RESEARCH ARTICLE

Evaluation of *BreastLight* as a Tool for Early Detection of Breast Lesions among Females Attending National Cancer Institute, Cairo University

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Abstract

Background: Breast illumination was suggested as a simple method for breast cancer screening. *BreastLight* is a simple apparatus for this purpose. Objective: To evaluate the diagnostic performance of *BreastLight* as a screening tool of breast cancer in comparison to mammography and histopathology. Materials and Methods: This hospital-based cross sectional study was conducted in the mammography unit of the radiodiagnosis department at National Cancer Institute, Cairo University. All participants were subjected to breast examination with the *BreastLight* tool, mammography and ultrasonography. Suspicious cases were biopsied for histopathological examination which is considered as a gold standard. Results: The mean age of the participants was 46.3±12.4 years. Breast illumination method had sensitivity, specificity, positive predictive value, negative predictive value and total accuracy of 93.0%, 73.7%, 91.4%, 77.8% and 88.2%, respectively in detection of breast cancer. Conclusions: Breast illumination method with *BreastLight* apparatus is a promising easy-to-use tool to screen for breast cancer suitable for primary health care physician or at-home use. It needs further evaluation especially in asymptomatic women.

Keywords: Breast cancer - early detection - mammogram - breast illumination methods

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Introduction

Breast cancer is the most common cancer in women; affecting one in nine women at some point in their lives (WHO, 2006). It is the second leading cause of cancer deaths in women after lung cancer (WHO, 2003). In Egypt, breast cancer is the most common cancer among women, representing about 19% of total cancer cases (37.5% in women and 0.9% in men) (Elatar et al., 2003).

Screening for breast cancer focuses on detecting occult cancer at an early stage with tumor size preferably smaller than 1 cm, negative lymph node status and with no evidence of distant spread to allow early therapeutic interventions and/or preventative measures (Michaelson et al., 2003). Mammography has been established as the primary method for screening. About 35-45% of non-palpable cancers are detected as microcalcifications in mammographic studies (Cheung et al., 2003). However, not every carcinoma is detected in breast cancer screening. Breast density is one of the factors leading to false-negative findings in mammography (Porter et al., 2007).

The screening strength of mammography is based on reported high negative predictive values (NPV) ranging from 99.8-100%. However, it has a wide range of positive predictive values (PPV) from 4.3-52.4% and false positive rates from 1.5-24.1% resulting in un-necessary biopsies. The overall sensitivity of mammography was 86.6% and specificity was 96.8% (Banks et al., 2004).

Breast examination; either clinical breast exams (CBE) by a health care provider or by self-exams were once widely recommended. They however are not supported by evidence and may - like mammography and other screening methods that produce false positive results - contribute to harm. The use of screening in women without symptoms and at low risk is thus controversial (Saslow et al., 2004). A 2003 Cochrane review found screening by breast self-examination or by clinical exam is not associated with lower death rates. It increased harms, in terms of increased numbers of benign lesions identified and an increased number of biopsies performed (Kösters and Gøtzsche, 2003).

Clinical evaluations have shown that *BreastLight* is capable of detecting lesions of 15 mm and above. The early clinical studies demonstrated that the breast illumination method is able to detect malignant tumors in women of all ages. Light absorption, determined by the number of blood cells per unit volume of breast, results in the detection of an opaque lesion. *BreastLight* was comparable

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to mammography in correctly confirming absence of cancer. *BreastLight* detection rate of malignant tumors was between 67% and 73%. Benign lesions (e.g. fibrous cysts) generally do not show up as positive with breast light (Brittenden et al., 1995; Kavanagh et al., 2000).

The aim of this study was to evaluate the diagnostic performance of *BreastLight* as a screening tool of breast cancer in comparison to mammography and biopsy.

Materials and Methods

This hospital-based cross sectional study was conducted in the mammography unit of Radiodiagnosis department at the National Cancer Institute (NCI), Cairo University. NCI is a tertiary specialized oncology public hospital, established in 1969 then expanded to be one of the biggest specialized hospitals in Egypt. The study involved 310 females attending mammography unit for screening, diagnosis or follow up of breast cancer in the period from 1st June 2012 to 30th February 2013. Pregnant females were excluded.

Study tools

All participants were subjected to breast examination with *BreastLight* followed by mammography. Suspicious cases with mammography were biopsied for histopathological examination.

BreastLight

BreastLight is a handheld device that trans-illuminates the breast with a visible harmless red-light (617 nm) that is absorbed by hemoglobin so that areas of high vascularity (such as malignant tumors) should appear black. Breast light made in United Kingdom-manufactured by PWB Health, of Dumbarton, Scotland-model BL801. It is used in a darkened room and held tightly to the skin. As it highlights dark areas where blood is present, it is therefore quite normal to see a pattern of veins but, if there is a dark cluster, this is a potential abnormality that should be checked out. Examination was performed by non-professional physician. Tool reliability was tested in 20 participants, were the researcher and another physician performed the examination and results showed inter-rater reliability (kappa) of 0.9, where only one case was diagnosed as negative by the researcher and assigned positive by the other physician.

Mammographic and ultrasound evaluation of the breast was done at the mammography unit of the radio-diagnosis department by a professional radiologist to all studied females. Suspicious cases were referred to surgery unit for biopsy followed by histopathological examination.

Data analysis and statistical methods

Data were analyzed using SPSS win statistical package version 17. Kappa measure was used to assess the agreement between breast illumination method and mammogram. The histopathology of biopsy was considered as a gold standard. Based on the results of biopsy sensitivity, specificity and predictive values and total accuracy of breast illumination and mammogram were calculated. Likelihood ratio was calculated; Likelihood Ratio for positive test (LR+)=sensitivity/(1-specificy) and Likelihood Ratio for negative test (LR-)=(1-sensitivity)/specificity.

Sample size estimation and sampling technique

In the calculation of the sample size, it was assumed breast light tool had a sensitivity of 80%. To achieve a 95% confidence level and a margin of error of 5%, the required sample size will be 246 cases. Adding 25% for possible losses during the study; a sample of 308 cases was sufficient.

Ethical issues

The study was approved by Institutional review board (IRB) of the NCI as the study poses no harm on the participants. Informed consent either verbal or oral was taken from the participants after explaining the purpose of the study, and the data will be presented anonymously and confidentially.

Results

The mean age of the participants was 46.3±12.4 years (range: 18-81 years). Most of studied group (87.1%) of the participants were housewives, 79.7% were married and 62.6% were illiterate (Table 1). About half of the participants (44.8%) complained of mass and 31.6% presented for follow up. The majority of the participants were referred by doctors (81.0%) (Table 2).

Out of 69 positive cases by mammogram, 56 cases (81.2%) were also positive by breast illumination method and out of 241 negative cases by mammogram, 221 (91.7%) cases were negative by breast light. Breast illumination and mammogram were concordant in 277/310 cases (89.4%) showing substantial agreement between the two tools (kappa=0.703, p value<0.001) (Table 3).

Biopsy and histopathological examination (the gold standard) were performed in 76 cases. Breast illumination method had sensitivity of 93% (53/57), specificity of 73.7% (14/19), positive predictive value (PPV) of 91.4% (53/58), negative predictive value (NPV) of 77.8% (14/18) and total accuracy was 88.2% in detection of breast cancer. The likelihood ratio for positive test (LR+) was 3.5 (93/26.3) while the likelihood ratio for negative test (LR-) was 0.09 (7/ 73.7) (Table 4 and Figure 1).

Mammogram had sensitivity of 94.7% (54/57), specificity of 26.3% (5/19), PPV of 79.4% (54/68), NPV of 62.5% (5/8) and total accuracy of 77.6% in detection of

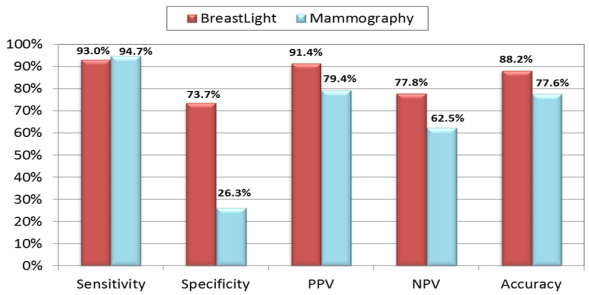

Figure 1. Sensitivity, Specificity, Predictive Values and Total Accuracy of Breast Illumination and Mammogram

Table 1. Socio-demographic Characteristic of the Participants

Characteristic		Total (n=310) n (%)
Age (years)	Mean±SD	46.3±12.4
Age groups	<50 years	193 (62.3)
	≥50 years	117 (37.7)
Residence	Urban	217 (70.0)
	Rural	93 (30.0)
Occupation	House wife	270 (87.1)
	Worker	40 (12.9)
Marital status	Single	13 (4.2)
	Divorced	13 (4.2)
	Widow	37 (11.9)
	Married	247 (79.7)
Education level	Illiterate	149 (62.6)
	Primary/preparatory	35 (11.6)
	Secondary/Faculty	80 (25.8)

*SD: standard deviation

Table 2. Complaint and Source of Referral of the Participants

Characteristic		Total (n=310) n (%)
Mass		139 (44.8)
Follow up		98 (31.6)
Discharge		30 (9.7)
Mastalgia		28 (9.0)
Others		15 (4.8)
Breast enlargement		8 (2.6)
Nipple retraction		3 (1.0)
Axillary swelling		3 (1.0)
Breast trauma		1 (0.3)
Source of referral of the participants	Doctor	251 (81.0)
	Self-referral	59 (19.0)

Table 3. Agreement between Mammogram and Breast Illumination Method

Breast illumination	Mammogram result		
	Positive	Negative	Total
Positive	56 (81.2%)	20 (8.3%)	76
Negative	13 (18.8%)	221 (91.7%)	234
Total	69 (100.0%)	241 (100.0%)	310

Table 4. Relation of Breast Illumination Method to Pathological Results of Biopsy

Breast illumination method	Pathology result		
	Malignant	Non-malignant	Total
Positive	53 (93.0%)	5 (26.3%)	58
Negative	4 (7.0%)	14 (73.7%)	18
Total	57 (100.0%)	19 (100.0%)	76

Table 5. Relation of Mammogram to Pathological Results of Biopsy

Mammogram	Pathology result		
	Malignant	Non-malignant	Total
Positive	54 (94.7%)	14 (73.7%)	68
Negative	3 (5.3%)	5 (26.3%)	8
Total	57 (100.0%)	19 (100.0%)	76

breast cancer. The likelihood ratio for positive test (LR+) was 1.35 (94.7/73.7). The likelihood ratio for negative test (LR-) was 0.201 (5.3/26.3) (Table 5 and Figure 1).

Discussion

This study evaluated a simple tool for screening of breast cancer; *BreastLight*. It is a tool for early detection of breast cancer designed to be used at home or in primary health care settings. The study found *BreastLight* to have a sensitivity of 93% and a specificity of 73.7% in detection of breast cancer.

Iwuchukwu et al. (2010) evaluated breast light on 300 subjects referred to the breast clinic in Sunderland hospital. Breast-light detected 12 out of 18 malignant tumors confirmed as positive using biopsy giving a sensitivity of 67% and correctly identified as negative 240 out of 282 breasts giving a specificity of 85%.

Trans-illumination of the female breast has been evaluated since the 1980s as an aid in the diagnosis of breast lesions. Angquist et al. (1981) performed breast-illumination of a series of 259 of symptomatic women. They detected carcinoma of the breast in 26 women. The number of false positive cases was high with this early breast-illumination procedure. Later on, Greene et al. (1985) examined 467 women with clinically apparent breast disease using three imaging techniques; mammography, sono-mammography, and breast-illumination. The three techniques showed no significant differences in predicting benign or malignant disease in terms of sensitivity, accuracy, and specificity. Breast-illumination by light scanning allowed for consistently correct interpretation of cases proven to be histologically malignant and showed a false-negative rate comparable with x-ray mammography. They concluded that breast-illumination is a sensitive and reliable indicator of both benign and malignant breast; it can be used without the potential problems of radiation exposure. Dowle et al. (1987) reported similar results of breast illumination with a sensitivity of 87.8%.

Brittenden et al. (1995) assessed the use of telediaphanography (breast illumination method) in conjunction with Doppler ultrasound (TDDU) to detect breast carcinomas. Light absorption, determined by the number of blood cells per unit volume of breast, results in the detection of an opaque lesion. Subsequent Doppler ultrasound detects the neovascularization at the periphery of tumors. The sensitivity and specificity were: breast illumination alone 73% and 82%; TDDU 61% and 92%, respectively.

However, Alveryd et al. (1990) tested light scanning against mammography in 2568 women in a Swedish multicenter study. Mammography alone falsely diagnosed cancer in 6.9% of the patients whereas light scan falsely diagnosed cancer in 19.1%.

Breast-illumination was recommended to be used combined with mammography as the use of both mammography and breast-illumination reduced the number of false negatives from 11.8% to 5.5%23. In the present study, mammogram had a sensitivity of 94.7% and specificity of 26.3%. Breast illumination had a specificity of 73.7%. It can be a tool for improving the low specificity of mammography. However, small number of negative biopsies may have a negative impact of this conclusion. Both tests had a comparable sensitivity. They

have agreement in 81.2% of positive cases. Jarlman et al. (1992) have previously tested the diagnostic accuracy of light scanning of 610 breasts. They reported sensitivity of 86% of light scanning and 88% of mammography. Breast illumination method and mammography were in agreement in 77% of cancer cases.

In conclusion, breast illumination method with *BreastLight* apparatus seems a promising way to screen for breast cancer that needs further evaluation especially in asymptomatic women. It could be a valuable aid to a women's personal breast awareness which is considered to be an important tool in the early detection of breast cancer, in particular it would be of great assistance to women for whom palpation is not an effective way to identify suspicious masses. It is an easy-to-use tool suitable for primary health care physician or at-home use.

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