

Service Screening with Mammography in Sweden

Evaluation of Effects of Screening on Breast Cancer Mortality in Age Group 40–49 Years

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The aim of the study was to develop a model for estimating the effect of the nation-wide service screening program with mammography on breast cancer mortality in Sweden. In 1997, the introduction of population-based service screening had been completed in all 26 counties. In approximately half of the counties suitable for evaluation, the lower age limit for invitation was 40 years (study population) and in the other half the age limit was 50 years (control population). The numbers of females aged 40–49 years for the two populations were 202152 and 237279, respectively (1988). The study and control populations were compared for the period 1986–1996 with regard to refined breast cancer mortality. To adjust for geographical differences, the period 1976–1986 was used as reference. With a mean follow-up time of 8 years, the estimated relative risk of breast cancer death in relation to invitation to service screening among women aged 40–49 years at breast cancer diagnosis was 0.91 (95% confidence interval 0.72–1.15). These findings were compatible with those presented in the previous overview of the Swedish randomized studies.

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During the past decade nation-wide mammography screening programs have been established in the United Kingdom, The Netherlands, Finland, Iceland and in Sweden. Pilot projects are ongoing in most of the EC member states in order to build up mammography screening for all women in the age groups 50–64 years, with the expectation that this will reduce the number of deaths from breast cancer. Based on results from the controlled trials in terms of mortality reduction, the consensus is that the age group invited to screening should include women aged 50–69 years. However, because of uncertainties about the effect of screening in 40–49-year-olds, this age group has been the target of interest in recent years. Some randomized studies with prolonged follow-up have indicated a mortality reduction in women aged 40–49 years at entry to the study (1–3).

The outcome measures applied in the evaluation of the effect of population-based mammography screening on a routine basis (so-called service screening) have mostly been limited to surrogate measures such as attendance rates, (4) cancer detection rates, (5, 6) interval cancer rates, (7, 8) and incidence of advanced cancers (9). There is no consensus on how the effect of service screening programs should

be evaluated in terms of reduction of breast cancer mortality.

A study (comprising 10% of the Swedish population) with the aim of evaluating the Swedish service screening program was conducted in the northern part of the country. This study showed that invitation to screening was associated with a statistically significant reduction in breast cancer mortality in the age group 50–69 years (10). The mortality reduction was quantitatively comparable to that reached in the randomized studies, but since the material was too small and the follow-up too short for an evaluation of the age group 40–49 years, it was considered of interest to extend the study to include the whole country.

The aim of the study was to develop a model to evaluate and estimate the effect on breast cancer mortality of the nation-wide service screening program with mammography in the age group 40–49 years in Sweden.

MATERIAL AND METHODS

When the first results from the two-county study in Sweden became known (11), the National Board of Health and Welfare issued nation-wide recommendations for mammography screening. The guidelines included recommen-

Table 1

Female population aged 40–49 years (1988), time of screening start, years of follow-up in the study, cumulative number of breast cancer deaths, mortality rates (refined mortality) and number of person-years in the geographical areas for the reference and the study periods, respectively

Geographical area	County	No. of women 40-49 years, 1988	Starting month/year	Years of follow-up	Reference period		Study period		
					Person-years *1 000	Cum. no. of bc deaths	Person-years *1 000	Cum. no. of bc deaths/ 100 000	Cum. No. of bc deaths/ 100 000
Geographical areas with 40 as lower age limit for invitation to screening									
Eksjö/Nässjö	Jönköping	7 065	8/86	10	90	11	123	8	79
Kalmar	Kalmar	15 689	10/86	10	192	24	125	18	80
Västmanland	Västmanland	18 220	10/86	10	215	19	88	36	140
Jönköping/Ryhov	Jönköping	12 722	4/87	9	134	15	101	22	126
Trelleborg	Malmöhus	9 928	4/87	9	90	11	110	18	130
Örebro	Örebro	18 965	10/87	9	186	12	58	28	107
Uppsala	Uppsala	18 761	10/88	8	143	20	112	26	98
Södra Älvsborg	Älvsborg	18 234	11/88	8	158	17	86	23	92
Norrbottn	Norrbottn	17 686	3/89	7	142	13	64	15	64
Lund	Malmöhus	16 023	4/89	7	104	11	74	9	42
Södermanland	Södermanland	17 834	11/89	7	130	12	65	14	59
Västernorrland	Västernorrland	17 776	1/90	7	140	12	60	11	48
Helsingborg	Malmöhus	9 960	3/91	5	49	6	61	7	55
Landskrona	Malmöhus	3 289	9/93	3	10	0	0	0	0
Total		202 152			1 781	183		2 229	235
Geographical areas with 50 as lower age limit for invitation to screening									
Bohus	Göteborg/Bohus	21 105	11/86	10	237	34	144	45	147
Halland	Halland	17 014	1/89	10	189	32	169	40	160
Skaraborg	Skaraborg	17 923	4/89	10	211	23	109	25	97
Ängelholm	Kristianstad	6 103	5/89	10	70	6	85	13	145
Danderyd	Stockholm	22 731	8/89	10	221	26	118	55	174
Karolinska	Stockholm	22 156	8/89	10	226	24	106	44	145
Skärholmen/ Huddinge	Stockholm	27 746	8/89	10	319	47	147	43	113
Sabbatsberg/ St Göran	Stockholm	19 830	3/90	10	207	19	92	39	136
Kronoberg	Kronoberg	11 430	8/90	10	139	23	166	36	216
Kristianstad	Kristianstad	12 745	11/90	10	153	12	78	30	163
Värmland	Värmland	18 498	4/93	10	235	32	136	27	101
Norra Älvsborg	Älvsborg	11 589	11/93	10	134	19	142	20	121
Västerbotten	Västerbotten	16 137	2/95	10	201	18	90	26	111
Jämtland	Jämtland	8 556	5/96	10	105	14	134	26	211
Gotland	Gotland	3 716	5/97	10	43	6	140	7	129
Total		237 279			2 690	335		3 383	476

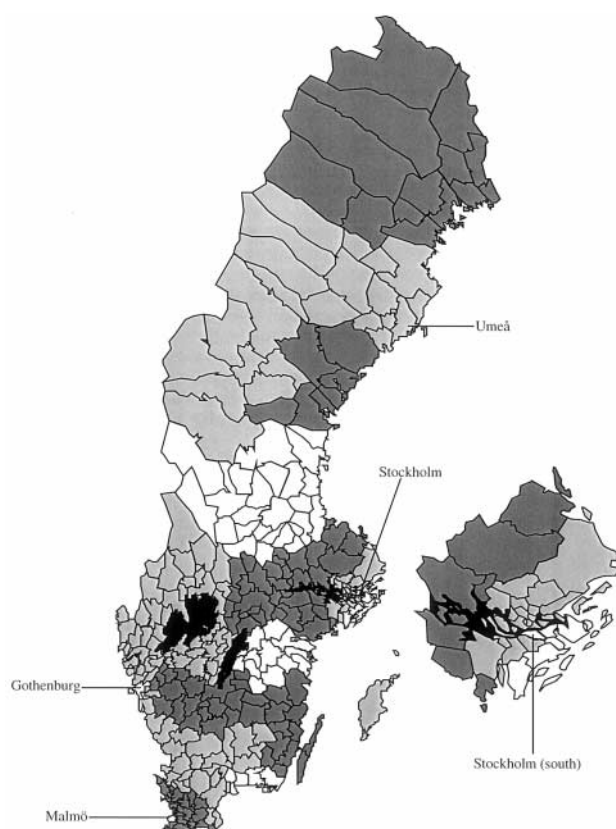


Fig. 1. Geographical areas (divided into municipalities) where the lower age limit for mammography screening was 40 years (dark grey) and 50 years (light grey). The white areas refer to the counties excluded from the study.

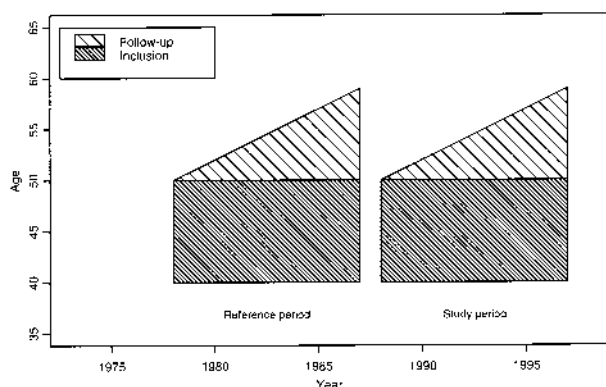


Fig. 2. Schematic illustration of the inclusion and follow-up of a cohort where invitation to screening started in January 1988, reference and study periods.

dations for a lower age limit not below 40 years and not over 50 years, and an upper age limit not below 69 years. Service screening in Sweden started in 1986 in the first counties and by 1997 it had been introduced in all 26 counties.

From the potential study population consisting of all 26 counties, we excluded counties or parts of counties where

randomized studies had already been performed (Kopparberg, Östergötland and the cities of Stockholm (south), Gothenburg and Malmö), and the counties of Gävleborg and Blekinge, which left us with 20 counties or parts of counties suitable for evaluation of screening effects. The reason for excluding Gävleborg was that population-based screening had already been introduced there in 1974, whereas Blekinge was excluded because, there, the lower age limit for invitation to screening was 45 years.

Some of the counties applied two or more screening programs that differed in starting year and lower age limit. We therefore had to divide those counties into smaller geographical areas to obtain more homogeneous units (Table 1). The geographical distribution of the different areas can be found in Fig. 1.

One advantage was that approximately half of the studied geographical areas had 40 years as the lower age limit for invitation to screening and the other half had 50 years. In 1988 the female population aged 40–49 years was 202152 in geographical areas with 40 years as the lower age limit and 237279 in geographical areas starting at 50 years.

Furthermore, in the geographical areas where women were invited from the age of 40, the screening started earlier than in those where women were invited from the age of 50 years (Table 1). In 12 out of 14 of the geographical areas the screening intervals in the age group 40–49 years were shorter than 24 months (18–22 months), with a mean screening interval of 20 months.

Screening data (time of start of screening program, progression of the activities within the geographical areas, age limits, interval between screening rounds, etc.) were obtained from the screening centres using a questionnaire. For each breast cancer case data on diagnosis and death were obtained from the nation-wide Swedish Cancer Registry. Aggregated population data by calendar year and 5-year age groups were obtained from Statistics Sweden.

All organized mammography screening in Sweden is population-based. The geographical areas where the lower age limit for screening was 40 years formed the basis for the study population, and the geographical areas which started screening at age 50 years constituted the control population (Fig. 1, Table 1). We have studied two time periods, 1976–1986 (reference period) and 1986–1996 (study period). The time of start of screening in the study population varied between 1986 and 1993 and was on average July 1988 (Table 1). The study population was defined as a cohort for each geographical area during the study period, illustrated by the rectangles in Fig. 2, comprising all women of 40–49 years of age from the month when invitation to screening started and through 1996. Corresponding cohorts were also defined in the reference period with the same delays due to screening start in the respective geographical areas. For each geographical area in the control population, cohorts were defined in the same

way, including all women of 40–49 years of age in 1977–1986 and 1987–1996 for the reference and the study period, respectively. The cohorts in the reference period were followed with respect to breast cancer death through 1986 and the cohorts in the study period through 1996 (Fig. 2). The reason for choosing a later start in the reference cohorts was that in the study population no geographical area had been followed for 11 complete years. For all geographical areas the time of start of follow-up was set to 0.

We did not utilize individual data on the population cohorts defined above, but among the breast cancer cases individual information was used on date, age and residence at breast cancer diagnosis, date of death and cause of death. For the computation of person-years aggregated population data were used.

A breast cancer case was defined as a case of invasive breast cancer (site code = 174 in the International Classification of Diseases, ICD-9 and histopathological code = 096 according to WHO/HS/CAN/24.1) diagnosed at age 40–49 years during the reference or the study periods. If a woman had two breast cancer diagnoses in one of the periods 1976–1986 or 1986–1996, the second cancer was excluded. A breast cancer death was defined as a case reported to the Cause of Death Register with breast cancer as the underlying cause of death not later than December 31, 1996.

Age-specific breast cancer mortality/100000 was plotted for the study and the control group. This was based on the total number of breast cancer cases each year, here referred to as *total mortality*. The breast cancer mortality of cases diagnosed after a certain time point is referred to as *refined mortality* (10, 12)

Cumulative refined breast cancer mortality/100000 was computed with the mean number of person-years as denominator and cumulative relative risks were estimated. In contrast to total mortality, refined mortality can of course not be given the same interpretation for different years of follow-up. The important thing, however, is to achieve comparability between the study and control groups given the same follow-up time. To adjust for possible geographical differences in breast cancer mortality between the study group and the control group, the relative risk for the study period was divided by the relative risk for the reference period. This ratio is the relative risk owing to invitation to screening, assuming multiplicative effects between the groups and the time periods.

The refined breast cancer mortality was analysed in a multiplicative Poisson model with the annual number of breast cancer deaths as dependent variable and year of follow-up, geographical area and time period as covariates, all categorical (13). The screening effect was measured by a dummy variable taken = 1 for the study group cohorts in the study period and 0 elsewhere. The number

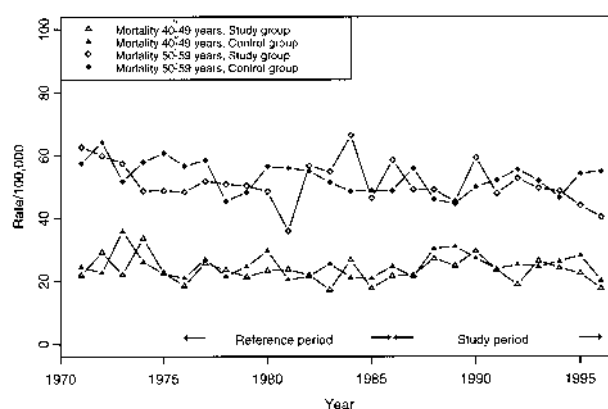


Fig. 3. Annual total breast cancer mortality/100000 1971–1996 in Sweden for women aged 40–49 years and 50–59 years at death. The figure is based on counties where Älvsborg is not included and Stockholm county as a whole is included in the control group.

of person-years defined by the cohorts and the follow-up were taken as offset.

The computations and statistical analyses were done using the program S-Plus (14).

RESULTS

As background information, the annual age-specific total breast cancer mortality rates for women aged 40–49 and 50–59 years for the study group and the control group during the period 1971–1996 are presented in Fig. 3.

The follow-up in the study period was measured from the month of start of invitation to screening in each study area and from January 1987 for the control areas. This was 10 years for the control areas and varied from 3 to 10 years within the study areas. The mean follow-up time in the study areas was 8.0 years.

During the study period, 1986–1996, there were 235 breast cancer deaths observed in the study cohorts and 476 in the control cohorts. The cumulative number of breast cancer deaths and the cumulative breast cancer mortality (refined mortality) by geographical area and period are presented in Table 1 and the cumulative refined breast cancer mortality for the study group and the control group in the two time periods is given in Fig. 4. Owing to the large variation in the estimates for each geographical area, only the aggregate measures for the study and control cohorts were used. The cumulative refined breast cancer mortality per 100000 at 10 years was 105.4 and 140.7 for the study group and the control group in the study period. In the reference period the figures were 102.7 and 124.5, respectively. Hence the relative risk in the screening group was 0.91 $(105.4/140.7)/(102.7/124.5)$ and the 95% confidence interval 0.72–1.15.

In the study group three geographical areas were followed for 10 years. The corresponding cumulative refined breast cancer mortality rates per 100000 for these three geograph-

Table 2

Goodness-of-fit statistics for the different models

Model	Terms included in the model	Degrees of freedom	Deviance	Compared models	Difference in deviance	p-value
	Null	517	761.7	—		
1.	Year of follow-up	508	513.0	Null-1	248.7	<0.001
2.	1+ Geogr. area	480	469.7	1-2	43.3	0.03
3.	2+ Time period	479	466.9	2-3	2.8	0.09
4.	3+ Screening	478	466.3	3-4	0.6	0.44

ical areas compared to the control group were 106.1 and 108.8 in the study period and the reference period, respectively. Hence the relative risk at 10 years was 0.86 $(106.1/140.7)/(108.8/124.5)$ and the 95% confidence interval 0.58–1.27.

The refined mortality data were also fitted in a multiplicative Poisson model and the results are presented in Table 2. Only two covariates were found to be statistically significant, namely year of follow-up ($p < 0.001$) and geographical area ($p = 0.03$). The estimated relative risk as a result of invita-

tion to screening from this model was 0.91 (95% confidence interval 0.72–1.15). Thus, taking into account the year of follow-up and geographical area did not change the result.

DISCUSSION

There are many justifications for undertaking this study in Sweden. The nation-wide cancer registration, which started in 1958, has a documented high level of validity (15, 16). The Cause of Death Register contains information on all deceased individuals since 1952 and the official authorities hold continuously updated population registers. All these registers are available for scientific research. Furthermore, the unique personal identification number that is assigned to all citizens and which is used in all population statistics allows for easy record linkages between the registers.

In a previous study, a 19% estimated reduction in total breast cancer mortality associated with mammography screening in women aged 50–74 years was found by comparing breast cancer mortality data in counties having participated in the randomized studies with data in those that had not (17). A study in England and Wales found a 12% reduction in total breast cancer mortality 7 years after start of screening (18). A study in Finland showed a 0.24% reduction in refined breast cancer mortality for a screening program covering women aged 50–59 years (12). Another study from northern Sweden (10) indicated a 33% reduction in excess refined mortality related to breast cancer in a service-screened population in comparison with an unscreened population for women aged 50–69 years. These studies showed a mortality reduction comparable with the randomized studies for women aged 50 or more, also indicating that there is no reason to anticipate any major differences between the randomized studies and routinely performed service screening.

The present study of service screening with mammography in Sweden showed no significant effect on refined breast cancer mortality with a mean follow-up of 8 years after start of invitation to screening in women aged 40–49 years who were diagnosed with breast cancer. Assuming the length of the first round to be 2 years, the average individual follow-up from first invitation to screening was 7 years. In the latest overview of all Swedish randomized studies the observed effect on mortality was evident after 8 years of follow-up after randomization (1). The latest follow-up of the randomized trials in Malmö and Gothenburg have shown significant

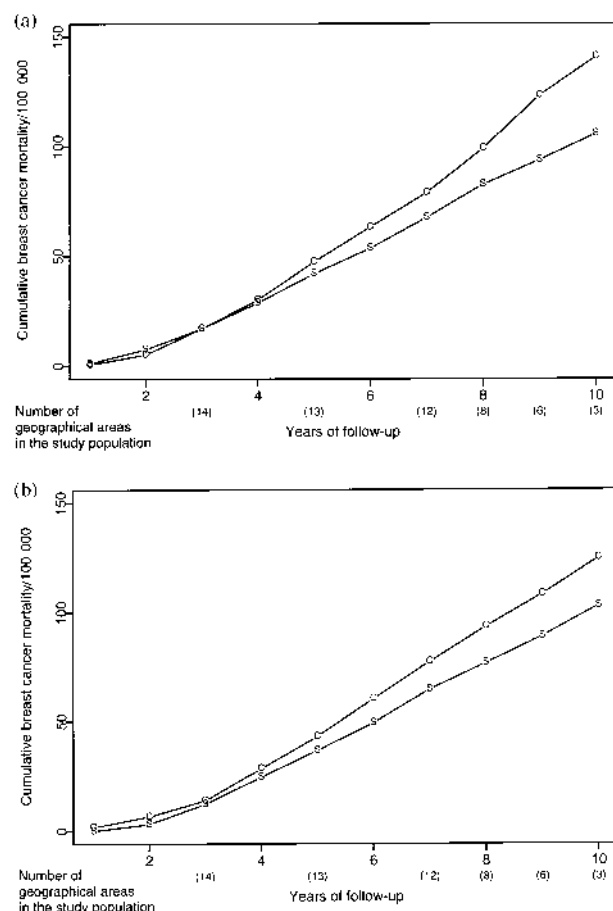


Fig. 4. Cumulative number of breast cancer deaths/100 000 (refined) for women aged 40–49 years at diagnosis for the study population (S) and the control population (C) by year since start of follow-up. Study period 1986–1996. (a) Reference period 1976–1986. (b) The study population is adjusted to the delay of screening start in the study period.

effects on breast cancer mortality in women aged 40–49 years at entry (1–3).

The follow-up differed in length between the two groups, being on average 8 and 10 years, respectively, for the study and the control groups. If the annual refined mortality rate is not constant during the follow-up, this can cause a bias. Although this possible bias should be corrected for by the adjustment using the reference period, we also derived the relative risk when all the geographical areas in the control group were followed for 8 years. The estimated relative risk became 0.97, which suggests that this possible bias might have increased the mortality reduction.

In the present study, service screening was routinely investigated. We found no obvious differences in quality indicators such as attendance rates, recall rates, screening intervals, cancer detection rates, etc., between the service screening and the randomized trials.

An important factor to take into account is the use of mammography in the control population. In a survey from Stockholm, it was shown that the majority of mammography examinations performed outside the organized screening program were in the age group 40–49 years (19). If very frequent in the control population, such opportunistic 'wild' screening will of course dilute potential differences in breast cancer mortality between study and control populations. Opportunistic screening is a phenomenon that mainly occurs in large cities, e.g. Stockholm, which in the present study constitutes 39% of the control group.

Another reason for dilution of the results stems from difficulties in defining the studied population at the beginning, since it takes the first screening round progressively to include all the women within a screening area (Fig. 5). We included all incident breast cancer cases after start of

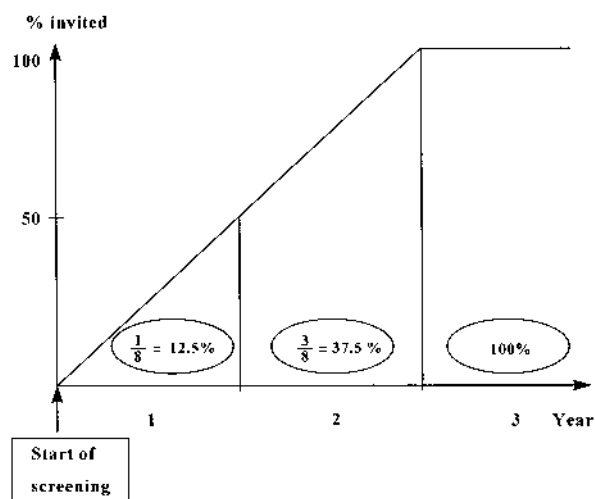


Fig. 5. Schematic illustration of proportion of women exposed to screening during the first and second year after start of screening when the screening interval is 24 months. The indicated proportions are in relation to the total area for the two years.

invitation to screening within a geographical area, which implies the inclusion of an unknown number of cases diagnosed before invitation to screening during the first round. This will, of course, lead to a dilution of the potential benefits of screening, since a number of not yet invited breast cancer cases were included within the screened population. The magnitude of the problem was estimated by simulation, using the assumption that the length of the first screening round was two years. For a given calendar period of two years, we assumed an individual random time point for invitation for each woman diagnosed with breast cancer to be uniformly distributed over 0–2 years. The cumulative refined breast cancer mortality among the women diagnosed with breast cancer before invitation in the period was then determined. This was replicated 200 times in each of the periods 1982–1983 and 1984–1985 and the mean cumulative refined breast cancer mortality was computed. Breast cancer cases in the combined study and control groups were used. This estimated mortality made it possible to calculate an expected number of breast cancer deaths in the study cohorts among the cases diagnosed before they were invited to screening, which was 56 (24% of the observed number of breast cancer deaths in the study cohorts during the study period, O). If the relative risk is formulated as O/E , where E is the corresponding expected number in the study period without screening we can do a straightforward correction of the relative risk (RR). The corrected relative risk becomes $(O - \psi/O)/(RR - \psi)$ where ψ is the expected number of breast cancer deaths of women diagnosed with breast cancer before invitation to screening during the first 2 years. This calculation reduces the relative risk from 0.91 to 0.88.

In randomized studies the analysis is made according to age at randomization, i.e. at entry to the study. Thus women aged 40–49 years at randomization may have been over 50 years when the cancer diagnosis was made, thereby in reality belonging to the age group 50-years and above. In some studies a distinction is made between women diagnosed with breast cancer before the age of 50 and those diagnosed at 50 years or later (1, 3, 20). In none of these studies has a significant reduction in breast cancer mortality been shown for women with breast cancer diagnosed before the age of 50. In the present study we included only those women diagnosed before the age of 50.

In the present study, age was defined as age at diagnosis, suggesting that a lead-time bias might have been introduced. If women in the study areas who were diagnosed with breast cancer and died during the study period had been diagnosed at an earlier stage of the disease than those in the control areas, a case may have been classified as belonging to the age group 40–49 years if diagnosed before age 50 in the group invited to screening, whereas a corresponding woman in the control group might have been over 50 years at diagnosis, even though she had an

otherwise comparable cancer and died from it at the same time. The mean survival time among women who died from breast cancer was 0.11 years longer in the study population during the study period for prevalent breast cancer cases aged 40–49 years at diagnosis than in the control population. In this material this difference in survival time suggests that one (0.4%) of the women in the study group who died of breast cancer during the study period was more than 49.89 years of age at diagnosis and hence would have been more than 50 years of age if the diagnosis had not been made earlier by mammography, assuming the same lead time for every woman. This corresponds to a reduction in the estimated relative risk of 0.4%.

To summarize: in the Swedish service screening program with a mean screening interval of 20 months and a mean follow-up of 8.0 years, the reduction in refined breast cancer mortality was estimated at 9%. This may be an underestimated effect due to opportunistic screening in the control cohorts, the inclusion of cases in the study cohorts diagnosed before invitation and the lead time bias in the study cohorts. The effect is not incompatible with the previous results of the Swedish randomized, controlled trials.

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