Adults aged 18 or older, who died of an onco-haematological neoplasia between 1 April 2017 and 30 March 2018 were included. We assessed the use of chemotherapy over the course of the last 14 days of life, defined as the administration of at least one dose of chemotherapy (including oral targeted therapies and biotherapy). Gender, age, prescribing unit, primary malignancy, last type of treatment (chemotherapy, biotherapy or both), route of administration (parenteral, oral) and temporal interval between the last chemotherapy administration and death of the patient were collected.

For descriptive analysis, the statistical program SPSS version 23.0 was used.

Results A total of 298 patients died between the prespecified period in the Haematology and Oncology units, of whom 60.4% were male, with a median age of 65±13 years (range 30–87). The hospital unit of origin was Oncology for 86.9% (n=259) and Haematology for 13.1% (n=39) of the cases. Tumours with the highest number of deaths were lung (24.4%), breast (15.4%) and colon (9%).

A total of 28.2% (n=11) of haematological and 25.9% (n=67) of oncological patients received chemotherapy during the last 14 days before death. Overall rate was 26.2% (n=78). In these patients, the most widely used therapeutic regimen was classic chemotherapy, administered in 79.5% of patients (67.7% intravenous treatment).

Conclusion The outcomes confirm that the proportion of patients receiving chemotherapy in the last 14 days of life is high, showing excessive aggressiveness at the end-of-life care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-130 PALBOCICLIB COMBINED WITH HORMONAL THERAPY FOR METASTATIC BREAST CANCER TREATMENT

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Background The first-in-class oral inhibitor of cyclin-dependent kinases 4 and 6 (CDK4/6) palbociclib, combined with hormonal therapy, is a new standard of treatment in the first and second line for hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (mBC).

Purpose To describe the effectiveness and safety of palbociclib combination therapy for mBC in clinical practice.

Material and methods Retrospective and observational study in which the effectiveness and safety of palbociclib was tested by reviewing medical and pharmaceutical records of all patients treated with the drug from December 2015 until April 2018 in a tertiary hospital. Dispensation data was obtained from the Pharmacy Department's software, Farmatools. Collected data included: age, ECOG performance status, number of cycles received, duration and prior lines of treatment. Effectiveness endpoint was progression-free survival (PFS) according to

RECIST version 1.1. Adverse events (AEs) related to treatment with palbociclib and registered in the patient's medical records were included in the study. Toxicity was evaluated as defined by the NCI-CTCAE, version 4.0.

Results

Abstract 4CPS-130 Table 1

Patients	n (%)
Female	29 (100%)
Age (mean)	57 (38–71)
ECOG	
0	23 (79.3%)
1	4 (13.8%)
2	2 (6.9%)
Phenotype	
Luminal A	5 (17.2%)
Luminal B	24 (82.8%)
Menopausal stage	
Peri	5 (17.2%)
Post	24 (82.8%)
Concomitant hormonal therapy	
Fulvestrant	17 (58.6%)
Aromatase inhibitor	12 (41.4%)
Naive	
Yes	6 (20.7%)
No	23 (79.3%)
N of prior lines (mean)	1 (0–10)
Initial dose	
125 mg	29 (100%)
Dose reductions	
Yes	14 (48.3%) ¹
No	5 (16.7%)
Suspension/cause	
Progression	9 (31.0%)
Toxicity	1 (3.5%)
N° cycles (mean)	9 (1–21)
Median treatment duration (95% CI) (months)	6.3 (0.1–19.2)
Median PFS (95% CI) (months)	7.7 (0.1–19.2)

Abstract 4CPS-130 Table 2

Adverse events	Frequency n (%)	Grade 1 2 ≥3
General		
Asthenia, fatigue	10 (34.5%)	4 1 2
Headache		3
Gastrointestinal		
Nausea	8 (27.6%)	4 2
Constipation		2
Haematological		
Neutropenia	16 (55.2%)	4 12
Skin and mucous membranes		
Alopecia	9 (31.0%)	2
Mucositis		4
Dermatitis		1 2
Infections		
Urinary tract infection	4 (13.8%)	2
Tonsillitis		1
Sepsis		1

Conclusion A significant difference in PFS was observed compared to published clinical trials PALOMA-2 (PFS 24.8 months) and PALOMA-3 (PFS 11.2 months). Otherwise, palbociclib showed a similar safety profile. However, further studies are required to establish effectiveness in clinical practice as 19/29 patients are still receiving treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Palbociclib: EPAR-Summary for the public. EMA.
2. Pivotal studies PALOMA-2 and PALOMA-3.

No conflict of interest.

4CPS-131 RUXOLITINIB AS SALVAGE THERAPY IN PAEDIATRIC PATIENTS WITH STEROID-REFRACTORY GRAFT-VERSUS-HOST DISEASE

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Background Steroid-refractory graft-versus-host disease (GVHD) is a significant complication of allogeneic haematopoietic stem cell transplantation (HSCT) and a leading cause of morbidity and non-relapse mortality.

Adult clinical trials with ruxolitinib have demonstrated benefit in this population, but there are no paediatric reports describing this effectiveness.

Purpose Analyse effectiveness and safety of ruxolitinib in paediatric patients, with steroid-refractory GVHD.

Material and methods Retrospective study including patients diagnosed with GVHD treated with ruxolitinib from January 2017 to October 2018. Demographic and clinical data were collected from electronic medical records and pharmacy software: sex, age, weight, type, location and severity of GVHD, previous treatments, dosing, duration of treatment, response and toxicities.

Results Seven patients were included, 5 boys and 2 girls, with a median age of 11 years (5–18); and a median weight of 40 kg (15–63). One patient developed severe acute intestinal GVHD (aGVHD) and six chronic GVHD (cGVHD), moderate (n=1) and severe (n=5). The median number of affected organs per patient was three (1–4): skin (n=6), gastrointestinal tract (n=4), joints (n=2), lungs (n=2) and liver (n=1).

Median number of treatments used before ruxolitinib was four (2–5), always including corticosteroids as the first option. Treatments in the second or third line were: extracorporeal photoapheresis, mesenchymal stem cells, immunosuppressants and infliximab.

Four patients started with 5 mg/12 hour increasing to 10 mg/12 hour if they weighed >25 kg. One started at 1.25 mg/12 hour because they were in treatment with posaconazole increasing to 2.5 mg/12 hour, and two started directly at 10 mg/12 hour. The median treatment's duration was 10 months (3–19). All cGVHD were still in treatment at the end of the study.

All patients responded to ruxolitinib: the only patient with aGVHD and one patient with cGVHD had complete response, and the remainder had partial response.

Digestive, cutaneous and joints symptoms showed improvement, while GVHD affecting the lungs and liver did not.

No patient died during the study. Only two patients presented with leukopenia and two suffered reactivations of cytomegalovirus, but there was no dose reduction due to toxicity.

Conclusion In our patients ruxolitinib has proven to be an effective and safe treatment option, but well-designed clinical trials are necessary to know its real benefit in paediatric patients with steroid-refractory GVHD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-132 INTERACTIONS BETWEEN ALTERNATIVE THERAPIES AND PRODUCTS IN CLINICAL TRIAL IN ONCO-HEMATOLOGY

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Background The development of oral cancer treatments (OCT) is sizeable, with many molecules in clinical trials. More and more patients wish to combine OCT to alternative therapy products (to reduce side effects, improve therapeutic effects). However, their use is associated with risks when combined with OCT: additional toxicities, drug interactions. Dispensing drugs included in clinical trials, the hospital pharmacist is responsible for their proper use, particularly the lack of interaction, with the help of documents supplied by the sponsor (investigator's brochure, protocol and prescription forms).

Purpose The main objective of this study was to analyse information given by sponsors on the use of alternative therapy products in association with OCT in clinical trials.

Material and methods We did an inventory of all documents given by sponsors checking if the use of alternative therapy products were mentioned. They were recorded qualitatively and quantitatively, and their readability has been assessed as easy (<5 min), mild (5–10 min) or complex (>10 min).

Results The study was completed in our centre in May 2018, including 73 active trials with at least one OCT (61 OCT in monotherapy, 11 in bitherapy and one in tritherapy). Thirty-four trials (56%) in haematology, seven in onco-dermatology, the others for solid tumours. At least one information related to alternative therapy products was found in 57% of protocols, 14% of investigator's brochure and 4% of prescription forms. Grapefruit was mentioned in 72% of documents, 76% for St. John's Wort and 30% for bitter oranges. The other alternative therapy products were mentioned in less than 8% of documents. Only two protocols mention possible interaction with 'herbal medicines products'. In more than 70% of cases, the information was easy to find. The protocol is the document where information was the most easily readable (92%).

Conclusion The key document to find information on alternative therapy products is the protocol, where information is easily readable. However, only grapefruit and St John's Wort are mentioned in the main cases. In view of their rising uses, additional training should be offered to the pharmacist and a particular mention should be indicated on the prescription