

Varied Clinical Presentation of Granulomatous Mastitis- A Retrospective Cohort Study

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ABSTRACT

Introduction: Granulomatous Mastitis (GM) is a infrequent chronic inflammatory breast disease with unidentified aetiology. It has varied clinical presentations from a completely benign breast abscess to a presentation mimicking locally advanced malignant tumour. As there is no definitive radiological feature which clinches the diagnosis of GM and even the lack of specific cytological features, every case is diagnosed and managed differently.

Aim: To present the varied clinical presentations of granulomatous mastitis.

Materials and Methods: A retrospective cohort study was conducted at JSS Teaching Hospital, Mysore, India. Histopathological database in Pathology Department was reviewed from January 2017 to December 2020 and all the cases diagnosed with GM were enlisted. Their case files, data in the hospital information system were reviewed and the patients were telephonically interviewed. The data was analysed for incidence rates of various clinical presentations, surgeries and expressed in percentages.

Results: On reviewing the histopathological database, there were 22 cases of GM. All the patients were married females of age 22-57 years with duration of symptoms ranging from four days to five years. Most common complaint was breast lump 22 (100%) followed by pain 12 (54.54%). Based on the symptoms and signs, clinically seven different diagnoses were made and granulomatous mastitis was suspected only in 6 (27.27%) cases. All the patients were primarily subjected for surgical treatment [lumpectomy 12 (57.14%), incision and drainage with wall biopsy 6 (28.57) and wide local excision 3 (14.28)]. Telephonic interview could be done for 12 (54.54) patients, of which, 9 (75) patients had remained asymptomatic and 3 (25) patients had multiple recurrences. Eventually, 2 (9.09) patients were treated with antitubercular treatment and became recurrence free. None of the patients were given steroids as primary treatment or during the episodes of recurrence.

Conclusion: While managing breast lump cases, either painful or painless, the surgeons should keep the possibility of granulomatous mastitis, as it varies widely in clinical manifestation.

Keywords: Inflammatory breast diseases, Mimicking carcinoma breast, Recurrent breast disease, Tubercular mastitis

INTRODUCTION

Granulomatous Mastitis (GM) is a rare chronic inflammatory breast condition that was first described in 1972 [1]. Since, then the identification and reporting of GM has been increasing. However, the exact aetiology which triggers the onset of GM is not known. Certain risk factors such as autoimmune process, infection, childbirth, lactation, hyperprolactinaemia and antipsychiatry medications have been implicated in the aetiology and acceleration of the of idiopathic GM disease [2,3]. The condition is commonly seen among multiparous, premenopausal women with history of lactation in the previous five years and uncommonly reported among nulliparous women, postmenopausal women and very rarely among men [3]. As the disease is chronic and rare, conducting studies with large numbers is difficult. Hence, majority of the published studies are of retrospective case series type. The main pathology finding is lobulocentric inflammation with non caseating granulomas and inflammatory cell infiltrates [4,5].

The commonest presentation is breast lump with or without pain and the consistency varying from soft to hard texture. The other clinical features are breast pain, nipple retraction, various inflammatory signs, skin ulceration, sinus formation, pus discharge and less commonly axillary lymphadenopathy [1,3,5]. Hence, in most of the cases, the clinical diagnosis will be made as acute mastitis, breast abscess, lump for evaluation, chronic mastitis and sometimes even as carcinomas because of the inflammatory induration giving rise to a hard feel on palpation [1,6,7]. Imaging features are often variable and most of the times reported as mastitis or as malignancy [2,8]. Fine Needle Aspiration Cytology (FNAC) may be helpful for faster diagnosis; however, it is not as specific as core needle

biopsy. Hence, Core Needle Biopsy (CNB) is reported as the gold standard preoperative diagnostic modality in literature [8]. However, if the clinical presentation is similar to an acute abscess or mastitis where surgery or conservative treatment may be planned based on the clinical and imaging findings, patient may not be subjected to preoperative cytopathological evaluation. Therefore, it may not be possible to diagnose GM in mastitis abscess like presentation preoperatively. Hence, studies have been conducted retrospectively recruiting the cases, based on final histopathological diagnosis [6]. In the same group of patients, thinking it could be simple breast abscess, biopsy for routine histologic examination may not be sent and hence, it may be missed postoperatively as well, leading to repeated recurrences later on.

Since, GM is known for recurrence, early diagnosis helps the surgeon to select the appropriate treatment modality, counsel adequately about recurrence to keep the patients on regular follow-up. In certain patients when pathology findings are obvious, tubercular mastitis may be diagnosed and treated with anti tubercular treatment postoperatively. Here the authors are reporting a study on GM that was conducted with an aim to describe the varied clinical presentations, treatment aspects and the follow-up status.

MATERIALS AND METHODS

It was a retrospective cohort study conducted at a JSS Teaching Hospital, Mysore, India. The data was collected and analysed from November to December 2021 after obtaining Institutional Ethical Committee clearance (no. JSSMC/IEC/17112021/52 NCT/2021-22). The histopathological database was reviewed for four years from January 2017 to December 2020.

Inclusion criteria: All the cases diagnosed with granulomatous mastitis on final histopathologic examination of excised specimens from operated cases admitted in General Surgery Department.

Exclusion criteria: Cases diagnosed with specific cause of granulomatous mastitis like tubercular mastitis on final histopathology.

Using the above criteria, list of GM cases with inpatient numbers was prepared. Respective case files and data in the hospital information system were reviewed. Clinical details of age, sex, presenting symptoms, clinical signs and provisional diagnosis; surgical details of type of surgery and intra operative findings; FNAC data; imaging data on ultrasound breast were collected. Telephonic interview was attempted for all the cases, to obtain information on the current status and regarding the recurrence rate.

STATISTICAL ANALYSIS

The data was stored in Microsoft excel. Descriptive analysis of the data was done; continuous variables were expressed in mean, Standard Deviation (SD) and range in which the categorical data was expressed in the form of percentages then presented in the form of tables and charts.

RESULTS

On reviewing the data, 20 cases were found, operated for different preoperative diagnosis with 22 histopathological diagnoses of GM (one had bilateral disease, another had recurrent disease). Age of the patients varied from 22-57 years with mean age of 37 years (SD=11.1) [Table/Fig-1]. All the patients were married females, 19 were multiparous, 1 was nulliparous and none of them were pregnant or lactating at the time of presentation. The risk factors found were multiparity (n=19), premenopausal status (n=16) and history of lactation in the previous five years (n=10). Uncommon risk factors observed among patients include nulliparity (n=1), postmenopausal status (n=4) and treatment with anti depressants (n=1). None of them were smokers. Duration of symptoms varied from as short as four days to as long as five years (Mean duration=4.82 months; median=1.5 month). Equal number of patients had single or multi quadrant involvements without predominance to any one side (left=9, right=10, bilateral=1, recurrent=1 on left side, single quadrant=11, multiple quadrants=11). The main clinical features were lump and pain in the breast. Clinically, lump was significantly tender in 12 patients with varying consistencies (soft, firm and hard). Skin changes included erythema, oedema, engorged veins, peau d'orange appearance, tethering and brawny induration. Multiple sinuses with pus discharge were present in four patients and nipple retraction was noted in four patients. Axillary lymphadenopathy was present only in two patients [Table/Fig-2].

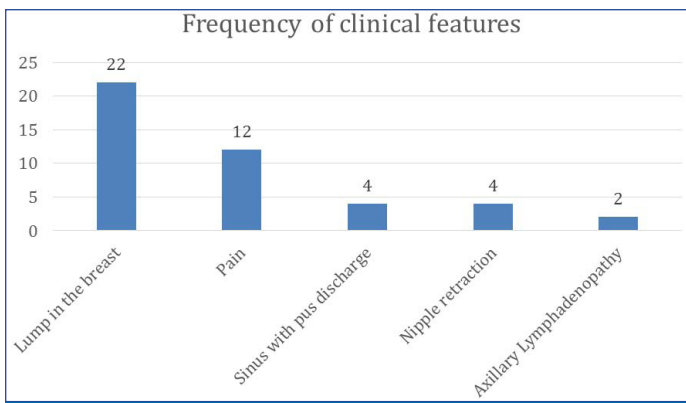
Clinically, seven different clinical diagnoses were made, such as GM, carcinoma, breast abscess, antibioma, fibroadenoma, traumatic fat necrosis and lump for evaluation; only six cases were suspected to have GM [Table/Fig-3]. Ultrasonography of the breast was done in 11 patients and the features described were those of abscess (n=7), mastitis (n=3) and antibioma (n=1) and none was suspected to have GM [Table/Fig-4a and 4b]. The FNAC was done in eight patients, out of which four were reported as GM, two as acute suppurative mastitis, one as fibrocystic disease of the breast and one as tubercular mastitis. Core needle biopsy was done only for two cases; in one case where there was suspicion of malignancy and in another case where, she developed rhythm disturbances on table before induction and surgery was abandoned. For 20 patients, surgery was performed as primary treatment and the most common surgery done was lumpectomy followed by incision and drainage with wall biopsy and wide local excision [Table/Fig-5]. Common intraoperative findings included abscess cavities, fibrotic changes and firm to hard lumps [Table/Fig-6]. Only one patient who developed rhythm disturbances on table, surgery was abandoned and core

Case no.	Age (yrs)/ Sex	Clinical symptoms and signs	Provisional diagnosis at admission
1	50/F	Lump in the left breast x1 year, pain x1 month. 8x4cm tender lump with nipple retraction, multiple sinuses, peau d'orange appearance with axillary LNs +.	Carcinoma breast with chronic mastitis
2*	50/F	Recurrent lump in the left breast x2 months; Fever +, Multiple sinus openings with pus discharge +, Nipple retraction +	Recurrent GM
3	22/F	Painful lump in left breast for two months Multiple sinuses with Pus discharge +, nipple retraction +, induration +	GM
4	26/F	Lump in the right breast x1 months, fever + Diffuse engorgement of the breast with brawny induration	GM
5	47/F	Lump in right breast with mild pain x2 months. Purulent discharge + 4x5 cm tender, soft, lump	GM
6	30/F	Lump in the left breast x6 months; 5x6 cm oval shaped lump	Antibioma breast
7	57/F	Lump in the left breast x1 month; 6x4 cm lump, regular borders, slightly warm and tender	Breast lump for evaluation
8	29/F	Lump in the right breast x1 month; 5x3 cm mobile, firm, non tender lump	Fibroadenoma
9	40/F	Rt breast lump x1 month, h/o trauma three months ago; hard 10x5 cm lump, fixed to breast tissue; skin tethering+	Traumatic fat necrosis
10	37/F	Painful left breast lump x2 weeks; fever +, painful erythematous lesions over both lower limbs x2 weeks; discrete 5x5 cms lump	GM Erythema nodosum
11	39/F	Left breast lump x4 days, fever +; tender lump with local rise in temperature +	Breast abscess
12	35/F	Painful Lump in right breast x2 weeks 5x5 cm firm, non tender, lump	Lump in the breast for evaluation
13	25/F	Pain in the right breast-1 month, Lump in right breast x2 weeks; 5x4 cm hard lump	Breast lump for evaluation
14	42/F	Painful left breast lump x5 days; 4x4 cm tender lump with erythema over the skin	Breast abscess
15	27/F	Painful rt breast lump x 2 months, Fever+; tender lump, mobile with regular borders	Right breast lump for evaluation
16	56/F	Pain in the left breast x3 months, lump in the breast x1 month, blisters ruptured discharging pus with ulceration; 2x3 cm hard lump with multiple sinus openings with pus discharge, erythema +, nipple retraction +; another swelling of 1x2 cms	Carcinoma breast with mastitis
17	27/F	Lump in the right breast x5 days; 3x3 cm mobile, slightly tender cystic lump	Breast lump for evaluation
18 (case no. 17, left breast)	27/F	Painful left breast lump x15 days, pus discharge from nipple, fever +; 4x4 cm tender, warm lump, fluctuant, erythema +, purulent nipple discharge +	Breast abscess
19	32/F	Painful lump in the right breast x5 months; 3x2 cm solitary tender lump +	GM
20	28/F	Right breast lump x5 years, pus discharge from nipple x2 months; 5x6 cm lump with nodular surface, with variable consistency, Axillary LN +	Antibioma Chronic breast abscess
21	35/F	Left breast lump x3 months; 8x7 cm, firm to hard, non tender, discrete lump +	Carcinoma, GM
22	56/F	Rt breast Lump x8 days, pain x5 days; 5x5 cm tender lump +	Breast abscess

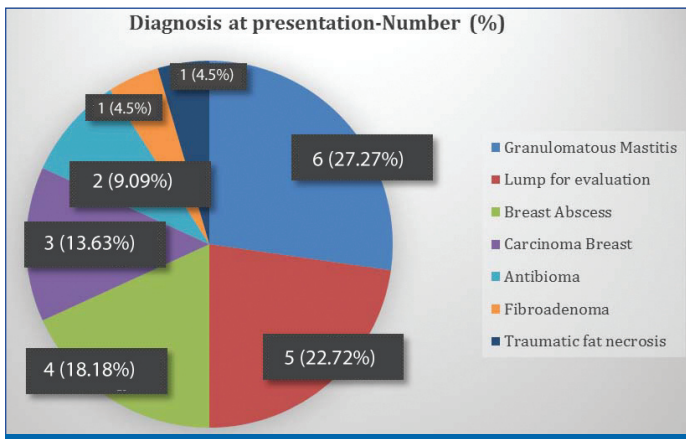
[Table/Fig-1]: Varied clinical manifestations and diagnosis at admission.

*case no. 2 is same as case no.1 (who had come with recurrence); GM: Granulomatous mastitis.

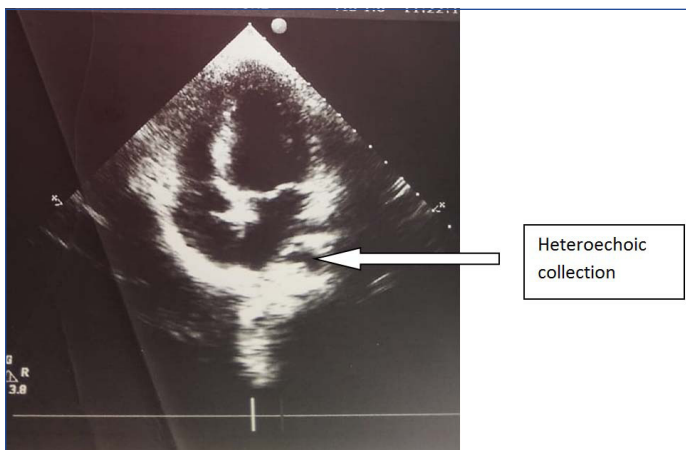
needle biopsy was done. Then she was treated with antibiotics and other supportive treatment with satisfactory recovery. Pus for culture was sent for 15 patients, who had frank pus intraoperatively. Out of which, four had grown different strains of *Staphylococci*, and



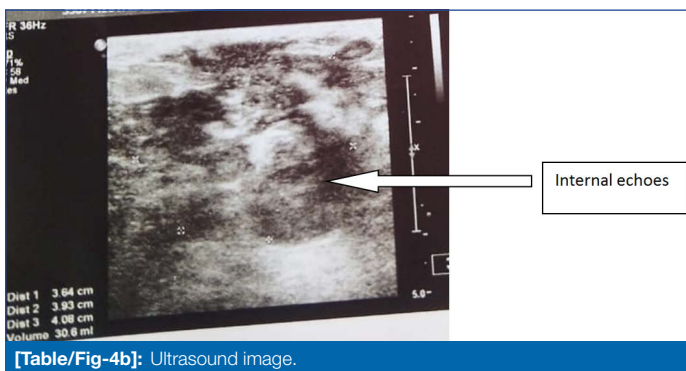
[Table/Fig-2]: Summary of important clinical features of GM.



[Table/Fig-3]: Different diagnosis at presentation.



[Table/Fig-4a]: Ultrasound images.



[Table/Fig-4b]: Ultrasound image.

the rest were sterile. Telephonic call was attempted for collecting the follow-up data. Out of 20 patients (one had recurrence, the other one had bilateral disease, hence 22-2=20 patients), 12 (60%) patients could be interviewed. Out of those, 9 (75%) patients had remained asymptomatic without any recurrence, including the one who had not undergone surgery. However, three patients had multiple recurrences and had undergone minor surgeries and were

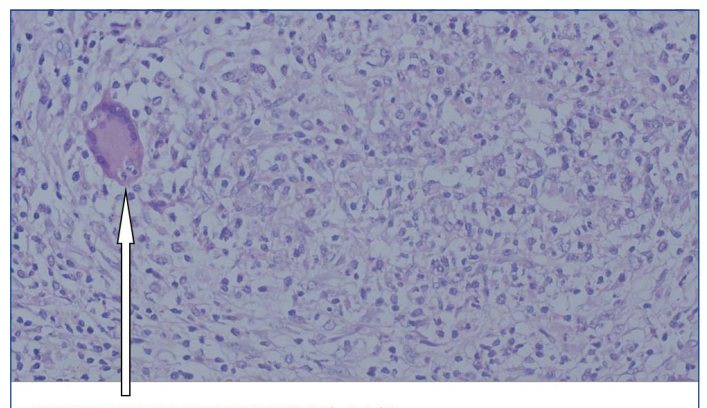
S. no.	Treatment	Total No. (%)
1	Lumpectomy	12/21 (57.14)
2	Incision and drainage with wall biopsy	6/21 (28.57)
3	Wide Local Excision (WLE)	3/21 (14.28)
4	Conservative treatment with antibiotics	1

[Table/Fig-5]: Treatment modalities.

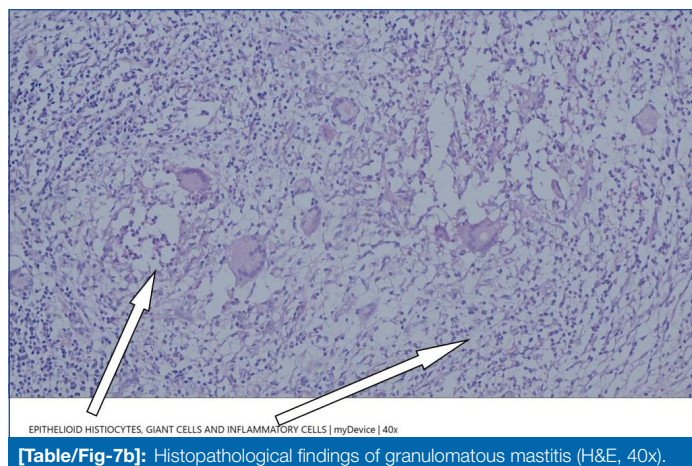
Case no.	Intraoperative findings
1	Two separate abscess cavities present with 5 mL of pus
2	Lump, gritty hard in consistency with extension till retromammary space with sinus tracts.
3	20 mL of pus from a single cavity was drained
4	Abscess cavity noted in the deeper planes with 20-30 mL of thick pus, whole breast was fibrosed, thickened, diffuse fibrocystic changes +.
5	Cystic lesion identified, cystic fluid suctioned and cyst excised.
6	Hard fibrosed lump with thick yellowish pus of 20-30 mL at 9-10 O'clock position.
7	Lump of size 7x8 cm present with greenish pultaceous material seen oozing out from tumor.
8	Abscess noted, about 10 mL of pus drained
9	Multiloculated abscess with necrosed fat.
10	Firm lump of size 5x4 cm
11	25 mL of pus collection mixed with blood with fibrotic changes in the surrounding tissue.
12	Lump of 3x4 cm- multiple cysts filled with thick purulent aspirate.
13	Lump with necrotic material found.
14	Abscess cavity with 70 mL of pus.
15	20 mL of pus drained, fibrous tissue noted.
16*	Surgery was not done as she did not withstand the induction.
17	Left breast: 40 mL of pus with necrotic tissue.
18 (case no 17)	Right breast: lump along the with breast tissue excised, pus drained from lobules
19	3x2 cm firm lump
20	5x6 cm firm to hard lump with pus
21	4x4 cm, firm to hard lump with fibrotic changes.
22	150-200 mL pus in a single large cavity.

[Table/Fig-6]: Intraoperative findings.

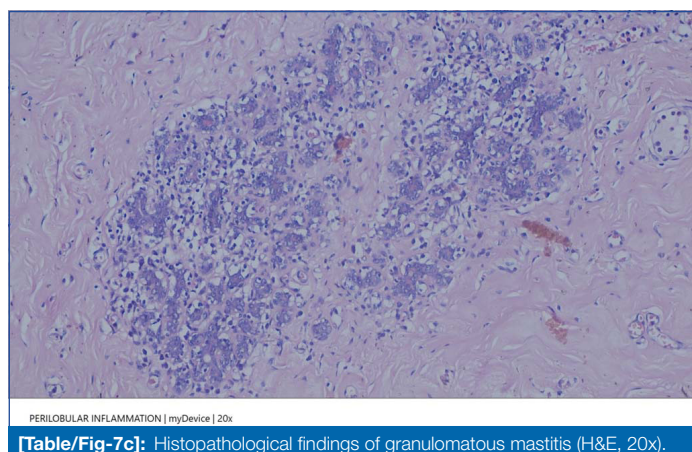
treated with multiple courses of antibiotics lasting for one year. Eventually, two patients were started on anti tubercular treatment based on clinical suspicion. After which, they had no recurrences. However, all the patients were symptom free and the asymptomatic period lasted for 1½ to 2½ years. The Haematoxylin and Eosin (H&E) stains used for histopathological findings described were 'non caseating granulomas composed of Langhan's giant cells, multinucleated giant cells, epithelioid histiocytes, lymphocytes and plasma cells along with perlobular lymphoplasmacytic infiltration' [Table/Fig-7a-c].



[Table/Fig-7a]: Histopathological findings of granulomatous mastitis (H&E, 20x).



[Table/Fig-7b]: Histopathological findings of granulomatous mastitis (H&E, 40x).



[Table/Fig-7c]: Histopathological findings of granulomatous mastitis (H&E, 20x).

DISCUSSION

Granulomatous mastitis was first described in 1972 by Kessler E and Wolloch Y in Israel. It was reported as a case series of five patients where all were women in child bearing age with 1 ½ to five years after their last lactation, who had presented with a hard lump in the breast, simulating carcinoma clinically. Surgical excisions were done and the final histopathological examination had revealed non caseating granulomas, giant cells and epithelioid cells, with inflammatory infiltrates of numerous neutrophils, few eosinophils and lymphocytes. Few cases had showed central areas filled with neutrophils with abscesses formation. Two patients had even received radiotherapy prior to surgery [1]. After this there has been steady increase in the publication of GM. Various diseases are known to cause granulomatous lesions in the breast and when all are excluded, the term idiopathic GM is used to describe the condition [9]. Tubercular mastitis, a rare cause, should be excluded, particularly in endemic areas like India [10]. In the present case study, two of the patients, who continued to have recurrences following surgery, were treated with Anti Tubercular Treatment (ATT) for six months following which they remained recurrence free. One of them had manifestations of erythema nodosum, that also subsided completely.

Aetiology and risk factors: The exact pathophysiology of GM is yet to be found. However, an autoimmune reaction to the extravasated milk from the lobules is strongly believed and discussed as the cause of GM in most of the literatures. It is supported by lobulocentric inflammatory infiltration and response to steroid therapy. The other risk factors that have been implicated in the pathogenesis of GM are occurrence in premenopausal women, infection with *Corynebacterium kroppenstedtii*, hyperprolactinaemia with galactorrhoea, treatment with antidepressants and lactation in the previous five years [1-3]. However, these risk factors may not be present in all the cases [3]. In the present study, risk factors found were multiparity (n=19), premenopausal status (n=16) and history of

lactation in the previous five years (n=10). Uncommon risk factors observed among present case, patients include nulliparity (n=1), postmenopausal status (n=4) and treatment with antidepressants (n=1).

Clinical presentation: The most important factor deciding the outcome is early diagnosis and the institution of appropriate treatment. However, the variable clinical presentation in GM can lead to delayed diagnosis and treatment. GM commonly presents as unilateral breast mass with or without pain. In the present study, 21/22 patients had unilateral discrete swelling in the breast with size ranging from 1×2 cm to 10×5 cm [Table/Fig-1]. Pain was the second most common symptom in GM. In the present study, 12 patients had significant pain in the breast and remaining patients had mild or no pain. Along with painful breast mass, inflammatory skin signs mimicking abscess and mastitis are frequently described in GM [7]. In the present study, skin signs were seen in eight patients. Ulceration and sinus formation with pus discharge are common features of tuberculosis breast [11]. Those changes were present in six patients in the present study. However, only two patients were diagnosed with tuberculosis of the breast eventually during follow-up. Painful mass with acute brawny induration was typically seen among cases of acute lactation mastitis and inflammatory breast carcinoma. It was seen in one patient who had history of lactation in the previous five years. Painless mass with induration is a typical feature of carcinoma, especially in the absence of other inflammatory signs. There were three patients who had similar features which led to high clinical suspicion of malignancy and created anxiety among the patients during counselling. Another classical sign of breast malignancy is presence of non tender axillary lymphadenopathy, in the presence of painless hard lump in the breast. In current study, axillary lymphadenopathy was present in 2/22 patients. In the literature, axillary lymphadenopathy has been reported in 15-50% of cases of GM [2,12]. Hence, varying symptoms and signs at presentation lead to clinically seven different diagnoses [Table/Fig-1,3]. Though, in the early literatures, breast lump in GM cases was described as painless hard masses mimicking carcinomas, in the recent years, its presentation has been more frequently like painful breast mass with mastitis/abscess picture [1,6,7].

Imaging: The imaging features in GM are typically non specific and frequently reported as mastitis, breast abscess or as breast carcinoma, in Ultrasonography (USG), Mammography (MMG), Computed Tomography (CT) scan and Magnetic Resonance Imaging (MRI). However, efforts are being made to characterise the cardinal features of GM on different imaging studies. Hovannesian Larsel LJ et al., described findings frequently found in GM as an irregular hypoechoic mass associated with multiple tubular hypoechoic structures with finger like extensions in USG and focal or global asymmetry in mammography. They have also recommended the utility of these imaging studies to assess the treatment response and for follow up surveillance of GM cases [8,13]. In current study 11 patients underwent USG and were reported as abscess in seven cases, mastitis in three cases and benign breast lump in one case. However, none were evaluated with MMG, CT or MRI.

Cytopathology: FNAC is a first line invasive investigation for the evaluation of all breast lumps after imaging. Cytological features of granulomatous mastitis are non specific. GM is suspected when there are epithelioid cells granulomas, multinucleated giant cells and numerous neutrophils. Though, making the diagnosis of GM is difficult in FNAC, it helps to exclude certain benign and malignant diseases of the breast. Some authors claim that in the presence of granulomas, finding of predominantly neutrophilic infiltrates or finding of high numbers of single epithelioid histiocytes in the absence of granulomas can be considered for making the diagnosis

of GM [13-15]. Ail DA et al., concluded that FNAC along with special stain must be advocated as the primary tool of diagnosis in cases of GM [16]. In current study eight patients underwent FNAC and GM was diagnosed in four of them with classical findings.

Role of Core Needle Biopsy (CNB): For definitive diagnosis, histological examination is the gold standard [17]. As CNB provides sufficient material, it is possible for the pathologists to diagnose and confirm GM with considerable accuracy. The typical histopathological findings seen in GM were granulomas composed of Langhans giant cells, multinucleated giant cells, epithelioid histiocytes, lymphocytes and plasma cells along with perlobular lymphoplasmacytic infiltration [Table/Fig-7a-c]. Sometimes, predominantly neutrophilic infiltration in the background with necrotic debris has been described. Where there was clinical suspicion of malignancy or GM, performing CNB was ideal to confirm the diagnosis. In current study, only two patients underwent CNB. This was probably because CNB was done in the institution for those cases where there was discordance between clinical, imaging and FNAC findings. In none of the current cases, malignancy was suspected on USG, hence CNB was not done in a good number of cases.

Treatment modalities: Broadly there are two treatment options for GM; surgery and steroid therapy. Surgery: Surgical procedures planned for GM vary from incision and drainage to wide local excision. Infrequently mastectomies have been done when the carcinoma was suspected [1]. The advantages of surgery are removal of the painful, anxiety inducing breast swelling rapidly and lesser recurrence rate. However, the disadvantages could be delayed healing and unacceptable scarring in some cases. Surgical treatment, particularly wide local excision, was considered by many to be the first and best line of treatment for GM [3,7,18,19]. However, in most of the cases, the diagnosis comes as histopathological surprise postoperatively. In current study, 21 out of 22 breasts were operated and only four of them were diagnosed as GM preoperatively by FNAC. One patient, who was not fit for surgery, received conservative treatment with antibiotics and minimal bedside cleaning of the wound after core needle biopsy and resolved without recurrence. Higher tendency for choosing surgical treatment was probably because of maximum number of patients had presented with breast lump with features of either abscess or benign lump.

Corticosteroids: Steroids are the drugs of choice for autoimmune disorders and chronic inflammatory conditions. As the aetiology of GM is thought to be autoimmune reaction to the extravasated milk protein or fat by many, it should respond to steroids. As per literature, initially steroids were started whenever there was delayed wound healing or recurrences [9]. Eventually, in certain cases, they have been chosen as first choice of treatment in the absence of contraindications [8,19]. Advantages are avoidance of mutilating surgery and its complications. Disadvantages are steroid induced complications such as pulmonary thrombosis, drug induced hyperglycaemia, cataract, vulnerability to infection and immunosuppression. Low dose and high dose regimens have been tried and found that those who were started on high dose regime were associated with no or lesser recurrences compared to that of lower dose regime [20]. However, the response to treatment was found to be not uniform among the patients as well as the recurrence rates. The less popular conservative treatment options are methotrexate and prolactin lowering medications [21,22]. Only when the diagnosis of GM is made preoperatively, the conservative treatment with steroids or other immunosuppressive agents, can be chosen for certain patients and unnecessary surgery and associated complications can be avoided [2,8,17,23,24]. Hence, the treatment is presently individualised and an universal protocol is yet to be devised for the management of GM.

In present study, corticosteroids were not given to any of the patients. The reasons could be-

1. Many of the patients presented as abscess and were planned for surgery without further investigation.
2. Excision biopsy was preferred when the lump size was bigger.
3. Most of the patients were diagnosed as GM postoperatively.
4. Routinely steroids were not used as first line treatment for GM cases.

Limitation(s)

All patients could not be interviewed telephonically, to obtain the recurrence details. We also could not get details as to why steroids were not chosen during the episodes of recurrences.

CONCLUSION(S)

Granulomatous mastitis can clinically mimic any condition in the breast from benign as abscess, fibroadenoma to malignant conditions like carcinoma. It is found both in pre and post menopausal women, of all the ages, presenting either as acute or chronic breast conditions. Varied clinical manifestation of granulomatous mastitis makes it difficult to suspect clinically. Therefore, in all breast cases, the possibility of granulomatous mastitis should be kept in mind. Since, tissue diagnosis is the gold standard for diagnosing GM, either preoperative core needle biopsy or sending biopsy from all operated breast cases enhances the diagnosis rate of granulomatous mastitis.

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