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 11patients). 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 21patients). 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 Salgüero-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

1. Salgüero-Fernández I, *et al*. https://doi.org/10.1016/j.ad.2018.02.019

No conflict of interest.

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

[1]R Fernandez Caballero*, [1]N Martin-Gutierrez, [1]G Sanchez-Hernandez, [1]S Jimenez-Cabrera, [2]A Navarro-Bailón, [2]B Rey-Búa, [1]M Martin-Gil, [1]D Peña-Lorenzo, [1]L Pedraza-Nieto, [1]MJ Otero-López. *[1]University Hospital of Salamanca, Pharmacy Service, Salamanca, Spain; [2]University Hospital of Salamanca, Haematology Service, Salamanca, Spain*

10.1136/ejhpharm-2020-eahpconf.218

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

[1]AI Gago-Sanchez*, [1]M Cardenas, [1]MD Aumente, [2]P Font, [1]JR Del Prado, [3]MA Calleja. *[1]Reina Sofia Universitary Hospitalimibic/University, Pharmacy, Cordoba, Spain; [2]Reina Sofia Universitary Hospitalimibic/University, Rheumatology, Cordoba, Spain; [3]Macarena Universitary Hospital, Pharmacy, Sevilla, Spain*

10.1136/ejhpharm-2020-eahpconf.219

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

(DDIs) but it would be interesting to know which ones are real and have clinical outcomes.

Aim and objectives The main objective of the study was to determine the prevalence of real DDIs between immunosuppressants and other drugs in transplant patients. Secondary objectives were to evaluate clinical impact, categorise the type of DDIs, identify drugs involved and propose alternative therapeutic strategies.

Material and methods A prospective, observational 1 year study (February 2018 to February 2019) was conducted at a third level hospital, including all new transplanted patients. DDIs were detected by a computer application. To determine real clinical DDIs, patient medical records were reviewed, looking for data on monitoring blood concentrations of immunosuppressive drugs and adverse drug events (ADEs) caused by DDIs. DDIs were classified in C, D or X according to the Lexi interact score (C=monitor therapy, D=consider therapy modification, X=avoid combination). The clinical importance of the real DDIs was expressed in terms of patient outcomes: percentage of patients with ADEs due to real DDIs. Data were analysed using SPSS V.17.0 (Chicago, Illinois, USA).

Results A total of 309 transplant patients were included with a mean age of 52±14 years (13–79) and 69.9% were men. The prevalence of real DDIs was 21.68%. The number of real DDIs between immunosuppressants and other drugs was 71. The largest type of real DDIs was category D (52 (73.23%)).

Immunosuppressive drugs administered with antifungal azoles and tacrolimus with nifedipine had a great clinical impact due to the fluctuation in trough immunosuppressant blood concentrations (C_0) of the immunosuppressants.

The most common clinical outcomes were nephrotoxicity (12%), hyperkalaemia (10%) and hypertension (5%). Suggestions to avoid D and X for real DDIs included: immunosuppressant dose change, consider therapy modification and using paracetamol instead of non-steroidal anti-inflammatory drugs. A statistically significant linear correlation was detected between number of prescribed drugs and real and clinically important DDIs.

Conclusion and relevance There are many potential interactions described in the literature but only a small percentage have been proved to be real DDIs, based on patient outcomes, which were detected by determining the variations in C_0 of immunosuppressants and ADEs caused by DDIs. Few patients suffered ADEs due to the close pharmacokinetic monitoring of immunosuppressants. The results allow us to identify the pharmacological groups that caused real DDIs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-119 'REAL WORLD' EXPERIENCE OF TOFACITINIB AND BARICITINIB IN THE TREATMENT OF RHEUMATOID ARTHRITIS: EFFECTIVENESS AND SAFETY EVALUATION

[1]S Garcia Garcia*, [1]I Cardona Pascual, [1]M Larrosa Garcia, [1]JB Montoro Ronsano, [2]R Caparros Ruiz, [1]C Alonso Martinez, [1]J Vidal Otero, [1]S Gamarra Calvo, [1]MR Gomez Domingo, [1]C Alerany Pardo. *[1]Vall D'hebron University Hospital, Hospital Pharmacy Department, Barcelona, Spain; [2]Vall D'hebron University Hospital, Rheumatology Department, Barcelona, Spain*

10.1136/ejhpharm-2020-eahpconf.220

Background and importance Tofacitinib and baricitinib are oral Janus kinase inhibitors (JKi) approved for the treatment of rheumatoid arthritis (RA), offering an alternative in patients who have not responded or tolerated previous treatment lines because of adverse effects, complications or other reasons. In pivotal clinical trials, patients had higher DAS28-ESR than our patients and were less pretreated with biologic disease modifying antirheumatic drugs (bDMARDs). Lower effectiveness in real world compared with clinical trials has been reported. We conducted a retrospective study to evaluate effectiveness in our patients.

Aim and objectives To assess the effectiveness and safety of JKi in patients with RA in a clinical setting.

Material and methods This observational retrospective study included patients with RA in a third level hospital, from 2016 to 2019. Clinical data were collected from the hospital medical records and 'patient and treatments registry programme' of our local government: demographic, indications, previous and current treatments, discontinuity of treatment and reasons, effectiveness and safety data.

Clinical disease impact, defined by the disease activity score, DAS28-ESR, was evaluated during patient monitoring. Mean (SD) DAS28-ESR at baseline and at follow-up after JKi treatment were analysed.

Variance analysis (ANOVA) and the χ^2 test were applied (SPSS) to evaluate treatment effect (time=0 vs follow-up data).

Results Fifty-three patients were included with a mean age of 63.9±13.3 years and 46 (86.8%) were women. Previous non-bDMARDs treatments were: methotrexate (n=39, 73.6%), leflunomide (n=34, 64.2), hydroxychloroquine (n=15, 28.3%) and sulfasalazine (n=9, 17.0%).

Disease activity was categorised as: remission (DAS28-ESR <2.6), low disease activity (2.6< DAS28-ESR <3.2), moderate disease activity(3.2< DAS28-ESR <5.1) and high disease activity (DAS28-ESR >5.1). At the beginning of the study, one patient had DAS28-ESR <2.6 (1.9%) and during the monitoring period, nine patients reached DAS28-ESR <2.6 (17.0%) at some point. Mean DAS28-ESR was 4.97±1.32 at baseline; during follow-up, mean DAS28-ESR decreased to 0.69±1.44 (10.3±30.8%) (p<0.001).

Patients were classified by treatment received: tofacitinib group (TofG (n=44, 83.0%)) and baricitinib group (BarG (n=9, 17.0%)). Number of bDMARDs used before JKi:

-TofG: 0 (n=7, 15.9%), 0–3 (n=22, 50.0%), >3 (n=15, 34.1%).

-BarG: 0 (n=2, 22.2%), 0–3 (n=3, 33.3%), >3 (n=4, 44.4%).

At follow-up, mean DAS28-ESR decreased: TofG, 0.64 ±1.44 (9.3±32.0%) and BarG, 0.98±1.44 (15.6±23.0%).

Twelve patients discontinued JKi: baricitinib (n=3, 33.3%) and tofacitinib (n=9, 20.5%). Reasons for discontinuation, baricitinib and tofacitinib, respectively, were due to:

-lack of effectiveness (n=2, 22.2%) and (n=5, 9.4%);

-lack of adherence (n=1, 11.1%) and (n=2, 3.8%);

-adverse effects (n=0, 0%) and (n=1, 1.9% oedema and dyspnoea); and

-patient´s choice (n=0, 0%) and (n=1, 1.9%).

Conclusion and relevance Our study suggests that JKi could be effective in real world settings after switching from other multiple bDMARDs. The results showed a modest benefit of JKi in complicated and over treated patients with diverse backgrounds, as found in daily practice.