Assessment of pain in rheumatic diseases

T. Sokka

Tuulikki Sokka, MD, PhD, Research Assistant Professor, Vanderbilt University, Nashville, and Consultant Rheumatologist, Jyväskylä Central Hospital, Jyväskylä, Finland.

Please address correspondence and reprint requests to: Tuulikki Sokka, MD, PhD, Vanderbilt University / Rheumatology, 203 Oxford House, Nashville, TN 37232-4500, USA.
E-mail: tuulikki.sokka@vanderbilt.edu

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ABSTRACT
Pain is the most prominent symptom in people with musculoskeletal disorders, and the most common motivation for patients seeking medical help. However, pain generally is not recorded quantitatively in routine medical care. Over the last three decades, self-report questionnaires have been developed in which a patient may record quantitatively a pain score at baseline and over time to determine whether their condition has improved, remains unchanged, or has worsened. The most robust quantitative pain measure appears to be a simple 10 cm visual analog scale (VAS), which can be completed by the patient and scored by a health professional in less than 10 seconds. Quantitative data concerning pain cannot be obtained from any source other than the patient. Quantitative assessment of pain at each visit in routine rheumatology care, along with the assessment of functional disability, global status, and other patient variables, using a patient self-report questionnaire might lead to improved patient care.

Introduction

Pain is the most prominent symptom in the majority of people with arthritis (2-5), a common reason for primary care consultation (6-8), and a major source of health care costs (9). Musculoskeletal pain appears to be much more common now than 40 years ago (10). Nonetheless, quantitative information concerning pain, which is required to assess and document possible improvement, stabilization, or worsening of pain over time, is generally not recorded in routine medical care. In a survey of U.S. emergency department visits in 1999, 52% included no recorded information concerning the presenting level of pain (11).

In acute medical situations, the primary setting for most medical education and training, the quantitative assessment and recording of pain levels may appear unnecessary. A patient with a fracture or myocardial infarction can provide clinical information concerning pain, and changes can be observed over the next few hours and days without the apparent need for quantitative data. Pain and other symptoms are regarded as "subjective," based on data obtained from the patient, and are viewed by the clinician largely as preliminary to critical "objective" data obtained from the physical examination, laboratory tests, or imaging procedures. This view is consistent with what has been termed the traditional "biomedical model" (12), which has been applied so successfully in acute medical care during the 20th century that it is often applied to chronic diseases as well.

At this time, chronic diseases are the most important problem in medical care. In the management of chronic diseases, the "biomedical model" is not as useful as in acute diseases in guiding diagnosis and management and has substantial limitations. For example, the most effective predictors of mortality in patients with rheumatoid arthritis (RA) include data from a patient questionnaire concerning the patient's physical function and level of formal education, rather than data from a physical examination, laboratory tests or radiograph (13-16). In the management of chronic rheumatic diseases, it is virtually impossible to assess pain over long periods without quantitative data to estimate whether or not a patient's condition is improved, unchanged or worse over months to years.

A clinical science of pain assessment using patient self-report questionnaires has been developed over the last few decades to facilitate qualitative and quantitative assessment of pain status at any given time (17-27). Despite limitations which are intrinsic in any scientific measurement, pain questionnaires have proven valuable in the study of the mechanisms underlying the causes and control of pain.

In this essay, we review patient self-report questionnaires as quantitative

measures of pain. We summarize the results generated using these questionnaires in RA, osteoarthritis (OA), and fibromyalgia (FM). We also summarize data which reveal significant associations between pain scores and the physical examination, and radiographic and laboratory data. Such associations appear weaker, however, than the associations of pain scores with measures of functional and psychological status.

Assessment of pain using patient questionnaires

The Minnesota Multiphasic Personality Inventory and the McGill Pain Questionnaire

The Minnesota Multiphasic Personality Inventory (MMPI) (28) is an early patient self-report questionnaire. Although not strictly a pain questionnaire, the MMPI represents one of the first widely used patient questionnaires which gained acceptance over the last half-century.

The McGill Pain Questionnaire (17, 18) constituted a major advance in clinical research on pain. The questionnaire is complex and completion requires 15-20 minutes, even in its short form (29). Therefore, it is not easily administered in a non-research clinical setting, and simpler measures – such as a visual analog pain scale – have become more widely accepted for use in clinical research, clinical trials, and clinical care.

Visual analog pain scales

A visual analog pain scale was initially used in psychology by Freyd and others since the early 1900s. Huskisson and colleagues developed the use of a pain VAS in rheumatology through a series of investigations in the late 1970s (19, 20, 30-33), pointing out that "only the patient can measure [pain] severity" (30). These investigators described a variety of visual analog scales, including vertical and horizontal scales, and scales with equally spaced lines with the indications of mild, moderate and severe pain. They concluded that numbers should not be included. They also suggested that assistance from a health professional is helpful the first time a patient completes a visual ana-

log scale, but that generally self-reporting is adequate thereafter.

The standard visual analog scale is a 10 cm scale with a border on each side. To the left of the "0" mark appears the indication "No pain at all", and to the right of the "10" mark "Pain as bad as it could be". There are occasional distortions through photocopying and printing, but adjustments can be made so that the total score is 10.

Huskisson and colleagues also pointed out that an alternative descriptive pain relief scale – based on the indications "complete", "moderate", "slight" and "no pain" relief – was possible, but much less sensitive than the visual analog scale. A number of studies have established that data from self-report visual analog scales are reproducible (34, 35). In one study (35) an absolute visual analog scale was found to be more reproducible than a comparative visual analog scale.

With the development of optical scanning technology for the automated computer entry of scores, visual analog scales have been presented in a format of 21 small boxes or circles for patients to assess their pain from 0-10 (or 100). Although formal direct comparative studies have not been performed to analyze the results of automated optical scanning, they appear to have criterion validity. The visual analog pain scale has proven a great advance in the assessment of pain.

The Health Assessment Questionnaire (HAQ) and its derivatives: The Modified Health Assessment Questionnaire (MHAQ), Multi-Dimensional Health Assessment Questionnaire (MDHAQ), and Health Assessment Questionnaire (HAQ-II)

The HAQ was developed in the 1970s by Fries and associates and published in *Arthritis and Rheumatism* in 1980 (21). This questionnaire provided a milestone in the development of a methodology based on patient self-reporting to obtain information concerning functional disability, pain and global status. The HAQ includes visual analog scales for pain, as well as global status, although it was primarily designed to measure functional disability. Several

derivations of the HAQ have been developed, including a modified HAQ (M-HAQ) (36), a multidimensional HAQ (MDHAQ) (37), and the HAQII (38). The HAQ and its derivative versions are discussed in greater detail in other chapters in this supplement.

The Arthritis Impact Measurement Scales (AIMS)

The Arthritis Impact Measurement Scales (AIMS) was developed by Meenan and colleagues (22) to assess the physical, emotional and social well-being of individuals with arthritis, with scores for 9 categories: mobility, physical activity, social activity, social role, activities of daily living, pain, dexterity, anxiety, and depression. Each score is based on 4 to 6 items with response alternatives on Likert-format scales.

The AIMS pain category includes 4 questions: "During the past month, how often have you had severe pain from your arthritis ?"; "During the past month, how would you describe the arthritis pain you usually have ?"; "During the past month, how long has your morning stiffness usually lasted from the time you wake up ?" "During the past month, how often have you had pain in two or more joints at the same time ?"

The AIMS index has excellent psychometric validity and greater reliability than the HAQ and its derivatives, and has been used in clinical trials to document the sensitivity of patient questionnaires to changes in clinical status. However, the HAQ and its derivatives are more easily completed by patients and more easily scored by health professionals in clinical trials and in routine care, and used considerably more widely than the AIMS.

The Western Ontario McMaster (WOMAC)

The Western Ontario McMaster (WOMAC) questionnaire was developed, based on a survey of 100 patients with primary OA of the hip or knee, initially for use in OA clinical trials (23, 24). The WOMAC consists of 24 items: 5 to assess pain, 2 to assess stiffness and 17 to assess physical function. The questions concerning pain include "walking

on flat surfaces", "going up and down stairs", "at night while in bed", "sitting or lying", and "standing upright".

The WOMAC has been administered as a Likert Scale with 5 or 7 response options, and as a series of 10 cm visual analog scales. It has been extensively used in OA clinical trials throughout the world, and is regarded as the "gold standard" for the assessment of OA of the lower extremities.

Nottingham Health Profile (NHP)

The Nottingham Health Profile (NHP) was introduced in the early 1980s (25) as a generic health status questionnaire. Generic health status questionnaires were developed for use in many types of diseases, in contrast to the HAQ and AIMS, which were developed for use in patients with rheumatic diseases. The NHP is based on patient perceptions of health, and was designed to help people express how they feel when experiencing various states of ill health. The pain section of the NHP includes 8 questions concerning pain with the response alternatives "yes" and "no". The scoring includes a weighting of all "yes" responses with a certain population specific value, and adding the scores of individual questions together. The final score for each concept ranges from 0, indicating good health, to 100, which indicates poor health.

The NHP has been used in clinical research, although it also has a floor effect, i.e. it is poorly sensitive to small degrees of change in health (39). Furthermore, the questionnaire is long and incorporates a complicated scoring system, and hence is not practical for use in most clinical trials and routine clinical care.

Short-Form 36 (SF-36)

A 36-item questionnaire called the Short-Form 36 (SF-36) was developed by Ware and associates (26), initially for use in health policy surveys. The SF-36 assesses 8 health concepts: 1) physical activities; 2) social activities; 3) role activities; 4) bodily pain; 5) general mental health; 6) role activities because of emotional problems; 7) vitality; and 8) general health. The pain section includes two questions: "How

much bodily pain have you had during the past four weeks?" with response options 1 =none; 2= very mild; 3= mild; 4 = moderate; 5 = severe; 6 = very severe, and "During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework) ?" with response options 1 = not at all; 2 = a little bit; 3 = moderately; 4 = quite a bit; 5 = extremely.

The SF-36 has documented validity in normal healthy populations and diverse patient groups and is widely used. It is sensitive to changes in clinical status, and occupies a well-earned place in clinical trials. The scoring procedure is complex, with recoding of the responses according to instructions on a scale of 0-100, where 100 indicates "the best" and 0 "the worst" health situation, and calculation of the mean value for the recoded responses. The complicated scoring system makes the SF-36 unfeasible for use in standard clinical care.

Rheumatoid Arthritis Pain Scale (RAPS)

The Rheumatoid Arthritis Pain Scale (RAPS) (27) was developed to measure pain in adult patients with RA. The domains of RAPS include physiologic, affective, sensory-discriminative, and cognitive components, and consists of 24 items that are scored using a 7-point Likert scale ranging from "0 = never" to "6 = always", which is considered to represent a greater severity of pain. The RAPS, like the McGill pain questionnaire, clearly provides more information than a visual analog pain scale and is useful in clinical research, but less so outside specialized research settings.

Associations of pain and other measures of clinical status

The dominant paradigm of 20th century medicine is the "biomedical model", in which symptoms are regarded as being explainable by "objective" information from a physical examination, radiographs, imaging studies, laboratory tests, and other high technology procedures. This paradigm is expressed optimally in acute infectious diseases, in which a test identifies a pathogen, as

well as a drug to treat the patient. It is less perfectly expressed, but regarded as valid, in tests such as the cardiogram, or assays for serum glucose and rheumatoid factor, in which there is a strong probability of a diagnosis based on a positive finding in a test, but not an absolute correlation.

Analyses of scores for pain in RA indicate that there does exist a statistically significant correlation between pain scores and findings on radiographs and other objective measures. The assessment of pain and its correlation with traditional measures is discussed in greater detail below for the three most common rheumatic diseases – rheumatoid arthritis, osteoarthritis and fibromyalgia.

Pain in rheumatoid arthritis

Pain is the major reason for patients with RA to seek medical care (2-5, 40), although these patients experience many other symptoms such as joint swelling, tenderness, deformities, and morning stiffness. Furthermore, pain is the area of health in which most of patients with RA would like to see improvement (5, 40). Fries *et al.* (41, 42) showed that DMARDs are the best drugs in the long-term for relieving pain in RA. More frequent visits to rheumatologists were associated with greater improvements in pain and functional capacity over one year (43). Several recent clinical trials of DMARDs showed statistically significant improvement in pain over 6 to 24 months in treatment groups compared to groups that received control medications or placebo (1). Data concerning pain independent of other measures are not often reported in clinical trial results, as data are presented in the form of pooled indices such as the ACR response criteria.

Pain follows the same pattern of development as other parameters of disease activity in groups of patients with RA (44). After initial improvement, pain scores deteriorate over the years. Borg and Dawes (45) found that pain at the onset of the disease did not predict the pain level at 3 years, while in another study baseline pain in early disease was the only significant predictor of cumu-

Table I. Pain in selected longitudinal observational studies over 5 years or more in patients with rheumatoid arthritis.

	Mean disease duration at baseline, years	Duration of follow-up, years	Pain measure	Pain at baseline	Pain at evaluation	P-value for paired data
Egsmose *et al.*, 1995 (48)	0.8 (all < 2 years)	5	VAS, scale 0-100	Early: 44 Delayed: 51	17 40	< 0.001 < 0.02
Eberhardt and Fex, 1995 (49)	0.9 (all < 2 years)	5	VAS, scale 0-3	1.4	1.0	0.01
Lindqvist *et al.*, 2002 (50)		10 (included 168 patients)	VAS, Scale 0-3	1.2	1.2	NS
Muhlerin *et al.*, 1996 (51)	2.4 (range 0.2-12.0)	6	VAS, scale 0-100	47	32	< 0.005
Callahan *et al.*, 1997 (52)	9.7	5	VAS, scale 0-100	52	47	NS
Munro *et al.*, 1998 (53)	Range 0-2 years Range 2-5 years Range > 5 yrars	5	VAS, scale 0-3	1.7 1.8 1.9	1.1 1.5 1.5	< 0.01 0.313 0.039
Leirisalo-Repo *et al.*, 1999 (44)	0.7 (all < 2 years)	8-9	VAS, scale 0-100	43	17	
Uhlig *et al.*, 2000 (54)	2.2 (all < 4 years)	5	AIMS, pain scale 0-10	4.6	4.7	0.12
*Heiberg *et al.,* 2005 (55)	Disease duration was 13 years in patients with data at baseline, and 14 years in patients who were evaluated 7 years later.		VAS, scale 0-100	46	36	Significant; p-values not provided
**Pincus *et al.,* 2005 (47)	Median disease duration was 7 years in patients included in the first evaluation (1985) and 9 years in the second (2000)		VAS, scale 0-100	52	49	0.38

VAS: Visual Analog Scale for pain; AIMS: Arthritis Impact Measurement Scales; NS: not significant.
*Study was cross-sectional in part; **study was entirely cross-sectional.

lative pain over a year (46). A cross-sectional quantitative assessment of consecutive RA patients seen in 1985 versus 2000 in the same clinic indicated significantly better status in the joint count, radiographic, laboratory, patient questionnaire, and physical function measures in 2000 compared to 1985, but not in the pain scores (47). On the general population level, musculoskeletal pain is much more common now than 40 years ago (10).

Changes in pain levels over 5 years or more have been reported in long-term follow-up studies during the last decade (44, 47-55) (TableI). Overall, improvement in pain over 5 years is more significant in patients with early disease, while improvement in pain is less pronounced in patients with a longer disease duration at the outset of observation.

Although significant correlations can be seen between pain scores and the ESR and radiographs in patients with RA(Table II) (49, 56-64), r levels < 0.3 indicate that less than 10% of the variation in pain scores can be explained by the variation in radiographic scores or laboratory tests. In some studies, a stronger association has been seen between pain scores and joint swelling and tenderness, up to r = 0.4-0.6, indicating an explanation of 15%-35% of the variation in these measures by the variation in pain scores (57, 59). However, the strongest associations between pain scores and other variables in RA are seen in the scores for functional status, and in the scores for the psychological constructs of anxiety, depression, helplessness and lack of self-efficacy (Table II).

The absence of joint pain is included in the ACR remission criteria for RA(65). On a 100 mm VAS scale, < 10 has been interpreted as "no pain" (66). The 6th OMERACT conference suggested that a pain VAS < 20 mm is a useful cut-off point for pain (67). In a study that included patients with inflammatory and degenerative rheumatic conditions, 75% of patients considered their status as "acceptable" when their pain level was < 25mm (68). The estimated average level of pain was 20 on a 100 mm VAS in the elderly general population (69). Therefore, it appears that a score of "0" for pain is not a realistic goal, and a score of 10-25 on a 100 mm VAS may indicate normal status.

Pain in osteoarthritis
Pain is the most important determinant of disability in patients with OA (70-73). OAis not inevitably a progressive, degenerative disease, but rather a collection of heterogenous conditions with a dynamic course that may also include repair and periods of structural stability (74-76).
Structural changes such as cartilage

Table II. Correlation coefficients between pain and other measures in rheumatoid arthritis.

| | Pain measure | No. pts. | Correlation coefficients between pain and other measures | | | | | | | | | | |
			Age	Disease duration	Education	HAQ/ MHAQ	Patient global	Disease activity, pooled	ESR	SJC	TJC	AM	x-rays
Callahan *et al.*, 1987 (56)	VAS	385	-0.06	0.17	-0.14	0.55	0.53	-	0.24	0.33	0.34	0.24	-
Hagglund *et al.*, 1989 (57)	AIMS pain scale	53	-	-	-	-	-	-	0.14	0.45	-	-	-
Serbo and Jajic 1991 (58)	VAS	61	-	-	-	0.52	-	-	-	-	-	-	-
Stenström *et al.*,1992 (59)	VAS, activity induced pain	69	0.08	0.12	-	0.55	-	-	0.06	0.04	0.66	-	0.21
Hakala *et al.*, 1994 (60)	VAS	103	-	-	-	0.36	-	-	-	-	-	-	-
Smedstad *et al.*, 1995 (61)	VAS	238	-	-	-	-	-	-	-	-	0.06	-	-
Eberhardt and Fex,1995 (49)	VAS	67 (baseline)	-	-	-	0.44	-	-	-	-	-	-	-
		67 (at 5 years)	-	-	-	0.59	-	-	-	-	-	-	-
Rojkovich and Gibson, 1998 (62)	VAS	Daytime movement n=251	0.14	0.16	-	-	-	-	0.17	0.03	0.25	-	0.09
		Daytime rest n=232	0.19	0.02	-	-	-	-	0.18	0.03	0.25	-	0.16
		Nocturnal n=181	0.02	-0.13	-	-	-	-	0.25	0.21	0.36	-	0.08
Sokka *et al.*, 2000 (63)	VAS	141	-	-	-	0.65	-	-	-	-	-	-	0.01
Sarzi-Puttini *et al.*, 2002 (64)	VAS	105	0.04	0.07	-	0.42	0.57	-	0.38	0.05	0.04	0.43	0.06

–: not available.

VAS: visual analog scale; AIMS: Arthritis Impact Measurement Scales; HAQ: Health Assessment Questionnaire; MHAQ: Modified Health Assessment Questionnaire; ESR: erythrocyte sedimentation rate; SJC: swollen joint count; TJC: tender joint count; AM: morning stiffness.

Table III. Rationale to assess pain on a self-report questionnaire.

• Pain is the most prominent symptom in people with musculoskeletal disorders, and the most common reason for seeking medical help, but is rarely quantitatively measured or recorded in routine medical care.

• Since pain is a personal experience, estimated changes in levels of pain over long periods in patients with rheumatic diseases cannot be obtained from any source other than the patient.

• Several self-report questionnaires have been developed to measure pain and disability, and are well-documented tools for clinical trials.

• Short questionnaires that do not involve complicated scoring systems are the most feasible instruments for implementation as a part of routine care.

• The MDHAQ is a one-page, two-sided questionnaire which includes a visual analog pain scale. It can be completed by the patient as a self-report questionnaire in less than 10 minutes in the waiting room and can be scored by a health professional in less than 30 seconds.

loss, periarticular bone growth, osteophyte formation and sclerosis, are only weakly correlated with the severity of symptoms, including joint pain, use-related stiffness, and disability (77-79). A population-based study of OA derived from the US National Health and Nutrition Examination Survey (NHANES1) (80) indicated that 53% of individuals who had radiographic findings of stage 3-4 OA according to the Kellgren-Lawrence scale did not report any knee pain. Conversely about 85% of people who reported significant knee pain did not have significant radiographic abnormalities. Clearly a higher proportion of patients who seek clinical care because of pain have radiographic abnormalities, but the correlation is far from perfect.

Furthermore, De Bock *et al.* (81) found a low association between a patient's perception of pain and the physician's assessment of pain in patients with OA.

Although pain and structural damage in OA have been significantly correlated in groups of patients, many patients with minimal pain may have considerable structural damage while others may report extensive pain with little damage. Therefore, it appears reasonable to use patient questionnaires to document the amount of pain and disability in these patients, not only in clinical trials but also in standard clinical care. In a clinical trial comparing two study drugs in OA(82), differences in the results of treatment based on a VAS pain scale were as substantial as those based on the WOMAC scale, suggesting that a simple pain VAS is more than adequate in standard care (83).

Pain in fibromyalgia

FM is a syndrome characterized by widespread pain, which often involves all four quadrants of the body as well as the axial skeleton, and diffuse tenderness, but without evidence of structural damage such as that seen in OA or inflammation as seen in RA. The etiology and pathogenesis of pain in FM are unknown. Reports using positron emission tomography and functional magnetic resonance imaging (fMRI) suggest that a group of brain structures are activated during painful conditions (84-89).

One approach to identifying patients with FM is suggested by a study which reported higher scores for pain relative to scores for functional disability in about 50% of patients with FM compared to RA (90). Furthermore, the ratios of scores for fatigue on a VAS compared to MHAQ were also considerably higher in patients with FM compared to RA (91). Indeed, receiver operator curve data indicated that the results compared favorably with the use of ESR to distinguish patients with FM from patients with RA.

FM pain is persistent, and complete sustained remission of pain is rare (92). One study (93) which focused on chronic widespread pain in the population indicated that subjects with widespread pain who were more than 50 years old and reported daytime tiredness and somatic symptoms initially were most likely to have chronic widespread pain 7 years later; 77% of the subjects who reported chronic widespread pain initially also reported chronic widespread pain after 7 years. Although not clinically examined to establish the diagnosis, it appears likely that most of these subjects had FM.

The use of patient self-report questionnaires in routine clinical care

Differences exist between research questionnaires, which may be very lengthy and require complex scoring systems, and simple questionnaires designed for use in standard clinical care. In routine clinical care and for most clinical research, a visual analog scale score appears to capture just as much information as more elaborate questionnaires designed to measure pain, and is often more sensitive to changes in clinical trials and clinical care. The longer questionnaires are of value to analyze the mechanisms and pathophysiology of pain, but a VAS scale for pain appears to capture all of the information needed in a clinical study, including clinical trials.

The evidence that scores for pain are not directly correlated with objective data indicates that data concerning pain should be derived from the patient rather than from efforts to measure pain through objective measures. The most reproducible data on pain are derived from patients rather than from a health professional.

Conclusion

Pain is a personal experience. Therefore, information about pain can be obtained best from the patient. Several self-report questionnaires – including lengthy research questionnaires and a simple visual analog pain scale – have been developed over the last few decades, and all of them constitute well-documented tools for research purposes. It is recommended that a quantitative assessment of pain be carried out at each visit in routine rheumatology care, along with an assessment of functional disability, the global status, and other patient variables, using a patient self-report questionnaire, which provides clinically useful information to the doctor in treating patients with rheumatic conditions. A rationale to assess pain on a self-report questionnaire is presented in Table III.

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