Impact of Patient Reported Outcome Measures on Anterior Cruciate Ligament Reconstruction effect estimates

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Background: Patient-reported outcome measures (PROMs) provide self-reported, subjective data from the patients themselves, without interpretation by clinicians or others[1-2]. PROMs with poor or unknown measurement properties may be clinically misleading, potentially resulting in harm to the patient and, inappropriate use of resources from a health systems perspective. The main objective of this study is to assess how varying PROM quality influences treatment effect estimates in randomized trials of patients with Anterior Cruciate Ligament (ACL) injury and secondly to identify variables that modify this relationship.

Method: A search into existing randomized trials on anterior cruciate ligament injury repairs was done from the top five 2022 impact factor orthopaedic journals. We accessed only studies including human subjects, published in English, from January 2019 to September 2023, and used PROMS associated with ACL. Data extracted include sample size, length of follow up, estimates of effects and associated measure of variance, numeric rating of PROMs obtained from a prior publication on Psychometric quality[3]. Study eligibility, methodological quality of included studies and data extraction were independently accessed by two reviewers with a third reviewer resolving any disagreements. We performed mixed effect linear regression with an alpha of 0.1 as cut off for significance, to access the relationship between PROM quality and effect estimate.

Result: we screened 4038 non-duplicate studies for inclusion, resulting in a total of 25 RCTs reporting 165 separate outcomes from six PROMs. Mean follow up was 35 (95% CI: 30 to 39) months, mean sample size was 54.7 (95%CI: 48.6 to 60.8), psychometric quality scores ranged from -2 to 5, average risk of bias score 7 out of 10 and the standardized mean effect estimate was 6.79 (90% CI: 3.89 to 9.68). The multi-level linear regression presents some evidence that PROM with high quality is associated with reduced effect estimates -0.57(90%CI: -1.20 to 0.18), in addition, both prolong follow up and increased proportion of females in the studies are significantly associated with decrease in effect estimates -0.10 (90% CI: -0.19 to -0.014) and -0.16 (90% CI: -0.31 to -0.007) respectively. A sensitivity analysis revealed that increased scores of International Knee Documentation Committee (IKDC) subjective form, Tegner Activity Level, Marx Activity Rating Scale and Cincinnati Knee Rating System scales are significantly associate with increase effect estimate 3.0 (90% CI: 1.77 to 4.24) with 108% over estimation of treatment effect whereas scores from Knee Injury and Osteoarthritis Outcome Scores (KOOS) and Lysholm Knee Questionnaire are associated with slight increase in treatment effect 0.082 (90% CI: -1.008 to 1.170).

Conclusion: This study demonstrated that poor or unknown quality of Patient Reported Outcome Measure, overestimates treatment effect of Anterior Cruciate Ligament injuries by 8.4% (-0.57/standardized mean effect estimate). Valid estimation of treatment effect depends on the Patient Reported Account Measure used.

References

1. Johnston BC, Patrick DL, Devji T, Maxwell LJ, Bingham III CO, Beaton D, Boers M, Briel M, Busse JW, Carrasco-Labra A, Christensen R, da Costa BR, El Dib R, Lyddiatt A, Ostelo RW, Shea B, Singh J, Terwee CB, Williamson PR, Gagnier JJ, Tugwell P, Guyatt GH. Chapter 18: Patient-reported outcomes. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). *Cochrane Handbook for Systematic Reviews of Interventions* version 6.4 (updated August 2023). Cochrane, 2023. Available from www.training.cochrane.org/handbook.

2. Johnston BC, Patrick DL, Busse JW, Schünemann HJ, Agarwal A, Guyatt GH. (2013) Patient-reported outcomes in meta-analyses--Part 1: assessing risk of bias and combining outcomes. Health Qual Life Outcomes, Jul 1;11:109. doi: 10.1186/1477-7525-11-109. Review. PubMed PMID: 23815754; PubMed Central PMCID: PMC3708764.

3. Gagnier JJ, Shen Y, Huang H. Psychometric Properties of Patient-Reported Outcome Measures for Use in Patients with Anterior Cruciate Ligament Injuries: A Systematic Review. JBJS Rev. 2018 Apr;6(4):e5. doi: 10.2106/JBJS.RVW.17.00114. PMID: 29634589