RESEARCH ARTICLE

BreastLight Apparatus Performance in Detection of Breast Masses Depends on Mass Size

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Abstract

Background: Accurate measurement of breast mass size is fundamental for treatment planning. We evaluated performance of BreastLight apparatus in detection breast of masses with this in mind. Materials and Methods: From July 2011 to September 2013, a total of 500 women referred to mammography unit in Yazd, Iran for screening were recruited to this study. Performance of BreastLight in detection breast masses regard their sizeing, measured with clinical breast examination (CBE), mammography and sonography, was assessed. Sonographic and mammography examinations were performed according to breast density among women in two groups of women younger (n=105) and older (n=395) than 30 years. Size correlations were performed using Spearman rho analysis. Differences between mass size as assessed with the different methods (mammography, sonography, and clinical examination) and the BreastLight detection were analyzed using X^2-trend test. Results: Performance of the BreastLight in detection of lesions smaller than or equal to 1 cm assessed by CBE, mammography and sonography was 4.4%,7.7% and 12.5% and for masses larger than 4 cm was 65%, 100% and 57.1%, respectively. The performance of BreastLight in detection was significantly increased with larger masses (p<0.001). Conclusions: We conclude that clinical measurement of breast cancer size is as accurate as that from mammography or ultrasound. Accuracy can be improved by the use of a simple formula of both clinical and mammographic measurements.

Keywords: Breast masses - BreastLight - mammography - sonography - clinical breast examination

Introduction

Breast cancer is one of the major health complications among women worldwide (Fouladi et al., 2013). The American Cancer Society's estimates indicate approximately 1.3 million new cases of invasive breast cancer were diagnosed globally in 2007; and nearly 500,000 women died from the disease.

Breast cancer size is one of the main prognostic indicators and a determining factor for surgical treatment planning (Nguansangiam et al., 2009; Luparia et al., 2013). The ability to accurately and reliably measure the size of the breast cancer prior to any surgical treatment or primary medical therapy is essential. With the development of minimally invasive breast surgical techniques and the increasing adoption of neoadjuvant therapy, the ability to correctly determine maximum tumor dimension noninvasively is becoming more important (Hieken et al., 2001; Azizun-Nisa et al., 2008; Tham et al., 2009). The decision to offer patients primary medical therapy for operable breast cancer depends principally on tumour size at presentation, with tumour size greater than 30mm often used as a cut-off to recommend primary medical therapy (Snelling et al., 2004).

Several studies were published concerning the accuracy of mammography, sonography, and clinical examination for breast tumor size measurement (Fornage et al., 1987; Finlayson et al., 2000; Hieken et al., 2001; Snelling et al., 2004; Parajuly et al., 2010). Overall, the accuracy of CBE is influenced by patient and observer factors and is not useful for clinically occult tumors. Mammographic assessment of tumour size may be less reliable than clinical or ultrasound measurement due to variation in the distance between the tumor and the film, indistinct tumor boundaries, compression during examination or because standard imaging projections do not capture the maximum tumor diameter (Hieken et al., 2001; Sofi et al., 2012). However, to date ultrasound measurement of tumour size is considered a more accurate imaging modality (Snelling et al., 2004).

The BreastLight performance for accurate masses size estimation in women requires validation. Our hypothesis was that, the measurement of lesion size using BreastLight apparatus could be useful and more accurate as adjuvant

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to the other modality systems. The purpose of our study was therefore to compare the performance of BreastLight with mammography, sonography and clinical breast examination at discriminating between a tumour greater or smaller than 40mm was analysed.

Materials and Methods

Between July 2011 and September 2013, 500 women with mastalgia presented to the outpatient clinic of Mansoura University Hospital. The mean (SE) age at enrollment was 37±4.2 years, with a range of 19 to 55 years.

Clinical, mammographic, and sonography assessments of the masses size were performed prior to BreastLight. All masses were measured clinically, mammographically, and sonographically by three different experienced physicians blinded to the results of other modalities. All of the masses were documented in two dimensions, and the maximum size was compared with the maximum BreastLight size. In women who did not have a detectable mass with a specific measurement method, the tumor size was assumed to be 0cm for the diagnostic method concerned. In this series, of 500 women, mammography examinations were performed in 395 women older than 30 years and sonography was performed in 105 women younger than 30 years due to the breast density. The mammograms were reviewed with regard to breast density by a single expert radiologist.

A written informed consent obtained from all the participants. Furthermore, this study was approved by the ethics committee of Medical Faculty, Shahid Sadoughi University of Medical Sciences and Health Services, Yazd, Iran.

Clinical breast examination

Examination of the breast was done by the same surgeon in all cases. With the patient in the supine position and one arm raised, the physician thoroughly palpates breast tissue on the raised-arm side in the superficial, intermediate, and deep tissue planes; axilla, supraclavicular area, neck, and chest wall at least for 5 minutes. In premenopausal women, the CBE is best performed the week following menses, when breast tissue is least engorged. The larger diameter was used as the clinical masses size.

Mammography

Conventional film-screen mammography was performed with at least two views per breast (mediolateral oblique and craniocaudal views). Additional views or spot compression views were obtained where appropriate. The largest dimension was determined from these views with a ruler. Mammograms were obtained with dedicated mammography units (Alpha RT Imaging, General Electric Medical Systems, Milwaukee). Patients younger than 30 years were excluded, because mammography is not performed in this age group.

Sonography

High-resolution ultrasound was performed by an experienced physician. All breast sonographic evaluations were performed with the patient in a supine position for the medial parts of the breast and in a contralateral posterior oblique position with arms raised for the lateral parts of the breast. The sonograms were obtained using real-time technique with 7.5 to 13 MHz transducers (Siemens Elegra, GE Logic 500, and ATL HDI 5000; Siemens, Erlangen, Germany). The probe was held orthogonal to the skin and the two largest diameters of the mass were measured with the machine's electronic calipers and recorded on the static images (results were rounded up to the nearest millimeter). For measurement purposes, the mass edge was defined as the end of the hypoechoic mass before the wide border denoting the transition between the mass and the healthy surrounding tissue.

Statistical analysis

The Statistical Package for the Social Sciences (SPSS) version 12.0 (SPSS, Inc., Chicago, IL, USA) was used for all statistical analyses. Differences between the masses size as assessed with the different methods (mammography, sonography, and clinical examination) and the BreastLight detection were analyzed using X^2-trend test with $p<0.05$ considering to be statistically significant.

Results

A total of 500 women were included in the study. The participants' mean age was 39.2 years (standard deviation [S.D.] 13.1 years). In Table 1 are shown that, most (more than 50%) of the larger lesions than 1cm assessed in CBE were identified on Breastlight. Our study shows that the performance of the Breast light in detection lesions smaller than or equal to 1cm assessed by CBE is 4.4%, for masses 1-2cm, 2-3cm, 3-4, and >4cm are 52.2%, 59.3%, 63.2% and 65%, respectively. The performance of Breast light in detection masses assessed by CBE significantly increased with larger masses (p=0.0001). Therefore, these results demonstrated a statistically significant positive correlation between Breastlight and CBE.

In Table 2 are shown that, most (more than 50%) of the larger lesions than 1cm assessed in Mammography were identified on Breastlight. Our study shows that the performance of the Breastlight in detection lesions smaller than or equal to 1cm assessed by Mammography is 7.7%%, for masses 1-2cm, 2-3cm, 3-4, and >4cm

Table 1. Performance of the BreastLight in Detection of Masses Assessed by CBE

Detection	Lesions Size					
	<1	2	3	4	>4	Total
Lesions size by CBE	207 (52.4)	59 (14.9)	91 (23.1)	28 (7.1)	10 (2.5)	395 (100)
Breast light						
Detected	16 (7.7)	26 (44.1)	71 (78.1)	24 (85.7)	10 (100.0)	147 (37.2)
Not detected	191 (92.3)	33 (55.9)	20 (21.9)	4 (14.3)	0 (0.0)	248 (62.8)

Table 2. Performance of the BreastLight in Detection of Masses Assessed by Mammography

Detection	Lesions Size					
	<1	2	3	4	>4	Total
Lesion size by Mammography	207 (52.4)	59 (14.9)	91 (23.1)	28 (7.1)	10 (2.5)	395 (100)
Breast light						
Detected	16 (7.7)	26 (44.1)	71 (78.1)	24 (85.7)	10(100.0)	147 (37.2)
Not detected	191 (92.3)	33 (55.9)	20 (21.9)	4 (14.3)	0 (0.0)	248 (62.8)

Table 3. Performance of Breastlight in Detection of Masses Assessed by Sonography

Detection	Lesions Size					
	<1	2	3	4	>4	Total
Lesions size by Sonography	32 (30.5)	9 (8.6)	35 (33.3)	22 (21.0)	7 (16.7)	105 (100)
BreastLight						
Detected	4 (12.5)	2 (22.2)	11 (31.4)	10 (45.5)	4 (57.1)	31 (29.5)
Not detected	28 (87.5)	7 (77.8)	24 (68.6)	12 (54.4)	3 (42.9)	74 (70.5)

are 44.1%, 78.1%, 85.7% and 100%, respectively. The performance of Breast light in detection masses assessed by Mammography significantly increased with larger masses (p=0.0001). Therefore, these results demonstrated a statistically significant positive correlation between Breastlight and Mammography in detection breast masses.

In Table 3 are shown that, most (more than 50%) of the larger lesions than 1cm assessed in Sonography were identified on Breastlight. Our study shows that the performance of the Breast light in detection lesions smaller than or equal to 1cm assessed by Sonography is 12.5%, for masses 1-2cm, 2-3cm, 3-4, and >4cm are 22.2%, 31.4%, 45.5% and 57.1%, respectively. Overall, BreastLight detected 29.5% of masses detected by sonography. Therefore, these results demonstrated, there are not statistically significant positive correlation between BreastLight and Sonography.

Discussion

Tumor size is commonly measured by palpation, but this method varies among observers, is influenced by many factors such as skin thickness, depth of mass, edema, and obesity and is prone to overestimation of tumor size (Shoma et al., 2006).

To date, only a few investigators have assessed the association between masses size and detection rate for different modality systems. It reported that the size of breast masses influence radiologist and surgeon sensitivity, it may also influence the tumor detection rate of different modality systems. Furthermore, Breast cancer survival and treatment is strongly associated with masses size at detection. It is reported that clinical assessment must take into account skin thickness and the depth of the tumor within the breast. In addition, clinicians can only palpate two (length and width) axes of a three-dimensional tumor, compared to ultrasound, which can provide three-dimensional measurement including assessment of tumor depth (Snelling et al., 2004). Also, studies have shown that clinicians tend to overestimate the size of breast tumors (Pain et al., 1992; Finlayson et al., 2000; and Snelling et al., 2004). Previous studies results suggest that the tumor detection rate may be associated with lesion size (Malich et al., 2003). Highest detection rates were observed for 10-30-mm tumor masses and for invasive ductal carcinomas

and noninvasive cancers (Malich et al., 2003). Ultrasound is a well-established method to assessment of masses and tumor size at presentation. It is considered a more accurate measure for wholetumor size compared to clinical remeasures estimated that manual palpation tends to underestimate tumor size and the largest standard deviation. In the difference, ultrasound and mammography used to underest masses and tumor size had had minimum standard variation of the difference. Underestimation of tumor size may result in incomplete excision, leading to re-excisions or higher local recurrence rate. However, detection of tumor size may result in reexcisions of the large, than required, leading to a poor cosmetic outcome (J. et al.,

In this study we examine masses size influence on BreastLight performance. Its highest detected rates was observed for >4-mm masses. It found that Breastlight performance is similar with mammography and clinical examination in determining breast masses size. Also, it found that BreastLight cannot to detect masses that identified by sonography. However, it shown that sonography had underestimation in masses size assessment.

In 56 of the patents the size of the lesions was estimated by the use of callipers and the detection rates using the breast illumination method were 100% for tumors with >2cm and 83.3% for tumors with <2cm (Bundred et al., 1986). Recently, Labib et al reported that the BreastLight 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 (Labib et al., 2013). Published trials on Breastlight demonstrate that light-based technology can deliver high sensitivity levels (82%) in lesions over 1.5cm and useful levels (29%) in non palpable lesions (Iwuchukwu et al., 2009). In a study counducted in the sundeland city hospital with 115 breasts; of these 84 (73%) were Breastlight negative and 31 (27%) were BreastLight positive. Breastlight positive lumps were significantly larger than Breastlight negative lumps (p=0.02,); Breastlight positive lumps were on average 18mm compared with Breastlight negative lumps which were 11mm on average (Iwuchukwu et al., 2009). In the subgroup of 18 malignant lumps, there was no significant difference between the size of detected (median 26.5mm) and not detected masses by Breastlight (median 23.5mm)

(P=0.9). Breastlight detection rate for malignant lesions was between 0.7cm and 3.6cm (Iwuchukwu et al., 2009).

The percutaneous methods including laser, radiofrequency, and cryoablation of eradicating breast tumors rely on accurate sonographic guidance for their efficiency. However, It has been observed that the sonographic underestimation of the histological tumour size (Hieken et al., 2001; Bosch et al., 2003; and Shoma et al., 2006). With regard to breastlight, our study concurs with previous authors, an underestimation of the sonography result of >4 mm, although this was not found to be significant (Table 3). Also, the mammographic size estimation is also negatively affected by breast density. The study by Hieken et al. (2001) have shown a size underestimation with mammography, which was attributed to the high compression of the breast during the examination. It is estimated that the tumour size with mammography and sonography was underestimated in 14% and 18% of the results respectively (Boetes et al., 1995).

Ib conclusion, breastLight can detect breast masses that can be identified by mammography or clinical examination. BreastLight examination is a noninvasive and accurate way to evaluate primary masses size with high patient acceptance. However, BreastLight assessment should be used as an accurate adjunct to clinical examination in outpatient breast clinics.

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