Feedback from a point-of-care test for nicotine intake to reduce smoking during pregnancy

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Abstract

Background Smoking is the most important modifiable risk factor for adverse pregnancy outcome in the UK. New tools are needed to improve smoking cessation advice. The aim was to investigate a point-of-care urine test for smoking, to provide feedback to women, to improve awareness about the effects of smoking during pregnancy and to relate the test results to pregnancy outcome.

Methods A cross-sectional randomized controlled trial involving 856 pregnant women. All intervention patients were interviewed at their initial visit and tested for smoking. The test provided visual and numerical feedback. Smokers were followed up and retested at subsequent visits. The control group received anti-smoking counselling as part of routine care, but their smoking was monitored using the test. Both groups were interviewed and retested at 36 weeks' gestation.

Results Self-reported cigarette consumption fell significantly (P < 0.001) in the intervention group, with 16.2% giving up and 33.3% significantly reducing their cigarette consumption. There was a significant fall in test results from 'booking' to 36 weeks' gestation (P < 0.0001). In the control group, only 8% reported stopping and 23% reducing their cigarette consumption. Combined smoking test results at 36 weeks correlated significantly with birth weight (P = 0.006) and body length (P = 0.011).

Conclusions Point-of-care testing and feedback coupled with counselling can significantly reduce smoking during pregnancy and increase birthweight.


Introduction

Smoking is the foremost modifiable risk factor for adverse pregnancy outcome in the UK,¹ being responsible for low birthweight as a result of intrauterine growth retardation.² At least a third of women who smoke will continue to do so during pregnancy, despite knowing many of the risks involved. Routine advice is clearly inadequate, and new strategies, with a coordinated and consistent effort from the medical profession, are urgently needed.¹

Pregnant women who smoke are often pressurised to reduce or stop smoking and the incentive to mis-report may be greater than in the past.⁴ Furthermore, the assessment of smoking behaviour is far more complex than merely asking about cigarette consumption, as this does not take into account: the yield of cigarettes smoked, the method of smoking (puff topography), depth of inhalation, efficiency of absorption and metabolism.⁵ Because of these difficulties, smoking cessation interventions in pregnancy are turning towards biochemical measurements to verify self-report and to quantify tobacco intake. A US study which measured serum cotinine (a major metabolite of nicotine) found that non-disclosure varied from 28% at enrolment to 35% at 36 weeks' gestation. This may reflect the fact that some patients react to interventions by providing the desired response to questions at follow-up.⁶ This, and a number of studies, have found a closer dose–effect relationship between birthweight deficits and nicotine metabolite levels in serum and urine than with self-reported cigarette consumption.⁷⁸ Serum cotinine concentration at 16 weeks' gestation was also found to have a high positive predictive value for small-for-gestational age deliveries, which was double that for self-reported smoking habit and independent of associated maternal characteristics.⁹ This led to the recommendation that
biochemical verification of self-reported quitting is essential to the evaluation of smoking cessation interventions and may be a useful predictor of poor pregnancy outcome.\textsuperscript{6,9}

Biochemical testing for smoking is currently of little value to the patient. The laboratory tests are time-consuming for the midwives, and the impact is reduced because of the delay in obtaining the result. Point-of-care testing is an increasingly common mode of providing biomedical information to patients, and various approaches have been shown to be effective in changing patients’ smoking behaviour.\textsuperscript{10} Feedback is thought to offer important information, to create a sense of caring, to increase engagement in educational materials, to boost motivation and to provide comparisons and norms.\textsuperscript{11,12}

We have developed a simple-to-use, point-of-care test that measures nicotine and its breakdown products, including cotinine, in urine.\textsuperscript{13} Our aim was to investigate, for the first time, the clinical use of this test by assessing its effectiveness at reducing smoking during pregnancy and to determine any resultant improvement in birthweight and other birth parameters, the assumptions being that benefits could be derived from feedback and monitoring change.

**Subjects and methods**

**Point-of-care test**

We developed a 6-min, disposable point-of-care test that measured nicotine and its breakdown products, including cotinine, in urine (SmokeScreen \textsuperscript{8}, Mermaid Diagnostics Limited, Birmingham, UK). A 2-mL urine sample added to dried chemicals contained within a patented testing device produced a concentration-dependent pink/orange derivative. The absorbance change at 510 nm was monitored by a portable colorimeter. The test was quantitative by comparison with a cotinine standard, and included a compensation factor for urine dilution. The assay detected the presence of a pyridine ring, a common biochemical feature of nicotine metabolites. Collectively, compared with a cotinine standard curve, the concentration of metabolites was referred to as cotinine equivalents (mg/L). The urine concentration was monitored by light absorption to assess the concentration of urine chromophores and referred to as urine absorbance. The test result was expressed as cotinine equivalent concentration/urine absorbance ratio.

The results ranged from 0 to 275, with a baseline of 10 taken to indicate an active smoker. The results correlated with self-reported cigarette consumption ($r = 0.69$, $P < 0.0001$) and nicotine yield of cigarettes smoked ($r = 0.14$, $P < 0.001$), and independent cotinine measurements by gas chromatography ($r = 0.89$, $P < 0.001$). The test had a sensitivity of 89.9% and specificity of 98.9%.\textsuperscript{13}

**Subjects**

New referrals to three large inner-city hospital antenatal clinics were randomized on the basis of their allocated hospital unit number, even numbers being placed in the case or intervention group, or those who were provided with feedback from the smoking test at point of care. Initially, a pilot study was undertaken to assess the attitude of intervention smokers to the test, and determine whether the result and feedback did have any effect on smoking behaviour. After encouraging results, the pilot study was extended with a revised protocol.

**Intervention**

The intervention group, smokers and non-smokers alike, were seen at their initial visit and given a brief verbal explanation of the test and the aims of the research (see Fig. 1). Each was asked to give verbal consent for inclusion in the study. After agreeing, they were asked for a sample of urine, which they usually had brought with them to clinic, for routine testing. The 6-min test was carried out in their presence, during which time the patient was asked about current and previous smoking habit, and other social and demographic details, which were entered onto a short questionnaire.

On completion, the women were shown the resultant colour of the test and told the numerical result. This was illustrated as a point on a graph showing a previously compiled wide range of smoking test results against reported daily cigarette consumption (see Fig. 2). This distribution is similar for any biochemical measure of smoking and to a great extent represents the variations in smoking behaviour and nicotine metabolism. Current smokers and those with a positive result were enrolled in the study. All non-smokers with a negative result were further excluded.

A specific 'quit date', usually within the next 14 days, was chosen by mutual agreement, and this was written on the test result sheet. The women were given a printed leaflet containing practical advice on how to reduce their smoking and invited to return for measurement at their next and subsequent visits. A positive, friendly attitude was taken to smoking, with emphasis on trying to empower the smoker, with information, feedback and encouragement, to change her smoking behaviour. This protocol was repeated whenever the patient returned to the clinic, up to and including the 36-week visit, with measurement, questioning about changes in smoking, specific events on the 'quit date' and reinforcement of advice.

By comparison, the women assigned to the control group were not seen at their initial visit, but had their urine measured. They therefore did not have the
benefit of seeing the test or its result. They received counselling about smoking in pregnancy from their hospital midwife and from the obstetrician as part of usual care. Control patients were traced throughout pregnancy and interviewed at their 36-week visit. Like the intervention women, they were interviewed and the nature of the study explained. The fact that their urine had been previously tested was also made clear and at this point verbal consent was obtained. They were asked about changes to their smoking throughout pregnancy, and about the frequency and source of any anti-smoking advice.

Data analysis
Birth details, including gender, birthweight, length and head circumference, together with gestation, type of delivery and Apgar scores at 1 and 5 min, were collected post-partum from the medical records. All
data were entered into a database and analysed with the statistical software, ANOVA, ANCOVA and Wilcoxon sign rank test. The intervention group showed an increase in smoking cessation (median 37.6%, P < 0.001) compared to the control group (median 3.4%, P < 0.001). Smoking test results showed that at 36 weeks in the intervention group, 43% of the women were smokefree, while 33% of the women were smokefree in the control group (P < 0.001). Smoking test results also showed that at 36 weeks, 51% of the women in the intervention group and 46% of the women in the control group were smokefree (P = 0.05).

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(r = −0.23, P = 0.04) and infant length (r = −0.24, P = 0.04). Combination with the control group provided a larger group for analysis (n = 158). Nicotine intake, as measured by the smoking test, was related to birthweight (r = −0.22, P = 0.006) and body length (r = −0.20, P = 0.011), and its relationship with head circumference approached significance (r = −0.154, P = 0.056). There was no significant relationship between the smoking test result and gender, gestation, type of delivery or Apgar scores.

Adjustment for nicotine metabolite results in the two groups using ANCOVA revealed a significant difference in birthweight between the intervention group (3.26 kg) and the control group (3.08 kg, P < 0.03). This would suggest that the intervention had an overall effect of improving birthweight irrespective of nicotine metabolite values.

**Discussion**

Biochemical measurement of smoking, by the laboratory assessment of nicotinic metabolites such as cotinine, is increasingly used in the research antreatment of smoking-related conditions, in particular smoking during pregnancy. Such measurements are of little value to the patients because of time delays in returning the result. We developed a 6-min point-of-care test for smoking, measuring nicotine and all its metabolites, based on a colorimetric assay in urine to provide immediate feedback about smoking habit.

This randomized controlled trial of the use of the smoking test provided both visual and numerical feedback to both patient and investigator and formed the basis for counselling which took into account the individual's smoking behaviour. An encouraging and non-judgemental approach improved the quit rate, and resulted in a reduction in cigarette consumption compared with the control group. The smoking test results demonstrated a highly significant reduction in nicotine intake, not only among those who quit or cut down, but also in a proportion of women who reported maintaining their smoking habit. Discussions with this group suggested that changes in cigarette use were evident, despite cigarette consumption remaining the same.

In the control group, only a few women remembered receiving any advice about smoking in pregnancy, except perhaps the generalized statement that they should stop. All agreed this had little or no effect on their smoking behaviour, particularly as no further advice on how the women might achieve this was offered.

Analysis of birth parameters showed that the test result at 36 weeks was related to birthweight and body length and to a lesser extent head circumference, and we found that quitters had significantly heavier and larger babies than those who continued to smoke. Adjustment for smoking test results showed a significant difference in birthweight between both groups, implying that the provision of tailored advice coupled with friendly practical guidance from a dedicated counsellor improved the pregnancy outcome.

Our approach was based on a number of previous studies, one of which advocated the use of designated counsellors who taught specific cessation skills and reinforced advice with follow-up contact and printed material specifically for the pregnant smoker. A study by Haddow et al. verified self-reported smoking by serum cotinine measurement using a laboratory method, and sent the results to the woman's physician, along with an interpretation of its meaning and an estimate of her relative risk due to smoking. This intervention led to a significant reduction in smoking and an increase in birthweight. We concurred with recommendations that immediate and complete cessation is too demanding for most smokers, and that cessation must be viewed as a process of stages of change, in order to understand the smoker's point of view, to motivate her progress and to respond to the patient's needs.

A recent study by Moore et al. evaluated the effectiveness of a self-help approach to smoking cessation found that specifically designed booklets given or sent out at particular times during pregnancy were ineffective. The cotinine-validated rates of cessation were substantially lower than self-reported rates. This study lends weight to the theory that individually tailored advice and feedback about smoking levels could be a better approach.

The advantages of using the smoking test are, firstly, that it correctly identifies the vast majority of smokers. Considering that denial is an important problem during antenatal care, we observed a 10.3% denial rate of smoking to midwives during routine history-taking. The visual and numerical feedback increased the smoker's awareness of her smoking, and repeat testing monitored any changes to smoking habit. Feedback has recently been described as offering important information to create a sense of a caring and helping relationship, to reach more directly decisional considerations, to increase engagement with the materials, to increase motivation, or to provide social comparison and norms.

We emphasized to the patients that the test was not a 'lie detector' but merely an assessment of baseline smoking from which to progress, with advice, support and encouragement at all stages. The demonstration of the presence of smoke components in pregnant women in a clinic has previously been considered to be a valuable adjunct to cessation efforts.

Our cessation rates in the intervention group of 22% compared with 7% in controls are similar to those achieved in other cotinine-validated interventions, but we were able to show that some women, although
consuming their usual amount of cigarettes, did alter their smoking habit by smoking less effectively. That is, not smoking the whole cigarette or inhaling less deeply following the initial 'hit'. A rise in nicotine metabolite levels observed in a control group towards the end of pregnancy had been noted previously, but the authors concluded that this rise was a manifestation of physiological changes during pregnancy.\(^8\)

Unfortunately, this study was not controlled, and a fall in the intervention group was not observed. A possible explanation for this is that smokers reduce their smoking at the onset of pregnancy, but in the last trimester, when anxiety, immobility and boredom are a problem, smoking increases, especially when smoking habit is not verified.

Recent studies have indicated that nicotine metabolism is altered in pregnancy, with the clearance of nicotine and cotinine being significantly higher in pregnant women and the half-life of cotinine being much shorter, 8.8 h compared with 16.6 h in the non-pregnant state.\(^1\)

The present study evaluated a novel point-of-care test as a tool to reduce smoking in pregnancy. The test provided a simple-to-use, inexpensive means of correctly identifying the vast majority of smokers, assessing their baseline nicotine intake and monitoring adherence to anti-smoking advice. The programme of advice centred on the smoking test contributed to a significant improvement in smoking cessation, and reduced cigarette consumption. In women who reported maintaining their cigarette consumption, a third had significantly lower test results at their return visit, reflecting a decrease in nicotine intake despite consuming the same number of cigarettes. The study identified, for the first time, an increase in nicotine metabolite excretion towards the end of pregnancy in the control group, suggesting it to be a true reflection of an increase in smoking, probably due to enhanced anxiety and boredom, not as a physiological function of pregnancy, as was previously thought.\(^8\)

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Conflict of interest

GFC is one of the joint inventors of SmokeScreen and is employed by Mermaid Diagnostics Limited, a company partially owned by the University of Birmingham, which now manufactures the test.

References


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