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# An Assessment of Randomized Controlled Trial Quality in The Journal of Bone & Joint Surgery: Update from 2001 to 2013

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## Abstract

**Background:** The quality of reporting of randomized controlled trials (RCTs) published in The Journal of Bone & Joint Surgery (JBJS) from 1988 to 2000 was previously analyzed. The purpose of this current study was to analyze the quality of reporting of RCTs published in JBJS from 2001 to 2013 to identify trends over time and potential areas of improvement for future clinical trials.

**Methods:** A manual search of the JBJS database identified RCTs published between January 2001 and December 2013. Quality assessments, using the Detsky quality-of-reporting index (Detsky score), a modified Cochrane risk-of-bias tool, and abstraction of relevant data identifying predictors of quality, were conducted.

**Results:** A total of 5,780 publications were identified in JBJS from 2001 to 2013, with 285 RCTs (4.9%), representing an increase from the prior 13-year period. The overall mean transformed Detsky score (and standard error) increased significantly ( $p < 0.001$ ) from  $68.1\% \pm 1.67\%$  to  $76.24\% \pm 0.72\%$ . The percentage of multicenter RCTs decreased from 67% to 31%. The percentage of positive trials also decreased from 80% to 50.5%, as did the mean sample size (212 to 166). Regression analysis indicated that trials with an epidemiologist as the first author and nonsurgical trials were significantly associated ( $p = 0.001$ ) with a higher overall trial quality score. The categories of the lowest mean methodology scores were randomization and concealment, eligibility criteria, and reasons for patient exclusion, as identified with the Detsky score, and patient and assessor blinding, as identified with the risk-of-bias assessment.

**Conclusions:** The quantity and quality of published RCTs in JBJS have increased in the 2001 to 2013 time period compared with the previous time period. Although these improvements are encouraging, trends to smaller, single-center trials were also observed. To efficiently determine the efficacy of orthopaedic treatments and limit bias, high-quality randomized trials of appropriate sample size and rigorous design are needed.

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