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Clinical Characteristics of Non-Puerperal Mastitis: A Retrospective Analysis of 724 Patients

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Objective: The aim of this study is to retrospectively analyze the clinical characteristics of non-puerperal mastitis.

Methods: A retrospective study was undertaken to investigate 724 cases of non-puerperal mastitis in patients hospitalized from April 2004 to December 2021 at the Mammary Gland Department of Shuguang Hospital, which is affiliated with Shanghai University of Traditional Chinese Medicine. Employing statistical methodologies including mean ± standard deviation, median, and one-sample *t*-test, the study sought to analyze and delineate factors associated with morbidity, such as age, childbirth, lactation, and body mass index (BMI).

Results: The average age of the 724 patients was 33.4 ± 5.5 years. Among them 54.94% were aged 30–39 years, 65.16% were within five years after delivery, and 62.56% were breastfeeding for less than 6 months. The BMI of patients aged 30–39 years was higher than that of the general Chinese population ($P < 0.05$). There was no significant correlation between smoking, oral contraceptives, trauma, and the incidence of the disease in this group.

Conclusion: Non-puerperal mastitis is more prevalent among women of childbearing age, specifically those aged 30–39 years, who breastfed for less than 6 months within the first five years after childbirth. In this age group, higher BMI is linked to increased morbidity.

Keywords: mastitis, clinical feature, non-puerperal, retrospective study, pathogenesis related factors

Introduction

Non-puerperal mastitis (NPM) refers to a group of benign breast disorders with an unclear etiology, affecting non-pregnant or non-lactating women. NPM presents with a diverse range of clinical features, including breast lumps, abscesses, fistulas, lipid-like discharge, and non-cyclical breast discomfort. These clinical symptoms often persist and recur. The natural course of NPM typically spans 9–12 months, with frequent recurrences.[1]

NPM has diverse etiological theories and controversial treatment approaches.[2] Recent research indicates that NPM pathogenesis mammary duct wall stimulation by trapped secretions. Leakage of lipid-like material from the lumen of a ruptured duct may trigger an antigenic reaction in the glands. The disease is classified as an autoimmune disorder due to significant infiltration of plasma cells and macrophages. Factors associated with its occurrence include ductal obstruction, abnormalities in the immune system, and infections.[3,4] Despite limited extensive clinical data sets supporting the variable roles in the disease's pathogenesis, known causes allow for targeted therapeutic interventions which may be used to reduce or eradicate it. The absence of an established cause complicates diagnosis, differentiation, and treatment of this illness. Consequently, researching the pathogenic cause of NPM is crucial.

In this study, we retrospectively analyzed the clinical characteristics of 724 patients with NPM who were hospitalized in the Department of Mammary Gland at Shuguang Hospital affiliated with Shanghai University of Traditional Chinese Medicine between April 2004 and December 2021. Our initial investigation focused on factors associated with the NPM pathogenesis, based on general and clinical patient data.

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Data and Methods

Clinical Data

This retrospective study included 724 patients with NPM admitted to the Department of Mammary Gland at Shuguang Hospital affiliated with Shanghai University of Traditional Chinese Medicine between April 2004 and December 2021, all of whom met the diagnostic criteria.

Methods

Diagnostic Criteria

The diagnostic criteria are in accordance with the clinical practice guidelines for diagnosis and treatment of patients with NPM (2021) issued by the Breast Health and Disease Prevention and Treatment Group of the Chinese Preventive Medicine Association Women's Health Branch:[1] 1) clinical manifestations include breast masses, nipple retraction, nipple discharge, and breast pain. Breast masses could advance to abscess development stemming from chronic conditions, and in the late stages, abscess rupture could lead to the formation of breast fistulas, sinuses, or ulcers, persisting for an extended duration. 2) In terms of histopathology, patterns aligned plasma cell mastitis, periductal mastitis or idiopathic lobular granulomatous mastitis.

Inclusion Criteria

Inclusion criteria: 1) non-pregnant or lactating women; 2) clinical diagnosis of NPM; 3) There was a definite pathological diagnosis of plasma cell mastitis or idiopathic lobular granulomatous mastitis.

Exclusion Criteria

Exclusion Criteria: 1) concurrent severe primary diseases affecting the cardiovascular, cerebrovascular, hepatic, renal, and hematopoietic systems; 2) coexistence of life-threatening diseases (such as tumors or HIV/AIDS); 3) severe mental illness; 4) coexistence of other breast diseases with surgical indications; 5) incomplete medical history.

Morbidity-Related Factors

The variables considered in this study include age, BMI, history of marriage and childbearing, breastfeeding history, smoking history, oral contraceptive history, and trauma history.

Morbidity

The study includes statistics related to clinical stage, disease duration, lesion location, and local characteristics (such as nipple inversion, nipple overflow, breast lump, skin color change, abscess formation, and whether accompanied by pain or not), along with accompanying symptoms.

The criteria for classifying nipple inversion are as follows:[5] Type I involves partial nipple inversion, where the nipple neck is present and easily extruded. The extruded nipple size resembles that of a healthy person. Type II describes complete nipple sinking into the areola, yet manual extrusion remains possible. In this case, the nipple is smaller than usual, and the nipple neck is predominantly absent. Type III denotes complete nipple burial beneath the areola, rendering extrusion impossible.

Laboratory Indicators

The normal value standards for blood routine and serum pituitary prolactin level were as follows: White blood cell (WBC): 3.69–9.16×10^9/L, neutrophil (N): 50–70%; PRL (prolactin): 102–496 mIU/L.

Statistical methods

All the data were analyzed using SPSS 21.0 statistical software. The mean ± standard deviation (X ± SD) was used for the statistical description of the measurement data that followed a normal distribution; while the median, maximum, and minimum values were used for data that did not conform to a normal distribution. A one-sample *t*-test compared BMI to the mean ± standard deviation of the normal population, and a p-value of < 0.05 was considered statistically significant.

Results

Factors Associated with Morbidity

Age

A total of 724 non-puerperal, non-pregnant women aged 13 to 81 years were included in the study, with a mean age of 33.4 ± 5.5 years. The majority of the patients fell in the 30–39 age group, comprising 54.97% (398/724), followed by 33.15% (240/724) in the 20–29 age group and 18.23% (132/724) in the 40–49 years old (Table 1).

BMI

The height and weight data of 647 patients with NPM were collected. Among them, 162 (25.04%) were overweight, and 65 (10.05%) were obese. Thus, 227 (35.09%) patients exceeded the normal weight range. The mean and standard deviation of the BMI of the 647 patients in this group were compared with those of the general Chinese population across all age groups. Notably, the BMI of the 30–39 age group surpassed that of the general Chinese population. The one-sample *t*-test indicated that the difference between the 30–39 age group was statistically significant (Table 2).

Marriage and Childbearing

The marital and childbearing status data of the 724 patients were collected. Among them, 153 were unmarried with no children, 40 were married with no children, and 531 (73.34%) were married with children. Out of the total cases, 230 cases (31.77%) had a history of abortion. Information on the time of the last birth was available for 531 patients. The shortest interval between the last birth and disease onset was 6 months, while the longest was 56 years, with a median time of 3.5 years. The time between the last birth and the onset of the disease was mostly distributed within 5 years of childbirth, accounting for 65.16% (346/531, Table 3).

Table 1 Age Distribution of NPM Cases

Age (Years)	Number of Cases (n)	Percentage (%)	Mean Age (X ± SD)
<20	15	2.07	18.5±1.8
20~29	240	33.15	27.4±3.2
30~39	398	54.97	33.8±3.4
40~49	132	18.23	44.2±2.5
50~59	64	8.84	54.1±3.0
≥60	3	0.41	67.3±6.5
Total	724	100	33.4±5.5

Table 2 Comparison of Mean BMI Between Patients with NPM and the General Chinese Population by Age Group

Age (Years)	*n (Percentage)*	BMI		
		Patients	General Population	p value
20~29	206/31.84	22.5±3.1	22.7±5.5	0.152
30~39	315/48.69	24.2±3.5	22.8±3.1	0.039*
40~49	117/18.08	22.8±3.0	23.5±3.4	0.164
50~59	7/1.08	23.8±2.9	23.8±3.8	0.998
60~69	2/0.31	24.2±1.4	23.9±3.9	0.791

Note: *P < 0.05.

Table 3 Distribution of Time from Last Birth to the Onset of NPM

Time from Last Birth to the Onset (Years)	Number of Cases (n)	Percentage (%)
0~1	76	14.31
1~2	96	18.08
2~3	85	16.01
3~4	53	9.98
4~5	36	6.78
>5	185	34.84
Total	531	100

Breastfeeding on the Affected Side

Breastfeeding status of the affected breast was collected from 211 patients with children. Among them 27.01% (57/211) were not breastfeeding, and the duration of breastfeeding ranged up to 18 months. The average duration of breastfeeding was 5.1 ± 4.6 months. A total of 132 patients (62.56%) breastfed for less than 6 months (Table 4).

Smoking and Oral Contraceptive Use

Among the 724 patients in this group, 15 had a significant smoking history. Additionally, 3 patients briefly used oral contraceptives, but NPM onset occurred well after their contraceptive use.

Trauma to the Lesion Site

A total of 6.63% (48/724) of the patients had a history of trauma shortly before or during NPM onset, with varying degrees of impact.

Morbidity

Disease Staging and Progression

Based on the initial patient diagnosis Chinese medicine staging criteria from *Practical Chinese Medicine Surgery*, NPM was classified into four stages: overflow, mass, abscess, and fistula. Among the 724 patients, the shortest NPM duration was 4 days, the longest was 18 years, and the median duration was 3.0 months, with an average of 5.6 months. Most patients presented within 3 months of NPM onset. The abscess stage was the most prevalent, accounting for 45.03% (326/724), followed by the mass stage and fistula stage, accounting for 27.03% (196/724) and 27.49% (199/724), respectively. The overflow stage only accounted for 0.41% (3/724, Table 5).

Table 4 Distribution of Breastfeeding Time on the Affected Side in NPM

Breastfeeding Time (Months)	Number of Cases (*n*)	Percentage (%)	Mean (X ± SD)
0	57	27.01	0
1~3	36	17.06	1.8±0.8
4~6	39	18.48	5.3±0.9
7~9	30	14.22	8.1±0.6
10~12	40	18.96	11.1±0.9
>12	9	4.27	14.4±1.8
Total	211	100	5.1±4.6

Table 5 Distribution of Disease Duration Across Different Clinical Stages of NPM

Clinical Stage		Duration of Disease (Months)				Total (n/%)
	0~3	3~6	6~9	9~12	>12 Month	
	n	*n*	*n*	*n*	*n*	
Overflow stage	0	3	0	0	0	3/0.41
Lump stage	93	74	8	12	9	196/27.03
Abscess stage	205	58	14	25	24	326/45.03
Fistula stage	124	37	9	16	13	199/27.49
Total (n/%)	422/58.29	172/23.76	31/4.28	53/7.32	46/6.35	724/100

Lesion Location

Among the 724 patients, most experienced unilateral NPM onset. Specifically, 357 cases (49.31%) were left-sided, 325 cases (44.89%) were right-sided, and 42 cases (5.80%) were bilateral. Among patients with bilateral NPM onset, 20 cases had simultaneous NPM onset at the time of consultation, while 22 cases experienced NPM recurrence on the opposite side of the body, ranging from 3 months to 6 years.

Local Conditions of the Disease

Based on diagnostic criteria and typical symptoms of NPM, we developed a standardized symptom and sign record sheet to document disease local manifestations. Among the patients in this group, there were 528 cases of nipple inversion (72.93%), 386 cases of nipple discharge (53.31%), 721 cases of breast lump (99.59%), 623 cases of redness of skin (86.05%), 525 cases with abscess formation (72.51%), and 683 cases accompanied by pain (94.34%, Table 6).

Comorbid Conditions

According to the statistical results, patients with NPM commonly presented with fever, cough, and erythema nodosum on the lower limbs. Specifically, 51 cases (7.04%) had fever, 8 cases (1.10%) had cough, and 30 cases (4.14%) had erythema nodosum on the lower limbs.

Table 6 Local Condition of NPM

Symptoms and Signs	Degree and Extent	Number of Cases (n)	Percentage (%)
Nipple discharge	No	196	27.07
	Type I	195	26.93
	Type II	175	24.17
	Type III	158	21.82
Nipple overflow or secretion substance	No	338	46.69
	Yes	386	53.31
Lump	No	3	0.97
	1 quadrant	240	33.15
	2 quadrants	186	25.69
	≥3 quadrants	295	40.75

(*Continued*)

Table 6 (Continued).

Symptoms and Signs	Degree and Extent	Number of Cases (n)	Percentage (%)
Redness of skin	No	101	13.95
	1 quadrant	292	40.33
	2 quadrants	296	40.88
	≥3 quadrants	35	4.83
Abscess	No	199	27.49
	Not ulcerated	326	45.03
	Ulcerated	149	20.58
	Repeated ulceration	50	6.91
Pain	No	41	5.66
	Yes	683	94.34

Previous History of Breast Disease

Breast hyperplasia, which impacted 19.75% (143/724) of the patients, emerged as the most common condition. Breastfeeding mastitis followed as the second most prevalent ailment at 10.78% (78/724). Furthermore, 4.83% (35/724) of patients had previously undergone removal of a breast fibroadenoma or breast cyst. Notably, 22 patients experienced plasmacellular mastitis in the contralateral breast and were successfully treated (Table 7).

Laboratory Tests

Before initiating therapy, data from 644 patients' PRL reports and 724 patients' blood reports were collected. The WBC counts were typically normal before treatment, accounting for 77.41% (233/724) of cases. However, there were 61 cases with elevated counts, the highest being 17.5×10^9/L, and 7 cases with low counts, the lowest being 3.1×10^9/L. The average WBC count was $7.3 \pm 2.6 \times 10^9$/L. Neutrophils were normal before treatment in 57.48% (173/301) of cases. However 86 cases had elevated neutrophil percentages with a maximum of 83.1%, while 42 cases were low with a minimum of 28.9%. The mean neutrophil percentage was 61.9 ± 10.7%. Notably, most patients exhibited varying degrees of elevated PRL levels (Table 8).

Discussion

Lactation mastitis is the most frequent acute inflammatory breast ailment. However, NPM, also referred to as comedo-mastitis in Chinese medicine, is a less common chronic suppurative breast disease that manifests outside the puerperal or pregnant period.[6] The two primary pathogenic forms of NPM are granulomatous lobular mastitis (GLM) and periductal mastitis (PDM).[7] Prof. Gu Bohua was the first to describe this condition as "chronic recurrent areolar fistula with nipple

Table 7 Previous Breast Disease History (n = 724)

Type of Disease	Number of Cases (*n*)	Percentage (%)
Breast hyperplasia	143	19.75
Lactational mastitis	78	10.78
Breast fibroadenoma/galactoma	35	4.83
Plasmacellular mastitis	22	3.04

Table 8 Laboratory Indicators of NPM

Laboratory Indicators	Number of Cases (*n*)	Percentage (%)
WBC ($\times 10^9$/L) (n = 724)		
Normal	533	73.62
Low	7	0.97
High	184	25.41
Neutrophil ratio (%) (n = 724)		
Normal	376	51.93
Low	10	1.38
High	338	46.69
PRL (mIU/L) (n = 644)		
<102	9	1.40
102~496 (normal range)	358	55.69
497~1000	53	8.23
1001~3000	219	34.01
>3000	5	0.78

inversion" in China in 1958.[8] Subsequently, Professors. Gu Bohua and Lu Deming incorporated this illness "comedo-mastitis" in the *Practical Chinese Medicine Surgery* in the 1980s.[9]

NPM is a relatively uncommon breast condition. The prevalence of NPM is progressively increasing over the years, constituting 0.3–1.9% of all breast disorders globally, while in China it accounts for 2–5% of all breast lesions.[10] The subtle onset of symptoms and the heightened risk of clinical misinterpretation often lead to confusion with other breast conditions. Therefore, a thorough understanding of NPM's clinical features is crucial for accurate diagnoses and effective treatment strategies.

NPM has an elusive etiology and its exact origin remains unknown. Previous studies have proposed several potential causative factors, including nipple deformity, breast degeneration, bacterial infection,[11,12] breast trauma,[13] smoking,[14,15] oral contraceptive pills,[16] and autoimmune disorders.[17] Some studies have shown that bacterial infection is a significant contributor to the pathogenesis of PDM and GLM. According to our previous research, the occurrence of NPM for women younger than 20 may be associated with elevated levels of prolactin, nipple invagination, trauma, and bacterial infection. Notably, nipple invagination, increased prolactin levels, and trauma emerge as significant risk factors for adolescent onset. The unique clinical characteristics of adolescent NPM primarily manifest in abscess formation accompanied by evident local inflammatory response, a high inflammatory index, rapid healing process, favorable prognosis and low recurrence rate.[18] Bacteria such as Corynebacterium, Enterococcus, anaerobic bacillus, and Streptococcus play a role in NPM, often through mixed bacterial infections.[19,20] In addition to mentioned etiologies, the association with hyperprolactinemia, mostly due to pituitary adenomas is overlooked. Though prolactin has been tied only to the granulomatous subset, the immunomodulatory effect of prolactin on immune cells results in such perpetual inflammation.[21] Long-term use of antipsychotics may increase PRL levels, and lead to GM. It is vital to assess PRL level and reduce PRL to normal in patients with GM.[22] Results of a retrospective study showed that the difference of PRL level before and after treatment is the independent risk factor of recurrence. Clinical examination of hormone levels especially the PRL level should not be ignored during and even after the treatment of GLM.[23] The results of this study showed that more than one-third of patients had increased pituitary prolactin levels by more than two times. There are no imaging studies for pituitary adenomas (prolactinoma) in the medical records. These patients did not receive treatment

(surgery or dopaminergic agonists) during their hospitalization. Patients with elevated pituitary prolactin are referred to the neurology department during outpatient follow-up. A study aimed to explore the etiology of granulomatous lobular mastitis (GLM). The study found that the main pathogenic factors of GLM is Corynebacterium kroppenstedtii infection, but other unusual pathogens (such as Pseudomonas oleovorans, Human gammaherpesvirus 4, Acinetobacter baumannii, Tepidiphilus thermophilus) are likely to be closely related to GLM, especially "Human gammaherpesvirus 4 (EBV)-associated mastitis" may be a new entity of mastitis. Abnormal levels of sex hormones and autoimmune are also common causes. Thus, lipophilic antibiotics (rifampicin) and prolactin inhibitor may be an effective medicine.[24]

The present study did not establish a correlation between smoking, oral contraceptives, and the development of NPM. This may be due to the relatively small number of smokers and oral contraceptive users included in the study, as well as the smoking ban in public places in China, which limit the proportion of smokers in the patient population.

The age distribution of patients with NPM in this study ranged from 13 to 81 years, with a mean age of 33.4 ± 5.5 years, emphasizing that NPM can manifest in women of all ages. Notably, a higher proportion of patients fell in the 30–39 years age group. The peak period for NPM onset occurred 5 years postpartum, often associated with breastfeeding for less than 6 months. Furthermore, this study found that patients with NPM had a higher BMI. Clinical observations have also highlighted increased lipid-like secretions in some patients with NPM. Additionally, research findings indicate that HDL levels are significantly lower, but lipoproteins are elevated in patients with NPM.[2,25] These observations suggest a potential association between NPM and disorders of lipid metabolism, which may trigger an inflammatory response. There is no standard treatment regimen for NPM. A prospective clinical trial demonstrated the effectiveness of a combination therapy involving rifampicin, isoniazid, and ethambutol in patients with NPM.[26] However, the authors' team does not recommend the use of anti-tuberculosis drugs for NPM.

In the present study, the BMI of patients with NPM was calculated following the BMI diagnostic criteria specified in the *Guidelines for the Prevention and Control of Overweight and Obesity in Chinese Adults*. These guidelines were issued by the Department of Disease Control of the Ministry of Health of the People's Republic of China in 2003.[27] The foundation for these diagnostic criteria was established using data from a 10-year sample survey conducted between 1990 and 2000 by the Data Aggregation and Analysis Collaborative Group of the Chinese Obesity Working Group of the International Life Sciences Institute China Office in 2002.[28] The survey included a total of 239,972 individuals aged 20–70, representing a diverse sample population from 22 provinces, municipalities, and autonomous regions, including Shanghai. These individuals were grouped into 10-year increments, resulting in 6 age groups based on gender, each comprising more than 10,000 people. This sample is considered representative of the current body weight distribution in the general population of China and is therefore treated as the total population in China.

The present study is retrospective and focuses on a limited number of variables. In the future, we will conduct more comprehensive exploratory studies into the factors associated with NPM, such as the labor and delivery environment, traumatic injuries, autoimmune diseases, and other relevant factors. Our aim is to gather evidence for the diagnosis and treatment of NPM.

Conclusion

NPM predominantly affects women of childbearing age, particularly those between 30 and 39 years old. The peak period for NPM onset occurs within 5 years after delivery, often associated with breastfeeding for less than 6 months. There is a correlation between the incidence of NPM and a higher BMI in the 30–39-year-old age group.

Abbreviations

NPM, non-puerperal mastitis; BMI, Body Mass Index; WBC, white blood cell; PRL, prolactin; GLM, granulomatous lobular mastitis.

Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki. The study was approved by Ethics Committee of the Shuguang Hospital Affiliated to Shanghai University of Tradition Chinese Medicine (No. 2020-803-10-03). All

participants provided written informed consent for their involvement in the study. In cases where participants were under the age of 18, informed consent was additionally obtained from their parents or legal guardians.

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Disclosure

The authors declare that they have no competing interests.

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