PAPERS AND ORIGINALS

Changes of smoking habits and cough in men smoking cigarettes with 30% NSM tobacco substitute

S FREEDMAN, C M FLETCHER

British Medical Journal, 1976, 1, 1427-1430

Summary

The effects of smoking cigarettes with 30% of the tobacco replaced by NSM tobacco substitute, which lowered their tar and nicotine delivery, were studied by comparing them with the effects of conventional cigarettes in a controlled crossover trial lasting 20 months. Chest symptoms, cigarette consumption, and forced expiratory volume in one second (FEV₁) were measured each month. Two-hundred men began the trial and 159 completed it. The test cigarettes were acceptable to all but one of the men. In a subsample of 35 men estimates of nicotine intake were obtained from monthly analyses of cigarette stubs. On changing from NSM to control cigarettes six of the 17 men, who were accustomed to low nicotine, kept their nicotine intake down by some change in smoking habit. Before the crossover and this change in smoking habit the men smoking NSM cigarettes had a small but significant reduction of cough.

Cigarettes containing 30% NSM and delivering only 1 mg of nicotine are likely to be acceptable to smokers and may reduce coughing. Further trials are needed to confirm these findings and establish what long-term effects such cigarettes may have on smokers' health.

Introduction

Despite the conclusive epidemiological and experimental evidence incriminating cigarette smoking as a main cause of chronic bronchitis with airways obstruction and the considerable publicity given to this and to the other dangers of this habit there has been no appreciable fall in cigarette sales except in social classes I and II,¹ and even if improved methods of dissuading people from smoking cigarettes are developed, many

will probably continue to indulge in this habit. It is therefore important to develop less harmful cigarettes to combat smoking-related diseases, and we welcomed the opportunity to see whether respiratory symptoms or ventilatory capacity were affected in the short term by cigarettes containing an artificial non-tobacco substitute. This NSM tobacco substitute was developed by New Smoking Materials Ltd and is made from cellulose. The effect of adding this to tobacco is to dilute the products of pyrolysis of the tobacco and thus reduce the amount of nicotine and, to a lesser degree, the tar delivered by each cigarette. We report here a controlled crossover trial in which conventional cigarettes were compared with cigarettes containing 30% NSM and 70% tobacco.

Methods

MAIN SAMPLE

The volunteers for our study were recruited by sending a simple questionnaire to all men aged 25-57 on the lists of six local general practitioners. The questionnaire contained 12 questions about smoking habits, and from the replies we selected all those men who smoked at least 10 cigarettes a day, most of whom admitted to some cough. These men were then visited in their homes by trained fieldworkers twice over three months in the summer of 1972. At each visit the fieldworkers administered a detailed questionnaire about smoking habits, respiratory symptoms, and chest disease, based on the MRC questionnaire on respiratory symptoms,² and measured ventilatory capacity, cough frequency, and sputum volume using techniques described below. They also tried to persuade the men to stop smoking. Some men had participated in similar studies of other cigarettes and had originally been recruited in the same way. After the second visit we wrote to over 94% of the men (about 300) who had said they were unwilling or unable to stop smoking and who had no history of chest disease other than bronchitis or emphysema asking them to co-operate in the rest of the study. They agreed to smoke only cigarettes provided by us without charge for about one year. This was the first occasion on which the question of cigarette supplies were raised. From those who were willing to participate 200 men were selected and matched into pairs, as described below. The men were regularly supplied with cigarettes and were visited every four weeks for a repeat of the measurements performed at the initial visits. The study continued for 20 months.

MEASUREMENTS

At each visit forced expiratory volume in one second (FEV₁) and vital capacity (VC) were measured using a portable dry spirometer

Department of Medicine, Royal Postgraduate Medical School, Hammersmith Hospital, London W12 0HS

S FREEDMAN, PHD, MRCP, lecturer (present address: Department of Medicine, Chase Farm Hospital, Enfield, Middlesex)

C M FLETCHER, MD, FRCP, professor of clinical epidemiology

(Garw Ltd). Three measurements were made at each visit. The values were all recorded and the maxima subsequently selected and used. The frequency of coughing (cough score) was estimated using a method described by Field³ based on a technique developed by Ingham⁴ for quantifying symptoms. This technique consisted of devising a series of statements on cough frequency and amount of phlegm ranging, for cough, from "I don't remember coughing at all today" to "I haven't stopped coughing all day," and, for phlegm, from "I have not brought up phlegm since this time yesterday" to "I have brought up more than an egg-cupful of phlegm since this time yesterday." There were intermediate statements representing very small gradations of frequency of cough or amount of phlegm. These statements were typed in adjacent pairs on cards and presented in random order to each subject, who was asked to say which of the two statements on the card was closer to his cough during the past day or his phlegm on each day during the past week.

A crossover point was recorded when the subject changed from choosing the higher to choosing the lower of the paired questions and this point was taken as his score. The cough score provided a scale of 11 points and the phlegm score one of eight points.

SUBSAMPLE

Twenty men from each group were picked out at random and asked to save their cigarette stubs on the day before the fieldworkers' monthly visit. The tips were subsequently analysed for nicotine content by the research department of Imperial Tobacco Ltd. The smokers' dose of nicotine was calculated from the tip content and a "tip retention factor." This was based on the proportion of the total nicotine retained by the tip when the cigarettes were smoked in a standard way by a machine.

CIGARETTES

The control cigarette was a 70-mm long 25-mm circumference filter-tipped cigarette. The test cigarette was a blend of 70% tobacco and 30% NSM. Preliminary trials had shown that cigarettes containing a higher percentage of NSM were unacceptable to most smokers largely because of their extremely fine ash, which was difficult to control. The test cigarette had a 16% reduction in tar (total particulate matter free of water and nicotine) and a 27% reduction in nicotine delivery compared with the control cigarette (table I). Carbon monoxide and acrolein deliveries of the two cigarettes were identical, but other constituents of the vapour phase, including acetic acid and acetaldehyde, were reduced in the test cigarette.

The cigarettes were identical in appearance and packaging. They were delivered to the men every two weeks. Each man was initially supplied with slightly more cigarettes than his average consumption in the pretrial period, and subsequent deliveries increased or decreased according to the previous cigarette consumption, the aim being always to supply about three packets a fortnight more than the number said to have been smoked. Any unsmoked cigarettes were reclaimed at the next delivery.

EXPERIMENTAL DESIGN AND ANALYSIS

Out of about 300 men who were available for inclusion in the trial 200 were selected and matched in pairs by a computer programme. The matching was on the basis of five initial characteristics: age, cigarette consumption, FEV₁, cough score, and sputum score. For each of these indices two or three grades were chosen, and the matching was such that each pair had the same grades of all initial characteristics. Each member of a matched pair was allocated at random to either the test (group 1) or control (group 2) cigarettes. After nine months, including a complete winter, the cigarettes supplied were crossed over, so that the men in group 1 who had been smoking test cigarettes smoked control cigarettes and vice versa. The men were then told only that they might notice some differences in the cigarettes which were to be supplied. The experiment continued for a further 12 months in the hope that significant differences in cough score might reappear. We are concerned here mainly with results obtained at the 2nd to 8th and 11th to 19th surveys.

Results

During the trial 41 men (20 from group 1, 21 from group 2) lapsed from the trial for various reasons, most of them because they moved

out of the neighbourhood. Only one of them found the test cigarette unacceptable. The results are given for the remaining 160 men.

CIGARETTE CONSUMPTION

The men were heavy smokers. Before the trial they smoked an average of 33 cigarettes a day. Those in group 1 averaged one cigarette a day more than those in group 2. In spite of the fact that all men were receiving free cigarettes, average consumption remained almost constant throughout the trial and was no greater than that observed before free cigarettes were issued (fig 1). There were temporary small increases each January attributable to slightly heavier smoking over the preceding Christmas holiday. There was little difference in the average consumption of the two cigarettes in the first 15 months, but in the last five months there was a small but insignificant increase in consumption of the test cigarettes.

FIG 1—Mean monthly cigarette consumption of men in groups 1 and 2 before and during study.

ACCEPTABILITY OF NSM CIGARETTES

The pretrial smoking habits had been recorded at the initial interview and analysis of these data from 30 men, chosen at random, showed that they had smoked an average of 34.3 cigarettes per day with average tar and nicotine yields of 19.4 and 1.40 mg respectively per cigarette (calculated from the tar and nicotine table issued by the Department of Health and Social Security). These yields were similar to those of the control cigarette (table I). There were no significant differences between the types of cigarette previously smoked by men in group 1 and those smoked by men in group 2. At the time of the crossover no one complained or even commented on the change. A questionnaire at the end of the trial, returned by 154 of the 175 men available, showed that 64% of men on NSM and 56% on control cigarettes had occasionally smoked other brands of cigarettes during the trial. Seventy per cent of these men on NSM cigarettes and 71% on control cigarettes had preferred the trial cigarettes to other cigarettes.

A more detailed study was made of the effects of smoking the test and control cigarettes on mean cigarette consumption and estimated nicotine intake in 35 of the 40 men who were asked to save their stubs for analysis each month and did so before and after the crossover often enough for reliable analysis. Reliable results were available only for the seven months before and for the 3rd and 10th months after the crossover. Men in group 2 in this sample, who started with the control cigarette, obtained an average of 1.4 mg nicotine per cigarette before the crossover, and when they changed to the NSM cigarettes their nicotine intake fell commensurately and uniformly to an average of

TABLE 1—Average yield per cigarette when machine-smoked (35 ml puff volume)

	Nicotine (mg)	Particulate matter, free of water and nicotine* (mg)	Carbon monoxide (v/v)
NSM cigarettes	1.01	16.64	4.7%
Control cigarettes	1.39	19.82	4.7%

*"Dry tar."

TABLE II—Mean nicotine intake, cigarette consumption, estimated tar intake, and cough score in subsamples of men before and after crossover

	Cigarette	Before crossover		After crossover	
		Sample group	Values	Sample group	Values
Nicotine intake cigarette (mg)	NSM	1	1.03	2	1.08
	Control	2	1.40	1	1.12
Cigarettes day	NSM	1	32.5	2	31.6
	Control	2	31.8	1	32.8
Nicotine intake day (mg)	NSM	1	33.5	2	34.1
	Control	2	44.5	1	36.7
Estimated* tar intake day (mg)	NSM	1	552	2	573
	Control	2	636	1	524
Mean cough score	NSM	1	4.22	2	4.81
	Control	2	5.06	1	4.04

*Estimate derived from (nicotine intake nicotine yield) $\times$ tar delivery $\times$ cigarettes per day.

1.08 mg per cigarette (table II and fig 2). These two intakes were close to those expected from the nicotine delivery of the two cigarettes (1.39 and 1.01 mg) measured by a smoking machine and suggest that these men made no change in the way they smoked their cigarettes. Since their cigarette consumption remained constant, they appear to have accepted without demur a considerable decline in their daily nicotine intake. The men in group 1 behaved in a similar fashion in changing from the cigarettes they had previously smoked, with a mean nicotine delivery of 1.4 mg per cigarettes, to the NSM cigarettes, dropping their mean nicotine intake to 1.03 mg (1.06 mg excluding two men who had exceptionally low intakes). When they changed to the control cigarettes 11 kept to their previous smoking habits and thus increased their mean intake to 1.35 mg per cigarette. The other six men dropped their mean intake to 0.9 mg. The overall mean intake of the men in group 1 sample while they were smoking the control cigarettes was thus kept down to only 1.12 mg (or 1.18 mg excluding the two men with exceptionally low nicotine intakes). Since the measured delivery of the cigarettes was 1.39 mg and the men did not change their average number of cigarettes a day, about one-third of them, accustomed to a low nicotine intake for nine months, kept their intake down on changing to cigarettes with a higher nicotine delivery. This must have been done by some change in their smoking habits—for example, by taking fewer puffs from each cigarette to leave a longer stub or taking shorter puffs.

This change in smoking habits must also have reduced the expected increase of tar intake on changing to the control cigarettes. These intakes may be estimated from the ratio between the intake and the delivery of nicotine in the two halves of the trial (see table II) and indicate that men in group 2 may well have had a higher daily intake of tar by about 15% in the first half and 9% in the second half of the study.

SYMPTOMS

During the first half of the study a significant difference was found in cough score from the third month of the trial till the month before the crossover (fig 3). Thereafter there were no significant differences in the cough scores between the two groups. There was an expected seasonal increase in cough scores in the first winter of the experiment, which had been observed in a similar study,³ but this was absent in the second winter, after the crossover. No significant differences were found between monthly values of group 1 and group 2 men either in matched pairs or in all men in sputum score, frequency of chest illnesses, FEV₁, VC, or FEV₁:VC.

Discussion and conclusions

Two main findings from our survey are of practical interest. Firstly, cigarettes made of 30% NSM and 70% tobacco were acceptable to all but one of the 200 men. Earlier trials of cigarettes containing 45% or more of NSM showed that they were much less acceptable, largely because of their fragile ash. The free issue of cigarettes does not seem to have affected their acceptance much, for cigarette consumption did not increase during the trial. Secondly, changing to cigarettes with a 30% lower nicotine yield at the beginning of the trial and at the crossover resulted in no subjective complaint or apparent change in smoking habits.

FIG 2—Estimated nicotine intake of subsample of men from groups 1 and 2 while smoking NSM and control cigarettes.

FIG 3—Mean monthly cough scores of men in groups 1 and 2 during study. *Significant differences in cough score ($P < 0.05$).

Our findings are different from those of previous reports of short-term trials in which greater changes in nicotine yield did affect smokers' habits in ways which increased their nicotine intake.⁶⁻⁸

Only one longer-term study has been published.⁹ Guillermin *et al* persuaded 75 people with an average smoking history of 30 pack-years to switch from cigarettes yielding 1.7 mg of nicotine to others yielding 0.7 mg.⁹ Seventy-three of their subjects were able to keep this up for five weeks and, although almost half of them increased their cigarette consumption, the average change was only from 32 to 34 cigarettes a day. When our men changed from control to test cigarettes with nicotine yields of 1.39 and 1.01 mg respectively their nicotine intake, as measured by stub analysis, dropped proportionately. This analysis measures only nicotine drawn through the stub and the men might have kept up their nicotine intake by deeper inhalation of the same amount of smoke drawn through the filter of the lower nicotine cigarettes, but this would require a complex change of smoking habit, which is not very likely. It is remarkable that when the 17 men who had been smoking the lower nicotine NSM cigarettes switched back to the higher nicotine cigarettes six of them seemed to have changed their smoking habits so that they kept their intake of nicotine down to the lower levels to which they had become accustomed. These findings indicate that many smokers would be quite content with cigarettes yielding only 1 mg of nicotine.

We consider that a study on cigarettes supplied free is relevant

to smoking habits of the general population for although this could have encouraged acceptance of NSM cigarettes at the beginning of the study it could not have been responsible for the absence of any awareness of the change of cigarettes at the crossover.

The wide range of estimated nicotine deliveries calculated from stub analyses (fig 2) indicates that individual intakes of nicotine and other substances in cigarette smoke cannot be safely deduced from measurements of their yields when the cigarettes are smoked in a standard way by machines. Methods for accurate quantification of individual smoking habits without affecting them are essential in further studies of this kind. Measurements of carboxyhaemoglobin might prove valuable for this purpose.

The reduction of cough score of the men smoking NSM cigarettes before the crossover was temporary and small. The largest difference was between a score of 4 and 5, which represented roughly the difference between "I can only remember coughing a couple of times today" and "I have coughed a few times today." A larger difference might perhaps have been observed if the average score had been higher. The lack of any divergences of score after the crossover may have been due to the small difference in estimated tar—and presumably of compounds of the smoke that cause cough—between the two groups (see table II). That spirometric tests showed no difference is not surprising since there is now evidence that about seven years are required to establish rates of change of these values with sufficient confidence to distinguish even between smokers and non-smokers,¹⁰ and it has been reported that the immediate increase of airways resistance on smoking NSM or conventional cigarettes is similar.¹¹

Our main conclusions are: firstly, since cigarettes containing 30% NSM were acceptable to 199 out of 200 heavy cigarette smokers, it is reasonable to suppose such cigarettes are likely to be generally acceptable and those who smoke them may benefit at least by some decrease in cough; secondly, cigarettes with a nicotine delivery of no more than 1.0 mg are also likely to be widely acceptable and smokers who change to this lower level from cigarettes delivering nearly 1.4 mg are unlikely to have any increased exposure to tobacco smoke, as previous studies have suggested.⁶⁻⁸ Furthermore, since on the reverse change some men changed their smoking habits to avoid a significant increase of nicotine intake, many smokers might in time become accustomed to an even lower yield of nicotine.

These conclusions are based on small samples but are unlikely to be grossly misleading. If correct they are important, for 79 out of 109 brands listed by the Department of Health and Social Security in their tar and nicotine tables in February 1976 delivered more than 1.0 mg nicotine and, with it, a larger dose of tar than most cigarettes delivering less nicotine. According to our findings, many smokers would be quite content and might suffer less harm to their health than at present if stronger brands of cigarettes were not available. Inclusion of NSM in cigarettes might make it easier for the manufacturers to reduce the tar and nicotine.

Further studies of this question are undoubtedly necessary, for our results are based on smokers who were not a random sample of any defined population. Longer trials lasting for as much as five to 10 years would be needed to assess the effects of smoking such cigarettes on lung function or mortality rates from smoking-related diseases. Our findings show how important it is that in such studies careful assessments should be made of any changes in smoking habits that may follow changes in the types of cigarettes smoked.

We would like to thank New Smoking Materials Ltd for their support and, in particular, Dr David Conning and Mr J V Gregg for help with the analysis. We are grateful to Mr Michael Healy of the Clinical Research Centre at Northwick Park Hospital for the statistical design of the study. We would also like to thank Mrs M Stuart, Mrs M Asher-Relf, and Mrs Mary Beyfus for all the help they gave in running the study.

References

- ¹ Todd, G F, *Changes in Smoking Patterns in the UK*. London, Tobacco Research Council, 1975.
- ² Medical Research Council's Committee on Research into Chronic Bronchitis. *Questionnaire on Respiratory symptoms and Instructions for its Use*. London, MRC, 1966.
- ³ Field, G B, *International Journal of Epidemiology*, 1974, **3**, 135.
- ⁴ Ingham, J G, *British Journal of Social and Clinical Psychology*, 1965, **4**, 131.
- ⁵ Freedman, S, Fletcher, C M, and Field, G B, *Journal of the National Cancer Institute*, 1972, **48**, 1805.
- ⁶ Ashton, H, and Watson, D W, *British Medical Journal*, 1970, **3**, 679.
- ⁷ Russell, M A H, et al, *British Medical Journal*, 1973, **4**, 512.
- ⁸ Frith, C D, *Psychopharmacologia*, 1971, **19**, 188.
- ⁹ Guillemin, R, et al, *Les Bronches*, 1974, **24**, 211.
- ¹⁰ Fletcher, C, et al, *The Natural History of Chronic Bronchitis and Emphysema*. London, Oxford University Press, 1976.
- ¹¹ Costello, J F, et al, *Lancet*, 1975, **2**, 678.

Low-tar medium-nicotine cigarettes: a new approach to safer smoking

M A H RUSSELL

British Medical Journal, 1976, **1**, 1430-1433

Summary

The logic of expecting people who cannot stop smoking to switch to cigarettes that have hardly any nicotine is questionable. Tar and nicotine yields of cigarettes available in Britain today correlate 0.93, and further

reduction of tar intake is limited by the reluctance of smokers to tolerate similar reductions in nicotine. A new approach would be to aim at lowering tar yields of cigarettes from the present average of 18 mg to around 6 mg but maintaining nicotine yields at around 1.0 to 1.2 mg, which would be acceptable to most smokers. This approach requires that emphasis be placed on tar: nicotine ratios as well as on the absolute yields. These ratios for brands on sale in Britain today average 14.2 and range from 9.6 to 20.8. They provide an additional guide for comparing the relative harmfulness of different brands. For example, 35% of cigarette smokers in Britain smoke either Embassy Filter or Players No 6 Filter; by changing to John Player Carlton King Size they could reduce their tar intake by more than 20% without having to suffer any nicotine deprivation.

Addiction Research Unit, Institute of Psychiatry, Maudsley Hospital, London SE5

M A H RUSSELL, MRCP, MRCPsych, senior lecturer and honorary consultant psychiatrist