Do Author Conflicts of Interest and Industry Sponsorship Influence Outcomes of Systematic Reviews and Meta-Analyses Regarding Glaucoma Interventions? A Cross-sectional Analysis

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whether an association exists between risk of bias and author COI and determine whether study sponsorship influences the reported results and conclusions.

MATERIALS AND METHODS

Transparency, Reproducibility, and Reporting

To ensure transparency and reproducibility, our a priori protocol and materials are available on the Open Science Framework.11 While composing our manuscript, we referred to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines12 and Murad and Wang13 guidelines for meta-epidemiological studies.

Training

All researchers completed online and in-person training developed by J.M.A. and M.W. Training included an outline of the study design, objectives, materials, and data extraction training for one example SR. This training session was recorded and is available for reference.11

Search Strategy

We searched MEDLINE (Ovid) and Embase (Ovid) on June 2, 2020, to identify SRs of glaucoma treatment with or without a meta-analysis. Supplemental Table 1 (Supplemental Digital Content 1, http://links.lww.com/JIG/A525) lists our search strategies. Records from these search strategies were uploaded to the SR screening platform Rayyan (https://rayyan.qcri.org/) for title and abstract screening.

Screening

Two of us (A.W. and D.M.) screened the search results by titles and abstracts in a double-blind manner to include all SRs on the treatment of glaucoma with and without meta-analysis. Following this initial screening, full-text versions were evaluated to determine final eligibility according to the criteria outlined in the next section. Third party adjudication was available, if necessary.

Eligibility Criteria

To be included, a study must have: (1) met the PRISMA-P definition of a SR or meta-analysis14; (2) been a direct comparison of one treatment to another single treatment, another combination treatment, a placebo, or a standard of care; (3) investigated a treatment for glaucoma; (4) been published between September 1, 2016, and June 2, 2020; (5) been published in the English language; and (6) included studies of human participants. The rationale behind the prespecified date range was based on the International Committee of Medical Journal Editors (ICMJE) recommendation to disclose any financial interest within 36 months of journal submission, regardless of whether the financial interest relate to the submitted study.15 Starting the prespecified date range at September 1, 2016 forward, allowed 36 months from the time of CMS Open Payments Database (OPD) when online in September 2013. Consequently, all eligible SRs in our study could be checked for author COI.

Data Extraction

Two investigators (A.W. and D.M.) extracted data in a masked, duplicate fashion using a pilot-tested Google form. The investigators analyzed the full-text of each SR for the following characteristics: (1) PubMed identification number and/or DOI; (2) journal name; (3) publication date; (4) author names; (5) treatment interventions being compared; (6) author institutional affiliation(s); (7) author country affiliation; (8) funding source; (9) complete COI statement; (10) whether the SR or meta-analysis addressed risk of bias; (11) the verbatim risk of bias statement; (12) whether an author also authored 1 or more of the primary studies included in the SR; (13) total number of self-cited primary studies; (14) primary outcome of the SR; (15) whether an overall pooled effect estimate was calculated; (16) statistical significance of the pooled effect estimate; and (17) whether narrative results and conclusions favored the treatment or comparison group (eg, placebo, standard of care, control). We used the term “conclusion” to describe both the discussion and conclusion sections of the SRs.

Favorability of Narrative Results of Conclusions

We appraised the SR results and conclusions as “favorable,” “unfavorable,” or “mixed/inconclusive.” SRs were coded as favorable if the narrative results only presented positive outcomes, unfavorable if they presented only negative outcomes, and mixed/inconclusive if they presented both positive and negative outcomes. SR conclusions were coded as favorable if they directly stated or implied preference for the treatment group, unfavorable if they stated or implied preference for the comparison group, and mixed/inconclusive if neither a favorable nor unfavorable rating applied (eg, positive subgroup analyses but negative overall population outcomes).

Identification of Undisclosed Conflict of Interest

Our search strategy to identify undisclosed COI was performed using the stepwise algorithm provided in Figure 1. We used the methodology of Mandrioli et al16 to develop this search strategy; with the inclusion of 3 additional databases: CMS Open Payments, Dollars for Profs, and the United States Patent and Trademark Office (USPTO). Supplemental Table 2 (Supplemental Digital Content 2, http://links.lww.com/JIG/A526) provides a description of these databases. We searched all authors using the stepwise algorithm, regardless of whether they disclosed a COI within the SR. To ensure accuracy and consistency of searches between investigators, A.W. and D.M. created standardized database search strings for the Google Patents, USPTO, and PubMed databases using the Python programming language (Python Software Foundation, https://www.python.org/). In accordance with ICMJE COI disclosure policies, we searched PubMed for studies published three years prior to the publication date to assess if the author had disclosed a COI in a previous study that was not disclosed in the SR from our sample. For searches yielding more than 10 manuscripts, random numbers were assigned to each, and then data were extracted from the first 10 publications of the randomized list. If at any time we were unable to verify a corresponding COI for an author in our sample, we considered the search inconclusive and continued our search process. If an undisclosed COI was identified, the search was terminated and the author identified as having an undisclosed COI. A similar search termination strategy was used by Mandrioli et al.16

Risk of Bias Evaluations

To assess risk of funding bias, we applied the Cochrane Collaboration’s criteria combined with the following four items from Mandrioli et al16: (1) whether explicit and “well-defined” criteria that could be replicated by others were used to select studies for inclusion or exclusion; (2) whether an adequate study inclusion method (eg, a minimum of 2 assessors selecting studies) was used; (3) whether search strategies were comprehensive (eg, included >1 database, used complete search strategies, had accessible key terms);
Search of Open Payments Database
Was an undisclosed COI found?

No

Search of ProPublica Dollars for Profs
Was an undisclosed COI found?

No

Search of United States Patent and Trademark Office
Was an undisclosed COI found?

No

Search of Google Patents
Was an undisclosed COI found?

No

Search of PubMed
Was an undisclosed COI found?

Yes

Author marked as having undisclosed COI; search terminated

No undisclosed COI were found for this author

FIGURE 1. Stepwise search for undisclosed conflict of interest (COI) among systematic review authors.

We used Stata 16.1 (StataCorp, LLC, College Station, TX) was used for all analyses.

and (4) whether methodological differences with the potential to introduce bias were controlled for. Each item was assigned a “yes,” “no,” or “unclear” response. Overall risk of bias was considered low if at least 3 of the 4 criteria were met and high otherwise.

Statistical Analysis
Results were quantified using descriptive statistics, and relationships were evaluated using The Fisher exact tests, when possible. Stata 16.1 (StataCorp, LLC, College Station, TX) was used for all analyses.

RESULTS
Our searches of MEDLINE (Ovid) and Embase (Ovid) returned 1467 records. Following removal of duplicates, 1089 records were screened by title and abstract. After this initial screening, 213 records were included for full-text analysis. Further review resulted in an additional 187 exclusions, leaving 26 systematic reviews and meta-analyses meeting inclusion criteria (Fig. 2).

Systematic Review Characteristics
Our study included 26 SRs and meta-analyses conducted by 108 authors and published within 16 journals. The 2 most common journals in our sample were The Cochrane Database of Systematic Reviews (4/26; 15%) and the Journal of Ophthalmology (3/26; 11%). Most (20/26; 76%) SRs in our sample reported no COI. The most common type of intervention investigated was pharmaceutical (11/26; 42%) or surgical (11/26; 42%). Table 1 provides further SR characteristics.

Author Characteristics and Completeness of COI Disclosures
The largest proportion of authors (52/108; 48%) listed China-based affiliations, followed by Taiwan (8/108; 7%) and the United Kingdom (8/108; 7%) (Supplemental Table 3, Supplemental Digital Content 3, http://links.lww.com/IJG/A527). Among all authors, 22 (22/108; 20%) were found to have a disclosed COI, undisclosed COI, or both. Of these, 6 (6/22; 27%) completely disclosed all COI within the SR, 3 (3/22; 14%) disclosed 1 or more COI but were found to have an additional undisclosed COI, and 13 (13/22; 59%) were found to have an undisclosed COI despite stating they had no COI to disclose in the SR.

Relationship Between COI and Favorability of Results and Conclusions
Of the 9 SRs with 1 or more conflicted authors, 3 (3/9; 33%) reported narrative results favoring the treatment group, and 5 (5/9; 56%) reported conclusions favoring the treatment group. Of the 17 SRs with no conflicted authors, only 1 (1/17; 6%) reported results favoring the treatment group, and only 2 (2/17; 12%) reported conclusions favoring the treatment group. Although the Fisher exact test demonstrated a statistically significant association between author COI and the favorability of the SR conclusions toward the investigated treatment group (P = 0.04), a similar association between author COI and favorability of narrative results was not found (P = 0.21). Table 2 summarizes the results.

Relationship Between Sponsorship and Favorability of Results and Conclusions
Fourteen (14/26; 54%) SRs received external funding, 3 (3/26; 12%) did not receive funding, and 9 (9/26; 35%) failed to provide a funding statement. The most common sources of sponsorship were from public (7/26; 27%) and industry (3/26; 12%) sources (Table 1). Two of the 3 (67%) industry-sponsored SRs contained results sections that were favorable toward the investigated treatment, whereas only 1 (1/3; 33%) contained favorable conclusions. Of the 11 reviews receiving nonindustry support, only 1 (1/11; 9%) reported results favoring the treatment group, whereas 2 (2/11; 18%) reported conclusions favoring the treatment group. Our results showed no statistically significant association between the presence of industry sponsorship and the favorability of results or conclusions. Table 3 summarizes the results.

Relationship Between Risk of Bias and Industry Sponsorship or Conflicts of Interest
Of the 3 industry-sponsored SRs, 1 (1/3; 33%) had a high risk of bias. None of the nonindustry sponsored SRs had a high risk of bias. Of the 17 SRs without a conflicted author, only 1 (1/17; 6%) was considered to have high risk of bias. Similarly, only 1 (1/9; 11%) SR with 1 or more conflicted authors was found to have a high risk of bias. We found no association between risk...
of bias and the presence of either industry-sponsorship or author COI (Table 3).

**DISCUSSION**

We found that SRs conducted by 1 or more authors with a COI were more likely to draw favorable conclusions about their studied interventions more often than SRs with no conflicted authors. Furthermore, our results suggest that COIs are common among authors of ophthalmology SRs, though these COIs are often incompletely disclosed at the time of journal submission. Despite multiple SRs in our sample receiving industry support, the presence of industry sponsorship did not appear to influence the nature of their results or conclusions. Here, we provide further discussion of how our findings contribute to the current literature surrounding author COI and offer future recommendations to better understand the influence that industry may have on outcomes of SRs within the field of ophthalmology.

Our findings contribute to the current literature on author COI in several ways. First, our results confirm those from previous studies suggesting that authors disclose all potential competing interests so that readers are fully aware of all conflicts when interpreting a study’s conclusions. For example, although we did not observe an association between author COI and a favorable narrative result, we did observe a positive link between an author COI and a favorable conclusion. These findings align with a previously published study investigating the influence of financial ties with pharmaceutical companies on the favorability of results and conclusions of meta-analyses investigating anti-hypertensive drugs. Yank and colleagues found no association between financial ties and the favorability of results in these meta-analyses, but they did find a positive association between financial ties and conclusions favoring the company’s drug. In addition, in a sample of review articles regarding the health effects of passive smoking, Barnes and Bero determined that author COI with the tobacco industry was the only factor associated with the review concluding that passive smoking is not harmful (odds ratio = 88.4; 95% confidence interval, 16.44-76.5; P < .001). Our finding similarly indicates that authors who have a COI may be more likely to frame their results in a favorable way, even if their data do not fully support such a conclusion.

Our findings suggest that COIs are regular occurrences in SRs investigating glaucoma interventions, though they are often not completely disclosed. Specifically, one-fifth of the authors in our sample were found to have a COI, most of which were omitted from the SR’s published COI disclosure statement. Previous studies have demonstrated a high rate of incomplete COI disclosure in the biomedical literature. For example, a 2018 study investigating the completeness of oncology drug trialists’ COI disclosures revealed that nearly one-third of trial authors failed to disclose payments received from the trial sponsor. Another study published in the *Journal of General Internal Medicine* found a 69% discordance rate between industry and author-reported COI disclosure statements. Given the influence that author COI may have on study outcomes, several influential stakeholders in academic medicine have tried to improve the accuracy of author COI disclosure; however, further efforts at addressing poor rates of COI disclosure are warranted.

Many influential bodies in the medical literature (eg, ICMJE, Institute of Medicine, World Association of Medical Editors, and Committee of Publication Ethics)
TABLE 1. Characteristics of Included Systematic Reviews (n = 26)

| Characteristic                        | Form Response | N (%) |
|---------------------------------------|---------------|-------|
| **Journal (n = 26)**                  |               |       |
| The Cochrane Database of Systematic Reviews | 4 (15)        |       |
| Journal of Ophthalmology              | 3 (12)        |       |
| The British Journal of Ophthalmology | 2 (8)         |       |
| Journal of Glaucoma                   | 2 (8)         |       |
| BMC Ophthalmology                     | 2 (8)         |       |
| Medicine                              | 2 (8)         |       |
| International Journal of Ophthalmology | 2 (8)        |       |
| Oncotarget                            | 1 (4)         |       |
| Open Medicine                         | 1 (4)         |       |
| Ophthalmic Research                   | 1 (4)         |       |
| Ophthalmology Glaucoma                | 1 (4)         |       |
| Clinical Ophthalmology                | 1 (4)         |       |
| Medwave                               | 1 (4)         |       |
| European Journal of Ophthalmology     | 1 (4)         |       |
| International Journal of Clinical and Experimental Medicine | 1 (4) | |
| Investigacion Clinica                 | 1 (4)         |       |
| **Accuracy of author COI disclosure statements (n = 108)** | 86 (80) | |
| No COI                               | 13 (12)       |       |
| All COI disclosed in systematic review | 6 (6)        |       |
| Disclosed 1 or more COI in systematic review, found to have additional undisclosed COI | 3 (3) | |
| **Intervention type (n = 26)**        |               |       |
| Pharmaceutical                        | 11 (42)       |       |
| Surgical Technique/Intervention        | 11 (42)       |       |
| Nonsurgical Device                    | 2 (8)         |       |
| Multiple                              | 2 (8)         |       |
| **Affiliation of first author (n = 26)** |             |       |
| Government                            | 6 (23)        |       |
| Private academic institution           | 3 (12)        |       |
| Government                            | 2 (8)         |       |
| Multiple                              | 1 (4)         |       |
| Private-for-profit                     | 1 (4)         |       |
| **Affiliation of last author (n = 26)** |             |       |
| Government                            | 5 (19)        |       |
| No affiliation                         | 5 (19)        |       |
| Private-for-profit                     | 2 (8)         |       |
| Government                            | 1 (4)         |       |
| Nonprofit                             | 1 (4)         |       |
| Private academic institution           | 1 (4)         |       |
| Multiple                              | 1 (4)         |       |
| **Source of funding (n = 26)**         |               |       |
| No statement listed                    | 9 (35)        |       |
| Public                                | 7 (27)        |       |
| No funding received                    | 3 (12)        |       |
| Private/Industry                      | 3 (12)        |       |
| Nonprofit                             | 2 (8)         |       |
| Multiple                              | 2 (8)         |       |
| **Conflict of interest statement (n = 26)** |             |       |
| Reports no conflicts of interest       | 20 (77)       |       |
| **Self-citation of primary studies (n = 26)** |             |       |
| Includes 1 or more authors with a COI | 5 (19)        |       |
| There is no conflict statement         | 1 (4)         |       |
| No, did not include self-cited primary studies | 24 (92) | |
| Yes, included 1 or more self-cited primary studies | 2 (8) | |

COI indicates conflict of interest disclosures.

TABLE 2. Relationship Between COI and Favorability of Systematic Review Results, Conclusions, and Risk of Bias (n = 26)

| Review Outcomes                     | COI Among Systematic Reviews |
|--------------------------------------|------------------------------|
| **Favorability of results**          | No COI (n = 17) | COI (n = 9) | Fisher Exact (P) |
| Results favor treatment group        | 1 (6)            | 3 (33)     | 0.21             |
| Results are mixed/inconclusive       | 2 (12)           | 0 (0)      | —                |
| Results favor placebo/control group | 14 (82)          | 6 (67)     | —                |
| **Favorability of discussion/ conclusions** |             |             |                   |
| Discussion favors treatment group    | 2 (12)           | 5 (56)     | 0.04             |
| Discussion is mixed/inconclusive     | 9 (53)           | 1 (11)     | —                |
| Discussion favors placebo or control group | 6 (35)     | 3 (33)     | —                |
| **Risk of bias**                     |                 |             |                   |
| High risk of bias                    | 1 (6)            | 1 (11)     | 1.0              |
| Low risk of bias                     | 16 (94)          | 8 (89)     | —                |

COI indicates conflict of interest.

Our findings offer future recommendations to better understand the influence that industry may have on outcomes of SRs in the field of ophthalmology. Our recommendations are 3-fold. First, recommendations are 3-fold. First, we recommend all journals adopt the ICMJE author COI disclosure policy to help standardize the definition of what constitutes a COI. Second, we urge ICMJE guideline writers to use more specific language (eg, authors should disclose “all” financial relationships) to eliminate any confusion surrounding which financial relationships may be considered COIs. Finally, we should adopt the ICMJE guidance for future SRs to include measures for verifying the accuracy of COI disclosures.
relationships warrant disclosure. Finally, we recommend journals adopt a verification process to ensure authors are completely forthcoming about all financial relationships prior to publishing a submitted manuscript. As part of this verification process, we support the use of predetermined consequences for noncompliance with journal COI disclosure policies (eg, publication of notice about noncompliance, manuscript rejection or retraction, prohibition from future manuscript submissions). If implemented correctly, this three-step process will help increase the completeness of author COI disclosure and the public’s trust in published ophthalmology literature.

Strengths and Limitations

Regarding strengths, we extracted data in a masked, duplicate fashion, which is regarded as the gold standard in meta research according to the Cochrane Handbook.31 In addition, we provided our study protocol and all other study materials on the Open Science Framework, thereby increasing transparency and reproducibility of our findings.11 With regard to limitations, our study was cross-sectional in design; therefore, selection of a different date range may have yielded varying results. Our study focused on SRs investigating head-to-head interventions for the treatment of glaucoma and thus may not be generalizable to the breadth of ophthalmology literature. Due to having a small sample size, careful interpretation of our findings as the lower bound estimate of the influence author COI may have on outcomes of SRs is warranted. Finally, we were unable to determine the accuracy of COI disclosure for non–US-based authors using the Open Payments Database, the source which we obtained most of the undisclosed COIs. It is possible some COI were missed, and therefore interpreting of our results as a lower-bound estimate of the true extent of COI within the ophthalmology field is warranted.

CONCLUSION

We found that SRs conducted by 1 or more authors with a COI were more likely to draw favorable conclusions about the investigated intervention, compared with SRs with no conflicted authors. COIs are common, yet often undisclosed, among authors of ophthalmology SRs. We contend that reforming the current COI definitions and disclosure policies is necessary to increase the transparency in the ophthalmology literature.

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