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.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Llovet JM, Ricci S, Mazzaferro V, *et al.* SHARP Investigators Study Group. Sorafenib in advanced hepatocellular carcinoma. *N Engl J Med* 2008;**359**:378–90. doi: 10.1056/NEJMoa0708857. PMID: 18650514.

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

¹C Valdazo Martín*, ¹JJ García Albás, ¹MÁ Andrés Moralejo, ²J Poyo Molina, ¹N Ramon Rigau, ¹M Rosado Ancín, ¹A Santaolalla Sánchez, ¹P Arenales Cáceres, ¹R Hernanz Chaves, ¹L Guisasaola Ron, ¹C Martínez Martínez. ¹Hospital Universitario Araba, Hospital Pharmacy, Vitoria-Gasteiz, Spain; ²Hospital Universitario Araba, Pneumology, Vitoria-Gasteiz, Spain

10.1136/ejhp-pharm-2021-eahpconf.135

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 (≥ 2 L) 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 ≥ 2 L 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 ≥ 2 L 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

A Luna Higuera*, MJ Morales Lara, C Fernández Cuerva, I Muñoz Castillo. Hru Carlos Haya, Pharmacy, Malaga, Spain

10.1136/ejhp-pharm-2021-eahpconf.136

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.