The WOMAC Knee and Hip Osteoarthritis Indices: Development, validation, globalization and influence on the development of the AUSCAN Hand Osteoarthritis Indices

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ABSTRACT

Clinical measurement in both clinical research and clinical practice requires tools and techniques that are valid, reliable and responsive. Patient-centred self-reported measures provide opportunity to evaluate consequences of osteoarthritis, that are important and relevant to patients with the condition. The WOMAC and AUSCAN Indices are health status measurement questionnaires that are valid, reliable and responsive, easy to complete, simple to score and available in multiple language forms and scaling formats. They provide opportunities to capture patient relevant information, relating to the impact of interventions, in clinical research and clinical practice environments. WOMAC data have also contributed to the development of proposed definitions for responder criteria and state-attainment criteria in osteoarthritis.

Introduction

Osteoarthritis has been designated as one of the key conditions for special attention during the World Health Organisation's (WHO) Bone and Joint Decade (2000-2010) (1), and is also one of three conditions prioritized in the Commonwealth Government of Australia's seventh National Health Priority Area; Arthritis and Musculoskeletal Conditions (2). One of the key themes of these two initiatives is to reduce the burden of disease due to osteoarthritis (OA). The burden of OA may be considered in terms of its prevalence and consequence, including its effects on health-related quality of life (HRQoL).

The quantification of HRQoL in OA, plays a key role in describing, predicting and measuring the severity and outcome of OA. In both clinical research and clinical practice, evaluation of the therapeutic benefit of interventions, used either alone or in combination, is of key importance. Reliability, validity, and responsiveness are essential attributes of health status measurement tools, while brevity, simplicity, and ease of scoring are regarded with high importance, particularly in clinical practice applications (3, 4).

Prior to 1981, measurement procedures for quantifying pain, stiffness, and physical disability in hip and knee OA in rheumatology were diverse, lacked standardization in content, format, and scaling, and were often available only in one or a few European languages, such as English (5). Furthermore, function, the second most important consequence of large joint lower extremity OA, was infrequently measured in trials of non-steroidal ant-inflammatory agents.

In 1982, I had the opportunity in the course of completing an MSc thesis to describe the development of a health status questionnaire termed the Western Ontario and McMaster (WOMAC) Osteoarthritis Index (6). The conceptualization of the WOMAC Index and proposal of an item inventory occurred between 1981 and 1982. Validation and implementation occurred in the years 1982-1999. The Index has undergone significant refinement over time, such that in 2005 there are a broad range of WOMAC tools available to meet different measurement needs. Indeed, twenty-three years later, the WOMAC Index has been extensively validated and has been translated and linguistically validated in over 65 alternate-language forms. The Index is available in 5-point Likert (LK), 100mm visual analog (VA), and 11-point numerical rating (NR) scaling formats; the majority of the validation work to date, having been completed with the LK and VA formats. There are several hundred citations (full manuscripts, abstracts, re-

views) in the literature to the use of WOMAC in validation studies, comparative studies against other health status measures, and in various clinical research and clinical practice settings to evaluate patient outcomes (7). The WOMAC LK3.1 and WOMAC VA3.1 versions of the Index, in particular, have been extensively used, particularly in assessing efficacy in clinical research environments and increasingly in clinical practice.

The original test version of the WOMAC Index contained five dimensions: pain, stiffness, physical, emotional and social function (8). In validation, the first four dimensions performed well, but the social dimension was excluded (9, 10). Of these four dimensions, pain, stiffness and physical function were selected for inclusion in the WOMAC 3.0 Index and those 24 items retained for further validation and ongoing development, in the 3.1 series of WOMAC health status questionnaires.

It is of note that while emotional function does not feature in core set clinical domains in the OMERACT (11) or OARSI (12) guidelines for clinical trials, it is one of the domains identified in the IMMPACT (13) recommendations. It may therefore be timely to reintroduce the emotional subscale of the WOMAC Index, as part of a WOMAC 4.1 Index (8-10,13). While the standard WOMAC Index contains 24 items within three dimensions, there are versions of the Index that are either shorter or longer, and containing either a greater or lesser number of dimensions. Experience has permitted the development of variations in the timeframe over which the patient is asked to recall their symptom experience. Thus, while the standard version uses a 48-hour timeframe, there are versions that use variations including last 24 hrs, last week, last seven days, since last visit, last two weeks and last month. The Index appears sufficiently robust to tolerate these variations in timeframe between 24 hrs and one month.

The widespread use of the WOMAC index probably relates to several factors:
* Extensive patient involvement in the development of the item inventory (8). This is perhaps the most important, since it reduces the potential influence of paternalism, and anchors the item content into aspects of the disease experience that are relevant to OA patients, and on which they place importance.
* The conduct of numerous studies evaluating different clinimetric properties of the Index, including validity, reliability, and responsiveness, comparative studies assessing LK versus VA scaling, blind versus informed presentation, tracking signal items versus complete index usage, parametric versus non-parametric analyses and time frame variations (7, 9, 10).
* The development and linguistic validation of numerous alternate-language forms of WOMAC VA3.1 and WOMAC LK3.1 Indices using a standard operating procedure based on forward and backward translation processes and linguistic validation.
* Continued research and development into content and administration issues including the application of WOMAC in telephone interviews (14), and different electronic data capture formats (15-17)
* Recognition of the WOMAC Index by groups such as OMERACT (11), OARSI (12) and IMMPACT (13), and regulatory agencies such as the FDA (18) and EMEA (19).
* Use of WOMAC data to support the development of internationally recognised definitions of response status (20-26) and state-attainment (26-29).
* Provision of the WOMAC Index, in the required scaling format, alternate-language form, and administration format for academic, industrial, clinical and educational applications, including pivotal projects and programmes such as the National Institutes of Health (NIH) Osteoarthritis Initiative.
* Ongoing user support, to provide the most appropriate form of the Index to meet specific user needs.

Trans-cultural adaptation of the WOMAC 3.1 Index, in particular, has been a complex process for which Health Outcomes Group, San Francisco, California, USA, have taken primary responsibility. Standard operating procedures have been applied to develop linguistically valid alternate-language translations of extremely high quality. The WOMAC Index appears capable of tapping into global commonalities that exist in OA symptoms. Nevertheless, it is clear that the impact of environmental challenges involved in, for example, stair climbing and transportation, are different in different parts of the world, and bathing and toileting habits are also quite variable. The index constructor therefore is faced with the dilemma of whether to modify the item content, or make minor accommodations in order to maintain a standard question battery. In the case of the WOMAC Index, the latter strategy has been followed, allowing where necessary, an acceptable degree of flexibility. For applications in large multinational clinical trials I believe this is the preferred solution. However, modification of the item inventory either at an individual question or group of questions (module) level, tailored to the needs of individuals, might provide advantage in some measurement situations. The performance of items self-selected by individual patients, a so-called signal strategy has been evaluated, and is a viable alternative. However, we have been concerned by the inconsistency with which patients adhere to the selected signal with the passage of time. While this likely reflects a genuine reprioritization, my recommendation at the present time, is to use the entire Index, rather than the signal form. This recommendation does not conflict with decisions to use only one or a few WOMAC questions on a consistent basis, but instead refers to the signal strategy, where signal selection may vary between patients and also within patients over time.

Commonly used scaling formats include adjectival (syn:Likert), horizontal VA and NR scales. There is general evidence that all three types of scales are responsive (30). Likert scaling provides a simple and easing scoring system, while the VA scale may be slightly more sensitive. For this reason we have created parallel forms of the WOMAC

3.1, making available both LK and VA formats for most language forms. Based on a comparative study of NR scales in OA (30), it appears that the NR scale may be intermediate in responsiveness between the VA and LK scales. There are several scaling challenges in trans-cultural adaptation. Word usage is different in different countries, and words such as "moderate" and "extreme" may be deemed appropriate in one context, but not in another. As a result the word "average" may be more appropriate than "moderate" and the word "very severe" may be more appropriate than "extreme" in some cultures. Obviously the more points there are in the Likert scale, the greater the challenge to find culturally equivalent words. The use of VA or NR scaling formats in trans-cultural adaptations, has the advantage that each requires only two terminal adjectival descriptors. In practice, the different scaling formats seem to be acceptable, at least in the different countries for which alternate-language translations of the WOMAC Index have been created.

Most users have received the WOMAC Index directly. In a minority of instances however, the Index appears to have passed indirectly from user to user, and occasionally in that process, the instrument has been altered in a variety of ways. Sometimes the modifications seem quite minor, while in others more radical alterations of the Index have been made such as rescaling, adding/ deleting questions or omitting pages. The concern in these aberrant versions is, that some modifications may actually degrade instrument performance, and certainly erode the level of standardization previously achieved. Regardless of the health status questionnaire concerned, it is advisable for users to obtain an authentic version directly from the originator, together with any user guide or manual outlining details of administration and scoring. Using this approach, it should be possible for users to receive, and appropriately apply, measurement tools that best meet their specific measurement needs.

In comparative analyses against performance-based measurement techniques the WOMAC Index has frequently been superior in performance (7). In comparisons against other disease-specific measures the Index has compared favourably, and against generic health status measures has often been superior in responsiveness (31-34). It is of note that responsiveness apart, and accepting that disease-specific and generic measures are generally used for different purposes, the combined use of the two types of instruments in a study can be particularly useful and informative. Several investigators have proposed modifications to the standard WOMAC Index. The analyses which have suggested opportunities for modification have largely been based on Rasch analysis, factor analysis and experimentation with short forms. It is noteworthy, that in each case, the results of analyses conducted by different investigators have not been in close agreement with one another. Thus the four Rasch analyses (35-38), three factor analyses (39-41) and four short form analyses (42-45), reach different conclusions. The differences may relate to the WOMAC version, culture, language or clinical research setting in which the studies have been conducted. While of interest, they do not provide a compelling reason to modify the WOMAC Index structure or content at this time. Furthermore, the consequence of any such modifications on Index responsiveness requires additional study, across a broad range of applications.

A role for the WOMAC Index in predicting future health status (46) and health resource utilization (47) has been suggested, but remains to be clarified. Similarly, an application of the WOMAC Index in the assessment of lower limb involvement in rheumatoid arthritis has been suggested, but remains to be verified (48).

The development of the WOMAC Index is dynamic, and it is therefore important to understand the acronyms used to identify different versions of the WOMAC Index. As noted, the developmental form of the WOMAC contained 5 subscales (WOMAC 5.0) (pain, stiffness, physical function, social function, emotional function), of which the first 3 were retained for further devel-

opment (WOMAC 3.0). The globalization of the WOMAC Index was associated with refinements resulting in the emergence of the WOMAC 3.1 Index, which has been the standard form of the Index for several years. We are considering reintroducing the emotional subscale in some environments to meet the recommendations of the IMMPACT group (WOMAC4.1). Experimentation using separate WOMAC indices for the study knee and the contralateral knee, and using separate WOMAC pain and stiffness subscales for the left and right knees but a common WOMAC physical function subscale have been informative, as has been the experience varying the time frame from 24 h to 48 h (WOMAC 3.1), past 7 days (WOMAC 3.1W), and past month (WOMAC 3.1M). They suggest that the Index is sufficiently robust to withstand these subtle modifications. Studies conducted with the signal versions (WOMAC 3.1S and WOMAC 3.1S), have been encouraging, and suggest that the WOMAC could form the basis of an approach to individualized measurement, based on patient-specified item prioritisation. The short form version is termed WOMAC SF3.1. It is useful when reading reviews of the WOMAC Index, and studies based on the WOMAC Index, to identify which version, scaling format and language form of the Index was used. The majority, since 1999, are likely, but not necessarily, to have been based on the WOMAC 3.1 Index.

The traditional approach to the analysis of data from OAclinical trials has been performed at the group level. More recently, attention has focused on individual patient reported outcomes. These can be considered as being of two general forms: responder criteria in which each patient is classified as a responder or non-responder to treatment, based on whether their change in health status exceeds a pre-defined threshold, and state-attainment criteria in which patients are classified, not on the basis of change (better, same, worse), but on the basis of when, whether, and/or for how long they achieve a certain pre-defined level of low symptom severity. Research in both areas is developmental

and can be considered proposals, rather than guidelines or requirements. Nevertheless, responder criteria and state-attainment criteria represent innovations in the analysis of clinical trial outcomes, and may provide a bridge between health outcomes assessment strategies in clinical research and clinical practice environments. WOMAC data have contributed significantly to the development of several definitions The relationship between changes registered on the WOMAC Index and the same patients' perceived global assessment of their response to therapy has been explored in the context of data from two RCTs (21). The analyses determined that the Minimum Perceptible Clinical Improvement (MPCI) for the WOMAC VA3.0 Index subscales in patients with hip and knee OA, was 9.7 mm (0-100 scale) for pain, 9.3 mm for function and 10 mm for stiffness (21).

The original OARSI responder criteria (Propositions A and B) (20), and the recently revised OMERACT-OARSI responder criteria were developed in part on WOMAC data. The initiative has resulted in the proposal of a single international simplified set of responder criteria for OAclinical trials, applicable to hip and knee OA, and independent of intervention class (22).

In order to further explore the application of responder criteria, two secondary analyses (23, 24) of the previously published pharmaco-economic evaluation of hylan G-F 20 (49, 50) have been undertaken. The evaluation of the WOMAC 20, 50, 70 response criteria in knee OA patients, based on the WOMAC LK3.0 Index, provided preliminary evidence, supporting the capacity of WOMAC 20, 50 and 70 responder criteria, to detect clinically important, statistically significant between-group differences in a pragmatic randomised trial (23).

In order to incorporate the patient's own perspective, a study was conducted, with colleagues in Europe and North America, and resulted in preliminary definitions for the Minimally Clinically Important Improvement (MCII) (25), in knee and hip OA. The definitions for physical function were entirely based on data captured by the WOMAC 3.0

Index. The following definitions for MCII (absolute change on 0-100 scales and relative % change) for knee and hip OArespectively, were suggested by the analyses: a) Pain -19.9 mm (-40.8%) and -15.3 mm (-32.0%); b) patient global assessment -18.3 mm (-39.0%) and -15.2 mm (-32.6%); and c) WOMAC physical function -9.1 mm (-26.0%) and -7.9 mm (-21.1%) (42). Likewise definitions of a Minimum Clinically Important Difference (MCID) have been developed by the same group, resulting in the following definitions for hip and knee OA respectively: a) Pain -17 mm (-47%) and -28 mm (-48%); and b) WOMAC physical function -12 mm (–28%) and -12 mm (-40%) (26).

An alternative approach is that based on state-attainment. The Minimal Clinically Acceptable State (MCAS) (26), Patient Acceptable Symptom State (PASS) (27), and Bellamy *et al.* Low Intensity Symptom State-attainment (BLISS) Index (28, 29) are examples of this approach. PASS is a novel concept, and is the 75th percentile of the symptom severity score of patients who consider their health state to be satisfactory. The following definitions for PASS (threshold values on 0-100 scales) for knee and hip OA, respectively, were suggested by the analyses: a) Pain 32.3 mm and 35.0 mm; b) patient global assessment 32.0 mm and 34.6 mm; and c) WOMAC physical function 31.0 mm and 34.4 mm (43). The Bellamy *et al.* Low Intensity Symptom State-attainment (BLISS) Index has been evaluated in both a hylan (28) and a COX-2 (29) environment. The BLISS Index employs a series of analyses based on the WOMAC Pain subscale. Pain state attainment is defined in terms of magnitude, velocity and durability. Magnitude is classified by normalised units (0-100nu) into the following categories 25nu, 20nu, 15nu, 10nu and 5nu. Velocity is assessed in terms of time to first being in the state, while durability is evaluated as follows: ever being in the state, in the state at termination, number of study visits in the state and proportion of time spent in the state. The BLISS approach potentially provides an opportunity to differentiate between treatment groups at low or

even at near symptom-free levels of symptom intensity using the WOMAC pain subscale. While the concept requires further development, and may involve cummulative state-attainment analyses, initial experience has been very encouraging. The development of state-attainment criteria (MCAS, PASS, BLISS), in OA, is very new. It is acknowledged that the concepts of response and state-attainment require further investigation and the propositions require further validation. Nevertheless, patient involvement in estimating the clinical importance of improvement, and the acceptability of different levels of symptom severity is innovative, meets the obligations and requirements for consumer involvement in decision making and establishes preliminary consumer-based definitions for response and state attainment in knee and hip OA.

Finally, the International Classification of Function (ICF) proposed by WHO, provides a conceptual framework for health status assessment (51). It is noteworthy that an ICF core set has been described for OA (52), and the WOMAC Index successfully mapped to the ICF framework (53).

An important consequence of the WOMAC development has been the advantage provided by that experience, in the rapid development of a comparable index, termed the Australian/Canadian (AUSCAN 3.0) Index (54, 55), for OA hand studies. The AUSCAN Index, like the WOMAC Index is a tridimensional self-completed, patient-centered health status questionnaire, tapping into pain, stiffness and physical function (56). The Index contains 5 pain, 1 stiffness and 9 physical function items and has been validated in both 5-point Likert and 100mm VA scaling formats. The AUSCAN Index is available in 26 alternate-language versions, and is recognised in current draft OARSI Guidelines for the conduct of clinical trials in hand OA. The AUSCAN Index, like the WOMAC Index has found application in both clinical research and clinical practice environments. Details of the AUSCAN Index can be located at www.auscan.org, and are also accessible through the WOMAC website at

www.womac.org. The aforementioned instrument development activities are indicative of a dynamic long-term commitment to advance and refine patient-centered outcome measurement in OA, for applications in clinical research and clinical practice environments.

In summary, the last 23 years development, validation and globalisation of the WOMAC has involved an extensive collaboration with colleagues in musculoskeletal medicine and other health disciplines, and the interest and commitment of many patients with knee and/or hip OA. In addition to providing a standardised tool for evaluating the response to treatment in various classes of interventions, WOMAC data have also been important in informing decisions regarding response criteria and state-attainment criteria. Finally the experience gained in the WOMAC development has also directed the development of a comparable 15-item, tri-dimensional self-completed patient-centered health assessment questionnaire for hand OA, termed the Australian/Canadian (AUSCAN) Hand OA Index. The principal challenge now is to make good measures even better, to broaden application of the WOMAC and AUSCAN Indices in clinical practice environments, particularly considering issues such as individualised response, shared goal setting, response and state attainment and personal and environmental modulators of outcome, as well as to meet emerging needs in clinical research in evaluating symptom-modifying and structure modifying interventions, and to take advantage of emerging technological opportunities, particularly in the area of electronic data capture. The WOMAC and AUSCAN Indices are well placed to meet current, and emerging OA measurement needs, in clinical research and clinical practice.

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