The following variables were recorded: age, sex, line therapy, location of the primary tumour and metastases, treatment duration and adverse events associated with panitumumab.

Treatment efficacy was assessed according to Response Evaluation Criteria In Solid Tumours (RECIST) (criteria, progression-free survival (PFS) and global survival (GS).

Panitumumab safety was assessed by adverse events described in the clinical history.

Results A total of 33 patients (21 males) were included, whose average age was of 72±9,42 years and the treatment duration was 6.1±3 months.

Patients were treated with panitumumab monotherapy (40%), in combination with FOLFOX (30%), with FOLFIRI (18%) or with other combinations (12%). Panitumumab was used as first-line therapy in 48% of the cases.

Main locations of primary tumour were: colon (36%), sigma (31%), rectum (21%), rectum-sigma (9%) and cecum (3%). Hepatic metastases were developed by 63% of the patients.

According to RECIST criteria, the assessment of efficacy was: partial response (40%), progressive disease (30%), stable disease (21%) and complete response (9%).

Median PFS and GS were 4.5 and 17.3 months respectively. In combination with FOLFOX, 5.3 and 17.4 months, with FOLFIRI 4.6 and 17.1 months and in monotherapy 4.5 and 17.2 months.

The most frequent adverse events were dermal toxicity (97%), diarrhoea (60%), hypomagnesaemia (27%), conjunctivitis (15%) and constipation (6%).

Conclusion Panitumumab monotherapy, and in combination with chemotherapy, is effective and well-tolerated in the treatment of patients with mCRC, despite the high incidence of dermal toxicity.

Although the number of patients is limited, results obtained are similar to published studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-047 NIVOLUMAB FLAT DOSE, CLINICAL-ETHICAL AND ECONOMIC IMPLICATIONS

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Background In Italy, on 2 May 2018, the use of nivolumab (Obdivo) was approved in monotherapy in a 240 mg dose every 2 weeks to replace the weight-based dosage (3 mg/kg) for all approved indications (melanoma, non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC)) and a dose of 480 mg every 4 weeks (melanoma and RCC). The dosage change was based on pharmacokinetic data that showed good safety up to a dose of 10 mg/kg. The previous dosage was defined as off-label.

Purpose The purpose of this study was to evaluate any change in the drug-related adverse (ADR) events and any additional costs after the transition to the flat dose.

Material and methods We collected data from the National Pharmacovigilance Network (NPN) from the 2 May to 15 October in the years 2016, 2017 and 2018. The number of reported ADRs and the percentage of severe ADR has been compared (deaths were not considered). For the estimation of costs we considered all patients who received nivolumab treatment from 2016. For the naive patients after the 2 May, the dose was calculated with the old scheme of 3 mg/kg. For patients who had already discontinued therapy, the dose difference was calculated with the flat dose. The price ex-factory per mg was € 13.44.

Results The reported ADRs in NPN were, respectively: 174 (35.1% serious), 192 (34.4% serious) and 175 (58.3% serious). For the estimation of costs, an average increase of 35.3 mg for a single administration, corresponding to an increase of € 474.43, was measured.

Conclusion Since the flat dose was calculated on a hypothetical patient weighing 80 kg, it was easy to view a rapid increase in direct costs related to the drug (11 out of 15 of the patients considered had lower weight). Despite the bias related to the applied methodology, it is possible to think that the costs associated with nivolumab will increase. Furthermore, it is not clear why the 3 mg/kg dosage is to be considered off-label. Furthermore, it is interesting to note that the number of serious ADRs has increased. However, pharmacovigilance monitoring is required to evaluate changes in the safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-048 REAL-WORLD SAFETY AND TOLERABILITY OF THE RECENTLY COMMERCIALISED PALBOCICLIB

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Background Palbociclib was commercialised in November 2017, for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant (in women who had received prior endocrine therapy).

Most common adverse events (AE) described in clinical trials (CT) were: haematological (neutropaenia (80.6%), leucopaenia (45.2%) and anaemia (27.6%)), and no-haematological, above all infections (54.7%). Neutropaenia was the most common AE, experienced in grade (G) 3 or 4 in 55.3% and 10.1% of patients, respectively. Median time for the first neutropaenia episode was 15 days, with a median duration of 7 days.

Purpose To evaluate the safety of palbociclib in real-world clinical practice and compare it with the results of CT.

Material and methods Prospective observational analysis (February to October 2018) on patients treated with palbociclib, in a regional hospital. Patients' demographics and treatment evolution related to toxicity were analysed. Toxicity grade was classified by CTCAE V5.0. In each visit, the pharmacist revised physician's prescription according to patient's analysis results and made recommendations.

Results Nine women (average age of 56) with metastatic breast cancer HR-positive/HER2-negative were included. Five patients had been previously treated: hormonal therapy (3/9), chemotherapy (1/9) or both (1/9). According to prior treatments,

five received palbociclib in combination with an aromatase inhibitor and four with fulvestrant. The median number of cycles received per patient was 4.5 (3–7). All presented neutropaenia in G3 (78%) or G1–2 (22%), experienced it after the first 15 days of treatment and although recovered, reappeared in ulterior cycles, leading to various discontinuations in seven patients (delays or interruptions of 7–14 days). Sixty-six per cent required dose reductions down to 100 or 75 mg, but no one had to stop treatment. Other AE with an incidence <24% were: rash and stomatitis G2, asthaenia, diarrhoea, leucopaenia and anaemia G1. No infections were reported.

Conclusion In clinical practice, the proportion of patients affected by neutropaenia was higher than in CT, with a 23% more incidence of G3. Close monitoring contributed to managing neutropaenia and preventing ulterior infections. In the future, it would be interesting to evaluate if discontinuations or dose reductions of palbociclib affect its efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-049 ATEZOLIZUMAB: EFFICACY AND SAFETY IN ADVANCED NON-SMALL CELL LUNG CANCER

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Background Results of the OAK study demonstrated that atezolizumab improved median overall survival and progression-free survival of patients with advanced non-small cell lung cancer (NSCLC).

Purpose Evaluate the efficacy and safety of atezolizumab treatment in patients with metastasic or advanced NSCLC in second and successive lines.

Material and methods Retrospective observational study in which patients with NSCLC were included who started treatment with atezolizumab in the second or successive line, during the period from April to September 2018. Data were collected on demographic variables (age and sex) and clinical variables (ECOG, smoking habit, previous chemotherapy, dose, number of cycles and adverse reactions) through clinical history (Selene) and the oncological prescription program (Farmatools). The descriptive statistical analysis was carried out through the SPSS vs22.0 program. Efficacy was evaluated in terms of progression-free survival (PFS) and overall survival (OS), calculated by the Kaplan–Meier method. To assess safety, the severity of adverse events (AA) was measured according to CTCAEv4.0

Results We analysed 14 patients, 9 males and 5 females. Ninety-three per cent were smokers or ex-smokers, and 7% had never smoked. Eleven patients had ECOG 0–1 and three ECOG 2% and 93% had metastases at the start of treatment with atezolizumab. All patients had received prior platinum-based chemotherapy as first-line treatment. The dose administered was 1200 mg every 3 weeks and the average of cycles was four. The median of PFS was 4.8 months (95% CI: 1.0 to 8.6) and the average of OS 4.5 months (95% CI: 3.6 to 5.4). 57.14% of the patients presented some AA of any degree and only 12.5% were grade 3–4. The most frequent were renal failure (37.5%), diarrhoea (25%), rash (25%), hypersensitivity (12.5%), thrombocytopaenia (12.5%), lung infection (12.5%), oedema (12.5%), emésis (12.5%) and decreased appetite (12.5%)

Conclusion The efficacy in terms of OS obtained was lower than that of the OAK study (13.8 months). However, when the PFS was analysed in our study, it was superior to that of the OAK study (PFS 2.8 months). In general, atezolizumab presents an acceptable safety profile, the most frequent AEs coincide with those described in the literature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-050 TOXICITY WITH 5-FLUOROURACIL AND IRINOTECAN: INTEREST OF GENOTYPING IN PATIENT CARE

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Background Twenty-five per cent of patients treated by 5-fluorouracil and 40% treated by irinotecan had serious adverse events (SAE).[1]. Forty per cent of 5-fluorouracil toxicities are due to a partial deficit of dihydropyrimidine dehydrogenase (DPD). Fifteen per cent of caucasians also have a uridine diphosphate glucuronosyltransferase 1A1 (UGT1A1) enzymatic polymorphism. When one of these deficits exists, patients require chemotherapy dosage adjustment in order to limit haematological and/or digestive toxicities. This year, new recommendations from our National Health Institute have been issued concerning the systematic prospective genotyping of DPD. Despite numerous SAE, this preventive genetic research is not systematically performed by oncologists.

Purpose This study highlights the medico-economic interest of the genetic screening for DPD and/or UGT1A1 deficits before the initiation of chemotherapy with 5-fluorouracil and/or irinotecan in order to optimise patients' therapeutic care.

Material and methods The patients from one oncologist who received genetic screening between January 2015 and April 2018 were analysed. The following criteria were collected: diagnosis, cancer status, prospective or retrospective screenings, screening results, types of SAE, dose reductions, shifts of chemotherapy treatments, and hospitalisations for adverse reactions and their costs.

Results For 40 months, 51 patients (average age: 66.4 years old) were genotyped out of 310 treated (132 by fluorouracil, two by irinotecan and 176 by both). Twenty of them were prospective. The study discovered 31 deficits: five DPD deficits, 21 UGT1A1 deficits and five combined deficits without complete deficit. Among them, 18 (58%) reported significant toxicities to chemotherapy with 5-fluorouracil and/or irinotecan while four (13%) had been screened before the initiation of chemotherapy. Half (n=9) required a shift to the next chemotherapy. Five hospitalisations were identified following a serious adverse event induced by the chemotherapy. Four of them (costing € 14,500) could probably have been avoided by prospective screening and a dosage adjustment at the initiation of treatment.