

Majority of systematic reviews published in high-impact journals neglected to register the protocols: a meta-epidemiological study

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Abstract

Objectives: To describe the registration of systematic review (SR) protocols and examine whether or not registration reduced the outcome reporting bias in high-impact journals.

Study Design and Setting: We searched MEDLINE via PubMed to identify SRs of randomized controlled trials of interventions. We included SRs published between August 2009 and June 2015 in the 10 general and internal medicinal journals with the highest impact factors in 2013. We examined the proportion of SR protocol registration and investigated the relationship between registration and outcome reporting bias using multivariable logistic regression.

Results: Among the 284 included reviews, 60 (21%) protocols were registered. The proportion of registration increased from 5.6% in 2009 to 27% in 2015 (P for trend < 0.001). Protocol registration was not associated with outcome reporting bias (adjusted odds ratio [OR] 0.85, 95% confidence interval [CI] 0.39–1.86). The association between Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA) adherence and protocol registration was not statistically significant (OR 1.09, 95% CI 0.59–2.01).

Conclusions: Six years after the launch of the PRISMA statement, the proportion of protocol registration in high-impact journals has increased some but remains low. The present study found no evidence suggesting that protocol registration reduced outcome reporting bias. © 2017 Elsevier Inc. All rights reserved.

Keywords: Systematic review; Meta-Analysis; PRISMA statement; Protocol registration; Outcome reporting bias; The PROSPERO registry

1. Introduction

The number of systematic reviews (SRs) is increasing drastically. Bastian et al. reported that an average of 11 SRs were published every day in 2010 [1]. SRs of intervention studies have the potential to induce a revision in treatment measures or clinical practice if their methodological quality is sufficiently high. However, several studies have suggested that a considerable number of SRs had outcome reporting bias [2–6], which occurs when the choice of reported outcomes is influenced by the results [7]. For

instance, among clinical trials, the reporting of trial outcomes was biased to favor statistical significance [8]. Kirkham et al. suggested the existence of outcome reporting bias in Cochrane SRs [6]. They compared the outcomes between protocols and published articles and found that the presence of discrepancies increased the likelihood of reporting statistical significance. Registration of SR protocols enables the reader to check for any outcome reporting bias by comparing the outcomes between the protocol and final published article [9]. Furthermore, protocol registration is considered to prevent unnecessary duplication of SRs [10–12]. A survey showed that a large number of meta-analyses had overlapping inclusion criteria regarding eligible interventions, settings, and types of studies [13]. Duplication in meta-analyses may lead to alpha error of intervention effects. Therefore, the registration of SR protocols is important for resolving these concerns [10,11].

A recent cross-sectional study that investigated the epidemiology and reporting characteristics of SRs reported

Protocol and registration: We used a prespecified protocol to conduct this review. The protocol was registered in the Universal Hospital Medical Information Network (UMIN) registry (UMIN-CTR UMIN000018189).

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What is new?**Key findings**

- Registration of systematic review (SR) protocols was increased, but the proportion is still low.
- Protocol registration may not prevent outcome reporting bias.

What this study adds to what was known?

- Protocol registration is important for ensuring transparency. High-impact journals suggest SR protocols be registered based on the Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA) statement. However, no study has examined whether or not protocol registration actually reduces outcome reporting bias.
- This meta-epidemiological study includes all SRs of randomized controlled trials for intervention published in high-impact journals after the launch of the PRISMA statement. The results suggested that although the proportion of registration has increased since the introduction of the statement, the majority of SR protocols are still not registered.
- This study provided empirical evidence showing that protocol registration did not significantly reduce outcome reporting bias.

What is the implication and what should change now?

- Given the nonsignificant association between registration and outcome reporting bias, this study supports the need to appraise both the text and protocol to detect reporting bias.

that only 11% of non-Cochrane therapeutic SR protocols were registered or made publicly available [14]. The idea of protocol registration was first disseminated as the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement in 2009 [15]. Following the publication of this statement, the UK Centre for Reviews and Dissemination developed the international prospective register of systematic reviews (PROSPERO) in 2011. The aim of this registry and statement was to minimize reporting bias through transparency in the review process and to reduce unplanned duplication of reviews [11]. Since then, the system supporting protocol registration has changed considerably. However, no study has examined the changes in the proportion of protocol registration over time. Furthermore, most of the previous studies that assessed the registration of SR protocols included journals with impact factors of less than 5.0 [14,16,17]. In addition,

whether or not protocol registration reduces outcome reporting bias remains unclear.

Here, to clarify the aforementioned points, we investigated the proportion of SR protocol registration after the publication of the Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA) statement and examined the relationship between registration and outcome reporting bias.

1.1. Types of reviews to be included

We selected the 10 general and internal medicine journals with the highest impact factors as determined by the Journal Citation Reports 2013. We included SRs of randomized controlled trials (RCTs) of all interventions published between August 1, 2009, and June 30, 2015. We excluded the Cochrane Database of Systematic Reviews because protocol registration is strictly performed for articles published in that database [7]. Studies were excluded if the reviews were performed for diagnostic test accuracy, meta-epidemiology, or updating. SRs including nonrandomized trials or observational studies were excluded. We also excluded abridged or republished reviews from the Cochrane Library.

1.2. Search methods

We searched MEDLINE (source: PubMed, between August 1, 2009, and June 30, 2015) using the journal names and “Search Strategy Used to Create the Systematic Reviews Subset on PubMed” last modified in February 2015 [18]. The search was not subjected to language restrictions. The details of the search terms are available in [Text A.1/Appendix A](#) at www.jclinepi.com.

1.3. Study selection

Two authors (Y.T. and H.T.) independently screened the titles and abstracts of articles identified by the initial search. They assessed the eligibility based on a full-text review. We resolved disagreements by discussion between the authors (Y.T. and H.T.), with another author (Y.K.) acting as an arbiter.

1.4. Data extraction and assessment

For each included review, two authors (Y.T. and H.T.) independently extracted the protocol registration information. We searched the terms “registration” or “protocol” in the text and checked whether the study protocol was registered or published. Each author checked the following factors potentially associated with registration: year of publication, PRISMA adherence, financial conflicts of interests (COIs), nation of corresponding author’s affiliation, number of primary studies included in the SR, and the statistical significance of the effect size of the outcome initially described in the Results section of the Abstract. We defined registration

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