



Management of Granulomatous Mastitis: A Series of 13 Patients Who Were Evaluated for Treatment Without Corticosteroids

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Granulomatous mastitis (GM) is a rare chronic inflammatory breast condition with unknown etiology. There is still no generally accepted optimal treatment for GM. Corticosteroid treatment and/or wide excision is most commonly reported in the literature. Incision and drainage or limited excision alone has little benefit because of a strong tendency of recurrence. Corticosteroids also have a high failure rate and possible side effects. In the current series, we treated GM patients without corticosteroids, except for one patient. We also devised multidirectional deep drainage for advanced and complicated abscesses, which are characteristic of GM. This retrospective study included 13 women who met the required histologic criteria of GM. The mean age of the patients was 41 years. All of the patients were premenopausal. Six patients had breast-fed in the last 5 years. Five patients were under medication with antidepressants. A total of 11 patients developed abscesses during the clinical course, and the abscesses penetrated the retromammary space in 4 patients. We treated 2 of these 4 patients with multidirectional deep drainage and obtained complete remission in 5 and 6.5 months, respectively. These times were much shorter than those in the other 2 patients. The time to resolution in 11 patients was 4 to 28 months. This overall outcome was comparable with that of corticosteroid treatment reported in the literature. Because the natural history of GM is thought to be self-limiting, close observation and minimally required drainage of abscesses without corticosteroid administration remain the treatment modality of choice.

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Granulomatous mastitis (GM) is a rare chronic inflammatory breast condition that was first described in 1972.¹ Granulomatous changes occur around lobules and ducts of the breast in the absence of specific infection, trauma, or evidence of sarcoidosis.² Because the etiology of GM is not clear, and the diagnosis is made by exclusion, GM can be a heterogeneous disease with variable clinical presentations.³ The most common clinical presentation is a firm, unilateral, and discrete breast mass that is often associated with an abscess or inflammation of the overlying skin and fistulae.

The treatment choices for GM include corticosteroids, antibiotics, abscess drainage, wide surgical resection, and even mastectomy.⁴⁻⁷ Several reports have described that corticosteroid administration and/or wide excision are effective. However, the optimal treatment of patients with GM is uncertain. Management of GM cases needs to be tailored according to the clinical presentations. Additionally, a differential diagnosis must be carried out parallel to the treatment. Although GM is a benign condition, it can present with local symptoms that mimic carcinoma. Moreover, because symptoms often recur, exclusion of cancer is not simple.

We present our experience with 13 cases of GM managed according to the clinical presentations. In patients in whom an abscess extended into the retromammary space and became complicated, we performed multidirectional deep drainage (MDD) under general anesthesia. We treated these patients without corticosteroid administration, except for one patient. We evaluated whether the outcome of our treatment of GM patients is comparable with that of corticosteroid treatment reported in the literature.

Patients and Methods

We retrospectively reviewed a pathology database covering 2001 to 2013. We identified patients who fit the histologic criteria of GM of noncaseating granulomas centered on lobules, with or without associated microabscesses. Patients were included in the study when all other possible causes of granuloma formation were excluded. The diagnosis was confirmed by either core needle biopsy (CNB) or excisional biopsy, or also from biopsy specimens taken from the abscess wall during drainage. All slides were examined with hematoxylin-eosin and

specific stains, such as Gram, Ziehl-Neelsen, and periodic acid-Schiff. All of the cases were reviewed by a pathologist. In total, 13 cases of GM were identified, and their incidence was evenly spread out during the 13-year period. To confirm the difference in clinical course between GM patients and other inflammatory breast disease patients, a retrospective review of the clinical database was also performed for the same period to identify patients with symptoms similar to these GM patients, according to the first diagnosis as “mastitis” or “breast abscess.” We identified 163 cases, including 11 GM cases. Clinical data on the presentation, histopathology, management, and outcome of these patients were analyzed by review of medical records. Follow-up information was obtained from clinical reviews. The types of symptoms, severity, and duration were documented. The data that were collected were then studied and the various parameters were compared retrospectively.

Results

The clinical characteristics of the 13 GM cases are shown in Table 1. The case number depends on the order of initial presentation. The mean age of the patients was 41 years (range, 30–52 years). All of the patients were premenopausal. Six patients had breast-fed in the last 5 years, but none were lactating at the presenting time. Among the rest of the patients, 5 were treated with antidepressants and 2 had a past history of galactorrhea. Four patients were not parous. None of the patients had used contraceptive medications or had a history of smoking. They had no history or medical findings of tuberculosis, sarcoidosis, or other connective tissue diseases, such as rheumatoid arthritis, Behçet disease, or erythema nodosum. All of the patients had a unilateral lesion. The common presenting symptom was a hard mass. Eight patients presenting with mastitis had inflamed hyperemic skin and pain. Abscess formation was seen in 7 patients, and 2 of the abscesses were ruptured. Ultrasonography (USG) was performed for all of the patients. USG showed an irregular hypoechoic heterogeneous mass in all cases, and a hypoechoic abscess in 7 cases. Six patients were examined with mammography. An ill-defined tumor was observed in 2 patients, and diffusely increased asymmetric density was observed in 4 patients. Enhanced computed

Table 1 Patients' background and initial symptoms

Case no.	Age, y	Parity	Less than 5 y from last pregnancy	Antidepressant use	Symptoms in addition to a mass at the first visit	
					Mastitis	Abscesses
1	47	0				
2	30	3	Yes			Yes
3	44	0		Yes	Yes	
4	38	1	Yes		Yes	
5	37	2	Yes			Yes
6	44	1	Yes		Yes	Yes (ruptured)
7	45	2		Yes	Yes	
8	32	1	Yes		Yes	
9	52	2		Yes	Yes	Yes
10	39	0		Yes		Yes
11	50	2				
12	44	0		Yes	Yes	Yes
13	36	4	Yes		Yes	Yes (ruptured)

tomography (CT) was performed in 8 patients. A total of 6 patients showed ill-defined heterogeneous enhancement with multiple low-density areas, and abscess formation at the retromammary space was confirmed in 4 patients. Bilateral breast magnetic resonance imaging (MRI) was performed in 3 patients. MRI showed a heterogeneous enhanced area with an irregular border in all of the patients. Because most of the clinical and radiologic findings were nonspecific, exclusion of malignancy was not simple. USG was used for evaluation of the depth of abscess and also for evaluation of resolution as previously recommended. Resolution was determined with disappearance of hypoechoic lesions or with stability of hypoechoic lesions for more than 6 months.

A histopathologic examination was performed on the specimens from CNB or excisional biopsy, and also from biopsies taken from the abscess wall during drainage. Microscopically, all of the patients showed noncaseating granuloma formation with variable numbers of Langhans-type multinucleated giant cells, neutrophil polymorphs, and lymphocytes around the breast lobules (Fig. 1). Fat necrosis

and microabscess formation were also observed. There was no evidence of primary vasculitis, squamous metaplasia, or keratin formation. Specific stains for microorganisms (Gram), tuberculosis (Ziehl-Neelsen), and fungal infections (periodic acid-Schiff) were negative. In all of the cases, microbiologic cultures of aspiration samples from closed abscess for aerobes and anaerobes showed no bacterial growth.

Treatments of the GM patients were managed according to the clinical presentations (Table 2). For the first treatment, 2 patients were treated with extirpation for excisional biopsy because the mass was relatively small and the inflammation was minimal. Four patients without an abscess were treated with empiric antibiotics after aspiration cytology or CNB, and were found to have benign mastitis. All of these 4 patients developed an abscess and surgical interventions were necessary at a later date. Among 7 patients with an abscess, 4 were treated with incision and drainage (I&D), 2 were treated with aspiration and observation, and 1 with an abscess in the retromammary space was treated

Fig. 1 CNB specimens of case no. 4 (hematoxylin-eosin). (a) Granulomatous inflammation within the lobule can be seen (scale bar = 0.2 mm). (b) A lobule with multinucleated giant cells and surrounding lymphocytes can be seen (scale bar = 0.1 mm).

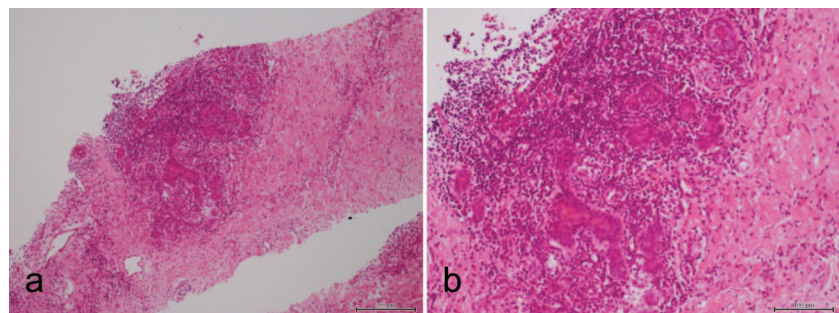


Table 2 Treatment and outcome of the patients

Case no.	Abscess penetrated to retromammary space	Treatment					Time to resolution, mo
		First	Second	Third	Fourth	Fifth	
1		Extirpation					0
2		I&D					5
3		Antibiotics	I&D				7.5
4	Yes	Antibiotics	I&D ×3	Steroid	DD	Steroid	28
5		I&D					4
6		I&D					4.5
7	Yes	Antibiotics	MDD				6.5
8		Antibiotics	I&D				11
9	Yes	Aspiration	I&D	Aspiration ×6			27
10		Aspiration					4
11		Extirpation					0
12		I&D					6
13	Yes	MDD					5

DD, deep drainage under general anesthesia.

with MDD for the first treatment. The time to resolution was 4 to 28 months (Table 2).

During the clinical course of 13 GM patients, in 4 patients (case nos. 4, 7, 9, and 13) an abscess developed in the retromammary space (Figs. 2–4 and Table 2).

In case no. 4, the patient was first treated with antibiotics but developed abscesses, and she required I&D 3 times. The diagnosis of GM was made with a second CNB. She was administered 0.5 mg of betamethasone for 2 weeks, but the main abscess penetrated the retromammary space. She was treated with deep drainage under general anesthesia. The main abscess was successfully drained, but surrounding multiple small abscess loculi remained, in contrast to our expectations. We continued betamethasone and increased the dose to 1.5 mg. Although the small abscesses soon disappeared, multiple hypoechoic lesions remained, and partial remission and exacerbation were observed several times according to an increase and decrease in corticosteroids during tapering. Total remission took 28 months. Additionally, pulmonary thrombosis was observed in an episode of care of GM, and she needed anticoagulant therapy. After this patient, we avoided using corticosteroids for the treatment of GM.

In case no. 7, the patient had a past history of galactorrhea 6 months ago as a side effect of a previous antidepressant. A pathologic report of the first CNB was mastitis without microorganisms, and culture of a specimen was also negative. She was treated with empiric antibiotics and observed. Multiple abscesses rapidly formed and were mainly localized at the peripheral part of the mammary

gland. USG revealed that one of the abscesses had progressed into the retromammary space and was connected to the other abscesses through thin channels. We treated her with MDD under general anesthesia. All of the abscesses were drained by an ultrasound-guided procedure. After observing multiple intraoperative CNB specimens, we concluded that the diagnosis of this patient was GM. She obtained resolution in 6.5 months without withdrawal of antidepressants.

In case no. 9, the patient was under medication with multiple antidepressants and sleep-inducing drugs. At the first presentation, she had a breast mass and an abscess in the center of the mass. We treated her with aspiration. Cytology was benign and the culture was negative. We decreased the antidepressants to the minimum dosage and treated her with antibiotics. We treated her with I&D because the abscess extended to the subcutaneous space. The diagnosis of GM was confirmed with CNB. The abscess further went into the retromammary space and extended multidirectionally. Although we proposed a radical procedure, such as MDD, she opted to be treated with repetitive aspiration of the abscess. We treated her with aspiration of multiple abscesses another 6 times. Remission was obtained after 27 months.

In case no. 13, the patient was referred from a clinic based on the suspicion of inflammatory breast cancer because she developed a breast abscess with tumor formation, even after several surgical interventions. Her breast abscess had already penetrated the retromammary space and into the skin (Fig. 3a), and complicated multiple abscesses had formed a large skin ulcer and a lump with a dull margin (Fig.

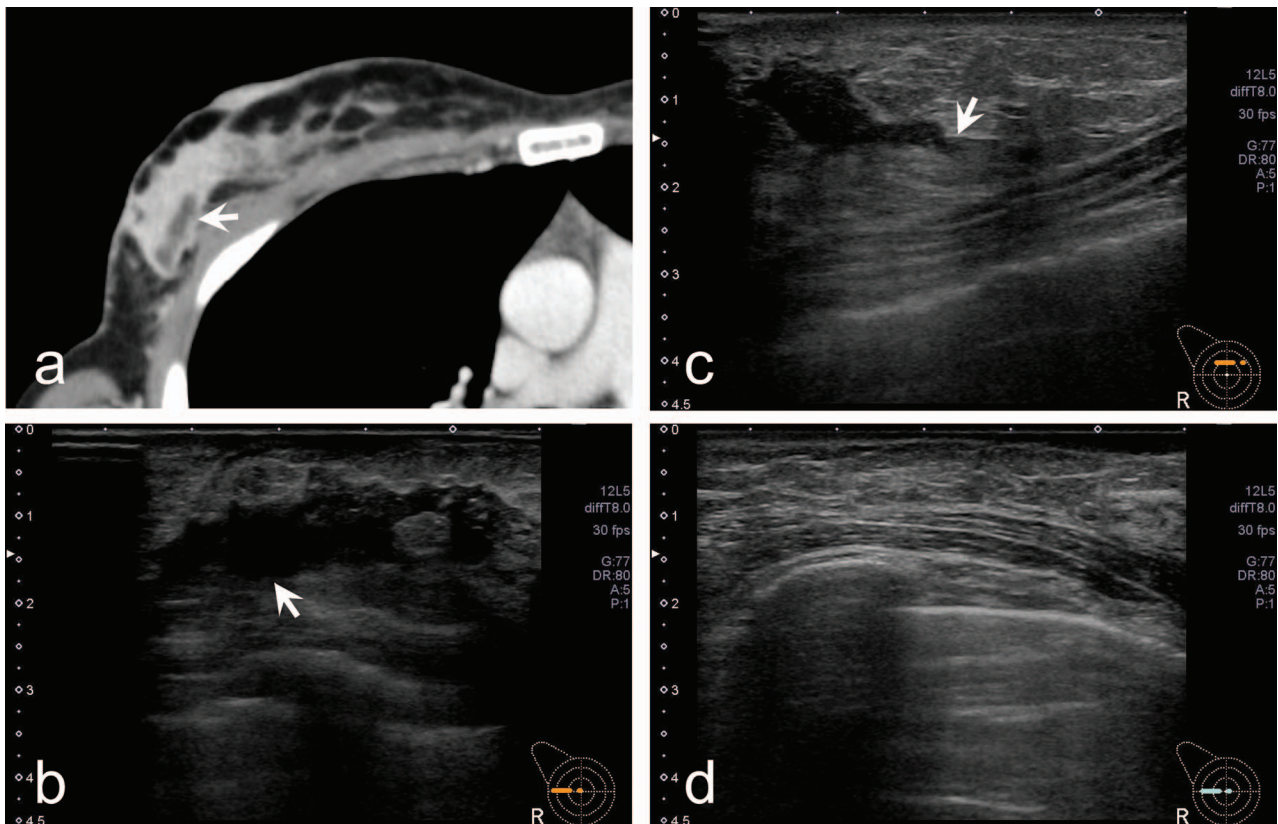


Fig. 2 Imaging findings of case no. 13 at the initial presentation (a–c) and 5 months later (d). (a) CT shows an abscess in the deep part (arrow) of the right mammary gland. (b) USG shows that the abscess has penetrated the retromammary space (arrow). (c) USG shows that the abscesses communicate through tiny channels (arrow), and hyperechoic small particles that flow through these channels can be seen. (d) USG surveillance of the same lesion as shown in b confirms the disappearance of the hypoechoic lesion.

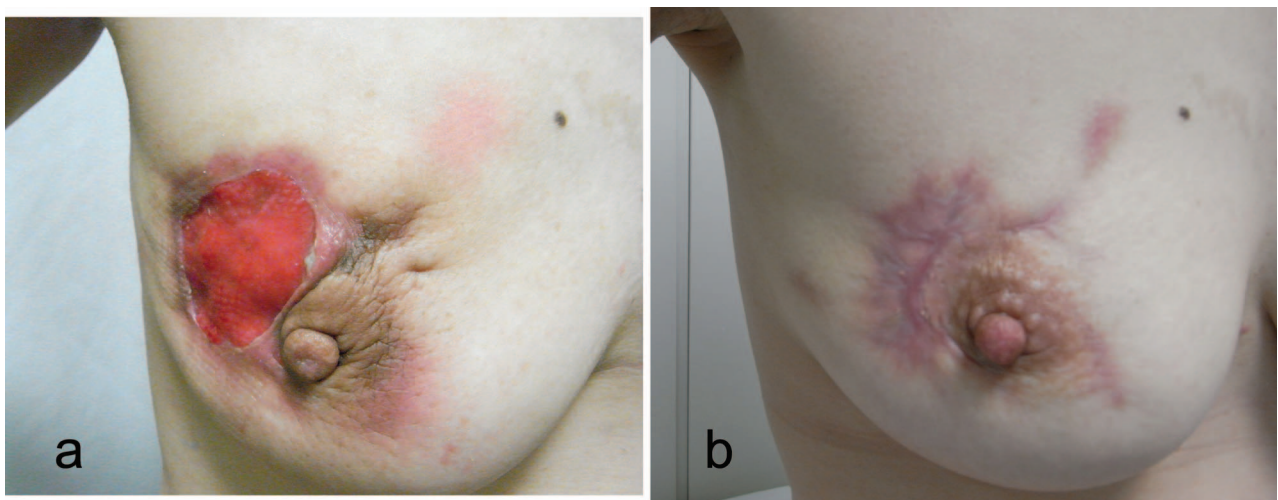


Fig. 3 View of the right breast in case no. 13 at the initial presentation (a) and 5 months later (b). (a) Multiple skin rashes and an ulcer due to the underlying abscess forming a large granuloma can be seen. (b) Complete remission was obtained with minimal volume loss and sequelae.

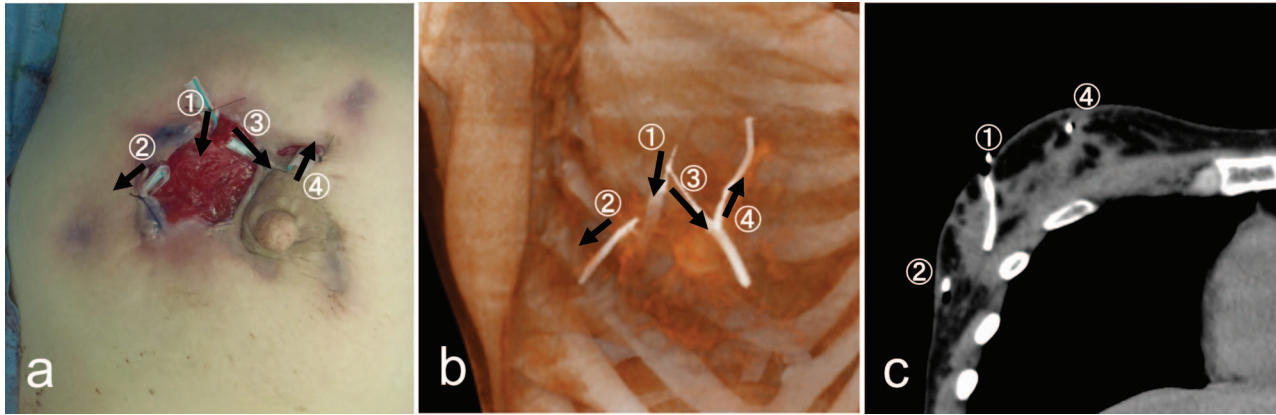


Fig. 4 MDD in case no. 13. The numbers 1, 2, 3, and 4 indicate the number of drainages, and the arrows indicate the direction of the drainage. Drainages are common in a, b, and c. (a) Photograph of post-MDD. (b) Three-dimensional reconstruction of CT shows the direction of the drains. (c) Multiplanar reconstruction of CT shows the deep part of drainage (1).

2a–2c). The diagnosis of GM was confirmed with CNB. We treated her with MDD (Fig. 4) and antibiotics. Resolution was obtained in 5 months, with minimum sequelae of scarring and deformity in her breast (Figs. 2d and 3b).

A total of 7 patients (case nos. 2, 3, 5, 6, 8, 10, and 12) were treated with I&D (6 patients) or aspiration (1 patient) and antibiotics. The abscesses remained in the mammary gland or subcutis, and there was no progress into the retromammary space. The mean time to resolution was 6 months (25 weeks; Table 3).

During the same period that the 13 GM cases were identified, 5663 patients first visited the breast unit of our department. The first diagnosis was made as “mastitis” or “breast abscess” for 163 patients. Among these, 71 patients underwent a pathologic evaluation, such as aspiration cytology, CNB, or excisional biopsy. Eleven patients received a diagnosis of GM, as explained above. A total of 15 patients received a diagnosis of having breast cancer. Of these 15 patients, 5 first received a diagnosis of benign disease, such as “purulent mastitis.” Among the 163 patients, surgical intervention was necessary for 35. Three of these patients eventually had breast cancer. As mentioned above,

they first received a diagnosis of a benign abscess by cytology. Their abscesses soon resolved by I&D. A follow-up with USG revealed a small low echoic lesion on the proximal part of each abscess, and they received a diagnosis of cancer by CNBs. Of the 35 patients, 11 received a diagnosis of GM. A total of 21 residual cases were benign inflammatory disease and called non-GM in this study (Table 3). In one non-GM case, the abscess developed into the retromammary space, and we treated the patient with deep drainage. In this case, the abscess was infected with methicillin-resistant *Staphylococcus aureus*, and it took 21 months for resolution. The other 20 patients were treated with I&D and antibiotics. Abscesses remained within the mammary gland and the mean time to resolution was 7 weeks, which was much shorter than that of GM with abscess with the same range of depth (Table 3).

Discussion

GM is considered as a rare, chronic, nonspecific, granulomatous process with unknown etiology, affecting the breast in relatively young, parous women. GM patients usually present with a tender, firm breast lump with a lobular distribution, and

Table 3 Range of depth of abscesses and time to resolution of GM and non-GM patients

	Total no. of cases of treated abscesses	Range of depth of abscesses and time to resolution			Mean time to resolution, wk
		Retromammary space, no. of cases	Mean time to resolution, mo	Intramammary region, no. of cases	
GM	11	4	16.6	7	25
Non-GM	21	1	21	20	7

this is frequently associated with inflammation of the overlying skin. GM was first described as a distinct clinical entity by Kessler and Wolloch in 1972.¹ Going *et al*⁴ have recommended the term *granulomatous lobular mastitis* to separate this lesion from the granulomatous form of periductal mastitis.⁴ However, to differentiate between these two conditions, a large specimen is necessary to detect specific changes implying the localization of inflammation.^{8,9} In this study, we adopted the term *granulomatous mastitis* instead of granulomatous lobular mastitis. We adhered to the histologic criteria for GM of noncaseating granulomas centered on lobules, excluding infections and specific causes. However, the specimens for pathologic examinations were CNB in most of the cases, and we consider that the specimens were not large enough to rule out periductal mastitis. Recently, a concept unifying these two conditions was proposed, and the term *mammary duct-associated inflammatory disease sequence* was introduced by Meguid and colleagues.¹⁰ The mammary duct-associated inflammatory disease sequence concept is that all of these disorders result from obstruction, distention, inflammation, and rupture of the lactiferous ducts. Regarding the background of the cases in this series, 5 patients with GM were undergoing antidepressant therapy, and 3 of them were not parous (Table 1). Previous studies have shown that the occurrence of GM without a history of recent pregnancy is uncommon.^{2,11} However, antidepressants can induce hyperprolactinemia¹² and may cause breast swelling and/or galactorrhea,¹³ as observed in 2 cases in this series. According to the concept of mammary duct-associated inflammatory disease sequence, certain conditions, such as pregnancy, breast-feeding, and drug-induced hyperprolactinemia or galactorrhea, might be associated with an increased risk of GM.

In our study, among the 13 GM patients who were identified from the pathologic database, 11 patients were identified out of 163 patients with inflammatory breast disease during the clinical course of treatment. The remaining 2 patients received a diagnosis with excisional biopsy as the first treatment. Differential diagnosis was carried out in parallel to treatment according to the clinical presentations. Although the top priority is exclusion of breast cancer, painful symptoms should also be relieved. The affected part of the breast was first examined by USG. Aspiration or I&D was performed in the abscess, and a culture was submitted. Cytology or CNB was performed, targeting the

tumorous lesions by an ultrasound-guided procedure. A serum examination was performed and empiric antibiotics were provided. Further radiologic examinations were considered when a painful symptom was relieved. Sometimes the mass and inflammatory symptoms disappeared so quickly that further radiologic examinations were not necessary in non-GM patients. Although GM can mimic breast cancer clinically, radiologic imaging is limited in distinguishing GM from malignancy.¹⁴ Findings of mammography are usually nonspecific.¹⁵ CT and MRI findings were also nonspecific in our study. USG may characterize GM lesions better than other modalities, especially when they are shown as tubular hypoechoic foci associated with an irregular hypoechoic mass.¹⁵ However, USG is still limited in excluding malignancy because associated carcinomas are sometimes obscured by the granulomatous reaction. Although the coexistence of GM and breast cancer has not been reported, we repeated pathologic examinations, even after the diagnosis of GM was confirmed during the clinical course, until complete remission was obtained.

There is still no generally accepted optimal treatment for GM. Wilson *et al*⁶ analyzed 116 cases of GM that were reported in the literature in 2007. A total of 9 patients were observed without medical intervention. The use of oral corticosteroids as primary therapy was reported in 26 patients, and 15 (58%) had only a partial response. Complete excision, including partial mastectomy, was the most commonly reported approach ($n = 75$), and 16 patients (21%) had recurrence. Mastectomy was reported in 3 patients. Although wide excision of the mass is traditionally performed, complete excision of the whole inflammatory mass with a negative margin might be impossible, especially when it involves more than one quadrant, because the cosmetic outcome would be unacceptable. Dixon *et al*^{16,17} argued that with a definitive diagnosis of GM, a nonsurgical approach is the ideal treatment option, with aspiration or I&D of abscesses performed only when required. However, the role of I&D is controversial because it may not improve the condition and may lead to intractable incision tracks, which subsequently lead to sinus formation.¹⁸ In our study, in 4 patients, the abscess penetrated the retromammary space, and in 2 patients this occurred after I&D (Table 2). In contrast to the abscesses in non-GM patients, the abscesses in GM patients were intractable, even if they remained within the mammary gland (Table 3). Baslaim *et al*³ described

abscesses in GM as differing from acute pyogenic abscesses; in GM, they are more diffuse and composed of multiple small loculi that communicate through tiny channels. In our cases, USG revealed such architecture of abscesses and demonstrated fluid flow through those channels (Fig. 3c). Drainage of these abscesses may become insufficient, and therefore abscesses may progress to a deep part of the breast or incision tracts may lead to sinus formation. We devised the MDD procedure to enable thorough drainage of whole abscesses (Fig. 4). Case no. 13 was a good representative candidate. This patient had a severe presentation with complicated deep abscesses and skin ulcers after several drainages of abscesses in other clinics. Intraoperative USG was necessary to ensure that drainage was sufficient and to perform multiple CNBs, which is important to rule out malignancy. This unique drainage, which matches the characteristic of abscesses of GM, enabled the thorough drainage of abscesses and was effective. Discharges were soon tapered and the plastic drains were removed in 1 or 2 weeks, although several irrigations were required. Abscesses in patients with GM should be treated with aspiration, I&D, and MDD according to the size and depth of the abscesses. The abscesses should also be sufficiently drained. Close observation and repeated minimally invasive surgical treatments, such as aspiration or I&D, might be sufficient for patients with abscesses remaining within the mammary gland. However, when a complicated abscess extends to the retromammary space, MDD might shorten the time to complete remission.

In our study, we prescribed corticosteroids in only 1 patient (case no. 4). The initial dose of corticosteroid might have been too short, even in consideration of the titer (betamethasone 0.5 mg = prednisone 5 mg). Her abscess did not resolve and penetrated into the retromammary space. Although increasing the dosage of corticosteroid was effective in this patient, tapering was not easy because of recurrence and pulmonary thrombosis. Thrombosis could be due to hypercoagulability, which is one of the side effects of corticosteroids, similar to glucose intolerance and Cushingoid features. After this patient, we avoided the use of corticosteroids in treating GM patients, despite the benefits reported in studies as described below, because of the risk of side effects.

Studies have reported that treatment with oral corticosteroids, alone or in combination with surgery, is effective.^{19–21} Satisfactory results have been reported with high dosages of prednisone

(60 mg/d for 2–3 weeks)^{21–23}; however, the recurrence rate can be as high as 50%.^{8,22} Sakurai *et al*²¹ reported a series of 8 patients with GM. They treated 7 of the 8 patients with only corticosteroids and obtained complete remission in 5 to 10 months. Most of the patients did not have abscess formation, which suggested that they were in the early stage of the clinical course of GM. They did not report any complications or side effects during corticosteroid therapy. However, in other reports, weight gain (3–8 kg) in 6 patients and hyperglycemia in 1 patient out of 25 patients,¹⁹ and oral candidiasis in 2 patients and gastritis in 1 patient out of 14 patients²⁰ were reported as side effects of corticosteroid treatment. If a side effect is not critical but ameliorable, the corticosteroid treatment can be completed. However, thrombosis could be critical, although it may initially be asymptomatic. Recently, Ogura *et al*²⁴ reported GM cases in which an infiltrate of immunoglobulin G4-positive (IgG4⁺) plasma cells was present, and speculated that patients with IgG4-related GM might benefit from corticosteroid therapy, as do those with IgG4-related autoimmune disorders. If prediction of the efficacy of corticosteroid therapy is possible, early recognition and administration of corticosteroid treatment might prevent invasive surgical treatment that deforms the breast. In our study, 4 patients who developed abscesses during observation might have been able to avoid surgical treatment if they had received corticosteroids. However, 8 patients, including 4 in our study who were treated with I&D and/or MDD, obtained complete remission in 4.5 to 11 months. This is comparable with responses reported in a series of excellent outcomes with corticosteroids.²¹ Al-Khaffaf *et al*²⁵ reported that 18 cases of GM spontaneously resolved in 11 to 105 weeks, regardless of the treatment used. Another report described a variable treatment response for GM, ranging from 3 to 27 months.¹⁸ These two overall outcomes are also comparable with our results. Because the natural history of GM is supposed to be self-limiting, our experience indicates that close surveillance with a minimally required surgical procedure might be the first-line treatment of GM.

In conclusion, GM is a rare benign breast disease that is difficult to distinguish from other inflammatory breast diseases or cancer. The side effects of corticosteroid treatment may be challenging in such a benign disease, which is curable by close observation and thorough drainage, in a time comparable

with that of corticosteroid treatment and with fewer complications. Therefore, observation and drainage without corticosteroids remain the treatment modality of choice for GM.

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