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 ILLUMINATE 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	ILLUMINATE
	Venetoclax+obinotuzumab vs clorambucil+obinotuzumab	Ibrutinib+obinotuzumab vs clorambucil+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 al¹ concluded that correlations between PFS and OS exist in patients previously treated, but not in naïve patients.
 - o MDR and CR: Langerat et al² 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 naïve 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) $\geq 50\%$. 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 $\geq 50\%$ 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%).

Median PFS of patients who started pembrolizumab as firstline therapy was 10 months (95% CI 7.1–12.92); in those treated as secondline and thirdline, median PFS was 4.2 months (95% CI 3.12–5.27).

AEs included asthenia grades 1–2 in 15.79%, arthralgia grades 1–2 in 13.16%, dermatitis in 7.89%, diarrhoea in 7.89%, hypothyroidism in 5.26%, pneumonitis in 5.26%, vomiting in 5.26%, anorexia in 5.26%, constipation in 5.26% and myalgia in 2.63%.

Conclusion and relevance Median PFS in our study was similar to the results of Keynote-024 (pembrolizumab as firstline treatment) 10 versus 10.3 months and Keynote-010 (pembrolizumab in previously treated patients) 4.2 versus 3.9 months. Pembrolizumab was safe and well tolerated; the safety profile was similar to that described in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

- doi: 10.1016/S0140-6736(15)01281-7
- doi: 10.1016/S1470-2045(17)30690-3.

No conflict of interest.

4CPS-100 ANTHRACYCLINE DOSING IN OBESE ADULT PATIENTS: A SYSTEMATIC REVIEW

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Background and importance Chemotherapy dosing for obese patients (body mass index (BMI) ≥ 30 kg/m²) remains undefined. Most recent publications discourage arbitrary dose reductions that can compromise efficacy. However, because of the dose dependent cardiotoxicity of anthracyclines and also the inherent obesity related cardiovascular risk factors, it is advisable to review the evidence available on toxicity in this population.

Aim and objectives To define the most adequate dose strategy for anthracyclines in obese adult patients based on efficacy and toxicity results and/or pharmacokinetic data.

Material and methods We conducted a systematic review in Pubmed, Scopus and Web of Science using predefined keywords ((obese or obesity) and (daunorubicin or doxorubicin or epirubicin or idarubicin)). We excluded paediatric and non-English papers. Moreover, we looked at studies with relevant information about safety and efficacy.

Results Ten articles on doxorubicin, 4 on epirubicin, 2 on idarubicin and 1 on daunorubicin were included. Doxorubicin pharmacokinetics was evaluated in two articles: clearance was reduced and area under the curve was increased in obese patients but there were no statistically significant differences (SSD). Regarding efficacy, obese patients had better response ratios with no dose reduction with daunorubicin and idarubicin, but the difference was not significant. Epirubicin showed a better response when the full dose was used in neoadjuvant chemotherapy but there was no difference in progression free (PFS) or overall (OS) survival. One article reported worse pathological complete response, PFS and OS when the dose was reduced in obese breast cancer patients. Another article did not show SSD in recurrence risk and mortality when using a full dose, except if BMI ≥ 35 kg/m² when mortality was higher ($p < 0.05$). Two articles found worse PFS in obese versus non-obese patients when receiving the full dose. Regarding safety, we found three articles that showed more

toxicity but without SSD. One meta-analysis reported an increase in cardiovascular risk with increasing BMI but could not establish if it was due to the use of full doses or obesity itself.

Conclusion and relevance The literature regarding safety and efficacy is not consistent. As there are better responses with full dose anthracyclines and toxicity can be monitored, dose reduction in obese patients is not recommended. However, the presence of other comorbidities may be a reason for dose reduction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-101 TRIFLURIDINE-TIPIRACIL FOR METASTATIC COLORECTAL CANCER: REAL WORLD DATA EXPERIENCE

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Background and importance Colorectal cancer represents a major health problem in developed countries. Median age at diagnosis is about 70 years. This creates new challenges in antineoplastic treatment, taking into consideration the characteristics of this group of patients: functional alterations that increase the toxicity of drugs, high comorbidity and polypharmacy. Trifluridine–tipiracil is an oral antineoplastic agent consisting of trifluridine and tipiracil. Tipiracil blocks the degradation of trifluridine by thymidine phosphorylase, which improves the bioavailability of trifluridine and allows for oral administration. A phase III study comparing trifluridine–tipiracil versus placebo in patients with metastatic colorectal cancer (mCRC) refractory to or intolerant to standard therapy ($n=800$) showed a modest benefit in overall survival and progression free survival compared with placebo.

Aim and objectives To assess the efficacy and safety of trifluridine–tipiracil in a cohort of 49 patients with mCRC treated in our institution.

Material and methods This was an observational retrospective study of patients treated with trifluridine–tipiracil as monotherapy from March 2018 to September 2019. The data collected, obtained from the electronic medical records, were sex, age, previous chemotherapy regimens, treatment duration and reason for discontinuation, adverse events and follow-up data.

Results Forty-nine patients, 33 men (67%), with a median age of 64 years (41–84), were treated with trifluridine–tipiracil monotherapy. The median number of previously administered chemotherapy regimens was 2, while trifluridine and tipiracil was administered for a median of 3 cycles. At evaluation after 3 cycles, 53% of patients showed progression of disease, 8% mixed response of metastatic site, 2% partial response and 4% stable disease. For 32% of patients the response was not evaluated due to early progression of disease or patients lost to follow-up. Twenty-four patients (49%) underwent subsequent therapies after treatment with trifluridine–tipiracil, mainly with raltitrexed (12 patients/50%), regorafenib and mitomycin C (3 patients/12%). Adverse events occurred in 23 patients (47%): haematological events ($n=14$, 47%), asthenia ($n=7$, 30%), dyspnoea ($n=2$, 9%) and hyperbilirubinaemia ($n=1$, 4%).