Conclusion Given the existing low degree of evidence, this study shows that there are no clear advantages of this medication in patients with cystic fibrosis and neuromuscular problems. Consequently, and given the high cost that palivizumab use implies, it would be necessary to establish protocols that define use condition and identification of patients that may benefit better from the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-100

QUALITY OF INTRATECT: IN VITRO EVALUATION OF BIOLOGICAL ACTIVITIES

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10.1136/ejhp-2019-eahpconf.249

Background Human normal immunoglobulin preparations for intravenous application (IVIG) such as Biotest's Intratect were initially developed as substitution therapy for primary and secondary immunodeficiencies. Over time the clinical use has broadened and now additionally includes treatment for a multitude of hyperinflammatory conditions, typically at higher doses.¹ Recently, chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) has become a formally approved indication.

Purpose Due to this change in use which involves increased doses, and in view of adverse events observed with other IVIG brands, we have re-evaluated quality parameters relevant for product safety and efficacy.

Material and methods Since thrombogenicity is a general risk identified for IVIGs, analyses of Intratect with globally-used coagulation tests, such as the thrombin generation Assay, were performed. Additionally, specific tests for the detection of potential impurities (e.g. prekallikrein activator (PKA)) were employed to assess the thrombogenic potential. The tests for anti-A and anti-B hemagglutinins complies with the European Pharmacopoeia (2.6.20).

Results Intratect was found to be free of procoagulant and other impurities. The content of blood group antibodies, which are associated with the risk of haemolysis, can be controlled by the manufacturing process. In Intratect these antibodies are consistently tightly controlled, and their content is far below the isoagglutinin titer threshold. Pathogen antigen recognition is a prerequisite for the anti-infective activity of immunoglobulins. Intratect was found to contain antibody titers against relevant viruses and bacteria. Quality characteristics of IVIG preparations differ from brand to brand but are typically consistent from batch to batch for a single brand.

Conclusion Multiple factors contribute to the quality of the IVIG preparations. Important quality attributes are associated with safety,^{2,3} and adequate antimicrobial activity. Different manufacturing processes determine differences in the quality, safety and efficacy of IVIG brands.

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Conflict of interest Corporate-sponsored research or other substantive relationships: all authors are employees of Biotest AG, Dreieich, Germany.

4CPS-101

INTRAVENOUS IMMUNOGLOBULINS USE FOR CHILDREN'S NEUROLOGICAL AND NEURODEVELOPMENTAL DISORDERS

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10.1136/ejhp-2019-eahpconf.250

Background Intravenous immunoglobulins (IVIG) indications are replacement therapy and as immunomodulatory therapy for several autoimmune disorders. It has been estimated that neurologic indications can account for up to 43% of IVIG used in clinical practice.¹

Purpose To evaluate the use of IVIG in paediatric patients from the neurology service of a children's care reference hospital.

Material and methods Based on medical history records, we collected and analysed retrospective data from January 2013 to December 2017 of all children who received IVIG patients followed by our neurology department.

We classified the patients according to their diagnosis and we contrasted the results with the recent published review about the IVIG use in paediatric neurological and neurodevelopmental disorders.²

Patients diagnosed during an enterovirus encephalitis spread during 2016 in our region were excluded because the patients were assigned to other paediatric departments.

Results A total of 60 patients met the inclusion criteria.

Their diagnostics were: twenty-nine peripheral nervous system indications: Guillain-Barré syndrome (22), peripheral nervous system indications (six) and myasthenia gravis (1).

Fourteen central nervous system indications: acute encephalomyelitis disseminata (four), refractory epilepsy (four), ataxia-telangiectasia (two), acute-cerebellitis (two) and anti-NMDA encephalitis (two).

Seventeen non-neurological specific indications: post-rituximab hypogammaglobulinaemia (four), opsoclonus myoclonus (four), infectious encephalitis (four) and other diagnostics (five).

All patients were treated with a correct dose as per immunomodulatory (1–2 g/kg/dose) or immune-replacement (0.3–0.5 g/kg/dose) therapy. Most of them tolerated well the IGIV administration (three mild-adverse events reported).

Conclusion IVIG are used in a large number of indications not labelled in Spain, although substantiated, in a high percentage, in solid evidence according to the reviews. Other diagnostics not associated with neurological disorders were classified and we need to ensure that other specialists validated the utilisation. Given the significant economic impact of using this therapy, it is necessary to protocolise and adapt its use to the

recommendations of the CPG, in order to carry out a rational use of health resources.

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No conflict of interest.

4CPS-102 MEASUREMENT OF HEALTH OUTCOMES OF POMALIDOMIDE, CYCLOPHOSPHAMIDE AND DEXAMETHASONE COMBINATION IN ADULT PATIENTS WITH RELAPSED AND REFRACTORY MULTIPLE MYELOMA

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10.1136/ejhp-2019-eahpconf.251

Background Multiple myeloma is a plasma cell malignancy that accounts for 1% of all cancers. Despite available therapies, the disease remains uniformly fatal, and patients who have received prior lenalidomide and bortezomib have a median overall survival of 9 months. Pomalidomide and low-dose dexamethasone (PomDex) is standard treatment for lenalidomide refractory myeloma patients who have received >2 prior therapies. Combination therapy is often used in clinical practice in an attempt to overcome drug/clone resistance.

Purpose To measure health outcomes in the combination of pomalidomide, cyclophosphamide and dexamethasone (PomCyDex) in adult patients with relapsed and refractory multiple myeloma (RRMM).

Material and methods Three-year prospective observational study of 31 cases of RRMM. To measure the health outcomes obtained with the PomCyDex combination in a third-level hospital we used median progression-free survival as the main variable to assess if the combination is effective. Age, number of previous treatment lines and most frequent adverse reactions were also measured.

Results Thirty-one RRMM cases were analysed, (48.3%: women; 51.6%: men). The mean age was 68 years. The health outcomes measured in our clinical practice were as follows: 38.7% of the patients were treated with PomCyDex in the third line, 12.9% in the fourth line, 25.8% in the fifth line, 19.3% in the sixth line and 3.2% in the seventh line. The mean number of PomCyDex cycles received was nine. The median PFS was 9.9 months. The PomCyDex combination was shown to improve PFS by an additional 5.9 months compared to PomDex-only patients receiving a 4 month PFS (MM-003). The most frequent adverse reactions observed were neutropaenia (38%), anaemia (11%) and thrombocytopaenia (5%).

Conclusion Health outcomes of the PomCyDex combination are similar to those published by Baz *et al*¹ and is considered an effective combination. The PomCyDex combination is well tolerated in most patients and is therefore considered a safe treatment.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-103 EVALUATION OF HEALTH OUTCOMES OF DARATUMUMAB IN MONOTHERAPY IN ADULT PATIENTS WITH RELAPSED REFRACTORY MULTIPLE MYELOMA

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10.1136/ejhp-2019-eahpconf.252

Background Immunotherapy has broken new ground in the treatment of multiple myeloma, with the introduction of monoclonal antibodies into the therapeutic arsenal, representing a paradigm shift in treatment. Daratumumab is a human monoclonal antibody IgG1κ, which binds to the CD38 protein that is expressed at a high level on the surface of multiple myeloma tumour cells.

Purpose To evaluate the health outcomes of daratumumab in monotherapy in the treatment of adult patients with relapsed refractory multiple myeloma (RRMM), who have previously received a proteasome inhibitor and an immunomodulatory agent, and who have experienced disease progression in the last treatment.

Material and methods Prospective observational study conducted over a period of 2 years in a third-level hospital. Eleven patients diagnosed with RRMM have been analysed. To evaluate the measurement of health outcomes, the following variables were measured: age, sex, number of previous lines, daratumumab cycles received, progression-free survival (PFS) and adverse reactions.

Results Eleven RRMM cases were analysed, (80%: men; 20%: women). The mean age was 63 years. The health outcomes measured in our clinical practice were: 50% of the patients received daratumumab in monotherapy in the third line, 30% in the fourth line and 20% in the sixth and seventh line. The mean number of daratumab cycles was seven, except for one patient who has now completed cycle 20. The median PFS was 4 months. Only mild gastrointestinal adverse reactions (nausea and vomiting) were observed (20% of patients). The correct pre-medication was performed before and after daratumumab infusion, including 10 mg oral montelukast (first infusion) and respecting the infusion times according to the technical datasheet.

Conclusion Health outcomes of daratumumab in monotherapy for the treatment of patients with RRMM are similar to those published in the combined trial gene 501 and SIRIUS. According to recent publications, daratumumab is likely to be more effective in combination with other drugs. Daratumumab is well tolerated in most patients and is therefore considered a safe treatment.

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No conflict of interest.

4CPS-104 CHEMOTHERAPY TREATMENT IN COLORECTAL CANCER PATIENTS OLDER THAN 70 YEARS AT A TERTIARY HOSPITAL

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10.1136/ejhp-2019-eahpconf.253