

A Survey of Reporting Guidelines and Trial Registration Among Cardiothoracic Surgery Journals

Jake Xavier Checketts, Cole Wayant, Nate Nelson, Matt Vassar, PhD

Oklahoma State University - Center for Health Sciences

Abstract

Purpose

The aim of this study was to evaluate the current state of two publication practices in cardiothoracic journals: reporting guidelines and clinical trial registration.

Methods

We extracted data from the web-based instructions for authors of the top twenty cardiothoracic surgery journals as defined by the Google Scholar Metrics h-5 index. Our primary analysis was to determine the level of adherence to reporting guidelines and trial registration policies by each journal.

Results

Of the twenty cardiothoracic surgery journals, ten (10/20, 50%) did not mention a single guideline within their instructions for authors, while the remaining ten (10/20, 50%) mentioned one or more guidelines. ICMJE guidelines (15/20, 75%) and the CONSORT statement (10/19, 52.6%) were mentioned most often. Of the twenty cardiothoracic surgery journals, nine (9/20, 45%) did not mention trial or review registration, while the remaining eleven (11/20, 55%) mentioned at least one of the two.

Conclusions

Our investigation of the adherence to reporting guidelines and trial registration policies in cardiothoracic journals demonstrates a need for improvement. Reporting guidelines have been shown to improve methodological and reporting quality, thereby preventing bias from entering the literature. We recommend the adoption of reporting guidelines and trial registration policies by all cardiothoracic journals.

Introduction

Cardiothoracic surgeons rely on results from well-designed, well-executed studies to provide informed patient care. Efforts should be made to ensure studies are conducted thoughtfully and published reports contain the necessary information to draw informed conclusions from the results. In 2006, Tiruvoipati et al. evaluated the reporting quality of randomized trials in cardiothoracic surgery journals, concluding that trials were suboptimally reported compared with the requirements of the Consolidated Standards of Reporting Trials (CONSORT) Statement.¹ Results from their survey of cardiothoracic trialists indicated that over 40% would likely have reported the trial differently had the journal required adherence to CONSORT. Over 50% of these trialists believed the reporting quality of trials would improve if cardiothoracic journals required CONSORT adherence. Since publication of this study, efforts have been made to improve the quality of reporting for many study designs. For example, the Enhancing the Quality of Transparency of Health Research (EQUATOR) Network was established to advance high-quality reporting for health research. To date, their collection of reporting guidelines for various study designs exceeds 300, including Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for systematic reviews, Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) for observational studies, and Standards for Reporting Diagnostic Accuracy Studies (STARD) for diagnostic accuracy studies.² Evidence from the International Journal of Surgery suggests that reporting quality improved following a change in the journal's policy to support adherence to reporting guidelines.³

A second mechanism to improve study design and execution is the registration of studies in a public repository prior to conducting them.^{4,5} In 2005, the International Committee of Medical Journal Editors (ICMJE) established a policy that participating journals require trial registration as a precondition for publication.⁶ Two years later, the United States Congress passed the Food and Drug Administration Amendments Act, which mandated the prospective registration of applicable clinical trials prior to patient enrollment.⁷ Position statements from the World Health Organization and the United Nations Secretary-General's High Level Panel on Access to Medicines advocate for governments around the world to enact legislation requiring

clinical trial registration, including study protocols and trial data, regardless of the findings.^{6,8} Prospective registration is not limited to clinical trials. Following development of the PRISMA guidelines for systematic reviews, the Centre for Reviews and Dissemination established PROSPERO, a prospective register for systematic reviews.⁹ Similar to clinical trials, prospective registration of systematic reviews is designed to provide greater transparency and accountability, minimizing bias.⁹

Evidence indicates that many cardiothoracic trials are not correctly registered. Wiebe et al. found that a majority of trials were either registered during patient enrollment or after trial completion.¹⁰ This study also found that cardiothoracic trials were prone to selective reporting bias, a practice in which outcomes listed during registration are altered in the published report, often by amending outcomes to favor statistical significance.^{10,11} In this study, we investigated the policies of twenty cardiothoracic surgery journals regarding adherence to reporting guidelines and study registration with the intent of understanding if journals are using these mechanisms to minimize bias.

Materials and Methods

We performed a web-based extraction of the top twenty cardiothoracic surgery journals' policies and procedures regarding adherence to reporting guidelines and trial registration, as indexed in Google Scholar (accessed January 23, 2017). We chose Google Scholar because it continuously updates the top journals in each field using the H-5 index, which is a measure of the journal's overall impact. When relevant, we applied SAMPL guidelines (guidelines guiding proper reporting of statistical analyses in biomedical research) for descriptive studies.¹² This investigation did not meet criteria to necessitate IRB oversight as there were no human or living subjects being evaluated. This study has been prospectively registered on the University Hospital Medical Information Network Clinical Trial Registry (UMIN000026511).

All authors met initially to establish a protocol and extraction manual. A pilot test was conducted as a group to establish uniformity in data extraction. Adjustments were made by group consensus prior to individual data extraction began.

A data sheet with the journal titles, impact factor, and geographic location (defined by the primary location of the journal's editorial office, as indexed in the Expanded Science Citation Index).¹⁴ The extraction manual included: adherence to ICMJE uniform requirements for manuscripts, Animal Research Reporting of In Vivo Experiments (ARRIVE), Case Reports (CARE),

Consolidated Health Economic Evaluation Reporting Standards (CHEERS), CONSORT, Consolidated Criteria for Reporting Qualitative Research (COREQ), Meta-Analysis of Observational Studies in Epidemiology (MOOSE), PRISMA, Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P), Quality of Reporting of Meta-analyses (QUOROM), Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT), Standards for Quality Improvement Reporting Excellence (SQUIRE), Standards for Reporting Qualitative Research (SRQR), STARD, STROBE, and Transparent Reporting of a Multivariate Prediction Model for Individual Prognosis or Diagnosis (TRIPOD). When listed, we extracted any information regarding clinical trial registration and any specific registries mentioned.

Dual extraction and validation procedures were followed throughout the investigation. All authors were blinded to each other's data extraction. Each journal's instructions for authors (or equivalent) were independently surveyed to determine which types of articles were accepted. Often, broad descriptions such as "original research" were encountered, which warranted further investigation. The editor-in-chief of each journal was contacted to inquire as to which of the popular study types each journal accepted (randomized controlled trial, systematic review/meta-analysis, studies involving animals, case reports, diagnostic accuracy, observational studies in epidemiology, economic evaluations, qualitative studies, quality improvement studies, and protocols). If no response was received, two additional contacts were attempted at one week intervals to increase response rates, a suggestion to increase response rates by Dillman et al.¹³

After data extraction was complete, each statement extracted from a journal's website was reviewed and classified as to whether the journal required, recommended, was unclear, or did not mention adherence to a specific reporting guideline or trial registry. Phrases such as "must," "need," or any mention of adherence as a condition for publication were classified as required adherence. Phrases such as "should," "are encouraged," or "in accordance with the recommendation of" were classified as recommended adherence. Any deviation from these common phrases, if not able to be classified, was rated as unclear. Each author was blinded to the classification of the others. Following the completion of the process, the authors met to resolve discrepancies. Cross-tabulations and descriptive statistics were calculated using STATA 1.1 (StataCorp LLC; College Station, TX).

If a journal did not accept a specific study type, we did not consider the corresponding reporting guideline when computing proportions. For example, if a journal did not accept randomized controlled trials, we did not consider CONSORT guidelines for that journal in our tables or analysis.

Results

Our sample comprised Google Scholar's top twenty journals in the Heart and Thoracic Surgery subsection of Health and Medical Sciences. The h-5 index of these journals ranged from 12 to 65 (mean 24.3, standard deviation 15.9). Editorial offices were located in North America (6/20, 30%), United Kingdom (7/20, 35%), Europe (2/20, 10%), and Other (5/20, 25%) [Table 1]. Following a review of Instructions for Authors and editor-in-chief email inquiries (response rate 11/20, 55%), the following reporting guidelines were removed from computing proportions due to their study type not being accepted by the journal: STARD (1/20, 5.0%), TRIPOD (1/20, 5%), MOOSE (1/20, 5%), STROBE (3/20, 15%), COREQ (3/20, 15%), SRQR (1/20, 5%), ARRIVE (3/20, 15%), SQUIRE (1/20, 5%), PRISMA-P (5/20, 25%), CARE (2/20, 10%), CONSORT (1/20, 5%), EQUATOR (1/20, 5%), CHEERS (2/20, 10%), and SPIRIT (5/20, 25%).

Table 1. Responding Journals=*, X = Required/Compulsory, O = Recommended, ? = Unclear,
 Boxes filled with grey = journal does not accept the study design requiring these guidelines,
 Italicized journal name = does not mention any

Journal	H5-Index	Geographical Zone	Guideline														Registry						
			Equator Network	ICMJE	CONSORT	MOOSE	QUOROM	PRISMA	STARD	STROBE	ARRIVE	CHEERS	SRQR	SPIRIT	COREQ	TRIPOD	SQUIRE	PRISMA-P	CARE	ClinicalTrials.gov	WHO	Other/Generic (Trial)	PROSPERO
The Journal of Thoracic and Cardiovascular Surgery	65	NA	No	Yes	X			X											X		?		3/3/2016
The Annals of Thoracic Surgery	62	NA	Yes	Yes	O			O											O				3/3/2016
European Journal of Cardio-Thoracic Surgery	50	UK	Yes	Yes	O	O		O	O	O													3/3/2016
Interactive Cardiovascular and Thoracic Surgery	33	UK	Yes	Yes	O	O		O	O	O													3/3/2016
Journal of Cardiothoracic Surgery	25	UK	Yes	Yes	O			O	O	O	O	O	O	O	O	O	O	O	X	O	X	O	3/3/2016
Annals of Cardiothoracic Surgery	23	other	No	Yes	O			X											O		X		3/3/2016
The Thoracic and Cardiovascular Surgeon	20	Eur	No	Yes	O					O													3/3/2016
Perfusion	19	UK	Yes	Yes	O															X			3/3/2016

journals. Eight (8/20, 40%) journals required trial registration through any trial registry. Review registration through the PROSPERO platform as well as any review registry platform were each recommended by one (1/20, 5.0%) journal [Table 1].

Discussion

This study evaluated the current positions of cardiothoracic surgery journals on reporting guideline and study registration requirements as described in their instructions for authors. Our results suggest that half of the journals did not mention reporting guidelines. Moher et al. state, "The widespread poor reporting of medical research represents a system failure ... there is clearly a collective failure across many key groups to appreciate the importance of adequate reporting of research."¹⁵ Inadequate study reporting inhibits readers from accurately interpreting results or leads to inaccurate interpretation. Some have suggested that this borders on unethical practice when biased results receive false credibility.¹⁶ Zonta and De Martino argue that since surgical trialists dislike randomization because of the uncertainty it creates, "It seems doubly important that surgical trials should be scrupulously reported to allow interpretation of any potential bias."¹⁷ Since multiple studies have concluded that the use of reporting guidelines has beneficial effects, editors of cardiothoracic surgery journals would be well-advised to consider endorsing them.^{2,18,19} However, endorsement does not always translate to adherence.² To improve research reporting, all stakeholders in the research process must assume responsibility. While journals play an important role, academic and other research organizations, funders, regulatory bodies, and authors must become more proactive to ensure that research is accurately, completely, and transparently reported.²

Research from 2006 found that the reporting quality of randomized controlled trials in cardiothoracic surgery was suboptimal: allocation concealment was not described in 86% of trials, the process to generate a random allocation sequence was not described in 78%, and blinding of outcome assessors was not described or inadequately described in 63%.¹ In addition, nearly 60% of the trialists were unaware of the CONSORT statement, which has been shown to positively influence the manner in which randomized control trials were conducted.¹⁴ Our study found that half of the included journals did not mention the CONSORT statement or any other reporting guideline. Failure to adopt reporting guidelines in cardiothoracic surgery journals may continue to result in poorly reported, or worse, poorly conducted research, which may give these studies unwarranted credibility.^{1,15-17,20} As stated by Zonta and De Martino, "Poorly conducted trials are a waste of time, effort, and money. The most dangerous risk associated with poor-quality reporting is an overestimate of the

advantages of a given treatment. This could lead to the adoption of policies based off of unreliable evidence that directly harms patient care.”¹⁷ Study information in surgical specialties like cardiothoracic surgery should be carefully reported to allow readers to understand any potential bias and allow for honest interpretations of findings.¹⁷

Previous research has found that the use of reporting guidelines improves the completeness of study reporting. Agha et al. found that changes in the International Journal of Surgery’s policy on reporting guidelines resulted in an increase in the adherence to CONSORT by 50–70%, PRISMA by 48–76%, and STROBE by 12%.³ As of 2014, 28 journals from physical medicine and rehabilitation have formed a collaboration to improve research reporting.²¹ This collaboration requires that both authors and peer reviewers make use of reporting guidelines when writing and reviewing research studies. It would be reasonable for cardiothoracic surgery journal editors to consider forming such a collaboration, especially if evidence suggests that such collaborations improve the quality of research reporting.

Study registration requirements by journals were also examined in our study. Medical journal editors believe that prospective clinical trial registration is the single most important tool to ensure unbiased reporting, since this practice allows for the identification of potential outcome reporting bias and or other deviations from the study protocol.²² In 2007, clinical trial registration became a requirement for investigators in accordance with United States law.²³ The Food and Drug Administration Amendments Act requires all phase 2–4 trials involving FDA-approved drugs, devices, or biologics be registered on ClinicalTrials.gov before beginning the study.²³ Mathieu found that less than 50% of all studies were prospectively registered, and 25% of studies lacked registration.²⁴ Overall, trial registration rates vary between specialties, with many published randomized trials lacking prospective registration.^{10,25–29} In cardiothoracic surgery, Wiebe et al. found that nearly 60% of clinical trials were not prospectively registered.¹⁰ The listed pre-specified outcomes of the prospectively registered trials often conflicted with those in the published report, and outcome discrepancies were found in nearly 50% of the evaluated trials. Wiebe et al. states that “these conflicts could be the result of outcome reporting bias if the upgrade or downgrade of an outcome favors statistical significance.”¹⁰ Our study found that almost 50% of the included journals made no mention of prospective trial registration, leaving cardiothoracic surgery journals open to biased reporting of results. Improving the poor compliance of prospective registration in cardiothoracic surgery is contingent on further development and adherence to policies requiring registration of a trial before journal submission.

Although we attempted to contact journal editors to inquire about the types of articles they accepted, some never responded to our inquiry. Thus, when the instructions for authors were unclear of which studies were accepted by their journal, we may have inadvertently listed a journal as not mentioning a reporting guideline for an article type that the journal did not accept.

Future Research

Follow up studies evaluating the influence of reporting guidelines on research reporting may be warranted. For example, researchers could evaluate adherence to CONSORT criteria in journals requiring or recommending CONSORT and compare these results to CONSORT adherence in journals without policies regarding CONSORT. Evaluation should be performed before and after development of reporting guidelines or a trial registry policy to examine changes in adherence following the publication of these policies.

Conclusions

Nearly half of all cardiothoracic surgery journals made no mention of reporting guidelines or trial registration policies. This could place trials in cardiothoracic surgery at risk of methodological flaws or bias. We recommend cardiothoracic surgery journals without reporting guidelines or trial registration policies begin recommending and slowly implementing these policies.

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