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REVIEW

Reporting and Methodological Quality of Randomised Controlled Trials in Vascular and Endovascular Surgery

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WHAT THIS PAPER ADDS

As far as is known, no study has specifically evaluated the methodological and reporting quality of randomised controlled trials (RCTs) in vascular and endovascular surgery. The findings of this study are novel in vascular and endovascular surgery which highlight the need for better compliance of clinicians, researchers, journal editors, reviewers and the industry involved in studies to the reporting and methodological standards in future RCTs.

Background: Randomised controlled trials (RCTs) are subject to bias if they lack methodological quality. Moreover, optimal and transparent reporting of RCT findings aids their critical appraisal and interpretation.
Objectives: The aim of this study was to ascertain whether the methodological and reporting quality of RCTs in vascular and endovascular surgery is improving.
Methods: The most recent 75 and oldest 75 RCTs published in leading journals over a 10-year period (2003–2012) were identified. The reporting quality and methodological quality data of the old and new RCTs were extracted and compared. The former was analysed using the Consolidated Standards of Reporting Trials (CONSORT) statement, the latter with the Scottish Intercollegiate Guidelines Network (SIGN) checklist.
Results: Reporting quality measured by CONSORT was better in the new studies than in the old studies (0.68 [95% CI, 0.66–0.7] vs. 0.60 [95% CI, 0.58–0.62], $p < .001$); however, both new and old studies had similar methodological quality measured by SIGN (0.9 [IQR 0.1] vs. .09 [IQR: 0.2], $p = .787$). Unlike clinical items, the methodological items of the CONSORT statement were not well reported in old and new RCTs. More trials in the new group were endovascular related (33.33% vs. 17.33%, $p = .038$) and industry sponsored (28% vs. 6.67%, $p = .001$).
Conclusions: Despite some progress, there remains room for improvement in the reporting quality of RCTs in vascular and endovascular surgery. The methodological quality of recent RCTs is similar to that of trials performed >10 years ago.

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INTRODUCTION

Randomised controlled trials (RCTs) are the gold standard to compare the effectiveness of different interventions, if designed, conducted, and reported appropriately.[1] The communication of knowledge, exchange of information, and the evolution of research-informed healthcare entails that both patients and physicians are expected to make informed decisions based on best available evidence.[2] RCTs are subject to bias if they lack methodological quality. This, in turn, may impair the quality of systematic reviews and meta-analyses.[3] For accurate assessment of a trial, readers should be provided with complete, clear, and transparent information on its methodology and findings.[4]

Surgical RCTs are particularly subject to bias because of difficulties associated with blinding, recruitment, and crossover problems, differential placebo effects, type II errors, learning curves, poor internal and external validity, low sample size leading to inadequately powered studies, the logistics of investigating uncommon conditions, and

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emergency surgery.[5] Therefore, optimal reporting of surgical RCTs is extremely important in order to allow for interpretation of potential bias.

The Consolidated Standards of Reporting Trials (CONSORT) statement was developed by an international group of clinical trialists, statisticians, epidemiologists, and biomedical editors in response to concerns about suboptimal reporting of RCTs.[6] The CONSORT statement aims to facilitate complete and transparent reporting of RCT findings and aid their critical appraisal and interpretation.[7] The CONSORT statement was first published in 1996[8] and revised in 2001[9] and 2010[10] to incorporate new elements. The statement, which now consists of a 25-item checklist,[10] has been supported by the World Association of Medical Editors, the International Committee of Medical Journal Editors, the Council of Science Editors, and a significant number of journals worldwide,[11] and has resulted in improvement in the overall quality of RCT reporting.[12,13] In addition to the CONSORT statement, some authors have also suggested design and reporting standards for RCTs.[14,15]

Suboptimal reporting quality of RCTs in general surgery, cardiothoracic surgery, urology, and plastic surgery has been reported previously.[5,16–18] In addition, a recent systematic review reported inadequate compliance to the CONSORT statement in surgical RCTs.[19] Although there has been promising evidence[20] regarding improvement in the reporting quality of surgical RCTs since the development of the CONSORT statement, there remains much room for improvement. To our knowledge, no study has specifically evaluated the methodological and reporting quality of RCTs in vascular and endovascular surgery.

In this study we aimed to compare the reporting quality, measured by the CONSORT statement, and methodological quality, measured by the Scottish Intercollegiate Guidelines Network (SIGN) checklist, between old and new RCTs in vascular and endovascular surgery published in leading journals over a 10-year period.

METHODS

Literature search strategy

Medical journals were ranked from the "surgery" and "medicine, general, and internal" categories of journals established by the Institute of Scientific Information's Journal Citation Report (ISI-JCR). The 2012 JCR Science Edition was used. Three leading journals in vascular and endovascular surgery, four major journals of general surgery, and another four major journals in medicine with the highest impact factor were identified and selected as the data sources: *Journal of Vascular Surgery* (impact factors 2012/13: 2.88/2.98), *European Journal of Vascular and Endovascular Surgery* (2.82/3.07), *Journal of Endovascular Therapy* (2.70/3.59); *Annals of Surgery* (6.33/7.19), *British Journal of Surgery* (4.84/5.21), *Journal of the American College of Surgeons* (4.50/4.45), *JAMA Surgery* (4.10/4.30); *New England Journal of Medicine* (51.66/54.42), *Lancet* (39.06/39.21), *Journal of the American Medical Association* (29.98/30.39), and the *British Medical Journal* (17.22/16.38).

All randomised controlled trials published in these journals during a 10-year period between 2003 and 2012 were identified. Searches were performed by a clinical information specialist (M.M.).

Study selection

Titles and abstracts identified through the literature search were screened by a single author (P.G.). The full texts of potentially included studies were retrieved and assessed for eligibility. The results of study selection were discussed with the entire group.

The eligible studies were ranked based on their publication date from the oldest to the most recent. For the purposes of our study, the 75 most recent studies and 75 oldest studies were selected and grouped as "new studies" and "old studies", respectively.

Eligibility criteria

Studies were considered eligible if (a) they were randomised controlled trials, defined as studies in which a number of similar people are randomly assigned to two (or more) groups to test a specific drug or treatment (the definition of the National Institute for Health and Care Excellence [NICE] was applied)[21]; (b) they assessed the effects of surgical or endovascular interventions for the treatment of extracranial carotid or vertebral artery disease, disease of the remainder of the supra-aortic vessels, aortoiliac disease, disease of the renal and visceral vessels, upper or lower extremity arterial disease, venous disease of the lower limbs (including the pelvis) and the upper limbs (including the thoracic outlet), and in vascular access for haemodialysis; (c) they focused on the diagnosis or screening of vascular disease affecting the aforementioned anatomical territories; (d) they assessed medical treatments for vascular disease in anatomical areas described above; (e) they were conducted in humans; and (f) they were published as full text articles. Pilot or phase I trials, those reporting subgroup analyses of previously published reports, and trials not conducted in patients, such as those examining healthy volunteers, human cadavers, or physician training, were excluded. In cases where more than one publication from a single trial existed, the primary publication only was selected for data extraction and analysis.

Data extraction

An electronic dataset was created by one author (G.A.). Additional potential items for extraction and analysis were discussed and defined in a round table forum. The database was pilot tested in 10 randomly selected articles and adjusted accordingly. Data extraction was undertaken by two independent authors (Shahin H. and Shahab H.) and checked for quality assurance by a third author (G.A.).

Table 1. Bibliomertric characteristics of included studies.

Year of publication	All studies[a] (%)	New studies[a] (%)	Old studies[a] (%)	p[b]
2012	20 out of 150 (13.33)	20 out of 75 (26.67)	—	—
2011	22 out of 150 (14.67)	22 out of 75 (29.33)	—	—
2010	33 out of 150 (22.00)	33 out of 75 (44.00)	—	—
2005	28 out of 150 (18.67)	—	28 out of 75 (37.33)	—
2004	28 out of 150 (18.67)	—	28 out of 75 (37.33)	—
2003	19 out of 150 (12.67)	—	19 out of 75 (25.33)	—
Journal				
Vascular surgery journals	115 out of 150 (76.67)	61 out of 75 (81.33)	54 out of 75 (72)	.247
Non-vascular surgery journals	35 out of 150 (23.33)	14 out of 75 (18.67)	21 out of 75 (28)	.247
Subject area				
Arterial related (%)	98 out of 150 (65.33)	44 out of 75 (58.67)	54 out of 75 (72.00)	.122
Venous related (%)	43 out of 150 (28.67)	27 out of 75 (36.00)	16 out of 75 (21.33)	.070
Vascular access (%)	9 out of 150 (6.00)	4 out of 75 (5.33)	5 out of 75 (6.67)	1.000
Endovascular-related study (%)	38 out of 150 (25.33)	25 out of 75 (33.33)	13 out of 75 (17.33)	.038
Title reporting study findings (%)	18 out of 150 (12)	7 out of 75 (9.33)	11 out of 75 (14.67)	.452
Study design reported in title (%)	118 out of 150 (78.67)	58 out of 75 (77.33)	60 out of 75 (80)	.842
Number of pages (IQR)	7 (3)	8 (2)	7 (3)	.121
Number of references (IQR)	25.5 (13)	27 (14)	25 (13)	.374
Continent (%)				
Europe	121 out of 150 (8.67)	62 out of 75 (82.67)	59 out of 75 (78.67)	.680
North America	24 out of 150 (16.00)	10 out of 75 (13.33)	14 out of 75 (18.67)	.505
Asia	1 out of 150 (.67)	1 out of 75 (1.33)	0	1.000
Australia	3 out of 150 (2.00)	2 out of 75 (2.67)	1 out of 75 (1.33)	1.000
Africa	0	0	0	1.000
South America	1 out of 150 (.67)	0	1 out of 75 (1.33)	1.000
Number of institutions (IQR)	1 (3)	1 (3)	1 (3)	.803
International collaboration (%)	15 out of 150 (10)	8 out of 75 (1.67)	7 out of 75 (9.33)	1.000
Open access (%)	118 out of 150 (78.67)	55 out of 75 (73.33)	63 out of 75 (84)	.162
External funding (%)	87 out of 150 (58)	43 out of 75 (57.33)	44 out of 75 (58.67)	1.000
Industry sponsored (%)	26 out of 150 (17.33)	21 out of 75 (28)	5 out of 75 (6.67)	.001
Sample size (IQR)	103 (142)	118 (140)	100 (223)	.651
Positive primary outcome (%)	111 out of 150 (74)	55 out of 75 (73.33)	56 out of 75 (74.67)	1.000

IQR: interquartile range.

[a] Median for continuous data and proportions for binomial data.

[b] Mann—Whitney test and Fisher exact test were used for comparison of medians and proportions, respectively (confidence level: 95%).

Reporting quality data

Compliance of the selected trials with the CONSORT statement, was assessed by two independent authors (Shahin H. and Shahab H.). The most recent version of the CONSORT statement,[4] published in 2010, was used. This comprises a 25-item checklist, investigating the trial design, analysis, and interpretation. The CONSORT statement was used in conjunction with the CONSORT Explanation and Elaboration Document. Each item of the CONSORT checklist was answered with "yes" or "no", with each yes earning 1 point, for a maximum of 25 points. An overall reporting quality score was calculated for each study, by dividing the score achieved by the maximum possible score.

Methodological quality data

The methodological quality of the selected trials was appraised by two independent authors (Shahin H. and Shahab H.) using the SIGN checklist for randomised controlled trials.[22] This tool consists of two sections: section 1 comprises 10 questions and assesses the internal validity of the trials, whereas section 2 provides an overall assessment statement of the study. Each question in section 1 is answered with "yes", "no", or "can't say". Additionally, in section 2, the assessor grades the study as "high quality (++)", "acceptable (+)", or "unacceptable — reject (0)". The Notes on Methodology Checklist document was used in conjunction with the SIGN appraisal tool. For each of the questions answered with "yes", 1 point was achieved, whereas no points were earned for questions answered with "no" or "can't say". The maximum score possible was 10, and an overall methodological quality score was calculated by dividing the score achieved by the maximum score.

Statistical analysis

Statistical analyses were performed using Minitab 17 (Minitab 17.1.0). Categorical variables using proportions, continuous variables using the mean, and non-parametric data using the median were analysed. The Fisher exact test was used to compare proportions, the two-sample t-test to compare means, and the Mann—Whitney test to compare medians. The 95% confidence level was used to indicate statistical significance in all comparisons.

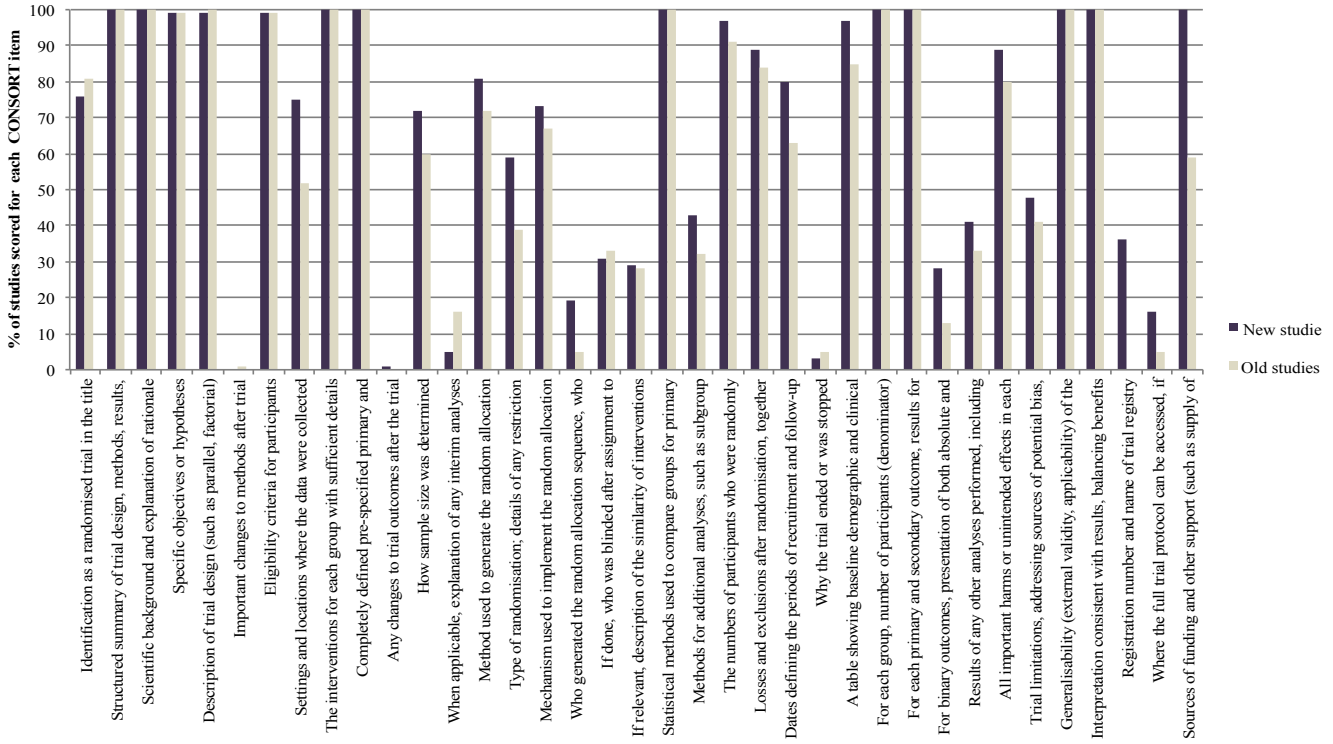

Figure 1. Comparison of CONSORT score between new and old studies.

RESULTS

A total of 150 randomised trials were included, of which 75 were grouped as new studies and 75 were grouped as old studies. Among the new studies, 26.67% were published in 2012, 29.33% in 2011, and 44% in 2010. Among the old studies, 37.33% were published in 2005, 37.33% in 2004, and 25.33% in 2003. There was no significant difference between the new and old studies in the bibliometric variables (Table 1). More trials in the new group were endovascular related (33.33% vs. 17.33, $p = .038$). Moreover, the new studies were more frequently sponsored by industry (28% vs. 6.67%, $p = .001$).

Reporting quality data

Reporting quality measured by CONSORT was better in the new studies. The mean overall CONSORT scores of the new and old studies were 0.68 (95% CI, 0.66—0.7) and 0.60 (95% CI, 0.58—0.62), respectively, ($p < .001$). In terms of individual CONSORT items, the new studies scored better than the old studies in the following items: "settings and locations where the data were collected" (75% vs. 52%, $p = .004$); "type of randomisation and details of any restriction" (59% vs. 39%, $p = .022$); "who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions" (19% vs. 5%, $p = .022$); "dates defining the periods of recruitment and follow-up" (80% vs. 63%, $p = .020$); "a table showing baseline demographic and clinical characteristics for each group" (97% vs. 85%, $p = .01$); "registration number and name of trial registry" (36% vs. 0%, $p < .001$); "sources of funding and other support (such as supply of drugs), role of funders" (100 vs. 59%, $p < .001$); and "for binary outcomes, presentation of both absolute and relative effect sizes is recommended" (28% vs. 13%, $p = .042$) (Fig. 1).

Methodological quality data

Both new and old studies had similar methodological quality measured by SIGN. There was no statistically significant difference in the median overall SIGN score between the new and old studies (0.9 [IQR: 0.1] vs. 0.9 [IQR: 0.2], $p = .787$). Moreover, the scores for each SIGN item did not differ significantly between two groups (Fig. 2). Both old and new studies scored poorly in terms of allocation concealment (73% vs. 69%), blinding (39% vs. 44%), intention to treat analysis (47% vs. 40%), and comparability of results in multicentre trials (45% vs. 43%). In terms of minimising bias, 81.33% of the new studies and 78.67% of the old studies were judged as high quality ($p = .839$); 14.67% and 16.00% as acceptable ($p = 1.000$); and 4.00% and 5.33% as unacceptable-reject ($p = 1.000$).

DISCUSSION

Although compliance to the CONSORT statement has improved the reporting quality of RCTs, suboptimal reporting of RCTs remains a problem. The challenging nature of conducting a surgical RCT and its higher subjection to bias highlight the importance of complete and transparent reporting of a surgical RCT in order to enable readers to interpret bias while analysing the study findings.

Our analysis of 150 trials demonstrated that the reporting quality of RCTs in vascular and endovascular surgery measured by the CONSORT statement has improved significantly over recent years. This improvement in reporting

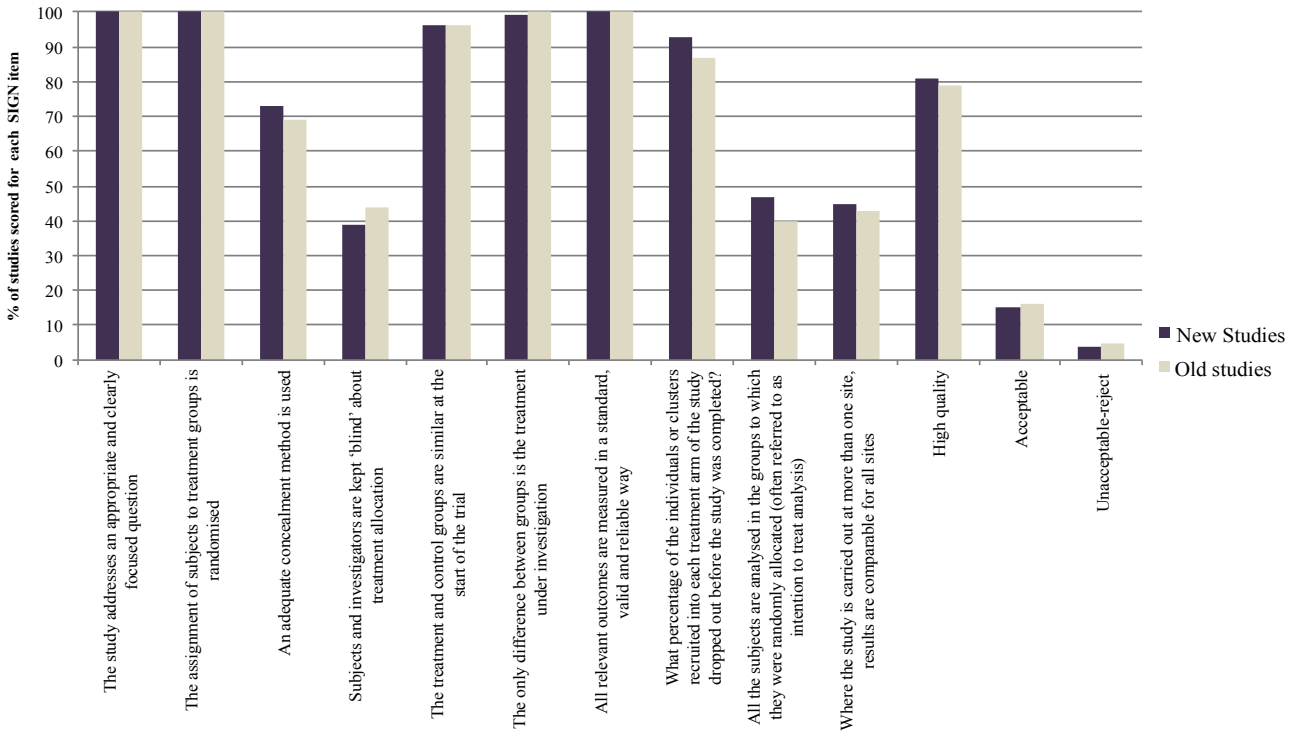

Figure 2. Comparison of SIGN score between new and old studies.

quality suggests a promising trend in minimising the potential for overestimation of treatment effect and erroneous conclusions in vascular and endovascular surgery RCTs.

The mean overall CONSORT score of both groups (old and new studies) in our study was higher than the mean scores reported by other studies in other surgical disciplines. Adie et al.[18] investigated the CONSORT compliance in 150 surgical RCTs and reported a mean adjusted CONSORT score of 0.55, whereas in this study the mean score in the new and old studies was 0.68 and 0.60, respectively. Moreover, Agha et al.[5] reported mean CONSORT scores of 0.50 and 0.51 in urological RCTs and in non-urological surgical RCTs, respectively, which are lower than the mean scores in the present study. In the Agha et al. study, of 74 non-urological RCTs 15 were vascular RCTs, having a mean CONSORT score of 0.54. Furthermore, in another study, Agha et al.[18] demonstrated suboptimal reporting quality of 57 plastic surgery RCTs with a median CONSORT score of 0.50. Although this suggests better compliance to the CONSORT statement in the RCTs included in the present study, it should be taken into account the most recent version of the CONSORT statement containing a 25 item-checklist has been used, whereas other studies used the older version consisting of a 22 item-checklist.

Although there is an overall improvement in the reporting quality of vascular and endovascular RCTs, some CONSORT items are still poorly reported. This includes information about changes to study methods or outcomes after trial commencement; interim analyses and stopping guidelines; randomisation sequence generation; blinding; methods for additional analyses; presentation of both absolute and relative effect sizes; trial registration and protocol. This finding, which has been consistent among old and new RCTs in this study, supports the argument that clinical aspects of reporting are more commonly considered than methodological aspects by reporting authors.[23]

Despite significant improvement in reporting quality of vascular and endovascular RCTs, no significant difference in methodological quality between new and old RCTs was found. The proportion of high-quality RCTs in the new studies was higher than that in the old studies but this difference did not reach significance ($p = .839$).

It has been reported that allocation concealment, blinding, and attrition analysis, which have significant impact on methodological quality of RCTs, are poorly reported in most trials.[24,25] The findings support this argument as both old and new studies did not score adequately for these items. The possible explanation for this could be either these items are not actually addressed appropriately within the study or they are not reported in detail in the corresponding published paper.

Undoubtedly, reporting of RCTs can provide clues on their methodological quality since the assessment of the methodological quality of a RCT is closely associated with the quality of reporting.[24] However, a clear distinction should be made between these two items. Huwiler-Muntener et al.[24] investigated the relationship between reporting quality and methodological quality of 60 RCTs and found that similar quality of reporting may hide important differences in methodological quality, as well-conducted trials may be reported badly. Similarly, Soares et al.[26] demonstrated that the methodological quality of 56 RCTs was better than their reporting quality. As an example, they showed that adequate allocation concealment was achieved in all included RCTs but reported in only 42% of papers.

The new RCTs in this study were sponsored by industry more frequently than the old studies. This difference may be due to either an increase in industry funding or a reduction in other sources of sponsorship in recent years. We did not analyse the association between industry sponsoring and reporting or methodological quality of trials was not analysed. An association between industry funding and better reporting quality has been reported by some authors.[23,27,28] Whether industry sponsoring is associated with better trial quality or whether the better reporting quality of RCTs achieved as a result of industry funding outweighs the publication bias associated with industry sponsoring remains an interesting subject that is beyond the scope of our study and requires further exploration. In this study, more trials in the new group were endovascular related. The advent of minimally invasive surgery, technological achievements, and evolution of techniques and therapies may explain the difference in the proportion of endovascular-related trials between old and new RCTs.[29]

In order to achieve high quality of reporting and methodology in RCTs, not only the authors but also journal editors and reviewers have crucial roles. The researchers need to ensure that they design, conduct, and report their study in line with methodological and reporting standards. Moreover, journal editors and reviewers as "Gate keepers" for published materials should only allow publication of RCTs that are compliant to the methodological and reporting standards. This can be facilitated by recommending appropriate methodological and reporting quality assessment tools and checklists as instructions for authors.

This study has some limitations. Only the oldest 75 and the most recent 75 RCTs published during a 10-year period were included. In addition, only journals with the highest impact factors were considered. It was assumed that each reporting or methodological item has equal impact on the overall quality of each trial; therefore, a maximum score of 1 was allocated to each item. However, some items may have greater impact than others; therefore, the overall reporting or methodological quality of each trial may have been over- or underestimated. This method, therefore, is at risk of some selection bias. Although two independent authors were involved in data extraction and quality assessment of the included studies, there is always a possibility for measurement errors, as scoring of some items in the CONSORT and SIGN checklists are somewhat subjective.

CONCLUSIONS

The reporting quality of RCTs in vascular and endovascular surgery has improved significantly since the development of the CONSORT statement. Unlike clinical items, the methodological items of the CONSORT statement are not well reported; therefore, there remains room for improvement in the reporting quality of RCTs in vascular and endovascular surgery. The methodological quality of RCTs on vascular and endovascular surgery remains unchanged over a 10-year period. Future RCTs should particularly focus on improvement in allocation concealment, blinding, and intention to treat analysis in their methodology and reporting. These are novel findings in vascular and endovascular surgery that highlight the need for better compliance of clinicians, researchers, journal editors, and reviewers to the reporting and methodological standards in future RCTs.

CONFLICT OF INTEREST

None.

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