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Diagnosis and Treatment Modalities for Aberrations of Normal Development and Involution of the Breast: A Clinical Study

Dr. Sheik Salman Raghib[*1], Dr. Biswadeep Lenka[2], Dr. Tajma Afzal[3]

[*1]Assistant Professor, Department of General Surgery, IMS & SUM Hospital,Campus 2, Phulnakhara, Bhubaneswar

[2]Assistant Professor, Department of General Surgery, IMS & SUM Hospital, Campus 2, Phulnakhara, Bhubaneswar

[3]Assistant Professor, Department of Obstetrics & Gynaecology, SCB Medical College & Hospital,Cuttack

***Corresponding Author:**

Dr. Sheik Salman Raghib

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ABSTRACT

Background: Benign breast disorders are frequent conditions that occur as a result of aberrations in normal development and involution (ANDI) of breast tissue. It is crucial to know their clinical presentation, diagnosis, and treatment modalities for proper management. The purpose of this study is to assess the spectrum of benign breast diseases, their diagnostic methods, and treatment results with the ANDI classification.

Methods: Prospective observational study was done on 250 female patients with benign breast disorders. Clinical assessment, imaging (ultrasonography and mammography), and fine-needle aspiration cytology (FNAC) were used for diagnosis. Conservative treatment, surgical excision, and antibiotic therapy were used as and when indicated for management. Patients were followed up for six months to evaluate treatment response and rates of recurrence.

Results: The most frequent benign breast condition was fibroadenoma (38.0%), followed by fibrocystic changes (22.4%) and mastitis/abscess (12.8%). Duct ectasia was seen in 8.4%. FNAC was accurate in 92.4%, and ultrasonography was the most common imaging technique used. Conservative treatment succeeded in 64.8% of patients, while surgical excision was necessary in 35.2%. Symptoms resolved in 89.6% of patients, and recurrence was 6.8%.

Conclusion: Most benign breast disorders occur in young and middle-aged women, with the most common diagnosis being fibroadenoma. ANDI classification offers an organized method of differentiation between physiological variations and pathological conditions. Early diagnosis and tailored treatment plans lead to beneficial clinical results with minimal recurrence.

Keywords: *Benign breast disease, ANDI classification, fibroadenoma, fibrocystic changes, fine-needle aspiration cytology, breast imaging.*

1. INTRODUCTION

Benign breast diseases represent a complex category of conditions appearing as a consequence of physiological changes, developmental anomalies, and involutional processes in the mammary gland. All these conditions are referred to as Aberrations of Normal Development and Involution (ANDI) and account for the majority of clinical breast complaints in women of any age (Hughes et al., 1987) [4]. The ANDI system was introduced to provide an accurate description of benign breast diseases as normal physiological changes and not as distinct pathological disorders (Hughes, 1991) [2]. The system enables one to distinguish between benign breast conditions appearing as a consequence of developmental anomalies and involutional changes associated with aging and true pathological disorders.

Benign breast diseases (BBD) demonstrate a wide variation in clinical presentation, such as mastalgia, palpable breast lumps, nipple discharge, and distortion of the architectural pattern in the breast tissue. Although benign diseases, they will cause marked patient distress and worry, with unwarranted treatments (Hamed & Fentiman, 2001) [5]. Diagnosis of BBD is made on the combination of clinical presentation, imaging procedures like mammography and ultrasonography, and cytological examination by fine-needle aspiration cytology (FNAC) (Lee & Wang, 1998) [7]. FNAC lacks distinction between benign lesions of different types, and so histopathological diagnosis becomes an absolute requirement to make accurate diagnoses. The terminology of benign breast diseases is not standardized and has varied over the years, and the ANDI system provides

a comprehensive system by categorizing the disorders as developmental, cyclical, and involutional changes. The classification system has been utilized to a very large extent in the clinic to increase the diagnostic yield and develop proper management protocols (Hughes et al., 1987) [4]. Observational studies in different populations, including Indian women, have established the utility of the system in characterizing the epidemiology and clinical presentation of BBD (Kaur et al., 2012) [1]. Association of benign breast diseases with hormonal imbalance, reproductive life, and genetic factors also reflects the multifactorial nature of the conditions (Murillo Ortiz et al., 2002) [3].

Even though non-malignant, benign breast diseases must be adequately evaluated and treated to alleviate symptoms and prevent unnecessary surgery. BBD treatment ranges from conservative, like lifestyle alteration and hormonal treatment, to surgical removal in symptomatic or possible malignant lesions. Familiarity with the natural history of the diseases is critical in the provision of evidence-based care and prevention of overtreatment (Ali & Faraj, 2023) [6]. Adolescent patients should also be given special consideration since presentation and treatment of breast disease in adolescents are unique from older women (Duflos et al., 2012) [8].

The aim of this study is to evaluate the diagnosis and treatment modalities of abnormalities of normal development and involution of the breast with special reference to the clinical importance of the ANDI classification system. By means of an integration of clinical, radiologic, and pathologic data, this study aspires to enhance the comprehension of benign breast disorders and to provide a rational approach to their management.

2. METHODS

Study Design and Setting

This study was conducted as a prospective clinical study in a **** with focus on identification and management of benign breast diseases under the Aberrations of Normal Development and Involution (ANDI) model. Institutional ethics committee approval for the study was obtained, and written informed consent was obtained from all the subjects prior to their recruitment. The study was conducted over a span of two years, during which patients with breast complaints were systematically screened.

Study Population

The study included female patients of all ages with clinical presentations suggestive of benign breast disease like mastalgia, palpable mass, nipple discharge, and breast asymmetry. Patients with a history of malignancy, previous history of surgery for breast cancer, or with inconclusive histopathological examination results were excluded from study. Adolescent patients with breast pathology were also included to assess the spectrum of developmental abnormalities. Recruitment was both from inpatient and outpatient departments to have wide coverage of cases.

Clinical Diagnosis and Assessment

All patients had a complete clinical evaluation, which included a complete history-taking and physical examination. History was centered on duration of symptoms, menstrual cycle relationship, use of hormonal therapy, family history of breast disease, and other associated medical illnesses. Clinical breast examination was conducted to evaluate features of the lump, tenderness, nipple change, and skin change. The benign breast disease was classified using the ANDI system, which categorized the conditions as developmental, cyclical, or involutional changes.

Radiological investigations like ultrasonography and mammography were performed based on clinical suspicion. Ultrasonography was performed mainly in younger women and women with dense breasts, while mammography was performed in older women or those with suspicious clinical exams. Fine-needle aspiration cytology (FNAC) was performed in cases where imaging was suggestive of further evaluation. Core needle biopsy was performed when FNAC was not diagnostic or when histopathological diagnosis was necessary.

Therapeutic Approaches

The plan of management was individualized based on the clinical presentation, imaging, and histopathological examination. Patients with mastalgia or fibroadenosis were managed conservatively with the use of analgesics, dietary modification, and reassurance. Hormonal therapy in the form of danazol or evening primrose oil was used for chronic mastalgia. Symptomatic cystic lesions were aspirated under ultrasound, while fibroadenomas were removed by surgery in the presence of rapid growth or at patient request. Wide local excision was performed for phyllodes tumor or recurrent cysts with atypical features.

In ductal ectasia or nipple discharge, removal of the duct was considered indicated in the case of persistence. Surgical treatment was performed as indicated in developmental disorders, e.g., macromastia or juvenile hypertrophy. Involving changes such as sclerosing adenosis or fat necrosis were managed according to the severity of symptoms, with surgery being reserved for cases of diagnostic uncertainty.

Data Collection and Statistical Analysis

Demographic and clinical data were recorded in a standardized manner, including patient age, presenting complaints,

diagnostic findings, and therapeutic outcomes. Statistical analysis was done using computer software packages, and categorical variables were presented as frequency and percentage. Continuous variables were presented as mean ± standard deviation. The correlation between different benign breast disorders and patient parameters was determined using the relevant statistical tests, with $p < 0.05$ considered as the significance level.

3. RESULTS

Demographic and Clinical Characteristics of Patients

A total of 250 female patients presenting with benign breast disorders were included in this study. The age of participants ranged from 12 to 65 years, with a mean age of 32.8 ± 10.5 years. The majority of patients (48.4%) belonged to the 20–40 years age group, followed by 35.2% in the 41–60 years age range. Adolescents comprised 10.8% of the study population, whereas postmenopausal women accounted for 5.6%. The most frequent presenting symptom was mastalgia (52.0%), followed by a palpable breast lump (43.2%) and nipple discharge (8.8%). Bilateral involvement of the breasts was noted in 18.4% of the cases, while unilateral involvement was more prevalent (81.6%).

Table 1. Demographic and Clinical Characteristics of Patients

Characteristic	Frequency (n = 250)	Percentage (%)
Age Group (years)		
12–19	27	10.8
20–40	121	48.4
41–60	88	35.2
>60	14	5.6
Presenting Symptoms		
Mastalgia	130	52.0
Palpable Lump	108	43.2
Nipple Discharge	22	8.8
Skin/Nipple Changes	18	7.2
Breast Involvement		
Unilateral	204	81.6
Bilateral	46	18.4

Distribution of Benign Breast Disorders

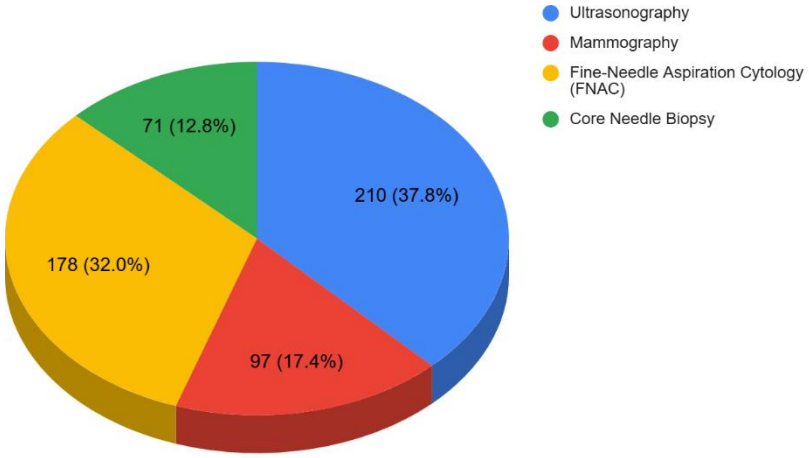
Of the several benign breast disorders under the ANDI system, fibroadenoma was the most frequent diagnosis, representing 38.0% of the cases. Fibrocystic changes were seen in 22.4% of the patients, whereas mastitis and abscesses were seen in 12.8%. Other diagnoses were duct ectasia (8.4%), phyllodes tumor (4.0%), and fat necrosis (3.6%). Developmental anomalies like juvenile hypertrophy and macromastia were seen in 6.8% of the cases, while involutional changes like sclerosing adenosis were seen in 4.0%.

Table 2. Distribution of Benign Breast Disorders Based on ANDI Classification

Diagnosis	Frequency (n = 250)	Percentage (%)
Fibroadenoma	95	38.0
Fibrocystic Changes	56	22.4
Mastitis/Abscess	32	12.8
Duct Ectasia	21	8.4
Phyllodes Tumor	10	4.0
Fat Necrosis	9	3.6
Juvenile Hypertrophy	11	4.4
Macromastia	6	2.4
Sclerosing Adenosis	10	4.0

Diagnostic Modalities and Their Efficacy

The most frequently used imaging technique was ultrasonography and was done in 84.0% of cases, with mammography being carried out in 38.8% of patients, predominantly among patients over the age of 40 years. FNAC was carried out in 71.2% of cases, with a total diagnostic yield of 92.4%. Core needle biopsy was performed in 28.4% of the cases, primarily for lesions with FNAC that were inconclusive or phyllodes tumor-suspected. There was statistical significance between imaging findings and histopathology ($p < 0.05$), thereby establishing the validity of combination diagnostic procedures.

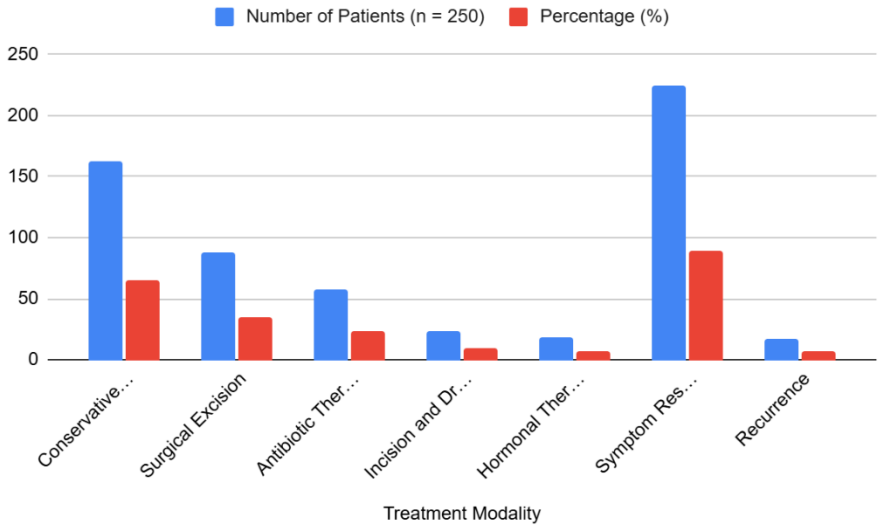


Graph 1. Distribution of Diagnostic Modalities Used in the Study

Treatment Modalities and Outcomes

Of all the patients, 64.8% were treated conservatively by symptomatic management, reassurance, and follow-up. Surgical removal was carried out in 35.2% of the cases, such as fibroadenomas greater than 3 cm, symptomatic phyllodes tumors, recurrent cysts, and refractory ductal ectasia. Antibiotics were given to patients with abscesses and mastitis, and incision and drainage were necessitated in 9.2% of the cases. Hormonal therapy, such as danazol, was prescribed in selected cases of

severe cyclic mastalgia. Post-treatment follow-up over six months showed symptom resolution in 89.6% of patients, with recurrence observed in 6.8% of cases.



Graph 2. Treatment Modalities and Their Distribution

These observations bring to the fore the clinical picture of benign breast diseases and the efficacy of a methodical diagnostic and treatment strategy. The study emphasizes the significance of the ANDI classification in directing the management of the patient and eliminating unnecessary procedures to provide the best possible patient results.

4. DISCUSSION

The results of this study identify the clinical spectrum of benign breast pathology and underscore the utility of the Aberrations of Normal Development and Involution (ANDI) classification in directing diagnosis and management. The most frequent benign breast disease found in this study was fibroadenoma, at a prevalence of 38.0%. This result is in line with the work of Khan et al. (2003) [9] in Nepal, where fibroadenoma was the most common benign breast condition. In other populations, too, fibroadenoma has been shown to be the most common diagnosis in young women, highlighting its correlation with hormonal factors and breast growth.

Fibrocystic changes were the second most frequent benign breast disorder, occurring in 22.4% of cases. This prevalence is consistent with earlier studies that have shown fibrocystic changes to be one of the most common breast conditions, especially in women of the reproductive age group (Carter et al., 1988) [10]. Fibrocystic changes have been attributed to hormonal changes and cyclical changes in breast tissue, which may result in different clinical presentations like mastalgia and nodularity. The widespread presence of fibrocystic alterations in this series is additional evidence supporting the theory that these changes represent a physiological rather than an actual pathologic process.

Duct ectasia, occurring in 8.4% of this series, has been identified as an important benign breast disorder, especially in women of advancing age. The results are similar to those found by Petersen et al. (1993) [11], who did a prospective study of duct ectasia and observed comparable prevalence figures. The presentation of duct ectasia, i.e., nipple discharge and local inflammation, has been well documented, with work such as Ramalingam et al. (2015) [13] in Indian women highlighting its connection with periductal mastitis. The occurrence of duct ectasia among postmenopausal women implies that involutional processes play a significant role in its pathogenesis, consistent with the ANDI classification system.

In addition, the research presented cases of mastitis and breast abscesses in 12.8% of the patients. Such prevalence is consistent with the results of Prpić et al. (1992) [12], who reported a high number of cases with inflammatory breast disease. Infections like mastitis occur more frequently among lactating women, but also among non-lactating women as a result of ductal obstruction and secondary bacterial infection. The results of this study again support the significance of bacterial colonization in the causation of inflammatory breast diseases requiring antibiotic treatment and, in a few instances, surgical drainage.

Fine-needle aspiration cytology (FNAC) was performed in 71.2% of cases and had a diagnostic accuracy of 92.4%. This finding is consistent with Maygarden et al.'s (1994) [14] study, which compared histopathological diagnoses with FNAC findings and observed high rates of accuracy in the differentiation between various subtypes of benign breast disease. Although it was useful diagnostically, FNAC was limited in classifying some proliferative breast diseases, as observed by

Mridha et al. (2006) [15], who highlighted the value of histopathological correlation. Core needle biopsy was done in instances where FNAC was inconclusive in this research, adding further diagnostic accuracy.

Treatment modalities were also different depending on the type of benign breast disorder. Conservative treatment was the most used method in 64.8% of instances, especially for conditions like mastalgia and fibrocystic changes. This strategy concurs with findings of earlier studies on the self-limiting course of most benign breast conditions and the importance of avoiding overtreatment (Carter et al., 1988) [10]. Surgical excision was carried out in 35.2% of patients, mainly for fibroadenomas greater than 3 cm, phyllodes tumors, and recurrent cystic lesions. These results point to the need for individualized treatment plans based on clinical severity and patient choice.

Six-month follow-up of the patients revealed a rate of resolution of symptoms at 89.6%, with a recurrence rate of 6.8%. These findings are in keeping with current literature, which indicates that recurrence of benign breast pathology is low if proper management is in place (Ramalingam et al., 2015) [13]. The findings of the present study are in agreement with the ANDI classification as a valuable tool in separating physiological changes from pathological conditions and enabling rational management decisions and better outcomes for patients.

In general, the findings of the study add to the expanding literature on benign breast disorders and their clinical management. By combining clinical, radiological, and cytological methods, the study highlights the value of a multidisciplinary approach in both the diagnosis and management of benign breast disease. The findings are in accordance with other studies, validating the continued role of the ANDI classification in ensuring that the treatment protocol for these conditions is standardized. Additional future studies with larger populations and long-term follow-up are required to confirm these data and investigate new trends in the epidemiology and management of benign breast conditions.

5. CONCLUSION

This work underscores the clinical presentation of benign breast disorders and the importance of the Aberrations of Normal Development and Involution (ANDI) classification in the management and diagnosis. Fibroadenoma was found to be the most prevalent benign breast disorder, followed by fibrocystic changes, mastitis, and duct ectasia. The results confirm that benign breast diseases most often occur in women of reproductive age, and hormonal factors play a central role in their pathogenesis. Diagnostic modalities like ultrasonography, mammography, and fine-needle aspiration cytology (FNAC) were highly accurate and helped differentiate between different breast conditions. Conservative treatment was successful in most cases, and surgery was reserved for symptomatic or progressive lesions. The overall results of treatment were good with a high percentage of resolution of symptoms and low recurrence. By reaffirming a systematic approach to benign breast disease, this study highlights the value of early diagnosis, judicious choice of treatment, and patient education to minimize unnecessary procedures and enhance clinical results. Additional research with long-term follow-up is necessary to optimize management techniques and advance patient care.

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