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7 **Idiopathic Granulomatous Mastitis**

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

9 ***Mahmood M. Al Awfi¹ and Salim K. Al Rahbi²**

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11 ¹Department of General Surgery, Oman Medical Specialty Board, Muscat, Oman; ²Department
12 of Surgery, The Royal Hospital, Muscat, Oman

13 *Corresponding Author's e-mail: mahmood.alawfi@gmail.com

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 1st of January 2012 to 31st 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 confirmed 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 ± 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 2nd 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 ± 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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259

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 342

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

Patient's characteristics	n (%) or Mean ± SD
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 st hand smoking	0 (0%)
History of 2 nd 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

Patient's characteristics	n (%) or Mean ± SD
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%)

346 *14 patients had missing data

347

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

Patient's characteristics	n (%) or Mean \pm SD
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%)

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

Accepted Article