(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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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%), asthaenia (27.5%), thrombocytopaenia (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

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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/m^2/day) or 5-FU (225 mg/m^2/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 erythrodysesthaesia (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.

[a]values are mean (SD).

Abstract 4CPS-125 Table 1

	GRADE	CPC n (%)	5-FU n (%)
Anorexia	G1–2	4 (12.5)	8 (18.2)
	G≥3	0 (0.0)	0 (0.0)
Diarrhoea	G1–2	7 (21.9)	15 (34.1)
	G≥3	1 (3.1)	0 (0.0)
Dysgeusia	G1–2	1 (3.1)	2 (4.6)
	G≥3	0 (0.0)	0 (0.0)
Fatigue	G1–2	14 (43.8)	19 (43.2)
	G≥3	0 (0.0)	0 (0.0)
Haematologic alteration	G1–2	0 (0.0)	2 (4.6)
	G≥3	0 (0.0)	0 (0.0)
Maculopapular rash	G1–2	1 (3.1)	2 (4.6)
	G≥3	0 (0.0)	0 (0.0)
Mucositis	G1–2	2 (6.3)	3 (6.8)
	G≥3	0 (0.0)	0 (0.0)
Nausea/vomiting	G1–2	3 (9.4)	5 (11.4)
	G≥3	0 (0.0)	0 (0.0)
PPE	G1–2	4 (12.5)	3 (6.8)
	G≥3	1 (3.1)	1 (2.3)
Administration	–	–	2 (4.6)

Conclusion While the CPC group had a lower incidence of AE except for PPE, they had more dose reduction and treatment interruption. A posterior analysis showed that dose reduction and treatment interruption in the CPC group happened in the last week of treatment. In disagreement with previous studies, 5-FU patients had a higher incidence of diarrhoea.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-126 EFFECTIVENESS AND SAFETY OF NAB-PACLITAXEL IN PATIENTS WITH METASTATIC ADENOCARCINOMA OF THE PANCREAS IN A REAL-WORLD SETTING

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Background Nab-paclitaxel was approved for the treatment of metastatic adenocarcinoma of pancreas (mPAC), as a first treatment in combination with gemcitabine

Purpose To evaluate the effectiveness and safety of nab-paclitaxel in patients with mPAC in a real-world setting.

Material and methods Retrospective observational study of mPAC patients treated with nab-paclitaxel 125 mg/m^2+gemcitabine (March 2013 to September 2018). Variables: age, sex, ECOG, treatment line, number of cycles and dose reduction. Efficacy endpoints: progression-free survival (PFS) and overall survival (OS). For safety profile assessment, adverse effects (AE) that forced a dose reduction or treatment suspension were collected, also hospital recovering caused by nab-paclitaxel toxicity.

Results Thirty-six patients were included, 56% males. Average age: 64±10 years. Thirty-three per cent started with ECOG 0% and 67% with ECOG≥1. The treatment lines were: first (47%), second (36%) and ≥third (17%). The average number of cycles was 3.7±2. The median duration of treatment was 16 weeks (95% CI: 11 to 22). The median OS was 36 weeks (95% CI: 24 to 47), data for 33% of the patients was censored. The median PFS (mPFS) was 20 weeks (95% CI: 11 to 30). mPFS was compared in different groups: 33 weeks versus 20 in the first line compared to second or later lines (p=0.443) and 24 weeks versus 20 in ECOG 0 patients compared to ECOG≥1 (p=0.295).

Dose reduction was performed in 72% of patients. Causes: neurotoxicity (38%), blood toxicity (58%), poor tolerance to previous cycles (8%) and bad performance (3%). Sixty-one per cent of patients were hospitalised because of nab-paclitaxel toxicity and nine had to discontinue treatment because of neurotoxicity (n=3), blood toxicity (n=2), performance worsening (n=3) and hepatic toxicity (n=1).

Conclusion The results obtained in our study are consistent with the ones obtained in the pivotal trial: mOS 36 versus 34 weeks, mPFS 20 versus 22 weeks, duration of treatment 16 versus 16 weeks. The results of PFS seem to be better when nab-paclitaxel is used as a first line and in patients with ECOG 0, but the differences are not statistically significant (p=0.443, p=0.295). A bigger sample would be needed to confirm all results. The AE described were similar to those published in the literature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-127 DEVELOPMENT OF A STRATIFICATION MODEL FOR AMBULATORY ONCOLOGY PHARMACY PATIENTS

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Background To our knowledge, there is no pharmacy stratification model for patients in the oncology ambulatory setting.

Purpose To develop a tool to stratify oncology patients that helps us to implement ambulatory clinical pharmacy services.

Material and methods Phase I: a literature review was performed to identify risk factors for hospital admissions or emergency department (ED) visits in oncology patients and patients with care coordination requirements. Phase II: a panel of experts selected the variables of the model based on their impact on clinical pharmacy services and the feasibility of obtaining the data. Relative weight of each of the variables was assigned. Phase III: the stratification model was retrospectively tested on the population of patients that received care in the unit on a random day (13 June 2018). Three cut-offs were established to provide different levels of patient needs.

Results The variables were categorised under four domains (table 1).