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American College of Rheumatology (ACR) and American Association of Hip and Knee Surgeons (AAHKS)  
Guidelines for Perioperative Management of Rheumatic Disease Medications in Total Joint Arthroplasty of the Hip and Knee  

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ORGANIZATIONAL LEADERSHIP AND SUPPORT  

This collaborative project of the American College of Rheumatology (ACR) and the American Association of Hip and Knee Surgeons (AAHKS) has the broad objective of developing guidelines for the management of rheumatic disease medications for patients with systemic autoimmune rheumatic diseases with inflammatory arthritis undergoing total hip and total knee arthroplasty, to improve outcomes and decrease adverse events linked to anti-rheumatic therapy.  

BACKGROUND  

Advances in therapy have improved the quality of life for patients with rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), and spondyloarthritis (SpA), yet total hip (THA) and total knee arthroplasty (TKA) remain important interventions undertaken to relieve pain and restore function when joints have been severely damaged. For RA, the rate of THA has remained high, and the rate of TKA has increased, despite the wide utilization of disease modifying anti-rheumatic therapy (DMARDs) and biologics (2,3). For patients with ankylosing spondylitis, rates of THA have increased by 50%, and the age at which patients undergo arthroplasty has increased (2). For patients with SLE, rates of arthroplasty have also increased, proportionate with the overall doubling of the rate of arthroplasty for non-inflammatory conditions (4). Anti-rheumatic medication use in patients with rheumatic diseases has increased; 10% of RA patients were prescribed methotrexate in 1985, compared to 76% in 2000 (5). At the time of arthroplasty in a high-volume orthopedic hospital, 46% of RA patients were on biologics, and 67% were on DMARDs, with only 14% of the total on no anti-rheumatic therapy (5,6,7). For patients with SLE, survival has increased, a change attributed to improved medical management (8), and 75% of SLE patients undergoing THA or TKA were on immunosuppressive medications at the time of surgery (9). Taken together, this indicates that patients with systemic autoimmune inflammatory arthritis and SLE will continue to undergo arthroplasty, and the majority will be on immunosuppressant therapy at the time of surgery. In this setting, guidelines have become needed for the perioperative management of anti-rheumatic therapy, pertaining to adult patients with RA, AS and other forms of spondyloarthritis, JIA, and SLE, who are undergoing elective THA and TKA. We will not specifically include patients with other systemic autoimmune inflammatory diseases such as dermatomyositis, vasculitis, or scleroderma, as these are unusual diseases with disease courses that do not typically lead to arthroplasty. We will also not address unicompartmental knee arthroplasty, as it is not relevant for patients with systemic autoimmune inflammatory arthritis. This will not include recommendations for hip hemiarthroplasty, as this is not performed in the elective setting.  

Patients with SLE and RA have an increased risk of adverse events after surgery. For SLE patients, the risk is greatest in those with SLE related hospitalizations within six months of surgery, including septicemia (OR 3.43, 95% CI2.48,4.74), venous thromboembolism (VTE) (OR 4.86, 95%CI 1.20,19.7), and acute renal failure (OR 7.23, 95% CI 4.52,11.6), suggesting that disease activity or severity is a risk factor for adverse events (10). Using data from large administrative databases, RA increased the risk of infection for TKA patients (RA 1.26% vs. OA 0.84%) and for dislocation in THA patients (RA 2.45% vs. OA 1.21%) (11). In addition, RA patients have higher odds of readmission within 90 days of arthroplasty compared to osteoarthritis patients, and risk of readmission increased between 2009 (OR 0.89(95%CI 0.46–1.71) and
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2011 (OR of 1.74(95%CI 1.16–2.60), with infection as the most common diagnosis leading to readmission (12). Given the prevalence of immunosuppressant use at the time of arthroplasty and the increase in complications in patients with inflammatory arthritis and SLE, decisions made about perioperative medication management may provide an opportunity to decrease adverse events.

Patients with RA and SLE are at increased risk of atherosclerotic cardiovascular disease (ASCVD) and VTE (13,14). For patients with RA, cardiac risk is associated with disease activity status, with risk reduction associated with long term disease control (15). However, although the prevalence of vascular disease is high, perioperative major acute coronary events (MACE) are not increased (16,17,18,19,20). Using the National Inpatient Sample that includes over 7,000,000 cases, cardiac events after intermediate risk surgery, a category that includes arthroplasty, occurred in 0.34% of RA patients compared to 1.07% of patients with diabetes, despite the similar prevalence of ASCVD between groups (21). Similarly, no increase in DVT risk has been reported for RA, suggesting that for RA, current perioperative risk reduction strategies for MACE and VTE have been successful (22). For SLE patients, however, post-operative VTE, cardiac events and death are increased (10,23). While patients with inflammatory arthritis and SLE are at high risk, with a high prevalence of ASCVD and high risk for VTE, there is no evidence to link these outcomes to anti-rheumatic therapy in the perioperative period. Cardiac risk can be assessed using the American College of Cardiology (ACA)/American Heart Association (AHA) Guidelines, with the inclusion of IA and SLE as risk factors. The ACA/AHA guidelines suggest ascertaining cardiac functional status by history. As patients prior to arthroplasty are rarely able to achieve 4 metabolic equivalents (METS) (activity levels achieved by walking briskly or carrying groceries upstairs) as considered necessary by the ACA/AHA to demonstrate adequate cardiac function, further assessment of cardiac risk is frequently required (24). While patients with IA and SLE should be assessed and treated as high risk for VTE and MACE, this guideline will not address specific cardiac or anti-thrombotic therapy, which are covered in existing guidelines prepared by the AHA/ACA, American Academy of Orthopedic Surgeons and the American Academy of Chest Physicians (25,26).

Continuing anti-rheumatic immunosuppressive therapy may increase perioperative infection risk, but discontinuing anti-rheumatic therapy can result in disease flares. Post-arthroplasty flares occur in 60% of RA patients after THA and TKA, with the highest risk in those discontinuing biologics (27). Active RA may decrease the ability to participate in rehabilitation, might contribute to poor long-term outcomes, and may increase infection risk (28). For SLE patients, high disease activity and severity might increase the risk of adverse events. Perioperative medication management decisions must balance the likelihood of disease flares with the risk of perioperative infection. Prosthetic joint infection is a significant burden and optimal arthroplasty outcomes are a clear priority for those undertaking this procedure. As use of immunosuppressive anti-rheumatic therapy is highly prevalent in IA and SLE patients at the time of arthroplasty, recommendations to guide perioperative management of these drugs in patients with rheumatic diseases are needed for patients and their physicians at the time of arthroplasty.

This guideline does not address indications for surgery, nor the criteria with which to determine medical suitability to undergo the stress of surgery. The guidelines presented here refer to anti-rheumatic medication management only, and do not address VTE or MACE risk. They are to be applied to those
patients undergoing THA or TKA after the decision has been made by the patient, rheumatologist and orthopedist. The objective of this project is to develop recommendations for the perioperative management of anti-rheumatic therapy in patients with systemic autoimmune rheumatic diseases with inflammatory arthritis (including AS, SpA, PsA, RA, JIA) and SLE undergoing elective THA and TKA, for use by surgeons, rheumatologists and perioperative physicians.

**OBJECTIVES**

Specifically, we aim to:

1. Develop recommendations for the perioperative use of glucocorticoids, non-biologic traditional and biologic disease-modifying anti-rheumatic drugs (DMARDs), and immunosuppressant medication used in systemic autoimmune inflammatory diseases with inflammatory arthritis by:
   a. Assessing the risk of disease flare when anti-rheumatic therapy is discontinued; and
   b. Assessing the risk of infection and delayed wound healing when anti-rheumatic therapy is continued.

2. Develop recommendations for the perioperative use of glucocorticoids, non-biologic traditional and biologic disease-modifying anti-rheumatic drugs (DMARDs) in subpopulations of high-risk patients with systemic autoimmune inflammatory diseases with inflammatory arthritis and SLE undergoing THA and TKA.

3. Develop recommendations for the perioperative use of supra-physiologic corticosteroid dosing ("stress-dose") in patients with previous steroid use.

4. Analyze the optimal timing of discontinuation and resumption of DMARDs pre-/post-operatively by:
   a. Assessing the pharmacokinetics and pharmacodynamics of steroids and DMARDs; and
   b. Assessing the risk of flare and infection with different durations of drug discontinuation and resumption.

5. Develop recommendations for "rescue" medication use for post-op flares.

6. Specify differences in recommendations between patients with RA and other forms of inflammatory autoimmune arthritis and SLE for perioperative medication management.

7. Consider perioperative management decisions that will decrease the risk of 90-day readmissions.

8. Identify knowledge gaps and areas for future research in perioperative medication management.
**Methods**

**Identification of Studies**

Literature search strategies, based on PICO questions (Population/patients, Intervention, Comparator, and Outcomes; see Appendix A) will be developed by the principal investigators, the systematic review leaders, and a research librarian, with input from the core leadership team. The search strategies will be peer reviewed by another medical librarian using Peer Review of Electronic Search Strategies (PRESS) (29). 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 will be 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 and again at some point after the voting panel meeting but prior to publication of the guideline, to ensure completeness.

**Inclusion/Exclusion Criteria**

See PICO questions (Appendix A), which outline the defined patient population, interventions, comparators, and outcomes. Only English language studies will be included.

**Management of Studies and Data**

References and abstracts will be imported into bibliographic management software (Reference Manager) (30), duplicates removed, and exported to Distiller SR, a web-based systematic review manager (29). Screening and data abstraction forms will be created in Distiller SR. Search results will be divided among reviewers, and two reviewers will screen each title/abstract, with disagreements at the title/abstract screening stage defaulting to inclusion for full manuscript review. Disagreements at the full
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1. A search for randomized controlled trials and observational studies about prevention and treatment of glucocorticoid-induced osteoporosis, including special populations who have risk factors that make treatment decisions more complicated or who may have contraindications to certain treatment options, will be performed to determine existing studies covering outcomes of interest. Subsequently, identified studies will be assessed using the RevMan (31) and GRADE Pro tools (32).

2. Chosen studies will be quality-assessed using the Cochrane Risk of Bias Tool (33), the Cochrane Effective Practice and Organization of Care Risk of Bias Tool (34) or the Newcastle-Ottawa Scale (29).

3. Additionally, recently published systematic reviews covering outcomes of interest will also be sought and used for reference cross-checking.

GRADE Methodology

GRADE methodology will be used in this project to grade available evidence and facilitate development of recommendations. The quality of evidence will be graded as high, moderate, low or very low. The strength of recommendations will be graded as strong or conditional. 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 systematic 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) (30) and GRADEprofiler (GRADEpro) software (35). 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 number needed to treat, and the quality of evidence for each critical and important outcome (i.e., high, moderate, low or very low).

The evidence profile documents the quality of the evidence across studies for each critical and important outcome and summarizes the quality factors (i.e., limitations of study design, inconsistency, indirectness, imprecision and other considerations).

Development of Recommendation Statements

PICO questions will be reversed into drafted recommendation statements. Using the GRADE Evidence Profiles and Summaries of Findings tables, the voting panel, consisting of four rheumatologists, four orthopedic surgeons, one infectious disease expert, one systemic lupus erythematosus expert and two patient representatives, will consider the drafted recommendation statements in two stages. The first
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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 PI, the panel will discuss the evidence in the context of their clinical experience and expertise to arrive at consensus on the final recommendations. The voting panel meeting discussions will be supported by the systematic review leadership, the GRADE expert, and selected members of the systematic 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 guidelines will include: principal investigators Dr. Susan Goodman and Dr. Bryan Springer as the lead authors; Dr. Jas Singh and Dr. Adolph Yates, literature review leaders; and Dr. Gordon Guyatt, GRADE expert. Members of the systematic 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.
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APPENDIX A

PICO Questions

Population: Systemic autoimmune rheumatic diseases with inflammatory arthritis (RA, juvenile inflammatory arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS) and other spondyloarthropathies, and SLE.

Questions 1-4 pertain specifically to patients undergoing THA and TKA. Questions 5 and 6 to provide indirect evidence regarding risks associated with surgery and risks associated with the use of candidate drugs.

Definitions of populations, interventions (medications), and outcomes are listed below.

1. In patients with RA, AS, PsA, JIA, severe or not severe SLE undergoing THA or TKA and who are receiving one or more of the candidate drugs, what is the effect of stopping the drug prior to surgery?
   - Intervention: Stop medication
   - Comparator: Continue medication
   - Outcomes: Outcomes listed below, including renal failure in lupus

2. In patients with RA, AS, PsA, JIA, severe or not severe SLE undergoing THA or TKA who are receiving one or more of the candidate drugs in whom one has decided to stop the drug, what is the effect of stopping the drug early* prior to surgery?
   - Interventions: Stopping early*
   - Comparator: Stopping late*
   - Outcomes: All outcomes listed below, including renal failure in lupus
   - *timing definition (early vs. late) will be determined by the literature review

3. In patients with RA, AS, PsA, JIA, severe or not severe SLE undergoing THA or TKA who are receiving one or more of the candidate drugs in whom one has decided to stop the drug, what is the effect of restarting the drug early after surgery?*
   - Interventions: Restarting early*
   - Comparator: Restarting late*
   - Outcomes: All outcomes listed below, including renal failure in lupus
   - *timing definition will be determined by the literature review
4. In patients with RA, AS, PsA, JIA, severe or not severe SLE undergoing THA or TKA who are receiving chronic glucocorticoids, what is the effect of administering supra-physiologic doses of glucocorticoids perioperatively (stress-dose corticosteroids) vs. continuing the usual glucocorticoid dose?

Interventions: Perioperative stress dose
Comparator: Usual dose continued in the perioperative period
Outcomes: All our outcomes, adding hypotension, transfer to a higher level of care, syncope, electrolyte abnormalities

5. Indirect evidence – What is the background risk for serious adverse events, including infections or hospitalization, associated with use of each of the candidate drugs, limiting the search to systematic literature reviews and meta-analysis (can include observational studies in lupus)?

Patients: RA, AS, PsA, JIA, severe or not severe SLE
Interventions: Standard care + candidate drug
Comparator: Standard care
Outcomes: Serious adverse events-infection, and in particular admission for infection, death

6. Indirect evidence – What is the background risk for adverse events associated with THA or TKA independent of use of candidate medications in the first 6 weeks, 3 months, 1 year and 2 years after surgery?

Patients: RA, AS, PsA, severe or not severe SLE
Interventions: Hip or knee arthroplasty surgery
Outcomes: All outcomes listed below, and renal failure in lupus

Definitions

Populations

Systemic autoimmune rheumatic diseases with inflammatory arthritis (RA, JIA, PsA, AS and other spondyloarthropathies, and SLE)

Severe systemic lupus erythematosus (SLE): Currently treated (induction or maintenance) for severe organ manifestations: lupus nephritis, central nervous system lupus, severe hemolytic anemia (Hgb<9.9), PLT<50,000, vasculitis (other than mild cutaneous vasculitis), including pulmonary hemorrhage, myocarditis, lupus pneumonitis, severe myositis (with muscle weakness, not just high enzymes), lupus enteritis (vasculitis), lupus pancreatitis, cholecystitis, lupus hepatitis, protein losing enteropathy, malabsorption, orbital inflammation/myositis, severe
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427 keratitis, posterior severe uveitis/retinal vasculitis, severe scleritis, optic neuritis, anterior ischemic optic neuropathy. (this uses the  
428 SELENA_SLEDAI flare index and BILAG)
429
430 Not severe SLE: Not currently treated for above manifestations
431
432 THA: Total hip arthroplasty including resurfacing
433
434 TKA: Total knee arthroplasty
435
436 We will not discuss unicompartmental knee replacement (not indicated in tricompartmental inflammatory arthritis) or hip hemiarthroplasty  
437 (treatment for fracture)
438
439 Medications are grouped together, but we anticipate that the literature review will lead to differing recommendations for the  
440 listed drugs.
441
442 Medications for SLE:
443
444 1. Mycophenolate mofetil, mycophenolic acid (myfortic), azathioprine, mizoribine, cyclosporine, tacrolimus (Prograf), tacrolimus,  
445 cyclophosphamide, methotrexate
446 2. Rituximab, belimumab
447 3. Hydroxychloroquine and other antimalarials (quinacrine, chloroquinechloroquine, etc.)
448
449 Medications for inflammatory arthritis:
450 1. Non-immunosuppressive DMARDs: sulfasalazine (SSZ), hydroxychloroquine (HCQ), Doxycycline
451 2. Immunosuppressive DMARDs: methotrexate (MTX), leflunomide (LEF), azathioprine
452 3. Oral synthetic small molecule = tofacitinib (and others pending approval, such as baricitinib)
453 4. Apremilast
454 5. Anti-TNF biologic therapy = adalimumab, etanercept, golimumab, certolizumab pegol, infliximab
455 6. Non-TNF anti-cytokine biologic therapy = abatacept, tocilizumab, anakinra , secukinumab, ustekinumab
456 7. Rituximab
457 8. Low dose glucocorticoid <= 15 mg/day of prednisone equivalent
458 9. Moderate dose glucocorticoid >15, <40
10. High dose glucocorticoid = up to 60 mg/day

Outcomes

1. Disease flare
2. Infection
   - Serious (deep) surgical site infections (at 3 months, 1 year, 2 years)
   - Superficial surgical site infections
   - Minor, non-surgical site infections (UTI)
   - Serious, non-surgical site infections (e.g. pneumonia, bacteremia/sepsis)
   - Delayed wound healing
3. Death (3 months?)
4. SLE – acute kidney injury
5. Need for revision surgery (within 2 years)
6. Return to OR (re-operation)
7. Readmission within 90 days/30 days
8. Transfer to a higher level of care
9. Length of stay
10. Long-term arthroplasty outcomes – pain and function scores

APPENDIX B

Participant Disclosures
DISCLOSURES OF RELATIONSHIPS

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.

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<td>Michael Mont, MD</td>
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