Patient questionnaires in osteoarthritis: what patients teach doctors about their osteoarthritis on a multidimensional health assessment questionnaire (MDHAQ) in clinical trials and clinical care

T. Pincus, J. Schmukler, I. Castrejon

ABSTRACT
A patient history generally provides the most important information in diagnosis and management of patients with most rheumatic diseases, including osteoarthritis (OA). Patient history components can be expressed as quantitative, structured, “scientific” data, rather than “subjective” narrative descriptions, using patient self-report questionnaires. The Western Ontario McMaster (WOMAC) questionnaire is used in all OA clinical trials, and the health assessment questionnaire (HAQ) in all rheumatoid arthritis (RA) clinical trials, as “disease-specific” questionnaires. However, both questionnaires include scores for physical function function and pain; physical function scores are correlated highly significantly at r=0.73 in OA and r=0.71 in RA. Therefore, the WOMAC and HAQ may be regarded as largely “generic” questionnaires, at least for people with arthritis. Since it is not feasible to ask patients with different diagnoses to complete different care questionnaires in busy clinical settings, a single multidimensional HAQ (MDHAQ), derived from the HAQ visual analogue scale (VAS) pain scores at r=0.73 in OA and r=0.71 in RA. Therefore, the MDHAQ to recognise fibromyalgia similarly to formal fibromyalgia criteria, as well as the ineffectiveness of opioids in OA, and similar prevalence of depression and other psychological issues in OA to RA. These findings also illustrate the value of a database of MDHAQ data for retrospective analysis of serendipitous observations from routine clinical care.

Introduction
A patient history generally provides the most important information in diagnosis and management of patients with most rheumatic diseases. In a survey of 313 physicians (154 rheumatologists and 159 primary care physicians), rheumatoid arthritis (RA) was the only disease among 8 for which a patient history among 5 elements of a clinical encounter – the others were vital signs, physical examination, laboratory tests, and ancillary studies – was noted to account for 50% of clinical decisions in diagnosis and management (1). [Hypertension was dominated by vital signs, diabetes and hyperlipidaemia by laboratory tests, and pulmonary fibrosis, ulcerative colitis, congestive heart failure and lymphoma by ancillary studies (1)].

Osteoarthritis (OA) was not included in the physician survey (1). Nonetheless, patient history information may be even more prominent in the management of OA than of RA for at least 2 reasons: a) Most people develop radiographic OA with aging, which often is asymptomatic (2) or not explanatory of patients symptoms, as seen with radiographic changes in the cervical spine in patients with fibromyalgia. b) No biomarker has been shown to be informative in routine patient management of OA (3), while biomarkers are of value in management of some patients with

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The health assessment questionnaire (HAQ) was developed to assess RA (14) and the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) questionnaire was developed to assess OA (16) as disease-specific questionnaires. Both questionnaires include 2 scores for physical function and pain among 3 measures; the third score is a patient global assessment on the HAQ and stiffness on the WOMAC. The WOMAC has been incorporated into most OA clinical trials and clinical research, and the HAQ into most RA clinical trials and clinical research over the last 3 decades.

Although developed as “disease-specific” patient questionnaires, scores for WOMAC function and HAQ function are correlated highly significantly at r=0.78 in both RA and OA patients, and WOMAC pain scores with HAQ visual analogue scale (VAS) pain scores at r=0.73 in OA and r=0.71 in RA (17). These correlations are quite high for any two clinical measures [for reference, a correlation of erythrocyte sedimentation rate (ESR) with C-reactive protein (CRP), two biomarkers that are often used interchangeably in RA clinical trials is 0.50 (18)]. The data indicate “generic” properties of the WOMAC and HAQ in patients with many rheumatic diseases (19), a property that appears to apply to derivatives of the HAQ, such as HAQii (20) and multidimensional HAQ (MDHAQ) (21-23) (which are largely identical to the HAQ other than some physical function items). Furthermore, the results of two OA clinical trials indicate virtually identical results according to the MDHAQ and WOMAC (24, 25). The MDHAQ, as well as the HAQ, appears informative in all rheumatic diseases in which it has been studied (23, 26-29), including in OA (13).

This review presents 3 sections: a) A summary of 3 patient questionnaires used in OA research, the WOMAC, used in all OA clinical trials and most OA clinical research as well as the HAQ, used in all RA clinical trials and most RA clinical research, and MDHAQ, used in routine care for most reported evidence that disease burden in OA is similar in OA and RA (11, 12, 29). b) Data from clinical trials which illustrate the value of the MDHAQ to assess and monitor patients with OA (24-26). c) Some further applications of the MDHAQ in routine care to recognize similar burden of disease in OA and RA (11-13), clues to fibromyalgia (30), the relative ineffectiveness of opioids in OA (31), and similar prevalence of depression and other psychological issues in OA and RA (21).

1. Self-report questionnaires widely-used in clinical trials, clinical research, and clinical care of patients with OA

A brief description of questionnaires which have been used in clinical trials, clinical research, and clinical care of patients with OA, the WOMAC, HAQ, and MDHAQ, is presented below (Figs. 1-3, Table I):

a. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

The WOMAC (16) (Fig. 1, Table I) was reported in 1988 and has become the “gold standard” for assessment of patients with OA. The WOMAC scores 3 dimensions: pain, stiffness, and physical function with 5, 2, and 17 queries, respectively. A Likert version of the WOMAC is rated on an ordinal scale of 0 to 4, with lower scores indicating lower levels of symptoms or physical disability. Each subscale is summed to a maximum score of 20, 8, and 68, respectively.

An index score or global score may be calculated by summing the scores for the 3 subscales. A visual analogue scale (VAS) version of the WOMAC is also available, as in Figure 1. The questionnaire is self-administered, requires about 5 to 10 minutes to complete, and has been translated into many languages.

b. The health assessment questionnaire (HAQ)

The health assessment questionnaire (HAQ) (15) (Fig. 2, Table I) was reported in 1980, and has been incorporated into almost all clinical trials and most clinical research in RA over the last 3 decades. The HAQ physical function scale includes 20 activities of daily living (ADL), grouped into 8 categories of 2 or 3 each, scored on a 0–3 scale (0 = without any difficulty, 1 = with some difficulty, 2 = with much difficulty, 3 = unable to do). The physical function score is the mean 0-3 score of the highest ADL score for each of the 8 categories, termed the HAQ disability index (HAQ-DI).

The short, or 2-page HAQ comprises only the HAQ-DI and two 0–10 cm visual analogue scales (VAS) for pain and...
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**Fig. 1.** WOMAC osteoarthritis index used in all clinical trials in patients with osteoarthritis. Source: ref. (16) Bellamy et al.: Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to anti-rheumatic drug therapy in patients with osteoarthritis of the hip or knee. WOMAC queries may be presented to patients as a Lickert scale or visual analogue scale (VAS). This version involves VAS.

**Fig. 2.** Health Assessment Questionnaire (HAQ). Source: ref. (15) Fries et al.: Measurement of patient outcome in arthritis.
MDHAQ® (Multi-Dimensional Health Assessment Questionnaire) (MDHAQ)

This questionnaire includes items not available from blood tests. Exams, or any source other than you. Please try to answer each question, even if you do not think it is related to you at this time. Try to complete as much as you can yourself, but if you need help, please ask. There are no right or wrong answers. Please answer exactly as you think or feel. Thank you.

1. Please check (X) the ONE best answer for your abilities at this time:

<table>
<thead>
<tr>
<th>WITHOUT</th>
<th>WITH SOME DIFFICULTY</th>
<th>MUCH DIFFICULTY</th>
<th>UNABLE TO DO</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Dress yourself, including shoes and socks, and comb your hair</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>b. Get in and out of bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>c. Lift a full gall up or glass to your mouth</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>d. Walk outdoors on flat ground</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>e. Wash and dry your entire body</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>f. Bend down to pick up clothing from the floor</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>g. Turn regular faucets on and off</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>h. Get in and out of car, bus, train, or airplane</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>i. Climb three or five stairs</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>j. Participate in recreational activities and sports</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>k. Bend or stoop</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>l. Sit on the toilet, flush, and wash</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>m. Get a good night’s sleep</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>n. Deal with feelings of anxiety or being nervous</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>o. Deal with feelings of depression or feeling blue</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

2. How much pain have you had because of your condition OVER THE LAST WEEK? Please indicate below how severe your pain has been:

<table>
<thead>
<tr>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

3. Please place a check (X) in the appropriate spot to indicate the amount of pain you have been having in each of the joint areas listed below:

- LEFT shoulder:
- RIGHT shoulder:
- LEFT elbow:
- RIGHT elbow:
- LEFT hand:
- RIGHT hand:
- LEFT fingers:
- RIGHT fingers:
- LEFT thumb:
- RIGHT thumb:
- LEFT big toe:
- RIGHT big toe:

4. Considering all the ways in which illness and health conditions may affect you at this time, please indicate below how you are doing:

<table>
<thead>
<tr>
<th>VERY</th>
<th>MUCH</th>
<th>A LOT</th>
<th>SOME</th>
<th>A LITTLE</th>
<th>VERY POORLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

5. Please check (X) if you have experienced any of the following over the last month:

- Foot pain:
- Leg pain:
- Buttock pain:
- Hip pain:
- Lower back pain:
- Upper back pain:
- Knee pain:
- Elbow pain:
- Shoulder pain:
- Hand pain:
- Finger pain:

6. When you awakened in the morning OVER THE LAST WEEK, did you feel well?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

7. How do you feel TODAY compared to OVER THE LAST WEEK? Please check (X) only one.

<table>
<thead>
<tr>
<th>Much Better (1)</th>
<th>Better (2)</th>
<th>No Change (3)</th>
<th>Worse (4)</th>
<th>Much Worse (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

8. How often do you experience emotional distress, increased heart rate, shortness of breath, or at least one negative life event in the past month? Please check (X) only one.

<table>
<thead>
<tr>
<th>Never</th>
<th>Once a month</th>
<th>Most weeks</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

9. How much of a problem does UNEMPLOYMENT, fatigue, or depression cause for you OVER THE LAST WEEK?

<table>
<thead>
<tr>
<th>No Problem</th>
<th>Minimal</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

10. Over the last 6 months have you had:

Please check (X) all that apply:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

11. What are your current medications or recent hospitalizations?

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
<th>Reason</th>
<th>Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12. Please indicate any “yes” response below, or indicate any other health matter that affects you:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>DEPENDENT</th>
<th>INDEPENDENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Fig. 3. Multi Dimensional Health Assessment Questionnaire.

Sources: ref. (21) Toward a multidimensional Health Assessment Questionnaire (MDHAQ): assessment of advanced activities of daily living and psychological status in the patient-friendly health assessment questionnaire format.
(22) Further development of a physical function scale on a MDHAQ for standard care of patients with rheumatic diseases.

The MDHAQ was developed initially after introducing the HAQ into routine clinical care in 1980, a few weeks after publication of the HAQ, as a possible advance for clinical care, much as a new laboratory test.

The clinic receptionist was instructed to ask each patient with RA to complete the HAQ in the waiting area before seeing the rheumatologist. It quickly became apparent that the goal to have each RA patient complete the HAQ was feasible only if the receptionist requested all patients (with any diagnosis), rather than select RA patients, to complete the questionnaire. Although initially an unexpected finding, the questionnaire was found to be informative in patients with all rheumatic diseases, which was subsequently documented in later reports (23, 28, 34-36).

A number of changes were initiated on the HAQ, based on the developer’s experience in developing a radio immunoassay for DNA antibodies (37-39), and managing a clinical immunology laboratory, in which minor changes of the ionic strength or pH of a buffer were made to improve the sensitivity and specificity of an assay without documenting these changes. The evolution of the HAQ into the MDHAQ over 25 years from 1980–2005 differed from most patient questionnaires such as the WOMAC and HAQ, which resulted from research efforts with psychometric testing prior to use (40).

Development was based on principles of continuous quality improvement (CQI) (40), incorporating features that appeared useful in clinical care and feedback from patients, rather than as a research activity, although psychometric criteria for validity and reliability were met (21, 22), and advances in clinical research results emerged (11-13, 28, 29, 41-45). After recognition of physical function as far more significant than laboratory tests or imaging data in the prognosis of work disability and premature mortality in RA (46-50), it was felt appropriate to include a patient questionnaire as a requirement for each visit, analogous to a laboratory test used in clinical care (51). Since the MDHAQ was developed in the clinic, feasibility and provision of clinically-relevant information were emphasised.
Details of development of the MDHAQ has been presented in several reports (21, 22, 51-53); and features on the MDHAQ not found on the HAQ are summarised in Table I and below:

The physical function scale includes 10 items, 8 from the original HAQ, one from each HAQ category, and 2 complex activities, “walk 2 miles or 3 kilometers,” and “participate in recreation and sports as you would like” (21, 22); the 10 activities are scored 0–3, with a 0–30 total function score, converted to 0–10 (21, 22). This change was made during the 1990s, as clinical status of rheumatology patients had improved since the 1970s when the HAQ was developed (21), and scores of “zero” (floor effects) reported by 23% of patients on the MHAQ and 16% of patients on the HAQ, while function was not entirely normal in most patients, and a score of zero was reduced to <5% on the MDHAQ (21).

Three mental health queries were added in the user-friendly HAQ format, concerning sleep quality, anxiety and depression, scored 0–3, rather than 0–3, to provide a 0–9.9 “psychological HAQ” (21, 22). These items and other features of the MDHAQ are similar to the content of some more generic questionnaires such as the Short Form 36 (SF-36) (54) and Patient-Reported Outcomes Measurement Information System (PROMIS29) (55, 56), which include more extensive items concerning psychological distress.

The VAS for pain and patient global assessment were converted to visual numerical scales (VNS) of 21 circles, each numbered at 0.5 intervals, for ease of scoring and photocopying (which often hindered scoring on the HAQ). The VAS for pain and patient global assessment were converted to visual numerical scales (VNS) of 21 circles, each numbered at 0.5 intervals, for ease of photocopying (which often hindered scoring on the HAQ). A 4-page version, which serves as a standard medical “intake” questionnaire, concerning past illnesses, surgery, family history, allergies, medications and demographic data (41).

MDHAQ information can improve documentation, and facilitate a focus on issues of concern to the patient and physician for higher quality visits with better communication, saving time for both (68). Furthermore, the MDHAQ has been used in OA clinical trials with results comparable to a WOMAC, and databases of MDHAQ data from routine clinical care have been used to document similarity of disease burden in OA and RA, clues to the presence of fibromyalgia, recognition of ineffectiveness of opioids in OA, and similar levels of depression and psychological distress in OA and RA, as presented below.

II. Use of the MDHAQ in OA clinical trials based on observations in routine clinical care

a. Documentation that self-report data in OA are more sensitive to change in clinical status than observer-assessed data

In the mid-1980s, a clinical trial was conducted to compare the results of 2
forms of aspirin in the management of OA (26). At that time, the traditional measures chosen by the pharmaceutical company sponsor to assess possible efficacy included pain on active motion, pain on passive motion, joint tenderness, joint swelling, joint crepitus, and walking time (26) (Table II).

An investigator (TP) suggested the inclusion of a modified version of the HAQ (15) termed the MHAQ (69), which was being used in routine care and appeared informative in patients with all rheumatic diseases (35, 40). Although there was some initial resistance, based on the HAQ being regarded as a “disease-specific” instrument for RA, the sponsor agreed to add this measure to the clinical trial protocol. The results indicated median “improved status” according to the 7 traditional observer-reported measures of 23% (range 3–43%) versus 43% (range 12–59%) for the patient-reported measures, and median “unchanged status” for the traditional observer-reported measures of 73% (range 47–90%) versus 25% according to the MDHAQ patient-reported measures (26). Significant correlations were seen between the observer-reported physical measures and self-report questionnaire measures, indicating that both types of measures detect similar information (26) (Table II).

These observations may be regarded as a “proof of concept” study that patient self-report questionnaires appear valid, sensitive, and more informative than traditional observer-reported measures in OA. A brief report was published in 1988 (26), ironically the same year as the publication of the WOMAC (16). It was appropriate that the WOMAC became the “gold standard” instrument of choice for OA, based on extensive psychometric analyses of validity and reliability in the original and subsequent reports (70-72), while further development of the MHAQ was pursued in routine clinical care (36, 51).

At this time, it would be unthinkable to perform a clinical trial or any clinical research in OA without a WOMAC, but inclusion of a patient questionnaire did not begin until the mid-1980s. The findings further indicate that the HAQ and its derivative MHAQ and MDHAQ appear quite informative to describe clinical status and changes in OA. A brief report was published in 1988 (26), ironically the same year as the publication of the WOMAC (16).
OA. Ultimately, the MDHAQ has been used in recent years to document prospectively the similar disease burden in OA compared to RA (11-13).

b. Two osteoarthritis clinical trials in which the results appear quite similar according to MDHAQ pain scores, WOMAC, and SF 36 questionnaires

In the late 1990s, a multicentre, crossover clinical trial was conducted to compare the efficacy of diclofenac/misoprostol (Arthrotec) to acetaminophen in ambulatory patients with OA of the hip or knee (24), who had Kellgren/Lawrence radiographic grade 2–4 (73) and a score of >30 mm on a 100-mm visual analogue pain scale (74, 75). Patients were randomised to one of two groups in a crossover design to receive either medication for 6 weeks each. The primary outcome was the WOMAC target joint, the validity of which had been established in OA clinical trials. In addition, patients were assessed according to the MDHAQ pain V AS and the SF 36 bodily pain score. The SF-36 is a 36-item “generic” patient self-report questionnaire (54), with 8 scales grouped as 4 physical component summary (PCS) scores – vitality, physical function, bodily pain, general health, and 4 mental component summary (MCS) scores – physical role function, emotional role function, social role function, and mental health. In contrast to most other scales such as the WOMAC, HAQ and MDHAQ, higher scores indicate better status, e.g. a score of 100 is equivalent to no disability and zero to maximum disability. Based on lessons learned in the earlier OA clinical trial, no investigator-reported measures were included in the study (24).

In 227 patients, significantly higher levels of improvement were seen for patients treated with diclofenac/misoprostol compared to those treated with acetaminophen (Fig. 4). Results were virtually identical according to the WOMAC, MDHAQ pain V AS, or SF-36 bodily pain scores (higher scores on the SF-36 indicate better status, unlike WOMAC and MDHAQ) (Fig. 4). The data suggest that any of the 3 questionnaires could be used to assess patients with OA, to document in detail that diclofenac/misoprostol was rated as “better” or “much better” by 57% of the 174 patients who provided such ratings for both treatment periods, while acetaminophen was rated as “better” or “much better” by 20% of these patients, and 22% reported no difference (p<0.001) (24).

A subsequent clinical trial with a similar design was conducted to compare 6 weeks treatment of celecoxib versus acetaminophen versus a placebo arm according to either the targeted joint WOMAC or an MDHAQ pain V AS (SF-36 was not included) (25). Results indicated superior efficacy for celecoxib compared to acetaminophen compared to a placebo according to both WOMAC target joint and MDHAQ pain V AS. Again, results were similar according to either measure, although changes according to the MDHAQ pain V AS generally were greater than according to the WOMAC target joint (25).

In routine clinical care, it is not feasible to attempt to use different questionnaires in different patients with different diagnoses. Furthermore, scores for patient functional status, pain, fatigue, morning stiffness and other measures can be most informative as a baseline measure at an initial visit of a “new” patient, when the patient often does not have a diagnosis, particularly before seeing the rheumatologist. Availability of baseline initial visit scores is desirable, particularly as maximum improvement in patient status often is seen within the first 3 months of rheumatologic care. This goal can be accomplished most feasibly by using the same questionnaire in all new (and return) patients.

Unexpected observations from MDHAQ used in routine care, stored in databases, and analysed retrospectively to provide new insights into OA

OA is as severe as RA

Five studies reported between 1989 and 2019 are among 8 reports reviewed elsewhere in this supplement (13), which document that disease burden according to the MDHAQ is substantial in OA and comparable to RA (11, 12, 17, 27, 35, 36). Four of these studies were based on data collected in routine care and analysed retrospectively (11, 12, 35, 36); one involved prospective analyses of the initial visits of new patients with OA or RA (or other rheumatic diseases), and follow-up visits 2 months later (29). The primary focus to analyse properties of the MDHAQ at sites at which all patients are asked to complete an MDHAQ at all visits to inform clinical decisions.

A pain VAS was higher in OA compared to RA in 10/11 patient groups in these reports, while MDHAQ physical function and RAPID3 were slightly higher in RA in studies before 2009 and higher in OA in later reports [see (13)]. Therefore, disease burden of pain and functional disability appear generally similar in OA to RA. In addition, the findings
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Fig. 5. Receiver operating characteristic (ROC) curves to compare the capacity of all MDHAQ based composite indices to discriminate between patients with or without FM according to the 2011 revised criteria as reference standard.

AUC: Area under the ROC curve; RADA1: Rheumatoid arthritis disease activity index self-report painful joint count, “MDHAQ-SSS”: sum of fatigue, problems with thinking/memory, good night sleep, headaches, stomach pain/cramps and depression; “MDHAQ-WPT”: self-report painful joint count including back and neck (0–54), divided by 3; “MDHAQ-PSD”: the sum of “MDHAQ-SSS” and “MDHAQ-WPT”; MDHAQ-FM4P: FAST3P cumulative index including pain, self-report painful joint count and symptom checklist; MDHAQ-FM3F: FAST3F cumulative index including fatigue, self-report painful joint count and symptom checklist; MDHAQ-FM4: FAST4 cumulative index including pain, fatigue, self-report painful joint count and symptom checklist. Source: ref. (30).

reflect the potential value of using identical patient questionnaire measures in all patients at all visits in routine care settings, analogous to using the same laboratory tests such as erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) in all rheumatic diseases, and maintaining a database of the results for later analyses.

Recognition of fibromyalgia in OA and other rheumatic diseases

Early observations in routine clinical care indicated that patients with high, often the highest, scores on certain MDHAQ scales were seen in patients with fibromyalgia (76). Some observers suggested that these phenomena indicated that patient questionnaires were highly limited (or entirely useless) in clinical rheumatology. Several fibromyalgia-specific questionnaires were developed (77-79), and the 2011 and 2016 updated criteria for fibromyalgia are based exclusively on patient questionnaire scores for widespread diffuse musculoskeletal pain, but no patients with RA (76). In 2004, it was recognised that scores on a 0–10 fatigue VAS and 0–60 symptom checklist were significantly higher in 78 patients with fibromyalgia than in 149 patients with RA (66). Patients with fibromyalgia also had a lower ESR than patients with RA, but patients with fibromyalgia were distinguished from patients with RA by patient questionnaire data as effectively as by the ESR (66). The relative acceptance of RAPID3 by the rheumatology community suggested the possibility of a further MDHAQ index that might be useful in fibromyalgia. Such an index has been reported recently as a FAST (fibromyalgia assessment screening tool) index (30, 83). Over a 6-month period, the one-page questionnaire used to score the revised 2011 fibromyalgia criteria (80) termed a polysymptomatic distress scale (PSD) [composed of a symptom severity scale (SSS) and widespread pain index (WPI)], was added to the MDHAQ in 566 patients seen in routine care for comparison with the MDHAQ scales. The MDHAQ items showing the highest agreement with the 2011 fibromyalgia criteria according to the “area under the curve” (AUC) on receiver operator characteristic (ROC) curves were compiled into FAST indices (30, 83).

The highest AUC were seen, in order, for 60 symptom checklist, RADA1 self-report painful joint count, pain VAS, and fatigue VAS (30, 83). All FAST indices include the 60 symptom checklist and RADA1 self-report painful joint count; FAST3-P adds a pain VAS score, FAST3-F a fatigue VAS score, and FAST4 both pain and fatigue VAS scores (30, 83). Results of ROC curves indicate an AUC greater than 0.9, as high agreement as seen in clinical medical measures (Fig. 5). Cut points of symptom checklist ≥16, painful joint count ≥16, pain VAS ≥6 and fatigue VAS ≥6 were identified as providing optimal sensitivity and specificity. Scores are 1 point each for compiling into 0–3 FAST3 indices or a 0–4 FAST4 index; scores of ≥2 for FAST3 and ≥3 for FAST4 (45, 83) are in agreement with the 2011 fibromyalgia criteria at levels greater than 80% (30, 83).
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MDHAQ in osteoarthritis / T. Pincus et al.

Table III. Responses to 202 patients with osteoarthritis to the query: “Which drug was most helpful for your arthritis?”

<table>
<thead>
<tr>
<th>Drug</th>
<th>no. of patients who took this drug</th>
<th>no. of patients who named this drug “most helpful”</th>
<th>Percentage of patients who named a drug “most helpful” who named this drug</th>
<th>Percentage of all patients who named this drug “most helpful”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen (Motrin, Advil, Nuprin)</td>
<td>223</td>
<td>40</td>
<td>20%</td>
<td>13%</td>
</tr>
<tr>
<td>Naproxen (Naprosyn, Naprolyn, Aleve)</td>
<td>177</td>
<td>28</td>
<td>14%</td>
<td>9%</td>
</tr>
<tr>
<td>Nabumetone (Relafen)</td>
<td>80</td>
<td>18</td>
<td>9%</td>
<td>6%</td>
</tr>
<tr>
<td>Diclofenac (Voltaren)</td>
<td>63</td>
<td>15</td>
<td>7%</td>
<td>5%</td>
</tr>
<tr>
<td>Piroxicam (Feldene)</td>
<td>54</td>
<td>11</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Etodolac ( Lodine)</td>
<td>NA</td>
<td>10</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Arthrotec</td>
<td>NA</td>
<td>8</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Oxyaprozin (Daypro)</td>
<td>54</td>
<td>8</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Aspirin</td>
<td>113</td>
<td>5</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Indomethacin</td>
<td>28</td>
<td>4</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Flurbiprofen</td>
<td>20</td>
<td>4</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Salsalate (Disalcid)</td>
<td>7</td>
<td>4</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Sulindac (Clinoril)</td>
<td>33</td>
<td>2</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Tolmetin</td>
<td>7</td>
<td>2</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Ketoprofen (Orudis)</td>
<td>25</td>
<td>2</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Diclofenac (Cataflam)</td>
<td>NA</td>
<td>1</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Fenoprofen (Nalfon)</td>
<td>NA</td>
<td>1</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Total, NSAID</td>
<td>161</td>
<td>80%</td>
<td>80%</td>
<td>54%</td>
</tr>
<tr>
<td>Analgesic drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>210</td>
<td>31</td>
<td>16%</td>
<td>10%</td>
</tr>
<tr>
<td>Other analgesics</td>
<td>NA</td>
<td>3</td>
<td>1.5%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Tylenol with codeine (#3)</td>
<td>NA</td>
<td>3</td>
<td>1.5%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>NA</td>
<td>2</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Darvocet</td>
<td>NA</td>
<td>2</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Total, analgesic drugs</td>
<td>41</td>
<td>20%</td>
<td>20%</td>
<td>14%</td>
</tr>
<tr>
<td>Grand total</td>
<td>202</td>
<td>100%</td>
<td>100%</td>
<td>67%</td>
</tr>
</tbody>
</table>

Source: ref. (30) Preference for non-steroidal anti-inflammatory drugs versus acetaminophen and concomitant use of both types of drugs in patients with osteoarthritis.

Table IV. Mean scores of 162 patients with rheumatoid arthritis and 63 patients with osteoarthritis on MDHAQ 3 psychological items.

<table>
<thead>
<tr>
<th>Patients with …</th>
<th>n</th>
<th>Sleep</th>
<th>Anxiety</th>
<th>Depression</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumatoid arthritis</td>
<td>162</td>
<td>2.13</td>
<td>1.69</td>
<td>1.66</td>
<td>1.82</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>63</td>
<td>1.97</td>
<td>1.67</td>
<td>1.66</td>
<td>1.77</td>
</tr>
</tbody>
</table>

Source: ref. (21) Toward a multidimensional Health Assessment Questionnaire (MDHAQ): assessment of advanced activities of daily living and psychological status in the patient-friendly health assessment questionnaire format. Data are mean scores on a 0–3 scale.

Further studies appear needed to determine an optimal FAST index – or the possibility that different scores may be optimal in different situations. The proportion of patients with fibromyalgia on both the PSD 2011 fibromyalgia criteria questionnaire and FAST indices on the MDHAQ was higher in OA than in RA or systemic lupus erythematosus patients, emphasising again the significant disease burden of patients with OA (Schumaker, manuscript in preparation). The MDHAQ again appeared to provide unexpected value to better characterise patients with OA.

Poor results in use of opioids compared to NSAIDs in the management of OA

Introduction of selective cyclooxygenase2 (Cox2) inhibitor non-steroidal anti-inflammatory drugs (NSAIDs) in 1999 initially was regarded as a major advance in OA therapeutics, with efficacy comparable to traditional NSAIDs and lesser likelihood of adverse gastrointestinal events. However, by the early 2000s, a significantly higher rate of cardiovascular events was recognised as associated with these drugs compared to traditional NSAIDs (84). This phenomenon led to withdrawal of several Cox 2 selective drugs from the market, and recommendations to avoid those that remained in favour of alternatives, including opioids.

Over the decade from 2001–2011, OA patients were treated with a substantially lower likelihood of any type of NSAID (Cox 2 selective or not) accompanied by a concomitant substantial increase in opioids (85). Several studies documented that falls and fractures were 3–4 times more likely in OA patients who took opioids compared to those who took NSAIDs (85-87). Furthermore, evidence was presented that opioids did not appear efficacious for many patients, including a Cochran systematic review of randomised trials showing a 0.7 cm improvement on a pain VAS, below the minimal clinically important difference of 0.9 cm (88).

Further details concerning the use of opioids in OA and general issues with contemporary opioid crisis at this time are beyond the scope of this article. We do point out that a survey of OA patients reported in 2000 indicated that 80% of 202 OA patients responded to a query concerning which drug that was “most helpful for your arthritis” by naming an NSAID (including 20% ibuprofen and 14% naproxen), while only 20% named an analgesic drug (including 16% acetaminophen and fewer than 4% an opioid (Table II) (31). These data were assembled using a simple questionnaire amended to an MDHAQ, similar to the fibromyalgia criteria PSD to the MDHAQ in recent studies (30, 83). Of course, an extensive Cochran review provides considerably stronger evidence than a simple survey of 202 patients. Nonetheless, the conclusion that opioids are unlikely to be effective for most OA patients, with both limited efficacy and frequent adverse events, appears quite similar. The results of the patient survey appear never to have been cited in discussions of the limited

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value of NSAIDs and adverse events of Cox-2 selective inhibitors, with possible alternative therapies for OA. Perhaps the substantial increase in the use of opioids for OA might have been lesser if this information had been more widely known.

It is possible that greater respect for data from patients exists at this time than 2 decades ago. In any event, the findings provide another example that one can gain informative clinical data from patients using simple questionnaires.

Recognition of similar levels of depression and psychological distress in patients with osteoarthritis as in patients with rheumatoid arthritis

As noted above, the MDHAQ introduced 3 psychological items in the user-friendly HAQ format, in large part to reduce “floor effects”, i.e. scores of 0 in 23% of patients on the MHAQ and 16% on the HAQ, to less than 5% (21, 22). Mean 0-3 scores in the initial 1999 MDHAQ report for 3 specific queries concerning sleep quality were 2.13 in patients with RA and 1.97 in patients with OA; scores for anxiety were 1.69 in RA and 1.67 in OA; and scores for depression were 1.66 in both RA and OA (Table IV) (21). Mean overall psychological distress scale scores were 1.8 in RA and 1.77 in OA (Table IV) (21). These observations again reinforce the similarity of OA to RA (21). Mean scores for depression in patients with OA and overall psychological distress scores were higher than seen in patients with vasculitis or scleroderma, which are regarded as severe rheumatic diseases (21). The data emphasize again that OA is a severe rheumatic disease, and a need for change in perception by the medical community and general public concerning OA.

In conclusion, scores on an MDHAQ report have documented the severity of OA, comparable to RA in consequences of functional disability and pain, clues to recognition of fibromyalgia, poor results compared to NSAIDs in treatment of OA, and psychological distress in OA versus RA. Advantages of MDHAQ in routine care include the feasibility of using the same patient questionnaire for all patients with all diagnoses, and the MDHAQ has proven informative in all rheumatic diseases in which it has been studied (7, 23). The primary use of the MDHAQ is to inform clinical decisions in patient care, but additional creation of a long-term database can provide quantitative data which are not available from a non-quantitative, non-structured medical history, laboratory tests, imaging data, or other information in the medical record.

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