

Completion and Publication Rates of Randomized Controlled Trials in Surgery An Empirical Study

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Resumen

Objective: To investigate the prevalence of discontinuation and nonpublication of surgical versus medical randomized controlled trials (RCTs) and to explore risk factors for discontinuation and nonpublication of surgical RCTs.

Background: Trial discontinuation has significant scientific, ethical, and economic implications. To date, the prevalence of discontinuation of surgical RCTs is unknown.

Methods: All RCT protocols approved between 2000 and 2003 by 6 ethics committees in Canada, Germany, and Switzerland were screened. Baseline characteristics were collected and, if published, full reports retrieved. Risk factors for early discontinuation for slow recruitment and nonpublication were explored using multivariable logistic regression analyses.

Results: In total, 863 RCT protocols involving adult patients were identified, 127 in surgery (15%) and 736 in medicine (85%). Surgical trials were discontinued for any reason more often than medical trials [43% vs 27%, risk difference 16% (95% confidence interval [CI]: 5%-26%); P = 0.001] and more often discontinued for slow recruitment [18% vs 11%, risk difference 8% (95% CI: 0.1%-16%); P = 0.020]. The percentage of trials not published as full journal article was similar in surgical and medical trials (44% vs 40%, risk difference 4% (95% CI: -5% to 14%); P = 0.373).

Discontinuation of surgical trials was a strong risk factor for nonpublication (odds ratio = 4.18, 95% CI: 1.45-12.06; P = 0.008).

Conclusions: Discontinuation and nonpublication rates were substantial in surgical RCTs and trial discontinuation was strongly associated with nonpublication. These findings need to be taken into

account when interpreting surgical literature. Surgical trialists should consider feasibility studies before embarking on full-scale trials.

Palabras clave

Palabras clave de autor: discontinuation; publication; randomized controlled trial; recruitment

KeyWords Plus: CLINICAL-TRIALS; STOPPING

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