



Legal claims for malignant mesothelioma: Dealing with all cases

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ABSTRACT

Background: Apart of medical reasons, a definitive diagnosis of malignant mesothelioma may be required as a basis for a claim of financial compensation although a pathological source of conclusive evidence is missing. Clinical assessment of all available data is then the only option to come to a final conclusion. We evaluated the diagnostic work-up of a large cohort of Dutch patients who applied for financial compensation due to mesothelioma. We determined how often a pathological or clinical diagnosis can be made, and which factors are associated with making the final diagnosis malignant mesothelioma.

Methods: A flow diagram of the diagnostic work-up was constructed for patients that applied to the Dutch institute for asbestos victims between 2005 and 2008 ($N = 1498$). Both pathological and clinical factors that may influence the diagnostic outcome were assessed.

Results: In 97 of the 1498 patients (6%) no pathologic diagnosis could be established because of an uncertain diagnosis ($N = 54$), inadequate ($N = 22$) or unavailable tumor samples ($N = 21$). A final pathological diagnosis of malignant mesothelioma could most often be made when biopsy samples were available compared to those in whom only cytological material was available. In patients in whom no conclusive diagnosis could be made, clinical assessment was performed. Eighty percent of patients (66/83) who were clinically assessed were considered to have mesothelioma. None of the clinical features analyzed were strongly associated with a confirmed diagnosis of malignant mesothelioma.

Discussion: Our study shows that only in a small number of the patients who applied no pathologic diagnosis could be obtained. Based on judgment of clinical experts in the majority of these cases a near to certain diagnosis could be made. Moreover, it is reasonable to obtain biopsy material from patients to increase the chance to obtain a confirmed diagnosis. Therefore, it is important to refer patients early for diagnostic procedures.

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1. Introduction

Malignant mesothelioma is a malignancy known for its long latency period after asbestos exposure [1]. Patients who have developed malignant mesothelioma as a result of occupational or environmental asbestos exposure may seek compensation for their losses and suffering by pursuing legal action. As the burden of malignant mesothelioma will remain high in the coming decade [2,3], compensation for those exposed in the past will remain an important issue.

The diagnosis of malignant mesothelioma is normally confirmed with use of pathologic material [4]. However, a definite pathological diagnosis may not always be feasible, either because of diagnostic difficulties or because of inadequate or unavailable tumor samples. To obtain a diagnosis, clinical assessment by some kind of 'diagnostic expert panel' is the only option to determine whether malignant mesothelioma is very likely or not.

In The Netherlands, patients with apparent malignant mesothelioma can apply to the Dutch institute for asbestos victims for financial compensation. For each applicant, the diagnosis of malignant mesothelioma first needs to be confirmed by a 'national panel of pathologists', using both histological and cytological samples. If a diagnosis of malignant mesothelioma cannot be made on the basis of cytological or histological evaluation (for whatever reason), subsequently a panel of 'clinical experts' evaluates all available clinical and radiological data, to ultimately determine whether the

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presence of malignant mesothelioma is more likely than some other diagnosis [5]. Accordingly, in The Netherlands, both patients with a pathologically or clinically confirmed diagnosis are candidates for a financial reimbursement. In this paper we evaluate the diagnostic work-up of a large cohort of almost 1500 Dutch patients who applied for financial compensation, to determine how often a pathological or clinical diagnosis can be made, and which factors are associated with making a final diagnosis malignant mesothelioma.

2. Methods

2.1. Patients

The Dutch institute for asbestos victims was founded in 2000 and its primary task is to support malignant mesothelioma patients in the legal claim process. Patients apply to the institute when they are diagnosed with, or are suspected, of a malignant mesothelioma based on judgment of the referring hospital. If this diagnosis is confirmed (see below), the patients or their relatives are entitled to financial compensation mediated by the institute for asbestos victims. Since 2000 (until 2008), a total of 3475 patients applied to the institute for asbestos victims. Findings from the years 2000–2004 have been described before [5]. Here we focus on the diagnostic work-up and obtained final diagnoses, plus associated factors over the years 2005–2008 ($N = 1498$). From each patient, informed consent was obtained.

2.2. Diagnostic outcome

2.2.1. Pathological assessment

For each patient who applies for financial compensation, representative tumor samples are requested from the referring hospital, and reviewed by a national expert panel of pathologists: the so-called Dutch National Mesothelioma Panel (NMP). The reviewed slides may include cytological or histological (biopsy) material. The NMP classifies the diagnosis of each patient to one of the following categories:

- I. Definite malignant mesothelioma;
- II. probable malignant mesothelioma;
- III. uncertain diagnosis of malignant mesothelioma; not able to differentiate malignant mesothelioma from e.g. mesothelial proliferation or an other type of malignancy;
- IV. no malignant mesothelioma (a diagnosis other than malignant mesothelioma);
- V. insufficient pathological material for making the diagnosis malignant mesothelioma.

In The Netherlands, a patient can only be accepted for any financial compensation when the diagnosis malignant mesothelioma is confirmed (in case of category I and II). The request is rejected for all cases of category IV. In case of category III or V the clinical expert panel is subsequently asked to make a final diagnosis.

2.2.2. Clinical assessment

When pathological material is not available, insufficient or the pathological diagnosis by the NMP was uncertain a final diagnosis is reached by the so-called 'Mesothelioma Clinical Expert Panel of the Dutch Thoracic Society' (DTS) [5]. This panel consists of 12–15 independent pulmonologists skilled in diagnosing malignant mesothelioma. By random assignment, three independent members of the Clinical Expert Panel evaluate all available clinical and radiological data to conclude that either or not malignant mesothelioma is the (most likely) final diagnosis (yes/no diagnosis of malignant mesothelioma). Clinical features that are taken into

account include e.g. gender, age, smoking status, asbestos exposure, chest pain, dyspnea, weight loss, progress of disease, other diseases that may explain symptoms. Radiological data may include features from X-thorax and CT-scans such as calcified pleural mass, irregular pleural thickening, interlobar fissure invasion, loss of volume of the hemithorax, pleural effusion. Finally, if available, pathological reports are considered. None of these three specialists may have been involved in the initial diagnostic procedures or treatment of the patient. Based on their medical expertise they conclude if a patient has yes or no malignant mesothelioma. A patient is considered to have a final diagnosis of malignant mesothelioma if at least two of the three specialists independently confirm the diagnosis. To obtain insight in the clinical decision making the specialists use a standardized form in which they assign whether a clinical feature is present and if it is suggestive for malignant mesothelioma.

2.3. Analyses

A flow diagram of the diagnostic work-up was constructed for the patients that applied to the institute for asbestos victims between 2005 and 2008. Subsequently, both pathological and clinical factors that may influence the diagnostic outcome assessment were analyzed, using cross tabulations with Chi-square testing and risk ratio's with 95% confidence intervals.

3. Results

3.1. Patients

In the period between 2005 and 2008, 1498 patients with apparent malignant mesothelioma applied for a financial compensation to the Dutch institute for asbestos victims. After submission a diagnostic tract starts as shown in Fig. 1.

Pathologic material was available of 1477 patients. Among them, the NMP confirmed the diagnosis in 1308 (89%) patients (category I and II of the flow diagram) and definitely ruled it out in 93 (6%) patients (category IV). The pathologic diagnosis remained uncertain in 76 patients because of diagnostic difficulties (category III ($N = 54$)) or inadequate tumor samples (category V ($N = 22$)). Moreover, no pathologic material was available for 21 patients. Thus, in 97 (6%) of the 1498 patients no pathologic diagnosis could be established. Of these 97 patients, 83 patients underwent clinical assessment. A diagnosis of malignant mesothelioma based on clinical assessment was confirmed in 66 of these 83 patients (80%).

Most of the patients that underwent clinical assessment were alive at time of clinical assessment (66%). Reasons that patients did not have any pathologic material or only cytological material available were mainly due to a poor condition of the patient or unwillingness to undergo invasive diagnostic procedures. However, patients with pathologic material available but no established diagnosis of malignant mesothelioma had a higher probability to get a confirmed diagnosis of malignant mesothelioma based on clinical assessment compared to patients without any pathologic material available (54 of 62 patients (87%) versus 12 of 21 patients (57%)).

3.2. Factors influencing the diagnostic outcome

3.2.1. Association pathological material and final diagnosis in patients with pathological assessment

Tables 1 and 2 show that patients with only cytological material available significantly more often did not score a category I or II diagnosis (malignant mesothelioma considered present) as compared to patients for whom (also) biopsy material was available. However, among patients with only cytological material available,

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