ORIGINAL ARTICLE

An Observational Study of Granulomatous Mastitis in a Philippine Breast Care Center

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ABSTRACT

Background. Granulomatous mastitis (GM) of the breast has long posed a clinical dilemma in terms of diagnosis and management. GM can range from acute to chronic inflammations, which will have treatment implications. Inflammation of the breast may clinically mimic breast carcinomas and pyogenic abscesses. Thus, in the absence of known etiology, such as trauma or breastfeeding, GM may be difficult to diagnose. Currently, the incidence of GM is 2.4 per 100,000 women and 0.37% of the total population in the US. The rarity of GM contributes to it being a poorly understood disease. It has no definite clinical features and is often confused with a neoplasm or infection clinically and radiologically.

Objective. The study aimed to describe the clinical characteristics of GM seen in the Breast Care Clinic in the Philippine General Hospital (PGH) from January 2015 to June 2019. This study would initially provide institutional data on GM that is relevant in the Philippines

Methods. This is a retrospective observational study of patients with GM seen in the Philippine General Hospital, a national tertiary referral hospital, from January 2015 to June 2019.

Results. A total of 43 patients with pathological findings of GM from January 1, 2015 to June 15, 2019 were recorded. Among these 43 patients, 98% were female. The median age was 38.9 ± 11.3 years old. In 60.5% (26 out of 43) of patients, the initial impression was breast malignancy. The most common clinical presentation in 69.8% (30 out of 43) of the subjects was a breast mass. In more than 50% of the patients, breast ultrasonography was the initial imaging performed. The histopathologic profile of the patients showed inflammation, of which, the greatest were that of chronic granulomatous inflammation (46.5%, n-20). Treatment options performed were tended more medical (53.5%, n-23) than surgical (16.3%, n-7).Among those who received medical treatment, the therapeutics given were antitubercular medications (34.9%, n-15) and antibiotics (16.3%, n-7), while the others had a combination of antitubercular and antibiotic regimen medications (2.3%, n-1); unknown treatment (25.6%, n-11) and none (11.6%, n-5). For patient outcomes, no mortalities were recorded during the study period. However, most patients had inconsistent follow-ups. Approximately 7%-23% of the patients who had followed up within the six months showed improvement or resolution of symptoms.

Conclusion. This study assessed the clinical profiles of patients with GM in a national tertiary referral hospital. Internationally, there is still no consensus on the algorithm and management of GM patients. However, the authors recommend a close follow-up every two weeks to re-evaluate patient response to the medical regimen being administered. The authors recommend a prospective study with a longer follow-up period to gain a deeper understanding of GM in Filipinos.

Keywords: granulomatous mastitis, breast tuberculosis, Asian, Filipino

** Dr. Cua-De Los Santos and Dr. Viray shared first authorship for this manuscript.*

Poster presentation – 22nd Meeting of American Society of Breast Surgeons, April 29-May 2, 2021 (Virtual).

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INTRODUCTION

Granulomatous mastitis (GM) is a rare inflammatory breast disease first described by Kessler and Wolloch in 1972.[1] GM is common in young parous women, with an incidence of 2.4 per 100,000 women and 0.37% of the total population in the US.[2] Predisposing factors considered are lactation and oral contraceptive use. GM can range from acute to chronic inflammation, which will have treatment implications. GM of the breast has long posed a clinical dilemma in terms of diagnosis and management as it may mimic conditions such as breast carcinomas and pyogenic abscesses, especially in the absence of known etiology such as trauma or breastfeeding. The rarity of GM makes it a poorly understood disease, with no defined clinical features. GM is often confused with a neoplasm or infection both clinically and radiologically.[3] The majority of cases reported in the literature suggest that GM occurs in women of childbearing age (median age: 30 years old), usually with a history of breastfeeding (two years after breastfeeding).[3]

GM most commonly presents as a unilateral painful lump in the retroareolar area. Up to 50% of patients present with erythema and swelling, and 37% present with signs of an abscess.[4] Other symptoms include hyperemia, areolar retraction, fistula, and ulceration. Lymphadenopathy is present in up to 15% of patients.[5] The gold standard for the diagnosis of GM is a histopathological diagnosis obtained from a core needle biopsy (CNB).[4] Biopsies show a granulomatous formation in combination with localized infiltration of multinucleated giant cells, epithelioid histiocytes, and plasma cells. For those with Langhans cells or caseation necrosis, breast tuberculosis (BTB) is a differential and is confirmed by bacteriological culture of breast tissue with Ziehl-Neelsen (ZN) stain.[6] Radiologic tools like mammography, computed tomography scan (CT scan), and magnetic resonance imaging (MRI) have been used in diagnostic work-up of the breast. Mammography and ultrasound of the breast may demonstrate a dense sinus tract connecting an ill-defined breast mass to localized skin thickening. However, radiological tools cannot delineate GM from malignancy and the findings are always non-specific.[3]

When GM is diagnosed, two treatment options are discussed in the literature: a conservative strategy involving medical therapy with corticosteroids or antibiotics versus a surgical approach. In 1980, De Hertogh et al. first recommended a high-dose corticosteroid therapy with prednisolone (30 mg/day) for at least two months, and this approach became the standard of care.[7] The use of methotrexate is considered an alternative for patients who have failed corticosteroid therapy. Another alternative is the wide excision of the lesion. Minimal surgical intervention is required for drainage of breast abscess or biopsy from the abscess wall, scraping of sinuses in the breast, and incisional or excisional biopsy. Residual lump following anti-tubercular drugs may require surgical removal. Simple mastectomy with or without axillary clearance is rarely required for extensive disease with a large, painful, ulcerated mass involving the entire breast and draining axillary lymph node rendering organ preservation impossible. The disease stage at which surgery is performed and the choice of surgical technique (e.g., wide excision, mastectomy) depends on the individual clinical appraisal of the patient. The decision on whether surgery or medical treatment is preferred may also depend on divergent regional resources, the patient's expectations, and surveillance opportunities.[3] Since GM is a rare disease, there currently is no protocol for treatment.

Thus, our study aimed to describe the clinical characteristics of GM seen in the Breast Care Clinic in the Philippine General Hospital (PGH) from January 2015 to June 2019. This study will initially provide institutional data on GM that is relevant in the Philippines. Though reportedly rare, GM should still be included in the differential diagnosis of clinicians dealing with breast masses and wounds.

MATERIALS AND METHODS

This is a retrospective observational study of patients with GM seen in PGH, a national tertiary referral hospital, from January 2015 to June 2019. After obtaining approval from the institution's Research Ethics Board (2019-542-01), cases were identified by the researcher from the Integrated Surgical Information System from January 1, 2015 to June 30, 2019. All patients with histopathologic profiles consistent with chronic granulomatous inflammation (including Langhans giant cell) were included in the study. We performed complete enumeration by including all patients with histopathologic confirmation of granulomatous mastitis during the study period. This approach minimized selection bias by ensuring that every eligible case was included, capturing the full spectrum of cases diagnosed within the specified timeframe. The slides were reviewed by a single pathologist to ensure uniformity and reliability in the diagnosis.

To address potential information bias, a standardized data collection form collecting information about demographics, clinical data (history of disease, initial presentation, physical examination, disease progression), imaging (mammogram, ultrasound), management (surgical, medical), and clinical outcomes (resolution, morbidity, mortality) throughout the course of the disease was utilized. Histopathologic records of the breast tissues in the outpatient and inpatient laboratory were reviewed by the researchers. Identified patients' medical records were retrieved for review of the clinical characteristics at baseline. Follow-up information was collected exclusively through a review of patient charts, relying on documented clinical encounters and visits recorded by attending physicians during the study period. Unknown treatment status was documented for patients whose medical records lacked details on the interventions performed, while those lost to follow-up were categorized separately as patients who did not return for any further consultations.

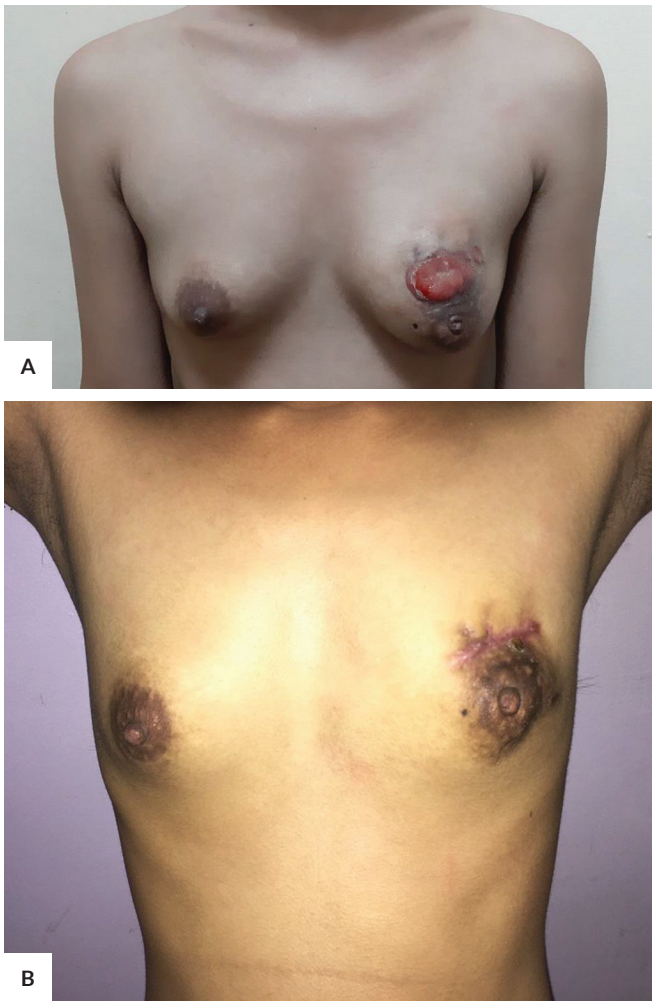

Figure 1. GM patient showing skin changes. **(A)** Image taken at the time of diagnosis, demonstrating significant erythema, skin thickening, and an open ulcerative lesion with visible necrotic and inflamed tissue, highlighting the disease's severity at presentation. **(B)** Image taken six months after initiation of the anti-tubercular regimen, showing resolution of the inflammatory changes with improvement in skin texture and color.

For outcomes, "No resolution" was defined as persistent symptoms without clinical improvement, "improving" referred to a documented reduction in symptom severity or size of the breast mass during follow-up visits, and "resolved" indicated complete resolution of symptoms and/or the absence of any palpable mass or inflammation as noted in the follow-up records. All information were recorded in a data sheet (Appendix). Patient characteristics were summarized using frequency and percentage for categorical variables, and median with range for continuous variables. Differences for dichotomous and categorical variables between those with and without recurrence were tested using the Chi-square test (i.e., sex) or Fisher's exact test. Difference in age was tested using Mann-Whitney U test. A p-value < 0.05 was considered significant and STATA14 was used for data analysis.

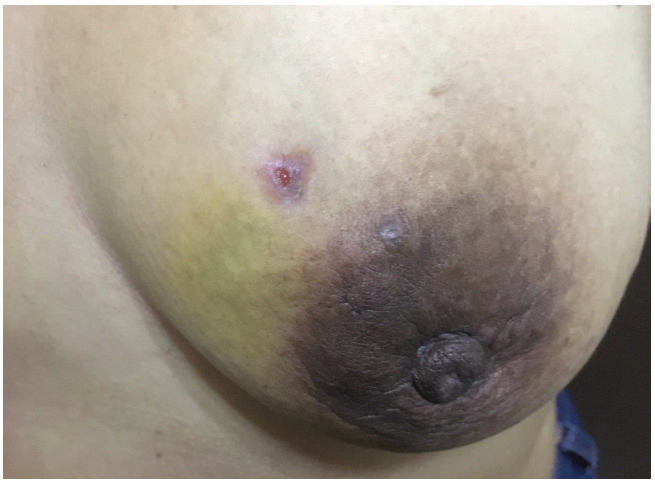

Figure 2. GM patient demonstrating a breast sinus. The image demonstrates an external opening on the breast skin connected to an underlying abscess or fistulous tract.

RESULTS

Out of the approximately 15,000 annual consults of the PGH Breast Care Clinic, a total of 70 histopathologic results showing chronic granulomatous inflammation, caseation necrosis, or Langhans giant cell were retrieved. There were five cases of concomitant breast cancer that were excluded. A total of 43 patients with GM from June 1, 2015 to June 30, 2019 was recorded, with clinical characteristics detailed in Table 1. The majority (98%) were females, and the average age in our patients was 38.9±11.3.[3] Primary considerations were either breast malignancy (26 out of 43) or breast infection (14 out of 43). The most common clinical presentation was breast mass (30 out of 43) or breast wound (11 out of 43) (Figure 1), although two patients presented with multiple sinuses (Figure 2). In our series, it most commonly mimics abscess or malignancy due to skin changes and nipple retraction.

In our study, the most common imaging requested was ultrasonography (20 out of 43), mammography (6 out of 43), and combined mammosonography (5 out of 43). We note that in 12 out of 43 patients, no imaging was done. There were four patients who had both tissue culture and tissue acid-fast bacilli (AFB) done, two who had only tissue culture, and two who only had tissue AFB done. No patients had a tuberculous polymerase chain reaction (TB-PCR) done. Results showed only one had growth of *E. coli* and none of the tissue samples showed AFB. Chest radiography was done in nine patients and only one showed pulmonary tuberculosis. Sputum AFB was performed in four patients, but none were positive.

Treatment received by patients was either observation (1 out of 43), medical only (23 out of 43), surgical only (7 out of 43), or combined medical and surgical (1 out of

Table 1. Demographic and Clinical Profile of Adults who had Granulomatous Mastitis in the Philippine General Hospital from January 1, 2015 to June 30, 2019 (N=43)

Parameters	Frequency	Percentage
N (total)	43	
Gender		
Male	1	2.3
Female	42	97.7
Initial Diagnosis		
Breast CA	26	60.5
Breast infection	14	32.6
Benign breast mass	3	7.0
Others	0	0.0
Clinical Presentation		
Breast mass	30	69.8
Breast wound	11	25.6
Breast sinus	2	4.7
Others	0	0.0
Imaging		
Ultrasound	20	46.5
Mammogram	6	14.0
MRI	0	0.0
CT scan	0	0.0
Ultrasound and mammogram	5	11.6
None	12	27.9
Histopathologic profile (initial)		
Caseation	0	0.0
Chronic granulomatous inflammation	20	46.5
Langhans giant cell	9	20.9
Non-specific inflammation	8	18.6
Xanthogranulomatous mastitis	6	14.0
Treatment		
Medical	23	53.5
Surgical	7	16.3
Lost to follow-up	2	4.7
Unknown	9	20.9
Observation	1	2.3
Medical + Surgical	1	2.3
Medication		
Steroids	1	2.3
Antibiotics	7	16.3
Anti-Koch's	15	34.9
Others	3	7.0
None	5	11.6
Unknown	11	25.6
Antibiotics + Anti-Koch's	1	2.3
Outcome at 1 month		
No resolution	0	0.0
Improving	9	20.9
Resolved	6	14.0
Lost to follow-up	22	51.2
Unknown	6	14.0
Outcome at 3 months		
No resolution	0	0.0
Improving	6	14.0
Resolved	9	20.9
Lost to follow-up	22	51.2
Unknown	6	14.0
Outcome at 6 months		
No resolution	0	0.0
Improving	3	7.0
Resolved	10	23.3
Lost to follow-up	24	55.8
Unknown	6	14.0
Outcome at 12 months		
No resolution	0	0.0
Improving	3	7.0
Resolved	4	9.3
Lost to follow-up	30	69.8
Unknown	6	14.0

43) management. Notably, 2 out of 43 patients were lost to follow-up while 9 out of 43 patients had unknown management. Since most of the patients have an initial impression of breast infection, some (16.3%) of our patients received antibiotics during the start of their treatment. Only one patient received corticosteroids, while 15 of our patients received anti-tubercular treatment even if only nine showed Langhans giant cells in histopathology. On the other hand, eight patients underwent surgical treatment. It should be noted that in our series, the indication for surgery was due to the impression of an abscess or tumor, and the finding of GM was incidental.

Patients in our study had inconsistent follow-ups. After 12 months of follow-up, approximately 70% of the patients were lost to follow-up. Among those who followed up (7-9.3% of our study population), patients showed either improvement or resolution of symptoms.

DISCUSSION

Our study was able to describe the clinicopathologic profile and clinical outcomes of adult Filipino patients with histopathologically proven GM in our institution. Their clinical characteristics, treatment, and outcomes were described.

In our study, the majority (98%) were females, consistent with the literature, as there have only been two reports of male GM.[8] The average age in our patients is 38.911.3 years, which is comparably higher as the literature reports that GM mainly occurs in women of childbearing age and occurs around two years after breastfeeding.[3] Consistent with our findings, previous studies[3] report that 50% of patients develop erythema and swelling as symptoms of inflammation of the involved breast, and 37% present with signs of abscess.[9] The location of the lesion was not extracted in our series

but literature[3] suggests that the lesion is mostly present in the retroareolar region from where it extends radially and commonly occurs unilaterally. Lymphadenopathy was not noted in our series but may be present in up to 15% of patients.[10]

Radiologic imaging of GM commonly shows non-specific findings.[4] Typical ultrasound findings were multiple contiguous hypoechoic masses with posterior acoustic shadowing or posterior acoustic enhancement, and in advanced cases, with sinus and fistula. Mammogram findings are also often inconclusive due to dense breast.[4] Thus, the gold standard for diagnosing GM is core needle biopsy of the lesion, showing 96% sensitivity.[5] Histopathologic examination is the most critical differentiating factor for GM versus other important differential diagnoses. As supported by our study, GM commonly appears as chronic granulomatous inflammation without evidence of malignancy, as seen in 20 (46.5%) of our patients. It is worth noting that only nine (20.9%) of our patients had chronic granulomatous inflammation with Langhans giant cell and none demonstrated caseous necrosis, supportive of BTB. It is important to distinguish GM from BTB since the treatment of GM involves steroids, but steroids can exacerbate BTB. Histologically, BTB demonstrates more fibrosis, eosinophils, and necrosis. Mycobacteria may incite chronic and granulomatous inflammatory responses more like those of a fungus rather than pyogenic bacteria, and one may postulate that eosinophils would play a more significant role in the cellular immune response. Conversely, for GM, the etiology is more likely to be autoimmune, which would call into play humoral responses, and hence, would demonstrate the presence of more plasma cells. Caseation necrosis as a result of tissue damage is a hallmark of tuberculosis and can also be seen in tuberculous meningitis.[13]

In GM lesions, *Corynebacterium kroppenstedtii* has often been isolated and plays a fundamental role in inducing this disease. Furthermore, in a study by Wong et al.[10], 37% of patients with *C. kroppenstedtii*-associated mastitis had a psychiatric history requiring medication. Thus, concern about whether this medication puts a patient at risk for GM remains to be explored. GM is challenging for the pathologist and clinician as one must differentiate GM from autoimmune and granulomatous conditions including tuberculosis, sarcoidosis, and Wegener's granulomatosis.

GM is a sterile inflammatory disease. Thus, antimicrobials will usually fail for its treatment.[14] In our patient group, only one of the patients received corticosteroids. In the 1980s, prednisone (30 mg/day) for at least two months was the standard of care.[7] However, due to the side effects of corticosteroids, lower doses and duration were investigated. A German poster presentation demonstrated the success of high-dose therapy with prednisolone up to 1 mg/kg/day, with a duration of 2-6 months, reporting a recurrence rate of 15%.[15] A trial addressing the need for further decrease in dosage of corticosteroid exposure investigated topical 0.1%

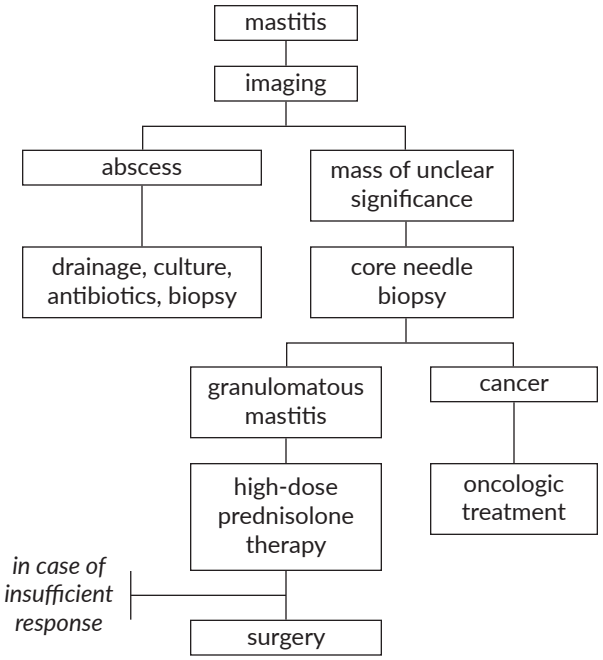

Figure 3. Proposed algorithm for the management of GM by the Breast Unit of Kliniken Essen-Mitte.[4]

hydrocortisone butyrate cream twice a day on alternate days, in contrast to wide local excision.[16] The application of methotrexate is an alternative for patients who failed corticosteroid therapy. However, women of childbearing age will have limited use of methotrexate.[5] It can be noted that 15 of our patients received anti-tubercular treatment even if only nine showed Langhans giant cells in histopathology. Due to the prevalence of tuberculosis (TB) in the country, and the idiopathic nature of the disease, the decision to start an anti-tubercular regimen on the patient was based on expert opinion. In endemic countries like ours, TB is recognized as having diverse clinical presentations and pathways of infection, including TB mastitis, which may result from a bloodstream infection or an adjacent tuberculous process. Failure to respond to conventional or conservative therapy despite negative microbiological investigations, such as AFB smear microscopy, culture, and TB-PCR, should prompt clinicians to consider tuberculous treatment.

In our study, eight patients received surgical treatment. The indication for surgery was due to an impression of an abscess or tumor, and the finding of GM was incidental. In literature, surgery is an alternative approach and the decision to perform this surgery depends on individual clinical appraisal, personalized regional resources, and surveillance opportunities. Most authors suggest performing wide excision when medical treatment fails. Corticosteroid therapy has a success rate of 66-72% with a pooled recurrence rate of 20%. Surgery alone or in combination with corticosteroids shows the lowest recurrence rate of 6.8% and 4%, respectively.[17] A promising algorithm developed by the Kliniken Essen-

Mitte (Figure 3)[4] showed a relatively good outcome favoring conservative management and reserving surgery to cases with insufficient response. A total of five patients underwent close observation in our series, as supported by multiple reports in literature demonstrating resolution without intervention.[18]

The current study has several limitations. This is a single-center study and only a small number of cases were identified. Thus, cases in the selected institution may not be representative of the general population of patients with GM since patients in PGH are mostly indigent patients belonging to the lower socioeconomic class. The observed lack of association between clinicopathologic data may also be due to the low power of statistical tests because of the small sample size. Furthermore, since the current study used secondary data from patient medical records, the completeness and accuracy of information relied heavily on how correctly these data were previously recorded. Predisposing factors were also not extracted from the data.

CONCLUSION

Forty-three patients with chronic GM from 2015 to 2019 were identified. In our study, the most common presentation mimics breast infection or carcinoma, and the majority (53.5%) of our patients were managed medically only, with 34.9% receiving anti-tubercular medications. Internationally, there is still no consensus on the algorithm and management of GM patients. However, the authors recommend a close follow-up every two weeks to re-evaluate patients and observe their response to the regimen being administered. The authors recommend a prospective study and longer follow-up of these patients to gain a deeper understanding of GM in Filipinos.

Acknowledgments

The authors would like to acknowledge the help of the Philippine General Hospital Department of Laboratories for their assistance in retrieving the tissue slides included in this paper.

The authors would also like to extend their immense gratitude to the people and staff of the UP-PGH Division of Surgical Oncology, Breast Care Clinic, Department of Pathology, and the Division of Infectious Diseases.

Statement of Authorship

All authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

All authors declared no conflicts of interest.

Funding Source

None.

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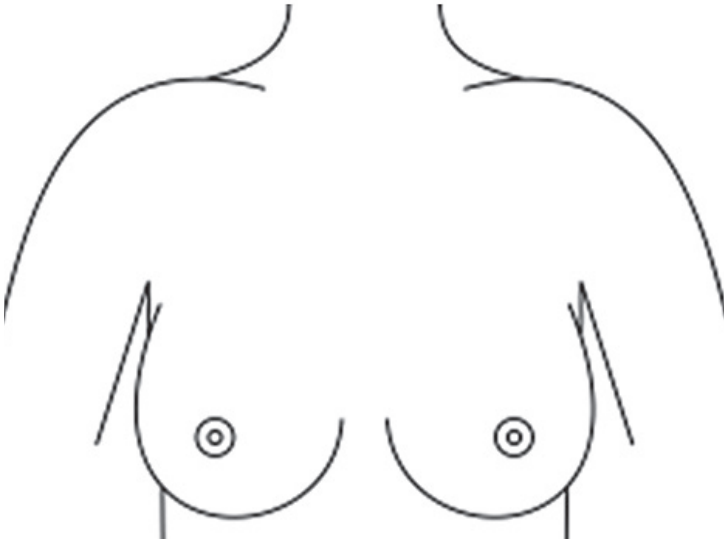
APPENDIX

Data Collection Sheet

<table>
<tr><td colspan="4">An Observational Study of Granulomatous Mastitis in a Philippine Breast Care Center

DATA SHEET</td></tr>
<tr><td>Case #</td><td colspan="3"></td></tr>
<tr><td>Age</td><td></td><td>Sex</td><td></td></tr>
<tr><td colspan="2">Chief complaint</td><td colspan="2"></td></tr>
<tr><td colspan="2">Concise history</td><td colspan="2"></td></tr>
<tr><td colspan="2">Clinical presentation</td><td colspan="2">  </td></tr>
<tr><td rowspan="4">Imaging</td><td>Mammogram</td><td colspan="2"></td></tr>
<tr><td>Ultrasound</td><td colspan="2"></td></tr>
<tr><td>CT-Scan</td><td colspan="2"></td></tr>
<tr><td>MRI</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Histopathologic profile</td><td>Biopsy done by</td><td colspan="2">_____ FNAC
_____ CNB
_____ Incision
_____ Excision</td></tr>
<tr><td>Results</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Management</td><td>Medical</td><td colspan="2"></td></tr>
<tr><td>Surgical</td><td colspan="2"></td></tr>
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