Background

The results from clinical trials show that in patients with advanced non-small-cell lung cancer and with activating EGFR mutations-first line use of tyrosine kinase inhibitors (TKI) provides significant advantages in terms of response and progression free survival compared to standard double chemotherapy.1012 However, testing of all newly diagnosed patients with advanced NSCLC has been considered as a financial burden in daily clinical routine.

Objectives

The rate of EGFR-testing in daily practice was analysed by institution type, histology, individual patient characteristics and by federal state. The EGFR testing process was analyzed with respect to sampling, quality of samples, referral to the certified pathologists, reimbursement and coverage of cost.

Method

The survey was performed in a representative sample of centers with treatment decisions in advanced NSCLC in the 3rd quarter of 2011. The basis for the sample was compiled from the C-A-I address database with decision making physicians in hospitals and office-based practices. In order to construct the sample, eligible physicians were contacted and an adequate sample size was found in 209 oncologists, 151 pulmonologists, 85 radiologists and 42 internists at university hospitals at 682 centers (university hospitals, non-university hospitals, office-based practices and clinics) were informed of the project via telephone and invited to participate.

112 sites were recruited (a response rate of 54.5%); with a maximum of 1 physician per institution (decision makers in NSCLC in 88/100 only). 102 sites distributed regionally according to population density participated: 22 university hospitals, 44 non-university hospitals, 19 traditional hospitals, 40 oncologists, 34 pulmonologists, 14 internists, 7 radiologists and 1 information provided the data.

The total of NSCLC pts, stage IIIB/IV, reported in this sample amounts to 3834 pts. This sample covers 14% of the treated prevalence of NSCLC pts, stage IIIB/IV, in the 3rd quarter of 2011 in Germany (estimated as 27700 pts). Physicians took part in an online survey (KeyPoint Version 5.5, optionally paper and pen) based on a structured questionnaire.

The statistic analysis was performed with Stata 12.1 (StataCorp LP, College Station, TX, USA) and Visualise Onmics®.

The importance of the predictive factors (days to availability of test, density of hospitals or specialists physicians, the type of test-initiating institution) on the likelihood of testing was assessed separately for each potentially relevant factor by using a two-sided Chi-square test. For all comparisons a p-value of less than 0.05 was considered to be statistically significant. Both the field work and the preparation of the data (monitoring of completeness and accuracy, queries) for the statistical analysis and presentation were carried out entirely by O.I.s. (O.I.).

Results

The time to obtaining the test results is 9.2 days (median) in average, the time does not differ significantly (p=0.013) regarding type of institution: 3.9 days [2.3–10.1] in UH, 8.7 d in NUR (Range: 3–21 d), 9.8 d in lung clinics (Range: 3–14 d) and 11 d in OBD (Range: 4–30 d). The reported mean time to availability of test results varies considerably among the federal states: 5 days to 14 days, the ratio of the time to obtaining the test results by patient vs. center is to be higher in Germany (mean 40% in 3rd quarter 2011), but the regional disparities remained. In Germany the data was compared with the Dutch data (from 17.5% to 83%).

According to the analysis of reported data the treated prevalence was distributed among the institutions as follows: 3% university hospitals (UH), 54% non-university hospitals (NUR), 28% office based oncologists (OBD), 13% lung clinics. The majority of pts. in advanced NSCLC is treated outside of academic or specialised centres in NUR or in OBD.

Conclusions

Due to the distribution of patients at different institutions the reimbursement patterns vary considerably: the hospitals calculate the test costs within DROS, the vast majority of office-based practices (insure the compulsory health insurance (GHG), smokers status (OBD), gender (12%)), Furthermore, the patients eligible for the EGFR-testing were selected by individual characteristics as: performance status (0–2% centres), compliance (28% centre), age (13%) and preceding treatment (10%).

In general reported by 91% centres the test was performed only in pts. with specific clinical criteria (100% lung clinics, 95% UH, 95% NUR, 85% OBD). The clinical criteria used most frequently are the known predictors for clinical response: histology (88% centres), smoker status (OBD), gender (12%). Furthermore, the patients eligible for the EGFR-testing were selected by individual characteristics as: performance status (0–2% centres), compliance (28% centre), age (13%) and preceding treatment (10%).

In a German age the structure of the population differs significantly by federal states, we performed a regional analysis for population older than 65 years, as the majority of cancer patients is older than 65 years. In federal states with test rates of <40% (mean value) the population >65 y per hospital is significantly higher (mean value 84.0%, p<0.010) than in states with a test rates >40% (780 inh./<5 inh./y). The regional analysis indicates a predicting value of health care situation on the access of patients to the EGFR-mutation testing. The federal states with a lower density of hospitals present a test ratio below the mean level of 40%.

Only a minority of patients with NSCLC IIIB/IV (40%) had an access to EGFR testing in 1st quarter of 2011 and to the respective treatment in case of mutation. Reasons may be the long waiting-time for test results (mean 5.2 d) or the inappropriate reimbursement of testing, eg. in lung clinics physicians select the patients not only by predictors for clinical response but in addition by individual patient characteristics, perhaps, likely, in order to avoid the costs of testing. The regional data analysis indicates that the patient access to the EGFR-mutation testing is significantly related to the health care structure in the respective federal state. Inappropriate reimbursement and funding situation of cancer and diagnostics have led to significant regional disparities. However, the large regional disparities revealed a detailed analysis of regional health care structures in oncology.

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