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ACCURACY OF DIAGNOSTIC MAMMOGRAPHY IN BREAST CANCER

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ABSTRACT

Backgrounds: Diagnostic mammography is an important investigation and part of the "Triple Assessment Protocol" especially in symptomatic over 40 women with inconclusive breast pathology on clinical and ultrasonography assessment. **Aim:** This study aims at evaluation of the accuracy of diagnostic mammography in breast cancer. **Design and Setting:** An Observational Comparative Prospective Analysis conducted in the "surgical consultation clinic" and the "Breast clinic" of Al-Yarmouk Teaching Hospital; a tertiary center in Baghdad/Iraq over the period from 1st of Dec. 2013 till 31st of Dec. 2014. **Patients and Methods:** A cohort of 57 female patients with a mean age of 46.9 ± 10.7 years, who are complaining of breast symptoms and signs suggestive of malignancy, were included. Personal data collected and the results of clinical examination and mammography were reported and analyzed. The result of histopathological examination is considered as the "Gold Standard" against which the accuracy of mammography is evaluated. Whenever possible; statistical analysis using "Independent t-test", "Pearson's chi-square test" or "Fisher exact test" were performed and a p-value less than 0.05 was considered significant. **Results:** According to histopathology; two groups of patients are verified; a "Cancer" and "No Cancer" group. The mean age, smoking, positive family history and history of contraceptive pills therapy were significantly higher in the cancer group. Mass(s) is the most common pathology. Among mammography descriptions, only "well definition" of the mass attained a statistical significance supporting benign rather than malignant pathology. The only mammographic sign of malignancy which was statistically significant was presence of microcalcification(s). BIRADS grade 4 and 5 of the mammography reports proved significant in discriminating malignant from benign lesions. Statistical analysis of the results concluded a sensitivity of 78.6%, a specificity of 72.4%, a Positive Predictive Value of 73.3% and a Negative Predictive Value of 77.8%. Consequently; Diagnostic Mammography has an overall accuracy of 75.4% in this setting. **Conclusions:** Accuracy was lower than the reported figures for a diagnostic mammography setting. The result is partly attributed to the nature of patients sample and partly to the inconsistency of the mammography reports.

KEYWORDS: Breast Cancer; Diagnostic mammography; Sensitivity; Specificity; Accuracy; BIRADS grading.

INTRODUCTION

Definition

Mammography is a special type of x-ray imaging used to create detailed images of the breast. It uses low dose x-rays that is filtered and posed on high-contrast, high-resolution x-ray film.[1] It has been used in North America since the 1960s, and the techniques used continue to be modified and improved to enhance image quality.[1] It uses low-dose ionizing radiation, which may impose a potential theoretical risk to the patient, however; the risk of radiation exposure from a mammogram is considered virtually nonexistent; any negligible risk is far outweighed by its potential benefits.[2]

There are 2 types of mammography examinations: screening and diagnostic. Screening mammography is done in asymptomatic women and is recommended every 1-2 years for women once they reach 40 years of age and every year once they reach 50 years of age.[3]

Studies have shown that regular mammograms may decrease the risk of late-stage breast cancer in women 80 years of age and older. Many studies have shown that

having regular mammograms increases a woman's chances of finding breast cancer in an early stage, when it is more likely to be curable.[3] It has been estimated that a mammogram may find a cancer as much as two years before it can be felt. The American Cancer Society, American College of Radiology, American College of Surgeons and American Medical Association recommend annual mammograms for every woman beginning at age 40.[4] Below age 40, breasts tend to be "radiographically dense," where it is difficult to see many details, however; it might be recommended in high risk group younger than 40 years.[5]

This study aims at assessing the diagnostic accuracy of mammography as an important tool in the investigation of patients with suspected breast malignancy.

PATIENTS AND METHODS

The study is conducted at Al Yarmook Teaching Hospital; a tertiary center in Baghdad/Iraq over the period between 1st of Dec. 2013 till 31st of Dec. 2014.

It is an observational comparative study that had been prospectively designed to assess the accuracy of diagnostic mammography in the evaluation of female patients with suspected breast malignancy.

A cohort of 57 female patients with a mean age of 46.9 (± 10.7 SD) years was included in this analysis. They were selected from patients who are attending the "Surgical Consultation Clinic" in the hospital or referred from the "Breast Clinic" either for further assessment or because of a new finding in the course of "screening program" for early detection of breast cancer. Only symptomatic patients with positive finding on clinical examination were included in this analysis.

Personal data were collected and recorded for each patient. It specifically included the age, the parity, the chief complaint; the use of contraceptive pills, smoking, family history of breast cancer and previous history of breast problems or breast surgery.

A complete physical examination is performed along with a focused examination for both breasts and axillae. Findings were recorded for each patient. After history and physical examination; the clinical impression was also reported for each case.

Apart from US, a diagnostic mammography examination was ordered and the mammography descriptions of the findings along with the "BIRADS" classification of the report were recorded for each case.

The "BIRADS" class of the report is taken as a determinant point in considering a positive mammography supporting malignant rather than benign findings. Consequently; for the purpose of statistical analysis; BIRADS class 3, 4, and 5 are considered potentially positive for malignancy.

After mammography, each patient was specifically inquired about any pain or extra pain inflicted by the examination.

Fine Needle Aspiration Cytology (FNAC), cytology of nipple discharge, and tissue diagnosis by a Tru-Cut (Core-cut) or excisional biopsy were obtained accordingly and reports of the pathologist were recorded for each patient. The tissue diagnosis; be it a result of evaluating a Tru-Cut or an excisional biopsy specimen, was considered the "**Gold Standard**" against which accuracy of mammography is assessed.

Whenever possible; statistical analysis using "Independent t-test", "Pearson's chi-square test" or "Fisher exact test" were performed and a p-value less than 0.05 was considered as significant.

Patients who failed to complete the assessment or missing mammography or tissue diagnosis reports were excluded from this analysis.

According to the final tissue diagnosis; the 57 patients were verified in to two main groups; "**Cancer**" and "**No Cancer**" groups.

RESULTS

The median age of the study group was 43 years with a minimum of 28 and a maximum of 70 years. The mean age of the patients was 46.9 ± 10.7 (SD). The majority of patients included are over 40 years. The statistical analysis of the age of the cohort of 57 patients included in this study is displayed in table (1).

Table 1: statistical analysis of the age of the cohort of 57 patients.

Age (years)	Statistics
Number	57
Mean	46.9
Median	43
Std. Deviation	±10.7
Minimum	28
Maximum	70

The final tissue diagnosis verifies the patients in to two groups.
"**Cancer**" group which included 28 (49.1%) patients.
"**No Cancer**" group of 29 (50.9%) patients. This result is displayed graphically in Figure (1).

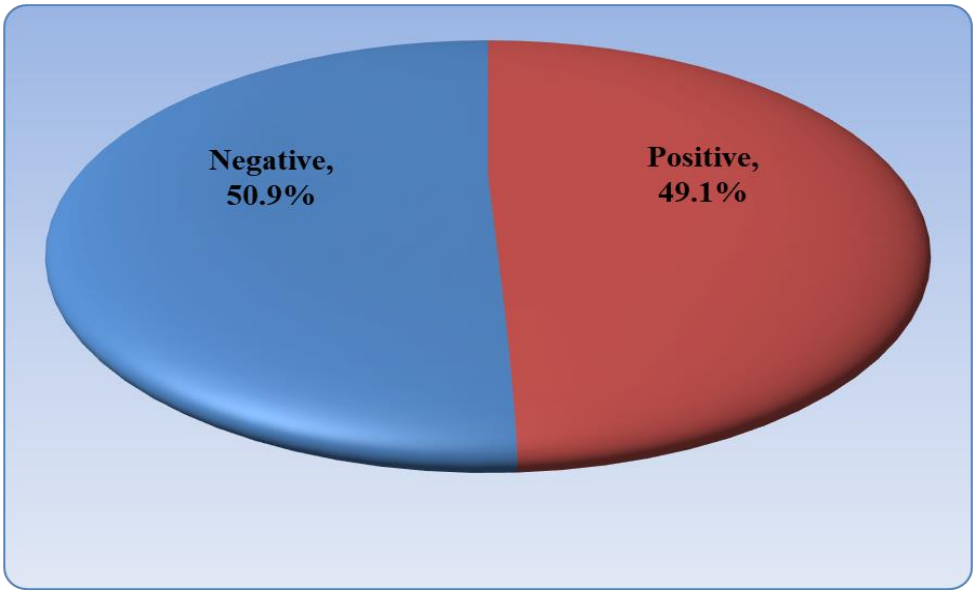

Figure (1): Distribution of the included females according to the results of biopsy for breast cancer, n=57.

The majority; 49 (86%) of patients were consulting for the first time while the rest of 8 (14%) of patients were referred during the course of screening for early detection of breast cancer; Table (2).

Table 2: Comparison of counseling and referral during screening between the study groups according to the result of biopsy, n=57.

Parameters	Cancer (n=28) No. (%)	No Cancer (n=29) No. (%)	Total (n=57)
Consultation for 1st time	23 (82.1)	26 (89.7)	49 (86%)
Referred during Screening	5 (17.9)	3 (10.3)	8 (14%)

Personal data of the patient selected for analysis is displayed in Table (5); the mean age for patients in "Cancer" group was 50.0(±9.7 SD) years while it was 44(±10.8 SD) years for the "No Cancer" group. This was statistically significant (p-value 0.032). Smoking, positive family history and the history of contraceptive pills therapy were also significant on comparison between "Cancer" and "No Cancer" groups (p-value of 0.004, 0.012 and 0.041 respectively). Parity as such fails to show a statistically significant difference between the two groups (Table 3).

Table 3: Comparison of Personal data between the two groups according to the results of biopsy, n=57.

Parameters	Cancer (n=28) Mean±(SD)	No Cancer (n=29) Mean±(SD)	p-value
Age	50.0±(9.7)	44.0±(10.8)	**0.032*,a**
Parity	**No. (%)**	**No. (%)**	
0 - 1	3 (10.3)	3 (10.3)	0.889 (NS)¥
2 - 5	17 (60.7)	16 (55.2)	
>5	8 (28.6)	10 (34.5)	
Smoking	7 (25.0)	0 (0.0)	**0.004*,†**
Positive family history	8 (28.6)	1 (3.5)	**0.012 †**
Use of contraceptive pills	8 (28.6)	2 (6.9)	**0.041*,†**

SD= Standard deviation, [a] Independent t-test, ¥ Pearson's chi-square, † Fisher exact test, NS= not significant, * significant at α <0.05.

Clinical examinations revealed breast masses in most patients, with no significant differences between groups (p=0.487). Other physical findings also showed similar occurrences. However, a clinical impression of "possibly malignant" was noted in 42 patients (73.7%). In the "Cancer" group, 92.9% had malignancy suggested, while 55.2% in the "No Cancer" group did, with significant statistical variation (p=0.001).

Table (4): Comparison of main suggestive physical signs of breast cancer between the study groups according to the results of biopsy, n=57.

Parameters	Cancer (n=28) No. (%)	No Cancer (n=29) No. (%)	p-value
Breast mass	28 (100.0)	27 (93.1)	0.487 (NS) †
Nipple discharge	2 (7.1)	4 (13.8)	0.67 (NS) †
Palpable axillary lymph nodes	8 (28.6)	4 (13.8)	0.171 (NS) ¥
Breast tenderness	9 (32.1)	6 (20.7)	0.326 (NS) ¥
Nipple retraction	3 (10.7)	0 (0.0)	0.112 (NS) †
Clinical impression of malignancy	26 (92.9)	16 (55.2)	**0.001*,¥**
Clinical impression of no malignancy	9 (32.1)	6 (20.7)	0.326 (NS)¥

¥ Pearson's chi-square, † Fisher exact test, NS= not significant.

The above findings are graphically displayed in Figure (2) below.

Findings on mammography were recorded, reviewed and verified according to the frequency of appearance in the reports (Table 5).

Seven main mammography findings (descriptions) were verified; these are a breast mass or masses, microcalcifications, macrocalcifications, prominent vascularity, a radiological opacity or opacities, retroareolar aggregation and description of positive axillary lymphadenopathy; in one or both breasts (Table 5). The total number of these findings (105) outnumbers the 57 patients in both groups because more than one finding had been reported in some patients.

Table 5: Comparison of mammography findings between both groups.

Parameters	Total	Cancer (n=28) No. (%)	No Cancer (n=29) No. (%)	p-value
Breast mass	47	24 (85.7)	23 (79.3)	0.525(NS) †
Micro-calcification	25	23 (82.1)	2 (6.9)	**<0.001*,¥**
Macro-calcification	12	4 (14.3)	8 (27.6)	0.171(NS) ¥
Radiological opacity	6	4 (14.3)	2 (6.9)	0.363(NS) †
Prominent vessels	5	3 (10.7)	2 (6.9)	0.67 (NS) †
Retro-areolar aggregation	2	0 (0.0)	2 (6.9)	0.157(NS) †
Axillary LNs	8	7 (25)	1 (3.5)	0.063(NS) †

¥ Pearson's chi-square, † Fisher exact test, NS= not significant. * Significant at α <0.05.

Table 5 analysis revealed that breast masses were the most common finding in mammographic reports, with 47 out of 57 reports noting a mass. Among these, 24 (85.7%) were from the "Cancer" group, which was not statistically significant compared to the "No Cancer" group (23, 79.3%) with a p-value of 0.525. Microcalcifications showed significant results, with 23 (82.1%) in the "Cancer" group versus 2 (6.9%) in the "No Cancer" group ($p < 0.001$). Macrocalcifications occurred in 12 reports, with no significant findings. Other factors like prominent vascularity and lymph node conditions were also insignificant. Furthermore, a categorization analysis identified three types of breast masses, with well-defined masses being more frequent in the "No Cancer" group (24.1%) than in the "Cancer" group (3.6%), yielding a p-value of 0.045, while speculations were excluded from the analysis due to their singular occurrence in one group.

Table 6: Comparison of breast mass categories seen by the mammogram between the study groups according to the result of biopsy, n=57.

Findings in mammography reports	Cancer (n=28) No. (%)	No Cancer (n=29) No. (%)	p-value
Ill-defined mass	4 (14.3)	6 (20.7)	>0.05 (NS)†
Well defined mass	1 (3.6)	7 (24.1)	**4.01, 0.045*,¥**
Heterogeneous mass	8 (28.6)	4 (13.8)	2.81, >0.05 (NS) *,¥
Hyper dense mass	-	2 (6.9)	Not valid
Fat density mass	2 (7.1)	-	Not valid
Lobulated mass	2 (7.1)	-	Not valid
Oval mass	-	4 (13.8)	Not valid
Speculated mass	7 (25.0)	-	Not valid

[¥] Pearson's chi-square, [†] Fisher exact test, NS= not significant, * significant at α <0.05. χ^2 = 23.22, p-value≤ 0.00155 is highly significant

The comparison of "BIRADS" classifications between two groups revealed that "BIRADS 1" and "BIRADS 2" were exclusive to the "No Cancer" group, with only one "BIRADS 1" report and 18 (62.1%) "BIRADS 2" reports. "BIRADS 0" was also limited to this group with 2 (6.9%) reports. Statistically significant differences were observed only in the "BIRADS 4" class: 10 (35.7%) for the "Cancer" group and 1 (3.4%) for the "No Cancer" group, and the "BIRADS 5" class: 14 (50%) for "Cancer" and 1 (3.45%) for "No Cancer".

Table 7: Comparison of BIRADS grade between the study groups according to the result of biopsy for diagnosis of breast cancer, n=57.

BIRADS grade	Cancer (n=28) No. (%)	No Cancer (n=29) No. (%)	p-value
BIRADS 1	0 (0.0)	1 (3.4)	NV
BIRADS 2	0 (0.0)	18 (62.1)	NV
BIRADS 0	0 (0.0)	2 (6.9)	NV
BIRADS 3	4 (14.3)	6 (20.7)	0.525 (NS) [†]
BIRADS 4	10 (35.7)	1 (3.45)	**0.002*[,¥]**
BIRADS 5	14 (50.0)	1 (3.45)	**<0.001*[,¥]**
BIRADS 6	0 (0.0)	0 (0.0)	NV

[¥] Pearson's chi-square, [†] Fisher Exact Test, NS= Not Significant, NV=Not Valid (contain zero), * Significant at α <0.05. Total Chi-square = 44.24, p-value < 0.00001

It was found that 22 out of 28 patients (78.6%) with positive biopsy results had positive mammography reports. Conversely, only 8 out of 29 patients (27.6%) with negative biopsy results had positive mammography findings, while 21 patients (72.4%) received negative mammography results. Statistical analysis indicated significant results with a p-value of less than 0.001.

Table 8: Comparison between the results of Biopsy and Mammography for confirmation of breast cancer, n=57.

		Biopsy		Total No. (%)
		Positive No. (%)	Negative No. (%)	
Mammography	Positive	22 (78.6)	8 (27.6)	30 (52.6)
	Negative	6 (21.4)	21 (72.4)	27 (47.4)
Total		28 (100)	29 (100)	57 (100)

Pearson's chi-square = 14.854 p<0.001 (Significant at α <0.05)

The overall assessment of the reliability (TP, TN, FP, FN, PPV, NPV and accuracy) of diagnostic mammography in the present context contrasted with the "Gold Standard" biopsy test is displayed in Table 9 below.

Table 9: Comparing reliability of Mammography with the results of Biopsy (a gold standard test) for confirmation of breast cancer, n=57.

		Patients with breast cancer (as confirmed by biopsy)		
		Condition positive	**Condition negative**	
Mammogram (Diagnostic)	Test outcome positive	**True positive** (TP) = 22	**False positive** (FP) = 8	Positive predictive value **73.3%**
	Test outcome negative	**False negative** (FN) = 6	**True negative** (TN) = 21	Negative predictive value **77.8%**
		Sensitivity **78.6%**	Specificity **72.4%**	Accuracy **75.4%**

Accordingly; the diagnostic mammography in the cohort of 57 patients had recorded a sensitivity of 78.6%, a specificity of 72.4%, a PPV of 73.3% and a NPV of 77.8%. Consequently; it has an overall accuracy of 75.4%.

Regarding pain after the examination; on inquiring patients after returning from mammography 17 (30%) of patients reported pain or increased pain after the examination. The majority (15 patients) were already having breast pain and tenderness as a part of their

presenting symptoms. Consequently; this finding is statistically insignificant (p-value more than 0.05).

The total number of patients originally included in this prospective analysis was 65. A total of 8 Patients were lost to follow-up or fail to present their mammography films and reports or refuse to complete the examination, hence they were excluded from this study.

Finally; it is important to mention that most of the mammography reports available for this analysis did not included a specific "BIRADS" breast density classification that is why it was not assessed in this work.

DISCUSSION

Reviewing the outcome of clinical examination in the cohort of patient selected for this analysis (Table 4); the commonest finding was breast mass(s). Other findings included localized breast tenderness, nipple discharge, nipple retraction and palpable axillary lymph nodes. These findings occurred in both groups and more than one finding may be present in the same patient. On statistical analysis; none of them succeeded in demonstrating significance among the studied groups. These results can be partly attributed to the nature of the selected patient sample. However; it is important to state that nodal involvement had been considered to be the single most important prognostic indicator in women with breast cancer.[6] In more than 95% of breast cancers; cells metastasize to the axilla in a progressive manner from level I to level III and clinical examination of the axilla is 50-70% reliable in identifying metastatic lymph nodes.[6]

In our cohort of patients; the finding of microcalcification proved to be a strong evidence of malignant changes {23 (82.1%) versus 2 (6.9%) in the "Cancer" and "No Cancer" groups respectively} which is a statistically significant result with a p-value <0.001. none of the other findings attain a statistical significance in the present analysis.

The findings of "Microcalcifications" with or without a mass had been extensively reviewed in the literature with a wide range of different descriptions concerning the shapes and distribution of this important finding. Descriptions of the shape included pleomorphic, heterogeneous, fine granular, fine linear or branching (casting). Descriptions of the distribution were specified as grouped (clustered), linear, segmental, regional or diffuse.[7] There are also many reports trying to correlate specific shapes or distributions with a specific pathology of breast cancer. Most of the microcalcification lesions showed no significant morphological differences between invasive and noninvasive breast cancer but fine linear and fine linear branching calcifications and mixed malignant calcifications were more common in invasive breast carcinoma. However; the distribution of the microcalcifications showed significant different patterns between invasive and noninvasive breast carcinoma characterized by segmental and clustered distribution of the lesions respectively.[7]

Contrasted with microcalcifications; macrocalcifications are considered rather a benign finding until proved otherwise by histopathology. They are coarse larger calcium deposits that are most likely due to changes in the breast caused by aging of the breast arteries, old injuries including surgical excisional biopsies, or following inflammation and suppuration (breast abscess). In large screening series; Macrocalcifications are encountered in about 50% of women over 50 in contrast with 10% of women under 50.[55]

In the present analysis; in addition to macrocalcifications, none of the other mammographic findings proved any significance in discrimination of possible malignant changes. It should be announced that there were a lot of overlapping in the findings and 2 or more findings had been reported in the same patient.

Descriptions of the general definition of the mass were mainly "ill defined" versus "well defined" mass lesion. Description of a "Heterogeneous mass" appeared unopposed. Reports of the mammography described the density of different mass lesions (compared to the density of the examined breast tissue) as "Hyper dense" and "Fat density" lesion. Descriptions for the margins appeared as "Oval", "Lobulated" and "Speculated" mass lesions. On contrasting such findings between the two groups; the description of a "Well Defined" mass was the only finding that attained a statistical significance among the two groups.

Irregular or speculated margins and heterogenicity are mammographic signs of malignancy. Additional specific mammographic features that suggest a diagnosis of cancer include the "stellate" feature within a mass and asymmetric thickening of the breast skin overlying a questionable mass lesion.[8]

It had been stated that the contour of the mass plays the most important role in the diagnosis of the nature of different mass lesions. Many efforts had been reported that are directed towards further differentiation of the contour and determination of the extent of speculation or smoothness on mammography.[9] Recently; the effect of changing the pixel resolution on texture features of breast masses on mammogram had been reported.[10]

Various descriptions for the "Density" of the mass lesions, relative to the density of surrounding breast tissue, had been described. "Hyperdense", "Isodense" and "Hypodense" or "high- density" and "Low-density" are in common use in the literature. Difficulties in characterization in a "dense breast" are obvious.[11] US can be a helpful adjunct but recent efforts like introduction of the Computed Tomographic Laser Mammography (CTLM) are also reported.[12]

In the present analysis; apart from the description of "Well Defined mass" which was statistically significant among the studied groups, some descriptions like "Heterogeneous" or "Speculation" appeared predominantly in reports related to the "cancer" group, however; its frequency did not support significance on statistical analysis.

The "BIRADS" grades for the reports of the 57 patients were documented, verified and contrasted between the two groups. "BIRADS 4 and 5" reports were significant among both groups which refer to a reliable accuracy in discriminating the malignant nature of the breast pathology in the examined patients (a p-value of 0,002 and <0.001 for "BIRADS 4" and "BIRADS 5" respectively).

It is very evident that the risk is higher the higher the BIRADS grade. For diagnostic mammography; again BIRADS 4 and 5 categories are highly significant regarding cancer discrimination while the yield of "BIRADS 3" may be increased by additional imaging work-up if indicated. Category "0" is the inconclusive mammogram; the so called "Gray BIRADS" where additional imaging is always indicated (additional views and/or US).[13] Many strategies to more accurately characterize the risk of breast cancer in "BIRADS 0" mammograms are being continuously evaluated including MRI and digital tomosynthesis and some concluded that BIRADS 3, 4, and 5 categories correlate significantly with a tissue diagnosis of malignancy. The relationship between BIRADS categories 3, 4, and 5 and histopathology was statistically highly significant (p-value less than 0.0001) but the main priority for such a risk assessment is given to screening rather than diagnostic mammography.[14]

CONCLUSIONS

Accuracy was lower than the reported figures for a diagnostic mammography setting. The result is partly attributed to the nature of patients sample and partly to the inconsistency of the mammography reports. For a better evaluation of accuracy; more number of patients is required and reviewing the consistency of mammography reports is highly recommended.

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