

Conclusion and relevance Biosimilar rituximab showed an effectiveness and safety profile similar to brand rituximab. Nevertheless, the small sample limits the statistical power and suggests a larger study is required to confirm these results, which we are currently working on.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-053 OFF-LABEL USE OF RITUXIMAB IN SYSTEMIC AUTOIMMUNE DISEASES

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Background and importance A large number of patients with systemic autoimmune diseases (SAD) do not respond or relapse to firstline therapies. Current guidelines recommend the off-label use of rituximab for many severe refractory SAD even though most of the available data rely on observational studies and case reports

Aim and objectives The aim of this study was to analyse the efficacy and safety of the off-label use of rituximab for patients with severe refractory SAD in a tertiary hospital

Material and methods Off-label use of rituximab between January 2016 and December 2018 was reviewed. Clinical data were collected retrospectively. Therapeutic response was evaluated after 12 months of rituximab initiation based on clinical judgement: complete response was defined as no disease activity, partial response as a significant improvement (>50% of initial disease activity) and no response if there was no improvement or worsening of symptoms

Results A total of 52 applications were analysed. There were 28 men (54%) and 24 women (46%) with a mean age of 54.41 years (SD 15.31). The indications for rituximab included systemic lupus erythematosus (SLE) (17.3%), glomerulonephritis (15.4%), inflammatory myopathy (9.6%), cryoglobulinaemia (7.7%), polyneuropathy (7.7%) and other SAD. As for previous therapies, 42 patients (82.4%) received corticosteroids and 37 (71.2%) received at least one immunosuppressive drug.

From all patients with an assessable treatment (n=47), 70.2% achieved an improvement in disease after 12 months: 34% (n=16) a complete response and 36% (n=17) a partial response. The most favourable results were found in the treatment of SLE, glomerulonephritis, cryoglobulinaemia, multiple sclerosis and optic neuromyelitis in which >80% of patients obtained a complete or partial response.

Adverse events were reported in 22 patients (42.3%): the most frequent were infections (n=7) followed by infusion related reactions (n=3). No serious or death related adverse events were reported

Conclusion and relevance Rituximab had acceptable tolerance and reduced disease activity in some severe refractory SAD. Future controlled trials are needed to confirm the potential use of rituximab in patients with SAD. In the meantime, it is necessary to closely follow-up these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-054 EXAMINATION OF A NEW METHOD FOR ANALYSING IDENTITY AND CONCENTRATION OF DRUGS IN READY TO USE PREPARATIONS: PROOF OF CONCEPT OF THE DRUGLOG SYSTEM

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Background and importance The increasing awareness of drug therapy safety and at the same time immense skills shortages pose new challenges for hospital pharmacies. The number of ready to use preparations has increased, especially in high risk fields such as oncological and paediatric medicine. For immediate quality control, in accordance with the German and European Pharmacopoeia, there is a need for analytical methods which (1) do not require large volumes for testing and (2) are safe and fast in processing with accurate results. Pharmacolog (Upsala, Sweden) promotes the UV/Vis spectrometer DrugLog with these features.

Aim and objectives The aim of examining DrugLog was to test the reliability and precision of the method as well as the process for optimisation during quality control. As part of this, sample extraction without further processing in terms of everyday usability and safety, especially in the analysis of cytostatic drugs, was examined.

Material and methods The drugs norepinephrine, midazolam, atropine and cytarabine were tested during the first step. Standard curves of each drug were created in the system. Samples of ready to use preparations were analysed without further processing with 0.5 mL sample volumes each in micro UV single use cuvettes with a lid. For preparations of cytarabine cuvettes, Luer-Lock closures were used. The content as well as the identity of drugs were determined simultaneously in the instrument. The method of the DrugLog system was compared with the established methods.

Results All tested substances were analysed reliable with the new method. The cytostatic drug cytarabine was analysed without cytotoxic contamination of staff or equipment. Measurement of atropine was possible with the DrugLog system at a minimum concentration of 0.05 mg/mL even with low UV absorption. The total time required for the analyses was reduced by 50–75% compared with the established UV-Vis analysis, depending on the drug analysed.

Conclusion and relevance DrugLog simplified processing, provided maximum work safety when dealing with cytotoxic drugs and provided stable results for the tested drugs. Each drug required a separate calibration. For substances without UV activity or very similar spectra, the methodology has limitations. Future investigations are planned, in particular for application in paediatric settings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

German and European Pharmacopoeia.

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