



Canadian Association of Radiologists Journal 65 (2014) 315–320

CANADIAN ASSOCIATION OF RADIOLOGISTS JOURNAL

www.carjonline.org

Health Policy and Practice / Santé : politique et pratique médicale

The Burden of False-Positive Results in Analog and Digital Screening Mammography: Experience of the Nova Scotia Breast Screening Program

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Abstract

Purpose: The Canadian Task Force on Preventive Health Care released recommendations for breast cancer screening, in part, based on harms associated with screening. The purpose of this study was to describe the rate of false-positive (FP) screening mammograms and to describe the extent of the investigations after an FP.

Methods: A cohort was identified that consisted of all screening mammograms performed through the Screening Program (2000-2011) with patients ages 40-69 years at screening. Rates of FP screening mammograms were calculated as well as rates of further investigations required, including additional imaging, needle core biopsy, and surgery. Analyses were stratified by 10-year age group, screening status (first vs rescreen), and technology.

Results: A total of 608,088 screening mammograms were included. The FP rate varied by age group, and decreased with increasing age (digital, 40-49 years old, FP = 8.0%; 50-59 years old, FP = 6.3%; 60-69 years old, FP = 4.6%). The FP rate also varied by screening status (digital, first screen, FP = 12.0%; rescreen, FP = 5.6%), and this difference was consistent across age groups. The need for further investigation varied by age group, with invasive procedures being more heavily used as women age (digital, rescreen group, surgery: 40-49 years old, 1.1%; 50-59 years old 1.6%, 60-69 years old, 1.8%).

Conclusions: Both the FP screening mammogram rate and the degree to which further investigation was required varied by age group and screening status. Reporting on these rates should form part of the evaluation of screening performance.

Résumé

Objectif: Le Groupe d'étude canadien sur les soins de santé préventifs a formulé des recommandations en matière de dépistage du cancer du sein, notamment en raison des préjudices que pourraient occasionner les tests de dépistage. La présente étude vise à déterminer les taux de résultats faussement positifs des mammographies de dépistage et la mesure dans laquelle des investigations ont été menées à la suite d'un faux positif.

Méthodes: Une cohorte a été constituée par inclusion de toutes les mammographies de dépistage réalisées dans le cadre du programme de dépistage (de 2000 à 2011) chez des patientes âgées de 40 à 69 ans au moment de l'examen. Nous avons calculé les taux de résultats faussement positifs des mammographies et les taux associés aux autres mesures d'investigation requises, notamment aux examens d'imagerie complémentaires, aux biopsies au trocart et aux interventions chirurgicales. Les analyses ont été réparties en fonction de groupes d'âge de 10 ans, de l'étape de dépistage (premier examen ou examen subséquent) et de la technologie employée.

Résultats : Au total, 608 088 mammographies de dépistage ont été prises en compte. Le taux de résultats faussement positifs a varié selon le groupe d'âge, diminuant à mesure que l'âge augmentait (mammographie numérique, faux positifs chez les patientes de 40 à 49 ans = 8,0 %; faux positifs chez les patientes de 50 à 59 ans = 6,3 %; faux positifs chez les patientes de 60 à 69 ans = 4,6 %). Le taux de résultats faussement positifs a également varié en fonction de l'étape de dépistage (mammographie numérique, faux positifs lors du premier examen = 12,0 %; faux positifs lors d'un examen subséquent = 5,6 %), cette variation étant observée dans tous les groupes d'âge. La

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nécessité d'approfondir l'investigation a varié selon le groupe d'âge, le recours à une intervention effractive étant plus marqué à mesure que l'âge de la patiente augmentait (mammographie numérique, groupe des patientes ayant subi un examen subséquent, chirurgie chez les patientes de 40 à 49 ans = 1,1 %; chez les patientes de 50 à 59 ans = 1,6 %; chez les patientes de 60 à 69 ans = 1,8 %).

Conclusions: Le taux de résultats faussement positifs des mammographies de dépistage et la mesure dans laquelle il a été nécessaire d'approfondir l'investigation ont varié selon le groupe d'âge et l'étape de dépistage. La déclaration de ces taux doit être intégrée à l'évaluation de la performance du programme de dépistage.

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Key words: Breast screening; Mammography; Harms of screening; Organized screening; False-positive rate

In November 2011, the Canadian Task Force on Preventive Health Care issued guidelines for regular breast cancer screening [1]. The Canadian Task Force on Preventive Health Care issued its recommendations on the balance of harms and benefits for each age group but did not allow for differences in technology of the screening mammogram. The Canadian Breast Cancer Screening Network (CBCSN) of the Canadian Partnership Against Cancer, formerly the Canadian Breast Cancer Screening Initiative of the Public Health Agency of Canada, is the umbrella organization that sets standards for the provincial and territorial organized breast cancer screening programs [2]. Currently, the CBCSN does not include performance indicators that pertain to "harms" of screening in its regular reporting on organized screening program performance, nor are the performance indicators reported separately by technology of the screening mammogram [3,4].

The Nova Scotia Breast Screening Program (NSBSP) was established in 1991 and encompasses all screening mammography in the province as of October 2008 [5]. A province-wide implementation of digital mammography began in 2007 and was completed in 2012. The NSBSP information system contains data for all radiologic breast imaging procedures in the province, including breast screening. Data were extracted from this system and used to report on the false-positive (FP) rate of screening mammograms as well as the rate of further investigations required after the FP screening mammogram.

Methods

This study used a historical cohort of screening mammograms performed with women ages 40-69 years old at screen, in the period 2001 through 2011. This cohort was used to calculate the rates of FP screening mammograms and the rates of further investigation required after the FP screening mammogram. The NSBSP maintains an information system that contains data on breast radiologic procedures in the province, including screening mammography. The system also contains information on any subsequent investigations after an abnormal screening mammogram, including diagnostic and/or workup imaging, needle core biopsy (including pathology), and surgery (including pathology). In the period 2001 through 2011, the NSBSP collected information for 608,088 screening mammograms.

Data were extracted for all screening mammograms, including the results of the screen and, for abnormal screens, all investigations and results associated with an abnormal screening episode. An FP screening mammogram was defined as a screening mammogram with an abnormal result that was not associated with a final diagnosis of cancer. For each screen, the 10-year age group of the participant, the screening status (first vs rescreen) and the technology (analog vs digital) also were collected.

Rates of FP screening mammograms were calculated as well as rates of further investigation after the FP screening mammogram. All the rates were calculated stratified by 10-year age group, screening status (first vs rescreen), and technology of the screening mammogram (analog vs digital). Given that the sample is in fact an entire population and that an 11-year period of data was used rather than annual figures that can naturally fluctuate, no inference testing was performed (ie, no *P* values were calculated) and no confidence intervals were calculated. This study was submitted to the Capital Health Research Ethics Board and was granted a waiver on the basis that this work was part of quality assurance by the NSBSP.

Results

Among the 608,088 screening mammograms performed via the NSBSP in the period 2001 through 2011, 408,620 were performed by using analog technology and 199,468 were performed by using digital technology. The FP screening mammogram rate (FP rate) varied by 10-year age group, decreasing with increasing with age, as shown in Figure 1A and B. The FP rate also was higher among first screens compared with rescreens; this was true for all age groups. The trends across age groups and screening status were similar for both analog and digital screening mammography. However, analysis of the results suggests that the FP rate for patients in their 40s is lower for digital mammography compared with analog; there was little difference between the analog and digital methods for patients ages 50-59 years old and 60-69 years old. When further broken down by screening status, both 40-49 year old first and rescreen groups had lower FP rates for digital compared with analog technology. The first-screen FP rates were higher for both the 50-59 year old and 60-69

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