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

1C Schmidt, 2K Winterling, 1CC Heinz, 1M König, 3V Braun, 5S Kistner, 4MG Gerner*

1Biotest AG, Translational Research, Dreieich, Germany; 2Biotest AG, Investigational and Applied Biosciences, Dreieich, Germany; 3Biotest AG, Bioanalysis, Dreieich, Germany; 4Biotest AG, Preclinical Research, Dreieich, Germany

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 polyradiculo-neuropathy (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 haemagglutinins 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.

REFERENCES AND/OR ACKNOWLEDGEMENTS


Carolin Schmidt and Karina Winterling contributed equally to this work.

4CPS-101 INTRAVENOUS IMMUNOGLOBULINS USE FOR CHILDREN’S NEUROLOGICAL AND NEURODEVELOPMENTAL DISORDERS

1F Bossacoma Busquets, 2T Lozano Andreu, 3Na Julia Palacios, 1JA Marco, 1AComes Escoda, 1M Sánchez Celma*, 4A Deya Martinez, 4L Alaísa Manrique de Lara. 1Hospital Sant Joan de Déu, Pharmacy, Esplugues de Llobregat, Spain; 2Hospital de Bellvitge, Pharmacy, Barcelona, Spain; 3Hospital Sant Joan de Déu, Neurology, Esplugues de Llobregat, Spain; 4Hospital Sant Joan de Déu, Immunology, Esplugues de Llobregat, Spain

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 hipogammaglobulinaemia (four), opsonocyt 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