

DGI-029 EFFICACY AND SAFETY OF PROPRANOLOL IN INFANTILE HAEMANGIOMA

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Background Infantile haemangiomas are common vascular tumours in children. Only 10–15% should be treated due to any vital, functional or aesthetic complication. Oral corticosteroids have been the primary treatment of choice. However, excellent outcomes have been reported with propranolol, and using it as first-line treatment is still a matter of debate.

Purpose To evaluate the short-term efficacy and safety of propranolol in the treatment of infantile haemangioma.

Materials and Methods A retrospective study was carried out in the Pharmacy Service of the Hospital Clínico Universitario de Valladolid between June 2009 and August 2012. All patients with infantile haemangioma treated with propranolol during the study period were included.

Results 32 patients (20 female) were treated with propranolol for an average of 9 months. Patients started treatment at an average age of 6 months (1–15). 9/32 of the haemangiomas had segmental distribution and 23/32 were located in the head and neck. 4/32 patients were previously been treated with oral corticosteroids with little improvement. 8/32 of patients achieved complete remission after 11 ± 5 months of treatment. One of these patients had to discontinue treatment due to an increase in the size of the lesion. In the remaining patients the use of propranolol accelerated the involution of the haemangiomas and decreased colour, brightness and growth. Adverse events were mild and self-limiting. Only 2 patient discontinued treatment due to hypotension.

Conclusions Only a quarter of patients achieved complete remission.

The average duration of treatment until complete remission was 11 months.

Only one patient didn't achieve any improvement.

The use of propranolol is a safe alternative for treating haemangiomas.

No conflict of interest.

DGI-030 EFFICACY AND SAFETY OF TELAPREVIR IN PATIENTS WITH CHRONIC HEPATITIS C VIRUS GENOTYPE 1

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Background The addition of telaprevir to standard treatment considerably improves response rates and allows the duration of treatment to be reduced in a significant number of patients.

Purpose To assess the efficacy and safety of telaprevir in combination with peginterferon alfa-2b and ribavirin (RBV) in patients with hepatitis C virus genotype 1 (HCV).

Materials and Methods Retrospective observational study of patients mono-infected with HCV genotype 1, treatment-naïve and pretreated, who started treatment with telaprevir. The follow-up period was 24 weeks. Relapsed patients were defined as those with undetectable viral load at the end of treatment but detectable at 24 weeks' follow-up, partial responders as $\geq 2 \log_{10}$ decline in viral RNA at week 12 but without undetectable viral load at week 24 and null responders as $< 2 \log_{10}$ decline in viral RNA at week 12. Some of the variables were: degree of fibrosis, basal viral load, at week 4 and at week 12 (IU/ml), duration of treatment (weeks), basal dose of RBV (mg/day), basal haemoglobin at week 4 and at week

12 (mg/dl), need for blood transfusions and support with erythropoietin and skin toxicity (mild/moderate/severe).

Results We included 16 patients (81.3% men and 18.8% women). 15 patients presented undetectable viral load at weeks 4 and 12, reducing the duration of treatment to 24 weeks. RBV dose was reduced in 6 patients and 2 patients started with a dose of 600 mg, in both cases without compromising treatment success. 7 patients had anaemia, of whom 2 required transfusions and erythropoietin. 12 cases had skin toxicity (8 mild, 3 moderate and 1 severe with subsequent interruption of treatment at week 4).

Conclusions The data confirm those reported in the ILLUMINATE study, with high rates of rapid virological response and reduction of treatment from 48 to 24 weeks, but with a higher rate of skin toxicity although mostly mild to moderate.

No conflict of interest.

DGI-031 EFFICACY OF ORAL THALIDOMIDE IN PATIENTS WITH RECURRENT GASTROINTESTINAL BLEEDING

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Background Recurrent gastrointestinal bleeding caused by angiodysplasia, and not responding to standard treatment, currently lacks effective medical treatment.

Purpose To evaluate the efficacy of oral thalidomide in patients with gastrointestinal bleeding from angiodysplasia refractory to other treatments.

Materials and Methods Retrospective study for a year including all patients with recurrent gastrointestinal bleeding treated with oral thalidomide manufactured in the pharmacotechnic unit of a tertiary level hospital.

The information was obtained from the outpatient dispensing programme Farmatools, the Paracelso pharmacotechnics programme, and by reviewing medical records from the hospital 1, Archinet.

For each patient we extracted the diagnosis, treatments used for gastrointestinal bleeding, line and duration of treatment with thalidomide and transfusion requirements after treatment.

Results In the study period were identified 3 patients for whom the Digestive Service ordered thalidomide capsules 100 mg. The patients had not responded to standard treatments such as argon gas sessions and octreotide. They were introduced to thalidomide 100 mg daily for 4 months. One of them discontinued treatment for intolerance and the other 2 completed the course. There was a decrease in the number of transfusions after treatment with thalidomide in all 3 cases.

Conclusions Thalidomide appears to be a therapeutic alternative to consider when treating gastrointestinal bleeding caused by angiodysplasia in cases where there is no response to conventional treatments. One impediment to this treatment option is intolerance in some patients, leading to treatment discontinuation. Thalidomide is less aggressive than other drugs used and appears to decrease patients' transfusion requirements.

No conflict of interest.

DGI-032 EPIDEMIOLOGICAL MONITORING OF PEMETREXED USE IN MALIGNANT PLEURAL MESOTHELIOMA: A TOOL OF LOCAL DECISION MAKING

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Background Pemetrexed is an expensive oncological drug, used in combination with platinum derivatives (cisplatin/carboplatin) in the first line treatment of unresectable malignant pleural mesothelioma. In Italy, this indication is no longer subject to web-based monitoring (Onco-AIFA Register) to ensure its use appropriateness.

Purpose To assess the effectiveness in patients treated at the Istituto Oncologico Veneto (IOV) compared to the pivotal trial.

Materials and Methods This observational analysis was performed on all patients with pleural mesothelioma treated at the IOV from 01/12/2006 to 30/04/2011; the data were extracted from both paper and computerised medical records. The median Overall Survival (OS) and Time To Progression (TTP) were calculated as updated on 31/05/2012 according to the intention to treat.

Results All 46 patients (32 males and 14 females) were evaluated in terms of OS. TTP was calculated only for the 41 evaluable patients (29 males and 12 females); 5 patients lost owing to lack of information at follow-up.

The median OS/TTP values were respectively 14.2/8.9 months (vs. pivotal trial 12.1/5.7 months).

The majority of patients received the less toxic protocol pemetrexed+carboplatin, which contributed to the better OS/TTP. Better OS/TTP might be related to the use in a neoadjuvant regimen (16 patients: 10 males and 6 females); a specific stratified analysis showed TTP/OS median of 27.8/18.6 months.

Conclusions To confirm the better effectiveness of the carboplatin+pemetrexed protocol, further data on a greater number of patients, neoadjuvant treatment, treatment toxicity and patient performance status are needed.

Since the effectiveness of this high-cost oncological drug is not monitored at the national level, local monitoring is required to ensure appropriateness.

The computerised medical record is a pre-requisite for protocol standardisation and a tool of information standardisation/updating.

This work represents an easy, versatile methodological model with significant health implications.

A widely shared computerised medical record is a powerful tool for epidemiological investigations; an established network allowing benchmarking is a valid and independent decision-making tool.

No conflict of interest.

DOI-033 EVALUATION OF CRIZOTINIB TREATMENT IN PATIENTS WITH NON-SMALL CELL LUNG CANCER

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Background Crizotinib is a cytostatic oral ALK inhibitor, a newly-introduced oral cytostatic to treat non-small cell lung cancer (NSCLC) that has been accessible through an expanded use programme prior to marketing authorization.

Purpose To analyse the effectiveness and safety of crizotinib treatment in patients with NSCLC in a tertiary hospital.

Materials and Methods A retrospective descriptive study of patients taking crizotinib from August 2011 to July 2012. The following information was collected: demographic (gender and age), background (smoker/non-smoker), basal situation (Performance Status (PS), ALK-positive or negative), diagnosis and staging, dose of crizotinib, results (progress and current status) and adverse reactions. The average length of survival was determined using SPSS 20. The information sources were the electronic health records.

Results 4 patients were recruited. 3 (75%) were women. The mean age was 47. All the patients were non-smokers. Initial situation: 3 patients had a PS of 1 and the other one had 2. All of them were

ALK-positive and were diagnosed with stage IV NSCLC. 2 patients received crizotinib 250 mg/12 h and the other 2 200 mg/12 h. Evolution: in 2 (50%) patients the tumour mass in the lungs did not change. In 1 (25%) the lung tumour shrank slightly. To sum up: 3 (75%) patients presented stable disease and 1 died. Adverse reactions: 3 (75%) patients had gastrointestinal reactions (diarrhoea and mucositis), 2 (50%) patients presented asthenia and 1 (25%) visual disturbances. Lastly, the average length of survival was 6 months (IC95%, 2.33–9.66).

Conclusions Due to the low number of patients recruited the effectiveness of the treatment cannot be demonstrated. Nevertheless, it is important to highlight that the disease stabilised in 3 out of 4 patients. Gastrointestinal problems were the most frequent adverse reactions. It is important to detect ophthalmological adverse reactions in time to begin patient tracking. This treatment is well tolerated in patients with a bad prognosis and few treatment options.

No conflict of interest.

DOI-034 EVALUATION OF THE EFFICACY AND SAFETY OF MIFAMURTIDE IN OSTEOGENIC SARCOMA TREATMENT IN PAEDIATRIC PATIENTS

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Background Osteosarcoma is a relatively common bone tumour; with an incidence of 0.2 to 3/100 000, it is an orphan disease. Mifamurtide has managed to increase survival without increasing side effects.

Purpose To evaluate the safety and efficacy of mifamurtide in two paediatric patients diagnosed with osteogenic sarcoma.

Materials and Methods We conducted a prospective study of two paediatric patients diagnosed with osteogenic sarcoma. Weekly, we attended the oncology sessions and we tracked them during the chemotherapy, and after that, through the electronic clinical history.

Mifamurtide is indicated in children, adolescents and young adults for the treatment of high-grade resectable non-metastatic osteosarcoma after surgical resection. It is used in combination with post-operative chemotherapy.

In the two cases, the treatment followed the SEOP-SO-2010 guidelines of the Spanish Society of Paediatric Oncology for 37 weeks.

After surgery (week 15) mifamurtide was started as adjuvant treatment: 2 mg/m² twice weekly for the first 12 weeks and followed by once-weekly for an additional 24 weeks, for a total of 48 infusions in 36 weeks.

Results Chemotherapy started according to protocol, the patients were aged 12 and 15 years (July and November 2010, respectively).

One patient had a flu-like reaction after the first dose of mifamurtide, so the following doses were administered with premedication (acetaminophen and dexchlorpheniramine). Other side effects: anaemia and thrombocytopenia, requiring human stimulating factors and platelet concentrates; vomiting was treated with aprepitant.

When chemotherapy finished, the patients were in complete remission, this situation continues today, 10 and 13 months later.

Conclusions The SEOP protocol plus mifamurtide achieved complete remission in both cases.

The use of mifamurtide can be considered safe and it did not increase side effects, we observed only a flu-like reaction attributed to mifamurtide which resolved with premedication.