during the past 5 years. Collected variables: age, sex, ECOG, adjuvant chemotherapy, treatment line, dose reduction and adverse events (AE). Efficacy endpoints were progression-free survival (PFS) and overall survival (OS) obtained by the Kaplan–Meier method. Adverse effects (AE) were collected for safety profile assessment. Descriptive statistical analysis was performed using the SPSS Statistics program V22.0.

Results Forty-seven patients (30 men and 17 women) were included. The median age was 59 years (29–82). At the beginning of the treatment, more than 80% presented ECOG 0–1: 23.4% had received previous adjuvant chemotherapy (gemcitabine and/or fluoropyrimidines). They were treated with nab-paclitaxel 125 mg/m² and gemcitabine 1000 mg/m² on days 1, 8 and 15 every 28 days. In 89.4% of the patients it was prescribed as first-line treatment. Dose reduction was performed in 68.1%. The median duration of treatment was 4.5 months (0.5–22.9), with four long survivors (longer than 15 months). The median PFS was 9.1 months (95% CI 8.36 to 9.73) and the median OS was 9.11 months (95% CI 4.0 to 14.2). Eighty-three per cent of patients (n=39) had AE of some grade and 17% (n=8) of grade 3–4. The most common AE were: asthenia (n=17), neutropenia (n=16), thrombocytopenia (n=15), neuropathy (n=13), alopecia (n=5), diarrhoea (n=7), mucositis (n=3), vomiting (n=3), oedema (n=3) and dermatitis (n=2). These were grade 3–4: neutropenia (n=7), thrombocytopenia (n=4), mucositis (n=1), alopecia (n=1) and neuropathy (n=1). The causes of treatment discontinuation were mainly due to progression in 42.6% and deterioration of general health in 29.8%. At the end of the study, five patients continued treatment.

Conclusion The PFS obtained in our study is greater than those described in the pivotal trial MPACT or CA046. This difference may be due to the four patients with a considerably longer treatment than the average and a small sample. Regarding OS, there are no significant differences with the pivotal trial. The AE described were similar to those published in the literature

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-120 ERLOTINIB IN NON-SMALL-CELL LUNG CANCER WITHOUT EPIDERMAL GROWTH FACTOR RECEPTOR ACTIVATING MUTATIONS

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Background Erlotinib is indicated in patients without epidermal growth factor receptor (EGFR)-activating mutations who have had at least one previous chemotherapy treatment that has failed and when other treatments are considered unsuitable.

Purpose To analyse the effectiveness and safety of erlotinib in non-small-cell lung cancer (NSCLC) in patients without EGFR-activating mutations

Material and methods A retrospective observational study was conducted in a third-level hospital. We included patients

treated with erlotinib without EGFR-activating mutations from August 2012 to August 2018.

Following variables were recorded: age, sex, ECOG, histopathology, progression-free survival (PFS), smokers/non-smokers or ex-smokers, type of previous chemotherapy regimens, reported adverse events (AEs) and dose reductions between cycles.

We obtained data from electronic clinical records, the software where we register chemotherapy treatments (chemotherapy management software Oncogest) and the optimised computerised order entry ATHOS software.

AEs were classified according to the National Cancer Institute of Canada Common Toxicity Criteria v4.0.

Results Thirty-seven patients were included, with a median age of 64 years and 70% men. Fifty-seven per cent of patients presented ECOG 0 and the rest ECOG 1–2. Seventy-eight per cent of patients were smokers and/or ex-smokers. Ninety per cent of patients received erlotinib as the second line of treatment or subsequently, and the median PFS was 9.3 weeks. Previous chemotherapy regimens used before erlotinib in NSCLC were: taxane-based-chemotherapy 60%, platinum-based-chemotherapy 83% and both 74%. Forty-eight per cent of patients had at least one AE during treatment. The most frequent was skin rash g1–2 (60%). Thirty per cent of patients had dose reductions due to toxicity.

Conclusion In our patients, erlotinib median PFS was lower than in the BR21 trial. It could be explained because our patients received more previous regimens of chemotherapy for metastatic disease as well as our sample size was smaller. Regarding safety, erlotinib was well tolerated and in most of the cases, the AEs did not force a dose reduction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-121 COST-MINIMISATION ANALYSIS OF MAINTENANCE THERAPY OF ANTINEUTROPHIL CYTOPLASM ANTIBODY-ASSOCIATED VASCULITIDES

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Background The use of rituximab as maintenance treatment of antineutrophil cytoplasm antibody-associated vasculitides (AAVs) was supported by the MAINRITSAN trial. MAINRITSAN2 was a randomised, open-label, multicentre phase III trial which evaluated the difference between an individually tailored and a fixed-schedule maintenance therapy with rituximab. We found a large number of studies evaluating rituximab as a maintenance treatment in AAVs, but only a few looked at economic considerations. This cost-minimisation analysis (CMA) provides the best data available to date on the cost-saving option between a tailored-therapy and a fixed-schedule regimen with rituximab for the maintenance treatment of AAVs.

Purpose The present study used a cost-minimisation approach to examine the real-world costs of an individually tailored therapy compared to a fixed-schedule therapy with rituximab for remission maintenance of AAVs.

Material and methods We performed a CMA over an 18 month time period, estimating direct costs – drug acquisition, preparation, administration and monitoring costs – from the National Health Service perspective. We conducted a number of additional sensitivity analyses with different assumptions for unit costs, with two further scenarios including the interquartile range of the tailored-infusion group. In this analysis, we established a point of view of the health system without considering patients' preferences, or indirect and intangible costs.

Results The individually tailored maintenance therapy with rituximab was shown to be a cost-saving treatment compared to the fixed-schedule therapy (€ 6,048.36 vs. € 7,850.52). Savings resulted primarily from lower drug acquisition costs (€ 2,861.01 vs. € 4,768.35) and lower preparation and administration costs (€ 891.81 vs. € 1,486.35), due to the lower number of infusions per patient in the tailored-infusion regimen. In contrast, the tailored-infusion regimen presented higher costs in monitoring (€ 2,295.54 vs. € 1,886.70). This result was replicated in all assumptions considered in the sensitivity analysis.

Conclusion From the perspective of the health system, the tailored-therapy regimen would seem to be the preferable option in terms of costs. Further studies assessing all the costs associated to AAVs maintenance treatment with rituximab are needed to support clinical management and healthcare planning.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-122 EFFICACY AND SAFETY OF COBIMETINIB USED IN MONOTHERAPY FOR ERDHEIM-CHESTER DISEASE

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Background Erdheim-Chester disease (ECD) is a non-Langerhans cell histiocytosis characterised by the accumulation of foamy histiocytes in the retroperitoneum, long bones and large vessel areas. In wild-type (WT) BRAF patients, cobimetinib, a MEK inhibitor, has been used with success.

Purpose This study aims to evaluate the efficacy and safety of the MEK inhibitor cobimetinib used in monotherapy for ECD patients without the BRAF mutation.

Material and methods A total of three patients received cobimetinib alone. Through pharmacy software registration and electronic clinical history, we analysed the following variables: age, sex, date of diagnosis, presence of mixed histiocytosis, BRAF status, ECD manifestations, previous treatment and reasons to finish them, date of cobimetinib initiation, cobimetinib dose, initial-final creatinine level, evolution of histiocytic infiltrations and side effects. Cobimetinib efficacy was measured by monitoring histiocytic infiltrations and metabolic response with PET-CT scans. Safety was evaluated by number and severity of side effects.

Results Three patients, who are still on treatment, were included: two men and a woman, with a median age of 50 years. All of them were WT-BRAF and only one patient had mixed histiocytosis. Time from ECD diagnosis until

cobimetinib initiation was 11, 22 and 51 months. Manifestations included perirenal infiltration (n=2), long bones hypermetabolism (n=3), retroperitoneal fibrosis (n=2), cardiac involvement (n=1) and arterial affection (n=1). Before cobimetinib monotherapy, they had received pegylated interferon- α and discontinued it because of progression evaluated with PET-CT. All of them received cobimetinib 60 mg/day for 21 days of a 28 day cycle. One patient experienced complete response with three cycles, his creatinine level decreased significantly and he stopped dialysis. Another one reached an excellent metabolic response with three cycles. The third patient experienced stabilisation of perirenal infiltration. Adverse events registered were: rash (n=3), acne (n=2), arthralgia (n=2), diarrhoea (n=3), asthenia (n=2), cardiac failure (n=1) and erythema (n=1). No patient required dose reduction or stopped the treatment.

Conclusion Cobimetinib represents an option for WT-BRAF patients. However, its toxicity is considerable. Further research is certainly warranted to better define this therapeutic alternative.

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No conflict of interest.

4CPS-123 ANTIFIBROTICS IN IDIOPATHIC PULMONARY FIBROSIS MANAGEMENT: PIRFENIDONE AND NINTEDANIB

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Background Idiopathic pulmonary fibrosis (IPF) is an interstitial lung disease characterised by chronic, progressive fibrosis, progressive respiratory failure and high mortality. The main goal of treating IPF is to stabilise or reduce the rate of disease progression. Over the past 5 years, two novel antifibrotic therapies, pirfenidone and nintedanib, have been developed, providing treatment options for many patients with IPF.

Purpose To evaluate the efficacy and safety of the antifibrotic treatment with pirfenidone or nintedanib in patients affected by IPF.

Material and methods Retrospective observational study including all patients treated with antifibrotics until September 2018. Using the ATHOS program and their clinical history, we registered: sex, age, previous treatment, start date of antifibrotic, dose reduction, exacerbations experienced, and initial and final forced vital capacity (FVC) measured by a spirometry. Safety was evaluated by the adverse events reported. Efficacy was measured by comparing the initial and final FVC values. Data analysis was performed using the statistical package Excel for Windows 2010.

Results A total of 64 IPF patients were included (55 male, mean age 69 years): 43 in treatment with pirfenidone and 21 with nintedanib. The median duration of treatment (months) was 11 (3–47) with pirfenidone and 19 (3–46) with nintedanib. Patients with pirfenidone: 16 had no previous treatment; the mean FVC initial and final value was 72.7% and 79% respectively; one patient needed a dose reduction to control side effects; three patients suffered an exacerbation since pirfenidone initiation; most frequent adverse events were dyspnea