PAPERS AND SHORT REPORTS

Comparison of four methods of smoking withdrawal in patients with smoking related diseases

Report by a subcommittee of the Research Committee of the British Thoracic Society

Abstract

Four methods of smoking withdrawal were compared in patients with smoking related diseases attending a hospital or chest clinic. Reinforcing verbal advice with a booklet or with a booklet together with nicotine or placebo chewing gum did not result in greater success than verbal advice alone. Roughly a quarter of those patients who denied smoking had carboxyhaemoglobin and plasma thiocyanate concentrations typical of smokers. At the end of a year 150 out of 1550 patients (9·7%) had successfully stopped smoking.

Introduction

If patients with smoking related diseases stop smoking prognosis improves.[1-3] Simple advice to stop smoking resulted in 18-23% of patients attending a chest clinic claiming to have given up smoking for six months.[4] For patients recovering from myocardial infarction firm advice, reinforced with written advice and home follow up by a community nurse, resulted in 62% claiming abstinence at one year.[5] Several studies of smoking withdrawal have suggested that nicotine chewing gum (Nicorette) may be an effective aid.[6,7] The present study was designed to compare the physician's verbal advice to give up smoking with that advice reinforced by written advice and with the written advice supplemented by nicotine or placebo chewing gum.

Patients and methods

Patients eligible for the study were newly attending or re-referred outpatients or inpatients aged between 18 and 65 who smoked cigarettes and had a condition related to or aggravated by smoking—namely, chronic bronchitis and emphysema, asthma, repeated respiratory infections, industrial lung disease, ischaemic heart disease, hypertension, peripheral vascular disease, and peptic ulcer. Patients with neoplasm, any terminal or preterminal disease, psychiatric disorder contraindicating smoking withdrawal, and those unlikely to be able to attend for the whole follow up period were excluded, as were pregnant women.

Design and dosage—The study was multicentre and patients were allocated at random to one of four "treatment" groups: (1) usual advice from the physician about smoking and verbal instructions to stop (VA); (2) as (1) plus a booklet containing information about the dangers of smoking and advice on how to stop (VAB); (3) as (2) but supplemented by placebo chewing gum with instructions to substitute it for a cigarette when there was an urge to smoke (VABPG); (4) as (2) but supplemented by nicotine chewing gum (each piece containing 2 mg buffered nicotine) with instructions to substitute it for a cigarette when there was an urge to smoke (VABNG). Placebo and nicotine gums were indistinguishable in appearance and taste, and neither the physician nor the patient knew which gum had been issued.

METHODS

Each physician initially received a balanced block of 12 treatments. Once an eligible patient had agreed to complete a questionnaire on his smoking habits a numbered envelope notifying the allocated treatment was opened by the physician. The allocated smoking withdrawal strategy was then included as part of the discussion of the treatment of the patient's condition. One month's supply of gum was given to the patients in the chewing gum groups together with a leaflet explaining its use. Patients were subsequently seen one, three, six, and 12 months after entering the study. In addition to any routine clinical inquiries the physician or patient, or both, completed follow up forms at these visits. Patients in the gum groups received a two month supply of gum at the first follow up visit (at one month), but at three months they were given further gum only if they requested it. No further supplies were issued at the six month visit.

Venous blood for carboxyhaemoglobin and thiocyanate estimations was taken at the six and 12 month visits from those who said that they were not smoking. Estimations were performed at the anaesthetics laboratory of St Bartholomew's Hospital, London. Carboxyhaemoglobin was measured with an IL282 Co-Oximeter and thiocyanate by an automated modification of the Aldridge technique.[8,9] By using critical values for carboxyhaemoglobin and thiocyanate of 1·6% and 73 μmol/l (424 μg/100 ml), respectively, these analyses reflect smoking state accurately in over 95% of subjects.[10]

Tests of significance were by χ^2.

Definition of success—A patient was classified as successful in

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giving up smoking if (*a*) he claimed not to be smoking at six and 12 months *and* (*b*) he claimed not to have smoked between six and 12 months, *and if* (*c*) his claims were verified by the carboxyhaemoglobin and thiocyanate estimations at six and 12 months. If a blood test was omitted at one of these visits then the single verification was enough to allow classification as a success.

Results

During February 1980 to April 1981, 1618 patients were entered into the study by 150 physicians in 95 centres. Some 80% of them were outpatients, and 1019 (63%) were men. Their mean age was 49 years (SD 11·8), and 631 (39%) were 55 or older. The mean number of cigarettes smoked daily was 24 (SD 11·2), 1133 (70%) of the patients smoking 20 or more; 1424 patients (88%) had smoked for 10 or more years. Almost two thirds of the patients were from socioeconomic groups IV and V, and only a quarter were from groups I and II. A total of 1311 patients (81%) had diseases of the respiratory system (predominantly chronic bronchitis and emphysema), and 146 (9%) had ischaemic heart disease; the remaining cases were made up of peptic ulcer, hypertension, and peripheral vascular disease. Over two thirds of the patients were confident that they would be able to stop smoking for at least a year. There were no differences between the treatment groups in the above characteristics.

Withdrawals—Sixty eight patients were withdrawn from the study (table I), including 10 patients in the VA group and eight in the VAB group, who were prescribed Nicorette by their general practitioner. More patients were withdrawn from the non-gum groups than from the gum groups combined, but once those who were prescribed Nicorette in error were discounted the difference was no longer significant.

Outcome—A total of 1550 patients remained for analysis. Table II shows their progress in giving up smoking at one, three, six, and 12 months. Those who failed to attend for follow up were denoted as "uncertain." There was no significant difference between the groups in the numbers denoted as "uncertain." For analysis these patients were included in the population totals as smokers. Even if some non-smokers had failed to attend probably no one treatment group would have contributed more of these than any other, so the assumption of smoking state should not affect the comparison between treatments. More people in the gum groups claimed to have stopped smoking at one month ($p < 0·01$) and three months ($p < 0·05$), but the differences were smaller and not significant at six and 12 months. Differences between the active and placebo gums were not statistically significant on any of the follow up occasions.

Successes—As defined, 150 patients (9·7%) were successes (table III), the 95% confidence limits being between 8·30% and 11·25%. The results for each treatment were virtually within these limits. There were no significant differences among the four groups, nor was the difference between non-gum and gum groups significant at the 5% level.

TABLE I—*Patients withdrawn from analysis*

	Treatment group*				Total
	VA	VAB	VABPG	VABNG	
No entered	395	401	412	410	1618
No withdrawn	24	24	10	10	68
Died	9	7	3	6	25
Prescribed Nicorette	10	8			18
Moved away	4	7	6	3	20
Medical problems	1	2	1	1	5
No remaining for analysis	371	377	402	400	1550

*In this and subsequent tables VA = verbal advice alone, VAB = verbal advice plus booklet, VABPG = verbal advice plus booklet and placebo chewing gum, and VABNG = verbal advice plus booklet and Nicorette chewing gum.

TABLE II—*Smoking during follow up. Figures are percentages of patients*

	Treatment group*				Total
	VA (n = 371)	VAB (n = 377)	VABPG (n = 402)	VABNG (n = 400)	(n = 1550)
One month:					
Smoking	65	61	57	58	60
Uncertain	16	20	17	15	17
Claimed not smoking	19	19	26	27	23
Three months:					
Smoking	52	49	49	52	51
Uncertain	30	35	27	27	29
Claimed not smoking	18	16	24	21	20
Six months:					
Smoking	54	46	47	53	50
Uncertain	30	37	34	30	33
Claimed not smoking	16	17	19	17	17
Verified not smoking	11	12	13	12	12
Blood not taken	0	1	1	1	1
Twelve months:					
Smoking	56	53	54	56	54
Uncertain	27	32	27	26	28
Claimed not smoking	18	15	19	19	18
Verified not smoking	11	11	14	10	11
Blood not taken	4	1	1	4	3

*See text and table I for definitions.

TABLE III—*Success in stopping smoking (see text for definition of success)*

	Treatment group*				Total
	VA (n = 371)	VAB (n = 377)	VABPG (n = 402)	VABNG (n = 400)	(n = 1550)
No (%) of successes	33 (8·9)	32 (8·5)	46 (11·4)	39 (9·8)	150 (9·7)

*See text and table I for definitions.

Validation—Out of 260 patients claiming to be non-smokers at six months who had blood tests, 70 (27%) had results which suggested that they were smoking. At 12 months the proportion was 25% (58/232; table IV). Blood was sometimes taken in error from patients who said that they were smoking: mean carboxyhaemoglobin and thiocyanate values were 4·2 ± SD 2·0% and 108·3 ± 47·0 μmol/l (629 ± 273 μg/100 ml) respectively in these known smokers, and were similar to the mean values of 4·4 ± 2·0% and 102 ± 45·1 μmol/l (592 ± 262 μg/100 ml) in those claiming abstinence who were reclassified as smokers. Mean values in those accepted as validated non-smokers were carboxyhaemoglobin 0·7 ± 0·6% and thiocyanate 42·6 ± 21·4 μmol/l (247 ± 124 μg/100 ml).

TABLE IV—*Validation at six and 12 months*

Treatment group*	Six months		Twelve months	
	No claimed non-smokers having blood tests	% Claims not validated	No claimed non-smokers having blood tests	% Claims not validated
VA	59	27	54	20
VAB	61	26	51	22
VABPG	73	26	68	22
VABNG	67	30	59	34
Total	260	27	232	25

*See text and table I for definitions.

Patients' opinions of gums and side effects volunteered—Of the 802 patients given placebo and Nicorette chewing gums, just over half found them helpful; 481 (60%), however, found them unpleasant, with no significant difference between active and placebo in these respects. A total of 722 patients (90%) said that they were still using placebo or active gum at three months, but at six and 12 months these numbers had fallen to 72 (9%) and 32 (4%), respectively. Bad taste (15%), nausea (6%), and sore throat (2%) were experienced more often with nicotine than with placebo gum, but burning taste (6%), flatulence (5%), and dental problems (3%) were no more common with nicotine gum than with placebo.

Discussion

The primary object of this trial was to determine whether additional methods of helping patients to stop smoking would improve on the results of simple verbal advice given by the physician. The trial was carried out in hospitals and chest clinics distributed widely throughout Britain and was conducted in the course of routine clinical work. The main finding after

follow up for one year was that none of the other methods tested gave better results than verbal advice from the physician. The lack of difference between simple advice and other methods may have been due to physicians taking their advice giving role more seriously in a research project, even though participating physicians were asked to give their usual antismoking advice.

As others have found,[11] the claimed abstinence rates at one month were higher than at any later time. Chewing gum clearly aided abstinence then, as it did at three months, but there was no significant difference between active and placebo. By six months the superiority of chewing gum had disappeared, and this remained true at 12 months, with active and placebo preparations again having similar effects. Only 72 out of 802 patients were still chewing at six months, whereas 722 (90%) had still been using gum at three months: possibly the superiority of chewing gum would have persisted had more patients continued to use it beyond three months.

The overall success rate of 9·7% may appear to be low when compared with a previous chest clinic study[4] but several factors must be considered in relation to this. The criterion of success was stricter and included abstinence at both six and 12 months with validation of claims by carboxyhaemoglobin and thiocyanate analysis, whereas the earlier study reported unvalidated results after six months. In Raw's chest clinic study 20% of patients claimed abstinence three months after verbal advice[12] compared with 18% in our group given verbal advice alone, but there was no further follow up. Our success rate was much lower than the 62% claimed in patients recovering from myocardial infarction[5] but that, more select group was given intense reinforcement with home follow up, and there was no validation of non-smoking claims. Our results were an encouraging improvement on the 5% achieved in a study of patients visiting their general practitioners who were given verbal plus written advice and warned that they would be followed up.[13] Motivation may have been stronger in the patients in our study, which was hospital based and included only those with smoking related diseases.

Our success rate was also lower than the 20% or so noted in smoking withdrawal clinics before the introduction of nicotine chewing gum[14] and much lower than that recently reported from the Maudsley Hospital's smoking withdrawal clinic—16% with placebo gum, 38% with nicotine chewing gum.[15] The differences between our study and the smoking withdrawal clinic studies were probably the result of two main factors. Firstly, although our patients were attending hospital with a smoking related disease, they were seeking help for the symptoms of their disease and not for their smoking habit. Smokers who voluntarily attend smoking withdrawal clinics are highly motivated and are also preselected by the therapists. Secondly, in such clinics experienced therapists spend more time with subjects and see them more often, in a clinic provided specifically for stopping smoking, in contrast with hospital outpatients, where stopping smoking may be just one aspect of treatment.

With high motivation and the selection procedures and skill of a smoking withdrawal clinic, nicotine chewing gum apparently does have an effect over and above placebo, but when these other factors are not as strong this effect does not emerge.

Nicotine chewing gum may have done less well than expected because there might have been insufficient explanation of its use, even though written instructions were included. But if a method of treatment is to be classed as successful for general use it must be so in the average way in which it is to be used; few physicians will be able to devote more than a few minutes to explaining any treatment.

The importance of validating statements of abstinence objectively[16 17] was confirmed by our finding that in some 26% of patients such claims were shown to be invalid by carboxyhaemoglobin and thiocyanate estimations.

The patients in our study were new or re-referred patients, but probably some would previously have had antismoking advice from their general practitioner which they had not heeded. The success rate of 9·7% is thus not as depressing as it might at first appear. Given the improving climate of opinion, advice from the doctor to stop smoking will probably produce even better results in the future.

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References

1 Doll R, Peto R. Mortality in relation to smoking: 20 years' observations on male British doctors. *Br Med J* 1976;ii:1525-36.
2 Royal College of Physicians. *Smoking or health.* Tunbridge Wells: Pitman Medical, 1977.
3 Doll R, Gray R, Hafner B, Peto R. Mortality in relation to smoking: 22 years' observations on female British doctors. *Br Med J* 1980;**280**: 967-71.
4 Williams HO. Routine advice against smoking. A chest clinic pilot study. *Practitioner* 1969;**202**:672-6.
5 Burt A, Illingworth D, Shaw TRD, Thornley P, White P, Turner R. Stopping smoking after myocardial infarction. *Lancet* 1974;i:304-6.
6 Russell MAH, Raw M, Jarvis MJ. Clinical use of nicotine chewing gum. *Br Med J* 1980;**280**:1599.
7 Raw M, Jarvis MJ, Feyerabend C, Russell MAH. Comparison of nicotine chewing gum and psychological treatments for dependent smokers. *Br Med J* 1980;**281**:481-4.
8 Jarvis MJ, Russell MDH, Saloojee Y. Expired air carbon monoxide: a simple breath test of tobacco smoke intake. *Br Med J* 1980;**281**:484-5.
9 Casapieri P, Scott R, Simpson EA. The determination of cyanide ions in waters and effluents by an auto-analyser procedure. *Analytica Chimica Acta* 1970;**49**:188-92.
10 Saloojee Y, Vesey CJ, Cole PV, Russell MAH. Carboxyhaemoglobin and plasma thiocyanate: complementary indicators of smoking behaviour? *Thorax* 1982;**37**:521-5.
11 Fee WM, Stewart MJ. A controlled trial of nicotine chewing gum in a smoking withdrawal clinic. *Practitioner* 1982;**226**:148-51.
12 Raw M. Persuading people to stop smoking. *Behav Res Ther* 1976;**14**: 97-101.
13 Russell MAH, Wilson C, Taylor C, Baker CD. Effect of general practitioners' advice against smoking. *Br Med J* 1979;ii:231-5.
14 Raw M. The treatment of cigarette dependence. In: *Research advances in alcohol and drug problems.* New York: Plenum Publishing Corporation, 1978:441-85.
15 Jarvis MJ, Raw M, Russell MAH, Feyerabend C. Randomised controlled trial of nicotine chewing-gum. *Br Med J* 1982;**285**:537-40.
16 Sillett RW, Wilson MB, Malcolm RE, Ball KP. Deception among smokers. *Br Med J* 1978;ii:1185-6.
17 Wilcox RG, Hughes J, Roland J. Verification of smoking history after infarction using urinary nicotine and cotinine measurements. *Br Med J* 1979;ii:1026-8.

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THE VINE. The leaves of the English vine (I do not mean to send you to the Canaries for a medicine) being boiled, makes a good lotion for sore mouths; being boiled with barley meal into a poultice, it cools inflammations of wounds; the dropping of the vine, when it is cut in the Spring, which country people call Tears, being boiled in a syrup, with sugar, and taken inwardly, is excellent to stay women's longings after every thing they see, which is a disease many women with child are subject to. The decoction of Vine leaves in white wine doth the like. Also the tears of the Vine, drank two or three spoonfuls at a time, breaks the stone in the bladder. This is a very good remedy, and it is discreetly done, to kill a Vine to cure a man, but the salt of the leaves are held to be better. The ashes of the burnt branches will make teeth that are as black as a coal, to be as white as snow, if you but every morning rub them with it. It is a most gallant Tree of the Sun, very sympathetical with the body of men, and that is the reason spirit of wine is the greatest cordial among all vegetables. (Nicholas Culpeper (1616-54) *The Complete Herbal*, 1850.)