Discrepancy between Results and Abstract Conclusions in Industry- vs Nonindustry-funded Studies Comparing Topical Prostaglandins

TARIQ ALASBALI, MICHAEL SMITH, NOA GEFFEN, GRAHAM E. TROPE, JOHN G. FLANAGAN, YAPING JIN, AND YVONNE M. BUYS

• PURPOSE: **To investigate the relationship between industry- vs nonindustry-funded publications comparing the efficacy of topical prostaglandin analogs by evaluating the correspondence between the statistical significance of the publication's main outcome measure and its abstract conclusions.**

• DESIGN: **Retrospective, observational cohort study.**

• METHODS: **English publications comparing the ocular hypotensive efficacy between any or all of latanoprost, travoprost, and bimatoprost were searched from the MEDLINE database. Each article was reviewed by three independent observers and was evaluated for source of funding, study quality, statistically significant main outcome measure, correspondence between results of main outcome measure and abstract conclusion, number of intraocular pressure outcomes compared, and journal impact factor. Funding was determined by published disclosure or, in cases of no documented disclosure, the corresponding author was contacted directly to confirm industry funding. Discrepancies were resolved by consensus. The main outcome measure was correspondence between abstract conclusion and reported statistical significance of the publications' main outcome measure.**

• RESULTS: **Thirty-nine publications were included, of which 29 were industry funded and 10 were nonindustry funded. The published abstract conclusion was not consistent with the results of the main outcome measure in 18 (62%) of 29 of the industry-funded studies compared with zero (0%) of 10 of the nonindustry-funded studies ($P = .0006$). Twenty-six (90%) of the industry-funded studies had proindustry abstract conclusions.**

• CONCLUSIONS: **Twenty-four percent of the industry-funded publications had a statistically significant main outcome measure; however, 90% of the industry-funded studies had proindustry abstract conclusions. Both readers and reviewers should scrutinize publications carefully to ensure that data support the authors' conclusions. (Am J Ophthalmol 2009;147:33–38. © 2009 by Elsevier Inc. All rights reserved.)**

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From the Department of Ophthalmology and Vision Sciences, University of Toronto, Toronto Western Hospital, Toronto, Ontario, Canada (T.A., M.S., N.G., G.E.T., J.G.F., Y.M.B.); the Department of Ophthalmology, King Faisal University, King Fahad Hospital of the University, Riyad, Saudi Arabia (T.A.); the School of Optometry, University of Waterloo, Waterloo, Ontario, Canada (J.G.F.); and the Department of Public Health Sciences, University of Toronto, Toronto, Ontario, Canada (Y.J.).

Inquiries to Yvonne M. Buys, Toronto Western Hospital, 399 Bathurst Street, EW6-405, Toronto, Ontario, Canada M5T 2S8; e-mail: y.buys@utoronto.ca

FINANCIAL RELATIONSHIPS BETWEEN PHARMACEUTICAL companies and researchers and funding of medical research by drug companies has increased dramatically during the last two decades.[1–4] This can result in industry bias where the source of funding of clinical trials either affects the results in a systematic way or leads to selective presentation of the results. Industry funding often has been associated with proindustry results[2,5–20] and publication bias,[21–23] which can affect the interpretation and presentation of outcomes resulting in conclusions that overstate results without statistical support. The purpose of this study was to investigate the relationship between industry- vs nonindustry-funded publications comparing ocular hypotensive efficacy of the topical prostaglandin analogs (PGA) latanoprost 0.005%, travoprost 0.004%, and bimatoprost 0.03% by evaluating the correspondence between the statistical significance of the publication's main outcome measure and its published abstract conclusions.

METHODS

A MEDLINE SEARCH FROM 1966 TO THE SECOND WEEK OF November 2007 using any combination of the keywords *latanoprost*, *travoprost*, and *bimatoprost* was conducted. The title and abstracts from the initial search were reviewed and those included were English language publications comparing the intraocular pressure (IOP)-lowering efficacy of any combination of latanoprost; travoprost; or bimatoprost. The complete articles were obtained and the references also were searched to identify relevant publications missed during the initial search.

Each publication was reviewed by three independent observers using a standardized data collection sheet evaluating: source of funding, industry author, study quality, main outcome measure, statistical significance ($P < .05$) of main outcome measure, abstract conclusion, correspondence between statistical significance ($P < .05$) of main

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TABLE 1. Grading of Study Quality

Level	Criteria
1A: Meta-analysis (to assign this level, you must answer 'yes' to all questions)	Does the paper report a comprehensive search for evidence?
	Did the authors avoid bias in selecting articles for inclusion?
	Did the authors asses each article for validity?
	Does the paper report clear conclusions that are supported by the data and appropriate analysis?
1A: Large RCT (to assign this level, you must answer 'yes' to all questions)	Were patients randomly allocated to treatment groups?
	Was follow-up at least 80% complete?
	Were both the patients and the investigators blind to the treatment the patient received?
	Were the patients analyzed in the treatment groups to which they were assigned?
	Was the sample size large enough to detect the outcome of interest?
1B: NRCT	NRCT or cohort study with indisputable results
2: RCT	RCT or overview that did not meet level 1
3	NRCT or cohort study
4	Other (case series without controls, case report, expert opinion, etc.)

NRCT = nonrandomized controlled trial; RCT = randomized controlled trial.

TABLE 2. Summary of Industry– vs Nonindustry-funded Studies Comparing Topical Prostaglandins

Outcome Studied	Industry-funded (n = 29)	Nonindustry-funded (n = 10)	*P* value
Noncorrespondence of main outcome and conclusions	18 (62%)	0 (0%)	.0006[a]
Statistically significant ($P < .05$) main outcome	7 (24%)	2 (20%)	1.00[a]
Number of IOP comparisons, mean ± SD (median, range)	17.4 ± 11.6 (14, 1 to 45)	13.0 ± 11.4 (8, 1 to 30)	.31[b]
Mean study quality	2.4 ± 1.1	2.0 ± 0.7	.27[b]
Industry coauthor	18 (62%)	N/A	
Journal impact factor	2.14 ± 1.32	2.33 ± 1.51	.72[b]

IOP = intraocular pressure; N/A = not applicable; SD = standard deviation.
[a]Fisher exact test.
[b]Student *t* test.

outcome measure and abstract conclusion, total number of IOP outcomes compared, and journal impact factor. Any discrepancies between the three reviewers were resolved by consensus.

Funding was determined by published disclosure, or in cases of no documented disclosure, the corresponding author was contacted directly to confirm any direct funding of the study. In one case, the pharmaceutical company was contacted to verify funding. Study quality was assessed according to the criteria in Table 1.[24] Journal impact factors from 2006 were assigned to each publication.

The main outcome measure was the correspondence between the statistical significance of the publication's main outcome measure and its published abstract conclusion. Statistical analysis included the Fisher exact test for categorical data and the Student *t* test for continuous data.

RESULTS

A TOTAL OF 180 ARTICLES WERE IDENTIFIED BY THE ORIGINAL search. After reviewing the abstracts, 39 met the inclusion criteria and were included in the study. In reviewing the references of these publications, no additional publications were found. Of the 39 publications, 35 were studies that directly compared two or three of the PGAs and four were meta-analyses. Thirty-five of the publications included a disclosure statement, and four had no documented disclosure. The authors were contacted regarding these four publications; two publications[25,26] confirmed industry funding of the study and two reported no funding. One of the publications for which the author denied industry funding subsequently was discovered to have received industry funding after direct communication with the pharmaceutical company and was allocated to

industry funding. Twenty-nine (74%) of the publications were industry funded (18 by Allergan, Irvine, California, USA,[25–42] 10 by Alcon, Fort Worth, Texas, USA[43–52] and one by Pfizer, New York, New York, USA[53]) and 10 (26%) were nonindustry funded (nine had no funding[54–62] and one had government funding[63]). There was an industry coauthor in 18 (62%) of the industry-funded publications. The results are summarized in Table 2.

Statistically significant main outcome measures were reported in 7 (24%) industry-funded publications and in 2 (20%) nonindustry-funded publications ($P = 1.00$, Fisher exact test). Correspondence between the results of the main outcome measure and the abstract conclusions was found in 11 (38%) of the industry-funded publications vs 10 (100%) of the nonindustry-funded publications ($P = .0006$, Fisher exact test). Twenty-six (90%) of the industry-funded studies had proindustry conclusions.

The mean number of IOP comparisons reported were 17.4 ± 11.6 for industry-funded publications and 13.0 ± 11.4 for nonindustry-funded publications ($P = .31$, Student t test). The mean study quality was 2.4 ± 1.1 for industry-funded publications compared with 2.0 ± 0.7 for nonindustry-funded publications ($P = .27$, Student t test). The mean journal impact factor also was similar between industry-funded (2.14) and nonindustry-funded (2.33) publications ($P = .72$, Student t test).

DISCUSSION

WE FOUND THAT 62% OF THE INDUSTRY-FUNDED VS NONE of the nonindustry-funded studies' abstract conclusions did not correspond with the results of the main outcome measure ($P = .0006$, Fisher exact test). Although only 24% of the industry-funded publications had a statistically significant main outcome measure, 90% of the industry funded studies had a proindustry abstract conclusion.

The influence of industry on publications involving a wide range of diseases and drugs is well documented.[2,5–20] Kjaergard and Als-Nielsen reviewed 159 randomized controlled trials from 12 specialties and found that when financial interests were disclosed, the authors' conclusions significantly favored experimental intervention.[11] Lexchin and associates reviewed 30 pharmaceutical-sponsored studies and found "systematic bias to the outcome of published research funded by the pharmaceutical industry."[13] Als-Nielsen and associates evaluated 370 randomized controlled trials over a broad area of diseases and found that conclusions significantly favored experimental drugs in trials funded by for-profit organizations.[15] A review of 124 meta-analyses of antihypertensives found that industry support was not associated with more favorable results, but was associated with more favorable conclusions.[20] To our knowledge, ours is the first attempt to determine industry bias in ophthalmology publications.

Prostaglandin analogs currently are the first-line therapy for the treatment of glaucoma, representing 43.9% of glaucoma medications dispensed in Ontario, Canada, in 2007. Latanoprost 0.005% (Pfizer) was first available in Ontario in June 1997, followed by travoprost 0.004% (Alcon) in November 2001 and bimatoprost 0.03% (Allergan) in May 2002. These three medications belong to the same class and therefore are competing directly for the same market share. The use of PGAs is influenced by the number and quality of publications.

Of the 39 publications studied, 29 (74%) were industry funded. The high proportion of industry-funded studies is consistent with reports of increased funding of biomedical research by the biomedical industry.[1–4] Our definition of industry funding, however, may be considered conservative because we did not investigate the financial ties of each author and included only studies with direct industry funding. Evaluating financial disclosures of individual authors is difficult because many authors have support from several companies, although the amount of support per company may vary.

Similar to studies in other disciplines, we found no difference in significant main outcome measures,[10,16,20,23] study quality,[2,7,10,11,13,15,16,23] or journal impact factor[8,15] between industry- and nonindustry-funded studies comparing PGAs. Four of the seven industry-funded studies with significant main outcome measure were of the lowest level of quality (level 4).[29,35,37,40] There were no level four studies in the nonindustry-funded group. Six of the eight industry-funded publications with level four study quality were published in journals with a higher (> 2.2) impact factor.[29,35–37,40,52]

The discrepancy between the results of the main outcome measure and abstract conclusions stems from the interpretation of surrogate outcomes or multiple comparisons assigning undue attention to significant results while minimizing nonsignificant results.[21] This is commonly referred to as "spin." To evaluate for possible data dredging, we compared the total number of IOP outcome comparisons presented in the results and found no difference between industry- and nonindustry-funded studies. The mean number of IOP outcome measures was 17.4 ± 11.6 (range, one to 45) for industry-funded publications and 13.0 ± 11.4 (range, one to 30) for nonindustry-funded publications ($P = .31$).

This study raises concerns regarding undue industry influence in publications on PGAs. Less industry funding and increased funding by peer-reviewed governmental agencies or other organizations may remove this bias. Authors should provide transparency in the interpretation and conclusions of their study, and it is the role of journal editors and reviewers to ensure that data are not misrepresented. It is important that journals develop strong guidelines to limit potential bias by creating minimum standards in reporting disclosure and results. Full disclosure of both authors and reviewers and funding source of

the study is necessary. Three of the studies in our review were funded directly by industry; however, there was no published disclosure. The requirement of registration of all clinical trials at the time of design and before the collection of data and making available all data could minimize inappropriate data analysis and selective reporting of results. The inclusion in the abstract of a heading specifying the main outcome measure and the statistical results of the main outcome measure may improve transparency of the study findings. Ultimately, however, it is the responsibility of the reader to scrutinize abstract conclusions carefully to ensure that they are supported by the data reported in the RESULTS SECTION of the article.

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Biosketch

Dr Yvonne Buys completed her MD, ophthalmology residency, and glaucoma fellowship at the University of Toronto, Toronto, Canada. She is currently an Associate Professor at the University of Toronto, Department of Ophthalmology, Co-Director of the Glaucoma Unit at the University Health Network, and President of the Canadian Glaucoma Society. Dr Buys is involved in training ophthalmology residents and glaucoma fellows. She has published over 60 peer-reviewed papers and three book chapters in the area of glaucoma.

Biosketch

Dr Tariq Alasbali completed his MD, ophthalmology residency at King Faisal University and a glaucoma fellowship at King Khaled Eye Specialist Hospital (KKESH) in Saudi Arabia. Dr Alasbali completed a research fellowship and currently he is a clinical glaucoma fellow at the University of Toronto, Department of Ophthalmology. Dr Alasbali received a Canadian Ophthalmological Society award for excellence in ophthalmic research in 2007.