

The impact of resuscitative trauma research on clinical guideline development. CK Robinson, (MPH; MD, GS), AL Cralley MD, MJ Cohen, MD FACS, Dept. Surgery, University of Colorado, Denver, CO.

Traumatic injury is the leading cause of death in individuals <45 years. Clinical research in this population is challenging and few major advances in the treatment of trauma have been due to randomized clinical trials (RCTs). RCTs are the gold standard for evaluating practice change, however, the heterogeneity of trauma resuscitation results in few RCTs impacting clinical care guidelines (CCGs).

This critical analysis reviews RCTs that have been conducted in resuscitative medicine to determine if they have contributed to CCGs. Secondary objectives were to evaluate CCGs to determine if RCTs form the foundation for evidence-based medicine in trauma and determine the aspects of RCTs that increase the impact on guideline updates.

ClinicalTrials.gov was queried to identify RCTs. Trials were reviewed for inclusion based on primary outcome, and type and timing of intervention. Trials were scored based on degree of incorporation into CCGs. CCGs from ACS and EAST were used to determine the overall impact each trial had on advancing resuscitation guidelines. Guidelines were independently assessed to determine the basis of evidence for treatment recommendation.

RCTs in trauma impact CCGs significantly less than those in other practice areas. Different aspects of RCTs evaluated are in the table, with the probability of that aspect influencing CCGs. Two factors significantly correlate with the integration into CCGs: number of enrolled patients ($p=.002$) and number of publications ($p=.007$). CCGs are predominantly based on observational and retrospective research.

Resuscitative RCTs are failing to impact clinical practice. Characteristics of trial design may help to increase trial effectiveness. Improving development of RCTs and integration into CCGs will have a major impact on public health.

Table: Aspects of clinical trials related to overall effectiveness and probability of incorporation into practice guidelines.

Variable/Question	Hypothesis Test & Significance (sig. <.05)
Number of Participants vs. Overall Effectiveness	Logistic regression .002
Number of Publications vs. Overall Effectiveness	Logistic Regression .007
Intervention Type vs. Overall Effectiveness	Chi-squared (Fisher's Exact) .428
Intervention Model vs. Overall Effectiveness	Chi-squared (Fishers' Exact) .233