



Original Article

# The outcome of a quality-controlled mammography screening program: Experience from a population-based study in Taiwan

Huay-Ben Pan <sup>a,b</sup>, Kam-Fai Wong <sup>c</sup>, Tsung-Lung Yang <sup>a,b</sup>, Giu-Cheng Hsu <sup>d</sup>, Chen-Pin Chou <sup>a,b</sup>,  
Jer-Shyung Huang <sup>a</sup>, San-Kan Lee <sup>e</sup>, Yi-Hong Chou <sup>b,f</sup>, Chia-Ling Chiang <sup>a</sup>, Huei-Lung Liang <sup>a,b,\*</sup>

<sup>a</sup> Department of Radiology, Kaohsiung Veterans General Hospital, Kaohsiung, Taiwan, ROC

<sup>b</sup> National Yang-Ming University School of Medicine, Taipei, Taiwan, ROC

<sup>c</sup> Institute of Statistics, National University of Kaohsiung, Kaohsiung, Taiwan, ROC

<sup>d</sup> Department of Radiology, Tri-Service General Hospital, Taipei, Taiwan, ROC

<sup>e</sup> Department of Radiology, Taichung Veterans General Hospital, Taichung, Taiwan, ROC

<sup>f</sup> Department of Radiology, Taipei Veterans General Hospital, Taipei, Taiwan, ROC

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## Abstract

**Background:** A greater policy of emphasis on the early detection and treatment of breast cancer is prevalent among developed countries. To raise the screening performance with a potentially decreased mortality rate, it is crucial to evaluate and analyze the screening outcome after implementation. We report the clinical outcome of an 8-year nationwide mammography screening in Taiwan to help share our statistical information on breast screening worldwide, especially in Asia.

**Methods:** Taiwan has provided nationwide, free, biennial mammographic screening since 2004. A total of 2,392,789 consecutive screening mammography examinations were performed during this study period for women aged 50–69 years (2006–2009) and 45–69 years (from December 2009 onwards). The screening covers 33.2% of the target population in the most recent 2 years. The workload of every screening radiologist, the overall recall rate, positive predictive value (PPV1), cancer detection rate (CDR), cancer incidence rate (CIR) from the screening, 1-year interval cancer, sensitivity, and specificity of the screening mammography are calculated, and compared with the American College of Radiology (ACR) recommendation level and/or those of other screening mammographic series.

**Results:** The CDRs (%) and CIRs (%) increased from 3.94–4.08 and 4.80–5.04 to 4.71–5.04 and 5.71 after 2009, implying a high occurrence of breast cancer in the younger age group of 45–49 years. The recall rates (9.3–10.0%) in this review are within the ACR recommendation range (<10%) and the PPV1 has also reached the ACR recommended level (>5%) in the most recent 2 years. The improvement of the screening performance may be attributed to our peer auditing review and education program. The sensitivity of our screening mammography is slightly lower than that of the ACR recommended level (>85%), which is still comparable to the results of the Vermont area in the USA. Although the workload (screenees/screeners) for every radiologist each year has increased from 150 in 2004 to 1360 in 2012, it does not seem to worsen the quality outcome of this screening program.

**Conclusion:** From the outcome review of this national mammography screening, there is still room to ameliorate our performance through comprehensive and continued education, to improve the competence of cancer detection and decrease false negative (FN) cases.

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**Keywords:** breast screening; cancer detection rate; mammographic screening; medical audit; sensitivity

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\* Corresponding author. Dr. Huei-Lung Liang, Department of Radiology, Kaohsiung Veterans General Hospital, 386, Ta-Chung 1st Road, Kaohsiung 813, Taiwan, ROC.

E-mail address: [hliang@vghks.gov.tw](mailto:hliang@vghks.gov.tw) (H.-L. Liang).

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## 1. Introduction

Breast cancer is the most frequent cancer among women in both developing and developed countries.<sup>1,2</sup> Screening mammography contributes to the substantial decrease of 6% in breast cancer mortality, to 63% through early detection.<sup>3,4</sup> Mortality increases in regions without early detection programs.<sup>5</sup> Even for women in their 40s, screening mammography was reported to efficiently reduce breast cancer mortality by 29%.<sup>6</sup> Despite the fact that correlation of screening and mortality is still debatable,<sup>7</sup> a greater emphasis on the early detection and treatment of breast cancer is prevalent among developed countries.<sup>8</sup> To raise the screening performance and potentially decrease the mortality rate, it is crucial to evaluate and analyze the screening outcome after implementation.<sup>9</sup> Thereafter, we report the clinical outcome [including positive predictive value (PPV1), recall rate, cancer detection rate (CDR), early CDR, sensitivity, and specificity] of an 8-year nationwide mammography screening in Taiwan, to help share our statistical information on breast screening worldwide, especially in Asia.

## 2. Methods

### 2.1. Strategy of screening mammography

Since 2004, a nationwide, free, biennial screening mammography program has been offered for asymptomatic women aged 50–69 years (before December 2009) and aged 45–69 years thereafter. For the convenience of screenees and to increase the percentage coverage of participants, screening mobile vans have also been used since 2007. Four views of bilateral breasts in craniocaudal and mediolateral oblique projections are the standard of our screening mammography. Assessments are based on the Breast Imaging Reporting and Data Systems (BI-RADS) established by the American College of Radiology (ACR). In that system, categories 0, 4, and 5 are considered as positive assessments, representing either requiring further study or increasing risk of malignancy. Categories 1, 2, and 3 are considered as negative assessments, with requirement of a short follow up for the latter.<sup>10</sup>

To be qualified to attend the screening mammograms, all board-certified radiologists and radiographers are asked to attend a mammogram-interpretation or quality control education program yearly. The former are also required to have interpreted at least 1000 mammograms within 2 years.

### 2.2. Definitions<sup>10</sup>

True positive (TP) is tissue diagnosis of cancer within 1 year after a positive examination (BI-RADS Category 0, 4, or 5 for screening). False negative (FN) or interval cancer is tissue diagnosis of cancer within 1 year of a negative examination (BI-RADS Category 1 or 2 for screening, BI-RADS Category 1, 2, or 3 for diagnostic). Recall rate is reported as the percentage of positive interpretation (BI-RADS Category 0, 4, or 5; ACR recommended level to be <10%). PPV1 is the percentage of all positive screening examinations (BI-RADS

Categories 0, 4, and 5) that result in a tissue diagnosis of cancer within 1 year (ACR recommended level to be >5%). CDR from screening is the number of cancers correctly detected/1000 patients examined on mammography (=number of TP/number of screening). Cancer incidence rate (CIR) from screening is the number of cancers diagnosed from screening mammography in 1 year [(number of TP + number of FN)/number of screening]. Sensitivity [TP/(TP + FN)] is the probability of detecting a cancer when a cancer exists or the number of cancers diagnosed after being identified at mammography in a population within 1 year of the imaging examination, divided by all cancers present in that population in the same time period (ACR recommended level to be >85%). Specificity [TN/(TN + FP)] is the probability of interpreting an examination as negative when cancer does not exist, or the number of true negative mammograms in a population divided by all actual negative cases (those for which there is no tissue diagnosis of cancer within 1 year of the mammogram) in the population (ACR recommended level to be >90%).

### 2.3. Data collection

The study was approved by the Institutional Review Board at Kaohsiung Veterans General Hospital, Kaohsiung, Taiwan and was performed according to the Declaration of Helsinki principles. We collected data from the results of a free, nationwide population-based mammography-screening program funded and coordinated by Taiwan's Bureau of Health Promotion (received on May 2012) and National Cancer Registry. As the population of the participant women in the first 2 years (2004 and 2005) was small (<100,000) and/or was contaminated with symptomatic patients, we excluded the data from these 2 years for later analysis.

### 2.4. Statistical analysis

As the latest data (after 2010) of FN from the National Cancer Registry is lacking at the start of this study, we reported the numbers of screening, recall rate, PPV1, and CDR (TP) data from the years 2004–2012, and the CIRs, 1 year interval cancer (FN), sensitivity, and specificity from the years 2004 to 2010. Due to the size of the observations, the standard error was small, and thus there was little need to test statistical significance.

## 3. Results

Since the initiation of the screening program, the enrolled mammographic units in our country increased from 102 units in 2004 to 195 units in 2012, including 68 mobile vans. The digital mammographic system (CR or DR) was adopted at around 20%, initially to reach >95% in 2012 (163 DR, 86 CR, and 11 screen-film combinations). A total of 2,473,608 consecutive mammographic examinations for breast cancer screening were performed between 2004 and 2012 and 2,392,789 between 2006 and 2012. The target population had increased from 17,272 women in 2004 to 670,528 in 2012. In the years 2011 and 2012,

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