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ORIGINAL ARTICLE

Reporting quality and statistical analysis of published dose-response meta-analyses was suboptimal: a cross-sectional literature survey

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Abstract

Objectives: The objective of this study was to investigate the characteristics, methodological quality, and reporting of statistical analyses of published dose-response meta-analyses (DRMAs).

Study Design and Setting: We searched PubMed to identify DRMAs published in 2017. The reporting characteristics and methodological qualities were assessed by the PRISMA (27 items) and AMSTAR (11 items), respectively. We also summarized the reporting of statistical analyses of included DRMAs.

Results: We identified 93 DRMAs, most of which (59/93) were conducted by Chinese researchers and the main outcome was the incidence of cancers. Of the PRISMA and AMSTAR items, twenty and five were well complied (80% or more), respectively. The compliance rates of several PRISMA checklist items, such as structured summary, objectives, protocol and registration, and funding, were less than 50%. There were no criteria to estimate the doses for the open-ended intervals of exposure or intervention doses. When the restricted cubic splines were used to fit nonlinear dose-response relationships, there were also no criteria to determine the fixed knots.

Conclusion: The adherence to the methodological items of reporting guidelines and statistical analysis of published DRMAs were suboptimal. Development of reporting guidelines to assist authors in writing and readers in critically appraising the reports of DRMAs is timely.

Keywords: Dose-response meta-analyses; Methodological quality; Reporting characteristics; Statistical analysis; PRISMA; AMSTAR

1. Introduction

An increasing number of dose-response meta-analyses (DRMAs) have been published over the past several years [1]. When we research on observed associations between exposure and outcome, dose-response relationship is an important factor affecting the convincingness of clinical epidemiological evidence [2]. DRMAs were able to yield more precise estimates of putative dose-response effects when dose-specific findings from different studies on the same subjects were reported.

Generally, dose-response relationship may be linear or nonlinear. Linear dose-response analyses are performed by fitting generalized least squares for trend [3] model. There are generally three types of functions for fitting the nonlinear dose-response relationship: restricted cubic splines, natural quadratic function, and the fractional polynomials [4,5]. The most common nonlinear function is the restricted cubic splines with 3 or 4 knots inserted in the data distribution.

Although DRMAs was a type of meta-analyses quantitatively synthesizing results of multiple original studies, the

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What is new?

Key findings

- The methodological quality and statistical analysis of published DRMAs were suboptimal. The compliance rates of several PRISMA or AMSTAR checklist items, such as structured summary, objectives, funding, protocol and registration, and status of publication, were less than 50%.
- In these included DRMAs, there were no criteria to estimate the doses for the open-ended intervals of exposure or intervention doses. When the restricted cubic splines were used to fit nonlinear dose-response relationships, there were also no criteria to determine the fixed knots.

What this adds to what was known?

- A comprehensive appraisal evaluating the reporting characteristics, methodological quality, and statistical analysis of published DRMAs is imperative but reporting guidelines for DRMAs is lacking. Our study has summarized the reported key statistical analysis, which is the important difference between DRMAs and traditional meta-analyses. We proposed a brief recommendation to help further review authors to better conduct DRMAs.

What is the implication and what should change now?

- Our study clearly proposes to develop reporting guidelines specifically for DRMAs. Then there needs to have criteria for defining the dose for the open-ended intervals, simultaneously needs explicitly fixed knots for assessing restricted cubic splines when it comes to nonlinear dose-response relationship.

statistical analysis of DRMAs may be particularly different from traditional meta-analyses [6−11]. A comprehensive appraisal evaluating the reporting characteristics, methodological quality, and statistical analysis of published DRMAs is imperative but reporting guidelines for DRMAs is lacking. Recently, Xu et al. [12,13] assessed 529 DRMAs published from January 2011 to July 2017, using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [14], Meta-analysis Of Observational Studies in Epidemiology (MOOSE) [15], and A Measurement Tool to Assess Systematic Reviews (AMSTAR) [16]. However, currently there are no studies that have assessed the reported statistical analysis of DRMAs. The availability of such information is also critical for the development of reporting guidance for DRMAs because it is possible that the reporting quality of DRMAs might be improved over time [17].

Therefore, we conducted a methodological review of DRMAs published in 2017, to summarize their characteristics and methodological quality based on the AMSTAR (11 items) and the PRISMA (27 items), respectively. And to investigate the key statistical analysis reported in recently published DRMAs.

2. Methods

2.1. Eligibility criteria

We included meta-analyses that explicitly combined dose-response estimates from multiple original studies on the same subjects and reported the results of dose-response analyses. Brief reports (i.e., a short demonstration of research results), letter, and conference abstracts were excluded because such type of publication contained limited information of reporting items.

2.2. Literature search

We searched PubMed to identify DRMAs published from January 1st, 2017, to December 31st, 2017, using the following search strategy: (meta-analysis [Title/Abstract]) AND (dose-response [Title/Abstract]) AND (“2017/1/1” [Date - Publication]: “2017/12/31” [Date - Publication]).

2.3. Study selection

Literature search records were imported into the literature management software of ENDNOTE X7. Two independent reviewers (Q.J. and Q.L.) examined the title and abstract of retrieved records to identify potentially relevant DRMAs according to the eligibility criteria. Then, full-text versions of all potentially relevant DRMAs were obtained to further confirm the eligibility. All articles were renumbered: 001, 002, … 186 and divided into 93 groups with 2 numbers in each group. Randomly set a number “t” in the first group by systematic sampling. Then selected all “t + 2k” (k = 0, 1, 2, … 92) into a sample with a capacity of 93. Disagreements between the two reviewers were resolved by discussing with a third reviewer (S.C.).

2.4. Data extraction

We collected data from included DRMAs on general characteristics, including countries of corresponding author, categories of study outcome, database searched, the key reporting (PRISMA) and methodological (AMSTAR) components, and specific items about the statistical analyses of dose-response effects. A standard data abstraction form was created using Microsoft Excel 2013 (Microsoft Corp, Redmond, WA, www.microsoft.com). Two

investigators (Q.J., Q.L.) independently extracted the data. Any disagreements were resolved by discussion.

2.5. Data analyses

General characteristics of included DRMAs were summarized descriptively. Because no specific reporting guidelines for DRMAs were available, we assessed the reporting and methodology quality according to PRISMA and AMSTAR. We used the AMSTAR [16] to assess the methodological quality of the included DRMAs. The PRISMA statement is a checklist of 27 items that are recommended to be included in systematic reviews and meta-analyses to ensure that published reports contain all relevant information [14]. Each PRISMA item was rated with a "yes" or "no" response. A "yes" response means that the item was reported, and a "no" response means that the item was not reported. The AMSTAR tool is an 11-item questionnaire that is used to determine the methodological of systematic reviews and meta-analyses [16]. The original tool had four responses with each item, "yes," "no," "cannot answer," or "not applicable". As we included only meta-analyses, every item was applicable. A "yes" response means that the item is fulfilled, a "no" response means that the item is not fulfilled, and a "cannot answer" response means that it is inconclusive as to whether the item is fulfilled. In this study, we assigned "1" to "yes" response, and "0" to "no" or "cannot answer" response for each of the PRISMA and AMSTAR items. Therefore, every included DRMA has an overall PRISMA counts rated out of a maximum point of 27, and every included DRMA has an overall AMSTAR counts rated out of a maximum point of 11.

We calculated the adherence rates of individual AMSTAR and PRISMA items and showed results in figures. The calculation formula was as follows: adherence rate of an item = (the number of articles with a "yes" response to the item/the total number of articles)*100%. The AMSTAR and PRISMA counts of each article were also calculated.

To investigate the statistical analyses process of the included DRMAs, we descriptively summarized the methods of confirming dose, the methods used to estimate dose-response effects, and knots used when restricted cubic splines were used.

3. Results

3.1. Literature search

Initial literature search retrieved 292 citations. After removing duplicates and the title/abstracts screening, 248 publications were collected for the full-text screening. We excluded articles that did not explicitly combine dose estimates from multiple original studies on the same subjects, or did not report results of dose-response analyses. Finally, through a round of systematic sampling, 93 citations were included (Fig. 1).

3.2. General characteristics of included DRMAs

China was the most common country in which the included DRMAs were conducted (59/93, 63.4%), followed by Germany (6/93, 6.5%) and Italy (5/93, 5.4%) (Fig. 2). Cancer (31/93, 33.3%) was the most common disease outcome in the included DRMAs (Fig. 3). PubMed/Medline was the most common single database search, accounting for 98%, and it was frequently combined with a search of Embase (64/93, 68.8%). The details of databases searched are shown in Table 1.

3.3. Reporting quality based on PRISMA

The highest and lowest scores for a single article based on PRISMA were 26 and 17, and the average score and corresponding standard deviation were 22.83 and 1.96, respectively. About half of PRISMA items (13/27, 48.2%) were reported in the included DRMAs. 48.4% of DRMAs provided a structured summary and only 6.5% provided an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). 48.4% of DRMAs provided registration information on review protocols. 52.7% of DRMAs described methods used for assessing risk of bias of individual studies and 75.3% considered impact of possible risk of bias on the cumulative evidence (e.g., publication bias, selective reporting, and so on). In addition, 36.6% of DRMAs described sources of funding for the systematic review and other support. The percentages of adequately reported individual PRISMA items are shown in Fig. 4.

3.4. Methodological quality based on AMSTAR

Figure 5 shows the results of methodological quality assessment based on AMSTAR. The highest and lowest AMSTAR scores were 11 and 5, and the average score and corresponding standard deviation were 8.40 and 1.60. Of the included DRMAs, 53.8% provided an "a priori" design, about one-third did not perform a comprehensive literature search. Only 39.8% used the status of publications (i.e., gray literature) as an inclusion criterion. More than half of the included DRMAs considered the scientific quality and the conflict of interest in formulating conclusions, and assessed the likelihood of publication bias.

3.5. Statistical analysis of dose-response effects

The statistical reporting in dose-response meta-analysis is shown in Table 2. For the corresponding RR, approximately half of the included DRMAs (44/93, 47.3%) assigned the median or mean dose of exposure for each category. 57% of the included DRMAs used the midpoint

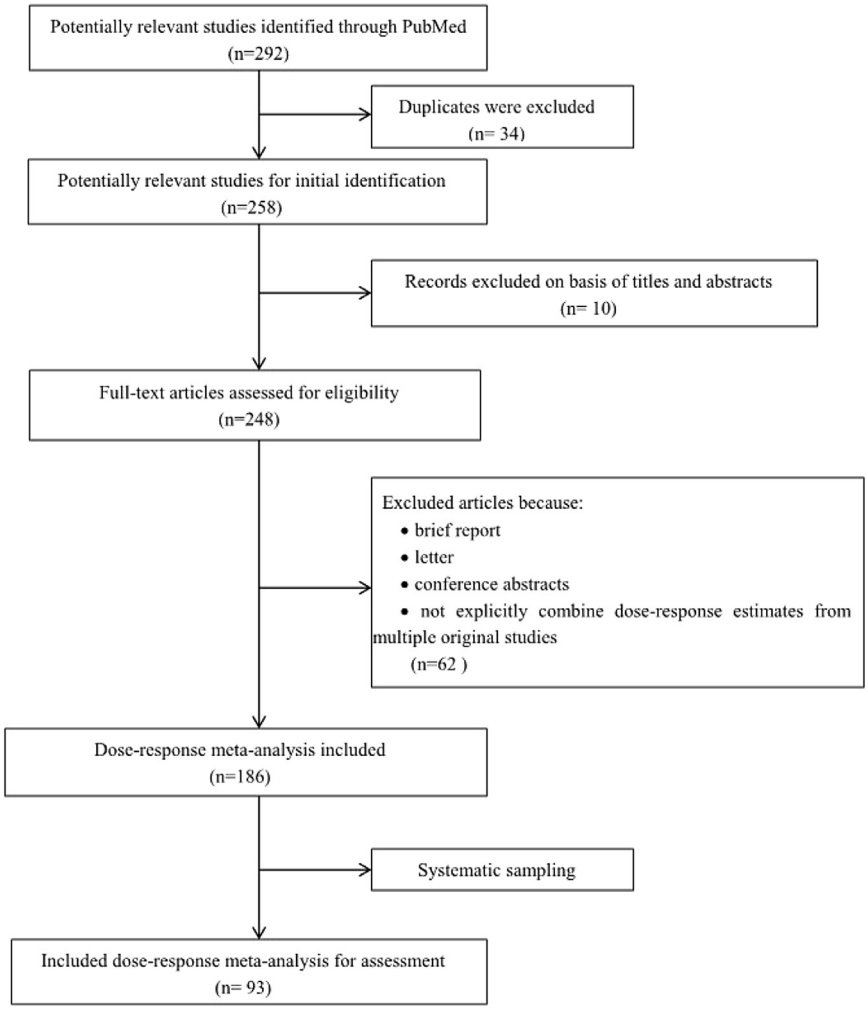

Fig. 1. The flow chart of literature selection.

as the dose when studies reported the exposure by range. When the highest category was open-ended, the most common method (42/93, 45.2%) to assign the dose was the sum of the low end of the interval plus half of the width of the adjacent category. When the lowest category was open-ended, 38 (40.9%) of the included DRMAs assumed the dose to be half of the high end of the interval, 14 (15.1%) set the lowest boundary as zero, and 41 (44.1%) did not mention the method used.

When it comes to dose-response assessment, 69.9% and 76.3% of the included DRMAs assessed linear and non-linear relationships respectively. Half of the included DRMAs used the restricted cubic splines with fixed knots

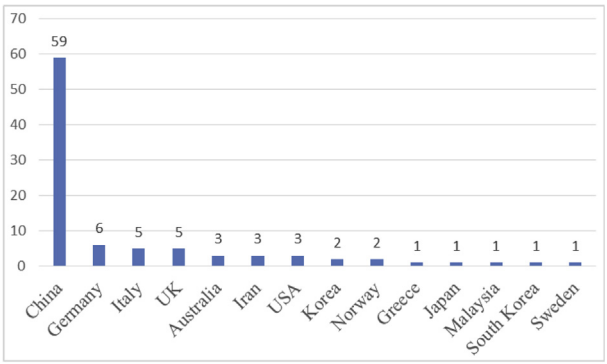

Fig. 2. Countries of included dose-response meta-analyses.

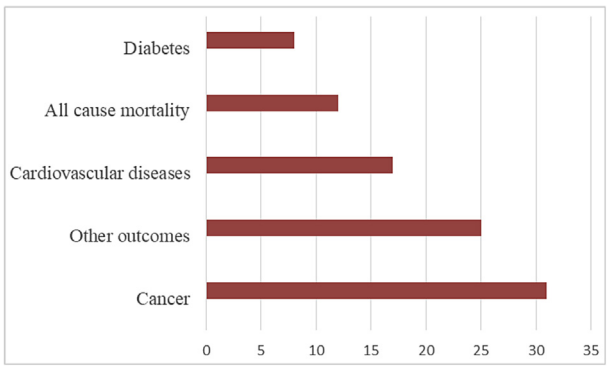

Fig. 3. Categories of outcome of included dose-response meta-analyses.

Table 1. Database searched

Items	Category	Frequency	Proportion (%)
Name of database searched	PubMed/Medline	91	97.85
	Embase	70	75.27
	Web of Science	38	40.86
	Cochrane library	23	24.73
	Scopus	11	11.83
	Ovid	8	8.6
	Google Scholar	8	8.6
	CNKI	7	7.53
	Wanfang	7	7.53
	Others	28	30.11
Common combination of database searched	PubMed/Medline + EMBASE	64	68.82
	PubMed/Medline + Web of Science	52	55.91
	PubMed/Medline + Embase + Web of Science	46	49.46
	PubMed/Medline + Embase + Cochrane Library	22	23.66
	PubMed/Medline + Embase + Google Scholar	19	20.43
	PubMed/Medline + Web of Science + Cochrane Library	16	17.2
	PubMed/Medline + Web of Science + CNKI + WANFANG	7	7.53

to assess the potential nonlinear dose-response effects. The most common knots adopted (32/47, 68.1%) were 10th, 50th, and 90th percentiles, followed by 5th, 35th, 65th and 95th percentiles (9/47, 19.2%). Almost half of the included DRMAs (45/93, 48.4%) assessed the indication of non-linearity. Dose-response plots were not presented in 14 (15.1%) of the included DRMAs.

4. Discussion

4.1. Summary of findings

Generally speaking, the overall adherence rates of the PRISMA and AMSTAR were relatively suboptimal. Findings from our study demonstrated that there were deficiencies in methodological compliance and statistical

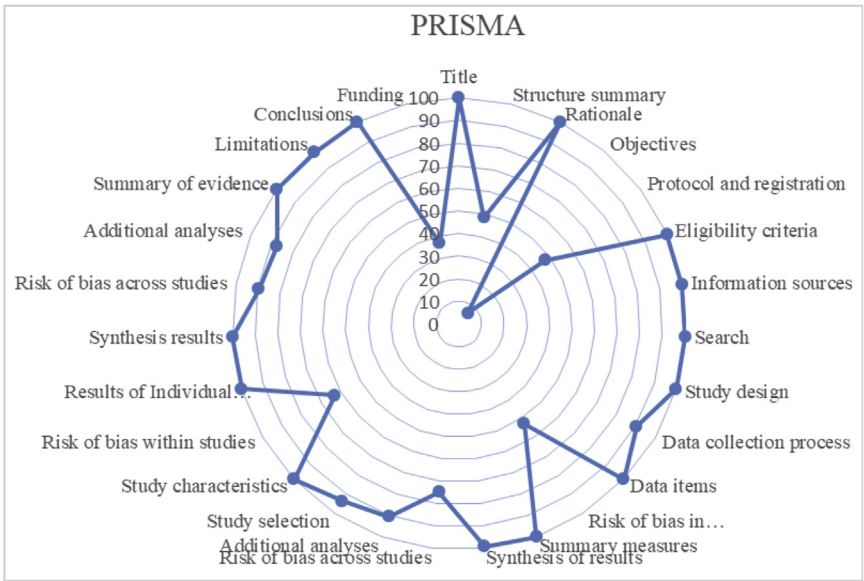

Fig. 4. The percentage of adequately reported individual items based on PRISMA.

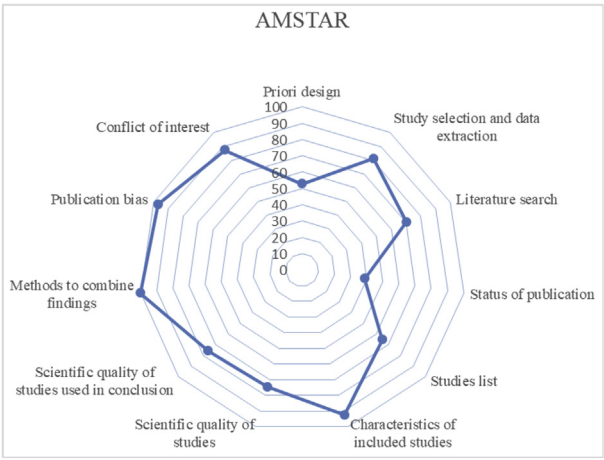

Fig. 5. The percentage of adequately reported individual items by AMSTAR.

analysis methods in published DRMAs. Development of reporting guidelines on DRMA is required to assist authors in writing and readers in critically appraising the reports of DRMAs.

4.2. The strengths and limitations of reporting quality

In our study, abstracts of the included DRMAs were not comprehensive. Almost half of the DRMAs lacked a structured summary, making it impossible for researchers to understand research content comprehensively and intuitively from the abstract. Owing to no requirements for some magazines in structured abstracts, authors might fail to provide it. Less than one-tenth of the included DRMAs provided an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). Most DRMAs did not provide the information about protocol and registration. Relevant research results showed that prospective registration could effectively improve the overall methodological quality of systematic reviews, and it could slightly improve overall reporting quality [18]. Protocol registration reduced the risk of multiple reviews addressing the same research question, identified publication bias, and provided greater transparency when updating systematic reviews [19] and avoided duplication of effort [20]. Hence, it is necessary to treat preregistration as a mandatory checkpoint for future meta-analyses to be published. It is a promising measure worth researchers' attention which might lead to a significant improvement of quality.

Meta-analyses regularly have the intrinsic limitation of heterogeneity and conclusions could be misleading because of the additional analyses. Most of the meta-analyses did report the quantified heterogeneity using I^2 value or other tests; the source of heterogeneity was not routinely explored. Subgroup analysis and metaregression can be performed to explain the source of the significant heterogeneity [21,22]. The interaction between the subgroups was one of the issues to be considered in the quality of meta-analysis, whereas the dose-response meta-analysis currently has no effective means for detection and adjustment.

About a third of DRMAs described sources of funding and other support (e.g., supply of data), as well as the roles of funders. The sources of the funding and the conflict of interests had an obvious impact on the results of the research. Giving information about funds can help users better identify them; it needs to be reported explicitly in all studies. Not reporting risk of bias assessment may be due to a lack of good quality assessment tools for dose-response studies.

4.3. The strengths and limitations of methodological quality

The overall AMSTAR adherence rate was suboptimal; some methodological flaws were emerged. It was not hard to understand that "a priori" design can make sure the researchers have a clear thinking and well-organized action. Having a protocol or "a priori" design can partially obligate the authors from post hoc modification of inclusion criteria and analytic methods [10]. Approximately one-third of the included DRMAs did not perform a comprehensive literature search. There may be good grounds for only using major database searching without gray literature in DRMAs. Avoiding research on questionable quality may lead to the low percentage of AMSTAR results. Perfect retrieval is reflected in two aspects: first, the elements of retrieval strategy should be complete; second, the scope of retrieval should be wide. Suboptimal compliance of item 4 should also be noted because exclusion of gray literature from meta-analyses can lead to exaggerated estimates of intervention effectiveness [7]. AMSTAR item 5 (list of studies) were underreported, it gave partial search strategies such as keywords used as MESH terms. Part of the reason was that authors only considered the lists of included studies and neglected the lists of important excluded studies [23].

Most of the included DRMAs assessed and documented the scientific quality. The scientific nature of a single study can affect the overall outcomes, and the quality grade of the original literature directly reflected the strength of evidence in systematic review. So the scientific nature of individual research needs to be further improved. It is reasonable to develop a methodological guideline of DRMA to help authors to form a clear thinking pathway.

4.4. Developing a reporting guideline specifically for DRMAs

There were no generally accepted methods to estimate doses for open-ended highest or lowest categories currently. The indicated dose should in principle use the mean provided in the original studies, and if not provided, the

Table 2. Statistical reporting in dose-response meta-analysis (*n*/%)

Items	Frequency (*n*)	Proportion (%)
Was the median or mean dose of exposure for each category was assigned to the corresponding RR for every study? (yes)	44	47.31
For studies reporting the exposure by range, was the midpoint of the range used as the dose? (yes)	53	56.99
If the highest category was open-ended, how to confirm the dose?		
The dose was assigned as 20% higher than the low end of the interval	4	4.30
The dose was assigned as 25% higher than the low end of the interval	3	3.20
The dose was assigned as 50% higher than the low end of the interval	5	5.34
The dose was assigned as the sum of the low end of the interval plus half of the width of the adjacent category	42	45.20
The dose was calculated as the lower bound plus 1.5 times the width of the adjacent category	1	1.10
Not mentioned	38	40.86
If the lowest category was open-ended, how to confirm the dose?		
The dose was assigned as half of the high end of the interval	38	40.86
The lowest boundary was set at zero	14	15.05
Not mentioned	41	44.09
Dose-response assessment		
Was the linear dose-response relation assessed? (yes)	65	69.90
Was the nonlinear association assessed? (yes)	71	76.34
Were both the linear and nonlinear association assessed? (yes)	45	48.39
Neither the linear nor the nonlinear association was mentioned	12	12.90
Was the potential nonlinear dose-response relationship assessed using restricted cubic splines with fixed knots?	47	50.54
If the potential nonlinear dose-response relationship was assessed using restricted cubic splines with fixed knots, the knots were:	47	50.54
5th, 35th, 65th and 95th percentiles	9	19.15
25th, 50th, and 75th percentiles	3	6.38
10th, 50th, and 90th percentiles	32	68.09
5th, 50th and 95th percentiles	1	2.13
First, 25th, 50th, 75th, and 99th percentiles	1	2.13
10th, 60th, and 90th percentiles	1	2.13
Was the indication of non-linearity assessed? (yes)	45	48.39
Was the Dose-response Figure presented in the article? (yes)	79	84.95

median of the extracted dose interval should be used instead. For the open interval of the end, it is usually necessary to make an estimate or hypothesis. Such as taking 1.2 or 1.5 times the cutoff point as the specified dose for the interval, or assuming the same width as the adjacent interval and then taking the median. In our research, the methods used for interval selection and dose determinations were inconsistent or unclear. When the highest category was open-ended, it was often to assign the sum of the low end of the interval plus half of the width of the adjacent category as the dose. On the other hand, when the lowest category was open-ended, many DRMAs assumed the dose to be half of the high end of the interval. There were also doses specified as 20%, 25%, and 50% higher than the low end of the interval. The dose-response mapping process was generally fitted by a restricted cubic spline method, defining a smooth inflection point in the curve fit as a knot. Using an insufficient number of knots is difficult to show detailed changes in the dose response, and using too many knots will result in imprecise fitting. Therefore, 3 or 4 knots were generally used in the dose response mapping [5]. There were several different methods for knots selection, including 5th, 35th, 65th, and 95th percentiles, as well as 10th, 50th, and 90th percentiles. There was also a lack of criteria to determine the fixed knots that assessing restricted cubic splines when it comes to nonlinear dose-response relationship.

The complex nature of statistical analysis of DRMAs raised the necessity to develop a guideline about the reporting of statistical analysis of DRMAs. The authors may have used the appropriate method, but omitted important details in published reports, or there was no strict research process record. The figures and tables related to the dose-response should also be presented in the article. In addition, having a

reporting guideline makes the peer review process more efficient and more informed.

Overall, the adherence to the methodological items of reporting guidelines and statistical analysis of published DRMAs were suboptimal. Some methodological flaws had been identified in the published DRMAs, especially regarding to the priority design, comprehensive literature search, and the status of publications. Meanwhile, some shortcomings in reporting quality had also come to light, particularly about the structured summary, objectives, protocol, and registration. Further improvement could potentially be achieved by strictly adhering to PRISMA guideline and having ''a priori'' protocol. We propose to develop a reporting guideline specifically for DRMAs, with relevant criteria to define the dose for the open-ended intervals, and explicitly fixed knots to assess restricted cubic splines when it comes to nonlinear dose-response relationship.

CRediT authorship contribution statement

Qingqing Jiang: Conceptualization, Methodology, Writing - original draft, Writing - review & editing. **Qiaoyan Liu:** Conceptualization, Methodology, Writing - original draft, Writing - review & editing. **Fan Chen:** Data curation, Formal analysis, Writing - review & editing. **Xiantao Zeng:** Data curation, Formal analysis, Writing - review & editing. **Fujian Song:** Methodology, Writing - review & editing. **Zuxun Lu:** Conceptualization, Methodology, Writing - review & editing. **Shiyi Cao:** Conceptualization, Funding acquisition, Methodology, Writing - review & editing.

Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jclinepi.2019.07.008.

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