Conclusion and relevance ICI demonstrated a clinical benefit in terms of PFS and OS. The most frequent grade ≥3 AR were asthenia and pneumonitis. Our study suggested a high percentage of compliance with the criteria established.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-098 INDIRECT TREATMENT COMPARISONS OF IBRUTINIB–OBINOTUZUMAB VERSUS VENETOCLAX–OBINOTUZUMAB IN NAIVE CHRONIC LYMPHOCYTIC LEUKAEMIA

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Background and importance Venetoclax and ibrutinib are relatively new drugs and are currently elective treatments according to the guidelines for patients diagnosed with high risk chronic lymphocytic leukaemia (CLL).

Aim and objectives To conduct an indirect comparison of the efficacy of venetoclax (12 cycles)+obinotuzumab (6 cycles) compared with ibrutinib (until progression)+obinotuzumab (6 cycles) and its costs.

Material and methods The clinical trials CLL14 and ILUMINATE were reviewed, and the main outcome and similarity of the population (median age, percentage of high risk patients according to the Binet or Rai classification and percentage of patients with high risk cytogenetics) were evaluated.

An indirect comparison of median progression free survival (PFS), PFS at 24 months, minimal residual disease (MRD) in peripheral blood, overall survival (OS) and complete response was conducted.

Lastly, the cost of both 12 and 24 months of treatment were compared.

Results

	CLL14	ILUMINATE
	Venetoclax+obinotuzumab vs clorambucil+obinotuzumab	**Ibrutinib+obinotuzumab vs clorambucilo+obinotuzumab**
No of **patients**	432 1:1	229 1:1
Age (years) **(median)**	72	70
High risk (Binet/Rai) (%)	43	52
Patient with del p17 (%)	8	14
Patients with **tp53** (%)	9.5	15.5
Unmutated IGHV (%)	60	757
Indirect comparison		
PFS	HR 0.66 (95% CI 0.36 to 1.22, p=0.18) ibrutinib favoured	
PFS at 24 months	RR 0.64 (95% CI 0.32 to 1.08, p=0.09) ibrutinib favoured	
MRD peripheral blood	RR 1.41 (95% CI 0.85 to 2.32, p=0.18) venetoclax favoured	
CR	RR 0.85 (95% CI 0.39 to 1.86, p=0.69) venetoclax favoured	
Cost		
	Venetoclax+obinotuzumab	Ibrutinib+obinotuzumab
12 months (€)	76 374	76 786
24 months (€)	76 374	127 891

Conclusion and relevance

- Although in advance, populations could be comparable, limitations such as time of treatment with chlorambucil exist (6 months vs 12 months).
- No statistically significant differences were found between:
- o Median PFS and 24 month PFS: Beauchemin et al[1] concluded that correlations between PFS and OS exist in patients previously treated, but not in naïve patients.
- o MDR and CR: Langerat et al[2] concluded that "MRD status is associated with PFS and OS in CLL patients, and has the potential to act as a surrogate marker".
- Ibrutinib cost was superior after the first year of treatment.
- To conclude, it is necessary to obtain OS data to conduct an indirect comparison of greater quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. DOI: 10.1182/blood-2018-03-839688
2. DOI: 10.3747/co.22.2119.

No conflict of interest.

4CPS-099 REAL WORLD EVIDENCE OF PEMBROLIZUMAB AS MONOTHERAPY IN NON-SMALL CELL LUNG CANCER: EFFECTIVENESS AND SAFETY STUDY

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Background and importance In naive treated populations with advanced non-small cell lung cancer (NSCLC), pembrolizumab monotherapy is the recommended option for patients whose tumours express PD-L1 with a tumour proportion score (TPS) ≥50%. In a population previously treated with platinum based chemotherapy double, pembrolizumab (PD-L1 1%) is a valid option in those who have not been treated with firstline immunotherapy.

Aim and objectives To analyse the effectiveness and safety of patients with NSCLC treated with pembrolizumab in clinical practice.

Material and methods This was a multicentre, observational, retrospective study carried out between January 2017 and June 2019. All patients with NSCLC undergoing treatment with pembrolizumab as monotherapy were included. Patient data were taken from the clinical records. Variables included were age, sex, stage, line of treatment, dose administered and functional status (PS) according to the ECOG scale. Efficacy endpoints was progression free survival (PFS) assessed by RECIST 1.1 criteria. Adverse events (AEs) were also assessed. Analysis of PFS was performed using the Kaplan–Meier curve.

Results Thirty-eight patients were included with NSCLC: 81.58% were men, mean age was 62.34±11.68 years, 97.36% (n=37) had ECOG PS 0–1 and 100% had NSCLC stage IV.

The percentage of patients who started pembrolizumab as firstline therapy was 50% and their tumours expressed PD-L1 ≥50% TPS, 42.10% had pembrolizumab as secondline therapy and 7.90% as thirdline therapy. The median administered dose was 160 mg (108–200); 8 patients (21.05%) are still receiving treatment. Causes of treatment suspension in the remaining patients were disease progression (60.53%) or death (18.42%).