Selection of Instruments in the Core Set for DC-ART, SMARD, Physical Therapy, and Clinical Record Keeping in Ankylosing Spondylitis. Progress Report of the ASAS Working Group

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ABSTRACT. To select specific instruments for each domain of the core set for endpoints in ankylosing spondylitis (AS), we gathered all instruments described in the literature to assess the domains chosen as endpoints in AS and sent them to 43 members of the Assessments in Ankylosing Spondylitis (ASAS) Working Group. The following domains were taken into account: function, pain, spinal mobility, patient global assessment, morning stiffness, peripheral joints and entheses, acute phase reactants, x-ray spine, x-ray hips, fatigue. For each instrument the members were asked to judge if the instrument was feasible and relevant. If an instrument was judged to be not feasible or not relevant by more than 50% of the respondents the instrument was deleted from the list. These data were presented during an ASAS workshop and the final decisions were about which instruments to include in the core set. This process was repeated separately for the settings disease controlling antirheumatic therapy (DC-ART), symptom modifying antirheumatic drugs (SMARD) and physical therapy, and clinical record keeping. The response rate to the questionnaire was 72%. For each domain one or more instruments were selected, except for Entheses and Fatigue. The chosen instruments were similar for the 3 above settings. Core sets of specific instruments were selected for the OMERACT filter test for relevance and feasibility. For all these instruments the remaining aspects of the OMERACT filter (truth and discrimination) should be assessed by literature review and if needed by additional research. It is recommended to use these instruments in all research projects in AS. (J Rheumatol 1999;26:951–4)

Key Indexing Terms:
ENDPOINTS ANKYLOSING SPONDYLITIS OUTCOME METHODOLOGY

Many assessments are available to evaluate ankylosing spondylitis (AS) but there has been no consensus on a core set of variables. Therefore we started the Assessments in Ankylosing Spondylitis (ASAS) Working Group for the process of selection of a core set to be used in various settings. This preliminary core set for endpoints in AS has been published[1]. The settings are for disease controlling antirheumatic therapy (DC-ART), symptom modifying antirheumatic drugs (SMARD)/physical therapy, and clinical record keeping. After the selection of the domains for the core set a consensus procedure was initiated among the members of the ASAS Working Group to select specific instruments to be included for each domain. The aim of this step was to reduce the vast number of possible measures. The next step will be to assess the validity of the remaining measures by literature research and by initiating new studies on aspects of the OMERACT filter (truth and discrimination) if needed[2]. In the event the instruments fail the filter test, they will be modified and/or replaced.

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MATERIALS AND METHODS

The domains selected to be included in all core sets are function, pain, spinal mobility, stiffness, and patient global. The domains peripheral joints and entheses, and acute phase reactants should be added for the settings DC-ART and clinical record keeping, and the domains x-ray spine, x-ray hips, and fatigue for the DC-ART setting. All instruments found in the lit-

rature dealing with the assessment of each domain were described in detail n a syllabus with addition of figures and photographs if available. There were 3 separate sections: DC-ART, SMARD/physical therapy, and clinical ecord keeping. These 3 sections were offered in random order to all members of the ASAS group. The members were asked to answer aspects of validity for the 3 sections separately. The validity issues that were addressed were relevance and feasibility. Relevance was defined as: "Is this instrument relevant to answer the study question in the particular setting in which the measurement is to be done? Does this instrument indeed assess the domain that we want to address?" Feasibility was defined as: "Is this instrument achievable in this particular setting?" Moreover, participants were asked whether they were familiar with the measure, used the measure, and whether the instructions were clear. All 5 questions had to be answered by "yes" or "no." The questions on knowledge, use, and instruction of a measure were added to ensure all measures would get a fair chance and were not excluded because of unfamiliarity with the instrument. An instrument was excluded if > 50% of the participants answered either relevance or feasibility with no.

RESULTS

DC-ART core set. Forty-three questionnaires were sent to the ASAS members and 31 (72%) completed and returned. The following instruments were found in the literature for the domains of the core set for DC-ART. In parentheses are the number of instruments excluded according to the 50% rule for relevance or feasibility (Table 1): Function 4 (1), Pain 15 (2), Spinal Mobility 32 (15), Stiffness 15 (8), Patient Global 10 (0), Peripheral Joints and Entheses 18 (4), Acute Phase Reactants 3 (1), x-ray Spine 3 (0), x-ray Hips 1 (0), Fatigue 4 (4). Thereafter, the remaining instruments were ordered per domain from highest to lowest percentage of relevance, and secondly from highest to lowest percentage of feasibility. For the domain spinal mobility this ranking was done separately for global instruments, measures assessing chest, cervical, thoracic, and lumbar spine mobility. For the domain pain it was grouped according to the type of scale [visual analog scales (VAS), etc.], the time span of the question (last week, etc.), the site of the complaint (spine, etc.), and when the pain occurred (during rest, etc.). The results were presented during an ASAS workshop (The American College of Rheumatology National Meeting 1997, Orlando). Based on these rankings and after discussion agreed upon by the participants, it was decided that for each domain the instruments presented in Table 2 are advised as minimum instruments to be included. In general, VAS were chosen and if a time frame was needed, "on average last week," was advised.

The choices per domain are discussed below:

- For the domain Physical Function either Bath Ankylosing Spondylitis Functional Index (BASFI) or Dougados Functional Index (FI Dougados) can be used[3,4].
- For the domain Pain two 100 mm VAS are advised: one on pain at night due to AS on average last week, and the other on pain (without time restraints) due to AS on average last week.
- Three instruments were selected to represent the domain Spinal Mobility: chest expansion, modified Schober, and occiput to wall distance. Many modifications of Schober test measuring anterior flexion of the lumbar spine exist. The one chosen here is performed as follows: With the patient standing erect, make a mark on the back in the midpoint on the imaginary line joining the posterior superior iliac spines. Make another mark 10 cm above the first. Ask the patient to maximally bend forward, keeping the knees fully extended. With the spine in fullest flexion, measure the distance between the 2 marks. The normal distance is now greater than 15 cm due to stretching of the skin overlying the mobile lumbar spine.
- The patient global assessment was specified by a VAS and the time span "on average last week."
- The number of swollen joints, based on the 44 joints count (right and left sternoclavicular, acromioclavicular, shoulder joints, elbows, wrists, knees, ankles, 10 metacarpophalangeal joints, 10 proximal interphalangeal joints, 10 metatarsophalangeal joints) without grading or weighting was selected to assess peripheral joints[5]. No specific instrument was selected to assess entheses, as the only described enthesis index according to Mander, *et al*[6] was judged as a relevant instrument by only 48% of the respondents.

Table 1. Selection of specific instruments for each domain of the DC-ART ASAS core set based on the judgment of relevance and feasibility by participants.

Domain	Available Instruments (n)	Excluded due to Relevance < 50%	Excluded due to Feasibility < 50%	Remaining Instruments
Physical function	4	1	0	3
Pain	15	2	1	13
Spinal mobility	32	14	11	17
Peripheral joints/entheses	18	4	0	14
Radiographs spine	3	0	0	3
Patient global assessment	10	0	0	10
Spinal stiffness	15	8	0	7
Radiographs hips	1	0	0	1
Fatigue	4	4	2	0
Acute phase reactant (AUC)	3	1	1	2

AUC: area under the curve.

Table 2.
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Table 2. Specific instruments for each domain in core sets for DC-ART, SMARD, physical therapy, and clinical record keeping.

Domain	Instrument
Function*	BASFI or Dougados Functional Index
Pain*	VAS, last week, spine, at night, due to AS
	and VAS, last week, spine, due to AS
Spinal mobility*	Chest expansion
	and modified Schober
	and occiput to wall distance
Patient global*	VAS, last week
Stiffness*	Duration of morning stiffness, spine, last week
Peripheral joints and entheses**	Number of swollen joints (44 joint count);
	currently no preferred instrument available for entheses†
Acute phase reactants**	ESR
Radiograph spine	AP + lat lumbar
	and lat cervical spine
	and X-pelvis (SI and hips)
Radiograph hips	See spine
Fatigue	Currently no preferred instrument available†

*Included in all 3 core sets for DC-ART, SMARD/physical therapy, and clinical record keeping.
**Included in core sets for DC-ART and clinical record keeping.
†These amendments were made by OMERACT IV[12].

- It was further decided that radiographs of the lateral cervical spine, anteroposterior, and lateral lumbar spine, and the pelvis should be taken. This ensures the 2 currently available radiographic scoring systems, Bath Ankylosing Spondylitis Radiology Index and Stoke Ankylosing Spondylitis Spinal Score, can be used concurrently until enough data are available to compare both methods[7-10]. The further evaluation of these scoring methods is one of the important issues on the research agenda. For the other 4 domains, the following instruments were selected.
- Duration of morning stiffness of the spine experienced "on average last week." The evaluation of adding "severity of morning stiffness" was placed explicitly on the research agenda.
- Erythrocyte sedimentation rate was considered the measure of choice for the domain of acute phase reactants, and C-reactive protein (CRP) was placed on the research agenda.
- Radiographs of the hips are already available since they are included when the radiograph of the pelvis is taken. The scoring method to assess destruction of the hips should be developed and validated further.
- None of the 4 measures used to assess fatigue in AS were judged relevant by more than 41% of the respondents. Therefore, no specific instrument is currently available that could be advised to assess fatigue.

So far only single instruments have been chosen. However, the value of combined indices such as the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), the Bath Ankylosing Spondylitis Metrology Index (BASMI), etc., should be investigated[7-11]. In general, these indices scored high in percentage of relevance and feasibility. However, the single components of the index often showed low percentages of relevance. As an example, the overall relevance for BASMI was 70%. Only 2 of the 5 assessments making up the BASMI (anterior flexion lumbar spine 15 cm segment and intermalleolar distance) showed a relevance of 60 and 70%, respectively, where the other 3 assessments (cervical rotation, tragus to wall, and lateral spinal flexion) showed a relevance ranging from 33 to 47% only. Moreover, the 15 cm segment to assess lumbar anterior flexion that is part of the BASMI was not the one preferred by most respondents (the preferred method was the modified Schober 10 cm segment, as described above).

To summarize, the following items were put on the research agenda to investigate their possible inclusion in the list of advised instruments: CRP, severity of morning stiffness of the spine on average last week, various scoring methods of radiographs, and BASDAI, BASMI and other indices.

SMARD, physical therapy, and clinical record keeping. The same process was followed for the domains of the core set for SMARD and physical therapy, and for clinical record keeping. There were only very minor differences in the results compared to the DC-ART setting and to each other (data not shown). The highest ranking in each domain was the same for all except for the domain peripheral joints and entheses. For clinical record keeping movements of the hips had the highest relevance (84%), followed by the number of swollen joints (44 joints) (77%), whereas this was the other way around for the DC-ART setting: hip movement relevance 73%, and number of swollen joints (44 joints) 83%.

To ensure comparability it was decided that the number of swollen joints based on the 44 joints score should be included as a minimum in every core set. Consequently, the specific instruments noted in Table 2 can also be applied to the settings of SMARD, physical therapy, and clinical record keeping for those domains that are included in that particular setting. The domains for SMARD and physical therapy are function, pain, spinal mobility, patient global, and stiffness; for clinical record keeping the same domains apply. but with addition of the domains peripheral joints and entheses, and acute phase reactants.

CONCLUSION

For all these instruments the remaining aspects of the OMERACT filter (truth and discrimination) should be assessed by literature review, and if needed additional research should be conducted[2]. If instruments do not pass the OMERACT filter test, these instruments will be modified or replaced wherever possible by other instruments.

Appendix. Members of the ASAS Working Group (in alphabetical order): A. Adebajo, UK; B. van Albada, The Netherlands; B. Amor, France; J. Barlow, UK; L. Benevolenskaya, Russia; H. Bird, UK; M. Boers, The Netherlands; A. Boonen, The Netherlands; M. Bosi-Ferraz, Brazil; J. Braun, Germany; P. Brooks, Australia; J. Bruckel, USA; R. Burgos-Vargas, Mexico; E. Collantes-Estevez, Spain; D. Clegg, USA; J. Darmawan, Indonesia; B. Dekker-Saeys, The Netherlands; B. Dijkmans, The Netherlands; A. Ebringer, UK; J. Edmonds, Australia; J. Engelman, The Netherlands; N. Feltelius, Sweden; N. Flato, Norway; P. Geher, Hungary; J. Gran, Norway; F. Guillemin, France; G. Husby, Norway; R. Juhlin, Sweden; Y. Kirazli, Turkey; L. Klareskog, Sweden; T. Kvien, Norway; M. Leirisalo-Repo, Finland; A. Linssen, The Netherlands; B. Michel, Switzerland; H. Mielants, Belgium; I. Olivieri, Italy; P. Peloso, Canada; P. van Riel, The Netherlands; F. Rogers, UK; A. Russell, Canada; E. Stanislawska-Biernat, Poland; C. Salvarani, Italy; G. Stucki, Switzerland; R. Sturrock, UK; G. Thomson, Canada; P. Tugwell, Canada; E. Veys, Belgium; H. Zeidler, Germany.

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