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Review

# Volume and methodological quality of randomized controlled trials in laparoscopic surgery: assessment over a 10-year period

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## Abstract

**BACKGROUND:** Measures have been taken to improve methodological quality of randomized controlled trials (RCTs). This review systematically assessed the trends in volume and methodological quality of RCTs on minimally invasive surgery within a 10-year period.

**DATA SOURCES:** RCTs on minimally invasive surgery were searched in the 10 most cited general surgical journals and the 5 most cited journals of laparoscopic interest for the years 2002 and 2012. Bibliometric and methodological quality components were abstracted using the Scottish Intercollegiate Guidelines Network. The pooled number of RCTs from low-contribution regions demonstrated an increasing proportion of the total published RCTs, compensating for a concomitant decrease of the respective contributions from Europe and North America. International collaborations were more frequent in 2012. Acceptable or high quality RCTs accounted for 37.9% and 54.4% of RCTs published in 2002 and 2012, respectively. Components of external validity were poorly reported.

**CONCLUSIONS:** Both the volume and the reporting quality of laparoscopic RCTs have increased from 2002 to 2012, but there seems to be ample room for improvement of methodological quality.


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Evidence-based medical practice entails that physicians make research-informed decisions. Meta-analyses and randomized controlled trials (RCTs) occupy the highest rank in the pyramid of evidence and are significant components of quality

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practice guidelines.[1] The medical community expects that measures are taken to minimize sources of bias in clinical research and to adequately report on methodological components.[2] Several assessment tools and algorithms have developed for this purpose. The Preferred Reporting Items in Systematic reviews and Meta-Analyses guidelines and the Consolidated Standards of Reporting Trials (CONSORT) initiative may be the most popular assessment tools for systematic reviews and RCTs, respectively.[3,4] A significant improvement in reporting quality has been observed among several disciplines, including general surgery, anesthesia, and intensive care medicine, although fields of further improvement have been identified.[5–7] Compliance with the CONSORT standards has been suggested as a factor of quality improvement in published RCTs.[8] A plethora of publications and an active endorsement of medical journal editors to comply with standards of reporting and methodological quality have contributed to a paradigm shift in medical publishing.

A systematic assessment of the trends of methodological quality of laparoscopic RCTs is lacking. Novel technological advances and the evolution of innovative techniques and approaches and the implementation of the findings of RCTs in clinical practice render such an approach essential. We hypothesized that the volume and methodological quality of RCRs in laparoscopic surgery would demonstrate an increasing trend through time, similar to other medical disciplines. This systematic review aims to evaluate the volume and methodological quality of RCTs in laparoscopic surgery within a 10-year period.

## Methods

### Study protocol

A protocol was established in a consensus meeting of members of the author team before initiation of the study. The primary author was responsible for the design of the study, and author team members proposed modifications, which were implemented when agreement was reached. This review conforms to the Preferred Reporting Items for Systematic reviews and Meta-Analyses statement standards.[3]

### Search of journal contents

Two independent investigators performed the literature search. For the purpose of the study, 10 journals with the highest impact factors according to the Thomson Reuters Journal Citation Report 2012 in the field of general surgery and the five highest impact factor minimally invasive surgery journals were selected: Annals of Surgery; The British Journal of Surgery; Journal of the American College of Surgeons; JAMA Surgery; Surgical Endoscopy; Surgery; Obesity Surgery; American Journal of Surgery; Journal of Gastrointestinal Surgery; International Journal of Colorectal Disease; World Journal of Surgery; Minimally Invasive Therapy & Allied Technologies; Journal of Laparoendoscopic & Advanced Surgical Techniques; Surgical Laparoscopy, Endoscopy & Percutaneous Techniques; and Journal of the Society of Laparoendoscopic Surgeons. The PubMed interface was used for the search of articles of interest because all journals were abstracted in MEDLINE. Relevant RCTs were searched using the filter "Randomized Controlled Trial" for the years 2002 and 2012.

### Inclusion and exclusion criteria

As per protocol, RCTs on laparoscopic, robotic, transluminal endoscopic, minimally invasive thyroid and parathyroid surgery were included. Studies on colonoscopy, esophagogastroscopy, and endoscopic transurethral procedures were excluded. No further inclusion or exclusion criteria were applied.

### Quality assessment

The Scottish Intercollegiate Guidelines Network (SIGN) checklist for controlled trials was used for quality assessment of the selected articles. This tool is organized into 13 components for evaluation of the internal and the external validity of the trial. Potential answers are "yes," "no," "can't say," and "does not apply." Based on this assessment, the study is characterized as "high quality," "acceptable," or "unacceptable–reject". Specific assessment of external validity was performed using five additional questions: (1) Does the study provide adequate details of the surgical intervention to allow reproducibility? (2) Does the study provide adequate details on preoperative care to allow reproducibility? (3) Does the study provide adequate details on postoperative care to allow reproducibility? (4) Does the study provide adequate information on the experience level of participating surgeons with the reported procedure? and (5) Does the study provide information on the case volume of the participating center(s)? Cohen's $\kappa$ coefficient was used to evaluate inter-rater agreement of the two assessors for 15% of the RCTs. The assessment was planned to be undertaken by a single reviewer, if moderate or high level of agreement would be evident ($\kappa > .41$).

### Data extraction and statistical analysis

The primary author's name, year of publication, journal of publication, bibliometric data, including title word count, number of authors, number of participating centers, country, and continent where the trial was conducted, interdisciplinarity, number of pages, and number of references; and study assessment data according to the SIGN checklist and the additional questions related to external validity were abstracted into an electronic datasheet using Microsoft Access. The spreadsheet was extracted to SPSS 18.0 (SPSS Inc, Chicago, IL), which was used for statistical analysis. Various RCT characteristics were summarized using descriptive statistics. Comparisons were made using the Pearson's