# TREATMENT MODALITIES AND OUTCOMES OF IDIOPATHIC GRANULOMATOUS MASTITIS

Azhin H. Tofiq A. Qadir [a] and Kamal A. Saeed [b]

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## ABSTRACT

### *Background*

Idiopathic Granulomatous Mastitis (IGM) is a benign chronic inflammatory breast disease. The etiologies of IGM are presently unclear, that is why treatment is still a challenge, Medical therapy, Wide Local Excision(WLE), abscess drainage, and even mastectomy were introduced to treat this disease.

### *Objectives*

To review clinical, diagnostic features and outcomes of treatments, also to indicate which method can be practical for treatment of IGM.

### *Patients and Methods*

This study is retrospective in which prospectively maintained in Breast Clinic in Sulaimani city. Ninety-three (93) female patients with histopathologically proved IGM and treated from 1st January 2014 till 15th March 2019. Mostly Core needle biopsy(CNB) and excisional biopsy were used for accurate diagnosis. Plans of the treatment were designed according to the presentations and results of the histopathology.

### *Results*

The baseline characteristics of 93 female patients revealed that the average age of the patients was 35.73±7.96 SD years old with the majority of patients (75%) being between 21 and 40 years old. Based on Fine Needle Aspiration Cytology (FNAC), Core Needle Biopsy and excisional biopsy, they were diagnosed with Idiopathic Granulomatous Mastitis. Medical and surgical therapies included use of antibiotic alone in 18(19.3%) cases, steroid in 26(28%) cases, anti-prolactin in 14 (15%) cases. One 1 (1%) of the patients underwent mastectomy, 39 (42%) of them underwent wide local excision after medical treatments failure, and 8 (8.6%) of them who had abscesses were drained. The overall cure rate in both treatment modalities were 75 (81%) and recurrence rate of 18 (19%).

### *Conclusion*

There is still no standard treatment for IGM, the results of this study concluded that wide local excision is the best treatment of choice. Most of the patients do not respond to one treatment modality and recurrence is common; that's why the disease is called 'idiopathic.' Thus, there are no known causes to have an effective treatment modality

**Keywords:** *Idiopathic Granulomatous Mastitis, Treatment modalities, Outcomes.*

[a] Breast Clinic in Sulaimani, Minisitery of Health, Kurdistan Region/Iraq
Correspondence: azhin.hama2017@gmail.com
[b] Department of Surgery, College of Medicine, University of Sulaimani, Kurdistan Region, Iraq.

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## INTRODUCTION

Idiopathic Granulomatous Mastitis (IGM) also called Granulomatous Lobular Mastitis. IGM is a benign chronic inflammatory breast disease, Kessler and Wolloch were described IGM in 1972 at first [1]. This disease usually affects women of childbearing age and rarely affects males [2]. IGM is mostly found in Asia and Mediterranean countries [3].

The etiological factors of IGM are presently unclear; the most accepted theory is that an initial injury to the ductal epithelial cells in the breast causes a transition of luminal secretions to the lobular breast stroma. This transition causes a local inflammatory response in the connective tissue, with macrophage and lymphocyte immigration to the region, and then a local granulomatous response [4]. Various precipitating factors have been determined and include pregnancy, lactation, hyperprolactinemia, α1-antitrypsin deficiency, oral contraceptive pills (OCCPs) use, local trauma, diabetes, smoking, and autoimmune diseases[4].

Patients with IGM usually present with a hard breast lump without clear signs of a systemic disease, but local sign and symptoms include pain, nipple retraction, inflammation of the overlying skin, nipple discharge, and enlarged lymph node. As the disease progresses nipple inversion, peaud'orange, ulcer, and fistula can occur that can simply be mistaken with cancer. IGM mostly occurs unilaterally [2, 5] rarely bilateral, with no tendency to a side and was found in every quadrant of the breast [6].

For diagnosis, radiologically; there is no pathognomonic ultrasonographic feature for IGM, most patients have irregular hypoechoic breast mass [7]. The most common mammographic findings were appeared to be asymmetric focal density with/without skin thickening, parenchymal distortion and diffuse asymmetric opacity with trabecular thickening [8]. Some authors offered Magnetic Resonance Imaging(MRI) for diagnosis of IGM, but some studies have shown that MRI does not give additional findings for the differentiation of IGM from breast cancer. Generally, histopathology is the cornerstone to confirm the diagnosis [5].

Histopathologically, IGM is described by the presence of epithelioid and multinucleated giant cell granulomas limited to the mammary lobules with micro-abscesses formation but without necrosis is pathognomonic [9]. However, confirmation of the diagnosis requires the exclusion of the malignancy and other possible causes of granulomatous breast diseases such as Tuberculosis, Parasitic and Fungal infections, Histoplasmosis, Sarcoidosis, Wegener's granulomatosis, Vasculitis, and foreign-body reactions [6].

Treatment of IGM is still a challenge; best treatment has not been yet found, while medical therapy, WLE, abscess drainage, and even mastectomy were introduced to treat this disease [2, 3] .Some of the medical treatments have been described including antibiotics, topical or systemic steroids, non-steroidal anti-inflammatory drugs (NSAIDs), and immunosuppressive agents, such as methotrexate (MTX) and azathioprine [3]. DeHertogh et al. were among the first who recommended corticosteroid treatment for IGM in the 1980s [7]. But, steroid therapy can aggravate Tuberculosis Granulomatous Mastitis (TBGM)[10]. WLE with or without corticosteroids has been described in the literature. In some cases, the disease recurs in more than half of patients when limited excision is done. While IGM is a benign disease, repeated surgical interventions lead to poor aesthetic outcome [11]. Recurrence is a common dilemma, and without surgical treatment, patients may go through a chronic progressive clinical course. Long-term follow-up is necessary [12]. This study aims to review clinical, diagnostic features, and to discuss the outcomes of treatments, also to indicate which method can be practical for treatment of IGM.

## PATIENTS AND METHODS

All statistical analysis was performed with SPSS 24. Descriptive statistics were used for the demographic data, choice of treatment and treatment outcomes. All quantitative data were described as a percentage and some of them as median ± SD.

This study is retrospective in which prospectively maintained in Breast Clinic in Sulaimani city. Ninety-three (93) female patients with histopathologically proved to have IGM and treated from 1st January 2014 till 15th March 2019. Baseline data were obtained from patients files records in the Breast Clinic, as well as on the telephone, including: age, occupation, marital status, obstetrical and gynecological history, history of breastfeeding, smoking, family history of breast cancer, history of comorbid diseases, history of autoimmune diseases, presenting clinical manifestations such as (breast mass, pain, erythema, swelling, hotness , tenderness, fever/rigor, nipple discharge and its color, nipple retraction, skin dimpling, ulcer and fistula

formation) with axillary lymphadenopathy.

All patients examined clinically and sent for Ultrasonography (USG) , prior to pathological examination at the time of presentation as a basic investigation and repeated with each follow-up visit, and those who are above 35 years old sent for Mammography (MMG), in accordance with the Breast Imaging-Reporting and Data System (BI-RADS) criteria. Then for confirmation of the diagnosis, one or more of these pathological examinations: (FNAC, CNB, or excisional biopsy) have done for them. Some laboratory tests were done to exclude other causes, including White Blood Cells (WBC), Erythrocyte Sedimentation Rate(ESR), Random Blood sugar(RBS), Serum prolactin, Thyroid Function Test (TFT))

Initial prescribed treatment, duration and response to treatment or recurrence were recorded. Plans of the treatment were designed according to the clinical presentations and result of the histopathological examination.

Patients with inflammatory findings but no evidence of an abscess were initially treated with an antibiotic. Aspiration or incisional drainage was performed in patients with an abscess at the time of diagnosis. In the cases that the diagnosis of an abscess was confirmed by US examination, if there was no response shifted to steroid treatment(prednisolone tablet), and the dose differed from one to another, then if there was no response shifted to surgical treatment either drainage(aspiration or incisional drainage) or WLE. Topical steroid or topical antibiotic was used in patients in whom the breast skin was also affected by extensive inflammation, fistulae, or erosions.

Good response to treatments is defined as fading of both clinical findings (swelling, erythema, pus collection, fistula, and sinuses) and sonographic findings (masses, collection pockets, parenchymal edema, and skin thickening).

## RESULTS

The baseline characteristics of 93 female patients revealed that the average age of the patients was 35.73±7.96 SD years old ranging from 23-63 years with the majority of patients (75%) being between 21 and 40 years old. Based on FNAC, CNB and excisional biopsy they were diagnosed with IGM. As shown in Table 1.

Of the total 93 cases with IGM, the vast majority 92 (99%) patients had a history of pregnancy at least once, with 7 (8%) patients being pregnant at the time of presentation, 90 (97%) cases had a history of breastfeeding with 2 (2%) cases of them being lactating at presentation. Eight (8.6%) cases had a history of ongoing OCCP use. Only 13 patients (14%) had co-morbidities, with a single case of Rheumatoid Arthritis (RA), a case of Crohns Disease (CD), a case of Vasculitis, a case of carcinoma of the breast and one more case of ovarian cancer. These Baseline patient characteristics along with other demographic features are shown in Table 1.

Regarding the clinical presentations, breast mass and pain were the most prevalent presentations, swelling, erythema, and tenderness are other common signs and symptoms; these features are almost present in combinations rather than separately. These data were presented in Table 2. And those signs are presented in Figure 1.

Regarding investigations, not all the patients have been sent for these values: hormonal essay, RBS, WBC, and ESR. However, among available results majority of patients had normal levels of those values. Considering the nature of this study and lack of control group to compare with, it is not possible to determine any association between these parameters and IGM as shown in Table 3.

To offer the diagnosis as a part of work up for breast mass, some patients had undergone FNAC, with majorities either had no the test or giving inconclusive results which mandated the use of CNB or excisional biopsy to provide a definite diagnosis, as shown in Table 4.

Concerning management modalities and outcomes. Analyzing patients outcome by treatment modalities (mostly medical initially with antibiotic and if it failed steroid before shifting to surgical intervention), rate of success and treatment failure(recurrence) and crossing between modalities. After confirmation of the diagnosis of IGM in (93) cases, medical therapy included use of antibiotic alone in 18 (19.3%) cases, steroid in 26(28%) cases, anti-prolactin in 14 (15%) cases. Other forms of treatment in this group included (topical steroid (Betamethasone), topical antibiotic (Fusidic acid)) used to treat skin complications of IGM and (Anti-TB drugs). As shown in Table 5.

Almost half 48(51.6%) of the patients received the surgical intervention, 39 (42%) patients were treated by wide local excision, and 8 (8.6%) patients were treated

by drainage of the abscess (it is either by aspiration of the pus or by incisional drainage), and 1 (1%) patient was undergone mastectomy. Surgical treatment modalities are shown in Table 6.

The overall cure rate in both treatment modalities were 75 (81%) and recurrence rate of 18(19%), Table 7.

**Table1. Baseline characteristics of (93) patients with Idiopathic Granulomatous Mastitis (IGM).**

| Characters | Frequency (N) | Percentage (%) |
|---|---|---|
| **Age** | | |
| ≤ 20 | 0 | (%) |
| 20-29 | 20 | (21.5%) |
| 30-39 | 44 | (47.3%) |
| 40-49 | 24 | (25.8%) |
| 50-59 | 3 | (3.2%) |
| 60-69 | 2 | (2.1%) |
| **Pregnancy** | | |
| Yes | 92 | (99%) |
| No | 1 | (1%) |
| **Recent or Previous lactation** | | |
| Yes | 90 | (97%) |
| No | 3 | (3%) |
| **OCCP** | | |
| Yes | 8 | (8.6%) |
| No | 85 | (91.4%) |
| **Smoking** | | |
| Yes | 1 | (1%) |
| No | 92 | (99%) |
| **Co-morbidities** | | |
| NO | 80 | (86%) |
| Hypertension(HT) | 4 | (4.3%) |
| Diabetes Mellitus(DM) | 4 | (4.3%) |
| Autoimmune diseases | 3 | (3.2%) |
| Cancer | 2 | (2.2%) |

**Table 2. Clinical presentations of (93) patients with IGM.**

| Presentations | No. (%) |
|---|---|
| **Signs and symptoms** | |
| Mass | 92 (99%) |
| Pain | 87 (94%) |
| Erythema | 29 (31%) |
| Nipple discharge | 23 (24.7%) |
| Swelling | 18 (19%) |
| Nipple retraction | 17 (18%) |
| Tenderness | 13 (14%) |
| Hotness | 8 (8.6%) |
| Fever&rigor | 7 (7.5%) |
| Skin dimpling | 6 (6.4%) |
| Fistula | 3 (3%) |
| Itching | 2 (2%) |
| **Nipple Discharge** | 23(25%) |
| Yes | 70(75%) |
| No | |
| **Axillary lymphadenopathy** | |
| Yes | 57(61.3%) |
| No | 36(38.7%) |

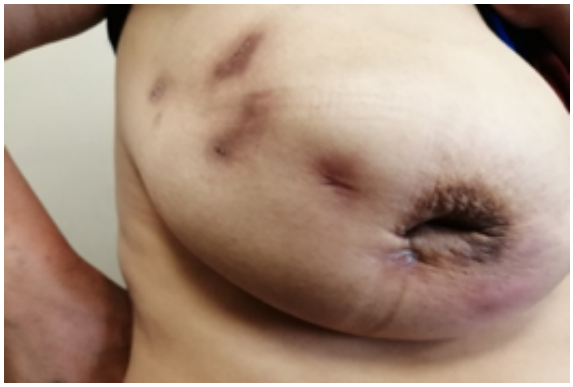

**Figure 1. Right nipple inversion, multiple scars of previous fistulae laterally, redness and swelling inferomedially with generalize edema of the breast.**

**Table 3. Laboratory values of (93) patients with IGM.**

| Variables | No. (%) |
|---|---|
| **Serum Prolactin** | |
| Normal | 53 (57%) |
| High | 6 (6.3%) |
| **Thyroid function test (TFT)** | |
| Normal | 13 (14%) |
| High | 0 (0%) |
| **RBS** | |
| Normal | 45 (48.4%) |
| High | 6 (6.5%) |
| **WBC** | |
| Normal | 13 (14%) |
| High | 4 (4.3%) |
| **ESR** | |
| Normal | 2 (2.1%) |
| High | 8 (8.6%) |

**Table 4. Results of FNAC, CNB, and excisional biopsy.**

| Pathological examinations | No. (%) |
|---|---|
| **FNAC** | 23(24.7%) |
| **CNB** | 58 (62%) |
| **Excisional biopsy** | 37(39.7%) |

***Some patients more than one pathological examinations were done for them.**

**Table 5. Medical treatments for (93) patients with IGM.**

| Medical Treatment | No. (%) |
|---|---|
| Antibiotic alone | 18 (19.3%) |
| Antibiotic+Surgery | 35 (37.6%) |
| Antibiotic+other medical teatments | 40 (43%) |
| Steroid | 26 (28%) |
| Anti-prolactin | 14 (15%) |
| Anti-TB | 3 (3.2%) |
| Topical steroid | 4 (4.3%) |
| Topical antibiotic | 5 (5.4%) |

**Table 6. Surgical treatments for (93) patients with IGM.**

| Surgical Treatments | No. (%) |
|---|---|
| **Drainage** | 8 (8.6%) |
| **WLE** | 39 (42%) |
| **Mastectomy** | 1 (1%) |

**Table 7. Outcomes of the (93) patients with IGM.**

| Cure No. (%) | Recurrence No. (%) |
|---|---|
| 75(81%) | 18(19%) |

## DISCUSSION

Idiopathic Granulomatous Mastitis (IGM) is a chronic inflammatory disease affecting one or rarely both breasts without a clear etiology [6, 13]. Many agents like: pregnancy, lactation, hyperprolactinemia, OCCPs use, local trauma to the breast, alpha-1 antitrypsin deficiency, smoking, DM, viruses, mycotic, and parasitic infections, have been considered to be precipitating factors of IGM, but an autoimmune reaction is superior [14] .

A breast mass and pain are the most common presentations in IGM. Nipple retraction, sinus formation, and axillary lymphadenopathy may be seen. For exclusion of other differential diagnoses specifically malignancy, the use of triple assessments that contain clinical, radiological and pathological examinations are required for the diagnosis of IGM [14]. In this study, the most common presentations were mass (99%) and pain (94%) almost most of them had both.

Clinical and imaging studies cannot differentiate IGM from breast cancer [15], so breast imaging should be performed for differential diagnosis. As most of the patients are younger than 40 years of age, breast ultrasonography is the favored method. Increased parenchymal echo pattern, with multiple irregular hypoechoic masses, are the most reported ultrasonographic findings in patients with IGM[13]. In this study, (abscess, irregular wall hypoechoic collection, ill-defined heterogenous mass, single dilated duct full of movable echo with edematous parenchyma, and skin thickening) are reported during USG for the patients, and according to the (BI-RADS) most of the cases 83 (90%) are having (BI-RADS U2-U3).

An ill-defined mass with asymmetric diffuse density and skin thickening are the most frequent mammographic findings [11]. In this study, 49(52.7%)of the patients MMG was done for them, (asymmetric density, ill-defined density, an irregular ill-defined lesion with distortion and nipple retraction with calcification inside the mass) are reported and according to the BI-RADS, 22(23.6%) cases are having (BIRADS-M4). Other studies have also used MRI and found that it does not give additional information for the differentiation of mastitis from carcinoma [11]. In this study only, 4(4.3%) cases MRI has been done for them, 2(2.1%) of them BIRADS-MR 4 given to them which means suspicious for malignancy, So USG, MMG and MRI are not

accurate diagnostic tool according to this study.

A definitive diagnosis can be made using FNAC, CNB, or an excisional biopsy, histopathologic confirmation using CNB is a critical step for IGM patients to plan for proper management [16]. In this study 23(24.7%) of the cases were diagnosed by FNAC, while 58(62% ) patients were diagnosed by CNB and 37(39.7%) of them by excisional biopsy.

Nowadays the treatment of IGM is still challenging as there is no standard treatment [3]. Several studies favor step-by-step treatment for the management as first with antibiotics and next steroids and finally surgery [13]. Lai et al. stated the spontaneous complete resolution in 50% of IGM cases after a mean interval of 14.5 months [17]. Lai et al. recommended that expectant, conservative management with close supervision might be the treatment of choice because of the self-limiting character of IGM. While, conservative management alone is a hard decision to make because of diagnostic confusion, and may even require excision[14]. No one in this study left to resolute by itself from the start, but most of them after using all treatment modalities left to resolute by itself without continuous treatments. Antibiotics are often the first line of treatment before the diagnosis of IGM is confirmed, because of the inflammatory character of the disease. Some patients may improve somewhat with this approach [1]. IGM is usually a sterile condition, and there are not enough data to support the routine use of antibiotics. The diagnosis of IGM is often reached after unsuccessful prolonged antibiotic therapy for supposed infectious mastitis. In a retrospective assessment of patients with histologically confirmed IGM who presented to a large tertiary care center for two years, none of the patients cured of multiple courses of antibiotics. Even in patients with concomitant infections or abscesses, the use of antibiotics alone is often failed in controlling the disease or improving symptoms[4]. In this study, 18(19.3%) of the cases used antibiotic alone, but few of them were improved, also antibiotic used with other medical and surgical treatments in the rest of the cases.

Once the diagnosis of IGM is recognized and infection has been excluded, management with steroid therapy may be started and is described to be a helpful treatment for IGM[4]. Many researchers have supported steroid therapy for IGM. In 1980, De Hertogh et al. followed by some other authors described the effectiveness of steroids (high dose of 60 mg per day for three weeks or long-term courses according to the response followed by gradual reduction of the dose) [6]. Acceptable results have been reported with high doses of prednisolone (60 mg/day for two weeks), but there has been reluctance due to adverse effects such as glucose intolerance and cushingoid features. Also, steroid treatment decreases the lesion sizes and enhances complete healing after excision[17]. In this study, 26 (28%) of the patients administered steroid, doses and duration were different by physicians and surgeons; generally, there was no good response to steroid. In a meta-analysis of all studies of IGM available between 1972 and 2010, the researchers reported full healing in 72% of the patients treated with corticosteroids[4]. Some reports advise that high doses of corticosteroids should be continued until complete resolution, but this treatment is often not easy because of the side effects. The strategy of using steroids is only practical in recurrent and complicated patients[14].

Methotrexate is an immunosuppressant that has been established to be useful, with or without concurrent corticosteroid therapy, for treatment of IGM. It is mainly useful in cases of steroid-resistant IGM and in patients who develop steroid-associated glucose intolerance or Cushing syndrome. Azathioprine is an immunosuppressant that can be used in patients who develop methotrexate-induced pneumonitis[4]. Limited data is available concerning methotrexate use in IGM. Two of three women treated by Wilson et al. recurred with this combined medical treatment, while Schmajuk and Genovese report successful treatment with methotrexate only used over several months for two women with IGM [1]. Due to the idea of the role of hyperprolactinemia in the pathogenesis and the recurrence of IGM, anti-prolactin medications (e.g.: cabergoline) were reported to be useful [6]. In this study none of the cases received immunosuppressants, but 14(15%) of them used anti-prolactin agents with or without hyperprolactinemia because only 6 (6.3)% of the cases were had high serum prolactin level.

Wide local excision with or without steroid therapy is the basis of the treatment in many kinds of literature[18], on the other hand, some authors reported that the classical approach of WLE (with or without steroids) is now being changed to primary medical therapy (steroids and immunosuppressive agents)[15]. WLE has revealed the shortest healing time, but a delay of wound healing and high recurrence rate were available in 10–50% and 8–38%, respectively [3]. Mastectomy is avoided in IGM, but yet has its indications for severe persistent wound infection, persistent fistula formation

and refractory cases [15]. In this current study, 1 (1%) of the patients undergone a mastectomy due to the severity of her condition, 39 (42) % of them undergone WLE after medical treatments failure, and 8 (8.6%) of them who had abscesses were drained either by aspiration or by incisional drainage. Tse et al. declared that surgery should be obligatory in IGM treatment and without surgical treatment patients may suffer from the chronic progressive disease [6]. In their experience, some surgeons find that WLE was associated with a lower complication rate than limited excision. WLE can be therapeutic also can be useful in providing an exact diagnosis. After excision, if there is no delayed wound healing, infection, or recurrence, more therapy is not required [14].

Recurrence is a well-recognized complication in IGM, with reported ranges from 5 to 67%, varying depending on the length of follow-up and initial treatment approach. Clinically, these recurrences may present months after treatment, with fistula formation or secondary infections with abscess formation. If reconstructive surgery is wanted, it is suggested to delay the operation until at least six months after the acute episode to be sure that all diseased tissue has been excised before reconstruction [1]. Some authorities stated that in the case of reconstructive surgery, implants are best avoided as they may act as foreign bodies and cause more granulomatous inflammation[15]. In this study, 75 (81%) of the patients cured after using most of the treatment modalities, and 18 (19%) of them recurred after treatment and followed up. It means that till now there is no main treatment for IGM and all treatments are given in the hope that may have an effect. Those with recurrence can be followed-up by repeating treatments for them or let it resolute by itself

In conclusions, Idiopathic Granulomatous Mastitis is an inflammatory disease of the breast, that cannot easily differentiate it with breast carcinoma. Histopathology is essential for a definitive diagnosis. There is still no ideal treatment for IGM, the results of this study concluded that WLE is the best treatment of choice. However complicated IGM with abscess, fistula, and diffuse involvement have the problem. Most of the patients do not respond to one treatment modality and recurrence is common; that's why the disease is called 'idiopathic' thus , there is no known cause to have an effective treatment modality.

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