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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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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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.

The following variables were recorded: age, sex, line therapy, location of the primary tumour and metastases, treatment duration and adverse events associated with panitumumab.

Treatment efficacy was assessed according to Response Evaluation Criteria In Solid Tumours (RECIST) (criteria, progression-free survival (PFS) and global survival (GS).

Panitumumab safety was assessed by adverse events described in the clinical history.

Results A total of 33 patients (21 males) were included, whose average age was of 72 ± 9.42 years and the treatment duration was 6.1 ± 3 months.

Patients were treated with panitumumab monotherapy (40%), in combination with FOLFOX (30%), with FOLFIRI (18%) or with other combinations (12%). Panitumumab was used as first-line therapy in 48% of the cases.

Main locations of primary tumour were: colon (36%), sigma (31%), rectum (21%), rectum-sigma (9%) and cecum (3%). Hepatic metastases were developed by 63% of the patients.

According to RECIST criteria, the assessment of efficacy was: partial response (40%), progressive disease (30%), stable disease (21%) and complete response (9%).

Median PFS and GS were 4.5 and 17.3 months respectively. In combination with FOLFOX, 5.3 and 17.4 months, with FOLFIRI 4.6 and 17.1 months and in monotherapy 4.5 and 17.2 months.

The most frequent adverse events were dermal toxicity (97%), diarrhoea (60%), hypomagnesaemia (27%), conjunctivitis (15%) and constipation (6%).

Conclusion Panitumumab monotherapy, and in combination with chemotherapy, is effective and well-tolerated in the treatment of patients with mCRC, despite the high incidence of dermal toxicity.

Although the number of patients is limited, results obtained are similar to published studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-047 NIVOLUMAB FLAT DOSE, CLINICAL-ETHICAL AND ECONOMIC IMPLICATIONS

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Background In Italy, on 2 May 2018, the use of nivolumab (Obdivo) was approved in monotherapy in a 240 mg dose every 2 weeks to replace the weight-based dosage (3 mg/kg) for all approved indications (melanoma, non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC)) and a dose of 480 mg every 4 weeks (melanoma and RCC). The dosage change was based on pharmacokinetic data that showed good safety up to a dose of 10 mg/kg. The previous dosage was defined as off-label.

Purpose The purpose of this study was to evaluate any change in the drug-related adverse (ADR) events and any additional costs after the transition to the flat dose.

Material and methods We collected data from the National Pharmacovigilance Network (NPN) from the 2 May to 15 October in the years 2016, 2017 and 2018. The number of

reported ADRs and the percentage of severe ADR has been compared (deaths were not considered). For the estimation of costs we considered all patients who received nivolumab treatment from 2016. For the naive patients after the 2 May, the dose was calculated with the old scheme of 3 mg/kg. For patients who had already discontinued therapy, the dose difference was calculated with the flat dose. The price ex-factory per mg was € 13.44.

Results The reported ADRs in NPN were, respectively: 174 (35.1% serious), 192 (34.4% serious) and 175 (58.3% serious). For the estimation of costs, an average increase of 35.3 mg for a single administration, corresponding to an increase of € 474.43, was measured.

Conclusion Since the flat dose was calculated on a hypothetical patient weighing 80 kg, it was easy to view a rapid increase in direct costs related to the drug (11 out of 15 of the patients considered had lower weight). Despite the bias related to the applied methodology, it is possible to think that the costs associated with nivolumab will increase. Furthermore, it is not clear why the 3 mg/kg dosage is to be considered off-label. Furthermore, it is interesting to note that the number of serious ADRs has increased. However, pharmacovigilance monitoring is required to evaluate changes in the safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-048 REAL-WORLD SAFETY AND TOLERABILITY OF THE RECENTLY COMMERCIALISED PALBOCICLIB

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Background Palbociclib was commercialised in November 2017, for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant (in women who had received prior endocrine therapy).

Most common adverse events (AE) described in clinical trials (CT) were: haematological (neutropaenia (80.6%), leucopaenia (45.2%) and anaemia (27.6%)), and no-haematological, above all infections (54.7%). Neutropaenia was the most common AE, experienced in grade (G) 3 or 4 in 55.3% and 10.1% of patients, respectively. Median time for the first neutropaenia episode was 15 days, with a median duration of 7 days.

Purpose To evaluate the safety of palbociclib in real-world clinical practice and compare it with the results of CT.

Material and methods Prospective observational analysis (February to October 2018) on patients treated with palbociclib, in a regional hospital. Patients' demographics and treatment evolution related to toxicity were analysed. Toxicity grade was classified by CTCAE V5.0. In each visit, the pharmacist revised physician's prescription according to patient's analysis results and made recommendations.

Results Nine women (average age of 56) with metastatic breast cancer HR-positive/HER2-negative were included. Five patients had been previously treated: hormonal therapy (3/9), chemotherapy (1/9) or both (1/9). According to prior treatments,