4CPS-300 EFFECTIVENESS AND SAFETY OF CEMIPLIMAB IN SQUAMOUS CELL CARCINOMA OF THE SKIN IN A THIRD LEVEL HOSPITAL

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Background and importance Squamous cell carcinoma (SCC) is the second most common skin cancer. This type of cancer is most often found in areas which have been exposed to sunlight, such as the neck, head and arms, although it can occur anywhere on the body. The high prevalence and the scarcity of treatments make new treatments necessary.
Aim and objectives To assess the efficacy and safety of cemiplimab in the treatment of squamous cell carcinoma.
Material and methods This was a retrospective observational study from January to August 2020 (8 months). The following variables were collected: sex, age, race, previous treatment, area, size, duration until response and stage. Effectiveness was measured by means of the Breslow index, Clark level and images from computerised axial tomography (TAC). Safety was assessed by the incidence of adverse drug reactions.
Results Outcomes were measured for seven patients (all men), with a mean age of 76.8 years and of Caucasian race. Previous treatments were: radiotherapy (50%) and surgery (50%). The average size of the carcinoma was 2.45 cm and stages II (57.2%), III (28.52%) and IV (14.28%). In terms of effectiveness, the Breslow index and Clark levels decreased by 57.14% and there was an improvement in CT images and in symptoms. In terms of safety, the appearance of diarrhoea in one patient was noteworthy.
Conclusion and relevance According to our results, it is possible to consider cemiplimab as an alternative treatment for squamous cell carcinoma. We believe that further studies are necessary to determine effectiveness.

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Conflict of interest No conflict of interest

4CPS-301 ASSOCIATION OF ANTIBIOTICS AND PROTON PUMP INHIBITORS ON CLINICAL ACTIVITY OF FIRSTLINE PEMBROLIZUMAB FOR NON-SMALL CELL LUNG CANCER: 2 YEARS OF REAL WORLD DATA

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Background and importance The gut microbiome plays a dominant role in modulating the therapeutic efficacy of immune checkpoint inhibitors (ICIs). The use of proton pump inhibitors (PPI) and antibiotics (ATB) can induce dysbacteriosis, which may attenuate the clinical outcomes of ICIs, as shown in previous publications.
Aim and objectives To investigate the predictive role of ATB and PPI on firstline pembrolizumab treatment in patients with metastatic non-small cell lung cancer (NSCLC) with real world data.
Material and methods Patients with metastatic NSCLC who received pembrolizumab as firstline treatment between July 2017 and January 2020 were retrospectively reviewed. Demographic data, PD-L1 expression, responses and survival rates, and other baseline variables were examined. Administration of ATB or PPI within a window of 30 days before and after the start of pembrolizumab was also collected, based on the criteria used in previous publications. Clinical outcomes were compared according to ATB or PPI co-administration.
Results 49 patients were included, 75.5% men, mean age 66.3 ±8.2 years, 53.1% expressed 50–75% PD-L1 and 46.9% expressed >75% PD-L1. 34.7% used ATB and 53.1% PPI. ATB compared with no ATB was associated with a shorter progression free survival (PFS) (median 12.1 vs 18.5 months, HR=0.46, 95% CI 0.20 to 1.06, p=0.068). No significant differences were observed in overall survival (OS) (HR=0.56, 95% CI 0.26 to 1.22, p=0,144). PPI compared with no PPI showed no significant differences in PFS (HR=0.98, 95% CI 0.43 to 2.21, p=0.953), but a significantly shorter OS (median 11.7 vs 17.9 months, HR=0.40, 95% CI 0.17 to 0.93, p=0.033). Multivariate analysis in all patients considering ATB, PPI, age and PD-L1 expression revealed that ATB were significantly associated with shorter PFS (HR=0.24, 95% CI 0.09 to 0.63, p=0.004) and shorter OS (HR=0.26, 95% CI 0.10 to 0.70, p=0.008). The use of PPI showed no significant differences in multivariate analysis.
Conclusion and relevance The data suggested that ATB use in patients with metastatic NSCLC may be associated with poor outcomes in terms of PFS and may influence the efficacy of pembrolizumab. The impact of PPI showed better results for OS for the group that did not receive them. These data are in line with previous publications. More studies with a larger sample of patients would be necessary to confirm these results as our limited sample size could have compromised the statistical power.

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4CPS-302 SORAFENIB IN HEPATOCARCINOMA: RESULTS IN A REAL WORLD SETTING

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Background and importance Hepatocarcinoma (HCC) is the leading cause of mortality in cirrhotic patients. Sorafenib has been shown to increase survival and is considered firstline therapy for patients with advanced unresectable HCC who are unsuitable for locoregional therapy and whose liver function is adequate to tolerate therapy (Child Pugh A/B).
Aim and objectives The aim of this study was to evaluate the effectiveness and safety of sorafenib in adults with metastatic HCC in our clinical practice, based on overall survival (OS) and report of adverse events.

Abstract 4CPS-302 Table 1

Age (years)	63 (46-81)
Sex M/F (n (%))	42 (91.5)/5 (8.5)
BCLC stage (n (%))	B (intermediate): 2 (4.3)
	C (advanced): 37 (78.7)
	Not evaluated: 8 (17)

Material and methods An observational, retrospective, descriptive study was conducted between January 2018 and October 2020. Age, sex, Barcelona Clinic Liver Cancer (BCLC) staging, adverse events (AEs), need for dose reduction or discontinuation, and time to progression or death were collected from our electronic records. None of the patients had received previous systemic therapy. The analysis was performed using R 4.0.3.

Results 47 patients with metastatic HCC were treated with sorafenib. Patient characteristics are shown in table 1.

Median overall survival (mOS) was 17.9 months (range 0.5–24.0; 95% CI 15.5 to not reached). The main AEs observed were: fatigue (42.5%), hand–foot skin reactions (42.5%), anorexia (40.4%), diarrhoea (38.3%), hypertension (14.9%), abdominal pain (14.9%), digestive bleeding (12.7%) and pruritus (10.6%). The most common reasons for treatment discontinuation were AEs (14 patients) and progression (22 patients). The rate of discontinuation due to AEs was 29.8%. 34 patients (72.3%) required dose reduction.

Conclusion and relevance In our setting, mOS was superior to that reported in the pivotal clinical trial even though baseline characteristics were similar. Some of the AEs were more frequent, such as fatigue, hand–foot skin reactions, hypertension and anorexia, although the rate of discontinuation due to AEs was lower than reported in the SHARP trial.

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Conflict of interest No conflict of interest

4CPS-303 EFFICACY AND SAFETY OF MONOTHERAPY WITH PEMBROLIZUMAB IN NON-MICROCYTIC METASTATIC LUNG CANCER IN CLINICAL PRACTICE

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Background and importance Pembrolizumab is an anti-PD1 antibody used to treat metastatic non-small cell lung cancer (m-NSCLC).

Aim and objectives To analyse the efficacy and safety of first (1L) or successive lines (≥2L) of treatment of m-NSCLC with pembrolizumab monotherapy.

Material and methods A retrospective observational study was conducted in 82 patients with m-NSCLC treated with pembrolizumab monotherapy between January 2018 and April-2020. Collected clinical data were analysed with SPSS V.23.0. Progression free survival (PFS), overall survival (OS), calculated with the Kaplan–Meier method, and objective response rate (ORR), using iRECIST criteria, were used to measure efficacy. To analyse safety, adverse effects (AEs) were evaluated using NCI-CTCAE-V.5.0 criteria. Results were compared with the clinical trials KEYNOTE-024 and KEYNOTE-010.

Results 45 (34 men) patients received 1L pembrolizumab (200 mg/3weeks). Median (Me) age=66 years (range (R)=32–83). Histology: 35 non-squamous, 6 squamous. PD-L1 expression: Me=80% (R=55–100%). None ALK, EGFR or ROS mutation. 35 patients presented ECOG=0–1 and 10 ECOG ≥2. Duration: Me=5 cycles (R=1–37). PFS was Me=5.1 months (95% CI=0.5 to not reached). Median OS was not reached, although the OS rate was 66% at 6 months and 60% at 12 months. ORR=40%. 15% of patients died within a month of treatment. 36 patients (80%) had AEs, the majority grade 1–2. 6 patients (13%) had grade 3–4 AEs.

37 (30 men) patients received ≥2L pembrolizumab (2 mg/kg/3 weeks). Age Me=67 years (R=46–90). Histology: 18 non-squamous, 14 squamous. PD-L1 expression: Me=10% (R=1–90%). Two EGFR mutations, no ALK or ROS mutations. Previous treatment always included a platinum doublet regimen. Three patients had received two or more previous lines, 34 only one. 30 patients presented ECOG=0–1 and 7 ECOG ≥2. Duration: Me=4 cycles (R=1–24). PFS was Me=3.4 months (95% CI=1.9 to 4.7) and OS was Me=9.1 months (95% CI=5.1 to 13.2). ORR=16%. 24 patients (65%) had AEs, the majority grade 1–2. 3 patients (8%) had grade 3–4 AEs.

Conclusion and relevance Pembrolizumab in 1L for m-NSCLC in our patients presented lower PFS and OS than those recorded in the KEYNOTE-024 study with similar ORR. This can be partially explained by the greater deterioration in our patients at the beginning of treatment (22% ECOG ≥2) compared with the KEYNOTE-024 study. Pembrolizumab in ≥2L had slightly lower PFS, SG and ORR than those recorded in KEYNOTE-010. AEs were mostly grade 1–2, and less frequent than in the clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-304 RITUXIMAB AS AN ALTERNATIVE IN NEUROLOGIC DISORDERS: LONG TERM STUDY

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Background and importance Rituximab is a chimeric, anti-CD20 monoclonal antibody. In addition to its approved indications, its off-label use has increased in the management of a variety of neurological diseases.

Aim and objectives To describe rituximab prescriptions in the neurology department, and to evaluate the scientific evidence for off-label indications to rationalise its use.

Material and methods A retrospective observational study can conducted in all neurology patients receiving rituximab treatment from January 2012 to January 2020. The following data were collected: demographics (sex and age), clinical (indication), therapy related (dose, posology, previous treatments and adverse events) and economic (annual cost). The Oxford 2011 levels of evidence (LE) was used to categorise evidence.