Background Colorectal cancer represents a major health problem in developed countries. The incidence increases with age. Median age at diagnosis is about 70 years. This creates new needs in the treatment antineoplastic, considering the characteristics of this group of patients: functional alterations that increase the toxicity of drugs, high comorbidity and polypharmacy.
Purpose To describe chemotherapy treatments in elderly patients with colorectal cancer.
Material and methods Descriptive, retrospective study in which patients selected were older than 70 years who had received chemotherapy treatment for colorectal cancer, in the period January 2016 to October 2017. Data collected: sex, age, treatment schemes, reduction in dosage, duration of treatment and side effects.
Results Thirty-four patients were included, mean age 72.97 ±3.36, 58.82% men (n=20). Baseline ECOG was 0 in 29.42% of cases, 1 in 66.64% and 2 in 2.94%. 64.70% patients were diagnosed with stage-IV, 26.47% stage-III and 8.83% stage-II.

Twelve patients in stage II–III were treated with adjuvant-chemotherapy: XELOX (oxaliplatin/capecitabine), FOLFOX6 (oxaliplatin/fluorouracil/folinate) or capecitabine monotherapy. Six patients relapsed: median to relapse was 11 months (4–20).

Patients in stage-IV: 50% liver metastasis, 27.27% lung-liver metastasis, 9.1% retroperitoneum-liver, 9.1% lung metastasis and 4.53% retroperitoneum metastasis.

7/22 patients received perioperative-chemotherapy: XELOX or mFOLFOX6. Four patients relapsed, median to relapse: 5.5 months (3–11).

Twenty-five patients received palliative chemotherapy, median of overall survival 24, (95% CI: 21 to 27). Median of lines of treatments was 3 (1–6). Schemes utilised in first-line: FOLFOX±cetuximab or bevacizumab, FOLFIRI±cetuximab or bevacizumab (irinotecan/fluorouracil/folinate), XELOX, capecitabine.

Fifty per cent of patients underwent dose reduction and 60% had delays of administration due to toxicity.

Side effects: 56% suffered from asthaenia (grade 2–3), 28% mucositis (grade 1–3), 44% neutropaenia (grade 2–3), 60% diarrhoea (grade 2–3), 20% nausea grade 1, 16% vomit (grade 1–2), 56% cutaneous toxicity associated with anti-EGFR drug (grade 1–3), 24% thrombocytopaenia (grade 1–2), 20% neurotoxicity (grade 1–3) and 20% paraesthesia (grade 1–2).
Conclusion There is a tendency to reduce drug doses in the elderly patient, although not always in an established manner. It would be interesting to undertake studies to adapt the intravenous chemotherapy treatment differently to the rest of the adult population, as well as to objectify the overall health, quality of life and functionality of the elderly patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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4CPS-105 PRESCRIBED ANTINEOPLASTIC AGENTS IN PAEDIATRIC PATIENTS

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Background Many medicines prescribed for children have not been formally studied. Therefore, most of them are not labelled to be used in paediatric patients (PP). The Regulation (EC) No 1901/2006 on medicinal products for paediatric use sets up several requirements, rewards and incentives to promote medicinal products being researched, developed and authorised covering the therapeutic needs of children.
Purpose To evaluate the prescription profile of antineoplastic agents in PP in two relevant hospitals in paediatrics that belong to a Regional Health Service.
Material and methods Descriptive study of antineoplasic drug prescription in the PP in the Oncology and Haematology Departments during 2017. Data collected: age and drug (brand/generic name and active substance). Indications and use conditions for the prescribed drugs were evaluated according to the EMA summary of product characteristics They were classified as approved, unlicensed or off-label. Unlicensed drug use was defined as the use of a non-marketed drug. Off-label drug use was defined as the use of a drug in unapproved conditions.
Results A total of 220 children were included (average age: 7.77 years). Six-hundred and forty-seven prescriptions (involving 52 different active substances (AS)) were evaluated. 68.32% of all prescriptions were approved drugs (26 different AS), 12.98% were unlicensed drugs (13 different AS) and 18.70% were off-label drugs (18 different AS). One-hundred and eighty-one children received at least one approved drug, 73 at least one unlicensed drug and 95 at least one off-label drug. Unlicensed and off-label drug use in younger children was higher: 51.24% in 0–4 year old children received at least one unlicensed or off-label drug against 45.57% of 12–17 year old children. Most commonly prescribed approved drugs were: vincristine (12.52%), cyclophosphamide (8.81%) and cytarabine (8.50%). Most commonly prescribed unlicensed drugs were: mercaptopurine oral solution (3.71%), dactynomicin (2.63%) and pegaspargase (2.16%). Most commonly prescribed off-label drugs were: carboplatin (3.71%), bevacizumab (2.78%) and ifosfamide (2.32%).
Conclusion Despite Regulation (EC) No 1901/2006, the results of our study show that around two-thirds of the children received at least one unlicensed or off-label antineoplasic agent.

Proper clinical studies demonstrating and supporting the use of effective and safe drugs on PP are required.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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4CPS-106 MULTI-STATE MODEL TO ESTIMATE THE OPTIMAL DURATION OF FIRST-LINE CHEMOTHERAPY IN ADVANCED GASTRIC CANCER: DATA FROM THE NATIONAL REGISTRY AGAMENON

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Background To date, there has been no phase III trial to establish the optimal duration of first-line chemotherapy for

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

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No conflict of interest.

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

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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

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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