Granulomatous Mastitis: A diagnostic and Therapeutic Challenge

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ABSTRACT

Objective: Granulomatous mastitis (GM), including idiopathic granulomatous mastitis (IGM) and tuberculous mastitis (TBM), is a rare and benign disease of the breast. Our aim is to highlight the nonspecific clinical presentations, diagnostic difficulties and therapeutic approaches of GM.

Methods: Sixty-eight women with GM (52 with IGM and 16 withTBM) were included in the study. All clinical characteristics, diagnostic methods, and therapeutic approaches were evaluated in detail.

Results: The patients with IGM had earlier onset in comparison to the patients with TBM. Suspicion of malignancy clinically was more frequent in patients with TBM than in those with IGM. While anti-TB therapy was quite effective in TBM patients, surgical excision had the lowest recurrence rate in patients with IGM.

Conclusion: GM usually poses a diagnostic and therapeutic challenge for the physicians. TB is still an important cause of GM, and should be always kept in mind in the differential diagnosis. Due to the diagnostic and therapeutic challenges, a multidisciplinary approach is needed to avoid mistakes and to obtain well outcomes.

Keywords: Diagnosis, granulomatous mastitis, idiopathic, tuberculous mastitis

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INTRODUCTION

The term, granulomatous mastitis (GM), defines a large group of diseases that are characterized with granulomatous inflammation and associated with various etiological factors. GM is not common, and can be divided into two main groups including specific and non-specific mastitis (1). Tuberculosis (TB), sarcoidosis, fungal infections and trauma consist the majority of specific GM. On the other hand, non-specific GM, also called as idiopathic granulomatous mastitis (IGM), refers to conditions for which the etiological causes cannot be identified. Today, tuberculous mastitis (TBM) remains a public health problem in certain areas of the world, and is often difficult to differentiate from IGM. In addition, the optimal treatment of GM has not been well demonstrated except TBM.

These two clinical entities have been generally reported as single case reports or small-scale series (2-4). Therefore, the long-term outcomes of treatment modalities have not been well described. In this paper, we aimed to reveal the clinical characteristics, diagnostic findings, and therapeutic outcomes of IGM and TBM in one of the largest series in the literature.

SUBJECTS AND METHODS

Patients

Between 2005 and 2015, sixty-eight female patients diagnosed with GM, including TB mastitis and IGM, were retrospectively evaluated. The patients' demographic characteristics, coexisting medical problems, presenting symptoms and findings, duration of complaints, smoke and alcohol use, oral contraceptive use, and the presence of pregnancy, lactation and breastfeeding were recorded. Written informed consents of the patients were waived due to the retrospective nature of the study.

Diagnosis

Detailed breast examination including the axillary region was routinely performed in all cases. While breast ultrasonography (US) was used in all patients, mammography (MM) was carried out in patients above 35 years of age. Definitive diagnosis was achieved by tru-cut biopsy or excisional/incisional biopsy and histopathological confirmation. All biopsy specimens were also subjected to Ziehl-Nielsen/Gram/PAS staining and culture for investigating of fungal and TB infections.

Treatment and follow-up

The patients presented with inflammatory process were initially administered antibiotherapy for an average of two weeks. In addition, surgical or US-guided drainage was performed for the patients with abscess formation. The patients with IGM were divided into three treatment groups: Antibiotherapy alone, steroid and surgery. Surgical intervention was performed for the patients with isolated breast mass. However, the cases with extensive disease such as multiple sinus formation, erosion and other skin changes were treated with prednisolone for a duration of three months (≤32 mg/day for the first month, and continued by a tapering schedule of usually 24, 16, 18, and 4 mg for the following two months). In addition, antibiotherapy plus observation was the choice of treatment for the patients who had mild disease or did not accept surgery or steroid therapy.

The patients diagnosed with TBM were consulted by a chest specialist, and then received a standard six-month anti-TB therapy (isoniazid 5 mg/kg day, max. 300 mg/day and rifampicin 10 mg/kg day, max. 600 mg/day for 6 months; pyrazinamide, 20-30 mg/kg day, max. 2 g/day and streptomycin 15 mg/kg day, max. 1 g/day or ethambutol 15-20 mg/kg day, max. 1.5 g/day for the first two-month period). Additional therapy of 3-6 months was needed for the patients whom had recurrent or persistent symptoms. All patients were checked by

regular intervals within the follow-up period, and response to therapy was evaluated by both clinically and radiologically.

Statistical analyses

The Statistical package for social science (SPSS 21.0) IL-Chicago- USA standard version was used for data analyses. Descriptive analysis was done for demographic, clinical and radiographic features, and results were presented as mean ± SD/percentages for continuous variables and number/percentage for categorical variables. Differences between the groups and subgroups were evaluated using Chi-square ($\chi 2$) test and Mann Whitney U test. Significance level was accepted as $p < 0.05$.

RESULTS

Sixty-eight patients (median age: 36.03 years, range: 19 to 64) diagnosed as GM were included in the study. Of these, 16 (23.5%) patients with a median age of 31.06 years were identified as TBM, and the remaining 52 (76.5%) cases with a median age of 37.56 years diagnosed as IGM. The patients with IGM had earlier onset in comparison to the patients with TBM (p=0.032). The presence of active extramammarian TB (p=0.002) and contact history of TB (p=0.011) were significantly frequent in the TBM group compared with the IGM group. All the demographic and clinical data of the patients in the two groups are presented in Table 1.

The most common presenting symptoms were breast pain and mass in each group. The mean duration of symptoms prior to admission was similar in the two groups (p=0.776). At admission, clinically suspicion of malignancy was more frequent in patients with TBM than in patients with IGM (p=0.003). All the clinical characteristics of the two groups are present in Table 2.

All patients in the two groups underwent ultrasonographic examination; however, MM was performed in 13 patients with IGM and 5 patients with TBM (Table 3). Irregularly hypoechoic mass was the most common sonographic finding in the two groups; however, it was more frequent in patients with TBM than in those with IGM (p=0.018). MM revealed an asymmetric density as the most frequent finding in each group. Radiologically suspicion of malignancy was found to be more frequent in TBM group compared with the IGM group (p=0.002).

Histopathological diagnosis was based on tru-cut biopsy in all patients, and it was diagnostic in 90.3% of the patients with IGM and %100 of the patients with TBM. Lobulocentric non-caseating granuloma composed of epithelioid histiocytes and multinucleated giant cells were the leading pathologic findings in IGM. On the other hand, diffuse granulomas with or without caseation necrosis were the main pathological finding in TBM. All specimens were also subjected to culture and Ziehl-Nielsen staining for identifying m. tuberculosis. Culture of breast tissue and AFB staining were positive in 31.2% (5/16) and 18.7% (3/16) patients with TBM, respectively. PCR analysis could be done in only 4 patients, with a positivity rate of 50%.

Antibiotic therapy for two weeks was initially received to the patients who presented with an acute inflammatory process (34 in IGM Group and 10 in TBM Group). Of those, 18 (15 in IGM Group and 3 in TBM Group) had also abscess formation, and therefore underwent US-guided drainage.

Three main treatment modalities were used in the patients with IGM (Table 4). In antibiotic group, only nine (50%) cases showed complete resolution of symptoms. Surgery and steroid therapies were performed in the remaining 4 and 5 patients, respectively. Twenty patients (38.5%) with IGM received steroid treatment as a first-line therapy for three months. Response to steroid therapy was achieved in 16 patients (80%); however, wide local excision

was needed in the remaining four cases (20%). Wide local excision was performed in 14 patients (26.9%) as a first-line therapy, and only two recurrences were seen during the follow-up period, as the lowest relapsing rate between the three treatment groups (p=0.047).

All of the patients with TBM received standard anti-TB therapy for 6 months. Extended treatment for 9-12 months was needed in 3 (18.7%) whom had discontinued drug therapy and had persistent symptoms and signs. However, only one (6.2%) patient underwent wide local excision due to persistent disease.

DISCUSSION

The women of childbearing age are often affected from GM (5), as was in our study population. In addition, we found TBM patients were significantly younger than those with IGM. Contrary, the patients with IGM had early onset in comparison to the cases with TBM in another study (4). GM has typically unilateral involvement; however, bilaterality has been rarely reported (6). In our study, bilateral involvement was found in only one patient with TBM.

Painful breast mass was the most common physical finding, consistent with the previous reports (7, 8). The other reported symptoms were inflammatory changes on the overlying skin such as erythema and swelling, fistulation, ulceration, and nipple retraction (9). Axillary lymphadenopathy may be present in a small number of patients (10). Similarly, we found enlarged lymphadenopathy in only 29% of the patients with IGM and one fourth cases with TBM. Additionally, GM may be presented as abscess formation. These abscesses are known to be sterile; however, secondary infections can be added. In our work, 30% of cases had a radiologically-detected breast abscess, and this presentation was statistically similar between the patients with IGM and TBM. GM can be also confused with breast cancer (2,

11). In our study, both clinical and radiological suspicion of malignancy were significantly higher in TBM patients than in IGM patients. Similarly, Seo et al (4) reported that 70% of the patients with TBM had a suspicious malignant neoplasm radiologically in their study.

The etiology of GM is often unclear except specific causes such as TB. Although Turkey was classified as a low prevalent country on TB (12), this disease remains an important public health problem in certain areas of the country. In the present study, TBM constituted approximately one fourth of all GMs. Breast TB is frequently associated with a past history of TB or active TB at another site of the body such as the lungs, pleura, and lymph nodes (4). Similarly, most of our cases had active extramammarian TB or a past/contact history of TB.

IGM, first described by Kessler and Wollock (13), has often been reported as small case series (3, 14, 15). To date, various associated conditions such as smoking, oral contraceptive use, pregnancy, breastfeeding, Corynebacterium infection, and α1-antitrypsin deficiency have been described (1, 9). Autoimmune disorders were also found to be associated with IGM (3,16) However, Asoglu et al (17) reported that all cases in their study were found to be negative for ANA and RF. Similarly, only one patient with IGM had a known autoimmune disease in our study. Oral contraceptive use, hyperprolactinemia, gestation and breastfeeding are all associated with hormonal alterations and hypersecretion. A case of hyperprolactinemia caused by a prolactinoma was described by Rowe (18), however none of the patients in the present study had a history of galactorrhea. Oral contraceptive use was noted in 42% of the cases with IGM in a study from Turkey (19). In contrast, some authors found that none of the patients had a history of oral contraceptive use in their studies (7, 20). We found that approximately one fourth of the patients with GM had a history of oral contraceptive use. On the other hand, approximately 10% of the cases had an active breastfeeding, and 13.5% of the patients had a history of breastfeeding within the last one

year. Additionally, only three patients were pregnant at the time of diagnosis. In a study by Baslaim et al (20), only one patient was pregnant, and four had an active breastfeeding; however, all cases had a history of breastfeeding.

GM usually has non-specific radiological findings. Irregular hypoechoic mass with inflammatory changes was the most common sonographic finding in both IGM and TBM consistent with the literature (4, 5). However, multiple hypoechoic masses, parenchymal heterogeneity, and fluid collection may be detected by US. In addition, increased asymmetrical density is the most commonly reported mammographic finding as was in our study (4, 7, 21).

The Mantoux test is usually positive in adults from endemic areas for TB, and is of no great help for the diagnosis of TBM (22). In addition, high false positivity rates in BCG-vaccinated people due to cross reaction with bacillus Calmette-Guérin (BCG) limits its use. In our study, seven patients with TBM had positive Mantoux test, and three of those were vaccinated.

Although fine needle aspiration cytology (FNAC) is widely used on the evaluation of breast lesions, some authors concluded that granulomatous inflammation cannot be confidently differentiated by FNAC, and hence a correct diagnosis may need a histological confirmation (23, 24). Similarly, tru-cut biopsy was performed in all patients, and granuloma formation was found to be the main pathological finding. However, non-caseating granulomatous lobulitis, defined as granulomatous inflammation centered on lobules with intact ductolobular architecture, was determined histopathologically in all patients with IGM. Although the gold standard diagnostic tool for TBM is bacteriological culture of breast tissue or Ziehl-Nielsen stain (25), TB bacilli can be isolated in only one fourth of the patients, and AFB positivity can be detected in only 12.0% of the cases at routine practice (23, 26). In our study, positivity of culture or AFB staining was consistent with the literature. The other one,

PCR, is known as a rapid diagnostic test, however high costs limit its general use. In the present study, PCR was used in only four patients with TBM, and positive results were obtained from two. As a result, demonstration of caseating granulomas in the breast tissue may be sufficient in the diagnosis of the majority of cases (27). Standard anti-TB therapy is the main treatment in TBM, and surgical approach is only indicated for extensive or persistent residual disease (28, 29). In our study, only one patient needed a surgical intervention due to recurrent disease. In addition, three patients required an extra anti-TB medication of three months due to incomplete resolution of symptoms.

Various therapeutic modalities including conservative management with using antibiotics, surgical interventions, corticosteroid and immunosuppressive therapies have been used in the treatment of IGM. However, optimal therapeutic approach has not clearly demonstrated yet. While surgical approach was the most effective treatment in many works, other medical therapies were reported to be the main therapeutic modality by some authors (7, 30, 31). Akcan et al (32) reported that systemic steroid therapy combined with surgical resection should be the first-line treatment strategy for IGM. However, Maffini et al (33) showed well outcomes by administering systemic antibiotherapy and low dose steroid. Some authors recommended steroid therapy for severe cases of GM or for recurrent disease after surgery (21, 34). In a study from Oman (35), systemic antibiotherapy for six weeks was received to all patients with IGM, and significant improvement was seen in 85% of those.

We also gave IGM patients with abscess formation or clinical signs of infection an antibiotherapy regimen of two weeks, and then planned a steroid therapy or surgery. On the other hand, conservative approach with watchful waiting was recommended by some authors due to self-limiting nature of the disease (36). We also gave the patients with mild and limited disease this option as a first line therapy. In our study, total excision with wide margins was performed in 14 patients; however, steroid therapy was administered in 20 cases. Our

recurrence rate of 20% for steroid therapy was consistent with the previous studies (4, 16). Although surgical approach is now being replaced by non-surgical therapies (37), the lowest recurrence rate was obtained from surgery group in our study.

CONCLUSION

GM usually poses a diagnostic and therapeutic challenge for the physicians. TB should be always kept in mind in the differential diagnosis of GM. Interdisciplinary approach to IGM is needed due to associated clinical conditions. Surgery seems to be the best therapeutic option for IGM patients in the present study, according to its low recurrence rate.

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AUTHOR'S NOTE

MÖ Kılıç conceived paper, oversaw data collection, conducted data analysis, wrote manuscript and approved final version. M Şen participated in study design, data analysis and interpretation, critically revised manuscript and approved final version. D İçen performed statistical analyses and approved final version. The authors declare that they have no conflicts of interest.

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Table 1. Baseline characteristics of the patients in the two groups

Characteristics	**IGM Group (n = 52)**	**TBM Group (n = 16)**	**p-value**
Age (year)	37.56 ± 9.79 (22-64)	31.06 ± 5.33 (19-39)	**0.032**
Educational status			0.076
Primary/Secondary school	13 (25%)	0	
High school	17 (32.7%)	8 (50%)	
University	22 (42.3%)	8 (50%)	
Marital status			0.573
Single	6 (11.5%)	3 (18.8%)	
Married	44 (84.6%)	13 (81.3%)	
Divorced	2 (3.8%)	0	
Menopausal status			0.075
Premenopausal	43 (82.7%)	16 (100%)	
Postmenopausal	9 (17.3%)	0	
Smoke use	7 (13.5%)	3 (18.8%)	0.433
Alcohol use	4 (7.7%)	0	0.332
Pregnancy at diagnosis	3 (5.8%)	0	0.441
Breastfeeding status			0.101
Present at diagnosis	5 (9.6%)	1 (6.3%)	
Present within last one year	7 (13.5%)	6 (37.5%)	
Oral contraceptives use	14 (26.9%)	4 (25%)	0.578
Comorbid disease (except TB)	7 (13.5%)	1 (6.3%)	0.391
Active TB	0	4* (25%)	**0.002**
Past history of TB	2 (3.8%)	2 (12.5%)	0.233
Contact history of TB	0	3 (18.8%)	**0.011**

Data are presented as mean ± SD for age and duration of diagnosis; n (%) for other variables.

Table 2. Clinical features of the patients in the two groups

Clinical features	**IGM Group (n = 52)**	**TBM Group (n = 16)**	**p-value**
Duration of symptoms prior to admission (day)	48.46 ± 56.5 (0-300)	40.44 ± 38.41 (7-150)	0.776
Symptoms and findings			
Pain	31 (59.6%)	10 (62.5%)	0.538
Mass	31 (59.6%)	11 (68.8%)	0.363
Inflammotary skin changes	14 (26.9%)	5 (31.3%)	0.482
Fistula and discharge	8 (15.4%)	7 (43.8%)	**0.024**
Abscess formation	10 (19.2%)	5 (31.3%)	0.246
Nipple retraction	4 (7.7%)	0	0.332
Fever	3 (5.8%)	2 (12.5%)	0.335
Location			0.159
Right	23 (44.2%)	8 (50%)	
Left	29 (55.8%)	7 (43.8%)	
Bilateral	0	1 (6.3%)	
Clinical suspicion of malignancy	17 (32.7%)	12 (75%)	**0.003**

Table 3. The radiologic findings of patients in the two groups

Radiological findings	**IGM Group**	**TBM Group**	**p-value**
Ultrasonographic findings	n = 52	n =16	
Inflammatory changes	16 (30.8%)	6 (37.5%)	0.415
Abscess	17 (32.7%)	4 (25%)	0.401
Irregulary hypoechoic mass	25 (48.1%)	13 (81.3%)	**0.018**
Axillary lymphadenopathy	15 (28.8%)	6 (37.5%)	0.358
Well-defined mass	6 (11.5%)	0	0.186
Mammographic findings	n = 13	n = 5	0.143*
Asymmetric density	5 (38.4%)	2 (40%)	
Well defined opasity	5 (38.4%)	0	
microcalcification	2 (15.3%)	1 (20%)	
Spiculary opasity	1 (7.7%)	1 (20%)	
normal	0	1 (20%)	
Radiological Suspicion of malignancy	27 (51.9%)	15 (93.8%)	**0.002**

*p-value of "mammographic findings" between groups was calculated as a whole due to the small number of each findings.

Table 4. The comparison of the treatment modalities in the patients with IGM

	Antibiotic alone	**Steroid**	**Surgery**	**p-value**
Number of patients	18 (34.6%)	20 (38.5%)	14 (26.9%)	
Mean Follow-up time (mo)	24.47	27.98	27.00	0.768
Relapse	9 (50%)	4 (20%)	2 (14.2%)	**0.047**

*mo: month