Original Article

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Pathology Section

Histopathological Spectrum and Treatment Outcomes of Idiopathic Granulomatous Mastitis: A Prospective Cohort Study

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ABSTRACT

Introduction: Idiopathic Granulomatous Mastitis (IGM) is a rare chronic inflammatory breast disease and a diagnosis of exclusion. Although traditionally described as a lobulo-centric disease, ductal involvement has not been systematically assessed. High recurrence rates and lack of consensus regarding optimal treatment remain major challenges. In this study, we have evaluated the detailed histopathological changes in IGM with emphasis on ductal pathology and assessed their association with treatment outcomes.

Aim: Primary aim of the study was to evaluate detailed histopathological changes in IGM with emphasis on ductal pathology and to assess their association with treatment outcomes.

Materials and Methods: The present prospective cohort study was conducted from January 2017 to December 2023 in the departments of Pathology and Surgery in two tertiary care hospitals in Eastern India. Eighty-nine histologically confirmed IGM cases were included after exclusion of specific granulomatous aetiologies. Patients were categorised into three treatment groups: steroid therapy, lumpectomy or segmental mastectomy, and Wide Local Excision (WLE) with partial or total duct excision. Statistical analysis was performed using Fisher's-exact test and logistic regression. A p-value <0.05 was considered statistically significant.

Results: A total of 59 cases of Duct ectasia (66.3%), 58 cases of periductal granulomas (65.2%), and 44 cases of duct disruption (49.4%) were common findings. Recurrence was highest in the lumpectomy group and lowest in the WLE with duct excision group. WLE with duct excision demonstrated significantly lower recurrence compared to lumpectomy (p <0.05).

Conclusion: IGM demonstrates significant ductal pathology in association with lobular changes as described in literature. WLE with complete duct excision may be associated with significantly lower recurrence rates and better outcomes. Further prospective multicentre studies are warranted.

Keywords: Breast diseases, Chronic inflammation, Corticosteroid therapy, Differential diagnosis, Recurrence; Surgical management

INTRODUCTION

The IGM is a chronic inflammatory breast disease of unknown aetiology [1]. Ductal pathology plays a central role in IGM pathogenesis and influences recurrence following different treatment modalities. This disease entity has considerable overlap with other benign and malignant diseases in terms of clinical presentation and imaging features [2]. The aetiologies of granulomatous breast diseases are summed up in [Table/Fig-1]. Since IGM is a diagnosis of exclusion, there is significant delay in the identification, diagnosis and management of these patients. Histopathology remains the cornerstone for diagnosis of this lesion, although differentiating it from other granulomatous conditions of the breast is difficult, specifically in developing countries like India where Tuberculosis is endemic [3,4]. Despite the painful, scarring and debilitating nature of this disease, prompt diagnosis and successful management remains challenging. The current treatment options include WLE, steroids and other immunosuppressive agents like methotrexate but recurrence remains a major issue till date [2,5,6]. Misdiagnosis of this disease may lead to erroneous treatment with adverse outcomes including mastectomy as well. Some recent studies suggest 17% recurrence rate which emphasises the importance of understanding the actual pathology of the disease [1]. The genesis of the granulomas in IGM is lobular, as is well known and documented, but the pathology of the associated mammary duct system has not been studied or specified in any of the available literature [2,4,7,8]. From the present experience, this has been had noted that there is associated gross involvement of small and large ducts in IGM, especially in sinus-forming and fistulising lesions. This has been hypothesised that ductal pathology plays a central role in IGM pathogenesis and influences recurrence rates following different treatment modalities. Therefore, the aim of the present study was to evaluate the histopathological spectrum of changes seen in IGM with emphasis on ductal findings and to find out their association with different treatment modalities and clinical outcome.

MATERIALS AND METHODS

The present Institutional based prospective cohort study was conducted from January 2017 to December 2023 in the departments of Pathology and Surgery in two tertiary care hospitals in Eastern India (SSKM hospital Kolkata and Diamond harbour Hospital, South 24 parganas). The study was conducted after obtaining informed consent from all participants and approval from the Institutional Ethics Committee (IEC No. IPGMER/275B/2017).

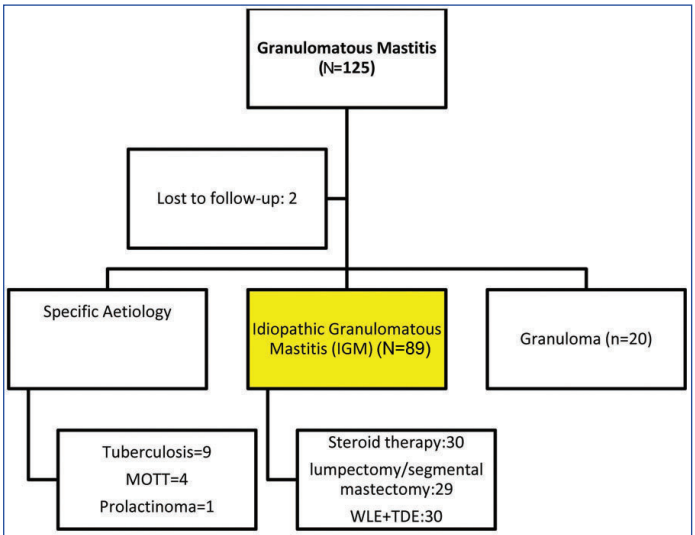
Sample Size: A total of 125 cases of granulomatous mastitis were initially identified from the departmental medical records during the study period. A total of 89 cases were finally shortlisted for the study.

Exclusion criteria: 16 cases had to be excluded where a specific aiteology was found {tuberculosis- 9 cases, Mycobacterium Other Than Tuberculosis (MOTT) infection- 4 cases, Sarcoidosis- 2 cases and Prolactinoma- 1 case}. In addition, there were 20 patients who had associated granulomatous inflammation elsewhere in the body, lymph nodes (n=15), lupus vulgaris (n=02) and lung (n=01) and were also excluded from the study. There were two patients who had no follow-up data.

Inclusion criteria: Patients included in this study were clinically and histologically confirmed cases of granulomatous mastitis involving different quadrants of the breast, where other causes of granulomas had been completely excluded by appropriate clinical, biochemical, microbiological and serological tests and had been followed up for atleast six months.

Study Procedure

The patient characteristics, clinical presentations, radiological findings, biochemical and microbiological workups, histopathology reports, treatment modalities, outcomes and follow up data obtained from the institutional records were thoroughly reviewed. The paraffin blocks and stained histopathology slides of all the patients were retrieved from the departmental archive. Telephonic conversation was also done with the patients or their family members to obtain other relevant demographic and clinical information wherever required. The marital and pregnancy status, lactational history at presentation, use of contraceptives, contact history and comorbidities were noted. The different treatment modalities included were antibiotics, steroids and surgery with or without total or partial duct excision. The follow-up data of the patients at six weeks, three months and six months and were reviewed to assess the outcome in the three treatment groups: steroid therapy, lumpectomy or segmental mastectomy, and WLE with partial or total duct excision. The outcomes evaluated in this study were time-to-healing and cure of disease- defined as complete healing of the lesion without clinical or radiological evidence of any inflammatory process. Recurrence of disease was defined as a recurrence of any of the disease symptoms like lump, mastitis, pain, ulcer or abscess after three months of cure. The distribution of Granulomatous Mastits has been presented in the flow chart diagram [Table/Fig-1].



[Table/Fig-1]: Flow diagram showing distribution of granulomatous mastitis patients. MOTT : Mycobacteria Other Than Tuberculosis; WLE: Wide Local Excision; TDE: Total Duct Excision.

Histopathologic Procedure

Among the 89 cases, core biopsy was done in 54 cases, of which 30 cases had received only medical therapy with antibiotics and steroids (included in Group-A) while surgical resection was done in 59 cases, which included lumpectomy (n=15), segmental mastectomy (n=14) and WLE with partial or total duct excision of the segment involved (n=30). The patients undergoing simple resection like lumpectomy or segmental mastectomy were grouped into Group-B (n=29) while patients who underwent WLE with partial or total duct excision were categorised into Group-C (n=30). The histopathologic changes were also assessed in the three treatments groups separately. There were 47 cases where both core biopsy and surgical resection specimen were available. A detailed histopathologic review of all the retrieved H&E slides was done. Freshly, cut 4-5 µm sections were also prepared from the retrieved paraffin blocks and stained by H&E stain, as and where required. The morphological changes were analysed with emphasis on the ductal pathology in patients undergoing partial or total duct excision. Different histological parameters were evaluated qualitatively which included severity of lobular inflammation (mild, moderate or severe), predominant cell type of inflammation (neutrophilic or lymphocytic), distribution and localisation of the granulomas (lobular, periductal or ducto-lobular) and presence of giant cells. The grade of inflammation was considered mild when inflammation was sparse and only focal, moderate when one or two foci of dense inflammation or multiple foci of mild inflammation was present or severe when widespread dense inflammation was present. In addition the presence or absence of periductal inflammation, duct disruption, intraductal exudates, necrosis, abscess formation and vasculitis, if any was assessed. The histopathologic examination was carried out by two expert pathologists independently, and discordance, if any was resolved by a common consensus.

STATISTICAL ANALYSIS

Data Analysis

A Cohen's Kappa coefficient >0.80 was considered as perfect agreement in case of categorical data and only these parameters were evaluated to find the statistical significance. The data analysis was done in Microsoft Excel 2021 and Jamovi (version 2.6; The jamovi Project; https://www.jamovi.org) statistical software. Descriptive data were used to describe demographic variables, treatment modalities and outcomes. All continuous variables were described in the table as percentage and median with range. For comparative data, Fisher's-exact test and logistic regression were used and a p-value of <0.05 was considered to be statistically significant.

RESULTS

The patients presenting with IGM belonged to varying age groups with a median age of 38 years (range- 19 to 53 years). Most of the patients were married 71(79.7%) cases with a history of prior childbirth 66 (74.1%) cases. There were twenty-five cases with some form of comorbidities, but none of the cases had any history of contact with tuberculosis. Breast lump was the most common presenting symptom (n=82, 92.1%) of which 12 cases were multifocal, followed by sinus or fistula formation (n=66, 74.1%) and chronic breast abscess (n=34, 38.2%). The other clinical findings were axillary lymphadenopathy, persistent breast ulceration, nipple inversion and peau d'orange formation, found in 21 (23.5%) cases, 15 (16.9 %) cases, 11 (12.4 %) cases and 6 (6.7%) cases, respectively. Co-existence of two or more symptoms was found in 58 (65.1%) cases. Ultrasound examination showed varying imaging findings which included hypoechoic to mixed echogenic mass with architectural distortion diffuse skin thickening, fluid collection and axillary lymphadenopathy. Radiologic interpretation of the breast lesion on ultrasound was reported as malignant [Breast Imaging Reporting and Data System (BI-RADS) 5] in 34 (38.2%) cases, while in 15 (16.8%) cases, there was a suspicion of malignancy (BI-RADS 4). All these 49 cases had been re-evaluated by Mammography or MRI. Mammography was done in 29 cases, out of which nine were inconclusive and MRI was inconclusive in two cases.

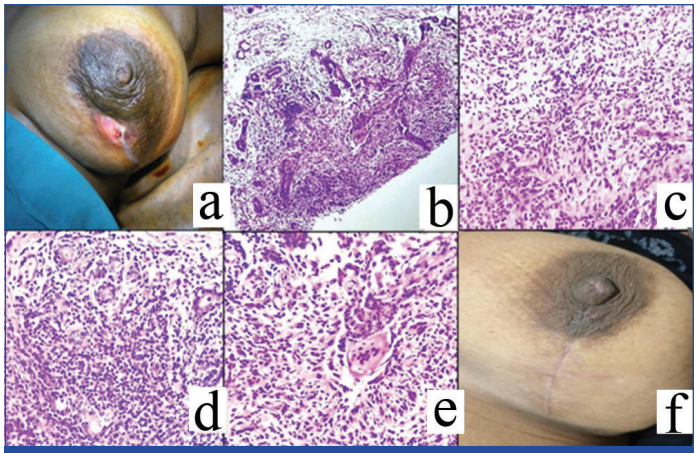
All the cases were reviewed and confirmed to be granulomatous mastitis on histopathology. There was diffuse infiltration of lymphocytes, plasma cells, macrophages, neutrophils and multinucleated giant cells mostly centred in the lobules. The severity of inflammation was variable with most cases showing marked and diffuse multifocal inflammation affecting more than two-thirds of the biopsy with neutrophils being the predominant inflammatory cell type (n=51, 57.3%). There was collection of epitheloid histiocytes with formation of non caseating granulomas in all the cases. The

inflammatory component as well as the granulomas was distributed in the lobules and also around the small and large ducts in majority of the cases (40 cases, 44.9%). There was associated presence of scattered giant cells in majority of the cases (n= 72, 80.9%) of which most were of Langhans type (n=40, 44.9%). The ductal morphology along with and the presence of inflammation and granulomas in relation to the ducts in all the three groups were carefully assessed. The ductal changes were more prominent in the patients who underwent surgical resection, with or without partial or total duct excision, in comparison to the patients undergoing only core needle biopsy. Duct ectasia, periductal granulomas and periductal inflammation were present in 59 (66.3%) cases, 58 (65.2%) cases and 54 (60.7%) cases respectively. However, compared within groups, these ductal changes were equivocal and variable in the core biopsy sections. Duct disruption with leakage and intraductal exudate was also more in the resection sections especially more prominent in the Group-C patients undergoing duct excision. None of the cases showed any foci of in-situ or invasive ductal or lobular carcinoma. There was no evidence of vasculitis in any of the cases. The detailed histopathologic changes have been elaborated and emphasised in [Table/Fig-2,3].

The follow-up data of all the patients were reviewed meticulously. A review of the follow-up data of these 89 cases revealed that the patients of Group-B (lumpectomy/segmental mastectomy) presented with the most recurrences, seen in as many as 19 out of 29 (65.5%) cases while 12 of 30 cases of Group-A patients (steroid therapy) showed recurrence of the disease after 24 weeks of steroid therapy. On other hand, only 03 cases among the Group-C patients (WLE+TDE) presented with disease recurrence (10% cases). On comparing the outcomes in terms of recurrence, simple lumpectomy or WLE as a single mode of treatment was significantly associated with higher risk of recurrence when compared to steroid treatment {Odds Ratio (OR): 2.85 (95% CI: 1.317–5.54), p-value=0.048}. WLE with partial or complete duct excision had significantly lesser

Parameters	Category	Group-A (n=30)	Group-B (n=29)	Group-C (n=30)	Total
Inflammation	Severe	15	10	10	35
	Moderate	9	7	12	28
	Mild	6	12	8	26
Inflammation type	Neutrophils predominance	17	16	18	51
	Lympho-plasmacytic predominance	13	13	12	38
Granulomas	Lobular	14	7	10	31
	Periductal	4	8	6	18
	Ducto-lobular	9	15	16	40
Giant cells	Langhans	13	12	15	40
	Foreign body	10	13	9	32
Periductal granulomas	Present	14	23	21	58
	Absent	16	6	9	31
Periductal inflammation	Present	17	19	18	54
	Absent	13	10	12	35
Duct disruption	Present	8	20	16	44
	Absent	22	9	14	45
Intraductal exudate	Present	7	16	19	42
	Absent	23	13	11	47
Duct ectasia	Present	10	20	29	59
	Absent	20	9	1	30
Necrosis	Present	9	8	7	24
	Absent	21	21	23	65

[Table/Fig-2]: Histopathological spectrum of idiopathic granulomatous mastitis (n=89).



[Table/Fig-3]: (a) Clinical photograph of patient presenting with multiple sinuses and mass in left breast; (b) Core biopsy from breast showing dense periductal inflammation and duct ectasia (H&E, 4×); (c-e) Periductal granulomas with duct disruption, intraductal exudates and giant-cell reaction (H&E, 40×); (f) Healed breast after Wide Local Excision (WLE) and total duct excision at 6 months follow-up.

recurrences than simple lumpectomy (OR: 0.06, 95% CI: 0.002–0.179); p-value <0.001} or steroid therapy OR: 0.16 (95% CI: 0.011–0.892); p-value=0.007} [Table/Fig-4]. Since duct excision surgery had significant prognostic implications, we reviewed the ductal changes separately in the three groups and compared the morphological alterations of the ducts with treatment outcomes.

Treatment Modality	Recurrence		Odds Ratio (95% CI)	p-value#
	Yes	No		
Steroid	12	18	Reference	
Lumpectomy/segmental mastectomy	19	10	2.85 (1.317-5.54)	0.048
WLE+TDE	3	27	0.16 (0.011-0.892)	0.007
Lumpectomy/segmental mastectomy	19	10	Reference	
WLE+TDE	3	27	0.06 (0.002-0.179)	<0.001

[Table/Fig-4]: Association of disease recurrence with different treatment modalities in IGM (n=89).
CI: Confidence Interval; WLE: Wide Local Excision; TDE: Total Duct Excision.
#Fisher's-exact test was used to find the p-value

DISCUSSION

The Idiopathic Granulomatous Mastitis (IGM) is a rare benign disease of the breast of unknown aetiology. The pathogenesis of IGM is not known and its clinical manifestations mimic those of malignancy. In our study we found that sinus formation and indurated lumps are the commonest mode of presentation in IGM. We found that radiological evaluation is a poor diagnostic modality with some cases of IGM being misinterpreted as malignant BI-RADS 4 or 5 lesions [7]. Moreover, imaging modalities can only suggest the lesion characteristics but is unable to put forward a definitive diagnosis in most cases [9-11]. The relatively complicated and advanced presentation also puts forward a treatment challenge both in terms of cure and cosmetic outcome [12].

IGM is a diagnosis of exclusion. Before considering IGM, all other causes of granulomatous mastitis should be ruled out. This is more relevant in tropical countries like India, where the prevalence of Tuberculosis is high and has to be ruled out in all cases of granulomatous mastitis. Initially we had enrolled 125 cases, of which nine cases were confirmed to be Tubercular and another four cases were diagnosed as Mycobacteria Other Than Tuberculosis (MOTT). which were eventually excluded from our study [13,14]. This study emphasises the fact that histopathological evaluation has to be done in every suspected case of IGM for confirmation. Even after diagnosis, the management of IGM remains a challenge for the clinicians and surgeons. Although multiple therapeutic modalities have been employed in the past, the long-term prognosis of IGM remains dismal, with high frequency of recurrences [15].

In this study, we delved into the pathology of IGM to better understand this enigmatic entity and correlate them with different diagnostic modalities. All available literature highlights the autoimmune nature of IGM and describes this entity as a lobulo-centric granulomatous lesion of unknown aetiology [15,16]. But had the disease been only restricted to the mammary lobules, there would not have been high recurrences after simple excision of the affected lobule or segment. With this background, we evaluated the spectrum of histologic changes in all diagnosed cases of IGM. We found that there was lobular as well as periductal inflammation in majority of the cases, with neutrophilic predominance. Although necrosis and abscess formation were present in 24 and 47 cases, respectively, the necrosis was of suppurative type, while caseation necrosis was absent in all the cases. Granulomas were predominantly lobulo centric as described in literature, but 18 cases showed exclusive periductal granulomas and 40 cases showed both lobular and periductal distribution of granulomas. We found that the morphological changes of the ducts were quite characteristic. Duct ectasia and duct disruption were evident in 59 (66.3%) cases and 44 (49.4%) cases respectively. Periductal granulomas, periductal inflammation and intraductal exudate were found in 58 (65.2%) cases, 54 (60.7%) cases and 42 (47.2%) cases, respectively.

The pathogenesis of IGM is complex and thought to be multifactorial with atleast three postulated hypothesis-infectious, hormonal and autoimmune. Among these, the autoimmune hypothesis has been stressed upon, specifically because most patients show good clinical response to steroidsand immunosuppressants [17]. There have been studies which have also speculated the extravasation of lactational secretions for eliciting a granulomatous inflammatory response [17].

We postulate that IGM starts as ductal dilatation with ectasia followed by leaky ducts. There is cytokine liberation which causes periductal parenchymal destruction finally leading to single or multiple cutaneous sinus or fistula. The presence of non caseating epitheloid granulomas are the hallmark of IGM. In developing countries, mycobacterium tuberculosis is often related to breast granulomas and hence should be excluded before considering IGM. Negative acid-fast bacilli (AFB) staining and BACTEC (Becton Dickinson Automated Culture System) culture and absence of central caseation are pointers against tubercular aetiology.

This study establishes the “ductal origin” hypothesis of IGM. Blind lumpectomy is associated with worst outcome as seen in our series. In most circumstances, the recurrence is worse than the original presentation. Simple excision should not be considered in management of IGM. Use of steroid is based on the concept of treatment of autoimmune background of the disease. Steroid usage is associated with better outcome than lumpectomies but is poorer and more unpredictable than WLE with enbloc total/partial duct excision. Steroid use is further contraindicated in presence of pus discharging sinus and indurated mass with intralesional collections. The long-term side-effects of steroids is often an issue for young females and hence should be considered with limitations. Steroids, however, continue to have role in predominant lump-only lesions in younger age group. In comparison the best and most predictable curative outcome is evident in patients treated with WLE-duct excision technique. Statistically, it scores significantly over steroids as in our study. Mobilising the breast plate and apposition after large volume resections can also improve the cosmetic outcome. Multi- quadrant sinuses and fistulae remains a major surgical and medical challenge in the treatment of IGM. However, duct excision in individuals desirous of future child-birth and lactation can be a relative contraindication.

Limitation(s)

Limitations of the present study include retrospective design, limited follow-up duration, and absence of multivariate adjustment for confounders. As cases were selected from only two tertiary centres, the study has limited sample size when divided in three groups.

CONCLUSION(S)

IGM is of “ductal origin” rather than a lobulo-centric disease as thought before. It can be postulated that since the pathology of IGM indicates towards prominent ductal changes, so WLE along with enbloc duct excision is associated with significantly lesser chances of recurrences and has the best curative and cosmetic outcome.

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