

Breast-Light Device as an Adjuvant for Clinical Breast Examination in Breast Examination Clinic /Al-Yarmouk Teaching Hospital-Baghdad

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Abstract:

Background: The low survival rates of Breast cancer in less developed countries -like Iraq- are mainly attributed to lack of awareness programs, resulting in a high proportion of women presenting in late-stages, in addition to the limited capacity for early diagnosis and effective multimodality treatment.

Objectives: To compare outcome of clinical breast examination with breast light device use.

Patients and Methods: This descriptive hospital-based cross sectional study was conducted on a sample of 305 women attending breast examination clinic in al-Yarmouk teaching hospital-Baghdad, from 1st January to 30th July 2015. Study tools included "The Breast light" which is a handheld device that trans-illuminates breast with a red light that is absorbed by hemoglobin yielding dark shadows in areas of high vascularity (including malignancy). Breast-light device was used for breast examination, together with clinical breast examination.

Results: The study showed moderate agreement in detection of breast abnormalities between clinical breast examination and Breast light examination (kappa 43%). Neither breast mass size, nor its location showed significant differences when comparing the results of the two methods. Moreover, Mastalgia appeared to be the most frequent presentation in the examined women.

Conclusion: Detecting ability of breast abnormalities could be raised, when integrating clinical breast examination with breast light. In addition, breast light could be a valuable aid for family doctors at primary health care level, as it's easy to use, portable and not invasive.

Key words: Breast light, Clinical Breast exam, Breast examination clinic

Introduction:

Breast cancer is responsible for about one third of the registered Iraqi female cancers and almost one quarter of deaths within the last two decades. Its incidence has been increased to be one of the major threats to Iraqi female health. It is often diagnosed in advanced stages yielding high mortality incidence ratio^(1,2).

Screening tools include clinical and self-breast exams, mammography, genetic screening, ultrasound, and magnetic resonance imaging. Clinical breast exam (CBE) is a simple, noninvasive, & safe early detection measure (sensitivity 40-70%, specificity 86-99%) performed by a trained health care provider^(3,4). Clinical Breast Examination (CBE) in Primary Health Care Centers, along with diagnostic mammography in major hospitals for referred cases, could offer cost effective approaches for early detection of breast cancer in Iraq. The resources required to provide these services are within the reach of all countries with limited resources⁽³⁾.

The Breast Light introduced in 2012, is a handheld device that trans-illuminates the

breast with a red light (wavelength 617 nm) that is absorbed by hemoglobin yielding dark shadows in areas of high vascularity (including malignancy). Trans-illumination light scanning is a noninvasive modality with low-intensity emissions of red light to visualize breast tissues⁽⁵⁾. When a tumor takes hold in the breast, a new blood vessel grows to feed it.

The Breast light would show as a dark patch long before it can be felt, thus it provides additional dimension to palpation^(6,7). The normal image reveal the superficial blood vessels, the nipple and areola as dark shadows against a mainly red background. Owing to the angiogenesis in the malignant lumps, they should appear by that device as dense dark opacities within a bright red background⁽⁷⁾.

The Device is easy to use, relatively affordable, non-invasive, safe, portable, chargeable, lack radiation risk, and favorable in women with large breasts⁽⁷⁾. It can detect mass as small as 0.7 cm⁽⁶⁾. Breast light detection rate of malignant tumors ranges 67%-73%⁽⁸⁾. Age, menopause, breast size/density do not affect Breast light performance⁽⁸⁾. On the other hand, benign lesions without vascularity (e.g. simple

cyst) may not be detected, so as some malignancies not causing increase in blood flow. The current study aimed to assess breast-light imaging in comparison with clinical examination of the breast in terms of breast mass/shadow: its size, location & associated lymph nodes, for women attending breast examination clinic. **Patients &**

Methods

This is a cross sectional, hospital based, descriptive study with an analytic element conducted under official & ethical approvals, in Breast Examination clinic at Al-Yarmouk teaching hospital / Baghdad, from 1st January to 30th July 2015. A sample of 305 patients was included from women attending breast examination clinic. Sampling involves non-random selection of all women present during research days. A pilot study was carried out before the actual study to ascertain acceptability of women for breast light exam. Inclusion criteria involves any women aged ≥ 30 years attending breast clinic (referred or not), during the study period.

Pregnant women were excluded because breast light is not suitable during pregnancy, as the hormonal effects increase breast vascularity masking possible shadows. The researcher started by an interview with each participant. Privacy & confidentiality were considered after verbal consent. Women were given the right to withdraw from the study at any time.

The study relied on clinical breast examination, and breast light examination. Clinical breast examination was done for any palpable mass, location, site, & size (classified into: <2 , $2-5$, >5 cm), followed by breast light illumination in fully dark room, for any shadow, location, site, & size (<2 , $2-5$, >5 cm). The device is almost safe, because it is non-x ray, noninvasive modality, doesn't contain any radioactive materials, and uses low intensity emissions of red light at wave length 617 nm which it is safe for human tissue.

First, water lubricant based was applied on breast, then the breast light held tightly underneath the breast and against the skin with highest brightness setting indicator. Adjustment was done until reaching the suitable brightness level. Slowly, the device was moved around to see all the breast. The researcher reported any shadow noticed with its position and diameter in Sketch presentation. Statistical analysis was done using SPSS v.20, including data summarization, presentation, statistical tests for significance, and test of agreement (Cohen kappa), as it is generally thought to be a more robust measure than simple percent agreement calculation, takes into account the possibility of the agreement occurring by chance. P- Value of 0.05 cut off was used to denote significant result.

Results

Clinical breast examination results revealed breast mass in (28.5%) of them. Mass size was small in 78.2%, medium in (19.5%), and large in (2.3%) of women. The physical examination of the study group also showed that only 6.2% had palpable axillary lymph nodes. According to the breast light examination test, breast shadow appeared in 16.7% of 305 examined females. 80.4% of those shadows were small, 17.6% medium, and only 2% of them were found to be of large size. (Table 1).

Breast abnormalities detected by clinical breast examination moderately agreed with breast light exam ($k= 0.431$, $p<0.0001$), (Table 2). A non-significant difference between breast abnormalities locations also showed in comparison between clinical and breast light examination. The average of breast mass size, which had been measured by CBE and breast light, did not show any significant differences and they were approximately convergent in their mean size. Mean size of breast mass achieved by clinical examination were accessed by the researcher to the nearest 0.5 cm. (Table 3).

Tab 1: of Clinical Breast Exam & Breast light Findings among studied women:

Clinical features	Number	Percent
Breast mass		
No	218	71.5
Yes	87	28.5
Mass size		
Small (<2 cm)	68	78.2
Medium (2-5 cm)	17	19.5
Large (>5 cm)	2	2.3
Axillary lymph nodes		
Palpable	19	6.2
Not palpable	286	93.8
Breast light exam		
Breast shadow		
Absent	254	83.3
Present	51	16.7
Shadow size		
Small (<2 cm)	41	80.4
Medium (2-5 cm)	9	17.6
Large (>5 cm)	1	2.0
Total	305	100

Tab 2: Breast-light & CBE agreement for presence of breast abnormalities:

		Breast Light Exam		
		Shadow	No shadow	Total
Clinical Breast Exam	Abnormality	38	49	87
	No abnormality	13	205	218
	Total	51	254	305

Cohen's kappa= 0.431, p<0.0001(Moderate significant agreement)

Tab 3: Comparison between Breast Light & Clinical Breast Examination of included women for breast mass location & size:

Breast mass	Clinical Breast Exam	Breast light	Total
Mass Location	No. (%)	No. (%)	No. (%)
Upper median	22 (25.3)	6 (11.8)	28 (20.3)
Lower median	5 (5.7)	3 (5.9)	8 (5.8)
Lower lateral	15 (17.2)	8 (15.7)	23 (16.7)
Upper lateral	22 (25.3)	10 (19.6)	32 (23.2)
Sub axillary	23 (26.4)	24 (47.1)	47 (34.1)
Total	87 (100)	51 (100)	138 (100)
Chi square $\chi^2 = 7.41$, degree of freedom = 4, p value = 0.116			
Mass Size	(mm)	(mm)	
Mean \pm SD	18.3 \pm 9.5	17.7 \pm 9.3	
Range	(5-50)	(10-50)	
Independent t-test = 0.363, degree of freedom = 106.2, p value = 0.641			

Discussion

Personnel Breast light which has been recently used as an adjunct to BSE and CBE offers low income countries a good chance for implementing mass breast screening. Breast-light offers a potential for mass screening of younger, denser breasts for which mammography is not recommended⁽⁸⁾. When data of the current study was revised, there were 305 women from different age groups consulting breast clinic, about three quarters (74.4%) were younger than 50 years (not tabulated). This continuing trend for the disease to affect younger generations has been comprehensively illustrated in the Iraqi Cancer Registry and is a reflection of the younger demographic profile⁽⁹⁾. This was similarly documented in neighboring countries^(10,11,12). We should target our screening programs to younger women. The leading complaint for breast clinic visiting in the current study was Mastalgia (60%) (not tabulated) which agrees with a study conducted in turkey 2010⁽¹³⁾. Mastalgia disrupts the quality of life especially due to the worry of having cancer. Leading complain differ in other studies, e.g. a retrospective study in Sheffield⁽¹⁴⁾ which revealed that (66%) of women presented with a lump or mass. This reflects the weak practice of breast self-examination of Iraqi women who come only when Mastalgia starts. This goes in the same line with an Iraqi study in 2011 which showed that only 48.3% practiced BSE. The most common reason for not doing so was lack of knowledge of how to perform the technique correctly

⁽¹⁵⁾. The physical examination (CBE) of the studied group showed that (28.5%) of them had palpable mass. Nearly one fifth of them had moderate size breast mass. That reflects the late presentation and the weak practice of clinical breast examination at the primary health care level. It is known that CBE may be important for women who do not receive regular mammograms. Specifically, CBE presents an opportunity for health care providers to educate women about breast cancer, its symptoms, risk factors, and advances in its early detection, as well as normal breast composition and variability. It also lets clinicians discuss the benefits and limits of breast self-examination (BSE) and demonstrate BSE for women who elect to do it⁽¹⁶⁾. Among studied patients, examination by breast light revealed shadow in about one sixth of the studied sample. Majority of those shadows were small in size, and one fifth of them with no palpable mass detected clinically. Accordingly, breast light could be a valuable aid to the doctor at the primary health level to distinguish between normal breast tissue and areas where new blood vessels are present indicating potential abnormality even in small or not palpable breast mass⁽¹⁷⁾. This agrees with a hospital-based cross sectional study conducted in the National Cancer Institute (NCI), Cairo University (2013) which revealed that breast light would be of great assistance to women for whom palpation is not an effective way to identify suspicious masses. The study also stated that it is an easy-to-use tool suitable for primary health care

physician or at-home use⁽¹⁷⁾. Although cancer Research in Britain commended stopping their pharmacies from stocking this device due to full availability of mammogram & ultrasound resources, the device is not prohibited in Iraq and Middle East area. In Iraq, as one of the developing countries, resources for establishing a fully equipped nationwide early detection system for the target population at risk are limited, i.e., mammography machines and ultrasound. In addition to inadequate number of well-trained radiologists and radiographers and the insufficient standardized quality control procedures. Therefore, it is logical to search for a device easy to use as adjuvant to CBE at the primary health care level to detect breast abnormalities as early as possible.

The current study showed moderate agreement in detection of breast abnormalities between CBE and Breast light (kappa 43%). This agrees with another Iraqi study carried in Main Training and Research Centre for early detection of breast cancer in 2014 which conclude that the accuracy of the detection rate of the breast Light in palpable lumps detected by clinical examination was significant⁽⁷⁾. This finding can increase the chance of early detection of breast abnormalities by performing clinical breast examination alongside with Translumenation method. Thus by combining both, extra cases can be referred to be evaluated by the other imaging tests. The most common site for breast abnormalities detected by breast light was sub areolar area followed by upper outer quadrant. This disagrees with the fact which revealed that the upper outer quadrant is the most common site of origin of breast cancer followed by the central area⁽¹⁸⁾.

The mean of breast mass size in current study, which had been measured by CBE and breast light, did not show any significant differences and they were approximately convergent in their mean size. In Conclusion, detecting breast abnormalities would be raised, when integrating clinical breast examination with breast light. The study recommends its use for family doctors at PHC level.

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