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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to recognize any actual difference between the groups.[2] The sample size calculated by the author, based on an unpublished data of a pilot study, is much less compared with that suggested in previous literature.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

the 2-year follow up, the abstract suggests 74 patients, whereas the CONSORT flow chart and the text in the result section indicate that 75 patients were available.

We would like to conclude here by complimenting the author for presenting an essential research question. However, the readers of the article must be sensitized regarding the shortcomings of the study. Future studies in this topic should consider the point suggested in this letter to avoid any methodologic and reporting inaccuracies.

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

I would like to thank Datt, Jain, Morankar, and Digge for their interest in our article "A Prospective Randomized Trial Comparing Suture Bridge and Medially Based Single-Row Rotator Cuff Repair in Medium-Sized Supraspinatus Tears,"[1] and I wish to address their concerns.

First, regarding the concept of sample size calculation in a prospective randomized trial, one must distinguish a priori sample size calculation and the post-hoc power analysis. Estimation of sample size should be done before the data collection starts, which I conducted using our pilot data. On the other hand, *post hoc* sample size computation is not encouraged conventionally.[2] Regarding the study power, they cited a prospective randomized trial by Carbonel et al., recruiting 183 patients.[3] This study represents a massive effort and is laudable; however, the sample size calculation was not shown in the article. To answer a research question, a large sample size may detect the small difference between the treatment groups, but too large a sample is resource-intensive and may be unethical; thus, many randomized trials utilize small pilot study, personal experience, or expert opinions.

Second, Datt et al. criticized our randomization method, stating that "the author obtained an equal sample size in both the groups, which indicates that they must have implemented some kind of randomization blocking"; however, it is a misjudged assumption. Randomization was performed at the end of preparation: the procedure used for each patient was chosen by opening a sealed, randomly assigned envelope that indicated the suture-bridge or medially-based single-row technique and prepared the same number for each treatment arms ahead of time. A randomized trial is an essential tool for comparing the efficacy of treatment modalities.[4] With proper randomization, the validity of data analysis is ensured. Simple randomization can result in the imbalanced assignment of treatment groups because randomly assigned groups of smaller numbers of patients are more likely to result in different numbers of a patient in each group. The method used in our study is