Section 2: Selection, procurement and distribution

2SPD-001 HOW CAN WE BEST MANAGE SUPPLY SHORTAGES OF EXCLUSIVELY HUMAN MOLECULES FOR SUBSTITUTION? THE EXAMPLE OF IMMUNOGLOBULINS

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Background and importance Drug supply shortages that have increased over the past decade were worsened by the SARS-CoV-2 health crisis. Among the products affected are immunoglobulins (IG), essential for substitution in primary immune deficiencies in particular. In contrast with some plasmatic proteins, IG are only produced from blood donations that have decreased. Recently, IG supply was reduced, 42% in our case, mostly affecting intravenous IG (IVIG).

Aim and objectives To identify, among the existing clinical situations, those that should benefit from IG (subcutaneous IG (SCIG) preferentially in primary substitutions; IVIG treatment to as many patients as possible for whom there is no alternative).

Material and methods Meet physicians representing the most important prescribing departments. Take stock of consumption and supply. Identify ways to optimise the use of available IG.

Results The neurology, clinical haematology, internal medicine and paediatrics representatives were brought together at a Medicinal Products and Medical Devices Commission (MPMDC) session.

First 6 months of 2021, data on IVIG:

Patient number: 168. IVIG mass: 27.8 kg (70.4% of total IG). Treatment number: 510. On average: 27.6 g/patient/month; 3 cures/patient over 6 months.

IVIG use: off-label, 27.4%; immune deficiencies, 41.6% (secondary 9 times; primary 1 time); immunomodulation, 31% (of which: idiopathic thrombocytopenic purpura (ITP), 42.3%; Guillain-Barré syndrome, 9.6%; Kawasaki disease, 3.8%; chronic inflammatory demyelinating polyradiculopathy (CIDP), 38.5%; multifocal motor neuropathies, 5.8%).

Discussions at MPMDC led to the development of the following ways to cope:

1. 'Switch' as many patients as possible to SCIG.
2. As the dosage of 2 g/kg/cure is indicative, lower the doses gradually and/or space out the courses.
3. Use corticosteroids whenever possible.
4. Use IVIG for life–threatening authorised situations (eg, acute ITP).
5. Reactivate the plasma exchange pathway for immunomodulations.
6. Reduce off–label use.
7. For off–label indications, include patients in therapeutic trials of IVIG.
8. If life–threatening emergency immunomodulation off–label, treat with molecules such as rituximab and use IVIG only during the latency period.

Conclusion and relevance The implementation of these suggestions, while awaiting the publication of the IG indications' hierarchy by the relevant authorities, should optimise management of the shortage. European, or even international, recommendations would be welcome because of the globalisation of supply.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest No conflict of interest

2SPD-005 SIGNIFICANT DISCONTINUATION RATES IN PATIENTS INITIATING OR SWITCHING FROM CT-P13: A RETROSPECTIVE COHORT STUDY IN A UNIVERSITY HOSPITAL

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Background and importance CT-P13 is an infliximab biosimilar that received market authorisation in the European Union in 2013. CT-P13 has undeniable cost-saving opportunities and extensive literature supporting its equivalence to originator infliximab (OI) in terms of efficacy, safety and immunogenicity. Despite these elements, CT-P13 remains largely underused in our country, either underprescribed or discontinued after its introduction.

Aim and objectives The aim of this study was to explore the reasons behind the high discontinuation rate observed among the patients on CT-P13 in a large tertiary hospital.

Material and methods A retrospective cohort study using routinely collected data was carried out. Patients were eligible if they received OI or CT-P13 between September 2017 and December 2020. They were included if they had received at least two CT-P13 infusions during the same period. Patients were excluded if their medical history was incomplete prior to or 6 months after their first CT-P13 infusion and if they had an oncological main diagnosis.

Results 156 patients were included and classified into two groups: switchers that were treated with OI and were switched to CT-P13 (n = 85, 54%) and initiators that did not receive OI prior to CT-P13 treatment (n = 71, 46%). 23 (27%) switchers and 35 (49%) initiators discontinued CT-P13 after 12 months. Main reasons for CT-P13 discontinuation were lack of efficacy (n = 21, 36%) and secondary loss of response (n = 16, 28%). Lack of active training and coordination among healthcare professionals and little patient education may have exacerbated patients' subjective complaints and increased the CT-P13 discontinuation rate.
Conclusion and relevance Lack of efficacy and secondary loss of response were the main reasons for the high CT-P13 discontinuation rate observed in a large tertiary hospital. Coordination between the various healthcare professionals involved with the patients is a prerequisite for biosimilars to achieve their maximum cost-saving potential.

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2SPD-006 DEVELOPMENT OF A PRIORITISATION PROTOCOL FOR THE USE OF IMMUNOGLOBULINS IN VIEW OF THE GLOBAL SUPPLY PROBLEM

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Background and importance Highly purified immunoglobulins (95%) are obtained from the purification of human plasma extracted from healthy donors. The mechanism of action consists of an antigen-specific activity, exerting immunomodulatory functions in addition to those of the natural immunoglobulins. The increase in demand, the dependence exclusively on plasma donations, and the pandemic situation have reduced the supply of immunoglobulins worldwide.
Aim and objectives To elaborate a protocol at regional level (seven hospitals) to prioritise, rationalise and reduce the use of immunoglobulins in view of the worldwide supply problem.
Material and methods A multidisciplinary work team was created comprising professionals involved in the use of these therapies (immunologists, haematologists, internists, neurologists, paediatricians and pharmacists). The main pathologies involved were specified.

Subsequently, the indications depicted in the technical data sheet and the available scientific evidence were reviewed, to define three priority groups:

- Priority 1: Necessary treatment, there is no other therapeutic alternative.
- Priority 2: Pathologies or clinical situations where the use of immunoglobulins is recommended.
- Priority 3: Clinical situations without sufficient scientific evidence.

Finally, the indications and dose regimen of all patients under active treatment were reviewed.
Results The work team defined Priority 1 as follows:

- Chronic treatments: primary and secondary immunodeficiencies, CAR–T hypogammaglobulinaemia in paediatrics, pure motor chronic inflammatory demyelinating polyneuropathy (CIDP) and multifocal motor neuropathy.
- Acute treatments: Kawasaki disease, primary immune thrombocytopenia (PIT) before undergoing urgent surgery or PIT with severe thrombopenia/large bleeding diathesis.

Priority 2 included: Guillain-Barré syndrome, myasthenia gravis, PIT with high risk of bleeding, CIDP (excluding pure motor), severe neonatal sepsis, alloimmune haemolytic disease in neonates, alloimmune neonatal thrombocytopenia, haemophagocytic syndrome and paediatric multisystem inflammatory syndrome due to SARS-CoV-2.

Pathologies not mentioned above were considered Priority 3, being evaluated by a multidisciplinary Experts Committee.

After reviewing the active treatments, 21% of them were temporarily suspended. Since the protocol approval, eight new cases have been assessed as Priority 3, with only one of them being denied.
Conclusion and relevance The creation of the protocol has made it possible to rationalise the use of immunoglobulins, reducing their consumption and promoting the use of therapeutic alternatives. Thus, completely necessary treatments are guaranteed through equitable and equal access throughout the region.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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2SPD-008 NETWORK META-ANALYSIS OF IMMUNOTHERAPIES IN UNTREATED ADVANCED OR METASTARIC OESOPHAGEAL SQUAMOUS CELL CARCINOMA

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Background and importance ESCORT-1st trial reported a benefit for overall survival (OS) of camrelizumab plus chemotherapy (Cam+CT) combination over chemotherapy (CT) in September 2021. Regimens with platinum agents have been the standard first-line treatment for advanced or metastatic oesophageal squamous cell carcinoma (mESCC) for decades.
Aim and objectives To develop a network meta-analysis (NMA) to provide an efficacy comparison of treatments for untreated patients with mESCC.
Material and methods A review in Pubmed and UpToDate databases was conducted on 3 October 2021. Inclusion criteria: randomised clinical trials (RCTs) including immune checkpoint inhibitor therapies (camrelizumab, pembrolizumab, nivolumab and ipilimumab) as first-line treatment of mESCC. Exclusion criteria: RCTs without a common comparator linking cited drugs. Efficacy endpoint was OS. NMA used