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No conflict of interest.

4CPS-104 SWITCHING ORAL ANTIANDROGENIC TREATMENT IN PATIENTS WITH CASTRATE METASTATIC PROSTATE CANCER: AN ANALYSIS

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Background and importance Abiraterone is used in combination with prednisone, is metabolised by the liver (CYP3A4) and is an enzyme inhibitor (CYP2D6/CYP2C8). Enzalutamide is metabolised by the liver (CYP2C8/CYP3A4) and is a potent enzyme inducer (CYP3A4/CYP2B6/CYP2C9/CYP2C19). Both are used to treat castrate metastatic prostate cancer (CMPC).

Aim and objectives To analyse switching between two antiandrogenic drugs, abiraterone and enzalutamide, in patients with CMPC.

Material and methods This was an observational, retrospective, descriptive, unicentre study. The study included 127 patients with CMPC who began treatment with abiraterone or enzalutamide from January 2015 to March 2019. Clinical data from an outpatient pharmacy database and from the medical history were analysed. Reasons to switch were classified as safety, pharmacological interactions and galenic advantages.

Results A total of 127 patients were analysed: 50 began treatment with abiraterone and 77 with enzalutamide. Four of the 50 patients who started with abiraterone switched to enzalutamide (8%) for safety reasons (100%, n=4) because of side effects: digestive intolerance and diarrhoea (50%, n=2), oedema (25%, n=1) and uncontrolled diabetes (25%, n=1). The last case was probably due to prednisone.

Ten of the 77 patients who started treatment with enzalutamide switched to abiraterone (13%) for safety reasons in six patients (60%) because of side effects: memory loss and disorientation (20%, n=2), asthenia (10%, n=1), depression and anxiety (10%, n=1), hypertension (10%, n=1) and parkinsonism (10%, n=1). In three patients (30%) switching was due to drug interactions, which modified the efficacy and safety of enzalutamide and the other drug involved. Four drugs were involved, 2 (50%) were antihypertensives (manidipine and verapamil) and 2 (50%) were anticoagulants (rivaroxaban and acenocoumarol). In one patient (10%), switching was due to the galenic advantage of the smaller number and size of abiraterone tablets compared with enzalutamide capsules because of difficulty in swallowing in a case of oesophageal neoplasm.

Conclusion and relevance Switching between abiraterone and enzalutamide in our patients was mostly for safety reasons. Some side effects of the treatment with abiraterone and prednisone may have a steroidal origin. Enzalutamide is involved in pharmacokinetic and pharmacodynamic interactions with clinical relevance, so this is an important reason to switch. The smaller number and size of tablets could be a galenic advantage.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-105 TOLERANCE PROFILE TO ANTITHYMOCYTE IMMUNOGLOBULIN TREATMENT AND ITS RELATION TO INFECTIOUS PARAMETERS IN PAEDIATRIC PATIENTS

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Background and importance Rabbit antithymocyte immunoglobulin (ATG) is used to prevent or treat graft versus host disease (GVHD). There have been few studies on tolerance to administration of ATG in paediatric patients. It is related to immunomodulatory manifestations that cause an inflammatory response capable of triggering clinical and analytic manifestations similar to those of an infection, resulting in the administration of antibiotic in most patients.

Aim and objectives To describe the tolerance to administration of ATG in paediatric patients who underwent bone marrow transplantation (BMT) and to analyse its relationship with clinical and analytic manifestations similar to an infection.

Material and methods This was an observational retrospective study involving paediatric patients with BMT that received ATG (December 2010–February 2019). Variables collected were demographics (age/sex), BMT related variables (pathology, sources of haematopoietic stem cells (HSC), donor type), clinical symptoms (fever (secondary to ATG if 0–72 hours post-infusion), temperature), treatment (dose, premedication, side effects), analytics (maximum procalcitonin (PCT) and C reactive protein (CRP), liver and kidney function markers) and blood cultures. Variables were obtained from electronic/paper medical records and the oncohaematologic electronic prescribing programme.

Results Fifty-six patients were enrolled, 55.35% (31) men, with a median age of 7 years, and 92.8% (52) received ATG as prophylaxis and 7.2% (4) as refractory treatment of GVHD. The doses recorded were 1.25–2.5 mg/kg, with 2 mg/kg the most common dose (85.7%; 48) over 3 days (2 days if haploidentical BMT). All patients received premedication, full dose and no reduction in the rate of administration or discontinuation. The most frequent underlying diseases were oncological, mainly acute lymphoblastic leukaemia (57.1%; 32), and haematological (9 patients), mainly medullary aplasia (33.3%; 3). The main source of HSC was peripheral blood (50%; 28) and donor type was mismatched unrelated donor (39.28%; 22).

In 73.2% (41) of patients, fever ($38.5^{\circ}\text{C} \pm 0.5$) appeared 11.28 hours after the start of infusion and lasted 1.77 ± 0.84 days; 82.9% (34) of these patients received broad spectrum antibiotic treatment (mostly cefepime, amikacin, teicoplanin) over 7.61 ± 3.79 days, with positive blood culture in 7.3% (3). Markers of infection were altered in most patients, with average values for CRP of 97.55 ± 59.45 mg/dL and PCT of 35.57 ± 28.55 ng/dL.

Other side effects were hypertransaminasaemia (33.92%; 19), hyperbilirubinaemia (5.36%; 3), anaphylaxis (5.36%), capillary permeability syndrome (5.36%), alteration of renal function (1.78%; 1) and rash (1.78%).

Conclusion and relevance ATG treatment in paediatric patients was associated with mild side effects. ATG triggered analytical and clinically altered parameters that simulated infection and hence empirical antibiotherapy was initiated which could be stopped precociously in the event of toxic fever by ATG.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-106 ANALYSIS OF THE PRESCRIPTION AND SAFE DRUG ADMINISTRATION OF OCRELIZUMAB

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Background and importance Ocrelizumab is the first drug approved in Europe for the treatment of primary progressive multiple sclerosis (PPMS). It is an anti-CD20 monoclonal antibody whose use has also been authorised in early forms of PPMS and recurrent forms of MS.

Aim and objectives To evaluate the prescription of ocrelizumab and to describe its safe drug administration.

Material and methods This was a retrospective observational study of patients treated with ocrelizumab from May 2018 to March 2019. All patients who received the two initial 300 mg infusions of ocrelizumab were included. Age, sex and the variant of the disease were collected. The number of administrations of ocrelizumab and the previous use of other anti-CD20 drugs or disease modifying drugs (DMDs) were analysed. Safe drug administration was evaluated as the presence of adverse reactions during infusion or treatment according to the common terminology criteria for adverse events V5.0.

Results Twenty-seven patients were treated, 15 men (55.6%), with an average age of 49 ± 9.2 years. Nineteen patients were diagnosed with PPMS (70.4%), three with relapsing-remitting MS (22.2%) and two with secondary progressive MS (7.4%). Twenty patients were previously treated (74.1%): 14 were treated with one drug (51.9%), 5 with two drugs (18.5%) and 1 had received three different drugs previously (3.7%). One patient had previously been treated with an anti-CD20 drug (6.7%). Ocrelizumab was administered 67 times. Fourteen patients completed three administrations (51.9%). In terms of safety, nine reactions developed after infusion (13.3%): four were pruritus grade 1 (6.0%), two were palate irritation grade 1 (2.9%), two hypertensive episodes (2.9%) and one chest rash. In the first week after administration, three patients needed medical assistance due to gastrointestinal disorders, one episode of joint swelling and fever, and an influenza infection. One patient needed to be hospitalised 3 weeks after the second administration due to pericarditis.

Conclusion and relevance Ocrelizumab was used most commonly in PPMS, with the majority of patients been treated

with DMDs. Although infusional reactions appeared frequently, the incidence was less than that described in the pivotal trials. However, more experience is needed to determine the possible complications of its administration.

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4CPS-107 IMPACT OF A TOOL IN THE ELECTRONIC CLINICAL HISTORY FOR THE OPTIMISATION OF BIOLOGIC DRUGS IN RHEUMATOLOGY

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Background and importance Dosing optimisation means therapeutic benefit with the lowest possible dose for each patient, improving patient adherence and reducing adverse effects.

Aim and objectives To determine the impact of an implantation tool in the electronic medical history (ECHR) for rheumatology patients being treated with biologic drugs with or without optimisation.

Material and methods The multidisciplinary team defined optimisation strategies based on dose reduction or dosing interval. The tool was designed to be incorporated as an alert in the ECHR (Selene): 'B' for patients with biologic drugs (etanercept, infliximab, adalimumab, certolizumab, golimumab, tocilizumab, abatacept, secukinumab, baricitinib, tofacitinib, ustekinumab) and 'BO' for patients with optimised biological drugs. Eight months post-implementation, the impact of these tools on optimisation of treatments was assessed.

Results At the beginning of the study, the 'B' alert was included in the ECHR of 236 patients and 8 months later the 'B' alert was visible in 279 patients, an increase of 18%. The distribution of the drugs at the beginning and post-intervention were: etanercept (23% vs 22%), adalimumab (19% vs 21%), golimumab (14% vs 14%), certolizumab (13% vs 13%), secukinumab (9% vs 12%), infliximab (8% vs 6%), abatacept (6% vs 6%), tocilizumab (4% vs 4%), baricitinib (3% vs 2%) and tofacitinib (2% vs 3%).

For the 'BO' alert, at the beginning of the study it was included in 63 patients and in 91 patients at the end of the study, an increase of 44%. A total of 44% of patients were diagnosed with ankylosing spondylitis, 42% with rheumatoid arthritis and 14% with psoriatic arthritis. Drugs that were optimised were: adalimumab (54% vs 45%), infliximab (22% vs 14%), etanercept (21% vs 21%), certolizumab (2% vs 7%) and golimumab (3% vs 4%). This time, also optimised were: tocilizumab (3%), abatacept (1%), secukinumab (1%), tofacitinib (2%) and ustekinumab (1%). In 88% optimisation was performed by spacing of the dosing interval and in 12% by dose reduction.

Conclusion and relevance This tool has been shown to be effective in monitoring patients receiving treatment with biologic drugs and it has had a high impact on optimising these treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.