

5PSQ-064 INTENSIVE MONITORING OF AFATINIB – CASE REPORT

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Background The implementation of intensive monitoring programmes allows the identification of early occurrence of adverse drug reactions (ADR), in a comprehensive and exhaustive way. Afatinib was included in this pharmacovigilance programme (PP), which involves patient follow-up, carried out by pharmacists, to monitor the safety use of new drugs.

Purpose Analyse the results of afatinib in a PP.

Material and methods A retrospective study was carried out to analyse the follow-ups of a patient treated with afatinib. Data were collected by consulting the patient's clinical file and monitoring records of the pharmaceutical department.

Results Female patient, 88 years' old, caucasian with non-small cell lung cancer, with pleural metastasis and EGFR+. Started first-line treatment in December 2016 with oral vinorelbine, suspended in April 2017 due to gastrointestinal intolerance. Started afatinib 40 mg in April 2017 and was included in the PP. First follow-up performed by the pharmacist in May, patient showed erythematous/acneiform skin reaction dispersed in limbs and trunk, intense pruritus, nausea and ocular complaints. Pharmacist advised the oncologist and it was decided to oversight. Eye complaints continued in the second follow-up in June. The oncologist was called again, evaluated and referred the patient to ophthalmology. The patient was observed in July and diagnosed with keratitis with ulceration in the left eye, which led to the suspension of treatment in August. The patient resumed treatment with dose reduction (afatinib 30 mg) in November, with improvement of complaints. In the March 2018 follow-up, the patient referred to the pharmacist numbness, rash and face oedema. The oncologist was called and decided to maintain therapy and oversight. In the next follow-up the patient maintained the complaints and treatment was suspended. Both suspected ADR were reported to the national pharmacovigilance unit. An imaging control of the disease was programmed to further decisions concerning treatment. In July, there was evidence of biochemical progression, and the oncologist discontinued therapy.

Conclusion The early approval of drugs that covers therapeutic gaps reveals the necessity to implement effective and systematic methodologies that allow the surveillance of their use. Monitoring by the pharmacist promotes and contributes to safety and adherence in the use of medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

<http://www.ema.europa.eu>

No conflict of interest.

5PSQ-065 MANIC SYMPTOMATOLOGY INDUCED BY ALECTINIB: A CASE REPORT

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Background Alectinib is indicated as a second-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) anaplastic lymphoma kinase (ALK) positive, previously treated with crizotinib. Clinical safety data do not report adverse drug reactions (ADR) on the central nervous system. This drug is on the European list of medicinal products under additional monitoring.

Purpose Describe a case of manic episodes in a patient with advanced NSCLC treated with alectinib.

Material and methods Retrospective observation of a clinical case. The data – diagnostic tests, therapy and clinical course – were obtained by the review of medical records.

Results A 46 years' old female affected by NSCLC ALK positive with brain metastases began treatment with alectinib in December 2017. Treatment, four capsules twice a day, allowed cancer regression and metastasis disappearance. In March 2018, a CT scan with and without contrast agent (80 cc Ioversol 370 mg/mL), did not show pathological signs in intracranial space or grooves growth of the convexities. History was negative for psychiatric disorders but after the beginning of treatment, the patient developed an anxious depressive symptomatology and insomnia that worsened in the next months. Between February and May 2018, the patient was hospitalised four times at the Psychiatric Diagnosis and Treatment Service, and diagnosed with bipolar severe disorder: psychotic characteristics with persistently high mood, irritable and expanded, logorrhea, agitation, impairment of social functioning, delirium with ideas of grandeur and persecution. This ADR has been reported on the national pharmacovigilance network.

Psychotic symptoms were treated with Sodium Valproate 300 mg os, Aripiprazole 400 mg ev, Lithium Carbonate 300 mg os, and high doses of Lorazepam and Olanzapine up to 30 mg. The patient responded well but had recurrences after each hospital discharge. Although initially this could be supposed as poor treatment compliance, this was impossible due to long-acting injectable therapy with normal levels of valproataemia and lithaemia.

The patient continued the therapy with Olanzapine and Lorazepam.

Conclusion In the literature there are no cases of Alectinib neurological toxicity. For this reason, healthcare professionals need to monitor carefully any unexpected ADR that can manifest itself during treatment with new drugs, especially those under additional monitoring.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Pubmed; Abstract book EJHP; RCP Alectinib and clinical studies; RNFV.

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5PSQ-066 THE OTHER SIDE OF IMMUNOTHERAPY: SAFETY AND TOXICITY MANAGEMENT IN CLINICAL PRACTICE

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Background Nivolumab and Pembrolizumab are monoclonal antibodies that block the programmed-cell-death-ligand (PD-L1) and its receptor (PD-1) respectively, inhibiting the immune

checkpoint. They have demonstrated their efficacy and safety in the treatment of different solid tumours.

Purpose To evaluate the incidence of adverse events (AE) associated with immune checkpoint inhibitors and to analyse the management of the toxicity.

Material and methods Descriptive and retrospective study which included every patient treated with Nivolumab or Pembrolizumab between April 2015 and September 2018 in a third-level hospital. Demographics and clinical variables were collected from the electronic medical records: sex, age, type of tumour, number of cycles, causes of treatment suspension, AE and its severity, as well the need for referral to other specialist, pharmacological treatment or hospitalisation for its handling.

Results We included 71 patients (74.6% males), 60.6% were treated with Nivolumab and 39.4% with Pembrolizumab. Average age was 67.6 years (SD 10.3) and the median number of cycles was eight (1–70). The most frequent types of tumours were non-small-cell lung cancer (63.0%), bladder cancer (15.1%) and renal cancer (8.2%).

74.7% of patients presented >1 AE, all immunomediated: 79.1% with Nivolumab (8.9% grade 3) and 71.4% with Pembrolizumab (22.5% grade 3). The most common AE in both groups were asthenia (53.5% with Nivolumab and 32.1% with Pembrolizumab), skin toxicity (37.2% and 25% respectively) and diarrhoea (14% and 21.4% respectively). Immunemediated toxicity was the cause of permanent treatment suspension in 15.1% of patients (45.5% hepatitis and 18.2% pneumonitis).

Referral to other specialists was necessary in 20.9% of patients treated with Nivolumab and 25% with Pembrolizumab. 32.6% of patients with Nivolumab and 39.3% with Pembrolizumab required pharmacological management. Also, 7% of cases required hospitalisation to control AE due to Nivolumab and 25% due to Pembrolizumab.

Conclusion All treatment-related AE are immune-mediated. Despite being less frequent, there are certain AE which, due to their clinical relevance, led to the permanent suspension of treatment. The incidence of grade 3 EA was higher in patients treated with Pembrolizumab, as well as hospitalisation required. The role of a multidisciplinary team is essential in handling possible related EA, achieving an adequate treatment optimisation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5481296/>

No conflict of interest.

5PSQ-067 DETECTION OF ADVERSE NEUROPSYCHIATRIC REACTIONS ASSOCIATED WITH ABIRATERONE AND ENZALUTAMIDE TREATMENTS IN THE HOSPITAL

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Background Enzalutamide (ENZ) and abiraterone acetate (AA) are oral treatments indicated for metastatic castration-resistant prostate cancer (mCPRC). Both drugs can cause neurological and psychiatric adverse effects. Some publications suggest that some neuropsychiatric adverse reactions are more frequent with ENZ than with AA.

Purpose The aim of this study was to check the prevalence of these types of adverse reactions in patients treated in our hospital, by reviewing their clinical history.

Material and methods We selected those patients in treatment with ENZ or with AA in our hospital from January 2015 to September 2018. Clinical data were obtained by consulting their clinical history and the pharmacy service's computer program. The presence of any of these signs/symptoms was identified as adverse neuropsychiatric reaction: restless leg syndrome, anxiety, headache, insomnia, seizures, falls, dizziness, hallucinations, memory impairment.

Results During the study period, 53 patients received treatment with abiraterone and 61 patients received treatment with enzalutamide. The mean age was over 60 years in both groups. In the AA group, 12 patients (22.6%) with adverse neuropsychiatric-type reactions were detected: falls (eight patients), insomnia (six patients), headache (six patients) and memory loss (four patients). The ENZ group showed similar data, in 14 patients these types of alterations appeared (22.9%): insomnia (10 patients), headache (six patients), falls (six patients) and memory loss (five patients).

Conclusion After evaluating our results, it could be concluded that both abiraterone and enzalutamide show the same profile in terms of adverse neuropsychiatric reactions. But it is true that more studies are required to determine if these reactions are due to these drugs or to other factors such as age, the evolution of the disease or the patient's social situation.

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5PSQ-068 ADHERENCE TO DISEASE-MODIFYING THERAPIES IN SPANISH PATIENTS WITH MULTIPLE SCLEROSIS

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Background Like in other chronic diseases, the adherence to disease-modifying treatments in multiple sclerosis (MS) is essential to maximise its efficacy. The adherence is relevant for the symptoms' relief and delay in disease progression. It is essential to find out factors which could influence adherence rates in MS patients, in order to improve the management of the disease.

Purpose This study aims to evaluate the adherence to MS treatment in Spanish patients and find out variables that may influence it.

Material and methods Cross-sectional study conducted in MS Spanish patients receiving disease-modifying treatments ≥1 year before the inclusion. The recruitment was performed in hospitals and patients' associations by healthcare professionals and patient association's staff. Adherence was measured using the Morisky–Green scale (four questions with dichotomous answers, compliance was considered with these answers: NO/YES/NO/NO) and related factors using a questionnaire addressing demographic/disease characteristics, global perception of pathology, impact of medication on patient life,