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CLINICAL & BASIC RESEARCH

Idiopathic Granulomatous Mastitis

Six years of experience and the current evidence in literature

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abstract: ***Objectives:*** This study aimed to retrospectively describe the clinicopathological pattern and management experience of idiopathic granulomatous mastitis in women receiving care at the Royal Hospital, a tertiary care centre in Oman. The study then compared the researchers' experience with the current literature trends. ***Methods:*** The data of patients from January 2012 to December 2017 were reviewed retrospectively, after receiving ethical approval from the Centre of Studies and Research. ***Results:*** This retrospective study included 64 patients were confirmed to have idiopathic granulomatous mastitis. All patients were in the premenopausal phase, with only one being nulliparous. Mastitis was the most common clinical diagnosis; furthermore, half of the patients had a palpable mass. Most patients had received antibiotics during the span of their treatment. Drainage procedure was done in 73% of the patients, whereas excisional procedure was done for 38.7%. Only 52.4% of patients were able to achieve complete clinical resolution within six months of follow-up. ***Conclusion:*** There is no standardised management algorithm due to the paucity of high-level evidence comparing different modalities. However, steroids, methotrexate and surgery are all considered to be effective and acceptable treatments. Moreover, current literature tends towards multimodality treatments planned tailored case-to-case based on the clinical context and patients' preference.

Keywords: Granulomatous Mastitis; Mastitis; Breast Diseases; Oman.

Advances in Knowledge

- *The clinicopathological characteristics of Omani women with idiopathic granulomatous mastitis is similar to the international community.*
- *Multi-modality management of idiopathic granulomatous mastitis tends to have the best clinical outcome.*

Applications to Patient Care

- *Immunosuppressive therapy is important to ensure low-rate reoccurrence.*
- *Management plan should be tailored on a case-by-case basis, given the pros and cons of each treatment modality and according to patients' needs and expectations.*

Granulomatous mastitis is a relatively uncommon category of inflammatory breast conditions. Granuloma-based inflammation is the defining character of this inflammatory process; this can be further classified as specific or idiopathic.[1] Specific granulomatous mastitis is subcategorised as per the causative process to the granulomatous inflammatory reaction, which could be infections, autoimmunity or duct ectasis.[2] Whereas, if no cause was identified, then it is considered as idiopathic granulomatous mastitis (IGM).

Kessler and Wolloch were the first to set the bases of IGM in 1972 through reporting a series of five cases.[3] This condition tends to mimic inflammatory breast cancer and infectious breast conditions in the clinical presentation. Hence, IGM is a diagnosis of exclusion and histopathology examination is the gold standard for confirming diagnosis. IGM represent 1.8% of all benign breast conditions biopsied.[4] This condition was found to predominantly occur in women of childbearing age. Pregnancy and lactation history were noted in the majority in order to proceed with diagnosing the occurrence of IGM.[5]

Idiopathic granulomatous mastitis is an evolved term to declare the enigma behind its real aetiology. However, there have been some cases that reported IGM patients with common autoimmune clinical manifestations such as erythema nodosum and arthritis.[6] However, Altintoprak *et al.* observed no association between IGM patients and autoantibodies.[7] Accordingly, the reported autoimmune-related clinical manifestations could be attributed to another undiagnosed condition. Otherwise, the granulomatous mastitis is just the first manifestation of an autoimmune condition yet to flare completely.[8]

Aetiology-guided management is the standard of treatment for a specific type of granulomatous mastitis. While the idiopathic type of treatment is controversial, immunosuppressive treatment has lately emerged to be the mainstay of treatment. The

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role of surgical management is debatable. Yet, it is as vital an option as solo or combination therapy tailored according to a case-by-case basis.[9]

The aim of this study was to retrospectively describe the clinicopathological pattern and management experience of idiopathic granulomatous mastitis in women receiving care at The Royal Hospital, a tertiary care centre in Muscat, Oman.

Methods

Records of patient who attended The Royal Hospital, Muscat, Oman, were retrospectively reviewed from January 2012 to December 2017. The data collected included demographic data, past medical history, obstetric and gynaecological history, clinical manifestation history, radiological findings, microbiological findings, medical and surgical treatment along with the treatment outcome.

Data were obtained from the patient medical records system as well as from phone calls to complete missing history and related information. EpiData software, Version 4.4.2.1 (The EpiData Association, Odense, Denmark) was used for data entry and the Statistical Package for Social Sciences (SPSS) software, version 25.0 (IMB Corporation, Armonk, New York, USA) was used for statistical analysis. Categorical variables were expressed in percentages whereas continuous variables were expressed in mean with standard deviations.

Ethical approval for this study was received from the Centre of Studies and Research at the Royal Hospital (SRC#57/2018).

Results

A total of 65 patients with histopathological diagnosis of granulomatous mastitis were screened. One case was excluded from the analysis as granulomatous mastitis was due to a *mycobacterium tuberculosis* infection. The remaining 64 patients were confirmed to be idiopathic granulomatous mastitis by exclusion. The majority (96.8%) of patients responded to the phone calls inquiry form. The mean age of the study population was 35.56 ± 6.75 years and 95.3% of patients were Omani. The regional distribution of the patients was as follows: Al Batinah (40.6%), Muscat (28.1%), Al Sharqiyah and Al Dakhilia (10.9%), Al Dhahirah (6.3%), Al Buraimi and Dhofar (1.6%).

None of the patients had a history of tuberculosis infection. Only one patient had a resolved past diagnosis of an autoimmune condition (reactive arthritis). Diabetes mellitus was found in 10.9% of the patients. There was no history of smoking among the patients, but 22% gave a history of 2nd hand smoking. All of the women were premenopausal, 10.9% were pregnant and 31.3% were lactating at the time of presentation. Only one woman was nulliparous. The median number of parities was four. A history of abortion was present in 45.2% of patients and stillbirth in 6.5%; 76.2% have breastfed their children. A hormonal contraceptive was used by 51.7% of woman [Table 1].

The mean time for diagnosis was 11.44 ± 22.99 weeks. The most common clinical presentation was mastitis. All patient had a single breast affected which was almost equally distributed between each side. Half of the patients had a mass clinically and radiologically [Table 2]. About two-thirds had a surgical biopsy during a surgical intervention. Bacteriology testing was done and only 10.9% had a concomitant bacterial infection. Methicillin-sensitive *Staphylococcus aureus* was the most common isolated organism. Gram-negative organisms were isolated in two cases only, which were *Klebsiella pneumoniae* and *Proteus mirabilis*. Antibiotics were used in 93.8% of patients, whereas only 15.6% were treated with steroids. Severe inflammation was treated with 60 mg of prednisolone once per day for a week then gradually tapered off as

Table 1: Characteristics of the included idiopathic granulomatous mastitis patients (N = 64)

Characteristic	n (%)
Mean age at diagnosis in years ± SD	35.56 ± 6.75
Omani nationality	61 (95.3)
Diabetes mellitus	7 (10.9)
Autoimmune disease	1 (1.6)
History of tuberculosis	0 (0)
History of 1st hand smoking	0 (0)
History of 2nd hand smoking	13 (22)
History of abortion	28 (45.2)
History of stillbirth	4 (6.5)
Use of hormonal contraceptive	31 (51.7)
Hormonal treatment	3 (5.1)
Breastfeeding	48 (76.2)
Infertility treatment	7 (11.9)
Premenopausal	64 (100)
Mean time to diagnosis in weeks ± SD	11.44 ± 22.99
Pregnant at presentation	7 (10.9)
Lactating at presentation	20 (31.3)

SD = standard deviation.

Table 2: Clinical and radiological characteristics of the included idiopathic granulomatous mastitis patients (N = 64)

Characteristic	n (%)
Breast affected	
Left breast	31 (48.4)
Right breast	33 (51.6)
Clinical examination	
Mastitis	46 (71.9)
Abscess	29 (45.3)
Mass	44 (68.8)
Ultrasonography*	
Mastitis	42 (85.7)
Abscess	31 (63.3)
Mass	28 (56.0)

**14 patients had missing data.*

Table 3: Diagnostic work-up and management of the included idiopathic granulomatous mastitis patients (N = 64)

Characteristic	n (%)
Type of biopsy	
Core needle	25 (39.1)
Surgical	39 (60.9)
Positive bacterial culture*	
First culture	5 (10.9)
During follow-up	11 (23.4)
Medical management	
Antibiotics	60 (93.8)
Steroids	10 (15.6)
Surgical management	
Drainage†	46 (73.0)
Excision‡	24 (38.7)

**18 patients had missing data. †One patient had missing data. ‡Two patients had missing data.*

per patient response and tolerance. It was stopped once the patient reached clinical resolution or could not tolerate the treatment. Meanwhile, for mild-to-moderate inflammation, the starting dose was 20 mg of prednisolone once per day. Severity assessment was subjective to the treating surgeon. Drainage was done to 73% of patients. One-third of the patients had an excisional procedure [Table 3].

A total of 22 patients were lost to follow-up during the first six months. Out of 42 patients, 52.4% showed complete resolution, 23.8 % had partial resolution and 23.8% had persistence of IGM.

Discussion

Granulomatous mastitis is an infrequent diagnosis reached by exclusion of other, more common, breast condition with similar clinical manifestations. To diagnose a patient with idiopathic granulomatous mastitis, every effort should be made to exclude known cause of granulomatous infection as the treatment depends on it. Moreover, till date, the trigger of this granulomatous inflammation in this subset of patient population is unknown.

Granulomatous inflammation is a chronic inflammatory process due to ongoing cellular injury from a trigger, leading to granuloma formation with macrophages and multinucleated giant cells being the predominant inflammatory cells.[10] These pathohistological features explain the natural presentation of the disease as a chronic, recurrent and remittent infection. Plus, they tend to present with breast inflammation or mass or a combination of both.

IGM affects premenopausal childbearing woman. This was noticed in almost all studies as well in the present cohort.[1,2] The reason behind it is not clear yet, however, the breast features and cyclic changes of those women are unique and definitely have a vital environmental role for disease onset. Furthermore, it rarely affects nulliparous women. Most studies reported that the disease inception was a few years after pregnancy, but there were a few cases where disease onset was during pregnancy or lactation period.[4,5] There were a few reported cases where non-gestational- or non-lactational-related hyperprolactinaemia was responsible for the IGM which have resolved after normalisation of prolactin level.[11] All of this suggests that a fully mature breast is the best medium of disease onset and the elevation of prolactin level plays the role of a trigger.

Diabetes mellitus has not been reported to have any association with the occurrence of IGM. Instead, the presence of diabetes should urge the physician to rule out diabetic mastopathy, which is an important differential diagnosis of specific granulomatous mastitis to exclude.[12] Autoimmunity features and autoantibodies are occasionally found is some patients with IGM as stated earlier; therefore, excluding autoimmune disease is essential.[6–8] Additionally, autoimmune disease is known to occur more in women of childbearing age with a frequent occurrence of abortions and still-birth.[13] Furthermore, the IGM cohort was found to have a significant percentage of overall fetal loss (51.6%). Looking at the similarities

between IGM patients and those with autoimmune diseases indicates that IGM is probably a disease under the same umbrella that is yet to be understood well.

There is no known association between breastfeeding, use of oral contraceptive use, smoking and IGM. The cohort in this study had a similar rate of breastfeeding compared to other studies but a higher percentage of oral contraceptives, which could be due to culturally different preferences.[4,5,7] Most patients tend to present with mastitis with or without abscess as seen in the present cohort. Moreover, they are diagnosed late because of significant overlap with acute bacterial mastitis.

The radiological findings of IGM patients are non-specific with a wide range of features. On ultrasonography, the breast tends to have an altered echotexture with the presence of a single or multiple hypoechoic mass with single or multiple collections. In the present cohort, abscess was found more commonly than mass. In mammography, abnormal asymmetrical density is the most common finding.[14]

The usual microbiological work-up for granulomatous mastitis is to rule out fungal infection and tuberculosis infection as they are the most common infections causing a granulomatous reaction. Recent data is recommending routine testing to rule out *Corynebacterium* infections as well its association with a special type of recurrent granulomatous mastitis called cystic neutrophilic granulomatous mastitis (CNGM). This recommendation was based on the fact that those types of infections require a special antibiotics regimen for a longer duration. This type of organism is difficult to detect; however, new technology has made it easy, such as using 16S RNA sequencing and matrix-assisted laser desorption ionisation–time of flight mass spectrometry.[15] Once those cultures came to be negative, IGM diagnosis can be established; however, it's not uncommon to have a secondary bacterial infection.[5] The current researchers have also demonstrated a secondary bacterial infection and it was noted to be more common during the follow-up period. For that reason, bacterial cultures are needed on first encounter at every relapse as well in order to be treated.

IGM diagnosis is difficult to reach; as a result, most patients on their first encounter are treated with antibiotics plus aspiration or surgical drainage. Only when the patient does not respond to treatment or has recurrence that this diagnostic entity is considered. This is clearly noted in the present cohort, as 93.8% received antibiotics and 73% had drainage procedure.

However, the current literature is supporting the use of immunosuppression for the treatment of IGM, such as corticosteroids or other immunomodulators such as methotrexate.[16,17] Pandey *et al*., have reported that 80% of patients had complete resolution on systemic steroids only.[16] Additionally, Montazer *et al*., have reported in a small randomised clinical trial that high-dose steroids have achieved 93.3% remission rate with 0% recurrence within a 12-month follow-up period.[18] Tang *et al*. have also reported the effectiveness of intralesional steroid injection.[19] Steroids' effectiveness was also demonstrated in another randomised clinical trial to be above 80% with a recurrence rate of nearly 20%.[20] It was demonstrated in that trial that topical steroids are as effective as systemic steroids in terms of response rate, but with a prolonged recovery period and a lesser side-effect profile.

Non-steroidal immunosuppressive/steroid-sparing therapy have emerged to overcome the systemic steroids' side-effects from prolonged use. Of those groups, methotrexate so far have proven to be effective as monotherapy and in combination therapy. As monotherapy, Kundaktepe *et al*. reported a complete recovery rate of 81.25%, which is similar to the reported rates of steroidal treatment with a low and acceptable side-effect profile compared to steroids.[17] Furthermore, Kehribar *et al*. have demonstrated a remission rate of 87.9% with combination therapy of steroids and methotrexate with zero relapse during a 24-month follow-up period.[21] Unfortunately, in the present cohort, the use of immunosuppressive medications was minimal because it was only recently introduced to the unit, which could explain the poor remission rates.

Alternatively, surgical treatment is also an effective method to reach remission. Zhou *et al*. have demonstrated in their systematic review of 10 studies (1,101 patients) that there is no significant difference between non-surgical (including oral steroids, MTX, antibiotics and observation) and surgical (including excisional and drainage procedures) when comparing remission and relapse rates.[22] Nevertheless, Lei *et al*. reported in their meta-analysis of 15 studies that surgical treatment (excisional and drainage) had the highest complete remission rate and the lowest recurrence rate.[9] Ma *et al*. conducted another recent systematic review and meta-analysis of 21 publications that reported surgical treatment to be superior to non-surgical management.[23] Though, to reach such a high remission rate with low recurrence in surgical management, the patient would have to go for an excisional procedure with negative surgical margin for active disease.[24] This will lead to large breast tissue volume loss and a large surgical scar, which would be considered disfiguring in some cases. Thus, excisional procedures should be left for cases of failed medical

management or for patients unwilling to receive medical management or asking for a quick resolution. In the present cohort, 38.7% had excisional procedure.

There are studies that have demonstrated that IGM is self-limiting and can be observed only without treatment. Bouton *et al.* have reported the largest cohort of patients subjected to observation only, where 72% of patients achieved remission during an average time of 7.4 months, with 11% reoccurrence rate.[25] Those outcomes are comparable to some studies where steroids were used.[9]

The aforementioned are reasons why the treatment is still not standardised. Therefore, the patient is best treated with multi-modality treatment that are selected on a patient-to-patient basis.[26] Latest publications have looked into multi-modality treatments for this reason. For example, Wang *et al.* have reported the best clinical outcome in patients treated with surgery after steroid therapy.[27] Akcan *et al.* is another example where the researchers have reported superiority of wide local excision after steroidal therapy compared to surgery alone.[28] Likewise, Godazandeh *et al.* have reported, in their recent systematic review and meta-analysis, that steroids with surgery is superior to steroids alone.[29] Combination therapy does not only improve the remission rate and reduce the recurrence rate but also reduces the breast tissue volume loss and the size of the surgical scar.

Conclusion

Triple breast assessment is a necessity in all patients with breast complaints in order not to miss or delay a diagnosis of cancer or a chronic breast inflammatory disorder. Moreover, recurrent breast inflammation with or without mass should raise the suspicion of granulomatous mastitis and comprehensive work-up is essential. Once the diagnosis of idiopathic granulomatous mastitis has been established and other differential diagnoses are ruled out, an agreed multi-modality treatment plan should be commenced according to patient needs and preferences.

AUTHORS' CONTRIBUTION

MMA and SKR conceptualised and designed the study. MMA collected the data and drafted the manuscript. MMA and SKR edited and revised the manuscript. Both authors approved the final version of the manuscript.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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