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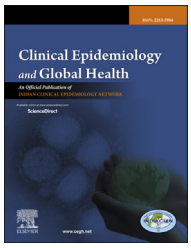

Original Article

Confirmation of self-reported non-smoking status by salivary cotinine among diabetes patients in Kerala, India

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ABSTRACT

Problem considered: There are no studies of tobacco cessation reported from low and middle income countries that have tested cotinine against self report in a patient population. We confirmed the accuracy of self report of smoking cessation by matching self reports against salivary cotinine test in diabetes patients.

Methods: The study was part of a randomized controlled trial among 224 diabetes patients in Kerala. Salivary cotinine level was measured among 35 diabetes patients who claimed to have not smoked even a single cigarette/bidi in the last 30 days before the test. Biochemical analysis of salivary cotinine was done using the Enzyme-Linked Immunosorbent Assay kit from Salimetrics. Cotinine value of >15 ng/ml was used as the cut-off point.

Results: Among the 35 patients, 26 (74%) were found to have a saliva cotinine level ≤15 ng/ml confirming self reports of non smoking status. Among the remaining nine patients, four reported being routinely exposed to secondhand smoke in their household or work place prior to cotinine testing. Interviews revealed that 12% of the variance between self report and the cotinine test results was attributable to routine exposure to second hand smoke.

Conclusion: Self report of non-smoking by diabetes patients in India was fairly reliable when validated against a cotinine test. Larger clinical trials are warranted to further evaluate the validity of self reported non-smoking status in different patient populations having different education levels.

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1. Introduction

Self-reports are widely used in different research settings as a measure of smoking status. The validity of self-reports has long been debated[1] as there is concern that smokers may misconstrue or underestimate the amount they smoke.[2,3] For this reason, validation of self reports with biochemical measurements is recommended when feasible. Cotinine is considered the best indicator of tobacco smoke exposure and has a high rate of sensitivity and specificity when compared to more intrusive biochemical tests.[3,4] Extensive research has been carried out to measure cotinine using a variety of techniques assessing cotinine levels in both saliva and urine.[5,6] Sensitivity values were consistently higher when cotinine was measured in saliva instead of urine or blood.[7]

Self reported smoking status using saliva cotinine has been validated several times in western countries,[8] but its use in low and middle income (LMIC) countries is limited. In India, only one validation study could be identified and that was among adolescents in an urban area.[9] No study that tested cotinine against self report in a patient population could be identified in LMICs. Given the widespread use of self report data in smoking studies of patients when the focus of cessation programs, it was deemed important to assess the accuracy of self report. In this paper, we assess the accuracy of self report in a high priority patient population targeted for cessation: diabetes patients. Patients with diabetes who smoke are far more likely to have a wide range of complications than those who do not smoke. They are eleven times more likely to have a heart attack or stroke than patients who don't have diabetes and don't smoke.[10]

During 2008–2011 Quit Tobacco International (QTI) (http://quittobaccointernational.org/) carried out a smoking cessation intervention in Southern Kerala, India in which 224 diabetes patients received diabetes specific cessation messages drawing attention to the link between diabetes complications and smoking. The study had two arms with messages either being delivered by doctors alone or doctors followed by a counseling session. The study demonstrated that a brief intervention by doctors is likely to result in a quit rate of about 10–13% and with additional support of counseling about 52% quit rate at six months based on self reports.[11] In the present study, we sought to confirm the accuracy of self report of smoking cessation by matching self reports against salivary cotinine test.

2. Methods

All the 224 diabetic patients in the original randomized controlled trail were contacted to gather their current smoking status. We were able to contact 87.5% ($n = 196$) of them. Among this group there were 76 nonsmokers. We contacted 60 of them by telephone requesting that they take part in a brief tobacco use survey followed by a salivary test to ascertain levels of nicotine residue in their body (a cotinine test). After fixing a particular date and time with each of the patients, we visited their households and collected the saliva sample. Excluding patients who refused to consent ($N = 8$), who had moved out of the study area ($n = 5$), or could not be available at the time of our visit ($N = 8$), we collected saliva samples from 39 patients who claimed to have not smoked even a single cigarette/bidi in the last 30 days for self report confirmation. All these 39 patients signed a written consent form for saliva collection. Four patients self-reported some form of smokeless tobacco use in the last week during interviews, although not smoking, and were excluded from the cotinine validation study. Eighty percent of the sample had high school education or above, which was commensurate with the high education level of the state of Kerala. On the day before the interview we contacted each subject once again and reminded them they would receive a salvia test to measure nicotine residue levels (cotinine test). Patients were instructed to take their main meal 1 h before the interview and saliva collection. They were also told to avoid alcohol 12 h before the home visit. During home visits we collected details about the patients' last tobacco consumption event, and exposure to secondhand smoke using a short structured interview schedule. This was followed by saliva collection.

Saliva was collected at the end of an interview on tobacco use history by a trained social worker. The following procedure was followed when collecting saliva samples. Prior to saliva collection, we instructed all the patients to rinse their mouth thoroughly with water and ensure that the food particles or other contaminants were removed fully from the mouth. Saliva samples were collected using a kit provided by Salimetrics which contains a Salimetrics oral swab (SOS) and sterile tube. During saliva collection we first removed the swab from the package and placed it under front of the patient's tongue for 2 min. After this, we placed the oral swab into the sterile tube marked with an individual code and placed it in storage box. Samples were transported to the laboratory within 4 h of collection wherever possible and put it in dry ice box otherwise. Saliva collection took approximately 3–5 min. After collecting the saliva we refrigerated the sample within 30 min and stored it at −80 °C until analysis.

Biochemical analysis of salivary cotinine was done using the Enzyme-Linked Immunosorbent Assay (ELISA) kit from Salimetrics, State College, PA 16803, USA.[12] The assay uses rabbit antibodies to cotinine and cotinine linked to horseradish peroxidase. The substrate used is tetramethylbenzidine. The ELISA kit used has a sensitivity of 99.85% and specificity of 93.37% (www.salimetrics.com). Saliva samples were evaluated at an independent reference laboratory at the Laboratory Medicine and Molecular Diagnostics division of Rajiv Gandhi Centre for Biotechnology (RGCB), Trivandrum. Cotinine value of >15 ng/ml was used as the cut-off point as recommended by the society for Nicotine and Tobacco Research.[13] All statistical analysis was conducted using SPSS version 17.0.

3. Results

The salivary cotinine of the 35 diabetic patients was assessed. The mean age of the sample was 54 years. Eighty percent of patients had a high school education and above, 60% were employed, 83% were from middle class families, and most were currently married (97%). Cotinine values of all sample patients are presented in Fig. 1. Out of the total sample, 26 (74%) were found to have a saliva cotinine level ≤15 ng/ml in

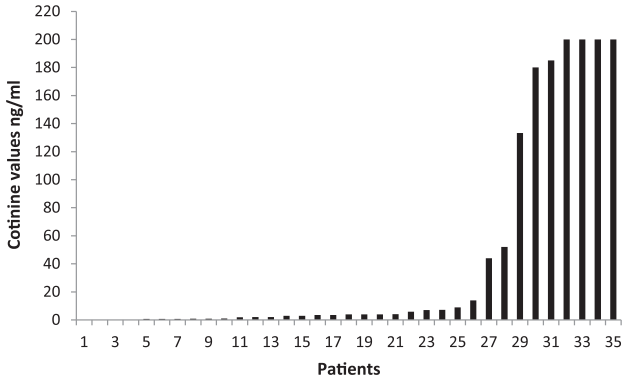

Fig. 1 – Cotinine values of the sample patients in ng/ml.

the cotinine test result, which indicated confirmation of self reported non-smoking status. The socio-demographic characteristics were not associated with the cotinine level. Among the 35 patients 12 were exposed to secondhand smoke. Of these 12, four patients had a saliva cotinine level of >15 ng/ml and the remaining eight patients had cotinine levels ≤15 ng/ml. Nobody reported alcohol consumption 12 h before the saliva collection.

4. Discussion

To our knowledge, this is the first study to examine the use of a saliva cotinine test to confirm self reported smoking status among diabetes patients in India or any LMIC. We found an agreement rate of 74%, which was lower than the 89.2% reported from Western Countries.[1] Interviews revealed, however, that 12% of the variance between self report and positive cotinine test results was attributable to routine exposure to second hand smoke in one's home or workplace. Those who did not participate this study were unlikely to be different from those who participated.

In sum, this study documented that self reports of smoking cessation by diabetes patients in Kerala were fairly comparable with the saliva cotinine test.

Larger studies with patients having different health problems and levels of education are needed to further evaluate the substantiation of self reported smoking cessation with cotinine test.

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Ethical approval

The Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum provided the ethical approval for this study.

Conflicts of interest

All authors have none to declare.

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