Use of AMSTAR-2 in the methodological assessment of systematic reviews: protocol for a methodological study

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Background: Systematic reviews (SRs) with or without meta-analyses (MAs) are widely used in resolving questions in various healthcare areas (such as, traditional Chinese medicine, public health and surgery), and they are the cornerstone of evidence-based healthcare. However, the reliability of SRs is typically influenced by their methodological quality. AMSTAR (A Measurement Tool to Assess Systematic Reviews) and AMSTAR-2 tools can assess the methodological quality of SRs, and the use of AMSTAR has been investigated. However, AMSTAR-2 is now widely used to evaluate the methodological quality of SRs, but the use of AMSTAR-2 for determining the methodological quality of SRs has not yet been investigated and assessed thoroughly. Thus, we designed the present study to investigate the use of AMSTAR-2 in studies that assessed the methodological quality of a sample of SRs with the AMSTAR-2 and provide references to potential users of AMSTAR-2 tool.

Methods: Four commonly used electronic databases including PubMed, EmBase, the Cochrane Library, and Web of Science will be searched following a comprehensive search strategy to identify and retrieve studies that have used AMSTAR-2 tool for evaluating the methodological quality of SRs. Two independent authors will retrieve bibliometric information and methodological data, including all author names, time of publication, and journal names, whether a specific score value was given for each item, and whether overall quality assessment was performed. Descriptive statistical analyses will be used to present the study results, e.g., frequencies and percentages, mean and standard deviation (SD) or median and interquartile range (IQR). In addition, subgroup analyses will be performed to identify the methodological differences (e.g., the reporting of study designs included in SRs) between overviews and methodological studies. The risk ratio (RR) with 95% confidence interval (95% CI) will be calculated to measure the methodological differences. Cytoscape 3.7.1 software tool will be used to construct collaboration network maps. Further, Microsoft Office Excel 2016 and Stata 12.0 will be used to manage and analyze data.

Discussion: The results of this study will identify any gaps in the use of AMSTAR-2 and important bibliometric features, such as active researchers and journals, provide guidance to researchers in various healthcare areas (such as, traditional Chinese medicine and public health) for using AMSTAR-2 tool and help them in developing cooperation and submitting their manuscripts.

Keywords: Systematic reviews (SRs); quality; AMSTAR-2; healthcare; traditional Chinese medicine; public health; surgery

Introduction

According to the National Academy of Medicine, a systematic review (SR) is "*a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies*" (1). The meta-analysis (MA) is a statistic method that aims to quantitatively pool individual results from homogeneous primary studies, and SRs are often but not always accompanied with MAs (2). At present, SRs mainly include qualitative SRs, traditional paired MAs, MAs of individual patient data, and network MAs, among others (3-5). SR and MA had been widely used in resolving questions in various healthcare domains, such as public health, surgery and traditional Chinese medicine (3,6,7). These SRs can provide evidence to support decision-making, and are the cornerstone of evidence-based clinical practice and evidence-informed policymaking. However, it is noteworthy that not all SRs are reliable and valuable, and only well-designed, strictly performed, unbiased SRs are excellent evidence resources that can provide scientific evidence to support evidence-based healthcare (1,8).

Studies have shown that quality of SRs can be influenced by many factors (9-11), e.g., quality of included primary studies, preregistration, predesigned protocol, completeness and clarity of reporting, and control of potential bias. Fortunately, the reporting and methodological quality of SRs can be assessed using corresponding checklists or scale tools, such as PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) (12) and its extensions (13,14), ROBIS (Risk Of Bias In Systematic reviews) (15), AMSTAR (A Measurement Tool to Assess Systematic Reviews) (16) and AMSTAR-2 (17). Thus, all potential targeted users in healthcare domains, such as peer-reviewers, editors, clinicians, and health decision-makers, can judge the reliability of existing SRs using the abovementioned tools. Moreover, authors can refer to these tools to improve the quality of their manuscripts; further, evidence has revealed that the quality of publications has been improved with the use of these relevant tools (18-20).

In particular, AMSTAR and AMSTAR-2 tools focus on the methodological quality of SRs, and their reliability and validity have been verified (21,22). AMSTAR was originally developed for SRs of RCTs for interventions and was introduced in 2007 (16). The tool consists of 11 items, involving prospective design, study selection and information abstraction, study search, grey literature, list of primary studies, study characteristics, quality assessment,

combination of study results, publication bias, and conflicts of interest. The answers for these 11 items include "Yes", "No", "Cannot Answer", and "Not Applicable". AMSTAR was widely used to assess the methodological quality of SRs, but was not only limited to SRs of randomized controlled trials (RCTs) for interventions, such as SRs of non-randomized studies (23). On the use of AMSTAR, some limitations of this tool were identified; therefore, a revised tool, AMSTAR-2 was introduced in 2017 (17). According to the original report (17), AMSTAR-2 was developed to assess SRs of randomized and/or non-randomized interventional studies, but was not intended for use in assessing other types of SRs, such as MAs of diagnostic test accuracy, MAs of individual patient data, network MAs, scoping reviews. On comparing with AMSTAR, which comprises 11 items, AMSTAR-2 comprises 16 items, and seven of them are critical items, including prior protocol, comprehensive literature search, justification of excluding studies, assessment of RoB for individual studies, appropriate meta-analytic methods, consideration of RoB in results and impact of publication bias. One of following four options could be used to answer the questions of items: "Yes", "Partial Yes", "No" or "No meta-analysis conducted". Furthermore, based on critical items, the overall confidence in the results of SRs can be divided into four levels: high, moderate, low, and critically low. After getting published, the AMSTAR-2 tool has been widely employed to evaluate the methodological quality of SRs (6,24-26), for example, Luo *et al.* (25) assessed the quality of SRs of acupuncture for women with polycystic ovarian syndrome using AMSTAR-2 and PRISMA (Preferred Reporting Items for Systematic review and Meta-Analyses), and authors concluded that identified SRs had the poor methodological and reporting quality.

The correct use and complete reporting of assessment tools are critically important (21,27). For example, whether a specific score value should be given for each item and whether the overall quality assessment of SRs should be based on a total score are always topics of debate (21). Pieper *et al.* (21) identified 247 publications and investigated the use of AMSTAR in them; the study found that the use of AMSTAR varied greatly, and outreached the original purpose defined by the introduced paper; the study suggested that stakeholders including authors, peer-reviewers, and editors should pay more attention to the correct use and complete reporting of AMSTAR. However, although AMSTAR-2 is now widely used in overviews or methodological studies for assessing the methodological

quality of SRs, the use of AMSTAR-2 in the methodological assessment of SRs has not been thoroughly investigated so far. Furthermore, as it is a relatively new tool, early detection and correction of problems while using the tool are particularly important. In addition, bibliometric analysis is an important method that can find the key features of a set of studies, such as, core researchers and their collaboration network (also named as social network), and journals, can provide guidance for developing cooperation and submitting manuscripts for researchers (26,28). Therefore, by combining the bibliometric methods, the present methodological study was designed to investigate the use of AMSTAR-2 in studies that assessed the methodological quality of a sample of SRs with the AMSTAR-2 and provide references to potential users of AMSTAR-2 tool.

Objectives

(I) to analyze bibliometric characteristics (such as authors and journals) of studies that assessed the methodological quality of a sample of SRs with the AMSTAR-2; (II) to investigate how AMSTAR-2 is used in studies that employ AMSTAR-2 for assessing the methodological quality of SRs; and (III) to analyze whether the use of AMSTAR-2 goes beyond the original purpose defined by the original study.

Methods

The reporting of this protocol was according to the PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocols) guideline (see Supplement I) (29), although some items were different from the original tool. Because the present study is a methodological study rather than a SR, we did not register it in an open public website.

Eligibility criteria

The study aims to investigate the use of AMSTAR-2 in the methodological assessment of SRs; therefore, we will include published papers that have used AMSTAR-2 to assess the methodological quality of SRs. Based on our previous experience, we will include two large groups publications, the first group will include overviews, also known as SRs of SRs (5,21), where AMSTAR-2 is often applied to assess the methodological quality of included SRs, and the other group will include methodological

studies focusing the methodological quality of SRs for a given topic, such as surgery (6), or a type of SRs (26). In this study, psychometric studies will be classified as methodological studies (22,30). In other words, all publications in English will be considered if they have used AMSTAR-2 to assess the methodological quality of SRs. We will exclude conference abstracts, letters, comments, protocols and other paper documents in which we cannot retrieve the data that we need.

Search strategy

To identify as many eligible publications as possible, four commonly used electronic online databases including PubMed, EmBase, the Cochrane Library, and Web of Science, will be searched systematically using a comprehensive search strategy. An initial search was conducted on October 14, 2019. The initial search yielded 186 records. Further, we will also check the lists of references of these included studies to supplement potential eligible studies. We will then update the search will by scanning these databases again after the completion of data extraction. We have presented the search strategy using PubMed as an example in *Table 1*. The search strategy will be adapted to fit other online databases as well. There will be no other limitations for search methods.

Study selection

The selection of studies will comprise two stages. First, all hits from these four online databases will be downloaded and imported into Endnote X9 software tool (Thomson Reuters, New York, NY, USA) for deduplication. Second, full texts of studies will be retrieved from journal websites or electronic databases after deduplication to assess their eligibility according to the abovementioned inclusion criteria. These two stages will be accomplished by two independent authors, and any disagreement will be solved by a discussion or by consulting a third author.

Data extraction

Two authors will extract relevant information from included studies using a predesigned data form. The data form will be piloted and improved using 5–10 included studies for convenience. The following information will be retrieved from each included study: (I) bibliometric data: all author names, author's institutions, author's countries, publication

Table 1 Search strategy of PubMed database

#1	meta-analysis [Title/Abstract] OR meta-analyses [Title/Abstract] OR "systematic review" [Title/Abstract] OR "systematic reviews" [Title/Abstract] OR overview* [Title/Abstract] OR review* [Title/Abstract]
#2	"AMSTAR 2" [All Fields] OR "AMSTAR2" [All Fields] OR AMSTAR-2 [All Fields]
#3	#1 AND #2

time, journal names, journal impact factor (IF), clinical topics (such as, surgery or acupuncture or psychology), and references of AMSTAR-2 (original paper or not); (II) methodological information: study types included in the present study (overview or methodological study), searched databases and included SR types (SR without MA, MA, network MAs, etc.) in overviews or methodological studies, study designs included in SRs (only RCT, non-randomized studies, or both), rationales of using AMSTAR-2, versions of AMSTAR-2 (original or modified), methods of assessment (independently assessed, or assessed by one group and the results checked by the other group), number of reviewers using AMSTAR-2, inter-rater reliability (IRR), whether a specific score value was given for each item (e.g., "Yes" =1 point, "Partial Yes" =0.5 point, or "No" =0 point), whether and how the overall assessment was conducted, whether comments were provided for assessment, whether the tool was used in conjunction with other tools [such as, PRISMA or GRADE (Grading of Recommendations Assessment, Development and Evaluation) (31)], whether the results or conclusions of SRs were reported, whether limitations were considered while scoring, and whether limitations were commented on with regard to the use of AMSTAR-2 (e.g., to assess the quality of network MAs). In this study, all data will be based on published documents; therefore, authors of included studies will not be contacted to acquire any additional information on the included studies.

Data analysis

Descriptive statistical analyses will be used in this study. For categorical data, frequencies and percentages will be used, and for continuous data, mean and standard deviation (SD), or median and interquartile range (IQR) will be presented according to the included data. Because overviews and methodological studies typically have different purposes (21), subgroup analyses will be performed to identify the methodological differences between overviews and methodological studies. The risk ratio (RR) with 95% confidence interval (95% CI) will be calculated and

used to measure the methodological differences, e.g., whether the reporting of study designs included in SRs in overviews was different from that included in SRs in methodological studies. Microsoft Office Excel 2016 (Microsoft Corporation, Redmond, WA, USA) will be used to manage and analyze data. Cytoscape 3.7.1 will be used for visualization of social-network relationship (32). Stata 12.0 (Stata Corporation, CollegeStation, Texas, USA) will be used to calculate RR values and present forest plots.

Discussion

To the best of our knowledge, this is the first study to investigate the use of AMSTAR-2 tool for assessing the methodological quality of SRs. The results of this study will identify any gaps in the use of AMSTAR-2 and important bibliometric features, such as active researchers and journals, provide guidance to researchers in various healthcare domains (such as, traditional Chinese medicine, public health and surgery) for using AMSTAR-2 tool to improve their manuscripts' quality and help them in developing cooperation and submitting their manuscripts. This methodological study will only include publications in English language; therefore, the results of the study may be biased.

Presenting and reporting of results

The results of this study will be reported according to the PRISMA guideline (25). A flow chart will be used to present the process of the screening and selection of the eligible studies.

Acknowledgments

Footnote

uniform disclosure form (available at http://dx.doi.org/10.21037/atm-20-392a). The authors have no conflicts of interest to declare.

Ethical Statement: All authors are accountable for all aspects of this work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The present study will not involve any patients and/or the public. No ethical approve or informed consent is required for the purposes of the present study.

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Supplement I PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No.	Checklist item	Location in manuscript
Administrative information			
Title			
Identification	1a	Identify the report as a protocol of a systematic review	Title page
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	Not applicable
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Not applicable
Authors			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Title page
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	"Contributions"
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Not applicable
Support			
Sources	5a	Indicate sources of financial or other support for the review	Not applicable
Sponsor	5b	Provide name for the review funder and/or sponsor	Not applicable
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Not applicable
Introduction			
Rationale	6	Describe the rationale for the review in the context of what is already known	"Introduction"
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	"Introduction" and "Objectives", not relevant to PICO
Methods			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	"Eligibility criteria"
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	"Search strategy"
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	"Table 1"
Study records			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	"Study selection"
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	"Study selection"
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	"Data extraction"
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	"Data extraction"
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	"Data extraction"
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Not applicable
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	"Data analysis"
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	"Data analysis"
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	"Data analysis"
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	"Data analysis"
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Not applicable
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Not applicable

*, it is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0. From: Shamseer L, Moher D, Clarke M, *et al.* Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ* 2015;349:g7647.