QUALITY OF PUBLISHED RANDOMIZED CONTROLLED TRIALS IN CRITICAL CARE MEDICINE: A SYSTEMATIC REVIEW
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Introduction: To help inform clinical decisions, intensivists rely on data from studies published in the medical literature, a combination of physiologic principles, and best medical judgment. When properly conducted, randomized controlled trials (RCTs) are considered to be among the most robust and informative medical evidence. RCTs of a weaker methodological quality are at increased risk of bias estimates of treatment effect. [1,2]

Objectives: The aims of this study are to evaluate the methodological quality of RCTs published in field of critical care medicine and to examine the relationship between specific journal characteristics and year of publication on methodological quality.

Methods: We performed a MEDLINE search of all critical care medicine RCTs published in the English language between 1998 and 2008. Of 1928 records, we randomly selected 182 RCT according to 3 journal categories: a) the 5 top ranked general medical journals; b) the 5 top ranked critical care journals; and c) journals not included in the first 2 categories. We then performed a descriptive methodological evaluation using 15 methodological items.

Results: Of our sample of 182 RCTs, 36.3% of RCTs were blinded, 43.4% had adequate allocation generation and 28.6% had adequate allocation concealment. 58.8% of studies provided a sample size justification and 58.2% provided an explicit definition of primary outcome. Only 39.6% of trials respected the intention to treat principle for the analysis of their primary outcome. For every pre-defined characteristic of methodological quality, the proportion of trials reports with adequate methodology was significantly higher for trials published among the 5 top ranked general medical journals, except for the use of blinding and pertaining to the complete assessment of data. There was no significant improvement in methodological quality over time.


Figure 1: Modified PRISMA flow-chart

Records identified through database searching (n = 1928) –> Records randomly excluded (n = 1325)