

Axial Spondyloarthritis: Disease State

Module 1

Defining and diagnosing axSpA

Module 2

Pathogenesis, clinical presentation, and disease burden

Module 3

axSpA Disease Assessments

Module 4

axSpA Disease Management

Lilly

Module 3

Assessment Tools Used in Clinical Trials and Clinical Practice

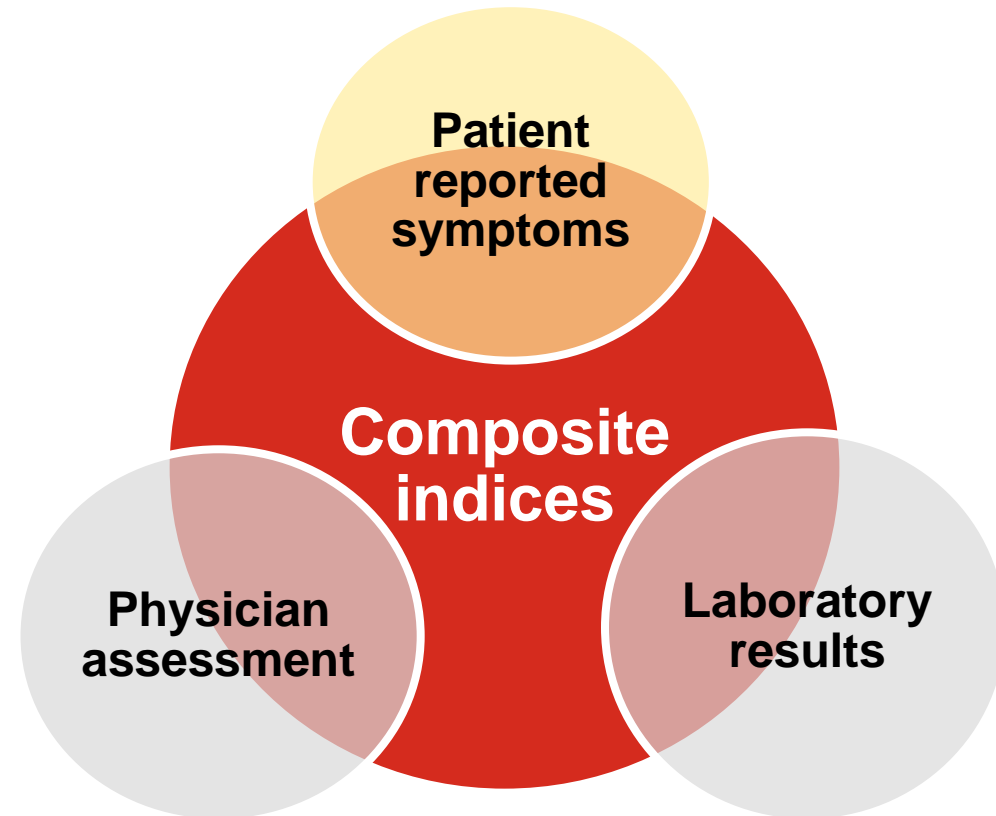
Learning Objectives



- Explore the variety of outcomes measures available in axSpA.
- Understand the different components to the assessment tools.
- Discuss strengths and weaknesses of various assessment tools.

Clinical Disease Activity Assessments Tools

- There is no assessment tool that is considered the “gold standard” for measuring disease activity.
- To quantify disease activity in axSpA, it is necessary to consider many aspects, one variable or individual tool is not enough to assess the entire disease.



Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

- Patient-reported measure published 20 years ago.¹
- Easy to complete.¹⁻³
- Measures only part of the disease activity domain.^{1,2}
- Does not weigh individual clinical manifestations.⁴
- Lacks specificity for inflammatory processes.⁵

BASDAI50 Response²

- Proportion of patients achieving $\geq 50\%$ improvement from baseline in the BASDAI score (on a 0 to 10 scale).
- Used to measure response to biologic therapy after 3 months of treatment.

Purpose: Validated test to measure disease activity and response to therapy.¹



For the Patient: Simple measure using 6 questions to assess 5 major symptoms of axSpA.^{1,3}



axSpA=Axial Spondyloarthritis; BASDAI=Bath Ankylosing Spondylitis Disease Activity Index.

1. Garrett S, et al. *J Rheumatol*. 1994;21:2286-2291. 2. Landewé R, van Tubergen A. *Curr Rheumatol Rep*. 2015;17(7):47. 3. Sieper J, et al. *Ann Rheum Dis*. 2009;68(Suppl II):ii1-ii44.

4. Marona J, et al. *RMD Open*. 2020. 6(1):e001145. 5. Ghosh N, Ruderman EM. *Arthritis Res Ther*. 2017.19(1):286.

Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

Relating to the past week, score out of 10 for each question (0 = None, 10 = Very Severe)^{1,2}

| | Score / 10 |
|---|------------|
| 1. How would you describe the overall level of <u>fatigue/tiredness</u> you have experienced? | |
| 2. How would you describe the overall level of <u>AS neck, back or hip pain</u> you have had? | |
| 3. How would you describe the overall level of pain/swelling in joints <u>other than</u> neck, back or hips you have had? | |
| 4. How would you describe the overall level of <u>discomfort</u> you have had from any areas tender to touch or pressure? | |
| [A] Total of Q1 to Q4 (out of 40) | |
| 5. How would you describe the overall <u>level of morning stiffness</u> you have had from the time you wake up? | |
| 6. <u>How long</u> does your <u>morning stiffness</u> last from the time you wake up? (0 = 0 hours, 10 = 2+ hours) | |
| [B] Total of Q5 to Q6 divided by 2 (out of 10) | |
| BASDAI = Total Score out of 50 [A+B]/5 | |

Interpretation^{1,2}

- **The score ranges from 0 (no disease activity) to 10 (very active disease).**
- A cut-off of 4 is frequently used to define active disease for purposes of clinical trial entry.

AS=Ankylosing Spondylitis; BASDAI=Bath Ankylosing Spondylitis Disease Activity Index; Q=Question.


1. Sieper J, et al. *Ann Rheum Dis.* 2009;68(Suppl II):ii1–ii44. 2. Landewé R, van Tubergen A. *Curr Rheumatol Rep.* 2015;17(7):47.

The Ankylosing Spondylitis Disease Activity Score (ASDAS) is a Frequently Used Instrument in Clinical Trials

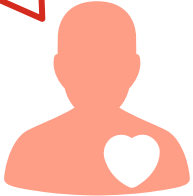
Data-driven index that combines PROs and other measures in a weighted manner:

1. Back pain
2. Peripheral pain/swelling
3. Duration of morning stiffness
4. Patient global assessment of disease activity
5. CRP (ASDAS-CRP) or ESR (ASDAS-ESR)

ASDAS-CRP is recommended by the ASAS organization for clinical practice.



Purpose: Composite index to assess disease activity and response to treatment.

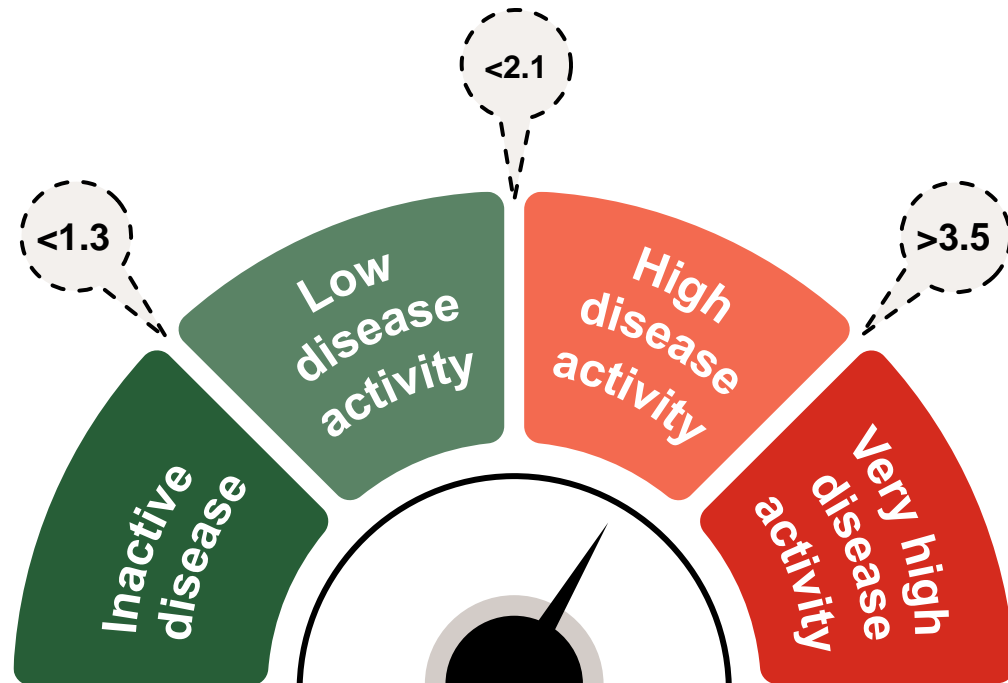


For the Patient: Allows for evaluation of disease activity and definition of improvement.

ASAS=Assessment in Spondyloarthritis International Society; ASDAS=Ankylosing Spondylitis Disease Activity Score; ASDAS-CRP=Ankylosing Spondylitis Disease Activity Score-C-reactive Protein; ASDAS-ESR=Ankylosing Spondylitis Disease Activity Score-Erythrocyte Sedimentation Rate; CRP=C-reactive Protein; ESR=Erythrocyte Sedimentary Rate; PRO=Patient-reported Outcome.
Landewé R, van Tubergen A. *Curr Rheumatol Rep.* 2015;17(7):47.

Ankylosing Spondylitis Disease Activity Score (ASDAS)

ASDAS disease activity states^{1,2}



ASDAS-CRP: $0.121 \times \text{total back pain} + 0.110 \times \text{patient global} + 0.073 \times \text{peripheral pain/swelling} + 0.058 \times \text{duration of morning stiffness} + 0.579 \times \text{Ln(CRP)} + 1$

ASDAS improvement criteria^{1,2}

$\Delta \geq 1.1$

Clinically Important Improvement

$\Delta \geq 2.0$

Major Improvement

ASDAS-ESR: $0.113 \times \text{patient global} + 0.293 \times \sqrt{\text{ESR}} + 0.086 \times \text{peripheral pain/swelling} + 0.069 \times \text{duration of morning stiffness} + 0.079 \times \text{total back pain}$

ASDAS=Ankylosing Spondylitis Disease Activity; ASDAS-CRP=Ankylosing Spondylitis Disease Activity Score-C-reactive Protein; ASDAS-ESR=Ankylosing Spondylitis Disease Activity Score-Erythrocyte Sedimentation Rate; ESR=Erythrocyte Sedimentation Rate; Ln(CRP)=Natural Logarithm C-reactive Protein.

1. Landewé R, van Tubergen A. *Curr Rheumatol Rep*. 2015;17(7):47. 2. ASAS. <https://www.asas-group.org/clinical-instruments/asdas-calculator/>. (Accessed on January 16, 2024).

ASAS Response Criteria for Measuring Response and Remission

ASAS40 Improvement Criteria (4 domains)^{1,2}

- An improvement of $\geq 40\%$ and an absolute improvement of ≥ 2 units (on an NRS scale of 0-10) in ≥ 3 domains with no worsening of $\geq 20\%$ and ≥ 1 unit in the remaining domain.

ASAS20 Improvement Criteria (4 domains)^{1,2}

- An improvement of $\geq 20\%$ and an absolute improvement of ≥ 1 unit (on an NRS scale of 0-10) in ≥ 3 domains, with no worsening of $\geq 20\%$ and ≥ 1 unit in the remaining domain.
- Domains:
 1. Patient global
 2. Pain
 3. Function (assessed by BASFI),
 4. Inflammation (mean of BASDAI question 5 and 6)

ASAS Partial Remission (4 domains)^{1,2}

- Very low disease activity
- Value of ≤ 2 (on a 0 to 10 scale) for each domain:
 1. Patient global
 2. Pain
 3. Function (assessed by BASFI),
 4. Inflammation (mean of BASDAI question 5 and 6)

ASAS5/6 Improvement Criteria (6 domains)^{1,2}

- $\geq 20\%$ improvement in ≥ 5 of 6 domains
 1. Patient global
 2. Pain
 3. Function (assessed by BASFI),
 4. Inflammation (mean of BASDAI question 5 and 6)
 5. CRP
 6. Spinal mobility (assessed by lateral spinal flexion)

ASAS=Assessment of SpondyloArthritis International Society; BASDAI=Bath Ankylosing Spondylitis Disease Activity Index; BASFI=Bath Ankylosing Spondylitis Functional Index; CRP=C-reactive Protein; NRS=Numeric Rating Scale.

1. Sieper J, et al. *Ann Rheum Dis*. 2009;68 Suppl 2:ii1-44. 2. Landewé R, van Tubergen A. *Curr Rheumatol Rep*. 2015;17(7):47.

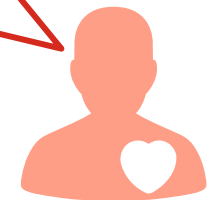
Bath Ankylosing Spondylitis Functional Index (BASFI)

- The BASFI scores range between 0 (easy) and 10 points (impossible).^{1,2}
- A higher score indicates a higher degree of functional limitations.^{1,2}
- Improvement of >2 points is clinically important improvement.³



Purpose: Validated instrument to assess the degree of functional limitation in patients.^{1,2}

For the Patient: Patient reported survey to measure functional limitation.^{1,2}



BASFI=Bath Ankylosing Spondylitis Functional Index.

1. Sieper J, et al. *Ann Rheum Dis*. 2009;68 (Suppl 2):ii1-44. 2. Landewé R, van Tubergen A. *Curr Rheumatol Rep*. 2015;17(7):47. 3. Ramiro S, et al. *ACR Convergence*. 2022. 74 (suppl 9). [Abstract Number: 1009].

Bath Ankylosing Spondylitis Functional Index (BASFI)

Items to be scored by the patient:

- Putting on your socks or tights without help or aids (e.g., sock aid).
- Bending forward from the waist to pick up a pen from the floor without an aid.
- Reaching up to a high shelf without help or aids (e.g., helping hand).
- Getting up out of an armless dining room chair without using your hands or any other help.
- Getting up off the floor without help from lying on your back.
- Standing unsupported for 10 min without discomfort.
- Climbing 12 to 15 steps without using a handrail or walking aid. One foot at each step.
- Looking over your shoulder without turning your body.
- Doing physically demanding activities (e.g., physiotherapy, exercises, gardening or sports).
- Doing a full day's activities, whether it be at home or at work.

The BASFI is the mean of 10 item scores completed on a numerical rating scale.

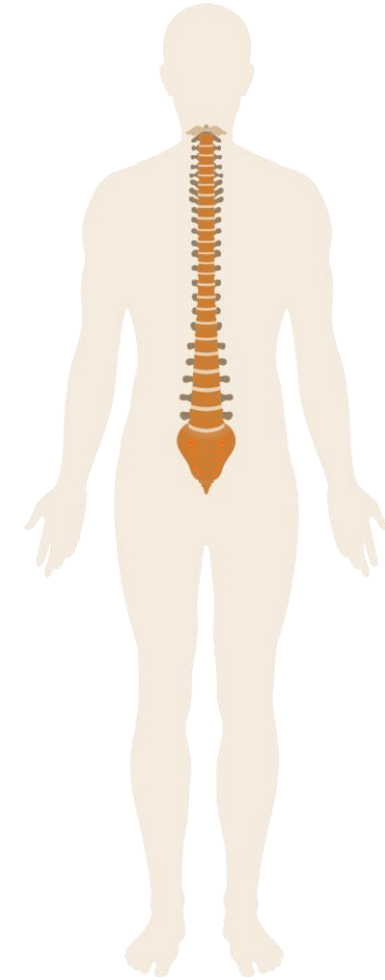
Numerical rating scale

Easy Impossible

Alternatively, a VAS between 0 and 100 can be used. ASAS prefers to use an NRS.

Bath Ankylosing Spondylitis Metrology Index (BASMI)

- Composite score based on 5 clinical measures reflecting spinal mobility:¹
 - Lateral lumbar (spinal) flexion
 - Tragus-to-wall distance
 - Lumbar flexion (modified Schöber)
 - Maximal intermalleolar distance
 - Cervical rotation angle
- 3 different definitions:²
 - 2-step (3-point scale; $BASMI_2$)
 - 10-step (11-point scale; $BASMI_{10}$)^a
 - Linear (continuous measure; $BASMI_{lin}$)^a
 - $BASMI_{lin}$ and $BASMI_{10}$ supersedes original $BASMI_2$ method



^aRecommended by ASAS.

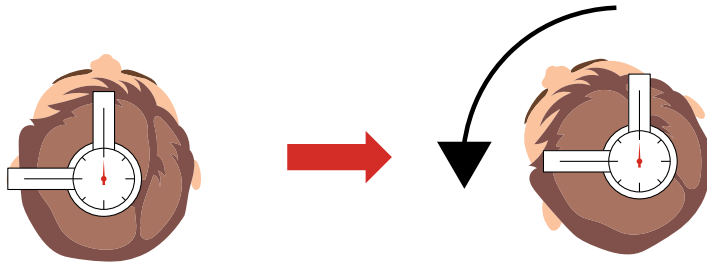
ASAS=Assessment of SpondyloArthritis International Society; BASMI=Bath Ankylosing Spondylitis Metrology Index.

1. Sieper J, et al. *Ann Rheum Dis*. 2009;68 Suppl 2:ii1-44. 2. Landewé R, van Tubergen A. *Curr Rheumatol Rep*. 2015;17(7):47

Bath Ankylosing Spondylitis Metrology Index (BASMI)

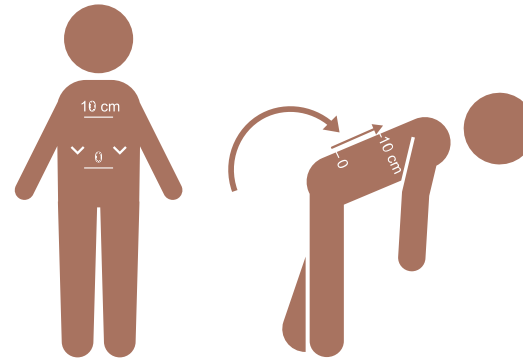
Assessing a Patient (1 of 2)

Cervical rotation angle



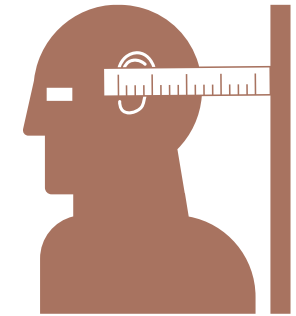
1. Patient sits straight on chair, chin level, hands on knees.
2. Goniometer placed on top of head in line with the nose.
3. Patient rotates head to the left as far as possible; record angle between sagittal plane and new plane after rotation.
4. Repeat for rotation to the right.
5. The mean of left and right is recorded in degrees (0-90°).

Lumbar flexion (modified Schöber)



1. Mark made at sacral dimples and 10 cm above while patient standing erect.
2. Patient bends forward maximally.
3. Measure distraction of the two marks.
4. Report the better difference of 2 tries in cm (to the nearest 0.1 cm).

Tragus-to-wall distance

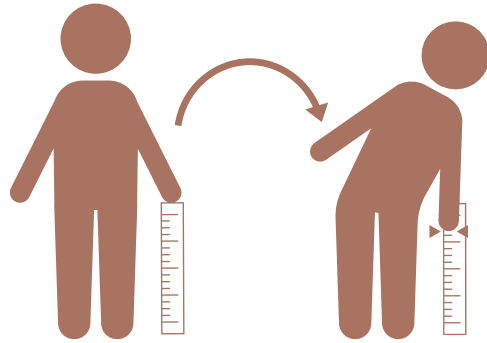


1. Heels and back rest against the wall.
2. Chin at usual carrying level.
3. Maximal effort to move the head against the wall.
4. Report the better of 2 tries (in cm) for the tragus-to-wall distance.

Bath Ankylosing Spondylitis Metrology Index (BASMI)

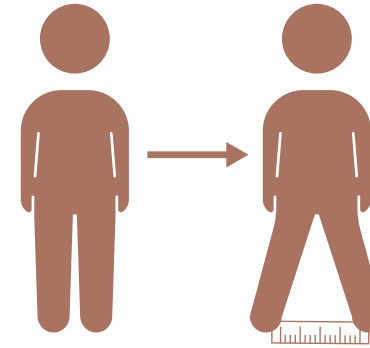
Assessing a Patient (2 of 2)

Lateral lumbar (spinal) flexion



1. Patient stands with heels and back against wall
 - a. Place a mark on the thigh.
 - b. Bend sideward without bending knees or lifting heels.
 - c. Place a second mark; record the difference.
2. Report the better of 2 tries for left and right separately.
3. The mean of left and right is calculated in cm (to the nearest cm).

Maximal intermalleolar distance



1. Patient is lying down with the legs separated as far as possible with knees straight and toes pointing upwards (preferred method).
2. Alternatively, the patient stands and separates the legs as far as possible.
3. Measure distance between the medial malleoli.

Comparing Outcome Measures

| | BASDAI ¹⁻⁴ | ASDAS ¹⁻⁴ | ASAS ¹⁻⁴ |
|---|---|---|--|
| What is the measure used for? | Assess disease activity and response to treatment. | Assess disease activity and response to treatment. | Measure response to treatment. |
| How is it scored? | A mean is derived from the sum of components; higher scores indicate more active disease. | Components are weighted; calculator computes score; higher scores indicate more active disease. | Criteria for measuring response vary across defined categories of improvement. |
| Do specified criteria include... | | | |
| ...spinal pain? | <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes |
| ...morning stiffness? | <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes |
| ...patient global assessment? | <input type="checkbox"/> No | <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes |
| ...fatigue? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> No |
| ...joint pain/swelling? | <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| ...localized tenderness/enthesitis? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> No |
| ...function (BASFI)? | <input type="checkbox"/> No | <input type="checkbox"/> No | <input checked="" type="checkbox"/> Yes |
| Spinal mobility? | <input type="checkbox"/> No | <input type="checkbox"/> No | <input checked="" type="checkbox"/> Yes |
| CRP in mg/L (or ESR)? | <input type="checkbox"/> No | <input checked="" type="checkbox"/> Yes | Variable* |

*Inclusion of CRP is dependent on the definition used.

ASAS=Assessment of SpondyloArthritis International Society; ASDAS=Ankylosing Spondylitis Disease Activity; BASDAI=Bath Ankylosing Spondylitis Disease Activity Index; BASFI=Bath Ankylosing Spondylitis Functional Index; CRP=C-reactive Protein; ESR=Erythrocyte Sedimentary Rate.

1. Garrett S, et al. *J Rheumatol.* 1994; 21:2286-2291. 2. Sieper J, et al. *Ann Rheum Dis.* 2009; 68:ii1-ii44. 3. Landewé R, van Tubergen A. *Curr Rheumatol Rep.* 2015;17(7):47.

4. ASAS. <https://www.asas-group.org/clinical-instruments/asdas-calculator/>. (Accessed on January 16, 2024).

Comparing Outcome Measures

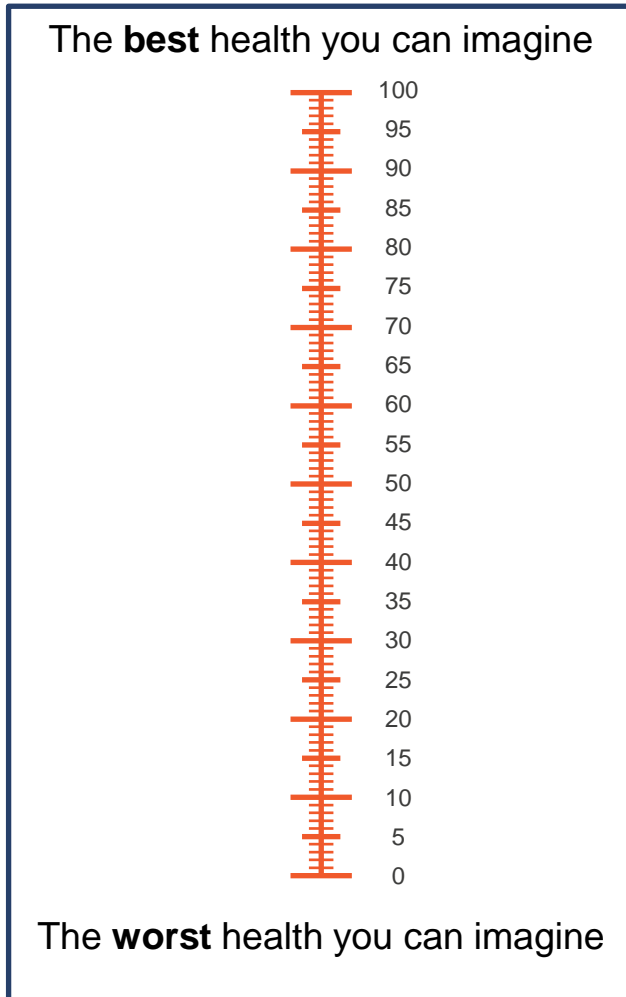
| BASDAI ¹⁻⁴ | ASDAS ¹⁻⁴ | ASAS ¹⁻⁴ |
|--|---|---|
| <p>Active disease: ≥ 4 Clinical trial entry threshold</p> | <p>Low: < 1.3 Moderate: 1.3 to 2.1 High: $> 2.1 - 3.5$ Very high: > 3.5</p> | <p>ASAS20: Improvement of $\geq 20\%$ and ≥ 1 unit in ≥ 3 of 4 domains No worsening of $\geq 20\%$ in remaining domains</p> |
| <p>BASDAI50: $\geq 50\%$ improvement of the total BASDAI score</p> | <p>Major Improvement: $\Delta \geq 2.0$ points</p> | <p>ASAS40: Improvement of $\geq 40\%$ and ≥ 2 unit in ≥ 3 of 4 domains No worsening in the last domain</p> |
| <p>Clinically Important Improvement: $\Delta \geq 2$ points</p> | <p>Clinically Important Improvement: $\Delta \geq 1.1$ points</p> | <p>Partial Remission Score of ≤ 2 for each of the 4 domains</p> |
| | | <p>ASAS5/6 Improvement Criteria $\geq 20\%$ improvement in ≥ 5 of 6 domains</p> |

ASAS=Assessment of SpondyloArthritis International Society; ASDAS=Ankylosing Spondylitis Disease Activity; BASDAI=Bath Ankylosing Spondylitis Disease Activity Index.
 1. Garrett S, et al. *J Rheumatol*. 1994; 21:2286-2291. 2. Sieper J, et al. *Ann Rheum Dis*. 2009; 68:ii1-ii44. 3. Landewé R, van Tubergen A. *Curr Rheumatol Rep*. 2015;17(7):47.
 4. ASAS. <https://www.asas-group.org/clinical-instruments/asdas-calculator/>. (Accessed on January 16, 2024).

European Quality of Life-5 Dimensions (EQ-5D-5L)

Assessing a Patient

EQ VAS



- Comprised of 5 dimensions of overall health.
- Consists of 2 scores:
 - Descriptive system of the respondent's health.
 - Rating of current health state using the EQ VAS (0-100 mm).
- 5 levels (options) for each dimension.

EQ-5D-5L Dimensions



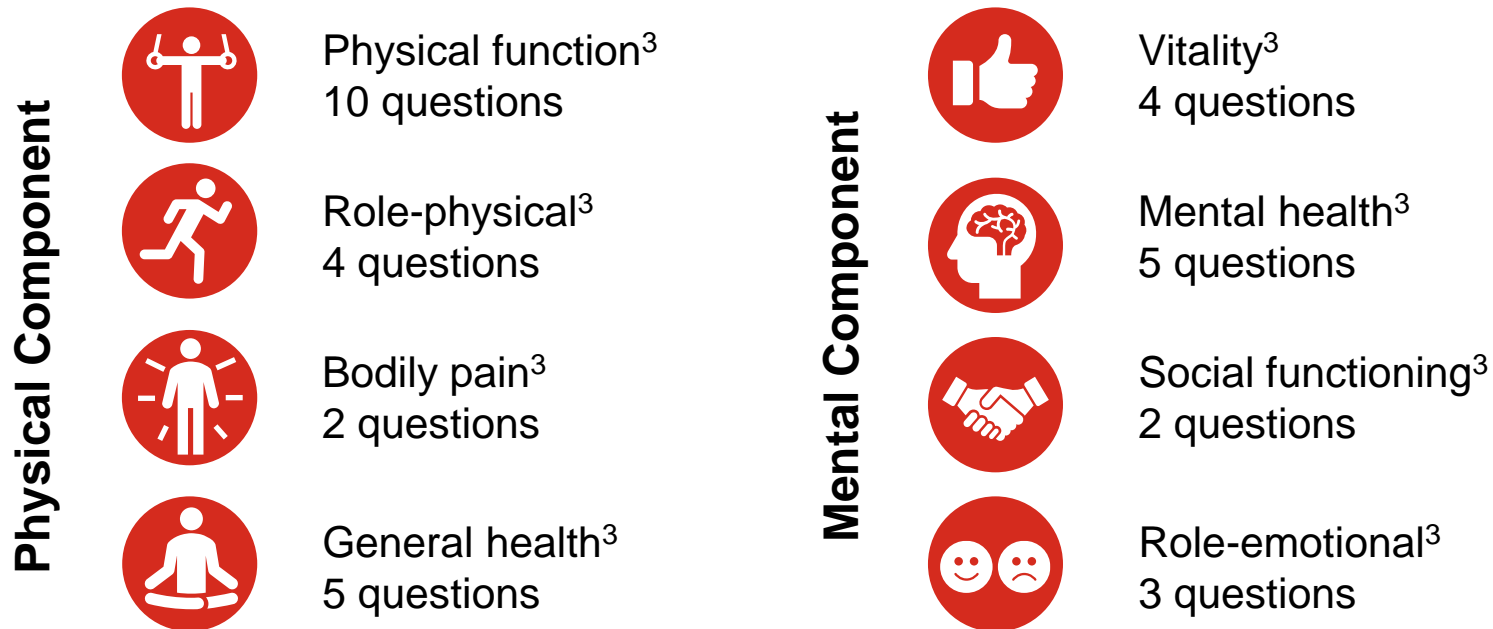
EQ VAS=European Quality Visual Analog Scale.

Oemar M, Janssen B. EQ-5D-5L. https://www.unmc.edu/centric/_documents/EQ-5D-5L.pdf. (Accessed January 29, 2024).

Medical Outcomes Study-Short Form (36 Items) Health Survey (SF-36)

Assessing a Patient


- Patient self-administered questionnaire using a 1-week recall period.^{1,2}
 - Consists of 36 questions (items) in 8 domain scales.
 - 2 summary measures (physical component score and mental component score).
- For each of the 8 domain scales an aggregate percentage score is produced.¹
 - Range from 0 (lowest or worst possible level of functioning) to 100 (highest or best possible level of functioning).



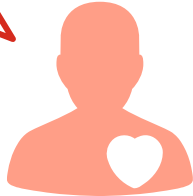
1. Kiltz U, Braun J. *J Rheum Dis.* 2020. 27(1): 22-29. 2. Keller SD, et al. *Health Serv Res.* 1997;32(3):367-384. 3. Ware JE Jr, Sherbourne CD. *Med Care.* 1992;30(6):473-483.

Assessment of SpondyloArthritis International Society Health Index (ASAS HI)

- ASAS HI provides an overall picture of impairments, limitations, and restrictions in activities or social participation.
- 17 items address categories of pain, emotional function, sleep, sexual function, mobility, self-care, community life, and employment.
- The ASAS HI is a patient-reported, composite index that can be used in clinical trials or in daily clinical practice.



Purpose: Assessment of physical functioning, performance of daily activities, and social participation in AS.



For the Patient: How well they are functioning in life.

ASAS Health Index (ASAS HI)

How to Get and Interpret the Results

1. Pain sometimes disrupts my normal activities.¹
 - I agree
 - I do not agree
2. I find it hard to stand for long.
 - I agree
 - I do not agree
3. I have problems running.
 - I agree
 - I do not agree
4. I have problems using the toilet facilities.
 - I agree
 - I do not agree
5. I am often exhausted.
 - I agree
 - I do not agree
6. I am less motivated to do anything that requires physical effort.
 - I agree
 - I do not agree
7. I have lost interest in sex.
 - I agree
 - I do not agree
 - Not applicable; I do not want to answer
8. I have difficulty operating the pedals in my car.
 - I agree
 - I do not agree
 - Not applicable; I cannot/do not drive
9. I am finding it hard to make contact with people.
 - I agree
 - I do not agree
10. I am not able to walk outdoors on flat ground.
 - I agree
 - I do not agree
11. I find it hard to concentrate.
 - I agree
 - I do not agree
12. I am restricted in traveling because of my mobility.
 - I agree
 - I do not agree
13. I often get frustrated.
 - I agree
 - I do not agree
14. I find it difficult to wash my hair.
 - I agree
 - I do not agree
15. I have experienced financial changes because of my rheumatic disease.
 - I agree
 - I do not agree
16. I sleep badly at night.
 - I agree
 - I do not agree
17. I cannot overcome my difficulties.
 - I agree
 - I do not agree

- Each item consists of one question.¹⁻³
- Patient responds with either “I agree” (score of 1) or “I do not agree” (score of 0).¹⁻³
- A score of “1” is given where the item is affirmed, indicating adverse health.¹⁻³
- All item scores are summed to give a total score or index ranging from 0 (good health) to 17 (poor health).¹⁻³
- A score of ≤ 5 has been proposed to define good health.¹⁻³
- An improvement of 3 or more points is defined as a clinically important improvement.³

Work Productivity and Activity Impairment-Ankylosing Spondylitis (WPAI-SpA)



- **Quantitative** assessment of **work and activity impairment** due to general health or a specific health problem.
- The WPAI measures 4 main variables:
 - Absenteeism (work time missed)
 - Presenteeism (impairment at work)
 - Work productivity loss
 - Activity impairment
- WPAI-SpA has been modified to assess work productivity in patients with AS.

- 6 questions, most of which ask respondents about their experiences in the **previous 7 days**.
- Higher scores indicate greater impairment and less productivity.
 1. Current employment (YES/NO)
 2. Hours of work missed due to AS
 3. Hours of work missed for other reasons
 4. Total hours worked
 5. How much has AS affected productivity while working? (scale of 0-10)
 6. How much has AS affected other regular activities? (scale of 0-10)

Imaging Modalities in AS/r-axSpA and nr-axSpA

AS=Ankylosing Spondylitis; nr-axSpA=Non-radiographic Axial Spondyloarthritis; r-axSpA=Radiographic Axial Spondyloarthritis.

The Role of Imaging in axSpA Diagnosis

Initial presentation and progression of axSpA is heterogeneous and may not be visible by radiograph¹

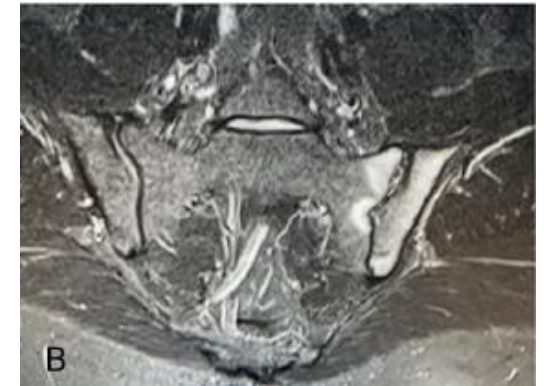
Some HCPs require an MRI where the X-ray findings are not clear.¹

- nr-axSpA presents a particular challenge to detection and diagnosis.¹
- In a subset of patients, nr-axSpA develops into r-axSpA over time, but this is not always the case.¹
- MRI may detect active inflammatory changes (osteitis or bone marrow edema) using STIR^{2,3} and structural changes (subchondral fat and erosions) using T1.^{2,4}

Imaging findings in a female patient with nr-axSpA⁵



Pelvis radiograph



MRI of the SIJ

Imaging lacks enough sensitivity and specificity to be the sole basis for diagnosis, but can play an important diagnostic role.^{2,3}

axSpA=Axial Spondyloarthritis; HCP=Healthcare Professional; nr-axSpA=Non-radiographic Axial Spondyloarthritis; MRI=Magnetic Resonance Imaging; r-axSpA=Radiographic Axial Spondyloarthritis; SIJ=Sacroiliac Joint; STIR=Short tau Inversion Recovery.

1. Michelena X, et al. *Rheumatology (Oxford)*. 2020;59 (Suppl. 4):iv18-iv24. 2. Poddubnyy D. *Rheumatology (Oxford)*. 2020;59 (Suppl. 4):iv6-iv17. 3. Marzo-Ortega H. *Rheumatology (Oxford)*. 2020;59 (Suppl. 4):iv1-iv5.

4. Lukas C, et al. *RMD Open*. 2018;4(1):e000586. 5. Navarro-Compán V, et al. *Ann Rheum Dis*. 2021;80(12):1511-1521.

Ordering Guide

| Modality ¹⁻³ | | Structural/Chronic Changes ¹⁻³ | Inflammatory/Acute Changes ¹⁻³ | Usage Considerations ¹⁻³ |
|---------------------------------|---------------------------------|---|---|---|
| Conventional Radiography | | Some diagnostic value | Not used for assessment | <ul style="list-style-type: none"> Usually appropriate modality for initial imaging. Valuable for monitoring. |
| CT (low dose) | | Valuable for diagnosis | Not used for assessment | Consider if radiographs are negative <i>or</i> for sensitive evaluation of structural changes. |
| MRI^a | T1 | Valuable for diagnosis | Limited diagnostic value | <ul style="list-style-type: none"> May be appropriate for initial imaging.^b Recommended if radiographs are negative. Valuable for monitoring. |
| | STIR/T2-FS | Some diagnostic value | Valuable for diagnosis | |
| | 3D acquisition or 3D UTE | Valuable for diagnosis | Not used for assessment | |

^aA complete MRI protocol should include T1-weighted images and STIR or T2-weighted FS images.¹ ^bIn cases of younger patients or those with a shorter symptom duration¹; may not be used in certain populations (ie, pregnancy).⁴
 3D=3-Dimensional; CT=Computed Tomography; FS=Fat Saturated; MRI=Magnetic Resonance Imaging; SpA=Spondyloarthritis; STIR=Short Tau Inversion Recovery Sequence; 3D UTE=3-dimensional Ultrashort Echo Time.
 1. Khmelinskii N, et al. *Front Med (Lausanne)*. 2018;5:106; 2. Kucybala I, et al. *Rheumatol Int*. 2018;38(10):1753-1762. 3. Schwaiger BJ, et al. *Eur Radiol*. 2021;31(7):4680-4689.
 4. Ghadimi M, Sapra A. In: *StatPearls [Internet]*. 2023.

Grading of Radiographic Sacroiliitis: The New York Grading Scale

| Grade | Description ¹ |
|-------|---|
| 0 | Normal |
| 1 | Suspicious changes |
| 2 | Minimal abnormality – small localized areas with erosion or sclerosis, without alteration in the joint width |
| 3 | Unequivocal abnormality – moderate or advanced sacroiliitis with 1 or more of: <ul style="list-style-type: none">• Erosions• Evidence of sclerosis• Widening, narrowing, or partial ankylosis |
| 4 | Severe abnormality – total ankylosis |

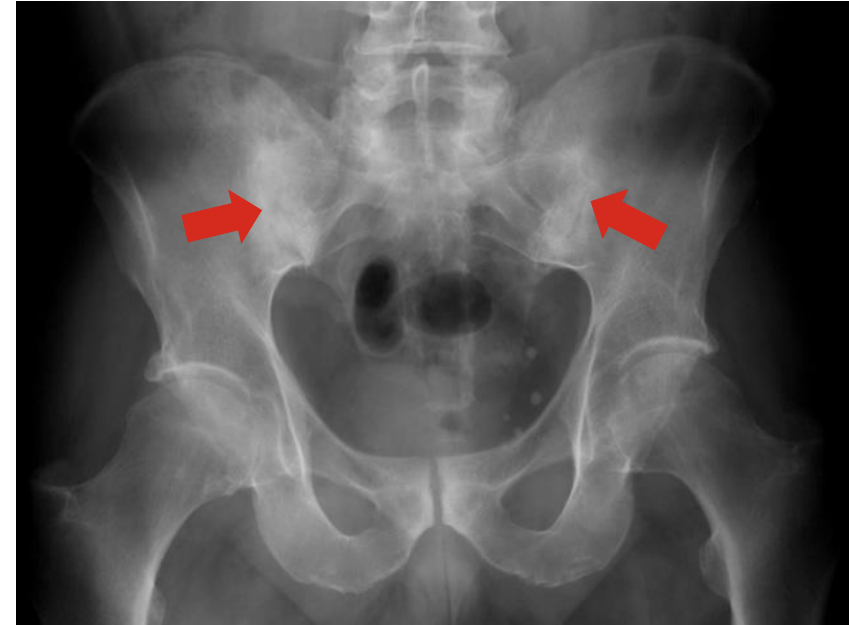
The 1984 modified New York criteria is the current standard grading scale for radiographic sacroiliitis.^{1,2}

1. Sieper J, et al. *Ann Rheum Dis*. 2009; 68:ii1-ii44. 2. Shenkman Y, et al. *Medical Image Analysis*. 2019;57:165-175.

Radiographs of Sacroiliac Joint and Spine to Confirm Sacroiliitis



No definite radiographic sacroiliitis as defined by the mNY criteria (grade 0)¹



Definite radiographic sacroiliitis as defined by the mNY criteria (grade 3 bilaterally)²

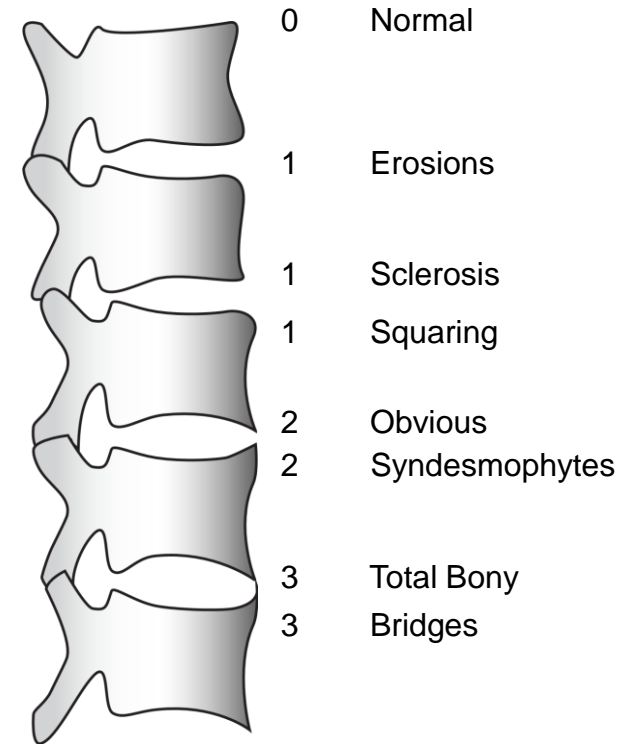
Radiography is the main diagnostic method used to confirm presence of sacroiliitis and to follow characteristic spinal changes in AS.²

AS=Ankylosing Spondylitis; mNY=modified New York.

1. Sieper J, Poddubnyy D. *Lancet*. 2017;390(10089):73-84. 2. Sieper J, et al. *Ann Rheum Dis*. 2002;61(Suppl 3):iii8-iii18.

Spine Radiograph: modified Stoke AS Spine Score (mSASSS)

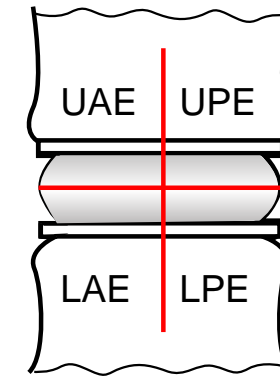
- The anterior parts of the cervical and lumbar spine at a lateral view are scored for the presence of:
 - Squaring and/or erosion and/or sclerosis (1 point/site).
 - Non-bridging syndesmophytes (2 points/ site).
 - Bridging syndesmophytes (3 points/site or 6 points/vertebral unit).
- The total score ranges from 0 to 72.



MRI for the Assessment of Spinal Inflammation

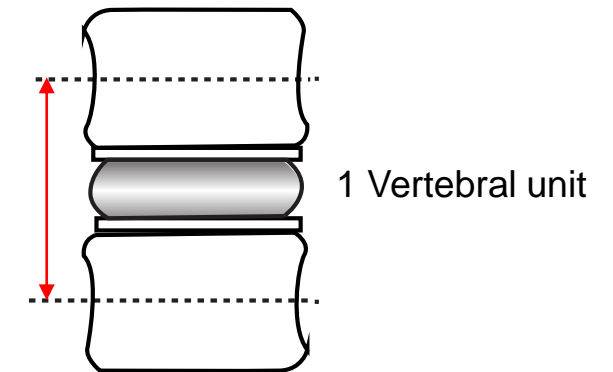
MRI-SPARCC¹

- Uses **T2-weighted** STIR MRI spine sequences
- Six discovertebral levels selected for scoring after entire spine scanned.
- Abnormal increased signal represents increased concentration of “free water” (BME).



ASspiMRI-Berlin²

- Use of **STIR technique (symmetry assessment of SIJ) and/or T1-weighted (structural damage)** imaging after injection of gadolinium contrast agent.
- Score is based on grading of both disease activity and chronicity on a scale of 0-6 for every vertebral unit.



ASspiMRI=Ankylosing Spine Magnetic Resonance Imaging; BME=Bone Marrow Edema; LAE=Lower Anterior Endplate; LPE=Lower Posterior Endplate; MRI=Magnetic Resonance Imaging; SIJ=Sacroiliac Joint; MRI-SPARCC=Magnetic Resonance Imaging-Spondyloarthritis Research Consortium of Canada; STIR=Short tau Inversion Recovery; UAE=Upper Anterior Endplate; UPE=Upper Posterior Endplate.

1. Maksymowych WP, et al. *Arthritis Rheum.* 2005;53(4):502-509. 2. Braun J, et al. *Arthritis Rheum.* 2003;48(4):1126-1136.

Summary



- In axSpA, as in other medical conditions, it is important to periodically assess and monitor the disease and treatment.¹
- Structural changes may take years to occur and there is no agreement among the readers with the progression observed in the X-ray intervals.²
- There is not one "gold standard" assessment tool for axSpA.¹
- Many assessments are performed as part of the protocol in clinical trials.³
- Assessment tools include disease activity, response to therapeutic interventions, functionality, mobility, and HRQoL.^{3,4}
- Imaging modalities are used to assess for objective inflammatory changes as well as for evaluation of structural progression.^{3,4}

axSpA=Axial Spondyloarthritis; HRQoL=Health-related quality of life.

1. Braun J, et al. *Clin Exp Rheumatol*. 2014;32(5 Suppl 85):S96-104. 2. Micheroli R, et al. *RMD Open*. 2022;8(2):e002551. 3. Sieper J, et al. *Ann Rheum Dis*. 2009;68;ii1-ii44.

4. Landewé R, van Tubergen A. *Curr Rheumatol Rep*. 2015;17(7):47

US Medical Education

For additional resources on axSpA, scan the code



SCAN HERE

