

Article

Clinical, diagnostic and therapeutic management of patients with breast tuberculosis: Retrospective analysis of 16 Cases

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Abstract: Breast tuberculosis (TB) is a rare form of extrapulmonary tubercular infection. The clinical presentations, diagnostic difficulties and therapeutic approach of breast TB are not well understood. This study aimed to review the nonspecific clinical presentations, diagnostic difficulties and therapeutic approach of breast TB. Sixteen female patients diagnosed with breast TB between 2016 and 2019 were retrospectively reviewed. The mean age of the patients was 36.4 years, and the most common complaints were breast mass and pain. While 31.2% of the cases had a physical examination with suspicions for malignancy, 43.5% of the patients had Breast Imaging Reporting and Data System (BIRADS) 3 lesions that suggested malignancy radiologically. Definitive diagnosis was based on histopathologic examination through core needle biopsy, excisional biopsy, and open biopsy taken from the abscess wall during drainage. All patients were treated with standard anti-TB therapy for 6 months. Thirteen patients recovered with standard therapy, while extended treatment for 9 to 12 months was needed in 3 (18.8%) cases. Surgery was carried out in 6 cases, and 2 patients developed recurrence. Breast TB can be easily confused with breast cancer, suppurative abscess, and other causes of granulomatous mastitis, both clinically and radiologically. A multidisciplinary approach is required to prevent diagnostic delays and unnecessary surgical interventions. Although anti-TB therapy is the mainstay treatment of breast TB, surgery is usually indicated in patients refractory to medical treatment.

Keywords: Breast tuberculosis; Diagnostic difficulties; Therapeutic approach; Multidisciplinary approach; Anti-TB therapy.

1. Introduction

Tuberculosis (TB) remains a major global health concern, with an estimated 1.3 million deaths worldwide each year [1]. Although breast TB is a rare form of extrapulmonary tuberculosis, it has been recognized as a distinct clinical entity since the early 19th century [2]. The incidence of breast TB varies widely, ranging from 0.025% to 1.04% of all breast pathologies [3]. Breast TB can be classified as either primary or secondary, with the latter being more common and usually associated with other primary sites of TB infection, such as the lungs, pleura, or lymph nodes.

Despite its rarity, breast TB can be easily misdiagnosed due to its variable clinical presentations, which can mimic other breast diseases such as breast carcinoma or pyogenic breast abscess [4]. Misdiagnosis can result in delayed treatment, unnecessary surgery, or increased risk of disease progression. Therefore, accurate diagnosis of breast TB is crucial for effective management and prevention of complications. Diagnosis of breast TB is usually based on a high index of clinical suspicion, coupled with laboratory and imaging tests, as well as histopathological examination.

In this study, we aimed to analyze the clinical features, diagnostic difficulties, and therapeutic outcomes of breast TB in a retrospective cohort of 16 patients diagnosed with breast TB between 2016 and 2019 at MKCG Medical College and Hospital in Behampur, India. The main objectives of this study were to highlight

the nonspecific clinical presentations of breast TB, to identify the diagnostic challenges associated with this condition, and to evaluate the efficacy of standard anti-TB therapy for breast TB. By shedding light on the clinical and diagnostic aspects of breast TB, this study can provide valuable insights for clinicians and researchers working in the field of infectious diseases, particularly in areas with a high prevalence of TB.

2. Materials

2.1. Inclusion criteria

All cases of diagnosed breast tuberculosis in women who attended the outpatient department or were admitted to the MKCG Medical College and Hospital in Berhampur, Ganjam, Odisha, India, between 2016 and 2019 were included in this study.

2.2. Exclusion criteria

The following cases were excluded from this study:

1. Cases with other co-morbid conditions such as deranged liver function test, cardiac problems, and psychiatric illness, among others.
2. Cases with a known history of drug allergies.
3. Cases who were pregnant or in the lactational period.

Note that these exclusion criteria were established to ensure the safety and wellbeing of the patients involved in the study and to avoid any potential confounding factors that could affect the results.

3. Methods

3.1. Patients

We conducted a retrospective review of medical records of 16 breast TB patients who received treatment between 2016 and 2019 at MKCG Medical College and Hospital in Berhampur, Odisha, India. Informed consents were waived due to the retrospective nature of the study. We recorded patients' demographic data such as age, gender, marital status, employment status, educational status, past and contact history of TB, and comorbid diseases. We also documented the initial clinical findings and radiological investigations including breast ultrasonography (US) and mammography (MM). All patients were evaluated for coexisting pulmonary TB using chest x-ray and culture of respiratory secretions.

3.2. Diagnosis

The diagnosis of breast TB was primarily based on histopathological findings from core needle biopsy and excisional biopsy of the abscess wall during drainage. Smear and culture of breast tissue or discharge were also used in the diagnostic workup. The histopathological findings of epithelioid cell granulomas, Langhans' giant cells, and lymphohistiocytic aggregates confirmed the diagnosis.

3.3. Treatment and Follow-up

All patients received a standard anti-TB regimen comprising isoniazid (5 mg/kg day, max. 300 mg/day) and rifampicin (10 mg/kg day, max 600 mg/day) for 6 months. In the first 2 months, patients also received pyrazinamide (20 to 30 mg/kg day, max. 2 g/day) and streptomycin (15 mg/kg day, max. 1 g/day) or ethambutol (15 to 20 mg/kg day, max. 1.5 g/day). If there was no full resolution of symptoms and *Mycobacterium tuberculosis* was still present in any specimen, a treatment of 3 months was added. Patients were invited for regular follow-up after the end of the treatment, and all complications during the follow-up period were recorded.

3.4. Statistical Analysis

We used the statistical package for social science (SPSS 21.0 IL, Chicago, USA) standard version for data analyses. Descriptive analysis was performed for demographic, clinical, and radiographic features. The

results are presented as mean SD/percentages for continuous variables and number/percentage for categorical variables. We used Chi-square (χ^2) test, Fisher's Exact test, and Mann-Whitney U-test to test for the significance of the association between the two anti-TB treatment groups (patients who healed with standard anti-TB therapy for 6 months and those who needed extended therapy of 9 to 12 months). A significance level was considered $p < 0.05$.

4. Data Analysis and Results

All cases were females with a mean age of 36.4 years. Table 1 presents all demographic and clinical data of the patients. The mean duration of symptoms prior to admission was 35.5 days (range 0 to 180). Breast lump (14, 87.5%) and pain (2, 12.5%) were the most common presenting symptoms. Clinically apparent breast abscess was the initial presentation in two (12.5%) cases. The left breast was more frequently affected than the right breast, as shown in Table 2.

Breast ultrasound was the initial radiological investigation in all patients, while mammography could only be performed in 4 (25%) cases due to age limitations. Sonographic examination of the breast revealed abnormal findings in the majority of patients (91.3%). All radiological findings are presented in Table 3.

The definitive diagnosis was mainly based on histopathological examination in all patients. Core needle biopsy ($n=10$) was the most frequently used diagnostic tool, with an accuracy rate of 93.5%. In cases of inconclusive core needle biopsy, small nonpalpable masses ($n=4$) underwent excisional biopsy with wide margins for diagnosis. Open biopsy taken from the abscess wall during drainage was carried out in two patients. Epithelioid cell granulomas with or without caseous necrosis and multinucleated giant cells were the leading histopathological findings. All specimens were also subjected to culture and Ziehl Nelsen staining for identifying *M. tuberculosis*. Culture of breast tissue and acid-fast bacilli (AFB) staining were positive in 56.2% (9/16) and 25% (4/16) patients, respectively. In addition, nine patients underwent smear examination of discharge (from nipple or fistula), and positive Ziehl Nelsen staining was obtained in five of those. Polymerase chain reaction (PCR) analysis was only performed in four patients with a 50% positivity rate.

All patients were treated with standard anti-TB therapy for 6 months. Thirteen patients achieved healing with the standard 6-month therapy, while extended treatment for 9 to 12 months was required for 3 patients (18.7%) who had discontinued drug therapy and had persistent symptoms and signs. There were no statistically significant differences between the patients who achieved healing with standard 6-month anti-TB therapy and the patients who had discontinued drug therapy and had persistent symptoms and signs ($p > 0.05$). Furthermore, there were no statistically significant differences between the patients who healed with standard 6-month anti-TB therapy and those who required extended treatment in terms of clinicopathological features ($p > 0.05$). Four patients underwent surgery, including total excision of mass for 3 patients and repeated aspirations of abscess in one patient. During the follow-up period, two of the 16 patients experienced recurrence, which presented as mass formations in both cases and were totally excised. These two patients were then treated with anti-TB therapy for 8 months ($2H_3R_3Z_3E_3S_31H_3R_3Z_3E_35H_3R_3E_3$), and no recurrence was observed during their follow-up periods.

5. Discussion

Breast TB is typically seen in women of reproductive age, although it can occur in young girls, elderly women, and even in males [5]. In our study, all patients were female with a mean age of 36.4 years, and only two were in their postmenopausal period. While secondary breast TB is more commonly reported than primary breast TB [6], 31.2% of our patients had coexisting pulmonary TB, past TB history, or contact history of TB. However, it should be noted that the primary focus of the disease is usually not detectable radiologically or clinically [7]. In our opinion, the presence of coexisting pulmonary TB, past TB history, or contact history of TB should always be investigated in the initial evaluation of patients with breast TB.

The etiopathogenesis of breast TB is associated with various risk factors, including multiparity, lactation, and pregnancy [7–9]. Of these, lactation appears to be more strongly associated with the development of breast TB, with reported incidence rates of up to 30% [10]. This may be due to increased vascularity of the breasts during lactation and lacerations at the areola, which increase susceptibility to tubercular infection.

Breast TB typically presents unilaterally, with no difference in incidence between the two sides [4,11]. In our study, most patients had a left breast lesion, and no patient had bilateral involvement. The upper outer

Table 1. Baseline characteristics of patients (n = 16). Patient characteristics n(%)

Patients Characteristics	n (%)
Age (y)	36.4, (24 to 62)
Marital status	
Single	2 (12.5%)
Married	13(81.3%)
Divorced	1 (6.2%)
Employment status	
Housewife	15 (93.7%)
Employed	1 (6.2%)
Educational status	
Primary/secondary school	13(81.3%)
High school	02 (12.5%)
University	1 (6.2%)
Menopausal status	
Premenopausal	14(87.5%)
Postmenopausal	2(12.5%)
Location	
Rural	13(81.3%)
Urban	3(18.7%)
Coexisting pulmonary TB	3 (18.7%)
Past history of TB	5 (31.2%)
Contact history of TB	7 (43.7%)
Presence of BCG vaccination	15 (93.7%)
PPD positivity	14(87.5%)
BCG-Bacillus Calmettee Guerin, TB-Tuberculosis PPD-Purified protein derivative	

Table 2. Presenting symptoms and signs of the patients with breast TB

Clinical findings	n (%)
Presenting symptoms and findings	
Breast lump with sinuses	2 (12.5%)
Breast lump without sinuses	8 (50%)
Breast pain with nodularity	1(6.2%)
Breast pain without nodularity	1 (6.2%)
Sinus formation	2 (12.5%)
Nipple discharge	8 (50%)
Axillary lymphadenopathy	4 (25%)
Fever	3 (18.5%)
Incidental	1 (6.2%)
Side of the disease	
Left	10 (62.5%)
Right	6 (37.5%)
Quadrant of the disease	
Upper-outer	10 (62.5%)
Upper-inner	2 (12.5%)
Lower-outer	2 (12.5%)
Lower-inner	2 (12.5%)
Clinical suspicion of malignancy	5 (31.2%)

Table 3. Radiological findings of the patients with breast TB

Radiologic findings	n (%)
Chest x-ray (n = 16)	
Sequelae findings of past TB	3(18.5%)
Radiopacity	2(12.5%)
Pleural effusion	1(6.2%)
Normal	10(62.2%)
Ultrasonographic findings (n = 16)	
Hypoechoic mass with irregular border	4(25%)
Nonspecific inflammatory changes	2(12.5%)
Axillary lymphadenopathy	1(6.2%)
Abscess	2(12.5%)
Well-defined mass	5(31.2%)
Normal	2(12.5%)
Mammographic findings (n = 4)	
Asymmetric density or poorly defined mass	1(6.2%)
Distortion	1(6.2%)
Spiculated mass	1(6.2%)
Circumscribed mass	1(6.2%)
Radiological suspicion of malignancy (BI-RADS 4-5)	3(18.7%)

quadrant of the breast was the most common location, consistent with previous studies [12,13]. Multicentric presentation was also frequent in our study population.

The patients with breast TB often experience symptoms for several weeks or months prior to diagnosis. The mean duration of symptoms in our study was similar to that reported in many other case series [6,8,10].

Breast TB can be classified into nodular, disseminated, and sclerosing forms based on clinical, radiological, and pathological findings [14]. The sclerosing type, characterized by extensive fibrosis, is rare and often found in elderly women [15]. The nodular form, which is the principal clinical manifestation, is characterized by a well-defined, painless, slow-growing breast mass [16]. Similarly, breast mass and pain were the most common physical findings in our case series. However, a significant number of patients had breast examination consistent with malignancy. The breast lump may be accompanied by multiple sinuses with or without discharge, ulcers, nipple or skin retraction, and discharge from the nipple. Ipsilateral axillary lymph node involvement is found in approximately one-third of patients with breast TB [15,17]. In our study, approximately one-sixth of the patients had enlarged axillary lymph nodes on the affected side, which differs from previous reports. A small number of patients may present with an initial complaint of a fluctuant breast abscess [17]. In our study, 12.5% of the patients presented with a fluctuated breast abscess as their initial complaint. Due to the variable presentations, breast TB is often confused with malignancy and pyogenic breast abscess clinically.

Breast TB has nonspecific radiological findings. Ultrasonography is often used as the initial imaging method, which shows a heterogeneous hypoechoic lesion with irregular borders and internal echoes in most cases of breast TB. However, nonspecific stromal coarsening, asymmetric density, and ill-defined nodules are among the most common mammographic findings, which are not specific to breast TB. Additionally, both mammography and ultrasonography have limited value, as the findings are often indistinguishable from other differential diagnoses such as breast carcinoma [6]. In our study, ultrasonography was used in all patients, and mammography was the choice of imaging modality for only four cases above the age of 35. The radiological findings in our study population were also in line with the data in the literature, with approximately half of the cases having radiologically suspected lesions.

The diagnosis of breast TB can be challenging due to the nonspecific and variable clinical, radiological, and laboratory findings. For example, patients with breast TB are often symptomatic prior to diagnosis for several weeks or months, and the mean duration of symptoms in the present study was similar to other case series. Breast TB can be classified as nodular, disseminated, and sclerosing forms based on clinical, radiological, and pathological findings. The disseminated form is characterized by multiple lesions associated with sinus

formation, while the nodular form is the principal clinical manifestation characterized by a well-defined, painless, slow-growing breast mass. Breast mass and pain were the most common physical findings in our case series, but physical examination of the breast was consistent with malignancy in a significant number of patients. Ipsilateral axillary lymph node involvement is found in approximately one-third of patients with breast TB, but in our study, approximately one-sixteenth of the patients had ipsilateral enlarged axillary lymph nodes. Abscess formation may be the initial clinical presentation in a small number of patients, and in accordance, 12.5% of our study population presented with a fluctuated breast abscess as an initial complaint. Due to the variable presentations, breast TB is often confused with malignancy and pyogenic breast abscess clinically.

Breast TB has nonspecific radiological findings, and both mammogram and ultrasound are of limited value as the findings are often indistinguishable from other differential diagnoses such as breast carcinoma. In our work, ultrasound was used in all patients; however, mammogram was the choice of imaging modality only for 4 cases > 35 years of age. The radiological findings of our study population were also in parallel with the data in the literature, and approximately half of the cases had radiologically suspected lesions.

The Mantoux test may not be helpful in the diagnosis of breast TB as it is often positive in patients from endemic areas for TB, and the high false positivity rate of this test in BCG-vaccinated people limits its widespread use. In our study, most of the patients had a positive Mantoux test, and almost all of those patients had previously been vaccinated. Therefore, this test did not provide any significant diagnostic value in our work.

Although detection of tuberculous bacilli by Ziehl Neelsen staining or culture is accepted as the gold standard diagnostic method in breast TB, these tests have some limitations. Culture of *M. tuberculosis* requires a lot of time and frequently gives negative results, and low positivity rates of AFB staining have been reported in previous studies. Our results of AFB staining and culture were also similar to these previous reports. PCR is known as a rapid diagnostic test, but its low sensitivity and high costs are the disadvantages for its general use. However, it can be considered in cases with negative culture results or for differential diagnosis between other forms of granulomatous mastitis. In the present study, PCR was used in only four patients, and positive results were obtained from two. As a result, definitive diagnosis was mainly based on histopathology by core biopsy and open (incisional or excisional) biopsy in our study population. Although fine needle aspiration cytology (FNAC) has been reported as a method with high diagnostic yield, some authors concluded that definitive diagnosis of breast TB may need a histological confirmation by larger tissue samples because granulomatous inflammation cannot be confidently differentiated by FNAC. In accordance, we usually used core needle biopsy in the diagnostic algorithm and obtained a high diagnostic yield. It should be noted here that the recognition of tuberculosis does not exclude concomitant cancer, and in our study, biopsy specimens revealed no cancer diagnosis.

Mantoux test is often positive in patients from endemic areas for TB, therefore may not be helpful in the diagnosis of breast TB [18]. Additionally, high false positivity rate of this test in BCG-vaccinated people due to cross reaction with bacillus Calmette-Guérin (BCG) limits its widespread use. In the present study, most of the patients had positive Mantoux test, and almost all of those patients had previously been vaccinated. Therefore, this test did not provide any significant diagnostic value in our work.

Although detection of tuberculous bacille by Ziehl Neelsen staining or culture is accepted as the gold standard diagnostic method in breast TB [19], these tests have some limitations. It is well known that culture of *M. tuberculosis* requires a lot of time and frequently gives negative results [7,20]. Similarly, low positivity rates of AFB staining have been reported in previous studies [3,11]. Our results of AFB staining and culture were also similar to these previous reports. The other method, PCR, is known as a rapid diagnostic test, but its low sensitivity and high costs are the disadvantages for its general use. However, it can be considered in cases with negative culture results or for differential diagnosis between other forms of granulomatous mastitis. In the present study, PCR was used in only four patients, and positive results were obtained from two. As a result, definitive diagnosis was mainly based on histopathology by core biopsy and open (incisional or excisional) biopsy in our study population. Although fine needle aspiration cytology (FNAC) has been reported as a method with high diagnostic yield, some authors concluded that definitive diagnosis of breast TB may need a histological confirmation by larger tissue samples because granulomatous inflammation cannot be confidently differentiated by FNAC [21]. In accordance, we usually used core needle biopsy in the diagnostic algorithm, and obtained high diagnostic yield. It should be noted here that the recognition of tuberculosis does

not exclude concomitant cancer. In our study, biopsy specimens revealed no cancer diagnosis. Standard antiTB therapy for 6 months is accepted as a main treatment modality with reported very high success rates [15,22]. This standard regimen was also administered all the patients in the present study. Extended therapy of 9 to 12 months was needed in 3 cases due to the incomplete resolution of the symptoms. Surgical intervention is generally indicated for drainage of breast abscess, diagnosis of the lesion, and excision of residual sinuses or masses. Segmental or total mastectomy may be indicated in patients with extensive disease or poor response to antiTB therapy [23]. In our study, the number of patients who received extended antiTB therapy may be considered as high. Incompatibility of the patients in drug intake may have led to this situation because, there was no significant differences between the patients who healed with standard 6-month antiTB therapy and the patients who received extended treatment, in terms of all clinicopathological characteristics.

6. Conclusion

Isolated breast TB is an uncommon entity, even in TB endemic areas. Diagnosis is usually based on high degree of clinical suspicion. A multidisciplinary approach is important to prevent diagnostic delays and unnecessary surgical interventions. The principal differential diagnosis is that of breast carcinoma. Other breast diseases such as fat necrosis, suppurative abscess, and idiopathic granulomatous mastitis may be confused with breast TB, both clinically and radiologically. Although anti TB therapy is the main stay treatment of breast TB, surgery may be required for patient's refractory to medical treatment.

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Conflicts of Interest: "Authors declare that they do not have any conflict of interests."

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