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ORIGINAL ARTICLE

Industry funding and the reporting quality of large long-term weight loss trials

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Background: Quality of reporting (QR) in industry-funded research is a concern of the scientific community. Greater scrutiny of industry-sponsored research reporting has been suggested, although differences in QR by sponsorship type have not been evaluated in weight loss interventions.
Objective: To evaluate the association of funding source and QR of long-term obesity randomized clinical trials (RCT).
Methods: We analysed papers that reported long-term weight loss trials. Articles were obtained through searches of Medline, HealthStar, and the Cochrane Controlled Trials Register between the years 1966 and 2003. QR scores were determined for each study based upon expanded criteria from the Consolidated Standards for Reporting Trials (CONSORT) checklist for a maximum score of 44 points. Studies were coded by category of industry support (0 = no industry support, 1 = industry support, 2 = in kind contribution from industry and 3 = duality of interest reported). Individual CONSORT reporting criteria were tabulated by funding type. An independent samples *t*-test compared the differences in QR scores by funding source and the Wilcox–Mann–Whitney test and generalised estimating equations (GEE) were used for sensitivity analyses.
Results: Of the 63 RCTs evaluated, 67% were industry-supported trials. Industry funding was associated with higher QR score in long-term weight loss trials compared with nonindustry-funded studies (mean QR (s.d.): industry = 27.9 (4.1), non-industry = 23.4 (4.1); $P<0.0005$). The Wilcox–Mann–Whitney test confirmed this result ($P<0.0005$). Controlling for the year of publication and whether the paper was published before the CONSORT statement was released in the GEE regression analysis, the direction and magnitude of effect were similar and statistically significant ($P=0.035$). Of the individual criteria that prior research has associated with biases, industry funding was associated with greater reporting of intent-to-treat analysis ($P=0.0158$), but was not different from nonindustry studies in reporting of treatment allocation and blinding.
Conclusion: Our findings suggest that the efforts to improve reporting quality be directed to all obesity RCTs, irrespective of funding source.
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Keywords: randomized clinical trials; CONSORT; reporting quality; weight loss; industry funding

Introduction

> *Research studies in biomedical journals are increasingly scrutinised, not only for their scientific findings and clinical and public health implications, but also because of … concerns about misleading reporting of industry-sponsored research.*[1]

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The above quotation, the opening line in an editorial in the *Journal of the American Medical Association* (*JAMA*), evinces strong concern regarding potential influence of industry sponsorship in the literature. The editors of *JAMA*, in reaction to the concern, suggested policies of extra scrutiny for industry-funded research. In response, an editorial in *BMJ* decried this as unfair and absurd.[2]

For the scientific community and society at large, to benefit maximally from biomedical research, the quality and integrity of each step in the research process must be maximised. Such steps include (1) selection of relevant questions; (2) design of research suitable to address those

questions; (3) rigorous execution of the design; (4) faithful recording of the data; (5) appropriate statistical analysis of the data; (6) a decision to publish a report of study; (7) clear, accurate and thorough reporting of the study and (8) reasonable 'second-level' dissemination and interpretation of the findings in press releases, mass media coverage, scholarly reviews, expert testimony, blue ribbon panels and other venues. In each of these steps, there is an opportunity for some factors to inappropriately exert influence.

One such factor that is frequently discussed is financial duality (a.k.a 'conflict') of interest (DOI).[3] Indeed, at least three papers[4–6] suggest that in nutrition and obesity research, published papers in which authors were funded by or had other financial ties to industry were more likely than were other papers to contain results or interpretations that favor the industry or company producing the product or service under study. Similar findings have been observed on multiple occasions in other areas of biomedical research.[7,8] The reasons for and appropriate interpretation of these findings remain open to question.[9] Nevertheless, concern about inappropriate influences (be they from financial or other DOIs) remains. The most common suggestion for dealing with the potential for inappropriate influence because of financial DOIs is disclosure of the DOI. However, disclosure is likely to be at best ineffectual[5] and at worst antithetical to focusing on scientific method,[10] derogatory toward industry-funded authors,[11] and possibly productive of exactly the biases it is intended to diminish.[12]

Hence, we believe it will be more fruitful to identify factors that lead to better or poorer performance in each of the stages listed above hopeing that identification of such factors may lead to ideas about policies and practices that can minimise inappropriate influences and maximise performance. If we are to maintain the public trust, crucial for many reasons,[13] we must investigate this area.

In this paper we focus on step 7 of the list of research steps presented above and ask whether industry funding leads to better or worse reporting of large, long-term randomized clinical trials (RCTs). We focus on RCTs for obesity treatment. This is an especially important area. Obesity is quite prevalent and causes a number of ill effects including earlier mortality.[14] New and better obesity treatments are needed and, as NIDDK wrote, 'Well conducted clinical trials are the fastest and safest way to find improved treatments and preventions.'[15]

Methods

Reports evaluated

The database[16–78] of the papers evaluated has been described earlier.[79] In brief, studies were selected by searching Medline (from 1966 to September 2003), HealthStar (from 1975 to September 2003) and the Cochrane Controlled Trials Register (from 1990 to September 2003). Inclusion criteria were (a) a randomized controlled trial; (b) a sample consisting of overweight or obese adults with a mean body mass index $\geqslant 25\,kg/m^2$; (c) investigation of a weight loss intervention and (d) duration of patient follow-up $\geqslant 1$ year. Exclusion criteria were (a) patients were required to attain a weight loss target to qualify for study enrollment; (b) the weight loss intervention was not approved for clinical use and (c) the weight loss intervention was approved only for short-term use.[79]

Primary outcome measure

The primary outcome measure was quality of reporting (QR). QR was independently determined by two reviewers and summarized earlier by Thabane *et al*.[79] Briefly, the authors used the CONSORT statement[80,81] to assess QR. For each trial, through an independent double review, the authors determined whether each of 44 detailed CONSORT reporting criteria contained within the checklist were satisfied. Eight of the 44 CONSORT criteria associated with methodologic quality from the Results and Methods sections were examined. The CONSORT statement is considered as the medical industry standard of reporting and contains elements that have been used to evaluate methodologic quality of RCTs.[82,83] Face and content validity have been evaluated for the CONSORT statement, which has been endorsed by numerous peer-reviewed journals and scientific organizations.[83]

Assessment of industry support

A full copy of each paper was independently reviewed by each of two authors and placed into one of the four categories defined in Table 1. The two reviewers then compared their codings of funding source, which was determined from financial information disclosed in each publication and an agreement of more than 89% (56 of 63 publications) was obtained. The remaining seven publications were reexamined and consensus was reached between the two reviewers. In all but two cases, the discrepancies were the result of a transcription error or oversight on the part of one coder and were corrected. In the last two cases, the disagreement entailed a question regarding 'whether funding from a for-profit foundation established by, but

Table 1 Categories of industry support

Category 0. None. No industry support was noted in the paper, and no author was an employee of a for-profit company making the product or service under study.
Category 1. Industry supported. Industry was listed as funding the study; an author was employed by a for-profit company making the product or service under study, or both.
Category 2. In Kind contributions. The study was not industry-supported as defined in category 1, but a for-profit company making the product or service under study donated product for use in the study.
Category 3. Duality of Interest reported. The study did not fit into categories 1 and 2 as defined above but one or more authors disclosed a financial tie to a for-profit company making the product or service under study.

Table 2 Descriptive statistics of reporting quality scores by industry support

Category of industry support	*n*	*Mean QR Score*	*s.d. QR*	*Min*	*Max*	*5th Pctl*	*25th Pctl*	*50th Pctl*	*75th Pctl*	*95th Pctl*
0. None	21	23.4	4.1	16.0	34.0	17.0	21.0	23.0	25.0	29.0
1. Industry funded	38	27.9	4.1	19.0	34.0	19.0	25.0	29.0	31.0	34.0
1a. Drug studies	22	29.5	2.5	25.0	34.0	25.0	28.0	30.0	31.0	34.0
1b. Nondrug studies	16	25.7	4.9	19.0	34.0	19.0	22.0	24.5	29.5	34.0
2. In kind contribution	2	26.0	7.1	21.0	31.0	—	—	—	—	—
3. Duality of interest	2	26.0	1.4	25.0	27.0	—	—	—	—	—

Pctl, percentile; —, percentiles not meaningful; QR, quality of reporting.

Table 3 Summary of inferential testing—estimated mean difference of industry funded verses nonindustry funded and *P*-values

	Category 0 (n = 21) vs 1. All studies (n = 38)	*Category 0 (n = 21) vs 1. Only nondrug studies (n = 16)*	*Category 0, 2, 3 (n = 25) vs 1. All studies (n = 38)*
Estimated mean difference (95% CI)	4.49 (2.25–6.72)	2.31 (−0.70 to 5.31)	4.07 (1.95–6.19)
P-values			
t-test	<0.0005	0.1287	<0.0005
Wilcox–Mann–Whitney test	<0.0005	0.1951	<0.0005
GEE[a]	<0.0005	0.0847	<0.0005
GEE controlling for year and for before 1996[a]	0.0354	0.5711	0.0388

Abbreviation: GEE, generalised estimating equations. Category of industry funding: 0, none; 1, industry funded; 3, in kind contribution; 4, duality of interest. [a]Some models failed to converge because of small cell counts.

independent of, a for-profit pharmaceutical company constituted industry support'. Owing to the difficulty in reaching a definitive decision on this and because there were only two such studies, we ran all analyses twice, first with these coded as nonindustry and then in a sensitivity analysis coding these studies as industry-funded.

Statistical analysis

Descriptive statistics (mean and s.d.) are tabulated (Table 2). The primary inferential analysis consisted of a simple independent samples *t*-test on the QR scores comparing category 0 (no industry funding) with category 1 (industry funded). Subsequently, a number of sensitivity and secondary analyses were conducted including (1) repeating the primary analysis with a nonparametric Wilcox–Mann–Whitney test; (2) repeating the primary analysis using generalised estimating equations (GEE)[84] to account for possible clustering within journals to allow for possible correlation in the residuals by journal; (3) using the GEE regression to control for both, whether the paper was published after the 1996 publication of the CONSORT guidelines[80,81] on reporting of RCTs and year of publication; (4) repeating all analyses using only nondrug studies (there were no drug studies in category 0); (5) repeating all analyses after recoding studies in categories 2 and 3 as in category 0 (i.e., nonindustry funded); (6) repeating all analyses after excluding four nonindustry studies where funding source was not specified. The criterion for statistical significance was set at a two-tailed α of 0.05. All analyses were done using SPSS (version 15.0).

Results

Table 2 contains descriptive statistics. As can be seen, the majority (close to 2/3) of long-term weight loss studies are industry-funded. The variances in QR scores are almost identical for industry- and nonindustry-funded studies, but QR scores tend to be higher (i.e., better reporting) for industry-funded studies. QR scores for industry-funded drug studies tended to be higher than industry-funded nondrug studies.

The *t*-test strongly indicated that the average QR was significantly higher for industry-funded than nonindustry-funded studies ($t = 4.02$; $P < 0.0005$; $df = 57$), with no evidence of heteroscedasticity by Levene's test ($P = 0.640$). This was confirmed by the Wilcox–Mann–Whitney test ($P < 0.0005$) and the GEE analysis ($P < 0.0005$). In a GEE regression analysis conditioning on year of publication and an indicator variable for whether the paper was published after the 1996 CONSORT statement was released, the result was in the same direction and remained statistically significant ($P = 0.0354$). When examining only nondrug studies, the statistical significance was diminished with the much smaller sample size, but again, results were in the same direction (see Table 3). In addition, all analyses were repeated

recoding the two aforementioned studies supported by for-profit foundations established by pharmaceutical companies as being industry supported. Finally, all analyses were repeated after excluding four nonindustry studies, where the funding source was unspecified. Results from the final two analyses were virtually identical to those of other analysis strategies (data not shown).

Discussion

The results of this study show that industry funded studies are associated with higher QR on average. In this relatively small sample of weight loss studies restricted to both those that were relatively large and long-term, it was difficult to disentangle the independent effects or association of industry funding from that of whether the study was a drug study, both associated with better reporting.[79] Nevertheless, even when examining only nondrug studies, the numerically superior QR was found for industry-funded research, though the statistical significance was diminished. Future research should evaluate whether such associations exist for shorter-term studies and smaller studies.

For the scientific process to proceed effectively, it is important that all studies, both industry-funded and not, be reported with the highest quality possible. This is because it is through the comprehension of published research reports that the scientific community at large can judge the merits and import of the findings.[10] If industry-funded reporting was of lower quality than nonindustry-funded reporting, this would exacerbate existing concerns about potential biases being created by industry funding.[5] In contrast, our results suggest that, if anything, industry funding is associated with higher reporting quality. This suggests that, while continued efforts to improve reporting quality are warranted, such efforts should be directed at nonindustry-funded research at least as much as at industry-funded research. A benefit of the greater funding offered by industry, the greater scrutiny of industry, or perhaps greater concern or training of industry personnel for rigorous reporting may be an enhancement of the overall reporting quality in the literature, at least for long-term weight loss studies.

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Competing interests

LT is the clinical trials mentor for the Canadian Institutes of Health Research. DBA has received grants, honoraria, consulting fees and donations from numerous food, pharmaceutical and other companies as well as nonprofit organizations and government agencies with interests in obesity-related issues. Ethical approval is not required.

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