Consensus on a Core Set of Domains for Psoriatic Arthritis

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ABSTRACT. A psoriatic arthritis (PsA) module was convened at OMERACT 8 in order to achieve consensus on the core domains that should be included in randomized controlled trials and longitudinal observational cohorts of subjects with PsA. Following a plenary session at which current status of measures used to assess PsA were reviewed, and discussion at breakout groups, the group achieved consensus on 6 core domains: peripheral joint activity, skin activity, pain, patient global assessment, physical function, and health-related quality of life. In addition the following domains were considered important but not mandatory: spinal disease, dactylitis, enthesisitis, fatigue, nail disease, radiography, physician global assessment, and acute-phase reactants. A research agenda was proposed to include development and validation of instruments for the domains where none existed, and in particular further research was recommended for the following areas: magnetic resonance imaging and ultrasound of joints, enthesitis, skin and synovial tissue analysis, and “participation.” (J Rheumatol 2007;34:1167–70)

Key Indexing Terms: PSORIATIC ARTHRITIS CORE SET DOMAINS CLINICAL MEASUREMENTS INSTRUMENTS

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Psoriatic arthritis (PsA) has been considered a mild form of arthritis, but recent evidence supports the notion that PsA is more common and more severe than previously thought. Recent therapeutic advances including the availability of anti-tumor necrosis factor and anti-T cell agents have heightened interest in PsA in recent years, and have raised the issue of appropriate outcome measures for PsA. Therefore, it is of utmost importance that we identify a core set of domains for the assessment of patients with PsA, and that we select and/or develop appropriate instruments to assess these domains.

Following a successful workshop on PsA at OMERACT 7, during which the domains that should be included in both clinical trials and longitudinal observational cohorts were outlined (Table 1), a PsA module was included in OMERACT 8.

The objectives for the PsA module at OMERACT 8 were: (1) Achieve consensus on the core set of domains to be assessed in randomized controlled trials (RCT) and longitudinal observational studies (LOS) in PsA; (2) Review and endorse outcome measures to assess these domains based on evidence derived from RCT; and (3) Set up a new research agenda to identify and/or develop other assessment tools.

Prior to presentations at OMERACT 8, a series of questions was posed to the audience regarding domains to be included in RCT (Table 1). Philip Mease presented an analysis based on phase 2 trials with etanercept and infliximab, showing that tender and swollen joint counts, American College of Rheumatology 20/50/70 responses and Disease Activity Score (DAS), as well as the EULAR response criteria using the DAS score functioned well, as did the Psoriatic Arthritis Response Criteria (PsARC). In these RCT, C-reactive protein did not function well in distinguishing the active treatment group from the placebo treated patients. Dafna Gladman presented results of spinal assessment from INSPIRE (International Spondyloarthritis Inter-rater Reliability Exercise), which found that measurements of spinal mobility used in ankylosing spondylitis (AS) are also reliable in PsA. Paul Healy presented the Leeds Dactylitis Index (LDI), which has proven reliable both in a study from Leeds and in the INSPIRE study. Additionally, in a longitudinal study, counting digits with dactylitis identified improvement, as did the more specific LDI. Philip Helliwell presented data on the reliability of methods to assess enthesitis in PsA. Will Taylor discussed the concept of “participation” and work to date to assess this domain in PsA, and briefly reviewed the measurement properties of health-related quality of life (HRQOL) instruments and physical function scales used in PsA clinical trials. New data were presented suggesting that Medical Outcomes Study Short Form-36 Health Survey Physical Function (SF-36 PF) subscore may be a better generic measure of physical function than the Health Assessment Questionnaire-Disability Index (HAQ-DI) in PsA. Jerry Krueger presented data comparing instruments to assess skin involvement in PsA, including the Psoriasis Activity and Severity Index (PASI) and National Psoriasis Foundation (NPF) scoring system. Desiree van der Heijde presented the results of comparing 4 methods to read a set of radiographs from the Infliximab Multinational Psoriatic Arthritis Controlled Trial (IMPACT). While there was good reproducibility among readers for each method, it was not possible to identify a preferred method. This may be due in part to the very short duration of placebo treatment for comparison — a further study is required. Oliver FitzGerald presented data from tissue analyses in PsA. Four PsA patients from the US, Canada, UK, and Sweden were invited to participate, along with rheumatoid arthritis patients, in the OMERACT meeting. From that group, Peter Grimm presented the patient perspective.

Following the plenary presentation participants voted again on domains for assessment in PsA RCT, with some changes, most notably for acute phase reactants (Table 1). In comparison to the voting at OMERACT 7, there was more enthusiasm for inclusion of measures to assess HRQOL, dactylitis, and physician global assessment of disease activity.

Breakout groups then reviewed and discussed domains and instruments for their assessment, with emphasis on: peripheral joints (2 groups); spinal involvement (2); HRQOL and participation (2); radiographic and magnetic resonance imaging (MRI) (1); and tissue analysis (1).

The discussions at the breakout groups confirmed the need to assess peripheral joint disease. All breakout groups confirmed that it was an important domain. It was further recommended that the 68 tender/66 swollen joint count be performed.

Enthesitis and dactylitis were also considered important domains in PsA. For enthesitis, several instruments exist that have been used in AS. These instruments partially meet the requirement of the OMERACT filter. One group discussed the “truth” aspect of the OMERACT filter, noting that ultrasonographic enthesitis does not always correlate with tenderness at the insertion of the enthesis, and vice versa. Data on responsiveness and reliability of the Mander, Maastricht AS Enthesitis Score, Berlin, and Spondyloarthritis Research Consortium Canada (SPARCC) enthesitis indices were pre-

### Table 1. Results of voting at the PsA module plenary session at OMERACT 8 compared to OMERACT 7 workshop results.

<table>
<thead>
<tr>
<th>Item</th>
<th>2004 (%)</th>
<th>1st Vote (%)</th>
<th>2nd Vote (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral joint activity</td>
<td>99</td>
<td>97</td>
<td>96</td>
</tr>
<tr>
<td>Patient global</td>
<td>96</td>
<td>95</td>
<td>95</td>
</tr>
<tr>
<td>HRQOL</td>
<td>78</td>
<td>92</td>
<td>92</td>
</tr>
<tr>
<td>Skin assessment</td>
<td>86</td>
<td>91</td>
<td>86</td>
</tr>
<tr>
<td>Enthesitis</td>
<td>60</td>
<td>81</td>
<td>63</td>
</tr>
<tr>
<td>Imaging</td>
<td>66</td>
<td>74</td>
<td>72</td>
</tr>
<tr>
<td>Dactylitis</td>
<td>48</td>
<td>77</td>
<td>66</td>
</tr>
<tr>
<td>Spinal disease</td>
<td>61</td>
<td>75</td>
<td>59</td>
</tr>
<tr>
<td>Physician global</td>
<td>41</td>
<td>71</td>
<td>57</td>
</tr>
<tr>
<td>Acute phase reactants</td>
<td>64</td>
<td>56</td>
<td>9</td>
</tr>
<tr>
<td>Tissue analysis</td>
<td>38</td>
<td>19</td>
<td>9</td>
</tr>
</tbody>
</table>
sented, and their relative merits discussed. The group felt that
the Mander index was too time-consuming, thus failing the
feasibility aspect of the filter. A new index, derived from
patients with PsA, was presented; in this index only 6 sites are
used to assess for entheseal tenderness. After much discussion
the group rated the SPARCC and the new Leeds enthesis
index (LENIN) most highly. In another group the recommenda-
tion was for simple enthesis scores. All of these measures
require further validation in clinical trials.

The instruments available to measure dactylitis are less
extensive and their psychometric properties are less well
established. A number of measures exist, ranging from a sim-
ple counting of dactylitic digits to a new instrument that mea-
sures the circumference of the affected digit and also assesses
the degree of tenderness. In a recent clinical trial all available
measures were compared. The new LDI is the only measure
with reliability data and, although not performing as well as a
simple count (in terms of effect size), was thought to be the
best option for clinical trials since it provides the best approx-
imation to “truth.” While in one group it was recommended
that a simple approach may suffice, the conclusion of another
breakout group was that valid instruments are available to
assess enthesis and dactylitis in PsA. These instruments
await validation in clinical trials.

Radiographs of hands and feet were considered useful for
scoring bone damage in PsA. They have a role in clinical tri-
als. Current scoring methods rely on the measurement of peri-
articular erosions, and there is a need for more research into
the effect of the biologic agents on entheseal new bone for-
mation, bone fusion, and periostitis. MRI was still viewed as
a research tool in PsA. There was no consensus on ultrasound,
but its potential value for the assessment of enthesis was recog-
nized.

Patient reported outcomes such as the patient global
assessment (PGA) and pain assessment were considered
important. The PGA is very dependent on the wording, and no
consensus was reached regarding the use of a single PGA or a
separate one for skin and joint manifestations. Pain was also
considered important, but whether a visual analog scale or a
numeric rating scale should be used was not clear. Fatigue was
also thought to be an important domain, but it was concluded

<table>
<thead>
<tr>
<th>Item</th>
<th>Vote in favour (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core set</td>
<td>72</td>
</tr>
<tr>
<td>Peripheral joint assess-</td>
<td></td>
</tr>
<tr>
<td>ment</td>
<td></td>
</tr>
<tr>
<td>Skin assessment</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
</tr>
<tr>
<td>Patient global</td>
<td></td>
</tr>
<tr>
<td>Physical function</td>
<td></td>
</tr>
<tr>
<td>Health-related quality of life</td>
<td></td>
</tr>
<tr>
<td>Spinal assessment</td>
<td>80</td>
</tr>
<tr>
<td>Dactylitis</td>
<td>80</td>
</tr>
<tr>
<td>Enthesitis</td>
<td>78</td>
</tr>
<tr>
<td>Physician global</td>
<td>65</td>
</tr>
<tr>
<td>Radiological assessment</td>
<td>86</td>
</tr>
<tr>
<td>Acute phase reactants</td>
<td>67</td>
</tr>
<tr>
<td>Fatigue</td>
<td>70</td>
</tr>
<tr>
<td>Tissue analysis</td>
<td>45</td>
</tr>
<tr>
<td>Participation</td>
<td>not available</td>
</tr>
</tbody>
</table>

Figure 1. Domains for PsA. PGA: physician global assessment, MRI: magnetic resonance imaging, CT: computed tomography, US: ultrasound.
that further research was necessary to identify its relationship
to pain and to determine the best instrument to assess it.
HRQOL was deemed important. Whether a disease-specific or
a generic instrument was better was not resolved. Physical
function was also considered important. Both the HAQ-DI
and the physical function component of the SF-36 are suitable
to measure physical function in PsA. One of the groups felt
that there was enough information to determine that the SF-36
was more responsive to short-term changes in perceived
health than the HAQ-DI. Participation was an important con-
cept but more research was needed. No firm consensus was
reached regarding specific measures of HRQOL, although
subsequent plenary discussion strongly recommended that
RCT data be made available to apply the OMERACT filter to
HRQOL instruments used in these studies.

Following the breakout group discussions, the list of
important domains was long, and limited because there were
no available validated instruments for some of the domains.
Participants then considered 3 categories: “inner core,” “outer
core,” and research agenda (Figure 1). The items included in
the inner core must be included in all RCT and LOS; other
domains recommended but not mandatory are included in the
outer core. Some of these items require further study. A set of
items requiring further research were put in the research agen-
da (outer circle, Figure 1).

It was proposed that peripheral joint activity, skin activity,
pain, PGA, physical function, and HRQOL be included in the
core set. Spinal disease, dactylitis, enthesitis, fatigue, nail dis-
ease, radiography, physician global assessment, and acute-
phase reactants were in the middle core set. Other imaging
techniques such as MRI and ultrasound of joints and entheses
should be researched, as should tissue analysis and participation.

Of 137 members present, 72.3% voted in favor of the core
set proposed above (Table 2, Figure 1). Thus this core set of
domains must be included in RCT and LOS in PsA. Table 3
shows the results of votes for individual items to be included
in the outer core and research agenda. The results of the PsA
module are shown in Figure 1.

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1. Biomarkers and Surrogate Endpoints
2. Imaging
3. Outcome Measures
4. Workshops and Special Interest Groups

Parts 1 and 2 appeared in the March and April issues; Part 4 will