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

Por: Rosenthal, R (Rosenthal, Rachel)¹ ¹Rosenthal, Rachel); Kasenda, B (Kasenda, Benjamin)² ³Kasenda, Benjamin); Dell-Kuster, S (Dell-Kuster, Salome)¹ ²Dell-Kuster, Salome); von Elm, E (von Elm, Erik)⁴ Von Elm, Erik); You, J (You, John)⁵ ⁶You, John); Bluemle, A (Bluemle, Anette)⁷ Bluemle, Anette); Tomonaga, Y (Tomonaga, Yuki)⁸ Tomonaga, Yuki); Saccilotto, R (Saccilotto, Ramon)² R (Saccilotto, Ramon); Amstutz, A (Amstutz, Alain)¹² Amstutz, Alain); Bengough, T (Bengough, Theresa)⁴ Bengough, Theresa)²...Más

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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 TRIALS; EFFICACY; DISCONTINUATION; REASONS; BENEFIT; DESIGN

Información del autor

Dirección para petición de copias: Rosenthal, R (autor para petición de copias)

Dept Surg, Spitalstr 26, CH-4031 Basel, Switzerland.

Direcciones:

[ 1 ] Univ Basel Hosp, Dept Surg, CH-4031 Basel, Switzerland
[ 3 ] Univ Basel Hosp, Dept Oncol, CH-4031 Basel, Switzerland
[ 7 ] Univ Med Ctr Freiburg, German Cochrane Ctr, Dept Med Biometry & Med Informat, Freiburg, Germany
[ 8 ] Univ Zurich, Inst Social & Prevent Med, CH-8006 Zurich, Switzerland
[ 9 ] Univ Helsinki, Dept Publ Hlth, Helsinki, Finland
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[11 ] Univ Helsinki, Helsinki, Finland
[12 ] Pontificia Univ Catolica Chile, Dept Internal Med, Santiago, Chile
[13 ] Univ Chile, Fac Dent, Evidence Based Dent Unit, Santiago, Chile
[14 ] McMaster Univ, Dept Family Med, Hamilton, ON L8S 4L8, Canada
[16 ] Amer Univ Beirut, Dept Internal Med, Beirut, Lebanon
[17 ] SUNY Buffalo, Dept Med, Buffalo, NY 14260 USA
[18 ] Univ Childrens Hosp, Ctr Pediat Clin Studies, Dept Neonatol, Tubingen, Germany
[19 ] Univ Zurich Hosp, Div Neonatol, CH-8091 Zurich, Switzerland
[20 ] McMaster Univ, Dept Anesthesia, Hamilton, ON, Canada
- [21] McMaster Univ, Michael G DeGroote Inst Pain Res & Care, Hamilton, ON, Canada
- [22] Hosp Gen Valle Hebron, Dept Cardiol, Epidemiol Unit, Barcelona, Spain
- [23] CIBER Epidemiol & Salud Publ CIBERESP, Barcelona, Spain
- [24] Univ Sherbrooke, Ctr Rech Clin Etienne Le Bel, Sherbrooke, PQ J1K 2R1, Canada
- [25] Univ Sherbrooke, Dept Med, Sherbrooke, PQ J1K 2R1, Canada
- [26] Univ Hosp Bern, Inst Nucl Med, CH-3010 Bern, Switzerland
- [27] Univ Hosp Bern, Dept Clin Res, CH-3010 Bern, Switzerland
- [28] IRCCS, Orthoped Inst Galeazzi, Milan, Italy
- [29] Univ Toronto, Hosp Sick Children, Dept Anesthesia & Pain Med, Toronto, ON M5G 1X8, Canada
- [30] Univ Toronto, Inst Hlth Policy Management & Evaluat, Toronto, ON M5G 1X8, Canada
- [31] Stanford Univ, Dept Med, Stanford Prevent Res Ctr, Stanford, CA 94305 USA
- [32] Univ Basel Hosp, Acad Swiss Insurance Med, CH-4031 Basel, Switzerland
- [33] Sichuan Univ, West China Hosp, Chinese Evidence Based Med Ctr, Chengdu 610064, Peoples R China
- [34] Innlandet Hosp Trust Div Gjovik, Dept Med, Oppland, Norway
- [35] Norwegian Knowledge Ctr Hlth Serv, Oslo, Norway

**Direcciones de correo electrónico:** rachel.rosenthal@unibas.ch

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