

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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No conflict of interest.

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.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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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