adverse reactions (AR) such as aseptic meningitis (AM) are described in the product information (PI).

Purpose To describe and analyse five cases of AM in patients treated with IVIg in our centre.

Material and methods A literature search was conducted on the AR of IVIg. The case analysis was established using the Karch–Lasagna algorithm.

Results There were five cases notified of AM in a 3 month period (80% females). Clinical manifestations included headache, fever, nausea and vomiting, and in some cases photophobia. Symptoms usually commenced within 48 hours after infusion. In all cases lumbar puncture was compatible with AM. Two patients had to be hospitalised due to AM, one of them prolonged hospitalisation.

All patients received IVIg of the same brand, presentation and even some of the same batch. All of them received an individualised administration form prepared by the pharmacist including premedication information and the rate of administration of the IVIg calculated according to patient weight and PI.

The Karch–Lasagna algorithm in these cases established a possible causal relationship between IVIg and the occurrence of AM.

Every case reported had a neurological-based pathology: myasthenia gravis, nystagmus, multiple mononeuropathy, Parsonage–Turner syndrome and sensitive-motor polyneuropathy. Nevertheless, in our centre the other five patients with no neurological pathology received the same presentation and batch of IVIg during the same period and did not present AM. The analysis leads us to suspect that patients with basic neurological diagnosis have a higher risk of suffering from AM.

The preventive measures adopted were to reduce the speed of individualised administration and to insist that good hydration is important in preventing this adverse effect.

Conclusion IVIg have demonstrated efficacy and a good safety profile in clinical trials. However, possible AR due to its use can be observed. The role of the pharmacist is important in the individualised information by patients concerning the administration of immunoglobulins. In order to reduce the incidence of AM, it is suggested to start the initial infusion at a slow rate, prehydration and premedication therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-045 SAFETY PROFILE OF SUNITINIB IN REAL CLINICAL PRACTICE

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10.1136/ejhp-pharm-2019-eahpconf.478

Background In long-term safety studies of sunitinib, most adverse events (AE) occurred initially between the first 6 months and 1 year, and remained stable or decreased in frequency over time.

Purpose To analyse the safety and tolerability of sunitinib in real clinical practice.

Material and methods Retrospective descriptive and observational analysis. All patients treated with sunitinib from April 2010 to September 2018 were selected. Variables collected were: sex, age, diagnosis, line of treatment, date of beginning and end of treatment with sunitinib, reasons for suspension, dose reductions and AE. To assess safety, frequency of adverse reactions, median time to treatment suspension due to AE, median time to dose reductions and the reasons were taken into account. Data was collected from the electronic medical record (DIRAYA) and the prescription program (FARMIS and PRISMA).

Results Thirty-five patients were included, 66% males, with an average age of 62 years. Eighty per cent of patients (n=28) had metastatic renal cell cancer (mRCC), 11% (n=4) gastrointestinal stromal tumour (GIST) and 3% (n=1) pancreatic tumor, unknown n=2. Seventy-seven per cent (27) of patients received sunitinib as first-line therapy, 20% (seven) received it as second-line and 3% (one) as third-line. Most frequent AE were asthenia (21 patients), hypertension blood pressure (HBP) (12 patients), mucositis (nine patients), anaemia (eight patients), bleeding and plantar-palmar-syndrome (six patients respectively). Ten patients discontinued treatment due to AE, median time to treatment suspension due to AE was 3.42 months (0.47–95.43) because of poor tolerance, unacceptable toxicity, haemorrhages, osteonecrosis of the jaw, asthenia, mucositis, anorexia and liver toxicity. Of these patients, only three had previous dose reductions. Eight patients required dose reduction, with a median time to dose reduction of 1.78 months (0.97–87.37). The main cause of reduction was asthenia (5/8). One patient had a second dose reduction 1 month after the first reduction due to poor quality of life.

Conclusion Reported AE were within the expected range, with asthenia and hypertension as the most frequent. About one-third of patients discontinued treatment with sunitinib due to AE in the first 4 months of treatment and in most cases without prior dose reductions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ema.europa.eu/documents/product-information/sutent-epar-product-information_en.pdf

No conflict of interest.

5PSQ-046 EFFICACY AND SAFETY OF PANITUMUMAB IN METASTATIC COLORECTAL CANCER TREATMENT

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10.1136/ejhp-pharm-2019-eahpconf.479

Background The use of panitumumab in the treatment of metastatic colorectal cancer (mCRC) remains controversial because of its risk/benefit profile.

Purpose The aim of this study was to investigate the efficacy and safety of panitumumab in patients with wild-type KRAS gene in the treatment of mCRC.

Material and methods For this retrospective and observational study, patients diagnosed with mCRC treated with panitumumab monotherapy and in combination with chemotherapy during the period from January 2009 to March 2017 were selected.

Only patients treated with panitumumab for a period longer than 12 weeks were included in the study.