

Validity of Self-reported Smoking Status among Participants in a Lung Cancer Screening Trial

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Abstract

Lung cancer remains a devastating disease associated with substantial morbidity and mortality. Recent research has suggested that lung cancer screening with spiral computed tomography scans might reduce lung cancer mortality. Studies of lung cancer screening have also suggested that significant numbers of participants quit smoking after screening. However, most have relied solely on self-reported smoking behavior, which may be less accurate among participants in lung cancer screening. To assess the validity of self-reported smoking status among participants in a lung cancer screening trial, this study compared self-reported smoking status against urinary cotinine levels. The sample included 55 consecutive participants enrolled in a randomized clinical trial comparing annual spiral computed tomography and chest X-ray for lung cancer screening. Participants were a mean of 59 years of age and predom-

inantly Caucasian (96%) and male (55%). Self-reported smoking status was assessed before and after participants learned of the purpose of the biochemical verification study. Using urinary cotinine as the "gold standard," the sensitivity and specificity of self-reported smoking status were 91% and 95%, respectively ($\kappa = 0.85$, $P < 0.001$, 95% confidence interval = 0.71-0.99). Total misclassification rate was 7%. However, three of the four misclassified participants reported concurrent use of nicotine replacement strategies. Eliminating these cases from the analysis revealed sensitivity of 100% and specificity of 95% ($\kappa = 0.96$, $P < 0.001$, 95% confidence interval = 0.88-1.00). In conclusion, self-reported smoking status among participants in a lung cancer screening trial was highly consistent with urinary cotinine test results. (Cancer Epidemiol Biomarkers Prev 2006;15(10):1825-8)

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Lung cancer is a devastating illness associated with substantial morbidity and mortality. In 2006, ~174,470 Americans will be diagnosed with lung cancer, and another 162,460 will die from the disease (1). Improved survival with early diagnosis has prompted exploration of lung cancer screening technologies (2-5). In addition to the medical implications of early detection, participation in screening programs may be associated with decreased smoking rates (6-9), although some have suggested that negative screening results may actually lead to continuation of or return to smoking (6).

Most studies exploring changes in smoking status associated with screening have relied solely on participant self-report of smoking status. The veracity of self-reports is often questionable in situations involving social pressure or medical disapproval (10-13). In these high-demand situations, studies have consistently suggested that smoking behavior is underreported (12-18). Although inaccurate self-reported smoking status in the general population occurs relatively infrequently (15, 19), the lung cancer screening context may constitute a high-demand

situation, a condition under which biochemical verification is recommended (16). Thus, the veracity of self-report among participants in screening programs should be explored to determine accurately any effects of participation in lung cancer screening on smoking behavior. This question is especially important given the expanding opportunities for lung cancer screening and the ongoing National Lung Screening Trial.

Only one study exploring the effects on smoking behavior of participation in lung cancer screening has employed biochemical verification of smoking status (9) using testing of carbon monoxide levels. Although findings suggested that self-reported smoking status among participants in lung cancer screening was valid, carbon monoxide testing is not recommended in some contexts due to limited sensitivity and specificity, as well as inability to detect use of smokeless tobacco products (16).

More specific and sensitive measures of tobacco use involve testing for cotinine, a metabolite of nicotine that can be measured in plasma, saliva, or urine (16). Cotinine has a half-life of ~20 hours, allowing detection in smokers for up to a week from the last smoking episode (20). Studies comparing nonsmokers and smokers have consistently reported that cotinine in the urine, saliva, or plasma can distinguish active smokers from nonsmokers (13, 14, 20-24). In addition, cotinine has been shown to be more sensitive and specific than carbon monoxide monitoring for measuring smoking status (10, 16). One inexpensive, reliable, and valid measurement tool for cotinine is the urinary cotinine test strip. Test strips have been shown to compare favorably to gas chromatography/mass spectrometry testing for cotinine (18, 25), with sensitivity and specificity of urinary cotinine test strips ranging from 90% to 97% in identifying smokers when used with a 100 ng/mL threshold.

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Research Question

The accuracy of self-reported smoking behavior among participants in lung cancer screening has not been thoroughly explored. This study compared self-report and biochemical verification using urinary cotinine levels measured with the NicAlert strip (Nymox, Maywood, NJ). The research question addressed whether self-reported smoking status among a sample of participants in a randomized clinical trial of lung cancer screening would be concordant with biochemical measurement of smoking status.

Materials and Methods

Procedure

Parent Study: Jewish Hospital Lung Cancer Screening and Early Detection Study. The current report describes a substudy of the Jewish Hospital Lung Cancer Screening and Early Detection Study (JH-LCSS; 26), a randomized prospective trial of lung cancer screening comparing annual chest X-ray to annual spiral computed tomography scanning in patients at high-risk of developing lung cancer. The JH-LCSS is unique in its focus on a sample of individuals at very high-risk of lung cancer, as defined by a minimum 30-pack-year smoking history and impaired respiratory function (FEV₁/FVC ratio of <70% or FEV₁ <80% of predicted normal values). Participants in the JH-LCSS were recruited using community and regional advertising efforts, including television, newspaper, radio, and direct mailings. Following a negative or stable baseline chest X-ray, participants were randomly assigned to receive annual chest X-ray or spiral computed tomography for a period of 3 to 5 years.

Biochemical Validation of Self-reported Smoking. Participants due for annual screening in September 2004 were eligible for this substudy, which was approved by a human studies committee at the University of Louisville. In late August, all 104 eligible participants were informed by mail of the opportunity to participate in a substudy. The purpose of the substudy was not disclosed in the letter. A research assistant met 55 of the 58 participants who attended their scheduled screening appointments in September; three participants attended appointments but were missed by the research assistant, and the remaining 46 potential participants did not attend their screening appointments. Each of the 55 participants provided informed consent, completed a substudy questionnaire, and provided a urine sample. Gift certificates valued at US\$20 were provided to substudy participants.

Measures. Data from two questionnaires were used in these analyses. Within the 30 days preceding the substudy, participants had completed the parent study questionnaire (Annual Survey of Smoking Behavior or ASSB), given annually by mail in the month before screening. On the day of screening, participants completed the substudy questionnaire (Substudy Smoking Behavior Questionnaire or SSSBQ). The use of two questionnaires allowed the important comparison of self-reported smoking status before and after participants were informed of the biochemical validation component of the substudy.

ASSB. A single item from the parent study annual questionnaire was used: self-reported smoking status. Participants selected their current smoking status from three options: current smoker, quit <6 months ago, or quit >6 months ago. This item was used to compare self-reported smoking status before and after being informed of the purpose of the substudy.

SSSBQ. Each participant completed a questionnaire regarding smoking and smoking-related behaviors before biological sample collection. The principal item measuring current self-

reported smoking status was identical to the item used in the ASSB, described above. Additional items on the SSSBQ included (a) readiness to quit; (b) smoking point prevalence (24 hours, 7 days, and 30 days); (c) number of cigarettes smoked per day; (d) use of other forms of tobacco; (e) environmental smoke exposure; (f) use of nicotine replacement therapy (NRT); and (g) employment-related tobacco exposure (i.e., handling tobacco).

Biochemical Validation. To assess the validity of self-reported smoking, urine samples were collected from participants and immediately analyzed using the NicAlert strip (Nymox) for urinary cotinine levels. The NicAlert testing system provides a semiquantitative measure of cotinine in urine for the purpose of determining if an individual has been exposed to tobacco products, such as cigarettes, pipes, or chewing tobacco within the past 48 hours. NicAlert test strip zones range from zone 0 (0-10 ng/mL, nonsmoker) through zone 6 (>10,000 ng/mL, a very heavy smoker). The cut point concentration for the NicAlert test indicating a positive result is 100 ng/mL (zones 3-6). From each participant, ~25 mL of a midstream sample of urine were collected. Urinary cotinine level was recorded by dipping the NicAlert strip for 20 seconds in the urine sample to a depth of 0.5 inch while holding the strip with gloves. Results were read after allowing the strip to develop by laying the strip on a nonabsorbent surface for 10 to 15 minutes. The lowest numbered zone displaying a red color was documented as the NicAlert test result. Consistent with the 100 ng/mL cut point, participants with outcomes in zone 2 (30-100 ng/mL) or below were considered negative and classified as nonsmokers.

Data Analysis. As recommended in reviews of this literature (12, 15), two contingency tables were formed: (a) comparison of self-reported smoking status measured with the ASSB versus the SSSBQ and (b) comparison of self-reported smoking status with classifications obtained with NicAlert test results. Overall agreement between ASSB and SSSBQ self-reported smoking status was assessed using kappa statistics, which provide a measure of concordance corrected for chance. (Kappa statistics near 1.0 suggest very high levels of agreement.) Sensitivity and specificity of self-reported smoking status were calculated using classification by cotinine levels as the "gold standard." Overall classification rates were also assessed. Data were reviewed for alternative sources of nicotine exposure in cases yielding false-positive and false-negative results.

Results

Sample Demographic Characteristics. Participants' mean age was 59 years (SD = 8.4, range = 43-73). The majority of participants were Caucasian (95%, *n* = 52), male (55%, *n* = 30), and in the spiral computed tomography arm of the JH-LCSS (67%, *n* = 37). Most participants (73%, *n* = 40) were in the third year of screening, with the remainder split evenly between the second and fourth years.

The 55 participants in the substudy did not differ from the 49 eligible but unenrolled parent study participants on any measured characteristics (i.e., age, sex, race, study arm, smoking status, pack-years, or length of participation in parent study). Compared with the full sample of parent study participants, the 55 substudy participants were highly similar in all characteristics except study arm (*P* < 0.05). This finding is related to higher screening adherence rates within the computed tomography group. These comparisons suggest that the subsample used for this study was representative of the larger sample of high-risk screening participants.

Self-reported Smoking Behavior: SSSBQ. See Table 1 for a thorough summary of self-reported smoking behaviors from the SSSBQ. Three participants (6%) reported having quit smoking within the prior 6 months, whereas 36% (*n* = 20)

Table 1. SSSBQ: self-reported smoking behavior

Smoking behavior	Smoking status		Total (N = 55)
	Current (n = 32)	Former (n = 23)	
Intentions to quit using tobacco			
Within 30 d	9	—	9
Within 6 mo	15	—	15
None	8	—	8
Use of tobacco other than cigarettes			
Cigars	3	—	3
Other	1	—	1
Use of NRT			
Gum	1	1	2
Patch	1	0	1
Lozenge	0	2	2
Other	1	0	1
Second-hand smoke exposure			
Yes	21	7	28
No	11	16	27

NOTE: Second-hand smoke exposure refers to self-reported exposure to second-hand smoke within the prior 24-hour period.

reported having quit >6 months ago. Current smokers reported smoking between 1 and 50 cigarettes per day, with a median of 16.

Self-reported Smoking Status: SSSBQ versus ASSB. Smoking status reports on the ASSB (completed before substudy participation) and the SSSBQ (completed after being informed of the purpose of the substudy) were perfectly consistent. No discrepancies were noted between the self-report items on the two measures. Because results were identical, only data from the SSSBQ were used for the remainder of analyses.

Smoking Status: Urinary Cotinine versus SSSBQ Self-report. See Table 2 for the initial classification results comparing self-report and urinary cotinine measures of smoking status. The sensitivity and specificity of self-reported smoking status were 91% and 95%, respectively ($\kappa = 0.85$, $P < 0.001$, 95% confidence interval = 0.71-0.99). The total misclassification rate was 7%: three participants who reported negative smoking status were classified as smokers by their urinary cotinine levels, and one participant who reported positive smoking status was classified as a nonsmoker by the urinary cotinine test. Further exploration of the data revealed that the three participants with positive test results but negative self-reports all reported concurrent use of NRT. Eliminating these cases from the analysis resulted in self-report sensitivity of 100% and specificity of 95% ($\kappa = 0.96$, $P < 0.001$, 95% confidence interval = 0.88-1.00). These results are depicted in Table 3. Review of questionnaire responses revealed that the remaining misclassified case self-reported very infrequent tobacco use, but still self-identified as a current smoker; this participant's urinary cotinine level (zone 1 = 11-29 ng/mL) was below the cut point and resulted in classification as a nonsmoker via the biochemical measure.

Discussion

In this study of participants in a randomized controlled trial of lung cancer screening, self-reported smoking status was compared with biochemical verification using urinary cotinine levels measured with the NicAlert test strip (Nymox). Results showed strong concordance between self-reported smoking status and the urinary cotinine measure.

Previous studies have shown that discrepancies between self-reported smoking status and biochemical verification are

minimal among the general population (15, 19). However, increased demand characteristics are associated with under-reporting of smoking in certain populations and contexts, leading to recommendations of biochemical validation in studies of smoking cessation among such populations (16). Participants in lung cancer screening are similar to these "special groups" in that they have histories of smoking, are likely to have other smoking-related illnesses, and are in contact with medical professionals for early detection of disease directly related to smoking history. Therefore, the lung cancer screening context may constitute a high-demand situation in which the veracity of self-reported smoking status may be in question. No previous studies exploring associations between lung cancer screening participation and smoking behavior have used the highly sensitive and specific method of cotinine testing for biochemical validation.

Results of the current study indicated that self-reported smoking behavior among participants in a randomized trial of lung cancer screening exhibited a high level of agreement with smoking status ascertained by test strips measuring urinary cotinine levels. The sensitivity of self-reported smoking status measured against biochemical verification ranged from 91% to 100%. Specificity ranged from 95% to 100%.

An important issue arose regarding assessment for use of NRT when using cotinine screening to validate smoking status. As cautioned in several reviews of the utility of cotinine screening (15, 16), use of NRT in a nonsmoking individual can raise levels of cotinine beyond the threshold for categorization as a smoker. In this study, three cases were initially misclassified as smokers due to increased cotinine levels secondary to NRT. Although carbon monoxide monitoring in general is a less sensitive and specific measure of smoking (10, 16), it does have an advantage in that use of NRT does not trigger erroneous positive test results. Consideration of NRT use in this investigation allowed a reduction of the original overall misclassification rate from 7% to 2%. This example highlights the need for attention to NRT use when using cotinine testing methods to validate self-reported smoking status biochemically (16).

Access to participants' previous responses to questionnaires in the parent study allowed comparison of self-reported smoking status on two measures: one obtained before participation in the substudy and one obtained after participants were informed of the biochemical verification component of the substudy. The two separate self-reports of smoking behavior (ASSB and SSSBQ, completed before and during substudy participation, respectively) were perfectly consistent, providing further support for the veracity and reliability of self-reported smoking status in this population.

These findings suggest that extensive use of biochemical verification of smoking status may not be necessary in this population. Validity of self-reported smoking status was supported with a high-risk sample who may have been motivated to underreport smoking. This result is consistent with findings of high concordance rates in population-based

Table 2. Initial classification table: SSSBQ self-reported smoking status and urinary cotinine test results

SSSBQ self-reported smoking status	Urinary cotinine test result		Total (N = 55)
	Positive	Negative	
Positive	31	1	32
Negative	3	20	23
Total	34	21	

NOTE: Using urinary cotinine as the gold standard, self-reported smoking status had sensitivity of 91% and specificity of 95% ($\kappa = 0.85$, $P < 0.001$, 95% confidence interval = 0.71-0.99). Assuming smoking prevalence in the lung cancer screening population was represented in this sample, the positive predictive value of self-report was 97%, and the negative predictive value was 87%.

Table 3. Revised classification table: excluding three cases due to NRT

SSSBQ self-reported smoking status	Urinary cotinine test result		Total (N = 52)
	Positive	Negative	
Positive	31	1	32
Negative	0	20	20
Total	31	21	

NOTE: Using urinary cotinine as the gold standard, self-reported smoking status had sensitivity of 100% and specificity of 95% ($\kappa = 0.96$, $P < 0.001$, 95% confidence interval = 0.88-1.00). Assuming smoking prevalence in the lung cancer screening population was represented in this sample, the positive predictive value of self-report was 97%, and the negative predictive value was 100%.

studies (15, 19) and in a prior lung cancer screening study using a different biochemical measurement approach (9). Lung cancer screening may not constitute a high-demand situation, even for participants at high-risk for lung cancer and other smoking-related illnesses. Although increased cessation rates have been reported among lung cancer screening participants (6-9), the lack of planned cessation intervention components in most screening programs may diminish any demand characteristics typically associated with medical interventions for tobacco-related conditions (16).

Limitations. The study had several limitations, which should be considered when interpreting results. First, the sample was relatively small, consisting of 55 of the 813 participants from the parent study of lung cancer screening. In addition, a convenience sample of consecutive participants was used, rather than a random sample of participants from the parent study. This substudy was initially planned for a later phase of the JH-LCSS (26). However, early closure of the screening component of the parent study limited opportunities for participant accrual to those scheduled for annual screening in the final month. The study was conducted in Kentucky, which has the highest prevalence of adult smoking in the United States (27). It is possible that lung cancer screening participants in Kentucky are less likely to misrepresent smoking status than screening participants in other regions. The high prevalence of smoking in the state may reduce the social and cultural pressure typically associated with high-demand situations. Investigations in additional geographic regions may elucidate whether this lack of misrepresentation is similar in other areas. Finally, participation in the JH-LCSS parent study may have increased the likelihood of accurate self-report among study participants, who were followed for several years and completed multiple annual self-report questionnaires addressing smoking behavior. Future studies could focus on newly recruited participants entering screening trials to provide additional information about the validity of self-reported smoking status among lung cancer screening participants.

Conclusions. In conclusion, self-reported smoking status and biochemical validation measured via urinary cotinine levels were highly concordant among a high-risk sample of participants in a lung cancer screening trial. Self-report data on smoking status may be used with reasonable confidence in further investigations of the psychological and behavioral correlates of participation in lung cancer screening. Given the validity of self-reported smoking status, future analyses will explore possible changes in smoking behavior associated with participation in a randomized clinical trial of lung cancer screening.

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