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The Predictive Value of Preoperative Systemic Immune-Inflammation Index in Patients with Granulomatous Mastitis

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Purpose: The systemic immune-inflammation index (SII) comprehensively reflects the balance between immune status and host inflammation. We aimed to investigate the potential predictive value of the SII in the prognosis of granulomatous mastitis (GM).

Patients and Methods: We enrolled 245 patients with GM who underwent surgery between 2015 and 2020 in this study. Using the receiver operating characteristic (ROC) curve, we divided the patients into low SII groups (SII≤836×10^9/L) and high SII groups (SII>836×10^9/L). The associations between SII and clinical parameters were assessed using chi-squared or Fisher's exact tests. Kaplan-Meier plots and Log rank tests were performed to investigate the clinical outcomes of cumulative no-recurrence rates. Risk factors were analyzed by using logistic regression analysis.

Results: We found a correlation between the recurrence of GM and the preoperative level of SII, and the high SII group exhibited a higher recurrence rate than the low SII group. To further explore the factors affecting the risk of recurrence, we found that young age at disease onset, skin rupture, and the postoperative use of corticosteroids could increase the risk of GM recurrence. Multivariate logistic regression analysis suggested that young age and postoperative corticosteroid use were the risk factors for disease recurrence.

Conclusion: As a noninvasive and readily available clinical parameter, the preoperative SII level has great significance in evaluating the efficacy and prognosis of surgical treatment for GM combined with age and postoperative corticosteroid use, which provides valuable insights for making treatment decisions.

Keywords: Granulomatous mastitis, Surgical treatment, Systemic immune-inflammation index, Prognosis

Introduction

Breast diseases commonly include tumors and inflammation. Granulomatous mastitis (GM) is a distinct type of inflammation that differs from soft tissue infections or breast abscesses. GM is a chronic inflammatory disease characterized by the presence of noncaseating granulomas with microabscess formation dispersed in the breast lobules.[1,2] The first cases of GM were described by Kessler and Wolloch in 1972.[3] Patients with this disease frequently present with painful palpable masses, tumorous indurations, or nipple retractions. A mass in the breast may be complicated by fistula formation and abscesses. Since then, the etiological factors of this disease are currently unclear. Although many studies have reported relevant research results, most of them are retrospective studies and the number of cases is relatively small. The early clinical and imaging manifestations of granulomatous mastitis often mimic malignant breast tumors or acute breast inflammation, which may disturb diagnosis and treatment.

Management strategies for GM vary among centers, which may confuse the patients and prolongs the disease course. The usual treatments for GM include observation, antibiotics, corticosteroids, nonsteroidal Immunosuppressants, surgery.[4–7] The best choice, a single treatment mode, a combination treatment, or a flexible choice based on changes in the condition remains unclear. Thus, disease treatment has not yet reached a consensus, and there is no good prognostic observation parameter for available treatments, which makes the evaluation of curative effects difficult. In

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particular, the prevalence of GM is 2.4 per 100,000 and the recurrence rates of GM were reported 15.4–24.8% in literatures.[8–11] Consequently, there is a pressing need to develop reliable and accessible biomarkers to stratify GM prognosis.

The pathogenesis of GM is often associated with an autoimmune disease due to its occurrence in young females, similarity to other autoimmune diseases, and response to steroid treatment, suggesting a link to local inflammatory responses.[7,12–15] The local inflammatory response is a complex pathophysiological process in the focal microenvironment. In recent years, inflammation has been recognized as a potential critical mechanism in the pathogenesis of carcinomas and inflammatory diseases. The balance between the anti-inflammatory action of the aggregation of immune cells and inflammatory damage determines disease development. Therefore, the immune response induced by the recruitment of local inflammatory cells plays an important role in the dynamic observation and prognosis of the disease.

Hematological parameters exhibit specific changes in some tumors, inflammation, and autoimmune diseases. Several studies have reported that inflammatory biomarkers such as neutrophil, lymphocytes, platelet-to-lymphocyte ratio (PLR), and neutrophil-to-lymphocyte ratio (NLR) are prognostic factors for GM.[16,17] However, these parameters only consider local inflammatory damage and do not evaluate the immune repair process of diseased tissue. A novel systematic parameter named the systemic immune-inflammation index (SII = N×P/L), calculated by neutrophil (N), platelet (P), and lymphocyte (L) counts, can reflect the balance between immune status and host inflammation and can offer a comprehensive prognostic indicator in various diseases.[18–21] In this study, we aimed to explain the predictive value of this preoperative systemic immune-inflammation index in the prognosis of granulomatous mastitis.

Material and Methods

Study Population

In this retrospective analysis, we gathered data from 245 patients who were diagnosed with GM by histopathological examination after partial mastectomy at Yichang Central People's Hospital from 2015 to 2020. All data were gathered from the patients' medical records in the hospital and were approved by the hospital ethics committee (Medical ethics number: 2024–469-01), which comply with the declaration of Helsinki. Informed consents were obtained from all enrolled patients prior to this study.

The inclusion criteria were as follows: (1) all patients underwent partial mastectomy and were histopathologically diagnosed with GM after surgery; (2) all patients were diagnosed with GM for the first time; (3) all peripheral blood samples for hematology tests were collected within one week before surgery; and (4) all patients had complete clinical records and follow-up data.

The exclusion criteria were as follows: (a) patients who underwent clinical procedures such as abscess incision or puncture drainage before the operation; (b) patients with autoimmune disease or inflammatory diseases, such as systemic lupus erythematosus, soft tissue infection, and pneumonia.

Classification Criteria and Response Evaluation

Currently, there are no consensus criteria for cure or recurrence of GM. The long course of the disease makes it difficult to determine the time of disease outcome and the prognosis of treatment. Therefore, we divided the outcome of the disease into two levels: clinical cure (CC) and disease recurrence (DR). Clinical cure (CC) refers to the absence of the following conditions in the affected breast within 2 years after surgery: palpable painful masses, imaginal inflammatory areas, or formation of abscess cavities. Disease recurrence (DR) refers to the following: (a) re-emergence of clinical manifestations such as palpable painful masses, imaginal inflammatory areas, or the formation of abscess cavities on the affected breast; (b) the increasing range of inflammation; and (c) the rise of new inflammatory areas. The period between surgery and clinical cure (CC) was defined as the postoperative course of recovery.

Peripheral Venous Blood Parameters

Peripheral venous blood samples were taken within 1 week before surgical treatment. The blood samples were collected in the sterile EDTA tube, and analyzed by The XN-9000 hematology analyzer (Sysmex, Japan).

Follow-Up

All patients included in the study underwent partial mastectomy for GM at the hospital. Breast ultrasonography was performed every three months for 2 years after the surgery. Disease evaluation was performed at any time if the symptoms recurred.

Statistical Analysis

SPSS and GraphPad Prism software were used to perform statistical analyses. Receiver operating characteristic (ROC) curve analysis was used to determine the optimal cutoff value for the SII. Descriptive variables were presented as percentages (%). The chi-square test or Fisher's exact test was used to analyze the associations between SII and clinical parameters or recurrence of granulomatous mastitis. Kaplan-Meier plots and Log rank tests were used to explore the clinical outcomes of the cumulative no-recurrence rate to evaluate the prognostic value of SII. Logistic regression analysis was performed to investigate risk factors. $p<0.05$ was considered statistically significant.

Results

Clinical Parameter of All GM Patients

We retrospectively collected data from 245 patients with GM, all of whom were female who underwent surgery. We counted all clinical parameters before surgery, including age, blood type, birth mode, pathogenic site, lesion size, skin involvement, and time from birth to onset. We used the ROC curve to analyze the cutoff value of the SII and concluded that the cutoff value of the SII was 836×10^9/L. We then divided the 245 patients into two groups: a low SII group (SII≤836×10^9/L), with a total number of 163 patients (66.5%), and a high SII group (SII>836×10^9/L), with a total number of 82 patients (33.5%). According to the age of all patients at onset, we concluded that the median age was 33 years old, so we divided them into two groups: one group was less than or equal to 33 years old, and the other group was older than 33 years old. We found no statistically significant difference between the high and low SII groups in terms of age, blood type, birth mode, pathogenic site, skin involvement, and time from birth to onset. There was a significant difference in lesion size between the two groups ($\chi2=14.875$, $p=0.001$). The range of inflammation in the high SII group was greater than that in the low SII group. All clinical parameters are listed in Table 1.

Association Between SII and Recurrence of GM

We observed the recurrence and postoperative course of recovery in all patients to evaluate the prognosis of the disease after surgery. We divided the recovery time into 4 groups: less than or equal to 1 month, greater than 1 month and less than or equal to 3 months, greater than 3 months and less than or equal to 6 months, and greater than 6 months. The statistical analysis results showed that, as shown in Table 2, there was a significant difference in the recurrence rate between the low SII group and the high SII group ($\chi2=15.618$, $p=0.000$), and the high SII group had a higher recurrence rate than the low SII group. There was no statistically significant difference in postoperative recovery time between the two groups.

Correlation Between SII and Outcome of GM

Further analysis was conducted on the cumulative no-recurrence rate of the low SII group and high SII group within 24 months of surgery. We concluded that the cumulative no-recurrence rate in the total sample was 77.1% at 24 months (Figure 1A). The cumulative no-recurrence rate in the low SII group was higher than that in the low SII group (Hazard Ratio (HR) =2.873, 95% confidence interval (CI): 1.624–5.084, $p<0.0001$) (Figure 1B). This implies a high recurrence rate of GM in the high-SII group.

Table 1 Relationships Between SII and Clinical Parameters of All Enrolled Patients

Parameter Cases(n)	245	Low SII≤836	High SII>836	χ2	*p* value
		163 (66.5%)	82 (33.5%)		
Age (years)					
≤33	158	101 (63.9%)	57 (36.1%)	1.358	0.244
>33	87	62 (71.3%)	25 (28.7%)		
ABO blood type					
O	72	51 (70.8%)	21 (29.2%)	5.513	0.138
A	80	56 (70.0%)	24 (30.0%)		
B	64	35 (54.7%)	29 (45.3%)		
AB	29	21 (72.4%)	8 (27.6%)		
Birth mode					
Nonparous	14	9 (64.3%)	5 (35.7%)	0.146	0.975
Eutocia	97	64 (66.0%)	33 (34.0%)		
Caesarean	134	90 (67.2%)	44 (32.8%)		
Pathogenic site					
Right	122	81 (66.4%)	41 (33.6%)	0.002	0.964
Left	123	82 (66.7%)	41 (33.3%)		
Size of lesion (cm)					
≤2	61	50 (82.0%)	11 (18.0%)	14.875	0.001*
>2 and ≤5	144	95 (66.0%)	49 (34.0%)		
>5	40	18 (45.0%)	22 (55.0%)		
Skin involvement					
No	175	118 (67.4%)	57 (32.6%)	0.222	0.638
Yes	70	45 (64.3%)	25 (35.7%)		
Time from birth to onset (years)					
≤2	92	60 (65.2%)	32 (34.8%)	1.149	0.563
>2 and ≤5	108	70 (64.8%)	38 (35.2%)		
>5	45	33 (73.3%)	12 (26.7%)		

Note:*$p<0.05$.
Abbreviation: SII, systemic immune-inflammation index.

Univariate and Multivariate Analyses of Recurrence

In the previous section, we analyzed the relationship between GM recurrence and SII levels. Here, we further analyzed the factors that influence disease recurrence. These factors include age, blood type, birth mode, pathogenic site, lesion size, skin involvement, use of corticosteroids after surgery, and the time from birth to onset. We divided the patients into two age groups: ≤ 33 years and > 33 years. The recurrence rate in the younger group was higher than that in the older group ($\chi2=4.793$, $p=0.029$). Patients with skin involvement had higher recurrence rate than patients without skin

Table 2 Association Between SII and Recurrence of GM

Parameter Cases(n)	245	Low SII≤836	High SII>836	χ2	*p* value
		163 (66.5%)	82 (33.5%)		
Recurrence					
No	189	138(73.0%)	51(27.0%)	15.618	0.000*
Yes	56	25(44.6%)	31(55.4%)		
Postoperative course of recovery (months)					
≤1	96	68(70.8%)	28(29.2%)	1.580	0.664
>1 and ≤3	81	52(64.2%)	29(35.8%)		
>3 and ≤6	38	25(65.8%)	13(34.2%)		
>6	30	18(60.0%)	12(40.0%)		

Note:*$p<0.05$.
Abbreviations: SII, systemic immune-inflammation index; GM, granulomatous mastitis.

involvement (χ2=5.558, p=0.018). The use of corticosteroids after surgery increased the recurrence rate (χ2=5.868, p=0.015). There were no relationship between the remaining clinical parameters and the recurrence rates. We used a binary logistic regression model for the multivariate analysis to comprehensively study the factors that influence recurrence. We found that age and postoperative corticosteroid use significantly affected recurrence. The risk of recurrence in patients older than 33 years was lower than that in patients younger than or equal to 33 years (odds ratio (OR)=0.349, 95% CI: 0.162–0.75, p=0.007). The risk of recurrence in patients who received corticosteroids after surgery was higher than that in patients who did not (OR=2.298, 95% CI: 1.182–4.469, p=0.014). In contrast to the univariate analysis, skin aggression had no effect on increasing the risk of GM recurrence in the multivariate analyses (OR=1.997, 95% CI: 0.995–4.007, p=0.052) (Table 3).

Relationship Between SII Level and Outcome of GM in Different Subgroup

Through analysis, we found that there was an association between SII level and GM recurrence. We then performed univariate and multivariate analyses to reveal the influence of age and postoperative corticosteroid use on GM recurrence. Here, we performed a subgroup analysis to explore the relationship between SII levels and recurrence in different age groups and corticosteroid-using groups. The results showed that, no matter young group (HR=2.324, 95% CI: 1.243–4.346, p=0.0037) or elder group (HR=4.303, 95% CI: 1.141–16.22, p=0.0035), the cumulative no-recurrence rate of the high SII group was lower than that of the low SII group (Figure 2A and B). Similarly, for the postoperative

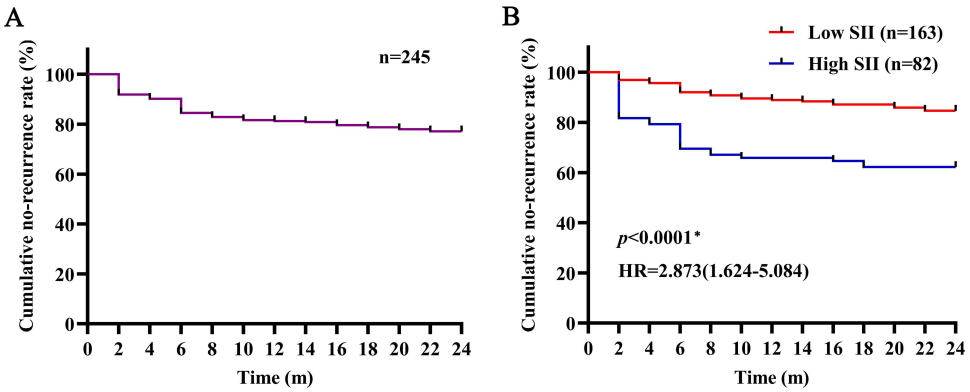

Figure 1 Correlation between SII and outcome of GM. (**A**). The cumulative no-recurrence rate of all patients within 24 months after surgery. (**B**). The cumulative no-recurrence rate of the patients with different SII within 24 months after surgery. (*$p<0.05$; HR, Hazard Ratio).

Table 3 Univariate and Multivariate Analyses for the Risk of GM Recurrence

Parameter Cases (n)	245	Recurrence		Univariate analysis		Multivariate analysis	
		NO	Yes	χ2	*p* value	OR (95% CI)	*p* value
Age (years)							
≤33	158	115 (72.8%)	43 (27.2%)	4.793	0.029*	1 (reference)	0.007*
>33	87	74 (77.1%)	13 (22.9%)			0.349 (0.162–0.75)	
ABO blood type							
O	72	57 (79.2%)	15 (20.8%)	0.978	0.806		
A	80	60 (75.0%)	20 (25.0%)				
B	64	51 (79.7%)	13 (20.3%)				
AB	29	21 (72.4%)	8 (27.6%)				
Birth mode							
Nonparous	14	10 (71.4%)	4 (28.6%)	0.767	0.677		
Eutocia	97	77 (79.4%)	20 (20.6%)				
Caesarean	134	102 (76.1%)	32 (23.9%)				
Pathogenic site							
Right	122	93 (76.2%)	29 (23.8%)	0.115	0.735		
Left	123	96 (78.0%)	27 (22.0%)				
Size of lesion (cm)							
≤2	61	44 (72.1%)	17 (27.9%)	2.27	0.321		
>2 and ≤5	144	111 (77.1%)	33 (22.9%)				
>5	40	34 (85.0%)	6 (15.0%)				
Skin involvement							
No	175	142 (81.1%)	33 (18.9%)	5.558	0.018*	1 (reference)	0.052
Yes	70	47 (67.1%)	23 (32.9%)			1.997 (0.995–4.007)	
Time from birth to onset (years)							
≤2	92	69 (75.0%)	23 (25.0%)	0.473	0.79		
>2 and ≤5	108	84 (77.8%)	24 (22.2%)				
>5	45	36 (80.0%)	9 (20.0%)				
Corticosteroid use							
No	156	128 (82.1%)	28 (17.9%)	5.868	0.015*	1 (reference)	0.014*
Yes	89	61 (68.5%)	28 (31.5%)			2.298 (1.182–4.469)	

Note:*$p<0.05$.
Abbreviations: GM, granulomatous mastitis; OR, odds ratio; CI, confidence interval.

corticosteroid use group or the non-corticosteroid use group, the cumulative no-recurrence rate of the high SII group was lower than that of the low SII group (HR=2.461, 95% CI: 1.128–5.368, p=0.0236 and HR=4.096, 95% CI: 1.706–9.833, p=0.0016, respectively) (Figure 2C and D).

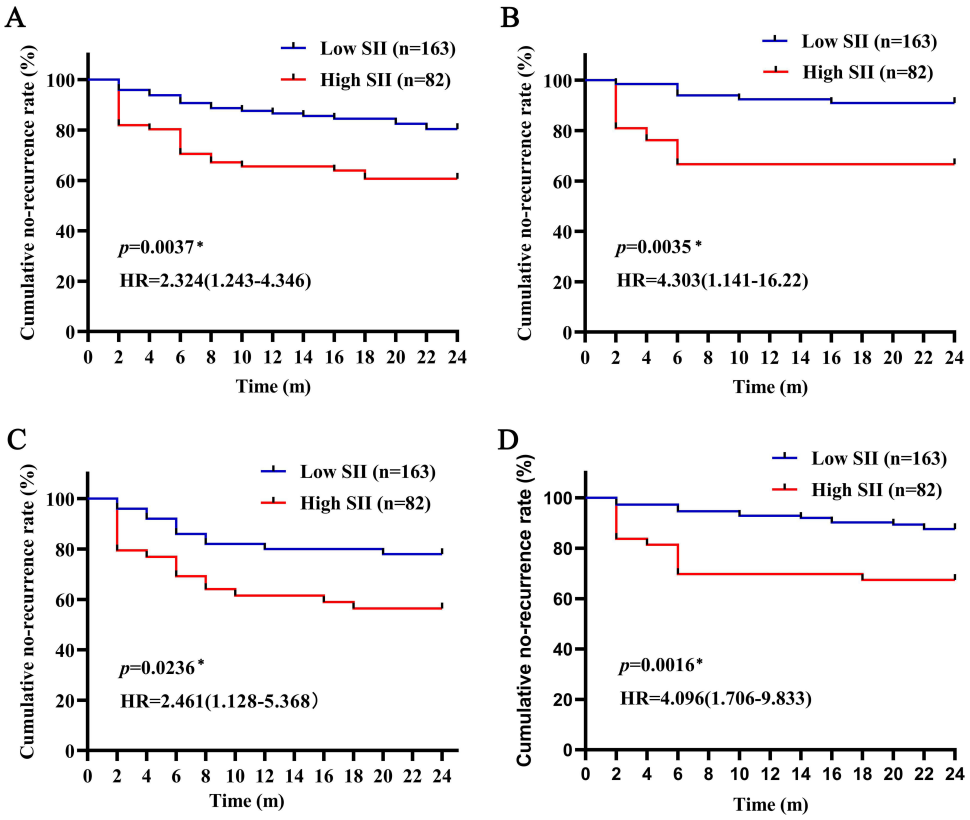

Figure 2 Relationship between SII level and outcome of GM in different subgroup. (**A**)The cumulative no-recurrence rate of patients less than or equal to 33 years old in different SII groups. (**B**). The cumulative no-recurrence rate of patients older than 33 years old in different SII groups. (**C**). The cumulative no-recurrence rate of patients used corticosteroid in different SII groups. (**D**). The cumulative no-recurrence rate of patients did not use corticosteroid in different SII groups. (*p<0.05; HR, Hazard Ratio).

Discussion

Granulomatous mastitis (GM) is a special type of inflammatory breast disease. However, its pathogenesis remains elusive and lacks a specific treatment regimen.[22] This dilemma results in patients enduring a prolonged disease course with a significant impact on their quality of life. Current treatments, such as observation, antibiotics, corticosteroids, immunosuppressants, or surgery, have shown limited effectiveness. Medical therapy is now widely accepted, while surgical treatment is controversial due to the existence of the risks of recurrence, scarring, and poor cosmetic. Whether need surgery or when need surgery is not clear.[23]

A meta-analysis was performed to compare the different between the surgical approaches and medical therapy, including corticosteroids and antibiotics and immunosuppressive therapy. They demonstrated that there is no significant difference in the recurrence of GM between the surgical and conservative approaches.[24] In fact, there are also dissenting views on whether surgical treatment is an alternative choice for GM. The approaches to treatment of GM should be applied according to the different clinical stage of GM. A study invited 66 international experienced multidisciplinary experts from 11 countries to establish evidence-based recommendations for the management of GM. They strongly recommend that surgery is the most effective in complex lesions with limited focus, sinus tract, and without abscess, including abscess excision and drainage, segmental dissection, enlarged dissection. Previous studies suggest that surgical resection is a little aggressive for the GM patients, but it has often been the next optimal choice if initial steroids treatment proves unsuccessful,[6,7] From another perspective, GM usually has a self-limiting process, and the overall goal of treatment is reassurance, symptomatic relief and support until the end of the course. Therefore, surgical treatment is likely to be successful when undertaken appropriately in those cases that do not respond to medical therapy, especially with persistent sinus tracts.[23] However, the surgical treatment not only leads to the loss of breast volume but also has

a high recurrence rate, which aggravates the anxiety of patients.[25] Thus, the essential consideration in surgical treatment is the evaluation of postoperative recurrence risk before surgery.

Several studies have assessed the risk factors for GM prognosis, such as the mean number of births, lactation duration, BMI, fistulas, abscess presence, and luminal inflammation.[26,27] However, their statistical data did not subdivide the prognostic factors of patients with GM according to the different treatment regimens. In our study, we analyzed the preoperative clinicopathological parameters of surgically treated patients to identify the risk factors for postoperative recurrence to provide guidance for treatment decisions.

Granulomatous mastitis, as an immune inflammation, engages in a complex interplay between the inflammatory and immunological responses. This relationship affects the local inflammatory responses and tissue repair processes, which can determine the prognosis of GM. The Systemic Immune-Inflammation Index (SII), calculated by neutrophil (N), platelet (P), and lymphocyte (L) counts, is a stable indicator of local immune response and systemic inflammation. Thus, it is usually used to predict the prognosis of patients with malignant tumors and infectious diseases.[28–30] Although previous studies have primarily focused on the platelet-lymphocyte ratio (PLR) or neutrophil-lymphocyte ratio (NLR), our study uniquely combined these three hematological parameters to evaluate GM prognosis through SII levels before surgery.

Our clinical sample analysis revealed a correlation between lesion size and preoperative SII levels, with larger lesions indicating higher SII. This association is logical, as the SII reflects the overall inflammatory indices, particularly elevated in the presence of larger lesions. Subsequent prognostic analysis revealed a higher recurrence rate in the high SII group than that in the low SII group. Although all patients were cured within two years post-surgery, the cumulative no-recurrence rate was 77.1% within 24 months after surgery, which was better than the recurrence rate of 50% reported in some studies,[31,32] indicating that surgery was a viable alternative treatment. Furthermore, the cumulative no-recurrence rate in the high SII group was lower than that of the low SII group. Since the SII was related to the recurrence rate of GM, we explored the factors affecting the recurrence of GM through univariate and multivariate analyses and further analyzed the subgroups with the influencing factors to determine the relationship between the SII and recurrence.

Further analysis identified age at disease onset and postoperative hormone use as the factors influencing GM recurrence. Younger patients exhibit a higher risk of recurrence, which may be related to a more severe inflammatory response to the stronger immunity of these young people. First, the scope of surgical resection may not cover the entire area of the lesions with inflammatory changes. Second, for young patients with severe local inflammation, surgeons might limit the scope of resection of inflamed breast tissue because of the aesthetic considerations of the breast. Although some meta-analyses revealed that many patients achieved complete remission with a combination of surgical management and corticosteroids,[33,34] we found that postoperative corticosteroid use could increase the risk of recurrence. The conclusion was different from the data of other research might be related to the timing of corticosteroid use. In the early stages of the disease, corticosteroids can rapidly reduce the scope of the inflammatory mass and create an opportunity for surgery, which could result in a better curative effect. However, postoperative hormone use disrupts the inflammatory repair. Furthermore, disease relapse occurs when drugs are interrupted.

Although skin involvement was associated with GM recurrence in the univariate analysis, the multivariate analysis suggested no significant effect between them. This inconsistency might arise from unaccounted confounding factors in the univariate analysis. Notably, nipple involvement, skin ulceration, and abscess formation have been reported as high risk factors for recurrence in other studies.[35] Thus, we could consider that skin ulceration was associated with GM recurrence by influencing other factors, but it might not be directly involved in disease recurrence.

This study had certain limitations. First, the patients were divided into a low SII group and a high SII group, which correlated with the lesion size. Thus, bias may be introduced in the subsequent analysis of recurrence risk in the low and high SII groups. Second, this study was a single-center design with a small sample size, which also limited statistical robustness. In addition, this study was a follow-up analysis based on cut-off values. It may be difficult to compare the conclusions for different cut-off values. Therefore, future large-sample prospective randomized controlled trials are essential to determine the prognosis of GM definitively. Larger prospective studies can be conducted to validate the findings and address limitations.

Conclusions

Our preliminary findings suggest an association between SII and GM recurrence. High SII levels can increase the risk of GM recurrence. Therefore, when considering the choice of surgical treatment, we can evaluate the SII level of GM patients. If it is at a high level, it is better to consider other treatment methods instead of surgical treatment. In addition, younger patients or patients with skin involvement exhibit a higher risk of recurrence, so we also need to be cautious in choosing surgical treatment. If surgery has been chosen as the treatment, the use of hormones after surgery should be avoided. To sum up, the preoperative SII, which is easily obtainable and prognostically meaningful, can guide treatment decisions when combined with patient age, skin involvement, and postoperative hormone use.

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Disclosure

The authors report no conflicts of interest in this work.

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