THE PLANET

Original Article

Clinical Characteristics and Associated Factors of Non-lactational Mastitis among Women Attending a Tertiary Care Hospital in Bangladesh

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ARTICLE INFO

Received: 11 October 2026
Accepted: 20 October 2026
Published Online: 03 November 2026

DOI: 10.5281/zenodo.23912027

Volume: 10, Number: 3, Page: 1084-1091

e-ISSN: 2789-5912
ISSN: 2617-0817

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ABSTRACT

Background: Non-lactational mastitis (NLM) is a heterogeneous group of inflammatory breast conditions, including granulomatous and periductal disease, that is frequently complicated by abscess formation. Data on its clinical profile in Bangladesh are scarce. **Objectives:** To describe the clinical characteristics of NLM among women attending a tertiary care hospital and to examine sociodemographic, reproductive and clinical factors associated with confirmed breast abscess. **Methods & Materials:** We conducted a hospital-based analytical cross-sectional study of 341 consecutively enrolled women aged 18 years or older with clinician-diagnosed NLM. Data were collected by interview, clinical examination and record review. The primary outcome was breast abscess confirmed by ultrasonography or aspiration/drainage. The proportion with abscess was estimated with an exact (Clopper-Pearson) 95% confidence interval. Groups were compared using chi-squared, Fisher's exact, Welch or Mann-Whitney U tests, and multivariable logistic regression was fitted with prespecified antecedent predictors. **Results:** Median age was 34 years (IQR 27 to 39); 61.0% lived in urban areas and 71.3% were homemakers. Abscess status was ascertainable in 340 women, of whom 235 had a confirmed abscess (69.1%; 95% CI 63.9 to 74.0). Breast pain (94.1%), swelling (83.9%) and a palpable lump (74.5%) were the commonest symptoms. Ultrasonography was done in 92.7%, biopsy in 45.5% and microbiology in 49.3%. The final diagnosis was idiopathic granulomatous mastitis in 34.3%, periductal mastitis in 29.0% and specific granulomatous mastitis in 4.7%. The proportion with abscess was highest in periductal mastitis (80.6%) and lowest in idiopathic granulomatous mastitis (60.7%) ($p = 0.031$, exploratory). Pain, erythema, larger lesion size and clinical suspicion were more frequent with abscess, but these are manifestations of the outcome and not antecedent factors. In the multivariable model ($n = 279$), no sociodemographic, reproductive or medical-history variable was significantly associated with abscess (all $p > 0.19$); discrimination was poor (AUC 0.61). **Conclusions:** About seven in ten women with NLM had a confirmed abscess at presentation, and abscess was not predicted by routinely collected background characteristics. Imaging confirmation should be pursued in every patient with a suspected collection, and pathological and microbiological work-up needs strengthening. Findings are associations only.

Keywords: *non-lactational mastitis; non-puerperal mastitis; breast abscess; granulomatous mastitis; periductal mastitis; Bangladesh.*

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INTRODUCTION

Breast inflammation that occurs outside the lactation period is clinically distinct from puerperal mastitis, which is driven mainly by milk stasis and infection of the lactating breast [1,2]. Non-lactational (non-puerperal) mastitis covers a spectrum that includes periductal mastitis, idiopathic granulomatous mastitis (IGM), specific granulomatous disease such as tuberculous mastitis, and other inflammatory lesions. These conditions share a presentation of pain, swelling, a lump and erythema, and can resemble carcinoma, which makes the diagnosis difficult [1,3].

The aetiology of NLM is incompletely understood. Autoimmune mechanisms, hyperprolactinaemia, hormonal contraception, local trauma and *Corynebacterium* infection have been proposed for IGM, but none is established [4,5]. Periductal mastitis has been linked to duct ectasia and, in particular, to cigarette smoking [6,7]. Because tuberculosis remains endemic in South Asia, breast tuberculosis must be actively excluded before granulomatous mastitis is labelled idiopathic [8]. The clinical course is often protracted, with abscess formation, sinus tracts, recurrence and repeated procedures, so that the burden falls on both patients and surgical services.

A recent retrospective series of 724 Chinese women with non-puerperal mastitis reported abscess formation in 72.5% [9]. Comparable data from Bangladesh are lacking, and the clinical profile, diagnostic work-up and case mix of patients attending Bangladeshi tertiary hospitals are largely undocumented. Local evidence is needed to inform diagnostic pathways, particularly the use of ultrasonography, biopsy and TB-specific testing, and to plan surgical and medical services.

A further methodological point guides this study. Abscess is a complication among women who already have mastitis, so factors associated with abscess within a mastitis population do not identify the causes of mastitis itself. In addition, many presenting features (pus discharge, ulceration, sinus formation, lesion size) are consequences of an abscess and should not be treated as antecedent risk factors. We therefore separated descriptive clinical features from prespecified antecedent characteristics in the analysis.

The objectives were (i) to describe the sociodemographic, reproductive and clinical characteristics of women with NLM; (ii) to estimate the proportions presenting with pain, swelling, lump, erythema, nipple discharge, confirmed abscess and sinus formation; (iii) to describe ultrasonographic, histopathological and microbiological findings and the documented diagnostic subtypes; and (iv) to assess associations between prespecified sociodemographic, reproductive and clinical characteristics and confirmed breast abscess.

METHODS & MATERIALS

Study design and setting

This was a hospital-based analytical cross-sectional study conducted in the Obstetrics and Gynaecology Department and Breast Surgery Unit of Chottogram Medical College Hospital, Bangladesh, between 10 January and 5 September 2026. Data were collected at a single index encounter from

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participant interview, clinician-confirmed examination findings and review of existing medical records. No follow-up was undertaken. The study is reported according to the STROBE statement for cross-sectional studies [10].

Participants

Women aged 18 years or older with clinician-diagnosed NLM, supported or refined by the available investigations, were eligible if they were not breastfeeding and had not breastfed in the preceding three months, and provided written informed consent. The three-month threshold was an operational definition agreed with the clinical team and not a universal clinical cut-off. We excluded women with lactational or puerperal mastitis, confirmed breast malignancy explaining the lesion, a mastitis diagnosis not supported after clinical assessment, or inability to consent. Eligible consecutive patients were approached until the target sample was reached; each woman was enrolled once and a screening log recorded reasons for non-participation.

Sample size

The sample size was calculated for estimating a single proportion [11]. Using an expected abscess proportion of 72.51% (525/724) from the Chinese series [9], 95% confidence ($Z = 1.96$) and absolute precision of 5%, the required sample was $n = Z^2 \times p \times (1 - p) / d^2 = 306.3$, rounded to 307. Allowing for 10% non-response (307/0.90) gave a final target of 341 women. This precision-based calculation does not guarantee adequate power for every regression comparison, and the multivariable analysis was therefore considered exploratory.

Variables and definitions

The **primary outcome** was the presence of a breast abscess at the index assessment, confirmed by ultrasonography or by documented aspiration or drainage. Women whose abscess status could not be ascertained (coded 8, not assessed) were reported separately and excluded from the denominator for the primary outcome and from binary comparisons; a suspected but unconfirmed abscess was not automatically classified as absent.

Candidate antecedent factors, prespecified on clinical grounds, were age, residence (urban or rural), education, parity, hormonal contraception in the preceding 12 months, diabetes mellitus, previous tuberculosis, previous non-lactational mastitis, previous breast surgery or procedure, personal tobacco use (current or former versus never), regular household exposure to tobacco smoke, breast injury or nipple piercing, body mass index (BMI) and symptom duration. Breast pain, swelling, lump, erythema, nipple discharge, fever, ulceration, pus discharge, sinus or fistula, lesion size and clinical suspicion of abscess were treated as clinical manifestations, described and compared but not entered in the regression model as risk factors. Symptom duration was measured in days from the first reported symptom to the index assessment. Final diagnosis was recorded as IGM, specific granulomatous mastitis, periductal mastitis, other non-lactational mastitis or unclassified/pending. IGM required the exclusion of specific causes, including tuberculosis, with the available tests; a negative work-up does not completely exclude tuberculosis.

Data collection and quality control

Trained interviewers administered a structured questionnaire (sociodemographic, reproductive, medical history and presenting symptom sections) translated into Bangla and pretested on 10 to 15 eligible patients. Examination and investigation sections were completed from clinician records and verified by the treating clinician. Investigations not undertaken were coded as "not performed" and never as negative. Data underwent range, consistency and duplicate checks. Empty fields were treated as not applicable or unknown as defined in the codebook, and responses coded "unknown" were treated as missing for analysis. The consistency checks identified 17 women recorded as ever pregnant with a gravidity of zero and 4 women with an ultrasonographic fluid collection who were not coded as having a confirmed abscess; these were retained as recorded and examined in a sensitivity analysis (section 3.7). Parity, rather than gravidity, was used as the reproductive predictor.

Statistical analysis

Analyses were done in Python 3 (SciPy and statsmodels). Categorical variables are presented as counts and percentages, calculated among participants with a known response, and continuous variables as mean (SD) or median (IQR) according to distribution (Shapiro-Wilk test and inspection). The proportion with confirmed abscess among women with ascertainable status was estimated with an exact Clopper-Pearson 95% confidence interval [12]; Wilson intervals were used as a check.

Women with confirmed abscess were compared with those without using the chi-squared test, or Fisher's exact test where any expected cell count was below 5 (2 × 2 tables). For tables larger than 2 × 2 with sparse cells, a Monte Carlo permutation chi-squared test (20,000 permutations) was used. Continuous variables were compared with Welch's t-test or the Mann-Whitney U test as appropriate. Because most continuous variables were right-skewed, the Mann-Whitney U test was used for all of them for consistency.

Multivariable logistic regression was fitted using all prespecified antecedent factors regardless of their univariable p-values, so that variable selection did not depend on the data. Estimates are reported as crude and adjusted odds ratios (aOR) with 95% confidence intervals, using complete cases. Sparse variables (immunosuppressant use, hyperprolactinaemia) were described and tested bivariately but not modelled. The event count for the smaller outcome group was considered against the recommended minimum of about 10 per variable [13]. Model performance was assessed with the likelihood-ratio test, the Hosmer-Lemeshow test [14], the area under the ROC curve (AUC), and variance inflation factors. We also computed the sensitivity, specificity and predictive values of clinical suspicion against confirmed abscess. Missing data are reported by variable. Two-sided $p < 0.05$ was an interpretive threshold, with no multiplicity adjustment, and p-values for secondary comparisons are descriptive and should be read with that in mind [15]. Results are interpreted as associations and not as causal effects.

RESULTS

Participants and primary outcome

A total of 341 women were enrolled, matching the target sample. Abscess status could be ascertained in 340 (99.7%); one woman (0.3%) was coded as not assessed and was excluded from the primary outcome and from binary comparisons. Of the 340 assessed women, 235 had a confirmed abscess, giving a proportion of **69.1% (95% CI 63.9 to 74.0)**; the Wilson interval was 64.0 to 73.8. This estimate is compatible with the 72.5% assumed for the sample size calculation. Confirmation was by ultrasonography alone in 68 women (28.9% of confirmed abscesses), by aspiration or drainage alone in 13 (5.5%), and by both in 154 (65.5%).

Sociodemographic, reproductive and medical characteristics

The median age was 34 years (IQR 27 to 39; mean 33.5, SD 8.5; range 18 to 58), and 38.7% were aged 25 to 34 years (**Table I**). Most women were married (85.3%) and homemakers (71.3%); 61.0% lived in urban areas. Educational attainment was mostly secondary level or below (68.1%), while 31.9% had completed higher secondary education or more. Median monthly household income was BDT 31,750 (IQR 20,500 to 44,125; 25 missing).

Nulliparous women made up 21.4% of the sample and 35.2% had three or more live births. Three quarters (75.4%) had ever breastfed, with a median of 97 months since last breastfeeding (IQR 42 to 145), and 16.7% of those with a known history reported earlier lactational mastitis or engorgement. A third (34.2%) used hormonal contraception in the previous 12 months and 4.5% were pregnant. A history of previous non-lactational mastitis was reported by 16.5%, diabetes by 8.4% and previous tuberculosis by 5.2%. Personal tobacco use was uncommon (5.0% current or former), whereas 40.2% reported regular household exposure to tobacco smoke. Median BMI was 25.3 kg/m² (IQR 22.4 to

28.0), and 15.2% were obese (BMI 30 or above).

Few background characteristics differed between women with and without abscess. Education level differed across the five categories (p = 0.035), but the pattern was not monotonic: women with primary education formed 18.3% of the abscess group and 32.4% of the no-abscess group, whereas those with no schooling formed 10.6% and 6.7%. When dichotomised, the association was weaker (p = 0.160 for primary or below versus secondary or above, crude OR 0.64, 95% CI 0.39 to 1.03, p = 0.066 in logistic regression). Previous tuberculosis was more frequent in the abscess group (6.7% vs 2.0%, p = 0.078). No other characteristic showed a difference (all p > 0.17).

Table I

Sociodemographic, reproductive and medical characteristics of women with non-lactational mastitis, overall and by confirmed abscess status.

Characteristic	All women (n = 341)	Abscess (n = 235)	No abscess (n = 105)	p-value
Age, years, median (IQR)	34.0 (27.0–39.0)	33.0 (27.0–39.0)	34.0 (28.0–39.0)	0.502
Age group, years				0.560
18–24	56 (16.4)	41 (17.4)	15 (14.3)	
25–34	132 (38.7)	93 (39.6)	38 (36.2)	
35–44	115 (33.7)	78 (33.2)	37 (35.2)	
≥45	38 (11.1)	23 (9.8)	15 (14.3)	
Residence				0.643
Urban	208 (61.0)	145 (61.7)	62 (59.0)	
Rural	133 (39.0)	90 (38.3)	43 (41.0)	
Marital status				0.774
Married	291 (85.3)	198 (84.3)	92 (87.6)	
Never married	27 (7.9)	19 (8.1)	8 (7.6)	
Divorced/separated	18 (5.3)	14 (6.0)	4 (3.8)	
Widowed	5 (1.5)	4 (1.7)	1 (1.0)	
Education				0.035
None	32 (9.4)	25 (10.6)	7 (6.7)	
Primary	77 (22.6)	43 (18.3)	34 (32.4)	
Secondary	123 (36.1)	90 (38.3)	32 (30.5)	
Higher secondary	69 (20.2)	46 (19.6)	23 (21.9)	
Graduate or above	40 (11.7)	31 (13.2)	9 (8.6)	
Occupation				0.936
Homemaker	243 (71.3)	167 (71.1)	75 (71.4)	
Employed	48 (14.1)	32 (13.6)	16 (15.2)	
Business	17 (5.0)	13 (5.5)	4 (3.8)	
Student	21 (6.2)	14 (6.0)	7 (6.7)	
Other	12 (3.5)	9 (3.8)	3 (2.9)	
Monthly household income, BDT, median (IQR)*	31,750 (20,500–44,125)	32,000 (21,000–45,750)	30,500 (20,500–39,000)	0.317
Parity				0.544
Nulliparous	73 (21.4)	53 (22.6)	20 (19.0)	
1–2 live births	148 (43.4)	104 (44.3)	44 (41.9)	
≥3 live births	120 (35.2)	78 (33.2)	41 (39.0)	
Gravidity, median (IQR)	2 (1–3)	2 (1–3)	2 (1–4)	0.377
Age at first birth, years, median (IQR)†	25.0 (19.0–31.2)	25.0 (19.0–31.0)	25.0 (19.0–33.0)	0.590
Ever breastfed	257 (75.4)	173 (73.6)	83 (79.0)	0.283
Months since last breastfeeding, median (IQR)‡	97 (42–145)	97 (42–146)	101 (42–143)	0.612
Prior lactational mastitis/engorgement§	42 (16.7)	30 (17.9)	11 (13.4)	0.373
Hormonal contraception, past 12 months	111 (34.2)	77 (34.1)	34 (34.7)	0.914
Currently pregnant	15 (4.5)	11 (4.8)	4 (3.9)	1.000
Diabetes mellitus	28 (8.4)	21 (9.2)	6 (5.8)	0.287
Previous tuberculosis	17 (5.2)	15 (6.7)	2 (2.0)	0.078
Previous non-lactational mastitis	55 (16.5)	42 (18.4)	13 (12.5)	0.178
Previous breast surgery/procedure	32 (9.4)	21 (8.9)	11 (10.5)	0.653
Breast injury or nipple piercing	20 (5.9)	14 (6.0)	6 (5.7)	0.930
Immunosuppressant use, past 6 months	12 (3.6)	9 (4.0)	3 (2.9)	0.760
Hyperprolactinaemia (diagnosed)	16 (4.8)	12 (5.2)	4 (4.0)	0.784
Household tobacco smoke exposure	137 (40.2)	96 (40.9)	41 (39.0)	0.754
Personal tobacco use				0.602
Current	9 (2.6)	6 (2.6)	3 (2.9)	
Former	8 (2.3)	7 (3.0)	1 (1.0)	
Never	324 (95.0)	222 (94.5)	101 (96.2)	
BMI, kg/m², median (IQR)	25.3 (22.4–28.0)	25.3 (22.4–28.5)	25.4 (22.6–27.6)	0.443
BMI category				0.345
<18.5 (underweight)	21 (6.5)	13 (5.9)	7 (7.0)	
18.5–24.9	126 (39.1)	86 (38.9)	40 (40.0)	
25.0–29.9	126 (39.1)	83 (37.6)	43 (43.0)	
≥30.0 (obese)	49 (15.2)	39 (17.6)	10 (10.0)	

Values are n (%) unless stated. Percentages use known responses as the denominator. The "All women" column includes one woman whose abscess status was not assessed, so the abscess and no-abscess columns sum to 340. "Unknown" responses

(hormonal contraception 16, diabetes 8, tuberculosis 14, previous non-lactational mastitis 8, immunosuppressants 12, hyperprolactinaemia 10, pregnancy 6) were excluded. Tests: chi-squared, Fisher's exact (2 × 2 with sparse cells), Monte Carlo chi-squared (larger sparse tables) and Mann-Whitney U. *25 missing. †Women with a live birth (n = 268). ‡Ever breastfed (n = 257). §Ever breastfed with known history (n = 251).

Clinical presentation

The presenting features are shown in *Table II* and *Figure 1*. Breast pain was almost universal (94.1%), followed by swelling (83.9%), a palpable lump (74.5%) and redness (67.4%). Fever was reported by 25.8%, nipple discharge by 21.1%, spontaneous pus discharge by 36.4% and skin ulceration by 14.4%. The left breast was affected in 49.6%, the right in 46.3% and both in 4.1%. The median duration of symptoms was 30 days (IQR 15 to 54; range 2 to 360) and women were seen by a qualified provider a median of 7 days (IQR 4 to 12) after onset. Almost half (44.3%) had visited another facility for the episode and 35.5% had already received treatment, mostly antibiotics (100 of 121 treated women, 82.6%) or analgesics (72, 59.5%); aspiration or drainage had been done in 14 (11.6%), steroids given to 8 (6.6%) and surgery performed in 6 (5.0%).

On examination, the lesion was most often in the upper outer quadrant (31.1%) or periareolar (16.4%), and 11.4% involved multiple quadrants. A single lesion was present in 76.5%. The median maximum lesion size was 3.7 cm (IQR 2.5 to 5.0). Erythema was present in 62.6% of women with a recorded finding, skin thickening in 56.1%, nipple retraction in 15.7%, sinus or fistula in 13.3% and axillary lymphadenopathy in 11.2%. The treating clinician suspected an abscess in 62.5%.

Pain (97.9% vs 85.7%, $p < 0.001$), redness (73.2% vs 55.2%, $p = 0.001$), erythema on examination (70.6% vs 45.1%, $p < 0.001$) and larger lesions (median 4.2 vs 2.7 cm, $p < 0.001$) were more frequent in women with abscess, as was clinical suspicion (84.6% vs 14.4%, $p < 0.001$). Fever (28.9% vs 19.0%, $p = 0.054$) and sinus or fistula (15.4% vs 7.7%, $p = 0.052$) showed borderline differences, and nipple retraction was less frequent in the abscess group (13.2% vs 21.2%, $p = 0.065$). Duration of symptoms, delay to first consultation, laterality, lesion site, pus discharge and ulceration did not differ. These features are manifestations of the outcome and are interpreted as descriptors of the abscess presentation and not as antecedent factors.

Table II

Presenting symptoms, healthcare seeking and examination findings by confirmed abscess status.

Feature	All women (n = 341)	Abscess (n = 235)	No abscess (n = 105)	p-value
Patient-reported symptoms				
Breast pain	321 (94.1)	230 (97.9)	90 (85.7)	<0.001
Breast swelling	286 (83.9)	202 (86.0)	83 (79.0)	0.110
Palpable lump	254 (74.5)	169 (71.9)	84 (80.0)	0.114
Breast redness	230 (67.4)	172 (73.2)	58 (55.2)	0.001
Nipple discharge	72 (21.1)	51 (21.7)	21 (20.0)	0.723
Fever during episode	88 (25.8)	68 (28.9)	20 (19.0)	0.054
Open wound/ulceration	49 (14.4)	36 (15.3)	13 (12.4)	0.476
Spontaneous pus discharge	124 (36.4)	88 (37.4)	36 (34.3)	0.576
Affected breast				0.612
Right	158 (46.3)	110 (46.8)	48 (45.7)	
Left	169 (49.6)	117 (49.8)	51 (48.6)	
Bilateral	14 (4.1)	8 (3.4)	6 (5.7)	
Healthcare seeking				
Symptom duration, days, median (IQR)	30 (15–54)	29 (15–52)	32 (17–58)	0.484
Onset to first qualified consultation, days, median (IQR)*	7 (4–12)	7 (4–12)	6 (4–11)	0.366
Visited another facility	151 (44.3)	102 (43.4)	49 (46.7)	0.576
Treatment before presentation	121 (35.5)	86 (36.6)	35 (33.3)	0.562
Examination findings				
Lesion location				0.738
Periareolar	56 (16.4)	39 (16.6)	17 (16.2)	
Upper outer quadrant	106 (31.1)	70 (29.8)	36 (34.3)	
Upper inner quadrant	47 (13.8)	33 (14.0)	14 (13.3)	
Lower outer quadrant	42 (12.3)	32 (13.6)	10 (9.5)	
Lower inner quadrant	31 (9.1)	24 (10.2)	7 (6.7)	
Multiple quadrants	39 (11.4)	24 (10.2)	15 (14.3)	
Other	20 (5.9)	13 (5.5)	6 (5.7)	
Maximum lesion size, cm, median (IQR)†	3.7 (2.5–5.0)	4.2 (3.2–5.3)	2.7 (1.6–3.6)	<0.001
Erythema on examination‡	209 (62.6)	163 (70.6)	46 (45.1)	<0.001
Skin thickening‡	188 (56.1)	133 (57.8)	55 (52.9)	0.399
Nipple retraction‡	52 (15.7)	30 (13.2)	22 (21.2)	0.065
Sinus/fistula‡	45 (13.3)	36 (15.4)	8 (7.7)	0.052
Axillary lymphadenopathy‡	37 (11.2)	24 (10.4)	12 (12.0)	0.675
Clinician-suspected abscess‡	208 (62.5)	193 (84.6)	15 (14.4)	<0.001

Values are n (%) unless stated. These features are manifestations of the abscess and are not antecedent risk factors. *8 missing. †17 missing. ‡Percentages exclude "not recorded" (2 to 10 per item).

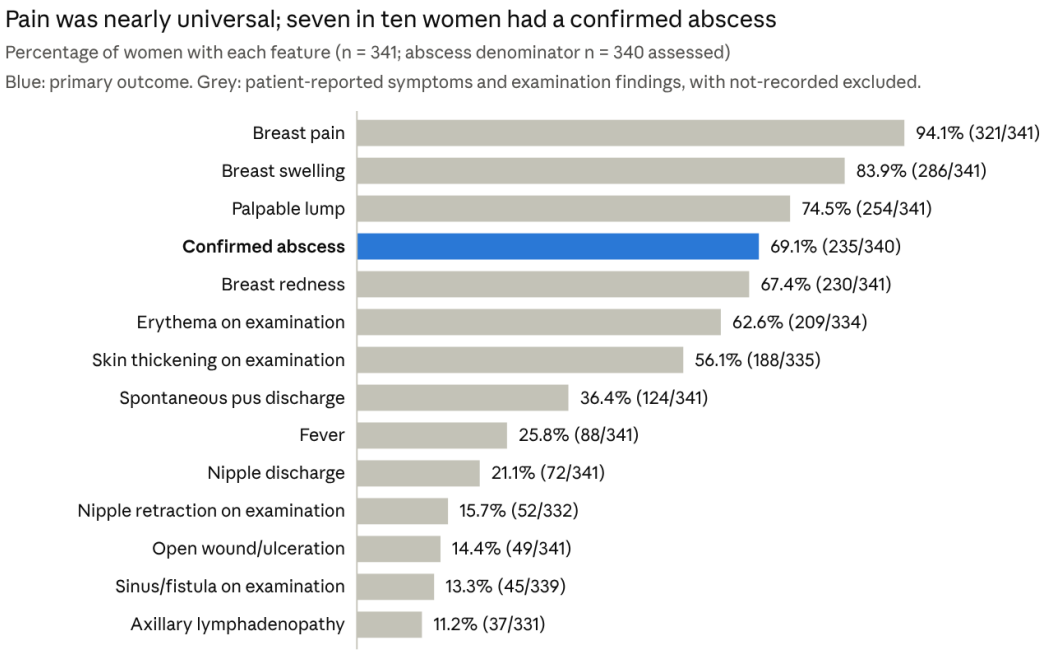


Figure 1 Prevalence of presenting symptoms, examination findings and confirmed abscess among women with non-lactational mastitis.

Investigations, diagnostic subtypes and clinical suspicion

Breast ultrasonography was performed in 316 women (92.7%) and showed a fluid collection in 69.9%, inflammatory change in 85.1%, ductal changes in 29.7% and a solid lesion in 12.3% (**Table III**). Biopsy was done in 155 women (45.5%); histology was granulomatous in 65.2%, non-granulomatous inflammatory in 28.4%, other in 3.9% and pending in 2.6%. Microbiology was performed in 168 women (49.3%) and was positive in 28.0% (47 of 168), negative in 67.3% and pending in 4.8%. TB-specific tests were done in only 82 women (24.0%): tuberculosis was confirmed in 9 (11.0%), no evidence was found in 71 (86.6%) and the result was indeterminate in 2 (2.4%).

The final documented diagnosis was IGM in 117 women (34.3%), periductal mastitis in 99 (29.0%), other non-lactational mastitis in 93 (27.3%), specific granulomatous mastitis in 16 (4.7%) and unclassified or pending in 16 (4.7%). All nine tuberculosis-confirmed women were in the specific granulomatous group. The extent of work-up differed by diagnosis: biopsy had been done in 90 of 117 women with IGM (76.9%) but in 23 of 99 with periductal mastitis (23.2%), and only 43 of 117 women with IGM (36.8%) had TB-specific testing. A definitive diagnosis was documented at the index visit in 289 women (84.8%); it was pending in 9 (2.6%) and not made in 43 (12.6%).

The proportion with confirmed abscess varied across diagnoses (**Figure 2**; p = 0.031, exploratory): it was 80.6% (95% CI 71.4 to 87.9) in periductal mastitis, 75.0% (47.6 to 92.7) in specific granulomatous mastitis, 67.7% (57.3 to 77.1) in other non-lactational mastitis, 62.5% (35.4 to 84.8) in unclassified cases and 60.7% (51.2 to 69.6) in IGM. Confidence intervals overlap widely, particularly for the two groups of 16 women. Among the 332 women with a recorded clinical impression and known abscess status, clinical suspicion had a sensitivity of 84.6% (95% CI 79.3 to 89.1), specificity of 85.6% (77.3 to 91.7), positive predictive value of 92.8% and negative predictive value of 71.8% against confirmed abscess. Because confirmation itself relied largely on ultrasonography, this comparison is subject to verification bias.

Table III

Diagnostic investigations and final documented diagnosis (*n* = 341).

Investigation / diagnosis	n/N	%
Breast ultrasonography performed	316/341	92.7
Fluid collection	221/316	69.9
Inflammatory changes	269/316	85.1
Ductal changes	94/316	29.7
Solid lesion	39/316	12.3
Breast biopsy performed	155/341	45.5
Granulomatous	101/155	65.2
Non-granulomatous inflammatory	44/155	28.4
Other	6/155	3.9
Pending	4/155	2.6
Microbiology performed	168/341	49.3
Positive	47/168	28.0
Negative	113/168	67.3
Pending	8/168	4.8
TB-specific tests performed	82/341	24.0
Tuberculosis confirmed	9/82	11.0
No evidence on available tests	71/82	86.6
Indeterminate	2/82	2.4
Abscess confirmation method (confirmed abscesses)		

Ultrasonography only	68/235	28.9
Aspiration/drainage only	13/235	5.5
Both	154/235	65.5
Final documented diagnosis		
Idiopathic granulomatous mastitis	117/341	34.3
Periductal mastitis	99/341	29.0
Other non-lactational mastitis	93/341	27.3
Specific granulomatous mastitis	16/341	4.7
Unclassified/pending	16/341	4.7

Investigations not performed were not coded as negative. A negative TB work-up on available tests does not exclude breast tuberculosis.

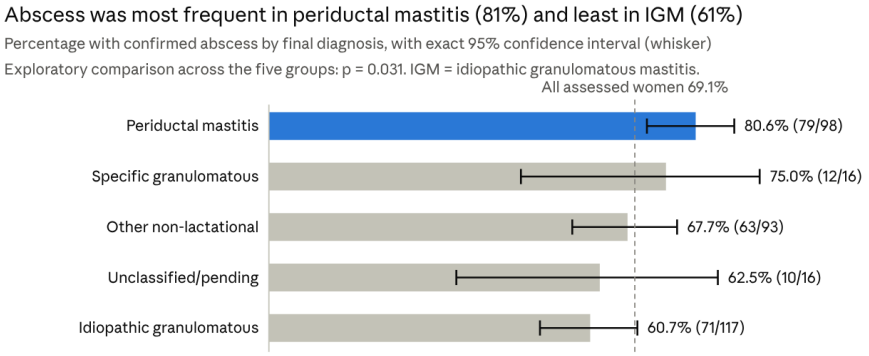


Figure 2 Proportion with confirmed abscess by final documented diagnosis.

Initial management

Medical treatment alone was documented for 34.0% of women, aspiration or drainage alone for 27.0%, a combination for 26.1%, observation for 7.6% and surgery for 5.3% (*Table IV*). Antibiotics were prescribed to 77.4%, corticosteroids to 19.1%, surgical referral was made for 48.4% and further investigations were planned for 22.6%. Management differed by abscess status, as expected: aspiration or drainage, alone or combined, was used in 70.6% of women with abscess and 14.3% of those without ($p < 0.001$); antibiotics (85.5% vs 59.0%) and surgical referral (59.1% vs 24.8%) were also more frequent (both $p < 0.001$), whereas corticosteroid prescription did not differ (17.9% vs 21.9%, $p = 0.382$). These differences reflect treatment following diagnosis and are not associations in the causal sense.

Table IV

Initial management by confirmed abscess status.

Management	All women (n = 341)	Abscess (n = 235)	No abscess (n = 105)	p-value
Management category				<0.001
Medical	116 (34.0)	46 (19.6)	69 (65.7)	
Aspiration/drainage	92 (27.0)	89 (37.9)	3 (2.9)	
Surgery	18 (5.3)	17 (7.2)	1 (1.0)	
Observation	26 (7.6)	6 (2.6)	20 (19.0)	
Combination	89 (26.1)	77 (32.8)	12 (11.4)	
Antibiotics prescribed	264 (77.4)	201 (85.5)	62 (59.0)	<0.001
Corticosteroids prescribed	65 (19.1)	42 (17.9)	23 (21.9)	0.382
Referral to breast/general surgery	165 (48.4)	139 (59.1)	26 (24.8)	<0.001
Further investigations planned	77 (22.6)	56 (23.8)	21 (20.0)	0.436

Values are n (%). The management category rows total 341 in the first column because one woman with unassessed abscess status received medical treatment.

Factors associated with confirmed abscess

Crude and adjusted associations for the 14 prespecified antecedent characteristics are shown in *Table V* and *Figure 3*. The complete-case multivariable model included 279 women (191 with abscess and 88 without); 61 of 340 assessed women were excluded because of missing or unknown values, mostly BMI (19), previous tuberculosis (14) and hormonal contraception (16). None of the characteristics was significantly associated with abscess after adjustment. The largest point estimates were for previous tuberculosis (aOR 2.80, 95% CI 0.59 to 13.26), diabetes (1.99, 0.63 to 6.27), personal tobacco use (1.83, 0.46 to 7.26) and previous non-lactational mastitis (1.57, 0.74 to 3.36), but all intervals were wide and included 1, reflecting the small number of women exposed (for example, 17 with previous tuberculosis and 17 tobacco users). Rural residence, lower education, parity, hormonal contraception, household smoke exposure, BMI, age and symptom duration had adjusted odds ratios close to 1.

The model as a whole did not explain abscess status: the likelihood-ratio test gave $p = 0.787$, McFadden pseudo-R^2 was 0.028, and discrimination was poor (AUC 0.61). The Hosmer-Lemeshow test showed no evidence of poor calibration ($\chi^2 = 10.46$, $p = 0.234$) and the largest variance inflation factor was 1.11, so collinearity was not a concern. With 88 women in the smaller outcome group and 14 parameters, the events-per-variable ratio was 6.3, below the conventional threshold of 10, and the model is therefore exploratory.

Table V
Crude and adjusted associations of antecedent characteristics with confirmed abscess (logistic regression).

Characteristic	n	Crude OR (95% CI)	p	Adjusted OR (95% CI)*	p
Age (per 5 years)	340	0.95 (0.83–1.09)	0.452	0.92 (0.79–1.08)	0.301
Rural residence (vs urban)	340	0.89 (0.56–1.43)	0.643	0.87 (0.51–1.49)	0.613
No/primary education (vs secondary or above)	340	0.64 (0.39–1.03)	0.066	0.81 (0.46–1.43)	0.469
Parous (vs nulliparous)	340	0.81 (0.45–1.44)	0.468	0.82 (0.42–1.58)	0.546
Hormonal contraception, past 12 months	324	0.97 (0.59–1.60)	0.914	1.06 (0.61–1.84)	0.830
Diabetes mellitus	332	1.66 (0.65–4.24)	0.292	1.99 (0.63–6.27)	0.239
Previous tuberculosis	326	3.54 (0.79–15.76)	0.098	2.80 (0.59–13.26)	0.193
Previous non-lactational mastitis	332	1.58 (0.81–3.09)	0.181	1.57 (0.74–3.36)	0.243
Previous breast procedure	340	0.84 (0.39–1.81)	0.654	1.17 (0.45–3.04)	0.753
Tobacco use (current/former)	340	1.48 (0.47–4.65)	0.503	1.83 (0.46–7.26)	0.388
Household tobacco smoke exposure	340	1.08 (0.67–1.73)	0.754	0.93 (0.54–1.60)	0.801
Breast injury/nipple piercing	340	1.05 (0.39–2.80)	0.930	1.13 (0.36–3.60)	0.832
BMI (per kg/m²)	321	1.03 (0.97–1.08)	0.355	1.02 (0.96–1.08)	0.480
Symptom duration (per 30 days)	340	0.94 (0.84–1.06)	0.323	0.95 (0.83–1.09)	0.436

*OR = odds ratio. Outcome: confirmed abscess (235) versus no abscess (105). *Adjusted for all variables in the table; complete cases, n = 279. Likelihood-ratio p = 0.787; Hosmer-Lemeshow p = 0.234; AUC 0.61. Women with unknown responses were excluded from the corresponding crude estimate.*

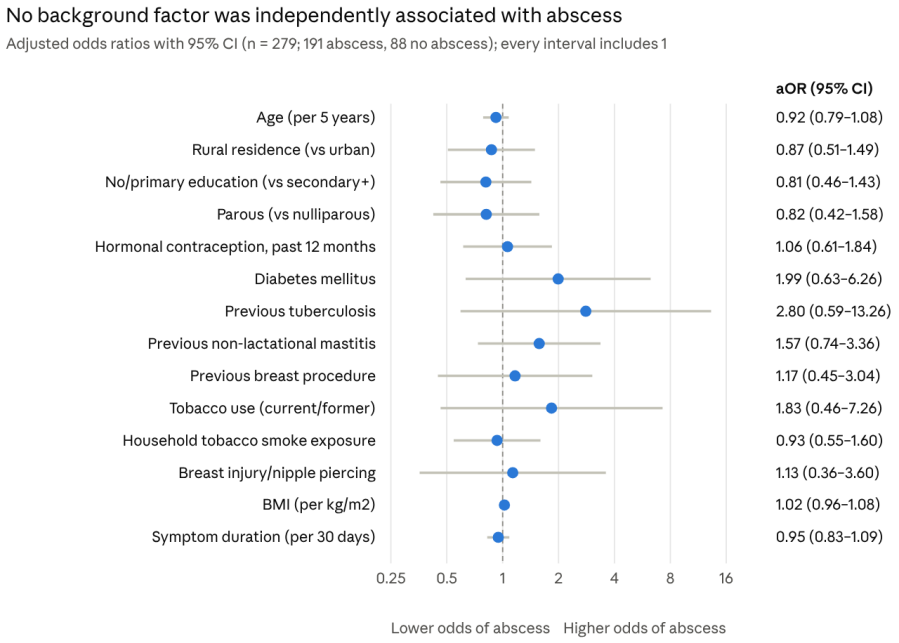


Figure 3 Forest plot of adjusted odds ratios for confirmed abscess.

Sensitivity analyses
Results were robust to two checks. Omitting BMI, which had the most missing values, increased the complete-case sample to 297 women and left the conclusions unchanged (no adjusted odds ratio with $p < 0.16$; for example, previous tuberculosis aOR 2.99, $p = 0.162$). Reclassifying the four women with an ultrasonographic fluid collection but no recorded confirmation as having an abscess gave 239 of 340 (70.3%) with abscess and, again, no significant adjusted association (all $p > 0.22$).

DISCUSSION

Principal findings
In this hospital-based sample of 341 women with NLM, roughly seven in ten (69.1%) had a confirmed breast abscess at the index assessment. Pain, swelling and a lump dominated the presentation, the upper outer quadrant and periareolar region were the commonest sites, and the typical woman presented about a month after symptom onset, often after another facility visit and a course of antibiotics. Granulomatous and periductal disease accounted for two thirds of the final diagnoses. The proportion with abscess differed little across background sociodemographic, reproductive and medical-history characteristics, and a model including 14 such factors discriminated poorly between women with and without abscess.

Comparison with other studies
The abscess proportion is close to the 72.5% reported in the Chinese retrospective series of 724 women with non-puerperal mastitis, and the confidence interval includes that figure [9]. The agreement is reassuring for the sample size assumption, although case definitions and referral patterns differ between settings, and a hospital-based proportion among mastitis patients is not a population prevalence. The diagnostic mix, with IGM and periductal mastitis predominating, is consistent with descriptions of non-lactational breast inflammation in tertiary breast services [2,5,17]. The higher abscess proportion in periductal mastitis than in IGM fits the clinical picture of periductal sepsis, in

which a subareolar abscess and recurrent fistulae are typical [6], although our subtype comparison was exploratory and the intervals overlap.

Several factors proposed in the literature were not associated with abscess here. Smoking has been linked to periductal sepsis and breast abscess [6,7], but only 5.0% of our participants reported tobacco use, so the study could not detect such an effect, and household smoke exposure was unrelated to the outcome. Diabetes and previous tuberculosis had positive but imprecise estimates, and the tuberculosis signal, although not significant, is in keeping with the need to exclude tuberculosis in granulomatous breast disease [8,18]. Hormonal contraception, parity, breastfeeding history and hyperprolactinaemia, often discussed as aetiological factors for IGM [4,5], showed no relation with abscess formation. These variables relate to the origin of mastitis, which this design cannot address, since every participant already had the disease.

Diagnostic work-up and clinical implications

The findings highlight gaps in the work-up. Fewer than half of the women underwent biopsy, half had microbiology, and fewer than one in four had TB-specific tests, including only about a third of women labelled as IGM. IGM is a diagnosis of exclusion that requires specific causes, notably tuberculosis, to be ruled out [4,8,17]. In a country with a high tuberculosis burden, untested women labelled idiopathic risk misclassification, which could lead to inappropriate corticosteroid treatment, a mainstay of IGM management [19]. We therefore suggest that tissue diagnosis and TB testing should be prioritised for women with non-abscess granulomatous presentations or lesions that fail to respond to drainage and antibiotics.

Ultrasonography was almost universal and, with aspiration, supplied the confirmation of abscess [20]. Clinical suspicion was reasonably but not perfectly accurate (sensitivity 85%, negative predictive value 72%), suggesting that more than one in four women in whom an abscess is not suspected may still have a collection. Imaging should be considered for every woman with a breast mass and inflammation, as is already common practice. The intensity of use of aspiration or drainage, antibiotics and surgical referral in women with abscess shows that abscess drives the pathway of care and the demand for surgical services.

Strengths and limitations

Strengths include the protocol-driven design with a prespecified outcome and analysis plan, consecutive recruitment, a sample size calculated for the primary estimate, the definition of abscess by imaging or aspiration, separation of antecedent factors from manifestations of the abscess, explicit coding of tests not performed, and transparent reporting of missing data and sensitivity analyses.

Several limitations apply. First, the study was cross-sectional, so temporality cannot be established, and associations should not be read as causal. Second, enrolment from one hospital with consecutive, non-probability sampling limits generalisability; tertiary referral concentrates complex and treatment-resistant disease. Third, investigations were done selectively (for example, biopsy in 45.5%), so diagnostic subtype may be misclassified and subtype comparisons are uncertain, and confirmation of abscess relied on imaging, introducing possible verification bias. Fourth, the precision-based sample size did not ensure power for regression: the events-per-variable ratio was 6.3 [13], confidence intervals for rare exposures were wide, and the absence of significant associations should not be interpreted as absence of effect. Fifth, we did not adjust for multiple comparisons, and the education and subtype p-values (0.035 and 0.031) could be chance findings [15]. Sixth, self-reported history may be affected by recall error, and complete-case analysis removed 61 women.

CONCLUSIONS

In this sample, abscess was present in about seven in ten women with non-lactational mastitis and was not predicted by routinely collected sociodemographic, reproductive or medical-history characteristics. The clinical picture is dominated by pain, swelling and a mass, with granulomatous and periductal disease the main diagnoses. Wider use of biopsy, microbiology and TB-specific testing would improve diagnostic certainty, particularly for granulomatous mastitis. Larger multicentre studies with prospective, standardised work-up are needed to define determinants and to guide management in Bangladesh.

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