



Original Research

No overdiagnosis in the Norwegian Breast Cancer Screening Program estimated by combining record linkage and questionnaire information in the Norwegian Women and Cancer study



Eiliv Lund ^{a,*}, Aurelie Nakamura ^a, Jean-Christophe Thalabard ^b

^a Institute of Community Medicine, UiT the Arctic University of Norway, Tromsø, Norway

^b MAP5, Université Paris Descartes, Paris, France

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Abstract *Background:* The Norwegian Breast Cancer Screening Program (NBCSP) was implemented across the country in 2005 and has been criticised for potential ‘overdiagnosis’, i.e. a breast cancer diagnosis that otherwise would not have been detected or treated in a woman’s lifetime. We aimed to estimate overdiagnosis in the NBCSP based on the Norwegian Women and Cancer (NOWAC) study using both questionnaire information and record linkage information from NBCSP.

Method: For 124,978 women aged 49–79 years from the NOWAC study, information on screened women could be cross-validated from the NBCSP database. Based on information from the NOWAC questionnaire, *unscreened women* were further divided into those who had *mammograms taken only outside the NBCSP* and those who had *never had taken a mammogram*. Breast cancers diagnosed in 2005–2013 were identified through linkage to the Cancer Registry of Norway; *in situ or DCIS* 417; *invasive* 2845; *combined* 3262. Cumulative incidence rates (CIRs) for ages 49–79 years of breast cancer were compared using the log-rank test.

Results: After exclusion of women with a family history of breast cancer, screened women had a CIR of 9.7% for combined breast cancer, non-significantly lower compared with unscreened women. Screened women had a 1.1% increased CIR or 13.0% increased relative risk of breast cancer diagnosis (significant) compared with women who had never had a mammogram, but for invasive breast cancer alone the difference was reduced to –0.2% (95% CI: –9.1; 8.8). Invasive breast cancers were significantly smaller (<2.5 cm) in screened versus unscreened

* Corresponding author.

E-mail addresses: eiliv.lund@uit.no (E. Lund), aurelienakamura@gmail.com (A. Nakamura), jean-christophe.thalabard@mi.parisdescartes.fr (J.-C. Thalabard).

women. There was a borderline significant decrease in lymph node positive cancer among screened ($p = 0.06$).

Conclusion: The findings of no significant overdiagnosis combined with smaller tumours and less lymph node metastases suggest that the prevailing view of overdiagnosis in the NBCSP should be challenged.

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1. Background

Recently, concerns about the side-effects of national breast cancer screening programs have increased [1], including concerns about potential overdiagnosis. Overdiagnosis is defined as a cancer diagnosis that is a result of screening and that would not have been detected in the woman's lifetime if screening had not taken place. The amount and severity of overdiagnosis is heavily debated [2–4]. Several reviews and meta-analyses have been published over the last few years. An independent meta-analysis of three early clinical trials reported a 19% increased incidence of breast cancer among screened women in the target screening population (50–69 years), which decreased to 11% when women older than the screening age limit were included [2]. These figures were more dramatic in a 2013 Cochrane review, which reported an estimated overdiagnosis and overtreatment of 30% [3]. However, the 2014 balance sheet from the EUROSCREEN working group showed that women screened biennially from 50 to 69 years of age and then followed up for breast cancer incidence until 79 years of age had only four overdiagnosed cases out of 1000 screened women [4]. The recent International Agency for Research on Cancer monograph reported overdiagnosis estimates of 15–25% [5] similar to the estimates generated for the Norwegian Breast Cancer Screening Program (NBCSP) as part of an evaluation made by the Research Council of Norway [6]. An ecological analysis from the SEER registries in the United States reported even higher estimates [7]. In a recent systematic review published as part of the development of the American Cancer Association guidelines [8], the conclusion was that there is large uncertainty about the magnitude of overdiagnosis associated with different screening strategies. The same uncertainty of the estimates was expressed in a recent review [9].

The potential for ecological fallacy attributable to the extensive use of grouped data, e.g. geography as a proxy for screening attendance, has often been neglected, and resultant associations interpreted as causal. The rapid increase and decrease of hormone replacement therapy (HRT) use around year 2000 could also add to the uncertainty of ecological analyses, as HRT reduces the

sensitivity and specificity of mammography [10]. In addition, most women with a family history of breast cancer are under specific surveillance outside of national screening programs; this is the case for a substantial portion of women with a family history of breast cancer in Norway [11]. As these women are followed regularly outside the NBCSP, they should not be included in analyses of overdiagnosis as unscreened. However, estimates of overdiagnosis *should* reflect the two different subgroups among unscreened women, as in reality, many unscreened women undergo opportunistic screening or wild screening outside national screening programs. Thus the best and most accurate reference group should consist of women who have *never* had a mammogram. Analyses of overdiagnosis should also take into consideration that *in situ* diagnoses are generally based on mammographic information, not clinical examination, and that mammographic diagnoses of *in situ* cancer are an expected effect of screening. Indeed, such diagnoses allow for the detection and removal of lesions before they progress to invasive cancer. The progression rate to invasive breast cancer is unknown, but early removal of *in situ* lesions should reduce later incidence of invasive breast cancer [12].

The aim of this analysis was to determine the presence of overdiagnosis in the NBCSP during its first 9 years of national coverage (2005–2013) based on information from the Norwegian Women and Cancer (NOWAC) study, one of the few studies with information on mammograms performed within and outside a national breast cancer screening program.

2. Methods

2.1. The Norwegian Breast Cancer Screening Program

The NBCSP started in 1996 in four Norwegian counties as a pilot program and was fully implemented across the country early in 2005. Women aged 50–69 years are invited to be screened by digital mammography within the NBCSP every other year. At the start of the study period (2005), prevalence screening had just been completed in the last two counties. Consequently, in the study period all women were first invited or screened at age 50 to 51.

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