

Presentation and Outcome of Granulomatous Mastitis in A Tertiary-Level Hospital

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ABSTRACT

Introduction: Granulomatous Mastitis (GM) is a rare chronic inflammatory breast disease that clinically mimics breast carcinoma, posing significant diagnostic and therapeutic challenges. There is no universally accepted treatment protocol, and management varies widely. To evaluate the clinical presentation and initial outcomes of Granulomatous Mastitis in patients attending a tertiary-level hospital. **Methods & Materials:** This descriptive observational study was conducted at the Department of Surgery, Comilla Medical College Hospital, from January to June 2019, involving 50 female patients aged 18-65 years diagnosed with GM by cytology or histopathology. Data were collected through face-to-face interviews, clinical examinations, and diagnostic investigations. Analysis was performed using SPSS version 23.0. **Results:** The mean age was 33.8±8.9 years, with most patients (38%) in the 21-30 years age group. Breast lump (52%) was the most common presentation, followed by breast abscess (44%). Core needle biopsy demonstrated superior diagnostic yield (91.7%) compared to FNAC (33.3%). Steroid therapy showed favorable initial response in 71.7% of patients, while antibiotic therapy alone was largely ineffective (4% success). Combination therapy with methotrexate and steroids achieved 71.4% success, and surgery for extensive refractory cases showed 100% success in a small subset. **Conclusion:** Giant Mastitis (GM) predominantly impacts women of reproductive age, often manifesting as breast lumps or abscesses. The preferred diagnostic approach is core needle biopsy, and corticosteroids are considered effective as initial treatment. The exclusive use of antibiotics should be discouraged.

Long-term prospective studies with extended follow-up are required to accurately determine recurrence rates and to establish optimal treatment protocols.

Keywords: Granulomatous Mastitis, Idiopathic Granulomatous Mastitis, Breast Lump, Core Needle Biopsy, Corticosteroid Therapy, Treatment Outcome

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INTRODUCTION

Granulomatous Mastitis (GM) is a rare chronic inflammatory breast disease that was first described by Kessler and Wolloch in 1972.^[1] This benign condition is clinically important because it mimics breast carcinoma and presents therapeutic challenges, especially with recurrent abscess and fistula formation.^[2] This rare benign disease of the breast is commonly observed in women of childbearing age, although perimenopausal women may also be affected.^[3] A number of risk factors have been described in the literature, including the use of oral contraceptive pills, pregnancy, breastfeeding, autoimmune origin, infection with unidentified pathogens, breast trauma, hyperprolactinemia, and alpha-1-antitrypsin deficiency. However, a definitive etiology has not yet been established.^[4]

Granulomatous inflammations can be idiopathic or result from breast diseases like periductal mastitis, infections, ruptured cysts, fat necrosis, or systemic disorders such as sarcoidosis and Wegener's granulomatosis. In developing countries, it often stems from persistent infections or endemic diseases like tuberculosis.^[5,6] Patients with idiopathic granulomatous mastitis (IGM) often have a hard, palpable breast mass lasting months, with or without

erythematous skin changes. Symptoms may also include pain, skin thickening, sinus formation, nipple retraction, and axillary lymphadenopathy.^[7,8] The disease is typically unilateral, although bilateral involvement has been reported.^[4] Diagnosing GM requires excluding other granulomatous breast lesions. Breast tuberculosis is rare and hard to distinguish from cancer, especially in high-risk or endemic populations, and should be considered in the differential diagnosis.^[9] Variation in the incidence of GM among different populations has been previously reported, with some authors proposing that racial factors may predispose to the development of GM.^[10,11] The most significant challenge regarding GM is that it may imitate breast cancer not only clinically but also radiologically.^[5,12] It is noteworthy that more than 50% of reported cases up to 2005 were initially mistaken for breast carcinoma.^[13] There is no universally accepted treatment for GM. Options include antibiotics, corticosteroids, methotrexate, azathioprine, wound drainage, wide surgical resection, mastectomy, and close follow-up. While aggressive surgery like wide resection or mastectomy is accepted, some prefer conservative management. Surgery provides diagnosis and treatment but can lead to high recurrence (up to 50%), poor

wound healing, sinus or abscess formation, and disfigurement. Corticosteroids may help shrink lesions before and after surgery for persistent masses.

GM raises important diagnostic and therapeutic dilemmas, as many of the reported cases at cancer institutes all over the world were initially mistaken for breast carcinoma. Occasionally, some patients may be subjected to mastectomy as a consequence of a false-positive fine-needle aspiration cytology (FNAC) result.^[14] Because clinical and imaging diagnoses have often been difficult, the definitive diagnosis must be obtained from histopathological diagnosis. There is still no commonly accepted treatment for GM. Wide local excision and systemic steroids are the better treatment choice if possible. But complicated IGM with abscess, fistula, and diffuse involvement poses a problem.^[15] The aim of the study is to evaluate the clinical presentation and initial outcome of Granulomatous Mastitis in patients attending a tertiary-level hospital.

METHODS & MATERIALS

This descriptive observational study was conducted in the Department of Surgery at Cumilla Medical College Hospital, Cumilla, over a period of six months from January 2019 to June 2019, to evaluate the clinical presentation and initial outcome of

Granulomatous Mastitis. The study population comprised patients diagnosed with Granulomatous Mastitis by cytology or histopathology who attended the indoor and outdoor departments. The sample size was initially calculated using the formula $n = (Z^2 \times p \times q)/d^2$, where $Z = 1.96$ at 95% confidence interval, $p =$ anticipated proportion of 50%, $q = 0.5$, and $d =$ allowable error of 0.05, yielding a calculated sample size of 384. However, due to time and financial constraints, the sample size was adjusted to 50 patients with acute breast conditions, selected through purposive sampling. Patients were included if they were female, aged 18 to 65 years, had mastitis occurring at least one year after cessation of last lactation, provided written informed consent, and were pathologically diagnosed with Granulomatous Mastitis. Exclusion criteria included unwillingness to participate, clinical evidence of autoimmune disease, history of breast trauma or breast implants, and malignant breast disease. Operational definitions were established, defining Granulomatous Mastitis as a rare benign breast condition marked by inflammation and a mass within the breast. It typically appears 2 to 6 years post-pregnancy and may be caused by infections like tuberculosis, malignancy, or systemic diseases such as sarcoidosis or Wegener's granulomatosis. Outcome variables included Granulomatous Mastitis, benign findings, abscess, excisional biopsy, FNAC, steroids, and surgical excision. Confounding variables encompassed age, BMI, diabetes mellitus, family history, other diseases, medications (steroids, cytotoxic, immunosuppressive, and others), septic focus, and potential selection bias from undetermined differences between the

sample and the broader community. Data collection involved several systematic steps. Each volunteer provided written consent before a standard questionnaire was used to gather demographic and patient characteristic information. The researcher conducted face-to-face interviews and recorded clinical signs on a checklist. Additional tests supported diagnoses, and questions were explained in the native language when needed to ensure clear understanding. The researcher personally collected all data to prevent errors, and participants were informed they could decline to answer or withdraw anytime without affecting their treatment. Confidentiality was guaranteed, and personal data would not be published. For data analysis, we used SPSS version 23.0 for Windows. Continuous variables were summarized using mean values, and quantitative data were presented as frequencies and percentages. A quality assurance process was followed, which included pretesting the data sheet before starting the main research, and final adjustments based on the pretest results. After collecting data, all entries were reviewed for errors, missing information, and inconsistencies. Omissions were addressed through re-taking histories, re-examining patients, or consulting senior consultants. Irrelevant or inconsistent data were removed to ensure accuracy. This study strictly followed ethical principles in line with the Helsinki Declaration for Medical Research Involving Human Subjects. The study's purpose and details were thoroughly explained to all participants, with voluntary participation strongly encouraged. Participants faced no physical, psychological, or social risks. Informed

written consent was obtained from each patient before enrollment, ensuring privacy, anonymity, and confidentiality of personal information. Patients could choose to participate, decline, or withdraw at any time without any penalty. Ethical approval was secured from the Institutional Review Board (IRB) of Cumilla Medical College Hospital before starting the research. All data were anonymized, kept confidential, and securely stored under the investigator's control for research use only. No experimental drugs or placebos were given, and all participants were treated with respect throughout the study.

RESULTS

This descriptive observational study enrolled 50 patients diagnosed with Granulomatous Mastitis at the Department of Surgery, Cumilla Medical College Hospital, from January to June 2019. The findings are summarized in seven tables with accompanying descriptions. Table 1 shows that the majority (38.0%) of patients belonged to the age group 21-30 years, followed by 34.0% in 31-40 years, 20.0% in 41-50 years, and 4.0% each in ≤ 20 years and > 50 years. The mean age was 33.8 ± 8.9 years, with a range from 19 to 53 years. Nearly two-thirds (62.0%) had a normal BMI ($18.5\text{--}24.9 \text{ kg/m}^2$), while 12.0% were obese ($\text{BMI} \geq 30 \text{ kg/m}^2$). The majority (42.0%) of patients completed HSC education, followed by 11(22.0%) SSC, 9(18.0%) graduate, 7(14.0%) primary, and 2(4.0%) were illiterate. More than half (52.0%) of the patients were service holders, 16(32.0%) were business owners, 4(8.0%) were housewives, 3(6.0%) were day laborers, and 1(2.0%) was unemployed.

Table 1
Demographic characteristics of the study patients by age ($n=50$).

	Parameters	Number of patients	Percentage
Age (in years)	≤ 20	2	4.0
	21-30	19	38.0
	31-40	17	34.0
	41-50	10	20.0
	> 50	2	4.0
	Mean $\pm$ SD	33.8 $\pm$ 8.9	
BMI (kg/m2)	Range (min-max)	19-53	
	< 18.5	4	8.0
	18.5-24.9	31	62.0
	25.0-29.9	9	18.0
	≥ 30	6	12.0
Educational status	Illiterate	2	4.0
	Primary	7	14.0
	SSC	11	22.0
	HSC	21	42.0
	Graduate	9	18.0
Occupational status	House wife	4	8.0
	Service holder	26	52.0
	Business	16	32.0
	Day laborer	3	6.0
	Unemployed	1	2.0

Table II shows that more than half (52.0%) of the patients presented with breast lump alone, followed by 22(44.0%) patients with

breast abscess, 18.0% with breast pain, 12.0% with nipple discharge, 10.0% with

breast lump and pain, and 8.0% with breast lump and nipple discharge.

Table II

Distribution of the study patients according to clinical presentation ($n=50$).

Clinical Presentation	Number of patients	Percentage
Breast lump	26	52.0
Breast abscess	22	44.0
Breast pain	9	18.0
Nipple discharge	6	12.0
Breast lump + pain	5	10.0
Breast lump + nipple discharge	4	8.0

Table III shows that more than two-thirds (68.0%) of patients had primary disease, followed by 14.0% with single sinus,

10.0% with multiple sinus, and 8.00% with recurrent disease.

Table III

Distribution of the study patients according to disease pattern ($n=50$).

Disease Pattern	Number of patients	Percentage
Primary	34	68.0
Single sinus	7	14.0
Multiple sinus	5	10.0
Recurrent	4	8.0

Table IV shows that 7(14.0%) patients had family history of breast cancer, followed by 3(6.0%) with ovarian cancer, 2(4.0%) with prostate cancer, and 1 (2.0%) with colon

cancer. Diabetes mellitus was the most common co-morbid condition (24.00%), followed by hypertension (14.00%), axillary lymphadenopathy (10.00%),

pulmonary tuberculosis (2.00%), and constitutional symptoms (2.00%).

Table IV

Distribution of the study patients according to family history of cancer and comorbid conditions ($n=50$).

Parameters	Number of patients	Percentage
Family history of cancer	Breast cancer	7
	Ovarian cancer	3
	Prostate cancer	2
	Colon cancer	1
	Total	13
Comorbid conditions	Diabetes	12
	Hypertension	7
	Axillary lymphadenopathy	5
	Pulmonary tuberculosis	1
	Constitutional symptoms	1

Table V shows that on ultrasonography, the majority (62.00%) of patients had hypoechoic lobulated mass, followed by

14.00% with irregular tubular mass and parenchymal distortion, 12.00% with parenchymal mixed echogenicity and skin

thickening, 8.00% with abscess collection and fistula tract, and 4.00% with axillary adenopathy.

Table V

Distribution of the study patients according to ultrasonography findings ($n=50$).

Ultrasonography Findings	Number of patients	Percentage
Hypoechoic lobulated mass	31	62.00%
Irregular tubular mass and parenchymal distortion	7	14.00%
Parenchymal mixed echogenicity and skin thickening	6	12.00%
Abscess collection and fistula tract	4	8.00%
Axillary adenopathy	2	4.00%

Table VI shows that core needle biopsy had the highest diagnostic yield (91.70%) compared to FNAC (33.30%). FNAC was performed in 9(18.00%) patients but was diagnostic in only 3(33.30%). Core needle

biopsy with or without ultrasound guidance was performed in 24(48.0%) patients, diagnosing GM in 22(91.70%). Surgical biopsy in 11(22.00%) patients diagnosed all cases (100.00%); however, 9(18.00%)

of these patients developed complications with multiple breast ulcers. No such complications occurred with FNAC or core needle biopsy.

Table VIDistribution of the study patients according to diagnostic procedures ($n=50$).

Diagnostic Procedure	Total	Diagnosis	No Diagnosis
FNAC	9 (18.00%)	3 (33.30%)	6 (66.70%)
Core needle biopsy	24 (48.00%)	22 (91.70%)	2 (8.30%)
Biopsy with surgery	11 (22.00%)	11 (100.00%)	0 (0.00%)

Table VII shows that the maximum duration of steroid treatment was six months. Antibiotic therapy alone was largely ineffective, with only 2 (4.00%) patients improving. Anti-TB treatment in 2 patients for six months was effective in

both (100.00%). Steroid therapy was successful in 33(71.74%) of 46 patients. Combination of methotrexate and steroid in 14 patients was effective in 10(71.40%). Bromocriptine with steroid in 4 patients showed response in only 1(25.0%). Wide

surgical excision in 3 patients with extensive disease who were nonresponsive to other therapies showed 100.0% success with coverage of steroids and antibiotics.

Table VIIDistribution of the study patients according to treatment outcomes ($n=50$).

Treatment Modality	n	Successful	Unsuccessful
Antibiotics	50	2 (4.00%)	48 (96.00%)
Anti-TB drug	2	2 (100.00%)	0 (0.00%)
Steroid	46	33 (71.74%)	13 (28.26%)
Steroid + Methotrexate	14	10 (71.40%)	4 (28.60%)
Steroid + Bromocriptine	4	1 (25.00%)	3 (75.00%)
Surgery + Steroid + Antibiotics	3	3 (100.00%)	0 (0.00%)

DISCUSSION

A hospital-based observational study was conducted in the Surgery Department at Cumilla Medical College Hospital involving 50 patients with palpable breast lesions. The study aimed to assess presentation and initial outcomes of Granulomatous Mastitis, including both inpatient and outpatient cases that met the inclusion and exclusion criteria.

In this study, it was observed that the majority (38.0%) of patients were aged 21-30 years. The mean age was found to be 33.8 ± 8.9 years, with a range from 19 to 53 years. Kok and Telisinghe's study reported the mean age of the 43 patients at presentation was 34 (range 22–47) years. Age at presentation is generally between 20 and 50 years; however, patients as young as 11 and as old as 83 years have also been reported.^[7,10] Aghajanzadeh et al. also reported similar observations: all affected women were of childbearing age, with a mean age of 32 years (22–40 years).^[16] Gurleyik et al. reported that the mean age of patients was 34.1 years (range, 27–59 years). Lai et al. observed a mean age of 45.7 years (range, 32–83 years).^[17] This study showed that the majority (42.0%) patients completed HSC education, followed by 11(22.0%) SSC, 9(18.0%) graduate, 7(14.0%) primary, and 2(4.0%) were illiterate. Uysal et al. reported that 257 (42.0%) patients completed primary school education.^[18]

Regarding clinical presentation, more than half (52.0%) of patients were found with a breast lump, followed by 9(18.0%) with breast pain, 6(12.0%) with nipple discharge, 5(10.0%) with a breast lump with pain, and 4(8.0%) with a breast lump with nipple discharge. Kok and Telisinghe observed that all patients presented with a

palpable breast lump; 24 (56%) of the patients also experienced pain in the lump, and 3 (7%) of the patients also had nipple discharge.^[19] Gurleyik et al. reported that nipple retraction was found in 5.3% of cases. Similarly, the most common presentation in previous studies was also a breast mass and pain.^[18] Aghajanzadeh et al. reported that the most common symptoms in the remaining 168 women in this study were breast mass (88%) and breast mass with pain, erythema, and inflammation (12%).^[17]

In the present study, it was observed that more than three-fourths (68.0%) of patients were found to have primary disease, followed by 7(14.0%) with a single sinus, 5(10.0%) with multiple sinuses, and 4(8.0%) with recurrence. Aghajanzadeh et al. reported that thirty-eight (18%) of the patients had a primary incisional biopsy and drainage with multiple non-healing ulcers due to the diagnosis of breast abscess. Recurrence developed in 11 (5%) patients.^[16] Gurleyik et al. observed that sinus formation was found in 15.8% of cases.^[17] Kok and Telisinghe reported Recurrence developed in 10 (23%) patients.^[19] In 8 patients, abscess recurred in the same location on the breast at a mean time of 14 (range 1–35) months after incision and drainage ($n = 3$) and lumpectomy ($n = 5$); and in 2 patients, fistula developed 10 and 32 months after incision and drainage. Recurrence rates of 16–50% after excision have been reported in the literature.^[8,10,11] In complicated and resistant cases, administration of corticosteroid treatment after excision of the recurrence has been advocated.^[12,20]

This study showed that 7(14.0%) patients had a family history of breast cancer, followed by 3(6.0%) with ovarian cancer,

2(4.0%) with prostate cancer, and 1(2.0%) with colon cancer. Gurleyik et al. reported that none of the patients had a family history of breast cancer.^[17] In the current study, 22(44.0%) patients were found to have a breast abscess. Kok and Telisinghe observed that thirteen (30%) patients presented with a clinical impression of a breast abscess (painful and tender breast lump with inflamed overlying skin). The majority of them also presented with breast abscess.^[19] In this study showed that 12(24.0%) patients had diabetes followed by 7(14.0%) had hypertension, 5(10.0%) had axillary lymphadenopathy, 1(2.0%) had pulmonary tuberculosis and 1(2.0%) had constitutional symptoms. Gurleyik et al. reported that axillary lymphadenopathy was found in 10.5% of cases.^[17] Uysal et al. reported that 4.0% had hypertension, 3.0% had autoimmune disease, 3.0% had other diseases, 2.0% had diabetes, and 0.4% had coronary artery disease.^[18]

Ultrasonography findings revealed that 62.0% of patients had a hypoechoic lobulated mass. Following this, 14% exhibited irregular tubular masses with parenchymal distortion, 12.0% showed mixed echogenicity and skin thickening, 8.0% had abscess collections and fistula tracts, and 4.0% presented with axillary adenopathy. Kok and Telisinghe reported that ultrasonography was performed in 22 patients (51%), revealing a hypoechoic nodular mass in 9 cases and a mass with mixed parenchymal echogenicity, suggestive of mastitis or abscess, in 13 cases.^[19] Gurleyik et al. identified a lobulated, irregular, tubular or oval hypoechoic mass in 13 patients.^[18] Memis et al. noted that common sonographic features include irregular hypoechoic masses and tubular hypoechoic areas

connecting to the main lesion.^[21] Aghajanzadeh et al. found that the most frequent ultrasound finding was a large irregular hypoechoic mass with tubular extensions in 59% of patients.^[16]

The study demonstrated that, among 50 patients, FNAC was performed in 9(18.0%) cases; however, it yielded a diagnostic result in only 3 (33.3%) cases. Core needle biopsy, with or without ultrasound guidance, was conducted in 24 (48.0%) patients, with 22 (91.7%) of these diagnoses confirming GM. Eleven (22.0%) patients underwent surgical biopsy, of whom nine (18.0%) presented with complications involving multiple ulcers in the breasts. Notably, these complications were not observed following FNAC or core needle biopsy procedures. The study by Kok and Telisinghe reported that 23 (53%) patients underwent FNAC on a breast mass.^[19] The findings indicated benign results in 21 patients, the presence of atypical cells in one patient, and blood only in another. Only 4 (91.7%) patients were diagnosed with GM via FNAC. Additional diagnoses included mastitis in 9 patients, abscess in 5, and fibrocystic disease in 3. Furthermore, four patients (9%) underwent core biopsy, with all diagnoses confirming GM. Gurleyik et al. observed that histopathological evaluation was performed through incisional biopsy from the abscess wall during surgical drainage for three patients.^[17] The remaining 16 patients underwent FNAC or core needle biopsy. Aghajanzadeh et al. reported that FNAC was performed in 33 (19.5%) patients, while core needle biopsy with or without ultrasound guidance was performed in 92 (55%) patients, with a success rate of 39% and 94.5%, respectively.^[16]

In this study, the maximum duration of steroid treatment was six months. Two patients received anti-TB drugs for six months, with two (4.4%) showing effective results. Fourteen patients (30.43%) were treated with a combination of methotrexate (5 to 10 mg weekly) and steroids for three to four months, resulting in 10 (71.4%) effective outcomes. Additionally, four patients (8.3%) were treated with steroids and prolactin-lowering medications like bromocriptine (5-10 mg daily), with one patient responding positively. Extensive disease cases not responding to steroids, methotrexate, or bromocriptine underwent wide surgical excision, leading to improvement when combined with steroids and antibiotics. Aghajanzadeh et al. reported that 38 women (18%) had taken antibiotics before diagnosis, but only 6 (3%) improved with antibiotics alone; 97% who did not respond to antibiotics were treated with steroids, with 72% of them improving.^[16] Similar to Hovanessian Larsen et al., antibiotic therapy showed limited benefit, with only 3%

improvement.^[7] Eleven patients (5.5%) with extensive disease improved with wide surgical excision plus steroids and antibiotics, consistent with other studies. Lai et al. indicated that surgical excision combined with steroids is the most common treatment.^[22] Earlier, high-dose steroids were used, but recent findings suggest steroids are more effective in recurrent or refractory cases. Gurleyik et al. performed local excisions after steroid therapy with good cosmetic results. Uysal et al. reported treatment distribution: 37% received antibiotics, 39% steroids, 13% both, 9% other therapies, 2% anti-tuberculosis therapy, and 1% methotrexate.^[17]

This study's limitations include a small, six-month, single-center sample at one hospital using purposive sampling, and limited generalizability. It only assessed initial outcomes without long-term follow-up, so recurrence rates or cures can't be confirmed. Additionally, heavy reliance on FNAC may cause case selection errors, and confounding variables like BMI, diabetes, and medications were not controlled, preventing causal conclusions about treatment effectiveness.

CONCLUSION

The study finds that Granulomatous Mastitis mainly affects women around 34 years old, presenting as a breast lump or abscess. Core needle biopsy is more effective (91.7%) than FNAC (33.3%) for diagnosis. Steroid therapy shows a good initial response (71.7%), but antibiotics are mostly ineffective. The study recommends using core needle biopsy for diagnosis, corticosteroids as first-line treatment for simple cases, and surgery for severe, resistant cases. It indicates the need for long-term studies, multicenter trials, routine testing for tuberculosis, and RCTs to determine best treatments. Increased clinician awareness, multidisciplinary clinics, and national guidelines are essential to prevent misdiagnosis as cancer and ensure consistent care.

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