ORIGINAL ARTICLES

The EpicliCP-2003 Study: a Multicenter Epidemiological and Clinical Study of Lung Cancer in Spain

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OBJECTIVE: Mortality due to lung cancer in Spain is increasing continuously. The aim of the present study was to collect information on the hospital incidence of lung cancer, as well as information on clinical management, in different regions of Spain.

MATERIAL AND METHODS: A prospective observational study of patients diagnosed with lung cancer in 2003 was carried out in 13 centers in 9 autonomous communities. Epidemiological, clinical, diagnostic, and therapeutic variables were assessed.

RESULTS: Of a total population of 2 726 601 inhabitants (1 346 483 men and 1 380 118 women), 1064 male and 125 female lung cancer patients were included. The incidence standardized to the world population varied between 42.4/100,000 and 61.8/100,000 in men and between 15.9/100,000 and 6.6/100,000 in women. Overall, 51% were aged over 70 years, and 97.5% of the men and 32% of the women were smokers or ex-smokers. Cytologic or histologic confirmation was obtained for 93.1% of the cases (20.8% of which were small cell lung cancers and 79.2% were non-small cell lung cancers). The main initial symptoms were cough, chest pain, and weight loss. In 13.7%, lung cancer was suspected because of abnormal chest x-ray. The percentage with clinical TNM stages I and II ranged from 6.3% to 26.9%. The most common stage was stage IV in all centers. The percentage of patients undergoing surgery ranged from 2.5% to 20.6%, with a mean of 14.8% (19.9% of whom were patients with non-small cell lung cancer); 27% received palliative treatment only.

CONCLUSIONS: The proportion of women suffering from lung cancer increased with respect to previous studies, with notable differences among regions. Despite diagnostic improvements, the percentage of patients undergoing surgery is low, though interregional variation is considerable.

Key words: Lung cancer. Stages. Epidemiology. Spain.

Estudio multicéntrico epidemiológico-clínico de cáncer de pulmón en España (estudio EpicliCP-2003)

OBJETIVO: La mortalidad por cáncer de pulmón en España aumenta ininterrumpidamente. El objetivo del presente estudio ha sido conocer su incidencia hospitalaria, así como otros datos de manejo clínico, en varias regiones españolas.

MATERIAL Y MÉTODOS: Se ha realizado un estudio prospectivo observacional de los pacientes diagnosticados de cáncer de pulmón en 2003 en 13 centros de 9 comunidades autónomas. Se evaluaron variables epidemiológicas, clínicas, diagnósticas y terapéuticas.

RESULTADOS: Se han registrado 1.064 varones y 125 mujeres correspondientes a una población total de 2.726.601 habitantes (1.346.483 varones y 1.380.118 mujeres). Las tasas estandarizadas según población mundial variaron entre 42.4 y 61.8/100.000 en varones y entre 15.9 y 6.6/100.000 en mujeres. El 51% tenía más de 70 años. El 97.5% de los varones y el 32% de las mujeres eran fumadores o ex-fumadores. Se obtuvo confirmación citohistológica en el 93.1% de los casos (20.8% microcíticos y un 79.2% no microcíticos). Los síntomas iniciales predominantes fueron tos, dolor torácico y pérdida de peso. En el 13.7% el diagnóstico se sospechó sólo por anormalidad radiológica. La proporción de estadíos TNM clínicos I y II varió entre el 6.3 y el 26.9%. El estadío IV fue el más común en todos los centros. La tasa de intervenciones varió entre el 2.5 y el 20.6%; el promedio fue del 14.8% (un 19.9% del total de no microcíticos). El 27.0% sólo recibió medidas paliativas.

CONCLUSIONES: Entre los casos de cáncer de pulmón aumenta la proporción de mujeres con respecto a estudios previos, con notable diferencias interregionales. Pese a las mejoras diagnósticas, la tasa de intervenciones, muy variable entre diferentes centros, es muy baja.
become more widely applied, although these advances in staging, and chemotherapy and radiotherapy have undergone notable changes with regard to diagnosis and treatment. In recent decades, clinical practice has changed significantly. Several epidemiological and clinical studies of lung cancer in Spain have been published.2,3,6 However, most of these are limited to provinces or regions of Spain and data collection methods vary, making comparative analyses difficult. In addition to providing current information on hospital incidence of lung cancer, the present study also aimed to prospectively record and analyze epidemiological and clinical data on lung cancer, data on clinical management and therapy, and data on variability among centers. Therefore, the same data collection protocol was applied to hospitals in different Spanish autonomous communities and in different regions. The other aim of the project, which is ongoing, is to analyze other aspects of the disease in the context of the participating centers. When a biopsy could not be obtained for confirmation of diagnosis, clinical data and complementary tests were required to rule out as far as possible alternative diagnoses. These cases were discussed by a panel with the participation of investigators from other centers of the study.

Introduction

The overall incidence of lung cancer in Spain increased continuously during the course of the last century, particularly among men. Although men are still much more likely to suffer lung cancer than women, the most recent mortality data unequivocally indicate that the number of women diagnosed with lung cancer is increasing.1 This is not surprising given that, for decades now, smoking has been growing in popularity among women. In recent decades, clinical practice has undergone notable changes with regard to diagnosis and treatment. Staging, and chemotherapy and radiotherapy have become more widely applied, although these advances have hardly had any impact on long-term survival.

Recently, several epidemiological and clinical studies of lung cancer in Spain have been published.2,3,6 However, most of these are limited to provinces or regions of Spain and data collection methods vary, making comparative analyses difficult. In addition to providing current information on hospital incidence of lung cancer, the present study also aimed to prospectively record and analyze epidemiological and clinical data on lung cancer, data on clinical management and therapy, and data on variability among centers. Therefore, the same data collection protocol was applied to hospitals in different Spanish autonomous communities and in different regions. The other aim of the project, which is ongoing, is to analyze other aspects of the disease in the context of the participating centers. When a biopsy could not be obtained for confirmation of diagnosis, clinical data and complementary tests were required to rule out as far as possible alternative diagnoses. These cases were discussed by a panel with the participation of investigators from other centers of the study.

According to the data collection protocol, epidemiological information (age, sex, profession, place of residence, smoking habits, and exposure to other carcinogens), clinical information (initial symptoms, time to diagnosis, medical history, and concurrent diseases), and diagnostic and therapeutic information were collected for all patients.

During the year of the study, quarterly meetings of the leaders from the participating centers were held to discuss the inclusion of cases without biopsy confirmation and to work out the details for assessment of certain complex variables. Before entering information into the database, a panel of investigators of the study group examined the case report forms to look for and correct possible differences in the evaluation of a variable.

A procedure was designed and discussed for coding all the variables and their possible values during the study period. Finally, a common database was set up in the SPSS program, version 9.0, and the investigators were given access to enable data entry.

According to the classification of smoking habits, an ex-smoker was someone who had not smoked for more than 6 months before diagnosis. For stratification, TNM staging was used. In addition to basic laboratory analyses and simple chest x-rays, chest computed tomography was available for 98.6% of the patients.

Material and Methods

Thirteen centers in 9 autonomous communities participated in this prospective observational study. Prior to the study, a common case report form had been drawn up with the consensus and input of investigators from the participating centers. This form defined the variables to be collected and the reporting procedure. Once the drafting procedure was complete, 3 months before the start of the study period, copies were distributed to the authors, along with a leaflet containing guidelines to serve as a brief instruction manual. The aim of this pilot phase was to familiarize the participants with the data recording procedures. The guidelines referred only to how the variables included in the study were assessed and coded. The corresponding service or the hospital applied its own protocols for diagnosis and treatment of lung cancer. Although this was an observational study that did not require any changes in the established procedures at any of the centers, authorization from the corresponding ethics committees was obtained.

Patients included the study had been diagnosed with primary lung cancer between January 1 and December 31, 2003 and lived in the health care areas corresponding to each of the participating centers. When a biopsy could not be obtained for confirmation of diagnosis, clinical data and complementary tests were required to rule out as far as possible alternative diagnoses. These cases were discussed by a panel with the participation of investigators from other centers of the study.

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Statistical Analysis

The SPSS program, version 9.0, was used. Data were standardized directly to the world population. Percentages were compared with the χ² test and means were compared with the Student t test.

Results

Of the 13 participating centers, 12 adhered satisfactorily to the established protocols for inclusion in the analysis. Thus, although 1307 patients were initially included, only 1189 attended by the 12 centers that reported their data before the deadline were actually analyzed. These centers had a corresponding population of 2,726,601 inhabitants (1,346,483 men and 1,380,118 women) in 8 autonomous communities.

Incidence Rates

All centers provided an extensive sample of patients diagnosed with lung cancer. However, only 5 centers met the conditions of a) being the only center in the health area served by the hospital and therefore having a well defined population assigned with limited overlap with other hospitals, and b) having ready case inclusion, so allowing an exhaustive registry to be drawn up. Therefore, we have only presented the calculated incidence rates for these 5 centers. Table 1 shows the crude and standardized rates (according to the standard world population) in these centers. The crude rates corresponding to the remaining hospitals ranged from 51.5/100,000 to 102/100,000 in men, and from 2.4/100,000 to 20/100,000 in women. These data are not presented in detail given that the criteria for reliability of the rates mentioned earlier were not met.
Age and Sex

As shown in Figure 1, the ratio of men to women varied greatly according to the different regions of the study. Thus, the ratio of men to women was 39:1 in Mérida compared to 4.1:1 in Orense. A total of 1064 men and 125 women with lung cancer were included, corresponding to a ratio of men to women of 8.5:1. The mean age was 67.8 years (interquartile range, 60-76 years) in men, 67.3 years (interquartile range, 57-78 years) in women, and 67.8 years (interquartile range, 60-76 years) in the overall population. Figure 2 shows the age distribution of cases according to 10-year intervals. These data are presented for the overall study population because there were no substantial differences between centers.

Smoking Habit

Smokers and ex-smokers accounted for 97.5% of the men and 32% of the women included in the study (Figure 3). These data are pooled for all centers, given that they hardly varied from center to center. The age when patients started smoking according to sex, the number of cigarettes smoked (expressed as pack-years) in smokers and ex-smokers, and the time since ex-smokers stopped smoking are shown in Table 2. In our study, 37.6% of ex-smokers had stopped smoking more than 10 years before diagnosis of lung cancer.

Distribution of Histological Types

Table 3 shows the percentage of patients diagnosed with lung cancer solely on the grounds of clinical or x-ray findings and/or endoscopic findings; that is
biopsy confirmation was not obtained. The data are presented separately for each center given that substantial differences were observed. Table 3 also shows the distribution according to the 2 main histological types of lung cancer.

Initial Signs and Symptoms of Lung Cancer

Often, the first finding suggestive of a possible diagnosis of lung cancer was an abnormality in a chest x-ray that was done for some reason other than suspected lung cancer (chronic obstructive pulmonary disease, heart disease, preoperative tests, etc). In such cases, clinical signs or symptoms attributable to lung cancer were not present according to the criteria of the local investigators. The percentage of patients who were asymptomatic on detection of lung cancer varied greatly from center to center. Table 4 shows the frequencies of the most common symptoms such as cough, chest pain, hemoptysis, weight loss, or signs and symptoms of distant metastasis by center and for the overall population.

Clinical TNM Staging

Figure 4 shows the percentage of patients in early and advanced stages according to the TNM classification from the clinical part of the study (clinical TNM staging) by center. The 1997 TNM classification adopted by the Spanish Society for Pulmonology and Thoracic Surgery (SEPAR) was used. Table 5 shows the distribution of stages according to the main histological types for the overall population. Although each hospital followed its own protocol for staging of
the lung cancer, resulting in differences between centers for the type of test used (with varying reliance on positron emission tomography, magnetic resonance spectroscopy, or other invasive tests), 98.6% of the cases had at least one computed tomography scan available for TNM staging.

**Table 5**  
Clinical TNM Stage According to Main Histological Types (All Patients Included)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Small Cell</th>
<th>Non-Small Cell</th>
<th>Without Biopsy Confirmation</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage I</td>
<td>6 (2.6%)</td>
<td>178 (20.3%)</td>
<td>12 (4.6%)</td>
<td>196 (16.5%)</td>
</tr>
<tr>
<td>Stage II</td>
<td>2 (0.9%)</td>
<td>39 (4.4%)</td>
<td>1 (1.2%)</td>
<td>42 (3.5%)</td>
</tr>
<tr>
<td>Stage IIIA</td>
<td>28 (12.2%)</td>
<td>109 (12.3%)</td>
<td>11 (13.4%)</td>
<td>148 (12.4%)</td>
</tr>
<tr>
<td>Stage IIIB</td>
<td>50 (21.7%)</td>
<td>219 (25.0%)</td>
<td>12 (14.6%)</td>
<td>281 (23.6%)</td>
</tr>
<tr>
<td>Stage IV</td>
<td>141 (61.3%)</td>
<td>310 (35.3%)</td>
<td>38 (46.3%)</td>
<td>489 (41.1%)</td>
</tr>
<tr>
<td>Not staged</td>
<td>3 (1.3%)</td>
<td>22 (2.5%)</td>
<td>8 (9.8%)</td>
<td>33 (2.8%)</td>
</tr>
</tbody>
</table>

**Table 6**  
Type of Treatment Administered

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Hospital in Albacete</th>
<th>Hospital in Ávila</th>
<th>Hospital in Cáceres</th>
<th>Hospital in La Coruña</th>
<th>Hospital in Guadalajara</th>
<th>Hospital in León</th>
<th>Hospital in Mérida</th>
<th>Hospital in Orense</th>
<th>Hospital in Oviedo</th>
<th>Hospital in Seville</th>
<th>Hospital in Torrelavega</th>
<th>Hospital in Vinaroz</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>135</td>
<td>45</td>
<td>146</td>
<td>170</td>
<td>60</td>
<td>101</td>
<td>80</td>
<td>168</td>
<td>61</td>
<td>108</td>
<td>75</td>
<td>40</td>
<td>1189</td>
</tr>
<tr>
<td>CT/RT</td>
<td>17.8</td>
<td>13.3</td>
<td>14.5</td>
<td>20.6</td>
<td>13.3</td>
<td>15.8</td>
<td>2.5</td>
<td>11.9</td>
<td>9.8</td>
<td>16.7</td>
<td>18.7</td>
<td>17.5</td>
<td>14.8</td>
</tr>
<tr>
<td>CT only</td>
<td>63.0</td>
<td>68.9</td>
<td>54.1</td>
<td>54.7</td>
<td>58.3</td>
<td>50.4</td>
<td>60.0</td>
<td>54.8</td>
<td>59.0</td>
<td>50.9</td>
<td>49.3</td>
<td>42.5</td>
<td>55.4</td>
</tr>
<tr>
<td>CT/RT</td>
<td>37.5</td>
<td>17.8</td>
<td>29.4</td>
<td>24.8</td>
<td>28.4</td>
<td>33.8</td>
<td>37.5</td>
<td>33.6</td>
<td>31.1</td>
<td>32.4</td>
<td>32.0</td>
<td>40.0</td>
<td>29.8</td>
</tr>
</tbody>
</table>

CT indicates chemotherapy; RT, radiotherapy.
†With or without pre- and postoperative CT and/or RT.

**Figure 4.** Percentage of patients in early stages (TNM I and II; dark columns) and advanced stages (TNM IV; grey columns), by center, expressed with respect to all patients in each center. ORE indicates Hospital in Orense; OVI, Hospital in Oviedo; VIN, Hospital in Vinaroz; TOR, Hospital in Torrelavega; LEO, Hospital in León; GU, Hospital in Guadalajara; SEV, Hospital in Sevilla; COR, Hospital in La Coruña; ALB, Hospital in Albacete; CAC, Hospital in Cáceres; AVI, Hospital in Ávila; MER, Hospital in Mérida.

**Discussion**

The National Institute of Statistics has been publishing lung cancer mortality rates in Spain for a number of years. Although incidence rates will be very similar to mortality rates given that survival is low, it is still important to have studies available that directly estimate the incidence. Such an approach can provide a further source of data which not only allows direct comparison with mortality rates but also provides other types of information. However, many Spanish autonomous communities do not keep a registry of the incidence of lung cancer and not all of the ones available comply with international guidelines. Therefore, only indirect and partial data on incidence are available and these data are often a few years out of date.

One of the aims of this study, as stated in the introduction to this article, was to estimate the actual hospital incidence in a group of centers located in different regions of Spain. Although some of the participating centers are the only ones in their health care area, and so the hospital incidence is close to the
incidence in the general population, in other centers this is not the case. When there are several hospitals in the same city, not only is it difficult to determine exactly the population covered by the hospital, but it is also impossible to control for patients changing from one center to another for whatever reason. Moreover, as was expected, the care provided to lung cancer patients was spread among different services of some hospitals, and so not all local investigators in the participating centers were able to draw up an exhaustive record of all patients diagnosed in their hospital. In view of these limitations and the strict criteria for case inclusion (only 6.9% did not have biopsy confirmation and these were examined carefully by a panel to avoid erroneous diagnosis), the figures calculated should be considered an underestimate of the true incidence. We therefore restricted our analysis to the 5 hospitals with a more complete registry to provide an estimate as close to the actual figure as possible. Such a registry was possible in these centers because they were the only ones serving their health care area and because their administrative structure allowed more reliable data collection. As shown in Table 1, the crude and standardized incidence rates were similar or greater than those published in some studies performed in a more limited area. There was also substantial variation from one autonomous community to another.

Overall, 51% of the patients diagnosed with lung cancer were aged over 70 years. In the 7 participating hospitals in which we could compare this percentage with data from 1990-1999, we observed an increase from 44% to 52.2% (P<0.0001). The overall percentage of women also increased from 7.2% to 10.9% (P<0.01). As reflected in Figure 1, there were notable differences between different Spanish regions. Thus, the ratio of men to women ranged from 4.1:1 in Orense to 39:1 in Mérida. These differences may well be closely related to the different structures within the health care system of different regions, with lower female participation in life-style risk factors being one possible explanation.2,4

In our patients, 68% of the women with lung cancer were nonsmokers, compared to only 2.5% of the men (Figure 3). In the Finnish study, 2% of the men and 29% of the women were nonsmokers.13 The possible influence of passive smoking has not been assessed in the present study. In men, the percentage of ex-smokers already slightly exceeds the percentage of current smokers, whereas only a few years ago, lung cancer was most common among current smokers.2 Both smokers and nonsmokers had nonetheless accumulated a very large number of pack-years at the time of diagnosis (Table 1), even though some ex-smokers had given up the habit more than 20 years before diagnosis of lung cancer.

Almost all epidemiological studies of lung cancer report nonnegligible percentages of patients whose diagnosis is not confirmed by biopsy. This percentage varies greatly according to the period and the type of study. In population registries in other European countries, percentages have been reported that range from 14% in Finland11 to 25.9% in Scotland.12 In recent publications by Spanish groups,2,6 lower percentages have been reported. This could be explained by the fact that the studies were done in a hospital setting within the pulmonology service.13 In this study, we observed marked differences between centers, differences that are attributable, at least in some cases (the centers with percentages of 0.0% and 1.0% [Table 3]), to incomplete inclusion of patients. It is also highly likely that the strict application of inclusion criteria led to the exclusion of some patients with lung cancer. To avoid this limitation, broader inclusion criteria would have to be adopted, but this would probably have led to patients without lung cancer being included.

Analysis of the initial reason for suspicion of lung cancer shows that it is increasingly likely for it to be detected fortuitously because of an abnormal finding in a chest x-ray even though the patient has no symptoms that can be attributed to the disease. This often occurs in patients with other underlying diseases (chronic obstructive pulmonary disease, heart disease, hypertension), and/or elderly patients who, for some reason other than suspicion of lung cancer, undergo tests in which an abnormality appears that is later confirmed to be due to lung cancer. Between 10% and 20% of the patients had signs or symptoms that led to suspicion of lung cancer in almost all participating hospitals. It is likely that the large difference between those figures and those from the few centers that reported a lower percentage can be explained by the incomplete inclusion of cases in these hospitals. Overall, 13.7% of the patients were suspected of having lung cancer, which is an increase with respect to previous studies.2,4 This rise, in addition to reflecting an increasing number of underlying associated diseases, as expected in a more elderly population, is also probably due in part to more extensive health care coverage and increasing use of diagnostic tests. Studies from other countries report percentages of asymptomatic patients ranging from 5% to 6%, although those were series of patients diagnosed decades before our study.14,15 Among the other initial signs and symptoms, cough was the most frequently reported (Table 4), in agreement with other studies.14,15 It is notable that up to 20.7% presented with weight loss, and 10.5% with signs and symptoms of distant metastasis at the time of diagnosis.

Although new imaging techniques and procedures can accurately determine the extent of lung cancer, we must bear in mind that clinical TNM staging is all too often inaccurate. This has important effects on therapeutic decisions, particularly when selecting candidates for surgery. Many patients are also diagnosed when surgery is clearly impossible or the cancer cannot be resected, or even when no other aggressive therapy can be applied. In such patients, it is pointless to perform expensive, invasive, or time-consuming tests that are not going to change the therapeutic approach. Even so, 98.6% of those included in this study underwent at least 1 computed tomography
scan. This percentage is probably so high because these were hospital patients. In patients included in the Scottish series in 1995, only 47% had undergone this examination. As can be seen in Figure 4, approximately 20% of our patients had TNM stage I or II lung cancer in all but one of the hospitals (the exception had a percentage of 6.3% in these stages). Previous studies in some of the centers that participated in this project had reported percentages of 27% to 37% with stage I or II disease. We cannot be certain about why fewer cases of lung cancer seem to be diagnosed in the early stages. One possibility is that the more limited resources available 10 years ago were responsible for less accurate stratification, and the decrease would therefore be more apparent than real. Moreover, in these previous studies, many of the patients had no TNM staging available. The number of patients with early stage IV disease in the present study (41% on average) was similar to the 39% reported in the United States of America for the period 1995 to 2000.

Overall, the percentage of patients undergoing surgery was 14.8%, but this percentage varied greatly from center to center. If only non-small cell lung cancers are considered, the percentage (19.9%) was closer to the expected rate. In contrast, no center operated on patients with small cell lung cancer. Only 3 of the 12 participating centers had thoracic surgery facilities in the hospital itself. The influence of this availability and other factors on the percentage of those undergoing surgery is worth analyzing but we cannot do so here because of space constraints. In any case, several of the participating centers with data available from previous registries had reported higher percentages of patients undergoing surgery. The most commonly used therapies were chemotherapy and radiotherapy, either alone or in combination in a range of regimens. Finally, 27% of all patients received only palliative measures. We think that this is a reflection of the clinical condition (extensive and severe underlying diseases, advanced age, etc) of many of the patients diagnosed with lung cancer.

REFERENCES