 49 women were diagnosed with IGM and received three treatment types. Those who were under observation or received surgery resolved without recurrence, and of the 44 who received steroids, 35 resolved completely.

Ethnicity Data in Age-Matched Controls

The ethnic prevalence was also examined to further investigate prior reports of Hispanic predominance and ethnicity data were collected in a case-controlled study with four age-matched controls for each case (Table 3). 80% of our cohort was Hispanic, whereas 57% of controls were Hispanic. Statistical analysis utilized a chi-squared test and the data revealed that patients in the IGM group are more likely to be Hispanic in origin than patients in the control group with an odds ratio of 3 (95% CI 1.42–6.24, p-value 0.0032).
Table 2. Summary of Treatment Prescribed and Outcomes

| Treatment outcomes                                      | Total (n = 49), n (%) |
|---------------------------------------------------------|-----------------------|
| Definitive treatment                                    |                       |
| Steroid therapy                                        | 44 (90)               |
| Observation only                                        | 3 (6)                 |
| Surgical excision                                       | 2 (4)                 |
| Final outcome with steroid treatment                    |                       |
| Initial response within 2 weeks                         | 44 (100)              |
| Complete resolution                                     | 35 (80)               |
| Lost to follow-up                                       | 6 (13)                |
| No resolution                                           | 3 (7)                 |
| Resolved with steroid + surgery                         | 1 (12)                |
| Still receiving steroids                                | 2 (5)                 |
| Recurrence‡                                             | 10 (23)               |
| Flare(s)†                                               | 11 (27)               |
| Time to resolution on steroid (in days, n = 35)§         |                       |
| <90                                                     | 5 (14)                |
| 90–180                                                  | 14 (40)               |
| 180–270                                                 | 6 (17)                |
| 270–360                                                 | 3 (9)                 |
| >360                                                    | 7 (20)                |
| Median time to resolution in days (IQR)§                 | 159 (120–241)         |

Recurrence and flare were only reported for those on steroids.

*Recurrence was defined as reoccurrence of symptoms after complete resolution and a symptom-free period.
‡Flare was defined as increase in symptoms while on treatment (excluding three patients who were missing data for flare).
§Time to resolution recorded only for patients who had complete resolution on steroid treatment.
IQR: interquartile range.

Ethnicity Data by State of Origin in Mexico

A total of 32 patients in the IGM data base reported their place of birth as Mexico. We found that they mostly originated from a cluster of states in the south, which is reflected in the map of Mexico (Fig. 7). To further explore this issue, we compared our cohort to the state of origin of Mexicans immigrating to Chicago with help from the Mexican embassy (19). We gathered data on general immigration patterns to Chicago by state of origin in Mexico. The most recent available data were collected in 2010. The top two most common states of birth in the IGM cohort were Guerrero and Michoacán, also the top two states from which Chicago has the most immigrants from. However, the trend was different beyond the top two states as shown in Table 4.

DISCUSSION

To date, this is the first prospective study of a large case series of women with IGM. Our data illustrate the diverse spectrum of presentation of IGM, unexplained higher prevalence in Hispanic women, and an effective nonsurgical treatment option with oral steroids. Furthermore, the study highlights the need for clinical decision making based on keeping a high index of clinical suspicion in cases of mastitis not responsive to antibiotics or other failed treatments. The clinical picture may be varied, although in our cohort, the most common presentation was a painful breast mass with overlying erythema, tenderness, and warmth. Clinical evidence of inflammation suggests acute infectious mastitis and 59% women in the study received single or multiple courses of antibiotics without any response. No association with breast feeding was noted and no microbiological evidence of tuberculosis was found with negative smears for acid fast bacilli. A majority of women responded to treatment with oral steroids over a 3- to 18-month period with complete resolution of the disease. Although IGM is a nonmalignant disease, it is aggressive in its course and duration and can last years with or without treatment, resulting in serious debilitation, scarring, and psychosocial problems (13,20–22). In our cohort, the majority of women were highly symptomatic with one or more painful breast mass(es), some of them long standing. For this reason, conservative measures such as serial observation for spontaneous resolution have not been well studied, but should be in the future, especially among patients without severe or highly symptomatic disease.

A higher prevalence in Hispanic women was noted as evident from the nested case–control study. Although nonwhite predominance has been suggested, there is only one published study that refers to a specific Hispanic predominance conducted in Indiana by CDC in a small case series of nine women with IGM, eight of whom were Hispanic (13). No commonality
other than ethnicity existed between these women that could indicate a possible etiologic factor. An editorial comment mentioned that like all cases of IGM, there was no obvious clear-cut cause for IGM in that cluster. Similar findings in our cohort indicate an absence of a possible common etiology. Response to steroids indicates a possible autoimmune cause, but further studies are needed to identify one or more common genetic, infectious, immunologic or environmental factors. Lack of published literature other than case reports and small case series limits any concrete discussion of this geographic clustering. There has been speculation that as majority of the women are immigrants from countries where tuberculosis is endemic and BCG vaccination common, there is a possibility that IGM occurred in response to a residual reaction to BCG or to past exposure to mycobacterium species. Absence of clinical evidence of active tuberculosis isolated to the breast indicates this to be a remote possibility.

On examining the ethnicity and place of birth of Mexican women with IGM, we found that the trend was reflective of the general trends of immigration patterns of Mexicans to Chicago. However, perhaps there were some nuances that were not quite the same. The notable exceptions make it impossible to exclude the possibility that environmental or social factors specific to some Mexican states may play a role in the later development of IGM. Women of other Hispanic countries were uncommonly seen in our cohort and there are no published data on any such studies done regarding IGM among Hispanic women of diverse origin. The dominant population seen at our institution is of Mexican origin.

This analysis is the largest case series in literature that has shown success with oral steroid treatment. The data are compelling enough for the authors to make a definitive recommendation in support of nonsurgical treatment of IGM with oral prednisone. In addition, surgery may be an option if medical treatment fails or as adjunct to medical treatment for the management of abscess, sinus, and ulcers. Other investigators have recently published smaller data supporting medical management with oral steroids (9,23,24). The strength of our study is that this is the largest prospective case series of IGM ever reported in which oral steroid therapy was examined in a systematic manner. We now have more than 70 women in our registry with newly diagnosed IGM, the majority of who have received prednisone as initial treatment.

The main limitation of the study was that these are observational data as the study was not designed as a clinical trial to compare different treatments. We did not routinely culture the tissue for tuberculous or atypical mycobacteria and fungus, although stains/smears

| Table 3. Self-Reported Ethnicities for IGM and Control Patients (Case–Control Study*) |
|---------------------------------|---------------------------------|
| Ethnicity          | IGM patients (n = 49), n (%) | Control patients (n = 196), n (%) |
| Hispanic          | 39 (79.6)                     | 111 (56.6)                   |
| Other             | 10 (20.4)                      | 85 (43.3)                    |

*OR 3 (95% CI 1.42–6.24, p-value 0.0032).

Figure 7. Mexico*. *http://www.istanbul-city-guide.com/map/country/mexico-map.asp; †States of origin of Mexican women with IGM.
id not support these infections. Detailed information on time from resolution to recurrence and duration of second cycle of prednisone therapy were not captured, although all women with a recurrence resolved subsequently. The reason for biopsy in this cohort of woman was the presence of a painful or painless breast mass that was a concern for breast carcinoma. Some may have not responded to empiric treatment with antibiotics for presumed infectious mastitis and an alternate etiology was considered. There is a possibility of selection bias based on age, ethnicity, presenting symptoms, and the fact that our institution predominantly serves a vulnerable population of diverse ethnicities and lower socioeconomic groups.

Based on our findings, the authors recommend a suggested approach to treatment: (a) Observation in those cases that are painless, with close monitoring with clinical breast examination and imaging to identify any change in clinical status that would require active treatment. (b) Oral steroid therapy as initial treatment, with the knowledge that this is a chronic disease that may require long-term steroid therapy with consequent adverse effects including gastritis, weight gain, and osteoporosis. (c) Surgical treatment should be limited to steroid refractory and/or recurrent disease and could be lumpectomy or mastectomy based on the extent of disease.

Table 4. State of Birth in Mexico

| Birth state of women with IGM* | Total (n = 32), n (%) |
|--------------------------------|----------------------|
| Guerrero                      | 7 (21)               |
| Michoacán                     | 5 (15)               |
| Mexico City                   | 5 (15)               |
| Hidalgo                       | 4 (13)               |
| Other†                        | 13 (38)              |

State of Origin of Mexican immigrants to Chicago (2010)(19)

| State                | Number |
|----------------------|--------|
| Michoacán           | 10,305 |
| Guerrero            | 8,419  |
| Guanajuato          | 7,874  |
| Jalisco             | 6,493  |
| Mexico City         | 6,078  |
| Veracruz            | 4,432  |
| Puebla              | 3,934  |
| Zacatecas           | 3,385  |
| Durango             | 3,385  |
| Coahuila            | 426    |

*Birth state in Mexico only recorded for patients from Mexico.
†Defined as n < 3 patients from reported state (Puebla, Aguascalientes, Veracruz, San Luis Potosi, Guanajuato, Zacatecas).

CONCLUSION

Idiopathic granulomatous mastitis is an infrequently reported nonmalignant but locally aggressive disease that has a diverse spectrum of presentation. It is predominant in women of childbearing age with an unexplained higher prevalence in Hispanics. In the largest prospective case series to date, we found that the majority of women did not need surgical treatment, which is a novel finding. Steroid therapy was explored in a unique and systematic manner and found to be an effective nonsurgical option. It is the opinion of the authors that oral steroid therapy is an effective breast-conserving treatment for IGM, although the duration of treatment may be long. In addition, etiology of this disease continues to be unknown, but the clustering of Hispanic females of childbearing age suggests an ethnic predisposition that may be genetic, infectious, immunologic, and/or environmental and warrants further study in a multi-disciplinary approach.

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