4CPS-322 ADALIMUMAB CONCENTRATIONS PRIOR TO THE IMPLEMENTATION OF THERAPEUTIC DRUG MONITORING IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

A Gracia Moya*, A Pau Parra, P Sánchez Sancho, I Cardona Pascual, P Garcia Ortega, B Torrecilla Vall-Llossera, MQ Gorgas Torner, M Miarons Font. *Vall D'hebron Hospital, Hospital Pharmacist, Barcelona, Spain*

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Background and importance Adalimumab (ADA), an anti-TNF agent, has been shown to effectively induce and maintain remission in patients with inflammatory bowel disease (IBD). The usual recommended dose in the maintenance phase is 40 mg every 14 days. The formation of anti-adalimumab antibodies (AAA) reduces plasma ADA serum concentrations (ADAsc), as well as its efficacy.
Aim and objectives The aim of the study was to analyse ADAsc and the presence of AAA in patients with IBD prior to the implementation of dose optimisation through therapeutic drug monitoring (TDM). The secondary objectives were to evaluate changes in the posology and to characterise the symptoms of IBD.
Material and methods A retrospective observational study was conducted in patients with Crohn's disease (CD) or ulcerative colitis (UC) on maintenance therapy with ADA during a follow-up period of 3 years (July 2016 to April 2019) before applying TDM in a tertiary referral centre. The concentrations of ADA and AAA were determined by enzyme linked immunosorbent assay. The therapeutic range (TR) of ADA, according to the hospital protocol, is 8–12 µg/mL. Biodemographic, analytical and clinical data were collected from the clinical history.
Results 165 patients (53.0% women) were included, 132 (80.0%) with CD. Mean age was 40.00 (SD 12.4) years. At the beginning of the study, 119 (72.1%) patients received ADA 40 mg every 14 days and 46 (27.1%) intensified regimens. The average concentration of ADA was 7.24 (SD 3.6) µg/mL and 82 (49.7%) patients had ADAsc outside the TR. We observed AAA in 16 (9.7%) patients. Of these, 15 (93.7%) had ADAsc outside the TR. During the study, regimen intensification was conducted in 34 (20.6%) patients. Finally, regarding patients with ADAsc outside the TR, 35 (42.7%) presented with abdominal symptoms and/or systemic manifestations.
Conclusion and relevance ADAsc outside the TR were observed in half of the patients, in approximately 1 in every 10 patients AAA were detected and 42.7% of patients with ADAsc outside the TR presented with symptoms. Implementation of a TDM might be a useful tool for managing patients with IBD on biologic therapy to reduce the number of patients with ADAsc outside the TR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-323 EVALUATION OF THE USE, ADHERENCE AND TOLERANCE OF 0.03% TACROLIMUS EYE DROPS

I Varela Rey*, M Gonzalez-Barcia, L García-Quintanilla, A Castro-Balado, M Busto-Iglesias, I Zarra-Ferro, A Fernández-Ferreiro. *Complejo Hospitalario Universitario De Santiago De Compostela, Hospital Pharmacist Service, Santiago De Compostela, Spain*

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Background and importance Tacrolimus is an immunosuppressant with many potential uses in ophthalmic diseases. It is an inhibitor of calcineurin phosphatases, which suppress the first phase of T cell activation and leads to a decrease in inflammatory activity. There are no commercialised eye drops in Spain so its formulation as a pharmaceutical compound has to be done by the hospital pharmacy services.
Aim and objectives To evaluate the use, tolerance and adherence of 0.03% tacrolimus eye drops as a pharmaceutical compound.
Material and methods A retrospective observational study was conducted in patients treated with 0.03% tacrolimus eye drops from January 2017 to March 2020. The eye drops were prepared and dispensed by the hospital pharmacy service. For the preparation, 0.6 mL of intravenous Prograf 5 mg/mL were diluted with Liquifilm to a final volume of 10 mL.

Demographic (sex and age) and clinical data (diagnosis, duration, adherence and tolerance) were recorded using electronic prescription and electronic medical records. Adherence was measured using registered dispensations as well as by follow-up controls by an ophthalmologist. We classified as the most compliant patients those with no delay in dispensation times in the pharmacist consultation.
Results 54 patients (57% men) with a mean age of 32±21 years used tacrolimus eye drops during the study period. Tacrolimus eye drops were used for the treatment of immune mediated ophthalmic inflammatory diseases in 61.8% of patients, of whom 49.1% were for atopic or vernal keratoconjunctivitis. 20.0% of the total number of patients used the eye drops for hyperaemia of unknown cause,12.7% were used for dry eye and the remaining 5.4% for the treatment of graft rejections.

Mean duration of treatment was 1.8±1.0 years. Tolerance was generally good. Only 24.07% of patients presented with itching, and 2 patients (3.70%) had palpebral dermatitis and miosis. 50% of patients were highly compliant (having no delay in dispensations), 38.89% had delayed dispensing at least once, 9.26% had delayed dispensing at least twice and 1.85% had irregular dispensations.
Conclusion and relevance 0.03% tacrolimus eye drops were used primarily for the treatment of vernal or atopic keratoconjunctivitis but they have wide potential uses in ophthalmology diseases. The formulation was well tolerated by most of patients and adherence was generally correct, as measured by the pharmacist consultations.

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4CPS-324 EFFECTIVENESS AND SAFETY OF IXEKIZUMAB IN MODERATE-TO-SEVERE PLAQUE PSORIASIS

[1]MDP Briceño Casado*, [2]MD Gil-Sierra, [1]B De La Calle Riaguas, [3]M Dominguez-Cantero. *[1]Hospital Nuestra Señora Del Prado, Hospital Pharmacy, Talavera De La Reina, Spain*; *[2]Hospital Doctor Jose Molina Orosa, Hospital Pharmacy, Lanzarote, Spain*; *[3]Hospital Universitario Puerto Real, Hospital Pharmacy, Cadiz, Spain*

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Background and importance Ixekizumab is a high affinity monoclonal antibody against interleukin 17A. It is used for the treatment of moderate-to-severe plaque psoriasis (MTSPP).

Aim and objectives To assess the effectiveness and safety of ixekizumab in MTSPP in clinical practice.
Material and methods A descriptive, retrospective, multicentre study was conducted. Patients with MTSPP receiving ixekizumab between 1 January 2017 and 30 September 2020 were included. Electronic clinical history and the prescription programme Farmatools were used to record data: sex, age, previous treatment, dosage and duration of therapy. Effectiveness was measured by the psoriasis area severity index (PASI): PASI-75 (≥75% reduction in baseline PASI), PASI-90 (≥90% reduction) and PASI-100 (total clearance of lesions) at weeks 12 and 36. Failure to achieve PASI-75 was considered no response. Safety was evaluated according to adverse events (AE) and discontinuations of treatment.
Results 46 patients were included, 27 (59%) were men. Mean age was 49 (23–74) years. Previous treatments: methotrexate (n=33), cyclosporine (n=29) and biological therapy (n=35). Mean number of prior biological drugs was 3 (1–5), including anti-TNF (etanercept, n=23; adalimumab, n=22; infliximab, n=3), anti-IL-12-23 (ustekinumab, n=16) and anti-IL-17A (secukinumab, n=7). All patients received ixekizumab with an induction dose of 160 mg at week 0 and then 80 mg at weeks 2, 4, 6, 8, 10 and 12. Maintenance dose was 80 mg every 4 weeks in 34 (74%) patients and every 6 weeks in 12 (26%). Mean duration of ixekizumab therapy was 17 (3–44) months.

Baseline PASI was >5 in all patients and >10 in 37 (80%) cases. Effectiveness was not evaluated in 5 (11%) patients at week 12 and in 8 (17%) patients at week 36 due to lack of information. At week 12: 1 (2%) patient presented PASI-75, 12 (26%) PASI-90, 23 (50%) PASI-100 and 5 (11%) no response. At week 36: 1 (2%) patient achieved PASI-75, 15 (33%) PASI-90, 16 (35%) PASI-100 and 6 (13%) no response. Regarding the safety profile, 3 (7%) patients presented AE: alopecia, eosinophilia and injection site reaction. No discontinuations of treatment were reported.
Conclusion and relevance Ixekizumab was effective and provided total clearance of MTSPP lesions to half of the patients by week 12, with this considerable response in more than a third of patients at week 36. Ixekizumab was well tolerated, with a low frequency of AE.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-325 EFFECTS ON ADHERENCE IN PATIENTS WITH ARTHROPATHIES CHANGING TREATMENT

J Olivares*, C Laura, S Ines, BDL Blanca, G Patricia, S Irene, M Irene, M Carmen. *Hospital Universitario De Mostoles, Hospital Pharmacy, Mostoles, Spain*

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Background and importance Arthropathies are a heterogeneous group of pathologies that affect a high percentage of the population, affecting their quality of life. New forms of administration for the treatment of these diseases allows different results to be obtained compared with conventional treatments. But there is not much evidence of the effect on adherence in these patients after a change in treatment.
Aim and objectives To compare the effect that a change in medication may have on adherence in patients with an arthropathy.
Material and methods A retrospective observational study was conducted that included patients who had been treated for arthropathy in our hospital from January 2019 to January 2020 and who had undergone a change of treatment in the same or previous years. We included the following variables: demographics, treatment before and after change, and adherence before and after change. The Mann–Whitney U test was used for statistical analysis to compare the means for adherence with non-parametric distribution and the simple χ^2 test for association between two categorical variables.
Results During the study period, treatment was modified in 83 patients (37% men, mean age 53 years). In 64 cases, the route of administration was the same (63 subcutaneous and one oral), and was modified in 19 (10 changed from subcutaneous to oral and 9 from oral to subcutaneous). For patients who continued with the same route of administration, adherence decreased from 91.98% to 91.6% (p>0.05) for subcutaneous administration and the percentage of patients with adherence greater than 90% decreased from 74.6% to 71.4% (p>0.05). Patients receiving oral administration improved their compliance from 70% to 100%.

For patients with a change in the administration route, from oral to subcutaneous administration, adherence decreased from 97.3% to 92.7% (p>0. 05) and the percentage of patients with adherence greater than 90% decreased from 88.9% to 77.8% (p>0.05). The change from subcutaneous to oral administration showed that adherence increased from 93.7% to 97.1% (p>0.05) and the percentage of patients with adherence greater than 90% from 80% to 90% (p>0.05).
Conclusion and relevance According to the modification of the route of administration, the data suggested an improvement in those cases where the subcutaneous route was modified to the oral route and worsening adherence from the oral to the subcutaneous route.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-326 ADALIMUMAB'S PERSISTENCE IN RHEUMATOLOGICAL DISEASES

C Pastor Mondéjar, C Iniesta Navalón, I Salar Valverde*, AM Martínez Soto, P Ortiz Fernández, M Gil Candel, L Rentero Redondo, M Onteniente Candela, M García Coronel, MDC Caballero Requejo, E Urbieta Sanz. *Reina Sofia General University Hospital, Hospital Pharmacy, Murcia, Spain*

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Background and importance Adalimumab is a human monoclonal recombinant antibody whose mechanism of action is mediated by binding specifically to tumour necrosis factor (TNF), neutralising its function. Adalimumab is indicated for the treatment of progression of pathologies such as rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis.
Aim and objectives To calculate the overall survival of adalimumab in patients diagnosed with rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis in our hospital.
Material and methods A retrospective study was performed in which all patients diagnosed with these pathologies who initiated treatment with adalimumab from January 2007 to December 2016 were included. Data for start date, date of discontinuation of treatment if suspension occurred, sex and