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Original article

Diagnostic delay of breast cancer – An analysis of claims to Swedish Board of Malpractice (LÖF)

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ABSTRACT

Aim: Delay in the diagnosis of breast cancer may have important clinical and medico-legal implications. This study examined the decisions made by reviewers at the Swedish agency (LÖF) that handles claims of medical malpractice where claimants seek compensation for alleged suffering and/or negative clinical impacts of diagnostic delays.

Material and methods: In 1995–2006 a total of 134 women filed claims for negative effects resulting from delays in the diagnosis of breast cancer. Review of the claims led to approval of delay in the primary diagnosis for 62 women and of recurrence for 28 women. The clinical symptoms that were overlooked and other causes of delay that had any relation to therapy, prognosis and economic compensation were identified. The verdicts reached were analysed.

Results: The median delay in the diagnosis of the primary disease was 11 months and for recurrent disease 3.5 months. Delay in diagnosis of the primary disease was considered to have an impact on the therapy in 23%. The prognosis was postulated to have been adversely affected 11% of the patients for whom the delay was longer than 12 months. Delay in diagnosing the recurrence was contributing to delay in starting therapy and to unnecessary suffering in 32%. The delay in diagnosis was mainly caused by incomplete clinical or radiological examination and by misinterpretations of the examination results. Economic compensation was given in 90%. There was a warning or admonition to the responsible doctor in a third of the cases referred to the judgement court.

Conclusion: This study demonstrates that claims for compensation for delay in diagnosis of breast cancer in Sweden occur in about 1/1000 new patient. The delay in the diagnosis of the primary tumour was considered to have an impact on the magnitude of therapeutic measures in almost 25% of the women who filed claims. Economic compensation for the patients' injuries was given in ninety percent of the cases. In women for whom there was a delay in diagnosing the recurrence there was consequently a delay in starting the palliative therapy.

Introduction

Breast cancer is the most common cancer in women in Sweden. There are annually about 7000 cases reported to the Swedish Cancer Register.[1] A screening program for women 40–70 years has been in use in Sweden since 1986.[2] Information on the importance of early diagnosis is continuously provided for the public to help them understand that any delay in the diagnosis of breast cancer may have negative consequences.

There is good evidence that patient delay of more than three months has a negative impact on survival. In contrast, a delay in the physician's diagnosis of breast cancer has not been found to lead to lower survival.[4–6]

Contradictory to the statement that doctor's delay is not important, there are retrospective studies in which a cancer was missed during the first mammogram examination, and adverse effects of the delay were identified in some cases. In cases, where the diagnostic delay was more than one year, the patient could have been treated with less mutilating breast conserving surgery if the diagnosis had not been missed.[7]

In Sweden a patient insurance system has been in effect since 1975 that offers compensation to patients who can demonstrate

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injuries caused by health-care practitioners. Patients who have been treated within the medical service system financed by the county medical councils can report their claims to the malpractice insurance review board referred to here as LÖF (*Landstingens Ömsesidiga Försäkringsbolag* or in translation to English *The County Council's Mutual Insurance Company*). They may request economic compensation for the suffering they experienced and/or negative impacts on the treatment and the prognosis of the disease. The insurance covers both physically and psychologically adverse effects. It must be shown that there is a causal relationship between the alleged injury and medical care and that it can be demonstrated that the injury could have been avoided.

The aim of this retrospective analysis was to explore the consequences of the patients' reports to the LÖF of delay in establishing diagnosis of breast cancer. The analysis was focused on treatment changes, impact on prognosis and economic compensation and also if claims to another agency, the Swedish Board of Malpractice (HSAN), had been analysed in the same manner and had led to similar judgements. An analysis of survival in two different delay-cohorts was calculated.

Material

During the period 1995–2006, 134 cases alleging delay in the diagnosis of breast cancer were registered with LÖF (the national insurance company for malpractice in Sweden, covering 95% of Swedish medical care). When the charts and reports of these cases were scrutinized, 44 were excluded for the following reasons: inability to demonstrate delay in diagnosis of primary disease ($n = 10$), delay in diagnosis of recurrence ($n = 5$), incomplete surgery or treatment complications ($n = 23$). In six individuals no cancers were diagnosed.

The alleged diagnostic delay was calculated from the date given in the patients' reports to the LÖF of delay in diagnosis of primary breast cancer or recurrence of disease. That date should be synchronous with the date for the medical consultation for the symptoms in available charts or the date for screening procedure to date of established diagnosis. The authors judged the impact of delay on prognosis and consequences on therapy without reference to statements made by reviewers at LÖF. If the delay had an impact on therapy or prognosis the authors judged that question separately. If there were incongruence in these judgements the term supposedly was added. There were no analyses of psychological harms on the individual patient.

Information from HSAN was received by a written request. HSAN is the official Swedish judge for investigating malpractice in medical care and if disciplinary punishment is justified, the sanction has two grades, major or minor verdict.

Data concerning survival were received from Swedish Cancer Register.

Statistics

The survival probability was analysed using the Kaplan–Meier method (Stat-view® 5.0).

Anova factorial (Stat-view® 5.0) was used for analysing differences between groups.

Results

There were 62 delayed diagnoses of primary tumour and 28 of recurrent or metastatic disease. The age distribution in four cohorts on the date of missed diagnosis is shown in Table 1 and the background symptoms for diagnostic delay are shown in Table 2. The predominant symptom for primary disease was identification of a mass in 49/62 (79%) and for recurrent disease reported bone pain in 17/28 (61%). Staging of the primary tumour ($n = 62$) and the duration of diagnostic delay (in months) in three cohorts (less than 4, 4–11 and more than 12 months) is shown in Table 3.

Table 1
Age cohort distribution for individuals at time for missed diagnosis of breast cancer – primary and recurrent disease.

Age (years)	Primary tumour (number)	Recurrent disease (number)	Total
<40	13	4	17
40–49	24	7	31
50–59	15	11	26
≥60	10	6	16
Total	62	28	90

The median alleged delay in diagnosis of the primary disease was 11.0 months (range 0.7–84) and of recurrent disease 3.5 months (0.5–38.7). The mean delay was significantly longer for primary than for recurrent disease (14.5 months vs 8.3 months) ($p = 0.0282$).

Thirty women of 62 with primary breast cancer filed claims for diagnostic delay of more than a year. Patients who had a cancer in stage 2 had the longest time for delay, twenty-two out of 36 (61%) had more than 12 months (mean 17 months) (Table 3). For recurrent disease the delay was less than 4 months in 13 patients (46%), 4–11 months in 8 and more than 12 months in 7 patients.

In cases with diagnostic delay of primary disease the delay was judged to have an impact on the extent of therapy in 14 of 62 cases (23%) mostly in the form of more extensive surgical procedures, i.e. mastectomy instead of partial resection (Table 4). For recurrent disease it was considered that the delay contributed to a later initiation of radiation therapy, of chemotherapy or of hormonal therapy in 9/28 (32%).

A negative impact of diagnostic delay on the prognosis of primary disease was estimated to be almost certain in 4 and less certain in 9 patients (in total 13/62, 21%). No impact on prognosis was identified for delayed diagnosis of recurrent disease (Table 5). In total 37 cases the diagnostic delay was more than 12 months. Of the 13 women with primary disease who were considered to have a probable detrimental delay on prognosis all but one had a delay of more than 12 months.

The Kaplan–Meier curves showed no significant impact on survival related to diagnostic delay of the primary tumour of more or less than 12 months.

Economical compensation for diagnostic delay was approved for 57/62 (92%) with delay of primary disease and in 24/28 (86%) with recurrent disease.

Table 2
Observed symptoms and signs (number) at time for missed diagnosis.

Symptoms	Primary tumour	Recurrent disease	Total
Cerebral symptoms	0	1	1
Chest pain	1	0	1
Dyspné	0	1	1
Follow up missed	0	1	1
Skeletal pain	1	17	18
Retracted nipple	2	0	2
Screening	8	0	8
Nipple secretion of blood	1	0	1
Tumour mass	49	7	56
Vertigo	0	1	1
Total	62	28	90