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Research Article

Clinicopathological Study Of Granulomatous Mastitis. A Case Series Study In A Tertiary Care Teaching Hospital In Kozhikode, Kerala.

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Abstract ***Background*:** Granulomatous lobular mastitis is a rare inflammatory breast disease that can mimic malignancy and tuberculosis. It is characterized by granulomatous inflammation with multinucleated giant cells and epithelioid histiocytes centered on breast lobules. It is characterized by non-necrotizing inflammation and must be differentiated clinically and histologically from simple mastitis and inflammatory carcinoma. No definitive classification or scoring system currently exists.***Methods:*** This prospective observational, histopathological study included 50 cases. Clinical examination parameters such as swelling, fever, weight loss, night sweats, consistency, tenderness, local rise of temperature, erythema, palatable lymph node, history of lactation, pus, necrotic material were recorded. Investigations included USG imaging, USG Bi-RADS and CBNAAT were performed. Fine needle aspiration cytology was performed in patients with breast lumps. Excised tissue, sinus specimens, or abscess slough were sent for histopathological examination. ***Results:*** Most patients were multiparous, aged 17–75 years. Clinically, lesions appeared malignant in 12 cases and benign in 38 cases. Right sided lesions were very common (n=32, 64%). Most patients (78%) had a history of contraceptive pill use. USG Bi-RADS showed 4 score in 70% and 3 score in 30% of cases. Swelling (100%), pain and tenderness (94%), presence of lump (84%) and erythema (38%) was observed among study cases. Histopathology showed idiopathic granuloma (32%) and fat necrosis (20%) were reported in many cases. ***Conclusion:*** Granulomatous lobular mastitis should be diagnosed carefully to avoid confusion with malignancy, tuberculosis, fungal infection, sarcoidosis, mammary duct ectasia, cystic breast changes, and puerperal mastitis. Although rare, accurate diagnosis requires thorough understanding by both surgeons and pathologists.

Keywords: Abscess, Granulomatous, Histopathology, Lobular, Mastitis, Breast

INTRODUCTION

Idiopathic granulomatous mastitis (IGM), also called granulomatous lobular mastitis, is an uncommon benign inflammatory disease of the breast with no clearly known cause. It was initially documented by Milward in 1970, followed by Kessler and Wolloch in 1972. In 1987, Going proposed the name granulomatous lobular mastitis, arguing it was more precise than terms like idiopathic granulomatous mastitis or granulomatous mastitis.(1,2)

Currently, cases can be divided into two categories based on cause: granulomatous lobular mastitis and specific granulomatous mastitis.(3) While the exact pathogenesis remains uncertain, potential contributing factors for granulomatous lobular mastitis include microbial involvement and autoimmune processes, along with alpha-1 antitrypsin deficiency, use of oral contraceptives, pregnancy, lactation, elevated prolactin levels, smoking, diabetes, and local injury or irritants. In contrast, specific granulomatous mastitis is linked to identifiable conditions such as tuberculosis, sarcoidosis, granulomatosis with polyangiitis, syphilis, Corynebacterium infections, foreign body reactions, vasculitis, and fungal or parasitic diseases.(4,5)

Clinically and radiologically, granulomatous mastitis can resemble breast carcinoma and may present with nipple discharge and irregular breast masses. Histopathological, it is characterized by granulomatous inflammation centered around the breast lobules with relative sparing of the interlobular stroma.(6) Definitive diagnosis is established through histopathological examination of a tissue biopsy specimen. Treatment depends on the underlying cause, extent of the lesion, and the presence of complications such as fistula or abscess formation. The idiopathic form of granulomatous mastitis remains a diagnostic and therapeutic challenge for clinicians and surgeons.(7)

IGM can present in different ways and often looks similar to breast cancer. It commonly appears as a lump in one breast and may later cause skin changes, sometimes along with enlarged lymph nodes. Biopsy is essential for confirming granulomatous mastitis, so histopathological examination should always be done.(8,9) The diagnosis of granulomatous mastitis requires ruling out infectious causes such as bacteria, fungi, and parasites.(10) Excluding these infections helps distinguish granulomatous mastitis from other diseases, including breast cancer. Because granulomatous lobular mastitis can resemble both abscesses and malignancy on physical exam and imaging, diagnosis can be challenging.(11,12) Hence, the present study aimed to evaluate the clinicopathological presentation and surgical outcomes of granulomatous mastitis in a tertiary care teaching hospital in northern Kerala.

Methods

The prospective observational study was conducted in the Surgery Department at Malabar Medical College Hospital and Research Centre, Modakkallor, Kerala over three years, from September 2022 to August 2025. A total of 50 patients were included.

Ethical considerations

Informed consent was obtained for all examinations and investigations while ensuring patient privacy and comfort. The Institutional Ethics Committee's approval for Research on Human Subjects was taken. Throughout the study, strict ethical norms were maintained. Written informed consent was taken from patient in local language.

Selection criteria

Inclusion Criteria

- Female patients of reproductive age
- Clinically diagnosed with granulomatous mastitis
- Adequate tissue samples for histopathological examination

Exclusion Criteria

- History of breast cancer or other breast diseases
- Insufficient or poor-quality tissue samples

Clinical examination

Patients were recruited from the outpatient and emergency units of the General Surgery Department. Detailed history-taking and focused clinical examinations were performed such as swelling, fever, weight loss, night sweats, consistency, tenderness, local rise of temperature, erythema, palatable lymph node, history of lactation, pus, necrotic material. Investigations included USG imaging, USG Bi-RADS(13) and CBNAAT(14) were performed.

Data collection

Fine needle aspiration cytology was performed in patients with breast lumps. Depending on the case, patients underwent lump excision, abscess drainage, or sinus excision in emergency or routine operation theatres. Excised tissue, sinus specimens, or abscess slough were sent for histopathological examination, while pus samples were sent for culture and sensitivity testing. All tissue sections were stained with Hematoxylin and Eosin (H&E), Ziehl-Neelsen, and PAS stains This histopathological study evaluated the features of granulomatous mastitis in 50 female patients presenting with symptoms such as painful breast lumps, abscesses, or sinus formation. Breast tissue samples were collected for analysis.

Histopathological Examination

Breast tissue samples were fixed in 10% formalin, embedded in paraffin, sectioned at 4–5 microns, and stained with Hematoxylin and Eosin (H&E) for routine histopathological examination. Special stains, including Ziehl-Neelsen, PAS, and Gram stain, were used to detect infectious agents. .(15,16) Two independent pathologists examined the stained sections under a light microscope. Histopathological features such as granulomas, giant cells, caseous necrosis, and other abnormalities were recorded, with special focus on identifying bacteria, fungi, and parasites.

Data analysis

Patient demographics, clinical presentation, histopathological findings, and infectious agents were systematically documented. Statistical analysis was performed to determine the prevalence of different histopathological features and to correlate these findings with clinical data. All the descriptive statistics were showed as frequencies, percentages and range.

RESULTS

Baseline demographic and clinical data of patients was showed in Table 1. A total of 50 patients were included in the study. The mean age of the participants was 38.06 ± 15.03 years, with an age range of 17–75 years. The mean lesion size was 5.4 ± 1.8 cm, ranging from 3 to 8 cm. Most lesions were located in the right breast (64%), followed by the left breast (28%), while bilateral involvement was observed in 8% of cases. The mean parity of the study population was 2.0 ± 1.0, with a range of 1–4.

Clinically, 76% of patients were diagnosed with benign lesions, whereas 24% were considered malignant. The most common initial diagnosis was mastitis, accounting for 88% of cases, followed by abscess (8%) and carcinoma (4%). Breastfeeding history was present in 30% of patients, while 70% were not breastfeeding at presentation.

Regarding contraceptive pill usage, 52% were former users, 26% were current users, and 22% had never used oral contraceptive pills. A breast mass was identified in all patients (100%), while necrotic material and nipple induration were observed in 48% and 16% of patients, respectively. On clinical examination, the consistency of lesions was predominantly firm (52%) or hard (46%), with only 2% presenting as soft lesions. Ultrasonography (USG) findings revealed hypoechoic lesions in 72% of cases and mixed echogenicity in 56%. Well-circumscribed margins were noted in 48% of lesions, whereas 60% were ill-circumscribed. Based on the USG BI-RADS classification, 70% of lesions were categorized as BI-RADS 4 and 30% as BI-RADS 3. CBNAAT cytology positivity was identified in 8% of patients, while 92% showed negative results.

Table 1: Baseline demographic and clinical data of patients

Category	Value (N=50)
Age in years	
Mean±SD	38.06±15.03
Range	17-75
Size of lesion, cm	
Mean±SD	5.4±1.8
Range	3-8
Lesion site	
Right	32 (64)
Left	14 (28)
Bilateral	4 (8)
Parity	
Mean±SD	2.0±1.0
Range	1-4
Clinical diagnosis, n (%)	
Benign	38 (76)
Malignant	12 (24)
Initial diagnosis, n (%)	
Mastitis	44 (88)
Abscess	4 (8)
Carcinoma	2 (4)
Breast feeding, n (%)	
Yes	15 (30)
No	35 (70)
Contraceptive pills use, n (%)	
Former user	26 (52)
Current user	13 (26)
Never	11 (22)
Clinical features, n (%)	
Mass	50 (100)
Necrotic material	24 (48)
Nipple induration	8 (16)

Consistency of the lesion, n (%)	
Hard	23 (46)
Firm	26 (52)
Soft	1 (2)
USG findings, n (%)	
Hypoechoic	36 (72)
Mixed exhogenicity	28 (56)
Well circumscribed	24 (48)
Ill circumscribed	30 (60)
USG Bi-RADS, n (%)	
4	35 (70)
3	15 (30)
CBNAAT cytology, n (%)	
Yes	4 (8)
No	46 (92)

USG: Ultrasonography; Bi-RADS: Breast Imaging Reporting and Data System;
CBNAAT: Cartridge Based Nucleic Acid Amplification Test

Clinical signs and symptoms of study cases was showed in Table 2. Swelling was the most common presenting symptom and was observed in all patients (100%). Pain and tenderness were reported in 94% of cases, while a palpable lump was present in 84% of patients. Erythema was noted in 58% of cases, and fever was observed in 46%. Palpable lymph nodes were identified in 38% of patients, whereas sinus formation was present in 28%. Suppuration occurred in 20% of cases. Constitutional symptoms such as weight loss and night sweats were reported in 16% and 14% of patients, respectively. A local rise in temperature was observed in 14% of cases, while pus discharge was present in 12% of patients.

Table 2: Clinical signs and symptoms of study cases

Signs and symptoms	**Frequency (%) (N=50)**
Swelling	50 (100)
Pain and tenderness	47 (94)
Lump	42 (84)
Erythema	29 (58)
Fever	23 (46)
Palatable lymph node	19 (38)
Sinus	14 (28)
Suppuration	10 (20)
Weight loss	8 (16)
Night sweats	7 (14)
Local rise of temperature	7 (14)
Pus	6 (12)

Histopathological evaluation and diagnosis among cases was showed in Table 3. Histopathological examination demonstrated interlobular inflammation in 24% of cases, making it the most common finding. Fat necrosis and neutrophilic cyst formation were each observed in 16% of patients. Eosinophilic infiltration and microabscess formation were identified in 10% of cases each. Caseous necrosis, ductal ectasia, and lactational changes were each reported in 8% of patients. These findings reflected a spectrum of inflammatory and degenerative changes within the breast lesions.

Histopathological diagnosis revealed idiopathic granuloma as the most common diagnosis, accounting for 32% of cases. Fat necrosis and ductal papilloma were each identified in 20% of patients. Eosinophilic granuloma was observed in 14% of cases. Tubercular granulomatous mastitis constituted 8% of the diagnoses, while sarcoid granulomatous mastitis and

fungal granulomatous mastitis were less common, accounting for 4% and 2% of cases, respectively. These findings indicate that idiopathic and inflammatory etiologies predominated among the histopathological diagnoses.

Table 3: Histopathological evaluation and diagnosis among cases

Histopathological evaluation	Frequency (%)	Histopathological diagnosis	Frequency (%)
Interlobular inflammation	12 (24)	Idiopathic granuloma	16 (32)
Fat necrosis	8 (16)	Fat necrosis	10 (20)
Neutrophilic cysts	8 (16)	Ductal papilloma	10 (20)
Eosinophilic infiltration	5 (10)	Eosinophilic granuloma	7 (14)
Microabscess formation	5 (10)	Tubercular	4 (8)
Caseous necrosis	4 (8)	Sarcoid granulomatous mastitis	2 (4)
Ductal ectasia	4 (8)	Fungal granulomatous mastitis	1 (2)
Lactational changes	4 (8)		

Image showing breast abscess with accumulation of Pus (Figure 1), microscopic image (Figure 2) appears to show multiple slender pink/red rod-shaped organisms against a blue background, which is suggestive of acid-fast bacilli (AFB) on a Ziehl–Neelsen stain. The histopathological image of breast tissue showing the idiopathic granulomatous mastitis (Figure 3), lobulocentric granulomatous mastitis (Figure 4), ductal papilloma with granulomatous mastitis (Figure 5), eosinophilic granulomatous mastitis (Figure 6) and fatty spaces with multiple fat necrosis (Figure 7)

Figure 1: Image showing breast abscess with accumulation of Pus

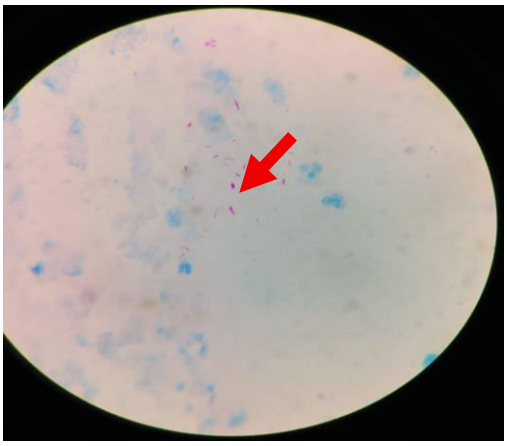

Figure 2: Microscopic image showing positive for acid-fast bacilli on a Ziehl–Neelsen stain

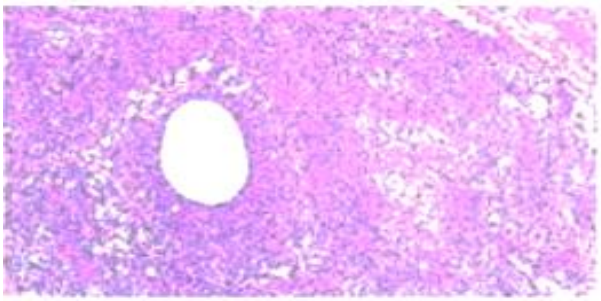

Figure 3: Histopathological section of breast tissue showing idiopathic granulomatous mastitis (H&E stain, ×100)

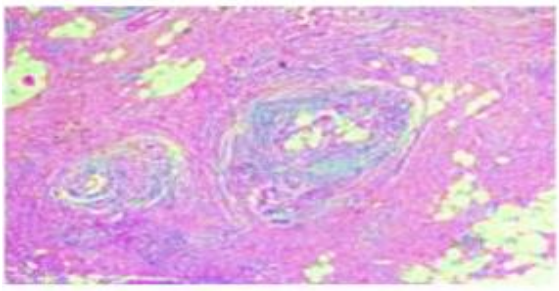

Figure 4: Histopathological section of breast tissue showing lobulocentric granulomatous mastitis (H&E stain, ×100)

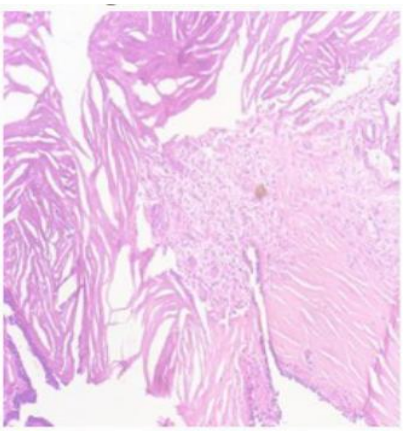

Figure 5: Histopathological section of breast tissue showing ductal papilloma with granulomatous mastitis (H&E stain, ×100)

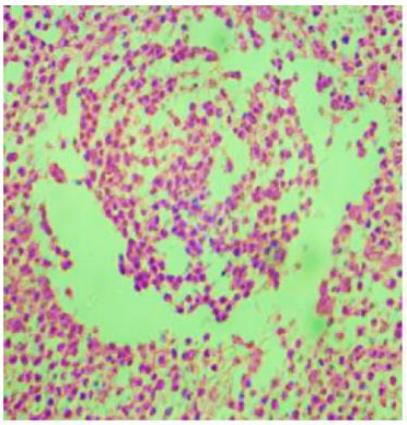

Figure 6: Histopathological section of breast tissue showing eosinophilic granulomatous mastitis (H&E stain, ×400)

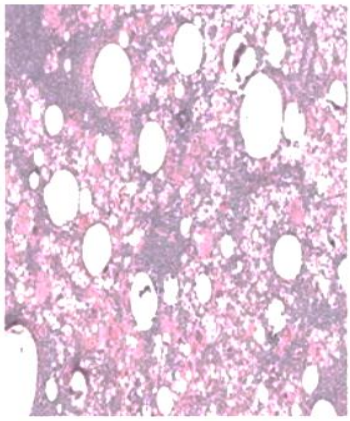

Figure 7: Histopathological section of breast tissue showing fatty spaces with multiple fat necrosis (H&E stain, ×100)

DISCUSSION

Granulomatous mastitis has an uncertain cause in many patients and often creates difficulty in diagnosis. Several conditions such as mycobacterial, fungal, and parasitic infections, sarcoidosis, IgG4-related disease, autoimmune disorders, squamous metaplasia of lactiferous ducts, foreign body reaction, and fat necrosis can involve the breast and produce granulomatous inflammation, making differential diagnosis important.(17)

Fine needle aspiration biopsy (FNAB) may be less sensitive when granulomas are located deep within the breast tissue, whereas core needle biopsy is more reliable for confirming the diagnosis and excluding malignancy. Incisional and excisional biopsies are also useful for locating granulomas and assessing tissue architecture. Fat necrosis is identified by the presence of lipid-filled foamy histiocytes along with clinical findings. In extensive foreign body giant cell reactions, the usual histological features may not always be clearly visible.(18)

Cystic neutrophilic granulomatous mastitis (CNGM) typically shows lobulocentric mixed inflammatory infiltrates containing lymphocytes, neutrophils, multinucleated giant cells, and lipid vacuoles surrounded by neutrophils and epithelioid histiocytes. Since these findings are not unique to CNGM, further investigations for fungal, mycobacterial, and bacterial infections are necessary. Tuberculous mastitis mainly affects the ducts rather than lobules and may present with necrotizing or non-necrotizing granulomas. Diagnostic confirmation can be achieved using EZN staining, culture studies, or PCR.(19,20)

Eosinophilic mastitis is a rare inflammatory breast disorder characterized by marked eosinophilic infiltration around ducts and lobules, often associated with hypereosinophilic syndromes. Although sarcoidosis during pregnancy is uncommon, breast involvement may occur. Patients with idiopathic granulomatous mastitis usually present with a breast lump that can initially resemble breast carcinoma, making imaging studies important for evaluation. The inflammatory process in IGM begins around the lobules and later extends into the ductal lumens and interstitial tissue.(21)

Management of granulomatous mastitis may include complete surgical excision or open biopsy combined with corticosteroid therapy. Immunosuppressive drugs such as methotrexate, azathioprine, leflunomide, cyclophosphamide, and thalidomide may also be used. Anti-inflammatory antimicrobial agents, including antimalarials and tetracycline derivatives, can serve as additional treatment options.(22,23)

Granulomatous lobular mastitis primarily affects women in their reproductive years and frequently correlates with pregnancy and breastfeeding. Al-Khaffaf et al. reported that in their cohort of 18 patients with this condition, the average age was 36 years.(24) Granulomatous lobular mastitis commonly manifests as tender lumps affecting one breast. Patients may also develop additional features including nipple discharge, nipple skin changes or rash, swelling, nipple retraction, peau d'orange appearance, and enlarged lymph nodes. These lesions are not restricted to a specific area and can occur in any quadrant of the breast, with bilateral involvement possible.

On gross examination, the lesion is readily differentiated from surrounding healthy breast tissue. It generally appears grey-white and exhibits a somewhat irregular, nodular margin. Microscopically, granulomatous lobular mastitis is defined by lobule-centered granulomas composed of lymphocytes, plasma cells, epithelioid histiocytes, and multinucleated giant cells. Neutrophils are frequently identified within these granulomas. While necrosis can be present, it is typically non-caseating.(7,21)

There is still no consensus on the optimal management of granulomatous lobular mastitis. Initial therapy typically includes corticosteroids. For patients who fail to respond to steroid treatment or experience relapse, immunosuppressive drugs like methotrexate or azathioprine can be considered. Surgical excision remains a possibility in refractory cases, but it is not advised as first-line management due to risks of long-term complications such as fistula development, poor aesthetic results, and a higher likelihood of recurrence.(22)

CONCLUSION

Granulomatous mastitis is distressing for both patients and physicians. Currently, there is no clear consensus on its aetiology, classification, or severity. The absence of a standardized classification system makes it difficult to assess recurrence risk and choose appropriate treatment. This study may support future efforts to develop a definitive classification and scoring system for granulomatous mastitis, improving treatment planning and outcomes. Such a system could help identify low-risk patients suitable for medical management and high-risk patients who may benefit from early surgical intervention. The diagnosis of granulomatous lobular mastitis must be made carefully to avoid confusion with conditions such as malignancy, tuberculosis, fungal infection, sarcoidosis, mammary duct ectasia, cystic breast changes with over-palpation, and puerperal mastitis. Although rare, accurate identification requires thorough understanding by both pathologists and surgeons.

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