Research Square

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A Breast Clinical Scoring System to Identify Women with Idiopathic Granulomatous Mastitis

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Abstract

Purpose

Idiopathic granulomatous mastitis (IGM) is a benign inflammatory breast condition that can resemble mastitis or malignancy clinically and radiographically. We aimed to develop a quantitative scoring system, based off the Komen Inflammatory Breast Cancer (IBC) scoring system[1], evaluating clinical and radiologic features to distinguish IGM from benign and malignant breast conditions.

Methods

We conducted a retrospective chart review of biopsy-proven IGM patients diagnosed from 2014 to 2025 via institutional electronic medical records. Clinical symptom onset, features, and diagnostic imaging were analyzed. A continuous scoring scale (1–50) was created, encompassing three categories: symptom onset, clinical features, and radiographic findings. Scores of IGM patients were compared with those of patients diagnosed with IBC, mastitis (lactational and non-lactational), and locally advanced breast cancer (LABC). Welch's two-sample t-test assessed statistical differences, and Youden index identified the optimal score threshold for predicting IGM.

Results

Among 148 IGM patients, predominantly Hispanic (56.8%) and Asian (26.7%), the mean age was 37.2 years, older than mastitis patients and younger than IBC patients. Key clinical features included pain or painful breast mass (100%), fistula or draining wound (77.7%), erythema (94.6%), and phlegmon (87.8%). Imaging revealed mass with collection in 84.6% and multiple masses/collections in 38.9%. The mean IGM score (35.5) was significantly higher than scores for IBC, mastitis, and LABC groups (14.4, 18, and 15.2, respectively; $p \leq 0.05$). A score ≥ 24.5 predicted IGM with 93% sensitivity and 95% specificity.

Conclusions

This novel scoring system provides an objective framework to differentiate IGM from similar breast conditions, facilitating early diagnosis and guiding appropriate management.

Introduction

Granulomatous mastitis (GM) is a rare benign inflammatory breast condition that poses diagnostic and therapeutic challenges due to its clinical and radiologic similarities to acute mastitis and breast malignancies. Idiopathic granulomatous mastitis (IGM) is a subset of GM characterized histologically by lobulocentric granulomatous inflammation in the breast parenchyma[2]. The term IGM is used when this granulomatous lobular inflammation is present on core biopsy and other infectious, systemic, and malignant causes of granulomatous disease have been excluded[2, 3]. In this study, we focus on evaluating and diagnosing IGM, defined as granulomatous mastitis without an identifiable etiology after appropriate evaluation.

The clinical and radiologic presentation of IGM is similar to those of locally advanced breast cancer. IGM is commonly characterized by a unilateral breast mass with associated pain, erythema, fistulas or sinus tracts[4]. Some patients can present with nipple retraction, enlarged axillary lymph nodes, or have extramammary symptoms, such as fevers, arthralgias, or erythema nodosum. Common sequelae include scarring of the skin, retraction of nipple and skin, and overall shrinkage of the entire breast[5]. The variable and nonspecific presentation of IGM can mimic the erythema, warmth, and tenderness seen in infectious mastitis or peau d'orange and skin thickening encountered in inflammatory breast cancer (IBC). The presence of an ill-defined mass with overlying skin changes may similarly appear in locally advanced breast cancer. These overlapping clinical and radiographic features frequently lead to delays in the diagnosis of IGM and can result in inappropriate management, including unnecessary surgical procedures or prolonged antibiotic therapy[6].

Radiologic features of IGM are also varied and nonspecific. On ultrasound, IGM can present as parenchymal heterogeneity and/or one or multiple ill-defined hypoechoic or heterogenous masses with tubular hypoechoic extensions connecting the dominant mass to other smaller masses[7]. These can be associated with fluid collections and sometimes with tubular hypoechoic extensions to the subcutaneous tissues and skin[7]. On mammogram, focal asymmetric density is the most common pattern found. While a diffuse increase in breast density can also be seen, this more commonly raises the suspicion of malignancy[7]. On breast MRI, IGM typically manifests as rim-enhancing masses or clustered ring-like non mass enhancement often associated with ductal ectasia and periductal enhancement. Recent MRI studies demonstrate that dynamic enhancement patterns and diffusion-weighted imaging parameters of IGM overlap substantially with invasive cancers, indicating that breast MRI has limited discriminatory value and tissue diagnosis is often needed for distinguishing IGM from malignancy and other conditions[8].

Histopathologic analysis of core needle biopsy is essential in diagnosing IGM. It is histologically characterized by non-caseating granulomatous inflammation centered on the breast lobules and may be accompanied by microabscesses and suppurative necrosis but often does not have identifiable microorganisms[5]. Though most cases of IGM are not associated with a bacterial infection, there is a small subset of patients that have a strong correlation with a Corynebacterium infection[9]. This subtype has been classified as cystic neutrophilic granulomatous mastitis (CNGM); histopathologic characteristics of CNGM include lipid vacuoles within granulomas and cystic spaces lined by neutrophils and epithelioid histiocytes[10]. Importantly, the histopathologic features of IGM may overlap with other breast pathologies, including infective and non-infective mastitis, vasculitis, post-partum duct ectasia, squamous metaplasia of lactiferous ducts, and systemic autoimmune granulomatous diseases, such as sarcoidosis[11]. The presence of atypical features should prompt re-evaluation of diagnosis. Additionally, malignant conditions may cause inflammation and granulomatous reactions in the adjacent breast parenchyma and co-occurrence of IGM and breast carcinoma has been reported.

Current management for IGM includes intralesional steroid injections, or in more resistant cases—oral corticosteroids, immunomodulatory agents, such as methotrexate, azathioprine, and TNF inhibitors, and

aspirations or surgical excisions. Surgical intervention, however, should only be reserved for refractory cases. Though options exist for the treatment of IGM, there are limited evidence-based guidelines for the management of this condition[10].

As there are several confounding factors to diagnosing IGM, we propose a novel scoring system to offer a standardized approach to diagnosing IGM based on clinical and radiologic features that can distinguish it from other benign and malignant breast conditions to enhance patient stratification and treatment planning.

Methods

A retrospective cohort study was performed for patients with biopsy-proven GM and fit the defined criteria for IGM with histologic findings of granulomatous inflammation, and no alternative cause of granulomatous inflammation was identified based on clinical history, imaging, or pathology. These patients were diagnosed between January 2014 and October 2025 and were identified through institutional electronic medical records using a structured query incorporating relevant diagnosis codes and pathology reports. Additional cohorts of patients with definitive diagnoses of mastitis, locally advanced breast cancer (LABC), and inflammatory breast cancer (IBC) were identified for comparison. Comparator cohorts were identified using diagnosis codes and pathology reports for mastitis, IBC, and LABC, and only cases with definitive pathologic confirmation of IBC and LABC and clear documentation of mastitis were included.

Demographic and reproductive variables including age, body mass index (BMI), ethnicity, smoking status, number of pregnancies and live births, current or prior use of birth control, and current or prior history of breastfeeding was obtained from the EMR. Data on onset of symptoms, clinical features, and diagnostic imaging findings were also obtained, and imaging modalities from which data was collected included mammogram, ultrasound, and magnetic resonance imaging (MRI).

To systemize the clinical presentation of IGM, a continuous scoring system was developed and was validated exclusively within the IGM population that met the definition criteria above. The score ranging from 1 to 50 was based on the most frequently reported clinical features identified in the IGM cohort. The initial structure of the scoring system was adapted from the Komen IBC diagnostic score[1] with modifications to reflect features most relevant to IGM. The proposed IGM scoring system incorporated three categories: onset of symptoms, clinical features, and radiographic findings (Table 1). These variables were selected from routinely documented clinical and radiologic findings that were highly prevalent, diagnostically informative in IGM, and consistent with published descriptions of IGM[12]. Each variable was assigned a base score (1–3), where 1 is least specific for IGM and 3 is definitely associated with IGM. This base score was multiplied by a priority factor (1–3) to generate a weighted score. Features that were common and strongly associated with IGM (pain or painful breast mass, and fistula or draining wound) received the highest weights, while nonspecific findings (nipple retraction) were given the lowest weights. Similarly, intermediate symptom duration and imaging features, including a mass

with associated fluid collection or multiple masses/fluid collections, were given higher weights because they occur more frequently in IGM and help differentiate it from mastitis or malignancy.

Table 1
Idiopathic granulomatous mastitis (IGM) scoring system.

Category	Feature	Score		Priority Factor	Weighted Score
Onset of symptoms	≤ 1 week	1		x1	1
	> 1 week ≤ 3 mo	3		x2	6
	4–6 mo	2		x2	4
	> 7 mo	1		x2	2
Clinical Features		**P**	**NP**		
	Pain or painful breast mass	3	0	x3	9
	Fistula or draining wound	3	0	x3	9
	Erythema	2	0	x2	4
	Phlegmon	2	0	x2	4
	Nipple retraction or asymmetry	1	0	x1	1
Imaging Findings	Mass with collection	3	0	x2	6
	Multiple collections or masses	2	0	x2	4
Total Score					50
**P – Present; NP – Not Present*					

An IGM score was calculated for each patient with biopsy-proven IGM and compared with scores from three comparator groups: patients diagnosed with mastitis, including both lactational and non-lactational forms, inflammatory breast cancer (IBC), and locally advanced breast cancer (LABC) using the same EMR query strategy. Base scores (1–3) and priority factors (1–3) were determined a priori by a multidisciplinary team including breast surgeons, breast radiologists, and rheumatologists based on perceived specificity for IGM and frequency within our cohort. We then examined distributions of each feature and its association with biopsy-proven IGM versus comparator diagnoses to confirm that higher weighted items demonstrated stronger differentiation, and we refined weights when discordance was observed. To determine the optimal score threshold for identifying IGM, we calculated Youden's J statistic across all possible cutoff values and selected the score that maximized combined sensitivity and specificity.

The treatment of IGM was then categorized and stratified by mean IGM score. Treatment modalities included: immunomodulatory medications (methotrexate, azathioprine, adalimumab, or infliximab), corticosteroid therapy (intralesional or oral steroids), antibiotics, aspiration or incision and drainage, and no treatment. For treatment comparisons, Welch's two-sample t-tests were used to compare mean IGM scores for each treatment modality with the overall IGM cohort.

Non-parametric comparisons were performed using a chi-squared test. Parametric comparisons were performed using Welch's two-sample t-tests. A two-sided p-value of less than 0.05 was considered statistically significant. All statistical analysis was performed using Python (version 3.12) with SciPy (version 1.14.1) and pandas (version 2.2.2) software.

The study was approved by the institutional review board, and the requirement for individual informed consent was waived given the retrospective nature of the analysis.

Results

A total of 148 patients with biopsy-proven IGM were identified and compared with 6 patients with mastitis (lactational and non-lactational), 8 patients with inflammatory breast cancer, and 5 patients with locally advanced breast cancer (LABC). Baseline patient characteristics are summarized in Table 2.

Table 2
Patient demographics and characteristics amongst Idiopathic Granulomatous Mastitis (IGM), mastitis, Inflammatory Breast Cancer (IBC), and Locally Advanced Breast Cancer (LABC) cohorts. Bold is significant at $p < 0.05$.

Patient characteristics		**IGM (n = 148)**	**Mastitis (n = 6)**	**p-value**	**IBC (n = 8)**	**p-value**	**LABC (n = 5)**	**p-value**
Age, mean (SD)		37.2 (8.3)	31.5 (2.7)	**0.002**	51.5 (13.6)	**0.02**	51.4 (16.9)	0.14
BMI, mean (SD)		30.3 (6.8)	24.6 (3.7)	**0.01**	27.2 (4.9)	0.12	31.7 (3.3)	0.41
Race/ Ethnicity, n (%)	White	26 (17.6)	0 (0)	0.59	3 (37.5)	0.15	1 (20)	1
	Hispanic	84 (56.8)	3 (50)	1	1 (12.5)	**0.03**	1 (20)	0.19
	Asian	38 (26.7)	2 (33.3)	0.64	1 (12.5)	0.68	1 (20)	1
	Other	7 (4.7)	1 (16.7)	0.27	3 (37.5)	**0.008**	2 (40)	**0.03**
No. of pregnancies, mean (SD)		2.3 (1.6)	1.3 (0.8)	**0.03**	2.3 (2.8)	0.92	1.8 (36)	0.53
Current Breast-feeding, n (%)		4 (2.7)	5 (83.3)	**< 0.0001**	0 (0)	1	0 (0)	1
History of breastfeeding, n (%)		108 (73.0)	6 (100)	0.32	5 (62.5)	0.8	3 (60)	0.89
Current or prior birth control, n (%)		93 (62.8)	0 (0)	**0.009**	5 (62.5)	1	4 (80)	0.72
Current smoker, n (%)		3 (2.0)	1 (16.7)	0.37	0 (0)	1	0 (0)	1

Clinical and radiologic features of patients are shown in Table 3. For IGM patients, the most common clinical features included painful breast mass (100%), fistula or draining wound (77.7%), erythema (94.6%) and phlegmon (87.8%). On imaging, 85.1% demonstrated a mass with an associated fluid collection while 39.2% of patients presented with multiple masses or multiple fluid collections.

Table 3
Number of patients with clinical and radiologic features related to Idiopathic Granulomatous Mastitis (IGM) according to the IGM scoring system. Bold is significant at $p < 0.05$.

Clinical and radiologic features		IGM, n (%)	Mastitis, n (%)	IBC, n (%)	Locally advanced breast cancer, n (%)
Onset of symptoms	≤ 1 week	0 (0)	6 (100)	0 (0)	1 (16.7)
	> 1 week ≤ 3 mo	118 (79.7)	0 (0)	4 (50)	1 (16.7)
	4–6 mo	14 (9.5)	0 (0)	2 (25)	0 (0)
	> 7 mo	17 (11.5)	0 (0)	2 (25)	3 (60)
Pain or painful breast mass		148 (100)	6 (100)	5 (62.5)	3 (60)
Fistula or draining wound		115 (77.7)	0 (0)	0 (0)	2 (33.3)
Erythema		140 (94.6)	6 (100)	8 (100)	3 (60)
Phlegmon		130 (87.8)	5 (83.3)	0 (0)	0
Nipple retraction or symmetry		27 (18.2)	0 (0)	2 (25)	2 (33.3)
Mass with collection		126 (85.1)	0 (0)	0 (0)	0 (0)
Multiple masses or collections		58 (39.2)	0 (0)	0 (0)	1 (16.7)
Mean IGM Score (SD)		35.5 (6.9)	18 (2.5)	14.4 (5.0)	15.2 (11.5)
p-value			**< 0.0001**	**< 0.0001**	**0.016**

In comparison, pain or painful breast mass and erythema were common across all groups, whereas the presence of a fistula or draining wound was seen most in the IGM cohort (77.7%), followed by the LABC cohort (33.3%), but not in the mastitis or IBC cohorts. On imaging, a mass with associated fluid collection was characteristic of IGM (85.1%) but not observed in the other cohorts. Multiple masses or fluid collections seen were uncommon in all cohorts but were the most characteristic of the IGM group (39.2%).

The mean IGM score was significantly higher in the IGM cohort than the mastitis, IBC, and LABC cohorts with a score of 35.5 vs 18, 14.4, and 15.2, respectively ($p \leq 0.05$). Using Youden's J index across all possible score thresholds, a cutoff of 24.5 best distinguished IGM from the comparator groups, yielding

a sensitivity of 93% and specificity of 95% (Fig. 1). The area under the receiver operating characteristic curve (AUC) was 0.977, indicating very high discriminative ability of the model to distinguish between patients with and without IGM.

Among the 148 patients with biopsy-proven IGM, 66.9% of patients were treated with immunomodulatory therapy with at least one of the following: methotrexate, azathioprine, adalimumab, or infliximab. 33.8% of patients were treated with other therapies including intralesional or oral corticosteroids (19.6%), antibiotics with aspiration or incision and drainage (10.1%), or no treatment (3.4%) (Table 4). The IGM score was stratified by treatment group and overall, those treated with immunomodulatory therapy had a higher mean score of 35.9 compared to patients treated with other modalities.

Table 4
Mean IGM scores according to treatment modality in patients with Idiopathic Granulomatous Mastitis (IGM).

Treatment modality	N (%)	Mean IGM score (SD)	p-value
Immunomodulatory medications	99 (66.9)	35.9 (6.3)	0.64
Other	49 (33.8)	34.5	0.65
Intralesional steroids/oral steroids	29 (19.6)	35.8 (6.6)	0.82
Antibiotics/aspiration/I&D	15 (10.1)	33.9 (8.5)	0.49
No treatment	5 (3.4)	28.8 (11.0)	0.25

Discussion

IGM is a rare, benign chronic inflammatory lesion of the breast that manifests clinically and radiographically as palpable breast masses in young women, making it challenging to differentiate from either mastitis or malignancy[13]. In this study, we developed a clinical quantitative scoring system designed to differentiate IGM from other inflammatory and malignant breast conditions by integrating clinical features, symptom onset, and imaging findings into a weighted scale. This tool aids in enhancing the diagnosis of IGM, which is challenging as the clinical presentation of IGM can overlap with infection and malignancy, thereby delaying appropriate treatment. The IGM score was significantly higher than those of the other cohorts, demonstrating a distinct clinical profile in this disease process.

In this cohort, IGM demonstrated a distinct demographic profile compared with mastitis, IBC, and LABC cohorts, suggesting several potential risk factors. Though IGM is seen globally, there is a higher racial predilection in Latin and Asian women[7]. IGM most commonly affects women of reproductive age, typically presenting in the mid-late thirties[4, 14] In our cohort, patients with IGM were significantly older that those with lactational mastitis, 37 years vs 31 years, supporting the notion that IGM affects parous women beyond the very young reproductive years. Its incidence is often higher within five years postpartum, suggesting a strong association with recent pregnancy and lactation[14]. In our study, IGM patients had a greater number of pregnancies than women with mastitis, reaffirming that greater parity is

a risk factor for the occurrence of IGM[15, 16]. This may be a result of several proposed pathways involving a repetition of lactational cycles, hormonal fluctuations and milk stasis, which can trigger inflammatory responses, microinjury, and granuloma formation, further exacerbated by repeated pregnancies and breastfeeding episodes, which may cause ductal damage in breast tissue[15]. In our study, IGM was also associated with a higher BMI, implicating possible metabolic or inflammatory pathways, which may play a factor in disease recurrence[16].

Consistent with previous reports, our findings affirm that IGM typically presents with a constellation of inflammatory symptoms including palpable breast masses, focal tenderness, localized or regional erythema, development of a phlegmon, and fistula or draining wounds[7]. Imaging characteristics such as the presence of masses with collections and multifocal lesions further support the inflammatory nature of IGM[17]. Many IGM patients develop recurrent abscesses and draining sinuses over weeks to months, which may be confused for recurrent episodes of mastitis[12]. These clinical and radiographic features were all common in the IGM cohort and less characteristic of the comparator groups, but by contrast, variables such as erythema and phlegmon by themselves are not specific on their own, reinforcing a need for a composite scoring approach. Our proposed scoring system adds value by integrating symptom evolution, recurrence, and radiographic features that are less typical of mastitis and malignancy.

The standard treatment strategy for IGM continues to evolve due to its rare occurrence and heterogeneous presentation. Systemic corticosteroids are frequently first-line treatment due to the rapid onset of anti-inflammatory and immunosuppressive effects, that can lead to complete or partial remission[18]. Though steroids are an effective non-surgical option, steroid toxicity also poses a problem with some studies recommending methylprednisolone 20mg for approximately 3 months resulting in a cumulative steroid dose of 2250 mg[19]. Avascular necrosis, osteoporosis, gastrointestinal bleeding. cardiovascular events are examples of risks associated with cumulative prednisone exposure of greater than 430 mg[20]. Studies demonstrate that immunosuppressive agents, such as methotrexate, have emerged as effective therapies in refractory IGM cases with remission rates up to 75%[21]. This has led to an increasing use of immunomodulatory medications, including azathioprine, adalimumab, and infliximab, particularly when prolonged corticosteroid use is undesirable[10]. Use of intralesional corticosteroids have also demonstrated efficacy, with studies reporting a clinical response exceeding 90%[22].In our cohort, 66.4% of patients required treatment with immunomodulatory medications, demonstrating refractory disease with initial therapies, including one or more of the following: antibiotics, aspirations, intralesional or oral steroids. Lastly, surgical excision may be used in cases refractory to medical management and may involve local excision versus mastectomy for patients with more extensive disease[10, 23].

Despite the lack of statistically significant differences in mean IGM scores across treatment modalities, the observed consistency of scores—ranging from 28.8 to 35.9—validates the proposed scoring system. The lack of significance is owed to the heterogeneity in the management of IGM and the small sample size of the cohort. However, while not statistically significant, there is a trend of increasing IGM scores

with escalating treatment. The lower mean IGM score of 28.8 aligns with clinical observation, emphasizing that milder cases of IGM may resolve spontaneously, while the higher scores of 35.9 warranted immunomodulatory therapy. This suggests that, beyond its primary role as a diagnostic aid, this scoring system has the potential to be used in risk stratifying patients and identifying patients who are more likely to benefit from early immunomodulatory therapy. The overall uniformity supports the score's validity as an objective diagnostic tool applicable at presentation, and even though it may not be able to guide clinicians towards the exact modality of treatment yet, it will be able to facilitate earlier intervention. Furthermore, prospective data could clarify how specific score thresholds guide clinicians towards specific management pathways.

The primary intent of this scoring system is to provide a structured, quantitative framework that reflects the characteristic clinical and imaging trajectory of IGM, rather than replace clinical judgement at a single time point. While some features, such as fistula or draining wound, may not be fully appreciable at the first encounter, they capture the protracted course that differentiates IGM from most cases of mastitis and malignancy over time. In practice, the score can be calculated at initial presentation and updated as additional information, such as symptom evolution, becomes available, thereby supporting diagnostic refinement and longitudinal risk stratification.

This scoring system is intended for use as a point of care decision-support tool, where clinicians must decide whether a patient's presentation is more consistent with IGM, mastitis, or malignancy, and whether to pursue biopsy, specialist referral, empiric treatment, or timely initiation of immunomodulatory therapy. The IGM score was significantly higher in the IGM cohort than in the mastitis, IBC, and LABC cohorts, and a threshold of 24.5 provided 93% sensitivity and 95% specificity, underscoring its value as an objective tool, especially when clinical and radiologic findings are ambiguous. We do not advocate forgoing tissue diagnosis in patients with suspicious clinical or radiologic features; rather, a high IGM score may prompt early multi-disciplinary involvement including breast surgery, radiology, and rheumatology and stratify patients who would benefit from additional imaging and biopsy. Because the component variables are routinely documented, this score can be calculated at initial presentation without additional testing or cost, making it feasible to incorporate into clinical practice.

Limitations of this study include a small single-center sample size and retrospective design. We recognize that the comparator sample sizes are small and may not fully capture the heterogeneity of mastitis, IBC, and LABC. Given that the base scores and priority factors in the scoring system were determined by consensus of the study team, future validation in larger, multi-institutional cohorts and prospective settings is warranted to confirm the clinical applicability of the scoring system.

Conclusion

Overall, IGM is a chronic inflammatory breast condition that is challenging to diagnose and has varied management strategies. This novel scoring system combines symptom chronology, clinical characteristics, and radiographic features to guide clinicians to more effectively identify patients with

IGM and distinguish them from other benign and malignant diagnoses, thus supporting earlier diagnosis, improving referral pathways, and reducing unnecessary delays in the management of this rare disease. Our proposed scoring system demonstrated a significantly higher score for those with IGM compared to those with mastitis or malignancy, therefore validating its utility.

Declarations

Clinical Trial number

not applicable

Competing Interests

The authors have no relevant financial or non-financial interests to disclose.

Ethics Approval

This is an observational study. The Stanford Research Ethics Committee has confirmed that no ethical approval is required.

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Author Contribution

All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by S.M, J.S, C.Y, and J.T. The first draft of the manuscript was written by S.M and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data Availability

The data that support the findings of this study are not publicly available due to patient privacy but are available from the corresponding author upon reasonable request.

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Figures

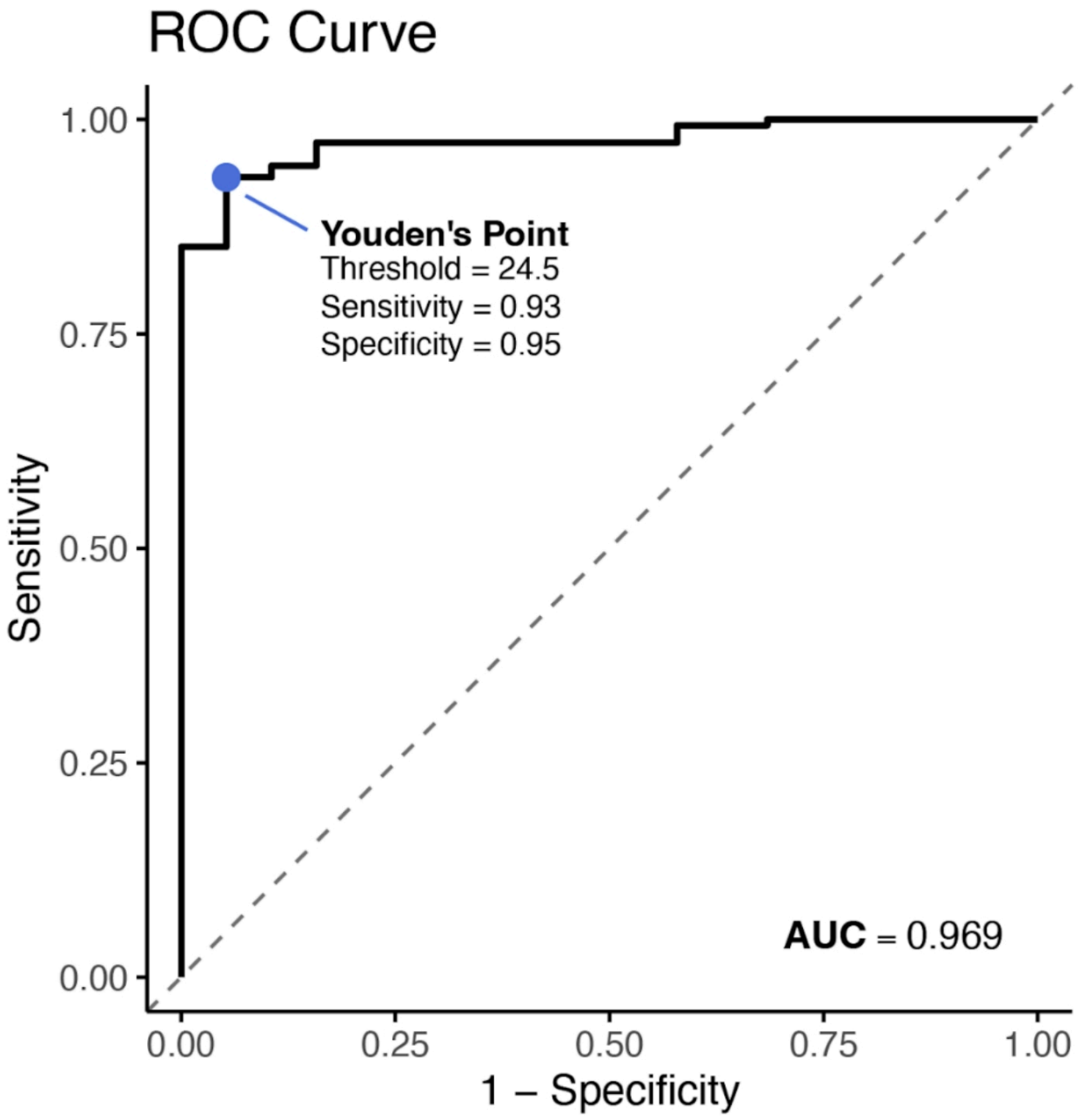


Figure 1

Determination of optimal IGM score cutoff using Youden's J statistic. Receiver operating characteristic (ROC) analysis was performed across candidate thresholds. AUC is area under the curve.

Supplementary Files

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