THU0099

DEVELOPMENT OF A NEW PATIENT-GENERATED OUTCOME MEASURE TO IDENTIFY DISEASE-SPECIFIC DISTRESS IN PEOPLE WITH RHEUMATOID ARTHRITIS

Linda Silke1, Othman Kirress2, Jackie Sturt3, Heidi Lempp4, 1King’s College London, Academic Department of Physiotherapy, London, United Kingdom; 2King’s College London, Academic Department of Rheumatology, London, United Kingdom; 3King’s College London, Florence Nightingale Faculty of Nursing and Midwifery, London, United Kingdom; 4King’s College London, Department of Inflammation Biology, London, United Kingdom.

Background: Rheumatoid Arthritis (RA) is a progressive inflammatory disease which causes pain, joint damage and disability. Patients with RA may experience psychological distress in addition to their physical symptoms. They may also experience disease-specific distress (DSD), which is related to the burden of living with their life-long illness. This phenomenon has been identified in patients with other long-term conditions, e.g. cancer, Irritable Bowel Disease, and Diabetes. In type 1 and 2 diabetes elevated DSD is associated with poorer clinical outcomes, and effective interventions can reduce diabetes distress. Patient involvement in the development of patient generated outcome measures (PGOM’s) is important, as they may have different perspectives about their health condition that researchers and/or health care professionals may not have considered. Previous secondary data analysis of patient interviews has suggested that DSD does seem to exist in people with RA, as an entity distinct from other forms of psychological difficulties.

Objectives: The aim of this study was to develop a PGOM, based on previously reported domains of distress, to identify DSD in people with RA for use in clinical and research practice. The study aimed to involve patients in the development of the new outcome measure.

Methods: A three-phase qualitative study was conducted. In Phase 1 items were generated from secondary data analysis of patient interviews. In Phase 2, a focus group of people with RA were consulted with the aim to establish initial face and content validity of the measure and perform item reduction. In Phase 3, individual cognitive interviews (n=9) with people with RA were conducted to further establish face and content validity of the Scale, refine items if necessary and ensure the questionnaire ‘made sense’ to participants. A psychometrician was consulted to consider the development of the new Scale.

Results: In Phase 1, 44 items were initially created to form the Rheumatoid Arthritis Distress Scale (RADS). After Phase 2 and 3 focus group and cognitive interviews respectively, items were reduced from 44 to 39 and three additional supplementary questions were created, to include items such as time since diagnosis and disease activity. Dimensions were classified into five domains of RA distress. Overall participants reported the content of the RADS to be clear and relevant, and that DSD is a valid concept in RA, distinct from clinical depression or anxiety.

Conclusion: DSD appears to be an important concept in RA. The 39-item RADS currently demonstrates acceptable face and content validity in this patient group. It may be beneficial to establish face and content validity in a more diverse patient sample before proceeding with further psychometric testing. The RADS may be a useful tool for healthcare professionals to identify DSD in patients with RA. Direct patient involvement and their commitment have been instrumental in the development of new outcome measures.

Acknowledgement: This work was supported by King’s College London and submitted in partial fulfilment for the MSc Degree in Advanced Neuromusculoskeletal Physiotherapy.

Disclosure of Interests: None declared.

Disclosure of Interests: Marlene Stephan: None declared, Koray Tasclilar: None declared, Melanie Hagen: None declared, Judith Haschka: None declared, Michaela Reiser: None declared, Fabian Hartmann: None declared, Amr Kleyer Granther: None declared, Lilly Consulting for: Lilly, Speakers bureau: Abbvie, Axel Hueber Grant/research support from: Novartis, Pfizer, Consultant for: Lilly, Speakers bureau: Lilly, Novartis.

Janssen, Abbvie, Bernhard Manger: None declared, Camille Figureuero: None declared, Jayme Cobra: None declared, Hans-Peter Tony: None declared, Eli Lilly Consulting for: Eli Lilly and Company, Speakers bureau: Eli Lilly and Company, Stephanie Finzel: None declared, Stefan Kleinert Grant/research support from: Novartis, Consultant for: Novartis, UCB, Chugai, Celgene, Medac.

Roche, Abbvie, Speakers bureau: Novartis, UCB, Chugai, Celgene, Medac, Roche, Abbvie, joerg Wendler: None declared, Florian Schuch Consulting for: Celgene, Lilly, UCB, Roche, Sanofi-Aventis, Abbvie, Novartis, Speakers bureau: Celgene, Lilly, UCB, Roche, Sanofi-Aventis, Abbvie, Michael Rottensteiner: None declared, Martin Fleck: None declared, Martin Fleck: None declared, Wolfgang Ochs: None declared, Matthias Schmitt-Haendle: None declared, Hanns-Martin Lorenz: None declared, Hubert Nuesseish: None declared, Rike Alten Grant/research support from: Bristol-Myers Squibb, Speakers bureau: Bristol-Myers Squibb, Jorg Henes: None declared, Klaus Krueger: None declared, Georg Schuch: None declared, Consultant for: Bristol-Myers Squibb and Celgene (greater than $10,000), Consultant for: Bristol-Myers Squibb, Celgene, Chugai, GlaxoSmithKline, Janssen, Eli Lilly, Novartis, Roche, Sanofi Aventis, and UCB (in total more than $10,000), Speakers bureau: Bristol-Myers Squibb, Celgene, Chugai, GlaxoSmithKline, Janssen, Eli Lilly, Novartis, Roche, Sanofi Aventis, and UCB (in total more than $10,000).


THU0101
TORQUE TENO VIRAL LOAD FOR MONITORING OF BIOLOGICAL THERAPIES IN RHEUMATOID ARTHRITIS

Paul Studenic1, Gregor Bond2, Andreas Kerschbaumer1, Manuel Becede3, Karel Pavelka2, Dmitry Katereev4, Jutta Stieger5, Rudolf Puchner6, Rudiger Muller7, Elisabeth Puchhammer-Stickl8, Martina Durechova9, Michaela Loiskandl2, Thomas Perkmann2, Jürgen Rech9, Martin Ronneberger9, Martin Feuchtenberger9, Hanns-Martin Lorenz: None declared, Hubert Nuesseish: None declared, Rike Alten Grant/research support from: Bristol-Myers Squibb, Speakers bureau: Bristol-Myers Squibb, Jorg Henes: None declared, Klaus Krueger: None declared, Georg Schuch: None declared, Consultant for: Bristol-Myers Squibb and Celgene (greater than $10,000), Consultant for: Bristol-Myers Squibb, Celgene, Chugai, GlaxoSmithKline, Janssen, Eli Lilly, Novartis, Roche, Sanofi Aventis, and UCB (in total more than $10,000), Speakers bureau: Bristol-Myers Squibb, Celgene, Chugai, GlaxoSmithKline, Janssen, Eli Lilly, Novartis, Roche, Sanofi Aventis, and UCB (in total more than $10,000).

Background: The apathogenic and highly prevalent Torque Teno Virus (TTV) is associated with the immunocompetence of its host and has been proposed for immunologic monitoring in solid organ transplantation. Objectives: Herein we explore TTV levels in rheumatoid arthritis (RA) patients receiving biological disease-modifying anti-rheumatic drugs (bDMARDs) in the context of clinical response. Methods: The BIOBIO study was designed to evaluate biomarkers for prediction of clinical response in patients with RA. Within this multicentre open-label trial, patients with insufficient response to MTX were randomised to T NF1 (infliximab; INF), anti-IL-6 receptor (tocilizumab; TCZ), CTLA4-Ig (abatacept; ABA) or RTX (rituximab; RTX) in addition to MTX. TTV in peripheral blood samples was quantified at baseline and 3 months by RT-PCR.

Results: TTV was measured in 95 RA patients [INF (n=23), TCZ (n=22), ABA (n=27) or RTX (n=23)]. Median TTV levels at baseline were 4.2x10^4 c/ml with no difference between the treatment groups. After 3 months of treatment with patients with INF (p=0.018), ABA (p=0.071) and RTX (p=0.001) showed an increase in TTV levels compared to baseline. There was no change in TTV in patients with TCZ, who were omitted from further analyses. TTV at 3 months after treatment was higher in patients achieving a SDAI85 response at month 6 (p=0.012). Levels of above 5.6x10^5 c/ml at month 3 showed a 67% specificity and 81% sensitivity for a SDAI85 response at month 6, corresponding to a positive likelihood ratio of 2.6 (95% CI: 1.6-4.1). Patients in the top tertile of month 3 TTV (>7.8x10^5 c/ml) had lower SDAI, CDAI and DAS28 and higher SDAI85 response rates at month 6 (OR: 1.41-16.42; p=0.012). The highest non-response rates were found in patients within the lowest TTV tertile (Table A), and the highest remission rates were found in the highest TTV tertile (Table B).

Table B

<table>
<thead>
<tr>
<th>TTV</th>
<th>CDAI</th>
<th>DAS28</th>
<th>SDAI</th>
<th>SDAI85</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10^4</td>
<td>3</td>
<td>35</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>10^4-10^5</td>
<td>3</td>
<td>30</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 10^5</td>
<td>3</td>
<td>25</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Conclusion: Our data suggest that TTV levels in patients with RA treated with INF, ABA or RTX at month 3 are associated with clinical responses at month 6, and thus may constitute a biomarker for therapeutic monitoring.

THU0102
PATIENT DISEASE TRAJECTORIES IN BARICTINIB-TREATED PATIENTS WITH RHEUMATOID ARTHRITIS AND INADEQUATE RESPONSE TO METHOTREXATE

Peter C. Taylor1, Paul Emery2, Michael E. Weinblatt3, Eduardo Myster4, Andrea Rubben-Roth5, Bochao Jia6, Luna Surf7, Yushi Liu8, Yun-Fei Chen8, Stephanie Finzel9, Stefan Kleinert Grant/research support from: AbbVie, Bristol-Myers Squibb, and Roche, Consultant for: Lilly, Amgen, AstraZeneca, Astro, Celgene, Elly Lilly, GlaxoSmithKline, ILTCO, Janssen, Medimmune, MSD, Novartis-Sandoz, Pfizer Inc, Roche, Samsung, Sanofi, UCB, Speakers bureau: AbbVie, Amgen, AstraZeneca, Astro, Celgene, Elly Lilly, GlaxoSmithKline, ILTCO, Janssen, Medimmune, MSD, Novartis-Sandoz, Pfizer Inc, Roche, Samsung, Sanofi, UCB, Daniel Aletaha Grant/research support from: AbbVie, Bristol-Myers Squibb, and MSD, Consultant for: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Medac, Merck, MSD, Pfizer Inc, Roche, and UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Medac, Merck, MSD, Pfizer Inc, Roche, and UCB.

Background: In RA-BEAM phase 3 study, baricitinib (bari) 4mg demonstrated clinical efficacy in patients (pts) with rheumatoid arthritis (RA) and an inadequate response to methotrexate. ARA, selective Janus kinase 1/2 inhibitor, is approved for the treatment of moderate to severe active RA in adults in >50 countries. For improved treatment strategy, it is important to understand whether the pt population is composed of distinct pt groups with differing treatment responses and associated baseline characteristics.

Objectives: To identify different treatment trajectories, based on CDAI improvement, in bari 4mg treated pts over 52 weeks; and examine the associated clinical disease measures, structural damage score and baseline characteristics. Methods: Growth Mixed Model (GMM), a novel latent class mixed model, was used to classify the longitudinal disease patterns instead of...