Published in final edited form as:
Asian Pac J Cancer Prev. 2011 ; 12(10): 2551–2554.

Using Salivary Cotinine to Validate Self-Reports of Tobacco Use by Indian Youth Living in Low-Income Neighborhoods

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Abstract

Background—Self-reported tobacco use among young people can underestimate the actual prevalence of tobacco use. Biochemical validation of self-reports is particularly recommended for intervention studies where cessation outcomes are to be measured. Literature on biochemical validation of self-reports of multiple forms of tobacco use in India is sparse, particularly among young people.

Methods—The study was conducted during the baseline household survey of a community based tobacco prevention and cessation intervention trial for youth (10–19 years old) residing in slum communities in Delhi, India in 2009. Salivary cotinine measurement on 1224 samples showed that youth were under-reporting use of chewing and smoking tobacco.

Results—Self-reports had a low sensitivity (36.3%) and a positive predictive value of 72.6%. No statistically significant difference in under-reporting was found between youth in the control and intervention conditions of the trial, which will be taken into consideration in assessing intervention outcomes at a later time point.

Conclusion—Biochemical validation of self-reported tobacco use should be considered during prevention and cessation studies among youth living in low-income settings in developing countries like India.

Impact—The future results of biochemical validation from Project ACTIVITY (Advancing Cessation of Tobacco in Vulnerable Indian Tobacco Consuming Youth) will be useful to design validation studies in resource-poor settings.

Keywords

Tobacco; Youth; Saliva; Cotinine; India

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Conflict of Interest Policy

All contributing authors declare that none of them had any competing interest that would influence the results of this study.

Introduction

Most estimates of youth tobacco use are based on self-reports, either in schools or households (Reddy et al., 2006; Warren et al., 2006). Although generally considered reliable, self-reported estimates of drug use can be less sensitive and reliable among adolescents as compared to adults (Caraballo et al., 2004). This is particularly true for socially undesirable behaviors or when there are laws banning certain behaviors (Gorber et al., 2009). Therefore, several studies, especially in developed countries like the United States, corroborate self-reported tobacco use using actual biochemical validation or a bogus pipeline procedure (Adams et al., 2008). Biochemical validation is particularly recommended in intervention studies, where cessation outcomes need to be assessed and for special population groups like children and pregnant women (Benowitz et al., 2002).

Of the available markers for validation of tobacco use, a cotinine measurement is most commonly used in population studies. Cotinine is a metabolite of nicotine with a long half-life (15–19 hours) that can be measured in body fluids such as saliva, urine and plasma. Measurement of salivary cotinine is commonly used in population studies, given the ease of sample collection and minimal discomfort to study subjects (Iqbal et al., 2007). Biochemically assessed cotinine levels can be an indicator of active smoking, smokeless tobacco use, exposure to secondhand smoke or use of pharmaceutical nicotine (Jarvis et al., 2008; Post et al., 2005).

In developing countries like India, young people are particularly vulnerable to initiation and addiction to tobacco products (Reddy et al., 2006; Reddy and Gupta, 2004; Sinha etal., 2008; Stigler et al.,2007). Studies have shown that between 4 to 75 % of 13–15 year old students in India report lifetime use of some tobacco product (Reddy and Gupta, 2004). It is also known that persons from lower socioeconomic strata are more likely use tobacco (Mathur et al., 2008; Mishra et al., 2005; Subramanian, 2004). With this background, an intervention trial, Project ACTIVITY (Advancing Cessation of Tobacco in Vulnerable Indian Tobacco Consuming Youth) funded by the National Institutes for Health (NIH), was started among disadvantaged youth living in slums in Delhi, India in 2009 (Arora et al., 2010). The objective of this trial is to test the efficacy of a comprehensive community-based intervention for prevention and cessation of tobacco use among adolescents and young adults (10–19 years old) (Arora et al.,2010). A baseline household survey, including salivary cotinine testing on a sub-sample, was conducted to measure the prevalence of tobacco use in intervention and control communities, before the start of the intervention. The aims of the salivary cotinine testing were (i) to compare estimates of tobacco use prevalence based on self-reports vs. biochemical testing, and (ii) to assess whether misreporting of tobacco use by self-reports, if any, differed by trial condition. Given the study location and sample enrolled in this study, this paper extends the current body of research on biochemical validation of self-reported tobacco use to developing-country settings where tobacco use is on the rise, particularly among youth.

Methods

Ethical clearances were obtained for Project ACTIVITY from the Independent Ethics Committee in India and the Institutional Review Board at the University of Texas Health Science Center at Houston.

Participants

A total of 4191 households with 8702 youth between 10 to 19 years were randomly selected for baseline household surveys in seven control and seven intervention slum communities in Delhi. Two communities were randomly selected from the intervention and control

conditions for biochemical validation. Given budgetary constraints, saliva was only collected from a convenience sample of 1250 youth from four communities (2 intervention and 2 control) for cotinine measurement.

Data collection

Informed consent for interview and salivary sample collection was obtained from the youth and also parents (for 10–17 year old youth). Once the study team reached a sample size of 1250 across all four communities, interviewers stopped requesting for further salivary samples. Confidential subject identification numbers were used on both the interviews and the saliva sample tubes. Self-reported use of smoking tobacco (cigarettes and bidis) and chewing tobacco (Gutkha, Kahini, Zarda etc.) was assessed in the interviews. Current use was defined as use in the past month by asking, “During the past 30 days, did you smoke cigarettes/bidis/chew tobacco?” A dichotomous tobacco use variable was created for each product and assigned a ‘0’ for those who reported never using these products and ‘1’ for those who did. A composite variable for ‘any tobacco use’ was created with a ‘0’ for those who did not report using any tobacco products and ‘1’ for those who used one or more.

Saliva samples were collected using the kits provided by Salimetrics (Salimetrics, 2009) which contained a piece of chewable cotton stick in a sterile tube. Stimulated saliva samples were collected by asking the subject to chew the cotton stick for two minutes and then placing the cotton back in a sterile tube. Samples were transported to the laboratory within ten hours of collection. Saliva sample collection took approximately 2–3 minutes per study subject and was done at the end of the interview, which lasted about 30 minutes.

Data analysis

Salivary cotinine was biochemically analyzed using Enzyme-Linked Immuno Sorbent Assay (ELISA) kit from Salimetrics, USA (Dhar, 2004; Salimetrics, 2006)). All statistical analyses were conducted using SAS (version 9.1). Cotinine value of 15 ng/ml was used as the cut-point, as recommended by the Society for Nictoine and Tobacco Research (Benowitz et al., 2002). Sensitivity analyses were also conducted using lower (10, 12 ng/ml) and higher (20 ng/ml) cut points recommended in other studies (Jarvis et al., 2008). Kappa statistics were computed to compare overlap between the self-reported and biochemically confirmed use of any tobacco product. Cochran-Mantel-Haenszel test procedure with Breslow-Day test for homogeneity of odds ratio was used to test whether discrepancies between self-reported and biochemically confirmed tobacco use differed by trial condition. A chi-square p-value <0.05 was set as the statistical significance level.

Results

Of the self-reported data and biochemical samples that were collected from 1250 youth, 26 biochemical samples could not be included in this study due to insufficient amount of saliva for testing. The 1224 youth in the final sample for biochemical validation included 611 control subjects (49.9%), 626 boys (50.12%), and 1004 school-going youth (80.38%). 652 (52.20%) of this sample were 10–14 years old. These demographic data were compared by trial condition, and no statistically significant differences were found.

Prevalence of tobacco use

Table 1 presents the prevalence of tobacco use. Self-reported current use of smoking (bidis or cigarettes) was 2.25% and that of chewing tobacco (Gutkha, Khaini, Zarda etc.) was 3.21%. Self-reported current use of any tobacco product was 4.11%. Mean value of salivary cotinine was 76.24 ng/ml for self-reported smokers; 121.74 ng/ml for self-reported tobacco chewers and 101.21 ng/ml for subjects who reported either smoking or chewing tobacco.

Among youth who reported no tobacco use in the past month at the interviews, mean saliva cotinine was 8.6 ng/ml.

When results of the biochemical tests were reviewed, 8.33% (n=102) of the youth were identified as tobacco users at 15 ng/ml as the cut-point. Changing the cut point to 20, 12 and 10 ng/ml did not make much difference in prevalence rates (7.92%, 8.58% and 8.91%, respectively).

Self-report vs. biochemically confirmed tobacco use

At the cut-point of 15 ng/ml, agreement (the kappa statistic) between the self-reported and biochemically confirmed use of any tobacco product was 0.45 (95% C.I. 0.35 – 0.55). Changing the cut-points to 10, 12 or 20 ng/ml did not affect this finding.

Table 2(A) compares self-reported tobacco use to biochemical testing. Using the salivary cotinine test as gold standard, sensitivity and specificity of self-reported use of any tobacco product was 36.3% and 98.8% respectively. Assuming that the prevalence of tobacco use in this sample was representative of that in the population from which the subjects were drawn, the interviewer administered questionnaire had a positive predictive value of 72.6% and negative predictive value of 94.5% for self-reported use of any tobacco product. Sensitivity and specificity of self-reports was similar between the younger subjects (10–14 years old) as compared to the older subjects (15–19 years old).

Self-report vs. biochemically confirmed tobacco use, by trial condition

As shown in Table 2(B), no statistically significant differences ($p>0.05$) in the relationship between self-reported and biochemically confirmed prevalence were found between subjects in the two study conditions, at salivary cotinine level of 15 ng/ml. That is, we found no statistical evidence for differential misreporting of tobacco use by study condition at the baseline survey for Project ACTIVITY.

Discussion

Consistent with previous studies, biochemical validation of self-reported tobacco use using salivary cotinine found that youth were under-reporting tobacco use, overall (Caraballo et al., 2004; Behera et al., 2003). The difference of −4.2% is close to the mean difference between self-reported and salivary cotinine-based prevalence estimates found by a 2009 systematic review −4.8 (Gorber et al.,2009) . Over 60% of youth who were confirmed to be tobacco users based on salivary cotinine levels self-reported themselves as non-users, although they gave consent at the beginning of the interviews for salivary sample collection.

The sensitivity of self-reported tobacco use in this study sample was lower than some previous studies (Caraballo et al., 2004; Kandel et al., 2006). Sensitivity of self-reports of current smoking in youth maybe lower when the overall prevalence and frequency of smoking is low, as in this study sample (Jarvis et al.,2008). Previous studies have suggested that youth are more likely to underreport socially stigmatized behaviors like tobacco use in household settings due to reduced anonymity with presence of parents, family and neighbors (Caraballo et al., 2004; Kann et al., 2002). In our study, although field workers were instructed to find a secluded spot away from the homes of the youth to conduct the interviews, this was often challenging, given the overcrowded setting in the slums. In addition to privacy concerns, youth may also underreport tobacco use behaviors since sale of tobacco to minors (under 18 years old) is now illegal in India (Tobacco Control Act of India, 2003). Some studies have reported higher sensitivity of self-reported tobacco use for older adolescents, but our results showed no significant differences by age group (Malcon et al.,

2008). As was also reported by the SRNT, sensitivity and specificity in this study did not vary by much over a range of cut-points (10–20 ng/ml) (Gorber et al., 2009).

Comparison by trial condition showed that there was no differential misreporting of self-reported tobacco use at baseline between study conditions. This will need to be monitored at subsequent surveys after interventions are implemented, and if misreporting differs between study conditions, appropriate statistical correction will be applied in evaluation of Project ACTIVITY (Benowitz et al.,2002).

A few limitations should be taken into consideration here. The communities for participation in the trial were selected using certain eligibility criteria with non-random sampling methods. However, assignment to intervention or control condition, as well as selection of households with youth for interviewing was randomized (Arora et al., 2010). Tobacco smoking within the seven days preceding sample collection is generally considered to be the cut-point at which cotinine can be detected (Benewitz et al, 2002). However, our baseline surveys only used ‘past 30 days use’ as current use (Post et al., 2005; Kandel et al., 2006). Also, no information was available regarding exposure to environmental tobacco smoke and nicotine dependence levels, which would help in interpreting discrepancies in self-reports (Molina et al.,2010).

To our knowledge, this study is among the first from India to use salivary cotinine tests in a community-based household survey and future results of biochemical validation from Project ACTIVITY will be useful to design validation studies in resource-poor settings.

Conclusions

Biochemical validation of self-reported tobacco use among youth should be used at baseline and follow-up in any tobacco cessation intervention trial to effectively monitor and evaluate the potential impact of the interventions, as well as correct for any differential misreporting between control and intervention groups. Although there is no full substitution for self-reported tobacco use in tobacco surveillance studies, examining the validity of self-reported tobacco use would be beneficial to tobacco surveillance, research and interventions among adolescents in developing country settings like India, where tobacco use among youth is on the rise.

Acknowledgments

We are thankful to our partner NGOs: Prayas Juvenile Aid Centre Society, MANCH, All India Asaya Mahila Sahyog Samiti, Ankur who coordinated and supported us in implementation of the project. We would also like to thank our field staff and the community leaders who made this project successful. This research would not have been possible without the participation of children, young adults and their parents in selected communities of Delhi.

Financial Support

The research was funded by a grant from Fogarty International Centre, National Institutes of Health, USA (Award Number RO1 TW007933).

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Table 1

Prevalence of Current Use of Tobacco Products According to Different Measurement Tools (n=1224)

Tools	Classification		Prevalence	Saliva cotinine ng/ml
		N	% (95% CI)	Mean (SD)
Interviewer administered questionnaire	Cigarettes/Bidis	28	2.3 (1.4 – 3.1)	76.2 (81.5)
(Self-reported current use)	Chewing Tobacco	40	3.2 (2.3 – 4.4)	121.7 (85.3)
	Any Tobacco	51	4.1 (3.0 – 5.2)	101.2 (87.0)
	None	1173	95.8 (94.7 – 97.0)	8.6 (33.1)
Salivary Cotinine	> 10 ng/ml	109	8.9 (7.3 – 10.5)	121.1 (78.5)
	> 12 ng/ml	105	8.6 (7.0 – 10.2)	125.3 (76.9)
	> 15 ng/ml	102	8.3 (6.8 – 9.9)	128.6 (75.5)
	> 20 ng/ml	97	7.2 (6.4 – 9.4)	134.3 (73.1)

C.I. Confidence Interval; SD, Standard Deviation.

Table 2(A)

Agreement and discrepancy between self-reported tobacco use and salivary cotinine concentration among 10–19 year old youth (n=1224) for overall sample. Salivary cotinine used as 'gold standard'.

Self-reported tobacco use status[a]	Cotinine level > 15 ng/ml	Cotinine level <=15 ng/ml	
	N	N	Total
	Column % (95% C.I.)	Column % (95% C.I.)	
User	37	14	51
	36.3 (32.9 – 39.7)	1.2 (0.2 – 2.3)	
Non-user	65	1108	1173
	63.7 (60.3 – 67.1)	98.8 (97.7 – 99.8)	
Total	102	1122	1224

C.I., Confidence Interval.

[a] For any tobacco product, past 30 days.

Sensitivity = 37/102 = 36.3%, specificity = 1108/1122 = 98.8%, positive predictive value = 37/51 = 72.6%, negative predictive value = 1108/1173 = 94.5%.

Table 2B

Agreement and discrepancy between self-reported tobacco use and salivary cotinine concentration among 10–19 year old youth (n=1224) by trial condition[b] . Salivary cotinine used as ‘gold standard’.

Self-reported tobacco use status	Salivary cotinine					
	Control (n=611)			Intervention (n=613)		
	>15ng/ml	<=15ng/ml	Total	>15ng/ml	<=15ng/ml	Total
User	25	7	32	12	7	19
Non-user	34	545	579	31	563	594
Total	59	552	611	43	570	613

[b] Chi^2 p-value = 0.37(Used Breslow-Day test)