Letter to the Editor: Is Criticism About Inherent Biases in Rigorous Orthopaedic Trials Prone to Biases?

The field of orthopaedics has seen a surge of rigorous randomized controlled trials (RCTs) comparing commonly performed arthroscopic procedures with nonoperative treatment or sham surgery. Challenging old paradigms always meets fierce objection, and questioning the efficacy of surgery for degenerative conditions in the shoulder and knee is no different. Critics usually focus on various flaws in the trials that did not find evidence of benefits. "Inherent biases" invalidate the results, and hence the procedures that "have stood the test of time" should not be abandoned—we just know they work, and it's all about selecting the right patients.[1]

In recent discourse, Hohmann et al. called for "credible, reliable, reproducible, and valid evidence."[2] We find it paradoxical that while they ask for reliable evidence, they first discredit moderate- to high-certainty evidence from a systematic review and base their own claims that subacromial decompression (SAD) is an effective procedure with "proven long-term outcomes" on 2 observational studies and 2 selected RCTs.[3-6]

Regarding the long-term benefits, a Cochrane review that included the 2 studies also cited by Hohmann et al.[2] found moderate-certainty evidence that SAD probably does not improve pain compared with exercises (mean difference [MD] in visual analog scale of 1 point; 95% confidence interval [CI] −0.25 to 2.25) and low-certainty evidence that surgery may improve function compared with exercises at 10 years (MD in Constant score of 9.5 points; 95% CI 1.9 to 17.1).[7] However, there was considerable risk of bias as well as imprecision.

It seems that Hohmann et al.[2] favor the positive findings from a single study by Farfaras et al.,[4] while they see countless flaws in all of the other studies, including rigorously conducted placebo-controlled trials.[8,9] We wonder if the bias assessment by Hohmann et al.[2] is biased to favor trials showing benefits.

Further, Hohmann et al.[2] elaborate their narrative with critical shoulder angle (CSA), which has nothing to do with reliable evidence supporting the use of SAD over nonoperative treatment. The concept of CSA has also been discussed in this journal.[10-12] CSA is an arbitrary measurement assessed in planar x-rays. Even the meta-analysis cited by Hohmann et al.[2] concludes that "evidence is poor,"[13] and there is no existing evidence suggesting that CSA would modify the treatment effect when surgery is compared with exercises or placebo surgery.

"Optimal patient selection" can be considered a myth until evidence of effect modifiers arises. We argue that if there were subpopulations that benefit from these procedures, we would have already identified them after 4 decades of using modern arthroscopy. It is simply not plausible that a meaningful effect keeps hiding because no one is able to define optimal inclusion criteria for efficacy studies. Mounting evidence shows that surgical treatment of degenerative conditions should not be automatically considered beneficial. We should require evidence from rigorous trials, just as we do elsewhere in medicine, before the procedures become accepted treatments. There is no room for double standards.

It may be time for a paradigm shift: Embrace the natural course and accept degeneration until effective treatments arise.

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Author Reply to "Is Criticism About Inherent Biases in Rigorous Orthopaedic Trials Prone to Biases?"

We thank Drs. Reito and Karjalainen for their letter to the editor with regards to our level V evidence clinical guideline.[1,2] Subacromial arthroscopic decompression (SAD) in the presence of an intact rotator cuff is a controversial topic, and we welcome debate. In their letter to the editor, Reito and Karjalainen expressed concerns about biases and fierce resistance when "accepted treatments that stood the test in time" are challenged.[1]

The most updated definition of evidence-based medicine was revised in 2000 and defined evidence-based medicine as the "integration of best research evidence with clinical expertise and patient value."[3] This means that the current best evidence also may be obtained from clinical studies such as case series, retrospective comparative studies, and basic science research.[3] The term "clinical expertise" implies that skills from clinical experience should not be ignored.[4,5] This is where interpretation of the published evidence comes into play. It will always include an element of subjectivity and inevitably result in myside or confirmation bias. This basically means that we evaluate but also generate evidence in a manner biased toward our own personal opinions and attitudes.[6] Are we not all suffering from this problem? Different experiences, training, cultural and health environments, and practice patterns imprint our beliefs and behavior.[7]

We admit that we interpret the current available evidence in favor of SAD as a proven surgical intervention if the indications for surgery are correct.[2,8] As we have outlined in our response to van den Bekerom and Poolman[9] and in the clinical guideline, strong evidence to either support SAD or nonoperative treatment is clearly missing.[2,8]

In our level V guideline,[2] we have very carefully considered the available evidence, summarized the supporting evidence in favor of and against SAD, and merely suggested to consider SAD if 5 specific points are met. Reito and Karjalainen[1] argue that the placebo-controlled trials by Beard et al.[10] and Paavola et al.[11] were rigorously conducted and of high evidence. Unfortunately, this is fundamentally wrong. As we have outlined already previously,[8] the study by Beard et al.[10] has been criticized by multiple German Speaking