Revisiting Large Trials: Novel Insights With the Win Ratio

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Purpose: Many orthopaedic trials use unplanned reoperation as the primary outcome, but this overlooks other patient-important outcomes. Using a high-quality hip fracture trial, we demonstrate how the relative importance of multiple outcomes can be effectively incorporated into data analysis, providing a more comprehensive understanding of treatment impact.

Methods: The FAITH trial randomized 1079 patients older than 50 years with a low-energy femoral neck fracture to treatment with a sliding hip screw (SHS) or cancellous screws (CS), with unplanned revision surgery as the primary outcome. Our analysis instead used a composite outcome of all-cause mortality at 4 months, ambulation status at 10 weeks (measured by the EQ-5D mobility dimension), and days at home within 4 months. Days at home were calculated by subtracting the average length of hospital stay (including initial surgery, reoperations, and adverse events) from the last known observation within 4 months. We assessed outcomes hierarchically using the win ratio method, comparing each patient with every other patient in the alternative treatment group in a pairwise manner. Subgroup analyses explored smoking status as a potential effect modifier at 4 months.

Results: Of 1079 participants, 741 had EQ-5D data available, yielding 137,114 pairwise comparisons. SHS was superior to CS in 65,158 (47.5%) comparisons, inferior to CS in 63,378 (46.2%) comparisons, and tied in 8578 (6.3%), leading to a win ratio of 1.03 (95% CI: 0.86–1.23), but this difference was not statistically significant ($p = 0.76$). Mortality (5.5% vs 7.3%), ambulation status (no problems walking: 18.3% vs 16.2%), and days at home (111.7 vs 111.0) were similar between groups. In the subgroup analysis, SHS was superior to CS in current smokers (win ratio 1.41, 95% CI: 0.92–2.17), but this difference was not statistically significant ($p = 0.09$).

Conclusion: This analysis approach should be considered for future orthopaedic trials as it was consistent with the FAITH primary analysis findings but yielded a more nuanced interpretation of composite data and offers deeper insights into intervention effectiveness. The bounds of the 95% CI meet many standard definitions of equivalence, suggesting surgeons can assume similar patient-important outcomes with either treatment.