Objectives: The purpose of the present study was to compare the correlation between ultrasound-detected synovitis and joint tenderness or swelling at the wrists and hands in RA patients.

Methods: Twenty-two joints, including bilateral wrists, proximal interphalangeal (PIP) and metacarpophalangeal (MCP) joints, were respectively evaluated at the wrists and hands in RA patients. All patients had at least 1 tender or swollen joint out of 22 joints. Synovitis was detected by using semi-quantitative scoring systems in a total of 5676 joints assessed, 968 swollen joints (17.05%) and 1296 tender joints (22.83%) were found, while on ultrasonography GS synovial hyperplasia was present in 801 (14.11%) joints. The rank correlation coefficient was observed in joint swelling (r=0.367, p<0.01) with ultrasound-detected synovitis compared with tenderness. Joint swelling is more associated with ultrasound-detected synovitis than tenderness. However, swelling had better agreement with ultrasound than tenderness. The treatment strategy included a total of twenty-one evidence-based, interdisciplinary recommendations for the management of rheumatoid arthritis (RA).

Results: Consensus was reached on recommendations, including a standardized treatment strategy according to the RA severity, activity and prognostic factors in the individual patient. In this updated interdisciplinary guideline for RA the treatment strategy was considered the cornerstone in these recommendations (figure 1). RA patients should reach clinical, ultrasonographic and functional remission. Treatment decisions should incorporate the disease activity status, structural damage progression (radiologic/sonographic), comorbidities, quality of life and patient motivation.

Conclusion: The treatment strategy included a total of twenty-one evidence-based interdisciplinary recommendations for management of RA (figure 1), and is accompanied by a more in-depth discussion of key management principles. These recommendations provide a step-wise approach to treatment, to enable practitioners to develop and support the most effective method of achieving and maintaining remission in RA patients. These recommendations are not to remove the physician’s autonomy, and physicians must select the most appropriate therapeutic option, taking into consideration the patient’s preferences.
REFERENCES:


Disclosure of Interests: None declared


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SYSTEMATIC ANALYSIS OF INJECTION-SITE PAIN CAUSED BY SUBCUTANEOUS ADMINISTRATION OF THE ADALIMUMAB BIOSIMILAR FKB327 VERSUS ADMINISTRATION OF THE ADALIMUMAB REFERENCE PRODUCT VIA DIFFERENT DELIVERY METHODS

Rieke Alten1, Mark C. Genovese2, Malcolm Boyce3, Takuma Yonemura4, Takahiro Ito5, Herbert Kellner6.

1University Medicine Berlin, Berlin, Germany; 2Stanford University, Division of Immunology and Rheumatology, Palo Alto, CA, United States of America; 3Hammersmith Medicines Research, London, United Kingdom; 4Souseikai Sumida Hospital, Tokyo, Japan; 5Fujifilm Kyowa Kirin Biologics., Herbert Kellner Grant/research support from: Bristol-Myers Squibb, Speakers bureau: Bristol-Myers Squibb, Mark C. Genovese; Grant/research support from: sanofi-genzyme, Genentech/Roche, RPharm, Consultant for: sanofi-genzyme, Genentech/Roche, RPharm, Malcolm Boyce: None declared, Takuma Yonemura Grant/research support from: I have received a research grant from FKB for conducting the clinical study., Takahiro Ito Employee of: I am an employee of Fujifilm Kyowa Kirin Biologics., Herbert Kellner Grant/research support from: Roche, Consultant for: Roche

Background: FKB327 is a proposed biosimilar of the adalimumab reference product (RP). Several studies in both healthy volunteers and patients with active rheumatoid arthritis (RA) were undertaken, the results of which have been reported elsewhere. The formulation excipients of the RP, double-blind, multiple-dose study in patients with active RA. This was followed by Study FKB327-003, in which patients were rerandomized to receive either FKB327 with PFS or the RP in the randomization phase, followed by an open-label extension phase of the study, in which AI was introduced. As patients continued receiving treatment or switched treatments during the course of the FK327-002 and -003 studies, injection-site pain was assessed at the first dosing occasion of FKB327 or the RP (n = 691). Data from all 4 studies were examined by meta-analysis of the visual analog scale (VAS) using a 100-mm horizontal scale for FKB327 versus the RP and for comparison of AI, PFS, and RS.

Methods: Data from 4 studies, FKB327-001, -002, -003, and -004, were pooled in an effort to compare injection-site pain upon subcutaneous administration of FKB327 versus the RP (citrate-containing formulation of the RP [40 mg/0.8 mL]). Study FKB327-001, in healthy volunteers (n = 180), involved a single subcutaneous dose of either FKB327 or the RP. Study FKB327-004 was a similar study in healthy Japanese volunteers (n = 130). Study FKB327-002 was a randomized (FKB327 with RS or the RP), double-blind, multiple-dose study in patients with active RA. This was followed by Study FKB327-003, in which patients were rerandomized to receive either FKB327 with PFS or the RP in the randomization phase, followed by an open-label extension phase of the study, in which AI was introduced. As patients continued receiving treatment or switched treatments during the course of the FK327-002 and -003 studies, injection-site pain was assessed at the first dosing occasion of FKB327 or the RP (n = 691). Data from all 4 studies were examined by meta-analysis of the visual analog scale (VAS) using a 100-mm horizontal scale for FKB327 versus the RP and for comparison of AI, PFS, and RS.

Results: Data were analyzed from a total of 2007 assessments in 1001 subjects. A linear model of the VAS in mm for the RP versus FKB327 across all 4 studies showed a 12.6-point lower pain score for FKB327 versus the RP (95% confidence interval [CI], –14.3 to –10.8; P < .001). For the AI and PFS used for FKB327 administration, AI showed a 1.7-point lower pain score in the VAS compared with PFS (95% CI, –3.3 to –0.1; P = .035). Gender, age, body weight, and population (healthy subject or patient) were not identified for differences in injection-site pain intensity.

Conclusion: FKB327 showed a significant advantage in terms of injection-site pain intensity compared with the RP, as well as lack of inferiority for both AI and PFS versus RS.

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