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EDITORIAL

The reporting of outcomes in randomised controlled trials

THE SWITCH AND THE SPIN

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The randomised controlled trial (RCT) is considered the benchmark approach to determine the comparative efficacy of various clinical interventions. Rigorously designed RCTs are powered to detect a difference in a pre-defined primary outcome. Other secondary outcomes may be explored, but with the caveat that the study may not be powered to detect a difference between treatment groups for the secondary outcomes. Primary and secondary outcomes should be clearly specified and defined at the time of trial registration on ClinicalTrials.gov. This allows for accountability in reporting of the outcomes once the study is complete and the results are published.

It has become apparent in the surgical and orthopaedic literature that pre-registration of RCTs suffer from deficiencies,[1] and that there are inconsistencies between the primary outcome registered and the primary outcome reported.[2] This may occur because the findings for the primary outcome were not found to be statistically significant, and therefore the authors report any positive secondary outcome finding in lieu of reporting the primary outcome. This maneuvering of outcomes is termed 'spin' and is common in the medical literature.[3] However, primary outcomes may indeed be negative[4-7] and secondary outcomes may be positive, and can legitimately be reported as such.[8,9] Transparent registering and reporting of outcomes, whether negative or positive, can alleviate the tendency to 'spin' results.

The candid reporting of outcomes in RCTs is imperative for various reasons. Outcomes may have an effect on patient management.[10-12] In addition, reported outcomes can help design future RCTs, with and without patient involvement in protocol development.[13,14] However, not all outcomes need to be considered primary or secondary. Smaller feasibility trials can be exploratory and report multiple pre-defined outcomes;[15] however in these exploratory studies, the authors should not specify a primary outcome and should indicate that the trial is meant to generate hypotheses for further larger trials. Pilot RCTs are another form of RCT that do not report primary outcomes, but instead report feasibility metrics such as recruitment and protocol adherence.[16-18]

However, in the case of adequately powered RCTs with a pre-defined primary outcome, it is the responsibility of the authors to report the primary outcome with minimal bias. A blinded and independent central adjudication committee can adjudicate all clinically significant outcomes, both primary and secondary, in order to maintain the integrity of the outcomes reporting and minimise bias in outcomes assessment.[19] For these large RCTs, clear and transparent reporting of outcomes will allow the data reported to be included in meta-analyses,[20,21] which are the most likely study types to be considered in clinical practice guidelines and drive change in clinical practice.

Outcomes reporting in RCTs can be a complex and tricky business. Because orthopaedic surgeons are busy clinicians, often only the conclusions of an RCT will be quickly digested, and the methodology considered a less important read. However, a quick cross reference on ClinicalTrials.gov can determine that the primary outcome reported was pre-defined, and that the primary and secondary outcomes were not 'switched' in the reporting process. Such a rapid check as can instill confidence in the findings of the RCT and therefore improve translation of the findings into clinical practice when practice change is feasible and supported by biological rationale and patient preferences.

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