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THE EFFECT OF ENGLISH-LANGUAGE RESTRICTION ON SYSTEMATIC REVIEW-BASED META-ANALYSES: A SYSTEMATIC REVIEW OF EMPIRICAL STUDIES

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Objectives: The English language is generally perceived to be the universal language of science. However, the exclusive reliance on English-language studies may not represent all of the evidence. Excluding languages other than English (LOE) may introduce a language bias and lead to erroneous conclusions.
Study Design and Setting: We conducted a comprehensive literature search using bibliographic databases and grey literature sources. Studies were eligible for inclusion if they measured the effect of excluding randomized controlled trials (RCTs) reported in LOE from systematic review-based meta-analyses (SR/MA) for one or more outcomes.
Results: None of the included studies found major differences between summary treatment effects in English-language restricted meta-analyses and LOE-inclusive meta-analyses. Findings differed about the methodological and reporting quality of trials reported in LOE. The precision of pooled estimates improved with the inclusion of LOE trials.
Conclusions: Overall, we found no evidence of a systematic bias from the use of language restrictions in systematic review-based meta-analyses in conventional medicine. Further research is needed to determine the impact of language restriction on systematic reviews in particular fields of medicine.

Keywords: Language bias, Methodology, Meta-analyses, Conventional medicine

English is perceived generally to be the universal language of science (5;6). The top international medical journals, by Journal Citation Reports impact factor, are English-language publications (9). On the other hand, systematic reviews that rely exclusively on English-language studies may miss important evidence on a health intervention. Comprehensive searches to identify all relevant studies and minimize biases are essential for systematic reviews (1;8). Papers reporting positive results are more likely to be published in English-language journals, while papers reporting negative results are more likely to be published in non-English-language journals. While one study found higher estimates of effectiveness in non-English language trial reports (11), other studies found no significant difference between meta-analyses that included non-English versus English-only trials in conventional medicine, but did find a difference in trials in alternative medicine (12;19). Systematic bias due to the selection of studies in a particular language is called a language bias (4). The potential for this type of bias in English-language only study selection is called a "Tower of Babel" bias (7) or "English-language" bias (5). Bias may lead to an over- or underestimation of an intervention's effectiveness, and ultimately, to inappropriate health policy decisions or patient care (7).

Barriers to including trials published in languages other than English (LOE) in systematic reviews are the time and costs required to obtain and translate studies. Whether these additional resources are justified to minimize bias is not clear. Health technology assessments usually involve systematic reviews or meta-analyses, thus examination of English-language bias may be helpful for researchers in this field.

This review was led by the Canadian Agency for Drugs and Technologies in Health (CADTH). CADTH is an independent, not-for-profit agency funded by Canadian federal, provincial and territorial governments to provide credible, impartial advice and evidence-based information about the effectiveness of drugs and other health technologies to Canadian healthcare decision makers. For more information, visit www.cadth.ca.

OBJECTIVES

The objective of this work was to examine the impact of English-language restriction on systematic review-based meta-analyses

(SR/MA). It is based on an earlier assessment of language restrictions in systematic reviews (16).

METHODS

Literature Search Strategy

The literature search included bibliographic databases such as: MEDLINE, PubMed, The Cochrane Library, EMBASE, Biosis Previews, and CINAHL. Search terms included controlled vocabulary (e.g., "selection bias" and "publication bias") and additional keywords (e.g., "non-English" and "LOE"). No language or study type limits were applied. Project team information specialists reviewed the search strategy. The search timeframe was from January 1990 until March 2011, and monthly update searches were run using Ovid AutoAlerts. The grey literature search included health technology assessment agency Web sites, meeting abstracts, Google, and bibliographies in relevant papers. Details are reported in Morrison et al. (16).

Selection Criteria

Studies were eligible for inclusion if they measured the effect of excluding randomized controlled trials (RCTs) in LOE for one or more outcomes in SR/MA of conventional medicine.[1] Outcomes measured included summary treatment effect, methodological quality, and statistical heterogeneity.

Selection and Data Extraction

In the first screen, two reviewers (A.M., and K.M. or M.C.) independently reviewed titles to remove obviously irrelevant references. In the second screen, two reviewers (K.M., M.C.) scanned titles and abstracts and applied selection criteria. Information was extracted by two reviewers (K.M., A.M.) using a structured form, checked for discrepancies, and tabulated (Table 1). When necessary, reviewers contacted study authors for additional information. Differences were discussed and resolved by consensus.

Quality Assessment

A checklist (3) validated for human analytic studies was adapted for this review and applied by two reviewers (A.M., J.P.). Questions were associated with domains of reporting and internal validity. Differences were discussed and resolved by consensus.

Data Analysis Methods

Studies were detailed in evidence tables and a structured discussion of the data was prepared.

[1] We used the US National Cancer Institute's definition of conventional medicine: "[A] system in which medical doctors and other healthcare professionals (such as nurses, pharmacists, and therapists) treat symptoms and diseases using drugs, radiation or surgery."(17)

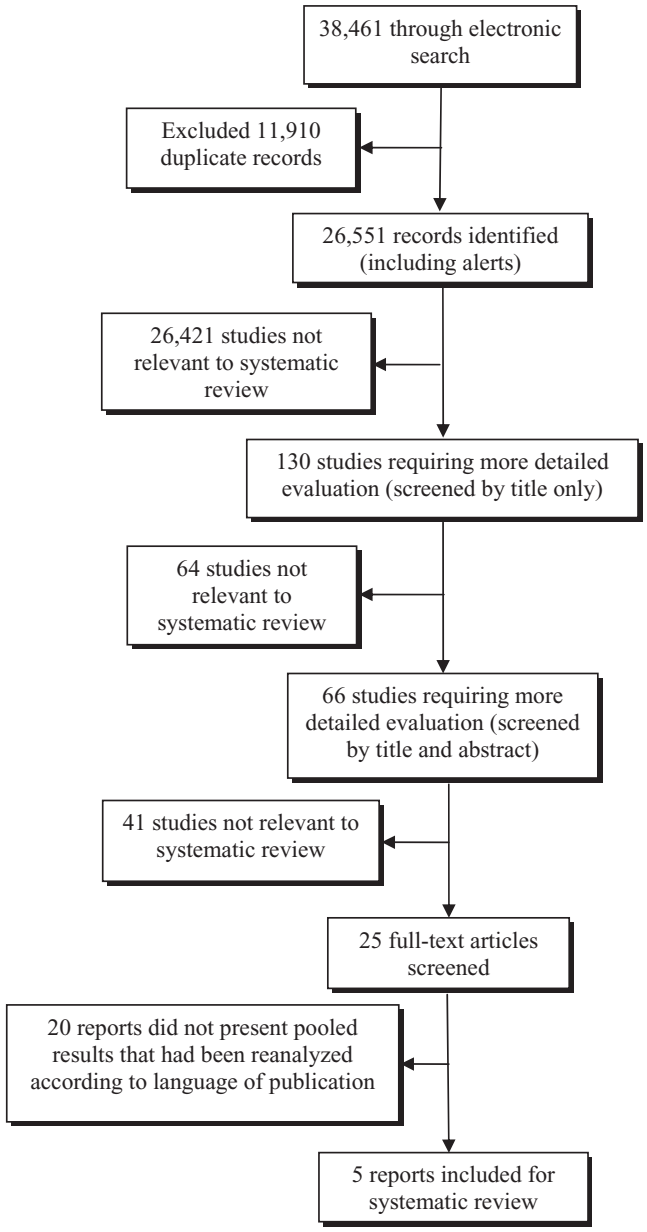

Figure 1. Selection of included studies.

RESULTS

Quantity of Research Available

The PRISMA flowchart (Figure 1) shows the selection process. From 26,551 unique citations identified in the literature search, twenty-five full-text papers were reviewed. Five reports (4;11;12;15;19) describing three unique studies (11;12;15) were included.

Study Characteristics

Table 1 summarizes the characteristics of the five included reports.

Study Design. All reports identified meta-analyses through literature searches and application of selection criteria. The

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Table 1. Characteristics of Selected Reports

First author, country of origin, source of funding	Selection criteria	Databases searched	Search years	Meta-analysis (number), RCTs (number)	Non-English languages included	Disease areas or medical specialties (number)
Moher,(14) Canada, Medical Research Council of Canada	SR/MA of 2 to 99 RCTs reporting binary outcomes	MEDLINE, CDSR	1966 to 1996	79, NR	Chinese, Danish, Dutch, French, German, Italian, Spanish	Infectious disease (10), circulatory disease (26), pregnancy and childbirth (8), other (35)
Jüni,(6) United Kingdom, National Health Service Research & Development Health Technology Assessment Programme	Replicable MA of $\geq$ 5 RCTs with complete search	Hand-searching medical journals, UK NHS R&D HTA, CRD, CDSR	1994 to 1998	50, 600	Chinese, German, French, Italian, Japanese, Spanish, Portuguese, Other	Tobacco addiction (69), obstetrics and gynecology (73), cardiology and angiology (136), infectious disease (137), neurology (54), psychiatry (40), rheumatology and orthopedics (56), other (35)
Egger,(9) Switzerland, National Health Service Research & Development Health Technology Assessment Programme	Any-language replicable MA with complete search	MEDLINE, EMBASE, CRD, CDSR, UK NHS R&D HTA, hand-searching medical journals	1994 to 1998	60, 783	Chinese, German, French, Italian, Japanese, Spanish, Portuguese, Other	Obstetrics and gynecology (125), cardiology and angiology (144), infectious disease (78), neurology (52), psychiatry (79), rheumatology and orthopedics (63), neonatology (39), gastroenterology (39), oncology (54), other (110)
Moher,(7) Canada, National Health Service Research & Development Health Technology Assessment Programme	English SR/MA of RCTs with stated language restriction	MEDLINE, EMBASE, CDSR, CISCOM	1985 to 1999	130, NR	Danish, German, French, Italian, Japanese, Portuguese, Spanish	Circulatory disease (37), infectious disease (10), digestive (14), pregnancy and childbirth (12), genitourinary (10), mental health (9), nervous system and sense organs (6), neoplasms (6), respiratory (4), other (22)
Pham,(8) Canada, National Health Service Research & Development Health Technology Assessment Programme	English-language SR/MA of RCTs with stated language restriction and LOE outcome data	MEDLINE, EMBASE, CDSR, CISCOM	1985 to 1999	42, 662	NR	Conventional medicine (34), complementary & alternative medicine (8)

CDSR, Cochrane Database of Systematic Reviews; CISCOM, Centralised Information Service for Complementary Medicine; CRD, Centre for Reviews and Dissemination; HTA, health technology assessment; LOE, languages other than English; MA, meta-analysis; NHS R&D, National Health Service Research and Development; NR, not reported; RCT, randomized controlled trial; SR/MA, systematic review-based meta-analyses.

meta-analytic endpoint of a binary outcome in each meta-analysis was compared using an odds ratio to the same meta-analysis re-analyzed after removing data from LOE trials. Bias was expressed as a summary effect measured across all SR/MAs combined meta-analytically and reported as a ratio of odds ratios (ROR).

Selection Criteria. In two reports, SR/MAs were included if they were published in English, the main data sources were RCTs, and the review stated whether only English-language trials were eligible for inclusion or whether LOE trials were also considered (11;19). Pham et al. included English language systematic reviews which included at least one LOE trial on the meta-analytic outcomes of interest (19). Moher et al. considered meta-analyses that included between two and 99 trials and reported binary outcomes (15). Their study included meta-analyses that excluded LOE studies, and those that included LOE (whether or not LOE trials were used in the analysis) (15). Jüni et al. (11) and

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Egger et al. (4) included meta-analyses with information to allow replication of the meta-analysis (4;11).

Databases Searched. All reports searched the Cochrane Database of Systematic Reviews; four searched MEDLINE (4;11;12;19), and three searched EMBASE (4;12;19). Moher et al. (12) and Pham et al. (19) included searches of the Centralized Information Services for Complementary Medicine. Searches covered literature from 1966 (15) to 1999 (19).

Number of Studies Reviewed. The number of meta-analyses in the reports ranged from 42 (19) to 130 (12). The number of randomized controlled trials (RCTs) ranged from 600 (11) to 783 (4).

Languages of Studies. Systematic reviews in four of the reports considered RCTs published in German, French, Italian, and Spanish (4;11;12;15). Other languages included Chinese (4;11;15), Portuguese (4;11;12), and Danish (11;12). Of the LOE trials in Jüni et al. (11) and Egger et al. (4), forty-two trials (36.5 percent) were in German, twenty-nine (25.2 percent) in French, twelve (10 percent) in Italian, eight (7 percent) in Japanese, seven (6.1 percent) in Spanish, six (5.2 percent) in Portuguese, eight (7 percent) in four other European languages, and three (2.6 percent) in Chinese. Of the 1,383 trials included in these two reviews, 115 (8.3 percent) were in LOE. Other reviews did not state the proportion of LOE trials (12;15;19).

Disease Areas and Medical Specialties. The diseases areas included infectious diseases (four reports) (4;11;12;15), and circulatory diseases (two reports) (12;15). Two reports included systematic reviews of complementary and alternative medicine (12;19). None of the reports described the RCTs or patient populations of included studies.

Country of Origin. Three reports were published in Canada (12;15;19), one in the United Kingdom (11), and one in Switzerland (4).

Source of Funding. Moher et al. received funding from the Medical Research Council of Canada (15); other reports were funded by the UK National Health Service Research & Development Health Technology Assessment Program (4;11;12;19). No reports declared a conflict of interest.

All reports were methodologically sound and most met all quality assessment criteria for reporting (e.g., objectives, outcomes, study characteristics, confounders and findings were clearly stated) and validity (e.g., estimates of random variability, probability values and statistical tests for main outcomes). The quality assessment checklist is described elsewhere (16). We noted flaws in two areas: sample power calculation and distribution of confounders. Two reports (12;19) reported a sample power calculation, and another (19) did not describe the distribution of confounders though it did refer to another report with this information.

Data Synthesis and Analyses

The impact of including or excluding LOE trials are presented below. Table 2 summarizes each report findings.

Bias in Summary Treatment Effects. None of the reports found major differences in summary treatment effects between English-language only meta-analyses and LOE-inclusive meta-analyses (4;11;12;15;19).

Moher et al. (15) found that language-restricted meta-analyses did not differ in the estimate of benefit of effectiveness of an intervention (ROR 0.98, 95 percent confidence interval [CI] 0.81 to 1.17). This suggested an average 2 percent difference between treatment estimates with or without language restrictions. Language inclusive meta-analyses had narrower CIs (average width 0.79; 95 percent CI 0.51 to 1.07) compared with English-language only meta-analyses (average width 0.92; 95 percent CI 0.53 to 1.32; relative difference of 16 percent; $p = .045$)—probably because meta-analyses without language restrictions typically include more trials.

Egger et al. (4) and Jüni et al. (11) found treatment effect estimates in LOE trials showed more benefit (ROR 0.84; 95 percent CI 0.74 to 0.97; $p = .011$). Significant heterogeneity was present between meta-analyses ($p = .003$), with pooled effect estimates of LOE trials ranging from 90 percent more to 147 percent less benefit compared with English-language trials. Changes in the pooled estimates of individual meta-analyses when LOE trials were excluded ranged from a 42 percent increase (less benefit) to a 22.7 percent decrease (more benefit) of the associated estimates relative to treatment effect. In 58 percent of the sixty meta-analyses the changes were less than 5 percent. Among the twenty-one remaining meta-analyses, five showed more benefit and sixteen showed less benefit, and average precision of pooled estimates decreased from 8.34 to 7.68 after LOE trials were excluded. The authors (4;11) compared pooled estimates in cardiology and angiology (ROR 0.78, 95 percent CI 0.64 to 0.94), infectious disease (ROR 0.83, 95 percent CI 0.68 to 1.00), neurology (ROR 0.68, 95 percent CI 0.40 to 1.13), obstetrics and gynecology (ROR 1.00, 95 percent CI 0.61 to 1.65), psychiatry (ROR 0.63, 95 percent CI 0.39 to 1.02), rheumatology (ROR 1.02, 95 percent CI 0.80 to 1.30), and tobacco addiction (ROR 0.75, 95 percent CI 0.50 to 1.13). The extent of overestimation of effect sizes in LOE trials (an ROR of less than one) varied by field. Accordingly, the proportion of LOE trials incorporated in the meta-analyses ranged from 10.1 percent (tobacco addiction) and 12.3 percent (obstetrics) to 35 percent (psychiatry) and 35.7 percent (rheumatology). The LOE trials contributed an average of 17.5 percent of the weight in the meta-analyses (median 10.2 percent, range 1.2 to 81.1 percent).

Pham et al. (19) found that excluding LOE trials from meta-analyses did not affect results in conventional medicine. Bias was not detected in estimates of effectiveness in systematic reviews that excluded or included LOE (random effects ROR

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Table 2. Summary of Main Report Findings

First author	Number of included studies and patients	Methodological quality	Publication status	Statistical heterogeneity
Egger (9)	Trials published in LOE included fewer participants than English language trials but were more likely to show statistically significant results.	Not reported	Not reported	Not reported
Jüni (6)	English language trials had significantly higher samples sizes compared with trials published in LOE.	Methodological quality of LOE language trials tended to be lower than trials published in English; English language papers reported a better frequency of allocation concealment.	Not reported	Not reported
Pham (8)	Not reported	Not reported	No evidence of funnel plot symmetry was found.	No significant relationship between the restrictions on the language of publication and statistical heterogeneity were found.
Moher (7)	Language inclusive reviews included a higher number of trials and a larger number of participants than reviews limited to English language trials.	Only minor differences in the quality of reports were detected between English and LOE trials; Language-inclusive reviews were of a higher quality and included more comprehensive searches than reviews limited to English studies.	No evidence of funnel plot symmetry was found.	No significant relationship between the restrictions on the language of publication and statistical heterogeneity was found.
Moher (14)	Language inclusive reviews included a higher number of trials than reviews limited to English language trials.	No statistically differences between English and LOE trials were detected.	Not reported	Not reported

LOE, Language other than English.

1.02, 95 percent CI 0.83 to 1.26). English-language trials reported smaller effect sizes than LOE trials.

Number of Included Studies and Patients. Four (4;11;12;15) reports examined the number of patients and studies in meta-analyses that included LOE trials versus those that did not.

Moher et al. (12) found that language-inclusive systematic reviews included more trials (median 17, interquartile range [IQR] 9 to 25) and more participants (median 1,658, IQR 112 to 40,341) than English-language only reviews (median 11 RCTs, IQR 6 to 23, median 971 patients, IQR 112 to 52,869). Moher et al. (15) reported medians of nine trials per meta-analysis (IQR 6.5 to 18) in language-inclusive reviews, compared with medians of six studies (IQR 4 to 9.25) in language-restricted reviews. Egger et al. (4) noted that trials in LOE had fewer participants than English-language trials but were more likely to show statistically significant results. Jüni et al. (11) found that English-language trials had significantly higher mean (269 ± 487 compared with 147 ± 195; $p < .01$) and median (116 compared with 88; $p < .01$) sample sizes compared with LOE trials.

Methodological Quality. Two reports (11;12) assessed the quality of the RCTs or the meta-analyses.

Moher et al. (12) detected small differences in reporting quality. Language-inclusive systematic reviews were higher quality and had more comprehensive searches than language-restrictive reviews (12). Small differences were detected in the reporting quality of English-language trials compared with those in other languages.

Moher et al. (12) found no statistically significant differences between English-language and LOE trials in likelihood of reporting a valid approach to patient randomization (90 percent compared with 83 percent; $p = .13$), accounting for patient withdrawals and losses to follow-up (64 percent compared with 57 percent; $p = .43$), or reported use of double-blinding (57 percent compared with 50 percent; $p = .29$). The authors compared RCT quality scores using the Jadad scale (10). Percentages of low-quality studies (Jadad score 0 to 2; 52 percent of English RCTs and 60 percent of LOE RCTs) and high-quality studies (Jadad score 3 to 5; 48 percent of English RCTs and 40 percent of LOE RCTs were comparable ($p = .23$). Allocation concealment was inadequate or unclear in 87 percent (English) and 96 percent (LOE) of trials.

In contrast, Jüni et al. found that English-language trials tended to be of higher methodological quality than those published in other languages (11). Specifically, 88 English-language

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trials (35.7 percent) indicated adequate concealment of allocation compared with twelve LOE trials (25.0 percent) ($p = .15$), and 153 English-language trials (66.5 percent) were double- or assessor-blinded compared with twenty-three LOE trials (46.9 percent) ($p = .016$) (11).

Publication Status. Two reports (12;19) found no evidence of publication bias in English-language only meta-analyses, or LOE-inclusive meta-analyses with or without LOE contribution to the quantitative analysis (12;19).

Statistical Heterogeneity. Moher et al. (12) used I^2 to compare the statistical heterogeneity of English-language restricted meta-analyses or LOE-inclusive meta-analyses. The I^2 statistic quantifies the percentage of variation across studies due to heterogeneity instead of chance. Between-study heterogeneity is considered substantial if I^2 is 50 percent or more (2). They found that between-study heterogeneity increased by 2.4 percent with the inclusion of LOE RCTs in thirty-four systematic reviews in conventional medicine. Pham et al. (19) found no significant association between language of publication restrictions and statistical heterogeneity.

DISCUSSION

One limitation of this review is that no studies examined single fields of medicine, preventing analysis of LOE trials in particular specialties. Egger et al. demonstrated that LOE trials are important in psychiatry, rheumatology, and orthopedics (4). Pan et al. concluded that Chinese studies are crucial in molecular medicine (18). These studies indicate that the influence of LOE trials in different specialties may vary. Although the primary computation of RORs in several included articles did not identify significant changes in overall pooled measures of effectiveness, stratified analyses showed the impact of LOE trials is heterogeneous across medical specialties and there are more LOE trials in some areas of medicine (11;12;19).

There is conflicting evidence about the methodological and reporting quality of trials published in English versus those in LOE. Moher et al. (13;14) detected no differences in the reporting of randomization, double-blinding, dropouts, withdrawals, and allocation concealment. Previously, Moher et al. (14) found an association between poor reporting of methods and exaggerated estimates of efficacy. Jüni et al. (11), however, found English-language trials were of higher methodological quality than LOE trials. The discrepancy may be due to the different quality measures used and the inclusion of alternative medicine SR/MA in the Moher report.

Some studies included meta-analyses where one or two trials reported in LOE were identified. This may not represent all available foreign-language studies, and may be due to a lack of resources for foreign language translation. Thus, the true "exposure" of meta-analyses to LOE data may be limited.

Another limitation to this review is that the reports are now relatively old with literature searches ranging from 1996 to 1999. Publishing practices may have changed, and research methods have since improved with greater adherence to guidelines for systematic reviews (8).

Two reports did not search EMBASE (11;15). EMBASE covers more European journals (20) and relevant studies may have been missed as a result.

Searching for studies in LOE may have other benefits, including increasing the external validity for specific clinical specialties where LOE studies are known to be important, and increasing awareness of the number and quality of LOE studies.

CONCLUSIONS

We found no evidence of systematic bias from the use of language restrictions in SRs/MAs in conventional medicine. There were conflicting findings about the methodological and reporting quality of English-language versus LOE trials. These findings do not rule out the potential for language bias when language restrictions are used. Searches should include LOE studies when resources and time are available to minimize the risk of a biased summary effect. More research, in different medical specialties, will provide better evidence on the effect of language restriction on systematic reviews.

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CONFLICTS OF INTEREST

Michelle Fiander is employed by the Cochrane Effective Practice and Organisation of Care (EPOC) Group. The other authors report they have no potential conflicts of interest.

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