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## 7 **Idiopathic Granulomatous Mastitis**

8 *A six-years' experience and the current evidence in literature*

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### 16 **Abstract**

17 **Objective:** This study aims to retrospectively describe the clinicopathological pattern and  
18 management experience of idiopathic granulomatous mastitis in women attending care at royal  
19 hospital, a tertiary care center at sultanate of Oman. Then to compare our experience with the  
20 current literature trends. **Methods:** The data of patient were retrospective reviewed from 1st of  
21 January 2012 to 31st of December 2017, after receiving ethical approval from the center of studies  
22 and research. **Results:** Sixty-four patients were conformed to have idiopathic granulomatous  
23 mastitis. All of our patients were in the premenopausal phase with only one being nulliparous.  
24 Mastitis was the most common clinical diagnosis and half of them had a palpable mass. Most of  
25 our patient had received antibiotics during their treatment span. Drainage procedure was done in  
26 73% of the patient, whereas excisional procedure was done for 38.7%. Only 52.4% of our patient  
27 were able to achieve complete clinical resolution within 6 months of follow-up. **Conclusion:** There  
28 is no standardized management algorithm, due to the paucity of high-level evidence comparing  
29 different modalities. However, Steroids, Methotrexate and surgery are all considered to be

30 effective and acceptable treatments. Moreover, current literature tends towards multi-modality  
31 treatments planned tailored case-to-case based on the clinical context and patient's preference.

32 **Keywords:** Granulomatous; Mastitis; Chronic breast infection.

33

### 34 **Advancement in knowledge**

- 35 • The clinicopathological characteristics of Omani women's care similar to the international  
36 community.
- 37 • Multi-modality management of idiopathic granulomatous mastitis tend to have the best  
38 clinical outcome.

### 39 **Application to Patient Care**

- 40 • Immunosuppressive therapy is important to ensure low-rate reoccurrence.
- 41 • Management plan should be tailored case-by-case, given the pros and cons of each  
42 treatment modality, according to patients' need and expectations.

43

### 44 **Introduction**

45 Granulomatous mastitis is a relatively uncommon category of inflammatory breast conditions.  
46 Granuloma based inflammation is the defining character of this inflammatory process. This entity  
47 can be further classified as specific or idiopathic (1). Specific granulomatous mastitis is  
48 subcategorized as per the causative process to the granulomatous inflammatory reaction, which  
49 could be Infections, autoimmunity or duct ectasis (2). Whereas, if no cause was identified, then it  
50 is considered as idiopathic granulomatous mastitis (IGM).

51

52 Kessler and Wolloch were the first to set the bases of this diagnostic entity in 1972 through  
53 reporting a series of five cases (3). This condition tends to mimic inflammatory breast cancer and  
54 infectious breast conditions in the clinical presentation. Hence, IGM is a diagnosis of exclusion  
55 and histopathology examination is the gold standard to conform the diagnosis. IGM represent 1.8%  
56 of all benign breast conditions biopsied (4). This condition was found to predominantly occur in  
57 childbearing age women. Pregnancy and lactation history were noted in majority to proceed the  
58 occurrence of IGM (5).

59

60 Idiopathic granulomatous mastitis is an evolved term to declare the enigma behind its real etiology.  
61 However, there have been some cases reported IGM patients with common autoimmune clinical  
62 manifestation such as erythema nodosum and arthritis (6). However, Altintoprak F and colleagues  
63 observed no association between IGM patients and autoantibodies (7). Accordingly, those reported  
64 autoimmune related clinical manifestation could be attributed to another undiagnosed condition.  
65 Otherwise, the granulomatous mastitis is just the first manifestation of autoimmune condition yet  
66 to flare completely (8).

67  
68 Etiology guided management is the standard of treatment for specific type granulomatous mastitis.  
69 Whereas, the idiopathic type treatment is controversial. However, immunosuppressive treatment  
70 has lately merged to be the mainstay of treatment. The role of surgical management is debatable.  
71 Yet, it is a vital option as solo or combination therapy tailored to case base (9).

72  
73 The aim of this study is to retrospectively describe the clinicopathological pattern and management  
74 experience of idiopathic granulomatous mastitis in women attending care at royal hospital, a  
75 tertiary care center at sultanate of Oman.

76  
77 **Methods**  
78 Patient records were retrospectively reviewed from 1<sup>st</sup> of January 2012 to 31<sup>st</sup> of December 2017,  
79 after receiving ethical approval from the center of studies and research. Data collected included,  
80 demographic data, past medical history, obstetric and gynecological history, clinical manifestation  
81 history, radiological findings, microbiological findings, medical and surgical treatment along with  
82 the treatment outcome.

83  
84 Data were obtained from patient medical records system, plus from phone calls to complete  
85 missing history related information. EpiData software v4.4.2.1 was used for data entry and SPSS  
86 statistics software v25 used for statistical analysis. Categorical variables were expressed in  
87 percentages whereas, continuous variables were expressed in mean with its' standard deviation.

88

89 **Results**

90 Our search revealed a total of 65 patients with histopathological diagnosis of granulomatous  
91 mastitis. One case was excluded from the analysis as granulomatous mastitis was due to  
92 mycobacterium tuberculosis infection. The remaining 64 patients were conformed to be idiopathic  
93 granulomatous mastitis by exclusion. 96.8% of the woman responded to the phone calls inquiry  
94 form. The mean age of our population was  $35.56 \pm 6.75$  years old. 95.3% of patients were Omani's.  
95 The regional distribution of our patients was as follow, Al Bitanah 40.6%, Muscat 28.1%, Al  
96 Sharqiyah & Al Dakhilia 10.9%, Al Dhahirah 6.3%, Al Buraimi & Dhofar 1.6%.

97  
98 None of our patients had previous history of tuberculosis infection. Only one patient had a resolved  
99 past diagnosis of autoimmune condition, which was reactive arthritis. Diabetes mellites was found  
100 in 10.9% of the patients. There was no history of smoking among our patients but 22% gave history  
101 of 2<sup>nd</sup> hand smoking. All of the woman was premenopausal, 10.9% were pregnant and 31.3% were  
102 lactating at time of presentation. Only one woman was nulliparous. The median number of parities  
103 was four. History of abortion was present in 45.2% and still birth in 6.5%. Seventy six percent  
104 have breastfed their children. Hormonal contraceptive was used by 51.7% of woman (Table 1).

105  
106 The mean time to diagnosis was  $11.44 \pm 22.99$  weeks. The most common clinical presentation was  
107 mastitis. All of our patient had a single breast affected and almost equally distributed between each  
108 side. Half of our patients had a mass clinically and radiologically (Table 2). About two thirds had  
109 a surgical biopsy during a surgical intervention. Bacteriology testing done and only 10.9% had a  
110 concomitated bacterial infection. Methicillin-sensitive Staphylococcus aureus was the most  
111 common isolated organism. Gram-negative organisms were isolated in two cases only which were  
112 klebsiella pneumoniae and proteus mirabilis. Antibiotics were used in 93.8% of our patients,  
113 whereas only 15.6% were treated with steroids. Severe inflammation was treated with 60  
114 milligrams once per day of prednisolone for a week then gradually tapered as per patient response  
115 and tolerance. It would be stopped once patient reach clinical resolution or could not tolerate the  
116 treatment. While, mild to moderate inflammation the starting dose was 20 milligram once per day  
117 of prednisolone. Severity assessment was subjective to the treating surgeon. Drainage was done to  
118 73% patients. One third of patients had an excisional procedure (Table 3).

119

120 Twenty-two patients have lost follow up during the first 6 months. Out of 42 patients, 52.4%  
121 showed complete resolution, 23.8 % had partial resolution and 23.8% had persistence of disease.

122

### 123 **Discussion**

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

129

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

135

136 IGM affects the premenopausal childbearing woman. This was noticed in almost all studies as well  
137 in our cohort. The reason behind it is not clear yet, but those women breast features and cyclic  
138 changes are unique and defiantly has a vital environmental role for disease onset. Furthermore, it  
139 rarely affects the nulliparous woman. Most studies reported the disease inception was few years  
140 after pregnancy, but there were few cases where disease onset was during pregnancy or lactation  
141 period (4-5). There were few reported cases where non-gestational/non-lactational related  
142 hyperprolactinemia were responsible for the IGM which have resolved after normalization of  
143 prolactin level (11). This all suggest that a full mature breast is the best medium of disease onset  
144 and elevation of prolactin level have a triggering role.

145

146 Diabetes mellitus have not been reported to have any association between it and the occurrence of  
147 IGM. Instead, the presence of diabetes should stimulate the physician to rule out diabetic  
148 mastopathy, which is an important differential diagnosis of specific granulomatous mastitis to  
149 exclude (12). Autoimmunity features and Autoantibodies are found is some patients with IGM  
150 occasionally as stated earlier, therefore excluding autoimmune disease is essential (6-8).

151 Additionally, autoimmune disease is known to occur more in childbearing age women and that  
152 abortions and still births are known to be of frequent occurrence in them (13). Furthermore, we  
153 found in our IGM cohort to have a significant percentage of overall fetal loss reaching to 51.6%.  
154 Looking at the similarities between IGM patient and autoimmune disease patient, give the  
155 indication that IGM probably is a disease under the same umbrella that is yet not well understood.

156  
157 There is no known association between breastfeeding, oral contraceptive use, smoking and IGM.  
158 Our cohort similar rate of breastfeeding compared to other studies but a higher percentage of oral  
159 contraceptive than other studies, which could be due to culture different preference only (4-5, 7).  
160 Most patients tend to present with mastitis with or without abscess as seen in our cohort. Moreover,  
161 they are diagnosed late because of significant overlap with acute bacterial mastitis.

162  
163 The radiological findings of IGM patient are non-specific with wide range of findings. On  
164 ultrasonography, the breast tends to have an altered echotexture with the presence of a single or  
165 multiple hypoechoic mass with single or multiple collections. In our cohort abscess was found  
166 more commonly than a mass. In mammography, abnormal asymmetrical density is the most  
167 common finding (14).

168  
169 The usual microbiological work-up for granulomatous mastitis is to rule out fungal infection and  
170 tuberculosis infection, because those are the most common infections causing granulomatous  
171 reaction. Recent data is recommending routine testing to rule out *Corynebacterium* infections as  
172 well due its association with special type of recurrent granulomatous mastitis called, cystic  
173 neutrophilic granulomatous mastitis (CNGM). This recommendation was based on the fact that,  
174 those types of infections require special antibiotics regimen for longer duration. This type of  
175 organisms is difficult to be detect, however new technology made it easy, using 16S RNA  
176 sequencing and matrix-assisted laser desorption ionization–time of flight mass spectrometry  
177 (MALDI-TOF MS) (15). Once those cultures came to be negative then IGM diagnosis can be  
178 established, however it's not uncommon to have a secondary bacterial infection (5). We have also  
179 demonstrated secondary bacterial infection and it was noted to be more common during the follow  
180 up period. For that reason, bacterial cultures are needed on first encounter at every relapse as well,  
181 in order to treat as well.

182

183 IGM diagnosis is a difficult to reach, as a result most of patient on their first encounter are treated  
184 with antibiotics plus aspiration or surgical drainage. Only when the patient does not respond to  
185 treatment or has reoccurrence, this diagnostic entity is thought off. This is clearly noted in our  
186 cohort, as 93.8% received antibiotic and 73% had drainage procedure.

187

188 However, the current literature is supporting the use of immunosuppression for the treatment of  
189 IGM, such as corticosteroid or other immunomodulatory such as methotrexate (16-17). Pandey et  
190 al (16), have reported 80% of patients had complete resolution on systemic steroids only.  
191 Additionally, Montazer et al (18), have reported in a small randomized clinical trial that high dose  
192 steroids have achieved 93.3% remission rate with 0% reoccurrence within 12 months follow-up  
193 period. Interestingly, Tang et al (19) have also reported the effectiveness of Intralesional steroid  
194 injection. Steroid's effectiveness was also demonstrated in another randomized clinical trial by  
195 Çetin et al (20) to be above 80% with reoccurrence rate of near 20%. They have demonstrated in  
196 their trial that topical steroids are as effective as systemic steroids in terms of response rate, but  
197 with prolonged recovery period and lesser side effect profile.

198

199 Non-steroidal immunosuppressive/steroid-sparing therapy have emerged to overcome the  
200 systemic steroids side-effect from prolonged use. Of those group, methotrexate so far have proven  
201 efficacy as monotherapy and as combination therapy. As monotherapy, Papila Kundaktepe et al  
202 (17), reported a complete recovery rate of 81.25%, which similar to the reported rates of steroidal  
203 treatment, with low acceptable side-effect profile compared to steroid. Furthermore, Kehribar et  
204 al (21), have demonstrated a remission rate of 87.9% with combination therapy of steroids and  
205 methotrexate with zero relapse during 24-months follow-up period. Unfortunately, in our cohort  
206 the use of immunosuppressive medications was decimal because it was only recently introduced  
207 to the unit and this could explain the poor remission rates.

208

209 On the other hand, surgical treatment is also an effective method to reach remission. Zhou et al  
210 (22), have demonstrated in their systematic review of 10 studies (1101 patients), that there is no  
211 significant difference between non-surgical (includes; oral steroids, MTX, antibiotics, and  
212 observation and surgical (includes; excisional and drainage procedures) when comparing

213 remission and relapse rates. Nevertheless, Lei et al (23), reported in their meta-analysis of 15  
214 studies that surgical treatment (excisional & drainage) had the highest complete remission rate and  
215 the lowest reoccurrence rate. Ma et al (24), is another recent systematic review and meta-analysis  
216 of 21 publications, that reported surgical treatment is superior to non-surgical management.  
217 Though, to reach to this high remission rate with low reoccurrence rate in surgical management,  
218 the patient would have to go for an excisional procedure with negative surgical margin for active  
219 disease (25). This will lead to large breast tissue volume loss with large surgical scar, which would  
220 be considered disfiguring in some cases. Thus, excisional procedures should be left for cases failed  
221 medical management, not willing for medical management or patients asking for a quick fix. In  
222 our cohort, 38.7% had excisional procedure.

223  
224 Fascinatingly, there are studies that have demonstrated that IGM is self-limiting and can be  
225 observed only without treatment. Bouton et al (26), have reported the largest cohort of patients  
226 subjected to observation only, where 72% of patients achieved remission during an average time  
227 of 7.4 months, with 11% reoccurrence rate. Those outcomes are comparable to some studies  
228 outcome from the use of steroids.

229  
230 Those are the reasons why the treatment is still not standardized. Therefore, patient is best treated  
231 with multimodality treatment and those treatments are selected patient-to-patient base (27). For  
232 this reasons, latest publications have looked into multi-modality treatments. For example, Wang  
233 J., and colleagues have reported best clinical outcome in patients treated with surgery after steroid  
234 therapy (28). Akcan et al (29), is another example, where they have reported superiority of wide  
235 local excision after steroidal therapy when compared to surgery alone. Likewise, Godazandeh G,  
236 and colleagues have reported in their recent systematic review and meta-analysis, that steroids with  
237 surgery is superior to steroids alone (30). The combination therapy dose not only improve the  
238 remission rate and reduce the reoccurrence rate, but they also reduce the breast tissue volume loss  
239 and the surgical scar.

240

## 241 **Conclusion**

242 Triple breast assessment is a necessity in all patients with breast complain in order not to miss or  
243 delay a diagnosis of cancer or a chronic breast inflammatory disorder. Moreover, recurrent breast

244 inflammation with or without mass should raise the suspicion of granulomatous mastitis and  
245 comprehensive work-up is essential. Once the diagnosis of idiopathic granulomatous mastitis has  
246 been established and other differential diagnoses were ruled out, an agreed multi-modality  
247 treatment plan should be commenced according to patient needs and preference.

248

#### 249 **Authors' Contribution**

250 MMA and SKR conceptualized and designed the study. MMA collected the data and drafted the  
251 manuscript. MMA and SKR edited and revised the manuscript. Both authors approved the final  
252 version of the manuscript.

253

#### 254 **Conflict of Interest**

255 The authors declare no conflicts of interest.

256

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 342

343 **Table 1:** Demographic and baseline characteristics of our IGM patients

<b>Patient's characteristics</b>	<b>n (%) or Mean ± SD</b>
Age at diagnosis in years	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 1 <sup>st</sup> hand smoking	0 (0%)
History of 2 <sup>nd</sup> had 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%)
Time to diagnosis in weeks	11.44 ± 22.99
Pregnancy at presentation	7 (10.9%)
Lactate at presentation	20 (31.3%)

344 **Table 2:** Clinical and radiological characteristics of our IGM patients  
 345

<b>Patient's characteristics</b>	<b>n (%) or Mean ± SD</b>
<b>Breast affected</b>	
Left breast	31 (48.4%)
Right breast	33 (51.6%)
<b>Clinical examination</b>	
Mastitis	46 (71.9%)
Abscess	29 (45.3%)
Mass	44 (68.8%)
<b>Ultrasonography*</b>	
Mastitis	42 (85.7%)

Abscess	31 (63.3%)
Mass	28 (56.0%)

346 \*14 patients had missing data

347

348 **Table 3:** Diagnostic work-up and management of our IGM patients

<b>Patient's characteristics</b>	<b>n (%) or Mean <math>\pm</math> SD</b>
<b>Type of biopsy</b>	
Core needle	25 (39.1%)
Surgical	39 (60.9%)
<b>Positive bacterial Culture*</b>	
First culture	5 (10.9%)
During follow-up	11 (23.4%)
<b>Medical Management</b>	
Antibiotics	60 (93.8%)
Steroids	10 (15.6%)
<b>Surgical Management</b>	
Drainage**	46 (73.0%)
Excision***	24 (38.7%)

349 \*18 patients had missing data; \*\*1 patient had missing data; \*\*\*2 patients had missing data

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