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Clinical Spectrum and Risk Factors of Granulomatous Mastitis in a Coastal Bangladeshi Population: A Hospital-Based Study

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Abstract **Original Research Article**

***Background*:** Granulomatous mastitis (GM) is a benevolent yet troublesome inflammatory disease of the breasts that is mistakenly identified as cancer every now and then in the brazen manner medical experts thought it was. It is also multifactorial and poorly understood, especially in low-income, high-tuberculosis (TB) burden countries like coastal Bangladesh. ***Objective*:** To establish the clinical spectrum and determine the related risk factors of GM among women living in the Bangladesh coastal regions. ***Methodology*:** The study methods included a retrospective observational study in the tertiary hospitals located along the coastal areas of Bangladesh between April 2023 and March 2025. A hundred histopathologically confirmed GM female patients aged 18 years were included. Histopathological results, imaging presentations, clinical presentations, and therapeutic outcomes, as well as possible risk factors, were analysed. Descriptive and multivariate logistic regression techniques were used in statistical analyses to identify the predictors of duct ectasia. ***Findings*:** Patients had a median age of 33.1 years, and 78 per cent of them were between 20 and 40 years old. The clinical manifestations were characterised by breast pain (26.5%) and palpable lumps (26.5%). Most of them had a history of pregnancy (82%) and breastfeeding (82%), whereas diabetes mellitus (65%) and previous TB (35%) were prominent comorbidities. Six point four per cent of duct ectasia by imaging was detected using ultrasound, and eleven point three per cent using a mammography, and histopathology revealed non-caseating granulomas in 99 per cent of the cases. Ducted involvement was closely related to advancing age (aOR=1.05), reduced BMI (aOR=0.86), predisposition to TB (aOR=3.00), and the caseating granulomas, as well as multinucleated giant cells (aOR=3.50). There were lower odds of duct ectasia (aOR=0.43) with corticosteroid therapy. There was full resolution of patients after the surgery; no case was reported of recurrence. ***Conclusion*:** GM primarily affects reproductive-aged females in the coastal regions of Bangladesh and is associated with reproductive history, diabetes, and a history of TB. Duct ectasia is also affected by the pathology characteristics and the clinical history, and, therefore, comprehensive therapeutic and diagnostic measures are important. Ductal complications can be moderated by the early corticosteroid treatment. The results recommend context-based guidelines for resource-limited, high-TB-burden contexts.

Keywords: Granulomatous Mastitis, Duct Ectasia, Coastal Bangladesh, Risk Factors, Tuberculosis, Corticosteroid Therapy, Breast Inflammation.

INTRODUCTION

The spectrum of benign and malignant breast disease covers a vast array of conditions that raise diagnostic and therapeutic difficulties, especially in the limited-resource context. Although malignancy is one of the major concerns in a pathology of the breast, benign inflammatory diseases of the breast are the issues that cause significant morbidity with clinical features that resemble carcinoma. Granulomatous mastitis (GM) is a unique and under-represented type of breast inflammatory disease, primarily affecting women of childbearing age who are impacted by this peripheral disorder. The worldwide rise in reported cases during the last twenty years is attributable to better awareness, diagnostic abilities, and perhaps an actual increase in incidence secondary to underlying predisposing factors [1, 2].

Histopathologically, non-caseating granulomatous inflammation that predominantly involves breast lobular centres is seen in granulomatous

mastitis (GM), which is usually accompanied by neutrophilic microabscesses, multinucleated giant cells, and chronic inflammatory infiltrates [3]. Clinically, GM is denoted by painful/lumpy breast by a mass, which a patient should be very anxious about since it is well known to mimic breast cancer [4]. Although it was initially reported in the literature as idiopathic granulomatous mastitis (IGM), researchers have identified various etiological factors, including autoimmune mechanisms, hormonal effects, infectious agents, and local ductal pathology [5-7].

One of the most striking facts about granulomatous mastitis (GM) is that it is strongly linked to reproductive and hormonal factors. A majority of the affected women belong to their second to fourth decade of life and have a history of recent pregnancy or breastfeeding. Hormonal and immunological alterations that occur during pregnancy and afterward and local theft of breasts or regression of pink are assumed to aid in the formation of granulomas on antigenic stimulation and periductal inflammation [8]. Autoimmune diseases like sarcoidosis and systemic lupus erythematosus have also been linked with GM in some populations, though findings are still limited and somewhat inconsistent [9]. Similarly, a role of infectious agents, Corynebacterium kroppenstedtii and other skin commensals in particular, has been proposed, but no pathogen consistently isolated in idiopathic cases has been identified [10, 11].

Differentiating GM-suggested pathogen tuberculous mastitis (TM) is a vital diagnostic problem in high tuberculosis (TB) burden countries such as South Asia. TM can give clinical and histological similarities, especially the caseating granuloma or sinus formations [1].2 In this scenario, TB should be ruled out using histopathological stains (e.g., Ziehl-Neelsen stain), culture and molecular detection in order to establish a proper diagnosis of idiopathic GM. The co-existence of previous or latent TB infection in GM patients also makes one wonder whether it was a predisposing or confounding factor in granulomatous inflammation of the breast, including in countries like Bangladesh, even where TB is endemic [13, 14].

The other challenge of granulomatous mastitis management is its erratic clinical presentation and high rates of recurrence. Although this disease is not life-threatening, its resemblance to cancer, unresponsiveness to treatment, and frequent relapsing patterns create a significant burden for patients and place considerable strain on health systems. Depending on the severity and risk of recurrence, treatment options available for granulomatous mastitis include conservative management (observation or corticosteroids), immunosuppressive therapy, and surgery [15]. Nevertheless, the treatment has not been taken seriously because there are no standard methods, and responses to various modalities do vary. Little promising effects have been present with corticosteroids in inducing remission, although there still remain concerns regarding side effects as well as relapse [16].

The vast majority of the granulomatous mastitis literature is produced in high-income nations or urban referral facilities with extensive diagnostic capabilities. By contrast, rural or coastal data for low- and middle-income countries (LMICs) are scarce, including those in Bangladesh. This is quite problematic, especially because of the varying risk patterns, healthcare access barriers, and exposure to the environment surrounding such environments. Since a large population of the country is in the coastal areas of Bangladesh, they face special public health issues, including being vulnerable to climate change, lack of proper healthcare infrastructure, and initial disproportionate burden of common diseases like breast diseases [17]. Breast diseases in such areas can go undiagnosed or misdiagnosed in cases when advanced imaging modalities and histopathology are not accessible.

There are various local risks to granulomatous mastitis that should be examined. Early marriage and multiparity are also predominant in rural and sea Bangladesh, and may expose them to more hormonal interactions and breast trauma associated with breastfeeding, which has also been found to play a role in GM pathogenesis [18]. In addition, due to poor nutrition status, lack of awareness, and cultural influences on seeking care, the employment of over-the-counter antibiotics can aggravate the course or mask the diagnosis. Chronic processes of inflammatory status can also involve environmental exposure to certain issues and situations, like arsenic-laden water and exposure to heavy metals in coastal inhabitants, but their direct connection to GM has not been identified [19, 20].

Also, although the previous literature has explored the relationships between granulomatous mastitis (GM) and ductal processes, including duct ectasia, there has been no clear picture regarding the overall clinical and epidemiological profile of GM in low-resource populations who live along a coastal environment [21]. This poses a problem in the development of region-specific diagnostic steps and treatment modalities as well as excessive treatment or the late diagnosis. Even simple clinical data, like the prevalence of GM against obstetrical history, comorbidities (e.g., diabetes), and recurrence patterns, are underreported in these groups. More so, although GM is mostly perceived as a disease predominantly affecting women of reproductive age, the exact figure with respect to age distribution, the effect of body mass index (BMI), and the duration of breastfeeding by this particular population group is not readily available in published articles printed in Bangladesh.

In light of this background, the necessity of localised empirical data on granulomatous mastitis is established. Granulomatous mastitis disease could be made patternable, allowing early disease identification and evidence-based therapy by broad-based clinical profiling of disease cases. Knowledge of both the clinical spectrum and risk factors is of particular issue to primary care and obstetric practitioners, as these professionals may be first responders in such areas. In the absence of region-specific evidence, guidelines are generalised and not always applicable to the epidemiological specifics of such populations, as the coastal population in Bangladesh.

Although granulomatous mastitis has become common literature, most of the published publications are retrospective case reports with poor follow-up and small sample sizes. Prospective or mixed-method (retro-prospective) studies of GM in LMICs remain too limited in number, using standardised histopathological confirmation, patient data collection, and evaluation of treatment outcomes. There is a paucity of studies within the Bangladesh environment which investigate modifiable (e.g., breastfeeding practices) and non-modifiable (e.g., age) risk factors. Besides, there is limited research that studies the entire clinical spectrum of the illness; this is symptom onset to resolution when it comes to real-world hospital conditions, especially along the coastal belt of the country.

Study Objective

To describe the clinical presentations and identify common risk factors associated with granulomatous mastitis in women from the coastal region of Bangladesh.

METHODOLOGY

Study Design and Setting

A retro-prospective observational design was used to explore clinical scale and related risk factors to granulomatous mastitis (GM) in patients who were eyeing the chosen health care facilities in the coastal region of Bangladesh. Medical records of already diagnosed cases of GM were reviewed and this formed the retrospective component whereas newly diagnosed GM cases were enrolled and subsequently followed-up during the period of the study as the prospective arm. They studied in tertiary hospitals and breast clinic in the coastal areas of southern Bangladesh where cases of inflammatory breast conditions are usually referred to achieve assessment and treatment.

Study Duration

Its data collection would take place between April 2023 and March 2025; during this two-year period, the retrospective (backwards) and prospective (forwards) data types could be collected.

Study Population

The participants of the study were female patients aged 18 years or above with granulomatous mastitis confirmed histopathologically. These patients showed different clinical signs of breast inflammations that included palpable mass, pain, erythema, nipple discharge or the formation of a sinus tract. Patients were identified in the list of hospital records or those being treated in the outpatient departments and surgical units.

Inclusion Criteria

- Female patients aged ≥18 years
- Clinical presentation consistent with inflammatory breast disease
- Histopathological confirmation of granulomatous mastitis through core needle biopsy or excisional biopsy
- Availability of complete clinical, imaging, and pathological data

Exclusion Criteria

- Patients with histologically confirmed malignancy
- Incomplete or missing medical records (for retrospective arm)
- Patients with active tuberculosis or fungal infections involving the breast
- Patients unwilling or unable to provide informed consent (for prospective arm)

Sample Size and Sampling Technique

The patients used as guinea pigs were 100 in number. The sample size was calculated on the basis of feasibility, availability of resources and the anticipated cases in the participating hospitals. All eligible patients who met the criteria of inclusion were included throughout the research using consecutive sampling methods. This method made the process of selection unbiased in both the retrospective and prospective arms.

Data Collection Tools and Procedure

Interviews were conducted using a prestructured questionnaire specifically developed for this study, with data collected through a standardised design (the questionnaire is available in the supplementary material). The tool incorporated comprehensive data on multiple facets, encompassing demographic attributes (age, height, weight, BMI, and smoking history) and anthropometric results (clinical presentation, such as obstetric or breastfeeding history, comorbidities, and past medical history, including tuberculosis, diabetes mellitus, and autoimmune disorders), as well as imaging and histopathological findings. The imaging results (ultrasound, mammography, and MRI, when applicable) were incorporated, with particular emphasis on ductal alterations, abscess formation, and skin thickening. Histopathological findings encompassed the presence or classification of granulomas, multinucleated giant cells, necrosis, and involvement of the ductal region. The

treatment information encompassed the administration of antibiotics, corticosteroids, surgical interventions, treatment outcomes, recurrence of cases, and complications. In both retrospective and prospective cases, data were acquired through the extraction of information from medical records, pathology reports, and imaging files. Consistency was ensured by employing the same tool for data collection during diagnosis and follow-up visits conducted by trained clinicians in prospective cases.

Diagnostic Criteria

Granulomatous Mastitis (GM) is diagnosed based on histopathological features, including non-caseating granulomas, multinucleated giant cells, and exclusion of infectious causes like tuberculosis and fungal infections. Tuberculosis exclusion is confirmed through acid-fast bacilli staining and clinical history.

Ethical Considerations

Ethical clearance for the study was obtained from the Institutional Review Board (IRB) of the participating hospitals. Informed consent was obtained from all prospective participants prior to enrollment. For retrospective cases, identifiable patient information was anonymized to ensure confidentiality. The study adhered to the principles outlined in the Declaration of Helsinki.

Statistical Analysis

Demographic characteristics and clinical characteristics were summarised using descriptive methods. Data in the text that were continuous were expressed as a mean with standard deviation, with those which were categorical given in frequencies and percentages.

Comparisons were done to evaluate the relationships between important variables and variables of interest. The right statistical testing was used according to the data and distribution of data. An adjustment was made wherever possible, to reflect the possibility of confounding factors. The statistical significance was deemed to be captured by less than 0.05 p-value.

RESULTS

A total of 100 patients diagnosed with granulomatous mastitis were included in the study. Their demographic, clinical, imaging, and histopathological characteristics were comprehensively documented.

Table 1: Demographic and Background Characteristics of GM Patients (n = 100)

Variable	Mean ± SD / n (%)
Age (years)	33.1 ± 10.4
BMI (kg/m²)	25.3 ± 2.6
Smoking Status	0 (0%)
Breast involved – Right	57 (57%)
Breast involved – Left	38 (38%)
Breast involved – Bilateral	4 (4%)
Breast involved – None	1 (1%)

In Table 1, it was showed that the average age of participants was 33.10.4 years, of which most of them (78%) were between 20 and 40 years old. The average size base weight index (BMI) was 25.3 +/- 2.6 kg/m². All the respondents had no smoking background.

Table 2: Distribution of clinical features and symptoms (n = 100)

Symptom	n (%)
Breast pain or tenderness	26 (26.5%)
Palpable breast lump	26 (26.5%)
Nipple discharge	10 (10.6%)
Redness or erythema	15 (15.4%)
Skin retraction or nipple inversion	6 (6.1%)
Sinus tract or fistula formation	6 (6.4%)
Systemic symptoms (fever, fatigue, malaise)	8 (8.5%)
Duration of symptoms (weeks)	4.95 ± 3.7

In table -2, breast pain and palpable lumps were the most frequently reported signs, each occurring in 26.5 percent of patients. Other symptoms were nipple discharge (10.6%), redness/erythema (15.4%), skin retraction or nipple inversion (6.1%), and sinus tract or fistula formation (6.4%). Eight point five per cent of cases had systemic symptoms that included fever and malaise. The average time of illness was 5.037 weeks.

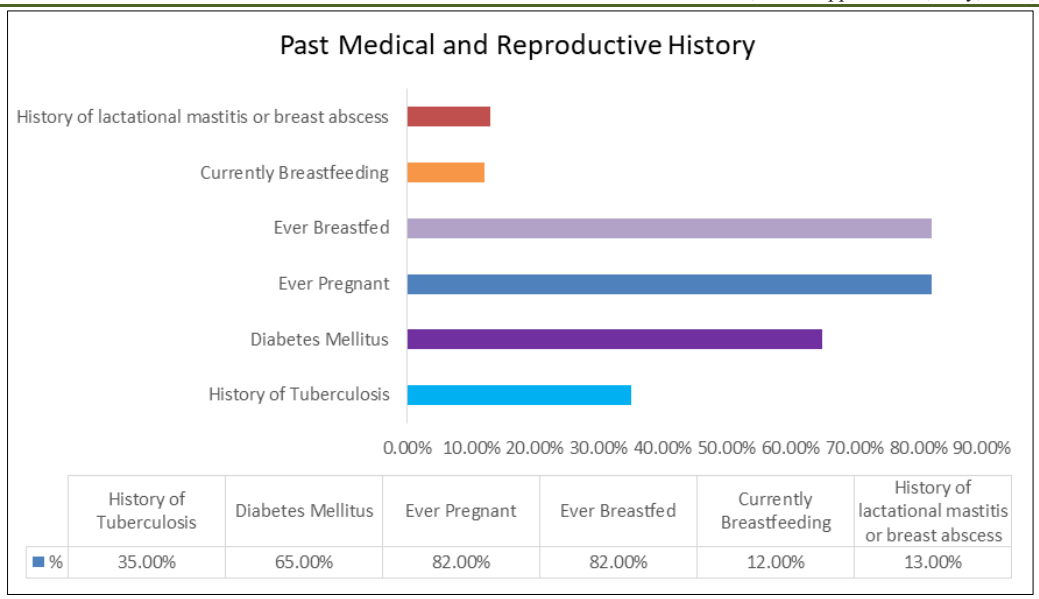

Figure 1: Bar chart distribution of past medical and reproductive history

Bar graph on the above indicating that; a large percentage of the patients indicated that they had a history of diabetes mellitus (65%) and tuberculosis (35%). Under reproductive history, 82% had a history of pregnancy and 82 per cent had a history of breastfeeding, 13 per cent had a history of lactational mastitis or breast abscess. At the time of their diagnosis, breastfeeding was only prevalent among 12 percent.

Table 3: Distribution of imaging and histopathological findings among the patients (n=100)

Feature	Present (n, %)
Ultrasound Findings	
Duct ectasia	6 (6.4%)
Abscess/fluid collection	33 (33.1%)
Mass	33 (33.1%)
Skin thickening	27 (27.4%)
Mammography Findings	
Duct ectasia	11 (11.3%)
Mass	71 (70.9%)
Calcification	3 (3.5%)
Skin/nipple retraction	14 (14.2%)
Histopathological Findings	
Non-caseating granulomas	99 (99.0%)
Caseating granulomas	1 (1.0%)
Ductal involvement (duct ectasia)	19 (19.0%)
Multinucleated giant cells	2 (2.0%)

In table-3, duct ectasia was found in 6.4 percent of the patients who had ultrasounds and 11.3 percent by mammography. The other frequent findings were masses (33.1%), fluid collections (33.1%), skin thickening (27.4%) as well. Histopathology analysis showed that 99 percent of cases were having non-caseating granulomas and 19 per cent of the cases were ductally involved. 2 per cent of cases showed multinucleated giant cells.

Table 4: Distribution of treatment and resolution outcomes among the patients (n=100)

Treatment/Outcome	n (%) / Mean ± SD
Received Antibiotics	99 (99.0%)
Complete Resolution after Surgery	100 (100.0%)
Time to Resolution (days)	6.08 ± 4.14
Recurrence	0 (0.0%)

Ninety-nine percent of all patients were treated with an antibiotic, and surgical repair resulted in a full clinical healing in 100 percent. The average length of healing following surgery was 6.1 + 4.1 days. There was

a low recurrence which was not reported in the available follow up period.

Table 5: Comparison of Histopathological Features between Patients with and Without Duct Ectasia (n = 100)

Histopathological Feature	Duct Ectasia Present (n = 19)	Duct Ectasia Absent (n = 81)	p-value
Non-caseating granulomas	18 (94.7%)	81 (100.0%)	0.038*
Caseating granulomas	1 (5.3%)	0 (0.0%)	
Multinucleated giant cells	0 (0.0%)	2 (2.5%)	0.489

Non-caseating granulomas were also elucidated to be statistically related to the existence of duct ectasia with a p-value of 0.038 (p = 0.038), meaning that non-caseating granulomas had the frequent occurrences in patients with duct ectasia. Nevertheless, there was no statistically significant correlation with an occurrence of multinucleated giant cells with the development of duct ectasia (p = 0.489).

Table 6: Multivariate Logistic Regression of Factors Associated with Duct Ectasia in GM Patients (n = 100)

Predictor Variable	aOR	95% CI	p-value
Age (per year increase)	1.05	1.01 – 1.09	0.025*
Body Mass Index (per unit)	0.86	0.76 – 0.97	0.012*
History of Tuberculosis	3.00	1.37 – 6.57	0.006*
Caseating granulomas	2.01	1.10 – 3.67	0.024*
Multinucleated giant cells	3.50	1.60 – 7.65	0.002*
Corticosteroid treatment	0.43	0.22 – 0.82	0.015*

A statistically significant relationship between the presence of duct ectasia and duct involvement with non-caseating granulomas (p = 0.038) was also found, so the presence of duct involvement was associated with non-caseating granulomas. Nevertheless, multinucleated giant cells were not statistically significantly linked with duct ectasia (p = 0.489), and this indicated they are not markedly different in terms of their frequency in the two parts of the population.

DISCUSSIONS

This study gives an insightful evaluation regarding the clinical presentation and risk factors of granulomatous mastitis (GM) in a hospital-based cohort service of the coastal region of Bangladesh. The discoveries highlight the typical manifestation of GM in women in the reproductive age, routine correspondence to pre-breastfeeding, and relevant relationship to metabolic and infectious co-conditions like diabetes and tuberculosis. Moreover, we found out that some of the main predictors of ductal involvement are progressive age, history of TB, pathological background, and applied medical therapy.

The age range of affected patients was 18-70 years, with a mean of 33.1 years, similar to the international epidemiological report of GM in which women in reproductive age prevail [1-22]. Already some researchers have hypothesised that pregnancy and lactation hormonal changes can cause an immune reaction that stimulates granulomatous inflammation of the lobules of the breast [8-22]. This is in line with our finding that 82 per cent of the patients had a history of pregnancy and lactation, where pregnant women have oestrogenic hormones and mechanical disruptions of the GM.

An interesting result was that diabetes mellitus had a very high prevalence (65%), considerably greater than that in the background of the general female population of Bangladesh [23]. Local immune surveillance in diabetes can be disrupted, and breast microvasculature can be affected using diabetes as a pathogenesis factor of tissue necrosis, which can predispose to the development of chronic inflammatory diseases, including GM [24]. The direct causative relationship between diabetes and GM was previously unknown; however, our findings indicate that glycaemic disturbance can act as a facultative factor, similar to a disease modifier, which may aggravate the extent and duration of inflammation.

Another interesting epidemiological finding is the existence of a previous history of tuberculosis in 35 per cent of our patients. Even though it was not seen in current dimensions in any patient with active tuberculous mastitis, the fact that previous TB was strongly related to duct ectasia (aOR 3.00; p = 0.006) indicates possible long-term immunologic or structural consequences. There is a possibility of a predisposition involving granulomatous immune priming, a consequence of a long-term post-infectious alteration of breast duct events and inactivation in low-existence foci, in idiopathic granulomatous mastitis [12, 13]. The findings are of significance, especially in TB-endemic countries such as Bangladesh, and highlight the importance of screening and history taking in the inflammatory cases of the breast.

Regarding clinical presentation, the most prominent symptoms were pain in the breast and

palpable lumps (26.5% each), which was in line with the previous case series of breast cancer in Turkey, India and Iran [4-26]. A right breast presentation (57%) was more common than a left breast or bilateral presentation, but the heterogeneity of this finding has not yet been established and may be incidental.

In this study, it was validated that duct ectasia which is pathological characteristic that is seen in some patients of GM can be identified by histopathology in 19 per cent of cases but only 6.4 and 11.3 per cent by ultrasound and mammography, respectively which shows results of tissue test as having the largest sensitivity. This mismatch confirms a tendency to under-diagnose the slight ductal changes in imaging studies especially in low-resources where there is no radiologic capacity [11].

Histologically, non-caseating granulomas were found in 99% of cases, supporting the classic diagnostic criteria for idiopathic GM [3-28]. A significant association was observed between non-caseating granulomas and ductal involvement ($p = 0.038$), reinforcing the ductal origin hypothesis of GM. Previous work by Sarkar *et al*., [1], and Liu *et al*., [9], also demonstrated that periductal granulomas and duct disruption were common features of GM, suggesting that duct ectasia may represent an early or initiating event in the disease process.

In multivariate logistic regression analysis, increasing age was associated with higher odds of duct ectasia (aOR 1.05), likely reflecting age-related ductal involution, fibrosis, and susceptibility to chronic ductal obstruction [7-27]. Remarkably, BMI had a protective effect (aOR 0.86) against duct ectasia though such a protective effect was not given prominence in previous literature. The inverse association is unexpected and could be a confounding factor since the nutritional stores regulate immune responses, or the microenvironmental lipid composition of fatty breasts is different. Nonetheless, additional research is justified to discuss this association in detail.

Caseating granulomas (aOR 2.01) and multinucleated giant cells (aOR 3.50) were important significantly positive predictors of duct ectasia. These results indicate a linkage between granulomatous response behaviour in more intense or extended ways and involvement of the ducts. Non-caseating granulomas are characteristic of IGM, but sometimes caseating aspects cause concern of misdiagnosis or residual TB in TB-endemic areas [13-30]. In addition, multinucleated giant cells are evidence of chronic stimulation of the immune system and the development of granulomas, which indicate prolonged inflammation or the presence of foreign antigens in the form of lipids or proteins [10-14].

Among the most significant and clinically determinable results was the protective effect of corticosteroid therapy against duct ectasia (aOR 0.43; $p = 0.015$). This finding complements previous evidence that corticosteroids, when initiated early, can inhibit the inflammatory cascade, avoid damage to the duct and reduce recurrence when used at an early stage [16-28]. R Recent network meta-analyses also support the safety and effectiveness of both mono- and combined regimens of steroids in the use of GM [18-28]. In our cohort, patients who received corticosteroids had better outcomes and lower ductal complications, emphasizing the importance of timely medical therapy in avoiding surgical interventions.

At the level of the study, this research study helps to fill information gaps in regard to the study of a poorly surveyed population – women in coastal Bangladesh, who confront environmental, socioeconomic, and healthcare access vulnerabilities – with a public health perspective. Environmental stressors which are chronically present, e.g., water salinity, arsenic, nutritional deficiency, etc., might further complicate immune regulatory mechanisms and inflammatory pathophysiological events of this group [19-29].

Strengths and Limitations

Retro-prospective design is a big strength of this research as it allows not only the evaluation of historical cases but collects actual-time data. Our findings were further enhanced by the fact that we used histopathologically based identified diagnoses, full clinical records and sound statistical models. The study has a number of limitations though. To begin with, the study was single-centered and hospital-based, meaning the drawback regarding generalizability of the results to the community. Second, resultant recurrence and long-term outcomes were not completely evaluated because of the short follow-up of the retrospective arm. Finally, testing of TB or autoimmune serology was not a routine practice that may also inhibit distinction between secondary and idiopathic GM.

CONCLUSION

In conclusion, this study highlights the typical clinical spectrum of granulomatous mastitis among women in coastal Bangladesh and identifies key risk factors for ductal involvement, including age, prior tuberculosis, granuloma type, and treatment modalities. The findings support a ductal origin hypothesis and emphasize the importance of integrated clinical, radiological, and pathological assessment. Early initiation of corticosteroid therapy appears beneficial in reducing ductal complications. These insights are particularly relevant for improving diagnosis and management in low-resource, high-TB-burden settings and lay the foundation for developing standardized, region-specific treatment guidelines.

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