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F.A. Al Mulhim,[1,2] A. Syed,[1,2] W.A. Bagatadah[1,2] and A.F. Al Muhanna[1,2]

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ABSTRACT Programmes for early diagnosis of breast cancer are lacking in most countries in the Eastern Mediterranean Region. This paper reviews a nongovernmental screening programme launched in October 2009 in the Eastern Province of Saudi Arabia, in which 14 health centres were covered by 2 mobile mammography machines. Annual screening was offered to all women aged 40 years and above. Up to February 2014 a total of 8061 women were screened, an uptake rate of 15.0%. The recall rate was 7.9%. The number of cancers detected was 47, a cancer detection rate of 5.83 per 1000 women screened; 70.2% of the cancers detected had either no mass or the lesions were smaller than 2 cm. The mean age of women with cancer was 50.4 (SD 7.6) years. The screening parameters of our study correlated well with international standards. Despite the controversies regarding universal breast cancer screening, a national breast cancer screening programme for Saudi Arabia is needed.

Programme de dépistage du cancer du sein : expérience de la province orientale en Arabie saoudite

RÉSUMÉ Les programmes visant à réaliser le diagnostic précoce du cancer du sein sont inexistants dans la plupart des pays de la Région de la Méditerranée orientale. La présente étude examine un programme de dépistage non gouvernemental lancé en octobre 2009 dans la province orientale de l'Arabie saoudite où deux appareils de mammographie mobiles couvraient 14 centres de santé. Un dépistage annuel était proposé à toutes les femmes âgées de 40 ans au plus. Du début du programme à février 2014, un total de 8061 femmes avaient fait l'objet d'un dépistage, soit un taux de participation de 15,0 %. Le taux de rappel était de 7,9 %. Le nombre de cancers dépistés était de 47, soit un taux de dépistage de 5,83 pour 1000 femmes examinées ; 70,2 % des cancers dépistés ne présentaient pas de masse ou avaient des lésions inférieures à deux centimètres. L'âge moyen des femmes atteintes de cancer était de 50,4 ans (E T 7,6 ans). Les paramètres de dépistage de notre étude s'accordaient bien avec les normes internationales. En dépit des controverses concernant le dépistage universel du cancer du sein, un tel programme au niveau national est nécessaire en Arabie saoudite.

[1]Department of Radiology, King Fahd Hospital of the University, University of Dammam, Dammam, Saudi Arabia (Correspondence to F.A. Al Mulhim: fammulhim@yahoo.com).

[2]Saudi Cancer Foundation, Al Khobar, Saudi Arabia.

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Introduction

Breast cancer is a global health problem. It is the leading cancer in women worldwide, including Saudi Arabia (1). There has been a steady increase in the incidence of breast cancer in Saudi Arabia in the last few decades. This is particularly true in the Eastern Province, which has the highest incidence of carcinoma of the breast in the country (2). Another major concern is that, in the absence of a national screening programme, combined with a lack of education about cancer prevention and a number of cultural barriers to screening, most of the breast cancer cases in Saudi Arabia present at a more advanced stage than in developed countries (2).

Screening programmes are instrumental in reducing breast cancer mortality (3). Despite recent controversies regarding the efficacy of universal screening (4), mammography screening

remains an effective means of early detection of breast cancer. In October 2009 the Saudi Cancer Foundation, which is a nongovernmental charity organization, launched a limited breast cancer screening programme in the Eastern Province of Saudi Arabia which is continuing to date. This paper reviews the scheme and presents some of the results from the first 5 years, focusing on uptake and cancer detection rates.

Methods

This study includes data from October 2009 to February 2014. Approval for this study was obtained from the institutional review board of King Fahd Hospital of the University and University of Dammam.

Pre-screening awareness initiatives

Prior to starting the screening programme multiple public outreach activities were undertaken by female volunteers, who included doctors, nurses and students. Lecturers and interactive sessions about breast cancer awareness and screening were carried out in universities, schools, residential compounds and shopping malls. Information brochures in Arabic and English were also distributed. Similar activities were undertaken by male volunteers. As Saudi Arabian society is deeply patriarchal, it was imperative to educate the male population about the advantages of early detection of breast cancer. These activities were not a one-time effort but continued throughout the year. The Pink Eastern initiative was started to boost awareness about breast cancer and is held in October (every year), which is the breast cancer awareness month.

Setting and systems

Two mobile screening vans were used and were stationed near primary health care centres in the areas covered by the screening programme. Initially, in the year 2009–2010, only 4 centres were covered. However by October 2013, 14 centres were covered by the screening programme (located in Al Khobar, Dammam, Qatif, Al-Ahsa, Abqaiq, Jubail, Ras Tanura, Dhahran, Hafar Al-Batin, Khafji, No’ayriyah, Urayra, Qaisumah and Qarya Al-Olaya). Prior to the arrival of the mobile vans in a particular area, their visit was publicized in the local media.

Participants

All women were self-referred. No formal invitation was given for screening, as this was a nongovernmental initiative. Annual screening was offered to all females aged 40 years and above. No upper limit was set for screening. Women with a strong family history of breast cancer were offered earlier screening, at age 35 years. The exclusion criteria were age less than 35 years, pregnancy, lactation, symptomatic patient, and suspicious findings on clinical examination. Data from all women who enrolled in the screening programme were included in

this study. Verbal consent for participation was taken from all of them.

Data collection and screening

Prior to mammogram examination, a detailed history was taken from each woman. The history included demographic data, age of menarche, age at first child and history of breastfeeding. A trained nurse examined the woman and recorded her weight and height. As the vans reached a few remote areas and as the Saudi Cancer Foundation is a charity organization, some symptomatic patients (who did not have access to mammography due to financial or distance constraints) were also imaged. However, the symptomatic patients were excluded from this study. Figure 1 summarizes the work-up plan followed during the screening programme.

The screening vans were equipped with Lorad Selina™ mammography systems (Hologic). Standard full-field digital mammography was done for all women. Standard craniocaudal and mediolateral oblique views of each breast were obtained. Symptomatic women and those with positive findings were referred to breast clinics for diagnostic workup.

All mammograms were read by a senior radiologist with more than 25 years' experience of breast imaging. A random second reading was done by radiologists with breast imaging experience ranging from 3 to 6 years. The standard American College of Radiology (ACR) lexicon and Breast Imaging Reporting and Data System (BI-RADS) categories were used in reporting. In case of a difference in BI-RADS grading, the higher BI-RADS grade was recorded. All mammograms were initially reported as BI-RADS 0 (incomplete), BI-RADS 1 or BI-RADS 2.

Post-screening and follow-up

Women with BI-RADS category 1 and 2 were reassured and were instructed to do routine annual screening. Those with BI-RADS category 0 were evaluated by additional views and/or ultrasound. Following further evaluation of the BI-RADS 0 cases they were further characterized into BI-RADS 1 to 5. Women with BI-RADS 3 were given short-term follow-up by ultrasound or mammogram as required. Those with BI-RADS 4 and 5 were biopsied either under ultrasound or stereotactic guidance, and also given a surgical consultation.

The follow-up examinations were done mainly in King Fahd Teaching Hospital, Al Khobar (affiliated to the University of Dammam). Some women preferred to be followed up in centres closer to their homes. Further imaging including additional mammographic projections, tomo-synthesis, ultrasound evaluation or magnetic resonance imaging. Only 2 cases were diagnosed in other hospitals (Qatif region) and only their final histopathological diagnosis was

available in our records. Stereotactic and ultrasound-guided biopsies were also done in King Fahd Teaching Hospital. For stereotactic biopsies, 9 or 12 gauge vacuum-assisted needles were used. For the ultrasound-guided biopsies 12 or 14 gauge needles were used. Figure 2 sums up the algorithm followed in mammogram interpretation.

Results

Screening uptake

The number of females above the age of 40 years in the Eastern Province was 233 695 according to the Central Department of Statistics and Information's Demographic Research Bulletin of 2007. The target population in the areas covered was estimated to be 53 800. The total number of women screened from October 2009 to February 2014 was 8061. The uptake rate of screening was therefore 15.0%. However, if we included symptomatic women and those with findings on clinical examination (n = 1053) the uptake rate became 16.9%. Most of the women (n = 7819) had one screening and only 3.0% (242 women) were given a second screening. Table 1 summarizes the results of the screening programme.

Background characteristics of screened women

The number of Saudi women screened was 6823 (84.6%), while other nationalities were 1238 (15.4%). The age range was 37–78 years, with the mean age being 47.5 (standard deviation 9.4) years. The highest number of women screened was in the age group 41–50 years. Body mass index data were available only for 3948 women. The majority of these women were overweight, obese or morbidly obese (66.5%). A majority (95.5%) of the study women had 1 or more children; only 5.5% of women were nulliparous. The breast density in the majority (77.0%) of the women was predominantly fatty (less than 25% glandular tissue) with only 4.0% having heterogeneously dense or very dense breasts.

Recall rate

A total of 636 women were called for further work-up, and thus the recall rate was 7.9%. The highest number of women recalled was in the age group 41–50 years.

Screening results

Among the recalled women, 63 were advised to have biopsy, resulting in a biopsy rate of 10.3% (Table 1). Two cases were diagnosed in another hospital and the nature of their biopsy (surgical or ultrasound guided) is not known. All the remaining biopsies (n = 61) were either ultrasound-guided core biopsies or stereotactic core biopsies. Positive biopsies were obtained in 47 women. The positive biopsy rate was therefore 74.6%. Out of these 47 cases, 46 cases were diagnosed during the first (prevalent) screening and only 1 case was diagnosed on subsequent screening. Of these 39 were Saudi nationals while 8 were of other nationalities.

The size of the lesions ranged from 0.8 × 0.5 cm to 3.5 × 3 cm. In 9 cases no mass was detected. They either had architectural distortion, asymmetrical density or microcalcifications. Ten women had lesions less than 15 mm, while 14 women had lesion between 15 mm to 20 mm and in 14 women the lesions were more than 20 mm. Thus 70.2% of cancer patients had either no mass lesions or lesions smaller than 2 cm.

Table 2 demonstrates the prevalent cancer distribution by age. The mean age of women with cancer was 50.4 (SD 7.6) years; the median age was 50 years. The youngest patient was 38 years old while the oldest was 66 years old. The highest number of cancers was detected in the age group 41–50 years, with 53.2% cancers being detected in this age group.

The commonest location of carcinoma was in the upper outer quadrant. Invasive ductal carcinoma was the commonest carcinoma (37 cases: 78.7%), followed by ductal carcinoma in situ in 7 cases (14.9%). The rest of them were either invasive lobular carcinoma (1 case, 2.1%), lobular carcinoma in situ (1 case, 2.1%) or low-grade papillary carcinoma (1 case, 2.1%).

Cancer detection rate

A total of 47 breast cancer cases were diagnosed by screening 8061 women from October 2009 to February 2014. Thus, the cancer detection rate in our study was 5.83 per 1000 women screened. There were 46 cancers which were prevalent cases detected by screening 7819 women, a cancer detection rate of 5.88 per 1000. Only 1 cancer was detected on subsequent screening in 242 women, a cancer detection rate of 4.13 per 1000 screened.

The results of symptomatic women and those with clinical findings are briefly documented here. A total of 1053 women who attended the screening programme had clinical findings (n = 903) or were symptomatic (n = 78) and were referred for further evaluation. Of these, 72 patients were lost to follow-up and the remaining 981 were studied. The commonest findings/symptoms in this group were as follows: lump in breast (818 cases) followed by nipple discharge (54 cases), skin changes (43 cases), nipple retraction (30 cases), localized breast pain (23 cases) and lump in axilla (13 cases). The most common age group was 41–50 years. Women with cyclical breast pain were not considered symptomatic. In this group 17 malignancies were detected, 1 of which was Hodgkin lymphoma of the axilla. Therefore, a total of 16 breast cancers were detected in 980 women. This is a cancer detection rate of 16.3 per 1000 women with symptoms or clinical findings, which is almost 3 times the detection rate in asymptomatic patients. Four cancers were detected in the symptomatic women, with a cancer detection rate of 51.5 per 1000. A detailed analysis and discussion of patients with findings/symptomatic patients is beyond the scope of

this article. Tables 3 and 4 provide a brief summary of findings in this group.

Discussion

Despite recent controversies regarding the efficacy of mammography screening in the reduction of mortality from breast cancer (4), mammography remains the mainstay for the early diagnosis of breast cancer (3). The World Health Organization in its report for the Eastern Mediterranean Region (EMR) has stressed early diagnosis to prevent breast cancer mortality (5). Unfortunately, a formal national screening programme is lacking most countries of the EMR.

The Eastern Province of Saudi Arabia has experienced an rise in the number of breast cancer cases. The province has the highest number of newly diagnosed breast cancer cases compared with other regions of the country, an age-standardized rate of 33.1 per 100 000. Most of the breast cancer cases in Saudi Arabia present late, at stages 3 or 4 (2). As such, there is an urgent need for prevention and early diagnosis of this disease. Considering these factors, the Saudi Cancer Foundation, a nongovernmental organization, started the pilot screening programme described here in October 2009.

The national breast cancer screening policy of Saudi Arabia is still being formulated, and so the age at which mammographic screening should start in our country remains a grey area. The Saudi Cancer Registry in 2009 and 2011 reported that the median age of breast cancer cases in Saudi Arabia was 48 years (2). Our scheme therefore offered screening to all women aged 40 years or above, in keeping with the ACR and American Cancer Society recommendations (6,7). Both of these advocate screening mammography for the general population after the age of 40 years. In contrast, the National Health Service (NHS) in the United Kingdom (UK) offers screening mammography to the general population only after the age of 50 years (8). A pilot screening programme in Qasim region of Saudi Arabia offered screening to women aged 35–60 years. In another screening study in Riyadh, the age at which screening started was not specified; however, the age of their study women ranged from 19–91 years (9).

The uptake rate of screening in our study was only 15.0%, which much lower than the international standards of 75% (8,10). However, it was similar to that reported by Akhtar et al. in a pilot screening study undertaken in Qasim region of Saudi Arabia which showed an uptake rate of 17.9% (11). A variety of sociocultural factors may be responsible for the low uptake. Saudi Arabian society is patriarchal and conservative, making it is difficult for women to discuss issues related to breast cancer. Restrictions in travelling alone and lack of public transport hamper the ability of women to attend for screening. Many women are reluctance to disclose this to their male guardians. Furthermore, Ravichandran et al. reported that knowledge about breast cancer was very low in the Saudi Arabian female population (12); 69.7% of women

surveyed were not aware of breast self-examination, only 14.2% had had a clinical breast examination and only 8.1% had had a mammogram. Al Mulhim et al., in a study among female schoolteachers in the Eastern Province, concluded that even educated women had deficient knowledge about screening mammography (13).

Knowledge about breast cancer early detection and screening mammography is also lacking among physicians in Saudi Arabia. Al-Amoudi et al. reported that only 11.3% of primary health care (PHC) physicians had done breast examination in routine physical examinations of their patients and that mammograms requested by women above 40 years of age were performed in only 34% of cases (14). The uptake rate in any screening programme will depend on the target population's awareness about it. The PHC physician is a very important source of information in this regard. Greater efforts are needed to increase knowledge about breast cancer early detection at the level of PHC providers in particular and the target population in general.

Another important factor that could be responsible for the low uptake rate in our programme was that no formal invitation to screening could be issued as this was a nongovernmental initiative. This is in contrast to the screening programmes in the UK and other European countries, which are state-sponsored.

As 97% of the women in the study came for initial screening, our study may be regarded as a prevalent disease screening. The recall rate for our study was 7.9%. This is comparable to international standards. The European Union recommends a recall rate of 7% or less for prevalent screening and 5% or less for subsequent screening (10). In practice, however, recall rates vary greatly even in developed countries. A comparative study of international screening programmes in 2004 found that the recall rate at the initial or prevalent screen varied from 1.4% in the Netherlands to 15.1% in the United States of America (15). A similar review of European screening programmes found that recall rates in European screening programmes varied from 1.3% to 18.4% (16). The UK NHS reported a recall rate of 8.6% for the initial screen in its annual report of 2008 (7). This is comparable to our study.

Akhtar et al. reported a high recall rate of 31.6% in their pilot programme in Saudi Arabia (11). They believed that low-volume readings by radiologists and fear of malpractice litigations were the main causes of the high recall rate. Another study in the Riyadh region did not disclose the recall rate (9). However, they recalled 10.9% of even BI-RADS 1 and 2 mammograms due to dense breasts, so their true recall rate is likely to be high. In contrast, the recall rate in our study is comparable to international standards. This is because standard digital mammography machines were used and all cases were read by a highly experienced radiologist with more than 25 years' experience in mammography, the technical staff were well trained and random

double-reading was used.

The benign biopsy rate per 1000 patients screened in our study was 1.98, which is less than the recommended 3.6 (8). Akhtar et al. reported a high benign biopsy rate of 12.3. The UK NHS in 2008 had a benign biopsy rate in the initial screening of 2 (8).

The mean age of our breast cancer patients was 50.4 (SD 7.6) years and the median age was 50 years with a range of 38–66 years. According to the Saudi Cancer Registry the median age for breast cancer was 48 years in 2011 (2). Our findings correlate well with the national figures. Just over half of cancers in our study (53.2%) were found in the age group 41–50 years and the highest cancer detection rate of 6.46 per 1000 screened was found in the age group 46–50 years. The UK Cancer Research Organization reported that nearly half (47%) of female breast cancer cases were diagnosed in the 50–69 age group (17). Our study confirms the finding that breast cancer occurs a decade earlier in the EMR population as compared with European/North American populations. This strengthens the argument for starting screening programmes in the EMR at 40 years instead of 50 years as done in European countries.

A majority of the cancers detected in the screening programme (78.7%) were invasive ductal carcinomas. The number of ductal carcinomas in situ detected in our study was 14.9%. This correlates well with the UK NHS study (8). Table 5 compares the salient parameters of our screening programme with the UK statistics (8), Akhtar et al.'s study (11) and the recommended UK standards.

The rate of screen-detected carcinomas in our study was 5.9 per 100 patients screened at the initial screen. This figure is high compared with that reported by Akhtar et al. in Saudi Arabia (11). Among international studies the cancer detection rates vary from 3.7 to 10.6 per 1000 at the initial screen (15). The UK reported a screen detected carcinoma rate of 8.3 per 1000 screened in 2012–13 (18). Other countries in Europe have reported much lower cancer detection rates, e.g. 3.7 per 1000 screened in Finland and 3.6 per 1000 screened in Hungary (19,20). A similar study in Egypt had a cancer detection rate of 4.3 per 1000, which is comparable to our study (21).

The rate of screen-detected cancer in our study is high when we consider the lower prevalence of breast cancer in Saudi Arabia as compared with developed countries. The reasons for this could include the fact that most our study population was urban. The rate of obesity was also quite high in the study group. Screening was offered to all nationalities, and some of the

nationalities screened (e.g. Pakistani) have a high incidence of breast cancer which is similar to that of more developed nations. Due to advance publicity our study population may have included women who were in a higher risk group. It will be interesting to evaluate the causes of the high cancer detection rate in a further study.

A high proportion of cancers detected in our study (70.2%) had either no mass or were smaller than 2 cm. The exact benefits accrued by early detection of these cancers will require long-term follow-up and further research. In general, early detection of cancer in other studies has been associated with reductions in morbidity and mortality (3,8). The benefit of universal mammography screening, however, remains a hotly debated topic. Miller et al. have questioned the role of mammography in reduction of breast cancer mortality (4). However, Otto et al., in a case–control study in 2012 in the Netherlands, concluded that “women who receive at least three screening mammograms have a 49% lower risk of dying from breast cancer” (22). Pace et al., in a systematic review of mammography from 1964–2014, found that “mammography screening is associated with a 19% overall reduction of breast cancer mortality” (23). They also stated that over-diagnosis is an important limitation of screening programmes and that further research needs to be done to limit it. The NHS report of 2008 however estimated that 1400 lives were saved annually in the UK as a result of mammographic screening (8).

The preliminary results of our screening programme are very encouraging. Most of the parameters in our study, except for the uptake rate, are comparable to the international standards. The low uptake emphasizes that we need more public awareness programmes to educate people about breast cancer and its early detection. Our finding that 70.2% of cancers detected had either no mass or were smaller than 2 cm highlights the fact that screening detects breast cancer early, at a stage when it can be cured. Introduction of a national breast cancer screening programme in Saudi Arabia needs to be considered.

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