SWELLING OR TENDERNESS, WHICH ONE CORRESPONDS BETTER WITH ULTRASOUND-DETECTED SYNOVITIS?

Xiaoying Sun, Xuering Deng, Wenhui Xie, Yu Wang, Zhoui Zhang, Peking University First Hospital, Beijing, China

Background: Ultrasound (US) is a sensitive method for detecting joint inflammation in patients with rheumatoid arthritis (RA). The relationship between tender or swollen joints and ultrasound-detected synovitis has not been well explored in patients with RA.

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 by physical examination (PE) and ultrasound scan in 258 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 defined as GS ≥2 and/or PD ≥1. All correlations among US variables and clinical variables were assessed using Spearman’s rank correlation test. Cohen’s kappa (κ) between clinical and sonographic findings was calculated.

Results: Their median age was 51.2 years, median disease duration was 57 months, with 83.33% females. The mean (SD) Disease Activity Score based on 28 joints (DAS28)-ESR and DAS28-CRP were 4.47±1.62 and 3.95±1.51, respectively. 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, positive PD in 476 (8.38%) joints. There were more tender joints without swelling (n=574) than those swollen joints without tenderness (n=246). In all joints, higher κ coefficient was observed in joint swelling (κ=0.367, p<0.01) with ultrasound-detected synovitis compared with tender-only joint without swelling. This discrepancy tends to be more significant in MCP2, MCP3, and MCP4 joints (κ=0.05).

Conclusion: In RA patients with at least 1 tender or swollen joint of wrists and hands, a higher frequency of joint tenderness was observed than swelling. However, swelling had better agreement with ultrasound detected synovitis compared with tenderness. Joint swelling is more associated with ultrasound-detected synovitis than tenderness. Without swelling, joint tenderness tends to be less associated with ultrasound-detected synovitis.

REFERENCE:
OBJECTIVES:

1. Treat-to-target strategies of RA aiming to reach sustained clinical remission (as defined by the American College of Rheumatology (ACR)/EULAR Boolean or index criteria) or low disease activity.
2. Implement comprehensive, shared decision-making and education are very critical in treatment strategy.
3. Regular close monitoring of RA patients every 1-3 months then every 3-6 months after achieving treatment target to assess disease activity and damage, functional ability, comorbidities and complications is very important.
4. Ultrasoundography has an important role in RA diagnosis, monitoring activity, damage and response to treatment.
5. Start the first line of treatment strategy with monotherapy using methotrexate. Shared decision making is advisable to agree which methotrexate administration form is preferable (oral vs subcutaneous vs intramuscular).
6. In patients with a centralized review to MTX or show intolerance to, start leflunomide or sulfasalazine as first-line of treatment strategy.

WHEN the treatment target (remission or low disease activity) has not been achieved despite dose escalation by 3 months, adding another DMARD or use combination DMARD therapy uses. 

- Short-term glucocorticoids should be considered when initiating or changing coDMARD.
- Consider the use of oral corticosteroids in patients with active RA who require rapid reduction of corticosteroids.

The formulation excipients of the biosimilar product differ from those of the RP, and different injection-site pain intensity compared with the RP, as well as lack of inferiority for both AI and PFS versus RS.

RESULTS: Data were analyzed from a total of 2007 assessments in 1001 subjects. A linear mixed 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.

REFERENCES:

Disclosure of Interests: None declared

FRI0075
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., Tokyo, Japan; 6Specialist Practice in Rheumatology and Gastroenterology, Munich, Germany

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 biosimilar product differ from those of the RP, and different injection-site pain intensity with subcutaneous injection has been reported.

Objectives: The current meta-analysis examines pooled data from these studies in relation to the amount of injection-site pain resulting from using a prefilled syringe (PFS) versus an auto-injector (AI) versus a regular syringe (RS), and the proposed biosimilar, FKB327, versus the RP.

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 vs 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 FKB327-002 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 mixed 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.

REFERENCES: Rieke Alten 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


FRI0076
THE RISK OF TUBERCULOSIS IN PATIENTS WITH IMMUNE-MEDIATED RHEUMATIC DISORDERS RECEIVING BIOLOGICAL THERAPY: A 15-YEAR EXPERIENCE IN A ROMANIAN COHORT

ANCUȚĂ CODRINA1,2, Cristina Pomileanu1,2, Georgiana Strugaru1, Luița Petriță1,2, Raluca Pâlud1, Eugen Anucă1, Codruța Brână1, Rodica Chiriaceș1,
1Clinical Rehabilitation Hospital, Iasi, Romania; 2Grigore T Popa University of Medicine and Pharmacy, Iasi, Romania; 3Elena Doamna Clinical Hospital, Iasi, Romania; 4Suceava Emergency Hospital, Iasi, Romania; 5SANOCARE Medical and Research Center, Iasi, Romania

Background: The risk of tuberculosis (TB), either reactivation of latent TB or de novo infection, remains a point of interest in patients with immune-mediated rheumatic pathology in biological therapy, particularly TNFα inhibitors.

Objectives: We aimed to evaluate the risk and to identify predictors for TB in biologics users among patients with rheumatoid arthritis (RA),...