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CORRELATION OF THE FINDINGS OF BIOFIELD BREAST CANCER DIAGNOSTIC SYSTEM (BDS) WITH CLINICOPATHOLOGICAL PARAMETERS OF MAMMARY CARCINOMA IN IRAQ

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ABSTRACT

Background: Breast cancer is the most common malignant tumor and the leading cause of cancer deaths in women worldwide, including Iraq. Early detection of breast cancer has been recommended by the WHO as one of the major tools to control the disease. The Biofield Diagnostic breast cancer System (BDS) has been recently introduced in Iraq. It is a non-invasive device that measures the level of DC voltage skin surface electropotentials associated with suspicious breast lumps. The main objective of its use is to distinguish between benign and malignant breast lesions detected clinically or radiologically. **Aim of Study:** To determine the utility of BDS in the diagnosis of breast cancer and to correlate the findings of BDS with: The Triple Assessment Test (which comprises clinical parameters, ultrasonography &/or mammography and FNAC) of palpable breast lumps, Clinicopathological parameters including staging, grading and type of breast carcinoma and the Results of Ag NOR cytochemical marker. **Patients and Methods:** This is a prospective study of 50 cases collected from the Main Training Center for Early Detection of Breast Cancer in the Medical City Teaching Hospital. For each patient a full questionnaire was prepared including all demographic and clinical data. All patients were subjected to the Triple Assessment Test and BDS test. **Results:** In this study, the BDS findings displayed "Probably Benign" in three cases (6%); "Probably Malignant" in 36 cases (72%) and "Malignant" in eleven cases (22%). The clinical level of suspicion was classified as III in 44 cases for the 50 cases studied (88%) and level II in six cases (12%). The ultrasound level of suspicion was recorded as level III in 38 cases (76%) and level II in eleven cases for the 50 cases studied (22%). The mean age for the "Probably Benign" category was (31 years); for the "Probably Malignant" category was (45.5 years) and for the "Malignant" category was (55.5 years). The fine needle aspiration cytology results showed ductal carcinoma in 49 cases out of 50 cases studied (98%) and lobular carcinoma in only one case. The mean Ag-NOR count was (7.86) for "Probably Benign" category, (8.23) for "Probably Malignant" category and (8.5) for "Malignant" category. Histopathological diagnosis was available for only 24 cases out of the 50 cases of this study (48% of total cases examined). Those findings are comparable to those displayed in another previous report which was carried out within the Main Training Centre for Early Detection of Breast Tumors in the Medical City Teaching Hospital (Qadir 2005). The latter was the only published report from Iraq which dealt with BDS. Our results were compatible as well with those recorded in other studies from USA (Roswell 1998) & (Alpharetta 2004). *The sensitivity of the BDS test in our study was superior to the sensitivity of clinical breast examination (94% versus 88%)* Breast cancer isthe most common type of malignancy among Iraqi women accounting for about one third of the registered female cancers (according to the results of the latest Iraqi Cancer registry) Traditional approaches to the diagnosis of breast cancer include clinical examination, imaging techniques, fine needle aspiration cytology and histopathological examination of the surgical specimens. The detection of a breast mass in an apparently healthy woman before it is palpable is a technique that saves lives and saves breasts. All women are candidates for screening since all women are at risk for breast cancer development. **Conclusions:** The BDS could provide additional discriminatory information regarding the malignant nature of the disease process in suspicious breast lesions and could serve as a marker of cellular proliferation. We conclude that The BDS test should be an adjunct tool to CBE and not to compete with the other diagnostic utilities of the breast cancer and BDS should reduce the number of unwanted biopsies in cases where CBE, FNAC and BDS show benign changes.

KEYWORD: Bio field Breast Cancer Diagnostic System, Mammary Carcinoma, Iraq.

INTRODUCTION

Background: Breast cancer is the most common malignant tumor and the leading cause of cancer deaths in women worldwide, including Iraq. Early detection of breast cancer has been recommended by the WHO as one of the major tools to control the disease. The Bio field Diagnostic breast cancer System (BDS) has been recently introduced in Iraq. It is a non-invasive device that measures the level of DC voltage skin surface electropotentials associated with suspicious breast lumps. The main objective of its use is to distinguish between benign and malignant breast lesions detected clinically or radiologically.

The Ag-NOR represents a cytochemical marker of both DNA and the level of its transcription. It is used as a useful tool for the study of variations in the nucleolar activity. Qualitative and quantitative variations in Ag-NOR distribution and number has been studied in breast carcinoma and positively correlated with other markers of cellular proliferation including Ki67 immunoreactivity, hormone receptor contents etc.

AIM OF STUDY

1- To determine the utility of BDS in the diagnosis of breast cancer.
2- To correlate the findings of BDS with:

- The Triple Assessment Test (which comprises clinical parameters, ultrasonography &/or mammography and FNAC) of palpable breast lumps.
- Clinicopathological parameters including staging, grading and type of breast carcinoma.
- Results of Ag NOR cytochemical marker.

PATIENTS AND METHODS

This is a prospective study of 50 cases collected from the Main Training Center for Early Detection of Breast Cancer in the Medical City Teaching Hospital. For each patient a full questionnaire was prepared including all demographic and clinical data. All patients were subjected to the Triple Assessment Test and BDS test.

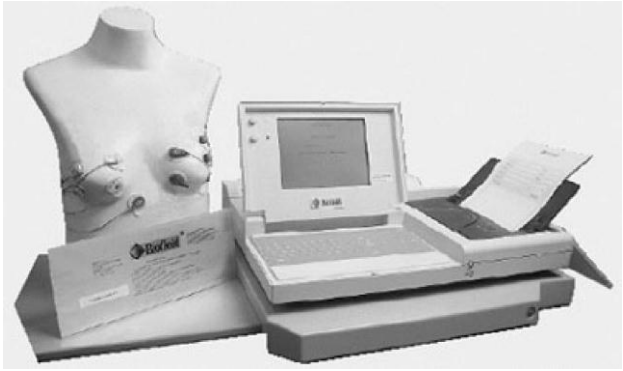

Figure 1: The BDS equipment.

After excision of the breast mass, histopathological examination of the tissue was carried out; recording the type, grading and TNM staging of mammary carcinoma.

Table 1: The Adjusted Level of Suspicion.

BDS Index	Level of Suspicion I :Normal/ANDI	Level of Suspicion II :Probably Benign	Level of Suspicion III :Probably Malignant
-5.0 to -1.7	Probably Benign	Probably Benign	Probably Benign
-1.6 to +0.2	Probably Benign	Probably Benign	Probably Malignant.
+0.3 to +1.5	Probably Benign	Probably Malignant.	Malignant.
+1.6 to +5.0	Probably Malignant.	Probably Malignant.	Malignant.

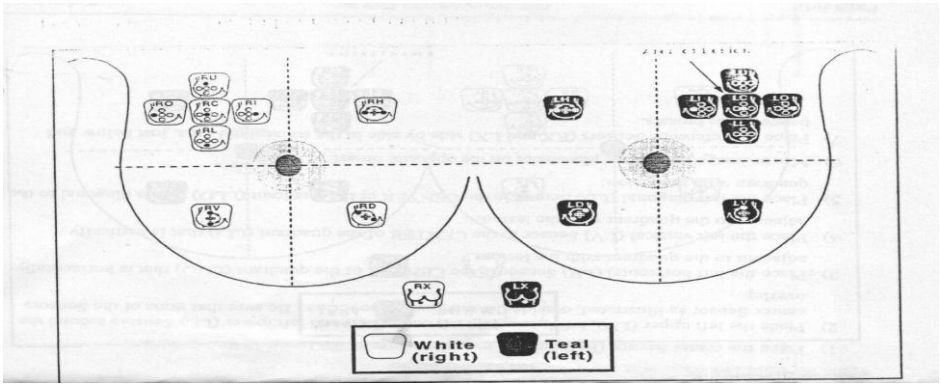

Figure 2: Sensor placement when the lesion is located in the upper outer quadrant of the left breast.

RESULTS

In this study, the BDS findings displayed "Probably Benign" in three cases (6%); "Probably Malignant " in 36 cases(72%) and "Malignant" in eleven cases(22%). The clinical level of suspicion was classified as III in 44 cases for the 50 cases studied (88%) and level II in six cases (12%). The ultrasound level of suspicion was recorded as level III in 38 cases (76%) and level II in eleven cases for the 50 cases studied (22%). The mean age for the "Probably Benign" category was (31 years); for the "Probably Malignant" category was (45.5 years) and for the "Malignant" category was (55.5 years).

The fine needle aspiration cytology results showed ductal carcinoma in 49 cases out of 50 cases studied (98%) and lobular carcinoma in only one case. The mean Ag-NOR count was (**7.86**) for "Probably Benign" category, (**8.23**) for "Probably Malignant" category and (**8.5**) for "Malignant" category. Histopathological diagnosis was available for only 24 cases out of the 50 cases of this study (48% of total cases examined).

McKee cytolopathological grading showed concordance with the histopathological grading system in 91.7% of ductal carcinomas.

The current study demonstrated as well a significant association between BDS findings, Ag-NOR counts, pathological grading and staging of breast cancer.

The sensitivity of BDS was superior to Physical breast examination (94 % for the former versus 89% for the latter).

Table 2: Clinical and Imaging levels of Suspicions versus and other clinico-pathological parameters in 50.

Case No.	Age (years)	Clinical level	U/S level	BDS Index	BDS Result	FNA Result*	Ag-NOR count	Cytological grade	Histologic grade	Stage
1	56	III	III	-0.4	PM	DC	7.6	G II	G III	II
2	32	III	III	-0.7	PM	DC	8.1	G II	G II	II
3	67	III	III	+0.5	M	DC	8.6	G II	-	-
4	60	II	II	+2.0	PM	DC	8.5	G II	-	-
5	39	III	III	+0.3	M	DC	8.7	G III	G III	IV
6	47	III	III	+0.2	PM	DC	7.3	G II	G II	II
7	67	III	III	+0.8	M	DC	8.4	G III	G III	III
8	45	II	III	+2.9	PM	DC	8.4	G II	-	-
9	48	III	II	-0.5	PM	DC	8.8	G II	G II	II
10	38	III	III	-1.6	PM	DC	8.3	G III	G III	IV
11	57	III	III	-0.1	PM	DC	8.6	G III	G III	III
12	73	II	III	+1.8	PM	DC	8.5	G II	-	-
13	35	III	II	-1.3	PM	DC	8.6	G II	-	-
14	47	III	II	-0.0	PM	DC	6.1	G II	G II	III
15	59	III	II	-0.1	PM	DC	8.8	G III	-	-
16	43	III	III	-1.4	PM	DC	7.9	G II	G II	II
17	36	II	I	-1.0	PB	DC	7.0	G II	G I	III
18	70	III	III	-1.0	PM	DC	8.6	G III	G III	IV
19	43	III	III	-1.6	PM	DC	8.8	G III	-	-
20	52	III	III	-0.4	PM	LC	8.3			
21	36	III	II	-1.2	PM	DC	7.9	G III	G III	IV
22	65	III	III	-0.1	PM	DC	7.9	G II	G II	II
23	33	II	II	-1.4	PB	DC	8.3	G II	G II	III
24	44	III	III	-1.0	PM	DC	8.1	G III	-	-
25	55	III	III	+0.9	PM	DC	8.9	G III	G III	III
26	50	III	III	-0.3	PM	DC	8.2	G II	G II	III
27	30	II	II	-1.8	PB	DC	8.3	G II	-	-
28	56	III	III	-0.0	PM	DC	8.3	G II	G II	III
29	55	III	III	-1.1	PM	DC	8.7	G II	G II	III
30	48	III	III	-0.4	PM	DC	8.1	G II	-	-
31	37	III	III	-1.6	PM	DC	7.3	G II	G II	III
32	42	III	III	+0.2	M	DC	8.5	G III	G III	IV
33	33	III	III	-1.1	PM	DC	8.6	G III	G III	III
34	33	III	III	-1.1	PM	DC	8.3	G II	-	-
35	57	III	III	-1.0	PM	DC	8.2	G III	-	-
36	62	III	III	+0.7	M	DC	8.3	G III	G III	III

37	57	III	III	+0.5	M	DC	7.9	G II	G II	II
38	46	III	III	-0.2	PM	DC	8.5	G III	-	-
39	32	III	II	+0.0	PM	DC	7.8	G II	-	-
40	40	III	III	+0.5	M	DC	8.8	G II	-	-
41	53	III	III	+0.8	M	DC	7.8	G III	-	-
42	45	III	II	-0.6	PM	DC	8.2	G II	-	-
43	43	III	III	-1.6	PM	DC	8.9	G III	-	-
44	62	III	III	+0.5	M	DC	8.9	G III	-	-
45	49	III	III	-0.2	PM	DC	8.8	G II	-	-
46	47	III	II	-0.2	PM	DC	7.8	G II	-	-
47	42	III	III	-0.6	PM	DC	8.9	G II	-	-
48	70	III	III	+2.7	M	DC	8.9	G II	-	-
49	39	III	III	+0.5	M	DC	8.7	G III	-	-
50	45	III	III	+0.1	PM	DC	8.7	G II	-	-

Table 3: Descriptive statistics of the different BDS results.

BDS Results	**No. of cases**	**%**	**Mean BDS Index**	**S.D**	**Min.**	**Max.**	**Range**
Probably Benign	3	6	-1.4	0.4	-1.8	-1.0	0.8
Probably Malignant	36	72	-0.394	0.989	-1.6	2.9	4.5
Malignant	11	22	+0.791	0.657	0.3	2.7	2.4
Total	50	100					

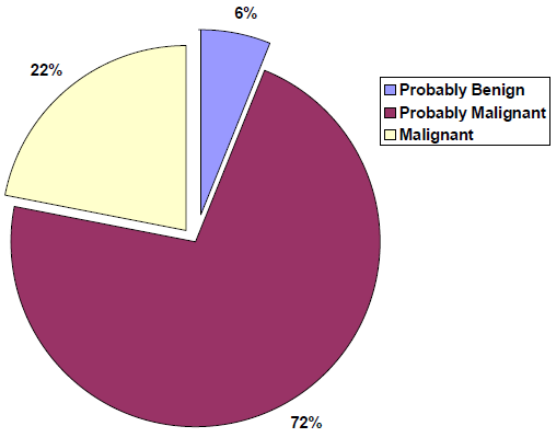

Figure 3: Percentages of different BDS results.

DISCUSSION

Breast cancer is about one third of the most common type of malignancy among Iraqi women the registered female cancers (according to the results of accounting for the latest Iraqi Cancer registry).

Traditional approaches to the diagnosis of breast cancer include clinical examination, imaging techniques, fine needle aspiration cytology and histopathological examination of the surgical specimens.

The detection of a breast mass in an apparently healthy woman before it is palpable is a technique that saves lives and saves breasts. All women are candidates for screening since all women are at risk for breast cancer development.

Detection and diagnosis of breast cancer has typically relied on a combination of physical examination, mammography, ultrasound, and tissue-sampling techniques such as fine-needle aspiration cytology (FNAC).

In this study the BDS results were obtained from the application of the technique to 50 patients with suspicious breast lumps. The findings were Probably Benign findings in three cases (6%); Probably Malignant in 36 cases (72%) and Malignant in eleven cases (22%). Those findings are comparable to those displayed in another previous report which was carried out within the Main Training Centre for Early Detection of Breast Tumors in the Medical City Teaching Hospital (Qadir 2005). The latter was the only published report from Iraq which dealt with BDS. Our results were compatible as well with those recorded in other studies from USA (Roswell 1998) & (Alpharetta 2004).

The sensitivity of the BDS test in our study was superior to the sensitivity of clinical breast examination (94% versus 88%).

CONCLUSIONS

The BDS could provide additional discriminatory information regarding the malignant nature of the disease process in suspicious breast lesions and could serve as a marker of cellular proliferation.

1. The BDS test should be an adjunct tool to CBE and not to compete with the other diagnostic utilities of the breast cancer.
2. BDS should reduce the number of unwanted biopsies in cases here CBE, FNAC and BDS show benign changes.

3. The Staff of operators who perform the test should be well trained under the supervision of the specialist.
4. This diagnostic tool should be supplied to underserved health centers and women in remote areas where other diagnostic tools such as mammography and/or ultrasound are not available. In these populations, there should be nation wide education for both health staff and women on its benefits.
5. Further studies with larger cohorts are recommended to compare the findings of BDS with other proliferative markers including HER-2neu, PCNA, nuclear DNA ploidy, Ki67 etc.

RECOMMENDATIONS

1. The BDS test should be an adjunct tool to CBE and not to compete with the other diagnostic utilities of the breast cancer.
2. BDSM should reduce the number of unwanted biopsies in cases where CBE, FNAC and BDS show benign changes.
3. The Staff of operators who perform the test should be well trained under the supervision of the specialist.
4. This diagnostic tool should be supplied to underserved health centers and women in remote areas where other diagnostic tools such as mammography and/or ultrasound are not available. In these populations, there should be nationwide education for both health staff and women on its benefits.
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