Outcome measures of disease activity in inflammatory arthritis

ABSTRACT

The most common types of chronic inflammatory arthritis are rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. In order to assess the activity of these diseases and tailor therapy, several outcome measures have been developed. They include composite scores based on clinical findings, biochemical markers and patient questionnaires. This article discusses the most commonly used outcome measures and looks at their limitations in quantifying the complex clinical features of different types of inflammatory arthritis, focusing in particular on rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis.

Inflammatory arthritis broadly encompasses rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. These are chronic autoimmune inflammatory conditions, which if left untreated lead to severe morbidity and increased mortality. One third of patients newly diagnosed with rheumatoid arthritis stop work within 2 years (National Collaborating Centre for Chronic Conditions, 2009). Early detection and aggressive immunosuppression with disease-modifying antirheumatic drugs is required in order to achieve remission and reduce joint damage. To attain this goal and prevent the overuse of immunosuppressive medications, which have their own risks, several outcome measures assessing disease activity have been developed. The outcome measures used in rheumatological practice frequently include composite scores, based on clinical findings, biochemical markers and patient-reported outcome measures. There are numerous outcome measures for rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis (*Table 1*). This article discusses the most commonly used ones, including when they should be used in routine practise, their benefits and limitations.

Dr Geraint A Brown, Registrar, Department of Rheumatology, University College London Hospital NHS Trust, London

Ms Alice Cotton, Clinical Research Nurse, Department of Rheumatology, University College London Hospital NHS Trust, London

Mrs Jesusa Guinto, Clinical Research Nurse, Department of Rheumatology, University College London Hospital NHS Trust, London

Dr Arti Sharma, Clinical Trial Coordinator, Department of Rheumatology, University College London Hospital NHS Trust, London

Dr Coziana Ciurtin, Consultant, Department of Rheumatology, University College London Hospital NHS Trust, London NW1 2PQ

Correspondence to: Dr C Ciurtin (c.ciurtin@ucl.ac.uk)

Rheumatoid arthritis

Rheumatoid arthritis is a chronic systemic inflammatory disease characterized by multiple joint involvement. Its presentation is highly variable within individuals and between patients. Patients often experience significant joint pain, stiffness, fatigue and functional impairment. Since the first composite disease activity measurement tool was developed in the 1950s, researchers have designed and validated another 63. Of these, the most commonly used and recommended by the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) are:

1. Disease Activity Score with 28 joint counts (DAS28)
2. Clinical Disease Activity Index (CDAI)
3. Patient Activity Scale (PAS)
4. Routine Assessment of Patient Index Data 3 (RAPID3)
5. Simple Disease Activity Index (SDAI) (Anderson et al, 2012).

These measurement tools can guide clinicians' treatment decisions and indicate when clinical remission is reached.

The DAS28 score is the most recognized disease activity score and incorporates twenty eight joints that are assessed for tenderness and swelling (*Figure 1*). The patient is asked to score the severity of his/her disease (global health) on a scale of 0–100. Blood markers of inflammation (erythrocyte sedimentation rate or C-reactive protein) are incorporated and using these four variables, a complex mathematical formula is used to produce the overall disease activity score. A DAS28 score >5.1 implies active disease, a score between 3.2–5.1 signifies moderate disease activity, less than 3.2 equates to low disease activity, and <2.6 implies remission. A DAS28 score should be performed on all patients with newly diagnosed rheumatoid arthritis, and this should be repeated at monthly treatment intervals until a low disease activity target is reached (National Collaborating Centre for Chronic Conditions, 2009). The National Institute for Health and Care Excellence recommends that patients with a DAS28 score greater than 5.1 on two conventional disease-modifying antirheumatic drugs are eligible for biologic therapy.

The CDAI score incorporates the assessment of 28 joints for tenderness and swelling. The patient is asked to provide a global assessment of disease activity on a scale of 0–10, and the assessor grades the patient's global disease activity out of 10. All of the above values are added up to give a total score. Scores 22.1–76 equal high disease activity, 10.1–22 define moderate activity, 2.9–10 represent low disease activity, and 0–2.8 suggest remission (www.rheumatology.org/Portals/0/Files/CDAI%20Form.pdf). This assessment tool is quick to use as it does not include

Table 1. Outcome measures for inflammatory arthritis

Condition	Peripheral joint involvement	Axial joint involvement	Quality of life outcome measures
Rheumatoid arthritis	N/A	Tender joint count (/28 or 44 or 68) Swollen joint count (/28 or 44 or 66) Physician global rating (visual analogue score) Patient global rating (visual analogue score) Patient pain rating (visual analogue score) DAS28 Clinical disease activity index (CDAI) Simple disease activity index (SDAI) Routine assessment of patient index data 3 (RAPID3) ACR20, ACR50, ACR70 EULAR and ACR response criteria Boolean remission criteria Inflammatory markers Radiographic progression (Steinbrocker, Sharp/Larsen scores) Magnetic resonance imaging progression (Rheumatoid Arthritis-MRI scoring system score)	Health Assessment Questionnaire Medical Outcomes Study Short Form 36 European Quality of Life 5 Domain score
Psoriatic arthritis	Tender joint count (/68) Swollen joint count (/66) Physician global rating (Likert scale) Patient global rating (Likert scale) DAS28 ACR20, ACR50, ACR70 EULAR and ACR response criteria Dactylitis (Leeds Dactylitis Score) Enthesitis (LEI, Maastricht Ankylosing Spondylitis Enthesitis Score; 13 points) Nail disease (nail psoriasis severity index) Inflammatory markers Radiographic progression (modified Steinbrocker, Sharp/Larsen, PARS scores) Magnetic resonance imaging progression (PsAMRIS score)	BASDAI BASFI BASMI Spinal pain (visual analogue score) Ankylosing Spondylitis Disease Activity Score Assessment of Spondyloarthritis 20, 50, 70 Spinal stiffness (stiffness question on BASDAI) Spinal enthesitis (MEI) Inflammatory markers Radiographic progression (mSASSS) Magnetic resonance imaging progression (ASspiMRI-a, Berlin and Spondyloarthritis Research Consortium of Canada scores)	Health Assessment Questionnaire Psoriatic Arthritis Assessment of Quality of Life Medical Outcomes Study Short Form 36 European Quality of Life 5 Domain score
Ankylosing spondylitis	Tender joint count (/68) Swollen joint count (/66) Enthesitis (LEI, Maastricht Ankylosing Spondylitis Enthesitis Score; 13 points, MEI, enthesitis question on BASDAI) Inflammatory markers Radiographic progression (Steinbrocker, Sharp/Larsen scores)	BASDAI BASFI BASMI Spinal pain (visual analogue score) Ankylosing Spondylitis Disease Activity Score Assessment of Spondyloarthritis 20, 50, 70 Spinal stiffness (stiffness question on BASDAI) Spinal enthesitis (MEI) Inflammatory markers Radiographic progression (mSASSS) Magnetic resonance imaging progression (ASspiMRI-a, Berlin and Spondyloarthritis Research Consortium of Canada scores)	Health Assessment Questionnaire Medical Outcomes Study Short Form 36 European Quality of Life 5 Domain score Ankylosing Spondylitis Quality of Life

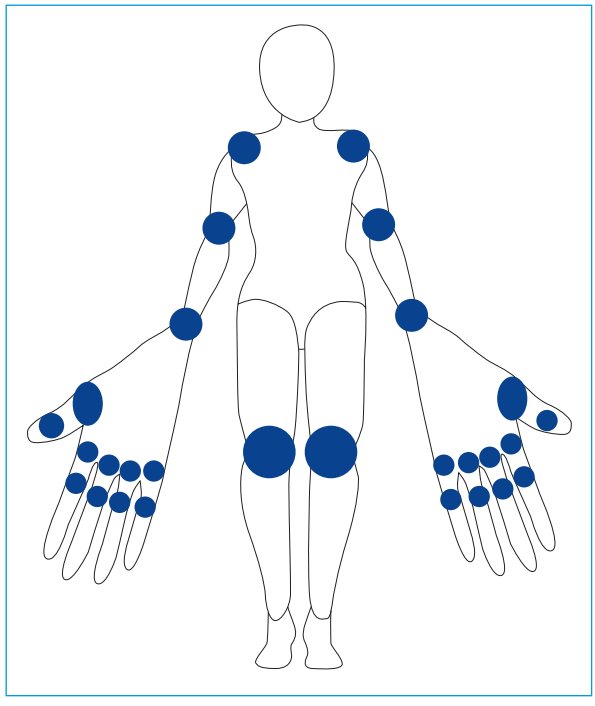
ACR = American College of Rheumatology; ASspiMRI-a = Ankylosing Spondylitis spine Magnetic Resonance Imaging-activity; BASDAI = Bath ankylosing spondylitis disease activity index; BASFI = Bath ankylosing spondylitis functional index; BASMI = Bath ankylosing spondylitis metrology index; CDAI = clinical disease activity index; DAS28 = Disease activity score for 28 joints; EULAR = European League Against Rheumatism; LEI = Leeds Enthesitis Index (6 points); MEI = Maastricht Ankylosing Spondylitis Enthesitis Score (66 points); mSASSS = modified Stoke Ankylosing Spondylitis Spine Score; PARS = Psoriatic Arthritis Ratingen Score; PsAMRIS = Psoriatic arthritis- MRI scoring system

inflammatory markers, and hence is particularly useful when no recent blood test results are available.

The SDAI score is similar to the CDAI score except that it incorporates the patient's C-reactive protein value, which is assumed to be within the interval 0–10 mg/dl, giving a maximum score of 86. Once again, scores are grouped into remission, low, moderate and high disease activity.

RAPID3 score is a patient-reported outcome comprising numerous questions about the patient's function in the last week, his/her level of pain and his/her global health. Scores are allocated depending on the patient's answers and are weighted. The maximum total score is 10, indicating high severity of disease if above 4, moderate severity if more than 2.3 and less than 4, and near remission if lower than 1. This

Figure 1. Disease Activity Score with 28 joint counts.



assessment is quick to perform and can be completed by patients while awaiting their rheumatology consultation.

Another tool used for appreciation of disease severity in rheumatoid arthritis is PAS, which is a functional assessment of the patient's everyday activities, walking ability and use of equipment aides, need for assistance and level of pain over the last week.

The consensus is that the best outcome measure scores involve a combination of patient and physician assessments (Anderson et al, 2012). However, clinical assessment of disease performed by a trained health professional can be time consuming despite being more accurate and thus patient-reported outcome measures have been implemented in practice. It can be argued that making patients responsible for their own assessment provides greater patient-centred care, and improves engagement and therapy compliance. A systematic review of patient-reported outcome measures used to assess disease activity in rheumatoid arthritis found that the patient-derived disease activity score with 28 joint counts, rheumatoid arthritis disease activity index and RAPID 3 score had the strongest and most extensive validation (Hendrikx et al, 2016).

The ACR criteria of response are the standard benchmarks used to measure the effectiveness of various disease-modifying antirheumatic drugs. There are three main criteria, designated ACR20, ACR50 and ACR70 response criteria. The numbers signify the percentage of improvement of disease activity between two discrete time points. The ACR criteria measure tender and swollen joints, patient and physician's disease activity assessments on a scale 0–10, pain severity on scale 0–10, disability or functional scores and inflammatory markers (erythrocyte sedimentation rate or C-reactive protein).

The EULAR response criteria classifies patients as either non-responders, moderate or good responders depending on two DAS28 scores taken between two discrete time points. The DAS28 score is a measure of disease activity at a certain time point rather than a measurement of change like the ACR response criteria (Fransen and van Riel, 2005). Both assessments allow clinicians to determine whether certain treatments are effective or not. The ACR and EULAR criteria are therefore used in clinical trials and current practice, and when compared with each other, there was less than 3% discrepancy in their appreciation of patient response to treatment (van Gestel et al, 1999).

Ankylosing spondylitis

Ankylosing spondylitis is a chronic inflammatory disease of unknown aetiology characterized by inflammation of spinal joints and adjacent structures, which untreated leads to progressive bony fusion of the spine (Davis, 2005). Ankylosing spondylitis has a genetic predisposition proven by its strong association with human leukocyte antigen B27 (HLA-B27).

The assessment of ankylosing spondylitis activity comprises objective signs of inflammation and assessment of the severity of patients' subjective symptoms. This includes the number of swollen and/or tender joints, the number of inflamed entheses, spinal pain, fatigue, and duration of morning stiffness. Laboratory markers of inflammation may be helpful, but are not incorporated in all outcome measure scoring systems used in ankylosing spondylitis, as they do not always correlate with the objective evidence of spinal inflammation. Outcome measures are important to guide selection of disease-modifying antirheumatic drug therapies in patients with ankylosing spondylitis (van der Heijde et al, 1997). Disease activity in patients with ankylosing spondylitis is measured by several scores; the most used ones are detailed below.

The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) (Garrett et al, 1994) (*Figure 2*) is a patient-reported outcome questionnaire using a visual analogue scale of 0–10 to assess the following criteria:

A. Fatigue
B. Spinal pain
C. Joint pain
D. Enthesitis
E. Qualitative morning stiffness
F. Quantitative morning stiffness.

The BASDAI score is calculated using the following formula: BASDAI = 0.2 (A + B + C + D + 0.5[E + F]). Patients who have a BASDAI score greater than 4 despite non-steroidal anti-inflammatory drugs may be eligible for biologic disease-modifying antirheumatic drug therapy.

The Bath Ankylosing Spondylitis Functional Index (BASFI) appreciates the physical function of patients with ankylosing spondylitis through a self-assessment questionnaire, and it is reported as the mean score of 10 questions answered using a visual analogue scale 0 to 10. Eight questions relate to the patient's functional ability, and

Figure 2. Bath Ankylosing Spondylitis Disease Activity Index (BASDAI). From Garrett et al (1994). AS = ankylosing spondylitis.

Please tick the box which represents your answer. All questions refer to the **past week**.

1. How would you describe the overall level of **fatigue/tiredness** you have experienced?

0	1	2	3	4	5	6	7	8	9	10
None										very severe

2. How would you describe the overall level of AS neck, back or hip pain you have had?

0	1	2	3	4	5	6	7	8	9	10
None										very severe

3. How would you describe the overall level of pain/swelling in joints other than neck, back, hips you have had?

0	1	2	3	4	5	6	7	8	9	10
None										very severe

4. How would you describe the overall level of discomfort you have had from any areas tender to touch or pressure?

0	1	2	3	4	5	6	7	8	9	10
None										very severe

5. How would you describe the overall level of morning stiffness you have had from the time you wake up?

0	1	2	3	4	5	6	7	8	9	10
None										very severe

6. How long does your morning stiffness last from the time you wake up?

0 hours	½	1	1½	2 or more hours

Please add the scores (take the mean of stiffness questions 5 and 6) to give a score out of 50. Then multiply by 2 and divide by 10 to give a total BASDAI out of 10

two questions relate to the patient's capacity to cope with everyday life. Any increase in the reposted score between two different time points indicates worsening disease (Calin et al, 1994).

The Bath Ankylosing Spondylitis Metrology Index (BASMI) is an aggregate score of five different objective measures of spinal mobility which include lateral lumbar flexion, tragus-to-wall distance, lumbar flexion (modified Schober's test), intermalleolar distance and cervical rotation angle. Each parameter is calculated as a mean of right and left measurement. BASMI was used to determine the minimum number of clinically appropriate measurements that assess accurately axial mobility status to define clinically significant changes in spinal movement (van der Heijde et al, 2008).

The Maastrich Ankylosing Spondylitis Enthesitis Score (MASES) index (Heuft-Dorenbosch et al, 2003) was developed to assess enthesitis (inflammation of entheses) in patients with ankylosing spondylitis. The MASES index helps evaluate for the presence and absence of pain at the site of entheses, by applying local pressure to the following areas: first costochondral joint (left and right), seventh costochondral joint (left and right), posterior superior iliac spine (left and right), anterior superior iliac spine (left and right), iliac crest (left and right), fifth lumbar spinous process, and proximal insertion of Achilles tendon (left and right). MASES index scores range from 0 to 13.

Psoriatic arthritis

Psoriatic arthritis is a seronegative chronic inflammatory arthritis, which can manifest as peripheral joint inflammation, enthesitis, dactylitis and axial inflammation. Up to 40% of patients also have skin and nail involvement (Coates et al, 2013). Core outcome measures and domain sets have been set out by the collaborative research Group of Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and the Outcome Measures in Rheumatology group (Mease, 2011). They have attempted to standardize measurements of disease used in randomized clinical trials to reflect both patients' and physicians' priorities. However, specific guidance for the use of outcome measures and domain sets in routine clinical rheumatology practice is lacking. There are few instruments specifically designed for measuring disease severity. Many outcome measures (such as peripheral joint disease, patient and physician global assessments, and axial

disease) are adapted from scores used in rheumatoid arthritis and ankylosing spondylitis (Mease, 2011).

Evaluation of disease activity should include assessment of joints (peripheral arthritis, enthesitis, dactylitis and spinal symptoms) and skin (severity of psoriasis, including psoriatic nail disease) (Gladman et al, 2004). Other domains include pain, patient and physician global assessment, physical function, health-related quality of life, fatigue and systemic inflammation (Orbai et al, 2016).

Peripheral joint disease

There are no widely validated and specific measures of peripheral joint disease for psoriatic arthritis (Gladman et al, 2007). In clinical practice, a 28-joint count as in rheumatoid arthritis is often performed. However, an extended joint count score assessing 66 joints for swelling and 68 joints for tenderness is frequently used in research settings (Gladman et al, 2007). The Psoriatic Response Criteria (PsARC), which was designed initially for a clinical trial of sulfasalazine, is another tool used for assessment of response to treatment in psoriatic arthritis, although it has not been validated (Gladman et al, 2007). PsARC measures tender and swollen joint scores, physician global and patient global assessments of disease activity (0–5 point Likert scales). Overall improvement is defined as an improvement in a minimum of two of the four items, one of which must be joint count, without worsening of any items.

Dactylitis

Dactylitis, or sausage digit, is a hallmark clinical feature reported in 16–48% of psoriatic arthritis patients (Gladman et al, 2007). It is described as a uniform diffuse swelling of the soft tissues between metacarpophalangeal, proximal and distal interphalangeal joints – the Leeds Dactylitis Instrument (LDI) provides an objective assessment by measuring the diameter (cm) of each digit affected and its tenderness score. A 10% difference in diameter between bilateral finger measurements indicates dactylitis. The LDI has good inter- and intra-observer reliability and provides an objective measure of this feature (Gladman et al, 2007).

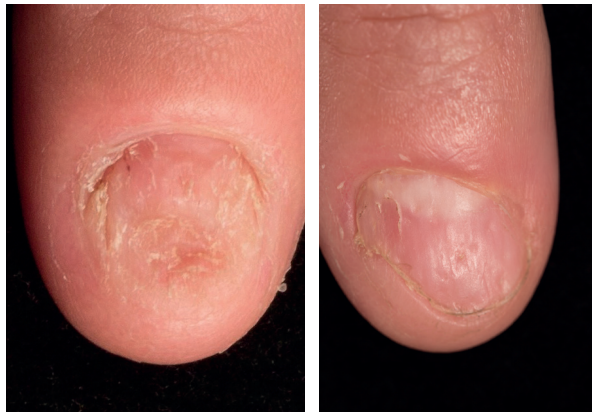
Enthesitis

Enthesitis is characterized as inflammation at the sites of tendon, ligament and joint capsule fibre insertion into the bone (Mease, 2011). Although enthesitis is a common feature of psoriatic arthritis, the enthesitis scores used in psoriatic arthritis have been adapted from those for ankylosing spondylitis. The Leeds Enthesitis Index (LEI) assesses the presence or absence of tenderness on palpation at six key sites: both lateral epicondyles, medial epicondyles and Achilles tendons. The LEI score showed good sensitivity to change following effective treatment (Gladman et al, 2007).

Axial disease

The incidence of spinal involvement in psoriatic arthritis is reported as between 20 and 70% patients (Gladman et al, 2007). Although axial disease is considered to be less severe in patients with psoriatic arthritis than in those with ankylosing spondylitis, many of the outcome measures used in ankylosing spondylitis are applicable to psoriatic arthritis.

Figure 3. Two psoriatic nails with pitting, crumbling and onycholysis.



Nail disease

Psoriatic nail changes are associated with higher joint counts and disease activity (Sandre et al, 2015). The Nail Psoriasis Severity Index (NAPSI) is a simple objective tool to evaluate changes in colour, the thickness and features of the nail plate and matrix (Gladman et al, 2007). Features of nail psoriasis include nail pitting, crumbling, onycholysis, oil drop dyschromia, splinter haemorrhages, leukonychia and red spots (*Figure 3*). The modified NAPSI score (m-NAPSI), improved following GRAPPA focus group discussions, has enhanced its feasibility and face validity.

Skin assessment

Skin assessment is not a direct measure of psoriatic arthritis activity in rheumatology settings, as psoriasis is only present in 40% of patients with psoriatic arthritis. The Psoriasis Area and Severity Index (PASI) is the most widely used assessment tool for skin psoriasis (Mease, 2011). It measures the erythema, induration, scale and area affected by psoriasis, and can be re-measured at regular intervals to evaluate the effectiveness of treatment (Hughes and van Onselen, 2001). Rheumatologists often use subjective measures including patient and physician global assessment of psoriasis disease activity, comprising visual analogue scales.

Conclusions

Disease-activity measuring tools allow clinicians to assess the severity of rheumatic conditions, which can give guidance on when to escalate or reduce medical therapy. Low disease activity scores indicate disease remission, reassuring the clinician that the risk of long-term irreversible joint damage is significantly reduced. They play an important role in research studies as standardized assessment tools, allowing potential new therapies to be compared to current treatment. Composite outcome measures can also offer information about the impact of the disease on the patient's

quality of life. These assessments can support clinicians in involving members of the multidisciplinary team in the provision of patient care, ultimately improving patient outcomes. Patients can also complete some assessment tools before seeing a rheumatologist, therefore maximizing the time and quality of the consultation.

However, these tools have their limitations. First, a patient's scores often include pain as a reported outcome, which is subjected to wide variations in the patient's perceptions of pain. A stoical patient's pain score will significantly underestimate underlying disease activity, as opposed to a patient with a low pain threshold. Those patients with multiple comorbidities are also difficult to assess clinically, as how they feel may be related to other conditions than just their underlying rheumatic disease. The same applies to those with chronic pain or fibromyalgia. Second, there can be variations between assessors in their perception of swelling and pressure applied to elicit joint tenderness, depending on the level of skills and experience of the assessor.

Inflammatory arthropathies encompass a wide variety of presentations that pose challenges in assessing overall disease activity. An objective measure may assess a single aspect of the disease but does not include the psychological impact of the disease on the patient's quality of life. The health assessment questionnaire is recommended by National Institute for Health and Care Excellence for use in practice, as it identifies physical limitations of everyday tasks. It should be performed every 6 or 12 months. Another patient questionnaire, the Quality of Life Index, is a very useful tool to assess psychological wellbeing, as depression is common in patients with arthritis. Radiographic damage scores also have a role as outcome measures in arthritis, and it is useful to request X-rays at the time of diagnosis, with further imaging performed when new symptoms arise or at set time points, to identify irreversible joint changes that would suggest ongoing chronic inflammation. There is also an emerging role in the use of joint ultrasound examination in patients with rheumatoid arthritis and psoriatic arthritis, which can detect sub-clinical synovitis. Use of composite scores, combining clinical and imaging outcomes, is likely to become more common.

Overall, there is no doubt that tools which measure disease activity are of significant benefit, and allow quantification and comparisons between a patient's disease activity levels over time and between larger populations. The authors recommend regular use of DAS28, PsARC and BASDAI in follow-up appointments for patients with inflammatory arthritis, as validated scores that were shown to improve therapeutic decisions and disease control over time were associated with a significant patient benefit. **BJHM**

Conflict of interest: none.

KEY POINTS

- Outcome measures of disease activity are useful tools to quantify active disease and tailor therapy to induce remission.
- Outcome measures should be used in conjunction with a patient's psychological state and quality of life when assessing disease activity and considering treatment options.
- The authors recommend DAS 28, BASDAI and PsARC as outcome measures for rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis respectively.

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