Surgery 165 (2019) 965–969

Contents lists available at ScienceDirect

Surgery

journal homepage: www.elsevier.com/locate/surg

Cardiac

Quality of reporting in randomized controlled trials of therapeutic cardiovascular medical devices ☆

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ARTICLE INFO

Article history:
Accepted 21 September 2018
Available online 30 October 2018

ABSTRACT

Background: Therapeutic medical devices play an important role in the treatment of cardiovascular diseases. The reliability of the randomized controlled trial, which is the best design for assessing treatment effects, largely depends on the information found in published reports. Limited information regarding the quality of reporting about therapeutic medical devices in trials was provided.

Method: A cross-sectional study was conducted to assess the reporting quality of randomized controlled trials that tested the effects of therapeutic cardiovascular medical devices. The quality of reporting was assessed against a modified Consolidated Standards of Reporting Trials checklist, including 47 items from the Consolidated Standards of Reporting Trials statement and Consolidated Standards of Reporting Trials extension. We also examined the specific items regarding medical devices. Univariable and multivariable linear regressions were undertaken to explore potential factors associated with Consolidated Standards of Reporting Trials scores.

Result: Some 115 randomized controlled trials were identified. The mean (standard deviation) Consolidated Standards of Reporting Trials score was 20.5 (5.0). The extent of compliance with the Consolidated Standards of Reporting Trials reporting guideline differed substantially across items: 5 of the 47 items were reported adequately across trials (more than 90%), and 10 were reported adequately in less than 5% of trials. Less than 50% of the trials reported additional items related to the medical device. Multivariable regression analysis showed that trials published in general journals (coefficient 7.44, 95% confidence interval [CI]: 5.50–9.38), with larger sample sizes (coefficient 2.30, 95% CI: 0.76–3.83), and multiple-center studies (coefficient 3.14, 95% CI: 1.27–5.01) were associated with a higher quality of reporting.

Conclusion: The overall reporting quality in randomized controlled trials of therapeutic medical device trials is suboptimal, particularly in terms of items regarding surgeons and hospitals. We suggest that the existing Consolidated Standards of Reporting Trials and extension should be modified to be more applicable to therapeutic medical devices.

Introduction

Worldwide, about 234.2 million major surgical procedures were performed in 2004,[1] and 312.9 million procedures were performed in 2012.[2] Nearly 30% of clinical studies of surgeries aimed to assess therapeutic medical devices (TMDs),[3] among which orthopedic and cardiovascular devices were the most investigated.[4,5]

TMDs, which are high-risk devices, play an important role in the treatment of cardiovascular diseases. A systematic review conducted in 2009 examined the strength of evidence from the US Food and Drug Administration (FDA) of premarket approval of cardiovascular devices and found that most premarket FDA approval of cardiovascular devices was based on studies of inadequate strength (eg, 27% of studies were randomized, 14% were blinded, and 65% were based on a single study).[6]

Randomized controlled trials (RCTs) are recognized as the best design for evaluating treatment effects. Moreover, the assessment of RCT reliability is largely dependent on the information reported

☆ Supported by the Thousand Youth Talents Plan of China (Project No: D1024002), National Natural Science Foundation of China (Grant No: 71573183, Grant No: 71704120)

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https://doi.org/10.1016/j.surg.2018.09.010
0039-6060/

in publications. The Consolidated Standards of Reporting Trials (CONSORT), a guideline to improve the reporting of RCTs, was developed in 1996[7] and updated in 2001 and 2010.[8,9] To address issues specific to nonpharmacologic treatments, a CONSORT extension was issued for nonpharmacologic treatments in 2008,[10] and an updated version for nonpharmacologic trial abstracts was published in 2017.[11]

Several studies have explored the reporting of RCTs of therapeutic medical devices,[3,12–14] and a limited number of studies examined some specific issues of reporting (eg, selective reporting or limited reporting of adverse events).[15,16] Moreover, none has systematically investigated the extent to which RCTs with medical devices adhere to reporting guidelines (eg, CONSORT). In addition, the existing guidelines were not specifically developed for TMDs,[17] and important issues are not recommended to be reported by those guidelines (eg, device information, learning curves, surgical setting, and quality of surgery).[18]

Therefore, we conducted a cross-sectional survey to explore the quality of reporting (compliance with the CONSORT statement) in RCTs of cardiovascular TMDs published in 2015, focusing on items relevant to TMDs, and explored factors associated with better reporting.

Methods

Eligibility criteria

Parallel RCTs published in English were eligible for inclusion if they specifically investigated effects of therapeutic cardiovascular medical devices (eg, stent, balloon, valve, and pacemaker). No restrictions were applied to type of study (superiority, noninferiority, equivalence) or sample size. We required the effects of the therapeutic cardiovascular medical devices to be tested in a manner that did not confuse the effect of the devices with the design. We excluded reports published as a study protocol or a conference abstract.

Data sources and study procedures

We searched for potentially eligible reports published in the 5 leading general journals and 124 cardiovascular journals between January 1, 2015, and December 31, 2015. The top 5 general journals were selected based on the 2015 impact factor from the Institute for Scientific Information Web of Knowledge Journal Citation Reports: *The New England Journal of Medicine, The Lancet*, the *Journal of the American Medical Association* (*JAMA*), *Annals of Internal Medicine*, and the *British Medical Journal* (*BMJ*).The 124 cardiovascular journals were contained in a category defined by Web of Science as "Cardiac & Cardiovascular Systems."[19] We applied the Cochrane Highly Sensitive Search Strategy for identifying RCTs included in MEDLINE.[20] The search strategy is available in Supplementary Appendix 1.

Two groups of well-trained reviewers independently followed standardized, piloted forms that included detailed instructions to screen titles, abstracts, and full texts for eligibility and extracted data from eligible studies. Discrepancies were resolved by a third party.

Data collection and measurement of reporting

We collected the following general information from the trial publications: journal name, number of authors, authors' affiliation and country, whether an international study, number of centers, sample size, type of device, type of comparison (ie, device, medical therapy, surgical procedures, or others), funding sources (industry, not-for-profit institute, not funded, or not reported), and whether the main effect of the primary outcome was statistically significant ($P < .05$) was noted. The primary outcome was chosen according to published criteria[21] (Supplementary Appendix 2).

We assessed the quality of reporting by using a modified CONSORT checklist. The checklist included items from the standard CONSORT statement (CONSORT 2010), the CONSORT Extension for Trials Assessing Non-Pharmacological Treatments (2008), and the CONSORT Extension for Non-Pharmacologic Trial Abstracts (2017). For the modified checklist, we included all 37 items from the CONSORT 2010 Statement checklist and 10 items from the CONSORT Extensions. The 10 additional items were eligibility criteria for centers and care providers, standardization of intervention, adherence to protocol, sequence generation of care providers, blinding of administering cointerventions, number of care providers or centers allocated to each trial group, details of the experimental treatment, baseline data of care providers if blinding was not possible, description of any attempts to limit bias, and delay between randomization and intervention (Supplementary Appendix 3). A total of 47 items were collected for the modified CONSORT checklist. Each item scored 1 point if it met the proposal and 0 if it did not. We defined adequate reporting as more than 75% of trials meeting the criteria.

To explore issues specific to TMDs, we additionally verified the reporting against six device-specific items, including device information, learning curves, preoperative and postoperative care, anesthetic management, and surgeons experience according to IDEAL-D[18] (Supplementary Appendix 4).

Statistical analysis

We calculated proportions for categorical variables and mean (and standard deviation [SD]) or median (interquartile range [IQR]) for continuous variables. We used χ^2 or Fisher exact tests to analyze categorical variables. The Wilcoxon rank sum test was used for analysis of continuous data with a non-normal distribution, and the t test was used for those data with a normal distribution.

We prespecified 6 factors to explore their association with quality of reporting, measured as total scores of the modified CONSORT guidelines (47 items). These factors were as follows: type of journal (general medicine journals versus specialty journals), sample size ($\geq$ 240 versus $<$ 240, 240 as median sample size), authors with statistics or epidemiology affiliations (clearly yes versus no), multicenter study (yes versus no), funding (not-for-profit versus industry versus none/unclear), and significance of primary outcome (yes versus no). We conducted both univariable and multivariable linear regression analyses.

The distribution of CONSORT scores was verified to ensure normality by the skewness and kurtosis tests. All the data were analyzed using SPSS v 23 (IBM Corp, Armonk, NY, USA).

Results

This study included 115 articles selected from 9,500 articles published between January 1, 2015, and December 31, 2015, by the search (Fig. 1 and Supplementary Appendix 5). Of those 115 trials, 19 were published in general journals and 96 in specialty journals; the median sample size was 240 (IQR: 100–500), 39 (33.9%) were international studies, 82 (71.3%) were multicenter studies, 32 (27.8%) included investigators with affiliations in epidemiology or statistics departments, and 59 (51.3%) were funded by industry (Table 1).

The mean (standard deviation) scores of the standard CONSORT and the modified CONSORT were 20.5 (5.0) and 21.8 (5.5), respectively. The extent to which the trials met the CONSORT reporting guidelines differed substantially across items (Table 2). Among the 47 items, only 5 were reported rather adequately ($>$ 90% of

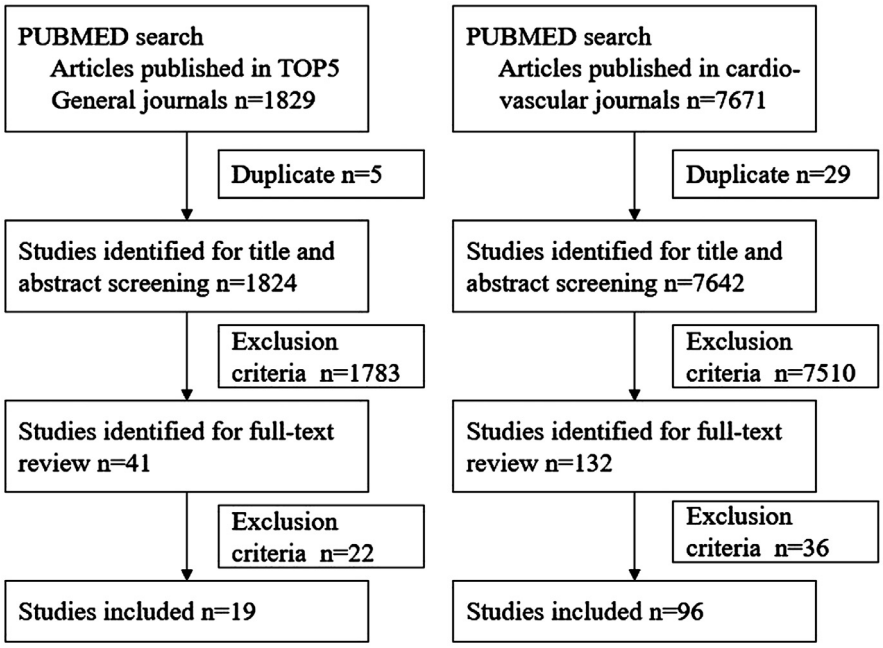

Fig. 1. Flow of study screening.

Table 1
Characteristics of included trials.

	Total $n = 115$
Number of authors*	14 (10–19)
Sample size*	240 (100–500)
Sample size	
<240	57 (49.6)
≥240	58 (50.4)
Journal	
General	19 (16.5)
Specialty	96 (83.5)
Author with epidemiology or statistics affiliation	32 (27.8)
International study	39 (33.9)
Multicenter study	82 (71.3)
Country	
United States	24 (20.9)
Netherlands	9 (7.8)
United Kingdom	8 (7.0)
South Korea	6 (5.2)
Others†	68 (59.1)
Device	
Stent	47 (40.9)
Balloon	13 (11.3)
Valve	12 (10.4)
Others‡	43 (37.4)
Type of comparison	
Device	74 (64.3)
Surgical procedures	32 (27.8)
Medical therapy	9 (7.8)
Funding resource	
Industry	59 (51.3)
Not-for-profit institutes	22 (19.1)
Industry and not-for-profit institutes	9 (7.8)
Clearly stated: not funded	5 (4.3)
Not reported	20 (17.4)

NOTE: Values in parentheses are percentages unless indicated otherwise; *n*, number of studies.

* Values are median.

† Included Canada, Denmark, Switzerland, Spain, India, Israel, Germany, Poland, Japan, Italy, China, Turkey, Finland, Malaysia, The Czech Republic, Brazil, Croatia, Austria, Russia, and Belgium.

‡ Included pacemaker, hemostasis device, oxygenator, catheter, percutaneous mitral valve repair device, thrombus or stent retrieve devices, baroreflex activation therapy system, endotracheal tube, biocompatible bone adhesive, vein sheaths, left atrial appendage occlusion, centrifugal pump.

trial reported): the description of scientific background and explanation of rationale (99.1%), description of statistical methods (99.1%), presentation of baseline characteristics (97.4%), participant flow (95.7%), and specification of hypothesis objectives (94.8%).

The reporting was poor for 10 items (< 5% of trial was reported): information about sequence generation of care providers (0), level of adherence of care providers to the protocol (0.9%), participant flow statement (0.9%), important changes to methods after trial commencement with justifiable reasons (1.7%), delay between randomization and initiation of intervention (1.7%), any changes to trial outcomes after trial commencement with reasons (2.6%), similarity of interventions (2.6%), blinding of those administering cointerventions (3.5%), why the trial ended or was stopped (3.5%), and baseline data about care providers and centers (volume) in each group (3.5%).

Of 106 trials comparing alternative devices or procedures, 45 (42.5%) reported information about the devices. A total of 76 (71.7%) and 80 (75.5%), respectively, referred to postoperative care and preoperative care, and 19 (17.9%) presented details regarding anesthetic management. However, no trials reported information about learning curve evaluation (Table 2).

The *P* value of skewness and kurtosis tests of the modified CONSORT scores (47) was .200 and .198, respectively, confirming the normality of the modified CONSORT score. Univariable linear regression analyses showed that general journal publication (coefficient 9.28, 95% confidence interval [CI]: 7.16–11.40), larger sample size (coefficient 4.93, 95% CI: 3.11–6.74), authors with statistics or epidemiology affiliations (coefficient 2.70, 95% CI: 0.49–4.91), multicenter studies (coefficient 6.48, 95% CI: 4.59–8.38), and industry funding (as opposed to none or unclear) were statistically associated with better reporting. Multivariable analyses showed better reporting with general medicine journal publication (coefficient 7.44, 95% CI: 5.50–9.38), larger sample size (240 or more) (coefficient 2.30, 95% CI: 0.76–3.83), and multicenter studies (coefficient 3.14, 95% CI: 1.27–5.01) (Table 3).

Discussion

A substantial proportion of trials suffered from limitations in quality of reporting in our survey. A total of 12 items (25.5%) were reported adequately (eg, title, abstract, statistic methods, etc),

Table 2
Adherence of trial reporting.

	Total ($n = 115$)
Modified CONSORT items	
1 Title	69 (60.0)
2 Structured abstract	90 (78.3)
3 Scientific background	114 (99.1)
4 Specific objectives	109 (94.8)
5 Trial design	25 (21.7)
6 Important changes	2 (1.7)
7 Eligibility criteria for participants	101 (87.8)
8 Settings and locations	28 (24.3)
9 Centers and care providers*	10 (8.7)
10 Interventions	101 (87.8)
11 Standardization of intervention*	38 (33.0)
12 Adherence to protocol*	1 (0.9)
13 Prespecified primary and secondary outcome	100 (87.0)
14 Any changes to trial outcomes	3 (2.6)
15 Sample size	84 (73.0)
16 Interim analyses	12 (10.4)
17 Generation of the random allocation sequence	60 (52.2)
18 Type of randomization	57 (49.6)
19 Sequence generation of care providers*	0 (0)
20 Allocation concealment	51 (44.3)
21 Method of implementation of allocation	22 (19.1)
22 Blinding	72 (62.6)
23 Description of the similarity of interventions	3 (2.6)
24 Blinding of administering cointerventions*	4 (3.5)
25 Any attempts to limit bias†	22 (19.1)
26 Statistical methods	114 (99.1)
27 Subgroup analyses	28 (24.3)
28 Participant flow: numbers of participants	110 (95.7)
29 Losses and exclusions after randomization	75 (65.2)
30 Number of care providers or centers*	1 (0.9)
31 New details of the experimental treatment*	69 (60.0)
32 Delay between randomization and intervention†	2(1.7)
33 Dates defining the periods of recruitment and follow-up	54 (47.0)
34 Why the trial ended or was stopped	4 (3.5)
35 A table showing baseline demographic	112 (97.4)
36 A description of care providers*	4 (3.5)
37 Numbers analyzed	80 (69.6)
38 Outcomes and estimation	64 (55.7)
39 Presentation of absolute and relative effect sizes	8 (7.0)
40 Ancillary analyses	41 (35.7)
41 All important harms or unintended effects	75 (65.2)
42 Trial limitations	91 (79.1)
43 Generalizability	57 (49.6)
44 Interpretation	68 (59.1)
45 Registration	90 (78.3)
46 Protocol	90 (78.3)
47 Funding	96 (83.5)
Additional items‡	
48 Device information	45 (42.5)
49 Learning curve	0 (0)
50 Preoperative care	76 (71.7)
51 Postoperative care	80 (75.5)
52 Anesthetic management	19 (17.9)
53 Operator experience	26 (24.5)
Summarized scores§	
Standard CONSORT scores (37)	20.5 (5.0)
CONSORT scores (1–47)	21.8 (5.5)

NOTE: Values in parentheses are percentages unless indicated otherwise.
* Items extracted from the CONSORT extension for nonpharmacologic treatment.
† Items extracted from the CONCORT extension for nonpharmacologic trials abstract.
‡ $n = 106$.
§ Mean and SD (standard deviation).

which were similar to medical and surgical research.[3,12–14] Items related to methodologic domains, such as randomization, allocation, and blinding, were reported in less than half of the included trials. The main aspect of underreporting lay in the items related to care providers according to the CONSORT extension, such as the description of eligibility criteria for centers and those performing the intervention, adherence of the care provider to the protocol, sequence generation of care providers, and the description of care providers (eg, case volume, qualifications, expertise, etc) in each group.

We identified that authors' expertise with epidemiology or statistics was associated with higher-quality trials, which probably related to the strict quality control of the trials. This finding was consistent with earlier studies.[3] The regression also reported that trials published in general journals related to higher reporting quality. These findings probably reflect increasing awareness of publication in general journals compared with specific journals.[21] Multicenter studies and large numbers of participants were associated with a statistically higher quality of reporting.

RCTs are the gold-standard method of comparing efficacy in the postmarketing reevaluation,[22,23] especially for those first-in-field and successor, high-risk therapeutic devices. Clear, transparent, and comprehensive reporting makes an important effort to improve the quality of evidence and applicability of findings. Moreover, the contextual factors—characteristics of the surgeons, patients, and institutional setting—make evaluation and reporting of TMDs more complex than pharmaceuticals, even more so than trials comparing alternative surgical procedures.[18,24,25] Inadequate reporting of these factors could substantially weaken the quality and limit the applicability of the findings.

The CONSORT statement and its extensions improved the reporting quality of some RCTs, especially for those on pharmaceuticals. However, a limited length of article in number of words and absent special items related to surgical treatments and medical devices also compromised the reporting quality, such as the adherence of care providers to the protocol, important changes to methods after trial commencement, the baseline data of the care provider and center, the standardization of intervention, the introduction of medical devices that specifies the nature (eg, first in field or successor), and the details of learning curve (eg, lifetime experience, the surgeons' annual volume, and the hospital's volume). We recommend that journals modify the word count requirements, specifically for surgical/device RCTs, or provide online sources to allow authors to provide these important omitted components.

Although the quality of reporting in RCTs of TMDs is unsatisfactory, controversy about this design in surgical trials remains (eg, difficulty in recruiting participants, randomization, formidably time consuming and costly). We continue to recommend RCTs as the preferred design to confirm treatment effect in ideal environments. Meanwhile, modified RCTs or alternative designs should be suggested in studies in which most of the potential confounders are known, such as those based on expertise and pragmatic RCTs, parallel, nonrandomized studies, interrupted–time series studies, or stepped-wedge designs.[26–28] The Idea, Development, Evaluation, Assessment, and Long-term follow-up (IDEAL) framework and recommendations provide an evaluation pathway for surgical innovation or devices (IDEAL-D). This framework provided an optimal study design for devices in varied steps.[18]

In our study, we used rigorous methods to identify eligible studies systematically and collect information thoroughly from trial reports. We used well-established CONSORT guidelines for assessing reporting and explored issues specific to devices and surgery. We also examined the factors associated with the quality of reporting and focused on how to improve the reporting quality of TMD studies.

Our study also has several limitations. First, we included only trial reports published in the year 2015, which limited the application to those published earlier. Second, the information obtained about statistical and epidemiologic participation was based on details presented in the authors' introduction and acknowledgments sections; therefore, the true extent of these types of input may

Table 3
Univariable and multivariable linear regression analyses of factors associated with the quality of reporting (measured with the modified CONSORT checklist).

	Univariable analysis		Multivariable analysis	
	Coefficient	*P*	Coefficient	*P*
Type of journal (general versus specialty)	9.28 (7.16 to 11.40)	< .001	7.44 (5.50 to 9.38)	< .001
Sample size (≥ 240 versus < 240)	4.93 (3.11 to 6.74)	< .001	2.30 (0.76 to 3.83)	.004
Authors with statistics or epidemiology affiliations (yes versus no)	2.70 (0.49 to 4.91)	.017	0.18 (−1.44 to 1.81)	.825
Multicenter study (yes versus no)	6.48 (4.59 to 8.38)	< .001	3.14 (1.27 to 5.01)	.001
Funding				
Not-for-profit versus industry	−1.98 (−4.47 to 0.50)	.116	−1.28 (−3.13 to 0.56)	.171
None/unclear versus industry	−4.67 (−7.05 to −2.30)	< .001	−1.02 (−3.02 to 0.98)	.316
Significance of primary outcome (yes versus no)	1.65 (−0.42 to 3.71)	.117	0.13 (−1.29 to 1.55)	.855

NOTE: Values in parentheses are 95% confidence intervals.

be underestimated. Third, we gave each item equal weight, which may underestimate the influence of true effect from some important items.

Although surgical journals may insist on the generalization of a CONSORT checklist, the overall quality of reporting of therapeutic cardiovascular medical device trials is suboptimal, according to the existing reporting guidelines. Further guidelines or checklists for reporting should be developed, including more important information about device-related items, especially about device information and surgeons.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.surg.2018.09.010.

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