41664. Neurosurgical Prospective Registry is an Alternative to the Randomized Controlled Trial

- Ephraim W. Church MD, Samer G. Zammar MD, Elias B. Rizk MD, Robert E. Harbaugh MD, Michael J. Glantz MD
- Department of Neurosurgery, Penn State Health
Disclosures

• None
Introduction

• Despite numerous resource-consuming randomized controlled trials (RCTs), widespread disagreement persists regarding many neurosurgical interventions.
• The flaws afflicting surgical RCTs (poor allocation concealment, lack of masked outcome assessment, idiosyncratic outcome measures, insufficient power) are increasingly recognized.
• Registry trials, which harness data collected in large prospective observational databases (PODs), are less expensive, more versatile, and can account for variables such as evolving technology and surgeon judgement and experience.
• Despite their increasing popularity, there exists no level of evidence grading scheme for registry studies.
• We propose a registry grading system analogous to those currently available for RCTs.
Methods

• We performed a systematic, evidence-based literature review of RCT grading schemes and registry guidelines.
• We then developed a registry grading scheme capable of differentiating quality (Class I to Class IV).
• We then applied our scheme to registry-based studies appearing in the neurosurgical literature over the last 12 months.
Results

• Numerous RCT grading schemes exist, but there is no comparable registry grading system.
• Like RCTs, registry studies can be evaluated for existence of a control group, equivalence between treatment arms, reliability of the outcome measure, and loss to follow up, but cannot be evaluated for randomization, allocation concealment, or use of an intention to treat model.
• High quality registry studies use clear and standardized outcomes, a quality control process, unbiased patient selection, and an articulated process for modifying the registry as knowledge accumulates.
• The large majority of registry studies in the current neurosurgical literature ignore many of these criteria and provide poor-quality evidence.
Summary

• POD-based registry trials are an increasingly popular response to the shortcomings and expense of surgical RCTs.
• We propose a simple, “automated” registry study grading calculator capable of analyzing the quality of a registry trial (class I to IV).
• High quality registry studies will powerfully advance the science of neurosurgical practice.