http://jmscr.igmpublication.org/home/
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v7i10.99

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Research Article

Triple assessment in Diagnosis of Benign Breast Diseases: An Institutional Study

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Abstract

Background: *Benign breast disease is the most common cause of breast problems in females and it is more frequent than the malignant ones. Benign breast disorders are usually seen in the reproductive period of life are largely thought to be hormone induced and there is dramatic fall in the incidence after the menopause. Benign Breast lesions deserve attention because of high prevalence, their impact on patient's life and due to cancerous potential of some high risk breast lesions. This study was aimed to evaluate the different types of benign breast diseases in females based on clinical, radiological and pathological findings and to assess the overall efficacy of the triple assessment in diagnosing the benign breast diseases.*

This prospective study was conducted between February 2014 and September 2015 at Shri ram murti smarak institute of medical sciences, Bareilly.

Results: *A total of 250 female patients of benign breast disease were studied. The mean age was 36 years and fibroadenoma was most common benign breast disease followed by fibrocystic disease. Breast lump was most common presentation. Clinical breast examination had senstivity of 90%, specificity of 98% and radiological breast examination had senstivity of 86.6% and specificity of 97.2%. FNAC is an excellent method for diagnosing breast lesions with a sensitivity ranging between 89% and 98% and specificity between 98% and 100%. When clinical, radiological and pathological examinations were combined together, the diagnostic accuracy approached 100%.*

Conclusion: *Triple assessment by clinical, radiological and pathological examination can be useful in the diagnosis of benign breast lesions.*

Introduction

Benign breast diseases constitute heterogeneous group of disorder including developmental abnormalities, epithelial and stromal proliferations, inflammatory lesions and neoplasms.[1]. Benign breast diseases are traditionally considered less relevant diseases as compared to malignancy of breast.[2]. It is the most common cause of breast problems in females and it is 10 times more common than breast cancer in the western world[3]. Of all the diagnosed breast diseases, benign lesions account for 90%.[4] Approximately 30-40 percent of the women suffering from BBDs required treatment at some time in their life.[5]

Fibroadenoma is found to be the most common benign breast disease followed by fibrocystic disease followed by breast abscess and mastalgia.[6] The incidence of benign breast diseases begins to rise during the second decade of life and peaks in the fourth and fifth decade.[7] The most common symptoms are pain and palpable breast lumps. Other clinical features include nipple discharge, nipple deformity such as retraction and occasional skin changes (dermatitis in some form of mastitis as well as dimpling in fat necrosis and fibrosis)[8]. Certain benign proliferative disorders of breast can have a risk of progression to malignancy.[9] Hence, thorough evaluation of breast lumps is essential. Clinical examination is the first step in the assessment of breast disorders.[10] With the advent of imaging modalities, Ultrasound (USG) of breast has become an important diagnostic tool.[11] The triple assessment consisting of clinical evaluation, breast imaging and fine needle aspiration cytology (FNAC) has been recommended as a diagnostic tool for evaluation of patients with palpable breast lumps[12]. When the three assessments are performed adequately and produce concordant results, the triple assessment diagnostic accuracy approaches 100% and definitive treatment can be started before histology.[12]

Material and Methods

The present prospective study was done in department of Pathology, SRMS IMS Bareilly from February 2014 to September 2015.

Inclusion Criteria

All female patients diagnosed clinically as having benign breast diseases were included in the study irrespective of any age after obtaining their written consent.

Exclusion Criteria

1) Cases which were proved as having malignant breast disease during clinical, radiological and pathological examination were excluded from this study.
2) Women with an obvious malignant disease or those who had been treated for malignancy earlier were excluded from this study.

A total of 250 patients were attended with breast symptomatology i.e., breast lump, vague nodularity with pain and discharge over a period of months. These patients were sent to us by surgery outpatient department for fine needle aspiration cytology and then cases were studied. Wherever we were not sure of the diagnoses or in suspicious cases, we advised for histopathological examination. Subsequently these patients also underwent ultrasound and mammography of both breasts. 250 cases of benign breast lumps were studied in relation to age group, clinical, radiological and pathological assessment and their comparison with final histopathological diagnosis.

Observations

This study comprised of 250 patients of benign breast diseases. In these cases initial clinical examination followed by radiological examination and pathological examination was conducted.

Age Distribution

The highest incidence of benign breast diseases was in the age group of 30-39 years (33.33%). The overall range is from 12 years to 65 years and mean age was 36 years.(Table 1)

Table 1: Age distribution of benign breast disease

Age group (years)	No of cases	Percentage (%)
11-19	17	6.66
20-29	42	16.66
30-39	83	33.33
40-49	75	30
>49	33	13.33

Patterns of BBDs

The highest number of cases of benign breast diseases were of fibroadenoma (53.33%) followed by fibrocystic disease (23.33%) and duct ectasia (10%).(Table 2)

Table 2: Disease pattern of benign breast diseases

Diseases	No of cases	Percentage(%)
Fibroadenoma	134	53.33
Fibrocystic Disease	58	23.33
Gallactocele	8	3.33
Phyllodes tumor	8	3.33
Duct ectasia	25	10
Breast abscess	17	6.66

Distribution of mode of Pattern

In our study, most common presenting symptom was lump (53.33%) followed by lump and pain (23.33%), pain (13.33%) and nipple discharge (10%) and maximum number of patients presented with their symptoms having duration of 1-6 months (46.66%). In our study, the most common quadrant involved was the upper outer quadrant (60%). (Table 3, 4)

Table 3: Symptoms of benign breast diseases

Symptom	No of cases	Percentage(%)
Lump	134	53.33
Pain	33	13.33
Lump +Pain	58	23.33
Nipple Discharge	25	10

Table 4: Quadrant involved

Quadrant	No of cases	Percentage(%)
Upper outer	150	60
Upper inner	25	10
Lower outer	17	6.66
Lower inner	25	10
Central	33	13.33

Clinical and Pathological Correlation

In our study, clinical diagnosis was same as pathological diagnosis in 132 out of 134 cases of fibroadenoma. In 58 cases of fibrocystic disease, clinical diagnosis was correct in 57 .In case of galactoclele, phyllodes tumor, duct ectasia and breast abscess, clinical diagnosis was same as pathological diagnosis. (Table 5)

Table 5: Clinical diagnosis as compared with pathological diagnosis

Pathological diagnosis (cases)	Clinical diagnosis					
	Fibroadenoma	Fibrocystic Disease	Gallactocele	Phyllodes tumor	Duct ectasia	Breast abscess
Fibroadenoma	132	-	-		-	-
FibrocysticDisease	-	57	-	-	-	-
Gallactocele	-	-	8	-	-	-
Phyllodes tumor	-	-	-	8	-	-
Duct ectasia	-	-	-	-	25	-
Breast abscess	-	-	-	-	-	17

P<0.001 (significant)

Radiological and Pathological Correlation

In our study, radiological diagnosis was same as pathological diagnosis in 131 out of 134 cases of fibroadenoma. In 58 cases of fibrocystic disease, clinical diagnosis was correct in 57 .In case of galactoclele, phyllodes tumor, duct ectasia and breast abscess, radiological diagnosis was same as pathological diagnosis. (Table 6)

Table 6: Radiological diagnosis as compared with pathological diagnosis

Pathological diagnosis (cases)	Radiological diagnosis					
	Fibroadenoma	Fibrocystic Disease	Gallactocele	Phyllodes tumor	Duct ectasia	Breast abscess
Fibroadenoma	131	-	-		-	-
Fibrocystic Disease	-	57	-	-	-	-
Gallactocele	-	-	8	-	-	-
Phyllodes tumor	-	-	-	8	-	-
Duct ectasia	-	-	-	-	25	-
Breast abscess	-	-	-	-	-	17

P<0.001(significant)

Table 7: Table Statistical analysis of clinical diagnosis

Diseases	Measure						
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	+ LHR	-LHR	Kappa (%)
Fibroadenoma	87.5	92.8	93.3	86.6	12.25	0.13	80
Fibrocystic disease	85.7	91.3	75	95.4	9.85	0.15	73.3

PPV:Positive Predictive Value, NPV:Negative Predictive Value, +LHR: Positive Likelihhod Ratio, -LHR: Negative Likelihood Ratio

In our study, clinical examination in cases of fibroadenoma has sensitivity and specificity of 87.5% and 92.88% respectively. In cases of fibrocystic disease, clinical examination had sensitivity and specificity of 85.7 % and 91.3% respectively. In cases of galactocele, phyllodes tumor, duct ectasia and breast abscess, clinical examination had sensitivity and specificity of 100%. (Table 7).

Table 8: Statistical analysis of radiological diagnosis

Diseases	Measure						
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	+ LHR	-LHR	Kappa (%)
Fibroadenoma	81.2	92.8	93.3	86.6	12.25	0.13	80
Fibrocystic disease	85.7	91.3	75	95.4	9.85	0.15	73.3

PPV:Positive Predictive Value, NPV:Negative Predictive Value, +LHR: Positive Likelihhod Ratio, -LHR: Negative Likelihood Ratio

In our study, radiological examination in cases of fibroadenoma had sensitivity and specificity of 81.2% and 92.8% respectively. In cases of fibrocystic disease, radiological examination had sensitivity and specificity of 85.7% and 86.9% respectively. In cases of galactocele, phyllodes tumor, duct ectasia and breast abscess, radiological examination had sensitivity and specificity of 100%. (Table 8)

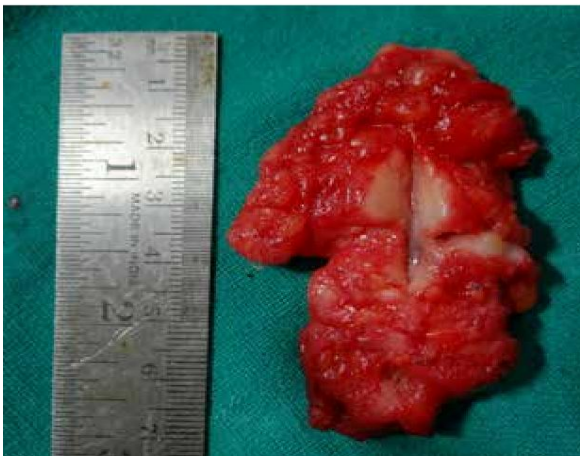

Figure A: Gross Specimen of Fibroadenoma Breast

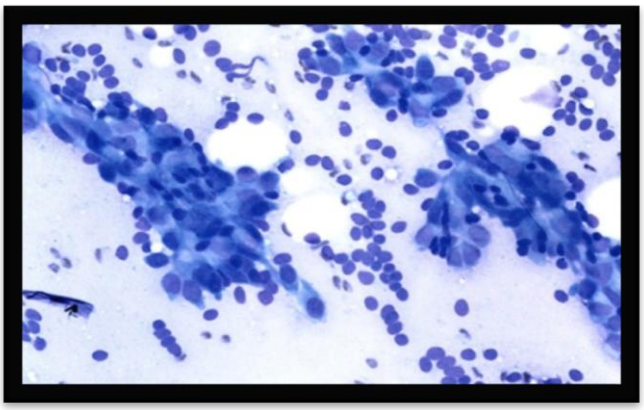

Figure B: Microscopic View of Fibroadenoma on FNAC

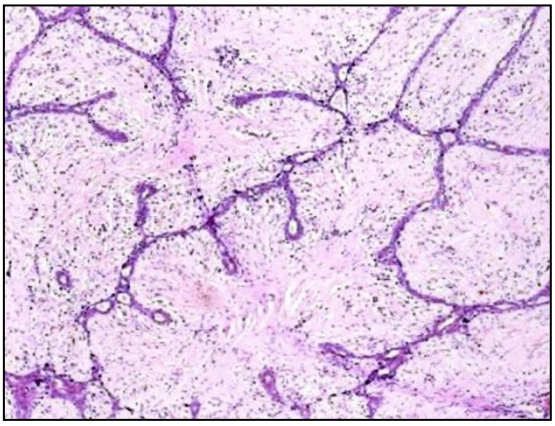

Figure C: Microscopc View of Fibroadenoma on Histopathologylogy

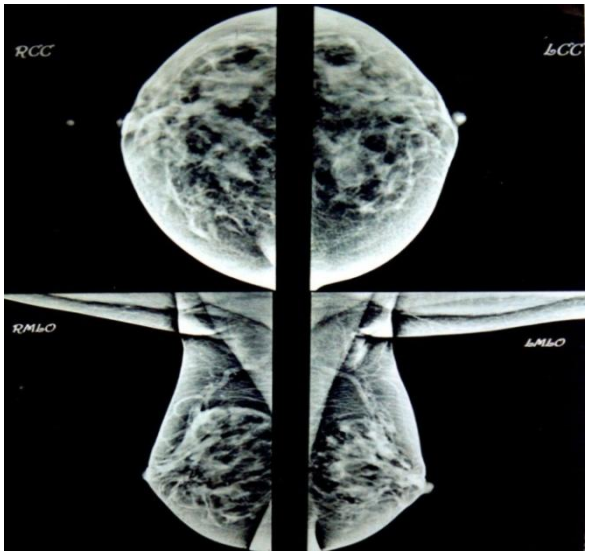

Figure D: X Ray Mammogram Showing B/L Fibrocystic Changes

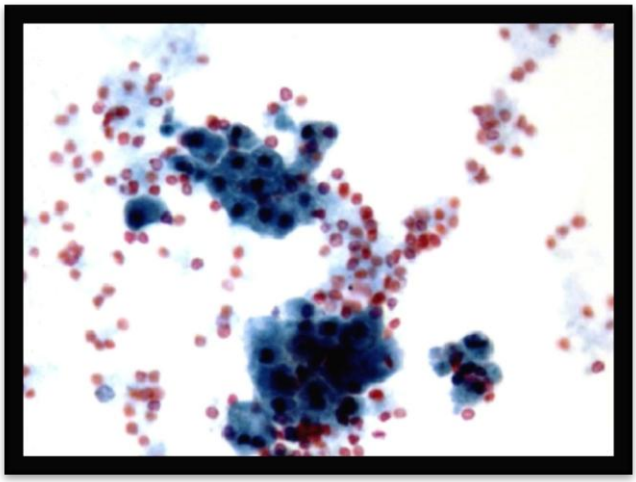

Figure E: Microscopic View of Fibrocystic Disease on FNAC

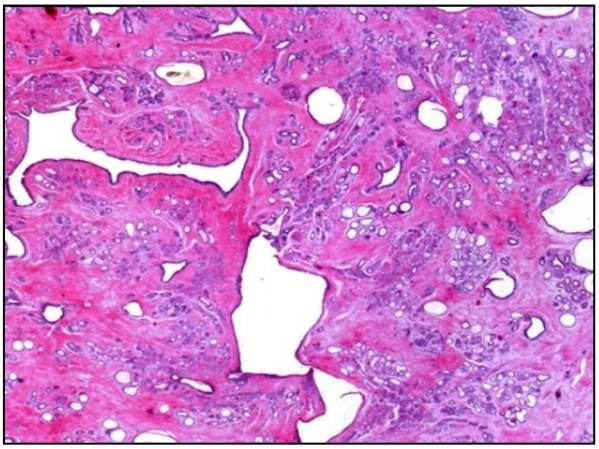

Figure F: Microscopic View of Fibrocystic Disease on Histopathology

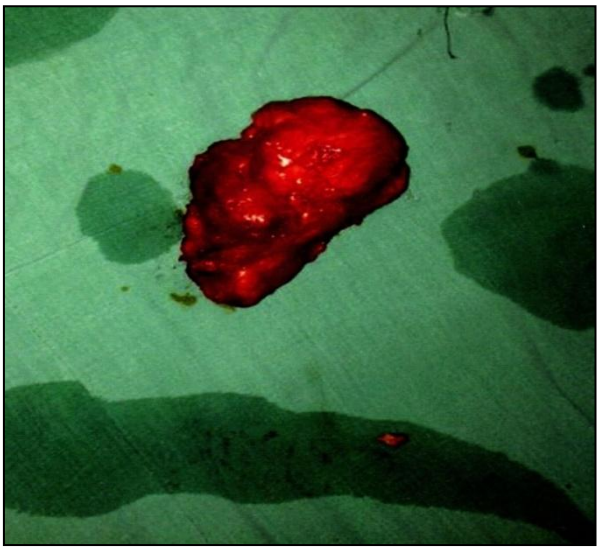

Figure G: Gross Specimen of Phyllodes Tumor

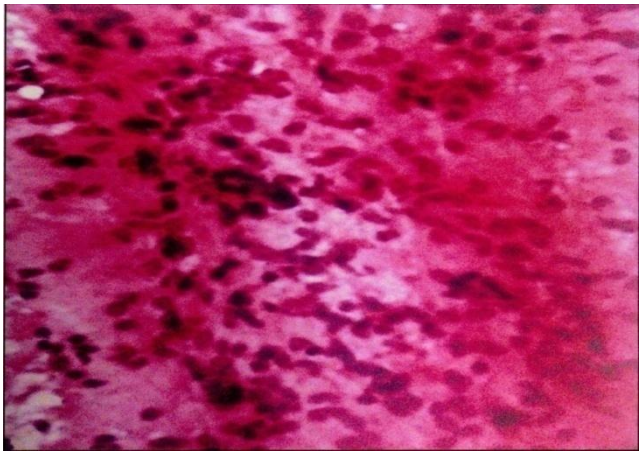

Figure H: Microscopic View of Phyllodes Tumor on FNAC

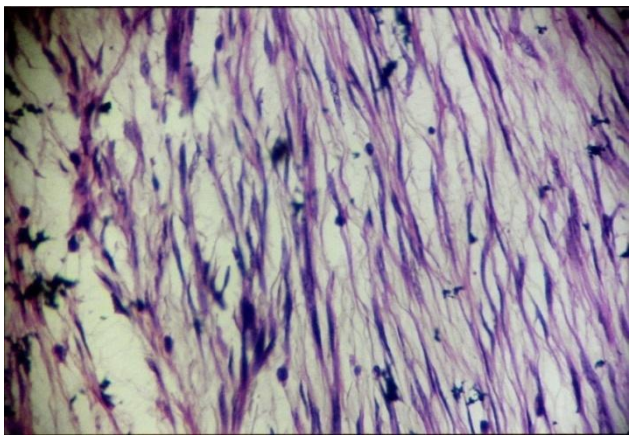

Figure I: Microscopic View of Phyllodes Tumor on Histopathology

Discussion

In our study 250 patients were included. Clinical breast examination and breast ultrasonography were performed in all the patients. X-ray mammography was done in 247 patients while FNAC was performed in all patients. Wherever required, excision biopsy of the involved benign breast lesion was performed and the specimen was sent for histopathological examination.

We compared the accuracy and other statistical parameters of clinical examination, radiological examination and pathological examination, evaluated either individually or in combination, in diagnosing benign breast diseases in female patients.

In our study of 250 patients, it was found that the incidence of benign breast diseases was more in the age group of 30-49 years (63.3%) which was

in accordance with the study conducted by **Najeeb S Jabbo (2010),** in which incidence of benign breast diseases was more in the age group of 30-49 years (56.92%).[13] Patients with benign breast diseases in our study had peak incidence in the 4th and 5th decades of life. Studies conducted by **Bartow SA et at (1987), London SJ et at (1992) and McDivitt RW et at (1992)** concluded that the incidence of benign breast lesions begins to rise during 2nd decade of life and peaks in the 4th and 5th decades.[14,15,16]

Median age in our study was 36 years which was in accordance with the study conducted by **Najeeb S Jabbo (2010)**, in which the median age was 35.39 years.[13]

In our study, the common presenting symptom was breast lump having 53.3% incidence. Lump and pain were the main symptom in 23.3% of cases. This was in accordance with the study conducted by **Onukak EE (1989)**, in which breast lump was the most common symptom having incidence of 49%, followed by lump and pain having incidence of 28%[17]. Pain in the breast as the only presenting symptom was seen in 4 cases (13.3%) of our study. This was not in accordance with the study conducted by **Najeeb S Jabbo (2010)**, in which pain in the breast was present in 7% of the cases[(13)]. Nipple discharge was present in 10 % of cases in our study. The studies conducted by **Hussain AN (2006)** and **Najeeb S Jabbo (2010)** showed an incidence of nipple discharge as 7% and 8.8% respectively.[18,13]

In our study, 46.6% of the patients had involvement of left breast and 43.3% had involvement of the right breast, while as only 10% of the patients had bilateral benign breast diseases. This was in accordance with the study conducted by **Onukak EE (1989)**, in which the incidence of benign breast diseases was found to be more on left (48%) as compared to right (43.8%) and bilateral[17]

The upper outer quadrant of the breast was involved in 60% of the cases in our study. This was in accordance with the studies conducted by **Oluwole SF (1979),**[19] **Hague et al (1980),**[20] **Gupta et al (1983)**[21] and **Iyer et al** (2000)[22], in which the upper outer quadrant was the most commonly involved part of the breast.

Fibroadenoma was the most common breast lesion (53.3%) in our study. This was in accordance with the studies conducted by **Najeeb S Jabbo (2010)**[13] and by **Rangabashyam N' et al (1983)**[23] in which fibroadenoma was the predominant lesion having an incidence of 61.4% and 57% respectively. **Pawan Tiwari** in 2013 also observed fibroadenoma as the predominant lesion in benign breast diseases.[24]

Fibrocystic disease was the second most common (23.3%) benign breast lesion seen in our study. This was in agreement with study conducted by **Pawan Tiwari (2013)**,[24] in which fibrocystic disease was the second common (25.7%) benign breast lesion. Study conducted by **Rangabashyam N et al (1983)**[23] also showed fibrocystic disease as the second common (16.3%) benign breast lesion.

In our study, duct ectasia was present in 10% of cases. This was in accordance with the study conducted by **Najeeb S Jabbo (2010)**,[13] in which duct ectasia was present in 8.78% of cases. This finding was not in agreement with the studies conducted by **Pawan Tiwari (2013)**[24] and **Mima MBS et at (2013)**,[25] in which incidence of duct ectasia was 4.4% and 6% respectively.

In our study, non-lactational breast abscess accounted for 6.6% of benign breast lesions. This was in accordance with the study by **Siddiqui MS et al (2003)**,[26] in which breast abscess accounted for 6.8% of cases. This was also in agreement with the study by **Bagale P (2013)**,[27] which had 6.5% of benign breast lesions as breast abscess. **Ochicha O et al (2002)**[28] reported 8% of lesions as breast abscess.

Incidence of galactocele was 3.3% in our study. This was not in agreement with the study conducted by **Khanna S et al (1988)**,[29] who reported the incidence of galactocele as 1.2% and study conducted by **Pawan Tiwari (2013)**,[24] who showed incidence of galactocele as 1.3%.

In our study, Phyllodes tumor accounted for 3.3% of benign breast lesions. This was in accordance with the study of **Rangabashyam N et al (1983)**, [23] in which 2.3% of cases were of phyllodes tumor. This finding was not in agreement with the study conducted by **Akhator et al (2007)**,[30] in which incidence of phyllodes tumor was 0.65%.

In our study, common presentation of fibroadenoma cases was lump in the breast (87.5%). Common presentation of fibrocystic disease was pain in the breast (57.5%). Only case of galactocele presented as lump in the breast. In only case of phyllodes tumor, presentation was lump and pain in the breast. In all cases of duct ectasia, nipple discharge was the presenting complaint. Cases of breast abscess presented with lump and pain in the breast.

In our study, clinical examination of cases of fibroadenoma had a sensitivity of 87.5% and specificity of 92.8%. It had a positive predictive value of 93.3% and a negative predictive value of 86.6%. The P value of clinical diagnosis as compared to pathological diagnosis was statistically significant ($p<0.001$) in cases of fibroadenoma. This was in accordance with the study by **Mima MBS et al (2013)**,[25] in which the sensitivity of clinical diagnosis in cases of fibroadenoma was 92%. However, in study conducted by **Iyer et al (2000)**,[22] clinical diagnosis in cases of fibroadenoma had sensitivity of 95.4% which was not in accordance with our study.

In our study, radiological examination of cases of fibroadenoma had a sensitivity of 81.2% and specificity of 92.8%. It had a positive predictive value of 92.8% and a negative predictive value of 81.2%. The P value of radiological diagnosis as compared to pathological diagnosis was statistically significant ($p<0.001$) in cases of fibroadenoma.

Clinical examination correctly diagnosed 132 cases (87.5%) of fibroadenoma, the remaining 2 cases (12.5%) were not diagnosed as fibroadenoma clinically. Radiological examination correctly diagnosed 131 cases (81.2%) of fibroadenoma, the remaining 3 cases (18.75%) were not diagnosed as fibroadenoma radiologically. Pathological examination diagnosed all the 134 cases of fibroadenoma correctly.

However, 2 cases of fibroadenoma which were not diagnosed clinically were diagnosed radiologically and 3 cases of fibroadenoma missed radiologically were diagnosed clinically. Clinical or radiological examination cannot give us 100% diagnosis in cases of fibroadenoma. Hence, all the three means of examination i.e. clinical, radiological and pathological should be combined to achieve 100% results.

In our study, clinical examination of cases of fibrocystic disease had a sensitivity of 85.7% and specificity of 91.3%. The P value of clinical diagnosis as compared to pathological diagnosis was statistically significant ($p<0.001$) in cases of fibrocystic disease. This was in agreement with the study by **Mima MBS et al (2013)**,[24] in which the sensitivity of clinical diagnosis in case of fibrocystic disease was 81.8%. In study conducted by **Iyer et al (2000)**,[22] clinical diagnosis in cases of fibrocystic disease had sensitivity of 100% which was not in agreement with our study.

In our study, radiological examination of cases of fibrocystic disease had a sensitivity of 85.7% and specificity of 86.9%. The P value of radiological diagnosis as compared to pathological diagnosis was statistically significant ($p<0.001$) in cases of fibrocystic disease.

Clinical examination correctly diagnosed 57 cases (85.7%) of fibrocystic disease, the remaining one case (14.2%) was not diagnosed as fibrocystic disease clinically. Radiological examination correctly diagnosed 57 cases (85.7%) of fibrocystic disease; the remaining one case (14.2%) was not diagnosed as fibrocystic disease radiologically. Pathological examination diagnosed all 58 cases of fibrocystic disease correctly.

However, one case of fibrocystic disease which was not diagnosed clinically was not diagnosed radiologically also. Clinical or radiological

examination cannot give us 100% diagnosis in cases of fibrocystic disease. Hence, all the three means of examination i.e. clinical, radiological and pathological should be combined to achieve 100% results.

In our study, in cases of galactocele, phyllodes tumor, duct ectasia and breast abscess, the clinical examination had a sensitivity and specificity of 100% each. In study conducted by **Iyer et al (2000)**,[22] clinical diagnosis in cases of galactocele and phyllodes tumor had sensitivity of 100% which was in accordance with our study and sensitivity was 81.8% in case of breast abscess which was not in accordance with our study.

In our study, in cases of galactocele, phyllodes tumor, duct ectasia and breast abscess, the radiological examination had a sensitivity and specificity of 100%.

So there was a strong agreement between clinical, radiological and pathological examination in all of these cases.

In our study, overall clinical breast examination in cases of benign breast diseases had a sensitivity of 90% and specificity of 98% as compared with pathological examination and the p value of overall clinical diagnosis as compared to pathological diagnosis was statistically significant ($p<0.001$). This was in agreement with the study by **Mima MIS et at (2013)**,[24] in which the overall sensitivity of clinical diagnosis was 91.9%.

In our study, overall radiological breast examination in cases of benign breast diseases had a sensitivity of 86.6% and specificity of 97.2% as compared with pathological examination and the p value of overall radiological diagnosis as compared to pathological diagnosis was statistically significant ($p<0.001$). This was in accordance with the study conducted by **Najeeb S Jabbo (2010)**,[13] in which the overall sensitivity and specificity of radiological examination was 85% and 95% respectively. Whereas, the combination of clinical and radiological examination had an overall sensitivity of 93.3% and specificity of 98%. Hence, all the three means of examination i.e. clinical, radiological and pathological should be combined to achieve 100% diagnostic accuracy.

The sensitivity and specificity of FNAC as compared to histopathology was 100% in our study. Study conducted by **Najeeb S Jabbo (2010)**[13] showed that sensitivity of FNAC was 85% and specificity was 95%. **Handa Uma and Mohan Harsh (2000)**[31] showed that the sensitivity of Fine needle aspiration procedure in breast diseases was 95.6% and specificity was 100%. Their results indicated that Fine needle aspiration cytology of breast was a diagnostically accurate procedure and it decreased the necessity of open surgical biopsy for definitive diagnosis. **Abdel-Hadi et al (2010)**[32] concluded that FNAC is an excellent method for diagnosing breast lesions with a sensitivity ranging between 89% and 98% and specificity between 98% and 100%. So, we must not unnecessarily subject the patient to excision biopsy for diagnosis of benign breast lesion as FNAC, which is less traumatic and is acceptable to the patient can also give equivalent results. However, in suspicious cases excision biopsy should be done.

Conclusion

In our study, the overall clinical breast examination had sensitivity of 90% and specificity of 98%.Overall radiological breast examination had sensitivity of 86.6% and specificity of 97.2%. Whereas the combination of clinical and radiological examination had an overall sensitivity of 93.35 and specificity of 98%.When clinical, radiological and pathological examinations were combined together, the diagnostic accuracy approached 100%. Hence, combination of all three diagnostic modalities i.e. clinical, radiological and pathological examination is essential to give reassurance about the benign nature of the disease, remove the anxiety of harbouring malignancy and also helping her in diagnosing the pattern of benign breast lesions.

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