

Citations to trials of nicotine replacement therapy were biased toward positive results and high-impact-factor journals

Jean-François Etter^{a,*}, John Stapleton^b

^aFaculty of Medicine, Institute of Social and Preventive Medicine, University of Geneva, CH-1211, Switzerland

^bDepartment of Epidemiology and Public Health, Health Behaviour Research Centre, University College, London, UK

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Abstract

Objective: To study variations in the number of times trials of nicotine replacement therapy (NRT) were cited, and which characteristics of trials predicted the number of citations and the impact factors of journals in which articles were published.

Study Design and Setting: We used all 105 randomized controlled trials in the Cochrane review of NRT for smoking cessation. We obtained impact factors from the Journal Citation Reports and the number of citations from ISI Web of Knowledge and Google Scholar.

Results: Trials were cited from 0 to 632 times (median 23 times). Trials were cited more often when results were statistically significant than when they were not (median = 41 vs. 17 times, $P < 0.001$), and when impact factors were higher (10.2 more citations per impact factor point, $P < 0.001$). Patch trials were cited more often than gum trials (median = 29 vs. 17 times, $P = 0.001$), and trials funded by the pharmaceutical industry were cited more often than other trials (median = 28 vs. 16.5 times, $P = 0.001$). Trials with statistically significant results were published in journals with higher impact factors than trials with nonsignificant results (median impact factor = 2.80 vs. 1.81, $P = 0.011$).

Conclusion: Citations were biased toward trials with positive results and toward trials published in high-impact-factor journals. © 2009 Elsevier Inc. All rights reserved.

Keywords: Tobacco; Smoking; Nicotine; Bibliographic; Bibliometrics; Bias; Review; Tobacco use disorder

1. Introduction

Tobacco smoking is the major avoidable cause of death in developed countries [1]. Meta-analyses show that nicotine replacement therapy (NRT), a widely used treatment of tobacco dependence, is effective both in the short and long term [2,3]. In meta-analyses, all trials are treated equally and “democratically”, as an effort is made to locate all trials (universal eligibility), and as the only factor influencing trial weight is the variance of the effect, which depends largely on the sample size (one man, one vote). However, some trials are cited more often than others and are therefore more influential [4]. An analysis of citation counts has seldom been conducted in the field of smoking cessation treatments [5], and it is therefore not clear whether citations to NRT trials are biased, and why some NRT trials are cited more often than others.

Assessing the quality of research is an important but difficult task. Citation counts and impact factors are frequently

used as quality indicators to judge journals and institutions, for the academic promotion of scientists, and for the attribution of research grants [6,7]. Given the importance attached to citations for judging the quality of research and for the career of scientists, studying whether and why some articles are cited more often than others seems to be a useful goal. The use of citation counts as a quality indicator is based on the assumption that the citing author actually read the original document, and that citation reflects merit (quality, originality, clinical significance) [8]. However, the practice of citation may deviate from this ideal, and the weaknesses of citation counts and impact factors are well known [9]. If, for instance, trials showing larger effects were cited more frequently, then readers of the scientific literature may be misled and left with the impression that treatments are more effective than they actually are.

In this review, we addressed two questions: how much variation is there in the number of times NRT trials are cited, and which characteristics of trials predict the number of times they are cited and the impact factors of the journals that publish them.

* Corresponding author. Tel.: +41-379-59-19; fax: +41-22-379-59-12.
E-mail address: Jean-Francois.Etter@imsp.unige.ch (J.-F. Etter).

What is new?

Key findings

- Articles reporting nicotine replacement therapy trials for smoking cessation were more often cited when results were positive and when published in high-impact journals, rather than when the trial was large.
- What this adds to what was known: This study adds to the relatively small body of empirical research on this topic, and indicates a severe weakness in citation counts as a measure of the quality of research in the field of tobacco dependence.

2. Methods

2.1. Reviewed studies

We considered the 105 randomized, controlled trials (RCTs) of the effect of NRT vs. placebo or a no-treatment control included in the Cochrane review [2]. For each trial, we extracted the following information from the Cochrane review: odds ratio for smoking abstinence with 95% confidence interval (coded by us as statistically significant vs. not significant), sample size, amount of behavioral support (high or low), type of product: patch, gum, or newer products (tablet, lozenge, inhaler, nasal spray), and year of publication. Smoking abstinence was defined by the authors of the Cochrane review using the strictest criteria available in each study. When biochemical validation was conducted, only subjects with biochemically confirmed abstinence were considered successful. Wherever possible, the Cochrane review used sustained abstinence over the period of follow-up, rather than short-term point prevalence of abstinence. Patients lost to follow up were regarded as smoking. Smoking cessation rates were assessed after 12 months, and for trials without 12-month follow-up, 6-month data were used. Trials with less than 6 months of follow-up were excluded [2]. We obtained the original articles for all 105 trials, and extracted the following information from the original articles: funding source (pharmaceutical industry vs. nonprofit or government agency), and country where the trial was conducted. The methods used to extract and code this information were reported previously [3,10].

2.2. Citation counts and impact factors

For each trial, we used the articles listed in the Cochrane review [2]. We obtained the number of times each article was cited from ISI Web of Knowledge (<http://portal.isi-knowledge.com>) in April 2006 and from Google Scholar (<http://scholar.google.com>) in September 2006. For each article, we extracted the journal impact factor from the SCI Journal Citation Reports, for the year when each article

was published [11]. The impact factor is the mean citation count of all articles published in a journal. It is calculated by dividing the number of citations to citable items published in a journal during the preceding 2 years by the number of articles published in those 2 years by that journal [12]. Impact factors are produced by a commercial firm, the Institute for Scientific Information (ISI), in Philadelphia, USA [12].

When there were several articles for the same trial, we used only the article with the highest citation count (thereafter, “reference article”), because in general, only one article per trial was widely cited, and the other articles were often secondary in importance (e.g., methodological articles, duplicate publications, long-term follow-up, conference proceedings). Using the average citation count across all articles from a given trial would have unfairly disadvantaged trials that had several secondary publications.

Using the total number of citations may bias the analysis in favor of older articles, because recently published articles have had fewer years during which they could be cited. Therefore, we also computed for each article the average number of citations per year since it was published, by dividing the total citation count by the number of years since publication. We did not retrieve the year of publication of each of the 4,928 citations to the 105 NRT trials.

2.3. Statistical analyses

The distributions of citation counts and impact factors were asymmetrical, as a small number of articles had a high number of citations and high impact factors. Therefore, we reported medians rather than means and used Mann–Whitney *U* tests to compare medians. We used univariate linear regression models to identify variables that predicted the number of citations and the impact factors, and multivariate models to identify predictors after adjustment for the other variables in the models. Given our relatively large sample size, regression models are unlikely to be biased by non-normal distributions [13].

3. Results

The 105 reference articles were published in 44 different journals (and two were published as conference proceedings only). Only eight journals published five or more NRT trials each, and these eight journals published 51% of all the reference articles (54 of 105; Table 1).

Most studies ($n = 72$, 69% of 105) were reported in only one article, 23 studies (22%) were reported in two articles and 10 studies (10%) were reported in three or more articles. Eleven trials (10% of 105) were never cited according to ISI Web of Knowledge, and eight trials (8% of 105) were never cited according to Google Scholar. The articles were cited a median of 31 times (25th and 75th centiles: 17 and 75 times) according to ISI Web of Knowledge and 23 times (25th and 75th centiles: 8 and 47 times) according to Google Scholar. The correlation between the number of citations reported in

Table 1
Journals that published RCTs of nicotine replacement therapy for smoking cessation

Journal title	Number of trials
<i>Addictive Behaviors</i>	8
<i>Archives of Internal Medicine</i>	8
<i>British Medical Journal</i>	8
<i>Journal of Consulting and Clinical Psychology</i>	8
<i>Journal of the American Medical Association</i>	6
<i>Preventive Medicine</i>	6
<i>Addiction</i>	5
<i>European Respiratory Journal</i>	5
<i>New England Journal of Medicine</i>	4
<i>American Journal of Public Health</i>	3
<i>Nicotine & Tobacco Research</i>	3
<i>Archives of Family Medicine</i>	2
<i>Chest</i>	2
<i>Journal of General Internal Medicine</i>	2
<i>Practitioner</i>	2
<i>Respiratory Medicine</i>	2
<i>Thorax</i>	2
Conference proceedings	2
Other journals, one article each	27
Total	105

ISI Web of Knowledge and Google Scholar was $r = 0.87$ ($R^2 = 0.75$, $P < 0.01$). Excluding one outlier (a comparison of NRT with bupropion, cited 475 times in ISI and 632 times in Google Scholar) [14], this correlation was reduced to $r = 0.76$ ($R^2 = 0.58$, $P < 0.001$).

According to Google Scholar, the 14 most cited articles (13% of 105) accrued 49.5% of all citations (1,804 of 3,647 citations), and the 54 most cited articles (51% of 105) accrued 89% of all citations (3,245 of 3,647 citations). According to ISI Web of Knowledge, the 17 most cited articles (16% of 105) accrued 52% of all citations (2,570 of 4,928 citations), and the 53 most cited articles (50% of 105) accrued 90% of all citations (4,442 of 4,928 citations).

One third of the trials (35%, 37 of 105) were published in journals that had no impact factor for the year of publication of the reference articles. The 68 available impact factors ranged from 0.05 to 28.9 (25th, 50th, and 75th centiles: 1.28, 2.35, and 3.80).

3.1. Predictors of the number of citations, according to ISI Web of Knowledge

There was a strong association between the impact factor and the number of times articles were cited (9.7 more citations for each additional impact factor point, $P < 0.001$ from a linear regression model). Articles were cited more often when their results were statistically significant than when they were not significant (median = 38.5 vs. 22.5 times, $P = 0.053$). None of the other variables considered (funding source, level of behavioral support, country, product type, publication year) predicted the number of citations reported in ISI Web of Knowledge.

3.2. Predictors of the number of citations, according to Google Scholar

Similarly, there was a strong association between the impact factors of journals and the number of times articles were cited in Google Scholar (10.2 more citations for each additional point of impact factor, $P < 0.001$, from a linear regression model). Articles were cited more often when their results were statistically significant than when they were not significant (median = 28 vs. 16.5 times, $P = 0.001$), when participants received high rather than low-intensity behavioral support (26.5 vs. 16 times, $P = 0.014$), and when trials were funded by the pharmaceutical industry rather than by government or nonprofit agencies (28.0 vs. 16.5 times, $P = 0.001$; Table 2). Patch trials were cited more often than gum trials (29 vs. 17 times, $P = 0.002$), and trials of the newer products (tablet, lozenge, inhaler, nasal spray) were cited more often than gum trials (50.5 vs. 17 times, $P = 0.009$). Trials published in the 1990s and 2000s were cited more often than older trials (27 vs. 16 times, $P = 0.002$). In a multivariate model, the impact factor remained the only statistically significant predictor of the number of citations.

Financial support from the pharmaceutical industry was more frequent in recent years, as 67% of the trials

Table 2
Associations between trial characteristics, the total number of times reference articles were cited, and the impact factors of journals in which trials were published

Medians ^a	Total times cited: ISI Web of Knowledge	Total times cited: Google Scholar	Impact factor
<i>N</i> included studies	94	97	68
All studies, median	31	23	2.36
Publication year			
1970s–1980s	38.5	16	1.85
1990s–2000s	29.5 (ns)	27**	2.37 (ns)
Statistical significance			
Significant results	38.5	41.0	2.80
Nonsignificant results	22.5*	17.0***	1.81**
Funding source			
Government or nonprofit	21.0	16.5	1.81
Pharmaceutical industry	38.0 (ns)	28.0***	2.59*
Behavioral support			
Low	24	16	2.33
High	39 (ns)	26.5*	2.17 (ns)
Country			
USA, UK, or Canada	29.5	23.0	2.56
All other countries	34.0 (ns)	21.0 (ns)	2.05 (ns)
Product			
Gum	24.0	17.0	1.49
Patch	34.5	29.0	2.38
Other products	39.0	50.5	4.13
(tablet, lozenge, inhaler, nasal spray)	P vs. G (ns) G vs. O (ns) P vs. O (ns)	P vs. G (**) G vs. O (**) P vs. O (ns)	P vs. G (*) G vs. O (***) P vs. O (ns)

* $P \leq 0.05$; ** $P \leq 0.01$; *** $P < 0.001$; ns: not statistically significant ($P > 0.05$).

^a All values indicate medians and all comparisons are based on Mann–Whitney *U* tests.

published in the 1990s and 2000s were funded by the industry, compared with 41% of the trials published in the 1970s and 1980s (chi-square = 6.5, $P = 0.011$). The association between funding source and number of citations in Google Scholar was significant only when the analysis was limited to the more recent trials, published in the 1990s and 2000s (industry funded in the 1990s and 2000s: median = 38 citations, nonindustry: median = 16.5 citations, $P = 0.012$). For older trials, published in the 1970s and 1980s, there was no association between funding source and number of citations (industry vs. nonindustry, median = 16 vs. 17 citations, $P = 0.52$).

3.3. Prediction of the impact factor

Articles were published in journals with higher impact factors when their results were statistically significant (median impact factor = 2.80 vs. 1.81 for nonsignificant trials, $P = 0.011$), when trials were funded by the pharmaceutical industry rather than by government or nonprofit agencies (median impact factor = 2.59 vs. 1.81, $P = 0.029$), and when trials tested the patch rather than the gum (median impact factor = 2.38 vs. 1.49, $P = 0.020$) or when they tested the newer products rather than the gum (median impact factor = 4.13 vs. 1.49, $P = 0.001$).

3.4. Citations per year

Using the number of citations per year, each passing year after publication was associated with 0.44 fewer citations per year, according to ISI Web of Knowledge ($P = 0.02$ from linear regression model), and with 0.65 fewer citations per year according to Google Scholar ($P = 0.004$). Trials published in the 1990s and 2000s were cited more often per year than older trials, and trials of the newer NRT products (lozenge, tablet, inhaler, nasal spray) had more citations per year than patch and gum trials (Table 3). Otherwise, results based on the number citations per year were similar to results based on the total number of citations. Again, in a multivariate model, the only significant predictor of the number of citations per year was the impact factor.

4. Discussion

The publication of NRT trials was distributed over 44 different journals, that ranged from generalist medical journals (e.g., *BMJ*, *JAMA*), to addiction journals (e.g., *Addiction*, *Addictive Behaviors*), to specialist journals (e.g., *Thorax*, *Journal of Consulting and Clinical Psychology*), and from local journals (e.g., *Revista Clinica Española*, *Croatian Medical Journal*) to prestigious, high-impact-factor journals. There was apparently no common strategy in the choice of journals by the authors of the trials. It is quite possible that the publication of NRT trials in specialist journals (e.g., psychology or respiratory medicine) reflects the

Table 3

Associations between trial characteristics, the average number of times reference articles were cited *per year* since publication, and the impact factors of journals in which trials were published

Medians ^a	Times cited <i>per year</i> : ISI Web of Knowledge	Times cited <i>per year</i> : Google Scholar
<i>N</i> included studies	94	97
All studies, median <i>N</i> times cited per year	3.7	2.5
Publication year		
1970s–1980s	1.9	0.7
1990s–2000s	4.3***	4.1***
Statistical significance		
Significant results	5.8	4.7
Nonsignificant results	2.5**	1.7**
Funding source		
Government or nonprofit	2.3	1.2
Pharmaceutical industry	4.4*	3.9***
Behavioral support		
Low	2.6	1.1
High	4.0 (ns)	3.2**
Country		
USA, UK, or Canada	3.7	2.5
All other countries	2.4 (ns)	2.2 (ns)
Product		
Gum	1.7	1.0
Patch	4.8	4.4
Other products (tablet, lozenge, inhaler, nasal spray)	7.6	6.7
	P vs. G***	P vs. G***
	G vs. O**	G vs. O***
	P vs. O (ns)	P vs. O (ns)

* $P \leq 0.05$; ** $P \leq 0.01$; *** $P < 0.001$; ns: not statistically significant ($P > 0.05$).

^a All values indicate medians and all comparisons are based on Mann–Whitney *U* tests.

professions of the main authors. Many trials were published in journals that were too small, too local or too specialized to be read by many specialists in the field of tobacco dependence.

The impact factor was a better predictor of the number of citations than any other characteristic of NRT trials. The impact factor was also the only highly statistically significant variable that was associated with the number of citations both in Google Scholar and in ISI Web of Knowledge. This confirms that the journal in which an article is published is a key determinant of the dissemination of results [4]. Despite wide accessibility to articles in electronic databases, citation was still more strongly influenced by the reputation of the journal than by any other factor. In addition, journals with high impact factors were more likely than less prestigious journals to publish trials with positive results, either because they received more submissions of positive trials, or because they were more prone to select articles with positive outcomes for publication. Consequently, positive trials, being published in more prestigious journals, are cited more often. In return, prestigious journals receive more citations as they publish more articles with positive outcomes. Conversely, a good study with null

results published in a minor journal might not receive the attention it deserves.

NRT trials were more often cited when their results were positive, which is in congruence with previous reports on other treatments [15,16]. Biased citation of positive trials may leave readers of the scientific literature with the impression that NRT is more effective than it actually is. This adds to previous reports showing that meta-analyses may overestimate the impact of NRT, because most of the included studies reported short-term (i.e., 6 or 12 months) outcomes only, and did not take late relapse into account [3]. Also, research showed that some industry-sponsored NRT trials with small or null effects may have never reached publication [10]. Registers have been set up to prevent the nonpublication of null results, but registers will not affect the selective publication of positive trials by prestigious journals, or the preferential citation of studies with positive results.

4.1. Citation counts as quality indicators

In our data, sample size, which is an indicator of quality, did not predict the number of citations or the impact factor. This could mean that authors and editors were able to identify the originality and importance of a study independent of its sample size. On the other hand, several previous reports found no, or only weak associations between the quality of articles and the number of citations they received [4,8]. In the field of addictions in particular, the correlation between quality ratings established by experts and the number of times articles were cited was close to zero [5]. Thus, a basic assumption underlying the use of citation counts as quality indicators is not verified, as the number of citations is in fact a poor indicator of quality [5].

This and previous reports suggest that citations are determined by many factors other than quality. Citations may be selected because of their accessibility, for example, in electronic databases, or for even more prosaic reasons. In particular, researchers may select the articles they cite because they have a professional interest in promoting a given line of research, or because of the utility of a citation to support a particular opinion, to influence peers or decision makers. An article may also be cited because it is written by a productive research group whose members often cite each other, or simply because it was published in a prestigious journal, even though journals with higher impact factors do not appear to publish trials with higher levels of methodological quality [5,17].

4.2. Skewed distribution of citations

A small minority of NRT trials accrued half of all citations, and half the trials accrued almost all the citations. This result closely matches research from other fields, showing that half the citations were obtained by 15% of the articles, and that 90% of the citations were obtained by half of the articles, whereas many articles were never cited [18,19].

The concentration of citations on a small number of articles may in part be explained by copied citations, that is, the practice of extracting citations from reference lists in other articles. As a consequence, an article that was ever cited is more likely to be cited again. Statistical models showed that, as a result of copied citations, the whole process of citation is largely random [20,21]. The concentration of citations on a small number of studies also suggests that journals may obtain a high impact factor by the frequent citation of a limited number of their articles only [19]. Assigning the same score (i.e., the journal impact factor) to all articles in the same journal masks these differences and defeats the very purpose of the evaluation [9].

4.3. Other characteristics of the trials

Citations to NRT trials were not biased toward U.K. or North American studies, which confirms an analysis of the Science Citation Index [22], but is at odds with previous reports showing that the ISI database is skewed toward North American journals [9], that US scientists are particularly likely to cite each other [9], and that articles in the field of addictions were more frequently cited if they came from the USA, Canada, Australia or the UK, rather than from the rest of the world [5].

Older articles were cited less often than recent ones, and they were published in journals with lower impact factors, which may reflect the general inflation over time in the number of journals, published articles, and impact factors [23]. Trials funded by the pharmaceutical industry were more often cited than nonindustry trials, but this result should be interpreted with caution, because it was observed only for citations in Google Scholar, and not for citations in ISI Web of Knowledge. Furthermore, almost all trials of the newer products (tablet, lozenge, inhaler, nasal spray) were sponsored by the industry, and these trials tended to be published in high-impact-factor journals and to be often cited. Nevertheless, professional ghostwriting is probably more frequent for industry-sponsored trials, and professionally crafted manuscripts are more likely to be accepted by prestigious journals [24].

Patch trials were more often cited than gum trials, but this association was not significant after adjustment for the year of publication. This association may only reflect that gum trials were older trials, often conducted in the 1970s and 1980s.

4.4. Limitations

We did not rate the articles for their quality, but instead used a single indicator of quality, sample size. Most of the 105 NRT trials under review were seriously underpowered [10], thus, sample size is a useful indicator of quality in this context. In addition, all the included studies were RCTs, and previous research showed that RCTs are more often cited than other types of studies [25,26]. Thus, our results

may not apply to other types of studies. The correlation between citation counts produced by Google Scholar and by ISI Web of Knowledge was less than impressive. This may result from the different methods used to extract references. In particular, the automatic referencing system used by Google Scholar may lack reliability, Google may exert a less rigorous quality control than ISI over its collection of publications, and Google has been criticized for the limited information it provides on its methodology [27,28].

The list of source journals used to compute impact factors contains only a small proportion of all scientific journals [29], which explains why one-third of the articles analyzed in this study were published in journals that did not have an impact factor at the time of their publication. The Institute for Scientific Information has been criticized because some fields are almost entirely excluded from the list of source journals, and for the Anglo-American bias in the selection of source journals [29].

Several limitations of citation counts and impact factors have been identified [6,7,9,17,19]. In particular, the 2-year time window for impact factors means that disciplines that have longer research cycles, such as tobacco dependence treatment, are disadvantaged. Disciplines are also disadvantaged if they count fewer researchers, fewer journals, less money and therefore fewer articles that cite each other, or if articles in a given field have shorter reference lists. Perversely, an article can be cited precisely because it makes unacceptable or provocative claims that need to be refuted. Thus, the impact factor is vulnerable to manipulation, as editors can artificially boost the impact factor of their journal by publishing controversial articles. In addition, the impact factor is not corrected for self-citation, which can represent a substantial part of all citations [30]. Finally, there is an important variability in citation rates of individual articles in any given journal [31], which suggests that even though the impact factor may be a useful tool to evaluate the quality of journals, it is not a valid quality indicator for individual articles [6,32]. The impact factor, which was developed commercially to compare competing journals, should therefore not be used to assess the quality of individual articles or the output of research groups or of individual researchers. Alternative methods have been suggested, such as postpublication peer-review ratings [7], or the assessment of the level of noncitation [33]. These approaches deserve to be explored further.

4.5. Conclusion

This article adds to the relatively small corpus of empirical work that has been undertaken on citation counts, and indicates that citations to NRT trials are biased toward articles published in high-impact-factor-journals, and toward articles with positive results. This phenomenon may produce a biased evaluation of the effectiveness of treatments by readers of the scientific literature.

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