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Original article

Granulomatous mastitis: Presentations, diagnosis, treatment and outcome in 206 patients from the north of Iran

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ABSTRACT

Objectives: The aim of this study is to review the clinical presentations, diagnostic methods, treatment options and outcome of patients with Granulomatous Mastitis (GM).
Material and methods: In a retrospective study, we indentified 206 women who met the required histological criteria of (GM).
Results: Thirty eight (18%) of these women had taken antibiotics before their diagnosis of GM. The most common symptoms in remaining 168 symptomatic women were breast mass. The most common ultrasonographic and mammographic finding was large irregular hypo echoic masses and an irregular mass, respectively. As a diagnostic tool, fine needle aspiration (FNA) was performed in 33 (19.5%) and core needle biopsy with or without ultrasound was done in 92 (55%) of patients while successful rate was 13 (39%) and 87 (94.5%), respectively. The remaining 43 (25.5%) of women underwent surgical excisions. Only 6 (3%) patients improved with antibiotics and 200 (97%) of women who did not respond to antibiotics, were treated with steroid and among them 144 (72%) improved. Treatment with combination of methotrexate and steroid was done in 56 (28%) patients and was effective in 40 (71%) of them. Sixteen (8%) patients were treated with a combination of steroid and bromocriptine which was effective in 5 (31%) patients. A wide surgical excision was performed in 11 (5.5%) patients who were nonresponsive to steroid and methotrexate and bromocriptine therapy.
Conclusion: Our findings indicate that clinical and imaging findings of (GM) have overlapped with malignancy. The best diagnostic method is core needle biopsy. Corticosteroids are in the first line of treatment with a good therapeutic response.

Introduction

Granulomatous mastitis as a rare inflammatory disease of the breast was first defined by Kessler and Wolloch in 1972 [1]. Granulomatous mastitis usually affects women of child-bearing age or in women who consume oral contraceptive drugs [1–3]. The pathologic characteristic of (GM) is chronic granulomatous inflammation of the lobules without any necrosis [4,5]. Although the cause of (GM) is unclear, it may be due to autoimmune diseases and localized immune reactions to breast tissue [3,6,7]. Fever, polyarthralgia and erythema nodosum occurring in several cases of (GM) [3,8]. The clinical presentation and radiologic findings of (GM) are similar to those of breast cancer, so misdiagnoses often delay the proper and well-timed treatment [3,9]. Nipple retraction and discharge, pain, inflammatory changes of skin, abscess formation, fistula of breast and

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lymadenopathy are other possible symptoms and peau d'orange-like changes were seen in rare cases [5,7]. In some cases, it is very difficult to differentiate the lesion from breast cancer [3,5,9] and other pathology (like tuberculosis, syphilis, corynebacterial infection, mycotic infection, sarcoidosis, Wegener's Granulomatosis and foreign body reaction) [5,7,9]. Effective diagnostic tools include FNA, core needle biopsy with or without ultrasound and surgery [3,9,10]. Before 1980, surgical excision of the entire lesion was performed [6,10] but, these days FNA and core needle biopsy are the first line of tissue diagnosis [3,11]. Treatment with steroids is lengthy and usually lasts about 6 months, however some literature report very good success with steroids therapy [12–15]. Treatment with topical steroids to prevent adverse effects was also reported in one case [14]. Methotrexate alone or in combination with steroids has been used with good success [16,17]. Combination therapy with glucocorticoids and prolactin lowering medications such as bromocriptine or cabergoline was used with good results as well [18,19]. Recurrence rates have been reported 5–50% in surgical cases [3,7,8]. The purpose of this study is to review and describe the clinical, imaging and pathologic features and diagnostic protocols and management of granulomatous mastitis. As the incidence of granulomatous disease such as sarcoidosis is high in our area [20], so incidence of GM is higher than other area of our country and is a health problem among young women.

Materials and methods

In a retrospective review, we collected records of all patients with the histologic diagnosis of Granulomatous Mastitis from four referral histopathology laboratories in Rasht- Iran from January 2006 to April 2013. Records of 206 women were collected. All of the patient's data (age, symptoms, signs, diagnostic procedures, treatment and outcome) was provided by the patient's surgeon's records.

At first, breast examination was done for all women to identify palpable lumps, skin thickening, abscess formation, fistulae or infected tract and axillary lymphadenopathy. In the next step, an ultrasound imaging was used for both breasts (using an ultrasound scanner with a 10- to 12-MHz transducer). Mammography was the next imaging technique in some of the women (older than 35 years). Two standard views (mediolateral oblique and craniocaudal) of each breast were performed. Definitive diagnosis was achieved by fine-needle aspiration (FNA) using an 21-gauge needle aspiration before 2010, as well as cytological evaluation of the suspicious breast lesions, percutaneous ultrasound-guided core needle biopsy (16-gauge), and core needle biopsy with or without ultrasound or surgical excision. Specimens were taken from the abscess wall during drainage. The slides were examined with specific stains (Kinyoun acid-fast bacilli (AFB), Gomori methenamine silver and Gram), with cultures for bacteria and AFB and immunohistochemistry. All patients with tuberculosis, foreign body, fungal diseases and other infections were excluded. Based on the review of medical records, clinical presentations, route of diagnosis, histopathological findings, management protocols, recurrences and outcome of patients were analyzed retrospectively. Follow-up information was obtained from clinical reviews at monthly intervals (range, 3–6 months).

Results

All affected women were in child-bearing age with a mean age of 32 years; (22–40 years). None of the patients had a history of oral contraceptive consumption. At the time of presentation, two patients were pregnant, one of them was 28 week-pregnant and had bilateral involvement and five of the patients were in the lactation period. None of these patients were on any medication or hormonal treatment. The duration of symptoms ranged from 32 days to 6 months. (The mean duration was 4 months).

Clinical characteristics

Thirty eight (18%) of the patients had a primary incisional biopsy and drainage with multiple non healing ulcers due to diagnosis of breast abscess. The most common symptoms in remaining 168 of women in this study were breast mass in (88%) and breast mass with pain, erythema, and inflammation in (12%). Draining sinus tracts were seen in 14%, axillary adenopathy was noted in 28% and breast mass with nipple discharge and ulceration were seen in 12% and 16% of the patients, respectively.

Upon palpation, there was a firm mass found in 68% of the women. These lesions were unilateral with a tendency to occur in subareolar regions of the breast in 44% of the women. The size of the mass ranged from 1 to 10 cm with a mean of 5.5 cm. The right side involvement was more common than the left ((126 (61%) versus 78 (38%) and bilateral involvement in 2 (1%)). Pregnancy in two women (01%) who were treated with antibiotic was observed. None of the women had any systemic disorder or history of a specific infection.

Imagings

Ultrasonography was done in all patients. Ultrasound examination showed abnormal lesions in all 206 women. The most common finding of ultrasound examination was a large irregular hypo echoic mass with tubular extensions in 122 (59%) of patients. Other findings were summarized in Table 1. In ultrasonography more than half of the lesions were located in the central portion of the breast, and the remaining lesions were seen in the peripheral location.

Mammography was done in 186 patients. The major mammographic finding was an irregular mass in 118 (63.5%) of patients (Fig. 1). Other findings were shown in Table 1.

Diagnostic methods and histopathological evaluation

For diagnosis of the remaining 168 patients (81.5%) FNA was performed in 33 (19.5%) of them but it was diagnostic only in 13 (39%). Core needle biopsy with or without guided ultrasound was

Table 1
The radiologic findings of patients with GM.

Ultrasonography findings	**No. (%)**
No. of patients	206
A large irregular hypoechoic mass with tubular extensions	122 (59%)
A lobulated or irregular mass	30 (14.5%)
Heterogeneously hypoechoic mass	9 (4.5%)
Parenchymal distortion with acoustic shadowing and no discrete mass	8 (4%)
Skin thickening and edema	9 (4.5%)
Axillary adenopathy	28 (13.5%)
Mammography findings	
No. of patients	186
An irregular focal mass	118 (63.5%)
Asymmetric density and heterogeneously	16 (8.5%)
Dense or extremely dense parenchymal breast pattern	8 (4.5%)
Axillary adenopathy	28 (15%)
An irregular or lobulated mass	6 (3.5%)
Skin thickening or edema	10 (5%)

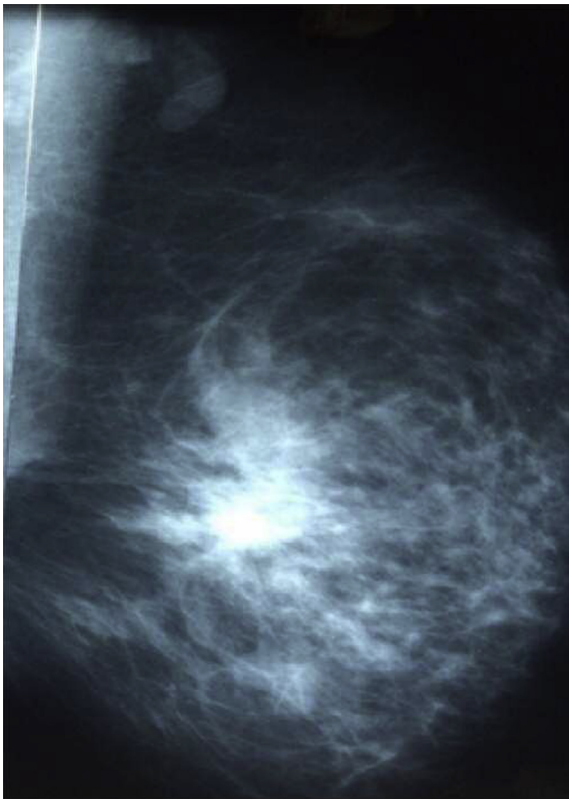

Fig. 1. Irregular mass with axillary node in mammography.

Table 2
Diagnostic procedures in 168 patients.

Procedures	NO. (%)	Diagnostic	No diagnostic
FNA	33 (19%)	13 (39%)	20 (61%)
Core needle biopsy without US	40 (24%)	37 (92.5%)	3 (7.5%)
Core needle biopsy with US	52 (31%)	50 (96%)	2 (4%)
Biopsy with surgery	43 (25.5%)	43 (100%)	NO

done in 92 (55%) of the patients, among them 87 (94.5%) patients were diagnosed for (GM). Forty three (25 0.5%) of the patients underwent a surgical biopsy that nineteen (44%) of them was complicated with multiple ulcers in the breasts. These complications did not happen in FNA or core needle biopsy procedures. The diagnostic procedures are summarized in Table 2. In all patients, Granulomatous Mastitis was the final diagnosis and was characterized microscopically by the presence of lobulocentric non-necrotizing granulomas (clusters of epithelioid histiocytes) in which no microorganisms or features of other pathologic entities were identified. Additional microscopic findings included lymphocytes, plasma cells, neutrophils and giant cells. The inflammation often extended into adjacent para lobular and interlobular tissues.

Treatment and outcome

Thirty eight (18%) of women had taken antibiotics before having a diagnosis of GM. The clinical diagnosis of these patients was breast infection or abscesses, so an incision and drainage had been performed for them. However, despite the treatment with antibiotic, these abscess or infectious processes, had failed to improve and symptoms persisted in spite of several courses of various antibiotics (clindamycin, tetracyclin, cefixim and ciprofloxacin) and complicated with multiple ulcers in 24 of 38 cases. The final diagnosis in these patients was (GM).

Treatment with only antibiotic (cloxacillin, cephalexin, ciprofloxacin or clindamycin) was done in all the patients for 20 days, but symptoms and signs resolution occurred only in 6 (3%) of them. Two hundred (97%) of the women who failed to respond to antibiotics therapy were treated with steroid (10–20 mg prednisolone) three times a day, and symptoms in 144 (72%) patients resolved and then, prednisolone was tapered slowly during two to three months along with clinical improvement (Fig. 2). The maximum duration of treatment with steroid was six months. Treatment with a combination of methotrexate (7/5 to 10 mg once a week) and steroid was done in 56 (28%) patients for two to four months and was effective in 40 (71%) of them. Sixteen (8%) of the patients were treated with a combination of steroid and prolactin lowering medications such as bromocriptine (5–10 mg daily) and five of the patients responded positively. A wide surgical excision was performed in 11 (5.5%) of the patients with extensive disease because these patients were nonresponsive to steroid, methotrexate and bromocriptine therapy and these patients improved with coverage of steroids and antibiotics therapy and wide surgical excision (Table 3). In this study, responses to treatment with steroid were excellent.Complications of steroid therapy happened in 12 (6%) patients as Cushing's syndrome, weight gain and dyspepsia. After tapering of steroid, complications were removed. Post treatment response was monitored clinically with clinical examination, ultrasound and mammography between 3 and 6 months. Only 174 (84%) of patients were available for follow-up for 9–18 months. Recurrence in contralateral breast happened in two (0.97%) and in ipsilateral breast in nine (4%) patients during follow-up and retreatment with steroid showed good response.

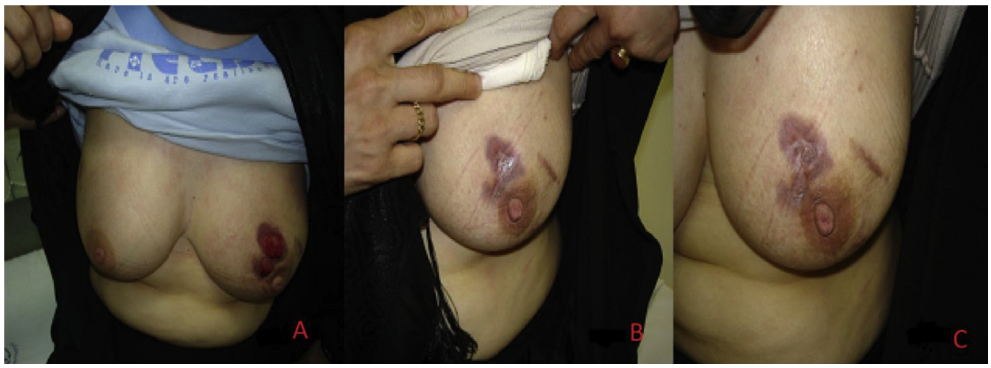

Fig. 2. A. one month after treatment with prednisolone, B: 3 months after treatment, C: 5 months after treatment.

Table 3
Results of treatment in 206 patients.

Treatment options	Successful	Unsuccessful
Antibiotics	6	200
Steroid	144	56
Steroid + methotrexate	40	16
Steroid + bromocriptine	5	11
Surgery + steroid + antibiotics	11	0

Discussion

Granulomatous mastitis is a rare benign inflammatory breast disease [1]. Granulomatous mastitis usually affects women of childbearing age or who consume oral contraceptive drugs [1–3]. The possibile etiology of the (GM) may be due to some autoimmune reactions to protein secretions in the ducts, undetected organisms, oral contraceptives or may be a reaction to childbirth [1,5,10]. The improvement of (GM) with treatment by steroids and methotrexate is in favor of this autoimmune hypothesis [12].

In this study, the affected women usually are in their childbearing ages (the mean age of our patients was 32 years). In contrast to literature, none of the patients had a history of oral contraceptive consumption. Common presentations of (GM), within our participants included: a breast mass with or without pain, skin thickening, fistula, sinus tract and abscess formation or axillary adenopathy as evidenced in other studies [3,13,21]. Many of the women were initially thought to have carcinoma of breast.

There aren't any specific radiologic findings for diagnosis of GM, However, in some clinical setting the findings can be suggested by radiologists. In current study, ultrasound was the first imaging technique which we used to identify a lesion in all women. The most common finding of ultrasound examination was a large irregular hypo echoic mass with tubular extensions. These findings were similar to those reported by Han et al. [18], Yilmaz et al. [19], and Lee et al. [22].

Mammographic findings are considered nonspecific in (GM) [18]. Our study showed that the most common mammographic finding were an irregular focal mass. A study by Han et al. described multiple small masses or a large focal asymmetric density [18]. In two additional studies by Yilmaz et al. and Memis et al., a focal asymmetric density was identified as the most frequent pattern [9,19]. More recently, in a study by Lee et al. it was shown that the most common finding was an irregular well-defined mass which was consistent with our findings [22].

It should be noted that clinical and imaging studies cannot diagnose (GM) definitely [10]. FNA is still an option for tissue sampling [3,11,23] and may be helpful in differentiating malignancy from other inflammatory diseases. In addition, it's worth notating that FNA's usefulness and reliability has been debated. In our study, FNA was the first tool for diagnosing, because FNA is more available than Core needle biopsy and provide faster results. Core needle biopsy was diagnostic in 87 (94.5%) of patients, however, FNA was diagnostic only in 13 (39%) of patients. These results show that FNA has no role apart from a historical one in the diagnosis of GM. We found that the diagnosis rate is very poor and put patient through unnecessary and valueless test. FNA may not always differentiate between GM and other granulomatous disease of the breast and definite diagnosis requires negative microbiological examinations, histological samples and clinical correlations. So histology is the main foot of diagnosis either by core or open biopsy [5,21,24]. Histologically Granulomatous Mastitis is characterized by the presence of nonnecrotizing granulomas in the breast lobules. This pathologic finding overlaps with those of a variety of breast diseases such as bacterial and mycobacterial infections, trauma, fat necrosis, ruptured breasts cyst, foreign body reaction, plasma cell mastitis, Wegener's Granulomatosis, sarcoidosis and carcinoma [3] and these disease must be excluded and a negative special microbiologic stain is required.

The role of open biopsy and drainage is controversial because it may lead to increased scarring and non-healing ulcer of incision site which subsequently leads to the formation of multiple sinus tracks and ulcers of the involved breasts [3,16,17]. We also found 19 women with multiple ulcer or sinus tracts in multiple locations in the same breast after open biopsy or surgical drainage for a single lesion. It is for previously stated reasons that, we did not recommend the aforementioned procedures.

In a review of the literatures, we found that a few articles have described treatment protocols for (GM) [10,25,26] and there isn't an established optimal treatment yet because of its rarity. The treatment protocols that were usually used included observations, antibiotics, steroids, drainage, excision and mastectomy [26]. As a part of procedure before treatment, other causes of granulomatous lesions in the breast must be excluded.

Thirty eight of patients in our study had taken antibiotic therapy with clinical diagnosis of infectious mastitis and these patients underwent open drainage of abscess and biopsy and therefore diagnosis of GM had been established. In addition, antibiotic therapy was not beneficial and only 6 (3%) of women showed improvement similar to Hovanessian Larsen et al. study [3].

In our series, the most effective nonsurgical treatment was steroid, because 144 of patients showed improvement similar to Hovanessian Larsen et al. study [3]. One pregnant patient with mild symptoms was treated with coloxacillin with close observation and imaging surveillance and showed improvement. Methotrexate was used in patients who were resistant to steroid therapy after three months as well as for recurrence after initiation steroid therapy, as in other studies [15,27]. We also used prolactin lowering medications such as bromocriptine in 16 (8%) of patients who were resistant to steroid and methotrexate therapy similar to others [16,17]. Eleven (5.5%) of our patients with extensive disease improved with wide surgical excision and coverage of steroids and antibiotics therapy which was similar to other studies [13].

According to the findings of this study, our treatment plan for women diagnosed with (GM) included: A course of prednisone, 30–60 mg/day for 4 weeks; this course is tapered over 3, 5 and 6 weeks. If prednisone therapy is failed, the second course of steroid was repeated. If improvement was still minimal or failed after the second steroid therapy, we consider adding methotrexate, 7.5–10 mg once a week. If the prednisone and methotrexate therapy failed, we recommend adding prolactin lowering medications such as bromocriptine (5–10 mg/day) to prednisone. Methotrexate alone or in combination with steroids has been used with good success and its principal mechanism of action is immunomodulation activity [14].

If recurrences happened, we began a course of prednisone, 30–60 mg/day and then tapered. In patients who are prone to recurrence we use long-term low-doses of steroids with methotrexate and topical steroid.

It seems that a randomized clinical trial requires to comparison wide local excision corticosteroid administrationin and observation in order to optimize the diagnosis and treatment of GM.

In the literature review, recurrence rates varied from 5.5 to 50% after excision [24]. In this study, recurrence developed in 11 (5%) patients.

Conclusion

In conclusion, (GM) is a challenging condition. Clinical and imaging findings of Granulomatous Mastitis are similar to breast

carcinoma and must be excluded from other causes of Granulomatous diseases of the breast in biopsy findings. For the best treatment of (GM), radiologist, surgeon and pathologist can work together. In our series we proposed core needle biopsy with or without ultrasound for diagnosis. However, we do not recommend surgical procedure because it's complications. Treatment with steroids must be started as soon as a definitive diagnosis is established. Responses to steroids have proven to be very high in this study. In Guilan province (a highly prevalent geographical area for sarcoidosis), we recommended vigorous investigation for clinical sarcoidosis along with TB and other granulomatous disease in any patient with GM.

Ethical considerations

The study was approved by the Regional Committee for Medical Research Ethics.

Role of the funding source

There are no sources of funding to declare.

Conflict of interest statement

The authors declare that they have no Conflicts of interest.

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