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Accuracy of Hopelight (Mammolight) Imaging in Detection of Breast Cancer

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Abstract: ***Background: hopelight (mammolight device) is a transillumination of breast tissue with low intensity light for detection of breast lesions; however, its value has not been well established. Objectives: to determine the diagnostic accuracy and sensitivity of hopelight in detection of breast cancer with radiologic-pathologic correlation. Patients and methods: a prospective study was performedin Radiology department at the Oncology Teaching Hospital, Medical City Complex in Baghdad (the main tertiary referral public center for breast disease in Iraq). This study enrolled 100 females attending mammography and ultrasound unit for screening, diagnosis or follow up of breast lesions in the period from March 2014 to November 2014. Breast examination was initially performed for each patient by hand-held hopelight device followed by mammography and/or ultrasound study and results were classified from normal to highly suspicious breast lesions according to breast imaging reporting and data system (BIRADS) then fine needle aspiration cytology or biopsy was acquired for BIRADS-IV and BIRADS-V lesions for histopathological review and final diagnosis. Results: demographic, clinical and imaging findings were reported and statistical analysis obtained and sensitivity, specificity and accuracy were 66.66%, 51.06% and 52% respectively with 8% positive predictive value and 96% negative predictive value. False positive results were detected in 46% of the patients whereas false negative outcomes were 2%. Conclusions: hopelight device cannot be safely used for screening of breast cancer and cannot be used alone because of high false positive outcome and low sensitivity, specificity and overall accuracy in detection of breast cancer.***

Key wards: hopelight, mammolight, breast

1. Introduction

At present, the annual new diagnosed cases of breast cancer worldwide were 1.3 million According to the latest edition of Globocan, an estimated 1.67 million females were newly diagnosed with breast cancer; being the most common malignancy among women worldwide[1]. In Iraq, it is the most prevalent cancer among the population in general and the leading cause of cancer-related mortalities in women [2, 3]. TheAmerican cancer society has established rules for detecting breast cancer in women aged 40 and above, which consist of a yearly mammogram, clinical breast examination (CBE) once a year and a voluntary self-breast examination (SBE) [4] Mammography has been recognized as the principal technique for screening of breast cancer regardless of false negative results that were obtained due to high breast density on mammogram.

Hopelight is a handheld light scanner or transilluminator that is electrically powered and emits low intensity visible red light. The device is used to illuminate the mammary tissue in a darkened environment to locate any areas in the breast that are unusual in their ability to transmit light. That domestic checker was designed for breast cancer awareness to be utilized by women themselves at home. The translilluminated light at a wavelength of 617 nm is absorbed by haemoglobinyielding dark shadows in the areas of high vascularity i.e., (angiogenesis in malignancy). The manufactures claimed that the results were favorable in women with lumpy breasts [5].

Theidea of emerging portable, non-radiative, low price, and hand-held optical devices for early detection of breast cancer was initiatedin the late 1990s by Tromberg's research group [6-8].Transilluminationlight scanning of the breast has been requested to be mostlyappreciated in young women with dense breasts and considered as a non-invasive prescreening tool to complement CBE/SBE since CBE and SBE have high false-positive rates [9].

Various research groups have developed hand-held optical scanners for breast imaging for prescreening, detection and diagnosis of breast lesions [10,11]. Breast illuminators used visible red light to transmit the breast tissue and made-up the visual contrast by means of the naked eye according to the neo-angiogenesis and molecular biology of the tumor [12,13]. Nevertheless, published earlier studies highlighted their alarming misleading resultsdue to their low specific false positive findings [14,15].

The aim of the current study was to determine the diagnostic accuracy and sensitivity of the hopelight device in the detection of breast lesion; correlating the findings with mammography, +/- ultrasound and fine needle aspiration cytology on basis of breast imaging reporting and data system.

2. Patients and Methods

A prospective study was piloted in the Main Referral Center for Early Detection of Breast Tumors and the

Radiology Department at the Oncology Teaching Hospital, Medical City Complex in Baghdad (the main tertiary referral public center for breast disease in Iraq). This study enrolled100 females attending mammography and ultrasound unit for screening, diagnosis or follow up of breast lesions in the period from March 2014 to November 2014. The institutional approval for conduction this study was achieved by the National Cancer Research Center of Baghdad University. Verbal and/or written consentswere obtained from the participants after clarifying the goals of the study during the direct interviews and examinations.Breast examination was initially performed for each patient by hopelight device followed by mammography and/or ultrasound study and results were classified from normal to highly suspicious breast lesions according to breast imaging reporting and data system (BIRADS). Fine needle aspiration cytology and/or biopsy was conducted on those patients diagnosed as having BIRADS-IV and BIRADS-V lesions who were referred for histopathological review and final diagnosis.

Hopelight, as a handheld probe, created visible red light (617 nm) transilluminatingthe breast tissue through absorption of this light by hemoglobin and accordinglyillustrating the vascularity of the breast lesions; the darker lesion indicating high vascularity, the more likely it is to be a malignanttumor. Examination was performed in a dark room with the probe turned on and pressed tightly against the skin to visualize all areas of the breast including the nipple. After completing the examination, the resultant images were reviewed by the examiner who had no previous idea about the results of mammogram, ultrasound scanning or clinical examination. The results were classified as negative (absent of dark area) or positive (presence of dark area) then the routine mammography and/or ultrasound performed according to previous appointment. In all patients, examination with the device was performed prior to fine needle aspiration to avoid hematoma that leads to false positive results with the light device. During the examination, any dark spots or shadows were recorded.

Patients were then subjected to the routine triple assessment examination and the findings of the Hopelight device were compared with the results of mammography, ultrasound, and cytopathology; the latter being utilized as the gold standard for the sensitivity and specificity. For the purpose of calculating the results, only cytological samples that exhibited frank malignant mammary cells were considered as positive. Statistical analysis was performed with excel Microsoft office 2010, the sensitivity, specificity, positive predictive value, negative predictive value and accuracy of hopelight in detection of breast lesions was calculated accordingly.

3. Results

Hundred patients were involved in this study with a mean age of 48 (SD ± 11.3) years; 70% of them were aged 40 years and over. Breast pain was the most common presenting clinical symptom (77%). Only 10% of sample of the study attended the breast care center for screening purpose. The demographic and clinical characteristics of the study sample are summarized in table (1).

Table 1: Demographic and clinical characteristics of the sample of the study

Parameter			No. (%) Total No. = 100
Age group (years)		Under 40	30 (30)
		40 or above	70 (70)
Occupation		House wife	64 (64)
		Employer	36 (36)
Clinical presentation	Symptoms	Pain	77 (77)
		Mass	19 (19)
		Nipple discharge	4 (4)
	Asymptomatic (screening)		10 (10)

Table 2: Correlating Hopelight scanning results with the Cytopathologic findings

Hopelight Results	Pathological Results		Total
	Malignant	Non-malignant*	
Positive	4	46	50
Negative	2	48	50
Total	6	94	100

*non-malignant results were included normal and benign findings

Hopelight imaging of the breast revealed (66.66%) sensitivity, (51.06%) specificity, (8%) positive predictive value (PPV) and (96%) negative predictive value (NPV). The overall accuracy was (52%).

Figure 1: Hand-held hopelight (mammolight) device

4. Discussion

Although, in 1995, the breast transilluminators considered as class-III device in FDA federal registers (60 FR 3171) [16], the Obstetrics and Gynecology discussion panel meeting in 1991 identified 3 major risks of breast light scanners that included: misdiagnosis, delayed diagnosis and delayed treatment. That panel recommended that breast transilluminators be placed in class- III [high-risk device with no reasonable assurance of safety and effectiveness] [17]. However, other literature reviews performed within the last two decades about the value of light scanners in the detection of breast cancerdemonstrated the promising role of optical imaging of the breast used either alone or combined with other imaging modalities [18-20].

In the current study, we determined that the hopelight scanningsensitivity, specificity, positive predictive value, negative predictive value and accuracy were equivalent to 66.6%, 51.06%, 8%, 96% and 52% respectively. The recorded sensitivity and specificity rates may be overestimated due to the fact that our results were based

mainly upon cytopathology and BIRADS imaging classification system; being not confirmed by histopathology in all cases. The observed findings were not consistent with the results that obtained by Bartrumet al study in 1984 [21] in which their sensitivity and specificity were 76%and 83% respectively whereas PPV and NPVapproached to (12%) and (99%) respectively. Athanasiou et al in 2007 [22] revealed very low specificity (38%) and higher sensitivity (73%) than ours. Alveryd et alin 1990 [9] showed that the sensitivity and specificity of the light scanner were 84.1% and 88.9% respectively. This wide range of variation in sensitivity was might be attributed to the discrepancy of interpretation blinded reading of breast light scanners probably without mammography.Nevertheless, more recently in 2014, Alwan et al examined 150 Iraqi patients by the device reporting false positive and false negative rates equivalent to 46.5% and 19.4% respectively; thus yielding a sensitivity reaching to 80.6% with a specificity of 53.5% [15].They concluded that the observed high false positive detection rate and the significantly low specificity in excluding malignancy preclude the safe utilization of the hopelight as a screening tool for breast cancer.

Interestingly, while the false positive results of the light scanner in this study (46%) was very close to that displayed by Alwan et in 2014, false negative results compared to mammography and/or ultrasound were significantly lower (2%); probably because the observed faint shadows during hopelight examinations were disregarded in the present study. Athanasiou et al study [22] recognized false negative results higher than that in our results (26.4%) and much lower false positive results [15.3%]. The high false positive result represents a principal drawback as blood will absorb the light unrelated whether it is in a benign or malignant tumor, in vein, skin lesion or free in the breast. These false positive findings often result in serious anxiety and phobia experienced by the patient while the lesion is non-specific or benign [15]. Other reported hazards associated with mal use of such devices include the risks of electrical shock and thermal or eye injuries [23]. Within that respect, Cancer Research in Britain commanded stopping their pharmacies from stocking the Breast Light device [14, 15].

On the other hand, false negative results in our study could be easily attributed to the fact that 64% of our study sample were housewives, probably multiparous women and 70% were 40 yearsand over; the resulting large breast size hence could obscure the penetration and distribution of the light evenly through the whole breast specifically in cases of deeply situated breast lesions. In addition, the small-sized breast lesions that were detected on follow up mammography were not simply visualized by the transilluminator device. Other recorded limitations include the degree of the compression created on the tested breast and proper view selection during each examination depending on size of the breast and site of palpable lumps[16,17].Only four malignant breast lesions were detected by the blinded hopelight devicewhich might be attributed to selection bias of the sample; given that the majority of the study sample (90%) were symptomatic women attendingthe breast care clinic and 19% of those patients in fact had palpable lumps on clinical or breast self-examinations.

5. Conclusions

Although hopelight scanner (mammolight) of the breast seems to be promising simple handheld tool for early detection of the breast lesions at home or in primary health care centers; however, hopelight device cannot be safely used for screening of breast cancer and cannot be used alone because of the high false positive outcomesand the significantly low sensitivity, specificity and overall accuracy in diagnosing breast cancer.

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Author Contributions

Abdullateef Aliasghar, Author makes substantial contributions to acquisition of data, and/or analysis and interpretation of data and drafting the article and revising it critically for important intellectual content (chief author).

Nada A S Alwan, Author initiated the study, designed the questionnaire, instructed co-authors on the use of the Hopelight device and supervised the cytopathological diagnosis of cases, in addition to her critical comprehensive revision of the draft providing it with its final intellectual content.

Khaleel Ibraheem Mohson, Author participates in examination of the patients by hopelight device (mammolight) and reports the main findings according preform case sheet.

Enam Azez Khalel, Author participates in examination of the patients by ultrasound and mammography and reports the main findings according preform case sheet.