

Estimating the Effect of Smoking Cessation on Weight Gain: An Instrumental Variable Approach

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Objective. To propose and test a method that produces an unbiased estimate of the average effect of smoking cessation on weight gain. Previous estimates may be biased due to unobservable differences in attributes of quitters and continuing smokers. An accurate estimate of weight gain due to cessation is important for policymakers, health managers, clinicians, consumers, and developers of smoking cessation aids.

Study Setting. Our analysis consisted of an instrumental variables (IVs) approach in which treatment assignment in randomized smoking cessation trials served as a random source of variation in probability of quitting.

Data Collection. We searched the medical literature for previously conducted smoking cessation trials that contained data suitable for our reanalysis.

Principal Findings. We identified one trial for our reanalysis, the Lung Health Study, a randomized smoking cessation trial with 5,887 smokers aged 35–60 from 1986 to 1994 in several sites across the United States. In our IV reanalysis, we estimated a 9.7 kg weight gain over 5 years due to cessation, as compared with the conventional estimate of 5.3 kg.

Conclusions. The true effect of smoking cessation on weight gain may be larger than previously estimated. This result indicates the importance of fully understanding the possible weight effects of cessation and underscores the need to accompany cessation programs with weight management interventions. The result, however, does not overturn the conclusion that the net health benefits of quitting are positive and very large. The application of the IV technique we propose is likely to be useful in a variety of contexts in which one is interested in the effect of one health condition on another.

Key Words. Smoking cessation, weight gain, instrumental variables

Healthy People 2010 identifies tobacco use and obesity as important focus areas for the United States public health community (U.S. Department of Health and Human Services 2000). The two priorities share an important link. Over the past 25 years, a number of studies have documented the changes in body weight that result from smoking cessation. The research has generally

concluded that smoking cessation is associated with a statistically significant increase in body weight among quitters (Coates and Li 1983; Manley and Boland 1983; Albanes et al. 1987; Klesges et al. 1989; Shimokata, Muller, and Andres 1989; Moffart and Owens 1991; Williamson et al. 1991; Flegal et al. 1995; Klesges et al. 1997, 1998; Froom, Melamed, and Benbassat 1998; Mizoue et al. 1998; Froom et al. 1999; Hudmond et al. 1999). Estimates of postcessation weight gain range considerably. A review of the smoking and body weight literature by Klesges et al. (1989) found that estimates of weight gain associated with cessation range from 0.2 to 8.2 kg depending on the sample, study design, and follow-up period. Through their meta-analysis of these studies, the authors concluded that smokers gain an average of 2.9 kg after quitting.

In these studies researchers took the basic approach of comparing average weight gain of quitters to that of continuing smokers. Typically the analyses controlled for differences across the two groups with variables including age, sex, and baseline body weight. A problem with this approach is that the two groups are likely to differ in unmeasured variables—such as general concern for health or present versus future orientation—that may be related to weight gain. These differences could confound estimates of the true causal effect of cessation on weight gain.

Unmeasured confounders could cause the estimates derived from comparing quitters to continuing smokers to be biased either upwards or downwards. Quitters are known to be less concerned on average about weight gain than continuing smokers, particularly in the case of women (Meyers et al. 1997). This suggests quitters may be more prone to weight gain than continuing smokers, implying that the comparison between the two groups would be biased upwards from the true causal effect. On the other hand, quitters have been shown to be different from continuing smokers in three ways that could produce a downward bias in estimated weight gain. First, a primary motivation for quitting smoking is general concern about health (McCaul et al. 2006). Second, quitters are more future-oriented on average (Bickel, Odum, and Madden 1999). Third, quitters are less impulsive on average (Wurtman 1993; Cinciripini et al. 2003; Terracciano and Costa 2004). All three of these factors

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could mean that quitters, compared with continuing smokers, are less prone to weight gain.

One other factor could produce a bias, but it is not clear in which direction. Quitters tend to be less depressed and exhibit less negative affect at the time of successful quitting than continuing smokers (Cinciripini et al. 2003). These differences in emotional states have been associated in various studies with both weight loss and weight gain (Wurtman 1993; Barefoot et al. 1998). Indeed, the *Diagnostic and Statistical Manual of the American Psychiatric Association*, 4th Edition (DSM-IV) cites “significant weight loss/gain” as one of the nine symptoms of depression (American Psychiatric Association 1994, p. 161).

Depending on their relative magnitudes, the confounding factors described above could produce an overestimate or underestimate of the true effect of cessation on weight gain. It is also theoretically possible that the cofounders offset each other, causing the conventional estimates to be accurate. Thus, we do not know whether previous estimates are too high, too low, or just right. The only way to answer this question definitively is to examine a situation in which people have been randomized to be quitters or continuing smokers, thus ensuring that unmeasured confounders are equal on average across the groups being compared. In this study we adopt a variant of this approach by applying an instrumental variables (IVs) method to previously published randomized cessation trials.

METHODS

While ethical and practical limitations prevent researchers from literally randomizing subjects to quitting or continuing to smoke, successful smoking cessation trials effectively randomize subjects to having a higher probability of quitting (if they are in the intervention arm) or lower probability of quitting (if they are in the control arm). An IV analysis applied to such trials can yield an unbiased estimate of the effect of quitting on weight gain.

IV analysis applied to randomized trials is essentially intention to treat (ITT) analysis taken one step further. In ITT analysis, outcomes are compared based on the initial treatment assignments, despite the fact that some subjects may not have adhered to their assignments (Fisher et al. 1990). IV analysis scales up the ITT estimate of the treatment effect by dividing it by the difference across groups in probabilities of receiving the treatment, recognizing that the ITT estimate is likely to be an underestimate of the true treatment effect. Newhouse and McClellan (1998) provide an overview of the

application of IVs to health outcomes research. The use of the technique in this field has grown in recent years (McClellan, McNeil, and Newhouse 1994; Schoenbaum et al. 2002; Brooks et al. 2003; Hadley et al. 2003).

The validity of the IV approach rests on two assumptions (Angrist, Imbens, and Rubin 1996). First, the IV must be correlated with the treatment being evaluated. Second, the IV must be correlated with the outcome of interest only through the IV's relationship with the treatment. That is, the IV must not have a direct effect on the outcome of interest.

In the context of our analysis of smoking cessation trials, the IV is the random assignment to the intervention or control, the "treatment" is whether a person successfully quits smoking, and the outcome of interest is weight gain. The IV estimate of the effect of quitting on weight gain is thus the ITT estimate (difference in average weight gain across the intervention and control groups) divided by the difference in probabilities of quitting across the two groups.

In our primary analysis we defined quitters as "sustained quitters." These individuals did not smoke at any follow-up points in their respective study periods. In sensitivity analysis, we expanded the definition to "cross-sectional quitters." These were people who had quit as of the last follow-up, but not necessarily as of intermediate follow-ups.

We sought to reanalyze data from previous studies using this IV approach. We searched the medical literature for smoking cessation randomized control trials that would be suitable. Such studies had to fulfill several criteria. First, they had to satisfy the two critical assumptions in IV analysis: (1) the smoking cessation intervention had to be effective (i.e., the IV—assignment to the intervention—had to be correlated with the "treatment," quitting); (2) the intervention could not have a significant direct effect on body weight (i.e., the IV had to be correlated with weight gain only through its effect on the "treatment," quitting).

Regarding the first criterion, we considered an intervention "effective" if it produced quit rates at least 15 percent higher than in the control group. In general, a high correlation between the IV and the "treatment" is necessary because the standard errors of the estimated treatment effect are inversely related to the strength of this correlation (Angrist, Imbens, and Rubin 1996). As a result of the second criterion, we excluded studies in which the central component of the intervention included pharmaceutical cessation aids, because we assumed that these were likely to have direct effects on body weight. Even though some nicotine replacement strategies are not clearly associated with weight changes (Fiore et al. 2000), we chose to be conservative by assuming that nicotine in any form may act as an appetite suppressant. We also

excluded studies explicitly designed to modify multiple lifestyle risk factors instead of just smoking.

In addition we confined attention to studies for which the data necessary to construct IV estimates were available. In particular, we needed the following information to construct an IV estimate: (1) average weight gain for the intervention group; (2) average weight gain for the control group; (3) quit rate for the intervention group; (4) quit rate for the control group. As noted earlier, previous studies of weight gain associated with smoking cessation have focused on the comparison between quitters and continuing smokers, ignoring the randomized assignments. Thus, in most published studies the first two pieces of information listed above were not available. Finally, we required that the studies include the data necessary to construct the conventional estimate of the effect of cessation on weight gain, for comparison purposes, and that the follow-up period be at least 6 months. This last condition reflected our interest in more lasting changes in body weight.

We searched Medline for all smoking cessation studies published since 1975 that included information on weight gain. We performed additional searches based on lists of references in these articles. In cases in which published studies did not display all the data necessary for our study but appeared potentially suitable, we contacted the authors to inquire about unpublished data.

RESULTS

Our search identified only one study fitting the criteria described above, the Lung Health Study. This study was conducted in the United States between 1986 and 1994 (O'Hara et al. 1998). The intervention and control groups were virtually identical in mean values for all variables measured at baseline, suggesting that the randomization process was successful (Anthonisen et al. 1994). In addition to a behavioral smoking cessation intervention, the Lung Health Study included an inhaled bronchodilator (ipratropium) that was intended to improve lung function. We did not view the presence of this medication as a reason to exclude the study from our reanalysis because ipratropium was not considered part of the smoking cessation component (and thus was not expected to induce differential cessation rates). Moreover, change in body weight is not among its known side effects (MedlinePlus 2005).

The characteristics of the study and the results of our IVs reanalysis are summarized in Table 1. After 5 years the difference in weight gain between the

Table 1: Application of an Instrumental Variables Approach to the Lung Health Study

<i>Setting</i>	<i>United States</i>
Time period	1986–1994
<i>N</i>	5,887
Sample description	Smokers aged 35–60 with evidence of early stage chronic obstructive pulmonary disease
Exclusion criteria	Body weight >150% of normal; consumption of 25+ alcoholic drinks per week
Special intervention (SI)	Counseling and temporary use of nicotine gum
Biochemical validation of self-reported smoking	Carbon monoxide and salivary cotinine
Follow-up period	5 years
SI quit rate	21%
Usual care (UC) quit rate	5%
Difference in quit rates	16%
SI average weight gain	4.25 kg
UC average weight gain	2.70 kg
Difference in average weight gains	1.55 kg
Instrumental variables (IV) estimate (= difference in average weight gains/ difference in quit rates)	9.7 kg
Conventional estimate (= average weight gain of quitters – average weight gain of continuing smokers)	5.3 kg

intervention and control groups was 1.55 kg and the difference in sustained quit rates across the groups was 16 percent (calculations using results published in O'Hara et al. 1998). Thus, the IV estimate of the effect of quitting on weight gain was 9.7 kg (1.55 kg/0.16).

The conventional estimate (comparing weight gains of sustained quitters versus nonquitters, ignoring initial randomization) was 5.3 kg in the Lung Health Study (calculations using results published in O'Hara et al. 1998). The difference between this estimate and the IV estimate suggests that the conventional estimate may have been an underestimate of the true weight gain effect. Using unpublished information from the authors on the standard deviations of weight gains, we calculated the 95 percent confidence interval for the conventional estimate as (4.9, 5.6). We were not able to calculate standard errors for the IV estimate without the individual level data, but we note that even if this confidence interval were 10 times wider than that for the conventional estimate (i.e., 6.2–13.2), we would still reject the hypothesis that the conventional estimate is greater than or equal to the IV estimate at $p = .01$.

We were also not able to obtain the data necessary to reanalyze the study using the cross-sectional, rather than sustained, definition of quitters. However, we were able to verify that the difference in quit rates between the intervention and control groups did not change much under the alternative definition of quitters (18 versus 16 percent). This suggests that the estimated difference in quit rates was not very sensitive to how we defined quitting.

DISCUSSION

Our findings provide preliminary evidence that the method typically used in previous studies underestimates the true effect of smoking cessation on weight gain. Underestimation could be due to unmeasured differences between quitters and continuing smokers in characteristics such as concern for health, self-discipline, and valuation of the future.

This result, however, should not be interpreted as evidence that continuing to smoke can be beneficial to one's health. Considered collectively, epidemiological evidence suggests that the health benefits associated with quitting easily exceed the harms of extra weight, even if such extra weight were on the order of 10–15 kg (Jousilahti et al. 1996; Jacobs et al. 1999). It is also important for potential quitters to keep in mind that the average weight gain “effect” estimated here is not an immutable biological law but rather a response that can be mitigated through, for example, healthy eating and physical activity.

While the conclusion that smoking cessation is beneficial to one's health is unambiguous, there are important reasons to estimate the weight gain caused by quitting as accurately as possible. Policymakers and health plan leaders need this information to accurately calculate cost-benefit estimates for smoking cessation programs, and to know how much to invest in weight counseling programs accompanying smoking cessation programs. Policymakers also would benefit from an improved understanding of how the smoking–weight relationship can explain a small part of the rise of obesity in the United States. Moreover, consumers and clinicians need reliable information to aid decisions about weight control efforts when attempting to quit smoking.

The main limitation of this analysis is the lack of data available with which to implement the proposed method. Only one cessation study was identified in an extensive literature search, and individual-level data with which to calculate standard errors for the IV estimate were unavailable. We

could not calculate a confidence interval for the IV estimate, but we noted that it would have to be more than 10 times wider than that of the conventional estimate for us not to have rejected the hypothesis that the conventional estimate is equal or larger.

Even though we sought to reanalyze only studies with interventions that were not intended to control weight, it is possible that the intervention in the Lung Health Study did affect subjects' weight to a minor extent. For example, quitters in the intervention group who gained weight were offered weight management counseling twice a year (O'Hara et al. 1993). Additionally, during the first few months of the trial, subjects in the intervention group were offered nicotine gum. Nicotine gum has been shown to attenuate postcessation weight gain (Fiore et al. 2000). Despite the availability of counseling and gum, we still deemed the LHS suitable for our IV reanalysis because the direction of the bias, if any, corresponding to our estimates would clearly be negative. Also, weight management was not an intensive component of the intervention, and nicotine gum use was discouraged after 6 months. These considerations suggest that the IV estimates in our study, though larger than the conventional estimates, may have still underestimated the true weight gain effect of quitting.

Another possible source of bias could be an effect stemming from treatment assignment. For example, subjects assigned to the usual care group may have become upset or unmotivated, thus affecting their weight gains. Again, this might have biased our estimate downwards, but we have no means to evaluate this possibility.

It is important to recognize that the IVs estimate is only applicable to the subset of people whose smoking status was affected by their assignment to the intervention or control group. The average effect of quitting on weight gain may be different for these people than it is for other people in the population. While this issue may appear to be a limitation of IV analysis, it can also be viewed as an advantage. The analysis tells us the average weight gain for exactly the population whose smoking behavior is most likely to respond to cessation interventions. In this sense the IV estimate is more policy-relevant than a hypothetical estimate representing a population-wide average effect (Newhouse and McClellan 1998).

The Lung Health Study's fairly specific exclusion and inclusion criteria (as shown in Table 1) and the lack of racial and ethnic information indicate that our results should be applied with caution to other populations. Despite this potential shortcoming, our approach should have strong internal validity. We view this as an important improvement over conventional approaches in previous studies, which are likely to be biased by unobserved differences

between continuing smokers and quitters. We also note that, despite the selection criteria for the Lung Health Study, the sample was representative at baseline in terms of average body mass index for adults of the corresponding age group in the United States (O'Hara et al. 1998).

The true effect of quitting on weight gain for a wide range of populations will remain uncertain until more data are available to analyze this issue. Future randomized trials of smoking cessation should consider analyzing their results using the approach described here. Furthermore, this approach is likely to be useful on a much broader level. In any situation in which one would like to know the effect of health-related behavior or condition A on health condition B, one can apply the method, under two conditions: (1) there is an effective intervention for reducing A; (2) the intervention does not directly affect B. Even if the intervention directly affects B, one may be able to sign the bias with confidence. One example of where this approach would be useful is studying the effects of various physical health conditions on mental health conditions such as depression.

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