More than Just Minutes of Stiffness in the Morning: Report from the OMERACT Rheumatoid Arthritis Flare Group Stiffness Breakout Sessions

Ana-Maria Orbai¹, Serena Halls², Sarah Hewlett², Susan J. Bartlett^{1,3}, Amye L. Leong⁴, Clifton O. Bingham III¹, and the RA Flare Group Steering Committee*

¹Johns Hopkins University, Baltimore, Maryland, USA

²University of the West of England, Bristol, UK

³McGill University, Montreal, CA

⁴Healthy Motivation, Santa Barbara, USA

⁵Schlosspark-Klinik, University Medicine Berlin, Germany

⁶Hospital for Special Surgery, New York, USA

⁷Cardiff University, Cardiff, UK

⁸Musculoskeletal Statistics Unit, The Parker Institute, Copenhagen University Hospital at Frederiksberg, Copenhagen F, Denmark

⁹UCLA Medical School, Los Angeles, USA

¹⁰University of Sydney, Sydney, Australia

¹¹Leading Edge Clinical Research, Stuart, USA

Abstract

Objective—Stiffness was endorsed within the RA Flare core domain set at OMERACT11. Two stiffness breakout-groups at the OMERACT2014 RA Flare workshop discussed results of new qualitative studies in RA stiffness.

Methods—Results from two independent studies of RA stiffness were presented to breakout group participants, followed by group discussions about stiffness measurement.

Results—Both studies identified stiffness as complex and variable with disease activity, and encompassing impact, intensity, timing, location, and duration. Impact on multiple dimensions of health was a common finding. Participants agreed stiffness is an important aspect of RA flare. Whether measuring only morning stiffness duration, the traditional approach in RA, was sufficient

Corresponding Author: A. Orbai, MD MHS, Johns Hopkins Arthritis Center, 5501 Hopkins Bayview Circle, AAC-1B, Baltimore, Maryland USA 21224, aorbai1@jhmi.edu.

*OMERACT RA Flare Group Steering Committee Members: Rieke Alten⁵, Susan J. Bartlett^{1,3}, Clifton O. Bingham III¹, Vivian P. Bykerk⁶, Ernest H. Choy⁷, Robin Christensen⁸, Daniel E. Furst⁹, Sarah Hewlett², Amye L. Leong⁴, Lyn March¹⁰, Thasia G. Woodworth¹¹

in coverage of the concept was unclear. Groups agreed more research on stiffness measurement is needed considering the importance patients place on impact of stiffness.

Conclusion—Results from independent studies highlight stiffness impact as an important feature of RA, in addition to intensity, timing, location, and duration. Additional work is needed to identify optimal ways to assess stiffness in RA and other rheumatologic diseases.

Keywords

Omeract; Rheumatoid Arthritis; Stiffness; Flare

At OMERACT11, the proposed Rheumatoid Arthritis (RA) Flare Core Domain Set received endorsement to measure symptoms and impacts representing disease worsening of sufficient intensity and duration to require consideration of (re)initiation, change, or increase in therapy (Figure 1) (1-3). Identifying appropriate methods to measure each domain has been the focus of the OMERACT RA Flare Group research over the past two years (4, 5).

There are multiple ways for assessing stiffness in RA. Most often in randomized clinical trials (RCTs), patients indicate the duration of morning stiffness (6, 7), but stiffness intensity has also been used (8). Measures of stiffness have not been consistently linked to therapeutic response in RCTs (7-9). The overall concept of stiffness in RA remains poorly defined. It is unclear whether assessing morning stiffness duration and intensity adequately reflects the heterogeneity of the construct (10, 11).

During the OMERACT2014 RA Flare Workshop, two breakout groups reviewed new qualitative findings of RA stiffness and discussed whether a new measurement approach may be needed. Qualitative study results are particularly relevant to ensure that the content of measures adequately reflects the concept being measured in PROs (12, 13).

Methods

During the OMERACT2014 RA Flare Workshop plenary, stiffness data were compared between patients with RA in flare vs. not in flare in two longitudinal observational studies (LOS) and 1 RCT. The stiffness question, developed by the Flare Steering Committee, asked people to “Circle the number that best describes the stiffness you have felt due to your rheumatoid arthritis during the past week” (0-10 numeric rating scale where 0 = none and 10 = extreme). Two break-out groups were held to discuss these results and new qualitative studies conducted in the US and UK (10, 11) in relation to stiffness measurement.

Results

Qualitative Studies

Results from two independent qualitative studies of stiffness in people with RA conducted independently were presented to both groups in a common 10-minute session. A US study was comprised of 4 focus groups with 20 patients; a UK study included one-on-one interviews with 16 patients.

In both studies, patients described stiffness as a common RA feature, which varied within and among individuals, and with levels of RA disease activity, results consistent with our earlier foundational qualitative studies and Delphi exercises on RA flares (14, 15). Changes in stiffness were often associated with changes in other symptoms, especially pain. Many people reported stiffness that was not limited to the morning, but occurred at various times or throughout the entire day. Furthermore, stiffness was not always limited to specific joints, but could vary in location. Exacerbating factors included weather and immobility, and alleviating factors and self-management strategies were described, also consistent with earlier work for multiple RA flare symptoms (2, 15, 16). Of note, in both studies participants described stiffness most often in terms of its *impact* on day-to-day life activities including getting dressed, driving, cooking, attending (or not) a social event. This is in line with prior OMERACT work that emphasizes the importance of evaluating symptom impact, rather than just symptom amount or severity (17).

Breakout Group Discussions

The two parallel groups (N=20 and N=16) discussed quantitative and qualitative results. Although in the plenary, data from RCTs and LOSs showed that stiffness intensity was clinically and statistically higher in flaring patients vs. those not in flare, there was uncertainty in both groups whether only measuring intensity adequately characterizes stiffness across individuals, and with varying levels of disease activity. Similarly the usefulness of querying only duration of morning stiffness in RCTs was also questioned but no consensus was achieved.

There was general agreement that further research is needed to identify an optimal approach to measuring relevant aspects of stiffness in RA (e.g., duration, intensity, impact) that includes incorporation of terms that patients use (e.g. restricted movement, joint tightness) to describe stiffness. There was also recognition that stiffness is a feature of several rheumatic conditions (PMR, AS, PsA, OA), and of the value of exploring common aspects of stiffness across diseases. Finally, there was endorsement of interest in creating an OMERACT Stiffness special interest group to coordinate further research across conditions.

Discussion

Qualitative and quantitative studies have confirmed that stiffness is an important symptom experienced by most patients with RA (14, 15, 18), and was included in the RA Flare Core Domain Set ratified at OMERACT11 (15, 19). Two qualitative studies were conducted by members of our group to further explore the experience of stiffness in RA (10, 11). Similar themes were identified in both studies and incorporated into conceptual frameworks encompassing the heterogeneous experience of stiffness impact, intensity, timing, location and duration in people with RA. Moreover, stiffness could independently affect physical, emotional, and social health, distinct from other RA symptoms. The measurement of stiffness is challenging due to the complexity of the experience and narrow focus of existing measures. The extent to which there is overlap among the different stiffness dimensions (duration, intensity, impact, location, timing) requires additional study. Key areas that remain unclear include: Is morning stiffness duration a proxy for intensity? Does a measure

of stiffness impact provide additional explanatory information beyond intensity and/or duration? Other aspects of stiffness that require additional examination are: Does the relative importance of stiffness vary according to overall levels of disease activity? Is there a difference in terms of importance or magnitude for stiffness in disease worsening vs improvement? Answering these questions is necessary to determine how many aspects must be measured to adequately reflect the construct in RA in different contexts (e.g. RCT vs LOS, different RCT study designs).

In summary, a growing body of evidence suggests that additional work may be needed to better characterize and measure stiffness in RA and other rheumatic diseases. While people who are experiencing an RA flare report significantly higher levels of stiffness, other factors such as impact on quality of life, timing, location, and duration may also be important. A new OMERACT SIG would be well positioned to develop this research agenda and identify optimal ways to measure stiffness in RA and other rheumatic diseases.

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Circle the number that best describes the stiffness you have felt due to your rheumatoid arthritis during the past week:

None — — — — — — — — — Extreme

Figure 1. Stiffness Intensity Numerical Rating Scale