Title of Research
Rasch Analysis of APPRAISE Power Doppler Ultrasound Data

Lead Researcher
Maria Antonietta D'Agostino

Primary Affiliation
University Paris Ouest-Versailles-Saint-Quentin-en-Yvelines and Rheumatology Department of Ambroise Paré Hospital, APHP, Boulogne-Billancourt, France

Data Sharing Agreement Date
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Summary of Research
The researchers propose to analyze data from the BMS APPRAISE (**A**ssess the OMERACT-EULAR **P**DUS score for **e**arly signs of **i**mprovement of **s**ynovitis in **R**A **p**atients treated with **a**batacept) study (NCT00767325). APPRAISE was a 24-week, Phase IIIb, open-label, multicenter, single-arm study investigating the responsiveness of the proposed global EULAR-OMERACT composite power Doppler/greyscale ultrasound (PDUS) score (GLOESS). Subjects were biological-naïve patients (≥18 years) with active rheumatoid arthritis (RA) and an inadequate response to methotrexate (MTX) therapy starting abatacept.[1] This composite score – using synovitis, or inflammation of the synovial membrane within a joint – was developed to predict disease activity outcomes in rheumatoid arthritis (RA).

Modern psychometric tools allow such measurement systems to be comprehensively assessed for validity, reliability and responsiveness. The GLOESS has not yet been formally assessed using an item response theory framework. The Rasch model – a mathematical modeling approach – sets out rules for making measurements and permits assessment of new scales. Fit to the Rasch model allows interval-scaled estimates of synovial inflammation to be derived.

Study Design
The APPRAISE study offers an excellent data source in which to test to the GLOESS system. A total of 44 joints were assessed, and patients had poorly-controlled, established RA, which might be expected to result in a wide range of GLOESS scores being measured.

There are three study objectives: to assess fit to the Rasch model for GLOESS scores; to identify joints which misfit the Rasch model and remove them from the analysis; and having identified a reduced set of eligible joints fitting the model, to assess responsiveness and compare to the full joint assessment and existing reduced sets.

Study Population
The study will analyze rheumatoid arthritis patients aged 18 or above, who were incomplete responders to MTX, at stable dose and biological naïve, who were included in the APPRAISE trial and who received at least one intravenous abatacept injection.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4860864/

Funding Source of Research
N/A

Requested Study
IM101-179 (NCT00767325): Multi-Center, Open Label Study to Assess Early Response to Abatacept With Background Methotrexate Using Power Doppler Ultrasonography in Patients With Active Rheumatoid Arthritis and Inadequate Response to Methotrexate