ORIGINAL RESEARCH PAPER

Surgery

"EVALUATION OF THE EFFICACY AND UTILITY OF TRIPLE ASSESSMENT IN BENIGN BREAST DISEASE"

KEY WORDS:

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ABSTRACT

Breast health awareness has resulted in increasing detection of early breast cancer and corresponding decrease in breast cancer morbidity. About 80% of breast biopsies result in a benign pathology. Practically every woman during a lifetime is either clinically or radiologically evaluated for a breast lesion. The most common symptoms are pain, lumpiness or a lump. Symptomatic breast lesions are traditionally evaluated by clinical, cytological and radiologic methods. Approximately 95% of symptomatic breast lesions will be diagnosed using one of these modalities.

The role of FNAC and USG in the diagnosis and management of breast disease is increasing. But each of these diagnostic modalities by itself has an appreciable false negative rate. This inaccuracy in diagnosis of breast disease can be overcome by combination of these diagnostic methods, by which sensitivity increases. A triple assessment combining all the three modalities is normally done in a breast lesion suspected to be malignant. It remains to be seen if the application of triple assessment in all breast lesions including benign, can be of help in coming to a correct diagnosis and would be cost effective.

This study includes 60 cases of benign diseases which were admitted and treated In our institute between 1 Jan 2015 to 30 June 2016. Patients with inflammatory breast conditions, gynecomastia and carcinoma breast have been excluded. All patients were of the female sex.

Incidence of benign breast disease was found to be more in age group of 11-20years (24 patients i.e. 40%) followed by 21-30 years and then 31-40 years. All cases of fibrocystic disease of breast were seen in the age group of 21-40 years. 81.12% of cases were fibroadenomas were observed in 11-30 years' age group.

Common presenting complaint was breast lump constituting about 56 cases (90%), 4 cases presented with pain (6.7%) and 2 presented with discharge (3.3%).

In the present study, of the 60 cases, right breast was involved in 26 cases (43.34%), 32 on the left side (53.33%) and 2 cases presented with bilateral involvement (3.33%).

Most lesions (58 cases) were solitary (96.66%) and multiple lesions were present in 2 cases (3.33%) on clinical examination. On USG breast, multiple lesions were detected in 4 cases (6.67%) and single lesions in 56cases (93.33%).

FNAC was done in all the cases and was diagnostic (100%). In the present study, USG could clearly suggest if the lesion was cystic or solid but further tying of the lesion had limitations, however fibroadenoma would be diagnosed accurately on USG.

We have studied 60 cases of BBD, who have been subjected to clinical examination, USG breast and FNAC/HPR. The accuracy of BBD diagnosis increases when all the three modes are employed. These Triple assessments may avoid many unnecessary surgeries for benign lesions.

AIMS AND OBJECTIVES

1) To determine the value of triple assessment as a tool of evaluation in all patients attending OPD, wards and clinically diagnosed with benign breast disease.
2) To statistically assess and evaluate the efficacy and utility of all the three individual modalities used in triple assessment specifically in benign breast disease with respect to reaching the diagnosis and providing correct treatment.
3) To study the clinical profile of patients attending the hospital with benign breast disease.

MATERIALS AND METHODS
Method of collection of data-
Detailed history of the patient will be noted to find out reasonable risk factor and complaints will be recorded in chronological order.

Clinical examination will be done to find out various modes of presentation followed by Imaging studies (mainly USG and/or Mammography) and Tissue sampling (Cytological-FNAC or Core-cut needle biopsy or Histological) Analysis.

Source of data-
Consecutive male or female patients with breast disease who have attended opd or who were admitted to wards in dept. of surgery in medical college and hospital.

Study duration-
Study has been conducted in our institute between 01/01/2015 to 30/06/2016(18 months).

Inclusion criteria-
All cases diagnosed clinically as benign breast disease irrespective of age are included in this study

Exclusion criteria-
Patients who are clinically diagnosed to have malignant disease or suspected of malignant disease or have been treated for malignancy earlier will be excluded in this study.

OBSERVATIONS AND RESULTS
Commonest age group-11-20 years **(72%)**
Commonest complaint-breast lump **(87%)**
Most common pathology- fibroadenoma **(95%)**
Location-right breast (48%), left breast (40%), both breasts **(12%)**
The accuracy of triple assessment in benign breast lump was **91.95%**

Table No. 1: Age Distribution Of Bbd

AGE DISTRIBUTION (YEARS)	NO OF CASES	PERCENTAGE (%)
1-10	0	0
11-20	24	40
21-30	20	33.3
31-40	16	26.7
41-50	0	0

Graph No. 1: AGE DISTRIBUTION OF BBD
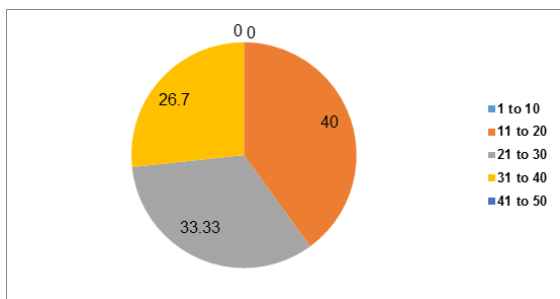
Table No. 2: Symptomatology Of Bbd

SYMPTOM	NO OF CASES	PERCENTAGE (%)
LUMP	54	90
PAIN	4	6.6
DISCHARGE	2	3.3

Graph No. 2: Symptomatology Of Bbd
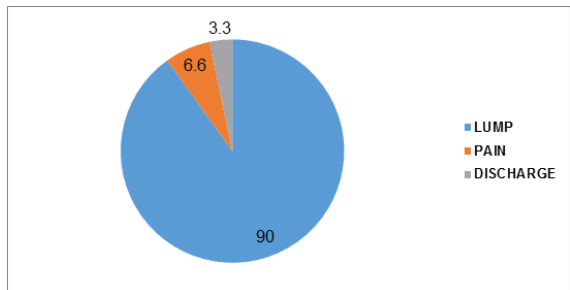
Table No. 3: Lump Size

SIZE OF LUMP (cms)	NO OF CASES	PERCENTAGE (%)
<3	36	60
3-5	16	26.7
>5	8	13.3

Graph No. 3: Lump Size
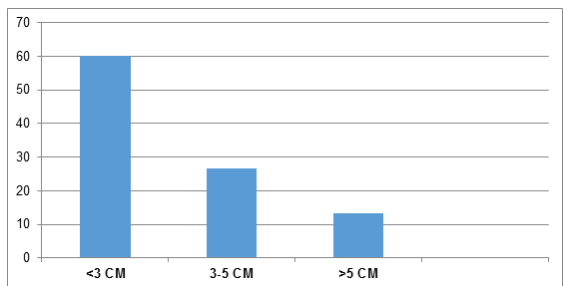
Table No. 4: Disease Pattern Of Bbd

DISEASES	NO OF CASES	PERCENTAGE (%)
FIBROADENOMA	44	73.34
FIBROADENOSIS	8	13.32
NON SPECIFIC MASTITIS	6	10
GALACTOCELE	2	3.34
DUCTAL PAPILLOMA	0	0

Graph No. 4: Disease Pattern Of Bbd
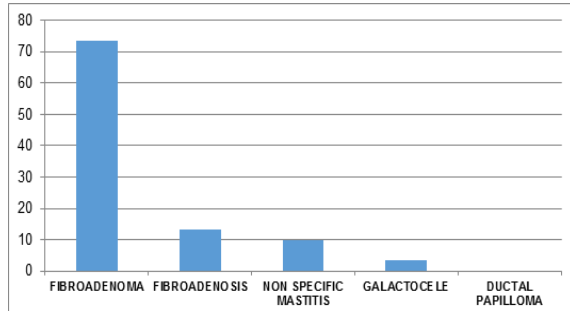
Table No. 5: Clinical Vs Usg Vs Fnac Diagnosis Of Bbd

DIAGNOSIS	CLINICAL	%	USG	%	FNAC	%
FIBROADENOMA	50	83.3	44	73.3	44	73.3
FIBROADENOSIS	4	6.7	0		8	13.3
NON SPECIFIC MASTITIS	0	0	0		6	10
GALACTOCELE	6	10	2	3.3	2	3.4

Graph No. 5: CLINICAL VS USG VS FNAC DIAGNOSIS OF BBD
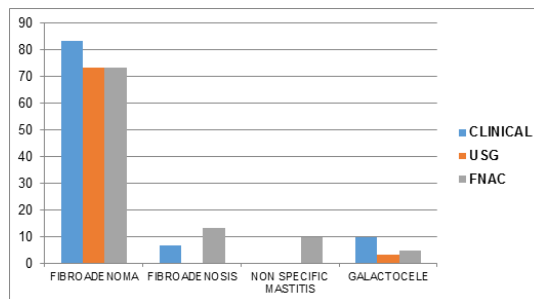
In this present study, 50 cases (83.3%) of fibroadenoma were diagnosed on clinical examination, but USG gave diagnosis in only 44 cases (73.3%). This was confirmed on FNAC.

Only 2 cases of galactocele were picked on USG among 6 cases on clinical ground, which was confirmed on FNAC. The present study USG had sensitivity of 100% and specificity of 75%.

Table No. 6: Comparative Studies Of Sensitivity Of Fnac

STUDY	CASES(%)
Eltair et al[1]	97.3
Imie U et al[2]	98.3
Present study	100

USG BREAST
- On USG a spectrum of benign finding was noted.
- In the present study, USG could clearly suggest if the lesion was cystic or solid but further typing of the lesion had limitations, even though fibroadenoma would be diagnosed accurately.
- Most cases being fibroadenoma (73.34%) and one case of galactocele.
- On USG breast, multiple lesions were detected in 2 cases (6.67%) and single lesions in 28cases (93.33%).
- This USG finding cor-relates with Thomas et al [3] study, with 92.3% solitary lesion and 7.6% of multiple lesion.
- They are commonly (18 cases out of 22) seen in women under 30 years of age.
- This study does not correlate with Ibitoye et al [4] in which fibroadenoma was the commonest disease, occurring in 62.2% of the patients, with a mean age of 29.1 years.
- In benign palpable masses Klein et al [5] states 97 percent diagnostic accuracy on USG.
- Eltair et al study [1] USG was sensitive in 88.9% and specific in 97.4% of cases, which correlates, with the present study of sensitivity is 100% and specificity of 75%.
- In Malik et al study [6] sensitivity of ultrasonography for breast masses was 92% for benign, specificity was 92.4%.

DISCUSSION
Benign breast diseases are a common disease affecting women in our country.

This study includes 60 cases of benign diseases which were admitted and treated in our institute between 1 Jan 2015 to 30 June 2016.

SEX DISTRIBUTION
In the present study, inflammatory breast conditions, gynecomastia and carcinoma breast have been excluded. There were 60 cases of benign breast diseases all patients were of the female sex. A study done by Khanna et al [7], in which they have analyzed 1031 cases of benign breast diseases in which 94% were females and 6% were male.

Table No. 7: Sex Distribution:

Sex	Present Study	Khanna et al[7]
Female	100%	94%
Male	00%	06%

AGE DISTRIBUTION:
On analysis of the present study, it was found that incidence of benign breast disease was found to be more in age group of 11-20years (24 patients i.e. 40%) followed by 21-30 years and then 31-40 years.

Correlation of age distribution with Khanna et al [7] study.

Table No. 8: Age Distribution:

Age group	Present Study	Khanna et al [7]
1- 10 yrs	00.00%	00.3%
11-20 yrs	40.00%	25.25%
21-30yrs	33.30%	40.06%
31-40 yrs	26.70%	19.56%
41-50yrs	00.00%	09.98%

All cases of fibrocystic disease of breast were seen in the age group of 21-40 years. This did not correlate with study by Khanna et al (7) 58.53% patients presented within the age group of 20-40 years. Another study by Rangabashyam et al (8) showed that maximum number of cases (70%) were between the age group of 20-30 years.

Around 81.12% of fibroadenomas were observed in 11-30 years' age group in the present study. In an Indian study by Rangabashyam et al (8) maximum number of cases (75.39%) were noted in 11-30 years' age group. Similarly, in the study by Khanna et al (7), 82.78% of fibroadenomas were seen in the age group of 11-30 years. Majority of the cases in the present study were in the reproductive age group. 2 cases complained of irregular menstrual cycles and none of them had any significant change in the size of the swelling during or before menstruation.

DISEASE PATTERN
Relative incidence of Benign Breast diseases in females in various reported series (%)

Table No. 9: Disease Pattern

Author & Year	No. of cases	Fibroadenoma	Cystosarcoma phyllodes	Fibrocystic disease	Sclerosing adenosis	Others
Funderburle[9] (1976)	195	35.9	0.4	38.4	-	17.3
Rangabashyam[8] (1983)	215	57.0	2.3	16.3	-	13.4
Khanna[7] (1988)	971	40.8	13.8	13.8	5.0	4.0
Present study (2015-16)	60	74.0	-	13	-	13

SYMPTOMATOLOGY:
In the present study, most common presenting complaint was breast lump constituting about 56 cases (90%), 4 cases presented with pain (6.7%) and one presented with discharge (3.3%). All the fibroadenoma cases presented as lump, whereas two fibroadenosis presented with lump and pain. A single case of galactocele presented with discharge. However, the study done by Khanna [7] et al. showed that common presenting complaint in benign breast disease was lump constituting about 77.4% in their study.

LATERALITY AND NUMBER OF LESIONS:
In the present study, of the 60 cases, right breast was involved in 26 cases (43.34%), 32 on the left side (53.33%) and 2 case presented with bilateral involvement (3.33%). This does not correspond to most of the studies which states that right breast is commonly involved with lesions compared to left breast [7,8]. Most lesions (58 cases) were solitary (96.66%) and multiple lesions were present in 2 cases (3.33%) on clinical examination. On USG breast, multiple lesions were detected in 4 cases (6.67%) and single lesions in 56 cases ((93.33%).

FNAC:
It is a useful investigation in the diagnosis of the benign breast disease. FNAC was done in all the cases and was diagnostic (100%).

Comparative studies of sensitivity of FNAC
Eltair et al (1)- 97.3%
Uma et al (2)- 98.3%
Present study- 100%

USG BREAST
On USG a spectrum of benign finding was noted. In the present study, USG could clearly suggest if the lesion was cystic or solid but further typing of the lesion had limitations, even though fibroadenoma would be diagnosed accurately. Most cases being fibroadenoma (73.34%) and one case of galactocele.

On USG breast, multiple lesions were detected in 4 cases (6.67%) and single lesions in 56 cases (93.33%). This USG finding correlates with Thomas et al [3] study, with 92.3% solitary lesion and 7.6% of multiple lesion. They are commonly (36 cases out of 44) seen in women under 30 years of age. This study does not correlate with Ibitoye et al [4] in which fibroadenoma was the commonest disease, occurring in 62.2% of the patients, with a mean age of 29.1 years. In benign palpable masses Klein et al [5] states 97 percent diagnostic accuracy on USG. Eltair et al (1) study USG was sensitive in 88.9% and specific in 97.4% of cases, which correlates, with the present study of sensitivity is 100% and specificity of 75%. In Malik [6] et al study sensitivity of ultrasonography for breast masses was 92% for benign, specificity was 92.4%.

SUMMARY
This study includes 60 cases of benign diseases which were admitted and treated in our institute between 1 Jan 2015 to 30 June 2016. Patients with inflammatory breast conditions, gynaecomastia and carcinoma breast have been excluded. All patients were of the female sex.

Incidence of benign breast disease was found to be more in age group of 11-20years (24 patients i.e. 40%) followed by 21-30 years and then 31-40 years. All cases of fibrocystic disease of breast were seen in the age group of 21-40 years. 81.12% of cases were fibroadenomas were observed in 11-30 years' age group.

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We have studied 60 cases of BBD, who have been subjected to clinical examination, USG breast and FNAC/HPR. The accuracy of BBD diagnosis increases when all the three modes are employed. These Triple assessments may avoid many unnecessary surgeries for benign lesions.

CONCLUSION

The accuracy of BBD diagnosis increases when all three modes i.e. Clinical examination, USG and FNAC are employed. Triple assessment may avoid many unnecessary surgeries for benign lesion.

The management of breast disease has been influenced by breast imaging and fine needle aspiration cytology (FNAC) for preoperative diagnosis. We have studied 60 cases of BBD, who have been subjected to clinical examination, USG breast and FNAC/HPR.

The accuracy of BBD diagnosis increases when all the three modes are employed.

From this present study of BBD, it can be concluded that USG can be employed to differentiate solid and cystic lesions. All cystic lesions and majority of the fibroadenoma can be diagnosed on sonography. Triple assessment may avoid many unnecessary surgeries for benign lesion

CONSENT

अनुमतिपत्र

1. मैं इस अनुमति पत्र द्वारा **"Evaluation of the efficacy and utility of triple assessment in benign breast disease"** इस वैद्यकिय उपक्रम में शामिल होने कि सहमति दे रहा/रही हूँ|

2. मुझे इस उपक्रम कि पुरी जानकारी " दी गई है और इसमें आवश्यक सभी प्रकार कि जाँचें तथा इनकी गंभीरता एवं संभावित हानि से अवगत किया गया है|

3. इस उपक्रम के दरम्यान होनेवाली सभी दुष्परिणाम; तकनीकी या वैद्यकिय, स्थायि या अस्थायी, तुरंत या दूरगामी के बारे में मुझे जानकारी दी गई है और मुझे प्रश्न पूछने का मौका दिया गया है|

4. मैं यह सभी जानकारी समझने के बाद पुरे होशोहवास में स्वखुशि से इस अनुमतिपत्र पर सही कर रही हूँ

सम्मतीपत्र

1. मी या सम्मतीपत्रद्वारे **"Evaluation of the efficacy and utility of triple assessment in benign breast disease"** या संशोधनात्मक अभ्यासामध्ये भाग घेणारा एक रूग्ण म्हणून सम्मती देत आहे.

2   या संशोधनात्मक अभ्यासाची माहिती मला दिली आहे. यात आवश्यक असलेल्या सगळ्या चाचण्या व त्यांची सम्भावित हानी बहल मला कल्पना दिलेली आहे.

3. या अभ्यासादरम्यान उदभवु शकण्या-या संभाव्य, तंत्रीक व वैद्यकिय, स्थायी अथवा अस्थायी, त्वरित किंवा दुर्गामी परिणामाची माहिती मला दिलेली आहे व मला प्रश्न विचारण्याची संधिही दिलेली आहे.

4. ही सर्व माहिती समजल्यानंतर मी स्वखुशीने या सम्मतीपत्रावर स्वाक्षरी करत आहे

CONSENT FORM

1. I am willing to participate as one of the case for the research study entitled "Evaluation of the efficacy and utility of triple assessment in benign breast disease"
2. I have been informed in detail about this research study by audio-visual means.
3. I have also been informed about the various complications; medical or technical, temporary or permanent, immediate or long term etc which may arise during the course of this study and has been allowed to ask questions regarding the study.
4. This has been explained to me in the language of my understanding.
5. After understanding all information, i am signing this consent letter without any force or coercion.

Signature of the Patient: -   Signature of Witness: -
Date: Date

LIST OF ABBREVATIONS USED

FNAC- Fine needle aspiration cytology
USG- Ultrasonography
BBD- benign breast diseases
no -number
CBE - clinical breast examination
CNB – core needle biopsy
cms - centimeter
Viz – such as
i.e. – that is

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