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The Accuracy of Clinical Breast Exam

An Evidenced-Based Practice Project

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Introduction

Breast cancer is the second leading cause of death in American women (Mayo Foundation for Medical Education & Research, 2007). The National Cancer Institute (NCI) (2008) estimates 182,460 new cases of breast cancer and 40,480 deaths from breast cancer in 2008. Breast cancer rarely arises in women under the age of 30, accounting for only about 0.3% of occurrences. As age increases, the incidence of breast cancer begins to escalate, especially in women 35 years and greater (Kopans, 2007). The American Cancer Society (ACS) (2008) recommends clinical breast examination (CBE) for early cancer detection. It is well established that CBE has identified breast cancers that were not noticed on mammography (Kopans, 2007). Women in their twenties and thirties are advised to have a CBE by a healthcare professional as part of their health maintenance exam every three years. Women in their forties and older are urged to have a CBE annually (ACS, 2008). Other factors associated with an increased risk of breast cancer include family history, genetics, past medical history, menstrual history, and pregnancy (Tierney, McPhee, & Papadakis, 2005).

Early detection and diagnosis is the key to long-term survival in women with breast cancer. There are several techniques valuable in identifying, describing, and diagnosing these areas of concern. Mammography is the most reliable means of identifying this disease before a mass is palpable and may be able to decrease deaths by as much as 50% (Tierney et al., 2005; Kopans, 2007). Randomized controlled trials have consistently proven the benefits of mammography (Kopans, 2007). Breast ultrasound is an evaluation tool that can further assist in characterizing a breast mass seen on mammography and can ultimately contribute in resolving specific management questions (Kopans, 2007). Radiologic image guided biopsies which include ultrasound guided core biopsy and stereotactic mammatome biopsy are procedures in which a

specimen is taken from the area of concern in the breast and is pathologically inspected thus rendering a tissue diagnosis. Even given the usefulness of these methods, women are still dying of breast cancer, and research is needed to develop further systems in order to detect this disease prior to metastases (Kopans, 2007).

The ACS (2008) asserts that CBE, finding and reporting breast changes early, along with the use of mammogram in low-risk women and magnetic resonance imaging (MRI) in high-risk women provides them with the greatest opportunity to lessen their risk of dying from breast cancer. While ACS promotes CBE, Kopans (2007) reports it is a challenging examination to do well and most CBE is performed incompletely. The execution of the CBE varies markedly from provider to provider due to individual skill, and the likelihood of standardization is minimal (Kopans, 2007). Studies do not afford much evidence to sustain CBE (Day, 2008). While mammography misses 10% to 20% of asymptomatic breast cancers in women, it is important for research to be conducted concerning CBE and the potential valuable information that can be gleaned from it in order for women to be cared for at the highest levels (Day, 2008). This paper will explore CBE in relation to the assessment and diagnosis of benign and malignant breast conditions. By determining the current best evidence regarding assessment and diagnosis of breast disease, the accuracy and efficacy of CBE will be evaluated.

Purpose

Breast cancer is a monumental health concern for women and those individuals caring for them. Early detection is paramount for their survival. CBE is routinely performed by primary care providers as well as obstetricians and gynecologists as part of annual healthcare evaluations and by radiologists when further assessment is warranted due to patient and/or provider concern or abnormal mammographic findings; however, it is unclear as to what benefit this evaluation

specifically offers. Given the ambiguity concerning this entity, the purpose of this evidence-based inquiry is to evaluate the current best evidence-based literature related to CBE. The clinical problem that will guide this review is the identification of the diagnostic accuracy of CBE in correlation with mammography, sonography, and /or radiographic guided biopsy in detecting benign versus malignant breast disease in women who have been referred to a diagnostic breast imaging clinic due to a palpable breast mass discovered either through prior self breast exam (SBE) or CBE.

Justification

Each year more than 211,000 women discover that they have breast cancer (NCI, 2008). Often women are referred for a diagnostic radiologic evaluation due to abnormal assessment findings by their provider or a concerning discovery by the woman herself. This time between detection and diagnosis is one of great worry and distress for many women. Breast cancer, unlike some other cancers, provokes considerable fear and anxiety due to concern for body image, physical well-being and the perceived horrors of the treatment connected to this disease. Women fear the “body-mutilating” procedure of the mastectomy which many view as taking away what makes them female-their breasts (Remennick, 2006, p. 103). As nurse practitioners and members of the health care team, a great effort to tear down these monumental deterrents needs to occur.

Future prospective studies are essential in providing data that will guide health care professionals in treating women with both malignant and benign breast health issues. Evaluation of the accuracy of CBE in recognizing and predicting levels of breast conditions and/or abnormalities when performed by a trained health professional could assist in eventually identifying a lexicon for clinical descriptors. These descriptors could assist in treading a path toward attempting to standardize methods of CBE, contribute in increasing the specificity of

CBE in benign breast disease and sensitivity of CBE in malignant breast disease, but most importantly, they could potentially provide evidence for reliable exclusion and/or diagnostic criteria that could allow providers to confidently relay immediate, sound medical advice to women with the hope to allay fears and anxieties that are consistently present in most of these situations. There have been great strides made in the area of mammography and the various other technologies that assist doctors and nurse practitioners in the field of radiology in detecting, characterizing, and diagnosing both benign and malignant breast disease. Our sights should now focus on what we have at our fingertips.

Definition of Terms

For the purposes of this project the following terms were defined:

1. Clinical breast examination (CBE)—This is an examination of the breasts performed by a trained health care professional; the length of a properly conducted examination is dependent on breast size and composition and usually requires approximately 10 minutes (ACS, 2007; Kopans, 2007).

2. Benign breast disease—This encompasses non-cancerous conditions of the breast including disorders such as fibrocystic disease, fibroadenoma, galactorrhea, phyllodes, abcess, and fat necrosis (Tierney et al., 2005).

3. Malignant breast disease—This requires a pathologic tissue diagnosis of malignancy. Pathologic subtypes of breast cancer include ductal, lobular, medullary, papillary, and mucinous carcinomas (Tierney et al., 2005).

4. Screening mammogram—The most sensitive method for detecting early stage breast cancer (overall sensitivity of 75%) (Dow, 2006). It is a low-dose radiographic procedure that allows one to visualize images of the internal structures of the breast (ACS, 2007). The ACS

guidelines recommend yearly mammographic evaluation for women ages 40 and older (ACS, 2007)

5. Breast ultrasound—This is an evaluation using high-frequency sound waves that penetrate into and through tissues of the breast producing a visible image (Kopans, 2007).

6. High risk for breast cancer—Those women who have a known BRCA1 or BRCA2 gene mutation; have a first degree relative (mother, father, brother, sister, or child) with a BRCA1 or BRCA2 gene mutation and they themselves have not had genetic testing; have a lifetime risk of breast cancer of 20-25% or greater according to risk assessment tools which are based mainly on family history; had radiation treatment to the chest between the ages of 10 and 30 years; have Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvlacaba syndrome, or have a first degree relative with one of these syndromes (ACS, 2007).

7. Magnetic Resonance Imaging (MRI)—This is a radiology imaging technique that uses magnetism and radio waves instead of radiation to visualize internal structures of the breast (Kopans, 2007). It is used in women that meet the "high-risk" criteria for breast cancer (Dow, 2006). This study has a high sensitivity but low specificity (Kopans, 2007).

8. Self breast examination (SBE)—This is an examination of an individual's own breasts. The ACS (2007) no longer recommends that all women perform monthly SBE's.

9. Ultrasound guided core needle biopsy—This is the preferred method, aside from excisional biopsy, in making precise diagnostic evaluations of breast tissue (Kopans, 2007). A needle is placed in the breast in the area of concern under direct ultrasound guidance. This method is used for only those breast lesions perceivable by sonographic evaluation.

10. Stereotactic mammatome biopsy—This method is utilized when concerning breast masses or calcifications are visible on mammography. A needle is placed in the breast under x-ray guidance.

Methodology

A review of literature was conducted searching various data bases such as Up to Date, MEDLINE, OVID, Index Medicus, Pub Med, CINAHL, and ScienceDirect. A combination of descriptor terms were used to identify eligible resources. The following inclusion criteria for determining eligibility for this review of literature are: literature from 1995 to present, English only, and peer reviewed. Keywords such as efficacy and/or predictability of clinical breast examination, clinical breast exam, physical breast examination, and breast cancer were included in the search. A total of five studies including four retrospective evaluations as well as one non-randomized prospective study were included.

Review of Literature

While CBE has been retrospectively evaluated in the literature, there are only minimal prospective studies that have discussed CBE and its accuracy in the diagnosis of benign and malignant breast disease. The following is a brief review of articles relevant to this topic of discussion.

Contribution and Cost of CBE

Feigin, Keating, Telford, and Cohen (2006) retrospectively evaluated the cost of CBE and its involvement in the detection of breast cancer in 60,027 consecutive asymptomatic patients who had undergone screening mammography at Memorial Sloan-Kettering between January 1, 1997 and December 31, 1998 and between January 1, 2001 and December 31, 2002. This study excluded women referred for mammography on the basis of SBE or CBE. All of these

patients had received CBE by one of six nurse practitioners with master's degrees in science and nursing and certified by the American Nurses Credentialing Center. Of the 60,027 patients without symptoms, 474 had abnormal findings at CBE requiring conversion to diagnostic evaluation. The diagnostic evaluation was adapted to effectively study the clinical finding, and an image-guided breast biopsy was performed for all lesions deemed category 4 and 5 according to the Breast Imaging Reporting and Data System (BIRADS). Subsequent review of the patients' evaluations that needed diagnostic assessment was performed separately by two of the authors, and the number of ensuing breast cancer diagnoses was determined.

Screening mammographic recall was determined by three radiologists who were blinded to the patients' subsequent study findings. If none or one of the three radiologists would have recalled the patient for a diagnostic workup on the basis of screening mammographic evaluation alone, then this was considered a finding detected completely by CBE. If at least two of the radiologists would have recalled the patient for a diagnostic workup on the basis of screening mammographic evaluation alone, then this was considered a finding detected by both CBE and mammography. The estimated cost of CBE was based on the cost of the diagnostic workup incurred due to positive CBE findings.

The results of this evaluation confirmed the importance of CBE. Four hundred seventy-four patients with positive findings at CBE, 44 (9%) had breast cancer in the same quadrant, and two patients each had two palpable masses at CBE both of which were cancer; therefore, 46 cancers in 44 patients was diagnosed with CBE which yielded a cancer detection rate of 0.77 per 1000 patients screened. The CBE finding in 45 of the 46 cancers was a palpable mass. The mean tumor size was 1.7 cm. According to the retrospective review findings, thirty-two tumors in 31 of the 44 patients with cancer would have been diagnosed with mammographic evaluation alone

even in the absence of CBE. The direct medical cost of CBE per additional cancer detected was $122, 598.

This study is classified as a 3a in the hierarchy of evidence. Much of the data collected in this retrospective cohort evaluation coincided with previous studies published in the literature (homogeneity) (Straus, Richardson, Glasziou, & Haynes, 2005). Bias was present in this study because the radiologists reading the mammographic studies were aware that the studies were associated with previous positive clinical findings. Regarding cost of CBE, the researchers felt that the higher value reflected the relatively high salaries of the nurse practitioners due to the high cost of living in New York.

A retrospective cohort study by Barton, Elmore, and Fletcher (1999), was performed at Harvard Pilgrim Healthcare, a large HMO in New England, in order to determine how regularly women present with breast symptoms, how these symptoms are evaluated, and how frequently cancer is diagnosed. A cohort of 2400 women ages 40-69 enrolled in the HMO from July 1, 1983 to June 30, 1993 were selected. Women were excluded if they had insurance coverage in addition to the HMO, had breast cancer before July 1, 1983, or had reduction mammoplasty or prophylactic mastectomy before or during the study period.

Records of the participants were reviewed, and the reason for each visit was determined as screening (asymptomatic) or diagnostic (symptomatic or abnormality noted by clinician or mammography). Patient's symptoms were classified as well as the clinician's diagnostic interpretation. Breast cancer outcomes were also determined.

Over the ten year period, 372 (16%) women presented with breast symptoms. The most common symptoms were pain followed by mass, skin or nipple change, lumpiness, and other symptoms. A total of 188 providers initially evaluated the breast symptoms. On physician

examination, the providers detected a mass in 184 (34%) episodes, skin changes or nipple discharge in 43 (8%) episodes, fibrocystic changes in 112 (21%) episodes, and other findings in 32 (6%) episodes. Clinicians interpreted physical findings as normal in 33% of episodes, abnormal-benign in 27%, indeterminate in 35%, and suspicious for cancer in 6%. They recommended further evaluation for 391 (73%) breast symptom episodes. The most common evaluations consisted of repeat clinical examination and imaging studies with an estimated total cost of $221, 248, or $410 per symptom and $9619 per case of cancer diagnosed. Breast cancer was diagnosed in 23 (6.2%) of the 372 women who initially presented with breast symptoms. Among these women, clinicians found a mass in 22 (96%), skin changes in 2 (9%), fibrocystic changes in 3 (13%), and other findings in 2 (9%). Cancer was diagnosed in 22 of 216 (10%) episodes initially assessed as indeterminate or suspicious and in 2 of 316 (1%) initially assessed as normal or abnormal-benign.

This study revealed that clinical breast exam along with other evaluation practices result in substantial breast cancer detection in this population of women with breast symptoms ages 40-69. Because clinical breast exams were not classified by a standard method, inferences by the researchers had to be made. They suggested a possible development of a standardized system for clinical breast exam in the future.

The level of hierarchy of evidence for this retrospective review is a 3a (Straus, et al., 2005). This research examined a single group of women who were patients of a selected HMO. Each participant's information was compared to others in the same group. Findings in this study confirm those of other similar studies. No data was collected on women younger than 40 therefore these results cannot be generalized to that population of women; however, this analysis had a large sample size therefore increasing the power of the study.

Outcome Prediction of CBE

A non-randomized prospective study was performed by Seltzer (1997) in order to assess the accuracy of an experienced breast surgeon in predicting the presence or absence of breast cancer prior to open breast biopsy. From September 1, 1987 to December 31, 1993, 6787 new patients were evaluated in the author's private surgical practice of which 2247 underwent open breast biopsy. Prior to performing the procedure, the author committed his preoperative diagnosis on a piece of paper of either benign or suspicious for malignancy. The diagnosis was based on information from medical history, physical examination (CBE), and mammographic evaluation. Of the 2247 patients who underwent biopsy, 55% presented with a breast lump and 35% with an abnormal mammogram. The ability of the author to accurately assess the possibility of breast carcinoma was limited to a positive predictive value (PPV) of 0.49 for patients who underwent open biopsy. It was more difficult to accurately predict findings in younger than older women. The PPV for patients younger than 50 was 0.35 compared with 0.59 for 50 years of age and older.

Patients were also evaluated according to their presenting chief complaint: a lump, breast pain, nipple discharge, an abnormal mammogram, and miscellaneous. For patients with a breast lump the overall PPV was 0.68. The greatest PPV (0.89) was found in patients older than 50 with a breast lump. For those younger than 50, the PPV was 0.45. For patients with nipple discharge, the PPV was 0.13 for all patients, 0.15 for those 50 years and older and 0.07 for those younger than 50. The relatively low PPV for preoperative prediction of breast cancer is multifactoral. Physical as well as mammographic findings are many times inconclusive in patients younger than 50 years of age. It is surmised that there is a need for better evaluation methods and management systems for younger women.

This non-randomized prospective observational study represents a 2b in the hierarchy evidence (Straus et al., 2005). There was no control group. The surgeon's goal was to assess his ability to predict biopsy outcomes based on clinical judgment. This was a simply designed study which did not yield much in the way of CBE but does provide for somewhat of a template to follow in designing the proposed evidence-based inquiry.

Sensitivity and Specificity of CBE

Oestreicher, et al. (2002) conducted a retrospective cohort review of 468 women enrolled in the Breast Cancer Screening Program (BCSP) at Group Health Cooperative (GHC) of Puget Sound in western Washington State. Their screening visit consisted of a mammogram and a CBE by an experienced nurse. The women were eligible for inclusion into the study if they had undergone at least one screening CBE (and associated screening mammogram) between January 1, 1988 and December 31, 1993. Eligible study participants were women diagnosed with a first primary invasive breast cancer within 12 months of a screening evaluation and before their next BCSP visit. The study was confined to women without a history of breast cancer, who remained continuously enrolled at GHC for at least 12 months following their index screening examination or who had died from any cause during the 12-month period subsequent to the index screening examination. Women were classified as having a 'true positive' CBE result if their breast cancers were diagnosed within 12 months after a 'positive' or 'indeterminate' CBE. A false negative CBE classification was given to women who were diagnosed with cancer within 12 months of a 'negative' CBE. Data on histology, tumor size, location, and stage were obtained from the SEER cancer registry.

The results of the study revealed the following data regarding CBE sensitivity. Of the 468 women diagnosed with breast cancer within a year of a screening CBE, 165 had a true positive

CBE result, for a sensitivity of 35%. Of the CBE detected tumors, 84% were also detected by screening mammography. Of those tumors missed by mammography, 37% were detected by CBE. Women with a true positive CBE result had a less favorable stage distribution and a higher frequency of lymph node metastases at the time of diagnosis than women with a false negative CBE result. Tumor size at diagnosis was the strongest predictor of CBE detection (21% sensitivity for tumors 1.0 cm or smaller, 40% for tumors 1.1-2.0 cm and 58% for tumors larger than 2.0 cm). CBE equally detects cancers missed by screening mammography (about 40%) in women with either fatty or dense breasts. The highest sensitivity observed was among women 50-59 years and sensitivity was significantly lower in women 40-49 years and 80 years and older. The findings of this study suggest that certain groups of women might benefit more than others from CBE depending on age.

The level of hierarchy of evidence of this retrospective review of patients enrolled in the Breast Cancer Screening program is a 3a (Straus et al., 2005). Their reported CBE sensitivities were lower than other similar cited studies. This could have been due to the community based setting (not in a research setting). CBE's reviewed were performed by registered nurses rather than trained physicians or nurse practitioners which could have influenced technique.

Fenton et al. (2007) conducted a retrospective cohort study of 1,484 breast-cancer-free female health plan enrollees in 5 states (WA, OR, CA, MA, and MN) ranging from ages 35-65 years who received CBE from 1979-1992. The purpose was to estimate the specificity of screening and diagnostic CBE in clinical practice and identify factors associated with specificity. Abstractors coded examination results into one of four categories based on clinician's recorded impressions and follow-up recommendations: (1) normal, (2) abnormal benign (fibrocystic changes not requiring further evaluation), (3) indeterminate (e.g., new abnormality requiring

diagnostic testing or follow-up), or (4) suspicious for cancer. CBE results were described as positive if coded indeterminate or suspicious and coded as negative if CBE results were normal or abnormal benign.

The results indicated that over one-third (34.8%) of women who received screening CBE had either a family history of breast cancer or a personal history of breast biopsy and were classified as increased risk for breast cancer. Among women who received diagnostic CBE, two-thirds (65.5%) were considered increased risk by these criteria. Among 930 average risk women who received 1,387 screening CBE's, 9 (0.7%) were interpreted as indeterminate and none were interpreted as suspicious for cancer. Among 497 increased risk women who received 819 screening CBE's, 23 (2.8%) were indeterminate and 1 (1.0%) was suspicious for cancer. The specificities among average and increased risk women, respectively, were 99.4% and 97.1%. Among 61 average risk women who received 115 diagnostic CBE's, 36 (31.3%) were indeterminate and none were suspicious for cancer. Among 116 increased risk women who received 266 diagnostic CBE's, 100 (37.6%) were indeterminate and 15 (5.3%) were suspicious for cancer. The specificities of diagnostic CBE were 68.7% among average risk women and 57.1% among increased risk women.

This retrospective review is a 3a in the level of hierarchy of evidence (Straus et al., 2005). The findings of this study suggest that CBE in community practice has substantially higher specificity than in clinical trials of breast cancer screening. Diagnostic CBE is rather non specific. It is important for clinicians to perform high-quality CBE, noting that this will require more time and skill. The specificity of CBE was much lower for women at increased risk for breast cancer. This could have been due to perceived risk increase by providers in these women.

Conclusion

The research available concerning the accuracy of CBE principally consists of retrospective studies and reviews of large databases. These evaluations jointly represent the importance of CBE in the realm of caring for women and their special and specific needs. Because large databases are available, these retrospective evaluations are able to assess significant numbers of women over long periods of time and form conclusions based on large sample sizes.

The single prospective study discussed in the literature review dealt with the ability of an experienced physician in predicting the presence or absence of breast cancer prior to an open biopsy procedure. This study produced beneficial data, but the surgeon considered other aspects such as the patient's medical history and mammogram results along with CBE prior to making the prediction. The proposed evidence-based inquiry will make predictions preceding the consideration of mammographic findings in hopes that the efficacy of the CBE will be better understood. Although accurately performed CBE alone has not been proven to decrease the breast cancer rate, it is highly likely that it can detect a fair amount of early breast cancers that might not be recognized otherwise (Kopans, 2007). Kopans (2007) states, "Only those who are interested in its performance and are willing to be trained and spend the time should be relied on to perform CBE's" (p. 742). This profound statement is a challenge to advanced practice nurses and other health care professionals performing CBE to improve upon physical examination skills and consider this an evaluation deserving of great time, effort, and attention.

Much of the literature pointed out that CBE has not been evaluated separate from mammography. The proposed analysis will attempt to look at CBE as a single entity prior to correlating the findings from this exam with mammography and other techniques necessary for

precise diagnosis and treatment. Standard of care will therefore not be compromised. Other studies that could be forthcoming from this evaluation and supported by the previous literature cited are prospectively evaluating the sensitivity and specificity of CBE, developing CBE training programs, and eventual assessment of CBE cost effectiveness in conjunction with other technologies. The implications for nurse practitioners practicing in the discipline of radiology as well as in women's health, primary care and other specialties rests on raising the standards of skill and knowledge in the field of breast health with the focus on the basic CBE. This awareness has the potential to positively touch the lives of women in an area that is known but feared by many, a topic alive and vibrant among populations all over the world. The literature suggests that CBE is a crucial part of the breast assessment and provides a necessary supplement to mammography. Prospective studies are needed to document the potential contributions of CBE when performed by providers with sufficient knowledge and skill.

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