AAOS Rotator Cuff Clinical Practice Guideline Misses the Mark

The American Academy of Orthopaedic Surgeons Clinical Practice Guideline (CPG) on Optimizing the Management of Rotator Cuff Problem was developed using the best available evidence to improve treatment in keeping with current evidentiary practice standards. This is a laudable and necessary effort. Unfortunately, the CPG process produces inconclusive recommendations supported by relatively low-levels of evidence. The CPG “assessment of the current scientific and clinical information” does not result in an accurate description of “accepted approaches to treatment.” This is because accepted approaches to treatment, or guidelines, must be based on adequate evidence to set standards of practice. Yet significant high-level evidence does not exist. Our rationales for treatment rest on a wealth of lower level evidence that demonstrate the efficacy of our treatments for rotator cuff repair. The dilemma is to produce meaningful direction for clinical decision making and at the same time make sure such recommendations are based on rigorous scientific analysis. The CPG process as currently configured unnecessarily calls our treatments into question, notwithstanding the Clinical Practice Guideline Disclaimer.

A respected friend, mentor, teacher, and member of the Academy Board of Directors, when presented with this controversy, asserted off the record that our editorial opinion may be “off base.” He pointed out, that, as noted in the published guideline, “the recommendations were developed using systematic evidence-based processes designed to combat bias, enhance transparency, and promote reproducibility.” While we agree that these are evidence-based methods, we have a concern that because of a relative lack of adequate evidence, there is a methodological flaw that undermines the claim of a “summary of recommendations” or “guidelines.”

The purpose of a study is to answer a question. However, this guideline has “inconclusive” recommendations. One example is subacromial corticosteroid injection. The guideline reads, “We cannot recommend for or against subacromial injections for patients with rotator cuff tears. Strength of Recommendation: Inconclusive.” In the opinion of the editors, inconclusive recommendations do not make a guideline.

Your editors received a telephone call from our co-author, Louis F. McIntryre, M.D., Health Policy and Practice Committee Chairman for the Arthroscopy Association of North America. Dr. McIntryre suggested that we review the AAOS Clinical Practice Guideline and the published commentary by its lead author, Robert A. Pedowitz, M.D., Ph.D. We were intrigued because Dr. Pedowitz is also a member of the Arthroscopy Editorial Board and Journal Board of Trustees. We were even more intrigued when we read his title, “Commentary and Perspective: Does Every Question Need a Level-I Answer? Pragmatic and Ethical Considerations of Clinical Practice Guidelines. Commentary on an article by Robert A. Pedowitz, MD, PhD, et al.: ‘American Academy of Orthopaedic Surgeons Clinical Practice Guideline on Optimizing the Management of Rotator Cuff Problems.’” We do not recall ever seeing a letter to the editor by an author on the subject of his own publication.

Dr. Pedowitz shares his “personal perspective on the guidelines process to facilitate proper utilization by our key stakeholders: patients, providers, and payors . . . [who] might infer coverage denial . . . pending better evidence.” He adds, regarding the guideline, “there is not sufficient proof, according to EBM [evidence-based medicine] rules, to make a declarative statement. Nothing more.”

Dr. Pedowitz continues, “The terminology used to wordsmith guidelines is pre-scripted (to give some
inference about the associated level of evidence for each recommendation), which makes some statements awkward, noncommittal, and bland. All questions posed at the beginning of the process must be addressed by a written guideline at the end (even when no evidence exists), tending to dilute the impact of the resultant document. Expert opinion is discouraged. An important objective of the clinical guidelines process is identification of gaps in our knowledge base, which can stimulate high-quality outcomes research. In summary, stakeholders must be careful about the use, and the potential abuse, of clinical practice guidelines. These are serious and laudable efforts, but like all research, there are substantial limitations.2

Our editorial opinion is that we agree with the Pedowitz commentary3 on Pedowitz et al.1 Yet, this becomes more confusing because other authors of the guideline3 then published their own commentary to counter the Pedowitz commentary2 on Pedowitz et al.1 Clearly a controversy exists, and we encourage our readers to study the issue. This controversy matters because, as the experts on musculoskeletal health care, we must be the ones to set the standards for the treatment of our patients. If the experts can’t agree on what constitutes the basis for our interventions, then the intellectual integrity of our profession may become compromised. At any rate, we strongly agree with Dr. Pedowitz’s analysis3 that an “important objective of the clinical guidelines process is identification of gaps in our knowledge base.” Our opinion is that the real conclusion of the Guideline1 is that future and better research is required. But then, isn’t this always the case?

One of us (J.H.L.) attended the American Orthopaedic Society for Sports Medicine (AOSSM) Council of Delegates meeting during the Academy meeting in San Francisco this past February. AANA Secretary William Beach, M.D., in his role as Chair of the AOSSM Health Policy and Ethics Committee, gave his report. Dr. Beach announced that his committee had concerns similar to ours regarding the guidelines, as did, by a unanimous vote, the Board of Specialties representing all of the subspecialty societies of the AAOS including, but not limited to, AANA, AOSSM, and the American Shoulder and Elbow Surgeons, and that the Board of Specialties was requesting that the AAOS refrain from publishing Clinical Practice Guidelines for lack of evidence, risk of misinterpretation, and potential for misuse. In a follow-up personal conversation, Dr. Beach said that, as a result of advocacy, subspecialty societies are cooperating with the AAOS to clarify the Clinical Practice Guidelines, and develop more specific “Appropriate Use Criteria,” which may aid arthroscopic and related surgeons in interpreting the literature. The goal is that in the future, surgeons may treat patients in a consistent, evidence-based manner and, pending clear published evidence, in a manner based on sage clinical consensus combined with specific application of clinical knowledge to the fine distinctions specific to the individual patient. Dr. Beach encourages us to “Embrace Appropriate Use Criterion,” and clarifies his position in Inside AANA, the AANA Newsletter.4

The AAOS Rotator Cuff Clinical Practice Guideline1 is controversial, and the good news is that some of the recommendations achieve moderate consensus founded on moderately high-quality level of evidence. For example, according to the Guideline, “Surgery—Acromioplasty ... We suggest that routine acromioplasty is not required at the time of rotator cuff repair. Strength of Recommendation: Moderate.”

In this issue of Arthroscopy, Drs. Chahal, Mall, MacDonald, Van Thiel, Cole, Romeo, and our newest Associate Editor Nikhil Verma, of Rush University Medical Center in Chicago describe, “The role of subacromial decompression in patients undergoing arthroscopic repair of full-thickness tears of the rotator cuff: A systematic review and meta-analysis” (Level I evidence). They found “no statistically significant difference in subjective outcome following arthroscopic rotator cuff repair with or without acromioplasty at intermediate follow-up.”5

Also in this issue, Drs. Shin, Oh, Chung, and Song, of Seoul National University Bundang Hospital in Korea publish, “The efficacy of acromioplasty in the arthroscopic repair of small- to medium-sized rotator cuff tears without acromial spur: Prospective comparative study” (Level II evidence). They report that “Arthroscopic repair of small to medium size rotator cuff tears provided pain relief and improved functional outcome with or without acromioplasty. Clinical outcomes were not significantly different and acromioplasty may not be necessary in the operative treatment of patients with small to medium size rotator cuff tears in the absence of acromial spur.”6

Both of these studies5,6 are of high-level evidence, but not all randomized controlled trials are Level I6 Quality studies have specific inclusion and exclusion criteria, but clinical research study conclusions may not necessarily be applied to individual patients. Arthroscopy authors, editors, and readers understand the difference between research conclusions and guidelines.
What is the difference? Conclusions are based on the specific and limited findings of a given study whereas guidelines synthesize a recommendation from the breadth of the medical literature in an attempt to aid the physician treating an individual with a real problem. Research is dynamic and has limitations. We still do not know all the answers. We are still learning. Thus, in medicine, we focus on continuing to learn, and admit that today's conclusions may prove to be incorrect. In the research environment, to mandate guidelines is to risk misrepresenting current evidence (which is still evolving) as proven fact. Also, to diminish the value of lower level evidence unnecessarily risks limiting access to important information with negative consequences for patients. Medical literature must be filtered by medical experts in a discerning manner, despite the potential bias inherent in that analysis.

For example, returning to the question of the role of subacromial decompression in patients undergoing arthroscopic repair of full-thickness tears of the rotator cuff, let us consider the question of the rate of reoperation. The topic is defined as a “secondary” outcome by Chahal et al., but is of equal importance to many patients and surgeons. Chahal et al. report: “Of the 4 included studies, 2 reported on the need for repeat surgery.” MacDonald et al. reported that 4 of 45 patients (9%) in the group not treated with SAD were offered repeat surgery over a 2-year follow-up period compared with 0 patients in the decompression group (P = .05). Of these 4 patients, 2 had a repeat rotator cuff tear that was repaired, and 3 of the 4 had an acromioplasty. One patient declined surgery. Of the 4 patients who were offered repeat surgery, 3 had a type III acromion.

“In the trial by Tetteh et al., 6 of 114 patients (3 in the SAD group and 3 in the non–SAD group) have undergone repeat surgery, 2 of whom had a type III acromion. Among patients treated with SAD in this latter study, 1 patient underwent revision RCR, 1 patient had a total shoulder replacement, and another had a capsular release and revision decompression. In the group treated without SAD, 2 patients required a revision RCR and 1 patient had a capsular release.

“A meta-analysis of the need for repeat surgery shows that there is no difference in reoperation rates between patients treated with SAD and those treated without it among patients undergoing repair of full-thickness tears of the rotator cuff (risk ratio, 0.46; 95% CI, 0.08 to 2.69; P = .39).”

Yet, is there really “no difference”? Readers who are not statisticians may share our difficulty in fully understanding the meaning of “risk ratio, 0.46; 95% CI, 0.08 to 2.69; P = .39.” However, a quick glance at Figure 2C of Chahal et al. in this issue makes it very clear that, based on the slim evidence currently available (only 10 patients in total), the chance of avoiding a reoperation “favors acromioplasty.” The senior one of us, Dr. Poehling, makes his opinion clear: “If you ask me, I want an acromioplasty if I have a rotator cuff tear.” We need expert opinion and analysis in deriving meaningful guidelines and recommendations.

And tomorrow, future research is clearly required. In summary, we believe that evidence is obligatory before a conclusion can be represented as a guideline. Therefore, clear evidence based on additional research is required before current conclusions may be characterized as Guidelines.

JAMES H. LUBOWITZ, M.D.
Assistant Editor-in-Chief

LOUIS F. MCINTYRE, M.D.
AANA Health Policy and Practice Committee Chair

MATTHEW T. PROVENCHER, M.D.
Deputy Editor

GARY G. POEHLING, M.D.
Editor-in-Chief

REFERENCES


---

**Submitting a manuscript to Arthroscopy**

**REMEMBER TO INCLUDE A VIDEO!**

Also...

when submitting that image of your interesting case for the Journal Cover,

**REMEMBER TO INCLUDE A VIDEO!**

*See our Instructions for Authors for details*