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

plaque psoriasis (MS-PP) has occurred. In our country, the prescription of ustekinumab has increased greatly since its approval in 2009. Therefore, it is now time to reflect on its use and to assess the real world setting, before the arrival of newly approved drugs.

Aim and objectives The primary end point was to assess drug survival for ustekinumab for MS-PP treatment. The secondary end point was to assess the effectiveness of ustekinumab for MS-PP treatment.

Material and methods A retrospective observational study was conducted. All patients who had started treatment with ustekinumab for MS-PP from January 2009 to December 2017 were included. Data collected were demographics, line of biological treatment, dates for therapy start and discontinuation, reason for discontinuation, intensification, optimisation, and psoriasis area severity index (PASI) before starting ustekinumab and at weeks 24, 52 and at the last evaluation available.

Drug survival was analysed using Kaplan–Meier plots and effectiveness was evaluated by PASI50, 75, 90 and 100. Subsequently, data were analysed with SPSS21.

Results A total of 130 patients were included, 64.6% men, with a mean age of 44.4 (11–83) years. Treatment line of ustekinumab: firstline 65.4%, secondline 23.1%, third and subsequent lines, 11.5%. Intensification and optimisation was performed in 59.2% and 53.1%, respectively. Mean drug survival was 6.7 years (95% CI 6.06–7.42).

Effectiveness was calculated for 101 patients because of lack of data. Mean PASI at the start was 11.3 (SD 6.8). At week 24, the relation of PASI 50/75/90/100 achieved was 74.3%/67.3%/56.4%/45.5%, respectively (no data available for 11 patients). At week 52, the relation of PASI 50/75/90/100 achieved was 90.0%/75.0%/62.5%/51.3%, respectively (no data available for 21 patients). At the end of the study, 84 patients continued treatment with ustekinumab and their mean PASI at that time was 1.2 (SD 2.3). Reasons for discontinuation were drug failure in 20.8%, no reason described in 7.7%, improvement in 3.1%, neoplasms in 2.3%, intolerance in 0.8% and patient preference in 0.8%.

Conclusion and relevance The PHOENIX trials opened the window to PASI90 and we have confirmed the effectiveness of ustekinumab in real life. Furthermore, the results reported here indicated that this effectiveness persisted for a long time, as recently reported data by Salguero-Fernandez. Therefore, this fact should be an unbiased factor to consider before changing psoriasis therapy to newer drugs based on our long term data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-117 CASE REPORT: USEFULNESS OF THERAPEUTIC DRUG MONITORING OF VEDOLIZUMAB IN MANAGING ACUTE GRAFT VERSUS HOST DISEASE

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Background and importance Acute graft versus host disease of the gastrointestinal tract (aGVHD-GI) is one of the most

common complications in patients undergoing allogeneic haematopoietic stem cell transplantation (HSCT).

Vedolizumab is proposed as a therapeutic alternative in patients with aGVHD-GI resistant to multiple lines of treatment.

Aim and objectives To describe the usefulness of therapeutic drug monitoring (TDM) of vedolizumab to optimise treatment in one patient with aGVHD-GI.

Material and methods A 42-year-old with acute lymphoblastic B leukaemia admitted for allogeneic HSCT developed grade 4 aGVHD-GI. Vedolizumab was administered as sixthline treatment after corticosteroid therapy, mesenchymal stem cells plus mycophenolate mofetil, infliximab, and extracorporeal photopheresis plus ruxolitinib.

Response was measured by clinical criteria (resolution of diarrhoea), imaging tests (gastroscopy and colonoscopy) and inflammatory biochemical markers (faecal calprotectin). Partial response to treatment (PR) was defined as resolution of overall aGVHD in one or more organs without worsening of others, and complete response (CR) as resolution of symptoms in all organs.

Trough vedolizumab serum concentrations (VSC) were determined by ELISA. Vedolizumab clearance (CL) and volume of distribution (Vd) were estimated using a Bayesian population pharmacokinetic approach that incorporated a validated population pharmacokinetic model in patients with inflammatory bowel disease, due to the lack of population data in aGVHD-GI. VSC >30 µg/mL in the induction phase and >14 µg/mL in the maintenance phase were considered therapeutic.

Results Vedolizumab 300 mg was administered as an intravenous infusion during the induction phase at weeks 0, 1, 4 and 6, based on the estimated pharmacokinetic parameters (CL=0.159 L/day; Vd=3.19 L). VSC measured at week 3 was 44 µg/mL. The patient presented a PR and initiated oral tolerance that week. He achieved CR of his grade 4 aGVHD in week 6. The maintenance phase was initiated administering vedolizumab every 4 weeks. VSC measured at weeks 10, 14 and 26 were 3.8, 31.3 and 53.4 µg/mL, respectively. Starting on week 26, vedolizumab was administered every 6 weeks, obtaining a VSC of 22.4 µg/mL. The patient maintained CR during this phase.

Conclusion and relevance TDM of vedolizumab is a valid tool for individualising treatment in patients with aGVHD-GI, avoiding early therapeutic failure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-118 REAL CLINICAL IMPACT OF DRUG–DRUG INTERACTIONS OF IMMUNOSUPPRESSANTS IN TRANSPLANT PATIENTS

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Background and importance The risk of drug interactions in transplant patients is extremely high as they are polymedicated. The characteristics of immunosuppressants constitute an added risk. There are many potential drug–drug interactions