

## Effect of incorporating a 10 minute point of care test for salivary nicotine metabolites into a general practice based smoking cessation programme: randomised controlled trial

Kristian D Barnfather, Graham F Cope, Iain L Chapple

### Abstract

**Objective** To investigate the effect of immediate feedback from a point of care test for salivary nicotine metabolites in promoting smoking cessation and reduction in tobacco use.

**Design** Prospective, operator blinded, randomised controlled trial.

**Setting** General dental practice, London.

**Participants** 100 adult smokers.

**Interventions** Participants completed a questionnaire on smoking, undertook a clinical examination, and received counselling in smoking cessation. Saliva samples were analysed at presentation and at eight weeks for salivary nicotine metabolites using a 10 minute semiquantitative point of care test.

**Main outcome measures** Smoking cessation measured by salivary nicotine metabolite values (scale 0-6), patient feedback on the perceived value of the test (visual analogue scale) in quitting, and reduction in tobacco use.

**Results** A higher smoking quit rate was achieved with the point of care test (23% cases *v* 7% controls;  $P < 0.039$ ), and overall tobacco use also decreased (68% cases *v* 28% controls;  $P < 0.001$ ). Baseline values for salivary nicotine metabolites did not differ between the groups (cases, mean 4.1, SD 1.3 and controls, 4.3, 1.4;  $P = 0.51$ ). 87 participants reattended at eight weeks (44 cases, 43 controls). Mean nicotine metabolite values at eight weeks were 2.58 (2.0) for cases and 4.29 (1.8) for controls ( $P < 0.001$ ).

**Conclusion** Incorporation of individualised personal feedback using a point of care test for salivary nicotine metabolites into a general practice based smoking cessation programme increased quit rates by 17% at eight weeks and reduced tobacco use.

### Introduction

The World Health Organization estimates that tobacco kills around 4.9 million people a year, and that this will rise to 10 million by 2030.<sup>1</sup> As dental surgeons are often in contact with the population they are in an ideal position to provide counselling and advice on smoking cessation. A study published in the early 1990s reported that dental practitioners were less

prepared than their medical colleagues to provide advice on smoking cessation,<sup>2</sup> but recent data have shown major improvements in dental practitioners' attitudes to counselling for smoking cessation.<sup>3</sup>

Biofeedback of patient specific information on exposure to tobacco, and in particular nicotine levels, provides personalised evidence of smoke derived toxins and seems to improve patients' willingness to quit.<sup>4</sup> Laboratory based analytical tests to evaluate smoking habit are available<sup>5</sup> but introduce a delay in the delivery of information, particularly to the patient. Immediate access to results through point of care testing provides rapid biofeedback and facilitates the provision of treatment and patient education at the same visit. Monitoring the amount of carbon monoxide in expired air using handheld monitors discriminates between smokers and non-smokers. The short half life of carboxyhaemoglobin (2-4 hours) and its lack of specificity for tobacco, however, reduce its diagnostic accuracy.<sup>5</sup>

We have reported on a 10 minute point of care test for salivary nicotine metabolites, including cotinine.<sup>6</sup> This type of testing can also be used to overcome the physiological complexities of the inhalation, absorption, and distribution of tobacco derived chemicals throughout the body. The test (Surescreen Diagnostics; Derby, £3 per test) effectively condenses such variables and avoids reliance on self report by providing a single value for immediate use.

We assessed the effect of providing smokers with visual and personalised feedback in a primary care setting on their salivary nicotine metabolite values and on quitting, and we assessed their opinions on the utility of a point of care test in helping them to quit smoking.

### Participants and methods

Our study was an operator blinded, randomised controlled trial of two interventions in a sample of 100 sequentially recruited smokers within a general dental

Editorial by  
Coleman

General Practice,  
6 Harcourt House,  
London W1G 0PN  
Kristian D  
Barnfather  
*general dental surgeon*

Wolfson Applied  
Technology  
Laboratory, Queen  
Elizabeth Medical  
Centre, Edgbaston,  
Birmingham  
B15 2TH

Graham F Cope  
*research fellow*

Periodontal  
Research Group,  
University of  
Birmingham,  
St Chad's  
Queensway,  
Birmingham  
B4 6NN

Iain L Chapple  
*professor of  
periodontology*

Correspondence to:  
I L Chapple  
I.L.C.Chapple@  
bham.ac.uk

BMJ 2005;331:999-1001



Table showing percentage changes in smoking is on bmj.com



This is the abridged version of an article that was posted on  
bmj.com on 6 October 2005: [http://bmj.com/cgi/doi/10.1136/  
bmj.38621.463900.7C](http://bmj.com/cgi/doi/10.1136/bmj.38621.463900.7C)

practice. KDB randomly assigned the first 100 volunteers who were current daily cigarette smokers, as reported in a self completed questionnaire, but with no specific desire to quit smoking. Participants were allocated to either the case group (n=50) or the control group (n=50). Allocation was determined by selecting sequential numbers from two hats (one containing the participant's number (1-100) and one for group allocation) and creating a randomisation list.

### Protocol

After randomisation the participants were recalled for their baseline visit (enrolment). The study dentist (KDB) was informed of the participants' study number but remained blind to their booking details and randomisation. The practice manager allocated participants according to the randomisation schedule. The participants were given verbal counselling on smoking cessation, information about the effects of smoking on oral health (including photographs of smoking related disease), and literature packs. They were provided with a plastic container and asked to provide 2 ml of saliva by expectoration.

At this point the dentist was informed of the participants' allocated groups. Before discharge the controls were informed that they would be given their result at the next visit. The cases were shown the test procedure and given an interpretation of their salivary nicotine metabolite result before discharge. Data were entered into coded folders for all participants by a third member of staff, who was blind to the code allocation. The participants were recalled after eight weeks. They were asked if they had used, or were using, nicotine replacement therapy, as this can give a positive result on the test. The operator asked participants to provide a saliva sample for testing. A third member of staff entered the results into the folders and a spreadsheet before breaking the code and analysis.

### Assay and main outcome measures

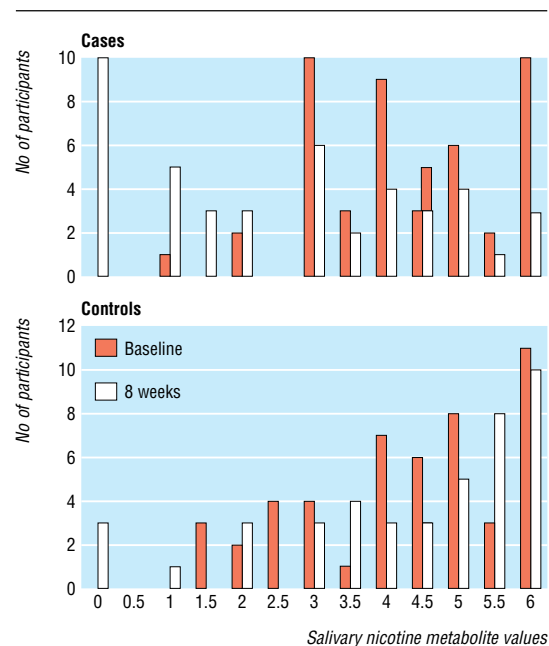
The saliva was analysed using a previously reported salivary nicotine metabolite assay, which utilises a colorimetric chemical reaction and direct visual comparison of six colours on a chart, indicating varying concentrations (0-2.5 µg/ml), expressed as cotinine equivalent concentration.<sup>6</sup>

To evaluate the perceived value of the test, all cases who reattended at eight weeks completed a questionnaire with the aid of a 100 mm visual analogue scale (0 = no use, 10 = very useful).<sup>7</sup>

The primary outcome measure was smoking cessation as measured by self report and confirmed by a salivary nicotine metabolite value of zero. Secondary outcomes were participants' perceived value of the test in quitting, and reduction of tobacco use as measured by self report and the test.

### Results

Overall, 97 of 100 patients invited to participate in the study (48 cases, 49 controls) attended the baseline visit (see [bmj.com](http://bmj.com)). No participants used nicotine replacement therapy at presentation or throughout the study. We found no clinically significant difference between baseline salivary nicotine metabolite values for the cases (4.1, SD 1.3) and controls (4.3, SD 1.4). Overall, 87 participants reattended at eight weeks.



Salivary nicotine metabolite values at baseline and eight weeks for cases (n=44) and controls (n=43) who attended the recall visit

At eight weeks the mean salivary nicotine metabolite values for the case and control groups were 2.58 (2.0) and 4.29 (1.8) ( $P < 0.001$ ). For cases with a decreased nicotine metabolite value (n=30), 10 (23%) had quit and 20 (45%) had reduced their tobacco use (figure). The mean reduction in nicotine metabolite values for the case group was 2.55 (1.2) between baseline and recall ( $P < 0.001$ ). For cases with increased nicotine metabolite values (n=3, 7%), the mean increase was 0.83 (2.8): 11 cases showed no change in values.

For controls with a decreased nicotine metabolite value (n=12), three (7%) had quit and nine (21%) had decreased their tobacco use (figure). The mean reduction in nicotine metabolite values for controls was 1.21 (SD 1.3). For controls with increased nicotine metabolite values (n=13, 30%), the mean increase was 1.08 (SD 0.86) between baseline and recall: 18 showed no change. Overall, the group showed no significant change in nicotine metabolite values.

A higher quit rate was achieved when the point of care test was used, and overall reductions in smoking as measured by change in values for salivary nicotine metabolites in cases compared with controls were also higher (see table on [bmj.com](http://bmj.com)). All 44 cases completed the questionnaire. In total, 88% thought that the point of care test provided clear, easy to interpret results, and 33% thought that the combination of observing the test, talking to the dentist, and reading the antismoking literature was the most informative and supportive method. No participants thought that sole observation of the test would modify their smoking, and 21% thought that none of the information provided would alter their perception of tobacco use.

The results from the visual analogue scale showed that 9% found the test to be of "no use," whereas 27% found it was a "very useful" aid to counselling in smoking cessation. Overall, most of the participants believed that the point of care test was beneficial. We found a

significant correlation between the extent of change in the salivary nicotine metabolite values and the perceived benefit of using the test.

## Discussion

The use of a point of care test for measuring salivary nicotine metabolites within a primary care setting to provide individualised feedback on exposure to nicotine, improved quit rates by 17% at eight weeks and was well received as an adjunct to counselling for smoking cessation.

Although we present data on rates of abstinence and reduction of tobacco use, complete cessation is the goal for all smokers and was the primary outcome measure in our study.

At eight weeks the point of care test showed that quit rates had improved significantly, with 23% of cases quitting compared with 6% of controls. Furthermore, 45% of the cases had lower salivary nicotine metabolite values at eight weeks compared with only 21% of controls, and only 7% of the cases had higher values compared with 30% of controls. This increase in nicotine intake in the control group is consistent with previous findings using the point of care test.<sup>8</sup> These results compare favourably with other reported outcomes for intensive advice on smoking cessation that include follow-up appointments,<sup>9</sup> whereas the results for the intervention are significantly better than those from non-pharmacological intervention studies.<sup>10 11</sup>

One limitation of our study arises from the eight week recall time. Although this follow-up period is twice that of the Department of Health guidelines for recording cessation rates, it is still likely to overestimate true quit rates compared with longer recall periods. Owing to the short follow-up, we cannot conclude on the efficacy of the strategy long term. Nevertheless, studies in primary care settings have shown quit rates of 7% at 12 months with counselling alone.<sup>11</sup>

One study concluded that smoking as measured by self report was likely to be unreliable and that in the future biochemical validation would yield more reliable data.<sup>12</sup> The use of biochemical verification of smoking to overcome the weakness inherent within self reported data is recommended.<sup>3 13 14</sup> Although cotinine is a more sensitive and specific biomarker than carbon monoxide for tobacco use, patients must realise that nicotine is not the main cause of smoking related disease. Such diseases are due to some of the thousands of constituents of tobacco, and therefore such risks are not incurred by using nicotine replacement therapy.

We found a significant relation between the perceived value of the test and a smoker's ability to reduce tobacco use or to quit. Most participants who witnessed the test at baseline thought that immediate and personalised feedback was beneficial and that it reinforced the counselling, placing them in a more encouraging environment for quitting. This supports the theory that feedback creates the sense of a caring and helping relationship, which increases motivation.<sup>4</sup>

The use of a point of care test to measure salivary nicotine metabolite values is likely to form a useful tool for clinicians involved with the care and management of patients who regularly use tobacco. It is important to realise, however, that as the test can detect nicotine

## What is already known on this topic

Around 4.9 million people die from tobacco related diseases a year

Dental surgeons are well placed to give advice on smoking cessation as they are often in contact with the population

## What this study adds

A point of care test for measuring salivary nicotine metabolites improved smoking quit rates by 17% at eight weeks

Personalised feedback on exposure to tobacco derived toxins can improve motivation to quit smoking

Immediate and personalised biofeedback from the test reinforced counselling and placed potential quitters in a more supportive environment

metabolites, the utility of the test is limited in people who use nicotine replacement therapy.

We thank Julia Carvalho (receptionist), Iwonka Stelmaszczyk (practice nurse), and Denise Aleksoski (practice manager) for their practical assistance during the study.

Contributors: See bmj.com.

Funding: This work was supported by a grant from the Oral and Dental Research Trust, British Society for Dental Research.

Competing interests: GFC was an employee of the founding company (Mermaid Diagnostics) that manufactured the assay device and is currently employed by Surescreen Diagnostics, the current manufacturer. His role in this study was as an adviser in the establishment of protocols for using the device and the scientific background to usage of the device. He was not involved in data analysis or its interpretation, but proof read the manuscript and made valuable contributions to its accuracy.

Ethical approval: This study received ethical approval from Riverside research ethics committee, London.

- 1 World Health Organization. *Annual report from WHO's tobacco free initiative*. Geneva: WHO, 1999.
- 2 Secker-Walker RH, Solomon LJ, Flynn BS, Dana GS. Comparisons of smoking cessation counselling activities of six types of health-professionals. *Prev Med* 1994;23:800-8.
- 3 John JH, Thomas D, Richards D. Smoking cessation interventions in the Oxford region: changes in dentists' attitudes and reported practices 1996-2001. *Br Dent J* 2003;195:270-5.
- 4 DiClemente CC, Marinilli AS, Singh M, Bellino LE. The role of feedback in the process of health behavioral change. *Am J Health Behav* 2001;25:217-27.
- 5 Jarvis MJ, Tunstall-Pedoe H, Feyerabend C, Vesey C, Saloojee Y. Comparison of tests used to distinguish smokers from non-smokers. *Am J Pub Health* 1997;77:1435-8.
- 6 Cope G, Nayyar P, Holder R, Brock G, Chapple I. A near patient test for nicotine and its metabolites in saliva to assess smoking habit. *Ann Clin Biochem* 2000;37:666-73.
- 7 Revell SJ, Robinson JO, Rosen M, Hogg MJ. Reliability of linear analogue scales for evaluation of pain. *Anaesthesia* 1976;31:1191-8.
- 8 Cope GF, Nayyar P, Holder R. Feedback from a point of care test for nicotine intake to reduce smoking during pregnancy. *Ann Clin Biochem* 2003;40:674-9.
- 9 Raw M, McNeill A, West R. Smoking cessation guidelines for health professionals. A guide to effective smoking cessation interventions for the health care system. *Thorax* 1998;(suppl 5):1-38.
- 10 Russell MAH, Stapleton JA, Feyerabend C. Targeting heavy smokers in general practice: randomised controlled trial of transdermal nicotine patches. *BMJ* 1993;306:1308-12.
- 11 Smith SE, Warnakulasuriya KAAS, Feyerabend C, Belcher M, Cooper DJ, Johnson NW. A smoking cessation programme conducted through dental practices in the UK. *Br Dent J* 1998;185:299-303.
- 12 Spiekerman CF, Hujoel PP, DeRouen. Bias induced by self-reported smoking on periodontitis-systemic disease associations. *J Dent Res* 2003;82:345-9.
- 13 Binnie V, McHugh S, Macpherson L, Borland B, Moir K, Malik K. The validation of self-reported smoking status by analysing cotinine levels in stimulated and unstimulated saliva, serum and urine. *Oral Diseases* 2004;10:287-93.
- 14 Vartiainen E, Seppälä T, Lillsunde P, Puska P. Validation of self-reported smoking by serum cotinine measurement in a community-based study. *J Epidemiol Comm Health* 2002;6:167-70. (Accepted 10 August 2005)

doi 10.1136/bmj.38621.463900.7C