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A Systematic Review and Analysis of Factors Associated with Methodological Quality in Laparoscopic Randomized Controlled Trials

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Key Words
Methodological quality · Reporting quality · CONSORT · Randomized trial · Laparoscopy · Minimally invasive surgery

Abstract
Several methods for assessment of methodological quality in randomized controlled trials (RCTs) have been developed during the past few years. Factors associated with quality in laparoscopic surgery have not been defined till date. The aim of this study was to investigate the relationship between bibliometric and the methodological quality of laparoscopic RCTs. The PubMed search engine was queried to identify RCTs on minimally invasive surgery published in 2012 in the 10 highest impact factor surgery journals and the 5 highest impact factor laparoscopic journals. Eligible studies were blindly assessed by two independent investigators using the Scottish Intercollegiate Guidelines Network (SIGN) tool for RCTs. Univariate and multivariate analyses were performed to identify potential associations with methodological quality. A total of 114 relevant RCTs were identified. More than half of the trials were of high or acceptable quality. Half of the reports provided information on comparative demographic data and only 21% performed intention-to-treat analysis. RCTs with sample size of at least 60 patients presented higher methodological quality ($p = 0.025$). Upon multiple regression, reporting on preoperative care and the experience level of surgeons were independent factors of quality.

Introduction

The concept of laparoscopic surgery has evolved from the 1970s but it has gained popularity in the field of general surgery only during the past two decades [1]. Reduction of the surgical scar has been shown not only to provide improved cosmetic results but also to decrease surgical stress and inflammatory response [2–5]. Furthermore, laparoscopy view allows for detailed operative view and facilitates precision in surgical fields difficult to access, such as the esophageal hiatus and the pelvis. Nonetheless, the penetration of a wide spectrum of laparoscopic procedures in the surgical community has been low, mainly due to the steep learning curve of advanced procedures

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and the scarcity of high-quality evidence in several domains [6–12].

During the same time as the evolution of minimally invasive surgery, the scientific community has identified shortcomings in the design, conduction, implementation and reporting of randomized controlled trials (RCTs) [13]. Several tools have been developed with the objective to improve these parameters and to provide a platform for the production of high-quality RCTs, such as the Jadad scale, the CONSORT checklist and the Balas scale [14–16]. A recent systematic review of the surgical literature has identified variables associated with reporting quality, such as power calculation, random sequence and length of article [17]. Similar reports are available in the fields of oncology, intensive care medicine, orthopedics and anesthesia, among others [18–21]. Such an assessment in the field of laparoscopic surgery is lacking. The development of novel concepts and technologies, such as robotics, single incision laparoscopic surgery and natural orifice transluminal surgery suggest a continuing evolvement of minimally invasive techniques. Adequate quality of related evidence may be considered a prerequisite and a decisive factor for the safe and effective dissemination of laparoscopic techniques.

The present systematic review was conducted with the objective to identify bibliometric data and study characteristics associated with methodological and reporting quality as assessed by the Scottish Intercollegiate Guidelines Network (SIGN) tool for RCTs, in the field of minimally invasive surgery.

Materials and Methods

A protocol was constructed by the author team after manual literature review and presentation of relevant published data by the primary author. The study conformed to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement standards [22].

Literature Search

The literature search was performed by two independent investigators. Ten journals with the highest impact factors according to the Thomson Reuters Journal Citation Report 2012 in the field of general surgery, and the 5 highest impact factor journals with focus on minimally invasive surgery were included: Ann Surg; Br J Surg; J Am Coll Surg; JAMA Surg; Surg Endosc; Surgery; Obes Surg; Am J Surg; J Gastrointest Surg; Int J Colorectal Dis; World J Surg; Minim Invasive Ther Allied Technol; J Laparoendosc Adv Surg Tech A; Surg Laparosc Endosc Percutan Tech; JSLS. The contents of all included journals are indexed in Medline, and thus the PubMed search engine was used to search for relevant articles. The filter 'Randomized Controlled Trial' was employed to identify RCTs from the selected journals for the year 2012.

Inclusion and Exclusion Criteria

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

Quality Assessment and Inter-Rater Agreement

The Scottish Intercollegiate Guidelines Network (SIGN) checklist for controlled trials was used for quality assessment of the selected articles [23]. This tool is organized into 13 domains – questions, which evaluate the internal and external validity of the study. Potential answers are 'yes', 'no', 'can't say' and 'does not apply'. Based on this assessment, the study is considered 'high quality', 'acceptable' or 'unacceptable – reject'.

A specific assessment of external validity was performed using a relevant question of the SIGN checklist ('results directly applicable to the patient group targeted') and 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 κ 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 assessor, if moderate or high agreement would be evident ($\kappa > 0.41$).

Data Extraction and Statistical Analysis

The primary author's name, year of publication, journal of publication and study assessment data according to the SIGN checklist were abstracted into an electronic datasheet using Microsoft Office Access. The following data were then extracted from each article: country of publication, continent, number of countries, number of participating centers, number of words in title, number of authors, reporting of interdisciplinarity, number of pages, number of references, sample size, funding and domain. Upon completion, the data were exported to SPSS 21.0 (SPSS Inc., Chicago, Ill., USA), which was used for statistical analysis. Various RCT characteristics were summarized using descriptive statistics. Continuous variables were presented as median (range). Univariate comparisons between quality of the study (acceptable/non-acceptable) and RCT characteristics were performed using Pearson's Chi-square test of independence and the non-parametric Mann-Whitney test. Multiple logistic regression with dependent variable the study quality (acceptable/non-acceptable) and independent variables various RCT characteristics was performed, if the p value at univariate analysis was lower than 0.1. Data processing and statistical analyses were performed by an independent statistician. Statistical significance was set at a p value of 0.05.

Results

Search Results

The electronic search of the Medline database retrieved 278 results. A total of 150 articles did not meet the inclusion

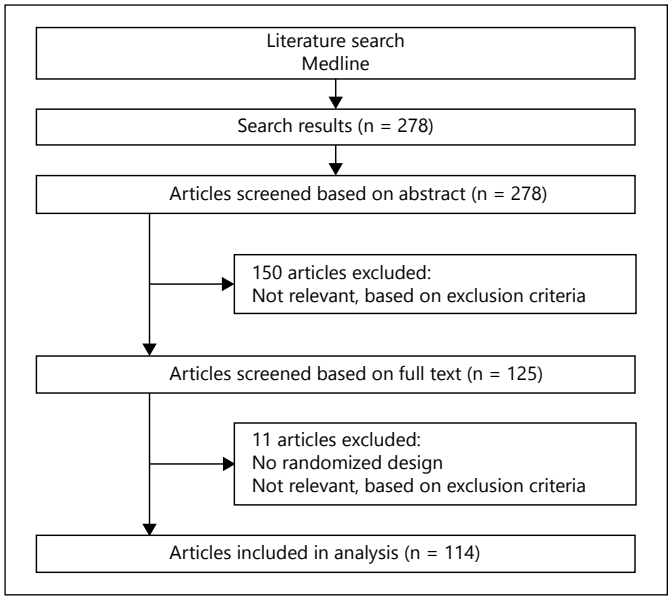

Fig. 1. Flow chart of search history.

Table 1. Distribution of published RCTs among journals

Journal	No. of RCTs
Surg Endosc	49
Ann Surg	11
Surg Laparosc Endosc Percutan Tech	11
Br J Surg	8
J Laparoendosc Adv Surg Tech A	8
Am J Surg	6
J Gastrointest Surg	6
Obes Surg	5
World J Surg	3
Minim Invasive Ther Allied Technol	2
JSLS	2
Surgery	1
J Am Coll Surg	1
Int J Colorectal Dis	1
Total	114

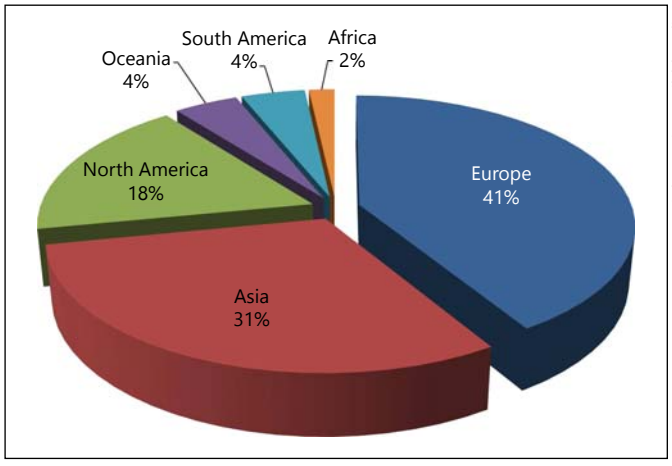

Fig. 2. Continent of origin of laparoscopic RCTs.

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criteria based on their title and abstract. The remaining 125 full-text articles were assessed for eligibility. Eleven articles did not report on a randomized study design or reported on gastrointestinal endoscopy and were therefore discarded, leaving a total of 114 RCTs for further assessment. The study selection process is outlined in the flow chart of figure 1.

Inter-Rater Agreement

The percentage of inter-rater agreement was 75%, with a κ-value of 0.5 (95% confidence interval (CI) 0.304–0.696), suggesting moderate inter-rater agreement. Further assessment of RCTs was undertaken by a single author.

Study Characteristics and Quality Assessment

The majority of RCTs was published in Surg Endosc (43%), followed by Ann Surg (9.7%) and Surg Laparosc Endosc Percutan Tech (9.7%); Br J Surg (7%) and J Laparoendosc Adv Surg Tech A (7%) (table 1). European countries were the most prolific, contributing 41% of RCTs (n = 47). Asia (35, 31%) and North America (20, 18%) ranked second and third, respectively (fig. 2).

Eighty-eight percent of studies were conducted in one country, whereas 12% were international initiatives. Multicenter studies represented the minority of published RCTs accounting only for 17% of the total number of studies. About half of the RCTs (56%) followed an interdisciplinary approach.

Biliary surgery was the most common domain (22%), followed by colorectal surgery (19%), laparoscopic training (18%), bariatric (10%) and antireflux surgery (10%) (table 2). No difference was noted when domains related to basic laparoscopic procedures (biliary, gastroesophageal reflux disease, spleen, hernia) and domains related to advanced laparoscopic procedures (esophageal, robotics, gastric, bariatric) were pooled (p = 0.468). Information on whether the study was funded and the respective funding sources was provided by 35% of the RCTs. No difference in quality was evident between studies that were funded or not funded (p = 0.923). National authorities were the main source of funding among studies that provided relevant data (55%), followed by the industry (18%) and scientific societies (15%) (fig. 3).

Table 2. Distribution of published RCTs among domains

Domain	No. of RCTs
Biliary	25
Colorectal	22
Training	21
Bariatric	11
GERD	11
Hernia	7
Gastric	4
Esophageal	1
Robotics	1
Spleen	1
Other	11
Total	114

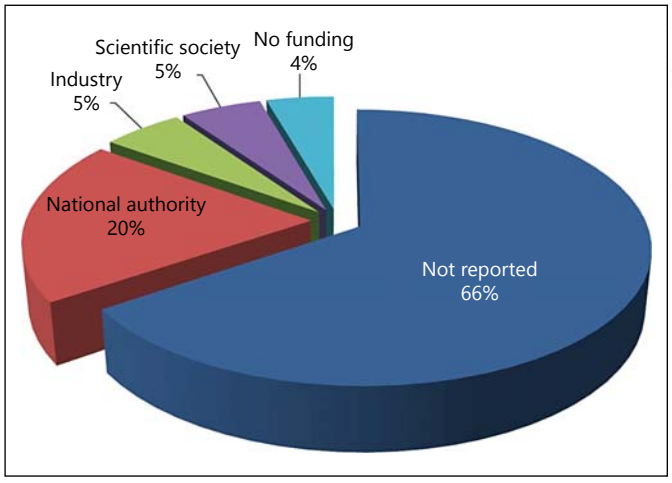

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Fig. 3. Source of funding of laparoscopic RCTs.

The number of authors ranged between 1 and 42 (median 6, $Q_1 = 5$, $Q_3 = 8$), the sample size between 10 and 794 (median 60, $Q_1 = 39$, $Q_3 = 101$), and the number of references between 8 and 49 (median 26, $Q_1 = 20$, $Q_3 = 34$). More than half of the RCTs were of acceptable (39%) or of high quality (16%), whereas 46% were regarded as of insufficient quality. Table 3 presents the association between individual SIGN domains and overall quality.

Univariate and Multivariate Analyses

Neither the number of countries nor the number of participating centers was associated with study quality. No association between bibliometric characteristics and quality was observed. The median split (n = 60) was used for the consideration of the independent variable sample size as categorical; RCTs reporting on a sample size of more than 60 patients presented higher methodological quality (p = 0.025). Three of 6 questions related to external validity were associated with quality on univariate analysis. A backward linear regression analysis was performed, removing insignificant independent variables

Table 3. Univariate analysis of individual SIGN domains and overall quality (acceptable/unacceptable)

	Unacceptable n (%)	Acceptable n (%)	p value
Appropriate and clearly focused question			0.461
No	6 (37.5)	10 (62.5)	
Yes	46 (47.4)	51 (52.6)	
Randomized			–
No	0 (0)	0 (0)	
Yes	52 (100)	62 (100)	
Adequate concealment method			<0.0001
No	47 (62.7)	28 (37.3)	
Yes	5 (12.8)	34 (87.2)	
Subjects and investigators blinding			0.001
None	43 (55.8)	34 (44.2)	
Both	2 (10)	18 (90)	
Only one of each	7 (41.2)	10 (58.8)	
Groups similar at the start of the trial			<0.0001
No	39 (69.6)	17 (30.4)	
Yes	13 (22.4)	45 (77.6)	
Only difference between groups is the treatment			<0.0001
No	34 (81)	8 (19)	
Yes	18 (25)	54 (75)	
Outcomes measured in standard valid and reliable way			<0.0001
No	14 (87.5)	2 (12.5)	
Yes	38 (38.8)	60 (61.2)	
Percentage of dropouts			–
Not reported	34 (66.7)	17 (33.3)	
<20	15 (26.3)	42 (73.7)	
≥20	3 (50)	3 (50)	
Intention to treat analysis			<0.0001
Does not apply	9 (24.3)	28 (75.7)	
No/can't say	41 (67.2)	20 (32.8)	
Yes	2 (12.5)	14 (87.5)	
Results comparable for all sites			–
Does not apply	45 (46.9)	51 (53.1)	
No/can't say	7 (43.8)	9 (56.3)	
Yes	0 (0)	2 (100)	
Overall effect due to study intervention			<0.0001
No/can't say	41 (69.5)	18 (30.5)	
Yes	11 (20)	44 (80)	
Results directly applicable to the patient group targeted			<0.0001
No/can't say	16 (100)	0 (0)	
Yes	36 (36.7)	62 (63.3)	

one by one. Three variables were found to independently predict study quality: applicability to patient group targeted (regression coefficient 0.56, 95% CI 0.33–0.79); reporting on preoperative care (regression coefficient 0.26, 95% CI 0.06–0.47); and reporting on experience level of surgeons (regression coefficient 0.31, 95% CI 0.12–0.50). Results of univariate and multiple regression analyses are presented in table 4.

Discussion

The present analysis identified factors associated with reported methodological quality in laparoscopic RCTs. Methodological shortcomings of surgical trials may be influenced by various factors. Time constraints of clinicians may result in non-rigorous methodological approaches. Implementation of clinical trials by dedicated clinical researchers, participation of research assistants and adequate education of participants in research quality might improve methodological rigorousness. Such measures are also related to research funding, which may be inadequate or depend on industry sponsors, thereby imposing a potential source of bias. Scientific societies, national and international authorities may play a more active role in planning and sponsoring trial projects. Internal factors associated with methodological insufficiency are related to lack of surgical equipoise and poor awareness of alternative therapeutic approaches, which may be overcome by continuing medical education, involving modern principles of evidence-based medicine. Shortcomings in reporting quality are independent from those factors and may be improved by efficient dissemination and subsequent incorporation of reporting guidelines, such as the CONSORT statement. Consideration of trial and protocol registration as a prerequisite for publication in peer-reviewed journals is a step toward improved reporting quality of surgical trials.

It is noteworthy, that dimensions of external validity, namely reporting on surgeons' experience and details on perioperative care were identified as significant factors of quality, although these elements are not included in commonly used assessment tools of RCTs [14–16]. In the ever-evolving field of minimally invasive surgery, the presence of surgical expertise in the implementation of RCTs might bias outcomes and be potentially harmful when extrapolating clinical evidence into surgical practice. Considering that RCTs are a major component of the evidence basis of clinical guidelines, reporting of the level of available surgical experience in laparoscopic RCTs might help developing user-focused, objective clinical guidelines. The development of an ad hoc guide for laparoscopic clinical trials of interventions, or a modification of currently existing platforms, such as the CONSORT checklist that would include dimensions of external validity might be reasonable.

Information on perioperative care was another factor associated with quality in the present analysis. Details on perioperative care, such as antibiotic prophylaxis, bowel preparation, bladder catheterization and muscle relaxation might as well have an impact on operative morbidity and surgical outcomes. Furthermore, information on postoperative care, including details on analgesia, patient mobilization and drain removal, allow for reproducibility of clinical trials and implementation of evidence into clinical practice. Perioperative care may also be underappreciated in assessment tools of RCTs, usually being included in the generic domain of external validity.

This systematic review further demonstrates that geographic origin and study design data of laparoscopy RCTs are not different than those in general surgery. The distribution of RCTs among regions approaches that of general surgical RCTs [24]. European countries were the most productive, followed by Asia and North America. The proportion of international studies is also similar; however, there seems to be a different trend in the conduction of multicenter trials. Although 40% of RCTs in general surgery were multicentric in 2009, the respective proportion in laparoscopic RCTs was only 18% in 2012 [24]. Collaborative works have been recently endorsed by associations of endoscopic surgery worldwide and are expected to improve quality of novel evidence, considering that power calculation and sample size have also been identified as factors predicting reported methodological quality [17].

The funding source was not reported in a great proportion of laparoscopic RCTs. Although this finding concurs with the paradigm of general surgical RCTs, the proportion of industry-sponsored laparoscopic studies (5%) is significantly less than the reported proportion in general surgery (25%) [17]. This might have two possible explanations; either the reported percentages are pragmatic and medical industry preferably sponsors general surgical trials rather than laparoscopic trials, or the results are biased by the proportion of laparoscopic RCTs published in different journals, several of which may or may not presuppose declaration of the source of funding. Nevertheless, national authorities fund a large proportion of laparoscopic RCTs, whereas scientific societies seem to be more stagnant in these terms.

Table 4. Correlation of bibliometric characteristics, study characteristics and attributes of external validity with methodological quality on univariate and multivariate analysis

	Univariate			Multiple regression	
	unacceptable n (%)	acceptable n (%)	p value	regression coefficient (95% confidence interval)	p value
Continent			–	–	–
Asia	8 (22.9)	27 (77.1)			
North America	11 (55.0)	9 (45.0)			
Europe	25 (53.2)	22 (46.8)			
South America	5 (100)	0 (0)			
Oceania	3 (60)	2 (40)			
Africa	0 (0)	2 (100)			
Number of countries			0.355	–	–
One	44 (44.0)	56 (56.0)			
Two or more	8 (57.1)	6 (42.9)			
Number of centers			0.579	–	–
Single centered	44 (46.8)	50 (53.2)			
Two or more centers	8 (40.0)	12 (60.0)			
Number of words in title*	16 (6–27)	15 (5–28)	0.884	–	–
Number of authors*	6 (3–42)	6 (1–13)	0.601		
Interdisciplinarity			0.430		
Yes	48 (49)	50 (51)			
No	45 (54.9)	37 (45.1)			
Number of pages*	7 (3–10)	7 (3–14)	0.679	–	–
Number of references	25.5 (9–48)	25 (8–49)	0.789		
Sample size*	53.5 (10–794)	79 (18–220)	0.083		
Sample size			0.025	0.16 (–0.01–0.33)	0.058
0–59	54 (60.0)	36 (40.0)			
≥60	39 (43.3)	51 (59.7)			
Funding			–	–	–
Not reported	34 (45.9)	40 (54.1)			
Scientific society	3 (50)	3 (50)			
National authority	7 (31.8)	15 (68.2)			
Industry	5 (71.4)	2 (28.6)			
No funding	3 (60)	2 (40)			
Domain			–	–	
Billiary	8 (32)	17 (68)			
Esophageal	1 (100)	0 (0)			
Robotics	0 (0)	1 (100)			
Training	14 (66.7)	7 (33.3)			
Colorectal	9 (40.9)	13 (59.1)			
Gastric	0 (0)	4 (100)			
Bariatric	7 (63.6)	4 (36.4)			
GERD	7 (63.6)	4 (36.4)			
Hernia	2 (28.6)	5 (71.4)			
Spleen	1 (100)	0 (0)			
Other	3 (30)	7 (70)			
Results directly applicable to the patient group targeted[†, ‡]			<0.0001	0.56 (0.33–0.79)	<0.0001
No/can't say	16 (100)	0 (0)			
Yes	36 (36.7)	62 (63.3)			
Details of surgical intervention[†, ‡]			0.287	–	–
No	20 (52.6)	18 (47.4)			
Yes	32 (42.1)	44 (57.9)			
Preoperative care[†, ‡]			0.001	0.26 (0.06–0.47)	0.012
No	40 (58)	29 (42)			
Yes	12 (26.7)	33 (73.3)			

Table 4. (continued)

	Univariate			Multiple regression	
	unacceptable n (%)	acceptable n (%)	p value	regression coefficient (95% confidence interval)	p value
Postoperative care†, ‡			0.006	0.01 (0.21–0.23)	0.928
No	44 (53.7)	38 (43.6)			
Yes	8 (25)	24 (75)			
Experience level of surgeons†, ‡			0.068	0.31 (0.12–0.50)	0.001
No	43 (50.6)	42 (49.4)			
Yes	9 (31)	20 (69)			
Case volume of participating centers†			0.499	–	–
No	52 (46.4)	60 (53.6)			
Yes	0 (0)	2 (100)			

* Median values (min.–max.).
† Attributes of external validity.
‡ Overall likelihood ratio χ^2 (d.f. = 4) 19.60, p = 0.0006; pseudo R^2 = 0.1247, based on 114 observations.
Overall likelihood ratio χ^2 (d.f. = 5) 10.44, p < 0.0001; adjusted R^2 = 0.2946, based on 114 observations.

Fifty-five percent of RCTs were considered of adequate quality in the present analysis. In a similar assessment of RCTs published between 2001 and 2010 in the field of intensive care medicine, only 30% of trials were graded with a Jadad score of 3 or more [19]. Similarly, 25% of reports in the field of traumatic and orthopedic surgery were considered of acceptable quality, as defined by fulfilling more than 12 CONSORT items [21].

Although almost half of the trials were of acceptable quality, individual SIGN components were not satisfied by a significant proportion of RCTs. The majority of studies (61%) did not report on whether a blinding approach was applied and 84% of the remaining trials were patient-blinded, assessor-blinded or double blind. Only 34% reported on an adequate concealment method. Only half of the reports provided comparative demographic information of the trial arms and only 21% reported on an intention-to-treat analysis method, a similar proportion reported for RCTs in the field of intensive care medicine [19]. Furthermore, from the 18 multicenter trials, only 2 provided comparative outcomes for the participating centers.

The results of the present analysis are constrained by inherent study design limitations. Although the highest impact factor Medline-listed laparoscopic journals and the ten highest impact surgical journals were considered, a number of laparoscopic RCTs are published in several non-surgical or lower impact journals. Furthermore, the selection of articles was performed by two authors, who undertook an independent quality assessment. Inter-rater agreement was only moderate as indicated by the κ-value, which might challenge the objectivity of assessment by a single author. Nevertheless, a meticulous search approach was followed, which relied on a pre-specified protocol. The assessors provided blinded assessments of randomly selected articles, whereas statistical analysis was performed by an independent biostatistician.

Conclusion

There is a need for further improvement of reporting and methodological quality in laparoscopic RCTs. The development of an evidence-based guidelines tool for researchers interested in the conduction and implementation of RCTs might reduce associated bias. Important factors of external validity need to be taken into account, especially in the constantly evolving field of laparoscopic surgery.

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Conflicts of Interest

None.

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