MCID/Low Disease Activity State Workshop: Low Disease Activity State in Rheumatoid Arthritis

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ABSTRACT. The MCID (minimal clinically important difference) module of OMERACT 5 developed a research agenda that led to the conclusion that a state of low disease activity for rheumatoid arthritis (RA) would need to be defined. To develop such a definition the various concepts and terminologies, the process for developing an operational definition, and the availability and design of longitudinal datasets for validation needed to be considered. This article describes the process of the MCID/Low Disease Activity State Workshop at OMERACT 6 to develop such a definition. (J Rheumatol 2003;30:1110–1)

Key Indexing Terms:
DISEASE ACTIVITY RHEUMATOID ARTHRITIS OUTCOME ASSESSMENT

Background/Rationale

The MCID/Low Disease Activity State Workshop at OMERACT 6 was a direct result of the MCID (minimal clinically important difference) module of OMERACT 5. The MCID module developed a research agenda with one of its goals to define a level of improvement that would be considered truly important in rheumatoid arthritis (RA). This led to the conclusion that a state of low disease activity would need to be defined.

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A low disease activity state is an intermediate step between high disease activity and remission, and could also be called "partial remission." The importance of such a concept cannot be overstated. As interest in longterm followup and prognosis increases, so does the importance of defining and prospectively validating states (and a minimum time in such a state) as a treatment target. Describing the number of patients achieving and maintaining such a state for a specified period of time will add useful information for the practising physician and aid in the interpretation of trial and longitudinal results.

Any definition should be a compromise that best reflects the opinion of patients and physicians. The process to come to such a definition consists of 3 basic steps: conceptual definition, operational definition, and prospective validation. First, from the conceptual perspective, the definition of low disease activity is anchored to the clinical experience of the physician and personal experience of the patient: for the physician it is linked to treatment decisions and to prognosis; and for the patient it is linked to satisfaction and adaptation. One suggestion is to define low disease activity as that state deemed a "useful target" of treatment by both the physician and patient given current treatments and knowledge. Second, to determine an operational definition a data-driven consensus process will be required and 2 fundamental approaches can be taken: the judgmental approach that gauges the opinion of patients and physicians on a useful target using methods such as direct questioning, patient profiles, physician submitted cases, and direct observation of clinical practice; or the statistical approach that considers the range of states obtained using the judgmental approach, applied in existing datasets to determine which best distinguishes a weak from a strong treatment. Third, in order to prospectively validate the definition, longitudinal datasets will be required that determine whether being in a

state for a period of time leads to benefits in terms of functional disability and structural damage.

Objectives

The objectives of this workshop are designed to meet the many challenges that exist in determining a low disease activity state:

1. To review the concepts and terminologies associated with a low disease activity state.
2. To determine the processes for developing an operational definition of low disease activity state.
3. To review and design longitudinal datasets useful for validating a low disease activity state.

The Workshop Process

In addition to the above introduction and rationale for the definition of a low disease activity state, a background article was made available to workshop participants on the methods and procedures for deriving an operational definition of low disease activity state[1].

The workshop began with a plenary session introducing the objectives and reviewing the concepts and terminologies. In particular, concepts and terminologies such as reduction in signs and symptoms, major clinical response, complete clinical response, remission, prevention of disability, and prevention of structural damage were clarified; and the role of time and disease duration were critically reviewed.

Participants were then divided into breakout groups. They were able to select from 1 of 4 groups designed to take their current interests into consideration as they relate to developing an operational definition of low disease activity. The MCID working group believes that developing a research agenda for such an operational definition is critical and these breakout sessions will result in setting a successful agenda. The 4 breakout groups each had a separate goal and focus of interest.

Group 1. Group 1 considered low disease activity from a patient perspective. Various patient scenarios were critically reviewed and discussed by the participants, with the goal to ensure that any definition takes into consideration the patient perspective and ultimately is acceptable to patients.

Group 2. Group 2 considered the methods and the consensus process that can be used for developing an operational definition of low disease activity. A wide range of possible judgmental and statistical approaches were discussed, with the goal to develop a comprehensive methodological strategy to be implemented for the development of an operational definition.

Group 3. Group 3 reviewed measures that could be used in the definition of a low disease activity. Starting with core measures used in indexes such as the ACR20 (American College of Rheumatology remission criteria) and the Disease Activity Score, participants reviewed other potential measures, such as fatigue, with the goal of drawing up a comprehensive and parsimonious list of candidate measures for use in a definition.

Group 4. Group 4 reviewed actual definitions of a low disease activity state. The measures that were included in the definition were given, and participants focussed on the levels and combinations of the measures used in the definition with the goal of providing examples of definitions of low disease activity state that have face validity.

Each group generated a report from their breakout session. A *rapporteur* for each breakout group reported back in a closing workshop plenary. The reports of the breakout groups were centered on specific questions such that when merged they would provide a framework of a research agenda for developing an operational definition low disease activity state. This framework was presented at the conference plenary.

Other reports will result from this workshop. In particular, a research agenda for determining a low disease activity state and issues related to prospectively validating a definition of low disease activity state are planned.

Outcomes

The anticipated outcome of the workshop was a research agenda for developing an operational definition of a low disease activity state[2]. This research agenda will be implemented and conducted after OMERACT 6 with the presentation of the results and consensus building as a possible module for OMERACT 7.

REFERENCES

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