POTENTIAL APPLICATION OF INFLIXIMAB TDM AND BIOMARKER MONITORING IN JAPANESE RHEUMATOID ARTHRITIS PATIENTS: A RETROSPECTIVE REAL-WORLD COHORT STUDY

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Background: Infliximab (IFX) therapy has considerably improved the treatment of rheumatoid arthritis (RA). Although previous studies have reported a relationship between serum IFX levels and therapeutic efficacy, the potential applications of IFX therapeutic drug monitoring (TDM) in clinical practice remain unclear. The purpose of this study was to investigate the potential applications of IFX TDM and biomarker monitoring by analyzing a Japanese real-world cohort database. **Methods:** Data of 84 patients were collected retrospectively from the Kyoto University Rheumatoid Arthritis Management Alliance cohort between 2011 and 2020. Serum IFX levels were measured using a liquid chromatography-tandem mass spectrometer LCMS-8060. An electrochemiluminescence assay was used to measure tumor necrosis factor-a (TNF-a), interleukin-6 (IL-6) and anti-drug antibodies. This study was approved by the Medical Ethics Committee of Kyoto University Graduate School and Faculty of Medicine (R0357). **Results:** A primary response was observed in 95% of the patients, and 12% of the patients showed secondary non-response to IFX. Serum IFX levels were significantly higher in responders than in non-responders. An optimal cut-off value was determined to be 0.32 μg/mL based on a receiver operating characteristic curve. At the IFX measurement point, a better therapeutic response was observed in High-IFX group than in Low-IFX group. Conversely, at the maximum effect point, when the disease activity score was the lowest between IFX introduction and measurement points, there were no differences in responder proportions between two groups. One-year IFX persistence after blood sampling was similar between groups stratified using IFX levels, TNF-a levels, IL-6 levels and anti-drug antibodies positivity. The group with low IFX and high IL-6 levels had the worst therapy persistence and the most frequent disease worsening. **Conclusions:** In clinical practice, the IFX primary ineffectiveness could be avoided without TDM. IFX TDM can be useful to facilitate the identification of patients with loss of response. The present data support the clinical utility of measuring both IFX and IL-6 levels for assessing the effectiveness of long-term maintenance therapy for RA. **Key Words:** infliximab, real-world data, rheumatoid arthritis, therapy persistence

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