

**Background and importance** Selective cyclin dependent kinase (CDK) inhibitors, palbociclib and ribociclib, were recently approved to treat advanced or metastatic breast cancer. The hospital pharmacist plays an important role in the revision of the treatment at consultation, in order to ensure the safety and effectiveness of the treatment.

**Aim and objectives** To analyse potential drug interactions (PDI) before starting palbociclib or ribociclib treatment and to evaluate physician acceptance of pharmacist recommendations.

**Material and methods** This was a retrospective observational study including all patients who started treatment with palbociclib or ribociclib in a second level hospital until September 2019. At the beginning of treatment, the pharmacist interviewed patients and reviewed their medication in the pharmaceutical consultation. All PDI detected were analysed, making an intervention as therapeutic recommendations.

PDI were identified using Lexicomp, Stockley's Drug Interactions, Micromedex and CheckTheMeds. PDI were classified as moderate (pharmacological effects must be controlled) or severe (drug combination should be avoided). Follow-up of the recommendations was made 1 month after the beginning of treatment at the pharmaceutical consultation.

**Results** Twenty-eight patients started palbociclib (50%) or ribociclib (50%) treatment in our hospital (95.9% women; mean age 63.6±9.8 years). Sixteen (57%) were polymedicated; the average number of medications per patient (not including endocrine and CDK inhibitors therapy) was 6.25. Thirty-one PDI were detected in 18 different patients (64.3%). There were 14 (45.2%) severe PDI and 17 (54.8%) moderate PDI. The most common types of drugs involved were statins (22.6%), proton pump inhibitors (22.6%), antidepressants (12.9%) and pyrazolones (16.1%).

Eleven severe PDIs were accepted (78.6%). Moderate recommendations led to a reduction in antidepressant dosage (5.9%) and two change of drugs involved in the interaction (11.8%).

**Conclusion and relevance** This study showed that more than half of patients that started treatment with CDK inhibitors has at least one PDI. Clinical pharmacists are essentials in detecting PDI, which is a positive influence on physician prescriptions and patient treatment outcomes, improving the safety and effectiveness of the oncological treatment.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

#### 4CPS-075 IBRUTINIB ASSOCIATED ATRIAL FIBRILLATION: INCIDENCE AND MANAGEMENT IN THE REAL LIFE CLINICAL SETTING

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**Background and importance** Atrial fibrillation (AF) is one of the most common side effects of ibrutinib, a drug that has improved the prognosis of chronic B cell malignancies. The incidence of ibrutinib related AF (IRAF) is not well known in the 'real life' setting, and management is challenging, especially due to the risk of bleeding with ibrutinib and its pharmacological interactions with antiarrhythmics and anticoagulants.

**Aim and objectives** To determine the incidence of IRAF, and to analyse the characteristics and treatment of this arrhythmia in a real life clinical setting.

**Material and methods** A retrospective observational study was conducted including patients treated with ibrutinib. Patient characteristics and the management of IRAF were recorded using the electronic medical history. Numerical variables were expressed as mean (SD) and categorical as frequencies (percentages).

**Results** Twenty-eight patients were treated with ibrutinib and 5/28 (17.8%) patients developed IRAF. Patient characteristics are shown in table 1.

Abstract 4CPS-075 Table 1

	Patients without IRAF=23 (85.2%)	Patients with IRAFN=5 (17.8%)
Age (years)	73±11	75±6
Sex (M/F)	12/11	4/1
Previously AF (n (%))	1 (4.4)	1 (20)
Indication LLC (n (%))	20 (86.9)	4 (80.0)
Ibrutinib duration (months)	13.7±11.2	18.6±9.7

Of the 5 patients who developed IRAF, 2 were grade 3 requiring electric cardioversion and discontinuation of treatment until recovery to grade 1. The other three cases were grade 1 or 2 and treatment was not suspended. In all 5 patients, anticoagulant was initiated (apixaban in 3, rivaroxaban and low molecular weight heparin in 1 patient, respectively). Treatment with beta-blockers was started in 3 patients and in 1 patient the arrhythmia was recurrent, requiring new cardioversion, initiation of amiodarone treatment and ibrutinib dose adjustment. Median time for the appearance of IRAF was 13 months. No major bleeding events occurred.

**Conclusion and relevance** This study showed a higher prevalence of IRAF similar to other studies in real life, but with a longer median onset, justifying close monitoring during the first months but also throughout treatment with ibrutinib.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

#### 4CPS-076 INDIRECT COMPARISON BETWEEN PEMBROLIZUMAB MONOTHERAPY AND PEMBROLIZUMAB CHEMOTHERAPY REGIMENS IN SQUAMOUS LUNG CANCER

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**Background and importance** Pembrolizumab monotherapy (Pb) showed benefit in terms of overall survival (OS) and progression free survival (PFS) compared with chemotherapy alone (CT) in untreated metastatic non-small cell lung cancer (mNSCLC) with PD-L1 ≥50% expression. The Pb-CT

combination presented benefit in terms of OS and PFS in untreated metastatic squamous NSCLC (mSNSCLC), regardless of PD-L1 expression. No randomised clinical trials (RCTs) of Pb-CT versus Pb alone have been done.

**Aim and objectives** To assess the comparative efficacy of Pb and Pb-CT in untreated mSNSCLC patients with PD-L1  $\geq 50\%$  using an adjusted indirect treatment comparison (ITC).

**Material and methods** A bibliographic search was conducted in the Pubmed database (2 October 2019). Inclusion criteria were phase III RCTs, Pb and Pb-CT treatments, similar mSNSCLC population (with PD-L1  $\geq 50\%$ ), follow-up period and end points (OS or PFS). Exclusion criteria were mSNSCLC population with EGFR or ALK mutations. An ITC was developed using Bucher's method. Delta value ( $\Delta$ ), maximum acceptable difference as a clinical criterion of no inferiority, was set at 0.70 (and its inverse, 1.43), used to calculate the sample size in the Pb-CT trial. The Shakespeare method was used to estimate the probability of the results out of the  $\Delta$  margins.

**Results** Two studies, one for each regimen,<sup>1 2</sup> were found in the literature search. Limitations found between Pb-CT and Pb trials included populations (all patients vs only patients with PD-L1  $\geq 50\%$ , respectively, subgroup data used for ITC) and small size of the squamous subgroup. No OS data were available for the squamous subgroup in the Pb trial. PFS was taken as the primary end point for ITC. Results of RCTs and ITC are shown in table 1.

Abstract 4CPS-076 Table 1

Reference	PFS
Pb-CT vs CT <sup>1</sup>	HR=0.37 (95% CI 0.24–0.58, PD-L1 $\geq 50\%$ subgroup)
Pb vs CT <sup>2</sup>	HR=0.35 (95% CI 0.17–0.71, squamous subgroup)
Pb-CT vs Pb (ITC)	HR=1.06 (95% CI 0.46–2.45)

No significant differences in PFS between Pb-CT and Pb were found. The 95% CI exceeded  $\Delta$  on both sides (high level of uncertainty). The probability of a result out of  $\Delta$  were 24.14% below and 16.54% above.

**Conclusion and relevance** ITC did not show significant differences in PFS between Pb-CT and Pb. No evidence of clinically relevant benefit from one or other regimen was found. Considering the toxicity related to the addition of CT, Pb monotherapy would be preferable in untreated mSNSCLC with PD-L1  $\geq 50\%$ .

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No conflict of interest.

#### 4CPS-077 DETECTION AND COMMUNICATION OF CONCOMITANT USE OF CAPECITABINE AND PROTON PUMP INHIBITORS

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**Background and importance** Recent data suggest that the concurrent use of proton pump inhibitors (PPI) may reduce the efficacy of capecitabine by decreasing its absorption. It was associated with poorer progression free survival (PFS) and overall survival in a secondary analysis of the TRIO-013 trial.

Univariate analysis of a retrospective study of patients treated with capecitabine for colorectal cancer found that PPI use was associated with a decrease in 5 year PFS. Although the authors concluded that a significant interaction exists, after multivariate analysis, PPI use was no longer associated with worse PFS. No interaction was observed with magnesium–aluminium hydroxide containing antacid. According to this, the probability of interaction may be doubtful. However, because the possible outcome may be serious, we suggested an intervention to alert oncologists.

**Aim and objectives** A protocol was implemented to detect the concurrent use of PPI in outpatients treated with capecitabine and to communicate the drug interaction to oncologists. The aim of this study was to describe the pharmacist intervention and its results.

**Material and methods** Pharmacists developed the following protocol: (1) Identification of patients treated with capecitabine and PPI: pharmacists actively reviewed the electronic clinical records for the presence or absence of PPI prescriptions for each patient treated with capecitabine.

(2) Designing an informative note: the note included information about the possible drug interaction and patients identified in the previous phase. We recommended monitoring the effectiveness of capecitabine, routinely ascertaining the need for PPI use and PPI suspension or replacement with an alternative antacid treatment, whenever possible.

(3) Diffusion of the information to oncologists via email.

**Results** Over 1 year, we detected 71 patients treated with capecitabine, of whom 46 (65%) presented concomitant use of PPI (78% omeprazole, 13% pantoprazole, 7% esomeprazole and 2% rabeprazole). The reasons for capecitabine prescription were: 52% colorectal, 24% gastric or oesophageal, 13% breast and 11% pancreatic cancer. In all patients, monitoring the effectiveness of capecitabine was the preferred option.

**Conclusion and relevance** Most patients treated with capecitabine were also receiving treatment with PPI. In our case, oncologists preferred to monitor the effectiveness of capecitabine rather than discontinue PPI. This study reflects how pharmacists, as part of the multidisciplinary team, can participate in achieving better health outcomes.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

#### 4CPS-078 EFFECTIVENESS AND SAFETY OF ERIBULIN FOR ADVANCED BREAST CANCER TREATMENT

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**Background and importance** Eribulin is used, as monotherapy, in the secondline treatment of locally advanced or metastatic breast cancer (mBC) in patients who have previously received an anthracycline and a taxane or these are contraindicated.

ESMO-MCBS scores eribulin as level 2 (low clinical benefit) according to the EMBRACE study (Cortes et al, 2011).