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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

Associations because of its multiple biases, as we have also highlighted in our guideline.[2] Similar, the study by Paavola et al. could hardly be defined as being conducted rigorously.[11] Twelve percent of patients in the placebo group and 21% of patients in the exercise group eventually crossed over and had surgery.[8,11] An intention-to-treat protocol was used for analysis, and these protocols have been widely criticized for violating the principle of randomization, introduction of bias, and effective reduction in sample size and study power.[12,13] Furthermore, sham-controlled studies have methodologic deficiencies, possibly invalidating their conclusions.[14] Of course this does not mean that the studies supporting SAD are better designed or have less limitations.

With regards to the critical shoulder angle (CSA), the guideline has summarized the available evidence and clearly stated that is a hotly debated topic. In our recommendations we have been very careful in suggesting that a lateral acromioplasty should be considered. We agree with Reito and Karjalainen[1] that the concept of CSA is new and evolving. For a more balanced perspective on the quoted meta-analysis that was used by Reito and Karjalainen to argue against lateral acromioplasty, it has to be mentioned that the conclusions also state that the pooled data showed a relationship between greater CSA and full-thickness rotator cuff tears with a possible greater re-tear rate following rotator cuff repair.[15]

Reito and Karjalainen[1] argue that a Cochrane review from 2019 came to the inevitable conclusion that SAD surgery does not improve pain when compared with exercises.[17] The mean difference in visual analog scale score was 1 point, with a 95% confidence interval ranging from −0.25 to 2.25.[16] In addition, there was low certainty that surgery may improve function.[16] As already outlined in our response to the letter[8] by van den Bekerom and Poolman,[9] 75% of the included studies had a high risk of bias, and because of imprecision of the results, the certainty of evidence was downgraded by the authors of the Cochrane Review.[16]

The Cochrane Handbook states that high risk of bias is concerning and therefore lowers the confidence in the results of the analysis.[17] One way to mitigate is to restrict the primary analysis to low-risk studies or to perform sensitivity analysis to show how conclusions might be affected if studies with a high risk of bias were included.[17] The cited Cochrane review has included a sensitivity analysis. Pain at 6 months favored surgery, but the 95% confidence interval was wide (−0.31 [−0.75, 0.12]); pain at 1 year clearly favored surgery (−0.58 [−1.05, −0.12]); function at 6 months favored conservative treatment but the confidence intervals were wide (1.05 [−3.77, 5.87]); function at 1-3 years favored conservative treatment (3.21 [−0.81, 7.23]); and pain at 5 years favored surgery (−0.78 [−1.17, −0.39]).[16] We note that the co-author of this letter to the editor was also the main author of the Cochrane review.[16] Could the authors suffer from confirmation bias themselves? We leave the answer to the readers.

SAD for impingent remains a controversial topic, and it appears that many of us are strongly opinionated. This certainly reflects the lack of agreement but also the lack of strong and reliable evidence. It may not be time for a paradigm shift but time to create this evidence. Given the difficulties of designing a watertight randomized trial and including most of the potential confounders, this may not be possible in the near future. Until then, we have to rely on interpreting research evidence to the best of our knowledge taking our clinical experience and patient expectations into consideration.[3]

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Regarding "A Prospective Randomized Trial Comparing Suture Bridge and Medially Based Single-Row Rotator Cuff Repair in Medium-Sized Supraspinatus Tears"

We read with great interest the article "A Prospective Randomized Controlled Trial Comparing Suture Bridge and Medially Based Single-Row Rotator Cuff Repair in Medium-Sized Supraspinatus Tear" published recently in your journal.[1] The article compared clinical and imaging outcomes between 2 commonly used knot configurations. However, we would like to raise several concerns that need to be addressed by the author.

The study is highly underpowered (power = 0.08, based on the UCLA score). Thus, it may be unlikely to recognize any actual difference between the groups.[2] The sample size calculated by the author, based on an unpublished data of a pilot study, is much less compared with that suggested in previous literature. For instance, according to the data extracted from similar research by Carbonel et al.,[3] 183 patients are required in each group to achieve a statistical power of 0.8 (effect size: 0.29, and the probability of type 1 error: 0.05).

The author didn't discuss the particulars of randomization. The author obtained an equal sample size in both the groups, which indicates that they must have implemented some kind of randomization blocking. Furthermore, there is an improper description regarding the method of sequence generation and allocation concealment. All these factors should be explained more, as they increase the chances of selection bias.[4] The latter can reverse the randomization process, leading to biased estimations of treatment effect and inaccurate inferences.[4]

Preoperative group characteristics that are potential confounders, including the proportion of degenerative tear, fatty infiltration in the rotator cuff, delamination of the tendon, and tendon retraction, should have been reported by the author.[5] These descriptions would have also allowed us to access the success of randomization processes, and to judge for generalizability of the data.[6] Furthermore, the author didn't discuss regarding inter-evaluator calibration, which can make the results less reliable.

Lastly, there is a discrepancy in the number of patients present in the study for review. According to the abstract, Results section, Table 1, and Table 3 of Yamakado et al.,[1] 92 patients were available for analysis after 1 year. However, after the exclusion of 15 patients (as per the CONSORT flow chart), 91 patients should have been present at 1-year follow-up. Furthermore, at