



Commentary

The mockery that confounds better treatment of confounding in epidemiology: The change in estimate fallacy

Igor Burstyn^{*}

Department of Environmental and Occupational Health, Dornsife School of Public Health, Drexel University, Philadelphia, PA, United States of America

A B S T R A C T

Confounding is one of the most infamous bugbears of epidemiology, used by some to dismiss the field's utility outright. The subject has received considerable attention from epidemiologists and the field boasts a remarkable arsenal for addressing the issue. However, it appears that there are still misconceptions about how to identify variables that cause confounding (a lack of exchangeability) in epidemiologic practice. In this commentary, I examine whether analysis of the properties of change-in-estimate method for identification of confounding, exemplified by two highly cited papers, has been appropriately cited in published reports and whether it was utilized to improve epidemiologic practice. I conclude that the myth that a change-in-estimate criterion of 10 % is legitimate for identifying confounding persists in epidemiological practice, despite having been discredited by several independent research groups decades ago. Speculations on possible solutions to this problem are offered, but my work's main contribution is identification of a problem of how methodological advances in epidemiology may be misapplied. There currently do not exist any universal criteria for identification of confounding! "Citation without representation" or biased presentation of conclusions of methodological research may be pervasive.

Background

Lewis the Dauphin. Mort de ma vie! all is confounded, all!

Reproach and everlasting shame.

Sits mocking in our plumes. O merchant fortune!

Do not run away.

[A short alarum].

Constable of France. Why, all our ranks are broke.

Lewis the Dauphin. O perdurable shame! let's stab ourselves.

Be these the wretches that we play'd at dice for?

(*Henry V* [IV, 5] by W. Shakespear [1])

Several concerns are apparent to me in reading epidemiologic literature. The first one is unthinking referencing without reading in methodological and substantive matters. A second issue is mechanical or proceduralist application of statistical tests without thinking. It is typically impossible to tell the two possible sources of error apart from the published work. I examine these issues in detail in the current manuscript using two case-studies of control for confounding (a lack of exchangeability). There is a third question of whether residual confounding is an inescapable problem for epidemiology. We are never going to get past residual confounding if we are unthinking and mechanical, since we will then announce that we have dealt with confounding without having properly thought about it, only mechanically applied some test. Therefore, the two issues that I examine in the case

studies, necessarily lead to the third one. I do not advocate use of data-driven methods the ignore substantive knowledge [2]. I note that there is a problem with use of the term "confounders". It invites a traditional approach to handling confounding, which first labels variables that meet the given definition and then mandates that all these so-called confounders are somehow adjusted for in study design or data analysis. It is for this reason that I refer to confounding as the phenomenon being addressed, while admitting that in current analysis the situation that is considered assumed that a variable that a candidate variable that can control for confounding (confounder) has been correctly articulated.

Confounding is one of the most infamous bugbears of epidemiology, used by some to dismiss the field's utility outright [3]. The subject has received considerable attention from epidemiologists and the field boasts a remarkable arsenal for addressing the issue (e.g., see the latest editions of the key textbooks by Lash et al. [4,5]). Some observers [6–8] suggested that the change-in-estimate to select confounders is on decline with more subtle methods gaining favor. However, one cannot escape the impression that most of these advances are yet to penetrate practice such that the criticism that confounding still plagues the field has merit. Precisely because the presence or absence of confounding is empirically unverifiable without strong alternative assumptions, there will and should always be a concern of uncontrolled confounding. However, it is incumbent upon epidemiologists to use the best available methods to tackle this, instead of proforma approaches that apply discredited

^{*} Corresponding author.

E-mail address: ib68@drexel.edu.

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methods. Instead of focusing on dissemination of the totality of these advances, I will comment on an equally important subject: the persistence and perpetuation of statistical malpractice, evidenced by inappropriate citation of articles aimed at remedying bias that arises due to confounding. (If an inappropriate method is supported by a reference that refutes it in a peer-review publication, this inappropriate citation encourages others to do the same by normalizing avoidable errors.) I do this by examining citation patterns of two papers which, in my opinion, should have helped advance epidemiological practice but did not [9,10]. Both articles are technically sound and are among the most cited of their authors. I view them as a succession of analyses that build upon each other to advance both the knowledge and the tools that can be used in epidemiological practice.

Maldonado & Greenland [9], building on work of Mickey & Greenland, [11] set out to test in simulations various approaches for identification of confounders. After examining many scenarios, they concluded that among the five studied approaches,

At least one variation of each strategy that was examined performed acceptably. The change-in-estimate and equivalence-test-of-the-difference strategies performed best when the cut-point for deciding whether crude and adjusted estimates differed by an important amount was set to a low value (10 %). The significance test strategies performed best when the alpha level was set to much higher than conventional levels (0.20).

This result has entered epidemiologic folklore to mean that change-in-estimate criterion (CIE) with cutoff of 10 % or greater is an acceptable default for confounder identification. However, it is obvious that even smaller changes can be important, e.g., when they qualitatively alter interpretation as when crude odds ratio is 1.04 and switches direction upon adjustment to 0.96 (assuming both have narrow confidence limits). Maldonado & Greenland [9] discussed the bias that the CIE approach produces and warned against application of their findings outside of their simulation framework; indeed their work was partially motivated by the limited scope of an earlier simulation study on the same topic by Mickey & Greenland [11]. It is unfortunate that a nuanced conclusion of methodological exploration proved too subtle for many practicing epidemiologists. One recommendation that I can already make based on this experience is for the methodologists, schooled in subtle matters, to be blunter when conveying their findings to a technically less sophisticated reader. According to the publisher (Oxford University Press), the article has been cited about more than 2000 times, and has “High Attention Score compared to outputs of the same age (84th percentile)” (<https://oxfordjournals.altmetric.com/details/24929258>; accessed 5/26/2023).

Lee & Burstyn [10] built on a publication of [12] who questioned whether the CIE approach with a cutoff of 10 %, commonly used to identify confounders is appropriate. Lee [12] recommended a simulation-based approach to customize the change-in-estimate criterion and concluded that for a fixed type I error rate, the,

cutoff points for the change-in-estimate criterion (CIE) varied according to the effect size of the exposure-outcome relationship, sample size, standard deviation of the regression error, and exposure-confounder correlation.

Lee and Burstyn [10] described how to adapt the simulation-based approach of [12] to a accommodate measurement error in predictors (e.g., an exposure and a potential confounder). After considering common practices in the field (significance criteria with cutoff levels of p -values of 0.05 or 0.20, and CIE criterion with a cutoff of 10 %) under a range of conditions, the authors concluded:

No a priori criterion developed for a specific application is guaranteed to be suitable for confounder identification in general. The customization of model-building strategies and study designs through simulations that consider the likely imperfections in the data, as well as finite-sample behavior, would constitute an important improvement on some of the currently prevailing practices in confounder identification and evaluation. [10]

Thus, even if a reader did not understand or even read the entire paper, the abstract should leave no doubt that Lee and Burstyn [10] do not support any of the common confounder identification and model

selection strategies that are not customized to a specific dataset or problem. They provide computer code that allows one to undertake customization at no cost, and therefore give helpful advice on what to do, not just admonish for applying an incorrect test. The article was published open access and has been accessed close to 10,000 times and cited 55 times as of May 2023 (according to Springer).

In this commentary, I examine whether critique of change-in-estimate methods for identification of confounding has been appropriately cited in published reports and whether it was utilized to improve epidemiologic practice.

Methods

Citations were identified via the “Web of Science” (Clarivate; ISI Thomson Reuters Web of Knowledge, accessed via Drexel University library) search conducted on May 25, 2023. I examined a simple random sample of 100 citation of Maldonado & Greenland [9] and all citations of that Lee and Burstyn [10]. I further limited review to citations in peer reviewed journals and in English language. Each unique citation was categorized into “contrary to author’s conclusion” (e.g. “independent variables with a $p < 0.20$ in the univariate analyses were entered into the multivariate analysis”, “a 10% change-in-estimate criterion was used to determine whether to include confounders in subsequent analyses”), “not misleading but missing the main finding, citing in support of matters that are the pretext not findings” (e.g. “criteria for defining confounders are notoriously elusive”), “appropriate use of the main result”, and “advancement on the main result”; citations by the original authors were noted.

In deciding whether citations were appropriate, I looked for reference to performance of variable selection methods under specific conditions that were studied in simulations of Maldonado & Greenland [9] and Lee and Burstyn [10]. Therefore, any statements that said that confounders were selected based on CIE $< 10\%$ and/or some fixed value without any justification for this choice, promulgating the myth that these are universally applicable criteria, where judged to be “contrary to author’s conclusion”.

Results

Maldonado & Greenland [9], were cited primarily in public health (504 citations), with the distant seconds in oncology (121 citations) and general internal medicine journals (117 citations). Most citations were by authors based in the US (943 citations) and Canada (324 citations), but there was a wide geographic coverage. Lee & Burstyn [10] were cited primarily in public health (23 citations) and healthcare services (19 citations) journals, but with a large invocation in medical journals scattered across specialties and only a few in mathematics (12 citations). Most citations were by authors based in the US (18 citations) and China (14 citations), but there was a wide geographic spread covering all continents.

Among the sample of citations of Maldonado & Greenland [9], 8 were excluded (6 were not in English, two were book chapters), leaving 92 for analysis of context in which it was cited (**Supplemental Table 1**). The majority, almost 90 % (82/92), were invoked in support of claims that were either not supported or refuted by Maldonado & Greenland [9]. The typical invocations involved claiming support for either 5 % or 10 % CIE cut-offs and use of various p -value thresholds in forward and backward model-building selection procedures. Most of these appear in medical and public health journals. There were four citations that attempted to argue for why a specific criterion used by Maldonado & Greenland [9] was appropriate for their context. This seems more in the spirit of the cited paper that urged authors to consider the peculiarities of each research question and dataset, but in none of these cases the adopted method was rigorously supported (e.g., not even by simulations). Three citing articles appropriately cited the main claims and further offered methodological improvements. These methodological

improvements included considerations of stability of the effect estimates and parsimony [13], testing of difference in effect estimates during model-building instead of only considering point estimates [14], and a replication of refutation of stepwise selection of logistic model in “small” datasets, when model selection is based on p -values approach via simulations. [15].

The vast majority, more than 80 % of the citations (45/55), of Lee & Burstyn [10] supported claims that were rejected in the cited article (Supplemental Table 2). This was an *en masse* misrepresentation of the work and thus the high degree of citation is a measure of harm its use has caused may have to epidemiology, by lending legitimacy to wrong methods and undermining reputations of the authors by attributing to them the views they openly rejected. The article by Lee and Burstyn [10] was used most often by authors from China and Africa, who invoked it to support erroneous claim that Lee and Burstyn [10] provided evidence for use of pre-set p -values and 10 % CIE cut-offs to select variables into regression models. This is the opposite of what Lee and Burstyn [10] recommended, i.e., most of the citing authors appear to be perpetrating a fraud. Some of the more egregious misrepresentations of the work and errors in logic committed in doing so were found in the medical journals, especially in commentaries and correspondences (I purposefully do not cite them here, but they can be readily observed in the supplemental materials). A few (7/55, 12.5 %) articles repeated premises of Lee & Burstyn [10] which do not constitute their findings, re-stating the well-established notion that model selection is complicated by measurement error and/or that confounding may exist in epidemiology. Two citations were by one of the authors: they correctly uses past precedent to encourage simulations to aid in design of study design [16] and supported a prior theory-based (rather than statistical) model-building [17]. None of the citations advanced the original work, built on it to develop new insights, or even applied it as recommended, using freely provided computer code that can be implemented at no cost.

It appears that the most inappropriate citations attempted to give support of firm, prescriptive, guidance on building the best statistical model. This desire for certainty is understandable as it is one of the pivotal steps in data analysis for which modern statistics does not have a definitive answer: there is no evidence that there is a method that will ensure optimal selection of a statistical model. Perhaps many authors who are not comfortable with statistical concepts either felt that they had to invoke external authority to justify their choice or were coerced into doing so by their peers, teachers, or journal editors and reviewers. There is certainly a pattern of authors replicating their methods based on their prior success, via self-referencing. It would be better if in such cases the authors explained why their method of model selection was appropriate, without simply justifying their choices by incorrectly invoking an authoritative source.

Discussion

Most of the citation of [9,10] were inappropriate and were misused to support analytical decisions that were contrary to the recommendations of the authors. To set the record straight (for those who read this far): neither Maldonado & Greenland [9] nor Lee & Burstyn [10] derived criteria for identification of confounders in *all* epidemiologic studies and regression models, but instead they showed how to develop such criteria for each specific study, under some explicitly articulated assumptions. *There currently do not exist any universal criteria for identification of confounders that rely solely on empirically verifiable assumptions and that guarantee optimal performance under all circumstances!* One can argue that such a method will never exist. This can be proved quite easily with an example of two causal models that produce the same factual data distribution yet exhibit different values of the estimand and where there is confounding according to one model but not the other.

I accidentally discovered a bizarre case of discontinuity in learning about confounder identification in epidemiology. An evaluation of CIE via simulations by Talbot et al. [18] from 2021 did not cite [10,12], but

relied on earlier work of [9,11]. Talbot et al. [18] was cited 5 times (as of May 2023), once inappropriately, twice again supporting a claim contrary to result of [18] that CIE approach is not to be trusted, and twice in a manner that is related to Talbot et al. [18] but did not advance their work, i.e. on utility of not using data-driven model-selection. [19,20] None of the authors citing [18] demonstrated the knowledge of history of the matter, i.e. did not cite [9–12]. Thus, the “broken telephone” of confounder identification practices appears to thrive despite mounting published sound advice. There is evidence that poor practices, including CIE and p -value screening are common in published epidemiology papers, [7] which I do not find surprising, given the lack of evidence of transfer of the relevant knowledge (ironically reported by Talbot et al. [7] in 2019).

We will never know whether persons who wrongly cited these methodological papers even made an honest attempt to apply their results or were just seeking some reference to justify what they want to do regardless of advice of others, a form of appeal to authority when one is not able or willing to defend their own methodological choices.

Our observations are based on a very limited case study of confounder identification in observational studies. As such, our conclusions may not apply to all innovations aimed at addressing confounding, let alone other methodological issues in epidemiology. But it appears that one critical failure, which I demonstrated, is sufficient to undermine our confidence in how well and earnestly many epidemiologists and medical researchers are working to limit the impact of confounding on the results of the observational studies. To the best of my knowledge, uptake of modern methods to address another persistent problem in epidemiology, measurement error in exposure, is likewise poor to non-existent. [21,22] A related matter that illustrated that my observations are not isolated related to the misuse of words of Austin Bradford Hill [23]. It is commonplace to mention Austin Bradford Hill’s “criteria” in arguing causation in epidemiology. This is exactly the kind of egregious error that I am describing in my case studies and a symptom on a widespread problem in epidemiology. Hill explicit that they were not criteria, could not be regarded as either necessary or sufficient either jointly or severally, and he called them “viewpoints”. Yet epidemiologists publish papers and testify in court with the nine “criteria” ticked off, completely the opposite of what Hill was urging: to think deeply and not simplify the most subtle of arts in science to mere finder-counting. Thus, I have reason to believe that I did not observe an isolated phenomenon. The matter appears to deserve additional attention: if publishing methodological work is seen as an intervention, there must follow an evaluation of its impact.

An anonymous reviewer of the manuscript posited that my analysis does not allow concluding that the examined papers truly did not help advance epidemiological practice. Indeed, citations in scientific journals are an incomplete measure of the contributions to knowledge. For example, the papers may have been cited in course materials to recommend not using the change-in-estimate method and thus have had a positive impact of epidemiologic practice. The papers may have also been consulted by epidemiologists and led them to not use the change-in-estimate when analyzing their data. We are also not able to examine a counter-factual world in which some of the methodological papers were not published. Yet there is affirmative evidence in my analysis that work remains to be done to ensure that methodological research on confounder identification in epidemiology is not misused.

These findings make one question the value of access to publications per se (either free “open” or after paying for it) in the dissemination of knowledge, as opposed to a more laborious yet proven method: mentoring and collaboration during graduate education and beyond. Even the abstracts of the published papers, if read and understood, would have prevented the misdeeds of most of the citing authors. Thus, the solution does not seem to be with open access to scientific reports but the lack of expertise – often apparent functional illiteracy – among the vast numbers of consumers of this freely available information. For analogous reasons, it seems doubtful that free access to software for

quantitative bias analysis under unmeasured confounding would materially alter epidemiologic practice. [24] However, “open” access to published scholarship (in whichever form it takes place) is obviously an pre-requisite to any effective mentoring; it is just that access to static texts is likely not enough for effective pedagogy.

“Citation without representation” or biased presentation of conclusions of methodological research may be pervasive. It may well date back to least the misunderstanding of what signifies an important finding (e.g., the $p < 0.05$ “dichotomania” [25]), and is likely a social phenomenon where science is seen as a contest of authorities rather than arguments and evidence. The desire for simplistic answers to complex scientific questions is also likely a social phenomenon, in which a simple solution is seen as preferable even if it is of questionable rigor. Simple solutions to the intricacies of confounding appear to have a lasting appeal, as seen in a proposal to reduce the evaluation of the problem to judgment on a single number, [26] but there is evidence of uptake of some of the more sophisticated (and in my view, appropriate) methods. [24] It is legitimate to seek practical solution to epidemiologic problems, because epidemiology is an applied science, so long as one acknowledges the imperfections of such solutions and strives to overcome them. Unfortunately confounding seems to be a problem for which empirically driven solutions that make “weak” assumptions do not exist. It is important to note in this context that intuitively and aesthetically appealing Occam’s Razor – preference for simple methods and theories – does not lack detractors. [27]

It appears that I observed a massive, missed opportunity for advancement in epidemiology: teaching practitioners and scientists the importance of reading and understanding what they cite, and/or taking responsibility for accurately representing intellectual contribution of their peers. Nobody wants to be known for claiming “X is true” when they wrote “X is not true”! It may be productive to engage with those who misrepresent work done by others to better understand their motivations and causes of their academic malpractice.

Others investigated misrepresentation of research beyond mere misuse of statistics, [28,29] but they did not appear to consider inappropriate justification of methods and improper invocation of prior research. However, the malpractice of “‘beautification’ of methods” appears to be akin to what I observed here:

Scientists could also engage in what we characterize as “beautification” of the methods, when they report the methods as if they were complying with the highest standards when in fact they were not. [30]

The solutions offered to address the issue are a familiar mixture of changes to incentives, research culture, education, and checks-and-balances; [28–30] it is unclear which of these may prove effective. Nissen et al. set out to “explore the process by which a claim becomes fact” in science, which can be applied to claim that a method of analysis is valid. They modeled the community’s confidence in a claim and observed that the remedy for “false claims ... canonized as fact” was to publish negative results, allowing for “true and false claims” becoming “more readily distinguished”. I see important parallel in methodological research: description of a method that fails to achieve stated goal is nearly impossible to publish; there is simply no outlet for failed biostatistical and methodological efforts, with all such literature being a litany of successes and none of the failures. It is understandable why it is impossible to publish a failed proof of a theorem. However, it may be of vital importance to create means by which all efforts of advance methods enter public record and the reason for various failures are openly debated, with credit given to their authors for a valiant attempt replacing judgment for any apparent failures to reach stated methodological aims. There must be a reward for effort, not just achievement: “Learning is its own greatest reward.” [31].

Conclusions

The myth that a change in estimate criterion of 10 % is legitimate for identifying confounding persists in epidemiological practice despite

having been discredited by several independent researchers.

It appears that mere access to publications describing methodological advances is an inefficient and possibly harmful approach to improving epidemiologic practice. Better training of epidemiologists could be the answer, but I am uncertain how to effectively achieve this. There is also a possibility that reducing publication bias in methodological work, i.e., publishing methodological efforts that failed and debating limitations of existing ones, may help those practicing epidemiologists to become more discerning consumers of methodological research.

Until there is a tangible uptake by the majority of epidemiologists and medical researchers of the methods devised to address confounding and a collaborative effort to improve (not beautify) such methods, confounding will remain the “everlasting shame” [1] of epidemiology. A pessimist may also wonder if methodological work in this area can make a positive contribution, absent any motivation to apply it and when there is no cost to abusing it. Yet I remain optimistic because I believe it important to be able to.

... bear to hear the truth you’ve spoken.

Twisted ...

to watch the things you gave your life to, broken,

And stoop and build ‘em up with worn-out tools.

(If by Kipling [32])

CRedit authorship contribution statement

Igor Burstyn: Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Investigation, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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