

Language of publication restrictions in systematic reviews gave different results depending on whether the intervention was conventional or complementary

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Abstract

Objective: To assess whether language of publication restrictions impact the estimates of an intervention's effectiveness, whether such impact is similar for conventional medicine and complementary medicine interventions, and whether the results are influenced by publication bias and statistical heterogeneity.

Study Design and Setting: We set out to examine the extent to which including reports of randomized controlled trials (RCTs) in languages other than English (LOE) influences the results of systematic reviews, using a broad dataset of 42 language-inclusive systematic reviews, involving 662 RCTs, including both conventional medicine (CM) and complementary and alternative medicine (CAM) interventions.

Results: For CM interventions, language-restricted systematic reviews, compared with language-inclusive ones, did not introduce biased results, in terms of estimates of intervention effectiveness (random effects ratio of odds ratios ROR = 1.02; 95% CI = 0.83–1.26). For CAM interventions, however, language-restricted systematic reviews resulted in a 63% smaller protective effect estimate than language-inclusive reviews (random effects ROR = 1.63; 95% CI = 1.03–2.60).

Conclusion: Language restrictions do not change the results of CM systematic reviews but do substantially alter the results of CAM systematic reviews. These findings are robust even after sensitivity analyses, and do not appear to be influenced by statistical heterogeneity and publication bias. © 2005 Elsevier Inc. All rights reserved.

Keywords: Bias; Quality; Language of publication; Type of intervention; Complementary therapies; Alternative medicine; Traditional medicine

1. Introduction

Systematic reviewers have little control over random errors but can exert some influence over systematic errors (bias). Including only a portion of all available evidence in a systematic review may introduce bias into the review process and threaten its validity. The most comprehensive search strategies would include all relevant literature, regardless of language of publication, but identifying, obtaining, and translating non-English language reports can significantly increase the time, cost, and effort required for investigators working in English. Grégoire et al. [1] reported that 78% of identified systematic reviews had language of publication restrictions. The majority (93%) of these restrictions were at the expense of excluding reports of randomized controlled

trials (RCTs) published in languages other than English (LOE).

The question of whether language restrictions are a sensible policy for systematic reviewers has been explored in two methodological directions. In earlier work from our group, Moher et al. [2] set out to address whether the quality of reporting in LOE differs in some meaningful way from English-language (EL) reports. Their findings provide little ground for the language-restriction policy, because there were no differences between LOE and EL reports in quality of reporting with respect to randomization, double-blinding, dropouts and withdrawals, and allocation concealment.

In another methodological direction, several authors have examined the impact of excluding reports in LOE on the meta-analytical results of systematic reviews. Case studies on the issue result in varying conclusions. Excluding LOE reports did not change estimates of the intervention effectiveness in two systematic reviews, one examining the efficacy of beta-blockers and the other examining the efficacy of intravenous

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streptokinase for acute myocardial infarction [3,4]. The addition of LOE reports in four language-restricted systematic reviews changed the treatment effect estimate in one review [1].

Members of our group have approached this issue in a systematic way. We earlier [5] identified 18 systematic reviews that explicitly stated using no language restrictions in their search to identify RCTs and included reports in LOE in their data synthesis (i.e., language-inclusive systematic reviews). Results of each systematic review were examined in which LOE reports were either included or excluded from the analysis. That earlier review provided no evidence that language-restricted systematic reviews lead to different estimates of intervention effectiveness, compared with language-inclusive ones. Most (68%) of the systematic reviews we examined in that study, however, included only a single LOE report. We then suggested additional research to replicate our study using different sampling frames, clinical areas and interventions [5].

We further report here on the extent to which including LOE reports influences the results of systematic reviews using a broad dataset of language-inclusive systematic reviews, including both conventional medicine (CM) and complementary and alternative medicine (CAM) interventions. Using this dataset, we have examined whether language restrictions affect the estimates of an intervention's effectiveness, whether any such impact is similar for CM and CAM interventions, and whether the results are influenced by other issues in the systematic review process, including publication bias and statistical heterogeneity.

2. Methods

2.1. Systematic review eligibility criteria

A systematic review was included if it was published in English, if the primary data sources were reports of RCTs, and if the methodology section of the report explicitly stated whether only English reports were eligible or whether trials reported in other languages were considered. In addition, the language-inclusive systematic reviews had to include at least one LOE report on the meta-analytic outcomes of interest to us.

2.2. Search strategy

The search strategy aimed to identify systematic reviews of RCTs published in English between 1985 and 1999. Eligible reviews were identified from the collection of systematic reviews already assembled by our research group [6] and through additional searching of Embase and the Centralised Information Service for Complementary Medicine (CISCOM) database. The CISCOM database was searched for systematic reviews of RCTs published since 1985. This database was developed by the U.K. Research Council for Complementary Medicine and contains articles on CAM

published in the medical literature. Additional details regarding the search strategy can be found elsewhere [7].

2.3. Classification of CM and CAM interventions

In categorizing interventions as either CM or CAM, we used a typology proposed by Kemper et al. [8]. Accordingly, CM interventions included surgical and/or pharmaceutical products. An intervention was considered CAM if the intervention dealt with biochemical (e.g., herbs), lifestyle (e.g., mind–body), biomechanical (e.g., chiropractic), or bioenergetics (e.g., acupuncture).

2.4. Sample size

We estimated that 45 language-inclusive systematic reviews would be required to detect a 25% difference in the ratio of intervention effect odds ratios (ROR) between LOE and EL trial reports, on a log scale. The sample size calculation was derived using OR estimates from our previous work [5]. The median intervention effect OR was 0.5 (i.e., -0.7 with a standard deviation of 1.13 on a log-odds scale) in favor of the intervention. We wished to observe an ROR effect modifier of 0.75 (i.e., a 25% reduction on the log-odds ratio scale) associated with language of publication, assuming a random effects model, a two-sided *t*-test, a false-positive error of 5%, and power of 80%. A total of 484 trials are required under these conditions, or 40 systematic reviews (approximately). Given an estimated prevalence of reports in LOE of ~14%, a 10% increase in sample size was built in to compensate for the unbalance between the numbers of EL and LOE reports.

2.5. Language restriction and estimates of intervention effectiveness

For each systematic review, the effect of language restriction on the estimates of an intervention's effectiveness was derived as follows [9,10]. First, a pooled odds ratio [11] and its standard error [12] were computed for the LOE trials. If there was a single LOE trial, the odds ratio from a 2×2 table was used [13]. A similar approach was used to derive corresponding estimates for the EL trials. The log ratio of the two odds ratio estimates for EL vs. LOE (i.e., ratio of odds ratios, ROR) was then computed. This approach enables a graphical display of the review specific RORs and aids in the interpretation of the pooled ROR [9].

The pooled ROR weighted mean of these systematic review specific estimates yields the average effect of language restrictions across all the included reviews. In addition, a DerSimonian–Laird random effects version of the weighted mean was derived (including a test for heterogeneity) [14].

In all analyses, a trial's odds ratio was calculated from the 2×2 table including the numbers of unwanted events and participants in the intervention and control arms of the

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