

Response to Public Comments

From the Core Leadership Team for the ACR/SPARTAN/SAA Axial SpA Guideline Development Project July 2013

We thank members of the rheumatology community for their interest in the proposed treatment recommendations for patients with axial spondyloarthritis (axSpA) including ankylosing spondylitis (AS). In general, the public comments could be categorized into four main themes: the scope of the project, specific clinical questions, methodological issues, and relationship to existing guidelines.

Many respondents, including guideline experts external to the field of rheumatology, voiced the opinion that the scope was too broad and overly ambitious. We had intended for these guidelines to be a comprehensive assessment of the major clinical questions faced in the treatment of patients with AS/axSpA, but we also recognize the importance of depth and timeliness. We have, therefore, reduced the scope of the current effort, and now will focus on 56 clinical questions (see attached). Questions were eliminated from each section of the project by consensus of the steering committee. In addition, we elected to exclude the questions related to axSpA in children and adolescents, in recognition of the added expertise needed to evaluate the literature regarding these patients and the unsettled nature of the classification of these conditions. We hope that all the questions we regretfully needed to drop will be addressed in future updates of these guidelines. We encourage respondents to actively participate in these future efforts, especially if they have specific expertise that is requested at that time.

Also with regard to the scope, we will seek to add more physical therapy/rehabilitation expertise to the panel, and we intend to explicitly identify knowledge gaps that may guide future research. Finally, although cost of care may be considered by the panel as they weigh the evidence and formulate recommendations, it will not be their charge to make formal cost-related recommendations because cost assumptions exhibit tremendous variations across states/regions, payers, and time, and are most often best addressed separately from the clinical guidelines themselves.

Many respondents suggested additional topics for research questions. Although many of these questions are important, we are limited in our ability to expand the current scope. We will retain these suggestions so they can be considered in future updates of these guidelines.

Several respondents provided advice on methodological issues. We will carefully assess for publication bias, and we will aim *not* to exclude articles on the basis of language, pending available resources to support this additional effort. We will not include recommendations for medications that are not approved by the U.S. Food and Drug Administration, per ACR policy (e.g., etoricoxib, apremilast, etc.). In addition, given that there are separate literatures for AS and axSpA, we will retain these as separate foci of the PICO questions. Regarding the question about literature team participation in the voting panel meeting, the literature review leader and perhaps 1 other literature expert will attend the meeting, where their role will be to work with the project librarian to provide support to panelists who request references or study details during their deliberations. The selection of the additional expert will be by consensus of the Core Leadership Team, based on the person's expertise and effort during the literature review phase of the project.

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Lastly, there was a question of how the proposed guidelines may relate to existing guidelines for the management of AS, including the ASAS/EULAR guidelines. Given the different processes involved between methods used here (including the GRADE approach) and those of previous guidelines, the differences in timing of the literature reviews, and the different geographical target audiences, we do not believe our efforts will be redundant. Indeed, analogous to taking a patient's history in a new clinical encounter, it is advantageous to ask questions independently, rather than relying solely on the previous physician's history. If the recommendations agree, we may have added confidence in the results. If the recommendations differ, we will need to investigate the reasons for the differences.

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Pharmacological Therapy

1. In adults with active AS, are NSAIDs more effective than no treatment with NSAIDs in improving outcomes?
2. In adults with active AS, are certain NSAIDs more effective than other NSAIDs in improving outcomes?
3. In adults with active or stable AS, is continuous treatment with NSAIDs more effective than on-demand treatment with NSAIDs in improving outcomes?
4. In adults with AS and isolated active sacroiliitis despite treatment with NSAIDs, is treatment with local corticosteroids more effective than no treatment with local corticosteroids in improving outcomes?
5. In adults with AS with stable axial disease and active peripheral arthritis despite treatment with NSAIDs, are locally administered parenteral corticosteroids more effective than no treatment with local corticosteroids in improving outcomes?
6. In adults with AS with stable axial disease and active enthesitis despite treatment with NSAIDs, are locally administered parenteral corticosteroids more effective than no treatment with local corticosteroids in improving outcomes?
7. In adults with active AS despite treatment with NSAIDs, are DMARDs more effective than no treatment with DMARDs in improving outcomes?
8. In adults with active AS despite treatment with NSAIDs, are TNFi more effective than no treatment with TNFi in improving outcomes?
9. In adults with active AS, are certain TNFi more effective than other TNFi in improving outcomes?
10. In adults with active AS despite treatment with a first TNFi agent, is switching to a different TNFi more effective than adding a DMARD in improving outcomes?
11. In adults with active AS despite treatment with a TNFi agent, is switching to a different TNFi more effective than switching to non-TNFi biologics or than changing to a new DMARD in improving outcomes?
12. In adults with active AS despite treatment with NSAIDs and who have contraindications to TNFi, is treatment with a non-TNFi biologic more effective than treatment with DMARDs in improving outcomes?
13. In adults with stable AS on treatment with TNFi and NSAIDs, is continuing both medications more effective in improving outcomes than continuing treatment with TNFi alone?
14. In adults with stable AS on treatment with TNFi and DMARD, is continuing both medications more effective in improving outcomes than continuing either TNFi or DMARD alone?
15. In adults with active AS, are systemic corticosteroids more effective than no treatment with systemic corticosteroids in improving outcomes?

Rehabilitation/Physical Therapy

16. In adults with active AS, is any form of PT more effective than no PT in improving health status and functional status?

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17. In adults with active AS, are active PT interventions (supervised exercise) more effective than passive PT interventions (massage, ultrasound, heat) in improving health status and functional status?
18. In adults with active AS, are aquatic PT interventions more effective than land-based PT interventions in improving health status and functional status?
19. In adults with stable AS, is any form of PT more effective than no PT in improving health status and functional status?
20. In adults with active or stable AS, are unsupervised back exercises more effective than no exercise in improving health status and functional status?
21. In adults with active or stable AS, is spinal manipulation (chiropractic or osteopathic) more effective than no spinal manipulation in improving health status and functional status?

Surgical Treatment

22. In adults with AS and hip arthritis, is total hip arthroplasty more effective than no surgery in improving outcomes?
23. In adults with AS and severe kyphosis, is spinal osteotomy more effective than no surgery in improving outcomes?

Special Populations

Iritis

24. In adults with AS, is treatment of acute episodes of iritis by an ophthalmologist more effective in decreasing the severity, duration, or complications of episodes compared to no ophthalmologist care?
25. In adults with AS, is prescription of topical corticosteroids for prompt at-home use in the event of eye symptoms effective in decreasing the severity or duration of iritis episodes compared to no at-home use?
26. In adults with AS, are TNFi monoclonal antibodies more effective in decreasing the occurrence or rate of recurrence of episodes of iritis than etanercept?
27. In adults with AS who develop iritis while treated with a TNFi, is switching the TNFi more effective in decreasing recurrences of iritis than continuing the same TNFi?

Inflammatory Bowel Disease

28. In adults with AS and inflammatory bowel disease, are certain NSAIDs more likely to worsen IBD symptoms than other NSAIDs?
29. In adults with AS and inflammatory bowel disease, are certain TNFi more effective in improving outcomes than other TNFi?

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Non-radiographic SpA

30. In adults with active non-radiographic axial SpA, is treatment with NSAIDs more effective than no treatment with NSAIDs in improving outcomes?
31. In adults with active non-radiographic axial SpA, are certain NSAIDs more effective than other NSAIDs in improving outcomes?
32. In adults with active or stable non-radiographic axial SpA, is continuous treatment with NSAIDs more effective than on-demand NSAID treatment in improving outcomes?
33. In adults with non-radiographic axial SpA and isolated active sacroiliitis despite treatment with NSAIDs, is treatment with local corticosteroids more effective than no treatment with local corticosteroids in improving outcomes?
34. In adults with non-radiographic axial SpA and active peripheral arthritis despite treatment with NSAIDs, are locally administered parenteral corticosteroids more effective than no treatment with local corticosteroids in improving outcomes?
35. In adults with non-radiographic axial SpA and active enthesitis despite treatment with NSAIDs, are locally administered parenteral corticosteroids more effective than no treatment with local corticosteroids in improving outcomes?
36. In adults with active non-radiographic axial SpA despite treatment with NSAIDs, are DMARDs more effective than no treatment with DMARDs in improving outcomes?
37. In adults with active non-radiographic axial SpA despite treatment with NSAIDs, are TNFi more effective than no treatment with TNFi in improving outcomes?
38. In adults with active non-radiographic axial SpA, are certain TNFi more effective than other TNFi in improving outcomes?
39. In adults with active non-radiographic axial SpA despite treatment with the first TNFi agent used, is switching to a different TNFi more effective than adding a DMARD in improving outcomes?
40. In adults with active non-radiographic axial SpA despite treatment with NSAIDs and who have contraindications to TNFi, is treatment with a non-TNFi biologic more effective than treatment with DMARD in improving outcomes?
41. In adults with stable non-radiographic axial SpA on treatment with TNFi and NSAIDs, is continuation of both medications more effective in improving outcomes than continuing treatment with TNFi alone?
42. In adults with stable non-radiographic axial SpA on treatment with TNFi and DMARD, is continuation of both medications more effective in improving outcomes than withdrawing one treatment and continuing either TNFi or DMARD alone?
43. In adults with active non-radiographic axial SpA, are systemic corticosteroids more effective than no treatment with systemic corticosteroids in improving outcomes?
44. In adults with active non-radiographic axial SpA, is any form of PT more effective than no PT in improving health status and functional status?

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45. In adults with active non-radiographic axial SpA, are active PT interventions (supervised exercise) more effective than passive PT interventions (massage, ultrasound, heat) in improving health status and functional status?
46. In adults with active non-radiographic axial SpA, are aquatic PT interventions more effective than land-based PT interventions in improving health status and functional status?

Preventive Care

47. In adults with AS, is group or individual self-management education more effective than no formal self-management education in improving outcomes?
48. In adults with AS, is screening for osteopenia/osteoporosis with DEXA scanning yearly, every other year, every five years, more effective than screening after insufficiency fractures or no screening in improving outcomes?
49. In adults with AS and syndesmophytes or spinal fusion, is screening for osteopenia/osteoporosis with DEXA scanning of the hip or other non-spine sites more effective than DEXA scanning of the spine in improving outcomes?
50. In adults with AS, is fall evaluation and counseling more effective than no evaluation and counseling in improving outcomes?
51. In adults with AS, is screening for cardiac conduction defects with electrocardiogram at diagnosis, yearly, every other year, or every five years more effective than no screening in improving outcomes?
52. In adults with AS, is screening for valvular heart disease with echocardiogram at diagnosis, yearly, every other year, or every five years more effective than no screening in improving outcomes?

Disease Activity Monitoring

53. In adults with active or stable AS, is regular interval use and monitoring of the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) or AS Disease Activity Score (ASDAS) more effective than usual care without monitoring of the BASDAI or ASDAS in improving outcomes?
54. In adults with active or stable non-radiographic axial SpA, is regular interval use and monitoring of the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) or AS Disease Activity Score (ASDAS) more effective than usual care without monitoring of the BASDAI or ASDAS in improving outcomes?
55. In adults with active or stable AS, is regular interval use and monitoring of C-reactive protein (CRP) levels or erythrocyte sedimentation rate (ESR) more effective than usual care without CRP or ESR monitoring in improving outcomes?
56. In adults with active or stable non-radiographic axial SpA, is regular interval use and monitoring of C-reactive protein (CRP) levels or erythrocyte sedimentation rate (ESR) more effective than usual care without CRP or ESR monitoring in improving outcomes?