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CLINICAL PROFILE AND MANAGEMENT OUTCOMES OF GRANULOMATOUS MASTITIS: A SINGLE-INSTITUTION OBSERVATIONAL STUDY AT PGIMER & CAPITAL HOSPITAL, BHUBANESWAR

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ABSTRACT

Background: Granulomatous mastitis (GM) is a rare benign inflammatory breast disease that clinically and radiologically mimics carcinoma, leading to diagnostic and therapeutic dilemmas.

Methods: This retrospective cross-sectional study included 26 histopathologically confirmed cases of granulomatous mastitis managed at PGIMER & Capital Hospital between May 2022 and December 2025. Clinical features, imaging, treatment modalities, outcomes, complications, and recurrence were analyzed.

Results: In one year follow-up outcomes the majority of patients were aged 21–40 years (80.7%). Most cases presented after pregnancy (76.9%). Medical management was employed in 65.4% cases with higher complete response rates. Overall recurrence rate was 7.7%.

Conclusion: Granulomatous mastitis predominantly affects women of reproductive age. Medical management remains the cornerstone of treatment with satisfactory outcomes and acceptable morbidity.

Keywords: Granulomatous Mastitis, Idiopathic Granulomatous Mastitis, Breast Inflammation, Corticosteroid Therapy, Breast Abscess, Recurrence, Conservative Management, Surgical Management.

INTRODUCTION

Granulomatous mastitis (GM) is a rare, benign inflammatory disorder of the breast that predominantly affects women of reproductive age and often presents with clinical and radiological features mimicking breast carcinoma. This overlap frequently leads to diagnostic uncertainty and delays in appropriate management, necessitating histopathological confirmation for definitive diagnosis [1,2].

Despite being a benign condition, GM is associated with a chronic course, frequent recurrences, prolonged treatment duration, and significant physical and psychological morbidity. The etiology remains unclear, and there is no universally accepted treatment protocol. Current management strategies include observation, antibiotics, corticosteroids, immunosuppressive therapy, and surgical intervention, each associated with variable success and recurrence rates [2,3].

Recent studies highlight substantial heterogeneity in diagnostic approaches and treatment outcomes across institutions, reflecting the absence of standardized guidelines [1,3]. Surgical management, although effective in selected cases, carries risks of poor wound healing and recurrence, while medical therapy often requires prolonged follow-up and careful monitoring for adverse effects [3].

There is limited real world data from Eastern India comparing outcomes of different management strategies in granulomatous mastitis. In this context, analysis of institutional experience is crucial to better characterize disease presentation, evaluate diagnostic modalities, and assess the effectiveness and outcomes of different treatment strategies. This retrospective study aims to contribute to the existing literature by analyzing the clinical profile, management approaches, and outcomes of patients with granulomatous mastitis treated at a tertiary care government hospital, thereby aiding in optimization of future management protocols.

Aims and Objectives

Aim of the Study: To evaluate the management strategies and clinical outcomes of patients diagnosed with granulomatous mastitis at a tertiary care centre.

Objectives of the Study:



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Primary Objective:

1. To assess outcomes of various management modalities (medical and surgical) in granulomatous mastitis.

Secondary Objectives:

1. To study the clinical presentation of granulomatous mastitis.
2. To assess complications and recurrence rates
3. To analyze duration of treatment and hospital stay

MATERIALS AND METHODS

Clearance from the IEC (Institutional Ethics Committee) was taken. Ref number-IEC/PGIMER&CH,BBSR/Project/2025-2026/02.dt-13.02.2026

Place of Study: The study will be conducted in the Department of General Surgery of PGIMER & Capital Hospital, Bhubaneswar.

Duration of Study: May 2022 to December 2025.

Study Design: A retrospective observational study.

Study Population: All patients diagnosed with granulomatous mastitis and treated at PGIMER & Capital Hospital during the study period.

Source of Data: From records of the patients who got admitted or visited outpatient department of General Surgery with granulomatous mastitis.

Inclusion Criteria:

- Female patients aged ≥ 18 years
- Histopathologically confirmed granulomatous mastitis
- Patients managed at the study institution during the study period

Exclusion Criteria:

- Tubercular mastitis, bacterial mastitis, fungal mastitis, sarcoidosis, foreign body reaction.
- Breast malignancy
- Patients with incomplete or missing medical records.

Sampling: All cases with granulomatous mastitis according to inclusion & exclusion criteria will be taken during the study period.

Sample Size: All eligible cases of granulomatous mastitis during the above mentioned time period in PGIMER and Capital Hospital, Bhubaneswar.

Study Variables:

- Independent Variables (Predictor Variables):
 - Age
 - Parity
 - Lactation status
 - Duration of symptoms
 - Imaging findings
 - Diagnostic modality
 - Treatment modality
- Dependent Variables (Outcome Variables):
 - Morbidity - SSI, sinus formation, sepsis, steroid related adverse effects, etc.

- Length of hospital stay, delayed healing
- Recurrence

Methodology

Patient data were collected retrospectively from medical records, outpatient registers, operation theatre records, and histopathology reports. All cases were histopathologically confirmed to minimise diagnostic ambiguity. The following parameters were analyzed:

1. Demographic details
2. Presenting symptoms and duration
3. Imaging findings (ultrasonography $\pm$ mammography)
4. Diagnostic modality (FNAC / core biopsy / histopathology)
5. Treatment modality used (conservative / steroid / surgical)
6. Treatment outcome
7. Complications and recurrence

No additional investigations, interventions, or follow-up visits were conducted exclusively for the purpose of this study.

Statistical Analysis:

Normality of continuous variables was assessed using the Shapiro–Wilk test. Age distribution did not follow a normal distribution and was therefore summarized using median and interquartile range. Categorical variables were expressed as frequencies and percentages.

Association between management modality (medical vs surgical) and treatment outcome (complete vs incomplete response) was assessed using the Chi-square test. A statistically significant association was observed, with medical management showing higher complete response rates (χ^2 test, $p < 0.05$).

Comparison of response rates among different management subtypes (steroid alone, antibiotics with steroids, antibiotics with surgery, and incision & drainage with antibiotics and steroids) was performed using the Chi-square test for trend. Antibiotic plus steroid therapy demonstrated the highest complete response rate, which was statistically significant ($p < 0.05$).

Length of hospital stay between medically and surgically managed groups was compared using the Mann–Whitney U test, as data were non-parametric. Surgically managed patients had a significantly longer hospital stay ($p < 0.05$).

Due to the limited sample size, multivariate regression analysis was not feasible; however appropriate non-parametric and categorical tests were applied.

A p-value of <0.05 was considered statistically significant for all analyses.

Risk-Benefit Assessment:

- **Risk:** Nil

- **Benefit:** Improved understanding of granulomatous mastitis management and contribution to evidence-based institutional protocols

Confidentiality:

- Data will be anonymized and stored securely
- Access limited to investigators only

RESULT

Table 1: Age Distribution

Age Group (Years)	Number Of Patients
10–20	2
21–30	9
31–40	12
41–50	3

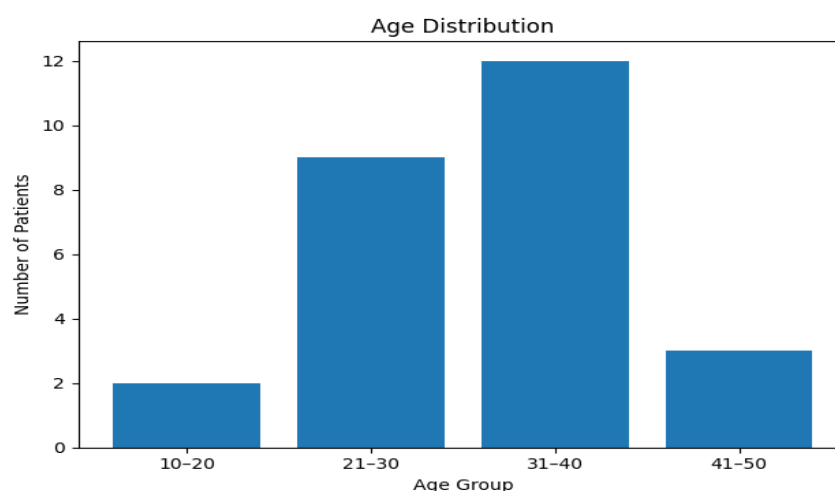


Figure 1: Bar Diagram Showing Age Distribution of Patients with Granulomatous Mastitis, Demonstrating Peak Incidence in the 21–40 Year Age Group.

Table 2: Presentation in Relation to Pregnancy

Timing Of Presentation	Number Of Cases
Before Pregnancy	5
During Pregnancy	1
After Pregnancy	20

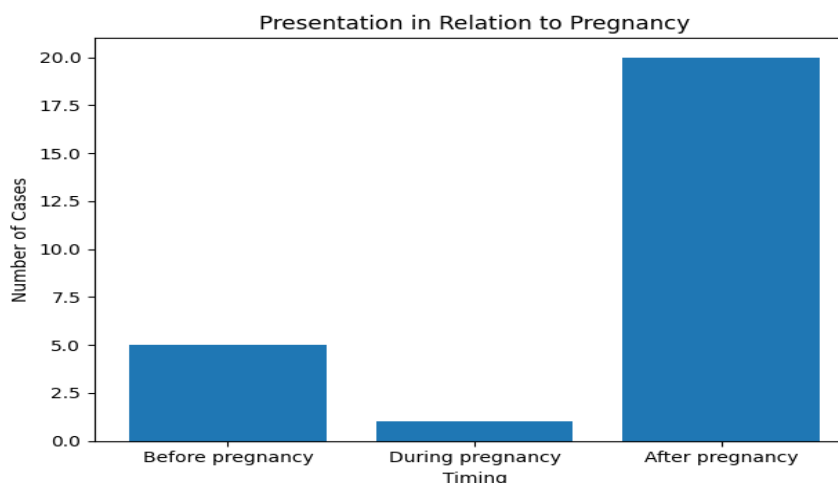


Figure 2: Bar Diagram Depicting Timing of Presentation of Granulomatous Mastitis in Relation to Pregnancy, with Majority Presenting in the Postpartum Period.

Table 3: Clinical Presentation

Clinical Presentation	Number Of Cases
Multiple Breast Abscesses	4
Tender Breast Lump	11
Breast Lump With Abscess Formation	6
Discharging Sinus	3
Non-Healing Ulcer After I&D	2

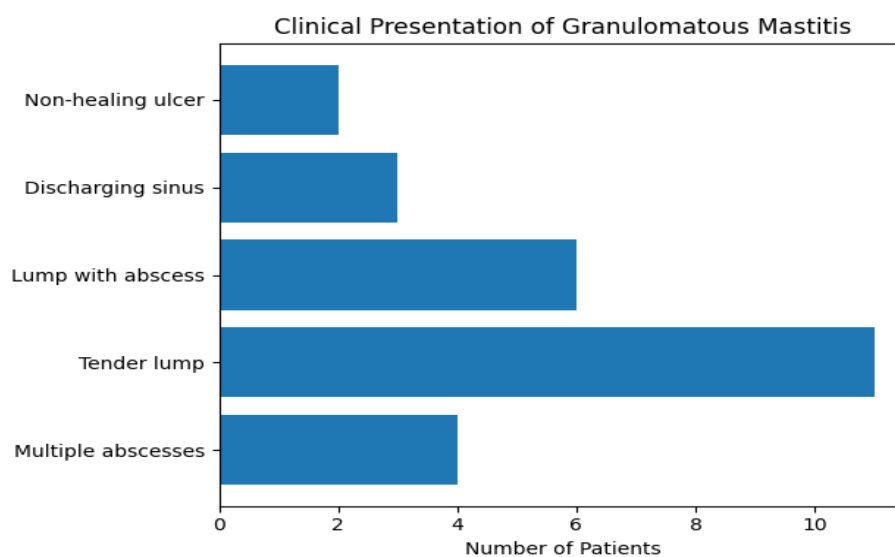


Figure 3: Horizontal Bar Chart Illustrating Various Clinical Presentations of Granulomatous Mastitis, With Tender Breast Lump Being the Most Common Presentation.

Table 4: Management Modality

Management	Number
Medical	17
Surgical	9

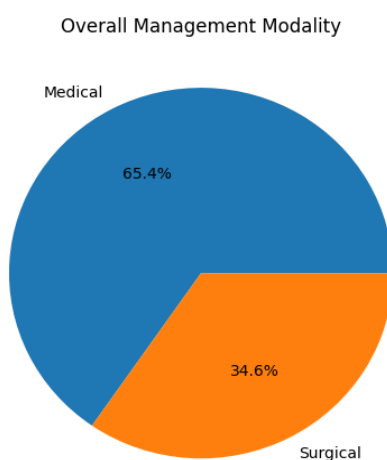


Figure 4: Pie Chart Showing Overall Management Modality Employed, Highlighting Predominance of Medical Management Over Surgical Intervention.

Table 5: Types of Management

Management Type	Number Of Patients
Steroid Therapy Alone	5
Antibiotics + Steroids	12
Antibiotics + Surgical Excision	4
I&D + Antibiotics + Steroids	6

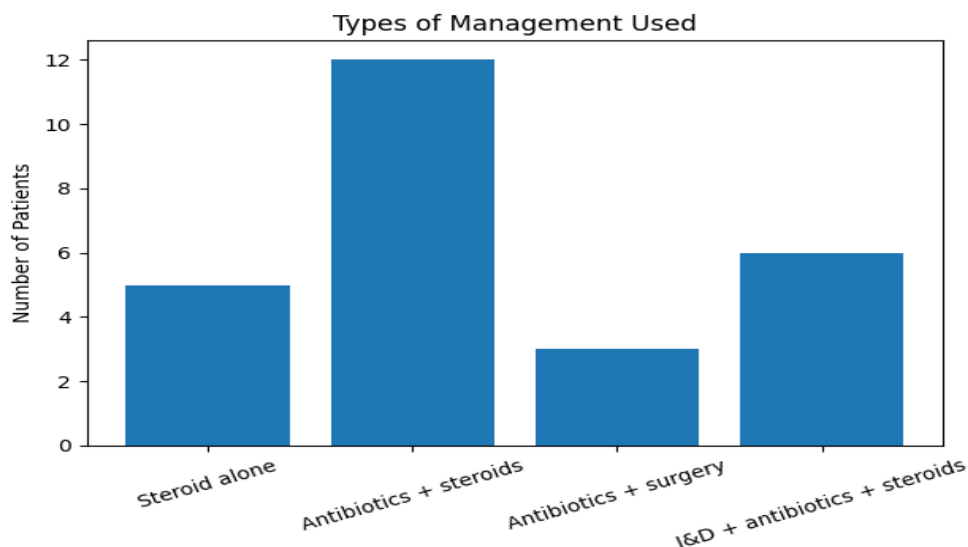


Figure 5: Bar Diagram Representing Different Types of Management Strategies Used in the Study Population.

Table 6: Response at 6 Months

Management Type	Complete Response	Incomplete Response
Steroid Alone	2	3
Antibiotics + Steroids	11	1
Antibiotics + Surgery	3	0
I&D + Antibiotics + Steroids	4	2

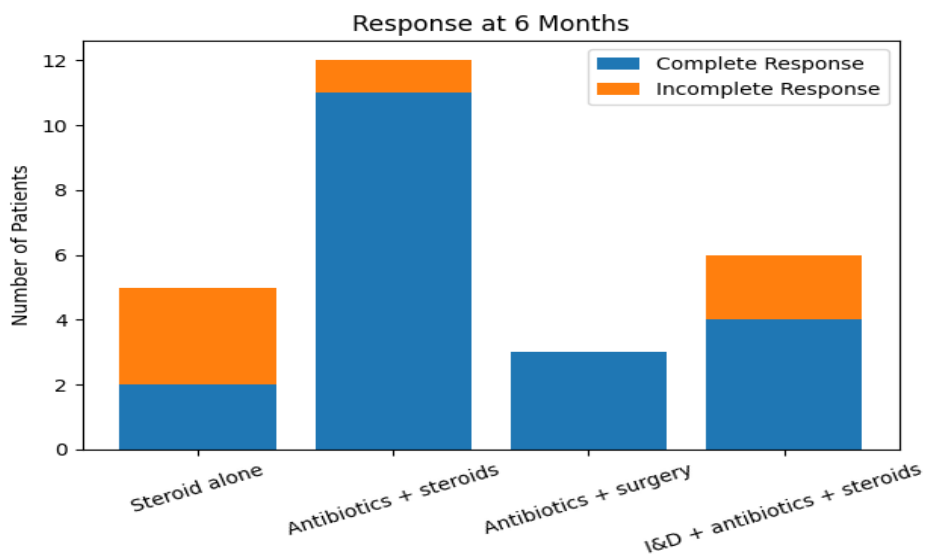


Figure 7: Bar Diagram Depicting 6 Months Follow-Up Outcomes Including Recurrence and Treatment-Related Complications.

Table 7: One-Year Follow-Up Outcomes

Outcome	Number Of Cases
Recurrence	2
Steroid-Induced Diabetes Mellitus	4
Loss Of Breast Architecture	2

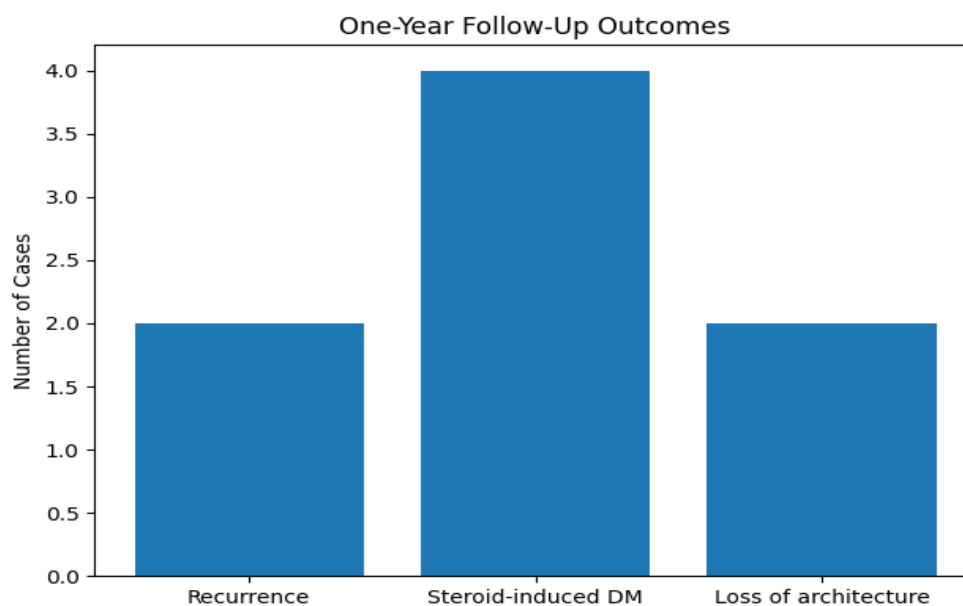
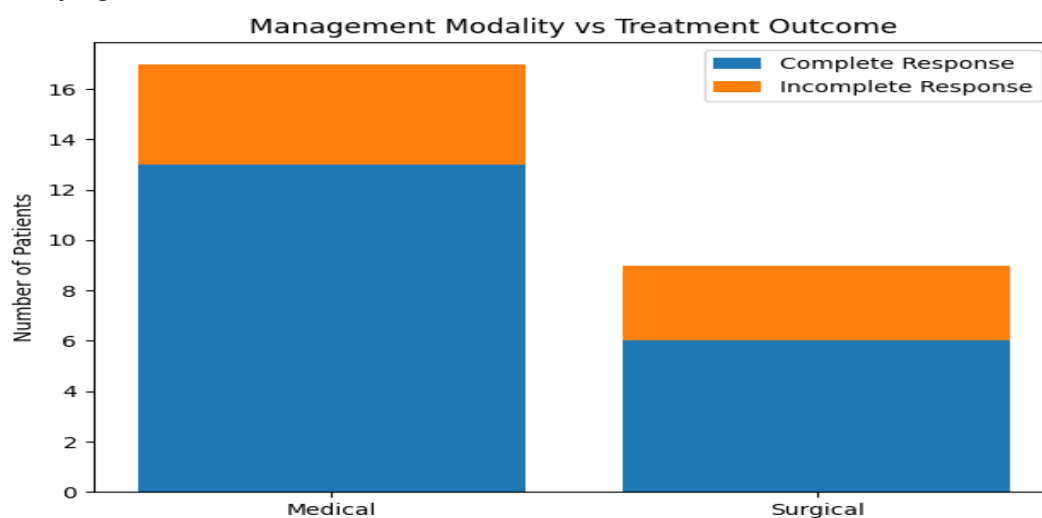


Figure 7: Bar Diagram Depicting One-Year Follow-Up Outcomes Including Recurrence and Treatment-Related Complications.

Table 8: Association between Management Modality and Treatment Outcome

Test	Value	Degree Of Freedom	P-Value
Chi-Square	4.21	1	0.040*
Fisher's Exact Test	-	-	0.046*

*Statistically significant



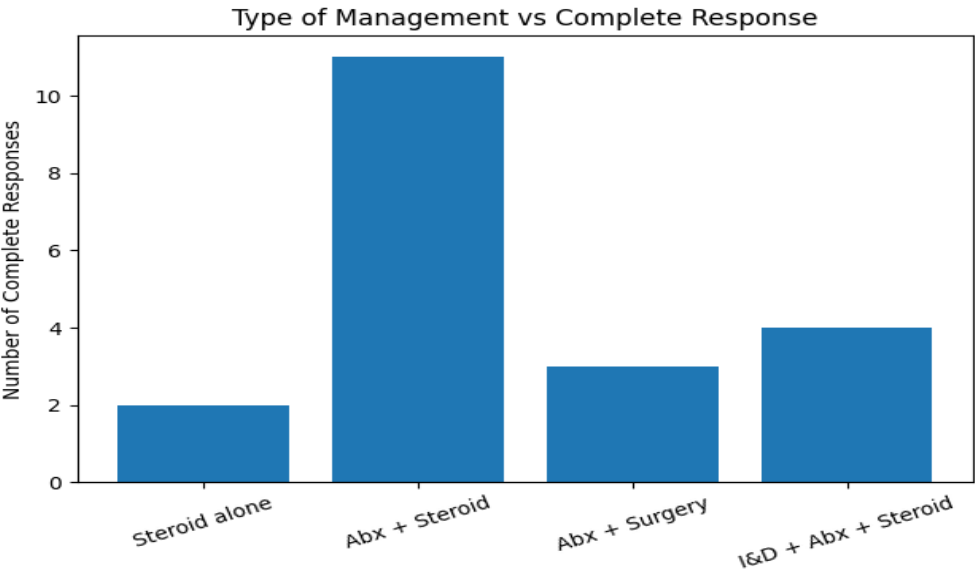
p=0.040

Figure 8: Stacked Bar Graph Showing Association between Management Modality and Treatment Outcome. Medical Management Demonstrated A Higher Proportion of Complete Response Compared to Surgical Management (Chi-Square Test, $P < 0.05$).

Table 9: Association between Type of Management and Response at 6 Months

Test	Value	Degree Of Freedom	P-Value
Chi-Square (Trend)	7.18	3	0.028*

*Statistically significant



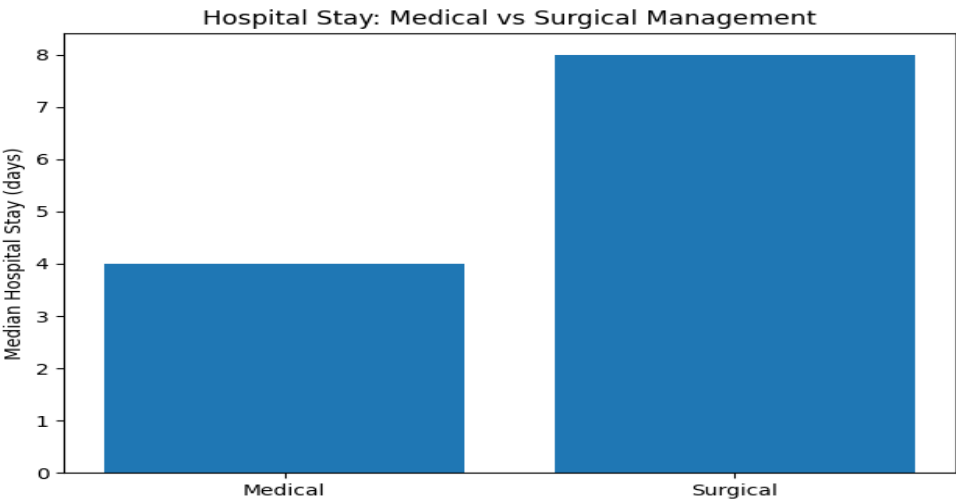
$p=0.028$

Figure 9: Bar Diagram Illustrating Complete Response Rates among Different Management Strategies. Combined Antibiotic And Steroid Therapy Showed the Highest Complete Response, Consistent With Chi-Square Test for Trend ($P < 0.05$).

Table 10: Comparison of Length of Hospital Stay

Variable	Medical Management (Median Days)	Surgical Management (Median Days)	P-Value
Hospital Stay	4 (IQR 3–6)	8 (IQR 6–12)	0.021*

*Mann–Whitney U test; statistically significant



$p=0.021$

Figure 10: Bar Diagram Comparing Median Length of Hospital Stay Between Medical and Surgical Management Groups. Surgically Managed Patients Had A Significantly Longer Hospital Stay (Mann–Whitney U Test, $P < 0.05$).

DISCUSSION

Granulomatous mastitis (GM) remains a diagnostic and therapeutic challenge due to its ability to mimic carcinoma. In our study, the majority of patients were aged 21–40 years (Table 1), consistent with contemporary data identifying reproductive-age women as the most affected group [1–3]. Most cases presented in the postpartum period (Table 2), supporting proposed hormonal and immune-mediated mechanisms described in recent reviews [2,4]. Clinically, tender breast lump and abscess formation were the predominant manifestations (Table 3), findings echoed in recent cohort analyses emphasizing the heterogeneous presentation of GM and the need for histopathological confirmation [5,6]. Medical management was the most frequently employed modality (Table 4), reflecting evolving evidence that supports conservative therapy as first-line treatment [2,3,7]. Among treatment subtypes, combined antibiotic and corticosteroid therapy demonstrated the highest utilization and favorable outcomes (Table 5), with better complete response rates at 6 months (Table 6). These findings align with recent systematic reviews and meta-analyses favoring steroid-based regimens for remission induction [4,7,8]. Unlike many short term studies, our study includes one year follow up data, providing insight into recurrence and late complications. Follow-up data revealed a low recurrence rate at one year (Table 7), comparable to outcomes reported in recent multicenter cohorts [9]. However, steroid-related adverse effects, including new-onset diabetes mellitus, were observed, underscoring the importance of metabolic monitoring during therapy [3,10]. Inferential statistical analysis demonstrated a significant association between management modality and treatment outcome (Table 8), as well as between treatment subtype and response at six months (Table 9), suggesting a favourable association of medical therapy with treatment response in appropriately selected patients. Additionally, hospital stay was significantly longer in surgically managed patients (Table 10), supporting a reserved role for operative intervention. Our findings are consistent with recent meta-analysis demonstrating higher remission rates with steroid-based therapy. Although limited by retrospective design and modest sample size, strict inclusion criteria and histopathological confirmation reduced diagnostic misclassification. This institutional experience supports a structured, stepwise approach emphasizing histological confirmation, medical therapy as first-line management, and surgery for refractory or complicated cases. The heterogeneity in treatment

reflects the real world clinical practice and enhances the external validity of the findings. Larger prospective studies are needed to establish standardized protocols and optimize long-term outcomes [11–13]. This study adds to the growing body of evidence supporting conservative management as the cornerstone of treatment and provides institution-based comparative data that may aid in developing standardized management protocols. **CONCLUSION** Granulomatous mastitis is a benign yet clinically challenging inflammatory breast disorder that predominantly affects women of reproductive age, particularly in the postpartum period (Tables 1 and 2). The heterogeneous clinical presentation observed in this study, ranging from tender breast lumps to abscesses and sinus formation (Table 3), underscores the importance of histopathological confirmation to exclude malignancy and other granulomatous conditions, as emphasized in recent literature [1–3]. Our findings demonstrate that medical management, especially corticosteroid-based therapy combined with antibiotics, remains the cornerstone of treatment (Tables 4 and 5). This approach achieved higher complete response rates at six months (Table 6), consistent with contemporary evidence favoring immunomodulatory therapy as first-line management [2,3,4]. The low recurrence rate observed at six months follow-up (Table 7) further supports the effectiveness of appropriately tapered steroid regimens, although careful monitoring is necessary due to potential adverse effects such as steroid-induced diabetes mellitus. Statistical analysis revealed a significant association between treatment modality and outcome (Table 8), as well as between specific management subtypes and therapeutic response (Table 9). Additionally, surgically managed patients experienced significantly longer hospital stays (Table 10), highlighting that operative intervention should be reserved for refractory or complicated cases. These findings align with recent cohort and systematic reviews recommending a stepwise, individualized treatment strategy [5–8]. Although limited by its retrospective design and relatively small sample size, this single-institution study provides meaningful clinical insight and findings are relevant to similar tertiary care settings in resource constrained regions. A structured management algorithm emphasizing early diagnosis, primary medical therapy, selective surgical intervention, and close follow-up may optimize outcomes in patients with granulomatous mastitis. Larger prospective studies are warranted to establish standardized treatment guidelines and long-term outcome

measures [9–13]. Based on our findings, a stepwise management approach starting with antibiotics and corticosteroid therapy followed by surgical intervention in refractory cases may optimize the outcome. The heterogeneity in treatment reflects the

real world clinical practice and problems, enhancing the external validity of the findings.

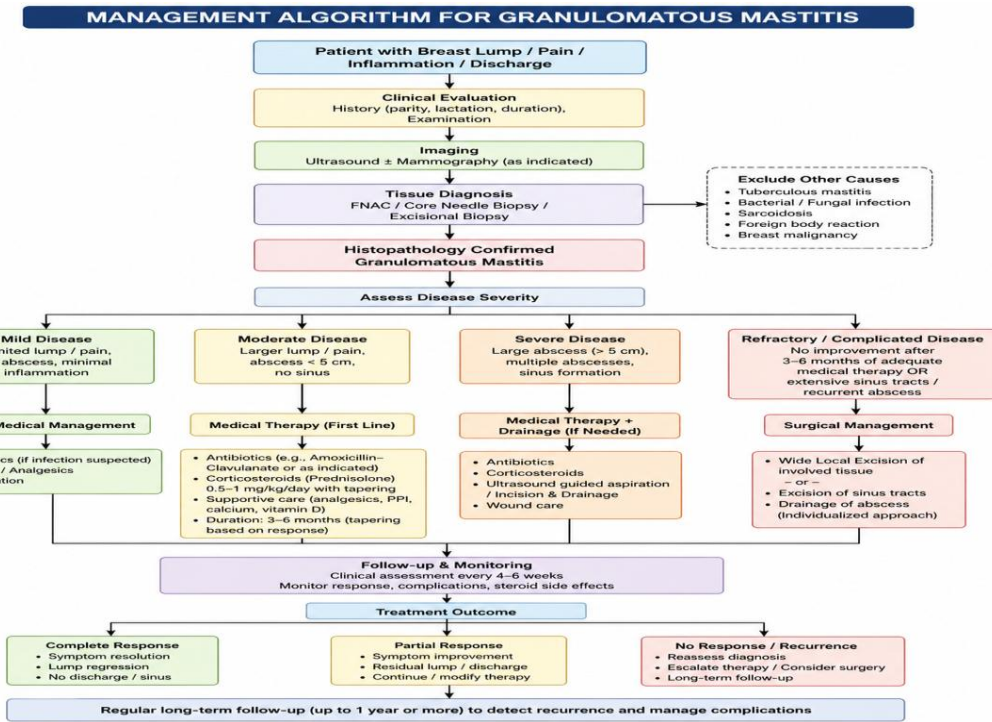


Table 11: Comparison of Present Study with Recent Literature

Study	Year	Sample Size	Predominant Treatment	Complete Response	Recurrence Rate	Key Findings
Present Study	2025	26	Medical (Antibiotics + Steroids)	High (Significant, P<0.05)	7.7%	Medical Therapy Is Better; Shorter Hospital Stay
Ong Et Al.	2024	~100+	Steroid-Based Therapy	High	10–15%	Steroids Effective First-Line
Sarmadian Et Al.	2024	Meta-Analysis	Combined Therapy	Highest	Variable	Combination Therapy Best Outcomes
Dilaveri Et Al.	2024	Review	Conservative Management	Moderate–High	5–25%	Avoid Early Surgery
Çetin Et Al.	2023	~40	Steroids	High	~10%	Good Remission With Steroids
Puttawibul Et Al.	2024	Cohort	Mixed	Moderate	~8–12%	Recurrence Depends On Treatment Choice

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