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REVIEW

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

S. Hajibandeh [*,a], S. Hajibandeh [a], G.A. Antoniou, P.A. Green, M. Maden, F. Torella

Liverpool Vascular and Endovascular Service, Royal Liverpool University Hospital, Liverpool, UK

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

[a] These authors contributed equally to this article.
* Corresponding author. Liverpool Vascular and Endovascular Service, Royal Liverpool University Hospital, Prescot Street, Liverpool L7 8XP, UK.
E-mail address: shahin_hajibandeh@yahoo.com (S. Hajibandeh).
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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.).