(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 EMTANSIN IN LOCALLY ADVANCED OR METASTATIC HER2 POSITIVE BREAST CANCER

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10.1136/ejhp-pharm-2019-eahpconf.273

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 (55%), 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 CHEMORADIO THERAPY TREATMENT: COMPARING CAPECITABINE WITH 5-FLUOROURACIL IN NEOADJUVANT THERAPY FOR STAGE II–III RECTAL CANCER

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10.1136/ejhp-pharm-2019-eahpconf.274

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 men. 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 erythrodysesthesia (PPE) and three patients discontinued the treatment for diarrhoea, PPE and fatigue with anorexia; and one patient in the 5-FU group reduced doses for PPE.

^avalues are mean (SD).