OBJECTIVE: To examine the responsiveness to change of the Spanish version of the Juniper Mini Asthma Quality of Life Questionnaire (Mini-AQLQ). METHODS: 253 patients with mild to moderate uncontrolled asthma (patients with symptomatic and/or need for short-acting f²-agonists) were included in the study (61% women, mean age 36 years). A full history and physical examination were performed and montelukast was added at the baseline visit. All subjects completed the Mini-AQLQ questionnaire twice: at recruitment and after two months. Differences in patient scores before and after the montelukast addition were analysed using paired t-test. Responsiveness was assessed by calculating the standardized effect size (SES). A within-subject change in score of 0.5 is defined as the minimal clinically important difference (MCID). RESULTS: The Mini-AQLQ was responsive to changes over a two-month period. All Mini-AQLQ global and domain scores significantly improved after montelukast addition (p < 0.01 for all comparisons). Mini-AQLQ score changes were significantly different for patients who improved and those that remained stable or deteriorated (p < 0.001). The global score effect size was 0.91, ranging from 0.5 to 1.0 for the domains. The percentage of patients with mild and moderate asthma who were considered to have experienced a MCID in global score was 57.5% and 71.4% respectively, with average baseline scores of 5.0 and 4.3 respectively. The domain that experienced the greatest number of patients experiencing a clinically important improvement was Symptoms, with 65% and 78% of patients with mild and moderate asthma respectively. CONCLUSIONS: The Spanish version of the Mini-AQLQ is suitable for use in longitudinal studies where it is appropriate to assess the impact of asthma on the quality of life of individual patients with mild to moderate asthma. A high proportion of patients experienced a clinically meaningful improvement in their Quality of Life after addition of montelukast to their asthma therapy.

CANCER

ECONOMIC IMPACT OF ADOPTING PEMETREXED PLUS CISPLATIN FOR MALIGNANT PLEURAL MESOTHELIOMA INTO SCOTTISH CLINICAL PRACTICE
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OBJECTIVE: To undertake cost-effectiveness evaluation of pemetrexed/cisplatin (pem/cis) compared to cisplatin (cis) for patients with advanced malignant pleural mesothelioma (MPM) in Scotland. METHOD: The efficacy of pem/cis versus cis was evaluated in the first randomised phase III trial in patients with unresectable MPM (Vogelzang 2003). Emergent data early in the trial led to patients being fully supplemented with folic acid and vitamin B12. Survival benefit was assessed in fully vitamin-supplemented patients with advanced disease [FS (stage III/IV)]. A cost/life-year saved (LYS) analysis of FS (stage III/IV) cohort using the median survival gain from the clinical trial was undertaken. This cohort was chosen because it represented the most realistic use of pemetrexed in Scottish clinical practice: most MPM patients in Scotland have advanced disease at presentation (Aziz 2002) and vitamin supplementation is mandatory with pemetrexed treatment (ALIMTA SPC). Specific unit costs were applied to drug acquisition, administration, supportive care medication, hospitalisations for serious adverse events and post-study chemotherapy, with incidence derived directly from the clinical trial. A discount rate of 3.5% per annum was applied to all outcomes. RESULTS: The survival of pem/cis over cisplatin in this cohort was 13.2 versus 8.4 months (p = 0.003; HR 0.63 [95%CI 0.46–0.86]). The incremental per patient cost for pem/cis compared to cis was £8196. The incremental cost/LYS for this cohort is £20,844. The robustness of the model was tested using one-way sensitivity analyses on key variables affecting both cost and outcomes estimates in the cost-effectiveness model. Little variation in the incremental cost/LYS was found with the variables tested for the FS with advanced disease patients (£17,500–£25,000). CONCLUSIONS: The trial demonstrated clear survival gain for the cohort of fully supplemented pem/cis patients with advanced disease. This analysis demonstrates that the combination may be considered a cost-effective treatment for patients with advanced MPM.

LEAD TIME IN THE EVALUATION OF HISTORICAL SURVIVAL IMPROVEMENTS IN THE TREATMENT OF ADVANCED NON-SMALL CELL LUNG CANCER
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OBJECTIVES: Historical evaluations of patients in clinical trials suggest that patients with advanced nonsmall cell lung cancer (NSCLC) treated with chemotherapy can expect a two-week improvement of median survival. We postulated that, with the publication of randomized trials showing survival improvements, this apparent gain might be attributable to lead time effects; that is, patients being treated earlier in the natural history of their disease. METHODS: Patients with Stage IIIb and IV nonsmall lung cancer were identified from the SEER-Medicare database, and population-based cancer registry linked to Medicare claims. Survival for consecutive cohorts diagnosed between 1994 and 1999 was analyzed to determine differences from time of diagnosis to time of treatment and for overall time from diagnosis to death. RESULTS: During this period 11,995 patients were diagnosed with stages IIIb and IV NSCLC. The mean age was 75 years, 57% were males and distribution by race was: 82.4% white, 9.4% African Americans, 3.2% Asian, 1.2% Hispanic, and 3.7% others. 30% were treated with chemotherapy. The mean time to chemotherapy initiation in 1994 was 1.63 months while in 1999 was 1.34 (p = 0.0004). This change represents a difference in treatment initiation of 8.7 days, or almost 62% of the survival benefit observed in the historical clinical trial evaluation covering 25 years. CONCLUSIONS: Over time there has been a trend towards earlier initiation of chemotherapy following diagnosis in advanced NSCLC. If the date from chemotherapy initiation is used as a starting point for survival analyses, as is frequently the case, researchers might erroneously conclude that survival is improving due to treatment, when in fact much of the apparent gains are simply due to patients receiving treatment earlier in the history of their disease.

POPULATION-BASED BUDGET IMPACT MODEL OF APREPITANT (EMEND) IN HIGHLY EMETOGENIC CISPLATINE-BASED CHEMOTHERAPY
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OBJECTIVES: To evaluate the economic impact of the introduction in the French market in 2003 of the new agent Aprepitant for the prevention of acute and delayed nausea and vomiting associated with Highly Emetogenic cisplatin-based cancer