4CPS-112 ADHERENCE TO ADALIMUMAB, GOLIMUMAB AND USTEKINUMAB THERAPY IN INFLAMMATORY BOWEL DISEASE

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Background and importance Inflammatory bowel disease (IBD) is a group of chronic relapsing diseases. In the past 10 years, biologic agents such as adalimumab, golimumab and ustekinumab have meant a great change in their therapy. Correct adherence plays a critical role in achieving therapeutic effectiveness.

Aim and objectives To evaluate therapeutic adherence of patients that were dispensed adalimumab, golimumab and ustekinumab at the pharmacy department of a tertiary level hospital.

Material and methods An observational transversal study included patients who received treatment with adalimumab, golimumab or ustekinumab for at least 4 months, from January to June 2019. Variables recorded were age, sex, previous biologicals and adherence rate (%) provided by the electronic pharmacy programme. The Morisky–Green questionnaire was applied in patients who had a value $\leq 85\%$. The SPSS programme (V.25.0) was used for data analysis. The study was approved by a university ethics committee.

Results A total of 178 patients were included in the study, 60.1% (107) men, with a mean age of 46.08 (± 14.96) years: 30.9% (55) were previously treated with other biologic agents and infliximab was used in 40 patients (22.5%). Average adherence, according to the dispensation record, was 91.79 (± 11.62)%. For adalimumab, adherence was 91.15%, for golimumab, 91.74% and for ustekinumab, 95.05% ($p=0.045$). Forty-five patients (25.28%) were classified as poorly adherent ($\leq 85\%$). The Morisky–Green test was performed in 32 patients who signed the informed consent. Non-administration on the indicated date (62.50%) and forgetting (28.10%) were identified as the main reasons for lack of therapeutic compliance according to the result of the Morisky–Green test, and 15 patients (46.9%) were classified as poorly adherent. Female sex (OR=0.42; $p=0.013$) and length of treatment ($p=0.002$) were associated with worse medication adherence.

Conclusion and relevance The percentage of adherence obtained was high in the study population. A group of poorly adherent patients were identified who could receive interventions to improve their medication adherence. Statistical power should be increased to improve the validity of the results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-113 INOTUZUMAB–OZOGAMIZIN FOR THE TREATMENT OF RELAPSE B PRECURSOR ACUTE LYMPHOBLASTIC LEUKAEMIA IN AN ADULT PATIENT: A CASE REPORT

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Background and importance Inotuzumab–ozogamicin is an antibody–drug conjugate composed of a recombinant humanised

IgG4 kappa CD22 directed monoclonal antibody that is covalently linked to N-acetyl-gamma-calicheamicin dimethylhydrazide. It is indicated as monotherapy for the treatment of adults with relapsed or refractory CD22 positive B cell precursor acute lymphoblastic leukaemia (ALL).

Aim and objectives To describe a post-transplant relapsed adult case with B precursor ALL in which inotuzumab was successfully used as a bridging therapy to perform a second haematopoietic stem cell transplantation (HSCT).

Material and methods This was an observational retrospective study on the use of inotuzumab in a 32-year-old woman diagnosed with post-transplant relapsed B precursor ALL. The study variable was minimal residual disease (MRD) response, defined as MRD level $<10^{-4}$ at the end of treatment and complete remission. The data were obtained from the digital clinical history.

Results Initially the patient was treated according to HR-ALL PETHEMA-2011 <55 years protocol. The patient received phase 1 induction, phase 2 induction and phase 1 consolidation, achieving a negative MRD and complete remission. After this treatment, the patient underwent HSCT without early or late complications during follow-up. One year later, a bone marrow aspirate was performed that showed relapse of her leukaemia. The patient was started on treatment with donor lymphocyte infusion achieving a partial response, which was not maintained over time and the disease eventually progressed. Because this patient had a high level of expression of CD-22 B lymphocytes and based on the results of the INOVATE phase III clinical trial, she was treated with two cycles (28 day cycles) of inotuzumab. The drug was administered by intravenous infusion for 1 hour. The doses were administered on days 1, 8 and 15; the first dose was 0.8 mg/m² and the remaining doses were 0.5 mg/m². The patient achieved negative MRD and complete remission after the first cycle, but according to the summary of product characteristic, the patient received two cycles without suffering from hepatotoxicity.

Conclusion and relevance In this case of an adult patient with high risk ALL who relapsed after allogeneic transplantation of haematopoietic progenitors, the use of inotuzumab was found to be safe and effective, achieving MRD and complete remission and therefore the initial goal of the study. Nevertheless, more studies are needed to demonstrate its efficacy and safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-114 BELIEFS ABOUT MEDICATION AND QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS TREATED WITH NATALIZUMAB

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Background and importance Patient beliefs about medication tools can measure patient concerns and the necessity for different long term treatment options, and can be related to adherence and quality of life (QoL).

Aim and objectives To determine beliefs about medication and QoL of patients with relapsing–remitting multiple sclerosis (RRMS) receiving active treatment with natalizumab and to analyse possible associations.

Material and methods This was a descriptive observational study including patients diagnosed with RRMS on active treatment with natalizumab. Variables collected from the clinical records were age, sex, time since diagnosis, expanded disability status scale (EDSS), adherence and duration of treatment. Patients completed the validated beliefs about medicines questionnaire which evaluates perceptions of personal necessity for medication and concerns about potential adverse effects (AE). Each questionnaire contains five questions, with the total sum scored of 5–25. The QoL was measured by the EuroQol-5D scale which has five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) with values of 0–1 and a visual analogue scale (VAS) with scores of 0–100 points. Patient consent was requested for participation. The possible associations were analysed by multivariate analysis with SPSS.

Results Fourteen patients (median age 40 years (IR 17–76), 78.6% women) were included. Median time from diagnosis was 8.5 years (IR 3–37). Median duration of treatment was 37 months (range 1–69). Adherence was 98% (IR 88–100%). Patients were classified into three groups according to EDSS: group A, 0–3 (57.2%); group B, 3.5–5.5 (21.4%); and group C, >6 (21.4%).

The average for concern was 11.3 ± 4.5 and for necessity 16.8 ± 4.0 . The average QoL for EuroQol-5D was 0.59 ± 0.28 and for VAS 63.2 ± 9.5 . In subgroup analysis, concern in groups A and B (12.7 ± 4.3 and 13.3 ± 4.7) was higher than in group C (6.5 ± 0.7). Necessity followed the same distribution: groups A and B (17.3 ± 3.1 and 17.3 ± 4.9) were higher than group C (13.5 ± 7.8). Multivariate analysis showed that patients with longer treatments were less concerned about AE ($p < 0.05$). Significantly, patients with a higher EDSS had lower EuroQol-5D and VAS scores: group A (0.72 ± 0.23 and 71.1 ± 16.7), group B (0.37 ± 0.2 and 46.7 ± 5.8) and group C (0.36 ± 0.34 and 52.5 ± 31.8) ($p < 0.05$). Older patients with longer time since diagnosis had lower QoL values ($p < 0.05$).

Conclusion and relevance Most patients showed higher scores for perception of necessity for treatment than concern about the AE of natalizumab, which decreased with longer treatment. Patient disability, age and time significantly decreased QoL measures.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-115 THERAPEUTIC DRUG MONITORING OF ETANERCEPT BIOSIMILAR IN PSORIATIC PATIENTS

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Background and importance A limited number of studies have related serum biological levels to clinical response in psoriasis.

Studies on the clinical relevance of therapeutic drug monitoring for etanercept biosimilar (ETAb) are scarce.

Aim and objectives To analyse ETAb concentrations in patients with moderate to severe plaque psoriasis.

Material and methods This was an observational retrospective study of all psoriatic patients treated with ETAb (Erelzi) and monitored in the pharmacy service from January 2018 to September 2019. The ethics committee approved this study. Informed consent was obtained for all subjects before entry into the study. Patients received ETAb 50 mg every week. ETAb serum levels were assessed immediately prior to administration of drug (Ctough). Concentrations were quantified by capture ELISA immunoassay (Triturus analyser).

Data sources sex, age, weight, date of psoriasis diagnosis, previous treatment with biologic drugs, duration of ETAb treatment, dosage/weight (mg/kg), concomitant treatment (immunosuppressive drugs, oral corticosteroids, retinoids), psoriasis area and severity index scale (PASI) before the start of ETAb treatment (PASIb) and at blood extraction time (PASIe), ETAb concentration and adverse events.

Patients were classified into two groups in accordance with efficacy at the various blood assessment times: good responders ($>PASI75$) and non-responders ($<PASI75$).

Statistics descriptive analysis of variables (SPSS V.19.0), quantitative variables (median (range)) and qualitative variables (number (percentage)).

Results Ten patients (70.0% men, 28 blood samples) were aged 48.5 (26.0–68.0) years and weighed 73 (64–112) kg. Dosage/weight was 0.7 (0.5–0.8) mg/kg. Age at diagnosis was 25.5 (8.0–47.0) years and 100% were naive patients. Concomitant treatments were methotrexate ($n=3$) and ciclosporin ($n=1$). PASIb was 9.0 (3.0–17.3) and PASIe 1.2 (0.0–14.8), 14/28 PASIe=0.0 and %PASI variation with respect to basal value 92.3 (–82.7–100). Treatment time at blood extraction was 3.9 (0.9–14.0) months. ETAb concentration was 2.7 (0.6–4.8) µg/mL. Efficacy: 57.1% good responders and 42.9% non-responders. There were no significant differences in demographic data between the patient response groups. There were no significant differences with respect to ETAb levels: 2.7 µg/mL (range 1.8–4.4) versus 2.6 µg/mL (range 0.6–4.8), respectively ($p > 0.05$). No adverse events were reported.

Conclusion and relevance Drug concentrations were detected in all patients. No relationship was found between ETAb concentration and clinical response (efficacy and toxicity). Further research is needed to determine the clinical significance between ETAb concentration and clinical response, and hence the usefulness of therapeutic drug monitoring in psoriatic patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-116 TEN YEARS OF EXPERTISE IN USTEKINUMAB USE FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS

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Background and importance Over the past 10 years, a pharmacotherapy revolution in the treatment of moderate to severe