Idiopathic Granulomatous Mastitis: A Three-Year Experience at the National Cancer Institute, Egypt

Dr. Ihab Saad Hussein Ahmed[1], Prof. Dr. Mona Ali Sakr[2], Dr. Anthony Nozhy Ghalioum Abd El Messeh[1] Dr. Ibrahim Abdelaziz Ibrahim Malash[3]

[1]Surgical Oncology Department, National Cancer Institute, Cairo University, Egypt
[2]Surgical Pathology Department, National Cancer Institute, Cairo University, Egypt
[3]Medical Oncology Department, National Cancer Institute, Cairo University, Egypt
Ihab.saad@nci.cu.edu.eg; drihab2013@gmail.com

Abstract: Purpose: Idiopathic granulomatous mastitis (IGM) is a rare, benign, chronic, inflammatory lesion of the breast. This study is a retrospective analysis of diagnostic and therapeutic approaches of IGM at the National Cancer Institute (NCI), Cairo University. **Patients and Methods**: This retrospective study included 86 patients with IGM who attended the NCI during the period between January 2012 and January 2015. The medical records of these patients were revised to retrieve data concerning different diagnostic and therapeutic approaches. **Results**: The median age of the patients was 35 years (range 20-50 years). The lesion was unilateral in all patients, mostly presenting with an irregular breast mass (79.1%). Radiological findings (by ultrasonography or sono-mammography) were misleading; the main finding was an irregular, ill-defined suspicious breast mass (48.8%). Diagnosis was established only by biopsy and histopathological examination via core biopsy (n=48), FNAC (n=13), FNAC and core biopsy (n=5), or excisional biopsy (n=20). Two treatment approaches were offered; wide surgical excision (n=59, 68.6%) or medical treatment (n=26, 30.2%). One patient was treated by simple mastectomy. Following surgery, 37 cases (62.7%) did not suffer any recurrence clinically or radiologically. Eighteen patients (20.9%) received oral prednisolone tablets and 8 (9.3%) received antibiotics for two weeks (mostly amoxicillin) followed by steroid therapy. Recurrence rate was 30.7% after steroid therapy. **Conclusion**: Idiopathic granulomatous can be misdiagnosed as breast cancer due to ambiguous clinical and imaging profile. Biopsy is the only way to reach a definitive diagnosis. Wide local excision and steroid therapy had comparable results.
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1. Introduction

Idiopathic granulomatous mastitis (IGM) is a rare, benign, chronic, inflammatory lesion of the breast of unknown etiology.[1] It is commonly seen in women during the active reproductive years.[2] Suggested etiology includes autoimmune disease, bacterial or fungal infections, and hormone factors.[1] Idiopathic granulomatous mastitis usually represents a diagnostic dilemma due to the confusing non-specific clinical and radiological picture that may mimic a malignant mass.[3] A breast mass is the usual presentation. The mass appears hard and fixed to the skin. The associated axillary node enlargement and nipple retraction in some cases increase the probability of breast cancer.[4] Radiological imaging reveals a diverse appearance that depends on the timing of evaluation, the degree of inflammation, and prior intervention.[5,6] The final diagnosis is confirmed by histopathology where there is non-necrotizing granulomatous inflammation of lobules [3]. So far, no definite guidelines have been formulated either for diagnosis or management of this rare condition.[7]

Given the diagnostic and therapeutic difficulties of the disease, the present study presents a retrospective analysis of diagnostic and therapeutic approaches of Idiopathic Granulomatous Mastitis at the National Cancer Institute (NCI), Cairo University during a 3-year period from January 2012 to January 2015.

2. Patients and Methods

This retrospective study was carried out on 86 patients diagnosed with GM. The reviewed cases attended the surgical department and the breast clinics at the National Cancer Institute, Cairo, Egypt, during the period between January 2012 and January 2015. Diagnosis of GM was initially made clinically and radiologically and was later confirmed by histopathological examination.

Data retrieved included detailed reproductive history, family history and manifestations and history of GM. Clinical data included characteristics of the breast mass and ipsilateral axilla, examination of contralateral breast and axilla, both arms and cervical lymph nodes specially supraclavicular group.

Radiological findings of mammography and

ultrasonography were recorded with particular emphasis on characteristics of the mass (s), axilla status, BIRADS scoring, and lymph nodes features. Lymph nodes were suspicious of malignancy based on the presence of circular shape, thickened cortex and effaced fatty hilum with hypoechoic internal echo.

Pathological assessment of the reviewed cases included preoperative biopsy results - either true cut-needle biopsy or fine-needle aspiration cytology (FNAC) or even excisional biopsy - and surgical reports. Patients were subjected to different ways of management including wide local excision, mastectomy, and medical treatment. Treatment outcome was assessed as the rate of recurrence or disease progression during the first year after treatment.

Statistical methods:

Statistical analysis was done using IBM© SPSS© Statistics version 22 (IBM© Corp., Armonk, NY, USA). Numerical data were expressed as a mean and standard deviation or median and range as appropriate. Qualitative data were expressed as frequency and percentage.

3. Results

Eighty-six females were diagnosed with IGM during the study period; all of them were in the childbearing period. Their median age was 35 years (range 20-50 years). The majority of patients were between 30-40 years old (Figure 1).

At the time of presentation, none of the females were pregnant or within six months of giving birth. All women except six had a history of live births (Table 1). Seventy-nine women (91.9%) gave a history of breastfeeding while 7 cases (8.1%) did not. Fifty-one women (59.3%) were using oral contraceptive pills for at least two years. The remaining 35 women (40.7%) did not use OCPs or used them only for a few months.

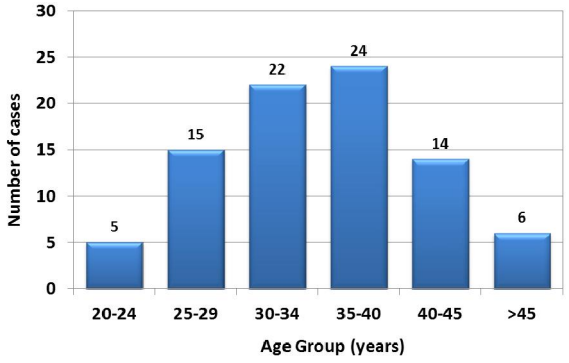

Figure 1: Patients' Age Groups

Granulomatous mastitis was unilateral in all women (Table 2). The most common presentation was an irregular non-tender breast mass with surrounding breast tissue scarring (n=44, 51.2%). Twenty-four patients (27.9%) had a tender, red, inflamed breast mass resembling a breast abscess. Ten women (11.6%) were complaining of axillary masses which proved by examination to be LNs with no specific visible breast lesion while 8 cases (9.3%) had sinuses discharging pus.

Table 1: Parity and history of breastfeeding of the 86 studied patients

	Number	Percentage
Parity		
Nullipara	6	7.0%
1	14	16.3%
2	23	26.7%
3	25	29.1%
4	10	11.6%
≥ 5	8	9.3%
Breast Feeding	**79**	**91.9%**

Table 2: Clinical and radiological characteristics of granulomatous mastitis in the studied group

	Number	Percentage
Laterality		
Right	44	51.2%
Left	42	48.8%
Presentation		
Breast mass	44	51.2%
Tender and red breast mass	24	27.9%
Axillary mass	10	11.6%
Brest Sinus discharging pus	8	9.3%
Radiological Findings		
Suspicious lesion	42	48.8%
Interconnected spaces with secretions	18	20.9%
Benign looking lesion	18	20.9%
Cystic mass	8	9.3%
BIRADS score		
3	28	32.5%
4	51	59.3%
5	7	8.2%

The initial radiological techniques done were ultrasonography (n=42) or combined Sono-mammography (n=44). Radiological findings of GM were misleading and variable from benign looking lesions to suspicious malignant ones. The main radiological finding was an irregular, ill-defined suspicious breast mass (48.8%). BIRAD score 4 was the most common (n=51, 59%). The seven lesions with BIRADS score 5 were described as a suspicious lesion with suspicious criteria of malignancy with suspicious LNs (Table 2).

Axillary lymph nodes were described to be suspicious in 33 patients (37.7%) with criteria of malignancy (effaced fatty hila with cortical

thickening). In 28 patients (32.9%) benign looking lymph nodes, likely inflammatory, were described (preserved fatty hila and normal cortical thickness), while no radiologically detected LNs were reported in 25 cases (29.4%). There was no specific radiological finding of GM was associated with particular nodal status. However, in patients with a radiologically suspicious breast mass, mostly there were also suspicious LNs.

Pathological assessment of the reviewed cases included preoperative biopsy results (either cut-needle biopsy or FNAC or even excisional biopsy). Core biopsy was done in 48 cases (55.8%), FNAC in 13 (15.2%), both FNAC and core biopsy in 5 (5.8%), and excisional biopsy in 20 (23.2%).

Twenty-seven cases had FNAC done; 9 of them (33.3%) had false negative results. They were referred to a core biopsy, where 7 cases were confirmed, and 2 cases needed an open surgical biopsy for proper diagnosis. Eighteen cases had true-positive FNAC results; 13 of them were diagnosed with FNAC only while 5 cases had both FNAC and core biopsy done.

Fifty-three cases (61.7%) were diagnosed by core biopsy; 41 had only core biopsy, 5 cases had core biopsy with FNAC, and 7 cases had core biopsy after -ve FNAC and proved the presence of GM. Core biopsy failed to diagnose GM in only 2 cases (2.3%); the biopsy showed a picture of suppurative inflammation without specific granulomatous type. These 2 cases showed false -ve results with FNAC as well.

Excisional biopsy was done in 20 cases; 17 cases as initial diagnostic test and 2 cases after false negative FNAC and one false negative core biopsy. Excision of lesions was done as a treatment option, and later on, they were proved to be GM. One case was diagnosed by examining a simple mastectomy specimen.

The patients were subjected to 2 different treatment approaches for GM; surgical excision (n=59, 68.6%) or medical treatment (n=26, 30.2%). All patients were currently under follow up at the NCI. Primary surgical treatment was wide local excision of the lesions. In 53 women (89.8%) primary wound closure was done, and six women (10.2%) had breast reconstruction; 5 LD flap and one mini LD flap (Figure 2).

One patient was treated by simple mastectomy. She was a 47 years old woman who had previous conservative breast surgery for invasive duct carcinoma followed by radiotherapy. During follow up, she developed suspicious mass suspected as recurrent breast cancer. So, mastectomy was done, and the final pathology report denoted GM.

During the 1st year post-surgical treatment, 37 cases (62.7%) did not suffer any recurrence clinically or radiologically. One patient had residual lesion immediately postoperative, and another patient was lost to follow up. Five patients (8.4%) had a recurrence within six months of treatment; 3 diagnosed radiologically and two clinically. Fifteen patients (25.4%) developed a recurrence within the 1st year; diagnosed radiologically in 2 cases and clinically in 13. Three of these 13 cases had sinuses discharging pus.

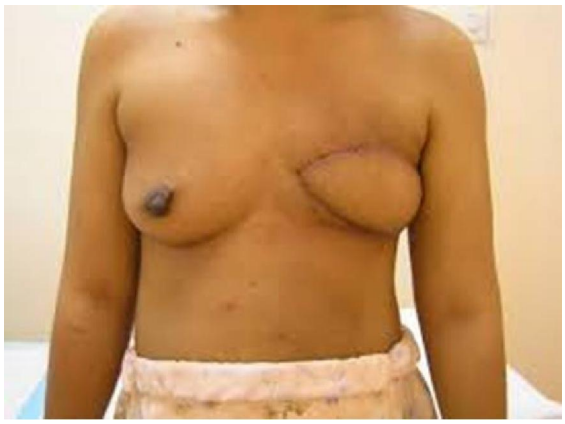

Figure 2: Post LD flap reconstruction

The five cases of radiological recurrence were kept under follow up every two months. The patients with clinical relapse were treated with either re-excision of recurrent lesions (n=7) or steroid therapy (n=5). Three patients refused treatment.

Out of the 53 patients had WLE and primary wound closure, only two were accepting the cosmetic appearance of their breasts after surgery and the remaining patients were not satisfied even the cases that did not experience recurrence.

Primary medical treatment was offered for 26 patients (30.2%) in the form of steroid therapy alone or with antibiotics. Eighteen patients (20.9%) received oral prednisolone tablets with a starting dose of 20 mg/day for one month. If good response was achieved, therapy was maintained for another two months followed by re-assessment. In cases of disease progression or non-responsive cases, dosage was increased to 30-40 mg/day for three months with careful monitoring of patients' response every two weeks and possible complications from steroids.

Seven patients showed complete resolution with no recurrence up to 1 year. Four patients showed marked regression of lesions with improvement of symptoms. Two patients showed recurrent lesions within six months and started another three months of steroid therapy. Three patients suffered recurrent lesions in imaging within one year and were kept under follow up. Two patients experienced disease progression and worsening of symptoms during

treatment and had surgical excision.

Another eight patients (9.3%) received antibiotics for two weeks (mostly amoxicillin) followed by steroid therapy as mentioned. Three patients showed complete resolution with no recurrence. Four patients showed marked regression of lesions and kept under follow up. One patient showed clinical recurrence after one year and had surgical excision of the lesion upon her request.

4. Discussion

This retrospective analysis identified 86 females with unilateral IGM during the 3-year study period. Their median age was 35 years, and the majority of them were parous women with positive lactating history. Most of the patient presents with an irregular breast mass with or without tenderness. Radiological findings on mammography or ultrasonography were variable and misleading. The final diagnosis was reached through histopathological examination of an FNAC (n=13), core biopsy (n=53) or excisional biopsy (n=20). Primary surgical treatment with wide local excision was performed for about 70% of cases, while the remaining, 30% received medical treatment in the form of corticosteroids with or without antibiotics. Recurrence rate within one year was 33.8% after surgical treatment and 23% after medical treatment.

The mean age of IGM patients in this study was 35 years; the fourth decade of life was the most commonly encountered age group. It is known that IGM is a disease of the reproductive age mostly in the third and fourth decades [1] Previous studies reported a similar age of onset of the disease.[8,9] The majority of women of the current series previously delivered (93%), and breastfed (92%). Previous studies indicated a positive history of childbirth and breastfeeding within the last five years in most women with IGM.[10]

In concordance with previous studies,[11,12] the lesions in the current study were unilateral in all patients. However, bilateral involvement is reported in the literature.[5,9,13] An irregular non-tender breast mass was the most frequent presentation in the current series (51%). In 28% of the patients, a tender mass in an inflamed breast was the presenting symptom. A breast mass is the most common presentation in granulomatous mastitis.[8,13,14] Occasionally, nipple retraction, axillary lymphadenopathy, peau d'orange change, erythema, scars, and sinus formation were reported.[15–18] In the current series, a sinus discharging pus was a rather common finding (9.3%). Also, axillary lymph nodes were the only presentation of 11.6% of cases. These findings exaggerate the suspicion of breast carcinoma.

Therefore, IGM can resemble a breast abscess, an inflamed breast, or breast cancer. For this reason, multiple assessments including clinical and cytologic examinations in addition to imaging modalities are required for diagnostic accuracy. Nevertheless, mammography and ultrasound examination usually yield a non-specific picture that may mimic other breast diseases. In the current study, radiological findings with mammography and ultrasound were quite misleading; the lesions were suspicious of malignancy in almost half of the cases. Common findings in mammography are asymmetric diffuse and skin thickness [19], asymmetric diffuse increased density of the fibroglandular tissue [13], focal or regional asymmetry [20,21], and single mass or masses [22]. On ultrasonographic examination, the most frequent findings are irregular hypoechoic masses with irregular margins or parenchymal heterogeneity and an area of mixed echo-pattern.[8,23]

Numerous studies described the use of magnetic resonance imaging (MRI) as a complementary diagnostic modality in breast imaging. But, IGM had variable appearances on MRI imaging. It may support the findings of ultrasonography and mammography but cannot confirm the diagnosis.[24] These challenges indicate that histological examination is still the only way to reach a definitive diagnosis in cases of IGM. Histopathologic diagnosis can be achieved by fine needle aspiration cytology (FNAC), core, incisional or excisional biopsy.[19]

In the current series, nearly half of the cases were referred for core biopsy to reach a diagnosis, while FNAC was utilized less frequently in about one-third of cases. However, FNAC failed to diagnose about 50% of the cases; all were referred to core biopsy. It is known that FNAC has a high false-negative rate in diagnosing IGM.[10,11,25] On the other hand, core biopsy failure rate was only 3.7%, i.e., 2 cases. In these two cases, histological examination showed a picture of suppurative inflammation without specific granulomatous type. Tse et al. reported a failure rate of 2 to 3% with core biopsy.[12]

There is no consensus about the ideal approach to treat IGM. Treatment options include antibiotics, steroids, methotrexate (MTX), wide surgical resection, and mastectomy.[25–28] In the current series, 60 patients had surgically excised lesions in the form of wide local excision with or without reconstruction by autologous flaps, and one patient had a simple mastectomy done. Surgical treatment achieved complete resolution in nearly 63% of cases. On the other hand, 26 patients had medical treatment; 18 patients had steroid therapy alone, and 8 had an antibiotic therapy for two weeks followed by steroid therapy. Patients with medical treatment showed a good response with no steroid-related complications mentioned by patients or noticed on them, two patients

showed disease progression during treatment and six patients suffered recurrence (30.7%) during the first year post-treatment.

Previous studies reported variable recurrence rates after wide local excision from 5.5% up to 50%.[8,13,29,30] However, surgical intervention may be associated with delayed wound healing and excessive scarring of the breast. In fact, in the current series, only two out of the 53 patients were accepting the cosmetic appearance of their breasts after surgery. We believe that the relatively high recurrence rate in the current study can be explained by the presence of residual disease in the remaining breast tissue. The possible infection or autoimmune etiology of the disease can be a logical explanation of the presence of multiple foci.

Therefore, the use of corticosteroids for the treatment of IGM was suggested. Yet, there is no agreement about the optimal dose and duration of steroid administration. Some studies suggested an initial dose of 30-60 mg/day of prednisone. Other studies reported favorable outcome with short-term, low-dose steroid therapy.[31] In the current study, treatment started with a starting dose of 20 mg/day. The dosage was increased to 30-40 mg/day if no response of progression occurs. The outcome of treatment was comparable between the two treatment modalities used in the current series.

In fact, the optimal treatment of IGM remains controversial. Some studies compared surgery and steroid therapy in these cases. In agreement with our results, Oran et al.[32] reported comparable treatment outcome of steroid therapy and surgery. Others preferred surgical excision that resulted in no recurrences compared to 11.7% after steroid therapy.[33] On the other hand, Akahane et al. [34] suggested steroid therapy as a first choice of treatment in IGM as they reported no recurrence in steroid group.

Conclusion

Therefore, we can conclude that idiopathic granulomatous mastitis is a rare benign inflammatory breast disease that can be misdiagnosed as breast cancer. Clinical examination and radiological imaging usually yield misleading results. The only way to reach a definitive diagnosis is through histopathological examination. Core or excisional biopsy rather than FNAC are recommended to obtain satisfactory tissue for pathological examination. Wide local excision and steroid therapy had comparable results.

Conflict of interest

I have no conflict of interest to declare

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