MEASURING TREATMENT RESPONSE IN RHEUMATOID ARTHRITIS

The use of patient-reported outcome measures

Martine Veehof

Thesis, University of Twente, 2008
© Martine Veehof
ISBN 978-90-365-2686-9

Cover design: Gea Bisschop
Printed by: Gildeprint B.V., Enschede

The studies presented in this thesis were performed at the department of Psychology & Communication of Health & Risk (PCHR) of the University of Twente (Enschede) and the departments of Rheumatology of the "Medisch Spectrum Twente" hospital (Enschede) and the hospitals of "Ziekenhuisgroep Twente" (Almelo and Hengelo).

The rheumatology research program of PCHR is financially supported by the Dutch Arthritis Association (Reumafonds). Parts of this thesis were financially supported by an unrestricted educational grant by Schering-Plough, CVZ (Health Care Insurance Board), "Stichting Reumaonderzoek Twente", and the European Union.

MEASURING TREATMENT RESPONSE IN RHEUMATOID ARTHRITIS

The use of patient-reported outcome measures

PROEFSCHRIFT

ter verkrijging van
de graad van doctor aan de Universiteit Twente,
op gezag van de rector magnificus,
prof. dr. W.H.M. Zijm,
volgens besluit van het College voor Promoties
in het openbaar te verdedigen
op donderdag 26 juni 2008 om 15.00 uur

door

Martine Maria Veehof

geboren op 4 januari 1976
te Enschede

Dit proefschrift is goedgekeurd door de promotor, prof. dr. M.A.F.J. van de Laar en de assistent-promotor, dr. E. Taal.

Promotiecommissie:

Promotor:	Prof. dr. M.A.F.J. van de Laar
Assistent-promotor:	Dr. E. Taal
Leden:	Prof. dr. J. Dekker, Vrije Universiteit Amsterdam Prof. dr. J.M.W. Hazes, Erasmus Universiteit Rotterdam Prof. dr. J.M.J.P. van der Linden, Universiteit Maastricht Prof. dr. J.S. Rietman, Universiteit Twente Prof. dr. E.R. Seydel, Universiteit Twente

Contents

1

General introduction

Rheumatoid arthritis (RA) is a chronic inflammatory joint disease of unknown etiology that affects approximately 1% of the adult population, with a higher prevalence observed in both older age groups and women. The disease is characterized by symmetric inflammation of the joints, particularly of the wrists, fingers and feet, leading to pain, swelling, stiffness and, in the longer term, to joint damage. More general symptoms are fatigue and morning stiffness. All of these symptoms may contribute to reduced functional ability and dependency upon others, both of which are important concerns for patients with RA.[1-3] Furthermore, psychological and social well-being may be reduced. The course of RA is unpredictable, and there is wide variation in its severity. Periods of exacerbation and remission of disease activity may alternate.

Treatment of RA primarily focuses on relieving symptoms, reducing inflammation, controlling joint damage, and maintaining or improving functional ability and psychosocial functioning. Presently, the ultimate treatment goal is remission of disease activity. There are convincing data suggesting that a stable remission prevents joint damage and functional disability. Although the efficacy of pharmacological treatments has increased rapidly over the past years, RA is still a progressive disease that leads to joint damage and functional disability in a considerable number of patients.[4] Therefore, in addition to drug treatment, non-pharmacological treatment remains necessary for some patients in order to cope with the consequences of the disease.[5,6] Non-pharmacological treatment encompasses a wide range of interventions, including physical exercises, joint protection strategies, orthoses, assistive devices, and psychological and self-management interventions. To justify these interventions from health care and health economic perspectives, it is necessary to assess their effects. Obviously, and in contrast to recently developed medications, evidence regarding responses to non-pharmacological treatment interventions is limited.[6,7]

To assess the response to treatment, reliable, valid, and responsive outcome measures are required. A distinction can be made between clinical outcome measures, including laboratory and radiographic assessments, and patient-reported outcome measures. The latter have become increasingly important in assessing the effects of treatment as they assess the burden of the disease from the patient's perspective.

This thesis is divided into three main parts. The first part focuses on the psychometric properties of commonly used patient-reported outcome measures in RA. The second and third parts focus on the effects of non-pharmacological interventions, with an emphasis on the use of orthoses and assistive devices, respectively. In this general introduction, the major themes and aims of the thesis are elucidated, and an outline of the thesis is given.

PSYCHOMETRIC PROPERTIES OF PATIENT-REPORTED OUTCOME MEASURES

Patient-reported outcome measures

In the past, responses of patients with RA to treatment were primarily assessed by the physician through the use of clinical, laboratory, and radiographic signs of the disease. Since the 1980s, it has been recognized that the impact of this disease on human life encompasses more than the biological process itself. Although physiologic measures provide important information about the disease at the tissue or impairment level, they do not necessarily reflect its impact on the patient. Over the past two decades, the perspective of the patient has gained considerable attention. Many patient-reported outcome measures have been developed and used as a supplement to physiologic outcome measures. These measures provide information on how the patient perceives his or her disease and its physical, psychological, and social consequences. Currently, patient-reported outcome measures are generally accepted. They belong to the American College of Rheumatology (ACR) core set of outcome measures in RA clinical trials.[8]

Most patient-reported outcome measures focus on the assessment of functional ability or health status. Functional ability or functional status refers to the ability to perform activities associated with daily living such as eating, dressing, grooming, and toileting.[9] Health status is a broader concept. It encompasses several health dimensions including symptoms (e.g., pain, fatigue), physical function (e.g., functional ability), psychological function (e.g., emotions, mood), and social function (e.g., social activities, roles). The term health status is frequently used interchangeably with the term health-related quality of life (HRQOL).[9] A distinction can be made between generic and disease-specific instruments.[10,11] Generic outcome measures focus on general issues of health. They are developed for any population or condition and allow for comparisons across different populations and conditions. Examples of generic instruments that intend to measure health status are the Short Form-36 Health Survey (SF-36),[12-14] the Nottingham Health Profile (NHP),[15,16] and the Sickness Impact Profile (SIP).[17-20] Disease-specific instruments, on the other hand, are developed for a specific disease or condition and contain items that are particularly relevant to the disease or condition of interest. Examples of disease-specific instruments that are designed to measure functional ability and/or health status in patients with RA are the Arthritis Impact Measurement Scales 2 (AIMS2),[21,22] the Health Assessment Questionnaire Disability Index (HAQ-DI),[23-26] and the Impact of Rheumatic diseases on General health and Lifestyle (IRGL).[27,28] An example of an instrument that does not assess functional ability or health status is the Rheumatoid Arthritis Disease Activity Index (RADAI).[29,30] The

RADAI is a disease-specific outcome measure developed to assess patient-reported disease activity.

Psychometric properties of outcome measures

The selection of an outcome measure for use in clinical practice or research depends, among other things, on its psychometric properties. First, an instrument should be valid and reliable. Validity refers to the ability of an instrument to measure the underlying concept of interest. Reliability reflects the degree of consistency of the results over time, assuming that the characteristic being measured is stable over time (test-retest reliability), and the degree of consistency among the items within a scale (internal consistency). Second, an instrument should be responsive. Presently, there is no consensus on the best definition of responsiveness. Husted *et al* distinguished two major types of responsiveness: internal responsiveness and external responsiveness.[31] Internal responsiveness describes the ability of a measure to change over a pre-specified time frame, whereas external responsiveness describes the relationship between change in a measurement and change in a reference measurement. The responsiveness of an instrument is especially important to consider when the aim is to measure changes over time. Because disease-specific instruments contain items that are particularly relevant to a disease or condition, they have the potential to be more responsive to intervention-related changes over time than generic measures.[10,11,32]

Aim and outline of the first part of this thesis

The aim of the first part of this thesis is to examine the psychometric properties of commonly used patient-reported outcome measures in rheumatology. Data were collected as part of the ongoing Dutch Rheumatoid Arthritis Anti-TNF Monitoring (DREAM) study. The DREAM study is a multicentre study that was started in April 2003 to prospectively monitor and evaluate the use of anti-tumour necrosis factor (TNF) treatment in patients with RA. In the DREAM study, all patients with RA beginning anti-TNF treatment were seen every three months by trained research nurses who collected data on disease activity, functional status, and health status using clinical and patient-reported outcome measures.

In *Chapter 2*, a comparison is made between the internal and external responsiveness of the SF-36, which is the most widely used generic instrument to assess health status, and the disease-specific AIMS2 and HAQ-DI. The AIMS2 and the HAQ-DI are widely and internationally used measures to assess health status and functional ability, respectively, and contain health domains that are comparable to the SF-36. In *Chapter 3*, the psychometric properties of the RADAI are described, and a comparison is

made between the RADAI and its short form (RADAI-SF). For a description of the content of the instruments of study, we refer to Table 1.

Table 1 Health domains and subscales of the generic SF-36 and the disease-specific AIMS2, HAQ-DI, and RADAI

	SF-36	AIMS2	HAQ-DI	RADAI
Number of items	36	58	20*	5
Health domains and subscales				
Physical function	X	X	X	
mobility		O		
walking and bending		O		
hand and finger function		O		
arm function		O		
self care		O		
household activities		O		
Pain	X	X		
Social function	X	X		
social activities		O		
social support		O		
Work / role		X		
role limitations physical	X			
role limitations emotional	X			
Vitality	X			
Psychological function	X	X		
level of tension		O		
mood		O		
General health perception	X	X		
Disease activity				X

SF-36, Short-Form 36; AIMS2, Arthritis Impact Measurement Scales 2; HAQ-DI, Health Assessment Questionnaire Disability Index; RADAI, Rheumatoid Arthritis Disease Activity Index; X = health domain; O = subscale.
*The HAQ-DI consists of 20 items on the performance of daily activities and 4 additional items on the use of assistive devices and received help from others.

EFFECTS OF NON-PHARMACOLOGICAL TREATMENT, WITH AN EMPHASIS ON ORTHOSES AND ASSISTIVE DEVICES

Since there is no definite cure for most patients with RA, non-pharmacological treatment is frequently recommended in addition to drug treatment in order to deal with the consequences of the disease.[5,6,33] Non-pharmacological treatment encompasses a wide range of interventions. Common interventions are physical exercises, joint protection strategies, orthoses, assistive devices, and psychological and self-management interventions. In Table 2 these interventions are further explained. Generally, studies on the effects of non-pharmacological treatment interventions are scarce and of poor methodological quality.[6,33] Small sample sizes, poor descriptions of the intervention, variable and non-validated outcome measures, non-controlled study

designs, and non-blinded assessments are common methodological limitations. Therefore, it is difficult to draw firm conclusions regarding the effects of specific interventions. Taking into account these methodological flaws, the strongest evidence is observed for the effects of physical exercises and self-management interventions, followed by joint protection programs and specific orthoses. Evidence on the effectiveness of assistive devices is absent.[6] As the second and third part of this thesis focus on the effects of orthoses and assistive devices, respectively, both will be discussed in detail below.

Table 2 Common non-pharmacological treatment interventions

Intervention	Aim(s)
Physical exercises	To improve muscle strength, range of motion and general physical condition[34]
Joint protection strategies (e.g., altering methods to perform activities, energy conservation, use of orthoses and assistive devices)	To reduce pain, inflammation and the risk of developing deformities, by reducing internal and external stresses on involved joints[35,36]
Orthoses (e.g., wrist working splints, hand resting splints, orthopedic footwear)	To support, align, position, immobilize, prevent or correct deformity, assist weak muscles or improve function[37]
Assistive devices (e.g., cane, walker, wheelchair, special cutlery, dressing device, elevated toilet seat, grab bars in bathroom/toilet, special bed)	To improve functional ability and maintain or regain independence by reducing pain, overcoming joint limitations, and compensating for muscle weakness and endurance limitations[6]
Self-management interventions (e.g., disease and drug therapy education, exercises, joint protection education, pain and fatigue management, cognitive symptom management, effective communication)	To provide patients the skills and knowledge to manage the symptoms, treatment, physical and psychological consequences, and life style changes inherent in living with a chronic condition[38,39]
Psychological interventions (e.g., cognitive behavioral therapy, pain and stress management, sexual and relationship counseling, and psychotherapy)	To assist the patient and his or her family in coping with the chronic pain and emotional distress from the disease, and to enhance their independence and quality of life[33]

ORTHOSES

An orthosis is defined as "any medical device added to a person's body to support, align, position, immobilize, prevent or correct deformity, assist weak muscles or improve function".[37] The term orthosis is frequently used interchangeably with the terms splint and brace. Several types of orthoses can be distinguished, including

several types of wrist and finger splints as well as special shoes and insoles. In this thesis, we focus on the wrist working splint (see Figure 1), which is the most commonly prescribed wrist splint for patients with RA in the Netherlands.[40] In the literature, this type of splint is also called the functional wrist splint or the activity splint.

Wrist working splints immobilize, support, and stabilize the wrist. They allow for movement of the finger and thumb joints, enabling the performance of daily activities. They are prescribed to patients with wrist arthritis in order to reduce wrist pain and inflammation, and improve functional ability.[40,41]

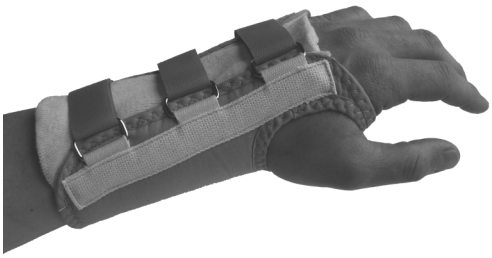

Figure 1 Example of a wrist working splint (Rolyan-D-Ring)

Evidence for the efficacy of wrist working splints

Evidence for the efficacy of wrist working splints is limited.[42,43] Most studies, which have been performed on the effects of wrist working splints, have focused on the effects measured immediately after provision of the splint.[44-50] Studies on the effects of wrist working splints measured after a period of splinting have been scarce.[47,49,51,52] Statistically significant positive effects on pain and splinted grip strength were only reported in one non-controlled study.[52] Controlled studies are mandatory to draw definite conclusions on the effects of wrist working splints after a period of splinting.[42,43,52]

A serious point of concern in efficacy studies is the adherence of the patients to the given treatment advice. Limited adherence affects outcome. Generally, adherence rates with splints have been shown to be low.[41,53] Knowledge of the determinants of adherence is necessary in order to improve adherence. Although many studies have been performed on the determinants of adherence to treatment regimens in general, studies on the determinants of adherence associated with the use of wrist working splints have been scarce.

Aim and outline of the second part of this thesis

The main aim of the second part of this thesis is to investigate the efficacy of the use of wrist working splints in patients with RA suffering from wrist arthritis after a period of splinting. In C*hapter 4*, the results of a qualitative descriptive study on the determinants of splint use are described. In-depth interviews were performed to gain insight into patients' motivations for and perceived barriers to using their wrist working splint. The results of this study were used to develop educational and behavioral strategies to increase adherence to the given splint wearing advice. These strategies were applied in a randomized controlled trial to investigate the effects of wrist working splints after four weeks of splint wearing. The results of this trial are presented in C*hapter 5.*

ASSISTIVE DEVICES

Assistive devices can be defined as "any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities".[54] The term "assistive devices" is frequently used interchangeably with terms such as assistive technology and adapted equipment. Examples of assistive devices used by patients with RA are mobility devices (e.g., crutches, wheelchairs), small tools for Activities of Daily Living (e.g., special cutlery, dressing devices), housing adaptations (e.g., grab bars in bathroom/toilet, raised toilet seats), and special furniture (e.g., special beds). They aim to improve functional ability by reducing pain, overcoming joint limitations, and compensating for muscle weakness and endurance limitations. Their ultimate goal is to allow patients with RA to maintain or regain independence.[6] Improved functional ability and independence may positively affect psychological well-being.

Evidence for the efficacy of assistive devices

The effects of assistive devices in patients with rheumatic conditions have been poorly studied. In a systematic review on the effects of occupational therapy in patients with RA, the investigators concluded there was insufficient data to determine the effectiveness of assistive devices.[42] The few non-controlled studies that have been performed on the effects of assistive devices have focused on physical functioning as an outcome measure. Both Thyberg *et al* and Nordenskiöld *et al* reported a reduction in perceived difficulty with daily activities when assistive devices were used.[55-57] The latter also reported a reduction in pain.[56,58] No attention has been given to the psychological and social effects of assistive devices among patients with arthritic conditions. This is

striking given the increasing interest in health status or HRQOL as an outcome measure in the assessment of the effects of treatment.

In the absence of evidence on the effects of assistive devices among patients with rheumatic conditions, prescription or possession seems to be primarily based upon common clinical practice and reimbursement rules in the health care system. Studies on the determinants of the possession of assistive devices among patients with rheumatic conditions have been scarce. Most studies have focused on the elderly. Only van der Esch *et al* reported on the determinants of the possession of assistive devices among rheumatic patients, although only walking devices were included.[59] Although the possession of assistive devices is suggested to be associated with societal mechanisms concerning prescription and reimbursement of assistive devices,[60] it is remarkable that the patient's country has never been investigated as a potential determinant. Better understanding of the mechanisms determining the possession of assistive devices and the effects of assistive devices is warranted in order to improve health care and HRQOL.

Aims and outline of the third part of this thesis

The aims of the third part of this thesis are to examine the determinants of the possession of assistive devices among patients with arthritic conditions, and to investigate the relationship between the possession of assistive devices and psychological well-being. A cross-sectional study was performed among patients with either RA or psoriatic arthritis (PsA) in both the Netherlands and Germany. In C*hapter 6*, the determinants of the possession of commonly used assistive devices are described, with an emphasis on the influence of the countries in which the patients resided. *Chapter 7* addresses the relationship between the possession of assistive devices and psychological well-being. In C*hapter 8*, the main findings of the preceding chapters (chapters 2 through 7) are summarized.

REFERENCES

1. Cornelissen PG, Rasker JJ, Valkenburg HA. The arthritis sufferer and the community: A comparison of arthritis sufferers in rural and urban areas. Ann Rheum Dis 1988;47:150-6.
2. Taal E, Rasker JJ, Seydel ER, Wiegman O. Health status, adherence with health recommendations, self-efficacy and social support in patients with rheumatoid arthritis. Patient Educ Couns 1993;20:63-76.
3. Melanson PM, Downe-Wamboldt B. Confronting life with rheumatoid arthritis. J Adv Nurs 2003;42:125-33.
4. Young A, Dixey J, Cox N, et al. How does functional disability in early rheumatoid arthritis (RA) affect patients and their lives? Results of 5 years of follow-up in 732 patients from the Early RA Study (ERAS). Rheumatology 2000;39:603-11.
5. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines of the Management of Rheumatoid Arthritis: 2002 Update. Arthritis Rheum 2002;46(2):328-46.
6. Vliet Vlieland TPM. Non-drug care for RA - is the era of evidence-based practice approaching? Rheumatology 2007;46:1397-404.
7. Hammond A. Rehabilitation in rheumatoid arthritis: a critical review. Musculoskeletal Care 2004;2:135-51.
8. Felson DT, Anderson JJ, Boers M, et al. The American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis clinical trials. Arthritis Rheum 1993;36:729-40.
9. Hawley DJ, Fontaine KR. Clinical care in the rheumatic diseases: Functional ability, health status, and quality of life. 3rd ed. Atlanta: Association of Rheumatology Health Professionals; 2006.
10. Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. Med Care 1989;27:S217-32.
11. Guyatt GH. A taxonomy of health status instruments. J Rheumatol 1995;22:1188-90.
12. Ware JE, Sherbourne CD. The MOS 36-item short-form health status survey (SF-36). 1. Conceptual framework and item selection. Med Care 1992;30:473-83.
13. Aaronson NK, Muller M, Cohen PD, et al. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. J Clin Epidemiol 1998;51:1055-68.
14. Ware JE Jr., Gandek B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. J Clin Epidemiol 1998;51:903-12.
15. Hunt SM, McEwen J. The development of a subjective health indicator. Sociol Health Illn 1980;2:231-46.
16. Erdman RA, Passchier J, Kooijman M, Stronks DL. The Dutch version of the Nottingham Health Profile: investigations of psychometric aspects. Psychol Rep 1993;72:1027-35.
17. Bergner M, Bobbitt RA, Carter WB, Gilson BS. The Sickness Impact Profile: development and final revision of a health status measure. Med Care 1981;19:787-805.

18. de Witte L, Jacobs H, van der Horst F, Luttik A, Joosten J, Philipsen H. De waarde van de Sickness Impact Profile als maat voor het functioneren van patiënten. Gezondheid & Samenleving 1987;8:120-7.
19. Jacobs HM, Luttik A, Touw-Otten FWMM, De Melker RA. De "Sickness Impact Profile": resultaten van een valideringsonderzoek van de Nederlandse versie. Ned Tijdschr Geneeskd 1990;134:1950-4.
20. de Bruin AF, de Witte LP, Stevens FCJ, Diederiks JPM. De bruikbaarheid van de sickness impact profile als generieke maat voor functionele toestand. T Soc Gezondheidsz 1992;70:160-70.
21. Meenan RF, Mason JH, Anderson JJ, Guccione AA, Kazis LE. AIMS2. The content and properties of a revised and expanded Arthritis Impact Measurement Scales Health Status Questionnaire. Arthritis Rheum 1992;35:1-10.
22. Riemsma RP, Taal E, Rasker JJ, Houtman PM, van Paassen HC, Wiegman O. Evaluation of a Dutch version of the AIMS2 for patients with rheumatoid arthritis. Br J Rheumatol 1996;35:755-60.
23. Fries JF, Spitz P, Kraines RG, Holman HR. Measurement of patient outcome in arthritis. Arthritis Rheum 1980;23:137-45.
24. Bruce B, Fries JF. The Stanford Health Assessment Questionnaire: A review of its history, issues, progress, and documentation. J Rheumatol 2003;30:167-78.
25. Bruce B, Fries JF. The Stanford Health Assessment Questionnaire: dimensions and practical applications. Health Qual Life Outcomes 2003;1:20.
26. Siegert CE, Vleming LJ, Vandenbroucke JP, Cats A. Measurement of disability in Dutch rheumatoid arthritis patients. Clin Rheumatol 1984;3:305-9.
27. Huiskes CJAE, Kraaimaat FW, Bijlsma JWJ. De ontwikkeling van de IRGL: een instrument om gezondheid te meten bij patiënten met reuma. Gedrag Gezond 1990;18:78-89.
28. Evers AW, Taal E, Kraaimaat FW, et al. A comparison of two recently developed health status instruments for patients with arthritis: Dutch-AIMS2 and IRGL. Arthritis Impact Measurement Scales. Impact of Rheumatic diseases on General health and Lifestyle. Br J Rheumatol 1998;37:157-64.
29. Stucki G, Liang MH, Stucki S, Bruhlmann P, Michel BA. A self-administered rheumatoid arthritis disease activity index (RADAI) for epidemiologic research. Psychometric properties and correlation with parameters of disease activity. Arthritis Rheum 1995;38:795-8.
30. Fransen J, Langenegger T, Michel BA, Stucki G. Feasibility and validity of the RADAI, a self-administered rheumatoid arthritis disease activity index. Rheumatology 2000;39:321-7.
31. Husted JA, Cook RJ, Farewell VT, Gladman DD. Methods for assessing responsiveness: a critical review and recommendations. J Clin Epidemiol 2000;53:459-68.
32. Hagen KB, Smedstad LM, Uhlig T, Kvien TK. The responsiveness of health status measures in patients with rheumatoid arthritis: Comparison of disease-specific and generic instruments. J Rheumatol 1999;26:1474-80.
33. Taal E, Bobiatynska E, Lloyd J, et al. Successfully living with chronic arthritis. The role of the allied health professionals. Clin Rheumatol 2006;25:189-97.
34. Vliet Vlieland TPM. Rehabilitation of people with rheumatoid arthritis. Clin Rheumatol 2003;17:847-61.

35. Melvin J, Jensen G. Rheumatologic Rehabilitation Series Volume 1: Assessment and Management. Bethesda: The American Occupational Therapy Association, Inc; 1998.
36. Hammond A. Joint protection education: what are we doing? Br J Occup Ther 1997;60:401-6.
37. Deshaies LD. Upper extremity orthoses. 5th ed. Baltimore: Lippincott, Williams and Wilkins; 2002.
38. Barlow J, Wright B, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Couns 2002;48:177-87.
39. Riemsma RP, Taal E, Kirwan JR, Rasker JJ. Patient education programmes for adults with rheumatoid arthritis. Br Med J 2002;325:558-9.
40. Spoorenberg A, Boers M, van der Linden S. Wrist splints in rheumatoid arthritis: a question of belief? Clin Rheumatol 1994;13:559-63.
41. Spoorenberg A, Boers M, van der Linden S. Wrist splints in rheumatoid arthritis: what do we know about efficacy and compliance? Arthritis Care Res 1994;7:55-7.
42. Steultjens EMJ, Dekker J, Bouter LM, van Schaardenburg D, van Kuyk MAH, van den Ende CHM. Occupational therapy for rheumatoid arthritis. Arthritis Care Res 2002;47:672-85.
43. Egan M, Brosseau L, Farmer M, et al. Splints / orthoses in the treatment of rheumatoid arthritis. Cochrane Database Syst Rev 2003:CD004018.
44. Nordenskiöld U. Elastic wrist orthoses. Reduction of pain and increase in grip force for women with rheumatoid arthritis. Arthritis Care Res 1990;3:158-62.
45. Pagnotta A, Baron M, Korner-Bitensky N. The effect of a static wrist orthosis on hand function in individuals with rheumatoid arthritis. J Rheumatol 1998;25:879-85.
46. Pagnotta A, Mazer B, Baron M, Wood-Dauphinee S. Static wrist splint use in the performance of daily activities by individuals with rheumatoid arthritis. J Rheumatol 2005;32:2136-43.
47. Stern EB, Ytterberg SR, Krug HE, Mullin GT, Mahowald ML. Immediate and short-term effects of three commercial wrist extensor orthoses on grip strength and function in patients with rheumatoid arthritis. Arthritis Care Res 1996;9:42-50.
48. Stern EB, Ytterberg SR, Krug HE, Mahowald ML. Finger dexterity and hand function: effect of three commercial wrist extensor orthoses on patients with rheumatoid arthritis. Arthritis Care Res 1996;9:197-205.
49. Kjeken I, Moller G, Kvien TK. Use of commercially produced elastic wrist orthoses in chronic arthritis: a controlled study. Arthritis Care Res 1995;8:108-13.
50. Anderson K, Maas F. Immediate effect of working splints on grip strength of arthritic patients. Aust Occ Ther J 1987;34:26-31.
51. Tijhuis GJ, Vliet Vlieland TPM, Zwinderman AH, Hazes JMW. A comparison of the futuro wrist orthosis with a synthetic thermolyn orthosis: utility and clinical effectiveness. Arthritis Care Res 1998;11:217-22.
52. Haskett S, Backman C, Porter B, Goyert J, Palejko G. A crossover trial of custom-made and commercially available wrist splints in adults with inflammatory arthritis. Arthritis Rheum 2004;51:792-99.
53. Belcon MC, Haynes RB, Tugwell P. A critical review of compliance studies in rheumatoid arthritis. Arthritis Rheum 1984;27:1227-33.

54. Scherer MJ. The change in emphasis from people to person: introduction to the special issue on Assistive Technology. Disabil Rehabil 2002;24:1-4.
55. Thyberg I, Hass UAM, Nordenskiöld U, Skogh T. Survey of the use and effect of assistive devices in patients with early rheumatoid arthritis: a two-year follow-up of women and men. Arthritis Rheum 2004;51:413-21.
56. Nordenskiöld U. Daily Activities in Women with Rheumatoid Arthritis. Aspects of patient education, assistive devices and methods for disability and impairment assessment. Scand J Rehabil Med Suppl 1997:1-72.
57. Nordenskiöld U, Grimby G, Dahlin-Ivanoff S. Questionnaire to evaluate the effects of assistive devices and altered working methods in women with rheumatoid arthritis. Clin Rheumatol 1998;17:6-16.
58. Nordenskiöld U. Evaluation of assistive devices after a course in joint protection. Int J Technol Assess Health Care 1994;10:293-304.
59. van der Esch M, Heijmans M, Dekker J. Factors contributing to possession and use of walking aids among persons with rheumatoid arthritis and osteoarthritis. Arthritis Rheum 2003;49:838-42.
60. Rogers JC, Holm MB. Assistive technology device use in patients with rheumatic disease: A literature review. Am J Occup Ther 1992;46:120-7.

2

Comparison of internal and external responsiveness of the generic Medical Outcome Study Short Form-36 (SF-36) with disease-specific measures in rheumatoid arthritis

M.M. Veehof
P.M. ten Klooster
E. Taal
P.L.C.M. van Riel
M.A.F.J. van de Laar

J Rheumatol 2008;35:610-7

ABSTRACT

Objective To examine the comparative internal and external responsiveness of the generic Medical Outcome Study Short Form-36 Health Survey (SF-36) and disease-specific measures in patients with rheumatoid arthritis (RA).

Methods Data were collected from 280 RA patients starting anti-tumor necrosis treatment. A total of 168 patients completed a questionnaire including the SF-36, the Arthritis Impact Measurement Scales 2 (AIMS2), the Health Assessment Questionnaire (HAQ), a visual analog scale for general health (VAS-GH), and an 11-point numerical rating scale for pain (NRS pain) at baseline and after 12 months. Internal responsiveness was evaluated with paired samples t-tests and standardized response means (SRMs). External responsiveness was investigated with receiver-operating characteristic statistics and Spearman rank-order correlation coefficients. A health transition item was used as the external indicator of change.

Results No significant differences in internal and external responsiveness were found between the SF-36 and disease-specific measures within the domains physical function, pain, and psychological function. In the domain social function, the SF-36 was more responsive than the AIMS2. In the domain general health, the SF-36 was less responsive (only internal) than the AIMS2 and VAS-GH.

Conclusion Our study showed comparable internal and external responsiveness of the SF-36 compared with disease-specific measures (AIMS2, HAQ, NRS pain) in all health domains, except social function and general health domains. The assumption that disease-specific measures are more responsive to detect intervention-related changes over time is not confirmed by our data.

INTRODUCTION

The impact of disease on human life encompasses more than the clinical manifestations of the disease or the pathophysiological process. Therefore, in the 1980s the concept of health-related quality of life (HRQOL) was introduced. HRQOL describes the influence of a disease on all dimensions of health, such as signs and symptoms, function, and psychological and social well-being. To date, the concept of HRQOL has been measured by self-administered questionnaires that provide information from the perspective of the patient. Measurement of HRQOL is warranted, on one hand, to better understand the effects of a disease and, on the other hand, to personalize treatment, assess a patient's progress, and evaluate the effects of treatment.

Several generic and disease-specific measures have been developed to assess HRQOL. Generic instruments focus on general issues of health and are developed for any population irrespective of disease or condition.[1,2] A commonly used generic measure is the Medical Outcome Study Short Form-36 Health Survey (SF-36).[3] Disease-specific instruments, on the other hand, are developed for a specific disease or condition and thus contain items of particular relevance to the disease or condition.[1,2] Disease-specific measures used frequently in rheumatology are the Arthritis Impact Measurement Scales 2 (AIMS2)[4] and the Health Assessment Questionnaire (HAQ).[5] Both generic and disease-specific measures have their own advantages and disadvantages. Where generic measures allow comparisons across different diseases and with the normal population, disease-specific measures have the potential to be more responsive to (intervention-related) changes over time.[1,2,6]

The responsiveness of a measure is an important factor to consider when deciding to use a generic or disease-specific measure in research or daily clinical care, particularly when the aim is to measure changes over time.[7,8] Presently, consensus on a definition of responsiveness and the best study design and analysis strategy to assess it is still lacking.[9-11] Husted, *et al*'s review concluded that 2 major types of responsiveness exist: internal responsiveness and external responsiveness. Internal responsiveness describes the ability of a measure to change over a prespecified timeframe, whereas external responsiveness describes the relationship between change in a measurement and change in a reference measurement of health status (external criterion).[9] Studies on the responsiveness of the SF-36 compared with disease-specific measures (AIMS2, HAQ) in patients with rheumatoid arthritis (RA) are scarce. The few studies that address this subject showed conflicting results and/or used different study designs and analysis strategies for responsiveness.[6,12-14] The aim of this study was to assess the internal and external responsiveness of the SF-36 in comparison with disease-specific instruments in patients with RA.

MATERIALS AND METHODS

Patients and study design

The data for this study were collected as part of the ongoing Dutch Rheumatoid Arthritis Anti-TNF Monitoring (DREAM) study, a register that started in April 2003 to prospectively monitor and evaluate the use of anti-tumor necrosis factor (TNF) in patients with RA in 12 hospitals in The Netherlands. Inclusion criteria for the DREAM study are: diagnosis of RA, active disease [Disease Activity Score 28 (DAS28) > 3.2)],[15] previous treatment with at least 2 antirheumatic drugs including methotrexate (MTX) at an optimal dose or intolerance for MTX, and no previous treatment with anti-TNF agents.

In the DREAM study, all RA patients starting anti-TNF treatment are seen every 3 months by independent trained research nurses, who collect data on patients' demographics (age, gender, disease duration), clinical condition (DAS28, functional class according to Steinbrocker), health status [SF-36, visual analog scale for general health (VAS-GH)], and functional status (HAQ). For this study, we used data from centers that additionally performed the AIMS2 and an 11-point numerical rating scale for pain (NRS pain) at baseline and at 3 and 12 months.

Measures

SF-36

The SF-36 is a generic health status questionnaire containing 36 items, 35 of which are combined into 8 scales: physical function, bodily pain, social function, mental health, general health, vitality, role physical, and role emotional.[3,16,17] Scale scores were calculated according to published scoring procedures[18] and range from 0 (poor health) to 100 (optimal health). Only scales that are identified by disease-specific measures were included for analysis: physical function, bodily pain, social function, mental health, and general health. The SF-36 has been shown to be a reliable, valid, and responsive questionnaire in patients with RA.[19-24] The responsiveness of the Dutch version of the SF-36 has never been investigated in RA.

SF-36: health transition item

A single item of the SF-36, the health transition item, gives an indication of perceived change in general health over the past 12 months. This item is scored on a 5-point scale ranging from "much better" to "much worse".[3,17] Fitzpatrick, *et al* provided evidence on the validity of the use of a transition item to assess change in health status in RA.[25]

AIMS2

The AIMS2 is a disease-specific measure developed for patients with arthritis.[4,26] This 57-item questionnaire contains 12 scales to assess 5 dimensions of health: physical function, symptom, affect, social interaction, and role. One additional item is included to assess general health perception. Component scores were calculated, ranging from 0 (good health) to 10 (poor health). The responsiveness of the Dutch AIMS2 has been investigated by Taal, *et al* and was shown to be satisfactory.[27]

HAQ

The HAQ is a disease-specific questionnaire developed to assess functional limitations in patients with rheumatic diseases.[5,28-30] The instrument contains 20 items on 8 domains of life (dressing, arising, eating, walking, hygiene, reach, grip, and common activities). The HAQ standard disability index (HAQ-DI) was calculated, which takes into account the use of aids and devices. The HAQ-DI yields a score from 0 to 3, with higher scores indicating more disability. The Dutch version of the HAQ has been shown to be a responsive measure.[31]

NRS pain

Arthritis pain was measured on an 11-point numerical rating scale with verbal anchors from "no pain" (0) to "extreme pain" (10). This scale is part of the Rheumatoid Arthritis Disease Activity Index (RADAI).[32]

VAS-GH

The VAS-GH is a 100 mm line with verbal anchors from "very good health status, could not be better" (0) to "very bad health status" (100). Patients were asked to rate their current general health.

Data analysis

Demographic and clinical characteristics and scores on outcome measures were described. Continuous data were presented as means with standard deviations (SD). Categorical data were presented as proportions. The Kolmogorov–Smirnov test was used to test the normality of the distribution of the scores on the outcome measures. In accordance with Husted, *et al*, we assessed the internal and external responsiveness of the SF-36 and corresponding disease-specific measures.[9] Since high scores on SF-36 indicate good health, while high scores on AIMS2, HAQ, NRS pain, and VAS-GH indicate poor health, we multiplied the change scores of SF-36 with -1, to facilitate comparison among the instruments. Analyses were performed using the statistical packages SPSS 12.0, S-PLUS 6.1, and MedCalc 8.1.

Internal responsiveness

The paired samples t-test (for the normally distributed measures) and Wilcoxon signed-rank test (for the non-normally distributed measures) were used to assess the ability of the measures to assess changes between baseline and 12-month followup assessments. Change was considered significant when $p \leq 0.05$. Further, standardized response means (SRMs) were calculated. The SRM is calculated as the mean change score divided by the standard deviation of that change score and is seen as an indicator of the ability to distinguish "signal" from "noise".[33,34] In accordance with the criteria of Cohen,[35] a SRM between 0.20 and 0.49 can be interpreted as a small effect, a SRM between 0.50 and 0.79 as a moderate effect, and a SRM equal to or greater than 0.80 as a large effect.[9] We applied a bootstrap procedure to obtain 95% confidence intervals (95% CI) for the SRMs.[36] Bootstrapping consists of resampling with replacement. We selected 1000 samples (each of 168 observations) with replacement and calculated the SRM for each sample. The SRMs of the bootstrap samples were ordered from lowest to highest and the 95% CI for the SRMs were obtained by reading the 25th and 975th observations. The comparative responsiveness of the SF-36 and the disease-specific measures was determined by comparing the SRMs and calculating a 95% CI for the difference in SRMs, using the 1000 bootstrap samples. SRMs were considered significantly different if the interval did not contain the value zero.[37]

External responsiveness

Receiver-operating characteristic (ROC) curves and Spearman rank-order correlation coefficients with 95% CI were computed to describe the relationship between changes in the measure and an external indicator of change. We used the health transition item of the SF-36 as external indicator. For the ROC curves this item was coded as a binary variable. Patients who judged their health after 12 months of anti-TNF treatment as "much better" or "somewhat better" were classified into the "improved health" group. Patients who judged their health as "about the same", "somewhat worse", or "much worse" were classified into the "non-improved health" group. The areas under the ROC curves (AUCs) were calculated to quantify the probability of the measures to correctly classify patients as improved or non-improved. The areas range from 0.5 (no accuracy in distinguishing improvers from non-improvers) to 1.0 (perfect accuracy). The comparative accuracy of the SF-36 and the disease-specific measures was determined by comparing the AUCs using the Wilcoxon signed-rank test.[38] A 95% CI was computed for the difference in AUCs. The areas were considered significantly different if the interval did not contain the value zero.

RESULTS

Patient characteristics

Two hundred and eighty patients were included in this study. Of them, 168 (60%) completed all the questionnaires at baseline and after 12 months of followup. There were no significant differences in demographic (age, gender) and baseline clinical characteristics (disease duration, DAS28, Steinbrocker functional class) between patients who did and who did not complete all questionnaires at both measurement times (data not shown). Data from patients who did not complete all questionnaires at baseline and after 12 months of followup were excluded from further analyses.

At baseline, 71% of the 168 patients were female and mean age and mean disease duration were 54.2 (SD 12.6) and 10.2 (SD 9.2) years, respectively. Mean DAS28 was 5.5 (SD 1.2), indicating high disease activity at study entry. The majority of the patients (81%) had mild disability and were classified into Steinbrocker functional class II.

Internal responsiveness

In Table 1 mean scores at baseline and 12-month changes are described. Results are shown for each domain of health separately. All measures showed significantly improved scores after 12 months of TNF-blocking treatment.

In Table 2 SRMs and 95% CI are presented. Within the domains physical function, pain, and psychological function the SRMs were quite similar and no significant differences were found between the SF-36 and the disease-specific measures (AIMS2, HAQ, NRS pain). A significant difference was found only between the AIMS2 pain scale and the NRS for pain. The AIMS2 was more responsive to detect improvement in pain than the NRS (difference in SRM = 0.20, 95% CI 0.02-0.38). Within the domains social function and general health the SRMs were quite different, and significant differences were found between the SF-36, the AIMS2, and the VAS-GH. In the domain social function, the SF-36 was more responsive than the AIMS2 (difference in SRM = 0.29, 95% CI 0.07-0.54). In the domain general health, the SF-36 was less responsive than the AIMS2 (difference in SRM = 0.43, 95% CI 0.21-0.62) and the VAS-GH (difference in SRM = 0.44, 95% CI 0.22-0.62).

External responsiveness

The health transition item indicated that the majority of the patients judged their health somewhat (30.2%) or much (30.8%) improved after 12 months of anti-TNF treatment. The remainder judged their health about the same (21.9%), somewhat worse (14.8%), or much worse (2.4%).

Table 1 Mean scores at baseline and 12-month changes for SF-36 and disease-specific measures. Values are means (SD)

Health domain	Baseline	12-month Changes
Physical function, n = 151		
SF-36 physical function	37.12 (22.06)	14.56 (19.49)
AIMS2 physical function	3.11 (1.63)	-0.75 (1.24)
HAQ-DI	1.43 (0.57)	-0.28 (0.48)
Pain, n = 167		
SF-36 bodily pain	37.91 (18.21)	18.53 (21.38)
AIMS2 symptom	6.62 (2.19)	-2.17 (2.29)
NRS pain	5.74 (2.59)	-2.30 (3.05)
Social function, n = 161		
SF-36 social function	65.02 (22.62)	11.26 (23.02)
AIMS2 social interaction	3.85 (1.37)	-0.22 (1.11)
Psychological function, n = 158		
SF-36 mental function	71.25 (17.07)	6.80 (14.72)
AIMS2 affect	3.50 (1.60)	-0.67 (1.32)
General health, n = 164		
SF-36 general health	44.42 (18.83)	4.03 (16.89)
AIMS2 general health	6.67 (2.31)	-1.68 (2.51)
VAS-GH	58.94 (21.99)	-18.84 (27.79)

All scores are significantly improved at 12-month followup assessments ($p \leq 0.05$). SF-36, Medical Outcome Study Short Form-36; AIMS2, Arthritis Impact Measurement Scales 2; HAQ-DI, Health Assessment Questionnaire Disability Index; NRS, numerical rating scale; VAS-GH, visual analog scale for general health.

Table 2 Responsiveness statistics for SF-36 and disease-specific measures

	Internal responsiveness	External responsiveness	
Health Domain	SRM (95% CI)	AUC (95% CI)	Spearman's rho
Physical function, n = 151			
SF-36 physical function	0.75 (0.59 to 0.94)	0.72 (0.64 to 0.81)	0.48 (0.34 to 0.59)*
AIMS2 physical function	0.61 (0.45 to 0.77)	0.75 (0.68 to 0.83)	0.51 (0.38 to 0.62)*
HAQ-DI	0.59 (0.37 to 0.75)	0.72 (0.64 to 0.81)	0.52 (0.40 to 0.63)*
Pain, n = 167			
SF-36 bodily pain	0.87 (0.68 to 1.04)	0.75 (0.67 to 0.81)	0.45 (0.32 to 0.56)*
AIMS2 symptom	0.95 (0.76 to 1.16)†	0.77 (0.70 to 0.83)	0.50 (0.38 to 0.61)*
NRS pain	0.75 (0.57 to 0.93)†	0.71 (0.64 to 0.78)	0.38 (0.24 to 0.50)*
Social function, n = 161			
SF-36 social function	0.49 (0.32 to 0.69)†	0.69 (0.61 to 0.76)†	0.33 (0.18 to 0.46)*
AIMS2 social interaction	0.20 (0.02 to 0.36)†	0.54 (0.46 to 0.62)†	0.07 (-0.09 to 0.22)
Psychological function, n = 158			
SF-36 mental function	0.46 (0.28 to 0.61)	0.68 (0.60 to 0.75)	0.33 (0.18 to 0.46)*
AIMS2 affect	0.50 (0.35 to 0.65)	0.71 (0.63 to 0.78)	0.36 (0.21 to 0.48)*
General health, n = 164			
SF-36 general health	0.24 (0.06 to 0.39)†‡	0.69 (0.61 to 0.76)	0.39 (0.25 to 0.51)*
AIMS2 general health	0.67 (0.51 to 0.85)†	0.75 (0.68 to 0.81)	0.43 (0.29 to 0.55)*
VAS-GH	0.68 (0.50 to 0.84)‡	0.75 (0.67 to 0.81)	0.45 (0.32 to 0.56)*

SRM, standardized response mean; AUC, area under the curve. For definitions of measures, see legend to Table 1.

†,‡ significant difference between measures; *$p \leq 0.01$.

Results of the ROC analyses are shown in Table 2 and Figure 1. The AUCs were quite similar within the dimensions physical function, pain, psychological function, and general health, and no significant differences were found between the SF-36 and disease-specific measures. Differences were more pronounced in the social function dimension. Comparison of the AUCs of the SF-36 and the AIMS2 showed significant differences. The SF-36 had higher accuracy than the AIMS2 to distinguish improvers from non-improvers (difference in AUC = 0.15, 95% CI 0.04-0.27, p = 0.01). Results of the correlation analyses (Table 2) confirmed this difference between the SF-36 and the AIMS2. Only the AIMS2 social interaction scale was not significantly correlated with the health transition item.

DISCUSSION

This longitudinal observational study among patients with RA who were starting anti-TNF treatment showed comparable internal and external responsiveness of the generic SF-36 compared with the disease-specific AIMS2 and HAQ within the domains physical function, pain, and psychological function. In the social function domain the SF-36 was more responsive than the AIMS2. In the general health domain the SF-36 was less responsive (just internal) than the AIMS2 and the VAS-GH.

We followed the suggestion of Husted, *et al* and differentiated between internal and external responsiveness.[9] Internal responsiveness, evaluated with the SRM, describes the ability of the measures to detect improvement in HRQOL after 12 months of anti-TNF treatment. The absolute value of the SRM is sample-dependent. This means that the SRM is dependent on the effectiveness of treatment and the variation in change scores. The lowest SRM scores were found in the dimensions social function and psychological function. This may suggest lack of responsiveness of these scales to detect changes in psychological and social function. On the other hand, anti-TNF treatment may have less influence on psychosocial function than on physical function and pain. The responsiveness of these scales needs to be investigated in more detail. External responsiveness describes the relationship between change in the measures and change in an external standard. In contrast to internal responsiveness, external responsiveness is not sample-dependent, but is dependent on the external criterion for judging clinical change. In the absence of a gold standard, we used a self-reported health transition item as external criterion of change, as suggested by Fortin, *et al*.[39] A health transition question describes the magnitude and direction of change in health status over a given time period. The use of self-reported change in health status as indicator of clinical change limits the value of our results. The judgement of change is difficult for the patient and may be determined by psychological factors (e.g., mood,

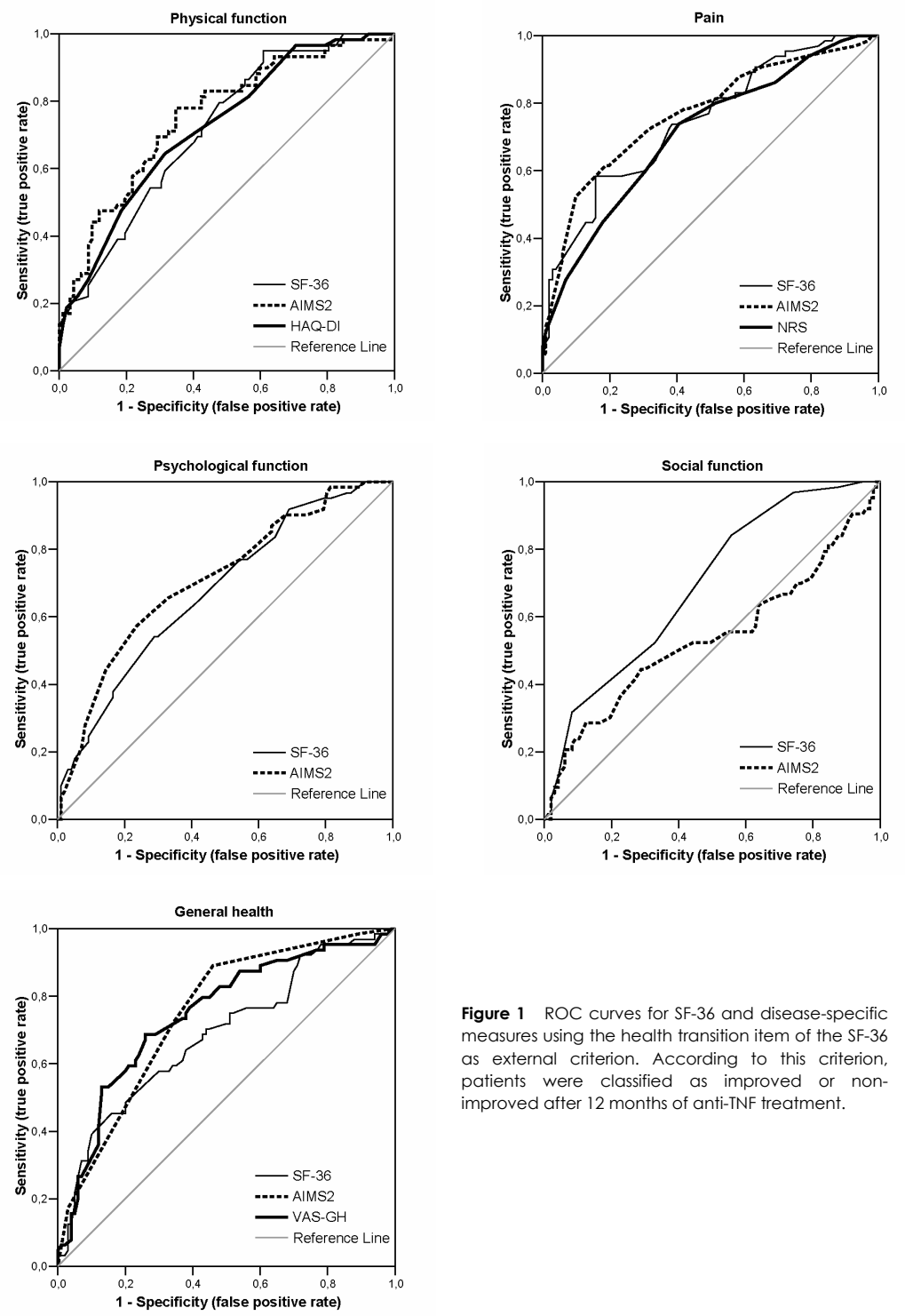

Figure 1 ROC curves for SF-36 and disease-specific measures using the health transition item of the SF-36 as external criterion. According to this criterion, patients were classified as improved or non-improved after 12 months of anti-TNF treatment.

expectations) and current health state.[40,41] On the other hand, self-reported change in health status is a widely accepted external criterion in the evaluation of the responsiveness of HRQOL measures. It has been used in a number of studies and conditions, including rheumatologic conditions.[9,42-51] Self-reported change in health status takes into account the patients' perspective, which is a main focus of HRQOL measures, and is more likely to correlate with HRQOL measures compared with clinical variables.[52,53]

To assess internal and external responsiveness, we used different indices of responsiveness. All methods produced a consistent ranking of the comparative responsiveness of the measures within each domain of health, except for the physical function domain. This means that all methods indicated the same measure as most or least responsive. We found differences, however, in the magnitude of the differences between the measures within a health domain across the indices of responsiveness. In the general health domain, significant differences were found in internal responsiveness between the SF-36, the AIMS2, and the VAS-GH. These differences did not appear using external indices of responsiveness. The same applied to significant differences found in internal responsiveness between the AIMS2 pain scale and the NRS for pain. These results support the conclusion of previous studies that the magnitude of responsiveness is highly dependent on methodological issues such as the definition of responsiveness (e.g., internal versus external responsiveness or general change versus clinically important change), the method to assess responsiveness, the external criterion of change, the study sample, and the effectiveness of the treatment.[9,10,54] Therefore, the absolute values of responsiveness indices cannot be easily compared across studies and should be interpreted with caution.

Our study is one of the first to investigate the comparative responsiveness of the SF-36, the AIMS2, and the HAQ in a cohort of patients receiving a treatment of proven efficacy. Anti-TNF agents have been shown to improve HRQOL in RA patients.[55-59] Most previous studies did not specifically aim at changes after an intervention of known efficacy but followed a group of patients over time.[6,13,14] Changes in HRQOL were less pronounced in these studies, which used disease activity (mostly self-reported) as the external criterion to distinguish patients whose health situation did not change from patients whose situation did improve or deteriorate. Results, which were presented for each subgroup separately, corresponded with our findings with regard to the comparative responsiveness of the measures. However, information on the dimensions social function[6,13] and general health[6,13,14] was not included in these previous studies. Because of differences in methodology, the absolute responsiveness values in these studies cannot be compared with our values. One previous study also focused on the responsiveness of the SF-36 versus a disease-specific instrument following an

intervention of proven efficacy.[12] Wells, *et al* investigated the responsiveness of the SF-36 and the HAQ in patients starting MTX therapy.[12] In contrast to our findings, they reported a moderate SRM for the SF-36 and a large SRM for the HAQ. These findings, however, were based on a small sample size, and the statistical significance of the difference was not reported. Moreover, they reported on the physical component summary score of the SF-36 only, and not on the physical scale score.

In our study, neither the generic nor the disease-specific instrument was consistently the most responsive measure within the 5 dimensions of health. The assumption that disease-specific measures are more responsive to detect improvements due to RA-specific interventions is not confirmed by our data. The choice for the generic SF-36 or the disease-specific AIMS2 and HAQ depends among other things on the health domain one is interested in. For most purposes the SF-36 is a suitable evaluation instrument. However, if general health is the primary domain of interest, the AIMS2 and VAS-GH are preferred above the SF-36. Moreover, if a specific aspect of physical function, such as arm and hand function, is the primary domain of interest, the AIMS2 and the HAQ are recommended. A disadvantage of the SF-36 is that the physical scale may not reveal all aspects of physical health relevant to arthritis patients. For instance, only few activities related to upper extremity function are included.[20] So, besides the health domain of interest, the specific concepts measured within a health domain should be considered when choosing between the generic SF-36 or the disease-specific AIMS2 and HAQ.

Our study showed comparable internal and external responsiveness of the generic SF-36 in comparison with the disease-specific AIMS2 and HAQ within the physical function, pain, and psychological function domains. In the social function and general health domains the SF-36 was, respectively, more and less responsive than the disease-specific measures. The hypothesis that disease-specific measures are more responsive to detect intervention-related changes over time is not confirmed by our study.

ACKNOWLEDGEMENTS

We thank T. van Gaalen, W. Kievit, and P. Welsing for their contribution to the organisation of the study and data management. We thank the following rheumatologists and research nurses for their assistance in patient recruitment and data collection: J. Alberts, C. Allaart, A. ter Avest, P. Barrera Rico, T. Berends, H. Bernelot Moens, K. Bevers, C. Bijkerk, , A. van der Bijl, J. de Boer, A. Boonen, E. ter Borg, E. Bos, B. Botha, A. Branten, F. Breedveld, H. van den Brink, J. Bürer, G. Bruyn, H. Cats, M. Creemers, J. Deenen, C. De Gendt, K. Drossaers-Bakker, A. van Ede, A. Eijsbouts, S. Erasmus, M. Franssen, I. Geerdink, M. Geurts, E. Griep, E. de Groot, C. Haagsma, H.

Haanen, J.Harbers, A. Hartkamp, J. Haverman, H. van Heereveld, A. van de Helm-van Mil, I. Henkes, S. Herfkens, M. Hoekstra, K. van de Hoeven, D.M. Hofman, M. Horbeek, F. van den Hoogen, P. Houtman, T. Huizinga, H. Hulsmans, P. Jacobs, T. Jansen, M. Janssen, M. Jeurissen, A. de Jong, Z. de Jong, M. Kleine Schaar, G. Kloppenburg, H. Knaapen, P. Koelmans, M. Kortekaas, B. Kraft, A. Krol, M. Kruijssen, D. Kuiper-Geertsma, I. Kuper, R. Laan, J. van de Laan, J. van Laar, P. Lanting, H. Lim, S. van der Linden, A. Mooij, J. Moolenburgh, N. Olsthoorn, P. van Oijen, M. van Oosterhout, J. Oostveen, P. van 't Pad Bosch, K. Rasing, K. Ronday, D. de Rooij, L. Schalkwijk, P. Seys, P. de Sonnaville, A. Spoorenberg, A. Stenger, G. Steup, W. Swen, J. Terwiel, M. van der Veen, M. Veerkamp, C. Versteegden, H. Visser, C. Vogel, M. Vonk, H. Vonkeman, A.Westgeest, H. van Wijk, N. Wouters.

REFERENCES

1. Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. Med Care 1989;27:S217-32.
2. Guyatt GH. A taxonomy of health status instruments. J Rheumatol 1995;22:1188-90.
3. Ware JE, Sherbourne CD. The MOS 36-item short-form health status survey (SF-36). 1. Conceptual framework and item selection. Med Care 1992;30:473-83.
4. Meenan RF, Mason JH, Anderson JJ, Guccione AA, Kazis LE. AIMS2. The content and properties of a revised and expanded Arthritis Impact Measurement Scales Health Status Questionnaire. Arthritis Rheum 1992;35:1-10.
5. Fries JF, Spitz P, Kraines RG, Holman HR. Measurement of patient outcome in arthritis. Arthritis Rheum 1980;23:137-45.
6. Hagen KB, Smedstad LM, Uhlig T, Kvien TK. The responsiveness of health status measures in patients with rheumatoid arthritis: Comparison of disease-specific and generic instruments. J Rheumatol 1999;26:1474-80.
7. Guyatt G, Walter S, Norman G. Measuring change over time: assessing the usefulness of evaluative instruments. J Chron Dis 1987;40:171-78.
8. Guyatt GH, Kirshner B, Jaeschke R. Measuring health status: what are the necessary measurement properties? J Clin Epidemiol 1992;45:1341-5.
9. Husted JA, Cook RJ, Farewell VT, Gladman DD. Methods for assessing responsiveness: a critical review and recommendations. J Clin Epidemiol 2000;53:459-68.
10. Terwee CB, Dekker FW, Wiersinga WM, Prummel MF, Bossuyt PMM. On assessing responsiveness of health-related quality of life instruments: Guidelines for instrument evaluation. Qual Life Res 2003;12:349-62.
11. Stratford PW, Riddle DL. Assessing sensitivity to change: choosing the appropriate change coefficient. Health Qual Life Outcomes 2005;3:23.
12. Wells G, Boers M, Shea B, et al. Sensitivity to change of generic quality of life instruments in patients with rheumatoid arthritis: preliminary findings in the generic health OMERACT study. J Rheumatol 1999;26:217-21.
13. Haavardsholm EA, Kvien TK, Uhlig T, Smedstad LM, Guillemin F. A comparison of agreement and sensitivity to change between AIMS2 and a short form of AIMS2 (AIMS2-SF) in more than 1,000 rheumatoid arthritis patients. J Rheumatol 2000;27:2810-6.
14. Salaffi F, Stancati A, Carotti M. Responsiveness of health status measures and utility-based methods in patients with rheumatoid arthritis. Clin Rheumatol 2002;21:478-87.
15. Prevoo ML, van 't Hof MA, Kuper HH, van Leeuwen MA, van de Putte LB, van Riel PL. Modified disease activity scores that include twenty-eight-joint counts. Development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. Arthritis Rheum 1995;38:44-8.
16. Aaronson NK, Muller M, Cohen PD, et al. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. J Clin Epidemiol 1998;51:1055-68.
17. Ware JE, Gandek B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. J Clin Epidemiol 1998;51:903-12.

18. Ware JE, Kosinski M, Keller SD. SF-36 physical and mental summary scales: a user's manual. Boston: The Health Institute, New England Medical Center; 1994.
19. Koh ET, Leong KP, Tsou IYY, Lim VH, Pong LY. The reliability, validity and sensitivity to change of the Chinese version of SF-36 in oriental patients with rheumatoid arthritis. Rheumatology 2006;45:1023-28.
20. Kvien TK, Kaasa S, Smedstad LM. Performance of the Norwegian SF-36 Health Survey in patients with rheumatoid arthritis. II. A comparison of the SF-36 with disease-specific measures. J Clin Epidemiol 1998;51:1077-86.
21. Ruta DA, Hurst NP, Kind P, Hunter M, Stubbings A. Measuring health status in British patients with rheumatoid arthritis: reliability, validity and responsiveness of the short form 36-item health survey (SF-36). Br J Rheumatol 1998;37:425-36.
22. Loge JH, Kaasa S, Hjermstad MJ, Kvien TK. Translation and performance of the Norwegian SF-36 Health Survey in patients with rheumatoid arthritis. I. Data quality, scaling assumptions, reliability, and construct validity. J Clin Epidemiol 1998;51:1069-76.
23. Talamo J, Frater A, Gallivan S, Young A. Use of the short form 36 (SF36) for health status measurement in rheumatoid arthritis. Br J Rheumatol 1997;36:463-9.
24. Tuttleman M, Pillemer SR, Tilley BC, et al. A cross sectional assessment of health status instruments in patients with rheumatoid arthritis participating in a clinical trial. J Rheumatol 1997;24:1910-5.
25. Fitzpatrick R, Ziebland S, Jenkinson C, Mowat A, Mowat A. Transition questions to assess outcomes in rheumatoid arthritis. Br J Rheumatol 1993;32:807-11.
26. Riemsma RP, Taal E, Rasker JJ, Houtman PM, van Paassen HC, Wiegman O. Evaluation of a Dutch version of the AIMS2 for patients with rheumatoid arthritis. Br J Rheumatol 1996;35:755-60.
27. Taal E, Rasker JJ, Riemsma RP. Sensitivity to change of AIMS2 and AIMS2-SF components in comparison to M-HAQ and VAS-pain. Ann Rheum Dis 2004;63:1655-58.
28. Bruce B, Fries JF. The Stanford Health Assessment Questionnaire: A review of its history, issues, progress, and documentation. J Rheumatol 2003;30:167-78.
29. Bruce B, Fries JF. The Stanford Health Assessment Questionnaire: dimensions and practical applications. Health Qual Life Outcomes 2003;1:20.
30. Siegert CE, Vleming LJ, Vandenbroucke JP, Cats A. Measurement of disability in Dutch rheumatoid arthritis patients. Clin Rheumatol 1984;3:305-9.
31. van der Heijde DM, van Riel PL, van de Putte LB. Sensitivity of a Dutch Health Assessment Questionnaire in a trial comparing hydroxychloroquine vs. sulphasalazine. Scand J Rheumatol 1990;19:407-12.
32. Stucki G, Liang MH, Stucki S, Bruhlmann P, Michel BA. A self-administered rheumatoid arthritis disease activity index (RADAI) for epidemiologic research. Psychometric properties and correlation with parameters of disease activity. Arthritis Rheum 1995;38:795-8.
33. Katz JN, Larson MG, Phillips CB, Fossel AH, Liang MH. Comparative measurement sensitivity of short and longer health status instruments. Med Care 1992;30:917-25.
34. Liang MH. Evaluating measurement responsiveness. J Rheumatol 1995;22:1191-2.
35. Cohen J. Statistical power analysis for the behavioural sciences. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.

36. Efron B, Gong G. A leisurely look at the bootstrap, the jackknife, and cross-validation. Am Statistician 1983;37:36-48.
37. Stratford PW, Kennedy DM. Does parallel item content on WOMAC's pain and function subscales limit its ability to detect change in functional status? BMC Musculoskelet Disord 2004;5:17.
38. Hanley JA, McNeil BJ. A method of comparing the areas under receiver operating characteristic curves derived from the same cases. Radiology 1983;148:839-43.
39. Fortin PR, Stucki G, Katz JN. Measuring relevant change: an emerging challenge in rheumatologic clinical trials. Arthritis Rheum 1995;38:1027-30.
40. Norman GR, Stratford P, Regehr G. Methodological problems in the retrospective computation of responsiveness to change: the lesson of Cronbach. J Clin Epidemiol 1997;50:869-79.
41. Guyatt G, Norman G, Juniper E, Griffith LE. A critical look at transition ratings. J Clin Epidemiol 2002;55:900-8.
42. Brazier JE, Harper R, Munro J, Walters SJ, Snaith ML. Generic and condition-specific outcome measures for people with osteoarthritis of the knee. Rheumatology 1999;38:870-7.
43. Garratt A, Ruta DA, Abdalla M, Russell I. SF-36 health survey questionnaire: II. responsiveness to changes in health status in four common clinical conditions. Qual Health Care 1994;3:186-92.
44. Garratt AM, Hutchinson A, Russell I. The UK version of the Seattle Angina Questionnaire (SAQ-UK): reliability, validity and responsiveness. J Clin Epidemiol 2001:907-15.
45. Haywood KL, Garratt AM, Jordan K, Dziedzic K, Dawes PT. Disease-specific, patient-assessed measures of health outcome in ankylosing spondylitis: reliability, validity and responsiveness. Rheumatology 2002;41:1295-302.
46. Garratt AM, Ruta DA, Abdalla MI, Russell IT. Responsiveness of the SF-36 and a condition-specific measure of health for patients with varicose veins. Qual Life Res 1996;5:223-34.
47. Locker D, Jokovic A, Clarke M. Assessing the responsiveness of measures of oral health-related quality of life. Community Dent Oral Epidemiol 2004;32:10-8.
48. Escobar A, Quintana JM, Bilbao A, Aróstegui I, Lafuente I, Vidaurreta I. Responsiveness and clinically important differences for the WOMAC and SF-36 after total knee replacement. Osteoarthritis Cartilage 2007;15:273-80.
49. Beaton DE, Hogg-Johnson S, Bombardier C. Evaluating changes in health status: reliability, and responsiveness of five generic health status measures in workers with musculoskeletal disorders. J Clin Epidemiol 1997;50:79-93.
50. Stavem K, Frøland SS, Hellum KB. Comparison of preference-based utilities of the 15D, EQ-5D and SF-6D in patients with HIV / AIDS. Qual Life Res 2005;14:971-80.
51. Hofer S, Benzer W, Schüssler G, von Steinbüchel N, Oldridge NB. Health-related quality of life in patients with coronary artery disease treated for angina: Validity and reliability of German translations of two specific questionnaires. Qual Life Res 2003;12:199-212.
52. Eichler HG, Mavros P, Geling O, Hunsche E, Kong S. Association between health-related quality of life and clinical efficacy endpoints in rheumatoid arthritis patients after four weeks treatment with anti-inflammatory agents. Int J Clin Pharmacol Ther 2005;43:209-16.

53. Kosinski M, Zhao SZ, Dedhiya S, Osterhaus JT, Ware JE. Determining minimally important changes in generic and disease-specific health-related quality of life questionnaires in clinical trials of rheumatoid arthritis. Arthritis Rheum 2000;43:1478-87.
54. Wright JG, Young NL. A comparison of different indices of responsiveness. J Clin Epidemiol 1997;50:239-46.
55. Lipsky PE, van der Heijde DM, St Clair EW, et al. Infliximab and methotrexate in the treatment of rheumatoid arthritis. Anti-Tumor Necrosis Factor Trial in Rheumatoid Arthritis with Concomitant Therapy Study Group. N Engl J Med 2000;343:1594-602.
56. Keystone EC, Kavanaugh AF, Sharp JT, et al. Radiographic, clinical, and functional outcomes of treatment with adalimumab (a human anti-tumor necrosis factor monoclonal antibody) in patients with active rheumatoid arthritis receiving concomitant methotrexate therapy: a randomized, placebo-controlled, 52-week trial. Arthritis Rheum 2004;50:1400-11.
57. Klareskog L, van der Heijde D, de Jager JP, et al. Therapeutic effect of the combination of etanercept and methotrexate compared with each treatment alone in patients with rheumatoid arthritis: double-blind randomised controlled trial. Lancet 2004;363:675-81.
58. Maini RN, Breedveld FC, Kalden JR, et al. Sustained improvement over two years in physical function, structural damage, and signs and symptoms among patients with rheumatoid arthritis treated with infliximab and methotrexate. Arthritis Rheum 2004;50:1051-65.
59. Heiberg MS, Nordvag BY, Mikkelsen K, et al. The comparative effectiveness of tumor necrosis factor-blocking agents in patients with rheumatoid arthritis and patients with ankylosing spondylitis: a six-month, longitudinal, observational, multicenter study. Arthritis Rheum 2005;52:2506-12.

3

Psychometric properties of the Rheumatoid Arthritis Disease Activity Index (RADAI) in a cohort of consecutive Dutch patients with RA starting anti-tumour necrosis factor treatment

M.M. Veehof
P.M. ten Klooster
E. Taal
P.L.C.M. van Riel
M.A.F.J. van de Laar

Ann Rheum Dis 2008;67(6):789-93

ABSTRACT

Objective To examine the psychometric properties of the self-administered Dutch Rheumatoid Arthritis Disease Activity Index (RADAI) and its short form (RADAI-SF) in patients with rheumatoid arthritis starting anti-tumour necrosis factor treatment.
Methods Internal consistency was assessed with Cronbach's α. A confirmatory factor analysis (CFA) was carried out to test the single-factor structure. Construct validity was examined by correlating RADAI and RADAI-SF scores with Disease Activity Score in 28 joints (DAS28). Internal responsiveness was evaluated with the paired t test and the standardized response mean (SRM). External responsiveness was assessed with receiver operating characteristic analysis and the SRM, using the EULAR response criterion as external criterion. Change scores were correlated with changes in DAS28.
Results At baseline and after 3 months' treatment, respectively, 191 and 171 patients completed the RADAI. The internal consistency of the RADAI and the RADAI-SF was satisfactory. CFAs confirmed the single-factor structure of both RADAI versions, but the short form provided the best model fit. Moderate correlations were found with the DAS28. SRMs of the RADAI and the RADAI-SF were, respectively, 0.76 and 0.80. Both versions had moderate accuracy to distinguish responders from non-responders. Changes scores were moderately correlated with DAS28 change scores.
Conclusions This study showed satisfactory psychometric properties of the Dutch version of the RADAI. Omission of the tender joint count (RADAI-SF) produced comparable results and is justified for research purposes. The tender joint count might be useful as additional clinical information in patient management.

INTRODUCTION

Disease activity is an important concept in the evaluation of patients with rheumatoid arthritis (RA) in clinical care and research. Because there is no "gold standard" of disease activity in RA, multiple single variables (core-set variables) and index measures are used. An index measure of disease activity combines single variables representing several aspects of the disease. Index measures are considered to be more informative than single measures and have the advantage of avoidance of multiplicity and increased sensitivity to change.[1-3]

A widely used and accepted index measure of disease activity is the Disease Activity Score in 28 joints (DAS28).[4] The DAS28, like most other indices of disease activity, primarily consists of physician-assessed and laboratory based variables. These variables are time consuming to assess, not always (directly) available and subject to inter-observer variation. Furthermore, these variables do not take into account a patient's perception of the burden of the disease, which has become increasingly important in the evaluation of treatment response and treatment management. The Rheumatoid Arthritis Disease Activity Score (RADAI) can be used as an alternative for, or complement to, these variables.[5,6]

The RADAI is a short and easy to complete self-administered index measure, combining a patient's perception of past disease activity, current disease activity as measured by swollen and tender joints, pain, duration of morning stiffness and tender joint count into a single measure of disease activity. The RADAI has primarily been developed for use in clinical and epidemiological studies where clinical assessments are not available or too demanding.[5,6] Nevertheless, the RADAI may also be useful in clinical practice.[6] For research purposes, the tender joint count (item 5), which is time consuming and adds little or nothing to the measure, can be omitted from the RADAI.[5]

Previous studies on the psychometric properties of the RADAI have primarily focused on the five-item version of the RADAI and not on its short form (RADAI-SF). The RADAI has been shown to have adequate reliability, validity and responsiveness among Swiss patients with RA.[5-7] Responsiveness was only investigated in patients showing worsening of disease activity over time.[7] The results of this study cannot be generalized to patients showing improvement of disease activity. Demonstration of the responsiveness to detect improvement of disease activity is mandatory, especially in the present era where remission has become an option for patients with RA. The aim of this study was to assess the reliability, validity and responsiveness of the Dutch version of the RADAI and its short form (RADAI-SF) in a cohort of consecutive patients with RA starting with tumour necrosis factor (TNF) blocking treatment.

PATIENTS AND METHODS

Patients

Participants were from the continuing Dutch Rheumatoid Arthritis Anti-TNF Monitoring (DREAM) study, a multicentre study that started in April 2003 to monitor and evaluate prospectively the use of anti-TNF in patients with RA. Inclusion criteria for the DREAM study are a diagnosis of RA,[8] active disease (DAS28 >3.2),[4] previous treatment with at least two antirheumatic drugs including methotrexate at an optimal dose or intolerance for methotrexate, and no previous treatment with anti-TNF agents.

Measures

In the DREAM study, patients are seen every 3 months by trained research nurses who collect data on core disease activity variables, including 28 tender joint count (28-TJC, range 0-28), 28 swollen joint count (28-SJC, range 0-28), erythrocyte sedimentation rate (ESR), patient's assessment of general health on a 100 mm visual analogue scale (VAS-GH), and Health Assessment Questionnaire Disability Index (range 0-3).[9,10] For this part of the study we used data from a subset of centres that additionally administered the RADAI at study entry and after 3 months.

RADAI

The RADAI is a disease-specific questionnaire developed to measure self-assessed disease activity in patients with RA.[5] The questionnaire has previously been translated into Dutch and was applied in several studies.[11-14] The RADAI contains five items on global disease activity during the past 6 months (item 1), current disease activity as measured by swollen and tender joints (item 2), current amount of arthritis pain (item 3), current duration of morning stiffness (item 4) and current number of tender joints in a joint list (item 5). The first three items are scored on an 11-point numerical rating scale, with verbal anchors from "no disease activity"/"no pain" (score 0) to "extreme disease activity"/"extreme pain" (score 10). The last two items are scored on a seven-point (item 4) and four-point (item 5) verbal rating scale. The scores on these two items range from 0 to 6 (item 4) and from 0 to 48 (item 5), and were transformed to a 0-10 scale, with higher scores indicating more disease activity. The total score of the RADAI was computed by summing the scores on the individual items and dividing this by five. The score of the short form (RADAI-SF) was computed by summing the scores of the first four items and dividing this by four, leaving out item 5 (tender joint count).

DAS28

From the 28-TJC, 28-SJC, ESR and the VAS-GH the DAS28 was computed. The DAS28 range is from 0 to approximately 10, where higher scores indicate more disease activity.[4]

Data analysis

Continuous data were presented as means with standard deviations (SDs) or medians with interquartile ranges (IQRs), depending on the distribution of the data (tested with the Kolmogorov–Smirnov test). Categorical data were presented as proportions. Analyses were performed using the statistical packages SPSS 12.0, LISREL 8.70, S-PLUS 6.1 and MedCalc 8.1.

Reliability

The internal consistency of the RADAI and the RADAI-SF was assessed with Cronbach's α coefficient using the data obtained from the baseline assessment. According to Nunnally and Bernstein, a value of 0.80 is sufficient for research purposes and a value of 0.90 is recommended when individual decisions are made based on specific test scores.[15]

Construct validity

A confirmatory factor analysis (CFA) using the maximum likelihood estimation procedure was conducted with LISREL to test the single-factor structure of the RADAI and the RADAI-SF. Covariances between the (transformed) item scores at baseline were used as input. As recommended, multiple fit indices were used to evaluate the fit of the data to a single-factor model.[16-18] We used the following fit indices: χ^2 statistic with degrees of freedom (df), non-normed fit index (NNFI) (comparable with Tucker-Lewis Index), comparative fit index (CFI), and root mean square error of approximation (RMSEA). A χ^2/df ratio < 2, combined with an NNFI value > 0.95, a CFI value > 0.90, and an RMSEA value < 0.08 indicate a good model fit.[18-20]

Correlation analysis was used to investigate further the construct validity. Pearson correlation coefficients were calculated between RADAI and RADAI-SF scores and DAS28 scores at baseline. Correlations ≥ 0.90 were interpreted as very high, 0.70-0.89 as high, 0.50-0.69 as moderate, 0.26-0.49 as low and ≤ 0.25 as little if any correlation.[21]

Responsiveness

In accordance with Husted *et al*, we distinguished between internal and external responsiveness.[22] Internal responsiveness refers to the ability of a measure to change over a prespecified time frame, whereas external responsiveness describes the

relationship between change in a measurement and change in a reference measure of disease activity.

Internal responsiveness was firstly assessed with the paired samples t test. Change between baseline and 3-month follow-up assessments was considered significant when $p \leq 0.05$. Second, the standardized response mean (SRM) was calculated. The SRM is calculated as the mean change score divided by the standard deviation of the change score and is seen as an indicator of the ability to distinguish "signal" from "noise".[23,24] An SRM between 0.20 and 0.49 can be interpreted as a small effect, an SRM between 0.50 and 0.79 as a moderate effect and an SRM ≥ 0.80 as a large effect.[22] We applied a bootstrap procedure with S-PLUS to obtain the 95% confidence interval for the SRM.[25]

External responsiveness was assessed with receiver operating characteristic (ROC) curve analysis and the SRM. We used the EULAR response criterion as external criterion for clinical change.[26] According to this criterion, patients were classified as (moderate or good) responders or non-responders, dependent on the individual change in DAS28 and the level of DAS28 reached. An ROC curve was created by plotting the true-positive proportion (sensitivity) versus the false-positive proportion (100 - specificity) for the discrimination between responders and non-responders for multiple cut-off points. The area under the ROC curve was calculated to quantify the discriminative accuracy. The area under the curve ranges from 0.5 to 1.0, where an area of 0.5–0.7 indicates low accuracy, 0.7-0.9 moderate accuracy and > 0.9 high accuracy.[27] SRMs were calculated for responders and non-responders. To further investigate the external responsiveness, change scores of the RADAI and the RADAI-SF were correlated with change scores of the DAS28.

RESULTS

At baseline and after 3 months, respectively, 191 and 171 patients fully completed the RADAI. Mean (SD) age of the patients at baseline was 54.5 (13.3) years and median disease duration was 7.0 (IQR 3.0-17.0) years. The majority of the patients (71%) were female and had mild disability according to Steinbrocker's functional classification (84% in class II). Table 1 shows the mean scores on disease activity measures at baseline and at 3 months.

Reliability

The internal consistency of the RADAI and the RADAI-SF, measured with Cronbach's α coefficients, was 0.84 and 0.82, respectively. Deletion of the items one by one did not change the coefficients substantially.

Table 1 Mean scores (SD) on disease activity measures at baseline and after 3 months*

Disease activity measures	Baseline	3 Months
RADAI, n = 171	5.27 (1.99)	3.60 (1.86)
RADAI-SF, n = 171	5.65 (2.18)	3.86 (2.03)
DAS28, n = 159	5.42 (1.07)	3.95 (1.27)
HAQ-DI, n = 165	1.45 (0.61)	1.13 (0.65)
VAS-GH, n = 150	57.87 (23.04)	41.62 (23.71)

DAS28, Disease Activity Score in 28 joints; HAQ-DI, Health Assessment Questionnaire Disability Index; RADAI, Rheumatoid Arthritis Disease Activity Index; RADAI-SF, RADAI-short form; VAS-GH, general health on a 100 mm visual analogue scale.
*All scores were significantly improved after 3 months ($p < 0.001$).

Construct validity

CFAs of the RADAI and the RADAI-SF showed that the RADAI-SF provided the best fit of the data to a single-factor structure (table 2). All fit indices of the RADAI-SF met the recommended criteria of acceptable model fit. For the RADAI, half of the fit indices (NNFI and CFI) satisfied the recommended criteria. The fit indices χ^2/df and RMSEA were nearly acceptable. Post hoc modification analysis of the RADAI showed that the assumption of uncorrelated error terms did not hold. Correlated error terms were found between items 2 (current disease activity as measured by swollen and tender joints) and 5 (current number of tender joints in a joint list) (r = -0.08), and items 3 (current amount of arthritis pain) and 5 (r = 0.09). Inclusion of an error covariance between the pair of items with the highest correlated error terms (items 3 and 5) provided an acceptable model fit by all fit indices (without further suggestions for modification). Figure 1 shows the standardized factor loadings and error terms of the RADAI (including its refined version with an error covariance) and the RADAI-SF. The lowest factor loadings were found for items 4 (duration of morning stiffness) and 1 (past disease activity).

RADAI and RADAI-SF scores correlated moderately (respectively 0.53 and 0.52) with DAS28 scores at baseline (n = 186).

Table 2 Fit indices for the one-factor structure of the RADAI and the RADAI-SF (n = 191)

Model	χ^2 (df)	χ^2/df	NNFI	CFI	RMSEA (90% CI)
RADAI	11.55 (5)	2.31	0.98	0.99	0.082 (0.014 to 0.150)
Refined RADAI	6.48 (4)*	1.62	0.99	1.00	0.054 (0.000 to 0.130)
RADAI-SF	1.16 (2)*	0.58	1.01	1.00	0.000 (0.000 to 0.120)

CFI, comparative fit index; 90% CI, 90% confidence interval; df, degrees of freedom; NNFI, non-normed fit index; RADAI, Rheumatoid Arthritis Disease Activity Index; RADAI-SF, RADAI-short form; Refined RADAI, addition of error covariance between items 3 and 5; RMSEA, root mean square error of approximation.
*$p \geq 0.05$ (significant χ^2).

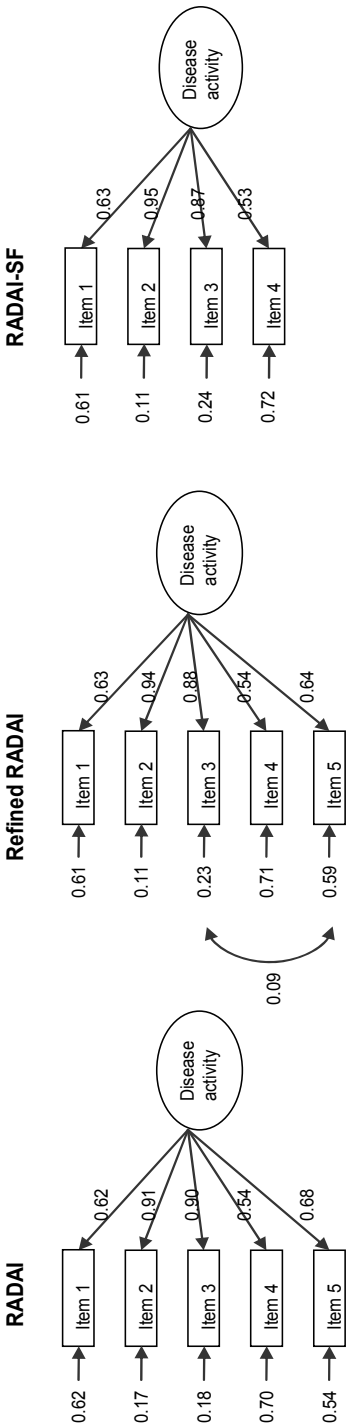

Figure 1 Standardized parameter estimates for the original and refined model of the Rheumatoid Arthritis Disease Activity Index (RADAI) and the model of the RADAI-short form (RADAI-SF).

Internal responsiveness

Scores on the RADAI, the RADAI-SF, and the DAS28 were significantly improved after 3 months of anti-TNF treatment ($p < 0.001$) (table 1). The SRMs were respectively 0.80, 0.76, and 1.09, indicating moderate to large effects (table 3).

External responsiveness

According to the EULAR response criterion, 71% of the patients were classified as responders (26% good responder; 45% moderate responder) after 3 months of anti-TNF treatment and 29% as non-responders. The responders showed significant improvement on both the RADAI (mean (SD) change score -2.17 (1.81)) and the RADAI-SF (mean (SD) change score -2.32 (2.05)). The non-responders showed no improvement on both versions (mean (SD) change score RADAI -0.29 (1.93); mean (SD) change score RADAI-SF -0.30 (2.17)).

Table 3 shows the external responsiveness indices for the RADAI and the RADAI-SF. The areas under the ROC curves show that the RADAI and the RADAI-SF had moderate accuracy to distinguish responders from non-responders (figure 2). The responders showed large improvements (SRM > 0.80) of disease activity on both the RADAI and the RADAI-SF. The non-responders showed no improvements (SRM < 0.20) of disease activity on both questionnaires. Change scores of the RADAI and RADAI-SF were moderately correlated with DAS28 change scores.

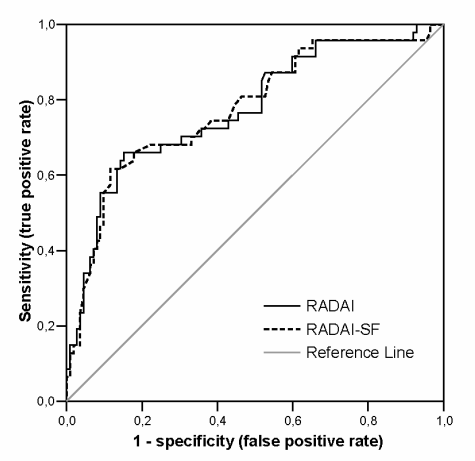

Figure 2 ROC curves for differences in RADAI and RADAI-SF scores between baseline and 3-month follow-up assessments using the EULAR response criteria as external criterion.

Table 3 Internal and external responsiveness indices (95% confidence intervals) for the RADAI and the RADAI-SF

	Internal responsiveness	External responsiveness			
	SRM (n = 171)	AUC (n = 159)	Pearson's *r* (n = 159)	SRM responders* (n = 112)	SRM non-responders* (n = 47)
RADAI	0.80 (0.62 to 0.97)	0.77 (0.69 to 0.86)	0.54 (0.42 to 0.64)	1.20 (0.97 to 1.40)	0.15 (-0.11 to 0.43)
RADAI-SF	0.76 (0.59 to 0.93)	0.78 (0.69 to 0.86)	0.51 (0.39 to 0.62)	1.13 (0.89 to 1.32)	0.14 (-0.15 to 0.42)

AUC, area under the receiver operating characteristic (ROC) curve; Pearson's r = Pearson's correlation coefficient between RADAI and RADAI-SF change scores and DAS28 change scores; RADAI, Rheumatoid Arthritis Disease Activity Index; RADAI-SF, RADAI-short form; SRM, standardised response mean.
*Responders and non-responders according to EULAR response criterion.[26]

DISCUSSION

This study shows that the RADAI and its short form (RADAI-SF) have satisfactory reliability, validity and responsiveness among Dutch patients with RA starting with anti-TNF treatment. Omission of the tender joint count in the RADAI-SF did not harm the psychometric qualities of the RADAI. Results of the CFA even showed that the RADAI-SF provided the best fit of the data to a single-factor structure. The fit indices of the RADAI reflected a nearly acceptable model fit and met the recommended criteria after addition of an error covariance between items 3 (current amount of arthritis pain) and 5 (tender joint count). Correlated error terms may reflect either the omission of one or more relevant factors or the presence of overlapping item content.[28] Since items 3 and 5 both asses current pain, the latter seemed most plausible. Leaving out the tender joint count, as earlier suggested,[5] seems therefore justified and is recommended for research purposes. The tender joint count is the most time-consuming item to complete and omission of this item reduces the burden for the patient. In clinical practice, however, inclusion of the tender joint count might be useful as additional clinical information.

Of the single items of the RADAI, item 1 (global disease activity during the past 6 months) and item 4 (current duration of morning stiffness) had the lowest factor loadings. Apparently, these items contributed less to disease activity than the other items. The RADAI might be improved by modifications in the wording of these items. With regard to item 1, a shorter time frame, over which disease activity is measured, could be considered. In RA, self-reported health status is usually measured over a period of 1 week or 1 month. Measurement of global disease activity over a shorter period of time is more likely to be related to current disease activity than the measurement over a period of 6 months. With regard to item 4, replacement of stiffness duration by severity of stiffness, as earlier suggested,[7] might be considered.

Results for the internal consistency and construct validity are in accordance with results reported in previous studies.[5,6] The construct validity was demonstrated by correlating RADAI scores with DAS28 scores. A moderate correlation was found. Although the RADAI and the DAS28 are both intended to measure disease activity, higher correlations were not expected because of the different content of the measures. Where the RADAI consists of patient-assessed variables on signs and symptoms, the DAS28 primarily consists of physician-assessed and laboratory variables.

Only one study has previously reported on the responsiveness of the RADAI. Fransen *et al* have shown that the RADAI is a responsive measure to increases in disease activity.[7] In this study we focused on the responsiveness of the RADAI to decreases in disease activity, which is an important feature to consider, especially if the aim is to assess treatment response. Since both studies differed from each other with

regard to study sample, treatment, responsiveness indices and external criterion of change, absolute responsiveness values cannot easily be compared with each other and should be interpreted with caution.[22,29,30] Two remarkable differences between the studies have to be mentioned, however. Fransen *et al* found comparable responsiveness of the RADAI and the DAS28 and a high correlation between the change scores of both measures. In our study we found less responsiveness of the RADAI than of the DAS28 and a moderate correlation between the change scores of both measures. Although these differences might be attributed to differences in methodology, the direction of change over which responsiveness is measured might also be of influence. An increase in disease activity, which is an unpleasant experience, is more likely to draw a patient's attention than a decrease in disease activity.[31] Therefore, the RADAI might be more responsive for worsening of disease activity than for improvement of disease activity.

In this study the responsiveness of the RADAI was evaluated over a period of 3 months. Because item 1 refers to global disease activity during the past 6 months, this item cannot expected to be very responsive. The responsiveness of the RADAI might have been underestimated. Especially if the aim is to measure treatment response, shortening of the time frame of 6 months seems necessary.

A limitation of this study concerns the generalisability of the results. For this study we used a cohort of consecutive patients with RA starting with anti-TNF treatment. At baseline, all patients had high disease activity, and major improvement was expected after 3 months of treatment. Therefore, the results should be generalised with caution to the whole population of patients with RA and other treatments.

In conclusion, this study supports the reliability, validity and responsiveness of the Dutch version of the RADAI. Omission of the tender joint count in the RADAI-SF produces comparable results and is justified and recommended for research purposes. The tender joint count might be useful as additional clinical information in patient management. Whether the RADAI can be improved by modification of the time frame of item 1 (past disease activity) and by replacement of stiffness duration by severity of stiffness (item 4) needs to be investigated. Moreover, to support the interpretation of RADAI scores in clinical practice and research, criteria for identifying low and high levels of disease activity and treatment response should be established in future research.

ACKNOWLEDGEMENTS

We thank T. van Gaalen, W. Kievit and P. Welsing for their contribution to the organisation of the study and data management. We thank the following rheumatologists and research nurses for their assistance in patient recruitment and data

collection: J. Alberts, C. Allaart, A. ter Avest, P. Barrera Rico, T. Berends, H. Bernelot Moens, K. Bevers, C. Bijkerk, , A. van der Bijl, J. de Boer, E. Bos, B. Botha, A. Branten, F. Breedveld, H. van den Brink, G. Bruyn, H. Cats, M. Creemers, J. Deenen, C. De Gendt, K. Drossaers-Bakker, A. van Ede, A. Eijsbouts, S. Erasmus, M. Franssen, I. Geerdink, M. Geurts, E. Griep, E. de Groot, C. Haagsma, J.Harbers, A. Hartkamp, J. Haverman, H. van Heereveld, A. van de Helm-van Mil, I. Henkes, S. Herfkens, M. Hoekstra, K. van de Hoeven, M. Horbeek, F. van den Hoogen, P. M. Houtman, T. Huizinga, H. Hulsmans, T. Jansen, M. Janssen, M. Jeurissen, A. de Jong, Z. de Jong, M. Kleine Schaar, G. Kloppenburg, H. Knaapen, P. Koelmans, M. Kortekaas, B. Kraft, A. Krol, M. Kruijssen, I. Kuper, R. Laan, J. van de Laan, J. van Laar, A. Mooij, J. Moolenburgh, N. Olsthoorn, P. van Oijen, M. van Oosterhout, J. Oostveen, P. van 't Pad Bosch, K. Rasing, K. Ronday, D. de Rooij, L. Schalkwijk, A. Spoorenberg, A. Stenger, G. Steup, W. Swen, M. Veerkamp, C. Versteegden, H. Visser, C. Vogel, M. Vonk, H. Vonkeman, H. van Wijk, N. Wouters.

REFERENCES

1. Fransen J, van Riel PLCM. DAS remission cut points. Clin Exp Rheumatol 2006;24:S29-S32.
2. Boers M, Tugwell P. The validity of pooled outcome measures (indices) in rheumatoid arthritis clinical trials. J Rheumatol 1993;20:568-74.
3. Roberts R. Pooled outcome measures in arthritis: the pros and cons. J Rheumatol 1993;20:566-7.
4. Prevoo ML, van 't Hof MA, Kuper HH, van Leeuwen MA, van de Putte LB, van Riel PL. Modified disease activity scores that include twenty-eight-joint counts. Development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. Arthritis Rheum 1995;38:44-8.
5. Stucki G, Liang MH, Stucki S, Bruhlmann P, Michel BA. A self-administered rheumatoid arthritis disease activity index (RADAI) for epidemiologic research. Psychometric properties and correlation with parameters of disease activity. Arthritis Rheum 1995;38:795-8.
6. Fransen J, Langenegger T, Michel BA, Stucki G. Feasibility and validity of the RADAI, a self-administered rheumatoid arthritis disease activity index. Rheumatology 2000;39:321-7.
7. Fransen J, Hauselmann H, Michel BA, Caravatti M, Stucki G. Responsiveness of the self-assessed rheumatoid arthritis disease activity index to a flare of disease activity. Arthritis Rheum 2001;44:53-60.
8. Arnett FC, Edworthy SM, Bloch DA, et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis Rheum 1988;31:315-24.
9. Fries JF, Spitz P, Kraines RG, Holman HR. Measurement of patient outcome in arthritis. Arthritis Rheum 1980;23:137-45.
10. Siegert CE, Vleming LJ, Vandenbroucke JP, Cats A. Measurement of disability in Dutch rheumatoid arthritis patients. Clin Rheumatol 1984;3:305-9.
11. Chorus AMJ, Miedema HS, Wevers CJ, van der Linden S. Labour force participation among patients with rheumatoid arthritis. Ann Rheum Dis 2000;59:549-54.
12. Chorus AMJ, Miedema HS, Wevers CWJ, van der Linden S. Work factors and behavioural coping in relation to withdrawal from the labour force in patients with rheumatoid arthritis. Ann Rheum Dis 2001;60:1025-32.
13. van Middendorp H, Geenen R, Sorb MJ, van Doornen LJP, Bijlsma JWJ. Emotion regulation predicts change of perceived health in patients with rheumatoid. Ann Rheum Dis 2005;64:1071-74.
14. van Middendorp H, Geenen R, Sorb MJ, Van Doornen LJP, Bijlsma JWJ. Neuroendocrine-immune relationships between emotion regulation and health in patients with rheumatoid arthritis. Rheumatology 2005;44:907-11.
15. Nunnally J, Bernstein I. Psychometric Theory. New York: MCGraw-Hill; 1994.
16. Hu L, Bentler PM. Fit indices in covariance structure modeling: sensitivity to underparameterized model misspecification. Psychol Methods 1998;3:424-53.
17. MacCallum RC, Austin JT. Applications of structural equation modeling in psychological research. Ann Rev Psychol 2000;51:201-26.

18. Hoyle RH, Panter AT. Writing about structural equation models. In: Hoyle RH, ed. Structural equation modeling: concepts, issues, and applications. Thousand Oaks, CA: Sage Publications; 1995:158-76.
19. Kelloway EK. Using LISREL for structural equation modeling: a researcher's guide. Thousand Oaks, CA: Sage Publications; 1998.
20. Browne MW, Cudeck R. Alternative ways of assessing model fit. In: Bollen KA, Long JS, eds. Testing structural equation models. Newbury Park, CA: Sage Publications; 1993:136-62.
21. Munro BH. Statistical methods for health care research. 3rd ed. New York: Lippincott Williams & Wilkins; 1997.
22. Husted JA, Cook RJ, Farewell VT, Gladman DD. Methods for assessing responsiveness: a critical review and recommendations. J Clin Epidemiol 2000;53:459-68.
23. Katz JN, Larson MG, Phillips CB, Fossel AH, Liang MH. Comparative measurement sensitivity of short and longer health status instruments. Med Care 1992;30:917-25.
24. Liang MH. Evaluating measurement responsiveness. J Rheumatol 1995;22:1191-2.
25. Efron B, Gong G. A leisurely look at the bootstrap, the jackknife, and cross-validation. Am Statistician 1983;37:36-48.
26. Fransen J, van Riel PLCM. The Disease Activity Score and the EULAR response criteria. Clin Exp Rheumatol 2005;23:S93-S9.
27. Swets JA. Measuring accuracy of diagnostic systems. Science 1988;240:1285-93.
28. Byrne BM. Testing for the factorial validity, replication, and invariance of a measuring instrument: a paradigmatic application based on the Maslach Burnout Inventory. Multivariate Behav Res 1994;29:289-311.
29. Terwee CB, Dekker FW, Wiersinga WM, Prummel MF, Bossuyt PMM. On assessing responsiveness of health-related quality of life instruments: Guidelines for instrument evaluation. Qual Life Res 2003;12:349-62.
30. Wright JG, Young NL. A comparison of different indices of responsiveness. J Clin Epidemiol 1997;50:239-46.
31. Schwartz AL, Meek PM, Mail LM, et al. Measurement of fatigue - determining minimally important clinical differences. J Clin Epidemiol 2002;55:239-44.

4

Determinants of the use of wrist working splints in rheumatoid arthritis

M.M. Veehof
E. Taal
M.J. Willems
M.A.F.J. van de Laar

Arthritis Care Res 2008;59(4):531-6

ABSTRACT

Objective To gain insight into the determinants of the use of wrist working splints among patients with rheumatoid arthritis (RA).

Methods A qualitative descriptive study was performed among 18 patients with RA who recently received a fabric wrist working splint because of pain due to arthritis of the wrist. Patients were interviewed at home using semistructured in-depth interviews. Interviews were audiotaped and transcribed verbatim and analyzed using the framework approach.

Results The majority of patients indicated that their splint use was dependent on the seriousness of the symptoms (pain, swelling, or tingling feelings) they perceived. Important reasons to wear the splint were reduction of symptoms, wrist support, and immobilization of the wrist. Important reasons to stop wearing the splint were reduced functional abilities using the splint and the performance of dirty or wet activities.

Conclusion The reasons for patients to wear and not wear wrist working splints are related to intentional decisions of the patients, which are primarily based on perceived benefits and barriers of splint wearing. The results of this study have been used to develop educational and behavioral strategies to increase adherence to wearing wrist working splints.

INTRODUCTION

Wrist working splints are frequently prescribed to patients with rheumatoid arthritis (RA) and wrist arthritis.[1] Their purpose is to reduce pain and inflammation and decrease the effort required to perform hand-related activities by providing rest, support, and stabilization of the wrist.[1,2] These splints permit movement of the metacarpophalangeal and finger joints, enabling the performance of activities. Studies on the efficacy of wrist working splints are scarce and are difficult to conduct. A serious methodological issue concerns patients' adherence to the advice on wearing these splints. Adherence rates with splints are relatively low.[1,3] Nonadherence will affect the effect of splint treatment.

Knowledge of the determinants of adherence is necessary to improve adherence. Several theories explain health-related behavior and (non)adherence in particular, including the social cognitive theory and the theory of planned behavior. These theories treat adherence as intentional decisions of the patient to comply with health-related advice. These decisions are based on beliefs that adherent behavior will lead to certain positively or negatively valued outcomes (outcome expectations), and that an individual has the skills and abilities to perform the behavior under a variety of circumstances (self-efficacy). Furthermore, perceived benefits and barriers and social influences may exert influence on the motivation of the patient to adhere to health-related advice.[4]

Many studies have provided evidence for the applicability of the above-mentioned theories on (non)adherence to treatment regimens in general.[4-6] Studies on the determinants of adherence associated with the use of wrist working splints are scarce. Agnew and Maas performed a quantitative study on adherence among patients with RA who were fitted with a custom-made elastic wrist working splint.[7] They concluded that the perceived benefit of splint wearing is the most important determinant of splint use, followed by the expectations of the doctor and family and ease of attaching the splint by means of loops. Moreover, patients tended to use their splints more with activities that place greater demands on the wrists and hands. Discomfort and appearance of the splint contributed little to adherence. It is questionable whether and to what extent these results can be generalized to Dutch patients and fabric (not custom-made) wrist working splints. Other studies have focused on perceived positive and negative aspects of several types of fabric splints, without relating this to (non)adherence.[1,8,9] Another study investigated the conditions under which patients were most likely to wear a wrist working splint (type unknown), without focusing on the conditions under which patients were not likely to wear a splint.[10] The results of these studies imply the following possible determinants of (non)adherence to splint wearing: relief of symptoms (pain, swelling), wrist support, increased hand strength,

splint fitting and comfort, problems with attaching and removing the splint, limited freedom of movement, type of activity, and sex. Conflicting results were reported with regard to functional ability, which might be deteriorated or improved by splint wearing. A search of the literature on hand resting splints revealed some additional possible determinants of adherence to splint wearing, namely, seriousness of symptoms, patients' personality (extraversion) and demographic (age, education) characteristics, disease duration, and therapist–client interaction.[11-14]

The primary goal of the present study was to evaluate patients' motivations for and perceived barriers to using their wrist working splint. Once the determinants of splint use are known, measures can be taken to increase adherence and to study the efficacy of wrist working splints.

PATIENTS AND METHODS

Patients and study design

Participants in this study were adult patients with RA who had recently (between 1 and 12 months earlier) received a fabric (commercially available) wrist working splint from their attending rheumatologist because of pain due to arthritis of the wrist. Eligible patients were identified from the hospital files and asked by mail by their rheumatologist to participate.

A qualitative descriptive approach, using in-depth interviews, was chosen to describe the experiences, knowledge, and opinions of patients with regard to the use of their splints.[15] Patients who gave informed consent were visited and interviewed by an independent researcher (MJW). The interviews were semistructured to ensure that all relevant aspects were addressed. The main topics of the interviews, which were developed after studying the literature on determinants of adherence in general and determinants of adherence to splint wearing, are shown in Table 1. The interview format was pretested in 2 pilot interviews, which were excluded from further analysis. All interviews were audiotaped and transcribed verbatim (MJW).

Analysis

The interview transcripts were analyzed using the framework approach.[16,17] This approach consists of 5 stages. The first stage involved familiarization with the data by reading the transcripts and identifying major responses/statements (MMV). The second stage involved the development of a thematic framework. Five transcripts were discussed in detail with another researcher (ET) to identify all themes and subthemes by which the data can be examined. The thematic framework was guided by the main

topics used in the interviews and by emerging issues from the familiarization stage. All themes and subthemes were given unique codes. In the third stage, called indexing, MMV and ET independently applied this thematic framework to the remaining 13 transcripts and coded all statements made by the patients. Interrater agreement on the codes was assessed by calculating kappa statistics. All statements to which initially different codes were ascribed were discussed by MMV and ET to fully reach consensus. Subsequently, the first 5 transcripts were coded using the thematic framework (MMV). In the fourth stage, all statements were grouped using the themes and sub themes from the thematic framework. The final stage consisted of interpretation of the results.

Table 1 Main topics of the interviews with examples of questions

Prescription and knowledge
Wearing advice
Purpose of the splint and reason for prescription
Other information given
Satisfaction
Example: What did the rheumatologist tell you about when you should wear the splint?
Splint use
Activities during which the splint is (not) worn
Example: Can you tell me during what activities you wear the splint?
Advantages and disadvantages of splint wearing
Reasons to wear and not wear the splint
Perceived and expected advantages and disadvantages
Example: Why do you wear the splint during these activities?
Appearance, comfort and fit of the splint
Example: Does the appearance of the splint influence your splint wearing?
Social environment
Verbal/nonverbal reactions
Example: How did your family and acquaintances react when you started to wear a splint?

RESULTS

Fifty-seven patients were invited by mail to participate in this study. Of them, 20 gave informed consent and were interviewed, 9 indicated that they did not wish to participate, and the remaining 28 did not respond. Reasons for nonparticipation were not investigated. Two interviews were used as pilot interviews and were excluded from further analysis. Mean ± SD age of the patients was 56.3 ± 16.4 years. Most patients were female (78%) and married (72%). The mean ± SD time interval between splint prescription and interview was 6.0 ± 3.5 months. Almost all patients had received a splint for 1 hand (n = 17). One patient had received a splint for both hands. The interview results are presented in accordance with the main themes of the interviews. Kappa values for agreement between the codings of the 2 raters ranged from 0.47 to 1.00, indicating moderate to perfect agreement.[18]

Prescription and knowledge

Two types of splints were prescribed. Sixteen patients received a Rolyan D-Ring (SproFit, Genk, Belgium) and 2 patients received a Futuro splint (BSN medical, Almere, The Netherlands). Both types of splints had a removable volar metal stay. Only a few patients tried more than 1 type of splint. Some patients reported that they did not receive advice from their rheumatologist on wearing the splint. Others were advised to wear their splint when they had a painful wrist, by day and/or night, or when performing heavy activities.

Almost all patients were able to discuss the purpose of the splint and the reason for prescription. Mentioned purposes were pain reduction, rest, immobilization, support, protection, and reduction of tingling feelings. Reasons mentioned for prescription were pain, inflammation/swelling, and tingling feelings. A few patients were uncertain about this or had inaccurate knowledge. Regarding the function of the splint, one patient said: "The splint fits very tightly around my wrist. But, if this is the reason why I have less pins and needles in my fingers, I don't know." Another patient stated: "If I had an inflammation in my wrist, I do not think that the splint would have influenced that." Some patients were uncertain about the washing of the splint or the wearing schedule. Reported remarks were as follows: "Do the fasteners still work when they get wet?"; "Can the fasteners be cut shorter?"; "If you have a painful wrist, do you have to wear the splint then, or is it better to wait?"; "How could I best stop or diminish my splint use?" Other patients had inaccurate knowledge about this: "You cannot put the splint into the washing machine"; "The fasteners may not get wet, because then they will not work anymore."

Few patients returned to the rheumatologist for control of their splint only. Most patients indicated not needing such a visit. Many patients stated that they already have to go to the hospital so many times that they call their rheumatologist when they have questions or experience problems. Finally, the majority of the patients stated being satisfied with the information they received during splint prescription. Only a few patients missed information on wearing advice, drying time after washing, and car driving.

Splint use

Many patients indicated that splint use is dependent on the seriousness of the symptoms they perceive. Splints were only worn during periods of pain, swelling, or tingling feelings. One patient stated: "Only if my wrist really hurts do I want to wear the splint. I believe that it's better to go without the splint if you don't have too much pain." Some patients used their splint on a daily basis and one patient indicated that

she did not wear the splint. If patients used their splint, they used it during heavy activities or the whole day and/or night.

Many patients indicated that they did not wear their splint during wet or dirty activities (such as cleaning windows, mopping, and cooking), during personal care activities (such as bathing, dressing, and using the toilet), and at night. One patient said: "When I'm peeling potatoes I can not wear the splint, because the splint will get dirty." Another patient remarked: "I don't wear the splint when I'm dressing, even if I am experiencing pain. It is just very impractical, because the fasteners stick to my clothes." Some patients indicated that they do not wear the splint at parties, when they are visiting people, or during meals.

Advantages

Reduction of symptoms appeared to be a major reason to wear the splint, as this was reported by all patients. Symptoms that patients mentioned to be reduced by splint wearing were pain, tingling feelings, and swelling/inflammation. One patient noted: "The pain is really annoying. But if I wear the splint, it becomes lessened. The pain is not completely gone, but it just has become lessened."

Many patients reported wrist support and rest/immobilization of the wrist as supplementary reasons to wear the splint. The latter, however, was simultaneously reported as a disadvantage of the splint by some of these patients. One patient remarked on the following as an advantage: "When I am driving in my car, I sometimes have to make a sudden movement with my wrist. This hurts a lot. When I am wearing my splint, this sudden movement is not possible because my wrist is fixed. So, I have less pain." The same patient also remarked on the following as a disadvantage: "One reason to take off my splint is inconvenience. It is, for example, not possible to fasten my bra because of a lack of mobility of my wrist."

Other mentioned advantages were improved functional abilities, prevention of overload of the wrist, increased strength, improved sleep, and less hard squeezing of other people's hands during hand shaking.

Disadvantages

Although some patients indicated that their functional abilities improved by wearing the splint, the majority of patients also experienced decreased functional ability. Examples of activities that were more difficult to perform were dressing; going to the toilet; fine motor activities such as picking up tiny objects, fastening buttons, or turning a page; cycling and driving; holding and using cutlery; cooking; writing; and computer activities. Almost all patients took off their splint when they experienced reduced

functional ability.

Two other major disadvantages and reasons to take off the splint were that the splint gets wet and dirty easily. One patient noted: "I always wear the sleeve of my sweater over my splint, so the splint does not get so dirty. If I do activities and the splint could get dirty, I always take off the splint." Another patient said: "Of course, when I am in contact with water, like with bathing or doing the dishes, I do not wear the splint."

Other reported disadvantages were long drying time, unpleasant physical contact with the splint because of the hard metal stay, sweating, wear and tear, difficulty wearing gloves and long-sleeved garments, inability to wear a watch, prohibited ability to drive a car, and inability to take off the splint independently. These disadvantages were (sometimes) reasons for patients not to wear the splint, except for wear and tear, difficulty wearing long-sleeved garments, and inability to wear a watch.

Expectations

Most patients reported having positive expectations with regard to the effectiveness of the splint in advance. Some patients stated that they did not believe that a splint would relieve their symptoms. Some patients reported that they did not wear their splint the whole time because they did not want to become used to the splint and were afraid that their wrist would grow stiff or weak.

Appearance, comfort, and fit

Most patients were neutral or negative on the appearance of their splint. Neutral patients judged the appearance of their splint as not important. Statements made by these patients were: "If you have pain, you gladly want to wear a splint, regardless of how it looks"; "The appearance of the splint does not interest me. If the splint is nice or not, the main point is that it is effective"; and "Even though the splint would be bluish purple with yellow dots, it does not interest me." For some patients who were negative on the appearance of their splint, appearance was reason to take the splint off during special occasions such as going out, dining, or visiting people. A few patients were positive on their splint and 1 patient was positive on her right splint but negative on her left one, which was another type of splint.

Many patients were generally positive about the comfort and fit of the splint. Nevertheless, negative remarks on material, straps and metal stay, and/or side effects of the splint were made by almost all patients. These complaints are summarized in Table 2. For some patients, these complaints were reason enough to take off the splint.

Table 2 Negative comments made by the patients on comfort and fit of the splint

Material
Not stain and waterproof
Sweaty
Straps
Stick to clothing
Difficult to release
Difficult to adjust equally
Too long
Metal stay
Feels hard, contact with splint not pleasant
Slips out of splint proximally
Decreases sense in palm of the hand
Makes splint slippery
Reduces grip
Side effects
Unpleasant feelings (e.g., tingling) and/or pressure points due to tight fit

Social environment

Almost all patients had heard responses from family members and acquaintances regarding their splint. Most reactions consisted of asking what is wrong with the wrist and why a splint is worn. Some people asked if they could help the patient and wanted to prevent the patient from overburdening his or her wrist. A minority of patients received attention from unknown people, such as staring or asking what is wrong. Many patients stated that the reactions of the social environment did not influence their splint use. One patient commented: "I do not care about the reactions of other people, the splint is for my own good." Some patients were persuaded by their partners to wear or not wear the splint in certain situations.

DISCUSSION

This study demonstrates that splint use is dependent on the seriousness of the perceived symptoms. If patients experience wrist-related symptoms, they wear their splint primarily to reduce these symptoms. Other reasons are to support and/or immobilize the wrist. Reasons to take off or not wear the splint are related to perceived barriers of splint wearing. Important barriers are decreased functional abilities and dirty or wet activities. Other reasons to take off the splint are concerns with comfort and fit.

In the absence of a theoretical model on splint use, we used the social cognitive theory and the theory of planned behavior as frameworks to establish the determinants of splint use.[4] The results of our study imply that splint use is related to patients' intentional decisions. This finding is fully in line with these theories. The social

environment, another important determinant according to these theories, was not mentioned by our patients as a major influence on the decision to wear or not wear the splint. To assess the role of the social environment, we evaluated the influence of the reactions of people in the environment on splint use. Furthermore, we asked patients if they were encouraged or discouraged by people in their environment to use the splint and if they complied with this influence. We did not engage patients' perceptions on the value that these people place on splint use (subjective norms) or the outcome expectations of these people. Future studies might address the influence of these factors.

As an alternative to the general models for explaining splint use, we might have used more specific models of assistive technology (AT) outcomes.[19-21] Many determinants of splint use that arose from our study are cited in these models. A specific model on the prediction of AT use has been introduced by Lenker and Paquet.[20] According to this model, the intention to use AT is a function of perceived advantages in terms of effectiveness, efficiency, satisfaction, and subjective well-being, and might be modified by personal characteristics, task, AT intervention strength (including characteristics of the device and associated services), and environmental factors.[20] An advantage of Lenker and Paquet's model over general models is that it provides a more detailed description of possible determinants of AT use. However, the model has not yet been validated. Validation and application of the model to splint use will require further attention in future studies.

The perceived advantages and disadvantages of splint wearing mentioned by our patients are largely in accordance with the results of previous studies on wrist working splints.[1,7-10] In this study, however, we also examined the relationship with splint use and nonuse. To the best of our knowledge, some perceived advantages, such as the rest resulting from immobilization the wrist and the experience of other people trying to prevent patients from overburdening their wrist (for example, by less hard squeezing during handshaking or by opening a door), have never been mentioned before. The same is applied to some disadvantages patients perceived: unpleasant physical contact with the splint because of the hard metal stay, long drying time, and fear that the splint will weaken or stiffen the wrist. Feelings such as being less tense, reported by Nordenskiöld,[8] were not mentioned by our patients. Furthermore, expectations of the doctor and family did not seem to be important determinants of splint use, in contrast to the findings of Agnew and Maas.[7] These differences between our study and previous studies might be explained by differences in applied research methods (qualitative versus quantitative, interviews versus written questionnaires), type of questions (open-ended versus close questions), type of wrist working splints, prescription process, and culture.

With regard to functional ability, both detrimental and beneficial effects were reported by the patients. Reasons to take off the splint during some activities were increased awkwardness and reduced wrist mobility, secure grip, and speed of performing activities. A reason to wear the splint was to enable the performance of some activities. Patients' perceptions concerning functional ability are largely in accordance with the results of clinical studies on the efficacy of wrist working splints. Detrimental effects were reported by Stern *et al*[22] and Pagnotta *et al*[23] with regard to time to accomplish daily activities. In contrast, Haskett *et al* reported no harmful effect on time needed to accomplish daily tasks.[24] Conflicting results with former studies might be attributed to differences in daily activities that have been carried out and the time between splinting and measurements.[24] According to Haskett *et al*, it takes some time to become accustomed to the use of a splint.[24] A small but positive effect of wrist splints was reported by Pagnotta *et al* with regard to endurance and perceived task difficulty.[25] The effect of splint wearing varied across the tasks, however. These studies demonstrate that perceived functional ability is likely to be task dependent. According to Pagnotta *et al*, splints are most detrimental for tasks that require a mobile wrist or a tight, secure grip of an object in the hand.[23,25] All in all, the results of these clinical studies emphasize the importance of informing the patients on the time needed to become accustomed to the use of a splint and the beneficial and detrimental effects of splints on functional ability to promote realistic expectations with regard to splint use and to increase adherence.

This study was performed among Dutch patients with RA with wrist pain due to wrist arthritis who were willing to participate in this study and who received a fabric wrist working splint at our rheumatology outpatient clinic. Splints were prescribed by the patients' attending rheumatologist, which is a usual practice in The Netherlands. Therefore, the results of this study should be generalized with caution to the entire population of patients with RA or all patients with an indication for a wrist working splint. However, barriers for splint use identified in this study (e.g., reduced functional ability, wet or dirty activities) are relevant for all patients who receive wrist working splints.

By knowing the determinants of splint use, measures can be taken to increase adherence. We focused on factors that could be changed, and developed educational and behavioral strategies to increase adherence (Table 3). Next to strategies derived from the results of our study and previous studies on wrist working splints, we included general adherence-enhancing measures, such as shared outcome expectations between therapist and patient,[13,26] verbal and written instructions,[5-7] monitoring adherent behavior,[4-6,27] and evaluation of the regimen.[5,6,13] All of these adherence-enhancing measures will be used in a randomized controlled trial on the efficacy of

wrist working splints.

Table 3 Educational and behavioral strategies to increase adherence to wrist working splint wearing

Splint prescription by an expert to optimize splint fitting and perceived comfort
Shared outcome expectations between occupational therapist and patient, and understanding of the regimen by the patient
Outcome expectations of the patient concerning benefits and working of the splint are evaluated and discussed if necessary
The daily activities of the patient are discussed and activities during which the splint will be worn are agreed upon
Clear information is given on washing of the splint and the importance of adherence
Understanding of the information is checked and the patient is given all opportunity to ask questions
Verbal and written instructions
Involvement of the patient in the selection of the splint
The patient tries on several splints and chooses the most comfortable, aesthetic splint and/or the easiest to put on/remove
Discussing and removing barriers to wear the splint
Patient's barriers for splint use are checked and removed if possible
More information on possible barriers is given (e.g., performance of dirty or wet activities, possible impeding effect on some activities, possible side effects, long drying time, sticking of straps to clothing, etc.)
As a solution for the performance of dirty and wet activities and a long drying time, the patient receives 2 identical splints
To prevent the splint from getting wet and dirty during wet and dirty activities, the patient tries on several gloves and receives the best fitting
To decrease the possibility that the straps will stick to clothing, and make it easier to release the fasteners, the straps are cut at the correct size and folded and sewn up at the end
Patients keep a daily log of splint use to monitor and stimulate adherence
Evaluation of splint use after 1 week of prescription
The patient is called by the occupational therapist to evaluate the perceived benefits and barriers of splint wearing, comfort and fit, and adherence; the occupational therapist takes measures/gives advice if necessary

ACKNOWLEDGEMENTS

The authors would like to thank the patients for their participation in this study.

REFERENCES

1. Spoorenberg A, Boers M, van der Linden S. Wrist splints in rheumatoid arthritis: a question of belief? Clin Rheumatol 1994;13:559-63.
2. Spoorenberg A, Boers M, van der Linden S. Wrist splints in rheumatoid arthritis: what do we know about efficacy and compliance? Arthritis Care Res 1994;7:55-7.
3. Belcon MC, Haynes RB, Tugwell P. A critical review of compliance studies in rheumatoid arthritis. Arthritis Rheum 1984;27:1227-33.
4. Baum A, Revenson TA, Singer JE. Handbook of health psychology. Mahwah, NJ: Lawrence Erlbaum Associates; 2001.
5. Sanderson CA. Health psychology. Hoboken, HJ: John Wiley & Sons; 2004.
6. Brannon B, Feist J. Health psychology: An introduction to behavior and health. 5th ed. Belmont: Wadsworth/Thomson Learning; 2004.
7. Agnew PJ MF. Compliance in wearing wrist working splints in rheumatoid arthritis. Occup Ther J Res 1995;15:165-80.
8. Nordenskiöld U. Elastic wrist orthoses. Reduction of pain and increase in grip force for women with rheumatoid arthritis. Arthritis Care Res 1990;3:158-62.
9. Stern EB, Ytterberg SR, Larson LM, Parke Portoghese C, Kratz WNR, Mahowald ML. Commercial wrist extensor orthoses: a descriptive study of use and preference in patients with rheumatoid arthritis. Arthritis Care Res 1997;10:27-35.
10. Nicholas JJ, Gruen H, Weiner G, Crawshaw C. Splinting in rheumatoid arthritis: I. Factors affecting patient compliance. Arch Phys Med Rehabil 1982;63:92-4.
11. Moon MH, Moon BAM. Compliancy in splint-wearing behaviour of patients with rheumatoid arthritis. N Z Med J 1976;26:360-5.
12. Feinberg J, Brandt, K.D. Use of resting splints by patients with rheumatoid arthritis. Am J Occup Ther 1981;35:173-8.
13. Feinberg J. Effect of the arthritis health professional on compliance with use of resting hand splints by patients with rheumatoid arthritis. Arthritis Care Res 1992;5:17-23.
14. Callinan NJ, Mathiowetz V. Soft versus hard resting hand splints in rheumatoid arthritis: pain relief, preference, and compliance. Am J Occup Ther 1995;50:347-53.
15. Sandelowski M. Whatever happened to qualitative description? Res Nurs Health 2000;23:334-40.
16. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, eds. Analysing qualitative data. London: Routledge; 1994:173-94.
17. Pope C, Ziebland S, Mays N. Qualitative research in health care: Analysing qualitative data. BMJ 2000;320:114-6.
18. Landis RJ, Koch G. The measurement of observer agreement for categorical data. Biometr 1977;33:159-74.
19. Fuhrer MJ, Jutai JW, Scherer MJ, DeRuyter F. A framework for the conceptual modelling of assistive technology device outcomes. Disabil Rehabil 2003;25:1243-51.
20. Lenker JA, Paquet VL. A new conceptual model for assistive technology outcomes research and practice. Assist Technol 2004;16:1-10.

21. Lenker JA, Paquet VL. A review of conceptual models for assistive technology outcomes research and practice. Assist Technol 2003;15:1-15.
22. Stern EB, Ytterberg SR, Krug HE, Mahowald ML. Finger dexterity and hand function: effect of three commercial wrist extensor orthoses on patients with rheumatoid arthritis. Arthritis Care Res 1996;9:197-205.
23. Pagnotta A, Baron M, Korner-Bitensky N. The effect of a static wrist orthosis on hand function in individuals with rheumatoid arthritis. J Rheumatol 1998;25:879-85.
24. Haskett S, Backman C, Porter B, Goyert J, Palejko G. A crossover trial of custom-made and commercially available wrist splints in adults with inflammatory arthritis. Arthritis Rheum 2004;51:792-99.
25. Pagnotta A, Mazer B, Baron M, Wood-Dauphinee S. Static wrist splint use in the performance of daily activities by individuals with rheumatoid arthritis. J Rheumatol 2005;32:2136-43.
26. Brus HLM, van de Laar MAFJ, Taal E, Rasker JJ, Wiegman O. Compliance in rheumatoid arthritis and the role of formal patient education. Semin Arthritis Rheum 1997;26:702-10.
27. Hanes B. Orthotics, splinting, and lifestyle factors. In: Walker JM, Helewa A, eds. Physical therapy in arthritis. Philadelphia: WB Saunders; 1996:175-90.

5

The efficacy of wrist working splints in rheumatoid arthritis: a randomized controlled study

M.M. Veehof
E. Taal
L.M. Heijnsdijk - Rouwenhorst
M.A.F.J. van de Laar

Arthritis Care Res, accepted pending revision

ABSTRACT

Objective The aim of this study was to investigate the efficacy of wrist working splints after a period of splinting in patients with rheumatoid arthritis (RA).

Methods We performed a four-week randomized controlled trial among 33 patients with RA suffering from wrist arthritis. Patients were randomly allocated to the splinting group (n = 17) or the control group (n = 16). Patients in the splinting group received a prefabricated wrist working splint and were instructed to use this splint as much as possible during the day. Primary outcome measure was average wrist pain during the past week, measured using a visual analogue scale (VAS). Secondary outcome measures were grip strength and functional ability. The latter was measured using the Disabilities of the Arm, Shoulder, and Hand questionnaire and the short version of the Sequential Occupational Dexterity Assessment (SODA-S). Measurements were performed at baseline and after four weeks. Performance tests (grip strength and SODA-S) were performed without splint. Differences in change scores between the splinting and the control group were analysed using analysis of covariance. To indicate the magnitude of the treatment effects, effect sizes were calculated.

Results A large and highly significant treatment effect on wrist pain was found. VAS pain scores decreased by 32% in the splinting group and increased by 17% in the control group. Small and non-significant treatment effects were found with regard to non-splinted grip strength and functional ability.

Conclusion This study demonstrates that prefabricated wrist working splints are highly effective in reducing wrist pain after four weeks of splint wearing among patients with RA suffering from wrist arthritis.

INTRODUCTION

Wrist arthritis is a prevalent health care problem. In rheumatoid arthritis (RA), 75% of the patients are suffering from wrist arthritis.[1] Arthritis is characterized by inflammation and proliferation of the synovial tissues. Clinical features are pain and swelling of the joint. Resulting features in the wrist are reduced grip strength and functional ability. Wrist working splints are prescribed as adjunct to drug treatment.[2] They aim to reduce pain and inflammation, and improve functional ability by providing rest, support and stabilization of the wrist.[1-3] Wrist working splints allow movement of the finger and thumb joints, enabling the performance of daily activities.

Two systematic reviews have been performed on the effects of wrist working splints in patients with RA.[4,5] In the first review, the investigators concluded there are indications that splints are effective in reducing pain, improving grip strength, and reducing dexterity.[4] Not only wrist working splints but different types of splints (also resting splints, air-pressure splints, antideformity splints) were included in this review. In the second review, the investigators indicated there is insufficient evidence to make conclusions about the effects of wrist working splints.[5] Most studies, that have been performed on the effects of wrist working splints, have focused on the effects measured immediately after provision of the splint.[6-12] In these studies, which were mostly non-controlled, measurements without and with splint were successively performed and compared. The results of these studies showed that the use of wrist working splints has positive effects on wrist pain,[6-8,11] positive effects on perceived task difficulty and endurance,[8] and negative effects on time needed to accomplish tasks.[7,10] Results with regard to grip strength were conflicting. Although the majority of the studies found an improvement of splinted grip strength,[6,11] some found a reduction of splinted grip strength,[9] or no effect.[12] Studies on the effects of wrist working splints measured after a period of splinting have been scarce.[9,11,13,14] In these studies, baseline measurements without splint were compared with measurements after a period of splinting (with and without splint). Statistically significant positive effects on pain and grip strength, measured while being splinted, were only reported in one non-controlled study.[14] No significant effects were found in the other studies. Controlled studies are mandatory to draw definite conclusions on the effects of wrist working splints after a period of splinting.[4,5,14]

Adherence to the given treatment advice is a serious point of concern in efficacy studies. Limited adherence affects outcome. Generally, adherence rates with splints are shown to be low.[2,15] Data on adherence with wrist working splints are scarce. Only Haskett *et al* reported detailed information on adherence.[14] They found that 96% of the patients (n = 45) wore the splint according to the prescribed advice of minimally 10

hours a week. Because splint wearing instructions vary across studies, this result should be interpreted with caution.

The aim of this study was to investigate the efficacy of wrist working splints after four weeks of splinting in patients suffering from RA. We used a randomized controlled study design. Since wrist working splints are primarily prescribed for pain relief,[2] our primary outcome was wrist pain. For optimal adherence to splinting instructions, adherence-enhancing strategies, based upon our preceding study on the determinants of splint use,[16] were applied.

PATIENTS AND METHODS

Study design and patients

A randomized controlled trial was conducted. Participants were patients attending the rheumatology outpatient clinic of the Medisch Spectrum Twente hospital (Enschede, the Netherlands) or the hospitals of Ziekenhuisgroep Twente (Almelo and Hengelo, the Netherlands). They were selected by their attending rheumatologist. Inclusion criteria were: 1) diagnosis of RA according to the 1987 revised American College of Rheumatology (ACR) criteria,[17] 2) clinical signs of active arthritis of the wrist due to RA (clinical judgment attending rheumatologist), 3) painful wrist (visual analogue scale (VAS) score ≥ 30), 4) stable DMARD therapy within the preceding three months and no expected changes for the next four weeks, 5) stable symptomatic therapy (NSAIDs and corticosteroids) within the preceding two weeks and no expected changes for the next four weeks, and 6) age ≥ 18 years. Potential participants were excluded if they: 1) received an injection of corticosteroid in the wrist or hand within the preceding month, 2) exhibited severe deformities of the wrist and/or fingers affecting hand function or requiring another splint than a prefabricated commercially available wrist splint, 3) had a history of wrist surgery, 4) had a diagnosis of carpal tunnel syndrome or another neurologic disorder affecting hand function, or 5) used a wrist splint within the two weeks prior to participation in the study.

Procedure

After obtaining informed consent, patients were randomly allocated to the splinting group or the control group. Block randomization with a block size of four was used to ensure balance in the numbers of patients allocated to the two groups. Group allocation was accomplished by the patients` selection and opening of sealed envelopes.

Directly preceding the baseline assessments, patients in the splinting group were seen by an occupational therapist (OT). The OT fitted the patient's most affected wrist

with a commercially available prefabricated wrist working splint at 10-20° of wrist extension. Because no particular splint suits all patients,[13,18,19] patients had the choice of the following splints: Rolyan D-Ring (Sprofit, Genk, Belgium), GM005H, GM008, and GM009 (all G.M. Medical Bracing, Best, the Netherlands). These splints have in common that they consist of a fabric gauntlet and have a removable volar metal stay. They differ in material, strapping method and/or color. Patients were instructed to wear the splint during the day as much as possible, especially during activities, for a period of four weeks. To stimulate splint use, several educational and behavioral strategies were applied by the OT (see Table 1). These strategies were established in a former study on the determinants of splint wearing.[16] Patients were asked to record the number of hours they had worn the splint in a daily diary.

Table 1 Strategies to increase adherence with wrist working splint wearing*

Splint prescription by an expert (occupational therapist) to optimize splint fitting and perceived comfort
Evaluation and discussion (if necessary) of outcome expectations of the patient concerning benefits and working of the splint
Evaluation of the daily activities of the patient and determination during which activities the splint will be worn
Involvement of the patient in the selection of the splint
Discussion and removal (if possible) of potential barriers (e.g., performance of wet and dirty activities, long drying time, sticking of the straps to clothing). At least the following solutions were offered:
Prescription of two splints (for the same wrist)
Plastic gloves
Adjustment of the straps (cutting them at the correct size and folding and sewing them at the end)
Distribution of written instructions on purpose and working of the splint, wearing instructions, potential barriers, and washing prescription
Explanation of the importance of adherence
Keeping a daily diary of splint use by the patient
Telephonic evaluation of splint use after one week of prescription by the occupational therapist. If necessary, advices are given and / or measures are taken

*Strategies were derived from a former study on the determinants of splint use in patients with RA.[16]

Patients in the control group received usual care for four weeks. After the study they were still offered a wrist working splint. The study protocol was approved by the Ethics Committee of the Medisch Spectrum Twente hospital, Enschede, the Netherlands.

Outcome measures

At baseline, information was collected on age, gender, and disease activity (Disease Activity Score 28 (DAS28).[20] Our primary outcome measure was wrist pain. Secondary outcome measures were grip strength and functional ability. Measurements were performed at baseline and after four weeks. Finally, the patient's perceived change was

noted afterwards. For obvious reasons, neither patients nor assessor were blinded for the treatment allocation.

Pain

Wrist pain was measured using a visual analog scale (VAS). The VAS pain is a 100 mm horizontal line with verbal anchors from "no pain" to "pain as bad as it can be". Patients were asked to mark with a vertical line the average amount of wrist pain they had perceived during the past week. The VAS pain belongs to the ACR core set of outcome measures for RA trials.[21]

Grip strength

Grip strength was measured in kPa using a Vigorimeter, which is a dynamometer with an air-filled rubber balloon. Patients were instructed to squeeze the balloon as hard as possible. The mean of three measurements was used. Measurements were performed without splint. The Vigorimeter has shown to be a reliable instrument to assess grip strength in patients with RA.[22]

Functional ability

Functional ability was measured with the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH), and the short version of the Sequential Occupational Dexterity Assessment (SODA-S). The DASH is a self-administered questionnaire designed to measure physical function and symptoms associated with any condition in the upper limb.[23,24] The 30-item questionnaire includes 21 physical function items (e.g., prepare a meal, turn a key), 5 symptom items (e.g., pain, weakness), and 4 social/role function items (e.g., extent to which arm, shoulder, or hand problems interfere with normal social activities with family and friends). The questionnaire has been validated in rheumatic conditions[25-27] and many languages, among which in Dutch.[27] The DASH score ranges from 0 (minimum disability) to 100 (maximum disability). The SODA-S is designed to measure bimanual hand function in RA.[28] The SODA-S consists of 6 standardized hand-related daily activities (3 unilateral, 3 bilateral), performed under controlled conditions without splint. A research nurse rated the patient's performance on each activity (4 = able to perform in the requested way; 1 = able to perform in a different way; 0 = unable to perform). The bilateral tasks were scored for each hand separately. The patient rated the level of difficulty with an activity (2 = not difficult; 1 = some difficulty; 0 = very difficult). The total score, which is a combination of these two scores, was computed, ranging from 0 (low dexterity) to 48 (high dexterity). The SODA-S pain score was computed by counting the number of activities that caused

pain (range 0 – 6). The psychometric properties of the SODA-S have shown to be acceptable.[28,29]

Patients' perceived changes

After four weeks, patients additionally completed several transition items to describe the magnitude and direction of perceived changes in wrist pain, grip strength, and functional ability over the four-week period. Patients were asked to compare their current situation with their situation four weeks ago. Perceived changes were scored on a 5-point scale (-2 = much deteriorated; -1 = a little deteriorated; 0 = unchanged; 1 = a little improved; 2 = much improved).[30, 31]

Statistical analyses

Power calculation yielded a target sample size of 54 patients (27 in each group) to detect a difference of 15 mm on the VAS for wrist pain with 80% power and a one-sided significance level of 0.05. For this calculation we used data from a previous study on wrist working splints (mean VAS pain at baseline = 54; SD = 22).[13] A difference of 15 mm corresponds to an improvement of approximately 30% which is considered clinically relevant.[32-35] Comparison of the splinting group and the control group at baseline was evaluated using the independent samples t-test and the Mann-Whitney U test for continues variables, and the Chi-square test for categorical variables.

Change scores were computed by subtracting baseline scores from scores at four weeks. Differences in change scores between the splinting group and the control group were analyzed using analyses of covariance with baseline scores of the outcome variable as covariate. Assumptions for performing parametric analysis of covariance were: normal distributed data, homogeneity of variance and homogeneity of regression. If the change scores of a variable did not fulfil the assumption of homogeneity of regression, nonparametric analysis of covariance was performed.[36-38] First, residuals were calculated by linear regression analysis with the change scores of this variable as dependent variable and the baseline scores as independent variable. The residuals were then used as data points and differences between the splinting group and the control group were analysed with the Mann-Whitney U test. The Mann-Whitney test U was also used to compare patients' perceived changes with regard to changes in wrist pain, grip strength, and functional ability.

To give an indication of the magnitude of the treatment effects, effect sizes or standardized mean differences (Hedges' g) were calculated as the difference between the mean change of the intervention group and the control group divided by the pooled standard deviation. A correction factor was applied to adjust for small and

unequal sample sizes.[39] An effect size of 0.2 is considered as a small effect, 0.5 as a moderate effect and 0.8 as a large effect.[40]

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS 12.0.1). Data were analyzed on an intention-to-treat basis.

RESULTS

A total of 33 patients were enrolled in this study. Seventeen patients were allocated to the splinting group and 16 to the control group. All patients completed the study. Mean (SD) age in the splinting and the control group was, respectively, 60.3 (10.8) and 55.1 (12.8) years. Mean (SD) disease duration was, respectively, 8.2 (6.8) and 5.0 (4.6) years. The majority of the patients in both groups were female (respectively 71% and 69%). Mean (SD) DAS28 scores at baseline were, respectively, 4.37 (1.01) and 4.34 (1.33), both indicating moderate disease activity. There were no significant differences in patient characteristics between the splinting and the control group at baseline ($p \geq 0.05$).

The majority of the patients (n = 10) in the splinting group were fitted with the Rolyan D-Ring. Three patients chose for the GM005H, three patients for the GM009, and one patient for the GM008. In most patients (n = 10), the dominant hand was splinted. Two patients did not (fully) complete the daily diary on splint use. One patient did not return the diary. The other patients wore the splint during 86% to 100% of the days. During these days they wore the splint for at least two hours, with a mean (SD) duration of 11.4 (2.5) hours a day.

During the treatment period, two patients in the control group reported changes in the usual treatment. One patient stopped prednisone treatment without exacerbation and another patient unsuccessfully decreased dosage prednisone and had to return to the old dosage. Replication of the analyses without these patients did not change the results substantially (data not shown).

Effects of splint use

Table 2 shows the scores on the outcome measures at baseline and the change scores at four weeks. No baseline differences were found between the splinting and the control group. Table 2 also shows the results of the analyses of covariance and the effect sizes.

Pain

In Figure 1 mean VAS pain scores at baseline and after four weeks are shown. In the splinting group, mean VAS pain scores decreased by 32% after four weeks of splinting. In the control group, mean VAS pain scores increased by 17%. Change scores were

Table 2 Baseline scores on outcome measures, changes at 4 weeks, and indices for the treatment effect*

	Splinting group (n = 17)			Control group (n = 16)			Treatment effect			
	Baseline	Changes At 4 weeks	p	Baseline	Changes at 4 weeks	p	F- value (1,30)	p	Power	Effect size (95% CI)
VAS wrist pain (0-100)	52.9 (16.8)	-16.8 (21.5)	0.005	42.4 (28.5)	7.4 (16.1)	0.087	11.07	0.002	0.90	-1.24 (-1.98 to -0.49)
SODA-S pain (0-6)	1.8 (1.5)	-0.9 (1.9)	0.074	1.7 (1.9)	-0.1 (1.3)	0.708	-†	-	-	-0.45 (-1.14 to 0.24)
Grip strength (kPa)	25.0 (15.5)	1.3 (7.4)	0.473	20.7 (17.4)	-1.6 (5.0)	0.232	2.32	0.138	0.31	0.45 (-0.25 to 1.13)
DASH (0-30)	39.0 (13.5)	-5.4 (11.9)	0.101	36.5 (17.5)	-2.8 (11.2)	0.347	0.25	0.625	0.08	-0.22 (-0.94 to 0.50)
SODA-S (0-48)	44.0 (5.1)	2.3 (4.0)	0.031	43.9 (4.3)	0.7 (5.3)	0.609	1.42	0.242	0.21	0.34 (-0.35 to 1.02)

95% CI, 95% confidence interval; DASH, Disabilities of the Arm, Shoulder, and Hand questionnaire; SODA-S, Sequential Occupational Dexterity Assessment short version; VAS, visual analogue scale.

*Scores on outcome measures and changes are presented as means (SD). P-values are shown for within-group differences, investigated with paired t tests, and between-group differences, investigated with analysis of covariance (ANCOVA). Power refers to the observed power (α = 0.05).

†ANCOVA was not carried out because the change scores did not fulfill the assumptions of ANCOVA. Nonparametric ANCOVA was performed and showed a non-significant treatment effect (p = 0.191).

significantly different between both groups ($F(1,30) = 11.1$; $p = 0.002$). The effect size was -1.24, indicating a large treatment effect of wrist working splints on VAS pain.

The number of SODA activities that were painful to perform decreased by, respectively, 50% and 6% in the splinting and the control group. Differences in change scores between both groups were not significant ($p = 0.191$). The effect size indicated a small treatment effect (Hedges' $g = -0.45$).

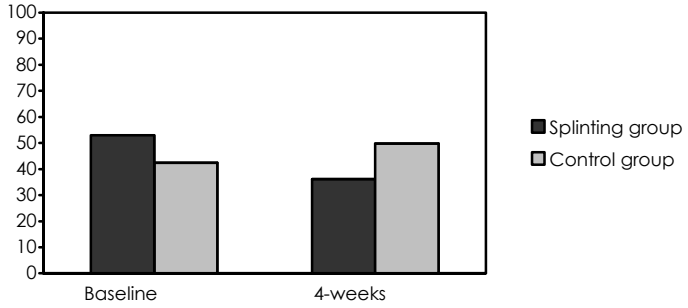

Figure 1 Bar graph representing mean VAS pain scores in the splinting and the control group at baseline and after 4 weeks.

Grip strength

Mean grip strength scores were slightly increased (5%) in the splinting group and slightly decreased (8%) in the control group. No significant differences were found between the change scores in both groups. The effect size indicated a small treatment effect (Hedges' $g = 0.45$).

Functional ability

In the splinting and the control group DASH and SODA-S scores were slightly improved after four weeks. Change scores were not significantly different between both groups. Treatment effects were small, as shown by the effect sizes (Hedges' $g \leq 0.34$).

Patients' perceived changes

In Table 3 patients' retrospective judgments of changes in wrist pain, grip strength, and functional ability are summarized. Patients in the splinting group generally judged their wrist pain and functional ability as improved, while patients in the control group judged their wrist pain and functional ability as deteriorated. These differences between both groups were significant ($p \leq 0.01$). No significant differences were found with regard to grip strength. Both the splinting and the control group judged their grip strength as unchanged.

Table 3 Patients' perceived changes over 4 weeks*

	Splinting group (n = 17)	Control group (n = 16)	p
Pain	0.59 (0.87)	-0.50 (0.63)	0.001
Grip strength	0.00 (0.87)	0.00 (0.89)	0.858
Dexterity	0.59 (0.87)	-0.50 (0.63)	0.001

*Data are presented as means (SD). Scores range from -2 (much deteriorated) to 2 (much improved). P values are shown for between-group differences, investigated with Mann Whitney U tests.

DISCUSSION

This is the first randomized controlled study that clearly reveals evidence that wrist working splints are effective in reducing wrist pain in patients with RA suffering from wrist arthritis. We empirically studied the effects of wrist working splints after a period of splinting. Although it is tempting to question the underlying mechanism, we can only generate hypotheses about this. Wrist working splints are supposed to reduce wrist motion and to provide rest, support, and stabilization of the wrist. On the one hand, this might reduce pain and improve function immediately, and, on the other hand, this might reduce pain and improve function by reducing local inflammation.

Because wrist working splints are mainly prescribed for pain reduction, wrist pain was our primary outcome measure.[2] As measure for wrist pain we used a VAS, which is a commonly used measure in pain and splint studies and belongs to the ACR core set of outcome measures for RA trials. We asked patients for their average amount of wrist pain during the past week. Patients in the splinting group showed an average pain reduction of 32%, where the controls showed an average increase in pain of 17%. This difference in change scores between both groups was significant and indicated a large and clinically meaningful treatment effect.[32-35] Since all patients in the splinting group used wrist working splints in the week preceding the final assessments, this treatment effect might both be attributed to the immediate effect of wrist working splints associated with reduced wrist motion, wrist support and stabilization of the wrist, and to reduced inflammation. As additional measure, we counted the number of SODA-S activities that caused pain. A small, but not significant, treatment effect was found. This might be explained by the small number of patients included in this study, and/or the lack of responsiveness of the selected outcome measure. Because all SODA-S activities were performed without splint, it might also be that wrist working splints only have an immediate effect on wrist pain and do not reduce inflammation. Our findings are largely in line with the results of previous studies on the effects of wrist working splints after a period of splinting. We have to note, however, that differences exist between our study and these studies with regard to amount of splint use, outcome

measures, and/or splinting period. Tijhuis *et al*[13] and Haskett *et al*[14] performed a non-controlled study and found reduced VAS pain scores after, respectively, two and four weeks of splinting. Only the results of Haskett *et al* reached statistical significance.[14] They focused on activity pain and compared measurements without splint at baseline with measurements with splint at follow-up. Whether Tijhuis *et al* assessed wrist pain with or without splint cannot be deduced from their study.[13] Kjeken *et al* performed a randomized controlled study and found no significant difference in VAS activity pain scores between patients who used a wrist working splint for six months and patients who did not.[11] Their follow-op measurements, however, were performed without splint. So, they did not include the immediate effect of wrist working splints. Further investigation of the underlying mechanism of the effect of wrist working splints after a period of splinting is recommended. This knowledge will help clinicians in giving adequate wearing instructions.

In this study, small and non-significant treatment effects were found with regard to non-splinted grip strength and functional ability. These findings are in accordance with previous studies. Although wrist working splints may immediately increase splinted grip strength,[6,11,14] they do not seem to affect non-splinted grip strength after a period of splinting.[9,11,13] As measure of functional ability we used the subjectively rated DASH and the more objectively rated SODA-S. Both measures intend to assess patient's ability to perform hand related daily activities. In literature, no "gold standard" measure of functional ability or dexterity exists. Several subjective and objective measures have been used to assess the effect of wrist working splints on functional ability.[7,8,10,11,14] No significant treatment effects on functional ability were found, measured after a period of splinting (irrespective of splint use).[10,11,14] Although different outcome measures were used, this finding is in line with our study results.

We used transition items as additional measures to assess the effects of wrist working splints. Transition items provide a retrospective assessment of perceived change. Although transition items have been criticized by their proneness to recall bias, they might be more responsive to detect small but important changes than change scores derived from repeated measurements.[31,41] The results with regard to pain and grip strength were highly in accordance with the results obtained with serial measurements. Results with regard to functional ability were conflicting, however. The transition item revealed significant differences between the splinting and the control group with regard to perceived changes from baseline, while the DASH and the SODA-S did not show these differences. As stated, this might be attributed to a lack of responsiveness of both measures for detecting small changes.

Patients in the splinting group were instructed to wear the splint during the day as much as possible, especially during the performance of daily activities, for the duration

of four weeks. This wearing time is supposed to be sufficient to capture the effects of wrist working splints after a period of splinting. Strength of this study is that we took into account the adherence of the patients to the given wearing instructions. First, by applying adherence-enhancing strategies. Second, by evaluating the amount of splint use with a daily diary. Generally, adherence was considered good, as shown by the number of hours the splints were worn during the day. We should note, however, that we cannot conclude with certainty that our adherence-enhancing strategies improved splint use.

As each study our study has a few limitations. The first possible limitation concerns the small sample size. We were not able to include the intended number of patients derived from the power analysis. The small sample size reduced the power of this study to find significant treatment effects (see Table 2). Another limitation concerns the possibility of expectation bias. Given the nature of the intervention, a double blinded study design was not possible. The results might therefore have been influenced by the expectation of a treatment effect.

In conclusion, this randomized controlled study shows that four weeks of splinting with a prefabricated wrist working splint has a large and significant effect on perceived wrist pain in patients with RA suffering from wrist arthritis. Small but non-significant treatment effects were found with regard to non-splinted grip strength and functional ability.

ACKNOWLEDGEMENTS

We thank the patients for their participation in this study. We thank the rheumatologists and research nurses of Rheumatology Twente for their assistance in patient recruitment and data collection.

REFERENCES

1. Flatt AE. The care of the rheumatoid hand. 7th ed. St. Louis: CV Mosby; 1968.
2. Spoorenberg A, Boers M, van der Linden S. Wrist splints in rheumatoid arthritis: a question of belief? Clin Rheumatol 1994;13(4):559-63.
3. Spoorenberg A, Boers M, van der Linden S. Wrist splints in rheumatoid arthritis: what do we know about efficacy and compliance? Arthritis Care Res 1994;7(2):55-7.
4. Steultjens EMJ, Dekker J, Bouter LM, van Schaardenburg D, van Kuyk MAH, van den Ende CHM. Occupational therapy for rheumatoid arthritis. Arthritis Care Res 2002;47(6):672-85.
5. Egan M, Brosseau L, Farmer M, Quimet MA, Rees S, Wells G, et al. Splints / orthoses in the treatment of rheumatoid arthritis. Cochrane Database Syst Rev 2003(1):CD004018.
6. Nordenskiöld U. Elastic wrist orthoses. Reduction of pain and increase in grip force for women with rheumatoid arthritis. Arthritis Care Res 1990;3(3):158-62.
7. Pagnotta A, Baron M, Korner-Bitensky N. The effect of a static wrist orthosis on hand function in individuals with rheumatoid arthritis. J Rheumatol 1998;25(5):879-85.
8. Pagnotta A, Mazer B, Baron M, Wood-Dauphinee S. Static wrist splint use in the performance of daily activities by individuals with rheumatoid arthritis. J Rheumatol 2005;32(11):2136-43.
9. Stern EB, Ytterberg SR, Krug HE, Mullin GT, Mahowald ML. Immediate and short-term effects of three commercial wrist extensor orthoses on grip strength and function in patients with rheumatoid arthritis. Arthritis Care Res 1996;9(1):42-50.
10. Stern EB, Ytterberg SR, Krug HE, Mahowald ML. Finger dexterity and hand function: effect of three commercial wrist extensor orthoses on patients with rheumatoid arthritis. Arthritis Care Res 1996;9(3):197-205.
11. Kjeken I, Moller G, Kvien TK. Use of commercially produced elastic wrist orthoses in chronic arthritis: a controlled study. Arthritis Care Res 1995;8(2):108-13.
12. Anderson K, Maas F. Immediate effect of working splints on grip strength of arthritic patients. Aust Occ Ther J 1987;34(1):26-31.
13. Tijhuis GJ, Vliet Vlieland TPM, Zwinderman AH, Hazes JMW. A comparison of the futuro wrist orthosis with a synthetic thermolyn orthosis: utility and clinical effectiveness. Arthritis Care Res 1998;11(3):217-22.
14. Haskett S, Backman C, Porter B, Goyert J, Palejko G. A crossover trial of custom-made and commercially available wrist splints in adults with inflammatory arthritis. Arthritis Rheum 2004;51(5):792-99.
15. Belcon MC, Haynes RB, Tugwell P. A critical review of compliance studies in rheumatoid arthritis. Arthritis Rheum 1984;27(11):1227-33.
16. Veehof MM, Taal E, Willems MJ, van de Laar MAFJ. Determinants of the use of wrist working splints in rheumatoid arthritis. Arthritis Care Res 2008;59(4):531-6.
17. Arnett FC, Edworthy SM, Bloch DA, McShane DJ, Fries JF, Cooper NS, et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis Rheum 1988;31(3):315-24.
18. Callinan NJ, Mathiowetz V. Soft versus hard resting hand splints in rheumatoid arthritis: pain relief, preference, and compliance. Am J Occup Ther 1995;50(5):347-53.

19. Stern EB, Ytterberg SR, Larson LM, Parke Portoghese C, Kratz WNR, Mahowald ML. Commercial wrist extensor orthoses: a descriptive study of use and preference in patients with rheumatoid arthritis. Arthritis Care Res 1997;10(1):27-35.
20. Prevoo ML, van 't Hof MA, Kuper HH, van Leeuwen MA, van de Putte LB, van Riel PL. Modified disease activity scores that include twenty-eight-joint counts. Development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. Arthritis Rheum 1995;38(1):44-8.
21. Felson DT, Anderson JJ, Boers M, Bombardier C, Chernoff M, Fried B, et al. The American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis clinical trials. Arthritis Rheum 1993;36(6):729-40.
22. Jones E, Hanly JG, Mooney R, Rand LL, Spurway PM. Strength and function in the normal and rheumatoid hand. J Rheumatol 1991;18(9):1313-8.
23. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (Disabilities of the Arm, Shoulder, and Hand). Am J Ind Med 1996;29(6):602-8.
24. Solway S, Beaton DE, Mc Connell S, Bombardier C. The DASH Outcome measure user's manual. 2nd ed. Toronto: Institute for Work & Health; 2002.
25. Beaton DE, Katz JN, Fossel AH, Wright JG, Tarasuk V, Bombardier C. Measuring the whole or the parts? Validity, reliability, and responsiveness of the Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure in different regions of the upper extremity. J Hand Ther 2001;14(2):128-46.
26. Navsarikar A, Gladman DD, Husted JA, Cook RJ. Validity assessment of the disabilities of the arm, shoulder and hand questionnaire (DASH) for patients with psoriatic arthritis. J Rheumatol 1999;26(10):2191-4.
27. Veehof MM, Sleegers EJA, van Veldhoven NHMJ, Schuurman AH, van Meeteren NLU. Psychometric qualities of the Dutch Language Version of the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH-DLV). J Hand Ther 2002;15(4):347-54.
28. van Lankveld WGJM, Graff MJL, van 't Pad Bosch PJI. The short version of the Sequential Occupational Dexterity Assessment based on individual tasks' sensitivity to change. Arthritis Care Res 1999;12(6):417-24.
29. van Lankveld W, van't Pad Bosch P, Bakker J, Terwindt S, Franssen M, van Riel P. Sequential occupational dexterity assessment (SODA): a new test to measure hand disability. J Hand Ther 1996;9(1):27-32.
30. Fitzpatrick R, Ziebland S, Jenkinson C, Mowat A, Mowat A. Transition questions to assess outcomes in rheumatoid arthritis. Br J Rheumatol 1993;32:807-11.
31. Fischer D, Stewart AL, Bloch DA, Lorig K, Laurent D, Holman H. Capturing the patient's view of change as a clinical outcome measure. JAMA 1999;282(12):1157-62.
32. Salaffi F, Stancati A, Silvestri CA, Ciapetti A, Grassi W. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. Eur J Pain 2004;8(4):283-91.
33. Tubach F, Ravaud P, Baron G, Falissard B, Logeart I, Bellamy N, et al. Evaluation of clinically relevant changes in patient reported outcomes in knee and hip osteoarthritis. Annals Rheum Dis 2005;64(1):29-33.

34. Felson DT, Anderson JJ, Boers M, Bombardier C, Furst D, Goldsmith C, et al. American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. Arthritis Rheum 1995;38(6):727-35.
35. Farrar JT, Young Jr. JP, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001;94(2):149-58.
36. Tsutokawa RK, Hewett JE. Quick test for comparing two populations with bivariate data. Biometrics 1977(33):215-9.
37. Hewett JE, Johnson JC. Appropriate use of covariate analyses in arthritis research. In: Symposium at 33rd National Scientific meeting of the Association of Rheumatology Health Professionals; 1998 November 8-12; San Diego; 1998.
38. Riemsma RP, Taal E, Rasker JJ. Group education for patients with rheumatoid arthritis and their partners. Arthritis Care Res 2003;49(4):556-66.
39. Hedges LV, Olkin I. Statistical methods for meta-analysis. Orlando: Academic Press; 1985.
40. Cohen J. Statistical power analysis for the behavioural sciences. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.
41. Guyatt G, Norman G, Juniper E, Griffith LE. A critical look at transition ratings. J Clin Epidemiol 2002;55:900-8.

6

What determines the possession of assistive devices among patients with rheumatic diseases? The influence of the country-related health care system

M.M. Veehof
E. Taal
J.J. Rasker
J. Lohmann
M.A.F.J. van de Laar

Disabil Rehabil 2006;28(4):205-11

ABSTRACT

Objective To identify the determinants of the possession of assistive devices among patients with various rheumatic conditions. In order to determine the influence of the country-related health care system, patients from two different countries were studied.
Methods Patients with rheumatoid arthritis (RA) or psoriatic arthritis (PsA) were selected from rheumatology outpatient clinics in two adjacent regions in The Netherlands and Germany. A total of 142 patients completed a self-administered questionnaire. Information on the possession of assistive devices and data on socio-demographics, clinical status and health status were obtained. Logistic regression analyses were used to identify determinants of the possession of assistive devices.
Results The majority (78%) of the patients possessed at least one or more assistive devices. Obviously, functional status was the most important determinant, followed by the country where the patient resided. More assistive devices were found in increasingly disabled patients as well as in patients living in The Netherlands.
Conclusion Functional status and the patient's country are the most important determinants of the possession of assistive devices among patients with rheumatic conditions. We hypothesize that the most likely explanation for the differences in possession rates between countries are differences in societal systems for the prescription and reimbursement of assistive devices.

INTRODUCTION

Disability and dependency upon others are important concerns for rheumatic patients.[1-3] These are often caused by painful joints or impairments in range of motion, muscle strength, endurance or joint stability. To improve the patient's functional capacity and independence, assistive devices can be used.[4-6] However, their efficacy and effectiveness are poorly studied. On the one hand prescription is based upon common clinical practice, and on the other hand it is based upon reimbursement rules in the health care system.

Although assistive devices are frequently used, data on patients with rheumatic diseases are scarce. Some studies investigated the possession of assistive devices and identified factors that influence use or non-use.[4,7-10] Others addressed the need for assistive devices as expressed by patients[5] or their effectiveness.[11-15] Limited data are published on the determinants of the possession of assistive devices. Van der Esch *et al* demonstrated that half of patients suffering from either rheumatoid arthritis (RA) or osteoarthritis (OA) possess a walking aid. They found disability, pain and age to be associated with the possession of walking aids.[9]

Many studies regarding the determinants of the possession or use of assistive devices focused on the elderly.[10,16-21] In these studies several potential determinants were investigated. Although the possession of assistive devices is suggested to be associated with societal mechanisms concerning prescription and reimbursement of assistive devices,[4] it is remarkable that the patient's country has never been investigated as a potential determinant.

The goal of this study is to identify variables that are associated with the possession of assistive devices among patients with rheumatic diseases with an emphasis on the patient's country.

PATIENTS AND METHODS

Patients

We performed a cross-sectional study among adult patients with either RA, according to the 1987 American College of Rheumatology (ACR) criteria, or psoriatic arthritis (PsA), according to the clinical experience of the attending rheumatologist.[22] Patients were randomly selected from the rheumatology outpatient clinics in two adjacent health care regions in Germany and The Netherlands. The first is the district of Borken, Steinfurt, and Grafschaft Bentheim (Germany), the latter the district Twente (The Netherlands).

Procedure

Selected patients were informed on this study by mail. Patients who gave informed consent were asked to fill in the Modified Health Assessment Questionnaire (MHAQ).[23] The MHAQ is a short version of the Health Assessment Questionnaire (HAQ) and consists of eight questions to assess the patient's ability to perform daily activities. Patients with a MHAQ score of zero, which means that they experienced no functional limitations, were excluded. Included patients received a second self-administered questionnaire. The study was approved by the Ethical Committee of Medisch Spectrum Twente Hospital, Enschede, The Netherlands.

Measures

The second questionnaire contained questions on independent variables, including socio-demographics, clinical status, and health status, and questions regarding the dependent variable; possession of assistive devices.

Socio-demographics

Questions on gender, age (years), living status (alone or with partner), net yearly income (below or above €18.000 [2002]), insurance (public or private), education (low: vocational training, medium: high school, or high: college or university), and country (Dutch versus German) were included.

Clinical status

A questionnaire on co-morbidity was included. Patients were asked to indicate which of the following chronic conditions they had: hypertension, heart disease, stroke, epilepsy, diabetes, cancer, lung disease, kidney disease, liver disease, stomach or intestine disease, blood disease and other diseases. We calculated the total number of co-morbidities per patient. Furthermore, we retrieved the rheumatological diagnosis (RA or PsA) and disease duration (years) from the patients' charts.

Health status

We included questionnaires on functional status, fatigue, and pain. Functional status was measured with the HAQ.[24-26] The HAQ is a frequently used questionnaire in rheumatology to assess the patient's ability to perform daily activities. The questionnaire consists of 20 questions divided into eight categories of activities: dressing, arising, eating, walking, hygiene, reach, grip and common activities. The questions are scored on a 4-point scale, ranging from "able to do without difficulty" (score 0) to "unable to do" (score 3). We calculated the Alternative Disability Index

(ADI) by summing up the highest score on each category and dividing this through the total number of categories. The HAQ has good psychometric properties.[24,27,28] Fatigue was measured by means of a 100 mm Visual Analogue Scale (VAS) with endpoints "no fatigue" (0) and "fatigue as bad as it could be" (100). The VAS fatigue scale is a suitable scale for use in clinical studies.[29] Pain was measured using the pain scale of the Arthritis Impact Measurement Scales (AIMS2), which is a valid and reliable questionnaire to assess health-related quality of life in arthritis patients.[30-33] The pain scale consists of 5 items, which are scored on a 5-point Likert scale, ranging from "no pain" (score 1) to "severe pain" (score 5) or from "never" (score 1) to "every day" (score 5). Pain scores were calculated by summing the individual item scores, and converting these sum-scores into a score ranging from 0 (no pain) to 10 (severe pain).

Assistive devices

Seventeen common assistive devices were included. The assistive devices could be categorized into mobility devices (cane, crutches, walker, wheelchair, scooter, orthopedic footwear), small tools for ADL (special cutlery, special writing pen, dressing devices, helping hand), housing adaptations (special kitchen, elevator, shower seat, grab-bar(s) in bathroom or toilet, special taps, elevated toilet seat), and special furniture (special bed). We did not include consumer products, assistive to perform household activities, because these are also often used by healthy people. We asked patients to indicate which of the devices they possess. Furthermore, we asked them if they need more information on assistive devices (yes or no) and if they want to have more assistive devices (yes or no).

Statistics

We used correlation analysis for each assistive device separately to test for significant associations between the possession of an assistive device and independent variables. Variables with significant associations were used for logistic regression analysis ($p \leq 0.05$ for any outcome). Logistic regression analysis (method forced entry) was done to identify variables that were independently associated with the possession of an assistive device. To determine the contribution of the country patients live in, controlling for confounding by other variables, significant independent variables were entered in the first block and the patient's country (if significantly associated) was entered in the second block.

Data analysis was performed with the Statistical Package for the Social Sciences (SPSS for windows, version 11.0).

RESULTS

A total of 327 patients were selected (186 Dutch, 141 German). A total of 218 (67%) responded and agreed to participate (132 Dutch, 86 German). A total of 165 of them (95 Dutch, 70 German) were eligible for inclusion in this study (MHAQ score > 0) and received a questionnaire. Completed questionnaires were returned by 142 patients (85 Dutch, 58 German). Patient characteristics are summarized in Table 1. Significant differences between Dutch and German patients were found regarding age, education, functional status, and fatigue.

Table 1 Patient characteristics[a]

	Total group (n = 142)	Dutch patients (n = 85)	German patients (n = 57)
Sociodemographics			
Age, years	60.5 (12.1)	62.4 (11.5)*	57.6 (12.6)*
Female gender, %	66	69	61
Living with partner, %	85	82	90
Yearly net income below €18.000 (2002), %	53	53	55
Education level, %			
low	58	49*	72*
medium	30	38*	19*
high	12	13	9
Clinical status			
Diagnosis, %			
RA	58	53	67
PsA	42	47	33
Disease duration, years	15.5 (11.0)	16.3 (11.6)	14.2 (9.9)
Co-morbidity, number	1.4 (1.4)	1.4 (1.4)	1.4 (1.5)
Health status			
Functional status (HAQ) (0-3)	1.3 (0.8)	1.5 (0.8)*	1.0 (0.7)*
Fatigue (VAS) (0-100)	50.6 (23.9)	54.0 (22.6)*	45.5 (25.1)*
Pain (AIMS2) (0-10)	6.4 (2.2)	6.5 (2.0)	6.4 (2.4)

[a]Values are means (SD) unless otherwise indicated; *Significant difference ($p \leq 0.05$) between Dutch and German patients.

Possession of assistive devices

The percentages of patients possessing specific assistive devices are summarized in Table 2. A total of 56% of the patients (n = 142) had one or more mobility devices, 33% had one or more tools for ADL, and 60% had one or more housing adaptations. Some 22% of the patients had no assistive devices (data not shown). The Dutch patients possessed more assistive devices than the German patients. Differences were most pronounced for housing adaptations, a wheelchair and a special bed.

Table 2 Numbers and percentages of patients possessing assistive devices

	Total group (n = 142)	Dutch patients (n = 85)	German patients (n = 57)
Mobility devices			
Scooter mobile	16 (11%)	15 (18%)	1 (2%)
Walker	15 (11%)	11 (13%)	4 (7%)
Cane	20 (14%)	14 (17%)	6 (11%)
Crutch(es)	24 (17%)	13 (15%)	11 (19%)
Wheelchair	25 (18%)	23 (27%)	2 (4%)
Orthopedic footwear	56 (39%)	33 (39%)	23 (40%)
Tools for ADL			
Helping hand	13 (9%)	11 (13%)	2 (4%)
Special cutlery	13 (9%)	9 (11%)	4 (7%)
Special writing pen	21 (15%)	15 (18%)	6 (11%)
Dressing device(s)	26 (18%)	15 (18%)	11 (19%)
Housing adaptations			
Elevator	10 (7%)	9 (11%)	1 (2%)
Adapted kitchen	19 (13%)	16 (19%)	3 (5%)
Shower seat	41 (29%)	34 (40%)	7 (12%)
Grab-bar(s) in bathroom/toilet	60 (42%)	43 (51%)	17 (30%)
Special tap(s)	61 (43%)	51 (60%)	10 (18%)
Elevated toilet seat	64 (45%)	53 (62%)	11 (19%)
Special furniture			
Special bed	43 (30%)	35 (41%)	8 (14%)

The majority of the patients (56%) indicated that they do not need more information on assistive devices. The need for additional information in German patients was considerably higher than in Dutch patients (57% vs. 36 %). A minority (27%) of the patients (Dutch 23%, German 33%) indicated that they desired more assistive devices.

Correlation analyses were done for assistive devices that were possessed by more than 14% of the patients (data not shown). The results indicate that owners of an assistive device were more disabled than non-owners regardless of what kind of assistive device they possessed. Other variables that were significantly related to the presence of various assistive devices were country, gender, diagnosis, disease duration, pain and fatigue. Owners of assistive devices were more likely to live in The Netherlands, be female and suffer from RA than non-owners. Furthermore, owners had longer disease duration, had more pain and were more fatigued compared to non-owners.

The findings of the logistic regression analyses for the possession of assistive devices are presented in Tables 3 and 4. The data indicate that functional status was a determinant of the possession of almost all assistive devices analysed (crutch(es), wheelchair, orthopedic footwear, special bed, dressing device(s), grab-bar(s), shower seat, raised toilet seat). Another frequently found determinant was the patient's country. Wheelchairs, special beds, shower seats, special taps and raised toilet seats were more likely to be present in Dutch patients than in German patients. The

contribution of the patient's country to the total proportion explained variance was 9% for the possession of a wheelchair (total proportion explained variance = 68%), 5% for the possession of a special bed (total proportion explained variance = 43%), 8% for the possession of a shower seat (total proportion explained variance = 49%), 12% for the possession of special taps (total proportion explained variance = 49%), and 17% for the possession of a raised toilet seat (total proportion explained variance = 60%). Another determinant of the possession of assistive devices was diagnosis RA. Wheelchairs, orthopedic footwear, special beds and raised toilet seats were more frequently present in patients with RA than in patients with PsA. Finally, disease duration was a determining variable for the possession of orthopedic footwear, special writing pens and special taps.

DISCUSSION

Functional status and the patient's country are the most important determinants of the possession of assistive devices among patients with RA and PsA. During the 1980s, the general public became aware of the fact that independence is an essential element of the lives of many elderly people and of those with chronic illnesses like RA or PsA.[1] Assistive devices are intended to improve or maintain the patient's functional abilities and independence. Understanding the mechanisms determining the possession of assistive devices is warranted to improve health care and quality of life of patients. We addressed this issue by performing a cross-sectional study in patients suffering from two different rheumatic diseases living in two adjacent countries, with different health care systems. This study design is able to reveal possible explaining variables but is not able to draw definite conclusions.

The majority of our patients appeared to possess at least one or more assistive devices. Adaptations in the bathroom and toilet (special tap(s), shower seat, grab-bar(s), and elevated toilet seat) are most frequently present, along with orthopedic footwear and a special bed. Strikingly, relatively few patients possess small tools for ADL compared to mobility devices and housing adaptations. This finding can not fully be explained by functional status and disease duration (proportion explained variance ≤ 27%). More variables might influence the possession of ADL tools. Variables to consider include costs, awareness of available ADL tools, patient's preference for human assistance in ADL, and expectations on the effectiveness of ADL tools.

Obviously, functional status was found to be an important determinant of the possession of assistive devices. This finding is in line with preceding studies either in rheumatology or in geriatrics.[9,17-21] More strikingly is the suggestion that the patient's country is an additional determining variable. Not only in univariate analyses but also

Table 3 Results logistic regression analyses for the presence of mobility devices and small tools for ADL[a]

	Odds ratio (95% confidence interval)				
	Crutches	Wheelchair	Orthopedic footwear	Dressing devices	Special writing pen
Female gender	-	4.3 (0.7 to 28.5)	-	-	0.4 (0.1 to 1.5)
Diagnosis RA	-	**16.9 (1.7 to 165.9)***	**2.4 (1.0 to 5.6)***	-	-
Age	-	-	-	-	-
Income	-	0.5 (0.1 to 2.8)	-	-	-
Disease duration	-	1.0 (0.9 to 1.1)	**1.1 (1.0 to 1.1)***	1.0 (1.0 to 1.1)	**1.1 (1.0 to 1.1)***
Co-morbidity	-	-	-	-	
Functional status	**2.0 (1.2 to 3.3)***	**6.2 (1.4 to 28.8)***	**1.9 (1.0 to 3.8)***	**2.8 (1.4 to 5.5)****	1.0 (0.5 to 2.0)
Pain	-	-	1.0 (0.8 to 1.3)	1.1 (0.8 to 1.4)	1.3 (1.0 to 1.7)
Fatigue	-	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.0)	-	-
Country (NL)	-	**37.7 (2.4 to 588.5)****	-	-	-
R^2	0.07	0.68	0.27	0.27	0.19
R^2 change	n.a.	0.09**	n.a.	n.a.	n.a.

R^2 = Nagelkerke R^2 = pseudo measure for proportion explained variance; R^2 change = difference in Nagelkerke R^2 between models with and without patient's country as associated factor (if applicable); n.a. = not applicable.

[a]Independent variables (except the patient's country) with significant correlations ($p \leq 0.05$) with the possession of an assistive device were entered first, and the patient's country was entered second (if this variable was significantly related to the possession of an assistive device). Odds ratios of the final (significant) model were shown.

*significant at $p \leq 0.05$; **significant at $p \leq 0.01$.

Table 4 Results logistic regression analyses for the presence of housing adaptations and furniture[a]

	Odds ratio (95% confidence interval)				
	Special taps	Grab-bars	Shower seat	Elevated toilet seat	Special bed
Female gender	**3.6 (1.3 to 10.5)***	2.1 (0.8 to 5.9)	2.9 (0.9 to 9.1)	2.0 (0.6 to 6.2)	-
Diagnosis RA	-	2.1 (0.8 to 5.6)	2.2 (0.7 to 6.9)	**5.3 (1.7 to 16.5)****	**3.4 (1.2 to 9.7)***
Age	-	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.1)
Income	-	-	-	-	-
Disease duration	**1.1 (1.0 to 1.1)****	1.0 (1.0 to 1.0)	-	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.1)
Co-morbidity	-	1.2 (0.8 to 1.7)	1.2 (0.8 to 1.8)	1.2 (0.8 to 1.8)	-
Functional status	2.2 (1.0 to 4.9)	**4.7 (2.0 to 10.9)****	**3.2 (1.4 to 7.1)****	**4.3 (1.6 to 11.6)****	**2.0 (1.1 to 3.8)***
Pain	1.2 (0.9 to 1.5)	1.1 (0.8 to 1.4)	1.0 (0.7 to 1.4)	-	-
Fatigue	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	-
Country (NL)	**8.1 (2.8 to 23.2)****	-	**6.9 (1.9 to 24.7)****	**17.6 (5.0 to 61.9)****	**4.1 (1.4 to 12.2)***
R^2	0.49	0.48	0.49	0.60	0.43
R^2 change	0.12**	0.01	0.08**	0.17**	0.05**

R^2 = Nagelkerke R^2 = pseudo measure for proportion explained variance; R^2 change = difference in Nagelkerke R^2 between models with and without patient's country as associated factor (if applicable); n.a. = not applicable.

[a]Independent variables (except the patient's country) with significant correlations ($p \leq 0.05$) with the possession of an assistive device were entered first, and the patient's country was entered second (if this variable was significantly related to the possession of an assistive device). Odds ratios of the final (significant) model were shown.

*significant at $p \leq 0.05$; **significant at $p \leq 0.01$.

after controlling for differences in socio-demographics, clinical status and health status this association remains. Housing adaptations as well as wheelchairs and special beds are more common in Dutch patients than in German patients. This finding might be related to cultural differences between Dutch and German patients or the attitude of doctors and health professionals with respect to assistive devices. However, we consider another possible explanation likely: the differences in the country-related health care systems with respect to the prescription and reimbursement of assistive devices. In The Netherlands, as well as in Germany, several pieces of legislation and institutions are involved in the reimbursement of assistive devices. In The Netherlands, most assistive devices for use at home are covered by either health insurance (e.g., mobility devices, special bed) under the Health Insurance Act, or municipality (e.g., housing adaptations, wheelchair) under the Services for the Disabled Act. In Germany, most assistive devices for use at home are covered by health insurance. However, if patients are categorized as members of the long-term care insurance and the devices are intended to facilitate the provision of care, assistive devices are covered by long-term care insurance. The reimbursement of assistive devices is regulated in the Social Law Code. In both countries, only assistive devices included in a specific list of medical aids are covered by insurance. The reimbursement and thus necessity of applications is assessed by medical advisors. Differences between both countries exist among others in the kind of reimbursable devices, prescription rules, assessment, and additional payments. Small tools for ADL, for example, are reimbursed in Germany, but not in The Netherlands. Furthermore, a medical prescription from a physician is necessary for the application of assistive devices in Germany (except for devices covered by long-term care insurance). In The Netherlands, patients can apply for assistive devices covered by municipalities themselves, without medical prescription. Besides, in The Netherlands, patients are visited by a medical advisor of the municipality at home to judge if they need the devices they applied for. Finally, in Germany, co-payment is applied to all assistive devices. For assistive devices covered by health insurance patients pay 10% of the cost with a minimum of €5 and a maximum of €10 (before January 1 2004: 10% co-payment). For assistive devices covered by long-term care insurance patients pay 10% of the cost with a maximum of €25. In The Netherlands, many assistive devices covered by health insurance (e.g., mobility devices) are fully reimbursed. For assistive devices covered by municipality (e.g., housing adaptations) no standard rules for additional payment exist. Municipalities have a high degree of autonomy and are free to ask for co-payment or cost-sharing from applicants (except for wheelchair provision). Next to the above mentioned differences, differences might exist in the strictness of the guidelines used by the medical advisors to assess the necessity of the assistive devices patients applied for. Dutch patients might receive

(appropriately or inappropriately) sooner assistive devices at a certain disability level compared to German patients. In our study, we did not investigate if patients really needed all the devices they possessed, or if they could do as well with fewer.

Although our univariate analysis for age, gender and pain confirmed the relationship with the possession of various assistive devices as found by many others,[9,10,16-19,21] our multivariate analysis showed that these variables are not independently associated with the possession of assistive devices. The only exception we found is female gender which is independently associated with the possession of special taps.

One drawback of our study is that we did not investigate the determinants of the possession of all assistive devices included in the questionnaire. Assistive devices with possession rates smaller than 15% were excluded from logistic regression analysis.

In conclusion, our data suggest that functional status and the patient's country are the most important determinants of the possession of assistive devices. We hypothesize that the most likely explanation for the differences in possession rates between countries are the differences in country related health care systems. More research is necessary to investigate which characteristics of the patient's country are responsible for the differences in possession rates.

ACKNOWLEDGEMENTS

This study was an Interreg II project funded by the European Union. We want to thank all participating patients. Furthermore, we want to thank doctors H.J. Bernelot Moens, K.W. Drossaers-Bakker, R. Ernst, C.J. Haagsma, M.A. Hund, M.W.M. Kruijssen, G. Müller, J.C.M. Oostveen, U. Schoo, F. Schuhmann, and T.R. Zijlstra for their collaboration in this study including the selection of patients.

REFERENCES

1. Cornelissen PG, Rasker JJ, Valkenburg HA. The arthritis sufferer and the community: A comparison of arthritis sufferers in rural and urban areas. Ann Rheum Dis 1988;47:150-6.
2. Taal E, Rasker JJ, Seydel ER, Wiegman O. Health status, adherence with health recommendations, self-efficacy and social support in patients with rheumatoid arthritis. Patient Educ Couns 1993;20:63-76.
3. Melanson PM, Downe-Wamboldt B. Confronting life with rheumatoid arthritis. J Adv Nurs 2003;42:125-33.
4. Rogers JC, Holm MB. Assistive technology device use in patients with rheumatic disease: A literature review. Am J Occup Ther 1992;46:120-7.
5. Mann WC, Hurren D, Tomita M. Assistive devices used by home-based elderly persons with arthritis. Am J Occup Ther 1995;49:810-20.
6. Mann W. Assistive technology for persons with arthritis. In: Melvin J, Jensen G, editors. Rheumatologic rehabilitation series Vol. 1: Assessment and management. Bethesda, MD: American Occupational Therapy Association; 1998. pp 369-92.
7. Hollings EM, Haworth RJ. Supply and use of aids and appliances. A study of 119 patients with rheumatoid arthritis. Occup Ther 1978:336-9.
8. Rogers J, Holm M, Perkins L. Trajectory of assistive device usage and user and non-user characteristics: Long-handled bath sponge. Arthritis Rheum 2002;47:645-50.
9. van der Esch M, Heijmans M, Dekker J. Factors contributing to possession and use of walking aids among persons with rheumatoid arthritis and osteoarthritis. Arthritis Rheum 2003;49:838-42.
10. Haworth RJ, Hopkins R. Use of aids following total hip replacement. Occup Ther 1980;Dec:398-400.
11. Hass U, Brodin H, Andersson A, Persson J. Assistive technology selection: A study of participation of users with rheumatoid arthritis. IEEE Trans Rehabil Eng 1997;5:263-75.
12. Nordenskiöld U. Evaluation of assistive devices after a course in joint protection. Int J Technol Assess Health Care 1994;10:293-304.
13. Nordenskiöld U, Grimby G, Hedberg M, Wright B, Linacre JM. The structure of an instrument for assessing the effects of assistive devices and altered working methods in women with rheumatoid arthritis. Arthritis Care Res 1996;9:358-67.
14. Nordenskiöld U, Grimby G, Dahlin-Ivanoff S. Questionnaire to evaluate the effects of assistive devices and altered working methods in women with rheumatoid arthritis. Clin Rheumatol 1998;17:6-16.
15. Thyberg I, Hass UAM, Nordenskiöld U, Skogh T. Survey of the use and effect of assistive devices in patients with early rheumatoid arthritis: a two-year follow-up of women and men. Arthritis Rheum 2004;51:413-21.
16. Zimmer Z, Chappell NL. Mobility restriction and the use of devices among seniors. J Aging Health 1994;6:185-208.
17. de Klerk MMY, Huijsman R, McDonnell J. The use of technical aids by elderly persons in the Netherlands: An application of the Andersen and Newman model. Gerontologist 1997;37:365-73.

18. Edwards NI, Jones DA. Ownership and use of assistive devices amongst older people in the community. Age Ageing 1998;27:463-8.
19. Dekker J, Rijken M, van Poppel M, de Bruin A. The possession of technical aids among persons with a somatic chronic disease. Disabil Rehabil 2003;25:393-8.
20. Hartke RJ, Prohaska TR, Furner SE. Older adults and assistive devices. J Aging Health 1998;10:99-116.
21. Tomita MR, Mann WC, Fraas LF, Stanton KM. Predictors of the use of assistive devices that address physical impairments among community based frail elders. J Appl Gerontol 2004;23:141-55.
22. Brooks P, Hochberg M. Outcome measures and classification criteria for the rheumatic diseases. A compilation of data from OMERACT Outcome Measures for Arthritis Clinical Trials), ILAR (International League of Associations for Rheumatology), regional leagues and other groups. Rheumatology 2001;40:896-906.
23. Pincus T, Summey JA, Soraci SA, Wallson KA, Hummon NP. Assessment of patients satisfaction in activities of daily living using a modified Stanford Health Assessment Questionnaire. Arthritis Rheum 1983;26:1346-53.
24. Fries JF, Spitz PW, Young DY. The dimensions of health outcomes: the health assessment questionnaire, disability and pain scales. J Rheumatol 1982;9:789-93.
25. Siegert CE, Vleming LJ, Vandenbroucke JP, Cats A. Measurement of disability in Dutch rheumatoid arthritis patients. Clin Rheumatol 1984;3:305-9.
26. Lautenschlager J, Mau W, Kohlmann T, et al. Comparative evaluation of a German version of the Health Assessment Questionnaire and the Hannover Functional Capacity Questionnaire. Z Rheumatol 1997;56:144-55.
27. Ramey D, Fries J. The Health Assessment Questionnaire 1995 - status and review. Quality of life and pharmacoeconomics in clinical trials. Philadelphia, PA: Lippincott-Raven Publishers; 1995. pp 227-37.
28. Bruce B, Fries JF. The Stanford Health Assessment Questionnaire: A review of its history, issues, progress, and documentation. J Rheumatol 2003;30:167-78.
29. Wolfe F. Fatigue assessments in rheumatoid arthritis: Comparative performance of Visual Analog Scales and longer fatigue questionnaires in 7760 patients. J Rheumatol 2004;31:1896-902.
30. Meenan RF, Gertman PM, Mason JH. Measuring health status in arthritis. The arthritis impact measurement scales. Arthritis Rheum 1980;23:146-52.
31. Riemsma RP, Taal E, Rasker JJ, Houtman PM, van Paassen HC, Wiegman O. Evaluation of a Dutch version of the AIMS2 for patients with rheumatoid arthritis. Br J Rheumatol 1996;35:755-60.
32. Evers AW, Taal E, Kraaimaat FW, et al. A comparison of two recently developed health status instruments for patient with arthritis: Dutch-AIMS2 and IRGL. Arthritis Impact Measurement Scales. Impact of rheumatic diseases on general health and lifestyle. Br J Rheumatol 1998;37:157-64.
33. Jaeckel WH, Cziske R, Schochat T, Jacobi E. Assessing health status after inpatient rehabilitation in rheumatoid arthritis. Int Rehabil Med 1986;8:54-9.

7

Possession of assistive devices is related to improved psychological well-being in patients with rheumatic conditions

M.M. Veehof
E. Taal
J.J. Rasker
J. Lohmann
M.A.F.J. van de Laar

J Rheumatol 2006;33(8):1679-83

ABSTRACT

Objective To investigate the relationship between the possession of assistive devices and psychological well-being in patients with rheumatic conditions.
Methods Patients with rheumatoid arthritis (RA) and psoriatic arthritis (PsA) were selected from rheumatology outpatient clinics in 2 adjacent regions in The Netherlands and Germany. A total of 142 patients completed a questionnaire on the possession of assistive devices and psychological well-being. Questions on sociodemographics, clinical status, and health status were included. Hierarchical multiple linear regression analysis was used to determine the unique association between the number of assistive devices per patient and psychological well-being, controlling for confounding variables.
Results Univariately, the number of assistive devices per patient was negatively associated with psychological well-being. Multivariately, the number of assistive devices per patient was positively associated with psychological well-being. Functional status was a negative confounder of the relationship between the possession of assistive devices and psychological well-being.
Conclusion The possession of assistive devices was positively related to psychological well-being of patients suffering from rheumatic diseases, after controlling for differences in functional status.

INTRODUCTION

Rheumatologists and healthcare professionals (e.g., occupational and physical therapists) frequently recommend assistive devices to patients with rheumatic conditions.[1] Obviously their primary objective is to improve the patient's functionality in daily activities. Secondary goal is to maintain independence. Moreover, improving functionality and independence might positively affect quality of life (QoL). To justify the prescription of assistive devices from healthcare and health economic points of view, evidence on the effects of assistive devices is of great importance.

Most studies on assistive devices among patients with rheumatic conditions have focused on the possession and/or use of assistive devices.[2-8] A few studies have been performed to examine the effects of assistive devices on physical functioning. Nordenskiöld *et al* and Thyberg *et al* investigated the effects of assistive devices on perceived difficulty with the performance of activities of daily living (ADL) in patients with rheumatoid arthritis (RA).[9-11] Both studies reported a reduction of perceived difficulty with daily activities, measured with the self-administered Evaluation of Daily Activity Questionnaire (EDAQ). Nordenskiöld *et al* also reported a relief of pain when patients used assistive devices.[9,12] To our knowledge, no attention has been given to the psychological and social effects of assistive devices among patients with arthritic conditions. This is striking, given the increasing interest in the assessment of QoL as an outcome measure of the effectiveness of therapeutic interventions.[13,14]

Studies have shown that assistive devices contribute to improved physical functioning. Moreover, functionality is related to psychological well-being. Our hypothesis was that psychological well-being among disabled patients would be improved if patients had assistive devices. We investigated the relationship between psychological well-being and the possession of assistive devices in patients with rheumatic conditions.

MATERIALS AND METHODS

Patients

We performed a cross-sectional study among adult patients with either RA, according to the 1987 American College of Rheumatology (ACR) criteria, or psoriatic arthritis (PsA), according to the clinical experience of the attending rheumatologist. Patients were randomly selected from the archive of charts of rheumatology outpatient clinics in 2 adjacent healthcare regions. The first were the districts of Borken, Steinfurt, and Grafschaft Bentheim, Germany, the other the Twente district of The Netherlands.

Procedure

Selected patients were informed on this study by mail. Patients who gave informed consent were asked to fill in the Modified Health Assessment Questionnaire (MHAQ).[15] The MHAQ is a short version of the Health Assessment Questionnaire (HAQ) to assess patient's ability to perform daily activities. Patients with MHAQ score of 0, which meant that they experienced no functional limitations, were excluded. Included patients received another self-administered questionnaire. The study was approved by the Ethics Committee of Medisch Spectrum Twente Hospital.

Questionnaire

The questionnaire contained questions on psychological well-being and the possession of assistive devices. Questions on sociodemographics, clinical status, and health status were included.

Psychological well-being

Psychological well-being was measured with the level of tension and mood scales of the Arthritis Impact Measurement Scales 2 (AIMS2).[16-18] Both scales consist of 5 items, which are scored on a 5-point Likert scale, ranging from "always" (score 1 or 5) to "never" (score 5 or 1). Scale scores were calculated by summing the individual item scores and converting these sum-scores into a score ranging from 0 (bad health status) to 10 (good status). According to the standard procedure for the calculation of AIMS2 component scores,[16] psychological well-being was calculated by averaging the 2 scale scores of level of tension and mood.

Assistive devices

Seventeen common assistive devices, mainly derived from the HAQ, were included. The assistive devices could be divided into mobility devices (cane, crutches, walker, wheelchair, scooter, orthopedic footwear), small tools for ADL (special cutlery, special writing pen, dressing device(s), helping hand), housing adaptations (special kitchen, elevator, shower seat, grab bar(s) in bathroom and/or toilet, special tap(s), elevated toilet seat), and special furniture (special bed). We did not include consumer products assisting performance of household activities, because these are also often used by healthy people. We asked patients to indicate which of the devices they possess. We calculated the total number of assistive devices per patient.

Sociodemographics

Questions on sex, age, living status (alone or with partner), net yearly income [below or above €18.000 (2002)], education (low: vocational training, medium: high school, or high: college or university), and country (Dutch versus German) were included.

Clinical status

A questionnaire on comorbidity was included. Patients were asked to indicate which of the following chronic conditions they had: hypertension, heart disease, stroke, epilepsy, diabetes, cancer, lung disease, kidney disease, liver disease, stomach or intestine disease, blood disease, and other diseases. We calculated the total number of comorbidities per patient. Furthermore, we retrieved the rheumatological diagnosis (RA or PsA) and disease duration (years) from the patients' charts.

Health status

We included questionnaires on functional status, fatigue, and pain. Functional status was measured with the HAQ.[19-21] We assessed patients' ability to perform activities using a 4-point scale, ranging from "able to do without difficulty" (score 0) to "unable to do" (score 3). We calculated the Alternative Disability Index by summing up the highest score on each scale and dividing this by the total number of scales. High HAQ scores represented low levels of physical functioning. Fatigue was measured by means of a 100 mm visual analog scale (VAS) with endpoints "no fatigue" (0) and "fatigue as bad as it could be" (100).[22] Pain was measured using the pain scale of the AIMS2.[16-18] This scale consists of 5 items, which are scored on a 5-point Likert scale, ranging from "no pain" (score 1) to "severe pain" (score 5) or from "never" (score 1) to "every day" (score 5). Pain scores were calculated by summing the individual item scores and converting these sum-scores into a score ranging from 0 (no pain) to 10 (severe pain).

Statistical analyses

The normality of the distribution of the data was assessed with the Kolmogorov-Smirnov test. Correlation analyses were used to investigate the univariate relationship between psychological well-being and the number of assistive devices per patient and to investigate the univariate relationship of both variables with sociodemographic, clinical status, and health status variables. For the normally distributed variables, Pearson's correlation analyses were applied. For the not normally distributed variables, Spearman's correlation analyses were applied. For dichotomous variables (sex, living situation, income, country, diagnosis), the significance results of correlation analyses are exactly the same as comparing means by independent t tests (in the case of normally distributed variables) or median scores by Mann-Whitney U tests (in the case

of not normally distributed variables). Therefore, the results are reported in the correlational format for consistency.

The univariate relationship between the possession of assistive devices and psychological well-being might be affected by one or more confounding variables. Therefore, hierarchical multiple linear regression analysis with backward elimination of potential confounding variables was used to identify the unique association between the possession of assistive devices and psychological well-being. In the first block, the number of assistive devices per patient was entered. In the second block, potential confounding variables [variables that were univariately correlated ($p \leq 0.15$) with both psychological well-being and the number of assistive devices per patient] were entered. A p value of 0.15 was used to be sure that we did not miss any variables that might act as a confounder. Subsequently, all potential confounding variables were sequentially removed. The variable with the smallest partial correlation with psychological well-being was considered first for removal. If it met the criterion for elimination, that is, if it changed the regression coefficient (B) of the number of assistive devices per patient with less than 10%, it was removed. After the first variable was removed, the variable remaining in the equation with the smallest partial correlation was considered next. The procedure stopped if there were no variables in the equation that satisfied the elimination criterion. The remaining variables were considered to be confounders of the relationship between the possession of assistive devices and psychological well-being.

Data analysis was performed with the Statistical Package for the Social Sciences (SPSS for windows, version 11.0).

RESULTS

We selected 327 patients. Two hundred eighteen (67%) responded and agreed to participate. Of them, 165 were eligible (MHAQ score > 0) for study and received a questionnaire. Completed questionnaires were returned by 142 patients. Patient characteristics are shown in Table 1.

The percentages of patients possessing specific assistive devices are summarized in Table 2. Seventy-eight percent of the patients possessed 1 or more assistive devices. On average, patients possessed 3 to 4 assistive devices (Table 1). The findings of the correlation analyses are presented in Table 1. With the exception of psychological functioning, none of the variables was normally distributed. Therefore, we calculated Spearman's correlation coefficients. The data indicate that the number of assistive devices per patient was univariately negatively correlated with psychological well-being ($r = -0.18$; $p = 0.03$). Further, functional status, pain, fatigue, and comorbidity

were correlated ($p \leq 0.15$) with both psychological well-being and the number of assistive devices per patient. These variables were considered potential confounders of the relationship between the number of assistive devices per patient and psychological well being.

Table 1 Patient characteristics and their correlation with the possession of assistive devices and psychological well being (n = 142)

Patient characteristics	Values†	Assistive devices	Psychological well-being
Sociodemographics			
Age, years	60.5 (12.1)	0.27**	0.03
Gender, %		-0.32***	0.10
female (score 0)	66		
male (score 1)	34		
Living situation, %		-0.07	-0.15*
alone (score 0)	15		
with partner (score 1)	85		
Yearly net income (2002), %		-0.26***	0.04
below €18.000 (score 0)	53		
above €18.000 (score 1)	47		
Education level, %		-0.05	0.09
low (score 1)	58		
medium (score 2)	30		
high (score 3)	12		
Country, %		-0.31***	-0.08
the Netherlands (score 0)	60		
Germany (score 1)	40		
Clinical status			
Diagnosis, %		-0.36***	0.06
RA (score 0)	58		
PsA (score 1)	42		
Disease duration, years	15.5 (11.0)	0.41***	-0.04
Comorbidity, number	1.4 (1.4)	0.22***	-0.29***
Health status			
Functional status (HAQ) (0-3)	1.3 (0.8)	0.72***	-0.41***
Fatigue (VAS) (0-100)	50.6 (23.9)	0.43***	-0.51***
Pain (AIMS2) (0-10)	6.4 (2.2)	0.33***	-0.50***
Psychological functioning (AIMS2) (0-10)	6.0 (1.7)	-0.18**	-
Assistive devices (number in possession) (0-17)	3.7 (3.6)	-	-0.18**

HAQ, Health Assessment Questionnaire; VAS, visual analog scale; AIMS2, Arthritis Impact Measurement Scales 2.
†Values are mean (SD) unless otherwise indicated; *p ≤ 0.15; **p ≤ 0.05; ***p ≤ 0.01.

Results of the hierarchical multiple linear regression analyses are summarized in Table 3. The results show that only functional status was a confounder of the relationship between the number of assistive devices per patient and psychological well-being. Exclusion of functional status from the regression model decreased the magnitude of the regression coefficient (B) of the number of assistive devices per patient from 0.15 to -0.07. Exclusion of the remaining potential confounding variables

did not change the regression coefficient of the number of assistive devices per patient by more than 10% (data not shown). Therefore, these variables were not included in the final model. After controlling for confounding by functional status, the number of assistive devices per patient was significantly positively associated with psychological well-being ($r_{partial} = 0.22$; $p = 0.009$).

Table 2 Patients possessing assistive devices (n = 142)

	n (%)
Mobility devices	
Scooter	16 (11)
Walker	15 (11)
Cane	20 (14)
Crutch(es)	24 (17)
Wheelchair	25 (18)
Orthopedic footwear	56 (39)
Tools for ADL	
Helping hand	13 (9)
Special cutlery	13 (9)
Special writing pen	21 (15)
Dressing device(s)	26 (18)
Housing adaptations	
Elevator	10 (7)
Adapted kitchen	19 (13)
Shower seat	41 (29)
Grab bar(s) in bathroom/toilet	60 (42)
Special tap(s)	61 (43)
Elevated toilet seat	64 (45)
Special furniture	
Special bed	43 (30)

Table 3 Results of hierarchical multiple linear regression analysis for psychological well-being

	Block 1		Block 2	
	B (95% CI)	r	B (95% CI)	$r_{partial}$
Step 1				
Possession of assistive devices	-0.07 (-0.15 to 0.02)	-0.18	0.15 (0.04 to 0.26)*	0.22*
Step 2				
Functional status			-1.29 (-1.78 to -0.79)*	

B, regression coefficient; CI, confidence interval; r, correlation coefficient.
*$p \leq 0.01$.

DISCUSSION

After controlling for differences in functional status, the possession of assistive devices was significantly positively associated with psychological well-being. Surprisingly, the number of assistive devices per patient was univariately negatively correlated with psychological well-being. This can be explained by the high correlations of functional status with the number of assistive devices per patient (r = 0.72) as well as psychological well-being (r = -0.41). These relationships suppress the positive relationship between the number of assistive devices per patient and psychological well-being, and therefore this univariate relationship becomes negative. This is a case of negative confounding, where the removal of a confounding variable (functional status) from a regression equation decreases the magnitude of the relationship between an independent variable (number of assistive devices per patient) and a dependent variable (psychological well-being) or even changes the direction of the relationship.[23]

A possible way to explain the relationship between the availability of assistive devices and improved psychological well-being is that the use of assistive devices leads to increased physical functioning and maintained independence. This may lead to decreased negative emotional reactions to disability and improved psychological well-being. On the other hand, psychological well-being may facilitate the use of assistive devices. The direction of this cause-effect relationship between the availability of assistive devices and psychological functioning cannot be deduced from the results of our cross-sectional study. Causality can only be tested using an experimental study design.

The positive relationship between assistive devices and psychological well-being was confirmed in previous studies with patients with nonrheumatic conditions. Tomita *et al* investigated the relationship between the number of assistive devices per patient and psychosocial variables in a sample of physically impaired elderly people.[24] They found the number of assistive devices per patient to be inversely associated with depression, measured with the Center for Epidemiological Studies Depression Scale (CES-D), after adjusting for differences in sociodemographic variables and disability. Self-esteem, measured with Rosenberg's Self-Esteem Scale, was not independently associated with the number of assistive devices per patient. Jutai *et al* investigated the psychosocial influence of the use of several single assistive devices (e.g., wheelchairs, computer-assisted writing aids, electronic aids to daily living) in patients with degenerative diseases and spinal cord and brain injuries.[25,26] They concluded that the psychosocial effect of assistive devices for ADL, measured with the Psychosocial Impact of Assistive Devices Scale (PIADS), was dependent on the type of device and the degree of disability. Overall, the psychosocial impact of assistive devices was positive.

To assess psychological well-being, we used the psychological component of the AIMS2. The AIMS2 is a disease-specific questionnaire designed to measure health-related quality of life in arthritis patients. The questionnaire is not specifically developed to measure the effect of a particular intervention, such as the prescription of assistive devices. Assistive devices might affect different aspects of psychological well-being than other interventions such as surgery or pharmaceutical treatments. Therefore, health-related quality of life measures, like the AIMS2, might not be sensitive enough to assess relatively small differences in psychological well-being associated with the use of assistive devices.[27] Thus the relationship we found between the possession of assistive devices and psychological well-being might be underestimated. Intervention-specific outcome measures, like the PIADS[27] and the QUEST (Quebec User Evaluation of Satisfaction with Assistive Technology)[28] for assistive devices, are recommended in studies examining the effect of a particular intervention.

Device utilization is included into several frameworks for assistive device outcomes and is an important variable to consider when the effects of assistive devices are investigated.[29,30] In this study we assessed only the possession of a selection of commonly used assistive devices. We realize that some patients might not use the assistive devices they possess. Assistive devices that are not in use might not contribute to improved psychological well-being. So the relationship between assistive devices and psychological well-being might have been stronger if we had assessed the use, instead of the possession, of assistive devices. Although we cannot exclude the possibility that some patients might possess more or other devices, we do not consider it likely that these rare cases might have influenced our general conclusions.

Finally, we equated all assistive devices in this study and summed them up, despite their different functions and potential different enhancing effects on the stigma of disability. It is plausible that not all assistive devices have the same effect on psychological well-being. The magnitude of the relationship, as well as the direction of the relationship (positive or negative), might differ per assistive device. Nevertheless, we found a small positive overall relationship between the number of assistive devices patients possess and psychological well-being.

Our data show that the possession of assistive devices is positively related to psychological well-being of disabled patients with rheumatic diseases. More experimental studies are necessary to investigate this issue and confirm the hypothesis that psychological well-being is improved by the availability of assistive devices.

ACKNOWLEDGEMENTS

We thank all participating patients. We also thank doctors H.J. Bernelot Moens, K.W. Drossaers-Bakker, R. Ernst, C.J. Haagsma, M.A. Hund, M.W.M. Kruijssen, G. Müller, J.C.M. Oostveen, U. Schoo, F. Schuhmann, and T.R. Zijlstra for their collaboration in this study including the selection of patients.

REFERENCES

1. Mann W. Assistive technology for persons with arthritis. Bethesda, MD: American Occupational Therapy Association; 1998.
2. Hollings EM, Haworth RJ. Supply and use of aids and appliances. A study of 119 patients with rheumatoid arthritis. Occup Ther 1978:336-9.
3. Haworth RJ, Hopkins R. Use of aids following total hip replacement. Occup Ther 1980;43:398-400.
4. Rogers JC, Holm MB. Assistive technology device use in patients with rheumatic disease: A literature review. Am J Occup Ther 1992;46:120-7.
5. Rogers J, Holm M, Perkins L. Trajectory of assistive device usage and user and non-user characteristics: Long-handled bath sponge. Arthritis Rheum 2002;47:645-50.
6. Sutton D, Gignac MAM, Cott C. Medical and everyday assistive device use among older adults with arthritis. Can J Aging 2002;21:535-48.
7. van der Esch M, Heijmans M, Dekker J. Factors contributing to possession and use of walking aids among persons with rheumatoid arthritis and osteoarthritis. Arthritis Rheum 2003;49:838-42.
8. Veehof MM, Taal E, Rasker JJ, Lohmann J, van de Laar MAFJ. What determines the possession of assistive devices among patients with rheumatic conditions? The influence of the country-related health care system. Disabil Rehabil 2006;28:205-11.
9. Nordenskiöld U. Daily Activities in Women with Rheumatoid Arthritis. Aspects of patient education, assistive devices and methods for disability and impairment assessment. Scand J Rehabil Med Suppl 1997:1-72.
10. Nordenskiöld U, Grimby G, Dahlin-Ivanoff S. Questionnaire to evaluate the effects of assistive devices and altered working methods in women with rheumatoid arthritis. Clin Rheumatol 1998;17:6-16.
11. Thyberg I, Hass UAM, Nordenskiöld U, Skogh T. Survey of the use and effect of assistive devices in patients with early rheumatoid arthritis: a two-year follow-up of women and men. Arthritis Rheum 2004;51:413-21.
12. Nordenskiöld U. Evaluation of assistive devices after a course in joint protection. Int J Technol Assess Health Care 1994;10:293-304.
13. Oldridge NB. Outcomes measurement: health-related quality of life. Assist Technol 1996;8:82-93.
14. Scherer MJ. Outcomes of assistive technology use on quality of life. Disabil Rehabil 1996;18:439-48.
15. Pincus T, Summey JA, Soraci SA, Wallson KA, Hummon NP. Assessment of patients satisfaction in activities of daily living using a modified Stanford Health Assessment Questionnaire. Arthritis Rheum 1983;26:1346-53.
16. Meenan RF, Gertman PM, Mason JH. Measuring health status in arthritis. The arthritis impact measurement scales. Arthritis Rheum 1980;23:146-52.
17. Jaeckel WH, Cziske R, Schochat T, Jacobi E. Assessing health status after inpatient rehabilitation in rheumatoid arthritis. Int Rehabil Med 1986;8:54-9.

18. Riemsma RP, Taal E, Rasker JJ, Houtman PM, van Paassen HC, Wiegman O. Evaluation of a Dutch version of the AIMS2 for patients with rheumatoid arthritis. Br J Rheumatol 1996;35:755-60.
19. Fries JF, Spitz PW, Young DY. The dimensions of health outcomes: the health assessment questionnaire, disability and pain scales. J Rheumatol 1982;9:789-93.
20. Siegert CE, Vleming LJ, Vandenbroucke JP, Cats A. Measurement of disability in Dutch rheumatoid arthritis patients. Clin Rheumatol 1984;3:305-9.
21. Lautenschlager J, Mau W, Kohlmann T, et al. Comparative evaluation of a German version of the Health Assessment Questionnaire and the Hannover Functional Capacity Questionnaire. Z Rheumatol 1997;56:144-55.
22. Wolfe F. Fatigue assessments in rheumatoid arthritis: Comparative performance of Visual Analog Scales and longer fatigue questionnaires in 7760 patients. J Rheumatol 2004;31:1896-902.
23. MacKinnon DP, Krull JL, Lockwood CM. Equivalence of the mediation, confounding and suppression effect. Prev Sci 2000;1:173-81.
24. Tomita MR, Mann WC, Fraas LF, Stanton KM. Predictors of the use of assistive devices that address physical impairments among community based frail elders. J Appl Gerontol 2004;23:141-55.
25. Jutai J. Quality of life impact of assistive technology. Rehabilitation Engineering 1999;14:2-7.
26. Jutai J, Rigby P, Ryan S, Stickel S. Psychosocial impact of electronic aids to daily living. Assist Technol 2000;12:123-31.
27. Jutai J, Day H. Psychosocial Impact of Assistive Devices Scale (PIADS). Technol Disabil 2002;14:107-11.
28. Demers L, Weiss-Lambrou R, Ska B. The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0): An overview and recent progress. Technol Disabil 2002;14:101-5.
29. Fuhrer MJ, Jutai JW, Scherer MJ, DeRuyter F. A framework for the conceptual modelling of assistive technology device outcomes. Disabil Rehabil 2003;25:1243-51.
30. Jutai JW, Fuhrer MJ, Demers L, Scherer MJ, DeRuyter F. Toward a taxonomy of assistive technology device outcomes. Am J Phys Med Rehabil 2005;84:294-302.

8

Summary and general conclusions

Rheumatoid arthritis (RA) is a chronic inflammatory joint disease that may have major consequences for a patient's life. Treatment generally consists of pharmacological and non-pharmacological interventions, and focuses on relieving symptoms, reducing inflammation, controlling joint damage, and maintaining or improving functional ability and psychosocial functioning. To justify these interventions from health care and health economic perspectives, it is important to assess their effects using reliable, valid, and responsive outcome measures. This thesis consists of three main parts. The first part (C*hapters 2 and 3*) focuses on the psychometric properties of commonly used patient-reported outcome measures. The second (C*hapters 4 and 5*) and third (C*hapters 6 and 7*) parts focus on the effects of non-pharmacological treatment interventions, with an emphasis on the use of orthoses and assistive devices, respectively. In this final chapter, the main findings of the studies conducted within these themes are summarized.

PSYCHOMETRIC PROPERTIES OF PATIENT-REPORTED OUTCOME MEASURES

The patient's perspective has become increasingly important in the assessment of treatment response. Several patient-reported outcome measures have been developed and used as a supplement to physiologic measures. These measures provide information on how the patient perceives his or her disease and its physical, psychological, and social consequences. The selection of an outcome measure for use in clinical practice or research depends, among other things, on its psychometric properties. An instrument should be reliable, valid, and responsive to changes. The aim of the first part of this thesis is to examine the psychometric properties of commonly used patient-reported outcome measures. Data were collected as part of the ongoing Dutch Rheumatoid Arthritis Anti-TNF Monitoring (DREAM) study, a multi-center study that was started among all patients with RA beginning anti-tumour necrosis factor (TNF) treatment to prospectively monitor and evaluate the use of anti-TNF.

Summary of the studies

Chapter 2

In Chapter 2, the responsiveness of the Short Form-36 Health Survey (SF-36), the most widely used generic instrument to assess health status, is compared with the responsiveness of the disease-specific Arthritis Impact Measurement Scales 2 (AIMS2) and the Health Assessment Questionnaire Disability Index (HAQ-DI). The AIMS2 and the HAQ-DI are widely and internationally used instruments in rheumatology for the assessment of health status and functional ability, respectively. The results of our

analyses of 168 patients indicated that, within the health domains physical function, pain, and psychological function, no significant differences existed in internal and external responsiveness between the SF-36 and the disease-specific measures. In the domain social function, the SF-36 was more responsive than the AIMS2, and in the domain general health, the SF-36 was less responsive (just internal) than the AIMS2. So, the assumption that disease-specific instruments are more responsive to detect intervention-related changes in health status was not confirmed by our data. The decision of whether to choose the SF-36 or the disease-specific instruments for detection of changes in health status after a treatment of known efficacy depends, among other things, on the health domain of interest. Only if general health is the primary domain of interest, the AIMS2 is preferred above the SF-36.

Chapter 3

In Chapter 3, the psychometric properties of the Rheumatoid Arthritis Disease Activity Index (RADAI) are described and compared with its short form (RADAI-SF). The RADAI is a disease-specific questionnaire developed for patients with RA. It assesses the patient's perception of past disease activity, current disease activity in terms of swollen and tender joints, pain, duration of morning stiffness, and tender joint count and combines these parameters into a single measure of disease activity. In its short form, the RADAI-SF, the tender joint count is omitted. The results of our analyses of 191 patients showed that the RADAI had satisfactory internal consistency, construct validity, and internal and external responsiveness. Omission of the tender joint count in the RADAI-SF produced comparable results, and is justified and recommended for research purposes. In patient management, on the other hand, inclusion of the tender joint count may provide useful additional clinical information. Given the low factor loadings of items 1 (global disease activity during the past 6 months) and 4 (current duration of morning stiffness) in the confirmatory factor analysis, future studies should investigate whether the RADAI can be improved through modifications to the wording of these items.

In conclusion

The studies described above contribute to our knowledge of the psychometric properties of patient-reported outcome measures. This knowledge helps clinicians and researchers in selecting the most appropriate instrument to assess treatment response. The results further show that the magnitude of responsiveness is dependent on the definition of responsiveness (internal versus external) and the analysis strategy used for its assessment. Other factors that may influence responsiveness include the selected external criterion, the study sample (low versus high disease activity), and the efficacy

of the treatment. Therefore, the absolute values of the responsiveness indices cannot be easily compared across studies. The results of our studies stress the importance of comparative studies on the responsiveness of outcome measures to facilitate selection of the most appropriate instrument.

EFFECTS OF NON-PHARMACOLOGICAL TREATMENT, WITH AN EMPHASIS ON ORTHOSES AND ASSISTIVE DEVICES

ORTHOSES

Several types of orthoses or splints can be distinguished in the treatment of RA. A splint that is commonly prescribed to patients with wrist arthritis is the wrist working splint. This type of splint immobilizes, supports, and stabilizes the wrist in order to reduce pain and inflammation, and improve functional ability. The main aim of the second part of this thesis is to investigate the effects of wrist working after a period of splinting.

Summary of the studies

Chapter 4

Good adherence to splinting instructions is requisite for the efficacy of wrist working splints. Non-adherence will affect the response to treatment. In Chapter 4, the results of a qualitative descriptive study on the determinants of splint use are described. Semi-structured in-depth interviews were performed among 18 patients with RA who had recently received a commercially available prefabricated wrist working splint because of pain due to arthritis of the wrist. Patients were asked about their motivations for and perceived barriers to using their splint. The results showed that, for the majority of patients, splint use was dependent on the seriousness of the symptoms (pain, swelling, or tingling feelings) they perceived. If patients experienced wrist-related symptoms, they wore their splint primarily to reduce these symptoms. Second, wrist working splints were used to support and immobilize the wrist. Motivations for removing or not wearing the splint were related to perceived barriers associated with splint wearing. Important barriers mentioned by the majority of patients included decreased functional ability and the performance of dirty and/or wet activities. We concluded from this study that the reasons that patients wear or fail to wear wrist working splints are related to intentional decisions of the patients, which are primarily based on perceived benefits and barriers associated with splint wearing. The results were used to develop educational and behavioral strategies to stimulate adherence to splint wearing. These strategies were used to examine the effects of wrist working splints.

Chapter 5

In Chapter 5, the results of a 4-week randomized controlled trial on the efficacy of wrist working splints in patients with RA suffering from wrist arthritis are shown. Selected patients were randomly allocated to the splinting group (n = 17) or control group (n = 16). Patients in the splinting group received a commercially available prefabricated wrist working splint and used this splint for 4 weeks. The results showed a large and significant treatment effect (effect size = 1.24) on wrist pain, which was measured using a visual analogue scale (VAS). Pain scores decreased by 32% in the splinting group and increased by 17% in the control group. Small and non-significant treatment effects were found with regard to non-splinted grip strength and functional ability. We concluded from this study that wrist working splints are effective in reducing wrist pain after 4 weeks of splint wearing.

In conclusion

The studies described in the second part of this thesis were performed to investigate the efficacy of the use of wrist working splints. Since the most optimal splint wearing schedule is not known, we instructed the patients to wear their splint as much as possible, especially during the performance of activities, for a period of 4 weeks. We supposed that this wearing time would be sufficient to capture the potential effects of splint wearing. To stimulate splint use, adherence-enhancing strategies were developed and applied. The results show that wrist working splints are highly effective in reducing wrist pain after 4 weeks of splint wearing. No negative effects were observed. Adherence to splinting instructions was considered good, as shown by the number of hours the splints were worn during the day. We should note, however, that we cannot conclude with certainty that our adherence-enhancing strategies improved splint use. Further research on the cost-effectiveness of these strategies is recommended, especially if the aim is to use these strategies in clinical practice. Furthermore, now that the efficacy of wrist working splints on wrist pain has been demonstrated, the question arises as to what splinting instructions should be given in clinical practice. Until now, no general agreement exists on when to use wrist working splints. Further research on the most optimal splint wearing schedule is recommended for clinical practice.

ASSISTIVE DEVICES

The third part of this thesis focuses on the possession of assistive devices, with an emphasis on the determinants of the possession of assistive devices and the relationship between the availability of assistive devices and psychological well-being. A cross-sectional study was performed among disabled patients living in The Netherlands or Germany with either RA or psoriatic arthritis (PsA). A total of 142 patients completed the questionnaire. Seventeen common assistive devices were included, which could be divided into mobility devices (e.g., walker, wheelchair), small tools for Activities of Daily Living (e.g., special cutlery, dressing device(s)), housing adaptations (e.g., shower seat, elevated toilet seat), and special furniture (special bed).

Summary of the studies

Chapter 6

Chapter 6 discusses the determinants of the possession of assistive devices, with an emphasis on the influence of the country where the patient resides. The results, obtained from logistic regression analyses, indicated that functional ability was the most important determinant of the possession of an assistive device, followed by the patient's country of residence. Almost all assistive devices were more likely to be present in the homes of increasingly disabled patients compared to patients who were less disabled. Furthermore, housing adaptations (shower seat, special tap(s), and raised toilet seat), wheelchairs, and special beds were more likely to be used by Dutch patients compared to German patients. The contribution of the patient's country to the total proportion explained variance ranged from 5% for the possession of a special bed to 17% for the possession of a raised toilet seat. We concluded from this study that functional ability and the patient's country are the most important determinants of the possession of assistive devices among patients with arthritic conditions. We hypothesize that differences in the health care systems, with regard to the prescription and reimbursement of assistive devices, are the most likely explanation for the differences in possession rates between the two countries.

Chapter 7

In Chapter 7, the relationship between the possession of assistive devices and psychological well-being is described. Psychological well-being was measured using the level of tension and mood scales of the AIMS2. Multiple linear regression analysis with backward elimination of potential confounding variables was used to determine the independent association between the number of assistive devices possessed per patient and psychological well-being. The results showed that the number of assistive

devices possessed per patient was significantly positively associated with psychological well-being after controlling for differences in functional ability, which appeared to be a negative confounder. This finding supports the hypothesis that psychological well-being of disabled patients with rheumatic conditions is improved by the availability of assistive devices.

In conclusion

The studies described above contribute to a better understanding of the mechanisms determining the possession of assistive devices as well as the effects of assistive devices, an understanding that is warranted to improve health care and health status. The results show that, within the context of a rheumatic disease, functional ability, the availability of assistive devices, and psychological well-being are interrelated. Future research should focus on the causality of the relationship between the possession and/or use of assistive devices and psychological well-being, which can only be established using an experimental study design. Given the different functions of assistive devices and their potentially different enhancing effects on the stigma of disability, we recommend that their effects on psychological well-being will be examined for each (group of) device(s) separately.

Samenvatting

Reumatoïde artritis (RA) is een chronische ziekte die gekenmerkt wordt door gewrichtsontstekingen. Deze ontstekingen gaan gepaard met pijnklachten, zwelling en stijfheid en kunnen op den duur leiden tot onherstelbare gewrichtsschade. Meer algemene klachten zijn vermoeidheid en ochtendstijfheid. RA is een ziekte die ingrijpende gevolgen kan hebben op zowel het fysiek als het psychosociaal functioneren. De behandeling, die farmacologisch en niet-farmacologisch van aard kan zijn, richt zich op het verminderen van de ontstekingsactiviteit, het verlichten van de klachten en het handhaven of verbeteren van de functionele mogelijkheden en het psychosociaal welbevinden. Onderzoek naar het effect van een behandeling is noodzakelijk om de toepassing ervan te rechtvaardigen en de gezondheidszorg te verbeteren. Om het effect van een behandeling te kunnen meten, zijn betrouwbare, valide en responsieve meetinstrumenten nodig.

Dit proefschrift bestaat uit drie delen. Enerzijds richt het zich op de psychometrische eigenschappen van een aantal patiëntgerapporteerde meetinstrumenten (hoofdstukken 2 en 3). Anderzijds wordt het effect van twee niet-farmacologische interventies bestudeerd: het gebruik van polsspalken (hoofdstukken 4 en 5) en het bezit van hulpmiddelen (hoofdstukken 6 en 7).

PSYCHOMETRISCHE EIGENSCHAPPEN VAN PATIËNTGERAPPORTEERDE UITKOMSTMATEN

Bij het meten van het effect van een behandeling speelt de mening van de patiënt een steeds belangrijkere rol. Daar waar vroeger voornamelijk klinische maten en laboratoriumgegevens gebruikt werden om het effect van een behandeling vast te stellen, wordt er vanaf de jaren tachtig van de vorige eeuw steeds meer gebruik gemaakt van patiëntgerapporteerde maten. Patiëntgerapporteerde maten geven de beleving van de patiënt weer ten aanzien van zijn of haar ziekte en de fysieke, psychische en sociale gevolgen ervan. De keuze voor een meetinstrument wordt onder andere bepaald door de psychometrische eigenschappen van een instrument. Een geschikte uitkomstmaat is betrouwbaar, valide en responsief om veranderingen in de tijd waar te nemen. In het eerste deel van dit proefschrift worden de psychometrische eigenschappen van een aantal veelgebruikte patiëntgerapporteerde meetinstrumenten beschreven en vergeleken. De onderzoeksgegevens zijn verzameld als onderdeel van de lopende Dutch Rheumatoid Arthritis Anti-TNF Monitoring (DREAM) studie, een prospectief multi-center onderzoek onder alle patiënten met RA die starten met een anti-tumor necrosis factor (anti-TNF) behandeling.

Samenvatting van de studies

Hoofdstuk 2

In hoofdstuk 2 wordt de responsiviteit van de Short Form-36 (SF-36), wereldwijd het meest gebruikte generieke meetinstrument om gezondheidstoestand te meten, vergeleken met de responsiviteit van de ziektespecifieke Arthritis Impact Measurement Scales 2 (AIMS2) en Health Assessment Questionnaire Disability Index (HAQ-DI). Laatstgenoemde meetinstrumenten worden in de reumatologie veel gebruikt om respectievelijk gezondheidstoestand en fysiek functioneren vast te stellen. Er is onderscheid gemaakt tussen interne responsiviteit en externe responsiviteit. Interne responsiviteit geeft de mogelijkheid van een meetinstrument weer om veranderingen te meten over een bepaalde periode. Externe responsiviteit geeft de relatie weer tussen de veranderingen gemeten met een meetinstrument en de veranderingen gemeten met een extern criterium. De analyses onder 168 patiënten wezen uit dat er geen verschillen in interne en externe responsiviteit aanwezig waren tussen de SF-36 en de ziektespecifieke meetinstrumenten wat betreft het meten van veranderingen in het fysiek functioneren, pijn en het psychisch functioneren na 12 maanden behandeling met anti-TNF. Waar het ging om het meten van veranderingen in het sociaal functioneren en de algemene gezondheidstoestand, was de SF-36 respectievelijk meer en minder (alleen intern) responsief dan de AIMS2. De hypothese dat ziektespecifieke meetinstrumenten responsiever zijn dan generieke meetinstrumenten om interventiegerelateerde veranderingen in gezondheidstoestand waar te nemen, wordt dus niet bevestigd door de onderzoeksgegevens. De keuze voor de SF-36 of de ziektespecifieke meetinstrumenten om veranderingen in de gezondheidstoestand waar te nemen na een effectieve behandeling, is onder andere afhankelijk van het gezondheidsdomein waarin men geïnteresseerd is. Alleen als men primair geïnteresseerd is in het meten van de algemene gezondheidstoestand, wordt de AIMS2 verkozen boven de SF-36.

Hoofdstuk 3

In hoofdstuk 3 worden de psychometrische eigenschappen van de Rheumatoid Arthritis Disease Activity Index (RADAI) beschreven en vergeleken met die van de verkorte versie (RADAI-SF). De RADAI is een ziektespecifieke vragenlijst, ontwikkeld voor patiënten met RA om ziekteactiviteit te meten. De vragenlijst bestaat uit vijf vragen die ingaan op ziekteactiviteit in het verleden, huidige ziekteactiviteit in termen van gevoeligheid en zwelling van de gewrichten, pijn, duur van ochtendstijfheid en het aantal pijnlijke gewrichten. De RADAI kan verkort afgenomen worden door de laatste, vaak tijdrovende vraag, achterwege te laten. De resultaten van de analyses onder 191 patiënten lieten zien dat de psychometrische eigenschappen (interne consistentie, construct validiteit, interne en externe responsiviteit) van de RADAI toereikend waren.

De verkorte versie liet vergelijkbare resultaten zien. Het achterwege laten van de laatste vraag, naar het aantal pijnlijke gewrichten, is daarom gerechtvaardigd en wordt aanbevolen voor onderzoeksdoeleinden. In de klinische praktijk kan deze vraag echter aanvullende klinische informatie geven en wel bruikbaar zijn.

Tot besluit

De studies, beschreven in het eerste deel van dit proefschrift, dragen bij aan de kennis over de psychometrische eigenschappen van een aantal veelgebruikte patiëntgerapporteerde uitkomstmaten. Deze kennis helpt clinici en onderzoekers bij het selecteren van het meest geschikte meetinstrument om het effect van een behandeling vast te leggen. De resultaten laten verder zien dat de mate van responsiviteit afhankelijk is van de gekozen definitie van responsiviteit (interne versus externe responsiviteit) en de manier waarop het gemeten is. Andere factoren die van invloed kunnen zijn, betreffen het gekozen externe criterium, de onderzoeksgroep (hoge versus lage ziekteactiviteit) en het effect van de behandeling. Absolute waarden van responsiviteitsmaten, die gevonden zijn in verschillende studies, kunnen daarom niet zomaar met elkaar vergeleken worden. De resultaten van de beschreven studies onderstrepen het belang van vergelijkende studies naar de responsiviteit van verschillende meetinstrumenten.

EFFECTIVITEIT VAN NIET-FARMACOLOGISCHE BEHANDELINGEN: ORTHESEN EN HULPMIDDELEN

ORTHESEN

Er bestaan verschillende typen orthesen of spalken voor mensen met RA. Een veel voorgeschreven type spalk voor mensen met een ontstoken pols is de polsspalk. Dit type spalk wordt ook wel werkspalk genoemd. Een polsspalk immobiliseert, ondersteunt en stabiliseert het polsgewricht en wordt ingezet om pijnklachten en ontstekingsactiviteit te verminderen en functionele mogelijkheden te verbeteren. In het tweede deel van dit proefschrift staat de effectiviteit van het gebruik van een polsspalk centraal.

Samenvatting van de studies

Hoofdstuk 4

Om het effect van het gebruik van een polsspalk te kunnen meten, is het van belang dat de spalk volgens het voorschreven advies gedragen wordt. In hoofdstuk 4 worden de resultaten van een kwalitatief beschrijvend onderzoek naar de determinanten van het spalkgebruik beschreven. Er zijn diepte-interviews afgenomen bij 18 mensen met RA, die recentelijk een polsspalk voorgeschreven hebben gekregen in verband met een pijnlijke en ontstoken pols. De patiënten zijn ondervraagd over hun motieven om de spalk te dragen en de ervaren barrières. De meerderheid van de patiënten gaf aan dat het gebruik van de spalk afhankelijk is van de ernst van de klachten. Bij polsklachten (pijn, zwelling, tintelende gevoelens) werd de spalk in de eerste plaats gedragen om de klachten te verminderen. Verder gaven de patiënten aan de spalk te dragen om de steun en de rust / immobilisatie die de spalk geeft. Redenen om de spalk niet te dragen of de spalk af te doen hingen samen met de ervaren barrières. Verminderde functionele mogelijkheden en het nat en vies worden van de spalk waren de belangrijkste barrières die door de meerderheid van de patiënten genoemd werden. Concluderend kan gesteld worden dat het wel of niet dragen van de polsspalk een bewuste keuze van de patiënt is, die gebaseerd is op de ervaren voordelen en barrières. De resultaten van dit onderzoek zijn gebruikt om strategieën te ontwikkelen om het gebruik van de spalk te stimuleren. Deze therapietrouw bevorderende maatregelen zijn toegepast om het effect van het gebruik van polsspalken te onderzoeken.

Hoofdstuk 5

In hoofdstuk 5 worden de resultaten van een gerandomiseerd gecontroleerd onderzoek naar het effect van het gebruik van polsspalken bij mensen met RA met een ontstoken en pijnlijke pols beschreven. Geselecteerde patiënten zijn aselect toegewezen aan de spalkgroep (n = 17) of de controle groep (n = 16). De patiënten in de spalkgroep hebben, als aanvulling op hun gebruikelijke behandeling, gedurende vier weken een polsspalk gedragen. De analyses wezen uit dat het dragen van een polsspalk grote invloed heeft op de ervaren pijnklachten in de pols, gemeten met een visuele analoge schaal. Gemiddelde pijnscores gingen met 32% omlaag in de spalkgroep en met 17% omhoog in de controle groep. Verschillen tussen beide groepen waren significant. Er zijn geen significante effecten gevonden op handkracht (gemeten zonder spalk) en functionele mogelijkheden. Concluderend kan gesteld worden dat het dragen van een polsspalk gedurende vier weken een effectieve maatregel is om de pijnklachten in de pols te verminderen.

Tot besluit

De studies, beschreven in het tweede deel van dit proefschrift, zijn uitgevoerd om het effect van het gebruik van polsspalken te onderzoeken. Aangezien het meest optimale draagschema van polsspalken niet bekend is, hebben we de patiënten geïnstrueerd om de spalk gedurende een periode van vier weken zoveel mogelijk te dragen, maar vooral tijdens de uitvoering van activiteiten. We gaan ervan uit dat deze draagtijd voldoende is om het effect van polsspalken te kunnen meten. Om het gebruik van de spalk te stimuleren, zijn therapietrouw bevorderende maatregelen ontwikkeld en toegepast. De resultaten laten zien dat polsspalken effectief zijn in het verlagen van de pijnklachten in de pols. Er zijn geen negatieve effecten waargenomen. Gezien het aantal uren dat de spalk gemiddeld gedragen is, wordt de therapietrouw als goed beschouwd. We kunnen echter niet met zekerheid stellen dat onze therapietrouw bevorderende maatregelen bijgedragen hebben aan een verbeterd spalkgebruik. Verder onderzoek naar de kosteneffectiviteit van deze maatregelen wordt aanbevolen, zeker wanneer deze maatregelen in de klinische praktijk gebruikt gaan worden. Tenslotte is het de vraag welke draaginstructies in de praktijk gegeven moeten worden. Tot op heden bestaat er geen overeenstemming over wanneer en hoeveel een polsspalk idealiter gedragen moet worden. Nader onderzoek naar het meest optimale draagschema in de klinische praktijk wordt aanbevolen.

HULPMIDDELEN

Het derde deel van dit proefschrift richt zich op het bezit van hulpmiddelen, met speciale aandacht voor de determinanten van het hulpmiddelenbezit en de relatie tussen het hebben van hulpmiddelen en psychisch welbevinden. De resultaten van een cross-sectioneel onderzoek onder mensen met RA of artritis psoriatica, woonachtig in de grensstreek in Nederland of Duitsland, worden beschreven. In totaal hebben 142 patiënten met functionele beperkingen in het dagelijks leven een vragenlijst ingevuld naar het bezit van 17 veel voorkomende hulpmiddelen. Er is onderscheid gemaakt tussen mobiliteitshulpmiddelen (bijv. rollator, rolstoel), kleine hulpmiddelen voor de activiteiten van het dagelijks leven (bijv. speciaal bestek, kleedhulpmiddel(len)), aanpassingen in de woning (bijv. douchezitje, verhoogd toilet) en speciaal meubilair (bijv. verhoogd bed).

Samenvatting van de studies

Hoofdstuk 6

In hoofdstuk 6 worden de determinanten van het hulpmiddelenbezit besproken, met speciale aandacht voor de invloed van het land waarin de patiënt woonachtig is. Logistische regressie analyses wezen uit dat het bezit van een hulpmiddel voornamelijk bepaald werd door het fysiek functioneren van de patiënt, gevolgd door het land waarin de patiënt woonachtig was. Voor bijna alle hulpmiddelen gold dat de kans dat een patiënt een hulpmiddel in zijn of haar bezit had, groter was naarmate de patiënt meer functionele beperkingen ondervond. Bovendien hadden Nederlandse patiënten meer woningaanpassingen (douchezitje, speciale kraan, verhoogd toilet), rolstoelen en speciale bedden dan Duitse patiënten. De bijdrage van de variabele "land" aan de totale proportie verklaarde variantie varieerde van 5% voor het hebben van een speciaal bed tot 17% voor het hebben van een verhoogd toilet. Concluderend kan gesteld worden dat het fysiek functioneren en het land waarin de patiënt woont de belangrijkste determinanten van het hulpmiddelenbezit bij mensen met reumatische aandoeningen zijn. De verschillen tussen Nederlandse en Duitse patiënten, wat het bezit van hulpmiddelen betreft, hangen naar verwachting samen met verschillen in gezondheidszorgsystemen betreffende de aanvraag en vergoeding van hulpmiddelen.

Hoofdstuk 7

Hoofdstuk 7 gaat in op de relatie tussen het hebben van hulpmiddelen en psychisch welbevinden, gemeten met de stress en stemming schalen van de AIMS2. Een multipele lineaire regressie analyse met backward eliminatie van potentiële confounders is uitgevoerd om de onafhankelijke of zuivere relatie tussen het aantal hulpmiddelen en psychisch welbevinden vast te stellen. De resultaten wezen uit dat, na controle voor verschillen in fysiek functioneren, het aantal hulpmiddelen dat een patiënt in zijn of haar bezit had positief gerelateerd was aan het psychisch welbevinden. Functionele status bleek een negatieve confounder van de relatie tussen het hulpmiddelenbezit en psychisch welbevinden te zijn. De resultaten ondersteunen de hypothese dat hulpmiddelen het psychisch welbevinden van mensen met reumatische aandoeningen vergroten.

Tot besluit

Bovengenoemde studies dragen bij aan een beter begrip van de mechanismen die het hulpmiddelenbezit verklaren en van het effect van hulpmiddelen. Deze kennis is nodig om de gezondheid(szorg) te kunnen verbeteren. De resultaten laten zien dat, binnen de context van een reumatische ziekte, fysiek functioneren, het hebben van hulpmiddelen

en psychisch welbevinden met elkaar geassocieerd zijn. De causaliteit van de relatie tussen het hulpmiddelenbezit en psychisch welbevinden zal nader onderzocht moeten worden in een experimentele studie. Gezien de verschillende functies van hulpmiddelen en hun potentieel verschillende stigmatiserende effecten, wordt aanbevolen om het effect op psychisch welbevinden voor elk hulpmiddel of elke groep van hulpmiddelen apart te onderzoeken.

Dank!

Het proefschrift is af! Zonder de hulp en steun van velen was dit natuurlijk niet mogelijk geweest. Daarom wil ik iedereen bedanken die op enige wijze heeft bijgedragen aan de totstandkoming van dit proefschrift. Een aantal van hen wil ik hierbij graag bij name noemen.

In het bijzonder wil ik mijn promotor en assistent-promotor bedanken: Mart van de Laar en Erik Taal. Beste Mart, veel heb ik van jou geleerd, van onderzoeksvoorstel tot publicatie. Veel dank voor je vertrouwen en ondersteuning, maar vooral ook voor de mogelijkheid die je mij geboden hebt om het "promotiepad" te betreden. Beste Erik, jij was de afgelopen jaren mijn "dagelijks begeleider". Geen vraag was je teveel en je deur stond altijd voor mij open. Op alle fronten heb je met mij meegedacht en heb je mij geholpen. Bedankt voor je toegankelijkheid, ondersteuning, betrokkenheid en scherpe blik (zelfs de kleinste foutjes in een artikel ontgingen je niet!). Verder gaat mijn dank uit naar Hans Rasker die mij op het "onderzoekspad" heeft gebracht. Beste Hans, hartelijk dank voor de geboden kansen en je vertrouwen.

Verder wil ik alle mensen bedanken die betrokken zijn geweest bij de uitvoering van de verschillende onderzoeken. Op de eerste plaats wil ik alle patiënten bedanken voor hun medewerking. Zonder hun inzet was dit alles niet mogelijk geweest. Verder gaat mijn dank uit naar alle reumatologen van het Medisch Spectrum Twente en de Ziekenhuisgroep Twente voor de mogelijkheid die zij mij geboden hebben om klinisch onderzoek te verrichten en de ondersteuning die zij verleend hebben bij de inclusie van patiënten. Reumatoloog Jörg Lohmann dank ik voor de samenwerking en de inclusie van patiënten in Duitsland. Verder wil ik de reumatologen Hetty Baan en Monique Hoekstra en de onderzoeksverpleegkundigen Annet ter Avest en Anita Mooij bedanken voor de metingen die zij verricht hebben. Mede dankzij jullie liep alles gesmeerd! Hetty, de vele (eigen) uurtjes die je vrijgemaakt hebt voor dit onderzoek waardeer ik zeer. Linda Heijnsdijk wil ik bedanken voor het meedenken over de invulling van de ergotherapeutische interventie en de uitvoering ervan. Linda, ik vond het prettig om als ergotherapeuten onder elkaar met je van gedachten te wisselen over het onderzoek. Lisett Rietman, fijn dat je de honneurs van Linda wilde waarnemen bij haar afwezigheid. Marjanne Willems dank ik voor het afnemen van de diepte-interviews. Tenslotte gaat mijn dank uit naar de dames van het secretariaat van zowel de poli Reumatologie van het Medisch Spectrum Twente als de afdeling PCGR (voorheen Communicatiewetenschap) voor de geboden secretariële ondersteuning.

Prof. dr. J. Dekker, prof. dr. J.M.W. Hazes, prof. dr. J.M.J.P. van der Linden, prof. dr. J.S. Rietman en prof. dr. E.R. Seydel wil ik bedanken voor hun bereidheid om zitting te nemen in mijn promotiecommissie.

Collega's van de Universiteit Twente wil ik bedanken voor de fijne werksfeer en de geboden steun. In het bijzonder wil ik twee oud kamergenoten noemen met wie ik

jarenlang een kamer gedeeld heb: Lieke Christenhusz en Mark van Vuuren. Lieke en Mark, samen hebben we lief en leed (en niet te vergeten de nodige hoeveelheid apekoppen) gedeeld, zowel op wetenschappelijk als op persoonlijk vlak. Dank voor jullie steun en betrokkenheid. Elkaars verjaardagen zullen we wel blijven vergeten, maar laten we de etentjes met onze partners er vooral inhouden! Verder gaat mijn dank uit naar medepromovendus Peter ten Klooster (inmiddels doctor), bij wie ik altijd kon binnenlopen voor ondersteuning bij statistische en andere vraagstukken.

Medepromovendi van het Medisch Spectrum Twente en de Universiteit Twente, Tanja Effing, Marjolein Brusse-Keizer, Evelyn Monninkhof (inmiddels doctor), Astrid Boudrie, Yvette Bulthuis en Lieke Christenhusz (inmiddels doctor), wil ik bedanken voor hun (morele) steun. Onze etentjes en saunabezoeken vormden de basis voor een uitwisseling van vele ervaringen, zowel op wetenschappelijk gebied als daarbuiten. Dank voor deze gezellige momenten!

Arjan Veehof en Martine Postema-Thuis wil ik bedanken dat ze mijn paranimfen willen zijn. Lieve Arjan, lieve Martine, als broer en als vriendin van het eerste uur in Maastricht vind ik het super dat jullie mij op deze bijzondere dag willen bijstaan!

Mijn schoonouders wil ik bedanken voor alle uurtjes die ze op Tijn hebben gepast. Fijn dat ik altijd op jullie kon (en kan) rekenen!

Lieve papa en mama, zonder jullie was dit boekje er zeker niet geweest. Jullie hebben mij alle kansen gegeven om datgene te doen wat ik wilde doen. Bovendien stonden (en staan!) jullie altijd voor mij klaar. Geen verhuizing of oppasdagje was jullie teveel. Dank voor jullie onvoorwaardelijke steun en liefde!

Tenslotte het thuisfront. Lieve Eloy, de laatste loodjes waren zwaar. Het afronden van het proefschrift vergde veel energie en vrije tijd. Jouw begrip, steun en liefde hebben mij er doorheen geloodst. Duizendmaal dank! Lieve Tijn, hoe klein je nu ook nog maar bent, jouw komst heeft mij geleerd om te relativeren. Jouw lach maakt al het andere even heerlijk onbelangrijk. Vanaf nu meer tijd voor en met elkaar!

Martine Veehof,
juni 2008

Curriculum Vitae
List of Publications

1976	Born in Enschede
1988-1994	Secondary education (VWO) Scholengemeenschap het Assink, Haaksbergen
1994-1998	Student Health Sciences, main subject Movement Sciences Universiteit Maastricht
1998-2000	Student Occupational Therapy Hogeschool Rotterdam
2001-2003	Researcher Department of Rheumatology Medisch Spectrum Twente, Enschede
2004-2007	Researcher Department of Psychology & Communication of Health & Risk (PCHR) University of Twente, Enschede
2001-now	Occupational therapist Livio, location het Wiedenbroek, Haaksbergen

Veehof MM, Sibbel J, van de Putten MJ, van Meeteren NLU. De betrouwbaarheid van de Action Research Armtest. Nederlands Tijdschrift voor Ergotherapie 2001;29(3).

Veehof MM, Sleegers EJ, van Veldhoven NH, Schuurman AH, van Meeteren NL. Psychometric qualities of the Dutch language version of the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH-DLV). J Hand Ther 2002;15(4):347-54.

Veehof MM, Taal E, Rasker JJ, Lohmann J, van de Laar MAFJ. What determines the possession of assistive devices among patients with rheumatic diseases? The influence of the country related health care system. Disabil Rehabil 2006;28(4):205-11.

Veehof MM, Taal E, Rasker JJ, Lohmann J, van de Laar MAFJ. The possession of assistive devices is related to improved psychological well-being in patients with rheumatic conditions. J Rheumatol 2006;33(8):1679-83.

Veehof MM, Taal E, Rasker JJ, Lohmann J, van de Laar MAFJ. Reumazorg in Nederland: blijft de zorg een doolhof? Tijdschr Gezondheidsw (TSG) 2006;84(3):178-80.

Taal E, Bobiatynska E, Lloyd J, Veehof M, Rasker WJM, Oosterveld FGJ, Rasker JJ. Successfully living with chronic arthritis. The role of the allied health professionals. Clin Rheumatol 2006; 25(2):189-97.

Ten Klooster PM, Veehof MM, Taal E, van Riel PLCM, van de Laar MAFJ. Changes in priorities for improvement in patients with rheumatoid arthritis during 1 year of anti-tumour necrosis factor treatment. Annals Rheum Dis 2007; 66(11):1485-90.

Veehof MM, ten Klooster PM, Taal E, van Riel PLCM, van de Laar MAFJ. Comparison of internal and external responsiveness of the generic Medical Outcome Study Short Form-36 with disease-specific measures in rheumatoid arthritis. J Rheumatol 2008;35:610-7.

Veehof MM, Taal E, Willems MJ, van de Laar MAFJ. Determinants of the use of wrist working splints in rheumatoid arthritis. Arthritis Care Res 2008;59(4):531-6.

Veehof MM, ten Klooster PM, Taal E, van Riel PLCM, van de Laar MAFJ. Psychometric properties of the Rheumatoid Arthritis Disease Activity Index (RADAI) in a cohort of consecutive Dutch patients with RA starting anti-tumour necrosis factor treatment. Annals Rheum Dis 2008;67(6):789-93.

Ten Klooster PM, Veehof MM, Taal E, van Riel PLCM, van de Laar MAFJ. Confirmatory factor analysis of the AIMS2-SF in patients with rheumatoid arthritis. Arthritis Care Res 2008;59(5):692-8.

Veehof MM, Taal E, Heijnsdijk – Rouwenhorst LM, van de Laar MAFJ. The efficacy of wrist working splints in rheumatoid arthritis: a randomized controlled study. Arthritis Care Res, accepted pending revision.