THE NETHERLANDS

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Breast Implant Prevalence in the Dutch Female Population Assessed by Chest Radiographs

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Abstract

Background: Breast implant-related health problems are a subject of fierce debate. Reliable population-based estimates of implant prevalence rates are not available, however, due to a lack of historical registries and incomplete sales data, precluding absolute risk assessments.

Objectives: This study aimed to describe the methodology of a novel procedure to determine Dutch breast implant prevalence based on the evaluation of routine chest radiographs.

Methods: The validity of the new method was first examined in a separate study. Eight reviewers examined a series of 180 chest radiographs with (n = 60) or without (n = 120) a breast implant confirmed by a computed tomography or magnetic resonance imaging scan. After a consensus meeting with best-performing expert reviewers, we reviewed 3000 chest radiographs of women aged 20 to 70 years in 2 large regional hospitals in the Netherlands in 2015. To calculate the national breast implant prevalence, regional prevalence variations were corrected utilizing the National Breast Cancer Screening Program.

Results: Eight reviewers scored with a median sensitivity of 71.7% (range, 41.7%-85.0%) and a median specificity of 94.6% (range, 73.4%-97.5%). After a consensus meeting and a reevaluation by best-performing expert reviewers, sensitivity was 79.9% and specificity was 99.2%. The estimated national prevalence of breast implants among women between 20 and 70 years was 3.0%, ranging from 1.7% at 21 to 30 years to 3.9% between 51 and 60 years.

Conclusions: The novel method in this study was validated with a high sensitivity and specificity, resulting in accurate prevalence estimates and providing the opportunity to conduct absolute risk assessment studies on the health consequences of breast implants.

Level of Evidence: 2

2
Diagnostic

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Silicone breast implants were first introduced in 1964 by Cronin and Gerow and have since been implicated with various adverse events, including malignancies and autoimmune disorders.[1] Of these, only the association with anaplastic large cell lymphoma in the breast has been unequivocally supported by formal epidemiological studies,[2] whereas studies on associations with other disorders show highly variable results.[3,4] These studies, especially those focusing on absolute risks of breast implant-related health problems, are hampered by lack of information on the prevalence of women with breast implants and thereby of the population at risk.[5] Answering this seemingly simple question has proven to be a major challenge. Sales data are unreliable and incomplete because companies are reluctant to share sales data or market shares. In addition, the market is highly variable due to retraction by producers due to bankruptcies. Moreover, sales data do not provide information on primary placement, replacement surgery, and unilateral versus bilateral use. Breast implant surgery information from hospitals and clinics is also incomplete, because most implant surgery is performed in private clinics that do not maintain central administrative databases and remain outside the medical insurance system. Only recently, centralized national opt-out registries for breast implant surgery have been established in the Netherlands and Australia.[6,7] The Dutch Breast Implant Registry started in 2015 and is a quality benchmark in breast implant care.[8] It is a mandatory nationwide registration of all breast implant surgical procedures. In the future, such databases will be crucial to answer questions on breast implant-associated risks, but for now they cannot give sufficient information on implant prevalence.

In this study, we estimated breast implant prevalence in the Netherlands based on evaluation of routine chest radiographs. Chest radiographs are one of the most frequently requested diagnostic tests for a great diversity of indications in all adult age groups,[9] and women with breast implants most likely have a similar chance to undergo these diagnostics compared to women without implants. Therefore, screening chest radiographs for the presence of a breast implants was considered an unbiased method.[9] Because silicone is a radiopaque substance, it may be assumed that breast implants can reliably be identified on chest radiographs and that they constitute a feasible screening tool.[10,11]

The aim of this study was to provide a detailed description of the methodology of our novel approach. Firstly, we performed a validation study to determine the diagnostic accuracy of breast implant assessment based on chest radiographs. Subsequently, we conducted a large-scale chest radiograph evaluation study to assess the prevalence of breast implants by age in the Dutch population. Detailed information on the methodology used will allow broader applicability, which will benefit international studies assessing absolute risks of health problems associated with breast implants.

METHODS

This fully anonymized study was approved by the ethics review board in both participating institutions (Medical Spectrum Twente, Enschede and Maastricht University Medical centrum), and it was determined that the Dutch WMO does not apply to the study. The study was executed between December 2016 and October 2017.

Validation Study

To evaluate the validity of assessing chest radiographs for the presence of breast implants, we included women with a breast implant confirmed by computed tomography (CT) scan or magnetic resonance imaging (MRI) scan of the breast as the gold standard. Radiology databases of the Medical Spectrum Twente Hospital in Enschede and Zorg-Groep Twente Hospital in Hengelo, the Netherlands, were searched for CT and MRI reports of women (18-85 years, scanned between January 2013 and December 2015), using the search term “breast implant.” We then selected women with a CT or MRI of the breast positive for a breast implant who had a simultaneously conducted chest radiograph (±3 months to CT/MRI of the breast).

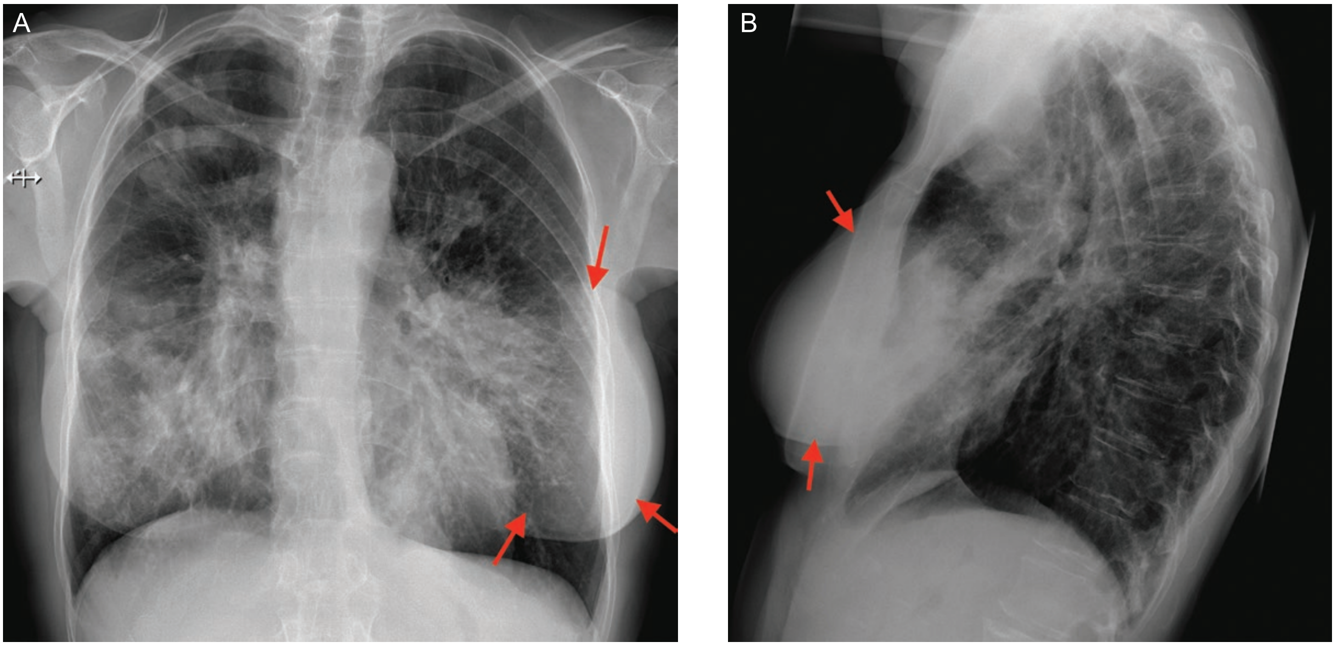

Figure 1. Standard chest radiograph taken in (A) posterior-anterior and (B) lateral view in this 62-year-old woman due to suspicion of bilateral pneumonia. The implant can be seen as asymmetrical densities in the basal lung fields with a focal opacified aspect (arrows).

Visual verification of the breast implant in each MRI and/or CT scan was conducted by a radiologist. The conventional chest radiographs with an anterior-posterior and a lateral view in these women were selected. The same procedure was employed to select a control group of women with a verified absence of a breast implant and with simultaneously conducted chest radiographs. The group of women with a simultaneously performed MRI and/or CT scan with a proven breast implant *and* a chest radiograph was relatively small. Therefore, we selected the first consecutive 60 women with a CT-/MRI-established implant who had a simultaneous chest radiograph of good quality, meaning an anterior-posterior and lateral image and a completely depicted chest. For each of these 60 selected chest radiographs, 2 chest radiographs of women without breast implants, matched on age and gender (±5 years), were manually selected. The manual identification of suitable negative controls (without breast implants based on CT/MRI images) for the validation study was performed as follows. We selected the first consecutive 120 women (based on date of radiological imaging) with a CT- or MRI-proven absence of breast implants who also had a subsequent chest radiograph within 3 months from the CT/MRI of the breast. Absence of a breast implant on CT/MRI image was confirmed by a visual check of the CT/MRI scan by a radiologist. Negative controls were selected from the same database as the 60 patients with proven presence of a breast implant. Exclusion criteria included poor image quality of chest radiographs (eg, impaired position of the chest on the image, incomplete inspiration, or supine position). The 180 chest radiographs were assessed for the presence of breast implants in random order by 2 specialized breast radiologists, 2 plastic surgeons, 2 residents, and 2 medical students, without previous training. Series were assessed in dual-headed working stations with high-resolution (2.5 K · 2 K), high-brightness monitors according to routine working procedures. Characteristics confirming implant presence were (1) projection lines following the contour of the breast implant within the breast, with or without asymmetrical densities in the basal lung fields with a focal opacified aspect, with or without evident absence of ptosis in the breast (Figure 1); (2) evident calcification in the periprosthetic capsule (Figure 2); or (3) the metal magnetized valve/port of the tissue expander (Figure 3).

Statistical Analysis

A correct evaluation of the chest radiograph by the reviewer was defined as detection of the presence of at least 1 to potentially up to 2 breast implant(s). The specificity and sensitivity were calculated per reviewer. Specificity was the percentage of correctly negatively assessed chest radiographs among the 120 women without implant, and sensitivity was the percentage of correctly positively assessed chest radiographs among the 60 women with implants.

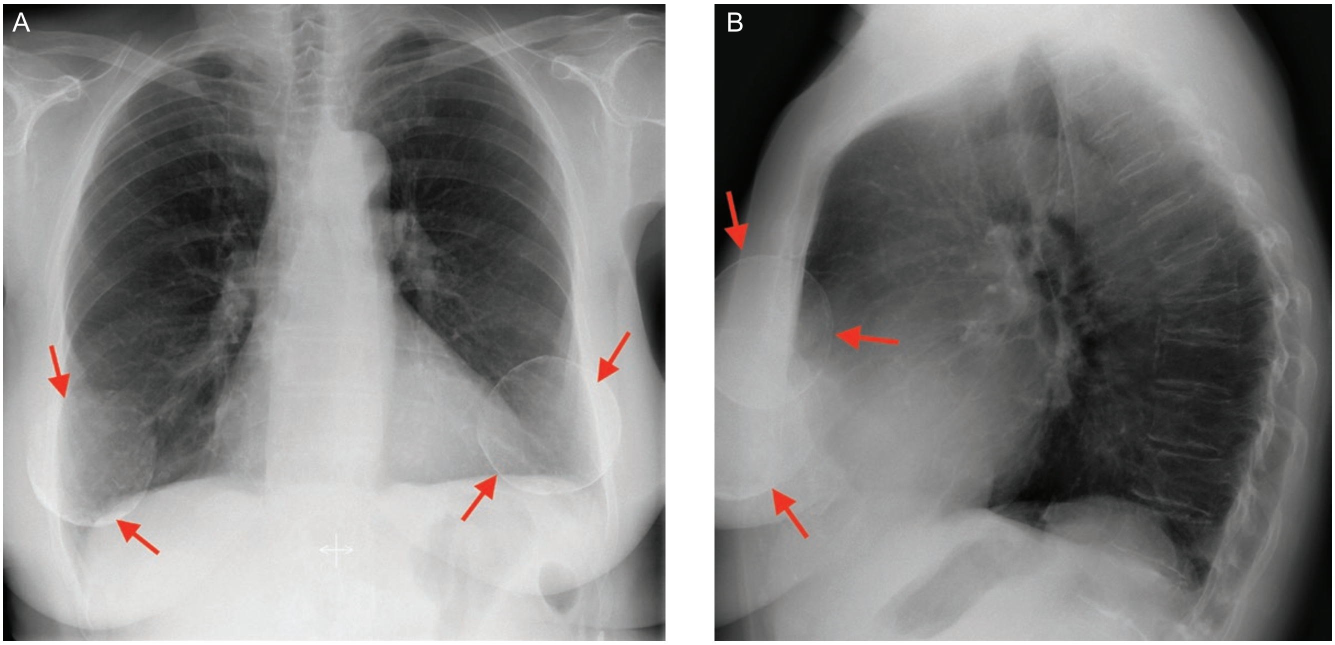

Figure 2. Standard chest radiograph taken in (A) posterior-anterior and (B) lateral view in this 70-year-old woman due to suspicion of exacerbated lung emphysema. The implant can be seen by the evident calcifications in the periprosthetic capsule (arrows).

After the first validation round, 3 selected expert reviewers (sensitivity >70.0% and specificity of >80.0%) held a consensus meeting based on the uniform scoring rules with respect to the characteristics confirming a breast implant and reevaluated all mutually discordant results in the validation series. We then determined the estimated prevalence of breast implants as a function of the sensitivity (sens), the specificity (spec), and the presumed true prevalence (p): $estimated\ prevalence = (1-p)*(1-spec) \pm p*sens$.

We also examined whether the indication (reconstructive after breast amputation or cosmetic [ie, the presence of a mammary gland]) and the laterality (unilateral or bilateral) of the breast implant could be assessed reliably.

Prevalence Study

The study population consisted of 2 regional study series of women aged 20 to 70 years who had chest radiographs between January and December 2015 in the Medical Spectrum Twente Hospital (east) or the Maastricht University Medical Center (south) in the Netherlands. In these hospitals, we selected 2 samples of n = 1525 conventional chest radiographs (305 per 10-year age category), which allowed for precise estimation of a breast implant prevalence of at least 1% with a sufficiently narrow confidence interval (0.5%-1.5%).

Per hospital, 2 expert reviewers, showing high sensitivity and specificity, independently assessed all chest radiographs per regional hospital for the presence of silicone breast implants. We selected reviewer A and B for the east region and reviewer B and C for the southern region. Series were assessed in dual-headed working stations with high-resolution (2.5 K · 2 K), high-brightness monitors. After independent assessment, consensus was reached for discordant results per 2 regional reviewers.

Breast implant prevalence per age group and per region (south or east) was calculated as the ratio of the number of positive chest radiographs by the total number of chest radiographs in the age group.

Assessment of Breast Implant Prevalence in the Netherlands in 2015

After assessing the breast implant prevalence rates per 10-year age group in the east and south of the Netherlands, the national breast implant prevalence in the general female population in the Netherlands was calculated by correcting for the other regions (north, west, and central regions). Region-specific coefficients for breast implant prevalence were provided by the Dutch National Breast Cancer Screening Program (BCSP).[12,13] The BCSP offers biannual mammography screening to Dutch females between age 50 and 75 years, with a national participation rate of 80%.[13,14] Between May 2014 and May 2016, breast implant prevalence was monitored in participating women in all 5 regions of the Netherlands (ie, north, east, south, west, and central).[13,14] Because it is known that women with breast implants less often attend breast cancer population screening programs, we could not utilize these prevalences directly.[14] However, we assumed that the relative differences between regions in BCSP-reported implant prevalence in the 50- to 75-year (mean age, 60.6 years)

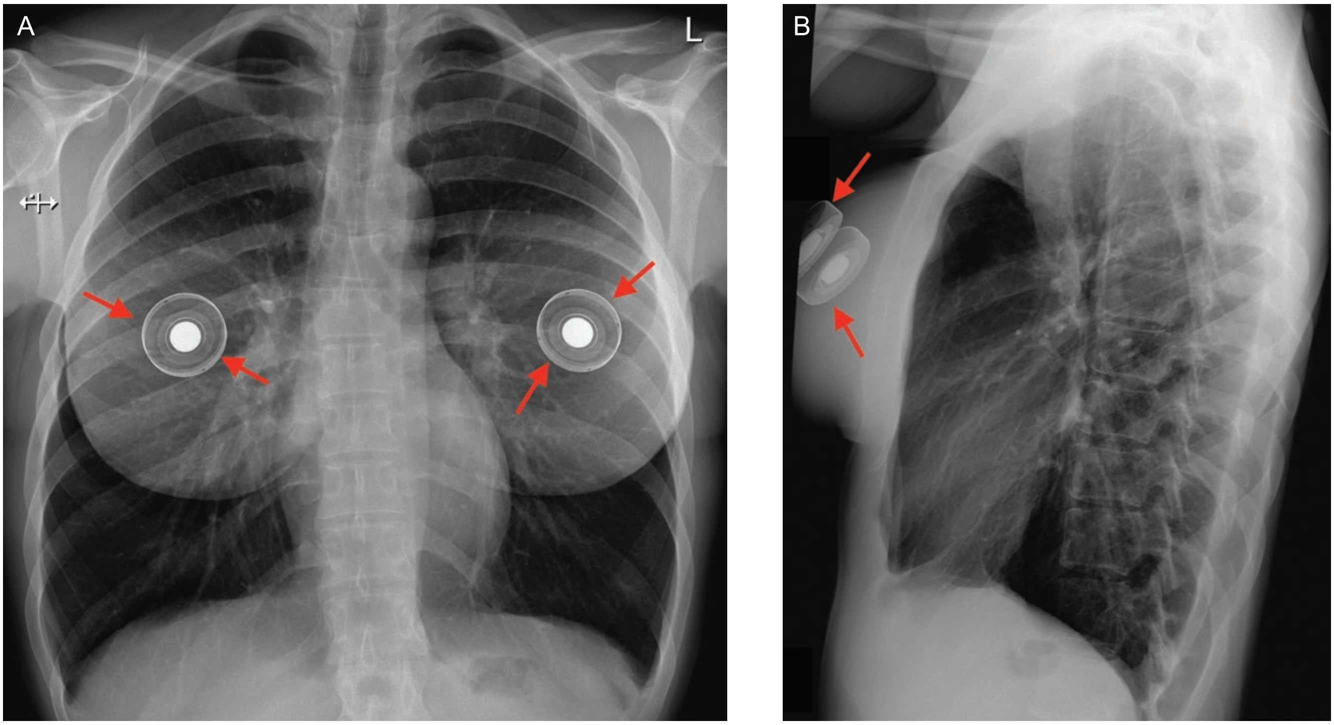

Figure 3. Standard chest radiograph taken in (A) posterior-anterior and (B) lateral view in this 32-year-old woman due to suspicion of bilateral pneumonia. The implant can be seen by the metal magnetized valve/port of the tissue expander (arrows).

Table 1. Sensitivity and Specificity Per Reviewer in the Validation Study Assessing the 180 Chest Radiographs

	Reviewer							
	A	B	C	D	E	F	G	H
Sensitivity (%)	71.7	76.7	71.7	71.7	70.0	85.0	46.7	41.7
Specificity (%)	81.7	94.2	94.2	95.0	95.8	73.4	96.7	97.5
Sensitivity after consensus meeting and reevaluation (%)	79.9			—	—	—	—	
Specificity after consensus meeting and reevaluation (%)	99.2			—	—	—	—	—

female populations approximated regional differences in the general population. The region-specific coefficients in for BCSP-North was 0.6%, BCSP-East = 0.7%, BCSP-South = 1.0%, BCSP-West = 1.1%, and BCSP-Central = 1.2%. For the eastern and southern regions, the age-specific breast implant prevalence was already determined in this study. For the northern, western, and central regions, both age-specific percentages of the east and the south were used as a baseline to extrapolate to a national breast implant prevalence. These age-specific baselines were multiplied by the regional BCSP-prevalences of the northern, western, and central regions and the regional population size.[15] From the subsequent combined regional age-specific breast implant prevalences as derived from the south and east, a mean breast implant prevalence was calculated.

RESULTS

Validation Study

In the first part of the validation study, 8 reviewers scored a median sensitivity of 71.7% (range, 41.7%–85.0%) and a median specificity of 94.6% (range, 73.4%–97.5%) (Table 1). Based on the CT/MRI reports, breast implants were bilateral in 65.0% of the women vs unilateral in 35.0% of the women in the positive group. Bilateral presence was correctly identified with a median score of 40.0% (range, 28.6%-77.1%), and unilateral presence was correctly identified with a median score of 50.0% (range, 21.1%-63.3%). Reviewers reported a cosmetic indication for a median percentage of 54.3% of women (range, 19.1%-74.2%) and a reconstructive indication

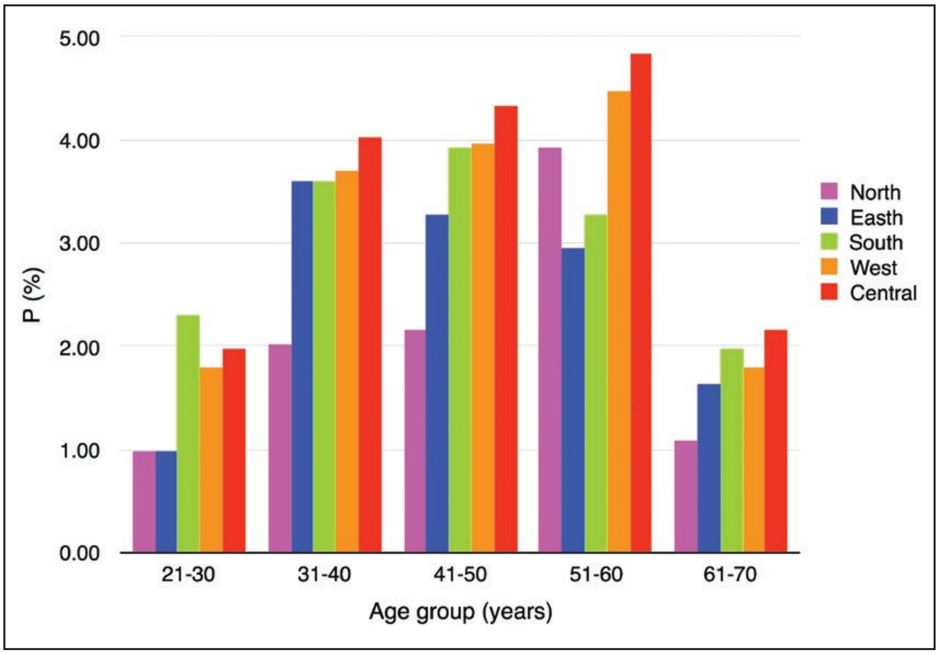

Figure 4. Regional breast implant prevalence in the Netherlands per age group. This figure shows the region-specific breast implant prevalence (P) in women between 20 and 70 years. The eastern and southern regional prevalences were derived from the prevalence study, and both age-specific prevalences were multiplied by the region-specific coefficients of the Breast Cancer Screening Program and the regional population size to calculate a mean for the northern, western, and central regions.

for a median percentage of 45.7% of women (25.8%-80.9%). Indication was unknown for 12.5% of women (range, 4.0%-28.0%). No information on breast implant indications was available from the CT/MRI reports; however, results among reviewers were widely spread without an evident trend of agreement. Laterality and indication were therefore omitted from the prevalence study.

Because sensitivity and specificity were low for some reviewers, only the reviewers with a sensitivity of at least 70.0% (range, 70.0%-76.7%) and a specificity of at least 80.0% (range, 81.7%-95.8%), similar to the scores of the specialized breast radiologists (D and E), were selected for further participation in this study. The 3 selected reviewers (A, B, and C) performed a consensus meeting and a blinded reevaluation of mismatched positive and negative chest radiographs in the validation study. After this reevaluation, sensitivity and specificity had increased to 79.9% and 99.2%, respectively. With these values, estimated implant prevalence would be 3.1% and 4.7%, for true prevalence rates of 3.0% and 5.0%, respectively.

Prevalence Study

In the 2 hospital populations, we assessed a total of n = 3050 chest radiographs in women between 20 and 70 years of age (n = 305 per age group; mean age, 46.5 years). Indications for chest radiographs included cardio-pulmonary problems (64.6%) (suspicion for pneumonia was a major indication), screening for tuberculosis (6.1%), trauma screening (8.6%), autoimmune diseases (5.6%), perioperative screening (3.3%), position of devices other than breast implants (2.6%), abdominal indications (1.4%), and oncological indications (6.4%), 1.2% of which were breast carcinoma patients (n = 36). Of these 36 women, 7 had a breast implant.

Breast implant prevalence for the series in the east of the Netherlands was assessed by reviewer A and B and for the south of the Netherlands by reviewer B and C. Reviewer B performed in both regions. Before consensus, reviewer A and B agreed on 37 women with a breast implant for the eastern region, whereas reviewer A reported 1 additional case and reviewer B reported 1 additional case. After consensus, the additional case reported by reviewer B was accepted, for a total of 38 women with at least 1 breast implant among 1525 chest radiographs.

Before consensus for the southern region, reviewers B and C agreed on 42 identical cases, whereas reviewer B reported 3 additional cases not reported by reviewer C, and reviewer C reported 1 case not reported by reviewer B. After consensus, 4 additional cases were added for a total of 46 women with at least 1 implant among 1525 chest radiographs. Interestingly, the radiological report mentioned the breast implant in only 35.7% (n = 30) of the women with at least 1 breast implant in the chest radiograph.

After consensus, observed prevalence rates in the eastern and southern regions were 1.0% (n = 3) and 2.3% (n = 7), respectively, for 20 to 30 years; 3.6% (n = 11) and

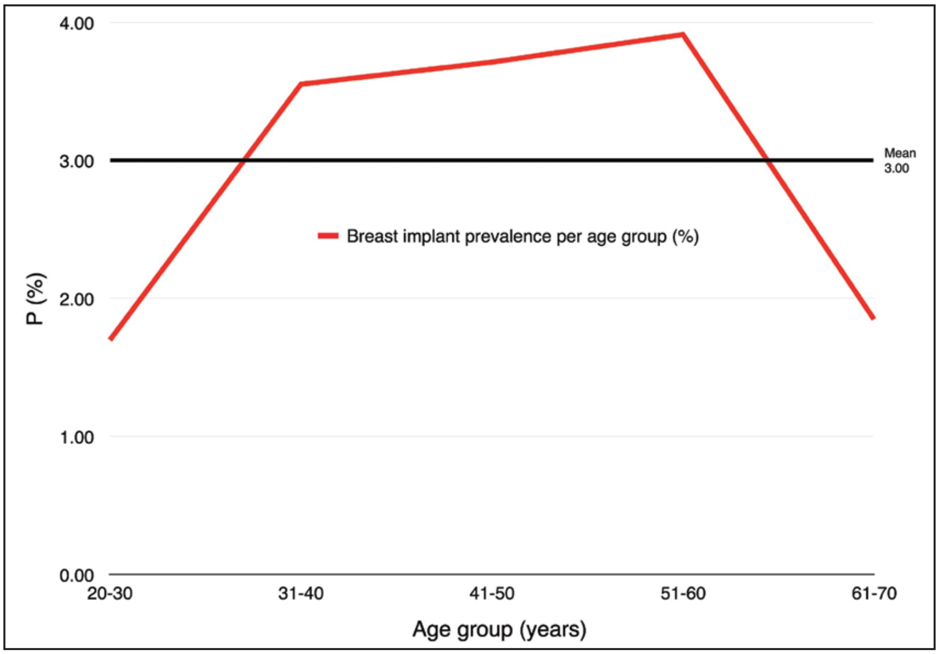

Figure 5. Estimated national breast implant prevalence in the Netherlands in 2015 among women between 20 and 70 years of age. The national breast implant prevalence (P) in Dutch women in the Netherlands between 20 and 70 years is shown, derived by combining differences in region-specific breast implant prevalence from the Breast Cancer Screening Program and regional prevalence from the prevalence study.

3.6% (n = 11), respectively, for 31 to 40 years; 3.3% (n = 10) and 3.9% (n = 12), respectively, for 41 to 50 years; 3.0% (n = 9) and 3.3% (n = 10), respectively, for 51 to 60 years; and 1.6% (n = 5) and 2.0% (n = 6), respectively, for 61 to 70 years. (Figure 4). Using these regional prevalence rates per age group, we extrapolated for the northern, western, and central regions by utilizing the region-specific coefficients of the BCSP and the region-specific population size (Figure 4). We extrapolated for the northern, western, and central regions as described in the Methods. Subsequently, we estimated the mean national breast implant prevalence in 2015 among women between 20 and 70 years at 3.0%, 1.7% for women between 20 and 30 years, 3.5% for 31 to 40 years, 3.7% for 41 to 50 years, 3.9% for 51 to 60 years, and 1.9% for women between 61 and 70 years (Figure 5).

DISCUSSION

Knowledge about breast implant prevalence is essential for assessing the absolute risk and public health impact of breast implant-related health problems. So far, data on the prevalence of breast implants were not available due to the absence of historical breast implant registries[8] and lack of reliable and complete historical implant sales data. Because there has been growing attention in the scientific and lay press recently on specific breast implant-related health problems such as anaplastic large cell lymphoma in the breast,[2] we found it very important to assess breast implant prevalence to enable reliable risk assessments in epidemiological studies. Searching the published literature, we observed a lack of information regarding breast implant prevalence. Although the American Society of Plastic Surgery reports a prevalence of 4.9% for women with breast implants in 2010, with an estimated 300,000 to 400,000 breast implant procedures per year,[16,17] the methodology or registration from which these numbers were derived were not clear. The Food and Drug Administration reported that, worldwide, from 1998 until 2011, approximately 5 to 10 million breast implants have been placed, but this estimate is relatively broad.[4] As for the Netherlands, the BCSP data could have provided insight into national breast implant prevalences; however, prevalence rates from the BCSP are an underestimation due to decreased participation of women with breast implants as a result of discomfort, risk of implant rupture, suboptimal mammography, clinical follow-up of women with breast cancer or high genetic risk for breast cancer, and a restricted participating age group (50-75 years; mean age, 60.6 years).[12-14] In summary, no studies or data sets were, thus far, eligible to accurately derive breast implant prevalence, emphasizing that our report provides unique and novel information.

In this study, we assessed the prevalence of breast implants in the Dutch female population employing a novel method based on routine chest radiographs, which we first validated with a sensitivity of 79.9% and a specificity of 99.2%. Prevalence was estimated at 3.0% among women between 20 and 70 years (Figure 5). Breast implant prevalence in this study varied by age, concurring with data in plastic surgery practices where most esthetic procedures are performed in women between 20 and 40 years of age and reconstructive procedures are performed in older age groups (50-70 years).[16,17] Regional differences might depend on urban and rural differences in accessibility and acceptability of (cosmetic) breast surgery. Compared with the overall prevalence of hip and knee arthroplasty in the United States in 2010 of 0.8% and 1.5%, respectively, or the prevalence of cardiac pacemakers exceeding 2.0% for patients older than 75 years in Western Australia in 2005, we can conclude that breast implants are used extensively.[18,19] Therefore, our data are key in providing answers to important questions about absolute risk assessment for breast implant-related health problems. Moreover, we provide a description of the detailed procedures employed in our novel implant assessment method as well as its validity. This is of prime importance for other investigators to obtain accurate estimates of breast implant prevalence, facilitating international epidemiological studies on breast implant-related health problems.

The current study differs from the present knowledge base because it establishes an age-specific nationwide breast implant prevalence independent from implant sales data. Because sales data are not representative for the number of women carrying breast implants, our approach contributes to new knowledge about breast implant prevalence, enabling adequate risk assessment. Furthermore, the strength of this study lies in the high sensitivity and specificity we demonstrated in the validation study. Because initial sensitivity and specificity were relatively low, it is of major importance to stress the need for expert reviewers, consider the significance of gaining experience, and organize consensus meetings. After these procedures, sensitivity and specificity increased to 79.9% and 99.2%, and these scores were obtained by radiologists as well as by residents and medical students, providing excellent prospects for a wider applicability of our novel assessment procedure. To put these results into perspective, the sensitivity of a chest radiograph to detect tuberculosis or pneumonia is approximately 80%,[20,21] whereas the sensitivity of a mammography for the detection of breast cancer is 77%.[22] Even though laterality of the breast implant has proven difficult to assess, this has not hampered our objective to estimate the number of women with at least 1 breast implant, which is the relevant parameter when assessing absolute risk in breast implant-related problems. The current literature in breast implant-related health problems focuses on the number of women with breast implant-related problems and not on the number of breast implants associated with breast implant-related problems (in a very likely unequal number of women). This relates to the problems involved in deriving breast implant prevalence from sales data, because sales data do not disclose whether implants were implanted bilaterally or unilaterally or if they were used for revision surgery.

Limitations

A potential limitation of the large-scale prevalence study is selection bias due to the indication for chest radiographs. For example, younger healthy females may undergo chest radiographs less frequently and the indication might be related to the presence or absence of breast implants. However, on assessing the indications for the chest radiographs (ie, malignancies) compared with trauma, suspected pneumonia, and work- or travel-related tuberculosis screening, the distribution of indications in younger age groups was comparable to older age groups, with the majority of indications being a suspicion of pneumonia. To our knowledge, there is no evidence that these indications are related to the presence of breast implants. Older age groups might more often undergo potential screening for lung metastases in the context of primary breast carcinoma associated with breast reconstruction, which might have resulted in a higher breast implant prevalence. However, in this study, only 36 women (1.2% of the study population) underwent a chest radiograph for oncological examination of metastasized breast cancer or had a reported history of breast cancer; of these women, 19.4% (n = 7) had a breast implant. Another potential source of bias in the prevalence study is that we selected reviewers who were not specialized breast radiologists. However, we selected reviewers with a similar score as breast radiologists in the validation study, demonstrating that nonexperienced individuals can easily be trained to perform our assessment method, which supports its broad applicability. Another potential limitation that might have influenced the prevalence study is a lack of actual breast implant assessment in the northern, western, and central regions. However, we corrected for this utilizing the regional BSCP coefficients as well as the weight of the regional population size. Moreover, we selected a sample size to detect a prevalence of at least 1%, assuring the reliability of the identified 3.0%.

CONCLUSIONS

With a validated novel method employing routinely available chest radiographs, we were able to derive accurate age-specific breast implant prevalence rates for Dutch women. The description of the methodology and validity of our measurement procedures enables wide application in other countries. This will benefit absolute risk assessments in epidemiological studies on the full spectrum of health consequences of breast implants.

Disclosures

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