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Original article

Evaluation of Breast Light Device Efficacy in Detection of Breast Lesions in Comparison with Breast Sono-Mammography

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Abstract

Background: Breast cancer is a significant public health concern, and early detection of breast lesions is crucial for improved patient outcomes. Various screening methods, including mammography and ultrasound, have been employed, but their limitations necessitate the exploration of alternative diagnostic tools. **This study aimed to** evaluate the diagnostic efficacy of the Breast light device during clinical breast examination (CBE) in comparison of mammography and Breast ultrasound in the detection of breast lesions (BLs). **Methods:** This prospective multi-centric study was conducted, involving 300 female patients from outpatient breast clinics. The patients underwent clinical breast examination and were examined using the Breast Light device. Additionally, bilateral breast ultrasound or bilateral breast sono-mammography were performed. **Results**: The data showed that the Breast Light device exhibited a sensitivity of 72.6% and 83.8% for detecting benign and malignant breast masses when compared to ultrasound, with a specificity of 98.6% and an accuracy of 86.6%. When compared to sono-mammography, the sensitivity was 72.9% and 89.5%, with a specificity of 92.5% and an accuracy of 85.3%. **Conclusion:** The Breast Light device demonstrates promise as an adjunct tool for detecting breast lesions, with high specificity. It can play a valuable role in conjunction with traditional imaging methods, particularly in settings where advanced equipment may be limited.

Keywords: Breast Light Device; Efficacy; Breast Lesions; Breast Sono-Mammography.

Introduction

Breast cancer holds the distinction of being the most commonly diagnosed cancer worldwide, and it stands as the leading cause of cancer-related mortality among women. The decline in breast cancer mortality can be partly attributed to the heightened awareness of breast cancer, improved screening methods, and advancements in treatment (1, 2).

Early detection of breast cancer is most effectively achieved through screening modalities, with mammography being the primary imaging tool for early-stage breast cancer screening (3). Research has demonstrated that early detection through mammography significantly reduces breast cancer mortality, with reported sensitivity ranging between 83% and 95% (4, 5). However, despite its relatively low cost, mammography's moderate sensitivity as a screening test for breast cancer leaves room for improvement. Various factors, such as age, breast density, tumor or lesion depth, and body mass index, can affect its sensitivity and lead to false negative results (6).

In efforts to enhance the sensitivity of breast cancer screening, combinations of mammography with other modalities, such as palpation, ultrasonography, or magnetic resonance imaging, have been explored. The inclusion of clinical breast examination (CBE) through palpation alongside mammography yields a 4% increase in sensitivity (7).

CBE has shown effectiveness in diagnosing suspicious lesions by increasing women's awareness of changes in their breasts. Sensitivity and specificity for CBE have been reported to range from 28% to 36%. Therefore, it is recommended to use CBE in conjunction with mammography or other diagnostic tests (8, 9).

A novel product, the Breast Light device, has been designed for home use to promote breast health awareness. This device emits a harmless red light at 617 nm that passes through breast tissue and is absorbed by hemoglobin. As a result, denser areas, including malignant tumors, appear as dark spots. A few studies have suggested that incorporating Breast Light into at-home breast self-examination (BSE) or CBE can lead to more positive screening results and increase women's awareness (10-12).

The aim of the work was to evaluate the diagnostic efficacy of the Breast light device during CBE in comparison of mammography and Breast ultrasound in the detection of breast lesions (BLs).

Patients and methods

This was a prospective study in which the patients were recruited from two clinical centers: the General Surgery Department at the Faculty of Medicine, Benha University Hospital, and the Surgical Oncological Department at Police Hospital. The recruitment took place over the period from May 2019 to May 2023.

The study aimed to involve 300 female patients who attended the outpatient breast clinic at Benha University Hospital or the Surgical Oncology Clinic at Police Hospital for breast examination, diagnosis, or follow-up of breast lesions.

An informed written consent was obtained from the patients. Every patient received an explanation of the purpose of the study and had a secret code

number. The study was done after being approved by the Research Ethics Committee, Faculty of Medicine, Benha University.

Inclusion criteria were female patients and those with complaints of any breast symptoms (mass, discharge, mastalgia, etc.).

Exclusion criteria were patients with recent breast surgery and patients who had undergone recent radiotherapy.

Sample Size:

The study aimed to involve 300 female patients who attended the outpatient breast clinic at Benha University Hospital or the Surgical Oncology Clinic at Police Hospital for breast examination, diagnosis, or follow-up of breast lesions.

Study Protocol:

All patients attended the outpatient breast clinic at Benha University Hospital or the Surgical Oncology Clinic at Police Hospital for breast examination, diagnosis, or follow-up of breast lesions.

All patients were asked about their full personal, menstrual, past, and family history.

Clinical breast examination was conducted, which included:

Inspection in a sitting position with hands in the waist and then hands raised behind the head. Palpation in a sitting position and then in a laying down position. Palpation of both breasts in four quadrants, nipple, areola, and both axillae. This was followed by the use of the Breast Light device for both breasts, involving:

The use of the light device in a sitting position in a completely dark room. Placing the device in direct contact with the breast from the back surface. Examining all areas of the breast in a longitudinal manner from the chest wall directed forward to the nipple. Separately examining the breast in detail.

All patients underwent bilateral breast ultrasound or bilateral breast sono-mammography according to their age.

Samples of Breast Light Findings

Light Device and used terms: Figure 1.

Definite Lesion: Figure 2.

Evaluation and follow-up

For all female patients, offering early full breast diagnosis was the main aim for evaluation with comparing the results with radiological findings.

Outcomes

The primary outcome was reaching diagnosis with least cost and efforts for more screening.

The secondary outcome was early detection of any breast lesions.

Ethical Approval Code: MS 9-12-2019

Statistical analysis

In the realm of data management and statistical analysis, the collected data were meticulously recorded, and subsequent processing was carried out using the Statistical Package for the Social Sciences (SPSS) 22.0 for Windows (SPSS Inc., Chicago, IL, USA). The process entailed several stages, including editing and coding, data entry into the computer, and the presentation of data in tables and graphs. To provide a comprehensive summary, the collected data were distilled into numerical and percentage terms. Qualitative data comparisons were executed using the Chi-Square test, defined as $\Sigma (O - E)^2 / E$, where O represents the observed value and E signifies the expected value, facilitating comparisons across various categorical groups, such as 2x2 tables or more. Furthermore, the sensitivity, specificity, and accuracy of the Light device were diligently calculated. Sensitivity gauged the device's capacity to accurately identify true positive cases while minimizing false negatives, while specificity measured the device's ability to correctly pinpoint true negative cases while minimizing false positives. All statistical tests employed a two-sided approach, and the level of significance considered for this study was set at $p < 0.05$, with $p \leq 0.001$ denoting a highly statistically significant result and $p > 0.05$ indicating a lack of statistical significance.

Results

The data reveals that 50% of the patients under study were younger than 35 years old, while 15.3% of them were over 50 years old. Furthermore, 78% of the subjects were married, and 5% of them were divorced. The findings also indicate that 10% of the patients had an irregular menstrual cycle, with 89.3% experiencing menarche at the age of 12 or older. Additionally, 84.3% of the patients were able to lactate naturally, and 55% of them used non-hormonal contraceptives.

The data shows that 79.7% of the patients had no family history of breast issues, whereas only 9% had a prior history of breast surgery. Furthermore, 12.7% and 6% of the patients were diagnosed with hypertension and diabetes, respectively. Regarding breast-related concerns, 52% of the patients reported breast masses, and 7.3% of them noticed these masses during routine examinations. **Table 1**

The data detected by Light device revealed that 49% of the patients included in the study did not exhibit any abnormalities detected by the Light device in their breasts. Also, 32% of them suggested having benign lesions and 19 % of them were suggested to have malignant breast lesion. **Figure 3**

The data diagnosed by sonography versus sono-mammography (according to the patients age) revealed that 25.4% and 18 & respectively of the patients in

the study exhibited no breast abnormalities, while 20.6% and 16% respectively of them were diagnosed with benign lesions, and 4% and 16% respectively had malignant lesions upon examination. **Figure 3**

The analysis of the personal, geographic, history and complaints of patients showed no significant results. **Table 1**

The analysis reveals that there were no significant differences in the radiological findings of the studied patients concerning their family history, past medical history, and history of chronic diseases ($p > 0.05$).

In contrast, the results demonstrate a highly significant difference in the radiological findings of the studied patients with respect to their complaints ($p = 0.001$). Among the patients with benign diseases, 68.2% reported a mass, with 6.4% detecting it during routine examinations. For patients with malignant diseases, 51.7% complained of a mass, with 5% detecting it during routine examinations. **Table 2**

The results indicate that the sensitivity of the light device in detecting benign and malignant breast masses among the studied patients, when compared to ultrasonography in patients less than 5 years old, is 72.6% and 83.8%, respectively. The specificity of the light device in detecting breast masses among the studied patients, compared to ultrasonography, is 98.6%. Additionally, the accuracy of the light device in detecting breast masses among the studied patients, when compared to ultrasonography, is 86.6%. **Table 3**

The results reveal that the sensitivity of the light device for detecting benign and malignant breast masses among the studied patients, in comparison to Sono-mammography in patients more than 35 years old, is 72.9% and 89.5%, respectively. The specificity of the light device for detecting breast masses among the studied patients, when compared to Sono-mammography, is 92.5%. Furthermore, the accuracy of the light device in detecting breast masses among the studied patients, as compared to Sono-mammography, is 85.3%. **Table 4**

Table 1: Distribution of age and marital status, menstrual, lactation and contraceptive history, family, past history and history of chronic diseases and Complain of the studied patients:

Variables N = 300		N.	%
Age (years)	**<35**	150	50.0
	35-50	104	34.7
	>50	46	15.3
Marital status	**Single**	28	9.3
	Married	234	78.0
	Divorced	15	5.0
	Widow	23	7.7
Menstrual Hx	**Regular**	270	90
	Irregular	30	10
Menarche	**<12 years old**	32	10.7
	≥12 years old	268	89.3
Lactation	**Artificial**	47	15.7
	Natural	253	84.3
Contraceptive	**Hormonal**	135	45
	Non-Hormonal	165	55
Family H\O	**+ve**	61	20.3
	-ve	239	79.7
Past history	**-ve**	273	91.0
	Breast Surgery	27	9.0
Chronic diseases	**No**	244	81.3
	DM	18	6.0
	HTN	38	12.7
Complain	**Mass**	156	52.0
	Pain	90	30.0
	Discharge	32	10.7
	Routine examination	22	7.3

Table 2: Differences between the studied patients according to their family, past history and history of chronic diseases and complain

Studied patients N.=300		Radiological diagnosis			Chi square test	P value
		NAD N.=130	**Benign N.=110**	**Malignant N.=60**		
Variables		**N. %**	**N. %**	**N. %**		
Family H\O	**+ve**	21 16.2%	30 27.3%	10 16.7%	5.17	.07
	-ve	109 83.8%	80 72.7%	50 83.3%		
Past history	**-ve**	122 93.8%	100 90.9%	51 85.0%	3.92	0.14
	Breast Surgery	8 6.2%	10 9.1%	9 15.0%		
Chronic diseases	**No**	110 84.6%	92 83.6%	42 70.0%	6.60	0.15
	DM	7 5.4%	5 4.5%	6 10.0%		
	HTN	13 10.0%	13 11.8%	12 20.0%		
Complain	**Mass**	50 38.8%	**75 68.2%**	**31 51.7%**	24.01	**0.001**
	Pain	49 37.6%	24 21.8%	17 28.3%		
	Discharge	19 14.7%	4 3.6%	9 15.0%		
	Routine examination	12 9.3%	**7 6.4%**	**3 5.0%**		

Table 3: Sensitivity and Specificity of Light device for diagnosis of breast mass in comparison to Ultrasonography

N.=150			Ultrasonography			Total
			NAD	**Benign**	**Malignant**	
Light device	**NAD**	94	49	38	7	
	Benign	45	21	24	0	
	Malignant	11	6	0	5	
Total		150	76	62	12	150
Sensitivity	**Benign mass**			72.6%		
	Malignant mass			83.3%		
Specificity for detection of breast mass				98.6%		
Accuracy for detection of breast mass				86.6%		

Table 4: Sensitivity and specificity of light device for diagnosis of breast mass in comparison to Sono-mammogram

N.=150			Sono mammogram			Total
			NAD	**Benign**	**Malignant**	
Light device	**NAD**	53	32	14	7	
	Benign	51	17	34	0	
	Malignant	46	5	0	41	
Total		150	54	48	48	150
Sensitivity	**Benign mass**			72.9%		
	Malignant mass			89.5%		
Specificity for detection of breast mass				92.5%		
Accuracy for detection of breast mass				85.3%		

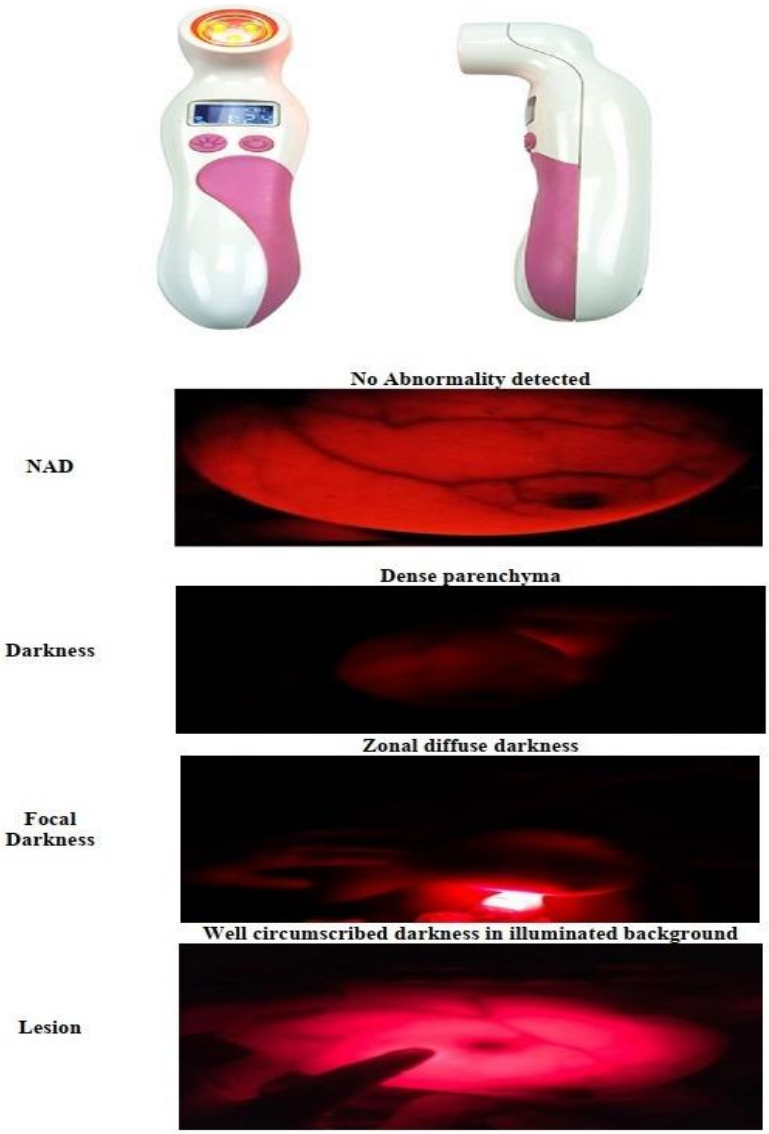

Fig. 1: Light Device and used terms

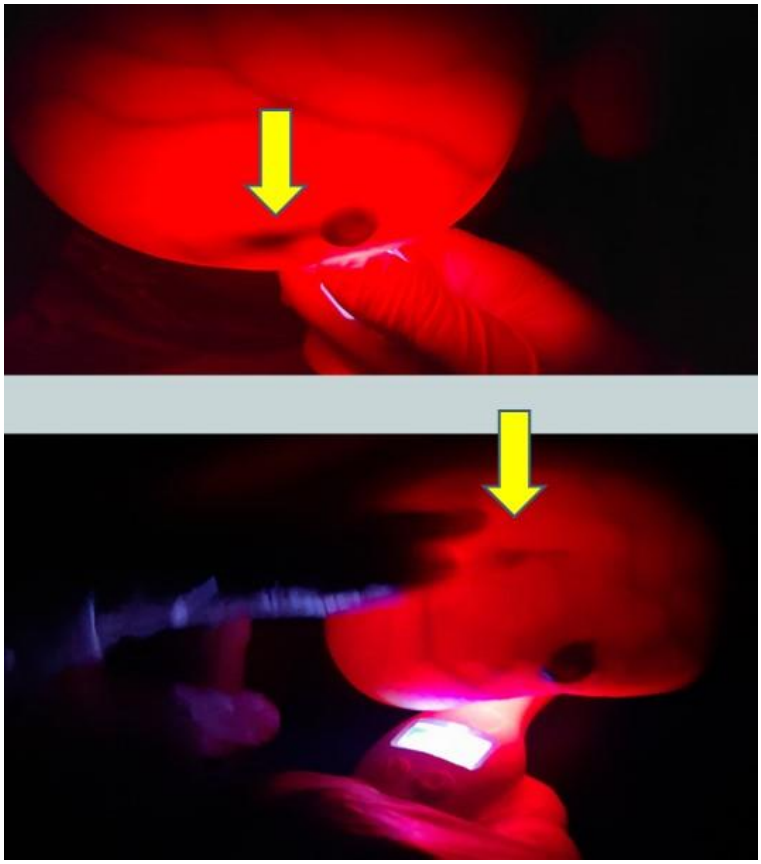

Fig. 2: Definite Lesion

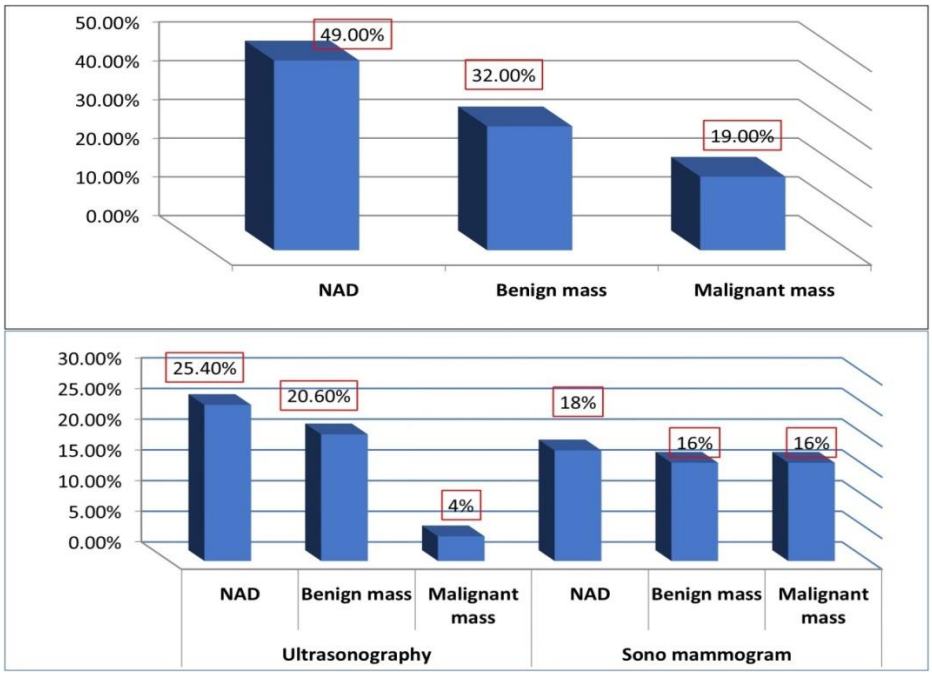

Fig. 3: Distribution of Light device Vs Radiological findings of the studied patients

Discussion

This study assessed the effectiveness of a simple breast cancer screening tool known as "Breast Light." This tool is designed for early breast cancer detection and can be used at home or in primary healthcare units.

Trans-illumination of the female breast has been evaluated as a diagnostic aid for breast lesions since the 1980s.

In a conference involving 300 subjects referred to the breast clinic at Sunderland Hospital, "Breast Light" detected 12 out of 18 malignant tumors confirmed through biopsy, resulting in a sensitivity of 67%. It also correctly identified 240 out of 282 non-cancerous breasts, giving it a specificity of 85% (13).

A study included breast illumination on 259 symptomatic women, detecting breast carcinoma in 26 of them. However, they noted a high number of false-positive cases with this procedure (14). A study examined 467 women with clinically apparent breast disease using three imaging techniques: mammography, Sono-mammography, and breast illumination (15). These three techniques demonstrated no significant differences in predicting benign or malignant diseases in terms of sensitivity, accuracy, and specificity. They concluded that breast illumination, performed by light scanning, was a sensitive and reliable indicator of both benign and malignant breast conditions without the potential problems associated with radiation exposure.

An early study reported similar results for breast illumination, with a sensitivity of 87.8% (16).

This is supporting our study which demonstrated a sensitivity of 72.6% for the detection of benign breast lesions when compared to ultrasonography in patients less than 35 years old, with a sensitivity of 83.8% for malignant lesions. The specificity of the light device for breast mass detection, compared to ultrasonography, was 98.6%. The accuracy of the light device in detecting breast masses, compared to ultrasonography, was 86.6%. Additionally, sensitivity of 72.9% for the detection of benign breast lesions when compared to Sono-mammography in patients more than 35 years old, with a sensitivity of 89.5% for malignant lesions. The specificity of the light device for breast mass detection compared to Sono-mammography was 92.5%. The accuracy of the light device in detecting breast masses compared to Sono-mammography was 85.3%.

A study evaluated the use of telediaphanography (breast elder illumination method) in conjunction with Doppler ultrasound for breast carcinoma detection. The sensitivity and specificity for breast illumination alone were 73% and 82%, respectively, while for Doppler ultrasound, they were 61% and 92%, respectively (17).

However, another study compared light scanning to mammography in a Swedish multicenter study involving 2568 women. Mammography alone falsely diagnosed cancer in 6.9% of the patients, whereas light scanning falsely diagnosed cancer in 19.1% of the cases (18).

Finally; it was recommended that breast illumination be used in conjunction with

mammography to reduce the number of false negatives from 11.8% to 5.5%.

Some researchers previously assessed the diagnostic accuracy of light scanning in 610 breasts, reporting a sensitivity of 86% for light scanning and 88% for mammography. The breast illumination method and mammography were in agreement in 77% of cancer cases (19).

Conclusion

In conclusion, the Breast Light method offers promise as a breast cancer screening tool, particularly for asymptomatic women, though it warrants further evaluation. It serves as a valuable aid to a woman's personal breast awareness, a crucial factor in early breast cancer detection, particularly for cases where palpation proves less effective. This user-friendly device is suitable for use by primary healthcare physicians and at-home screening. It can identify breast masses detectable by mammography or clinical examination, providing a noninvasive, patient-friendly method for assessing primary mass size. However, its most appropriate use is as an adjunct to clinical examination in outpatient breast clinics, rather than a replacement for mammography. While the Breast Light device is a valuable detector for large pendulous breasts and lesions located away from the chest wall, it may pose challenges for smaller breasts and lesions attached to the chest wall.

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