Informal Caregiving Burden in Advanced Non-small Cell Lung Cancer: The HABIT study

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Introduction: This study's aim was to assess economic data regarding the home assistance burden for advanced non-small cell lung cancer (NSCLC) patients in Italy.

Patients and Methods: One hundred four NSCLC patients in second-line chemotherapy (2LC) or in supportive therapy (ST) were enrolled in 18 Italian oncology departments and were observed for 3 months. The main caregiver's workload was assessed monthly by a task scale; other caregivers' activities were also registered. Eastern Cooperative Oncology Group performance status was assessed by physicians, and patients completed the Lung Cancer Symptoms (LCS) subscale. Formal caregiving time was valued according to market prices; informal caregiving hours were valued using the wage rate for an equivalent service. Covariance analysis was performed to check for influential factors in assistance costs.

Results: The mean age of the total sample was 65.5 years, and prevalence of males was over 80%. In over 70% of cases, the principal caregiver was patient's spouse, living with the patient and not working. Principal caregiver support was the main cost item: €2.368 in 2LC and €2.805 in ST, representing 74% of total tri-monthly assistance costs. Regression analysis showed a positive correlation between the severity of symptoms and the costs of assistance.

The caregiving burden was higher in patients with bone and/or cerebral metastases; other metastasis sites seemed to have no impact on assistance costs.

Conclusion: Considering quality of life as the ultimate health outcome, clinicians are challenged to contribute to a research and policy agenda that holds burden of care in due consideration.

Key Words: NSCLC, Informal caregiving, Assistance burden.

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Lung cancer is the leading cause of cancer-related mortality in both men and women because lung carcinomas are frequently diagnosed at an advanced stage, conferring a poor prognosis. The incidence of lung cancer in Italy in 2002 was about 37,000 new cases (65/100,000 inhabitants), and it is forecasted to increase in the coming years (71/100,000 inhabitants in 2010) because of the aging population.[1] Non-small cell lung cancer (NSCLC) represents roughly 80% of all lung cancer cases.[2]

Many studies assessed health care costs consequent to this disease,[3–6] and all report considerable resource consumption and, consequently, significant financial spending. A cost-of-illness study conducted in Italy, observing 189 patients with advanced NSCLC for 6 months or until death, reports a very high burden to the National Health System for patients treated with first- and second-line (2LC) chemotherapy, and also for patients receiving best supportive care.[7] Patients in best supportive care were found to require the highest monthly per-patient hospitalization costs (equal to €2298), whereas patients in 2LC generated the greatest chemotherapy-related adverse-event costs (up to €269 per month).

Cancer care is increasingly transferred from the inpatient to the outpatient setting,[8] and the burden of caring for cancer patients, especially elderly subjects, is falling increasingly on their families, with a continuous growth of informal assistance costs.[9] Few studies have examined this issue, highlighting that informal caregiving accounts for a substantial proportion of nonmedical costs incurred by cancer patients.[10–12]

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Time and difficulties encountered in performing caregiving tasks were evaluated among 78 family caregivers of patients with lung cancer.[13] The most time-consuming tasks for adults, children, and spouses were emotional support, transportation, and monitoring symptoms. The most difficult duties were emotional support, behavioral management, monitoring symptoms, and household tasks. Family caregiving is, therefore, a resource-consuming activity necessitated by cancer, and it should not be forgotten when assessing the direct costs of cancer.

The HABIT study (Home Assistance Burden in Lung Tumor) is a longitudinal, prospective, multicenter, national study aimed at assessing the costs of informal care in advanced NSCLC patients in Italy—either those treated with chemotherapy or those receiving supportive therapy (ST)—completing the information available on the direct medical costs of this disease and providing an estimation of the costs that the families or social security would have to support if the informal assistance could not be provided by family members.

PATIENTS AND METHODS

Study data were collected in 18 oncology centers all over Italy. Centers enrolled consecutive patients treated with 2LC or ST, referring for control visits, and observed them for 3 months or until death; patients' treatment changes were possible during the study period, but without affecting the initial assignment of such patients to the relevant group on enrollment. A detailed study flow chart is shown in Figure 1. Considering that supportive care patients can avoid controls at the center and receive only home care or be institutionalized in hospices, control of enrollment was centralized, with the aim of stimulating enrollment of supportive care subjects, if necessary, to prevent this treatment group from being too scarce and thus affecting the cost calculation. Exclusion criteria were concomitant participation in clinical studies, the absence of a regular caregiver, and the likelihood of an unfavorable prognosis in the next 3 months. The study protocol was approved by the ethics committees of all participating centers, and patients were asked to provide their written consent to personal data treatment before the start of data collection. Demographic and anamnestic data were reported by physicians on a paper case report form; performance status has been assessed monthly through the Eastern Cooperative Oncology Group (ECOG) performance scale.[14] Informal caregiving time was assessed through a task scale derived from Montgomery et al.[15]

The scale consisted of seven types of tasks (bathing and dressing, feeding, housework, moving inside the house, transportation, nursing, administrative tasks), and the caregivers were instructed to assess how many hours per week they spent performing each task. Furthermore, each main caregiver gave information about the presence of secondary supporting caregivers and of paid, specialized, or generic caregivers (e.g., nurse, physiotherapist, or housemaid). At baseline and at each monthly interview, each patient completed the Lung Cancer Symptoms (LCS) subscale of the FACT-L questionnaire,[16–18] which is available in Italian and is suitable for assessing symptoms in advanced NSCLC patients.

Data were inputted into an MS SQL server database through a Web application, which was made available only to authorized users and consisted of html pages with online control functions of the inputted information.

Statistical Analysis

The numbers of monthly and trimonthly hours of paid and informal caregiving (principal plus additional family caregivers) were calculated. To allow for 8 hours of sleep/personal care, a limit of 16 hours per day (112 per week) was imposed for any caregiver.

In the longitudinal analysis, patients were maintained in their respective initial assignment groups, and we analyzed the modifications of variables concerning patients' clinical status and assistance needs, from baseline to the end of observation period, in the two treatment groups.

Regarding patients' clinical situations (ECOG and LCS subscale of the FACT-L questionnaire), data were analyzed according to literature-based methods or to the scale manuals prepared by the authors of the questionnaires. The longitudinal analysis within groups described the scale scores at single visits and the variations in disease-specific symptoms, and each patient's performance status change between the baseline visit and the last assessment. Missing items of the LCS FACT-L scale were replaced (but only if at least four items were answered) by using the following formula: "Sum of items score × 7/number of answered items." Patients with a score variation of 2 or more were considered improved, whereas a score variation of less than 2 meant aggravation of the patient's condition.[19]

Cost Analysis

For each identified category, literature-based unit costs were set on resources, expressed in physical units (hours of assistance). For fee-based assistance, the relevant national

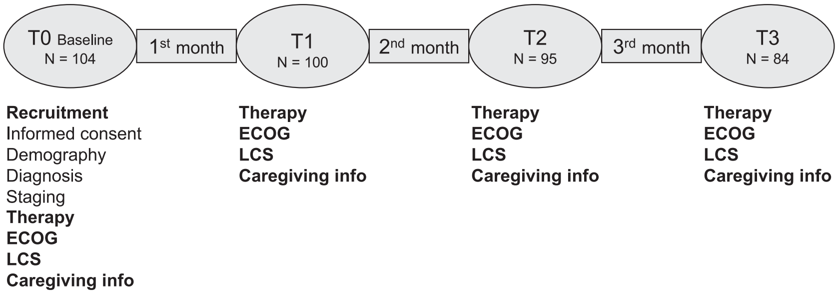

FIGURE 1. Study flow chart.