Are Patient Reported And Clinical Event Outcomes Appropriately Assessed in Randomized Trials of Interventions for ACL Injury?

A Scoping Review

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Faculty Disclosure Information

- Nothing to disclose

Background

- Patient reported outcome measures (PROMs) are a central feature of clinical research and frequently used as primary outcomes in studies investigating the treatment of ACL injuries.
- However, there are often no differences in PROMs reported between treatment groups.
- Re-injury and re-operation are highly important to patients, but that it is difficult to conduct adequately large studies to investigate these event outcomes.
- **Therefore, it is critical to understand whether both PROMs and event outcome are being appropriately assessed.**

Purpose

To investigate:

1. How PROMs and event outcomes are being assessed in randomized clinical trials investigating interventions after ACL injury

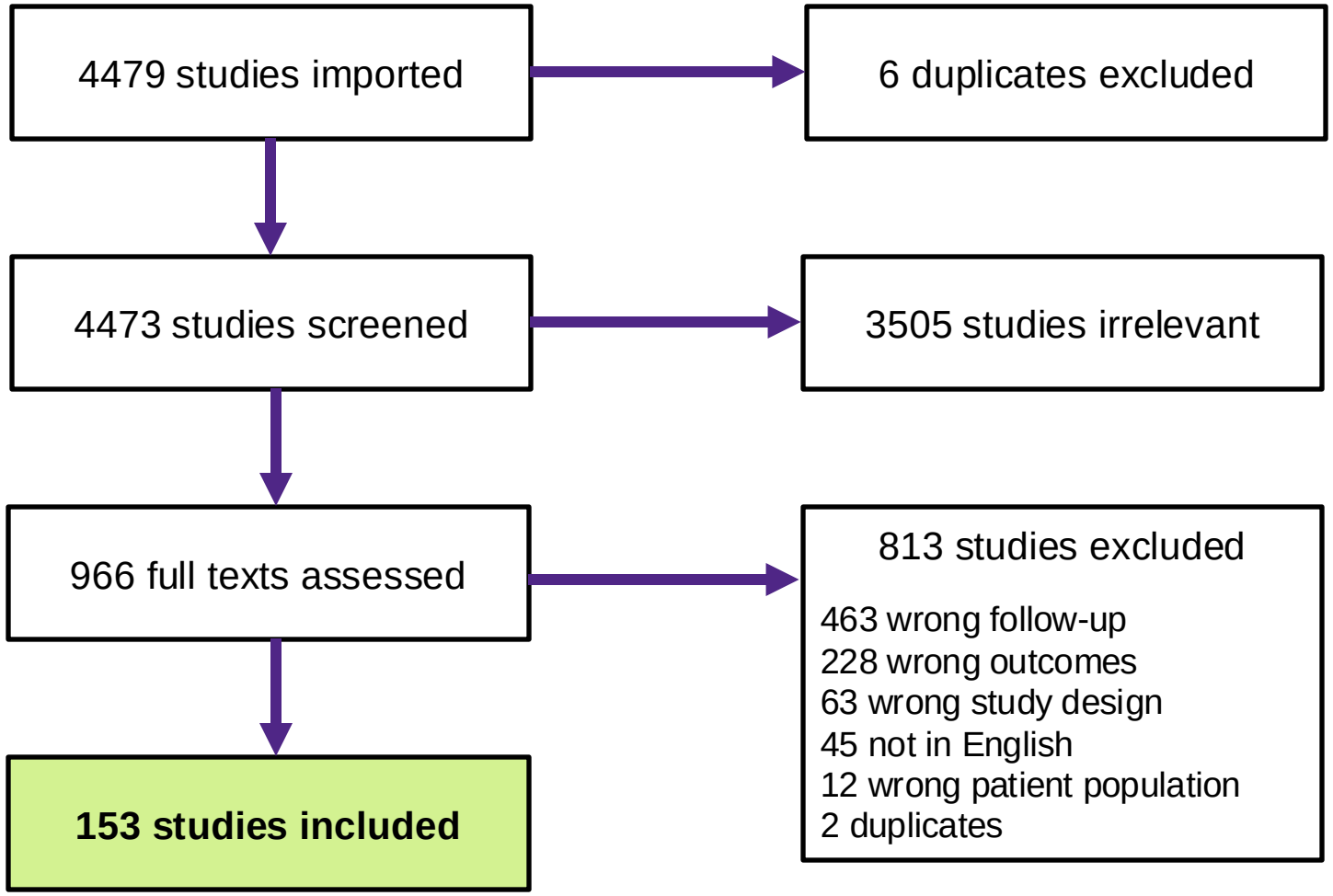
2. Whether PROMs and patient-important event outcomes reflect each other in between group differences

Methods

Inclusion Criteria	Exclusion Criteria
• Prospective randomized trial • Published since the year 2000 • Reported both a PROM and graft failure/rupture, contralateral ACL injuries, ACL revision surgery, or re-operation (event outcomes of interest • Follow-up between 1 and 5 years	• Cadaver or animal studies • Inclusion of participants with multi-ligament injuries • Not available in English

Results: PRISMA Flow Chart

- Articles were screened in duplicate by seven reviewers.
- Data related to study details, sample size, methods, analysis, population, intervention, outcomes, and results were extracted from each of the included studies by one of six reviewers.



Results: Methodology

- **39% (60/153) of studies excluded participants who experienced an adverse event from the follow-up analyses of PROM scores**
  - Meaning participants who are likely to have worse outcomes were not represented in the results

- 73% (111/153) of studies included a sample size or power calculation, **but no studies would be powered to detect differences in the primary outcome of ACL graft failure.**

Results: PROMS

- **The most common PROMs reported across 153 studies were:**
  - Lysholm (65%)
  - Tegner (59%)
  - IKDC (52%)
  - KOOS subscales (20%)
  - Visual Analog Scales (multiple constructs) (18%)
  - Cincinnati Knee Rating System (9%)

Only 10% (77/742) of between-group PROM comparisons were statistically significant

Results: Adverse Events

82% (237/289) of between-group adverse event comparisons had less than 5 events in each group

54% (156/289) between-group adverse event comparisons had 0 events in each group

Therefore, we were not able to calculate meaningful between group differences or to compare PROM and event outcome results.

Conclusions

- **Most (~90%) between group comparisons of PROMs indicate no significant difference in randomized trials investigating interventions for ACL injury**
  - Potential explanations for this finding include low event rates, poor outcome measures, response shift, or equivalence of interventions.
- Therefore, it is difficult to have confidence in recommendations based on individual study results.
- Randomized trials conducted with patients after ACL injury might not be appropriately designed or conducted to assess both patient-reported outcomes and event outcomes.
- **Multi-center, adequately powered, and appropriately designed studies** should be conducted to obtain the large samples required to accurately detect differences in event outcomes.

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