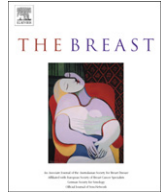




Contents lists available at ScienceDirect

The Breast

journal homepage: www.elsevier.com/brst

Original article

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

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ARTICLE INFO

Article history:

Received 17 November 2010

Received in revised form

9 June 2011

Accepted 26 June 2011

Keywords:

Diagnostic delay

Medico-legal consequences

Screening

Recurrent disease

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.

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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

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

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.

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

Table 3

Distribution of patients with primary tumour (number) in delayed time cohorts regarding staging at diagnosis.

Delay time (months)	Stage 1	Stage 2	Stage 3	Stage 4 (M+)	Total
<4	3	2	2	0	7
4–11	4	12	5	4	25
≥12	3	22	4	1	30
Total	10	36	11	5	62

The malpractice judgement court (HSAN) was involved in 48 cases and there was a verdict of malpractice in 15(31%). All except one of the patients in these cases got economic compensation by LÖF (Table 6).

Discussion

This study indicated that claims for compensation for delay in diagnosis of primary breast cancer in Sweden occur in about 1/1000 new patient. The delay in diagnosis of the primary lesion was mainly the result of clinical or radiological errors. In the majority of cases, the delay in diagnosis of the recurrence of disease was due to misinterpretation of bone pain from metastatic lesions. The delay in diagnosis of the primary tumour was considered to have an impact on the surgical procedure in almost a quarter of the patients. The consequences of the delay on prognosis were estimated to be in same range and all but one of them experienced a delay of more than 12 months. The delay in diagnosis of recurrence contributed to unnecessary suffering but had no consequences for prognosis. Economic compensation was paid to 90% of the claims.

The rate of delayed diagnosis of breast cancer reported in the literature varies widely. In a British breast clinic 1.4% of symptomatic patients experienced a diagnostic delay.⁷ Other studies have reported higher rates varying from 4 to 39%.^{8–10} From the present study it is not possible to draw any conclusion of the total rate of diagnostic delay of breast cancer in Sweden. However, it is noteworthy that during the analysed period the malpractice insurance (LÖF) processed fewer than six cases annually dealing with diagnostic delay of breast cancer of a total of 11,000 claims for medical malpractice per year. This low number has also to consider in light of the fact that in Sweden 7000 women are diagnosed annually with breast cancer. Thus approximately 0.1% (6/7000) claim economic compensation for diagnostic delay of breast cancer. Supposedly there are hidden statistics of women who refrain from filing claims.

In the reviewed series of 62 patients the presence or suspicion of a lump was incompletely investigated in almost 80% of the cases mainly because mammography and subsequent fine needle aspiration were not undertaken or because the findings were not correctly interpreted. In some cases the clinician did not pay enough attention to the patient's history, disregarding her report that she had felt a lump in her breast. In a few cases clear clinical signs of the presence of a malignant tumour were missed. In 8/62 (13%) the delay in diagnosis of the primary tumour was due to a false-negative assessment of the mammograms from the screening mammography

Table 4

Impact of delay on therapy on primary and recurrent disease.

	None	Supposedly	Yes	Total
Primary tumour	48	2	12	62
Recurrent disease	19	0	9	28
Total	67	3	20	90

Table 5

Impact of delay on prognosis on primary and recurrent disease.

	None	Supposedly none	Yes	Supposedly yes	Total
Primary tumour	43	6	4	9	62
Recurrent disease	25	3	0	0	28
Total	68	9	4	9	90

and in these cases the delayed diagnosis was objectified when the mammograms were analysed retrospectively. The magnitude of the enlargement was estimated in these eight patients. The tumour diameter was measured on two occasions with a time interval varying between 6 and 18 months. In the fastest growing tumour the diameter increased from 15 mm to 50 mm in 12 months and in the slowest there was no enlargement of a mass size 35 mm in 6 months. These findings indicated the great variation in tumour growth rate. In a Norwegian Breast Cancer Screening Program including 395,188 women, it was found that the mean time for a breast cancer to grow from 10 to 20 mm was 1.7 years.¹¹ It is self-evident that most breast cancer tumours are several years old when detectable and that physician's delay in diagnosis does not necessarily lead to a reduced survival.^{4–6} Mistakes arising in diagnosis based on interpretation of mammograms are inevitable. In a breast cancer screening multi-center study it was found that false-negative assessment varied from 5.0 to 9.1% between the participating hospitals.^{12,13}

The median duration of delay in diagnosis of primary disease was almost one year. The magnitude of the enlargement during this time could not be estimated in most of the cases. However, it was considered that more extensive therapeutic procedures were required in 23% of the cases, and consequently these patients were economically compensated. It has been found that women with a diagnostic delay tended to be younger with a higher proportion of smaller tumour.^{7,14} In the present study 60% of patients claiming a diagnostic delay of the primary cancer were younger than 50 years and that might explain that the tumours were less advanced at the time of surgery. One further explanation might be that the study was covering a long period (12 years) and the treatment has changed dramatically during this time, i.e. sentinel node technique has contributed to less axillary surgery. It is apparent that the delay in diagnosis of the primary lesion was detrimental to some patients as the delay undoubtedly contributed to tumour progress and the prognosis was thereby negatively influenced. The insurance company took this into account and 57 of 62 (92%) women were given economic compensation. Some patients were also compensated for the mental anguish she had suffered with respect to possible increased risk for recurrence and death.

There is conflicting information on the effect that diagnostic delays may have on the clinical outcome. In a Danish study of 7608

Table 6

Decisions taken by The malpractice judgement court (HSAN). The verdicts by HSAN are stated as major, minor or no correction. The Lex Maria statement is given when a correction was given to the profinder. Outlawed means that the claim was not submitted within statutory time.

	Major verdict	Minor verdict	No correction	Lex Maria ^a	Outlawed	Total
Primary tumour	4	4	16	4	3	31
Recurrent disease	1	2	14	0	0	17
Total	5	6	30	4	3	48

^a During the same time 4 claims were sent to the National Board of Health and Welfare.

patients with primary breast cancer the authors could not find that doctors' delays of more than 60 days had a negative effect on the outcome.³ A systematic review study from 1999 stated that a delay of 3–6 months was associated with poorer survival indicating that all causes of delay should be minimized.⁵ The (Kaplan–Meier) survival curves for the different cohorts of delay showed no impact on survival related to duration of diagnostic delay, which may be explained by the small and heterogeneous material on breast cancer in the present study.^{5,6,15–17}

To determine whether there has been significant effect on outcome one would need to know the pathological state and the patient's age at diagnosis and based on doubling time estimate the stage of the cancer at the time of the missed diagnosis. This calculation has its limits as there is no available way to calculate when the time for seeding of metastases to regional lymph nodes or systemically was established. It is reasonable to consider that the longer delay the more plausible is a negative impact on prognosis. It is established that the potential to metastasize may be present before the tumour is clinically detectable and the effect on survival of delay of any time is uncertain.¹⁶

The delay in the diagnosis of recurrent disease was shorter than that for primary tumour, with a median value of 4.7 months. In the majority of cases (61%), the delay was due to misinterpretation of bone pain from metastatic processes. It seems strange that such clear clinical signs of metastases as bone pain were disregarded or neglected in four cases for more than 12 months before adequate radiological examinations were undertaken. In most cases this had no serious implications apart from the fact that the patient had unnecessary suffering during the period of delay. In one case, where the patient had severe back pain, the correct diagnosis was established when the vertebral metastasis had caused a pathological fracture with spinal cord damage. Decompression surgery was performed but the patient was left with neurological sequela.

In this investigation the insurance company (LÖF) gave economic support in more than 90% of the cases whereas the malpractice disciplinary board (HSAN) penalized the provider in only about 30% of the cases reported to them. This discrepancy is explained by the fact that the two organisations have completely different aims for their activities. LÖF covers injuries when there is a relationship between the injury and medical care and when it can also be demonstrated that the injury could have been avoided. HSAN sends out an admonition or warning when it is considered that the medical care given is not commensurate with science and proven experience. LÖF has no disciplinary purpose, its aim is to evaluate if the injury was avoidable, which is the condition for compensation.

The strength of this analysis lies in that the data were collected from a well-established patient national-wide insurance system in Sweden. It covered a long period – ten years. The information was based both on the hospitals' records and on patients' reports to LÖF. The survival data were obtained from an authoritative organisation on national basis. The limitations to this study include the retrospective analyses associated with sometimes-incomplete data. Furthermore, the impact concerning prognosis and consequences of the treatment and course were based on the joint judgements of the authors independently of the primary statements made by the insurance company.

Conclusions

This study indicates 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. The delay in diagnosis of recurrent disease contributed mainly to unnecessary suffering. Impact on the prognosis was considered in a fifth of patients with delay in the diagnosis of the primary disease. Economic compensation for the patients' injuries was given in ninety percent of the cases.

Conflict of Interest Statement

The authors are responsible for the content and writing of the paper. Two of the authors (LOH, HJ) are medical experts in the Swedish Patient Claims Panel and one (JA) is permanently employed by The County Council's Mutual Insurance Company as medical director.

Acknowledgements

The authors thank Lena Lindberg and Jakob Ask for their assistance.

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