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 inter-quartile 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-infusion 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-123 EFFICACY AND SAFETY OF COBIMETINIB USED IN MONOTHERAPY FOR ERDHEIM–CHESTER DISEASE

M Muñoz Burgos*, T Desongles Corrales. Hospital Universitario Virgen del Rocio, Hospital Pharmacy, Seville, Spain

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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), asthaenia (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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(n=20), dry cough (n=12) and photosensitivity (n=7). Patients with nintedanib: eight had received pirfenidone before nintedanib; the mean FVC initial and final value was 71.6% and 69.4% respectively; one patient discontinued treatment for intolerance; two patients suffered an exacerbation since nintedanib initiation; and most frequent adverse events were diarrhoea (n=11), weight loss (n=7) and increase of the glutamic transaminase (n=6).

Conclusion Patients treated with pirfenidone improved their FVC, but they experienced more adverse events. Nintedanib stabilised the spirometric profile and was tolerated better than pirfenidone. Although they do not result in a significant FVC elevation and they have an important side-effect profile, both antifibrotics provide a treatment alternative for many patients with IPF.

REFERENCES AND/OR ACKNOWLEDGEMENTS
To my colleagues.
No conflict of interest.

4CPS-124 SAFETY AND EFFECTIVENESS OF TRASTUZUMAB EMETASIN IN LOCALLY ADVANCED OR METASTATIC HER2 POSITIVE BREAST CANCER
M Mejias Trueba, R Jimenez Galan, M Munoz Burgos*, AB Gil Vega Coca, AI Abdel Kader Martin, S Flores Moreno. Hospital Universitario Virgen del Rocio, Farmacia Hospitalaria, Seville, Spain
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Background TDM-1 was approved in November 2013 by the European Medicines Agency for the treatment of unresectable or metastatic breast cancer in patients who had previously received Trastuzumab and a taxane separately or in combination.

Purpose To evaluate the effectiveness and safety of TDM-1 in patients with advanced/metastatic HER2-positive breast cancer.

Material and methods Observational retrospective survey which included patients that received treatment with TDM-1 in the abovementioned conditions from January 2015 to June 2018. TDM-1 was administered intravenously (3.6 mg/kg) every 3 week cycle. Variables collected were: gender, age, expression hormonal receptor (HR), previous lines, progression and death date, adverse events (AD), treatment discontinuation and dose reductions. Progression-free survival (PFS) and overall survival (OS) were measured from time of the start of treatment with TDM-1 to date of first progression or death, respectively. PFS and OS were calculated by Kaplan–Meier analysis. Data analysis was performed using the statistical package SPSS 21.0 for Windows. Clinical data were obtained from digital clinical history and prescription software Farmis Oncofarm.

Results We included 40 patients, all of them women with a mean age of 55 years (SD=±13.7). Eighty per cent were HR+. 17.5% of patients received TDM-1 in the metastatic first line. The remaining 82.5% were previously treated with one or more therapies for metastatic disease; and the median number of previous chemotherapy lines was two (range 1–6). Previous HER2-targeted therapies included trastuzumab-based regimen (53%), pertuzumab/trastuzumab/taxane (47.5%), lapatinib/capecitabine (15%) and lapatinib/trastuzumab (7.5%). Mean follow-up was 15 months. Median PFS was 7 months (95% CI 4.3 to 9.7). No statistically significant differences were found in PFS according to HR status, age >65 years, number of previous lines or anti-HER2 therapy previously administered. Median OS was not reached, the 12 month OS was 73%.

AD occurred in 82.5% of patients, the most frequent being: anaemia (44%), hepatotoxicity (42.5%), asthenia (27.5%), thrombocytopenia (17.5%), peripheral neuropathy (15%) and arthralgia (12.5%). Dose reduction was necessary in 15% of patients. 17.5% discontinued treatment due to intolerable toxicities. Three patients presented grade 4 hepatotoxicity.

Conclusion Our results show lower median PFS and 12 month OS than those from randomised trials. Most of the patients presented with AD. Toxicity profile was similar to those previously described in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS
To my co-workers.
No conflict of interest.

4CPS-125 TOLERANCE TO CHEMORADIOThERAPY TREATMENT: COMPARING CAPECITABINE WITH 5-FLUOROURACIL IN NEOADJUVANT THERAPY FOR STAGE II–III RECTAL CANCER
L Perez Cordos*, S Marin Rubio, J Delgado Rodriguez, T Guerrera Roig, L Campins Bernadas, M Camps Ferrer. Hospital de Mataro, Pharmacy, Mataro, Spain
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Background The standard treatment for rectal cancer stage II–III is neoadjuvant chemoradiotherapy based on oral capecitabine (CPC) or continuous 5-fluorouracil (5-FU) infusion. While efficacy has been demonstrated to be equivalent between the two treatments, there is a discrepancy over safety.

Purpose To assess the incidence of adverse events (AE) between CPC and 5-FU in neoadjuvant chemoradiotherapy for rectal cancer to compare the safety profiles of both treatments.

Material and methods This was an observational, retrospective study on patients treated with CPC (1650 mg/m²/day) or 5-FU (225 mg/m²/day) from 2012 to 2018. Data was obtained from medical records and the oncology software Oncofarm. AE (reported as Grade 1–2 or ≥3), dose reductions, treatment interruptions and administration-related AE were assessed.

Results Seventy-six patients were included, 32 treated with CPC and 44 with 5-FU. Mean age was 63.1 (10.1) a in the CPC group and 62.3 (11.8) a in the 5-FU group. Sex: 24 (75.0%) in the CPC group and 34 (77.3%) in the 5-FU group were women. Adverse events: 36 AE G1–2 and 2 AE G≥3 were reported in the CPC group; and 61 AE G1–2 and one AE G≥3 were reported in the 5-FU group. Two patients in the CPC group reduced doses for diarrhoea and palmar–plantar eryrthodysaesthesia (PPE) and three patients discontinued the treatment for diarrhea, PPE and fatigue with anorexia; and one patient in the 5-FU group reduced doses for PPE.

‘values are mean (SD).