Study of Clinicopathological Profile of Benign Breast Disease Patients at a Tertiary Care Centre in Central India: An Observational Study

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ABSTRACT

Introduction: Historically, the focus of the medical fraternity had always been on the early diagnosis and treatment of breast carcinoma. However, most women coming with breasts related problems are diagnosed as having one or the other type of benign breast disease (BBD). Lack of awareness about BBDs causes most women to misunderstand the symptoms of the BBD to the carcinoma breast.

Material and Methods: This was a hospital-based, single-centre, descriptive study involving ninety women aged between 15-45 years diagnosed with benign breast disease. Data on age, presenting complaints, clinical findings and diagnosis were collected.

Results: The most common benign breast disease among enrolled women was fibroadenoma (65.6%), followed by fibroadenosis (17.8%), and mastalgia (5.6%), The mean age of women diagnosed with fibroadenoma and fibroadenosis was 26.9 and 25.9 years, respectively. About 83.3%, 21.1%, and 4.1% of the women enrolled in the study said that their chief concern was a pain in the breast, followed by breast lump and discharge from the nipple, respectively. The mean duration of symptoms among women diagnosed with fibroadenoma breast was 3.9 months. Most women had breast problem(s) limited to only one breast (unilateral) (92.2%), only, 7.7% of women complained of breast symptoms in both of their breasts. The breast problem was located mostly in the right breast and upper outer quadrant followed by the lower outer quadrant. Breast pain was positively associated with periods of menstruation in all women diagnosed with fibroadenosis.

Conclusion: BBD were most seen among young women in the second or third decade of life. The main complaint related to BBD was breast pain (with or without lump). Most women had unilateral symptoms.

Keywords: Clinicopathological Profile, Breast Disease

INTRODUCTION

As per the national cancer registry report 2020, the most common cancer among females in India was breast cancer followed by cancer of the cervix.[1] However, malignant diseases of the breast account for only one-fifth of the total neoplastic diseases.[1] Most neoplastic diseases of the breast are benign and are collectively referred to as 'Benign Breast Diseases' (BBD).[2] These diseases account for more than 80% of the breast-related complaints among women of the reproductive age group.[2,3] BBD (being false alarm) causes tremendous distress, anxiety, and panic among women.[4,5] For several years now, the month of October is celebrated as 'breast cancer awareness' month with tremendous enthusiasm.[6,7] Thus, awareness about early symptoms of breast cancer has increased significantly among young Indian women living in urban areas.[8,9] Nevertheless, most women coming with breasts related problems are diagnosed as having one

or the other BBDs. Lack of awareness about BBDs causes most women to misunderstand the symptoms of the BBD to the carcinoma breast.[5,10–12] Historically, the focus of the medical fraternity had always been on the early diagnosis and treatment of breast carcinoma, thus, for many decades no evidence-based recommendations were formulated for the screening, identification, management, prognosis, and reassurance for BBDs.[13]

Histologically, benign breast diseases are an extension of the normal histo-physiology of breast tissue.[14] In 1992, an international working group recommended a universal classification for these diseases. This classification came to be known as the "Aberrations of Normal Development and Involution (ANDI)" classification.[15] Later, Page et al. developed a separate classification to simplify the complicated 'ANDI' classification. According to Page's classification, all breast disorders are classified into non-proliferative,

proliferative without atypia and proliferative lesions with atypia.[16] This classification categorizes histological changes in breast tissue according to their probability to develop into malignant carcinoma breast.

Across geographical regions, significant variations have been noticed about the 'classic' presentation of different BBDs.[2,8,17–19] Most BBDs have an overarching spectrum of clinical presentation; however, the relative frequency of each symptom varies with the type of BBDs.[17-19] Further, the peak age for each of these BBDs varies from puberty to the postmenopausal period. Although national-, state-, and regional level statistics are available for carcinoma breast, no reliable data or registry is available to indicate the burden of disease and secular trends about BBD among the female population of India.[1] The morbidity burden due to BBDs is constantly changing secondary to ever-changing demography, dietary habits, reproductive practices, change in the prevalence of hormonal contraceptives, and increasing awareness.[20–22] Further, the prevalence of different BBDs varies in different geographical regions. Therefore, empirical data is needed to draft an evidence-based algorithm for screening, identification, and management of various breast problems. Towards this end, we need to know with reasonable accuracy who are affected, at what stage of life they are affected, what were their complaints, how long did it take to seek care and what was the diagnosis. Therefore, this study aimed to investigate the clinical, pathological, and epidemiological features of women diagnosed with benign breast disease.

MATERIAL AND METHODS

Study Design: This was an outpatient clinic-based, single-centre, descriptive, observational study.

Study Settings: The present study was conducted at the Department of General Surgery, JK Hospital affiliated with LN Medical College, Bhopal. It is a tertiary care institute.

Study Duration: The total duration of the study was 24 months.

Study Outcomes: Primary Outcome(s): The following primary outcome(s) were recorded. (i) Type of Benign Breast Disease (ii) Age (iii) Chief presenting problem

Sample Size Calculation: Using the prescribed formula for prevalence/proportion, the minimum required sample size for this study was calculated as equal to a total of 80 participants.[23] Sample size is calculated using following formula:

n = [DEFF*Np(1-p)]/ [(d²/$Z^2_{1-\alpha/2}$*(N-1)+p*(1-p)] (*** https://www.openepi.com/SampleSize/SSPropor.html); 4- square of standard-normally distribute @95% CI; p-expected prevalence; p= 5.5%; d- desired precision (d= 0.05 for 95% CI);

DEFF-Design Effect= 1; Minimum required sample size= 80.

Participants' recruitment: The participants were recruited into the study after verifying that they fulfilled the following selection criteria.

Inclusion Criteria
- Female patients
- Women aged between 18-45 years (both inclusive).
- Patients giving written informed consent to participate in the study.

Exclusion Criteria
- Women are already diagnosed with malignant breast disease and referred to OPD for further consultation.
- Women diagnosed with malignant breast cancer after an initial consultation at the present institute.

Informed Consent
A bi-lingual (Hindi & English) consent form was drafted following the prescribed guidelines for research on human participants. The consent form was given to all the participants to read. Thereafter, the contents of the consent form were explained to all the prospective participants. The participants were informed and explained that they have the right to withdraw from the study at any point in time. All the questions from participants about the study, procedure, disease(s), treatment, and data privacy were answered. Thereafter, willing participants were asked to sign the consent form.

Data Collection: The questionnaire had 4 parts as follows: (i) Demographic details. (ii) History of Presenting Complaint. (iii) Findings of clinical examination, (iv) Findings of radiological and laboratory examination

Plan and procedure
i **Enrolment of Participants:** After the initial registration, all prospective participants were seen in the OPD clinic. After the completion of the initial round of OPD consultation, each prospective participant was screened using the selection criteria. Those patients who fulfilled the primary screening filters were approached for consent to participate in the study.

ii **Data Collection:** The data was collected from participants who gave their consent for the study. The data was collected while ensuring the privacy and comfort of the participants.

iii **Source of data:** There were two sources of the data: clinical records and patient interviews. During the participants' interview, a separate consent was taken to obtain permission to collect the desired data from their clinical records.

End Point of Study: (i) A participant decided to withdraw from the study, (ii) Participants were diagnosed with a malignant carcinoma breast either after the clinical, radiological, or pathological examination. (iii) After the data collection was complete.

STATISTICAL ANALYSIS

The primary outcome was the identification of the type of

benign breast disease among the women presenting with breast-related complaints. The secondary aim was to describe the benign breast disease in terms of population, place, biology, presenting symptoms, and clinical findings. As mentioned earlier, the data were collected in a paper-based data collection form. Thereafter, the data were coded and entered in Microsoft Excel. The coded data were imported into Stata 16.1 version for analysis. For the interval and ratio data types, the author calculated the mean, median, mode, and standard deviation. For the nominal and ordinal data, the author calculated the frequency, percentage, and proportion. The data variables matching the characteristics of the normal distribution were presented as means and standard deviations.[24] Similarly, the data variables matching the characteristic properties of the non-normal distribution are described as median and the interquartile range. The interval and the ratio data variables were analysed using a student's t-test test. Categorical variables were analysed using chi-square (χ^2) tests.[25]

RESULTS

In the present study, a total of 90 participants were enrolled. The most common benign breast disease among enrolled women was fibroadenoma (65%), followed by fibroadenosis (17%), mastalgia (5.5%), and duct ectasia (4.4%) (Table 1). As can be noted from table 2, among the women diagnosed with fibroadenoma, the mean and median age of women was 26.9 ±8.3 years and 25 years, respectively. Further, most women who were diagnosed with fibroadenoma belonged

to the age group 15-25 years, and only 13.5% of women diagnosed with fibroadenoma were between 36-45 years. Among the women diagnosed with fibroadenosis, the mean and median age of women was 25.9 ±8.03 and 26 years, respectively. Among women diagnosed with fibroadenoma, 3.3% and 66.6% were residing in rural and urban areas, respectively. Among women diagnosed with fibroadenosis, 6.2% and 93.7 % were residing in rural and urban areas, respectively.

As can be seen from table 3, about 83.3%, 21.1%, and 4.4% of the women enrolled in the study said that their chief concern was pain in the breast, a breast lump, and discharge from the nipple, respectively. Among the women diagnosed with both fibroadenoma and fibroadenosis, the most common complaint was pain in the breast, followed by a lump in the breast and nipple discharge was the least common complaint. The mean duration of symptoms among women with breast pain was 14.6 (±18.2) months. More than 63.15 % of women had symptoms for less than 6 months. Most women (81.6%) with breast lumps presented within 3 months or less. Further, the mean duration among women with nipple discharge was 0.8 (±1.6) months. The majority of women complained of gradual progression of their symptoms: 67.4% of women diagnosed with fibroadenoma and 18.6% diagnosed with patients of fibroadenosis complained that their symptoms were gradually progressive. None of the patients had a rapidly progressive symptom in this study. However, on clinical examination about 85% of women had a breast lump: 80% of all women had just a single lump on clinical examination. A breast lump was not found in 1.6%, 18.7%, and 66.6% of the women diagnosed with fibroadenoma, fibroadenosis, and other BBD on clinical examination.

Most women had breast problem(s) limited to only one breast (unilateral), only, 8.8% of women had bilateral symptoms. About 44.4% of women had a complaint in the upper outer quadrant, 20.2% of women had a complaint in the lower outer quadrant, 10.7% of women had a complaint in the upper inner quadrant and 5.9% patients had a complaint in the lower inner quadrant. 19% of women had diffuse swelling Most of the women diagnosed with both fibroadenoma (81.9%) and fibroadenosis (4.9%) described the pain in their breast as a 'dull-aching' sensation. Breast pain was positively associated with periods of menstruation in all women diagnosed with fibroadenosis. In sharp contrast, none of the women diagnosed with either fibroadenoma or other types

Diagnosis	n	%
Fibroadenoma	59	65.6
Fibroadenosis	16	17.8
Mastalgia	5	5.6
Duct Ectasia	4	4.44
Breast Cyst	3	3.33
Breast Abscess	2	2.22
Galactorrhea	1	1.11
Total	90	100

Table-1: The diagnosis of the benign breast diseases among participants (n=90)

Age (Years)	Diagnosis			
	Fibroadenoma (n, %)	Fibroadenosis (n, %)	Other* (n, %)	Total (n, %)
15-25	37 (82.2)	7 (15.6)	1 (2.2)	45 (50.0)
26-35	14 (48.3)	7 (24.1)	8 (27.6)	29 (32.2)
36-45	8 (50.0)	2 (12.5)	6 (37.5)	16 (17.1)
Total	59 (65.6)	16 (17.8)	15 (16.7)	90 (100.0)
Mean (SD)	26.9 (±8.3)	25.9 (±8.03)	31.3 (±7.63)	
*- Include Breast abscess, Duct ectasia, Mastalgia, Cyst				
Table-2: Distribution of study participants by age (n = 90)				

Symptom	Diagnosis			
	Fibroadenoma (n, %)	Fibroadenosis (n, %)	Other (n, %)	Total (n, %)
Lump	7 (11.86)	4 (25.0)	8 (53.3)	19 (21.1)
Pain	57 (96.6)	13 (81.25)	5 (33.3)	75 (83.3)
Nipple Discharge	1 (1.69)	0 (0.0)	3 (20.0)	4 (4.4)
Total	59 (65.55)	16 (17.77)	15 (15.55)	90 (100.0)

Table-3: Distribution of study participants based on presenting symptom (n = 90)

Side	Diagnosis			
	Fibroadenoma (n, %)	Fibroadenosis (n, %)	Other (n, %)	Total (n, %)
Bilateral	2 (28.6)	1 (14.3)	4 (57.1)	7 (7.7)
Left	27 (65.9)	6 (10.8)	8 (18.9)	41
Right	30 (71.1)	9 (22.0)	3 (7.3)	42
Total	59 (66.66)	16 (17.77)	15 (15.55)	90 (100.0)

Table-4: Anatomical location of breast complain (n=90)

Pain	Diagnosis			
	Fibroadenoma (n, %)	Fibroadenosis (n, %)	Other (n, %)	Total (n, %)
Nature				
Dull aching	50 (82.0)	3 (4.9)	8 (13.1)	61 (67.8)
Throbbing	0 (0.0)	0 (0.0)	2 (100.0)	2 (2.2)
No Pain	9 (33.3)	13 (48.1)	5 (18.5)	27 (30.0)
Associated with Menstruation	0 (0.0)	16 (100.0)	0 (0.0)	16 (100.0)

Table-5: Distribution of study participants based on characteristics of pain (n = 90)

of BBD had breast pain that varied with different phases of the menstrual cycle.

DISCUSSION

In the present study, the most common benign breast disease among enrolled women was fibroadenoma (65.6%), followed by fibroadenosis (17.8%), and mastalgia (5.6%). In comparison, Kanpurwala SH et al. (2017) reported that among study participants 77% of women had fibroadenoma, 4.3% women had fibroadenosis and only 1% of the women were diagnosed with breast abscess.[26] In contrast, Khanzada et al. reported that among study participants were 27% of women received a diagnosis of fibroadenoma, 20% had fibroadenosis, 16% had breast abscess, and only 11% were diagnosed with mastalgia.[19] Singh et al. SB (2020) observed that among study participants most common type of BBD was fibroadenoma (66.7%), followed by fibroadenosis (16.7%) and breast abscess was diagnosed among 6% of women.[27] Selvakumaran et al. (2017) reported that the most common type of BBD among study participants was fibroadenoma (55.9%), distantly followed by fibroadenosis (20.8%), mastalgia 6.0% and only 4% of women were diagnosed with breast abscess 4.0%(17). Khanna et al. reported that the most common type of BBD among their participants was fibroadenoma diagnosed among about 40% of women.[28] Thus, the findings of the present study were comparable with other studies.

In the present study, age group-wise, about 50% of the women diagnosed with BBD were between 15-25 years of age and 32.2% of women were aged 26-35 years and only 17% of the women were aged between 36-45 years of age. In the present study, a declining trend in the prevalence of BBD concerning age was observed among study participants. Each of the several types of BBD diagnosed among the women showed a different peak age of presentation. Kanpurwala et al. reported the most common age group among the women diagnosed with BBD were 21-30 years (43%), followed by 11-20 years (32%), and less than 1% of women diagnosed with BBD were older than 60 years of age.[26] Similarly, Khanzada et al. reported the most common age group among the women diagnosed with BBD was 21-30 years (43.6%), followed by 31-40 years (33.1%), and only 1.8 % of women diagnosed with BBD were older than 50 years of age.[19] Selvakumaran et al. also reported that most cases of BBDs were seen among women aged 21-30 years followed by 31-40 years.[17]

In the present study, most women diagnosed with fibroadenoma were between 15-20 years of age (45%) and most of the women diagnosed with fibroadenosis were between 21-30 years of age (50%). Kumar S et al. reported that fibroadenoma was most commonly (74%) seen among women aged 11-30 years.[9] Kanpurwala et al. reported that most cases of fibroadenoma among women were seen among those aged 21-30 years.[26] Selvakumaran et al. reported that most cases of fibroadenoma were seen among women aged

between 15-25 years.[17] In the present, only 5% of the women diagnosed with fibroadenoma were older than 40 years of age and none of the women aged 41-45 years was diagnosed with fibroadenosis. Kanpurwala et al. reported that only 2% of all cases of fibroadenoma was seen among women aged 41-50 years.[26] Bagale et al. also reported that only 4% of women diagnosed with BBD were older than 40 years.[29]

In the present study, most women who were diagnosed with fibroadenosis belonged to the age group 21-30 years, followed by 15-20 years, none of the women diagnosed with fibroadenoma were between 41-45 years. Kumar et al. (2010) reported that fibroadenosis was more commonly seen in the age group of 21-30 years (50.4%) followed by 31-40 years (27.7%) cases.[9] In the present study, most cases of breast abscess were seen among women aged 21-30 years. Bagale et al. also reported that most cases of breast abscess were seen among women aged 21-30 years.[29] In the present study, most of the women diagnosed with BBD were residing in urban areas (97.7%) and only 2.2% of women were living in rural areas. Kanpurwala et al., Sangma et al., and Prasad et al. (2016) also reported that most of the women diagnosed with BBD resided in urban areas.[26,30,31]

In the present study, the most common presenting complaint/symptom among women was a pain in the breast, followed by a lump in the breast, and only 4.4% of women complained of discharge from the nipple. In contrast to our findings, Kumar et al., Kanpurwala et al., Sangma et al., and Selvakumaran et al. reported that among women diagnosed with BBD, the most common complaints were lump, pain (with or without lump) and nipple discharge.[9,17,26,30]

In the present study, most women had breast problem(s) limited to only one breast (unilateral), only, 7.7% of women complained of breast symptoms in both of their breasts. For most women enrolled in the study, 46.6% had symptoms in the right breast and 45.5% in the left breast. Raju et al. observed that most women had unilateral symptoms: 47% had a problem in the right breast, 48% had symptoms in the left breast, and only 5% had a bilateral complaint.[18] Kanpurwala et al. reported that 48% complained of a lump in the left breast followed by right breast (45%) and bilateral symptoms were seen in 7% of women.[26] Selvakumaran et al. and Sangma et al. also reported most women had unilateral symptoms most commonly located in the right breast.[17,30] In sharp contrast to other studies, Bagale et al., Pai S et al. (2019) reported that symptoms and lesions were more common in the left breast.[8,29]

In the present study, most of the women had symptoms located in their upper outer quadrant (44.4%) followed by lower-outer quadrant (20.2%), 10.7% in the upper inner quadrant & 5.9% in the lower inner quadrant. Mudholkar et al., Kanpurwala et al., and Kumar et al. reported that the breast lesion was most commonly located in the upper outer quadrant.[26,32]

CONCLUSION

Among the women of the reproductive age group (15-45 years), the most common benign breast disease

among enrolled women was a fibroadenoma, followed by fibroadenosis, and mastalgia. Most women who were diagnosed with fibroadenoma belonged to the age group 15-25 years. In comparison, women who were diagnosed with fibroadenosis belonged to the age group 15-25 and 26-35 years equally. The three most common concern among women in our study was a pain in the breast, a lump in the breast and discharge from the nipple. Most of the women who complained of breast pain were between 15-20 years of age and only 8% of women who complained of pain were between 36-45 years of age. Among most women the breast problem was unilateral. In the present study, most of the women had symptoms located in their upper outer quadrant followed by lower outer quadrant, upper inner quadrant, and lower inner quadrant. Therefore, in the present study, most women complained of breast complaints in the upper outer quadrant of the right breast.

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