2018 ACR/SAA/SPARTAN Updated Recommendations for the Management of Axial Spondyloarthritis

Project Plan – November 2017

PARTICIPANTS

Core Oversight Team
Michael Ward, MD, MPH *(Principal Investigator)*
Liron Caplan, MD, PhD *(Literature Review Leader)*
Atul Deodhar, MD, MRCP *(Content Expert)*

Literature Review Team
Walter Maksymowych, MD
Jeff Oristaglio
Amit Aakash Shah, MD, MPH
Nancy Sullivan
Marat Turgunbaev, MD, MPH

ACR Staff
Robin Lane
Amy S. Miller
Regina Parker

Voting Panel
Ann Biehl, MS, PharmD, BCPS
David Borenstein, MD
Maureen Dubreuil, MD
Meika Fang, MD
Lianne Gensler, MD
Nigel Haroon, MBBS, MD, DM
Muhammad Khan, MD, FACP, MACP
Grant Louie, MD, MHS
Vikas Majithia, MD, MPH
Bernard Ng, MD
Runsheng Wang, MD, MHS
David Yu, MD
TBD *(Patient Representative)*
TBD *(Patient Representative)*

ORGANIZATIONAL LEADERSHIP AND SUPPORT

This updated guideline is being developed as a collaborative project of the American College of Rheumatology (ACR), the Spondylitis Association of America (SAA) and the Spondyloarthritis Research and Treatment Network (SPARTAN). The ACR and SAA are funding the project.

NOTICE OF INTENT

This announcement serves to notify ACR members, patients, and the larger rheumatology community of our plans to update and expand the 2015 ACR/SAA/SPARTAN Recommendations for the Treatment of Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis (1). While we welcome comments on this plan, the rapid timeline of this project will not permit us to include modifications to this proposal. However, we anticipate that recommendations from the community will be included in future updates of these recommendations.

BACKGROUND

Axial spondyloarthritis (axial SpA) is a form of chronic inflammatory arthritis characterized by sacroiliitis, extra-articular manifestations, and spinal and peripheral enthesitis; when these progress to sacroiliac joint and spinal fusion the condition is known as ankylosing spondylitis (AS) (2). Symptoms commonly include back and hip pain, peripheral joint pain, and fatigue, and are variable in severity. Spinal fusion develops gradually and may lead to reduced spine and neck flexibility.

The hallmarks of AS are symmetric sacroiliitis, more extensive spinal fusion, and a stronger association with HLA-B27 than in other types of spondyloarthritis (SpA) (3). The sacroiliac and spinal features are

emphasized in the modified New York criteria for the classification of AS (4). However, a limitation of these criteria is that these features may take years to develop, thereby excluding patients early in the course of SpA who may not yet have developed radiographically evident changes. Classification criteria that would apply to both early and later stage patients have been proposed by the Assessment of Spondyloarthritis International Society, included under the umbrella term axial SpA (5). These updated recommendations will be focused on patients with axial SpA (meeting the ASAS axial SpA criteria), including AS (meeting the modified New York criteria).

The goals of treatment of axial SpA are to reduce symptoms, improve and maintain spinal flexibility and normal posture, reduce functional limitations, and decrease complications of the disease. The mainstays of treatment have been nonsteroidal anti-inflammatory medications, exercise and physical therapy, and tumor necrosis factor-alpha inhibitors. Since the publication of the 2015 treatment recommendations, additional medications have become available, prompting a need to reevaluate previous recommendation and incorporate new medications into the recommendations. Consequently, this will be a selective update largely focused on pharmacological treatments, rather than a comprehensive update of all previous recommendations. However, we will also address some topics not included in the previous recommendations.

OBJECTIVES

The objective of this project is to develop updated recommendations for the treatment of patients with axial SpA, including AS. Specifically, we aim to:

1. Develop updated recommendations for the use of nonsteroidal anti-inflammatory medications, oral small molecules, and biologics (including biosimilars).
2. Develop recommendations for the role of magnetic resonance imaging and radiography in longitudinal patient management.
3. Develop recommendations for the role of a treat-to-target strategy in the care of patients.

METHODS

Identification of Studies

Literature search strategies, based on PICO questions (Population/patients, Intervention, Comparator, and Outcomes; *see Appendix A*) will be developed by a research librarian, with input from the Core Team, including the principal investigator and systematic literature review leader. The search strategies will be peer reviewed by another medical librarian using Peer Review of Electronic Search Strategies (PRESS) (6). Searches will be performed in OVID Medline (1946 +), Embase (1974 +), the Cochrane Library, and PubMed (mid-1960s +).

The search strategies will be developed using the controlled vocabulary or thesauri language for each database: Medical Subject Headings (MeSH) for OVID Medline, PubMed and Cochrane Library; and Emtree terms for Embase. Text words will also be used in OVID Medline, PubMed, and Embase, and keyword/title/abstract words in the Cochrane Library.

Search Limits

Only English language articles were retrieved.

Grey Literature

The websites of appropriate agencies, such as the Agency for Healthcare Research and Quality (AHRQ), will be searched for peer-reviewed reports not indexed by electronic databases.

Literature Search Update

Literature searches will be updated just before the voting panel meeting to ensure completeness.

Inclusion/Exclusion Criteria

See PICO questions (*Appendix A*), which outline the defined patient population, interventions, comparators and outcomes.

Management of Studies and Data

References and abstracts will be imported into bibliographic management software (Reference Manager) (7), duplicates removed, and exported to Distiller SR, a web-based systematic review manager (8). Screening and data abstraction forms will occur in Distiller SR. Search results will be divided among reviewers, and two reviewers are screening each title/abstract, with disagreements at the title/abstract screening stage defaulting to inclusion for full manuscript review. Following the same dual review process, disagreements at the full manuscript screening stage will be discussed and adjudicated by the literature review leadership, if necessary.

Phases

1. A search for randomized controlled trials and observational studies about interventions aimed at the pharmacologic and non-pharmacologic management of axial SpA will be performed to determine existing studies covering outcomes of interest. Subsequently, identified studies will be assessed using the RevMan (9) and GRADE Pro tools (10).
2. Chosen studies will be assessed for risk of bias using modified versions of the Cochrane Risk of Bias tool (11) and the Newcastle-Ottawa Scale (12).
3. Additionally, recently published systematic reviews covering outcomes of interest will also be sought and used for reference cross-checking.

GRADE Methodology

GRADE methodology (13) will be used in this project to grade available evidence and facilitate development of recommendations. The certainty in the evidence (also known as ‘quality’ of evidence) will be graded as high, moderate, low or very low. The strength of recommendations will be graded as strong or conditional. The strength of recommendations will not depend solely on the certainty in the

evidence, but also on patient preferences and values, and the weight between benefits and harms. A series of articles that describe the GRADE methodology can be found on the GRADE working group's website: www.gradeworkinggroup.org.

Analysis and Synthesis

The literature review team will analyze and synthesize data from included studies that address the PICO questions. An evidence profile, including a GRADE Summary of Findings table, will be prepared for each PICO question using Review Manager (RevMan) (7) and GRADEprofiler (GRADEpro) software (10). The Summary of Findings table contains the benefits and harms for each outcome across studies, the assumed and corresponding risk for comparators and interventions (95% CI), the absolute risk and relative effect (95% CI), the number of participants/number of studies, and the certainty in the evidence for each critical and important outcome (i.e., high, moderate, low or very low).

The evidence profile documents the overall certainty in the evidence for each critical and important outcome across studies and summarizes the rationale of the GRADE criteria for downgrading (risk of bias, inconsistency, indirectness, imprecision and publication bias), or upgrading the certainty in a body of evidence (large magnitude of effect, dose-response gradient, and all plausible confounding that would reduce a demonstrated effect).

Development of Recommendation Statements

PICO questions will be revised into drafted recommendation statements. Using the GRADE Evidence Profiles and Summaries of Findings tables, the voting panel, consisting of 11 rheumatologists, one pharmacist and two patient representatives, will consider the drafted recommendation statements in two stages. The first assessment will be done individually, and the results will be anonymous; this vote will only be used to determine where consensus might or might not already exist and develop the voting panel meeting agenda. At the face-to-face voting panel meeting, chaired by the principal investigator, the panelists will discuss the evidence in the context of their clinical experience and expertise, and considering patient values and preferences, to arrive at consensus on the final recommendations. The voting panel meeting discussions will be supported by the literature review leader and selected members of the literature review team, who will attend the meeting to provide details about the evidence, as requested.

PLANNED APPENDICES (AT MINIMUM)

A. Final literature search strategies
B. GRADE evidence profiles and summary of findings tables for each PICO question

AUTHORSHIP

Authorship of the guideline will include: principal investigator, Dr. Michael Ward, as the lead author; Dr. Liron Caplan, literature review leader; and Dr. Atul Deodhar, content expert. Members of the literature review team and voting panel will also be authors. The PI will determine final authorship, dependent on

the efforts made by individuals throughout the guideline development process, using international authorship standards as guidance.

DISCLOSURES/CONFLICTS OF INTEREST

The ACR's disclosure and COI policies for guideline development will be followed for this project. These can be found in the ACR Guideline Manual on this page of the ACR web site, under Policies & Procedures. *See Appendix B for participant disclosures.*

REFERENCES

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APPENDIX A – PICO Questions *(NOTE: The questions below are not numbered sequentially because this is an update of a previous guideline, and the numbers here correspond to the numbers of the same or similar questions from the previous guideline. New questions (#58-70) were given numbers that began at the end of the previous list.)*

PHARMACOLOGIC THERAPY:

PICO 1. In adults with active or stable AS, is continuous treatment with NSAIDs more effective than on-demand treatment with NSAIDs in improving outcomes? [no change in PICO, update lit review]

PICO 5. In adults with active AS, are certain TNFi more effective than other TNFi in improving outcomes? [update lit review and add TNF biosimilar data]

PICO 6. In adults with active AS despite treatment with NSAIDs, are TNFi more effective than no treatment with TNFi in improving outcomes? [update lit review and add TNF biosimilar data]

PICO 7. In adults with active AS despite treatment with NSAIDs, is treatment with an oral small molecule more effective than no treatment with an oral small molecule in improving outcomes? [update lit review and add tofacitinib data]

PICO 8. 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 an oral small molecule in improving outcomes? [update lit review and add tofacitinib and secukinumab data]

PICO 9. In adults with active AS despite treatment with the first TNFi agent used, is switching to a different TNFi more effective than adding methotrexate or sulfasalazine in improving outcomes? [update lit review]

PICO 10. In adults with active AS despite treatment with the first TNFi agent used, is switching to a different TNFi more effective than switching to a non-TNFi biologic in improving outcomes? [update lit review and add TNF biosimilar and secukinumab data]

PICO 11. In adults with stable AS on treatment with TNFi and NSAIDs, is continuing both medications more effective than continuing treatment with TNFi alone in improving outcomes? [no change in PICO, update lit review]

PICO 12. In adults with stable AS on treatment with TNFi and an oral small molecule, is continuing both medications more effective than withdrawing one treatment and continuing either TNFi or the oral small molecule alone in improving outcomes? [no change in PICO, update lit review]

PICO 33. In adults with active or stable non-radiographic axial SpA, is continuous treatment with NSAIDs more effective than on-demand treatment with NSAIDs in improving outcomes? [no change in PICO, update lit review]

PICO 37. In adults with active non-radiographic axial SpA, are certain TNFi more effective than other TNFi in improving outcomes? [update lit review and add TNF biosimilar data]

PICO 38. In adults with active non-radiographic axial SpA despite treatment with NSAIDs, are TNFi more effective than no treatment with TNFi in improving outcomes? [update lit review and add TNF biosimilar data]

PICO 39. In adults with active non-radiographic axial SpA despite treatment with NSAIDs, is treatment with an oral small molecule more effective than no treatment with an oral small molecule in improving outcomes? [update lit review and add tofacitinib data]

PICO 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 an oral small molecule in improving outcomes? [update lit review and add tofacitinib and secukinumab data]

PICO 41. 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 methotrexate or sulfasalazine in improving outcomes? [update lit review]

PICO 42. 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 switching to a non-TNFi biologic in improving outcomes? [update lit review and add TNF biosimilar and secukinumab data]

PICO 43. In adults with stable non-radiographic axial SpA on treatment with TNFi and NSAIDs, is continuing both medications more effective than continuing treatment with TNFi alone in improving outcomes? [no change in PICO, update lit review]

PICO 44. In adults with stable non-radiographic axial SpA on treatment with TNFi and an oral small molecule, is continuing both medications more effective than withdrawing one treatment and continuing either TNFi or the oral small molecule alone in improving outcomes? [no change in PICO, update lit review]

TREATMENT OF PATIENTS WITH SPECIFIC IMPAIRMENTS OR COMORBID CONDITIONS:

PICO 32. In adults with AS and inflammatory bowel disease, is treatment with certain biologics more effective than others in improving outcomes? [update lit review, add secukinumab data]

PICO 29. In adults with AS and recurrent attacks of uveitis, is treatment with certain biologics more effective than others in improving outcomes? [update lit review, add secukinumab data]

[NOTE: all questions below are NEW QUESTIONS, not similar to or the same as the PICOs in the previous guideline]

PHARMACOLOGIC THERAPY:

PICO 58. In adults with active AS despite treatment with NSAIDs, is treatment with secukinumab more effective than no treatment with secukinumab in improving outcomes?

PICO 59. In adults with active AS despite treatment with NSAIDs, is treatment with secukinumab more effective than treatment with TNFi in improving outcomes?

PICO 60. In adults with active AS despite treatment with NSAIDs, is treatment with tofacitinib more effective than treatment with TNFi in improving outcomes?

PICO 61. In adults with active AS despite treatment with NSAIDs, is treatment with tofacitinib more effective than treatment with secukinumab in improving outcomes?

PICO 62. In adults with active AS despite treatment with the first TNFi agent used, is switching to a different originator TNFi more effective than switching to TNFi biosimilar in improving outcomes?

PICO 63. In adults with stable AS on an originator TNFi, is continuation of treatment more effective than switching to a biosimilar TNFi in improving outcomes?

PICO 64. In adults with either active or stable AS on treatment with TNFi, is co-treatment with low-dose methotrexate more effective than no co-treatment with low-dose methotrexate in improving outcomes?

PICO 65. In adults with stable AS on treatment with a biologic, is tapering of the biologic dose more effective than no tapering in improving outcomes?

PICO 66. In adults with stable AS on treatment with a biologic, is discontinuation of the biologic more effective than no discontinuation in improving outcomes?

PICO 67. In adults with active AS, is a treat-to-target strategy using a target of ASDAS <1.3 (or <2.1) more effective than a symptom-prompted treatment strategy in improving outcomes?

IMAGING:

PICO 68. In adults with stable AS, is obtaining a spinal or pelvis MRI to confirm inactivity more effective than not obtaining an MRI in improving outcomes?

PICO 69. In adults with AS of unclear activity while on a biologic, is obtaining a spinal or pelvis MRI to assess activity more effective than not obtaining an MRI in improving outcomes?

PICO 70. In adults with active or stable AS on any treatment, is obtaining repeat spine radiographs at a scheduled interval (e.g., every 2 years) more effective than not obtaining scheduled radiographs in improving outcomes?

PHARMACOLOGIC THERAPY:

PICO 71. In adults with active non-radiographic axial SpA despite treatment with NSAIDs, is treatment with secukinumab more effective than no treatment with secukinumab in improving outcomes?

PICO 72. In adults with active non-radiographic axial SpA despite treatment with NSAIDs, is treatment with secukinumab more effective than treatment with TNFi in improving outcomes?

PICO 73. In adults with active non-radiographic axial SpA despite treatment with NSAIDs, is treatment with tofacitinib more effective than treatment with TNFi in improving outcomes?

PICO 74. In adults with active non-radiographic axial SpA despite treatment with NSAIDs, is treatment with tofacitinib more effective than treatment with secukinumab in improving outcomes?

PICO 75. In adults with active non-radiographic axial SpA despite treatment with the first TNFi agent used, is switching to a different originator TNFi more effective than switching to TNFi biosimilar in improving outcomes?

PICO 76. In adults with stable non-radiographic axial SpA on an originator TNFi, is continuation of treatment more effective than switching to a biosimilar TNFi in improving outcomes?

PICO 77. In adults with either active or stable non-radiographic axial SpA on treatment with TNFi, is co-treatment with low-dose methotrexate more effective than no co-treatment with low-dose methotrexate in improving outcomes?

PICO 78. In adults with stable non-radiographic axial SpA on treatment with a biologic, is tapering of the biologic dose more effective than no tapering in improving outcomes?

PICO 79. In adults with stable non-radiographic axial SpA on treatment with a biologic, is discontinuation of the biologic more effective than no discontinuation in improving outcomes?

PICO 80. In adults with active non-radiographic axial SpA, is a treat-to-target strategy using a target of ASDAS <1.3 (or <2.1) more effective than a symptom-prompted treatment strategy in improving outcomes?

IMAGING:

PICO 81. In adults with stable non-radiographic axial SpA, is obtaining a spinal or pelvis MRI to confirm inactivity more effective than not obtaining an MRI in improving outcomes?

PICO 82. In adults with non-radiographic axial SpA of unclear activity while on a biologic, is obtaining a spinal or pelvis MRI to assess activity more effective than not obtaining an MRI in improving outcomes?

PICO 83. In adults with active or stable non-radiographic axial SpA on any treatment, is obtaining repeat spine radiographs at a scheduled interval (e.g., every 2 years) more effective than not obtaining scheduled radiographs in improving outcomes?

APPENDIX B – Participant Disclosures

In order for the College to most effectively further its mission and to otherwise maintain its excellent reputation in the medical community and with the public, it is important that confidence in the College's integrity be maintained. The cornerstone of the ACR's Disclosure Policy is disclosure of actual and potential conflicts so that they can be evaluated by the College in order to avoid undue influence of potential conflicts. The purpose of the ACR's Disclosure Policy is identification of relationships which may pose actual or potential conflicts. These actual or potential conflicts can then be evaluated by the College so that adjustments can be made that will avoid any undue influence. This policy is based on the principle that, in many cases, full disclosure of the actual or potentially conflicting relationship will of itself suffice to protect the integrity of the College and its interests.

Participants	Role	Primary employer	Sources of personal income	Intellectual property	Research grants/contracts	Investments to include medical industry and nonmedical industry	Organizational benefit	Activities with other organizations	Family or other relations
Michael Ward	Core Team/PI	NIH/NIAMS/IRP	N/A	N/A	Patient Centered Outcomes Research Institute; NIH PO1 AR052915	N/A	N/A	BMJ/Amm Rheum Dis; J Rheumatology; Clin Exp Rheumatology	N/A
Liron Caplan	Core Team/Lit Review Lead	Denver Veterans Affairs Medical Center; Univ of Colorado Denver	N/A	N/A	Denver Veterans Affairs Medical Center; VA HSR&D; Fidelity Charitable Gift Fund	N/A	NW Arth & OP Inst.	SPARTAN	N/A
Atul Deodhar	Core Team/Content Expert	Oregon Health & Science University	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Jeff Oristaglio	Lit Review Team	ECRI	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Nancy Sullivan	Lit Review Team	ECRI	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Walter Maksymowych	Lit Review Team	University of Alberta	Abbvie; Janssen; Lilly; Merck; Novartis; Pfizer; UCB	Royalties from University of British Columbia	Pfizer; Abbvie	N/A	Abbvie; Janssen	Canadian Research Education (CaRE) Arthritis	Spouse
Amit Aakash Shah	Lit Review Team	ACR	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Marat Turgunbaev	Lit Review Team	ACR	N/A	N/A	N/A	N/A	N/A	N/A	N/A
David Borentein	Voting Panel	Arthritis & Rheumatism Associates	Pfizer; Novartis	N/A	N/A	Medimergent; Luma Cyte	N/A	N/A	N/A
Maureen Dubreuil	Voting Panel	Boston University Schl of Medicine; VA Boston Healthcare System	N/A	N/A	National Institutes of Health	N/A	N/A	N/A	N/A
Meika A. Fang	Voting Panel	VA Greater Los Angeles Healthcare System	N/A	N/A	Takeda	Mylan	N/A	N/A	N/A
Lianne S. Gensler	Voting Panel	UCSF	Janssen; Novaritis	N/A	Amgen; AbbVie; UCB	N/A	N/A	SPARTAN	N/A
Nigil Haroon	Voting Panel	University Health Network, Toronto; University of Toronto; Krembil Research Institute	Amgen; AbbVie; Jannsen; Merck; Novarits; Pfizer; UCB	N/A	CIHR; Krembil Foundation	N/A	N/A	N/A	N/A
Muhammad Khan	Voting Panel	CASE at MetroHealth Med Center	AbbVie; Novarits; Lily (future)	N/A	N/A	N/A	N/A	ASAS; SPARTAN; GRAPPA	N/A
Vikas Majithia	Voting Panel	University of Mississippi Medical Center; GV(Sonny) Montgomery VA medical Center, Jackson	American College of Physicians; American Board of Internal Medicine	N/A	Glaxo-Smith-Kline; National Institute of Health	N/A	N/A	N/A	N/A
Bernard Ng	Voting Panel	University of Washington	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Runsheng Wang	Voting Panel	Columbia University College of Physicians and Surgeons	N/A	N/A	Rheumatology Research Foundation	N/A	N/A	N/A	N/A
David Tak Yan Yu	Voting Panel	University of California Los Angeles School of Medicine	UpToDate	N/A	N/A	Amgen; Pfizer	N/A	N/A	N/A
Grant Louie	Voting Panel	Carroll Arthritis	Janssen; UCB	N/A	N/A	N/A	N/A	N/A	N/A
Ann Biehl	Voting Panel	National Institutes of Health; Food and Drug Administration	N/A	N/A	N/A	N/A	N/A	N/A	N/A