

Danish Centre for Evaluation and Health Technology Assessment

# USE AND PERFORMANCE OF CLINICAL MAMMOGRAPHY IN DENMARK

– a Health Technology Assessment – summary

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## Use and performance of clinical mammography in Denmark – a Health Technology Assessment

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# Summary

## The Study

The study was initiated in 1999 by the former Danish Hospital Evaluation Centre (DHEC) and carried out as a PhD-study at Institute of Public Health, University of Copenhagen and Centre of Diagnostic Imaging, University Hospital of Copenhagen in cooperation with Danish Centre for Evaluation and Health Technology Assessment under the National Board of Health. The study is a part of a wider evaluation of breast cancer diagnosis and treatment in Denmark. Other relevant studies of this area includes:

- a report of breast cancer treatment in Danish hospitals (published in 2000) (2)
- a report on standards for nursing care of women operated for breast cancer (published in 2004) (3)
- an evaluation of the Danish Cancer Action Plan, including efforts on the breast cancer front (published in 2004) (4)
- a report of patients view on treatment for breast lesions (published in 2004) (5).

This study evaluates the organisation, use and performance of clinical mammography in Denmark.

## Background and aims

Breast cancer is the most common cancer among Danish women, and about one in ten women will be diagnosed with breast cancer during lifetime (6). In 2001, 4230 Danish women were diagnosed with breast cancer (7), and 1333 women died of this disease (8). Since the 1940s, the incidence of breast cancer has doubled from 43 per 100,000 in 1943-47 to 80 per 100,000 in 1993-96, whereas the mortality has only increased from 36 to 43 per 100,000 women in the same period (7). Denmark is one of the countries in the world with the highest incidence and mortality of breast cancer.

Early and correct diagnosis of breast cancer is of great importance for the patient survival. Mammography is the most used examination type for diagnosis of breast cancer. It is used for two fundamentally different purposes, which are often mixed up even though they differ markedly in examination philosophy, organisation and structure. The two examination types are:

In the present report, we define a *Clinical mammography* as an examination consisting of 1) a physical examination and 2) diagnostic imaging (mammography and/or ultrasound). It is used to identify possible breast cancers in women who have signs or symptoms of this disease. Clinical mammography is often supplemented with needle biopsy examination, and these three examination types constitutes the most important modalities in the *breast assessment* which should be organised according to the principles for triple assessment (9). In Denmark, clinical mammography is available for all citizens free of charge after a referral from a general practitioner.

*Mammography screening* is used for asymptomatic women. The goal of mammography screening is to detect cancers, which are still too small to be felt by a woman or her physician, and thereby to reduce mortality from breast cancer. Today, mammography screening is often offered as organised mammography screening programmes where women in certain age intervals are invited to examination at specified time intervals. However, mammography screening may also be offered as *opportunistic mammography screening*, which is an examination of asymptomatic women outside an organised mammography screening programme.

The organisation and performance of mammography screening has been evaluated in several studies, whereas clinical mammography is rarely studied. Organisation of clinical mammography may vary considerable from one country to another, and only a few studies have evaluated the organisation of clinical mammography. In addition, little is known about how performance (sensitivity, specificity, accuracy and predictive values) of clinical mammography varies across different clinical settings, how performance vary across different communities, and how various organisational factors (e.g. type of clinic and activity volume) may influence the performance of clinical mammography. In addition, little is known about the mechanisms enhancing use of opportunistic screening.

A nationwide, community-based evaluation of diagnostic mammography and opportunistic screening has never been undertaken, possibly due to the potential complications in the collection of comprehensive data. In Denmark, we have the advantage of high quality population based and clinical based registers that can be linked by the unique Danish personal identification number.

A nationwide community-based evaluation of diagnostic mammography and opportunistic screening has never been undertaken, possibly due to the potential complications in the collection of comprehensive data. In Denmark, we have the advantage of high quality population based and clinical based registers that can be linked by the Danish unique personal identification number. In addition, the survival of Danish breast cancer patients is low compared with that of breast cancer patients in e.g. the other Nordic countries (10). This seems in part to be due to more advanced tumours at the time of diagnosis (11, 12), which could indicate a low quality of the diagnostic procedures. This suspicion was supported by data from a survey undertaken in Denmark in the mid 1990s which found 1 in 5 mammograms to be of low technical quality (13).

Efforts are therefore warranted to study the use, organisation and performance of diagnostic mammography in Denmark.

The present register based study was therefore designed with the following aims:

#### **Sub study 1**

To evaluate the organisation of clinical mammography and breast assessment in Denmark, in particular:

- to evaluate compliance of clinical mammography and breast assessment in Denmark in the year 2000 and the year 2002 with Danish (9) and European (EUSOMA – European Organisation of Mastology) guidelines concerning: 1) general organisation, 2) assessment procedures, and 3) activity volume.

#### **Sub study 2**

To determine performance (sensitivity, specificity, accuracy, and predictive values) of clinical mammography in Denmark in 2000, in particular:

- to evaluate the overall performance of diagnostic mammography in Denmark
- to evaluate the variation in performance of clinical mammography across clinics
- to identify organisational determinants of high performance of clinical mammography.

#### **Sub study 3**

To evaluate the use and interactions between clinical mammography, organised mammography screening and opportunistic screening in Denmark, in particular:

- to determine whether non-attenders in organised mammography screening use diagnostic mammography outside the screening programmes
- to assess the contamination from organised mammography screening to non-invited age groups
- to measure the impact of local policy on opportunistic screening.

The study is based on individual data on all persons who had a diagnostic mammography performed in Denmark in the year 2000. The study is a register-based study where single patients have not been contacted on any time. For confidentiality reasons the identities of examined patients, radiologists, and clinics are all encrypted in the present study.

## Material

No central database covering all diagnostic mammography examinations performed in Denmark exists. Therefore, data on diagnostic mammography were collected directly from all clinics. The clinics were identified via the mandatory notifications of all x-ray equipment to the National Board of Ionizing Radiation. All clinics were contacted and after some negotiations, all clinics agreed to participate in the study. Permission to undertake the study was given by the Data Protection Agency and the National Board of Health.

Individual data on clinical mammography examinations were collected directly from each clinic or from each county, as some counties had a central registration of all clinics within the county.

Afterwards, data were merged into one homogeneous database with a uniform structure.

In the final database, all clinical mammography examinations were registered as one record. Hence, women with more than one clinical mammography examination were registered with more than one record. Each record contained the following basic variables:

- Personal Identification Number
- county of residence
- name of clinic
- type of clinic
- county of clinic
- date of examination
- type of imaging (mammography and/or ultrasound)
- diagnosis (normal, benign, atypical, suspicious of malignancy or malignant).

For sub study 1, data concerning the number of clinical mammography examinations performed at public clinics in 2002 were used. These data were collected by the National Board of Health to be used in an evaluation of the Danish Cancer Action Plan (4).

For sub study 3, data on women targeted by the organised mammography screening programmes in 2000 were retrieved from Kommunedata A/S for Copenhagen, and from the local health care database for the county of Fyn. In addition, data from one private company providing screening mammography as a part of a research programme were retrieved.

In total, 142,378 mammography examinations were performed in Denmark in 2000. Of these 62,053 were clinical mammography examinations and 80,325 were mammography screening examinations.

## Methods

### **Sub study 1: Guidelines for clinical mammography and breast assessment**

Compliance of the diagnostic mammography and breast assessment activity in Denmark in 2000 and 2002 with the EUSOMA guidelines concerning: 1) general organisation, 2) assessment procedures, and 3) activity volume, was evaluated.

### Sub study 2: Performance of clinical mammography

Performance of clinical mammography is determined by comparing the result of the clinical mammography with the woman's breast cancer status within a 2 year follow-up period. Performance was measured as sensitivity, specificity, accuracy, positive predictive value and negative predictive value. The performance measures are defined as:

1. sensitivity:  $\text{true positive}/(\text{true positive} + \text{false negative})$ . Sensitivity is the proportion of positive diagnostic mammographies among women who are diagnosed with breast cancer during the follow-up period
2. specificity:  $\text{true negative}/(\text{true negative} + \text{false positive})$ . Specificity is the proportion of negative diagnostic mammographies among women who are not diagnosed with breast cancer during the follow-up period
3. accuracy:  $(\text{true positive} + \text{true negative})/(\text{true positive} + \text{true negative} + \text{false positive} + \text{false negative})$ : Accuracy is the proportion of women both with and without breast cancer who were diagnosed correct
4. positive predictive value:  $\text{true positive}/(\text{true positive} + \text{false positive})$ . Positive predictive value is the proportion of women who were diagnosed with breast cancer during the follow-up period among women who had a positive diagnostic mammography
5. negative predictive value:  $\text{true negative}/(\text{true negative} + \text{false negative})$ . Negative predictive value is the proportion of women who were not diagnosed with breast cancer during the follow-up period among women who had a negative diagnostic mammography.

The overall performance and performance in each clinic was calculated. In addition, the influence of the following variables on performance of clinical mammography was considered:

- age
- annual utilisation rate of clinical mammography within the county
- type of clinic
- number of clinical mammographies performed per clinic per year (MAM/CLINIC)
- whether the clinic had at least one radiologist reading a certain number of clinical mammographies per year (MAM/RAD).

Logistic regression analysis was used to assess the impact of each determinant on sensitivity, specificity and accuracy in a multivariate model.

### Sub study 3: Opportunistic screening

All data were linked by the Danish personal identification number. In the two counties with organised mammography screening, we calculated the proportion of attenders and non-attenders in mammography screening using diagnostic mammography in 2000. A chi-square test was used to analyse differences in proportions. In order to assess the contamination from organised mammography screening to non-invited age groups and to measure the impact of local policy on opportunistic screening, graphically analysis was performed.

## Results and discussion

### Use of clinical mammography in Denmark

In total, 55,163 clinical mammography examinations among 53,658 unique persons were performed in Denmark in 2000. A total of 47,953 diagnostic mammography examinations were performed in 32 public clinics (87%), 6616 were performed in private 12 clinics (12%), and 594 were performed in 3 private hospitals (1%). More than half of the clinical mammography examinations were performed among women aged 40-59.

The proportion of women aged 20-89 using clinical mammography in 2000 was 2.6%. Studies from other European countries have found remarkably higher proportions. In general, use of clinical mammography has been relatively limited in Denmark. Since the mid 1980's, there has only been a slight increase in the number of diagnostic mammography examinations. The reasons for the low use of clinical mammography in Denmark is not known. However, mammography screening is frequently discussed in the Danish mass media, reflecting the heated discussion in the international scientific literature. This may have caused confusion among Danish women concerning the pros and cons of mammography, and could therefore be one reason for the low use of mammography in Denmark.

#### **Guidelines of clinical mammography and breast assessment**

Breast assessment in Denmark, has been markedly centralised in a fewer number of breast assessment centres from 2000 (32 centres) to 2005 (23 centres), whereas the number of private diagnostic mammography clinics performing basic diagnostic mammography has remained stable.

The majority of the public breast assessment centres complied with the guidelines concerning organisation (multidisciplinary activity and rapid diagnosis) and assessment procedures (triple assessment and ultrasound/stereotactic guided needle biopsy).

However, compliance with the activity volume requirements in public breast assessment centres was not optimal. Still in 2002, 14 of the 25 breast assessment centres did not meet the requirement of 2000 mammograms per year, and only about half of the breast assessment centres had a radiologist reading at least 1000 mammograms per year. Therefore, in 2002, still a marked proportion of the Danish breast assessment centres operates with less than optimal activity volume suggesting that further centralisation will be appropriate. Fortunately, centralisation is in progress, as 10 out of 15 counties had only one breast assessment centre in the beginning of 2004.

The situation in private diagnostic mammography clinics with an agreement with the public health insurance may cause concern, as our study showed that the majority of these clinics did not meet the activity volume requirements.

#### **Performance of clinical mammography in Denmark**

Within the 2-year follow-up period, clinical mammography had an overall sensitivity of 75%, a specificity of 99%, an accuracy of 98% and positive predictive value of 81% and a negative predictive value of 99%.

Despite the presence of uniform guidelines from the National Board of Health and DBCG (9, 15), our study revealed a considerable variation in performance of clinical mammography across Danish clinics in 2000.

Only 2 American studies have evaluated the performance of diagnostic mammography at the community level. Compared with these two studies, clinical mammography in Denmark was at the same level, whereas the specificity was markedly higher in Denmark. Definitions used, patient populations, and methods of follow-up vary slightly between our study and the two US studies making comparison difficult. However, the results shows that a significant lower number of Danish women gets a false positive diagnosis compared with the women included in the 2 US studies. This may indicate different weights given in the US and in Denmark to on the one hand the fear of false negative test and on the other hand the risk of false positive tests.

Concerning the organisational factors, the presence of at least one high volume-reading radiologist increased accuracy. Clinics with a high volume-reading radiologist thus performed better, and they missed fewer cancers without increasing the burden of extra tests and/or operations in healthy women. Clinics with a medium number of clinical mammography examinations performed per year had the highest accuracy. Type of clinic did not affect accuracy.



Based on these results, it may cause some concern that only 28% of the public breast assessment centres in 2000 and 56% in 2002 complied with the EUSOMA requirement of having a radiologist employed reading at least 1000 mammograms per year. Among private clinics, only 25% of the clinics complied with the EUSOMA requirement of having a radiologist employed reading at least 500 mammograms per year. As the results in the present study showed that the presence in a clinic of a high-volume reading radiologist increased accuracy of the clinic, action should be taken to increase the radiologist experience in Danish clinics.

#### **Interactions between clinical mammography and mammography screening**

Non-attenders in organised mammography screening did not seek mammography outside the programmes, as only 3% of the non-attenders in Copenhagen and 1% in Fyn used diagnostic mammography in 2000. Use of diagnostic mammography is therefore not a major predictor of non-attendance in organised mammography screening programmes. In addition, our study showed that a positive policy towards opportunistic screening did not increase the proportion of women using diagnostic mammography, nor did an organised mammography screening programme induce opportunistic screening in non-invited age groups. Therefore, our results add further evidence to existing knowledge that the only reasonable way to achieve high mammography coverage is through a well-organised mammography screening programme.

#### **Perspectives**

As data covering clinical mammography and breast assessment in Denmark has a decentralised structure, the collection of data used in the present study has been very time demanding and is not suited for routine evaluation of performance of clinical mammography and other aspects of clinical mammography/breast assessment.

Future evaluations of clinical mammography would therefore strongly benefit if a central register containing data on patient characteristics, radiological data, and follow-up data on breast cancer was implemented. The combination of a central database and the Danish and European Guidelines for clinical mammography and breast assessment would thereby be a very helpful tool in order to improve the organisation and performance of clinical mammography and breast assessment in Denmark.