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Idiopathic Granulomatous Mastitis; Radio-pathologic Findings and Grading Based on Clinical Presentation and Treatment Outcome in 224 Patients

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ABSTRACT

Background: Idiopathic granulomatous mastitis (IGM) is a rare inflammatory disease of the breast with unknown etiology. Clinico-radiologic findings can mimic breast cancer. Further pathologic evaluation to rule out malignancy is mandatory. Recognizing the severity of the disease is crucial to choosing the most effective therapeutic modality. The aim of this study is to evaluate clinical and radio-pathologic features of IGM, and the treatment outcome in a large series of IGM patients in Iran.

Methods: The retrospective charts of 243 patients suspicious of IGM, between December 2007 and September 2017 were reviewed. Patients with confirmed diagnosis of IGM were classified into four grades of severity. Demographic information, clinical and radio-pathologic findings, severity and treatment outcomes were collected.

Results: Overall, 224 patients were confirmed to have IGM. Breast mass and erythema were the most common clinical findings. Mammographic findings mimicked malignancy in 34%. Lobulo-centric non-caseating granulomas were the most common pathologic finding. Also, 61.5% of the patients had mild to moderate symptoms and 49.5% of them recovered completely by observation. In addition, 53 (25.9%) patients had severe symptoms and 30.8% of them were resistant to treatment.

Conclusion: IGM is a diagnostic challenge. Its diagnosis is based on exclusion and a close cooperation between the clinician, the radiologist and the pathologist. Mild to moderate cases can be managed conservatively; however, severe cases may need further aggressive medical or surgical treatments.

INTRODUCTION

Idiopathic granulomatous mastitis, also called granulomatous lobular mastitis, is a rare benign and chronic inflammatory breast disease that mainly involves women of childbearing age.[1,2] Although it is a well-known clinical entity, first described in 1972 by Kessler and Wollock, its etiology is still unknown.[3] IGM remains a diagnostic challenge for clinicians. There is a delay in diagnosis of around 6-8 months on average.[4]

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Al-Khaffaf *et al.* support the possibility of a race-related predisposing factor for IGM. Other ethnic associations have been made anecdotally, as many of the reported cases have come from Asia, Turkey, Jordan, and Iran.[5]

Although the etiology of IGM is unknown, some etiologic factors have been stated including: infectious diseases, reaction to chemical materials such as OCP, autoimmune diseases, immunologic response to milk leakage from the breast's lobule, trauma, and foreign-body reaction.[6,7] The most widely adopted theory considers IGM to be a local autoimmune disease that involves both humoral and cell-mediated immunity and results in non-caseating granulomas.[8]

IGM usually presents as an ill-defined firm large mass, usually in the upper outer quadrant or sub-areolar zone of the breast, and is often associated with concurrent inflammatory signs that may lead to nipple retraction and dimpling.[5,7] In addition, Ultra-sonographic (US), mammographic, and even MRI features are not specific and could be mistaken for malignant changes; for example, common mammographic findings include skin thickening and asymmetric diffuse lesions. [1]Imaging and clinical findings are confounding and cannot distinguish IGM from malignancy.[9] Therefore, confirmed diagnosis can only be achieved through histopathologic study.[10]

Core-needle biopsy (CNB) has a well-established role in the diagnosis of IGM, with up to 94%–100% accuracy reported in several studies. It also enables more extensive testing to be performed in cases of infection, malignancy, and other noninfectious inflammatory breast diseases.[9] IGM is a diagnosis of exclusion requiring careful histopathology review of biopsy specimens, as well as microbiological analysis. TB, sarcoidosis, fungal infection, and malignancy must be ruled out to confirm the diagnosis of IGM. Histologically, IGM is characterized by non-necrotizing granuloma formation with a localized infiltration of multi-nucleated giant cells, plasma cells, epithelioid histiocytes and lymphocytes. A neutrophilic infiltration may also occur with formation of organized micro-abscesses.[8]

These features make the differential diagnosis challenging, resulting in not only a diagnostic and therapeutic dilemma, but also increased risk of psychological stress and unnecessary surgical procedures for the patients.[10]

The aim of this study is to evaluate clinical and radio-pathologic features of IGM, and the treatment outcome in a large series of IGM patients in Iran.

METHODS

The medical records of 243 patients suspicious for idiopathic granulomatous mastitis (IGM) referred to two referral breast clinics, Imam Khomeini Hospital and Kaviani Breast Disease Institute, were assessed. We retrospectively evaluated our database from December 2007 to September 2017. Pathologically confirmed IGM patients were included. The patients were excluded under the following situations: the presence of other possible etiologies of granuloma formation, e.g., tuberculosis, fungal infections, sarcoidosis, etc. and having a simultaneous breast cancer disease or bacterial mastitis.

The medical and demographic data of all patients were gathered in Hakim software (Pegahsoft, Mashhad, Iran). Mammography had been carried out for 96 patients based on the ACR indication for mammography. Gram staining culture for anaerobes, TB and fungal infection was performed for all the patients before antibiotic therapy. The patients with a positive result were excluded. The patients were visited serially. Signs and symptoms observed at serial examinations were registered and classified into three different levels of severity:[4,11]

- Inflammatory: pain, redness, erythema, peau d'orange, skin thickening, axillary lymphadenopathy
- Cutaneous destruction: thin red skin, superficial collection, ulcer, fistula
- Soft tissue: Deep collections, tissue thickening, mass, skin dimpling, nipple retraction. This group needs to be studied by clinic-radiologic investigations. They can be considered mild when the collection is single with minimal inflammatory reaction around it, moderate when the collections are multiple in a single quadrant and severe when the collections can be seen in more than one quadrant.

The severity of the disease is classified as previously presented by Kaviani *et al.*,[4] (presented in the supplementary file). We considered the disease mild (Grade I) when there was no cutaneous destruction and the skin and soft tissue signs and symptoms were mild. If the inflammatory and soft tissue signs and symptoms were moderate and no destructive signs were found, we classified patients as moderate (Grade II). Any sign of skin destruction was assigned as severe disease (Grade III). All the patients who had systemic symptoms including erythema nodusom, arthralgia and fever were considered stage IV.

The management of the disease for all the patients at both centers was performed according to the protocol recently published based on the severity of the disease.[11,12] (supplementary file), which was approved by the medical ethics committee, surgery department, Tehran University of Medical Sciences.

The data were analyzed by SPSS 21.0 software. The recorded data were presented as mean, with standard deviation (SD) and number (%). All the data of this manuscript are available and will be provided upon request.

RESULTS

Demographic results

In this study, 243 patients matched the inclusion criteria. Pathologic evaluation of the specimens of the breast lesions was performed in all the patients which was non-diagnostic in nineteen patients for whom the excision of the lesion was performed. Four of these patients were found to have invasive ductal carcinoma simultaneously, four other patients had intraductal papilloma and one patient had atypical ductal hyperplasia (ADH) and were excluded.

Gram stain of the secretions was positive for bacteria in nine (3.72%) patients and appropriate antibiotic was administered and they were excluded. Specific stains and culture of the secretions, for tuberculosis (Ziehl-Neelsen), and fungal infections (periodic acid–Schiff) were performed in all the patients. One patient was positive for TB and was excluded and none of the patients were positive for fungi.

Finally, 224 patients were analyzed. Their general characteristics are summarized in Table 1. The mean age of the patients was 36.2±7.7 years ranging from 20 to 62 years, 221 patients (91.3%) were premenopausal, 197 patients (81.4%) had a history of lactation, and three patients were lactating at the study time. The mean duration of breast feeding was 31+/-22 months. Three patients were pregnant at the time of diagnosis. Among the patients, 50.4٪ had a history of hormonal therapy, including contraceptive drugs, and thyroid hormones. One patient had a positive history of medical treatment for infertility.

Table 1. General characteristics of the patients

Characteristic	Mean	Std. Deviation
Age	36.16	7.75
BMI	27.46	4.23
Age at first pregnancy	23.48	5.01
Age at menarche	13.69	1.66
Hormonal therapy length (months)	26.47	
Laterality		
Right	107 (48.4)	
Left	90 (40.75)	
Bilateral	14 (6.3)	
Lactation length (months)	31.32	22.45

Patients' symptoms

The most common complaint of the patients was pain, and the most common findings were mass and erythema; however, there were other findings including systemic symptoms, erythema, thickening, nipple discharge, dimpling, ulcer, fistula, nipple retraction, erythema nodosum, and arthralgia. Bilateral lesions were seen in 6.6% of the patients, and also, 6.3% were multifocal. The most common site of the lesion was the upper outer quadrant (UOQ) of the breast (36%). Table 2 summarizes the signs and symptoms and the severity of the disease in this study.

Imaging finding

Ultrasonic (US) evaluation of the breast lesion was performed in all the patients. The most common US finding was skin and breast tissue edema and shadowing without a focal lesion followed by abscess and collection. The mass was hypo-echoic in 71% of the cases. The US features of the lesions sometimes (12.3%) mimicked malignant lesions and warranted further tissue sampling to rule out malignancy. In 96 patients, mammography was indicated according to the patient's age. A mass with ill-defined margins was the most common finding in mammography. Also, 33.9% of mammographies had a BIRADS 4 and above. Sonographic (US) and mammographic (MG) features of the patients are summarized in Table 3 and 4, respectively.

Pathologic findings

A histopathologic examination was performed on the specimens in all patients. Tissue sampling was performed using a core-needle biopsy (CNB) (55.7%), incisional biopsy (36.1%), and excisional biopsy (8.2%). CNB was diagnostic for IGM in 92.1% of the patients and the remaining patients needed an incisional biopsy or the excision of the lesion.

All the 242 patients' pathologic diagnosis was compatible with granulomatous mastitis. Non-necrotizing granuloma was present and diagnostic in all cases. Lobulocentric inflammation and terminal duct involvement and abscess formation were other common findings in pathologic reports (Figure 1, 2). The pathologic findings are summarized in Table 5.

Treatment and outcome

In this study, 48.3% had mild symptoms and 13.2% were classified as moderate. The patients with mild to moderate symptoms were managed conservatively and did not need any intervention. They did not show any recurrences during 24 months after the diagnosis.

Table 2. Signs and symptoms and the severity of the disease

Sign or symptom	Number	Percentage (%)
Soft tissue:		
Dimpling	12	4.96
Nipple discharge	14	5.79
Nipple retraction	23	9.50
Mass	127	52.48
Thickening	92	38.02
Inflammatory:		
Fever	45	18.59
Erythema	176	72.73
Edema	65	26.86
Tenderness	45	18.60
Cutaneous:		
Ulcer	30	12.40
Fistula	19	7.85
Systemic:		
Lymphadenopathy	118	48.76
Erythema nodosum	3	1.24
Arthralgia	23	9.50
Severity		
Grade I		
Grade II	99	48.3
Grade III	27	13.2
Grade IV	53	25.9
(Systemic symptoms)	26	12.7

Table 3. Sonographic findings.

US findings	Number	Percentage (%)
Suspicious for granulomatous mastitis	30	19.35
Abscess and collection	28	18.06
Edema and shadowing	26	16.77
Fibrocystic change	19	12.26
Suspicious for malignancy	13	8.39
Inflammation	13	8.39
Fibradenoma	6	3.87
Cyst	5	3.23
Inflammatory carcinoma	3	1.94
Malignant lesion	3	1.94
Others	9	5.81
Total	155	100
Mass echogenicity		
Hypo echo	89	71.2
Mixed echo	25	20
Hyper echo	6	4.8
Echo free	2	1.6
Internal echo	2	1.6
Iso echo	1	0.8

Also, 91(37.6%) patients with mild to moderate symptoms required aspiration drainage of the collection. Moreover, 18 patients (1.42%) with mild to moderate symptoms were resistant to treatment and underwent surgical resection of the lesion.

According to our classification, 53 patients (25.9%) had severe symptoms (Grade IV) and 30.2% of them were resistant to medical treatment. Medical treatment in this group consisted of oral prednisolone. There were 26 (12.7%) patients with systemic symptoms and 19.2% of them were resistant to medical treatment.

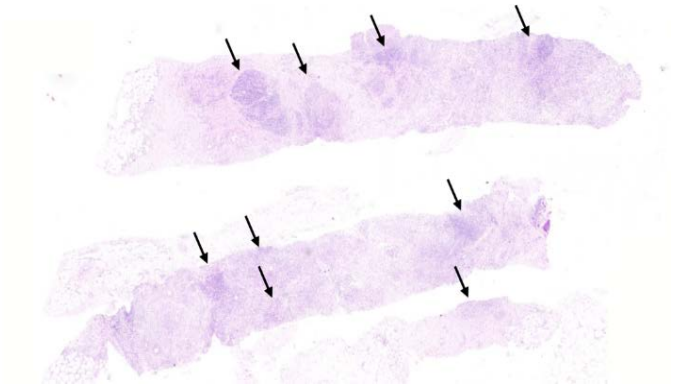

Figure 1. Core needle biopsy in a patient with IGM showing lobulo-centric inflammation. The arrows point to terminal duct-lobular units.

Table 4. Mammographic findings

MG finding	Number	Percentage (%)
Mass with ill-defined margins	79	54.48
High density mass	15	10.34
Skin thickening	16	11.03
Mass with well-defined margins	13	8.97
Asymmetry	7	4.83
Mixed density mass	4	2.76
Microcalcification	3	2.07
Spiculated mass	2	1.38
Low density mass	2	1.38
Tissue distortion	2	1.38
Iso-density mass	1	0.69
Total	145	100
BIRADS of Mammography		
0	18	30.51
I	4	6.78
II	10	16.95
III	7	11.86
IV	14	23.73
V	6	10.17

Overall, 59 patients (28.8%) failed to finish their 24 months of follow-up, 44 patients (21.5%) completely recovered, and 39 patients (19.1%) were resistant to treatment in 24 months of follow-up. The correlation between the response to therapy and the severity of the disease is illustrated in Table 6.

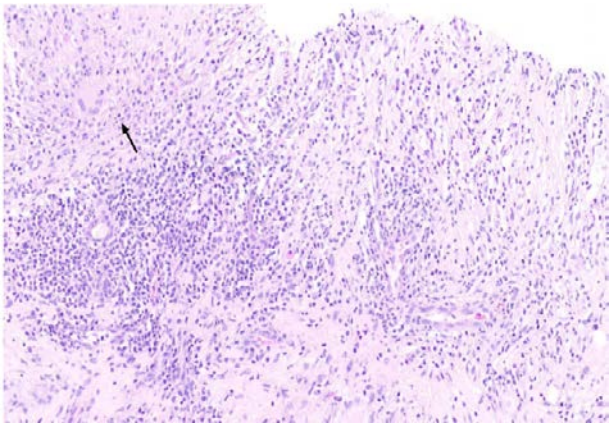

Figure 2. This high-power view shows a terminal duct lobular-unit with granulomatous inflammation (arrow) and mixed inflammatory infiltrate including lymphocytes, neutrophils, plasma cells and histiocytes.

DISCUSSION

This study revealed that IGM affects women of childbearing age. The patients usually have a history of pregnancy and breastfeeding or hormone therapy.[1,4] In this study, the duration of breast feeding was 31+/-22 months. In fact, the etiology of IGM is unknown; however, reaction to chemicals such as OCP, autoimmune diseases, immunologic response to milk leakage from the breast's lobule, trauma, and foreign-body reaction to be related to IGM.[1] Palpable breast mass was the most common clinical finding in our study. This finding was compatible with several other studies.[4,13] Although the imaging signs of IGM are non-specific, some studies suggest the possibility of a diagnosis of IGM using imaging features.[9] US finding was compatible with IGM in 19.4% of the cases in this study, and it was suspicious for a malignant lesion in 3.9% of the case. The low rate of diagnosis of IGM by US indicates that imaging findings are not sufficient for the diagnosis of IGM, and pathologic evaluation of the lesion is necessary to rule out malignancy and confirm the diagnosis. Various studies have reported that the most common US manifestation is an irregular hypo-echoic mass with tubular extension and interconnecting tracts.[6,9,14] Similarly, a hypo-echoic mass was the most common US finding in IGM patients in this study, followed by mastitis, abscess and collection.

Table 5. Pathologic features of the patients diagnosed with IGM

Pathologic findings	Number	(%)
Lobulocentric inflammation & terminal duct unit involvement	131	58.5
Abscess	69	30.8
Periductal involvement	8	3.6
Fat Necrosis	17	7.6
Significant Fibrosis	9	4.1
Non-necrotizing granuloma	224	100

The most prevalent finding on mammography was a mass with ill-defined margins followed by skin thickening, asymmetry and tissue distortion. In several studies, focal asymmetry has been described as the most common mammographic presentation. However, an obscured or irregularly shaped mass has been reported as the most common mammographic finding in a small number of studies.[1,9,14,15] In this study, 33.9% of the mammographies reported by the expert radiologists were BIRADS 4 and more. Skin thickening, focal or global asymmetry, irregular focal mass, trabecular coarseness or distortion in the parenchyma, smooth-edged mass, calcification, or lymphadenopathy findings may be found in a mammogram.[14] In dense breasts, mammography may not show any findings. Clinical and radiologic features can be confounding and are not diagnostic for IGM.

Radiologic imaging may not differentiate between breast carcinomas or specific subtypes of breast inflammation. Thus, an early pathologic confirmation is needed when antibiotics do not work.[16,17]

Table 6. Response to treatment according to severity

	Mild symptoms	Moderate symptoms	Severe symptoms	Systemic symptoms	Total Number (%)
Complete response	27 (27.3%)	6 (22.2%)	5 (9.4%)	6 (23.1%)	44 (21.4)
Good response	8 (8.1%)	3 (11.1%)	3 (5.7%)	3 (11.5%)	17(8.3)
Fair response	20 (20.2%)	7 (25.9%)	15 (28.3%)	4 (15.4%)	46(22.4)
Resistant	13 (13.1%)	5 (18.5%)	16 (30.2%)	5 (19.2%)	39(19.1)
Missing	31 (31.3%)	6 (22.2%)	14 (26.4%)	8 (30.8%)	59(28.8)

IGM is a diagnosis of exclusion requiring a careful histopathologic review of biopsy specimens, as well as microbiological evaluation. It was illustrated in this study that CNB could be diagnostic in 77.3% of the cases. Non-necrotizing granuloma is a common finding in pathologic evaluation. However, other findings such as lobulo-centric inflammation, micro-abscess formation, fat necrosis and fibrosis have been reported in pathologic reports, too. Non-necrotizing granuloma formation in breast lobules accompanied with neutrophilic aggregation and/or micro-abscess formation is the typical pathologic finding in IGM.[14,18] Typically, histologic findings in IGM include infiltration of multi-nucleated giant cells, plasma cells, epithelioid histiocytes, lymphocytes and neutrophils within the affected lobules.[14,19] This typical triad (i.e., granuloma formation, lobulocentric inflammation and neutrophilic infiltration) is neither necessary nor sufficient for a definite diagnosis. In some instances, because of extensive confluent areas of inflammation, it may be difficult, if not impossible, for the pathologist to discern the lobulo-centric nature of the pathologic process. Neutrophilic infiltrations and rare granulomas may not be identified, particularly in limited biopsy specimens.

Additionally, there are some histopathologic changes that are very unusual in IGM and their presence is suggestive of alternative diagnoses. These findings include extensive necrosis accompanied with vasculitis (in favor of rheumatologic disorders or vasculitis), the presence of acid-fast bacilli, fungal elements or bacterial colonies (these findings confirm infections), keloid-like stromal fibrosis, lobulo-centric lymphocytic infiltration and epithelioid myofibroblasts (favoring lymphocytic/diabetic mastopathy), the presence of foreign bodies (typical of foreign body granulomatous reaction), epithelioid granuloma associated with caseous necrosis (favoring tuberculosis), marked eosinophilic infiltration (suggestive of parasitic infestations), extensive neutrophilic infiltration and granulation tissue formation (suggesting abscess wall), naked granulomas accompanied with asteroid bodies (sarcoidosis may be considered), and ectatic ducts with xanthogranulomatous inflammation (consistent with mammary duct ectasia). Tuberculosis is the most important diagnosis to be ruled out before appropriate medication is started. IGM is mostly associated with the predominance of neutrophils in the background, and caseous necrosis is usually absent in IGM.[20]

It was shown in this study that almost half of the IGM cases (48.3%) had mild symptoms at presentation. They were self-limited in 67% of the incidents. Moderate cases were managed by repeated aspiration and drainage of the collections and only 18.5% of them were refractory and warranted further treatment. Also, 43.4% of severe cases had good or fair response to high dose steroids and 26.4% of them were resistant to treatment. Accordingly, we need to evaluate the severity of the disease to select the best treatment modality and modify it according to the response during the follow-ups.

The positive points of this study are the large sample size and the precise radiologic and pathological findings in all the cases and the grading system used for classification and treatment selection. There are some limitations in this study as well. It was conducted in a retrospective manner, and radiologic evaluations were performed by different radiologists and the reports were not uniform. Pathologic assessments were performed by different breast expert pathologists as well. Another limitation of this study is that some participants failed to finish the 24 months follow-up. We believe that further prospective trials are necessary to evaluate the benefits of our classification system in choosing the best treatment strategy.

CONCLUSION

IGM is a rare inflammatory disease of the breast. This condition mimics breast malignancy clinically and radiologically. Imaging and clinical findings are confounding and cannot distinguish IGM from malignancy. Thus, pathologic evaluation of the breast lesion is necessary to rule out malignancy. IGM is a diagnosis of exclusion. TB, sarcoidosis, fungal infection, and malignancy must be ruled out to confirm the diagnosis of IGM. Teamwork and close cooperation between the surgeon, the radiologist and the pathologist are mandatory to confirm the diagnosis and the severity of the disease. Patients with mild to moderate symptoms are managed conservatively in more than 50% of the cases. However, 25.9% present with severe symptoms and 30.2% of them are refractory to the treatment and require further aggressive medical and surgical treatments.

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CONFLICT OF INTEREST

There is no conflict of interest to be declared.

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