4CPS-157 IMPACT OF COVID-19 PANDEMIC ON PATIENTS TREATED WITH BIOLOGICAL DRUGS AND ENZYME REPLACEMENT THERAPIES

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Background and importance After the arrival of the pandemic, visits to the hospital were considerably reduced. This, added to the quarantine that patients could suffer, led to the discontinuation or delay of scheduled administrations in outpatients treated with biological drugs (BD).
Aim and objectives To evaluate the impact of the pandemic on patients treated with BD and enzyme replacement therapies (ERT).
Material and methods A retrospective observational study in which the incidents detected during 13 months (March 2020–April 2021) in the administration of vedolizumab, infliximab, ustekinumab, ocrelizumab, natalizumab, patisiran, dupilumab, abatacept, belimumab, reslizsaumab, sebelipab, agalsidase alpha and alpha-1 antitrypsin were collected.

All outpatient therapies with BD and ERT during the study period were included. The patients' clinical data in the electronic medical records and the data of preparation of the treatments of the Farmis-Oncofarm were analysed. Finally, the reason for the incidence in the administration of the treatment was analysed.
Results Incidences were registered in 178 patients in active treatment with BD and ERT and 530 administrations during the periods March–April 2020 and January–February 2021. 40 (7.5%) incidences were detected in 35 (19.7%) patients in whom there was delay or discontinuation of treatment. Delay in the administration of treatment was observed in 27 patients with an average delay of 3 weeks; 2 patients died from complications of their disease; and the remaining 6 patients discontinued treatment. Among the reasons for the delay or discontinuation in the treatments we observe the following: 5 patients could not receive the treatment due to active infection with COVID-19 and 2 patients because they had been in contact with another infected person; 17 did not come for fear of contagion; and the remainder did not do so for personal reasons. A worsening of the clinical situation associated with the disease was found in 10 patients during the delay or discontinuation of treatment.
Conclusion and relevance The global pandemic has had an impact on outpatients with chronic diseases who need intravenous treatment, and a delay or discontinuation of BD and ERT in 7.5% of scheduled administrations has been observed, the main causes being fear of contagion and personal motives.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-158 EVALUATION OF MEDICINE-RELATED INCIDENTS IN THE NATIONAL BONE MARROW TRANSPLANT CENTRE

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Background and importance The Sterile Compounding Centralised Unit (SCCU) at the National Bone Marrow Transplant Centre (NBMTC) prepares an average of 9000 sterile injectable preparations yearly. Many medicine-related incidents (MRI) with various levels of therapeutical and economic repercussions have been documented either in the clinical or the pharmacy departments.
Aim and objectives Evaluation of MRI in the NBMTC and economic analysis of medication losses.
Material and methods An 8-month retrospective study from January to August 2021. A MRI incident sheet was elaborated to document each incident for data collection and analysis.
Results A total of 35 incidents were reported during the study period. The main causes were: stopping the drug prescription by the treating doctor without informing the pharmacist in charge (42.85%), medication administration omission by the treating staff (20%) and cold chain breach (11.42%).

Of the 242 medication units' loss (instability after compounding or cold chain breach), the pharmacy department is responsible of 69.8% of losses, of which 98.8% were caused by the cold chain breach. The adult haematology department is responsible of 22.7% of the total units' loss whereas 7.4% of the losses are attributed to the paediatric haematology department. The most involved drug families in these incidents are anticancer drugs (45%) and antifungal drugs (20%). 43.3% of the MRI are non-hospital nomenclature drugs.

The cost evaluation of the incidents revealed a loss of an equivalent of € 37 615 representing 2.06% of the total medicines budget of the NBMTC and 3.2% of the sterile preparations prepared by the SCCU. An 85.9% cost loss was caused by a technical error in the NBMTCT power monitoring system.
Conclusion and relevance Establishing corrective solutions such as optimising medicine conservation and supply chain quality limits the occurrence of further MRI. The first step towards a more pertinent improvement in the prevention of the occurrence of further MRI is the total digitalisation of patient files.

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4CPS-161 BUDGETARY IMPACT OF PCSK9I DOSES REGIMEN OPTIMISATION

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Background and importance Hypercholesterolaemia produces a higher risk of atherosclerosis and cardiovascular events. The proprotein convertase subtilisin kexin type 9 inhibitors (PCSK9i), evolocumab and alirocumab, were approved by the European Medicines Agency in 2015, and they are available to manage patients who have not achieved the target cholesterol levels or who are intolerant to the standard treatment with statins or ezetimibe. Nevertheless, due to their high budgetary impact, it is crucial to find measures to optimise their use.
Aim and objectives The aim of the study was to analyse the effectiveness and costs of the optimised PCSK9i regimen compared to the standard dosage regimen.
Material and methods A retrospective cohort study was conducted in patients who began using PCSK9i between September 2017 and September 2021. In patients with a reduction

in low-density lipoprotein cholesterol (LDLc) greater than 50% or who have reached their target value, alirocumab 150 mg/4 weeks or evolocumab 140 mg/21 days were proposed for optimisation of the dosage. Demographic, clinical and pharmacotherapeutic data were collected. Treatment efficacy was calculated as percent reduction in LDLc from baseline at treatment initiation to the end of the study period. The collected data were analysed using a Student's test through the SPSS programme.

Results Twenty-two patients were included, 9 males, with a median age of 62 (range 42–82) years, median treatment time was 22.52 (1.27–49.30) months and initial LDLc values of 161 (101–237) mg/dL. Fifteen patients (68%) were treated with alirocumab. Two patients discontinued treatment. Two patients were excluded because the treatment was not effective. Nine patients (45%) were proposed to optimise doses. In these patients the mean LDLc value was 75.66±41.21 mg/dL and a reduction of 48.33%±26.87, while in patients on standard doses it was 90.72±59.70 mg/dL and 51.52%±26.72, respectively. The difference was not significant ($p>0.05$). The optimised doses involve a saving of € 2040.97/patient/year in alirocumab and € 1417.65/patient/year in evolocumab.

Conclusion and relevance The optimised use of PCKS9i is an effective measure and would mean a reduction in the direct costs in the treatment of hypercholesterolaemia.

It is necessary to search for strategies that help to reduce the budgetary impact to optimise health resources without damaging treatment effectiveness.

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4CPS-162 CYTOKINE RELEASE SYNDROME IN ONCO-HAEMATOLOGICAL PATIENTS TREATED WITH TOCILIZUMAB

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Background and importance Cytokine release syndrome (CRS) is a common and life-threatening toxicity directly related to new targeted therapies for onco-haematological diseases. Although the optimal therapy for CRS remains unknown, tocilizumab has demonstrated success.

Aim and objectives To assess the efficacy of tocilizumab in onco-haematological patients with CRS. Relationship between CRS and targeted therapies was also reviewed.

Material and methods Retrospective cohort study in a single centre. Cases of onco-haematologic patients who received tocilizumab for CRS treatment from 2019 to 2021 were studied.

Patient demographics, onco-haematological diagnosis and targeted therapy, CRS-related symptoms and tocilizumab treatment were collected from electronic patient files. CRS resolution after tocilizumab treatment was reviewed in order to evaluate the efficacy of therapy.

CRS severity based on the American Society for Transplantation and Cellular Therapies grading scale for CRS was compared between the groups of patients with different onco-hamatologic diagnoses and targeted therapies.

Results A total of 47 patients received tocilizumab (46 hematologic and 1 oncologic) for CRS. Main onco-haematological diagnoses were multiple myeloma (75.5%), lymphoma (10.2%) and acute myeloblastic leukemia (8.2%). Targeted therapy consisted of *chimeric antigen receptor T-cells* (CAR-T-cells) in 29 patients (61.7%), bispecific antibodies in 16 (34.0%) and haematopoietic stem cell transplantation (HSCT) in 2 (4.3%).

Nineteen patients (40.4%) developed CRS grade 1, 26 (55.3%) grade 2 and 2 (4.3%) grade 3.

Tocilizumab median dose was 8.0 (5.3–10.4) mg/kg. Twelve patients (25.5%) required a second tocilizumab dose. CRS resolution occurred in all patients.

CRS was more severe in the group of patients with a diagnosis of lymphoma, developing CRS grade 3 in 25% of patients versus 0% in the other groups ($p<0.05$). In the group of patients with multiple myeloma, CRS grade 1 occurred more frequently (48.5% vs 2.3%, $p<0.05$).

Severe CRS (grade 2 and 3) was more frequent in patients treated with bispecific antibody or HSCT than in those who received CAR-T-cell therapy (77.8% vs 51.9%, $p<0.05$).

Conclusion and relevance Tocilizumab is an effective treatment in CRS after new targeted therapies in onco-haematological patients.

Severity of CRS seems to be higher in patients with diagnosis of lymphoma and in those treated with bispecific antibodies and HSCT.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-163 EARLY EXPERIENCES IN SWITCHING BETWEEN MONOCLONAL ANTIBODIES IN CHRONIC MIGRAINE PREVENTIVE THERAPY

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Background and importance Monoclonal antibodies targeting the calcitonin gene-related peptide (CGRP-mAbs) have been introduced into the therapeutic arsenal of chronic migraine (CM) prophylaxis. Clinical trials report similar efficacy between them. Some patients with CM and multiple treatment failures do not respond to a first treatment with CGRP-mAbs, but there is no evidence for switching to a second CGRP-mAbs. These treatments are dispensed in hospital pharmacies, where pharmacists follow up these patients and the efficacy of these treatments.

Aim and objectives We aimed to describe the effectiveness of CGRP-mAbs (erenumab and galcanezumab) switching in preventive treatment for CM in clinical practice.

Material and methods A retrospective case series including patients with CM treated with CGRP-mAbs and switched to another CGRP-mAb between August 2020 and September 2021 in a third-level hospital in Spain. Effectiveness was established with ≥50% reduction of monthly migraine days (MMD) in respect to baseline, or ≥30% reduction of MMD and ≥5 points reduction of the HIT-6 with respect to baseline.

Results Twenty patients were included: 14 were treated with erenumab as first CGRP-mAb and were switched to galcanezumab; 6 were treated with galcanezumab and were switched to erenumab. The median duration of the first CGRP-mAb treatment was 7.8 (5.0–9.7) months. The reason for treatment switching was non-response in 15 cases and adverse events in