Digital documentation of the physical examination: moving the clinical breast exam to the electronic medical record

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Abstract

Background: Documentation of the clinical breast examination (CBE) has consisted of simple hand-drawings and stick figures without a common lexicon. There is a need for a device that can accurately depict the CBE in digital format while being objective, reproducible over time, and usable in the electronic medical record. This new device is called palpation imaging (PI).

Methods: We examined 110 patients with a complaint of a breast mass using PI. This laptop-sized device creates a real-time digital display of the palpable area in both video and still formats. The size, hardness, shape, homogeneity, and mass location may be extracted from the image.

Results: Of those with a true mass, PI identified the mass in 94% while physical examination identified 86%. The positive predictive value (PPV) for breast cancer using PI was 94% and 78% for physical examination. A survey of primary care physicians revealed the inclusion of the PI record in a consultation note implied competence, experience, and skill by the surgeon.

Conclusions: PI documented the CBE in a timely, efficient, and accurate manner. A reproducible record allows objective review by multiple examiners at varied times. Continued work will optimize examination methods. © 2006 Excerpta Medica Inc. All rights reserved.

Keywords: Palpation imaging; Clinical breast exam; Breast imaging; Breast lump; Electronic medical record; Mammography; Ultrasound; Breast mass

While the last 20 years have seen major improvements in breast imaging [1–8], the documentation of the clinical breast examination (CBE) has remained unchanged since the Halsted mastectomy 100 years ago [9]. Surgeons record a verbal description of their palpable findings along with a handwritten drawing. The verbal description suffers from the spectrum of descriptive words without standardized definitions. Terms such as “fibrous,” “thickened,” “dense,” and “glandular” may all describe the identical breast texture and are user dependent. Likewise, a hand drawing or stick figure of a breast mass may be interpreted differently by different observers. These subjective drawings may not communicate the same examination to a second examiner or even to the same examiner at a later date. Drawings are not standardized or consistent, and the descriptions have no common lexicon. Estimated sizes of drawn masses are not consistently given in either text or drawings.

A need exists for a device that accurately and objectively depicts the CBE in digital format which is reproducible over time, and able to be uploaded into various electronic medical records. There exists now a new device that can be utilized by breast surgeons to accurately record the CBE of palpable lesions [10,11]. Using this device results in an imaging method called palpation imaging (PI). The target of the current study was the creation of a consistent repeatable digital image of the CBE that may accompany the clinician’s verbal description.

PI obtains a digital image of the CBE and stores it in one of several digital versions. PI captures the characteristics of the palpable findings, including the estimated size and shape, the degree of firmness relative to the surrounding breast tissue, and the homogeneity of the mass. Use of this
method may aid in the documentation of the CBE and augment the clinical record making it more versatile, reproducible, consistent, and electronically useable. This can be used for chart documentation, communication with other physicians, education for patients, and as a medical record for insurers or medicolegal purposes.

Methods

Between October 2003 and October 2005, 110 patients referred to our breast clinic with a chief complaint of a breast mass were examined. In addition to CBE, ultrasound, and mammograms, each patient underwent PI. Some young patients did not have mammography.

After PI examination, each record was segregated into one of two groups based on the PI findings alone: those with the findings of a dominant mass (e.g., cyst, benign or malignant tumor) and those without findings of a dominant mass (e.g., fibrocystic change or other normal breast tissue). Those with a dominant mass were further separated into those highly suspicious for cancer and those with palpable masses. Final histologic and/or follow-up data (minimum 6 months) was correlated with preoperative PI. Statistical analysis used the chi-square calculator from Georgetown University.

Description of imaging device

The cornerstone of this report is the development of an imaging device that translates palpation findings into a visual record. To understand this device, it is necessary to deconstruct the CBE of a palpable mass. Upon finding a mass, the surgeon notes the location of the mass within the breast. Mass characteristics of size (in at least 2 dimensions), hardness, shape, and homogeneity are noted. PI re-creates the components of the CBE of a mass.

The palpation imager consists of a notebook computer-sized device attached to a broad-based transducer. After CBE targets a lesion, the transducer is passed over the palpable lesion. The transducer has almost 200 minute sensors able to record the pressure and location data. As the transducer scans, a real-time display of the palpable area is digitally recorded (Fig. 1). The transducer sensor data is converted to a color image in both 2- and 3-dimensional formats. Peak height of the image refers to increased firmness, while low height refers to less firm or soft tissues (Fig. 2). Images are reviewed to demonstrate the characteristics of size, hardness, shape, homogeneity, and location. The examination video and still-frame images are available for printed reports or single images may be incorporated into a consultation letter.

This palpation image can be translated into the components of the physical examination: size, hardness, shape, and homogeneity. The location within the breast is entered by the examiner (Fig. 3). The size of the lesion is demonstrated by the footprint seen on the image (Fig. 4). The hardness of a lesion is described by the absolute height of the peak.
pressure, as well as comparison of peak height to surrounding breast tissue height (surrounding breast firmness). The shape of the palpable findings may be demonstrated by a line drawn at an isobaric level surrounding the mass on a 2-dimensional image, seen as a black line in the examination result screen (Fig. 5). Homogeneity of the palpable mass is identified as the shape of the peaks within the image. Single smooth peaks are commonly seen in cysts and fibroadenomas, while images with multiple peaks within the mass suggest lobulations and nonhomogeneous masses such as cancers. PI reports describe all the building blocks of the CBE. This was not a blinded study but meant to identify any palpable abnormality and try to document its presence with PI. At no time was PI considered a substitute for biopsy, and biopsy should always be considered as the definitive test for the presence of breast cancer.

Physician survey

To assess the communication value of PI, sample breast consultations were sent out to a study set of 15 primary care referral physicians. Each of the referring physicians was provided breast surgical consultations on 3 different sample patients. All 3 had a chief complaint of a breast mass, each with a different cause; 1 had a palpable cancer, 1 had a benign palpable mass, and the third had an area of fibrocystic change.

Each sample patient was “examined” by 3 surgeons who provided different forms of consultations. Surgeon “A” wrote the consultation by longhand and included a hand-drawn picture of the palpable findings. Surgeon “B” typed the consultation in letter format without any drawings of the physical examination. Surgeon “C” also typed the consultation in letter format as surgeon “B,” but included a printed digital image and report of the physical examination using PI.

Each referral physician received 9 consultations in total, 3 on each of 3 patients. We asked each referral physician to rank the breast surgeons on each patient. Three questions were asked for each patient: (1) please rank these 3 breast surgeons in regards to their competence; (2) please rank these 3 breast surgeons in regards to their experience and innovation in the field of breast surgery; and (3) please rank these 3 breast surgeons in regards to their skill as a surgeon. Referring physicians were asked to avoid ties and to make choices as best as possible based on the submitted data.

Results

Table 1 of final diagnoses reveals the typical patient distribution seen in a breast clinic, including fibroadenomas, cancers, fibrocystic change, and cysts. Ninety-five of 110 patients were found to have lesions that might present as a mass as documented by pathology or other confirmatory tests. We included the patient with gynecomastia with this group. Although some of these lesions may be too small to detect, we considered these patients the potential pool of those with a dominant mass.

Each palpable finding on CBE was recorded as well as the PI results. After an initial learning curve, it was possible to recreate the digital image of the palpable findings. Because the surgeon obtained the digital image, an immediate
feedback process occurs while imaging. The surgeon can determine whether the image is a true representation of the palpable findings. During the examination, the surgeon may also examine the surrounding area with PI to confirm the absence of other palpable findings.

Identifying dominant masses

PI was used to separate patients into 2 groups: those identified with a mass and those without a mass. PI identified a dominant mass in 89/95 patients (positive predictive value [PPV] 94%). Physical examination identified 82/95 patients (PPV 86%). The sensitivity and specificity of identifying a dominant mass with PI were 88% and 88%, while the values were 81% and 81% for physical examination.

In addition, we examined clinically normal breast tissue without any mass to validate our assessment. Both methods were accurate in determining breast tissue without any mass. The negative predictive value of PI and for physical examination was 93% for both methods.

We tried to correlate the consistency of PI and CBE. For each category of PI, we noted the frequency of finding palpable masses. There was a direct correlation between the likelihood of palpating a mass on CBE and the PI firmness category, as noted in Fig. 6.

Identifying breast cancer as a mass

PI separated breast lesions into 4 categories: (1) those without a mass; (2) those with a soft mass; (3) those with a firm mass; and (4) those with a hard mass. Breast cancers were usually firm or hard with either a central single or multiple peaked image on PI. Of the 36 breast cancers examined, the PPV for PI was 94% and 78% for physical examination (Table 2). There were six cancers identified by PI that were not identified by physical examination (false negative rates of 6% and 22%, respectively).

Fibroadenoma, cyst, lipoma, seroma

PI of fibroadenomas, cysts and other benign oval nodules typically demonstrated a single smooth peak with a firm central mass. Of the 57 lesions in this group, we closely examined all fibroadenomas and cysts (n = 47) for evidence of these PI findings. All but 4 lesions (91%) demonstrated this classic PI pattern. The 4 lesions not visualized on PI included 2 cyst clusters and 2 small fibroadenomas.

PI may estimate size of the examined mass (Fig. 4). To assess the size correlation, we looked at the same group of fibroadenomas and cysts. Only 41 of 47 of these patients had an ultrasound measurement documented. We compared the length and width measurements as seen by palpation imaging with the ultrasound measurements. We classified the correlation as good when measurements on both PI and ultrasound were within 3 mm of each other. Those between 3 and 6 mm were considered fair, and those with a greater than 6-mm difference between the 2 measurements were considered poorly correlated. We found 32% of these patients had good correlation between PI and ultrasound measurements, while 46% varied by more than 6 mm between the 2 examinations. There was no difference between the ability of physical examination and PI to identify benign breast lesions (Table 3).

Primary care responses

Of the 15 clinicians surveyed, responses were received from 11. One clinician refused to respond due to concerns about commercial bias. Three others did not return their evaluation. Most clinicians favored the use of the typed consultation along with the PI report of surgeon “C.” They regarded this surgeon to have better “communication skills” and more “experience/innovation.” Of the responses received, 81% said surgeon “C” was the most experienced and 68% said he was the best communicator. Over 85% rated surgeon “A” as least experienced with the least communication skills. This was despite the fact that the written scripts were similar, essential findings were identical, and there was a neatly hand-drawn picture of the palpable find-

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**Table 1**

<table>
<thead>
<tr>
<th>Lesions that might present as a mass</th>
<th>Carcinoma</th>
<th>Fibroadenoma</th>
<th>Cyst</th>
<th>Lipoma</th>
<th>Hematoma/seroma</th>
<th>Radiation fibrosis</th>
<th>Gynecomastia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final diagnosis of examined patients</td>
<td>36</td>
<td>31</td>
<td>16</td>
<td>6</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Table 2**

<table>
<thead>
<tr>
<th>Lesions that might present as a mass</th>
<th>Carcinoma</th>
<th>Fibroadenoma</th>
<th>Cyst</th>
<th>Lipoma</th>
<th>Hematoma/seroma</th>
<th>Radiation fibrosis</th>
<th>Gynecomastia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>110</td>
<td>44</td>
<td>16</td>
<td>6</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

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### Fig. 6

Frequency a palpable mass is found by CBE according to PI firmness category. X-axis shows patients grouped by PI category. Y-axis shows percentage of PI category found to have a palpable mass by CBE.
The palpation image provides the opportunity for clinical review at a later time. This is useful if the referring ultrasound or mammogram are not available. When the films return, comparison to the PI physical examination can occur. Another use for PI is to communicate the physical findings to the patient. The image of the palpable findings is readily understandable by interested patients. Although the CBE has not been demonstrated to impact survival from breast cancer [9], the lack of a common documentation method and lexicon may contribute to the inability to document CBE value.

The objective documentation of PI may help some medical clinics that may have several doctors seeing the same group of patients. Using PI, a patient with a palpable finding may be followed more objectively by a series of doctors. Poor communication may occur when one surgeon’s hand drawings of a breast mass are read by another surgeon. Radiologists commonly communicate this way using serial image documentation. This may also aid doctors who are providing vacation coverage and other part-time clinicians.

PI requires training and skill to obtain accurate images. This is similar to correct positioning and exposure in mammography or proper gain and focal zone in ultrasonography. The proper examining technique and applied pressure is required for optimal PI. Ultrasound has similar requirements to obtain an optimal image. Surgeons skilled at ultrasound examination of the breast are likely to have little difficulty learning the technique of PI.

The basic examination technique is similar to the movements associated with breast ultrasound examination. Mechanical adjustments of the device are few. Calibration is required regularly but not daily. Since the device is the size of a laptop computer, it easily moves from one examination room to another. The creation of an initial image takes just minutes after the examiner identifies a lesion. Several images are obtained to confirm an accurate depiction has been obtained. Automatic storing of images occurs after the demographic information has been entered into the system. Recalling a previous examination is similar to opening a stored computer file.

The PI device is relatively inexpensive in relation to all other forms of imaging, being less costly than an entry-level portable ultrasound device. With the PI device comes the ability to document lesions, the ability to create and print a completed report of the CBE, and image storage for use later or inclusion in the EMR. Although reimbursement is not currently available for the use of this device, it adds value to the practice. This is similar to the cost of computerizing one’s office or converting to an EMR that is not reimbursed but adds value to the medical practice. Larger studies examining the impact of standardized CBE will hopefully answer the question of clinical value.

There are some disadvantages of the PI device, including no insurance reimbursement for this examination. Like other new technologies, reimbursement may follow at a
later date. Because PI is new, it will be necessary for other centers to validate and enhance the findings in this report. We noted some instances of PI examinations were consistent with the eventual pathologic findings. Very large cancers over 4 cm in size cannot be easily examined since there is no normal tissue to compare within the 4-cm probe area. The firmness of a large cancer will be viewed as an overall elevation of the baseline, since the entire surface under the PI transducer has similar hardness.

The other end of the spectrum is also difficult to image. Very small cancers that are not palpable on CBE may or may not be demonstrated on PI. A lower threshold of PI imaging capability exists that is dependent on many factors. These include the absolute hardness of the small tumor, the size of the breast, and the depth of location of the tumor. Small firm tumors that are closer to the skin surface in smaller breasts are easier to image even when not palpable on CBE.

A third group of breast cancers that may be difficult to identify are tumors with soft consistency. Colloid carcinomas or other low grade tumors that have little growth intensity may be difficult to visualize. These tumors, which are primarily found in older patients, may have similar firmness to surrounding breast tissue.

There are several clinical components that cannot be translated into a mechanical device. The palpation imaging device must be placed over the mass in question. This is similar to limitations of breast ultrasound. When an ultrasound sensor is placed on a surgical scar, the hypoechoic shadowing area will appear suspicious for cancer, even though it is typical surgical scar. The examiner must notify the ultrasonographer that the transducer is overlying the surgical scar. Likewise, PI will report the firmness of any lesion examined without the ability to know what portion of the body is being examined.

Similarly, placing the PI device directly on an exposed rib will create an image of an elongated hard mass. Although this may be an accurate representation of a rib, the device will document the palpable findings only. The examiner is responsible to identify the location that the probe is examining.

Additionally, exophytic skin lesions such as moles or the true nipple will give a palpable image of a mass. The examiner must note the presence of skin lesions or location of the nipple as is commonly included during mammography imaging.

This imaging device is intended to be used for documentation of the CBE and improved communication. With further research and experience, it may be possible to use the PI device to aid in the clinical grouping of palpable breast disorders. Characteristics of benign and malignant masses may be teased out of the data obtained from multiple examinations and may aid the breast surgeon in the future.

Conclusions

We describe the use of a unique tabletop PI device that documents palpable breast masses with high sensitivity and specificity. Patients with truly palpable masses (cancers, benign tumors, and firm cysts) were found to have increased firmness (decreased elasticity), while those with nodular breast tissue (fibrocystic change) had less firmness. The use of PI allowed initial separation between benign and suspicious truly palpable masses. A reproducible record of the breast physical examination is created that allows objective review by multiple examiners at varied times. Further work is necessary to optimize examination methods, improve real-time software interpretation, and define the array of diagnostic capabilities.

References