ueg week VIRTUAL 2021

Serum levels of infliximab and adalimumab biosimilars can be measured equivalently to originator drugs by Quantum Blue® rapid testing as tool for therapeutic drug monitoring

Leslie Anchling, Joëlle Jourdan, Florian Frei, Clara Moniz and Thomas Schuster
BÜHLMANN Laboratories AG, Schönenbuch, Switzerland

In the treatment of different chronic inflammatory diseases such as Inflammatory Bowel Disease (IBD), drugs targeting TNF-alpha had a marked impact on the treatment success and quality of life of patients. Optimal therapeutic drug levels are key to a successful therapy and therefore require monitoring (TDM). Both, the Quantum Blue® Infliximab and Quantum Blue® Adalimumab, initially validated for the originator drugs, offer rapid measurement of trough levels and allow for quick decision making and optimization of patient treatment. It has been previously shown that the Quantum Blue® Infliximab can be equally used to measure drug levels for the infliximab biosimilars CT-P13 (1) and SB2 (2). The aim of this study was to demonstrate the equivalent quantification of the infliximab biosimilar GP1111 and the adalimumab biosimilar adalimumab-adaz (Sandoz) as for their originators with the Quantum Blue® Infliximab and Adalimumab rapid tests using the Quantum Blue® Reader.

METHODS

Formulated infliximab (originator and biosimilar) and adalimumab (originator and biosimilar), kindly provided by the pharmaceutical companies, were quantified by human IgG measurement and used to spike normal, pooled serum samples. Spiked samples for infliximab and adalimumab originators and biosimilars with known concentrations were measured with the Quantum Blue® Infliximab and Quantum Blue® Adalimumab rapid tests (Figure 1). Results were compared to the expected values. A recovery <±30% was used as acceptance criteria.

RESULTS

For each spiked sample the expected concentration was calculated and compared to the obtained concentration (recovery). A mean relative bias of -1.9% was found for infliximab originator, with individual recoveries ranging from 79.2% to 112.9%. For the infliximab biosimilar a mean relative bias of -4.0% was found while individual recoveries range from 89.5% to 102.5% (See Figure 2 for one example). For adalimumab a mean relative bias of -6.7% was found for originator, with individual recoveries ranging from 81.8% to 116.9%, while for the biosimilar a mean relative bias of 1.0% was found with individual recoveries ranging from 80.1% to 118.9%. The mean bias between both analyzed biosimilar and originator pairs were within acceptance criteria. Bland-Altman analysis was used for method comparison to calculate the mean relative bias of the concentration (µg/mL) levels of the analyzed samples. For infliximab biosimilar and originator, the bias was -7.6% while the mean relative bias between adalimumab biosimilar and originator was 12.0%. The mean bias between both analyzed biosimilar and originator pairs were well below ±15%.

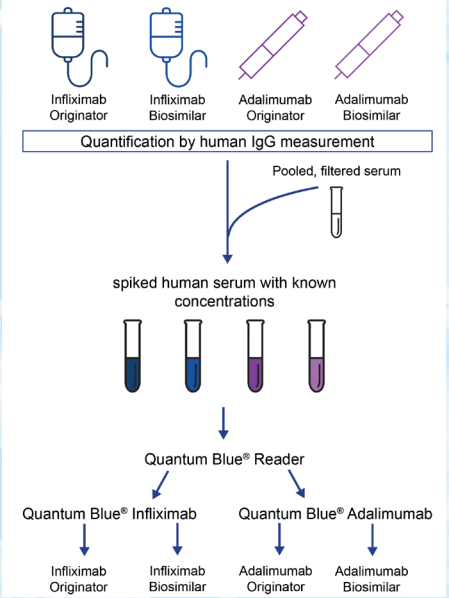

Fig. 1. Method for quantification of infliximab and adalimumab biosimilars with the Quantum Blue® rapid tests.

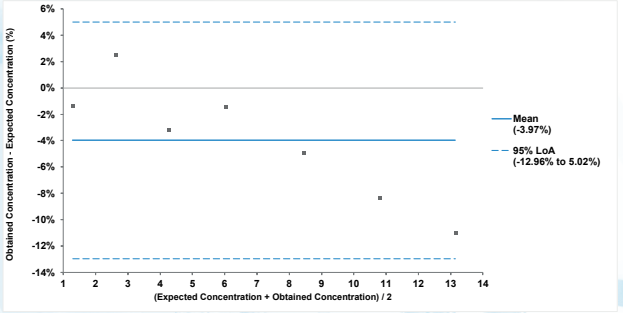

Fig. 2. Example of Bland-Altman analysis based of infliximab biosimilar recoveries obtained by comparing expected over observed concentrations.

CONCLUSION

The Quantum Blue® Infliximab and Quantum Blue® Adalimumab rapid tests are capable to detect quantitative trough levels of infliximab GP1111 and adalimumab-adaz biosimilars. Therefore, these tests offer equivalent quantification of infliximab and adalimumab originator drugs, as well as their biosimilars GP1111, SB2, CT-P13 and adalimumab-adaz allowing for identification of patients with suboptimal drug levels as part of their therapeutic drug monitoring.

References: 1) Afonso J. et al., The new infliximab point-of-care quantitative test can equally be used for therapeutic drug monitoring of biosimilar of infliximab, Journal of Crohn's and Colitis, 2017; 2) Magro F. et al., The new biosimilar of infliximab SB2 can be quantified by IFX-optimised therapeutic drug monitoring assays, Journal of Crohn's and Colitis, 2018

Conflict of interest: All authors are employees of BÜHLMANN Laboratories AG

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