RESEARCH COMMUNICATION

The Accuracy of Midwives' Clinical Breast Examination in Detection of Breast Lumps

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Abstract

Background: Screen-detected breast cancers are usually diagnosed at earlier stages. Therefore, countries with limited resources are recommended to implement clinical breast examination (CBE) as a screening method in conjunction with mammography. Since there are so many limitations to performance of CBE by surgeons in the health system and CBE by midwives is more feasible, this study was conducted to test the agreement of CBE by midwives and surgeons. Methods: One thousand and twenty seven patients with no personal history of breast cancer received breast physical examination by both a midwife and a surgeon and designed forms including patients' general information, cause of referral and abnormal physical findings were completed for each patient. Results: The inter-observer agreement (kappa) for mass detection was 36 % (95% CI= 31% to 41%), indicating a "fair" agreement exists between the midwife's and the surgeon's physical examination. Sensitivity, specificity, positive and negative predictive values of "midwife's physical examination" to detect abnormal breast masses in comparison to "surgeon's physical examination" as the gold standard were 75, 67, 48, and 87 percent respectively. Conclusions: The results of this study do not justify the replacement of general surgeons by midwives in the health care system as the first examiner for clinical breast screening. Decisions about this issue need more comprehensive studies considering cost-effectiveness and training procedures.

Key Words: Breast cancer - clinical examination - screening accuracy -midwife

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Introduction

Breast cancer is the most common cancer in women and the second cause of cancer death worldwide (Parkin et al., 2005). In Iran, it's the leading cause of non-skin cancers in females with the prevalence rate of 22.4 per 100000 women (Mehrabi, 2005). Since the stage at diagnosis of Iranian patients is higher and the age distribution of the disease shows more frequent younger patients, policy makers consider this disease as a major health problem in our country (Harirchi et al., 2004; Harirchi et al., 2000).

The efficacy of screening in reducing the morbidity and mortality of breast cancer is still under question (Bjurstam et al., 2003; Retsky et al, 2003; Olsen et al., 2001) though in many studies, screen-detected breast cancers are usually diagnosed at earlier stages (Miller, 2003; Aubard et al., 2002; Mittra, 1995). Most international organizations such as American Cancer Society recommend mammography as a basic method and Clinical Breast Examination (CBE) as the complementary technique in breast cancer screening (Smith et al., 2003), but in countries with limited resources, mammography is unlikely to be a cost-effective approach for early detection of breast cancer (Mittra, 1995). The recommendations of Global summit Conference for these countries are as follows: effective training of relevant staff in clinical breast examination (CBE) both for symptomatic and asymptomatic women; opportunistic screening with CBE; demonstration projects or trials of organized screening using CBE or breast self-examination; and finally, feasibility studies of mammographic screening (Smith et al., 2006). Limitations in available mammography equipments, trained personnel, or supplies for organizing a national screening program are among the most important problems of using mammography screening in these countries (Anderson et al., 2003).

Studies show that the sensitivity of mammography increases with age especially in postmenopausal women whose breasts are less dense (Carney et al., 2003). Since in Iran the age distribution of breast cancer patients has been shown to be lower (Harirchi et al., 2004; Harirchi et al., 2000), the efficacy of mammography comes into question. Therefore many advantages can be considered for CBE in

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this country such as low expenses, simplicity in technique and possibility of training health workers in a short period of time. CBE is commonly used as a screening method in some parts of the world. Duffy et al. have estimated that screening with CBE alone would lead to a 13% reduction in node-positive tumors and a 12% reduction in breast cancer deaths (Boyle, 2003).

Thus, although the relative benefit of CBE is only slightly greater in the limited-resource setting, the absolute reduction in deaths per case is about 70% higher. These findings suggest that a less sensitive tool might be expected to confer a breast cancer mortality reduction about half of that observed with mammography (Stephen et al., 2006). Although there is no randomized clinical trial to approve this effect, CBE has been introduced as an effective diagnostic method in asymptomatic patients (Day et al., 1995; Kuroishi et al., 2000). As a matter of fact, CBE detects some cancers that do not show up on mammograms, and as a result can decrease false negatives of mammography (Barton et al., 1999; Engel et al., 2001; Miller et al., 2000). In addition, CBE can help evaluate patients with breast symptoms (Boyd et al., 1981).

Because of the insufficient number and city bias of surgeons over our country on one hand and the wide and organized distribution of midwives in the health system on the other hand, we consider the latter as efficient personnel to be trained for CBE. This research was designed to evaluate the agreement between surgeons and midwives in breast mass detection through clinical breast examination.

Subjects and Methods

Patients

In this cross-sectional study, 1,027 women 20 years or older who referred consecutively to "Iranian Center for Breast Cancer" (ICBC) from April 2003 to May 2004, were evaluated. Institutional Review Board (IRB) approval was granted by the Research Ethic Committee of Tehran University of Medical Sciences and informed consent was received from all participants.

Participants

Four midwives with a bachelor degree in midwifery were selected among those who responded to the announcement. They were trained for three weeks by the surgery board of ICBC according to a designed protocol. At first, all midwives received a theoretical course on breast diseases and physical examination. It was followed by a practical education on 100 referred patients under direct supervision of surgeons. Finally, all midwives took a post-course test and two of them with the highest scores and the best performances were chosen to participate here. Three breast surgeons from the ICBC staff with at least a 3-year experience in breast disease diagnosis and treatment (seeing about 30 patients weekly) were also engaged in the study.

Evaluation

All women who signed the informed consent and had no previous history of breast cancer (n=1027) were recruited in the study. Afterwards, all received breast physical examination by a midwife and a surgeon respectively and designed forms including patients' general information, cause of referral and abnormal physical findings were completed for each patient. Midwives had a final question about the necessity of patient's referral to a surgeon according to her abnormal physical findings. Surgeons had an alternative item reflecting if patient's referral to them by a midwife was approved. Both surgeons and midwives were totally blind to each other's diagnosis. The quality of the data gathering process was monitored continuously by a general practitioner who was trained in this regard.

Data analysis

Data was double entered and processed by SPSS statistical package (version12). The agreement between midwives and surgeons in "diagnosis of abnormal breast masses" besides "the indication of patient's referral to a surgeon by a midwife" was estimated using the Kappa test. Sensitivity, specificity, positive and negative predictive values as well as positive and negative likelihood ratio were calculated. In general, values of kappa greater than 0.80 denote very good agreement beyond chance, values below 0.2 indicate poor agreement and values between 0.2-0.4, 0.4-0.6 and 0.6-0.8 represent fair, moderate and good agreement beyond chance, respectively.

Results

Totally, 1,027 women referring to The Iranian Center for Breast Cancer were examined by midwives and surgeons in this study. The patients aged between 20 and 76, with a mean age of 38.4 (±11.18). Breast pain and breast masses were the most common causes of referral to this centre. Prevalence of different complaints in our patients is presented in Table1.

The inter-observer agreement (kappa) for mass detection was 36 % (95% CI= 31% to 41%), which indicates that a "fair" agreement exists between the midwife's and the surgeon's physical examination (Table 2). The accuracy of "midwife's physical examination" to detect abnormal breast masses in comparison to "surgeon's physical examination" as the gold standard is summarized in Table 3.

Table 1. Prevalance of Breast Complaints Among Patients Referred to ICBC

Cause of referral	Number	Percentage
Pain	352	31.4%
Mass	295	26.3%
Nipple discharge	46	4.1%
Skin symptoms	11	1.0%
Asymmetry	5	0.4%
Routine exam	383	34.2%
Others	29	2.6%
Total	1,121	100%

Table 2. Interobserver Agreement for Mass Detection

	Midwife Mass Detected				
Surgeon	Present	Absent	Total	Kappa	P value
Mass present	219	71	290	36.4%	< 0.0001
Mass absent	241	496	737		
Total	460	567	1,027		

Table 3. Midwife's Physical Exam Accuracy Indicators for Different Age Groups

Age groups	Sens	Spec	PPV	NPV	+LR	-LR
≤35 Years	77%	61%	56.5%	80%	1.97	0.37
>35 Years	73%	71%	39%	91%	2.52	0.38
Total	75%	67%	48%	87%	2.31	0.36

Sens, Sensitivity; Spec, Specificity; PPV, Positive Predictive Value; NPV, Negative Predictive Value; LR, Likelihood Ratio

Table 4. Interobserver Agreement for Necessity of Referring Patients to a Surgeon

	Surgeon - Necessity for Referral				
Midwife	Yes	No	Total	Kappa	P value
Needs referral	454	32	486	38.3%	<0.0001
Doesn't need	286	240	526		
Total	740	272	1,012		

Table 5. Accuracy Indicators of "Patients' Referral" by Midwives for Different Age Groups

Age groups	Sens	Spec	PPV	NPV	+LR	-LR
≤ 35 Years	96%	42%	67%	89%	1.66	0.1
>35 Years	91%	48%	56%	88%	1.74	0.19
Total	93%	46%	61%	88%	1.72	0.14

For the "necessity of referring the patient to a surgeon", the kappa value was calculated 38% (95% CI= 34% to 42%) which is categorized as "fair" (Table 4). The accuracy of "midwife's judgment about necessity of referring patients to a surgeon" comparing to the" surgeon's implication" is shown in Table 5.

Discussion

World Health Organization has presented guidelines for early detection of breast cancer in countries with limited resources. In addition to educating the public, it is also considered important to educate health care providers, especially those with whom women are most likely to have contact. These providers may be physicians, nurses, midwives, traditional healers, or others. Evidence suggests, for example, that nurses can play a key role in breast health care programs in countries with limited resources. What these providers share in common across countries and regions is the trust that the community /people places in their advice (Benjamin et al., 2003). In many countries, health care providers do not routinely provide CBE. Therefore, in addition to general education about breast health, providers should be given instruction in CBE (Benjamin et al., 2003).

This prospective study challenges the notion whether the midwives can be used to detect breast masses and refer the patient to the surgeon if needed. In an effort to control costs, to avoid unnecessary appointments, and to maximize efficiency for patients and offices, especially in countries with limited resources in which women may not have easy access to the surgeons, midwives may diagnose and manage many common conditions, usually following established protocols. Fair agreement was seen between surgeons and midwives in diagnosis of breast masses (k=0.35). Also response to the question about the necessity of referring the patients to the surgeons showed fair agreement between midwives and surgeons (k=0.38).

Since the agreement depends on the frequency of the variable evaluated in the study population (Douglas et al., 1994), it is important to compare the reason for referral of patients in this study and the other ones. In a study performed by Newton et al, pain and breast mass were the most common reasons for referral of 508 patients with the frequency of 0.38 and 0.42 respectively (Newton et al., 1999). In another study in Iran, pain and breast mass were 34 and 25 percents of causes of referrals, respectively (Kaviani et al., 2001). In the present study, ignoring the screening cases, pain and breast mass with the frequency of 47 and 39 percent were the most common reasons of referrals.

Although the agreement between surgeons and the midwives for detection of breast mass and necessity for patients' referral are in fair category, it is mainly due to the cases that midwives diagnosed a mass but it was not approved by the surgeons (241 patients) and cases that their referral was considered necessary according to the midwives opinion but surgeons did not confirm this necessity (291 patients). The findings are presented in Tables 2 and 3. False-positive detections clearly are a problem for both the individual patient and the health care system. They generate fear and anxiety for the patient and consume scarce health care resources. However, when expressing concern about the problem of false negative detections, it must be remembered that false negative findings can end up to the death of the patient. More important are the cases that midwives considered healthy and did not refer the patients despite the need for referral according to the surgeons' opinion. These cases constituted 3% of the total (32 out of 1,027 patients).

The results of this study differ from the study of Miller et al. (1991). In that study, nurses performed breast physical examination to screen 67,740 women aged 50-59 and the sensitivity was 77-83%. The observed difference may be due to the different ages of the populations of the two studies and the different gold standards used. Furthermore, Miller's study was conducted on healthy population of Canada to screen the population but we examined the patients who referred to a breast clinic and mostly were symptomatic.
In another study performed by Naderi et al. (2003) in Iran,

2000 women aged 20 and more were examined by Behvarzes (health care providers) and gynecologists and the results of physical examination by gynecologists were considered as gold standard. The sensitivity and the specificity of the physical examination by Behvarzes were 95.8% and 99.5% respectively. The result of Naderi's study (Naderi et al., 2003) is quite different from our study. It may be due to the difference in study populations (asymptomatic women vs. women mostly presenting with a problem) or the different gold standards in the two studies (physical examination by gynecologists vs. general surgeons). In another study by Trapp et al (1999) the ability of trained nurses to detect masses in silicone breast models was evaluated. Even though the results were acceptable and confirmed the use of nurses in breast examination it must be remembered that the real situation differs from silicone models.

It must also be considered that the real situation of breast clinical examination by midwives in health care system is different from the study situation. So the agreement score may be different from real situation. For example there was no limitation in the time used for examination by midwives in this study but in real situation the midwives in the health care system are very busy and it is not possible to spend a lot of long time on examination for each patient. Since the time spent on breast examination is an independent factor in the accuracy of the results (Trapp et al., 1999), it seems that the real accuracy will be lower than this study. On the other hand it was a research project and examinations were done by interested midwives who were aware of evaluation of their performance and this may increase the accuracy of their examinations.

Although the results of this study do not justify the replacement of general surgeons by midwives in health care system as the first examiner at first glance, the decision about this issue on the national level needs more comprehensive studies considering cost-effectiveness of this replacement.

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