

There Might Be a Difference! Type II (Beta) Error Rates of Randomized Trials in Orthopaedic Trauma

Nathan P Olszewski MD; Jeansol Kang MD; Paul Tornetta MD

Boston University Medical Center, Boston, MA, United States

Purpose: Randomized controlled trials (RCTs) are considered the best method of assessing treatment effectiveness; however, they may be subject to beta (type II) error. Beta error is the erroneous conclusion that no difference between treatment groups exists when one actually does. Over a decade ago, reported potential beta error rates were above 90% in published orthopaedic trauma trials. The goals of this study were to evaluate the risk of beta (type II) error and to evaluate study power for the primary outcomes of published RCTs involving fracture care from January 2011 to June 2018 to determine if these rates have decreased.

Methods: We evaluated all published RCTs involving fracture care. We excluded those that did not have sufficient information to do a post-hoc power analysis and those reporting statistically significant differences (as these are not subject to beta error). Search Strategy: A search of PubMed was performed independently by 2 investigators to identify potentially relevant study titles. Data Abstraction: Baseline information obtained included journal, geographic location, and sample size. The primary outcome(s) stated in the manuscripts were evaluated. For studies without an explicitly stated primary outcome, one was agreed upon by the 2 reviewers. Study Power: For each study, a standard post-hoc power calculation was performed on the primary outcome by a standard published methodology for dichotomous and continuous variables. Acceptable study power was agreed a priori to be $\geq 80\%$.

Results: We identified 914 potentially relevant citations; 376 involved fracture care. 160 manuscripts were included for analysis after enlisting exclusion criteria. 70 of 160 articles (43.8%) identified 127 primary outcomes. A single outcome was chosen by the reviewers for the additional 90 manuscripts based on the introduction and perceived hypothesis of the article. Thus, 217 outcomes were evaluated. Of these, 133 (61%) were subject to potential beta error. This included 43% of dichotomous and 68% of continuous variables. 100 (63%) of the studies discussed the concept of power in their methods or discussion; however, only 37 (23%) specifically discussed if their study was acceptably powered and only 9 (6%) actually reported their power.

Conclusion: Although the potential beta (type II) error rate for reported outcomes of RCTs in orthopaedic trauma has improved slightly, it remains high at 61%. Additionally, only 23% of studies that reported no difference in their outcomes discussed if their study was sufficiently powered to support their conclusions. Reviewers and journal readers should be aware of the concept of power analysis when a study reports no difference in an outcome and the power of these findings should routinely be reported.