REPORT

OMERACT 7 psoriatic arthritis workshop: synopsis

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Outcome Measures in Rheumatology (OMERACT) conferences have developed a process by which outcome measures to be included in clinical trials are identified by consensus. During OMERACT 7, held in Asilomar, CA, USA, in May 2004, a workshop on outcome measures in psoriatic arthritis was held. Information derived through a previous Delphi exercise and nominal group process was shared with the participants, as were the results from a study using completed clinical trials with biological therapies. On the basis of the evidence presented and discussions in breakout groups at the OMERACT conference, a set of domains to be included in clinical trials in psoriatic arthritis was developed and a research agenda for further studies in psoriatic arthritis proposed.

Outcome Measures in Rheumatology Clinical Trials (OMERACT) was established at a conference in Maastricht, the Netherlands in 1992,[1] and represents an informal international network of clinicians and investigators in the field of rheumatology. At the Maastricht conference, the main topic was outcome measures in rheumatoid arthritis, and it reflected work done in the field in the preceding 10 years. In addition to describing outcome measures that had been developed, the conference developed consensus on a core set of measures that should be included in clinical trials in rheumatoid arthritis.

Since 1992, several OMERACT conferences have taken place and the focus has widened beyond rheumatoid arthritis. OMERACT 2 was held in Ottawa, Canada, in 1994 and focused on drug safety, measures of health status and health related quality of life, and economic evaluations.[2] OMERACT 3 took place in Cairns, Australia, in 1996 and focused on core sets of outcome measures in osteoarthritis and osteoporosis, and imaging.[3] OMERACT 4 was held in Cancun, Mexico, in 1998 and focused on longitudinal observational studies, rheumatoid arthritis response criteria, outcome measures in ankylosing spondylitis and systemic lupus erythematosus, and imaging.[4] OMERACT 5 was held in Toulouse, France, in May 2000 and concentrated on minimally clinically important differences, economic analyses, radiography, magnetic resonance imaging, and drug safety.[5] OMERACT 6 took place in Gold Coast, Australia, in 2002 and focused on outcome measures in systemic sclerosis and ankylosing spondylitis, and definitions of ''important improvement'' in rheumatoid arthritis. This conference included patient participants thus adding a new perspective to the assessment of outcome measures.[6] OMERACT 7, which was held in Asilomar, CA, USA, in May 2004 focused on outcome measures for PsA, fibromyalgia, systemic sclerosis, vasculitis, and gout, imaging in ankylosing spondylitis, as well as definitions of low disease activity in rheumatoid arthritis.

OMERACT: PROCESS

The OMERACT process involves achieving consensus on outcome measures and is based on the ''OMERACT filter'', which itself is based on a methodological framework described by Bombardier and Tugwell in 1982.[7] The OMERACT filter simplified that methodology into three concepts: truth, discrimination, and feasibility.[1] Truth encompasses face, content, construct, and criterion validity and addresses the question of whether the measure assesses what it was meant to in an unbiased and relevant way. Discrimination addresses the issue of reliability and sensitivity to change by answering the question of whether the measure discriminates between situations of interest. Feasibility relates to whether a measure can be applied pragmatically, given financial and interpretation constraints in longitudinal observational studies and randomised controlled trials. It is expected that measures used to assess rheumatological conditions will ''pass'' the OMERACT filter.

The OMERACT process thus begins with the accumulation of data on the outcome measures relevant to a disease in question. Following this the OMERACT filter is applied to the data. This evidence is shared with the participants at the OMERACT conference through plenary sessions. Then the participants discuss the information presented in breakout groups, add their own opinions, and begin to select domains and instruments important in the assessment of outcome. Subsequently a vote is carried out, with the help of an electronic voting system, which allows all participants to express their opinion on the relative importance of the proposed outcome measures.

OMERACT 7

The psoriatic arthritis workshop at OMERACT 7 was based on the information developed during the previous two exercises, the Delphi process[8] and the nominal group process[9] carried out through the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA). A review of assessment instruments used in psoriatic arthritis was provided to all participants prior to the conference.[10] The workshop began with a plenary session, at which the previous Delphi exercise and the nominal group process were presented by Dafna Gladman.[11] A review of the outcome measures and instruments used in clinical trials in psoriatic arthritis was presented by Philip Mease. Gerald Krueger presented a review of outcome measures and instruments used in psoriasis clinical trials. Desirée van der Heijde discussed radiological assessment in psoriatic arthritis. The participants were then divided into 12 groups, and each group was asked to discuss domains that should be included in clinical trials in psoriatic arthritis, beginning with the results of the work of GRAPPA. During a meeting of GRAPPA members at OMERACT, each group's scribe presented its deliberations. These were summarised into a composite table and presented at a second plenary session in which the final list of domains to be included in clinical trials in psoriatic arthritis was presented and ratified (table 1). Also, in this

Table 1 Results of Outcome Measures in Rheumatology Clinical Trials (OMERACT) voting on domains to be included in clinical trials in psoriatic arthritis

No	Item	Score
1	Joint activity	99%
2	Patient global	96%
	All three components (total, joints, skin)	76%
3	Pain assessment	94%
4	Physical function	91%
5	Skin disease	86%
6	Quality of life	78%
7	Structural damage	66%
8	Acute phase reactant	64%
9	Axial involvement	61%
10	Participation	61%
11	Enthesitis	60%
12	Fatigue	48%
13	Dactylitis	48%
14	Physician global	41%
15	Tissue histology	38%
16	Magnetic resonance imaging	34%
17	Morning stiffness	25%
18	Damaged joint count	20%

session, Christian Antoni presented the results of an analysis that related the domains and instruments used in two randomised clinical trials with antitumour necrosis factor agents: an etanercept trial that included 60 patients and an infliximab trial that included 102 patients. The results of the analysis revealed that in psoriatic arthritis, the American College of Rheumatology (ACR) joint count functions well using 68 joints. In terms of response criteria, the ACR 20, 50, and 70 response criteria, the Psoriatic Arthritis Response Criteria (PsARC) and the disease activity score (DAS) all functioned well, with the latter achieving the highest χ^2 value. Using receiver operator curves, the analysis demonstrated that the DAS was most accurate, and that the C-reactive protein was not a good measure in psoriatic arthritis. This work will be further developed and published in the near future.

RESULTS

A research agenda was developed from the proposed domains and the discussion at this GRAPPA meeting. The research agenda was also presented and accepted at the final plenary session at OMERACT 7.

Members of GRAPPA approved the list of domains and the research agenda at a subsequent GRAPPA meeting during the European League Against Rheumatism meeting in Berlin on 12 June 2004. At that meeting, committees were struck to address several issues on the research agenda, and these will be studied over the next 12–18 months.

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