patients with advanced gastric cancer (AGC): limited treatment, maintenance of some drugs or treatment until progression.

Purpose Assess prognostic factors and progression-free survival (PFS) in each stratum stablished according to the duration of the treatment.

Material and methods The sample comprises patients from the AGAMENON multicentre registry in which 31 Spanish and one Chilean centre participated. The eligibility criteria include adults (≥18 years) with a histologically confirmed unresectable or AGC and first-line polychemotherapy without progression in the second evaluation of response at approximately 6 months. Multi-state models were used to model processes in which participants undergo transitions from one state to another (e.g., from initiation to cessation of drugs, and from that point to progression or death). In order to examine time-varying states, a Markov multi-state model was used. On the cumulative scale, the transition probability matrix was established by the Aalen–Johansen estimator.

Results We analysed 415 patients treated between January 2008 and September 2017. The patients were divided into three strata: discontinuation of platinum and maintenance with fluoropyrimidine until progression (30%, n=123); complete treatment withdrawal prior to progression (52%, n=216); and full treatment until progression (18%, n=76). Compared to those receiving treatment until progression, no decrease in PFS was observed in participants who discontinued all treatment (HR 1.16, 95% CI, 0.70 to 1.92) or in whom platinum was suspended (HR 0.92, 95% CI, 0.54 to 1.58). With respect to PFS prognostic factors, a significant effect was observed for ECOG ≥2 in stratum 3 (HR 4.06, 95% CI, 1.40 to 11.7). The presence of ≥3 metastatic sites revealed a prognostic effect after discontinuing platinum (HR 1.65, 95% CI, 1.06 to 2.56) or all chemotherapy (HR 1.65, 95% CI, 1.06 to 2.56). Bone metastases were an adverse prognostic factor in all the strata (HR 1.64, 95% CI, 1.13 to 2.37). Complete response was a protective factor after withdrawing the entire regimen (HR 0.31, 95% CI, 0.16 to 0.57) or platinum (HR 0.12, 95% CI, 0.03 to 0.41). No significant interactions between covariates were detected.

Conclusion In this registry of AGC, treating until progression did not impact PFS compared to maintenance or discontinuation after a predefined number of cycles.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We thank all the researchers of the AGAMENON registry.

No conflict of interest.

4CPS-107 EFFECTIVENESS AND SAFETY STUDY OF NIVOLUMAB IN THE SECOND LINE OF ADVANCED NONSQUAMOUS NON-SMALL CELL LUNG CANCER

M Camean-Castillo*, C Martinez-Diaz, MD Gil-Sierra, MP Briceño-Casado, FJ Salmeron-Navas, S Fenix-Caballero, J Diaz-Navarro, E Rios-Sanchez, EJ Alegre-Del Rey, JM Borrero-Rubio. *H.U. Puerto Real, Pharmacy, Cádiz, Spain*

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Background After the approval of nivolumab some time ago it is necessary to analyse if the results of the randomised clinical trials are correlated with usual clinical practice.

Purpose In this study we assessed median progression-free survival, overall survival and safety in patients diagnosed with advanced nonsquamous non-small cell lung cancer who received the second line of treatment with nivolumab monotherapy in our hospital, comparing it with the results of the pivotal trial.

Material and methods A retrospective and descriptive review of patients treated with nivolumab in our centre from January 2016 to September 2018 was done. The patients received 3 mg/kg every 14 days. The following variables were collected from the unified clinical history and the cytostatic management programme: nonsquamous non-small cell lung cancer diagnosis, sex and performance status. The progression-free survival and overall survival curve was constructed using the Kaplan–Meier method, from which the median was obtained and compared to the pivotal trial (CheckMate 057). The main adverse events were collected.

Results Twenty-five patients were treated in the second line with advanced nonsquamous non-small cell lung cancer with nivolumab of whom 80% was male. Performance status was 0, 1 or 2 in 28%, 68% and 4% patients respectively. Median progression-free survival reached was 5.5 months, which was 3.2 months higher than the trial (2.3 months). Median overall survival reached was 12 months which was 0.2 months lower than the trial (12.2 months). The most prevalent adverse events were asthaenia (44%), nausea (20%) and diarrhoea (12%). There were two patients with grade 3 asthaenia, one patient with alanine aminotransferase increased grade 3 and one patient with pneumonitis.

Conclusion The effectiveness obtained measured with median progression-free survival was higher than that of the pivotal trial, and analogous measured as overall survival, however we must take into account the limitations of a study with a low number of patients. A small percentage of patients present adverse events grade 3.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-108 DABRAFENIB AND TRAMETINIB: COMBINATION THERAPY FOR METASTATIC MELANOMA

C Carriles Fernandez*, A Arias, C Rosado María, I Zapico García, B Zarate Tamames, R Menárguez Blanc, A Lozano-Blázquez. *Hospital Universitario Central de Asturias, Pharmacy, Oviedo, Spain*

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Background The BRAF inhibitor dabrafenib and the MEK inhibitor trametinib are indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF (V600) mutation. The combination of both drugs has shown more effectiveness and an increase in survival. These are used in first-line treatment for patients with mutated BRAF, and in the second line for patients with no-mutated BRAF.

Purpose To evaluate the effectiveness and tolerability of both dabrafenib and trametinib, based on the overall survival (OS) and progression-free survival (PFS) for metastatic melanoma.

Material and methods Retrospective study that included patients receiving a combination of dabrafenib and trametinib. The period of study was from May 2015 until 30 September 2018 (end of study). The required data was obtained from clinical electronic history Cerner Millennium and the variables

were: gender, age, wild or mutated BRAF, dose reductions, start date, adverse effects, progression and death date.

The Kaplan–Meier method was used to analyse PFS and OS. Statistical analysis was made with STATA.14.

Results There were 14 men and 18 women receiving the combination. Median age was 59.4 years (range 34.4–82.7) and V600-BRAF was mutated in all patients.

Most of the patients left the treatment, and only six are still receiving it. Patients that discontinued the treatment were 25 due to progression and two due to adverse effects. The median PFS is 7.38 months (95% CI: 5.51 to 11.44). During the study, 13 patients died. The median OS is 16.23 months (95% CI: 14.52 to not reached).

Many adverse effects appeared with this combination and 38% of the patients had to reduce dose due to toxicity. Most common side effects were: fever, dermatologic effects (such as eczema, rash, oedemas), neurological toxicity (such as cephalea, confusion, dizziness, loss of memory), visual alterations (photophobia, visual reduction) and asthaenia.

Conclusion Dabrafenib and trametinib are a good alternative for patients diagnosed with metastatic melanoma with BRAF mutation. Despite the toxicity, this is a serious conditioning for patients' life, and the results of PFS and OS are significant for patients without other options for years. More studies comparing dabrafenib and trametinib with other therapies in advanced melanoma, such as immunotherapy, are required to choose the best option for treating patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-109 POTENTIAL DRUG-DRUG INTERACTIONS INVOLVING TYROSINE KINASE INHIBITORS IN PATIENTS WITH CHRONIC MYELOID LEUKAEMIA TREATED AT A UNIVERSITY HOSPITAL

[1]N Dewulf*, [2]ACF Modesto, [2]NA Sousa. *[1]Pharmacy School – Federal University of Goias, Research Laboratory in Health Teaching and Services, Goiânia, Brazil; [2]Clinical Hospital of Federal University of Goiás, Pharmacy Division, Goiânia, Brazil*

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Background Chronic myeloid leukaemia (CML) is a chronic myeloproliferative haematological disease that uses tyrosine kinase inhibitors (TKI) as treatment. The patients' quality of life has improved satisfactorily, however, the use of them bring inherent risks. Drug interactions may compromise the patient's direct safety which could be undesirable and even irreversible, causing harm to the patient's health and even leading to death. More knowledge about these drug interactions are important in structuring a specified pharmaceutical service.

Purpose To analyse the potencial drug interactions (PDI) and its factors associated in patients with CML using TKI treated at a university hospital, aimed at improving patient safety.

Material and methods Cross-sectional analytical study with a sample of 101 patients. Data were collected in the patients' charts and the outcome variable was the presence of PDI, inquired in Micromedex database. Multivariate regression was performed using the Poisson multiple regression model.

Results One-hundred and five PDI were identified with a prevalence of 53.5%. Of the 43 PDI involving TKI, 19 different pairs of drug-drug interactions were observed: 13 (68%) were severe and six (32%) were moderate. The main conduct was therapeutic drug monitoring. The most prevalent pair among the severe ones was Imatinib Mesylate with Domperidone (20%) and among the moderate ones was Imatinib Mesylate with Levothyroxine (50%). The occurrence of PDI has been shown to be associated with female sex, the chronic phase of the disease, the use of Dasatinib and the use of more than five drugs concomitant with TKI.

Conclusion Results revealed a significant number of PDI among patients with CML. In addition, they suggest associated PDI risk factors commonly reported in the literature: chronic disease, female sex and polypharmacy. An important finding was the use of TKI Dasatinib. Most interactions can compromise patient safety, which highlights the importance of this topic and the need to evaluate and monitor the cancer patient's drug therapy.

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No conflict of interest.

4CPS-110 SAFETY AND EFFECTIVENESS OF OBINUTUZUMAB IN CHRONIC LYMPHOCYTIC LEUKAEMIA: OUR EXPERIENCE

C Fernandez Cuerva*, C Ortega de la Cruz, JC del Rio Valencia, B Mora Rodriguez, I Muñoz Castillo. *Hospital Regional Universitario de Málaga, Servicio de Farmacia, Málaga, Spain*

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Background Obinutuzumab is an anti-CD20 monoclonal antibody approved in combination with chlorambucil for patients with chronic lymphocytic leukaemia (CLL) and comorbidities, making them unsuitable for full-dose fludarabine-based therapy.

Purpose To analyse the safety and effectiveness of obinutuzumab combined with chlorambucil as first-line treatment in our hospital.

Material and methods Observational, retrospective, descriptive study. Inclusion criteria: adults (>18 years) that initiate treatment with obinutuzumab-chlorambucil. Study period: January 2017 to September 2018. Demographic variables: gender, age; clinical variables: diagnose and cumulative illness rating scale (CIRS); and therapy-related: adverse events and suspension. Safety was evaluated in all patients that received at least one obinutuzumab dose by analysing adverse events (AE) from clinical records, treatment delays and/or concomitant medication required. AE are classified following the 5.0 version of National Institute Cancer: Common Terminology Criteria for Adverse Events. Effectiveness was evaluated following International Workshop CLL; Halleck 2008 criteria a minimum of 3 months after the end of treatment.

Results Seven patients were included (four male and three female), median age: 72 years (rank 67–82). Median CIRS punctuation: 9 (rank 6–11). All patients received premedication with corticosteroids, antipyretic and antihistaminic to avoid infusion-related reactions (IRRs) and allopurinol as prophylaxis for tumour lysis syndrome.

During the first infusion, two patients presented hypertension, abdominal pain and cold as grade 1–2 IRRs requiring temporary interruption. IRRs were not recorded in the following perfusions.