

The Impact of Resuscitative Trauma Research on Clinical Guideline Development

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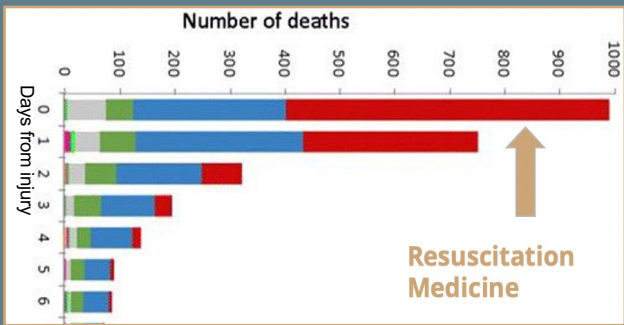
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“Regardless of the reasons cited for this phenomenon — structural, economic, or motivational — the result is the same: we are not reaping the full public health benefits of our investment in research.”

Background

Traumatic injury is **the leading cause of death** in individuals <45 years and costs society **\$143 billion** a year. Clinical research in this population is challenging and has resulted in limited treatment advances. Randomized control trials (RCTs) are the **gold standard** for evaluating practice change, however, the **heterogeneity of trauma** resuscitation results **limited impact on clinical care guidelines** (CCGs)



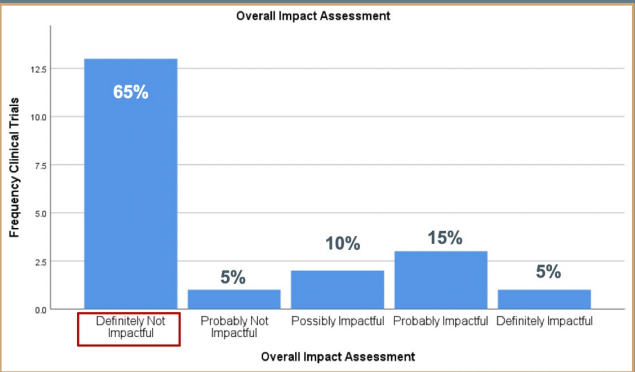
Purpose

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 design, conduction and collaboration that increase the impact on guideline updates.

Design	Badly Chosen	Surrogate Composite Subjective Complex Scales Lack of relevance to patients and decision makers
Methods	Badly Collected	Missing data Poorly Specified
Publication	Selectively reported	Publication Bias Reporting Bias Underreporting of Adverse events Switched Outcomes
Interpretation	Inappropriately interpreted	Relative measures Spin Multiplicity Core outcome sets

Methods

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, for example where they based on clinical trial or observational or retrospective research.



Results

Primary & Mortality Outcomes

20% reached significance
67% evaluated mortality as outcome
12.5% significantly impacted morality
Result Reporting

Better than average (**p<.05**)
No differences (**p>.05**)

Publication

50% of trials result in publication
Not significantly different (**p>.05**)

Clinical Development

54% fail in clinical development
Significantly less are incorporated (**p<.01**)

Conclusion: Resuscitative clinical trials impact clinical care guidelines **significantly less than those in other practice areas**. Characteristics and standardization of trial design help to increase impact on standards of treatment.

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 (Fisher's' Exact) .233