Primary care

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

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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 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.[1] Latest statistics indicate a 30% prevalence of smoking in UK adults, contributing to over 120 000 deaths a year and costing the health service £1.7bn ($3.0bn; €2.5bn).[2] Of great concern is the lack of success in targeting smoking cessation among young people; by the age of 15, 28% of males and 33% of females in England smoke.[3]

Smoking predisposes and contributes to cytopathic changes throughout the body. Smokers have a greater incidence of coronary heart disease, myocardial infarction, peripheral vascular disease, and reduced healing rates. People with diabetes and women who use oral contraceptives are at higher risk of circulatory problems, and respiratory disease is higher among smokers. Smoking increases the risk and severity of oral cancer, periodontal disease, and premalignancy in the oral cavity.

Among healthcare professionals, dental surgeons are often in contact with the population and are in an ideal position to provide counselling and advice on smoking cessation. Even basic measures aimed at smokers who are contemplating quitting have an important effect,[4] and further improvements in quit rates are reported when nicotine patches are used.[5] In one study, quit rates at six and 12 weeks predicted the quit rates at 52 weeks, but only half of the participants who had quit at 6-12 weeks remained tobacco-free at one year. Another study reported 6% quit rates with the provision of intensive support and nicotine replacement therapy and concluded that if all UK general practitioners routinely offered these, up to 190 000 people could quit each year.[6]

Brief advice in a dental practice setting led to quit rates of 4.8-7.7%, whereas lengthier counselling, advice on nicotine replacement therapy, and the prospect of a follow-up appointment increased abstinence rates to 9.6-16.9%.[7-9] A study published in the early 1990s reported that dental practitioners were less prepared than their medical colleagues to provide advice on smoking cessation,[10] but recent data have shown major improvements in dental practitioners' attitudes to counselling for smoking cessation.[11]

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.[12] Laboratory based analytical tests to evaluate smoking habit are available[13] 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.[13]

We have reported on a 10 minute, semiquantitative colorimetric point of care test for salivary nicotine metabolites, including cotinine, with sensitivity and specificity of 89.3% and 93.6%, respectively.[14] This type of biochemical testing can also be used to overcome the physiological complexities of the

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P+ *Table showing percentage changes in smoking is on bmj.com*

inhalation, absorption, and distribution of tobacco derived chemicals throughout the body, which give each smoker a unique method of absorbing the contents of a cigarette. The saliva 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 at the consultation visit, for future reference, and for counselling in smoking cessation.

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 practice. We determined that with 50 participants in each group our study would have an 80% power to detect differences in quit rates of 20% or more between the two groups. 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 (not a prerequisite for the study). 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. Participants were offered baseline assessments (enrolment), and efforts were made to ensure that members of medical staff were blinded to the participant's allocated group. We obtained written, informed consent from the participants before their inclusion in the study.

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 case record folders for all participants by a third member of staff, who was blind to the code allocation. The participants were recalled after eight weeks for repeat testing. They were asked if they had used, or were using, nicotine replacement therapy, as this can give a positive result on the point of care test. The operator asked participants to provide a saliva sample, which was then tested by the nurse. A third member of staff entered the results into the case record folders and a spreadsheet (Excel 97) before breaking the code and analysis.

Assay and main outcome measures

The participants were asked to refrain from consuming food or drink for 20 minutes before expectorating at least 2 ml whole, stimulated saliva into a plastic container. The saliva was analysed
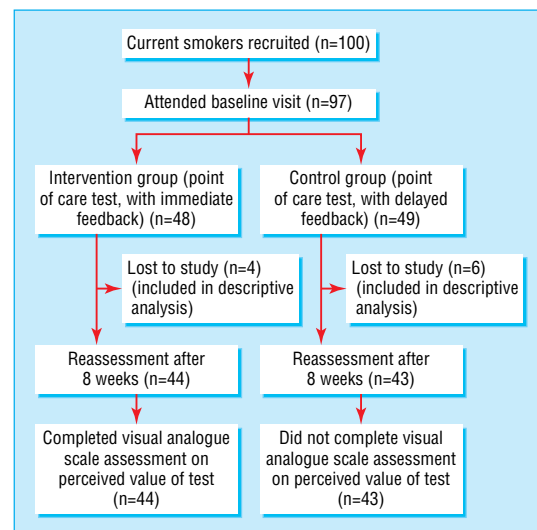

Current smokers recruited (n=100)

Attended baseline visit (n=97)

Intervention group (point of care test, with immediate feedback) (n=48)

Control group (point of care test, with delayed feedback) (n=49)

Lost to study (n=4) (included in descriptive analysis)

Lost to study (n=6) (included in descriptive analysis)

Reassessment after 8 weeks (n=44)

Reassessment after 8 weeks (n=43)

Completed visual analogue scale assessment on perceived value of test (n=44)

Did not complete visual analogue scale assessment on perceived value of test (n=43)

Fig 1   Flow of participants through trial

using a previously reported salivary nicotine metabolite assay, which utilises a colorimetric chemical reaction and direct visual comparison using a chart containing six colours, indicating varying concentrations (0-2.5 µg/ml), expressed as cotinine equivalent concentration.[14] The equipment is simple and consistent with that normally present in dental and medical surgeries.

To evaluate the perceived value of the test, all cases who reattended at eight weeks completed a questionnaire to assess their opinion of the point of care test using a 100 mm visual analogue scale (0 = no use, 10 = very useful).[15]

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 point of care test in quitting, and reduction of tobacco use as measured by self report and the point of care test.

Statistical analysis

As the changes in salivary nicotine metabolite values for controls were not normally distributed (one sample Kolmogorov-Smirnov test, two tailed significance, P = 0.025), we used the paired t test to analyse within group differences in salivary nicotine metabolite values and the Mann-Whitney test to analyse between group differences. We used the χ^2 test to analyse the questionnaire results.

Results

Overall, 97 of 100 patients invited to participate in the study (48 cases, 49 controls) attended the baseline visit (fig 1). Mean ages were 32.6 (SD 11.3) and 35.3 (11.3) years, respectively, with equal numbers of men and women in each group. 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: four cases and six controls failed to reattend.

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), respectively (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 (fig 2). The mean reduction in nicotine
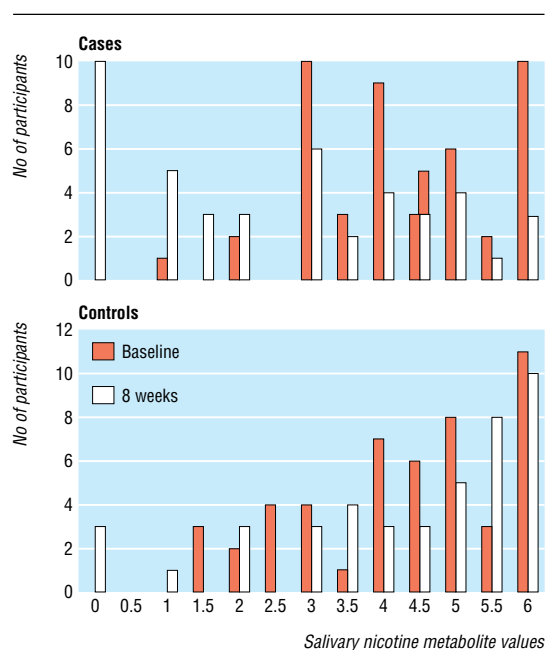
Fig 2 Salivary nicotine metabolite values at baseline and eight weeks for cases (n=44) and controls (n=43) who attended the recall visit

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 and four did not reattend.

For controls with a decreased nicotine metabolite value (n=12), three (7%) had quit and nine (21%) had decreased their tobacco use (fig 2). 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, and six did not re-attend for repeat testing. 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 (Mann-Whitney U test) were also higher (see table on 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 individual-ised 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. Tobacco use remains prevalent in the United Kingdom, and UK dental services have not yet fully embraced their role in the national smoking cessation programmes.[10 11] The dental team has an important part to play in the management of tobacco dependence and may be able to access younger, otherwise healthy smokers who attend regular dental recalls, but who do not necessarily attend general medical practice on a regular basis.

The identification, documentation, screening, and treatment of every tobacco user should become standard practice in all healthcare environments. Although our study has presented data on rates of abstention and reduction of tobacco use, complete cessation is the goal for all smokers and was the primary outcome measure in our study. Any adjunct used by the clinician that may improve the efficacy and effect of advice on smoking cessation must be welcomed.

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 (P<0.001). 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.[16] These results compare favourably with other reported outcomes for intensive advice on smoking cessation that include follow-up appointments,[6] whereas the results for the intervention are significantly better than those from non-pharmacological intervention studies.[5 9]

One limitation of our study arises from the eight week recall time. Although this follow-up period is twice the length of 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, and further studies are needed to investigate this in primary care settings. Nevertheless, studies in primary care settings have shown quit rates of 7% at 12 months with counselling alone.[9] Given that 50% of participants who successfully abstained at 6-12 weeks were still abstinent at a year,[5] it could be estimated that the abstention rates at 12 months in our study are closer to 11% in the cases and 3% in the counselling alone group, had reassessment at 12 months been feasible.

A recent Department of Health survey on smoking cessation reported that about 50% of the 359 000 smokers in England who were assessed had stopped smoking by the arranged quit date.[17] Although this is encouraging, the validity of such a study, where the recall was only four weeks after baseline and all data were provided by self report, is open to question. One study concluded that smoking as measured by self report was likely to be inconsistent and that in the future biochemical validation would yield more reliable data.[18] The use of biochemical verification of smoking to overcome the weakness inherent within self reported data is recommended.[11 19 20] 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

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

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.[12]

Healthcare professionals should be aware of the harmful consequences of smoking, especially given the lack of public awareness.[21] One study reviewed the economics of smoking cessation and concluded that clear evidence existed that interventions for smoking cessation were clinically effective and cost effective.[22] In our study, the use of a point of care test to measure salivary nicotine metabolite values at the initial counselling visit was recognised by participants as a valuable adjunct to counselling and improved quit rates and overall tobacco use. The assay 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 metabolites, irrespective of their source, the utility of the test is limited in people who use nicotine replacement therapy.

Such a method also lends itself to primary care medical practices and stop smoking services within primary care trusts. Point of care testing provides the healthcare professional (as well as the patient) with immediate results, thereby helping to gauge treatment and provide appropriate advice, as well as providing a means of monitoring change.

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