A Case Management Model for Patients with Granulomatous Mastitis: A Prospective Study

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Research Article

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Abstract

Background: Granulomatous mastitis is a chronic inflammatory mastitis disease with long-term treatment and high recurrence rate, there is no general agreement on effective clinical management, the new management model is worthy of investigation. The aim of this study to investigate the application of case management model in granulomatous mastitis and explore the related factors which are associated with the recurrence of granulomatous mastitis.

Methods: This is a prospective study of 152 Chinese women who were monitored during the whole process of case management. Demographic, clinical and laboratory information, treatment methods, follow-up time, and recurrence were collected and analyzed. The eight-item Morisky medication adherence scale (MMAS-8) was used to investigate patients' adherence to medications.

Results: Until October 2021, a total of 152 female patients with a mean age of 32 years have received the entire process of case management. The mean total course of case management was 24.54 (range, 15 - 45) months. Almost all the patients received medication treatment, except for one pregnant patient on observation therapy, and about 53.9% of the patients had medication plus surgery. The overall recurrence rate was 11.2%, and “high” medication adherence (RR=0.428, 95% CI: 0.224-0.867, P = 0.015) were significantly associated with a lower rate of recurrence while the rate of recurrence with surgical procedure + medication was higher than that with medication treatment (RR = 4.128, 95% CI: 1.026 - 16.610, P = 0.046).

Conclusion: case management model for patients with granulomatous mastitis was effective with a relatively low recurrence rate. “Low” medication adherence were significant risk factors for the recurrence of granulomatous mastitis. Patients with medication plus surgery are more likely to recur than with medication treatment alone. The optimal treatment approach should be planned for GM patient and patient's medication adherence should be of concern to medical staff.

Background

Granulomatous mastitis (GM) was firstly reported as a chronic inflammatory disease of the breast by Kessler and Wolloch in 1972 [1], accounting for approximately 1.8% of benign breast diseases [2]. Due to the rarity of the disease, most countries have not conducted large epidemiological surveys of granulomatous mastitis, with only 2.4 per 100,00 incidences reported from the Disease Control and Prevention in 2009 [3]. To date, the etiology of GM is unknown and may be associated with a history of pregnancy, autoimmune disease, breast trauma, hyperprolactinemia, and infection [15–16]. The disease progresses rapidly with a recurrent or prolonged natural course, which has a high recurrence rate of 5%-50%, is commonly seen in young women with a history of breastfeeding and childbirth [11, 17, 19, 33]. As recently been reported, there are racial differences in this disease, the incidence of GM in Middle Easterners (Egypt, Turkey, Iran) and Spaniards are higher than Western Caucasians (UK, USA, New Zealand) [5–7]. A large number of cases of granulomatous mastitis have been given descriptions, mainly

from Asian and Mediterranean countries, such as China, Iran, and Turkey [8–9]. However, there is no consensus on the management of the disease and no gold standard regarding the diagnosis and treatment of GM [12]. Currently, the main treatment options have included observation, medication therapy (steroids, antibiotics, methotrexate (MTX), and anti-molecular bacilli) or/and operative intervention (abscess incision and drainage, simple mass excision, enlarged mammary mass excision, etc.) [7, 18]. The main clinical presentation is a palpable, painful breast lump with concomitant skin erythema, nipple retraction, sinus tract formation, cellulitis changes, and axillary adenopathy formation [11–13], and in severe cases, there are usually multiple coexisting focal abscesses with skin inflammation and ulceration [13]. According to the severity of the disease, GM is clinically classified into the mass, the abscess, and the refractory type [14]. Patients often need to endure a long course of the disease, as well as changes in breast appearance brought about by the disease, which has serious physical and psychological effects on patients [16]. Meanwhile, the toxic side effects of long-term medication use have a significant impact on patients' quality of life, resulted in poor compliance with drug use, therefore, timely observation of medication use and changes in breasts is essential to achieve good recovery rates for GM patients [18–21].

Recently, case management has attracted more attention in medical practice as an approach to provide patients with regular and targeted disease monitoring and health guidance through follow-up visits and WeChat consultations [42]. In this model, nurse specialists is responsible for the overall coordination, management, and continuity of care for a specific treatment or intervention to meet the health needs of the individual, reduce health care costs and improve quality of service [22–23]. Currently, it is known that case management is widely applied to patients of breast disease, especially breast cancer [24–25], but is rarely to of GM. Since January 2018, case management model for GM patients had been explored and practiced in Chengdu Women's and Children's Central Hospital, which can provide patients with full management and seamless healthcare services.

Materials And Methods

Study design and participants

A prospective study on patients with granulomatous mastitis based on a case management model undertaken between January 2018 and November 2020 at the Breast Unit of the Chengdu Women's and Children's Central Hospital. According to characteristics of the disease, the whole process of case management presented in Figure 1 is divided into four key stages, including the diagnostic, the conservative, the perioperative, and the follow-up period. The entire period is led by case managers and tailored for patients, including evaluation, planning, integration, implementation, and evaluation of treatment plan. Participants were followed up by the whole process. At the diagnostic stage, case managers mainly based their decisions on clinical symptoms whether or not a register of initial medical history was created including age, pregnancy history, disease history, onset time, onset trigger, contact phone number. Patients whose diagnosis of granulomatous mastitis was confirmed by the results of pathological examination by core needle biopsy, and then case management file was established. At the

conservative treatment stage, case managers mainly: (1) followed up and recorded the results of ultrasound, abnormal laboratory test and breast signs, and explained the precautions and methods of medication administration according to the doctor's prescription; (2) surveyed GM patients for medication adherence at 2 months of drug use. Adherence was measured using the eight-item Morisky Medication Adherence Scale (MMAS-8) [44], translated into Chinese scale by Lin Chen et al [45], which has a high reliability and validity, and has been widely used in studies of various chronic diseases in China [45,46]. Three levels of adherence were considered based on the following scores: 0 to <6 (low); 6 to <8 (medium); 8 (high). (3) handed out notes of disease considerations related to diet, sleep, behavior, etc. in Table 1 [14, 27, 28]; (4) established a contact platform for GM patients to know and observe the changes of their breasts during the treatment at home, given psychological support and guidance. In the perioperative and the follow-up period, the case manager recorded the patient's information of surgery, medication, follow-up time and recurrence.

In this study, the qualification of case managers only three were: (1) nurses with Bachelor's degree or above, (2) nurses with intermediate title or above, (3) 5 years or more in the breast department, (4) nurses who have received the training including case management process, communication and health promotion skills, (5) nurses who were required to rotate through the breast clinic, ultrasound and pathology department, wound care unit and operating room, (6) nurses who have passed the hospital examination of case management. All patients who received case management were eligible for inclusion if they were older than 18 years and had clinical signs on the breast, confirmed diagnosis by core needle biopsy. They were ineligible if they had other complications of the breast, and had been treated in other institutions. The study was approved by the ethics committee of the Chengdu Women's and Children's Central Hospital (No. B2019(13)). All participants signed an informed consent form.

Case definition

Histopathologic examination is a necessary and gold-standard method for diagnosis of granulomatous mastitis (GM) [43], so definitive diagnosis of GM is largely being accomplished with core needle biopsy in this study. The disease may be locally invasive with a risk of recurrence, recurrence rates of 5 to 50% have been observed following various literature in recent years [17,19,33]. The following definition of recurrence was used in this study: the detection of new lesion(s) within the range of the primary location or

any other part of the ipsilateral breast 1 month following the termination of therapy.

Medication adherence can be defined as the behavior about taking drugs that fits with the physician's advice [31]. In a meta analysis by Lei et al. [41], oral drug therapy is an effective treatment modality of GM patients in both surgical and conservative treatment. As the majority of the duration of drug application varied between 2 and 12 months [47, 48,49,50], we chose to investigate medication adherence at 2 months of medication.

Statistical analysis

Statistical software package SPSS for Windows, version 19.0 (SPSS Inc., Chicago, IL) was used for statistical analysis. Clinical characteristics were described using mean $\pm$ standard deviation or mean (range) or number (and percentage) as appropriate. Continuous variables were compared between patients with and without recurrence using one-way ANOVA while categorical variables were compared using a Chi-square test and Fisher's exact tests. Logistic regression models were built for analysis of risk factors for the recurrence of GM.

Results

Characteristics of the patients

In this study, there were 204 symptomatic patients with granulomatous mastitis initially included in the diagnostic stage between January 2018 and November 2020. However, 4 patients were diagnosed as breast cancer, 8 dropped out and 42 still going on in case management. Ultimately, 152 patients have completed case management until September 2021. It is shown in Table 2 that the mean age of the patients was 32 years (range 22 – 48). It was observed that 71 (46.7%) patients had normal BMI, while 64 (47.4%) patients' BMI was higher than 25, which were considered as overweight or obese. It was detected that the period in which GM was most frequently seen was the first 2 – 5 years after birth with 94 patients (61.8%), followed by 30 patients (19.7%) for 0 – 2 years (4 patients in breastfeeding), 15 patients (9.9%) for pregnancy. The accompanying diseases were found in only 28 (18.5%) patients, such as diabetes mellitus, thyroid disease, psychoses, hypertension, and hyperprolactinemia accounted for 13.8% in the highest percentage of all comorbidities.

On physical examination, the most common finding was a palpable mass with pain (98.7%), the breast abscess was in 38.8% of patients, and 75% of patients suffered from skin lesion, and approximately 5% had fistulas and Erythema nodosum (Table 2). Based on clinical symptoms, the disease was typed as the mass (74, 48.7%), the abscess (66, 43.4%), and the refractory type (12, 7.9%). Unilateral involvement was observed mostly in 140 (92.1%) patients. In this study, 30.96% of patients reported that they had bad behaviors a week before disease onset, including breast trauma (8.6%), excitant food (14.47%), staying up all night (7.89%).

Treatments of the patients

It was seen in table 3 that different treatments were administered. Of 152 patients, only 1 (0.7%) recovered under observation without treatment, 82 (53.9%) recovered with medication plus surgery, 69 (45.4%) recovered solely with medical treatment. In the course of medication, 65 (42.8%) patients chose systemic steroids alone, 21 (13.7%) patients chose tubercle bacillus drug alone, while 65 (42.8%) patients required a combination or change of drug regimen due to ineffective treatment or drug side effects.

including erythema nodosum (5.3%), skin rash (5.3%), abnormal index of liver function (7.2%), abnormal uric acid (2.0%) and edema on the lips and face (0.7%).

Follow-up visits for the patients

The mean follow-up time was 25.55 months (range 15 – 45) in the patients treated with medication plus surgery, while it was 23.83 months (range 17 – 36) in the patients treated solely with medication. There was no statistically significant difference between them ($p = 0.570$). The recurrence rate in the series was determined as 11.2% with 17 patients. At 2 months of initial medication, medication adherence outcome of GM patients was “high” in 59 patients (39%), “Median” in 70 (46.4%), and “Low” in 22 (14.6%), shown in Table 4.

Factors associated with recurrence

All statistical significant variables related to BMI, treatments, medication and medication adherence (Table 5) were included in the multivariable logistic regression model. The results of the multivariable analysis are shown in Table 6, surgical procedure plus drug treatment ($RR=4.128$, 95% CI: 1.026-16.610, $P=0.046$) were independently associated with increased recurrence risk of granulomatous mastitis. In contrast, “high” medication adherence ($RR=0.428$, 95% CI: 0.224-0.867, $P=0.015$) was associated with decreased recurrence risk.

Discussion And Conclusion

This is the first study to report that a case management model is applied to GM. Although it is a benign disease, the recurrence of GM, one of the main challenges in patients’ management of the disease, has been reported to occur in 5%-50% of patients [17,19,33]. In our study, the recurrence rate of 11.2% lies in the low of this range. 17 patients with recurrence were including ten with new lesions in the ipsilateral breast and seven in the contralateral breast.

In recent years, the prevalence of granulomatous mastitis has been rapidly increasing, and most affected patients are women of childbearing age [64]. In two studies, Freeman et al. reported that up to 86% of GM patients had a history of pregnancy in the past 5 years [50]. Prasad et al. reported that 73 patients with GM had a mean age of approximately 33 years and a history of childbirth 4.6 years before mastitis on average [36]. In our study, the median age of patients was 32 years (range 22 - 48), 119 patients had a history of childbirth within 5 years, 15 patients had concurrent pregnancy, 4 patients were undergoing breastfeeding, which had similar characteristics as previously reported. It indicated that hormones play an important role and may be related to the secretion theory that has an important place in the pathophysiology of GM [33]. It has been postulated that GM results from a localized autoimmune response to the retained or extra vacated fat- or protein-rich secretion in the breast ducts during

childbearing age due to previous hyperprolactinemia in women [40]. Therefore, the breast care for women of childbearing age should deserve our attention.

GM patients mostly have mass and pain symptoms, skin lesion and abscess can be observed in the mass localization. Findings such as fistula, erythema nodosum, and nipple or skin retraction can also be observed [1, 2, 47]. In many studies, the most common complaint at the time of initial visit was reported as unilateral painful breast mass [26, 47]. Similarly, 98.7% of the patients had mass and pain complaint, 92.1% of the patients presented as a unilateral affected breast. The case managers would make initial judgments and tendentious guidance based on clinical presentations. At the initial visit, there were the mass (74, 48.7%), the abscess (66, 43.4%), and the refractory type (12, 7.9%), which were not associated with recurrence in the later stages ($P = 0.2$). As the disease progresses, 10 cases of the mass type turned to the abscess and 4 cases of the abscess turned to the refractory. The important thing for case managers is the care of the affected breast (shown in Fig. 2 and Fig. 3). Wound care should consist of managing drainage from fistulae with gauze and other non-adherent dressings. Tape should be avoided due to further abrasion and irritation of the skin [38]. Meanwhile, if the patient has a superficial abscess, a case manager percutaneously performs puncture aspiration, and how deep the abscess is, the mammographer is assisted by ultrasound guidance to perform puncture drainage, in order to create a path for drainage of secretions and reduction of pressure in the inflamed area due to the accumulation of inflammatory fluid.

Comparing the most recent publications on GM to older data, there is no new information on this benign breast disease. Therefore, the best management of this disease is still unclear [19,33]. The usual treatment for GM is close observation, medical treatment, surgical management, or a combination of both [7,11,37]. In the present study, only 1 (0.7%) recovered under observation, 82 (53.9%) recovered with medication plus surgery (such as shown in fig.2), 69 (45.4%) recovered solely with medication treatment (such as shown in fig.3). Multivariate analysis revealed that medication plus surgery was significantly associated with recurrence ($RR = 4.128$, 95% CI [1.026-16.610], $P = 0.0046$) (Table 6). Regarding the cause of recurrence, previous studies have ascribed the incompleteness of excision to the failure of surgical treatment, or it is likely that inconsistent follow-up times. In this study, case managers would assess changes in the size of the breast mass and the proportion of the mass size to the breast size and consider whether the patients can undergo surgical excision with minimal impact on the aesthetics of the breast. The breast lesion excision by minimally invasive surgery or open surgery were applied, which may be a risk of incomplete surgical excision. Akcan et al. and Yabanoğlu H et al. reported that complete excision of the breast or wide excision with or without medication achieved low recurrence rates [10,50], however, it is possible to cause appearance damage of breast due to excessive removal of tissues. Thereby, The biggest problem with surgical treatment is the contradiction between the surgical effect and the postoperative aesthetic effect. Whether surgery which procedure to choose increases the recurrence rate of GM, it is required that more evidences are to be further investigated.

Our study demonstrated that medical treatment is most prevalent, whether coupled with surgical treatment or not. The drug therapies have numerous side effects, such as Cushion's syndrome skin rash, abnormal liver enzymes and uric acid and so on [51]. In our study, there are 8 (5.3%) patients suffering skin rash, 11 (7.2%) abnormal liver enzymes, 3 (2.0%) abnormal uric acid, and 1 (0.7%) edema on the lips and face (shown in Table 3). In this stage, case managers serve as a treatment team by linking physicians, pharmacists, dermatologists, obstetricians, and general practitioners. They communicated with the multidisciplinary team immediately, and then guided the patient on their medications, and then finally most of the side effects disappeared within 1 week.

To the best of our knowledge, there are no studies investigating medication adherence in GM patients. In our study, it has been shown that the MMAS-8 was responded by 154 patients that had 39% high adherers, 46.4% medium adherers, and 14.6% low adherers. As a result of case manager guidance, "Low" medication adherence of GM was much lower than reported 30% and 50% of poor adherence to chronic disease in adults [29,30]. Furthermore, "High" medication adherence (RR=0.428, 95% CI: 0.224-0.867, P = 0.015) at two months of initial medication were significantly associated with a lower rate of recurrence in multivariate analysis. At the initial stage, the case managers paid more attention to the changes in the patient's breast symptoms than patient medication adherence, the medical staff's guidance and supervision of patient medication needs more improvement. Currently, several reports have demonstrated the importance of regular visits to the physician, adequate patient contact time in clinical practice, and patient education to improve medication adherence to treatment [4,32].

In this study, the results were found that 22 (14.47%) patients had excitant food before the onset of GM. The recent literature reported that bacterial interactions have been confirmed between the breast and gut [34,35,39]. Li XQ et al hypothesized that imbalances among the external environment, host, and microbiota lead to the occurrence of GM as follows: External factors disturb the balance between the immune microenvironment and breast flora and induce the release of inflammatory factors and milk secretion, resulting in damage to the mammary epithelium. The positive feedback between the immune and inflammatory reactions eventually induces GM [34]. Consumption of stimulating foods may disrupt intestinal flora and induce inflammation. Therefore, the patients with GM will be handed out notes of disease considerations related to dietary, sleep, behavior, etc. in Table 1. Due to the limitations of this study, it cannot be confirmed whether GM is related to dietary and lifestyle habits, which needs to be further investigated.

In conclusion, case management is effective for patients with GM. It made healthcare services and health information easy to access for GM patients and had relatively low recurrence rate. The optimal treatment approach should be planned for GM patient and patient's medication adherence should be of concern to medical staff.

Declarations

Ethics approval and consent to participate

This study was approved by the Institution Review Board of Chengdu Women and Children's Central Hospital Ethical approval (Grant No. B2019(13)). All participants signed an informed consent form before data collection. All procedures performed in this study were in accordance with the ethical standards.

Consent for publication

Not applicable

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Competing interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Author Contributions

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Tables

Table 1

Notes of disease considerations

Contents	Cautions
Dietary [14, 35]	<p>Meat: meat other than pork</p> <p>Seafood: seaweed, laver, etc.</p> <p>FaWu (name from China): mushrooms, bamboo shoots, etc.</p> <p>Tropical fruits: cinnamon, mango, durian, etc.</p> <p>Spicy food: hot pot, barbecue, etc.</p>
Behavior [27,28]	<p>Breast collision</p> <p>Consumption of alcohol and tobacco</p> <p>Poor sleep and emotions</p> <p>Pregnancy during the treatment period</p>

Table 2

Demographic and clinical characteristics of 152 patients

Variables	Patients (n=152)
Age, mean (SD) [range], y	32±4[22-48]
BMI(kg/m ²)	
≥30	8(5.3%)
25-30	64(42.1%)
18.5-24.99	71(46.7%)
<18.5	9(5.9%)
Time interval between birth and onset of GLM (years)	
Pregnancy	15(9.9%)
Breastfeeding	4(2.6%)
Time until last birth (y) (<2no breastfeeding)	26(17.1%)
Time until last birth (y) (2-5)	94(61.8%)
Time until last birth (y) (>5)	8(5.3%)
No birth	5(3.3%)
Comorbid disease	
Diabetes mellitus	1(0.7%)
Thyroid disease	1(0.7%)
Psychoses	3(2.0%)
Hypertension	2(1.3%)
Hyperprolactinemia	21(13.8%)
Side	
Left	81(53.2%)
Right	59(38.9%)
Bilateral	12(7.9%)
Sign and symptoms	
Palpable mass with pain	150(98.7%)
Skin lesion	114(75%)
Abscess	64(38.8%)
Fistula	8(5.3%)

Erythema nodosum	8(5.3%)
Mass size at onset[43]	
< 1 cm	6(4.2%)
1–2 cm	40(26.3%)
3–5 cm	69(45.6%)
> 5 cm	36(23.9%)
Laboratory tests before treatment	
C. kroppenstedtii	
Positive	28(18.4%)
White blood cell (WBC) mean [range], *10 ⁹ /L	9.77±3.33(3.59-17.55)
C-reactive protein (CRP) mean [range], mg/L	11.91±18.91 (1.0-139)
Prolactin(PRL) mean [range], ng/mL	22.70±19.72 (3.5-129.24)
Types of GM	
Mass type	74 (48.7%)
Abscess type	66 (43.4%)
Refractory type	12 (7.9%)
Behavior before the onset	
Breast trauma	13 (8.6%)
Excitant food	22 (14.47%)
Staying up all night	12 (7.89%)

Table 3

Treatments of patients

Variables	Patients (n=152)
Treatments	
Medication + surgery	80 (52.6%)
Medication	71 (46.7%)
Observation	1 (0.7%)
Medication	
Single steroids	84 (55.6%)
Single tubercle bacillus drug	20 (13.2%)
Combined medication (antibiotics and/or steroids and/or methotrexate and/or tubercle bacillus drug and/or immunosuppressants and/or bromocriptine)	47 (31.2%)
Surgery	
Breast lesion excision by minimally invasive surgery	20 (13.2%)
Breast lesion excision by open surgery	60 (39.5%)
Without surgery	72 (47.4%)
Side effects	
Skin rash	8 (5.3%)
Abnormal index of liver function	11 (7.2%)
Abnormal uric acid	3 (2.0%)
edema on the lips and face	1 (0.7%)

Table 4

Follow-up visit of patients

Variables	Patients (n=152)
Follow-up time, mean (SD) [range], m	24.54 (4.38) [15-45]
Medical + Breast lesion excision by minimally invasive surgery	26.38±8.27 [15-45]
Medical + Breast lesion excision by open surgery	24.72±3.97 [17-36]
Medical	23.83 (2.62) [16-30]
Observation	12
recurrence	
Yes	17 (11.2%)
No	135 (88.8%)
Medication adherence	
High	59 (39.0%)
Median	70 (46.4%)
Low	22 (14.6%)

Table 5

The characteristics in GM patients with and without recurrence

Variables	No recurrence	Recurrence	Test statistic	P
BMI(kg/m²)			$\chi^2 = 8.29$	0.028
18.5-24.99	80 (59.26)	5 (29.41)		
≤18.5	9 (6.67)	0		
25-29.99	39 (28.89)	11 (64.71)		
≥30	7 (5.18)	1 (5.88)		
Side			$\chi^2 = 3.234$	0.345
Right	53 (39.2)	6 (35.3)		
Left	73 (54.1%)	8 (47.1)		
Bilateral	9 (6.7)	3 (17.6%)		
Mass size at onset			$\chi^2 = 1.031$	0.797
< 1 cm	5 (3.7)	1 (5.9)		
1–2.9 cm	31 (22.9%)	4 (23.5)		
3–5 cm	65 (48.2)	7 (41.2)		
> 5 cm	34 (25.2)	5 (29.4)		
Laboratory tests before treatment				
C. kroppenstedtii			$\chi^2 = 1.317$	0.453
Positive	35 (24.6%)	1 (10%)		
Negative	107 (75.4%)	9 (90%)		
White blood cell (WBC) mean, *10 ⁹ /L	9.7±3.4	10.1±3.1	F = 0.197	0.658
C-reactive protein (CRP) mean, mg/L	12.3±19.9	8.8±6.9	F = 0.53	0.468
Prolactin (PRL) mean, ng/mL	22.1±19.8	27.2±19.0	F = 0.924	0.338
Types of GM			$\chi^2 = 4.857$	0.2
Mass type	65 (48.2%)	9 (52.9%)		

Abscess type	59 (43.7%)	7 (41.2%)		
Refractory type	11 (8.1%)	1 (5.9%)		
Treatments			$\chi^2 = 7.429$	0.02
Medical + Breast lesion excision by minimally invasive surgery	17 (12.7)	2 (11.8)		
Medical + Breast lesion excision by open surgery	50 (37.0)	12 (70.6)		
Medication	67 (49.6)	3 (17.6)		
Observation	1 (0.7)	0		
Medication			$\chi^2 = 7.175$	0.018
Single steroids	77 (57.0)	7 (41.2)		
Single tubercle bacillus drug	20 (14.8)	0		
Combined medication	37 (27.5)	10 (58.8)		
Without medication	1 (0.7)	0		
Medication adherence			$\chi^2 = 5.932$	0.046
Low	17 (12.7%)	6 (35.3%)		
Median	63 (47.0%)	8 (47.1%)		
High	54 (40.3%)	3 (17.6%)		
Follow-up time, m	24.55	24.41	F = 0.015	0.901

Table 6

Risk factors for GM recurrence by multivariate analysis

Variables	Rate ratio	95% CI	P
BMI(kg/m²)			
≤24.99	1	Reference	0.166
25-30	3.467	0.949 - 12.666	0.060
≥30	3.245	0.269 - 39.211	0.355
Treatments			
Medication		Reference	
Medical + surgery	4.128	1.026 - 16.610	0.046
Medication			
Single medication		Reference	
Multiple medication	2.556	0.821-7.957	0.105
Medication adherence			
Low		Reference	0.046
Median	0.656	0.160 - 1.182	0.064
High	0.428	0.224 - 0.867	0.015

Figures

Figure 1

the algorithm for the case management of granulomatous mastitis

Figure 2

The effect of medical and surgical treatment under the case management. The underlined part of the figure shows the scope of the lesion located by ultrasound.

Figure 3

The effect of medical treatment under the case management.