QUALITY-ADJUSTED TIME WITHOUT SYMPTOMS AND TOXICITY (Q-TWIST) OF FOTEMUSTINE COMPARED WITH DACARBAZINE IN PATIENTS WITH DISSEMINATED MALIGNANT MELANOMA

Simons WR1, Aamdal S2, Hauschild A3, Mohr P4, Grob JJ5
1Global Health Economics & Outcomes Research, Inc, Summit, NJ, USA; 2Cancer Clinic, Oslo, Norway; 3Universitats-Hautklinik, Kiel, Germany; 4Dermatologisches Zentrum, Buxtehude, Germany.

OBJECTIVES: This study compares effectiveness of fotemustine and dacarbazine in treatment of patients with malignant melanoma with or without brain metastases using a Quality Adjusted Time Without Symptoms and Toxicity (Q-TWiST) integrating efficacy, safety and quality of life (QoL) into a composite measure of effectiveness. METHODS: Clinical trial data from a published study of fotemustine versus dacarbazine were used to partition overall survival into time spent in specific health states including toxicity, no progression and disease progression. Time spent with toxicity or disease progression was weighted by an arbitrary utility weight of 0.5. Survival analyses were conducted on the partition components. Time spent with toxicity or brain metastases was another analysis. Utilities were varied for sensitivity analyses. RESULTS: The composite measure, taking into account both efficacy and safety, demonstrated that fotemustine (N = 112) was significantly more effective than dacarbazine (N = 117), with an increase in quality-adjusted survival compared with dacarbazine (7.35 versus 5.64 months; P = 0.044). After taking into account time spent with toxicities, disease progression was avoided for an additional 1.54 months compared with dacarbazine (P = 0.005), a gain that is clinically significant for patients with a life expectancy of 6 to 9 months. Additionally, the mean quality-adjusted time to brain metastases was 15.39 months for the fotemustine treated patients compared to 7.04 months for the dacarbazine treated patients, for a gain of 8.35 months (P = 0.057). The quality-adjusted survival adjusting for time spent with toxicity or with brain metastases also favored treatment with fotemustine, 8.03 months versus 6.25 months (P = 0.054). Sensitivity analyses demonstrated the results to be robust. CONCLUSION: Q-TWiST analyses integrates efficacy, safety and QoL into a measure more appropriate for the assessment of cancer treatment and confirmed that fotemustine is significantly superior to dacarbazine, and provides a good alternative for the treatment of patients with malignant melanoma.

RETROSPECTIVE CHART REVIEW OF THE MANAGEMENT OF HAND-FOOT SYNDROME IN THE TREATMENT OF COLORECTAL CANCER

Ralston SL1, Almond J2, Holtz D2
1Merck Serono, Feltham, Middlesex, UK; 2Merck Serono, West Drayton, Middlesex, UK

OBJECTIVES: Tegafur with uracil (Uftoral) and capecitabine are two oral fluoropyrimidine therapies approved by NICE for the treatment of first-line metastatic colorectal cancer. One primary difference between the tolerability profiles of the two oral treatments is the incidence of hand and foot syndrome (HFS) which occurs in patients treated with tegafur with uracil in less than 1% of cases, and 57% overall for those treated with capecitabine (17% grades 3/4). The primary objective of this research is to describe the health resource utilisation associated with the incidence of HFS in patients treated with capecitabine for colorectal cancer. METHODS: This study is a retrospective chart review of the management of HFS with a case vs. control, observational, retrospective design. Information is collected from patient notes by 50 oncologist treating colorectal cancer from across the UK. Information on an overall sample of 600 patients will consist of 480 patients with HFS and 120 without. RESULTS: Interim analyses of 277 patients are presented. This consists of 205 patients with HFS (74%) and 72 patients without HFS (26%). 55% of patients were male. Of the 205 patients with HFS, 18.5% of patients discontinued treatment, 45% of patients’ treatment was interrupted/ delayed and in 55% of patients the dose had to be reduced. 43% of patients with HFS had a highest grade of 3/4. For patients with HFS severity grade 3/4, 62% experienced interruptions in treatment and 75% of patients had their treatment discontinued. With regards overall health resources utilised, there is a distinct trend reported of increased resource use for increasing grade of severity of HFS versus patients with no HFS. CONCLUSION: The preliminary results of this UK research suggest that the incidence of HFS from capecitabine treatment impacts a greater burden and resource utilisation than otherwise expected.

ECONOMIC IMPACT OF SECOND- AND THIRD-LINE ERLOTINIB TREATMENT OF NON SMALL-CELL LUNG CANCER: A FRENCH OBSERVATIONAL STUDY

Choustead C1, Vergnenegre A2, Moser A2, Couray-Omnès C3
1CHU Saint Antoine, APHP, Paris, France; 2CHU Limoges, Limoges, France; 3Roche Pharma, Neuilly sur Seine cedex, France

OBJECTIVES: This study examined care consumption and management costs among patients who received second- or third-line oral erlotinib therapy for non small-cell lung cancer (NSCLC). METHODS: The study involved two observational cohorts of NSCLC second- or third-line treated patients. In the first, created in 2005 (before erlotinib became available), the patients received IV chemotherapy alone (IV cohort, 233 patients), while the patients in the second cohort, created in 2006, received oral erlotinib (oral cohort, 166 patients). Only direct costs (payer’s perspective) were taken into account. RESULTS: Treatment lasted a similar length during second-line treatment but was significantly longer in the oral cohort during third-line therapy (p < 0.008). The rate of conventional hospitalization was not different between the two cohorts. In contrast, during 100 days of management, the patients in the oral cohort tended to spend less time in hospital during second-line treatment (p = 0.057), and the difference was statistically significant during third-line treatment (p < 0.05). Regardless of the line of treatment, the oral cohort made significantly fewer stays in day care (p < 0.001), and received significantly less antiemetic treatment (p < 0.0001), erythropoietin (p < 0.005) and G-CSF (p < 0.001), but required more treatment for skin rash (p < 0.001). Monthly management costs per patient in the IV and oral cohorts were respectively 3126 and 2750 euros during second-line treatment and 3026 and 2823 euros during third-line treatment (no significant difference). A sensitivity analysis showed that the results in the IV cohort were dependent on the cost of chemotherapy. One limit of this study is that transport costs were not taken into account. CONCLUSION: In oral cohort, the cost of erlotinib is compensated by the reduction of day care hospitalization costs and the limited cost of adverse events medications. These results must be validated by prospective observational studies focusing on quality of life and the time spent in hospital.